Assessing physical therapy outcomes for women with urinary incontinence

Jodi Dusi

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ASSESSING PHYSICAL THERAPY OUTCOMES FOR WOMEN WITH
URINARY INCONTINENCE

A Dissertation
Submitted to the John G. Rangos Sr.
School of Health Sciences

Duquesne University

In partial fulfillment of the requirements for
the degree of Doctor of Philosophy

By
Jodi Dusi

May 2011
ASSESSING PHYSICAL THERAPY OUTCOMES FOR WOMEN WITH
URINARY INCONTINENCE

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ABSTRACT

ASSESSING PHYSICAL THERAPY OUTCOMES FOR WOMEN WITH URINARY INCONTINENCE

By

Jodi Dusi

May 2011

Dissertation supervised by Diane Borello-France, PT, PhD

The purpose of this study was to 1) determine the efficacy of physical therapy interventions to reduce pelvic symptoms and improve health-related quality of life and global impression of improvement in women with urinary incontinence; 2) determine the relationship between selected patient-related characteristics and treatment success; and 3) describe interventions utilized to manage the care of women with urinary incontinence.

Methods: A pragmatic study design was used to explore study aims. The physical therapy records of 100 female patients with urinary incontinence from Centers for Rehab Services provided data for this study. Data from routine clinical care was entered into an electronic database designed for quality improvement purposes. Outcome measures to determine improvements in pelvic symptoms and health-related quality of life included
the Pelvic Floor Distress Inventory-20 (PFDI-20) and Pelvic Floor Impact Questionnaire-7 (PFIQ-7), respectively. Global impression of improvement was recorded using the Patient Global Index of Improvement (PGI-I) administered post-intervention. The relationships between patient-related characteristics and treatment success were explored using logistic regression. Descriptive statistics were utilized to describe the interventions received by women.

Results: Mean pre- to post-intervention PFDI-20 and PFIQ-7 scores were significantly reduced indicating that women’s pelvic symptoms and health-related quality of life improved following physical therapy intervention. The median PGI-I score was “2” indicating symptoms were “much better” following intervention. Sixty-six percent of women met the study criteria for PGI-I defined treatment success. Women who achieved treatment success had a lower mean age (51.86±15.59 vs. 59.29±13.15 years) and had more physical therapy visits (9.05±5.51 vs. 5.74±2.55 visits) than those who did not perceive symptom improvement. Additionally, the distribution of the occurrence of barriers between women who did and did not perceive treatment success was different than would be expected by chance. When age, presence of barriers to intervention recommendations, and number of physical therapy visits were entered into the logistic regression model, only barriers to intervention recommendations (OR 12.82; 95% CI 4.05-40.55) and number of physical therapy visits (OR 1.26; 95% CI 1.07-1.50) were influential in predicting PGI-I outcome. Women in the study received a combination of treatments including education, exercise, modalities, and manual procedures.
ACKNOWLEDGEMENT

I would like to thank my husband and daughters, Gabriella Jean and Gianna Jo, for their support and patience.
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Chapter 1

Introduction

1.1 Background

Urinary incontinence (UI) is defined by the International Continence Society as an “involuntary loss of urine which is objectively demonstrable and a social or hygienic problem.”¹ UI affects approximately 20 million people in the United States² with economic costs of over $16 billion per year.² Moreover, UI leads to social isolation,³ poor self-rated health,⁴ decreased quality of life,⁵ and depressive symptoms.⁶ Physical therapists are involved in the clinical management of female UI because the impairments that these women demonstrate (i.e. decreased pelvic floor muscle strength; decreased endurance and/or coordination; and decreased awareness of lifestyle factors that contribute to UI) fall within the scope of physical therapy practice according to the Guide to Physical Therapist Practice.⁷ Consequently, there is a growing need to understand the efficacy of physical therapy interventions aimed toward reducing female UI symptoms and improving the quality of life.

There are three main types of UI – stress, urge, and mixed. Stress urinary incontinence (SUI) is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing.¹ Urge urinary incontinence (UUI) is the complaint of involuntary leakage accompanied by or immediately preceded by urgency.¹ Mixed urinary incontinence is the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing.⁸
SUI may develop from loss of structural support of the bladder or bladder neck which includes damage to the pelvic floor muscles, endopelvic fascia, or pudendal nerve. Conservative physical therapy interventions for SUI includes pelvic floor muscle exercises which may improve urethral closure and pelvic organ support. Some women with SUI have difficulty contracting their pelvic floor muscles. In these women, biofeedback or electrical stimulation may be utilized to augment pelvic floor muscle training.

UUI is a symptom of Overactive Bladder (OAB) syndrome which is characterized as urinary urgency with or without urge incontinence, as well as nocturia and urinary frequency (urinating more often than usual). OAB may be attributed to structural bladder changes that occur with age, pelvic organ prolapse, or neurological diseases that decrease the parasymptomatic control of the bladder. There are two general approaches to the management of UUI. The first, behavioral training, includes pelvic floor muscle (PFM) exercises to inhibit bladder contractions and other urge suppression strategies. The second approach, bladder training, focuses on restoring normal bladder function by modifying bladder habits using structured voiding schedules.

It is common for women with UI to have co-existing pelvic symptoms, including bowel (constipation or incontinence) and/or pelvic organ prolapse (bladder, bowel, and/or uterine). In addition, women may complain that their pelvic symptoms impact sexual function. Co-existing UI and fecal incontinence rates of 18-31% are reported, while the prevalence of co-existing constipation and UI in women ranges from 31-36%. Moreover, Ellerkmann and co-workers reported that 86% of women with pelvic organ prolapse had urinary urgency and frequency. In addition, women with urinary
symptoms have a 4-fold higher risk for sexual arousal dysfunction and a 7-fold higher risk for sexual pain with intercourse than women without urinary symptoms. Clinicians believe that physical therapy interventions may improve bowel, pelvic organ prolapse, and/or sexual function symptoms. The most common interventions for constipation include increasing fluid intake, increasing dietary fiber intake, and promoting bowel motility via abdominal massage. Limited research has been done investigating the efficacy of abdominal massage. However, one published case report documented the effectiveness of abdominal massage to restore normal bowel frequency in a female client with constipation after only five physical therapy visits.

Physical therapy interventions for fecal incontinence include PFM exercise, biofeedback, and electrical stimulation. PFM exercise with biofeedback has been shown to improve bowel symptoms, but there is a limited number of trials investigating the added effect of biofeedback with PFM training. Electrical stimulation has not been shown to be effective in the small number of clinical trials investigating its use for women with fecal incontinence. Recent practice guidelines by the American College of Gastroenterology suggest that electrical stimulation should be considered experimental and merits investigation within controlled clinical trials.

Women seldom seek physical therapy solely for sexual dysfunction or pelvic organ prolapse symptoms. Typically these symptoms and limitations accompany UI and are identified during the patient history and/or systems review. Consequently, few clinical studies have been performed that have examined the efficacy of physical therapy interventions for pelvic organ prolapse and sexual dysfunction. Thus, one primary aim of this study was to determine the efficacy of physical therapy interventions provided within
a pragmatic setting on global impression of improvement, pelvic symptoms, and health-related quality of life to women with UI.

Although separate interventions exist for bowel and bladder dysfunction, there are no published reports describing the efficacy of physical therapy interventions for women with UI and co-existing pelvic dysfunctions. Urinary, bowel, prolapse, and sexual dysfunction conditions are associated with damage to the pelvic floor either through mechanical disruption of connective tissue, or through direct and secondary muscle or nerve injury. Because urinary, bowel, prolapse, and sexual dysfunction conditions share common etiologies and risk factors, it is reasonable to speculate that physical therapy interventions aimed toward reducing UI will also contribute, along with other symptom-specific (bowel, prolapse, sexual dysfunction) interventions, to the reduction of co-existing bowel, prolapse, and/or sexual dysfunction symptoms.

Physical therapy interventions may not be equally beneficial to all women who seek treatment for UI and other pelvic floor disorders. Certain patient-related characteristics may be associated with poorer intervention outcomes. The number and/or type of risk factors a woman has for UI may be associated with poor physical therapy outcomes. Identified risk factors for UI include: age; childbirth; Caucasian race; smoking; daily or greater consumption of carbonated drinks; number of comorbidities; and presence of barriers to intervention recommendations.

Comorbidities refer to diseases or health conditions (as defined by the World Health Organization) that are associated with UI and include: obesity; respiratory disease/chronic cough; pelvic surgery; bowel dysfunction (chronic constipation; fecal incontinence; irritable bowel syndrome; pelvic organ
prolapse;\textsuperscript{30} pain (pelvic pain\textsuperscript{61, 66} and low back pain\textsuperscript{67}); neurological conditions;\textsuperscript{9, 60} and diabetes.\textsuperscript{9, 60} Barriers to intervention recommendations refer to the patient’s physical impairments, such as profound muscle weakness or sensory deficits that have the potential to impact the effectiveness of physical therapy interventions as well as personal barriers that prevent adherence to the physical therapist’s recommendations for exercise, change in urinary/bowel habits, and/or other lifestyle modifications. In addition, the number of physical therapy visits a woman attends may also influence physical therapy outcomes. According to a recent systematic review, treatment effect may be greater in women with SUI who received a longer duration of PFM training (6 months versus 8 weeks).\textsuperscript{17} Given the possible influence of patient-related characteristics on physical therapy outcomes, the second primary aim of this study was to determine the association between patient-related factors (selected risk factors for UI, selected comorbidities, barriers to intervention recommendations, and number of physical therapy visits attended) and physical therapy treatment outcomes.

Although physical therapy treatment interventions utilized in the management of women with UI have been well described (including PFM training,\textsuperscript{11, 13-18, 20, 22, 68-70} core stabilization training,\textsuperscript{71, 72} and patient education\textsuperscript{22, 73-76}), there are no published reports describing treatment interventions for women with UI and concomitant pelvic symptoms (bowel, prolapse, and/or pelvic pain). To describe the current physical therapy practice trend for women with various pelvic symptoms, it would be useful to gather such information from multiple physical therapists in a pragmatic setting. Consequently, the secondary aim of this study was to describe the interventions applied by physical
therapists to manage the care of women with UI and those with UI and coexisting bowel, prolapse, and pelvic pain symptoms.

1.2 Operational Definitions

Global impression of improvement. The patient’s global perception of improvement with physical therapy intervention was measured and defined as the post intervention Patient Global Impression of Improvement (PGI-I) score. The PGI-I was used as a primary outcome measure in this study. The PGI-I includes one question that asks the respondent to compare their condition now (at discharge) as to how it was prior to starting physical therapy. The PGI-I response range is 1-7, with 1 being “very much better” and 7 being “very much worse.” Thus, the lower the post-intervention PGI-I score, the more improved the patient perceives her condition following physical therapy intervention. In this study, treatment success is defined as a post-intervention PGI-I score of 2 indicating “much better” or 1 indicating “very much better.”

Pelvic symptoms. Three assessment instruments were used to measure pelvic symptoms associated with UI, bowel dysfunction, pelvic organ prolapse, and sexual dysfunction. Each assessment instrument was administered to subjects pre-and post intervention. The first instrument was the Pelvic Floor Distress Inventory (PFDI-20) which was used as one of the primary outcome measures in this study. The PFDI-20 has a score range from 0-300 with lower scores indicating fewer pelvic symptoms and symptom distress associated with urinary, bowel, and pelvic organ prolapse. Thus, pre-post intervention changes to lower PFDI-20 scores indicate improvement in pelvic symptoms. The two remaining assessment instruments measuring pelvic symptoms were secondary outcome...
measures in the study and included the Constipation Scoring System (CSS)\textsuperscript{79} and the pain subscale of the Female Sexual Function Index (FSFI).\textsuperscript{80} The CSS assesses constipation symptoms while the pain subscale of the FSFI measures pain with sexual intercourse. The range of CSS scores is 0-30, with higher scores indicating greater constipation symptoms. Thus, pre-post intervention changes to lower CSS scores indicate improvement in constipation symptoms. The range of scores for the FSFI subscale is 0-6, with a higher score indicating greater reduction in pain associated with sexual intercourse. Thus, pre-post intervention changes to higher scores indicate reduced sexual pain with intercourse.

**Health-related quality of life.** Health-related quality of life was measured by the Pelvic Floor Impact Questionnaire (PFIQ-7)\textsuperscript{78} and the PFIQ-7 will was used as a primary outcome measure in this study. The PFIQ-7 has a score range from 0-300, with lower scores indicating better perceived health-related quality of life.\textsuperscript{78} PFIQ-7 scores were obtained from patients pre- and post-intervention. Thus, pre-post intervention changes to lower PFIQ-7 scores indicate improved health-related quality of life.

**Barriers to intervention recommendations.** – Barriers to intervention recommendations refer to occurrences during the physical therapy intervention phase that have potential to interfere with the patient achieving improvements in pelvic symptoms, health-related quality of life, and/or global impression of improvement. Specific barriers recorded by the physical therapist during intervention included any of the following: a) patient did not attend all recommended physical therapy visits; b) patient was not adherent to home exercise program; c) patient did not adhere to recommended lifestyle modifications; d) cognitive impairments interfered with patient’s ability to follow the plan of care; e)
comorbidities contributed to UI or interfered with the patient’s ability to follow the plan of care; f) medications contributed to UI, limiting outcomes; g) sensory loss limited patient’s ability to recognize correct muscle contraction; and h) profound muscle weakness/muscle denervation limited potential for increase muscle function.

