

**On the Relationship between Pubovisceral Muscle Tears and Urethral
Closure Pressure in Women Following Vaginal Birth**

By

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DEDICATION

This dissertation is dedicated to my husband Jing Li, my daughter Cynthia Li, my parents Xuliang Sheng and Zhiping Cheng, and my parents-in-law Gang Li and Shuying Wu.

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ABSTRACT

Little is known about the implications of pubovisceral muscle tear on urethral closure pressure – the focus of this dissertation. The literature on interventions for stress urinary incontinence has focused almost exclusively on pubovisceral muscle strengthening with repetitive exercise for life, but to date reports on “strength change” and on “leakage reduction” fail to convincingly relate these two outcomes, and essentially none of the studies reported take into account pubovisceral muscle tear, which renders the muscle incapable of response to volitional contraction effort. These major limitations in the literature are largely due to a long struggle to find adequate valid, cost effective, acceptable, accessible, reliable measures for the constructs of pubovisceral muscle. Recent major advances have been made in the field of pubovisceral muscle measurement, but come with a history (70+ years) of measurement difficulties that have caused fixed ideas and misunderstandings.

This dissertation advances our understanding of measures of pubovisceral muscle structure (tears at the enthesis) and pubovisceral muscle function (loss of capacity for strength), suggests gold standard measures, advances the possibility of cost-effective clinical screening exams, and then for the first time examines in a sample of postpartum women known to have had obstetric high-risk factors at delivery the relationship of pubovisceral muscle tear to urethral closure pressure. The dissertation has three purposes: 1) reviewing past and current measures for assessing pubovisceral muscle strength and pubovisceral muscle tear; 2) estimating the odds of pubovisceral muscle tear (with gold standard magnetic resonance imaging) from clinical examination identifying using index finger palpatory assessment; and 3) determining predictive

value of pubovisceral muscle tear on urethral closure pressure both at rest and during volitional effort of pelvic muscle contraction.

The findings from the research suggest that there are gold standard measures (MRI and one-billed speculum) that are unsurpassed in meeting criteria of precise, valid, acceptable to women, but with some not broadly accessible in part due to prohibitive cost factors and lack of technology transfer from the research arena to the public. Quantified standing stress paper towel test and sagittal dynamic ultrasound for estimating pubovisceral muscle function in women with stress incontinence are suggested for adoption widely in the clinical setting, where currently implementation is nearly non-existent. The findings also suggest, for either scientific or clinical purposes, to avoid commonly used intravaginal instrument devices known to produce measures contaminated by intraabdominal pressure, making it impossible to isolate the pubovisceral muscle activities from non-pubovisceral muscle activity occurring simultaneously. The findings further suggest that index finger palpatory assessment can be used to initially identify pubovisceral muscle tear. Finally, the findings demonstrate the strong influence of the pubovisceral muscle tear (unstandardized coefficient = - 21.1; $p=.001$) on reducing a woman's ability to volitionally optimize urethral closure pressure at the moment of intraabdominal pressure rise (as in cough), to prevent stress-type incontinence. These findings establish the foundation for future prospective research on estimation of pubovisceral muscle status in parous women who have vaginal birth and have risk factors for pubovisceral muscle tear, as well as identifying the role of volitional urethral closure pressure for future prevention and intervention studies on stress incontinence. This dissertation provides crucial data to inform the field focusing on testing pubovisceral muscle tear and the tear's influences on the urethra, as well as the prevention and intervention for stress urinary incontinence.

Chapter 1

Introduction

Background

Childbirth is a miraculous event, but one that is associated with injuries to women. Birth-related injuries include musculoskeletal changes effecting muscles, nerves, ligaments, tendons, joints, and bones. These changes are important since the musculoskeletal system provides support and stability to the pelvis and to the organs held within it. Although birth-related musculoskeletal injuries do not cause a loss of life, they do have an impact on women's quality of life. One particular important effect is chronic urinary incontinence which is marked as a disease of silence and shame.

Although birth-related injuries are common, they can be difficult to detect because they are located inside of the body and most times there are no symptoms, such as pain, that are distinguishable from the general postpartum pain experienced by most women. Thus, it is important to find ways to detect these silent injuries. Detection and severity measurements are needed to provide information on incidence, prevalence, and extent of the injuries, whether chronic or acute. Measurements can also be used to determine the relationship between the injuries and other morbidities, such as incontinence symptoms. Moreover, measurements can provide critical information to inform development of preventions, interventions and decision making in treatment plans.

Despite the known need for and benefits of reliable and valid measurements, development has been problematic. Partly, this is due to the complex and until recently poorly understood anatomy in this part of the body, generally raising the thorny issue of validity. The composite of measurements developed over the past 70 years have nearly all suffered from a fundamental lack of understanding what it is that is actually being measured. For example, a standard test, for identifying levator ani wholeness was hampered in part by emphasis on a theoretical underpinning of atrophy (nerve injury) as the proposed underlying mechanism. It is only in 2015 that it was definitely established that muscle tear during childbirth was the primary underlying issue (Miller et al., 2015). The delay in discovery was related to a lack of measurement possibilities that were simple, low cost, valid, and reliable. The field has waited for not only adequate study design to address the problem, but also instruments. Although levator ani failure was noticed in early 20th century from dissections of cadavers by Halban J. and Tandler J. (1907) (J. DeLancey, personal communication, January 16, 2018), until 1940's and 1950's, Gainey documented levator ani injury using index finger palpatory assessment in a large cohort study with 1,000 postpartum women (Gainey, 1943 & 1955). However, the assessment of the injury did not further develop until 1990's. In fact, the injury occurs on the largest portion of levator ani named pubovisceral muscle (PVM) (i.e., pubococcygeal muscle). Kirschner-Hermanns et al. published first MRI description of abnormal PVM in women with stress urinary incontinence (SUI) in 1993. DeLancey has used magnetic resonance imaging (MRI), which was delayed in application to study of the childbirth-related pelvic MSK structures until MRI was identified that can be used to quantify the change of PVM during the puerperium (Tunn et al., 1999), followed by this team's continued seminal work (Chou & DeLancey, 2001; Morgan et al., 2007), and a switch to the most sophisticated MRI protocols of fluid sensitive scans in diagnosis

of childbirth-related pelvic injuries (Brandon et al., 2012; Miller et al., 2010; Miller et al., 2015). While Dietz has used three- and four dimensional (3D and 4D) ultrasound (Dietz, 2007; Dietz & Lanzarone, 2005), which came into accessible reach in quantification of morphological abnormalities of the PVM. None of these approaches have been translated into the routine clinical environments, either obstetrically or in the urogynecology practice arenas.

To begin to solve the measurement issues in the clinical arena, realities are that accessibility, acceptability and cost-effectiveness, must be kept forefront. In this dissertation, Chapter 3 presents a simple and low cost index finger palpatory assessment method of estimating wholeness of the most critical element of the PVM in attempt to fill this gap. Chapter 3 is prefaced by Chapter 2, which offers a full review of measures attempted in the field across the 70 years of instrument development, beginning in the days of Arnold Kegel's work emphasizing pelvic muscle exercises to strengthen the PVM post childbirth. Chapter 2 clarifies with great precision exactly what these many instruments are measuring in the attempt to obtain some measure of PVM function. With the literature riddled by imprecision, Chapter 2 bridges measurement history, present day state, and near future possibilities of achieving standardized, accurate, inexpensive, uncontaminated measure of PVM function. While it will take time for the field to move towards adaptation of a singular instrument, Chapter 2 proposes that in the meantime a shared language and understanding of each instrument, reporting on its data both historically and currently, can serve as ready reminders of the many limitations, biases, and even complete lack of validity that is reflected in some of the data from the literature. Said simply, if the part of the levator ani that is targeted for measurement of its function is in reality a torn muscle, such that no muscle body exists, then what is really being measured when an instrument reads out as the measure reflecting that its functional?

Childbirth-related PVM tear is common among women with certain risk factors such as maternal age greater than 33 years, and second stage during laboring greater than 150 minutes (Miller et al., 2015). The levator ani is a group of muscles in the pelvis that provides support and stability to the organs in the pelvis. The prevalence of PVM tear in parous women can be as high as 36% (Dietz & Lanzarone, 2005). PVM tear has been identified as a risk factor for SUI, though this remains controversial. Whether a cause or association with SUI, PVM tear logically would limit the ability of women to compensate for incontinence through use of the pelvic muscle contraction to suppress stress-type leakage (Miller, 2002; Miller, Ashton-Miller, & DeLancey, 1998).

Almost one in three women suffer from urinary incontinence, half of whom complain about symptoms of SUI (Bø & Herbert, 2013; Hampel et al., 2004; Reynolds, Dmochowski, & Penson, 2011). SUI is defined as involuntary urine loss due to physical exertion such as sporting activities, coughing or sneezing (Abrams et al., 2010; Haylen et al., 2010). This disorder is a hidden problem. Treatment is not easy. Simple, easy and appropriate measurements of PVM tear may help to early on and correctly identify the tear as a risk factor for development of the SUI. With early identification, there is potential to reduce health costs and improve health-related quality of life, if compensatory treatment can be identified.

Treatment for SUI has been guided by two main theories. One theory is the urethral stability theory. According to the theory, the pelvic muscle (i.e., PVM) needs to be strengthened to provide support to the urethra. This has traditionally involved treatment emphasis on respective pelvic muscle exercises, namely the well-known Kegel exercises (Bø & Herbert, 2013; Kegel, 1948; Pirpiris, Shek, & Dietz, 2010). Importantly, the treatment of strengthening pelvic muscles has been focused on for $\frac{3}{4}$ of a century as documented in the literature from

Arnold Kegel who is a pioneer American gynecologist from 1948 (Kegel, 1948). There is anecdotal report of the technique being introduced by lay midwives centuries prior to Kegel. Kegel exercises are considered to be a first line of treatment (Abrams et al., 2010), even though the condition of the PVM structure (if it is whole, torn, or partial tear?) has likely not been checked in a valid manner prior to the application of the physical therapy. Even if we believe that repetitive exercises could strengthen a muscle torn from its origin, data to support this is completely absent from the literature. Again, this problem is rooted in a lack of accessible, acceptable, valid, reliable, and inexpensive measures of the PVM wholeness. We can speculate that a torn PVM may be the main explanatory factor of why some women fail in achieving treatment success of their stress-type leakage with exercise to strengthen pelvic floor muscles to maintain urethral stability. The prevailing explanatory factor, instead, has been that women are not compliant enough (Bø, Kvarstein, & Nygaard, 2005; Kegel, 1956).

Alternatively, it may be that the emphasis on the PVM function as the most direct factor for preventing stress-type continence is wrong. The alternative theory of primary need for high urethral closure pressures (UCP) is a competing hypothesis, with some support in the literature. Although urethral closure theory was proposed in 1961 (Enhoring, 1961), its important role in stress continence maintenance has only recently been highlighted (DeLancey et al., 2008; Miller et al., 1998). UCP is defined as the difference between the point within the urethra of its most maximal pressure after subtracting off the pressure within the bladder measured at the same time. The most direct influence on this UCP is arguably the striated circumferential urethral muscles themselves. However, some contribution of PVM function has long been argued, and quantification of the degree of that contribution has again been stymied by measurement issues. It is known that the mechanism of the stress continence requires urethral pressure greater than

bladder pressure in order to close urethra and stop urine loss. The two theories of the urethral support (that is, PVM structural wholeness and functional capacity) and urethral closure (that is, urethral striated muscle structural wholeness and functional capacity in the face of intraabdominal pressure) are surely of some particular relative importance to maintain stress continence (Ashton-Miller & DeLancey, 2007). Both theories are needed to be taken into account in the treatment of SUI. Chapter 4 addresses this issue. Chapter 4 provides evidence of contribution of PVM on the UCP and presents quantification of the degree of PVM function on the UCP, which shows that a torn PVM decreases the UCP during a pelvic muscle contraction.

Knowledge Gap

It is currently not known how or whether PVM tear affects UCP following vaginal birth. In part this is due to the lack of a simple and low cost method for identifying PVM tear in the clinic. Appropriate measurements are needed to help us to better understand SUI and guide appropriate treatment, which in turn can improve health-related quality of life and reduce health costs.

Purpose

The purpose of this dissertation is to: a) estimate the likelihood of identifying a PVM tear using index finger palpatory assessment for estimating odds of PVM tear, and to b) examine the relationship between MRI-identified PVM tear and UCP among women who recently delivered vaginally and had at least one of the risk factors for PVM tear: maternal age greater than 33 years, second stage during labor greater than 150 minutes, infant weight greater than 4000 grams, instrumented delivery, or third or fourth degree anal sphincter injury. This dissertation employed data from the parent study, ‘Evaluating Maternal Recovery from Labor and Delivery (EMRLD)’ (Miller et al. 2015). EMRLD focused on the recovery from labor and delivery

through evaluation of the pelvic floor status and injuries, such as PVM tear. In EMRLD, data were collected at 7 week and 8 month clinical visits following the first vaginal delivery. This dissertation will focus on 7 weeks postpartum data on the exploration of index finger palpatory assessment for estimating odds of PVM tear and 8 months postpartum data on the relationship between PVM tear and UCP.

The dissertation consists of three parts:

1. A review of methods for assessing PVM status

The purpose of this review of instruments was to describe the current methods for assessing PVM structural integrity and strength (used to call as pelvic floor muscle strength). Findings of the part will be used to guide their use. This is to ensure that the right method is chosen for a particular purpose. The advantages and weaknesses of each method will be discussed.

2. A retrospective study estimating the odds of MRI-documented PVM tear identified by index finger palpatory assessment in postpartum women who were at high risk for PVM tear in their first vaginal delivery.

The purpose of this retrospective study was to use a simple, low cost examination to assess PVM tear, later confirmed by an MRI. Index finger palpatory assessment was used to estimate the occurrence of PVM tear. The findings provide evidence that the palpatory assessment can be used as a routine clinical examination, especially for postpartum during follow-up clinical visits.

3. The relationship between PVM tear and UCP in primiparous women with known risk for PVM tear during their vaginal delivery.

The purpose of this study was to examine the relationship between PVM tear and UCP both at rest and during a volitional pelvic muscle contraction, as measured by what we call resting and contracting UCP. Urethra closure is necessary to maintain continence. To the best of our knowledge, there is no previous study of the impact of the tears on contracting UCP. Findings of this study will draw attention to the reason of why vaginal birth is highly related to SUI and redirect interventions for SUI from focusing on optimizing PVM strength to focusing on optimizing urethral function.

These results will establish the foundation for future prospective research on estimations of PVM status after vaginal birth for women who are at high risk, as well as research on UCP leading to future intervention on SUI. This dissertation provides crucial data to inform research groups and clinicians on assessing PVM tear and its impact on the urethra, as well as the prevention of and interventions for SUI for postpartum women.

Aims

The following aims guided this dissertation:

Aim 1: To review a variety of methods used for assessing PVM tear and strength.

Aim 2: To estimate the odds of MRI-documented PVM tear identified using index finger palpatory assessment for identifying likelihood of MRI confirmed PVM tear in primiparous women recovering from a vaginal delivery at high risk for PVM tear.

Aim 3: To investigate in the women described in Aim 2 the relationship between PVM tear and UCP, measured with the women at rest and during attempt at volitional pelvic muscle contraction.

Overview of the Dissertation

This dissertation is organized as follows: Chapter 2 discusses the current methods used to assess for PVM structure and function. Chapter 3 discusses a simple and low cost examination palpatory assessment method to estimate the likelihood of PVM tear for postpartum women who are at risk for PVM tear during vaginal birth. A comparison is made to the most precise examination, that of MRI. Chapter 4 focuses on the degree to which contracting UCP is influenced by PVM tear. Chapter 5 is a general discussion of the overall results from the dissertation, how they extend the literature, the importance of measures selection relative to context and mechanistic hypotheses, implications of findings from the data-based chapters, strengths and limitations of the methods, and recommendations for future practice and research.

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Chapter 2

A Review of Methods for Assessing Structure and Function of Female Pubovisceral Muscle

Introduction

The levator ani consists of a group of muscles including the pubovisceral (also known as pubococcygeus), the iliococcygeus, and the puborectal muscles (Figure 2.1) (Ashton-Miller & DeLancey, 2007; Kearney, Sawhney, & DeLancey, 2004). For the purposes of this dissertation, the focus is on the most ventral region of the levator ani, namely the pubovisceral portion of the muscle because of its purported relationship to stress urinary incontinence (SUI) (Bø, 2004). In addition, pubovisceral muscle is the largest, strongest muscle in the female pelvis, which is the key muscle of the entire pelvic (Kegel, 1956). In the 1940's, two pioneer Gynecologists, Harold Gainey (1943) observed postpartum pelvic floor muscle damage and Arnold Kegel (1948) introduced into the literature the pelvic floor muscle exercises for postpartum recovery and prevention/treatment of incontinence which came to be known as Kegel exercises. They called the pelvic floor muscles as follows: "pubococcygeus," "perivaginal muscles" (Gainey, 1943&1955), "muscle of the perineum," "levator ani," "perineal muscles," "muscles of the vagina," and "anterior vaginal muscles" (Kegel, 1948). However, pelvic floor muscles became to replace what was called is the pubovisceral muscle that was not often used in area of the physical therapy of the SUI while the general term 'pelvic floor muscles' were used across literature. The "Kegel muscle" remains a popular term for lay population for what we now refer to as the pubovisceral portion of the levator ani. For the purposes of this chapter and consistency of terms

throughout the literature, we will simplify to abbreviate the pubovisceral portion of the levator ani muscle as “PVM.”

Kegel (1948) asserted that women with enough motivation could prevent or reverse symptoms of SUI by repetitively exercising the PVM, if they did them daily for life at a sufficiently high number of repetitions. Nearly three-quarters of century later, hundreds of studies have been conducted attempting to quantify the effect of Kegel exercises (also referred to in the literature as ‘pelvic muscle exercises’) on continence status (Dumoulin, Hay-Smith, & Habée-Séguin, 2014, Appendix 1. PFMT protocol). However, a sober analysis of the matter reveals that we still cannot conclude that repetitive exercise aiming to improve PVM strength is the mechanism underlying prevention or reduction of urine loss during a moment of “bladder stress” causing urine leakage due to intraabdominal pressure (IAP) rise. How can that be?

One reason is that there is a near complete lack of reporting on the actual statistical correlation between the outcomes of PVM status change (from resting to contracting, or from weak to strengthened) and its direct effect on reducing the magnitude of urine loss during an IAP rise. Only five manuscripts report any statistical parameter describing the relationship between change in PVM status from Kegel exercises and a change in continence status (Ahlund et al., 2013; Bø, 2003; Boyington, Dougherty, & Kasper, 1995; Dinc, Kizilkaya Beji, & Yalcin, 2009; Theofrastous et al., 2002) (Table 2.1). Of those five papers, only one showed a statistically significant correlation of modest size ($r = .34$) despite an intensive exercise regimen (Bø, 2003). The intensive exercise regimen required women to practice 8-12 pelvic muscle contractions three times daily, with additional 45 minutes of instructor-led training in groups once a week for six months (Bø et al., 1990a). The intensity of the exercise regimen and the cost of the 26 weekly

visits to instructor-led classes essentially preclude the use of such an intensive exercise regimen for American women with SUI.

A second reason is the near complete lack of standardized measurements for the outcomes of interest. In this chapter (Chapter 2) of the dissertation, it is this second matter which is addressed. The issue of PVM measures can be divided into measures of PVM structure and measures of PVM function, which can further be divided into high-technology, low-technology or clinical assessment measures. As Cochrane reviews of studies on Kegel exercises remind us (Dumoulin et al., 2014), until the scientific field begins to use standardized measures (i.e., valid, objective, affordable, accessible, and acceptable) for both PVM status and its direct relationship to continence during a stressor moment, conclusions from meta-analysis attempts are limited.

These issues are in part due to the historical limitations of technological tools amenable to this area of work. It is only in the early 1990's that use of magnetic resonance imaging (MRI) offered a first objective identification that a birth-related "defect" of the PVM could be seen in some postpartum women (Kirshner-Hermanns, Wein, Niehaus, Schaefer, & Jakse, 1993). That "defect" was only recently (Miller et al., 2015) shown conclusively to be in the critical ventral or PVM portion of the levator ani that is responsible for the pelvic floor "lifting function" (Betschart, Kim, Miller, Ashton-Miller, & DeLancey, 2014), the PVM having being torn from its origin at its pubic enthesis (its attachment at the pubic bone). The tear was demonstrably chronic when assessed serially to eight months postpartum by MRI, despite all of the women involved in the study being taught Kegel exercises (Miller et al., 2015). To date, there is no known surgical reattachment possibility (J. DeLancey, personal communication, January 16, 2018) because the surgical risks outweigh any benefit. The torn PVM quickly retracts, atrophies because it no longer carries load, thereafter becoming both non-accessible to the woman for voluntary

contraction and nonfunctional for reflex contraction. Prior to these MRI studies that were designed to characterize the PVM injury (i.e., a tear, rather than the previously presumed neurological or stretch injury [Allen, Hosker, Smith, & Warrell, 1990]) no consideration was given to the possibility that certain women did not have available pelvic muscles to them that could contract. Hence, of the prior century's literature on Kegel exercises, none took this possibility into consideration in either the study inclusion/exclusion criteria or the analysis of outcomes. This was for good reason -- because it was an unproven and unconsidered factor. The clarification had to await development of sophisticated imaging technology for adequate study. When it comes to the topic of whether or not Kegel exercises, when taught population wide help some, most of us (including Cochrane's reviews) will readily agree that the data are supportive. Where this agreement ends, however, is on the question of why the effect size is so small, why some women are helped but many are not, and why there is nearly never a "cure" of SUI with Kegel exercises alone.

The purpose of this chapter is to review the long history of attempts to discover and measure the status of the PVM so its relationship to continence during rise in IAP can be better understood, and to discuss how this more than 70-year journey in measurement issues cannot be separated from today's understandings of the literature. With a history of studies burdened by a lack of valid, objective, affordable, accessible, acceptable, and scientifically agreed upon measures of PVM status, scientists have done the best they could. But the view taken in this dissertation is that it is time now to critique these historical instruments, keep what is of worth, and discard those that impose limitations on advancing our current-day understandings (or misunderstandings) of the relationship between the PVM and SUI.

To do so, we divide the review into two parts: 1) Measurement of PVM status by structure; and 2) Measurement of PVM status by function. Within each of these categories, measures and instruments are presented in chronological order to place them into historical context and separated into two tables by whether the measures are primarily subjective (Tables 2.2a) or objective (Table 2.3). The instruments also can be further divided into three categories: clinical physical exam procedure (Table 2.2 and Table 2.4), devices that do or do not make measurements confounded by the effect of IAP, along with those that measure muscle myoelectric activity (e.g., electromyography) (Table 2.3), and imaging (Table 2.3).

Measures of PVM Structure

Without a description of the PVM structure one cannot evaluate PVM function. This is particularly important because regions of the pelvic floor muscles can sustain trauma during vaginal birth and sudden deceleration events such as landing parachute jumps. So without being able to quantify the structural integrity of the PVM, one cannot interpret functional measures of PVM activity. Measures of PVM function in the literature have largely been reported without consideration of PVM structural status of the individual woman: is it normal or does it have abnormalities? If it has abnormalities what are they, where are they, how do they affect function and what is their etiology? When it comes to evaluating PVM tears, various methods have been suggested for assessing their structural integrity including various finger palpatory assessments for estimating odds of PVM tear status, MRI, and three- or four-dimensional (3D or 4D) ultrasound.

Index finger palpatory assessment has long been used to assess PVM tear since the 1940s (Gainey, 1943). The fact remains that without knowing PVM tear status, and if one instead only relies on a measure of vaginal closure force, the findings of any intervention to “strengthen the

PVM” can only provide an incomplete understanding of what has changed, if anything. A lack of strengthening could be caused by many factors including poor Kegel exercises compliance, poor understanding, memory or ability to correctly identify and recruit the pelvic muscle, or even an unwillingness to recruit the pelvic muscle, so there are many explanations for ~20% of parous women (DeLancey, Kearney, Chou, Speights, & Binno, 2003; Gainey, 1943) having a PVM tear that makes a volitional pelvic muscle contraction impossible to perform. Given the likely relationship between PVM tear and lack of change in PVM strength with pelvic muscle exercises, it is important to diagnose a PVM tear and its severity. That is, to determine if the PVM enthesis is intact and connected to the body of the PVM, and if not, to what degree it is torn from its pubic origin.

Subjective Measures of PVM Structure

Index finger palpatory assessment for estimating odds of PVM tear. The PVM tear was first described as early as in 1943 by Harold Gainey who used palpatory assessment to examine 1,000 women who were vaginally delivered by him (Gainey, 1943 & 1955) (J. DeLancey, personal communication, January 16, 2018). Gainey termed the tear as ‘atrophy’ or ‘detachment’ at that time. He found PVM tears in ~20% of primiparous women examined by palpatory assessment. His estimate is consistent with the modern technology tests of today using MRI (DeLancey et al., 2003) and ultrasound (Dietz & Steensma, 2006). Information about how to perform the palpatory assessment was not given by Gainey (1943 & 1945) but he described two specific categories of damage on PVM: relaxation and atrophy. Importantly he stated relaxation as “when on palpation the muscles were intact but there was inability to accomplish effective contraction” and atrophy as “loss of muscle with a characteristic defect” (Gainey, 1955, p. 805).

Today, index finger palpatory assessment for estimating odds of PVM tear remains the only available subjective measure for directly assessing for a PVM tear. It is important to stress that palpatory assessment is different from finger placement techniques to assess PVM strength using measures such as the circumvaginal muscle rating scale, Brink digital exam, and modified Oxford scale discussed elsewhere in this Chapter. In contrast to those three techniques, which variously assess pressure, duration, and displacement on a passively placed finger(s), palpatory assessment involves inserting the index finger hooked just inside the vaginal introitus to evaluate either the right or the left side PVM by actively pressing the examining finger towards the muscle belly behind the vaginal wall. The PVM body bulk is typically palpated first at rest and then on asking the woman to contract, as confirmatory. If felt, the examiner can also follow the PVM body upwards, sweeping upwards towards its origin from the dorsal margin of the pubic bone for additional confirmatory appraisal of intact attachment (or not) to the pubic bone. If the PVM is torn, a “divot” is felt, and one feels the bone underneath where it should lie instead of the expected softer “give” of the belly of the muscle. Palpatory assessment for PVM tear is typically reported as “PVM present to palpation”, “PVM absent to palpation”, or “equivocal” (unsure). Although the PVM is small, having a diameter of a little finger, palpating it through the vaginal wall is subjective. Aside from Gainey, publications reporting palpatory assessment for evaluating PVM tear were absent until the 2000’s.

In 2006, identifying a PVM tear by palpatory assessment was described as finding “a palpable detachment of the most anterior and inferomedial fibers of the pubvisceral muscle from the inferior pubic ramus and/or as a gap in the continuity of the pubovisceral muscle between the pubic rami and the anorectum” (Dietz, Hyland, & Hay-Smith, 2006, p. 425) or “a detachment of the puborectalis muscle from its insertion on the inferior pubic ramus” (Dietz & Shek, 2008, p.

1098) or if there is “absence of muscle bulk at rest and during contraction” or “the bulk of the pubovisceral portion of the levator ani was found to be palpably different than that found by prior experience in assessing nulliparous women” (Kearney, Miller, & DeLancey, 2006a, p. 51).

DeLancey’s group palpated 29 women to assess whether a PVM tear (previously termed “defect,” the terms to describe the PVM tear will be discussed in Chapter 3) (Kearney et al., 2006a) was present. This study reported the inter-rater reliability of palpatory assessment to assess PVM tear between two physical examiners and validity the results as compared to MRI. The first physical examiner was an expert in the field of urogynecology with over 15-year experiences. The second examiner had trained with the expert for 6 months before palpating these women. The PVM was evaluated as presence of tear as “the pubovisceral muscle was palpated by placing the index finger laterally in the lower one third of the vagina (within approximately 2 – 3 cm of the hymen) so that the middle of the distal phalanx lies on the normal location of the pubovisceral muscle” (Kearney et al., 2006a, p. 51). Palpatory assessment was performed during both pelvic muscle rest and contraction and both the left and right sides of each muscle were evaluated. A tear was found “when the bulk of the pubovisceral portion of the levator ani muscle was found to be palpably different than that found by prior experience in assessing nulliparous women” (Kearney et al., 2006a, p. 51). However, the method of the palpatory assessment was not described. The results showed positive agreement for the presence of a PVM tear of 72% and negative agreement of absence of a PVM tear of 83% between the two physical examiners. They also reported a lower positive agreement, just above 27%, and negative agreement, of 87%, between the palpatory assessment and MRI.

The validity of the palpatory assessment was also reported by comparing results with 3D ultrasound imaging of the levator ani (Dietz et al., 2006; Dietz & Shek, 2008). Both Dietz et al.

(2006) and Dietz and Shek (2008) found that there was low agreement of the PVM tear using palpatory assessment and ultrasound. This could be due to the nature of the subjective of palpatory assessment or of artifact on reading the ultrasounds. Although other forms of the finger placement (for example, Brink digital exam and modified Oxford scale) were commonly used to assess the PVM strength in both teaching and clinical setting (Bø & Finckenhagen, 2001), palpatory assessment for estimating odds of PVM tear has not been used solely to evaluate the PVM tear (Lammers, Kluivers, Vierhout, Profop, & Futterer, 2013).

In older women PVM palpatory assessment can be used to detect the PVM tear as shown by Dr. Janis Miller who used index finger palpatory assessment for estimating odds of the PVM tear in her studies that will be described in Chapter 3 of this dissertation.

Palpatory assessment for estimating odds of PVM tears is easily accessible. However, it has largely been ignored by physicians dealing with pelvic floor disorders. With a single finger, the palpatory assessment can be done in just a few moments and could easily be implemented in routine clinical examination (see Table 2.2). Its advantages suggest that it has wider accessibility and could be done in a low level clinical setting for low-income population and rural areas. The concern is the low to moderate or low agreements with either MRI or ultrasound noted above. However, many factors can influence those agreements: data were mixed and study designs were weak with low numbers of actual tears. More definitive imaging could influence the agreements in the future, for with confirmation of the PVM tear from the high tech tests like MRI and ultrasound, training of palpatory assessment skill could be made much easier and trained examiners could likely improve the reliability and validity of the palpatory assessment (J. DeLancey, personal communication, January 16, 2018). It is certainly noteworthy that the finding that 20% of 461 primiparous women had abnormal PVM using palpatory assessment by

Gainey in 1943 (p.458) is highly consistent with the prevalence found today (20% & 15%) using high technology test MRI (DeLancey et al., 2003) and 3D ultrasound (Dietz & Steensma, 2006), respectively.

Imaging Measures of PVM Structure

Imaging modalities of the PVM and pelvic floor have advanced rapidly over the past 20 years. Because imaging by definition involves a picture that is often interpreted subjectively, it is acknowledged that reading images does have a subjective component to it until more objective methods have been developed. However, with the intensity of musculoskeletal radiology training, precision in high tech imaging equipment, the clarity of the pictures with 2 mm slices, and along with high-level expertise of readers of the images, the MRI and 3D or 4D ultrasound diagnostic accuracy for PVM tear is more valid. On MR or ultrasound images an PVM tear is defined as loss of visible muscle fiber and discontinuity of muscle (Brandon et al., 2012; Miller et al., 2015).

An MRI slice in “coronal, axial, and sagittal proton density-weighted sequence” including relaxation time in ms, echo time in ms, number of slice averages, slice thickness in mm, gap in mm, field of view in cm, matrix (Brandon et al., 2012) is used to evaluate if there is an PVM tear. An PVM tear is diagnosed on MRI if there is “asymmetry in the muscle’s appearance” compared with normal anatomy of pelvic floor (DeLancey et al., 2003; Kearney et al., 2006a). MRI was used to diagnose an PVM tear in a case study of a single woman (Tunn et al., 1999). At that time, the tear was identified as a “defect” seen on MRI, without certainty of what the visual alteration was associated with mechanistically. This work was followed by an additional observational study of SUI in primiparous women (DeLancey et al., 2003). In that study, half of primiparous women had objectively documented SUI (cases) while the control

women reported no incontinence. Of the total 160 primiparous women, 20% had an PVM tear on MRI.

The last technique used to diagnose the tear is 3D or 4D ultrasound. 3D or 4D ultrasound can be used to obtain the image to evaluate PVM tear intravaginally. An PVM tear can be diagnosed on ultrasound if there is “a discontinuity between the pubovisceral muscle and the pelvic floor sidewall at the level of the levator hiatus and for at least 5 mm above this level” (Dietz & Shek, 2008, p. 1098). Using ultrasound, Dietz and Lanzarone (2005) reported that 36% primiparous women who had recent vaginal birth had PVM tear. Dietz used the term ‘avulsion’—a term that would be disputed in favor of “tear” in the radiology musculoskeletal literature (C. Brandon, personal communication, 2010). The difference is that an avulsion is a complete tear of the PVM from the pubic bone, whereas a ‘tear’ allows one to define a partial tear from the bone that is not yet an avulsion.

It should be noted that with regards to quantifying PVM structure, the diagnostic modalities of all of these different imaging techniques within various machines (e.g., MRI machines, ultrasound machines), conditions (i.e., coils, transducers, etc.) and rater training background (e.g., radiologists, specialist clinicians, technicians or lay research staff) have not yet been rigorously compared to one another. Although beyond the scope of this dissertation to do so, this lack of strong comparative data and the explosion of new imaging techniques poses problems for conducting metaanalyses. Otherwise these would be a useful analytic technique considering the small sample sizes of many studies as a limiting factor as well as the bias of single examiner studies even if larger subject numbers are involved. Thus, issues of measuring PVM *structure* have some similarities with the long history of issues of measuring PVM *function* as reviewed elsewhere in this Chapter.

