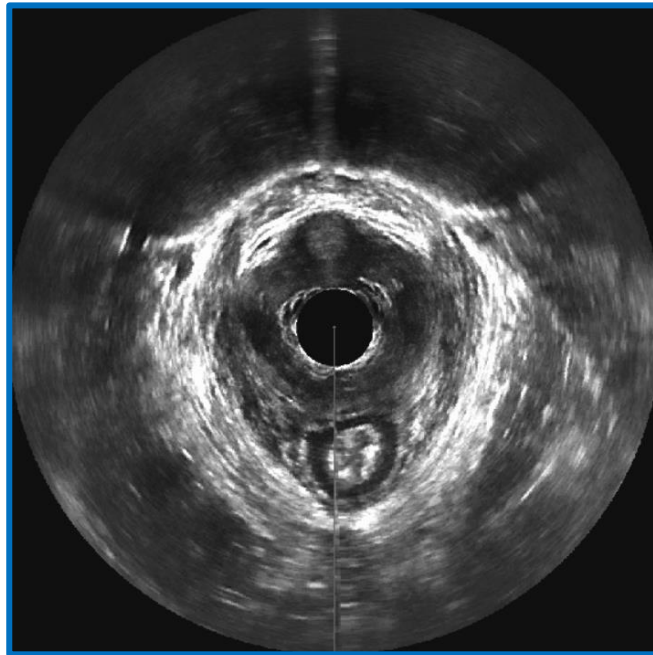


LEVATOR ANI DEFECTS IN PRIMIPAROUS WOMEN WITH TIME OF DELIVERY BEFORE OR AFTER "THE FINNISH INTERVENTION"



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STUDENT REPORT

Dansk resume:

Baggrund: I 2013 blev "Det finske håndgreb" indført på Regionshospital Nordjylland. Metoden anvendes i fødselens sidste fase, og indebærer støtte af perineum, mens caput fødes, hvilket også sænker hastigheden af caputs fødsel. Formålet var at mindske forekomsten af grad 3 og 4 sphincterrupturer. Forekomsten faldt fra 7,2 % i 2012 til 2,9 % i 2013.

Ved at anvende håndgrebet kan belastningen på levator ani musklerne øges, hvilket potentielt kan øge risikoen for defekter i musklerne i form af deenervering, devaskularisering og overrivning. Disse skader betegnes som levator ani defekter (LAD), og er beskrevet i tidligere studier. Formålet med dette studie er, ved hjælp af 3D endovaginal ultralyd, at evaluere tilstedeværelsen af LAD, hos primipara kvinder, som har født før og efter implementering af "Det finske håndgreb". Desuden vil der blive foretaget en objektiv vurdering af vaginal prolaps, samt evaluering af urogynækologiske symptomer herunder urininkontinens og prolaps.

Metoder: Primipara kvinder med fødselstidspunkt mellem 2008-2018, blev identificeret via deres diagnosekoder ($n=2518$) og inviteret til deltagelse via e-boks. Deltagerne blev inddelt i kohorte 1, som havde født før "Det Finske håndgreb" (2008-2013) og kohort 2, der havde født efter (2013-2018). De inkluderede kvinder fik udført en POP-Q måling for at kvantificere graden af eventuel vaginal prolaps samt en 3D endovaginal ultralydsscanning af levatormusklerne. Slutteligt besvarede deltagerne udvalgte spørgeskemaer omhandlende urogenitale problemstillinger. Herunder et generelt spørgeskema med demografisk information, samt the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF) og the International Consultation on Incontinence Questionnaire Vaginal Symptoms Module (ICIQ-VS).

Efterfølgende blev alle ultralydsscanninger evalueret med henblik på bedømme eventuel tilstedeværelse af LAD. Til dette formål blev levator ani musklerne opdelt i henholdsvis musculus pubovicalis og musculus puborectalis. Afhængig af defektens størrelse blev skaderne scoret fra 0-3, og scoren resulterede i opdeling af graden af defekt i hhv. ingen defekt, mild defekt og stor defekt.

Resultater: 114 primipara kvinder blev inkluderet i studiet. Der var statistisk signifikant forskel på tiden fra fødsel til inklusion mellem kohorterne. Der kunne ikke påvises statistisk signifikante forskelle mellem kohorte 1 og 2 med hensyn til alder, BMI eller tidligere operationer. Ligeledes fandtes ingen forskel i prolapsstype, prolapsgrad, subjektive symptomer eller forekomsten af LAD, mellem de to kohorter. Dog fandtes en relativ høj prævalens, da op mod 50% af de inkluderede kvinder havde LAD.