1.3 Limitations and Assumptions

1. A change score of 11 points on the PFDI-20 and 16 points on the PFIQ-7 was considered a minimum important difference for women with UI seeking physical therapy services.

2. Pre-to post-intervention score differences were attributable to the physical therapy interventions.

3. Patients completed the PGI-I, PFDI-20, PFIQ-7, CSS, and FSFI questionnaires accurately and honestly.

4. Patients may have failed to return all outcome questionnaires to the physical therapists contributing to missing data.

5. Physical therapists entered the data into the database accurately and honestly.

6. Physical therapists may have failed to enter data on all patients contributing to a smaller sample for analysis than projected. The ability to enter data on patients was linked to the computerized billing system. Data entry was not possible after an account was closed.

1.4 Delimitations

1. Data from 100 women were analyzed.
2. Fifteen physical therapists from twelve physical therapy sites entered data into the database.

3. The physical therapists provided input throughout the selection of outcome measures, standardization of forms/assessment procedures, and creation of database which assisted in maximizing compliance by the physical therapists.

4. The last documented data was used in the final analyses when data was missing.

5. Physical therapists were reminded monthly to enter data on all patients with UI in a timely manner.

6. Patients that did not return outcome questionnaires during their final physical therapy visit were asked to return them via postal mail.

1.5 Problem Statement

This study proposed the following primary aims:

a) To determine the efficacy of physical therapy interventions provided within a pragmatic setting on global impression of improvement, pelvic symptoms, and health-related quality of life to women with UI.

b) To determine the relationship between selected patient-related characteristics (age, parity, race, number of comorbidities, carbonated beverage intake, current smoking status, presence of barriers to intervention recommendations, and number of physical therapy visits) and treatment success. Treatment success was defined as a post-intervention PGI-I score of “much better” or “very much better;” a reduction in pelvic symptoms (reduction in PFDI-20 score at discharge) and improvement in health-related quality of life (reduction in PFIQ-7 at discharge).
The secondary aim was to document the percentage of women who received 4 possible interventions. Because intervention selection may be determined by the constellation of symptoms a woman possesses, separate percentages were calculated for 4 symptom-based categories of women. The categories included: UI symptoms only, UI + bowel symptoms, UI + pelvic pain, or UI + bowel symptoms + pelvic pain. Interventions included patient education, modalities, manual physical therapy procedures, and exercise.

1.6 Independent Variables

1. Treatment Intervention – Because this is not an experimental trial, the treatment interventions included those chosen by the physical therapists to manage the patients’ care. However, the treatment intervention was categorized into one or more of the following categories:

a. Patient Education: Patient education is determined by the physical therapist and may include education in body mechanics/posture; bladder/bowel schedule; diet modification (caffeine reduction, carbonated beverage reduction, fluid management [increase or decrease water intake as appropriate], and/or fiber intake (increase or decrease fiber as appropriate); relaxation techniques such as diaphragmatic breathing or progressive relaxation; SUI strategies (pelvic floor muscle contraction prior to activity that increases intra-abdominal pressure such as lifting or sneezing); UUI strategies (pelvic floor muscle contraction to decrease urgency and delay voiding); toilet strategies for constipation (appropriate toilet posture to promote bowel movement) and to void without straining; and soft tissue massage (abdominal massage for constipation, scar massage, or self-stretching of the vaginal introitus).
b. Modalities: The following modalities may be included in the physical therapy plan of care: biofeedback (to promote pelvic floor muscle strength and endurance, to increase pelvic floor muscle coordination, and/or to promote pelvic floor muscle relaxation) electrical stimulation (to improve pelvic floor muscle strength, to promote sensory awareness of the pelvic floor muscles, and/or to reduce pelvic pain), and heat/cold to reduce pelvic pain.

c. Manual physical therapy procedures: Manual physical therapy procedures may include soft tissue mobilization to decrease soft tissue restrictions and improve range of motion; and joint mobilization to improve joint range of motion.

d. Therapeutic exercises: Therapeutic exercises include PFM exercise to promote pelvic floor muscle strength, relaxation, and/or coordination (with manual intra-vaginal facilitation; in gravity eliminated or anti-gravity positions; or during functional tasks); trunk stabilization exercises to improve strength of the transverse abdominus, other abdominal muscles, multifidus, and/or to promote trunk stabilization during functional activities such as lifting; and flexibility exercises to increase mobility of the hip and/or lumbopelvic regions.

2. Patient-related characteristics with 8 sublevels: Patient-related characteristics include age (years), parity (nulliparous or parous), race (Caucasian or non-Caucasian), number of comorbidities (0-8), carbonated beverage intake (≥1 per week or <1 per week), current smoking status (smoker or non-smoker), presence of barriers to intervention recommendations (none or ≥1), and number of physical therapy visits.
1.7 Dependent Variables

The present study investigated three primary outcomes:

1. The post-intervention PGI-I score.
2. The difference between pre-intervention and post intervention values on the PFDI-20.
3. The difference between pre-intervention and post intervention values on the PFIQ-7.

As not all women represented in this study will experience bowel symptoms and/or sexual dysfunction, the present study also investigated two secondary outcomes:

1. The difference between pre-intervention and post intervention values on the CSS.
2. The difference between pre-intervention and post intervention values on the FSFI.

1.8 Hypothesis

Data collected for this study was used to test one specific hypothesis:

Women with UI receiving pragmatic physical therapy management will attain treatment success. Treatment success is defined as a post-intervention PGI-I score of “much better” or “very much better;” a reduction in pelvic symptoms (reduction in PFDI-20, FSFI, and CSS scores at discharge) and improvement in health-related quality of life (reduction in PFIQ-7 at discharge).

As the remaining study aims are descriptive in nature, no specific hypotheses for these aims are stated.
Chapter 2

Review of Literature

2.1 Introduction

Urinary incontinence (UI) is defined by the International Continence Society as a “involuntary loss of urine which is objectively demonstrable and a social or hygienic problem.” There are three main types of urinary incontinence – stress, urge, and mixed.

Stress urinary incontinence (SUI) is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing. During effort or exertion, the intra-abdominal pressure is raised and the urethral sphincter is unable to maintain a pressure higher than that exerted on the bladder. Subsequently, urine leakage occurs during everyday activities such as lifting, laughing, jumping, sneezing, or coughing.

Urge urinary incontinence (UUI) is the complaint of involuntary leakage accompanied by or immediately preceded by urgency. During bladder filling, the bladder contracts abnormally which creates a sensation to urinate that becomes progressively stronger, is very difficult to ignore, and ultimately results in urine leakage. UUI may be associated with overactive bladder syndrome (OAB). OAB is a symptom syndrome denoting urgency, frequency, and nocturia, with or without UUI. Urodynamically, OAB can be described as involuntary detrusor contractions during the filling phase. Literature investigating OAB with UUI is relevant in the discussion of UUI because OAB can produce contractions of the bladder that may contribute to UUI.

Finally, mixed urinary incontinence is the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing.
approximately 20 million people in the United States\textsuperscript{2} and the prevalence of UI in women ranges from 26-46\%.\textsuperscript{5, 54, 60, 82} Of women reporting UI, women complain of mixed urinary incontinence most often (50-56\%),\textsuperscript{2, 83} followed by SUI (33-27\%)\textsuperscript{2, 83} and UUI (9-13\%).\textsuperscript{2, 83} In addition, women experience an age-related increase in prevalence of UI with 67\% of post-menopausal women reporting unintentional urine leakage.\textsuperscript{59}

The economic costs of UI are substantial comprising over $16 billion per year in the United States. Most of the cost is attributed to resources for UI management such as absorbent pads, protection, and laundry.\textsuperscript{2} Subak and colleagues reported that community-dwelling women spend nearly $750 per year out of pocket for incontinence management. Nearly 85\% of the women reported absorbent pad use, 50\% of women reported additional loads of laundry due to UI, and 14\% reported additional dry cleaning each week due to UI.\textsuperscript{84} Incontinence costs increase with more frequent UI episodes.\textsuperscript{12, 13} Those with severe and very severe incontinence encounter a 2-fold greater cost than women with slight incontinence.\textsuperscript{82} Moreover, women were willing to pay more for greater reduction in UI episode frequency\textsuperscript{82, 84} from a mean of $31 per month for 25\% reduction, to $44 for 50\% reduction, and $118 for 100\% reduction.\textsuperscript{84}

UI also leads to social isolation,\textsuperscript{3} poor self-rated health,\textsuperscript{4} decreased quality of life,\textsuperscript{5} and depressive symptoms.\textsuperscript{6} Subak and colleague found women with UI scored substantially lower on the Health Utilities Index (mean score of 0.73)\textsuperscript{84} compared to the women aged 45 years and older with no chronic medical conditions (mean = 0.92). The Health Utilities Index utility measures global health-related quality of life on a scale from -0.36 to 1.0, where -0.36 is the worst possible state, 0 is associated with death, and 1.0 is the best attainable health.\textsuperscript{85, 86}
Fultz and colleagues asked community dwelling women with UI to indicate the degree to which they found their leakage to be bothersome on a scale of 1 to 5 where 1 is “not at all bothersome” and 5 is “extremely bothersome.” About half of the women were slightly bothered and 30% were moderately to extremely bothered by their symptoms. Those that were moderately to extremely bothered reported that their UI had a negative impact on physical activity, confidence, daily activities, and social activities indicating that UI affects more domains than simply health-related quality of life. Additionally, quality of life scores appear to diminish with increasing levels of UI frequency. Ragins and colleagues demonstrated that an increase in UI frequency (e.g. from less than monthly to monthly incontinence, from weekly incontinence to daily incontinence) is significantly associated with a decrease in quality of life as reported on the SF-36 and Incontinence Impact Questionnaire in women aged 40-69. In addition, increased UI frequency has been shown to be associated with increased bothersomeness of symptoms. Moreover, self-assessed health, sleep, fitness and satisfaction with work situation has been shown to decrease significantly with increased frequency of UI in women aged 20-59.

UI is an important problem faced by many women that affects their mental and physical well-being as well as their function in society. Physical therapists have become involved in the clinical management of UI in women because the presumptive underlying impairments (i.e. decreased pelvic floor muscle strength and/or endurance, decreased awareness of bladder irritants) fall within the scope of physical therapy practice according to the Guide to Physical Therapist Practice. Consequently, there is a growing
need to understand how physical therapy interventions impact women’s UI symptoms, impairments, and functional limitations.

2.2 Mechanism of UI

2.2.1 Anatomic

The continence mechanism is embedded within the pelvic floor therefore, it is necessary to define the three layers (deep to superficial) of the pelvic floor structure: endopelvic fascia, levator ani muscle (LA), and the perineal membrane or external anal sphincter.\textsuperscript{90} The endopelvic fascia attaches the cervix and vagina to the pelvic wall on each side of the pelvis dividing the pelvis into an anterior and posterior compartment (Figure 2.1). This continuous sheet-like mesentery extends from the uterine artery superiorly to the point at which the vagina fuses with the LA below as well as fanning laterally.\textsuperscript{91} Subsequently, the fascia is intimately associated with the pelvic organs as well as the second layer of the pelvic floor, the LA. The LA is a muscle made up of several smaller muscles that function as a group (Figure 2.2).\textsuperscript{90} The iliococcygeal and coccygeal portions form a horizontal shelf or hammock that spans from one pelvic sidewall to the other, attaching laterally to the ischial spines and arcus tendineus fascia. The pubococcygeus arises from the pubic bone on either side and extends into a sling or U-shape around the posterior rectum, attaching to the walls of the vagina, urethra, and rectum.\textsuperscript{91} The opening between the LA through which the urethra, vagina, and rectum pass is the urogenital hiatus. The urogenital hiatus is supported by the pubic bones and LA anteriorly and by the perineal membrane and external anal sphincter posteriorly.\textsuperscript{91} The perineal membrane is a dense triangular membrane located below the LA with a
central opening through which the vagina and urethra pass. The final member of the third layer is the external anal sphincter.