MRI. MRI can be used to diagnose an PVM tear by observing the connection between the PVM and the pubic bone as well as the muscle bulk. An PVM tear is diagnosed if the muscle is not fully connected to the pubic bone and there is loss of the muscle bulk through MRI. Kirschner-Hermanns used MRI to report abnormalities in PVM in 1993 (Kirschner-Hermanns, Wein, Niehaus, Schaefer, & Jakse, 1993) (J. DeLancey, personal communication, January 16, 2018). In Kirschner-Hermanns et al.'s study, although some information about the MRI and how to read the imaging was given, it is difficult for others to duplicate this test. This is because the examinations were "made with T1 weighted spin-echo sequences" and "The spatial resolution was 1.5 mm in every direction and the slice orientation was transverse. In each patient a series of 16 plain images was followed by a series of IV-Gd-DTPA-enhanced images (0.2 mmol/kg body weight)" (Kirschner-Hermanns et al., 1993, p. 715). They examined 24 SUI women and 6 healthy volunteers to test whether urethra was connected to the levator ani. They found 66% of the stress incontinent women lost a sharp dorsally-angulation of the levator sling. In 45% of these stress incontinent women, degeneration of the PVM was seen (Kirschner-Hermanns et al., 1993). The reliability and validity of how accurate the assessment of the PVM is using MRI were reported in later publications.

In the 1990s, DeLancey's group used MRI to report a complete loss of PVM in some parous women (Tunn et al., 1999). They did not give much information on how to perform the MRI test but they did detail how to read the images. Fourteen parous women were tested on PVM signal intensity and muscle thickness. The authors reported one woman with a complete bilateral loss of PVM and they suggested that the muscle loss might be a muscle tear. They also found no difference between intra- and interobserver measurements. The reliability of MRI evaluation of PVM tear has been reported in later publications.

MRI was used to diagnose the PVM tear by DeLancey (Chou & DeLancey, 2001) who called the broken connection and loss of the muscle bulk a “defect” at that time. DeLancey later assessed PVM abnormalities using MRI in 80 nulliparous and 160 vaginally primiparous women (DeLancey et al., 2003) and reported that PVM tears were seen in primiparous women but not in nulliparous women. They found that 20% of primiparous women had abnormalities on the PVM using 3 mm slices to find the muscle loss or missing. The results were categorized into four levels, from ‘no muscle loss’ to ‘complete muscle loss,’ and ranged from 0 to 3 for each side. Sum of the possible scores from both left and right sides therefore range from 0-6 for a two-side score: 0 indicating ‘no muscle loss’, 1-3 ‘minor muscle loss’, 4-6 (or one side score of 3) means ‘major loss’ (Kearney, Miller, Ashton-Miller, & DeLancey, 2006b). Both Morgan et al. (2007) and Lammers et al. (2013) reported good inter-rater reliability with weighted kappa=.86 and an intra-class correlation coefficients (ICC)=.76, respectively, among women with prolapse or other pelvic floor dysfunctions when the PVM tear was categorized into none, minor, and major tear. Lammers et al. also reported good intra-rater reliability with ICC=.80 among these women. The PVM tears were also categorized into 5 levels: ‘no tear’, ‘subtle tear’, ‘less than 50% tear’, ‘greater than 50% tear’, and ‘complete tear’ for each side. The degree of both left and right sides of the PVM was collapsed into four categories: ‘no tear’ or ‘subtle tear’ on both sides of PVM (coded as 0), ‘<50% unilateral tear’ (coded as tear level I), ‘<50% bilateral’ or ‘≥50% unilateral tear’ (coded as ‘tear level II’), and ‘≥50% bilateral tear’ (tear level III) (Low et al., 2014; Miller et al., 2015). These correspond to the prior categories proposed by DeLancey as ‘none’, ‘minor’, ‘minor both sides’ or ‘major one side’, and ‘major both sides’.

In summary, MRI is currently the gold standard test for evaluating PVM status (Yan et al., 2017) (see Table 2.3). MRI can provide images of the muscle structure and be used to

measure the degree of visible muscle loss. The degree of the tear along with other health information will provide the convenience for decision making. High technological test MRI helps us to better understand the PVM as well as its role on the etiology of the pelvic floor disorders, which will guide the prevention and treatment for the disorders. MRI (DeLancey) is more suitable for focus on to measuring the muscle loss located on the pubovesiceral portion (PVM) of the levator ani and the connection between the pubovesiceral portion and pubic bone. Expensive MRI machine, trained examiners, and image readers are required to complete these tests. MRI is not widely accessible. Taken together these factors limit the use of MRI. To implement MRI as a routine clinical examination in most healthcare settings is not simple and easy (Table 2.3).

3D or 4D ultrasound. 3D or 4D ultrasound is another high technological diagnostic technique to assess PVM injury. The first publication used 3D ultrasound in urogynecology was by Cardozo's group in 1994 (Khullar et al., 1994) that suggested that 3D ultrasound could be used to assess the urethra (Dietz, 2004). Later publications reported 3D ultrasound imaging of urethral and paraurethral tissues (Dietz & Steensma, 2003; Wisser, Schaer, Kurmanavicius, Huch, & Huch, 1999). However, few studies have focused on the imaging of the PVM by ultrasound (Dietz, 2004; Dietz, 2007 pp. 81-92). Dietz first found the PVM injury using ultrasound in November 2002 although he did not recognize the injury at that time (H. Dietz, personal communication, January 24, 2018). The idea of using ultrasound to diagnose PVM injury was first mentioned in a review paper by Dietz (2004). He first reported the PVM injury diagnosed by 3D/4D translabial (or transperineal) ultrasound in 2005 (Dietz & Lanzarone, 2005). In the 2005 study, nulliparous women at 36 - 40 weeks of gestation and after birth were tested. Information is given on the 3D/4D ultrasound machine and the methods for how to perform the

examination. However, no information was provided for how the images were read or how quantification of the loss of muscle continuity was given. An PVM injury was found if “there was a loss of continuity between muscle and pelvic sidewall in all volume data sets” (Dietz & Lanzarone, 2005, p. 709). The two-examiner test-retest reliability of PVM injury quantification via 3D translabial (or transperineal) ultrasound was reported as having a Cohen’s kappa of .83 (95% CI, .59–1.0) in a later study (Dietz & Steensma, 2006). Another study also reported good intra-rater reliability (ICC: .82–.91) for using ultrasound to assess PVM tear in postpartum women with recent vaginal birth, but a relative lower and wider inter-rater reliability (ICC: .13–.68) (van Delft, Shobeiri, Thakar, Schwertner-Tiepelmann, & Sultan, 2014). Although 3D/4D ultrasound may be less costly than MRI, other issues like having an experienced physician rater and uneven accessibility may deter its wider uptake in clinical setting.

Perineal ultrasound can be used to adequately visualize the PVM portion of the levator ani with images of the muscle structure that suffice for measuring the degree of visible muscle damage (Dietz & Lanzarone, 2005; Dietz & Steensma, 2006). It is still relative expensive and not widely accessible because it requires an ultrasound machine, trained operators, and image readers. These factors unfortunately restrict the use of ultrasound as a routine clinical examination in most healthcare settings (see Table 2.3).

Measures of PVM Function

PVM strength is one measure of PVM function. Generally, muscle strength is defined as the maximum contractile force that can be exerted against an immovable object (this is defined by muscle physiologists as static or isometric strength), the heaviest weight which can be lifted or lowered (dynamic strength), or the maximal torque which can be developed against a preset rate-limiting device (isokinetic strength) (Frontera & Meredith, 1989, pp. 319-331). It is

noteworthy that force has a magnitude and a direction. With the PVM hidden within the pelvic cavity, measures of PVM strength have relied almost exclusively on attempts to measure some form of change that happens within the vagina when a woman attempts to contract her pelvic muscles, the PVM portion of which slings around the vagina. That change is only measured isometrically as force if the object or construct used to make the measurement is placed intravaginally is essentially incompressible and measures force (in Newton). Some devices or constructs placed intravaginally to measure PVM strength have been designed to measure the pressure applied to the construct. It is noteworthy that pressure has magnitude but not direction. These pressure measuring devices include perineometer balloons. One drawback is that such balloons have compliance, thereby permitting the muscle to shorten during the strength test, thus not conducting the test in an isometric manner. If the object placed intravaginally is the examiner's finger(s), then the examiner can assess subjectively either the lifting force applied by the PVM against the finger(s) by the posterior vaginal wall, or (s)he might assess the pressure applied around the finger(s). Lastly, in a sagittal view, dynamic ultrasound or dynamic MRI can be used to objectively assess how much the subject can volitionally elevate or lift the distal posterior wall of the vagina. A displacement or movement of this type has units of distance, but not force or pressure, and it gives not information on strength.

In total, we could find 14 instruments that have been described for assessing the PVM function found on a search of the literature. All of these instruments attempt to measure the PVM 'strength' based on a pelvic muscle contraction that attempts to close the vagina, a strength that can also be describe the maximum vaginal closure force. For the past 15 years, most intervention studies for SUI reported on vaginal closure force using one of these types of instruments, either subjective or objective in nature. The subjective forms of PVM strength measures are reviewed

first. These are then followed by objective measures of same intent to quantify PVM function or functional change.

Subjective Measures of PVM Function

Subjective measures of PVM function all rely on the examiner making a judgment call regarding what is felt or seen by the examiner on exam. They can be divided into the measures that rely on placement of finger(s) passively into the vagina so the examiner can feel (a) pressure or (b) lift exerted on the finger(s) during a pelvic muscle contraction attempt (Dougherty's circumvaginal muscle grading scale, Brink's digital exam, and Laycock's modified Oxford scale), or alternatively measures that rely on visual demonstration of a lifting maneuver during a pelvic muscle contraction attempt (components of the above measures along with sagittal dynamic ultrasound measures).

Finger placements for assessing PVM strength. The use of finger placement for assessing the PVM strength in the field of SUI has a long history. Kegel (1956) used one finger to assess the PVM as a part of gynecological examination. Hendrickson (1981) used this one finger technique to assess the contraction of the pelvic muscle. Many research groups have since used finger placement (either one or two fingers) to assess PVM function (Brink, Sampsel, Wells, Diokno, & Gillis, 1989; Brink, Wells, Sampsel, Taillie, & Mayer, 1994; Laycock, 1994; Sampsel, Brink, & Wells, 1989; Worth, Dougherty, & McKey, 1986). The PVM function is assessed through quantifying the degree of pressure during a pelvic muscle contraction that is exerted by a woman on the examiner's finger(s). The most popular finger placement techniques are the Brink digital exam and the modified Oxford scale (Deegan et al., 2017). Another well-developed placement is that of Worth et al. (1986) who used one finger to assess circumvaginal muscle in healthy women.

Circumvaginal muscle rating scale. The circumvaginal muscle refers to a group of pelvic floor muscles that include the transverse perineal muscles, bulbocavernosus muscle, levator ani, and sphincter ani muscles (Cosner, Dougherty, & Bishop, 1991). A circumvaginal muscle rating scale was introduced to assess the circumvaginal muscle function using one finger during a gynecological examination in 1986 (Worth et al., 1986). In the study, information about how to score the circumvaginal muscle was given. Thirty healthy women were tested on four characteristics of circumvaginal muscle: “pressure,” “duration,” “muscle ribbing,” and “position of the examiner’s finger during examination” (Worth et al., 1986, p. 167). The circumvaginal muscle was scored using a 9-point circumvaginal muscle rating scale based on the four characteristics scored from 1 to 3: “1” means no pressure, or no duration, or no ribbing or muscle feels soft and flabby, or examiner’s finger easily slip out, “3” means a firm pressure, duration longer than 4 seconds, muscle feels distinct or ribbed muscle tissue, and finger is pulled upward. However, information about how to position women during the examination was not given. Thus, others may not easily repeat this gynecological examination. This study reported interrater reliability (“N=10, rho=.6, $p < .04$; N=10, rho=.7, $p < .05$ ”) and test-rest reliability (“N=10, rho=.9, $p < .003$ ”) (Worth et al., 1986, p.167). A positive correlation between the total score of the circumvaginal muscle rating scale and maximum pressure measured by intravaginal balloon device was reported in a follow-up study (McKey & Dougherty, 1986).

The circumvaginal muscle rating scale is a simple, low cost and accessible examination in clinical settings. Pressure is recorded as the intensity of the circumvaginal muscle contraction on the examining finger, but it may be difficult to differentiate the intensity of the circumvaginal muscle contraction from the increase in IAP due to an abdominal wall muscle contraction with or without the diaphragm. In addition, the pressure is from the groups of pelvic muscles other than

only PVM, which cannot represent the PVM strength. Furthermore, the scores of the pressure were recorded based on the examiner's sensation of the squeeze. It is an indirect method to assess strength (see Table 2.2).

Brink digital exam. The Brink digital exam was introduced to measure PVM function via inserting the index and middle fingers vaginally to measure contractile function during a voluntary pelvic muscle contraction by older women with urinary incontinence in 1989 (Brink, et al., 1989). In this study, detailed information about how to perform the exam was provided, so it could be duplicated by others. Gloved index and middle fingers were inserted vaginally on an antero-posterior plane to a depth of approximately 4 - 6 cm. Women were asked to contract the pelvic muscle as much force and as long as they can, the examining fingers felt the squeeze and checked the duration the contraction lasted. The PVM function was recorded as vaginal pressure, duration, and posterior vaginal wall displacement from the contraction. Brink digital PVM rating scale for these three characteristics were from 1 to 4: "1" means no pressure, or no duration, or no displacement, "4" means strong pressure from fingers compress, duration greater than 3 seconds, and fingers move up and are drawn in (Brink et al., 1989; Sampsel et al., 1989). The sum of the scores from the three characteristics represents the strength of the PVM. Test-retest correlation for the anteroposterior score was .65 ($p < .01$) with inter-rater reliability .91 ($p < .01$) when measuring older women with urinary incontinence (Brink et al., 1989). The inter-rater reliabilities when measuring pregnant women were from .67 ($p < .01$) to .771 ($p < .01$) (Sampsel et al., 1989).

The Brink digital exam was later updated to a second version to measure vaginal pressure for incontinent women (Brink et al., 1994). For this version, however, moderate and low reliabilities for pressure, duration, and displacement were reported. Lower inter-rater reliability

was also found in comparisons to a perineometer (Hundley et al., 2005). The validity of this exam was demonstrated by women with urine loss having lower scores than those who did not have urine loss. The validity was also tested by women who had given birth vaginally having lower scores than those who had cesarean births (Sampselle et al., 1989).

The Brink digital exam is one of the most common instruments used to assess vaginal pressure (Deegan et al., 2017). Brink digital exam is cost-effective, time-efficient and a less invasive method. It is also used as an indicator to evaluate the effectiveness of the treatment of pelvic muscle exercises for urinary incontinence. However, Brink digital exam has only limited capacity to evaluate vaginal closure pressure. It is a poor method for detecting changes outcomes such as maximum pressure because of the subjectivity of the assessment, unstable test-retest reliability and inter-rater reproducibility. The results from this exam also rely on the knowledge and experience that the examiner has. Tests that rely on finger placement have less reliability than dynamometric speculums because vaginal pressure is scaled based on the examiner's sensation and memory of the squeeze around the examining fingers. The felt pressure is generated from a pelvic muscle contraction, but it can be hard to differentiate from increases in IAP which naturally accompany a voluntary pelvic muscle contraction (Peschers, Gingelmaier, Jundt, Leib, & Dimpfl, 2001). This is an indirect measure of contractile capability since it measures the pressure from a pelvic muscle contraction on fingers (see Table 2.2).

Modified Oxford scale. Jo Laycock modified the general muscle Oxford scale to use for assessing the PVM. She introduced the modified Oxford scale in a book chapter (Laycock, 1994, pp. 42-48). In this book chapter, detailed information of how to use index and middle fingers to assess the PVM strength was given, however, the information of the “the index and middle fingers spread laterally, thus palpating the right and left pubococcygeus simultaneously”

(Laycock, 1994, p. 45) is hard to be duplicated. She also provided a figure with the location of the fingers for the examination, but she wrote about 'lift', 'move up' and 'repetitions' in the text. No participants or results were given in the chapter. She reported that the PVM strength was assessed by introducing the index and middle fingers intravaginally to a depth of 3 cm and assessing the "power (P), endurance (E), number of repetitions (R), and number of fast (F) (1 s) contractions; furthermore, every (E) contraction (C) is timed (T)," that was called the "P.E.R.F.E.C.T." assessment scheme (Laycock, 1994, p. 45). She graded the power (P) using 6-point scale from the Oxford grading system from 0 to 5, as follows: "0 = no contraction; 1 = flicker; 2 = weak; 3 = moderate; 4 = good; 5 = strong" (Laycock, 1994, p. 46). Power (P) indicates the pressure felt from compression of the examiner's fingers. She gave an explanation of how to differentiate each level of the power based on sensation from the examiner's fingers. Endurance (E) shows the time (in seconds) of a contraction, taken to be a measure of the slow PVM fiber activity. Number of repetitions (R) means the number of a woman can contract under the same power and endurance. Number of fast (F) tests is a measure of whether a woman can perform fast (1 s) contractions of the circumvaginal muscle up to 10 times, which purportedly tests the contractility of the fast twitch fibers. Histological studies show 5% fast twitch fibers and 95% slow twitch fibers in the PVM (Gosling, Dixon, Critchley, Thompson, 1981). Every (E) contraction (C) is timed (T) that represents holding contractions longer and improving the number of repetitions, which is similar the muscle re-education. Reliability and validity were reported later in Laycock and Jerwood (2001). High reliability was reported for power (inter-rater reliability, $r=.95, p<.001$; test-retest reliability $r=.93, p<.001$). A significant correlation was found between power and perineal lift ($r=.86, p=.031$), and perineometric pressure ($r=.79,$

$p=.001$) (Laycock & Jerwood, 2001) and this was taken as evidence that the modified Oxford scale was valid for assessing the PVM.

Reliabilities of measuring pelvic muscle contraction have been reported across the literature. For example, Devreese et al. (2004) reported high inter-rater reliability ($\kappa=.94$) of the modified Oxford scale for assessing the PVM 'strength' from both urinary continent and incontinent women. However, the modified Oxford scale has also been reported as having low inter-rater reliability for assessing PVM 'strength' in healthy young female students ($\kappa=.37$) (Bø & Finckenhagen, 2001) and ($\kappa=.33$) (Ferreira et al. 2011). Navarro Brazález et al. (2017) reported similar low Cohen's kappa ($\kappa=.27-.38$) for inter-rater reliability in nonpregnant women who had urinary incontinence, fecal incontinence and pelvic organ prolapse (Navarro Brazález et al., 2017). Devreese et al. (2004) appear to report high inter-rater reliability of the modified Oxford scale compared with three other studies mentioned above. This difference may be because of the following several reasons. First, participant variability needs to be taken into account for the different inter-rater reliabilities. Second, Devreese et al. (2004) included both continent and incontinent women while Navarro Brazález et al. (2017) included women who also had fecal incontinence and pelvic organ prolapse. Third, the status of a prolapse may affect their findings. Fourthly, how participants contracted their pelvic muscles will affect the rater's feeling. The ability to correctly contract pelvic muscles may help the rater to accurately rate the 'strength'. Fifthly, the results also can be affected by the rater's experiences. Well-trained rater may give relative higher reliability data. Last but not the least is the methodological variability in the different studies. The evaluation may be performed in the same visit that day, while others may be during different visit on different day, especially for women who are under treatment, so the effect of improvements in their treatment for either incontinence

or prolapse may not be taken into account. Thus, these factors may affect the evaluation of the PVM ‘strength’ using the modified Oxford scale to assess the PVM ‘strength’.

The modified Oxford scale is another common instrument to assess PVM strength (Deegan et al., 2017). Similar as Brink digital exam, the modified Oxford scale also is a simple, low cost and less invasive method. It is mostly used as an indicator to evaluate the effectiveness of the treatment of pelvic muscle exercises for urinary incontinence. Although Navarro Brazález et al. (2017) reported good intra-rater reliability ($\kappa = 0.78$) for assessment of vaginal pressure, it has both lower inter-rater and intra-rater reliabilities compared with those from manometry and dynamometry. The subjectivity associated with the use of fingers limits its use. The fairly good intra-rater reliability suggests that the assessment and reassessment by the same examiner using the finger placement for the ‘strength’ may be meaningful in clinical setting for the purposes of evaluation of healthcare service, but it is not sufficiently reproducible and valid to measure strength for scientific purposes (Bø & Finckenhagen, 2001). Similar to Brink digital exam, the modified Oxford scale is poor at detecting the change of the pressure because of examiner subjectivity, low test-retest reliability and inter-rater reproducibility. It is a less reliable method to measure the strength compared with dynamometric speculums (see Table 2.2).

Table 2.4 provides a visual portrayal of the similarities and differences between the three most commonly used forms of finger placement techniques used for assessing PVM function.

Objective Measures of PVM Function

Objective measures of PVM function all rely on the examiner placing a device of some sort into the vagina, the device then providing a change in output signal during a pelvic muscle contraction attempt. These devices include electromyography (EMG) electrodes and various forms of instrumented speculums, perineometers and intravaginal balloons. Unfortunately, the

readings of the majority of these devices are influenced by the increases in IAP within the vaginal cavity (Bø, Kvarstein, Hagen, & Larsen, 1990b) which co-occur with attempts at pelvic muscle contraction (see above). This contamination of one signal (i.e., changes in pressure due to PVM) by another signal (i.e., changes in IAP) is known as “crosstalk” and, depending on the magnitude of the crosstalk, this can cause a major problem in interpreting the output signal of a measurement device. For example, if half of the signal measured by an intravaginal device is due to IAP increase, then the error on the measured pelvic muscle contraction activity is $(0.5/0.5*100) = 100\%$; if one quarter of the signal is due to IAP, then the error is $0.25/0.75*100 = 33\%$. As we shall see, the one-billed speculum device is a rare exception in this regard (Ashton-Miller, Zielinski, Miller, & DeLancey, 2014). Intravaginal EMG electrodes include needle and surface types oriented to quantify PVM activity. However, depending upon electrode spacing (Basmajian, & De Luca, 1985), it can be difficult to isolate the PVM EMG signals from EMG signals arising from activity in adjacent muscles (Taverner & Smiddy, 1959) such as the obturator internus muscle.

Most Instruments for assessing PVM ‘strength’ are subject to crosstalk from IAP.

Many devices that have been used to assess PVM strength provide readings that are unfortunately contaminated by crosstalk from IAP. IAP at the intravaginal location where the device is placed is equal to the hydrostatic pressure head acting at that location plus any increase in that pressure due to abdominal wall and/or diaphragm contraction. In the resting supine position, the hydrostatic head is equal to the vertical distance from the device to the outer surface of the abdominal wall times the density of the abdominal contents along that vertical line times the gravitational constant. Activities such as a cough, sneeze, laugh, lift or a Valsalva maneuver

increase the hydrostatic pressure above the resting value due to the abdominal muscle contraction (Shaw et al., 2014).

For the purpose of this paper, we are concerned with the effect of IAP because it acts in all directions on the bladder and its contents, the vagina and, importantly, on the measuring intravaginal measuring device. It follows then that any intravaginal pressure measurements will be contaminated by the influence of IAP. For example a slight movement by a woman that requires abdominal muscle activity will be picked up by the intravaginal instrument as an increase in IAP. This increase could be misinterpreted as an increase in PVM activity. An intravaginal pressure transducer simply cannot differentiate between increases in IAP and increase in PVM activity. To counter this, the person making the measures can try to coach a woman to make no change in IAP (i.e., “don’t strain down or use extraneous muscles”) while measuring the pelvic muscle contraction. But, for some women following these instructions is difficult, if not impossible, to do. Moreover, if she has a completely torn PVM this may be impossible.

Most measurements of PVM ‘strength’ are performed during an attempt at a maximal voluntary pelvic muscle contraction. However, maximal contraction efforts often include the coactivation of adductor, gluteal, and abdominal muscles (Burgio, Robinson, & Engel, 1986) leading to measurement error of PVM ‘strength’. This is because abdominal muscle contractions are a normal response when pelvic muscles contract (Sapsford et al., 2001). So the contraction of these accessory muscles may elevate the IAP and this will be recorded as an increase in the vaginal closure pressure. Thus, the recording of the PVM ‘strength’ may contain within it an inseparable contribution of IAP (Peschers et al., 2001). The instruments that have been used to assess PVM ‘strength’ that do not exclude the influence from the IAP include all perineometers

and intravaginal balloon devices, Segovia or similar devices, the Ashton-Miller two-billed speculum, the Dumoulin speculum, and the Verelst speculum (see Table 2.3).

Perineometer. Perineometers (Figure 2.2a) first introduced in 1948 by Dr. Arnold Kegel, an obstetrician and gynecologist, were the first instruments to use to measure “the degree of contraction of the perineal muscles” (Kegel, 1948). In that study the perineometer was introduced to let postpartum women monitor how their contractile ‘power’ increased during pelvic muscle exercises through contractions, later named Kegel exercises. Information about the design of the perineometer and its use were provided. The perineometer is composed of a pneumatic vaginal chamber to receive the contraction that connects to a manometer to measure the force of the contraction from between 0 and 100 mm of mercury. The pneumatic chamber receives the pressure from the all points of the vagina. The perineometer measures maximum voluntary vaginal closure pressure during a voluntary pelvic muscle contraction. A woman can self-insert the pneumatic chamber into vagina and the results of her contractile ‘power’ while contracting will be seen immediately. Kegel used the perineometer to provide the woman immediate visual biofeedback of the woman’s pelvic muscle contractile activity that was used to encourage the woman to continue to perform the contractions. Kegel found that women varied greatly in their ability to contract the pelvic muscles. He also found that a woman had nearly linear increase of her contractile ‘power’ measured by the perineometer during an exercise period that gradually increased the pelvic muscle exercises. Reliability of measuring the vaginal closure pressure using the perineometer was reported in late publications.

Since the pneumatic chamber receives pressure from all parts of the vagina under the influence of IAP all Kegel’s measurements were contaminated by IAP. The perineometer was later refined by connecting a balloon catheter to pressure transducers, and a firm silicone tip was

added to the balloon catheter (Dougherty, Abrams, & McKey, 1986). However, Bø et al. (1990b) found that the balloon with a silicone reinforcement of the tip did not exclude the involvement of the IAP. This indicates that the silicone reinforcement of the tip did not reduce the influence of the IAP. Continued efforts have been made to modify the perineometer to improve the reliability of measurement. Examples include a silicone sensor perineometer with an arbitrary scale of 0–12 (Isherwood & Rane, 2000) and a Peritron perineometer with reading in centimeters of water (Hundley, Wu, & Visco, 2005; Ribeiro Jdos et al., 2016). Isherwood & Rane (2000) reported there was good agreement for measuring the PVM ‘strength’ between perineometer and Brink digital exam, while Hundley et al. (2005) found that perineometer has relative high inter-rater and intra-rater reliability compared with Brink digital exam. In addition, there was good inter-rater reliability (.80 and .79) for the mean value of three maximum voluntary pelvic muscle contractions and single maximum value of the three contractions during both first and second trimesters of pregnancy (Ribeiro Jdos et al., 2016).

The perineometer is commonly used to assess the PVM ‘strength’ via vaginal closure pressure (Deegan et al., 2017). It is easy to perform, so that women can use the perineometer to monitor how they contract at home. The advantages and limitations of the perineometer are shown in Table 2.3. However, the perineometer will always be an indirect method for measuring PVM ‘strength’ because of IAP crosstalk.

Intravaginal balloon device. Intravaginal balloon device (Figure 2.2b) was further developed from the perineometer to measure intravaginal closure pressure during a voluntary pelvic muscle contraction in 1986 (Dougherty, Abrams, & McKey, 1986). While those authors provided information about their laboratory procedures with the intravaginal balloon device, they failed to give information about the size of the balloon, its depth of insertion vaginally, and

confirmation of the location of the balloon in vagina. The intravaginal balloon device is a fluid-filled device whereby the balloon catheter was connected to pressure transducers. “A firm silicone in the posterior portion of the intravaginal balloon device” was added in the balloon catheter, which might reduce crosstalk from IAP. They tested 20 healthy parous and nulliparous women in the study. Maximal contraction and submaximal contractions were recorded during the examination. The authors found that variation in the women’s effort to contract the muscle was a challenge for this device. Some women may “put tremendous effort into the contraction”, but “others did not exert themselves” for the contraction (Dougherty et al., 1986, p. 206). The authors reported that no involvement of the IAP in the pressure record was seen by comparison of the “resting pressure,” “rate of rise,” “maximal pressure,” and “rate to return to baseline” with or without abdominal muscle contractions; however, this conclusion was later disaffirmed (Bø et al., 1990b). Test-retest reliability for the intravaginal balloon device conducted from 16 women was reported on the repeated maximal contractions on “resting pressure” ($r=.78, p<.05$), “maximal pressure” ($r=.85, p<.05$), and “rate to return to baseline” ($r=.52, p<.05$) (Dougherty et al., 1986). In the same year, another paper from this group about the intravaginal balloon device was published (McKey & Dougherty, 1986). In the study, they found a positive correlation between the intravaginal balloon device measures and the circumvaginal muscle rating scale total scores. They also found a negative correlation between intravaginal balloon device measured maximal pressure and age, and parity (McKey & Dougherty, 1986). However, Bø et al. (1990b) found that the balloon tip in Dougherty’s intravaginal balloon device did not reduce the crosstalk of the IAP although Bø concluded the balloon catheter was a reliable instrument to measure the vaginal closure pressure in another study (Bø, Kvarstein, Hagen, & Larsen, 1990c).

A balloon device may have a place for evaluating the effectiveness of clinical treatment for SUI. But the suspect validity of the intravaginal balloon device may limit its use for scientific purpose. Same as the perineometer, the intravaginal balloon device receives pressure from the all points of the vagina during the maximum pelvic muscle contraction that involves the IAP. The advantages and limitations of the balloon device are presented in Table 2.3.

Segovia. Segovia was introduced in Janis Miller's doctoral dissertation. In her dissertation study, the detail of composition of the Segovia and the using of the Segovia to measure the distal vaginal pressure was provided. Segovia (named due to the guitar-shaped silicone rubber casing) is a self-retaining intravaginal pressure recording device and to measure distal vaginal pressure under conditions simulating those in which SUI actually occurs (Miller, 1996, Chap IV, pp. 85-99). Segovia was a device that contained “a medical-grade pressure transducer (0-7 psi, 10 mm in diameter) contained centrally in a lightweight (<10 grams), semi-flexible silicon rubber casing 5 mm thick and about 40 mm long” (p. 90). The aperture of the sensor was inserted into vagina with “the pressure transducer oriented anteriorly” (p. 90). In the study, continent nulliparous premenopausal women and parous women with SUI were applied to test reliability and validity for the Segovia. Segovia had a fair criterion-related validity, divergent validity, and construct validity. Within-visit correlations of the distal vaginal pressure were from .52 for upright maximum vaginal contraction measures to .98 for upright static measures, within-visit repeated activities including rest, maximum vaginal contraction, deep cough, and Valsalva. From supine to upright position, the static change in distal vaginal pressure with mean (SD) 22.5 (23.5) cm H₂O was greater than the static change in the IAP with mean (SD) 10.34 (14.3) cm H₂O. Continent women ranked significantly higher in change in distal vaginal pressure than parous incontinent women during Valsalva activity.

The Segovia design was inexpensive, easily sterilizable and reusable. It was easy to use in various postural positions and dynamic activities that cause SUI. It had high acceptability by women and provided meaningful biofeedback for women. However, Segovia measured distal intravaginal pressure that was contaminated by the IAP, so Segovia was not used further (see Table 2.3).

Two-billed instrumented speculum. The two-billed instrumented speculum (Figure 2.2c) was invented in 2002 to measure vaginal closure force during a maximum volitional pelvic muscle contraction under the isometric conditions favored by muscle physiologists (Ashton-Miller, DeLancey, & Warwick, 2002). The speculum consists of a ventral bill (upper bill) and a posterior bill (lower bill), each equipped with sensors to measure the distal vaginal closure forces in the sagittal plane developed by the PVM as they elevate the posterior vaginal wall against the pubic symphysis. The speculum was covered by a disposable condom and to be inserted 5 cm vaginally, detailed information being provided about construction and performance of the device. The first results were reported in 2007 with the authors examining the test-rest reliability of the vaginal closure force measurement using the speculum (Miller, Ashton-Miller, Perruchini, and DeLancey, 2007). In that study 12 continent nulliparous women exerted maximum vaginal closure force with repeated measurements within the same day and across 3 days. Test-retest reliability was calculated using within- and between-visit repeatability of the maximum vaginal closure force. The best within-visit repeatability at maximal voluntary contraction was on the third day with a coefficient of repeatability of ± 3.75 N. For cross-visit repeatability, the best repeatability was comparison of visit 2 and 3 based on best of two within-visit scores with coefficient of repeatability ± 5.5 N. The two-billed speculum was a more accurate measure than perineometers, and more objective than finger placement methods. However, since the ventral

bill will respond to IAP, the recorded vaginal closure force includes the effect of IAP crosstalk. One way to minimize this is to only accept maximum vaginal closure force measurements when the increase in IAP was suppressed by the subject to less than 5 cm H₂O, the IAP being measured by a catheter in the bladder (Morgan et al., 2005). However, in discussing their results the authors were concerned that this 5 cm H₂O criterion may have inhibited subject's ability to develop maximum vaginal closure force. Because of this the two-billed instrumented speculum has not been widely used to measure vaginal closure force for SUI (see Table 2.3).

Dumoulin instrumented speculum. In 2003 a similar two-billed dynamometer was developed to measure PVM strength via recording vaginal closure force by Dumoulin et al. (Figure 2.2d) (Dumoulin, Bourbonnais, & Lemieux, 2003). Detailed information about the components of the speculum and the operation of the speculum were provided. Again, the device was to be inserted 5 cm into the vagina to measure vaginal closure force in the sagittal plane. The authors failed to provide information about the characteristics of the participants. The vaginal closure force was measured during a maximal pelvic muscle contraction while the two bills were held with a spacing of 5 mm and then of 15 mm. They reported the speculum as being a highly reliable measurement since there was no significant difference between repeated two session measurements. However, no information was provided about the inevitable crosstalk from IAP onto the vaginal closure force signal and this effect was not considered in the discussion as a limitation of the method.

