PUBLICATIONS OF
THE UNIVERSITY OF EASTERN FINLAND

Dissertations in Health Sciences

NINA KRISTIINA MATTSSON

THE EFFECT OF PELVIC ORGAN PROLAPSE SURGERY ON QUALITY OF LIFE

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Nina Kristiina Mattsson

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for public examination in City Hall Auditorium, Hämeenlinna
on 21st August, 2020, at 12 o'clock noon

Publications of the University of Eastern Finland
Dissertations in Health Sciences
No 566

Department of Obstetrics and Gynecology
University of Eastern Finland
Kuopio
2020

Distributor:
University of Eastern Finland
Kuopio Campus Library
P.O.Box 1627
FI-70211 Kuopio, Finland
www.uef.fi/kirjasto

Name of the printing office/kirjapaino
Grano, 2020

ISBN: 978-952-61-3398-0 (print/nid.)
ISBN: 978-952-61-3399-7 (PDF)
ISSNL: 1798-5706
ISSN: 1798-5706
ISSN: 1798-5714 (PDF)

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Mattsson, Nina
The effect of pelvic organ prolapse surgery on quality of life
Kuopio: University of Eastern Finland
Publications of the University of Eastern Finland
Dissertations in Health Sciences, 566.
ISBN: 978-952-61-3398-0 (print)
ISSNL: 1798-5706
ISSN: 1798-5706
ISBN: 978-952-61-3399-7 (PDF)
ISSN: 1798-5714 (PDF)

ABSTRACT

Bothersome descent of pelvic organs is a common condition among parous women, and more than one in ten women undergo pelvic organ prolapse surgery during their lifetime. In Finland, about 4,200 operations for POP are performed annually and it is one of the most common gynecological operations. There are numerous different methods to repair the prolapse and the rates of surgical methods vary significantly between countries. Surgery is performed either vaginally or abdominally and by using patient's own tissue or mesh to repair the decsended compartment of vagina. Studies that compare the different surgical methods have previously focused mainly on anatomical outcome of the surgey. However, the patient's satisfaction and experience of improvement of pelvic distress symptoms and quality of life are the most important outcomes of surgical treatment.

The aim of this thesis was to evaluate the impact of POP surgery on patient satisfaction and quality of life (QoL), and to determine the predictive factors for surgical outcome.

The surgical methods for POP in Finland and the predictive factors for the use of mesh were described. In addition, validation the prolapse-specific patient-reported outcome measures (PROMs) in the Finnish population was performed. The validated PROMs were used to evaluate the effect of POP surgery on generic and condition-specific QoL at 6 months and 2 years postoperatively and correlation of the results of different PROMs was studied.

The study was conducted as a national multicenter 1-year cohort study in which 41 out of 45 hospitals that performed POP surgery in Finland participated. Altogether 3,535 operations covering 83% of all operations for POP in Finland during the study period year 2015 were registered, and the surgical details were documented in electronic registry by the doctors. Prior to cohort study, a multistep-translation process in Finnish was performed for three widely used prolapse-specific health-related quality of life (HRQoL) questionnaires; Pelvic Floor Distress Inventory (PFDI-20), Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) and Pelvic Floor Impact Questionnaire (PFIQ-7). In a pilot study of 63 women suffering

from POP, we evaluated psychometric properties of these measures and studied which of them are valid in Finnish population. Validated PROMs were used in assessing the symptoms and health-related quality of life among 2,903 (83%) patients who returned the preoperative questionnaire. Moreover, the effect of surgery on subjective outcome at 6 months and 2 years after the surgery was assessed by calculating the change of scores of the HRQoL measures. The follow-up data was received from 2,528 (72%) participants at six months and 2,351 (67%) at two years after the operation. In addition, the patients' satisfaction and perception of improvement after surgery was assessed by global index (Patient Impression of Improvement; PGI-I). A regression analysis was performed to determine the factors for use of mesh and the predictive factors for favorable and unfavorable surgical outcome. Results of three different PROMs (15D, PGI-I and PFDI-20) were analyzed to evaluate the correlation of these PROMs in assessing the outcome of surgery.

Altogether 81% of the POP operations were performed by using patient's own tissue. Mesh augmentation was performed transvaginally in 12% and abdominally in 7% of the operations. Predictive factors for the use of mesh were previous surgery for POP and hysterectomy, bothersome bulge and advanced prolapse beyond hymen. Transvaginal mesh surgery was associated with advanced anterior vaginal prolapse and advanced age. Abdominal mesh surgery was performed in 91% via laparosocopy and associated with advanced apical prolapse and severe symptoms. We detected large variation in the rates of mesh surgery between different hospitals and hospital districts.

Finnish translations of PFDI-20 and PISQ-12 showed acceptable psychometric properties, whereas PFIQ-7 showed low response rate and floor effect.

Generic HRQoL was significantly lower among the study population of women with symptomatic POP than in age-standardized population. A marked improvement in 15D index was noted at 6-months follow-up but no more at 2 years. However, improvement in prolapse-related dimensions such as sexual activity, excretion and discomfort and symptoms persisted during the 2-year follow-up. Altogether 78% of patients received clinical meaningful improvement in condition-specific quality of life measured with PFDI-20 at six months and 72% at two years. Altogether 84% of patients were satisfied with surgical outcome at two years, and 90% felt their condition to be better than before the operation. Predictive factors for favorable outcome of surgery were advanced prolapse beyond hymen and bothersome bulge. At two-year follow-up, altogether 5% of the patients felt their condition worse compared to the preoperative situation and this was associated with smoking.

The results of generic HRQoL measure 15D showed low correlation with PDFI-20 and PGI-I.

In conclusion, surgical treatment for pelvic organ prolapse improves effectively patient's symptoms and quality of life and patient satisfaction is high. The Finnish practices in POP surgery methods follow the international recommendations, but due to large variation of mesh surgery rates, national guidelines of POP practices are

needed. The Finnish versions of PFDI-20 and PISQ-12 are valid tools to assess the outcome of POP surgery. However, the different PROMs have their own characteristics and the quantified effectiveness depends on the applied measure.

National Library of Medicine Classification: WA 30, WJ 146, WO 162, WP 155, WP 454
Medical Subject Headings: Pelvic Organ Prolapse; Uterine Prolapse; Urinary Incontinence; Reconstructive Surgical Procedures; Quality of Life; Patient Reported Outcome Measures; Patient Satisfaction; Pelvic Floor; Psychometrics; Surgical Mesh; Female; Finland; Cohort Studies

Mattsson, Nina
Gynekologisen laskeumakirurgian vaikutus elämänlaatuun
Kuopio: Itä-Suomen yliopisto
Publications of the University of Eastern Finland
Dissertations in Health Sciences, 566.
ISBN: 978-952-61-3398-0 (print)
ISSNL: 1798-5706
ISSN: 1798-5706
ISBN: 978-952-61-3399-7 (PDF)
ISSN: 1798-5714 (PDF)

TIIVISTELMÄ

Useampi kuin joka kymmenes nainen joutuu laskeumaleikkaukseen elämänsä aikana. Suomessa tehdään vuosittain noin 4200 leikkausta synnytinelinlaskeuman vuoksi ja ne ovat tavallisimpia gynekologisia leikkauksia. Leikkaustapoja gynekologisen laskeuman korjaamiseksi on lukuisia erilaisia ja niiden yleisyys vaihtelee merkitsevästi eri maissa. Leikkaus voidaan tehdä joko emättimen tai vatsaontelon kautta ja siinä voidaan käyttää potilaan omia kudoksia tai verkkomateriaalia. Leikkaustapoja vertailevissa tutkimuksissa päätetapahtumana on yleensä käytetty laskeuman anatomisen korjaantumisen astetta. Kuitenkin potilaan tyytyväisyys, kokemus leikkauksen tuomasta avusta oireisiin ja elämänlaadun paranemisesta ovat leikkaushoidon tärkeimmät tavoitteet.

Tämän tutkimuskokonaisuuden tarkoituksena oli selvittää laskeumaleikkausten vaikutus potilaiden tyytyväisyyteen, oireisiin ja elämänlaatuun sekä arvioida leikkaustulokseen vaikuttavia tekijöitä. Tutkimuksessa selvitettiin Suomessa käytettävien laskeumaleikkausmenetelmien yleisyys sekä tekijät, jotka vaikuttivat verkkomateriaalin käyttöön laskeumaleikkauksessa. Lisäksi validoitiin suomalaiseen väestöön sopiva potilaiden kyselylomake laskeumasta johtuvien oireiden ja elämänlaadun arvoimiseksi. Validoituja elämänlaatumittareita käytettiin leikkaushoidon vaikuttavuuden arvioimiseksi yleiseen ja tautispesifiseen elämänlaatuun 6 kuukauden sekä 2 vuoden kuluttua leikkauksesta. Hyvään ja huonoon leikkaustulokseen vaikuttavat tekijät analysoitiin ja arvioitiin, kuinka kolmen eri elämänlaatumittarin tulokset korreloivat keskenään.

Tutkimus toteutettiin kansallisena kohorttitutkimuksena. Siihen osallistui 41 sairaalaa ja 3515 potilasta, mikä vastaa 83 % kaikista vuonna 2015 gynekologisen laskeuman vuoksi leikatuista naisista. Heistä 2903 (83 %) palautti oireita ja elämänlaatua kartoittavan kyselyn ennen leikkausta, 2528 (72 %) kuusi kuukautta ja 2351 (67 %) kaksi vuotta leikkauksen jälkeen. Lisäksi leikkaavat lääkärit täyttivät sähköisen kyselyn yhteensä 3535 leikkaukseen liittyvistä tiedoista. Yhteensä 20 potilasta leikattiin kahdesti laskeuman vuoksi tutkimusajanjakson aikana. Ennen tutkimuksen toteutusta käännettiin suomen kielelle kolme yleistä laskeumapotilaan

oireita ja elämänlaatua kartoittavaa kyselylomaketta. Käännösten oikeellisuus tarkistettiin takaisinkäännöksellä. Suomennettujen elämänlaatukyselyiden käyttökelpoisuus sekä toistettavuus kartoitettiin 63 laskeumapotilaan aineistossa.

Tutkimuksessa todettiin, että Suomessa gynekologisista laskeumaleikkauksista 81 % tehtiin omia kudoksia apuna käyttäen. Verkkoleikkauksille altistavia tekijöitä olivat aikaisempi laskeumaleikkaus ja kohdunpoisto, hankala pullistuman tunne ja laskeuma yli hymentason. Emättimen kautta verkkoleikkauksia tehtiin 12 % ja sille altistivat hankala emättimen etuseinän pullistuma ja korkeampi ikä. Vatsaontelon kautta tehtäviä verkkoleikkauksia oli 7 % kaikista leikkauksista ja 91 % näistä tehtiin tähystysmenetelmällä. Tähän leikkausmenetelmään valikoituneet naiset kärsivät useimmiten hankalaoireisesta emättimen pohjan laskeumasta. Alueellisesti ja sairaalakohtaisesti todettiin merkittäviä eroja verkkoleikkausten yleisyydessä.

Terveyteen liittyvää elämänaatua laskeumapotilailla mittaavista kyselylomakkeista kaksi; Pelvic Floor Distress Inventory (PFDI-20) ja Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) todettiin käyttökelpoisiksi suomalaisessa väestössä. Sen sijaan kolmas kyselylomake, Pelvic Floor Impact Questionnaire (PFIQ-7) ei täyttänyt psykometrisiä vaatimuksia.

Seitsemällä kymmenestä leikatusta potilaasta laskeumaan liittyvä elämänlaatu parani merkittävästi kahden vuoden seurannassa, oirespesifisellä PDFI-20 kyselyllä mitattuna. Yleisessä elämänlaadussa todettiin paraneminen kuusi kuukautta leikkauksen jälkeen, mutta muutos ei ollut enää merkitsevä kahden vuoden kohdalla. Kuitenkin eritystoiminnoissa ja seksuaalisuuteen liittyvissä ulottuvuuksissa todettiin merkittävä paraneminen myös kahden vuoden seurannassa. Tyytyväisyys leikkaustulokseen oli korkea (84 %) ja jopa yhdeksän kymmenestä potilasta koki tilanteensa paremmaksi kuin ennen leikkausta. Hyvään leikkaustulokseen liittyviä tekijöitä olivat emättimen pohjan laskeuma yli immenkalvotason ja häiritsevä pullistuman tunne. Kahden vuoden seurannassa viisi prosenttia potilaista tunsi tilanteensa huonommaksi kuin ennen leikkausta ja tupakointi lisäsi riskiä tähän.

Käytetyistä mittareista yleistä terveydentilan paranemista arvioiva mittari Patient Global Impression of Improvement (PGI-I) ja PFDI-20 korreloivat keskenään kohtalaisesti, kun taas yleinen elämänlaatumittari 15D korreloi huonosti muiden mittareiden kanssa.

Yhteenvetona voidaan todeta, että laskeumaleikkaus parantaa tehokkaasti potilaan elämänlaatua. Pääosin suomalaiset käytännöt leikkaustavan valinnasta vastaavat kansainvälisiä suosituksia, mutta toimintatapoja leikkaustavan valinnassa tulisi yhtenäistää. Leikkaustuloksia arvioitaessa tulisi käyttää validoituja elämänlaatumittareita ja huomioida eri mittareiden ominaisuudet leikkaustuloksen vaikuttavuuden arvioinnissa.

Yleinen suomalainen ontologia: kohdunlaskeuma; leikkaushoito; vaikuttavuus; elämänlaatu; gynekologia; kohorttitutkimus; naiset; Suomi

ACKNOWLEDGEMENTS

This study was conducted in the Department of Obstetrics and Gynecology, Kanta-Häme Central Hospital, and the University of Eastern Finland. The research was organized and funded by the Finnish Society for Gynecological Surgery. In addition, funds were granted by Emil Altonen Foundation, Finnish Cultural Foundation, Häme Regional Fund and the Ministry of Health and Social Welfare in Finland via Medical Research Fund of Kanta-Häme Central Hospital. I want to express my gratefulness to the institutions of their support for this study.

My warmest gratitude goes to my supervisors, Docent Anna-Mari Heikkinen, Docent Kari Nieminen and Docent Jyrki Jalkanen. I have been especially lucky to be able to study topic that I felt clinically meaningful. You all together inspired and helped me through this huge process. Even though I met some difficulties, you engouraged and guided me at the times of desperate feelings. Kari and Jyrki, in addition to scientific support, you were there to help me in exceeding myself and sking to the highest mountain. Anna-Mari, in addition to teaching me surgical skills, you have taught me how to get back in the saddle again and keep on riding. You are my professional idol and I am sincerely grateful for our friendship.

I want to express my deepest gratitude to Professor Anna-Maija Tolppanen. Your enormous patience and academic scills have influenced me deeply. Without your professional attitude and advice in statistics I would never have been able to reach my goal.

I want to thank my co-recearchers M.D. Päivi Karjalainen and M.D. Olga Wihersaari. It has been enormously rewarding to share this scientific work with you and the work will carry on.

I am deeply grateful to Docent Päivi Härkki and Ph.D. Tea Brummer for your help and advice. Your experience in FINHYST study helped us together to establish the little sister, FINPOP.

I thank my co-writers Ph.D. Pia Suvitie, M.D. Marja-Leena Eloranta, Ph.D. Sari Koivurova and the whole group of the board of the Society for Gynecological Surgery for your support and friendship. I thank Professor emeritus Harri Sintonen for his co-operation in study III.

I am very grateful to the official reviewers of this thesis, Docent Jaana Vironen and Docent Seija Ala-Nissilä. Your thorough evaluation and valuable comments helped to improve the final result of this thesis.

I acknowledge my former principal chiefs in Kanta-Häme Central Hospital, Henrik Rosendahl and Merja Vainio. Thank you for believing in my skills. While I was a registrar, Henrik gave me his scientificial support and pushed me towards to clinical research. Later on, Merja gave the idea of the present study and transmitted to me her positive energy and enthusiastic approach regarding clinical research. In addition, I want to acknowledge my "mums" Kirsti Niemi, Helena Launiala and Marja Kupari for your friendship and colleagueship. Warm thanks to all my former

colleagues and nurses in Kanta-Häme Central Hospital. I thank nurses Riia Mattila and Elina Perä, and my friends Iris Juusela and Laura Juusela-Barnes for your important help in the validation study. Warm thanks to Kari Mikkonen in Kanta-Häme Central Hospital's library for your delightful attitude and enormous help that I have received during these years.

I am deeply grateful to all the Finnish doctors, nurses and patients around the country, who made this study possible. In particular, I want to acknowledge the work that was done by contact persons in participating hospitals: Pontus Molander, Maritta Pöyhönen-Alho, Tuuli Soini, Tapio Väyrynen, Esa Räty, Susanna Naukkarinen, Pia Heinonen, Elina Kuikka, Liisa Tikkala, Mari Vehviläinen, Kirsi Nissinen, Reijo Hiltunen, Seppo Varpuluoma, Marja Vainio, Pekka Staven, Timo Tiilikainen, Anu Hänninen, Pentti Kiilholma, Minna Kauko, Jari Sjöberg, Leena Häivä, Satu Laurila, Marko Niemimaa, Eila Knuuti, Pia Vittaniemi, Päivi Malmström, Johanna Haikonen, Katja Murtoniemi, Päivi Selänne, Anna Sorvaniemi, Helena Hieta-Heikurainen, Benyamin Ashraf, Signe Linkolm, Hannele Torkkeli, Pirkko Juvonen, Kari Österberg, Eija Lampela and Marja Tiihonen. Professor Tomi Mikkola and Ph.D. Riikka Aaltonen, thank you for being also the members of the follow-up committee of this thesis. Docent Pauliina Aukee, I'm deeply grateful for your important help in the beginning of the study.

I wish to express thanks to my sisters Piia and Viivi and all my dear friends who have supported me and shared all the sorrows and delights during the past years. Together we are strong.

Warmest thanks belong to my family, that means everything for me. I am sorry that you have had more or less absent-minded wife and mum for several years. I wish to come back to real life and be more present in future years. Aapo and Konsta, you are my greatest achievements and I'm so proud of you two. Tapani, thank you for supporting me even in the darkest moments, keeping vampires away from my door and showing me your deep love.

In Hämeenlinna, 14th May 2020

Nina Mattsson

LIST OF ORIGINAL PUBLICATIONS

This dissertation is based on the following original publications:

I Mattsson NK, Karjalainen P, Tolppanen A-M, Heikkinen A-M, Jalkanen J, Nieminen K. Methods of surgery for pelvic organ prolapse in a nationwide cohort (FINPOP 2015). Acta Obstet Gynecol Scand. 2019;98(4):451-459.

II Mattsson NK, Nieminen K, Heikkinen AM, Jalkanen J, Koivuranta S, Eloranta M-L, Suvitie P, Tolppanen A-M. Validation of the short forms of the pelvic floor distress inventory (PFDI-20), pelvic floor impact questionnaire (PFIQ-7), and pelvic organ prolapse/urinary incontinence sexual questionnaire (PISQ-12) in Finnish. Health Qual Life Outcomes. 2017;15:88.

III Mattsson NK, Karjalainen PK, Tolppanen AM, Heikkinen A-M, Sintonen H, Härkki P, Nieminen K, Jalkanen J. Pelvic organ prolapse surgery and quality of life – a nationwide cohort study. American Journal of Obstetrics and Gynecology. 2020;222:588.e1-10.

IV Mattsson NK, Karjalainen P, Heikkinen AM, Nieminen K, Jalkanen J, Tolppanen AM. Agreement between patient global impression scale of improvement, pelvic floor distress inventory and 15D in measuring the outcome of pelvic organ prolapse surgery. Neurourol Urodyn. 2020 Jul 22. doi: 10.1002/nau.24467.

CONTENTS

ABBREVIATIONS

AM	Abdominal Mesh
BMI	Body Mass Index
CRADI-8	Colo-Rectal-Anal Distress Inventory
CRAIQ-7	Colo-Rectal-Anal Impact Questionnaire
EQoL-5	5 dimensional EuroQoL instrument
FDA	The Food and Drug Administration of the United States
FIGO	International Federation of Obstetrics and Gynecology
HRQoL	Health Related Quality Of Life
ICC	Intra-class Correlation Coefficient
ICS	International Continence Society
IUGA	International Urogynecological Association
MID	Minimal Important Difference
NHP	Nottingham Health Profile
NTR	Native Tissue Repair
ODS	Obstructed Defecation Syndrome
PFDI	Pelvic Floor Distress Inventory
PFIQ	Pelvic Floor Impact Questionnaire
PISQ	Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire
PGI-I	Patient Global Impression of Improvement
PMFT	Pelvic Floor Muscle Training
POP	Pelvic Organ Prolapse
POPDI-6	Pelvic Organ Prolapse Distress Inventory
POPIQ-7	Pelvic Organ Prolapse Impact Questionnaire
PROM	Patient-Reported Outcome Measure
QALY	Quality-Adjusted Life Years
RCT	Randomized Controlled Trial
SF-36	The Medical Outcomes Trust Health-Related Quality of Life instrument
SSLF	Sacrospinosus ligament fixation

SUI	Stress Urinary Incontinence
TVM	Transvaginal mesh
UDI-6	Urinary Distress Inventory
UIQ-7	Urinary Impact Questionnaire
ULS	Uterosacral ligament suspension
15D	15 dimensional generic health-related quality of life questionnaire

1 INTRODUCTION

Pelvic organ prolapse (POP) means a descent of pelvic organs. It is caused by injury to the levator ani muscles occuring most often after vaginal childbirth, which leads to failure of the lateral connections between the pelvic organs to the pelvic sidewall. [1] It is a common health issue and affects millions of women. Even half of parous women are reported to have at least mild degree of prolapse on examination [2]. Most women with anatomical prolapse are asymptomatic and do not require surgical intervention. Mild cases can be treated with conservative treatment options including pelvic floor physiotherapy, local estrogen and pessaries. However, more than ten percent of women require surgical treatment for prolapse during their lifetime [3]. In Finland, about 4,200 operations for POP are performed annually and the lifetime risk for prolapse surgery is 13% [4], which is about the same as reported in other countries [35].

There are several different surgical methods to repair the prolapse but only limited evidence to guide clinicians to choose the best method for individual patients. The methods of POP surgery have changed dramatically during the 21st century, first towards to mesh surgery and then back to native tissue repair [67]. The problem with traditional native tissue repair methods is the high risk of recurrent prolapse and thus, mesh augmentation surgery methods have been developed and shown to lead to more permanent anatomic cure [8]. However, mesh augmentation is associated with vaginal erosions, which have been shown to relate especially with the transvaginal mesh (TVM) surgery. The total erosion rate in long term follow-up has been reported exeeding 23%, although mostly without symptoms .[9–11] It has been shown that approximately eight percent of patients that are treated with TVM require repeat surgery due to vaginal mesh exposure. [9] In addition, TVM is associated with higher rates of de novo stress urinary incontinence, bladder injury and reoperations than native tissue repair (NTR).

The use of transvaginal mesh in POP surgery increased mainly due to commercial mesh kit marketing and then decreased after 2011 when the FDA (Food and Drug Administration of the United States) gave a second warning on the adverse effects associated with the use of mesh in vaginal surgery [12]. Since then, transvaginal mesh use has been widely debated and even abandoned in some countries [13]. Simultaneously with decreased TVM use, the abdominal mesh (AM) surgery has moderately increased [7]. Abdominal sacrocolpopexy is shown to associate with lower risks of recurrent prolapse than the vaginal native tissue repair methods, such as sacropinosus fixation [14]. In addition, risk of stress urinary incontinence and dyspareunia after abdominal mesh surgery are shown to be lower than with a variety of other vaginal surgical methods for apical prolapse [14]. However, even 10% vaginal erosion rate has been reported with long-term follow-up after abdominal sacrocolpopexy [15].

Between different countries, a significant heterogeneity (>10-fold) exists in the rates at which the POP procedures and mesh surgery are performed [16]. Thus, different surgical techniques and national practices require further assessment in terms of effectiveness and safety.

Previously, in most studies of POP surgery, the main outcome has been the change in anatomical prolapse stage, assessed using e.g. the Pelvic Organ Prolapse Quantification (POP-Q) instrument [17]. Nowadays, patient-reported outcomes such as satisfaction and change in the health-related quality of life (HRQoL) are considered as the most important outcomes of surgical treatment [18]. Measurement of HRQoL using validated intruments is increasingly common also in POP surgery. However, a recent systematic review showed that patient-reported outcome measures (PROMs) are infrequently used in randomized trials (RCTs) evaluating surgical interventions for anterior compartment prolapse. Only 11 (14%) out of 67 RCTs reported patient satisfaction, 9 (17%) prolapse symptoms and 14 (17%) sexual dysfunction [19]. In addition, most of the studies with patient-reported HRQoL outcome measures compare selected surgical methods in one vaginal compartment prolapse [14,20]. However, most of the patients need multiple vaginal compartment prolapse repair [21]. Thus, prospective clinical studies reporting surgical outcomes of non-selected patients are needed.

The aim of this thesis was to evaluate the effect of female pelvic organ prolapse surgery on patient satisfaction and quality of life by using validated PROMs. In a nationwide cohort of 3535 POP surgeries in 2015, the methods of POP surgery in Finland were described and the factors that affect clinicians' choice to use mesh repair method were identified. Finnish translation and validation of the three condition-specific HRQoL instruments (Pelvic Floor Distress Inventory, PFDI-20; Pelvic Floor Impact Questionnaire, PFIQ-7 and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, PISQ-12) was performed by psychometric testing in a cohort of 63 women with symptomatic POP. The change in HRQoL measurements (15D and PFDI-20) was evaluated six months and two years after the surgery. In addition, patient satisfaction and Patient Global Impression of Improvement (PGI-I) were assessed after surgery and the baseline predictors of both favourable and unfavourable outcomes were determined. Furher on, the consistency of the three patient-reported outcome measures (15D, PGI-I and PFDI-20) in assessing the change in HrQoL following surgery were evaluated.

2 REVIEW OF THE LITERATURE

2.1 PELVIC ORGAN PROLAPSE

2.1.1 Epidemiology

Up to 50% of parous women have at least some degree of prolapse when based upon vaginal examination. Mild prolapse on examination is often asymptomatic. Only 10 to 20% of those women who have an anatomical prolapse seek treatment for their condition. [2] When defined by symptoms, prevalence of POP is 3–6% [22]. Over 200,000 surgeries are performed annually in the United States for POP [23]. Review by Barber et al. showed that significant variation exists in the prevalence and incidence of POP surgery in US population and the incidence of POP surgery ranged from 1.5 to 1.8 per 1000 women years [2]. Wu et al. found in US database study that risk of POP surgery increased progressively until age of 73 years when the annual risk was 4.3 per 1000 women. Cumulative lifetime risk for POP surgery was 12.6%. [3] Smith et al. [24] reported a lifetime risk of undergoing POP surgery as high as 19% in Western Australia, which is three times higher than reported by Olsen et al., 6.3% in the US. [5] Haya et al. found a 5-fold variation in the rate of prolapse interventions within OECD countries in 2012 [16]. In Nordic countries, the rate of POP surgery per 1,000 women was 2.0 in Sweden and 1.8 in Denmark [16]. In Finland, approximately 4,200 operations for POP are performed per year and the lifetime likelihood of POP surgery is 13% [4].

Ageing increases both the incidence and prevalence of POP surgery and the peak of POP surgery is at age of 60–69 years [2]. As the ageing population in developed countries is rapidly growing, the rate of POP surgery is estimated to increase. Based on demographic data, Kirby et al. estimated that the demand for care for pelvic floor disorders such as prolapse and urinary incontinence will increase by 35% between 2010 and 2030 in the United States [25].

Recurrence of prolapse is common. It has been shown that even 38% of patients have a recurrent prolapse on examination one to three years after native tissue reconstructive surgery and 19% are aware of the prolapse [9]. Based on administrative data of a large US healthcare system, Olsen et al. reported a lifetime risk for recurrent POP as high as 29.2% [5]. However, this data included also incontinence surgery and both recurrence in the same and another vaginal compartment. According to a large cohort study in the U.S., the reoperation rate after vaginal colporrhaphy is from 11.6 to 20.2% in ten year follow-up [26].

2.1.2 Definition, classification and evaluation

Pelvic organ prolapse means downward descent of one or more of the female pelvic organs (vagina, uterus, bladder and rectum) into or through the vagina (definition by IUGA/ICS Standardization and Terminology Committee) [27]. It is classified

depending on the involved vaginal compartment as shown in Figure 1. Anterior compartment prolapse is the most common type of POP and represents as a cystocele meaning descent of the bladder. Posterior vaginal wall defect associates with rectocele (anterior protrusion of rectum). In addition, sigmoidocele (protrusion of sigmoid colon), enterocele (protrusion of small intestine) or intussusception of anterior rectal wall may be present at the time of posterior compartment prolapse. [28]

Prolapse of apical compartment (uterine or vaginal vault prolapse) is defined as descent of the apex of the vagina into the lower vagina [29]. The apex of vagina can mean the uterus and cervix, cervix alone (after supravaginal hysterectomy), or vaginal vault (following total hysterectomy) [27]. Enterocele associates often with apical prolapse.

Prolapse of one vaginal compartment is often associated with prolapse of another compartment. Dallas et al. showed in a retrospective cohort study of nearly 100,000 women that even 56% of POP surgeries involve multi-compartment repairs [21]. Summers et al. studied the relationship of anterior and apical compartment prolapse by MRI and showed that even half of anterior prolapses may be explained by descent of apical compartment [30].

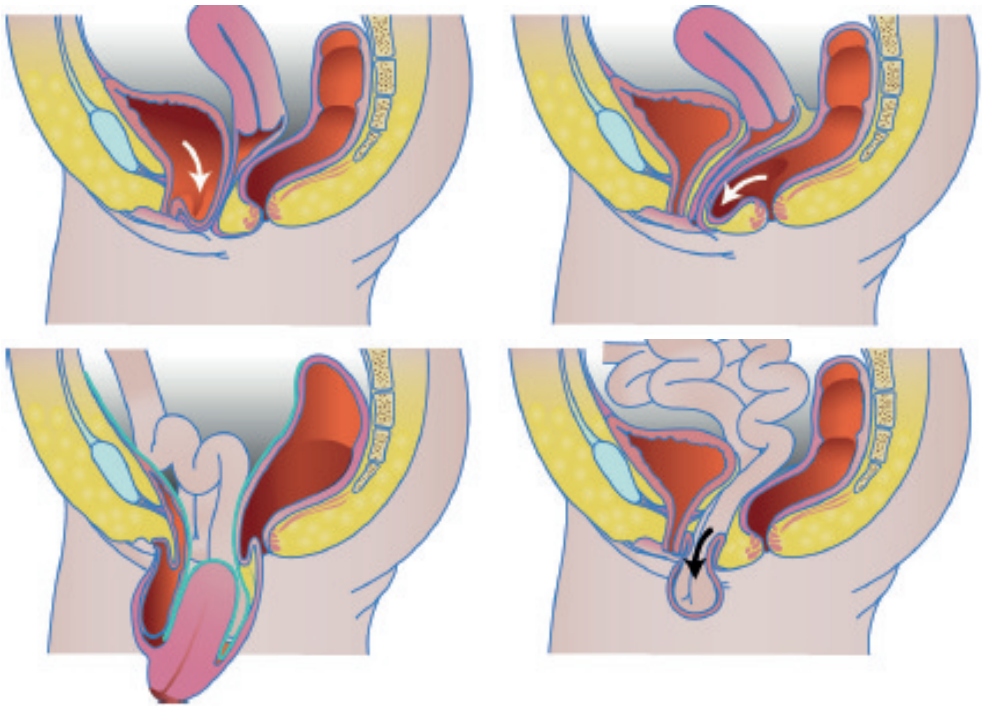

Figure 1. Types of pelvic organ prolapse. Cysteocele (up left), rectocele (up right), uterine prolapse (down left) and post-hysterectomy vault prolapse (down right).
Reprinted and modified with permission from Barber et al. BMJ 2016 [31].

The stage of the prolapse is usually evaluated when the patient is in the dorsal lithotomy position and then standing position if necessary. The speculum examination is performed first while patient is relaxed and then straining, by using Valsalva maneuver. The Baden–Walker Halfway Scoring System is a commonly used method to assess the stage of prolapse in clinical use [32]. Although descriptive, this scoring system has some deficits. For example, a strategically placed 1cm increase in prolapse results in an increase in the assigned stage. The interobserver agreement is not sufficient enough with the Baden–Walker scoring system and thus, nowadays the Pelvic Organ Prolapse Quantitation system (POP-Q) is the standard classification system in assessing the stage of the prolapse. [17,27] The topography of the vagina is described using six points as shown in Figure 2; two on the anterior vaginal wall (Aa and Ba), two on the posterior vaginal wall (Ap and Bp) and two on the apex of the vagina (C; cervix and D; vaginal vault). The location of these defined points is gauged relative to the hymenal ring while patient strains. In addition, measurements of genital hiatus (gh), perineal body (pb) and total vaginal length (tvl) are recorded on a grid (Figure 3). POP-Q provides a standardized tool that is used in documenting and comparing clinical findings. It has proven interobserver and intraobserver reliability and is the most commonly used system in trials. Although POP-Q system helps in defining the features of a prolapse, it is not very simple to use in routine care. Furthermore, correlation between POP-Q and urogenital symptoms based on validated questionnaires is shown to be weak. [33]

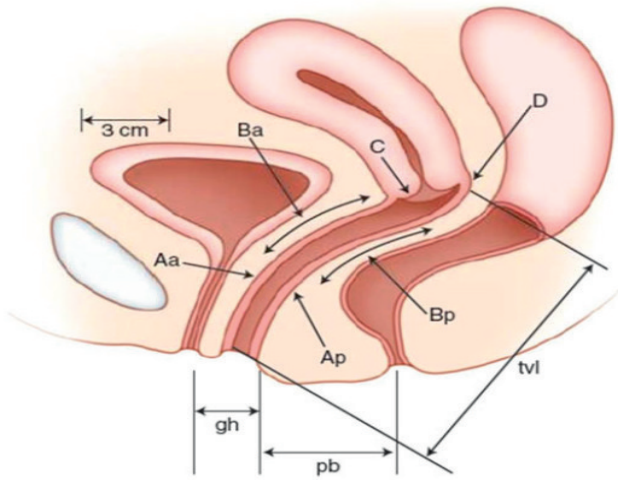

Figure 2. The POP-Q quantification. Six sites (points Aa, Ba, C, D, Bp, Ap), genital hiatus (gh), perineal body (pb), and total vaginal length (tvl) used for pelvic organ support quantitation.
Reprinted with permission from Haylen et al. Int Urogynecol J. 2016 [27].

Anterior wall Aa	Anterior wall Ba	Cervix or cuff C
Genital hiatus gh	Perineal body pb	Total vaginal length tvl
Posterior wall Ap	Posterior wall Bp	Posterior fornix D

Figure 3. Three by three grid presentation of POP-Q measurements. Adapted and modified from Bump et al. [17].

A simplified version of the POP-Q system (Figure 4) measures only four points: the anterior, posterior and up to two measurements of the apex, including both the cervix, in women who still have one, and posterior cul-de-sac. [34] Stage 1 prolapse means that the descent remains at least 1 cm above the hymenal remnants. In stage 2 the prolapse extends from 1 cm above to 1 cm below the hymenal remnants and in stage 3 the prolapse descends more than 1 cm past the hymenal remnants and stage 4 means complete vaginal vault eversion or complete uterine procidentia.

The maximum vaginal support loss (SLmax) represents the most distal presenting part of the vagina, in centimeters. The minimum value is -3 by definition meaning perfect vaginal support and higher values of support loss represent greater support loss. Brubaker et al. showed that this measure correlates well with POP-Q measurements and results of the Pelvic Organ Prolapse Distress Inventory and concluded that the single most distal POP-Q point may be preferable to POP-Q ordinal stages to summarize or compare group data [35].

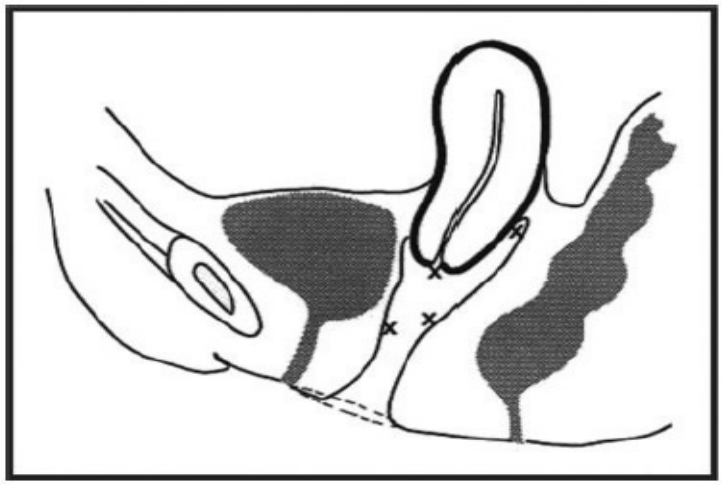

Figure 4. Simplified POP-Q. *Reprinted with permission from Haylen et al. Int Urogynecol J. 2016;27(4):655–684.* [27]

Imaging is indicated in cases of intercurrent pelvic floor disorders and may help the clinical assessment. Especially among women with POP and fecal incontinence functional anorectal evaluation is needed. [36] Rectal intussusception, mucosal prolapse, enterocele or spastic pelvic floor might be diagnosed by defecography or functional magnetic resonance. Perineal ultrasound imaging is a viable diagnostic tool for levator ani muscle trauma, ballooning of the genital hiatus and descent of pelvic organs on Valsalva maneuver. In addition, lower urinary tract sonographic evaluation including bladder postvoid residual volume, position and mobility of blabber neck and urethral funneling can be performed if needed. Women with complicated urinary tract dysfunction may be evaluated by urodynamic investigations. [27]

2.1.3 Risk factors

Higher parity, especially number of vaginal deliveries increases the risk of symptomatic POP [37]. Observational Oxford family planning study found that risk of developing POP was 8.4 fold for those women who had delivered two and 10.9 folf for those with four or more children compared to nulliparous women [38]. It has been estimated that three out of four prolapses among parous women can be attributed to pregnancy and delivery. Other pregnancy-associated risk factors for prolapse include high birth weight of an infant, prolonged second stage of labor, forceps delivery, and young age (< 25 years) at first delivery. [39]

Women with advancing age are more prone to develop symptomatic prolapse so that every additional 10 years of age confers an increased risk of prolapse of 40 percent. The number of women seeking treatment for prolapse and incontinence is shown to be highest at age of 60 to 70 years. [40]

Overweight and obese women are in elevated risk of POP [40]. A meta-analysis of 22 studies reported that obese women (BMI 30 or more) had a nearly 50% increased risk of pelvic organ prolapse, compared with their normal-weight counterparts [41].

It has been shown that hysterectomy may increase the risk of POP and after hysterectomy 6 to 12% of women will develop symptomatic vaginal vault prolapse [2]. Other factors reported to be associated with the development of POP are conditions that elevate the intra-abdominal pressure including constipation, chronic cough and constant heavy lifting [40]. A woman's family history of POP may increase the risk for prolapse by 2.5 fold [42]. Connective tissue abnormalities, degradation and devascularization due to aging and mechanical trauma lead to decreased strength and development of prolapse. In addition, decreasing estrogen concentrations has shown to associate with a reduction in total collacen content. [43]

Risk factors for prolapse recurrence after surgery are younger age, higher preoperative prolapse stage, family history of prolapse, levator muscle avulsion and wide levator hiatal area [44].

2.1.4 Symptoms of pelvic organ prolapse

Typically the symptoms of prolapse occur in situations when gravity makes the prolapse worse, such as after long periods of standing or exercising. In addition, abdominal straining like defecation, pushing or coughing may increase the symptoms of POP. Women often present a combination of pelvic floor disorder symptoms but others than vaginal bulging symptoms are not specific to POP. [31] In a cross-sectional study of 237 women evaluated for POP, 73% presented concurrent urinary incontinence, 86% urinary urgency/frequency, 34–62% voiding dysfunction and 31% fecal incontinence [45]. Treatment of one pelvic floor dysfunction may lead to worsening of another symptom. Thus, it is essential to assess all the symptoms before operative treatment.

Pelvic discomfort symptoms

The sense of bulge, i.e. patient tells that something falls down that can be seen and/or felt is the most common symptom of pelvic prolapse [2,40]. It is often accompanied with a sense of pelvic pressure [27]. Patients may complain a feel of increased heaviness, pain or discomfort in the pelvic area. The specificity of vaginal bulge symptoms for predicting an advanced prolapse beyond the hymen is high (from 99 to 100 percent). However, the sensitivity is low (from 16 to 35 percent) because some women with advanced prolapse report an absence of symptoms. [46]

Other symptoms that may be related to vaginal prolapse include splinting or digitation meaning that patient must digitally replace the prolapse to assist voiding or defecation. Ulceration of the prolapse may cause vaginal disharge, infections and bleeding. Low "menstrual-like" backache, especially if it is relieved when prolapse is reduced, may associate with vaginal prolapse. [27]

Urinary symptoms

Loss of support of the anterior vaginal wall or vaginal apex may affect bladder and/or urethral function. Thus women with mild prolapse (stage 1–2) often suffer from stress urinary incontinence (SUI). [45] In cases of advanced anterior or apical prolapse, urethra may be "kinked" and patients may complain symptoms of obstructed voiding. These symptoms include slow urine flow, the need to replace the prolapse manually or to change position during urination and a sensation of incomplete emptying of the bladder, and in rare cases even complete retention. [27] It has been shown that women with POP have a two- to fivefold risk of overactive bladder symptoms compared with the general population [47]. According to Haylen et al., the most common urinary tract symptoms related to POP include frequency, recurrent urinary tract infection, incomplete emptying or urinary retention and slow stream [27].

Defecatory symptoms

Defecatory symptoms are more prevalent in women with pelvic organ prolapse compared with the general population [48]. The most prelevant symptoms are constipation and incomplete emptying [45]. Other defecatory symptoms include fecal urgency, fecal incontinence (accidental bowel leakage), post-defecatory soiling and obstructive symptoms like straining, or the need to apply digital pressure to the vagina or perineum (splint) to enable complete evacuation of the distal rectum [27]. The stage of posterior vaginal wall prolapse is shown to correlate with these symptoms [49]. However, defecatory symptoms often associate with other conditions such as intussusception or prolapse of rectum [36].

Effects on sexual function

Women with symptomatic prolapse have shown lower sexual function scores in validated measures and they are less likely to engage in sexual relations than their asymptomatic counterparts. The sexual dysfunction typically worsens with increasing severity of pelvic organ prolapse. [50] Prolapse affects sexual arousal and orgasm, and can be associated with dyspareunia [51]. Women may complain loss of sexual desire, excessive vaginal looseness and impended penetrarion due to vaginal bulge [27]. Some women report that they even avoid sexual activity. Reason for this is often fear of discomfort or embarrassment associated with prolapse. Sexual inactivity is particularly common among those women who fear urinary or fecal incontinence during intercourse. [50,52]

2.1.5 Nonsurgical management options

Expectant management

Expentant management is a viable option for those women with tolerable symptoms of POP and who prefer to avoid treatment. Data suggest that the course of symptomatic POP is progressive until menopause. After menopause the degree of prolapse may follow a course of alternating progression and regression. Women with multiple risk factors for POP are likely to have progression. These include multiparity, previous hysterectomy for prolapse, obesity, and chronic constipation. [53] For obese women, weight loss does not appear to result in regression [54]. However, urinary incontinence symptoms and prolapse recurrence risk after the surgery may be diminished by weight loss [55]. Constipation should be managed especially in women with posterior wall prolapsed to avoid progression of the prolapse or recurrence after surgery.