Konklusion: "Det finske håndgreb" har hverken forværret eller bedret tilstedeværelsen af skader i levator ani musklerne på baggrund af fødslen. Dog er forekomsten af LAD høj i begge grupper og begge grupper rapporterer urogenitale gener, hvorfor området med fordel kan undersøges yderligere.

Abbreviations:

EVUS - endovaginal ultrasound

ICIQ-UI-SF - the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form

ICIQ-VS - the International Consultation on Incontinence Questionnaire Vaginal Symptoms Module

LAD - levator ani defect

LAM - levator ani muscle

PFD – pelvic floor dysfunction

POP - Pelvic organ prolaps

POP-Q - Pelvic Organ Prolapse Quantification

PR - puborectalis

PV – pubovicalis

QoL - Quality of life

Introduction

Female pelvic floor dysfunction (PFD) is a well-established postpartum risk in childbirth. PFD includes pain, pelvic organ prolapse (POP), sexual dysfunction as well as both urinary and fecal incontinence(1) (2) (3). These complications might gravely influence the quality of life (QoL) in the affected women. Contributors to PFD may be obstetric anal sphincter muscle injuries as well as levator ani muscle defects (LAD)(1)(4). Rupture of the anal sphincter occurs in up to 6% of vaginal deliveries(4), while LADs are seen in 36% of primiparous women.(5)

The primary musculatory compartment of the pelvic floor is the levator ani muscles (LAMs), which are critical in pelvic organ support. LAM inserts on the ramus ossis pubis, and forms a u-shaped muscle, which frames both the urethra, vagina and rectum(6). The LAM can be subdivided into the puborectalis muscle, the pubococcygeus muscle and the iliococcygeus muscle. When examining these muscles using endovaginal ultrasound (EVUS), the three muscles can be divided into: the puborectalis muscle (PR) and the pubovicalis muscle (PV). The PV includes both the iliococcygeus and the pubococcygeus muscle, since these cannot be differentiated in ultrasound imaging.(7)

During pregnancy and delivery, the LAM can stretch 2-3 times its own length(8). This significant distension might result in defects, such as tearing from the pubic bone as well as denervation and devascularization of the LAM, thus creating LADs. This poses a considerable problem since LADs have been linked to complications, such as POP and urinary incontinence, as well as recurrence of prolapse after surgical correction.(6)

Another muscle important for the support of the pelvic floor, is the anal sphincter, which is responsible for discharge of fecal matter and gas(7). To prevent sphincter injuries, the “Finnish intervention”, was introduced at the maternity ward at the North Denmark Regional hospital from January 1st, 2013. The intervention seeks to prevent tearing the sphincter muscles during delivery by manually applying pressure to the perineum in the final stage of delivery. This also decreases the speed at which the caput is born. The intervention has successfully been shown to decrease anal sphincter injuries from 7.2% to 2.9%.(9)

However, by applying pressure and holding back the caput, the time in which the LAM is stretched to the maximum, is prolonged. It can be speculated, that this also increases the degree of distension on the LAM, which might result in a higher risk of LADs and the previously described complications.

Therefore, the aim of this study was to compare urogynecological symptoms, objective signs of prolapse and LADs between two groups of singleton primiparous women, who have given birth in the North Denmark Regional Hospital from 2008-2018. The women were divided into cohort 1, with time of delivery prior to the implementation of the Finnish intervention, and cohort 2, who had a time of delivery after the implementation. The comparison was done through subjective symptoms of POP and urinary incontinence, and through the objective grading of prolapse by gynecological examination and LADs evaluated by endovaginal 3D ultrasound.

Methods

The study aimed to include 300 primiparous women, who had given birth vaginally, to only one child, at the North Denmark Regional Hospital, between January 1st 2008 and December 31st 2018. Participants were identified through the National Hospital Discharge register, based on the inclusion criteria and diagnostic codes (table 1). An invitation to participate in the study was sent to the digital mailbox (e-boks). Subsequently, a new invitation was sent to the non-responders within two months.