The reliability of the Dumoulin instrumented speculum was reported in a later publication in 2004 (Dumoulin, Gravel, Bourbonnais, Lemieux, & Morin, 2004). Parous women with SUI were tested for the vaginal closure force and endurance of the PVM using the speculum. Forces and endurance were repeatedly measured in three successive sessions with a 4-week interval

between each session. The maximal forces were measured at three dynamometer openings as 5 mm, 10 mm, and 15 mm between the two bills. The repeatability of the maximal force measurement was reported as having a high coefficient of dependability (a similar statistic to the classical intra-class correlation coefficient of type 2 for absolute agreement) of .88 with a low standard error of measurement (SEM) of 1.49 N at 10 mm opening between the two bills. And the reliability of maximal rate of force development was reported .86 with an SEM of 0.056 N/sec (Dumoulin et al., 2004). However, no information about the possibility of crosstalk from IAP onto the measured maximum force signal was provided, so a systematic bias of the measurements was not considered. Instrument validity was reported in another two publications. For example, Morin, Bourbonnais, Gravel, Dumoulin, and Lemieux (2004a) found that continent women had higher maximum closure force, higher absolute endurance, and higher rate of force development than incontinent women. In a second study, correlation coefficients of .73 and .45, for continent and incontinent women, respectively, were reported for the speculum and modified Oxford scale (scale range 0–5) (Morin, Dumoulin, Bourbonnais, Gravel, & Lemieux, 2004b). In summary, the Dumoulin instrumented speculum provides a measure of the vaginal closure force that is unfortunately contaminated by IAP. A drawback of the two-billed instrumented speculums is that they do not allow measurements of vaginal closure force in women with an unperforated hymen or in those with significant prolapse. Neither instrumented speculum is commercially available so they are not widely used in either research or clinical settings (see Table 2.3).

Verelst speculum. In 2004 Verelst and Leivseth (2004) reported an intravaginal device (Figure 2.2e) to measure passive and active vaginal closure force in the frontal plane. Detailed information on the device and measurement procedures was provided. The device again is

formed from two bills, in this case half-round stiff rods, in parallel. The outer diameter of the rods could be varied from 30 to 50 mm. One of the rods was divided into two parts spliced with a metal plate serving as a gage section with strain gauges. In the results, the authors tried to find a relationship between the passive and active vaginal closure force (in N) and the diameter of urogenital hiatus. Twenty healthy parous women were tested. Repeated measures tests were conducted with 2 – 4 days interval. Good repeatability of the device was concluded from the lack of a difference in active force measurements within-subjects and little variability in tests repeated test for all diameters. That passive and active forces increased with the increase of the diameters of the two rods was confirmed in a later study (Verelst & Leivseth, 2007) and the most appropriate diameter range was held to be 40 to 50 mm. Differences in active force but not passive force between women with and without SUI were reported (Verelst & Leivseth, 2007). A drawback of the Verelst speculum is that the authors cannot exclude the possibility that the increase in resistance at the wider rod spacings may simply reflect the rods acting directly against the bony pelvis in that region. This would represent a major systematic error in the measurement of vaginal closure force in the transverse plane. In addition, it is a limitation that the authors fail to acknowledge the possibility of crosstalk from IAP on their maximum vaginal closure force measurements. The instrument has not been widely used in general research or clinical settings (see Table 2.3).

Electromyography for assessing PVM activity. Another tool for assessing PVM activity is to measure PVM EMG. This of course does not give results in units of contractile force, but rather in terms of intensity of electrical activation of striated muscle. The first studies to measure the muscle action potentials during contraction of muscle tissue date from the middle of the 19th century (Floyd & Walls, 1953; Franksson & Petersen, 1953). Since then, needle, wire

and surface EMG electrodes have been used depending on the goal. EMG electrodes can be used to characterize individual motor unit activity (i.e., single discrete motor units) qualitatively as well as quantitatively (Housh, Housh, & deVries, 2017, pp. 63-79; Adel & Stachuk, 2013, pp. 89-112). They can also be used to measure the aggregate activity in a muscle qualitatively but also quantitatively in both the amplitude and frequency domains with sophisticated techniques (Basmajian, & De Luca, 1985). Qualitative EMG can be used to assess the continuous activity of muscle subjectively using a 4 or 5-point scale (Adel & Stachuk, 2013, pp. 89-112). Muscle activation measured from quantitative EMG is typically acquired in the microvolt range and then signals are amplified to the mV or V range for recording and display purposes. The followings are quantitative EMG methods.

Needle EMG. Needle EMG was first used to assess the electrical activity of the urinary bladder and ureter in humans in 1953 (Franksson & Petersen, 1953). Taverner et al. first used needle EMG to study the normal activity of the anal sphincter and pelvic diaphragm in men and women in 1959 (Taverner & Smiddy, 1959). In their work they defined the pelvic diaphragm as consisting of the levator ani and coccygeal muscle. No information was given about their EMG apparatus, but the following methodological information was provided. Participants were positioned on their left lateral side during the examination and the “steel needle electrodes were inserted concentrically into right quadrant of the external sphincter, and posteriorly into the puborectalis muscle” (Taverner & Smiddy, 1959, p. 154). The voluntary contraction of the external sphincter and the pelvic diaphragm was measured in mV, but reliability data were not provided. Taverner and Smiddy (1959) thus measured the electric activity of both external sphincter and puborectalis muscle but not vaginal closure pressure or force. In 1985, needle EMG was used to assess PVM of stress incontinent parous women to evaluate the Kegel

exercises and biofeedback therapy (Burns, Marecki, Dittmar, & Bullough, 1985). Burns et al. provided technical details and measured electrical activity during maximal voluntary pelvic muscle contractions and sustained maximal voluntary contraction in order to quantify muscle ‘strength’. (Editorial note: It is not possible to measure contractile force using EMG. But if one measures contractile force one can correlate that force with quantified EMG activity, after which one can use the EMG to estimate muscle force as a percent of maximal contraction (Thelen, Schultz, Fassois, & Ashton-Miller, 1994). The needle results showed that EMG during a sustained voluntary contraction was increased after the 4 weeks of treatment from 3.9 to 5.9 uv for the ‘cured’ cases and from 2.1 to 10 uv for a woman with ‘improved’ symptoms.

It is hard to interpret needle EMG measures of PVM without monitoring IAP recordings simultaneously. Unless visually guided using ultrasound imaging, the location of the needle electrodes inserted into the muscle is uncertain. Thus, the repeatability of measurements is unreliable and one has the risk of infection (see Table 2.3).

Surface EMG. Floyd and Walls were the first to use surface EMG to examine external anal sphincter activity in males in 1953 (Floyd & Walls, 1953). Likewise, Kiesswetter was the first to use surface EMG to record the electric activity of the PVM and the external anal sphincter in both females and males in 1976, however little methodological information was provided on the vaginal tampon electrodes used for females or the rectal electrodes used for males (Kiesswetter, 1976). The EMG activity of the PVM was recorded as being “action” or “no action” at voluntary contraction and during slow bladder filling, and no reliability data were provided. Later, Thorp and colleagues used surface EMG with acrylic plug surface electrodes to test 41 asymptomatic nulliparous women (Thorp, Bowes, Droegemueller, & Wicker, 1991). Surface EMG recorded the activity in the muscle surrounding the rectum and vagina. Eight

women were randomly chosen to have a second testing session. Between-visit intra-class correlation coefficients ranged from .76-.97.

Surface EMG also was used to explore the influence of the PVM and external anal sphincter activity on postural and respiratory function (Hodges, Sapsford, & Pengel, 2007). In the study, they talked about how to recode EMG of PVM under a series of arm movements and respiratory tasks. They also mentioned that the crosstalk from other muscles such as gluteus maximus and hip adductors has been avoided. One male and six females were tested in the study. For females, “surface electrodes (Periform Intra-Vaginal Probe, NEEN HealthCare, England, UK) inserted into the vagina” and “a pair of pre-gelled disposal surface electrodes (Medtronic, Minneapolis, MN) inserted into the anus and attached laterally to the anal mucosa” to recode the activity of external anal sphincter (Hodges, Sapsford, & Pengel, 2007, p. 363). Women performed several arm movements and respiratory tasks while standing with feet shoulder width apart to recode the PVM EMG. They found the PVM EMG was correlated with arm movements. Both vaginal EMG and anal EMG recodes increased during both inspiration and expiration. They recommended the results could be meaningful to explain the relationship of incontinence, back and pelvic pain. However, statistical significance in the study should be alerted since they only had seven participants.

While surface EMG can record the electric activity of PVM one cannot avoid picking up crosstalk from the electrical activity in adjacent muscles (Fowler et al., 2002; Peschers et al., 2001) (see Table 2.3). And depending on placement, surface EMG may not even record the muscles meant to induce vaginal closure (Bø & Finckenhagen, 2001); however, this may have been due to the effect of IAP causing increases in measured vaginal closure pressure without

recruitment of PVM. While surface EMG can assess PVM activity it cannot be used to assess vaginal closure force without a special calibration alluded to in the Editorial Note above.

Instrumented speculum for measuring vaginal closure force with minimal crosstalk from IAP. An improved two-billed instrumented speculum that would not pick up IAP was invented by Ashton-Miller et al. (2002) to eliminate IAP crosstalk when measuring vaginal closure force (Ashton-Miller et al., 2014). This has been called the ‘one-billed speculum’ (Figure 2.2f) because it functionally has one long bill and one short bill to measure maximum voluntary vaginal closure force whereby IAP acts equally on all sides of the long bill therefore cancelling its effect out, while IAP does not act on the short bill. Ashton-Miller et al. (2014) provided detailed information on the technical improvement: briefly, the upper bill was divided in two parts. Its distal part was connected to the distal end of the (long) lower bill. The proximal part of the (short) upper bill nearest the handle was then “positioned in the mid-sagittal plane so that its tip lies immediately dorsal to the inferior aspect of the symphysis pubis” (Ashton-Miller et al., 2014, p. 1149). To minimize the force from IAP on the modified lower bill, “the IAP acts normally on both the cranial and caudal surfaces of the modified lower bill that extend dorsal to the pelvic symphysis” (Ashton-Miller et al., 2014, p. 1149). The one-billed speculum was used to measure the effect of PVM on the vaginal closure force (in N) in the mid-sagittal plane by measuring the PVM force lifting the perineal body and distal vaginal wall toward the pubic symphysis at rest and at maximum voluntary pelvic muscle contraction. The authors tested 40 incontinent women to evaluate the validity and reliability of the one-billed speculum and checked whether IAP influences the vaginal closure force record. The maximum voluntary vaginal forces were measured during two visits with one-month interval. They found no significant correlation ($r = -.26, p = .109$) between the IAP (measured as intravesical pressure) and

the vaginal closure force. Women with strong muscle had significant higher mean maximum vaginal closure forces than those with weak PVM “(3.8 [1.7] vs. 1.9 [0.8] N respectively, $p < .01$)”, strong and weak muscle having been categorized via finger placement. There was not a significant difference in between-visit measures “(3.4 [1.8] and 3.4 [1.6] N, respectively)” and the between-visit repeatability coefficient was 3.1 (range: 0.7-9.1) N (Ashton-Miller et al., 2014).

The design of the one-billed speculum demonstrated that its measurement of vaginal closure force measured in the sagittal plane was independent of IAP crosstalk and is the most accurate method to date to measure vaginal closure force. Despite a strong intra-rater reliability it is not widely used in the clinical setting (see Table 2.3).

Sagittal view (real time, dynamic) perineal ultrasound for assessing PVM function.

Perineal ultrasound was first introduced in the literature by Kohorn and colleagues in 1986 as a way to visualize bladder neck mobility during a Valsalva maneuver. They tested 30 patients using a 3.5 MHz linear array ultrasound transducer. The transducer was placed on the vulva in a sagittal orientation in order to obtain a view of the bladder, bladder base, urethrovesical junction, and the pubis. Bladder neck mobility under IAP ‘stress’ during a Valsalva was thought to be an indicator of PVM function, an observation of hypermobility being considered a risk factor for stress incontinence. Although the latter hypothesis has not been consistently supported, this was a novel introduction of perineal ultrasound for pelvic floor evaluation. Numerous studies followed (Chen, Su, & Lin, 1997; Mouritsen & Rasmussen, 1993; Pregazzi et al., 2002; Reddy, DeLancey, Zwica, & Ashton-Miller, 2001; Schaer, Koechli, Schuessler, & Haller, 1995; Yalcin, Hassa, & Tanir, 2002), with all focusing on stabilization of the bladder neck during activities that increased IAP such as a cough or Valsalva. However, in 2006, Armstrong et al. introduced observation of elevation of the bladder neck during a volitional pelvic muscle contraction. They

suggested that perineal ultrasound, with minimal discomfort or detriment to the patient, provides a wealth of information on the function and dysfunction of the pelvic floor, and should be explored to its capacity as a minimally invasive technique. Although their goal was to develop a repeatable method to quantify degree of bladder neck elevation, the article concluded that best use of perineal ultrasound evaluation was in providing qualitative information. Since the “lift” that is seen with a correct pelvic muscle contraction and the “downward motion” with maneuvers that elevate IAP in the presence of relaxed PVM are opposing motions, it is quite simple for both examiner and patient to visualize PVM function (or lack of function) using ultrasound biofeedback on a screen during the examination (see Table 2.3).

Sagittal dynamic perineal ultrasound fell out of favor in the mid-2000s because of lack of reproducibility in quantifying hypermobility in an objective fashion, so the relationship between hypermobility and stress incontinence has never been reliably quantified. However, a few clinicians routinely use a sagittal dynamic perineal ultrasound image as a form of biofeedback to teach identification of the PVM to a woman attempting to contract the right thing when asked to do a pelvic muscle contraction. That is, if she sees the “lift” of the bladder neck, she is doing the pelvic muscle contraction maneuver correctly, and if she relaxes the PVM and sees the return of the bladder neck to its original position she has confirmed her volitional motor control of her pelvic muscle. With high quality, high resolution ultrasound machines now becoming readily available, reintroduction of this tool for use in qualitative manner should perhaps be reconsidered as one of the best indicators clinically of a functional PVM.

Instruments for Measuring the Relationship between PVM Function and SUI (Condition of IAP Rise and Need for Optimizing Urethral Closure Pressure)

Quantified Standing Stress Paper Towel Test

The quantified paper towel test was developed in 1998 to quantify urine loss from cough, without and then with volitional pelvic muscle contraction performed simultaneous to coughing (Miller, Ashton-Miller, & DeLancey, 1998a; Miller, Ashton-Miller, Carchidi, & DeLancey, 1999). Detailed information about the test's development, procedures, standardization, and calculations to ml loss of urine were provided. The paper towel test was designed to measure urine leakage during an increase of the IAP by a stressing activity such as cough or sneeze. It is a variation on a standing stress provocation test to evaluate a cough-related urine loss, but it offers the ability to quantify the volume as a continuous measurement, rather than a simple "yes" "no" for leakage. It is especially sensitive for small volume losses down to a single drop. Six experiments were conducted to examine the paper towel test in eight older women with mild SUI (Miller et al., 1998a). Women placed a trifolded brown paper towel slightly against perineum during three single coughs while in standing posture. The wetted area on the paper towel resulting from the coughing was modeled as an ellipse shape and calculations made in cm^2 from measured length and width. From calibrations, measures of the paper towel using known volumes, area can then be converted to volume (ml). The test-retest repeatability within- or across-visits was less than 1 ml. This maneuver, known by many names, is expected to induce immediate reduction in stress-type leakage. Measurements of urine leakage volume reduction using the paper towel standing stress test following an intervention were first reported in 1998 (Miller, Ashton-Miller, & DeLancey, 1998b). The reduction of urine loss observed when the woman coughs first without and then with active volitional contraction of the pelvic muscle measures the functional capacity of the PVM for improving the margin of continence required during an IAP rise (Kim, Ashton-Miller, Strohbehn, DeLancey, & Schultz, 1997). Successful reduction of leakage using this volitional timed pelvic muscle contraction maneuver is a strong

indicator of normal striated urethral muscle and, perhaps, normal PVM functional capability. Denervated urethral striated muscle and, perhaps, an PVM tear may also explain the phenomenon of women who cannot reduce the wetted area on a paper towel by a volitionally timed contraction. This test indicates that a woman contracts the striated urethral muscle and PVM contraction when performing the Knack to reduce urine loss during a cough. It is unclear how much PVM contraction is added to reduce urine loss during a cough. This may be indirectly found when measuring the urethral striated muscle function while blocking PVM effect using a posterior weighted speculum to hold the posterior vaginal wall back during the cough. This paper towel test is simple and inexpensive and lends itself for testing the active use of the striated urethral muscle and, perhaps, the PVM to reduce mild-moderate cough-related urine loss. Advantages and limitations of the paper towel test are shown in Table 2.3. Urethral closure pressure was measured using urethral pressure profile that will be talked in Chapter 4.

Discussion

Measurements to quantify a voluntary pelvic muscle contraction are challenging due to wide variation across women in the ability to contract the pelvic muscle volitionally and because a concomitant rise IAP can confound an effort to prevent urine leakage. Historically, measurement techniques have tried to quantify the pelvic muscle contraction force, but this has proven challenging. Methods that rely on finger placement (for example, circumvaginal muscle rating scale, Brink digital exam, and modified Oxford scale) all have the common issue that they are subjective scores of the pelvic muscle contraction intensity, using “zero” to “five” or “poor” to “excellent” but they do not objectively quantify the vaginal closure force that is the best indicator of maximum pelvic muscle contractile force or strength. The subjective score depends on the examiner’s experience and finger placements may not necessarily be reproducible.

Instruments with a balloon device inserted into the vagina target vaginal closure pressure but not force, and they fail to measure the PVM under isometric conditions because muscle physiologists know that muscle force can vary systematically with muscle length, and this could happen as the intravaginal balloon diameter is compressed by a pelvic muscle contraction. In addition, the balloon cannot be used to differentiate the increase in pressure from the pelvic muscle contraction from the increase in IAP due to recruitment of abdominal wall muscles or diaphragm (Peschers et al., 2001). Locating the balloon in the distal vagina is a challenge because the vagina widens proximally and contraction of the distal pelvic muscle (circumvaginal muscles) will tend to force the balloon proximally (Luo, Betschart, Ashton-Miller, & Delancey, 2016) to an area not surrounded by muscle. Instruments that use EMG measure the intensity of muscle recruitment in terms of electric activity, not pelvic muscle contractile force and so cannot directly measure muscle contractile strength. Instrumented speculums are meant to measure the vaginal closure force and posterior wall displacement, but only one does so without IAP crosstalk and they are not widely available. To the best of our knowledge, no normal range of PVM strength was set from the measures.

It is quite difficult to make a maximum pelvic muscle contraction without extraneous muscle co-activation (Sapsford, Clarke, & Hodges, 2013). When PVM fatigues, even highly trained women recruit their abdominal muscles in order to try to compensate and maintain the maximum pelvic muscle contraction (Laycock, 1994, pp. 42-48) often with the co-activation of the abdominal muscle (Sapsford et al., 2001). Thus measurements during a voluntary pelvic muscle contraction may involve the influence from IAP crosstalk. For research purposes the IAP can be measured using a dual sensor tipped catheter pressure device placed in the bladder to monitor intravesical pressure (Morgan et al., 2005) or a wireless intra-vaginal pressure

transducer (Coleman et al., 2012). A measure of the IAP at same time can provide examiners the ability to minimize IAP crosstalk onto the vaginal closure force (Morgan et al., 2005). But women should be taught the correct technique for how to correctly contract the pelvic muscle during expiration in order to minimize the IAP crosstalk and prevent a Valsalva or bearing down effort (Laycock, 1994, pp. 42-28).

Taken together, the results of this review indicate that it is a challenge to measure PVM activity without artefact or systematic bias. The ideal instrument should be valid, yet it should be simple, widely available and cost effective. We have seen that it is important for examiners to have knowledge and experience to use the instrument properly. Current instruments may be good at assessing one aspect of the PVM, but have disadvantages for others. An instrument may work for a particular population, moment or situation. One aspect of this review was to evaluate measures based on the patients, accessibility of the measure, time availability, and accuracy. A second aspect of this review was to assess the advantages and limitations of each instrument so that there is transparency within clinical scientific community when interpreting results of the different studies. We may therefore need to consider the following ideas when we choose an instrument: availability of equipment, the influence of experimental conditions, the type of measurement, the ability to quantify scales reliably, the examiner's experience and pelvic floor conditions. The choice of instrument should be based on the context of a research study or a clinical setting.

The most important finding from this review was that there is no perfect measurement or single measurement that can measure both PVM structure and function. In order to better understand the PVM, it is essential to have instruments for both assessing muscle tear status as well as PVM strength.

The instruments for best assessing the presence and extent of a tear include MRI, 3D or 4D ultrasound, as well as index finger palpatory assessment, depending on budget. In terms of precision and validity for assessing the effect of interventions on a PVM function aimed at improving PVM strength, the best option currently is the one-billed speculum, while the best option for assessing PVM structure is MRI (see Figure 2.3). The quantified standing stress paper towel test is the best inexpensive option for assessing urethral and, perhaps, PVM function related to incontinence because of its immediate objective feedback. The best screening measures for PVM function are Brink digital exam and modified Oxford scale and the best screening measures for PVM structure is 3D ultrasound and if, on a budget, index finger palpatory assessment for estimating odds of a PVM tear (see Tables 2.2a & 2.2b) (Figure 2.3), the initial measures are best for clinical settings. The sagittal dynamic ultrasound is good for assessing PVM function. Instruments contaminated by crosstalk from IAP or activities in adjacent muscles should be avoided: these include the circumvaginal muscle grading scale, perineometer, intravaginal balloon device, Segovia, the two-billed instrumented speculum, the Dumoulin instrumented speculum, the Verelst speculum, and EMGs.

The one-billed speculum is a research-grade instrument and not commercially available for clinical settings. Then, screening measures such as Brink digital exam and modified Oxford scale could be reasonable proxies. MRI, of course, is costly, so if it is not available then 3D ultrasound and index finger palpatory assessment should be reasonable proxies as long as their drawbacks are noted. Figure 2.3 represents this review in graphical form.

Strengths and Limitations of the Present Study

We have tried to include as many current instruments as possible in this review. We have given a historical overview for what they actually measure as well as their strengths and

weaknesses. This review should prove useful for choosing an appropriate instrument for future studies and clinical practices. However, like most of review studies, some limitations need to be noticed. First of all, we cannot include all the studies that used the instruments to analyze how each instrument was used. Second, literature comparisons were complicated by heterogeneous instruments, methods, patient groups and examiner skill levels.

Recommendations for Future Studies and Clinical Practice

- Because the 200+ prior studies of Kegel exercises in SUI (have cited Miller et al., 1998a) did not provide correlations of a relationship and relied on instruments that did not meet the criteria of valid, objective, affordable, accessible, acceptable, and agreed upon instruments, we are going to have to repeat them by doing them right. Ideally, a large prospective trial that starts post birth should accounts for the possibility of tears, differences in examiner and patient skill, PVM strengthening, and SUI with objective instruments and blinded investigators from start to finish.
- We recommend adoption in research studies of the gold standard high-tech instruments (for example, one-billed speculum & MRI or at least 3-D ultrasound), with accompanying “low-tech” clinical assessment instruments & skills so those can be assessed for sensitivity & specificity across a wide variety of examiners and populations.
- We recommend adoption in clinical settings of the simple, easy and low cost index finger palpatory assessment as an initial test for PVM status as long as proper examiner training is provided. Part of the battle is that examiners have to first learn what the real anatomy of the intact PVM is, and then learn how, when and where a tear can develop and they need to know where the largest belly of the PVM can be found (for example, Masteling et al, 2018, under review)

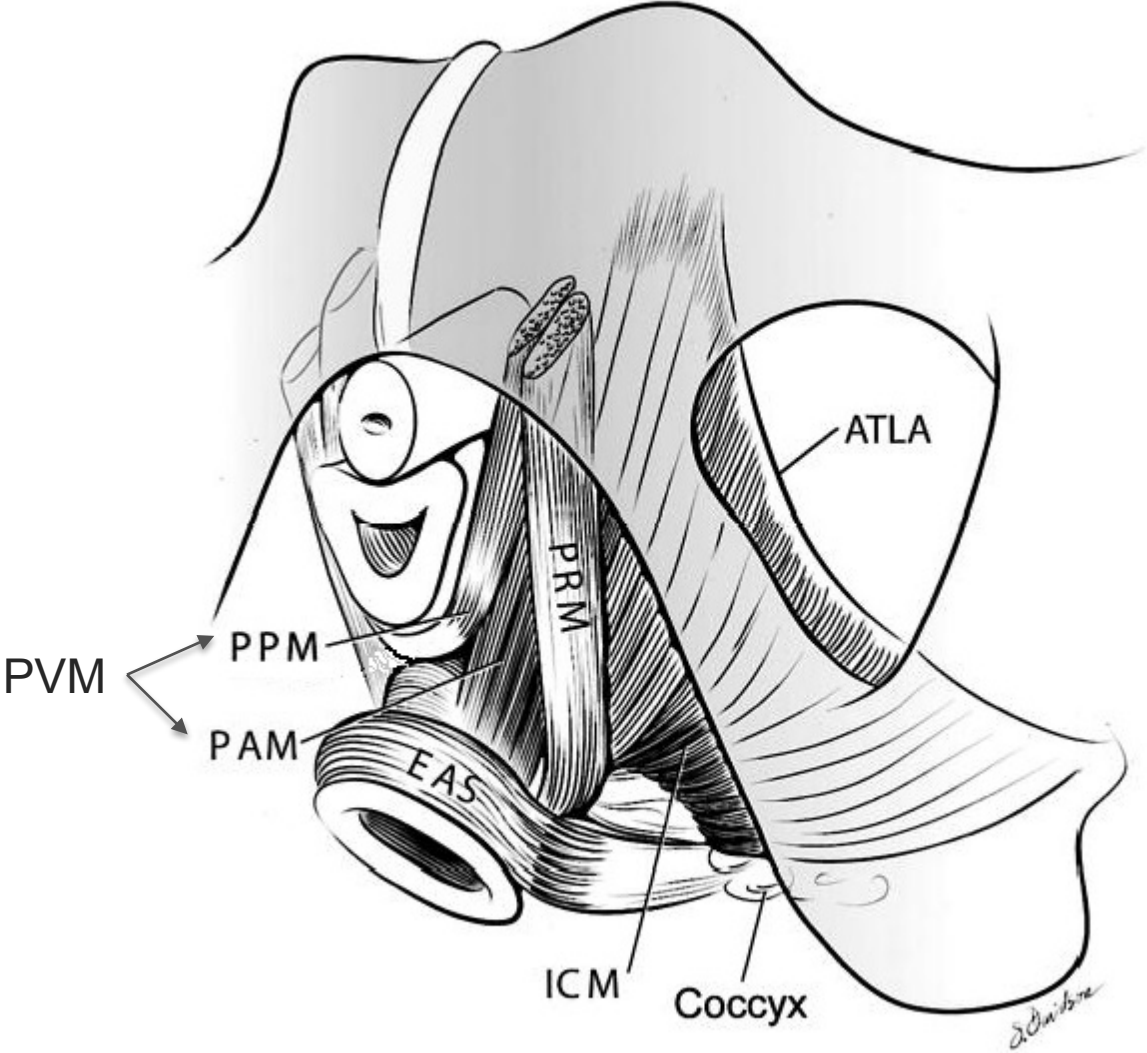
- We recommend a “revisit” of the existing literature with a critique that takes into account the limitations of the historical instruments/measures used, and the advances in the current understandings of the PVM physiology & biomechanics involved, given more recent insights gained from bench, imaging, anatomical and computer simulation research.
- We recommend bringing back sagittal dynamic perineal ultrasound as a noninvasive, clinically appropriate, quick *qualitative* assessment of PVM function so patients and examiner can together observe bladder neck elevation via biofeedback during attempted pelvic muscle contraction.
- We recommend quantified standing stress paper towel test should be performed without and then with pelvic muscle contraction for clinical quantitative appraisal of urethral striated muscle and PVM functional capacity in order to reduce leakage on IAP rise.

Conclusions

1. Measurement of PVM strength via vaginal closure force should not include signal contamination from IAP.
2. PVM strength cannot be measured using EMG.
3. Generally, the newer the instrument is, the more precise it has become. For example, MRI is better than index finger palpatory assessment. The choice of an instrument for a study should include full awareness of its advantages and weaknesses in reports. Further study can focus on which instrument will provide the most valid value for women who have specific condition like prolapse.
4. It is important to identify the presence of PVM tear using valid measures. MRI is the most valid method, followed by ultrasound and index finger palpatory assessment.

5. Future studies should focus on prevention and treatment of PVM tears, in addition to women who have PVM tears and pelvic floor disorders.
6. The scope of the PVM tear should help guide physical therapy.
7. Better measures are needed of volitional and resting urethral muscle function in women with SUI. Current urodynamic methods contain systematic bias due to the size and stiffness of the intraurethral catheter. Only then can one separate the effects of urethral muscle contraction from pelvic muscle contraction in reducing leakage during a cough (see Chapter 4).
8. Terms use as PVM when mean terminology article.

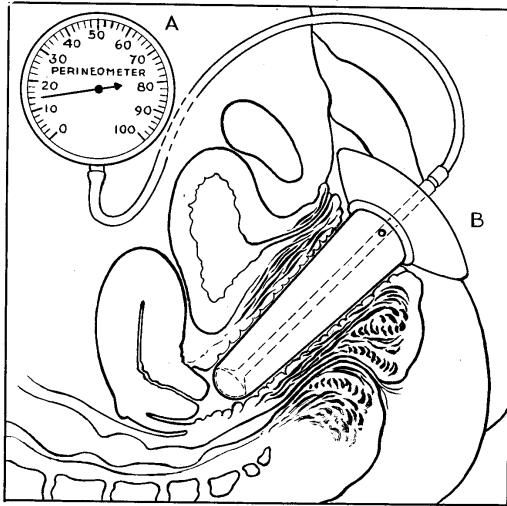
Figure 2.1 Schematic View of Levator Ani



Note. Arcus tendineus levator ani (ATLA); external anal sphincter (EAS); puboperineal muscle (PPM) and puboanal muscle (PAM) as two parts of pubovisceral muscle (PVM); iliococcygeal muscle (ICM); puborectal muscle (PRM). (© DeLancey 2003; Kearny et al., 2004)

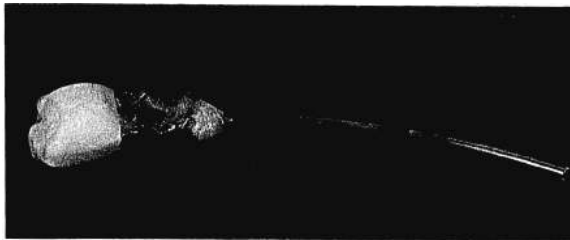
Figure 2.2 Devices for Assessing Pubovisceral Muscle Function

Figure 2.1a Perineometer*



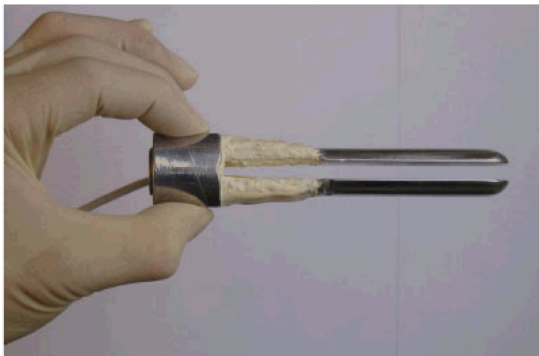
*A, the manometer B, the pneumatic vaginal chamber
(Kegel, 1948)

Figure 2.2b Intravaginal Balloon Device



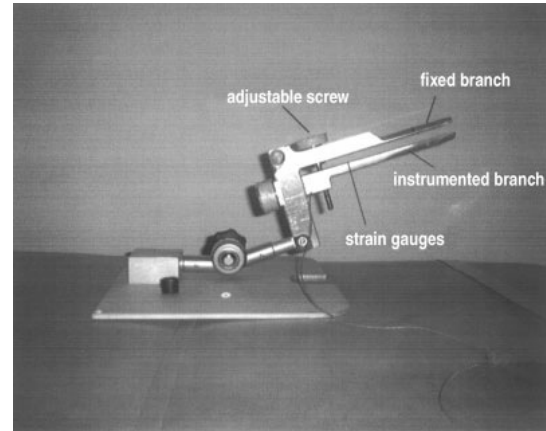
(Dougherty et al., 1986)

Figure 2.2c Two-billed Instrumented Speculum



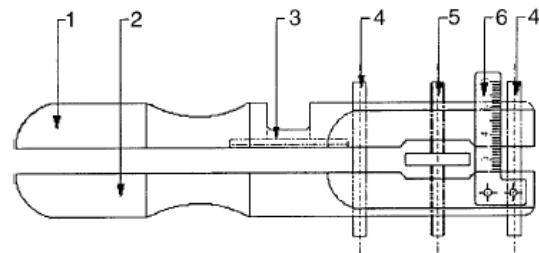
(Miller et al., 2007)

Figure 2.2d Dumoulin Instrumented Speculum



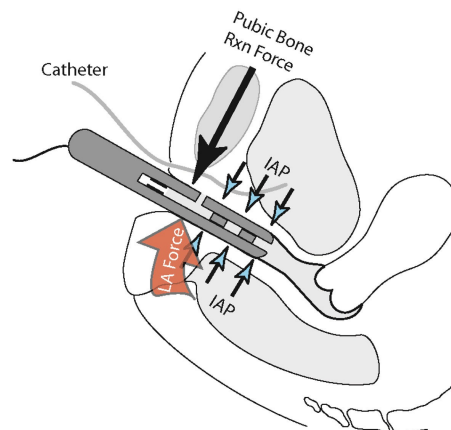
(Dumoulin et al., 2003)

Figure 2.2e Vereslt Speculum*



*Semi-round rods (1 and 2); metal plate with strain gauge (3); bracing pins (4); center pin to regulate the diameter (5); ruler (6).
(Vereslt & Leivseth, 2004)

Figure 2.2f One-billed Speculum*



*IAP = intraabdominal pressure. LA = levator ani. (Ashton-Miller et al., 2014)

Table 2.1 Correlation between Pubovisceral Muscle Strength and Urine Loss

Author	Study design	Sample	Time period	Instruments for vaginal closure pressure (postulated as PVM strength)	Strength increase	Incontinence reduction	r value
Boyington, Dougherty, & Kasper, 1995	RCT	65 women with SUI	16 weeks	Intravaginal balloon devise	Mean (SD) from 18.9 mmHg (10.4) to 29.5 mmHg (12.9), $t = 4.86$, $p = .0009$	Urine loss (g/24h) from mean (SD) 14.1 (14.1) to 2.4 (1.4), $t = -2.51$, $p = .03$	Correlation between PVM strength and urine loss, baseline $r = .33$ and 16 weeks $r = -.25$, non significantly
Theofrastous et al., 2002	RCT	134 women with SUI or MUI	12 weeks	Audiotaped instructions and two water-filled silicone balloon devices	95% CI for increase in sustained (10-second) contraction pressures were 2.2–5.4 mm Hg for maximum contraction and 1.7–8.1 mm Hg for mean contraction; 95% CI for increase in fast (3-second) contraction pressures were 1.4–5.3 mm Hg for maximum contraction and 1.2–8.0 mm Hg for mean contraction	A reduction from 16.8 ± 17.1 to 9.4 ± 14.0 incontinence episodes/week, $p = .002$	Between reduction in incontinence episodes/week and maximum sustained vaginal pressure $r = .32$, $p = .04$; no correlation between reduction in continence episodes/week or pad weights and increases in pelvic muscle strength ($p > .3$)
Bø, 2003	RCT	52 with SUI	6 month	A vaginal balloon catheter connected to a microtip transducer in supine position	Responders versus non-responders, Maximal PVM strength 24.0 H ₂ O (95% CI: 18.1-29.9) versus 12.7 (95% CI: 6.8-18.6), $p < .0001$; respectively; PVM strength increase 14.8 cm H ₂ O (95% CI: 8.9-20.7) versus 5.0 (95% CI: -2.6 to 12.6), $p = .03$, respectively.	Referred from Bø & Larsen 1992, maximum sum score was 5 based on improvements from urethral closure pressure, patient self report, pad test, leakage index, and social activity index. Responders with sum score 4 and 5 and non-responders with sum score 0 and 1.	Maximal PVM strength and leakage index, $r = .34$ ($p < .01$); leakage reduction, $r = .23$ ($p = .05$)

Author	Study design	Sample	Time period	Instruments for vaginal closure pressure (postulated as PVM strength)	Strength increase	Incontinence reduction	r value
Dinc, Kizilkaya Beji, & Yalcin, 2009	RCT	68 pregnant women with SUI	From baseline (34 th week of pregnancy) to postpartum 6 th to 8 th week	Perineometer	Mean (SD) -15.8 ± 6.8 (Z = -5.16, p=.00)	Difference of mean (SD): pad test (grams of leakage) 2.80 ± 3.91 (Z = -3.43, p=.001); Number of incontinence episodes 1.03 ± 0.86 (Z = -4.4, p=.00)	r between PVM strength difference and urine leakage in volume and in number of episodes was .06 (p=.75) and -.17 (p=.34), respectively.
Ahlund et al., 2013	RCT	84 postpartum women with SUI	From 3 and 9 months after vaginal delivery	Perineometer (vaginal squeeze pressure)	Median maximally voluntary contraction changes from 16.2 to 26.0 cm Hg for the intervention group (home-based Exercise) and 12.1 to 18.2 cm Hg for the control group (only written postpartum instruction), p<.05	For intervention group, leakage frequency changes in median from 3 (0-9) to 2 (0-9) and incontinence score changes from 7 (1-16) to 4 (1-15), p<.05; for control group, leakage frequency changes in median from 4 (0-9) to 3 (0-7) and incontinence score changes from 7 (2-16) to 4 (0-12), p<.05	No correlation between maximally voluntary contraction and self-reported urinary incontinence, at baseline, r =.06; follow up, r =.07

RCT = randomized controlled trial. SUI = stress urinary incontinence. MUI = mixed urinary incontinence. CI = confidence interval. SD = standard deviation.