Vaginal pessaries

Conservative management options for POP include vaginal pessary use and pelvic floor muscle training [56,57]. Vaginal pessaries are mechanical devices that are inserted into the vagina to support the pelvic organs. They are a treatment option for symptomatic women who do not desire surgery or are not eligble for operative treatment. The pessaries have been used in past history to relieve the symptoms of POP and still offered as the first-line treatment for symptomatic prolapse by approximately 75% of gynecologists in the US [58]. They can be categorized into two types: support and space-filling. The most commonly used support is the silicone ring pessary as it is easy to insert and remove. Space-filling Gelhorn pessary or vaginal cubes may be offered as the second-line pessary to women who retain a ring support pessary. Common side effects of pessary use include vaginal discharge and erosions, which are reported by up to 24% of the users. Risk factors for pessary displacement are stage III or IV prolapse, apical-predominant prolapse, and a large genital hiatus. About 80% of patients can be fit for a pessary and approximately 40% of those discontinue pessary use within one to two years of use. [59] Predictive factors of pessary use continuing after one year include age more than 65 years, severe comorbidities and maintenance of urinary continence [60].

Pelvic floor muscle training

Pelvic floor muscle training (PFMT) appears to result in some improvement in POP-associated symptoms and especially the urinary incontinence symptoms [61]. However, no significant improvement in quality of life is reported in the randomized studies that compare the perioperative PMFT and usual care among patients with symptomatic POP [62,63]. A recent meta-analysis found only low-quality evidence that postpartum PMFT may improve POP symptoms, but it likely reduces incontinence symptoms and improves sexual function compared to watchful waiting [64].

Local estrogen

Local vaginal estrogen is often administered for women with prolapse. A Cochrane review evaluated the use of local estrogens for the treatment of pelvic floor disorders and found only few small trials evaluating the effect of local estrogens on prolapse [65]. One trial found that local estrogen three weeks before the operation reduced the risk of postoperative cystitis [66]. Thus, only limited evidence exists to support the use of systemic or local estrogens for the prevention or management of POP.

2.2 PELVIC ORGAN PROLAPSE SURGERY

2.2.1 Indications and classification

Surgical treatment is usually reserved for women who have an advanced prolapse (at least stage 2 on examination), report bothersome pelvic symptoms, and have failed or declined conservative treatment [8]. The goal of POP surgery is to restore the normal pelvic anatomy, and most importantly, improve the quality of life of the patients by eliminating the POP-related symptoms and pelvic dysfunction.

According to The International Continence Society (ICS) report, the surgery for POP should be classified as 1) primary surgery and 2) further surgery [29]. Primary surgery means the first procedure that is required for the prolapse in any vaginal compartment. Further surgery means subsequent procedures that the patient undergoes either directly or indirectly relating to the primary surgery. This is subdivided to surgery for prolapse in a different compartment following previous surgery, repeated surgery for the same compartment, surgery for complications and surgery for non-prolapse related conditions such as urinary or fecal incontinence. [29]

Surgery for POP can be performed transvaginally or transabdominally, via laparotomy or laparoscopy. Nowadays approximately 90% of the surgical interventions for POP are performed via the transvaginal approach. [5,16,67,68] Laparoscopy can be done with or without robotic assistance. Most interventions are reconstructive. Obliterative procedures, such as colpocleisis, are reserved for those women who cannot tolerate more extensive surgery because of co-morbidities and who are not sexually active. [31]

The repair is mainly performed by using patient's own native tissue, but in some cases synthetic mesh is used via transvaginal or abdominal approach. Polypropylene low-weight mesh is shown to be most usable and is used in all the mesh kits available. The advantage of the use of mesh is the lower risk for recurrent POP. [9] However, transvaginal mesh surgery has come under scrutiny by national regulatory agencies and professional medical societies in recent years. This is due to an increased risk of adverse events compared to the native tissue repair that is reported in several studies [969]. The Food and Drug Administration (FDA) of the United States provided warning on the adverse effects of transvaginal mesh use in 2008 and repeated it in 2011[12]. After this, most of the commercial transvaginal mesh kits have been withdrawn from the market. The rate of TVM surgery has diminished dramatically in US and other countries [6]. Also abdominal mesh is associated with risk of mesh exposure as high as 10,5% [15]. Thus, international recommendations consider that native tissue repair is the principal surgical method for POP surgery [69,70]. A synthetic mesh may be considered in complex cases and with recurrent prolapse in the same compartment [71].

2.2.2 Surgical methods

Anterior prolapse

Anterior colporrhaphy is the procedure of choice to repair the midline or central defect of anterior vaginal wall. Prospective studies regarding isolated traditional colporrhaphy have reported a range of success rates at one- to two-year follow-up of 37 to 83 percent. [9] Anterior TVM has superior objective outcomes compared to anterior colporraphy, but there is no significant difference in the functional outcomes and the reoperation rate for complications is increased compared to NTR [10,72–74].

Patients with anterior vaginal prolapse often represent urinary tract symptoms such as incontinence. Combination of POP surgery with midurethral sling reduces the risk of postoperative stress incontinence, but adverse events and voiding difficulties occur more often. [75] In addition, it has been shown that SUI symptoms may be releaved after POP surgery alone in one of three patients and thus the incontinence procedure may be unnecessary [76]. Thus, according to recent Cochrane review, it might be feasible to perform a delayed incontinence procedure if needed [77].

Posterior prolapse

Surgical techniques to repair posterior vaginal compartment prolapse include vaginal, transperineal, transanal and abdominal (open or laparoscopic) approach. The transvaginal route, posterior colporrhaphy is the most common method to repair rectocele. [78,79] It has an anatomic cure rate of 76 to 96 percent [20]. A perineorrhaphy is sometimes included to the posterior colporrhaphy procedure, especially in case of wide vaginal hiatus. It slightly increases the functional length of the posterior vaginal wall, but extensive perineorrhaphy may constrict the vaginal introitus and the risk of de novo dyspareunia is reported to increase from 8 to 26%. [80] Symptoms related to defecation often resolve after posterior colporraphy [49]. However, new bowel symptoms are reported to develope in 11% [81]. Due to high risk of mesh-related complications, use of transvaginal reconstructive materials (synthetic or biologic) to augment repair of posterior vaginal wall prolapse is not recommended [20].

At the time of abdominal surgery, the posterior compartment can be repaired by laparoscopic ventral rectopexy, in which the posterior mesh is extended down to the rectovaginal septum and fixated to the levator muscles. This method is superior over stapled transanal rectal resection in the treatment of obstructed defecation syndrome associated with rectal intussusception and posterior vaginal compartment prolapse such as rectocele or enterocele. [82]

Apical prolapse

Isolated apical defect is rare, but it is often accompanied by descent of the anterior or posterior vaginal wall and exists often in women with POP that extends beyond the hymen [30]. Studies have demonstrated that if the vaginal muscularis is well suspended at the apex, at the same time many anterior defects and some posterior defects will be resolved [83].

There are several different surgical techniques to repair the apical defect and each technique has its own risk-benefit profile [14]. No consensus exists regarding which surgical technique is superior. [31] Primary apical prolapse repair is often performed by *vaginal hysterectomy with McCall culdoplasty*. The vaginal cuff is suspensed by shortening the uterosacral and cardinal ligaments and fixating the ligaments to the vaginal fornix. In a uterine-preserving *Manchester-Fothergill procedure* the ligaments are shortened and fixated in front of amputated cervix. These procedures are accompanied with anterior and/or posterior colporrhaphy if needed.

Other transvaginal approaches to repair apical prolapse with native tissue and sutures are *uterosacral ligament suspension* (ULS) and *sacrospinous ligament fixation* (SSLF). A recent large multicentre (OPTIMAL) trial showed that the anatomic and subjective outcomes of these two techniques were similar and in five years follow-up the estimated surgical failure rate was 62-70% [63]. A Danish database study with 5 year follow-up showed higher reoperation rates for sacrospinous hysteropexy compared to vaginal hysterectomy and Manchester operation (30%, 11% and 7%, respectively) [84]. *TVM* may be used in selected cases with high recurrence risk of apical prolapse [14]. However, a Cochrane review showed no clear evidence that use of apical mesh decreases the awareness of prolase or repeated surgery for prolapse compared to vaginal surgery methods without mesh [14].

The most commonly used abdominal method to repair apical prolapse is *sacrocolpopexy* in which the upper vagina is suspended to the sacrum with mesh. According to Cochrane review, sacrocolpopexy results in a lower rate of recurrent POP compared to the vaginal techniques, but transvaginal repair has a shorter recovery and less morbidity [14]. However, this review includes mostly studies of open procedures whereas nowadays sacrocolpopexy is most often performed via laparoscopy [16]. Laparoscopic sacrocolpopexy is associated with quicker recovery and lower blood loss than open surgery and the anatomical cure rate after laparoscopic sacrocolpopexy is comparable to laparotomy [85,86]. The use of robotic assistancy has showed no benefits compared with the conventional laparoscopic approach [87].

2.2.3 Definition of success

Traditionally, the definition for cure after POP surgery in clinical trials has been based on strict anatomic criteria. [17] POP-Q stage less than two, meaning that the most distal portion of the prolapse is more than 1 cm above the level of the hymen, has been considered as a cure in most of the randomized studies of POP surgery. [88]

However, a significant part of the women who do not meet this criteria, are asymptomatic and satisfied with their condition after the surgical treatment [18].
Current opinion is that the definition of success after POP surgery should include the absence of bulge symptoms and the absence of re-treatment [2]. The hymen as a threshold for anatomical success is shown to be relevant. Barber et al. showed that the question: *Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?* had a high specifity of 99%. However, the sensitivity was only 35% for prolapse beyond the hymen (grades II and III). [2] The International Urogynecological Association (IUGA) and International Continence Society (ICS) joint report on terminology recommends using patient-reported outcomes (PROs), particularly the presence or absence of vaginal bulge symptoms, as well as satisfaction, quality of life, and perioperative data for reporting surgical outcomes in urogynecological research [29].

2.3 HEALTH-RELATED QUALITY OF LIFE AND PATIENT-REPORTED OUTCOMES

2.3.1 Definition and types of measures

Health-related quality of life (HRQoL) is defined as a multidimensional concept that is evaluated by patient-assessed measures of health. These measures include physical and social function, emotional or mental state, burden of symptoms and sense of well-being. [89] It is distinct from quality of life as a whole, which includes also perception of immediate environment such as adequate housing and income. Because HRQoL is a subjective matter, people themselves should assess the grade of how illness or treatment affect these dimensions of life quality.

Patient-reported outcome is a report of the status of a patient's health condition that comes directly from the patient. Patient-reported outcome measures (PROMs) are instruments that are used to report different aspects of disease and therapeutic impact such as symptom bother and frequency, HRQoL or treatment satisfaction. [90] There are numerous available PROs and it is of utmost importance to select the PRO measure that is relevant and applicable to the performed procedure and desired outcome. [91,92]

There are two types of PROMs that evaluate HRQoL: generic and condition-specific questionnaires [93]. *Generic HRQoL questionnaires* are designed as general measures, providing a summary of HRQoL. They can be used in various populations regardless of the disease concerned and thus allow economic evaluation and comparison of different courses of action. *Condition-specific HRQoL questionnaires* are designed for a particular patient group, to measure the impact of a specific disease on HRQoL. These measures focus on aspects that are specific to the condition or

disease and are therefore more accurate to reflect the clinical important change in response to treatment of the specific condition.

2.3.2 Psychometric assessment of patient-reported outcome measures

Requirements for PROMS include feasibility and general applicability, meaning that the questionnaires are easy to use. The ability of a HRQoL measure to improve decision-making in clinical research relies on the psychometric strength of the measure to capture the burden of treatment. Thus, it is essential to assess the reliability and validity properties of the instruments before taking them into use. [93] The appraisal criteria of the assessment of the psychometric properties of PROMs are listed in Table 1.

Reliability means the extent to which a measure yields the same number or score each time it is administered when the construct being measured has not changed. It is assessed by *internal consistency* meaning homogeneity of items in a scale. This is statistically assessed by calculation of Cronbach's alpha. α-values below 0.7 indicate too high heterogeneity, while values above 0.9 indicate too high similarity between items. Thus, the preferred range of α is between 0.7 and 0.9. [94]

Validity examines whether the instrument measures what it is intended to measure and not something else. It includes three dimensions: content validity, criterion validity and construct validity. *Content validity* means representation of the contents; that the measure is readily understood and unambigious to the target population and there is low level of missing data. Another way of expressing content validity is the extent to which an instrument measures the appropriate content and represents the variety of attributes that make up the measured construct. *Criterion validity* refers to the extent to which the measure agrees with an external standard measure, i.e. that the measure correlates with another applicable measure. [94] *Construct validity* means that the measure reflects differing levels of symptoms in differing populations [93]. To ascertain that a measure reflects a clinically important change in patient condition, *responsiveness* is studied [94]. At least 80% completeness of the data show that the PROM is accepted enough. The responsiveness of an instrument may be compromised by *ceiling effect*, which means that patients with the best score may have substantial HRQoL impairment. *Floor effect* means that patients with worst score may deteriorate further. Futhermore, HRQoL measures are language- and culture-dependent questionnaires. If a questionnaire is used in a different language, it should be carefully translated by using the multistep translation process and pretested before taking it into use in particular population. [93]

Table 1. Properties of validated PROMs assessing the subjective outcome of POP surgery. Adapted from Poku et al.2017 [95].

Psychometric property	Subdomain	Tresholds
Reliability	Test-retest reliability	Intraclass correlation ≥ 0.70
	Internal consistency	Cronbach's α 0.70-0.90
Validity	Content validity	Evidence that instrument measures appropriate content
	Construct validity	Correlation coefficient ≥ 0.60
	Criterion validity	Correlation coefficient ≥ 0.70
Responsiveness	Floor effect	No floor effect: < 15% achieve the lowest score
	Ceiling effect	No ceiling effect: < 15% achieve the highest score
	Acceptability	Completeness of data ≥ 80%

2.3.3 Patient-reported outcomes in pelvic organ prolapse treatment

Condition-specific questionnaires

Several condition-specific HRQoL questionnaires have been developed to reflect the outcome following urogynecological surgery [90]. However, there are only few validated questionnaires available which record both symptom distress and QoL including sexual function among the women with POP.

The Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ) are the two most frequent questionnaires that have been shown to be psychometrically valid and reliable instruments for measuring the extent to which pelvic floor disorders affect the quality of life [19]. PFDI evaluates the range of POP symptoms and the inconvenience they cause, whereas PFIQ covers the impact of POP on daily life. [96] The short versions of these questionnaires have also been validated and become more popular in clinical studies and practice nowadays because of a decreased number of questions [97]. PFDI-20 consists of three separate scales: Pelvic Organ Prolapse Distress Inventory (POPDI-6) of six questions about the inconvenience of the prolapse, Colorectal-Anal Distress Inventory (CRADI-8) with eight questions concerning difficulties of defecation, and the Urinary Distress Inventory (UDI-6) with six questions about difficulties in urination. Respectively, the PFIQ-7 consists of three scales. Each of them contains seven questions: the Pelvic Organ Prolapse Impact Questionnaire (POPIQ-7), the Colorectal-Anal Impact Questionnaire (CRAIQ-7) and the Urinary Impact Questionnaire (UIQ-7).

In PDFI-20 and PFIQ-7 questionnaires, the score range of each subscale is 0–100 and maximum total score is 300. Higher scores indicate more bothersome symptoms.

However, the change in summary scores of these instruments that indicates clinically meaningful change in symptoms (minimal important difference, MID) is not clearly defined. Barber et al. demonstrated that the mean decline in summary scores for women who indicated that their postoperative condition was better than before the operation was 45 for PDFI-20 and and 36 for PFIQ-7 [97]. Utomo et al. found in Dutch population that decrease of 22.9 or more points was a true clinically relevant change in total PFDI-20 scores and 28.6 for PFIQ-7 [98]. Among women representing mild prolapse and suitable for conservative treatment a decrease of 13.5 points in total PFDI-20 scores showed to be clinically meaningful [99].

Sexual function of women suffering from POP and/or urinary incontinence is most commonly evaluated by Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) [100,101]. The short version of PISQ contains 12 questions about sexual activity, satisfaction and problems caused by prolapse or urinary incontinence [102]. More recent IUGA-revised validated form of PISQ-12 (PISQ-IR) is usable for both sexually active and inactive and thus may replace the PISQ-12 in future [103].

PFDI-20, PFIQ-7 and PISQ-12 are nowadays widely used and they help investigators to evaluate the efficacy of a particular therapy for POP and to compare symptom severity between patients or groups. [104] These questionnaires have been translated in several languages and tested in different populations [98,105–110]. Other validated prolapse-specific HRQoL measures include Prolapse Quality of Life questionnaire (P-QOL), which includes twenty questions representing nine quality of life domains [111]. In addition, several validated disease-specific questionnaires to evaluate lower urinary tract dysfunction exist [90,112].

Generic HRQoL questionnaires

The use of generic QoL instruments in POP treatment allows broad comparisons between different populations and across other surgical fields and disciplines [90,113]. In addition, it allows the count of utility preference scores for cost-effectiveness research. Until recently, the generic HRQoL questionnaires have not been widely used in POP surgery research [19]. Questionnaires that have been used are The Medical Outcomes Trust instrument (SF-36), Nottingham Health Profile (NHP), EuroQoL-5D (EQoL-5) and 15D.[19] The SF-36 (also known as RAND-36) instrument includes 36 items that cover eight dimensions; physical functioning, role limitations due to physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems and mental health. The short form of this HRQoL measure (SF-12) is widely used in clinical research. Two summary scores, the physical and mental component can be computed. [114] NHP contains a relatively large amount of questions, 38 items covering six dimensions (physical mobility, pain, emotional reactions, social isolation, energy and sleep) [115].

EQoL-5 is a five-dimension questionnaire and each dimension contains three ordinal categories of severity corresponding to no, moderate, or severe problems [116,117]. The single index score represents health utilities using valuations elicited from

a sample of the general public. Recent study by Harvie et al. showed that EQoL-5 provided valid measurements for utility scores in women with POP [118].

The 15D instrument has been widely used and developed in Finland. In gynecology, 15D has showed improved quality of life among women undergoing hysterectomy with or without concominant POP surgery [119,120] and anti-incontinence surgery [112]. The health state description of this instrument includes 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech (communication), excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity [113]. The respondents have five levels to choose in each dimension that describes best his/her state of health at present. The index score range is from 0 to 1 (1 = full health, 0 = being dead) is calculated from the health state descriptive system by using a set of population-based preference or utility weights. The values can be compared to the age-standardized sample population data that comes from the National Health 2011 Health Examination Survey [121]. The MID in the 15D scores are defined ±0.015 [122]. The 15D scores are shown to be highly reliable, sensitive and responsive to change, generalisable at least in Western-type societies [113].

The advantage of 15D is that it can be used as a profile and single index score measure. Compared to EQoL-5, 15D has shown to be superior in discriminatory power in general public and responsiveness to change. [123] The completion rates for the 15D have been at least as high as for the NHP, SF-12 and EQoL-5 and it is roughly comparable to NHP and SF-12 in the responsiveness to change. [113] Both 15D and EQoL-5 are valid for deriving quality-adjusted life years (QALYs), which are widely used in economic evaluation enabling to assess the value for money of health technologies. The main advantage of this concept is that it combines both survival and HRQoL benefits of treatments in a single indicator. However, a study of cardiac surgery showed that 15D and EQoL-5 may lead to significantly different estimates concerning the number of QALYs gained. [124] The evidence of estimating QALYs in prolapse surgery is limited. In a Nordic study of women undergoing mesh surgery for apical prolapse, 15D was shown to correlate with improvements with PFDI-20 and its subscales, and the authors concluded that the instrument may be used in cost-utility and cost-effectiveness analysis of urogynecological surgery [125].

Global index

Patient Global Impression of Improvement (PGI-I) is a single item question that asks persons to rate their improvement after treatment on a seven-point Likert scale (1 = very much better, 2 = much better, 3 = a little better, 4 = no change, 5 = a little worse, 6 = much worse, 7 = very much worse). PGI-I has been shown to be valid in several fields of surgery including urinary incontinence and POP surgery. [126,127] It has showed good correlation with Incontinence Quality of Life Questionnaire and King´s Health Questionnaire [126,128]. Opposite findings were reported in a Danish database study,

which showed higher satisfaction after urogynecological surgery measured by PGI-I compared to International Consultation on Incontinence Questionnaire [129].

2.4 IMPACT OF PELVIC ORGAN PROLAPSE AND TREATMENT ON QUALITY OF LIFE

2.4.1 Generic health-related quality of life

Symptoms of POP greatly affect women's body image. They may affect personal, social, and sexual activities, which can result in reduced physical and social activity. Some women even stop these activities. [50] It has been shown that even one-third of postmenopausal women with symptomatic POP are depressed [130].

Few studies have examined the impact of POP on QoL with a generic QoL tool (Table 2). The frequency of POP symptoms has been shown to associate with poorer QoL. This was found by Xavier et al. in a French cohort of 2,640 women aged 50–61 in which the generic QoL was measured by NHP [131]. In a case-control study by Jelovsek et al., there was an impairment of physical QoL scale, measured by SF-12 [50]. Altman et al. showed significant improvement of QoL measured by 15D one year after apical prolapse mesh surgery [125]. Rahkola-Soisalo et al. found that the mean 15D index improved among those 124 women who underwent hysterectomy for POP, but the difference was no more significant at 10 years [120]. OPTIMAL trial, a randomized study comparing two native tissue vaginal prolapse apical suspensions with midurethral sling surgery, showed improvement in generic QoL at each postoperative time point (6, 12 and 24 months). Clinically and statistically significant improvements from baseline occurred in both mental and physical subscales of the generic QoL. [132]

2.4.2 Condition-specific quality of life

Studies using condition-specific measures have demonstrated improvement of HRQoL following POP surgery (Table 2). These are descriptive studies or randomized trials comparing different surgical interventions for selected vaginal compartment prolapse. Maher et al. reported a significant improvement in condition-specific and generic QoL measures after SSLF and abdominal sacrocolpopexy [133]. Also the CARE trial that compared outcomes of sacrocolpopexy with or without prophylactic urinary incontinence procedure (Burch colposuspension) demonstrated significant improvements in QoL following surgical treatment [134]. So far, the longest follow-up reporting QoL following POP surgery is five years. In OPTIMAL trial, the PFDI summary and subscale scores exceeded minimum clinically important differencies at 5 years and there was no significant difference between the two vaginal approaches of apical prolapse repair (ULS and SSLF). Measured by PGI-I, the

amount of patients reporting “very much better” or “much better” condition than before the operation was also at similar level (56.9 and 54.1%, respectively). [63]

Surgical repair of POP is generally associated with improvement of sexual dysfuction and dyspareunia, whereas the nonsurgical treatments of POP (pessary use and pelvic floor muscle training) show limited improvement of sexual function. [101] The improvement of sexual function after POP repair is multifactorial and is related to improved body image as well as reversal of physical symptoms [50]. Incidence of de novo dyspareunia following POP surgery is reported to be from one to 28 percent. Possible mechanisms include nerve injury, vaginal narrowing or shortened length. Levatorplasty procedure during posterior colporrhaphy has been associated with de novo postoperative dyspareunia. [135] The impact of mesh surgery on sexual function is not clear and some evidence exists that both transvaginal and abdominal mesh augmentation may result in a decline in sexual function and worsening dyspareunia [101]. However, according to Cochrane review, abdominal sacrocolpopexy is associated with a lower rate of dyspareunia than vaginal sacrospinosus fixation [8].

Table 2. Studies including validated patient-reported outcomes assessing the subjective outcome of surgery for pelvic organ prolapse.

Type of measure	Reference	N	Follow-up	Surgical POP procedure(s)	Results
Generic HRQoL					
SF-36	*Brubaker 2008* [134]	322	2 y	sacrocolpopexy	improvement
	Maher 2004 [133]	95	2 y	colpopexy	improvement in physical scores
EQoL-5	*Paraiso 2011* [87]	78	1 y	sacrocolpopexy	improvement
15-D	*Altman 2018* [125]	169	1 y	TVM	improvement
	Rahkola-Soisalo 2019 [120]	124	10 y	hysterectomy	Improvement
Condition-spesific HRQoL					
PFDI-20	*Kissane 2018* [136]	327	3 y	apical NTR	significant improvement (median decrease of scores 54 and 88)
	Rahkola-Soisalo 2017 [137]	164	5	TVM	significant improvement (median decrease of scores 57)
	Paraiso 2011 [87]	78	1 y	sacrocolpopexy	significant improvement (mean decrease of scores 79 and 84)
	Paraiso 2007 [81]	105	1 y	TVM	significant improvement (mean decrease of scores 80-93)
PFIQ-7	*Paraiso 2011* [87]	78	1 y	sacrocolpopexy	significant improvement
	Paraiso 2007 [81]	105	1 y	TVM	significant improvement
PFDI and PFIQ	*Barber 2006* [104]	64	6 m	NTR	significant improvement
	Brubaker 2008 [134]	322	2 y	sacrocolpopexy	improvement
	Nguyen 2018 [138]	222	1 y	all	significant improvement
	Jelovsek 2018 [63]	244	5 y	ULS/SSLF	significant improvement
Global Index					
PGI-I	*Kissane 2018* [136]	327	3 y	NTR	median PGI 2 (much better)
	Larsen 2016 [129]	2581	3 m	all	0.77 (converted scale 0-1)
	Jelovsek 2018 [63]	244	5 y	ULS/SSLF	PGI 1-2: 57 and 54%

EQoL-5; 5 dimensional EuroQoL instrument, HRQoL; health-related quality of life, PFDI; pelvic floor distress inventory, PFIQ; pelvic floor impact questionnaire, PGI-I; patient global impression of improvement, NTR; native tissue repair, POP; pelvic organ prolapse, SF-36; The medical outcomes trust health-related quality of life instrument, SSLF; sacrospinosus ligament fixation, TVM; transvaginal mesh, ULS; uterosacral ligament suspension.

3 AIMS OF THE STUDY

The aim of the study was to evaluate the effect of female pelvic organ prolapse (POP) surgery on health-related quality of life (HRQoL). Furthermore, we wanted to describe the methods of surgery in a Finnish nationwide cohort of women undergoing surgery for POP in 2015 and evaluate the generally used HRQoL measures in the study population.

The specific aims of the study were:

1. To describe the methods used for POP surgery in Finland and to identify the factors that affect clinicians' choice to use either a native tissue repair or mesh repair method (Study I).

2. To translate three commonly used prolapse-specific HRQoL questionnaires (PFDI-20; Pelvic Floor Distress Inventory-20, PFIQ-7; Pelvic Floor Impact Questionnaire and PISQ-12; Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire) into Finnish and to evaluate the validity of these translated questionnaires among Finnish women with symptomatic POP (Study II).

3. To describe patient satisfaction and change in HRQoL, and to determine predictive factors of favorable and unfavorable surgery outcome six months and two years after the POP surgery (Study III).

4. To evaluate the consistency of the two general patient-reported outcome measures (15D and PGI-I; Patient Global Impression of Improvement), and PFDI-20 in assessing the change in HRQoL following pelvic organ prolapse surgery (Study IV).

4 SUBJECTS AND METHODS

4.1 SUBJECTS

Studies I, III and IV
The population was based on a national multicenter study (FINPOP 2015) in which all the women undergoing surgery for pelvic organ prolapse during year 2015 in 41 participating Finnish hospitals were recruited. The inclusion criteria included age more than 18 years and the ability to communicate in written and oral Finnish or Swedish. The study population (n = 3,515 patients, 3,535 operations) covered 83% of all 4,240 women who were operated on for POP in 2015 in Finland. The preoperative questionnaires were filled by 2,931 (83%) patients. In follow-up, altogether 2,528 (72%) patients were eligble for analysis at six months and 2,351 (67%) at two years.

Study II
Sixty-three native Finnish-speaking adult female patients who were waiting for POP surgery participated in the study II. They represented POP in all compartments. The participants were recruited from four hospitals: Turku University Hospital, Kuopio University Hospital, Oulu University Hospital and Kanta-Häme Central Hospital, of which the first three are tertiary university hospitals and the last one is a secondary hospital. All of these hospitals performed urogynecological surgery in 2015 and represented different district areas of Finland: western, eastern, northern and southern part of Finland, respectively.

4.2 METHODS

The patient-reported outcome measures that were included to the study are presented in Table 3.

4.2.1 Studies I, III and IV

The national prospective FINPOP 2015 cohort study was organized by the Finnish Society for Gynecological Surgery and the study period was between 1.1.2015 and 31.12.2015. The study protocol of a national multicenter study with local doctors in charge was adapted from a previous national study of hysterectomies (FINHYST) that was organized by the Society in 2006. All the 45 Finnish hospitals that performed surgery for POP were invited to the study.

The study was implemented with questionnaires that were completed by both doctors and patients. The surgeons completed an electronic questionnaire of the surgical treatment and patient characteristics. The degree of prolapse was assessed by using a simplified Pelvic Organ Prolapse Quantification (POP-Q) system in which the surgeons record the single most distal POP-Q point of all three vaginal compartments (anterior, posterior or apical) in centimeters from the hymen. [27] The operative method was described with a code from the Nordic Classification of Surgical Procedures (NCSP).

At baseline, the severity of symptoms and quality of life were assessed by using validated HRQoL questionnaires including condition-specific Pelvic Floor Distress Inventory (PFDI-20) [97] and generic HRQoL measure 15D [113]. The participants completed the questionnaires either as an electronic or paper form based on their own preferences. The women also reported their worst symptoms related to pelvic floor dysfunction. The options included awareness of a bulge or a feeling of pelvic pressure, urinary or defecation problems, pain, or other symptoms. The information of height (cm), weight (kg), chronic diseases, medication, parity, mode of delivery, and smoking status was reported by the participants in preoperative questionnaire.

The 2,931 patients that answered the preoperative questionnaire received a follow-up questionnaire at six and 24 months postoperatively. Changes in the scores were calculated for those who answered the postoperative questionnaire at either six (n = 2,528) or 24 months (n = 2,351). Patients were asked to assess satisfaction on a 7-likert scale (highly satisfied – satisfied – fairly satisfied – not satisfied nor unsatisfied – fairly unsatisfied – unsatisfied – very unsatisfied) and Patient global index of improvement (PGI-I)[126] was administered six and 24 months after the operations. In addition, the questionnaires included queries of the postoperative complications, hospital admission and reoperations.

4.2.2 Study II

The validity of the HRQoL questionnaires suitable for evaluation of the effect of POP surgery in Finnish population were tested in a study that was performed in 2014, as a pilot study of FINPOP 2015 study. First, a Finnish translation process of the forms of three commonly used HRQoL measures (Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7), and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) was conducted. A multistep translation with four translations of PFDI-20, PFIQ-7 and PISQ was performed. Two of the translations were done by independent professional translators and two by gynecologists experienced in urogynecology. These translations were compared and pretested by a panel of two urogynecological nurses and two native Finnish-speaking nonprofessionals, of which one was bilingual (Finnish–English). The panel was asked to give their comments and opinion on the best translation of each question in all three questionnaires. The final Finnish translation was based on these comments and was approved by the study group of key-in gynecologists. Finally, a

professional medical translator performed back-translations in English and those were compared to the original questionnaires.

The Finnish translated questionnaires (Appendix 1-3) were tested for validity in a study population of 173 women waiting for surgical treatment for POP. Postal questionnaires including two pre-stamped envelopes were sent to the patients. The patients were asked first to fill out and return the test questionnaires. Then, after two weeks, they were asked to fill out and return the re-test questionnaires. The participants gave their informed consent by returning the written questionnaires and the questionnaires were paired by a code number and analysed anonymously.

Table 3. Patient-reported outcome measures (PROMs) that were used in the Studies I–IV.

PROM	PFDI-20	PFIQ-7	PISQ-12	15D	PGI-I
Type of measure	Condition-specific QoL	Condition-specific QoL	Condition-specific QoL	Generic QoL	Global Index
Measures	Symptoms and inconvience related to POP	Impact of POP in daily life	Sexual function	15 dimensions of heath	Condition related to preoperative situation
Subscales	POPDI-6 UDI-6 CRADI-8	POPIQ-7 UIQ-7 CRAIQ-7			
Scoring	0-300 (subscales 0-100)	0-300 (subscales 0-100)	0-48	0-1	Likert scale 1-7

CRADI-8; Colo-Rectal-Anal Distress Inventory, CRAIQ-7; Colo-Rectal-Anal Impact Questionnaire, PFDI-20; Pelvic Floor Distress Inventory (short version), PFIQ-7; Pelvic Floor Impact Questionnaire (short version), PGI-I; Patient Global Impression of Improvement, PISQ-12; Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, POPDI-6; Pelvic Organ Prolapse Distress Inventory, POPIQ-7; Pelvic Organ Prolapse Impact Questionnaire, UDI-6; Urinary Distress Inventory, UIQ-7; Urinary Impact Questionnaire, 15D; 15-dimensional generic health-related quality of life questionnaire.

4.2.3 Statistical analysis

For studies I, III and IV, the patient characteristics and surgical details were analyzed in the whole study group, and the scores of patient-reported measures were calculated at baseline, and in studies III–IV at 6 months and 2 years. The differencies between groups were assessed by using Levene's test and Q-Q plots to assess the distribution of continuous variables.

In study I, the operative details, patient baseline characteristics and PFDI-20 scores were compared between three surgical methods (NTR, TVM and AM), and the differencies between the groups were tested with χ^2-test. The Bonferroni method was applied in assessing the pairwise comparisons in equal variances and Brown-Forsythe test and Dunnett's 3 for comparison of unequal variances. Binary logistic regression was used to identify the predictors for the use of a mesh. The results were

adjusted for age, previous surgery for POP and hysterectomy, sexual activity, degree of bulge symptom, type of hospital and health care district.

In study III, the results of patient characteristics were compared between the respondents and those who dropped out at 2-year follow-up. The Kruskall-Wallis test was used for variables with a skewed distribution. Independent sample t-test was used to assess the difference in the mean of 15D score and its dimensions between the study population and age-standardized population data that was derived from the National Health 2011 Examination Survey [139]. Baseline predictors of favorable and unfavorable outcome of surgery were studied with logistic regression analysis. The results were adjusted for age, BMI, parity, smoking, sexual activity, the degree of prolapse and type of hospital. In study IV, correlations between change of scores in 15D, PGI-I, PFDI-20 and PFDI-20 subscales and 15D dimensions were investigated with Spearman's method. The analyses were restricted to women who had responded to all three questionnaires at baseline and 24 months (N = 2,248 main analyses).

In study II, the scores of PISQ-12, and of PFIQ-7, PDFI-20 and their subscales were calculated at baseline and 2 weeks and tested for construct validity and reliability. Spearman's rank correlation and corrected item-total correlations ≥0.3 were considered as evidence of convergent validity. Intra-class correlation coefficient (ICC) was used to assess the reliability and Cronbach α was used to assess the internal consistency and the preferred range of α was set from 0.7 to 0.9.

All statistical analyses were performed by the study group (NM and A-MT) using SPSS (IBM Corp., Armonk, NY, USA), version 21.0 in Study I, 24.0 in Study II and 25.0 in Studies III–IV. A paired-sample t-test was used to test the statistical significance of difference in the means of outcome measures (e.g. at different point of time). The level of significance was set at $P < 0.05$.

4.2.4 Ethical approval

Both pilot and FINPOP 2015 studies were approved by the Ethical committee of University of Eastern Finland (2014/5), and they followed the ethical standards of the Helsinki Declaration. The Finnish Ministry of Social Affairs and Health approved the study protocol and institutional approval of each participating hospital was obtained. The study is included in the ClinicalTrials.gov protocol registration system (NCT02716506). Written informed consent was obtained from each patient. Timing of the study process, follow-up studies and publications, is described in Figure 5.

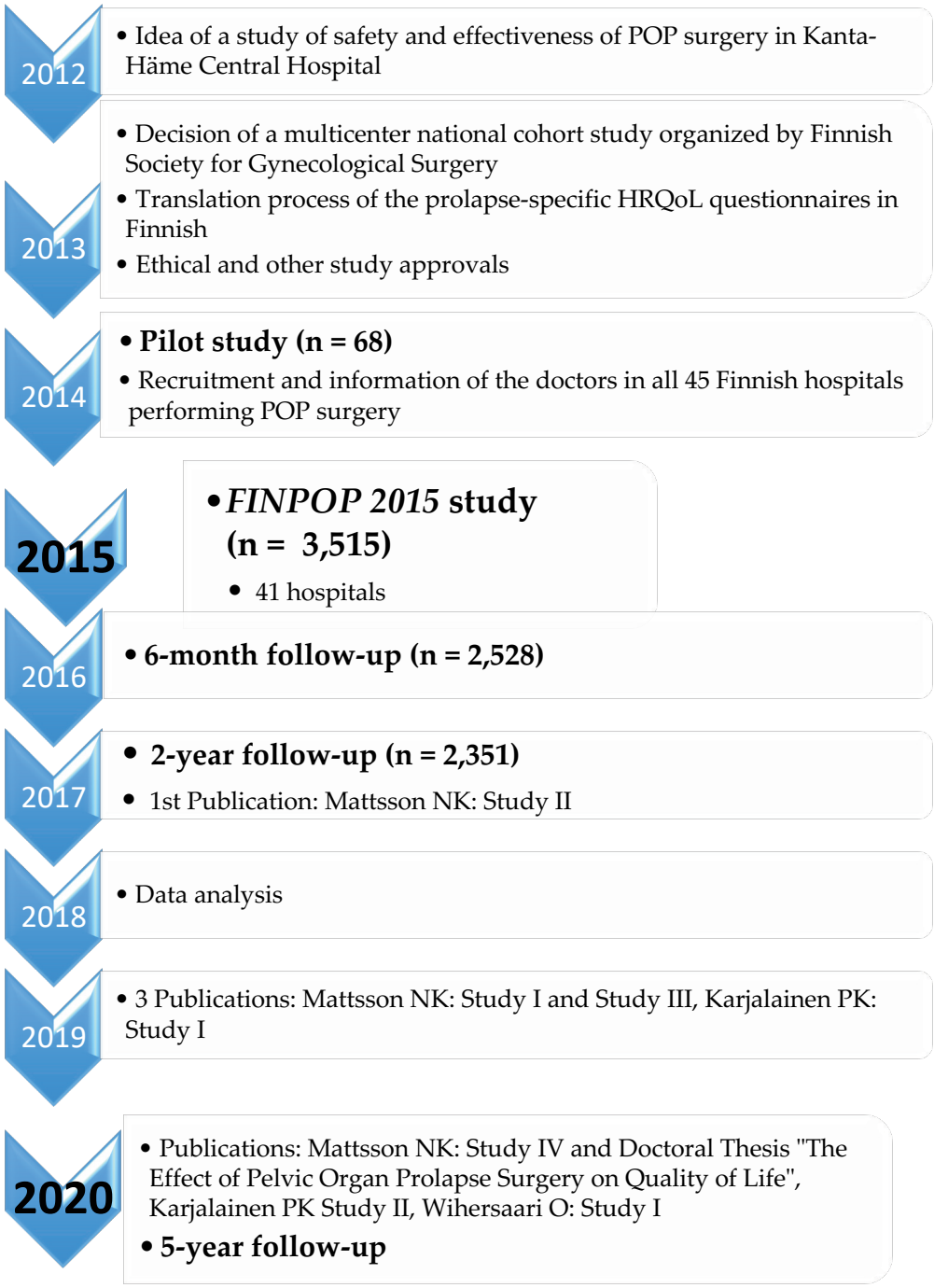

Figure 5. The FINPOP 2015 study process.

5 RESULTS

5.1 METHODS OF SURGERY FOR PELVIC ORGAN PROLAPSE (STUDY I)

Altogether 3,535 (83%) out of all 4,240 operations that were performed in Finland in 2015 were included in the study. The study flow is showed in Figure 6. In 41 centers, the participation rate varied from 42 to 100%.

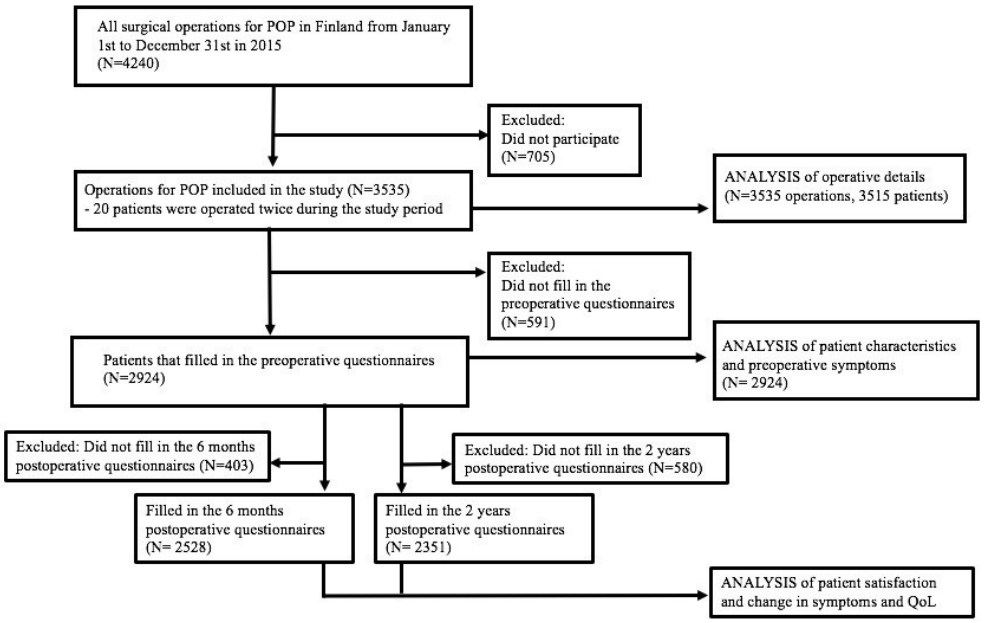

Figure 6. The study flow.

The surgical methods are shown in Figure 7. Native tissue repair (NTR) was the most common surgigal method for pelvic organ prolapse (N = 2,855; 81%), followed by transvaginal mesh (TVM, N = 429; 12%) and abdominal mesh (AM, N = 251; 7%). Approximately 92% of those who underwent primary prolapse surgery were operated with NTR.

