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Ingrid Volløyhaug

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Pelvic Floor, Incontinence & Prolapse 15-24 Years after Delivery

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NTNU
Norwegian University of
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Thesis for the Degree of
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Thesis for the Degree of Philosophiae Doctor

Trondheim, June 2016

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Pelvic Floor,

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15-24 Years after Delivery

EXTRA STIFTELSEN

NTNU
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Norwegian Women's Public Health Association

ST. OLAVS HOSPITAL
TRONDHEIM UNIVERSITY HOSPITAL

Image Page 1: detail from “Du sang I” by May Bente Aronsen

Summary

Background: Up to 20% of women in western countries have been subject to surgery for urinary incontinence and pelvic organ prolapse by the age of 85 years, and many receive conservative treatment or do not seek professional health care. Cesarean delivery is associated with lower prevalence, and operative vaginal delivery is associated with increased prevalence of prolapse and incontinence symptoms, but a distinction between forceps and vacuum deliveries has only been made in a few small studies. Pelvic floor muscle trauma, i.e. levator avulsion and increased levator hiatal area demonstrated by ultrasound are risk factors for prolapse. Studies on urogynaecological patients and puerperal women have demonstrated higher prevalence of muscle trauma after forceps, but not after vacuum deliveries. We found no previous studies addressing a difference in anatomical prolapse between forceps and vacuum deliveries. There is a lack of studies on women from the normal population on the association between muscle trauma and symptoms and signs of prolapse. Palpation and perineometry are used to assess pelvic floor muscle contraction, but there is a lack of a gold standard to assess muscle contraction.

Aims: To study the prevalence of symptoms and signs of prolapse, urinary and fecal incontinence and pelvic floor muscle trauma among women from the normal population 15-24 years after delivery in association to delivery mode. Define a scale to measure pelvic floor muscle contraction with ultrasound.

Methods: We conducted a cross sectional study among parous women from the normal population that had delivered their first child at Trondheim University Hospital between 1990 and 1997, when doctors were equally trained in vacuum and forceps. A total of 1641 women responded to a postal questionnaire regarding symptoms of prolapse and incontinence and 608 women were examined with grading of prolapse, 4D transperineal ultrasound for the diagnosis of pelvic floor muscle trauma, and assessment of pelvic floor muscle contraction by palpation, perineometry and ultrasound.

Main results: Paper I: Cesarean delivery was associated with decreased risk and operative vaginal delivery with increased risk of prolapse and incontinence symptoms. There was no difference between forceps and vacuum delivery. Paper II: Cesarean delivery had decreased risk for prolapse stage 2 or surgery and for levator avulsion, and smaller hiatal areas compared to normal delivery. Forceps had increased risk for prolapse stage 2 or surgery and for levator avulsion, and larger hiatal areas compared to vacuum and normal vaginal delivery. There was no difference between vacuum and normal delivery. Paper III: Many women from the normal population had symptoms and signs of prolapse 15-24 years after first delivery, and pelvic floor muscle trauma was associated with symptoms and signs of prolapse. Paper IV: We found moderate to strong correlation between ultrasound measurements and palpation and perineometry for assessment of pelvic floor muscle contraction. The proportional change in anteroposterior levator hiatal diameter was the ultrasound measurement with strongest correlation to palpation and perineometry. We defined a contraction scale for ultrasound measurements based on the proportional change in anteroposterior diameter.

Conclusion: There was no difference in prevalence of prolapse and incontinence symptoms between forceps and vacuum deliveries. There was more pelvic floor muscle trauma and anatomical prolapse after forceps than vacuum deliveries. The association between pelvic floor muscle trauma and symptoms and signs of prolapse was confirmed in women from a normal population.

There was a moderate to strong correlation between palpation, perineometry, and ultrasound assessment of pelvic floor muscle contractions. We defined a four-point contraction scale using the proportional change in anteroposterior levator hiatal diameter on ultrasound, which can form the basis for a validation of a contraction scale for ultrasound measurements.

Sammendrag

Bakgrunn: Opp mot 20% av kvinner i den vestlige verden har gjennomgått kirurgi for urininkontinens eller descens ved fylte 85 år, og enda flere behandles konservativt, eller de søker ikke legehjelp. Keisersnitt er asossiert med lavere forekomst og operativ vaginal fødsel er assosiert med økt risiko for symptomer på descens og inkontinens, men det er ikke undersøkt for forskjell mellom tang og vakuum i tidligere studier. Skader på bekkenbunnsmuskulaturen, dvs. levatoravrivning og økning i levator hiatusareal som diagnostiseres ved ultralyd, er risikofaktorer for descens. Studier blant urogynekologiske pasienter og kvinner postpartum har vist høyere forekomst av avrivningsskader og større hiatusareal etter tang, men ikke etter vakuumfødsler. Det har ikke vært undersøkt om det er økt forekomst av descens etter tang sammenliknet med vakuum. Det mangler studier på sammenheng mellom bekkenbunnsmuskelskader og symptomer og tegn på descens hos kvinner fra normalbefolkningen. Palpasjon og perineometri brukes for å måle bekkenbunnskontraksjon, men det mangler en gullstandard for å undersøke kontraksjon.

Mål: Studere forekomst av descens, urin- og avføringsinkontinens og bekkenbunnsmuskelskader hos kvinner fra normalbefolkningen 15-24 år etter fødsel i assosiasjon til forløsningsmetode. Definere en skala for å måle bekkenbunnskontraksjon med ultralyd.

Metode: Vi gjennomførte en tverrsnittstudie av kvinner fra normalbefolkningen som hadde født sitt første barn ved St. Olavs Hospital i perioden 1990-97, da obstetrikere var like godt trenet i både tang og vakuum. Totalt 1641 kvinner svarte på et spørreskjema om symptomer på descens og inkontinens, og 608 kvinner ble undersøkt med gradering av descens, 4D ultralydundersøkelse for diagnose av bekkenbunnsmuskelskade, og gradering av muskelkontraksjon med palpasjon, perineometri og ultralyd.

Hovedresultater: Artikkel I: Keisersnitt var assosiert med redusert risiko og operativ vaginal fødsel med økt risiko for symptomer på descens og inkontinens. Det var ingen forskjell mellom tang og vakuum. Artikkel II: Keisersnitt hadde redusert risiko for descens grad 2 eller kirurgi, levatoravrivning, og mindre hiatusareal sammenliknet med normal fødsel. Tang hadde økt risiko for descens grad 2 eller kirurgi, levatoravrivning, og større hiatusareal enn vakuum og normal vaginal fødsel. Det var ingen forskjell mellom vakuum og normalfødsel. Artikkel III: Mange kvinner fra normalbefolkningen hadde symptomer og tegn på descens 15-24 år etter første fødsel, og bekkenbunnsmuskelskade var assosiert med symptomer og tegn på descens. Artikkel IV: Vi fant moderat til sterk korrelasjon mellom ultralydmål og palpasjon og perineometri for mål av bekkenbunnskontraksjon. Prosentvis endring i anteroposterior levatorhiatus diameter var ultralydmålet som hadde sterkest korrelasjon med palpasjon og perineometri. Vi definerte en kontraksjonsskala for ultralydmål basert på prosentvis endring i anteroposterior levator diameter.

Konklusjon: Det var ingen forskjell i forekomst av symptomer på descens og inkontinens mellom tang og vakuum. Det var mer bekkenbunnsmuskelskader og objektivt descens etter tang enn etter vakuum og normal fødsel. Sammenhengen mellom bekkenbunnsmuskelskader og symptomer og tegn på descens ble bekreftet hos kvinner fra normalbefolkningen 15-24 år etter fødsel.

Det var moderat til sterk korrelasjon mellom palpasjon, perineometri og ultralyd for mål av bekkenbunnskontraksjon. Vi definerte en kontraksjonsskala for prosentvis endring i levator anteroposterior diameter som kan være grunnlag for å validere en kontraksjonsskala for ultralydparametre.

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Contents

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ST. OLAVS HOSPITAL
TRONDHEIM UNIVERSITY HOSPITAL

Trondheim, December 2015,
Ingrid Volløyhaug

List of papers

Paper I

Volløyhaug I, Mørkved S, Salvesen Ø, Salvesen K.

Pelvic organ prolapse and incontinence 15-23 years after first delivery: a cross-sectional study.

BJOG. 2015 Jun;122(7):964-71. DOI: 10.1111/1471-0528.13322. Epub 2015 Feb 16.

Paper II

Volløyhaug I, Mørkved S, Salvesen Ø, Salvesen KÅ.

Forceps is associated with increased risk of pelvic organ prolapse and muscle trauma: a cross-sectional study 16-24 years after first delivery.

Ultrasound Obstet Gynecol. 2015;46(4):487-95. DOI: 10.1002/uog.14891. Epub 2015 Apr 29.

Paper III

Volløyhaug I, Mørkved S, Salvesen KÅ.

Association between pelvic floor muscle trauma and pelvic organ prolapse 20 years after delivery.

Int Urogynecol J. 2016;27(1):39-45. DOI 10.1007/s00192-015-2784-8. Epub 2015 Jul 22.

Paper IV

Volløyhaug I, Mørkved S, Salvesen Ø, Salvesen KÅ

Assessment of pelvic floor muscle contraction with palpation, perineometry and transperineal ultrasound: a cross-sectional study.

Ultrasound Obstet Gynecol. DOI: 10.1002/uog.15731. Epub 2015 Aug 24.

Abbreviations

2D	Two dimensional
3D/4D	Three dimensional/ four dimensional
AI	Anal incontinence
ANCOVA	Analysis of covariance
AP	Anteroposterior
BMI	Body mass index
CD	Cesarean delivery
CI	Confidence interval
CRADI	Colorecatal-anal distress inventory
EMG	Electromyography
FD	Forceps delivery
FI	Fecal incontinence
MD	Mean difference
aMD	Adjusted mean difference
uMD	Unadjusted mean difference
MOS	Modified Oxford scale
MRI	Magnetic resonance imaging
NVD	Normal vaginal delivery
OASIS	Obstetric anal sphincter injuries
OR	Odds ratio
aOR	Adjusted odds ratio
cOR	Crude odds ratio
OVD	Operative vaginal delivery
PFD	Pelvic floor disorders
PFDI	Pelvic floor distress inventory
PFIQ	Pelvic floor impact questionnaire
PFMT	Pelvic floor muscle trauma
POP	Pelvic organ prolapse
sPOP	Symptomatic pelvic organ prolapse
POPDI	Pelvic organ prolapse distress inventory

POP-Q	Pelvic organ prolapse quantification
POP-Q≥ 2	Pelvic organ prolapse equal to or larger than stage two
SD	Standard deviation
UI	Urinary incontinence
SUI	Stress urinary incontinence
UUI	Urge urinary incontinence
UDI	Urinary distress inventory
VD	Vacuum delivery

1 Introduction

I started working in the field of urogynecology in 2007 and learned how to examine urogynecological patients and treat urinary incontinence and pelvic organ prolapse with conservative treatment and with surgery. I soon realized that there is no "easy fix" for prolapse and incontinence. Many women do not have the desired effect of conservative treatment such as physiotherapy, ring pessaries and medication. Recurrence after surgery is common, in particular after prolapse surgery, where up to 20-30% of patients need more than one procedure. This made me reflect that prevention of prolapse and incontinence must be better than treatment of a condition that has already occurred. What causes prolapse and incontinence? I knew some obstetrical factors such as parity and vaginal delivery, and also some non-obstetrical factors such as high body mass index (BMI), heredity, heavy lifting and menopause could be risk factors for pelvic floor disorders and pelvic organ prolapse.

Among obstetricians and gynecologists there had been much focus on instrumental vaginal deliveries and episiotomies in relation to obstetric anal sphincter injuries, as sphincter tearis one of the main risk factors for anal and fecal incontinence later in life. A common argument was that "It is not the forceps doing the damage, it is the monkey on the other side", which was used to argue that doctors should get more training in forceps deliveries to prevent sphincter trauma to occur. There was never any concern about the Levator ani musculature or future pelvic organ prolapse and urinary incontinence, despite these conditions being more frequent than fecal incontinence.

I got the opportunity to be a visiting scholar at the Sydney Medical School Nepean, Nepean Hospital, Penrith, Australia for 5 weeks in October/ November 2011. I learned pelvic floor ultrasound in a very inspiring environment from Professor Dietz and his co-workers, who have developed this technique. After five weeks I had many new questions that I was eager to find the answer to. During 2012 I developed the protocol for this project, and hoped to find answers to some of my questions:

- Does forceps cause more trauma than vacuum to the pelvic floor?
- Do women have more prolapse symptoms and incontinence after forceps than after vacuum delivery?
- Do women have more anatomical prolapse after forceps than after vacuum delivery?

- Do we find the same associations between pelvic floor muscle trauma and symptoms and signs of prolapse in women from the normal population as we do in urogynecological patients?

We had a good opportunity to study women who delivered their first child at Trondheim University Hospital from 1990-97, when doctors were equally trained in both methods.

Assessment of pelvic floor muscle contraction is important in the evaluation of the urogynecological patient. Palpation depends on the experience of the examiner and perineometry is influenced by the placement of the probe and by increased abdominal pressure. Previous studies had demonstrated that ultrasound could be used to assess muscle contraction. One idea was therefore: Can we define an ultrasound scale for measurement of pelvic floor contraction as a more objective measurement of pelvic floor muscle contraction?

The following pages describe the project that was conducted to address these questions.

2 Background

2.1 The female pelvic floor – functional anatomy

2.1.1 Anatomy

The female pelvic floor provides a functional support for the urinary tract, female genital tract and the rectum. The bony structures, connective tissue and muscles of the pelvic floor interact to provide this functional support [1]. The function of the muscles is to provide resting tone, contraction and relaxation. Pelvic floor muscle resting tone and contraction are important components of the mechanism that prevents descent of the pelvic organs and maintains continence [1-8]. Relaxation is also important, in order to favour micturition, defecation and parturition.

Bone: A natural lordosis of the spine forces the pelvic organs towards the symphysis. The bony pelvis provides attachment for muscles and fascia. The female pelvis has a wider diameter and a more circular shape than the male pelvis, facilitating parturition, but also predisposing to subsequent pelvic floor weakness [1].

Connective tissue: The uterosacral and cardinal ligaments are strong condensations of connective tissue that support the uterus and apex of the vagina [5, 9]. The pubocervical (vesico-vaginal) fascia provides lateral attachment of the middle part of the vagina, preventing cystocle, and the rectovaginal fascia, in the lower part of the vagina, prevents rectocele [9].

Pelvic floor muscles: The levator ani muscle complex provides a firm, but elastic base for the pelvic organs [5]. The most median part of the levator ani, immediately surrounding the urethra, vagina and rectum, is referred to as the Puborectalis or Pubococcygeus muscle, see Figure 1. This part of the muscle provides a firm muscular closure of the pelvic outlet or urogenital hiatus, preventing descense of the pelvic organs [7]. The superficial perineal muscles (M. Bulbocavernosus, M. Transversus perinei) support the distal part of the vagina. The superficial perineal muscles fuse with the external anal sphincter to form the perineal body, which is a fibromuscular structure in the midline between the anus an the vagina providing support to the distal part of the posterior vaginal wall [1], see Figure 1.

Levator hiatus: The levator hiatus, or urogenital hiatus, is the opening in the pelvic floor muscles that is traversed by the urethra, vagina and anorectum [1]. It is the largest potential hernia portal in the body. The puborectalis muscle, which forms the inner border of the hiatus, is a curved sling, and therefore the levator hiatus has a warped shape [10], see Figure 2.

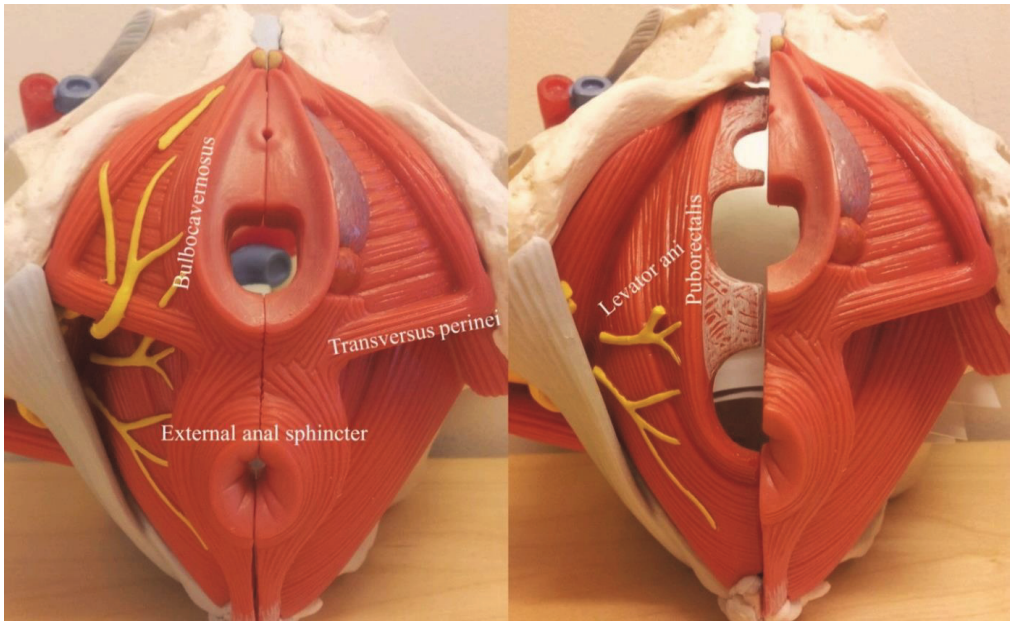


Figure 1 *Pelvic floor muscles. The photo to the left demonstrates the superficial muscle layer: Bulbocavernosus, Transversus perinei and external anal sphincter. In the photo to the right, the superficial muscles have been removed to visualize the deep muscle layer: Levator anii with Puborectalis.*
Photo of a female pelvis model from 3B Scientific® by Volløyhaug.

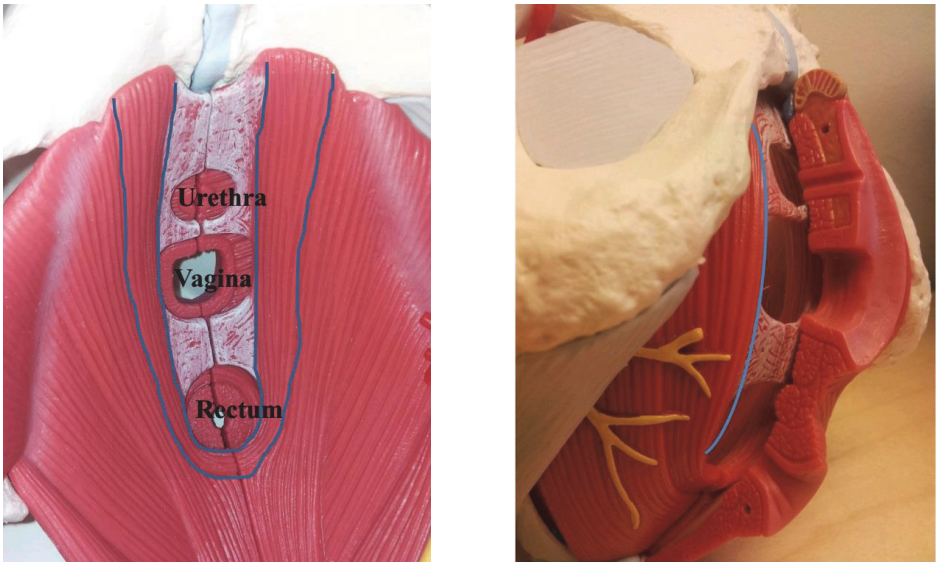


Figure 2 *Levator hiatus. The levator hiatus, or urogenital hiatus, is the opening in the pelvic floor muscles that is traversed by the urethra, vagina and anorectum. In the photo to the left the Puborectalis muscle is outlined in blue. In the photo to the right, the curved shape of the puborectalis muscle is demonstrated with the blue line.*
Photo of a female pelvis model from 3B Scientific® (Volløyhaug).

Nerves: The S2-4 segments of the spinal cord provide a direct innervation of the levators, coccygeus and urogenital diaphragm. The S2-4 also fuse to form the N. Pudendalis, which innervates the external anal sphincter [11].

Three levels of vaginal support: DeLancey has described a widely accepted model of three levels of vaginal support [9] (Figure 3): Level I consists of the cardinal and uterosacral ligaments, and suspends the vaginal apex. Level II consists of the endopelvic fascia connections to the arcus tendineus fascia pelvis, which attaches the vagina to the aponeurosis of the levator ani. Level III consists of the perineal body and includes interlacing muscle fibers of the bulbospongiosus, transversus perinei, and external anal sphincter.

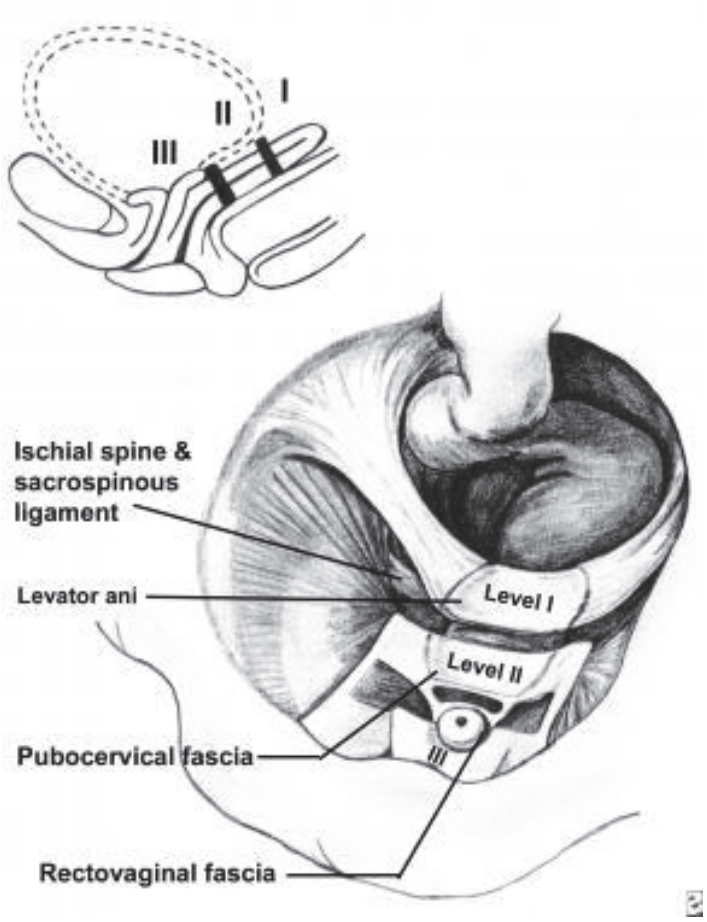


Figure 3 *DeLancey levels of vaginal support*
From: http://img.medscapestatic.com/pi/meds/ckb/30/38130tn.jpg

2.1.2 Examination of pelvic floor muscle anatomy and function

Pelvic floor muscle anatomy, contraction and strength can be assessed by different techniques.

Palpation: Muscle integrity or injury can be palpated at pelvic floor muscle contraction. The Modified Oxford Scale developed by Laycock, is the most commonly used scale for assessment of pelvic floor muscle strength [12] (Table 1). An intact muscle may be difficult to palpate if it cannot contract or is traumatically over-distended. A graded scale for assessment of resting tone was developed by Dietz in concordance with the grades of the Modified Oxford Scale (MOS) [13, 14], (Table 2). Palpation is easy to perform and does not require other diagnostic tool than the examiner's fingers, but interpretation of findings is subject to interrater differences [13].

EMG: Electromyography (EMG) is the study of potentials produced by the depolarization of the muscle membrane. Surface or needle electrodes may be used. Innervation deficits are indicated by abnormal potentials observed in resting or active muscle [15]. Concentric needle EMG and pudendal nerve conduction tests can also be used to diagnose nerve injury [16]. Examination of pudendal neuropathy is technically complex, invasive and difficult to interpret and therefore not used in clinical practice. EMG is measuring recruitment of motor units, and not muscle strength.

Perineometry: The perineometer or manometer is a pneumatic apparatus that registers muscle contraction. Perineometry was originally described by Kegel, who constructed the perineometer specifically for the exercise of birth canal muscles [17]. The perineometer has been used to measure pelvic floor muscle strength [18, 19]. A vaginal balloon is connected to a fiberoptic pressure transducer and measures the vaginal squeeze pressure (Figure 4). Correct measurement by perineometry requires observation of inward/ upward lift of the perineal muscles, but measurements could be biased by concomitant increasing intraabdominal pressure [19].

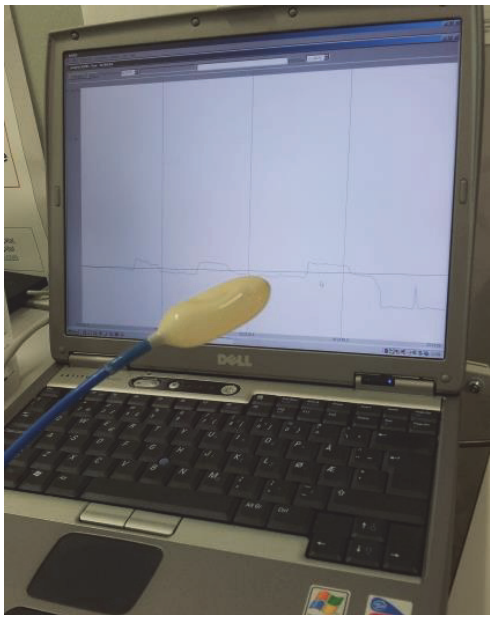


Figure 4 *Perineometer. Vaginal balloon connected to a fiberoptic pressure transducer. Photo by Volløyhaug.*

Table 1 *Modified Oxford Scale for assessment of pelvic floor muscle strength by palpation*

Grade	Description	
0	Nil	Muscle not palpable
1	Flicker	Muscle palpable, but very flaccid, wide hiatus, minimal resistance to distension
2	Weak	Hiatus wide, but some resistance to distension
3	Moderate	Hiatus fairly narrow, fair resistance to palpation but easily distended
4	Good	Narrow hiatus, muscle can be distended, but high resistance to distension, no pain.
5	Strong	Hiatus very narrow, no distension possible, “woody” feel, possibly with pain: “vaginismus”.

Table 2 *Scale for assessment of resting tone by palpation*

Grade	Description	
0	Nil	Lack of any discernible response in the perivaginal muscles
1	Flicker	Fluttering, quivering of the muscles
2	Weak	Contraction which is not fluttering
3	Moderate	Moderate increase in pressure, compressing the examiner’s fingers and incorporating a small degree of lift, as the fingers are moved in a cranial direction
4	Good	Firm contraction causing lifting of the pelvic floor muscles up and against resistance
5	Strong	Very strong grip of the examiner’s finger and positive movement in a cranial direction against strong resistance.

Pelvic floor ultrasound: Imaging of the pelvic floor is usually performed by transperineal ultrasound, with a 3D curved array abdominal transducer placed on the perineum and introitus of the patient. This technique has been developed by Prof. Dietz, and we have used the image orientation suggested by him in the present study [20, 21], see Figure 5.

2D ultrasound can be used to obtain a sagittal view of the symphysis, urinary bladder, urethra, vagina, rectum and posterior aspects of the puborectalis muscle, see Figure 5.

3D/4D ultrasound is used to obtain an ultrasound volume that can be viewed in three sectional planes (sagittal, coronal, transverse /axial) or in a rendered 3D volume, see Figures 6 and 8. The 4th dimension is the time aspect, which are cineloops of 3D volumes.

"The plane of minimal hiatal dimensions" is used as a reference plane, see Figure 6. The sagittal plane is used to identify the inferior edge of the symphysis pubis ventrally and the anorectal angle dorsally, i.e. the shortest distance between the symphysis and the anterior border of the puborectalis muscle as it passes behind the rectum [22]. The corresponding angled axial image, representing the levator or urogenital hiatus, is then used for measurements.

Tomographic ultrasound imaging (TUI): This technique is used to examine for injury to the levator ani in the plane of minimal hiatal dimensions and the planes 2.5 and 5 mm cranial to this [23], see Figure 7. TUI can also be used for imaging of the anal sphincters, See Figure 16.

Rendered imaging: The levator hiatal areas are by convention measured in the plane of minimal hiatal dimension in a rendered volume of 1-2 cm thickness, due to the warped shape of the levator hiatus [24], see Figure 8.

Differences between rest and contraction in levator hiatal areas, diameters and bladder neck shift can be measured by ultrasound, and gives a measure of pelvic floor contraction [25-29], see Figure 24. There is no established scale to quantify contraction by ultrasound. Ultrasound can alo be used to examine the distensibility of the pelvic floor muscles on Valsalva maneuver. Changes in ultrasound measurements between rest and Valsalva maneuver give an indication of distensibility of the muscles [30].

Magnetic Resonance Imaging (MRI): MRI can be used for imaging of hiatal anatomy and dimensions [31]. There is good correlation between ultrasound and MRI measurements [32]. MRI is more expensive, more time consuming and less available in clinical practice.

Pelvic floor muscle contraction and strength can be assessed by different techniques. All techniques have disadvantages, and there is no gold standard [8, 33].

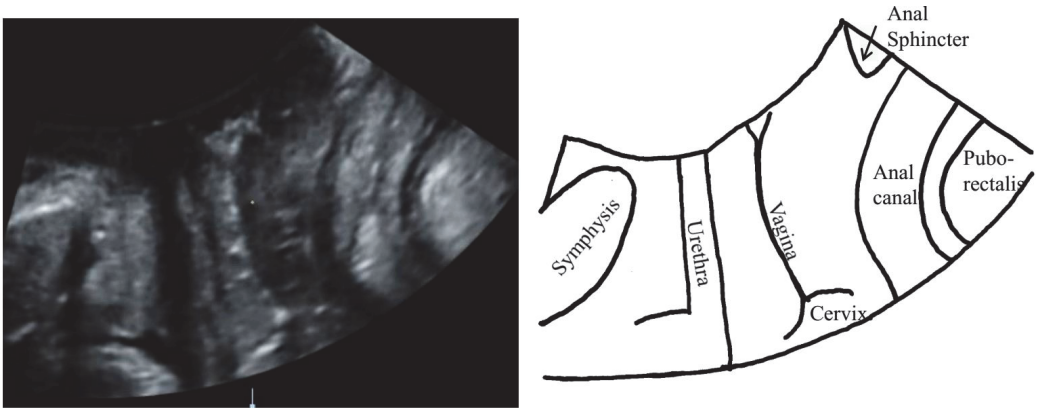


Figure 5 *Two dimensional (2D) sagittal view of the pelvic floor structures. The figure to the right is a schematic drawing of what we see in the ultrasound picture.*
Imaging by Volløyhaug.

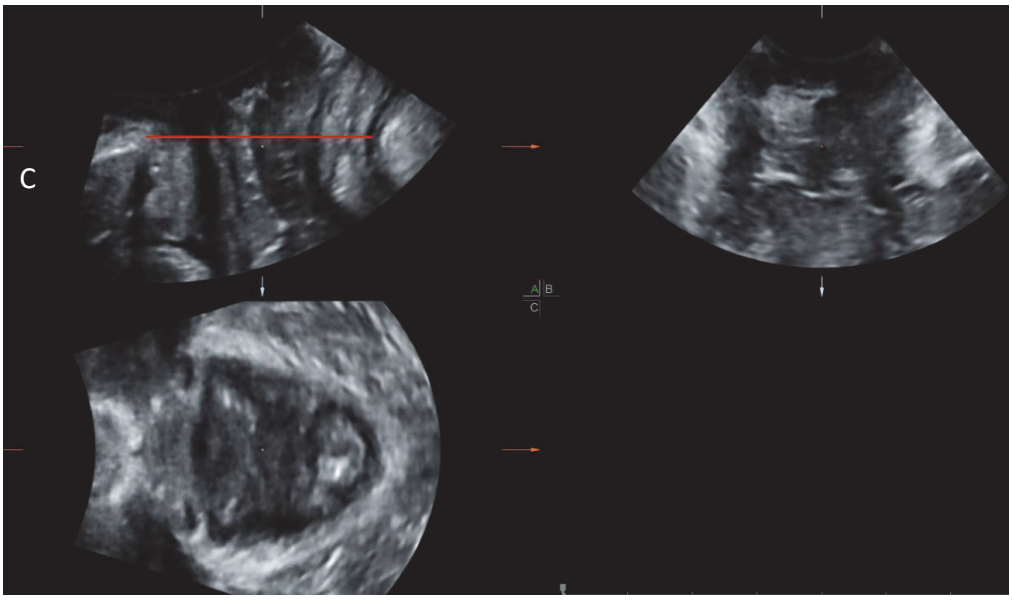


Figure 6 *Three dimensional (3D) imaging, sectional planes. A) Image in the sagittal plane, with horizontal line indicating the plane of minimal hiatal dimension. B) Image in the coronal plane. C) Image in the axial plane.*
Imaging by Volløyhaug.

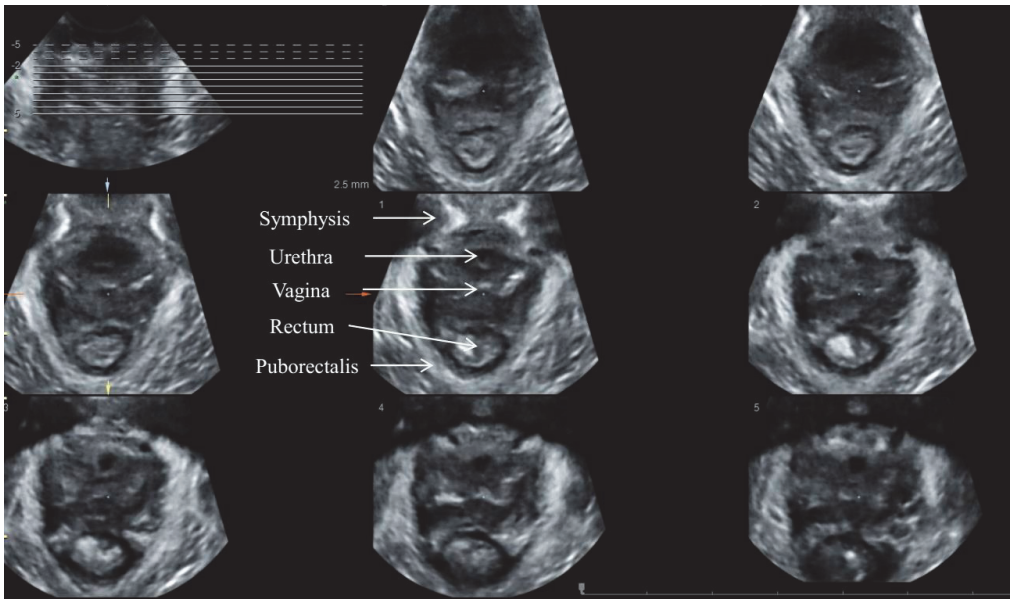


Figure 7 *Tomographic ultrasound imaging (TUI) in the angled axial plane.*
Imaging by Volløyhaug.

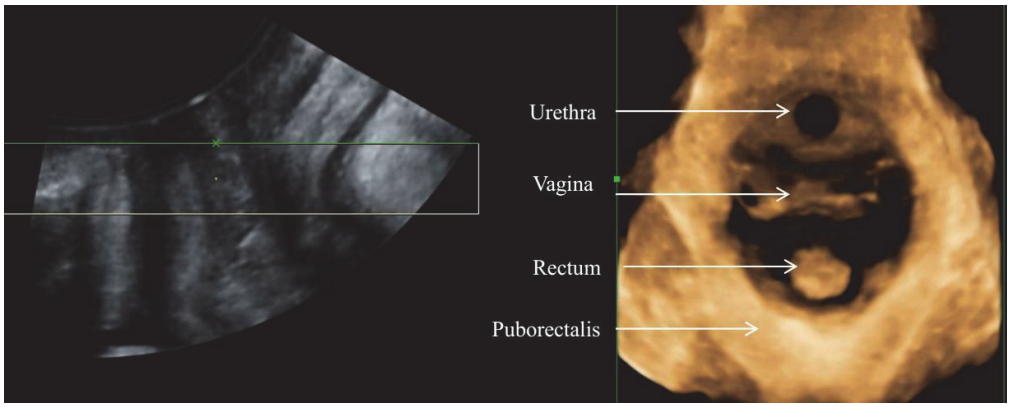


Figure 8 *Rendered image in the angled axial plane to the right.The image to the left demonstrates the 1-2 cm thickness of the rendered image*
Imaging by Volløyhaug.

2.2 Pelvic floor dysfunction

Pelvic floor dysfunction (PFD) or disorders may include clinical conditions such as urinary incontinence, anal/fecal incontinence, pelvic organ prolapse, sensory and emptying abnormalities of the lower urinary tract and defecatory dysfunction [34]. Some authors also include sexual dysfunction and chronic pain syndromes, including vulvodynia [35, 36]. The three most common and definable conditions encountered clinically are urinary incontinence (UI), anal incontinence (AI) (comprising both leakage of stool, fecal incontinence (FI), and gas) and symptomatic pelvic organ prolapse (sPOP) [34, 36]. Overlapping of symptoms of two or three conditions is common [37-39].

Diagnosis: In clinical practice there is a wide variety of algorithms to classify and quantify PFD, which comprises more or less structured questions and clinical examinations. The International Urogynecological Association (IUGA) and the International Continence Society (ICS) have produced a joint report on the terminology on female pelvic floor dysfunction [35], which includes over 250 separate definitions. For research purposes, it is important to indicate which diagnostic criteria have been used. Many investigators have defined their own diagnostic criteria based on questionnaires or single questions. The ideal is to use a validated tool for diagnosis (and quantification) of PFD.

In Norway the **severity index** has been validated for diagnosing UI [40]. The severity index has also been validated against international questionnaires for UI [41]. For AI/FI, the **St. Marks score** has been used in previous studies also in Norway [42]. A symptom–bother questionnaire for sPOP concerning frequency of mechanical, bladder, bowel and sexual problems was developed in Denmark by **Mouritsen et al** , and has been used in previous studies in Norway [43]. The scales referred above are scales used for diagnosis of single PFDs. There are few diagnostic systems that provide a series of questionnaire modules to assess pelvic problems with validated international standard questionnaires for lower urinary tract dysfunction, vaginal symptoms and lower bowel dysfunction. One such system is the **International Consultation on Incontinence Modular Questionnaire** (ICIQ), which comprises questionnaire modules for POP, UI and FI [44-46]. Only the UI part has been validated for use in Norway [41]. Another system, which seems to be more widely used, is the **Pelvic floor distress inventory** (PFDI), comprising subscales for prolapse (POPDI), urinary- (UDI) and anal/fecal incontinence and bother (CRADI) and the **Pelvic Floor Impact Questionnaire** (PFIQ) [47]. This has previously been used by other Norwegian investigators, and is currently being validated for use in Norway. The PFDI has been developed in women with pelvic floor disorders and not in women from the normal population.

