Ultrasound Imaging of the Pelvic Floor:

linking anatomical findings with clinical symptoms

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het verband tussen anatomische afwijkingen en klinische symptomen

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Aan mijn ouders

Drie keer is scheepsrecht...

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Introduction to pelvic floor imaging

1.1 2D Transperineal Ultrasound

For evaluation of pelvic floor and lower urinary tract dysfunction the use of transabdominal ultrasound was first documented in the early eighties, with the translabial [1], transrectal [2] and transvaginal [3, 4] techniques developing somewhat later. To obtain a translabial or transperineal image of the pelvic floor, the transducer (ideally a 3.5-6 MHZ curved array abdominal probe) is placed on the perineum, after covering the transducer with an unpowered glove or thin plastic wrap for hygienic reasons. The terms translabial, transperineal and perineal are considered synonymous and are used interchangeably in the following text.

Imaging is usually performed in the supine position, with the hips flexed and slightly abducted, or sometimes in the standing position if the patient finds it difficult to perform a full Valsalva manoeuvre. Bladder filling should be specified, and imaging after voiding is preferable. The presence of a full rectum may impair accuracy and sometimes requires a repeat examination after bowel emptying. The preferred image orientation is with the symphysis pubis (cranioventral) to the left, and the anorectal canal (dorsocaudal) to the right as first shown by Kohorn [2] and Grischke [4] (Figure 1).

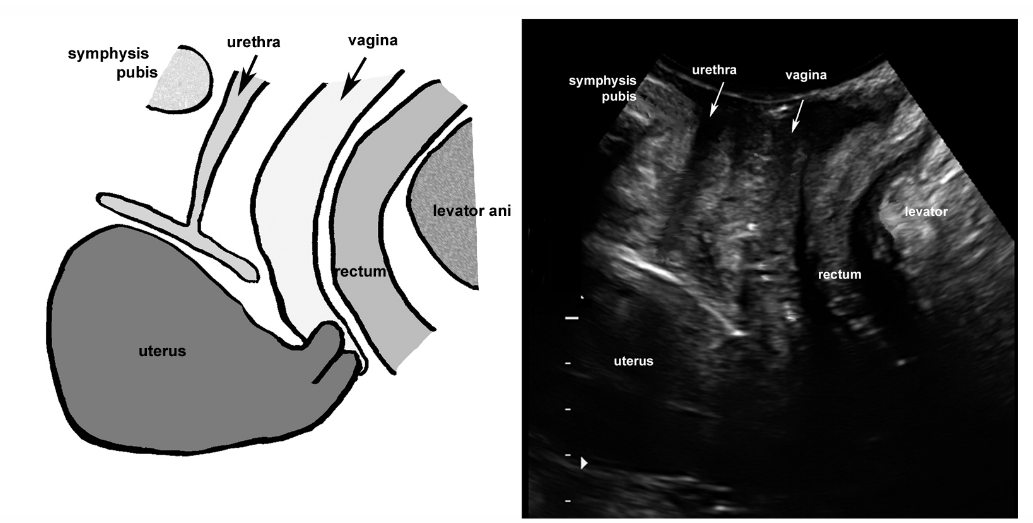
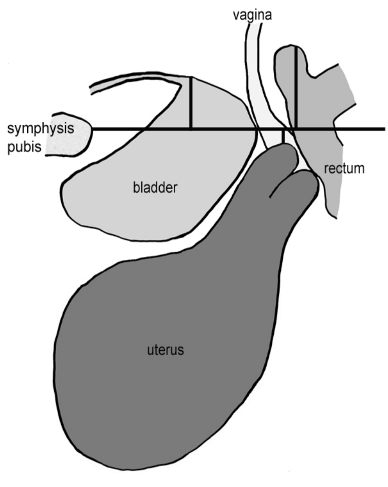


***Figure 1**: The standard midsagittal field of vision includes the symphysis pubis anteriorly, the urethra, vagina, rectum and the levator ani.*

Acquisition is most conveniently performed with the main axis of the transducer in the midsagittal plane, showing the inferior margin of the pubis, urethra and bladder neck as well as the levator ani muscle posterior to the anorectal junction. On 2D imaging a single volume can be obtained with the acquisition angle to be set at 70° or higher, allowing visualization of the entire levator hiatus as the area of interest. Imaging is obtained at rest, on maximum contraction and at valsalva. A cineloop function and a split screen option can be helpful for assessment of valsalva or contraction manoeuvres as well as for the possibility to select the best image at maximum contraction and/or valsalva.

1.1.1 Prolapse Assessment

For assessment of descent of the three compartments the structures to be imaged in the mid-sagittal plane are the bladder neck or the leading edge of a cystocele for the anterior compartment, the cervix or the lowermost point of the pouch of Douglas for the central compartment and the rectal ampulla for the posterior compartment. All these structures can be reliably imaged in the midsagital plane on valsalva. The inferior margin of the symphysis pubis serves as a point of reference. At maximum valsalva the maximum descent of the bladder, cervix or pouch of Douglas and rectum are then measured (Figure 2) for



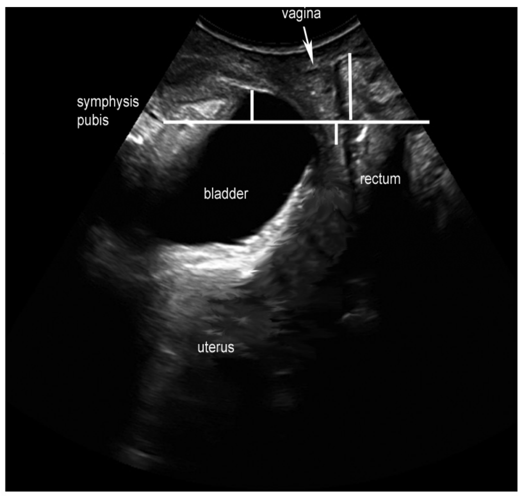


***Figure 2**: Pelvic organ descent as measured with transperineal ultrasound on valsalva in the mid-sagittal view of a 44 yr old patient complaining of prolapse symptoms. The reference line is set at the inferior margin of the symphysis pubis. This image shows typical findings of a third degree cystocele, grade two uterine descent and a third degree rectocele. Maximum descent of the bladder is measured at -1.42cm, cervix at 0.43cm, and the rectum at -2.20cm.*

evaluation of pelvic organ prolapse. By convention measurements below or caudal to the symphysis are negative, measurements above are positive.

Good correlations between the prolapse quantification system of the International Continence Society (ICS POP-Q) and transperineal ultrasound, i.e. for the central and anterior compartment, r=0.72 for anterior vaginal wall, r= 0.77 for uterine prolapse and r= 0.53 for posterior vaginal wall have been described [5]. Descent of the bladder to ≥ 10 mm and a descent for the rectum ≥ 15 mm below the symphysis pubis are strongly associated with symptoms of prolapse and have been proposed as cut offs for the diagnosis of significant prolapse on ultrasound [6].

1.1.2 Levator contraction

Observing a pelvic floor muscle contraction on ultrasound provides visual biofeedback to the patient and can be used for pelvic floor muscle training and for quantification of pelvic floor muscle activity. In the midsagittal plane a cranioventral shift of the pelvic organs is observed as well as a narrowing of the levator hiatus and changes in bladder neck position. In 2D images a pelvic floor muscle contraction can be quantified using displacement of the

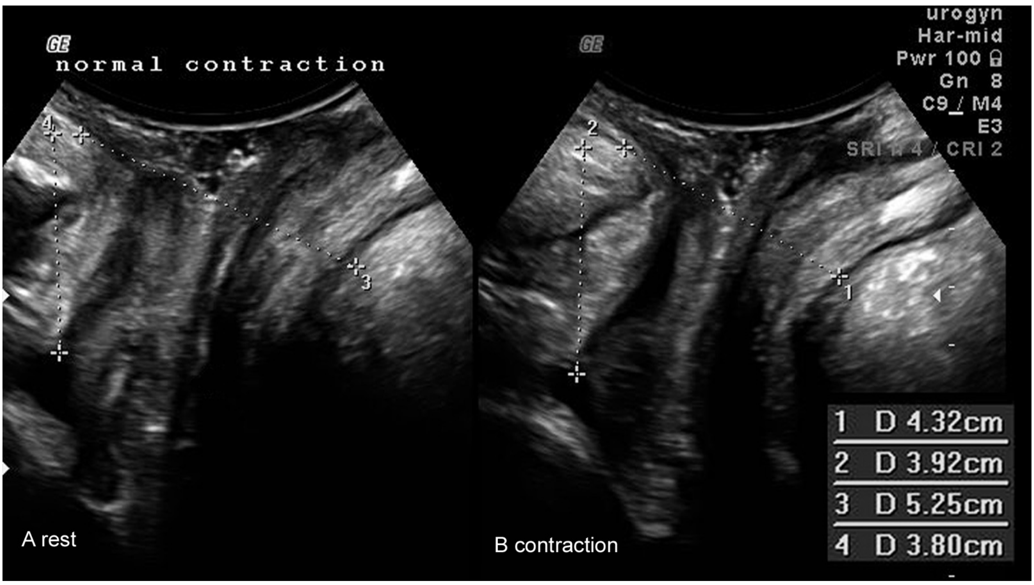


Figure 3: *Levator contraction on pelvic floor ultrasound, A at rest and B in contraction. Measurements for contraction are taken at the level of the bladderneck (measurement 2 and 4) and at the level of minimal hiatal dimension (measurement 1 and 3), using the inferior margin of the pubic bone as reference point.*

bladder neck, as well as a reduction of the midsagittal diameter (Antero – Posterior, AP) of the levator hiatus at the level of minimal hiatal dimensions [7, 8] (Figure 3). In 3D volumes the AP, the Left – Right (LR) transverse diameter as well as the hiatal area can be measured [9] (Figure 14).

1.1.3 Bladder Neck Descent

For the etiology of stress urinary incontinence (SUI), it is of importance to perform an evaluation of bladder neck mobility, as hypermobility is thought to play an important role in the pathophysiology of this condition. Although several other factors influence stress continence, vaginal childbirth is considered to be the most significant environmental factor [10].

Bladder neck position and mobility can be assessed with a good degree of reliability on ultrasound with reported intraclass correlation of 0.75 [11, 12]. Imaging is usually performed using the split-screen function, allowing comparing the image at rest with the image at maximum valsalva. The calculated difference between the horizontal measurement

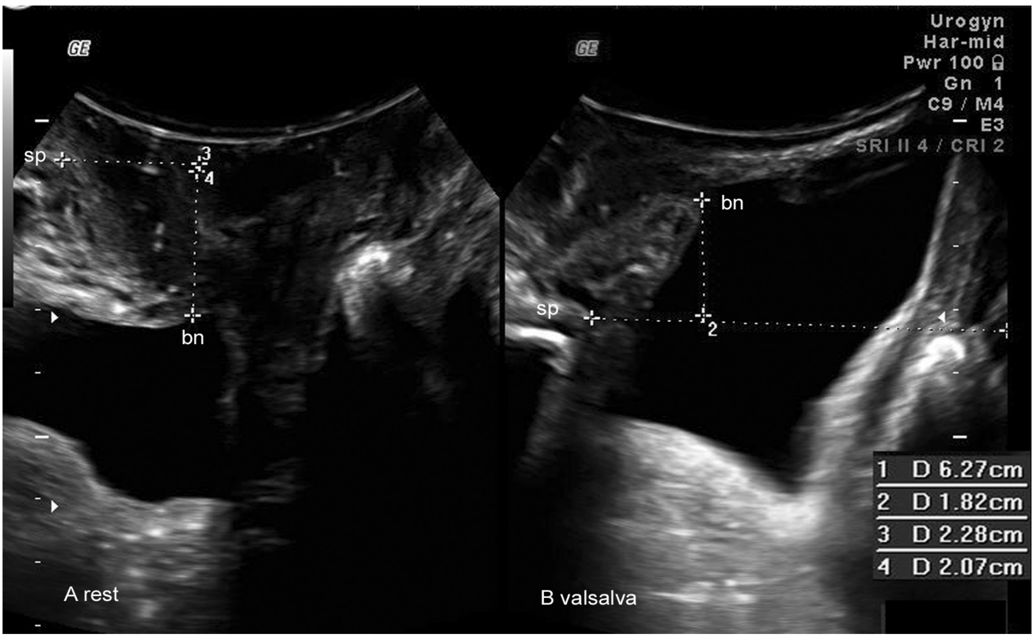


***Figure 4**: Marked bladder neck descent as shown on sonography, A at rest and B on on maximum valsalva. Horizontal bladder neck descent is 39.1 mm, (20.7 (rest) – (-18.2 (valsalva)). = 39.1 mm).*

of the bladder neck position at rest and at maximum valsalva yields the value for bladder neck descent (Figure 4). To define hypermobility, the cut off value is set at 30 mm [13].

Stress urinary incontinence can also be observed using Color Doppler for demonstrating urine leakage through the urethra [14]. Funneling of the internal urethral meatus may be observed in patients complaining of SUI, but also have been described in patients with urge incontinence [15].

A range of other abnormalities can be detected. It is relatively easy to measure the residual volume of the bladder after voiding according the formula, ((AP x LR x 5.6) – 14.9 ml = RV ml) [16]. Other findings can include detrusor wall thickness, urethral diverticula, gartner duct cysts or bladder tumor [13,17].

1.1.4 Cystocele

Cystocele is described as a marked descent of the bladder on maximum valsalva. The extent of rotation of the bladder neck, also called the retrovesical angle, can be measured by comparing the angle between the proximal urethra and the trigone. Two entities of cystoceles have been described, the first with an intact retrovesical angle (90 - 120°) of the bladder neck and secondarily with opening of the bladderneck to 160 – 180° [13]. This rotational descent of the intermal meatus can be associated with funneling and is more frequently seen by patients who also complain of stress urinary incontinence [13]. It has been conjectured that this differences might be related with two different anatomical abnormality, i.e.

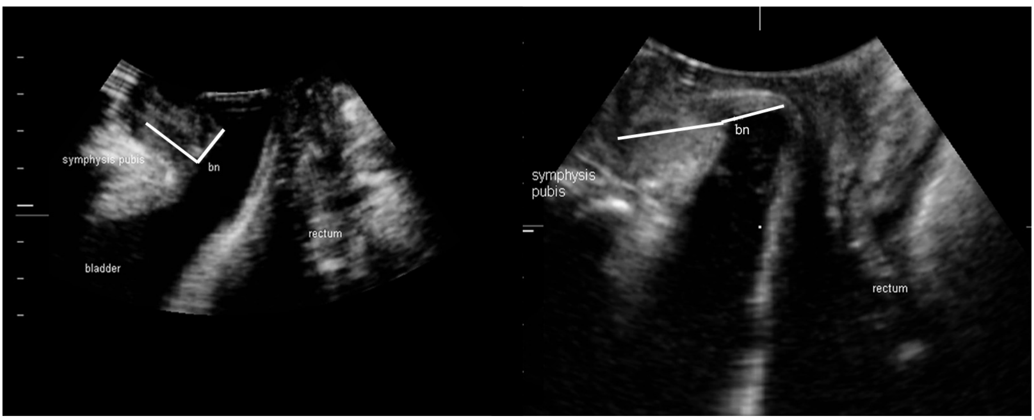


Figure 5*: Cystocele, on the left with an intact retrovesical angle of 90°, on the right with a retrovesical angle of 170°.*

either a central or paravaginal fascial defect but this still needs further investigation [13].

In patients who have undergone surgery for SUI, such as a Burch colposuspension, the bladder neck often is largely fixed, and the cystocele will develop between the bladder neck and cervix or pouch of Douglas (high cystocele).

1.1.5 Enterocele

Enterocele is described as a herniation of fluid containing peritoneum, small bowel, sigmoid or omentum into the vagina, separating the vagina from the rectal ampulla (Figure 6). In the midsagittal plane a maximum valsalva will demonstrate downward movement of iso- or hyperechoic abdominal contents anterior to the anorectal junction. Small bowel peristalsis may help with the identification of structures filling the hernia, and occasionally intraperitoneal fluid will conveniently outline the cul de sac.

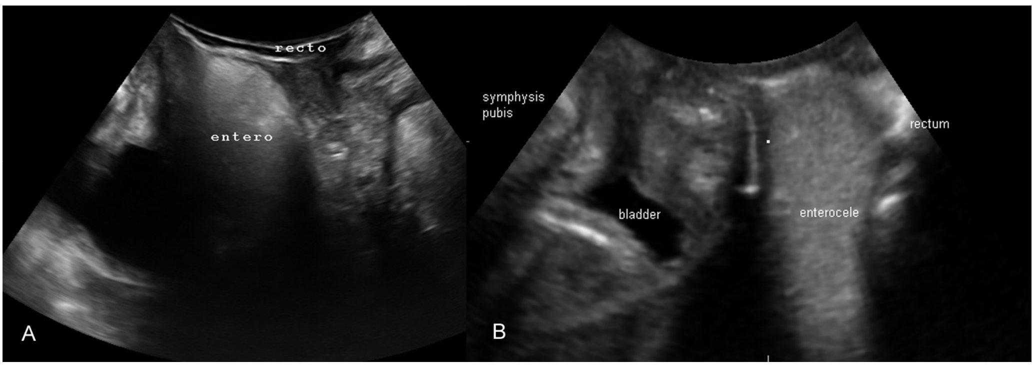


Figure 6*: Enterocele, In image A a herniation of small bowel anterior to a rectocele and in B an obvious sigmoid enterocele in a very wide hiatus.*

Hysterectomy is considered to be a risk factor for developing an enterocele and the majority will have other concomitant pelvic floor abnormalities [18]. The relationship with symptoms remains unclear. Enterocele is frequently overlooked on clinical examination but it is of importance to be able to differentiate between different anatomic abnormalities such as enterocele and rectocele, especially in regards to the surgical intervention needed for treatment of the patient.

1.1.6 Anterior rectocele

Rectocele is seen as a sharp discontinuity in the ventral contour of the anorectal muscularis at the level of the anorectal junction, and they usually occur transverse (Figure 7). Quantification of the rectocele includes width and depth of the rectocele using a line extending from the cranioventral aspect of the internal anal sphincter as a base line. A cut off level of 10 mm is used for detecting clinically relevant rectocele [19].

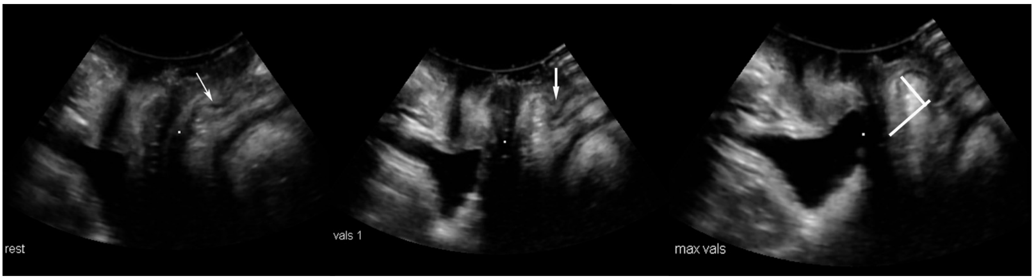


***Figure 7**: Anterior Rectocele on ultrasound, developing at the level of the anorectal junction (arrow on the left image at rest, more clear during valsalva (in the middle) and measurements at maximum valsalva (picture on the right).*

Correlations between clinical prolapse grading and ultrasound may not be quite as good for the posterior compartment, but it is possible to distinguish between 'true' and 'false' rectocele, i.e., a defect of the rectovaginal septum and perineal hypermobility without fascial defects [19]. True rectoceles may be present in young nulliparous women but are more common in the parous [20]. In some women they clearly arise in childbirth, and if they are present before the delivery, defects tend to enlarge [21, 22]. Many are asymptomatic. There is a significant association between bowel symptoms as incomplete bowel emptying and manual evacuation and fascial defects [23]. Defect specific repair closes defects but may not affect concomitant perineal hypermobility.

1.1.7 Posterior rectocele

Posterior rectocele is a common finding in children with constipation and evacuatory dys function but in adolescence an anterior rectocele is more common. As in anterior rectocele the area of pocketing is very close to the anorectal junction but seems to develop posteriorly or dorsally (Figure 8).

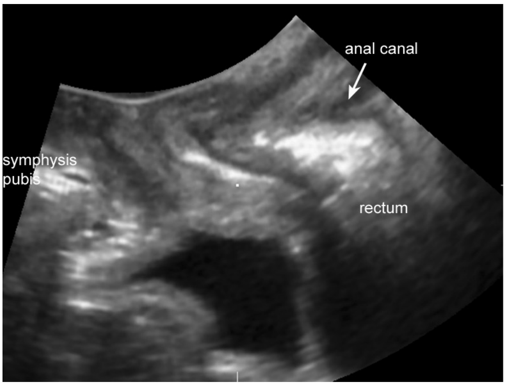


Figure 8: *Posterior rectocele on ultrasound*

1.1.8 Rectal intusussception and rectal prolapse

Normally the anal canal is tubular, with little difference between luminal diameters along most of its length. In less marked cases, mucosal rectal/anal intussusception may be seen as intra-abdominal contents (such as sigmoid, small bowel or even an abnormally mobile uterus) protruding into the anal canal and producing an arrow shaped distension or 'splaying of the anal canal' on Valsalva (Figure 9). In more pronounced cases, full thickness rectal wall may prolapse into and through the anal canal and the external sphincter resulting in clinically apparent rectal prolapse [18]. Rectal intussusception is a relatively common

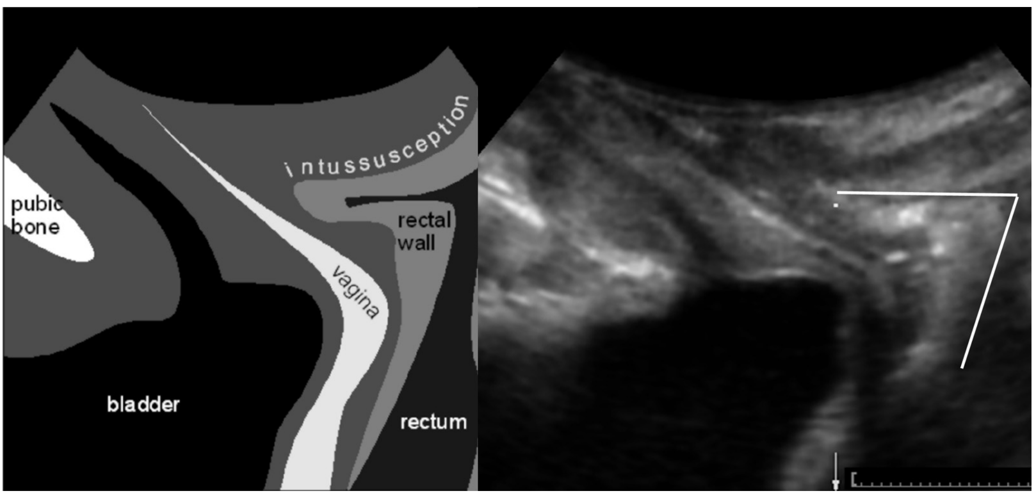


Figure 9: *Anal intussusception shown as on translabial ultrasound.*

finding in both symptomatic and asymptomatic patients and its relation to clinical symptoms remains unclear [24]. However, in patients with obstructed defecation more advanced morphological abnormalities have been described in comparison with controls [25].

1.2 3D/4D Realtime Transperineal Ultrasound

So far pelvic floor imaging has been limited to the midsagittal plane. With the introduction of 3D and 4D real time imaging, we are now able to access the axial plane for describing the normal and abnormal morphology of the levator ani complex and levator hiatus (Figure 10). Up until recently imaging of the levator ani complex was limited to magnetic resonance imaging. Due to its limited availability and cost, information about the normal and abnormal levator ani complex was limited.

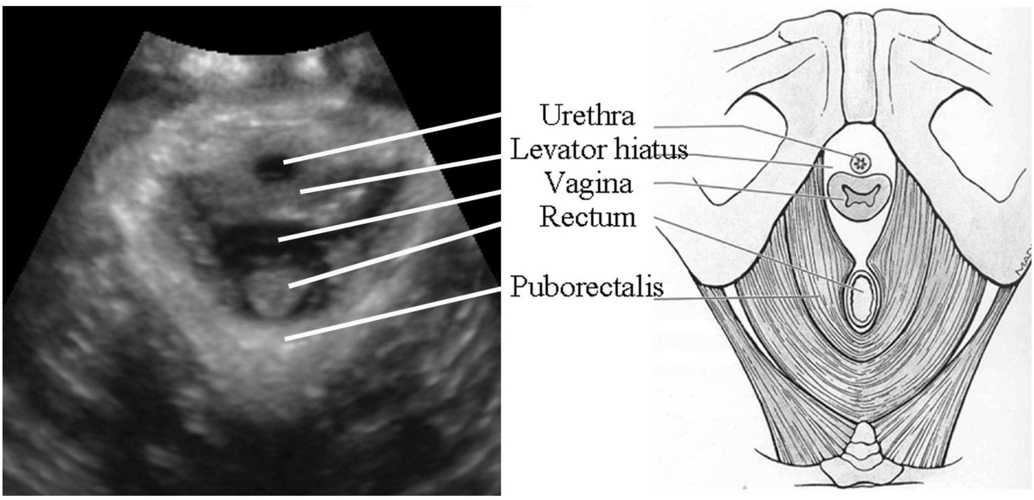


Figure 10*: Normal 3D anatomy of the pelvic floor in the axial plane as seen on transperineal ultrasound.*

The technique used for acquiring 3D/4D imaging is the same as prescribed for obtaining 2D imaging. The acquisition angle is set at 85˚ to include the entire levator hiatus. The three orthogonal images are complemented by 'a rendered image', i.e. a semitransparent representation of all voxels in an arbitrarily definable 'box (Figure 11).

On 3D ultrasound static imaging planes can be varied in order to enhance the visibility of a

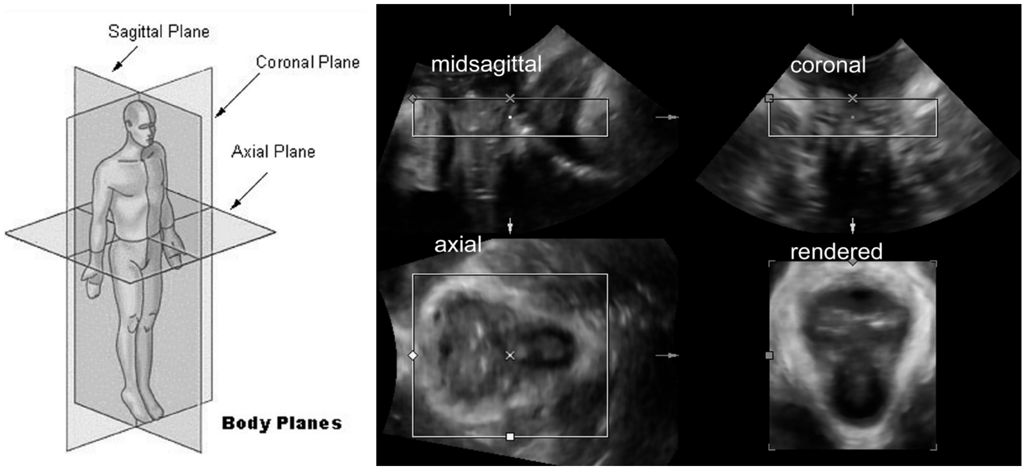


***Figure 11**: Normal anatomy as acquired with the volume cine technique.*

give anatomical structure either at the time of acquisition or at a later time during offline analysis. Four dimensional (4D) real-time imaging allows the investigator to obtain a dynamic assessment of the pelvic floor. Observations of manoeuvres such as levator contraction and valsalva allow assessment of levator function and delineate levator or fascial trauma more clearly. Detachment of the puborectalis muscle component of the levator ani from the pubic bone, described as an "avulsion injury or defects" may be most clearly visible at levator contraction, and defects of the rectovaginal septum are often visible only on valsalva.

Enhancement of tissue contrast resolution like CrossXBeam (CRI) and/or Speckle Reduction Imaging (SRI) and techniques like volume contrast imaging (VCI) and the recent development of tomographic ultrasound imaging (TUI) now allow spatial resolutions close to or even superior to MRI in orthogonal planes.

