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Dissertations6-19	
Abstracts 20-36	

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August 2022, NO-BTX-210131\_2

#### Friday 30th September 2022

#### Gunhild Felde (NO): Thesis: Urinary incontinence in relationship with anxiety and depression in women

#### Summary of the thesis

Urinary incontinence (UI) affects a large proportion of women during their lives. Pregnancy and parity, obesity and increasing age are regarded as the most important and best documented risk factors for UI in women. Many co-morbid conditions are associated with increased prevalence of UI, such as diabetes, coronary heart disease, cerebral stroke, asthma/COPD, rheumatoid arthritis and chronic musculoskeletal pain. Studies have also shown an association between symptoms of anxiety and depression and UI. Especially urgency UI and overactive bladder have been investigated in relationship with anxiety and depression. The serotonergic and noradrenergic system has a place in the pathophysiology in both UI, anxiety, and depression, which supports the epidemiological substrate. The documented effect of treatment with the serotonin- and noradrenaline reuptake inhibitor duloxetine on stress UI, also strengthens the hypothesis of a common underlying biological association between the conditions. This thesis is an epidemiological study of the associations between anxiety and UI and depression and UI in women.

#### The aims of the thesis were

- To determine if anxiety and depression is associated with UI in middle-aged women, and to investigate a possible association with type and severity of UI.

- To investigate the association between anxiety/depression and UI in a 10-year follow-up study.

- To determine the association between anxiety/depression and UI in a population with women 20 years+, and to investigate if the associations are influenced by using psychotropic drugs.

Our studies are based on data from The Hordaland Health Study (HUSK) (Paper I), the Nord-Trøndelag Health Study (HUNT) (Paper II and Paper III) and the Norwegian Prescription Database (NorP) (Paper III). The questions about UI were identical in these surveys and consisted of an opening question if the women had experienced leakage of urine and further questions about type, frequency and amount of leakage. The Norwegian version of the questionnaire Hospital Anxiety and Depression Scale (HADS) was used in both serveys to measure the level of anxiety and depression.

Paper I

Felde G, Bjelland I, Hunskaar S. Anxiety and depression associated with incontinence in middle-aged women: a large Norwegian cross-sectional study. International Urogynecology Journal 2012; 23:299-306.

Paper I is based on data from HUSK. The study population consisted of 5321 women 40-44 years of age who answered the questionnaire, which contained both the HADS- and UI-questions. The prevalence of UI was 26%. Of these, 53% had stress UI, 9% urgency UI and 30% mixed UI. We found an association both between anxiety and UI, and between depression and UI, strongest for mixed UI, urgency UI and severe UI. Of the whole study-population 20% had anxiety and 8% depression, among women with mixed UI, 32% had anxiety and 17% depression, and in the group with severe UI, 34% had anxiety and 16% depression.

Paper II

Felde G, Ebbesen MH, Hunskaar S. Anxiety and depression associated with urinary incontinence. A 10-year follow-up study from the Norwegian HUNT study (EPINCONT). Neurourology and Urodynamics 2017; 36:322-328. Paper II was based on data from both HUNT2 and HUNT3. The study population consisted of 16.263 women who had answered the questionnaires about UI, anxiety and depression in HUNT2 and HUNT3. We wanted to compare the development of anxiety and depression over the 10-year follow-up among those who had UI in HUNT2 compared with those who were continent in HUNT2. We also wanted to compare development of UI among those with anxiety and among those with depression in HUNT2, compared with development of UI among those without anxiety and depression in HUNT2 was associated with increased risk of development of UI, strongest for the urgency component of UI. This association was strongest in the groups with the highest HADS-scores. UI in HUNT2 was also associated with increased risk of development of anxiety and depression.

#### Continued

#### Gunhild Felde (NO): Thesis: Urinary incontinence in relationship with anxiety and depression in women

#### Paper III

Felde G, Engeland A, Hunskaar S. Urinary incontinence associated with anxiety and depression: the impact of psychotropic drugs. Cross-sectional study from the Norwegian HUNT study. BMC Psychiatry 2020 Nov 2;20(1):521. Paper III was based on data from the HUNT3 and the NorPD. 21803 women who had answered the UI-questions in HUNT3 were linked to NorPD. From the NorPD we got information about all prescriptions dispensed for all individuals in the study. The prevalence of UI was 29% in the total group, 38% in the group with moderate/severe anxiety and 44% in the group with moderate/severe depression. Mixed UI was strongest associated with anxiety and depression. The prevalence of UI did not increase significantly in the subgroups with anxiety/depression using an antidepressant or anxiolytic drug compared with non-users in the same subgroups. We found increased prevalence of UI among users of many psychotropics compared with non-users. After adjustments, however, UI was positively associated with the use of antidepressants. We found a weak, negative association with use of anxiolytics.

**Our results** show that UI is associated with anxiety and depression. Also, anxiety and depression are predictors for development of UI in the longitudinal study. The association is strongest for severe UI and mixed UI. Use of psychotropic drugs does not seem to significantly influence the cross-sectional associations.

#### Friday 30th September 2022

#### Ole A Dyrkorn (NO): Thesis: "The Impact of Childbirth before and after Mid-Urethral Sling Surgery"

Urinary incontinence (UI) is a common pelvic floor disorder, substantially impacting women's quality of life, productivity, socializing, and sexuality. Stress urinary incontinence (SUI), defined as "involuntary loss of urine on physical exertion, sneezing, or coughing", is a subtype of urinary incontinence, affecting 10 – 39 % of the adult female population. SUI is most commonly found in women between 25 and 49 years of age. Insufficient support of the urethra is considered the primary underlying mechanism for SUI. These changes are believed to be induced by loss of or trauma to the connective tissue or muscular structures in the female pelvic floor. Childbirth, especially operative vaginal birth, is considered a significant risk factor.

In 1996, the mid-urethral slings (MUS) were introduced as a new surgical procedure to correct SUI, in which a synthetic mesh tape is implanted to support the mid-urethra. Today, MUS is considered the standard surgical treatment for SUI due to its high effectiveness, long-term durability, and lower repeat surgery rates than other surgical incontinence procedures. Conservative therapy is the preferred first-line treatment option, but surgical treatment is usually recommended if the woman has not achieved sufficient improvement.

Women, who have not completed childbearing, are usually advised to postpone surgical treatment, as a subsequent pregnancy is believed to impose a high risk of SUI recurrence. Secondly, there is no consensus regarding the preferred mode of delivery in a subsequent pregnancy. After a successful MUS operation, several surgeons will often recommend a cesarean delivery even though the scientific evidence is limited. Furthermore, we currently have little knowledge of whether a woman's history of childbearing and deliveries before an incontinence surgery with MUS could potentially impact the surgical result. Might it be possible that the same obstetrical risk factors leading to SUI also significantly impact the outcomes of a MUS operation after the completion of childbearing? Norway and the Nordic countries have long traditions with mandatory notification to population-based central health registries. Over the last decades, medical quality registers have gained increased popularity in monitoring and improving the quality of health services. Several registries also include unique personal identifiers, enabling linkage between registries. Health registries have proved to be an essential source for research, but the value of a health registry extensively depends on the quality of the contained data. The Norwegian Female Incontinence Registry was established in 1998. The Registry has served as a source for several research projects. However, no studies had been conducted before this thesis to examine the registry's accuracy and completeness.

This thesis's main aim was to increase the knowledge of the potential clinical impact of pregnancies before and after mid-urethral sling operations. Norway has a birth registry covering all deliveries by mandatory notification (MBRN; Medical Birth Registry of Norway) and an extensive female incontinence quality registry (NFIR; Norwegian Female Incontinence Registry). Connecting these registries offers an opportunity to investigate associations that otherwise cannot be studied in randomized controlled trials for ethical and practical reasons. By combining data from these registries (from 1998 to 2016), we assessed the long-term subjective and objective clinical outcomes, including complications, in women with one or more completed pregnancies after MUS surgery. We could also examine if there were any differences in SUI recurrence risk based on the mode of delivery. Furthermore, we wanted to explore the potential impact of various obstetrical factors associated with SUI development on MUS surgeries' short-term subjective and objective failure rates. However, there was also a need to assess the data quality of the NFIR and ensure that the Registry was an acceptable research tool before we could rely on the results generated by such registry data. Consequently, the validation process of NFIR became the logical and necessary secondary aim of this thesis.