Prevalence: Estimates of the prevalence of PFD varies widely depending on definitions, epidemiological method used and study population [36]. The prevalence is reported to be 3-12% for sPOP, 15-35% for UI and 3-14% for FI [37-39, 48-51].

2.3 Pelvic organ prolapse

Pelvic organ prolapse (POP) is defined as a downward descent of the pelvic organs that results in a protrusion of the vagina and or uterus [52]. Figure 9 and 10 illustrate different types of prolapse. Commonly used terms to describe specific sites of female genital prolapse include [53]:

Anterior compartment prolapse: Herniation of the anterior vaginal wall. This is usually associated with descent of the urinary bladder (cystocele).

Posterior compartment prolapse: Herniation of the posterior vaginal wall. This is often associated with descent of the rectum (rectocele) or an enterocele, hernia of the intestines, through the vaginal wall.

Apical or middle compartment prolapse: Descent of the apex of the vagina into the lower vagina, to the hymen, or beyond the vaginal introitus. The apex can be both the uterus and cervix, the cervix alone, or the vaginal vault after previous hysterectomy. Apical prolapse is often associated with enterocele.

Uterine procidentia: Complete herniation of the uterus, and of all three compartments through the vaginal introitus.

The terms anterior vaginal wall prolapse and posterior vaginal wall prolapse are preferred to cystocele and rectocele because vaginal topography does not reliably predict the location of the associated viscera in POP [53, 54].

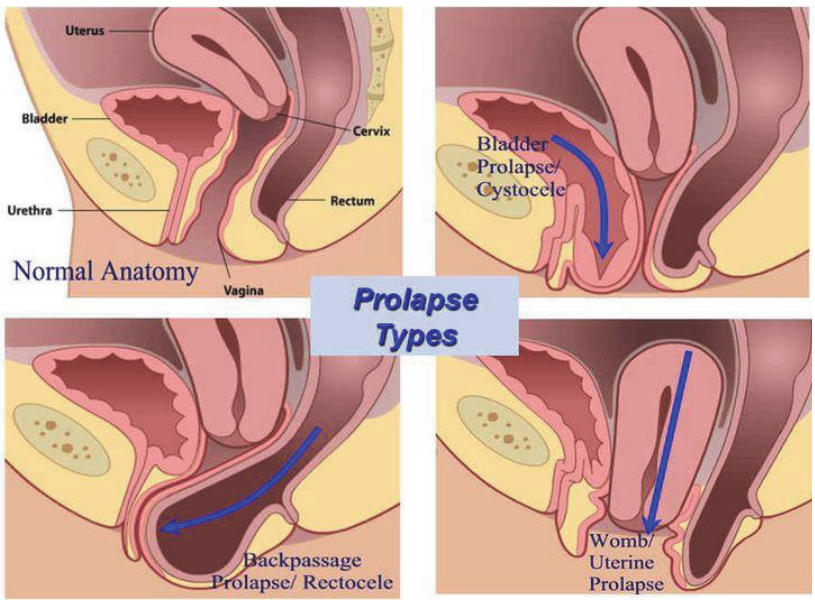


Figure 9 *Schematic illustration of different types of prolapse.*

From: http://www.bendandmend.com.au/physiotherapy/pop-pelvic-organ-prolapse/

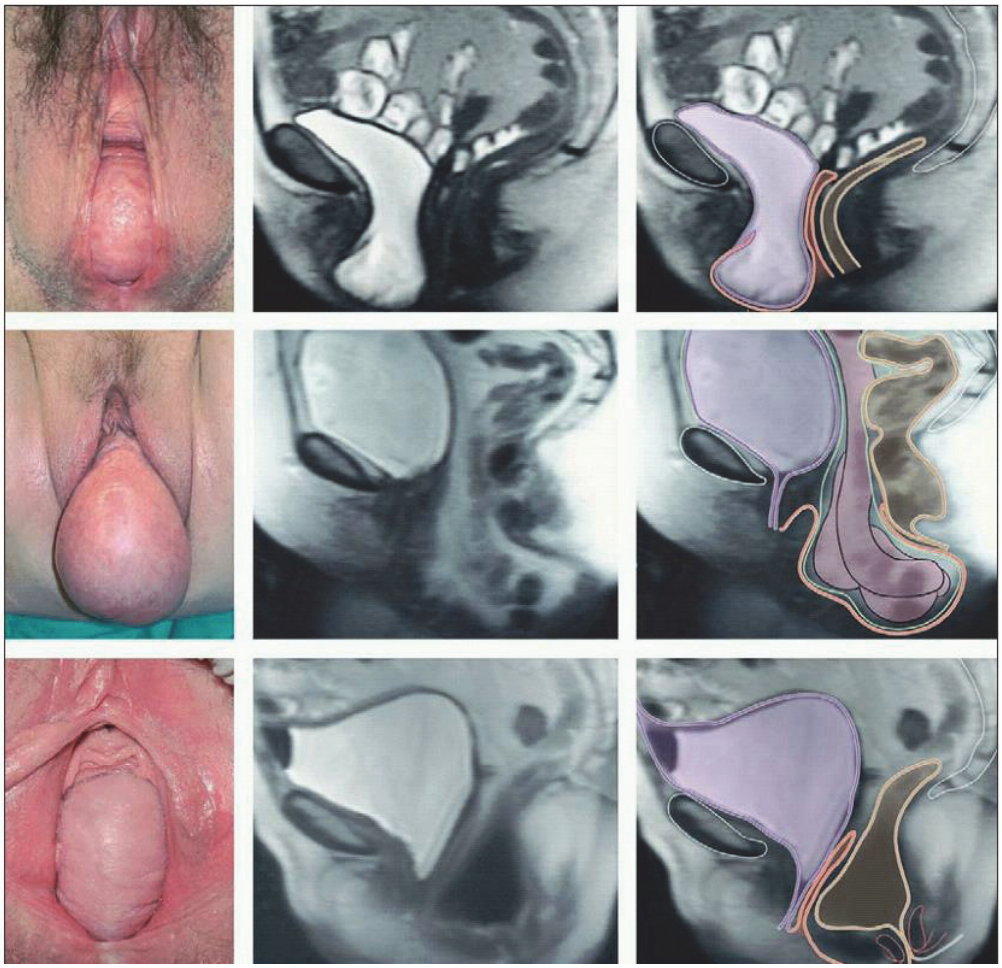
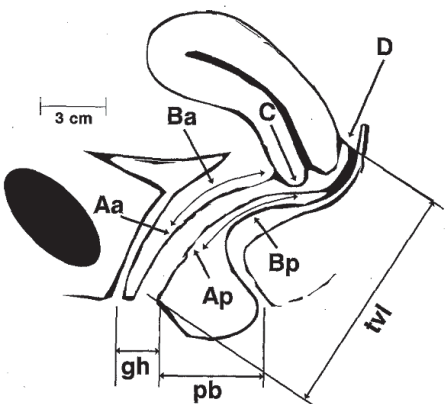


Figure 10 *Photographs in lithotomy position and sagittal MRI showing vaginal-wall prolapse. Prolapse might include (top to bottom): bladder (cystocele), small bowel (enterocele), or rectum (rectocele). Colour codes include purple (bladder), orange (vagina), brown (colon and rectum), and green (peritoneum).*
From Jelovsek et al 2007: Pelvic organ prolapse, with permission from Elsevier

Diagnosis: Since 1996 there has been a standardization of terminology of POP quantification (POP-Q) [53]. This standardized terminology requires the description of six points (two on the anterior vaginal wall, two in the superior vagina, and two on the posterior vaginal wall) with reference to the plane of the hymen, thus a quantification of prolapse at straining in each compartment separately, see Table 3 and Figure 11. Positions are expressed as centimeters above or proximal to the hymen (negative number) or centimeters

below or distal to the hymen (positive number) with the plane of the hymen being defined as zero. In addition to the points in the vagina, three lengths are measured (Table 3 and figure 6).

POP-Q provides a staging of POP according to the most severe portion of the prolapse when the full extent of protrusion is demonstrated: Stage 0 (no prolapse demonstrated), stage 1 (most distal part of the prolapse >1 cm above the hymen) stage 2 (most distal part of the prolapse ≤1 cm above or below the plane of the hymen), stage 3 (most distal part of the prolapse >1 cm below the hymen) and stage 4 (complete eversion of the vagina and uterus).



anterior wall **Aa**	anterior wall **Ba**	cervix or cuff **C**
genital hiatus **gh**	perineal body **pb**	total vaginal length **tvl**
posterior wall **Ap**	posterior wall **Bp**	posterior fornix **D**

Figure 11 *Six points (Aa, Ba, C, D, Ap, Bp) and three lengths (gh, pb, tvl) measured for pelvic organ prolapse quantification.*
From Bump et al 1996: The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction, with permission from Elsevier.

Prevalence: The prevalence of anatomical prolapse depends on the definition used. Commonly used definitions for significant prolapse are prolapse to or beyond the plane of the hymen [55] or prolapse stage 2, which also includes prolapses that descend to 1 cm above the hymen [56]. The prevalence is reported to vary between 2-63% in different populations [55-59]. Cystocele is most frequent, followed by rectocele and uterine prolapse [59].

Table 3 *Points and measurements included in the standardized terminology of pelvic organ prolapse quantification (POP-Q)*

Two points are on the *anterior vaginal wall*	
Aa	A point located in the midline of the anterior vaginal wall 3 cm proximal to the external urethral meatus. By definition, the range of position of point Aa relative to the hymen is -3 to +3 cm
Ba	A point that represents the **most distal position** of any part of the upper anterior vaginal wall from the vaginal cuff or anterior vaginal fornix to point Aa. By definition, point Ba is at -3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff in women with total posthysterectomy vaginal eversion
Two points are in the *superior vagina*. These points represent the most proximal locations of the normally positioned lower reproductive tract	
C	A point that represents either the most distal edge of the **cervix** or the leading edge of the **vaginal cuff** (hysterectomy scar) after total hysterectomy
D	A point that represents the location of the **posterior fornix** (or pouch of Douglas) in a woman who still has a cervix.
Two points are on the *posterior* vaginal *wall*	
Bp	A point that represents the **most distal position** of any part of the upper posterior vaginal wall from the vaginal cuff or posterior vaginal fornix to point Ap. By definition, point Bp is at-3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff in a woman with total posthysterectomy vaginal eversion.
Ap	A point located in the midline of the posterior vaginal wall 3 cm proximal to the hymen. By definition, the range of position of point Ap relative to the hymen is -3 to +3 cm
Three lengths are measured	
Gh	Length of the **genital hiatus** from urethra to posterior border of hymen expressed in cm
pb	Length of the **perineal body** from posterior border of hymen to the anus expressed in cm
tvl	**Total vaginal length** measured from the posterior fornix or vaginal cuff to the hymen

Symptoms: Many women with anatomical prolapse are asymptomatic. The most common and most specific symptom of prolapse is a sensation of pelvic pressure/ heaviness or seeing/ feeling a protrusion of tissue from the vagina [52]. The proportion of women reporting symptom of vaginal bulge increases with increasing prolapse grade [60]. Other typical, but not specific, symptoms of POP are urinary tract symptoms and symptoms related to bowel function, listed in Table 4 [52, 53]. Symptoms do not necessarily correlate with compartment-specific defects, and increasing severity of pelvic organ prolapse is weakly to moderately associated with symptoms that are related to urinary incontinence and voiding, defecatory, and sexual dysfunction [61, 62]. Common symptoms related to pelvic organ prolapse are listed in Table 4.

Table 4 *Symptoms related to pelvic organ prolapse*

Vaginal symptoms
Seeing and or feeling a vaginal bulge
Pelvic pressure and heaviness
Urinary tract symptoms
Incontinence
Frequency
Urgency
Weak or prolonged urinary stream
Hesitancy
Feeling of incomplete emptying
Manual reduction of prolapse to start or complete voiding
Position change to start or complete voiding
Bowel symptoms
Incontinence of flatus, or liquid or solid stool
Feeling of incomplete emptying
Straining during defecation
Urgency to defecate
Digital evacuation to complete defecation
Splinting, pushing on or around the vagina/perineum, to start or complete defecation
Feeling of blockage or obstruction during defecation
Sexual symptoms
Dyspareunia
Mechanical problems

2.4 Pelvic floor muscle trauma

Three major groups of pelvic floor muscle trauma (PFMT) are described: Macrotrauma /levator avulsion, levator microtrauma and obstetric anal sphincter injuries (OASIS).

2.4.1 Macrotrauma - levator avulsion

Levator avulsion is defined as an injury to the inferomedial aspects of the pubovisceral/puborectalis muscle, that is a detachment of this muscle from its insertion on the arcus tendineus fasciae pelvis, see Figure 12 [63, 64].

Levator avulsion was first described by Gainey in 1943, and originally diagnosed by palpation [65]. In some cases it is possible to diagnose levator avulsions by inspection and palpation immediately after delivery [66], but a tear of the puborectalis muscle does not necessarily involve injury to the vaginal mucosa, and is therefore usually not detected immediately after delivery [66]. An avulsion injury can be unilateral or bilateral, complete or incomplete. Levator avulsion can be diagnosed by ultrasound using the TUI mode or on MRI [23, 64, 67, 68], see Figure 13 and 14. When, on 3D ultrasound, all three central slices (in the plane of minimal hiatal distension and 2.5-5.0 mm cranial to this) on TUI show abnormal muscle insertion, the levator avulsion is defined as *complete*, see Figure 13. Measurement of the levator-urethral gap can be used when there is doubt about avulsion diagnosis, as it has been demonstrated that a distance >25 mm between the center of the urethra and the levator insertion on the symphysis is strongly associated with levator avulsion [69]. It is also possible to use palpation to detect avulsion several years after delivery [67], and a measurement of Gh + Pb >8.5cm could help identify women with levator avulsion [70].

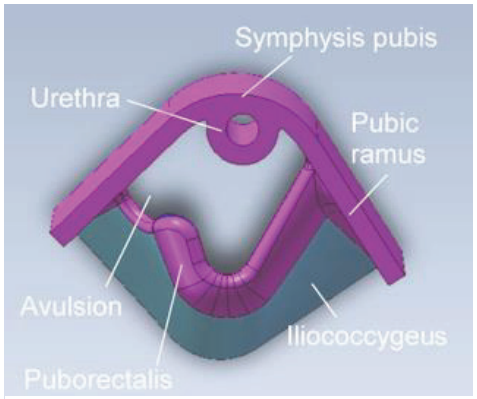


Figure 12 *Schematic illustration of levator avulsion.*
From: http://sydney.edu.au/medicine/nepean/research/obstetrics/pelvic-floor-assessment/Pelvic_Floor_Assessment/Klinische_Untersuchung_des_Levator_Ani.html

Prevalence: The prevalence of levator avulsion is different after different modes of delivery. It does not occur after Cesarean delivery (CD). The prevalence is 6-20% after Normal vaginal delivery (NVD) [71, 72], 9-41% after Vacuum delivery (VD) [71, 73] and 35-89% after forceps delivery (FD) [71, 73].

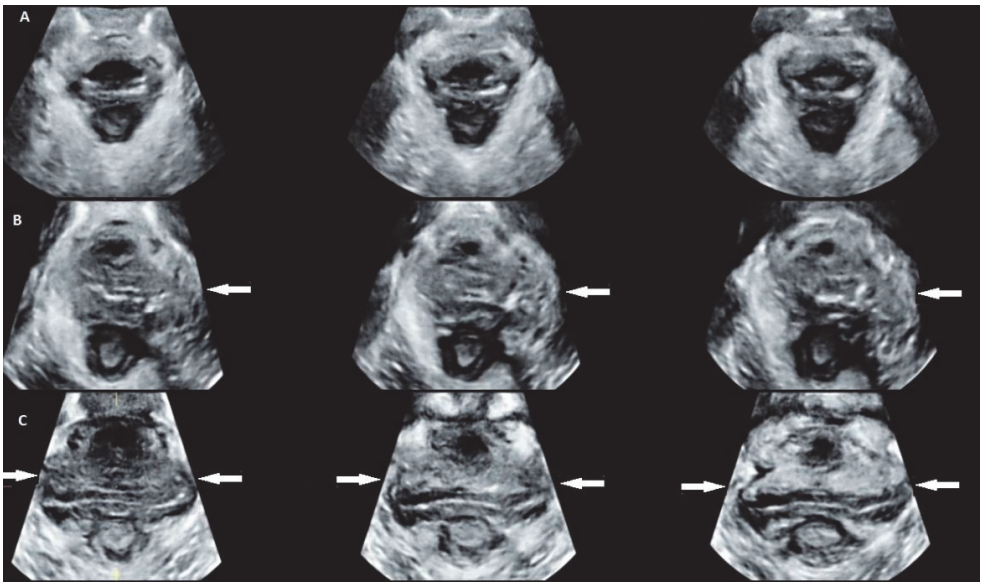


Figure 13 *Tomographic Ultrasound Imaging. Levator avulsion is indicated by arrow. A) Intact levator, B) unilateral and C) bilateral avulsion in the three central planes on ultrasound.*
From Volløyhaug et al 2015: Forceps is associated with increased risk of pelvic organ prolapse and muscle trauma, with permission from John Wiley and sons. Copyright © 2015 ISUOG.

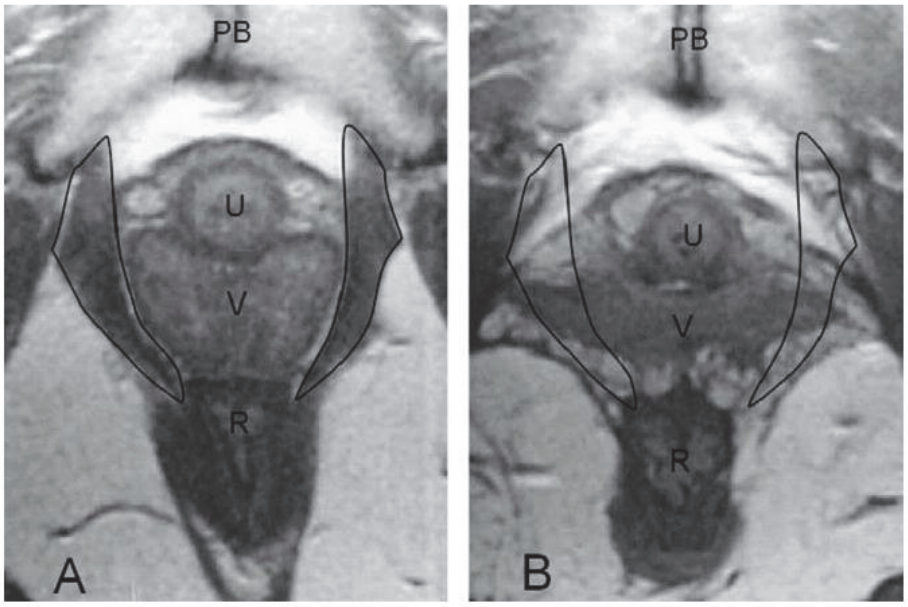


Figure 14 *Axial Magnetic Resonance Image on left shows normal pubococcygeal muscle with the muscle outlined at the level of the midurethra. On the right is a similar image from a woman with complete loss of the pubococcygeal muscle (expected location of pubococcygeal muscle shown by outline).*
From DeLancey 2005: The hidden epidemic of pelvic floor dysfunction: Achievable goals for improved prevention and treatment, with permission from Elsevier. Copyright © 2005 Elsevier

2.4.2 Microtrauma and abnormal distensibility

Diagnosis of microtrauma and abnormal distensibility of the levator hiatus requires examination of the patient when performing a Valsalva maneuver, i.e. preforming a moderately forceful exhalation against a closed airway with simultaneous relaxation of the pelvic floor with a minimum of 6s duration [74].

Levator microtrauma is defined as >20% increased hiatal area on Valsalva after delivery on ultrasound [73], and examination of women both prior to and after delivery is necessary.

Diagnosis of abnormal distensibility has been described as "ballooning" of the levator hiatus at Valsalva on ultrasound, and requires examination at only one time point [75]. A hiatal area on Valsalva of 25–29.9 cm^2 has been defined as 'mild', 30– 34.9 cm^2 as 'moderate', 35–39.9 cm^2 as 'marked' and ≥ 40 cm^2 as 'severe' ballooning or overdistention [75].

Both definitions describe increased distensibility of the levator hiatus, either in relation to a previous measure in the same individual, or to a reference population. A levator avulsion contributes to increased levator hiatal area, but women can have increased hiatal areas without levator avulsion [30]. Figure 15 demonstrates the difference in levator hiatal areas at rest, contraction and Valsalva in three different women: one with intact levator, one with unilateral avulsion and one with bilateral avulsion.

MRI can also be used to measure levator hiatal areas [32]. An easier way to diagnose, but not quantify, overdistension is by palpation of a wide hiatus, or by measuring the Gh+Pb distance at Valsalva, where a cutoff of 7 cm for Gh+Pb has been proposed as a clinical definition of excessive levator hiatal distensibility [76].

Prevalence: The prevalence of hiatal overdistension depends on the cutoffs used, and in the litterature hiatal areas are usually described as continuous variables. When applying >20% peripartum increase in hiatal area on Valsalva as the cutoff, 29% of vaginally parous women were diagnosed with irreversible overdistension in a previous study [73]. By applying cut offs for ballooning previously established, 12% had mild ballooning and 4% had severe ballooning of the levator hiatus [75].

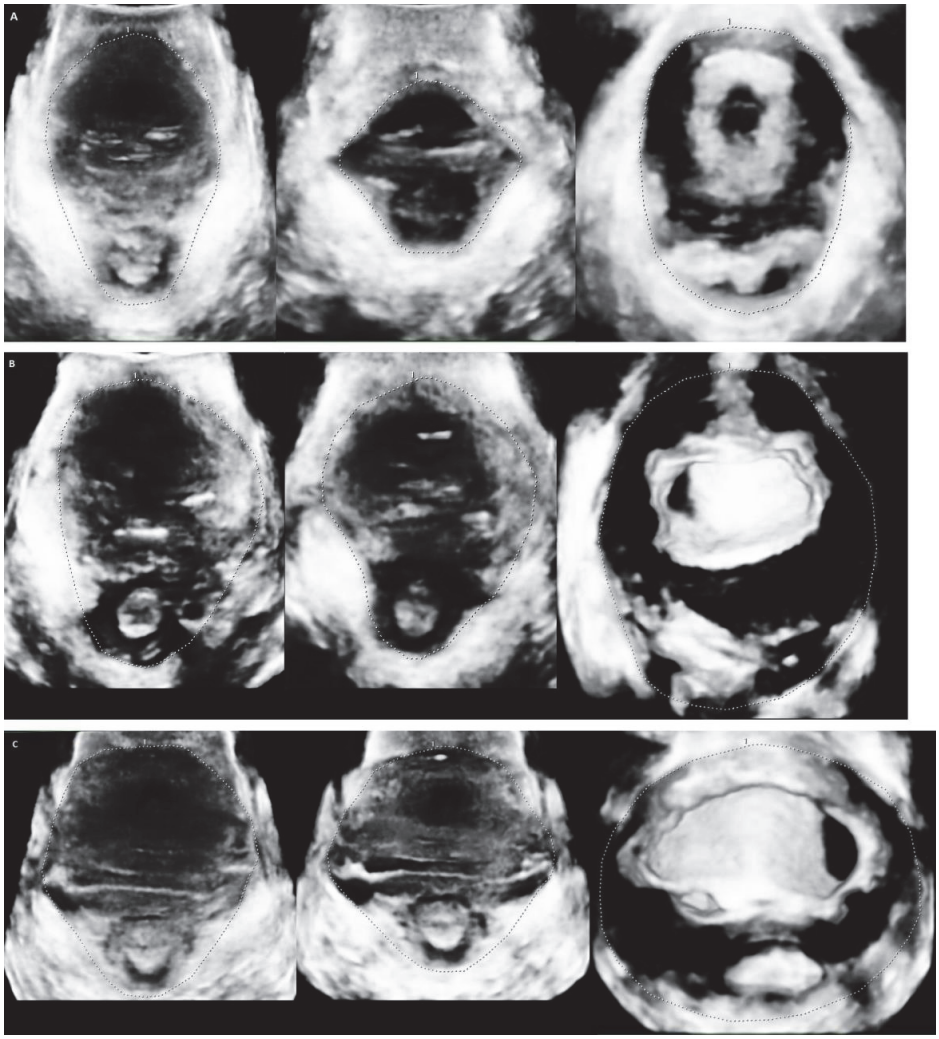


Figure 15 *Hiatal areas at rest, pelvic floor muscle contraction and Valsalva maneuver in women with a) intact levator (19.7 cm^2, 9.6 cm^2, 23.8 cm^2) b) unilateral avulsion (27.3 cm^2, 19.8 cm^2, 46.1 cm^2) and c) bilateral avulsion (27.3 cm^2, 25.6 cm^2, 47.3 cm^2)*
From Volløyhaug et al 2015: Forceps is associated with increased risk of pelvic organ prolapse and muscle trauma, with permission from John Wiley and sons. Copyright © 2015 ISUOG.

2.4.3 Obstetric anal sphincter injuries

OASIS are tears of the external and/or internal anal sphincters. OASIS are defined as grade three or four perineal tears, according to the extent of the injury [77]. A third degree tear is a disruption of the anal sphincter muscles, and is further subdivided into 3a: <50% thickness of external sphincter torn, 3b: >50% thickness of external sphincter torn, 3c: external and internal sphincter torn. A fourth degree tear is a third degree tear with disruption of the anal epithelium.

OASIS are usually diagnosed immediately after delivery by palpation and inspection. Transanal ultrasound has traditionally been used to detect defects in the sphincters [78], but more recently transperineal ultrasound has become a diagnostic tool [79], see Figure 16. Some authors have described occult OASIS, which is sphincter tears that are *not* diagnosed immediately after delivery, but visible on ultrasound examination in distance from delivery [80]. Defects in the sphincters may also persist after correct diagnosis and proper suturing and are evident by ultrasound [81].

Prevalence: OASIS only occurs in women with vaginal deliveries, and the prevalence of OASIS differs in different countries. In Norway the occurence of obstetric anal sphincter injuries increased from 0.5% in 1967 to 4.1% in 2004, and was higher after operative vaginal deliveries (OVD) compared to NVD [82]. Studies on occult OASIS have shown a prevalence of 20% after NVD and close to 50% after OVD, with higher prevalence after FD than VD [83].

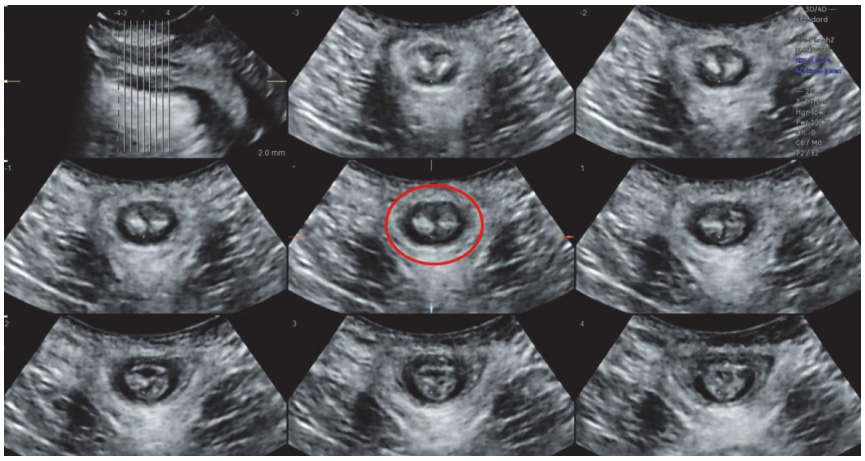


Figure 16 *Tomographic ultrasound imaging (TUI) of the anal sphincters. The external anal sphincter is outlined with the circle. The internal anal sphincter is the darker ring structure, and the white structure in the middle is the anal mucosa. Imaging by Volløyhaug.*

2.5 Birth mechanics

2.5.1 Muscle stretch during vaginal delivery

The pelvic floor undergoes remarkable changes to allow a baby to be passed down the birth canal. When assuming the average diameter of the molded fetal head is 9 cm, then the cross-sectional area is approximately 63 cm^2 [84]. This means that a great enlargement of the levator hiatus, which measures 12-16 cm^2 in pregnant women, is needed during delivery. A computer model has been used to quantify pelvic floor muscle stretch induced during the second stage of delivery as a model fetal head progressively engaged and then stretched the levator ani muscles [85], see Figure 17. This showed that the medial part of the levator ani muscles undergoes the largest stretch during vaginal birth. These muscles are therefore at the greatest risk for stretch-related injury [85].

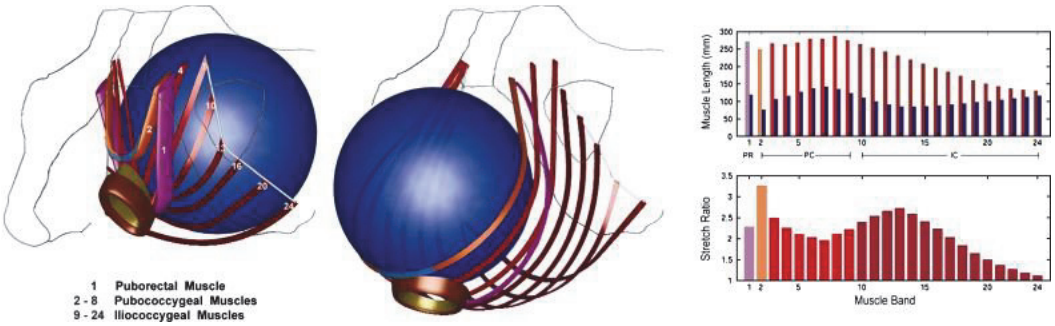


Figure 17 *Left, computer model of selected levator ani muscle bands before birth with muscle fibers numbered and the groups identified* middle*, muscle band lengthening present at the end of the second stage of labor;* right*, graphic representation of the original and final muscle (top) and the stretch ratio (bottom), indicating the degree to which each muscle band must lengthen to accommodate a normal sized fetal head.*
From DeLancey 2005: The hidden epidemic of pelvic floor dysfunction: Achievable goals for improved prevention and treatmen,with permission from Elsevier. Copyright © 2005 Elsevier

2.5.2 Episiotomy

The reason to perform an episiotomy is to prevent perineal trauma and in particular anal sphincter tears. There are two ways of making an episiotomy; medial and mediolateral. The mediolateral episiotomy is associated with less OASIS, and is commonly recommended [86]. The anatomical structures incised when performing a mediolateral episiotomy include the vaginal epithelium, transverse perineal and bulbocavernosus muscles, and perineal skin [87], see Figure 18. The major advantage of the mediolateral episiotomy is that the surgical incision is

directed away from the maternal anal sphincter, thereby partially protecting the sphincter and the rectum from injury due to extension. The levator ani muscles are not incised when performing an episiotomy. Restrictive use of episiotomy is probably better than routine episiotomy, associated with less AI and local symptoms [88]. Episiotomy may extend into a anal sphincter tear or a deep vaginal tear, which can include the levator ani.

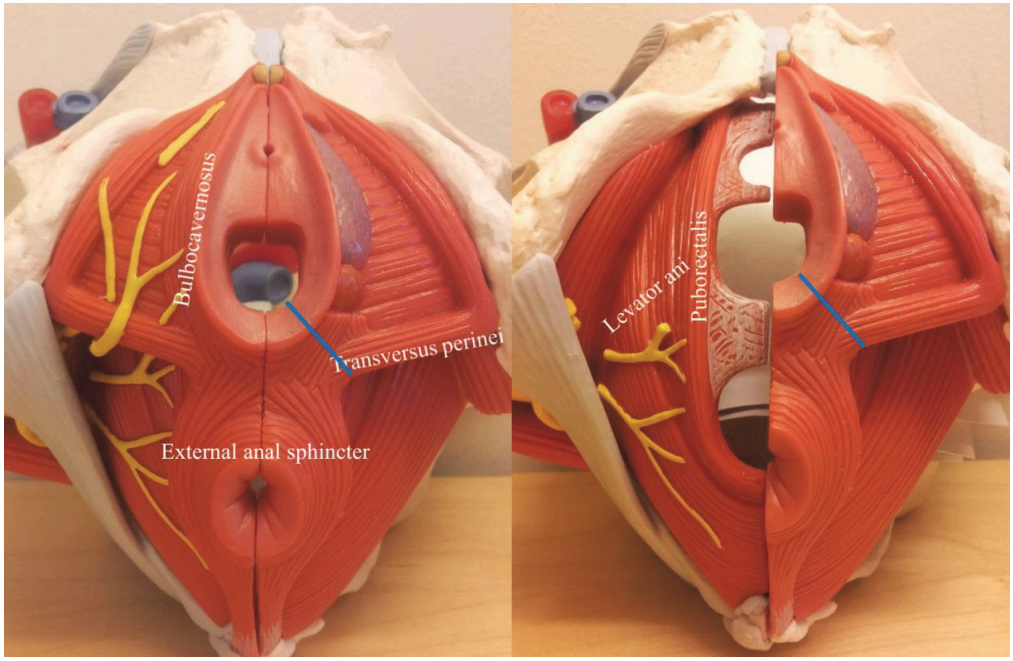


Figure 18 *The anatomical structures incised when performing a mediolateral episiotomy include transverse perineal and bulbocavernosus muscles, but not the levator ani muscles.*
Photo of a female pelvis model from 3B Scientific® by Volløyhaug.

2.6 Patophysiology –risk factors

2.6.1 Pelvic floor disorders in association to obstetric and non obstetric risk factors

PFD prevalence increases with advancing age, obesity, parity and is different for different ethnic groups [37-39, 48-52, 89-92]. Congenital malformations such as spina bifida and urinary bladder extrophy predispose to PFD [93], and connective tissue disorders such as Marfan or Ehler Danlos syndrome are risk factors [94]. Heridity could play a role, and women are more likely to develop urinary incontinence if their mother or older sisters are incontinent [95].

Pregnancy, and in particular childbirth are risk factors for PFD, and mode of delivery is associated with the prevalence of PFD. Previous studies have shown that CD is associated with lower prevalence of PFD in later life, and some studies have suggested that OVD is associated with increased prevalence of prolapse and incontinence [39, 89, 90, 96-99]. Increased risk after OVD is controversial, and the distinction between FD and VD had only been made in few studies prior to 2013 and mainly with focus on FI short time after delivery [78, 100-102]. It was not stated whether doctors were equally trained in both methods in these studies.

In the Tables 5-7 both established and potential or controversial risk factors for each PFD, based on information from UpToDate® prior to the start of our study in 2013 are listed [103, 104]. It was well known that pelvic floor disorders were associated with pregnancy and child birth, nevertheless it was stated that "the available literature cannot distinguish the effects of pregnancy from the effects of child birth" [104].

Obesity is the strongest risk factor for incontinence [37, 105]. The strongest risk factors for POP are parity, advancing age and obesity [52]. Anal and fecal incontinence is usually multifactorial (dysfunction in anal sphincters, abnormal rectal compliance, decreased rectal sensation, altered stool consistency) [106]. It is therefore difficult to state one main risk factor for AI/FI. OASIS is one important risk factor for anal sphincter weakness in women. Advancing age, obesity and pregnancy, regardless of delivery mode, are common risk factors for all PFD. Parity is a stronger risk factor for POP than for UI, as demonstrated in Figure 19 [107].

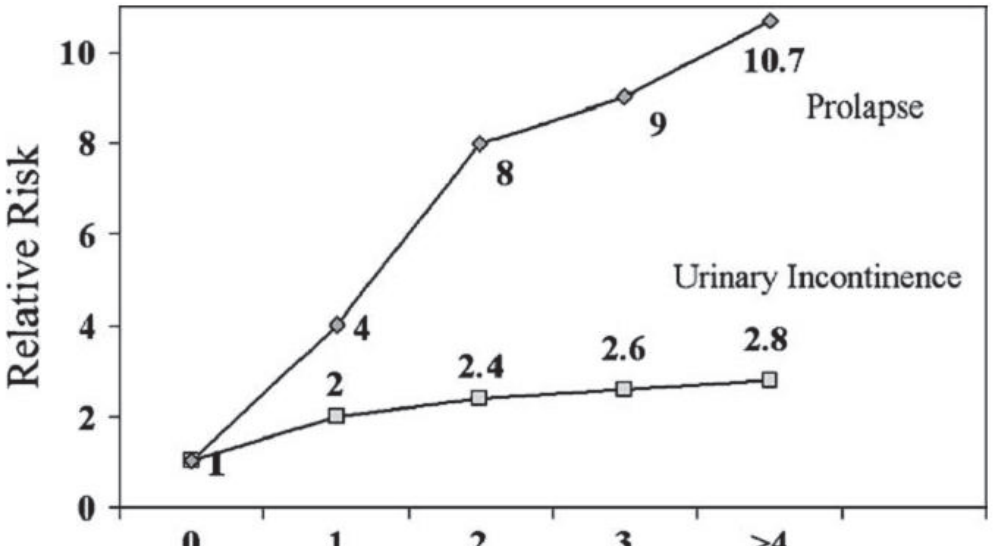


Figure 19 *Graph of the effect of vaginal parity on the development of urinary incontinence and pelvic organ prolapse.*
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Table 5 *Risk factors for urinary incontinence*

Established risk factors for UI:	
Obesity	37, 38, 90, 92, 105, 108-114
Parity	37-39, 97, 110, 114
Delivery mode	90, 96, 97, 99, 109, 110
Age	37-39, 51, 110, 112, 114, 115
Family history	95, 115
Potential/controversial risk factors for UI:	
Ethnicity	38, 91, 111, 112
Coffein	113
Smoking	38, 113, 116
Diabetes	38, 108
Surgery/ hysterectomy	38, 112, 117
HRT	38

Table 6 *Risk factors for symptomatic and anatomic pelvic organ prolapse*

Established risk factors for POP	
Parity	37, 38, 48, 55, 57-59, 89, 98, 118-121
Delivery mode	52, 58, 89, 90, 96, 98-100, 119, 121
Age	37, 48, 52, 55, 56, 58, 59, 89, 90, 118, 119, 121
Obesity	52, 56, 59, 118, 119, 121
Potential/controversial risk factors for POP	
Chronic constipation	120
Congenital malformations/ connective tissue	93, 94
disorders	55-58
Infant birth weight	37, 38, 56, 59, 120, 121
Ethnicity	56
Heavy lifting	122
Family history	58, 59, 123
Hysterectomy	

Table 7 *Risk factors for fecal incontinence*

Established risk factors for FI	
Age	37, 38, 49, 50, 109, 110
Obesity	50, 108-110, 124, 125
Lung disease	124
Irritable bowel, diarrhoea	49, 124, 126
UI	49, 109, 124-126
Delivery mode	81, 90, 96, 101, 110, 125, 127
OASIS	81, 109, 128-130
Potential/controversial risk factors for FI	
Ethnicity	37, 49, 90, 109, 124, 126
Parity	49, 50, 110
Menopause	50
Episiotomy	88, 100

2.6.2 Levator trauma in association to obstetric risk factors

Vaginal delivery is the main risk factor for PFMT [63, 131, 132]. Levator avulsion injury may occur during normal vaginal delivery, and forceps delivery carries higher risk of trauma to the pelvic floor muscles compared to normal vaginal delivery [71-73, 133-138]. There were only few studies indicating prevalence of **levator avulsions** separately after FD and VD prior to 2013 [71, 73, 134, 138]. Few women with FD or VD were included, ranging from a minimum of 12 to a maximum of 48 in each delivery group (Kearney 2006: 18 FD 12 VD, Shek 2010: 20 FD 34VD, Eisenberg 2011: 27 FD 17 VD, Chan 2012: 14 FD 48 VD), and they had a short follow up of maximum one year. Previous studies had also found that **hiatal areas** were increased after forceps delivery [73, 136, 137], but not vacuum [73], but also for hiatal areas there was a lack of direct comparison between FD and VD prior to 2013. Other factors related to vaginal delivery are listed in Table 8.