1.2.1 Levator Avulsion

The pubovisceral part of the levator ani muscle (m. puborectalis and m. pubococcygeus) is thought to play a major role in pelvic floor dysfunction. Major morphological abnormalities of these muscles were first described on MRI [14,15,16]. Rendered images obtained by translabial ultrasound give good visualization of the attachments of the puborectalis muscle to the pelvic sidewall. Defects mainly occur as a detachment of the puborectalis on the anteromedial part of the attachment of the levator ani to the pubic bone. These defects can

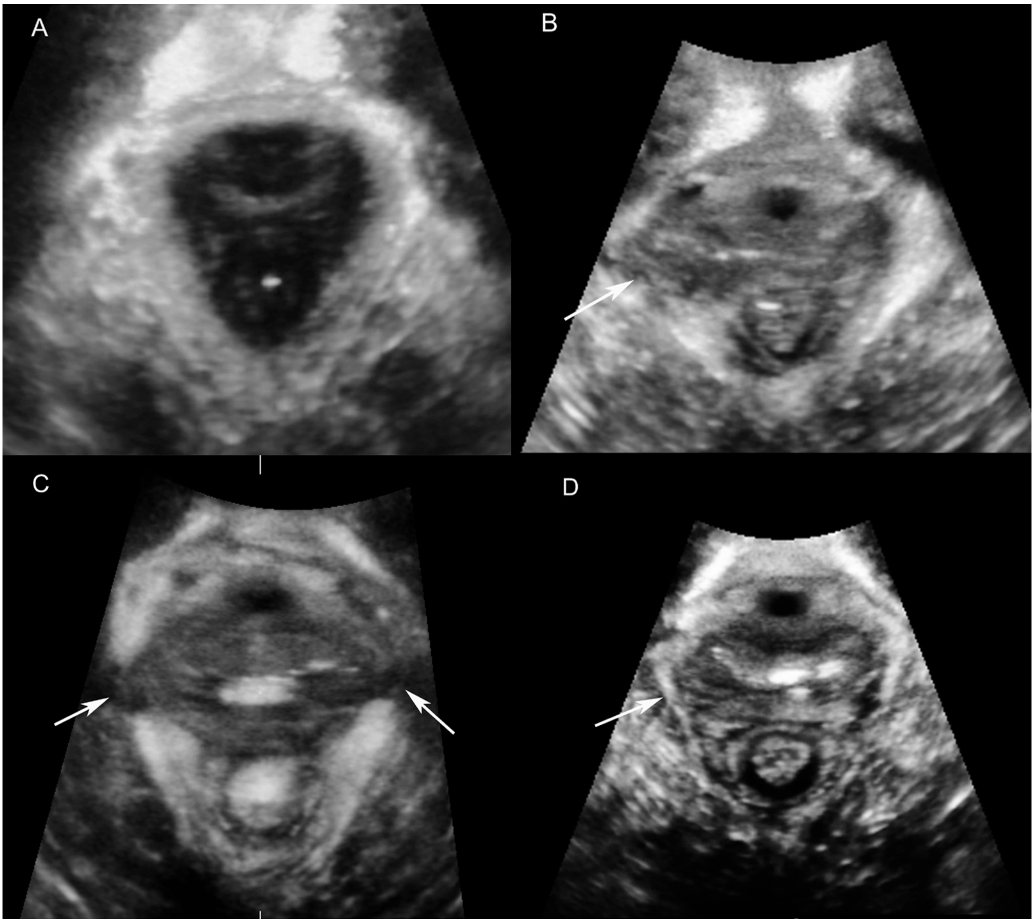


***Figure 12**:Imaging of the levator ani with the VCI technique using a slice thickness of 3 mm. In A: a normal levator, B: a unilateral defect on the right, C: a bilateral defect and D shows possible bilateral levator atrophy.*

be either unilateral, left or right, or bilateral (Figure 12).

Reported prevalence of defects varies between 15 – 35 %, and they seem to occur only in women after vaginal childbirth [26, 27].

1.2.2 Tomographic Ultrasound Imaging

Levator defects can be quantified using Tomographic Ultrasound Imaging (TUI), a multislice technique comparable with Computed Tomography scanning.

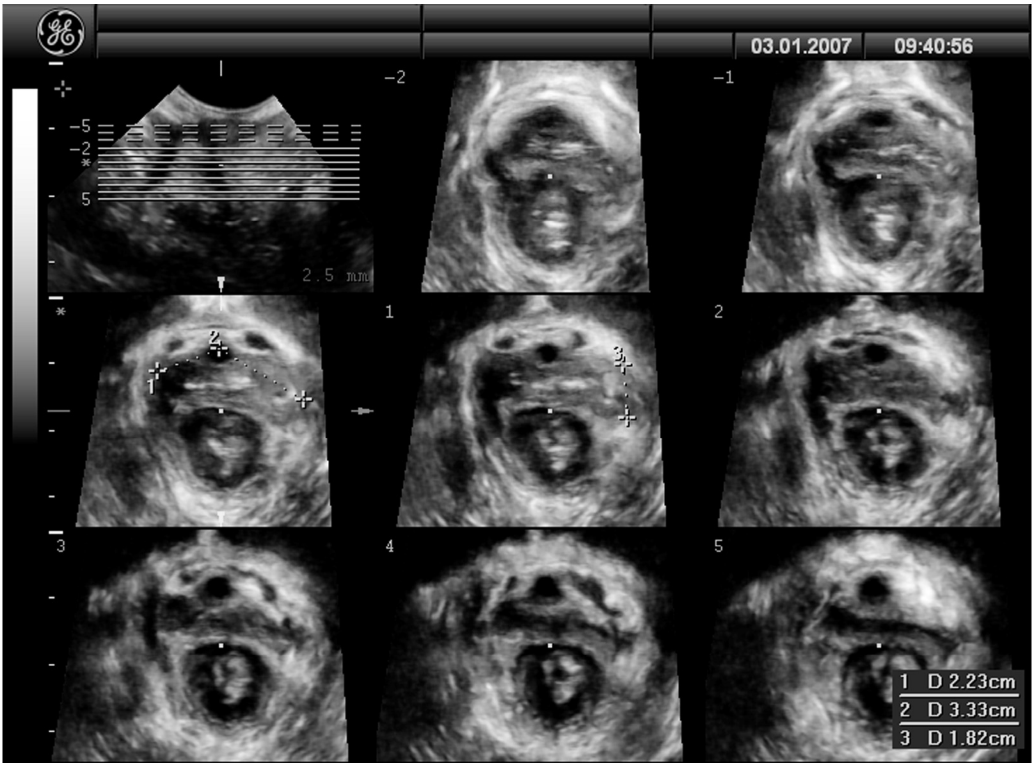


***Figure 13**: TUI imaging, with an obvious defect on the left (TUI score of 8), the width of the levator urethral gap is 2.23cm on the right and on the left 3.33cm. The depth of the defect is on the left is 1.82cm.*

In a volume on maximal levator contraction (at the level of minimal hiatal dimension) a set of 8 slices is obtained with an interslice interval of 2.5 mm, from 5 mm below to 12.5 mm above the hiatal plane. A score of 0 is used if there are no defects on either side and a total score of 16 indicates a complete bilateral avulsion [28]. The levator urethral gap, i.e., the distance between the central urethra and the insertion of the puborectalis, can be measured at the level of minimal hiatal dimension (0 level, is marked with a *) (Figure 13). A proposed cut-off of 25 mm can be used for the diagnosis of levator defects [29]. The width and the depth seems to be associated with symptoms and signs of prolapse, but not with stress urinary incontinence [28].

1.2.3 Levator hiatus

The levator hiatus is the area between the arms of the V of the puborectalis muscle and contains the urethra anteriorly, the vagina centrally and the anorectum posteriorly. For

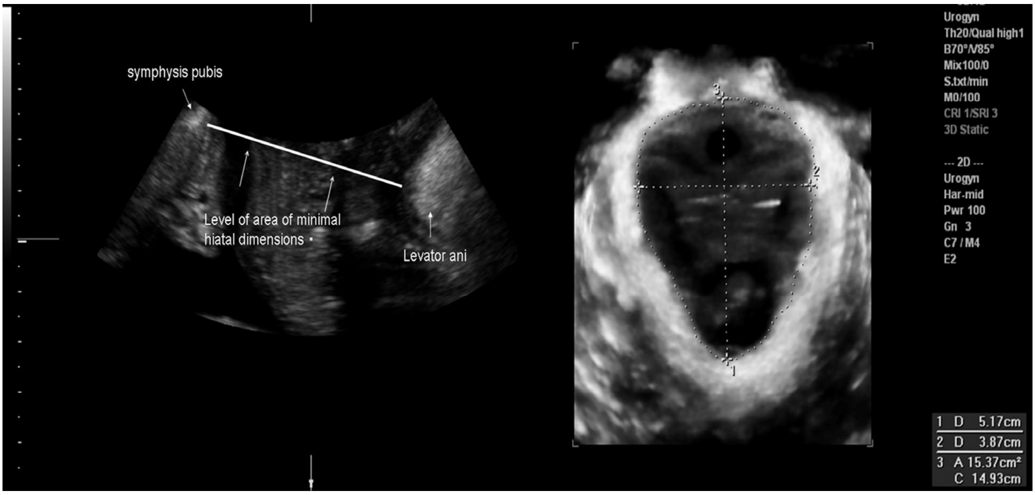


***Figure 14**: Measurements of a normal levator hiatus at the level of minimal hiatal dimension (left 2D and right 3D). Measurements 1 in 3D is the anteroposterior diameter (AP, 5.17 cm). measurement 2 is the coronal diameter (3.87cm) and 3 is the hiatal area (15.37 cm^2).*

identifying the area of minimal hiatal dimension, the minimal antero posterior (AP) diameter should be determined in the mid-sagittal image. The axial plane image is then utilized to obtain minimum Antero - Posterior and transverse Left - Right dimensions as well as the hiatal area of the levator (Figure 14) [9].

The area of the levator hiatus varies markedly. In a series of 52 nuliparous women (age 18 - 24) the mean hiatal area at rest was 11.25 (range 6.34 - 18.06) cm^2 increasing to a mean of 14.05 (6.67-35.01) cm^2 on Valsalva manoeuvre (P = 0.009). The levator area at rest correlated with the increase of the levator area at valsalva and with pelvic organ descent [30].

1.2.4 Anal Sphincter Imaging

Anal sphincter defects are associated with childbirth, aging and mode of delivery and can cause fecal incontinence [31, 32]. The anal sphincter is generally imaged by endo-anal ultrasound, using high –resolution 10 MHz 360˚ rotational probes inserted in the rectum. This method is firmly established as one of the cornerstones of a colorectal diagnostic workup for anal incontinence [33]. However this technique it is not widely available and invasive for the patient. Recent investigations have shown that transperineal imaging is a feasible and acceptable non invasive method for visualization of the anal sphincter complex with good repeatability [34-36]. An advantage of this method is that there is no distortion of the anal canal, and it is possible to perform a dynamic investigation. The technique used is the same as described above. Transducers include a high frequency transvaginal (2D or preferable 3D), a small parts high frequency 2D/3D probe or a paediatric convex array of 5-10 MHz. Using 3D volume acquisition allows the investigator to perform offline analysis and reduces operator dependence.

In 3D/4D transperineal imaging of the anal sphincter complex, the internal mucosa (M) is visualized as the 'mucosal star' created by the folds of the empty anal lumen. The internal anal sphincter complex (IAS) is visualized as a hypoechoic ring, the external sphincter complex (EAS) as an echogenic ring around the mucosa of the rectum [34] (Figure 15).

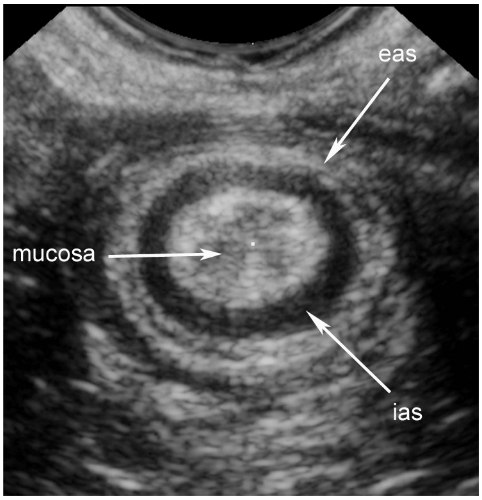


***Figure 15**: Normal anal sphincter: the outside hyperechoic ring is the external anal sphincter, the inside hypoechoic ring the internal anal sphincter and inside the mucosal star is visible.*

The multislice TUI technique, volume rendering and the VCI static technique have all been utilized for analyzing abnormalities of the anal sphincter [34, 35, 37]. Volume datasets can be rotated to a standard reproducible orientation; the preferred method is to have the cross-sectional transverse image in the A plane, both longitudinal in the B and Cl field of view [34]. Scrolling through the volumes in the axial plane from caudal to cranial, i.e from the anus to the level of the puborectalis sling, allows the investigator to evaluate the total length of the anal sphincter complex. It facilitates locating the extent of the defect. There is a clear difference in appearance of the sphincter at the level of the superficial external sphincter in comparison with the appearance at the level of the m. puborectalis [38] (Figure 16).

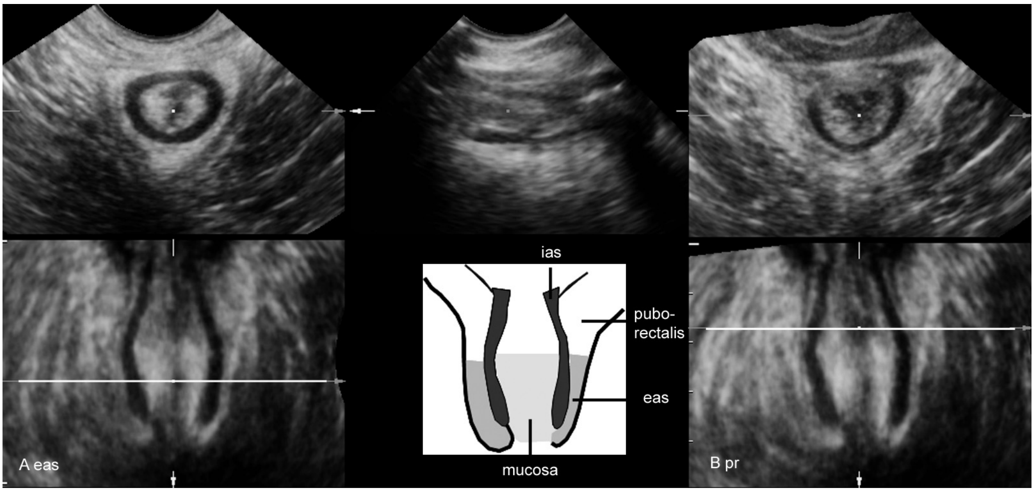


Figure 16: *Normal anal sphincter acquired with 3D VCI static imaging (2mm); A at the level of the external anal sphincter and in B at the level of the pubrectalis muscle.*

The ability to perform a dynamic assessment is of great advantage compared to endo-anal sphincter imaging. On contraction the length of the anal sphincter shortens and defects of the sphincter will become more obvious (Figure 17) [39].

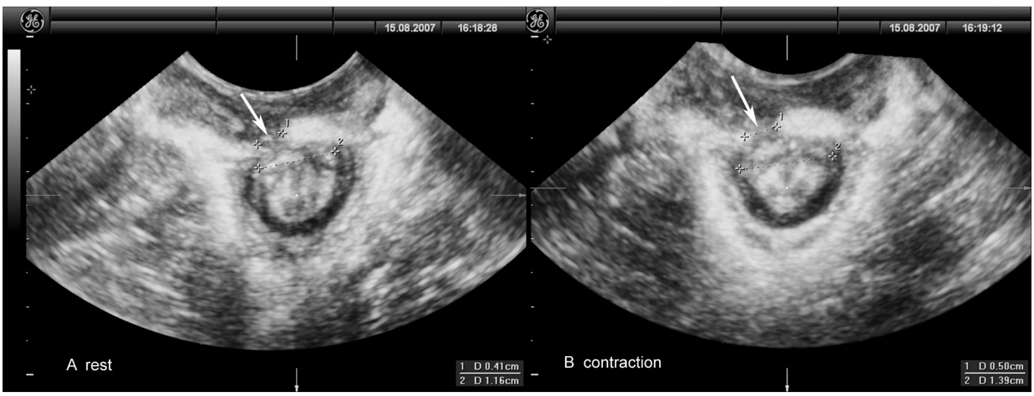


Figure 17: *EAS and IAS anal sphincter defect on the left in rest and on the right in contraction, width of the defect of the EAS in rest is 0.41 cm, and in contraction 0.58 cm, respectively for the IAS 1.16 and 1.39 cm.*

1.3 Outline of this thesis

Transperineal ultrasound provides a widely accessible non invasive investigation of the pelvic floor. It provides the opportunity to investigate normal or abnormal dynamic function and to detect anatomical abnormalities of the pelvic floor and correlate this findings with symptoms of pelvic floor dysfunction.

Chapter 2 will describe the different entities of anatomical abnormalities of the posterior compartment in symptomatic patients with a clinical rectocele investigated with transperineal ultrasound.

Chapter 3 investigates the level of agreement for detection posterior compartment disorders between evacuation defecography and transperineal ultrasound.

Chapter 4 describes the prevalence of levator abnormalities in symptomatic patients on ultrasonography.

Chapter 5 investigates the ''normal value" for levator hiatal area and the relationship with prolapse symptoms in symptomatic patients.

Chapter 6 prescribes the prevalence of levator abnormalities in patients with an underactive function as opposed to patients with an normal function and the relationship with faecal and stress incontinence.

Chapter 7 investigates the prevalence of anal sphincter defects and/or levator sphincter defects in patients with faecal incontinence.

Chapter 8 contains a general discussion.

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2

Posterior compartment prolapse on two-dimensional and three-dimensional pelvic floor ultrasound: the distinction between true rectocele, perineal hypermobility and enterocele

Ultrasound in Obstetrics and Gynecology 2005; 26: 73–77.

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Anneke. B. Steensma

Abstract

Objectives: Posterior compartment descent may encompass perineal hypermobility, isolated enterocele or a 'true' rectocele due to a rectovaginal septal defect. Our objective was to determine the prevalence of these conditions in a urogynaecological population.

Methods: One hundred and ninety-eight women were clinically evaluated for prolapse and examined by translabial ultrasound, supine and after voiding, using three-dimensional capable equipment with a 7–4-MHz volume transducer. Downwards displacement of rectocele or rectal ampulla was used to quantify posterior compartment prolapse. A rectovaginal septal defect was seen as a sharp discontinuity in the ventral anorectal muscularis.

Results: Clinically, a rectocele was diagnosed in 112 (56%) cases. Rectovaginal septal defects were observed sonographically in 78 (39%) women. There was a highly significant relationship between ultrasound and clinical grading ($P < 0.001$). Of 112 clinical rectoceles, 63 (56%) cases showed a fascial defect, eight (7%) showed perineal hypermobility without fascial defect, and in three (3%) cases there was an isolated enterocele. In 38 (34%) cases, no sonographic abnormality was detected. Neither position of the ampulla nor presence, width or depth of defects correlated with vaginal parity. In contrast, age showed a weak association with rectal descent ($r = -0.212$, $P = 0.003$), the presence of fascial defects ($P = 0.002$) and their depth ($P = 0.02$).

Conclusions: Rectovaginal septal defects are readily identified on translabial ultrasound as a herniation of rectal wall and contents into the vagina. Approximately one-third of clinical rectoceles do not show a sonographic defect, and the presence of a defect is associated with age, not parity.

Introduction

Rectocele is traditionally regarded as the archetypal traumatic pelvic floor lesion. It is assumed that fascial defects in the rectovaginal septum are the result of childbirth, occurring as the fetal head crowns [1–3]. This appears plausible since the levator hiatus has to distend from a resting area of 6–18 cm^2 in young nulligravid women [4] to an area of 70–90 cm^2 in order to admit passage of a term-sized fetal head. In this process, it is thought that the lateral insertion of the rectovaginal septum may be shorn off the puborectalis muscle, and that transverse tears open up in the septum itself during crowning, or that the septum is physically detached from the perineal body [1].

Rectocele does exist in nulliparous women however, and in these women it is attributed to longstanding abnormal defecation habits [3, 5]. There is little information on prevalence and etiology [3], the investigation of which is complicated by the fact that a clinically apparent rectocele may be due to perineal hypermobility or a true defect of the rectovaginal septum, and occasionally may even be due to an isolated enterocele [6]. While defecation proctography is regarded by some as the 'gold standard' in the diagnosis of rectocele [7], it is relatively costly, unpleasant and involves radiation exposure. Consequently, this diagnostic modality is rarely used by gynaecologists and urogynaecologists. There is a clear need for other, simpler diagnostic modalities [3]. Ultrasound can replace defecation proctography with little cost and minimal discomfort to the patient [8, 9], correlates well with this older technique [9] and delivers superior information on surrounding soft tissues at the same time [10]. The advent of three-dimensional (3D) ultrasound now means that fascial defects can be sought in all three primary planes (axial, sagittal and coronal), and that rendered volumes can graphically demonstrate the site and extent of fascial defects (Figure 1).

The objective of this study was to determine the prevalence of all potential causes of posterior compartment descent in a group of women seen with symptoms of pelvic floor dysfunction such as incontinence, voiding dysfunction and prolapse. In addition, the observed anatomical alterations were correlated with age and parity in an attempt to gain insights into etiology.

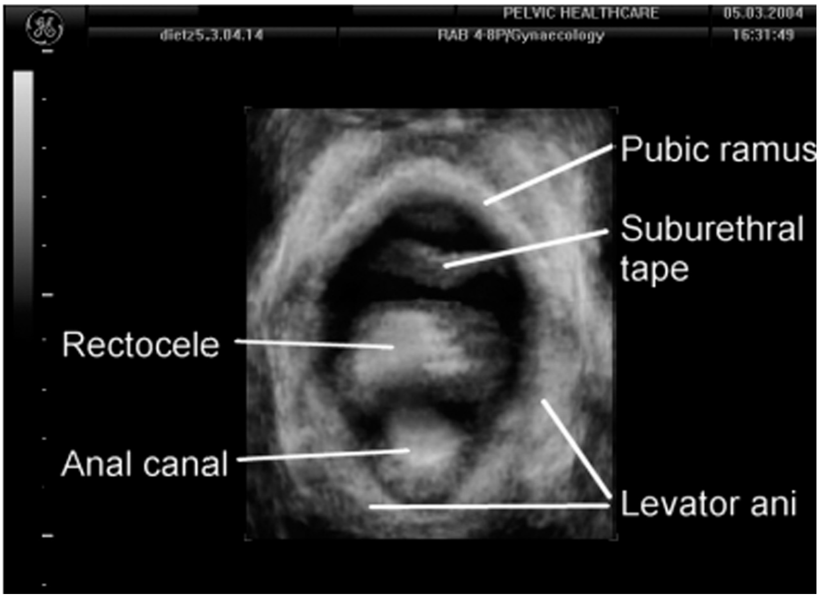

***Figure 1**: A translabial, three-dimensional ultrasound image (7–4-MHz volume transducer) of the pelvic floor showing a rectocele viewed from caudally, i.e. as if the patient was examined in lithotomy. The space of the levator hiatus is largely taken up by a third degree rectocele. There is also a suburethral tape anteriorly.*

Methods

Two hundred and seven women attending urogynaecological clinics for a first visit were evaluated for prolapse according to a modified Baden–Walker classification. They were then examined by translabial ultrasound, supine and after voiding, using 3D capable equipment (GE Kretz Voluson 730, GE Kretztechnik GMBH, Zipf, Austria and Medison SA8000, Medison, Seoul, South Korea) with a 7–4-MHz volume transducer. Volumes were obtained at rest, on levator contraction and on maximal Valsalva, with the effectiveness of manoeuvres assessed on two-dimensional (2D) imaging in the sagittal plane. The 3D ultrasound methodology used for this study has been described in greater detail in a recent review article [11]. Evaluation of volumes was later performed by the second author, blinded against all clinical data, with the help of specialized software (4D View, GE Kretztechnik GMBH, Zipf, Austria). Measurements obtained by analysis of volume ultrasound data have recently been shown to be comparable to those obtained on live examination [12].

Downwards displacement of a rectocele on Valsalva, or in its absence, of the rectal ampulla or its contents, was used to quantify posterior compartment prolapse. A defect of the rec-

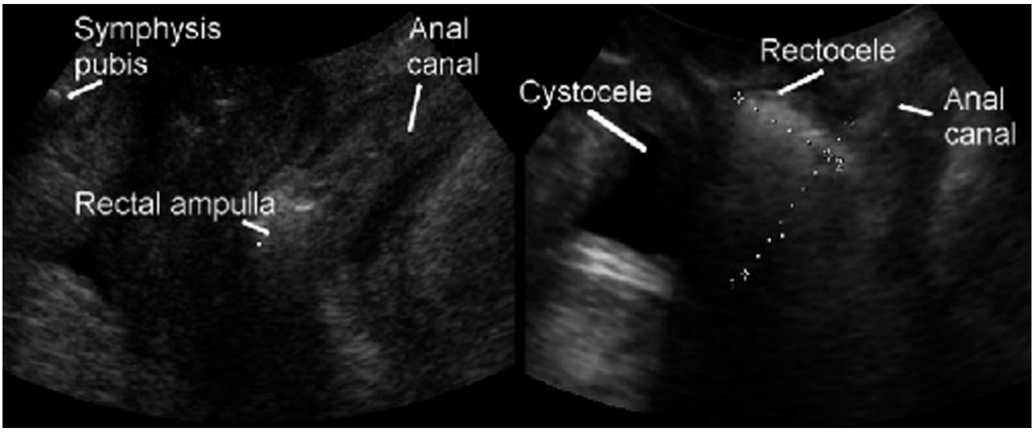

***Figure 2**: Quantification of a true rectocele on translabial ultrasound (mid-sagittal plane, with the transducer surface resting on the perineum). Measurements indicate width (3.3 cm) and depth (1.9 cm) of a true rectocele which is apparent as a discontinuity in the anorectal muscularis. Left image is at rest; right image is maximal Valsalva.*

tovaginal septum was rated present if there was a sharp discontinuity in the ventral contour of the anorectal muscularis, and if the resulting herniation measured ≥10 mm in depth (Figure 2). This low cut off was chosen due to the fact that many defects of the rectovaginal septum measure less than 20 mm in depth, the figure used for defecation proctography [13]. The measurement of rectocele depth on translabial ultrasound has been reported by others [8], is similar to techniques used on defecation proctography and correlates well with measurements obtained by that technique [9].

If there was displacement of ampullary contents (hyperechogenic stool or air) below a reference line through the inferior symphyseal margin without evidence of an actual fascial defect, this was defined as perineal hypermobility (Figure 3). Ampullary descent below the symphysis pubis has been shown to be associated with clinically evident pelvic organ descent [14]. The inferior margin of the symphysis pubis was chosen as reference rather than the central axis since the latter is often difficult to image in conjunction with a rectocele due to the limited footprint of most abdominal transducers, and since the central axis is frequently impossible to identify in postmenopausal women due to calcification of the interpubic disk [10]. If a herniation of abdominal contents developed anterior to the anterior anorectal muscularis and extended below the above-mentioned reference line, this was defined as an enterocele (Figure 4).

As all data in this study were obtained on routine urodynamic testing (which in our unit comprises 3D pelvic floor imaging), the project was deemed exempt from formal ethics

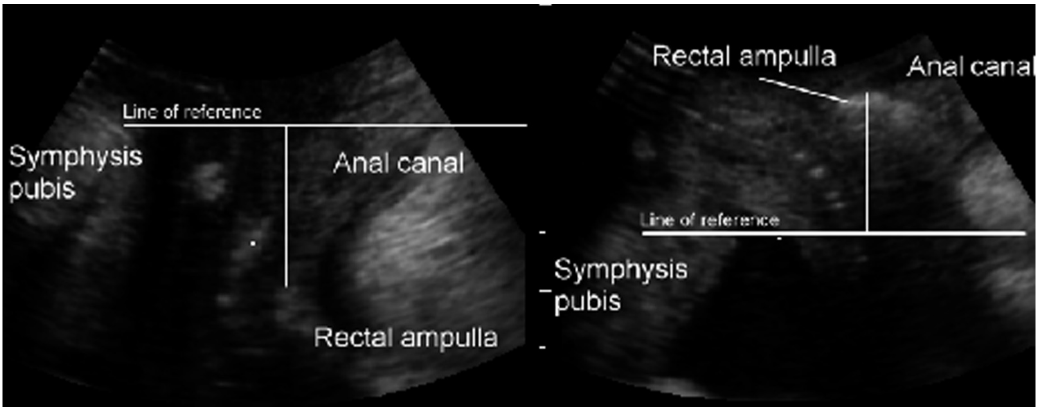

Figure 3*: Rectal and/or perineal hypermobility without true rectocele as imaged on translabial ultrasound. The line of reference signifies the level of the inferior margin of the symphysis pubis. There is descent of the rectal ampulla below this level, without formation of a herniation into the vagina, as there is no discontinuity of the anterior wall of the anorectum similar to that seen in Figure 2. The transducer has been pushed off the symphysis pubis by the posterior compartment descent. This is admissible and will not alter measurements as long as the transducer is not angled.*

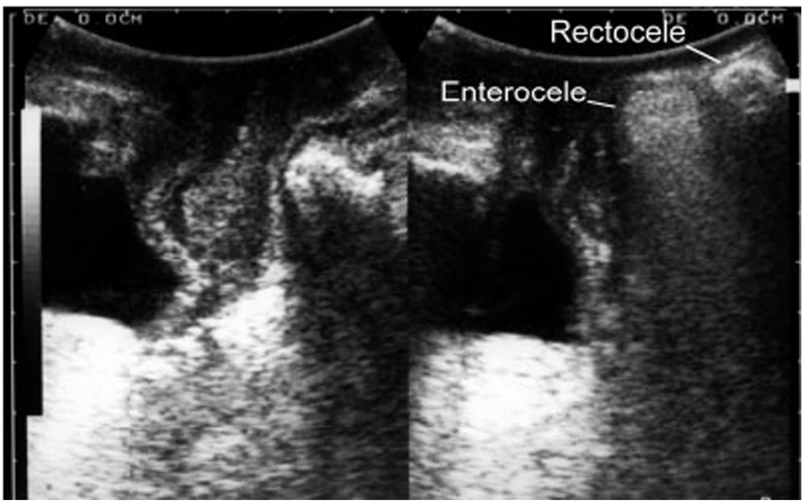

Figure 4*: Distinguishing enterocele and rectocele on translabial ultrasound (left image is at rest; right image is maximal Valsalva). It is evident that the contents of an enterocele appear generally more homogeneously iso- to hyperechogenic compared with a rectocele that is filled with stool and air, resulting in strong echoes with distal shadowing and occasionally reverberations.*

committee approval. Statistical analysis was performed after Normality testing (histogram analysis and/or Kolmogorov–Smirnov testing), using Minitab V13 (Minitab Inc, State College, PA, USA). Pearson's correlations were used to compare normally distributed continuous variables. Analysis of variance, Student's *t*-test and Chi-squared test statistics were also employed. $P < 0.05$ was considered statistically significant.

Results

Of 207 datasets, seven were excluded due to incomplete clinical data, and two could not be evaluated due to poor image quality. All data therefore refer to the remaining 198 patients. Mean age was 54 (range, 25–87) years. Median parity was 2 (range, 0–7). Clinically, a rectocele was diagnosed in 112 (56%) cases (Grade 1, n = 88; Grade 2, n = 22; Grade 3, n = 2).