The anatomy of the continence system can be organized into those structures that provide normal support to the lower urinary tract, and those that determine urethral closure force. The structures providing normal support include the 3 layers of the pelvic floor discussed previously. Structures that determine urethral closure force include the internal and external urethral sphincters and mucosal vasculature. The continence system works to maintain closure of the urethral lumen. At the vesical neck, the lumen is held closed by the trigonal ring and detrusor loop muscles which are smooth, involuntary muscles controlled by alpha-adrenergic receptors of the sympathetic nervous system.
During bladder storage, activation of the sympathetic nervous system increases the tonic activity or the internal urethral sphincter to assist in preventing urine leakage. The external urethral sphincter encircles the urethra in its midportion and distally the fibers diverge to insert in the walls of the vagina and the perineal membrane. The external urethral sphincter is constantly active promoting closure of the urethral lumen.\(^9\)

2.2.2 Neurophysiologic

Urinary continence is maintained by an intimate relationship involving anatomical support as well as neurophysiology. The lower urinary tract is innervated by 3 sets of peripheral nerves: pelvic parasympathetic nerves (S2-S4 segments) which excite the bladder; lumbar sympathetic nerves which inhibit the bladder and excite the internal urethral sphincter; and the pudendal nerves which excite the external urethral sphincter and pelvic floor muscles.\(^9\) As the bladder fills with urine, there is little change in the intravesical pressure due to viscoelastic properties of the bladder smooth muscles. As filling continues, the \(\beta\)-receptors in the body of the bladder (causing relaxation) and the \(\alpha\)-receptors in the bladder neck (causing contraction) are stimulated. This sympathetic stimulation also inhibits the parasympathetic nerves to prevent excitation of the bladder. As bladder filling progresses, somatic discharge to the pudendal nerve increases. This leads to increased activity in the external urethral sphincter and effective urethral closure.\(^9\)

Voiding is initiated by relaxation of the urethral sphincters followed by bladder contractions. When the bladder contracts, there is decreased \(\alpha\)-adrenergic stimulation of the bladder neck which promotes a funnel appearance of the bladder neck. The bladder
contraction is divided into 2 phases: a short, rapid rise in intravesical pressure and a second prolonged period of maintained pressure in which the bladder empties. Voiding involves coordination of parasympathetic efferent stimulation of the bladder, inhibition of sympathetic outflow, and inhibition of pudendal somatic outflow to the external urethral sphincter.92

2.3 Pathophysiology of SUI

The main anatomic hypotheses for development of SUI include loss of structural support and the hammock hypothesis.9 Supportive structures to the bladder neck and urethra are necessary to maintain urethral closure pressure. Intact attachments of the suburethral fascia to the fascia of the arcus tendineus and the LA construct the firm shelf that remains stable when faced with increased forces generated by a cough or sneeze.90 Disruption to this shelf, such as weakness to LA or damage to fascial attachments could result in UI. Aging and childbirth injury are the main etiological factors for LA weakness. When the LA is weak, the urethra is shifted to a lower, more dependent position. Thus, increased intra-abdominal pressure during a cough or sneeze is then transmitted unequally to the bladder and urethra. Greater pressure is absorbed by the bladder, bladder pressure exceeds urethral pressure, and urine leakage occurs.9

In the hammock hypothesis, the position of the urethra remains constant but there is decreased compression of the pelvic floor muscles and fascia supporting the urethra. During anatomic dissection, DeLancey reported that the urethra lies on a supportive layer comprised of endopelvic fascia and the anterior vaginal wall. Stability of the layer is gained via lateral attachment to the arcus tendineus fascia pelvis and levator ani muscle.
In an intact support system, intra-abdominal pressure pushes the urethra against the hammock-like supportive layer and the urethral lumen closes, not allowing urine to pass. However, if the supportive layer is not intact, the lumen will not close completely, resulting in urine leakage.\textsuperscript{10}

The main neural hypothesis for development of SUI is pudendal nerve injury. The pudendal nerve innervates the external urethral sphincter. Injury to the nerve presumably causes denervation and dysfunction of the urethra including decreased urethral resistance and SUI.\textsuperscript{9} Damage to the pudendal nerve is associated with recent vaginal delivery and SUI. In a study of pregnant women, vaginal delivery resulted in prolonged pudendal nerve terminal motor latencies in 89/128 women.\textsuperscript{93} It has been suggested that pudendal nerve damage persists over time. Significantly higher pudendal nerve terminal latencies have been observed in multiparous women with vaginal births both 48 hours and 5 years after delivery compared with nulliparous controls. Moreover, 35\% of these women had developed SUI over the 5 year period.\textsuperscript{94}

2.4 Risk Factors for SUI

2.4.1 Childbirth

Considering that loss of structural support is a main etiological factor in SUI, it is not surprising that parity is associated with SUI. Waetjen and colleagues reported that childbearing women were nearly twice as likely to report SUI compared to nulliparous women (OR 1.91; 95\% CI 1.31-2.79).\textsuperscript{54} Minassian demonstrated that parity was a significant independent risk factor for moderate and severe SUI. Women with moderate and severe SUI were 2.7 (adjusted OR 2.79; 95\% CI 1.48-5.29 for moderate SUI and
adjusted OR 2.74; 95% CI 1.41-5.31 for severe SUI) times more likely to report history of childbirth compared to women without incontinence.\textsuperscript{48} Furthermore, women who have delivered more than one child are at higher risk for SUI than women who delivered only one child. Schytt and colleagues reported a higher risk for SUI in multiparous than in primiparous women (RR 1.3; 95% CI 1.1-1.5).\textsuperscript{53} Similarly, Pregazzi and colleagues reported that the prevalence of SUI in multiparous women was significantly higher than primiparous women (20.25% versus 8.18%, P=0.0001).\textsuperscript{51}

Regarding mode of delivery, there is an increase risk for SUI with vaginal delivery, but a cesarean section does not completely protect against UI. Schytt\textsuperscript{53} and Rortveit\textsuperscript{95} reported that women having a vaginal delivery were two times more likely to report SUI compared to those who delivered via cesarean section (RR 2.2; 95% CI 1.6-3.1\textsuperscript{53} and OR 2.4; 95% CI 1.7-3.2\textsuperscript{95} respectively). However, in Rortveit’s and Schytt’s studies, 7% and 10% of the women who delivered by cesarean section reported SUI respectively. The presence of SUI in the absence of the mechanical trauma of vaginal delivery suggests that other factors during pregnancy may contribute to the development of SUI and those with cesarean delivery are also at risk for SUI. Borello-France reported that women who delivered by cesarean section had similar prevalence rates for SUI compared to those with vaginal births at both 6 weeks and 6 months post-partum.\textsuperscript{12} When compared to no deliveries, both vaginal deliveries and cesarean sections were associated with higher rates of SUI (OR 3.0; 95% CI 2.5-3.5 and OR 1.4; 95% CI 1.0-2.0 respectively) in the age-adjusted analysis of 15,307 women participating in the EPINCONT (Epidemiology of Incontinence in the Country of Nord-Trondelag) study.\textsuperscript{51}
Consequently, it appears that women who have had vaginal deliveries or women who have had cesarean sections are at risk for SUI.

2.4.2 Age

Although prevalence of any UI increases with age, the trend varies in regard to type of UI. In a national survey of a representative sample of US women, Minassian, Walter, and Wood reported that prevalence of SUI peaked in the fifth decade of life and gradually decreased with older age in women.\(^48\) This is similar to Hannestad and colleagues who demonstrated that SUI symptoms were highest among women between 25 and 49 years of age, with subsequent relative decrease with increasing age.\(^47\) Minassian also investigated risk factors separately for women with mild, moderate, and severe UI, where severity was defined by frequency of incontinent episodes. For those with moderate SUI, age was a significant risk factor from age 40+.\(^48\) Hannestad reported that among those with severe SUI, severity increased with age from 10% of women aged 25-44 reporting severe SUI compared to 15% and 33% reporting severe symptoms in age groups 45-59 and 60+, respectively.\(^47\)

2.4.3 Decreased Collagen & Decreased Elasticity

It is believed that dysfunction of connective tissue in the endopelvic fascia or pelvic ligaments may lead to loss of structural support of the pelvic organs, and subsequently SUI. Connective tissue is comprised of collagen and elastin fibers, ground substance, and cellular substances. Collagen primarily provides strength, but may also provide some flexibility due to collagen fiber arrangement. Elastin weaves in and out of the collagen
fibers and primarily provides flexibility. Elastin fibers follow the direction of stretch in tissues and once the stretching force is removed, assume their original shape.

Investigators have demonstrated altered morphological features and decreased collagen content in women with SUI. FitzGerald and colleagues demonstrated frequent alterations in the ultrastructural morphological characteristics of urethral collagen in 9 of the 15 women with SUI consenting to urethral needle biopsy specimens. The collagen patterns differed from those observed in continent women. Observations included an obscured pattern where collagen fibrils were difficult to visualize, a dense pattern in which collagen fibrils appeared to be collapsed on one another, and a degenerative pattern in which collagen fibrils were rare. Differences in cervical collagen between continent and incontinent women has also been reported. Wong and colleagues compared cervical collagen from women with pelvic organ prolapse with and without SUI (who underwent hysterectomy) to that from a control group. Women with pelvic organ prolapse with and without SUI were found to have significantly less cervical collagen than their unaffected counterparts.

2.4.4 Race/Ethnicity

The few studies that have compared the prevalence of UI in women of different ethnicities have demonstrated an increased risk for Caucasian women. Sampselle and colleagues reported that Caucasian women were more likely to report UI compared to African American, Chinese, Hispanic, and Japanese women in cross-sectional study of 3302 women. Using prevalence in Caucasian women as the reference, women of other ethnicities were approximately two to three times less likely to report any incontinence.
When taking account subsets of UI, there appears to be a greater association between Caucasian race and SUI. After adjusting for age, BMI, parity, hormone replacement, smoking, and medical history, a cross-sectional study of 2875 women found that Caucasian women had an increased risk for SUI compared to African American women.\(^{48}\) Additionally, a study of 2763 postmenopausal women found that Caucasian women had a threefold greater prevalence of SUI than postmenopausal black women (OR 2.9, 95% CI 1.6-5.0).\(^{59}\)

2.4.5 Obesity

Many studies have found that obesity is associated with increasing rates of SUI. In a study of postmenopausal women, Brown and colleagues reported that a higher body mass index (OR 1.1 per 5 units; CI 1.01-1.27) was associated with increased prevalence of SUI.\(^{59}\) Additional studies, cross-sectional and longitudinal, have demonstrated an association with obesity and SUI. In a large study of 12570 women, women who were overweight (BMI >25-30) or obese (BMI >30) had a significantly higher risk for SUI (OR 1.2; 95% CI 1.0-1.5 and OR 1.7; 95% CI 1.4-2.1 respectively). Women who had an acceptable BMI at baseline but became obese one year later were 2.3 times more likely to develop SUI.\(^{50}\) Similarly, a 1-yr longitudinal study of 7046 UK women found, those who became obese (BMI >30) in 1-yr were 1.74 times more likely to develop have SUI than those with acceptable weight.\(^{57}\) Interestingly, this study also found the absence of self-reported BMI a significant risk factor for the onset of SUI.\(^{57}\)

A link between obesity and SUI symptom severity has also been reported. After adjusting for age, ethnicity, parity, hormone replacement, smoking, and medical history,
women who were obese were nearly twice as likely to have moderate SUI (adjusted OR 1.93; 95% CI 1.06-3.51) and over 4 times as likely to have severe SUI (OR 4.22; 95% CI 2.28-7.81) compared to women of normal body mass index.\textsuperscript{48}

2.4.6 Smoking, Chronic Cough, Respiratory Disease

It is postulated that respiratory disease, chronic coughing, and smoking may cause damage to the urethral and bladder supportive structures, causing UI. Two large epidemiologic studies have demonstrated that older women with chronic obstructive pulmonary disease\textsuperscript{98} and respiratory symptoms (coughing and sneezing)\textsuperscript{60} have a significantly higher risk for UI. This association has also been described in younger women, specifically in regard to SUI. After controlling for age, parity, menopausal status, waist circumference, medical history, and surgeries, Zhu and colleagues reported that history of respiratory disease was a significant risk factor for SUI (OR 1.34; 95% CI 1.03-1.75) in younger women (mean age = 45yrs).\textsuperscript{61} Additionally, a prospective cohort study of older women (mean age of 59.5) found breathlessness significantly associated with prevalent SUI (OR 1.4; 95% CI 1.1-1.9).\textsuperscript{50}

2.4.7 Pelvic Surgery

The prevalence of women with pelvic surgery is significantly higher in women with UI compared to continent women.\textsuperscript{60} An association between pelvic surgery and SUI is not surprising based on the premise that surgical insult to the pelvis may decrease pelvic organ support. Pelvic surgery may include procedures such as hysterectomy, radical pelvic surgery, vaginal surgery, perineal trauma surgery, or radiation.\textsuperscript{62}
Hysterectomy may or may not be associated specifically with SUI. Minassian reported that a history of hysterectomy was independent risk factor for severe SUI (OR 1.90, CI 1.07-3.37) in women (mean age = 50.8 years). However, van der Vaart and colleagues found an association between hysterectomy and prevalence and incidence of UUI, not SUI. Exposure to pelvic surgery regardless of type of surgery may increase risk for developing SUI. After controlling for age, parity, menopausal status, waist circumference, medical history, and gynecological events, women with pelvic surgery were at significantly higher risk for SUI (OR 1.28; 95% CI 1.14-1.43) compared to those without pelvic surgery.