Table 8 *Risk factors for pelvic floor muscle trauma*

Established risk factors	
Vaginal delivery	30, 63, 131, 132
Potential/controversial risk factors	
Mode of vaginal delivery	71-73, 133-138
High infant birth weight and head circumference	73
Epidural, protective effect?	73, 134
Prolonged 2nd stage	72, 73, 134
Oxytocin	73, 134
Episiotomy, protective or aggravating effect?	73, 134
High maternal age at delivery	134, 136

2.6.3 Levator trauma in association to symptoms and signs of pelvic organ prolapse

PFMT diagnosed by ultrasound and MRI is a risk factor for POP [23, 68, 75, 133, 139-143], but previous studies on association between PFMT and POP have only been conducted in urogynecological patient populations or among women a few months after delivery [23, 68, 75, 133, 139-143]. POP usually occurs several years after delivery. We found no studies confirming the association between PFMT and POP among healthy women several years after delivery.

2.6.4 Summary of risk factors for pelvic floor disorders, pelvic organ prolapse and pelvic floor muscle trauma

Figure 20 illustrates the influence of risk factors on anatomical structures and anatomical (PMFT and POP) and functional consequences (PFD).

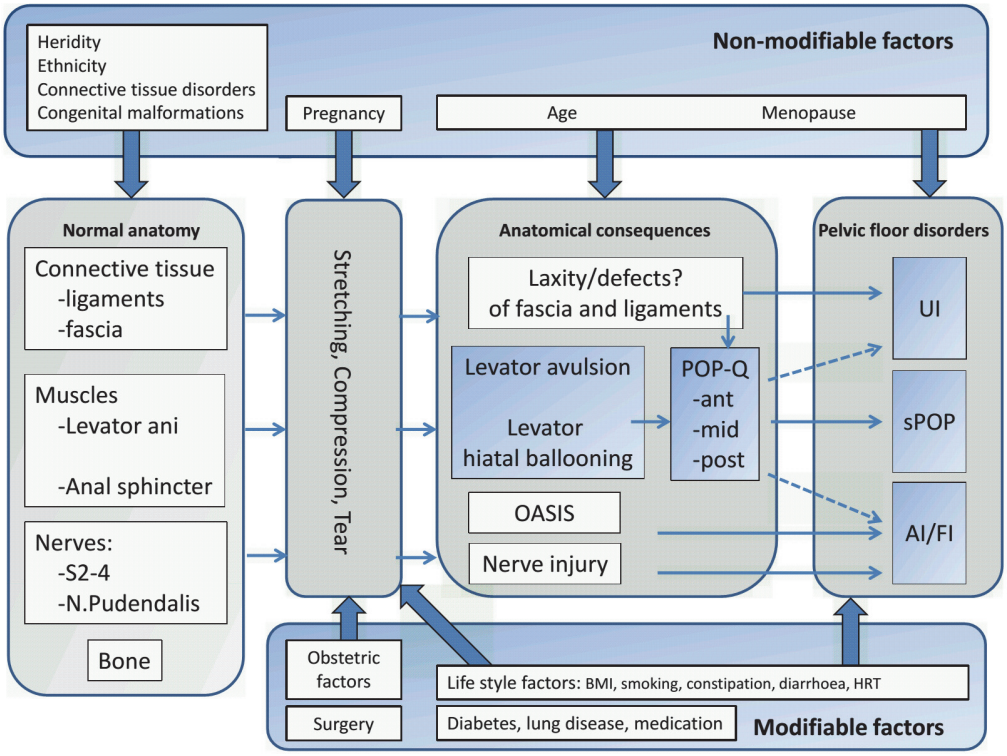

Figure 20 *Schematic illustration of pelvic floor anatomy, modifiable and non-modifiable risk factors for pelvic floor muscle trauma (levator avulsion and levator hiatal ballooning), pelvic organ prolapse (POP-Q-ant,-mid,-post) and pelvic floor disorders (urinary incontinence (UI) symptomatic pelvic organ prolapse (sPOP) and anal/fecal incontinence (AI/FI). Volløyhaug 2015.*

2.7 Gaps of knowledge

There is lack of studies on:

1) PFD in association to delivery mode, in particular with a distinction between FD and VD and many years after delivery.
2) PFMT and POP-Q in association to delivery mode in women from a normal population, in particular with a distinction between FD and VD. Previous studies have only been conducted on patient populations or puerperal women.
3) Association between PFMT, POP-Q and sPOP in women from a normal population. Previous studies have only been conducted on patient populations or puerperal women.
4) Quantification of changes in ultrasound parameters in relation to other validated scales for pelvic floor muscle contraction.

Studies comparing assessment of pelvic floor muscle contraction by ultrasound, digital assessment, and perineometry are sparse, and we have not found any validated scale for pelvic floor muscle contraction using ultrasound measurements.

3 Aims

3.1 General objectives

The main aim of the study was to explore the anatomical and functional status of the pelvic floor in women from a normal population15-24 years after their first delivery, and to study a possible association to mode of delivery.

3.2 Specific objectives

3.2.1 Paper I

The aims were to study the association between PFD and mode of delivery and to calculate the risks of PFD comparing CD and OVD to NVD 15-23 years after child birth. A subgroup analysis comparing FD and VD was planned.

3.2.2 Paper II

The aims were to study possible associations between mode of delivery and POP-Q≥ 2 and PFMT 16-24 years after first delivery and in particular study differences between FD and VD.

3.2.3 Paper III

The aims were to establish the prevalence and investigate a possible association between PFMT and sPOP and POP-Q≥ 2 in women from the normal population 16-24 years after first delivery.

3.2.4 Paper IV

The aims were to study the correlation between palpation, perineometry and transperineal ultrasound for assessment of pelvic floor muscle contraction and to develop a contraction scale for ultrasound measurements.

4 Material and methods

4.1 Design

This was a cross sectional study of women who had their first delivery 15-24 years prior to data collection.

4.2 Participants

A total of 11185 women delivered their first baby at Trondheim University Hospital between January 1st 1990 and December 31st 1997. Women who were still alive and had postal address in Norway in 2013 were identified from the Hospital Patient Administrative System. We included all primiparous women with OVD or CD during 1990-97, and all primiparous women with NVD from 1 January to 1 July of each calendar year, to include a similar number of women with NVD stratified by year of first delivery. A total of 3268 women were invited to participate.

The reason for choosing women who delivered during this time period, was that doctors were performing FD and VD at approximately the same rate between 1990-97 (3-5% of all deliveries), and we assumed they were equally trained in both methods, see Figure 21. In addition, development of PFD and POP usually takes some time. A time interval of 15-24 years was considered sufficient.

Exclusion criteria were stillbirth, breech delivery and infant birth weight < 2000g at the index birth, but women were not excluded if these conditions occurred in subsequent pregnancies. Women were also excluded if Trondheim University Hospital was not their primary hospital at the index delivery.

We defined three main study groups: NVD, CD and OVD, and the OVD group was divided into FD and VD for subgroup analysis. Women were allocated to groups considering all their deliveries (the first delivery in 1990-97 and all subsequent deliveries) and were placed in the delivery group that was likely to have caused most harm to the pelvic floor: CD<NVD<OVD. Women in the CD group had only delivered by Cesarean section and never had a vaginal delivery. Women in the NVD group had at least one normal vaginal delivery (including deliveries with oxytocin augmentation, epidural analgesia, episiotomy and/or perineal tears) and other deliveries could be NVD or CD, but not OVD. A group of 195

women were allocated to the NVD group after previous CD. Women in the OVD group had delivered by either FD or VD, and other deliveries could be any mode of delivery (NVD, CD or OVD). In the subgroup analysis, we divided women into a FD group and VD group according to their first delivery. We excluded women with prior NVD (n=8) or CD (n=28) and women having had both vacuum and forceps (n=22), but not women with subsequent same type of OVD, NVD or CD.

The women invited to clinical examination belonged to four clearly defined delivery groups where delivery mode at first delivery defined delivery group: 1) CD only, 2) NVD at first delivery, and other deliveries could be NVD or CD, but not OVD, 3) FD at first delivery, subsequent deliveries could be FD, NVD or CD but not VD, and 4) VD at first delivery subsequent deliveries could be VD, NVD or CD but not FD.

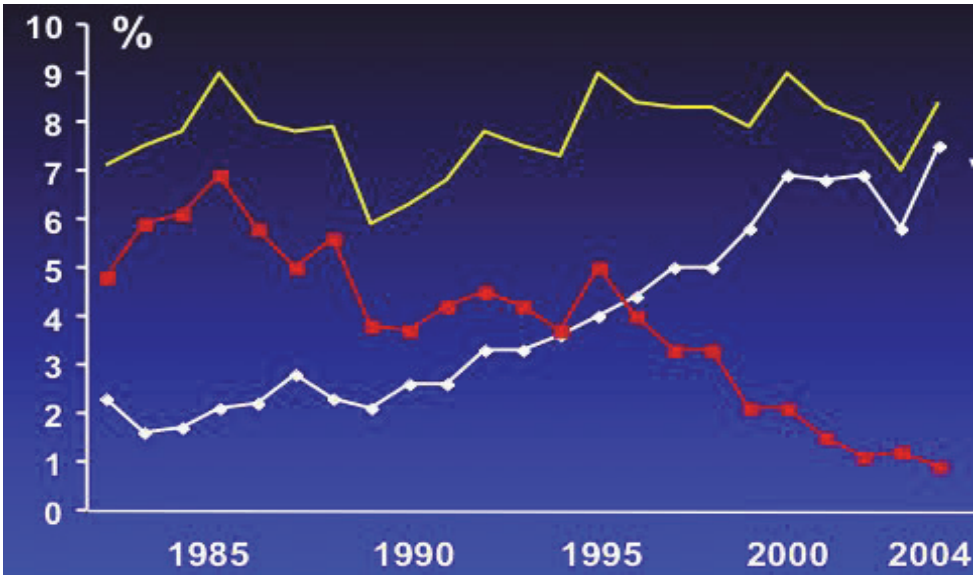

Figure 21 *Prevalence of operative vaginal deliveries at Trondheim University Hospital 1984-2004, yellow line. Forceps prevalence in red line, and vacuum prevalence in white line. Data were collected from hospital records.*
Personal communication from K.Å. Salvesen.

Torsdag 5. september 2013 | Adresseavisen

Livmor-fremfall

Tarmer

Urinblære

Tarm

Livmor

Livmoren har sunket ned på grunn av svekket bindevev og muskulatur i bekkenet.

Normalt liggende livmor

Tarmer

Livmor

Urinblære

Tarm

Fødsel påvirker tabu-sykdom

Urinlekkasje og livmorfremfall rammer mer enn hver tiende kvinne. Nå vil forskere i Trondheim finne ut mer om hvordan de tabubelagte sykdommene kan forebygges.

– Vi vet at svangerskap og fødsel i seg selv er en risikofaktor, sier doktorgradsstipendiat og overlege Ingrid Volløyhaug.

– Men vi vet lite om hvilke forhold ved fødselen som fører til at kvinnene kan komme til å utvikle livmorfremfall eller urinlekkasje.

Volløyhaug har sendt brev til 3000 kvinner som fødte sitt første barn ved St. Olavs Hospital (tidligere RiT) i perioden 1990–1997. Hun understreker at forskerne er interessert i kontakt både med kvinner som er plaget og de som ikke har merket noe.

Pinlig og hemmende

Mens det er velkjent at litt eldre kvinner ofte plages av urinlekkasje, er livmorfremfall mindre kjent. Det vil si at livmoren nærmest faller ned, og kan bli liggende på utsiden av skjeden. I begge tilfellene er det snakk om en lidelse som oppleves som både pinlig og hemmende.

– Som gynekolog ser jeg at mange kvinner sliter med disse plagene. Men det er et tabubelagt tema som en nødig snakker om. Derfor er det viktig å få frem kunnskap om hvordan sykdommen kan forebygges. Er for eksempel bruk av tang ved fødselen mer skadelig for bekkenbunnen enn sugekopp? Ofte kan vi fødselsleger velge metode, sier Volløyhaug.

Både urinlekkasje og fremfall av livmor, endetarm eller blære har sammenheng med at bekkenbunnen blir skadet eller svekket. Vanligvis opptrer plagene mange år etter fødselen.

Ulike fødselsmetoder

Deltakerne i studien vil bli delt inn etter hva slags fødselsmetode som ble brukt: keisersnitt, tang, vakuumsug eller normal, spontan fødsel.

Alle deltakerne skal fylle ut et spørreskjema og et utvalg vil også bli innkalt til en klinisk undersøkelse av bekkenbunnen.

– Hvis vi oppdager tendenser til fremfall, vil deltakeren bli henvist til videre undersøkelse. Det kan være en fordel å starte behandling på et tidlig tidspunkt, sier Volløyhaug.

– Hva slags behandling er aktuelt?

– Ringpessarbehandling kan hjelpe ved livmorfremfall. Man setter inn et pessar i skjeden som holder livmoren på plass. Ved urinlekkasje vil det være aktuelt med bekkenbunnstrening slik at musklene styrkes og dermed hindrer lekkasje. Men for ti prosent av den kvinnelige befolkningen blir plagene så alvorlige at de må gjennomgå operasjon for urinlekkasje eller fremfall før fylte 80 år. For noen opptrer plagene allerede i 40-årsalderen eller enda tidligere, sier Ingrid Volløyhaug.

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Kvinnesykdom: Vi trenger mer kunnskap om hvilke fødselsmetoder som øker risikoen for å utvikle urinlekkasje eller livmorfremfall senere i livet, sier Ingrid Volløyhaug.

Figure 22 *Adresseavisen, the largest newspaper in the region, published a commentary on the study timed with the last mailing cycle. From: www.adressa.no/ Photo and text by Agnete Weisser.*

4.3 Recruitment

Questionnaires were sent in three mailing cycles; in March 2013, and in June and September 2013 reminders were sent to non-responders. It was possible to answer the questionnaire on a paper form or on a web form. To increase the response rate we lotted an iPad among the responders. We also used the local newspaper to inform women of the study at the time of the last mailing cycle, see Figure 22.

One problem was that addresses obtained from the Hospital Patient Administrative System were not linked to the Civil Population registry. We were able to find new addresses for most of the women from http://www.1881.no/, but we know that 148 women did not receive any invitation to participate and we suspect that several more women never got invitation letters due to problems with the postal service. Some women gave reason for unwillingness to participate, such as not having PFD, having other diseases or knowing the investigator, but most women gave no reason for unwillingness to participate.

Questionnaire responders accepting clinical examination were invited if they did not live too far from Trondheim, defined by postal code. Some women cancelled the appointment because they did not have the time to participate, had no pelvic floor problems or other reasons. “No show” women were contacted by telephone, and were offered a new visit if they were willing to participate.

4.4 Data sources and variables

The study data were obtained mainly from two sources:

1) Postal questionnaire on PFD, previous surgery and life style factors (paper I and III).
2) Clinical and sonographical examination of muscle anatomy and function and of POP-Q (paper II, III and IV).

Additional information about perineal tears and indication for OVD at first delivery was obtained from the hospital records, and information about subsequent deliveries (delivery mode, infant birth weight, head circumference, parity, elective or emergency CD, and year of delivery) was obtained from the Norwegian Medical Birth Registry. Figure 23 illustrates the main study variables, their sources, and the published papers.

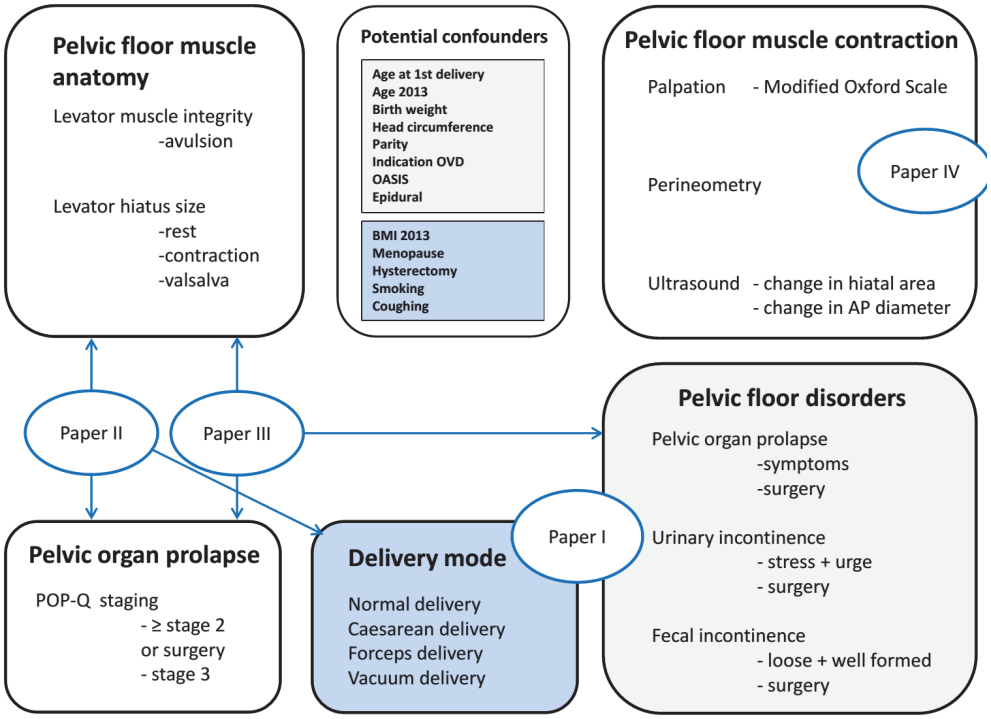


Figure 23 *Variables of interest and their contribution to each paper. Variables obtained from questionnaire in light grey. Variables obtained from the Norwegian medical Birth Registry and Hospital records in light blue. Variables obtained from clinical and sonographical examination in white. Volløyhaug 2015.*

4.4.1 Postal questionnaire

The questionnaire included questions about all the women's deliveries (parity, infant birth weight and delivery method), menopause and use of hormone replacement therapy, weight, height, smoking habits, chronic coughing, hysterectomy and surgery for pelvic organ prolapse, urinary and faecal incontinence, see Appendix 2. Information from the questionnaires regarding delivery method and infant birth weight was cross-checked with the Hospital Patient Administrative System and the Norwegian Medical Birth Registry. After this comparison there was a discrepancy for mode of first delivery in 13 women, and individual hospital records were scrutinized and delivery mode confirmed.

The questionnaire included a Norwegian translation of the PFDI and of the PFIQ [47]. Mean scores for POPDI, CRADI and UDI was calculated, with a possible range from 0-100 for each subscale and 0-300 for the PFDI total score. PFIQ score was not used in the analyses.

Diagnosis of sPOP, UI and FI was based on five key questions from the PFDI. A positive response to "seeing or feeling a vaginal bulge" qualified for the diagnosis of sPOP. Positive response to "urinary incontinence at urgency" or "urinary incontinence at coughing, sneezing, laughing" qualified for the diagnosis of UI, and positive response to "incontinence for loose stool" or " incontinence for well formed stool" qualified for the diagnosis of FI, counting any positive response as diagnostic without regard to severity of symptoms.

The main outcome variables were three composite variables consisting of symptoms and/or having had surgery:

1) *sPOP:* Symptomatic pelvic organ prolapse and/or current use of ring pessary and/or having had surgery for pelvic organ prolapse.

2) *UI:* Urge and/or stress urinary incontinence and/or having had surgery for urinary incontinence.

3) *FI:* Incontinence for loose and/or well-formed stool and/or having had surgery for fecal incontinence.

4.4.2 Clinical examination

Study participants presented with an empty urinary bladder and bowel and were asked to withhold any information regarding previous deliveries, prolapse and incontinence symptoms, pelvic floor muscle exercise, and gynecological surgeries until the examination had been completed. They were examined in the supine position in a gynecological examination chair, with knees and hips semiflexed and abducted.

The gynecological examination included digital assessment of pelvic floor muscle integrity and contraction, perineometry, staging of pelvic organ prolapse according to the POP-Q system [53] and a 4D pelvic floor ultrasound scan. All women were instructed regarding correct pelvic floor muscle contraction: to squeeze their pelvic floor muscle (pull in and lift up the urethra, vagina, and rectum, or imagine trying to control passing gas). The same instructions were used during all assessments of pelvic floor muscle contraction. They were also instructed in performing a Valsalva maneuver of minimum 6 seconds duration without coactivation of pelvic floor muscles. All examinations were performed by one person, who was blinded to demographical and clinical background data at the time of the examination.

Digital assessment of pelvic floor muscle integrity, resting tone and contraction was performed by the examiner inserting the index and middle finger approximately 4 cm into the vagina (only the index finger in the case of very narrow hiatus) and palpating the puborectalis muscle at each side of the vagina at rest and during contraction. The palpation method proposed by Dietz was used to assess levator muscle integrity [13] and resting tone [14]. The Modified Oxford Scale (MOS) was used to rate pelvic floor muscle contraction on a scale of 0–5[12]. The mean MOS (right + left/2) was used for the correlation analysis.

Perineometry was conducted by using a vaginal balloon catheter connected to a fiberoptic microtip transducer (Camtech AS, Sandvika, Norway) placed in the vagina, with the middle of the balloon located approximately 3.5 cm inside the introitus [18]. Study participants performed three maximal pelvic floor muscle contractions, and the strongest contraction (creating the highest intravaginal pressure) was used.

The POP-Q provided *quantification of prolapse* from stage 0 to 4 in each compartment (anterior, middle, posterior). Measurements were performed in 0.5 cm intervals. Data from the POP-Q were analyzed for each compartment separately, and the presence of *POP-Q≥ 2* in at least one of all three compartments was registered and counted as clinically relevant prolapse. Some had undergone prolapse surgery and were objectively cured (POP<grade2). We did not check their hospital records for POP stage before surgery, but in Norway the agreed indication for POP surgery is POP ≥ stage 2 with concomitant prolapse symptoms. We defined a composite outcome variable combining *POP ≥ stage 2 or previous surgery*. The registration of POP stage 3 included women with more severe prolapses.

Ultrasound volumes were acquired with a GE Voluson S6 device using the RAB 4-8rs abdominal 3D probe and acquisition angle of 85° placed on the perineum. Volumes were acquired at rest, during pelvic floor muscle contraction and during Valsalva maneuver of minimum 6 seconds duration [74]. Three volumes were acquired for contraction (including a

relaxed state at the beginning of each volume) and Valsalva, yielding a total of six volumes per woman.

Offline analysis of the ultrasound volumes was performed 6-14 months after the ultrasound scan on a computer using the 4Dview Version 14 Ext.0 (GE Healthcare, Austria) software. The analysis was done by one person, who at the time of the analysis was blinded to clinical and demographical data. PFMT was defined by either levator avulsion or larger levator hiatal areas.

TUI technique was used to identify levator avulsion at pelvic floor muscle contraction. Avulsion was diagnosed if all three central slices; the slice in the plane of minimal hiatal dimensions (ie. where the distance between the posterior border of the symphysis and the anterior border of the puborectalis muscle is shortest) and the slices 2.5 and 5.0 mm cranial to this, showed abnormal muscle insertion [23]. Avulsion was diagnosed as unilateral or bilateral (see Figure 13), and the number of women with unilateral or bilateral levator avulsion was registered.

Hiatal area was measured in the plane of minimal hiatal dimensions in a rendered volume of 1-2 cm thickness as described previously [24]. All six volumes for rest, contraction and Valsalva were analyzed. Examples of ultrasound images defining the hiatal area at rest, contraction and Valsalva in women without or with unilateral or bilateral avulsions are presented in Figure 15. The largest hiatal area at rest and during Valsalva maneuver was registered for each woman. The smallest hiatal area, representing the best contraction, was registered for pelvic floor muscle contraction. Some women were unable to perform a proper Valsalva maneuver without co-activation of the pelvic floor muscles. When the hiatal area produced at Valsalva maneuver was smaller than the area at rest, the hiatal area during Valsalva was defined as invalid and registered as missing. We also registered all women with hiatal rea >40 cm^2, as this cut off previously has been used to diagnose women with severe hiatal overdistension [75].

For ultrasound assessment of pelvic floor muscle contraction, we examined three volumes per woman, starting at rest and recording the maximal pelvic floor muscle contraction. Hiatal area and antero-posterior (AP) diameter both at rest and during maximal pelvic floor muscle contraction were measured in the rendered axial plane of the minimal hiatal dimensions as previously described [24], see Figure 24. The strongest pelvic floor muscle contraction, creating the largest difference in the levator hiatal area between rest and contraction for each woman was used. We first calculated the absolute difference in hiatal area and the AP diameter between rest and pelvic floor muscle contraction. Subsequently, we

used the formula suggested by van Delft et al. to calculate the proportional (percent) difference in measurements between maximum contraction and rest: proportional difference = $((Measure_{rest} - Measure_{squeeze})/Measure_{rest}) \times 100\%$ for both hiatal area and AP diameter [144].

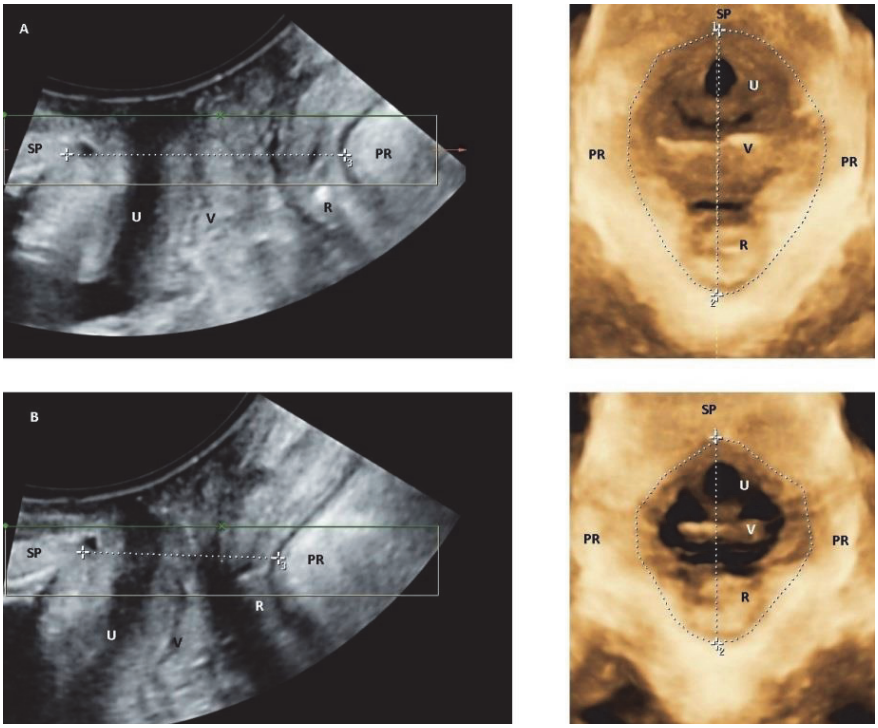


Figure 24 *Ultrasound imaging of pelvic floor muscle contraction. The images on the right demonstrate measurements of the hiatal area and the antero-posterior (AP) diameter at (a) rest and (b) contraction in the oblique axial plane of minimal hiatal dimensions in a rendered volume of 1-2 cm thickness. The images to the left demonstrate measurements of AP diameter from the upper border of the symphysis pubis to the puborectalis muscle in a corresponding 2D image in the mid-sagittal plane. SP: symphysis pubis; PR: puborectalis muscle; U: urethra; V: vagina; R: Rectum.*
From Volløyahug et al 2015: Assessment of pelvic floor muscle contraction with palpation, perineometry and transperineal ultrasound: a cross-sectional study, with permission from Johns Wiley and Sons

4.5 Study size

4.5.1 Power calculation for data from questionnaire

A power calculation was based on previous studies of primiparous women indicating a higher risk of PFMT after FD (35%) than after NVD (13%) and VD (9%) [73], and a study demonstrating that ultrasound verified PFMT doubled the risk for POP [139]. We assumed a lower prevalence of symptomatic than anatomical POP. Assuming a precvalence of sPOP of 12.0% in the OVD group and 5.5% in the NVD group we found that 296 women in each group would be sufficient to detect a statistically significant (p<0.05) and clinically relevant difference between groups with power 80%. The prevalence of UI is higher than for sPOP and the FI prevalence is similar to sPOP. Thus, the study should be sufficiently powered to detect clinically important differences between groups for UI and FI as well.

4.5.2 Power calculation for data from clinical examination

A power calculation was based on one previous study of primiparous women indicating a higher risk of PFMT after FD (35%) than after NVD (13%) and VD (9%) [73], and a study identifying ultrasound verified muscle trauma as a factor doubling the risk for POP [139]. To detect a similar difference in prevalence of levator avulsion between delivery groups (35% vs 13%), we would need 58 women in each group with a power of 80% and 5% significance level. We assumed a smaller difference in POP prevalence (12.5 % in the normal vaginal delivery group and 25.0% in the forceps group) and found that a sample size of 152 women in each delivery group would be sufficient to find a statistically significant and clinically relevant difference between delivery groups with power 80% and significance level 5%. We did not perform power calculations for the detection of differences in hiatal area.

4.6 Statistical analyses

Statistical analyses were performed with IBM SPSS statistics version 21 (IBM SPSS, Armonk, NY, USA). Continuous variables were tested for normal distribution. We used the two sample *t*-test for continuous variables and the chi-square test or Fisher's exact test for categorical variables to identify any differences between study groups in demographics and clinical background data. $P<0.05$ was considered statistically significant. When data were missing, analyses were run on study participants with complete data. Table 9 summarises all statistical analyses that was done for each paper.

4.6.1 Statistical analyses Paper I

The prevalence of the outcome variables was compared between CD, OVD and NVD, and in a subgroup analysis FD was compared with VD. The main outcome variables (sPOP, UI, FI) were analysed using univariable logistic regression for calculation of crude odds ratios (cOR) for delivery modes. In addition, multivariable logistic regression analysis was used to correct for possible confounding factors and calculate adjusted odds ratio (aOR) with 95% confidence intervals (CI). On the basis of clinical knowledge and results from previous studies, we selected parity (number of deliveries), maternal age at delivery, current BMI, hysterectomy, menopause, smoking habits, chronic coughing and infant birth weight (the largest infant delivered by each woman) as possible confounders. Univariable logistic regression was used to test their association to main outcome variables one by one before entering into the multivariable regression model. The woman's age in 2013 was omitted from the model because of correlation with age at delivery and menopause. Head circumference was omitted because of correlation to birth weight. Smoking and chronic coughing were independent variables and both were entered into the final regression model. A low percentage of the women provided reliable information on the use of hormone replacement therapy, and therefore no analysis was done for this potential confounder. For comparison of FD and VD the following potential confounders were added into the model; indication for OVD (fetal distress or prolonged second stage of labour), OASIS, and the largest infant delivered vaginally, excluding any infants delivered by CD.

Table 9 *Summary of statistical analyses performed for each paper*

	Background data		Variables of interest	Aim	Statistical analysis	Outcome measure	Confounders in multivariable analysis
	Descriptive statistics	Comparison between delivery groups					
Paper I	Prevalence in % or mean and SD	Testing of normal distribution.	PFD Delivery mode	Find prevalence of PFD	Descriptive statistics	Prevalence, %	
	-according to delivery group	t-test for continuous variables and chi-square test for categorical variables		Test association between PFD and delivery mode	Simple and multiple logistic regression	cOR, 95% CI aOR, 95% CI	Age at 1st delivery BMI 2013 Birth weight Parity Menopause Hysterectomy Indication for OVD Smoking Coughing OASIS
Paper II	Prevalence in % or mean and SD	Testing of normal distribution.	POP-Q≥ 2 PFMT Delivery mode	Find prevalence of PFMT and POP-Q≥ 2	Descriptive statistics	Prevalence, % Mean, SD	
	-according to delivery group	t-test for continuous variables and chi-square test for categorical variables		Test association between levator avulsion, POP-Q≥ 2 and delivery mode	Simple and multiple logistic regression	cOR, 95% CI aOR, 95% CI	Age 2013 BMI 2013 Birth weight Parity
				Test association between hiatal areas and delivery mode	Univariable and multivariable ANCOVA	uMD, 95% CI aMD, 95% CI	
Paper III	Prevalence in % or mean and SD		POP-Q≥ 2 sPOP PFMT	Find prevalence of PFMT, POP-Q≥ 2 and sPOP	Descriptive statistics	Prevalence, %	
	-for the whole study population			Test association between PFMT, POP-Q≥ 2 and sPOP	Chi-square test (Multiple logistic regression)	cOR, 95% CI aOR, 95% CI	Age BMI Birth weight Parity Hysterectomy
Paper IV	Prevalence in % or mean and SD		MOS Perineometry Ultrasound measurements	Find mean score for MOS, perineometry and Ultrasound measurements	Descriptive statistics Testing of normal distribution	Mean, SD	
	-for the whole study population			Test correlation between different assessment methods for muscle contraction	Spearman's rank correlation	Correlation coefficient	
				Establish an ultrasound contraction scale	Calculation of percentage	Cut off's range 0-100% AP change	

4.6.2 Statistical analyses Paper II

The primary statistical analysis was to compare POP, levator avulsion and hiatal area between FD and VD. Secondary analyses were comparisons of outcomes between CD, FD, VD and NVD.

We used univariable logistic regression for calculation of cOR for delivery modes. Multivariable logistic regression analysis was used to correct for possible confounding factors and calculation of aOR with 95% CI. Analysis of covariance (ANCOVA) was used to test for significant differences between delivery modes for hiatal areas at rest, contraction and Valsalva. Both univariable ANCOVA for unadjusted mean difference (uMD) with 95% CI between delivery groups and multivariable ANCOVA corrected for possible confounding factors for adjusted mean difference (aMD) with 95% CI are reported. When the numbers were small (eg. POP grade 3), the Fisher's Exact test for calculation of cOR with 95% CI was used (http://www.r-fiddle.org/#/).

On the basis of clinical knowledge and results from previous studies we considered several potential confounding variables. Univariable logistic regression was used to test their association to POP≥ stage 2 or surgery and levator avulsion one by one before entering into the multivariable model. ANCOVA was used to test the association of each factor to hiatal area on Valsalva. For comparison of risk between delivery groups in the final logistic regression model and for the multivariable ANCOVA analysis we selected age (2013), parity, BMI, and largest infant's birth weight. Head circumference was omitted because of correlation to birth weight, and both menopause and age at delivery were omitted because of correlation to age in 2013. Other potential confounding variables (smoking, coughing, hysterectomy, epidural, indication for operative vaginal delivery and perineal tears) showed no statistically significant association to the main outcome variables and were not entered into the multivariable regression model. Reliable information on the use of hormone replacement therapy, oxytocin augmentation during delivery and episiotomy was not available.

4.6.3 Statistical analyses Paper III

We used the Chi-sqare test to calculate cOR for the associations between PFMT and POP-Q≥ 2 and sPOP, and for the association between sPOP and POP-Q≥ 2. When numbers were small, the Fisher's Exact test for calculation of cOR with 95% CI was used (http://www.r-fiddle.org/#/). Multivariable logistic regression analysis was then performed for calculation of aORs with 95 % CI for the associations between possible confounding factors (age, BMI, parity,

infant birth weight and hysterectomy, chosen on the basis of clinical knowledge and results of previous studies) and PFMT and POP-Q≥2, sPOP and POP surgery.

4.6.4 Statistical analyses Paper IV

Data from ultrasound parameters were normally distributed, but MOS and perineometry data were not. Thus, the Spearman's rank test was used to assess the correlation between the methods. Increasing rank correlation implied increasing agreement between the tests: $r_s = 0$, no agreement; $r_s > 0.3$, weak agreement; $r_s > 0.5$; moderate agreement; $r_s > 0.7$, strong agreement; $r_s = 1$, perfect agreement.

After determination of the ultrasound method with the strongest correlation to digital assessment, we calculated cut offs corresponding with palpation. The International Continence Society has recommended that quantification of contractions by digital palpation should be divided into four categories (absent, weak, normal, strong) [8], and we used these four categories when defining cut offs for an ultrasound scale, yielding the same percentage of women in each category. For this purpose, mean MOS = 0 was classified as absent, 0.5-2 was weak, 2.5-4 was normal and 4.5-5 was strong.

4.7 Ethical considerations

Informed consent was obtained from all participants included in the study. The study was approved by the Regional Committee for Medical and Health Research Ethics (REK midt 2012/666). A potential benefit for study participants was the clinical examination which had the potential to reveal conditions or diseases and refer women to further diagnosis and treatment if necessary. The examination had no known side effects. It was not painful, but could be experienced as uncomfortable for some women. Study participants were not given any economic compensation for travelling costs or taking time off from work.

4.8 Data registration

The study was registered in Clinical Trials with ClinicalTrials.gov Identifier: NCT01766193. The questionnaire could be answered either on paper form (Appendix 2) or web form: http://www.nsfm.no/uropro/. The paper version was scanned and entered into an SPSS-file. Data from the web responses were entered manually into the SPSS file.

Data from the Norwegian Medical Birth Registry were obtained on encrypted SPSS files. Once these files were merged with the questionnaire files, all information that could identify a woman was deleted, keeping only the study participant number.

Data from the clinical examination were registered on a paper form during examination (Appendix 3), and immediately after the woman left, data were entered into a web crf on https://webcrf.medisin.ntnu.no, with a woman's study participation number and without any information that could identify the woman. At the end of the data collection this was converted into an SPSS file.