A test-retest series conducted by both authors reviewing the volume datasets of 50 women, while blinded against clinical data and the other author's findings, yielded a Cohen's kappa of 0.72 for the diagnosis of a defect of the rectovaginal septum. The intraclass correlations between measurements of ampullary descent was 0.75, of rectocele depth 0.93 and of rectocele width 0.91.

The rectal ampulla descended on average to 5.3 mm above the symphysis pubis on Valsalva. True defects of the rectovaginal septum were observed sonographically in 78/198 (39%) women. These defects were 23 mm wide and 16 mm deep on average. Table 1 shows ultrasound data stratified for clinical rectocele grading. There was a statistically significant relationship between all ultrasound data and clinical assessment (all $P < 0.001$ on ANOVA).

In 16 (8%) women, we diagnosed an enterocele which was most often combined with a 'true rectocele' or fascial defect (n = 11). In four women, the enterocele was isolated, i.e. there was neither perineal hypermobility nor a true rectocele, and in one case the enterocele was so large as to preclude assessment of the anorectum altogether.

Women who had delivered vaginally were more likely to be diagnosed with a clinical rectocele ($P = 0.008$ on Chi-squared testing). However, neither position of the rectal ampulla on ultrasound, nor presence, width or depth of rectovaginal septal defects correlated with parity or vaginal childbirth. In contrast, the presence of a rectovaginal septal defect was associated with age (57.3 (SD 12.2) vs. 51.4 (SD 13.6) years; $P = 0.002$), as was the depth of fascial defects ($r = -0.258$, $P = 0.02$) and descent of the rectal ampulla ($r = -0.212$, $P = 0.003$). The

Table 1: *Clinical rectocele grading against sonographically determined position of rectal ampullary contents on Valsalva ('ampulla'), presence, width and depth of rectovaginal septal defects.*

Rectocele grade (n)	**Ampulla* (mm)**	**Defect (%)**	**Width (mm (range))**	**Depth (mm (range))**
0 (86)	13.5	15 (17)	18.3 (0–34)	13.9 (10–23)
I (88)	–0.2	48 (55)	21.8 (8–50)	15.6 (10–33)
II (22)	–3.7	13 (59)	28.4 (15–59)	19.9 (11–44)
III(2)	–6.7	2 (100)	49.8 (49)	29.6 (28–32)
P	<0.001	<0.001	<0.001	<0.001

**Measurements describe position relative to the inferior margin of the symphysis pubis, with negative numbers implying descent below this level. The P-values indicate highly significant relationships between clinical grading and ultrasound measurements with ANOVA and Chi-square tests.*

sonographic diagnosis of enterocele (n = 16) was associated with a history of hysterectomy (P = 0.02) and age (64.8 (SD 10.3) vs. 53 (SD 13.3) years; P < 0.001), but again there was no significant association with parity.

Of those 112 women who were clinically diagnosed with a rectocele, only 63 (56%) showed a true defect of the rectovaginal septum. In 38 (34%) women, no sonographic abnormality was detected, in eight (7%) there was perineal hypermobility without fascial defect, and in three (3%) we found an isolated enterocele.

Discussion

The current situation with regard to the diagnosis and treatment of 'rectocele', i.e. a protrusion of the posterior vaginal wall, is nothing short of confusing. Generally, gynaecologists rely on the clinical diagnosis of rectocele. Whilst some practitioners postulate the presence of a fascial defect [15], most techniques described for the repair of rectocele do not attempt to identify a defect and very likely fail to close such a defect when one is present. Hence, it is not surprising that even illustrations in major textbooks of vaginal surgery bear little resemblance to actual reality as documented on imaging [1].

Fortunately, the technical means for accurate diagnosis of posterior compartment prolapse are available in virtually all gynaecology departments in the developed world. The sonographic diagnosis of rectocele was first described more than 10 years ago [16], and it has been known for a number of years that translabial ultrasound can distinguish between rectocele and enterocele [14]. Over the last few years, colorectal investigators have begun to realize the potential of this simple technique in the investigation of anorectal disorders [8,9]. Most recently, it has become clear that translabial ultrasound can define the presence and extent of a defect of the rectovaginal septum, and that such defects are not uncommon even in young nulliparous women [17].

True defects of the rectovaginal septum can be identified in the mid-sagittal plane as herniations of the rectal wall and contents into the vagina at the level of the anorectal junction. A test-retest series conducted by the two authors showed very good repeatability, with most disagreements in results due to findings close to our arbitrarily defined cut-off of 10 mm. Because a very small defect of a depth of 9 mm will not be rated as a defect, but one measured at 10 mm will be, such discrepancies are not surprising.

The depth and width of a herniation can be determined on maximal Valsalva, and the repeatability of this measurement in this series was very high, with intraclass correlation coefficients (ICCs) of over 0.9 determined in a blinded test-retest series. The measurement of downwards displacement of the rectal ampulla also seems highly reproducible, with an ICC of 0.75. However, it is recognized that bowel filling and stool consistency may alter appearances, and in order to define the magnitude of this confounder further test-retest studies may be necessary. Another confounder is transducer displacement with higher degrees of prolapse. Clearly, any ultrasound method of prolapse assessment is of limited usefulness in assessing the precise extent of third degree anterior, central or posterior compartment descent, total vault eversion or procidentia [10]. However, even if there is major prolapse, one can often observe the development of a fascial defect at lower Valsalva pressures before it becomes obscured by artifact.

Rendered volumes at the level of the levator hiatus, i.e. in the axial plane, can show the total extent of the defect and demonstrate asymmetries, which incidentally, seem rather uncommon. Downwards displacement of the rectal ampulla without actual development of a herniation can be diagnosed as rectal or perineal hypermobility (Figure 3), and an enterocele is clearly evident as a downwards herniation of (usually iso- to hyperechogenic) abdominal contents anterior to the anorectal junction (Figure 4).

Defects of the rectovaginal septum are common. In this group of 198 women seen for urodynamic assessment, defects of 10 mm or more in depth were observed in 39% of cases. This compares with data obtained by radiological means [5–7], and is in contrast to a recently determined prevalence of 12% in young nulliparae [17]. However, it is rather surprising that in this series, all ultrasound measures of posterior compartment descent and presence/depth of a true rectocele correlated weakly with age, not parity. It appears likely that childbirth plays less of a role in the pathogenesis of rectocele than previously assumed. From the ultrasound data presented here and elsewhere [16], one can hypothesize that defects of the rectovaginal septum may be congenital or acquired over long periods of time, rather than caused by the single event of traumatic childbirth. This also raises interesting questions for other forms of female pelvic organ prolapse – although the situation for cystocele or uterine prolapse may well be much more complex than in the case of the 'true rectocele'.

As regards the clinical finding of posterior vaginal wall descent, our results show that very different entities may cause the impression of a rectocele. Whilst the most common ultrasound finding was a defect of the rectovaginal septum (56%), in about one-third of patients, no significant downwards displacement of rectal ampulla or pouch of Douglas was observed. In many women, the appearance of a rectocele may be due to perineal deficiency rather than abnormalities of the anorectum, a so-called 'pseudorectocele'1. Less frequently, we observed downwards displacement of the rectum without fascial defects (perineal or rectal hypermobility; 7%) and an isolated enterocele (3%) as the sonographic correlation of a clinical diagnosis of rectocele. Overall, it is evident that the clinical diagnosis of posterior compartment descent may encompass a number of different conditions, a finding that strongly supports the use of preoperative diagnostic imaging.

Clearly, if a clinical 'rectocele' can be due to at least four different anatomical situations in any particular patient, then one ought to individualize treatment according to the anatomical situation. A defect of the rectovaginal septum should be closed, an enterocele opened and ligated. Perineal hypermobility is most likely to respond (if at all) to a levatorplasty, and a deficient perineum requires a perineoplasty. It has to be acknowledged, however, that the clinical relevance of any new diagnostic method has to be shown in intervention trials. In the case of ultrasound for posterior compartment descent, this would require a randomized controlled trial to test the effect of preoperative ultrasound for surgical planning on functional and anatomical cure rates.

In conclusion, translabial ultrasound can distinguish between different forms of posterior compartment prolapse. The technique will likely assist the further research into pathophysiology and treatment of this condition, and help in the clinical management of posterior compartment prolapse. The etiology of defects of the rectovaginal septum, hitherto assumed to be due to intrapartal trauma, may have to be re-examined.

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3

Assessment of Posterior Compartment Prolapse; a Comparison of Evacuation Proctography and 3D Transperineal Ultrasound

Colorectal Disease 2009; in press.

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Abstract

Introduction: Evacuation proctography (EP) is considered to be the gold standard investigation for objective diagnosis of posterior compartment prolapse. With 3D transperineal ultrasound (3DTPUS) imaging of the pelvic floor it is possible to perform a non-invasive investigation for detection of pelvic floor abnormalities. This study was designed to assess the level of agreement between EP and 3DTPUS in diagnosing posterior compartment prolapse.

Methods: In a prospective observational study patients with symptoms related to posterior compartment prolapse were seen for standardized interview, clinical examination, 3DTPUS, as well as for an EP. Both exams were analysed offline and separately by two experienced investigators, blinded against the clinical data and against the results of the other imaging technique. After the examinations, all patients received a standardized questionnaire concerning subjective patients' experience.

Results: Between 2005 and 2007 75 patients were included with a median age of 59 years (range 22 - 83). Regarding enteroceles a good Cohen's kappa index was found (k = 0.65), for rectoceles the level of correlation was moderate (k = 0.55). For the detection of intussusception the level of correlation was fair (k = 0.21). The majority (87%) of patients indicated EP as less well-tolerated exam. EP caused significant more discomfort than 3D ultrasound.

Conclusion: This study showed moderate to good agreement between 3DTPUS and EP for detecting enterocele and rectocele. Based on these data and patient friendly characteristics, we suggest considering 3DTPUS as the first diagnostic tool for investigation of patients with symptoms related to posterior compartment prolapse.

Introduction

Patients complaining of pelvic organ prolapse symptoms will be referred to an uro- gynaecologist or colorectal surgeon for investigation and treatment. For the classification of pelvic organ prolapse a subdivision into 3 pelvic compartments is utilized; the anterior, middle, and posterior compartment. Different symptoms are commonly contributed to prolapses of those 3 pelvic compartments. Voiding dysfunction and urinary incontinence are commonly related to prolapse of the anterior compartment [1]. Pelvic discomfort, such as feelings of a lump, heaviness and pelvic pressure, is attributed to all pelvic compartments. Symptoms related to defaecatory dysfunction, including obstructed defaecation and faecal incontinence, have been correlated with the posterior compartment [2-4]. It is of importance, to be able to differentiate between different anatomic abnormalities, especially with regards to the surgical intervention needed for treatment of the patient.

Evacuation proctography, with opacification of the small bowel and vagina, has been claimed to be the gold standard investigation for objective diagnosis of posterior compartment prolapse. Evacuation proctography is relatively invasive, uncomfortable for the patient and requires exposure to ionizing radiation. Furthermore, this technique, without opacification of the bladder, lacks the ability to visualize the anterior and central compartment.

Recently, more advanced imaging techniques, such as dynamic MRI and 3D ultrasound, are reported [5, 6]. These examinations are able to demonstrate all 3 pelvic compartments. Furthermore, these examinations are less invasive and ionizing radiation exposure is not required. However, dynamic MRI, especially open-architecture MRI, is very expensive and not generally available. 3D transperineal ultrasound enables dynamic investigation of all 3 pelvic compartments, at low cost. Dietz et al. [6, 7] reported that 3D transperineal ultrasound can differentiate between different forms of posterior anatomic abnormalities, i.e. rectocele and enterocele. Until now, 4 studies [8-11] have been published to assess the level of agreement between evacuation proctography and transperineal ultrasound, however patient groups are small in most of these studies. Another drawback of these studies is the selected group of studied patients, with almost all patients having a history of longstanding obstructed defaecation.

The current study was designed to assess the level of agreement between evacuation proctography and 3D transperineal ultrasound in diagnosing posterior compartment prolapse in patients with related symptoms.

Patients and methods

All women with symptoms related to posterior compartment prolapse, referred to our tertiary pelvic floor unit, were included in this prospective observational study. All patients were interviewed using a standardized questionnaire, concerning medical history, urinary function, pelvic discomfort and bowel function. A clinical examination was performed according to the International Continence Society guidelines, using the POP-Q system [12]. All patients underwent standardized evacuation proctography, as well as dynamic 3D transperineal ultrasound, with a maximum interval of 6 months. After both examinations all patients received a standardized questionnaire concerning subjective patients' experience. Written informed consent was obtained from all participants. This study was approved by the hospital's human research ethics committee (MEC-2006-345).

Evacuation proctography was performed by a standardized technique with opacification of the rectosigmoid, small bowel and vagina, using liquid barium contrast. Imaging was acquired at rest, during pelvic floor contraction and during straining, and a video recording was obtained during evacuation of contrast. Quantitative measurements were made for comparison with 3D transperineal ultrasound. Enterocele was described as a herniation of small bowel or rectosigmoid into the vagina. Rectocele was defined as a herniation of the anterior rectal wall into the lumen of the vagina and intussusception was defined as an infolding of the rectal wall into the rectum or anus, when an external component was present

Table 1: *Grading system for enterocele, rectocele and intussusception.*

Prolapse	Description
Enterocele	
Grade 1	Most distal part descending into upper 1/3 of the vagina
Grade 2	Most distal part descending into middle 1/3 of the vagina
Grade 3	Most distal part descending into lower 1/3 of the vagina
Rectocele	
Grade 1	Depth < 2 centimeters
Grade 2	Depth 2 – 4 centimeters
Grade 3	Depth > 4 centimeters
Intussusception	
Grade 1	Most distal part remains completely intrarectal
Grade 2	Most distal part descending into anal canal

it was called complete rectal prolapse. Enterocele, rectocele and intussusception were classified into grades, see table 1 [13, 14]. Rectocele depth was measured perpendicular to the expected contour of the anterior rectal wall in a lateral projection. All video files were analyzed by one colorectal surgeon (WRS), blinded against all clinical data and the results of the 3D transperineal ultrasound (Figure 1).

3D transperineal ultrasound was performed using a GE Kretz Voluson 730 expert system (GE Healthcare, clinical systems, Hoevelaken, the Netherlands), using an abdominal 4-8 MHz probe. Patients were examined after voiding and in supine position. 2D cine loop vol-

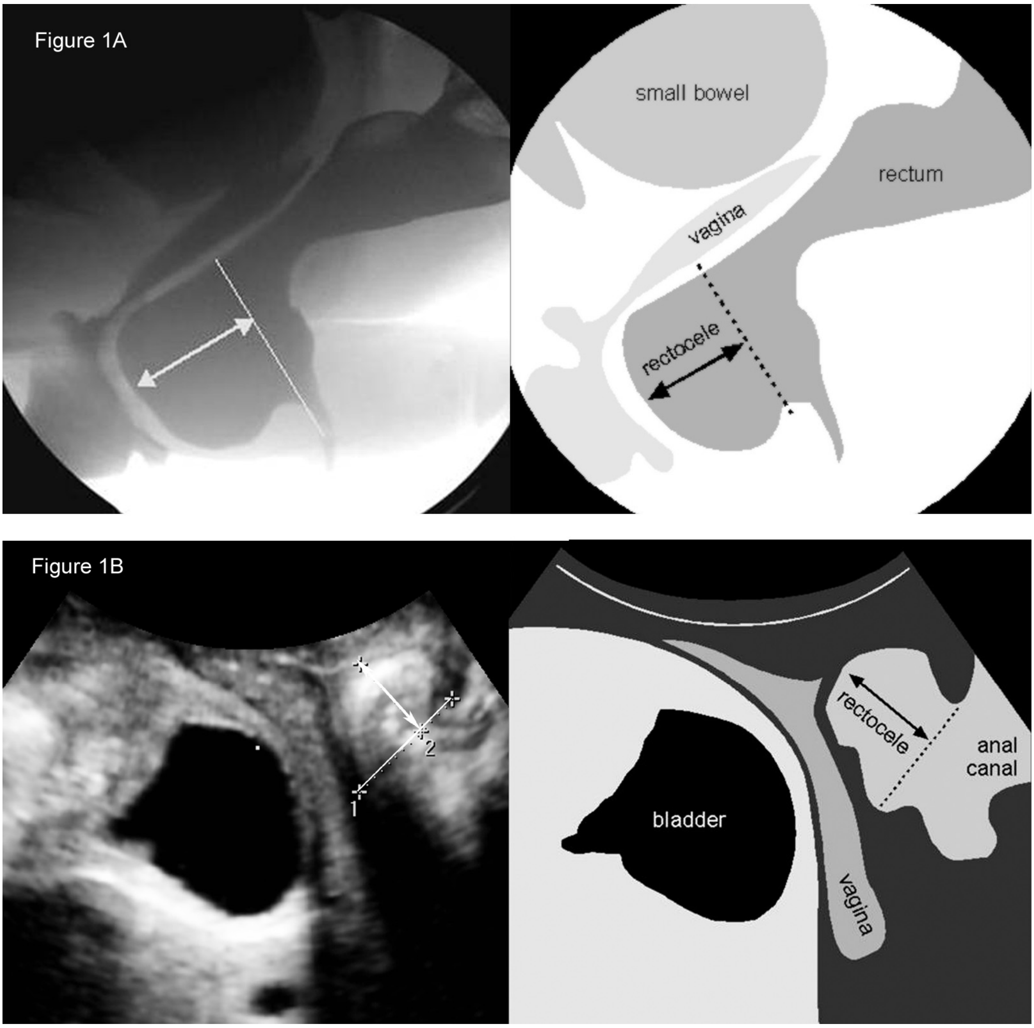

***Figure 1**: Rectocele, as demonstrated by evacuation proctography (Figure 1a) and transperineal ultrasound (Figure 1b). Arrow indicates rectocele depth.*

umes (3D) were obtained at rest, during levator contraction and during maximal Valsalva's manoeuvre as previously described by Dietz *et al.* [6, 7]. Off line evaluation of the cine loop volumes was performed by one gynaecologist (ABS), blinded against all clinical data and the results of evacuation proctography, using 4D view software (GE Healthcare). Enterocele was diagnosed if a herniation of abdominal contents developed anterior to the anorectal junction and extended into the vagina. Rectocele was defined as a defect in the rectovaginal septum. This defect was seen as a sharp discontinuity in the ventral contour of the anorectal muscularis, which resulted in a herniation of ≥ 10 mm in depth [7].

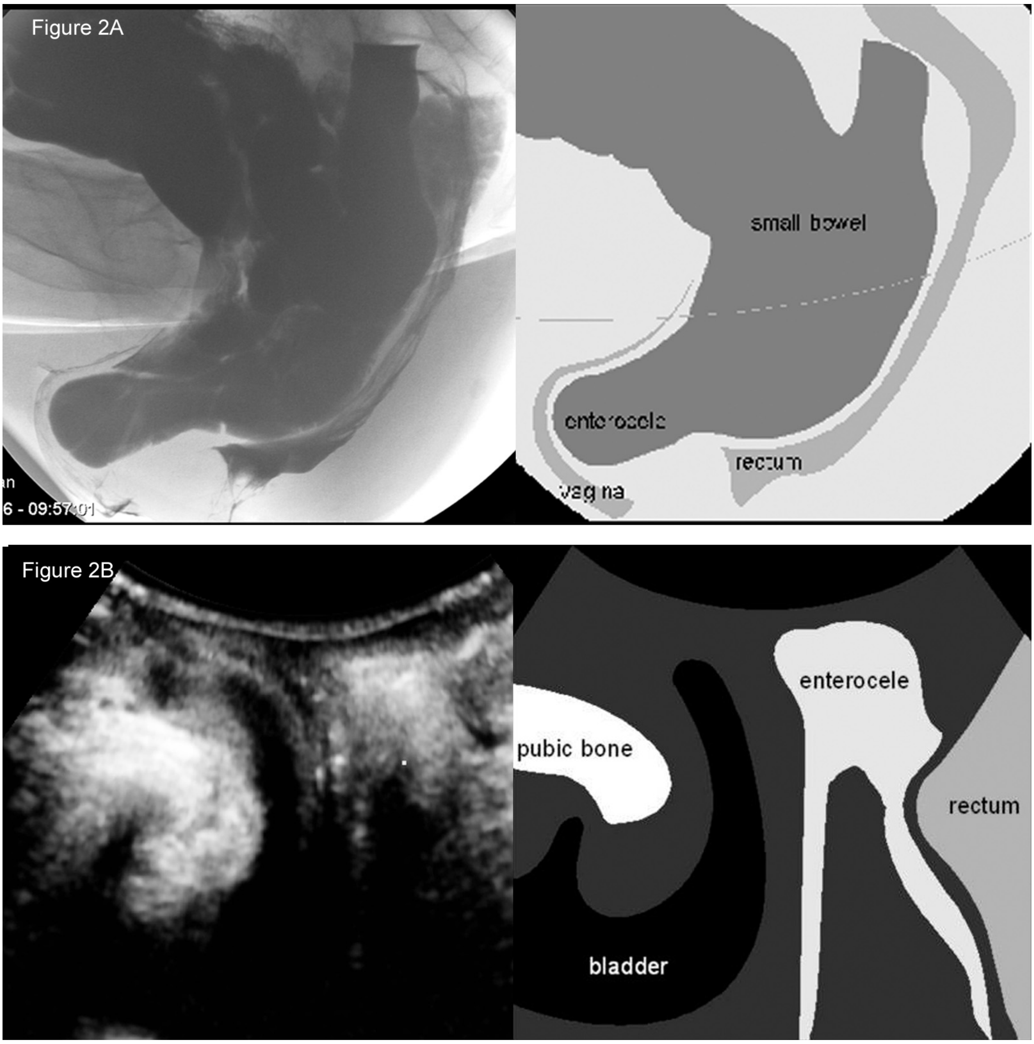

***Figure 2**: Enterocele, as demonstrated by evacuation proctography (Figure 2a) and transperineal ultrasound (Figure 2b).*

Measurement of rectocele depth was performed similar to the technique as described by evacuation proctography. Intussusception and complete rectal prolapse were identified similar as with evacuation proctography. Enterocele, rectocele and intussusception were graded in concordance with table 1. In addition, abnormalities of the anterior and central prolapse were described [6].

After both examinations all patients received a written standardized questionnaire about patient's expectations, inconvenience, and discomfort concerning both imaging techniques. Patients were asked to rate their discomfort on a visual analogue scale (VAS), 0 meaning no discomfort at all, and 10 meaning severely uncomfortable.

Statistical analysis was performed using the SPSS software package (14.0 version, SPSS Inc., Chicago, IL, USA). The Cohen's kappa coefficient index was obtained to compare evacuation proctography and 3D transperineal ultrasound in the detection of enterocele, rectocele and intussusception (Table 2). Spearman's correlation coefficient was used to calculate the level of correlation between mean rectocele depths. To compare questionnaires, chi-squared test was used. Wilcoxon signed ranks test was used for comparing VAS scores. Results were considered statistically significant when $p \le 0.05$ (two-sided). Evacuation proctography was considered as the gold standard investigation to calculate the sensitivities and specificities for detection of different prolapses with 3D transperineal ultrasound.

Table 2: *Cohen's kappa coefficient index*

Agreement	**Value**
poor agreement	≤ 0.20
fair agreement	0.21 - 0.40
moderate agreement	0.41 - 0.60
good agreement	0.61 - 0.80
excellent agreement	0.81 - 1.00

Results

Between September 2005 and July 2007, 75 women referred to our tertiary pelvic floor unit with symptoms related to posterior compartment prolapse were included in this prospec-

***Table 3**: Symptoms as reported by patients, n = 75*

Symptom	n	%
Stress urinary incontinence	38	51
Urge urinary incontinence	25	33
Pelvic discomfort	50	67
Obstructed defaecation	36	48
Faecal incontinence	26	35

tive study. These symptoms included pelvic discomfort, obstructed defaecation, and faecal incontinence or a combination of these symptoms. The median age of these women was 59 years (range: 22 to 83 years). Patients' history revealed a previous hysterectomy in 31 women (41%) and prior pelvic organ prolapse repair in 37 patients (49%). Median vaginal parity was 2 (range: 0 – 10 vaginal deliveries); there were 4 nulliparous women. Patients' symptoms are described in table 3.

Concerning the posterior compartment, clinical examination showed absence of prolapse in 16 patients (21%), stage 1 prolapse in 27 patients (36%), stage 2 in 21 patients (28%) and stage 3 in 11 patients (15%). Evacuation proctography revealed in 7 out of the 16 patients in whom no prolapse was found during clinical examination (stage 0) some form of posterior compartment prolapse (44%). 3D ultrasound revealed some form of prolapse in 6 of these patients (38%). The clinical diagnose of posterior compartment prolapse, patients with stage 1 to 3, was confirmed by evacuation proctography and 3D ultrasound in 83 and 81% respectively.

Evacuation proctography revealed an enterocele in 25 of the patients (33 %), rectocele in 36 (48%) and intussusception in 27 patients (36%). In 25 patients a second, concomitant form of posterior compartment prolapse was found. 3D transperineal ultrasound showed an enterocele in 18 of the patients (24%), rectocele in 37 (49%) and intussusception in 11 % (n=8). A second, concomitant form of posterior compartment prolapse was found in 24 patients. Furthermore, 3D ultrasound revealed in 23 patients some type of (concomitant) prolapse of the anterior or central compartment, which could not be detected with evacuation proctography (31%). Neither examination revealed any complete rectal prolapses.

Comparing both methods (Table 4), a Cohen's kappa coefficient index of 0.65 was found for diagnosing all enteroceles (grade 1,2,3). It appeared that small, grade 1 enteroceles were not adequately detected with 3D ultrasound. Of the nine grade 1 enteroceles detected by evacuation proctography, seven were not detected by ultrasound (78%). However, only two

***Table 4**: Findings of 3D transperineal ultrasound in comparison with evacuation proctography in diagnosing posterior compartment prolapse.*

	Evacuation proctography (n)		**Kappa value**
3D transperineal ultrasound	**yes**	**no**	**k**
Enterocele			
Yes	16	2	0.65
No	10	48	
Rectocele			
Yes	28	9	0.55
No	8	30	
Intussusception			
Yes	6	2	0.21
No	21	46	

out of 16 grade 2 and 3 enteroceles detected with evacuation proctography were not detected with transperineal ultrasound, resulting in a Cohen's kappa value of 0.77 for detection of grade 2 and 3 enteroceles. Furthermore, 3D ultrasound revealed an enterocele in two other patients, which were not diagnosed by evacuation proctography. Overall, we found a sensitivity of 64 % and a specificity of 96 % for the detection of all enteroceles with 3D ultrasound.

A Cohen's kappa coefficient of 0.55 was found for detection of rectocele. The mean rectocele depth was 2,82 centimetres at evacuation proctography and 2,32 centimetres with ultrasound, resulting in a level of correlation of $r = 0.47$ ($p < 0,05$). Eight rectoceles detected at evacuation proctography were not detected by ultrasound, however nine rectoceles detected by ultrasound were not found by evacuation proctography. Of all grade 2 and 3 rectoceles, 87% was confirmed with 3D ultrasound, whereas only 25% of all grade 1 rectoceles was confirmed with ultrasound. Disregarding grade 1 rectoceles, a Cohen's kappa index of 0,60 was found. The sensitivity and specificity of diagnosing rectocele with 3D ultrasound in general was respectively 78 % and 77 %.

For the detection of intussusception a Cohen's kappa index of 0.21 was found. No differences could be found in the detection of grade 1 and grade 2 intussusceptions. Overall, the detection rate of intussusceptions with 3D ultrasound was low, 21 of the 27 intussusceptions (78 %) detected with evacuation proctography were not confirmed with 3D ultrasound. The sensitivity and specificity of diagnosing intussusception with transperineal ultrasound were 22 % and 96 % respectively.

Questionnaire

Sixty-four patients responded to the questionnaire (85 %). Evacuation proctography caused significantly more discomfort for the patients ($p < 0.001$). VAS scores concerning discomfort for evacuation proctography were rated at median 4,0 / 10 (range: 0 – 10), whereas VAS scores for 3D ultrasound were rated at median 1.0 / 10 (range: 0 – 9). Evacuation proctography was indicated as a less tolerated exam in regards to 3D transperineal ultrasound in 87% of the patients, for 8% the 3D transperineal ultrasound was less tolerated ($p < 0.001$). Significant more patients preferred to have a repeat ultrasound as compared to evacuation proctography ($p < 0.003$).

Discussion

This study showed good agreement between 3D transperineal ultrasound and evacuation proctography for diagnosing enterocele, moderate agreement for diagnosing rectocele and fair agreement for detecting intussusception.

The absence of a real gold standard against which to compare these results is a major problem in the assessment of the differences between 3D transperineal ultrasound and evacuation proctography. Different levels of agreement have been reported for evacuation proctography. Poor inter-observer reliability has been reported [15], on the other hand, other authors found good inter-observer agreements for this imaging technique [16, 17]. Regarding 3D transperineal ultrasound, Dietz and Steensma recently showed good repeatability for detection of rectoceles in a test-retest series [7]. However, further data about inter-observer reliability of 3D ultrasound is lacking. Further research should reveal whether the differences found in the present study implies under- or over-diagnosis by one of the imaging techniques.

Our findings for diagnosing enteroceles are comparable with the results recently reported by other authors (Table 5). Regarding detection of rectocele and intussusception varying Cohen's kappa values, both lower and higher levels of agreement, are reported. These differences may be explained by the use of rectal contrast media during transperineal ultrasound by some authors. Beer-Gabel *et al.* performed transperineal ultrasound after injection of ultrasound contrast medium into the rectum and reported higher levels of agreement for the detection of rectocele and intussusception [8, 10]. Another possible explanation may be the selected group of patients used in almost all studies, which results in selec-

Table 5: *Overview of literature*

Author	Year	n	Enterocele (k)	Rectocele (k)	Intussusception (k)
Beer-Gabel *et al.* [8]	2004	33	0.7	0.88	0.88
Grasso *et al.* [9]	2007	43	-	0.41	0.91
Beer-Gabel *et al.* [10]	2008	62	0.78	0.78	-
Perniola *et al.* [11]	2008	37	-	0.26	0.09
This study	2008	75	0.65	0.55	0.21

k = Cohen's kappa coefficient index

tion bias. In 3 studies only patients with longstanding complaints of obstructed were included [8, 10, 11], whereas in another study only patients without prior history of pelvic organ prolapse were included [9]. Our study is the first one to include all patients with posterior compartment prolapse symptoms.