2.4.8 Chronic Constipation

Constipation has been linked as a possible etiological cause of SUI. In those with chronic constipation, prolonged defecatory straining has been shown to contribute to progressive neuropathy and dysfunction. Diokno and colleagues reported that older women, aged 60-80+, with UI were significantly more likely to have constipation than women without UI. Specifically, it appears that constipation may be more of a risk for SUI. In a cohort study of 2390 parous women, those with post-partum constipation were more likely to have SUI 1 year after childbirth. Moreover, in a large cross-sectional survey of 20,000 Chinese women, women with chronic constipation were at significantly higher risk for SUI (OR 1.17; 95% CI 1.02-1.34) after controlling for age, parity, menopausal status, waist circumference, medical history, and surgeries.
2.4.9 Carbonated Drinks

In a study of 7046 women, (median age = 58), those who drank carbonated drinks daily or more were significantly more likely to have SUI than those who drank them less than once per week. Women drinking carbonated drinks daily or more had a 2-fold increased risk for prevalent SUI (OR 2.10; 95% CI 1.57-2.81); and a 60% increased risk (OR 1.62; 95% CI 1.18-2.22) for developing SUI at the 1-year follow-up.\textsuperscript{57}

2.5 Pathophysiology of OAB and UUI

OAB is considered a symptom syndrome characterized as urgency with or without urge incontinence, as well as frequency and nocturia.\textsuperscript{27} Urodynamically, OAB is defined as involuntary detrusor contractions during the filling phase.\textsuperscript{9} There are two main pathological etiologies of OAB: neurogenic and non-neurogenic causes. Neurogenic OAB is associated with the effects on neurologic control by a variety of conditions including spinal cord injury, stroke, Parkinson’s disease, Alzheimer disease, diabetes, spinal stenosis, and multiple sclerosis or similar demyelinating disease.\textsuperscript{27} Non-neurogenic causes of OAB include infection, interstitial cystitis, urolithiasis, bladder and urethral changes associated with age, bladder outlet obstruction, and pelvic floor disorders.\textsuperscript{9}

The bladder itself undergoes structural changes with age that may contribute to overactivity.\textsuperscript{9} Elbadawi, Yalla, and Resnick examined detrusor biopsy specimens by electron microscopy from women and men ages 65-96 years. They found structural changes associated with age, including excessive deposits of elastic fibers between widely separated muscle cells which may contribute to increased bladder distensibility.
and chronic retention. Additionally, older women have decreased urethral closure pressure and urogenital atrophy. DuBeau proposed that the decrease in number and density of urethral striated muscle fibers with age may contribute to OAB.

Bladder outlet obstruction in women is due to advanced prolapse or increased outflow resistance following continence surgery. Ultimately, the outlet obstruction affects neurological activity by increasing the sensitivity of the detrusor muscle to acetylcholine, which binds to detrusor muscle cells to facilitate detrusor contraction. Subsequently, the detrusor is in a highly-excitable state resulting in involuntary detrusor contractions. Finally, there is an inverse relationship between activation of the pelvic floor muscles and the detrusor. Afferent activity from the pelvic floor muscles and the urethra causes quieting of the detrusor during bladder filling. If afferent activity is decreased due to pelvic floor muscle laxity, detrusor contractions may result.

2.6 Risk Factors for OAB
2.6.1 Age

Epidemiological studies have reported an association between age and OAB. After adjusting for ethnicity, body mass index, medical history, parity, and smoking, age has been shown to be a significant independent risk factor for women with UUI. In a large cohort study of 12,570 women, those with OAB were more likely to be older (OR 1.1; 95% CI 1.0, 1.2); and for every 10-year increase in a woman’s age, the risk for developing OAB increased by 1.2 (OR 1.2; 95% CI 1.1, 1.3). A different study reported that for every 5-year increase in age, a postmenopausal woman has a 1.2 increased risk for onset UUI (OR 1.2, 95% CI 1.1-1.3). Moreover, the severity of UUI
appears to increase with age. Hannestad reported that among women with severe UUI, 8% were 25-44 years of age, 18% were 45-59 years of age, and 45% 60+ years of age.47

2.6.2 Hysterectomy

According to a systematic review by Brown and colleagues, the odds of developing any UI after hysterectomy is about 40% higher compared to women who have not undergone hysterectomy.100 The literature is unclear as to whether there is a direct connection between hysterectomy and SUI, as SUI appears to be linked to pelvic surgeries and not specifically hysterectomy. (See section 2.4.7). However, an association exists between hysterectomy and UUI. In a cross-sectional study of 2,322 women aged 35-70, women with a hysterectomy reported a significantly higher rate of any UUI as well as bothersome UUI (P<0.0001) compared to those not having a hysterectomy. After adjusting for age, parity, and educational level, women with a hysterectomy had nearly a 2-fold higher risk for any UUI (OR 1.93; 95%CI 1.40-2.63) and over a 2.5-fold risk for bothersome UUI (OR 2.63; 95%CI 1.39-4.41) compared to those without a hysterectomy.63

2.6.3 Neurological conditions

Women with neurological conditions also have an increased risk for UI as certain neurological disorders interfere with the normal tonic inhibitory pathways controlling micturition.9 Specific neurological conditions that may interfere with these pathways include stroke, Parkinson’s, brain tumors, traumatic brain injury, Alzheimer’s dementia, cerebral palsy, and multiple sclerosis.9 Diokno and colleagues demonstrated that the
percentage of women, aged 60 to 80+, with diseases of nerves and/or muscles was significantly higher in women with UI compared to continent women.\textsuperscript{60}

Specifically, bladder dysfunction is a very common problem in those with multiple sclerosis (MS), with as high as 84\% of persons with MS reporting bladder symptoms.\textsuperscript{101} The most common underlying bladder abnormality in persons with MS is neurogenic detrusor overactivity, affecting 37-99\% of those with bladder dysfunction.\textsuperscript{102} Neurogenic detrusor overactivity refers to a voiding dysfunction due to neurologic damage from trauma or disease. Irritative symptoms associated with neurogenic detrusor overactivity include urgency to urinate, frequent urination, nocturia, and urge incontinence. Patients with MS may also demonstrate detrusor-sphincter dyssynergia in which there is incomplete bladder emptying because the external urethral sphincter does not relax during detrusor contraction. Patients with detrusor-sphincter dyssynergia experience obstructive voiding symptoms of urinary hesitancy and interrupted urinary flow as well as urinary retention.\textsuperscript{103, 104} Obstructive symptoms affect between 34-79\% of patients with MS.\textsuperscript{102} Additionally, approximately 51\% of women with MS experience both detrusor overactivity and detrusor-sphincter dyssynergia demonstrating symptoms both of failure to store and failure to empty.\textsuperscript{102}

2.6.4 Caffeine & Carbonated Drinks

Arya, Myers, and Jackson reported an association between high caffeine intake and OAB.\textsuperscript{56} Women with urodynamically confirmed OAB consumed significantly more caffeine (484 mg/day) than women without OAB (194 mg/day, p=0.002). After controlling for age and smoking, women with high caffeine intake (> 400 mg/day) were
2.4 times (OR 2.4, 95% CI 1.1-6.5) more likely to have OAB than women with minimal caffeine intake (<100 mg/day). To put the amount of caffeine in perspective, a 5 ounce cup of brewed coffee with caffeine has 128 mg, a 8-oz glass of iced tea has 47 mg of caffeine, and a 8-oz glass of cola soft drink has 25 mg.

Women consuming just 2-6 carbonated beverages per week are at increased risk for OAB. When examining the impact of carbonated beverages alone, Dallosso and colleagues found that women who consumed 2-6 carbonated beverages per week had nearly a 50% increased risk for onset OAB (OR 1.44; 95% CI 1.12-1.85) compared to those consuming less than one beverage per week. Risk increased to 70% for women consuming at least one carbonated beverage daily. When considering carbonated beverages along with other potential risk factors, women consuming at least one carbonated beverage daily increased their risk for onset OAB 1.4 times (OR 1.41; 95% CI 1.02-1.95) compared to those drinking less than one such beverage per week.

2.6.5 Lifestyle Habits: Smoking and Obesity

Women who smoke are also at higher risk for OAB. Data suggests that women with urodynamically diagnosed OAB were significantly more likely to be current smokers compared to those without OAB (p<0.04). Those who were current smokers were nearly twice (OR 1.9; CI 1.0-3.8) as likely to demonstrate OAB compared to those that never smoked. Similarly, Dallosso and colleagues reported that current smokers were 1.44 times more likely to develop OAB than nonsmokers (OR 1.44, 95% CI 1.05-1.98).
Obesity is significantly associated with an increased risk of OAB. Women that are obese have a significantly increased risk of onset OAB (OR 1.46, 95% CI 1.02-2.09) compared to those who are of acceptable weight. Waetjen and colleagues reported that an increased body mass index was a significant risk factor for prevalent and incident UUI. For every unit increase in BMI, the prevalent and incident risk was 1.03 (adjusted OR 1.03; 95% CI 1.00-1.60).

2.6.6 Functional Status: Decreased mobility, decreased ADLS, & Arthritis

Mobility issues vary significantly between incontinent and continent elderly women. Goode and colleagues investigated risk factors for UI over a 3 year period in older women (mean age = 75 years). Participants completed an in-home interview and in-home physical tests. Women with a slower time for 5 chair stands were at a significantly higher risk (OR 1.3; 95% CI 1.0-1.6) for developing UI. The status of mobility may possibly impact women with UUI more than SUI. In another study, older women (aged 60 to 80+) with UUI reported more assistive device use (wheelchair, cane, crutches, or walker) compared to those with SUI or mixed UI.

Logically, co-morbidities affecting mobility may also have an impact on continence status. Diokno and colleagues demonstrated that the percentage of women, aged 60 to 80+, with a medical diagnosis of arthritis was significantly higher in women with UI compared to continent women. With respect to type of UI, arthritis may have more of an association on UUI than SUI. In a study of women with a median age of 50.8 years, those who reported having arthritis were 2.32 times (adjusted OR 2.32; 95% CI
1.17-4.63) more likely to report severe UUI compared to women without incontinence. Such an increased risk was not apparent for SUI.\(^4^8\)

### 2.7 Non-specific risk factors for UI

#### 2.7.1 Pelvic Organ Prolapse

Pelvic organ prolapse (POP) is defined as the descent of the apex of the vagina or cervix (or vaginal vault after hysterectomy), anterior vaginal wall, or posterior vaginal wall; and can occur in association with UI.\(^1\) As the prolapse advances, organs can protrude outside the vaginal canal. Women with POP may describe a feeling of a lump, low backache, heaviness, dragging sensation, or the need to digitally replace the prolapse to void or defecate.\(^1\) The inter-relation between POP and pelvic floor symptoms can be generally explained by the following scenarios:\(^1^0^6\)

1. POP is the direct cause of the symptom (i.e. vaginal bulging, pelvic pressure).
2. Loss of vaginal support contributes dysfunction of nearby organs (i.e. SUI in women with anterior vaginal prolapse).
3. A common pathogenic mechanism is shared by POP and the condition causing the symptoms (i.e. muscular injury and pelvic floor denervation after vaginal delivery as a cause of prolapse and fecal incontinence).
4. The symptom is a contributor to the development of POP (i.e. chronic straining to defecate).
5. There is no causal relationship between vaginal prolapse and the condition causing the symptoms, but both conditions are common and are seen together in a subset of women (i.e. chronic low back pain).
Normal pelvic organ support depends upon the integrity of the LA, supportive connective tissue (endopelvic fascia), and normal innervations.\textsuperscript{91} If the LA functions normally, the urogenital hiatus narrows and the connective tissue is under minimal tension, able to stabilize the organs in their position above the LA. If the LA relaxes or is damaged, the urogenital hiatus opens and the vagina must be held in place by the fascia. Although the fascia can sustain the load for short periods of time, the connective tissue eventually fails, resulting in prolapse.\textsuperscript{91} Loss of connective tissue support\textsuperscript{107} and/or LA function\textsuperscript{91} have been proposed as mechanisms for POP.

Urinary symptoms are common among women with POP. The anterior vaginal wall supports the bladder and urethra and loss of this support may lead to urethral hypermobility which may contribute to SUI.\textsuperscript{106} Mechanical obstruction of the urethra may contribute to UUI; and the obstruction may be due to either anterior or posterior vaginal prolapse. Anterior vaginal prolapse may cause the urethra to kink, while posterior vaginal prolapse may cause direct urethral compression rather than kinking.\textsuperscript{106} Over time, the obstruction may result in structural changes of the bladder or urethra leading to OAB.\textsuperscript{9} Typically, when the prolapse is mild, SUI coexists. Conversely, when the prolapse extends beyond the hymen, women are less likely to report SUI but more likely to report UUI as the prolapse is obstructing the urethra. In a study of 237 women with symptomatic POP, a significant inverse correlation was observed between the severity of prolapse and SUI. Additionally, as prolapse worsened, direct correlations were noted with symptoms indicative of UUI including hesitancy, intermittent flow, and difficulty voiding.\textsuperscript{30}
2.7.2 Medications

Older women are more likely to take medications that may cause UI. Approximately 60% of older men and women take at least one prescribed medication. About one third of older adults take more than five prescribed medications, and many also take over-the-counter and naturopathic/herbal drugs. Medication that affects cognition, mobility, fluid balance, coughing, detrusor contractility, or sphincter function can impair continence. Several medications are associated with UI in women including: diuretics, estrogen, benzodiazepine, tranquilizers, antidepressants, hypnotics, laxatives, and antibiotics. Medications may impair detrusor contractility (anticholinergics, narcotics, calcium channel blockers, nonsteroidal anti-inflammatory agents), cause urinary retention (anticholinergics, narcotics, calcium channel blockers), or promote nocturia from pedal edema (calcium channel blockers, gabapentin and pregabalin, thiazolidinediones, nonsteroidal anti-inflammatory agents).