The long-term subjective outcomes and clinical complications in women with one or more childbirths after MUS were published in Paper I. In this observational registry-based cohort study, women registered with childbirths after MUS during the years 1998 - 2016 were identified and invited to a follow-up study. The study included a case group of 72 women that had given birth after MUS. They were compared to a matched control group of women at a 1:3 ratio that underwent a MUS operation without subsequent childbirths. The women completed a structured telephone interview using a validated short-form urinary incontinence disease-specific questionnaire. The outcomes were subjective cure rate, symptom load if not cured (both stress and urgency incontinence symptoms), and any MUS-related complications during the pregnancy. The study revealed reassuring long-term subjective cure rates for women giving birth after MUS and comparable with the control group, regardless of delivery mode. In addition, we did not identify any long-term adverse effects of the MUS related to pregnancy and vaginal delivery. However, giving birth to more than one child after MUS was associated with a significant decline in SUI cure rates.

#### Continued

#### Ole A Dyrkorn (NO): Thesis: "The Impact of Childbirth before and after Mid-Urethral Sling Surgery"

The data quality of NFIR was assessed by selecting a random sample of 300 women operated for urinary incontinence and reported to the Registry between 1998 and 2016 (with follow-up through 2017). We then compared data previously recorded in the national NFIR for ten selected key variables to the source data, which were the patient's medical record at the reporting hospital. The Registry's completeness was estimated by comparing surgical procedures registered in NFIR and the Norwegian National Patient Registry (NPR). The NPR is an administrative registry with a compulsory notification containing health-related data such as diagnoses and codes for surgical procedures. We found excellent accuracy for both continuous variables and categorical variables. The Registry's completeness has improved over time, and it now includes information on nearly all women in Norway who have received urinary incontinence surgery. The results from the evaluation of data accuracy and coverage were published in Paper II. We concluded that the registry data in NFIR were well suited for research and qualified for merging with data from the MBRN to answer our main aim for the thesis.

The impact of previous obstetrical history on the short-term subjective and objective failure rates after MUS surgery was examined in the third paper. Using merged data from NFIR and MBRN, a cohort of 14,787 women were included. We found that several obstetrical factors impacted both subjective and objective outcomes in the univariate logistic regression analyses. However, in the multivariate model, being nulliparous before MUS surgery remained the only significant risk factor and only for objective failure. In addition, constitutional factors, previously well documented in the literature, such as high body mass index (BMI) at time of surgery, non-retropubic slings, high preoperative urgency symptom load, and surgical complications, were all significant risk factors for both subjective and objective failure.

In conclusion, this thesis demonstrates that the Norwegian Female Incontinence Registry has a high degree of accuracy and is valid as a research tool. Furthermore, by using data from the Registry, we have shown that the long-term outcomes for women giving birth after MUS are reassuring, independent of delivery mode. Therefore, MUS seems to be a feasible option for women who have not completed childbearing. This conclusion, however, is likely most relevant in settings where the indication for surgery is strong and where conservative options have failed.

Also, we found that obstetrical factors associated with SUI development do not seem to impact the short-term outcomes of primary MUS operations. However, being nulliparous was an exception to this conclusion, indicating a different underlying SUI pathogenesis in these women.

We believe this thesis provides more accurate information on expected MUS outcomes in women with stress urinary incontinence, hopefully empowering both surgeons and women in the decision process when considering surgical treatment for SUI.

#### Friday 30th September 2022

#### Porgerður Sigurðardóttir (IS) Thesis: "Postpartum pelvic floor symptoms and early physical therapy intervention"

#### Aims

The overall objective of this doctoral project was to study the prevalence of pelvic floor dysfunction and bother related to this, and to investigate associations with delivery factors, in first-time mothers during the first months after childbirth. Another main objective was to study the influences of early physical therapy intervention on pelvic floor symptoms in a subgroup of symptomatic women. A third goal was to study the influence of pre-delivery physical stress on childbirth outcomes among athletes. Three articles are included in this thesis, based on three separate studies. The specific aims of these studies were:

Study I: To study the prevalence of pelvic floor dysfunction and related bother in Caucasian primiparous women 6-10 weeks postpartum and compare vaginal delivery and cesarean section in this respect.

Study II: To study the effects of individualized physical therapist-guided pelvic floor muscle training in the early postpartum period on urinary and anal incontinence and related bother, as well as pelvic floor muscle strength and endurance.

Study III: To study delivery outcomes, including emergency cesarean section rates, the length of the first and second stages of labor and the risk for severe perineal tears, in first-time pregnant elite athletes compared to non-athletes.

#### Methods

Study I was a cross-sectional study with a sample of 721 first-time mothers with singleton births set in the greater capital area of Reykjavik, Iceland. From April 2015 to March 2017 participants answered an electronic questionnaire at home 6-10 weeks after birth. Reports on urinary- and anal incontinence, pelvic organ prolapse, sexual dysfunction and related bother, along with delivery information, were collected and analyzed. The main outcome measures were prevalence of postpartum pelvic floor dysfunction and related bother. Study II was an assessor-blinded parallel randomized controlled trial evaluating effects of pelvic floor muscle training lead by a physical therapist on the rate of urinary and/or anal leakage (primary outcomes). Bother related to the primary outcomes, muscle strength and endurance in the pelvic floor and were secondary outcomes. Between 2016-2017 women participating in Study I were screened for eligibility 6-10 weeks after childbirth. Of those identified as urinary incontinent 95 were invited to participate of whom 84 agreed. Forty-one and 43 women were randomized to respctively the intervention and control groups. Three and one participants withdrew from each respective group. The intervention, starting at 9 weeks postpartum consisted of 12 weekly sessions with a physical therapist after which the main outcomes were assessed (endpoint, 6 months postpartum). Additional follow-up was conducted at 12 months postpartum. The control group received no instructions after the initial assessment. Study III was a retrospective case-control study comparing birth outcomes of primiparous female elite athletes engaging in high- and low-impact sports, compared to non-athletic controls. The athletes had prior to birth competed at national team level or equivalent. There were 248 participants; 89 high- and 41 low-impact elite athletes, and 118 controls. Participant characteristics and frequency of training for at least three years before a first pregnancy were collected via a self-administered questionnaire. In all studies relevant information of delivery outcomes was retrieved from the Icelandic Medical Birth Register.

#### Result

In Study I the prevalence of any urinary and anal incontinence was 48% and 60%, respectively, with 27% and 56% of the total sample experiencing such symptoms as bothersome. Pelvic organ prolapse symptoms were experienced by 29%, with 13% of all the women finding it bothersome. Of sexually active women, 66% reported pain during intercourse. Among all participants, 48% found sexual issues to be bothersome. Urinary incontinence along with subtypes and pelvic organ prolapse symptoms were more prevalent in women who delivered vaginally compared to by cesarean section. No differences in prevelance were observed for anal incontinence and pain during intercourse between the groups. Compared to women of normal weight (BMI<25kg/m2) being obese was a significant predictor for urinary incontinence among women delivering vaginally (OR 1.94; 95% CI 1.20-3.14).

#### Continued

#### Porgerður Sigurðardóttir (IS) Thesis: "Postpartum pelvic floor symptoms and early physical therapy intervention"

For vaginal birth, birthweight above the 50th percentile was also predictor for urgency urinary incontinence (OR 1.53; 95% Cl; 1.05-2.21). Use of episiotomy was a significant predictor of anal incontinence (OR 2.19; 95% Cl; 1.30-3.67). No associations between maternal and delivery characteristics were associated with pelvic floor dysfunction among women undergoing cesarean section. In Study II, when measured at endpoint, urinary incontinence was less frequent in the intervention group with 21 (57%) still symptomatic compared to 31 (82%) of the controls (p=0.03), as was bladder-related bother with 10 (27%) in the intervention vs. 23 (60%) in the control group, p=0.005. Anal incontinence was not influenced by pelvic floor muscle training (p=0.33), nor was bowel-related bother (p=0.82). The mean differences between groups in terms of measured pelvic floor muscle strength changes at endpoint was 5 hPa (95% CI 2-8; p=0.003), and for pelvic floor muscle endurance changes, 50 hPa/sec (95% CI 23-77; p=0.001), both in favor of the intervention group. The mean between-group difference for anal sphincter strength changes was 10 hPa (95% CI 2-18; p=0.01), and for anal sphincter endurance changes 95 hPa/sec (95% CI 16-173; p=0.02), both in favor of the intervention. At the follow-up visit 12 months postpartum, no differences were observed between the groups regarding rates of urinary and anal incontinence, or related bother. Pelvic floor- and anal muscle strength and endurance favoring the intervention group were maintained. In Study III no significant differences were found between the groups regarding incidence of emergency cesarean section or the length of the first and second stages of labor. The incidence of 3rd-4th degree perineal tears was significantly higher (23.7%) among low-impact athletes than in the high-impact group (5.1%, p=0.01), but no significant differences were seen when the athletes were compared to controls (12%, p=0.09 for low-impact and p=0.12 for high-impact athletes). The frequency of exercise before and during pregnancy, maternal age and BMI had no significant association with any delivery outcome.