It seems that enteroceles and rectoceles were in a more advanced stage when detected with 3D ultrasound than with evacuation proctography. These findings are in concordance with those recently reported by others [9]. Possibly, this can be explained by the supine position during the ultrasound examination in contrast with the sitting position during evacuation proctography. It is conceivable, that this non-physiologic supine position will lead to under diagnosis of prolapses. Evacuation proctography seems more physiologic; the patient is asked to sit on a special seat and is asked to defaecate. However, patient's can feel embarrassed to defaecate in this "public" situation and therefore cooperation is also required for this type of examination [18]. Furthermore, evacuation proctography is unlikely to produce complete physiological defaecation because of the lack of real urge to defaecate and the non-physiologic liquid substance of the barium contrast. In addition, it is suggested that evacuation proctography can result in over-diagnosis of posterior compartment prolapse. For example, rectoceles smaller than 2 cm have been widely reported with evacuation proctography in asymptomatic females [19]. Therefore, the question rises whether under-diagnosis of grade 1 rectoceles and grade 1 enteroceles with 3D ultrasound implies important clinical consequences. In our opinion, these grade 1 rectoceles and enteroceles are often asymptomatic, and therefore they do not require treatment.

The majority of intussusceptions found with evacuation proctography were not adequately detected with 3D ultrasound. Doubt has risen about the clinical significance and required treatment for this anatomic abnormality. Rectal intussusception has been reported in up to 50 percent of normal volunteers [19]. Furthermore, a recent study showed that evacuation parameters fall within the normal range in the majority of patients and that obstructed defaecation do not imply proctographic evidence of occlusion [20].

Retrospective evaluation of those enteroceles that were missed with ultrasound (n=2) revealed that 1 patient did not perform an adequate Valsalva's manoeuvre during the exam and that the other patient had a severe uterine prolapse, which could be reasons for missing the enterocele. Both patients in whom an enterocele was "missed" with evacuation proctography showed an intussusception on evacuation proctography, which was probably seen as an enterocele on 3D transperineal ultrasound. An adequately performed Valsalva's manoeuvre is essential for the right interpretation. An inadequately performed Valsalva's manoeuvre can be an important cause of under-diagnoses of abnormalities with both examinations.

A major advantage of 3D ultrasound in comparison with evacuation proctography is the prevention of the use of ionizing radiation. Goei and Kemerink reported a mean effective radiation dose of 4,9 mSv for women during evacuation proctography [21]. To compare, a single chest X-ray results in an organ dose of 0.01 mSv and an abdominal CT scan results in 10mSv. Although a radiation dose of 4.9 mSv is indicated as considerable, but not extreme high, prevention of exposure to ionizing radiation is preferable, especially in young female patients of reproductive age.

3D transperineal ultrasound revealed (concomitant) pathology in the anterior and central compartment in 31% of the patients. Evacuation proctography, as performed in the present study, lacks the ability of visualization of those 2 compartments. Evacuation proctography can be supplemented by opacification of the bladder, so called colpo-cysto-defaecography, to include imaging of the anterior compartment. However, this procedure is even more invasive, poorly tolerated by the patients and requires an additional radiation dose.

Another advantage of 3D ultrasound is the patient friendly character of this imaging technique, as shown in this present study. The majority of patients indicated 3D transperineal ultrasound as the less unpleasant examination. No endovaginal or endoanal contrast is used and no evacuation of this contrast is warranted for imaging of posterior compartment prolapse.

In recent years, other techniques, such as MRI and MR defaecography, have been used for the detection of anatomic abnormalities in patients with pelvic organ prolapse. MRI provides a good and direct demonstration of all three compartments and does also not involve the use of ionizing radiation [22]. Furthermore, MRI is capable of visualizing the soft tissues and the levator ani muscle similar to 3D ultrasound, whereas with evacuation proctography (without opacification of the bladder) no information on the anterior compartment will be obtained at all. A drawback of dynamic MRI is the lateral or supine position of the patient during the examination, which is demonstrated not as accurate as evacuation proctography [23]. MR defaecography can be performed with the patient in the physiological sitting position, however this examination requires an open configuration technique, which is very expensive and not generally available [24]. Furthermore, to date standardized reference points and normal values for pelvic dynamic MRI or MR defaecography are lacking [25]. Compared with MRI, 3D ultrasound offers a less expensive investigation, ensures an optimal Valsalva's manoeuvre and is therefore easier to control for confounders.

In conclusion, this study showed good agreement for detection of clinical relevant enteroceles and rectoceles. A fair agreement was found for detection of intussusception, however the clinical relevance of this incomplete rectal prolapse is unknown. Besides this, 3D transperineal ultrasound is significantly better tolerated by patients. Therefore, 3D transperineal ultrasound could be considered as alternative to evacuation proctography in clinically relevant posterior compartment prolapse and may be used as first diagnostic tool for of symptomatic patients. However, further examination is required when a discrepancy between symptoms, clinical findings and 3D transperineal ultrasound is found.

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4

The prevalence of major abnormalities of the levator ani in urogynaecological patients

BJOG 2006; 113:225–230.

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Abstract

Objectives: While morphological abnormalities of the pubovisceral muscle have been described on magnetic resonance imaging (MRI), their relevance remains unclear. This study was designed to define prevalence and clinical significance of such abnormalities in urogynaecological patients.

Design: Prospective observational study.

Setting: Tertiary urogynaecological clinic.

Population: Three hundred and thirty-eight consecutive women referred for urodynamic assessment.

Methods: Participants underwent a clinical assessment, multichannel urodynamics and imaging with 3D translabial ultrasound. Blinded offline analysis was performed with the software 4D View (GE Kretztechnik, Zipf, Austria). Main outcome measures Major morphological abnormalities of the pubovisceral muscle.

Results: Defects of the pubovisceral muscle were found in 15.4% of parous women. They were exclusively anteromedial (uni- or bilateral), only occurred among women who had delivered vaginally and were associated with anterior and central compartment prolapse (all $P < 0.001$). There was no association with symptoms of bladder dysfunction or urodynamic findings.

Conclusions: Major morphological abnormalities of the pubovisceral muscle are common in parous urogynaecological patients. They are associated with prolapse of the anterior and central compartment, but not with symptoms of bladder dysfunction or urodynamic findings.

Introduction

The pubovisceral or puborectalis/pubococcygeus muscle complex is thought to play a major role in pelvic floor dysfunction.[1] However, to date assessment has been limited to palpation and magnetic resonance imaging (MRI), [2–6] and due to cost and logistic problems the latter modality has mostly been employed for the investigation of small series of patients.

Pelvic floor ultrasound [7,8] can now also be used to assess levator morphology, and due to its ease of use and limited cost the method holds considerable promise in the investigation of pelvic floor disorders. While morphological abnormalities of the pubovisceral muscle have been described on MRI, [4,6,9] the prevalence of such defects in the general population and their clinical relevance remains unclear. Childbirth is assumed to be the main aetiological factor, and own data have recently confirmed this hypothesis [10].

This study was designed to define the prevalence of major abnormalities of the pubovisceral muscle in a series of women referred for urogynaecological assessment with complaints suggestive of pelvic floor and/or bladder dysfunction, and to analyse clinical and urodynamic data for potential associations with levator defects.

Material and methods

In a prospective observational study, we assessed 338 consecutive women referred for urodynamic assessment with complaints of pelvic floor and/or bladder dysfunction. They underwent a standardised interview covering obstetric history, bladder and bowel symptoms as well as symptoms of prolapse (lump/dragging sensation/sensation of fullness). We also performed multichannel urodynamic assessment using a Neomedix Acquidata Minim 4/8 fluid-filled system (Neomedix, Sydney, Australia) and a clinical prolapse assessment, supine and after bladder emptying, using the Baden–Walker classification. Imaging was undertaken by 2D and 3D translabial pelvic floor ultrasound. Two types of volume imaging capable systems, Medison SA 8000 (Excelray, Sydney, Australia) and GE Kretz Voluson 730 (GE Medical Ultrasound, Sydney), were used with a 7- to 4-MHz volume transducer. Imaging was performed with the patient supine and after bladder emptying. All assessments were conducted by the first author, at rest, on maximal Valsalva and on levator contraction. A

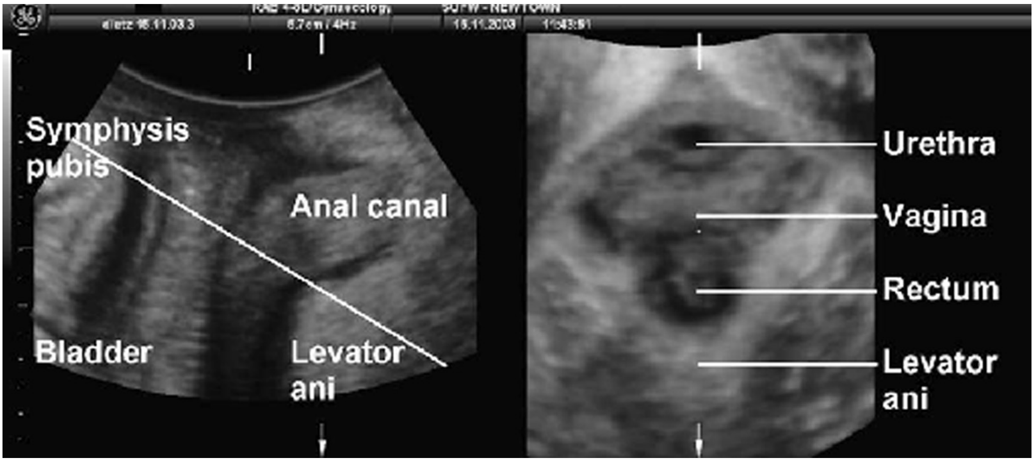

Figure 1*: Translabial ultrasound, GE Kretz Voluson 730 expert, 8–4 Mhz volume transducer. The oblique line traversing the midsagittal image on the left represents the axial plane as shown on the right. It is evident that, in order to obtain optimal imaging of the pubovisceral muscle, it is often necessary to use an oblique plane.*

more detailed description of the methodology has been published elsewhere [11]. Figure 1 demonstrates the approximate location of the oblique axial plane used for imaging of the pubovisceral muscle. This plane is optimised by interrogating the entire volume and will vary slightly from one patient to the next. The process is therefore quite different from MRI, which results in a finite number of slices, not volume data. Figures 2 and 3 demonstrate comparisons of axial views obtained by ultra-sound and on MRI, the first in an asymptomatic nulliparous volunteer, the second in patients with major avulsion defects of the pubovisceral muscle. While the second set of images was obtained in different patients, both figures show the relative appearance of the lower aspects of the levator ani in the axial plane, between the midurethra and the bladder neck.

Acquisition angles were set at the transducer maximum of 70 to allow inclusion of the whole levator hiatus. In cases where marked widening of the hiatus on Valsalva made visualisation of the anterior aspects of the pubovisceral muscle difficult, separate volumes were obtained for the left and right aspect of the muscle. Volumes were analysed by the second author (who was blinded against examination and urodynamic data), several months after the clinical assessment. Analysis was performed with the software 4D View V 2.1 (GE Medical Kretztechnik, Zipf, Austria) on a PC.

Levator avulsion was diagnosed in rendered axial volumes if there was an obvious detachment of the muscle from the pelvic sidewall (Figure 3 for unilateral, Figure. 4 for bilateral defects). Avulsion was rated as present or absent for both sides separately, and it was only

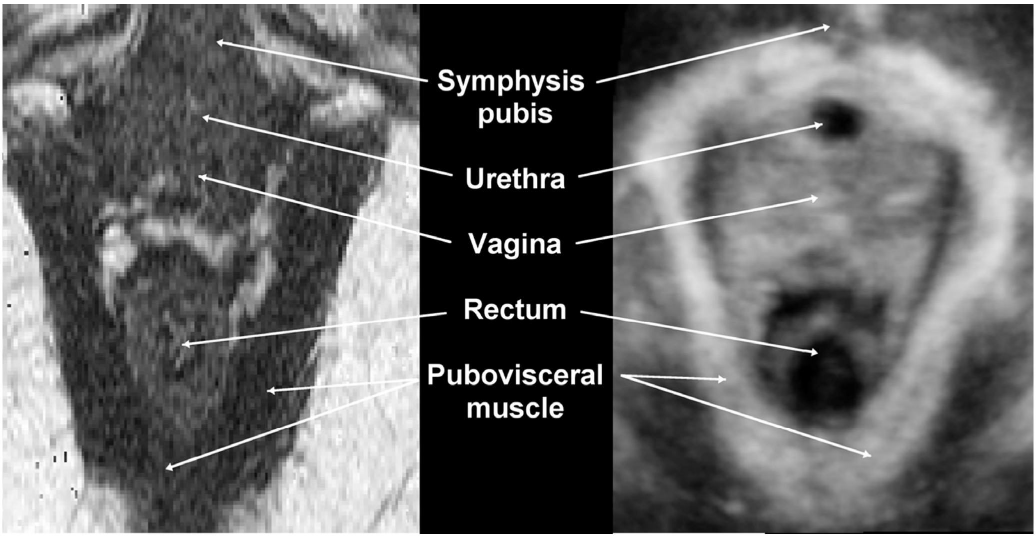

***Figure 2**: Comparison of MRI (left) and volume translabial ultrasound (right) of the puborectalis/pubococcygeus complex in a young asymptomatic volunteer (MRI image courtesy of J. Kruger, Department of Sports and Exercise Science, Auckland University).*

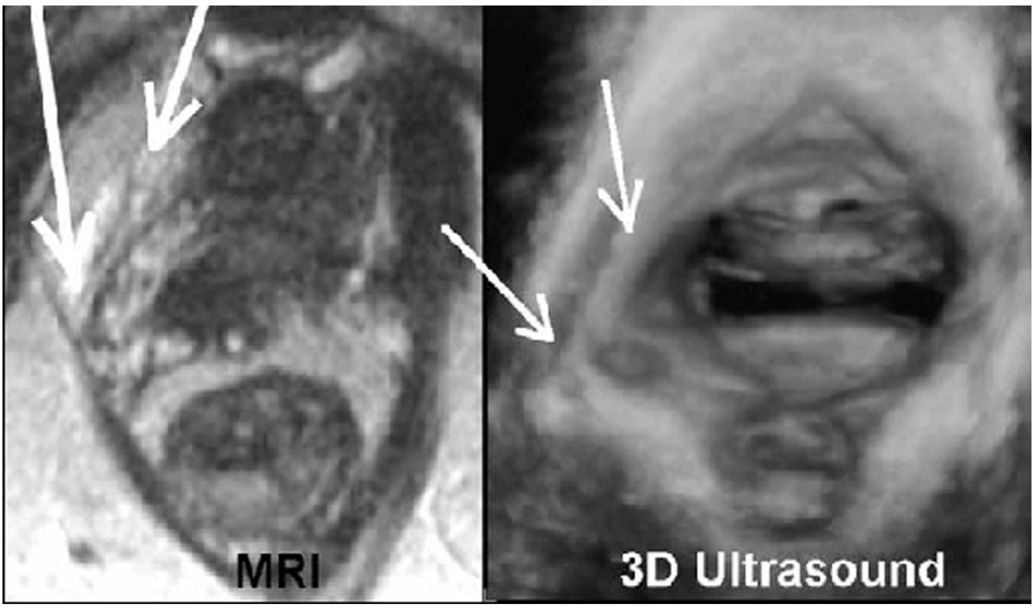

***Figure 3**: Detachment/avulsion of the insertion of the right pubovisceral muscle (arrows) on MRI (left) and 3D pelvic floor ultrasound (rendered image, right). These images were taken in different patients but represent a typical injury as seen on MRI and ultrasound. MRI image courtesy of Dr Ben Adekamni, Plymouth, UK.*

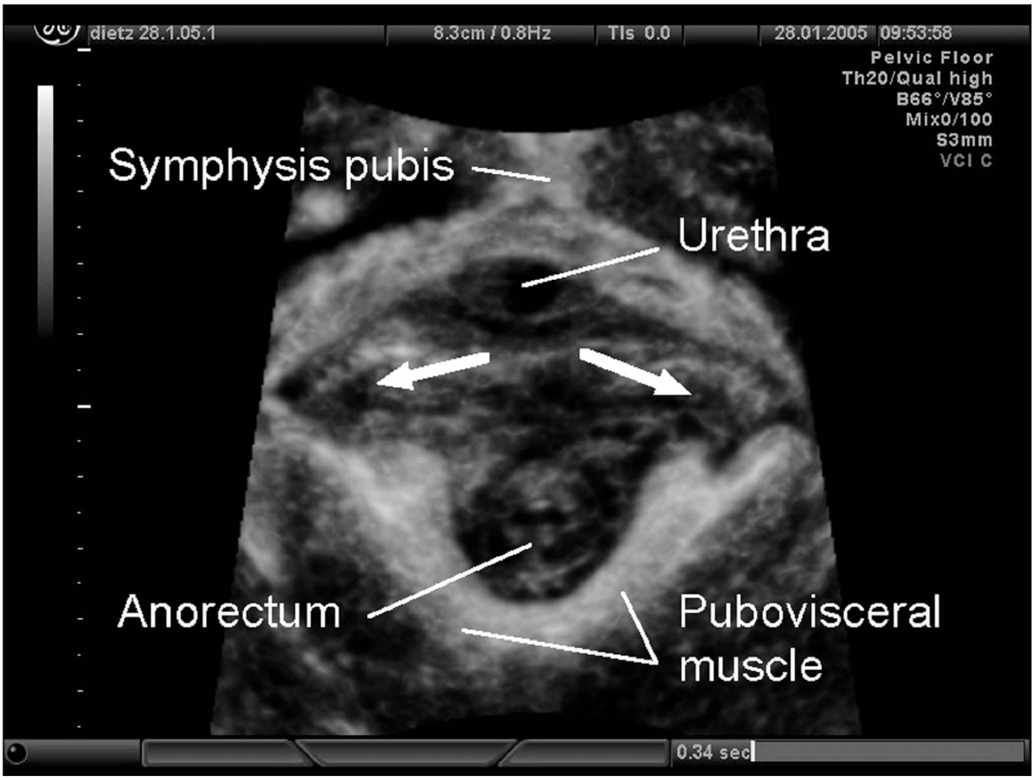

***Figure 4**: Bilateral avulsion injury of the pubovisceral muscle (see arrows) after rotational forceps delivery. This image was obtained using the latest innovation in 3D ultrasound, Volume Contrast Imaging, which was not yet available for this study. Volume Contrast Imaging allows resolutions close to, if not equivalent to, MRI in the axial plane, while enabling distance, area and volume measurements in any user-defined plane. In combination with 4D imaging, temporal resolutions of several frames a second are possible. Reprinted from Dietz HP and Wilson PD. Pelvic floor dysfunction, best practice and research in obstetrics and gynaecology. In: Childbirth and Pelvic Floor Trauma [in press]. (Copyright permission from Elsevier).*

rated as present if an abnormality was detected in all three or more volumes (i.e. at rest, on Valsalva and on levator contraction). In the authors' opinion, the volume obtained on pelvic floor muscle contraction was particularly useful in evaluating more difficult cases as the defect resulting from avulsion injury seems to become more defined on contraction of the muscle.

All data in this study were obtained as part of routine urodynamic assessments. Formal ethics approval was obtained from the local Human Research Ethics Committee (reference Sydney West, Nepean Campus, 05/029).)

Statistical analysis was performed after normality testing when necessary (histogram analysis and/ or Kolmogorov–Smirnov testing), using Minitab Version 13 (Minitab, State College, PA, USA). Analysis of variance, Student's t test and χ^2 table statistics were employed. For test–retest analysis of the qualitative finding of levator defects, we used Cohen's kappa. A kappa of less than 0.4 signifies poor agreement, of 0.4–0.59 is moderate and 0.6–0.79 is substantial agreement, while a kappa of 0.8 or higher is classified as almost perfect agreement. A $P < 0.05$ was considered statistically significant. Data are presented as mean [SD] or median (range).

Results

Five volume data sets could not be evaluated due to technical problems (corrupt data sets, incomplete imaging of the hiatus, poor imaging conditions in very elderly women), leaving 333 data sets of at least three volumes each for analysis. The average age was 52.8 [13.3], median parity was 3 (0–8), with 35 women being nulliparous.

Patients complained of stress incontinence (81%), urge incontinence (74%), frequency (40%), nocturia (49%), symptoms of voiding dysfunction (36%) and of prolapse (25%). Forty-two (13%) had had previous anti-incontinence surgery, and 104 (31%) a hysterectomy. Mean bladder neck descent was 29.4 mm (0.5–58). A test–retest series of 50 volumes conducted by the two authors yielded a Cohen's kappa of 0.83 (95% confidence interval, 0.59–1.0) for the detection of levator defects or avulsion, which by definition signifies excellent agreement.

***Table 1**: Association between vaginal parity and avulsion injury (P = 0.045 on ANOVA). Values are presented as n (%).*

	No avulsion n = 283	**Levator avulsion n = 44**
Vaginal parity (data available on 327 women)		
0	35	0
1	30	5 (17)
2	80	17 (21)
3	80	11 (14)
4	33	4 (12)
5+	25	7 (28)

Defects of the pubovisceral muscle were found in 46 women (14% overall, or 15% of parous women). Thirteen were bilateral such as the one shown in Figure 4, 18 unilateral on the right (as in Figure 3) and 15 unilateral on the left. There were 16 women who had had only caesarean section deliveries, and none of them showed an avulsion injury. Defects only occurred among women who had delivered vaginally (P = 0.007) and were weakly associated with the number of vaginal deliveries (P = 0.045 on ANOVA) (Table 1). Women with avulsion defects showed increased bladder neck descent (34.8 [13.3] vs 28.5 [12.6] mm, P = 0.004) and cystocele descent on ultrasound (–10.2 [17.6] vs 0.6 [15.9] mm, P = 0.001) compared with those without (Table 2). As regards clinical examination data, higher grades of prolapse of the anterior (χ^2 test for trend, P < 0.001) and central compartment (χ^2 test for trend, P < 0.001) were more common in women with levator avulsion, but there was no association between avulsion and posterior compartment prolapse (Table 2). Equally, there

***Table 2**: Association between vaginal parity and avulsion injury (P = 0.045 on ANOVA). Values are presented as n (%).*

	No avulsion n = 288		Levator avulsion n = 45		P
Bladder neck descent	28.5	(12.6)	34.8	(13.3)	0.004
Mean cystocele descent	-0.6	(15.9)	-10.2	(17.6)	0.001
Anterior compartment descent					
0	94		6	(6)	
1	113		12	(11)	
2	50		16	(32)	
3	31		11	(35)	<0.001*
Uterine/vault descent					
0	247		31	(13)	
1	35		9	(26)	
2,3**	6		5	(83)	<0.001*
Posterior compartment descent					
0	117		15	(13)	
1	116		21	(18)	
2	37		7	(19)	0.72
3	18		2	(11)	n.s.

χ^2test for trend, else t test.

***Grades 2 and 3 combined due to low numbers.*

***Table 3**: Symptoms of bladder and pelvic floor dysfunction and uro- dynamic data in women with and without levator avulsion.Values are presented as n (%). P values are for Fisher's exact test.*

	No avulsion n = 288	**Levator avulsion n = 45**	**P**
Stress incontinence	233 (81)	36 (80)	n.s.
Urge incontinence	213 (74)	32 (71)	n.s.
Frequency	107 (37)	25 (56)	0.02
Nocturia	140 (49)	21 (47)	n.s.
Voiding dysfunction*	104 (36)	14 (31)	n.s.
Symptoms of prolapse	68 (24)	15 (34)	n.s.
Urodynamic stress incontinence	198 (69)	29 (64)	n.s.
Detrusor overactivity	69 (24)	13 (29)	n.s.
Voiding dysfunction**	80 (28)	15 (33)	n.s.

**Symptoms of voiding dysfunction were hesitancy, straining to void, poor stream, incomplete emptying. **Voiding dysfunction was diagnosed if maximum flow rate centiles on free flowmetry were below the 5th centile of the Liverpool nomogram,12 or if at least two residuals over 100 mL were documented during urodynamic testing.*

was no association with urodynamic findings or symptoms of bladder dysfunction or prolapse (Table 3), with the exception of a weak association between avulsion injury and frequency.

Discussion

As a result of recent advances in ultrasound technology, it has now become possible to demonstrate major abnormalities of levator anatomy by 3D translabial ultrasound. Rendered images in the axial plane give good visualisation of the attachments of the puborectalis/pubococcygeus or pubovisceral muscles to the pelvic sidewall (Figures 1–3). Both hiatal dimensions [7] and the qualitative finding of levator detachment from the pelvic sidewall can be determined with good reproducibility. The most common abnormality seems to be a detachment of the pubovisceral muscle from the pelvic sidewall although it is recognised that localised atrophy could conceivably result in similar appearances. We termed this type of abnormality an 'avulsion injury'.

Such abnormalities of the pubovisceral muscle as shown in Figures 3 and 4 were seen in 15% of parous women in this series of patients presenting for urodynamic assessment. While there has been a considerable body of work on the appearance of the levator ani in symptomatic and asymptomatic women, this is not true for discrete abnormalities as defined in this study. There is currently no other published data on the prevalence of such defects as imaged by 3D pelvic floor ultrasound, but results compare well with those of the one MRI study to date which allows an estimate of prevalence in parous women.6 In this study, 18% of parous women were shown to have defects of the pubovisceral muscle, compared with 15% in our series. Direct comparison is limited by different study designs as the quoted MRI study assessed a cohort of primiparous women, only 50% of which were symptomatic for stress incontinence. Our population consisted exclusively of women symptomatic of pelvic floor disorders, with 81% complaining of stress incontinence. Furthermore, it is recognised that neither of the two studies allow estimation of the prevalence of such defects in the general parous population. Clearly, further work is needed to define the incidence of levator avulsion in childbirth and its long term significance.

Interestingly enough, in the 1940s and 1950s, Howard Gainey, a Kansas City Obstetrician, reported an incidence of 14–21% for trauma to the m. pubococcygeus, [13,14] as determined by physical examination in primi- and multi-parae. While his communications were regarded as seminal at the time, they were not followed up and had no effect on clinical practice. D.H. Nichols stated in the 1996 edition of his book 'Vaginal Surgery' that Gainey's studies still awaited confirmation, and that 'this failure to consider the relationship between obstetric events and maternal injury does not seem compatible with usual professional points of view' [15] Clearly, Gainey's original findings are compatible with modern imaging data, and we finally may have the means to investigate causation and clinical relevance of such trauma further—two generations after he first presented his findings.

If one limits conclusions to the population examined in this study (i.e. women presenting with symptoms of bladder and pelvic floor dysfunction sufficiently severe to warrant urodynamic assessment), then our data does allow insights into the clinical relevance of major levator trauma, despite the obvious limitations mentioned above. Avulsion of the pubovisceral muscle off the pelvic sidewall was associated with increased mobility of the anterior vaginal wall (both on clinical examination and on ultrasound) and uterus, but not with any specific symptoms or findings on urodynamic testing apart from a weakly significant association with the symptom of urinary frequency. This may well be spurious in view of the number of tests performed.

While it is acknowledged that a true cross-sectional study would be necessary to investigate the relevance of morphological abnormalities of the levator ani in the general population, it is interesting that avulsion defects as seen on 3D pelvic floor ultrasound were associated with prolapse rather than incontinence, paralleling the findings of epidemiological studies which consistently show a stronger association between prolapse and childbirth than between parity and incontinence [16–20].

As regards causation of the observed abnormalities, this study has again confirmed that such defects of the inferomedial aspects of the levator ani seem to be limited to women who have delivered vaginally, in agreement with imaging studies employing MRI.6 In a recently completed study examining primiparous women before and after childbirth, we have been able to confirm that such defects do in fact arise in childbirth [10] This is in accordance with MRI computer modelling showing that the most inferomedial aspects of the pubovisceral muscle are those parts of the levator ani subjected to the most marked mechanical strain on crowning of the fetal head [21] Forceps delivery will further increase this strain—Figure. 4 for an example of bilateral avulsion injury after rotational forceps.

In conclusion, major morphological abnormalities of the pubovisceralmuscle are common in a urogynaecological population. Such abnormalities are associated with prolapse of the anterior and central compartment, but not with symptoms of bladder dysfunction or urodynamic findings.

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5

Ballooning of the levator hiatus

Ultrasound in Obstetrics and Gynecology 2008; 31: 676–680.

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Abstract

Objective: The levator hiatus defines the 'hernial portal' through which female pelvic organ prolapse develops. Hiatal area may therefore be an independent etiological factor for this condition. In this retrospective study we defined 'normality' for hiatal area by assessing its relationship with symptoms and clinical signs of prolapse.

Methods: Datasets of 544 women seen in a tertiary urogynecological unit were assessed. Patients had undergone an interview, clinical examination and three-/fourdimensional (3D/4D) pelvic floor ultrasound imaging. All analysis was performed off-line, blinded against clinical data.

Results: Information on prolapse symptoms was available for 538 women and 171 (32%) of these complained of such symptoms. There was a strong statistical relationship between hiatal dimensions, both at rest and on Valsalva manoeuvre, and prolapse symptoms (all $P < 0.001$). Receiver–operating characteristics (ROC) curve analysis yielded an area under the curve of 0.65 (95% CI, 0.60–0.70) for hiatal area at rest and 0.71 (95% CI, 0.66–0.76) for hiatal area on Valsalva. Cut-offs of 25 and 30 cm2 on Valsalva gave sensitivities of 0.55 and 0.34 and specificities of 0.77 and 0.86, respectively, for detecting symptomatic prolapse. Similar values were obtained when significant prolapse (Grade 2 or higher) was used as the state variable.