Medications that may promote SUI symptoms include ACE inhibitors and α-blockers. ACE inhibitors may cause excessive coughing, while α-blockers can cause sphincter relaxation. Medications that may lead to UUI symptoms include: β-blockers, which irritate the bladder; cholinergics and diuretics which promote high urine flow; and sedatives-hypnotics, antipsychotics, narcotics, and alcohol, which depress the central nervous system.

2.7.3 Fluid Intake

The amount, timing, and type of beverages consumed may increase a woman’s risk for UI. Some women believe that drinking excessive amounts of water will promote
health and weight loss. Unfortunately, this behavior may lead to polyuria and exacerbated urinary frequency and urgency. Other women may limit fluid intake to decrease their bladder symptoms.\textsuperscript{62} Yet, dehydration leads to concentrated urine within the bladder and low urine production. Low urine volume will limit bladder expansion, and over a period of time can lead to reduced bladder capacity, decreased detrusor tone, and increased bladder wall thickness.\textsuperscript{109} These structural changes may contribute to further continence problems. Additionally, low fluid intake may contribute to urinary tract infection and fecal impaction which may irritate the detrusor causing urgency and frequency. Concentrated urine can aggravate the bladder mucosa and trigone and lead to urgency and frequency. It is recommended that patients avoid extreme fluid intake. Instead it is recommend that adults consume 30mL per kg of body weight (or 0.5 oz per lb of body weight).\textsuperscript{62}

The timing of fluid intake is crucial for women with nocturia. Nocturia is the complaint of waking at night one or more times to void.\textsuperscript{1} It affects up to 90\% of older women by age 80.\textsuperscript{99} Older women have delayed fluid excretion, and tend to void later in the day, evening, and night.\textsuperscript{110} 50\% or more of their 24-hour urine output may occur during the night.\textsuperscript{99} Subsequently, women consuming most of their fluids later in the day may be more prone to UI episodes in the evening or night. Regarding type of fluid, carbonated drinks increase the risk of SUI\textsuperscript{57} and OAB,\textsuperscript{57} while caffeine increases the risk for OAB.\textsuperscript{56}
2.7.4 Fecal Incontinence

Women with fecal incontinence (FI) are at a higher risk for UI. When controlled for age, parity, antidepressant use, and previous hysterectomy, FI has been shown to be independently associated with UI (OR 6.3; 95% CI 2.6-19.1) in women with POP or UI.\textsuperscript{33} Markland and colleagues demonstrated that in overweight and obese women (mean age = 53 years), FI was independently associated with increased urinary tract symptoms.\textsuperscript{32} Conversely, women having more frequent UUI symptoms have increased risk (OR 1.2; 95% CI 1.0-1.3) of FI.\textsuperscript{64} Women with both FI and UUI scored significantly lower on the Urinary Distress Inventory compared to women who have isolated UUI\textsuperscript{64} indicating greater symptom impact. This finding gives strength to the presumption that dual incontinence may have more impact on urinary distress than having UI alone.

2.7.5 Pelvic Pain

According to the American College of Obstetricians and Gynecologists, chronic pelvic pain (CPP) is a descriptive diagnosis that refers to pain of 6 months or more that is localized to the anatomic pelvis, anterior abdominal wall at or below the umbilicus, the lumbosacral back, or the buttocks and is of sufficient severity to cause functional disability or lead to medical care.\textsuperscript{111} After controlling for age, parity, alcohol consumption, waist circumference, constipation, menopausal status, and medical history, chronic pelvic pain was found a significant risk factor (OR 1.53; 95% CI 1.36-1.72) for SUI in a large cross-sectional survey of 20,000 Chinese women.\textsuperscript{61} In a smaller cross-sectional survey (319 Iranian women, mean age = 33.8), women with pelvic pain reported
statistically significant higher rates of SUI and OAB symptoms (urgency, frequency) than women without pelvic pain.\textsuperscript{66}

2.8 Co-existing pelvic symptoms

2.8.1 Dual Incontinence and Pelvic Organ Prolapse (POP)

A varying proportion of women will experience UI, FI, and/or POP. Jackson and colleagues found that among 247 women with either UI or POP, coexisting FI occurred in 31\% and 7\% of those UI and with POP, respectively.\textsuperscript{31} Ellerkmann and co-workers reported that 86\% of women with POP had urinary urgency and frequency, while 31\% reported co-existing FI.\textsuperscript{30} Finally, Markland reported that presence of dual incontinence (UI and FI) was 18\% in women (mean age = 57) participating in a treatment study for UUI.\textsuperscript{64}

The rationale for why pelvic symptoms co-exist is complex. These conditions are associated with damage to the pelvic floor either through mechanical disruption of connective tissue, or through direct and secondary muscle or nerve injury. Because the conditions share common etiologies, they also share many common risk factors.\textsuperscript{46} Vaginal delivery, POP, higher body mass index, and UUI symptoms have been reported as significant risk factors for dual incontinence (DI).\textsuperscript{64} Ng and colleagues reported similar findings, identifying vaginal delivery, POP, and urinary symptoms to be predictors of FI in women (mean age 45) with SUI, OAB, or mixed incontinence. Difficulties in ADLS, depressive symptoms, chronic diarrhea, and higher co morbidity scores have been correlated with DI older women.\textsuperscript{112}
2.8.2 Constipation

Prevalence rates of constipation in women with urinary symptoms are much higher than in the general population, with typical U.S prevalence rates ranging from 15-19%. In a study of 302 women (mean age = 60 yrs) with either POP or UI, 36% had constipation as defined by the Rome II criteria, a symptom-based questionnaire developed by clinical consensus. Similarly, Ng and colleagues reported 31.5% of women with SUI or OAB (mean age = 45 yrs) experienced co-existing constipation defined as ≤3 bowel movements per week. The literature linking constipation as a co-existing symptom is based on the premise that straining during defecation may lead to pudendal nerve damage and subsequent denervation of the pelvic floor. Such etiologies have also been implicated in UI, FI, and POP.

2.8.3 Sexual Dysfunction

Women with UI or lower urinary tract symptoms (LUTS) have a higher rate of sexual dysfunction compared to the general, healthy female population without urinary symptoms. Women aged 19-66 years with UI or LUTS have been found to score lower on the Female Sexual Function Index when compared to healthy controls. Specifically, women with UI or LUTS had lower scores for items assessing sexual desire, lubrication, and sexual satisfaction as well as significantly higher scores for sexual pain. Moreover, in a large national survey of 1749 women aged 18-59 years, those with urinary tract symptoms had a 4-fold higher risk for sexual arousal dysfunction (OR 4.20; 95% CI 2.75-5.89) and a 7-fold risk for sexual pain with intercourse (OR 7.61; 95% CI 4.06-14.26) after adjusting for health and lifestyle factors, social status, and sexual
experience. Pain with sexual intercourse, termed dyspareunia, can be classified as a subset of chronic pelvic pain provided that the patient has symptoms for ≥6 months.

2.8.4 Chronic Pelvic Pain

In women, several causes of chronic pelvic pain (CPP) are recognized, and many disorders of the reproductive tract, urological organs, and gastrointestinal, musculoskeletal, and psychological systems may be associated with CPP. The most frequent causes of CPP include interstitial cystitis,\textsuperscript{116-118} irritable bowel syndrome,\textsuperscript{116,117} post-operative adhesions,\textsuperscript{117} pelvic varices,\textsuperscript{117} vulvodynia\textsuperscript{116,118} and musculoskeletal issues.\textsuperscript{118} There is controversy whether to include endometriosis as a cause of CPP as most consider endometriosis to be its own entity.\textsuperscript{117} Endometriosis is the presence of extrauterine endometrial tissue and usually presents with symptoms concurrent with the menstrual cycle.\textsuperscript{116} This condition affects other organ systems causing bowel motility issues, bladder dysfunction, and pain. Unlike other causes of CPP, endometriosis can be treated effectively with drugs, surgery, or both.\textsuperscript{117}

2.8.4.1 Sources of CPP

Interstitial cystitis: According to the National Institute of Diabetes, Digestive and Kidney diseases, interstitial cystitis is pain, pressure, or discomfort of the bladder and the surrounding pelvic region. Symptoms include urinary urgency and/or urinary frequency in addition to pressure, discomfort, or tenderness in the bladder area.\textsuperscript{119} The National Institute of Diabetes, Digestive and Kidney diseases research-related definition of interstitial cystitis has inclusion and exclusion criteria based on cystoscopic, urodynamic,
and other laboratory tests.\textsuperscript{116} Because of this strict definition, there is acknowledgement of a more generic painful bladder syndrome which simply refers to painful urinary symptoms. In interstitial cystitis/painful bladder syndrome, the bladder wall may become irritated causing scarring and glomerulations. People with severe cases of interstitial cystitis/painful bladder syndrome may urinate up to 60 times a day and complain of nocturia.\textsuperscript{119} In addition, about 10-15\% of patients with interstitial cystitis/painful bladder syndrome have OAB.\textsuperscript{117}

Irritable bowel syndrome: Irritable bowel syndrome is a disorder in which abdominal discomfort or pain is associated with defecation or altered bowel habits. Approximately 35\% of women with CPP have irritable bowel syndrome.\textsuperscript{120} The diagnosis is based upon the Rome II criteria. The patient must experience over the past 12 weeks abdominal discomfort or pain that has at least two out of the three following features: relieved with defecation, onset associated with a change in frequency of stool, and/or onset associated with a change in form (appearance) of stool.\textsuperscript{121} The suggested etiology of irritable bowel syndrome includes altered bowel motility, visceral hypersensitivity, and psychological factors. Pain may be produced from the visceral hypersensitivity of the intestinal wall and/or degranulation of activated mast cells\textsuperscript{117} whose contents aggravates nociceptors via the inflammatory response. Additionally, the overdistention of the colon wall by bowel content and gas may stimulate stretch receptors.\textsuperscript{117}

Post-operative adhesions: Adhesions in the pelvis may be caused by acute or chronic inflammatory disorders (i.e. tubo-ovarian infections and endometriosis) or a physico-chemical trauma such as surgery. The role of adhesions in CPP is controversial and although adhesions are found in 25-50\% of women with CPP, it is unclear whether the
association is causal. It has been postulated that intraperitoneal adhesions may cause pain with activities such as running or sexual intercourse due to the stretching of the peritoneum or visceral serosa at the adhesion’s attachment site. When the peritoneum is compressed or stretched, nociceptors in the adhesion become activated potentially signaling pain. However, although adhesions contain nerve fibers, the presence of nerve fibers alone is not evidence of a causative role as pain perception requires a complex linking network.\textsuperscript{117}

Pelvic varices:\textsuperscript{117} Pelvic congestion syndrome is a myriad of pain symptoms associated with presence of ovarian and pelvic (internal iliac) varices and result in decreased function of the venous system. The pain related to pelvic congestion syndrome is possibly due to pelvic congestion, leading to dilation and stasis that aggravate the local inflammatory response. The etiology of pelvic congestion syndrome is unknown but it is hypothesized that psychological, sexual, and genetic-biological factors may be related. Approximately 30\% of patients with CPP have pelvic varices as the source of their CPP, and an additional 12\% have pelvic varices in addition to other pelvic pathologies.\textsuperscript{117}

Patients with pelvic varices as the source of their CPP complain of a changing location of pain, congestive dysmenorrhea, deep dyspareニア and post-coital pain, and a dull chronic pain exacerbated after activities of pelvic engorgement including prolonged standing and working for many hours in a sitting position.\textsuperscript{117}

Vulvodynia: The International Society for the Study of Vulvar Disease defines vulvodynia as “chronic rawness, irritation, burning and soreness in the absence of abnormal finding except redness at times.”\textsuperscript{122} Two broad categories exist for further defining this condition: secondary and primary vulvodynia. Secondary vulvodynia is
pain that is due to an observable vulvar or vaginal lesion and include dermatological conditions which cause inflammation, ulceration, blisters, fissures and adhesions, and conditions that cause vaginitis. Primary vulvodynia is pain that is experienced in the absence of any observable vulvar pathology and may include neuropathic pain, referred pain, and introital dyspareunia in patients with a normal vulva. Women with vulvodynia may experience allodynia or hyperalgesia in conjunction with the symptoms of rawness, irritation, and burning. In women with neuropathic pain, it is postulated that injury to sensory nerves to the vulva (ilioinguinal and genitofemoral from L1-2) or to the pudendal nerve is the source of the condition. In women with referred pain to the vulva, it is postulated that the low back or bladder may be the primary source of the dysfunction. Additionally, women with vulvodynia may complain of frequency, urgency, and burning on urination due to alterations of sensation to nearby viscera.