All ultrasound volumes were stored with the woman's study participation number on the ultrasound machine and copied to a separate hard disk with regular intervals. All ultrasound volumes were deleted from the ultrasound machine at the end of the study after copying the volumes on a separate back up hard disk. After analysis of ultrasound volumes, data were entered manually into an SPSS file.

5 Results

5.1 Response rate

The response rate for the questionnaire was 53% (1641/3115) and 72% (608/847) of women invited for clinical examination participated. A flow chart of study participants is presented in Figure 24. The questionnaire response rate was similar for all delivery groups (NVD 51%, FD 53%, VD 57%, CD 52%), however slightly higher in the VD group compared to NVD (p=0.02) and CD (p=0.04). There was no difference in participation rate at clinical examination between delivery groups: NVD 71% (217/306), CD 73% (101/139), FD 72% (159/220), VD 72% (131/182).

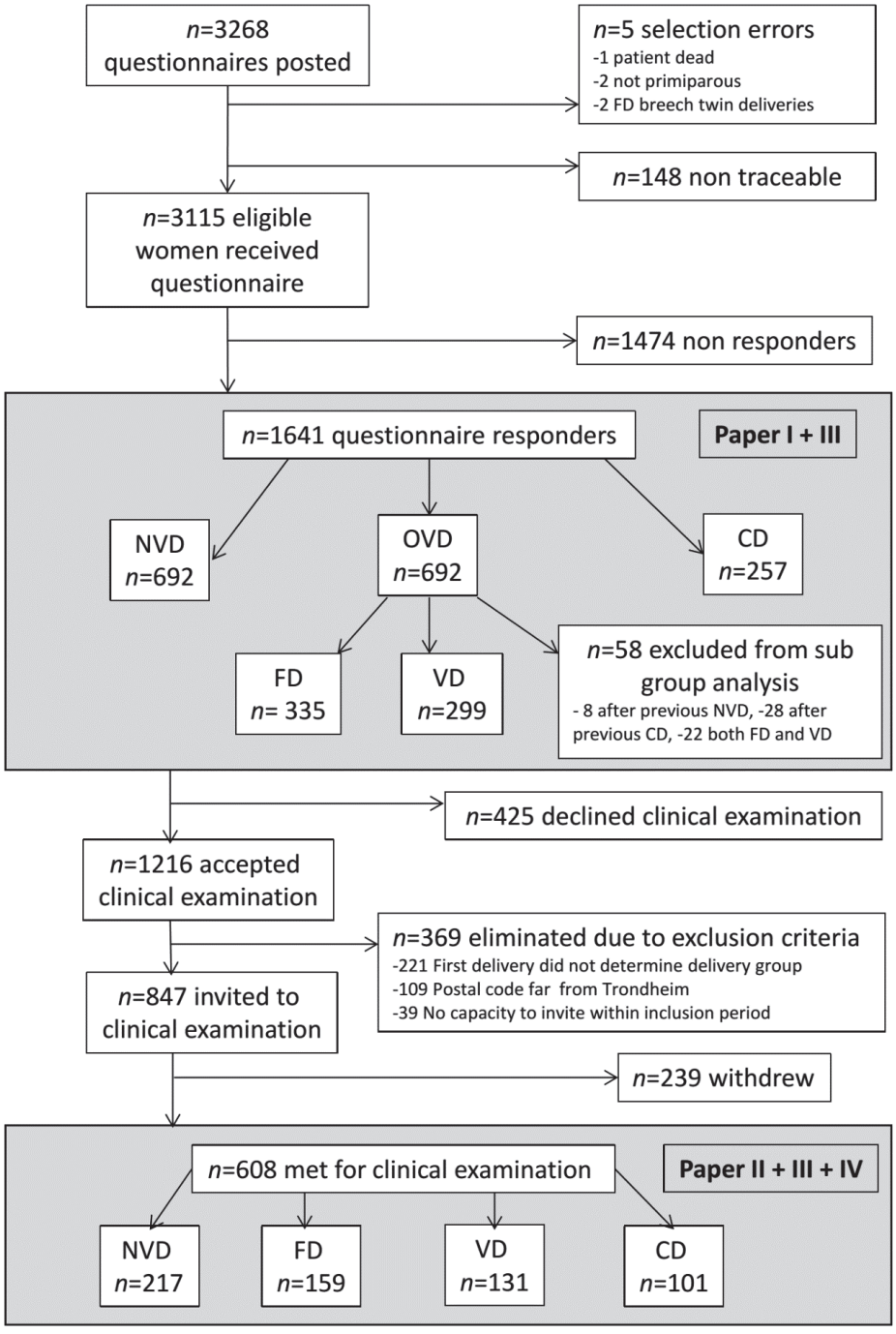


Figure 24 *Flow chart of study participants*

5.2 Background characteristics

Background characteristics for questionnaire responders and for women attending clinical examination are presented in Table 10. Non-responders had mean age 46 years and were significantly younger than responders (mean age 47 years, $p<0.01$). Also more non-responders lived far from Trondheim in 2013 according to their postal code (17% vs 13%, $p<0.01$). Further data for comparison of non-responders was not available.

Table 10 *Characteristics for questionnaire responders and women attending clinical examination.*

	Questionnaire responders	Women examined Mean (SD) or % (N)
Age in 2013 (years)	47.3 (4.9)	47.9 (4.9)
Age at 1st delivery (years)	27.7 (4.5)	28.3 (4.6)
Parity (N of deliveries)	2.2 (0.8)	2.2 (0.8)
Largest infant`s birth weight (g)	3834 (524)	3861 (506)
Head circumference largest infant (cm)	36.4 (1.5)	36.5 (1.4)
BMI (kg/m^2)	25.8 (4.7)	25.8 (4.5)
Menopause	20% (299/1499)	23% (126/541)
Hysterectomy	4% (63/1632)	5% 30/606)
Smoking	18% (297/1630)	20% (119/606)
Chronic coughing	4% (67/1630)	6% (34/606)
Outcome variables		
sPOP	11% (172/1580)	15% (87/589)
UI	47% (752/1603)	51% (303/592)
FI	9% (145/1594)	11% (65/593)

The women examined were significantly older than the background population of questionnaire responders and older at first delivery, but there were no statistically significant differences for parity, largest infant's birth weight or BMI.

Women in the NVD group were significantly younger, had lower BMI and higher parity compared to other delivery groups. Women in the CD group were older, had higher BMI and lower parity than the vaginal delivery groups. Women in the FD and VD groups

were comparable for age, BMI and parity, but infants were significantly larger in the VD group. There was no significant difference in indication for OVD, OASIS prevalence and use of epidural analgesia between FD and VD.

Significantly more women with sPOP were included in the clinical examination part of the study compared to the background population of questionnaire responders (15% vs. 11%, p=0.01), see Table 10. There was also a tendency towards more FI and UI among women that were examined, but the difference was not statistically significant.

Episiotomy was performed as routine for OVD during the study period, and episiotomy rates were reported to be between 73-82% from 1995 through 97, with no reliable data prior to 1995. Analysis including episiotomy as a variable was not possible.

5.3 Paper I

Main results

Cesarean delivery was associated with decreased risk of pelvic floor dysfunction 15-23 years after first delivery.

Operative vaginal delivery was associated with increased risk of pelvic floor dysfunction 15-23 years after first delivery.

There was no difference between forceps and vacuum delivery.

Overall, the prevalence of the main outcomes was: sPOP 11% (172/1580), UI 47% (752/1603) and FI 9% (145/1594), and 47% (727/1549) of women were asymptomatic. Prevalence according to delivery group is presented in Table 11.

Table 11 *Prevalence of pelvic floor disorders according to delivery group*

	Normal vaginal delivery	Cesarean delivery	Operative vaginal delivery	Vacuum delivery	Forceps delivery
Pelvic floor disorder					
Symptomatic pelvic organ prolapse	9% (61/666)	5% (11/245)	15% (100/669)	15% (43/289)	16% (51/325)
Urinary incontinence	48% (323/676)	39% (99/251)	49% (330/676)	51% (149/291)	47% (156/329)
Fecal incontinence	6% (41/671)	9% (22/246)	12% (82/677)	12% (36/292)	13% (42/329)
Number of pelvic floor disorder					
0	48% (313/651)	58% (139/241)	42% (275/657)	40% (114/282)	42% (134/321)
1	42% (276/651)	33% (80/241)	42% (276/657)	43% (120/282)	42% (134/321)
2	9% (57/651)	8% (20/241)	14% (93/657)	15% (42/282)	14% (46/321)
3	1% (5/651)	1% (2/241)	2% (13/657)	2% (6/282)	2% (7/321)

The prevalence of single PFDs and overlaps of two or three PFDs are presented in Figure 25. There was a large degree of overlap between symptoms of sPOP and UI, and of FI and UI: 60% (101/169) of women with sPOP had UI, 72% (100/139) of women with FI had UI. There was a lower degree of overlap between sPOP and FI, where 17-20% of women had both symptoms. Most women with UI (75% (543/724)) had not other symptoms. Among women with at least one PFD, 2% (20/822) had all three PFDs.

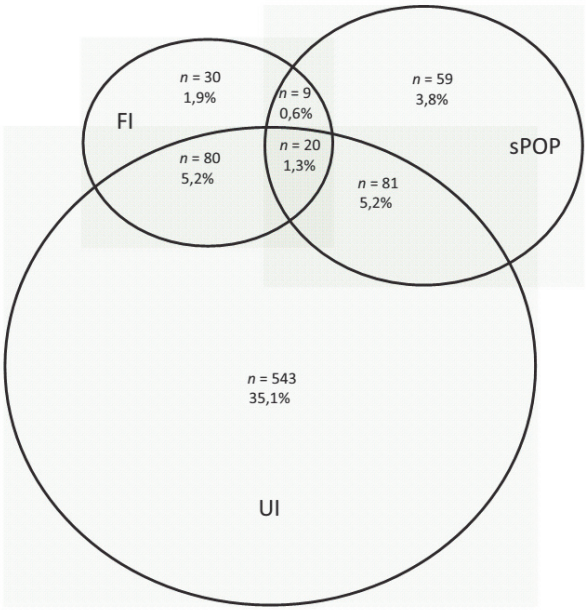


Figure 25 *Prevalence of urinary incontinence (UI), fecal incontinence (FI) and symptomatic pelvic organ prolapse (sPOP) and overlap of symptoms among 1549 women who had responded to questions regarding all three pelvic floor disorders.*

CD was associated with decreased risk for sPOP and UI compared to NVD. OVD was associated with higher prevalence of sPOP and FI compared to NVD. There was a higher prevalence of asymptomatic women in the CD group and higher prevalence of women with two PFDs in the OVD group when compared to NVD. There were no differences between FD and VD groups for any of the PFDs or number of disorders.

In addition to delivery mode, chronic coughing was a significant contributing risk factor for sPOP. BMI was a borderline significant risk factor for sPOP and statistically significant for UI. Also parity and the largest infant's birth weight were risk factors for UI, but parity did not remain significant in a multivariable logistic regression analysis and infant birth weight was only borderline significant. Smoking and OASIS were statistically significant risk factors for FI after multivariable logistic regression.

See Paper I for numeric details.

5.4 Supplementary analyses paper I

As a response to a "letter to the Editor", a subgroup analysis was done to calculate the prevalence of different types of UI, Stress Urinary Incontinence (SUI) and Urge Urinary Incontinence (UUI) (Appendix IV)[145, 146]:

For SUI the prevalence according to delivery group was: CD: 30% (77/256), NVD: 41% (280/688), OVD: 38% (262/688), FD: 37% (122/333) and VD: 41% (123/297). The differences between groups were similar as for the composite variable UI (UUI, + SUI + surgery).

For UUI the prevalence according to delivery group was: CD: 27% (68/256), NVD: 26% (176/678), OVD: 27% (187/682), FD: 26% (87/332) and VD: 30% (87/293). There were no statistically significant differences between the groups for urge urinary incontinence.

We originally planned to analyze differences between delivery groups in mean symptom score. The range is 0-100 for each subscale (POPDI, UDI, CRADI), and 0-300 for PFDI total. Data were not normally distributed and Mann Whitney-U test was therefore used. It was not possible to adjust for confounders. Table 12 and 13 present the mean, SD and Range for each subscale for delivery groups, and differences between groups. There was no significant difference in mean values for any of the scales comparing CD to NVD. The only significant differences between groups were mean POPDI and CRADI score which was higher after OVD compared to NVD, and this difference was also significant for the total PFDI-score. There was no significant difference in mean values for any of the scales comparing FD to VD. We observed that the highest upper border of the range, and close to maximal scores, were found in the CD group for POPDI, CRADI and PFDI total, but we have no information *why* one woman in the CD group had high scores.

Table 12 *Comparison between Cesarean delivery (CD), normal vaginal delivery (NVD) and operative vaginal delivery (OVD) by Mann Whitney-U test for symptoms scores of pelvic floor disorder: Pelvic Organ Prolapse Distress (POPDI), ColoRectal-Anal Distress (CRADI), Urinary Distress (UDI) and total score for Pelvic Floor Distress (PFDI).*

Scale	CD			NVD			OVD			CD vs NVD	OVD vs NVD
	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	*p*	*p*
POPDI	2.5	7.4	0-96	2.4	6.0	0-83	2.7	5.0	0-50	0.22	0.02
CRADI	10.8	15.3	0-100	10.2	13.3	0-75	13.5	16.0	0-84	0.82	<0.01
UDI	9.4	14.3	0-75	10.1	13.9	0-79.2	11.5	15.3	0-75	0.10	0.19
PFDI-total	22.7	31.5	0-271	22.6	27.2	0-207	27.5	29.8	0-172	0.28	<0.01

Table 13 *Comparison between forceps (FD) and vacuum delivery (VD) by Mann Whitney-U test for symptoms scores of pelvic floor disorder: Pelvic Organ Prolapse Distress (POPDI), ColoRectal-Anal Distress (CRADI), Urinary Distress (UDI) and total score for Pelvic Floor Distress (PFDI).*

Scale	FD			VD			FD vs VD
	Mean	SD	Range	Mean	SD	Range	*p*
POPDI	2.9	4.9	0-35	2.8	5.4	0-50	0.83
CRADI	14.6	16.8	0-84	12.8	15.3	0-69	0.19
UDI	12.3	15.7	0-75	11.3	15.3	0-71	0.62
PFDI-total	29.8	31.2	0-160	26.6	29.4	0-172	0.19

5.5 Main results for women attending clinical examination

The prevalence of POP ≥ stage 2 for all women examined was 45% (275/608) in one or more compartments. Among these women 28% (172/608) had POP ≥ stage 2 in the anterior compartment, 5% (29/608) in the middle compartment and 25% (154/608) in the posterior compartment. POP stage 3 was found in 11 women (1.8%), 7 in the anterior compartment, 5 in the middle compartment and 1 in the posterior compartment. No women had POP stage 4.

In all, 607 ultrasound datasets of 6 volumes each were analyzed. One dataset had not been stored properly, and in one dataset there was an artefact making avulsion analysis impossible, but analysis of hiatal areas was possible. Levator avulsion was diagnosed in 18.6% (113/608) of the women, 56 (9.2%) were unilateral and 57 (9.4%) were bilateral. Fifty-three women were unable to perform a proper Valsalva maneuver without levator co-activation. The hiatal area on Valsalva was measured in 554 women. Mean hiatal area for the whole study population was: at rest 23.07 cm^2, SD 4.98, at contraction 15.90 cm^2, SD=4.73 and at Valsalva 34.32 cm^2, SD 10.27. Hiatal areas were normally distributed. A total of 164 women (30%) had Area > 40 cm^2. In all, 195/553 (35%) had levator avulsion or Area > 40 cm^2, and 79/553 (14%) had both levator avulsion and Area > 40 cm^2.

Due to technical problems with the perineometer, registrations were missing for 49 women. Perineometry was not available from 05.02.2014 through 11.02.2014, and for 8 women outside this time period the data were not stored properly. A total of 559 women were examined with perineometry. The mean vaginal squeeze pressure was 29.6 cm H_2O, (SD 19.7, Range 0-129). All women were examined with palpation, and the mean MOS was 3.1 (SD 1.3, Range 0-5). Perineometry and MOS data were not normally distributed.

5.6 Paper II

Main results

Cesarean delivery had decreased risk for prolapse stage 2 or surgery, levator avulsion and smaller hiatal areas compared to normal delivery.

Forceps had increased risk for prolapse stage 2 or surgery, levator avulsion and larger hiatal areas compared to vacuum and normal vaginal delivery.

There was no difference between vacuum and normal delivery.

Table 14 gives the prevalence for PFMT and POP according to delivery group. FD was associated with increased risk of POP ≥ stage 2 or surgery when compared to VD and NVD and for POP ≥ stage 3 compared to VD. FD also had a fourfold increased risk for avulsion injury when compared to both VD and NVD. The mean hiatal areas both at rest, contraction and Valsalva were significantly larger after FD than after VD and NVD. There were no statistically significant differences in prevalence of POP ≥ stage 2 or surgery, levator avulsion or hiatal areas between VD and NVD. CD was associated with a decreased risk of POP ≥ stage 2 or surgery, levator avulsion and hiatal areas were significantly smaller when compared to NVD.

The study was not powered to study differences between elective (n=23) and acute (n=78) CD, but there was no difference in POP prevalence (2/23 and 4/78) and hiatal areas were similar in the two CD subgroups as demonstrated in Table 15.

Age in 2013 was associated with increased risk of POP ≥ stage 2 or surgery and with levator avulsion in a multivariable logistic regression model. Infant birth weight was associated with POP≥ stage 2 or surgery, avulsion and larger hiatal areas. The contributing effect of parity on POP≥ stage 2 or surgery disappeared after adjusting for other confounding variables in the multivariable regression model. BMI was a significant confounder only for hiatal area.

For numeric details, see Paper II.

Table 14 *Prevalence for pelvic floor muscle trauma and pelvic organ prolapse (POP) according to delivery group.*

	Forceps delivery N=159	Vacuum delivery N=131	Normal vaginal delivery N=217	Cesarean delivery N=101
POP anterior compartment				
≥ stage 2	60 (38%)	36 (28%)	72 (33%)	4 (4%)
≥ stage 3	4 (3%)	0 (0%)	3 (1%)	0 (0%)
POP mid compartment				
≥ stage 2	13 (8%)	6 (5%)	10 (5%)	0 (0%)
≥ stage 3	3 (2%)	0 (0%)	2 (1%)	0 (0%)
POP posterior compartment				
≥ stage 2	54 (34%)	42 (32%)	56 (26%)	2 (2%)
≥ stage 3	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)
POP in any compartment				
≥ stage 2	97 (61%)	67 (51%)	105 (48%)	6 (6%)*
≥ stage 3	7 (4%)	0 (0%)	4 (12%)	0 (0%)
Previous prolapse surgery	8 (5%)	2 (2%)	5 (2%)	0 (0%)
-cured	3 (2%)	0 (0%)	2 (1%)	0 (0%)
-still POP ≥ stage 2	5 (3%)	2 (2%)	3 (1%)	0 (0%)
POP ≥ stage 2 or previous prolapse surgery	100 (63%)	67 (51%)	107 (49%)	6 (6%)*
Levator avulsion				
-Any	65 (41%)	19 (15%)	29 (13%)	0 (0%)
-unilateral	29 (18%)	10 (8%)	17 (8%)	0 (0%)
-bilateral	36 (23%)	9 (7%)	12 (6%)	0 (0%)
Hiatal area cm^2				
-rest	25.17 (5.5)	22.64 (4.5)	23.30 (4.6)	19.85 (3.8)
-contraction	17.82 (5.4)	16.02 (4.3)	15.86 (4.3)	12.83 (3.2)
-Valsalva	38.81 (9.8)	34.27 (10.5)	34.52 (9.5)	26.50 (7.6)

*2/23 after acute and 4/78 after elective Cesarean delivery

Table 15 *Mean hiatal areas in women after elective and acute Cesarean delivery (CD)*

	Elective CD N= 78 Mean (SD)	Acute CD N= 23 Mean (SD)
Hiatal area cm^2		
-rest	19.9 (3.4)	19.7 (4.9)
-contraction	12.7 (3.2)	13.3 (3.5)
-Valsalva	26.5 (7.3)	26.5 (8.6)

5.7 Paper III

Main results

Many women from the normal population had symptoms and signs of pelvic organ prolapse 15-24 years after first delivery.

Pelvic floor muscle trauma was associated with symptoms and signs of pelvic organ prolapse in women from the normal population.

Levator avulsion was more strongly associated with POP-Q≥ 2 than sPOP. Also levator hiatal Area > 40 cm^2 was more strongly associated with POP-Q≥ 2 than sPOP. Bilateral avulsion was a stronger risk factor than unilateral avulsion for POP≥ 2, and the presence of both avulsion and severe hiatal ballooning further increased the risk for prolapse. We found the strongest association for avulsion and Area > 40 cm^2 for mid compartment and anterior compartment prolapse and a weaker but significant association to posterior compartment prolapse. Levator avulsion and Area>40cm^2 were independently associated with POP-Q≥2 when entered simultaneously into the multivariable regression model. For sPOP only Area>40cm^2 remained an independent risk factor after entering all other factors into the model. POP-Q≥ 2 was a risk factor for sPOP. For numeric details, see Paper III.

We had decided to use POP-Q≥2 as indicative for clinically relevant prolapse in this study. By using other cut offs, the positive response to seeing or feeling a vaginal bulge would be more sensitive, see Table 16.

Table 16 *Sensitivity of "seeing or feeling a vaginal bulge" depends on cut off used to define significant pelvic organ prolapse*

Definition used	Proportion of prolapse detected by positive response to question	Sensitivity
POP-Q≥ 2	56/270	21%
POP-Q to the hymen	36/135	27%
POP-Q> 0.5cm beyond the hymen	11/21	52%
POP-Q> 1 cm beyond the hymen= grade 3	9/11	82%

In all, 227 of 544 women with complete dataset had no PFMT or POP-Q≥2 and were asymptomatic. Among these women, there were 79 (89%) of 89 women who had delivered exclusively by CD, 44 (38%) of 117 women delivered by VD, 71 (38%) of 188 women with NVD, and 33 (22%) of 150 delivered by FD. Differences between delivery groups were statistically significant (p<0.01), see Figure 26.

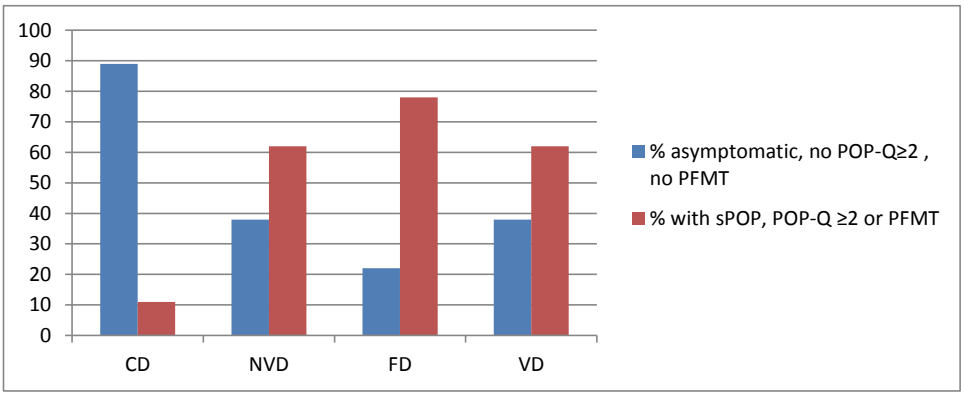


Figure 26 *Symptoms and signs of pelvic organ prolapse (sPOP and POP-Q ≥2) and pelvic floor muscle trauma (PFMT) present and absent according to delivery groups.*

Figure 27 illustrates the association between PFMT, sPOP and POP-Q≥2 or 3 among 544 women with complete datasets. We found that most women with sPOP had PFMT and POP-Q≥ 2, but for 12 (17%) of 69 symptomatic women we did not find any PFMT or POP-Q≥ 2. Most women (209/263= 79%) with POP-Q≥ 2 were asymptomatic, and 2 (18%) of 11 women with POP-Q grade 3 were asymptomatic.

Figure 28 illustrates the correlation between POP-Q and levator avulsion and levator hiatal area >40cm^2 separately. Nineteen percent of women with Area >40cm^2 did not have POP-Q≥ 2, and 13% of women with avulsion did not have POP-Q≥ 2. All women with POP=3 had levator avulsion.

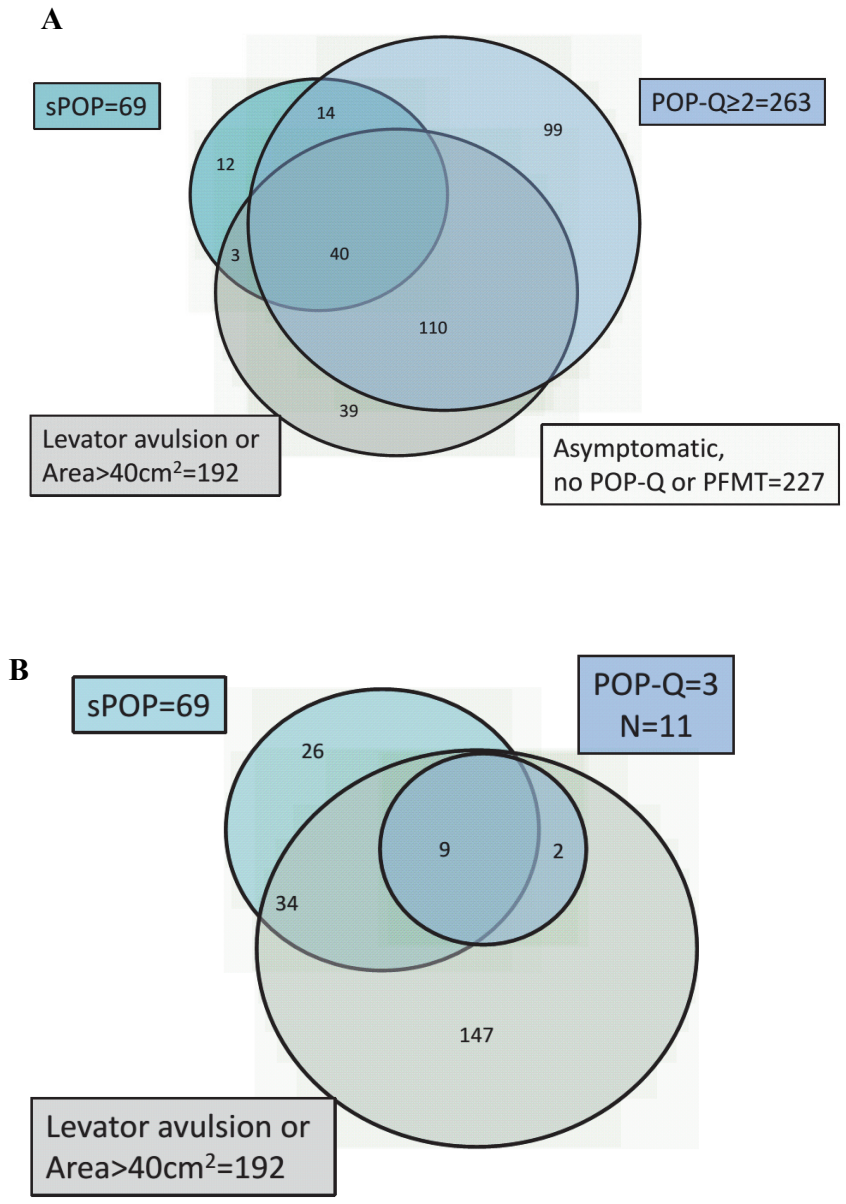
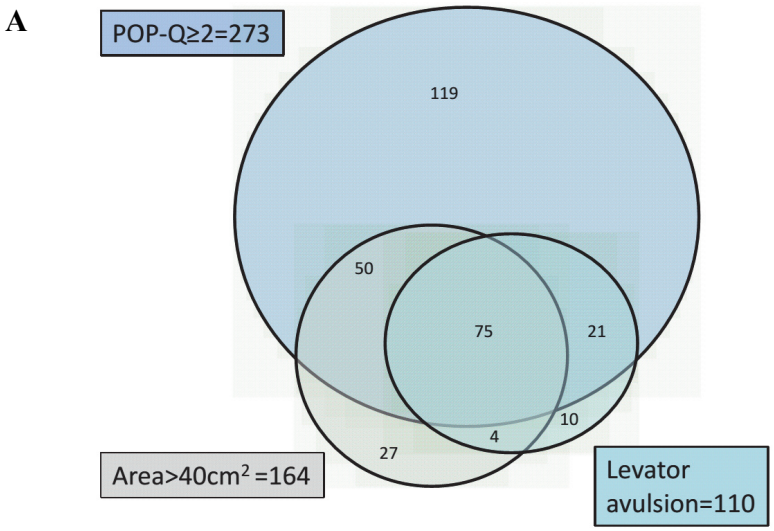


Figure 27

A) Correlation between pelvic organ prolapse grade 2 or larger (POP-Q≥ 2) and symptoms of pelvic organ prolapse (sPOP), pelvic floor muscle trauma (PFMT)

B) Correlation between pelvic organ prolapse grade 3 (POP-Q=3) and symptoms of pelvic organ prolapse (sPOP), pelvic floor muscle trauma (PFMT)



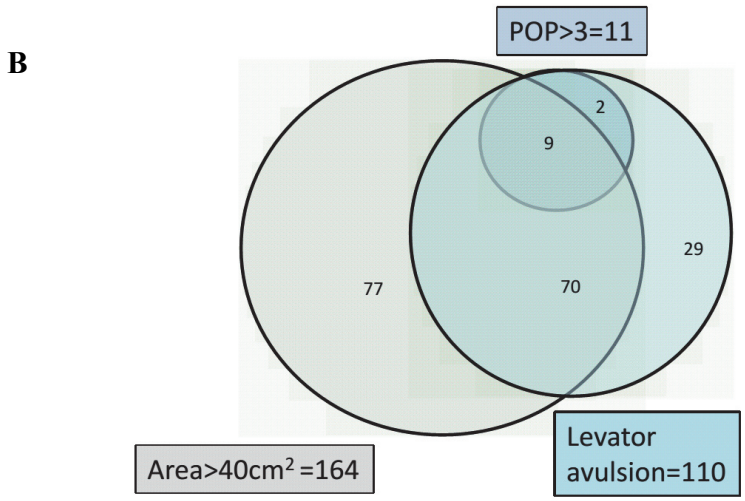


Figure 28

A) Correlation between pelvic organ prolapse grade 2 or larger (POP-Q≥ 2) and levator avulsion and levator hiatal area >40 cm²

B) Correlation between pelvic organ prolapse grade 3 (POP-Q=3) and levator avulsion and levator hiatal area >40 cm²

5.8 Paper IV

Main results

We found moderate to strong correlation between ultrasound measurements and palpation and perineometry.

The proportional change in levator hiatal anteroposterior diameter was the ultrasound measurement with strongest correlation to palpation and perineometry

We defined a contraction scale for ultrasound measurements based on the proportional change in levator anteroposterior diameter.

Values for different assessment methods for pelvic floor muscle contraction are presented in Table 17. Statistically significant correlations were found between all assessment methods. The strongest correlation was found between MOS and perineometry. The Spearman's rank correlation coefficient between ultrasound measurements and both MOS and perineometry is presented in Table 18. MOS had stronger correlation than perineometry to all ultrasound parameters, and the proportional change in hiatal AP diameter had the strongest correlation to MOS. Mean proportional change in the AP diameter with 95% CI in relation to mean MOS is presented in Table 19. Figure 29 presents the correlation between mean MOS and proportional change in AP diameter graphically.

Cut offs for proportional change in AP diameter according to a four point scale based on the proportions allocated to each category by palpation was: Proportional change in AP diameter < 7% corresponded to absent contractions, 7-18% corresponded to weak contractions, 18-35% corresponded to normal contractions, and >35% corresponded to strong contractions, see Table 20. When applying these cut offs, the correlation between palpation and proportional change in AP diameter remained good, and 65% of the contractions were allocated to the same category by the two methods; furthermore, for only two contractions a discrepancy of more than one category was found between the two methods.

Table17 *Results for different assessment methods for pelvic floor muscle contraction*

Assessment method	Mean	SD	Range
Mean Modified Oxford Scale (n=608)	3.1	1.3	0-5
Perineometry (cm H_2O) (n=559)	29.6	19.7	0-129
Change in hiatal area (cm^2) (n=607)	7.2	3.2	0-21.1
Change in AP diameter (cm) (n=607)	1.6	0.7	0-3.4
Change in hiatal area (%) (n=607)	31.1	12.1	0-64.0
Change in AP diameter (%) (n=607)	24.4	9.8	0-50.9

Table 18 *Spearmans correlation (r_s) between ultrasound measurements and Modified Oxford Scale and perineometry*

	Mean Modified Oxford Scale (n=607)	Perineometry (n=558)
Change in hiatal area on ultrasound (cm^2)	0.54	0.46
(%)	0.67	0.60
Change in AP diameter on ultrasound (cm)	0.63	0.58
(%)	0.69	0.66

Table 19 *Mean proportional change in the hiatal anteroposterior diameter with 95% confidence interval (CI) in relation to mean Modified oxford Scale*

Mean Modified Oxford Scale	Number of women	Percent change in anteroposterior diameter Mean	SD	95% CI
0	21	10.70	6.8	7.6-13.8
0.5	16	11.33	8.0	7.1-15.6
1	23	12.48	6.0	9.9-15.1
1.5	40	16.37	6.9	14.2-18.6
2	61	17.52	7.0	15.7-19.3
2.5	31	21.64	6.0	19.5-23.8
3	131	23.62	7.2	22.4-24.9
3.5	28	26.28	6.3	23.8-28.7
4	177	29.24	7.2	28.2-30.3
4.5	7	36.60	10.0	27.3-45.9
5	72	34.54	7.1	32.8-36.2

Table 20 *Proposed contraction scale with cut offs for percent change in hiatal anteroposterior (AP) diameter on ultrasound*

4 graded scale	Number (%) by palpation	Cut offs for %AP change
Absent	21 (3.5%)	<7%
Weak	140 (23%)	7- 18%
Normal	367 (60.5%)	18-35%
Strong	77 (13%)	>35%

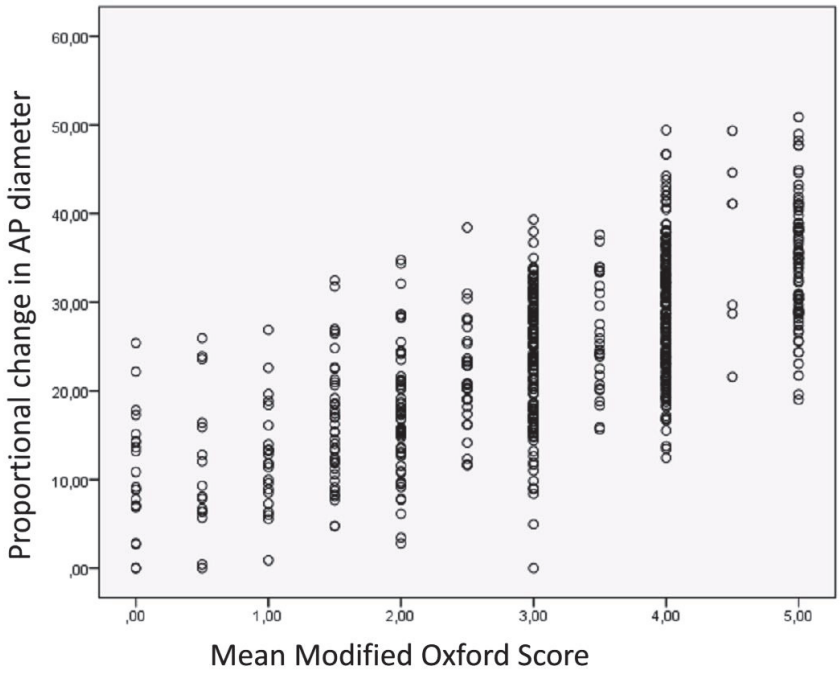


Figure 29 *Correlation between the Mean Modified Oxford Scale (MOS) and proportional (percentage) change in antero-posterior (AP) diameter. From Volløyhaug et al 2015 Assessment of pelvic floor muscle contraction with palpation, perineometry and transperineal ultrasound: a cross-sectional study, with permission from John Wiley and Sons.*

6 Discussion

6.1 Main strengths and weaknesses

Main strengths

The study had a long follow up of 15-24 years after first delivery.

Study participants were recruited from the normal population of parous women.

The doctors were equally trained in forceps and vacuum when the women delivered.

The response rate was similar for all delivery groups.

This is the hitherto largest study comparing forceps and vacuum for pelvic floor disorders, pelvic organ prolapse and pelvic floor muscle trauma.

Main weaknesses

The response rate was 53%, and the external validity is therefore not optimal

The cross sectional study design only permits to establish association, not causation

6.2 Methodological considerations

6.2.1 Study design

A weakness of this study was the cross-sectional study design. A cross-sectional study design can only find an association between delivery mode and PFD, PFMT and POP. The ideal would be to conduct a randomised study to establish causal inferences between delivery mode and PFD, POP and PFMT.

6.2.2 Bias regarding diagnostic criteria

A validated translation into Norwegian of questionnaires on sPOP, UI and FI was not available when the study was conducted. We chose a translation of the PFDI used by other Norwegian investigators, however not yet published. PFDI is not a screening questionnaire, but for the analyses we extracted five clearly formulated key questions and counted any positive response without calculation of scale scores. Counting any positive response as diagnostic for PFD without regard to severity of symptoms, may have contributed to the relatively high prevalence of PFD in our study population introducing a possible misclassification bias. The PFDI questionnaire was developed for use in patient populations, and this could explain why women in the present study had a low mean score on all three subscales, and why the scores were not normally distributed.

All women were examined in a standardized way by the same examiner applying uniform diagnostic criteria. The person who performed the examinations was blinded to all background data regarding delivery mode, parity and symptoms. The women were covered with a cloth to hide surgical scars on the abdomen, but in some women it was possible to see a scar after episiotomy. Episiotomy was routine for all OVDs and also frequent for NVDs in the period 1900-97. Seeing a scar implied that a woman did not belong to the CD group, but she could belong to any of the vaginal delivery groups.

The person who performed the examinations had long experience in examining women with POP according to the POP-Q criteria, and adequate training in pelvic floor ultrasound for assessment of hiatal areas and levator avulison [70]. Offline analysis of the ultrasound volumes was performed 6-14 months after the ultrasound scan, and the person who performed the analyses was blinded to clinical and demographical data.