Conclusions: Levator hiatal area as measured by 3D translabial pelvic floor ultrasound examination is strongly associated with symptoms and clinical signs of prolapse. Based on the ROC curves that we obtained, we suggest that a hiatal area of >25 cm2 on Valsalva be defined as abnormal distensibility or 'ballooning' of the levator hiatus.

Introduction

The levator ani muscle is thought to be of central importance for pelvic organ support [1]. It has recently been shown that trauma to this structure, i.e. detachment or 'avulsion' of the muscle from its insertion on the inferior pubic ramus and pelvic sidewall, predisposes women to prolapse, especially of the anterior and central compartments [2,3]. In fact, levator trauma is likely to be the 'missing link' explaining the epidemiological association between childbirth and female pelvic organ prolapse, with prolapse patients showing a much higher likelihood of levator trauma [4], and with trauma conferring a near doubling of the risk of significant prolapse (Grade 2 or higher) [5].

However, even in the absence of overt avulsion injury it is probable that the biomechanical properties of the levator ani muscle influence the likelihood of female pelvic organ prolapse as postulated in the form of the 'ship in dock' theory [1]. Measuring hiatal distensibility of the levator ani is one of the most basic approaches to determining biomechanical properties of this muscle, although it is understood that many factors influence this parameter, not just passive compliance or stiffness. Regardless of the role of active factors such as striated muscle activation, excessive distensibility of the levator hiatus ('ballooning') is a striking observation on translabial ultrasound imaging in the axial plane. When we consider that the levator hiatus is a potential hernial portal it is not surprising that the phenomenon should affect pelvic organ mobility.

Highly significant correlations have been demonstrated between female pelvic organ prolapse and levator hiatal dimensions [2,6], agreeing with clinical data on dimensions of the urogenital hiatus [7,8]. This relationship is not limited to hiatal dimensions on Valsalva manoeuvre, which may be explained as a passive phenomenon, but has also been confirmed for dimensions at rest, and it is true both for asymptomatic nulliparous women and patients symptomatic of pelvic floor dysfunction [2]. Childbirth increases hiatal distensibility even in the absence of overt levator trauma[10], and hiatal dimensions in turn seem to influence the course of labor [11,12]. It is therefore probable that hiatal distensibility is an independent etiological factor in the development of pelvic organ prolapse. However, to date there have been no published data on how to define 'normal' and 'abnormal' hiatal dimensions. We therefore conducted a retrospective study with the aim of defining 'normality' for the parameter of 'hiatal area on Valsalva' by assessing its relationship with the symptoms and clinical signs of pelvic organ prolapse.

Patients and methods

We retrospectively analyzed the data of 544 women seen in a tertiary urogynaecological unit for symptoms of pelvic floor and/or urinary tract dysfunction. A subset of this population had previously been studied for the prevalence of levator trauma [2]. All patients had given a medical history and undergone clinical examination for prolapse (International Continence Society (ICS) pelvic organ prolapse quantification (POP-Q) grading) and levator integrity and function (modified Oxford Grading), as well as three-/four-dimensional (3D/4D)pelvic floor ultrasound using Medison SA 8000 (Medison,Seoul, Korea) and GE Kretz Voluson 730 Expert (GE Medical Systems, Zipf, Austria) systems. Symptoms of pelvic organ prolapse were defined as 'the sensation of a lump in the vagina' and/or 'a dragging sensation in the vagina'. Ultrasound data acquisition was performed as described previously [9], with data acquired after bladder emptying, supine, at rest and on maximal Valsalva manoeuvre. Great care was taken to avoid levator co-activation [13]. Acquisition angles were set to the system-specific maximum (70◦ for the SA 8000 and 85◦ for the Voluson 730 Expert).

Analysis of data was performed off-line using the 4D View v 2.1–5.0 software (GE Medical Systems), weeks to months following clinical assessment, blinded against all clinical data. Hiatal dimensions were determined according to a previously published methodology [9] (Figure 1), which has been shown by several authors to be highly repeatable[14–16] and probably superior to magnetic resonance imaging [17]. Figure 2 illustrates different degrees of hiatal ballooning. We focused on hiatal area since it is clearly amore inclusive measure of levator biometry. Axial diameters have the advantage that they can be obtained by two-dimensional ultrasonography, but the relationship between axial diameter on Valsalva with prolapse and prolapse symptoms is less strong (own unpublished data), probably owing to the effect of avulsion injury, which impacts much less on axial diameters in comparison to area. Coronal diameters are another potential choice, but the 'warped' nature of the plane of minimal dimensions is likely to act as a potential confounder.

This study is an analysis of data obtained in a parent study undertaken for a different purpose and approved by the institutional Human Research Ethics Committee (SWAHS ref 05/029).

Statistical analysis was undertaken using SPSS v. 14 (SPSS Inc., Chicago, IL,USA) and Minitab v. 13 (Minitab Inc., State College, PA,USA). All quantitative data were found to be normally distributed on Kolmogorov–Smirnov testing. We used Student's *t*-tests to evaluate the relationship between pelvic organ descent and prolapse symptoms, and receiver–operating

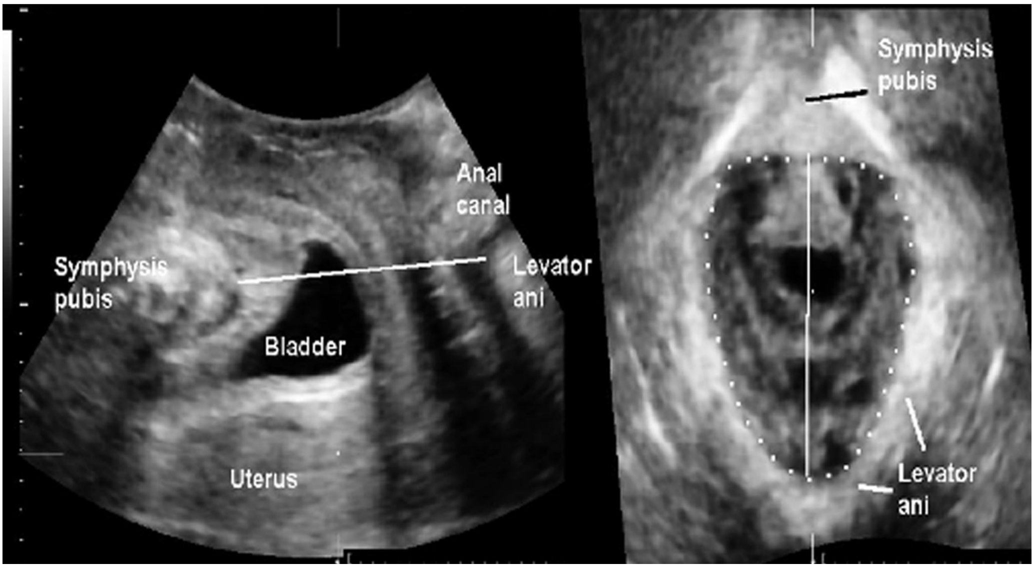

***Figure 1**: Translabial three-dimensional ultrasound images in the midsagittal plane (a) and oblique axial plane (b) showing identification of the plane of minimal hiatal dimensions on Valsalva manoeuvre. (a) The horizontal line illustrates the identification of the plane of minimal hiatal dimensions in the midsagittal plane and is equivalent to the vertical line in b. (b) The dotted line illustrates the minimal hiatal area on Valsalva, which was measured at 19 cm2, indicating normal distensibility of the hiatus.*

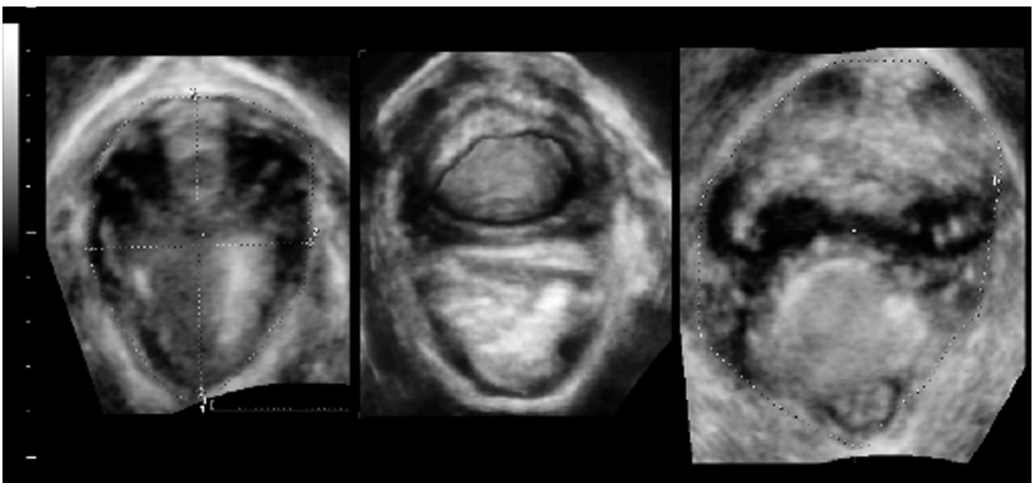

***Figure 2:** Three-dimensional pelvic floor ultrasound images in the axial plane showing mild (26.2 cm2) (a), moderate (34.4 cm2) (b) and severe (42.8 cm2) (c) hiatal ballooning on Valsalva manoeuvre in patients with symptomatic prolapse. Image (c) also shows the effect of aright-sided avulsion injury whereas (a) and (b) show a macroscopically intact (if excessively distensible) hiatus.*

characteristics (ROC) curve analysis to examine the relationship between hiatal dimensions and reported symptoms of prolapse, in order to obtain a plausible estimate of 'normality' for hiatal dimensions.

Results

The mean age of the study population was 53.2 (range,17–89) years, and median vaginal parity was 2 (range,0–8). Information regarding prolapse symptoms was available for 538 women, with 171 (32%) complaining of such symptoms. Objective clinical examination revealed:185 Grade 1, 102 Grade 2 and 68 Grade 3 cystoceles; 61 women with Grade 1, 16 with Grade 2 and eight with Grade 3 uterine prolapse; and 187 Grade 1, 81 Grade 2 and 29 Grade 3 rectoceles. In a total of 250 women (46%) we found prolapse of Grade 2 or higher. In 497 out of 538 women we were able to correlate hiatal dimensions with clinical prolapse grading. The other 41 cases were accounted for by corrupt or inadequately identified ultrasound datasets (n = 29), which occurred almost exclusively during the first few months of the study period; a patient's inability to perform an adequate Valsalva manoeuvre (n = 11); and operator difficulties in evaluating the volume dataset (n = 1).

Data analysis revealed statistically significant relationships between reported symptoms of prolapse and pelvic organ descent, both on ultrasound (Table 1) and on clinical examination (all $P < 0.001$).

Table 1: *Relationship between reported symptoms of prolapse and pelvic organ descent (as determined by translabial ultrasound)*

	Reported prolapse symptoms		
Type of descent	*Yes*	*No*	P*
Cystocele	−9.6 ± 19.5	−0.1 ± 19.5	<0.001
Uterine	−3.2 ± 14.7	+4.5 ± 13.1	<0.001
Rectocele	−6.9 ± 17.1	+0.9 ± 17.2	<0.001

*All measurements are in mm, given as mean ± SD relative to the inferior margin of the symphysis pubis, as described previously [19]. *Student's t-test.*

***Table 2**: Relationship between reported symptoms of prolapse and levator hiatus parameters*

	Reported prolapse symptoms		
Parameter	*Yes*	*No*	P*
Anteroposterior diameter at rest (cm)	5.70 ± 0.88	5.37 ± 0.86	<0.001
Coronal diameter at rest (cm)	4.44 ± 0.60	4.07 ± 0.59	<0.001
Hiatal area at rest (cm2)	17.49 ± 5.03	14.98 ± 4.26	<0.001
Anteroposterior diameter on Valsalva (cm)	6.63 ± 1.12	6.01 ± 1.15	<0.001
Coronal diameter on Valsalva (cm)	5.36 ± 0.88	4.67 ± 0.80	<0.001
Hiatal area on Valsalva (cm2)	27.14 ± 8.69	21.01 ± 7.82	<0.001

*Values are mean ± SD. *Student's t-test.*

There was also a strong statistical relationship between reported prolapse symptoms and hiatal dimensions both at rest and on Valsalva (all P < 0.001, Table 2). ROC analysis confirmed this relationship, with an area under the curve (AUC) of 0.65 (95% CI, 0.60–0.70) for hiatal area at rest and 0.71(95% CI, 0.66–0.76) for hiatal area on Valsalva. Cut-offs of 25 and 30 cm^2 on Valsalva gave sensitivities of 0.55 and 0.34 and specificities of 0.77 and 0.86, respectively (Figure 3).

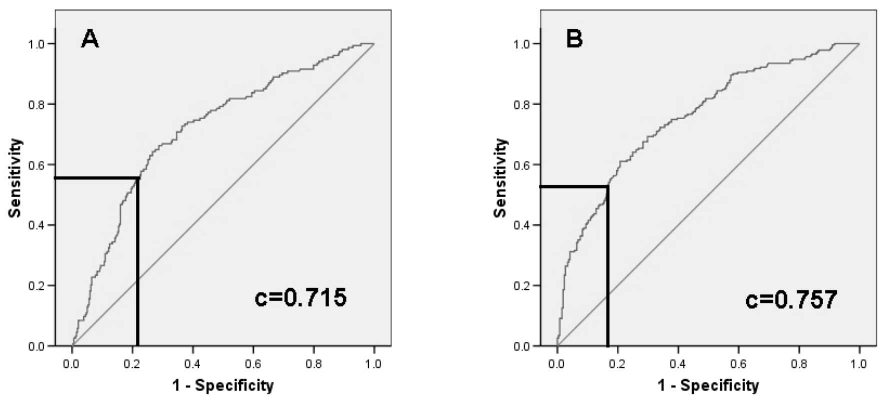

***Figure 3**: Receiver operator curves and the performance of a proposed cut-off of 25 cm^2 for the diagnosis of abnormal hiatal distensibility ('ballooning') on the basis of symptoms of prolapse on the left (A) and objective prolapse (POP-Q Grade 2+) on the right (B).*

***Table 3**: Prevalence of pelvic organ prolapse stages (maximal stage for any compartment) relative to hiatal ballooning in 497 women for whom both clinical prolapse assessment and hiatal imaging on Valsalva manoeuvre were available*

		Grade				
Extent of ballooning		*0*	*1*	*2*	*3*	*Total*
<25 cm^2	(normal)	82 (24)	140 (42)	76 (23)	38 (11)	336
25–29.9 cm^2	(mild)	6 (10)	17 (28)	24 (40)	13 (22)	60
30–34.9 cm^2	(moderate)	5 (10)	9 (18)	20 (40)	16 (32)	50
35–39.9 cm^2	marked)	1 (3)	3 (10)	13 (45)	12 (41)	29
≥40 cm^2	(severe)	0	2 (9)	7 (35)	13 (65)	22
Total		94	171	140	92	497

Values are n (%).

When significant objective prolapse (POP-Q Grade 2 or higher) was tested against hiatal area at rest and on Valsalva, similar ROC statistics were obtained. There was a fair relationship between area at rest and prolapse (AUC 0.64, 95% CI, 0.59–0.69), but the AUC on Valsalva was much higher (0.76, 95% CI, 0.72–0.80; Figure 3). A cut off of 25 cm^2 on Valsalva yielded a sensitivity of 0.52 and a specificity of 0.83 for detecting significant prolapse as diagnosed on clinical examination. The respective figures for a cut-off of 30 cm^2 were 0.35 for sensitivity and 0.93 for specificity. On the basis of our results we propose that a hiatal area on Valsalva of 25–29.9 cm^2 can be defined as 'mild', 30–34.9 cm^2 as 'moderate', 35–39.9 cm^2 as 'marked' and ≥40 cm^2 as 'severe' ballooning. In our dataset, this stratification resulted in 60 women having ballooning classified as 'mild', 50 as 'moderate', 29 as 'marked' and 22 as 'severe'. Table 3 shows the prevalence of maximal prolapse stages in each subgroup.

Discussion

The levator hiatus defines the largest potential hernial portal within the envelope of the abdominal cavity. Consequently, the static and dynamic properties of this muscle are likely to matter for the etiology and pathogenesis of any form of herniation through this portal. The most common forms of such herniation are subsumed under the term 'female pelvic organ prolapse', although rectal intussusception and rectal prolapse also constitute herniation through the levator hiatus. Levator hiatal dimensions are likely to reflect aspects of muscle compliance or elasticity, that is, they probably describe components of the biomechanical properties of this muscle [18].

We feel that any parameters describing the size and distensibility of the hiatus should be investigated more closely. This retrospective study was undertaken to define 'normality' for the parameter 'hiatal area on Valsalva', the measurement of which has been shown to be highly reproducible by the authors [9] and others [14,15] and which seems to be strongly associated with pelvic organ mobility [9], and this was again confirmed in this cohort of women.

Two standard approaches to determining 'normality' are:

1. to use a normal population and determine the 95th centile or, alternatively, to use the mean plus two standard deviations;
2. to determine optimal cut-offs with the help of ROC curves using symptoms attributable to the phenotypic observation in question.

On the basis of previously obtained data in young nulliparous women [9], a purely mathematical definition of the upper limit of normality (mean + 2 SD) yielded a figure of 25.8 cm^2. In this study we have attempted to define a cut-off for normality on the basis of symptoms of pelvic organ prolapse and of objectively determined significant (POP-Q Stage 2 and higher) pelvic organ prolapse, the presumptive main manifestation of excessive distensibility of the levator hiatus. We do not propose hiatal area on Valsalva as a test for prolapse (this would be nonsensical); the purpose of using ROC statistics was exclusively to determine normality. Interestingly, the optimal cut-off proved to be 25 cm^2, yielding a sensitivity of 0.55 and specificity of 0.77, with an AUC of 0.71, for predicting symptoms of female pelvic organ prolapse, and a sensitivity of 0.52 and specificity of 0.83 (AUC 0.76) for predicting objective prolapse on examination (Figure 3).

On the basis of the ROC curves and patient symptoms we therefore suggest that a hiatal area of ≥25 cm^2 on Valsalva manoeuvre be defined as abnormal distensibility or 'ballooning' of the levator hiatus. As already mentioned, our clinical experience would suggest that a hiatal area on Valsalva of 25–29.9 cm^2 can be defined as 'mild', 30–34.9 cm^2 as 'moderate', 35–39.9 cm^2 as 'marked' and ≥40 cm^2 as 'severe' ballooning. While it is understood that any such stratification is necessarily arbitrary, it has performed well in approximately 1000 clinical assessments in our unit to date, is easy to remember and seems to describe increasing degrees of abnormality as demonstrated by a progressively stronger association with pelvic organ prolapse (Table 3). Future studies should focus on the determinants of excessive distensibility of the levator hiatus and its use as a predictor (e.g. of recurrence after prolapse surgery) or as a surrogate outcome parameter in intervention studies aimed at altering the biomechanical properties of this muscle.

In conclusion, we have defined 'normality' for the biometric parameter 'area of the levator hiatus on maximal Valsalva' by using ROC analysis of the association between this parameter and the symptoms and clinical signs of female pelvic organ prolapse. We suggest a cut-off of 25 cm^2 for 'normal' distensibility of the levator hiatus.

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6

Prevalence of major levator abnormalities in symptomatic patients with an underactive pelvic floor contraction

Submitted.

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Abstract

Introduction: To evaluate the prevalence of major levator abnormalities in women with an underactive as opposed to a normal pelvic floor contraction and to determine a potential relation with symptoms.

Methods: A retrospective observational study was conducted including 352 symptomatic patients. Blinded off-line analysis was performed subjectively assessing pelvic floor contraction on transperineal ultrasound and scoring the contraction as underactive (absent or weak), or normal. For quantification of levator defects tomographic ultrasound imaging was used.

Results: An underactive pelvic floor muscle contraction was detected in 186 patients (55.5%). Major structural levator abnormalities were found in 53.8% women with an underactive versus 16.1% in patients with a normal contraction (P<0.001). An underactive contraction was associated with a reduction in hiatal area of 7% versus 25% in the normal group (P<0.001).

Conclusion: There was an association between faecal incontinence and underactive contraction, but this association was not depicted for stress incontinence.

Introduction

The levator ani muscle complex is attached to the internal surface of the true pelvis. It is divided into 3 parts according to their attachments and pelvic viscera to which they are related, i.e. the ileococcygeal, pubococcygeal and puborectal muscle. Appropriate contraction and relaxation result in optimal pelvic floor support and function. Contractility of the pelvic floor may play an important role in sustaining continence and/or preventing pelvic organ prolapse. Clinical assessment of pelvic floor function is typically performed by digital palpation, however with poor repeatability [1]. In 2005 Messelink et al. recommended to quantify contractions by the modified Oxford scale as either absent, weak, normal or strong [2]. Apart from a functional estimation, little is known about the relationship between levator ani structure (morphological and functional integrity), the quality of its contraction and the eventually relationship of the above with symptoms.

The levator ani can be visualized with magnetic resonance imaging as well as 3-dimensional (3D) transperineal ultrasound [3-5]. Whilst MRI is invasive, expensive and not widely available, 3D transperineal ultrasound offers equal resolution for the inferior components of the levator ani, is less expensive and well tolerated by the patient [6]. With increasing experience in both dynamic imaging methods, new insights have been gained in the function and anatomy of the pelvic floor function in patients with pelvic floor disorders. It is thought that damage to the levator ani muscle can lead to poor function and secondarily to symptoms such as urine incontinence, prolapse, and faecal incontinence [7-10].

To date, there is no information on the relationship between the integrity of the pelvic floor, and success of treatment [11]. Pelvic floor re-education and muscle training is a well accepted treatment for pelvic floor symptoms, especially for stress urinary incontinence [12]. In a number of patients conservative treatment fails, which has not been related to the underlying anatomic condition. We designed the present study to investigate an eventual relationship between anatomical and functional abnormalities of the levator complex, as well as their relation to pelvic floor disorders symptoms.

Materials and methods

Between August 2006 and April 2007 all patients who were referred to two tertiary pelvic floor clinics because of pelvic floor dysfunction, were included in this study. They underwent a standardized interview, clinical examination according the International Continence Society Pelvic-Organ-Prolapse Quantification (ICS POP-Q) staging. Stress Urinary Incontinence (SUI) was defined as more then once a week involuntary urine loss and faecal incontinence as involuntary loss of liquid or hard stool. Transperineal ultrasound was performed in the supine position and after voiding and 3D/4D volume datasets were acquired at rest, on pelvic floor contraction and on Valsalva manoeuvre, using GE Kretz Voluson 730 Expert system and a RAB 4-8 MHZ probe as previously prescribed by Dietz [13]. Off-line analysis was performed using the software GE Kretz 4D view 5.0 (GE Healthcare, Kretztechnik, Zipf, Austria) with the investigators blinded against clinical data.

The quality of pelvic floor muscle contractions was subjectively evaluated on the volume with the best contraction assessed on transperineal ultrasound independently by the first two authors (ABS and MLK). The standardized ICS terminology for assessment of pelvic muscle contraction was used, scoring the contraction as absent, weak, normal or strong [2, 12]. We defined a poor pelvic function an 'underactive pelvic floor contraction' if there was evidence of an absent or weak pelvic floor contraction on ultrasonography, a normal function of the pelvic floor was defined if there was a normal or strong contraction.

Measurements were taken at the level of the minimal hiatal dimension, using the inferior margin of the symphysis pubis as reference point in 2-dimensional (2D) and 3D datasets as described by Dietz et al [13, 14]. Antero-posterior (AP) diameter, and left- right transverse diameters as well as the hiatal area were measured at rest and during contraction (Figure 1 and 2). The percentage difference (value A rest – value A contraction) / value A rest) for con-

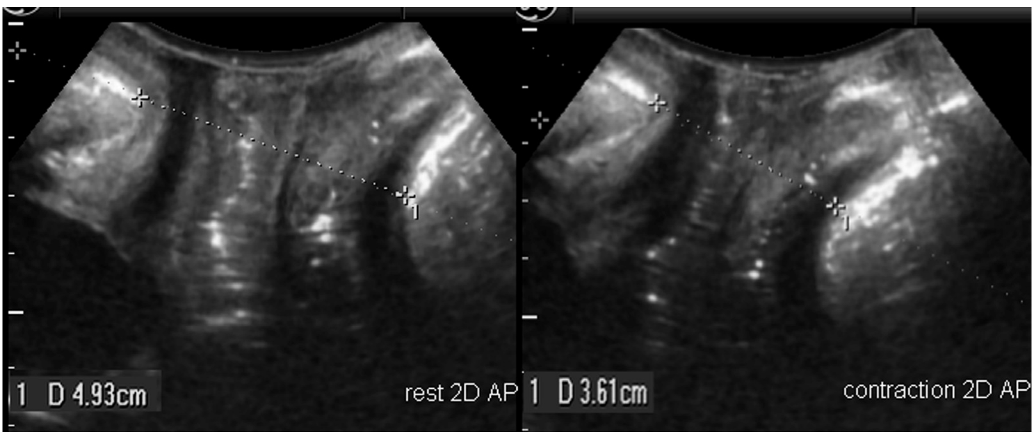

***Figure 1**: Antero-Posterior measurements in 2D at the level of minimal hiatal dimension in rest position (left panel) and during contraction (right panel).*

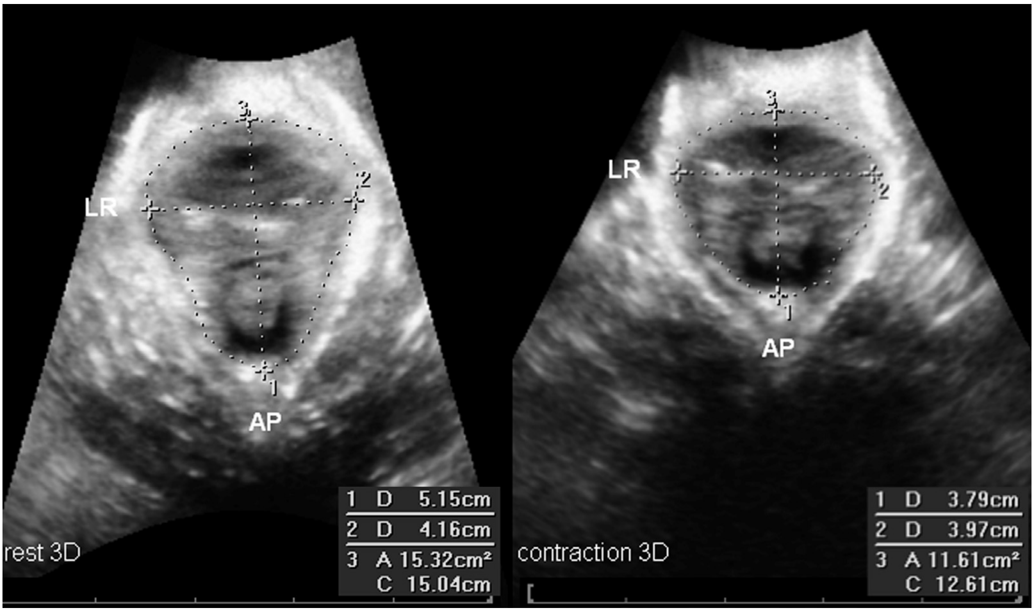

Figure 2: *Antero-posterior, transverse LR and hiatal area measurements in 3D at the level of the minimal hiatal dimension in rest position (left panel) and during contraction (right panel).*

traction was calculated as a measurement of pelvic floor muscle function. Levator defect or 'avulsion' was defined as an obvious detachment of the of the levator ani muscle anteromedial from the pubic bone, either unilateral or bilateral [4, 5]. For quantification of these levator defects, tomographic ultrasound imaging (TUI) was used [15]. A set of 8 slices with an interslice interval of 2.5 mm were obtained, from 5 mm below to 12.5 mm above the hiatal plane, in a volume obtained on maximal levator contraction (Figure 3). A score of 0 was used if there were no defects on either side and a total score of 16 indicated a complete bilateral avulsion.

A major levator defect was defined as a TUI score of 8 for unilateral (left or right) and 16 for bilateral defects. All TUI evaluations were performed by one investigator (ABS).

Both ABS and MLK performed off-line analysis of volume datasets of their own hospital, using the best contraction in the volume dataset of each patient. A test – retest series was conducted in 50 volume datasets between the first two authors for the subjective evaluation of underactive and normal contraction. ABS had already gained extensive experience in analyzing pelvic floor volumes and MLK was a trainee who did not have previous experience. Agreement was analyzed using Cohen's kappa.