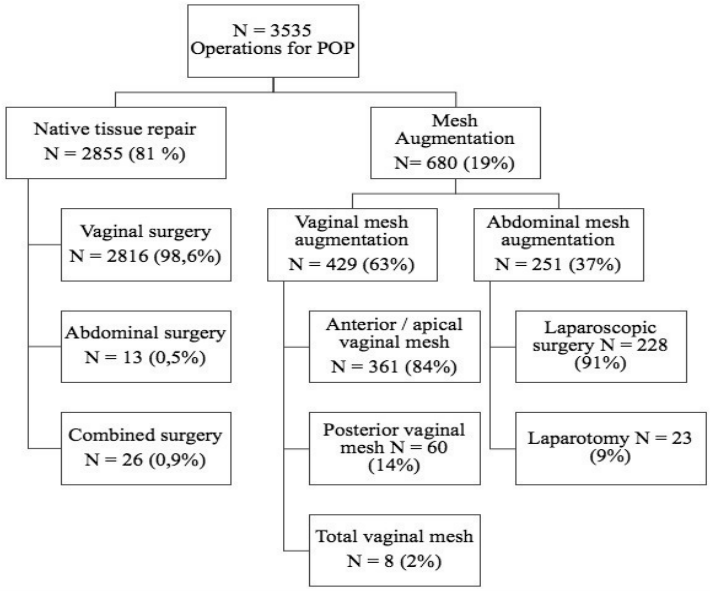

Figure 7. The surgical methods.

The mean age of the patients was 64.0 (±10.7) years. Altogether 1,054 (39.1%) were sexually active. One in four patients (N = 891) had undergone previous prolapse surgery, and all these patients were symptomatic. The anterior vaginal compartment prolapse was the most common form of prolapse. Multicompartment repair was performed in 41% (N = 1,469) of the operations.

The most common symptom of the prolapse was awareness of a bulge that was reported by 93% of all the patients and 69% (N = 2,003) assessed the feel of bulge or pressure to be the worst symptom related to their pelvic floor dysfunction. Urinary symptoms were reported to be the worst symptom by 16% of the patients, defecation symptoms by 10% and feeling of pelvic pain by 2%.

The strongest predictor of mesh surgery was history of previous prolapse surgery for the same vaginal compartment (adjusted OR 56, 95% CI 38–84 for TVM and adjusted OR 22, 95% CI 14–34 for AM). In addition, previous hysterectomy, severe bulge symptoms and advanced prolapse were associated with mesh surgery.

TVM associated with recurrent advanced prolapse in anterior compartment and AM with advanced prolapse in apical and/or posterior vaginal compartment including rectal intussusception. The women in TVM group were significantly older than in other groups, more often sexually inactive and on medication for chronic disease. Preoperative PFDI-20 scores were highest in AM group (108 vs 103 in the TVM and 98 in the NTR group, P = 0.012). In TVM group, the patients reported urinary symptoms more often compared to the patients in other surgical treatment groups. Differences in BMI or smoking habits between the groups were not detected.

There was significant variation in the practices between the hospitals and nearly 10-fold difference between the highest and lowest odds ratio for the TVM use

between the healthcare districts was detected (OR 3.08, 95%CI 1.98-4.80 and 0.33, 95%CI 0.18-0.61, respectively).

5.2 VALIDITY OF THE FINNISH VERSIONS OF PROLAPSE-SPECIFIC QUALITY OF LIFE QUESTIONNAIRES (STUDY II)

Altogether 90 (52%) patients returned the first questionnaire and 27 of those were exluded (17 patients did not return the second questionnaire, 8 patients returned the second questionnaire more than two weeks later, one patient described the symptoms first without and then without a prolapse ring and one patient that described symptoms before and after POP operation). The item response rate in PDFI-20 and PISQ-12 was high (99.8 and 98.9% for each, respectively). For PFIQ-7 the response rate was significantly lower, only 60.0%. In PFDI-20 the subscale scores could be calculated in 96.8% cases for POPDI-6, 98.4% for CRADI-8 and 100% for UDI-6. For PFIQ-7, scores that could be calculated for each subscale were much lower (82.5% of cases for UIQ -7, 77.8% for CRAIQ-7 and 79.4% for POPIQ-7).

Neither floor nor ceiling effects were observed with PFDI-20 or PISQ-12. With subscales of PFIQ-7, ceiling effects were not observed, but there was evidence of floor effect. Altogether 7% of the respondents reported the minimum value of zero in total PFIQ-7 scores and 16–18% in the subscales.

Construct validity was acceptable for PFIQ-7 and PFDI-20, based on the item-total correlations. PISQ-12 showed the lowest construct validity (r=0.138–0.711). The total scores of both PFDI-20 and PFIQ-7 correlated well with their respective subscales.

Reliability in the test-retest analysis was shown to be good for all the three instruments. Intra-class correlations were strong (range from 0.75 in PFIQ-7 to 0.92 in PFDI-20, $P < 0.001$ for all). The internal consistency of all the three instruments, measured by Cronbach's α indicated high homogeneity.

5.3 IMPACT OF PELVIC ORGAN PROLAPSE SURGERY ON QUALITY OF LIFE (STUDY III)

The follow-up questionnaires were received from 2,528 (72%) patients at six months and 2,351 (67%) at two years (Figure 6). The patients that did not participate the follow-up were younger and more often smokers compared to those who returned the 2-year questionnaire (mean age: 63.3 vs 64.4 years, $P = 0.004$ and smoking 11.9% vs 7.9%, $P = 0.001$). Patients that underwent mesh surgery participated the follow-up more often than those who were treated with native tissue repair (73.6% in the TVM and 73.0% in the AM group vs 65.4% in the NTR group, $P < 0.001$). In the baseline symptom scores or general HRQoL measures there were no significant differencies between the respondents and non-respondents. Altogether 7% of the respondents (N = 165) reported to have undergone repeated surgery for recurrent prolapse, but data on whether the recurrent prolapse occured in the same or different vaginal

compartment as the previous surgery was not available. In addition, possible conservative treatment options for recurrent prolapse were not asked postoperatively.

A significant reduction in symptoms was detected. The PFDI scores decreased both at the 6-month and the decrease sustained at 2-year follow-up (mean decrease 55.5 and 50.4 points, respectively). At 2 years, 72.2% of the patients had a clinically meaningful decrease of 23 or more points in total PFDI-20 scores. A total of 18.8% (N = 433) patients reported a bothersome bulge symptom. Altogether, 76.3% (N = 1756) of the patients that returned the 2-year questionnaire had no symptomatic bulge and reported no reoperation for prolapse.

The baseline 15D score showed significantly lower generic HRQoL among the study population than that of the age-standardized female population (mean 0.889 versus 0.904, $P < 0.001$). A clinical meaningful improvement in the 15D score at six months was observed (+0.019, 95% CI 0.017–0.012), but not anymore at the 2-year follow-up, when the total score was close to the baseline (mean 0.898, 95% CI 0.894–0.902). However, a marked improvement was observed also in 2-year follow-up in dimensions of sexual activity, excretion and discomfort and symptoms. The baseline and follow-up 15D scores are shown in Figure 8.

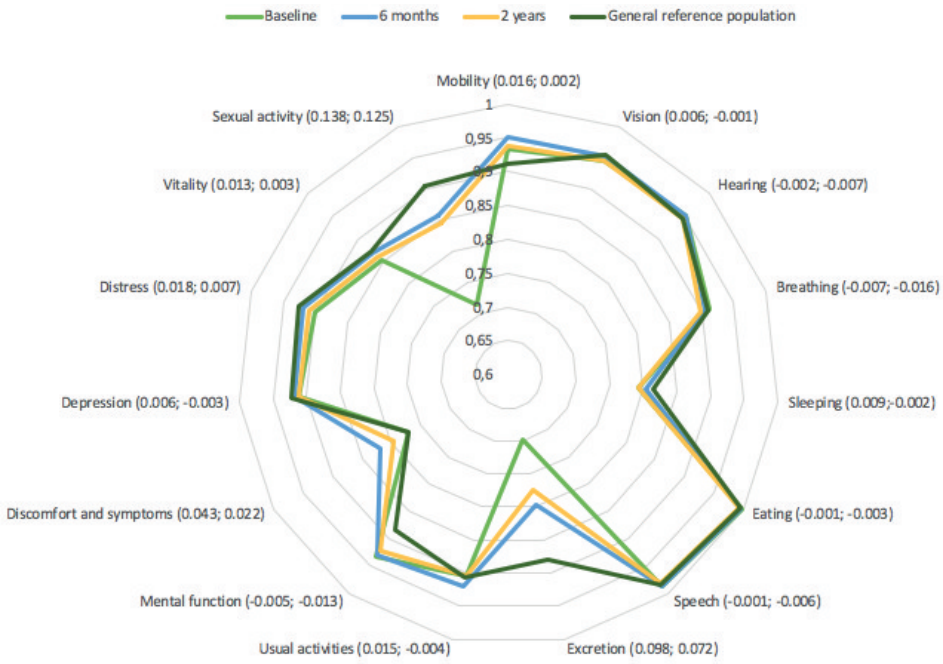

Figure 8. The generic HRQoL measured by 15D.

Altogether 90.1% of the patients considered their condition to be better and 4.8% considered it to be worse compared to the preoperative situation at two-year follow-up (PGI-I scales 1-3, Figure 9). Satisfaction with the operation was reported by 84.4% (N = 1,935) patients while 8.0% (N = 183) were unsatisfied. Recurrence of the prolapse was the most common reason for dissatisfaction and 40 patients were dissatisfied with the operation because of a complication. Altogether 93.8% (N = 2,127) of patients would recommend the operation to a close friend suffering from POP.

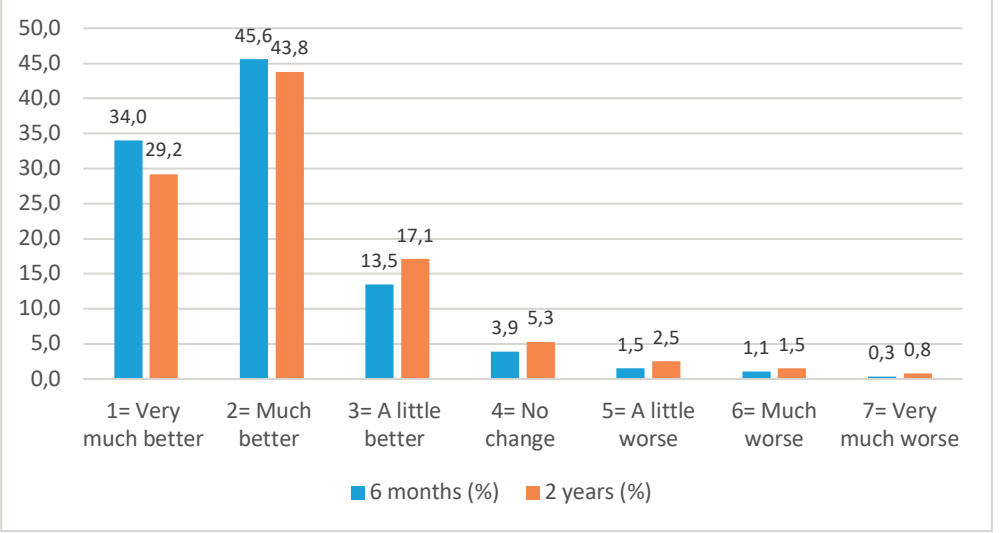

Figure 9. Patient global index of improvement (PGI-I) at 6 months and 2 years after the operation.

The most consistent predictive factor for a favorable outcome that was measured by all three instruments was apical prolapse beyond the hymen (RR 1.27–2.06). Correspondingly, the same factors that were shown to predict favorable outcome of surgery (especially advanced apical prolapse), reduced the risk of an unfavorable outcome of surgery (RR 0.48–0.78). Sexual activity was a preventive factor of an unfavorable outcome of surgery as evaluated by the 15D (RR 0.70, 95% CI 0.57–0.85, P < 0.001). Current smoking increased the risk of unfavorable outcome, evaluated by PGI-I (RR 1.69, 95% CI 1.02–2.81, P = 0.042).

5.4 CORRELATION OF THE PATIENT-REPORTED OUTCOME MEASURES OF POP SURGERY (STUDY IV)

The proportion of patients that reported "much better" outcome of surgery at 24 months follow-up varied significantly between the three outcome measures: 1,128 (50.2%) patients by PFDI-20, 1,638 (72.8%) by PGI-I and 675 (30.0%) by 15D.

The generic 15D instrument correlated weakly between the two other outcome measures (Spearman's rho<0.3 for all, P <0.001). The strongest association was observed with sexual activity and excretion subscales (rho 0.27–0.39, P <0.001). Correlation between PGI-I and changes in PDFI-20 was stronger (rho=0.39 for total score and 0.19–0.40 to its subscales, all P <0.001). The strongest correlations were observed between improvement in excretion dimension of 15D, PFDI-20 total scores and UDI-6 (rho=0.348–0.395, P <0.001), all other correlations were ≤0.3.

When the comparability of changes was assessed, the highest agreement between ratings was observed between PFDI-20 and PGI-I. The degree of change was rated identically for 50.6% of patients whereas for PFDI-20 and 15D it was 33.0%.

The results of the Studies I–IV measured by PROMs are presented in Table 4.

Table 4. Conclusions of the patient-reported outcome measures (PROMs) findings in studies I-IV.

PROM	PFDI-20	PFIQ-7	PISQ-12	15D	PGI-I
Study I	High scores associated to mesh surgery	NI	NA	NA	NA
Study II	Valid in Finnish	Not valid in Finnish	Valid in Finnish	NI	NI
Study III	Improved significantly in 78% of patients at 6 months and 72% at 2 yrs	NI	NA	Improvement in dimensions of Sexual activity, Excretion, Symptoms and discomfort	Median 2 (much better) at 2 yrs
Study IV	Weak correlation with 15D Moderate correlation with PGI-I	NI	NA	Weak correlation with PFDI-20 and PGI-I	Weak correlation with 15D Moderate correlation with PFDI-20

NA; Included, but not analyzed, NI; Not included

6 DISCUSSION

6.1 PELVIC ORGAN PROLAPSE SURGERY IN FINLAND

POP surgery incidence and previous surgery

Surgical treatment for female pelvic organ prolapse is common in all countries. During the study period of year 2015, the total amount of POP operations was 4,240 and the overall rate of prolapse surgery in Finland was 1.5 per 1,000 women. This is comparable to the results of a review by Barber et al. who reported incidence of POP surgery range from 1.5 to 1.8 per 1,000 women [2]. In a study of 15 OECD countries in 2012, the mean incidence rate was 1.38 per 1,000 women and in other Nordic countries, the rate was somewhat higher than in Finland (2.0 per 1,000 women in Sweden and 1.8 in Denmark). [16] The reason for this is not clear but may partly be explained by differencies in treatment methods and age distribution of the population between the countries. The PFDI-20 scores before the operation were at the same level (mean 99.7) as in other studies [98,99]. This suggests that the the patients who are selected to surgical treatment for POP suffer from bothersome symptoms and thus, the indications for POP surgery in Finland are comparable to other reports.

In our study, one in four of the patients had undergone previous surgery for POP, and altogether 17% of the patients had a recurrence in the same vaginal compartment. Although considerably high, this finding suggests a moderate recurrence rate after POP surgery in Finland compared to the widely cited study of Olsen et al. from year 1997, who reported recurrence rate of 29% in United States [5]. In a Finnish population-based register study by Kurkijärvi et al., altogether 9.8% had a subsequent operation for POP during the study period, 1997–2009 [4]. According to Cochrane review, the anatomic recurrence of prolapse is 38% over one to three years of follow-up after NTR and 19% are aware of the prolapse [9]. Majority of the recurrence is explained by lack of apical support. Correction of anterior or posterior prolapse alone does not repair apical descent. Thus, apical support must be carefully evaluated preoperatively in all patients to determine whether an apical suspension is indicated.

We found that previous hysterectomy was associated with advanced prolapse and mesh surgery. Some of the previous studies support the assumption that hysterectomy increases the risk of later prolapse surgery [140,141]. In a Danish cohort study, the uterine-preserving transvaginal Manchester-Fothergill procedure was associated with a lower recurrence rate than vaginal hysterectomy [142]. In our study population, relatively few (N = 37) Manchester operations were performed compared to vaginal hysterectomies (N = 1,271). Manchester procedure or hysteropexy may be

valuable in cases of apical prolapse without indication for hysterectomy. On the other hand, it has been shown that hysterectomy at the time of primary POP operation may decrease the risk for recurrence [21], but increase the risk of some perioperative complications [143]. Thus, the role of concomitant hysterectomy is controversial [144] and the method of surgery should be decided individually according to clinical findings, symptoms and patient's opinion.

Repair with native tissue or mesh

Current international recommendations suggest that native tissue repair should be the first choice of method for POP surgery [69]. Our results show that Finnish practices follow these guidelines; NTR was the commonest method of POP surgery in Finland in 2015; more that 80% of patients underwent vaginal native tissue reconstruction.

Due to increased risk of mesh-related complications reported with TVM, mesh is recommended to be used only after strict consideration and patient counsel in recurrent prolapse [78]. In a large retrospective cohort study of more than 43,000 women, there were about 12% mesh removal or revision rates but no differences in mesh complications between transvaginal and abdominal methods [145]. However, they showed a marked increase in repeat POP operations for TVM, whereas the risk did not differ between AM and vaginal native tissue apical repairs [145]. In our study, 680 (19%) of the operations were mesh operations, 12% transvaginal and 7% abdominal mesh. A recurrent POP in the same vaginal compartment was the strongest predictive factor for the use of a mesh in POP surgery (RR 56 for TVM and 22 for AM). This is in line with the recommendations [71].

An advanced anterior prolapse and increasing age were nother predictive factors for TVM in our study. There is limited evidence that TVM may be beneficial in advanced anterior prolapse since it is most prevalent and prone to failure after repairs [71,73]. However, anterior TVM has a mesh extrusion rate of about 10% with 6% requiring surgical correction [73]. Further on, most of the evaluated TVM kits are no more on the market and the newer available kits lack evidence of safety. Thus, according to recent recommendations, NTR is recommended method in anterior prolapse repair and use of mesh may be considered only after appropriate patient counseling in women with factors that significantly increase the risk of prolapse recurrence (e.g., obesity, large anterior wall defects) [9,70]. In apical prolapse, there is no clear evidence that use of mesh decreases the recurrence [14]. However, patients with advanced recurrent prolapse and high age or medical comorbidities that preclude more invasive and lengthier abdominal procedure may benefit from TVM [31,71].

In posterior compartment prolapse, it is not advisable to use TVM [20]. In line with this recommendation, posterior prolapse was a protective factor for TVM in our study. On the other hand, advanced apical and posterior vaginal compartment prolapse and rectal intussusception were predictive factors for AM, which also is in accordance with the recommendations [88]. In addition, high PDFI-20 scores indicate bothersome symptoms associated with AM. It must be remembered that the

preoperative evaluation of the bowel symptoms and co-operation with colorectal surgeons is essential for finding out the patients who may present coexisting intussusception and benefit from rectopexy.

In primary POP surgery, the use of TVM is not recommended. In our study, among the 2,644 primary POP operations a total of 206 (8%) were mesh surgeries. This is about the same as in a large Scottish retrospective cohort study of 18,986 women (7%) [146]. The regional differencies also in primary mesh surgery were wide and health district was a significant risk factor for primary TVM surgery. The hospital level did not influence the surgical method, whereas the rates varied significantly between hospitals. In many hospitals, few doctors are in response of the POP surgery and individual clinician's preferences may influence the rate of the surgical methods.

The incidence of mesh surgery varies significantly between countries [16]. In our study, the TVM rate of 0.15 was reasonably lower than in Sweden and higher than in Denmark (0.37 and 0.07 per 1,000 women, respectively), whereas the rate of sacral colpopexy was much lower in both countries compared to ours (0.090 vs. 0.015 in Sweden and 0.006 in Denmark) [16]. These findings indicate that TVM was used moderately and AM was a reasonably common procedure in Finland during the study period. Lower mesh rates in Denmark may be explained by centralization of the prolapse surgery in few hospitals and practices being regulated by the authorities. After the study period, most commercial transvaginal mesh kits have been withdrawn from the market. Thereby the rate of TVM surgery has diminished significantly in Finland, as in all countries. [7]

We observed an almost 10-fold regional variation in the rate of TVM use between the hospitals. Differences in the population and participitation rate of the centers may partly explain this, but obviously it implies different practices between hospitals. To our knowledge, the regional variations of POP surgery methods have not been reported in previous European studies. Brown et al. showed regional and racial differencies in rates of POP surgery and supposed it to reflect variations in physician practice, patient preference, and gynecologic care utilization in United States [68].

According to recent International Federation of Obstetrics and Gynecology (FIGO) recommendations, mesh augmentations should be restricted to multidisciplinary referral centers, and performed by surgeons with appropriate training [69]. Our findings of the high variation in POP surgical methods indicates a need for national guidelines also in Finland.

6.2 PATIENT-REPORTED OUTCOME MEASURES IN PELVIC ORGAN PROLAPSE SURGERY

Finnish versions of prolapse-specific outcome measures

In evaluating the effectiveness of treatment and comparing the results of different surgical methods, it is essential to measure the subjective outcomes. The patient-reported outcome measures (PROMs), rather than strict objective measures such as stage of anatomic outcome, are nowadays considered to be obligatory tools in prolapse intervention studies[18]. To ensure the reliability of the results, it is essential to use questionnaires that are shown to be reliable and valid [93]. Each population and language has unique features and inaccurate translations of the questionnaires may lead to bias. Thus, it is essential to validate the translated PROMs in the target population. In prolapse research, the most often used PROMs include PFDI-20, PFIQ-7 and PISQ-12 [97,102]. These questionnaires were not previously validated in Finnish. In Study II, the Finnish versions of PFDI-20 and PISQ-12 were found to be reliable and valid in evaluating the symptoms and the quality of life among Finnish women with pelvic organ prolapse.

Our results are comparable to other two Nordic studies, which showed acceptable psychometric strength for the Swedish translations of PFDI-20 and PISQ-12 and the Danish translation of PFDI-20 [106,107]. However, we found not acceptable validity of the Finnish translation of PFIQ-7. The response rate was only 60%, showing low validity. Ceiling effects were not observed, but all the three subscales of PFIQ-7 showed floor effect. This means that a significant part of participants reported minimal symptom scores in PFIQ-7. These results are partly comparable with previous validation studies of PFIQ. Similar to our results, significant floor effect was found in Dutch translation of PFIQ-7 [98]. Opposite difficulties were found in the Danish validation study, which showed a major ceiling effect for PFIQ-7 [106]. In comparison, the Swedish translation of PFIQ-7 showed acceptable psychometric properties [107]. Thereby, it can be concluded that some but not all the problems with the Finnish version of PFIQ-7 may not be due to cultural reasons. Future evaluation of PFIQ-7 instrument in the Finnish population is needed before it can be considered as a valid PROM in urogynecological research.

Comparison of patient-reported outcome measures in POP surgery

There are several different PROMs that are used in POP research and each have their own properties, strengths and limitations [90]. In FINPOP 2015 study, the outcomes of POP surgery were measured by three different instruments, PDFI-20, 15D and PGI-I, at six months and two years after the surgery. The Finnish validated version of PDFI-20 was used as outcome measure to evaluate the change of prolapse-related quality of life. In addition, generic HRQoL measure 15D and global index PGI-I were included, to increase the information of the effect of the surgery. All these patient-

reported instruments showed increased QoL compared to preoperative situation. However, the instruments were weakly correlated. This indicates that the quantified effectiveness depends on the PROM applied, which is essential to know in assessing the impact of treatment on QoL and comparing the results of different studies.

Generic QoL instrument 15D is widely used by Finnish researchers and utilized in several different therapeutic areas. It has been shown to be valid in assessing the effect of treatment and allows comparisons across a variety of conditions [113]. However, like all the generic HRQoL questionnaires, 15D lacks sensitivity of a specific condition. Thus, when applied to women with a specific condition such as POP, the effect of treatment may not be seen as a statistically significant improvement in 15D total score, although it may seem to be a clinically important improvement. This was reported by Rahkola-Soisalo et al. in a study assessing change of HRQoL ten years after hysterectomies (FINHYST) [120]. Altman et al. showed 15D to correlate with the change of PFDI-20 scores [125]. They found improvement in seven out of 15 dimensions of 15D in a one-year follow-up after mesh surgery for apical prolapse. These inconsistent findings compared to ours may be explained by the differences between the study populations. A more homogenous population in Altman's study with advanced prolapse selected to TVM surgery method may explain better correlation of these instruments than in our heterogenous study population.

In the present study, the overall changes in 15D were mainly explained by changes in sexual activity and excretion, which is similar to the findings of Rahkola-Soisalo et al. [120]. These dimensions are closely related to prolapse and the inconvenience of the pelvic distress symptoms. The other dimensions of HRQoL, such as vision and mobility, are not affected by prolapse, but the mental dimension could be affected as it has been shown to associate with depression in a previous study [130]. However, in the present study population, no change was detected after treatment for POP in mental dimension of 15D, neither impairment compared to the age-standardized population. This may be explained by the limited sensitivity of 15D instrument to detect symptoms of depression. Thus, the changes of QoL following POP surgery may not be detected by generic HRQoL instruments.

Most of the HRQoL measures are relatively long and require time and calculations to derive a score that is not interpretable instinctively to clinical treatment. Thus, global indexes that ask the patient to rate the response of her condition to the treatment have been developed. Such scoring systems have been validated for the evaluation of several medical and surgical fields and are widely accepted in the recent literature. [126] Advantage of the global index is that it is much more simple and easier to use than the HRQoL measures. It allows interpretation and comparison of the results across different research settings and clinical practice.

PGI-I has been shown to be valid in urogynecological research [127], but to our knowledge, it has not been evaluated in the Finnish population previously. This retrospective instrument consists of a single simple question and thus the cultural differencies may not be crucial. However, in the future, the validation process of PGI-I instrument in the Finnish population would be recommended. The advantages of

using a global index is that it provides the single best measure of significance of change in condition directly from the patient's perspective. In addition, it has been shown to be feasible both in research setting and in clinical practice as it is easy to fill in and less time-consuming than the more detailed multiple HRQoL questionnaires. [126]

Altough the global ratings can be precise when used to assess the same person over time, they have a degree of imprecision across the spectrum of individuals by whom they might be used [129]. In addition, the global indexes are completely retrospective measures, whereas HRQoL instruments can be used as outcome measures in prospective studies.

In conclusion, it is essential to acknowledge the properties of the PROMs and, if possible, use several validated measures in research purpose. However, in clinical use for assessing quality of treatment and patient satisfaction, the global index could be useful as a simple outcome measure. In addition, a simpler condition-specific instrument, for example the PFDI with fewer than 20 questions, might be useful.

6.3 EFFECT OF PELVIC ORGAN PROLAPSE SURGERY ON QUALITY OF LIFE AND PREDICTIVE FACTORS FOR SURGICAL OUTCOME

Condition-specific quality of life

Condition-specific QoL was evaluated by PDFI-20, which showed that concerning the symptoms related to POP, approximately seven out of ten patients experienced better quality of life two years after the surgery, compared to the preoperative situation. In a review of five RCTs, the mean decrease of PFDI-20 scores was 74.03, which is more than in our study (55.5 at six months and 50.4 at two years after the surgery) [147]. However, the RCTs are designed to evaluate the efficacy of specific surgical interventions. These studies often include a certain degree of prolapse of a specific vaginal compartment. Thus, the patients may have a greater potential for improvement after surgery than in a more heterogenous population that represents also the patients with multicompartment prolapse. Even 56% of the operations included multicompartment repair in a Scottish cohort study of nearly 100,000 women, compared to 46% in our study [21]. Therefore, data from this heterogenous cohort study with validated HRQoL instruments may be helpful for clinicians when they counsel patients about the outcomes of surgical treatment for POP.

Generic health-related quality of life

Our study confirms the previous findings that POP reduces the generic HRQoL, especially the sexual activity dimension [120,125]. In addition to sexual activity,

dimensions of excretion, and discomfort and symptoms showed marked improvement after POP surgery. These improvements sustained during follow-up, which is in line with the previous study by Lukacz et al. that showed improved body image and sexual function among 374 women who underwent transvaginal surgery for prolapse [132]. The follow-up of two years was similar to ours. However, the improvement of generic HRQoL was not that evident in our study. At six-month follow-up, the improvement in total 15D index suggested a clinically important improvement. At two-year follow-up, the total index was somewhat better than in the age-standardized population, but the difference was not clinically important anymore. The findings of a modest effect of POP surgery on QoL when assessed by 15D total index support the previous data [120] and show that generic QoL questionnaires lack sensitivity when they are applied for a specific condition [90].

Patient satisfaction and predictive factors for surgical outcome

Altogether 84% of the patients were satisfied with the outcome of surgery at two-year follow-up and even 94% would recommend the surgery for a close friend. These were somewhat better results than in a previous prospective cohort study of 222 women undergoing either vaginal or abdominal POP surgery (72.5% and 89.7%, respectively). However, approximately 25% of women in that study required additional therapy for pelvic symptoms during the one-year follow-up, and 8.2% were re-operated for recurrent POP. [138] In the present study, 7.0% of the patients reported that they had undergone a re-operation for prolapse during the two-year follow-up. Altogether 8.0% were unsatisfied with the surgical outcome, mostly due to recurrence of a symptomatic prolapse.

Patient satisfaction is shown to associate with preoperative expectations [148] and thus, patient counselling about the predictive factors of surgical outcome is important. An advanced apical prolapse beyond the hymen and vaginal bulge feeling were the strongest predictive factors for favorabble outcome of surgery. This finding is logical and supports the clinical assumption that bothersome prolapse should be treated surgically. Bohlin et al. studied factors influencing the outcome of POP surgery in a Swedish national database. They found that in a one-year follow-up, 75% of the patients were satisfied with the surgery, and sensation of a bulge was reported by 20% of the patients. Risk factors for recurrence of prolapse included prior hysterectomy, obesity, severe postoperative complication or infection, anterior vs posterior colporrhaphy and local vs. regional anesthesia. [55] Although obesity is a risk factor for POP and its recurrence, it has been shown that obese women have no difference in outcome of POP surgery compared with nonobese counterparts [37]. This is similar to our findings. Neither was ageing associated with outcome of surgery, which is in line with previous studies [136].

Use of mesh has shown to decrease the probability of recurrence [9,14]. Several studies have shown that mesh augmentation, especially TVM, associates with higher rate of complications [9,149]. However, the present study showed that women in TVM

surgery group were more likely to have a favourable outcome when the outcome was measured by PGI-I. On the other hand, there was no difference compared to women in other surgery groups when the outcome of surgery was measured by 15D and PFDI-20 in two-year follow-up. However, it must be remembered that mesh-related complications such as erosions may occur even several years after the operation [9].

In the present study, smoking was found to associate with an increased risk of unfavourable outcome of POP surgery, when the outcome was measured by PGI-I instrument. This finding may partly be explained by other health disadvantages of smoking. In addition, patients who smoked were less likely to return the 2-year follow-up questionnaire. Altough it is not clear why the association with unfavourable outcome of surgery and smoking was detected only in one out of three measures, this finding supports the previous studies among plastic reconstructive surgery; smoking decreases blood flow and healing of the wounds and thus may hinder recovery of a patient from the surgery [150]. In addition, smoking has been shown to be a risk factor for mesh erosion in prolapse surgery [151]. These results suggest clinicians to encourage the patients for smoking cessation when surgical treatment for prolapse is planned.

In conclusion, in this large nationwide cohort two years after POP surgery, patient satisfaction was as high as 84% and seven out of ten patients experienced better prolapse-related quality of life two years after the surgery. Moreover, nine of ten patients perceived their condition to be at least somewhat better than before the operation.

6.4 STUDY STRENGTHS AND LIMITATIONS

The major strength of this national cohort study is the data including 41 of all 45 hospitals that performed prolapse reconstructive surgery in Finland. The study population represents 83% of all women who were operated on for POP in 2015. To my knowledge, this is so far the largest published prospective cohort study that evaluates POP surgery outcome using validated patient-reported outcome measures. Although the study population is a good presentation of women with POP, it may lack a proportion of women who suffered from bowel symptoms and were admitted to colorectal surgeon.

Another strength of the study is the use of validated patient-reported outcome measures. As shown in study IV, the PROMs were weakly correlated, which indicates that the quantified effectiveness of the study is dependent on the instrument applied. Therefore, the use of multiple outcome measures increases the reliability of the study results and allows comparison with other studies. In addition to patient satisfaction query, altogether three different PROMs, both generic and condition-specific instruments, were applied.

Altough the participation rate for the follow-up questionnaires was high (72% at six months and 67% at two years), in cohort studies the loss of follow-up may not be entirely random. The only difference between responders and non-respondents was that the latter group was more likely to smoke and slightly younger. Thus, baseline characteristics of the respondents at two years was a good representation of the entire study population. Characteristics such as weight and height were reported by the patients and not checked during the surgical treatment, which may be considered a limitation.

The socioeconomic status and race of the patients was not recorded. Therefore, for example patients with higher education may be overpresented in the study. In this Finnish study population (mean age 64 years), the ethnicity and racial distribution is minimal, so it is racially homogenous respresenting white European women. Thus, it may be debatable if the results can be attributed to more heterogenous populations like in the US. Latin and white women have been shown to have higher risk for symptomatic prolapse than Afro-American women. However, there is no evidence that ethnicity associates with the outcome of the POP surgery. [152,153]

Various methods for POP repair, including both native and mesh augmentations in all vaginal compartments, were included to the analysis of surgical outcome. The heterogeneity of the surgical methods may be considered a limitation. However, the present study population reflects the real-life clinical setting and the results of the study can be used as an average outcome of surgery when counseling patients who consider undergoing an operation for POP.

The anatomical success of the surgery was not assessed, which can be considered a limitation. However, in the large cohort it might not be reasonable to assess this. On the other hand, the absence of vaginal bulge symptoms has been shown to be the most important outcome of surgical treatment of POP. It correlates strongly with the patient's assessment of overall improvement, whereas anatomical success alone does not.[18] In the postoperative questionnaires the need of conservative treatments for POP was not inquired. This is a limitation since definition of cure after POP surgery includes: no surgical or conservative treatment for recurrent POP or complication, no bulge symptom. [18] In future analysis, the use of conservative treatments, such as pessaries and physiotherapy should be asked, so that we can analyse the proportion of patients who can be considered as "cured".

A strength of the study II was the construct validation process that was performed using Finnish versions of the validated prolapse-specific QoL instruments. The translation of the questionnaires was performed by multistep translation process, which has been shown to lead to better translations than the translation/back-translation process [93]. Four different translations and a multi-professional team was used. In addition, the validation study was carried out as a multicenter basis so that the questionnaires were psychometrically evaluated in different areas of Finland, thus also representing different dialects of Finnish. A limitation is that the overall response rate was only 52%. This is comparable to the Danish study, in which the

recruiting process was similar to ours [106]. One reason for the low response rate may be that the questionnaires were posted to patients who were waiting for prolapse surgery. A personal contact was missing, which may decrease the person's willingness to participate. Additionally, no reminders were sent. However, the number of subjects was sufficient for the validation process.

6.5 CLINICAL IMPLICATIONS AND FUTURE PERSPECTIVES

Reconstructive pelvic surgery and health care in general evolve and strive for a more patient-centered attitude. Thus, patient satisfaction and improvement of quality of life are increasingly important outcome measures also in POP surgery. In addition, it is of utmost importance to follow the national practices and quality of treatment. In some countries like in Denmark, a national database is established to follow the quality of treatment for women undergoing urogynecological surgery [154]. Data from this dissertation showed that recent practices in Finland follow the international quidelines, the indications for use of mesh are reasonable and the outcomes of mesh surgery are acceptable. However, the differencies in rates of surgical methods varied significantly. In the future, national collaboration about the practices and establishing a Finnish national urogynecological database to ensure the high quality of POP treatment would be rational. In addition, multidisciplinary planning, including urogynegologist, colorectal surgeon, urologist, radiologist, physiotherapist and urotherapist, should be available in all the referral centers.

The assessment of surgical outcome in clinical research and practice should include HRQoL measures that are shown to be valid in the target population. The widely used condition-specific HRQoL instrument PFDI-20 is now shown to be valid in the Finnish population of women with symptomatic POP. Thus, the Finnish version of PDFI-20 can be used in research and clinical purposes and the results are comparable with those in other countries. Similarly, a Finnish version of PISQ-12 is validated and can be used in assessing the impact of pelvic floor disorders to sexual quality of life. However, PISQ-12 is usable only among sexually active heterosexual women. The IUGA-revised questionnaire (PISQ-IR) covers also the sexually inactive women and it has been translated and validated into several languages. [103] The validation process of PISQ-IR should be assessed also in Finnish context. Major limitations of the PFIQ-7 questionnaire were found and it can not be recommended to use it in the current form. However, this instrument is widely used and validated in several languages. [98,107] Thus, it may be reasonable to make another Finnish linguistic and cultural validation process in the future.

Patient counseling about the risk and benefits of the surgical treatment and the informed consent is essential. In some countries, a written informed constent is required from the patient berore the operation. Until now, this is not required in

Finland, but for example an electronical approval for surgical treatment might be used in the future.

Studies allowing patients to self-select goals for surgery demonstrate strong correlations between goal achievement, satisfaction, and condition-specific improvements in QoL measures. [155,156] Results of effectiveness of POP surgery and the predictive factors of surgical outcome presented in this dissertation can be used in counseling the patients with POP whether to undergo surgical treatment or not. For example, in clinical practise, it could be useful to ask the worst pelvic symptom. If it is the feel of bulge and she has a prolapse beyond hymen, the possibility of favorable outcome of surgery is high. On the other hand, the results suggest clinicans to inform the patients that smoking increases the possibility of unfavorable outcome of surgery.

So far, this dissertation includes outcomes of POP surgery on quality of life up to two years after the operation. However, further follow-up is currently ongoing. This large cohort allows evaluation of the long-term effect of POP surgery on QoL. In addition, subgroup analysis could provide more information about the outcomes of different surgical methods. Additionally, the long-term complications will be reported in the future and this information is essential in patient counseling.

7 CONCLUSIONS

On the basis of this thesis, the following conclusions can be drawn:

1. The Finnish practices of pelvic organ prolapse surgery follow the international guidelines that advocate native tissue repair as the principal surgical method. More than eight out of ten patients underwent native tissue reconstructive surgery and mesh augmentation was most often used in patients with recurrent and advanced prolapse with bothersome symptoms. However, there was large variation between the hospitals in the rates of mesh surgery, which implies a lack of sufficient evidence of the most suitable surgical method and indicates a need for national guidelines.

2. The Finnish translations of the short forms of Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) are valid in the Finnish population of women suffering from pelvic organ prolapse symptoms. The Finnish translation of Pelvic Floor Impact Questionnaire (PFIQ-7) is not usable in its current form.

3. Surgical treatment of pelvic organ prolapse effectively improves health-related quality of life and patient satisfaction is high. Nine out of ten patients reported better condition compared to the preoperative situation and approximately seven out of ten patients achieved significantly better condition-specific quality of life over a 2-year follow-up. Altogether 84% of patients were satisfied with outcome of surgery. Apical prolapse beyond the hymen and bothersome vaginal bulge are the most consistent predictors for favorable outcome of prolapse surgery. An association between smoking and unfavorable outcome of surgery was found.

4. All of the three patient-reported instruments (PFDI-20, 15D and PGI-I; Patient Global Impression of Improvement) show improvement in quality of life after POP surgery. However, these instruments correlated weakly, which indicates that the quantified effectiveness is dependent on the instrument applied.

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APPENDICES

APPENDIX 1. PDFI-20 IN FINNISH

APPENDIX 2. PFIQ-7 IN FINNISH

APPENDIX 3. PISQ-12 IN FINNISH

APPENDIX 4. PREOPERATIVE QUESTIONNAIRE FOR STUDY PARTICIPANTS

APPENDIX 5. FOLLOW-UP QUESTIONNAIRE AT 6 MONTHS

APPENDIX 6. FOLLOW-UP QUESTIONNAIRE AT 24 MONTHS

APPENDIX 7. PERIOPERATIVE QUESTIONNAIRE FOR DOCTORS

Lantionpohjavaivojen kartoitus (PFDI-20)

Ohjeet: Kysymysten tarkoituksena on kartoittaa mikäli teillä esiintyy tiettyjä tuntemuksia suolen, virtsarakon tai alapään alueelta, ja kuinka paljon nämä oireet teitä vaivaavat. Vastatkaa kysymyksiin laittamalla rasti sopivaan ruutuun. Vastatessanne kysymyksiin ottakaa huomioon oireenne **viimeisten kolmen kuukauden aikana.**

POPDI-6

1. **Onko teillä usein paineen tunnetta alavatsalla?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

2. **Esiintyykö teillä painon tunnetta tai särkyä (jomotusta) alapäässä?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

3. **Esiintyykö teillä pullistuma alapäässä, jonka voitte itse nähdä tai tuntea emättimen ulkosuulla?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

4. **Joudutteko koskaan painamaan emättimestä tai peräaukon läheltä saadaksenne ulostettua?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

5. **Tuntuuko teistä usein siltä, että virtsarakkonne ei tyhjene kokonaan?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

6. **Joudutteko joskus painamaan pullistumaa emättimen sisään aloittaaksenne virtsaamisen tai saadaksenne virtsarakon tyhjenemään?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

POPDI-6 pisteet **x 25=_____**

CRADI-8

7. **Joudutteko ponnistelemaan liikaa saadaksenne ulostettua?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

8. **Tuntuuko teistä ulostamisen jälkeen siltä, ettei suoli ole tyhjentynyt kunnolla?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

9. **Onko teillä vaikeuksia pidättää ulostetta , jos uloste on normaalia?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

10. **Onko teillä vaikeuksia pidättää ulostetta, jos uloste on löysää?**
    □ Ei □ Kyllä
    Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
    □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

11. **Karkaako teiltä usein kaasu peräsuolesta?**
    □ Ei □ Kyllä
    Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
    □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

12. **Onko ulostaminen teille usein kivuliasta?**
    □ Ei □ Kyllä
    Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
    □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

13. **Tuleeko teille pakottava ulostamistarve ja kiire vessaan ennen ulostamista?**
    □ Ei □ Kyllä
    Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
    □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

14. **Pullistuuko osa peräsuoltanne koskaan ulos peräaukosta ulostamisen aikana tai sen jälkeen?**
    □ Ei □ Kyllä
    Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
    □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

CRADI-8 pisteet x 25=_____

UDI-6

15. <u>Onko teillä tavallisesti tihentynyttä virtsaamistarvetta?</u>
□ Ei □ Kyllä
Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

16. <u>Karkaako virtsa silloin kun tunnette virtsapakkoa eli hyvin voimakasta virtsaamisen tarvetta?</u>
□ Ei □ Kyllä
Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

17. <u>Karkaako teiltä tavallisesti virtsaa yskiessä, nauraessa tai aivastaessa?</u>
□ Ei □ Kyllä
Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

18. <u>Karkaako teiltä tavallisesti pieniä määriä virtsaa (tipoittain)?</u>
□ Ei □ Kyllä
Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

19. <u>Onko teillä tavallisesti vaikeuksia tyhjentää virtsarakkonne?</u>
□ Ei □ Kyllä
Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

20. <u>Onko teillä tavallisesti kipua tai epämiellyttävää tunnetta alavatsalla tai alapäässä?</u>
□ Ei □ Kyllä
Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

UDI-6 pisteet x 25=_____

Pisteyttäminen: Laske kunkin osion pisteiden keskiarvo (0–4) ja kerro se 25:llä saadaksesi kokonaispistemäärän (asteikolla 0 – 100). Vastaamatta jääneitä kysymyksiä ei huomioida pistelaskussa, vaan keskiarvo lasketaan ainoastaan vastattujen kysymysten pisteistä.
PFDI-20 Pisteytyksen yhteenveto: Laske kaikkien kolmen osion pisteet yhteen saadaksesi kokonaispistemäärän (asteikolla 0 – 100).