Table 1: The inclusion and exclusion criteria used for selecting eligible participants

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none">- Age above 18- Primiparous- Delivery between 2008-2018- Virginal delivery- Birthplace at North Denmark Regional Hospital	<ul style="list-style-type: none">- Multiparous- Gemmeli pregnancy- Caesarian section- Current pregnancy- Vaginal pathologies complicating vaginal ultrasound such as skin disorders, tumors, and vulvodynia

The invitation included a Redcap-link, through which the participants could register their name and telephone number. The participants were contacted by telephone, to clear up any questions about the study, as well as schedule an appointment for examination.

The women were grouped in two cohorts according to time of delivery. Cohort 1 had given birth before the implementation of the Finnish intervention (2008-2012) and cohort 2 had given birth after (2013-2018). The examinations took place between July 1st 2021 and October 8th 2021.

Gynecological examination:

All participants had a pelvic examination performed to assess any possible POP. The Pelvic Organ Prolapse Quantification (POP-Q) system was used, and from these data the grade of prolapse was determined for each woman. This was done by measuring the lowest point of the anterior and posterior vaginal wall, as well as the lowest edge of the cervix during straining. Each measurement resulted in a grading of prolapse, if any, from 0 to 4 (0 being no prolapse and 4 total prolapse).(10)

Endovaginal ultrasound:

Subsequently, a 3D EVUS was performed to determine any LADs (7). The procedure was performed using a flex focus 500 ultrasound machine from BK medical, with a 8838 probe (9-13 MHz). Participants were placed in the dorsal lithomy position. The probe was then inserted into the vagina, until the vesicourethral junction was viewed in the axial plane, and the 3D ultrasound image was obtained. One or more images was obtained from each participant to ensure optimal image quality.

Questionnaires:

The participants were asked to fill out questionnaires evaluating symptoms of pelvic floor dysfunction. These included a general supplement questionnaire as well as two validated urogynecological questionnaires. The first questionnaire was the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF), which yields a total ICIQ-UI-SF score, describing the severity and bother of urinary incontinence symptoms. The score has a range between 0-21, with 21 being the most severe. Based on this score, the women were divided into the following categories: no symptoms (0), mild-moderate symptoms (1-12) and severe incontinence symptoms (13-21)(11). This questionnaire also evaluates type of incontinence (stress -, urge- and mixed urinary incontinence). The second questionnaire was The International Consultation on Incontinence Questionnaire Vaginal Symptoms Module (ICI-VS)(12), which evaluates vaginal prolapse on the following domains: a vaginal symptom score (range between 0 and 53, where 0 is no symptoms), a sexual matter score (score range 0-58, where 0 is no symptoms) and lastly, a QoL score assessed on a VAS scale (range 0-10).

Interpretation of ultrasound images:

Interpretation of the ultrasound images were performed offline by the main author and the main supervisor by using the software program BK3D viewer version 7.0 from BK Medical Aps. Both reviewers were blinded to cohort belonging and clinical findings. An example is seen in figure 1.