The cut off of levator hiatal area >40cm^2 to define abnormal hiatal overdistension was chosen arbitrary on the basis of a previous publication [75], and not defined from the mean of this study population for determination of the 95th centile (54.9cm^2) or the mean plus two

standard deviations (51.9 cm^2), which are definitions used to describe the normal range (https://en.wikipedia.org/wiki/Reference_range).

The levator-urethral gap was measured when doubt about avulsion diagnosis, and the measurement was used to compare the gap between the two sides [69]. We had the impression that women in this study population had a larger levator urethral gap than previously described even when the levator was intact, and the cut off of normality previously described (levator-urethral gap> 25 mm strongly associated with levator avulsion) was therefore not applied [69].

6.2.3 Selection bias

It has been demonstrated that symptomatic women are more prone to participate in studies [91]. This could lead to an overestimation of the prevalence of symptoms. Only 53% of invited women responded to the questionnaire. Non-responders were significantly younger than responders, and therefore they probably had less symptoms than responders, as PFD increases with advancing age. More non-responders lived far from Trondheim in 2013 according to their postal code, which probably reflect that women living far from Trondheim are less interested in studies at Trondheim University Hospital. This should not lead to a biased prevalence estimate. In all, 72% of women invited for clinical examination were examined. Significantly more women with sPOP met for examination compared to the background population of questionnaire responders. The women who were examined were also slightly older in 2013 and at first delivery. Women who met for examination could be a selection of more obedient women or women with an occupation permitting them to take time off and come for the examination.

6.2.4 Internal validity

The response rate to the questionnaire was similar for all delivery groups, but slightly higher in the VD group compared to NVD and CD. There was no difference in participation rate between delivery groups in the clinical examination. Since the questionnaire response rate was similar in the four delivery groups and the proportion of women who met for examination was equal between groups, it is reasonable to believe that the comparison between delivery groups is valid.

6.2.5 External validity

Women in the study were predominantly white European, and the results should be interpreted with caution for diverse ethnic groups [37, 38, 56, 59, 91, 120, 121, 147]. It is fair to assume that the prevalence of PFD, objective POP and PFMT could be over estimated due to the factors discussed under selection bias. All women in this study were parous, and one would expect a lower prevalence of PFD and POP, and no PFMT in nulliparous women.

6.2.6 Possible bias in disfavour of vacuum

Rotational forceps was not recommended at Trondheim University Hospital during 1990-97, and FD was only carried out for low or mid-cavity fetal head in occiput anterior or occiput posterior position. VD was allowed if the fetal head was at or below the spines and for all head positions. Higher stations and different positions may implicate higher risk of trauma and may have introduced bias in disfavour of VD. Another possible source of bias was better training and/or operative skills for FD. In 1980-1989 the FD:VD ratio was 3:1 at Trondheim University Hospital, whereas in 2000-2010 the FD:VD ratio was 1:8. Over a period of 15-20 years VD became the method of choice for OVD in this hospital. Theoretically doctors were better trained in FD than VD during 1990-97. Thus, both these possible biases would be towards more complications in the VD group.

6.3 Relation to other studies

6.3.1 Pelvic floor disorders in association to delivery mode

The present study is the hitherto largest epidemiological study addressing possible risk difference between FD and VD regarding PFD. The results support previous studies reporting that CD is associated with lower prevalence of PFD whereas OVD is associated with higher prevalence of PFD [89, 90, 96-99]. No statistically significant association between sPOP, UI or FI and mode of operative vaginal delivery (FD and VD) was found. Since the confidence intervals were large, it is not possible to rule out a clinically relevant difference in favour of either FD or VD. The present findings contrast the results from a smaller study demonstrating that FD, and not VD, increased the odds of PFD compared to NVD 5-10 years after delivery [100] and a randomised study demonstrating higher prevalence of FI after FD compared to VD [101]. Other studies with short time interval after delivery have demonstrated increased risk of FI after FD compared to VD [78, 101, 102].

Since the present study was planned, there are some recent publications from Sweden addressing risk differences for PFD between primiparous women delivered by CD and vaginal delivery with a long follow up demonstrating increased risk of sPOP, UI and FI after vaginal delivery [148-150]. Women delivered by forceps were not represented in that population. We found that CD was not protective against FI, and this is supported by other studies [50, 90, 110, 127].

6.3.2 Pelvic floor muscle trauma and pelvic organ prolapse in association to delivery mode

The association between PFMT and delivery mode was established prior to the start of the present study, but only in patient populations and puerperal women [72, 73, 133-137]. In this study the association was confirmed in women from a normal population. Prior to start of this study, there were only four studies distinguishing PFMT prevalence between FD and VD [71, 73, 134, 138]. During 2014-15 five new studies focusing on the difference between FD and VD were published and summarised in a recent review [151], see Table 19. The results from these studies are in concordance with our findings of increased prevalence of levator avulsion after FD when compared to VD and NVD, see Figure 30, even if most studies find an intermediate prevalence of levator avulsions after VD [72, 73, 133-137, 152-156]. Our study is the second largest of similar studies, and we have a longer follow up after delivery than all previous studies, which

is important, as it has been demonstrated that levator trauma can heal within the first years after delivery [157]. Another strength of the present study, not indicated in previous studies, is that doctors were equally trained in forceps and vacuum, and the procedures were performed for the same indications, and we can conclude that muscle trauma were method dependent, and not dependent on the indication for delivery or the doctors' skills, which could have been the case in previous studies.

Table 21 *Prevalence of avulsion of the puborectalis muscle. The last two columns give odds ratios and confidence intervals for avulsion in forceps (FD) vs. normal vaginal delivery (NVD) and forceps compared with vacuum extraction delivery (VD). Modified after: Dietz 2015: Forceps: towards obsolescence or revival? With permission from John Wiley and Sons © 2015 Nordic Federation of Societies of Obstetrics and Gynecology*

Author	Year	*n*	Follow up	% Full avulsion	FD vs NVD OR (95% CI)	FD vs VD OR (95% CI)
Dietz and Lanzarone	2005	50	4 months	36%; 4 FD only	–	–
Kearney et al.	2006	160	9–12 months	NVD 12%, VD 17%, FD 66%	15.3 (4.5–55)	10 (1.3–96)
Krofta et al.	2009	76	1 year	FD only, 64%	–	–
Shek et al	2010	367	4 months	NVD 12%, VD 9%, FD 35%	4 (1.3–12.4)	5.6 (1.05–32.9)
Valsky et al.	2010	210	3	19%; no FD	–	–
Albrich et al.	2010	159	2–3 days	40%; one FD only	–	–
Kearney et al.	2010	157	>1 year	NVD 6% (8/129), FD 53% (20/38)	16.8 (5.9–49.4)	–
Cassado G et al.	2011	164	?	NVD 15%, FD 50%; no VD	10.3 (3–37.4)	–
Blasi et al.	2011	52	1	31%; no FD	–	–
Eisenberg et al.	2011	73	1 year	NVD 20%, VD 41%, FD 89%	32 (4.5–301)	11.4 (2–74)
Chan et al.	2012	339	2 months	NVD 15%, VD 33%, FD 71%	13.7 (3.6–56)	5 (1.2–22.8)
Van Delft et al.	2014	191	3 months	NVD 10%, VD 13%, FD 48%	8.4 (2.5–29.3)	5.9 (1.3–29.1)
Caudwell Hall et al.	2014	844	4.6 months	NVD 13%, VD 13%, FD 44%	5 (2.6–9.4)	5.3 (2.3–12.6)
Memon and Handa	2014	79	10 years	no NVD; VD 15%,, FD 50%	–	5 (1.63–15.3)
Chung et al.	2014	289	2 months	no NVD; VD 17%, FD 40.5%	–	3.42 (1.6–7.3)
Durnea et al.	2014	202	1.8 years	NVD 6%, VD 18%, FD 55%	18.2 (5.3–67)	5.3 (1.6–18)

There has been less focus on differences in levator hiatal areas after different delivery modes [30, 158, 159]. Larger increase after delivery and, in general, larger hiatal areas after FD than VD has been described, but the effect could be partly explained by a higher prevalence of levator avulsions in the FD group, as levator avulsion contributes to larger hiatal areas [30]. Nevertheless, levator avulsions and larger levator hiatal areas have been described as independent risk factors for POP [140]. We found significant differences in levator hiatal areas both at rest, contraction and Valsalva between CD and NVD, and between FD and NVD/VD. Women were only examined once, and many years after delivery, it was therefore not possible to assess any difference in hiatal area before and after delivery in our study population. There are several arguments for hiatal areas *not* being larger in the FD group *prior* to delivery: 1) FD was performed at similar indications as VD. 2) There was a higher prevalence of PFMT after FD than VD, despite the fact that infants in the vacuum group were significantly larger. 3) Some authors have found an association between smaller levator hiatal areas in pregnancy and the need for operative vaginal delivery and CD [158, 160, 161]. We therefore assume that the larger hiatal areas seen in the FD after delivery is caused by the delivery method.

A plausible explanation is that PFMT is more likely to occur during FD due to a more traumatic effect of the blades of the forceps and the excessive traction force allowed, acting as a plough and causing more dilatation of the birth canal and more trauma to the levator ani muscles than the vacuum device, see Figure 30.

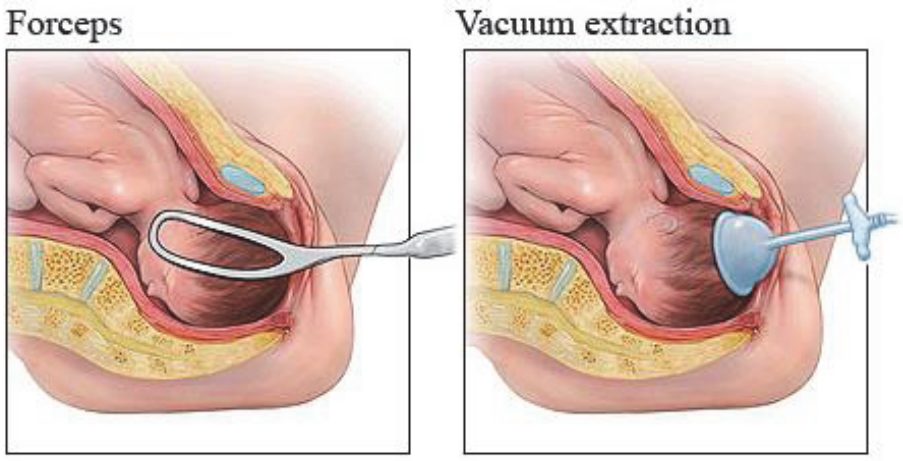


Figure 30 *Forceps delivery and vacuum delivery.*
From:
https://myhealth.alberta.ca/health/_layouts/15/healthwise/media/medical/hw/h9991588_001.jpg

Over all, we found larger hiatal areas compared to previous studies for all delivery groups [75, 158]. This could be explained by ethnical differences. Women examined were mainly of Norwegian (Caucasian) ethnic origin. Other authors have recently found significant differences in hiatal biometry between women of different ethnic origins [162]. We found similar hiatal areas as other researchers from Norway [163]. Another explanation is that women were examined many years after their first delivery, and hiatal dimensions could increase over time.

Studies comparing anatomical POP prevalence after FD and VD are sparse and the results are conflicting. One study demonstrated that FD, and not VD, was associated with higher prevalence of POP compared to NVD [100] whereas another study has found a protective effect of FD [119]. Both studies and had a shorter follow up (5-10 and 12 years) than the present study, and the number of OVDs was smaller in the first study (VD: 49, FD: 76) and similar in the second (VD: 190, FD: 392), with larger proportion of FD than VD in both studies. One previous study has demonstrated an association between prolapse surgery and FD, when compared to NVD, but no women with VD were included [164]. We found higher prevalence of prolapse surgery after FD (5.2%) than VD (1.6%), but because of small numbers we were not able to demonstrate a statistically significant difference between FD and VD for prolapse surgery alone.

6.3.3 Association between pelvic floor muscle trauma and symptoms and signs of pelvic organ prolapse

Previous studies on association between PFMT and POP have been conducted in urogynecological patient populations or among women a few months after delivery [23, 68, 75, 133, 139-143, 165, 166]. The analyses in the present study confirmed a similar association between sPOP, POP-Q≥ 2 and PFMT also in women from a normal population many years after delivery. Levator avulsions and larger levator hiatal areas have been described as independent risk factors for POP [140], and we reproduced this independent association in women from the normal population in Paper III, see also Table 22. Similar to previous studies we found that PFMT had strong association with anterior and mid compartment prolapse, and a weaker association with posterior compartment prolapse [68, 139-141, 165, 167]

The overlap between PFMT, sPOP and POP-Q≥ 2 was not complete. A discrepancy between symptoms and signs of POP was also found in other studies. Mouritsen et al investigated the association between mechanical, bladder, bowel and sexual problems to POP

symptoms and signs, and found that symptoms had little relation to prolapse in a specific compartment or to POP-Q value [43]. Glazener et al found a discrepancy between sPOP and objective measurement of POP [119]. They concluded that sPOP and objective prolapse are associated with different risk factors, and that symptoms are not necessarily related to the anatomical changes of POP. Similar to our findings Tan et al found that the proportion of women feeling a vaginal bulge increases with increasing prolapse grade [60].

6.3.4 Other factors' association to pelvic floor disorders, pelvic organ prolapse and pelvic floor muscle trauma

The contribution of other risk factors than mode of delivery to sPOP, UI, FI, POP-Q≥ 2 and PFMT found in the present study is summarised in Table 22.

Table 22 *Risk factors for symptomatic pelvic organ prolapse (sPOP), urinary incontinence (UI), fecal incontinence (FI), pelvic organ prolapse grade 2 (POP-Q≥ 2) and pelvic floor muscle trauma (PFMT). Crude and adjusted odds ratio (cOR, aOR,) and unadjusted and adjusted mean difference (aMD, aMD) with 95% confidence intervals (CI). Data from paper I*, II** and III***.*

Condition	Significant studied one by one cOR or uMD, 95%CI	Significant after multiple logistic regression aOR or aMD, 95% CI
sPOP	Coughing 2.59 (1.42-4.73)*	Coughing 2.33 (1.22-4.48)* BMI 1.03 (1.00-1.07)* Area >40 cm^2 2.33 (1.27- 4.31)***
UI	Parity 1.14 (1.01-1.28)* BMI 1.09 (1.07-1.12)* Infant birth weight 1.04 (1.02-1.06)*	 BMI 1.09 (1.06-1.12)* Infant birth weight 1.02 (1.00-1.04)*
FI	OASIS 2.07 (1.08-3.94)* Smoking 2.17 (1.48-3.17)*	OASIS 2.62 (1.27-5.42)* Smoking 2.10 (1.35-3.26)*
POP-Q≥ 2	Parity 1.29 (1.06–1.58)* Infant birth weight 1.04 (1.01–1.07)*	 Age 1.05 (1.01–1.09)* Infant birth weight 1.05 (1.01–1.09)* Levator avulsion 4.08 (2.17-7.69)*** Area >40 cm^2 3.32 (2.02-5.43)***
PFMT Avulsion Area on Valsalva	 Age 1.05 (1.00–1.09)** Infant birth weight 1.04 (1.01–1.07)** Parity 1.29 (1.06–1.58)** BMI uMD 0.24 (0.06–0.43)** Infant birth weight uMD 0.32 (0.15–0.48)**	 Age 1.08 (1.02–1.13)** Infant birth weight 1.06 (1.01–1.12)** BMI aMD 0.23 (0.05–0.41)** Infant birth weight aMD 0.28 (0.11–0.45)**

6.3.5.1 Other risk factors for symptomatic and anatomic pelvic organ prolapse

Parity has previously been described as a stronger risk factor for POP than for UI [114, 118]. In the present study parity was not a significant risk factor for sPOP, and the contributing effect of parity on POP-Q≥ 2 disappeared in the multivariable regression model. A study from 1997 on a large cohort of women followed up for at least two decades found increasing risk of sPOP with increasing parity [118]. Multiparous women were compared to nulliparous women, and delivery mode and infant birth weight were not studied. We found that women delivered by CD had lower parity than women after vaginal deliveries. This is supported by other studies [98], and it is well known that infant birth weight increases with parity [168]. The effect of parity found previously could therefore be explained partly by delivery modes associated to high (NVD) and low (CD) parity, and increasing infant birth weight associated with higher parity. Another study found a five-fold increased risk for prolapse symptoms after multiple vaginal births, but the largest step was found between nulliparity and primiparity [120], and with less effect of parity in women delivered by CD. An increasing risk for sPOP with increasing parity was also found in a recent study after correcting for delivery mode, but not infant birth weight, and the largest step was found between nulliparous and primiparous women [169]. Less than doubled risk between primiparous and multiparous women (18% vs 32%) has been found previously [37]. Tegerstedt et al also found an effect of parity and a non significant effect of infant birth weight on sPOP [89]. Samuelsson found an effect of parity and *high infant birth weight* on anatomical prolapse [55]. The effect of high infant birth weight has also been found by Swift et al [56], and more recently in a Swedish study of primiparous women [149]. We also found that increasing birth weight was a risk factor for POP-Q≥ 2. The effect of high infant birth weight could be via PFMT, see Paragraph 6.3.5.4.

Obesity is an established risk factor for prolapse [52, 56]. We found a borderline significant association between increasing BMI and sPOP, but no effect on POP-Q≥ 2. Recently, the effect of obesity on sPOP has been confirmed by Gyhagen et al [149]. Lonnee-Hoffmann found that obesity was a risk factor for prolapse surgery [170] and that asthma was a non significant risk factor for prolapse surgery. *Chronic coughing* more than doubled the odds for sPOP in our study. Both obesity and chronic coughing increase the intraabdominal pressure, which may contribute to a sensation of downward descent of the pelvic organs. Both conditions also increase the load on the pelvic floor and cause chronic strain, stretching and weakening the muscles, nerves and connective tissue, and may contribute to pelvic organ descent over time.

We found that *age* was associated with POP-Q≥ 2, in concordance with strong evidence from previous studies [52, 90, 98, 99], and supported by recent publications [147, 170, 171].

6.3.5.2 Other risk factors for urinary incontinence

Increasing BMI was the strongest risk factor for UI in addition to delivery mode in the present study. This is in concordance with previous studies that have described obesity as a strong risk factor for UI [37, 38, 92, 105]. The exact mechanism of the obesity-UI association is unknown, but could be similar to POP. Excess body weight increases abdominal pressure, which in turn increases bladder pressure and urethral mobility, causing SUI and also affecting detrusor instability causing UUI [105].

We found an effect of *parity*, as described by other investigators [38, 96, 114], but this effect disappeared in a multivariable logistic regression analysis, whereas *increasing infant birth weight* remained a borderline significant risk factor for UI.

We were not able to reproduce the effect of *age* described in previous studies [37, 51, 115]. This could be explained by the age distribution of study participants, with a normal distribution around the mean of 47.3 years, with 90% women between 40 and 56 years.

6.3.5.3 Other risk factors for fecal incontinence

The strongest risk factor for FI in our study population was *OASIS* at first delivery. Several previous studies have found similar results [81, 102, 129, 130, 172-176]. A protective effect of mediolateral episiotomy on FI has been suggested in previous studies [150], whereas others have demonstrated an association between high rates of routine episiotomy and anal incontinence [88]. Women with OVD in our study had a high rate of episiotomy, but meaningful analysis of this was not possible due to unreliable data.

An effect of *smoking* on FI has been found previously [177] and again in our study. Cigarette smoking may directly influence gastrointestinal motility, but may also be linked to other confounding factors such as educational level, physical activity, and alcohol consumption not controlled for in the present study.

6.3.5.4 Other risk factors for pelvic floor muscle trauma

Increasing age was associated with levator avulsion, probably reflecting that older age at delivery is associated with less elastic musculature. Higher prevalence of levator avulsion with increasing age has been described previously [134, 136].

Increasing infant birth weight was associated with both avulsion and larger hiatal areas. A similar effect of increasing infant birth weight on PFMT has also been described previously [73]. Larger babies are associated with more tissue injury and could also help explain the effect of larger babies on UI and POP-Q≥ 2. We found no contributing effect of indication for OVD (prolonged 2nd stage of labor or fetal distress) epidural or perineal tears, and data on oxytocin augmentation and episiotomy was not available. It seems plausible that women with prolonged second stage of delivery could have a relative feto-maternal disproportion, and thus be more prone to levator trauma. An effect of prolonged second stage of delivery as indication for OVD, epidural or perineal tears has been described by other authors [72, 73, 134].

Main findings regarding other risk factors

We found that body mass index, infant birth weight and age are the most important risk factors, in addition to delivery mode, for pelvic floor disorders and pelvic floor muscle trauma in our study.

Obstetric anal sphincter injury was an isolated risk factor for fecal incontinence.

The effect of parity may be less important than previously assumed, when taking delivery mode and infant birth weight into account.

6.3.6 Association between ultrasound measurements, palpation and perineometry

In most previous studies, palpation and perineometry have been tested against each other [8, 33]. Two previous studies examined palpation and prineometry against ultrasound measurements [28, 29], and found a stronger correlation between palpation and ultrasound than between perineometry and ultrasound measurements (r_s=0.58 vs r_s=0.43 and r_s=0.62 vs r_s=0.52). We also found a stronger correlation between palpation and ultrasound measurements than between perineometry and ultrasound measurements. Both studies, however, found a weaker correlation between assessment methods than we found in the present study, and this could be caused by other ultrasound measurements, bladder neck displacement, used in previous studies.

A publication from 2015 used measurements of the hiatal area and AP diameter at rest and at maximum contraction, and expressed differences in measurements as percentages [144]. This study included 459 pregnant or puerperal women, and the MOS on the weaker side was compared to changes in area and AP diameter. We used the average MOS and found a stronger correlation between the MOS and the proportional change in AP diameter (r_s= 0.69 in the present study versus r_s = 0.51 in the previous study) [144]. This could imply that average MOS is a better estimate of pelvic floor muscle contraction than MOS on the weaker side. On the other hand we found identical correlations between ultrasound measurements and MOS when we used either the strongest or the weakest side to calculate the correlation. Thus, the difference between these studies may be explained by a single examiner performing all palpations in our study. In the present study we found a greater proportional change in hiatal dimensions during pelvic floor muscle contractions than reported in other studies [25, 144]. This may be explained by different populations in the other studies.

6.4 Possible explanations and implications

6.4.1 Paper I

Explanations:

The increased risk of PFD after OVD may be due to a relative fetal maternal disproportion causing the need for OVD, or due to the mechanical effect of the forceps and vacuum devices on the pelvic floor connective tissue, muscles and nerves.

Implications:

It is recommended to avoid OVD in general, because OVD is associated with more PFD than NVD.

6.4.2 Paper II

Explanations:

The hiatal areas were larger and there was more levator avulsion and POP-Q≥ 2 after FD, despite the fact that infants in the VD group were significantly larger. A possible explanation is that PFMT is more likely to occur during FD due to a traumatic effect of the blades of the forceps and the traction force allowed.

Implications:

It is recommended to choose VD in a delivery situation where both methods could be an option, because FD is associated with more PFMT and POP-Q≥ 2 than VD.

6.4.3 Paper III

Explanations:

Intact pelvic floor muscle anatomy is important for pelvic floor function. Trauma to pelvic floor muscles cause disturbed support of the pelvic organs and is associated with anatomical POP-Q≥ 2, in particular of the anterior vaginal wall and of the uterus/mid compartment. PFMT is also associated with sPOP.

Implications:

It is recommended to avoid delivery modes that cause PFMT because PFMT is a risk factor for sPOP and POP-Q≥ 2.

6.4.4 Paper IV

Explanations:

We found a good, but not perfect, correlation between different modes of assessment of pelvic floor contraction. Digital palpation depends on the experience of the examiner. Perineometry

measures intravaginal pressure and is influenced by increased intraabdominal pressure which may be increased by a concomitant Valsalva maneuver.

Implications:

Ultrasound could be a new tool to assess and quantify pelvic floor muscle contraction. Ultrasound is easy to perform, and it is possible to perform the measurements off line. Measurement of levator hiatal AP diameter is an objective measure that is less prone to interrater bias than palpation, and ultrasound measurements are not influenced by increased intraabdominal pressure, as created by a concomitant Valsalva maneuver.

6.4.5 Elective Cesarean delivery to prevent pelvic floor disorders?

Explanations:

Women had significantly less PFMT and POP-Q≥ 2 after CD compared to vaginal deliveries, and CD was associated with a decreased risk of UI and sPOP when analysing the yes/no-response to these questions. When analysing the mean symptom scores, however, there was no difference between CD and NVD for any of the sub scores or total PFDI score. A possible explanation to this is the increased risk of PFD introduced by the pregnancy per se, and also that women in the CD group could have more PFD prior to delivery. CD would not protect against already present symptoms. A weakness of our study is that we did not know the indication for elective CD.

Implications:

Cesarean section will have a limited preventive effect on pelvic floor dysfunction at a population level [50, 119]. On the other hand, PFD caused by PFMT could be prevented by CD.

6.4.6 Associations of delivery mode to other maternal and neonatal conditions

We did not study any other effects of delivery mode on maternal or child health. Other authors have described increased maternal and neonatal morbidity after planned CD compared to planned NVD [178-180]. It has also been suggested that VD may be associated to more neonatal morbidity than FD, mainly cephalhematoma [181, 182], and no difference in morbidity was found at 5 years follow up between children delivered by FD and VD in a recent publication [183].

6.4.7 Discrepancy between anatomical prolapse and symptoms of prolapse

There was no complete overlap between symptoms and signs of POP in the present study. We used POP-Q≥ 2 as diagnostic for anatomical relevant prolapse. This definition is widely used by other authors. One could, however question whether POP-Q≥ 2 is clinically relevant, as only 21% of the women with POP≥ 2 in this study stated they could see or feel a vaginal bulge. This indicates that POP-Q≥ 2 is not necessarily a pathological finding. However, lower grades of prolapse can progress over time and lead to prolapse symptoms [184]. In our study population only a few women had prolapse beyond the level of the hymen, and it is difficult to draw conclusions when the numbers are small. However we found a clear tendency towards more symptoms as prolapses extended beyond the hymen. Despite this, only half the women with prolapses 0.5-1 cm beyond the hymen were symptomatic, and 82% of women with prolapses >1 cm beyond the hymen were symptomatic, as defined by seeing or feeling a vaginal bulge. This finding supports that only *symptomatic* prolapse needs treatment. However, other prolapse related symptoms, such as urinary tract and bowel dysfunction, should also be kept in mind in the clinical evaluation of patients.

6.4.8 Discrepancy between symptoms and signs of prolapse after forceps and vacuum deliveries

In Paper I we concluded that there was no difference in sPOP after FD compared to VD, but in paper II we found more PFMT and POP-Q≥ 2 after FD compared to VD. An important question is: ”Why do women have more PFMT and POP-Q>2 after FD than VD, but still do not experience more sPOP?”

One explanation could be that symptomatic and anatomical prolapse are different conditions, with different risk factors. Another explanation is that prolapse symptoms can develop over time. The mean age of women participating in this study was 47-48 years, whereas mean age at first prolapse surgery at Trondheim University Hospital is currently 63 years (own, unpublished data). Women were examined on average 28 years after their first delivery. Thomas et al have demonstrated an average latency of 33.5 years between the first delivery and prolapse surgery in women with avulsion [185].

6.5 What does this study add?

Main new findings

There was no difference in prevalence of pelvic floor disorders between forceps and vacuum deliveries 15-23 years after delivery

There was more pelvic floor muscle trauma and anatomical pelvic organ prolapse after forceps than after vacuum deliveries 16-24 years after delivery

The association between pelvic floor muscle trauma and symptoms and signs of pelvic organ prolapse was confirmed in women from a normal population.

There was a moderate to strong correlation between palpation, perineometry, and ultrasound assessment of pelvic floor muscle contractions.

We have defined a four-point contraction scale using the proportional change in levator hiatal anteroposterior diameter on ultrasound, which can form the basis for a validation of a contraction scale for ultrasound measurements.

7 Conclusions

We found that PFD was associated with mode of delivery. CD was associated with decreased risk of UI and sPOP 15-23 years after delivery compared to NVD. OVD was associated with increased risk of FI and sPOP compared to NVD. We found no difference between FD and VD for any PFD.

We found that CD was associated with decreased risk of PFMT and POP-Q compared to NVD 16-24 years after delivery. VD had similar risk to NVD, whereas FD had increased risk for PFMT and POP-Q≥ 2 compared to NVD and VD.

Furthermore we found that PFMT was a risk factor for symptoms and signs of POP in women from a normal population.

Pelvic floor ultrasound can be used to assess pelvic floor muscle contraction, and we found a strong association between proportional change in levator hiatal AP diameter between rest and contraction measured by ultrasound and digital assessment of pelvic floor muscle contraction using the MOS.

8 Future perspectives

8.1 Research questions that can be studied in this study population

8.1.1 Data from existing data set

The questionnaire contained one question on sexuality. We also acquired ultrasound volumes of the anal sphincters. These data in combination with presented data will give the possibility to answer the following questions:

- Are PFMT and muscle contraction associated with sexual dysfuncytion?
- Are PFD and POP-Q≥ 2 associated with sexual dysfuncytion?
- Is muscle contraction associated with PFMT?
- Are symptoms of UI, AI and sPOP related to PFMC in general or UI in particular?
- Is muscle contraction related to delivery mode? And can this provide a possible explanation to why women have more PFMT and POP-Q after FD than VD but not experience more PFD?
- Are persistent sphincter defects on ultrasound associated with FI and delivery mode?
- Are OASIS associated with delivery mode and FI?

8.1.2 Supplemental information from patient records

Other analyses could be done with supplemental information from patient records are:

- Is PFMT associated with obstetrician's experience (trainee, consultant)?
- Is PFMT associated with primary or secondary FD and VD?

8.1.2 Follow up study

We plan to conduct a follow up study of women included in the present study 10-15 years from now. The most important question is whether differences between delivery groups will become larger or smaller with advancing age? Some authors suggest that there is no progress of POP over time [186-188], whereas other studies have demonstrated a progression of POP with need for surgery [184]. FI has increasing prevalence with age [49, 50]. UI also becomes more frequent with advancing age, and in addition, UI has peak prevalence around menopause [51]. We found differences in PFMT and POP-Q between FD and VD, but no differences in symptoms of UI, FI or sPOP. It has been postulated that there is a mean time interval of 34

years between the initial PFMT and the need for prolapse surgery [185]. Thus, important future research questions are:

1) Will differences in PFD symptoms between delivery groups increase?
2) Will there be a progression in grade of anatomical POP?

8.2 Designing new studies

8.2.1 Is a randomized study feasible?

The ideal study design to determine causality between delivery mode and pelvic floor disorders is a randomized controlled trial. We are aware of two previous studies examining differences in OASIS between FD and VD [101, 181]. Randomization between different delivery modes is probably not possible because doctors in different countries tend to have preferances in operative delivery mode. Doctors need to be equally well trained in FD and VD before randomization. Another disadvantage of a randomized study is the long follow up period needed to investigate the long term consequences of the delivery mode.

8.2.2 Comparison of pelvic floor muscle trauma and pelvic organ prolapse to women from a patient population

At Trondheim University Hospital there is a local quality registry for women undergoing prolapse surgery. These data are limited to a simplified questionnaire of pre- and postoperative symptoms, a simple grading of prolapse in each compartment (grade 1-4), and questions regarding patient satisfaction and surgery related complications. We plan to conduct a study of women undergoing surgery during a 12 month period. Women will be asked similar questions prior to surgery and after 6 months. They will be examined in a standardized way including pelvic floor ultrasound. This study will improve the quality of the registry. We will also collect data that enable us to compare results from women from the normal population with the patient population.

8.2.3 Validation study of ultrasound scale for pelvic floor muscle contraction

We have proposed an ultrasound derived four graded contraction scale, which corresponds to the MOS. Further studies are needed to determine the most suitable ultrasound measurement (bladder neck descent, different angles, absolute and proportional changes in levator hiatal area and diameters) and if 2D could be used instead of 3D/4D ultrasound. Validation in

different populations is needed in order to determine validated cutoffs for an ultrasound scale for pelvic floor muscle contraction. We have planned to validate the ultrasound scale in three different groups:

1) Women planned for prolapse surgery
2) Women planned for incontinence surgery
3) Pregnant women.

Women will be assessed prior to surgery/ delivery, and six months after surgery/ delivery.

6.2.5 Is hiatal anatomy different for Norwegian women?

Are levator hiatal areas larger in Norwegian/Nordic women? Which cut offs are valid for the levator urethral gap for assessement levator avulsion in Norwegian/ Nordic women?

Most studies in the ultrasound field come from patient populations in Australia, and definitions used for diagnosing levator avulsions and levator hiatal ballooning are established in these populations, that differ ethnically from Norwegian or Nordic populations. There is a growing number of publications from China and European countries. A multicenter Nordic study is warranted.

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Errata

1) Correction regarding selection of potential study participants:

Paper I:

"We included all primiparous women with OVD or CD during 1990-97, and all primiparous women with NVD from January 1st to July 1st of each calendar year, to include a similar number of women with NVD stratified by year of first delivery."

Paper II

"…In that study we had invited all primiparous women with forceps, vacuum or Cesarean delivery during 1990-97 and all primiparous women with normal vaginal delivery from January 1st to July 1st of each calendar year…"

The correct statement in both papers is: "…and 130 consecutive women with normal vaginal delivery (NVD) from January 1st to March or April each calendar year…"

For the years 1996 and 1997 a sampling error occurred, and women with normal vaginal delivery after March or April were invited to participate.up to a total of 130 women per year.

2) Correction in thesis regarding the use of "mean" for symptom scores

Paragraph 5.4:

"There was no significant difference in mean values for any of the scales comparing CD to NVD". The word "mean" should be deleted

"The only significant differences between groups were mean POPDI and CRADI score….". Should be: "The only significant differences between groups were the POPDI and CRADI scores"

Paragraph 6.4.5:

"When analyzing the mean symptom scores…" should be: "When comparing the symptom scores…."

Papers

Paper I

Paper II

Paper III

Paper IV

Paper I

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Pelvic organ prolapse and incontinence 15–23 years after first delivery: a cross-sectional study

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Objective To study the association between pelvic floor dysfunction (PFD) and mode of delivery and to calculate the risks of PFD comparing caesarean delivery and operative vaginal delivery to normal vaginal delivery 15–23 years after childbirth. A subgroup analysis comparing forceps and vacuum delivery was planned.

Design Cross-sectional study.

Setting Postal questionnaire.

Population 1641 (53%) of 3115 women who delivered their first child in Trondheim, Norway, between January 1990 and December 1997.

Methods A questionnaire including questions on symptomatic pelvic organ prolapse, urinary and fecal incontinence and surgery for these conditions.

Main outcome measures Prevalence of PFD measured by symptomatic pelvic organ prolapse or surgery (sPOP), urinary incontinence or surgery (UI) and fecal incontinence or surgery (FI).

Results When caesarean delivery was compared to normal vaginal delivery the adjusted odds ratio (aOR) for sPOP was 0.42 (95% confidence interval, CI, 0.21–0.86) and the aOR for UI was 0.65 (95% CI 0.46–0.92). Operative vaginal delivery was associated with increased risk of sPOP (aOR 1.73, 95% CI 1.21–2.48) and FI (aOR 1.96, 95% CI 1.26–3.06) when compared with normal vaginal delivery. There were no differences in sPOP, UI or FI in a subgroup analysis comparing forceps and vacuum delivery.

Conclusions Caesarean delivery was associated with decreased risk and operative vaginal delivery with increased risk of pelvic floor dysfunction 15–23 years after first delivery, but there were no differences between forceps and vacuum delivery.

Keywords Fecal incontinence, forceps delivery, pelvic floor dysfunction, pelvic organ prolapse, urinary incontinence, vacuum delivery.

Linked article This article is commented on by R Rogers. To view this mini commentary visit http://dx.doi.org/10.1111/1471-0528.13318.

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Introduction

Pelvic floor dysfunction (PFD) includes symptoms of pelvic organ prolapse, urinary incontinence and fecal incontinence. PFD impacts daily life activities, sexual function and ability to perform exercise in many women, and the economic costs for individuals and society are high. A large number of women will have symptoms of PFD receiving conservative treatment or not even seeking professional health care[1–4] and 11–21% of women in western countries will undergo surgery for pelvic organ prolapse and urinary incontinence during their life time.[5–9]

The prevalence of PFD varies widely according to the population studied and the definition used[10] and is reported to be 3–12% for symptomatic pelvic organ prolapse, 15–35% for urinary incontinence and 3–14% for fecal incontinence.[11–20] Overlapping of symptoms of two or three conditions is common.[11,12,19,20] The prevalence of PFD is influenced by several risk factors such as age, body mass index, parity and ethnicity.[11–25]

Pelvic floor dysfunction prevalence increases with advancing age,[11–16,19–22] and symptoms of PFD will usually appear several years after delivery. Mode of delivery is associated with the prevalence of PFD. Previous studies have shown that caesarean delivery is associated with lower prevalence of PFD in later life[17,18,21,22] and some studies have suggested that operative vaginal delivery is associated with increased prevalence of prolapse and incontinence. However, this is controversial, and the distinction between forceps and vacuum deliveries has only been made in two small studies.[26,27] An association between operative vaginal delivery and PFD could be explained by excessive injury to the pelvic floor muscles during an operative vaginal delivery,[28] and muscle trauma is associated with a higher prevalence of PFD.[29] Arguably, forceps delivery carries higher risk of damage to pelvic floor structures than vacuum delivery, because the forceps branches may damage muscles, nerves and connective tissue in the birth canal.

The aim was to study the association between pelvic floor dysfunction (PFD) and mode of delivery and to calculate the risks of PFD comparing caesarean delivery and operative vaginal delivery with normal vaginal delivery 15–23 years after first delivery. A subgroup analysis was performed to study possible risk differences between forceps and vacuum delivery.

Methods

We conducted a cross-sectional study among 3115 women who delivered their first child at Trondheim University Hospital, Norway, between 1990 and 1997. Operative vaginal delivery assisted by forceps or vacuum was performed at approximately the same rate during this time period (forceps around 3% and vacuum in 3–5% of all deliveries).

We defined three main study groups; normal vaginal delivery (NVD), caesarean delivery (CD) and operative vaginal delivery (OVD), and the last group was divided into forceps delivery (FD) and vacuum delivery (VD) for subgroup analysis. Women were allocated to groups considering all their deliveries (the first delivery in 1990–97 and all subsequent deliveries) and were placed in the delivery group that was likely to have caused most harm to the pelvic floor: CD < NVD < OVD. Women in the CD group had only delivered by caesarean section and never had a vaginal delivery. Women in the NVD group had at least one normal vaginal delivery (including deliveries with oxytocin augmentation, epidural analgesia, episiotomy and/or perineal tears) and other deliveries could be NVD or CD, but not OVD. A group of 195 women were allocated to the NVD group after previous CD. Women in the OVD group had delivered by either forceps or vacuum or both, and other deliveries could be any mode of delivery (NVD, CD or OVD). In the subgroup analysis, we divided women into an FD group and a VD group according to their first delivery. We excluded women with prior NVD ($n = 8$) or CD ($n = 28$) and women having had both vacuum and forceps ($n = 22$), but not women with subsequent same type of OVD, NVD or CD.