POPDI-6 / CRADI-8 / UDI-6 **PFDI-20 PISTEET _____**
Center for Female Continence PFIQ-7
POTILAAN
NIMIKIRJAIMET_____PVM._____HENKILÖTUNNUS_____TUTKIMUSPAIKKA_____
Pre , 3 kk , 6 kk, 12 kk, 24 kk, 36 kk, 60 kk

Lantionpohjan kunnon merkitys -kysely

Täyttöohjeet: Jotkut naiset kokevat, että rakon, suoliston ja emättimen alueen oireilu vaikuttaa heidän toimiinsa, suhteisiinsa ja tunteisiinsa. Rastittakaa jokaisen kysymyksen kohdalla sellainen vastausvaihtoehto, joka parhaiten kuvaa sitä, kuinka suuri vaikutus rakko-, suolisto-, ja emätinoireilla on ollut teidän toimiinne, suhteisiinne tai tunteisiinne viimeisen kolmen kuukauden aikana. Merkitkää vastauksenne jokaiseen kolmeen sarakkeeseen kaikkien kysymysten kohdalla.

Kuinka paljon sarakkeisiin merkittyjen ruumiinosien oireilu tavallisesti vaikuttaa	Rakko ja virtsaaminen	Suoli ja peräaukko	Emätin ja lantion alue
1. Kykyynne tehdä kotitöitä (esim. ruuanlaitto, pyykinpesu, siivoaminen)?	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon
2. Kykyynne harrastaa liikuntaa, kuten esim. kävelyä, uimista tms.?	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon
3. Kykyynne käydä viihdetilaisuuksissa, kuten esim. elokuvissa tai konserteissa?	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon
4. Kykyynne matkustaa autolla tai bussilla kauemmas kuin 30 minuutin matkan päähän kotoanne?	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon
5. Kykyynne osallistua sosiaaliseen elämään muualla kuin kotonanne?	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon
6. Tunne-elämänne vaihteluihin (esim. jännittäminen ja masennus)?	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon
7. Turhautumisen tunteeseen?	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon	☐ Ei ollenkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

Lantionpohjan laskeuman /Pidätyskyvyttömyyden vaikutus seksielämään –kyselylomake

Tämä lomake sisältää kysymyksiä teidän ja partnerinne seksielämästä. Kaikki antamanne vastaukset ovat luottamuksellisia ja niitä käsittelevät ainoastaan lääkärit ymmärtääkseen, mitkä asiat potilaat kokevat tärkeiksi seksielämälleen. Kunkin kysymyksen kohdalla *rastittakaa vastaus, joka parhaiten vastaa omaa kokemustanne*. Vastatessanne kysymyksiin ottakaa huomioon seksielämänne viimeisen kuuden kuukauden ajalta.

Oletteko tällä hetkellä seksuaalisesti aktiivinen?
Rastittakaa sopivin vastausvaihtoehto

□ Ei, en kykene seksiin (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

□ En, minulla on liikaa kipuja (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

□ Ei, en ole halukas (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

□ En, minulla ei ole partneria (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

□ En, partnerini ei kykene seksiin (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

□ Kyllä

Jos vastasitte EI / EN, lomake on osaltanne täytetty.

Jos vastasitte KYLLÄ, jatkakaa vastaamalla seuraaviin 12 kysymykseen (PISQ-12).
Kysymykset alkavat seuraavalla sivulla.

1. **Kuinka usein tunnette sukupuolista halukkuutta?**
   Tunne voi käsittää toiveen seksistä, suunnitelmia seksin harrastamisesta, turhautuneisuus seksin puutteen takia, jne.
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

2. **Saatteko orgasmin ollessanne yhdynnässä kumppaninne kanssa?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

3. **Tunnetteko olevanne seksuaalisesti kiihottunut harrastaessanne seksiä kumppaninne kanssa?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

4. **Oletteko tyytyväinen seksielämäänne ja sen vaihtelevuuteen?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

5. **Tunnetteko kipua yhdynnän aikana?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

6. **Onko Teillä usein virtsakarkailua seksin aikana?**
□ Aina □ Usein □ Joskus □ Harvoin □ Ei koskaan

7. **Rajoittaako pelko ulosteen tai virtsan karkailusta seksuaalista aktiivisuuttanne?**
□ Aina □ Usein □ Joskus □ Harvoin □ Ei koskaan

8. **Vältättekö yhdyntää emättimen pullistuman vuoksi (rakon, peräsuolen tai emättimen ulosluiskahtamisen takia)?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

9. **Kun harrastatte seksiä kumppaninne kanssa, tunnetteko negatiivisia tunteita kuten pelkoa, vastenmielisyyttä, häpeää tai syyllisyyttä?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

10. **Onko kumppanillanne erektiohäiriö, joka vaikuttaa sukupuolielämäänne?**
□ Aina □ Usein □ Joskus □ Harvoin □ Ei koskaan

11. **Onko kumppanillanne ennenaikaisen siemensyöksyn ongelma, joka haittaa sukupuolielämäänne?**
□ Aina □ Usein □ Joskus □ Harvoin □ Ei koskaan

12. **Kuinka voimakkaita viimeisten kuuden kuukauden aikana tuntemanne orgasmit ovat verrattuna aikaisemmin saamiinne orgasmeihin?**
□ Paljon vähemmän voimakkaita
□ Vähemmän voimakkaita
□ Yhtä voimakkaita
□ Voimakkaampia
□ Paljon voimakkaampia

TIEDOTE TUTKIMUKSESTA 20.9.2014

Tutkimus*: FINPOP – Gynekologisten laskeumaleikkausten menetelmät, komplikaatiot ja vaikutus elämänlaatuun Suomessa vuonna 2015*

Pyyntö osallistua tutkimukseen

Teitä pyydetään mukaan tutkimukseen, jossa selvitetään gynekologisten laskeumien leikkausmenetelmiä, niihin liittyviä haittatapahtumia ja leikkaushoidon vaikuttavuutta oireisiin ja elämänlaatuun. Olemme arvioineet, että sovellutte tutkimukseen, koska Teille on suunnitteilla leikkaushoito lantionpohjan laskeuman vuoksi. Tämä tiedote kuvaa tutkimusta ja Teidän osuuttanne siinä. Perehdyttyänne tähän tiedotteeseen Teille järjestetään mahdollisuus esittää kysymyksiä tutkimuksesta, jonka jälkeen Teiltä pyydetään suostumus tutkimukseen osallistumisesta.

Tutkimusaloitteen tekijänä on Gynekologisen Kirurgian Seura Ry. Tutkimuksesta vastaava henkilö on dosentti Anna-Mari Heikkinen. Tutkijana sekä rekisterinpitäjänä toimii LL Nina Mattsson.

Pohjois-Savon sairaanhoitopiirin tutkimuseettinen toimikunta on arvioinut tutkimussuunnitelman ja antanut siitä puoltavan lausunnon.

Vapaaehtoisuus

Tutkimukseen osallistuminen on täysin vapaaehtoista ja voitte keskeyttää tutkimuksen koska tahansa. Tutkimuksesta kieltäytyminen tai sen keskeyttäminen ei vaikuta millään tavalla hoitoonne tai potilas-lääkäri-suhteeseenne. Mikäli keskeytätte tutkimuksen, keskeyttämiseen mennessä teistä kerätyt tiedot käytetään osana tutkimusaineistoa. Voitte myös peruuttaa suostumuksenne ja tällöin mitään teistä kerättyjä tietoja ei käytetä tutkimuksessa.

Tutkimuksen tarkoitus

Gynekologisia laskeumaleikkauksia tehdään Suomessa vuosittain noin 4000. Tämän tieteellisen tutkimuksen tarkoituksena on selvittää, mitkä monista leikkausmenetelmistä tuovat parhaan avun oireisiin kullekin potilasryhmälle. Tutkimukseen kerätään kaikkien luvan antaneiden vuonna 2015 leikattavien laskeumapotilaiden tiedot leikkauksesta sekä oireista ennen ja jälkeen leikkauksen.

Tutkimuksen kulku

Tämä tutkimus on kyselytutkimus. Tutkimukseen osallistuminen ei vaikuta lääketieteelliseen hoitoonne. Lääkärinne valitsee normaalien hoitokäytäntöjen mukaisen hoidon ja leikkausmenetelmän. Tutkittavat potilaat täyttävät kyselykaavakkeet ennen leikkausta ja 3-6 kk sen jälkeen. Voitte itse valita, haluatteko täyttää kaavakkeet paperilla vai sähköisenä versiona. Kyselylomakkeissa kartoitetaan laskeumaan, virtsaamiseen ja suolentoimintaa liittyviä oireita. Osa kysymyksistä käsittelee seksuaalisuuteen ja elämänlaatuun liittyviä oireita. Kaikkiin kysymyksiin ei ole pakollista vastata. Leikkaava lääkäri täyttää leikkauksen kulkuun liittyvän kyselylomakkeen.

Tutkimuksen mahdolliset hyödyt ja haitat

On mahdollista, ettei tähän tutkimukseen osallistumisesta ole Teille hyötyä. Tutkimus saattaa kuitenkin auttaa selvittämään mitkä leikkausmenetelmät ovat potilaan ja yhteiskunnan kannalta vaikuttavimpia.

Teille ei koidu tutkimukseen osallistumisesta haittaa. Mahdolliset postituskulut kyselykaavakkeiden palauttamiseksi huolehditaan tutkimuksen toimeksiantajan puolesta. Kyselykaavakkeiden täyttöön kuluu aikaa noin 15 minuuttia.

Tietojen luottamuksellisuus, säilytys ja tietosuoja

Keräämme teistä tietoa liittyen leikkaukseenne ja sen mahdollisiin komplikaatioihin sekä mahdollisiin uusintaleikkauksiin. Tietolähteinä käytetään sairaaloiden potilasasiakirjoja, terveydenhuollon hoitoilmoitusrekisteriä ja väestörekisteriä. Teistä kerättyä tietoa ja tutkimustuloksia käsitellään luottamuksellisesti henkilötietolain edellyttämällä tavalla eikä tunnisteellisia tietoja luovuteta ulkopuolisille.

Yksittäisille tutkimushenkilöille annetaan tunnuskoodi ja tieto säilytetään koodattuna tutkimustiedostossa. Tulokset analysoidaan ryhmätasolla, jolloin yksittäinen henkilö ei ole tunnistettavissa ilman koodiavainta. Koodiavainta, jonka avulla yksittäisen tutkittavan tiedot ja tulokset voidaan tunnistaa, säilyttää tutkimuksen rekisterinpitäjä eikä tietoja anneta tutkimuksen ulkopuolisille henkilöille. Tutkimuksessa kerättävistä tiedoista ja tutkimustuloksista ei tehdä merkintöjä sairauskertomukseenne. Tutkimustietoja säilytetään viiden vuoden aikajaksoissa niin kauan kun se on tutkimuksen suorittamisen kannalta välttämätöntä, jonka jälkeen ne hävitetään. Kuitenkin rekisteri hävitetään 30 vuoden kuluttua.

Tutkimuksen kustannukset ja rahoitus

Tutkimukseen osallistumisesta ei makseta palkkiota. Poliklinikka- ja osastohoitomaksut peritään Teiltä sairaalan normaalien käytäntöjen mukaisesti. Tutkimus rahoitetaan osittain Gynekologisen Kirurgian Seuran tukemana, muu rahoitus tutkimusapurahoilla. Tutkimuksen tavoitteena on väitöskirjatyö.

Tutkittavien vakuutusturva

Tutkittavat ovat vakuutettu normaalisti potilasvahinkovakuutuksen kautta.

Lisätiedot

Pyydämme Teitä tarvittaessa esittämään tutkimukseen liittyviä kysymyksiä tutkijalle.

Tutkijan yhteystiedot

Nina Mattsson
LL, naistentautien erikoislääkäri
K-HKS Naistentaudit
Puh. 040 7338307
Sposti: nina.mattsson@khshp.fi

Esitietolomake

Kysely sisältää leikkauksen ja toipumisen kannalta tärkeitä kysymyksiä, joihin toivomme vastauksianne. Vastaukset käsitellään luottamuksellisesti.

1. **Henkilötiedot**

Nimi _____

Henkilötunnus _____

Puhelinnumero _____

Osoite _____

Postinumero ja postitoimipaikka _____

2. **Miten toivotte Teihin otettavan tutkimuksen puitteissa yhteyttä (kyselykaavakkeiden täyttö) ?**

☐ Kirjeitse ☐ Sähköpostilla, osoitteeseen _____

3. **Henkilökohtaiset mittanne**
   Pituus _____ cm
   Paino _____ kg

4. **Tupakoitteko?**

☐ En ☐ Kyllä, _____ savuketta / vrk
☐Olen lopettanut tupakoinnin alle vuosi sitten
☐Olen lopettanut tupakoinnin yli vuosi sitten

5. **Onko Teillä jokin perussairaus?**

☐ Ei ☐ Kyllä, mikä perussairaus / sairauksia?

☐ Verenpainetauti
☐ Sepelvaltimotauti
☐ Sydämen rytmihäiriö
☐ Sydämen vajaatoiminta
☐ Astma
☐ Keuhkoahtaumatauti
☐ Epilepsia
☐ Aivoverenkierron häiriö (TIA)
☐ Diabetes
☐ Kilpirauhasen vajaatoiminta
☐ Kilpirauhasen liikatoiminta
☐ Reuma
☐ Munuaisten vajatoiminta
☐ Maksan vajaatoiminta
☐ Sairastettu aivohalvaus
☐ Muistisairaus
☐ Sairastettu laskimotukos (veritulppa / keuhkoveritulppa)
☐ Sairastettu syöpä, mikä
☐ Muu, mikä _____

6. Onko Teillä säännöllisiä lääkityksiä?

☐ Ei ☐ Kyllä, mikä / mitä säännöllisiä lääkkeitä?

☐ Insuliini
☐ Verenpainelääke
☐ Sydänlääke
☐ Kolesterolilääke
☐Kortisoni (suun kautta)
☐ Biologinen reumalääke
☐ Kilpirauhaslääke
☐ Verenohennuslääke, mikä / mitkä seuraavista:
  ☐ Marevan
  ☐ Miniasperiini (Primaspan / Asperin / Disperin/ Asasantin)
  ☐ Klopidrogeeli (Plavix / Clopidrogel)
  ☐ Pistoshoito (Klexane / Fragmin / Innohep)
  ☐ Uuden polven verenohennuslääke (Pradaxa / Xarelto)
☐ Muu lääke, mikä

☐ Virtsankarkailua estävä lääkitys
☐ Hormonikorvaushoito
☐ Ehkäisyvalmiste
☐ Hormonikierukka
☐ Paikallisestrogeenivalmiste
☐ Mielialalääke
☐ Ummetuslääke

_____

7. Synnytysten lukumäärä

Alatiesynnytyksiä _____ Keisarileikkauksia (sektio) _____

8. Mikä seuraavista on lantionpohjan toimintaan liittyvä pahin oireenne ? litkaa yksi vaihtoehto)

☐ Pullistuman tunne
☐ Kipu
☐ Virtsantulovaikeus
☐ Virtsankarkailu
☐ Ulosteen karkailu
☐ Ulostamisen vaikeus
☐ Jokin muu oire, mikä _____
☐ Minulla ei ole oireita

9. Kuinka kauan olette kärsineet laskeumaan liittyvistä oireista?

_____ vuotta _____ kuukautta

TERVEYTEEN LIITTYVÄN ELÄMÄNLAADUN KYSELYLOMAKE (15D©)

Ohje: Lukekaa ensin läpi huolellisesti kunkin kysymyksen kaikki vastausvaihtoehdot. Merkitkää sitten rasti (x) sen vaihtoehdon kohdalle, joka **parhaiten kuvaa nykyistä terveydentilaanne**. Menetelkää näin kaikkien kysymysten 1-15 kohdalla. Kustakin kysymyksestä rastitetaan siis yksi vaihtoehto.

KYSYMYS 1. Liikuntakyky

1 ( ) Pystyn kävelemään normaalisti (vaikeuksitta) sisällä, ulkona ja portaissa.
2 ( ) Pystyn kävelemään vaikeuksitta sisällä, mutta ulkona ja/tai portaissa on pieniä vaikeuksia.
3 ( ) Pystyn kävelemään ilman apua sisällä (apuvälinein tai ilman), mutta ulkona ja/tai portaissa melkoisin vaikeuksin tai toisen avustamana.
4 ( ) Pystyn kävelemään sisälläkin vain toisen avustamana.
5 ( ) Olen täysin liikuntakyvytön ja vuoteenoma.

KYSYMYS 2. Näkö

1 ( ) Näen normaalisti eli näen lukea lehteä ja TV:n tekstejä vaikeuksitta (silmälaseilla tai ilman).
2 ( ) Näen lukea lehteä ja/tai TV:n tekstejä pienin vaikeuksin (silmälaseilla tai ilman).
3 ( ) Näen lukea lehteä ja/tai TV:n tekstejä huomattavin vaikeuksin (silmälaseilla tai ilman).
4 ( ) En näe lukea lehteä enkä TV:n tekstejä ilman silmälaseja tai niiden kanssa, mutta näen kulkea ilman opasta.
5 ( ) En näe kulkea oppaatta eli olen lähes tai täysin sokea.

KYSYMYS 3. Kuulo

1 ( ) Kuulen normaalisti eli kuulen hyvin normaalia puheääntä (kuulokojeella tai ilman).
2 ( ) Kuulen normaalia puheääntä pienin vaikeuksin.
3 ( ) Minun on melko vaikea kuulla normaalia puheääntä, keskustelussa on käytettävä normaalia kovempaa puheääntä.
4 ( ) Kuulen kovaakin puheääntä heikosti; olen melkein kuuro.
5 ( ) Olen täysin kuuro.

KYSYMYS 4. Hengitys

1 ( ) Pystyn hengittämään normaalisti eli minulla ei ole hengenahdistusta eikä muita hengitysvaikeuksia.
2 ( ) Minulla on hengenahdistusta raskaassa työssä tai urheillessa, reippaassa kävelyssä tasamaalla tai lievässä ylämäessä.
3 ( ) Minulla on hengenahdistusta, kun kävelen tasamaalla samaa vauhtia kuin muut ikäiseni.
4 ( ) Minulla on hengenahdistusta pienenkin rasituksen jälkeen, esim. peseytyessä tai pukeutuessa.
5 ( ) Minulla on hengenahdistusta lähes koko ajan, myös levossa.

KYSYMYS 5. Nukkuminen

1 ( ) Nukun normaalisti eli minulla ei ole mitään ongelmia unen suhteen.
2 ( ) Minulla on lieviä uniongelmia, esim. nukahtamisvaikeuksia tai satunnaista yöheräilyä.
3 ( ) Minulla on melkoisia uniongelmia, esim. nukun levottomasti tai uni ei tunnu riittävältä.
4 ( ) Minulla on suuria uniongelmia, esim. joudun käyttämään usein tai säännöllisesti unilääkettä, herään säännöllisesti yöllä ja/tai aamuisin liian varhain.
5 ( ) Kärsin vaikeasta unettomuudesta, esim. unilääkkeiden runsaasta käytöstä huolimatta nukkuminen on lähes mahdotonta, valvon suurimman osan yöstä.

KYSYMYS 6. Syöminen

1 ( ) Pystyn syömään normaalisti eli itse ilman mitään vaikeuksia.
2 ( ) Pystyn syömään itse pienin vaikeuksin (esim. hitaasti, kömpelösti, vavisten tai erityisapuneuvoin).
3 ( ) Tarvitsen hieman toisen apua syömisessä.
4 ( ) En pysty syömään itse lainkaan, vaan minua pitää syöttää.
5 ( ) En pysty syömään itse lainkaan, vaan minulle pitää antaa ravintoa letkun avulla tai suonensisäisesti.

KYSYMYS 7. Puhuminen

1 ( ) Pystyn puhumaan normaalisti eli selvästi, kuuluvasti ja sujuvasti.
2 ( ) Puhuminen tuottaa minulle pieniä vaikeuksia, esim. sanoja on etsittävä tai ääni ei ole riittävän kuuluva tai se vaihtaa korkeutta.
3 ( ) Pystyn puhumaan ymmärrettävästi, mutta katkonaisesti, ääni vavisten, sammaltaen tai änkyttäen.
4 ( ) Muilla on vaikeuksia ymmärtää puhettani.
5 ( ) Pystyn ilmaisemaan itseäni vain elein.

KYSYMYS 8. Eritystoiminta

1 ( ) Virtsarakkoni ja suolistoni toimivat normaalisti ja ongelmitta.
2 ( ) Virtsarakkoni ja/tai suolistoni toiminnassa on lieviä ongelmia, esim. minulla on virtsaamisvaikeuksia tai kova tai löysä vatsa
3 ( ) Virtsarakkoni ja/tai suolistoni toiminnassa on melkoisia ongelmia, esim. minulla on satunnaisia virtsanpidätysvaikeuksia tai vaikea ummetus tai ripuli.
4 ( ) Virtsarakkoni ja/tai suolistoni toiminnassa on suuria ongelmia, esim. minulla on säännöllisesti "vahinkoja" tai peräruiskeiden tai katetroinnin tarvetta.
5 ( ) En hallitse lainkaan virtsaamista ja/tai ulostamista.

KYSYMYS 9. Tavanomaiset toiminnot

1 ( ) Pystyn suoriutumaan normaalisti tavanomaisista toiminnoista (esim. ansiotyö, opiskelu, kotityö, vapaa-ajan toiminnot).
2 ( ) Pystyn suoriutumaan tavanomaisista toiminnoista hieman alentuneella teholla tai pienin vaikeuksin.
3 ( ) Pystyn suoriutumaan tavanomaisista toiminnoista huomattavasti alentuneella teholla tai huomattavin vaikeuksin tai vain osaksi.
4 ( ) Pystyn suoriutumaan tavanomaisista toiminnoista vain pieneltä osin.
5 ( ) En pysty suoriutumaan lainkaan tavanomaisista toiminnoista.

KYSYMYS 10. Henkinen toiminta

1 ( ) Pystyn ajattelemaan selkeästi ja johdonmukaisesti ja muistini toimii täysin moitteettomasti.
2 ( ) Minulla on lieviä vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai muistini ei toimi täysin moitteettomasti
3 ( ) Minulla on melkoisia vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai minulla on jonkin verran muistinmenetystä
4 ( ) Minulla on suuria vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai minulla on huomattavaa muistinmenetystä
5 ( ) Olen koko ajan sekaisin ja vailla ajan tai paikan tajua

KYSYMYS 11. Vaivat ja oireet

1 ( ) Minulla ei ole mitään vaivoja tai oireita, esim. kipua, särkyä, pahoinvointia, kutinaa jne.
2 ( ) Minulla on lieviä vaivoja tai oireita, esim. lievää kipua, särkyä, pahoinvointia, kutinaa jne.
3 ( ) Minulla on melkoisia vaivoja tai oireita, esim. melkoista kipua, särkyä, pahoinvointia, kutinaa jne.
4 ( ) Minulla on voimakkaita vaivoja tai oireita, esim. voimakasta kipua, särkyä, pahoinvointia, kutinaa jne.
5 ( ) Minulla on sietämättömiä vaivoja ja oireita, esim. sietämätöntä kipua, särkyä, pahoinvointia, kutinaa jne.

KYSYMYS 12. Masentuneisuus

1 ( ) En tunne itseäni lainkaan surulliseksi, alakuloiseksi tai masentuneeksi.
2 ( ) Tunnen itseni hieman surulliseksi, alakuloiseksi tai masentuneeksi.
3 ( ) Tunnen itseni melko surulliseksi, alakuloiseksi tai masentuneeksi.
4 ( ) Tunnen itseni erittäin surulliseksi, alakuloiseksi tai masentuneeksi.
5 ( ) Tunnen itseni äärimmäisen surulliseksi, alakuloiseksi tai masentuneeksi.

KYSYMYS 13. Ahdistuneisuus

1 ( ) En tunne itseäni lainkaan ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
2 ( ) Tunnen itseni hieman ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
3 ( ) Tunnen itseni melko ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
4 ( ) Tunnen itseni erittäin ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
5 ( ) Tunnen itseni äärimmäisen ahdistuneeksi, jännittyneeksi tai hermostuneeksi.

KYSYMYS 14. Energisyys

1 ( ) Tunnen itseni terveeksi ja elinvoimaiseksi.
2 ( ) Tunnen itseni hieman uupuneeksi, väsyneeksi tai voimattomaksi.
3 ( ) Tunnen itseni melko uupuneeksi, väsyneeksi tai voimattomaksi.
4 ( ) Tunnen itseni erittäin uupuneeksi, väsyneeksi tai voimattomaksi, lähes "loppuun palaneeksi".
5 ( ) Tunnen itseni äärimmäisen uupuneeksi, väsyneeksi tai voimattomaksi, täysin "loppuun palaneeksi".

KYSYMYS 15. Sukupuolielämä

1 ( ) Terveydentilani ei vaikeuta mitenkään sukupuolielämääni.
2 ( ) Terveydentilani vaikeuttaa hieman sukupuolielämääni.
3 ( ) Terveydentilani vaikeuttaa huomattavasti sukupuolielämääni.
4 ( ) Terveydentilani tekee sukupuolielämäni lähes mahdottomaksi.
5 ( ) Terveydentilani tekee sukupuolielämäni mahdottomaksi.

Lantionpohjavaivojen kartoitus (PFDI-20)

Ohjeet: Kysymysten tarkoituksena on kartoittaa mikäli teillä esiintyy tiettyjä tuntemuksia suolen, virtsarakon tai alapään alueelta, ja kuinka paljon nämä oireet teitä vaivaavat. Vastatkaa kysymyksiin laittamalla rasti sopivaan ruutuun. Vastatessanne kysymyksiin ottakaa huomioon oireenne **viimeisten kolmen kuukauden aikana.**

1. **Onko teillä usein paineen tunnetta alavatsalla?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

2. **Esiintyykö teillä painon tunnetta tai särkyä (jomotusta) alapäässä?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

3. **Esiintyykö teillä pullistuma alapäässä, jonka voitte itse nähdä tai tuntea emättimen ulkosuulla?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

4. **Joudutteko koskaan painamaan emättimestä tai peräaukon läheltä saadaksenne ulostettua?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

5. **Tuntuuko teistä usein siltä, että virtsarakkonne ei tyhjene kokonaan?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

6. **Joudutteko joskus painamaan pullistumaa emättimen sisään aloittaaksenne virtsaamisen tai saadaksenne virtsarakon tyhjenemään?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

7. **Joudutteko ponnistelemaan liikaa saadaksenne ulostettua?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

8. **Tuntuuko teistä ulostamisen jälkeen siltä, ettei suoli ole tyhjentynyt kunnolla?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

9. **Onko teillä vaikeuksia pidättää ulostetta , jos uloste on normaalia?**
   □ Ei □ Kyllä
   Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
   □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

10. **Onko teillä vaikeuksia pidättää ulostetta, jos uloste on löysää?**
    □ Ei □ Kyllä
    Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
    □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

11. **Karkaako teiltä usein kaasu peräsuolesta?**
    □ Ei □ Kyllä
    Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
    □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

12. **Onko ulostaminen teille usein kivuliasta?**
    □ Ei □ Kyllä
    Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
    □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

13. **Tuleeko teille pakottava ulostamistarve ja kiire vessaan ennen ulostamista?**
    □ Ei □ Kyllä
    Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
    □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

14. **Pullistuuko osa peräsuoltanne koskaan ulos peräaukosta ulostamisen aikana tai sen jälkeen?**
    □ Ei □ Kyllä
    Jos vastasitte kyllä, kuinka paljon se haittaa teitä?
    □ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

15. Onko teillä tavallisesti tihentynyttä virtsaamistarvetta?

□ Ei □ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

16. Karkaako virtsa silloin kun tunnette virtsapakkoa eli hyvin voimakasta virtsaamisen tarvetta?

□ Ei □ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

17. Karkaako teiltä tavallisesti virtsaa yskiessä, nauraessa tai aivastaessa?

□ Ei □ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

18. Karkaako teiltä tavallisesti pieniä määriä virtsaa (tipoittain)?

□ Ei □ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

19. Onko teillä tavallisesti vaikeuksia tyhjentää virtsarakkonne?

□ Ei □ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

20. Onko teillä tavallisesti kipua tai epämiellyttävää tunnetta alavatsalla tai alapäässä?

□ Ei □ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

□ Ei lainkaan □ Jonkin verran □ Melko paljon □ Paljon

Lantionpohjan laskeuman /Pidätyskyvyttömyyden vaikutus seksielämään –kyselylomake

Tämä lomake sisältää kysymyksiä teidän ja partnerinne seksielämästä. Kaikki antamanne vastaukset ovat luottamuksellisia ja niitä käsittelevät ainoastaan lääkärit ymmärtääkseen, mitkä asiat potilaat kokevat tärkeiksi seksielämälleen. Kunkin kysymyksen kohdalla *rastittakaa vastaus, joka parhaiten vastaa omaa kokemustanne*. Vastatessanne kysymyksiin ottakaa huomioon seksielämänne viimeisen kuuden kuukauden ajalta.

Oletteko tällä hetkellä seksuaalisesti aktiivinen?
Rastittakaa sopivin vastausvaihtoehto

□ Ei, en kykene seksiin (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

□ En, minulla on liikaa kipuja (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

□ Ei, en ole halukas (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

□ En, minulla ei ole partneria (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

□ En, partnerini ei kykene seksiin (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

□ Kyllä

Jos vastasitte EI / EN, lomake on osaltanne täytetty.

Jos vastasitte KYLLÄ, jatkakaa vastaamalla seuraaviin 12 kysymykseen (PISQ-12).
Kysymykset alkavat seuraavalla sivulla.

1. **Kuinka usein tunnette sukupuolista halukkuutta?**
   Tunne voi käsittää toiveen seksistä, suunnitelmia seksin harrastamisesta, turhautuneisuus seksin puutteen takia, jne.
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

2. **Saatteko orgasmin ollessanne yhdynnässä kumppaninne kanssa?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

3. **Tunnetteko olevanne seksuaalisesti kiihottunut harrastaessanne seksiä kumppaninne kanssa?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

4. **Oletteko tyytyväinen seksielämäänne ja sen vaihtelevuuteen?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

5. **Tunnetteko kipua yhdynnän aikana?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

6. **Onko Teillä usein virtsakarkailua seksin aikana?**
□ Aina □ Usein □ Joskus □ Harvoin □ Ei koskaan

7. **Rajoittaako pelko ulosteen tai virtsan karkailusta seksuaalista aktiivisuuttanne?**
□ Aina □ Usein □ Joskus □ Harvoin □ Ei koskaan

8. **Vältättekö yhdyntää emättimen pullistuman vuoksi (rakon, peräsuolen tai emättimen ulosluiskahtamisen takia)?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

9. **Kun harrastatte seksiä kumppaninne kanssa, tunnetteko negatiivisia tunteita kuten pelkoa, vastenmielisyyttä, häpeää tai syyllisyyttä?**
□ Aina □ Usein □ Joskus □ Harvoin □ En koskaan

10. **Onko kumppanillanne erektiohäiriö, joka vaikuttaa sukupuolielämäänne?**
□ Aina □ Usein □ Joskus □ Harvoin □ Ei koskaan

11. **Onko kumppanillanne ennenaikaisen siemensyöksyn ongelma, joka haittaa sukupuolielämäänne?**
□ Aina □ Usein □ Joskus □ Harvoin □ Ei koskaan

12. **Kuinka voimakkaita viimeisten kuuden kuukauden aikana tuntemanne orgasmit ovat verrattuna aikaisemmin saamiinne orgasmeihin?**
□ Paljon vähemmän voimakkaita
□ Vähemmän voimakkaita
□ Yhtä voimakkaita
□ Voimakkaampia
□ Paljon voimakkaampia

SUOSTUMUS TUTKIMUKSEEN

FINPOP – Gynekologisten laskeumaleikkausten menetelmät, komplikaatiot ja vaikutus elämänlaatuun Suomessa vuonna 2015

Minua **(** **)** on pyydetty osallistumaan yllämainittuun tieteelliseen tutkimukseen, jonka tarkoituksena on selvittää gynekologisten laskeumaleikkauksien menetelmät ja niihin liittyvät haittavaikutukset sekä eri leikkausmenetelmien vaikutusta potilaan elämänlaatuun. Olen lukenut ja ymmärtänyt saamani kirjallisen tutkimustiedotteen. Tiedotteesta olen saanut riittävän selvityksen tutkimuksesta ja sen yhteydessä suoritettavasta tietojen keräämisestä, käsittelystä ja luovuttamisesta. Tiedotteen sisältö on kerrottu minulle myös suullisesti, minulla on ollut mahdollisuus esittää kysymyksiä ja olen saanut riittävän vastauksen kaikkiin tutkimusta koskeviin kysymyksiini. Tiedot antoi _____ __ / __/ 20 ___. Minulla on ollut riittävästi aikaa harkita osallistumistani tutkimukseen. Olen saanut riittävät tiedot oikeuksistani, tutkimuksen tarkoituksesta ja sen toteutuksesta sekä tutkimuksen hyödyistä ja riskeistä. Minua ei ole painostettu eikä houkuteltu osallistumaan tutkimukseen. Tiedän, että tietojani käsitellään luottamuksellisesti eikä niitä luovuteta sivullisille.
Ymmärrän, että osallistumiseni on vapaaehtoista. Olen tietoinen, että voin milloin tahansa sekä keskeyttää tutkimuksen että peruuttaa suostumukseni syytä ilmoittamatta eikä peruutukseni vaikuta kohteluuni tai saamaani hoitoon millään tavalla. Jos peruutan suostumukseni, minulla on oikeus pyytää, että siihen mennessä kerättyjä tietoja ei käytetä enää tutkimuksessa. Mikäli suostumuksen peruuttamisen sijaan keskeytän tutkimuksen, minusta keskeyttämiseen asti kerättyjä tietoja käytetään osana tutkimusaineistoa.

Allekirjoituksellani vahvistan osallistumiseni tähän tutkimukseen ja suostun vapaaehtoisesti tutkimushenkilöksi.

_____	_____	_____
Tutkittavan nimi	Tutkittavan syntymäaika	Tutkittavan osoite

_____	_____
Päivämäärä	Allekirjoitus

_____	_____	_____
Potilaan edustajan nimi (jos tarpeen)	Päivämäärä	Allekirjoitus

Suostumus vastaanotettu

_____	_____	_____
Tutkijalääkärin/hoitajan nimi (Suostumuksen vastaanottaja)	Päivämäärä	Allekirjoitus

Alkuperäinen allekirjoitettu tutkittavan suostumus sekä kopio tutkimustiedotteesta jäävät tutkijalääkärin arkistoon. Tutkimustiedote ja kopio allekirjoitetusta suostumuksesta annetaan tutkittavalle.

FINPOP 2015- Laskeumaleikkaustutkimus

Kysely toipumisesta ja tyytyväisyydestä leikkaushoitoon 6 kk leikkauksesta.

1. <u>Henkilötiedot</u>

Nimi _____

Henkilötunnus ☐☐☐☐☐☐ ☐☐☐☐

Puhelin/ Matkapuhelinnumero _____

Sähköpostiosoite _____

Osoite _____

Postinro ja -toimipaikka _____

2. Kuinka monta yötä vietitte sairaalassa toimenpiteen jälkeen? ☐☐ **yötä**

Laittakaa numero 0, jos kotiuduitte toimenpidepäivänä, 1 jos seuraavana jne.

3. Todettiinko Teillä leikkauksesta toipumiseen liittyviä ongelmia (komplikaatioita) <u>sairaalahoidon aikana</u>? ☐ Ei ☐ Kyllä

Jos vastasitte <u>Kyllä</u>, mikä leikkaukseen liittyvä komplikaatio / komplikaatioita?

☐ Kuume (>38 astetta)
☐ Virtsatietulehdus
☐ Virtsatievaurio
☐ Suolivaurio
☐ Haavatulehdus
☐ Haavatyrä
☐ Haavan aukeaminen
☐ Lantion tai vatsan alueen tulehdus
☐ Verinen vuoto emättimen haavan alueella
☐ Verenvuoto vatsaonteloon
☐ Syvä laskimotukos
☐ Keuhkoveritulppa
☐ Poikkeavan kova kipu leikkausalueella
☐ Puudutuksen jälkeinen päänsärky
☐ Hankala virtsantulon vaikeus
☐ Hankala virtsankarkailu / virtsan valuminen
☐ Hankala ummetus / suolen toiminnan lamaantuminen
☐ Ulosteen karkailu
☐ Muu, mikä _____

Tehtiinkö Teille uusintaleikkaus/leikkauksia komplikaation vuoksi?

☐ Ei ☐ Kyllä, mikä ?_____

4. Esiintyikö Teillä <u>myöhemmin</u> (kotiutumisen jälkeen) leikkaukseen liittyviä ongelmia?

☐ Ei ☐ Kyllä

Jos vastasitte <u>Kyllä</u>, mitä ongelmia Teillä liittyi leikkauksen jälkeiseen toipumiseen?

☐ Virtsatietulehdus
☐ Virtsantulon vaikeus
☐ Virtsankarkailu / virtsan valuminen
☐ Virtsatievaurio
☐ Suolivaurio
☐ Ulosteen karkailu
☐ Hankala ummetus
☐ Tulehdus vatsanpeitteiden haavassa
☐ Arpityrä vatsanpeitteissä
☐ Vatsanpeitteiden verenpurkauma (hematooma)
☐ Verinen vuoto emättimen haavasta
☐ Verinen vuoto vatsaonteloon
☐ Poikkeava kipu
☐ Kuume (> 38 astetta)
☐ Lantion pohjan tai vatsan alueen tulehdus
☐ Lantion pohjan verihyytymä (hematooma)
☐ Verkkoon liittyvä tulehdus
☐ Verkon esiintulo
☐ Puudutuksen jälkeinen päänsärky
☐ Syvä laskimotukos
☐ Keuhkoveritulppa
☐ Muu, mikä _____

Jos jouduitte hakeutumaan tutkimuksiin / hoitoon leikkaukseen liittyvän ongelman vuoksi, vaatiko se?

☐ Hoitajan kontaktin
☐ Oman lääkärin (tk-, yksityis- tai työterveyslääkäri) arvion?
☐ Poliklinikkakäynnin / käyntejä sairaalassa?
☐ Osastohoitojakson sairaalassa
☐ Uusintaleikkauksen, minkä? _____

5. Olitteko sairauslomalla leikkauksen jälkeen?

☐ En ole työelämässä
☐ Olen työelämässä, mutta en tarvinnut / halunnut sairauslomaa
☐ Kyllä, suunnitellun ajan
☐ Kyllä, pidempään kuin alun perin oli suunniteltu

Kuinka pitkään olitte sairauslomalla? ☐☐ **Vrk**

6. Kuinka tyytyväinen olette?	Erittäin tyytyväinen	Tyytyväinen	Melko tyytyväinen	Ei tyytyväinen eikä tyytymätön	Melko tyytymätön	Tyytymätön	Erittäin Tyytymätön
Saamaanne informaatioon ennen leikkausta	☐	☐	☐	☐	☐	☐	☐
Jonotusaikaanne ennen leikkausta	☐	☐	☐	☐	☐	☐	☐
Henkilökunnan ammattitaitoon	☐	☐	☐	☐	☐	☐	☐
Kohteluunne sairaalahoidon aikana	☐	☐	☐	☐	☐	☐	☐
Saamaanne informaatioon leikkauksen jälkeen	☐	☐	☐	☐	☐	☐	☐
Sairausloman pituuteen	☐	☐	☐	☐	☐	☐	☐
Leikkaustulokseen	☐	☐	☐	☐	☐	☐	☐

Jos ette ole tyytyväinen leikkaustulokseen, onko syy

☐ Laskeuman uusiutuminen
☐ En saanut apua oireisiini
☐ Leikkauksen jälkeen ilmenneet uudet oireet, mitkä _____
☐ Leikkauksesta toipumiseen liittyvät ongelmat (komplikaatiot)
☐ Muu, mikä _____

7. Onko Teillä <u>edelleen</u> lantionpohjan toimintaan liittyviä oireita?

☐ Ei ☐ Kyllä

Jos vastasitte Kyllä, mikä on <u>pahin</u> oireenne?

☐ Pullistuman tunne
☐ Painon tunne
☐ Kipu
☐ Virtsantulovaikeus
☐ Virtsankarkailu
☐ Ulosteen karkailu
☐ Ulostamisen vaikeus
☐ Jokin muu oire, mikä _____

8. Valitkaa numero, joka kuvastaa parhaiten nykyistä, leikkauksen jälkeistä vointianne verrattuna siihen, millainen se oli ennen leikkausta.

☐1 = hyvin paljon parempi
☐2 = paljon parempi
☐3 = vähän parempi
☐4 = ei muutosta
☐5 = vähän huonompi
☐6 = paljon huonompi
☐7 = hyvin paljon huonompi

9. Jos läheisellä ystävällänne olisi vastaava laskeumavaiva, suosittelisitteko leikkausta hänelle?
☐ Kyllä ☐En

2. TERVEYTEEN LIITTYVÄN ELÄMÄNLAADUN KYSELY (15D©)

Ohje: Lukekaa ensin läpi huolellisesti kunkin kysymyksen kaikki vastausvaihtoehdot. Merkitkää sitten rasti (x) sen vaihtoehdon kohdalle, joka **parhaiten kuvaa nykyistä terveydentilaanne**.
Menetelkää näin kaikkien kysymysten 1-15 kohdalla. Kustakin kysymyksestä rastitetaan siis yksi vaihtoehto.

KYSYMYS 1. Liikuntakyky

- ☐ Pystyn kävelemään normaalisti (vaikeuksitta) sisällä, ulkona ja portaissa.
- ☐ Pystyn kävelemään vaikeuksitta sisällä, mutta ulkona ja/tai portaissa on pieniä vaikeuksia.
- ☐ Pystyn kävelemään ilman apua sisällä (apuvälinein tai ilman), mutta ulkona ja/tai portaissa melkoisin vaikeuksin tai toisen avustamana.
- ☐ Pystyn kävelemään sisälläkin vain toisen avustamana.
- ☐ Olen täysin liikuntakyvytön ja vuoteenoma.

KYSYMYS 2. Näkö

- ☐ Näen normaalisti eli näen lukea lehteä ja TV:n tekstejä vaikeuksitta (silmälaseilla tai ilman).
- ☐ Näen lukea lehteä ja/tai TV:n tekstejä pienin vaikeuksin (silmälaseilla tai ilman).
- ☐ Näen lukea lehteä ja/tai TV:n tekstejä huomattavin vaikeuksin (silmälaseilla tai ilman).
- ☐ En näe lukea lehteä enkä TV:n tekstejä ilman silmälaseja tai niiden kanssa, mutta näen kulkea ilman opasta.
- ☐ En näe kulkea oppaatta eli olen lähes tai täysin sokea.

KYSYMYS 3. Kuulo

- ☐ Kuulen normaalisti eli kuulen hyvin normaalia puheääntä (kuulokojeella tai ilman).
- ☐ Kuulen normaalia puheääntä pienin vaikeuksin.
- ☐ Minun on melko vaikea kuulla normaalia puheääntä, keskustelussa on käytettävä normaalia kovempaa puheääntä.
- ☐ Kuulen kovaakin puheääntä heikosti; olen melkein kuuro.
- ☐ Olen täysin kuuro.