Table 2.2 Subjective Measures of Pubovisceral Muscle Status (Structure and Function) and Stress Incontinence Status (Presence and Degree)

Function or structure	Instruments common name	Author	What is really being assessed (unit)	Available test retest or repeatability (Yes or No)	Advantages of the instruments/measures	Limitations of the instruments/measures
<u>PVM structure:</u> PVM tear	Index finger palpatory assessment for estimating odds of PVM tear	Gainey, 1943 & 1955; Kearney et al., 2006a; Dietz & Shek, 2008	Degree of muscle missing through touch if there is connection of the pubic bone and the muscle (yes or no)	Yes	<ul style="list-style-type: none"> • Simple • Easy • Low-cost • High accessibility 	<ul style="list-style-type: none"> • Influenced by the examiner's knowledge and experience and the anatomical nature of the muscle • Requires relevant training and experience • Cannot be a diagnostic test • A confirmatory test is needed
<u>PVM function:</u> per finger passive placement Measures in which the examiner uses placement vaginally of two-fingers vertically positioned and without active palpation. The examiner reports on felt sensation on the finger(s) when the woman is asked to do a pelvic muscle contraction.	Circumvaginal muscle rating scale	Worth et al., 1986	Felt vaginal <u>pressure</u> (9-point scale ranging from 4-12)	Yes	<ul style="list-style-type: none"> • Simple • Low cost • Time-efficient • Accessible 	<ul style="list-style-type: none"> • Cannot differentiate from IAP • Not valid • Subjective
	Brink digital exam	Brink et al., 1989 & 1994	Vaginal <u>pressure</u> from muscle squeeze and posterior vaginal wall displacement (10-point scale with ranging from 3-12)	Yes	<ul style="list-style-type: none"> • Simple • Low cost • Less invasive • Commonly use 	<ul style="list-style-type: none"> • Influenced IAP • Subjective
	Modified Oxford scale	Laycock, 1994; Laycock & Jerwood, 2001	Grading <u>contraction, pressure</u> around fingers, Poisson effect (as muscle is contracted, it expands a bulging up) (6-point scale)	Yes	<ul style="list-style-type: none"> • Simple • Low cost • Less invasive • Commonly use 	<ul style="list-style-type: none"> • Influenced by IAP • Subjective

PVM = pubovisceral muscle. IAP = intraabdominal pressure.

Table 2.3 Objective Measures of Pubovisceral Muscle Status (Structure and Function) and Stress Incontinence Status (Presence and Degree)

Function or structure	Instruments common name	Author	What is really being assessed (unit)	Available test retest or repeatability (Yes or No)	Advantages of the instruments/measures	Limitations of the instruments/measures
<p><u>PVM structure: PVM tear</u></p> <p>Measures in which the examiner place imaging machine abdominally or vaginally. The device reports muscle imaging.</p>	*MRI	Kirschner-Hermanns et al., 1993; Tunn et al., 1999; DeLancey et al., 2003; Kearney et al., 2006a	Degree of visible muscle damage ('none', 'minor', or 'major'; or 4 level from '0' to '≥ 50%' bilateral tear)	Yes	<ul style="list-style-type: none"> • The most precise test to diagnose the PVM tear • Provides the image of the muscle structure • Immediate result • Painless 	<ul style="list-style-type: none"> • Expensive • Requires appropriate professional training • Low accessibility • Body in small space (claustrophobia)
	Ultrasound: 3D or 4D	Dietz, 2004; Dietz & Lanzarone, 2005; Dietz, & Steensma, 2006	Degree of visible muscle damage (yes or no)	Yes	<ul style="list-style-type: none"> • Relative precise test to diagnose the PVM tear • Provides the image of the muscle structure • Immediate result • Painless 	<ul style="list-style-type: none"> • Relatively expensive • Requires appropriate professional training, • Relatively low accessibility
<p><u>PVM function: per device placement, and inclusive of measuring IAP.</u></p> <p>Measures in which the examiner places a device vaginally. The device reports on signal occurring when the woman is asked to do a pelvic muscle contraction.</p>	Perineometer	Kegel, 1948	Maximum voluntary vaginal closure <u>pressure</u> (mm Hg)	Yes (reported later)	<ul style="list-style-type: none"> • Early used to measure vaginal closure pressure • Can be used by patients 	<ul style="list-style-type: none"> • Degree of pressure from all parts (points) during a volitional pelvic muscle contraction • Influenced by IAP • Indirect measure
	Intravaginal balloon device (IVBD)	Dougherty et al., 1986	Maximum voluntary vaginal closure <u>pressure</u> (mm Hg)	Yes	<ul style="list-style-type: none"> • Can use to assist treatment of SUI 	<ul style="list-style-type: none"> • Degree of pressure from all parts (points) during a volitional contraction • Influenced by IAP • Unsure location of the

Function or structure	Instruments common name	Author	What is really being assessed (unit)	Available test retest or repeatability (Yes or No)	Advantages of the instruments/measures	Limitations of the instruments/measures
						<ul style="list-style-type: none"> balloon in vagina • Indirect measure
	Segovia	Miller, 1996	Vaginal <u>pressure</u> (cm H ₂ O)	Yes	<ul style="list-style-type: none"> • Acceptable by women • Usable by women • Less expensive • Easily sterilizable and reusable • Noninvasive 	<ul style="list-style-type: none"> • Influenced by IAP • No commercial availability
	Two-billed instrumented speculum	Ashton-Miller et al., 2002; Miller et al., 2007	Vaginal closure <u>force</u> (Newton)	Yes	<ul style="list-style-type: none"> • Most accurate measure 	<ul style="list-style-type: none"> • Does not minimize the influence by IAP • Hard to place the bills for prolapse • No commercial availability
	Dumoulin instrumented speculum	Dumoulin et al., 2003&2004; Morin et al., 2004a	Vaginal closure <u>force</u> (Newton)	Yes	<ul style="list-style-type: none"> • Relative accurate measure 	<ul style="list-style-type: none"> • Influenced by IAP • Difficulty to locate the branches for prolapse • No commercial availability
	Verelst speculum	Verelst & Leivseth, 2004	Passive and active vaginal closure <u>force</u> (Newton)	Yes	<ul style="list-style-type: none"> • Relative accurate measure 	<ul style="list-style-type: none"> • Influence by IAP • No commercial availability
<p>PVM function: placement of needle or quantitative electromyographic device placement.</p> <p>Measures in which the examiner uses a form of</p>	Needle electromyography (EMG): quantitative EMG	Taverner & Smiddy, 1959; Burns et al., 1985	Muscle <u>electrical activity</u> from individual motor units (in mV units)	No	<ul style="list-style-type: none"> • Measure electric action of muscles 	<ul style="list-style-type: none"> • Influence by other muscles • Does not measure vaginal closure • Uncertain needle location • Indirect measure • Risk of infection

Function or structure	Instruments common name	Author	What is really being assessed (unit)	Available test retest or repeatability (Yes or No)	Advantages of the instruments/measures	Limitations of the instruments/measures
EMG in contact with or in proximity to the PVM. The device reports electrical signal when the woman is asked to do a pelvic muscle contraction.	Surface EMG: quantitative EMG	Kiesswetter, 1976	Muscle <u>electrical activities</u> from summated from many motor units (millivolt)	No	<ul style="list-style-type: none"> • Non invasive 	<ul style="list-style-type: none"> • Poor reproducibility • Involved activity from other muscles • Does not measure vaginal closure Indirect measure
<u>PVM function: per device placement, and independent of increases in IAP.</u> Measures in which the examiner places a device vaginally. The device reports on signal occurring when the woman is asked to perform a pelvic muscle contraction.	*One-billed speculum	Ashton-Miller et al., 2014	Sagittal vaginal closure <u>force</u> (units of N)	Yes	<ul style="list-style-type: none"> • Measures pelvic muscle contractile force under isometric conditions favored by muscle physiologists • Insensitive to crosstalk from rises in IAP • Valid 	<ul style="list-style-type: none"> • Only used for research purpose • Hard to place the bills for prolapse • No commercial availability
<u>PVM function</u> Measure in which the examiner places an ultrasound transducer probe on the vulva. The device visualizes bladder neck movement when the woman is attempts a pelvic muscle contraction.	Sagittal dynamic ultrasound	Kohorn et al., 1986; Armstrong et al., 2006	Cephalic displacement (in mm) of the bladder neck in a sagittal view available as biofeedback (as opposed to caudal movement observable when she pushes down instead)	Yes (report later)	<ul style="list-style-type: none"> • Noninvasive • Real time view • Immediate feedback 	<ul style="list-style-type: none"> • Hard to steadily place the transducer head • Reliability varies based on condition during measurement

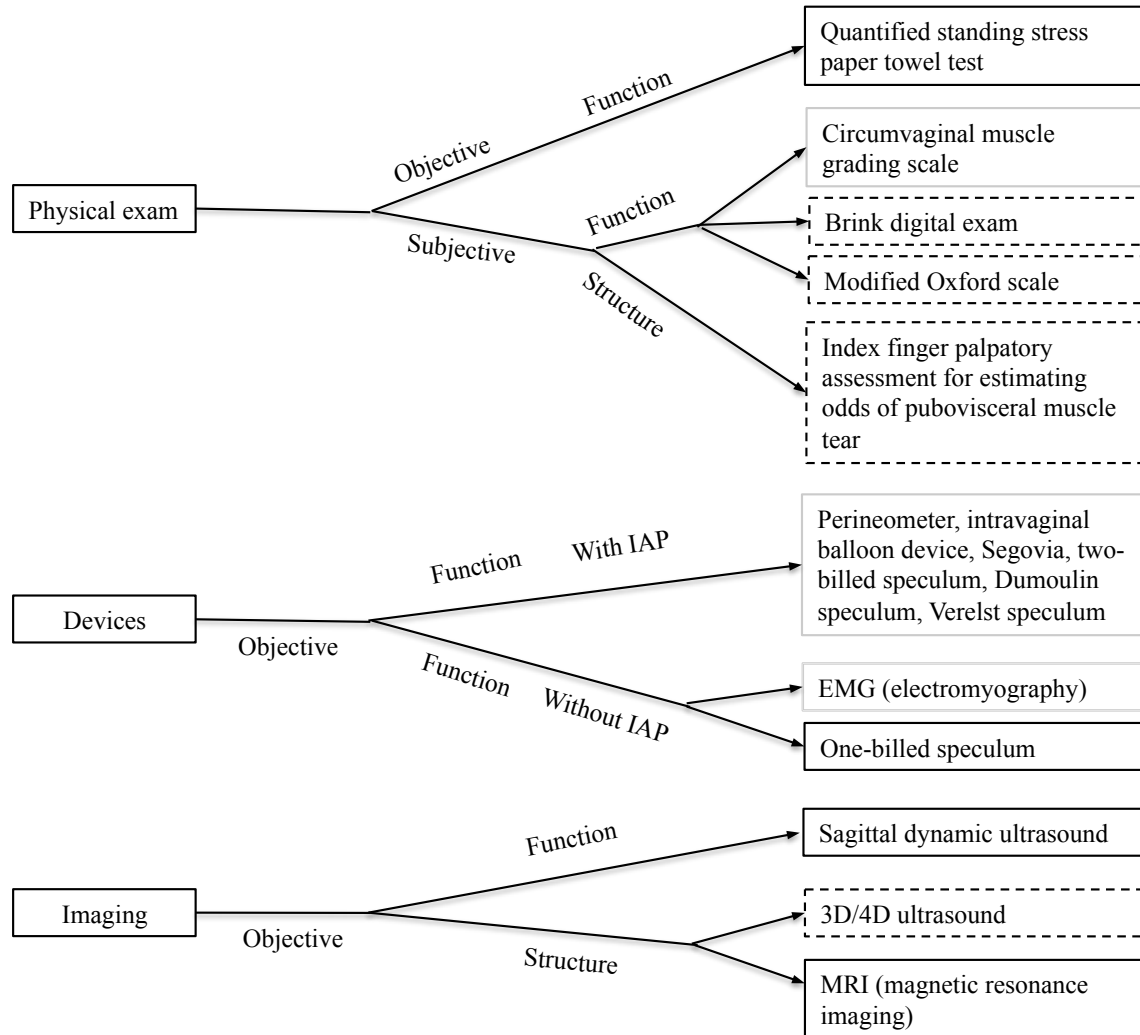
Function or structure	Instruments common name	Author	What is really being assessed (unit)	Available test retest or repeatability (Yes or No)	Advantages of the instruments/measures	Limitations of the instruments/measures
<p><u>PVM function</u></p> <p>Measure in which the woman places a paper towel slightly against perineal. The clinical physical exam reports volume of urine loss when the woman is asked to cough without and with a pelvic muscle contraction.</p>	Quantified Standing stress paper towel test	Miller et al., 1998a	Urine loss during a IAP rise (ml)	Yes	<ul style="list-style-type: none"> • Simple • Easy • Almost cost free • Immediate visual feedback • Noninvasive 	<ul style="list-style-type: none"> • Variations in bladder volume • Variations in cough and IAP

PVM = pubovisceral muscle. IAP = intraabdominal pressure. * Gold standard measure.

Table 2.4 Intravaginal Finger Placement Techniques for Evaluating Pubovisceral Muscle Function

	‘Power’ as Pressure	‘Power’ as Displacement	Repetitions (counts)	Duration (Time Holds) (seconds)	Oxford or strength
Dougherty’s circumvaginal muscle grading scale	‘Slight’ to ‘firm’ (score 1–3); ‘No ribbing’ to ‘ribbed muscle tissue’ (score 1–3)	Easily slip up to finger is pulled upward (score 1– 3)	---	None to greater than 4 seconds (score 1– 3)	10-level (pressure + displacement + time)
Brink digital exam	‘No response’ to ‘strong squeeze’ (score 1–4)	‘None’ to ‘whole fingers move anteriorly’ (score 1–4)	---	0 - \geq 3 seconds (score 1–4)	10 level (pressure + displacement + time)
Laycock’s modified Oxford scale	‘No’ to ‘strong power’ (grade 0–5)		Number of repetitions of maximum contractions lasting 5 seconds (long hold) intervals; fast 1 second maximum contraction up to 10	Up to 10 seconds	6 level (Power + pressure + displacement)

Figure 2.3 Best Option of Instruments for Assessing Pubovisceral Muscle*



*Boxes with dashed line mean the best screen measures in clinical setting. Boxes with solid black line mean the best measures for precision and highly validity for mechanics in clinical trial research. Boxes with light gray line indicate that the measures are contaminated by intraabdominal pressure (IAP) or other muscle activity, which should be avoided.

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Chapter 3

Retrospective Study Estimating the Odds of MRI-documented Pubovisceral Muscle Tear Identified by Index Finger Palpatory Assessment in Postpartum Women Who Were at High Risk for Pubvisceral Muscle Tear in Their First Vaginal Childbirth

Abstract

Background: Vaginal birth can cause pelvic floor injuries, such as pubovisceral muscle (PVM) tear, a known risk factor for developing pelvic floor disorders such as pelvic organ prolapse. Women with PVM tear may be asymptomatic before the pelvic floor disorders develop. The prevalence of the PVM tear can reach 36% among postpartum women. PVM tear evaluation is not a routine clinical practice.

Aims: The objective of this study was to estimate the ability to identify PVM tear on the basis of a clinical exam using index finger palpatory assessment of the PVM.

Methods: Eighty-five women participated in this planned data study and had at least one risk factor for PVM tear during delivery (e.g., maternal age ≥ 33 years, second stage labor lasting ≥ 150 minutes, instrumented delivery, infant weight ≥ 4000 gm, and third or fourth degree anal sphincter laceration). Measures were obtained approximately 7 weeks after the first vaginal birth. Magnetic Resonance Imaging (MRI) of the pelvis was done, as the gold standard measure of PVM status. PVM tears identified by MRI were initially categorized into 5 levels for each side: as no tear, subtle tear, less than 50% tear, greater than 50% tear, and complete tear for each side. Two sides of the tears were combined into four categories: no tear or subtle tear on both sides of

PVM (coded as 0), < 50% unilateral tear (coded as level I), < 50% bilateral or ≥ 50% unilateral tear (coded as tear level II), and ≥ 50% bilateral tear (level III). A clinical visit included index finger palpatory assessment of the PVM bilaterally (palpating through the vaginal wall) to assess for PVM wholeness by an experienced nurse practitioner. If the body of the muscle is clearly felt, then coded as “present” on that side. If the body of the muscle completely torn away from its origin, then scored as PVM “absent.” If the examiner was unable to completely certain of the “present” or “absent” of the muscle, then scored “equivocal.” This process and scoring is then repeated on the opposite side. If both sides of PVM were present, without loss it was coded as 0. If one side PVM was palpable but another side was labeled as equivocal, it was coded as level 1. If both sides of PVM were labeled as equivocal, or one side was not palpable, it was coded as level 2. If both sides of PVM could not be palpated, it was coded as level 3. Nurse practitioner and MRI radiologist were blind to each other’s findings. Data were analyzed using proportional odds modeling.

Results: Nine percent of the women were identified with “absent” PVM on both right and left sides by palpatory assessment while 20% of the sample were identified with “present” PVM on both sides. MRI results showed at least a partial PVM tear in 35% of the sample while the remainder had none or subtle tear on MRI. The odds ratio (OR) of MRI-documented PVM tear identified by palpatory assessment of the PVM for structural wholeness was 3.62 (95% CI 1.70 – 7.73), $p = .001$.

Conclusions: Index finger palpatory assessment at the site of the PVM can be used to estimate the odds of PVM tear in postpartum women with known PVM tear risk factors. With that information, an informed decision can be made for diagnostic tests, (for instance obtaining an MRI) and for decisions regarding clinical care. They may also be applicability to large research

studies for estimating odds of a PVM tear across various populations, especially if combined with a reported history of obstetric risk factors for PVM tear, such as forceps delivery.

Key words: Palpation, postpartum, pubovisceral muscle tear, levator ani, pelvic floor muscles, birth injuries, pelvic floor disorders

Introduction

The levator ani consists of the pubovisceral (known as pubococcygeus), the iliococcygeus, and the puborectal muscles and they are main components to form the levator hiatus (Ashton-Miller & DeLancey, 2007), which is believed to play a critical role in pelvic organ support and the maintenance of fecal and urinary continence. Tear on the levator ani often occurs in the inner surface of the pubic bone at the origin of pubovisceral muscle (PVM) (DeLancey, Kearney, Chou, Speights, & Binno, 2003; Dietz & Steensma, 2006; Kim, Betschart, Ramanah, Ashton-Miller, & DeLancey, 2015; Kim, Ramanah, DeLancey, & Ashton-Miller, 2011). The prevalence of PVM tear ranges from 13 - 36% of women who have had a vaginal delivery (Blasi et al., 2011; Dietz, & Lanzarone, 2005; Shek, & Dietz, 2010; Valsky et al., 2009). A higher prevalence of PVM tear is associated with older maternal age and a host of other variables indicative of a more complex vaginal birth (Kearney et al., 2010; Kearney, Miller, Ashton-Miller, & DeLancey, 2006a; Miller et al., 2015; Valsky et al., 2009; Volløyhaug, Mørkved, Salvesen, & Salvesen, 2015).

PVM tear is an abnormal muscle condition, which has been variously described as detachment, disconnection, avulsion and defect. The most frequent terms found in the literature are PVM defect (DeLancey et al., 2007; Kearney et al. 2010; Morgan et al., 2007) and PVM avulsion (Dietz, Bernardo, Kirby, & Shek, 2011; Dietz & Shek, 2009; van Delft, Sultan, Thakar, Shobeiri, & Kluivers, 2015; Yan et al., 2017). Avulsion has been defined as “abnormal insertion” as seen on ultrasound imaging slice (Dietz et al., 2011) and “using a combination of direct visualization of the insertion of the puborectalis muscle on the pelvic sidewall and measurement of the levator–urethra gap, with measurements > 2.5 cm being regarded as abnormal” (Dietz & Shek, 2009, p. 699). A complete PVM avulsion is a complete loss of connection to the pubis or

as complete loss of integrity of the PVM, as measured by perineal ultrasound (Dietz & Shek, 2009). However, avulsion implies that part of the muscle detaches from the bone. From musculoskeletal perspective, avulsion is not appropriate to describe injury PVM injury. On the other hand, PVM defect on magnetic resonance imaging (MRI) was defined as “asymmetry in the muscle’s appearance” compared with the normal anatomy of the pelvic floor (DeLancey et al., 2003; Kearney et al., 2006a). A scale of 0 - 3 was used to define severity of PVM defect from MRI as follow: 0 if “no visible muscle damage,” 1 if “a mild abnormality of the muscle was visible,” 2 if “a moderate defect was seen,” and 3 if “complete loss of visible muscle” (Kearney et al., 2006a). Later, the scale was modified as grade 0 if “normal muscle,” grade 1 if “less than half the muscle missing,” grade 2 if “more than half,” and grade 3 if “complete muscle bulk was lost” (DeLancey et al., 2007; Morgan et al., 2007). These studies show the defect as a loss of the muscle bulk located in the pubovesiceral portion as identified via MRI. The term “PVM defect” was used prior to definitive determination of the abnormality in the muscle being a tear (Miller et al., 2015).

In both PVM avulsion and defect, the focus is on muscle fiber loss and discontinuity of the muscle, which indicate a muscle tear characterized by discontinuity in terms of a visible loss of muscle bulk that can be observed on MRI, according to Brandon et al. (2012) and Miller et al. (2015). Brandon et al. (2012, p. 447) defined PVM tear as “muscle fiber loss in two or more adjacent 2-mm sections in both axial and coronal plane proton density-weighted sequences” and “a muscle tear was recorded if greater than 20% of the expected muscle volume was absent.” Miller et al. (2015, p. 188.e4) defined PVM tear as “discontinuity of muscle observed as loss of visible muscle in an area where it is known to occur.” DeLancey’s, Brandon’s and Miller’s work emphasize the estimation of the tear. A complete PVM tear is defined as a full disruption in the

attachment of its origin at the pubic bone. The term “PVM tear” may be more transparent to clinicians and women and easier to understand compared with “PVM defect” in a clinical setting. Thus, “PVM tear” could be the most appropriate term to describe the muscle condition, and hence the term will be used in this study.

PVM tear has been identified as a risk factor for two important pelvic floor disorders: pelvic organ prolapse and stress urinary incontinence (SUI), though the latter remains controversial (Schwertner-Tiepelmann, Thakar, Sultan, & Tunn, 2012; Miller et al., 2015). For decades, the predominant nonsurgical treatment for these pelvic floor disorders has been to strengthen the PVM, known as pelvic muscle exercises or pelvic floor muscle training. There is a lack of evidence to show whether women with a torn PVM actually benefit from pelvic muscle exercises in comparison to their peers whose PVM is not torn. This physiologic reality could logically explain precisely why women following the exercise regimen fail to improve on measures of strength, regardless of effort made.

PVM strength can be measured using several methods, such as the Perineometer, the Brink digital exam, and the modified Oxford scale. The strength of the PVM has been assumed to describe the PVM functional capacity for decades. In fact, these measurements for assessing the strength actually measure the force of vaginal closure. However, evaluation of the force without attention to a potential tear may lead to an incomplete understanding of the cause of a loss of PVM functional status.

This then raises the question of how to evaluate for PVM tear prior to embarking on a selected program of physical therapy for pelvic floor disorders. This can be considered the equivalent of evaluating for anterior cruciate ligament (ACL) tear prior to embarking on a selected program of physical therapy for knee disorders. In the case of ACL injury, a thorough

evaluation is needed, including reviewing an individual health history for risk factors and symptoms, and performing special tests to help determine the likelihood of ACL tear. Special testing typically starts with specific, low-cost, clinical assessments. These help determine the need for much costlier tests, such as MRI, to confirm the diagnosis. Confirmatory diagnosis provides the basis of physical therapy decisions, including the rationale for modifications to physical activity to reduce stress on a knee with a torn ACL.

During childbirth, the pelvic floor experiences several changes, which cannot be measured in vivo due to clinical, technological, and ethical reasons. The pelvic muscles require an exceptional degree of soft-tissue stretch to allow passage of a newborn, which may produce injury in some women. Biomechanical modeling may explain some phenomena associated with delivery and pregnancy. However, it is a challenge to manipulate the model due to the high complexity of human anatomy and soft biological tissues (Humphrey, 2003). Precise numerical modeling has also been developed and predicted that the PVM is at high risk for stretch-related injury during vaginal birth (Lien, Mooney, DeLancey, & Ashton-Miller, 2004; Lien, Morgan, DeLancey, & Ashton-Miller, 2005). A multitude of variables such as variations in maternal pelvic shape, fetal head shape, the degree of molding during delivery, symphyseal diastasis, and presenting orientation may affect the maximum muscle stretch ratios, thus affecting the final results of injuries (Tracy, DeLancey, & Ashton-Miller, 2016).

Costlier MRI and ultrasound tests to identify PVM tear are almost exclusively performed only in the research arena, not in clinic practice settings (Kearney et al., 2006a; Shek, & Dietz, 2010; van Delft et al., 2013). Lacking symptoms of pelvic floor disorders, postpartum women rarely receive the costlier tests to determine PVM status, though the prevalence of the PVM tear in postpartum women is as high as 36%, as determined from 3D/4D ultrasounds evaluation

(Dietz & Lanzarone, 2005). Early tear detection may help in constructing plans for delaying or preventing the pelvic floor disorders expected to occur over time for those with tear, providing beneficial effects on quality of life. What is therefore needed is a low cost, easily implemented test that can be done in a routine clinical examination.

One possible, low cost approach to predict PVM tear is to use the index finger to palpate the PVM. The history of using the index finger palpation to assess PVM status can be back to 1943. Gainey (1943 & 1955) used this technique to assess the PVM status for 1,000 parous women. Especially, to distinguish this active technique of palpation from currently popular passive finger placement assessments, such as Brink digital exam, this technique is referred to in this study as index finger palpatory assessment for estimating presence, absence, or equivocal (cannot clearly feel the muscle but not convinced of its complete absence) in terms of PVM tear. Similar to the analogy above of the clinical assessment of ACL tear, the index finger palpatory assessment offers a degree of certainty by the person palpating, definitely present, definitely absent, or unable to be completely sure of presence or absence. Gainey (1943 & 1955), a highly experienced obstetrician, used index finger palpatory assessment to estimate presence of PVM tear in 20% of primiparous women 75 years ago, which is consistent with percentages found today using the modern technology tests of MRI (DeLancey et al., 2003) and ultrasound (Dietz & Steensma, 2006). Although no modern study has used this form of palpatory assessment alone to diagnose PVM tear (Lammers, Futterer, Prokop, Vierhout, & Kluivers, 2012), Dietz and Shek (2008) have documented that the muscle tear is likely reachable by palpation. A tear may feel like a gap between the muscle and pubic ramus, discontinuity of the muscle, or thinness of the vaginal wall. van Delft et al. (2013) used palpatory assessment to check PVM tear by assessing the presence or absence of PVM bulk. They defined PVM tear when the inferior pubic ramus

cannot be felt after finger insertion. They found after appropriate training that the technique can be readily learned and reliably incorporated into the clinical and research settings. Since the results of palpatory assessment may be influenced by the observers' experience and knowledge, more precise and costlier tests like ultrasound and MRI are needed to confirm the diagnostic results of palpatory assessment, depending on degree of uncertainty by the provider, and purpose of diagnosis. For example, research studies on mechanism, typically with small numbers, would require the high validity and precision of MRI or 3D/4D ultrasound, whereas palpatory assessment along with history of risk factors may be adequate as a gross estimate of likelihood for existing tear in large epidemiological studies.

Some special obstetrical factors during vaginal birth play a critical role for PVM tear. For example, Low et al. (2014) has reported that birth risk factors including old maternal age and long second stage active pushing increased the likelihood of severe PVM tear. A conceptual idea (Figure 3.1) is that women who experienced recent vaginal birth and had additional risk factors (e.g., maternal age ≥ 33 years, second stage labor lasting ≥ 150 minutes, infant weight ≥ 4000 gm) need index finger palpatory assessment to estimate any equivocal or absent PVM. A confirmatory imaging test is a logical next step if the clinician is equivocal about tear, or wants to confirm the palpatory assessment estimate of absent PVM. In clinical settings, need for certainty would be dependent on whether care choices are dependent on the preciseness of diagnosis.

Paralleling the ACL example, the missing piece in the chain of evaluation for symptomatic postpartum women (with delivery-related risk factors for PVM tear) is an agreed upon, specific, low-cost, validated clinical assessment, which can help determine if costlier tests, such as MRI, are needed. To validate this inexpensive palpatory assessment technique, the aim of this study was to determine the extent to which palpatory assessment of the PVM through the

vaginal wall can inform the decision to order costlier and more precise tests, by the strength of its predictive capacity for MRI results.

Materials and Methods

Study Design

This study is part of a parent study, Evaluating Maternal Recovery from Labor and Delivery (EMRLD), which is an NIH-supported longitudinal observational cohort study that focuses on postpartum women. Participants were recruited from June 13, 2005 to March 14, 2012. Institutional Review Board approval from the University of Michigan was obtained, as was informed consent from all participants prior to participation in the study. Medical records were used to evaluate eligibility criteria. EMRLD collected data approximately 7 weeks and 8 months postpartum after a first vaginal birth. For our analysis, we used medical records to identify and select women who were at high risk for PVM tear during vaginal birth. For this study, the 7 weeks postpartum data are used in analyses.

Sample

Inclusion criteria included complete measurements on index finger palpatory assessment and MRI for PVM tear, along with those from the parent study (Miller et al., 2015): age of 18 years or older, postpartum women, without urinary incontinence, without genitourinary system pathology and urinary tract infection, having the ability to read and sign the consent forms, and having at least one of the following risk factors for PVM tear: maternal age greater than 33 years, second stage of labor greater than 150 minutes, infant weight greater than 4000 gm, forceps or vacuum delivery, or third or fourth degree anal sphincter laceration.

Exclusion criteria included: English was not primary healthcare language, birth before 36 weeks gestation, twin gestation, an infant admitted to the neonatal intensive care unit, women

with an untreated urinary tract infection, prior surgery for urinary incontinence or prolapse, unwillingness to undergo a pelvic exam, history of neurological conditions, multiparity, prior urogynecologic surgery or traumatic accident injury, medical conditions such as connective tissue disorders, or neurological conditions.

The parent study interviewed 1685 women in the antenatal outpatient clinics during the study. For this planned data analysis, of women who were screened for the parent study, 1,600 were ineligible or did not participate; 85 women met inclusion criteria and exclusion criteria (Figure 3.2).

Procedure

The examiner who performed the index finger palpatory assessment was a master's prepared non-researcher nurse practitioner. She had experience in performing the same assessment in approximately 200 non-postpartum incontinent women in a prior study. The prior study did not have MRI data for comparison, nor was the nurse practitioner given any access to the MRI data in the current study. She had no exposure to MRI images of the pelvic floor, aside from a few examples seen in power point presentations at conferences. She represents the general gynecological care provider in a primary care setting.