Musculoskeletal issues

Trigger points: CPP can be due to the presence of active myofascial triggers points in the external and internal muscles of the pelvic region. Trigger points are focal points of tenderness found at multiple sites in a muscle and the fascia of muscle tissue. Trigger points typically have a clear and consistent referred pain pattern; arise in response to acute or chronic overload; cause increased muscle tension, weakness, and limited range of motion; and disrupt the proprioceptive, nociceptive, and autonomic functions of the affected areas. Trigger points in the anterior pelvis may refer pain to the vagina and can cause entry dyspareunia and pain in the perineal region. Trigger points in the deeper pelvic muscles (LA, obturator internus) can affect bladder and bowel function.
manually releasing trigger points in the pelvic floor muscles in patients with severe urinary urgency and frequency, Weiss reported an 83% reduction in symptoms.\textsuperscript{125}

Pelvic floor muscle dysfunction: Pelvic floor muscle dysfunction refers to hypotonicity or hypertonicity of the pelvic floor muscles (LA and coccygeus). Hypotonic dysfunction may be due to hormonal factors, mechanical damage, weakness and are generally associated with UI, FI, and POP.\textsuperscript{46} Bernstein demonstrated that women with urinary symptoms and subpubic pain had significantly less pelvic floor muscle activity when asked to contract their pelvic floor muscles compared to controls.\textsuperscript{126} This suggests that hypotonus of the pelvic floor muscles may play a role in pelvic pain. More commonly, hypertonus or spasm of the pelvic floor muscles may contribute to CPP and has been implicated in interstitial cystitis,\textsuperscript{125,127} dyspareunia,\textsuperscript{128} severe urgency and frequency with/without urethral pain,\textsuperscript{125} and vulvodynia.\textsuperscript{123} Women with interstitial cystitis and hypertonicity of the pelvic floor muscles who underwent physical therapy consisting of intravaginal massages using the Thiele technique reported significantly decreased symptoms, improved quality of life, and significantly decreased pelvic floor muscle hypertonicity when compared to pre-treatment scores.\textsuperscript{127} Similarly, 10 women with interstitial cystitis who received Thiele massage to hypertonic pelvic floor muscles demonstrated post-treatment decreased pelvic floor muscle tone as measured by surface electromyography.\textsuperscript{125} Although it is acknowledged that intravaginal palpation and surface electromyography are not the gold standard for measuring muscle tone, such investigations shed light that pelvic floor tone may play a crucial role in the pathophysiology of CPP. The relationship between hypertonicity and pain is not completely understood. In response to pain, a muscle may contract or guard to protect
against further injury thus contributing to the pain-spasm-pain cycle. Persistent muscle overactivity can lead to excessive activity of gamma efferent neurons (gamma gain) which may cause muscle spindles to become hyperactive and lead to adaptive shortening of surrounding fascial tissue. Thus, pelvic floor muscle dysfunction may be primary or secondary generators of nociceptive signals. Although their role is not clearly defined as causal, it is evident the PFM dysfunction should be considered when treating patients with CPP.

Low back pain: Low back pain (LBP) can be considered part of CPP if, according to the CPP definition, it is greater than 6 months in duration and of sufficient severity to cause functional disability or lead to medical care. Additionally, low back pathology can refer pain to the pelvic floor and should be considered in differential diagnosis of CPP. Eliasson reported an association of LBP and UI. In a cross-sectional study of 200 non-pregnant women seeking physical therapy for LBP, those with LBP reported significantly more UI (p<0.001) and more severe UI (p<0.001) than a reference group of women without LBP of comparable age and parity. Additionally, women with LBP were 3 times more likely to have UI compared to the reference group (nulliparous OR 3.1; 95% CI 1.8-5.6; parous OR 2.7; 95% CI 1.6-4.5). Interestingly, women with LBP were significantly less able to interrupt the urine flow than the reference group; and the inability to interrupt urine flow was a significant risk factor for UI (nulliparous OR 1.8; 95% CI 1.3-2.5; parous OR 3.8; 95% CI 2.7-5.7).

Hip Pain: Gender differences exist in the anatomy of the hip and pelvis. Specifically, the female pelvis is broader than men, and those women who have even broader pelvises may have greater hip range of motion. In addition, women are more likely to have...
developmental dysplasia of the hip which also may contribute to hypermobility. Based on orthopedic treatment principles, if hypermobility exists, there is a need to increase strength of the surrounding muscles (in this case the pelvis) to reduce the hypermobility. Additionally, there may be a component of hypomobility in surrounding structures (i.e. pelvic floor muscles) that may need to be addressed. Moreover, hip pathology may refer pain to the pelvic floor muscles and when determining the source of CPP, the hip joint should be considered as possible etiology.

Postural and Movement Considerations: Poor posture, such as exaggerated lumbar lordosis or thoracic kyphosis, or poor body mechanics may cause excessive loading on the spine, hip or pelvic floor muscles leading to CPP. Faulty posture may cause muscle weakness and deconditioning, and lead to muscle imbalances and development of trigger points and hypertonicity. Hodges and colleagues observed a connection between the pelvic floor muscles to both postural and respiratory functions. Using surface EMG, Hodges reported that pelvic floor muscle (PFM) activity increased in anticipation of arm movements designed to challenge postural stability. Furthermore, PFM s remain active during sustained postural tasks (in this case, repetitive arm movements). During quiet breathing in the standing position, PFM activity was significantly increased during expiration verses inspiration. Compared to quiet breathing, PFM activity increased during larger breaths, increased tidal volumes, and expiration. Hodges’ work is the first to provide evidence that the PFMs play a role in both postural and respiratory functions; and to give insight into the coordination of posture, continence, and respiration. Based on this evidence, it is possible that changes in postural stability or
respiratory patterns may contribute to increased demands on the PFM. However, more research is necessary to support this assumption.

2.9 Interventions for SUI

2.9.1 PFM exercise

One of the most frequent treatments for SUI is PFM exercises or contraction of the LA. The premise of this intervention is that a strong LA contraction will improve urethral closure and pelvic organ support. It is hypothesized that compression of the urethra by contraction of the PFM will stop urine leakage if the contraction is of sufficient force and properly timed. Miller and colleagues reported a significant increase in mean urethral closure pressure during a PFM contraction in continent women (mean age = 55.7) measured urodynamically.\textsuperscript{20} In addition, mean urethral closure pressure was significantly lower in women with SUI than continent women. Moreover, urethral closure pressure had the largest effect size in differentiating between continent and incontinent women.\textsuperscript{19} Thus, if women with SUI have a reduced urethral closure pressure, interventions aimed at increasing this pressure (i.e. PFM contraction) may lessen urinary leakage. Additionally, contraction of the PFM may prevent urethral descent with abrupt rises in intra-abdominal pressures that occur with activities such as coughing, sneezing, and lifting. DeLancey and colleagues reported that women with SUI had greater urethral descent at maximal valsalva compared to continent women, however the trend did not reach statistical significance.\textsuperscript{19} Miller compared bladder neck mobility of 11 young, continent, nulliparous women to 11 older, incontinent parous women during coughs with and without a concomitant PFM contraction. Bladder neck mobility significantly

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decreased from a median 5.4 to 2.9 mm when the PFM contraction was performed.\textsuperscript{22} Thus, PFM contraction appears to minimize urethral descent, but whether or not it leads to reduced SUI symptoms has not been scientifically verified. However, hypertrophy of the PFM as a result of exercise may improve urethral closure pressure and structural support of the pelvic organs.

The levator ani (PFMs) muscles consist of type I and type II muscle fibers. The type I fibers contribute to the static function of the muscle which is to support the pelvic viscera. The type II fibers are associated with rapid, forceful muscle contraction. When LA biopsy specimens of women with SUI were analyzed by Koelbl et al, women with a greater diameter of type II fibers had significantly higher urethral closure pressures during coughing.\textsuperscript{134} This finding suggests that LA type II fiber size is associated with urethral sphincter performance. Because specific strength training exercises can affect type II muscle fiber size through hypertrophy, it seems likely that LA exercise could increase the compression function of the muscle. In this way, strengthening type II fibers of the LA could aid the urethral sphincter in maintaining continence. Additionally, intensive LA strengthening may increase connective tissue stiffness and muscle hypertrophy. These morphological and functional changes may improve structural support of the pelvis by elevating the LA to a permanently higher location. Subsequently, the increased support may assist in preventing downward descent during increases in abdominal pressure.\textsuperscript{21}

Practitioners treating persons with SUI frequently utilize PFM exercise, also known as Kegel exercises. PFM exercises are taught either by verbal instruction or manual palpation, and specifically elicit contraction of the LA. While PFM exercises are
a reasonable way to address SUI, this treatment is not uniformly effective. The severity of the incontinence being treated and characteristics of the exercise program itself influence the effectiveness of treatment.

It appears that PFM exercises are most effective when used to treat persons with mild incontinence. When women suffering from mild or severe SUI were treated with PFM exercises for three months, those with mild SUI reported symptom improvement 86% of the time, those with severe SUI only reported improvement 13% of the time.\textsuperscript{15} Moreover, those with mild SUI who improved with exercise also had significantly improved urethral closure pressures.\textsuperscript{15} Cammu et al studied outcomes of women with SUI following at least one session of PFM exercise training with a physical therapist.\textsuperscript{14} Approximately 50% of the women were treated successfully. Women with more severe incontinence, defined as $\geq 2$ episodes of leakage per day and having a leakage at first cough during a stress test, were more likely to have poor outcomes associated with PFM training. Similarly, Burgio reported that women with severe SUI (defined as having more than 10 incontinent episodes per week on bladder diary) were less likely to have a successful outcome with PFM exercise compared to those with lesser severity.\textsuperscript{13}

PFM exercise efficacy studies including women with mild to moderate SUI vary with respect to frequency and intensity exercise. For example, Goode and colleagues tested a protocol in a sample of women with mild to moderate stress and mixed UI that required women to perform 15 repetitions of 2-4 second contractions, three times per day for 8 weeks.\textsuperscript{16} These investigators reported at least 50% of women reported a 67% decrease in voiding frequency and an 80% reduction of incontinence. Eighteen percent of the women reported cure or 100% reduced symptoms. It must be noted that in
addition to PFM exercises, subjects were instructed in the “Knack” principle. The Knack or counterbracing technique is taught by clinicians to prevent leakage during increases in abdominal pressure. The patient is taught to contract the PFM just prior to the physical stress. For instance, if a woman is about to sneeze, she should contract her PFM just prior to and throughout the sneeze to prevent SUI. In theory, the PFM contraction increases the pressure of the urethra to assist in preventing leakage of urine.

A randomized controlled trial, performed by Miller et al, evaluated the effectiveness of the Knack alone to reduce SUI. In this study, women were taught to contract their PFMs before and during a cough. A paper towel test served as the study outcome measure and was compared between baseline and 1 week later. Using the Knack decreased urinary leakage by 98.2 % for a medium cough and 73.3% for a deep cough.73

Because Goode, et al incorporated the Knack, it is unclear what contribution each intervention (PFM exercises or behavioral training utilizing the Knack) made to reducing UI in the women observed. Other limitations of Goode, et al’s study include a short time period for muscle training. The maximal effect of strength training does not occur before 5 months of training.21 Thus, the duration of Goode’s study may have been insufficient to promote PFM hypertrophy. Additionally, this study did not include PFM muscle testing to support or discredit whether 8-weeks of PFM exercise increased PFM strength.

Studies that trained women longer and tested the impact of PFM exercise alone to reduce SUI have found favorable results. According to a Cochrane Review of PFM training, greater improvements occur when women receive a supervised PFM exercise program of at least three months.17 Bo et al. found that women with SUI who performed
PFM exercises were 17 times more likely to report cure than a control group. In Bo et al.’s study, subjective cure was defined as a condition that was “unproblematic” after treatment. Women in this study performed 8-12 high intensity PFM contractions, three times a day. In addition to the home exercises, they attended PFM training in groups once a week with a physical therapist over a 6 month trial period. Women who performed PFM exercises also demonstrated significant improvements in PFM strength, episodes of leakage, and quality of life.\textsuperscript{11}

Morkved, et al reported a 29\% subjective cure rate for women with SUI using a similar protocol of 10, high intensity PFM contractions three times a day, and additional training with a physical therapist (weekly for 2 months, then bi-weekly for 4 months).\textsuperscript{18} Women in the study also demonstrated significant improvements in gram leakage on a pad test and quality of life after treatment. Interestingly, the investigators utilized 3 time points to measure PFM strength: 0-3 months, 3-6 months, and 0-6 months. They found significant improvements in strength from baseline to 3 months and from baseline to 6 months. This suggests that perhaps hypertrophy gains in the PFM could be obtained in as little as 3 months or that the 3 month intervention increased neural activation of the PFM resulting in improved manual muscle testing scores.

Other investigators have demonstrated improvements in subjective cure rates and objective measures in women with SUI participating in a supervised program of PFM exercises for 3 months. Borello-France and colleagues found 41\% of women with SUI performing PFM contractions for 9-12 weeks experienced a 100\% resolution of SUI symptoms while another 20.5\% experienced at least a 75\% reduction in symptoms. Additionally, the women demonstrated significant improvements in the number of urine
leaks per week, PFM strength, and quality of life. Women performed a home exercise program ranging from 20-90 repetitions per day and attended weekly individual sessions with a physical therapist. It should be noted that the women were also taught the “stress strategy” which is the same strategy as the Knack, described previously. Yet, because Borello-France, et al observed women increased PFM strength, it is possible that PFM hypertrophy and not merely the Knack behavioral instruction contributed to reducing SUI. Additionally, the protocol utilized by Borello-France called for a high maximum exercise dosage. By visit 12, the maximum exercise prescription possible was 60 repetitions (3 sets of 20) of a 3-second contraction and 30 repetitions (3 sets of 10) of a 12-second contraction performed twice daily. Given the high number of exercises prescribed, hypertrophy of the PFM could have occurred and contributed to the effectiveness of the intervention. Another high exercise intensity protocol described by Aukee et al resulted in decreased UI measured by a 24-hour pad test. The protocol required women with SUI to perform PFM contractions 20 minutes per day, and attend 5 structured physical therapy sessions over a 12 week treatment period. This study also supports that a 3 month protocol of PFM exercise may be effective in decreasing SUI.