#### Conclusions

Bothersome pelvic floor dysfunction was prevalent among first-time mothers in the immediate postpartum period. This reflected on actual symptoms and on bother at this point in time after childbirth. This should be considered of clinical value and not ignored. In a subgroup of symptomatic women, postpartum pelvic floor mucle training had decreased the rate of urinary incontinence and related bother 6 months postpartum and it also increased muscle strength and endurance. Anal incontinence was, however, not influenced by the intervention. When analyzing another subgroup of women in relation to physical activity before the first childbirth, no association was found between participating in competitive sports at elite level and adverse delivery outcomes, including length of labor, the need for cesarean section during delivery or severe perineal tears. After childbirth women often show symptoms of relatively mild pelvic floor dysfunction which for most of them is likely to improve in the first year after childbirth. The subgroup with more bother and worse symptoms should be identified as they are likely to gain from targeted physiotherapy.

#### Friday 30th September 2022

#### Markus Jansson (SE) Thesis: "Pelvic Floor Dysfunction and Perineal and Vaginal Tears in Primiparous Women. Örebro Studies in Medicine xxx"

Pelvic floor dysfunction (PFD), including urinary incontinence, faecal incontinence (FI), and pelvic organ prolapse, is highly prevalent among parous women. There is evidence that pregnancy, vaginal delivery, and obstetric perineal tears increase the risk of pelvic floor dysfunction, but many of the studies in this field are retrospective. The overall aim of this thesis was to prospectively examine risk factors for perineal and vaginal tears and postpartum PFD in primiparous women.

Study I was a validation study of a protocol for documentation of perineal tears, including 187 primiparous women in 2015–2016. The coverage of documentation was higher in the protocol compared to the obstetric record system (ObstetriX). Incidence of second degree perineal tears was 26% according to the protocol and 11% according to ObstetriX.

Studies II–IV utilized a cohort of initially nulliparous women (n=1049) prospectively included in early pregnancy in 2014–2017. Women completed questionnaires on PFD in early and late pregnancy and at 8 weeks and 1 year postpartum.

Study II (n=644) showed that high foetal weight and vacuum extraction were risk factors for both second degree tears and OASI, suggesting that these tears should be viewed as a continuum rather than different entities. Risk factors for high vaginal tears were large foetal head circumference, vacuum extraction, and heredity of PFD/connective tissue deficiency.

Study III (n=670) found that vaginal delivery increased the risk of stress urinary incontinence (SUI) but not urgency urinary incontinence (UUI) 1 year postpartum. No single characteristic of the vaginal delivery was associated with SUI. SUI during pregnancy increased the risk of SUI postpartum, and UUI during pregnancy increased the risk of UUI postpartum.

Study IV (n=898) showed that FI increased by late pregnancy, and that this increase persisted 1 year postpartum. Obstructed defecation was associated with increased FI postpartum, suggesting that post-defecatory faecal loss may be an underlying mechanism of FI.

**Overall conclusion:** The extent to which pregnancy, vaginal delivery, and their respective characteristics contributed to the development of PFD differed between the pelvic floor disorders studied. For SUI, both the pregnancy and the vaginal delivery increased the risk, whereas for FI it was the pregnancy itself rather than the vaginal delivery that was demonstrated to increase the risk.

#### Friday 30th September 2022

#### Jwan Al-Muktar Othman (SE) Thesis: "Pelvic Floor Dysfunction in nulliparous women"

#### **Background:**

Pelvic floor dysfunction (PFD) is a public health problem affecting millions of women worldwide. In addition to personal suffering, it also creates an economic burden for health care systems and society. Parity and mode of delivery are well known risk factors for PFDs. Therefore, examining the prevalence of PFDs in women not exposed to childbirth provides insight into the natural history of the condition without the confounding effect of obstetric injury.

**Aim:** To obtain a detailed description of the age-related prevalence and predictors of PFDs in a large, national, randomly selected cohort of nulliparous women aged 25 to 64 years. This knowledge is necessary for comparisons with parous women to demonstrate the effect of pregnancy and the effect of vaginal delivery on future PFD.

**Material and methods:** This was a national cohort study where the study population was drawn from the Total Population Register by Statistics Sweden. The final study population consisted of 9,197 women registered in Sweden, with no births aged 25 and 64 years. Self-reported information regarding possible PFD was obtained via the web and by mail in 2014 using a 40-item questionnaire.

#### **Results:**

Paper I: Urinary function in nulliparous women deteriorated during the four most active decades of adult life. However, 75% remained continent by age 65. In women with a normal BMI this applied to >80%. Almost all aspects of urinary dysfunction increased with age. The most significant increase was observed for nocturia  $\geq$ 2, mixed urinary incontinence (MUI), leakage  $\geq$  1/week, leakage of more than a few drops of urine, and bothersome UI. Paper II: Symptoms indicating pelvic organ prolapse (sPOP) were experienced in all ages but surgical procedures for POP were rare. Bothersome sPOP was more prevalent in older women. The symptom of "bulging" was strongly associated with other irritative conditions from the genital area. These co-occurring symptoms increased with increasing frequency of "bulging".

*Paper III:* In nulliparous women with a history of childhood nocturnal enuresis (CNE), all the studied parameters of lower urinary tract symptoms and PFD were approximately doubled and acted as a strong marker for later PFDs. *Paper IV:* The predominant component of leakage in nullipara with faecal incontinence (FI) was liquid stool, which occurred in >90%. Solid stool leakage was rare. The pattern of distribution of different types of leakage was similar in all age groups. BMI and age were interacting risk factors for FI.

**Conclusion:** Over a 40-year period from age 25, the prevalence of all UI parameters increased in nulliparous women. Bothersome prolapse symptoms were rare in women who have not undergone childbirth. The strongest risk factor for fecal incontinence was abnormal stool consistency. Age, BMI and CNE were important risk factors for almost all PFDs.

Seema Mathew (NO): Thesis: Urinary and colorectal-anal distress in women - prevalence, risk factors and effect of pelvic floor muscle exercise in women with pelvic organ prolapse.

#### Background

The continence mechanism is complex. The influence of levator ani muscle (LAM) injury and other pelvic floor changes in the long-term development of urinary and colorectal-anal distress is not clear. Women with pelvic organ prolapse (POP) have concomitant symptoms of incontinence. The prevalence of anal sphincter defects and associated anal incontinence (AI) in women with POP needs further evaluation. Pelvic floor muscle training (PFMT) is the first line treatment for mild POP and urinary incontinence (UI). Whether intensive pelvic floor exercise improve urinary and colorectal-anal distress and quality of life in women with advanced POP needs further investigation.

#### Aims

1. Study possible associations between LAM trauma and urinary and colorectal-anal distress, including UI and fecal incontinence (FI). Study associations between structural changes in the bladder neck and UI among parous women. 2. Assess the prevalence of anal sphincter defects and association with AI in women with symptomatic POP undergoing POP surgery.

3.Explore the effect of preoperative PFMT on urinary and colorectal-anal distress and related quality of life in women scheduled for POP surgery.

#### Methods

Data were collected from two study populations; a cross-sectional study of 608 women examined 15-21 years after first delivery (Paper 1) and a randomized controlled trial of women with symptomatic POP undergoing POP surgery (Paper 2 and 3). All participants were assessed using pelvic organ prolapse quantification system, 3D/4D transperineal ultrasound, visual analogue scale and validated questionnaires. In the randomized controlled trial, the intervention group was given individual physiotherapist guided PFMT from inclusion to the day of surgery. Multivariable regression analysis, Mann-Whitney U test and mixed models analysis were used.

#### **Main results**

1: We found no associations between LAM injury and symptoms of UI and FI 15-24 years after first delivery, but urethral funneling was associated with stress UI.

2: 25% of women scheduled for POP surgery had anal sphincter defects. EAS and IAS defects were strongly associated with FI and flatal incontinence, respectively.

3: Symptoms and quality of life related to urinary and colorectal-anal distress improved for all women after POP surgery, regardless of PFMT.

#### Conclusion

The etiology urinary and colorectal-anal distress is multifactorial and not related to LAM trauma. Bladder neck funneling was indicative of stress UI. Women with severe POP have high prevalence of anal sphincter defects and sphincter defects were associated with AI. We found no evidence of additional advantages of preoperative PFMT for improving urinary and colorectal-anal distress in women with severe POP, beyond POP surgery.