Statistical analysis was performed using SPSS 15.0 (SPSS Inc., Chicago, USA). Pearson Chi-

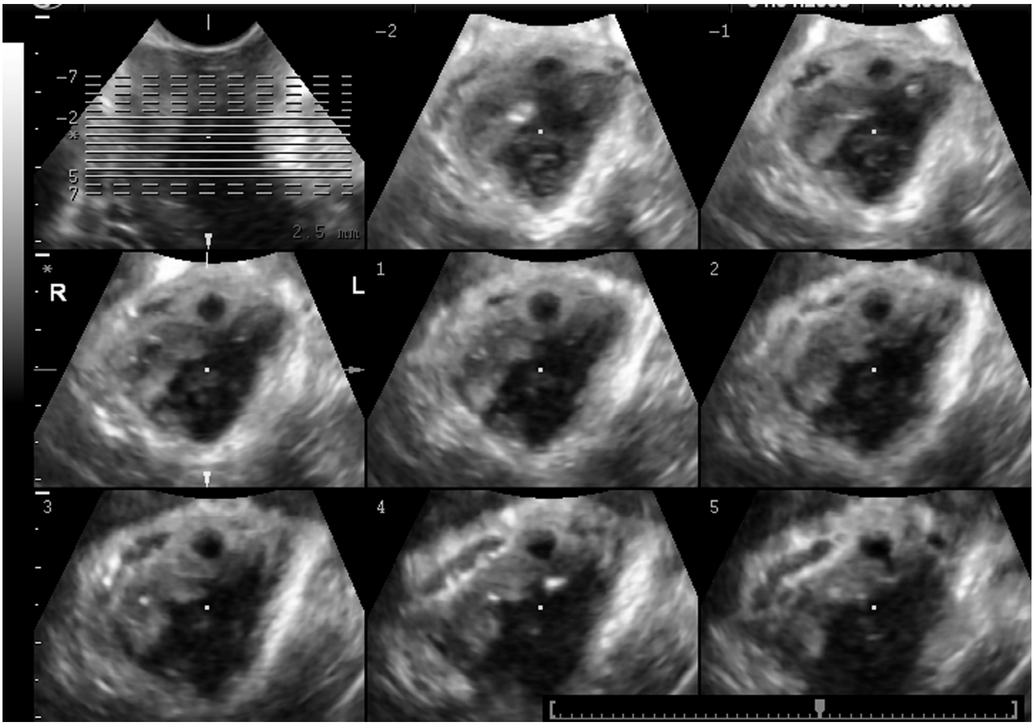

***Figure 3**: TUI imaging of the levator hiatus with an obvious unilateral defect on the right side (TUI score 8 for the right and 0 for left).*

square and Student–t correlations were used for comparison of normally distributed data and the Mann-Whitney U test for nonparametric data. $P<0.05$ (two-sided) was considered statistically significant.

Results

During the observation period, 352 patients were included for this study. Complete data-sets were available for 335 patients; 5% (n = 17) of the patients were excluded due to in-complete clinical data and/or bad imaging quality. 208 Patients attended the pelvic floor clinic in the Erasmus Medical Centre (Rotterdam, The Netherlands) and 127 patients in the clinic in UZ Leuven, Campus Gasthuisberg (Leuven, Belgium). The mean age was 55.2 years (20-87). Their leading complaints were urinary stress incontinence in 34% (n = 114), prolapse in 43.6% (n = 146) and faecal incontinence in 14.9% (n = 50). Hysterectomy had previously been performed in 31.3% patients. Severe prolapse on clinical assessment (POP-

***Table 1**: Subjective assessment of the pelvic floor contraction on transperineal ultrasound.*

contraction	n	%
absent	45	13,4
weak	141	42,1
normal	100	29,9
strong	49	14,6

Q stage two or more) was diagnosed in 43.6% (n = 146); either from the anterior (39.4%; n = 132), middle (19.1%; n = 64) and posterior (29.3%; n = 98).

On assessing volume ultrasound data an underactive pelvic floor muscle contraction was diagnosed in 186 patients (55.5%), of whom 13.4% (n = 45) had no visible (absent) pelvic floor contraction and 42.1% (n = 141) had a weak contraction on transperineal ultrasound (Table 1). A test-retest series for qualitative assessment of pelvic floor muscle strength on 3D ultrasound was conducted for 50 patients between the first two authors and demonstrated a Cohen's Kappa of 0.55.

A major levator defect was diagnosed in 37% (n = 124) of all patients. The defects were unilateral in 73 patients (38 on the right and 35 on the left) and bilateral in 51 patients. Patients with avulsion defects were significantly more likely to have an underactive pelvic floor muscle contraction on ultrasound, 53.8% (n = 100) versus 16.1 % (n = 24) ($P<0.001$). Those with an underactive pelvic floor contraction had a higher median defect score than those with normal contraction, 8.0 versus 1.2 ($P < 0.001$). All dimensions of the levator hiatus were reduced more effectively in women judged to have normal pelvic floor function as opposed

***Table 2**: Levator abnormalities as quantified with the TUI technique and mean percentage differences and 95% confidential intervals (CI) of the dimensions of the contraction;*

contraction	underactive (n= 186)		normal (n= 149)		P
TUI total (median)	8,0		1,9		P < 0.001
2D AP (% difference, 95% CI)	7%	(-3 - 16 %)	18%	(-3% - 17%)	P < 0.001
3D AP (% difference, 95% CI)	7%	(-2% - 19%)	19%	(7% - 33%)	P < 0.001
3D LR((% difference, 95% CI)	2%	(-10% - 15%)	10%	(-6% - 27%	P < 0.001
3D Hiatal area (% difference, 95% CI)	7%	(7% - 25%)	25%	(9% - 43%)	P < 0.001

2D AP: two-dimensional antero-posterior diameter; 3Dap: three-dimensional antero – posterior diameter; 3D LR; three-dimensional left-right diameter; 3D hiatal area: three dimensional hiatal area diameter (as measured in figure 1 and 2).

***Table 3**: Patient characteristics in women with underactive (poor) and normal pelvic floor contraction as subjectively assessed with ultrasound.*

contraction	underactive		normal		P
faecal incontinence % (n)	76%	(38)	24%	(12)	0,002
stress incontinence % (n)	63,7%	(93)	36,3%	(53)	ns
prolapse % (n)	53,9%	(76)	46.1%	(65)	ns
age (yr) (mean, SD)	56,1	(± 15.4)	54,8	(± 14.3)	ns
age del (yr) (mean, SD)	26,7	(± 5.5)	25,4	(± 4.8)	ns
max birthweigth (gr) (mean, SD)	3655	(± 670)	3630	(± 570)	ns
instrumental delivery	11,3%	(21)	12,1%	(18)	ns

to the women with a poor function. For the 2D AP dimension a reduction of 18% for normal contraction as opposed to 7% for an underactive contraction was found; and for the levator hiatal area a reduction of 25% for normal as opposed to 7% with a poor function (P<0.001) (Table 2).

As to patient symptoms, women complaining of faecal incontinence were more likely to have underactive pelvic floor muscle contraction on ultrasonography (P < 0.01). This was not the case for stress incontinence or symptoms of prolapse (Table 3). There was no association between age, age at first delivery, maximum birth weight and delivery mode and the presence of poor function.

Discussion

With transperineal ultrasound dynamic imaging can be performed to obtain information on pelvic muscle function and anatomic abnormalities of the pelvic floor. This study shows that there is an association between major morphological abnormalities of the levator ani (‘avulsion injury or defects’) and poor pelvic floor muscle contractility.

It has previously been shown that pelvic floor contraction can be quantified by transperineal ultrasound [16-18]. The present study demonstrates that it is also possible to perform qualitatively assessment of pelvic floor contraction as being normal or underactive, however with a moderate repeatability. In women with a normal pelvic floor contraction ability the hiatal area was reduced by 25%. This is in concordance with findings reported by Braekken et al. [17]. Women with underactive pelvic floor contraction were able to reduce the hiatal area by only 7%. To date no information has been obtained on normal values of underactive pelvic floor contraction in symptomatic or asymptomatic patients. In the present study the prevalence of poor function of the pelvic floor in a symptomatic population was 56%.

A limitation of current study is that we did not compare our ultrasound findings to those with digital palpation. However Dietz et al. [19] earlier demonstrated in a retrospective study on 1112 women, that there is a significant association between avulsion defects and a reduction in overall contractility ability, as evidenced by the Oxford score and assessed by digital palpation.

Underactive pelvic floor contractility coincided with a higher prevalence of major levator defects in 54% of women versus 16% in women who were able to contract the pelvic floor muscles normally on ultrasonography. This higher prevalence of defects in the group with poorer pelvic floor function is in concordance with a previous study reported by DeLancey et al. [8]. In this MRI imaging study, a case control study of 151 women with prolapse symptoms and 135 normal controls was performed; comparing levator ani muscle defects and pelvic floor function with an instrumental speculum. Women with levator defects generated also significantly less force than women without defects. Another limitation of the present study was that we did not perform a test-retest series for levator defects. However, several studies have shown that major levator defects can be determined with good reproducibility and inter- observer agreement including the first author and others [5, 20, 21].

We found a significant association between faecal incontinence and poor pelvic floor muscle function. Dysfunction of the pelvic floor in patients with faecal incontinence has previously been reported by other studies. Fernandez – Fraga et al. [22] reported reduced levator ani contraction, evaluated with a perineal dynamometer, in patients with faecal incontinence. Bharucha et al. [23] evaluated pelvic floor function with dynamic MRI in 52 patients with idiopathic faecal incontinence (FI) and 21 controls. They found impaired puborectalis function in 56% of patients with puborectalis atrophy. The present study did not focus on puborectalis atrophy and its relation with pelvic floor function. However, in women complaining of faecal incontinence poorer pelvic floor function might explain why pelvic floor muscle training in women complaining of faecal incontinence has been reported to be less successful [24, 25].

Urinary continence in women is believed to rely on intrinsic urethral function and urethra vaginal support [26, 27]. DeLancey et al. [27] recently claimed that poor intrinsic urethral function is the predominant factor associated with stress incontinence, and not the urethral support of the pelvic floor. This hypothesis seems to be supported by findings that morphological abnormalities of the levator ani were not associated with a higher prevalence of stress incontinence [5] and our results that poorer pelvic floor function does not correlate with increase of symptoms of stress incontinence. This is surprising, considering the initial management of stress incontinence involves pelvic floor muscle training. However, recently, it has been concluded that the immediate response to pelvic floor exercises is relatively modest [11, 24], and that initial success is often not sustained at long term follow-up [28, 29].

We performed a retrospective analysis in a selected patient population without a normal case control with several limitations. But, as our findings have been supported by previous studies, we believe that results in the present study could be helpful in selecting women who might or might not benefit from offering them conservative treatment with pelvic floor muscle training for their complaints of pelvic floor dysfunction.

In conclusion, the present study showed that pelvic floor function can be qualitatively assessed on pelvic floor ultrasound. An underactive pelvic floor contraction is associated with an increased prevalence of major abnormalities of the levator ani. There was an association between faecal incontinence and poorer pelvic floor function. However for stress incontinence this association was not depicted.

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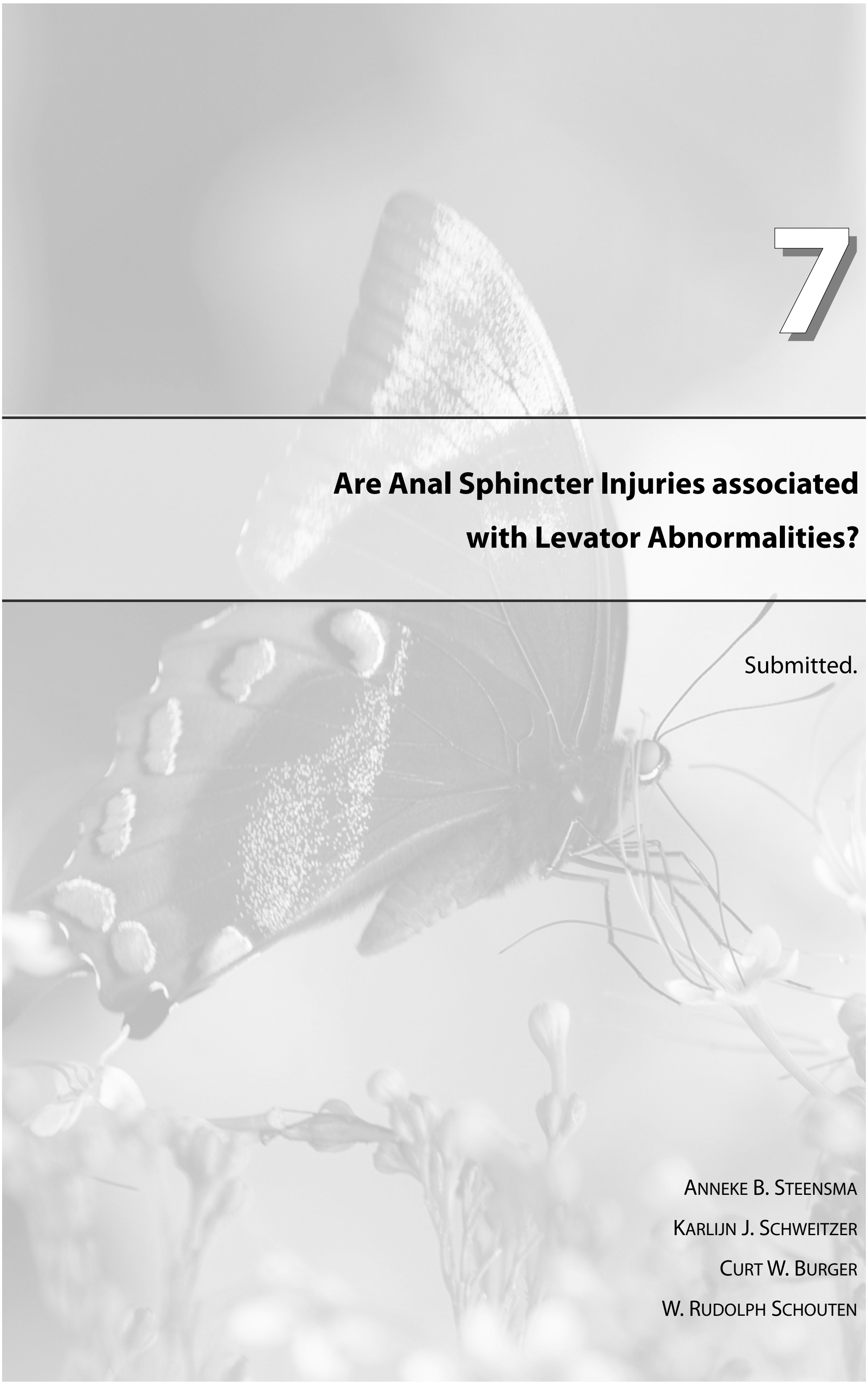

7

Are Anal Sphincter Injuries associated with Levator Abnormalities?

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W. Rudolph Schouten

Abstract

Objective: Extensive damage of the pelvic floor is related to childbirth and consists of anatomical abnormalities such as levator ani defects and/or anal sphincter injuries. Little is known about the association between sphincter injuries and levator defects and their relationship with faecal incontinence (FI). This study investigated the prevalence of both abnormalities in patients with FI.

Methods: In a prospective observational study undertaken at a tertiairy urogynaecological clinic, 373 consecutive women with pelvic floor dysfunction and/or FI underwent a standardized interview, clinical assessment and transperineal ultrasound imaging of the levator ani and anal sphincter complex. Blinded off-line analysis was performed using 4D view software (GE Kretztechnik, Zipf, Autria). Main outcome measures were the association between anal sphincter injuries and major levator defects.

Results: Anal sphincter injuries were found in 22% of patients. Major levator defects were found in 40% of women. Anal sphincter injuries were associated with major levator defects, 58% versus 36% in patients with no defects (P = 0.001). FI was associated with anal sphincter injuries (P= 0.002). In patient with an isolated anal sphincter defect, 53% developed FI; whereas only 39% of women with anal sphincter and levator defects. FI was not associated with major levator defects and with measurements for hiatal dimensions at contraction and valsalva.

Conclusions: Anal sphincter injuries are associated with levator abnormalities. An isolated anal sphincter injury was the most important factor for developing FI. No association was found between FI and major levator defects.

Introduction

Vaginal childbirth may lead to anatomical and neurological damage of the pelvic floor and the anal sphincter complex [1-3]. As a consequence, it may result in symptoms such as urinary incontinence, prolapse and/or faecal incontinence (FI) [4-7].

FI is a socially embarrassing condition and is reported to affect up to 12.6% of the population in the developed world [8]. The prevalence of FI increases with age [9,10].

Third and fourth degree lacerations of the anal sphincter after vaginal delivery, are a known risk factor for the development of FI [1]. As the external anal sphincter is continuous with the puborectalis muscle and both consist of striated muscle, one might assume that trauma of the anal sphincter could be associated with trauma of the levator ani complex [11]. Since both anal sphincter defects and levator abnormalities are related to vaginal delivery, it seems logical to expect that both abnormalities may coexist and could potentially act synergistically in causing symptoms.

3D/4D transperineal ultrasound is a non invasive investigation method, which has been shown to detect levator abnormalities and allow evaluation of defects of the anal sphincter [12,13]. It also provides the opportunity to assess dynamic pelvic floor function. Levator ani abnormalities are associated with anterior and central compartment prolapse [7], but little is known about the correlation between levator defects, pelvic floor function and FI.

Although there has been significant progress in our understanding of the pathophysiology of FI [11], it remains unclear whether disturbances in innervation of the anal sphincter complex, pelvic floor dysfunction, anatomic abnormalities of the anal sphincter complex and/or levator ani muscle contribute to the development of this condition [14]. The present study was conducted to investigate the prevalence of anal sphincter complex defects as well as levator ani abnormalities, in women with pelvic floor dysfunction with or without FI.

Materials and methods

In a prospective observational study, 373 patients with symptoms of pelvic floor dysfunction were referred to our tertiary pelvic floor clinic between October 2006 and July 2008 and included in this study. Our tertiary pelvic floor clinic is specialised in treatment of patients with FI. All patients were interviewed using a standardized questionnaire concerning medical history, urinary function, pelvic discomfort and FI. FI was defined as involuntary loss of liquid or hard stool. A clinical examination was performed according to the International Continence Society guidelines, using the Pelvic-Organ-Prolapse Quantification (POP-Q) system.

After voiding, in supine position a 3D/4D transperineal ultrasound was performed, using a GE Kretz Voluson 730 expert system (GE Healthcare, clinical systems, Hoevelaken, the Netherlands). A transabdominal RAB 4 – 8 MHz transducer was used to investigate the pelvic floor and a microconvex RNA 5 – 9 MHz transducer was used for the anal sphincter complex. Volume datasets were obtained at rest, during levator contraction and maximal valsalva manoeuvre. Off-line analysis was performed using the GE Kretz 4D view 5.0 (GE Healthcare, Kretztechnik, Zipf, Austria) software by investigators who were blinded against clinical data.

Measurements were performed at the level of minimal hiatal dimension, using the inferior margin of the symphysis pubis as reference point in 2D and 3D datasets as described by Dietz et al [15,16]. Avulsion injury or defects of the levator ani complex were defined as a detachment of the levator ani at the anteromedial attachment of the pubic bone. For evaluating defects, tomographic ultrasound imaging (TUI) was used with an interslice interval of 2.5 mm [17]. A score of 0 was used if there were no defects on either side and a total score of 16 indicated a complete bilateral avulsion. The TUI evaluation was performed by one investigator (ABS). A major levator defect was defined as a TUI score of 8 for unilateral defects and/or 16 for bilateral defects [17]. Volume Contrast static Imaging (VCI) with a slice thickness of 2 mm was used to analyse the anal sphincter complex. Volume datasets were rotated for a cross sectional (transverse) view of the anal sphincter in the A (transverse) plane and longitudinal views in the B (coronal) and C (axial) plane as previously described by Yagel et al [13] (Figure 1). A sphincter injury (SI) was defined as if there was a history of third or fourth degree anal sphincter tear and/or a sphincter defect on ultrasound. Anal sphincter defect (ASD) was defined as an interruption of the external and/or internal anal sphincter (Figure 2) as seen on ultrasound.

Statistical analysis was performed using SPSS 15.0 (SPSS Inc., Chicago, USA). Pearson Chi-square and Student t-tests were used for comparison of normally distributed data; the Mann-Whitney U test (two- sided) was used for non-parametric data. A P value below 0.05 was considered statistically significant.

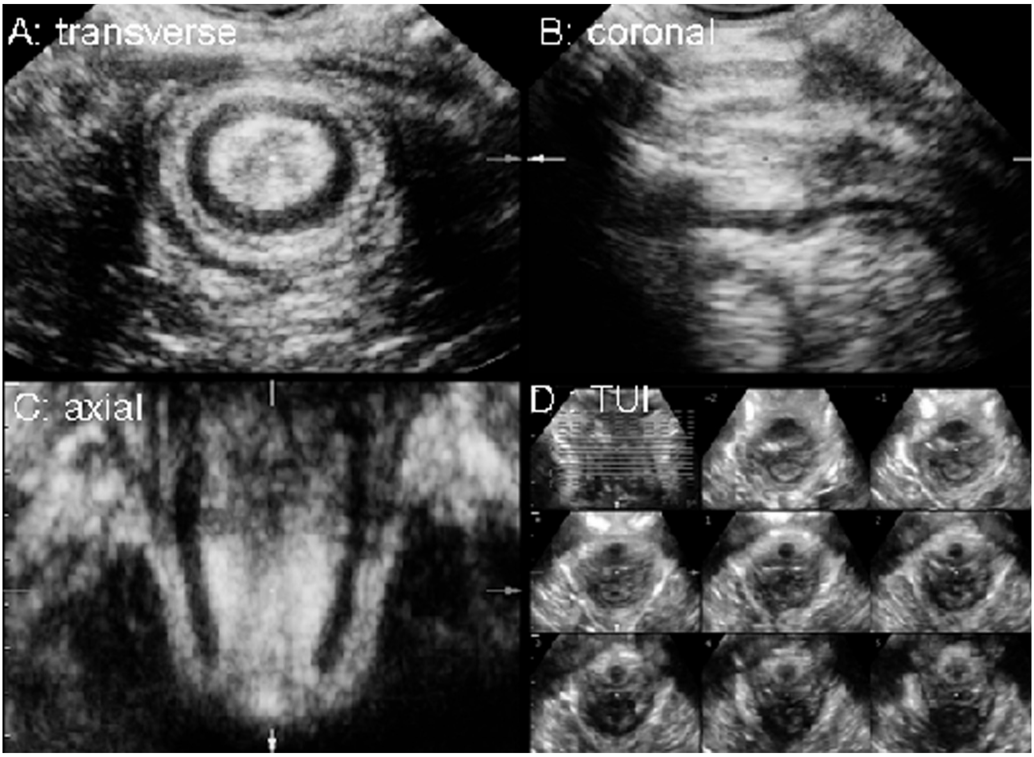

***Figure 1**: Transperineal imaging of the anal sphincter with VCI static with a slice thickness of 2 mm. A: transverse plane (cross sectional view). B and C: longitudinal view. D: TUI of a normal levator ani of the same patient.*

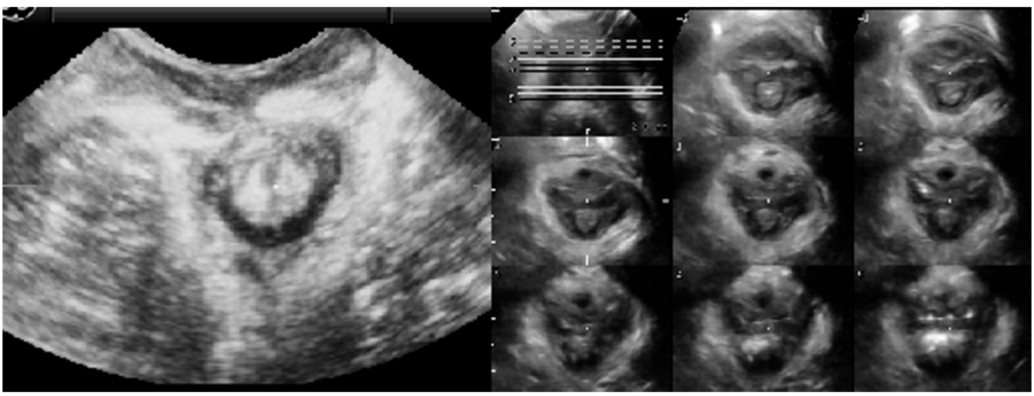

***Figure 2**: Patient (29 yr) complaining of faecal incontinence and with an obvious external and anal sphincter defect on the left of the image. On the right, the levator ani muscle with a partial defect on patient's left side is shown. The TUI Score for patient's right is 0, for the patient's left is 4.*

Results

Three hundred and seventy three patients were eligible for inclusion in this study. Nineteen datasets were excluded due to inconclusive or poor imaging of the anal sphincter. Nine of these patients complained of FI. Complete datasets were available for 354 patients. Demographic data are shown in table 1. FI was found in 30% (n = 105); 48% of whom also had urinary incontinence.

Seventy-six patients (22%) were defined as having an anal SI. An ASD and a history of a previous third or fourth degree tear was found in 36 patients, an ASD without a history of previous tear in 20 patients and finally, in 20 patients no ASD was found on ultrasound but these patients reported a history of previous anal sphincter tear (Figure 3). Of these 56 patients' women with ASD on ultrasound, 41 patients had both internal and external anal defects. One patient had an isolated internal ASD and 14 had an isolated external anal sphincter defect. Amongst the 76 patients with a SI, 34 (45%) complained of FI. SI was associated with younger maternal age as well as increased maternal age at the first delivery but not with birth weight or instrumental delivery (Table 2).

Anal SI were associated with major levator abnormalities; 58% in women with anal SI versus 36% in women without anal SI (P = 0.001). The median TUI score in women with anal SI was 8.0 versus 0.0 respectively (P < 0.004). Major levator defects (n = 143) were depicted in 40%

Tabel 1*: Patients demographics (n = 353)*

Age	52.2	(22 - 83)
Parity	2.0	(0 - 10)
Urinary symptoms	47 %	(166)
Faecal incontinence	30%	(105)
Prolapse symptoms	33%	(119)
Obstructed defecation	18.5%	(46)
Hysterectomy	8.8%	(31)
Prolapse surgery	10.2%	(36)
Previous 3rd 4th degree tear	15.8%	(56)
Sphincteroplasy	2.2%	(7)
Fistula surgery	0.9%	(3)
Clinical prolapse (POP Q > 2)	53.5%	(177)

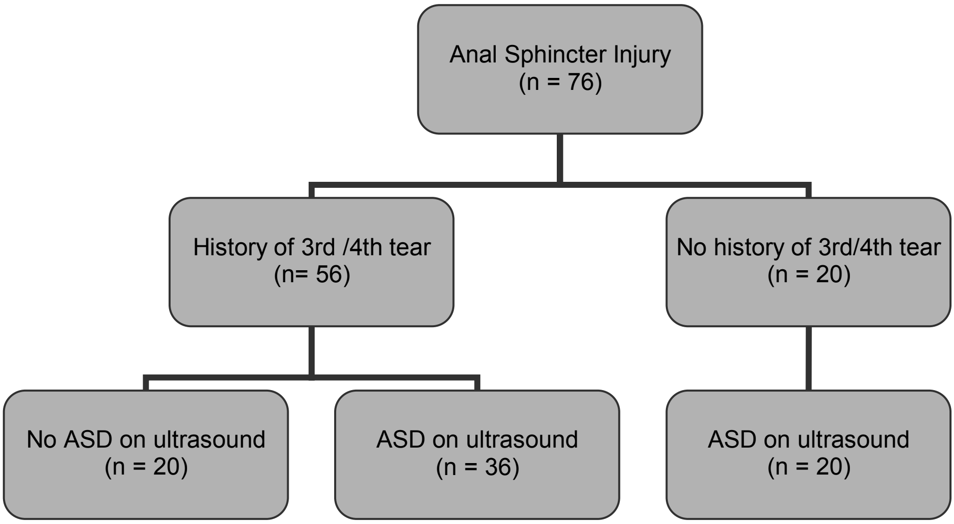

Figure 3: *Flow chart of patients with an anal sphincter injury (ASD = anal sphincter defect, US = ultrasound).*

of all cases. These defects were unilateral in 72 patients (35 on the right and 37 on the left) and bilateral in 71 patients.

FI was associated with an anal SI (P = 0.002) and higher fetal birth weight (P = 0.04). For the aetiology of FI, 53% of the patients with only an isolated anal SI did develop symptoms of FI versus 39% of women with both an anal SI and major levator defects (Figure 4). FI was not associated with major levator defects and also not with current age, age at first delivery and instrumental delivery (Table 3). Hiatal measurements of the levator ani at rest, during contraction and at valsalva for the antero-posterior dimension, the left-right dimension or the hiatal area of the levator ani for evaluation of pelvic floor function did not show any significant differences in women with or without FI.