It appears that PFM training is an effective conservative treatment for women with mild to moderate SUI. If the treatment protocol is over a longer period, for instance 6 months, then appropriate dosage of contractions may include 8-12 high-intensity repetitions performed three times a day. However, if the treatment protocol is over a shorter period, for instance 3 months, then it appears that similar results could be obtained if a more aggressive dosage is prescribed. Borello-France and colleagues utilized an individualized approach to exercise prescription. The physical therapist
determined the subjects’ level of fatigue when performing the PFM exercise based on performance on electromyography biofeedback. Based on the performance, the physical therapist prescribed the number of repetitions for the patients to perform during the home exercise program. Borello-France et al’s approach reflects common practice in physical therapy settings. The physical therapist evaluates the patient and prescribes exercises based on examination findings of the patient’s muscle performance. Additionally, Borello-France et al incorporated both 3-second maximum and 12-second submaximal PFM contractions to train both type II muscle fibers and type I muscle fibers respectively. Activation of type II muscle fibers may encourage hypertrophy, while activation of type I muscle fibers may contribute to pelvic organ support and prevent strain on pelvic ligaments and fascia. Both Morkved et al\textsuperscript{18} and Bo et al\textsuperscript{11} exercise protocols incorporated 3-4 fast PFM contractions on top of each 6-8 second muscle contraction. This protocol also incorporates both type I and type II muscle training. According to the Cochrane Review, it seems likely that treatment effectiveness will be enhanced if the exercise prescription is based on sound physiological principles.\textsuperscript{17} The studies mentioned in this review are consistent in incorporating both PFM endurance and strengthening principles. In summary, PFM training is better than no treatment, for women with SUI. Although exercise variables differ, an effective PFM training program should include both endurance and strengthening contractions, and may be more effective if the number of repetitions is individually based upon the patient’s level of fatigue during performance. Studies reveal that a 3-month regime is effective if sufficient repetitions are included in the program.
In addition to considering the intensity and duration of a PFM exercise program, physical therapists may also need to consider the body position in which woman exercise. Bo and Finckenhagen reported that mean resting vaginal pressure (cm HOH) was higher when recorded with women standing than when women were supine. The positions of standing or sitting did not affect the subjects’ ability to produce maximum squeeze pressure or maximum PFM contraction. Yet, the higher resting pressure recorded in standing suggests that vaginal pressure may be influenced by gravity. Borello-France and colleagues compared the efficacy of a PFM exercise progression that included practice in upright positions (supine, sitting, and standing) with the effectiveness of a PFM exercise program performed only in the supine position in reducing SUI. Women in both exercise groups achieved statistically significant improvements in urinary leakage, quality of life, and PFM strength. Position of PFM exercise did not impact outcomes indicating that perhaps exercise position may not play as important of a role in reducing UI. However, the authors did incorporate “Knack” training in both groups, which allowed women in the supine only exercise group the opportunity to contract their muscles in anti-gravity postures. This, combined with the high-intensity of both exercise regimes, may have reduced the impact of exercise position on study outcomes. Clinically, physical therapists utilize exercise progression from gravity-eliminated to anti-gravity when strengthening the PFM. Although one study disputed this common practice, the specificity theory regarding motor tasks states that greater gains in motor performance occur when practice most closely resembles the functional task. Thus, until additional studies corroborate the findings of Borello-France et al, exercise position should continue to be considered as a variable for PFM exercise.
2.9.2 SUI: PFM exercise and Biofeedback

Although PFM exercises are effective in reducing SUI in women with mild to moderate symptoms, the methods by which exercises are taught may contribute to the extent of effectiveness achieved. For example, verbal instruction of PFM exercise to women with and without incontinence was found ineffective 60% of the time, and led to incorrect techniques that could potentially increase symptoms.\textsuperscript{136} Correct contraction can be verified by biofeedback or manual palpation. In women, biofeedback can be obtained using small electrodes placed around the anus or by using an internal, vaginal electrode. Using biofeedback allows women to see almost instantly their muscle output during exercise. Incontinence rates obtained with the use of biofeedback range from 54% to 95%.\textsuperscript{137} For biofeedback to be successful, four conditions must be met: an easily measurable and detectable response, the ability to detect change in that response, a cue to control need, and a motivated client who is actively involved. Randomized controlled trials have found biofeedback assisted PFM exercise to be effective in reducing SUI. Women with SUI performing biofeedback-assisted PFM exercise 1 time per week for 8 weeks reported a significant decrease in UI episodes when compared to women in a no treatment control group.\textsuperscript{18, 108}

Although the effectiveness of biofeedback-assisted PFM exercise for women with SUI is established when compared to no treatment, conclusions regarding its efficacy when compared to PFM exercise alone are divided. Women with SUI performing biofeedback-assisted PFM exercise weekly for 8 weeks reported a similar decrease in UI episodes and percentage of improvement as those performing PFM exercise alone during 8 weekly sessions.\textsuperscript{24} Aukee and colleagues reported similar results in women with SUI
using a home biofeedback unit. In this study, one group received 5 supervised exercise sessions with a physical therapist over 12 weeks plus practice at home with a home biofeedback unit. The intervention for the comparison group did not include use of a home biofeedback unit. Groups did not differ in urine leakage or quality of life outcomes. The biofeedback group only showed a significant change in mean PFM EMG (electromyography) activity measured supine. No other differences were noted with reference to EMG activity in sitting or standing. This result may have reflected a training effect; those that used biofeedback may have done so in the supine position. As the study did not include tests for PFM force output, it cannot be concluded that women using biofeedback achieved greater strength than women not using biofeedback. Moreover, Pages and colleagues found no significant differences in incontinent episodes between women with SUI that participated in group exercise 5 times/week for 4 weeks that emphasized PFM exercise compared to women who received individual therapy sessions using biofeedback 5 times per week for 4 weeks. After 4 weeks, both groups of women continued the exercise program once daily at home for 2 months. Both groups demonstrated similar significant improvements in frequency of incontinence, PFM strength, and closure of the introitus.

Based on the literature, PFM exercise with biofeedback is not more efficacious than PFM exercise alone. However, PFM training with biofeedback may be a clinically useful and acceptable treatment for some women. A practical strategy may be to initiate PFM exercise with biofeedback for those who have difficulty understanding how to or are unable to contract their PFMs.
2.9.3 SUI: PFM exercise and electrical stimulation

Electrical stimulation is another intervention used by physical therapist to manage UI. The physiological goals of electrical stimulation (ES) are to build muscle hypertrophy, to normalize reflex activity of the lower urinary tract, and to increase circulation to muscles and the capillary system. The rationale for ES as an intervention for SUI is based on evidence that has shown ES of the pudendal nerve improves urethral closure by activating the PFM. It may also increase conscious awareness of the action of these muscles to yield an improved ability to perform a voluntary muscle contraction.

Results are mixed regarding the efficacy of ES in the treatment of SUI. Sand and colleagues found that women with SUI using home ES twice daily for 12 weeks reported significantly less UI based on pad test and voiding diary outcomes when compared to women using a sham device. Additionally, those using ES demonstrated significantly improved PFM strength compared to the sham group. On the contrary, Brubaker et al. reported no differences between women with SUI who used ES daily for 8 weeks compared to those who used a sham device based on changes in incontinent episodes, quality of life scores, and urodynamic diagnosis of SUI. Similarly, women with SUI using home ES one hour per day for 8 weeks demonstrated similar PFM strength, urine leakage based on pad test, and quality of life as women using sham ES.

Investigations that compared ES to PFM exercise, or combined ES and PFM exercise, have not shown superior results to PFM exercise used alone in the treatment of SUI. Goode et al. compared outcomes in women with SUI utilizing PFM training, PFM training and home ES, or a control condition consisting of a self-administered incontinence booklet. Women who received PFM training combined with ES reported
a mean 72% reduction in incontinent episodes. When compared with PFM exercise alone, the addition of ES did not improve the results. However, patients’ perception of progress was better for women receiving the ES combined with PFM exercise. Furthermore, Bo and colleagues reported greater improvements in pad test results, PFM strength, and subjective cure for women with SUI treated with PFM exercise compared to those receiving PFM exercise and ES. According to a recent systematic review, ES did not improve UI more than sham stimulation or PFM exercise. Based on the evidence, it may be most appropriate to utilize ES for women who are initially unable to contract their PFM. Once PFM activation is achieved, PFM exercise alone may be more effective.

2.10 Interventions for UUI

2.10.1 Behavioral Training

There are two general approaches to the management of UUI. The first is behavioral training which includes PFM exercises to inhibit bladder contractions and other urge suppression strategies. The second strategy is bladder training which focuses on restoring normal bladder function by modifying bladder habits using structure voiding schedules. Few studies have investigated the effectiveness of PFM exercise to reduce symptoms of urgency and/or UUI thus making it difficult to understand the mechanisms by which PFM exercise impact UUI. Aside from the potential to hypertrophy the LA muscle, PFM training along with urge suppression strategies are believed to reduce UI by inhibiting bladder contractions. Shafik and Shafik investigated the role of the PFMs in suppressing involuntary voiding in healthy controls and those with OAB and concurrent
UUI. In those with OAB the bladder was filled to a volume inducing involuntary detrusor contractions while vesical and urethral pressures were recorded. Subjects were then asked to perform a 10 second PFM contraction. With the addition of a PFM contraction, a significant decrease in bladder pressure and a significant rise in urethral pressure were observed. Moreover, those with OAB did not demonstrate involuntary voiding when incorporating the PFM contraction.

A main component of a behavioral intervention approach to UUI is PFM training. Once patients learn how to properly contract and relax their PFMs, they are instructed to contract them whenever they experience urgency to suppress detrusor contractions and prevent UUI. Urge suppression strategies also include informing patients of better ways to control the sense of urgency. For instance, instead of rushing to the bathroom when the urgency strikes, patients are advised to stop, sit down, relax their body, and contract their PFM to diminish the urge. After the urgency passes, patients are told to walk to the bathroom, but at a normal pace.

The effectiveness of behavioral training to reduce UUI has been tested in several clinical trials. Subak and colleagues evaluated the effect of a behavioral program for women with stress, urge, or mixed incontinence. The intervention consisted of six weeks of group instruction in bladder training, PFM exercise, and the use of urinary diaries to monitor UI episodes and voiding schedules. At 6 weeks, the behavioral treatment group experienced a 40% reduction in mean weekly UI episodes. Moreover, 31% of women were 100% improved after behavioral therapy. Even though these results are promising, there were several limitations to this study. First, PFM training was based on verbal and written instructions, rendering it impossible to verify if PFM
exercise was done appropriately. Second, the multi-component regimen had subjects set new voiding schedule goals each week (referred to as bladder training). Thus, it is difficult to ascertain which aspects of the intervention program contributed to the successful outcomes. Finally, the subjects had stress, urge, or mixed UI. Although the investigators state that no differences were found for type of UI, the relative small distribution of those with UUI may not be representative of results if only those with UUI were studied. Investigations focusing on persons with UUI and/or overactive bladder exclusively may provide more applicable results to the population in question.

Wang and colleagues investigated the efficacy of PFM training in the management of overactive bladder with accompanying UUI.\textsuperscript{76} Thirty-eight percent of subjects performing PFM exercise three times daily for 12 weeks reported a 100% resolution of UUI. The exercises were prescribed based on the results of an evaluation by a physical therapist. Specifically, the physical therapist utilized Laycock’s PERFECT scheme to grade PFM strength. This schema grades the subjects’ power (P), endurance (E), number of repetitions (R), and number of fast (1-second) contractions (F). Additionally, every (E) contraction (C) is timed (T). Thus, subjects were performing both fast and slow contractions with the repetitions and intensity individually based on performance at initial evaluation. Additionally, the subjects were instructed to contract their PFM during an urge to void, thus incorporating the urge suppression strategy.\textsuperscript{76} The generalizability of results of this investigation however, is limited. Women performed exercises at home and did not receive ongoing supervision. Thus, the investigators did not include a process for verifying that the subjects were indeed performing PFM exercise correctly. Additionally, Wang reported women adhered to exercise for only 14.5
days instead of the intended 84 days of training. Yet, it is promising that the investigators found positive results utilizing a home exercise program even with poor compliance. Thus, one would expect a supervised PFM exercise protocol to yield greater exercise adherence and UI outcomes.

Women with UUI participating in a home exercise program and four clinical visits over twelve weeks reported significant improvements in UI episodes per day, and improvements in nighttime frequency, PFM strength, and urge score on a leakage index. Specifically, women with UUI reported a 35% decrease in the number of UI episodes per day. Women were instructed to perform PFM exercises twice a day for 5 minutes each session. They were to begin with 4-second contractions and progress to 8-second contractions. In addition to the home exercise program, subjects were evaluated in the clinic at 4, 8, and 12 weeks. During these visits, they were instructed on increasing exercise efficiency and incorporating the PFM contraction into daily life. Although the intervention was focused on home exercise, the additional clinic visits served to reinforce correct PFM contraction and progress exercises which may have attributed to significant improvements in both subjective and objective measures. This study also included a long-term follow-up. At 6-months post-intervention, 50% of those who completed the treatment described their progress as excellent or good and desired no further treatment.