## Bjørn Holdø (NO): Thesis: "Surgical treatment of stress urinary incontinence in women- The shift from Burch colposuspension to the retropubic tension-free vaginal tape procedure"

Until the late 1990s, the Burch colposuspension was considered the gold standard for the surgical treatment of stress urinary incontinence (SUI) and stress-dominated mixed urinary incontinence (MUI) in women. In 1996, Ulmsten introduced the minimally invasive retropubic tension-free vaginal tape (TVT) procedure, and the first case series reported high safety and effectiveness of this procedure at 2-year follow-up. Despite the lack of data showing the superiority of the new method, the TVT procedure replaced the Burch colposuspension as the preferred surgical method worldwide within a few years.

We at the Department of Gynaecology at Nordland Hospital, Bodø, Norway, introduced the TVT procedure in 1998, and from 2000 onwards we stopped carrying out Burch colposuspensions completely. In order to confirm or reject the superiority of the new method, we applied data from surgeries performed before, during, and after this overlapping time period to compare the long-term treatment effectiveness of both surgical methods. In addition, we wanted to present short- and long-term safety and effectiveness data and to assess the risk factors for recurrence of SUI symptoms after the TVT procedure. Furthermore, the safety of the TVT procedure has been questioned, due to reports of serious and debilitating problems among women who underwent the procedure to treat urinary incontinence (UI). After the introduction of the TVT procedure, the number of women undergoing UI surgery increased rapidly, and the quality of this surgical treatment came into focus. We were particularly interested in the role of surgeon's experience on clinical outcomes after TVT surgery.

The study population comprised 748 primary incontinence surgeries performed at our department in the period 1994-2012. In the assessment of clinical outcomes in Paper I, we compared the last 5 years of the Burch colposuspension (n = 127, 1994-1999) with the first 5 years of the retropubic TVT procedure (n = 180, 1998-2002). In Paper II, we assessed long-term clinical outcomes (n = 596, 1998-2012) of the primary TVT procedure and performed an analysis of demographic, clinical, and perioperative risk factors for treatment failure. Paper III was an assessment of associations between surgeon's experience with the primary retropubic TVT procedure and both perioperative complications and recurrence rates.

The 3 papers were designed as patient series, and the statistical analyses were done using the Statistical Package for the Social Sciences, with a 5% level of statistical significance. We applied the t-test, Chi Square test, survival analysis, Cox regression analysis, and binary regression analysis.

In Paper I, we found a significant, higher cumulative SUI symptom recurrence rate at 12-year follow-up in women who received the Burch colposuspension compared to those who received the TVT procedure, when pure SUI was used as the indication for surgery. However, we did not find any significant difference in treatment effectiveness among women who received this procedure for MUI. In Paper II, we found that the TVT procedure had a high long-term durability, and that long-term complications were rare. Furthermore, we demonstrated that the TVT procedure was much more effective in women with SUI than MUI; the recurrence rate was two-fold higher among women with MUI. In Paper III, we observed that patients of surgeons who have less experience with the primary TVT procedure showed higher risk of bladder perforation and urinary retention, with less impact on long-term recurrence rates between women with MUI and SUI were similar for the two surgeons who had performed TVT procedures throughout the study period.

## Mette Hulbæk Andersen (DK): Thesis: "Developing and testing an online tool for patients with pelvic organ prolapse to support shared decision making "

#### Background

The concept of shared decision making (SDM) has the potential to support a more person-centred approach, by including patients' preferences.

We hypothesized that an online tool including patients' preferences and clinicians' best estimates could support SDM. The overall aim of the thesis was to develop and evaluate the tool for the use in the context of consultations with women suffering from pelvic organ prolapse.

#### **Materials and methods**

The development was inspired by the method of contextual design with participatory elements [1,2]. Patients, clinicians and other stakeholders from Danish gynecology outpatient clinics participated in the development and evaluation of the tool from 2016-2019. Data was generated from observational studies, exploratory interviews with prompt cards and five workshops. A project group of gynecologists and statisticians developed an algorithm for the tool using an existing web-based app (Mit Sygehus). The women and clinicians used mock-ups to test a draft of the tool iteratively for usability.

For the evaluation of the developed tool, a measure instrument for SDM was translated and adapted according to WHO's guideline. The instrument was validated in the context using factor analysis.

A pilot randomized controlled trial at three gynecological departments assessed the feasibility of a larger post-study to evaluate the tool. Recruitment rates, per-protocol use and women's perception of support for decision-making and of SDM was evaluated and a focus group interview with the participating gynecologists was conducted to assess feasibility in the context of consultations.

#### Results

Field data led to 16 questions for a generic pre-consultation questionnaire. An MCDA functionality converted the answers into option scores by using women's individualized home-based scores and pre-defined evidence scores (best estimates). Her individual option scores were presented in the health record as a graphical presentation. The measure instrument for evaluation of SDM was tested in the context (n=218) and had high reliability (Cronbach's alpha of 0.94) and factor analysis yielded a unidimensional factor.

A total of 226 women were invited for the randomized pilot trial and 46 were recruited. Women (59% high supportive or some support) felt the developed instrument supported their decision-making and more so if it was presented interactively during consultations. Gynecologists tended to use the instrument inconsistently (41% not per protocol).

#### Conclusions

The developed MCDA functionality had the potential to be supportive for preference-sensitive decisions. Even if women felt the tool was supportive for their decision-making, the add-on of the tool to consultations in this preliminary pilot trial did not seem to make any difference to their perception of SDM. Gynecologists were positive towards the development and the general idea of the tool they did not find it easy to apply it accordingly in the clinical set-up of decision-making.

We found the Danish SDM-Q-9 to be a well-accepted, reliable and valid instrument to measure a construct of SDM. However, to determine effect of the tool in a future trial, our pilot trial showed that a randomized trial would demand further actions, most importantly: additional support for the women to access their questionnaires and further exploration of how to increase usability of the tool inside consultations.

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Simonsen J, Robertson T. Routledge international handbook of participatory design. New York: Routledge; 2013.

#### Continued

## Mette Hulbæk Andersen (DK): Thesis: "Developing and testing an online tool for patients with pelvic organ prolapse to support shared decision making "

#### **Publications**

Hulbaek, M., Primdahl, J., Birkelund, R., et al. A preference-sensitive online instrument to support shared decision making for patients with pelvic organ prolapse – A pilot multicenter randomized controlled trial. Comput Inform Nurs. 2021 Jul 8. doi: 10.1097/CIN.00000000000789. Online ahead of print. PMID: 34238835

Hulbaek, M., Knutz, E., Ebbesen, N.T. et al. Pelvic organ prolapse and treatment decisions– developing an online preference-sensitive tool to support shared decisions. BMC Med Inform Decis Mak 20, 265 (2020). https://doi. org/10.1186/s12911-020-01264-1.

Hulbaek, M. et al. Danish Translation, Cultural Adaptation and Validation of the Shared Decision-Making Questionnaire - Patient Version (SDM-Q-9-Pat). European Journal for Person Centered Healthcare, 2018; Vol 6 Issue 3 pp 438-446.

Hulbaek, M. Developing and testing an online tool for patients with pelvic organ prolapse to support shared decision making. PhD thesis (2019). Faculty of Health Sciences, University of Southern Denmark, Odense, Denmark. Available at: SDUB Odense, P 32.784.

Etics

The project followed the ethical standards of the Helsinki Declaration (World Medical Association's meeting of October 2013) [124]. The need for approval from the Ethical Committee system was waived by the Regional Committee on Health Research Ethics (jnr. S-20162000-145). According to Danish law, an approval was not required as no biomedical intervention was performed. The protocol for the pilot RCT was registered at ClinicalTrials.gov ID: NCT03706716 and reflected the protocol of an RCT in a larger scale.

### Ea Papsø Løwenstein (DK): Thesis: Urinary incontinence in relation to diabetes mellitus and hypothyroidism in women

-Epidemiology, urodynamics and validation of a questionnaire

#### Summary

Urinary incontinence is a well-known problem, however not one that is often discussed. Up to one out of four women suffer from urine incontinence, where many go for several years with the problem before seeking medical help. Studies have shown that urinary incontinence can lead to psychological stress, social isolation, and consequently reduced quality of life regardless of whether the woman suffers from other chronic diseases.

Various studies have shown that urinary incontinence is more frequent in women with diabetes than in women without diabetes. Some suggest an association between diabetes and urinary incontinence. However, the studies investigating diabetes as a risk factor for urinary incontinence experience divergent findings, which may be due to the choice of method, patient population, and definition of urinary incontinence. Nonetheless, few selected studies of patients with diabetes hold evidence that urinary incontinence must be considered a frequent late complication of diabetes.

Hypothyroidism affects many of the body's organs. Evidence shows that TSH affects muscle cells, endothelial cells, and glomerular filtration. However, it is unknown how TSH and hypothyroidism affect urogenitalia and whether women with hypothyroidism have a higher prevalence of urinary incontinence.