Instruments

PVM tear status assessment by index finger palpatory assessment. Index finger palpatory assessment for estimating odds of PVM tear is a clinical assessment process to determine if the body of the PVM can be felt at its anatomically expected location. The examination was done with the study participant in lithotomy position. The examiner inserted the index finger into the vagina about 2 cm and hooked the finger to either right or left to palpate the body of the PVM on that side, lightly pressing to feel through the vaginal sidewall. The index

finger focused on the PVM and palpated for muscle wholeness. Figure 3.3 shows where the index finger is firstly located in the vagina, and then slips up toward to pubic bone, finally the finger will be located by 10 o'clock position and a tear could be identified. If the body of the muscle was clearly felt, this was a likely indication that the PVM was not torn on that side. The examiner continued to palpate to assess muscle bulking during a pelvic muscle contraction to offer additional confidence that the PVM was unlikely to be torn. These findings were considered as PVM “present” to palpation.

If the muscle cannot be definitively palpated at rest, nor during the woman’s attempt at pelvic muscle contraction, and instead there is a sense of indentation and/or feeling the hardness of the bony sidewall, this suggests to the examiner that the PVM may be completely torn away from its origin (at the pubic bone) on that side. These findings are scored as PVM “absent” to palpation. If the examiner was unable to completely certain of the “present” or “absent” of the muscle, then the finding is scored “equivocal” to palpation on that side. This process and scoring is then repeated on the opposite side.

PVM tear status assessment by MRI. PVM tear was measured by MRI, which served as dependent variable in this study. A 3-T Philips Achieva (Philips Medical System, Eindhoven, The Netherlands) with an 8-channel cardiac coil was positioned over the pelvis to perform the MRIs. The lower pelvis was imaged in the coronal, axial, and sagittal planes with proton density-weighted sequences. Additionally, tailored imaging was used to obtain a better definition of the anterior pelvic floor anatomy. The complete MRI protocol has been discussed in previously published reports (Brandon et al., 2012; Miller et al., 2010; Miller et al., 2015). PVM status was evaluated for discontinuity of muscle fibers that were observed as a loss of visible muscle (Figure 3.4). PVM tears were initially categorized into 5 levels for each side: no tear, subtle tear,

less than 50% tear, greater than 50% tear, and complete tear. The MRIs were read separately by 2 board-certified, fellowship-trained MSK radiologists who were blinded to birth data, risk category, and palpatory assessment results from the PVM.

Data Management and Analysis Methods

Determination of severity of PVM tear. The index finger palpatory assessment was graded as: present bilaterally, equivocal on at least one side and present on the other, equivocal on both sides or absent on at least one side, and absent on both sides. We combined both sides of index finger palpatory assessment. If both sides of PVM were present, without loss it was coded as 0. If one side PVM was palpable but another side was labeled as equivocal, it was coded as level 1. If both sides of PVM were labeled as equivocal, or one side was not palpable, it was coded as level 2. If both sides of PVM could not be palpated, it was coded as level 3.

We combined the two sides of PVM status as measured by MRI. The degree of PVM tear was divided into four categories: no tear or subtle tear on both sides of PVM (coded as 0), < 50% unilateral tear (coded as level I), < 50% bilateral or \geq 50% unilateral tear (coded as tear level II), and \geq 50% bilateral tear (level III) (Low et al., 2014; Miller et al., 2015).

Statistical methods. A proportional odds model was used to estimate the odds of MRI-documented PVM tear status (outcome measure on an ordinal scale) as predicted by the index finger palpatory assessment method (Agresti, 2010) for women with risk factors for PVM tear during vaginal birth. The risk factors have been reported elsewhere (Low et al., 2014). The regression coefficient from this model shows the association between log-odds of higher level PVM tear category with each increasing level in palpatory assessment measure. Cumulative odds ratio with 95% confidence interval as well as the significant value will be presented. Proportional odds assumptions were tested in the following methods. A chi-square score test was used to

determine whether the main proportional odds model assumption of one set of coefficients for all thresholds in an ordinal model was violated or not. A test of parallel lines (score test) compared the ordinal model that has the same coefficient across response categories to a model with different coefficients for each response category. The data satisfy the proportional odds assumption if the score test of the proportional odds assumption is not significant at the 5% level of significance. A comparison of a model with no explanatory variables (the baseline or intercept only model) against the final model with all the explanatory variables was conducted to check whether it significantly improved the fit of the data. Goodness-of-fit was used to test whether the observed data were consistent with the fitted model. Normality (for error, not outcome) was tested by normal Q-Q plot and also was checked with the goodness-of-fit tests, the Kolmogorov-Smirnov test, and the Shapiro-Wilk test. Homogeneity of variance was tested using Intelletus Statistics to plot the standardized residuals versus the predicted Y values, which can show whether points are equally distributed across all values of the independent variable or not. Homogeneity was also tested by Levene's test. Residual plots, leverage plots/statistics, and box plots were used to check if there were any other issues such as outliers in our data.

Baseline characteristics including maternal age, education level, race as well as birth factors such as length of second stage, baby's weight and forceps delivery were used as descriptive statistics. Continued variables such as age were reported as mean (SD) and range. Categorical variables such as MRI-documented PVM tear status and PVM status to palpatory assessment were reported as frequency and percentage. These analyses were carried out using SPSS (SPSS Inc, Chicago,) version 23. A significance level was $p < .05$ for two-sided analysis. The analysis was based on intention-to-treat and thus included all participants with available data.

Results

Final Sample Description

Characteristics of the participants are presented in Table 3.1. Average age was just over 29 years. 24 women were old than 33 years with mean age just over 36 years. The majority of the participants had a college education or higher. Most women were white. Birth factors were also reported. For risk factors for PVM tear in this sample of women who were recruited for having at least one risk factors, 38 women had long second stage labor with the mean just under 260 minutes. 11 women had a baby with a weight greater than 4000 grams with mean around 4300 grams. 40% (26/65) had anal tear. Instrumented delivery involved 6% (5/85) by vacuum and 2% (2/85) by forceps.

The descriptive results for the nurse practitioner's PVM palpatory assessment are shown in Table 3.2. Nine percent of the women were identified with "absent" PVM on both right and left sides by palpatory assessment while 20% of the sample were identified with "present" PVM on both sides. Table 3.3 shows MRI findings. Results were at least a partial PVM tear in 35% of the sample while the remainder had none or subtle tear on MRI.

Bivariate Proportional Odds Model Results

Results of the proportional odds model exploring the index finger palpatory assessment for its predictive value of PVM tear severity are shown in Table 3.4. The estimated odds of having a high level MRI-documented PVM tear category increased by 3.62 for each level increase in PVM loss status to palpatory assessment (95% CI 1.70 – 7.73, $p = .001$). The following reported that this proportional odds model was appropriate to analyze the data. The test of parallel lines for the proportional odds assumption ($\chi^2 = 1.01, p = .604$) showed that the data satisfied the assumption that the ordinal model had one set of coefficients for all thresholds.

The test of the baseline model without explanatory variables compared to a final model with all explanatory variables ($\chi^2 = 16.46, p < .001$) showed that the final model gave a significant improvement over the baseline intercept only model. The Pearson's chi-square statistics ($\chi^2 = 9.64, p = .291$) from a goodness-of-fit test indicated that the data and the model predictions were similar and the model was good.

Discussion

This study found that PVM status by index finger palpatory assessment done by an experienced nurse practitioner but without experience in viewing MRI results can be used to estimate the severity of PVM tear as confirmed by MRI, as studied within a sample of women with risk factors from a recent complex vaginal birth. This is consistent with the finding from a previous study that used palpatory assessment to assess the PVM tear and confirmed with an ultrasound (van Delft et al., 2015). Both ultrasound and MRI estimate complete PVM tear well, but MRI may be more precise in differentiating partial tears (Yan et al., 2017). MRI has been identified with a high level of agreements for diagnosis of the PVM tear spectrum (Morgan et al., 2007). Given the superiority of the MRI, it may be the best method to confirm PVM tear status initially suspected by either index finger palpatory assessment (low-tech) or by screening with ultrasound (high-tech).

Index finger palpatory assessment is easy to learn and can be an effective aid in providing feedback to patients. Clinicians can acquire proficiency in this examination through proper training and provide a timely initial estimate of PVM status post birth. Previous studies found that palpatory assessment had acceptable reliability to identify PVM tear for clinical incorporation after training (Kearney, Miller, & DeLancey, 2006b; van Delft et al, 2013). Although several methods exist to evaluate PVM functional status such as the instrumented

speculum, the modified Oxford scale, and the Brink digital palpation, they are designed to measure vaginal closure force as a response to volitional pelvic muscle contraction while palpatory assessment (at rest or during attempt at volitional pelvic muscle contraction) is intended to evaluate anatomical status including PVM tear. Moreover, unlike MRI where the cost may be prohibitive, palpatory assessment is low cost and can be readily available even in a rural clinical setting. With inserting approximately 2 cm of index finger vaginally, PVM loss status could be identified in minutes. Palpatory assessment of existing PVM tear does not mean women will display symptoms of pelvic floor disorders like pelvis pain or urinary incontinence. However, it may play a critical role for the development of pelvic floor disorders in later life.

Previous findings showed an association between PVM tear and underactive pelvic muscle contraction (Steensma et al., 2010) and vaginal closure force reduction (DeLancey et al., 2007; Dietz & Shek, 2008; Miller et al., 2015). With PVM tear, the PVM logically is not effective in contracting due to a discontinuity of its attachment at the origin. It follows that pelvic muscle exercises through repetitive contractions to strengthen the PVM will be ineffective for torn muscle. In order to increase the effectiveness of strength training, it is worthwhile to assess the PVM status before applying a treatment.

Evaluation of “strength” (vaginal closure force) without attention to a potential tear will fail to reveal the reasons for a loss of vaginal closure force. Women with torn PVM might best be instructed in, for instance, lifestyle factors/pessary support for pelvic organ support during high impact activities.

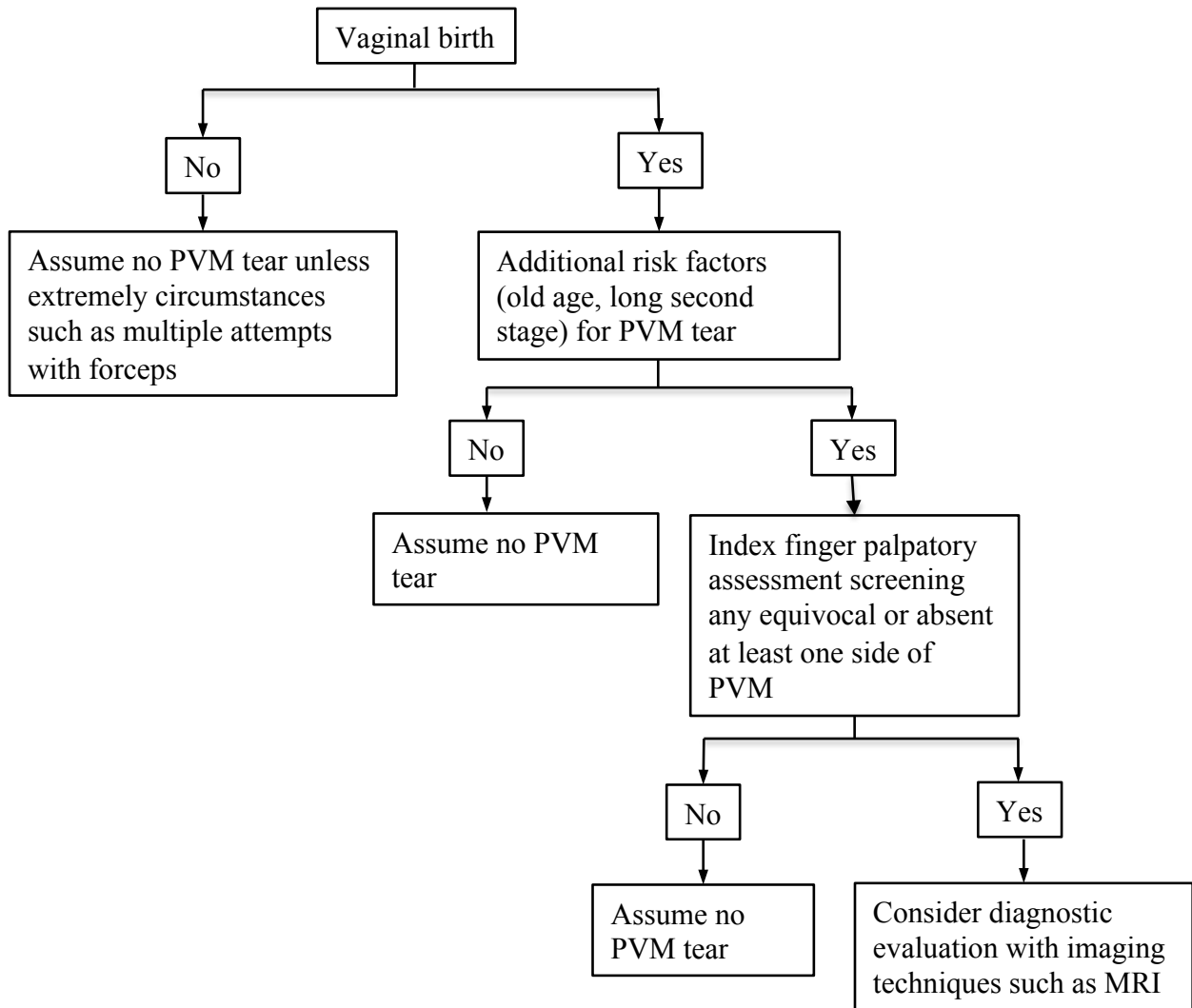
There are several limitations. Despite the fact that index finger palpatory assessment for estimating odds of PVM tear is a good method to estimate the occurrence of PVM tear, as with most physical examination assessment methods, the results of the palpatory assessment may be

influenced by the examiner's experience and understanding of the anatomy and anatomical disruption of a PVM tear. The second limitation is that all participants were healthy postpartum women. It would be of interest to explore this palpatory assessment in other populations of women, such as those who present clinically with symptoms, such as urinary incontinence, prolapse, or pain. Third, an interrater reliability cannot be evaluated in this study although we also have data at 8 months postpartum. This is because the 7 weeks is relatively early postpartum for assessing PVM in light of known edema and its gradual resolution over time. Although the PVM tear status did not significantly change in these participants, the degree of sensitivity of the patient to discomfort and vaginal swelling was at times dramatically different at the two timepoints (Miller et al., 2015). Analyzing interrater reliability requires that the data are presented with the same situation and phenomenon by the single data collector. Fourth, the odds ratio in this study was not adjusted for other confounding of the individual obstetric risk factors for PVM tear. The odds ratio of the risk factors for PVM tear has been reported elsewhere (Low et al., 2014). In this analysis, risk factors were defined as those that were used as inclusion criteria for entry into the parent study from which the data for this analysis was obtained. The last limitation is the small sample size. Interpretation of the findings in this study needs to be cautious since we have a large 95% confidence interval of odds ratio. However, it provides proof of concept. Larger scale studies are needed to confirm the findings. Important in this study is that it provides the evidence that index finger palpatory assessment can be used to initially estimate odds of PVM tear. Further research should investigate confirmation of our findings and determination of intra- and interrater findings of palpatory assessment as determined in a sample of women with unchanged condition over time.

Conclusions

1. Index finger palpatory assessment at the site of the PVM can be used to estimate the odds of PVM tear in postpartum women with known PVM tear risk factors. With that information, an informed decision can be made for additional diagnostic tests, (for instance obtaining an MRI) and decisions regarding clinical care.
2. Using index finger palpatory assessment to estimate the odds of PVM tear is a start point for decision making about appropriateness of strength training programs, which currently are typically recommended without regard to consideration of a condition of PVM tear.
3. Research studies on large numbers of women may be able to use index finger palpatory assessment to estimate odds of PVM tear across various populations, when combined with a reported history of obstetric risk factors for PVM tear, such as forceps delivery.

Figure 3.1 Conceptual Model of Who Needs Index Finger Palpatory Assessment to Clinically Estimate Pubovisceral Muscle (PVM) Status after Childbirth*



* Postpartum women with additional risk factors for PVM tear need index finger palpatory assessment for estimating odds of PVM tear to identify any equivocal or absent muscle, which would require a further diagnostic test like MRI to confirm the equivocal or absent muscle.

Figure 3.2 Flow Diagram for Study Participant Selection

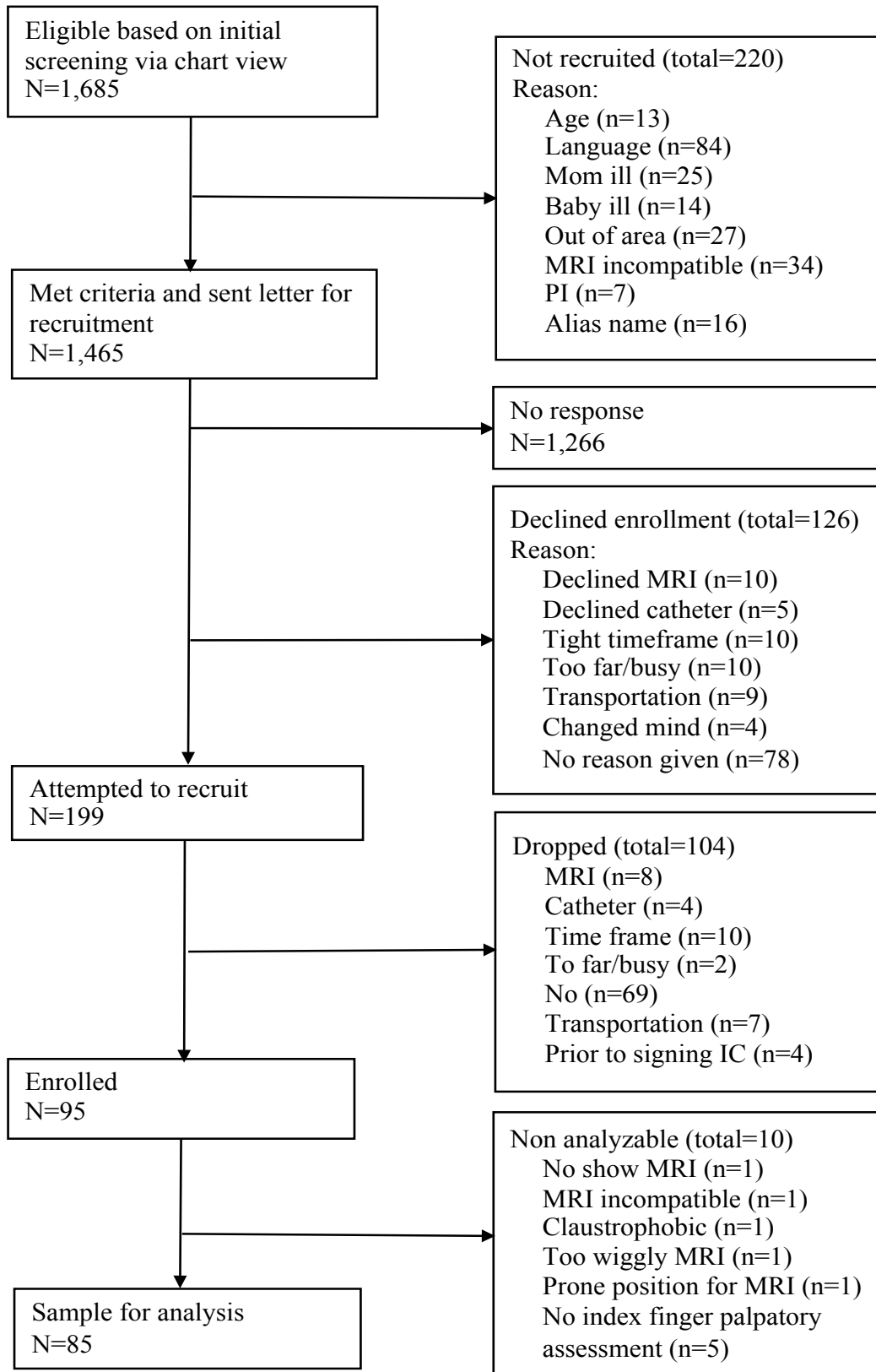
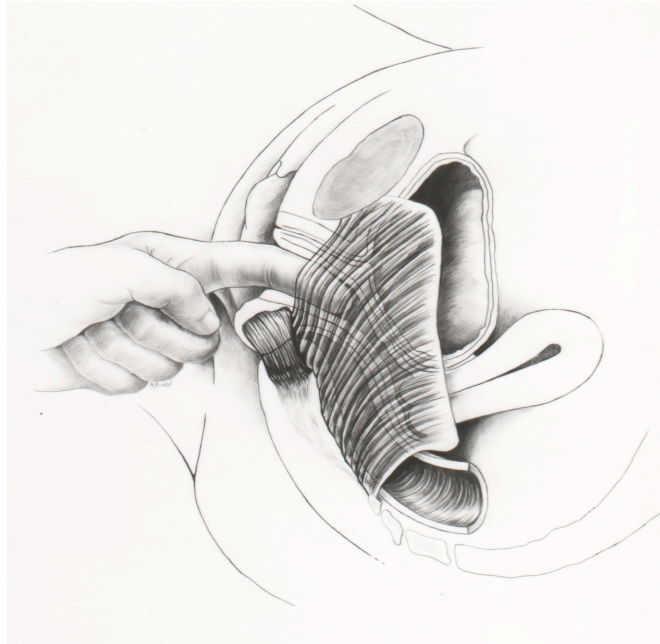


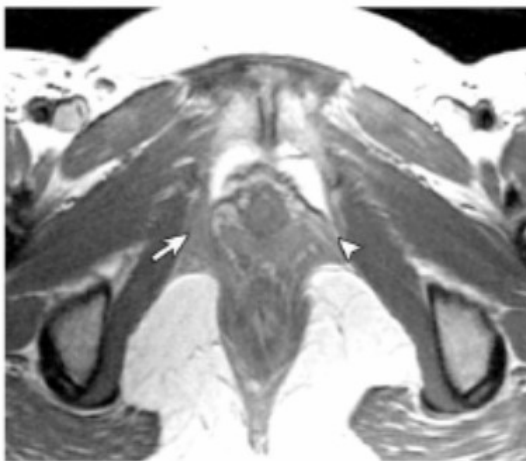
Figure 3.3 Index Finger Palpatory Assessment for Estimating Odds of Pubovisceral Muscle (PVM) Tear © DeLancey*



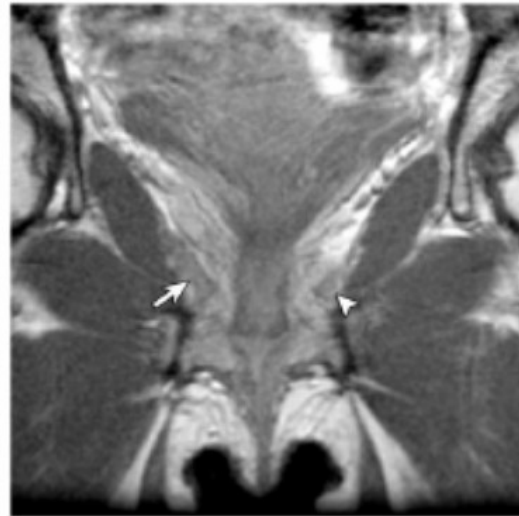
*The wholeness of PVM will be palpated as continuous soft tissue resistance between the PVM and pelvic sidewall. A tear will be palpated as bony at the inferior pubic ramus and there will be a thinness of the sidewall and the PVM dorsally.

Figure 3.4 Pubovisceral Muscle (PVM) Tear on MRI* (Miller et al., 2010)

3.4A



3.4B



* A, axial and B, coronal. Images from a 35-year-old women at 3 weeks after vaginal birth. Arrowhead: high grade left PVM tear; arrow: subtle right PVM tear.

Table 3.1 Demographic Characteristics

Characteristics	Count (N)	Mean (SD) or frequency	Range or %
Demographic			
Maternal age (year)	85	29.2 (5.7)	19 - 46
Maternal age (≥ 33 years)	24	36.3 (3.4)	33 - 46
Education	83		
High school graduate or less		12	15%
Some college		17	21%
College/technical school graduate		21	25%
Graduate school		33	40%
Race	84		
Black		5	6%
White		70	83%
Asian		5	6%
Other		4	5%
Birth factors			
Second stage (minutes)	84	150.6 (126.9)	5 - 518
Second stage (≥ 150 minutes)	38	257.8 (107.3)	152 - 518
Active pushing (minutes)	73	108.2 (86.1)	5 - 312
Passive pushing (minutes)	73	46.3 (74.2)	0 - 307
Baby's weight (gram)	84	3402.9 (541.7)	2100 - 4825
Baby's weight (≥ 4000 grams)	11	4284.6 (255.3)	4000 - 4825
Baby's head circumference (cm)	82	34.2 (1.7)	30 - 38

Characteristics	Count (N)	Mean (SD) or frequency	Range or %
Epidural (yes or no)	85	68	80%
Oxytocin (yes or no)	85	34	40%
Episiotomy (yes or no)	85	17	20%
Anal tear (yes or no)	65	26	40%
Vacuum (yes or no)	85	5	6%
Forceps (yes or no)	85	2	2%

Table 3.2 Index Finger Palpatory Assessment Results

Index finger palpatory assessment for PVM tear	
	N=85, % (n)
“ Present ” bilaterally	20% (17)
“ Present ” on one side and “ equivocal ” on the other side	8% (7)
“ Absent ” on one side or “ Equivocal ” on both sides	62% (53)
“ Absent ” on both sides	9% (8)

PVM = pubovisceral muscle.

Table 3.3 MRI Results

MRI-documented PVM tear	
	N=85, % (n)
No tear (No or subtle PVM tear)	65% (55)
Level I tear (<50% unilateral PVM tear)	11% (9)
Level II tear (<50% bilateral PVM tear or ≥50% unilateral PVM tear)	15% (13)
Level III tear (≥50% bilateral PVM tear)	9% (8)

PVM = pubovisceral muscle.

Table 3.4 Results of Proportional Odds Model Using MRI-documented Pubovisceral Muscle (PVM) Tear Status as Response Ordered Categories (4 Levels)*

	Odds ratio (OR)	95% CI of OR	<i>p</i>-value
Index finger palpatory assessment for estimating odds of PVM tear**	3.62	1.70 – 7.73	.001

Test of parallel lines for the proportional odds assumption: Chi-square = 1.01, df = 2, *p* = .604
 Goodness-of-fit test of overall model (Likelihood Ratio): Chi-square = 9.64, df = 8, *p* = .291,
 Pseudo R² = .202

Note. CI = confidence interval.

* Among Women at High Risk for PVM Tear, Evaluated as $P \leq .05$, N = 85.

** Treated as continuous data (0 to 3), 0 indicates pubovisceral muscle present and 3 indicates that pubovisceral muscle was not palpable.

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Chapter 4

The Relationship between MRI-documented Pubovisceral Muscle Tear and Urethral Closure Pressure in Primiparous Women with Known Risk for Pubovisceral Muscle Tear during Their Vaginal Delivery

Abstract

Background: Vaginal birth is a risk factor for developing incontinence due to birth-related injuries. Muscle tear is one common birth-related injury that often occurs on the pubovisceral portion of levator ani. Continence relies on optimization of urethral closure pressure (UCP) across women's activities. Pelvic muscle contraction to preempt leakage (e.g. during cough) has been shown to be effective. However, little is known about the degree to which pubovisceral muscle (PVM) tear affects potential for UCP with a volitional pelvic muscle contraction.

Purpose: To investigate the effect of PVM tear on ability to increase UCP by a volitional pelvic muscle contraction among women within the first year post vaginal birth who have known risk factors for PVM tear during that birth (e.g. forceps, long 2nd stage, and older age).

Methods: Fifty-six primiparas were evaluated at about 8 months postpartum in this secondary data analysis study. UCPs were measured by urethral pressure profile both at rest, which is called resting UCP and during effort to contract the pelvic muscle, which is volitionally contracting UCP. PVM tear was evaluated by magnetic resonance imaging (MRI) and was classified into one of five categories from none to >50% tear for each side. We coded MRI-documented PVM tear status into a dummy variable as 0 (without tear) and 1 (with tear) for two sides for simplicity

of presenting the data via multiple linear regression modeling. We tested whether PVM tear predicts contracting UCP after adjusting for resting UCP.

Results: There was no significant difference in resting UCP between no PVM tear and tear groups. Women without tear had higher contracting UCP compared to those with tear. Women with tear could not significantly increase contracting UCP. Regression modeling showed that the contracting UCP was associated with the PVM tear ($p = .001$), after adjusting for resting UCP ($p < .001$). A MRI-documented PVM tear decreases mean contracting UCP by on average 21 cm H₂O pressure, when controlling for the resting UCP constant. $R^2 = .42$ from the regression model indicated that 42% of the variation in the contracting UCP was explained by PVM tear and resting UCP.

Discussion: With PVM tear, women on average have reduced ability to increase contracting UCP at a moment of anticipated increased bladder pressure, as with sneeze or cough. Since lifetime continence requires adequate UCP, PVM tear may explain the reduced ability to compensate for known age-related loss of UCP over time.

Conclusion: Within the first year of vaginal birth, women with PVM tear are significantly less able to increase UCP by using a volitional pelvic muscle contraction.

Key words: Levator ani, levator ani tear, pubovisceral muscle tear, urethral closure pressure, vaginal childbirth, postpartum women, stress urinary incontinence.

Introduction

Urinary continence relies on a urethral support system and a urethral closure system (Ashton-Miller & DeLancey, 2007). The urethra is supported by the urogenital diaphragm that consists of both the levator ani and coccygeal muscle which provide structural support for the distal urethra. The levator ani is a group of muscles including the pubovesiceral (known as pubococcygeus), the iliococcygeus, and puborectal muscles (Ashton-Miller & DeLancey, 2007; Kearney, Sawhney, & DeLancey, 2004).

On the other hand, urethral closure pressure (UCP) is generated from the difference between urethral pressure and bladder pressure (Enhorning, 1961), which requires urethral pressure greater than bladder pressure in order to close the urethra to maintain urinary continence both at rest and during an increase in intraabdominal pressure (IAP) due to physical activities such as coughing or sneezing. The difference (UCP) at rest should be at least 20 cm H₂O to maintain stress continence since less than 20 cm H₂O of the resting UCP indicates a low-pressure urethra and intrinsic sphincter deficiency (Bump, Coates, Cundiff, Harris, & Weidner, 1977). A woman with a UCP at 40 cm H₂O is very likely to leak urine. At 60 cm H₂O, she may maintain continence. Above 80 cm H₂O is good for maintaining continence. Above 100 cm H₂O for UCP is best assurance for complete continence (J. Ashton-Miller, personal communication, March 1, 2018). Urethral pressure is the pressure in the urethra that is mainly generated from the urethral sphincter muscle that includes striated and smooth muscle. Active constriction of the urethral sphincter muscle maintains continence at rest (Ashton-Miller & DeLancey, 2007). Bladder pressure is mainly from detrusor muscle. IAP can be increased by physical activities. During physical activities, an IAP increase will stimulate the bladder; the bladder and urethra will respond to the increased IAP to maintain continence.

However, continence fails when these systems do not work well. Stress urinary incontinence (SUI) occurs when urethral pressure is not higher than the increased bladder pressure (Ashton-Miller & DeLancey, 2007), with prevalence estimates ranging from 5% to 61% of women (Reynolds, Dmochowski, & Penson, 2011). SUI is defined as an involuntary urine loss during physical activities, such as lifting, coughing, or sneezing (Abrams et al. 2010; Haylen et al., 2010).

To preempt leakage during coughing or sneezing, a volitional optimization of UCP is needed in response to the rapid increase in bladder pressure. This volitional increase in UCP as achieved through a volitional pelvic muscle contraction has been referred to previously in the literature as Kegel urethral closure pressure (KUCP) (Brincat, DeLancey, & Miller, 2011; Elser et al., 1999; Fantl, Hurt, Bump, Dunn, & Choi, 1986; Miller, Umek, DeLancey, & Ashton-Miller, 2004). In the three previous studies, KUCP was measured while asking the participants to perform a volitional pelvic muscle contraction. The volitional pelvic muscle contraction was suggested from the contraction of both the pelvic muscle and the urethral sphincter to increase the pressure in the urethra (Miller et al., 2004). In fact, the KUCP measured optimization of the difference between the urethral pressure and bladder pressure. Prior to measures of the KUCP, a maximum urethral closure pressure (MUCP) at rest was obtained. A volitional pelvic muscle contraction is performed to maximize UCP at a discrete moment in time.

A note about terms: MUCP has historically been defined as “maximum difference between the urethral pressure and the bladder pressure” (Abrams et al., 2002). The definition neglects detail regarding what is meant by “maximum.” A historical reference to Enhorning’s original work (1961) follows. Enhorning used “maximum” in term of precision about the procedure. The procedure was “pressure within the urethral portion where intra-urethral pressure

is highest” at a certain bladder reference pressure and “the greatest intra-urethral pressure, regardless of its location, is of special significance for closure, and is from now on referred to as urethral pressure” (Enhorning, 1961, p. 32). A pull-through of a pressure transducer down the entire length of the urethra to find a single point of highest pressure. Then, subtract bladder pressure from that. However, this single point of highest pressure was attained with the woman trying her best to be “at rest.” That is, not maximum in terms of optimizing her urethral pressure by a volitional contraction of her pelvic muscles. Therefore, the word “maximum” (meaning a procedural detail) is confusing in the context of the terms in this article, which addressed optimized pressure that is a woman’s personal “maximum” pressure under condition of contracting. Therefore, we make use of terms according to the condition when the urethral pressure was measured (condition at rest vs condition at contraction) and remove the term “maximum” and replace with resting UCP to distinguish the women’s volitional state when purposefully at “rest” and when purposefully “contracting” during the measure. Urethral pressure profile procedure is done under first the condition of purposefully resting and then repeated immediately thereafter while purposefully contracting. In the first condition at rest, the procedure is to use pull-through to find the point in the urethra where pressure is highest during resting. In the second condition at contracting, the procedure is to first position the pressure transducer at the point in the urethra where highest resting pressure was observed, and steady the transducer at that point while asking the woman to volitionally contract her pelvic floor muscles, to elicit contracting UCP. Thus, in this article, we use resting UCP to replace MUCP and contracting UCP to replace KUCCP based on the conditions when the measures were done.

To prevent urine loss, the timing of the pelvic muscle contraction influences its effectiveness. Women need to start to contract the pelvic muscle during an increase in IAP. This

will increase the UCP to respond to the increased bladder pressure. Moreover, to successfully perform the contraction requires awareness of what makes a woman leak and the ability to perform the timely contraction and hold it through those activities (i.e., the Knack) (Appendix A) (Miller, Ashton-Miller, & DeLancey, 1998; Miller, Sampsel, Ashton-Miller, Hong, & DeLancey, 2008). And even if she can master the timing and awareness, the optimization of contracting UCP may not be reached if she lacks the ability to perform the contraction.