A power calculation was based on previous studies of urogynaecological patients indicating a higher risk of pelvic floor muscle trauma after forceps delivery,[28] and a study demonstrating that ultrasound verified muscle trauma doubled the risk for pelvic organ prolapse.[29] We assumed a prevalence of sPOP of 12.0% in the OVD group and 5.5% in the NVD group and found that 296 women in each group would be sufficient to detect a statistically significant ($P < 0.05$) and clinically relevant difference between groups with power 80%. The prevalence of UI is higher than for sPOP and the FI prevalence is similar to sPOP. Thus, the study should be sufficiently powered to detect clinically important differences between groups for UI and FI as well.

Primiparous women delivering at Trondheim University Hospital between 1 January 1990 and 31 December 1997, who had postal address in Norway in 2013, were identified from the Hospital Patient Administrative System. We included all primiparous women with OVD or CD during 1990–97, and all primiparous women with NVD from 1 January to 1 July of each calendar year, to include a similar number of women with NVD stratified by year of first delivery. Exclusion criteria were stillbirth, breech delivery and infant birthweight <2000 g at the index birth, but women were not excluded if these conditions occurred in subsequent pregnancies. Informed consent was obtained from all participants included in the study. The study was approved by the Regional Committee for Medical and Health Research Ethics (REK midt 2012/666).

A postal questionnaire was sent to 3115 women in March 2013 with two further mailing cycles in June and September 2013 to non-responders. The questionnaire included questions about all their deliveries (parity, infant birthweight and delivery method), menopause and use of hormone replacement therapy, weight, height, smoking habits, chronic coughing, hysterectomy and surgery for pelvic organ prolapse, urinary and fecal incontinence. Information about perineal tears and indication for OVD at first delivery was obtained from the hospital records. Additional information about subsequent deliveries (delivery mode, infant birthweight, head circumference, parity, elective or emergency CD, and year of delivery) was obtained from the Norwegian Medical Birth Registry. Information from the questionnaires regarding delivery method and infant birthweight was cross-checked with the Hospital Patient Administrative System and the Norwegian Medical Birth Registry. After this comparison there was a discrepancy for mode of first delivery in 13 women, and individual hospital records were scrutinised and delivery mode confirmed.

The questionnaire included a Norwegian translation of the Pelvic Floor Distress Inventory (PFDI-20).[30] Diagnosis of symptomatic pelvic organ prolapse, urinary and fecal incontinence was based on five key questions from the PFDI-20. A positive response to 'seeing or feeling a vaginal bulge' qualified for the diagnosis of symptomatic pelvic organ prolapse. Positive response to 'urinary incontinence at urgency' or 'urinary incontinence at coughing, sneezing, laughing' qualified for the diagnosis of urinary incontinence and positive response to 'incontinence for loose stool' or ' incontinence for well-formed stool' qualified for the diagnosis of fecal incontinence, counting any positive response as diagnostic without regard to severity of symptoms.

The main outcome variables were three composite variables consisting of symptoms and/or having had surgery:

1 Symptomatic pelvic organ prolapse and/or current use of ring pessary and/or having had surgery for pelvic organ prolapse (sPOP)
2 Urge and/or stress urinary incontinence and/or having had surgery for urinary incontinence (UI)
3 Incontinence for loose and/or well-formed stool and/or having had surgery for fecal incontinence (FI)

For the subsequent paragraphs the abbreviations sPOP, UI, and FI indicate both symptomatic women and/or women having had previous surgery for these conditions.

Statistical methods

Statistical analysis was performed with IBM SPSS statistics version 21.0 (IBM SPSS, Armonk, NY, USA). To identify any differences between study groups in demographics and clinical background data, we used the two-sample *t*-test for continuous variables and the chi-square test for categorical variables. The prevalence of the outcome variables was compared between CD, OVD and NVD, and in a subgroup analysis FD was compared with VD. $P < 0.05$ was considered statistically significant.

The main outcome variables (sPOP, UI, FI) were analysed using univariable logistic regression for calculation of crude odds ratios (cOR) for delivery modes. In addition, multivariable logistic regression analysis was used to correct for possible confounding factors and calculate adjusted odds ratio (aOR) with 95% confidence intervals (CI). On the basis of clinical knowledge and results from previous studies, we selected parity, maternal age at delivery, current body mass index (BMI), hysterectomy, menopause, smoking habits, chronic coughing and infant birthweight (the largest infant delivered by each woman) as possible confounders. Univariable logistic regression was used to test their association to main outcome variables one by one before entering into the multivariable regression model. The woman's age in 2013 was omitted from the model because of correlation with age at delivery and menopause. Head circumference was omitted because of correlation to birthweight. Smoking and chronic coughing were independent variables and both were entered into the final regression model. A small percentage of the women provided reliable information on the use of hormone replacement therapy, and therefore no analysis was done for this potential confounder.

For comparison of FD and VD the following potential confounders were added into the model; indication for OVD (fetal distress or prolonged second stage of labour), perineal tears grade 3–4, and the largest infant delivered vaginally, excluding infants delivered by caesarean section.

When data were missing, those cases were omitted, and analyses were run on study participants who had responded to the actual question.

Results

In all, 1641 (53%) of 3115 invited women agreed to participate in the study. A flow-chart of study participants is presented in Figure 1. The response rate was similar for all delivery groups (NVD 51.1%, FD 53.1%, VD 57.2%, CD 51.6%) but it was slightly higher in the VD compared with NVD ($P = 0.02$) and CD groups ($P = 0.04$).

Demographics and clinical background data are given in Table 1. Non-responders had a mean age 46 years (SD 5) and were significantly younger than responders (mean age 47 years, $P < 0.01$). Also more non-responders lived a long distance from Trondheim in 2013 according to their postal code (16.7% versus 13.0%, $P < 0.01$). Further data for comparison of non-responders were not available.

Overall, the prevalence of the main outcomes were: sPOP 10.9% (172/1580), UI 46.9% (752/1603) and FI 9.1% (145/1594). In all, 46.9% (727/1549) of women were asymptomatic 15–23 years after their first delivery. The

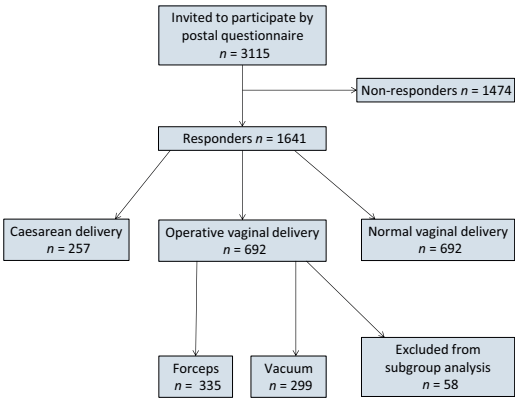

Figure 1. Flow chart of study participants. Excluded from subgroup analysis *n* = 58 (8 after previous NVD, 28 after previous CD, 8 FD after previous VD and 14 VD after previous FD).

Table 1. Demographics and clinical background data. Mean and standard deviation for continuous variables. Percent and number for categorical variables

Continuous variables	**Normal vaginal delivery (NVD) *n* = 692**	**Caesarean delivery (CD) *n* = 257***	**Operative vaginal delivery (OVD) *n* = 692**	**Vacuum (VD) *n* = 299**	**Forceps (FD) *n* = 335**	**Total *n* = 1641**	**T-test CD versus NVD *P***	**T-test OVD versus NVD *P***	**T-test FD versus VD *P***
Age 2013 (years), *n* = 1641	46.52 (4.47)	49.63 (5.46)	47.16 (4.75)	46.99 (4.89)	47.48 (4.67)	47.28 (4.87)	<0.01	0.01	0.20
Age at 1st delivery (years), *n* = 1641	26.74 (4.10)	29.80 (5.22)	27.81 (4.30)	27.85 (4.34)	27.97 (4.29)	27.67 (4.50)	<0.01	<0.01	0.73
Parity, *n* = 1641									
No. of children	2.47 (0.77)	1.90 (0.84)	2.24 (0.79)	2.24 (0.79)	2.18 (0.81)	2.28 (0.81)	<0.01	<0.01	0.33
No. of deliveries	2.44 (0.77)	1.80 (0.82)	2.20 (0.79)	2.21 (0.78)	2.16 (0.82)	2.24 (0.81)	<0.01	<0.01	0.41
Largest infant's birth weight (g), *n* = 1641	3837.73 (475.64)	3648.75 (669.92)	3899.91 (490.82)	3922.44 (480.00)	3833.09 (481.49)	3834.36 (523.57)	<0.01	0.02	0.02
Head circumference largest infant (cm), *n* = 1640	36.24 (1.30)	36.29 (1.69)	36.62 (1.47)	36.79 (1.53)	36.44 (1.38)	36.41 (1.45)	0.63	<0.01	<0.01
BMI (kg/m^2), *n* = 1608	25.45 (4.33)	26.51 (5.25)	25.97 (4.69)	25.95 (4.84)	25.92 (4.61)	25.83 (4.65)	<0.01	0.04	0.93
Categorical variables							**χ^2-test CD versus NVD *P***	**χ^2-test OVD versus NVD *P***	**χ^2-test FD versus VD *P***
Menopause, *n* = 1499	14.2% (91/639)	33.9% (79/233)	20.6% (129/627)	19.2% (51/266)	22.1% (67/303)	19.9% (299/1499)	<0.01	<0.01	0.39
Hysterectomy, *n* = 1632	3.1% (21/688)	7.1% (18/254)	3.5% (24/690)	2.7% (8/299)	4.5% (15/334)	3.9% (63/1632)	<0.01	0.66	0.22
Smoking, *n* = 1630	16.4% (113/689)	20.6% (52/253)	19.2% (132/688)	19.4% (58/299)	19.2% (64/333)	18.2% (297/1630)	0.14	0.18	0.96
Chronic coughing, *n* = 1630	4.1% (28/690)	2.4% (6/252)	4.8% (33/688)	4.0% (12/299)	5.7% (19/332)	4.1% (67/1630)	0.22	0.51	0.32
Perineal tear grade 3–4**, *n* = 634				9.7% (29/299)	11.0% (37/335)				0.58
Prolonged 2nd stage of labour**, *n* = 634				53.8% (161/299)	46.0% (154/335)				0.05
Fetal distress during labour**, *n* = 634				35.1% (105/299)	43.6% (146/335)				0.03

*Elective CD *n* = 76 (29.6%), Emergency CD *n* = 181 (70.4%).
**Prevalence of perineal tears, prolonged second stage and fetal distress during labour was calculated only by analysis of FD and VD groups.

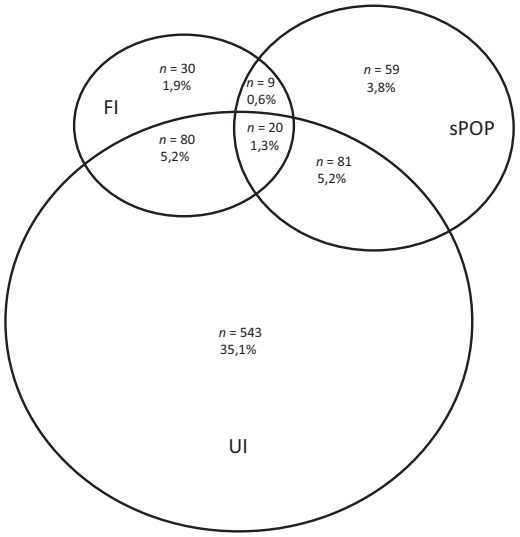

Figure 2. Prevalence of symptomatic pelvic organ prolapse (sPOP), urinary incontinence (UI) and fecal incontinence (FI) and overlap of pelvic floor disorders among 1549 women who responded to all three questions.

prevalence of single PFD and overlaps of two or three PFDs are presented in Figure 2.

Prevalence of none (asymptomatic women), one, two and three pelvic floor disorders for NVD, CD and OVD, and crude and adjusted odds ratios for these conditions are presented in Table 2. When CD was compared with NVD the adjusted odds ratio (aOR) for sPOP was 0.42 (95% CI 0.21–0.86) and for UI 0.65 (95% CI 0.46–0.92). OVD increased the risk of sPOP (aOR 1.73, 95% CI 1.21–2.48) and FI (aOR 1.96, 95% CI 1.26–3.06) compared with NVD. There was a higher prevalence of asymptomatic women in the CD group (aOR = 1.74, 95% CI 1.23–2.45) and higher prevalence of women with two PFDs in the OVD group (aOR = 1.60, 95% CI 1.09–2.33) when compared to NVD.

Table 3 presents the prevalence, cOR and aOR of PFD in the FD and VD groups. There were no differences between groups.

Analyses of possible confounders are presented in Supporting Information Table S1. In addition to delivery mode, chronic coughing was a significant contributing risk factor for sPOP in a multivariable logistic regression analysis (aOR 2.33, 95% CI 1.22–4.46). BMI was a borderline significant risk factor for sPOP (aOR 1.03, 95% CI 1.00–1.07) and was statistically significant for UI (aOR 1.09, 95% CI 1.06–1.12). Parity and the largest infant's birthweight were additional independent risk factors for UI but did not remain significant in a multivariable logistic regres-

Table 2. Prevalence of pelvic floor disorders. Crude odds ratio (cOR) with 95% confidence interval (CI) from univariable logistic regression analysis to test for differences in prevalence of main outcome variables. Adjusted odds ratio (aOR) with 95% confidence interval (CI) from multivariable logistic regression after correction for mother's age at delivery, parity, largest infant's birthweight, BMI, smoking, chronic coughing, menopause and hysterectomy

	Normal vaginal delivery	Caesarean delivery	Operative vaginal delivery	Caesarean delivery versus normal vaginal delivery		Operative vaginal delivery versus normal vaginal delivery	
				cOR (CI)	aOR (CI)	cOR (CI)	aOR (CI)
Pelvic floor disorder							
Symptomatic pelvic organ prolapse	9.2% (61/666)	4.5% (11/245)	14.9% (100/669)	0.47 (0.24–0.90)	0.42 (0.21–0.86)	1.74 (1.24–2.45)	1.73 (1.21–2.48)
Urinary incontinence	47.8% (323/676)	39.4% (99/251)	48.8% (330/676)	0.71 (0.53–0.96)	0.65 (0.46–0.92)	1.04 (0.84–1.29)	0.97 (0.77–1.23)
Fecal incontinence	6.1% (41/671)	8.9% (22/246)	12.1% (82/677)	1.51 (0.88–2.59)	1.10 (0.58–2.11)	2.12 (1.43–3.13)	1.96 (1.26–3.06)
Number of pelvic floor disorders							
0	48.1% (313/651)	57.7% (139/241)	41.9% (275/657)	1.47 (1.09–1.98)	1.74 (1.23–2.45)	0.78 (0.63–0.97)	0.83 (0.66–1.06)
1	42.4% (276/651)	33.2% (80/241)	42.0% (276/657)	0.68 (0.50–0.92)	0.62 (0.44–0.89)	0.98 (0.79–1.23)	0.94 (0.74–1.20)
2	8.8% (57/651)	8.3% (20/241)	14.2% (93/657)	0.94 (0.55–1.61)	0.81 (0.44–1.47)	1.72 (1.21–2.44)	1.60 (1.09–2.33)
3	0.8% (5/651)	0.8% (2/241)	2.0% (13/657)	1.08 (0.21–5.61)	0.85 (0.14–5.21)	2.61 (0.92–7.36)	2.58 (0.79–8.37)

Table 3. Prevalence of pelvic floor disorders in the forceps and vacuum delivery groups. Crude odds ratio (cOR) with 95% confidence interval (CI) from univariable logistic regression analysis to test for differences in prevalence. Adjusted odds ratio (aOR) with 95% confidence interval (CI) from multivariable logistic regression after correction for mothers age at delivery, parity, largest infant's birthweight, BMI, smoking, chronic coughing, menopause, hysterectomy, perineal tears grade 3–4, prolonged 2nd stage of labour and fetal distress during labour

	Vacuum delivery	Forceps delivery	Forceps delivery versus vacuum delivery	
			cOR (CI)	aOR (CI)
Pelvic floor disorder				
Symptomatic pelvic organ prolapse	14.9% (43/289)	15.7% (51/325)	1.07 (0.69–1.66)	0.89 (0.56–1.43)
Urinary incontinence	51.2% (149/291)	47.4% (156/329)	0.86 (0.63–1.18)	0.90 (0.64–1.28)
Fecal incontinence	12.3% (36/292)	12.8% (42/329)	1.04 (0.65–1.68)	0.95 (0.55–1.63)
Number of pelvic floor disorder				
0	40.4% (114/282)	41.7% (134/321)	1.06 (0.76–1.46)	1.06 (0.74–1.51)
1	42.6% (120/282)	41.7% (134/321)	0.97 (0.70–1.34)	1.04 (0.73–1.48)
2	14.9% (42/282)	14.3% (46/321)	0.96 (0.61–1.50)	0.87 (0.53–1.43)
3	2.1% (6/282)	2.2% (7/321)	1.03 (0.34–3.09)	0.74 (0.22–2.46)

sion analysis. Smoking (aOR 2.10, 95% CI 1.35–3.26) and perineal tears grade 3–4 (aOR 2.62, 95% CI 1.27–5.42) remained statistically significant risk factors for FI after multivariable logistic regression.

Discussion

Main findings

Caesarean delivery was associated with a significant risk reduction for sPOP (aOR = 0.42) and UI (aOR = 0.65) when compared with normal vaginal delivery. Operative vaginal delivery was associated with increased risk of sPOP (aOR = 1.73) and FI (aOR = 1.96) when compared with normal vaginal delivery. There were no significant differences between forceps and vacuum deliveries for any of the main outcome variables.

Strengths and limitations

The study population was large and data were collected from three different sources (questionnaires, the Norwegian Medical Birth Registry and the Hospital Patient Administrative System).

The present study is the hitherto largest epidemiological study addressing possible risk difference between forceps and vacuum deliveries regarding pelvic floor dysfunction. Since the prevalence of sPOP, UI and FI increases with age, one strength of this study was that women were followed up 15–23 years after their first delivery.

Doctors at Trondheim University Hospital performed FD and VD with a similar frequency (3–5% of all deliveries) between 1990 and 1997, and doctors were well trained in both methods during this period. Thus the comparison between FD and VD was done in a setting where any pelvic floor trauma most likely was a consequence of the delivery method.

Rotational forceps was not recommended at Trondheim University Hospital during 1990–97, and FD was only carried out for low or mid-cavity fetal head in occiput anterior or occiput posterior position. VD was allowed if the fetal head was at or below the spine and for all head positions. Higher stations and different positions may implicate higher risk of trauma and may have introduced bias against VD. Another possible source of bias was better training and/or operative skills for FD. In 1980–89 the FD:VD ratio was 3:1 at Trondheim University Hospital, whereas in 2000–2010 the FD:VD ratio was 1:8. Over a period of 15–20 years VD became the method of choice for OVD in this hospital. Theoretically doctors were better trained in FD than VD during 1990–97. Thus, both these possible biases would be towards more complications in the VD group.

The CD rate among primiparous women was stable (11–14%) between 1990–97. Episiotomy was performed as a routine for OVD, and episiotomy rates were 73–82% between 1995 and 1997, with no reliable data prior to 1995. Thus, correction for episiotomy as a potential confounder was not possible.

The response rate of 53% is considered acceptable for this type of study but may influence the generalisability of the results. It is known that symptomatic women are more prone to participate in studies[23] and it is therefore possible that the prevalence of symptoms was overestimated in the study population. Women in the study were predominantly white European, and the results should be interpreted with caution for diverse ethnic groups.[20,22,23] Since the response rate was similar in the four delivery groups, we contend that a comparison between groups is valid.

No distinction was made between elective and acute CD because the subgroups were too small. Other authors have shown no difference between acute and elective CD for PFD.[18,19,22]

A validated translation to Norwegian of questionnaires on pelvic organ prolapse, urinary and fecal incontinence was not available when the study was conducted. We chose a translation of the PFDI-20 used by other Norwegian investigators which has not yet been published. PFDI-20 is not a screening questionnaire, but for the analyses we extracted five clearly formulated key questions and counted any positive response without calculation of scale scores. Counting any positive response as diagnostic for PFD without regard to severity of symptoms, may have contributed to the relatively high prevalence of PFD in our study population.

A weakness of this study is that a cross-sectional study design may prove an association between delivery mode and prevalence of PFD, but not causality between the two.

Interpretation

Our results support previous studies reporting that CD is associated with lower prevalence of PFD and OVD is associated with higher prevalence of PFD. This may be due to a relative fetal maternal disproportion causing the need for OVD, or due to the mechanical effect of the forceps and vacuum devices on the pelvic floor connective tissue, muscles and nerves.

We found no statistically significant association between sPOP, UI or FI and mode of operative vaginal delivery (FD and VD). Since the confidence intervals in our study were large, we are unable to rule out a clinically relevant difference in favour of either FD or VD. Our findings contrast with the results from a smaller study demonstrating that FD, and not VD, increased the odds of PFD compared with NVD 5–10 years after delivery[26] and a randomised study demonstrating higher prevalence of FI after FD compared with VD.[27] A long-term follow-up of women may provide additional information, because the prevalence of symptoms and performed surgery will increase with advancing age.

There are several risk factors, which may act as confounding variables in the analysis of a possible association between mode of delivery and PFD. Studies have demonstrated a strong effect of parity on the prevalence of sPOP, UI and FI.[11–13,15,21,22] We found an association between sPOP and increasing parity, but this was not statistically significant. However, a statistically significant association between parity and UI was found in the present study. Large babies (increasing birthweight) only influenced the prevalence of UI in the present study, but other authors have demonstrated that high birthweight is a risk factor for sPOP and FI.[17,18,31] Obesity is an established risk factor for sPOP and UI.[11,12,17,18,24] We found a non-significant association between sPOP and increasing BMI and a significant association between increasing BMI and UI. Both obesity and coughing increase intra-abdominal pressure and the mechanical load on the pelvic floor. Coughing more than doubled the odds for sPOP in our study. An effect of smoking on FI has been found previously[25] and also in our study. Cigarette smoking may directly influence gastrointestinal motility, but may also be linked to other confounding factors such as educational level, physical activity, and alcohol consumption. A protective effect of mediolateral episiotomy on FI has been suggested in previous studies,[17,31] whereas others have demonstrated an association between high rates of routine episiotomy and anal incontinence.[32] Women with OVD in our study had a high rate of episiotomy, but meaningful analysis of this was not possible due to unreliable data. Perineal tear grade 3–4 was the risk factor with the strongest association with FI in our study, which is in concordance with previous studies.[3,17,31]

Conclusion

Caesarean delivery is associated with decreased risk and operative vaginal delivery with increased risk of pelvic floor dysfunction when compared with normal vaginal delivery. We found no statistically significant difference between forceps and vacuum deliveries. Further long-term follow-up studies will be needed to determine any clinically relevant differences in pelvic floor dysfunction after forceps or vacuum deliveries, and thereby advise on the method of choice during operative vaginal delivery.

Disclosure of interests

We declare no conflict of interest.

Contribution to authorship

IV and KÅS were involved in the conception and design of the study and acquisition of data. IV, KÅS, SM and ØS were involved in analysis and interpretation of data. IV and KÅS drafted the article and all authors were involved in critical revision of the manuscript. All authors approved the final version of the article.

Details of ethics approval

Ethical approval of the study was obtained from the Regional Committee for Medical and Health Research Ethics 23 March 2012, ref no.: REK midt 2012/666.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Possible confounder's contribution to outcome variables. ■

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Paper II

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Forceps delivery is associated with increased risk of pelvic organ prolapse and muscle trauma: a cross-sectional study 16–24 years after first delivery

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KEYWORDS: Cesarean delivery; forceps delivery; levator avulsion; normal vaginal delivery; pelvic floor muscle trauma; pelvic organ prolapse; vacuum delivery

ABSTRACT

Objectives *To study possible associations between mode of delivery and pelvic organ prolapse (POP) and pelvic floor muscle trauma 16–24 years after first delivery and, in particular, to identify differences between forceps and vacuum delivery.*

Methods *This was a cross-sectional study including 608 women who delivered their first child in 1990–1997 and were examined with POP quantification (POP-Q) and pelvic floor ultrasound in 2013–2014. Outcome measures were POP ≥ Stage 2 or previous prolapse surgery, levator avulsion and levator hiatal area on Valsalva. Univariable and multivariable logistic regression analyses and ANCOVA were applied to identify outcome variables associated with mode of delivery.*

Results *Comparing forceps to vacuum delivery, the adjusted odds ratios (aOR) were 1.72 (95% CI, 1.06–2.79; P = 0.03) for POP ≥ Stage 2 or previous prolapse surgery and 4.16 (95% CI, 2.28–7.59; P < 0.01) for levator avulsion. Hiatal area on Valsalva was larger, with adjusted mean difference (aMD) of 4.75 cm^2 (95% CI, 2.46–7.03; P < 0.01). Comparing forceps with normal vaginal delivery, the adjusted odds ratio (aOR) was 1.74 (95% CI, 1.12–2.68; P = 0.01) for POP ≥ Stage 2 or surgery and 4.35 (95% CI, 2.56–7.40; P < 0.01) for levator avulsion; hiatal area on Valsalva was larger, with an aMD of 3.84 cm^2 (95% CI, 1.78–5.90; P < 0.01). Comparing Cesarean delivery with normal vaginal delivery, aOR was 0.06 (95% CI, 0.02–0.14; P < 0.01) for POP ≥ Stage 2 or surgery and crude OR was 0.00 (95% CI, 0.00–0.30; P < 0.01) for levator avulsion; hiatal area on Valsalva was smaller, with an aMD of −8.35 cm^2 (95% CI, −10.87 to −5.84; P < 0.01). No differences were found between vacuum and normal vaginal delivery.*

Conclusions *We found that mode of delivery was associated with POP and pelvic floor muscle trauma in women from a general population, 16–24 years after their first delivery. Forceps was associated with significantly more POP, levator avulsion and larger hiatal areas than were vacuum and normal vaginal deliveries. There were no statistically significant differences between vacuum and normal vaginal deliveries. Cesarean delivery was associated with significantly less POP and pelvic floor muscle trauma than were normal or operative vaginal delivery.*

INTRODUCTION

Pelvic organ prolapse (POP) influences daily activities, sexual function and the ability to perform exercise in many women. POP may have a large impact on quality of life, and the economic costs for healthcare services related to POP are high. By the age of 85 years, 13–21% of women in western countries have been subjected to surgery for POP[1–3].

Several risk factors for POP have been established, such as age, body mass index (BMI), ethnicity, hysterectomy, constipation, smoking habits and chronic coughing[3–9]. POP is also associated with parity and mode

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of delivery[4–13], and studies have found a lower prevalence after Cesarean delivery than after normal vaginal delivery[9,11,13]. A few studies have compared the prevalence of POP after forceps and vacuum delivery and the results are conflicting. One study demonstrated that forceps, but not vacuum delivery, was associated with a higher prevalence of POP compared with normal vaginal delivery[10], whereas another study found a protective effect of forceps[11].

A higher prevalence of POP may be explained by the increased risk of pelvic floor muscle trauma during operative vaginal delivery. Levator avulsion injury and increased levator hiatal area are risk factors for POP as demonstrated by ultrasound[14–16] and magnetic resonance imaging (MRI)[17–19]. Studies among urogynecological patients and women a few months after delivery have demonstrated a higher prevalence of avulsion injuries and increased levator hiatal areas after forceps delivery, but not after vacuum delivery[18,20–28].

The aims of this study were to identify possible associations between mode of delivery and POP and pelvic floor muscle trauma in women of the general population, 16–24 years after their first delivery, and to study the possible differences between forceps and vacuum deliveries.

METHODS

We conducted a cross-sectional study in which 847 women delivering at Trondheim University Hospital between 1 January 1990 and 31 December 1997 were invited for a clinical examination, including a four-dimensional (4D) ultrasound examination, between June 2013 and January 2014. We recruited women from a previous study of pelvic floor disorders[29], in which women had been identified from the Hospital's Patient Administrative System. In the previous study, we had invited all women whose first child had been delivered using forceps, vacuum or Cesarean section during 1990–1997 and women whose first delivery was normal vaginal from 1 January to 1 July of each calendar year, to ensure a similar proportion of normal deliveries during the whole study period. Vacuum and forceps deliveries were performed at approximately the same rate (3–5% of all deliveries) in Trondheim University Hospital during 1990–1997.

We defined four study groups according to the delivery mode of the first child: normal vaginal delivery, Cesarean delivery, forceps delivery and vacuum delivery. In the normal vaginal delivery group, women were included who may have had subsequent normal vaginal deliveries and Cesarean deliveries after the first delivery, but no forceps or vacuum deliveries. The Cesarean delivery group included women who had only delivered by Cesarean section. The forceps group included women who may have had forceps, normal or Cesarean delivery after their first child, but no vacuum delivery. The vacuum group included women who may have had vacuum, normal or Cesarean delivery after their first child, but no forceps delivery.

Exclusion criteria were stillbirth, breech delivery and infant birth weight < 2000 g at the index delivery; however, women were not excluded if these conditions occurred in subsequent pregnancies. Women were excluded if their postal code indicated that they lived far from Trondheim in 2013. Informed consent was obtained from all participants. The study was approved by the Regional Committee for Medical and Health Research Ethics (REK midt 2012/666). A flowchart of study participants is presented in Figure 1.

All women in the current study had responded to a postal questionnaire in 2013 regarding symptoms of POP, urinary and fecal incontinence; these results have been published elsewhere[29]. The questionnaire included information on weight, height, smoking habit, chronic coughing, menopause and use of hormone replacement therapy, hysterectomy and surgery for POP and urinary and fecal incontinence. Information about delivery method, infant birth weight, epidural analgesia, perineal tears and indication for operative vaginal delivery at first delivery was obtained from the hospital records. Additional information about subsequent deliveries (delivery mode, infant birth weight, head circumference, parity, elective or emergency Cesarean delivery, year of delivery) was obtained from the Norwegian Medical

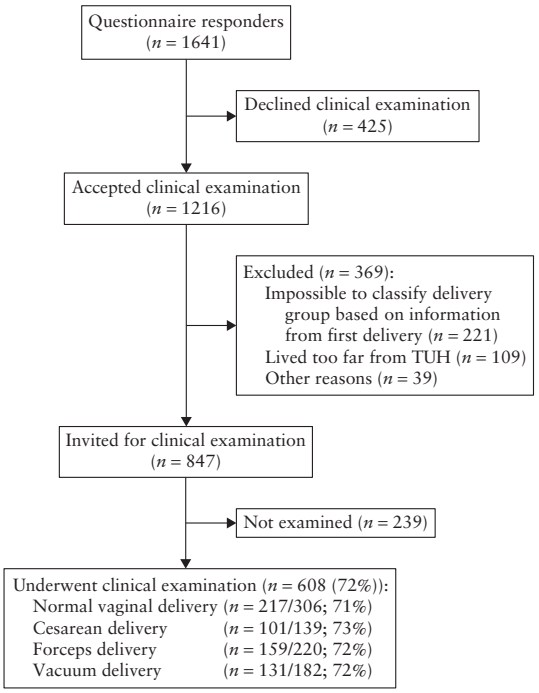

Figure 1 Flowchart of study participants, comprising women who had their first delivery during 1990–1997 at Trondheim University Hospital (TUH).

Birth Registry and cross-checked with the Hospital's Patient Administrative System.

A power calculation was based on a previous study of primiparous women indicating a higher risk of pelvic floor muscle trauma after forceps delivery (35%) than after normal vaginal delivery (13%) and vacuum delivery (9%)[22], and a study identifying ultrasound-verified muscle trauma as a factor that doubles the risk of POP[15]. To detect a similar difference in prevalence of levator avulsion between delivery groups (35% *vs* 13%), we would need 58 women in each group with a power of 80% and a 5% significance level. We assumed a smaller difference in POP prevalence (12.5% in the normal vaginal delivery group and 25.0% in the forceps group) and found that a sample size of 152 women in each delivery group would be sufficient to find a statistically significant and clinically relevant difference between delivery groups with power of 80% and significance level of 5%. We did not perform power calculations for the detection of differences in hiatal area.

All clinical and ultrasound examinations were performed by the first author (I.V.). At the time of the examination, I.V. was blinded to demographic and clinical background data. Women were asked to withhold any information regarding previous deliveries and gynecological operations until the examination had been completed. Women were examined in the supine position in a gynecological examination chair with an empty urinary bladder and bowel. The lower abdomen was covered with a cloth to hide any surgical scars.

The clinical examination included staging of POP according to the POP quantification (POP-Q) system[30]. This provided the following quantification of the prolapse in each compartment (anterior, mid, posterior): Stage 0 (no prolapse demonstrated); Stage 1 (most distal part of the prolapse > 1 cm above the hymen); Stage 2 (most distal part of the prolapse ≤ 1 cm above or below the plane of the hymen); Stage 3 (most distal part of the prolapse > 1 cm below the hymen); and Stage 4 (complete eversion of the vagina and uterus). Data from the POP-Q were analyzed for each compartment and the presence of POP in at least one of all three compartments (any POP) was registered. Five women had undergone prolapse surgery and were cured objectively (POP < Stage 2). We did not check their hospital records for POP stage before surgery, but in Norway the agreed indication for POP surgery is POP ≥ Stage 2 with concomitant prolapse symptoms. We defined a composite outcome variable, combining POP ≥ Stage 2 or previous POP surgery, hereafter referred to as 'POP ≥ Stage 2 or surgery'. POP Stage 3 included women with more severe prolapses.

After POP-Q staging had been performed, 4D ultrasound volumes were acquired with a GE Voluson S6 device (GE Medical Systems, Zipf, Austria), using the RAB 4–8RS abdominal three-dimensional probe and an acquisition angle of 85°. Volumes were acquired at rest, during pelvic floor muscle contraction and during Valsalva maneuver for a minimum of 6 seconds[31]. Three volumes were acquired for contraction (including a relaxed state at the beginning of each volume) and Valsalva, yielding a total of six volumes per woman.

Offline analysis of the ultrasound volumes was performed 6–14 months after the ultrasound scan on a computer using the 4D View Version 14 Ext. 0 software (GE Medical Systems). Analysis was performed by the first author (I.V.), who was blinded to clinical and demographic data at the time of the analysis. Pelvic floor muscle trauma was defined by either levator avulsion or larger levator hiatal area. Tomographic ultrasound imaging was used to identify levator avulsion on pelvic floor muscle contraction. Avulsion was diagnosed if all three central slices (the slice in the plane of minimal hiatal dimensions, i.e. where the distance between the posterior border of the symphysis and the anterior border of the puborectalis muscle is shortest, and the slices 2.5 and 5.0 mm cranial to this) showed abnormal muscle insertion[32]. Avulsion was diagnosed as unilateral or bilateral (Figure 2) and the number of women with levator avulsion (unilateral or bilateral) was registered. Hiatal area was measured in the plane of minimal hiatal dimensions in a rendered volume of 1- to 2-cm thickness, as described previously[33]. All six volumes for rest/contraction and Valsalva were analyzed. Ultrasound images defining the hiatal area at rest, on contraction and on Valsalva in women with or without unilateral or bilateral avulsions are presented in Figure 3. The largest hiatal areas at rest and during Valsalva maneuver were registered for each woman. The smallest hiatal area, representing the best contraction, was registered for pelvic floor muscle contraction. Some women were unable to perform a proper Valsalva maneuver without co-activation of the pelvic floor muscles. When the hiatal area produced on Valsalva maneuver was smaller than the area at rest, the hiatal area during Valsalva was defined as invalid and registered as missing.

Statistical analysis

The primary statistical analysis was to compare POP, levator avulsion and hiatal area in women with forceps delivery and those with vacuum delivery. Secondary analyses were comparisons of outcomes between Cesarean, forceps and vacuum deliveries and normal vaginal delivery.

Statistical analysis was performed with IBM SPSS statistics version 21 (IBM SPSS, Armonk, NY, USA). Continuous variables were tested for normal distribution. We used the two-sample *t*-test for continuous variables and the chi-square test or Fisher's exact test for categorical variables to identify any differences in demographics and clinical background data between study groups. $P < 0.05$ was considered statistically significant. Univariable logistic regression was used for calculation of crude odds ratios (cOR) for delivery modes. Multivariable logistic regression analysis was used to correct for possible confounding factors and calculation of adjusted odds ratios (aOR) with 95% CI. ANCOVA was used to test for significant differences between delivery

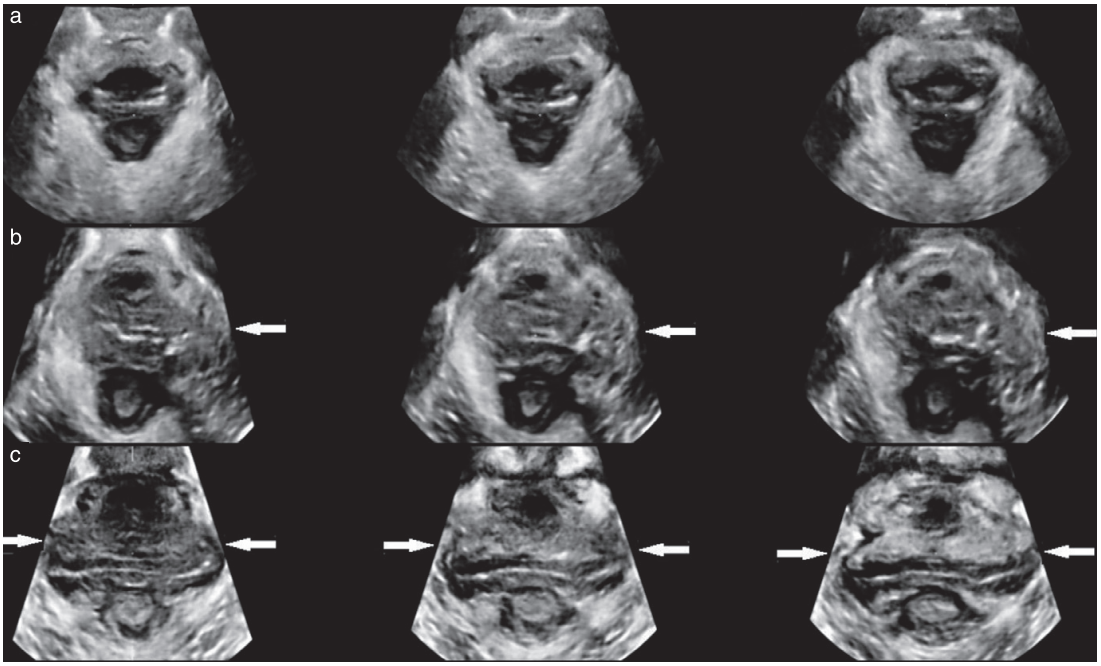

Figure 2 Three central slices on tomographic ultrasound imaging, showing intact levator (a), unilateral avulsion (b) and bilateral avulsion (c). Avulsion is indicated by arrows.

modes for hiatal areas at rest, on contraction and on Valsalva. Both univariable ANCOVA for unadjusted mean difference (MD) with 95% CI between delivery groups and multivariable ANCOVA corrected for possible confounding factors for adjusted MD with 95% CI are reported. When sample numbers were small (e.g. the number of women with POP Stage 3), Fisher's exact test was used for calculation of cOR with 95% CI (http://www.r-fiddle.org/#/).