With the data provided from the comprehensive Lolland-Falster Health study (LOFUS), it was possible to complete this dissertation. LOFUS aims to investigate the health, well-being, and morbidity of families from Lolland-Falster. This dissertation is an epidemiological study of the prevalence of urinary incontinence in women with and without diabetes and in women with hypothyroidism. Furthermore, it is a study of the association between diabetes and urinary incontinence, as well as hypothyroidism and urinary incontinence in women (Study II and III). In addition, we performed a psychometric validation of the questionnaire used to assess urinary incontinence (Study I). Finally, we examined the bladder function in incontinent women with and without diabetes.

**Study I:** the study was divided into six smaller studies, of which the participants were recruited from different sources; LOFUS, Social Media, and the local community on Lolland-Falster.

We found that ICIQ-UI SF had a good patient-interview agreement, good reliability (test-retest), and, internally, a good consistency. The questionnaire showed good sensitivity-to-change for women surgically treated for respectively stress urinary incontinence and urgency urinary incontinence. Some participants misinterpreted the word "leak." 19% of the women who considered themselves as continent were instead incontinent based on the questionnaire (ISIQ-UI SF), thus showing low construction validity. ICIQ-UI SF also showed low criterion validity compared with the urodynamic study.

**Study II:** The data collected consisted of excerpts from LOFUS combined with various Danish registers' data. Of 8,563 women, we included 7,699 in our analyses. The prevalence of urinary incontinence was significantly higher in women with diabetes than women without diabetes (50% vs. 39%). We found that women with diabetes had OR 1.56 (95% CI 1.27-1.92) for urinary incontinence in the unadjusted analysis. However, this association disappeared after adjusting for confounders: age, BMI, parity, previous gestational diabetes, physical activity, education, and smoking status (OR1.11, 95% CI 0.88-1.38). The adjusted analysis showed that diabetes was associated with mixed urinary incontinence (OR 1.49, 95% CI 1.08-2.06). Our subgroup analyses showed that diabetes was associated with frequent urinary incontinence (UI 2-3 times per week or more often, OR 1.33, 95% CI 1.03-1.74). Being a woman treated with multiple antidiabetic medications (severe diabetes) was strongly associated with UI (OR 2.75, 95% CI 1.38-5.48).

**Study III:** As in study II, the data collection consisted of excerpts from LOFUS combined with data from Danish registers. Of 8,573 women, we included 7,699 in our analyses. The prevalence of urinary incontinence in women with hypothyroidism, subclinical hypothyroidism, and a normal level of thyroid hormones was: 55%, 38%, and 39%, respectively. We found no association between hypothyroidism and urinary incontinence or between subclinical hypothyroidism and urinary incontinence.

#### Continued

### Ea Papsø Løwenstein (DK): Thesis: Urinary incontinence in relation to diabetes mellitus and hypothyroidism in women

#### -Epidemiology, urodynamics and validation of a questionnaire

Study IV: The data consisted of urodynamic studies of 511 women from LOFUS who had met the criteria of bothersome LUTS. We included data from 417 women with urinary incontinence (assessed from ICIQ-UI SF) in our analyses. Of those, 31 women had diabetes (7.4%). Women with diabetes indicated that they more frequently leaked urine daily and a greater amount compared with women without diabetes. We found that women with diabetes more often had a positive stress test in the supine position than women without diabetes. However, we found no difference between the other urodynamic parameters. There was no difference between the two groups when we compared the overall conclusion of the urodynamic examinations. 11

This dissertation has shown the importance of using validated questionnaires in research as well as in the clinic. In this way, you know the strengths and weaknesses of the instrument you use and what to be aware of concerning the data interpretation. In women with mixed urinary incontinence (any) and women with more frequent urinary incontinence, we found an association with diabetes, which continues to point at a causal link between diabetes and urinary incontinence. However, there is a lack of longitudinal studies in the area. To make this work possible, the goal is to eventually build the foundation for a LOFUS2.

## Effect of single doses of citalopram and reboxetine on urethral pressure: a randomized, double-blind, placebo- and active controlled three-period crossover study in healty women.

**Thea Christoffersen (DK)**, Jonatan Kornholt, Troels Riis, David Sonne Peick, Jesper Sonne, Niels Klarskov.

#### Background

Urethral closure function is essential for urinary continence in women and decreased urethral pressure is associated with stress urinary incontinence (SUI). For decades, the effects of serotonergic drugs on central neural control of urethral closure have been investigated and discussed. Epidemiological studies suggest that use of selective serotonin reuptake inhibitors, such as citalopram, is associated with SUI. However, literature findings are conflicting (1,2). This study aimed to evaluate citalopram's effect on opening urethral pressure (OUP) in healthy women.

#### **Material and methods**

A randomized, double-blind, placebo- and active-controlled, crossover study in 24 healthy women. On three study days, which were separated with eight days washout, the subjects received single doses of either 40 mg citalopram, 8 mg reboxetine, or placebo. At estimated time of peak plasma concentration of the study drugs, OUP was measured with urethral pressure reflectometry under both resting and squeezing condition of the pelvic floor.

#### Results

Compared to placebo, citalopram increased OUP by 6.6 cmH20 (95% confidence interval [CI] 0.04-13.1, p=0.048) in resting condition. In squeezing condition, OUP increased by 7.1 cmH20 (95% CI 1.3-12.9, p=0.01). Reboxetine increased OUP by 30.0 cmH20 in resting condition compared to placebo (95% CI 23.5-36.5, p<0.001), and 27.0 cmH20 (95% CI 21.2-32.8, p<0.001) in squeezing condition.

#### Conclusions

Citalopram increased OUP slightly compared to placebo suggesting that SSRI is unlikely to induce or aggravate SUI. Conversely, reboxetine induced a substantial placebo-corrected increase in OUP. Further research might explore the clinical benefit of reboxetine in treatment of women with both depression and SUI.

Effect of reboxetine and citalopram on anal opening pressure: A randomized, double-blind, placebo-controlled crossover study in healthy women.

**Thea Christoffersen (DK)**, Jonatan Kornholt, Troels Riis, David Sonne Peick, Jesper Sonne, Niels Klarskov.

#### Background

Drugs that enhance the anal sphincter function constitute a potential pharmacological treatment strategy for fecal incontinence. Anal acoustic reflectometry (AAR) is a new method to assess anal sphincter function, which has shown ability to detect pharmacologically induced changes in the anal opening pressure (AOP). The aim of this study was to assess the effect of citalopram (selective serotonin reuptake inhibitor) and reboxetine (noradrenaline reuptake inhibitor) on AOP in healthy females.

#### **Material and methods**

In a randomized, double-blind, placebo controlled three-period crossover study in 24 healthy women, we measured AOP during rest and squeeze with AAR after a single dose of citalopram (40 mg), reboxetine (8 mg) or placebo. AOP was measured at estimated time of peak plasma concentration of the study drugs. The washout period was at least 8 days.

#### Results

There were no dropouts and no serious adverse events. Most frequent adverse events were nausea, disturbed sleep, dizziness and headache. Compared with placebo, reboxetine increased resting AOP with 23.4 cmH2O (95% CI 15.1-31.6, p<0.001) and squeezing AOP with 23.4 cmH2O (95% CI 14.6-32.2, p<0.001). Citalopram did not increase the AOP significantly compared with placebo (3.9, 95% CI -4.1-12.4, p=0.4 [during rest] and 4.2 95% CI -4.9-12.7, p=0.5 [during squeeze].

#### Conclusions

Single dose reboxetine 8 mg increased the placebo-corrected AOP significantly, suggesting that reboxetine or other noradrenalin reuptake inhibitors may be efficacious in the treatment of fecal incontinence. However, clinical trials in patients with fecal incontinence are needed to evaluate the potential clinical benefit.

## Fecal incontinence and associated pelvic floor dysfunction during and one year after the first pregnancy: a prospective cohort study.

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#### Background

Fecal incontinence during late pregnancy (1) and bowel evacuation problems during pregnancy and postpartum (2) have been associated with postpartum fecal incontinence, but few studies followed these symptoms in women from early pregnancy. The aims of this study were to calculate prevalence of fecal incontinence (primary outcome), defecatory disorder and vaginal bulge during pregnancy and postpartum, and to assess the effect of progression of pregnancy, pregnancy characteristics, vaginal delivery and vaginal delivery characteristics on these symptoms at one year postpartum.

#### **Material and methods**

A prospective cohort study was conducted including 699 nulliparous women enrolled at maternity health care service in Region Örebro County, Sweden, from October 2014 to October 2017. Women responded to questionnaires in early and late pregnancy and at 8 weeks and 1 year postpartum. Generalized linear models and random effect logistic models were used.