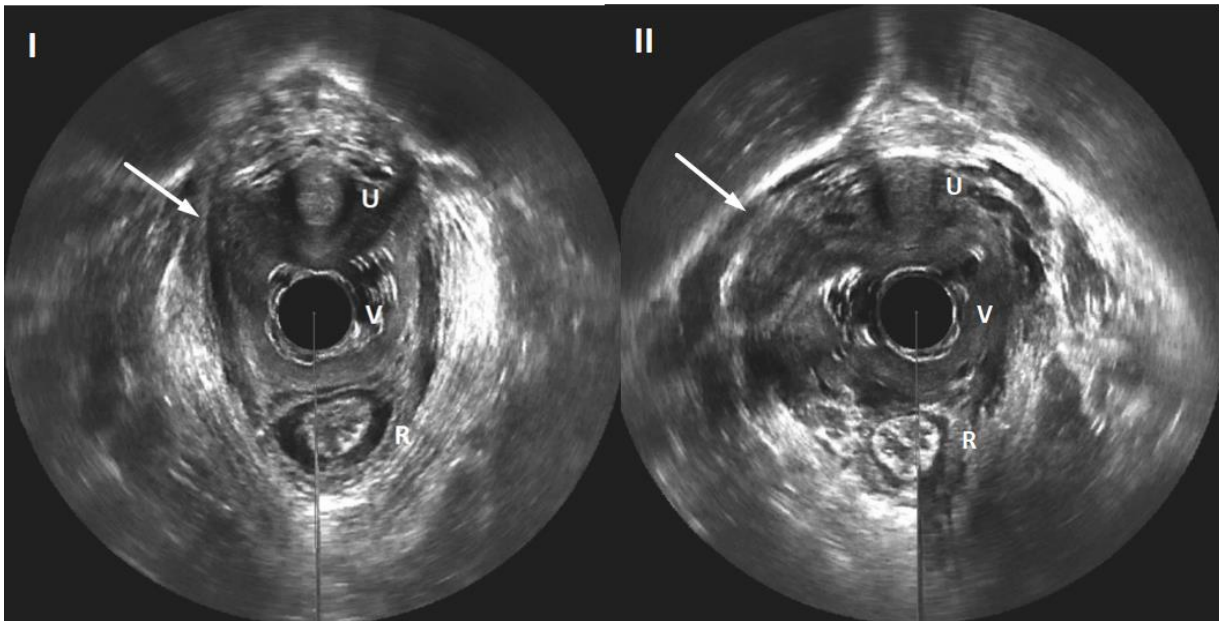


Figure 1: Ultrasound imaging used to determine LADs. U = urethra, V = vagina, R = rectum. I: example of intact LAM. II: example of LAD.

The assessment of LADs was made using the previously described muscular subdivisions of PV and PR muscles. The method of evaluation has been described by Morgan et. al(13) and validated by e.g. Rostaminia et al., (14). On each side, the PV and PR were individually scored from 0-3, as demonstrated in table 2, resulting in a score between 0-6 for each muscle pair. The score was used to determine the grade of defect: a score of 0 represented no defects, a score of 1-3 represented a mild defect, and a score of ≥ 4 or a unilateral score of 3 represented a major defect(14).

Table 2: The scoring system used to evaluate LAD for the subdivisions of PV and PR.

Range of muscle defect	Score
No defect	0
Defect less than 50%	1
Defect more than 50%	2
Absence of muscle	3

All statistical analyses were performed using IBM SPSS version 27 by the IBM corporation, New York, USA. The applied tests included: students t-test for the normally distributed data, the Chi squared test for categorical values, and the Mann-Whitney U test for the non-parametric data without normal distribution. Values of $p < 0,05$ were considered statistically significant.

Results

Based on diagnostic codes, 2039 vaginal deliveries, between year 2008-2018, from primiparous singleton women, were identified. A total of 286 women responded to the invitation and signed up in Redcap. Here, 172 women were excluded based on double registration, not answering the inquiry to schedule an appointment and due to not showing up for the scheduled appointments as well as due to not meeting the inclusion criteria. A total of 114 women participated in the physical examination. As a result of not being primiparous two women were later excluded, resulting in 112 final participants – 36 women in cohort 1 and 76 in cohort 2.

When comparing the two cohorts, no significant differences were found regarding age, body mass index (BMI), smoking history or prior surgery but a significant difference was found when evaluating time from delivery to inclusion (table 3). Regarding prior surgeries two women in cohort 1 had surgery for incontinence and one had surgery for POP, prior to the inclusion. No women in cohort 2 reported these surgeries.

Table 3: Demographic characteristics of cohort 1 and cohort 2.

	Cohort 1 n= 36	Cohort 2 N= 76	p-value
Age, mean (SD)	41.1 (6.1)	34.37 (5.7)	0.287 *
BMI median (range)	27.28 (19-48)	25.39 (19-50)	0.243**
Smoking			0.208***
Currently, n (%)	5/36 (13.9%)	18/76 (23.7%)	
Former, n (%)	15/36 (41.7%)	20/76 (26.3%)	
Never, n (%)	16/36 (44.4%)	38/76 (50%)	
Prior surgery			
Yes, n (%)	11/36 (30.6%)	12/76 (15.8%)	0.07***
Days between delivery and inclusion, mean (SD)	3951 (495)	1837 (600)	<0.001*

* = t-test, ** = Mann Whitney U test, *** Chi-squared test

Evaluated by the POP-Q measurement, none of the participants suffered from uterine prolapse. Regarding cystocele and rectocele no statistically significant differences were found between the two cohorts (figure 2).