KYSYMYS 4. Hengitys

- ☐ Pystyn hengittämään normaalisti eli minulla ei ole hengenahdistusta eikä muita hengitysvaikeuksia.
- ☐ Minulla on hengenahdistusta raskaassa työssä tai urheillessa, reippaassa kävelyssä tasamaalla tai lievässä ylämäessä.
- ☐ Minulla on hengenahdistusta, kun kävelen tasamaalla samaa vauhtia kuin muut ikäiseni.
- ☐ Minulla on hengenahdistusta pienenkin rasituksen jälkeen, esim. peseytyessä tai pukeutuessa.
- ☐ Minulla on hengenahdistusta lähes koko ajan, myös levossa.

KYSYMYS 5. Nukkuminen

- ☐ Nukun normaalisti eli minulla ei ole mitään ongelmia unen suhteen.
- ☐ Minulla on lieviä uniongelmia, esim. nukahtamisvaikeuksia tai satunnaista yöheräilyä.
- ☐ Minulla on melkoisia uniongelmia, esim. nukun levottomasti tai uni ei tunnu riittävältä.
- ☐ Minulla on suuria uniongelmia, esim. joudun käyttämään usein tai säännöllisesti unilääkettä, herään säännöllisesti yöllä ja/tai aamuisin liian varhain.
- ☐ Kärsin vaikeasta unettomuudesta, esim. unilääkkeiden runsaasta käytöstä huolimatta nukkuminen on lähes mahdotonta, valvon suurimman osan yöstä.

KYSYMYS 6. Syöminen

- ☐ Pystyn syömään normaalisti eli itse ilman mitään vaikeuksia.
- ☐ Pystyn syömään itse pienin vaikeuksin (esim. hitaasti, kömpelösti, vavisten tai erityisapuneuvoin).
- ☐ Tarvitsen hieman toisen apua syömisessä.
- ☐ En pysty syömään itse lainkaan, vaan minua pitää syöttää.
- ☐ En pysty syömään itse lainkaan, vaan minulle pitää antaa ravintoa letkun avulla tai suonensisäisesti.

KYSYMYS 7. Puhuminen

- ☐ Pystyn puhumaan normaalisti eli selvästi, kuuluvasti ja sujuvasti.
- ☐ Puhuminen tuottaa minulle pieniä vaikeuksia, esim. sanoja on etsittävä tai ääni ei ole riittävän kuuluva tai se vaihtaa korkeutta.
- ☐ Pystyn puhumaan ymmärrettävästi, mutta katkonaisesti, ääni vavisten, sammaltaen tai änkyttäen.
- ☐ Muilla on vaikeuksia ymmärtää puhettani.
- ☐ Pystyn ilmaisemaan itseäni vain elein.

KYSYMYS 8. Eritystoiminta

- ☐ Virtsarakkoni ja suolistoni toimivat normaalisti ja ongelmitta.
- ☐ Virtsarakkoni ja/tai suolistoni toiminnassa on lieviä ongelmia, esim. minulla on virtsaamisvaikeuksia tai kova tai löysä vatsa
- ☐ Virtsarakkoni ja/tai suolistoni toiminnassa on melkoisia ongelmia, esim. minulla on satunnaisia virtsanpidätysvaikeuksia tai vaikea ummetus tai ripuli.
- ☐ Virtsarakkoni ja/tai suolistoni toiminnassa on suuria ongelmia, esim. minulla on säännöllisesti "vahinkoja" tai peräruiskeiden tai katetroinnin tarvetta.
- ☐ En hallitse lainkaan virtsaamista ja/tai ulostamista.

KYSYMYS 9. Tavanomaiset toiminnot

- ☐ Pystyn suoriutumaan normaalisti tavanomaisista toiminnoista (esim. ansiotyö, opiskelu, kotityö, vapaa-ajan toiminnot).
- ☐ Pystyn suoriutumaan tavanomaisista toiminnoista hieman alentuneella teholla tai pienin vaikeuksin.
- ☐ Pystyn suoriutumaan tavanomaisista toiminnoista huomattavasti alentuneella teholla tai huomattavin vaikeuksin tai vain osaksi.
- ☐ Pystyn suoriutumaan tavanomaisista toiminnoista vain pieneltä osin.
- ☐ En pysty suoriutumaan lainkaan tavanomaisista toiminnoista.

KYSYMYS 10. Henkinen toiminta

- ☐ Pystyn ajattelemaan selkeästi ja johdonmukaisesti ja muistini toimii täysin moitteettomasti.
- ☐ Minulla on lieviä vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai muistini ei toimi täysin moitteettomasti
- ☐ Minulla on melkoisia vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai minulla on jonkin verran muistinmenetystä
- ☐ Minulla on suuria vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai minulla on huomattavaa muistinmenetystä
- ☐ Olen koko ajan sekaisin ja vailla ajan tai paikan tajua

KYSYMYS 11. Vaivat ja oireet

- ☐ Minulla ei ole mitään vaivoja tai oireita, esim. kipua, särkyä, pahoinvointia, kutinaa jne.
- ☐ Minulla on lieviä vaivoja tai oireita, esim. lievää kipua, särkyä, pahoinvointia, kutinaa jne.
- ☐ Minulla on melkoisia vaivoja tai oireita, esim. melkoista kipua, särkyä, pahoinvointia, kutinaa jne.
- ☐ Minulla on voimakkaita vaivoja tai oireita, esim. voimakasta kipua, särkyä, pahoinvointia, kutinaa jne.
- ☐ Minulla on sietämättömiä vaivoja ja oireita, esim. sietämätöntä kipua, särkyä, pahoinvointia, kutinaa jne.

KYSYMYS 12. Masentuneisuus

- ☐ En tunne itseäni lainkaan surulliseksi, alakuloiseksi tai masentuneeksi.
- ☐ Tunnen itseni hieman surulliseksi, alakuloiseksi tai masentuneeksi.
- ☐ Tunnen itseni melko surulliseksi, alakuloiseksi tai masentuneeksi.
- ☐ Tunnen itseni erittäin surulliseksi, alakuloiseksi tai masentuneeksi.
- ☐ Tunnen itseni äärimmäisen surulliseksi, alakuloiseksi tai masentuneeksi.

KYSYMYS 13. Ahdistuneisuus

- ☐ En tunne itseäni lainkaan ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
- ☐ Tunnen itseni hieman ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
- ☐ Tunnen itseni melko ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
- ☐ Tunnen itseni erittäin ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
- ☐ Tunnen itseni äärimmäisen ahdistuneeksi, jännittyneeksi tai hermostuneeksi.

KYSYMYS 14. Energisyys

- ☐ Tunnen itseni terveeksi ja elinvoimaiseksi.
- ☐ Tunnen itseni hieman uupuneeksi, väsyneeksi tai voimattomaksi.
- ☐ Tunnen itseni melko uupuneeksi, väsyneeksi tai voimattomaksi.
- ☐ Tunnen itseni erittäin uupuneeksi, väsyneeksi tai voimattomaksi, lähes "loppuun palaneeksi".
- ☐ Tunnen itseni äärimmäisen uupuneeksi, väsyneeksi tai voimattomaksi, täysin "loppuun palaneeksi".

KYSYMYS 15. Sukupuolielämä

- ☐ Terveydentilani ei vaikeuta mitenkään sukupuolielämääni.
- ☐ Terveydentilani vaikeuttaa hieman sukupuolielämääni.
- ☐ Terveydentilani vaikeuttaa huomattavasti sukupuolielämääni.
- ☐ Terveydentilani tekee sukupuolielämäni lähes mahdottomaksi.
- ☐ Terveydentilani tekee sukupuolielämäni mahdottomaksi.

3. LANTIONPOHJAVAIVOJEN KARTOITUS (PFDI-20)

Ohjeet: Kysymysten tarkoituksena on kartoittaa mikäli teillä esiintyy tiettyjä tuntemuksia suolen, virtsarakon tai alapään alueelta, ja kuinka paljon nämä oireet teitä vaivaavat. Vastatkaa kysymyksiin laittamalla rasti sopivaan ruutuun. Vastatessanne kysymyksiin ottakaa huomioon oireenne **viimeisten kolmen kuukauden aikana.**

1. Onko teillä usein paineen tunnetta alavatsalla?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

2. Esiintyykö teillä painon tunnetta tai särkyä (jomotusta) alapäässä?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

3. Esiintyykö teillä pullistuma alapäässä, jonka voitte itse nähdä tai tuntea emättimen ulkosuulla?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

4. Joudutteko koskaan painamaan emättimestä tai peräaukon läheltä saadaksenne ulostettua?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

5. Tuntuuko teistä usein siltä, että virtsarakkonne ei tyhjene kokonaan?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

6. Joudutteko joskus painamaan pullistumaa emättimen sisään aloittaaksenne virtsaamisen tai saadaksenne virtsarakon tyhjenemään?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

7. Joudutteko ponnistelemaan liikaa saadaksenne ulostettua?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

8. Tuntuuko teistä ulostamisen jälkeen siltä, ettei suoli ole tyhjentynyt kunnolla?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

9. Onko teillä vaikeuksia pidättää ulostetta, jos uloste on normaalia?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

10. Onko teillä vaikeuksia pidättää ulostetta, jos uloste on löysää?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

11. Karkaako teiltä usein kaasu peräsuolesta?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

12. Onko ulostaminen teille usein kivuliasta?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

13. Tuleeko teille pakottava ulostamistarve ja kiire vessaan ennen ulostamista?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

14. Pullistuuko osa peräsuoltanne koskaan ulos peräaukosta ulostamisen aikana tai sen jälkeen?

☐ Ei ☐

Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

15. Onko teillä tavallisesti tihentynyttä virtsaamistarvetta?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

16. Karkaako virtsa silloin kun tunnette virtsapakkoa eli hyvin voimakasta virtsaamisen tarvetta?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

17. Karkaako teiltä tavallisesti virtsaa yskiessä, nauraessa tai aivastaessa?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

18. Karkaako teiltä tavallisesti pieniä määriä virtsaa (tipoittain)?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

19. Onko teillä tavallisesti vaikeuksia tyhjentää virtsarakkonne?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

20. Onko teillä tavallisesti kipua tai epämiellyttävää tunnetta alavatsalla tai alapäässä?

☐ Ei ☐ Kyllä

Jos vastasitte kyllä, kuinka paljon se haittaa teitä?

☐ Ei lainkaan ☐ Jonkin verran ☐ Melko paljon ☐ Paljon

4. LANTIONPOHJAN LASKEUMAN/PIDÄTYSKYVYTTÖMYYDEN VAIKUTUS SEKSIELÄMÄÄN -KYSELY (PISQ-12)

Tämä lomake sisältää kysymyksiä teidän ja partnerinne seksielämästä. Kaikki antamanne vastaukset ovat luottamuksellisia ja niitä käsittelevät ainoastaan lääkärit ymmärtääkseen, mitkä asiat potilaat kokevat tärkeiksi seksielämälleen. Kunkin kysymyksen kohdalla *rastittakaa vastaus, joka parhaiten vastaa omaa kokemustanne*. Vastatessanne kysymyksiin ottakaa huomioon seksielämänne viimeisen kuuden kuukauden ajalta.

Oletteko tällä hetkellä seksuaalisesti aktiivinen?
Rastittakaa sopivin vastausvaihtoehto

☐ Ei, en kykene seksiin (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)
☐ En, minulla on liikaa kipuja (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)
☐ Ei, en ole halukas (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)
☐ En, minulla ei ole partneria (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)
☐ En, partnerini ei kykene seksiin (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)
☐ Kyllä

Jos vastasitte EI / EN, lomake on osaltanne täytetty.

Jos vastasitte KYLLÄ, jatkakaa vastaamalla seuraaviin 12 kysymykseen (PISQ-12).
Kysymykset alkavat seuraavalla sivulla.

1. **Kuinka usein tunnette sukupuolista halukkuutta?**
   Tunne voi käsittää toiveen seksistä, suunnitelmia seksin harrastamisesta, turhautuneisuus seksin puutteen takia, jne.
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

2. **Saatteko orgasmin ollessanne yhdynnässä kumppaninne kanssa?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

3. **Tunnetteko olevanne seksuaalisesti kiihottunut harrastaessanne seksiä kumppaninne kanssa?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

4. **Oletteko tyytyväinen seksielämäänne ja sen vaihtelevuuteen?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

5. **Tunnetteko kipua yhdynnän aikana?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

6. **Onko Teillä usein virtsakarkailua seksin aikana?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ Ei koskaan

7. **Rajoittaako pelko ulosteen tai virtsan karkailusta seksuaalista aktiivisuuttanne?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ Ei koskaan

8. **Vältättekö yhdyntää emättimen pullistuman vuoksi (rakon, peräsuolen tai emättimen ulosluiskahtamisen takia)?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

9. **Kun harrastatte seksiä kumppaninne kanssa, tunnetteko negatiivisia tunteita kuten pelkoa, vastenmielisyyttä, häpeää tai syyllisyyttä?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

10. **Onko kumppanillanne erektiohäiriö, joka vaikuttaa sukupuolielämäänne?**
    ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ Ei koskaan

11. **Onko kumppanillanne ennenaikaisen siemensyöksyn ongelma, joka haittaa sukupuolielämäänne?**
    ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ Ei koskaan

12. **Kuinka voimakkaita viimeisten kuuden kuukauden aikana tuntemanne orgasmit ovat verrattuna aikaisemmin saamiinne orgasmeihin?**
    ☐ Paljon vähemmän voimakkaita
    ☐ Vähemmän voimakkaita
    ☐ Yhtä voimakkaita
    ☐ Voimakkaampia
    ☐ Paljon voimakkaampia

FINPOP 2015 - Laskeumaleikkaustutkimus

Kysely toipumisesta ja tyytyväisyydestä leikkaushoitoon 2 vuotta laskeumaleikkauksen jälkeen.

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1. Lomakkeen täyttämispäivä ☐☐ pv ☐☐ kk ☐☐☐☐ vuosi

2. Henkilötiedot

Korjatkaa ystävällisesti henkilötietonne alla olevalle viivalle selvällä käsialalla, VAIN JOS yllä olevissa esitäytetyissä tiedoissa on virheitä

Nimi _____

Osoite _____

Postinumero-
postitoimipaikka _____

Pyydämme teitä vastaamaan alla oleviin kysymyksiin rastittamalla parhaiten soveltuvat kohdat.

Älkää vastatko kirjoittamalla, sillä tekstit eivät tule meille nähtäväksi.

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3. Oletteko joutunut vuonna 2015 tehdyn laskeumaleikkauksen jälkeen uusintaleikkaukseen joko laskeumaleikkaukseen liittyvän komplikaation tai uusiutuneen laskeuman vuoksi?

☐ En ☐ Kyllä

JOS vastasitte kyllä, oliko leikkaukseen syynä

☐ komplikaatio

☐ uusiutunut laskeuma

☐ jokin muu syy

4. Valitkaa numero, joka kuvastaa parhaiten nykyistä, leikkauksen jälkeistä vointianne verrattuna siihen, millainen se oli ennen leikkausta (lähtiessänne mukaan tutkimukseen vuonna 2015)

☐ 1 = hyvin paljon parempi
☐ 2 = paljon parempi
☐ 3 = vähän parempi
☐ 4 = ei muutosta
☐ 5 = vähän huonompi
☐ 6 = paljon huonompi
☐ 7 = hyvin paljon huonompi

5. Kuinka tyytyväinen olette hoitotulokseen?

Erittäin tyytyväinen	Tyytyväinen	Melko tyytyväinen	Ei tyytyväinen eikä tyytymätön	Melko tyytymätön	Tyytymätön	Erittäin tyytymätön
❑	☐	☐	☐	☐	☐	☐

JOS ette ole tyytyväinen hoitotulokseen, onko syy (voitte valita tarvittaessa useamman kohdan)

- ☐ En saanut apua oireisiini
- ☐ Leikkauksen jälkeen ilmenneet uudet oireet
- ☐ Laskeuman uusiutuminen
- ☐ Leikkaukseen liittyvät ongelmat (komplikaatiot)
- ☐ Jokin muu syy

6. Ottaen huomioon kaikki päivittäiset toimintanne sekä laskeumaan liittyvät oireenne, katsotteko, että nykyinen tilanteenne on riittävän hyvä?

☐ Kyllä ☐ Ei

7. Jos läheisellä ystävällänne olisi vastaava laskeumavaiva, suosittelisitteko leikkausta hänelle?

☐ Kyllä ☐ En

TERVEYTEEN LIITTYVÄN ELÄMÄNLAADUN KYSELY (15D©)

Ohje:
Lukekaa ensin läpi huolellisesti kunkin kysymyksen kaikki vastausvaihtoehdot. Merkitkää sitten rasti (x) sen vaihtoehdon kohdalle, joka **parhaiten kuvaa nykyistä terveydentilaanne**. Menetelkää näin kaikkien kysymysten 1-15 kohdalla. **Kustakin kysymyksestä rastitetaan siis yksi vaihtoehto.**

KYSYMYS 1. Liikuntakyky

- ☐ Pystyn kävelemään normaalisti (vaikeuksitta) sisällä, ulkona ja portaissa.
- ☐ Pystyn kävelemään vaikeuksitta sisällä, mutta ulkona ja/tai portaissa on pieniä vaikeuksia.
- ☐ Pystyn kävelemään ilman apua sisällä (apuvälinein tai ilman), mutta ulkona ja/tai portaissa melkoisin vaikeuksin tai toisen avustamana.
- ☐ Pystyn kävelemään sisälläkin vain toisen avustamana
- ☐ Olen täysin liikuntakyvytön ja vuoteenoma.

KYSYMYS 2. Näkö

- ☐ Näen normaalisti eli näen lukea lehteä ja TV:n tekstejä vaikeuksitta (silmälaseilla tai ilman).
- ☐ Näen lukea lehteä ja/tai TV:n tekstejä pienin vaikeuksin (silmälaseilla tai ilman).
- ☐ Näen lukea lehteä ja/tai TV:n tekstejä huomattavin vaikeuksin (silmälaseilla tai ilman).
- ☐ En näe lukea lehteä enkä TV:n tekstejä ilman silmälaseja tai niiden kanssa, mutta näen kulkea ilman opasta.
- ☐ En näe kulkea oppaatta eli olen lähes tai täysin sokea.

KYSYMYS 3. Kuulo

- ☐ Kuulen normaalisti eli kuulen hyvin normaalia puheääntä (kuulokojeella tai ilman).
- ☐ Kuulen normaalia puheääntä pienin vaikeuksin.
- ☐ Minun on melko vaikea kuulla normaalia puheääntä, keskustelussa on käytettävä normaalia kovempaa puheääntä.
- ☐ Kuulen kovaakin puheääntä heikosti; olen melkein kuuro.
- ☐ Olen täysin kuuro.

KYSYMYS 4. Hengitys

- ☐ Pystyn hengittämään normaalisti eli minulla ei ole hengenahdistusta eikä muita hengitysvaikeuksia.
- ☐ Minulla on hengenahdistusta raskaassa työssä tai urheillessa, reippaassa kävelyssä tasamaalla tai lievässä ylämäessä.
- ☐ Minulla on hengenahdistusta, kun kävelen tasamaalla samaa vauhtia kuin muut ikäiseni.
- ☐ Minulla on hengenahdistusta pienenkin rasituksen jälkeen, esim. peseytyessä tai pukeutuessa.
- ☐ Minulla on hengenahdistusta lähes koko ajan, myös levossa.

KYSYMYS 5. Nukkuminen

- ☐ Nukun normaalisti eli minulla ei ole mitään ongelmia unen suhteen.
- ☐ Minulla on lieviä uniongelmia, esim. nukahtamisvaikeuksia tai satunnaista yöheräilyä.
- ☐ Minulla on melkoisia uniongelmia, esim. nukun levottomasti tai uni ei tunnu riittävältä.
- ☐ Minulla on suuria uniongelmia, esim. joudun käyttämään usein tai säännöllisesti unilääkettä, herään säännöllisesti yöllä ja/tai aamuisin liian varhain.
- ☐ Kärsin vaikeasta unettomuudesta, esim. unilääkkeiden runsaasta käytöstä huolimatta nukkuminen on lähes mahdotonta, valvon suurimman osan yöstä.

KYSYMYS 6. Syöminen

- ☐ Pystyn syömään normaalisti eli itse ilman mitään vaikeuksia.
- ☐ Pystyn syömään itse pienin vaikeuksin (esim. hitaasti, kömpelösti, vavisten tai erityisapuneuvoin).
- ☐ Tarvitsen hieman toisen apua syömisessä.
- ☐ En pysty syömään itse lainkaan, vaan minua pitää syöttää.
- ☐ En pysty syömään itse lainkaan, vaan minulle pitää antaa ravintoa letkun avulla tai suonensisäisesti.

KYSYMYS 7. Puhuminen

- ☐ Pystyn puhumaan normaalisti eli selvästi, kuuluvasti ja sujuvasti.
- ☐ Puhuminen tuottaa minulle pieniä vaikeuksia, esim. sanoja on etsittävä tai ääni ei ole riittävän kuuluva tai se vaihtaa korkeutta.
- ☐ Pystyn puhumaan ymmärrettävästi, mutta katkonaisesti, ääni vavisten, sammaltaen tai änkyttäen.
- ☐ Muilla on vaikeuksia ymmärtää puhettani.
- ☐ Pystyn ilmaisemaan itseäni vain elein.

KYSYMYS 8. Eritystoiminta

- ☐ Virtsarakkoni ja suolistoni toimivat normaalisti ja ongelmitta.
- ☐ Virtsarakkoni ja/tai suolistoni toiminnassa on lieviä ongelmia, esim. minulla on virtsaamisvaikeuksia tai kova tai löysä vatsa.
- ☐ Virtsarakkoni ja/tai suolistoni toiminnassa on melkoisia ongelmia, esim. minulla on satunnaisia virtsanpidätysvaikeuksia tai vaikea ummetus tai ripuli.
- ☐ Virtsarakkoni ja/tai suolistoni toiminnassa on suuria ongelmia, esim. minulla on säännöllisesti "vahinkoja" tai peräruiskeiden tai katetroinnin tarvetta.
- ☐ En hallitse lainkaan virtsaamista ja/tai ulostamista.

KYSYMYS 9. Tavanomaiset toiminnot

- ☐ Pystyn suoriutumaan normaalisti tavanomaisista toiminnoista (esim. ansiotyö, opiskelu, kotityö, vapaa-ajan toiminnot).
- ☐ Pystyn suoriutumaan tavanomaisista toiminnoista hieman alentuneella teholla tai pienin vaikeuksin.
- ☐ Pystyn suoriutumaan tavanomaisista toiminnoista huomattavasti alentuneella teholla tai huomattavin vaikeuksin tai vain osaksi.
- ☐ Pystyn suoriutumaan tavanomaisista toiminnoista vain pieneltä osin.
- ☐ En pysty suoriutumaan lainkaan tavanomaisista toiminnoista.

KYSYMYS 10. Henkinen toiminta

- ☐ Pystyn ajattelemaan selkeästi ja johdonmukaisesti ja muistini toimii täysin moitteettomasti.
- ☐ Minulla on lieviä vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai muistini ei toimi täysin moitteettomasti.
- ☐ Minulla on melkoisia vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai minulla on jonkin verran muistinmenetystä.
- ☐ Minulla on suuria vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai minulla on huomattavaa muistinmenetystä.
- ☐ Olen koko ajan sekaisin ja vailla ajan tai paikan tajua.

KYSYMYS 11. Vaivat ja oireet

- ☐ Minulla ei ole mitään vaivoja tai oireita, esim. kipua, särkyä, pahoinvointia, kutinaa jne.
- ☐ Minulla on lieviä vaivoja tai oireita, esim. lievää kipua, särkyä, pahoinvointia, kutinaa jne.
- ☐ Minulla on melkoisia vaivoja tai oireita, esim. melkoista kipua, särkyä, pahoinvointia, kutinaa jne.
- ☐ Minulla on voimakkaita vaivoja tai oireita, esim. voimakasta kipua, särkyä, pahoinvointia, kutinaa jne.
- ☐ Minulla on sietämättömiä vaivoja ja oireita, esim. sietämätöntä kipua, särkyä, pahoinvointia, kutinaa jne.

KYSYMYS 12. Masentuneisuus

- ☐ En tunne itseäni lainkaan surulliseksi, alakuloiseksi tai masentuneeksi.
- ☐ Tunnen itseni hieman surulliseksi, alakuloiseksi tai masentuneeksi.
- ☐ Tunnen itseni melko surulliseksi, alakuloiseksi tai masentuneeksi.
- ☐ Tunnen itseni erittäin surulliseksi, alakuloiseksi tai masentuneeksi.
- ☐ Tunnen itseni äärimmäisen surulliseksi, alakuloiseksi tai masentuneeksi.

KYSYMYS 13. Ahdistuneisuus

- ☐ En tunne itseäni lainkaan ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
- ☐ Tunnen itseni hieman ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
- ☐ Tunnen itseni melko ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
- ☐ Tunnen itseni erittäin ahdistuneeksi, jännittyneeksi tai hermostuneeksi.
- ☐ Tunnen itseni äärimmäisen ahdistuneeksi, jännittyneeksi tai hermostuneeksi.

KYSYMYS 14. Energisyys

- ☐ Tunnen itseni terveeksi ja elinvoimaiseksi.
- ☐ Tunnen itseni hieman uupuneeksi, väsyneeksi tai voimattomaksi.
- ☐ Tunnen itseni melko uupuneeksi, väsyneeksi tai voimattomaksi.
- ☐ Tunnen itseni erittäin uupuneeksi, väsyneeksi tai voimattomaksi, lähes "loppuun palaneeksi".
- ☐ Tunnen itseni äärimmäisen uupuneeksi, väsyneeksi tai voimattomaksi, täysin "loppuun palaneeksi".

KYSYMYS 15. Sukupuolielämä

- ☐ Terveydentilani ei vaikeuta mitenkään sukupuolielämääni.
- ☐ Terveydentilani vaikeuttaa hieman sukupuolielämääni.
- ☐ Terveydentilani vaikeuttaa huomattavasti sukupuolielämääni.
- ☐ Terveydentilani tekee sukupuolielämäni lähes mahdottomaksi.
- ☐ Terveydentilani tekee sukupuolielämäni mahdottomaksi.

LANTIONPOHJAVAIVOJEN KARTOITUS (PFDI-20)

Ohjeet: Kysymysten tarkoituksena on kartoittaa, esiintyykö teillä tiettyjä tuntemuksia suolen, virtsarakon tai alapään alueelta, ja kuinka paljon nämä oireet teitä vaivaavat. Vastatkaa kysymyksiin laittamalla rasti sopivaan ruutuun. Vastatessanne kysymyksiin ottakaa huomioon oireenne **viimeisten kolmen kuukauden aikana.**

---

1. Onko teillä usein paineen tunnetta alavatsalla?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

2. Esiintyykö teillä painon tunnetta tai särkyä (jomotusta) alapäässä?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

3. Esiintyykö teillä pullistuma alapäässä, jonka voitte itse nähdä tai tuntea emättimen ulkosuulla?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

4. Joudutteko koskaan painamaan emättimestä tai peräaukon läheltä saadaksenne ulostettua?

☐En ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

5. Tuntuuko teistä usein siltä, että virtsarakkonne ei tyhjene kokonaan?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

6. Joudutteko joskus painamaan pullistumaa emättimen sisään aloittaaksenne virtsaamisen tai saadaksenne virtsarakon tyhjenemään?

☐En ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

7. Joudutteko ponnistelemaan liikaa saadaksenne ulostettua?

☐En ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

8. Tuntuuko teistä ulostamisen jälkeen siltä, ettei suoli ole tyhjentynyt kunnolla?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

9. Onko teillä vaikeuksia pidättää ulostetta, jos uloste on normaalia?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

10. Onko teillä vaikeuksia pidättää ulostetta, jos uloste on löysää?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

11. Karkaako teiltä usein kaasu peräsuolesta?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

12. Onko ulostaminen teille kivuliasta?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

13. Tuleeko teille pakottava ulostamistarve ja kiire vessaan ennen ulostamista?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

14. Pullistuuko osa peräsuoltanne koskaan ulos peräaukosta ulostamisen aikana tai sen jälkeen?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

15. Onko teillä tavallisesti tihentynyttä virtsaamistarvetta?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

16. Karkaako virtsa silloin kun tunnette virtsapakkoa eli hyvin voimakasta virtsaamisen tarvetta?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

17. Karkaako teiltä tavallisesti virtsaa yskiessä, nauraessa tai aivastaessa?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

18. Karkaako teiltä tavallisesti pieniä määriä virtsaa (tipoittain)?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

19. Onko teillä tavallisesti vaikeuksia tyhjentää virtsarakkonne?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

20. Onko teillä tavallisesti kipua tai epämiellyttävää tunnetta alavatsalla tai alapäässä?

☐Ei ☐Kyllä

JOS vastasitte kyllä, kuinka paljon se haittaa teitä?

☐Ei lainkaan ☐Jonkin verran ☐Melko paljon ☐Paljon

LANTIONPOHJAN LASKEUMAN/PIDÄTYSKYVYTTÖMYYDEN VAIKUTUS SEKSIELÄMÄÄN -KYSELY (PISQ-12)

Ohjeet: Tämä lomake sisältää kysymyksiä teidän ja partnerinne seksielämästä. Kaikki antamanne vastaukset ovat luottamuksellisia ja niitä käsittelevät ainoastaan lääkärit ymmärtääkseen, mitkä asiat potilaat kokevat tärkeiksi seksielämälleen. Kunkin kysymyksen kohdalla *rastittakaa vastaus, joka parhaiten vastaa omaa kokemustanne*. Vastatessanne kysymyksiin ottakaa huomioon seksielämänne **viimeisen kuuden kuukauden ajalta.**

Oletteko tällä hetkellä seksuaalisesti aktiivinen?
Rastittakaa sopivin vastausvaihtoehto

☐ Ei, en kykene seksiin (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

☐ En, minulla on liikaa kipuja (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

☐ Ei, en ole halukas (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

☐ En, minulla ei ole partneria (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

☐ En, partnerini ei kykene seksiin (Kiitos vastauksesta, lomaketta ei tarvitse täyttää)

☐ Kyllä

JOS vastasitte EI / EN, lomake on osaltanne täytetty.
JOS vastasitte KYLLÄ, jatkakaa vastaamalla seuraaviin 12 kysymykseen.
Kysymykset alkavat seuraavalla sivulla. *Kustakin kysymyksestä rastitetaan yksi vastausvaihtoehto.*

1. **Kuinka usein tunnette sukupuolista halukkuutta?**
   Tunne voi käsittää toiveen seksistä, suunnitelmia seksin harrastamisesta, turhautuneisuus seksin puutteen takia, jne.
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

2. **Saatteko orgasmin ollessanne yhdynnässä kumppaninne kanssa?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

3. **Tunnetteko olevanne seksuaalisesti kiihottunut harrastaessanne seksiä kumppaninne kanssa?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

4. **Oletteko tyytyväinen seksielämäänne ja sen vaihtelevuuteen?**
   ☐ Aina ☐ Usein ☐ Joskus ☐Harvoin ☐ En koskaan

5. **Tunnetteko kipua yhdynnän aikana?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

6. **Onko Teillä usein virtsakarkailua seksin aikana?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ Ei koskaan

7. **Rajoittaako pelko ulosteen tai virtsan karkailusta seksuaalista aktiivisuuttanne?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ Ei koskaan

8. **Vältättekö yhdyntää emättimen pullistuman vuoksi (rakon, peräsuolen tai emättimen ulosluiskahtamisen takia)?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

9. **Kun harrastatte seksiä kumppaninne kanssa, tunnetteko negatiivisia tunteita kuten pelkoa, vastenmielisyyttä, häpeää tai syyllisyyttä?**
   ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ En koskaan

10. **Onko kumppanillanne erektiohäiriö, joka vaikuttaa sukupuolielämäänne?**
    ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ Ei koskaan

11. **Onko kumppanillanne ennenaikaisen siemensyöksyn ongelma, joka haittaa sukupuolielämäänne?**
    ☐ Aina ☐ Usein ☐ Joskus ☐ Harvoin ☐ Ei koskaan

12. **Kuinka voimakkaita viimeisten kuuden kuukauden aikana tuntemanne orgasmit ovat verrattuna aikaisemmin saamiinne orgasmeihin?**
    ☐ Paljon vähemmän voimakkaita
    ☐ Vähemmän voimakkaita
    ☐ Yhtä voimakkaita
    ☐ Voimakkaampia
    ☐ Paljon voimakkaampia

Leikkaukseen liittyvä informaatio

1. Potilaan henkilöturvatunnus

2. Toimenpidepäivä

3. Onko potilaalla aiempia lantion alueen leikkauksia?

- Ei
- Kyllä

4. Mikä aiempi lantion alueen leikkaus?

- Aiempi laskeumaleikkaus
- Kohdunpoisto muusta syystä kuin laskeuman vuoksi
- Muu lantion alueen leikkaus
- Inkontinenssileikkaus
- Muu, mikä

5. Mikä aiempi laskeumaleikkaus?

- Vaginaalinen hysterektomia
- Kolporafia anterior
- Kolporafia posterior
- Sakrospinosusfiksaatio
- Operaatio Manchester
- Verkkoleikkaus
- Muu, mikä

6. Mikä aiempi laskeuman verkkoleikkaus?

- Anteriorinen verkko
- Posteriorinen verkko

- Totaaliverkko
- Sakrokolpopeksia
- Muu

7. Mikä oli aiemmin käytetty verkko (verkkomateriaali tai kauppanimi) ?

8. Mitä emättimen osaa nyt korjattava laskeuma käsittää?

- Etuseinä
- Takaseinä
- Apex

9. Nyt korjattava laskeuma on

- Primaari eli ei aikaisempia leikkauksia tähän emättimen osaan
- Residiivi eli sama emättimen osa on korjattu aiemmin
- Molemmat eli sekä uusi että aiemmin korjattu laskeuma

10. Mikä on laskeuman taso?

	ei laskeumaa	laskeutuu jonkin verran, mutta ei kliinistä merkitystä	laskeutuu merkittävästi	
Emättimen etuseinä	○	○	○	hymentasosta
Emättimen takaseinä	○	○	○	hymentasosta
Apex eli emättimen pohja / portio	○	○	○	hymentasosta

11. Jos kyseinen emättimen osa laskeutuu merkittävästi, kuinka monta senttimetriä sen alin osa sijaitsee verrattuna hymentasoon?

Hymentaso on taso 0, sen emättimen puoleinen taso ilmaistaan - ja ulospäin hymentasosta +.

Emättimen etuseinä

Emättimen takaseinä

Apex eli emättimen pohja / portio

12. Mikä on limakalvojen kunto?

- Hyvä
- Tyydyttävä *(atrofiset / ohuet, mutta ei haavaiset tai tulehtuneet limakalvot)*

- Huono *(limakalvoilla haavoja / eroosioita / tulehdusta)*

13. Oliko potilaalla ennen leikkausta (poisto < 1 kk preoperatiiviseti) käytössä jokin laskeuman konservatiivinen hoitomenetelmä?

- Ei
- Kyllä, laskeumarengas
- Kyllä, laskeumakuutio
- Muu, mikä _____

14. Onko potilaalla säännöllisessä käytössä käytössä estrogeenivalmiste?

- Ei
- Kyllä, paikallinen
- Kyllä, systeeminen

Leikkaukseen liittyvä informaatio

15. Laskeuman leikkaustapa / tavat

- ○ LEF01 Emättimen etuseinän korjaus etuseinäverkolla
- ○ LEF00 Emättimen etuseinän muovaus (KA)
- ○ LEF03 Emättimen takaseinän muovaus (KP)
- ○ LEF04 Emättimen takaseinän korjaus takaseinäverkolla
- ○ LEF05 Uusiutuneen emättimen etuseinän laskeuman korjaus ompelein
- ○ LEF06 Uusiutuneen emättimen etuseinän laskeuman korjaus verkolla
- ○ LEF08 Uusiutuneen emättimen takaseinän laskeuman korjaus ompelein
- ○ LEF09 Uusiutuneen emättimen takaseinän laskeuman korjaus verkolla
- ○ LEF10 Emättimen muovaus ja kohdunkaulan lyhentäminen (operaatio Manchester)
- ○ LCD10 Vaginaalinen kohdunpoisto
- ○ LEF13 Laskeutuneen kohdun poisto ja emättimen/välilihan muovaus (VH ja KA ja/tai KP)
- ○ LEF14 Vaginaalinen kohdunpoisto ja laskeumien korjaus verkoilla
- ○ LEF20 Osittainen emättimen sulkeminen
- ○ LEF23 Emättimen sulkeminen
- ○ LEF40 Enterocelen korjausleikkaus emättimen kautta
- ○ LEF41 Enterocelen korjausleikkaus vatsaontelon tähystyksessä
- ○ LEF51 Kohdun poiston jälkeisen emättimen pohjukan laskeuman korjaus vatsaontelon tähystyksessä
- ○ LEF53 Kohdun poiston jälkeisen emättimen pohjukan laskeuman korjaus emättimen kautta
- ○ LEF54 Apikaalisen prolapsin korjaus vaginaalisella verkolla
- ○ LEF60 Avoin hysteropeksia
- ○ LEF61 Laparoskooppinen hysteropeksia
- ○ LEF63 Vaginaalinen hysteropeksia ompelein
- ○ LEF64 Vaginaalinen hysteropeksia verkolla
- ○ LEF96 Muu kohdun ja emättimen laskeutuman leikkaus _____
- ○ LEF97 Muu kohdun ja emättimen laskeutuman leikkaus vatsaontelon tähystyksessä _____

16. Laskeuma korjattiin

- ○ Perinteisillä menetelmillä potilaan omia kudoksia käyttäen
- ○ Tukimateriaaleja apuna käyttäen

17. Tukimateriaalina käytettiin

- ○ Synteettistä verkkoa
- ○ Biologista materiaalia
- ○ Muu, mikä

18. Käytetty verkko oli

- ○ kaupallinen kitti, mikä (kauppanimi)
- ○ 'self tailored' eli itse leikattu verkko

19. Verkkomateriaali oli

- ○ Polypropyleeni
- ○ Polyesteri
- ○ Muu, mikä
- ○ Ei tietoa

20. Tehtiinkö laskeuman korjaamisen lisäksi muita toimenpiteitä?

- ☐ Ei
- ☐ Kyllä

21. Mitä muita toimenpiteitä tehtiin?

- ☐ Kohdunpoisto muusta syystä kuin laskeuman vuoksi
- ☐ Virtsainkontinenssileikkaus
- ☐ Suoliston toimenpide, mikä
- ☐ Adnex-toimenpide
- ☐ Kohdun kaavinta
- ☐ Lämpöpallohoito
- ☐ Muu, mikä

Leikkaukseen liittyvä informaatio

22. Leikkauksen kesto

min

23. Leikkausvuoto

ml

24. Käytettiinkö antibioottiprofylaksiaa?

- Ei
- Kyllä, pelkkä keftriaksoni
- Kyllä, keftriaksoni ja metronidatzoli
- Kyllä klindamysiini
- Muu, mikä

25. Käytettiinkö tromboosiprofylaksiaa?

- Ei
- Kyllä

26. Tromboosiprofylaksian aloitus

- Postoperatiivisesti leikkauspäivänä
- Preoperatiivisesti leikkausta edeltävänä päivänä
- Siltahoitona
- Muu, mikä

27. Tromboosiprofylaksian valmiste

- Klexane
- Fragmin
- Innohep
- Muu, mikä

28. Tromboosiprofylaksian annos

- ○ normaali
- ○ alennettu
- ○ korotettu
- ○ muu, mikä

29. Tromboosiprofylaksian kesto

vrk

30. Esiintyikö välittömiä leikkauskomplikaatioita?

- ○ Ei
- ○ Kyllä

31. Mitä välittömiä komplikaatiota esiintyi?

- ☐ Verisuonivaurio
- ☐ Virtsarakkovaurio
- ☐ Uretervaurio
- ☐ Suolivaurio
- ☐ Muu, mikä

32. Leikkauksen vaikeusaste

- ○ Helppo
- ○ Kohtalainen
- ○ Vaikea

33. Mikä leikkauksesta teki vaikean?

- ☐ Haastava anatomia
- ☐ Aikaisemmat leikkaukset / kiinnikkeet
- ☐ Tekniset ongelmat
- ☐ Muu, mikä

34. Leikkaava lääkäri (pääoperatööri)

- ○ Erikoistuva lääkäri
- ○ Erikoislääkäri

ORIGINAL PUBLICATIONS (I – IV)

I

Received: 9 May 2018 | Accepted: 8 December 2018

DOI: 10.1111/aogs.13520

ORIGINAL RESEARCH ARTICLE

Methods of surgery for pelvic organ prolapse in a nationwide cohort (FINPOP 2015)

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Funding information The study was funded by Finnish Society of Gynecological Surgery and supported by grants from the Emil Aaltonen foundation, the Finnish Cultural Foundation, Häme Regional Fund and the Ministry of Health and Social Welfare in Finland via Medical Research Funds of Kanta-Häme Central Hospital.

Abstract

Introduction: The management of pelvic organ prolapse (POP) varies significantly between countries. The objective of this study was to describe the methods used for POP surgery in Finland and to identify the factors that affect clinicians' choice to use either a native tissue repair (NTR) or a mesh repair method.

Material and Methods: This prospective cohort study included 3535 surgeries covering 83% of all POP operations performed in Finland in 2015. The operative details and patient characteristics, including the Pelvic Floor Distress Inventory (PFDI-20), were compared between three selected surgical methods: NTR, transvaginal mesh (TVM) and abdominal mesh (AM). The predictive factors for the use of mesh augmentation were also studied with logistic regression analysis.

Results: The most common method was NTR (n = 2855, 81%), followed by TVM (n = 429, 12%) and AM (n = 251, 7%). Approximately 92% of the patients who underwent primary prolapse surgery underwent NTR, and mesh surgery was used mainly for recurrent prolapse. The strongest predictor of mesh surgery was previous POP surgery for the same vaginal compartment (adjusted odds ratio [OR] = 56, 95% confidence interval [CI] = 38-84 for TVM; adjusted OR = 22, 95% CI = 14-34 for AM). Other predictive factors for mesh surgery were previous hysterectomy, healthcare district, severe bulge symptoms and advanced prolapse. TVM was associated with advanced anterior prolapse and older age. AM surgery was associated with advanced apical and/or posterior compartment prolapse. PFDI-20 scores were the highest in the AM group (108 vs 103 in the TVM group and 98 in the NTR group, $P = 0.012$), which indicates more bothersome symptoms than in the other groups.

Conclusions: The Finnish practices follow international guidelines that advocate NTR as the principal surgical method for POP. Synthetic mesh augmentation was mainly used in patients with recurrent and advanced prolapse with severe symptoms. The variation in the rates of mesh augmentation for POP surgery in different hospitals implies a lack of sufficient evidence of the most suitable treatment method and indicates a need for national guidelines.

KEYWORDS
hysterectomy, laparoscopy, prolapse, surgical techniques, urogynecology

Abbreviations: AM, abdominal mesh; NTR, native tissue repair; OECD, Organisation for Economic Co-operation and Development; PFDI, pelvic floor distress inventory; POP, pelvic organ prolapse; TVM, transvaginal mesh.