#### Results

TPrevalence figures are presented in table 1. Odds ratios for the outcomes from early to late pregnancy and to one year postpartum in women with vaginal delivery are presented in figure 1. Risk factors of fecal incontinence one year postpartum were fecal incontinence during pregnancy (risk ratio 7.7, 95% CI 4.2-13.9), defecation disorder during pregnancy (adjusted risk ratio [aRR] 2.3, 95% CI 1.2-4.3) and defecation disorder one year postpartum (aRR 2.4, 95% CI 1.3-4.5).

#### Conclusions

Fecal incontinence and vaginal bulge increased significantly both in late pregnancy and at one year postpartum compared to early pregnancy among women with vaginal delivery. Defecation disorder both during pregnancy and postpartum were risk factors of fecal incontinence at one year postpartum.

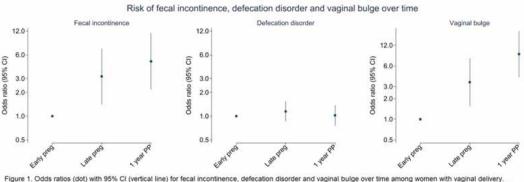


Figure 1. Odds ratios (dot) with 95% CI (vertical line) for fecal incontinence, defecation disorder and vaginal bulge over time among women with vaginal delivery. Early pregnancy is the reference, and late pregnancy and 1 year postpartum are compared with early pregnancy. Estimates are obtained from random effect logstic model. Abbreviations: CI, confidence interval; early preg, early pregnancy; late preg, late pregnancy; 1 year PP, 1 year postpartum

## Increased risk of stress-urinary-incontinence surgery after hysterectomy – a population-based cohort study.

#### Nanna Marie Christoffersen<sup>1,2</sup> (DK), Niels Klarskov, Kim Gradel Oren<sup>3,4</sup>, Karen Ruben Husby<sup>1,2</sup>.

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#### Background

The association between hysterectomy and stress urinary incontinence (SUI) has previously been established. SUI can be treated surgically and options have improved after introduction of the tension-free vaginal tape procedure in 1998. We aimed to estimate the risk of SUI surgery after hysterectomy for benign indication other than pelvic organ prolapse, in a contemporary context.

#### **Materials and methods**

We did a matched register-based cohort study including Danish women born 1947–2000. Hysterectomized women were matched to non-hysterectomized women 1:5 based on age and calendar year of hysterectomy. The risk of SUI surgery after hysterectomy was calculated. The joint effect of hysterectomy and parity was calculated in the main cohort and joint effects of hysterectomy and vaginal birth or cesarean section in a subcohort of women who only had one mode of delivery. Calculations were made using Cox proportional hazard model.

#### Results

We included 83,370 hysterectomized women and 413,969 reference women. The overall risk of SUI surgery was almost tripled for hysterectomized women (hazard ratio 2.7; Cl 95% 2.5-2.9). We found a trend of increased risk of SUI surgery with increasing parity in both groups. The hazard ratio was 15.6 (Cl 95% 11.0-22.1) for hysterectomized women with one vaginal birth while the hazard ratio for reference women with one vaginal birth was 5.7 (Cl 95% 4.0-8.0).

#### Conclusions

This study signifies that hysterectomy increases the risk of subsequent SUI surgery. Women should be informed and gynecologists include this knowledge in decision-making. Further precautions should be taken when treating parous women.

## Comparing risk of repeat surgery for stress urinary incontinence after mid-urethral slings and polyacrylamide hydrogel .

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#### Background

A synthetic mid-urethral sling (MUS) is the most used surgical method for correcting stress urinary incontinence (SUI) in Norway, but transurethral injection with polyacrylamide hydrogel is gaining popularity. This study compared risks of later surgery for persistent or recurrent stress urinary incontinence after retropubic slings, obturator slings and polyacrylamide hydrogel injections.

#### **Material and methods**

Surgical codes from The Norwegian Patient Registry were used. Women operated with MUS or polyacrylamide hydrogel injection in the period 2008-2017 were included. Main outcome was time to new surgery for persistent or recurrent SUI. Kaplan-Meier was used for unadjusted comparison, and Cox regression to adjust for hospital surgical volume and age at surgery.

#### Results

Retropubic MUS had lowest risk of later stress urinary incontinence surgery in the period (p < 0.01). The proportions of patients without any recorded new SUI procedure at five years were 97.7 % for retropubic MUS, 96.1 % for obturator MUS and 72.4 % for polyacrylamide hydrogel injections. After adjusting for age at surgery and hospital surgical volume, obturator slings (HR 1.8, 95 % Cl 1.4 - 2.4) and polyacrylamide hydrogel (HR 23.1, 95 % Cl 17.6 – 30.3) remained associated with higher risks of later incontinence surgery.

#### Conclusions

Both retropubic and obturator slings have low long-term risk of repeat incontinence surgery compared to polyacrylamide hydrogel injections. Retropubic slings had superior longevity of the surgical result.

## Treatment of stress urinary incontinence with polyacrylamide hydrogel in an office setting: patient perspectives.

#### Caroline Juhl<sup>1</sup> (DK) Karin Glavind<sup>2</sup>

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#### Background

Office setting (OS) provides the opportunity for surgeons to perform specific procedures more efficiently than in an operating theatre (OR). Consequently, health care systems are interested in altering surgical services from OR to OS. The impact on patient's satisfaction is more challenging to estimate.

Injections with polyacrylamide hydrogel, bulking procedure (BP), is an intervention for urinary stress incontinence. It was originally performed in the OR in general anesthesia (GA) or sedation. Today, BP is mostly done in local anesthesia and hence altering the setting from OR to OS became possible.

The aim of this study was to assess patient satisfaction when moving BP from OR to OS.

#### **Materials and methods**

From 15th. of September 2020 to 1st. of June 2021, 115 women underwent BP in the OS. Follow-up three months post-surgery for quality assurance is mandatory. Concurrently to routine follow-up, the OS experience was assessed.

#### Results

A total of 95.6 % (110/115, P<0.001) preferred the BP being performed in the OS. Main reason was the short waiting time 61.8% (68/110). Pain was the main reason not to prefer the OS. On a Visual Analogue Scale (VAS) from 0 to 10, (0 equals no pain, 10 maximum pain) the mean VAS for pain was 4.1.

#### Conclusions

The OS provides a patient friendly and comfortable place for the BP and is, despite pain, generally preferred over the OR. Important for the preference is the accessibility and minimal waiting time. The OS is therefore both convenient and efficient for surgeon and patient.

Surgeons experience and clinical outcome after retropubic tension-free vaginal tape – A case series.

**Bjørn Holdø (NO)** Kajsa Møllersen, Margareta Verelst, Ian Milsom, Rune Svenningsen, Finn Eigil Skjeldestad.

#### Introduction

The retropubic tension-free vaginal tape procedure has been the preferred method for primary surgical treatment of stress and stress-dominant mixed urinary incontinence in women since the late 1990s. In this study, we assessed associations between surgeon's experience with the primary tension-free vaginal tape procedure and both perioperative complications and recurrence rates.

#### **Material and methods**

Using a consecutive case-series design, we assessed 596 patients treated with primary retropubic tension-free vaginal tape surgery performed by 18 surgeons from 1998 through 2012, with follow up through 2015. We retrieved data on perioperative complications and recurrence of stress urinary incontinence within 10 years from medical records. Surgeon's experience with the tension-free vaginal tape procedure was defined as number of such procedures performed as lead surgeon (1-19, 20-49 and  $\geq$ 50 procedures). With a 5% level of statistical significance, we applied the Chi-square test in the assessment of perioperative complications and the regression analyses in the assessment of long-term effectiveness with separate analyses restricted to the three surgeons who performed  $\geq$ 50 procedures.

#### Result

We found a significantly higher rate of bladder perforations (P = .03) and a higher rate of urinary retentions among patients operated on by "beginners" (P = .06). We observed a significant reduction in recurrence rates with increasing number of tension-free vaginal tape procedures for one surgeon (P = .03).

#### Conclusions

Surgeon's experience with the tension-free vaginal tape procedure is associated with the risk of bladder perforation and urinary retention, and may be associated with the long-term effectiveness of the procedure.

#### Are levator hiatal dimensions in mid-pregnancy associated with mode of delivery?

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#### Backgrund.

Smaller levator hiatal dimensions are possible risk factors for slow progress and consequently operative delivery. Our aim was to explore associations between hiatal dimensions antenatally, duration of 2nd stage of labour and mode of delivery.

#### **Materials and methods**

Prospective cohort study of 56 nullipara examined at 20 weeks gestation. Levator hiatal anteroposterior diameter and area were measured using 2D/3D transperineal ultrasound and compared between women with normal vaginal delivery and operative delivery (cesarean and vacuum) using t.test. Cut offs predicting risk of operative delivery were derived from ROC analysis. We used Spearman's rank to explore correlations between hiatal dimensions and duration of 2nd stage.