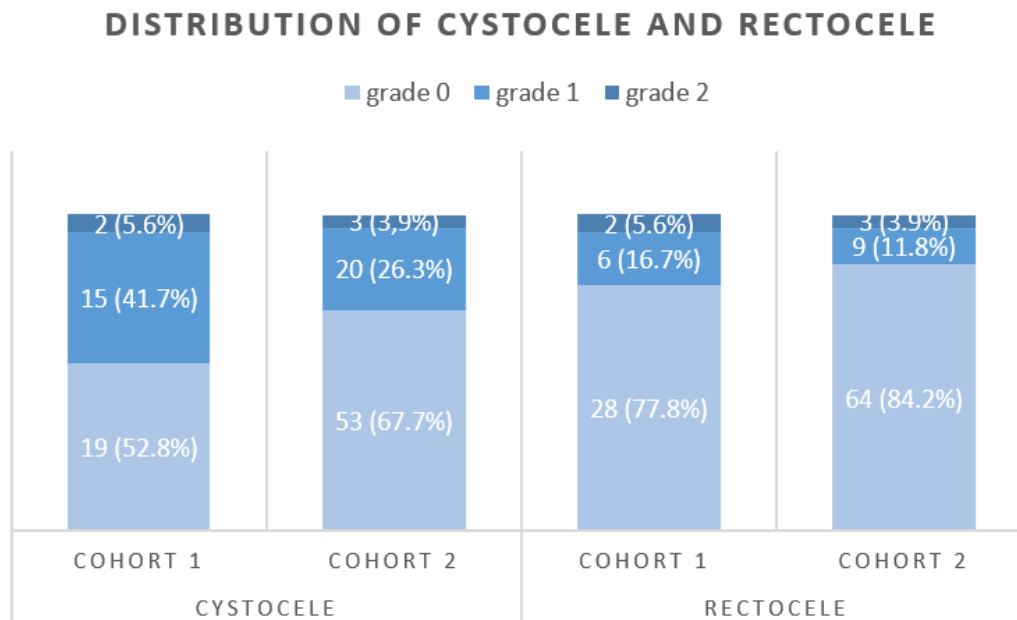


Figure 2: The distribution of cystocele and rectocele in the two cohorts (n (%)). No statistically significant difference was found (cystocele p-value=0.215 and rectocele p-value=0.709 evaluated by chi squared test).

The ICIQ-VS questionnaire was used to evaluate vaginal symptoms. Both cohorts had a median score of 8 (range 0-40 for cohort 1, and 0-31 for cohort 2, p=0.845), meaning relatively few vaginal symptoms reported in both cohorts. Regarding the sexual matters score, cohort 1 reported a higher score than cohort 2, however the difference was not statistically significant (median score value 21 (range 13-45) for cohort 1 vs. median score 13 (range 13-25) for cohort 2, p=0.872). Moreover, the two cohorts had a similar QoL-score, with a median of 1 (range 0-7 for cohort 1 and range 0-10 for cohort 2, p=0.823).

The ICIQ-UI-SF questionnaire was used to evaluate urinary incontinence symptoms. Based on the ICIQ-UI-SF total score, the women were divided into the categories: none, mild-moderate and severe urinary incontinence symptoms (figure 3). No significant difference between the two cohorts were found (p=0.182). Moreover, the distribution of incontinence type was similar in both cohorts, with stress incontinence being the predominant type, followed by mixed incontinence, and urge incontinence (table 4). Two patients in cohort 2 could not be categorized as either, since they did not report symptoms, consistent with either type of incontinence.

SEVERITY OF URINARY INCONTINENCE SYMPTOMS

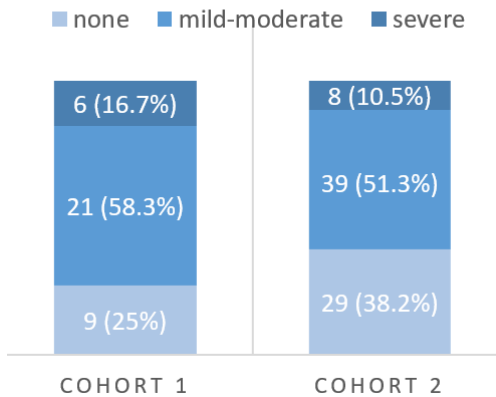


Figure 3: Severity of urinary incontinence symptoms, based on the ICIQ-UI-SF total score (n (%)). No statically significant differences were found ($p= 0.332$). The Chi squared test was used.