Table 2*: Comparison of patients with and without anal sphincter injury*

	sfincter injury (n= 76)		no injury (n = 278)		P
Age(mean, (SD))	45,7	(± 13,8)	54	(± 13,1)	< 0.0001
Age 1st delivery (mean, (SD))	27,3	(± 4,5)	25.1	(± 5,0)	0,001
Birth weigth (mean, (SD))	3740	(± 575)	3620	(± 590)	ns
Instrumental delivery (%, n)	21,1%	(16)	12,9 %	(36)	ns
Major defect (%, n)	57,9%	(44)	35,6%	(99)	0,0001
TUI tot (median, range)	8.0	(0 - 16	0	(0 - 16)	< 0.0001

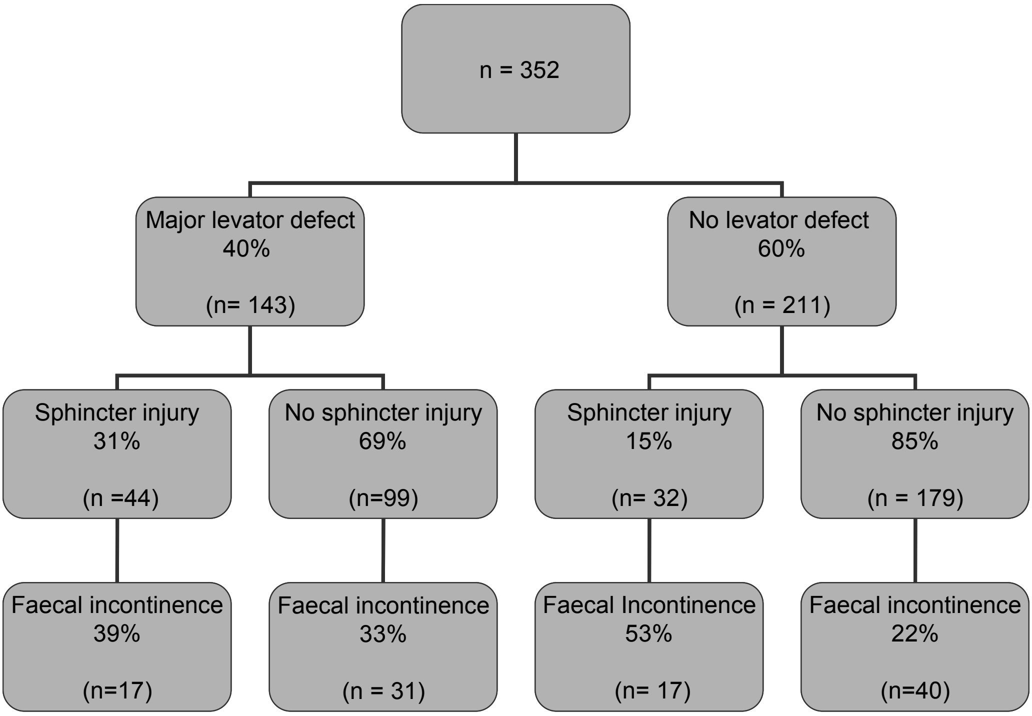

***Figure 4**: Flow chart demonstrates existence and coexistence of anal sphincters and/or levator defects for the aetiology of faecal incontinence.*

***Table 3**: Comparison of patients with and without faecal incontinence.*

	faecal incontinence (n= 105)		**no faecal incontinence (n = 249)**		**P**
Age (mean, (SD))	52,7	(± 12.7)	51,9	(± 14)	ns
Age 1st vaginal delivery (mean, (SD))	25,1	(± 4,2)	25,9	(± 5.2)	ns
Birth weight (mean, (SD))	3760	(± 635)	3600	(± 565)	0.04
Instrumental delivery(%, (n)	18.1%	(19)	13.3%	(33)	ns
Incontinence of gas (%, (n)	64.8%	(68)	44.6%	(111)	0.001
Sphincter injury (%, (n))	42.8%	(34)	16,9	(42)	0.002
Levator defect (%, (n))	45.7%	(49)	38.1%	(95)	ns

Discussion

This study investigates ASD and levator ani abnormalities visualized with TUI of patients complaining of symptoms of FI, urinary incontinence and prolapse. Anal SI are associated with major levator defects and developing FI but, contrary to the expectations, levator defects were not associated with FI.

In this study, we found a 22% prevalence of SI. Our prevalence of obstetric sphincter defects after delivery (OASIS) is somewhat lower than the estimated prevalence in a meta-analysis reported by Oberwalder et al, who estimated that after vaginal delivery, 27% of primiparous women and 33% of multiparous women have an anal sphincter damage [18]. A potential confounder in comparison with other studies is the relatively low age of our population (mean 52 years). This is likely due to the fact that we provide tertiary care, including sacral neuromodulation at our centre and we are therefore bound to see younger women referred for such treatment. Another explanation could be that other known risk factors for OASIS, such as instrumental forceps delivery and midline episiotomy, are not commonly performed in the Netherlands [19,20].

To date, no studies have been reported in the literature investigating transperineal imaging of the anal sphincter versus endoanal ultrasound imaging and/or MRI imaging of the anal sphincter. Translabial ultrasound imaging have shown to be able to detect ASD with a good interobserver reliability of 0.8 [21]. Both endoanal ultrasound imaging and MRI have also proven to be able to detect ASD [22,23] with a good reproducibility [24]. Both MRI and 3D/4D transperineal ultrasound have the advantage to visualise levator ani defects [2,12]. Major levator defects have been determined with good interobserver agreement by the first author and others [12,25,26]. Several studies have investigated the prevalence of ASD and levator abnormalities, using MRI imaging. The prevalence of 58% of major levator defects in patients with an ASD in the current study is in concordance with the prevalence of 62% found in women with an anal sphincter injury 9 to 12 months post first delivery by Kearney et al [27]. Terra et al [4] found a somewhat lower prevalence of 35% in a selected patient population of 105 women complaining of severe FI. The latter study also reported that an isolated ASD, in the majority of cases, was the most important factor contributing to FI similar to our findings and others [1,3,11,21,28,29].

A limitation of our study is that we did not use any validated questionnaire for evaluation of FI. The present study was an observational study of patients complaining of a variety of pelvic floor disorders and included patients having FI only with severe incontinence according to Parks score 3 and 4. However in the present study a prevalence of 45% was found for developing FI in patients with an anal sphincter injury which is in concordance with previous studies using a variety of questionnaires assessing FI (range of 20 – 47%) [30-34].

It is peculiar that we did not observe an association between levator trauma and FI, considering that the puborectalis muscle has long been regarded as important for anal continence due to its effect on the anorectal angle. FI relies on multiple factors and other important factors include an intact sensory and motor innervation of the sphincter complex [11,28]. A limitation of the present study is that we did not focus on atrophy of the anal sphincter and/or levator suggested to be an indication for denervation of the pelvic floor [4]. For the dynamic evaluation of the pelvic floor muscle function of our patients, we instructed them to perform a pelvic floor contraction and a valsalva manoeuvre. Our results did not show any significant differences in pelvic floor contraction and valsalva between both groups. Fernandez – Fraga et al [35] reported reduced levator ani contraction, evaluated with a perineal dynamometer, in patients with FI. An explanation for the findings in this study might be that we compared our incontinent patients with cases having pelvic floor symptoms rather than with normal controls. These patients already have a higher prevalence of levator ani abnormalities [5,7] and these abnormalities are associated with poorer function of the pelvic floor [36]. This also might be the reason that in this study no association was found for the prevalence of major levator defects in patients with and without FI.

As a conclusion, this study showed that anal sphincter injuries are associated with levator abnormalities. However, an isolated anal SI is the most important factor for developing symptoms of FI; and having both anal SI and levator defects showed to be of less importance. No association was found between FI and major levator defects.

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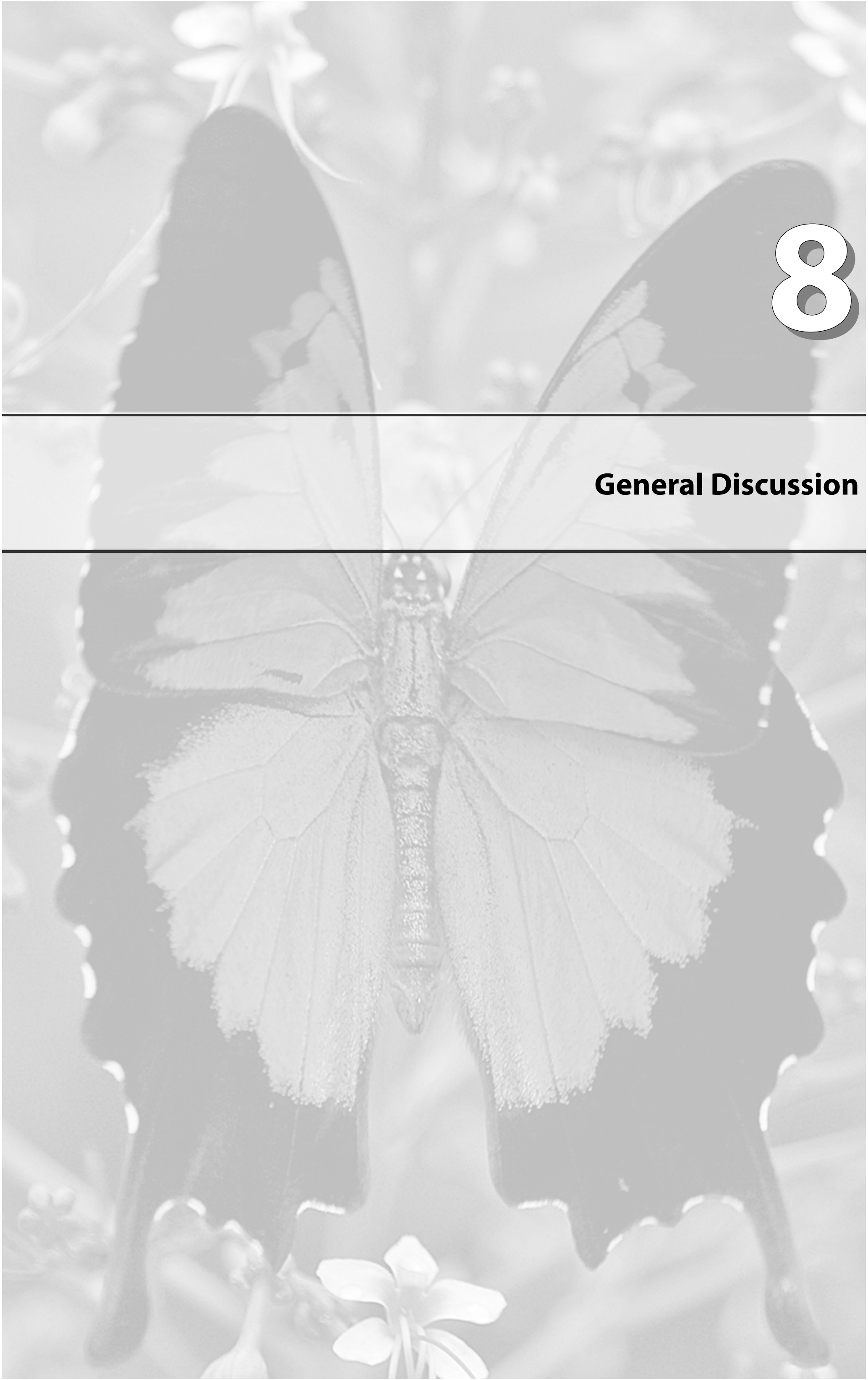

8

General Discussion

General discussion

Pelvic floor disorders affect a substantial proportion of women worldwide. In the literature estimated prevalence data vary widely depending how the condition is specified. Prevalence data for urinary incontinence vary from 24% to 45% [1-3], for faecal incontinence from 2.2% to 24% [4-6] and for prolapse from 3 to 11% [3, 7].

The prevalence of these conditions will increase with age from 10% under the age of 39 to 50% or higher at the age of 80 and older [3]. By 2030 more than one fifth of women will be 65 years or older [8], contributing to a much higher percentage of women that will need treatment for pelvic floor symptoms.

In 1997 Olsen et al reported [9] an estimated lifetime risk of 11% for American women to undergo at least one operation for urinary incontinence and/or pelvic organ prolapse. Recurrence rates are quoted at up to 30% [9-11]. This implies that in an ageing population urogynaecological problems will increase in prevalence. Prevention of pelvic floor disorders may become highly desirable.

In most gynaecological practices ultrasound systems are commonly available and used for gynaecological and obstetrical diagnosis and treatment. For assessment of urogynaecological symptoms however imaging techniques such as ultrasound, evacuation proctography and/or MRI are not part of daily routine practice. Assessment of pelvic floor disorders is usually performed by clinical examination only, using semi- quantitative methods such as the Baden-Walker or ICS Pelvic Organ Prolapse-Qualification system (POP-Q)[12, 13]. These methods quantify the prolapse into four stages depending on severity. However, in peer-reviewed literature non-standardized staging system are used in 50% [14]. The disadvantage of clinical examination that its only provides information on surface anatomy, without actually assessing pelvic floor structural anatomy and function. This might partly explain why about 30% of women will require procedures for recurrent prolapse or urinary incontinence. Ultrasound imaging allows the investigator to perform a non invasive objective investigation of structural pelvic floor anatomy and allows the operator to correct for pelvic floor co-activation, involuntary urinary loss, loss of flatus or stool. It also provides visual feedback which is a clear advantage for patients learning to activate or relax their pelvic floor muscles. This thesis explains why ultrasound may help improve surgical outcomes by allowing better diagnosis of with pelvic floor disorders.

Even when it comes to simply diagnosing maximum extent of prolapse, clinical examination alone often results in false negative findings which might have impact on surgical treatment, as shown in chapter 2. In 112 women with a rectocele on clinical examination only 56% showed a true rectovaginal septal defect by translabial ultrasound. In 3% an isolated enterocele was found and in 7% perineal hypermobility and 34% of the women had no fascial defect on ultrasound investigation. If ultrasound had not been performed before surgery, 44% of these women might have been treated with an inappropriate surgical procedure. To date, evacuation proctography has been the gold standard investigation for abnormalities of the posterior vaginal compartment. In chapter 3 we investigated the level of agreement between transperineal ultrasonography and evacuation proctography for diagnosing anatomic abnormalities of the posterior compartment. We found a good level of agreement between both methods for detecting clinical relevant enterocele and rectocele. Our findings were comparable with other investigations using the same methodology [15-17]. Not surprisingly the ultrasound examination was much better tolerated than evacuation proctography. The results of both studies imply that transperineal ultrasound may be utilized as a first-line, non invasive imaging technique for the evaluation of posterior compartment symptoms. In the future findings on ultrasound need to be correlated with intra-operative findings and success of treatment. It is likely that the width and depth of a rectovaginal defect and maximal descent of rectocele contents is of importance for the result of prolapse repair.

Clearly, the integrity of supporting structures such as the pubovisceral part (puborectalis muscle and pubococcygeus muscle) of the levator ani are important factors for pelvic organ support. Disruption of this muscle can lead to prolapse and excessive distensibility of the levator hiatus as shown in chapter 4 and 5. With the introduction of 3D/4D ultrasound we are able to visualize the levator ani in the axial plane and to measure dimensions and distensibility of the levator hiatus. Chapter 5 describes how 'normality' for hiatal area was determined using symptoms and signs of prolapse in 544 symptomatic women. Significant correlations were found for symptoms of prolapse and pelvic floor descent of all three compartments (anterior, central and posterior) as measured by ultrasound. Based on Receiver Operator characteristics Curves, a cut off value of ≥ 25 cm2 was suggested for the definition of abnormal or 'ballooning' of the levator hiatus. Severe ballooning of the hiatus was defined as a hiatal area of ≥40 cm2. These findings imply that distensiblity of the levator hiatus predisposes to female pelvic organ prolapse and may also influence recurrence rate after surgery.

For developing excessive distensibility, major levator ani defects seem to be the main environmentally determined factor. The prevalence of major levator ani defects detected with 3D transperineal ultrasound in 338 urogynaecological patients was investigated in chapter

4.

An excellent agreement of a Cohen's kappa of 0.83 between the two authors was found for the detection of levator defects. Such defects were found in 15.4% of all patients and were clearly associated with childbirth, as they only occurred in women delivered vaginally. Defects ('avulsion injury') were visualized anteromedially as a detachment of the levator ani off the pubic bone, as detected in imaging studies using MRI [18]. Levator defects in this study were associated with prolapse of the anterior and central compartment.

Surprisingly, levator defects were not related to symptoms of bladder dysfunction or urodynamic findings, as outlined in chapter 4. These finding were confirmed in chapter 6 as well as in other studies [19]. In Chapter 6 pelvic floor integrity was correlated with pelvic floor function in 335 symptomatic patients. We subjectively scored pelvic floor contractions as observed on ultrasound as underactive (absent or weak) and normal (normal or strong) and correlated these findings with objective dimensions of the levator hiatus in 2D and 3D volumes in 353 patients. Levator defects were strongly associated with poorer function on ultrasound. Our findings are comparable with those of a study investigating prevalence of defects in symptomatic patients versus normal controls [20]. This is surprising in view of the fact that the initial management of stress incontinence involves pelvic floor muscle training. It is generally assumed that urinary incontinence may be due to weak or damaged pelvic floor muscles. However, recently, it has been concluded that the immediate response to pelvic floor exercises is relatively modest [21, 22], and that initial success is often not sustained at long term follow up [23, 24]. Further research is warranted to investigate whether levator defects and/or poor function of the pelvic floor muscles will influence the success of conservative treatment in the short or long term.

For patients complaining of faecal incontinence however, a significant association with an underactive contraction of the pelvic floor was found. Underactive contraction on ultrasound was significantly correlated with symptoms of faecal incontinence suggesting that pelvic floor function is of importance for developing faecal incontinence. In chapter 7 we investigated the prevalence of anal sphincter injuries and the association of such trauma with avulsion injury of the levator ani in 354 symptomatic patients, and the relation of both with faecal incontinence. Transperineal ultrasound can also be utilized for the visualizing the anal sphincter complex. A prevalence of 22% for external anal sphincter injuries was found in this population, and levator defects were significantly associated with anal sphincter injuries. Major levator defects were detected in 40% of women, but rather surprisingly they were not associated with faecal incontinence. Clearly, anal sphincter trauma plays the main role in the aetiology of anal incontinence, and these findings were consistent with other reported results [25-30]. Further research is warranted to investigate if poor function of the pelvic floor simultaneously has an impact on the outcome of conservative and/or surgical treatment.

This thesis demonstrates that ultrasound imaging of the pelvic floor is able to detect a number of structural anatomic abnormalities. Still prevalence of these findings in asymptomatic patients are lacking and will need further evaluation. Future research assessing anatomical fascial defects preoperatively hopefully improves treatment outcome after surgical procedures and reduce re-operation for prolapse

Probably the most important finding of the research performed for this thesis was the finding that levator ani defects occurred after vaginal childbirth, may well be the 'missing link' between childbirth and developing pelvic organ prolpase. As attempts to date have been unsuccessful in fixing levator defects [31], there is a clear need to focus on preventing trauma to the pelvic floor. Levator ani defects are associated with higher maternal age at first delivery. An instrumental delivery subsequently will increase this risk two fold [32]. With increasing maternal age at first delivery, obstetricians need to be aware of the higher risk of levator ani trauma in these women. Recent investigations have shown that it may be feasible to predict emergency operative delivery [33]. Further research is necessary to corroborate these findings. It may even become possible to perform a risk assessment for major pelvic floor trauma, contributing to the prevention of pelvic organ prolapse.

In summary, ultrasound imaging of the pelvic floor can detect a number of clinically highly relevant structural anatomical abnormalities of pelvic floor components as well as abnormal function. Such findings may in future allow better treatment of pelvic floor disorders and likely also play an important role in prevention.

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Summary

Samenvatting

Summary

Transperineal ultrasound is a non-invasive investigational method for evaluating pelvic floor disorders. It can be used for the assessment of pelvic floor function, biofeedback, to correlate clinical symptoms with anatomic (ab)normalities such as female pelvic organ prolapse, and for basic research.

Chapter 1

In Chapter 1 an overview of Transperineal Imaging of the pelvic floor is presented. The chapter describes 2D and 3D ultrasound evaluation of the pelvic floor. On 2D ultrasonography it includes an quantative analysis of female pelvic organ prolapse (POP-Q) with ultrasonography, levator contraction and bladder neck descent. The appearance of prolapse of the anterior, central and posterior compartment is described on 2D ultrasound with imaging of a cystocele, enterocele, anterior- and posterior rectocele, rectal intussusception and rectal prolapse. In 3D ultrasonography the normal 3D muscle levator ani anatomy is described as well as the abnormal anatomic visualization of the levator ani, described as levator ani defects or avulsions. For quantification of these defects the tomographic ultrasound imaging (TUI) technique is described and also the method for analysis of the measurements of the levator ani hiatal dimensions. Imaging of the normal and abnormal anal sphincter complex with 3Dtransperineal ultrasound concludes this chapter.

Chapter 2

Rectocele, defined as a fascial defect in the rectovaginal septum, is traditionally regarded as the archetypal traumatic pelvic floor lesion. It is assumed that this defect is a result of childbirth but they also do exist in nulliparous women. Different entities may cause the impression of a rectocele. Posterior compartment prolapse may be due to perineal hypermobility, isolated enterocele or a true rectocele due to a rectovaginal septal defect.

In Chapter 2 207 patients attending an urogynaecological clinic for evaluating prolapse symptoms were evaluated. The prevalence of these different entities of the posterior compartment was determined using transperineal ultrasound after patients were clinically examined.

Of all patients a true defect of the rectovaginal septum was observed sonographically in 78 women (39%). There was a significant relationship between all ultrasound data and clinical grading (all P<0.001) A test-retest series conducted by the authors yielded a Cohen's kappa of 0.72 for the diagnosis of a defect of the rectovaginal septum.

A rectocele was clinically diagnosed in 112 patients (56%). Of these 112 clinical rectoceles, 63 women (56%) showed a fascial defect, eight (7%) showed perineal hypermobility without fascial defect. In the 16 women with a diagnosis of enterocele 11 also had a rectocele. In 3% an isolated enterocele was detected. In 38 women (34%), no sonographic abnormalities were depicted. The presence of a rectovaginal fascial defect was associated with age but not with parity.

Chapter 3

Since posterior compartment prolapse is often managed surgically it is of importance for the patient to be able to differentiate between the different anatomic abnormalities as described above. Evacuation proctography (EP). has been claimed to be the gold standard investigation for objective evaluation of posterior compartment anatomical abnormalities This investigation is invasive, of limited availability, and it requires exposure to ionizing radiation. Transperineal ultrasound is considered to be a less invasive investigation

In chapter 3 the level of agreement is described between evacuation proctography and transperineal ultrasound for detecting abnormalities of the posterior compartment. A prospective observational study was conducted in 75 patients with symptoms related to the posterior compartment. The Cohen's kappa was used for level of agreement. All patients underwent a standardized interview, clinical examinations, transperineal ultrasound and EP with opafication of the rectosigmoid, small bowel and vagina. After both exams patients received a standardized questionnaire concerning patients' experience with a response rate of 85%. Both exams were offline blinded analysed graded and quantificated by two experienced investigators. Grade 2 and 3 entero and rectocele were considered to be of clinical relevance.

For detecting enteroceles (gr 2,3) a good Cohen's kappa index of 0.77 was found. A sensitivity of 64% and a specificity of 96% was found for the detection of all enteroceles with 3D ultrasound. For rectocele (gr 2,3) the level of correlation was good (k = 0.60). Diagnosing all rectoceles with 3D ultrasound revealed a sensitivity of 78% and a specificity of 77%. The level of correlation for the detection of intussusception (gr 1,2) was fair (k = 0.21), and showed a sensitivity and specificity of 22% and 96% respectively. The majority of patients (87%) indicated EP as the less well tolerated examination, in 8% the 3D transperineal ultrasound was less tolerated (P< 0.001).

Chapter 4

Morphologic abnormalities of the pelvic floor to date mainly have been described on Magnetic Resonance Imaging (MRI). They were however first reported in the early 1940's by Howard Gainey, a Kansas obstetrician, who detected these abnormalities by palpation. While MRI imaging is costly and not generally available, this modality has mostly been employed for the investigation of only small series of patients. Transperineal ultrasound is a much more accessible method and as a result of advances in ultrasound technology it has become possible to demonstrate major levator abnormalities using the 3D/4D ultrasonography.

Chapter 4 describes the prevalence of major abnormalities detected with transperineal ultrasound and its relationship with clinical symptoms. A prospective observational study was performed of 338 urogynaecological patients. All patients were referred for urodynamic assessment for evaluation of their complaints. After a standardized interview concerning bladder, prolapse and bowel symptoms a transperineal ultrasound was performed. Major levator ani abnormalities were depicted in the rendered axial volume. A levator avulsion was diagnosed if there was an obvious detachment of the levator ani mucle anteromedial of its insertion of the pubic bone. These defects occurred either unilateral or bilateral.

Major levator defects were found in 46 of all vaginally parous women (15.4%) and none in women who only had delivered by caesarean section. A test-retest series conducted by the authors showed an excellent level of agreement of a Cohen's kappa of 0.83. Levator avulsions were associated with anterior and central compartment prolapse (P < 0.001). No associaton was found for symptoms of bladder dysfunction or urodynamic findings as stress or urge incontinence.

Chapter 5

The levator ani muscle is of clinical importance for support of the pelvic organs. Trauma to the levator ani seems to predispose women to pelvic organ prolapse. It is likely that levator trauma represents the 'missing link' between childbirth and developing pelvic organ prolapse.

In Chapter 5 'normality' for the parameter 'hiatal area on Valsalva' of the levator ani is assessed and the relationship with pelvic floor symptoms and prolapse. A retrospective observational study was performed in 544 women referred to a tertiair urogynecological unit for symptoms of pelvic floor and/or urinary tract dysfunction. All patients had given a medical history and undergone clinical examination for prolapse according the International Continence Society (ICS) pelvic organ quantification (POP-Q) grading. Significant prolapse was defined as a prolapse POP-Q grade 2 or higher. A 3D/4D ultrasound was performed for analysis of levator integrity and dimensions of the levator hiatal area.

171 Patients did have complaints of prolapse symptoms (32%). Prolapse symptoms were significantly associated with pelvic organ descent on clinical examination as well on ultrasound (all $P< 0.001$). A strong significant relationship between reported symptoms of prolapse and hiatal dimensions both at rest and on Valsalva was found for all three compartments (all $P < 0.001$).

A cut off value for hiatal area of 25 cm^2 on Valsalva yielded a sensitivity of 0.52 and a specifity of 0.83 for detecting significant prolapse (POP-Q ≥ 2) as diagnosed on clinical examination. The cut off value of ≥ 25 cm^2 was proposed to be used for abnormal distensibility or 'ballooning'. A hiatal area on Valsalva of 25 - 29.9 cm^2 was then defined as mild, 30 – 34.9 cm2 as moderate, 35 – 39.9 cm^2 as marked and a hiatus area of ≥ 40 cm^2 as severe ballooning.

Chapter 6

Contractility of the pelvic floor may play an important role in sustaining urinary and faecal continence and/or preventing pelvic organ prolapse. Appropriate contraction and relaxation result in optimal pelvic floor support and function. It is thought that damage to the levator ani muscle may lead to abnormal function and secondarily to symptoms such as urine incontinence, prolapse, and faecal incontinence.

In Chapter 6 a retrospective study was performed in 335 symptomatic patients referred to two tertiairy pelvic floor clinics. The aim of this study was to evaluate the prevalence of major levator abnormalities in women with an underactive versus a normal pelvic floor contraction and the relationship with symptoms. After a standardized interview a 3D/4D pelvic floor ultrasound examination was performed. Subjective evaluation of the best contraction in each dataset was then analyzed of each patient. The pelvic floor contraction was scored according the ICS standardisation as absent, weak, normal or strong. An underactive pelvic floor muscle contraction was defined as an absent or weak contraction. A normal contraction was defined as a subjectively scored normal or strong contraction on ultrasonography. Pelvic floor muscle contraction was then quantified via calculation of the percentage difference (value A rest – value A contraction) / value A rest) for all dimensions of the levator hiatus in the 2D and 3D volumes obtained on ultrasound. For quantification of major morphological levator abnormalites tomographic ultrasound imaging was used.

An underactive pelvic floor contraction was diagnosed in 186 patients (55.5%). A test retest series conducted for the subjective evaluation of contraction, between the first two authors, yielded a Cohen's kappa of 0.55. Major morphological levator abnormalities were found in 100 women with an underactive pelvic floor contraction (53.8%). In women with a normal contraction, only in 24 patients (16.1%) major levator abnormalities were detected ($P<0.001$).

An underactive contraction was associated with a reduction of hiatal area of only 7% versus 25% in the normal group ($P<0.001$). There was an association between faecal incontinence and poor pelvic floor function but this association was not depicted for patients complaining of stress incontinence.

Chapter 7

Extensive damage to the pelvic floor is related to childbirth and consists of anatomical abnormalities such as levator defects and/or anal sphincter injuries. As the external anal sphincter is continuous with the puborectalis muscle and both are striated muscle, there might be an association between trauma to the anal sphincter and trauma to the levator ani causing symptoms of faecal incontinence.

In Chapter 7 373 patients with pelvic floor symptoms were prospectively evaluated. This study is focusing on investigating the prevalence of anal sphincter injury as well as major levator abnormalities. And furthermore this study focused on their relationship with pelvic floor dysfunction, in essence for developing faecal incontinence. Faecal incontinence was defined as involuntary loss of soft or hard stool. All patients underwent a standardized interview and a transperineal ultrasound for evaluating the integrity of the levator ani and anal sphincter.

Anal sphincter injury was diagnosed if there was a defect on ultrasound depicted in the external or internal anal sphincter and/or a history of a previous 3rd of 4th degree anal sphincter tear. For quantification of levator defects tomographic ultrasound imaging was used.

Faecal incontinence was present in 105 patients (30%). Anal sphincter injuries existed in 77 patients (22%). A significant association between anal sphincter injuries and developing faecal incontinence was detected (P = 0.002). Major levator defects were found in 143 patients (40%). Patients with an anal sphincter injury were in 58% diagnosed with also major levator abnormalities whereas in patients with no anal defects major abnormalities were detected in only 36% (P = 0.001). No correlation was found for faecal incontinence and major levator defects.

For the aetiology of faecal incontinence an isolated anal sphincter injury was depicted to be the most important factor, and having both anal sphincter injury and levator abnormalities showed to be of less importance. In addition, faecal incontinence was associated with fetal birthweight, but not with age, instrumental delivery and measurements for hiatal dimensions.

Chapter 8

The general discussion emphasis the importance using transperineal ultrasound imaging for evaluation, treatment and prevention of pelvic organ prolapse, incontinence and pelvic floor (dys) function.

Samenvatting

Transperineale echografie is een non-invasieve methode die gebruikt kan worden voor onderzoek naar afwijkingen van de bekkenbodem.

De methode kan worden gebruikt voor de beoordeling van de bekkenbodemfunctie en voor biofeedback tijdens het onderzoek. Daarnaast kunnen anatomische afwijkingen worden gecorreleerd met klinische symptomen zoals verzakkingen van de blaas, baarmoeder of dikke en of dunne darm. Ook voor het verrichten van epidemiologisch en fundamenteel onderzoek van bekkenbodem pathologie is transperineale echografie een bruikbare methode.