1 | INTRODUCTION

More than one in 10 women undergo pelvic organ prolapse (POP) surgery in their lifetime.[1,2] In Finland, the lifetime likelihood of POP surgery is 13%, and approximately 4200 operations are performed annually.[3,4] There are numerous methods used for POP surgery.[5] Clinicians must choose between vaginal and abdominal surgical approaches, decide whether to use native tissue or a surgical mesh, choose to repair one or multiple sites of prolapse, and decide whether concomitant surgery, such as hysterectomy or incontinence surgery, is necessary. The operative method depends on the nature, site and severity of the prolapse and the symptoms affecting urinary, bowel or sexual function.[6] The patient's general health and individual needs and values should be considered when determining the operative method.[7,8]

There continues to be a limited level of evidence to guide clinicians in choosing the best surgical technique for a particular patient.[7] Furthermore, a surgeon's own preferences and capabilities influence the decision. There is significant heterogeneity (>10-fold) in the rates at which individual POP procedures are performed in different countries.[9] Recently, the risks related to mesh augmentation have caused debate regarding the safety of this method for POP surgery.[10] Thus, different surgical techniques and their safety and effectiveness require further assessment.

This nationwide prospective annual cohort study reports the methods used for POP surgery in Finland in 2015. The patient characteristics and symptoms were compared between women who were treated with native tissue repair (NTR), a vaginal mesh (TVM) or an abdominal mesh (AM) augmentation to identify the factors that affect clinicians' choice to use a mesh instead of NTR for POP surgery.

Key message

In Finland, pelvic organ prolapse is repaired vaginally with native tissue in eight of 10 surgeries. Mesh surgery is used mainly for recurrent prolapse and for patients with advanced prolapse and bothersome symptoms.

2 | MATERIAL AND METHODS

All Finnish hospitals that performed POP surgery in 2015 were invited to participate in this nationwide prospective multicenter study. The study was organized by the Finnish Society for Gynecological Surgery, and the study protocol of a national multicenter study with local doctors in charge was similar to a previous study of hysterectomies (FINHYST 2006).[11] The study period was between 1 January 2015 and 31 December 2015. We retrieved the actual total number of POP operations performed in Finland during this period from the Finnish Hospital Discharge Register of the National Institute for Health and Welfare.[4] The inclusion criteria for the patients were age older than 18 years and ability to communicate in written and oral Finnish or Swedish. Written informed consent was obtained from each patient.

The surgical treatment and patient characteristics were derived from questionnaires filled out by both doctors and patients. The usefulness and reliability of the questionnaires (paper and electronic forms) and the study protocol were tested in a pilot study performed in 2014 at Tampere University Hospital, Central Finland Central Hospital and Kanta-Häme Central Hospital. The data from the pilot study are not included in this analysis.

The surgeons completed an electronic study questionnaire. The degree of prolapse was assessed using a simplified Pelvic Organ Prolapse Quantification (POPQ) system.[6] The surgeons recorded the single most distal Pelvic Organ Prolapse Quantification point of all three compartments of the vagina (anterior, posterior or apical) in centimeters from the hymen. They also documented the operative method with a description and a code from the Nordic Classification of Surgical Procedures (NCSP).

The participants completed a questionnaire in either an electronic or paper form based on their own preferences. They reported their worst symptoms related to pelvic floor dysfunction, such as an awareness of a bulge or a feeling of pelvic pressure, urinary or defecation problems, pain or other symptoms. They also reported their height (cm), weight (kg), chronic diseases, medication, parity, mode of delivery and smoking status. We administered validated health-related quality of life questionnaires either in Finnish[12] or Swedish[13] and the short version of the Pelvic Floor Distress Inventory (PFDI-20),[14] which measures the severity of POP symptoms. The questionnaires were collected separately by the investigators and were not available to the surgeons. The surgical method was determined by the individual surgeon's preference based on clinical judgment.

2.1 | Statistical analyses

The operations were categorized into three groups: NTR, transvaginal mesh augmentation (TVM) and abdominal mesh (AM) augmentation. Patient characteristics and surgical details were analyzed in the whole study population and in each surgical method group. The statistical significance was set at $P < 0.05$. The differences in categorical variables between the surgery groups were tested with the χ^2 test. Q-Q-plots were used to assess the distribution of continuous variables, and Levene's test was used to assess the equality of variances in the different groups. When the variances were equal, the differences among continuous variables between the groups were tested with an analysis of variance, and the Bonferroni method was applied to assess pairwise comparisons. For variables with unequal variance, the Brown–Forsythe test was used to assess the differences between the groups, and Dunnett's T3 was used to assess pairwise differences. Binary logistic regression was used to identify the predictors for the use of a vaginal mesh or an AM. The results were adjusted for age, sexual activity, previous hysterectomy or POP surgery, degree of bulge symptoms, healthcare district and type of hospital. There were no indications of collinearity between the factors included in the model (all correlation

coefficients <0.4). All statistical calculations were performed with SPSS 24.0 (IBM Corp., Armonk, NY, USA).

2.2 | Ethical approval

The Research Ethics Committee of the Northern Savo Hospital District approved the protocol (Reference number 5//2014). Approval was also obtained from the Finnish Ministry of Social Affairs and Health and from the institutional review board of each participating hospital. The study was included in the ClinicalTrials.gov protocol registration system (NCT02716506) and followed the ethical standards for human experimentation established by the Declaration of Helsinki of 1964, revised in 2013.[15]

3 | RESULTS

Forty-one of the 45 (91%) hospitals performing POP surgeries in Finland participated: all 5 Finnish university hospitals, 17/18 secondary hospitals, 15/17 primary hospitals and 4/5 private clinics. Of the 3535 operations included in the study, 1169 (33%) were performed in tertiary, 1562 (44%) in secondary and 745 (21%) in primary hospitals, and 44 (1.3%) in private clinics. The participation rate varied between centers and was 42%-100% (Supporting Information Appendix S1). The flow chart of participant enrollment and data availability is presented in Figure 1. In 2015, altogether 4240 POP operations were performed in Finland, corresponding to a rate of 1.52 per 1000 women. The study population (n = 3515 patients, 3535 operations) covered 83% of all women that underwent surgery for POP in Finland in 2015. Approximately 83% (n = 2903) of the participants completed all the preoperative questionnaires including the PFDI-20 questionnaire.

The patient characteristics are given in Table 1. The patients who underwent TVM were significantly older, less sexually active and more likely to have cardiovascular diseases or be treated with medication for chronic disease than patients in the other groups were. There was no significant difference in the proportion of obese patients between the groups. The participants' smoking habits and parity did not differ between groups. Altogether, 1701 (48%) patients had a history of previous pelvic surgery. The total previous hysterectomy rate was 79% for the TVM, 76% for the AM and 23% for the NTR groups ($P < 0.001$). A total of 891 (25%) patients had undergone previous surgery for POP; all these patients were symptomatic. Prolapse of the anterior compartment of the vagina was the most common form of prolapse. More than one compartment of the vagina was reconstructed in 1460 (41%) of the operations.

Awareness of a bulge was reported by 93% of the patients (PFDI-20 question number 3). The patients' assessment of the worst symptom related to their pelvic floor dysfunction was as follows: feeling of a bulge or pressure (2003, 69%), urinary symptoms (468, 16%), defecation symptoms (297, 10%) and feeling of pain (60, 2%). The total PFDI-20 scores and subscales in the three surgical groups are shown in Table 2. The highest total PFDI-20 scores were observed in the mesh groups, indicating greater distress due to symptoms. In the AM group, the average score was 10 points (95% confidence interval [CI] = 0.3-20, $P = 0.041$) higher than that in the NTR group. The prolapse symptom (Pelvic Organ; Prolapse Distress Inventory [POPDI-6]) scores were also higher in the mesh groups. Urinary symptoms were significantly more common in the TVM group than in the other groups. Colorectal symptom scores (Colorectal-Anal Distress Inventory [CRADI-8]) were similar between the groups.

The types of operations performed are summarized in Figure 2. The most common method of surgery—vaginal hysterectomy and colporrhaphy—was performed in 1153 (33%) operations. Colporrhaphy

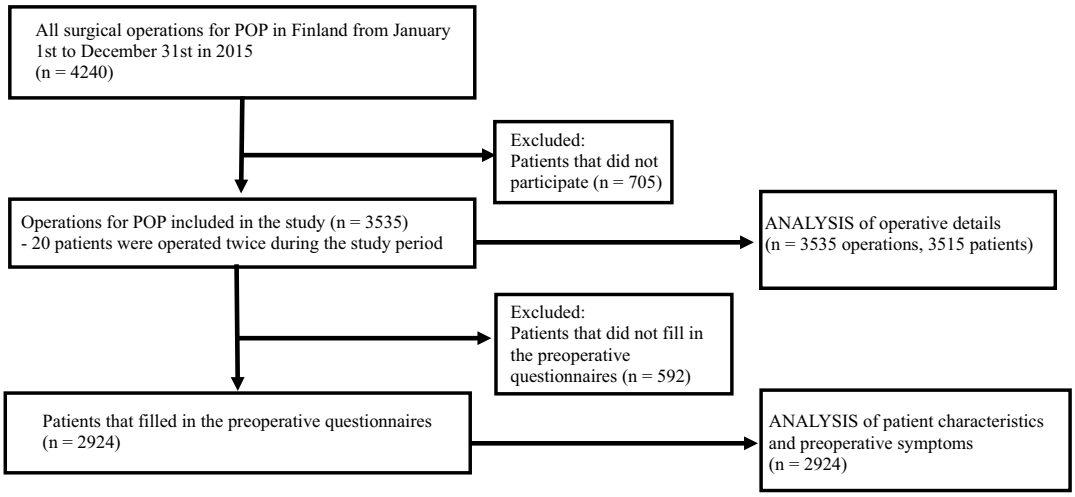

FIGURE 1 Flow diagram of enrollment and analysis of the study participants

TABLE 1 Patient characteristics

Characteristic	All (n = 3515)	NTR (n = 2850)	TVM (n = 421)	AM (n = 244)	*P*[a]	Data available, n (%)
Age at operation (y) (mean ± SD)	64.0 ± 1.7	63.3 ± 11.0	68.5 ± 7.7	63.9 ± 1.0	<0.001	3512 (100)
Min – max (y)	26.1-91.7	26.1-91.7	48.1-89.3	34.4-85.7		
<50 y, n (%)	361 (10.3)	340 (11.9)	2 (0.5)	169 (6.9)	<0.001	
50-64 y, n (%)	1403 (39.9)	1169 (41.0)	131 (31.1)	103 (42.2)	<0.001	
65-79 y, (%)	1556 (44.3)	976 (41.4)	257 (61.0)	111 (45.5)	<0.001	
≥80 y, n (%)	192 (5.5)	150 (5.3)	31 (7.4)	11 (4.5)	0.076	
BMI (kg/m^2) (mean ± SD)	26.9 ± 4.1	26.9 ± 4.1	27.0 ± 3.8	26.1 ± 3.7	0.022	2825 (80.4)
Min-max (kg/m^2)	16.0-59.5	16.0-59.5	18.3-42.5	16.9-36.9		
BMI < 25, n (%)	1010 (35.7)	813 (35.7)	112 (32.1)	85 (40.7)	0.121	
BMI 25-29.9, n (%)	1252 (44.3)	994 (43.7)	167 (47.9)	91 (43.5)	0.336	
BMI ≥ 30, n (%)	572 (20.2)	469 (20.1)	70 (20.1)	33 (15.8)	0.251	
Current smokers, n (%)	252 (8.7)	206 (8.7)	28 (7.9)	21 (9.9)	0.626	2913 (82.9)
Parity (mean ± SD)	2.55 ± 1.4	2.60 ± 1.5	2.30 ± 1.1	2.45 ± 1.4	0.122	2924 (83.2)
Min – max	0-16	0-16	0-8	0-11		
Vaginal deliveries, median (min – max)	2 (0-14)	2 (0-14)	2 (0-6)	2 (0-10)	0.666	
Cesarean sections, median (min – max)	0 (0-4)	0 (0-4)	0 (0-4)	0 (0-3)	0.830	
No deliveries, n (%)	13 (0.4)	11 (0.5)	0 (0)	2 (0.9)	0.566	
Medical history						
Cardiovascular disease, n (%)	1257 (43.0)	995 (42.3)	181 (50.7)	81 (37.2)	0.004	2924 (83.2)
Diabetes mellitus, n (%)	286 (9.8)	226 (9.6)	35 (9.8)	25 (11.8)	0.589	
Respiratory disease, n (%)	321 (11.0)	256 (10.9)	46 (12.9)	19 (9.0)	0.327	
Medication						
Medication for chronic disease, n (%)	2022 (69.1)	1600 (67.9)	273 (76.5)	149 (70.3)	0.004	2924 (83.2)
Anticoagulative medication, n (%)	309 (10.6)	246 (10.5)	43 (12.0)	20 (9.4)	0.564	
Hormone replacement therapy, n (%)	535 (18.3)	405 (17.2)	84 (23.5)	46 (21.7)	0.007	
Local estrogen therapy, n (%)	605 (20.7)	480 (20.4)	80 (22.4)	45 (21.2)	0.668	
Sexually active, n (%)	1054 (39.1)	877 (40.2)	93 (28.8)	82 (42.2)	<0.001	2698 (76.7)
Previous surgery						
POP surgery, n (%)	872 (24.8)	412 (14.4)	318 (77.2)	142 (58.2)	<0.001	3515 (100)
Same compartment operated previously, n (%)	604 (17.2)	200 (7.0)	287 (68.2)	117 (48.0)	<0.001	
Different compartment operated previously, n (%)	268 (7.6)	212 (7.4)	31 (7.4)	25 (10.2)	0.245	
Urinary incontinence surgery, n (%)	199 (5.7)	142 (5.0)	35 (8.3)	22 (9.0)	0.001	
Hysterectomy, n (%)	1170 (33.3)	654 (22.9)	332 (78.9)	184 (75.4)	<0.001	
Prolapse beyond the hymen						
Anterior vaginal wall (POPQ Aa or Ba > 0), n (%)	1731 (50.6)	1312 (47.7)	315 (73.8)	104 (42.2)	<0.001	3420 (97.3)
Posterior vaginal wall (POPQ Ap or Bp > 0), n (%)	985 (28.9)	791 (28.9)	83 (19.6)	111 (44.8)	<0.001	3409 (97.0)

(Continues)

TABLE 1 (Continued)

Characteristic	All (n = 3515)	NTR (n = 2850)	TVM (n = 421)	AM (n = 244)	P[a]	Data available, n (%)
Apex of the vagina (POPQ C > 0), n (%)	843 (25.9)	627 (32.2)	80 (18.8)	136 (54.4)	<0.001	3374 (96.0)
At least one of these >0, n (%)	2717 (79.0)	2121 (76.7)	376 (88.3)	220 (88.4)	<0.001	3441 (98.0)
Vaginal compartment of current surgery						
Anterior only, n (%)	655 (18.5)	554 (19.4)	101 (23.5)	0 (0)	<0.001	3515 (100)
Apical only, n (%)	242 (6.8)	154 (5.4)	12 (2.8)	76 (30.4)	<0.001	
Posterior only, n (%)	728 (20.6)	686 (24.0)	27 (6.3)	15 (6.0)	<0.001	
Anterior and posterior, n (%)	282 (8.0)	268 (9.4)	12 (2.8)	2 (0.8)	<0.001	
Apical and anterior, n (%)	778 (22.0)	574 (20.1)	170 (39.6)	34 (13.6)	<0.001	
Apical and posterior, n (%)	175 (5.0)	97 (3.4)	30 (7.0)	48 (19.2)	<0.001	
All three compartments, n (%)	673 (19.0)	521 (18.3)	77 (17.9)	75 (30.0)	<0.001	

Aa, anterior point of vaginal wall 3 cm proximal to the external urethral meatus; AM, abdominal mesh; Ap, a point located in the midline of the posterior vaginal wall 3 cm proximal to the hymen; Ba, most distal point of any part of the anterior vaginal wall from vaginal cuff to point Aa; BMI, body mass index; Bp, a point that represents the most distal part of posterior vaginal wall from vaginal cuff to point Ap; NTR, native tissue repair; POPQ, pelvic organ prolapse quantification system; TVM, transvaginal mesh.

[a]*P*-value was calculated for the difference between the surgical method groups (NTR, TVM, AM).

TABLE 2 Preoperative symptom scores from Pelvic Floor Distress Inventory (PFDI-20) with 20 questions. Higher scores indicate greater symptom distress

Symptom scores	All (n = 2903)	NTR (n = 2335)	TVM (n = 359)	AM (n = 209)	P[a]
POPDI-6, mean (95% CI)	40.9 (40.1-41.6)	40.2 (39.4-41.0)	42.7 (40.6-44.7)	45.5 (42.5-48.5)	<0.001
CRADI-8, mean (95% CI)	26.4 (25.7-27.1)	26.4 (25.6-27.2)	24.5 (22.7-26.4)	29.8 (26.8-32.9)	0.054
UDI-6, mean (95% CI)	32.4 (31.6-33.2)	31.8 (31.0-32.7)	35.9 (33.8-38.0)	33.1 (30.0-36.1)	0.003
Total PFDI-20 scores, mean (95% CI)	99.7 (97.9-101.5)	98.4 (96.4-100.3)	103.1 (98.3-108.0)	108.4 (100.7-116.1)	0.012

CRADI-8, colorectal-anal distress inventory with eight questions concerning difficulties of defecation; POPDI-6, pelvic organ prolapse distress inventory of six questions about the inconvenience of the prolapse; UDI-6, urinary distress inventory with six questions about difficulties in urination. Data were derived from filled in questionnaires for analysis of PFDI-20 scores (n = 2903).

[a]*P*-value was for the difference between the three different surgical modalities (NTR, native tissue repair; TVM, transvaginal mesh; AM, abdominal mesh).

without hysterectomy was performed in 1308 (37%) operations, with isolated posterior colporrhaphy being the most common technique (n = 600). Isolated anterior colporrhaphy was performed in 484 operations, and both anterior and posterior colporrhaphy were performed in 224 operations. Isolated vaginal vault repair with native tissue was rare (n = 157, 4%), and 118 operations included hysterectomy alone. The Manchester operation was performed for 37 patients, and obliterative surgery (such as colpocleisis and vaginal closure) was performed for 29 (0.8%) patients. More detailed figures of the native tissue surgical procedures are available in Supporting Information Appendix S2. The mesh surgeries were performed in 30 of 41 hospitals, and the number of mesh surgeries that were included in the study varied from 4 to 107 per center (Appendix S1). A transvaginal mesh was used in 429 operations, which corresponds to 0.15 per 1000 women; the most common method was anterior/apical mesh augmentation (n = 361, 84%). The TVM kits used during surgery are summarized in Supporting Information Appendix S3. An AM augmentation—sacrocolpopexy—was performed in 251 operations, and 91% of those were performed laparoscopically.

The factors affecting the use of a mesh are described in Table 3. The strongest predictor for the use of a mesh was a previous POP surgery of the same vaginal compartment (odds ratio [OR] 56 for TVM and 22 for AM). Other predictive factors were previous hysterectomy and severe bulge symptoms. TVM was associated with advanced anterior prolapse, whereas AM augmentation was associated with advanced apical and posterior prolapse. Regional differences in practices were found. The patient's healthcare district was a strong predictor of the use of mesh surgery; there was almost a 10-fold difference between the highest and lowest OR for the use of a transvaginal mesh. The hospital level did not explain the variation in the use of a mesh.

A total of 2644 (75%) operations were performed for patients without prior prolapse surgery, 92% of these performed using native tissue. A total of 206 (8%) participants received a mesh for primary prolapse, 103 received TVM and 103 received AM. The type

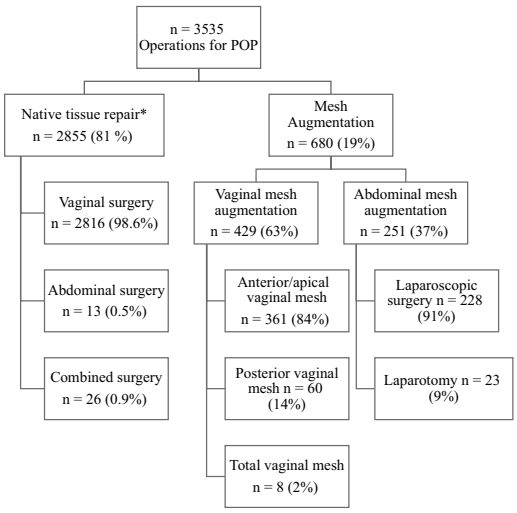

FIGURE 2 Surgical methods of operations for POP included in the study. *Native tissue repair methods are described in Appendix S2

of hospital did not affect the risk of primary TVM, but there was significant variation in the practices between hospitals (Appendix S1). Risk factors for TVM as the primary surgery were advanced anterior or apical prolapse, bothersome bulge symptoms and healthcare district (Table 3). An AM augmentation was more often used as the primary surgery for patients with rectal intussusception (OR = 20.1, 95% CI 12.9-31.6). Other predictive factors were advanced apical or posterior compartment prolapse. Previous hysterectomy was a risk factor for both transvaginal mesh and AM use during the primary surgeries.

4 | DISCUSSION

This nationwide prospective cohort study of 3535 operations showed that 81% of all patients and 92% of patients without prior prolapse surgery underwent vaginal native tissue reconstruction. The strongest predictors for the use of a mesh were recurrent POP, previous hysterectomy, healthcare district and severe bulge symptoms. TVM was associated with advanced anterior prolapse and older age. AM augmentation surgery was associated with advanced apical and/or posterior compartment prolapse; the highest total PFDI-20 scores indicated more bothersome symptoms than in the other groups. The median preoperative symptom scores were at the same level as in studies with selected patient groups, suggesting that the indications for POP surgery in Finland are comparable to those discussed in other reports.[15,16]

The overall rate of POP surgery in Finland in 2015 was 1.5 per 1000 women, which is comparable to the results of a study of 15 other Organisation for Economic Co-operation and Development (OECD) countries in 2012.[9] The data from other Nordic countries showed that the rate of POP surgery per 1000 women was 2.0 in Sweden and 1.8 in Denmark in 2012.[9] The rate of TVM was 0.19 and that of AM augmentation 0.048 per 1000 women in OECD countries,[9] whereas in the present study, the rates were 0.15 and 0.090 per 1000 women, respectively. This finding indicates that transvaginal mesh augmentation was used moderately in Finland during the study period. In comparison, in 2012, the rate of TVM per 1000 women was 0.37 in Sweden and 0.07 in Denmark, which was considerably higher in Sweden and lower in Denmark than the rate in the present study. Furthermore, the rate of sacral colpopexy per 1000 women was 0.015 in Sweden and 0.006 in Denmark both much lower figures than in Finland.[9] Unlike in Denmark, mesh augmentations are not centralized in Finland and Sweden, which may partly explain the higher mesh surgery rates than in Denmark. However, regional differences in POP surgical methods in Nordic countries have not been reported previously. We observed significant regional variation in the use of mesh augmentation. For transvaginal mesh surgery, this variation was almost 10-fold. This finding may be partly due to differences in the population, but it does imply different practices between hospitals. According to recent European recommendations, mesh augmentations should only be carried out by surgeons with appropriate training who are working in multidisciplinary referral centers.[17]

Recurrence of prolapse is common. Over 1–3 years of follow up after NTR, 38% of the patients had a recurrent prolapse on examination, and 19% were aware of this prolapse.[18] In the present study, 25% of the patients had undergone previous surgery for POP, and 17% of the patients had a recurrence in the same vaginal compartment. This finding suggests a moderate recurrence rate after POP surgery in Finland. Relatively few Manchester and obliterative procedures compared with vaginal hysterectomies were performed. In a Danish cohort study, vaginal hysterectomy was associated with a higher recurrence rate than the Manchester procedure, and this method of apical prolapse surgery should be considered if there is no indication for hysterectomy.[19]

The indications for the use of a mesh during POP surgery have been widely debated after the Food and Drug Administration (FDA) of the USA provided a second warning on the adverse effects of TVM surgery in 2011.[10] The rate of TVM surgery has diminished dramatically[20,21] and in some countries, transvaginal mesh use has been abandoned.[22] After the 2015 study period, most commercial transvaginal mesh kits were withdrawn from the market, and the rate of TVM surgery decreased in Finland.[4] Nevertheless, after critical evaluation and based on patient information, transvaginal mesh augmentation remains an option for patients with a high risk of prolapse recurrence.[8,18] In randomized studies, vaginal mesh augmentation has provided anatomic benefits and decreased prolapse awareness but is associated with higher rates of de novo stress urinary incontinence, bladder injury and reoperations compared with NTR.[18,23] Eight percent of patients require repeat surgery due to transvaginal mesh exposure.[18] Abdominal sacrocolpopexy is associated with lower risks of prolapse awareness and recurrence, postoperative stress urinary incontinence

TABLE 3 Factors affecting the use of mesh, compared with native tissue repair group

	Transvaginal mesh OR (95% CI) adjusted, *P*		Abdominal mesh OR (95% CI) adjusted, *P*	
Characteristic	**All operations**	**Primary operations**	**All operations**	**Primary operations**
Age at operation (y)				
<50 y, n (%)	0.07 (0.02-0.29)	0.11 (0.03-0.46)	1.10 (0.57-2.13)	0.66 (0.28-1.41)
50-64 y, n (%)	0.70 (0.49-0.99)	0.68 (0.50-0.93)	1.16 (0.78-1.71)	0.67 (0.29-1.59)
65-79 y, (%)	1.00 (reference), <0.001	1.00 (reference), 0.002	1.00 (reference), 0.484	1.00 (reference), 0.708
≥80 y, n (%)	0.35 (0.16-0.77)	0.60 (0.30-1.20)	0.54 (0.20-1.41)	0.86 (0.17-4.42)
Sexual activity				
No	1.00 (reference), 0.175	1.00 (reference), 0.519	1.00 (reference), 0.249	1.00 (reference), 0.065
Yes	0.78 (0.54-1.12)	0.90 (0.66-1.23)	1.25 (0.86-1.81)	1.64 (0.97-2.77)
Previous surgery				
No previous POP surgery	1.00 (reference), <0.001		1.00 (reference), <0.001	
Previous POP surgery				
Same compartment	56.31 (37.86-83.74)		22.19 (14.48-34.02)	
Different compartment	2.60 (1.53-4.43)		3.05 (1.76-5.28)	
Both same and different compartment	18.82 (9.60-36.90)		14.75 (7.30-29.79)	
No hysterectomy	1.00 (reference), <0.001	1.00 (reference), <0.001	1.00 (reference), <0.001	1.00 (reference), <0.001
Previous hysterectomy	12.97 (9.47-17.75)	12.93 (9.44-17.70)	14.61 (9.67-20.74)	6.22 (3.71-10.44)
Prolapse beyond the hymen				
Anterior vaginal wall (POPQ Aa or Ba > 0)	2.89 (2.09-4.25), <0.001	3.75 (2.72-5.16), <0.001	0.78 (0.54-1.12), 0.173	0.87 (0.52-1.46), 0.600
Posterior vaginal wall (POPQ Ap or Bp > 0)	0.56 (0.38-0.84), 0.004	0.42 (0.30-0.59), <0.001	1.97 (1.38-2.82), <0.001	1.74 (1.06-2.87), 0.030
Apex of the vagina (POPQ C > 0)	1.03 (0.68-1.56), 0.884	1.58 (1.07-2.31), 0.020	4.19 (2.90-6.05), <0.001	4.32 (2.48-7.53), <0.001
At least one of these >0	2.52 (1.58-4.01), <0.001	2.37 (1.58-3.56), <0.001	2.52 (1.49-4.26), 0.001	1.60 (0.80-3.20), 0.182
Prolapse symptom (bulge)				
No	1.00 (reference), 0.007	1.00 (reference), 0.017	1.00 (reference), 0.001	1.00 (reference), 0.013
Yes, not bothersome	1.88 (0.33-10.67)	1.74 (0.37-8.40)	0.00 (0.00)	0.00 (0.00)
Yes, some bother	2.49 (0.94-6.01)	2.17 (0.91-5.15)	1.25 (0.49-3.23)	1.26 (0.28-5.74)
Yes, moderately bothersome	3.77 (1.44-9.85)	3.13 (1.34-7.35)	1.85 (0.73-4.66)	1.78 (0.41-7.84)
Yes, very bothersome	4.42 (1.64-11.91)	3.30 (1.37-7.94)	3.31 (1.29-8.48)	3.74 (0.84-16.68)
Hospital type				
Tertiary	1.00 (reference), 0.149	1.00 (reference), 0.291	1.00 (reference), 0.021	1.00 (reference), 0.394
Secondary	0.79 (0.51-1.22)	0.81 (0.56-1.16)	1.18 (0.78-1.80)	1.35 (0.73-2.49)
Primary	1.28 (0.81-2.03)	0.98 (0.67-1.44)	0.46 (0.26-0.82)	0.69 (0.32-1.48)
Health district area				
District 1	1.00 (reference), <0.001	1.00 (reference), <0.001	1.00 (reference), 0.004	1.00 (reference), 0.013
District 2	0.84 (0.53-1.35)	1.20 (0.78-1.85)	0.52 (0.29-0.91)	0.38 (0.16-0.89)
District 3	0.33 (0.18-0.61)	0.50 (0.29-0.86)	0.43 (0.24-0.78)	0.35 (0.14-0.88)
District 4	3.08 (1.98-4.80)	2.71 (1.81-4.07)	0.91 (0.51-1.63)	0.76 (0.33-1.74)
District 5	0.59 (0.33-1.03)	0.66 (0.39-1.12)	1.13 (0.67-1.90)	1.15 (0.56-2.31)

Adjusted for the confounding factors including age, sexual activity, previous hysterectomy, previous POP surgery, bulge symptom degree, health distinct area and type of hospital.

and dyspareunia compared with a variety of other vaginal interventions for apical prolapse.[7]

In the present study, a recurrent POP in the same vaginal compartment was the strongest predictive factor for the use of a mesh. This finding is in line with recent recommendations.[8,17] For primary prolapse, the use of a synthetic mesh is controversial and studies do not support using TVM in anterior or posterior compartment repair.[24] In a Scottish retrospective cohort study of 18 986 women, 7% of the primary operations were mesh surgeries.[25] In our study, a similar number of primary POP operations were mesh operations. Posterior compartment prolapse was a protective factor for TVM and this finding is in line with recommendations to avoid the use of a mesh with these patients.[8] Advanced anterior prolapse is more prevalent and more prone to failure after repairs; thus, synthetic mesh may be beneficial.[8] In the present study, advanced anterior prolapse was a predictive factor for TVM. Advanced apical and posterior compartment prolapse and rectal intussusception were predictive factors for AM augmentation, also in accordance with the recommendations.[7] Previous hysterectomy was a strong predictive factor for mesh augmentation. This finding is in line with those of previous studies supporting the assumption that hysterectomy increases the risk of later POP surgery, especially posterior compartment prolapse repair.[26,27]

Our study has some limitations. The participation rate varied between hospitals, which may bias the comparison of treatment practices between hospitals. We did not record the socioeconomic or menopausal status of the patients. The surgical method was based on an individual surgeon's assessment and preferences, and the surgeons were not aware of the symptom scores reported on the forms completed by the patients; this may be a limitation but, on the other hand, reflects normal practice. Notably, 3% of the patients underwent vaginal hysterectomy alone. This finding may be due to a coding error or a practice pattern, but because of the nature of the study, we could not draw any further conclusions on how vaginal cuff suspension was performed in these cases.

The strength of our study is that this nationwide prospective cohort covered the majority of all POP operations performed in Finland, offering a holistic picture of practices within a country. The study protocol also included clinicians' assessments of the preoperative situation and validated health-related quality of life questionnaires. The previous large cohort studies were mainly based on retrospective databases and did not use symptom questionnaires.[25,28]

5 | CONCLUSION

The practices reported here follow international recommendations that consider NTR to be the principal surgical method for POP surgery.[17,18] A synthetic mesh was mainly used in complex cases with recurrent prolapse in the same compartment. However, there was regional variation between the rates of mesh augmentation for POP surgery. In our opinion, this implies a general lack of sufficient evidence regarding the most suitable treatment methods for POP and indicates a need for national guidelines.

ACKNOWLEDGMENTS

We want to express our appreciation to all the Finnish colleagues who participated in patient recruitment. In particular, we want to acknowledge the work done by contact persons in participating hospitals: Tomi Mikkola, Pontus Molander, Maritta Pöyhönen-Alho, Tuuli Soini, Tapio Väyrynen, Esa Räty, Susanna Naukkarinen, Pia Heinonen, Elina Kuikka, Liisa Tikkala, Mari Vehviläinen, Kirsi Nissinen, Reijo Hiltunen, Seppo Varpuluoma, Marja-Liisa Eloranta, Marja Vainio, Pekka Staven, Timo Tiilikainen, Anu Hänninen, Pentti Kiilholma, Minna Kauko, Jari Sjöberg, Sari Koivurova, Leena Häivä, Satu Laurila, Marko Niemimaa, Eila Knuuti, Pia Vittaniemi, Päivi Malmström, Johanna Haikonen, Katja Murtoniemi, Päivi Selänne, Anna Sorvaniemi, Helena Hieta-Heikurainen, Benyamin Ashraf, Signe Linkolm, Hannele Torkkeli, Pirkko Juvonen, Kari Österberg, Eija Lampela, Marja Tiihonen, Pauliina Aukee and Riikka Aaltonen.

CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

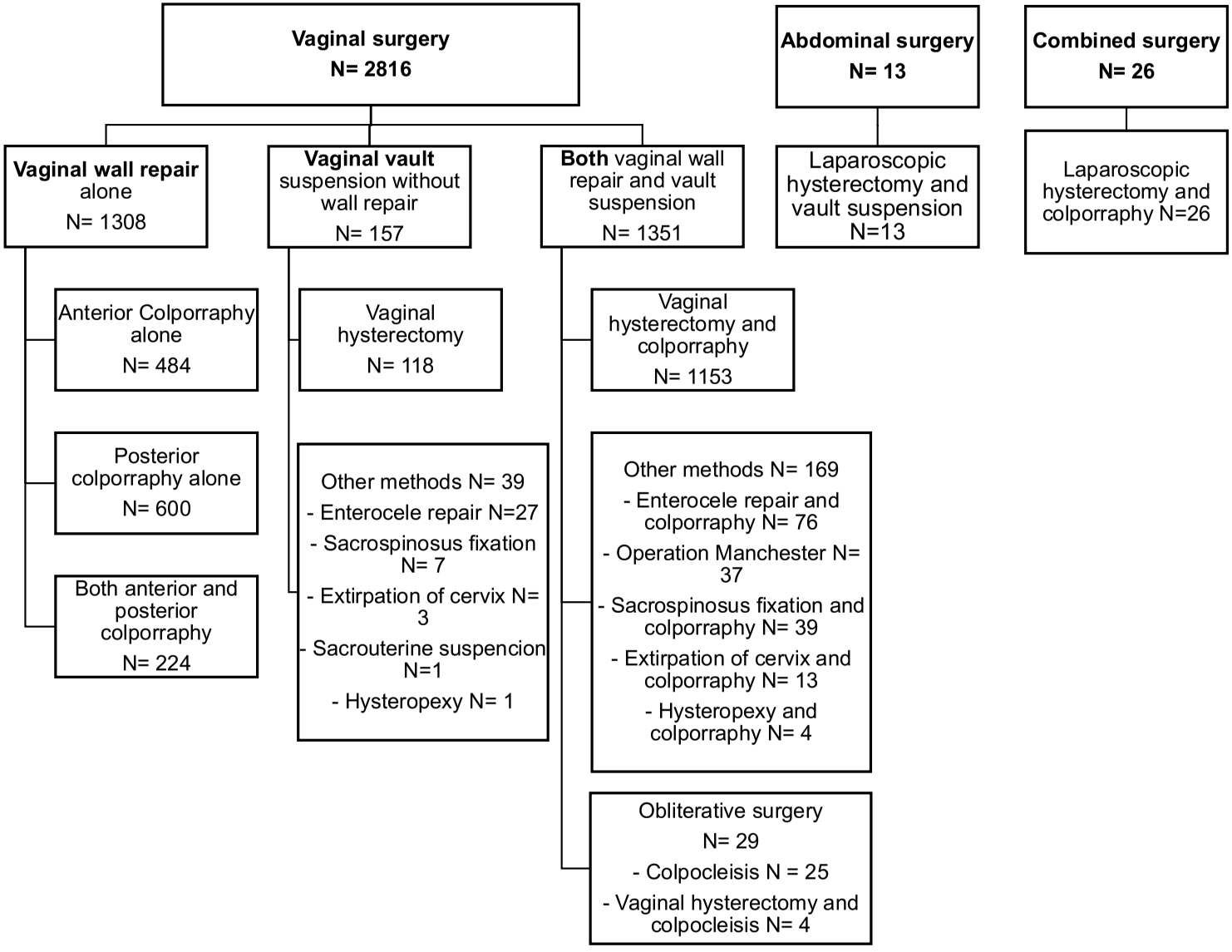
How to cite this article: Mattsson NK, Karjalainen P, Tolppanen A-M, et al. Methods of surgery for pelvic organ prolapse in a nationwide cohort (FINPOP 2015). *Acta Obstet Gynecol Scand*. 2019;98:451–459. https://doi.org/10.1111/aogs.13520

Appendix 1. Participating hospitals and number of POP surgeries that were included in the study.

Hospital	Operations, n	Transvaginal mesh		Abdominal mesh		Data available, %
		All operations, n (%)	Primary operations, n (%)	All operations, n (%)	Primary operations, n (%)	
Tertiary						
1	539	58 (10,8)	13 (2,4)	28 (5,2)	8 (1,5)	91
2	118	22 (18,6)	1 (0,8)	9 (7,6)	4 (3,4)	77
3	206	2 (1,0)	0	11 (5,3)	5 (2,4)	91
4	179	57 (31,8)	16 (8,9)	24 (13,4)	9 (5,0)	53
5	127	10 (7,9)	1 (0,8)	8 (6,3)	3 (2,4)	80
total	1169	149 (12,7)	31 (2,7)	80 (6,8)	29 (2,5)	
Secondary						
1	99	6 (6,1)	0	14 (14,1)	6 (6,1)	91
2	134	31 (23,1)	13 (9,7)	8 (6,0)	4 (3,0)	93
3	61	0	0	7 (11,5)	2 (3,3)	56
4	84	3 (3,6)	1 (1,2)	26 (31,0)	14 (16,7)	100
5	142	30 (21,1)	12 (8,5)	7 (4,9)	5 (3,5)	92
6	194	30 (15,5)	0	8 (4,1)	5 (2,6)	99
7	124	5 (4,0)	0	19 (15,3)	3 (2,4)	94
8	101	11 (10,9)	1 (1,0)	15(14,9)	3 (3,0)	100
9	55	0	0	0	0	95
10	81	6 (7,4)	1 (1,2)	0	0	100
11	100	23 (23,0)	5 (5,0)	7 (7,0)	0	74
12	125	34 (27,2)	7 (5,6)	4 (3,2)	0	95
13	66	5 (7,6)	1 (1,5)	0	0	87
14	191	15 (7,9)	4 (2,1)	44 (23,0)	29 (15,2)	96
15	153	4 (2,6)	0	7 (4,6)	2 (1,3)	97

16	50	11 (22,0)	4 (8,0)	0	0	93
17	35	2 (5,7)	0	2 (5,7)	0	88
total	1795	216 (12,0)	49 (2,7)	168 (9,4)	73 (4,1)	
Primary						
1	65	16 (24,6)	8 (12,3)	0	0	84
2	52	0	0	0	0	88
3	38	0	0	0	0	68
4	25	0	0	0	0	83
5	50	0	0	0	0	75
6	43	10 (23,3)	4 (9,3)	0	0	43
7	19	0	0	0	0	100
8	28	4 (14,3)	0	0	0	42
9	13	0	0	0	0	100
10	6	2 (33,3)	0	0	0	53
11	52	12 (23,1)	6 (11,5)	1 (1,9)	1 (1,9)	53
12	34	4 (11,8)	2 (5,9)	0	0	85
13	39	4 (10,3)	1 (2,6)	0	0	88
14	37	5 (13,5)	0	0	0	71
15	11	0	0	0	0	69
total	514	57 (11,1)	21 (4,1)	1 (0,2)	1 (0,2)	
Private						
1	4	2 (50,0)	1 (50,0)	0	0	80
2	12	0	0	0	0	100
3	23	4 (17,4)	0	0	0	74
4	5	0	0	1 (20,0)	0	71
total	44	6 (13,6)	1 (2,3)	1 (2,3)	0	

Appendix 2. Surgical methods of 2855 operations performed by native tissue reconstruction.



Appendix 3. Name, number and type of vaginal suspension of the used transvaginal mesh kits.

Name of TVM kit	**N (%)**	**Suspenced vaginal compartment**
Elevate anterior	325 (76.0)	anterior and apical
Elevate posterior	63 (14.7)	posterior
Uphold	20 (4.7)	anterior an apical
Avaulta	10 (2.3)	anterior
Prolift anterior	2 (0.5)	anterior
Prolift posterior	3 (0.7)	posterior
Prolift total	5 (1.2)	anterior, apical and posterior

II

Mattsson et al. Health and Quality of Life Outcomes (2017) 15:88
DOI 10.1186/s12955-017-0648-2

Health and Quality of Life Outcomes

RESEARCH Open Access

Validation of the short forms of the Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7), and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) in Finnish

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Abstract

Background: Although several validated generic health-related quality of life instruments exist, disease-specific instruments are important as they are often more sensitive to changes in symptom severity. It is essential to validate the instruments in a new population and language before their use. The objective of the study was to translate into Finnish the short forms of three condition-specific questionnaires (PFDI-20, PFIQ-7 and PISQ-12) and to evaluate their psychometric properties in Finnish women with symptomatic pelvic organ prolapse.

Methods: A multistep translation method was used followed by an evaluation of validity and reliability in prolapse patients. Convergent and discriminant validity, internal consistency and reliability via test-retest were calculated.

Results: Sixty-three patients waiting for prolapse surgery filled the three questionnaires within two weeks. Response rate for each item was high in PFDI-20 and PISQ-12 (99.8 and 98.9% respectively). For PFIQ-7 response rate was only 60%. In PFIQ-7, six respondents (9.5%) reached the minimum value of zero showing floor effect. None of the instruments had ceiling effect. Based on the item-total correlations both PFIQ-7 and PFDI-20 had acceptable convergent validity, while the convergent validity of PISQ-12 was lower, $r = 0.138–0.711$. However, in this instrument only three questions (questions 6, 10 and 11) had $r < 0.3$ while others had $r \geq 0.380$. In the test-retest analysis all the three instruments showed good reliability (ICC 0.75–0.92). Similarly, the internal consistency of the instruments, measured by Cronbach's α, was good (range 0.69–0.96) indicating high homogeneity.

Conclusions: Finnish validated translation of the PFDI-20 and PISQ-12 have acceptable psychometric properties and can be used for both research purposes and clinical evaluation of pelvic organ prolapse symptoms. The Finnish version of PFIQ-7 displayed low response rate and some evidence of a floor effect, and thus its use is not recommended in its current form.