#### Results

40 (71%) women had normal vaginal delivery and 16 (29%) operative delivery 2D anteroposterior diameter and 3D hiatal area at rest were smaller in women with operative delivery than normal delivery, 5.0 cm vs 5.7 cm, p=0.007 and 18.5 cm<sup>2</sup> vs 14.9 cm<sup>2</sup>, p<0.001. The cut off to predict operative delivery was 5.6 cm, (sensitivity=0.94, specificity=0.63) for 2D anteroposterior diameter and 17.6 cm<sup>2</sup> (sensitivity=0.94, specificity=0.65) for 3D hiatal area. We found an inverse correlation between 2nd stage of labour and anteroposterior diameter at rest, r=-0.330, contraction, r=-0.365, area at rest r=-0.324 and contraction r=-0.521, all p<0.05.

#### Conclusions

Smaller hiatal dimensions at 20 weeks gestation were associated with longer <sub>2</sub>nd stage of labour and increased risk of operative delivery in nullipara 2D anteroposterior hiatal diameter  $<_{5.6}$  cm and 3D hiatal area <17.6 cm<sup>2</sup> imply high risk of operative delivery and thereby suggesting increased risk of attention during delivery

#### Can transperineal ultrasound be used to predict symptom bother after prolapse surgery?

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#### Background

Levator injury is a risk factor for pelvic organ prolapse (POP) and for POP recurrence after surgery. Anal sphincter injury increases the risk of anal incontinence. POP surgery leads to symptom relief of prolapse and incontinence. Our aim was to examine the association between muscle injury and symptoms after surgery.

#### **Material and methods**

Prospective cohort study of 151 women examined 3 months before and 6 months after POP surgery with transperineal ultrasound for the diagnosis of levator and anal sphincter injury. Women answered the pelvic floor distress inventory (PFDI) for grading of symptoms related to POP (POPDI), colon-rectum-anus (CRADI) and the urinary tract (UDI).

#### Result

91 women (60%) had muscle injury; 75 (50%) levator, 35 (23%) anal sphincter.19 (13%) had double injury. At inclusion women with muscle injury had slightly higher PFDI score than women without defect: 111 vs. 99, p> 0.05. The total study population improved after surgery from 106 to 42, p<0.001. Postoperatively, women with double injury had more symptoms than women with intact muscles: 63 vs. 36, p= 0.01, with similar differences for all sub-scores: UDI 24 vs. 15, p= 0.05, CRADI 20 vs. 11, p= 0.02, POPDI 18 vs. 10, p= 0.05. The difference between women with one muscle injury was not significantly different from women with intact muscles: 46 vs. 36, p= 0.16.

#### Conclusions

Women with injury of both levator and anal sphincter had less symptom relief after POP surgery. Ultrasound can be used to provide information on how surgery may improve symptoms.

## Cervical amputation – a revival? Recurrent POP surgery in uterine prolapse: A nationwide register study.

#### Malin Brunes<sup>1</sup> (SE)

<sup>1</sup>Department of Clinical Science and Education Södersjukhuset<sup>,</sup> Karolinska Institutet

#### Background

One in three women with pelvic organ prolapse (POP) undergoing surgery have a relapse. Currently, no optimal surgical treatment has been identified for correcting an apical prolapse. This populationbased register study aims to compare the efficacy of different surgical techniques in women with uterine prolapse.

#### Methods

All women with apical uterine prolapse undergoing prolapse surgery in Sweden from 1 January 2015 to 31 December 2018, were identified from the Gynecological Operation Register (GynOp). The primary outcome was the number of recurrent POP surgeries up to 31 December 2020.

#### Result

Sacrospinous fixation (SSF) and sacrohysteropexy (SHP) were associated with a significantly higher rate of recurrent pelvic organ prolapse (POP) surgery (SSF: adjusted odds ratio, aOR 2.6, 95% confidence interval, CI 2.0-3.5; SHP aOR 2.6, 95% CI 1.8-3.7) and patients describing a sense of globe (SSF aOR 2.0, 95% CI 1.6-2.6; SHP aOR 1.8, 95% CI 1.1-3.1) compared to cervical amputation (CA). There was no difference in the reoperation rate or sense of a globe between vaginal mesh (VM) and CA with fixation to the uterosacral ql ligaments. Patients undergoing SSF had a higher frequency of 1-year postoperative complications compared to CA (aOR 2.0, 95% CI 1.6-2.6) and SHP (aOR 2.4, 95% CI 1.4-3.9). Moreover, the frequency of 1-year postoperative complications was higher in VM (aOR 1.6, 95% CI 1.1-2.2) than in CA.

#### Conclusions

CA was associated with a low rate of recurrent POP surgery, symptomatic recurrence and low surgical morbidity compared to other surgical methods in women with uterine prolapse.

## Effect of age and body mass index on symptoms of pelvic floor disorders after pelvic organ prolapse surgery.

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#### Background

Increasing age and body mass index (BMI) are risk factors for pelvic organ prolapse (POP) and incontinence. POP surgery reduces bother of prolapse and incontinence. We aimed to assess any effect of age and BMI on postoperative symptoms in women undergoing POP surgery.

#### **Material and methods**

A prospective cohort study of 151 women assessed 3 months before POP surgery and 6 months postoperatively with the Pelvic Floor Distress Inventory (PFDI-20) (0-300) and subscales: Pelvic Organ Prolapse Distress Inventory (POPDI), Urinary Distress Inventory (UDI), Colorectal Anal Distress Inventory (CRADI) (0-100). Age and BMI were dichotomized using cut-off 60 years and BMI 25 kg/m2. Scores between the groups were compared with t-test.

#### Result

Mean age was 60 years and BMI 26 kg/m<sup>2</sup>. Eighty-seven (58%) women were  $\geq$  60 years and 77 (51%) had BMI  $\geq$  25. Mean (SD) postoperative scores in women <60 vs.  $\geq$  60 years were: PFDI 51 (47) vs. 36 (34) p=0.04; POPDI 16 (19) vs. 9 (13), p=0.01; UDI 19 (22) vs.15 (17), p=0.16; CRADI 16 (18) vs. 12 (12), p=0.11. Scores in women with BMI <25 vs.  $\geq$  25 were: PFDI 35 (32) vs. 49 (38), p =0.04; POPDI 19 (13) vs. 14 (18), p=0.13; UDI 12 (15) vs. 21 (21), p=0.01; CRADI 23 (12) vs. 15 (17), p=0.55.

#### Conclusions

Overweight women experienced less relief of overall PFD and urinary tract symptoms postoperatively compared to women with normal BMI. Younger women experienced less relief of POP symptoms. No association was found between age, BMI and colorectal-anal distress.

## Pelvic Organ Prolapse as a result of Hysterectomy on Benign Indication – A National Matched Cohort Study

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#### Background

Hysterectomy on benign indications is a frequent procedure but increases the risk of pelvic organ prolapse (POP).<sup>1</sup> POP reduces life quality and lifetime risk of surgery is 18.7%.<sup>2</sup> This study wishes to investigate POP-surgery after hysterectomy and address how parity influences this as well as which compartments are affected.

#### Methods

This was a cohort study based on Danish registries. We identified women born from 1947 – 2000. Women who were hysterectomized on benign indication were matched 1:5 with a non-hysterectomized reference on age and calendar year. The women were followed from 1977-2018. We excluded women who emigrated had POP-surgery prior to their hysterectomy or had a gynaecological cancer diagnosed up till 30 days after hysterectomy.

The risk of pelvic organ prolapse surgery after hysterectomy was calculated using Cox's regression adjusting for age, income, education, and parity.

#### Result

Sacrospinous fixation (SSF) and sacrohysteropexy (SHP) were associated with a significantly higher rate of recurrent pelvic organ prolapse (POP) surgery (SSF: adjusted odds ratio, aOR 2.6, 95% confidence interval, Cl 2.0-3.5; SHP aOR 2.6, 95% Cl 1.8-3.7) and patients describing a sense of globe (SSF aOR 2.0, 95% Cl 1.6-2.6; SHP aOR 1.8, 95% Cl 1.1-3.1) compared to cervical amputation (CA). There was no difference in the reoperation rate or sense of a globe between vaginal mesh (VM) and CA with fixation to the uterosacral ql ligaments. Patients undergoing SSF had a higher frequency of 1-year postoperative complications compared to CA (aOR 2.0, 95% Cl 1.6-2.6) and SHP (aOR 2.4, 95% Cl 1.4-3.9). Moreover, the frequency of 1-year postoperative complications was higher in VM (aOR 1.6, 95% Cl 1.1-2.2) than in CA. We included 80,444 hysterectomized women and 396,303 references. The cohort was followed for an average of 15 years. The risk of POP-surgery was significantly higher for hysterectomized women, HR 1.4 95% Cl [1.4;1.5]. When analysed by compartment the risk of a posterior compartment prolapse was HR 2.2 [2.0;2.3] and risk of anterior compartment prolapse HR 1.1 [1.0;1.1]. The risk of subsequent POP-surgery increased with parity and were 40% higher in hysterectomised women for all parities compared to non-hysterectomized women.