Many factors decrease the ability to perform contractions that may influence the contracting UCP such as vaginal childbirth and aging. As is well known, aging muscle has reduced ability to contract that has been identified (Trowbridge, Wei, Fenner, Ashton-Miller, & DeLancey, 2007). Vaginal birth also increases the risk for developing urinary incontinence (Buckley & Lapitan, 2010). However, mechanism of how birth related pelvic floor injuries affect urinary incontinence and UCP remains unclear.

Birth-related PVM tear is well known. The PVM is a supportive structure for pelvic organs. During an IAP increase, the PVM contributed to the urethral closure by allowing the urethra and other pelvic organs to tightly compress against it. When the PVM is damaged, urethral support (urethral hypermobility) can be compromised. This is relevant for SUI because of the positive effect of PVM function on continence via intentional “pelvic muscle contraction” to preempt leakage (e.g. during cough). Although the association between PVM tear and SUI remains controversial, a reverse relationship between SUI and resting UCP has been well documented (e.g. DeLancey, 2010; DeLancey et al., 2008). Thus, women need good resting UCP to attain life-long continence. Women also need good contracting UCP to optimize the continence margin during an activity. However, little is known about the degree to which PVM tear affects the potential for a high UCP during a volitional pelvic muscle contraction to be

achieved. Figure 4.1 shows the conceptual framework for this study. This study focused on the relationship between PVM tear and contracting UCP. The aim of this study was to investigate the effect of PVM tear on the ability to increase contracting UCP among women within the first year post vaginal birth and who had known risk factors for PVM tear during that birth (e.g. forceps, long 2nd stage, and older age).

Materials and Methods

Study Design

This planned study was another part of the parent study called EMRLD. The design of the parent study was detailed in Chapter 3. For this study, the 8 months postpartum data are used in analyses, since this was when measures of urethral closure pressure were made.

Sample

The inclusion criteria were detailed in Chapter 3. The difference of the inclusion are women in Chapter 3 should have 7 weeks postpartum MRI-documented PVM tear and index finger palpatory assessment identified PVM status, while this study (Chapter 4) requires women at 8 months postpartum with MRI-documented PVM tear and UCPs measured by urethral pressure profile.

The parent study interviewed 1685 women in the antenatal outpatient clinics during the study. Fifty-six women had birth-related risk factors for PVM tear, completed an MRI and UCP measurement, and met the inclusion criteria. Their data will be analyzed in this study (Figure 4.2).

Instruments

Urethral pressure profile. Urethral pressure was first attempted to be measured by Bonney (1923). Later, several techniques were introduced to measure urethral pressure (Brown

& Whickhm, 1969; Enhorning, 1961 & 1964; Simons, 1936; Tanagho et al., 1969; Toews, 1967). All the techniques are able to record urethral pressure at rest, but not inappropriate to measure a rapid pressure change such as due to coughing (Hilton & Stanton, 1983). Hilton and Stanton (1983) introduced urethral pressure profile technique with “A silicone-rubber coated dual sensor microtransducer catheter (Gaeltec Ltd)” to measure urethral pressure and urethral closure pressure at rest and during stress (p. 921). This technique contained “7 French gauge and bears two microtransducers” (Hilton & Stanton, 1983, p. 921). One microtransducer is at the tip and another one is at 6 cm proximally. The microtransducer catheter was introduced “through the urethra and so that both transducers lie within the bladder oriented laterally,” which was “connected to a polygraph recorder with a chart speed of 2.5 mm/s” (Hilton & Stanton, 1983, p. 921). Urethral pressure and bladder pressure (i.e., intravesical pressure) were measured as well as UCP was recorded through an electronically derived from the subtraction of the latter from the former. In the study, Continent women had higher UCP at rest and during stress compared to SUI women. Age over 61 years had lower urethral function. This technique did not record the urethral pressure and UCP during a volitional pelvic muscle contraction. Fantl, Hurt, Bump, Dunn, & Choi (1986) and Elser et al. (1999) adapted the technique to measure the UCP during a pelvic muscle contraction, further modified by Miller et al. (2004). The protocol of the measure UCP during a volitional pelvic muscle contraction was described in Miller et al. (2004) and Brincat et al. (2011). The urethral pressure profile is the only available measure for urethral function.

The urethral function test in this study was conducted using the classic techniques described by Hilton and Stanton (1983). The complete urethral function protocol for this study has been discussed in previous studies (Brincat et al., 2011; Miller et al., 2004). To measure the

urethral pressures and bladder pressure, all participants had a Millar catheter with dual-tip transducer inserted in the bladder. Women were positioned semirecumbent lithotomy using the Millar catheter with dual-tip transducer directed laterally inserted in the bladder. Women were asked to remain relax. The catheter was manually pulled through from the bladder to air. A maximum point was obtained regardless its location in the urethra, which was determined the highest resting urethral pressure. Then, holding the transducer at the point of the highest resting urethral pressure, women were asked to perform a volitional pelvic muscle contraction, which was recorded as the contracting urethral pressure. Measures were recorded two times. The highest values of urethral pressure from the two times were chosen for this study. Contracting UCP was the difference between contracting urethral pressure and bladder pressure. And resting UCP was difference of the highest resting urethral pressure and bladder pressure.

PVM tear status assessment by MRI. For the MRI, a 3-T Philips Achieva (Philips Medical System, Eindhoven, The Netherlands) with an 8-channel cardiac coil was positioned over the pelvis. The lower pelvis was imaged in the coronal, axial, and sagittal planes with proton density-weighted sequences and additional tailored imaging was used to obtain better definition of the anterior pelvic floor anatomy. The complete MRI protocol has been discussed elsewhere (Brandon et al., 2012; Miller et al., 2010 & 2015).

PVM tear status was measured using MRI and evaluated for discontinuity of muscle fibers that were observed as loss of visible muscle. The PVM tear was initially categorized into one of five levels of tear: no tear, subtle tear, less than 50% tear, greater than 50% tear, and complete tear for each side. Tears were also graded as from 0% - <20% (none to subtle), 20% to <50% (low grade), or \geq 50% (high grade) for each side elsewhere (Low et al., 2014; Miller et al.,

2015). The MRIs were read by 2 board-certified, fellowship-trained MSK radiologists who were blinded to birth data and risk category.

Data Management and Analysis Methods

In this study, we chose the best values for both resting UCP and contracting UCP from two urethral pressure profile measures. We combined two sides of PVM tear into a dummy variable as follows. No tear: when there was no tear or a subtle tear on both sides of PVM, it was coded as 0. Any PVM tear was coded as 1 when there was any tear in either side or both sides of PVM.

Statistical analyses were carried out using SPSS (SPSS Inc. Chicago,) version 23. A multiple linear regression model was fitted for the continuous measure of the contracting UCP and to identify the relationship between the pressure and PVM tear while controlling resting UCP. A linear relationship between contracting UCP and PVM tear was checked by a plot of the standardized residuals versus the predicted Y values. Normality (for error, not outcome) was tested by normal Q-Q plot and was also checked with a goodness of fit test, Kolmogorov-Smirnov test, and Shapiro-Wilk test. Potential multicollinearity of independent variables was tested by the Variance Inflation Factor (VIF) statistic. Autocorrelation can be tested with the Durbin-Watson test ($1.5 < d < 2.5$ show no auto-correlation).

Mean (SD) and range were used to describe the UCP and age for all participants. Frequency and percentage were used to describe the distribution of MRI and other categorical data such as education level and race. An independent samples *t* test was performed to compare no PVM tear to any tear for both mean resting UCP and mean contracting UCP. Levene's test for equality of variances was used to test the equal variances between the two independent groups. Statistics ($p > .05$) indicated that we can report the equal variances between the two groups. To

compare the difference of the mean resting UCP and mean contracting UCP, a paired *t* test was used among tear group. Wilcoxon signed rank test was used to compare the difference between mean resting UCP and contracting UCP in the no tear group.

Results

Sample Descriptive

Table 4.1 shows the characteristics of the participants. The average age was just over 30 years old with a range of 19 – 46. Most participants had some college education and even higher. The majority of women were white. There were no differences in age, education, and race between no PVM tear group and tear group. Birth factors are reported in the Table 4.1 as well. For the urethral pressure profile descriptive results, average contracting UCP for the 56 women was just under 80 cm H₂O with range 24 – 159 cm H₂O. And an average resting UCP was just under 70 cm H₂O with range 24 – 128 cm H₂O. For the MRI descriptive results, of the 56 women, 35 (62%) women had none or only a subtle PVM tear and 21 (38%) had some degree of PVM tear. Among the 21 women with torn PVM, 4 (7%) women had <50% unilateral PVM tear, 13 (24%) women had <50% bilateral PVM tear or ≥50% had unilateral PVM tear, and 4 (7%) women had ≥50% bilateral PVM tear.

UCP

As predicted, the results from an independent student *t* test indicated that women without PVM tear ($M = 86.8$, $SD = 27.4$, $N = 35$) had higher contracting UCP than women with PVM tear ($M = 65.9$, $SD = 21.3$, $N = 21$), $t(54) = 2.993$, $p = .004$. There was no significant difference in the resting UCP for women without PVM tear ($M = 67.9$, $SD = 22.5$, $N = 35$) and with tear ($M = 68.2$, $SD = 19.0$, $N = 21$), $t(54) = -0.053$, $p = .958$ (Table 4.2). The paired *t* test showed that

there was a significant difference between resting UCP to contracting UCP among the no PVM tear group ($p < .001$), but no significant difference among tear group ($p = .602$) (Table 4.2).

The regression model showed that the contracting UCP was associated with PVM tear ($p = .001$), after adjusting resting UCP ($p < .001$) (Table 4.3 and Figure 4.3). An PVM tear decreased mean contracting UCP by an average of 21.1 cm H₂O pressure when holding resting UCP constant. A 10 cm H₂O pressure increase in resting UCP will increase an average of 6.7 cm H₂O pressure in contracting UCP, independent of PVM status. Forty-two percent of the variation in contracting UCP was explained by PVM tear and resting UCP in the regression model. The degree of how much PVM tear affected contracting UCP is also shown in Table 4.3. Since standardized coefficients (β) for independent variables can be used to compare the effect on dependent variable. The higher the absolute value of the β is, the stronger the effect of that independent variable on the dependent variable, controlling for other independent variables. The β of PVM tear $|-0.4|$ and resting UCP $|0.5|$ indicate that both PVM tear and resting UCP have relatively important effect on contracting UCP.

Additionally, we ran a sensitivity analysis using the PVM tears identified by index finger palpatory assessment (refer to Chapter 3 in this dissertation). The results were similar. Thirty-nine percent of the variation in contracting UCP was explained by the palpatory assessment identified PVM tear and resting UCP in the regression model. A woman with a palpatory assessment identified PVM tear will have an average of 20.9 cm H₂O pressure decreased in mean contracting UCP, while holding resting UCP constant ($p = .002$). A woman with 10 cm H₂O pressure increase in resting UCP will have an average of 7.2 cm H₂O pressure increase in contracting UCP ($p < .001$), independent of PVM status.

Discussion

In this study, the primiparous women with PVM tear had lower contracting UCP compared with women without tear within the first year post vaginal birth and with known risk factors for PVM tear during that birth (e.g. forceps, long 2nd stage during labor, and older maternal age). Among women with PVM tear, UCP did not increase through a voluntary pelvic muscle contraction compared with the resting UCP. These findings point to the possibility that PVM tear contributes to weakening UCP. This finding is similar with the finding from a previous study that reported a negative relationship between the degree of increased UCP during a pelvic muscle contraction and the PVM tear (Dietz & Shek, 2012). A systematic review found that the degree of increasing UCP during a volitional pelvic muscle contraction varies widely (Zubieta, Carr, Drake, & Bø, 2016), women who do not have significant increase or low mean increase in contracting UCP should consider the potential muscle tear. The ability to quickly increase UCP is necessary to respond to a sharp IAP increase during an activity, to maintain continence. The findings are different from those of previous studies that reported no significant difference in contracting UCP between the tear and no tear group in one year postpartum women (Brincat et al., 2011). The difference may be attributable to the larger percentage (38%) of women with PVM tear, which in a previous study (Brincat et al., 2011) was only 18%. A further difference is that the women in our sample had all received pelvic muscle contraction training and Knack urge and stress suppression techniques at 7 weeks postpartum. Thus, unlike in Brincat et al. (2011), where women were uncoached and unpracticed in the technique of pelvic muscle contraction and Knack suppression techniques, the women in this sample had experience with the technique and its potential for reducing leakage. The difference could also be explained by different study designs. The participants in Brincat et al. were part of a case control design (half with objectively

demonstrable SUI within one year postpartum and the other with no symptoms ever). Hence, when pooled it is conceivable that resting UCP of the Brincat et al.'s group differed (were lower, not randomly) from resting pressures of our sample before any of these women birthed. That is, they may have had a high propensity for intrinsic sphincter deficiency-related SUI going into vaginal birth. In exploring Brincat et al.'s analysis, rather simple ANOVA comparing mean contracting UCP, a true analysis warrants adjusting for both study design groups and resting UCP if their results are to be compared with our study.

The findings in the study reported here indicate that women with torn PVM had reduced ability to increase contracting UCP during a volitional pelvic muscle contraction. A previous study found that women with PVM loss had a 50% decreased ability to increase UCP by a volitional pelvic muscle contraction (Miller et al., 2004). This may put them at high risk for urine leakage during an activity since low urethral pressure during a volitional pelvic muscle contraction will very likely be lower than bladder pressure. The majority of previous studies (DeLancey, Kearney, Chou, Speights, & Binno, 2003; DeLancey et al., 2007) focused on resting UCP rather than contracting UCP among incontinence women although resting UCP was not suggested as a diagnostic test for SUI (Kapoor, Housami, White, Swithinbank, & Drake, 2012). The previous studies reported that the resting UCP was lower among women with SUI compared with continent women. And resting UCP has a reverse association with severity of SUI. In our study, resting UCP played a significant role in contracting UCP. It is possible that this lower resting UCP may be related to lower contracting UCP during an activity. This lower contracting UCP could possibly explain loss of urine due to an activity. Important here is that our findings demonstrate PVM tear may be the reason that childbirth is a risk factor for SUI. Others may argue that nerve injury to the urethra may reduce the ability to increase the contracting UCP

(Smith, Hosker, & Warrell, 1989); however, this has not been definitively shown and measurement issues for nerve injury have not been resolved.

This study also found that there was no association between PVM tear and resting UCP. This is consistent with a previous study (Brincat et al., 2011). However, our finding differs from the finding of the previous studies that reported women with major PVM tear had significant lower resting UCP compared to women with no or mild PVM tear (Hegde, Aguilar, & Davila, 2016; Morgan, Cardoza, Guire, Fenner, & DeLancey, 2010). The difference may be from the different population. Our study focused on young postpartum women, while the previous studies included older women. Aging may be the main contributor for the lower resting UCP in previous work since resting UCP decreases with age for both incontinent (Murphy, Culligan, Graham, Kubik, & Heit, 2004; Pfisterer, Griffiths, Schaefer, & Resnick, 2006) and nulliparous continent women (Kapoor, Housami, White, Swithinbank, & Drake, 2012; Trowbridge et al., 2007). A torn muscle in young women may not cause the problem, but with aging, the impact of the torn muscle on the ability to optimize UCP cannot be ignored. Furthermore, lower resting UCP and higher tear rate were found in incontinent women compared with those who were continent (DeLancey et al., 2003 & 2007). Lower resting UCP was found in stress incontinent women who may have PVM tear. Although the results of studies investigating the association between PVM tear and SUI are inconsistent, our study lends evidence supporting the likelihood that the PVM tear is a factor in increased UCP during a volitional pelvic muscle contraction.

For our participants, we do not know if women with torn muscle and low contracting UCP are more likely to develop SUI than women without torn muscle. Further study can focus on whether the torn muscle is a main factor on developing future SUI. Further research also can

focus on other factors that influence the increase in contracting UCP or prevention of PVM tear, treatment of PVM tear, or treatment for SUI in women with a torn PVM.

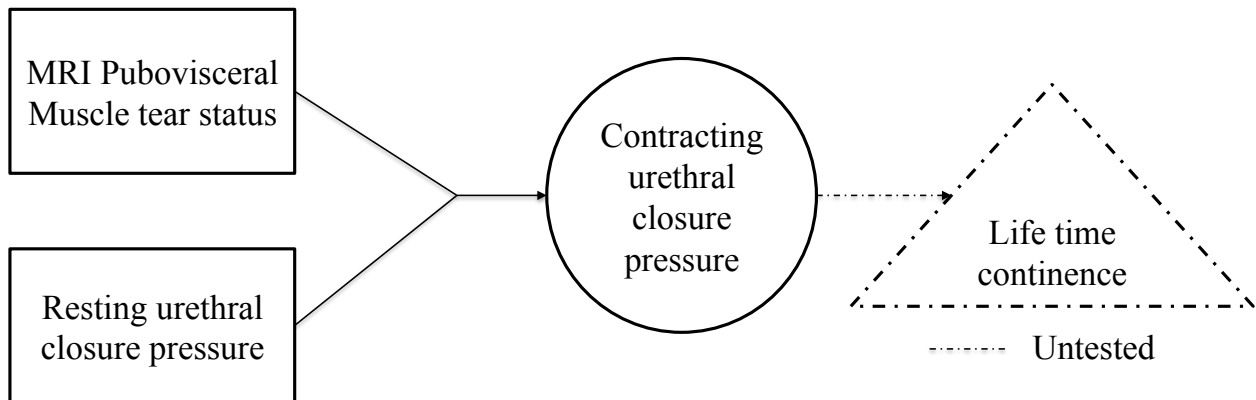
Strengths and Limitations

We only included reproductive women, which allowed us to avoid the influences of aging on UCP. Our focus on women with high risk for PVM tear may provide more power for the results. Our measure for the tear is the gold standard test that provides the most reliable indicator of PVM tear. However, limitations from this study should be acknowledged. We had small sample size and only focused on women with recent vaginal birth and with high risk for PVM tear during the birth. The findings may not be generalizable to other populations, especially older women, since aging plays a vital role on the UCP.

Conclusions

1. PVM tear due to childbirth has a negative impact on a woman's ability to increase UCP during a pelvic muscle contraction, especially for women with PVM tear and a recent vaginal birth.
2. Since lifetime continence requires adequate UCP (usually thought to be greater than at least 20 cm H₂O, better to greater than 60 cm H₂O), childbirth with PVM tear may explain the reduced ability to compensate for known age-related loss of UCP over time.
3. Our findings may encourage directing women with lower contracting UCP and SUI to a specialist for evaluation of the PVM status prior to referral to physical therapy.
4. Future research is recommended to focus on women with MRI-documented tear. Although there is no known surgical reattachment of the torn muscle possibility, other options for reducing progression to SUI may include pessary support and lifestyle alterations to reduce IAP, such as stopping cough inducing.

Figure 4.1 Conceptual Model*



*Relationship between contracting urethral closure pressure and pubovisceral muscle tear and resting urethral closure pressure. Life time continence is the long-term goal of why contracting urethral closure pressure is important.

Figure 4.2 Flow Diagram for Selection of Study Participants

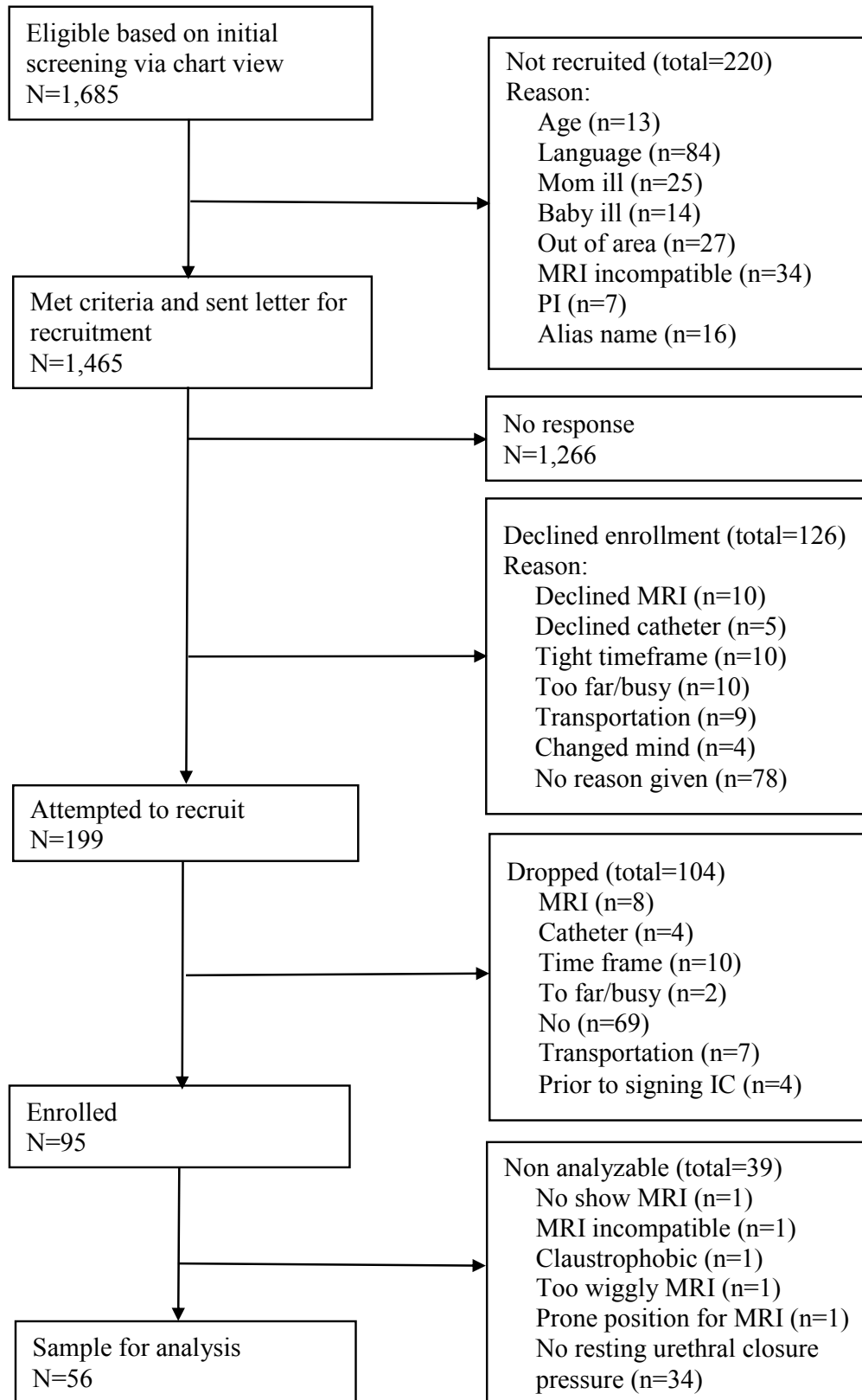


Table 4.1 Descriptive Characteristics

Characteristics	No pubovisceral muscle tear (N =35)		Pubovisceral muscle tear (N = 21)		p-value
	Mean (SD) or frequency	Range or %	Mean (SD) or frequency	Range or %	
Demographics					
Age (years)	30.1 (5.2)	22 - 42	31.8 (6.1)	19 - 46	.255
Education level					.700
High school graduate or less	1	3%	1	5%	
Some college	7	21%	4	19%	
College/technical school graduate	11	32%	4	19%	
Graduate school	15	44%	12	57%	
Race					.700
Black	2	6%	0	0%	
White	29	85%	19	90%	
Asian	2	6%	1	5%	
Other	1	3%	1	5%	

Note. No differences in age, education, and race between no pubovisceral muscle tear group and pubovisceral muscle tear group.

Table 4.2 Differences in Urethral Closure Pressures by Group and by Urethral Pressure Activity

UCP (cm H ₂ O)	No pubovisceral muscle tear, N = 35 Mean (SD)	Any pubovisceral muscle tear, N = 21 Mean (SD)	p-value
Resting UCP	67.9 (22.5)	68.2 (19.0)	.958*
Contracting UCP	86.8 (27.4)	65.9 (21.3)	.004*
p-value	< 0.001**	0.602***	

Note. Two forms of urethral closure pressure (at rest and at contraction) are represented within two groups of women at 8 months postpartum. One group had no pubovisceral muscle tear on MRI and the other group all had pubovisceral muscle tear on MRI.

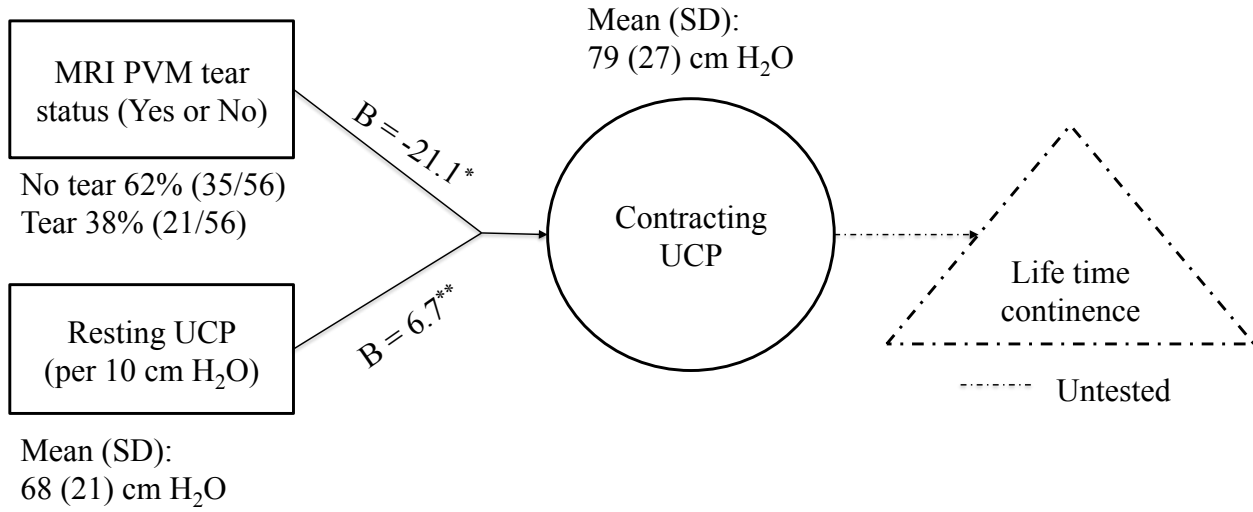
SD = standard deviation. UCP = urethral closure pressure. Significant at the $p < .05$ level, two-tailed. * Independent Student's t test. ** Wilcoxon signed rank test. *** Paired t test.

Table 4.3 Multiple Linear Regression Predicting Postpartum Contracting Urethral Closure Pressure*

Variables	Contracting UCP (cm H ₂ O) (N=56)			
	Unstandardized coefficients (B)	Std. error of B	Standardized coefficients (β)	p-value
MRI-documented PVM tear (yes coded 1 or no coded 0)	-21.1	5.8	-0.4	.001
Resting UCP (per each 10 cm H ₂ O)	6.7	1.4	0.5	< .001

Note. *Among Postpartum Women, Each with History of at Least One Risk Factor for Pubovisceral Muscle Tear During Her Vaginal Birth. Significant at the $p < .05$ level. $R^2 = .42$. UCP = urethral closure pressure. PVM = pubovisceral muscle.

Figure 4.3 Relationship between Pubovisceral Muscle Tear and Contracting Urethral Closure Pressure*



*PVM = pubovisceral muscle. UCP = urethral closure pressure. B = unstandardized coefficients. SD = standard deviation. $R^2 = .42$. $*p = .001$. $**p < .001$.

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Chapter 5

Synthesis and Conclusion

Summary of Research Findings

In the late 1940's, Arnold Kegel introduced into his clinical practice a systematic post-childbirth rehabilitation of the pelvic muscles (Kegel, 1948). His idea, that repetitive exercise of what is now known as the pubovisceral portion of the levator ani, was sensible, simple, and progressive. Rehabilitate the pubovisceral muscle (PVM) that was stretched during childbirth, to return it to its pre-birth level of support for the bladder, and then rely on that support to prevent or treat post-childbirth stress incontinence. In retrospect, we can easily see why he would have proposed what has become known as pelvic muscle exercises or to the lay public Kegel exercises. But, Dr. Kegel ran into some problems. As soon as he introduced the perineometer, Kegel conflated PVM strength and intraabdominal pressure (IAP). Over the next nearly 70 years, so did most others who tried to evaluate PVM function. And here is the difficult part: unknown to these historical investigators was that, in a not insignificant portion of women, the PVM was likely torn – a chronic injury. Logically then, in study after study, a wide variety of measures designed to evaluate PVM strength changes with Kegel exercises may not have been measuring that at all. As a group, studies showed significant change in perineometer mean scores – and the same with the many instruments that followed. But the changes in PVM function were never shown to correlate with reduction in stress urinary incontinence (SUI) symptoms, with only one study exception, even though the group mean scores for stress incontinence were reduced. Was

this because measures of PVM function were in reality inadvertently measuring rise in IAP from extraneous muscle use when a woman with a torn PVM was asked to contract it? Was this because the improved PVM strength was not applied intentionally to the moment of expected leakage to enhance bladder support at the moment when most needed – a skill that needed to be taught? Or, was it that some other latent factor was unmeasured and accounted for the variance in response?

In this dissertation, the goal was to begin to address these questions, and precursor issues of both historical and current understandings of what explains the risks for SUI. It is argued that it is a mistake to attribute SUI only to lack of a woman's motivation to exercise the muscle, or only to an injury of the PVM. It is pretty clear that the urethral pressure surely must be taken into consideration as a first line of defense in holding back urine under situations of IAP rise. Putting the urethral pressure at the core of the question reframes the history, and raises a different question. Instead of asking can the PVM function be improved with strengthening exercises, the question in this dissertation is: does loss of PVM function due to PVM tear impinge on a woman's ability to optimize her urethral pressure at a moment of need?

Thus, the overarching purpose of this dissertation was to find the relationship between functional and non-functional (torn) PVM and urethral closure pressure (UCP) among postpartum women, but to do so issues of measurement had to be addressed first. The major findings of the dissertation are the following according to each specific aim listed here:

Aim 1: To review a variety of instruments used for assessing PVM structure and function.

Aim 2: To estimate the odds of MRI-documented PVM tear identified using index finger palpatory assessment for identifying likelihood of MRI confirmed PVM tear in primiparous women recovering from a vaginal delivery at high risk for PVM tear.

Aim 3: To investigate in the women described in Aim 2 the relationship between MRI-documented PVM tears and UCP measured with the woman at rest and during attempt at volitional pelvic muscle contraction.

Aim 1: To review a variety of instruments used for assessing PVM structure and function.

The history of the development of the instruments for assessing PVM for both structure and function indicates that the PVM plays an important role in SUI. Across nearly three-quarters of century, minimal 17 methods have been developed for assessing the PVM status (chronologically, index finger palpatory assessment for PVM tear [1943], perineometer [1948], electromyography (needle and surface EMGs) [1959], circumvaginal muscle grading scale [1986], sagittal dynamic ultrasound [1986], intravaginal balloon device [1986], Brink digital exam [1989], modified Oxford scale [1994], Segovia [1996], quantified standing stress paper towel test [1998], magnetic resonance imaging (MRI) [1999], two-billed instrumented speculum [2002], Dumoulin instrumented speculum [2003], Verelst speculum [2004], 3D or 4D ultrasound [2004], and one-billed speculum [2014]). The history of development of the instruments shows that PVM strength has been the focus for decades and then PVM tear becomes the favorite in this field of SUI in the last approximately 15 years. This indicates that the PVM is believed to have an important role for SUI. Although how the PVM influences SUI is still unclear, people have been working on the development of the methods for assessing PVM for a very long time.

Key Finding: Among measures of PVM structure, MRI is the most valid measure for PVM tear while index finger palpatory assessment for PVM tear has long history and is the most accessible measure. MRI provides visible sense by using imaging to show the precise location and extent of PVM tears. MRI has good and high reliability and high validity for measuring PVM tears. It can demonstrate the requirement of reproducibility in the scientific research setting. On the other hand, index finger palpatory assessment is the earliest technique to assess abnormalities of the PVM after vaginal birth prior to that MRI was developed. The abnormalities of the PVM were initially called atrophy or relaxation but without confirmatory evidence attainable now from modern high technology and rigorous study design to confirm it. The palpatory assessment is valuable to use for the purpose of clinical screening for tear. Similarly to other subjective measures (Brink digital exam and modified Oxford scale) that rely on fingers, the palpatory assessment also relies on the examiner's experience to quantify the degree of structural muscle loss, with both partial and complete tears possible. With its limited reliability, repeating palpatory assessment cannot be guaranteed, which raises a caution for research purposes or definitive diagnostic needs clinically. It could, however, be the best screening indicator of PVM tear in the routine gynecological clinic since it is simple, easy, cost-efficient, and highly accessible. 3D/4D ultrasound is a more sophisticated measure for estimating numbers of women with PVM tear. 3D/4D ultrasound provides imaging of the PVM, but relative reliability and validity as compared to MRI is yet to be definitively determined. Ultrasound has the advantage of relative lower cost and accessibility compared with MRI.

The quantified standing stress paper towel test is unique in providing the only measure of PVM function in terms of its direct relationship to the reduction of urine leakage when conducted under two condition: first in coughing without volitionally contracting the pelvic

muscle and repeated under same coughing effort but with volitionally contracting the pelvic muscle. As such, it is an indirect indicator of possible PVM structural and functional capability. The quantified standing stress paper towel test has the advantage of giving immediate feedback to both the clinician and patient of whether a woman who leaks when she coughs can reduce that leakage with a pelvic muscle contraction performed simultaneous with the cough. It is simple, quick, and nearly cost-free.

Among measures of PVM function, the one-billed speculum is the most valid measure (assessed as force in units of Newtons), while Brink digital exam and modified Oxford scale are the most common instruments for assessing PVM strength subjectively.