Table 4 Type of incontinence in the two cohorts based on the answers from the ICIQ-UI-SF.

	Cohort 1 n=36	Cohort 2 n=76
None n (%)	9 (25.0%)	28 (36.8%)
Stress n (%)	15 (41.7%)	33 (43.4%)
Urge n (%)	4 (11.1%)	5 (6.6%)
Mixed n (%)	8 (22.2%)	8 (10.5%)
Unknown n (%)	0 (0.0%)	2 (2.6%)

Regarding the ultrasound images, data from four participants were unsuccessfully saved, resulting in a total of 108 images included in the analysis. To evaluate LADs in the puborectalis muscle in the affected participants, the PR-score was compared between the cohorts. No statically significant differences were found (the median score was 0 in both cohorts, with range 0-3 in both, $p=0.370$). The same was found for the PV score, evaluating LADs in the pubovicalis muscle (median score of 0, $p=0.734$, range was 0-6 for cohort 1 and 0-4 for cohort 2).

Based on the PV and PR score, the degree of muscle defect was divided into: no, mild and major defects as seen in figure 4. Upon comparison, no differences between the two cohorts were found in either the PV or PR muscles ($p=0.548$ for PV muscle defects and $p=0.264$ for PR muscle defects). Interestingly 33% in cohort 1 and 24% in cohort 2 had mild-major defects in the PR muscle. Moreover, an overwhelming presence of defects was seen in the PV muscles, where 44% had mild-major LADs in cohort 1, and this was also seen in 46% in cohort 2. This means that almost half of the included women suffer from LAD defects.