#### Conclusions

The study showed an increased risk of POP following hysterectomy on benign indications. Risk of posterior compartment prolapse was highest and parity amongst hysterectomized further increased the risk of POP.

Vaginal vault prolapse and recurrent POP surgery: A Swedish nationwide observational cohort study.

#### Malin Brunes<sup>1</sup> (SE)

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#### Background

To compare the efficacy of common surgical procedures in women with vaginal vault prolapse.

#### **Material and methods**

This is a nationwide, cohort study. All patients with a vaginal vault prolapse undergoing surgery, between 1 January 2015 and 31 December 2018, were identified from the Swedish National Quality Register of Gynecological Surgery, GynOp. The primary outcome was the frequency of recurrent pelvic organ prolapse (POP) surgery within 2 years post-operatively. Secondary outcomes included patient-reported vaginal bulging, operative time, estimated blood loss and 1-year post-operative complications.

#### Result

In 1,812 patients with vaginal vault prolapse 538 (30%) had a vaginal mesh (VM) 441 (24%) underwent sacrospinous fixation (SSF) and 200 (11%) underwent minimally invasive sacrocolpopexy (SCP). A significantly higher proportion of patients undergoing recurrent POP surgery was seen in SSF compared to VM (adjusted Odds Ratio (aOR) 2.2, 95% confidence interval (CI) 1.4-3.6). Patient-reported sensation of vaginal bulging 1 year after surgery, was higher in the SSF group than in the VM (aOR 1.9, 95% CI 1.3-2.8) and SCP group (aOR 2.0, 95% CI 1.1-3.4). Finally, we found a significantly higher rate of complications 1 year after surgery in SSF (aOR 2.3, 95% CI 1.2-4.2) and VM (aOR 2.2, 95% CI 1.2-4.2) compared to SCP.

#### Conclusions

In patients with vaginal vault prolapse SSF was associated with a higher frequency of recurrent POP surgery and subjective relapse compared to SCP and VM. Additionally, the complication rate 1 year after primary surgery was higher in both SSF and VM than in SCP.

#### Endometrial cancer after the Manchester procedure: A nationwide cohort study

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#### Background

The Manchester procedure (MP) may be the best way to treat uterine prolapse due to fewer recurrences compared to hysterectomy with suspension and sacrospinous hysteropexy. However, it is unknown how it affects the risk and prognosis of endometrial cancer.

The aim of this study was to investigate the risk and prognosis of endometrial cancer for women operated with Manchester procedure compared to women operated with anterior colporrhaphy (AC).

#### Methods

We conducted a historical cohort study based on the nationwide Danish registers. All Danish residents have a personal identification number permitting linkage of registers on individual level enabling epidemiological studies with lifelong follow-up. We identified all Danish women born 1947–2000 and living in Denmark during 1977–2018. We included women operated with MP during 1977–2018. Women operated with AC were included as references.

We performed Cox regressions to analyze the risk of endometrial cancer and the risk of death. The models were adjusted for age, calendar year, income level, and parity. A Chi-Square test for trend was performed to compare the diagnostic stage.

#### Result

This study cohort included 23,935 women operated with MP and 51,008 operated with AC.

The adjusted hazard ratio (HR) for endometrial cancer was 1.00 [95% confidence interval (CI) 0.86-1.16] and the HR for cancer specific death was 0.86 [95% CI 0.65-1.15]. The stage of the cancer at time of diagnosis was not significantly different between the two groups (p=0.18).

#### Conclusions

MP did not alter the risk or prognosis of endometrial cancer.

#### Enterocele in the anterior vaginal wall after radical cystectomy.

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#### Background

Enterocele in the anterior vaginal wall is a rare complication after cystectomy. Over the past two years we had the impression of increased prevalence of anterior wall enterocele. Our aim was to establish if this was related to a new surgical technique for cystectomy introduced in 2017.

#### Methods

We used Opplan and Doculive to identify women undergoing cystectomy for Ca. Vesicae and enterocele repair during 10 years (June 2011 – May 2021). We compared the prevalence of anterior wall enterocele after open and robotic assisted (more radical) surgical technique for cystectomy (Fishers exact test).

#### Result

A total of 85 women underwent enterocele repair, of whom 6 (7%) after cystectomy. Median age was 75 years, BMI 22 kg/m2 and parity 2.7. Median (range) interval from cystectomy to referral for enterocele was 11 (5-19) months and to enterocele repair 15 (9-50) months. 25 women underwent robotic cystectomy of whom 5 (20%) developed an enterocele, and 42 underwent open cystectomy of whom 1 (2%) developed an enterocele, p=0.02.

#### Conclusions

The survival after Ca. Vesicae improved substantially after introduction of robotic assisted radical cystectomy. This in turn was associated with an increased risk of anterior wall enterocele within 1 year after cystectomy. It is technically challenging to perform enterocele repair after radical cystectomy, since the fascia in the anterior vaginal wall has been removed. It is important to identify factors that may reduce the risk of enterocele after cystectomy and to optimise the surgical technique when performing anterior enterocele repair.

## Evaluation of reoperation rates for surgically treated anterior vaginal wall prolapse: a retrospective cohort study

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#### Background

Reported failure rates for anterior colporrhaphy range from 0 to 20% (1). In 2006 a group of urogynecologists at Landspitali University Hospital started to apply a combined repair method for anterior vaginal wall prolapse. Other urogynecologists continued to use classical midline plication. Aim of the study was to compare these two groups in terms of reoperation rates retrospectively.

#### Methods

Patients who underwent surgery for anterior vaginal wall prolapse from 01.02.2011 to 31.01.2019 were devided into two groups. Group 1 icluded patients who had midline plication. Group 2 included patients with complete reattachment of the endopelvic fascia. This technique addresses paravaginal and midline defects and supports the vaginal apex. Countrywide reoperation rates in both groups were compared during the study period. For statistical analysis logistic regression was used (Jamovi<sup>®</sup>).

#### Result

1004 women underwent anterior vaginal wall prolapse surgery during the study period (Group 1: 492, Group 2: 506, 6 excluded). Reoperation rate in group 1 was 8,73% and 2,56% in group 2. When comparing Group 2 to Group 1 logistic regression showed an odds ratio of 0,275 (p < 0,001, 95% CI 0,1462-0,519).

#### Conclusions

Prolapse surgery is common and costly (2). It is important to reduce reoperation rates if possible. This study showed that complete reattachment of the endopelvic fascia reduces the risk of reoperation by 72 % compared to midline plication.

## Is suturing device sacrospineous fixation for uterine prolapse equivalent to traditional technique? – A national cohort study

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#### Background

The difference in efficacy and safety of sacrospinous ligament fixation (SSF) performed with a suturing device or traditional technique for correction of uterine prolapse is previously not studied. Suturing instruments developed to simplify the SSF procedure are common, but have limited documentation.

#### Methods

In a register-based national cohort of all women undergoing SSF between 2006-2018 (n= 2756), data of assessment pre-operatively, hospital admittance, surgery, discharge and questionnaires at eight weeks and one year post-operatively, were extracted from the Swedish Quality Register of Gynecological Surgery. Register national coverage exceeds 98%. Demographic variables and surgical methods were included in multivariable logistic regression analyses.

#### Result

In the suturing device group (SDG, n=1,459), 74.4% were asymptomatic of recurrence after 1 year, as compared with 83.4% in the traditional SSF group (TSG, n=166), p= 0.016. The adjusted odds ratio (aOR) for being asymptomatic 1 year postoperatively was 1.90 (1.12-3.21, p=0.017). Patient satisfaction was significantly lower in the SDG than in the TSG (72.7% vs. 83.4%, p=0.011). In the TSG 3.7% were readmitted within 8 weeks compared to 8.0% in the SDG, p=0.063. Bleeding > 500 ml occurred in 0.7% in the TSG and 0.3% in the SDG, p=0.77.

#### Conclusions

Patients operated with traditional technique were more likely to be asymptomatic one year after SSF, and improvement rating and patient satisfaction was significantly higher in the TSG. Surgical complications did not differ between the methods. This national cohort study suggests suturing device SSF for uterine prolapse is inferior to traditional technique regarding symptomatic recurrence.

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