Most device measures assess PVM function through measuring contractile ability of PVM during a voluntary pelvic muscle contraction. The PVM is connected with the adductor, gluteal, and abdominal muscles by the common fascias, measurements of vaginal closure during the pelvic muscle contraction may involve the coactivation of these muscles (Burgio, Robinson, & Engel, 1986). Moreover, abdominal contraction is a normal response when the pelvic muscles contract (Sapsford et al., 2001). Based on our knowledge, only one-billed speculum minimizes the involvement of IAP by dividing the upper bill in two parts, while other devices including perineometer, balloon device, and other forms of speculums do not. They receive all directions of pressure from contraction of the pelvic muscles, abdominal muscle, adductor, and gluteal muscles. Therefore, they could not differentiate pressure from the pelvic muscles apart from pressure from other muscles contracting. EMG recorded the activity from perineal muscles other than the PVM, without differentiation of the activity from gluteal and adductor muscles. Therefore, device measures (perineometer, intravaginal balloon device, Segovia, two-billed instrumented speculum, Dumoulin instrumented speculum, Verelst speculum) without

minimizing involvement of other muscles are recommended to be abandoned for use in assessing PVM function, although accessibility of the one-billed speculum is a limiting factor.

Other than the objective device measures, people often choose finger placements to measure PVM function. Brink digital exam and modified Oxford scale are the most common finger placements for assessing PVM function. The PVM function is assessed through quantifying the degree of pressure during a pelvic muscle contraction that is exerted by women on examiners fingers. Finger placements can be completed just need of two fingers. The reason that they are often chosen is they are simple, easy, less invasive, and accessible. However, finger placements rely on the examiner's experience. They score PVM function subjectively and have limited reliability (Frawley, Galea, Phillips, Sherburn, & Bø, 2006) and their reproducibility for scientific purpose is not guaranteed. They have been suggested to use for clinical purpose and limited use for scientific purpose (Bø & Finckenhagen, 2001). Therefore, Brink digital exam and modified Oxford scale are best for screen measures for PVM function in clinical setting.

Both one-billed speculum and finger placements provide the results to show the degree of PVM function that women have while another objective measure of PVM function using the paper towel test without and with pelvic muscle contraction can give immediate result of the effect of both urethral striated muscle function and PVM function on decreasing volume of urine lost during the condition of volitional cough. Sagittal dynamic ultrasound measures of PVM function can be done through viewing real time bladder neck lift (an indicator of PVM function) during a volitional pelvic muscle contraction, and in contrast to bladder neck descent indicative of IAP rise, as occurs with straining down. Sagittal dynamic ultrasound is a relative simple objective measure for PVM function or lack of function clinically.

Key Finding: This review recommends assessment of the PVM should include both its structure and function characteristics, especially for the purpose of evaluating Kegel exercises treatment of SUI. This review suggests that for better understanding the treatment of SUI, measuring PVM tear status is essential. Among women in this dissertation, the severity of PVM tear related to the reduction of the vaginal closure force measured using one-billed speculum during a pelvic muscle contraction that was reported elsewhere (Miller et al., 2015). Based on our knowledge, to date no intervention study on SUI assesses the relationship of the PVM tear status to strength change with Kegel exercises. Moreover, most intervention studies heavily rely on an outcome of strength improvement to evaluate the effectiveness of Kegel exercises for SUI, rather than reporting degree of statistical correlation between strength improvement and SUI reduction.

Aim 2: To estimate the odds of MRI-documented PVM tear identified using index finger palpatory assessment for identifying likelihood of MRI confirmed PVM tear in primiparous women recovering from a vaginal delivery at high risk for PVM tear.

Key Finding: Index finger palpatory assessment could be the initial examination for assessing PVM tear. The technique of index finger palpatory assessment was already being used, though without widespread popularity, long before the high tech tests such as ultrasound and MRI were developed. The prevalence of abnormalities of the PVM after vaginal birth was 20% identified by the palpatory assessment (Gainey, 1943 & 1955), which is consistent with estimates of prevalence made today by MRI (DeLancey et al., 2003) and ultrasound (Dietz & Steensma, 2006). Index finger palpatory assessment is a subjective measure and without confirmed reliability and validity. Findings from review Chapter (Chapter 1) suggests that examiners can learn the technique with very little training, but having a comparative of actual

MRI results might offer improvement in examiner detection by palpatory assessment. With the confirmation of PVM tear tests, such as MRI, expert examiners may be able to master this technique to refined levels, especially when used in conjunction with obstetric history known to cause tear. Our findings provide evidence that women who were identified by the palpatory assessment as having PVM tear had high likelihood of having tear confirmed on MRI. Hence, evidence from the findings presented in Chapter 4 added support in the literature that a gross level of identification by index finger palpatory assessment may have a place in today's clinical environment.

Although our study did not study women with pelvic organ prolapse, it is known that PVM tear increases risk in developing prolapse and is associated with the recurrent prolapse (Notten, Vergeldt, van Kuijk, Weemhoff, & Roovers, 2017). In addition, over 50% of women with prolapse had PVM tear (DeLancey et al., 2007; Oversand, Staff, Sandvik, Volløyhaug, & Svenningsen, 2017). Thus, to identify for PVM tear is important for women who are at risk for SUI, but who may also be at risk long term for prolapse. Early identifying for PVM tear might lead to improved prevention for both of these pelvic floor disorders. And, prevention would have enormous impact on quality of care and reduction in health-related costs of these highly common disorders.

Aim 3: To investigate in the women described in Aim 2 the relationship between MRI-documented PVM tears and UCP both at rest and during a volitional pelvic muscle contraction, as measured by what we have called resting and contracting UCP.

Key Finding: PVM tears reduce the ability to deliberately and advantageously optimize the UCP with a momentary pelvic muscle contraction. Over the past 20 years, evidence of a childbirth-related “defect” of the PVM accumulated, as observed by MRI and

3D/4D ultrasound, and as early as 1943 by palpatory assessment. Only recently has the “defect” been shown to be an PVM tear (not predominantly a neurologic or compression injury), and the tear is chronic with no known physiologic nor surgical repair (Miller et al., 2015). This dissertation extends that work to show that this unrecoverable tear affects perhaps the most critical bodily defense against stress incontinence – optimizing UCP. We found that the group of women with PVM tear had lower contracting UCP than those who did not have PVM tear. This finding is consistent with the previous study that reported a negative relationship between the degree of increased UCP during a pelvic muscle contraction and the PVM tear (Dietz & Shek, 2012). But, our finding is different from Brincat et al.’s (2011) result of no significant difference in contracting UCP between women with PVM tear and women without PVM tear. This may be because Brincat et al. had only 18% of women with PVM tear, while we had over 30% of women with PVM tear. In addition, Brincat et al. found 70% of the women with tear had SUI, lending partial support to the theory that loss of ability to volitionally optimize UCP at the moment of increased IAP is a risk factor for SUI. A systematic review found that the increase in contracting UCP varies widely in seven studies (Zunieta, Carr, Drake, & Bø, 2016). All of these studies may include women who have possible tear on PVM. None of the seven studies (Benvenuti et al., 1987; Elser et al., 1999; Kuo, 2003; Moreno et al., 2004; Teleman et al., 2003; Wilson, Al Samarrai, Deakin, Kolbe, & Brown, 1987; Zahariou, Karamouti, Georgantzis, & Papaioannou, 2008) assessed for PVM tear. The PVM tear could be the potential factor for no significant increase from resting UCP to contracting UCP observed (Elser et al., 1999; Kuo, 2003; Moreno et al., 2004; Wilson et al., 1987; Zahariou et al., 2008).

Most previous studies focus on resting UCP other than contracting UCP (Bø, Talseth, & Holme, 1999; Schick, Tessier, Bertrand, Dupont, & Jolivet-Tremblay, 2003). They tried to find

the relationship between the resting UCP and SUI or whether programs of Kegel exercises increase resting UCP or the relationship between the resting UCP and urethral hypermobility. However, resting UCP failed to be a valid diagnostic test for SUI (Kapoor, Housami, White, Swithinbank, & Drake, 2012). SUI occurs during an IAP rise due to a stressor activity such as cough and sneeze, as the bladder responds to the increased IAP transferred to it. In order to prevent SUI, an increase in UCP (by a volitional pelvic muscle contraction, contracting UCP) is required at that moment of an IAP rise if the margin of continence (Kim, Ashton-Miller, Strohbehn, DeLancey, & Schultz, 1997) is to be increased throughout the moment of IAP increase. The increased UCP must be maintained substantially higher than the bladder pressure to reduce risk at that moment for leakage. Therefore, studies on the contracting UCP are essential for understanding its relationship to SUI, and this readily learned technique of momentary optimization taught to those able to contract. By contrast, a volitional though inadvertent “strain” from trying to contract the pelvic muscle when in reality it is torn, would be a counter-indicated maneuver that a woman may inadvertently use if she is unaware of her torn muscle and trying to follow instructions to “Kegel when you cough”.

Key Finding: We also found no difference in resting UCP between women with PVM tear and those who did not have tear. PVM tear did not influence the resting UCP, which is consistent with Brincat et al.’s (2011) finding as mentioned above. Our finding also extends the findings in Morgan, Cardoza, Guire, Fenner, and DeLancey (2010). Although Morgan et al. (2010) found that mean resting UCP trends lower in women with major PVM tear; it did not reach a statistically significant level. However, our finding is different from Hegde, Aguilar, and Davila (2017). Hegde et al. (2017) found significantly lower resting UCP in women with major PVM tear, but they interpreted the finding as due to age since the women with major

PVM tear were older compared to women without or only minor PVM tear in their study. This explanation seems reasonable since muscle fibers do decrease with age (Koelble, Strassegger, Riss, & Gruber, 1989, Schick et al., 2003), and particularly urethral striated muscle fiber (Perucchini, DeLancey, Ashton-Miller, Galecki, & Schaer, 2002). It is logical but not completely clear that the difference in the resting UCP is what causes de novo SUI with childbirth. It seems logical that additional factors are at play since resting UCP pre- and post-birth have not been shown to change. Variations in findings regarding PVM tear and resting UCP may be because women in the previous studies had either pelvic organ prolapse (Morgan et al., 2010) or SUI (Hegde et al., 2017) on entry into the study. Measurement issues regarding the urethral pressure profile for measuring resting UCP could also be questioned. The technique was developed and well documented in the 1960s (Enhorning, 1961), so it is dated. Nevertheless, while not thoroughly examined in this dissertation, the urethral pressure profile has stood well the test of time as the gold standard for estimating urethral adequacy.

Although the relationship between SUI, PVM and UCP is still unclear, for 75 years of development of instruments, the PVM is believed playing a critical role on SUI. This could explain why Kegel exercises strengthening the PVM is recommended as the first-line treatment for SUI. This dissertation found that the torn muscle along with resting UCP explained 42% of the variation in contracting UCP for young postpartum women. This finding indicates that women with torn muscle and low resting UCP could not have higher contracting UCP compared to women having high resting UCP and, being without PVM tear, have the option to optimize that UCP volitionally as readiness for an IAP rise that risks leakage. In addition, DeLancey et al. (2008) found that resting UCP was lower in women with SUI than continent women, but the PVM strength was not difference among women in their study. According to the mechanism of

stress continence that is the urethral pressure must be greater than bladder pressure both at rest and during activities (Ashton-Miller & DeLancey, 2007), women with lower UCP are at high risk for urine loss during a stress activity. Redirection of the treatment from strengthening the muscle to the learned skill of momentary optimization of UCP during an IAP rise could improve the treatment of SUI and reduce the prevalence of SUI among women. A treatment of such a timed volitional pelvic muscle contraction, coined the Knack skill (Miller, Ashton-Miller, & DeLancey, 1998) (Appendix A) has been shown repeatedly to be immediately effective in reducing volume of urine loss that occurs with coughing (Miller, Sampsel, Ashton-Miller, Son, DeLancey, 2008). And, while it remains unknown whether there is a certain level of innate PVM strength required, it is clear from the results in this dissertation that PVM attachment to its origin is needed for maximal effectiveness in the momentary increase in UCP that the Knack skill is founded on. As long as a woman does not have an PVM tear, there is potential from well-established pelvic muscle training programs to gain strength. Still, if the main purpose of strength is to use that strength for optimizing the contracting UCP, then a first step is to see if any particular woman has adequate strength to do so. Chapter 2 reveals that the quantified standing paper towel test is a no-cost, less than 5 minute test to do so. For women with weak PVM who are unsuccessful in reducing volume leaked by using the Knack skill, it is logical to think about a strengthening program. However, this dissertation highlights that there has been much confusion in the literature about “weakness” when in reality that “weakness” is a torn PVM, unamenable to either Kegel exercises or use in the Knack skill. It is only fair to women to find out if these interventions have essentially zero chance for success in that particular woman, despite evidence that shows mean score group success. In today’s era of personalized medicine, appropriate selection criteria for interventions, based on full diagnostic assessment, is a must for

both the woman's quality of life, and for health care cost control. Six months of physical therapy cost extends well beyond the cost of an MRI to confirm PVM tear, and can be demoralizing to a woman who despite much time and motivation is set up for failure.

In summary of findings from this dissertation, a PVM tear decreases the ability to increase contracting UCP during a voluntary pelvic muscle contraction. Women with PVM tear may not have pelvic disorder symptoms in the short term, but identifying this high-risk factor early offers the chance for developing interventions with promise for reducing or delaying symptom onset. For postpartum women, a simple screening test of palpatory assessment for potential PVM tear is arguably needed for incorporation into a regular gynecological examination in the clinical setting, especially when there is also accompanying risk factors from obstetric history. Early findings of a torn PVM, early prevention of SUI or pelvic organ prolapse will improve health-related quality of life for women. Although our study did not explore how to repair the tear, it will encourage future researches to explore it. It is also worthy to explore the understanding of the birth-related tear and prevention of the tear during vaginal birth.

For decades, we have worked under the assumption that PVM “weakness” is the main contributor for SUI, but recognizing that “weakness” and PVM tear might be essentially the same in a majority of women. This lack of recognition is understandable on examination of the thorny persistent issues of finding an objective measure of PVM function or “strength” that does not confuse IAP and pelvic muscle contraction within the same measure. Much can be learned from the history of persistent efforts to development these numerous methods, but each with its own failings. Since evaluation of treatments targeting strengthening of the PVM, which are abundant across the literature, were dependent on outcome measures showing strength change, (Oliveira, Ferreira, Azevedo, Firmino-Machado, & Santos, 2017), perhaps the most interesting

finding is the near complete lack of evidence (1 study out of hundreds) showing that strength change correlates with a reduction of incontinence episodes within the same time frame. None of literature offers a cutpoint for how much PVM strength is needed to keep continence. Although some studies reported that women with SUI have low PVM strength compared to those who do not have SUI, they do not give the explanation of how to explain that some women without SUI still have low PVM strength. This phenomenon may be explained by the theory of the urethral closure. Simply, leakage will be stop by closing the urethra. *Most scholars in the field believe that the PVM strength is the main contributor of SUI. As a result of this dissertation, low contracting UCP may be the main matter for continence.*

Therefore, in discussions of the treatment according to the etiology of SUI, a controversial issue is whether to strengthen the PVM (for reflexive urethral support) or to improve the urethra closure (via volitional timed pelvic muscle contraction at the moment of expected IAP). While some people argue that strengthening the PVM through Kegel exercises is the main treatment for SUI, others contend that to keep the urethra closed is the main physiologic need. If the urethra could not be closed at the moment of leakage, urine loss will happen. Since there is no final answer for the etiology of SUI, for women with SUI have weak PVM (or is it an PVM tear?), Kegel exercises may be the first choice to increase the strength as long as the PVM is not torn. While for women with adequate PVM function, the Knack may be the better treatment option for them.

Some components of Kegel exercises and the Knack are similar, but not all (see Table 5.1). They are similar in that both involve pelvic muscle contraction, but they can be distinguished by the following. First, the Knack requires an awareness of when a woman will leak, but Kegel exercises purport to rely on reflex (Bø, 2004). Second, the Knack requires timing

of pelvic muscle squeezing with conditional increasing IAP during a stress activity in order to close urethra, while Kegel exercises require repetitive contractions to strengthen PVM as a set-aside activity apart from any IAP event with intent to increase PVM strength and sustainment of urethral stability. Therefore, their routines are different. The Knack is a one-time voluntary pelvic muscle contraction that does not require repetitive pelvic muscle contraction routine. However, since women who do the Knack can be successful only if they are alerted to its need at the precise moment of IAP rise, it may be helpful for them to practice this skill during voluntary coughs, as a readiness technique for when that surprise cough or sneeze occurs. Kegel exercises are repetitive pelvic muscle contractions that should be done as much as 30 times per day or more, and with expectation to be routinely practiced over time to maintain its effect. Various practice regimens related to Kegel exercises depend on training programs. In a typical Kegel exercises practice, for example, there is no emphasis on awareness of leakage for women. They will be required to contract pelvic muscles with a 5-second hold and a 10-second relaxation, followed by fifteen rapid contractions with a 2-second hold and a 4-second relaxation. This routine should be performed three times at two minutes interval, three times per day. Last but not the least, one challenge with Kegel exercises is compliance (Morkved, Schei, & Salvesen, 2007). The Knack has the advantage of no required practice routine and instead emphasizes the lifelong habit of never cough or sneeze again without an added volitional contraction of the pelvic muscles at the same time – for urethral support and maximally activating the urethral striated muscle for optimizing closure pressure. The concept of the Knack is more fully fleshed out in the Appendix.

Strengths and Limitations

To the best of our knowledge, there is no previous study on the relationship between torn PVM and contracting UCP for young postpartum women. Previous studies found that the torn PVM negatively related to the resting UCP in women with SUI (Hegde et al., 2017; Morgan et al., 2010). Since SUI occurs during an increasing IAP due to a stress activity, with an increased bladder pressure responds to the increased abdominal pressure. Thus, our study focuses on the increased UCP from a pelvic muscle contraction, the relationship between the torn PVM and contracting UCP. We found that the torn PVM reduced the ability to increase the UCP during the pelvic muscle contraction, which indicates that there is highly likelihood that the contracting UCP will be lower than the increased bladder pressure.

However, several limitations of the study need to be recognized. First, only young postpartum women who were at high risk for PVM tear during vaginal birth were tested in our study. Thus, our findings may not be generalized to other populations since the variation of age (aging muscle), obesity and other chronic diseases may influence the results. Although the PVM tear did not recover at one year after vaginal birth in these postpartum women, we cannot answer whether or not the tear will be recovered without treatment in long term. Second, we cannot test the relationship between the women with SUI and the UCPs. We cannot compare among those with torn PVM how difference of the UCP between women with SUI and those who do not have SUI. In addition, we cannot test whether women with torn muscle and SUI have the lowest resting and contracting UCP. These tests conducted in much larger samples may help to further understanding the relationship between PVM tear and SUI. Third, woman in our study received both Kegel exercises and the Knack for prevention of SUI. We do not know whether either or both of these interventions influenced the tear to be worse or better nor whether the ability of

increasing the UCP during a pelvic muscle contraction was influenced, since all of the women had these standard of care instructions.

Although our study has limitations, the strengths of our study show benefit for both research and clinical settings and provide strong evidence that the PVM tear contributes to the risk for SUI in women by impacting ability to optimize UCP. The group of women in our study reduces the variation of the data in the literature, and helps close the gaps from other studies limitations to offer more reliable findings. Moreover, a thorough, historical review of the methods to measure PVM structure and function provides a solid basis for choices in future research to abandon certain methods and begin to narrow the discrepancies across the literature that arises from disparate measures. As such, this work calls for a close review of prior research findings reported in the literature. Findings from this dissertation offers a model of rigorous designs for future studies for the PVM structural and functional characteristics that are true risk factors for SUI such that better prevention and treatment interventions can be developed and rigorously tested with appropriate outcomes.

Directions of Future Research

Future studies may focus on the women with SUI after vaginal birth to assess the association among PVM tear, SUI and UCPs, which will add literature of etiology of SUI. This will provide the evidence support for decision making of treatments. More longitudinal studies are needed to substantiate where there can be any recovery of the tear for women after vaginal birth from a short time to a long time period (from young to old, and across more vaginal births).

Our study found that each method has advantages and limitations. Some methods may be prioritized above others, and rationale is provided to the scientific community. Consensus should be sought. The one-billed speculum is evaluated by the criteria presented in this dissertation to be

the best precise and valid measure for PVM function in research setting, while finger placements are a logical proxy in clinical settings where one-billed speculum measures are at the moment unavailable for quick low-cost appraisal. MRI is the gold standard test that is the best measure for scientific purpose of grading PVM tear from none to subtle to less than 50%, equal to or greater than 50%, or complete tear. 3D/4D ultrasound technology is rapidly progressing, and provides an additional option, though with arguably lesser ability to grade partial tears. While index finger palpatory assessment combined with history of obstetric risk factors and possibly 2D sagittal dynamic ultrasound view of function are good proxies for quick clinical screen and possibly incorporation into large epidemiology studies.

Instruments purporting to measure PVM function with balloon and other similar mechanisms should be avoided when there cannot be reasonable assurance that artifact from IPA or other muscle coactivation is eliminated. Sagittal dynamic ultrasound (not requiring 3D nor 4D machine) offers a quick, non-invasive, modest for the woman view of whether she can “lift” the bladder on effort to contract the pelvic muscles, and if perhaps the most direct cost-effective tool for seeing and teaching about pelvic muscle contraction skill. In women with SUI, a quantified paper towel test that the woman performs during coughs first without intentionally contracting the pelvic muscle and then repeating coughs with intentionally contracting the pelvic muscle, provides immediate objective demonstration to both the woman and the examiner of whether this quick skill trick or Knack skill is worth immediate implementation.

Future study on development of instruments for assessing the PVM could learn from the advantages and limitations of the current instruments. Future studies on SUI should choose the best precise measures both PVM structure and function for assessment in both clinical and

scientific arenas. Again, consensus from the scientific community is needed so that the literature can move towards true metaanalysis potential.

It is worthy to expand the finding in this dissertation that torn PVM predicts poor volitional increase in UCP with attempt at pelvic muscle contraction, but testing this finding in a comparative study of women with and women without SUI may help us to know if the theory of urethra closure is the main contributor of SUI. To test PVM tear for women who have de novo SUI post childbirth but allowing for longer time from delivery to develop symptoms will provide evidence whether the PVM tear is a true risk factor of SUI, as compared to matched controls without PVM tear. Future studies also may focus on prevention of SUI or pelvic floor prolapse for women with PVM tear.

Recommendations for Clinical Practice

Our findings suggest that index finger palpatory assessment for estimating odds of tear could be a regular examination during postpartum follow-up to assess the PVM status for women who experienced vaginal birth and at high risk for the last vaginal birth. Trained and experienced practitioners can give the valuable results from palpating the PVM. Although our study only tests young postpartum women with known history of obstetric risk factors for tear, the palpatory assessment technique may be recommended as a regular gynecological examination for women with SUI. It is recommend to use palpatory assessment to screen PVM tear. If a PVM tear is suspected, the results of the assessment can be confirmed by a more precise and high tech test such as MRI, if needed for decision-making about treatments. For instance, the question is raised as to whether women with PVM tear should undergo pelvic muscle exercises. 3D/4D ultrasound could be a substitute screen test for PVM tear in clinic, and technological advances in ultrasound

should be watched closely. Nevertheless, there is not definitive data to suggest that MRI and 3D/4D ultrasound have same findings.

For quick clinical assessment of PVM function, the Brink digital exam and modified Oxford scale remain useful. They can be easily completed during a clinical visit. Quantified standing stress paper towel test is recommended to evaluate whether stress incontinence women can reduce leakage by a volitional pelvic muscle contraction. Sagittal dynamic ultrasound gives quick assessment of PVM function from a real time bladder neck mobility (lift with pelvic muscle contraction) perspective, though in women with excellent support or poor ability to relax the PVM, it may be difficult to see much additional lift and this should not be misconstrued as evidence of PVM tear.

Conclusions

1. In summary, one-billed speculum and MRI are the most precise and reliable instruments for assessing PVM. PVM functional measures must be complemented by structural measures to adequate evaluation and treatment of SUI.
2. A simple, accessible, cost-efficient method index finger palpatory assessment for estimating odds of PVM tear could be a regular gynecological examination during postpartum clinical follow up. The torn PVM identified by the palpatory assessment could be confirmed by high tech test such as MRI.
3. Torn PVM decreases the ability to increase the contracting UCP, which indicates that women with torn PVM are highly likely over time to have loss of urine during an IAP rise.
4. Since torn PVM did not recover in one year after vaginal birth (Miller et al., 2015) and the prevalence of SUI grows with advancing age (Rortveit, Daltveit, Hannestad, & Hunskaar, 2003), older women who experienced vaginal birth and with SUI, it is worth to assess their

PVM status before applying Kegel exercises or even the lesser intensity intervention of Knack for incontinence, without proven results in short order.

Table 5.1 The Knack for Stress Urinary Incontinence Versus Kegel Exercises

		The Knack	Kegel Exercises
Similarity	Pelvic muscle contraction	Yes	Yes
	Intervention for stress urinary incontinence	Yes	Yes
Difference	Awareness of potential for urine loss	Yes	No
	Type of pelvic muscle contraction	A timed pelvic muscle contraction	Repetitive pelvic muscle contractions
	Target result from contraction	Urethral closure	Increased pubovisceral muscle strength
	Practice routine	One-time contraction, no routine practice required	Requires practice
	Ease of adherence	Yes	No

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APPENDIX A

The Knack for Stress Urinary Incontinence Suppression: A Concept Analysis

Abstract

Background: Stress urinary incontinence is the common complaint of urine loss among women who experience urine loss. Pelvic floor muscle training is recommended as the first-line treatment that include pelvic floor muscle exercises known as Kegel exercises that are time consuming and lack of long term effectiveness.

Purpose: The purpose of the concept analysis is to provide a well-defined definition of the Knack and assist clinicians to better understand the concept.

Methods: The method by Walker and Avant was used for this concept analysis.

Discussion: The Knack is a distinct strategy from pelvic floor muscle training to treat stress urinary incontinence.

Conclusion: The Knack may be an effective intervention for women with stress urinary incontinence. To perform the Knack requires awareness of triggers of leakage, skill and timing to perform a pelvic floor muscle contraction, and engage this method in life.

Keywords: Knack, precontraction, pelvic floor muscle training, Kegel exercises, stress urinary incontinence

Introduction

Urinary incontinence (UI) is a common complaint among women across all ages with global prevalence estimates ranging from 5% to 69% (Buckley & Lapitan, 2010). According to the International Continence Society and the International Urogynecological Association, UI is defined as “complaint of any involuntary leakage of urine” (Abrams et al., 2010; Haylen et al., 2010). There are many types of UI including stress UI (SUI), urge UI, and mixed UI (with symptoms of both SUI and urge UI). Among women with UI, almost half reported symptoms of SUI, which is defined as “involuntary leakage with effort or physical exertion, sneezing, or coughing” (Bø & Herbert, 2013; Hampel et al., 2004; Reynolds, Dmochowski, & Penson, 2011).

Although several treatments (e.g. medicines, devices, and surgeries) are available for SUI, the recommended first line of treatment is non-invasive: pelvic floor muscle training, consisting of pelvic muscle exercises (PME), or Kegel exercises which were introduced 60 years ago. However, PME has low long-term adherence. Even when women know how to effectively practice PME, studies have shown that it is hard for them to follow the exercise regimen (Agur, Steggle, Waterfield, & Freeman, 2008; Albers-Heitner, Berghmans, Nieman, Lagro-Janssen, & Winkens, 2008; Dumoulin, Glazener, & Jenkinson, 2011). Although it is unclear why PME is not generally effective long term, these low adherence rates may contribute. To this end, the Knack for SUI suppression was introduced almost twenty years ago (Miller, Ashton-Miller, & DeLancey, 1998a). The Knack involves elements of many of the PME treatment programs, but differs in that it offers more precise instruction.

Therefore, the purpose of this study is to conduct a formal concept analysis to clarify/describe the Knack for SUI suppression as a well-defined and distinct form of pelvic floor muscle training. We use the concept analysis method by Walker and Avant (2011) to guide this

analysis of the concept of the Knack for SUI suppression. By following this approach, this concept analysis will provide a rigorous definition for the Knack, and offer recommendations for better patient care and medicine as well as propose directions for future research.

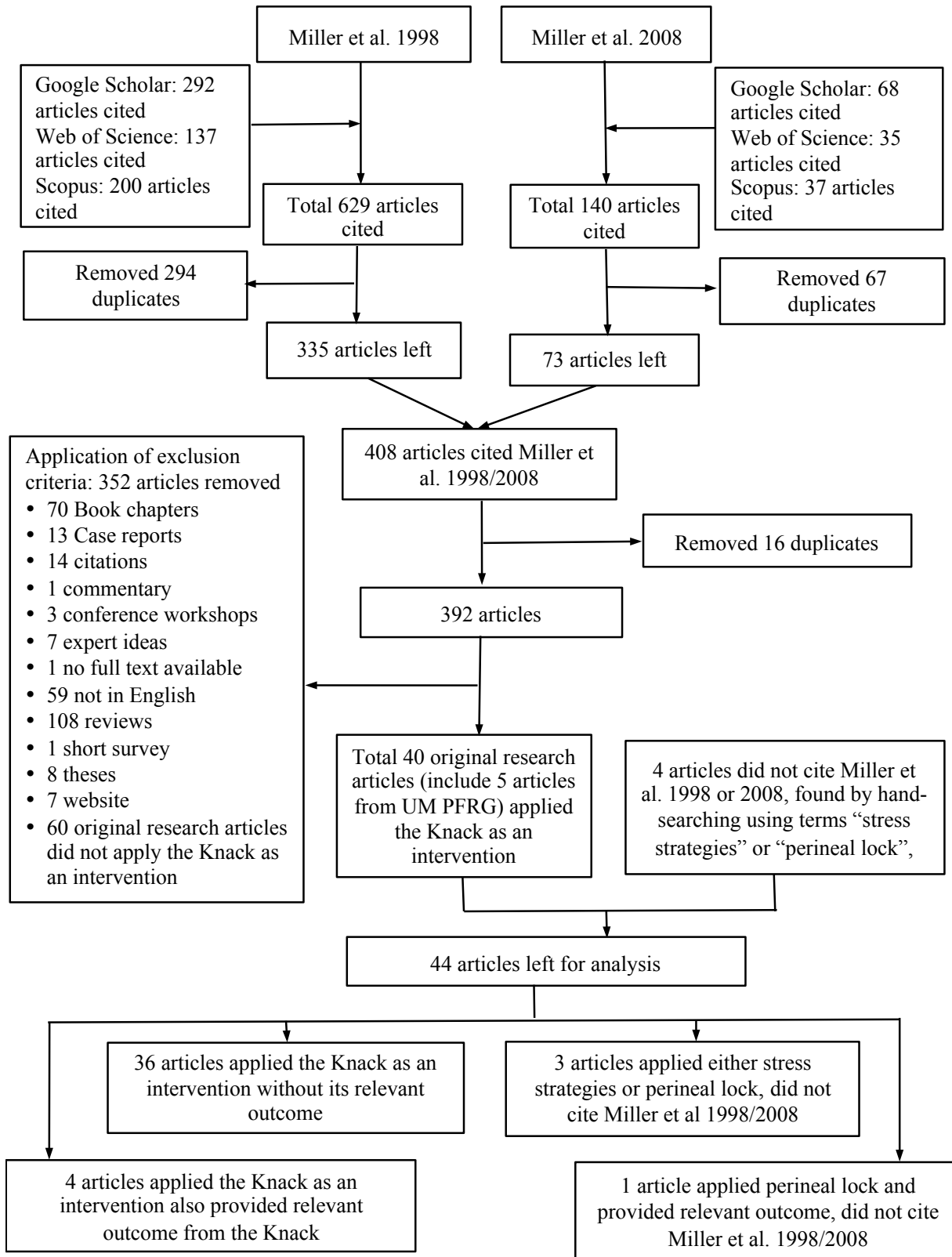
Methods

The Michigan team of Pelvic Floor Research Group introduced the term of the Knack in the manuscript published in 1998 (Miller et al., 1998a), and confirmed the immediate effect of the Knack for women with SUI from the later article (Miller, Sampsel, Ashton-Miller, Hong, & DeLancey, 2008). A search of the published literature that cited either Miller et al. 1998a or Miller et al. 2008 was conducted, using the following databases: Google Scholar, Web of Science and Scopus. Miller et al. 1998a has been cited by a total of 335 publications after removed 294 duplicate publications (see figure 1). Miller et al. 2008 has been cited by a total of 73 articles after removed 67 duplicate publications. A total of 408 articles were identified that have cited Miller et al. 1998/2008. A further analysis of the publications resulted in 368 excluded because they were duplicate publications (16), conference workshops (3), expert idea (7), citations (14), commentaries (1), book chapters (70), theses (8), case reports (13), not written in English (59), no full text available (1), reviews (108), short survey (1), website (7), original research articles without applying the Knack as an intervention (60). This left a total of 40 original research articles that have applied the Knack as an intervention and were published in English with full text available. In addition, 4 articles applied interventions called either stress strategies or perineal lock that had the same process and effectiveness as the Knack, but did not cite either Miller et al. 1998 or 2008, were identified by hand searching. A total of 44 articles were analyzed for this concept analysis. Of the 44 articles, 36 articles only applied the Knack as an intervention. Four articles applied the Knack, also provided its relevant outcomes. Three

articles applied either stress strategies or perineal lock without providing their relevant outcomes. One articles provided outcome from perineal lock.

A search of the published literature was also conducted from January 1948 to December 2017, using the following databases: CINAHL, Embase, Ovid Medline, ProQuest, PsycINFO, PubMed, Scopus, and Web of Science. The following terms that were used to describe the Knack were used: Knack, stress strategy, perineal lock, perineal blockage, quick Kegel, single Kegel, pre-contraction, perineal co-contraction, counterbracing, bracing, pelvic clutch, Kegel when you cough, squeeze when you sneeze, muscle clenching, and voluntary pelvic muscle contraction in response to a specific situation. Each of these terms was paired with urinary incontinence or stress incontinence. This approach initially resulted in over 3200 articles. After duplicates were removed, there were still over 2700 articles left. We found this approach was too broad to search the related information for the Knack. We skipped the articles that many of them were not even talked about the prevention and treatment for urinary incontinence in women. Based on our knowledge, currently, to find articles that cited Miller's work will be the best option to find the information that related to the Knack about the prevention and treatment of stress urinary incontinence.

Figure A.1 Flowchart of Literature Search



Note. UM PFRG = University of Michigan Pelvic Floor Research Group.