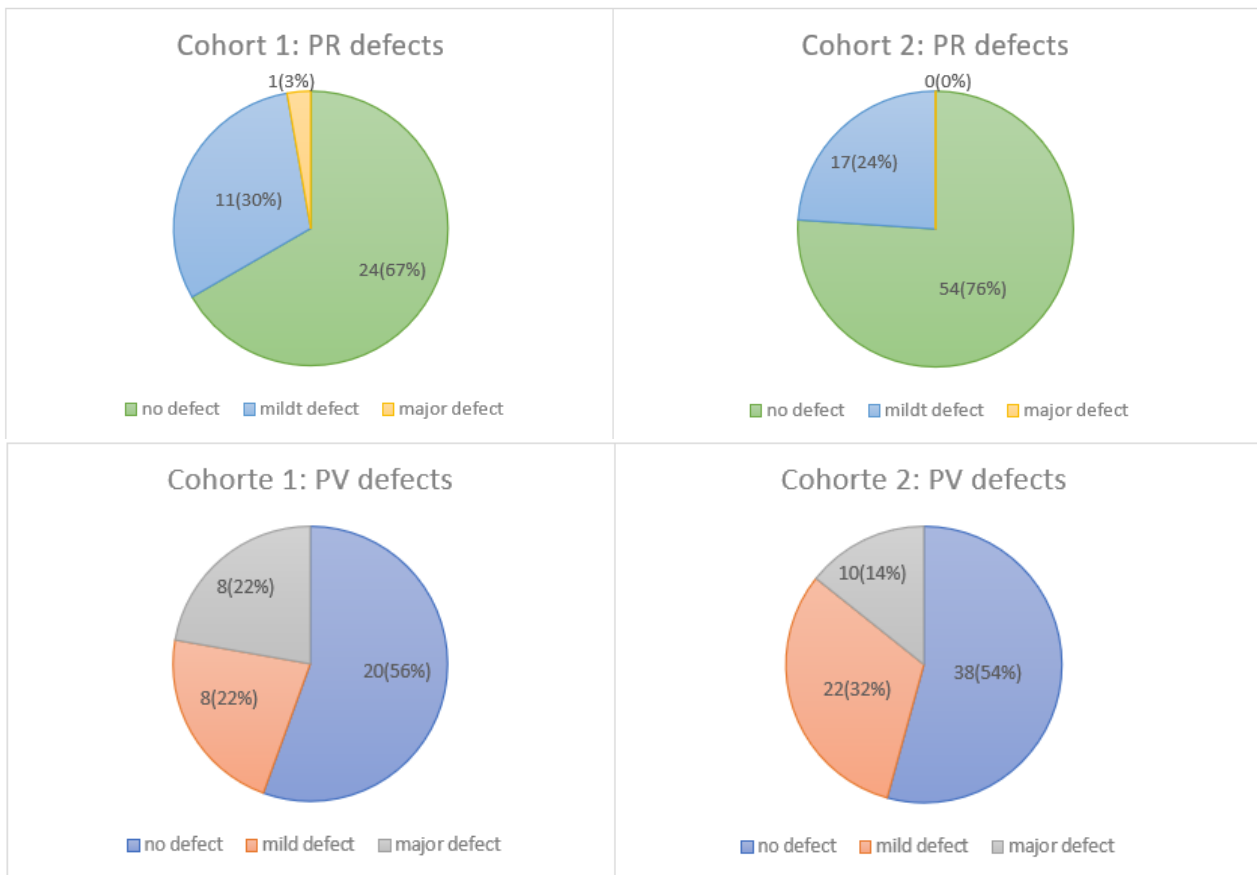


Figure 4: Puborectalis (PR) and Puboviceralis (PV) muscle defect type in cohort 1 and 2.

Discussion

In summary, it was not possible to detect any statistically difference between the two cohorts, regarding subjective symptoms of POP and incontinence or the objective presence of POP or LADs determined by EVUS. This could indicate that the Finnish intervention have not altered the symptoms of pelvic floor dysfunction or the presence of LADs. However, a noticeably high number of the included women, in our study, suffered from LADs. Since these defects can lead to complications such as POP and urinary incontinence as well negatively influence the QoL, this is of concern.

The majority of LAD were present in the PV muscle compared to the PR muscle in both cohorts, which is common. In our study, 44% in cohort 1 and 46% in cohort 2 had LAD in the PV muscle. These numbers are high, considering the participants were healthy women, who had given birth to only one child. Several theories could help explain why almost half the participants had LADs. It could be due to the study population, where matters such as tissue quality and size of the child can influence the development of LADs (5)(15). Another possibility is that women with symptoms, possibly caused by LADs, would be more prone to enlist, compared to women, with no symptoms. This would create a risk of selection bias in the study population, and could contribute to explain, why so many of the included women had LADs. The high presence of LADs could also be due to the evaluation of the ultrasound images, where factors such as experience from the examiner and the participants ability to lie still during the EVUS procedure might influence picture quality.

Other studies reporting on LADs, following vaginal delivery, found the presence to be between 13-36%. The study by Dietz et al.(16) found LADs in 36% of 39 women, and the study by Blasi et al.(17) reported 31.4% LADs in 56 women. Blasi et al. obtained ultrasound imaging merely 12 hours postpartum, whereas Dietz et al, obtained the data 6 months postpartum. Thus, the studies have relatively few participants, and they perform ultrasound imaging shortly after delivery, compared to our study. The study by Valsky et al.(15) included 210 women and showed LADs through ultrasound in 18.8%, and this was done 24-72 hours postpartum. Shek et al.(18) showed 13% presence of LADs on ultrasound imaging in 187 women 4 months after delivery. These studies are in contrast with our study, as we experience a higher number of women suffering from LADs. However, the mentioned studies performed scans on all women, who had given birth in the inclusion period, while our participants had to sign up, thus creating the risk of selection bias. Furthermore, these studies performed examinations close to time of delivery, and it is possible that our results differ, because our scans were made years after the delivery. This could potentially influence the results since the degree of LADs might increase over time through the use of the pelvic floor. Another explanation for the different results, could be the interpretation of the ultrasound images. Although similar methods of ultrasound imaging are applied in all the mentioned studies, different methods of evaluation are used in each study, including our own. To fully compare the presence of LADs between the studies, the method of evaluation should be taken into considerations. The subdivision of the LAM and the definition of LADs should also be aligned to fully compare results. However, many of the studies do not report on this, making a definitive comparison complicated. Demographic details such as ethnicity, maternal age, size of child and inclusion criteria, could also be clarified to further compare the results.

Although LADs are believed to be caused by vaginal delivery it should be noted that a study by Branham et.al found that 18% of nulliparous women, suffered from LAM abnormalities(19). This could indicate that some women are predisposed to LADs before pregnancy and delivery.