Based on clinical knowledge and results from previous studies, we considered several potential confounding variables. Univariable logistic regression was used to test the association of each variable with POP ≥ Stage 2 or surgery and levator avulsion before entering the variable into the multivariable model. ANCOVA was used to test the association of each factor with hiatal area on Valsalva. For comparison of risks between delivery groups in the final logistic regression model and for the multivariable ANCOVA analysis, we selected age in 2013, parity (number of deliveries), BMI and largest infant's birth weight. Head circumference was omitted because of correlation with birth weight, and both menopause and age at delivery were omitted because of correlation with age in 2013. Other potential confounding variables (smoking, coughing, hysterectomy, epidural, indication for operative vaginal delivery and perineal tears) showed no statistically significant association with main outcome variables and were not entered into the multivariable regression model. Reliable information on the use of hormone replacement therapy, oxytocin augmentation during delivery and episiotomy was not available. When data were missing, analysis was performed on study participants with complete data.

RESULTS

During 2013–2014, 608 (72%) of the 847 women who delivered in 1990–1997 attended the clinical examination. There were no differences in participation rate between delivery groups (Figure 1); however, a significantly greater number of women included in the present study had symptoms of POP compared with the background population (15% *vs* 11%; $P = 0.01$)[29]. The study women were older at examination (47.9 *vs* 47.3 years; $P < 0.01$) and at their first delivery, but there were no statistically significant differences for parity, largest infant's birth weight or BMI. In total, 607 ultrasound datasets of six volumes were analyzed. One dataset had not been stored properly, and in one dataset there was an artifact making avulsion analysis impossible, though hiatal area could be measured. Continuous variables were approximately normally distributed.

Demographics and clinical background data are shown in Table 1. Women in the normal vaginal delivery group were significantly younger at examination and first delivery, had lower BMI and higher parity compared with all other delivery groups. Women in the Cesarean delivery group were older at examination and first delivery, and had higher BMI and lower parity than the vaginal delivery

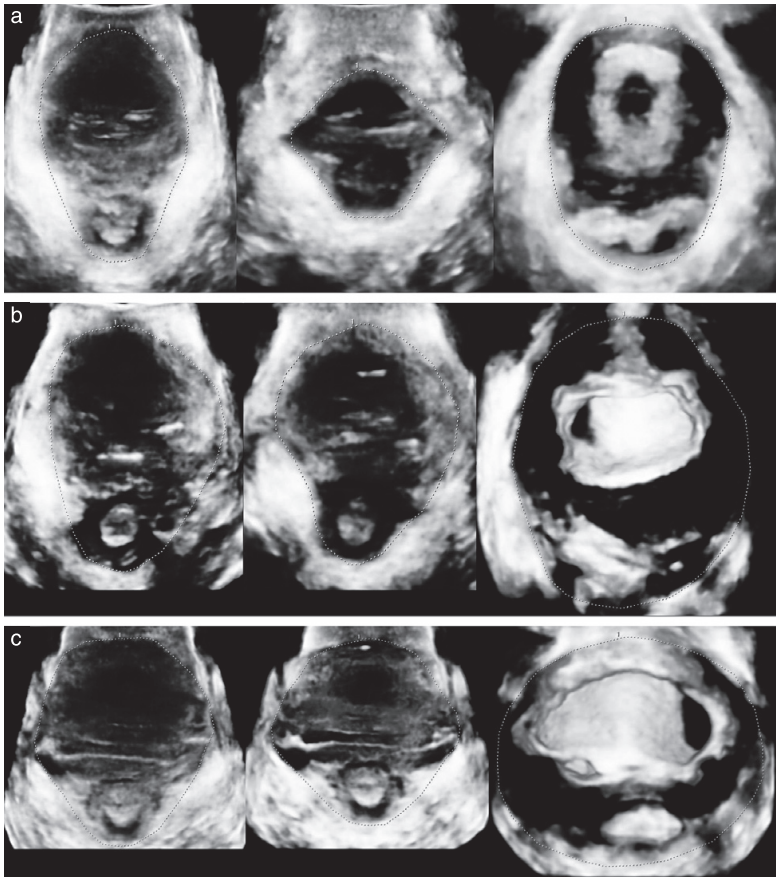

Figure 3 Tomographic ultrasound images of hiatal areas at rest, on pelvic floor muscle contraction and on Valsalva maneuver in women with: (a) intact levator (19.7, 9.6 and 23.8 cm^2, respectively), (b) unilateral avulsion (27.3, 19.8 and 46.1 cm^2, respectively) and (c) bilateral avulsion (27.3, 25.6 and 47.3 cm^2, respectively).

groups. Women in the forceps and vacuum delivery groups were comparable as to age, BMI and parity, but infants were significantly larger in the vacuum group.

Table 2 demonstrates the prevalence of POP in the anterior, mid and posterior compartments, previous prolapse surgery, levator avulsion and mean hiatal areas according to delivery group. No women were found to have POP Stage 4.

Table 3 presents comparisons between delivery groups for the main outcome variables. Forceps was significantly associated with an increased risk of POP $\geq$ Stage 2 or surgery when compared with vacuum (aOR, 1.72 (95% CI, 1.06–2.79); $P = 0.03$) and normal vaginal delivery (aOR, 1.74 (95% CI, 1.12–2.68); $P < 0.01$) and of POP $\geq$ Stage 3 when compared with vacuum delivery (cOR, ∞ (95% CI, 1.16–∞); $P = 0.02$). Forceps was also associated with an increased risk for avulsion injury when compared with both vacuum (65/159 after forceps *vs* 19/130 after vacuum; aOR, 4.16 (95% CI, 2.28–7.59); $P < 0.01$) and normal vaginal delivery (29/216 after normal delivery; aOR, 4.35 (95% CI, 2.56–7.40); $P < 0.01$). The mean hiatal areas were significantly larger after forceps than after vacuum or normal vaginal delivery (Table 3). There were no statistically significant differences in prevalence of POP $\geq$ Stage 2 or surgery, levator avulsion or hiatal areas between vacuum and normal vaginal delivery. Cesarean delivery was associated with a decreased risk of POP $\geq$ Stage 2 or surgery (aOR, 0.06 (95% CI, 0.02–0.14); $P < 0.01$), levator avulsion (cOR, 0.00 (95% CI, 0.00–0.30); $P < 0.01$) and hiatal areas were significantly smaller when compared with normal vaginal delivery. The study was not sufficiently powered to determine differences between elective ($n = 23$) and acute ($n = 78$) Cesarean deliveries, but no difference was found in POP prevalence (2/23 and 4/78, respectively) and hiatal areas were similar in the two Cesarean subgroups.

In Table S1, the contribution of other risk factors to POP $\geq$ Stage 2 or surgery, levator avulsion and hiatal area is presented. In a multivariable regression model, age in 2013 was associated with an increased risk of POP $\geq$ Stage 2 or surgery (aOR, 1.05 (95% CI, 1.01–1.09); $P = 0.02$)

Table 1 Background characteristics of 608 women who delivered their first child during 1990–1997 at Trondheim University Hospital and subsequently underwent a clinical pelvic examination in 2013–2014, according to mode of delivery

						P			
Characteristic	*Forceps delivery (n = 159)*	*Vacuum delivery (n = 131)*	*Normal vaginal delivery (n = 217)*	*Cesarean delivery (n = 101)**	*Total (n = 608)*	*Forceps* vs *vacuum delivery*	*Forceps* vs *normal vaginal delivery*	*Vacuum* vs *normal vaginal delivery*	*Cesarean* vs *normal vaginal delivery*
Age in 2013 (years)	48.18 ± 4.83	47.63 ± 5.03	46.82 ± 4.53	50.36 ± 4.64	47.94 ± 4.88	0.35	< 0.01	0.12	< 0.01
Age at 1st delivery (years)	28.52 ± 4.52	28.40 ± 4.67	27.02 ± 4.09	30.31 ± 4.80	28.25 ± 4.58	0.83	< 0.01	< 0.01	< 0.01
BMI (kg/m^2) ($n = 598$)	25.96 ± 4.42	26.41 ± 5.12	24.93 ± 4.17	26.56 ± 4.46	25.79 ± 4.54	0.43	0.02	< 0.01	< 0.01
Parity	2.15 ± 0.74	2.23 ± 0.76	2.45 ± 0.82	1.73 ± 0.73	2.20 ± 0.81	0.38	< 0.01	0.01	< 0.01
BW of largest infant (g)									
All deliveries	3832.8 ± 481.8	3962.5 ± 494.6	3842.4 ± 458.1	3814.4 ± 631.0	3861.1 ± 505.9	0.03	0.84	0.02	0.65
Vaginal deliveries ($n = 507$)†	3820.3 ± 484.9	3948.7 ± 490.6	3839.0 ± 454.3	—	3861.5 ± 475.5	0.03	0.70	0.04	—
HC of largest infant (cm)	36.47 ± 1.40	36.88 ± 1.68	36.23 ± 1.21	36.55 ± 1.49	36.48 ± 1.44	0.02	0.08	< 0.01	0.04
Menopause ($n = 541$)	37/138 (26.8)	26/115 (22.6)	30/200 (15.0)	33/88 (37.5)	126/541 (23.3)	0.44	< 0.01	0.09	< 0.01
Hysterectomy ($n = 606$)	12/158 (7.6)	3/131 (2.3)	7/216 (3.2)	8/101 (7.9)	30/606 (5.0)	0.04	0.06	0.61	0.07
Smoker ($n = 606$)	34/158 (21.5)	27/131 (20.6)	36/216 (16.7)	22/101 (21.8)	119/606 (19.6)	0.85	0.24	0.36	0.27
Chronic coughing ($n = 606$)	13/158 (8.2)	4/131 (3.1)	14/216 (6.5)	3/101 (3.0)	34/606 (5.6)	0.06	0.52	0.16	0.20
Epidural analgesia	33/159 (20.8)	35/131 (26.7)	16/217 (7.4)	—	84/507 (16.6)	0.23	< 0.01	< 0.01	—
Perineal tear grade 3–4‡	19/159 (12.0)	12/131 (9.2)	—	—	31/290 (10.7)	0.44	—	—	—
Prolonged 2nd stage of labor‡	75/159 (47.2)	76/131 (58.0)	—	—	151/290 (52.1)	0.07	—	—	—
Fetal distress in labor‡	70/159 (44.0)	50/131 (38.2)	—	—	120/290 (41.4)	0.31	—	—	—

Data are given as mean ± SD or *n*/*N* (%). Continuous variables were compared using *t*-test and categorical variables were compared using chi-square test. *23 elective and 78 acute Cesarean deliveries. †12 vaginally parous women delivered their heaviest child by Cesarean section: three in the normal vaginal delivery group, four in the forceps group and five in the vacuum group. ‡Prevalence of perineal tears, prolonged second stage labor and fetal distress in labor were analyzed for only forceps and vacuum groups. BMI, body mass index; BW, birth weight; HC, head circumference.

Table 2 Pelvic organ prolapse (POP), levator avulsion and hiatal area in women who delivered their first child during 1990–1997 at Trondheim University Hospital and subsequently underwent a clinical pelvic examination in 2013–2014, according to mode of delivery (normal vaginal, Cesarean, forceps or vacuum)

Outcome	*Forceps* (n = *159*)	*Vacuum* (n = *131*)	*Normal vaginal* (n = *217*)	*Cesarean* (n = *101*)	*Total* (n = *608*)
POP in anterior compartment					
≥ Stage 2	60 (37.7)	36 (27.5)	72 (33.2)	4 (4.0)	172 (28.3)
≥ Stage 3	4 (2.5)	0 (0)	3 (1.4)	0 (0)	7 (1.2)
POP in mid compartment					
≥ Stage 2	13 (8.2)	6 (4.6)	10 (4.6)	0 (0)	29 (4.8)
≥ Stage 3	3 (1.9)	0 (0)	2 (0.9)	0 (0)	5 (0.8)
POP in posterior compartment					
≥ Stage 2	54 (34.0)	42 (32.1)	56 (25.8)	2 (2.0)	154 (25.3)
≥ Stage 3	1 (0.6)	0 (0)	0 (0)	0 (0)	1 (0.2)
POP in any compartment					
≥ Stage 2	97 (61.0)	67 (51.1)	105 (48.4)	6 (5.9)	275 (45.2)
≥ Stage 3	7 (4.4)	0 (0)	4 (1.8)	0 (0)	11 (1.8)
Previous prolapse surgery (*n* = 593: 155, 129, 211, 98)*†	8 (5.2)	2 (1.6)	5 (2.4)	0 (0)	15 (2.5)
Cured	3 (1.9)	0 (0)	2 (0.9)	0 (0)	5 (0.8)
Still POP ≥ stage 2	5 (3.2)	2 (1.6)	3 (1.4)	0 (0)	10 (1.7)
POP ≥ stage 2 or previous prolapse surgery	100 (62.9)	67 (51.1)	107 (49.3)	6 (5.9)	280 (46.1)
Levator avulsion (*n* = 606: 159, 130, 216, 101)*					
Any	65 (40.9)	19 (14.6)	29 (13.4)	0 (0)	113 (18.6)
Unilateral	29 (18.2)	10 (7.7)	17 (7.9)	0 (0)	56 (9.2)
Bilateral	36 (22.6)	9 (6.9)	12 (5.6)	0 (0)	57 (9.4)
Hiatal area (cm^2)					
At rest (*n* = 607: 159, 130, 217, 101)*	25.17 ± 5.45	22.64 ± 4.50	23.30 ± 4.58	19.85 ± 3.79	23.07 ± 4.98
On contraction (*n* = 607: 159, 130, 217, 101)*	17.82 ± 5.42	16.02 ± 4.31	15.86 ± 4.26	12.83 ± 3.24	15.90 ± 4.73
On Valsalva (*n* = 554: 151, 120, 192, 91)*‡	38.81 ± 9.79	34.27 ± 10.45	34.52 ± 9.53	26.50 ± 7.60	34.32 ± 10.29

Data are given as *n* (%) or mean ± SD. *After total *n*, numbers are given in parentheses for forceps, vacuum, normal vaginal and Cesarean delivery groups. †15 women did not respond to the question on previous prolapse surgery. ‡53 women were not able to perform a proper Valsalva.

and levator avulsion (aOR, 1.08 (95% CI, 1.02–1.13); $P < 0.01$). The largest infant's birth weight was associated with POP ≥ Stage 2 or surgery (aOR, 1.05 (95% CI, 1.01–1.09); $P = 0.02$), levator avulsion (aOR, 1.06 (95% CI, 1.01–1.12); $P = 0.02$) and larger hiatal areas. The contributing effect of parity on POP ≥ Stage 2 or surgery disappeared after adjusting for other confounding variables in the multivariable regression model. BMI was found to be a significant confounder only for hiatal area.

DISCUSSION

We found statistically significant associations between delivery mode and POP ≥ Stage 2 or previous prolapse surgery, levator avulsion and hiatal areas. Forceps delivery had increased risks of POP or surgery and levator avulsion and was associated with larger hiatal area compared with vacuum and normal vaginal delivery. Cesarean delivery had decreased risks of prolapse or surgery and levator avulsion and was associated with smaller hiatal area when compared with normal vaginal delivery. There were no differences between vacuum and normal vaginal delivery.

We studied women from the general population 16–24 years after their first delivery; a long time interval is important when studying conditions that occur several years after delivery. A sufficient number of women were followed-up after forceps ($n = 159$) and vacuum ($n = 131$) deliveries, therefore a direct comparison was possible. The quality of data on delivery mode was good, as delivery mode was defined according to the Hospital's Patient Administrative System and the Norwegian Medical Birth Registry rather than from questionnaires or interviews 16–24 years after the delivery. All clinical and ultrasound examinations were performed by one skilled urogynecologist (I.V.) and women were examined in a standardized manner.

Women included in the present study had more prolapse symptoms than women in a previously published study comprising the same population[29]. However, we found the participation rate to be similar for all delivery groups. We argue that, although the external validity may be questioned, the internal validity (comparison between delivery groups) was good. Since Norwegian women are predominantly white Europeans, a cautious interpretation of the study results is necessary for other ethnic groups.

In the present study, vacuum delivery was permitted for all fetal head positions and at higher stages in the birth canal, whereas forceps delivery was only permitted when the fetal head was in the occiput anterior or posterior position at the pelvic floor. This gives a possible bias towards more complications in the vacuum group. In addition, forceps delivery was performed twice as often as vacuum delivery (5% *vs* 2.5%) in Trondheim University Hospital during 1985–1989 and at the same frequency (3–5%) between 1990–1997. Thus, doctors were possibly better trained in forceps than vacuum

Table 3 Univariable and multivariable logistic regression and ANCOVA analyses of pelvic organ prolapse (POP) in any compartment, muscle avulsion and hiatal areas in women who delivered their first child during 1990–1997 at Trondheim University Hospital and subsequently underwent a clinical pelvic examination in 2013–2014

Variable:	*Forceps* vs *vacuum delivery*		*Forceps* vs *NVD*		*Vacuum* vs *NVD*		*Cesarean* vs *NVD*	
Categorical	*cOR*	*aOR*	*cOR*	*aOR*	*cOR*	*aOR*	*cOR*	*aOR*
POP ≥ Stage 2 or previous surgery	1.62 (1.02–2.64) $P = 0.045$	1.72 (1.06–2.79) $P = 0.03$	1.74 (1.15–2.65) $P < 0.01$	1.74 (1.12–2.68) $P = 0.01$	1.08 (0.70–1.66) $P = 0.74$	1.04 (0.66–1.64) $P = 0.87$	0.07 (0.03–0.15) $P < 0.01$	0.06 (0.02–0.14) $P < 0.01$
POP Stage 3	∞ (1.16–∞)* $P = 0.02$	—	2.45 (0.71–8.53) $P = 0.16$	2.06 (0.57–7.52) $P = 0.27$	0.00 (0.00–2.55)* $P = 0.30$	—	0.00 (0.00–3.31)* $P = 0.31$	—
Levator avulsion (uni- or bilateral)	4.04 (2.26–7.22) $P < 0.01$	4.16 (2.28–7.59) $P < 0.01$	4.46 (2.70–7.37) $P < 0.01$	4.35 (2.56–7.40) $P < 0.01$	1.10 (0.59–2.06) $P = 0.76$	0.96 (0.50–1.83) $P = 0.89$	0.00 (0.00–0.30)* $P < 0.01$	—
Continuous	*uMD*	*aMD*	*uMD*	*aMD*	*uMD*	*aMD*	*uMD*	*aMD*
Hiatal area (cm^2)								
At rest	2.53 (1.36–3.71) $P < 0.01$	2.65 (1.56–3.75) $P < 0.01$	1.87 (0.52–2.89) $P < 0.01$	1.66 (0.64–2.60) $P < 0.01$	−0.66 (−1.65 to 0.33) $P = 0.19$	−1.03 (−2.07 to 0.003) $P = 0.05$	−3.44 (−4.47 to −2.41) $P < 0.01$	−3.71 (−4.90 to −2.53) $P < 0.01$
On contraction	1.79 (0.64–2.95) $P < 0.01$	1.87 (0.82–2.91) $P < 0.01$	1.96 (0.98–2.94) $P < 0.01$	1.77 (0.83–2.70) $P < 0.01$	0.17 (−0.77 to 1.10) $P = 0.73$	−0.10 (−1.09 to 0.89) $P = 0.84$	−3.03 (−3.9 to −2.09) $P < 0.01$	−3.25 (−4.39 to −2.12) $P < 0.01$
On Valsalva	4.54 (2.11–6.97) $P < 0.01$	4.75 (2.46–7.03) $P < 0.01$	4.30 (2.23–6.36) $P < 0.01$	3.84 (1.78–5.90) $P < 0.01$	−0.25 (−2.51 to 2.02) $P = 0.83$	−0.91 (−3.1 to 1.29) $P = 0.42$	−8.01 (−10.26 to −5.77) $P < 0.01$	−8.35 (−10.87 to −5.84) $P < 0.01$

Values in parentheses are 95% CIs. Crude odds ratio (cOR) calculated from univariable logistic regression analysis and adjusted odds ratio (aOR) from multivariable logistic regression. Unadjusted mean difference (uMD) of hiatal areas between delivery modes calculated from univariable ANCOVA and adjusted mean differences (aMD) from multivariable ANCOVA. aOR and aMD were adjusted for age in 2013, parity, body mass index and birth weight of largest infant. *cOR calculated by Fisher's exact test when numbers were low. NVD, normal vaginal delivery.

delivery at the beginning of the study period. However, since doctors were well trained in both methods, we argue that the comparison between forceps and vacuum deliveries was done in a setting in which any pelvic floor trauma was most likely a consequence of the delivery method rather than of the doctor's skill. The cross-sectional study design does not allow us to suggest a cause–effect relationship between mode of delivery and POP and muscle trauma.

We studied women with a longer time interval from delivery than other similar studies[9–11]. The POP prevalence in the present study was similar to that in two previous studies[6,11] but differed from others[5,7–10,12]. This may be explained by the use of different definitions for POP or differences in study populations regarding age, parity, ethnicity and mode of delivery. Our results support previous studies demonstrating a higher prevalence of levator avulsion and larger hiatal areas after forceps than vacuum and normal vaginal deliveries[18,20–28].

Our study also confirms the results from a smaller study that demonstrated an increased risk of POP after forceps compared with normal vaginal delivery, and no increase in risk after vacuum delivery[10]. One previous study found an association between prolapse surgery and forceps delivery[34]. We found a higher prevalence of prolapse surgery after forceps (5.2%) than vacuum (1.6%) delivery, but because of small numbers we were only able to demonstrate a statistically significant difference when prolapse surgery was combined with the outcome POP ≥ Stage 2. Mean age at first prolapse surgery at Trondheim University Hospital is currently 63 years (unpubl. hospital data), whereas women in the study had a mean age 48 years. A previous study demonstrated an average latency of 33.5 years between the time of first delivery and prolapse surgery in women with avulsion[35]. Thus, a longer follow-up (more than 16–24 years) would help clarify whether prolapse surgery occurs more often after a forceps than a vacuum delivery. A longer follow-up would also help explain the lack of differences in symptoms (POP and incontinence) between the forceps and the vacuum group observed in a previous report from this study population[29].

Hiatal area was larger and there were more cases of levator avulsion in the forceps group, despite the fact that infants in the vacuum group were significantly larger. A possible explanation is that pelvic floor muscle trauma is more likely to occur during forceps delivery due to a traumatic effect of the forceps blades and the traction force exerted. The findings in this study imply that the use of vacuum should be preferred to forceps in a delivery situation in which both methods may be an option. This is supported in a recent commentary on studies of prevalence of levator avulsion[36].

In conclusion, we found that mode of delivery was associated with POP and pelvic floor muscle trauma in women from a general population, 16–24 years after their first delivery. Forceps was associated with significantly more POP, levator avulsion and larger hiatal areas than were vacuum and normal vaginal deliveries. There were

no statistically significant differences between vacuum and normal vaginal deliveries. Cesarean delivery was associated with significantly less POP and pelvic floor muscle trauma than were normal or operative vaginal deliveries.

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SUPPORTING INFORMATION ON THE INTERNET

The following supporting information may be found in the online version of this article:

Table S1 Association of potential confounding factors with pelvic organ prolapse ≥ Stage 2 or previous prolapse surgery, levator avulsion and hiatal area on Valsalva

Paper III

Paper 3: Volløyhaug, Ingrid; Mørkved, Siv; Salvesen, Kjell Å. Association between pelvic floor muscle trauma and pelvic organ prolapse 20 years after delivery. International Urogynecology Journal 2016 ; Volum 27.(1) s. 39-45.

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Paper IV

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Assessment of pelvic floor muscle contraction with palpation, perineometry and transperineal ultrasound: a cross-sectional study

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KEYWORDS: Modified Oxford Scale; pelvic floor muscle contraction; perineometry; three-dimensional/four-dimensional ultrasound

ABSTRACT

Objective *To study the correlation between palpation, perineometry and transperineal ultrasound for assessment of pelvic floor muscle contraction and to define a contraction scale for ultrasound measurements.*

Methods *This was a cross-sectional study of 608 women examined with palpation of pelvic floor muscle contraction, using the Modified Oxford Scale, and measurement of the vaginal squeeze pressure with a vaginal balloon connected to a fiber-optic microtip transducer (perineometry). Transperineal ultrasound was used for measurements of levator hiatal area and anteroposterior (AP) diameter in the plane of minimal hiatal dimensions, at rest and on contraction. The pelvic floor muscle contraction was expressed as the percentage difference between values at rest and on contraction. Spearman's rank was used to test for correlation between the different methods of assessment.*

Results *Significant correlations were found between all assessment methods ($P < 0.001$). Palpation correlated with perineometry ($r_s = 0.74$) and with proportional change in hiatal area ($r_s = 0.67$) and AP diameter ($r_s = 0.69$) on ultrasound. Perineometry correlated with proportional change in hiatal area ($r_s = 0.60$) and AP diameter ($r_s = 0.66$) on ultrasound. We defined a contraction scale based on the proportional change in AP diameter. In this population, a change in AP diameter of < 7% corresponded to absence of contractions, 7–18% corresponded to weak contractions, 18–35% corresponded to normal contractions and > 35% corresponded to strong contractions.*

Conclusions *We found moderate to strong correlation between ultrasound measurements, palpation and perineometry for assessing pelvic floor muscle contraction. The proportional change in AP diameter was the ultrasound measurement with strongest correlation to palpation and perineometry and formed the basis for the contraction scale for ultrasound measurements. Copyright © 2015 ISUOG. Published by John Wiley & Sons Ltd.*

INTRODUCTION

Pelvic floor muscle anatomy and contractility are important for pelvic floor function[1–4]. Pelvic floor muscle resting tone and contraction are components of the mechanism that prevents descent of the pelvic organs and maintains continence[1–7]. Education on pelvic floor muscle contraction and exercise is the recommended first-line treatment for urinary and fecal incontinence as well as for mild pelvic organ prolapse[8,9].

Pelvic floor muscle contraction and strength are assessed commonly by digital palpation or perineometry (measurement of vaginal squeeze pressure)[10,11]. Both techniques, however, have disadvantages and there is no gold standard[12,13]. In recent years, ultrasound has been introduced for assessment of pelvic floor muscle contraction. Three-dimensional or four-dimensional (3D/4D) transperineal ultrasound can measure the reduction in hiatal area and anteroposterior (AP) diameter that is induced by pelvic floor muscle contraction[14–16]. Ultrasound assessment of the cranioventral shift of the bladder neck and/or change in the axis of the proximal urethra are other ultrasound techniques for assessment of levator

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muscle strength or contraction[17–19]. Studies comparing assessment of pelvic floor muscle contraction by ultrasound, digital assessment and perineometry are sparse, and we have not found any validated scale for pelvic floor muscle contraction using ultrasound measurements.

Our aim was to study the correlation between palpation, perineometry and ultrasound measurement for the assessment of pelvic floor muscle contraction and to define a contraction scale for ultrasound measurements.

SUBJECTS AND METHODS

From June 2013 to February 2014, we conducted a cross-sectional study in women recruited from a normal population of healthy women who delivered their first child at Trondheim University Hospital, Norway between 1990 and 1997. We used the same study population as for two previous studies designed to compare the prevalence of pelvic floor disorders and pelvic floor muscle trauma after different modes of delivery, and therefore a large proportion of women with operative vaginal deliveries (26% forceps, 21% vacuum and 17% Cesarean section) was included[20,21]. Sample size calculations were performed for the previous studies. Informed consent was obtained from all participants and the Regional Committee for Medical and Health Research Ethics (REK midt 2012/666) approved the study.

Study participants presented with an empty urinary bladder and bowel and were asked to withhold information regarding previous delivery, prolapse and incontinence symptoms, pelvic floor muscle exercise and gynecological surgeries until the examination had been completed. They were examined in the supine position in a gynecological examination chair, with knees and hips semiflexed and abducted. The gynecological examination included digital assessment of pelvic floor muscle contraction, perineometry and a 4D pelvic floor ultrasound examination. All women were instructed on the correct pelvic floor muscle contraction, i.e. to squeeze their pelvic floor muscle (pull in and lift up the urethra, vagina and rectum, or imagine trying to control passing gas). The same instructions were given during all assessments of pelvic floor muscle contractions. All examinations were performed by one examiner (I.V.) who was blinded to demographic and clinical background data at the time of the examination.

Digital assessment of pelvic floor muscle contraction was performed by the examiner inserting the index and middle fingers approximately 4 cm into the vagina (only the index finger in the case of very narrow hiatus) and palpating the puborectalis muscle at each side of the vagina during contraction. The Modified Oxford Scale (MOS) was used to rate pelvic floor muscle contraction on a scale of 0–5[11]: 0 = no contraction; 1 = minor muscle 'flicker'; 2 = weak muscle contraction; 3 = moderate muscle contraction; 4 = good muscle contraction and 5 = strong muscle contraction. The mean MOS of the right and left sides of the vagina was used for correlation analysis.

Perineometry was conducted using a vaginal balloon catheter connected to a fiber-optic microtip transducer (Camtech AS, Sandvika, Norway) placed in the vagina, with the middle of the balloon located approximately 3.5 cm inside the introitus[22]. Study participants performed three maximal pelvic floor muscle contractions and the strongest contraction (creating the highest intravaginal pressure) was used for analysis.

Finally, 3D/4D ultrasound volumes were acquired with a GE Voluson S6 device (GE Medical Systems, Zipf, Austria) using the RAB 4–8-MHz abdominal 3D probe at an acquisition angle of 85°. For assessment of pelvic floor muscle contraction, we acquired three volumes per woman, starting at rest and recording the maximal pelvic floor muscle contraction. Offline analysis of ultrasound volumes was performed 6–14 months after the examination, using the 4Dview Version 14 Ext.0 software (GE Medical Systems). The analysis was conducted by one examiner (I.V.) who was blinded to clinical and demographic data at the time of the analysis. Hiatal area and AP diameter both at rest and during maximal pelvic floor muscle contraction were measured in the rendered axial plane of the minimal hiatal dimensions, as described previously[23] (Figure 1). The strongest pelvic floor muscle contraction, which created the largest difference in levator hiatal area between rest and contraction, was used for each woman. We first calculated the absolute difference in hiatal area and the AP diameter between rest and pelvic floor muscle contraction. Subsequently, we used the formula suggested by van Delft *et al.*[16] to calculate the proportional (percentage) difference in measurements between maximum contraction and rest: proportional difference (%) = ((Measurement$_{rest}$ – Measurement$_{squeeze}$)/Measurement$_{rest}$) × 100, for both hiatal area and AP diameter.

Statistical analysis

Statistical analysis was performed with IBM SPSS statistics version 21 software (IBM SPSS, Armonk, NY, USA). Data from ultrasound parameters were normally distributed, but MOS and perineometry data were not; therefore, Spearman's rank test was used to assess the correlation between the methods. Increasing rank correlation implied increasing agreement between the tests: $r_s = 0$, no agreement; $r_s > 0.3$, weak agreement; $r_s > 0.5$, moderate agreement; $r_s > 0.7$, strong agreement; $r_s = 1$, perfect agreement. $P < 0.05$ was considered statistically significant.

After determination of the ultrasound method with the strongest correlation to digital assessment, we calculated cut-offs corresponding with palpation. The International Continence Society has recommended that quantification of contractions by digital palpation should be divided into four categories (absent, weak, normal, strong)[13] and we used these four categories when defining cut-offs for an ultrasound scale, yielding the same percentage of women in each category. For this purpose, mean MOS = 0 was

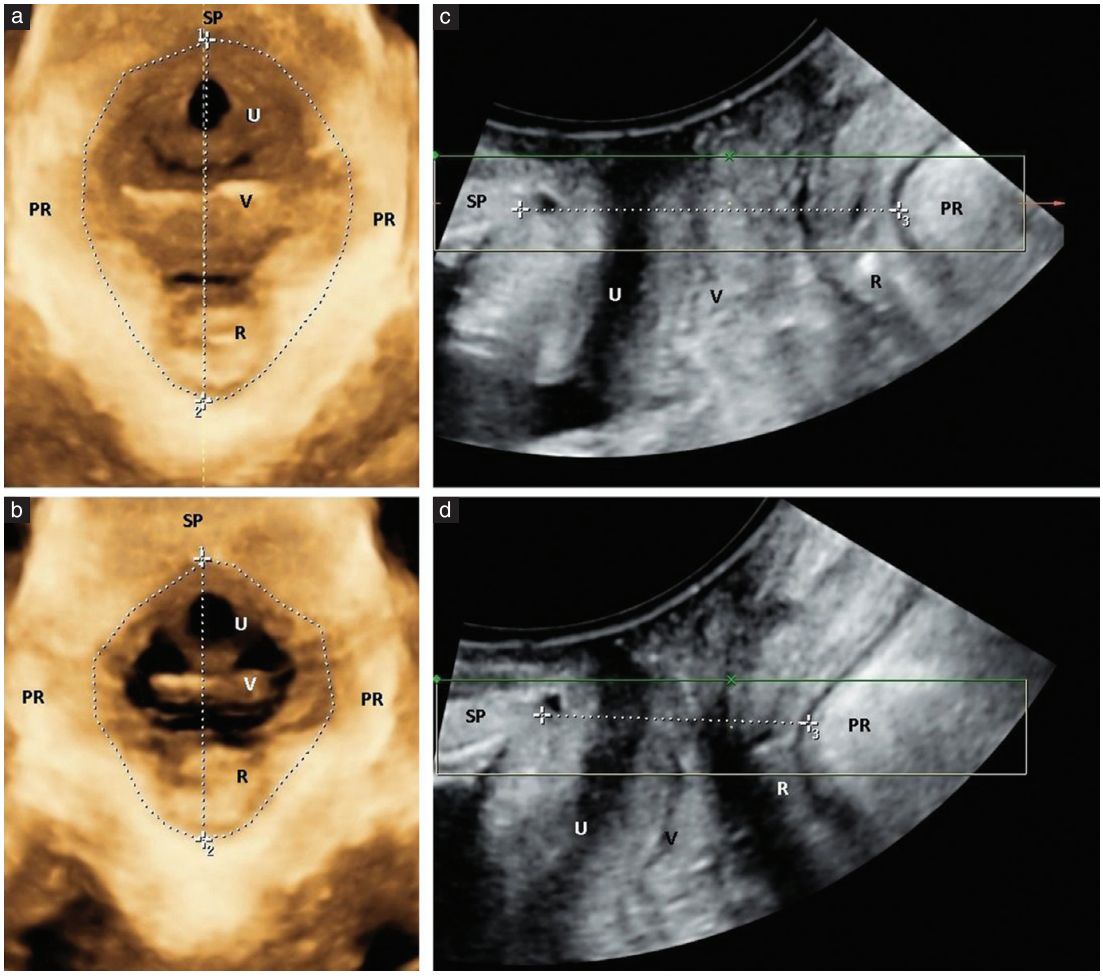

Figure 1 Transperineal three-dimensional ultrasound images in oblique axial plane of minimal hiatal dimensions in a rendered volume (1–2 cm thick), showing measurement of hiatal area and anteroposterior (AP) diameter at rest (a) and on contraction (b). Corresponding two-dimensional ultrasound images in mid-sagittal plane, showing measurement of AP diameter from upper border of symphysis pubis (SP) to puborectalis muscle (PR) at rest (c) and on contraction (d). R, rectum; U, urethra; V, vagina.

classified as absence of contraction, 0.5–2 was weak, 2.5–4 was normal and 4.5–5 was strong.

RESULTS

A total of 608 women underwent clinical examination. All women were examined by palpation, 607 ultrasound volumes were stored and 559 women were examined by perineometry. Mean age at examination was 48 (range, 35–64) years and mean body mass index was 26 (range, 16–47) kg/m^2. Mean parity was 2 (range, 1–5). Of those for whom information was available, 126/541 (23.3%) were postmenopausal, 30/606 (5.0%) reported a previous hysterectomy and 15/593 (2.5%) had undergone prolapse surgery.

Mean differences between relaxed state and maximal pelvic floor muscle contraction for the different assessment methods are presented in Table 1. The Spearman's rank correlation coefficients between ultrasound measurements and MOS and perineometry are presented in Table 2. Statistically significant correlations were found between all assessment methods ($P < 0.001$ for all correlations). The strongest correlation was found between MOS and perineometry ($r_s = 0.74$). MOS had a stronger correlation with all ultrasound parameters than did perineometry, and the proportional change in AP diameter correlated most strongly with MOS. Figure 2 presents graphically the correlation between mean MOS and proportional change in AP diameter. Mean proportional changes in AP diameter, with 95% CIs, in relation to mean MOS are presented in Table 3.

Table 1 Mean values for different assessment methods of pelvic floor muscle contraction

Assessment method	*Mean ± SD*	*Range*
Mean Modified Oxford Scale ($n = 608$)	3.1 ± 1.3	0–5
Perineometry (cmH_2O) ($n = 559$)	29.6 ± 19.7	0–129
Ultrasound ($n = 607$)		
Change in hiatal area (cm^2)	7.2 ± 3.2	0–21.1
Change in hiatal area (%)	31.1 ± 12.1	0–64.0
Change in AP diameter (cm)	1.6 ± 0.7	0–3.4
Change in AP diameter (%)	24.4 ± 9.8	0–50.9

AP, anteroposterior.

Table 2 Spearman's rank correlation coefficients (r_s) for mean Modified Oxford Scale (MOS) and for perineometry *vs* ultrasound measurement for assessment of pelvic floor muscle contraction

Ultrasound assessment	*Mean MOS (n = 607)*	*Perineometry (n = 558)*
Change in hiatal area (cm^2)	0.54	0.46
Change in hiatal area (%)	0.67	0.60
Change in AP diameter (cm)	0.63	0.58
Change in AP diameter (%)	0.69	0.66

Data are given as r_s. AP, anteroposterior.