Keywords: Pelvic organ prolapse, Symptom questionnaire, Validation, Psychometric evaluation, Reliability, Health related quality of life

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Background

Pelvic floor disorders (PFD) include variable symptoms such as urinary incontinence, feeling of a vaginal bulge, fecal incontinence, and other sensory and emptying abnormalities of the lower urinary and gastrointestinal tracts. The prevalene of women reporting at least one pelvic floor disorder is 23%, which proportion increases with age [1]. These symptoms can have a significant impact on the quality of life and they may cause problems in sexual life [2]. The prevalence of symptomatic pelvic organ prolapse (POP) is estimated to be 3–6% of adult women and up to 50% when based upon vaginal examination [1, 3]. It is necessary to consider not only the underlying anatomical disorder but also women's overall pelvic function and their health-related quality of life when making treatment decisions [3]. For this purpose, condition-specific quality-of-life instruments were developed and published in English 2001 [4, 5]. The Pelvic Floor Distress Inventory (PFDI), the Pelvic Floor Impact Questionnaire (PFIQ), and the Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) have shown to be psychometrically valid and reliable instruments for measuring the extent to which pelvic floor disorders affect quality of life [4, 5]. PFDI investigates the range of POP symptoms and the inconvenience they cause, while PFIQ covers the impact of POP on daily life. PISQ investigates the sexual function of heterosexual women suffering from POP and/or urinary incontinence. The short versions of these three questionnaires have also been validated [6, 7]. PFDI-20 consists of three separate scales: Pelvic Organ Prolapse Distress Inventory (POPDI) of six questions about the inconvenience of the prolapse, Colorectal-Anal Distress Inventory (CRADI) with eight questions concerning difficulties of defecation, and the Urinary Distress Inventory (UDI) with six questions about difficulties in urination. Similarly, the PFIQ-7 consists of three scales, each of them containing seven questions: the Pelvic Organ Prolapse Impact Questionnaire (POPIQ), the Colorectal-Anal Impact Questionnaire (CRAIQ) and the Urinary Impact Questionnaire (UIQ). The short version of PISQ contains 12 questions about sexual activity, satisfaction and problems caused by POP or urinary incontinence.

PFDI-20, PFIQ-7 and PISQ-12 are widely used and they help investigators to evaluate the efficacy of a particular therapy for POP or to compare symptom severity between patients or groups. These disease-specific instruments have been translated and validated in several different countries and in more than ten languages [8–20].

Validated tools for measuring the severity of discomfort of pelvic prolapse and assessing the effectiveness of therapy are not currently available in Finnish. The aim of this study was to translate PFDI-20, PFIQ-7 and PISQ-12 into Finnish and validate these translations among women with symptomatic POP.

Methods

For the translation process, a group of seven key in-country persons (authors NM, KN, A-MH, JJ, SK, M-LE, PS) were recruited among the board of Finnish Society of Gynecological Surgery. Translation permissions were obtained from the developers of the instruments, Dr. Barber [4] and Dr. Rogers [5]. The translation of the forms was conducted by multistep translation method [21]. Four forward translations of PFDI-20, PFIQ-7 and PISQ were done, two by independent professional translators with experience of translating patient-reported outcome (PRO) measures, and two by PhD gynecologist experienced in urogynecology. The four translations were tested on a group of four lay persons. Two of the lay persons were urogynecological nurses and two native Finnish-speaking nonprofessionals, one of whom was bilingual (Finnish-English). Each lay person picked the best translation alternatives of the questions or proposed their own alternative wording. One gynecologist (NM) compared lay persons´ interpretation and made the final review of the translation. A professional medical translator performed back-translations that were compared to the original questionnaires. The final versions of the translated instruments were approved by the group of key-in country persons (Additional files 1, 2 and 3).

A test-retest analysis was conducted among 63 native Finnish-speaking female patients waiting for surgery for symptomatic POP. The women were recruited from four hospitals: Turku University Hospital, Kuopio University Hospital, Oulu University Hospital and Kanta-Häme Central Hospital. The first three are tertiary university hospitals and the last one is a secondary hospital, all performing urogynecological surgery. The hospitals represent different areas of Finland: western, eastern, northern and southern part of Finland, respectively.

Postal questionnaires including two pre-stamped envelopes were sent to the patients waiting for prolapse treatment. The patients were asked first to fill and return the test questionnaires and then, after 2 weeks, to fill out and return the retest questionnaires. The questionnaires were paired by a code number and analysed anonymously. The participants gave their informed consent by returning the written questionnaires. The study was approved by the Ethical committee of University of Eastern Finland (2014/5), and it followed the ethical standards of the Helsinki Declaration [22].

Statistical and data analysis

The PFIQ-7, PFDI-20 and PISQ-12 questionnaires and the subscales of PFIQ-7 and PFDI-20 were tested for construct validity and reliability. The average scores in each scale were reported as means and standard deviations, as well as medians and interquartile range due to the skewed distribution of the data. Convergent and discriminant validity were investigated with Spearman's rank order correlation and the corrected item-total

correlations. Corrected item-total correlations ≥0.3 can be considered as evidence on convergent validity [23]. In addition, response rate, floor and ceiling effects, (i.e., persons obtaining minimum and maximum scores, respectively) were calculated. Overall response rate was defined as the proportion of the patients that returned the two questionnaires in two weeks. Item response rate was defined as the proportion of answered questions in each questionnaire. Reliability was assessed by test-retest analysis and intra-class correlation coefficient (ICC), while the internal consistency was measured with Cronbach's α. Cronbach's α was calculated separately for persons with missing data and those who completed all questions in the subscale forms. α-values below 0.7 indicate too high heterogeneity, while values above 0.9 indicate too high similarity between items [24]. Thus, the preferred range of α is between 0.7 and 0.9.

Statistical analyses were conducted with Stata 14.0 (Stata Corporation, College Station TX, USA) and IBM SPSS 21.0 (Chicago IL, USA).

Results

The formation of the study population is shown in Fig. 1. The final sample consisted of 63 women who returned both questionnaires. Twenty-seven of the 63 (42%) patients who returned both questionnaires were sexually active and completed the PISQ-12. The mean age of the patients was 64.1 years (median 64, range 25–86 years).

The item response rates were 99.8% for PFDI-20, 60.0% for PFIQ-7 and 98.9% for PISQ-12. In PFDI-20 factor scores without any imputations could be calculated in 96.8% cases for POPDI-6, 98.4% in cases for CRADI-8 and 100% in cases for UDI-6 (Table 1). For PFIQ-7, factor scores that could be calculated were 82.5% of cases for UIQ -7, 77.8% of cases for CRAIQ-7 and 79.4% of cases for POPIQ-7.

Floor or ceiling effects were not observed with PFDI-20 or PISQ-12 instruments. There was little evidence of floor effect with subscales of PFIQ-7 (15–17% responders with minimum value), but no significant floor effect was observed with the summary scale, with four respondents (7%) having the minimum value of zero (Table 2). Ceiling effects were not observed.

Based on the item-total correlations, both PFIQ-7 and PFDI-20 had acceptable convergent validity (Additional file 4: Table S1 and Additional file 5: Table S2). The correlations were $r = 0.601–0.878$ for UIQ-7, $r = 0.568–0.907$ for CRAIQ- 7, $r = 0.643–0.853$ for POPIQ-7 and $r = 0.513–0.865$ for the total PFIQ-7. Lower item–total correlations were observed with PFDI-20 ($r = 0.309$-0.579 for POPDI-6, $r = 0.371$-0.486 for UDI-6, 0.335–0.611 for CRADI

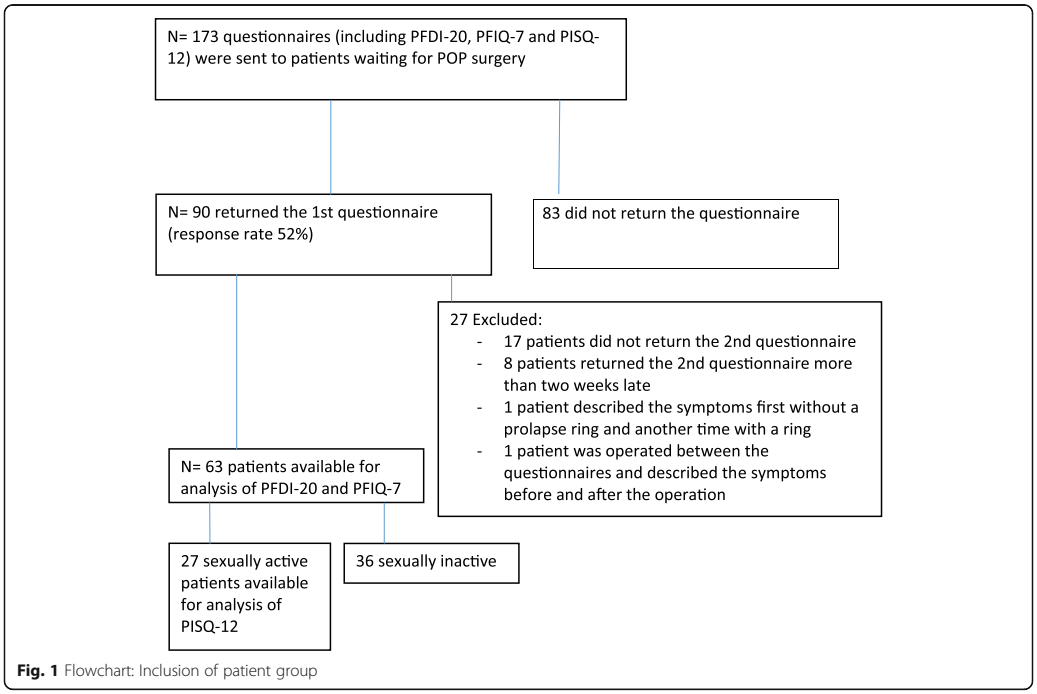

Fig. 1 Flowchart: Inclusion of patient group

Table 1 Results from the analyses for reliability (test–retest and internal consistency), for each instrument and subscale

Questionnaire	Test			Retest			ICC (95% CI) P
	n (missing values)	Mean (SD), median (IQR)	Cronbach's α [a]	n (missing values)	Mean (SD), median (IQR)	Cronbach's α [a]	
PFIQ-7	63 (11)	14.97 (14.42) 9 (4–22)	0.96 (0.96)	63 (9)	13.97 (15.07) 7 (4–21)	0.94 (0.93)	0.75 (0.62–0.84) <0.001
UIQ-7	63 (5)	6.03 (5.77) 5 (1–9)	0.92 (0.92)	63 (6)	5.49 (5.67) 4 (1–9)	0.93 (0.93))	0.82 (0.72–0.88) <0.001
CRAIQ-7	63 (9)	3.83 (4.83) 2 (0–7)	0.91 (0.91)	63 (7)	3.98 (5.93) 1 (0–6)	0.77 (0.77)	0.67 (0.51–0.79) <0.001
POPIQ-7	63 (5)	5.11 (5.23) 3 (1–8)	0.92 (0.92)	63 (8)	4.89 (5.44) 3 (0–7)	0.93 (0.93)	0.72 (0.57–0.82) <0.001
PFDI-20	63 (3)	105.46 (55.62) 93.75 (70.83–146.88)	0.88 (0.88)	63 (0)	105.52 (58.07) 92.71 (66.67–158.33)	0.89 (0.89)	0.92 (0.88–0.95) <0.001
POPDI-6	63 (2)	40.15 (21.25) 37.50 (25.00–50.00)	0.73 (0.74)	63 (0)	42.86 (23.44) 37.50 (25.00–62.50)	0.78 (0.78)	0.83 (0.73–0.89) <0.001
CRADI-8	63 (1)	29.07 (21.78) 25.00 (9.38–46.88)	0.80 (0.80)	63 (0)	28.47 (22.29) 25.00 (9.38–40.63)	0.83 (0.83)	0.90 (0.84–0.94) <0.001
UDI-6	63 (0)	34.19 (21.78) 35.00 (29.00–40.00)	0.71 (0.71)	63 (0)	34.19 (21.78) 33.33 (16.67–50.00)	0.69 (0.69)	0.89 (0.83–0.93) <0.001
PISQ-12	27 (2)	34.89 (6.32) 35 (29–40)	0.84 (0.84)	27 (3)	31.85 (6.39) 33.00 (26.00–37.00)	0.82 (0.84)	0.87 (0.73–0.94) <0.001

[a]Computed only for those with complete answers on all questions of the subscale

Table 2 Floor and ceiling effects of baseline scores

Questionnaire (scores min-max)	Factor scores calculated (*n*)	Floor, *n* (%)	Ceiling, *n* (%)
PFDI-20 (0–300)	63	0 (0)	0 (0)
POPDI-6 (0–100)	63	0 (0)	1 (1.6)
CRADI-8 (0–100)	63	5 (8)	0 (0)
UDI-6 (0–100)	63	5 (8)	1 (1.6)
PFIQ-7 (0–300)	58	4 (7)	0 (0)
POPIQ-7 (0–100)	58	10 (17)	0 (0)
CRAIQ-7 (0–100)	59	18 (31)	0 (0)
UIQ-7 (0–100)	59	9 (15)	2 (3.4)
PISQ-12 (0–48)	27	0 (0)	0 (0)

and $r = 0.309$-0.639 for the PFDI-20 total score). The lowest convergent validity was observed with PISQ-12, $r = 0.138$-0.711 (Additional file 6: Table S3). However, in this instrument only three questions (questions 6, 10 and 11) had $r < 0.3$, while others had $r \geq 0.380$.

Convergent validity was analyzed by correlation between the three instruments (Table 3). Correlation between PFDI-20 and PFIQ-7 was 0.743, and ranged between 0.492 and 0.929, including the subscales. In both of these questionnaires, the total score correlated well with their respective subscales. PISQ-12 was negatively correlated with PFDI-20 and PFIQ-7 total scores and subscales (r = -0.327 to -0.616). Based on the strenght and direction of the item-total correlations, both PFIQ-7 and PFDI-20 had acceptable convergent validity (Additional file 4: Table S1 and Additional file 5: Table S2).

In the test-retest analysis, all the three instruments showed good reliability (Table 1). Intra-class correlations were strong, varying from 0.75 (PFIQ-7) to 0.92 (PFDI-20). All ICCs were statistically significant ($p < 0.001$). Similarly, the internal consistency of the instruments, measured by Cronbach's α, was between 0.69-0.89 for PISQ-12 and PFDI-20 and its subscales. α-values for baseline PFIQ-7 and its subscales were 0.91-0.96, indicating high homogeneity.

Discussion

Pelvic organ prolapse itself, its treatment and complications related to it (for example de novo dyspareunia or vaginal mesh exposure following surgery) may have a significant effect on the patient's quality of life. Hence, it is essential to measure the symptoms and HRQOL related to POP with validated instruments, both in clinical practice and research settings. PFDI-20, PISQ-12 and PFIQ-7 have proven to be valid and reliable instruments for measuring symptom inconvenience caused by pelvic organ prolapse and the health-related quality of life [6, 7]. Until now, their Finnish translations have not been validated. In the present study we have translated these questionnaires in Finnish and assessed the reliability and validity of these Finnish versions among women suffering from symptomatic pelvic organ prolapse in the present study.

The item response rates for PFDI-20 and PISQ-12 were high (99.8 and 98.9%, respectively), whereas the response rate for PFIQ-7 was only 60%. Ceiling effects were not observed. Floor effect was observed with all three subscales of PFIQ-7, but it was less evident with the summary scales. Cronbach's α of PFIQ was 0.94 and 0.96 indicating that some of the items may be too similar. PFIQ also had the lowest ICC of 0.75, while the internal consistency of PFDI-20 and PISQ-12 was better (0.92 and 0.87, respectively). In addition, there was no evidence of too high homogeneity or heterogeneity of individual items in these scales, as indicated by Cronbach's α.

Our results show psychometric validity for PFDI-20 questionnaire and are comparable with previous validation studies [8–10]. In our study, PFIQ-7 had some limitations whereas Teleman et al found acceptable psychometric properties in the Swedish version of PFIQ-7 [9]. There was some evidence for a floor effect in our study, although 15–17% of respondents scored the minimum value with

Table 3 Results from the analysis of convergent validity, i.e. correlation between the three questionnaires (including subscales). Data are given as r (P)

Questionnaire	PFIQ-7	UIQ-7	CRAIQ-7	POPIQ-7	PFDI-20	POPDI-6	CRADI-8	UDI-6
UIQ-7	0.929 (<0.001)							
CRAIQ-7	0.756 (<0.001)	0.621 (<0.001)						
POPIQ-7	0.847 (<0.001)	0.702 (<0.001)	0.522 (<0.001)					
PFDI-20	0.743 (<0.001)	0.683 (<0.001)	0.688 (<0.001)	0.565 (<0.001)				
POPDI-6	0.565 (<0.001)	0.497 (<0.001)	0.526 (<0.001)	0.459 (<0.001)	0.861 (<0.001)			
CRADI-8	0.623 (<0.001)	0.538 (<0.001)	0.739 (<0.001)	0.406 (0.001)	0.821 (<0.001)	0.572 (<0.001)		
UDI-6	0.691 (<0.001)	0.708 (<0.001)	0.492 (<0.001)	0.538 (<0.001)	0.841 (<0.001)	0.624 (<0.001)	0.549 (<0.001)	
PISQ-12	-0.511 (0.006)	-0.506 (0.007)	-0.432 (0.025)	-0.339 (0.084)	-0.616 (0.001)	-0.640 (<0.001)	-0.496 (0.009)	-0.327 (0.096)

each of the subscales, which is considerably less than in the Dutch validation study [10], where the scales of the PFIQ-7 showed floor effects in 44–55% patients, though the summary score did not. Due et al. reported opposite difficulties with the Danish version of PFIQ-7, with a major ceiling effect and lack of items about health-related quality of life [8]. Thus, some but not all the problems with PFIQ-7 in our study may not be due to cultural reasons. It is not clear why the item response rate of PFIQ-7 was low in our study. In future, it may be reasonable to make another linguistic and cultural validation process for the PFIQ-7 to improve the usefulness of the Finnish translation of this instrument. The PISQ-12 showed acceptable psychometric properties as also evaluated in the Swedish study [9]. Limitation of both studies is the relatively small number of sexually active patients ($N = 25$ in reference [9], $N = 27$ in our study). Another limitation of PISQ-12 is that it measures the sexual function only among sexually active heterosexual women. Therefore, another instrument to measure pelvic floor disorders' impact on sexual activity for both sexually active and inactive women has been published [25]. This IUGA-revised questionnaire (PISQ-IR) [26] has already been translated and validated into five languages [25, 27–30]. In the future, it would be reasonable to conduct PISQ-IR translation and validation processes also in Finnish to assess its validity in the Finnish context.

The multistep translation method was one of the strengths of this study. The existing evidence supports this approach over the more simple translation – back translation process [21]. The translation and linguistic validation process was conducted in accordance with the guidelines for the translation and cultural adaptation of patient-reported outcome (PRO) measures [31]. We used four different translations and a multi-professional team in the translation process. Cognitive debriefing of the translated versions was done to ensure consistent and accurate interpretation and understanding of the questionnaires among respondents. One of the lay persons was bilingual with English as another home language. The study subjects of this multicenter study represent sufficiently different geographical areas and dialects of the Finnish language. The age distribution (mean 64.1 years, median 64 years) in our study represents the typical age of women suffering from symptomatic pelvic prolapse [3].

One limitation of the study was that we did not record the socioeconomic position of the patients. Hence, it may be possible that, for example, patients with higher education were over-presented in the study. Another, but in our opinion minor drawback in a study of this kind is the overall response rate of only 52%. In the Danish study of Due et al. [8], in which the recruiting process was similar to ours, the response rate was 60%. Reasons for the lower response rate may be the lack of personal contact with the subjects when the forms were sent and the fact that there were no reminders.

Conclusions

In conclusion, the Finnish versions of PFDI-20 and PISQ-12 are reliable, valid and feasible to evaluate the symptoms and the quality of life in women with pelvic floor disorders. Instead, the Finnish version of PFIQ-7 has some limitations and is not usable in its current form. We suggest that PFDI-20 and PISQ-12 should be used as a patient-reported outcome measure in research and clinical practice.

Additional files

Additional file 1: PFDI-20 in Finnish. (DOCX 114 kb)

Additional file 2: PFIQ-7 in Finnish. (DOCX 100 kb)

Additional file 3: PISQ-12 in Finnish. (DOCX 86 kb)

Additional file 4: Table S1. Item-total correlations for PFIQ-7 and its subscales. (DOCX 14 kb)

Additional file 5: Table S2. Item-total correlations for PFDI-20 and its subscales. (DOCX 15 kb)

Additional file 6: Table S3. Item-total correlations for PISQ-12. (DOCX 12 kb)

Abbreviations

CRADI: Colo-rectal-anal distress inventory; CRAIQ: Colo-rectal-anal impact questionnaire; HRQOL: Health related quality of life; PFDI: Pelvic floor distress inventory; PFIQ: Pelvic floor impact questionnaire; PISQ: Pelvic organ prolapse/urinary incontinence sexual questionnaire; POP: Pelvic organ prolapse; POPDI: Pelvic organ prolapse distress inventory; POPDI: Pelvic organ prolapse distress inventory; PRO: Patient-reported outcome; UDI: Urinary distress inventory

Acknowledgements

Not applicable.

Funding

This study was partly funded by The Finnish Society of Gynecological Surgery and The Emil Aaltonen Foundation.

Availability of data and materials

The datasets analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

All the authors took part in design of the study protocol, collection, analysis, and interpretation of the data. NM, KN, and A-MT had the main responsibility of preparing the manuscript, but the other authors carefully revised the manuscript. All the authors have reviewed the final version of the manuscript and approve it for publication.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

The Research Ethics Committee of the Northern Savo Hospital District approved the study on 20th of May 2014: (Reference number 5//2014). The participates gave their consent by answering the questionnaires. The study data was collected and analysed anonymously.

Endnotes
The Finnish versions of PFDI-20 and PISQ-12 are reliable, valid and feasible to evaluate the symptoms and the quality of life in women with pelvic floor disorders and should be used as a patient-reported outcome measure in research and clinical practice.

Publisher's Note

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Received: 14 September 2016 Accepted: 5 April 2017
Published online: 02 May 2017

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Additional file 1: Table S1 Item-total correlations for PFIQ-7 and its subscales

PFIQ-7	*r*	UIQ-7	*r*	CRAIQ-7	*r*	POPIQ-7	R
CRAIQ-7 Q7	0.513	Q1	0.601	Q6	0.568	Q2	0.643
CRAIQ-7 Q6	0.536	Q7	0.680	Q7	0.623	Q6	0.667
POPIQ-7 Q2	0.566	Q2	0.688	Q1	0.654	Q1	0.704
CRAIQ-7 Q2	0.618	Q6	0.707	Q2	0.689	Q7	0.714
UIQ-7 Q6	0.638	Q4	0.815	Q4	0.846	Q5	0.849
UIQ-7 Q1	0.640	Q5	0.866	Q5	0.893	Q4	0.849
POPIQ-7 Q6	0.651	Q3	0.878	Q3	0.901	Q3	0.853
POPIQ-7 Q1	0.658						
UIQ-7 Q2	0.678						
POPIQ-7 Q7	0.679						
CRAIQ-7 Q1	0.687						
UIQ-7 Q7	0.742						
UIQ-7 Q4	0.780						
CRAIQ-7 Q4	0.799						
UIQ-7 Q3	0.801						
CRAIQ-7 Q5	0.810						
CRAIQ-7 Q3	0.818						
UIQ-7 Q5	0.840						
POPIQ-7 Q5	0.842						
POPIQ-7 Q3	0.865						
POPIQ-7 Q4	0.865						

Additional file 2: Table S2 Item-total correlations for PFDI-20 and its subscales

PFDI-20	*r*	POPDI-6	*r*	CRADI-8	*r*	UDI-6	*R*
POPDI-6 Q3	0.309	Q3	0.309	Q8	0.335	Q3	0.371
POPDI-6 Q3	0.310	Q6	0.411	Q1	0.459	Q4	0.382
CRADI-8 Q8	0.322	Q4	0.465	Q7	0.502	Q6	0.410
POPDI-6 Q6	0.339	Q5	0.490	Q5	0.530	Q2	0.484
UDI-6 Q3	0.388	Q1	0.534	Q3	0.535	Q1	0.484
CRADI-8 Q1	0.403	Q2	0.579	Q6	0.567	Q5	0.486
POPDI-6 Q6	0.411			Q2	0.597		
UDI-6 Q4	0.429			Q4	0.611		
UDI-6 Q1	0.438						
CRADI-8 Q6	0.460						
CRADI-8 Q7	0.463						
CRADI-8 Q5	0.464						
POPDI-6 Q4	0.465						
UDI-6 Q6	0.470						
UDI-6 Q5	0.475						
POPDI-6 Q5	0.490						
POPDI-6 Q1	0.534						
POPDI-6 Q4	0.549						
POPDI-6 Q2	0.555						
CRADI-8 Q2	0.555						
POPDI-6 Q5	0.576						
POPDI-6 Q2	0.579						
UDI-6 Q2	0.598						
POPDI-6 Q1	0.606						
CRADI-8 Q4	0.615						
CRADI-8 Q3	0.639						

Additional file 3: Table S3 Item-total correlations for PISQ-12

PISQ-12	*R*
Q6	0.138
Q11	0.216
Q10	0.297
Q2	0.380
Q7	0.446
Q4	0.551
Q9	0.601
Q5	0.619
Q3	0.646
Q8	0.684
Q12	0.687
Q1	0.711

III

GYNECOLOGY

Pelvic organ prolapse surgery and quality of life—a nationwide cohort study

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BACKGROUND: Patient satisfaction and health-related quality of life are nowadays considered as the most important outcomes of pelvic organ prolapse treatment, and large, prospective clinical studies reporting the patient-reported surgical outcomes are needed.

OBJECTIVE: To evaluate the effect of female pelvic organ prolapse surgery on health-related quality of life and patient satisfaction and to determine predictors of outcome.

STUDY DESIGN: This prospective nationwide cohort study consisted of 3515 women undergoing surgery for pelvic organ prolapse in 2015. The outcomes were measured by validated health-related quality of life instruments (generic 15D, Pelvic Floor Distress Inventory-20, and Patient Global Impression of Improvement) at 6 months and 2 years postoperatively. The baseline predictors of outcomes were studied with logistic regression analysis.

RESULTS: In total, 2528 (72%) women were eligible for analysis at 6 months and 2351 (67%) at 2 years. The mean change in the total 15D score suggested a clinically important improvement at 6 months but not at 2 years. However, an improvement in sexual activity, discomfort and symptoms, and excretion was observed during both follow-up assessments. Altogether, 77% and 72% of the participants reported a clinically significant improvement in Pelvic Floor Distress Inventory-20 at the 6-month and 2-year follow-ups, respectively. A total of 84% were satisfied with the outcome and 90% reported an improvement in comparison with the preoperative state with Patient Global Impression of Improvement-I. The strongest predictive factors for a favorable outcome were advanced apical prolapse (adjusted odds ratio, 2.06; 95% confidence interval, 1.58—2.70) and vaginal bulge (1.90, 1.30—2.80). Smoking was associated with an unfavorable outcome as measured by Patient Global Index of Improvement-I (1.69, 1.02—2.81).

CONCLUSION: Pelvic organ prolapse surgery improved health-related quality of life in 7 of 10 patients over a 2-year follow-up period, and patient satisfaction was high. Apical prolapse beyond the hymen and vaginal bulge were the most consistent predictors for improvement. Our results suggest that patients should be encouraged to stop smoking to avoid an unfavorable outcome.

Key words: HRQoL, Patient Global Impression of Improvement, patient-reported outcome measure, patient satisfaction, Pelvic Floor Distress Inventory, pelvic organ prolapse, pelvic reconstructive surgery, PFDI-20, PGI-I, POP, quality of life, surgery, urogynecology, 15D

Pelvic organ prolapse (POP) is a common health issue; up to 50% of parous women have some degree of POP on examination.[1] Although most cases of POP are asymptomatic, more than 1 in 10 women require surgical treatment for POP during their lifetime.[2] The most frequently reported symptom of POP is the presence of vaginal bulge that can be seen or felt; urinary symptoms including voiding dysfunction, incontinence, urgency, and frequency and bowel symptoms like outlet obstruction and fecal incontinence are also common.[3,4] These symptoms greatly affect women's body image and may affect personal, social, and sexual activities, which can result in some women stopping these activities.[5,6] Furthermore, approximately one-third of postmenopausal women with symptomatic POP are reported to suffer from symptoms of depression.[7]

The primary goal of POP treatment is to reduce symptoms and improve health-related quality of life (HRQoL).[8] However, outcomes of randomized controlled trials on HRQoL have been inconsistent.[1,9] Most studies have focused on the anatomical outcomes of selected surgical methods in vaginal compartment prolapse.[10,11] Therefore, more evidence on the clinical and real-world impact of POP surgery on HRQoL is needed from representative, prospective studies with validated instruments.

We explored the effectiveness of POP surgery in terms of HRQoL in a nationwide prospective cohort study with validated HRQoL instruments 6 months and 2 years after surgery. Second, we evaluated patient satisfaction and predictive factors for both favorable and unfavorable outcomes of surgery.

Materials and Methods

Study design

This national, prospective multicenter longitudinal cohort study was organized and funded by the Finnish Society for Gynecological Surgery. All Finnish hospitals performing POP surgery were invited to join the study and, altogether, 41 of 45 hospitals participated. The inclusion criteria were age >18 years and the ability to communicate in written and oral Finnish or Swedish. The study population (n=3515 patients, 3535 operations) covered 83% of all women operated on for POP in 2015 in Finland. Altogether, 81% of the patients were treated by native tissue repair, 12% by transvaginal mesh, and 7% by abdominal mesh (sacrocolpopexy), of which 91% were laparoscopic. The surgical

Cite this article as: Mattsson NK, Karjalainen P, Tolppanen A-M. Pelvic organ prolapse surgery and quality of life—a nationwide cohort study. Am J Obstet Gynecol 2020

0002-9378/$36.00

https://doi.org/10.1016/j.ajog.2019.11.1285

AJOG at a Glance

Why was this study conducted?

The effect of pelvic organ prolapse surgery on the quality of life remains unclear. The predictive factors accounting for the differences in the changes in the health status are not well understood.

Key findings

The generic health-related quality of life among women with prolapse was worse than that of the age-standardized population; it improved after surgery. During the 2-year follow-up, 90% patients perceived their condition to be improved and 72% reported significant improvement in condition-specific quality of life. Apical prolapse beyond the hymen and vaginal bulge were the most consistent improvement predictors. Smoking was associated with unfavorable surgery outcomes.

What does this add to what is known?

Surgical treatment for pelvic organ prolapse improves health-related quality of life; patient satisfaction after surgery is high.

method was determined by the individual surgeon's preference based on clinical judgment. The study protocol, methods of surgery, and patient characteristics have been described previously.[12]

Ethical approval

The Research Ethics Committee of the Northern Savo Hospital District approved the study on May 20, 2014 (reference number: 5//2014). The study protocol was approved by the Finnish Ministry of Social Affairs and Health and institutional approval of each participating hospital. It was also included in the ClinicalTrials.gov protocol registration system (NCT02716506). The ethical standards for human experimentation established by the Declaration of Helsinki of 1964, revised in 2013, were followed.[13] Written informed consent was obtained from each patient.

Evaluation of HRQoL

The preoperative questionnaires were administered in electronic or printed form. We asked the patients to assess their worst pelvic distress symptom (awareness of a bulge, urinary or defecatory symptoms, pain, or other symptoms). The severity of symptoms was evaluated by a disease-specific Pelvic Floor Distress Inventory questionnaire (PFDI-20), which has been validated in several languages including Finnish.[14] PFDI-20 includes 6 questions about the inconvenience of the prolapse (Pelvic Organ Prolapse Distress Inventory, POPDI-6), 8 questions regarding difficulties in defecation (Colorectal-Anal Distress Inventory, CRADI-8), and 6 questions regarding difficulties in urination (Urinary Distress Inventory, UDI-6).[1] Each subscale ranged from 0 to 100, and the maximum total score is 300; greater scores are indicative of more bothersome symptoms. We evaluated the generic HRQoL using the validated 15-dimensional instrument (15D), which covers social, physical, and emotional health.[15] The health status description of this instrument includes the following 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech (communication), excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity. The respondents have 5 levels to choose in each dimension that describe best her status of health at present. The index score ranged from 0 to 1 (1=healthy, 0=death) and is calculated from the health status descriptive system using a set of population-based preference or utility weights. The 15D instrument has been shown to be valid for assessing patients who underwent pelvic reconstructive surgery.[16]

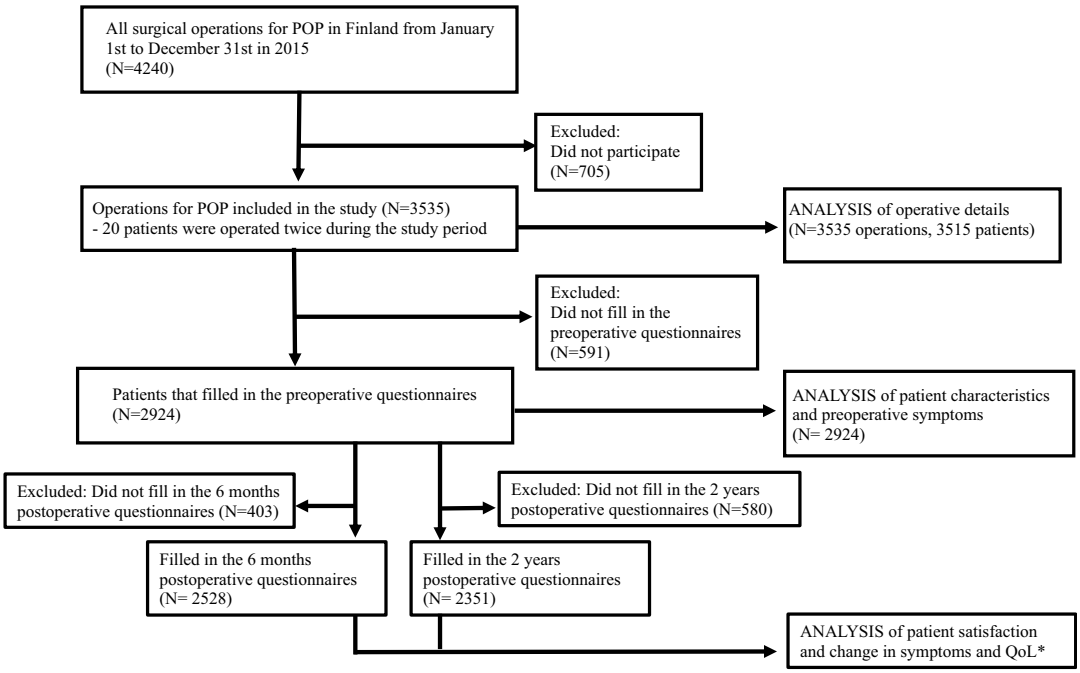
Patient follow-up

The 2931 patients who answered the preoperative questionnaire received a follow-up questionnaire at 6 months and 2 years after the primary operation. Changes in the scores were calculated for all those who answered the postoperative questionnaire at either 6 months (n=2528) or 2 years (n=2351). A threshold value for clinically important improvement in the PFDI-20 total score was set at a decrease of at least 23 points.[17] For the 15D total score, 0.035 indicated much better and 0.015 for slightly better health state.[18] These threshold values apply to the change or difference in the total 15D score only, not to changes in the dimension level values. In addition, we administered a patient global impression of improvement (PGI-I), a single-item question that asks persons to rate their improvement after treatment on a 7-point Likert scale. PGI-I is a validated instrument for assessing the outcome of surgery in several surgical fields, including incontinence surgery and prolapse surgery.[19] Patient satisfaction was assessed on a 7-point scale (highly satisfied — satisfied — fairly satisfied — not satisfied nor unsatisfied — fairly unsatisfied — unsatisfied — very unsatisfied). We asked patients whether they would recommend the operation to a close friend suffering from POP symptoms and to report any complications or surgical treatments after the primary operation.

Statistical analysis

Patient characteristics and surgical details were analyzed in the whole study population, including between those who responded to the 2-year follow-up and those who dropped out. The statistical significance was set at $P<.05$. The differences in categorical variables between the respondents and drop-outs were tested with the χ^2 test. Q-Q-plots were used to assess the distribution of continuous variables, and the Levene test was used to assess the equality of variances in the different groups (respondents and nonrespondents). For variables with a skewed distribution, the Kruskal—Wallis test was used. A paired sample t test was used to test the statistical significance of differences in the means of outcome variables at

FIGURE 1
Flow diagram of study enrollment and analysis of the study participants



*Analysis of change ofPFDI-20 scores was performed for 2522 patients at six months and 2337 at two years after the operation and of 15D index 2440 at six months and 2275 patients at two years.

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different points of time (eg, 6-month and baseline values). Statistical significance of differences in the means of the 15D score and dimension level values between the study cohort and an age-standardized sample of the Finnish general female population was tested with an independent samples *t* test. The population data came from the National Health 2011 Health Examination Survey.[20]

We used binary logistic regression to identify the predictors for favorable and unfavorable outcome of surgery. A favorable outcome of surgery at 2 years after the primary operation was defined separately for the different instruments as follows: PFDI-20, total score diminished more than 45 points compared with baseline; PGI-I, patients considered their condition to be much better or very much better than before the operation (PGI-I scale 1 or 2); 15D, total 15D score improved by 0.035 or more compared to baseline. Correspondingly, we defined an unfavorable outcome as no clinical improvement or worse situation than before the operation: PFDI-20, total symptom score diminished less than 23 points; PGI-I, patients considered their condition to be same or worse than before the operation (PGI-I scale 4−7); 15D, the change in the total 15D score was ˂0.015 compared with baseline. These threshold scores were based on previous studies defining the minimal important change of QoL instruments.[8,17,18]

We adjusted the results for age, body mass index, smoking, parity, sexual activity, degree of prolapse, and type of hospital. There were no indications for collinearity between the factors included in the model (all correlation coefficients <0.4). All statistical analyses were performed with SPSS 25.0 (IBM Corp, Armonk, NY).

Results

Patient characteristics

The study flow is shown in Figure 1 and patient characteristics in Appendix 1. The patients who did not return the questionnaire were younger than those who participated in the 2-year follow-up (mean age: 63.3 vs 64.4 years, *P*=.004). Those who were treated with mesh surgery were more likely to return the follow-up questionnaire than those who underwent native tissue repair (73.6% in the transvaginal mesh and 73.0% in the abdominal mesh group vs 65.4% in the native tissue repair group, *P*<.001). Smoking was less common

TABLE 1
Symptom scores from the PFDI-20 at baseline and at the 6-month and 2-year follow-up

	Score	Change of score from baseline	
PFDI scale	Mean (95% CI)	Mean (95% CI)	%
POPDI-6			
Baseline	40.8 (40.0–41.6)		
6 mo	10.9 (10.2–11.5)	−29.6 (28.7–30.4)	−72.5
2 y	13.2 (12.5–13.9)	−27.6 (26.7–28.5)	−67.6
UDI-6			
Baseline	32.4 (31.5–33.3)		
6 mo	16.7 (15.9–17.4)	−15.4 (14.6–16.1)	−47.5
2 y	18.6 (17.8–19.4)	−13.8 (12.9–14.7)	−42.6
CRADI-8			
Baseline	26.0 (25.1–26.8)		
6 mo	15.2 (14.5–15.8)	−11.0 (10.3–11.6)	−42.3
2 y	17.0 (16.3–17.8)	−8.9 (8.2–9.7)	−34.2
Total			
Baseline	99.2 (97.1–101.3)		
6 mo	42.7 (41.0–44.4)	−55.5 (53.7–57.3)	−55.9
2 y	48.8 (46.9–50.7)	−50.4 (48.4–52.4)	−50.8

CI, confidence interval; *CRADI-8*, Colorectal-Anal Distress Inventory with 8 questions concerning difficulties of defecation; *PFDI-20*, Pelvic Floor Distress Inventory; *POPDI-6*, Pelvic Organ Prolapse Distress Inventory with 6 questions about the inconvenience of the prolapse; *UDI-6*, Urinary Distress Inventory with 6 questions about difficulties in urination.

Greater scores indicate greater symptom distress.

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among the respondents (7.9% among respondents vs 11.9% among nonrespondents, $P=.001$). There was no difference in the symptom scores or generic HRQoL between the respondents and nonrespondents.

During the 2-year follow-up, 165 of 2351 patients (7.0%) reported that they underwent repeated surgery for recurrent POP. Data on whether recurrence occurred in the same or different vaginal compartment as the previous correction or on the use of conservative management for recurrent prolapse were not available. Awareness of a bulge was reported at baseline by 2574 of 2774 (93%) patients and assessment of the worst symptom was as follows: awareness of a bulge (1083; 63%), urinary symptoms (468; 16%), defecatory symptoms (297; 10%), feeling of pressure (200; 7%), and pelvic pain (60; 2%).

PFDI-20

The PFDI-20 scores are shown in Table 1. A significant reduction in the total mean PFDI-20 scores was observed at the 6-month follow-up and the difference remained at the 2-year follow-up. At 2 years, 433 of 2300 (18.8%) patients reported a bothersome bulge symptom. A total of 1756 (76.3%) patients that answered the 2-year questionnaire met the criteria of having no symptomatic bulge and no reoperation for prolapse.

Generic HRQoL

Changes in generic HRQoL are shown in Figure 2. The baseline 15D score of the patients was significantly lower than that of the age-standardized female population (mean [standard deviation] 0.889 [0.082] vs 0.904 [0.030], $P<.001$). The difference was also marginally clinically important. At 6 months, a clinical improvement in the 15D score was observed (+0.019, 95% confidence interval [CI], 0.017–0.012), resulting in a mean score of 0.908 (95% CI, 0.905–0.912). At the 2-year follow-up, the total score had decreased close to baseline level (mean 0.898, 95% CI, 0.894–0.902). A marked improvement was observed throughout the study period in sexual activity, discomfort and symptoms, and excretion. There was no difference in the mean change in symptom scores or generic HRQoL scores between those 165 women who were reoperated for recurrent prolapse during the 2-year follow-up period compared with the women who did not undergo repeated surgery (mean for PFDI-20 −45.39 vs −49.72, $P=.255$ and for 15D +0.0112 vs +0.0065, $P=.362$).

Patient global impression of improvement

Response to the surgical treatment measured by the PGI-I is shown in Figure 3. At 2 years, 90.1% of the patients considered their condition better and 4.8% considered it worse than before the operation. Altogether, 1935 (84.4%) patients answered that they were satisfied with the result of the operation at 2 years. The most common reason for dissatisfaction was the recurrence of prolapse (n=227) and 40 patients were dissatisfied because of a complication. Those who were reoperated during the 2-year follow-up period reported significantly worse outcome in PGI-I, but still 80.0% considered their condition to be better than that before the primary operation (vs 90.7% among those who were not reoperated, $P<.001$). At the 2-year follow-up, 2127 (93.8%) of the patients recommended the operation to a close friend experiencing POP.

Predictive factors for surgical outcome

The predictive factors for a favorable surgical outcome are shown in Table 2. Apical prolapse beyond the hymen was the most consistent predictor for a favorable outcome, measured by all 3 instruments, with risk ratios (RRs) ranging from 1.27 to 2.06. The same factors that predicted a favorable

FIGURE 2
Generic HRQoL measured using the 15D

Measurements were at baseline, 6 months, and 2 years after the operation. After each dimension, the changes in the 6-month- and 2-year-follow-up are listed in parentheses.