However, the study was limited by a small number of participants. To fully determine the effect of the Finnish intervention in development of LADs, any defects prior to pregnancy and delivery should be investigated further.

No differences between the two cohorts regarding uterine prolapse, cystocele or rectocele could be detected, based on the POP-Q measurements. This could mean, that while the Finnish intervention have not improved the presence of POP, it also has not worsened it. Some association between the presence of LADs and POP exist, but it has been shown, that the clinical sign and the symptoms do not always correlate.(20). It should also be kept in mind, that while LADs are a factor in the development of POP, they are not the sole reason since POP has a multifactorial etiology.(21)

When comparing the symptoms reported in the questionnaires ICIQ-VS and ICIQ-UI-SF, no statistically significant differences were found. This indicates that the women in both cohorts are influenced by these symptoms equally. Thereby, it appears that the use of the Finnish intervention did not alter the symptoms reported in the described questionnaires.

The primarily type of incontinence, reported by both cohorts through the ICIQ-UI-SF, was stress incontinence. Since the LAM has a constant muscle tonus and can contract immediately during increased abdominal pressure, e.g. during physical activity and coughing, the presences of LADs, can result in stress incontinence.

The study by Delft et al.(20) used both the ICIQ-VS and ICIQ-UI-SF to evaluate women with and without LADs. They reported that women with LADs in general scored higher in the questionnaires, compared to women without LADs, and that they did not experience the same improvements in these symptoms following childbirth. Furthermore, the study could conclude that women with major LADs reported more vaginal issues such as lack of sensation, looseness, and sexual dysfunction. It should however be noted that the study was conducted only three months after time of delivery, which means, that the symptoms could yet improve for the women with LADs. (20) . It could be interesting to further examine if the women in our study, who had LADs, were also the same women, who achieved the highest scores, regarding symptoms, in the questionnaire. Not much literature currently exists on the correlation between LADs and vaginal symptoms and more understanding is needed to further evaluate.

Our study has some limitations that need to be considered when interpreting the findings. An important issue to be considered, is the difference in time from delivery to study inclusion. This means that some of the included women had given birth within the last two years, but other women had given birth more than 10 years ago. Our data showed that a statically significant difference was seen in time from delivery to inclusion. This can influence the results, since it is well established, that the risk of complications, such as POP and urinary incontinence, increases with age(22). It is possible, that the women, who had LADs, but did not report any symptoms, might experience symptoms in the future. This could also mean, that while no statistically significant differences between cohort 1 and 2 was found, this could potentially change in the future. To further examine this, a follow up study could be designed.

In addition, it cannot be stated that all women in cohort 2 had given birth, with the Finnish intervention. Although it is common practice in the birth ward, the use can differ depending on

the delivery and the midwife or doctor attending the birth. This cannot be further documented, since there, as of now, is no requirement for the staff to report the use of the Finnish intervention in the patient journals.

When analyzing these results of the POP-Q measurement it should also be taking into consideration that, not all women were able to perform the Valsalva maneuver or cough correctly. This is necessary to use the standard POP-Q technique, as described by Chandrakant et al, and thereby ensure correct measurement. (10)

The study is also limited by having only 112 participants. This can increase the risk of type II errors and hereby not detecting a difference due to the population being too small. In the design of future studies, more participants could be included to validate the results further and to assess the effects of the Finnish intervention in LADs.

A strength in the study is the inclusion of participants, since all eligible women, who had given birth at the North Denmark Regional Hospital from 2008-2018, were identified through their diagnostic codes and invited. Thereby, all potential participants were presented with the possibility to enlist. Furthermore, all women were invited twice. This ensured the enrollment of most possible participants in the given time.

The demographics of the study population showed, no statistically significant difference between the two cohorts when comparing age, smoking habits, BMI and prior surgery, which made the two cohorts comparable, thus strengthening the results. It is also of advantage that the women were able to sit privately without the examiner, when answering the questionnaires, since these concerned very intimate and personal matters. Another strength is the pelvic examinations, which were all performed by the same staff member.

The study is also strengthened due to blinding of the reviewers before assessment of ultrasound imaging. This means that the reviewers were blinded to the cohort belonging, symptoms and clinical presentation of each participant, minimizing risk of bias in the assessment. Lastly, all methods of assessment from the questionnaires to the POP-Q measurement and the EVUS, are well-established and validated, which contributes to the strengthening of the study.

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