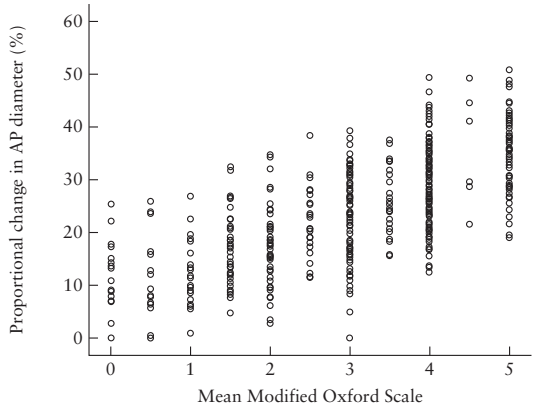

Figure 2 Correlation between mean Modified Oxford Scale and proportional change in anteroposterior (AP) diameter on ultrasound for assessment of pelvic floor muscle contraction in 607 women.

Cut-offs for proportional change in AP diameter according to a four-point contraction scale based on the proportions allocated to each category by palpation are presented in Table 4. Proportional change in AP diameter of < 7% corresponded to absent contractions, 7–18% corresponded to weak contractions, 18–35% corresponded to normal contractions and > 35% corresponded to strong contractions. When applying these cut-offs, the correlation between palpation and proportional change in AP diameter remained good ($r_s = 0.62$) and 65% of the contractions were allocated to the same category by the two methods; furthermore, for only two contractions was a discrepancy of more than one

Table 3 Mean proportional change in anteroposterior (AP) levator hiatal diameter in relation to mean Modified Oxford Scale (MOS) in 607 women

		Change in AP diameter (%)	
Mean MOS	n	*Mean (95% CI)*	*SD*
0	21	10.7 (7.6–13.8)	6.8
0.5	16	11.3 (7.1–15.6)	8.0
1	23	12.5 (9.9–15.1)	6.0
1.5	40	16.4 (14.2–18.6)	6.9
2	61	17.5 (15.7–19.3)	7.0
2.5	31	21.6 (19.5–23.8)	6.0
3	131	23.6 (22.4–24.9)	7.2
3.5	28	26.3 (23.8–28.7)	6.3
4	177	29.2 (28.2–30.3)	7.2
4.5	7	36.6 (27.3–45.9)	10.0
5	72	34.5 (32.8–36.2)	7.1

Table 4 Four-point contraction scale for categorizing proportional change in anteroposterior (AP) diameter on ultrasound during pelvic floor muscle contraction, according to proportions allocated to each category by palpation

*Contraction scale**	*Number according to palpation (n (%))*	*Cut-off for proportional change in AP (%)*
Absent	21 (3.5)	< 7
Weak	140 (23)	7–18
Normal	367 (60.5)	18–35
Strong	80 (13)	> 35

*Modified Oxford Scale: 0, absent; 0.5–2, weak; 2.5–4, normal; 4.5–5, strong.

category found between the two methods. According to the four-point contraction scale, more than half of the women were categorized as normal, and twice as many were categorized as absent or weak contraction compared with those categorized as strong contraction.

DISCUSSION

We found a statistically significant moderate-to-strong correlation between palpation, perineometry and ultrasound assessment of pelvic floor muscle contraction. Palpation had a stronger correlation with ultrasound measurements than did perineometry. The proportional change in AP levator hiatal diameter had the highest correlation with MOS. We have defined a four-point contraction scale using the proportional change in AP diameter.

All women in the study were examined by one examiner, thus eliminating interobserver variation. We did not perform any test–retest reliability analysis or inter-rater reliability analysis but this has been done in previous studies, which showed good reliability[15,24,25].

One strength of the study was that we examined a large number of women from a general healthy female population. Study participants were predominantly white Europeans and the results could be different for other

ethnic groups. The study was designed to include a large proportion of women with previous operative vaginal delivery and no nulliparous women were included, thus the composition of the study population is a potential bias that could influence the mean pelvic floor muscle contraction. Women who underwent examination had more prolapse symptoms than did the background population[21], and prolapse symptoms could be associated with different pelvic floor muscle contractility.

In spite of possible biases, we found the same median MOS as in two previous studies[16,26]. However, we found a greater proportional change in hiatal dimensions during pelvic floor muscle contraction than was reported in previous studies[14,16]. One previous study included 27 nulliparous asymptomatic women[14] and another study included 459 pregnant or puerperal women[16]. In the latter study, the MOS on the weak side was compared with changes in hiatal area and AP diameter. In our study, we used the average MOS and found a stronger correlation between MOS and the proportional change in AP diameter ($r_s = 0.69$ in the present study *vs* $r_s = 0.51$ in the previous study)[16]. The correlation with MOS was only moderate in another study using bladder neck movement during contractions measured by ultrasound[19].

To our knowledge, no previous study has defined a scale for ultrasound measurement of pelvic floor muscle contraction and we believe that our proposed scale is an important contribution for development of a clinically applicable scale for pelvic floor muscle contraction measured by ultrasound. However, further studies are needed to validate the cut-offs for a contraction scale based on ultrasound measurements.

In this study the correlation between MOS and the proportional AP difference was strong; however, for 21 women without palpable pelvic floor contractions, we found a shortening in the AP diameter implying that ultrasound is more sensitive to minimal changes in muscle contraction than is digital assessment.

One advantage of the use of the proportional change in AP diameter is that this measurement can be performed with a two-dimensional (2D) ultrasound transducer without acquisition, processing or interpretation of 3D/4D ultrasound volumes. The measurement can be obtained from a mid-sagittal plane in a 2D ultrasound image (Figure 1). However, it is possible that measurements from stored 3D and 2D images are not identical[23]. Ultrasound quantification of the proportional change in AP diameter is an objective measurement that can be performed offline with the use of cineloop and/or stored videoclips. It can also be demonstrated live for the woman and used as feedback for the interpretation of muscle contractions measured by palpation. In addition, ultrasound provides visual biofeedback and can be used to educate patients to correctly perform pelvic floor muscle contractions[17]. Ultrasound could also be helpful in teaching and training healthcare providers in palpation.

The reliability and validity of MOS depends on the experience of the examiner[12,27]. However, recent research has also shown good inter-rater agreement for this method[28]. MOS provides additional information such as muscle resting tone, pain, reduced sensation, texture of the muscle and muscular defects and should be used together with ultrasound for assessment of pelvic floor muscle contractions. Transperineal ultrasound should be the method of choice in women with an intact hymen or women with vaginismus and/or sexual dysfunction because ultrasound is less invasive than palpation.

The perineometer measures vaginal pressure but is influenced by any change in abdominal pressure, not just the squeezing pressure in the vagina. Measurements also depend on the correct placement of the vaginal balloon[22]. A valid measurement can be ensured by simultaneous observation of inward movement of the perineum[29]. However, in this study, the examination of ultrasound volumes revealed that some women exerted a push at the end of pelvic floor muscle contraction. This will elevate the measured pressure and could help explain the discrepancy between methods of assessment. We assert that perineometry does not add any important information when both palpation and ultrasound measurements are used to assess pelvic floor muscle contractions.

In conclusion, we found a moderate-to-strong correlation between ultrasound measurement and both digital examination and perineometry for assessment of pelvic floor muscle contraction. The proportional change in AP diameter was the ultrasound measurement with strongest correlation to digital assessment. We defined a four-point contraction scale for the proportional change in AP diameter, which agreed well with palpation; however, further studies are needed to validate a contraction scale for ultrasound measurements.

ACKNOWLEDGMENTS

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Appendices

I Study participant information

II Questionnaire

III Clinical examinations

IV Letter to editor and Authors' reply

Appendix I

UROPRO –Januar 2013

INFORMASJONSHEFTE

Forespørsel om deltakelse i studie

Detalj fra "du sang I" May Bente Aronsen

UROPRO
-en studie om
underlivsfremfall og lekkasje
hos kvinner

NTNU
Det skapende universitet

ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

Norske Kvinners Sanitetsforening

ExtraStiftelsen
Helse og Rehabilitering

UROPRO –Januar 2013

”Fødselstype og risiko for underlivsfremfall”

*Delivery method and risk for **uro**genital **pro**lapse*
UROPRO

Bakgrunn og hensikt
Dette er et spørsmål til deg om å delta i en forskningsstudie for å undersøke om fødsel med tang eller vakuum/sugekopp har innvirkning på utvikling av fremfall fra underlivet. Vi undersøker fire grupper av kvinner som fødte sitt første barn i perioden 1990-1997: Gruppe1: Tangfødsel, gruppe 2: fødsel med vakuum/sugekopp, gruppe3: vanlig fødsel og gruppe 4: keisersnitt. Du er valgt ut til å delta fordi du var førstegangsfødende i perioden 1990-1997 og tilhører en av de fire gruppene. Studien gjennomføres i regi av Kvinneklinikken ved St. Olavs Hospital og NTNU (Norges Teknisk Naturvitenskapelige Universitet)

Hva innebærer studien?
Studien er todelt.
Del 1: Alle studiedeltakere blir bedt om å fylle ut et spørreskjema. Dette kan fylles ut i vedlagt papirutgave og sendes i vedlagte konvolutt, eller besvares elektronisk ved å gå inn på websiden: www.nsfm.no/uropro og logge inn med deltakernummer, som du finner i øverste høyre hjørne på spørreskjemaet.
Spørreskjemaet inneholder spørsmål om fødsler og operasjoner i underlivet, inkontinens for urin og avføring og symptomer på fremfall fra underlivet. Utfylling av spørreskjema tar ca. 30 minutter.
Det er mulig å delta bare på del 1, uten å samtykke til å delta i del 2 av studien.

Del 2: Et utvalg av studiedeltakere, som på forhånd har samtykket til det, blir invitert til klinisk undersøkelse. Dette innebærer oppmøte ved Kvinneklinikken, St. Olavs Hospital i Trondheim. Det blir gjennomført en gynekologisk undersøkelse, der vi også undersøker styrke i bekkenbunnsmuskler, og måler grad av fremfall (hos dem som har denne tilstanden). I tillegg undersøker vi bekkenbunnsmusklene med ultralyd ved hjelp av en ultralydprobe som settes mot huden på utsiden av skjedeåpningen (ikke inne i skjeden). Undersøkelsen tar ca. 30-45 minutter.

Mulige fordeler og ulemper
Del 1: Det er ingen spesielle fordeler for studiedeltakeren med å utfylle spørreskjema. Ulempen er tiden det tar å fylle ut skjemaet.

Del 2: Fordelen med den kliniske undersøkelsen er at man får en grundig undersøkelse av bekkenbunnsmuskler og eventuelt fremfall, og at det er mulig å fange opp problemer hos den enkelte studiedeltaker og henvise til videre undersøkelser og behandling dersom det er ønskelig. Det er imidlertid ingen fullstendig gynekologisk undersøkelse med celleprøvetaking og ultralyd av eggstokker og livmor. Ulempene er tiden det tar å reise til sykehuset for å bli undersøkt, og noen vil kunne oppleve undersøkelsen som litt ubehagelig. Det er ingen risiko forbundet med undersøkelsen.

Blant de som samtykker til deltakelse i studien vil det bli trukket ut en heldig vinner av en iPad.

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste.
Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg.
Informasjonen om deg blir slettet etter at resultatene av studien foreligger.
Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte:

Studieleder:
Overlege Ingrid Volløyhaug, Kvinneklinikken, St. Olavs Hospital, Postboks 3250 Sluppen, N-7006 Trondheim
Telefon: 90 25 45 39
e-mail: uropro@stolav.no

Prosjektansvarlig:
Professor Kjell Å. Salvesen, Institutt for laboratoriemedisin, barne- og kvinnesykdommer, NTNU, N-7489 Trondheim

Ytterligere informasjon om studien finnes i kapittel *A* *– utdypende forklaring av hva studien innebærer.*
Ytterligere informasjon om biobank, personvern og forsikring finnes i kapittel B *– Personvern, biobank, økonomi og forsikring.*

Samtykkeerklæring følger med spørreskjemaet enten du svarer i vedlagt papirutgave eller elektronisk

Kapittel A- utdypende forklaring av hva studien innebærer

Kriterier for deltakelse
Førstegangsfødende ved RiT/St.Olavs Hospital i perioden 1990-1997
Vaginal fødsel; enten vanlig (normal) eller med tang eller vakuum/sugekopp, eller keisersnitt.
Bostedsadresse i en av følgende kommuner på det tidspunkt fødselen fant sted: Klæbu, Malvik, Melhus, Midtre Gauldal, Rissa, Selbu, Trondheim, Tydal, Åfjord
Studiedeltaker må kunne forstå norsk og være i stand til å fylle ut spørreskjema.

Bakgrunnsinformasjon om studien
Mange kvinner opplever plager av urinlekkasje og underlivsfremfall. En av ti kvinner vil ha behov for operasjon for disse plagene innen de fyller 80 år. Vi ønsker å finne ut mer om årsaken til at enkelte kvinner utvikler slike plager og andre ikke gjør det. Studier fra andre land har vist at visse forhold under fødsel kan ha innvirkning på utvikling av fremfall, men studiene er utført i land som driver fødselshjelp på en annen måte enn hva vi gjør i Norge. Vi vet at skader på bekkenbunnsmuskulaturen og styrke i bekkenbunnsmuskulaturen har betydning for utvikling av lekkasje og fremfall. Det er mangel på studier som undersøker kvinner så lenge som 15-20 år etter at de fødte sitt første barn.
Vi håper at resultatene fra studien kan gi oss informasjon som gjør at vi i større grad kan forebygge utvikling av urinlekkasje og underlivsfremfall i fremtiden.

Spørreskjema
Studien innebærer utfylling av spørreskjema med spørsmål om operasjoner i underlivet, overgangsalder, hormonbruk, røyking, høyde og vekt. Deretter følger spørsmål om urinlekkasje, symptomer på fremfall fra underlivet og avføringslekkasje, samt i hvilken grad slike symptomer eventuelt påvirker hverdagen din. Grunnen til at vi stiller spørsmål også om urinlekkasje og avføringslekkasje er at disse plagene ofte har sammenheng med symptomer på underlivsfremfall. Se vedlagt spørreskjema for detaljer.
Spørreskjemaet kan besvares enten ved å fylle ut vedlagte skjema og returnere i svarkonvolutt, eller ved å gå inn på websiden: nsfm.no/uropro og logge inn med din personlige kode som du finner i øverste høyre hjørne på spørreskjemaet. Når skjemaet besvares elektronisk og du trykker send inn, har du samtidig gitt ditt samtykke til å delta i studien.

Undersøkelser
Et utvalg av de som samtykker til deltakelse i del 2 av studien blir innkalt til klinisk undersøkelse. Dette er en gynekologisk undersøkelse som utføres av en erfaren kvinnelig gynekolog. Under undersøkelsen må du være avkledd nedentil, og du må ligge i gynekologisk undersøkelsesstol.
Gynekologen starter med å undersøke muskulaturen i bekkenbunnen med en finger i skjeden. Du vil bli bedt om å stramme bekkenbunnsmuskulaturen, og du får instruksjon om hvordan du skal gjøre dette. Når den som undersøker kjenner at du kniper riktig, vil det bli ført inn et lite ballongkateter i skjeden. Dette er på tykkelse med en finger, og du blir bedt om å knipe rundt ballongkateteret, slik at måling av muskelstyrken vises direkte på en dataskjerm.
Deretter vil du bli bedt om å slappe av i bekkenbunnsmusklene og trykke/presse nedover. Mens du gjør dette, blir det gjort mål med en målepinne i skjeden for å måle tendens til fremfall.

Til slutt gjennomføres en ultralydundersøkelse av bekkenbunnsmusklene. Gynekologen setter en ultralydprobe mot skjedeåpningen, og du vil bli bedt om å stramme bekkenbunnsmusklene og deretter å slappe av og trykke/presse nedover.

Tidsskjema
Del 1: Samtykkeerklæring og spørreskjema er vedlagt og returneres så snart som mulig og senest innen to uker etter at du har mottatt dette brevet. Alternativt kan samtykkeerklæring og spørreskjema fylles ut og leveres elektronisk på nsfm.no/uropro.

Del 2: Etter at vi har fått inn alle spørreskjema og samtykkeerklæringer, vil et utvalg av dem som har gitt sitt samtykke, bli innkalt til klinisk undersøkelse. Dette skjer i løpet av 2013. Du får beskjed i god tid (ca 3-4 uker) før den oppsatte timen.

Mulige fordeler
Det blir utført en grundig undersøkelse av bekkenbunnsmusklene og tendens til fremfall hos studiedeltakerne. Dersom det gjøres funn som tilsier videre utredning eller behandling, vil det bli gitt kontrolltime eller henvisning til riktig instans.

Mulige bivirkninger
Vi kjenner ikke til mulige bivirkninger av undersøkelsen

Mulige ubehag/ulemper
Ulempen er den enkelte studiedeltakers tidsbruk i forbindelse med utfylling av spørreskjema og fremmøte til klinisk undersøkelse.

Den kliniske undersøkelsen kan av enkelte oppleves som ubehagelig, men undersøkelsen er ikke smertefull.

Pasientens/studiedeltakerens ansvar
De som har sagt seg villlig til å delta i del 2 av studien, er ansvarlige for å møte opp til undersøkelse til oppsatt tidspunkt eller varsle studieleder eller sekretær dersom tidspunktet ikke passer.

Dersom situasjoner gjør at din deltagelse i studien blir avsluttet tidligere enn planlagt, vil du få beskjed om dette.

Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern
Opplysninger som registreres om deg er:
Del 1:
1) Opplysninger knyttet til din første fødsel. Dette er opplysninger vi finner i sykehusets Pasientadministrative System, PAS, og som kontrolleres opp mot journalopplysninger.
2) Opplysninger om operasjoner i underlivet, overgangsalder, hormonbruk, røyking, høyde og vekt. Opplysninger om urinlekkasje, avføringslekkasje og symptomer å fremfall fra underlivet. Dette er opplysninger du gir oss ved å besvare spørreskjemaet.
Del 2:
3) Opplysninger om styrke i bekkenbunnsmuskulaturen, objektive mål på fremfall, ultralydundersøkelse av bekkenbunnsmuskulaturen. Dette er opplysninger vi samler inn ved den kliniske undersøkelsen

Det kan bli aktuelt at studieleder går inn i journalen din for å kontrollere at studieopplysningene stemmer overens med tilsvarende opplysninger i din journal. Alle som får innsyn har taushetsplikt.

Andre forskere enn de som er tilknyttet den aktuelle studien vil ikke ha tilgang til opplysningene om deg.

St. Olavs hospital ved administrerende direktør er databehandlingsansvarlig.

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi og NTNU/ St. Olavs rolle
Ingen person, institusjon eller firma med interesse av egen økonomisk gevinst er involvert i studien.

Studien er finansiert gjennom forskningsmidler fra NTNU, St. Olavs Hospital, Norske Kvinners Sanitetsforening og Extrastiftelsen. Studieleder er lønnet av NTNU, St. Olavs Hospital, Norske Kvinners Sanitetsforening og Extrastiftelsen. Vi kjenner ikke til mulige interessekonflikter.

Forsikring
Vanlig pasientskadeforsikring gjelder for deltakerne i studien.

Informasjon om utfallet av studien
Som studiedeltager har du rett til å få informasjon om utfallet av studien.

Studien er godkjent av Regional komite for medisinsk og helsefaglig forskningsetikk Midt-Norge.

Appendix II

SPØRRESKJEMA

SAMTYKKEERKLÆRING

Detalj fra "du sang I" May Bente Aronsen

UROPRO
-en studie om
underlivsfremfall og lekkasje
hos kvinner

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ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

Norske Kvinners Sanitetsforening

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Helse og Rehabilitering

Deltaker 130001

UROPRO

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

Del 1 spørreskjema ☐ Ja ☐ Nei

Del 2 klinisk undersøkelse ☐ Ja ☐ Nei

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

25.01.2013 ---

(Signert, prosjektleder, dato)

Generell del

Deltaker 130001

1) Fødsler

a) Hvor mange barn har du født totalt? Antall ☐☐

b) Ditt første barn ble forløst med: (Kryss av i en rute)

☐ Vanlig/normal fødsel
☐ Tangfødsel
☐ Fødsel med vakumsug
☐ Keisersnitt
☐ Husker ikke

Fødselsvekt på ditt første barn (g) ☐☐☐☐

c) Hvilken type fødsel hadde du for dine påfølgende barn?
(Kryss av i en rute for hver fødsel, og fyll inn fødselsvekt dersom du husker det)

Fødselsvekt (g)

Barn nr 2 Type fødsel:
☐ Vanlig/normal fødsel ☐ Vakum/ sugekopp ☐ Husker ikke
☐ Tangfødsel ☐ Keisersnitt
☐☐☐☐

Barn nr 3 Type fødsel:
☐ Vanlig/normal fødsel ☐ Vakum/ sugekopp ☐ Husker ikke
☐ Tangfødsel ☐ Keisersnitt
☐☐☐☐

Barn nr 4 Type fødsel:
☐ Vanlig/normal fødsel ☐ Vakum/ sugekopp ☐ Husker ikke
☐ Tangfødsel ☐ Keisersnitt
☐☐☐☐

Barn nr 5 Type fødsel:
☐ Vanlig/normal fødsel ☐ Vakum/ sugekopp ☐ Husker ikke
☐ Tangfødsel ☐ Keisersnitt
☐☐☐☐

Barn nr 6 Type fødsel:
☐ Vanlig/normal fødsel ☐ Vakum/ sugekopp ☐ Husker ikke
☐ Tangfødsel ☐ Keisersnitt
☐☐☐☐

2) Overgangsalder

a) Har du kommet i overgangsalder (dvs. mer enn ett år siden siste menstruasjon)?
☐ Ja ☐ Nei ☐ Vet ikke

b) Hvis ja, hvilket år var siste menstruasjon? ☐☐☐☐

c) Har du tidligere brukt hormoner, enten tabletter eller i skjeden? ☐ Ja ☐ Nei

d) Bruker du hormontabletter nå? ☐ Ja ☐ Nei

e) Bruker du krem/tabletter/vagitorier som inneholder østrogen i skjeden nå?
☐ Ja ☐ Nei

3) Operasjoner

Deltaker 130001

a) Har du fjernet livmoren? ☐ Ja ☐ Nei

Hvis ja, hva var årsaken til at livmoren ble fjernet?
(Vennligst kryss av alt som passer for deg):

- ☐ Muskelknuter
- ☐ Blødningsforstyrrelser
- ☐ Smerter
- ☐ Fremfall/descens/nedsunken livmor
- ☐ Kreft
- ☐ Annet _____

b) Er du operert for urinlekkasje? ☐ Ja ☐ Nei

Hvis ja, hvor mange ganger? ☐

c) Er du operert for avføringslekkasje? ☐ Ja ☐ Nei

Hvis ja, hvor mange ganger? ☐

d) Er du operert for fremfall av skjedevegg/urinblære/ livmor/tarm? ☐ Ja ☐ Nei

Hvis ja, hvor mange ganger? ☐

e) Har du brukt ringpessar for fremfall? ☐ Ja ☐ Nei

f) Bruker du ringpessar nå? ☐ Ja ☐ Nei

4) Er du seksuelt aktiv? *(Kryss av i en rute)*

- ☐ Ja
- ☐ Nei, pga symptomer fra underlivet (fremfall, lekkasje av urin, luft eller avføring)
- ☐ Nei, av annen årsak

5) Høyde/vekt

Oppgi så nøyaktig som mulig din aktuelle høyde og vekt

Høyde ☐☐☐ cm Vekt ☐☐☐ kg

6) Røyk

Røyker du? ☐ Ja ☐ Nei

Hvis ja, hvor mange sigaretter per dag? ☐☐

7) Hoste

Har du kronisk hoste/ astma/KOLS? ☐ Ja ☐ Nei

Kartlegging av besvær fra bekkenbunnen.

Deltaker 130001

Instruksjoner
Vær så snill og svar på spørreskjema så fullstendig som mulig. Spørsmålene viser om du har symptomer fra urinblære, tarm eller underliv og i så fall hvor mye disse plager deg. Sett en X i passende boks. Når du svarer skal du gå ut i fra dine symptomer de siste 3 måneder.

Eksempel

For det følgende spørsmål

Om du vanligvis ikke har hodepine, kryss bare i "Nei"-boks

Har du vanligvis hodepine?

☒ Nei ☐ Ja Hvis ja, hvor mye det plager det deg?
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

Om du vanligvis har hodepine, kryss i "Ja"-boks og angi hvor mye hodepinen plager deg. I dette eksempelet er hodepinen middels plagsom.

Har du vanligvis hodepine?

☐ Nei ☒ Ja Hvis ja, hvor mye plager det deg?
☐ Ingenting ☐ Lite ☒ Middels ☐ Mye

8. Opplever du vanligvis trykk i nedre del av buken?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

9. Har du vanligvis tyngdefølelse i underlivet?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

10. Har du vanligvis en kul i skjeden som du kan se eller kjenne i skjedeåpningen?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

11. Må du dytte av og til rundt endetarmen eller skjedeåpningen for å få tømt tarmen?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

12. Kan det vanligvis kjennes ut som om urinblæren ikke blir skikkelig tømt?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

Deltaker 130001

13. Har du noen gang trengt å dytte opp en kul i skjeden for å få tømt urinblæren fullstendig?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

14. Må du trykke mye for å ha avføring?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

15. Føler du at tarmen ikke blir fullstendig tømt når du har avføring?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

16. Lekker du vanligvis avføring når den er fast?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

17. Lekker du vanligvis avføring når den er løs?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

18. Har du vanligvis problemer med å holde på luft?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

19. Har du vanligs smerte når du har avføring?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

20. Opplever du iblant en så sterk trang til å ha avføring at du må skynde deg til toalettet?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

21. Opplever du iblant at noe tarm kan komme ut av endetarmen under eller etter avføring?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

22. Må du tisse ofte?

☐ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

Deltaker 130001

23. Lekker du vanligvis urin når du får slik sterk vannlatningstrang?

☐ Nei ☐ Ja **<u>Hvis ja</u>, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

24. Lekker du vanligvis urin ved hoste, nysing eller når du ler?

☐ Nei ☐ Ja **<u>Hvis ja</u>, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

25. Lekker du vanligvis urin dråpevis?

☐ Nei ☐ Ja **<u>Hvis ja</u>, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

26. Opplever du vanligvis vanskeligheter med å få tømt urinblæren?

☐ Nei ☐ Ja **<u>Hvis ja</u>, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

27. Har du vanligvis smerte elle ubehag i nedre del av buken eller i underlivet?

☐ Nei ☐ Ja **<u>Hvis ja</u>, hvor mye plager det deg?**
☐ Ingenting ☐ Lite ☐ Middels ☐ Mye

Bekkenbunnbesvær og innvirkning av det i din hverdag

En del kvinner synes at symptomene fra urinblære, tarm eller skjede påvirker deres aktiviteter, relasjoner og følelser. Marker med en X det svar som best beskriver hvor mye din hverdag blir påvirket av symptomer eller plager fra urinblære, tarm eller skjede de siste 3 måneder. Vær så snill å kontroller at du markerer ett svar i alle 3 kolonnene for hvert spørsmål

Hvordan bruker vanligvis symptomer eller besvær fra <u>urinblære eller urin (blærekontroll)</u> påvirke din

28. Evne til å gjøre husarbeid?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

29. Mulighet for fysisk aktivitet som f.eks. å gå turer, svømming, osv?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

30. Mulighet til å gå på kino, konserter eller annen underholdning?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

31. Evnen til å reise med bil eller buss lenger enn 30 min. hjemmefra?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

32. Deltagelse i sosiale arrangement utenfor hjemmet?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

33. Mentale helse (nervøsitet, depresjon osv)?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

34. Følelse av frustrasjon?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

Hvordan bruker vanligvis symptomer eller besvær fra <u>tarm eller endetarm</u> påvirke din

35. Evne til å gjøre husarbeid?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

36. Mulighet for fysisk aktivitet som f.eks. å gå turer, svømming, osv?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

37. Mulighet til å gå på kino, konserter eller annen underholdning?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

38. Evnen til å reise med bil eller buss lenger enn 30 min. hjemmefra?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

39. Deltagelse i sosiale arrangement utenfor hjemmet?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

40. Mentale helse (nervøsitet, depresjon osv)?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

41. Følelse av frustrasjon?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

Hvordan bruker vanligvis symptomer eller besvær fra <u>skjede eller bekken</u> påvirke

42. Evne til å gjøre husarbeid?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

43. Mulighet for fysisk aktivitet som f.eks. å gå turer, svømming, osv?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

44. Mulighet til å gå på kino, konserter eller annen underholdning?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

45. Evnen til å reise med bil eller buss lenger enn 30 min. hjemmefra?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

46. Deltagelse i sosiale arrangement utenfor hjemmet?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

47. Mentale helse (nervøsitet, depresjon osv)?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

48. Følelse av frustrasjon?
☐ Ikke i det hele tatt ☐ Lite ☐ Middels ☐ Mye

Appendix III

Fødselsnummer:__ __ __ _ _ _ _ _
Deltakernummer:_ _ _ _

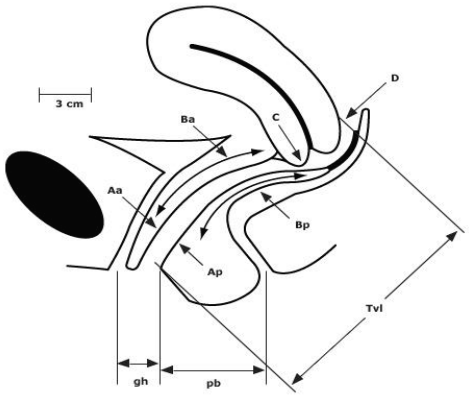
Klinisk undersøkelse
Fødselstype og risiko for underlivsfremfall

Hva betyr muskelskade som oppstår under fødsel for utvikling av descens 15-20 år senere?

Delivery method and risk for **uro**genital **pro**lapse 15- 20 years later

1) Gradering av descens.

POP-Q



Aa	Ba	C
Gh	Pb	Tvl
Ap	Bp	D

Grad	**0**	**1**	**2**	**3**	**4**
Cystocele	□	□	□	□	
Uterusdescens/ellongatio	□	□	□	□	□
Rectocele	□	□	□	□	
Enterocele	□	□	□	□	
Vaultprolaps	□	□	□	□	□

2) <u>Palpasjon og måling av styrke og integritet av levatormuskulaturen</u>

Hviletonus 0-5 av 5 H □ V □

palpasjon

0= muskel ikke palpabel, **1=**muskel palpabel, men veldig slapp, vid hiatus, minimal motastand ved strekk, **2=** vid hiatus, men noe motstand ved strekk, **3=** Hiatus temmelig smal, middels motstand, men lett å strekke, **4=** Hiatus smal, muskelen kan strekkes, men høy motstand mot strekk, ingen smerte, **5=** Hiatus veldig smal, ingen strekk mulig, "treet" følelse, mulig med smerte: "vaginisme"

Muskelstyrke Oxford 0-5 av 5 H □ V □

palpasjon

0=ingen kontraksjon, **1=**flakkende, **2=**svak, **3=**moderat, **4=**god, **5=**sterk

Muskelintegritet

palpasjon:	avrivning	H □	V □
	Delvis avrivning	H □	V □
	Intakt	H □	V □

Muskelstyrke

v bruk av apparat (Camtech) max av tre kontraksjoner: □ cm H2O

3) <u>3D/4D ultralydundersøkelse av levatormuskulaturen</u>

<u>Avulsion/ avrivning:</u>

Levator:	<u>Intakt</u> i minst ett av de tre sentrale plan	H □	V □
	<u>Avrivning</u> i alle tre sentrale plan	H □	V □

Unilateral avrivning □ Bilateral avrivning □

<u>Ballooning/ økt strekkbarhet:</u>

Hiatusareal:	Største av 3 areal v Valsalva.	□ cm²
	Minste av 3 areal v kontraksjon	□ cm²
	Hvilearelal:	□ cm²

4) <u>3D/4D ultralydundersøkelse av sfinktermuskulaturen</u>

Residualdefekt >/=30* i 4 av 6 bilder ytre sfinkter □

Residualdefekt >/=30* i 4 av 6 bilder indre sfinkter □

Appendix IV

characterise the evolution of the contribution of each group to the overall CS rate. As stated in the recent World Health Organization statement, which recommends the use of TGCS at the local level, 'this classification can help health care facilities to optimise the use of caesarean section by identifying, analysing and focusing interventions on specific groups of particular relevance for each health care facility".[3] In our centre, as also reported in our national study and in most studies using TGCS in developed countries, the focus should be on group 1 (Nulliparous with single cephalic pregnancy, ≥37 weeks of gestation in spontaneous labour), group 2 (Nulliparous with single cephalic pregnancy, ≥37 weeks of gestation who either had labour induced or were delivered by CS section before labour) and group 5 (All multiparous with at least one previous uterine scar, with single cephalic pregnancy, ≥37 weeks of gestation). We are convinced that the assessment of the CS rate using TGCS should be continuous and performed every year, to be effective. However, to take into account population changes over time, adjustment on maternal characteristics (especially maternal age and body mass index) as performed in our paper, is needed when possible.

Finally, we agree that audits of CS should be conducted, in addition to the analysis with the TGCS. This can be performed, as described by Nair et al.[2] in their letter, only for deliveries by CS in the Robson subgroups identified or for all CS. In our centre, we review all caesarean deliveries performed over the last 24 hours at a daily meeting with all the medical staff. We also perform a weekly meeting to prospectively check the indications of planned CS to avoid the medically unjustified ones. These two types of clinical audit are complementary. Clinical audit of CS indications seems indeed an effective intervention to decrease rate of CS without adverse effects on maternal and neonatal outcomes as demonstrated by a recent multifaceted trial conducted in Quebec.[4] ■

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Re: Pelvic organ prolapse and incontinence 15–23 years after first delivery: a cross-sectional study

Sir,

We read with great interest the article by Volløyhaug et al.[1] on pelvic organ prolapse and incontinence 15–23 years after first delivery. We believe this is an important topic to investigate as the prevalence of pelvic floor dysfunction is high, has probably previously been under-reported and has a huge impact on the quality of women's lives.[2] The size of the study population and triangulation of data collection is to be commended. It also highlights pertinently that there is no significant difference in the pelvic floor dysfunction (PFD) outcomes between forceps and vacuum delivery.

However, we would like to draw your attention to two areas. First, the study excluded small babies (<2000 g), stillbirths and breech deliveries at the index pregnancy from the analysis. We believe there to be value in including these groups for comparison. For example, it would be interesting to compare the PFD outcomes between small babies delivered vaginally with those delivered via caesarean section. Likewise, stillbirths should be included, as many indications for operative vaginal delivery will be similar. Furthermore, if the numbers of vaginal breech deliveries were sufficient, the PFD outcomes could be compared where the delivery is carried out using forceps or using the Mauriceau–Smellie–Veit manoeuvre. The authors do not state why they excluded these groups.

Secondly, an opportunity was missed in analysing urinary incontinence, to distinguish between 'urinary incontinence at urgency' and 'urinary incontinence at coughing, sneezing, laughing' or mixed incontinence in a further sub-analysis. It is well known that operative vaginal deliveries can result in pelvic floor muscle and sphincter damage leading to stress incontinence[3] yet there is very limited literature separating stress only, urge only, and mixed types of urinary incontinence when comparing vaginal and caesarean section. Analysis of the type of incontinence in terms of the woman's mode of delivery, may have offered valuable insight into the origin and aetiology of the different types of urinary incontinence. The large sample size of this study may have allowed sufficient power to draw statistical conclusions. In the context of an increasing incidence of caesarean section, the results could be instrumental in

guiding future practice and advice given to women.

In conclusion, we believe that this is a well conducted and relevant study, but there may be some missed opportunities with regard to further information that could be gleaned from the available data. ■

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Authors' reply

Sir,

We thank Georgiou et al. for their interest in our recent paper published in *BJOG*[1]. We acknowledge their comments on possible missed opportunities regarding further information that could be obtained from the available data. Our considerations are presented in the following paragraphs.

The reason why we excluded women with stillbirths and small babies (<2000 g) were mainly for ethical considerations. Small babies carry a higher risk of perinatal deaths or neurological problems, and we did not want to bother women with questions related to those births. Another reason for excluding small babies was that delivering a small baby probably carries a lower risk of pelvic floor injury and thus pelvic floor disorders than normal-sized or larger babies. Less than 3% of the babies delivered at Trondheim University Hospital in the actual time period weighed <2000 g.

Comparison of cephalic and breech vaginal delivery was not the aim of this paper, and the number of vaginal breech deliveries would have been too small to analyse for a difference between breech deliveries assisted by forceps and not.

A subgroup analysis on stress urinary incontinence (SUI) and urge urinary incontinence (UUI) was not a pre-specified analysis, and thus not included. The results of sub-group analyses of the prevalence of SUI and UUI are given here: *For SUI we found:* caesarean delivery (CD): 77/256 = 30.1%, normal vaginal delivery (NVD): 280/688 = 40.7%, operative vaginal delivery (OVD): 262/688 = 38.1%, forceps delivery (FD): 122/333 = 36.6%, vacuum delivery (VD): 123/297 = 41.4%. We found similar differences between groups as for the composite variable (UUI and/or SUI/ and or previous surgery). *For UUI we found:* CD: 68/256 = 26.6%, NVD: 176/678 = 26.0%, OVD: 187/682 = 27.4%, FD: 87/332 = 26.2%, VD: 87/293 = 29.7%. There were no statistically significant differences between the groups for urge urinary incontinence, which implies that CD does not protect against UUI, as was also found in a review from 2007.[2]

In conclusion we agree with your comments. In particular, analysis of pelvic floor disorders after different modes of breech delivery and comparison to cephalic delivery is lacking and deserves future research. ■

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Re: The Hayman uterine compression suture

B–Lynch suture: how to coin a concept in medicine

Experience may lead several obstetricians to a similar idea or concept. Having your name coined as the first inventor of something in medical history, however, may require the following: grasping its significance, continuing to hold it, and publishing it.

Obstetric practice of postpartum haemorrhage markedly changed after 1997, when B–Lynch et al.[1] first described the B–Lynch uterine compression suture. During 1992–1996 (the era of my assistant professorship) I sometimes helped Dr Yano, the only obstetrician–gynaecologist in a local facility, to perform caesarean section, when we encountered a case of severe uterotonic nonreacting atonic bleeding. We tightly 'wound round' the uterus with absorbable threads (Figure 1). We performed this procedure in a total of three cases, with all achieving haemostasis. Our fundamental concept, 'compressing the uterus by thread', was similar to that of the B–Lynch suture,