Hoofdstuk 1

In hoofdstuk 1 wordt een overzicht gepresenteerd van transperineale echografie van de bekkenbodem. Het hoofdstuk beschrijft de 2D en 3D echografische evaluatie van de bekkenbodem. Met 2D echografisch onderzoek wordt de kwantificering van bekkenbodem-verzakkingen volgens de POP-Q met behulp van echografie beschreven, evenals de contractiekracht van de musculus levator ani, de belangrijke bekkenbodemspier en de mobiliteit van de blaashals. Verzakkingen van het voorste, middelste en achterste compartiment, zoals een verzakking van de blaas, een enterocele, voorste en achterste rectocele, rectale intussusceptie en rectumprolaps kunnen met deze diagnostische methode worden onderzocht. Met de 3D echografie wordt eerst de normale en vervolgens de afwijkende anatomie van de levator ani beschreven. Bij afwijkende anatomie wordt met name gedacht aan levator ani-defecten of -avulsies. Ter kwantificering van deze afwijkingen wordt de zogenaamde tomographic ultrasound imaging (TUI) techniek beschreven en ook de methode voor het analyseren van de afmetingen van de levator ani hiatus. Tot slot wordt beschreven hoe de normale en abnormale anale sfincter zich laat afbeelden op 3D transperineale echografie.

Hoofdstuk 2

Een rectocele wordt gedefinieerd als een defect in de fascie van het rectovaginale septum. Dit defect wordt traditioneel beschouwd als het archetype trauma van bekkenbodemafwijkingen. In het algemeen wordt er van uitgegaan dat dit defect een gevolg is van een vaginale bevalling, maar ze worden ook beschreven in nullipare vrouwen Verschillende entiteiten kunnen de indruk geven van een rectocele. Een achterste-compartimentprolaps kan zijn veroorzaakt door perineale hypermobiliteit, een geïsoleerde enterocele of een echte rectocele met een rectovaginaal fascie defect.

In hoofdstuk 2 worden de bevindingen van 207 patiënten die zijn verwezen naar een urogynaecologische kliniek beschreven. In deze populatie werd de prevalentie van deze verschillende entiteiten van het achterste compartiment met behulp van transperineale echografie vastgesteld nadat er klinisch onderzoek had plaatsgevonden voor evaluatie van hun verzakkingsklachten.

In 78 patiënten werd er echografisch een anatomisch fascie defect gevonden (39%). Er was een significante relatie tussen echografisch gevonden afwijkingen en gradering van de rectocele bij klinisch onderzoek (allen $P< 0.001$). Een test-retest onderzoek tussen de twee auteurs voor het vaststellen van een fascie defect toonde een goede Cohen's kappa waarde van 0.72.

Een rectocele werd klinisch gediagnosticeerd in 112 patiënten (56%). Van de 112 klinische rectoceles hadden er 63 patiënten (56%) een rectovaginaal fasciedefect. Er bleek bij acht patiënten (7%) een perineale hypermobiliteit aanwezig te zijn zonder een fasciedefect. Van de 16 patiënten met een enterocele werd bij 11 patiënten ook een rectocele gezien. In 3% van de patiënten werd een geïsoleerde enterocele gediagnosticeerd. Bij 38 patiënten (34%) werden geen echografische afwijkingen geconstateerd. De aanwezigheid van een rectovaginaal fasciedefect was geassocieerd met de leeftijd van de patiënt, maar niet met pariteit.

Hoofdstuk 3

Het achterste-compartimentdefect wordt vaak operatief wordt behandeld. Daarom is het van belang voor de patiënt om onderscheid te kunnen maken tussen de tussen de verschillende anatomische afwijkingen zoals in hoofdstuk 2 is beschreven. Tot nu toe is het gouden standaardonderzoek voor evaluatie van deze anatomische afwijkingen een defaecogram. Dit onderzoek is echter invasief, beperkt beschikbaar, en het vereist blootstelling aan ioniserende straling. De transperineale echografie wordt beschouwd als een minder invasief onderzoek voor de patiënt.

In hoofdstuk 3 wordt de mate van overeenstemming vergeleken tussen het defaecogram en het transperineale echografisch onderzoek voor het vaststellen van afwijkingen van het achterste compartiment. In een prospectieve, observationele studie worden de diagnostische resultaten beschreven van 75 patiënten met symptomen die veroorzaakt worden door een achterste-compartimentdefect. De Cohen's kappa waarde werd gebruikt voor de mate van overeenstemming. Alle patiënten werden na een gestandaardiseerd interview met betrekking tot hun klachten klinisch onderzocht. Hierna ondergingen ze zowel een transperineale echografie van de bekkenbodem als ook een contrastdefaecogram waarbij het rectosigmoid, de dunne darm en de vagina werden afgebeeld. Patiënten kregen nadat ze beide onderzoeken hadden ondergaan een enquête opgestuurd voor subjectieve evaluatie van hun ervaring met beide onderzoeken met een respons percentage van 85%. De onderzoeken werden off line geblindeerd geanalyseerd, gegradeerd en gekwantificeerd door twee ervaren onderzoekers. Een entero en rectocele graad 2 en 3 werden beschouwd als klinisch relevant.

Voor het opsporen van enteroceles (gr 2,3) werd een goede Cohen's kappa waarde van 0.77 gevonden. Een sensitiviteit van 64% en een specificiteit van 96% werd gevonden voor het waarnemen van alle enteroceles met 3D echoscopie. Voor de rectocele (gr 2,3) was de mate van overeenkomst goed, namelijk een kappa waarde van 0,60. Voor het echografisch vaststellen van alle rectoceles werd een sensitiviteit van 78% en een specificteit van 77% bepaald. De mate van correlatie voor de opsporing van intussuseptie (gr 1,2) was slecht (k = 0,21) en toonde respectievelijk een sensitiviteit en specificiteit van 22% en 96%.

De meerderheid van de patiënten (87%) beschreef het ondergaan van een defaecogram onderzoek als een significant minder goed te verdragen onderzoek en slechts in 8% werd het echo onderzoek slechter verdragen (P< 0.001).

Hoofdstuk 4

Morfologische afwijkingen van de musculus levator ani zijn tot op heden voornamelijk beschreven met behulp van Magnetic Resonance Imaging (MRI). Maar al in het begin van de veertiger jaren van de vorige eeuw werden deze afwijkingen gemeld door Howard Gainey, een gynaecoloog uit Kansas, die deze afwijkingen ontdekte door middel van palpatie van de bekkenbodem. Omdat MRI beeldvorming duur is en niet voor algemeen gebruik beschikbaar, is deze techniek meestal alleen gebruikt voor kleine patiënten series. Transperineale echografie is een veel toegankelijkere methode. Door voortschrijdende verbeteringen van echografische afbeeldingstechnieken is het mogelijk geworden om met behulp van 3D/4D echografie ernstige afwijkingen van de m. levator ani zichtbaar te maken.

Hoofdstuk 4 beschrijft de prevalentie van ernstige ‘major’ afwijkingen van de m. levator ani waargenomen met bekkenbodem echografie en hun relatie tot klinische symptomen. In dit onderzoek werden 338 patiënten met urogynaecologische klachten prospectief geëvalueerd. Alle patiënten werden verwezen voor een urodynamisch onderzoek ter evaluatie van hun klachten. Na een gestandaardiseerde anamnese met betrekking tot blaas, verzakkings- en of darm klachten werd een 2D/3D translabiale echografie van de bekkenbodem verricht. Levator avulsie werd gediagnosticeerd in de “rendered” axiale volumes. Een levator avulsie werd gediagnosticeerd als er een duidelijke afscheuring (defect) van de m. levator ani werd gezien anteromediaal van de insertie van de levator aan het os pubis. Dit defect kon zowel eenzijdig als tweezijdig optreden.

Major m. levator ani afwijkingen werden gevonden in 46 van alle vaginaal bevallen vrouwen (15,4%) en in geen van de patiënten die niet vaginaal waren bevallen. Er werd een uitstekende Cohen’s kappa van 0.83 tussen de twee auteurs waargenomen voor het vaststellen van deze afwijkingen. Deze defecten werden geassocieerd met voorste- en centrale-compartimentprolaps (P <0,001). Er werd geen associatie gevonden met blaassymptomen of urodynamische bevindingen, zoals stress- en/of urge incontinentie.

Hoofdstuk 5

De musculus levator ani is van klinisch belang voor ondersteuning van de bekkenbodemorganen. Traumata aan de m. levator ani, zoals defecten of avulsies, lijken te predisponeren voor het ontstaan van bekkenbodemverzakkingen. Het lijkt zeer waarschijnlijk dat dit levator trauma de oorzakende factor, de 'missing link' vertegenwoordigd, waardoor patiënten na een vaginale bevalling verzakkingsklachten ontwikkelen.

In hoofdstuk 5 wordt getracht de 'normaal waarde' voor de parameter 'oppervlakte van de levator ani hiatus in Valsalva' en de relatie met bekkenbodem symptomen en prolaps te bepalen. Een retrospectieve observationele studie, uitgevoerd bij 544 vrouwen die verwezen werden naar een tertiaire urogynaecologie kliniek met bekkenbodem- en/of urineweg-symptomen wordt beschreven in dit hoofdstuk. Na afnemen.van de anamnese ondergingen allen een klinisch onderzoek voor prolapsgradering volgens de Internationale Continence Society (ICS) pelvic organ prolapse quantification (POP-Q). De aanwezigheid van een significante objectiveerbare prolaps werd vastgesteld indien er sprake van een POP-Q gradering van 2 of hoger. Hierna werd een 3D/4D echoscopisch onderzoek van de bekkenbodem uitgevoerd voor de beoordeling van de integriteit van de m. levator en voor het bepalen van de afmetingen van de levator hiatus oppervlakte.

171 Patiënten hadden prolapsklachten (32%). Prolapsklachten waren significant gerelateerd met klinisch en echografisch gevonden verzakkingen (allen $P < 0.001$). Een sterke statistische relatie werd gevonden tussen de afmetingen van de levator hiatus, zowel in rust als bij Valsalva en prolaps symptomen van alle compartimenten (allen $P < 0,001$).

Een cut-off waarde van 25 cm2 bij Valsalva toonde een sensitiviteit van 0.52 en een specificiteit van 0.83 voor het detecteren van een klinisch significante prolaps (POP-Q ≥ 2). Het voorstel is daarom om de cut off waarde voor hiatus oppervlakte van ≥ 25 cm2 te gebruiken voor abnormale uitzetting, ook wel "balloonning" genoemd. Een oppervlakte van de hiatus bij Valsalva tussen 25– 29.9 cm2 wordt dan gedefinieerd als milde ballooning, 30-34.9 cm2 als "moderate", 35 – 39.9 cm2 als "marked" en een waarde ≥ 40 cm2 wordt geclassificeerd als ernstige ballooning van de levator hiatus.

Hoofdstuk 6

Contractiliteit van de bekkenbodem kan een belangrijke rol spelen bij het behoud van urine- en fecale continentie en/of het voorkomen van bekkenbodemverzakkingen. Een goede aanspanning en een goede ontspanning resulteren in alle waarschijnlijkheid in een optimale ondersteuning van de bekkenbodemorganen en -functie. Er wordt gedacht dat schade aan de levator ani spier kan leiden tot een abnormale functie en in tweede instantie tot symptomen zoals urine incontinentie, prolaps, en fecale incontinentie.

In hoofdstuk 6 wordt een retrospectieve studie beschreven bij 352 symptomatische patiënten die waren verwezen naar twee tertiaire bekkenbodemklinieken. Het doel van deze studie was om de prevalentie te vergelijken van 'major' m. levator ani afwijkingen tussen een groep vrouwen met een normale bekkenbodemspieractiviteit en een groep vrouwen met een verlaagde activiteit van deze spier, en hun relatie met symptomen. Na een gestandaardiseerde anamnese werd door middel van dynamische 3D transperineale echografie de bekkenbodemcontractie van elke patiënt subjectief geëvalueerd. Deze contractie werd gescoord volgen het ICS scoringssysteem en beoordeeld als afwezig, zwak, normaal of sterk. Een verlaagde bekkenbodemspiercontractie werd gedefinieerd als een afwezige of zwakke contractie van de m. levator ani. Een normale contractie werd gedefinieerd als een subjectief gescoorde normale of sterke contractie op echografisch onderzoek. De contractiekracht van de bekkenbodem werd vervolgens gekwantificeerd door middel van het berekenen van het procentuele verschil (waarde A in rust – waarde A bij Valsalva / waarde A in rust) voor alle afmetingen van de levator hiatus gemeten in 2D en 3D volumes, verkregen bij echografisch onderzoek. Kwantificering van 'major' morfologische afwijkingen van de m. levator ani werden geëvalueerd met behulp van tomographic ultrasound imaging zoals in hoofdstuk 1 is beschreven.

In dit onderzoek werden bij 186 patiënten (55,5%) een verlaagde bekkenbodemcontractiekracht gezien. Een test-retest serie verricht door de eerste twee auteurs voor de subjectieve analyse van de contractiekracht leverde een Cohen's kappa waarde op van 0.55. 'Major' afwijkingen van de m. levator ani werden gevonden in 100 van de vrouwen met een verlaagde bekkenbodemcontractiekracht (53,8%). Van de vrouwen met een normale contractiekracht bleken er slechts 24 (16.1%) 'major' afwijkingen van de m. levator ani te hebben ($P < 0{,}001$).

Een verlaagde contractiekracht werd geassocieerd met een vermindering van het hiatale oppervlak van slechts 7% versus 25% in de patiënten groep met een normale bekkenbodem kracht ($P < 0{,}001$). Er werd een verband gevonden tussen faecale incontinentie en slechtere bekkenbodem functie, maar deze associatie werd niet gevonden voor patiënten met klachten van stress incontinentie.

Hoofdstuk 7

Uitgebreide schade aan de bekkenbodem is gerelateerd aan een vaginale bevalling en bestaat uit anatomische afwijkingen zoals levator defecten en/of een anaal sfincter trauma. Omdat de externe anale sfincter verbonden is met de puborectalisspier van de musculus levator ani en beide een dwarsgestreepte spier zijn, zou het mogelijk zijn dat er een verband is tussen een trauma aan de anale sfincter en een trauma aan de levator ani. Hierdoor zouden er eerder symptomen van fecale incontinentie kunnen optreden.

In hoofdstuk 7 werden 373 patiënten met bekkenbodemklachten prospectief geëvalueerd. De studie richtte zich op de prevalentie van zowel anaal sfincter letsel als ook 'major' m. levator ani afwijkingen. Daarnaast werd de relatie met dysfunctie van de bekkenbodem onderzocht, waarbij specifiek werd gekeken naar het ontwikkelen van klachten van fecale incontinentie.

Fecale incontinentie werd gedefinieerd als onvrijwillig verlies van zachte of harde ontlasting.

Alle patiënten ondergingen een gestandaardiseerde anamnese en een transperineaal echografisch onderzoek voor beoordeling van de integriteit van de levator ani spier en van de anale sfincter.

Anaal sfincter letsel werd gedefinieerd als een defect in de externe en of interne sfincter, afgebeeld met transperineaal echografisch onderzoek en/of een voorgeschiedenis van een 3e of 4e graads totaalruptuur. ‘Major’ m. levator ani afwijkingen werden geanalyseerd met behulp van de TUI methode.

Faecale incontinentie was aanwezig in 105 patiënten (30%). Anaal sfincterletsel werd gevonden in 77 patiënten (22%). Er was een significant verband tussen anaal sfincterletsel en het ontstaan van fecale incontinentie (P = 0,002). ‘Major’ levator ani defecten werden gevonden in 143 patiënten (40%). Bij patiënten met een anaal sfincterletsel werd in 58% ook een ‘major’ levatorafwijking gevonden terwijl bij patiënten zonder anaal letsel dit percentage maar 36% was (P = 0,001). Er werd geen correlatie gevonden voor fecale incontinentie en ‘major’ m. levator ani defecten.

Voor de etiologie van fecale incontinentie bleek echter een geïsoleerd anaal sfincter letsel te gelden als de meest belangrijke factor. Het aanwezig zijn van zowel een anaal sfinctertrauma als levator ani-afwijkingen blijkt een minder belangrijke factor te zijn. Daarnaast was fecale incontinentie geassocieerd met geboortegewicht, maar niet met leeftijd, kunstverlossingen en afmetingen van de oppervlakte van de levator hiatus.

Hoofdstuk 8

In de algemene discussie komen de belangrijke voordelen van transperineaal echografisch onderzoek aan de orde. Dit geldt voor het stellen van een diagnose, de behandeling en preventie van bekkenbodem verzakkingen incontinentie en (ab) normale functie van de bekkenbodem.

Abbreviations

AP	Antero – Posterior
ASD	Anal Sphincter Defect
AUC	Area under the curve
bn	bladder neck
CRI	CrossXBeam
2D	Two-dimensional
3D	Three-dimensional
4D	Four-dimensional
EAS	External Anal Sphincter
EP	Evacuation Proctography
FI	Faecal Incontinence
IAS	Internal Anal Sphincter
ICC	Intraclass Correlation Coefficient
ICS	International Continence Society
k	Cohen's kappa index
LR	Left – Right
M	Mucosa
MRI	Magnetic Resonance Imaging
n	number
OASIS	Obstetric sphincter defects after delivery
POP-Q	Pelvic Organ Prolapse Quantification
pr	puborectalis

ROC	Receiver–Operating Characteristics
SD	Standard Deviation
SI	Sphincter Injury
SRI	Speckle Reduction Imaging
SUI	Stress Urinary Incontinence
TUI	Tomographic Ultrasound Imaging
VAS	Visual Analogue Scale
VCI	Volume Contrast Imaging

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Curriculum Vitae

Anneke Steensma werd geboren op 8 juli 1962 in Leeuwarden. Het VWO voltooide zij in 1980 aan het Stedelijke Scholen Gemeenschap in Leeuwarden. Van 1980 tot 1984 studeerde zij fysiotherapie aan de Academie voor Fysiotherapie te Leeuwarden. Hierna volgde een studie geneeskunde die zij begon in 1984 aan de Rijks Universiteit te Groningen (UMCG). Voor haar coschappen stapte zij in 1988 over na het Leids Universitair Medisch Centrum (LUMC). Een onderzoeks project over risico's van bevallen in 1990 in Tomohon North Sulawesi, Indonesie, initieerde haar belangstelling voor (gynaecologische) internationale onderzoeksprojecten en reizen. Haar studie ronde zij in 1991 Cum Laude af.

Haar eerste baan als arts assistent in het Leyenburg Ziekenhuis te Den Haag onder leiding van W.V.A. Vandenbroucke creëerde haar belangstelling voor de echografie. In 1993 begon zij met haar opleiding tot gynaecoloog, eerst in het Leyenburg Ziekenhuis te Den Haag (opleiders Dr. J.P. Holm en Dr. J.P. de Jong) en vervolgens in het LUMC (opleiders Prof. dr. E.V. van Hall en Prof. dr. H.H.H. Kanhai). Van 1999 tot 2002 werkte zij als fellow in de laparoscopische chirurgie op de afdeling endogynaecologie van het Royal Hospital for Women in Sydney, Australië (opleider ass Prof. dr. T.G. Vancaillie). Gedurende deze stage kwam zij in contact met mede fellow Hans Peter Dietz en zijn ervaring met pelvic floor ultrasound. Dit resulteerde uiteindelijk in 2004 in een onderzoeks project in 3D echoscopie en bekkenbodem afwijkingen in het Royal Prince Alfred Hospital in Sydney waar de basis gelegd werd voor dit proefschrift.

Sinds juli 2005 is zij werkzaam als staflid bij de afdeling gynae-oncologie in het Erasmus Medisch Centrum te Rotterdam (NL). Daarnaast werkt zij op consultancy basis in het UZ Gasthuisberg te Leuven, Belgie, voor de ondersteuning van de bekkenbodem echoscopie op de afdeling urogynaecologie.

Curriculum Vitae

Anneke Steensma was born in Leeuwarden, on July 8th, 1962. She graduated in 1980 from secondary school at the Stedelijk Scholen Gemeenschap (VWO) in Leeuwarden. She attended the Academie voor Fysiotherapie in Leewarden from 1980 till 1984. She commenced her Medical School at the University in Groningen (UMCG) in 1984. In 1988 she switched to the Leids Universitair Medisch Centrum (LUMC) for her internship. A research project in Tomohon, North Sulawesi, Indonesia in 1990 about risk of deliveries, initiated her interest in internationally research projects in gynaecology and overseas travelling. She graduated Cum Laude in 1991.

Her first experience with ultrasound she encountered as a resident supervised by W.V.A. Vandenbroucke at the Leyenburg Hospital in the Hague. Her training as a registrar in Obstetrics and Gynecology started at the Leyenburg Hospital in the Hague in 1993 (supervisors Dr. J.P. Holm and Dr. P.A. de Jong), and then at the LUMC in Leiden (supervisors Prof. dr. E.V.van Hall and Prof. dr. H.H.H. Kanhai). From 1999 till 2002 she obtained a fellowship in laparoscopic surgery at the department of endogynaecology at the Royal Hospital for Women in Sydney, Australia, supervised by ass. Prof. dr. T.G. Vancaillie. During this fellowship she was introduced to pelvic floor ultrasound by Hans Peter Dietz. Subsequently in 2004 she conducted a research project in 3D pelvic floor ultrasound and pelvic floor disorders at the Royal Prince Alfred Hospital, which was the basis for this thesis.

She is currently working as a Consultant at the Department of Gynae-Oncology at the Erasmus Medical Center in Rotterdam, the Netherlands. She also works as a consultant in pelvic floor ultrasound at the urogynaecology department at the UZ Leuven, Gasthuisberg Leuven, Belgium.

Appendix

Cases for “ Virtual Scanning” using 4D View

Appendix

Cases for " Virtual Scanning" using 4D View

A DVD that contains a version of the software 4D View, courtesy of GE Medical, Kretz Ultrasound, Zipf Austria can be obtained by the author of this thesis.

To allow your practice with this software the author has included 15 de-identified volume data sets on the DVD.

If you do have problems with installation of the software, ensure that the requirements as listed in the Installation Manuals are met (available at http://www.volusonclub.net/4dview/downloads).

An user manual is listed on the DVD and will give you an overview of the functionality of the software and take first-time users through the basic steps of performing an analysis in patients with pelvic floor dysfunction.

CASE 1

History

This 28 year old lady was referred because of pain. She has occasionally stress urine incontinence less then once a week but no other complaints of pelvic floor dysfunction. She is one year post a normal vaginal delivery.

Clinical examination revealed a strong pelvic floor contraction with a non relaxation of her pelvic floor

Findings

1 Vol cine Volume: Strong levator ani contraction. No levator avulsions. Normal anatomy at valsalva.

CASE 2

History

A 28 year old female delivered 3 months ago. She now has complaints of occasional stress leakage more then once a week. She had a quick delivery of a boy with a birth weight of 4500 gram. Before she delivered and during her pregnancy she did not have any complaints of stress incontinence.

Findings

2A VCI Volume: with a normal contraction of the pelvic floor

2B VCI Volume:On valsalva she did have an obvious bladder neck descent of 2.2 cm and funneling. No other evidence of pelvic organ descent. Normal levator ani.

CASE 3

History

This lady (43) is complaining of urge incontinence. Her history includes a caesarean delivery of her only child. No complaints of stress or prolapse symptoms..

Clinical examination did not reveal any abnormalities..

Findings

3A Vol cine Volume: Normal anatomy. On Valsalva an obvious cocontracion, without relaxation of the pelvic floor. No pelvic organ descent.

3B Vol cine Volume: Normal anatomy of the anal sphincter in rest and contraction.

CASE 4

History

This patient has been referred with symptoms of obstructed defaecation. She had one child delivered by caesarean. She also has the feeling of a lump in her vagina.

Clinical examination showed a second degree cysto and rectocele.

Findings

4A Vol cine Volume: shows a normal contraction on ultrasound. On valsalva she has a mild descent of her uterus with a mild intussusception of the uterus into her rectum. No obvious rectovaginal fascial defect Normal levator ani.

4B Vol cine Volume :normal anal sphincter in rest and contraction.

CASE 5

History

A 34 year old woman presenting with symptoms of heaviness and feeling of a lump. Post delivery of her first child (4100 gram), at the age of 31, she did not have any complaints She was then seen for follow/up of an ovarian cyst and diagnosed with a bilateral levator avulsion and a weak pelvic floor contraction. Her second delivery , at the age of 33, reported a shoulderdystocia and a cervical tear She is now complaining of increased prolapse symptoms.

Clinical examination revealed a third degree cystocele, a second degree uterine prolapse and a third degree rectocele.

Findings

5 Vol cine Volume: She has a weak contraction. On valsalva an obvious cystocele, uterine descent and rectocele can be seen. She has an obvious bilateral defect of the levator ani. On valsalva the hiatal area is now is 41 cm2. As her hiatal area after her first delivery was 29 cm2 there is a marked increase, which can be the explanation for her symptoms

CASE 6

History

This very nice 38 year old woman was referred 3 months post delivery of her first child. She had a Vontuse delivery of her first child with a birthweight of 3570 gram, and with a third degree anal tear. She currently does not have any complaints of stress, faecal incontinence or prolapse.

Clinical examination did not show any abnormalities.

Findings

6A Vol cine volume. She has a weak pelvic floor contraction with an obvious unilateral defect on the right side and partial defect on the left (TUI score, 8 for the right and 5 for the left. No pelvic organ descent.

6B Vol cine Volume :anal sphincter imaging does not show any defects after her surgery.

CASE 7

History

This lady is 28 year of age and now pregnant of her second child. She had a normal vagina delivery, 4310 gram, with a third degree anal sphincter tear. She does not have any complaints of pelvic floor dysfunction. Clinical examination is normal

She is requesting a caeseran section.

Findings

7A VCI Weak contraction of her pelvic floor. Obvious bilateral levator ani defect.

7B Vol cine Volume: Anal sphincter imaging shows a persistent defect of her external anal sphincter.

CASE 8

History

This 35 year old patient was referred for discussing the mode of delivery of her second child. She has a history of a 3rd degree tear. Her first baby she delivered at the age of 32 year and this baby is mentally retarded. No complaints of faecal incontinence

Clinical exam did not show any abnormalities. Anal manometry was abnormal and did not show any increased pressures on contraction.

Findings

8 3D Volume: shows an obvious persistent defect of the internal and external anal sphincter.

CASE 9

History

This 32 year old lady is referred with complaints of faecal incontinence. Her history includes a Vontuse delivery and a third degree anal tear. Last year she underwent an anterior sphincteroplasty, but she still has complaints of severe incontinence.

Findings

9A: Vol cine Volume: She shows a weak pelvic floor contraction and no capability to perform a valsalva manoeuvre. No obvious levator ani defects.

9B Vol cine Volume: Persistent defect of the external and internal anal sphincter after both repairs.

CASE 10

History

This 38 year old lady was referred because of symptoms of prolapse. No stress incontinence or obstructed defaecation symptoms.

Clinical examination revealed a cystocele grade 2 and a rectocele grade 1.

Findings

10 VCI Volume: On valsalva an three compartment prolapse with an obvious rectovaginal defect. Rectocele at – 1.70 cm, cystocele at – 0.70 cm, and the uterus at 0.50cm. Obvious ballooning with a levator area of 45 cm2.

CASE 11

History

A 74 year old lady referred because of symptoms of faecal incontinence and prolapse. She is para 4 and underwent 18 years ago a Burch colposuspension. Her history includes loosing faeces after coughing.

Clinical examination revealed a large recto-enterocele

Findings

11 VCI.Volume: On valsalva an obvious large rectovaginal defect of the posterior compartment. No avulsions. An enterocele could not be excluded.

Evacuation proctography revealed a big rectocele and no signs of an enterocele.

CASE 12

History

This 64 year old lady was referred because of faecal incontinence. She did have three normal vaginal delivery. Her history includes an abdominal hysterectomy and an anterior rectopexie 10 years ago. Post defaecation she has to repositionize her rectum. She has a daily bowel frequency of 4 – 8 times

Clinical examination revealed an obvious mucosa prolapse.

Findings

12 Vol cine Volume: On valsalva an obvious intussussception of a mucosal rectal prolapse can be seen.

CASE 13

History

This 50th year old lady is referred because of symptoms of prolapse and faecal incontinence.

Her history includes a vaginal hysterectomy with anterior and posterior repair. She has been diagnosed with Crohn's disease. She had three normal vaginal deliveries, with her first baby at the age of 24 and a maximum birth weight of 4000 gram.

Clinical examination revealed a large enterocele.

Findings

13 Vol cine Volume: Obvious sigmoid enterocele, and a severe ballooning hiatus (≥ 40 cm2). Left sided unilateral levator avulsion

CASE 14

History

This 72 year old lady is complaining of urge urinary incontinence, voidingdysfunktion, prolapse and faecal incontinence.Her history includes twice a normal vaginal delivery and an abdominal hysterectomy.

Clinical examination reveals an obvious entero and rectocele.

Findings

14 Vol Cine Volume: obvious recto and enterocele on valsalva with a ballooning hiatus of 40 cm 2. No levator avulsions.

Evacuation proctography revealed the same findings.

CASE 15

History

The history of this 71 year old lady includes twice a normal vaginal delivery. 17 Years ago she underwent an abdominal hysterectomy. She is now 1 year after surgical repair of her prolapse with a vaginal mesh (prolift totalis) and a TVT-O. She currently has no complaints and clinical examination does not show any recurrence of prolapse.

Findings

15 Vol cine volume: Patient performs a normal contraction of the pelvic floor. No levator abnormalities. On valsalva no recurrence of prolaps, and TVT and the anterior and posterior mesh are clearly visible.

On the DVD

Case 1	normal anatomy
Case 2	stressincontinence, bladderneck descent funneling
Case 3	urge incontinence cocontraction on valsalva
Case 4	obstructed defaecation uterine intussusception
Case 5	prolapse, bilateral avulsion
Case 6	history of 3rd degree tear, normal anal sphincter
Case 7	history of 3rd degree tear, anal sphincter defect
Case 8	anal sphincter defect (eas and ias)
Case 9	faecal incontinence anterior sphincteroplasty
Case 10	prolapse symptoms rectocele
Case 11	faecal incontinence and prolapse large rectocele
Case 12	faecal incontinence mucosa prolapse
Case 13	prolapse sigmoid enterocele
Case 14	prolaps entero- rectocele
Case 15	post surgical repair tvt, prolift totalis