15D, 15-dimensional generic quality of life instrument; *HRQoL*, health-related quality of life

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outcome of surgery, especially advanced apical prolapse, had inverse associations with an unfavorable outcome of surgery (RR, 0.48−0.78) (Appendix 2). Sexual activity was also a preventive factor of an unfavorable outcome of surgery as evaluated by the 15D (RR, 0.70; 95% CI, 0.57−0.85, $P<.001$). The need of reoperation for recurrent prolapse during the follow-up period did not affect the favorable outcome, as measured by PFDI-20 and 15D. The retrospective assessment using PGI-I showed that the reoperation rate during the 2-year follow-up period was a predictive factor for unfavorable outcomes. Reoperation also doubled the risk of unfavorable outcomes, as measured by PFDI-20. Current smoking status was associated with an unfavorable outcome as evaluated by PGI-I (RR, 1.69; 95% CI, 1.02−2.81, $P=.042$).

Comment

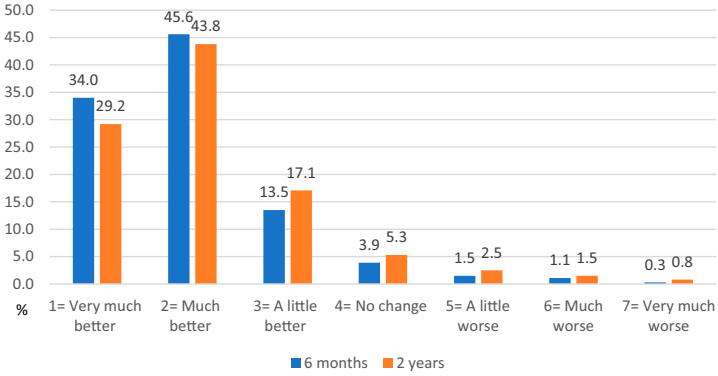
Principal findings

This large nationwide cohort study provides evidence that the surgical treatment of POP effectively improves the associated symptoms and HRQoL. At 2 years after the operation, 90.0% of patients perceived their condition to be improved. Altogether, 72% of patients reported a clinically significant improvement in condition-specific QoL compared with the preoperative situation. Consequently, the patient satisfaction was high.

Results of the study in the context of other observations

Surgical intervention of prolapse can improve the overall QoL in women with POP according to a systematic review.[21] In this review of 5 randomized controlled trials (RCTs), the mean change in the PFDI-20 score for surgical treatment was 74.03 (66.3−81.6). Due to different methods and outcome-measure reporting, comparing the results between this study and the RCT results is challenging, as these

FIGURE 3
PGI-I at 6 months and 2 years after the operation



PGI-I, Patient Global Impression of Improvement.

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randomized studies have evaluated the outcomes of a selected vaginal compartment repair with selected surgical methods.[11,21,22] Furthermore, as RCTs are designed to evaluate the efficacy of an intervention, they have lower heterogeneity, and due to exclusion and inclusion criteria (such as certain degree of prolapse in a specific compartment), the patients often have greater potential for improvement than in a more heterogeneous, real-world sample; therefore, the benefits observed in RCTs often are diluted. In reality, prolapse often involves multiple vaginal compartments and the surgical method is chosen based on clinical judgment. In our study, 46% of operations covered more than 1 vaginal compartment. This was also observed in a recent retrospective cohort study of nearly 100,000 women, in which 56% of women underwent multicompartment repairs.[23] The improvement in the PFDI-20 in our study was smaller than that reported in RCTs (55.5 at 6 months and 50.4 at 2 years after the operation). However, our results are in line with a cohort study of patients with POP undergoing apical mesh surgery with a 5-year follow-up,[24] where the mean decrease in the PFDI-20 score was 56.9 and 78.8% of participants achieved a minimally important change, compared with 72.2% observed in our study. Still, when comparing the study results, it is important to acknowledge that certain surgical methods have their own characteristics.

Our study also shows that POP reduces generic HRQoL. The average 15D score at baseline, as well as its changes over the follow-up period, are comparable with a previous Nordic study on apical prolapse mesh surgery.[16] Similar to previous studies, we showed a marked improvement in prolapse-related 15D dimensions (sexual activity, excretion, and discomfort and symptoms) at 6 months. These improvements were sustained during the 2-year follow-up. In addition, we found that sexually active women were less likely to have an unfavorable outcome of surgery as evaluated by the 15D. This is in line with a previous study showing that surgical treatment improves QoL, sexual function, and body image among women suffering from POP.[25]

Consistent with improvements in these patient-reported instruments, the patient satisfaction was high: 84.4% were satisfied with surgery and 93.8% would recommend the treatment to a close friend. In a previous prospective POP database study, 72.5% were satisfied with surgery and 89.7% would recommend the treatment to a friend.[26] However, in that study, 1 in 4 women requested additional therapy in the first year after POP repair and 8.2% were treated surgically for recurrent POP or incontinence. In the present study, the most frequent cause for dissatisfaction was recurrence of the prolapse and pelvic floor symptoms. In randomized studies, mesh augmentation has shown to decrease the probability of a recurrent prolapse but is associated with greater complication and reoperation rates.[11,27] In the present study, women undergoing transvaginal mesh surgery were more likely to have a favorable outcome, as measured by PGI-I. However, before drawing conclusions on the surgery methods, it is important to acknowledge that unmeasured confounding factors between surgical groups may remain despite adjustments, and the recurrence of prolapse and mesh associated complications may occur years after the surgery.[11]

The strongest predictive factors for a favorable outcome of surgery were advanced apical prolapse beyond the hymen and vaginal bulge. We found that smoking was associated with an increased the risk of unfavorable outcomes of surgery, as measured by PGI-I. In contrast, no association between smoking and increased symptoms measured by PFDI-20 was found. This may be partly explained by other health-related disadvantages of smoking. However, smoking decreases blood flow and wound healing and thus may hinder recovery from the surgery, which has been shown previously in plastic reconstructive surgery.[28] Smoking also has been shown to be a significant risk factor for mesh erosion in POP surgery.[29] These observations support the previous recommendations that when planning surgical treatment, smoking cessation should be encouraged.[28]

Strengths and limitations

To our knowledge, this is the largest prospective cohort study of prolapse surgery and QoL that has been published. The strength of this study is that we evaluated the outcome of surgery using several validated patient-reported

TABLE 2
Associations of patient characteristics and favorable surgery outcome[a] measured with the PFDI-20, PGI-I, and 15D

Characteristic	PFDI-20 aOR[b] (95% CI)	PGI-I aOR (95% CI)	15D aOR (95% CI)
Age (per year)	1.00 (0.99–1.01)	1.00 (0.98–1.01)	0.98 (0.97–1.00)
BMI (per 1 kg/m^2)	1.02 (1.00–1.04)	0.98 (0.96–1.01)	0.99 (0.97–1.01)
Parity (vs nulliparous)	1.04 (0.98–1.11)	1.06 (0.98–1.14)	1.05 (0.98–1.12)
Current smoking (vs nonsmokers)	0.92 (0.66–1.28)	0.71 (0.49–1.01)	1.15 (0.81–1.63)
Sexual activity (vs sexual inactive)	1.08 (0.89–1.32)	1.17 0.94–1.47)	1.15 (0.81–1.63)
Previous POP surgery (vs no previous surgery)			
Same compartment	0.93 (0.66–1.29)	0.74 (0.52–1.07)	0.97 (0.68–1.41)
Different compartment	1.31 (1.04–1.66)	1.10 (0.84–1.44)	0.85 (0.67–1.09)
Degree of prolapse (vs prolapse in hymen or above it)			
Anterior prolapse beyond hymen	0.95 (0.78–1.17)	1.33 (1.08–1.64)	1.19 (0.99–1.43)
Posterior prolapse beyond hymen	1.09 (0.88–1.36)	1.01 (0.72–1.42)	1.06 (0.78–1.45)
Apical prolapse beyond hymen	1.71 (1.38–2.12)	2.06 (1.58–2.70)	1.27 (1.01–1.59)
Any compartment beyond hymen	1.18 (0.95–1.48)	1.56 (1.23–1.97)	1.00 (0.79–1.28)
Bothersome bulge[c] (vs no bothersome bulge feeling)	2.04 (1.39–3.01)	1.90 (1.30–2.80)	1.19 (0.78–1.81)
Method of surgery			
Native tissue repair	1.00 reference	1.00 reference	1.00 reference
Transvaginal mesh	1.31 (1.00–1.71)	1.54 (1.11–2.15)	0.95 (0.71–1.29)
Abdominal mesh (vs native tissue repair)	1.36 (0.98–1.88)	1.19 (0.81–1.74)	1.02 (0.71–1.45)
Reoperation (vs no reoperation during follow-up)	0.85 (0.60–1.22)	0.46 (0.32–0.67)	1.14 (0.78–1.67)
Hospital type			
Tertiary	1.00 reference	1.00 reference	1.00 reference
Secondary	0.96 (0.78–1.18)	1.51 (0.91–1.45)	0.96 (0.76–1.20)
Primary	1.02 (0.80–1.30)	1.30 (0.98–1.72)	0.93 (0.71–1.21)
Private	0.78 (0.34–1.82)	1.55 (0.56–4.27)	0.61 (0.22–1.67)

15D, 15-dimensional generic quality of life instrument; *aOR*, adjusted odds ratio; *BMI*, body mass index; *CI*, confidence interval; *PFDI-20*, Pelvic Floor Distress Inventory-20; *PGI-I*, Patient Global Impression of Improvement; *POP*, pelvic organ prolapse.

[a] Definition of favorable outcome: PFDI-20: Total PFDI-20 scores diminished more than 45 points. n=1164 (49.8%). PGI-I: Patients felt their condition to be much improved or very much more improved than before the operation (PGI-I index 1 or 2). n=1693 (73.0%). 15D: Total 15D score improved 0.035 or more. n= 697 (30.6%); [b] aOR adjusted with age, BMI, parity, smoking, sexual activity, degree of prolapse, method of surgery, and hospital type; [c] Definition of bothersome bulge: answer "yes, bothers somewhat/moderately/quite a bit" for PFDI-20 question number 3 ("usually have a bulge or something falling out that you can see or feel in your vaginal area?").

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instruments in addition to patient satisfaction. To improve the generalizability of our results, we included all surgical pelvic reconstructive surgery methods in all vaginal compartments. There were large differences in the surgical approaches for both native tissue and mesh augmentation surgeries. This may be considered a limitation; however, it does reflect the real-life clinical setting. Furthermore, anatomical success rates were not assessed. We do not consider this as a major limitation because the absence of vaginal bulge symptoms postoperatively significantly correlate with the patient's assessment of overall improvement, whereas anatomical success alone does not.[8] A limitation regarding the assessment of cure after prolapse surgery was that we did not ask the patients whether they had undergone any conservative treatment, such as pessaries or physiotherapy, after the surgery. In future follow-up studies, we plan to include this information. Retreated women were included in the original analyses, as we wanted to describe the effectiveness of POP surgery among all women undergoing surgery, including those who require retreatment to provide more realistic information on the effect of POP surgery on the HRQoL. Despite the need for reoperation, these women also reported significant improvement in the HRQoL measures. The participation rate was high, but as often happens in cohort studies, the loss to follow-up may not be entirely random. However, the baseline characteristics of the respondents at 2 years was a good representation of the whole study population. So far, our study only

includes outcomes up to 2 years after surgery, but follow-up is currently ongoing.

Conclusion and clinical implications

In conclusion, our results show that surgical treatment of POP effectively improves HRQoL, resulting in high patient satisfaction. Our large cohort with a high response rate offers a holistic picture of one nation's practice and patient-reported outcomes of POP surgery. These results could be used in patient counseling on whether to undergo surgical treatment for POP. ■

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Received Sept. 4, 2019; revised Nov. 26, 2019; accepted Nov. 27, 2019.

H.S. is the developer of the 15D and obtains royalties from its electronic versions. The other authors report no conflict of interest.

The study was funded by Finnish Society for Gynecological Surgery and supported by grants from the Emil Aaltonen's foundation, the Finnish Cultural Foundation, Häme Regional Fund and the Ministry of Health and Social Welfare in Finland via Medical Research Funds of Kanta-Häme Central Hospital.

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SUPPLEMENTAL TABLE 1

Patient characteristics at baseline: Comparison of baseline characteristics made between respondents and nonrespondents for 2-year follow-up

Patient baseline characteristic	All patients	Data available, n (%)	Patients that answered the 2-year follow-up	Data available, n (%)	*P* value[a]
Age at operation, y, mean±SD	64.0±10.7	3512 (100)	64.4±10.1	2350 (66.9)	<.001
BMI, kg/m^2, mean±SD	26.9±4.1	2825 (80.4)	26.8±4.0	2281 (64.9)	.186
Current smokers, n (%)	252 (8.7)	2913 (82.9)	184 (7.9)	2342 (66.6)	.001
Parity, mean±SD	2.55±1.4	2924 (83.2)	2.58±0.1	2310 (65.7)	.227
Sexually active, n (%)	1054 (39.1)	2698 (76.7)	866 (39.7)	2179 (62.0)	.072
Previous POP surgery, n (%)	872 (24.8)		603 (25.6)		.185
Same compartment n, (%)	604 (17.2)		423 (18.0)		
Different compartment, n (%)	268 (7.6)		180 (7.7)		
Prolapse beyond the hymen					
Anterior vaginal wall, (POPQ Aa or Ba >0), n (%)	1731 (50.6)	3420 (97.3)	1143 (50.2)	2277 (64.8)	.616
Posterior vaginal wall, (POPQ Ap or Bp >0), n (%)	985 (28.1)	3409 (97.0)	636 (28.1)	2262 (64.4)	.106
Apex of the vagina, (POPQ C>0), n (%)	843 (25.9)	3374 (96.0)	545 (24.3)	2244 (63.8)	.224
At least 2 of these >0, n (%)	2717 (79.0)	3441 (98.0)	1802 (66.7)	2288 (65.1)	.691
PFDI-20 baseline scores, mean (95% CI)	99.2 (97.1-101.3)	2903 (82.6)	98.7 (96.7-100.8)	2346 (66.7)	.466
15D baseline scores, mean (95% CI)	0.889 (0.886-0.892)	2865 (81.5)	0.891 (0.889-0.894)	2310 (65.7)	.187
Method of surgery		3515 (100)		2351 (66.9)	<.001
Native tissue repair, n (%)	2855 (80.8)		1863 (79.2)		
Transvaginal mesh	429 (12.2)		310 (13.2)		
Abdominal mesh	251 (7.1)		178 (7.6)		
Hospital type		3515 (100)		2351 (66.9)	.153
Tertiary, n (%)	946 (32.5)		750 (31.9)		
Secondary, n (%)	1303 (44.7)		1060 (45.1)		
Primary, n (%)	627 (21.5)		504 (21.4)		
Private, n (%)	37 (1.3)		28 (1.2)		

15D, 15-Dimensional generic quality of life instrument; *BMI*, body mass index; *CI*, confidence interval; *POP*, pelvic organ prolapse; *POPQ*, Pelvic Organ Prolapse Quantification system; *PFDI-20*, Pelvic Floor Distress Inventory; *SD*, standard deviation.

[a] *P* value is counted for the difference of baseline characteristics between participants who answered the questionnaire at 2 years' follow-up and drop-outs.

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SUPPLEMENTAL TABLE 2

Regression analysis for unfavorable outcome[a] of surgery and patient baseline characteristics: adjusted with age, BMI, parity, smoking, sexual activity, degree of prolapse, method of surgery, and hospital type

Characteristic	PFDI-20 aOR (95% CI)	PGI-I aOR (95% CI)	15D aOR (95% CI)
Age	1.01 (1.00–1.02)	1.03 (1.01–1.05)	1.02 (1.01–1.03)
BMI	1.00 (0.97–1.02)	1.01 (0.97–1.05)	1.01 (1.00–1.03)
Parity	0.94 (0.87–1.02)	0.94 (0.83–1.06)	0.97 (0.91–1.03)
Current smoking	1.03 (0.71–1.49)	1.69 (1.02–2.81)	1.20 (0.86–1.68)
Sexual activity	0.99 (0.79–1.24)	0.90 (0.64–1.26)	1.47 (1.20–1.80)
Prior POP surgery			
Same compartment	1.32 (0.92–1.89)	1.33 (0.96–1.83)	1.32 (0.93–1.86)
Different compartment	1.00 (0.72–1.38)	1.21 (0.97–1.51)	1.20 (0.89–1.62)
Degree of prolapse			
Anterior prolapse beyond hymen	0.75 (0.61–0.92)	0.64 (0.46–0.87)	0.94 (0.78–1.32)
Posterior prolapse beyond hymen	1.17 (0.90–1.39)	1.01 (0.72–1.42)	0.94 (0.77–1.15)
Apical prolapse beyond hymen	0.54 (0.41–0.70)	0.48 (0.31–0.74)	0.78 (0.63–0.96)
Any compartment beyond hymen	0.71 (0.58–0.90)	0.52 (0.37–0.73)	1.10 (0.88–1.38)
Bothersome bulge	0.40 (0.28–0.57)	0.46 (0.28–0.77)	0.89 (0.62–1.29)
Method of surgery			
Native tissue repair	1.00 reference	1.00 reference	1.00 reference
Transvaginal mesh	0.86 (0.63–1.18)	0.79 (0.49–1.27)	1.07 (0.77–1.50)
Abdominal mesh	0.94 (0.65–1.36)	0.62 (0.32–1.21)	1.12 (0.75–1.68)
Reoperation during follow-up	1.94 (1.20–3.15)	2.71 (1.69–4.34)	0.78 (0.51–1.17)
Hospital type			
Tertiary	1.00 reference	1.00 reference	1.00 reference
Secondary	0.91 (0.72–1.14)	0.82 (0.58–1.15)	0.62 (0.25–1.53)
Primary	0.82 (0.62–1.08)	0.77 (0.50–1.17)	0.51 (0.21–1.28)
Private	1.30 (0.54–3.14)	1.20 (0.34–4.23)	0.55 (0.22–1.36)

15D, 15-Dimensional generic quality of life instrument; *aOR*, adjusted odds ratio; *BMI*, body mass index; PFDI-20, Pelvic Floor Distress Inventory; *PGI-I*, Patient Global Impression of Improvement; *POP*, pelvic organ prolapse.

[a] Definition of unfavorable outcome: PFDI-20: Total PFDI-20 scores decreased less than 23 points, N=649. PGI-I: Patients felt their condition to be the same or worse than before the operation (PGI-I scale 4–7), N=232. 15D: Total 15D score increased less than 0.015, N=1286.

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Received: 20 April 2020 | Accepted: 12 July 2020

DOI: 10.1002/nau.24467

ORIGINAL CLINICAL ARTICLE

Neurourology Urodynamics ICS SUFU WILEY

Agreement between patient global impression scale of improvement, pelvic floor distress inventory and 15D in measuring the outcome of pelvic organ prolapse surgery

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Abstract

Aims: To evaluate the correlation between three commonly used patient-reported outcome measures, two generic and one condition-specific instrument, in assessing the change in health-related quality of life following pelvic organ prolapse surgery.

Methods: The generic health-related quality of life measure 15-dimensional instrument (15D), Patient Global Impression of Improvement (PGI-I), and prolapse-specific Pelvic Floor Distress Inventory (PDFI-20) were used to assess the effectiveness of pelvic organ prolapse surgery in the national FINPOP study of 3535 surgeries (83% of all pelvic organ prolapse operations) performed in Finland in 2015. Spearman correlations between PGI-I, change in 15D and its dimensions and change in PFDI-20 and its subscales over a 2-year follow-up were investigated. The proportion of concordant ratings was also studied by investigating the proportion of women rated similarly (worse/no change/better/much better) by two instruments according to validated cutoffs.

Results: Among 2248 women for whom the 2-year change in all instruments could be measured, changes in PFDI-20 and 15D and its dimensions were weak ($\rho < 0.2$ for all except excretion; $\rho = 0.39$ and sexual activity; $\rho = 0.27$). PFDI-20 change ($\rho = 0.39$) and its subscales ($\rho = 0.19$-0.40, all $P < .001$) were more strongly correlated with PGI-I. The proportion of fully concordant ratings were higher for PFDI-20 and PGI-I (50.6%) than for PFDI-20 and 15D (33.0%).

Conclusion: The weak correlations between 15D, PGI-I, and PDFI-20 observed in this study show that the quantified health gains are strongly dependent on the chosen patient-reported outcome measures. This demonstrates

the importance of using condition-specific sensitive outcome measures in assessing the impact of surgical treatment in pelvic organ prolapse.

KEYWORDS

15D, Health-related Quality of Life, HRQoL, Patient Global Index of Improvement, Patient-Reported Outcome Measure, Pelvic Floor Distress Inventory, pelvic organ prolapse, pelvic reconstructive surgery, PFDI-20, PGI-I, POP, PROM, QoL, Quality of Life, surgery, urogynecology

1 | INTRODUCTION

Pelvic organ prolapse (POP), defined as the descent of vaginal wall or apex, is a common gynecological disorder affecting millions of women. The lifetime risk for surgery for POP is from 11% to 13%.[1] POP symptoms, including vaginal bulge sensation and urinary and bowel symptoms may cause a significant decrease in health-related quality of life (HRQoL).[2] POP can affect women's body image and cause restrictions in personal, social, and sexual activities and some women even stop these activities, which may expose them to depression.[3] Thus, the impact of POP on HRQoL is not restricted to its direct consequences, such as excretion and sexual functions.

Traditionally, the efficacy of POP surgery has been measured by anatomic outcomes, using the Pelvic Organ Prolapse Quantification (POP-Q) instrument.[4] Nowadays, the role of patient's expectations and their perception of the result is being more commonly recognized. This is of particular importance when the intervention is being performed simply to improve QoL, like in POP surgery. Use of validated patient-reported outcome measures (PROMs) is increasingly common in studies evaluating the effectiveness of POP surgery.[5] In particular, measuring the presence or absence of vaginal bulge symptoms, as well as patient satisfaction, and change in QoL after surgical treatment is essential.[6]

As there are numerous PROMs available, it is of utmost importance to select the PROM(s) relevant to the performed procedure. The criteria for the recommendation of questionnaires is that they have been shown to be valid, reliable, and responsive to change on psychometric testing.[7] However, it is unknown how consistently different validated questionnaires evaluate the changes in HrQoL after POP surgery. We[8] and others[2,9] have previously shown that POP surgery leads to improvement in both generic and disease-specific PROM measures, but it is unknown how strongly these measures are correlated, that is, whether those among whom improvement in generic HRQoL is detected are the same women who report symptom alleviation. Furthermore, as many generic instruments such as 15-dimensional instrument (15D) measure also sexual function and excretion symptoms, it is important to assess whether they capture the symptom alleviation detected by symptom-specific instruments such as Pelvic Floor Distress Inventory-20 (PFDI-20) and its subscales.

We evaluated how consistent are two generic instruments (15D and PGI-I; Patient Global Impression of Improvement), and one condition-specific HRQoL instrument (PFDI-20) in assessing the change in HrQoL following pelvic organ prolapse surgery. The specific aims of this study were to evaluate the correlation of different instruments and the proportion of concordant ratings between different instruments.

2 | MATERIALS AND METHODS

2.1 | Study design

This national prospective multicenter study was organized and funded by the Finnish Society for Gynecological Surgery. The study period was between 1 January 2015 and 31 December 2015. All Finnish hospitals performing POP surgery were invited to join the study and altogether, 41 of 45 hospitals participated. The inclusion criteria were age more than 18 years and the ability to communicate in written and oral Finnish or Swedish. The study population (n = 3515 patients, 3535 operations) covered 83% of all women operated on for POP in 2015 in Finland.

HRQoL was measured with validated instruments as described previously.[10] Disease-specific symptom burden was assessed with the PFDI-20, which consists of three subscales distress caused by prolapse symptoms (Pelvic Organ Prolapse Distress Inventory, POPDI-6), difficulties of defecation (Colorectal-Anal Distress Inventory, CRADI-8), and difficulties in urination (Urinary Distress Inventory, UDI-6).[11] Generic HrQoL was measured by a validated 15D, consisting of 15 dimensions (mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity).[12] The 15D instrument has previously shown to

be valid in assessing the impact of pelvic floor reconstructive surgery.[9] Patients completed these instruments at baseline, and 6 and 24 months after operation. In addition, the PGI-I was administered 6 and 24 months after the operations. PGI-I is used in several surgical fields and has also been validated in prolapse surgery.[13]

At baseline, that data were available from 2924 (83%) of 3515 study participants. At 6 months, the change in PFDI-20 and 15D scores were available from 2522 (72%) and 2440 (69%) women, respectively. At 2 years, PFDI-20 data were available for 2337 (66%) and data on 15D for 2275 (65%) women, respectively. The data on PGI-I was available for 2525 (72%) at 6 months and 2321 (66%) participants at 2 years.

To ensure the comparability of agreements in different comparisons (ie, PFDI-20 vs 15D, PFDI-20 vs PGI-I, and 15D vs PGI-I), analyses were restricted to women who had responded to all three questionnaires at baseline and 24 months ($N = 2248$ main analyses). In addition, sensitivity analyses were conducted among those 2425 women who had responded to these questionnaires at baseline and 6 months to assess whether the correlations were stronger with shorter follow-up time.

2.2 | Ethical approval

The study was approved by the Research Ethics Committee of the Northern Savo Hospital District on the 20th of May 2014 (reference number: 5//2014) and the study protocol was approved by the Finnish Ministry of Social Affairs and Health and institutional approval of each participating hospital. The study was also included in the ClinicalTrials.gov protocol registration system (NCT02716506) and the ethical standards for human experimentation established by the Declaration of Helsinki of 1964, revised in 2013, were followed.[14] In addition, we obtained written informed consent from each participant.

2.3 | Statistical analysis

Statistical analyses were performed with Stata MP14.0. To investigate the agreement between 15D, PFDI-20, and PGI-I, the 2-year changes in 15D and PFDI-20 were scaled to the same dimension so that negative values indicate improvement. Correlations between change in 15D, PGI-I, PFDI-20, and PFDI-20 subscales and 15D dimensions were investigated with Spearman's method. To evaluate whether the strength of correlation was affected by the type of surgery or prolapse severity, we stratified analyses according to the surgery method and whether the prolapse of any compartment was beyond hymen. 95% Confidence interval (CI) were estimated by 1000-fold bootstrapping, in addition to correlations, we evaluated the proportion of agreeing ratings by crosstabulations.

In addition to correlations, we evaluated the proportion of agreeing ratings by crosstabulations. For this purpose, the 15D total index was categorized as "worse" (change > 0.015), "no change" (0.0149 to −0.0149), "slightly better" (−0.015 to −0.035) and "much better" (<−0.035).[15] Change in PFDI-20 was categorized as "much better" (decrease > 45 points), "better" (decrease 23-45 points), "no change" (decrease 22.9 points-increase 22.9 points), and "worse (increase 23 ≥ points). These threshold scores were based on previous studies defining the minimal important change (MIC) of total PFDI-20 scores.[11,16] Agreement between changes in 15D and PFDI-20 was evaluated by calculating the proportion of fully concordant ratings (eg, both 15D and PFDI-20 reported as "much better", ie, degree of improvement considered), and partially agreeing ratings (eg, 15D rated as "much better", PFDI-20 as "much better" or "slightly better"; ie, degree of improvement ignored). For the 7-level PGI-I, we considered values 1 to 2 (very much or much better) to correspond with "much better" in PFDI-20 and 15D, and value 3 (a little better) with "slightly better".

3 | RESULTS

Of the 2248 women included in the main analyses, 1128 (50.2%) patients reported a "much better" outcome of surgery measured by PFDI-20, 1638 (72.8%) by PGI-I and 675 (30.0%) by 15D. The proportion of patients in different outcome categories are shown in Figure 1.

3.1 | Correlation between PGI-I, 15D, and PFDI-20

Two-year change in the symptom-specific PFDI-20 and its subscales correlated weakly ($\rho = 0.188$-0.386) with changes in 15D total index and PGI-I (Table 1). The more generic instruments, PGI-I, and 15D correlated also weakly with each other ($\rho = 0.275$). The strength of correlation did not differ between procedure type or disease severity (Figure S1).

In general, similar results were observed with the 6-month changes, except for POPDI-6 and PGI-I which were not correlated in the 6-month data. The correlations between PFDI-20 and its subscales and specific dimensions of 15D were also modest, with both 2-year (Figure 2A) and 6-month follow-up (Figure 2B). The strongest correlations were observed between improvement in excretion and PFDI-20 and UDI-6 ($\rho = 0.348$-

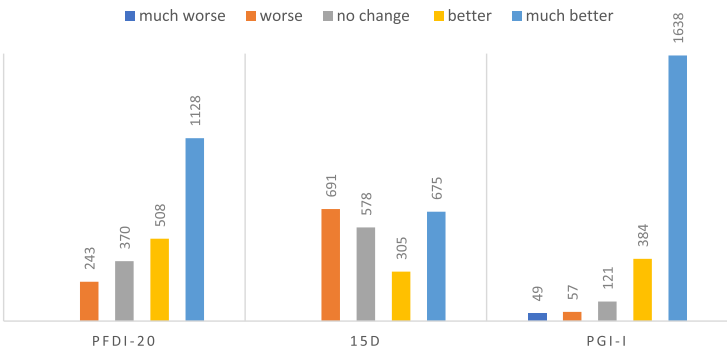

FIGURE 1 The distribution of patients (n = 2249) that concluded all the outcome measures at 24 months, categorized* by the outcome of three different outcomes; PFDI-20, 15D, and PGI-I. 15D, 15-dimensional instrument; PFDI-20, prolapse-specific Pelvic Floor Distress Inventory; PGI-I, Patient Global Impression of Improvement

0.395, $P < .001$), all other correlations were lesser than or equal to 0.3.

3.2 | Agreement between ratings

When the comparability of 2-year changes was assessed, the highest agreement was observed between PFDI-20 and PGI-I. The degree of change was rated identically for 50.6% of persons. If the degree of improvement is ignored (ie, "much better" and "better" are considered to be similar ratings), the change was rated similarly by 72.8% of persons (Figure 3A). The level of agreement was approximately 5% higher with 6-month follow-up data (55.5% and 74.2%, respectively, Figure S1A). The agreement between PFDI-20 and 15D (Figure 3B) was lower, with 33.0% of women rating the change in HRQoL similarly with both instruments. If the degree of improvement was ignored, the similarity was 45.9%. The categorized HRQoL change measured by PGI-I and 15D was the same for 31.1% of persons when the degree of improvement was considered and 45.0% when it was ignored (Figure 3C). The degree of similarity was comparable, with 2% to 5% higher agreement when the 6-month changes were assessed (Figure S2B-C).

TABLE 1 Spearman correlations between PGI-I, and changes in 15D index, PFDI-20, and its subscales over 2 years (6 months)

	Change in 15D	PGI-I
PGI-I	0.275 (0.229)	
Change in PFDI-20	0.363 (0.331)	0.386 (0.316)
Change in POPDI-6	0.304 (0.181)	0.395 (0.022, NS)
Change in UDI-6	0.281 (0.278)	0.290 (0.258)
Change in CRADI-8	0.265 (0.233)	0.188 (0.108)

Note: All $P < .001$ unless otherwise indicated.
Abbreviations: 15D, 15-dimensional instrument; CRADI-8, Colorectal-Anal Distress Inventory; PFDI-20, prolapse-specific Pelvic Floor Distress Inventory; PGI-I, Patient Global Impression of Improvement; POPDI-6, Pelvic Organ Prolapse Distress Inventory; UDI-6, Urinary Distress Inventory.

4 | DISCUSSION

4.1 | Principal findings

Pelvic organ prolapse surgery has been shown to improve in both generic and disease-specific patient-reported outcome measures,[2,8,9] but the findings of this study demonstrate that the quantified health gains are dependent on the chosen patient-reported outcome measure. In our study, the three patient-reported measures (PFDI-20, 15D, and PGI-I) were only weakly correlated, and the proportion of concordant ratings between instruments varied between 31.1% and 72.8%.

4.2 | Results of the study in the context of other observations

The HRQoL in relation to POP surgery has been investigated mainly using condition-specific instruments. With these instruments, pelvic floor dysfunction and quality of sexual life have been shown to improve significantly.[2] However, the application of generic QoL instruments is valuable as it allows comparisons across different conditions and enables assessment of health gains beyond the dimensions captured by condition-specific measures. For example, with a generic instrument, the effectiveness of POP surgery can be compared with the effectiveness of procedures from different surgical fields.[12] However, the problem with applying generic measures in POP surgery research can be that they lack sensitivity to the aspects characteristic of pelvic floor dysfunction and thus may be unable to detect clinically important improvement.[17] Another challenge in their application, particularly in long-term outcome assessment, is

the age range of treated women. In our study, the average age was 64 years, when significant changes in general health status can occur during 2 years as ageing correlates with increasing morbidity.[12] Thus, discomfort related to other conditions than POP explains the decreasing general HRQoL.

In our study, the overall changes in 15D were mainly explained by changes in sexual activity and excretion. This is expected, as the correction of the pelvic floor should lead to improvement in urinary and bowel symptoms. In addition, symptoms of POP greatly affect women's body image and sexuality.[18] Some women report that they avoid sexual activity due to a fear of discomfort or embarrassment associated with POP, or in particular with urinary or fecal incontinence during sexual activity.[19] Although generic instruments such as 15D capture these dimensions that are strongly affected by POP, our findings on the weak correlation between these dimensions and PFDI-20 and its subscales underline the importance of using also symptom-specific outcome measures. PFDI-20 is specifically developed for assessing the symptoms, including difficulties in excretion and pelvic bulge/pressure discomfort, among women suffering from POP, and to detect the degree and change of discomfort and symptoms associated to POP, whereas 15D is intended for the general adult population, regardless of their age or sex.

Previously, Altman et al[9] showed that improvement in PFDI-20 was associated with improvement in 15D in a Nordic multicenter study of apical prolapse mesh surgery. The weaker correlation in our study may be explained by the differences in study populations. Women selected for transvaginal mesh surgery tend to be older, have more often advanced prolapse, and report higher scores in condition-specific questionnaires compared to women who undergo native tissue repair.[20] We have previously shown an association between advanced apical prolapse and favorable surgery outcome with both PFDI-20 and 15D.[8] Thus, a more homogenous population with advanced prolapse may show a better correlation of these instruments. However, the preoperative 15D single-index mean score of 0.888 in the Altman study was similar to ours (0.889).

PGI-I has been shown to correlate well with the PROMs that are used in urinary incontinence research.[21] The opposite findings was found in a Danish database study that showed higher satisfaction after urogynecological surgery measured by PGI-I compared with the disease-specific questionnaire (ICIQ, International Consultation on Incontinence Questionnaire score).[22] They concluded that PGI-I score overestimates the improvement following urinary incontinence and prolapse

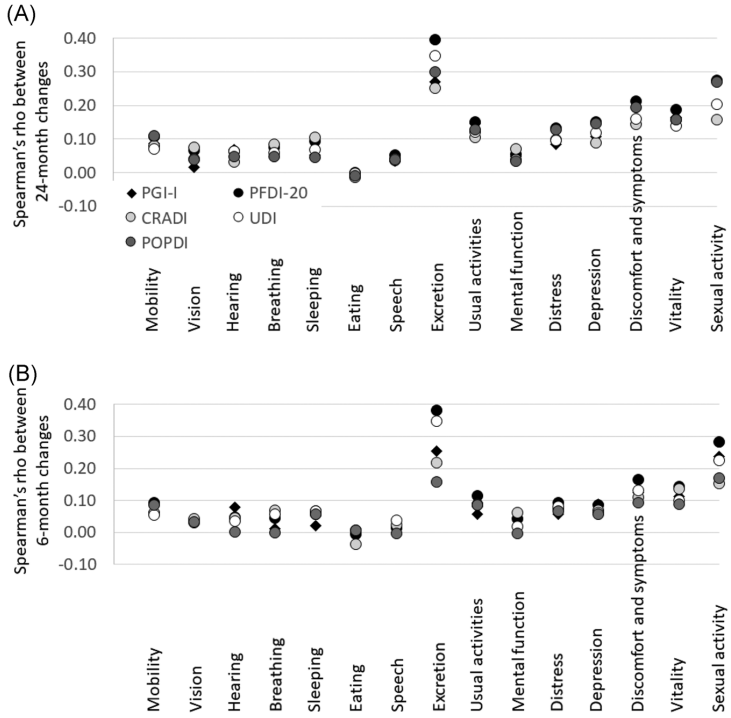

FIGURE 2 Correlation between changes in 15D dimensions and PGI-I and changes in PFDI-20 and its subscales during (A) 2-year follow-up and (B) 6-month follow-up. 15D, 15-dimensional instrument; CRADI-8, Colorectal-Anal Distress Inventory; PGI-I, Patient Global Impression of Improvement; PFDI-20, prolapse-specific Pelvic Floor Distress Inventory; POPDI-6, Pelvic Organ Prolapse Distress Inventory; UDI-6, Urinary Distress Inventory

(A)

2-year PGI-I	Category of PFDI-20 change, % (n)			
	worse	no change	better	much better
much worse	0.8 (17)	0.8 (17)	0.2 (4)	0.5 (11)
worse	0.5 (11)	1.1 (25)	0.5 (11)	0.4 (10)
no change	0.9 (21)	2.4 (55)	1.1 (24)	0.9 (21)
better	1.2 (28)	6.4 (143)	4.0 (91)	5.4 (122)
much better	0.9 (20)	12.3 (276)	16.8 (378)	42.9 (964)

Fully concordant ratings 50.6%
Concordant ratings (degree of improvement ignored) 72.8%
Opposite ratings 3.7%

(B)

Category of 15D change	Category of PFDI-20 change, % (n)			
	worse	no change	better	much better
worse	2.7 (61)	10.8 (243)	7.1 (159)	10.1 (228)
no change	0.7 (16)	6.3 (142)	6.7 (151)	12.0 (269)
better	0.3 (0.7)	2.5 (57)	3.3 (74)	7.4 (167)
much better	0.6 (13)	3.3 (74)	5.5 (124)	20.6 (464)

Fully concordant ratings 33.0%
Concordant ratings (degree of improvement ignored) 45.9%
Opposite ratings 18.1%

(C)

2-year PGI-I	Category of 15D change, % (n)			
	worse	no change	better	much better
much worse	1.4 (32)	0.3 (7)	0.2 (5)	0.2 (5)
worse	1.4 (32)	0.5 (12)	0.2 (4)	0.4 (9)
no change	2.7 (61)	1.2 (26)	0.7 (15)	0.8 (19)
better	8.1 (182)	4.4 (99)	1.6 (99)	3.0 (68)
much better	17.1 (384)	19.3 (434)	10.9 (434)	25.5 (574)

Fully concordant ratings 31.1%
Concordant ratings (degree of improvement ignored) 45.4%
Opposite ratings 26.2%

FIGURE 3 Proportions of fully concordant (degree of improvement considered), concordant (degree of improvement ignored) and opposite ratings for (A) categorized change in PFDI-20 and PGI-I, (B) categorized change in PFDI-20 and 15D, (C) categorized change in 15D and PGI-I during two-year follow-up. 15D, 15-dimensional instrument; PGI-I, Patient Global Impression of Improvement; PFDI-20, prolapse-specific Pelvic Floor Distress Inventory

surgery. However, the ICIQ that was used to measure the disease-specific HRQoL outcome, is a simplified tool that covers only the impact of urine incontinence and bulge symptoms.[23] Many aspects of treatment response, such as de novo incontinence and persistent pain may not be reflected in the ICIQ, and it has been discussed if the PGI-I provides a more global overview of treatment success, potentially more fully encompassing the range of harms and benefits of the surgical treatment.[24] The PFDI-20 covers a more holistic picture of the pelvic floor symptoms than ICIQ and thus, a comparison of the results of PGI-I and PFDI-20 provides a more realistic overview of the accuracy of the global index. In concordance with Larsen et al, our data showed "much better" outcome of surgery for PGI-I significantly more often than for PFDI-20 and the results of PGI-I and PFDI-20 were concordant in 72.8% of cases. It must be remembered though, that the PGI-I is a completely retrospective assessment, and it is affected by other aspects such as patient's experience of the treatment and nursing. In our opinion, these two measures reflect different aspects of the outcome of surgery, and it is useful to use both measures in clinical studies. The advantage of PGI-I in clinical practice is that it is easy for the patient to fill in and it is less time consuming than the more detailed multiple HRQoL questionnaires.

The correlations were stronger, and the proportion of concordant ratings higher for PGI-I and PFDI-20 than for PGI-I and 15D. This is likely explained by the fact that PGI-I is anchored to the specific treatment being assessed (ie, POP surgery in our case). Thus, with PGI-I, the patient likely focuses on evaluation of POP related symptoms, and the bother related to them. Instead, 15D measures several domains, the majority of which are not related to pelvic floor dysfunction. PGI-I is thought to capture the global perception of the change and is typically used as an anchor when assessing the validity of

other measures.[13] One challenge of PGI-I is that as a retrospective measure it may be affected by recall bias whereas PFDI-20 measures current symptom burden and thus may be the preferable measure. However, global ratings of change are shown to provide the single best measure of significant change from the patient's perspective.[25]

4.3 | Strengths and limitations

Among the strengths of our study are the nationwide and prospective setting. To our knowledge, this is the largest study comparing different patient-reported outcome measures that are used in prolapse surgery. The participation rate was high and the baseline characteristics of the respondents at 2 years were fairly representative of the whole study population.[8] One possible limitation is the definition of PFDI-20 total scores. The thresholds were obtained from two previous studies. Barber et al, defined a decrease of more than 45 points as a better outcome by studying the relationship between the change of PFDI-20 scores and subject's global assessment of improvement among 100 patients 3 to 6 months after surgery,[11] while Utomo et al performed a ROC analysis among 111 patients 6 months after surgery and thus defined that a decrease of 23 points or more indicates a clinically meaningful improvement in QoL.[16] These cutoffs are based on two separate, relatively small studies and thus their robustness and generalizability to other samples are currently unknown.

5 | CONCLUSIONS

In conclusion, our findings demonstrate that the choice of outcome measurements is important and the quantified health gains are directly affected by this choice. Although the dimensions of generic instruments may appear to capture condition-specific symptoms, such as symptoms and consequences of POP, using condition-specific PROMs is essential.

ACKNOWLEDGMENTS

The study was funded by the Finnish Society for Gynecological Surgery and supported by grants from the Emil Aaltonen's foundation, the Finnish Cultural Foundation, Häme Regional Fund and the Ministry of Health and Social Welfare in Finland via Medical Research Funds of Kanta-Häme Central Hospital.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

How to cite this article: Mattsson NK, Karjalainen P, Heikkinen A-M, Nieminen K, Jalkanen J, Tolppanen A-M. Agreement between patient global impression scale of improvement, pelvic floor distress inventory and 15D in measuring the outcome of pelvic organ prolapse surgery. *Neurourology and Urodynamics*. 2020;1–8. https://doi.org/10.1002/nau.24467

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PUBLICATIONS OF
THE UNIVERSITY OF EASTERN FINLAND
Dissertations in Health Sciences

ISBN 978-952-61-3398-0
ISSN 1798-5706