Findings

Definition

According to the Merriam-Webster (2015) online dictionary, a knack is defined as “a talent, a skill, and a clever way to do something; a special ready capacity that is hard to analyze or teach.” The essence of a knack is that it is a most efficacious way to solve problems. Drawing from this definition, the Knack was created to begin to solve urine loss of women not being able to adhere to PME programs, while at the same time improving symptoms of SUI (Miller, Ashton-Miller, & DeLancey, 1998a). The Knack is a quick, single pelvic muscle contraction (Kegel exercise) that is performed at the onset of increasing intra-abdominal pressure during an activity (e.g. sneezing or coughing) that would traditionally elicit leakage.

Uses of Concept in the Literature

The Knack has been reported as a successful intervention component in many pelvic muscle training programs for women with SUI (Balmforth, Mantle, Bidmead, & Cardozo, 2006; Cammu, Van Nysten, Blockeel, Kaufman, & Amy, 2004; Junginger, Seibt, & Baessler, 2014; Rosqvist, Aukee, Kallinen, & Rantanen, 2008). For example, a ten-year follow-up research showed that long-term effect of PME combined with the Knack was almost half (53%) success that was defined as no leakage or much improved (e.g. occasional wetness); the Knack appeared to be responsible for most of the success (Cammu, Van Nysten, & Amy, 2000) (see Table 1). In addition, Bø, Kvarstein, & Nygaard, 2005 and Miller et al. 2008 showed that the Knack provided a partial cause of the success in their studies. An additional study found that the Knack reduced leakage in UI women just over 73% during a medium cough and nearly 100% during a deep cough, compared women who used and those who did not use it. In a later study, the Knack was confirmed as a specific minimalist intervention for SUI in women (Miller et al., 2008). Four

original research articles that cited Miller et al 1998 or 2008 provided the results that were related to the Knack focused on its effectiveness and how to improve to performing it (Table 1). Junginger and colleagues (2014) found 71% of women reported less SUI symptoms and more patient satisfaction with the Knack. Moreover, Rosquist and colleagues (2008) reported high compliance of performing the Knack that women practiced it almost every day during their study period. In addition, current researches reported that pelvic floor muscle exercises may improve skill of performing the Knack (Bertotto et al. 2017) and cognitive rehabilitation may improve the timing of performing the Knack (Villot et al. 2016).

A review of literature on the Knack shows that the concept has existed under a variety of names such as “stress strategy” (Borello-France et al., 2013; Burgio et al., 2002; Goode et al., 2003), “perineal lock” (Cammu, et al., 2000 & 2004), “perineal blockage” (Bourcier, Juras, & Jacquetin, 1999), “quick Kegel” (Kincade, Dougherty, Carlson, Hunter, & Busby-Whitehead, 2007), “single Kegel,” “pre-contraction” (Junginger et al. 2014), “perineal co-contraction,” or “counterbracing” (Hung, Hsiao, Chih, Lin, & Tsauo, 2011). While these descriptions and the research that accompanies them are informative, they do not indicate the specific moments that women need to begin and end the pelvic muscle contraction, which means that although women may know how to contract the muscle, if they don’t know when, the action will be rendered ineffective. To address this problem, the Knack is described in this concept analysis in detail.

Table A.1 Research Articles Provide Results Related the Knack

Author, year, and title	Participants	Aim	If cited Miller et al. 1998a or 2008	Term of the Knack	Interventions from Method section	Result
Cammu et al., 2000	45 women with SUI who had undergone PFM training 10 years earlier	To determine the outcome of 10 years after PFM exercises for SUI	None	Perineal lock (an active voluntary PFM contraction before a sudden intra-abdominal pressure rise)	PFM exercises and perineal lock	<ul style="list-style-type: none"> • 24 of 45 (53%) had success from physiotherapy. • 16 of the 24 women remained satisfied with their UI • 2 of the 24 women had undergone surgery • 21 of 45 (47%) failed. • 5 of the 21 women had improved symptoms • 13 of the 21 had undergone surgery • Perianal lock appeared to be responsible for most of the success
Rosqvist et al., 2008	11 women with self-report UI	To pilot test the feasibility and acceptability and follow the compliance of the 56 days pelvic floor muscle and bladder training programme	Both	The Knack	Strengthening exercise daily at least for the first 14 days (in order to strengthen the muscles so that they could be used in the Knack) and the Knack daily for 8 weeks; and individualized bladder training	<ul style="list-style-type: none"> • High compliance: 10 of 11 participants did the strengthening exercise for 13 or 14 days. One did the exercise for 10 days. • All participants practiced the Knack at least 54 days. • Lengthened void interval for 3 participants • Reduced the number of involuntary urine leakages (0.88 ± 1.02 to 0.30 ± 0.59) • Decreased perceived negative impact of UI on life ($30.1\% \pm 17.5$ to $11.6\% \pm 17.1$)
Junginger et al., 2014	55 women included 9 with SUI, 9 with overactive bladder symptoms, and 37 with mixed symptoms	To evaluate the effectiveness of a pelvic floor rehabilitation program consisting of pelvic floor and transverse abdominal muscle precontraction, coordination training and sustained submaximal contractions, SUI and overactive bladder symptoms	Both	Precontraction	A bladder neck effective contraction, precontraction before coughing, co-contraction of the transverse abdominal muscle, and integration of the precontractions into daily life; and behavioral advice	<ul style="list-style-type: none"> • 71% (39/55) routinely did precontraction before coughing or lifting. And they more likely reported fewer SUI symptoms. • Significant correlation between frequency of precontraction and patient satisfaction with treatment. • Of 46 women with SUI (pure or mixed), 31 (67%) were cured or improved. • 36 of 46 (78%) women with overactive bladder symptoms ceased or improved. • 91% (50 of 55) reported subjective improvement of bladder function.

Author, year, and title	Participants	Aim	If cited Miller et al. 1998a or 2008	Term of the Knack	Interventions from Method section	Result
Villot et al. 2016	39 healthy women	To evaluate whether cognitive rehabilitation (dual-task method) could prevent the effect of a mental distraction task on the reaction time of PFM contraction.	Both	Voluntary PFM contraction	Dual task cognitive (an attention test, the n-back test, and PFM exercises) rehabilitation	<ul style="list-style-type: none"> Improved the timing of performing the voluntary PFM contraction Decreased reaction time between stimulus and external anal sphincter contraction during voluntary PFM contraction, with distraction task, from 461.11 ms to 290.74 ms (ratio 0.63, $p > 0.05$)
Bertotto et al., 2017	49 postmenopausal women with SUI	To compare the efficacy of PFM exercises with and without electromyographic biofeedback (BF) in increasing muscle strength, improving myoelectric activity and precontraction and quality of life in postmenopausal women with SUI	Miller et al. 1998a	precontraction	Eight twice-weekly, 20-min one-on-one sessions	<ul style="list-style-type: none"> Increase muscle strength, precontraction during coughing ($p < 0.0001$), maximum voluntary contraction, duration of endurance contraction, ICIQ-SF scores. PFM exercises +BF was associated with significantly superior improvement of the above outcomes.

Note. SUI = stress urinary incontinence; PFM = pelvic floor muscle; ICIQ-SF = International Consultation on Incontinence Questionnaire short form

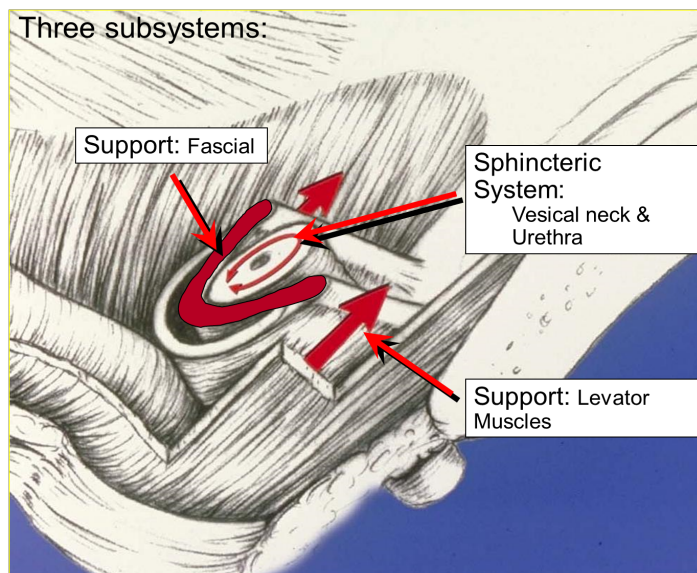
Mechanisms of Continence and the Knack

In healthy individuals, the bladder retains urine when urethral closure pressure is greater than bladder pressure (Ashton-Miller & DeLancey, 2007). The continence mechanism is a complex system that consists of three subsystems (Ashton-Miller, Howard, & DeLancey; 2001, Cundiff, 2004; DeLancey, 1997) (see Figure 2). The urethral sphincter closure system emphasizes functional etiology and consists of the urethral external sphincter (urethral striated muscle), urethral internal sphincter (urethral smooth muscle) and vascular elements within the submucosa (Enhorning, 1961; Miller, Ashton-Miller, & DeLancey, 1998a). The other two subsystems focus on anatomic etiology. They are the urethral support systems and they support urethral stability and hypermobility (Bø & Herbert, 2013; Kegel, 1948; Pirpiris, Shek, & Dietz, 2010). The urethral support systems include levator ani muscles/pelvic muscles and fasciae to maintain the urethra above the attachment of pubourethral ligaments to the pubic bones during rest. Together, these subsystems maintain the resting urethral closure pressure. During a stress event (such as lifting, laughing, jumping, sneezing, or coughing (Cannon & Damaser, 2004)), intra-abdominal pressure is raised, resulting an increase in bladder pressure. If the urethral sphincters are damaged, they will be unable to maintain a urethral pressure higher than the increased bladder pressure, leading to a failure to keep the vesical neck and urethra closed which will result in urine leakage. On the other hand, poor pelvic muscle support will cause urethra hypermobility, meaning the urethra will fall below the attachment of pubourethral ligaments to the pubic bone, also resulting in urine leakage.

Given that each subsystem could account for leakage, interventions need to be designed in consideration of the possible cause of leakage. If the urethral support system needs to be improved, PME and Kegel exercises are designed to increase pelvic muscle strength, reduce

urethral hypermobility and provide urethral stability and prevent urine loss. If urethral closure system needs to be improved, the Knack emphasizes the closure of the urethra to prevent urine loss (Bø, 2004). Another difference between the Knack and Kegel exercises is that Kegel exercises increase pelvic muscle strength, reduce urethral hypermobility, and maintain urethral stability in short-term treatment, which has been well studied (Bø & Herbert, 2013). However, the Knack is a recently highlighted form of pelvic floor muscle training approach to treat SUI. This contraction develops sufficient urethral closure pressure to stop urine flow, thus preventing urine loss (Miller et al. 2001; Miller, Perucchini, Carchidi, DeLancey, & Ashton-Miller 2001).

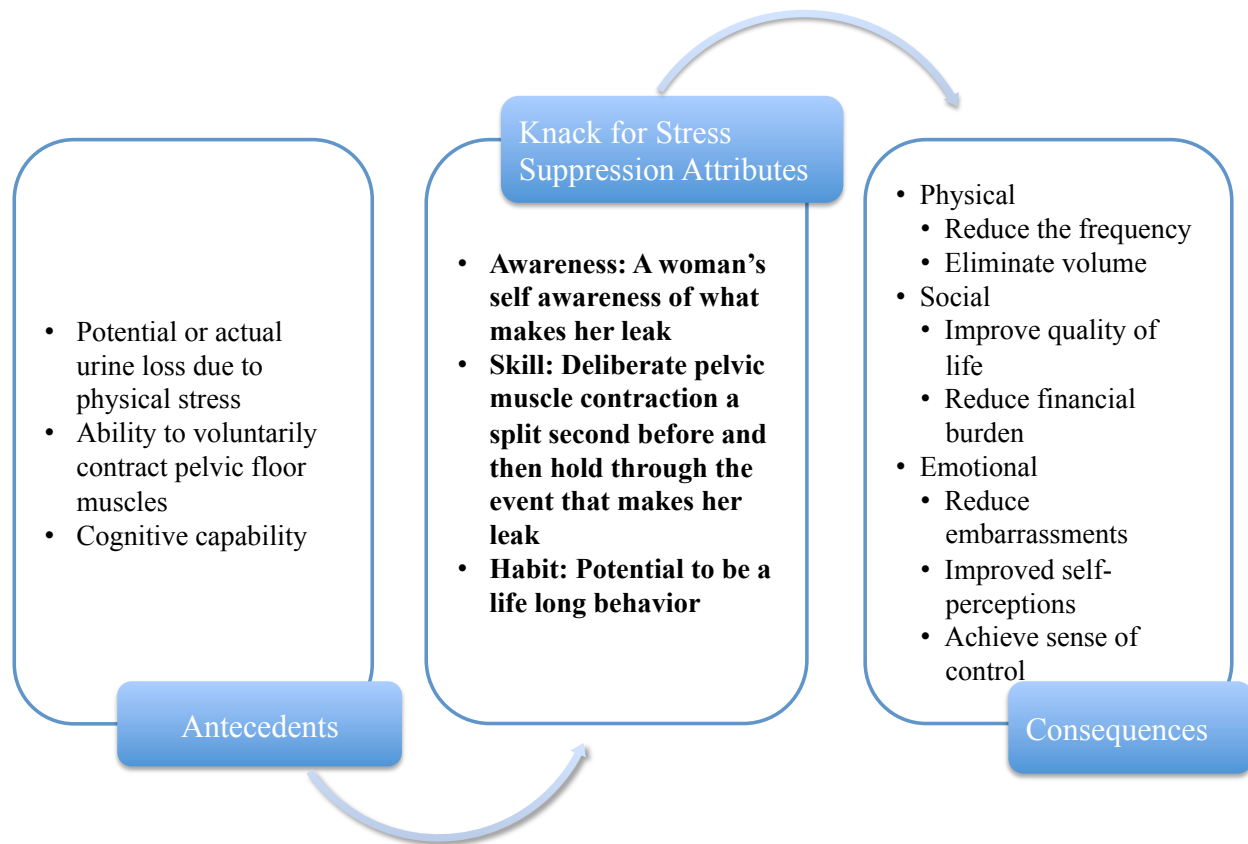
Figure A.2 Stress Continence Mechanism © DeLancey



Defining Attributes

To determine the benefit of the Knack for SUI suppression, 3 attributes are crucial (Walker & Avant, 2011) (see Figure 3): 1) awareness: a woman's self-awareness of what makes her leak; 2) skill: ability to perform a timely pelvic muscle contraction and then hold through the event that makes her leak; 3) habit: potential to be a lifelong behavior.

Figure A.3 The Knack for Stress Urinary Incontinence Concept Components



Constructed Cases

Cases are a valuable means to examine the concept and help readers to easily understand it. According Walker and Avant (2011), in a concept analysis cases are distinguished in term of what they contain and how they are presented. The more attributes they contain, the closer they are to the concept, which in this paper is the Knack for SUI suppression.

Model Case and Analysis

A model case contains all of the defining attributes that clearly present an example of the concept of interest (Walker & Avant, 2011). The following describes a model case for the Knack for SUI suppression.

Ms. AB leaked urine while she was coughing and sneezing. She was treated by using a single timed pelvic muscle contraction just before coughing or sneezing and holding the contraction during the event, to prevent urine loss through urethral closure. She

recognized that coughing and sneezing elicited an increase in her intra-abdominal pressure, resulting in urinary leakage. She was told she must use the single pelvic muscle contraction in a timely manner in order to close the urethra to prevent leakage. She was able to voluntarily contract her pelvic muscles just before an increase in intra-abdominal pressure when coughing or sneezing, and she could hold the contraction until the cough or sneeze ceased. After practice, she was able to perform this method to prevent her leakage during coughing or sneezing. She learned that awareness of leakage and timely contraction are the keys for success in continence. She was able to volitionally perform this method in her daily life and her quality of life improved.

This model case study fully demonstrates all three attributes of the Knack: awareness of the causes of leakage; knowledge of how, when, and how long to contract pelvic muscles; and sustained application in daily life. First, Ms. AB identified that she experienced urine leakage while sneezing or coughing, which disrupted her daily life. When she sought help, she learned the Knack and was able to correctly perform the contraction. She used this method for leakage control in her life.

Borderline Case and Analysis

A borderline case contains most of the defining attributes or even all, but at least one is substantially different upon close examination (Walker & Avant, 2011). This case helps to clearly identify the defining attributes.

Ms. CD had SUI. She was told that a well-timed pelvic muscles use could reduce her urine leakage. After she practiced, she was able to contract her pelvic muscles and knew that she had to contract simultaneously with her stressor event such as coughing, sneezing or laughing. She tried to incorporate the Knack in her daily life. However, sometimes, she contracted only after she noticed her leakage. Since she was not aware that she was about to be leaking, her leakage was not significantly reduced.

Ms. CD's story exemplifies a borderline case. Only two of three attributes of the Knack are realized. She was able to contract her pelvic muscles in a timely manner when she was aware of triggers of urine leakage and she could automatically contract her pelvic muscles in her daily life. However, sometimes she was not aware of when she was about to leak. She failed to do an intentional pelvic muscle contraction just before her leakage. This explains why her symptoms were not successfully improved and she still suffered the bothersome problem of urine loss.

Contrary Case and Analysis

A contrary case is an example that serves as a contrast to the concept (Walker & Avant, 2011). The following example is clear that the woman had SUI; but the Knack is not appropriate to apply for her.

Ms. GG experienced documented stress urine loss with coughing on exam in clinic, but she notes that she hardly ever coughs in everyday life and this is not what is bothersome to her. Rather, she simply “finds herself wet.” She complained to the clinician that “after years of people telling her to contract her pelvic floor muscles and several rounds of physical therapy she finds she has no confidence in the technique and no longer wants to try.” On exam of the levator ani muscles by digital palpation through the vaginal wall, the clinician could not identify any bulking of the muscles on either right or left side either without or with Ms. GG’s attempt at pelvic muscle contraction. An MRI was obtained that confirmed bilateral complete levator ani loss.

The contrary case does not meet any of the three attributes of the Knack for stress incontinence suppression, since Ms. GG 1) lacks awareness of when intraabdominal pressure rise causes leakage issues for her, 2) lacks ability to perform a pelvic muscle contraction timed with an activity that elicits stress-type leakage, and 3) lacks a motive to develop a lifelong habit of Knack use with physical stressors that might cause leakage.

Related Cases and Analysis

A related case contained characteristics that are very similar or close to the defining attributes but they are different when examined closely (Walker & Avant, 2011). The following example of Kegel exercises (or PME) does not require awareness of leakage, well-timed pelvic muscles use or hold the contraction during coughing or sneezing.

Ms. EF has been experiencing urine loss when coughing and sneezing for four years. She joined a pelvic muscle exercise program that required her to practice Kegel exercises by following a special exercise regimen. She practiced 15-second pelvic muscle contractions and relaxed 15 seconds; repeated 10 times, 3 times per day. Six months later, her symptoms of UI were improved. Once the program ended, she didn’t make time for the exercises and figured she didn’t need to since her symptoms had already improved. One year later, she recognized that her symptoms had not changed very much from when she had initially started the pelvic muscle exercise program.

MS. EF's story is a related case to understand the Knack. This related case only describes the pelvic muscle contraction, or Kegel exercises. Ms. EF had to contract her pelvic muscles to treat UI. She was not aware of what made her leak or when she leaked. She was unaware of when she needed to contract her pelvic muscles or for how long she needed to hold the contraction. The case participant established her practice regimen and followed it daily during a short time period. However, she had a hard time adhering to the practice regimen once her program ended and her symptoms were not improved after one year of joining the pelvic muscle exercise program.

Kegel exercise is an approach related to the Knack. Sixty years ago, Arnold Kegel first claimed pre- and post-operative physiotherapy combined with gynecological surgery worked for patients experiencing vaginal, urethral, and rectal incompetence. In later decades, many pelvic muscle exercise programs applied Kegel exercises in various forms as their main physiotherapy. Nearly all SUI researchers agree that Kegel exercises improve pelvic muscle strength, with the potential of alleviating symptoms of SUI in women.

Some of components of Kegel exercises and the Knack are similar, but not all (Table 2). They are similar that both involve pelvic floor muscle contraction, but they can be distinguished by the following. First, the Knack requires an awareness of when a woman will leak, but Kegel exercises do not. Second, the Knack requires timing of pelvic muscles squeezing with conditional increasing intra-abdominal pressure during a physical stress in order to close urethra, while Kegel exercises require repetitive contraction to strengthen pelvic muscles in order to increase the muscle strength, resulting in establishing urethral stability. Therefore, their routines are different. The Knack is a one-time voluntary contraction that does not require practice routine. Women do the Knack any time when they are alerted to the physical stress. However,

Kegel exercise are repetitive contractions that should be done as much as 30 times per day and routine practice is required over time to maintain its effect. Various practice regimens related to Kegel exercises depend on training programs. Women practice Kegel exercises following their practice regimen. In a typical Kegel exercises practice, for example, there is no awareness of leakage for women. They will be required to contract pelvic muscles with a 5-second hold and a 10-second relaxation, followed by fifteen rapid contractions with a 2-second hold and a 4-second relaxation. This routine should be performed three times at two minutes interval, three times per day. Last but not the least, one challenge with Kegel exercises is compliance (Morkved, Schei, & Salvesen, 2007). The Knack has the advantage of no required practice routine and can be a lifelong habit. The above case of how the Kegel exercises work on treatment of SUI will help to understand how the two approaches are related.

The second related case presented here describes how another type pelvic muscle suppression addresses UI focused on urgency.

Ms. GH has urge UI. She was unable to hold her urine once she felt the urge to urinate. She leaked before she reached the toilet. She was taught the strategy of urge suppression by squeezing her pelvic muscles. When she felt the urge to urinate, she was encouraged to pause and take a few slow deep breaths, stay still or sit down if possible, and quickly, tightly, repeatedly squeeze her pelvic muscles until the urge subsided. Then she relaxed her whole body. When the feeling of urgency was eliminated, she could walk to the restroom at a normal pace. If the urge occurred again, she was told to repeatedly squeeze to control it. Urge suppression strategies helped Ms. GH to manage her urgency, avoid embarrassment, and improve her social life.

This case reflects how urge suppression relates to the Knack. When Ms. GH felt an urge to urinate, she quickly contracted her pelvic muscles and performed the contractions. However, the awareness of potential urge leakage is different from the awareness surrounding the Knack. Ms. GH's awareness consisted of the feeling of an urge to void, while awareness of the Knack is related to the physical stress that causes leakage. Ms. GH had to quickly, tightly, and repeatedly

squeeze her pelvic muscles to delay the urgency until the feeling of urgency was eliminated, instead of a timed voluntary pelvic muscle contraction before and during the stress event such as coughing or sneezing. Therefore, urge suppression is performed for urge incontinence, while the Knack is performed for stress incontinence. The similarities and differences between these two strategies are found in Table 3.

Urge suppression strategies can be effective in delaying the feeling of a sudden urge or a strong desire to urinate (Borello-France et al., 2010; Burgio et al., 1998). In this method, squeezing and relaxing pelvic muscles are intended to inhibit detrusor contraction and then to reduce urgency (Borello-France et al., 2010; Burgio et al., 1998). This is thought to be effective because the way that the muscles are squeezing will signal the bladder to relax and give women the feeling of control, and then prevent urine loss. Borello-France and colleagues (2010) found that 92% of women who were taught and used this squeeze were able to prevent an urge incontinence episode. Similar to the Knack (Table 3), the urge suppression requires a woman's awareness of urgency and timing a pelvic muscle contraction to close the urethra. Urge suppression also can be performed when needed in daily life. However, there are differences between the Knack and urge suppression in terms of the awareness and the timing of pelvic muscle contraction. Urge suppression requires an awareness of the urgency and then quick, tight squeeze of the pelvic muscles to delay the sensation of the urgency. The Knack, however, requires awareness of the physical stress and a contraction of pelvic muscles just before an increase in intra-abdominal pressure resulted in the need to close the urethra. The ways to perform the two interventions also are different. The urge suppression consists of quick, tight, repeated squeezes until the feeling of urgency is eliminated, while the Knack is a single

Table A.2 The Knack for Stress Urinary Incontinence Versus Kegel Exercises

		The Knack	Kegel Exercises
Similarity	Pelvic muscle contraction	Yes	Yes
	Intervention for SUI	Yes	Yes
Difference	Awareness of potential for urine loss	Yes	No
	Type of pelvic muscle contraction	A timed pelvic muscle contraction	Repetitive pelvic muscle contractions
	Target result from contraction	Urethral closure	Increased Pelvic muscles strength
	Practice routine	One-time contraction, no routine practice required	Requires practice
	Ease of adherence	Yes	No

Table A.3 The Knack for Stress Urinary Incontinence Suppression Versus Urge Suppression for Urge Urinary Incontinence

		The Knack	Urge Suppression
Similarity	Awareness of potential urine loss	Yes	Yes
	Timed Pelvic muscle contraction	Yes	Yes
	Practice routine	No	No
	Ease to adherence	Yes	Yes
Difference	Moment of Awareness of potential urine loss	Stressor	Urgency
	Type of pelvic muscle contraction	A single voluntary pelvic muscle contraction	Quick, tight, repeated squeezes of pelvic muscles
	Target result from contraction	Confront increased bladder pressure resulted from increased intra-abdominal pressure	Delay the sensation of the urgency
	Intervention	SUI	Urge UI

voluntary pelvic muscle contraction held until the stress releases. Ms. GH's story will describe how the urge suppression is effective in urge UI.

Antecedents and Consequences

The primary antecedent of the Knack is potential or actual urine loss due to a physical stressor. For the Knack to be successful, a woman should have the ability to volitionally contract her pelvic muscles. In addition, her pelvic muscle strength needs to be strong enough to contract muscles. A woman with weak or torn pelvic muscles may not be able to successfully contract her muscles. Furthermore, women should have cognitive capability in order to self volitionally contract the pelvic muscles. Some reliable scales can be used to measure the antecedents of this concept (Table 4).

There are significant physical, social, and emotional outcomes that can be gained from performing the Knack. The physical consequences include improvement in SUI symptoms such as reducing frequency and volume of leakage. The main component of the social consequences is an improvement in the quality of life. Additionally, the quality of life of women with SUI has been improved when using the Knack (Sari & Khorshid, 2009). Social consequences also include a reduced financial burden and maintenance of good relationships with others including friends, colleagues, and spouses. Emotional consequences are also important and include reducing embarrassment, improving self-perception, and achieving a sense of control. Some of these consequences can be quantified by reliable scales (Table 4).

Empirical Referents

There are some scales (Table 4) that can be used to measure the defining attributes for the Knack. The Michigan Incontinence Symptom Index (M-ISI) is a 10-item incontinence

Table A.4 Measures for the Knack of Stress Urinary Incontinence Suppression Concept Components

	Measure	Reference
Antecedents		
<ul style="list-style-type: none"> • Urine loss with stress 	Stress test Paper towel test	Miklos, Sze, & Karram, 1995; Miller, Ashton-Miller, & DeLancey, 1998b
<ul style="list-style-type: none"> • Contract ability 	Brink digital pelvic floor muscle assessment	Brink, Wells, Sampsel, Taillie, & Mayer, 1994
<ul style="list-style-type: none"> • Cognitive ability 	Mini-mental state exam (MMSE)	Folstein, Folstein, & McHugh, 1975
Attributes		
<ul style="list-style-type: none"> • Awareness 	Items 1, 2, & 3 from Michigan incontinence symptom index (M-ISI)	Suskind et al, 2014
<ul style="list-style-type: none"> • Skill 	Bladder stress test	Swift & Yoon (1999)
<ul style="list-style-type: none"> • Habit 	Questions whether routinely contract pelvic muscles	--
Consequences		
<ul style="list-style-type: none"> • Frequent 	3-day bladder diary	Wyman, Choi, Harkins, Wilson, & Fantl, 1988
<ul style="list-style-type: none"> • Volume 	Paper towel test; Pad test	Miller, Ashton-Miller, & DeLancey, 1998b; Wall, Wang, Robson, & Stanton, 1990)
<ul style="list-style-type: none"> • Quality of life 	Items 9 & 10 from M-ISI	Suskind et al., 2014
<ul style="list-style-type: none"> • Finance burden 	--	--
<ul style="list-style-type: none"> • Embarrassment 	Item 10 from M-ISI	Suskind et al., 2014
<ul style="list-style-type: none"> • Self-concept 	--	--
<ul style="list-style-type: none"> • Sense of control 	Self-efficacy scale from Evaluating Maternal Recovery from Labor and Delivery	--

questionnaire that assesses frequency of symptoms, pad use, and bother caused by urinary incontinence. Items 1 to 3 from M-ISI assess whether a woman knows when she leaks during a stress event, which can be used to measure awareness. Bladder stress test change score from leakage to reduced leakage can be used to assess whether a woman is able to contract her pelvic muscles enough to perform the Knack. To understand habit, the questions of whether a woman routinely contracts her pelvic muscles during coughing, sneezing provide information to assess if performing the Knack can be a lifelong behavior.

Discussion

How could we know if a woman can do a proper pelvic muscle contraction? According to the literature, a pelvic muscle contraction can be measured both subjectively (Amaro, Oliveira Gameiro, & Padovani, 2003) and objectively (Pauliina, Jorma, Paula, & Olavi, 2001). A subject measure could involve self-reports of whether a woman has fully contracted her pelvic muscles. Researchers can set up the contraction levels considering the time. For example, a contraction sustained less than 3 seconds is mild, 3-5 seconds moderate, and over 5 seconds normal. Intravaginal probes have been used to measure pressure when a woman was asked to do three 5-second quick maximal contractions. However, this approach does not test the timing of an increase of intra-abdominal to do a pelvic muscle precontraction, which is not appropriate way to measure the Knack.

To determine whether a woman correctly performs the Knack, the best instrument may be a visual ultrasound. Ultrasound examination can measure the pressure change during coughs with and without the Knack in the bladder, urethra, as well as the vaginal walls, which together constitute a complex process. Other than these methods, we can measure leakage reduction from no use to use of the Knack. Women will be asked to place a brown paper towel against perineum

during three single coughs in a standing position, and then change another dry brown paper towel to place under perineum during three coughs simultaneously perform the Knack, and then calculate the reduced wetted area from the two paper towels, which is known as the paper towel test (Miller, Ashton-Miller, & DeLancey, 1998b; Sheng & Miller, 2016, p. 533).

Implications for Clinical Practice

The Knack is an approach that can effectively treat SUI in women. Awareness and timing are the key elements of this method. Although researchers and clinicians have used the method with their study participants, many articles have provided incomplete understanding of the method (Agur et al., 2008; Borello-France et al., 2013; Cammu et al., 2000; Kincade et al., 2007; Schiotz, Karlsen, & Tanbo, 2008). Incomplete understanding the concept may result in failure to perform the method, leading to the failure of its unique effect as a minimalist intervention for SUI. This analysis of the concept can help clinicians correctly apply this method in routine clinic activities and develop better health care that promotes health outcomes physically and psychosocially. Clinicians have the ability to teach women with SUI how to correctly perform the method and should encourage women to correctly contract pelvic muscles at the critical moment in order to benefit from its optimal effectiveness. The steps for teaching and learning the Knack are shown in Box 1 (Sheng & Miller, 2016, p. 538). Clinicians and women with SUI may find the method is the simplest strategy compared to others such as Kegel exercises which requires routine practice to maintain effectiveness (Cammu et al., 2000). Current research suggests that the Knack may work better by itself or combined with other conservative treatments for SUI in women.

Box 1. Steps in Teaching/Learning the Knack

1. Confirm voluntary control: The clinician palpates the levator ani muscle bilaterally through the vaginal wall while the woman attempts a pelvic muscle contraction. A bulking of the muscle should be felt. If not, or if she bears down (Valsalva maneuver), instruct her in an easy flick of the muscles, the same maneuver she would use to hold back gas, to see if this elicits correct isolation. If unable to contract, Knack instruction should be discontinued.
2. Maximize the contraction: The woman should be taught to contract the pelvic muscles as deeply into the vagina as she is able. In some women, this is most easily accomplished by learning a stacking contraction. Start with a small flick-and-release maneuver and then build into stacking two to three small flicks. This is commonly known as the “elevator” technique (imagined as moving from one floor to the next). For other women, a smooth continuous inward pull of the muscles seems to work better. Teach her to maintain a steady hold of the pelvic muscle contraction while inhaling and exhaling. Remind her to avoid the tendency to incorrectly hold her breath during the pelvic muscle contraction.
3. Begin to coordinate: Two different coordination maneuvers are required for suppression of leakage risk scenarios. One is to be able to reduce urge sensations. The Knack urge suppression skill uses small, gentle, pelvic muscle contractions (not strong holds). Several contractions (3-5) are usually sufficient for urge suppression. After a few seconds rest, an additional set of 3-5 may be needed. Two is to be able to reduce leakage during a moment of intraabdominal pressure rise. The Knack stress suppression skill uses a single strong pelvic muscle contraction timed precisely with a secondary activity that increases intraabdominal pressure rise, such as a cough or sneeze.
4. Establish the habit: Women can practice the Knack urge suppression skill prior to turning on the water faucet, upon arriving home to suppress latchkey urgency, or at end of toileting to suppress post-void dribbling. Practicing Knack stress suppression skill can be done during planned maneuvers such as blowing the nose, voluntary coughing, lifting, rising from a chair, or momentarily stopping exercise (e.g., jogging) for a moment to “reset the pelvic floor” with a volitional pelvic muscle contraction. As skills with this technique develop, women will be ready to handle the triggers for urge UI and the surprise cough, sneeze that typifies stress UI.

Data from Miller, J. M., Ashton-Miller, J. A., & DeLancey, J. O. L. (1998a). A pelvic muscle precontraction can reduce cough-related urine loss in selected women with mild SUI. *Journal of the American Geriatrics Society*, 46(7), 870-874.

Conclusion

This concept analysis has identified the antecedents, defining attributes, and consequences of the Knack, which then serves to enhance our knowledge of management of SUI for both clinicians and women to understand correctly. It also describes the correct performance of the Knack, while providing a clear understanding of the concept, which may be useful for research. As demonstrated by this analysis, the Knack is an approach that can prevent involuntary urine loss, improve quality of life, reduce embarrassments, and improve self-perception. Clinicians can better incorporate it into routine clinic practice for optimal effect and determine its effectiveness in research studies independent of other pelvic muscle training protocols, such as repetitive Kegel exercises. When performed properly, the Knack can prevent severe SUI and may avoid surgery in the subsequent decades.

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