Another common treatment for UUI is drug therapy. Burgio and colleagues performed a prospective randomized clinical trial that compared the effectiveness of a behavioral intervention to drug therapy for UUI. All subjects received 4 clinic visits at 2-week intervals during an 8-week period. The behavioral training group was instructed in PFM exercise with the use of biofeedback and urge suppression strategies, Women
were provided a home exercise program consisting of 45 pelvic muscle exercises daily. The drug group received oxybutynin, a commonly prescribed drug for UUI, and the control group only attended clinic visits. Behavioral training resulted in a mean 80.7% improvement in UUI episodes, and was significantly more effective than drug treatment (68% improvement) and the control condition (39% improvement). Of the women in the behavioral training group, 30% reported 100% improvement. Additionally, Burgio et al demonstrated women in the behavioral group achieved increased bladder capacity by 17 mL. Thus, in this group of community dwelling women with UUI, behavioral training (including PFM exercise) was found to be more effective at improving patient’s perception of incontinence than drug therapy or a control group. Only a relatively small percentage of patients in the behavioral treatment group indicated they would like to receive another form of treatment (14%), while much larger proportions in the drug (75%) and control groups (75%) desired another form of treatment at the conclusion of the study. According to commentary in the Cochrane Review discussing Burgio’s study, querying subjects about their desire for additional treatment may yield richer information than asking about cure rates. This type of question may help clinicians between patients who are better and satisfied from those who are better but not sufficiently so to be satisfied with the treatment outcome. Burgio’s protocol utilized an individualized approach to PFM training as well as structured, supervised clinic visits which may attribute to the large success in the study. The clinician determined the subjects’ level of fatigue when performing the PFM exercises and prescribed the appropriate intensity level for the PFM contraction. This approach parallels common
practice by physical therapists who prescribe exercises based on examination findings of the patient’s performance.

2.10.2 UUI: PFM exercise and Biofeedback

The effectiveness of PFM exercise as an intervention for UUI may be enhanced by the use of biofeedback. Women with OAB and associated UUI that participated in a graded PFM home exercise regimen for 12 weeks, along with 4 clinic visits that included biofeedback, reported a 57% decrease in the number of UI episodes per week. This study suggests that this particular protocol, which utilized biofeedback, is an effective treatment for women with overactive bladder. The study could not determine if the addition of biofeedback was beneficial because it lacked a comparison group.

Burgio and colleagues investigated behavioral training with and without biofeedback for the treatment of UUI. The behavioral training with biofeedback group underwent 4 clinic visits at 2-week intervals for 8 weeks and utilized biofeedback in the clinic to assist with PFM exercises. Additionally, subjects were taught urge suppression strategies and a home exercise program. The behavioral training only group utilized the same protocol but instead of biofeedback during the clinic visits, received verbal feedback based on vaginal palpation. The control group utilized a self-administered behavioral program booklet. All groups experienced a reduction in UI frequency, with the biofeedback group having a 63% decrease; behavioral training group a 69% decrease; and the control (booklet) group having a 38% decrease. Thus, the treatment groups had greater UI reduction compared to the control group by 40-55%. Bladder capacity was improved in all 3 groups, with the biofeedback group demonstrating a 42% greater
improvement than the control group; and the behavioral group demonstrating a 23% greater improvement than the control group. Moreover, patient satisfaction was higher in the behavioral training alone and the biofeedback groups. Patient satisfaction included comfort with treatment, satisfaction with progress, and less activity restriction. Thus, from this particular study of women with UUI, both biofeedback and vaginal palpation were effective means of teaching PFM exercises. Furthermore, both treatment groups demonstrated improved outcomes when compared to the control group. Additionally, women with overactive bladder participating in PFM exercises with and without biofeedback demonstrated similar improvements regarding UI episodes, voiding frequency, urgency episodes, and number of continence pads used. However, the biofeedback group demonstrated significantly higher quality of life scores based on the total score of King’s Health Questionnaire. No significant differences were noted when comparing the subscales of this questionnaire between the groups.

The studies cited above and a recent meta-analysis strongly suggest that the addition of biofeedback may not produce better results compared to PFM exercise alone. However PFM with biofeedback is a common and clinically acceptable intervention for women with UUI. A practical strategy may be to initiate PFM exercise with verbal or tactile feedback, and utilize biofeedback only for those who do not respond to this form of teaching or do not progress as anticipated.

2.10.3 Bladder Training

The second main approach for treatment of UUI is bladder training. Bladder training focuses on restoring normal bladder function by changing voiding habits,
specifically decreasing voiding frequency and increasing bladder capacity. When a woman has UUI, she experiences an overwhelming urgent sensation to void thereby leading to frequent voids, decreased bladder capacity, and detrusor overactivity. Ultimately, this cycle makes it very difficult for the patient to suppress bladder contractions. Bladder training attempts to break this cycle by having the patient resist the sensation of urgency in order to postpone urination and gradually increasing the voiding interval. Subsequently, bladder capacity is increased and detrusor overactivity minimized. The key component of bladder training is helping the patient set a reasonable voiding schedule with an eventual voiding interval goal of 3 to 4 hours. Patients are instructed to empty their bladder on waking and at the end of each time interval subsequently during the day. If they have to void sooner, they are told to use urge suppression techniques (i.e., distraction, relaxation, or self-affirming statements) to get them through to the next scheduled voiding time. Specific urge suppression examples include having the patient concentrate on a task they want to complete (i.e. making dinner), take 5 deep breaths, or perform 5 PFM contractions quickly. The effectiveness of bladder training has been demonstrated in a randomized trial by Fantl and colleagues. These investigators found bladder training alone reduced UI episodes by 57% and the volume of fluid loss by an average of 54% in older women compared to an untreated control group. A remarkable finding in this study was that the improvement in UI episodes occurred in absence of urodynamic improvement.
2.11 PFM exercises and the Transverse Abdominus connection

There is a growing body of evidence that suggests a relationship between the PFM and transverse abdominus (TA) muscle. Specifically, there appears to be a concurrent increase in TA muscle activity with PFM contraction. Neumann and Gill demonstrated a 66% increase in normalized TA activity recorded by intramuscular EMG when healthy women positioned supine were asked to perform a PFM contraction.\textsuperscript{149} Similarly, Sapsford and colleagues demonstrated an increase in normalized intramuscular TA EMG amplitude between 32-42% when 7 healthy women performed a maximal PFM contraction in supine.\textsuperscript{150}

Since a concurrent increase in TA activity occurs with PFM activity, it may be logical to assume a reversal relationship; specifically, that a concurrent increase in PFM activity occurs with TA activity. When 6 healthy women and 1 man performed a TA contraction in supine, PFM EMG activity, measured using a vaginal or anal surface electrode, increased above the resting level. Subjects performed different intensities of the TA contraction (gentle, moderate, strong), and the concurrently PFM activity increased in gradation of the different TA intensities. Moreover, the PFM activity recorded during a strong TA contraction did not differ from that recorded while subjects strongly contracted the PFM in isolation.\textsuperscript{151} Similarly, Neumann and Gill\textsuperscript{149} and Sapsford\textsuperscript{150} demonstrated increased PFM activity when healthy women performed a TA contraction in supine. Interestingly, one subject in Sapsford’s study inadequately performed the TA contraction, achieving only minimal intramuscular TA EMG activity. However, this subject demonstrated an 8% increase in PFM activity\textsuperscript{150} suggesting that a less than ideal TA contraction may coincide with a small rise in PFM activity.
In a theoretical paper, Sapsford proposed that weak abdominal muscles may relate to the development of SUI. Sapsford noted that during coughing and nose-blowing, the abdominal wall of women with SUI bulges forward, especially when they are in a slumped supported position, without pretensioning of the abdominal muscles. In comparison, healthy women will pull their abdomen inward and contract their PFMs to increase intra-abdominal pressure to maintain continence. Other recent studies confirm that PFM activity is influenced by sitting posture in women with and without SUI. Specifically, PFM activity was significantly decreased in slumped supporting sitting verses upright sitting in healthy women and those with SUI, but a significantly greater decrease was noted in those with SUI. Additionally, women with SUI demonstrated a trend for increased activity in the superficial rectus abdominus in both slumped sitting and upright sitting. Activation of the rectus abdominus may increase the intra-abdominal pressure, thus making it more difficult for women with SUI to maintain continence during activities that elevate intra-abdominal pressure. The increased activity of the rectus abdominus was not observed in continent women which suggests that women with SUI may demonstrate altered abdominal muscle recruitment. Thus, Sapsford proposed a rehabilitation program for women with SUI that utilizes the abdominal muscles to initiate PFM activity. Inclusion of TA exercises into the intervention plan for women with SUI may contribute to improved PFM recruitment and better outcomes. However, this approach has not been investigated for efficacy in improving outcomes for women with SUI.
2.12 Lifestyle Measures to decrease SUI and UUI

2.12.1 Caffeine and Fluid Intake

Anecdotal reports have led to a list of potential dietary triggers for UI including chocolate, citrus fruits and juices, tomatoes and tomato-based products, vinegars, dairy products, aspartame, and spicy foods. However, none of these have been linked scientifically as bladder irritants. Caffeine and overall fluid intake however have been investigated for their impact on UI.

Swithinbank and colleagues investigated the effect of fluid manipulation in women with SUI and OAB. The four week study included a baseline week followed by 3 weeks of caffeine restriction and alterations in fluid intake. During week 2, participants drank normally, without fluid manipulation. During week 3 or 4, participants either increased decaffeinated fluids to 20 cups per day or decreased fluids to 5 cups per day. Decreasing fluid intake significantly improved urinary frequency, urgency, and incontinence, and quality of life in those with OAB; and decreased urinary frequency in women with SUI. Alternatively, increasing fluid intake significantly increased voiding frequency, UI episodes, and urgency in those with OAB compared to baseline and the week of decreased fluids. In those with SUI, increased fluid intake significantly worsened UI episodes when compared to the week of decreased fluid. In another study, women and men with OAB who participated in a prospective, cross-over trial were required to alter fluid intake by drinking 25% and 50% less than baseline, as well as 25% and 50% more than baseline. A significant reduction in urgency, frequency, and nocturia occurred when subjects decreased their fluid intake by 25%. As expected, a significant increase in daytime UI episodes was reported when fluid intake was
increased. Conversely, Dowd and colleagues reported no improvement in UI symptoms with fluid manipulation. However, a significant proportion of participants did not adhere to the protocol. Similarly, Dallosso showed no association between total fluid intake and either OAB or SUI in women aged >40 years. The literature is conflicting regarding the efficacy of fluid manipulation in treatment of UUI. It appears that decreasing fluid intake may decrease symptoms of UUI more so than symptoms of SUI. Therefore, it is reasonable to advise patients to maintain adequate fluid hydration to prevent dehydration.

Although the stimulatory effect of caffeine has been shown to directly influence the bladder by increasing bladder pressure during filling, altering caffeine intake does not necessarily decrease UI symptoms. Swinthinbank and colleagues also investigated the role of caffeine restriction in 110 women with SUI and OAB. Changing from caffeine containing to decaffeinated drinks produced no improvement in urinary symptoms. Similarly, Dowd found no association between caffeine intake and UI episodes in 32 women >50 years. After controlling for other lifestyle factors, Dallosso showed no relation between caffeine and OAB or SUI. Although evidence regarding effectiveness of caffeine restriction is lacking, there is an association between caffeine and OAB. Arya and colleagues reported a significant association between high caffeine intake (>400mg) and OAB. An 8-ounce cup of brewed/drip coffee has a caffeine content range of 71-280mg or a mathematical mean of 175.5mg per cup. Thus, consuming 2.5 cups of coffee per day would yield a high caffeine intake of >400mg and for those with OAB, consuming high amounts of caffeine should be considered a risk factor.
2.12.2 Weight Loss

There is a growing body of evidence supporting weight-loss for overweight and obese women as a lifestyle intervention for UI. Obese and overweight women with UI participating in an intensive 6-month weight-loss program consisting of diet, exercise, and behavior modification reported significantly less UI symptoms when compared to controls.\textsuperscript{157} Women in the weight-loss group lost a mean of 8\% of body weight, and reported significantly less UI episodes and smaller volume of urine leaks. Moreover, when compared to controls, women in the weight-loss group reported less UI symptom impact and higher satisfaction with the improvement in continence status.\textsuperscript{157} Overweight pre-diabetic women participating in a weight-loss program demonstrated significantly less UI episodes than women taking an anti-diabetic drug or placebo drug.\textsuperscript{158} Women in the weight-loss program lost an average of 3.7\% of body weight (7.49 pounds) and reported significantly less weekly UI episodes than those in the drug or placebo groups. After adjusting for baseline hormone therapy use, general health status, and post-challenge glucose categories, women in the weight-loss group had significantly lower odds of weekly UI compared with women in the placebo group (OR 0.76; 95\% CI 0.61-0.95).\textsuperscript{158} It appears that even small amounts of weight loss in overweight and obese women may significantly decrease UI and improve patient perception of UI symptoms. Thus, a decrease in UI episodes may be another benefit among the numerous health benefits associated with weight reduction.
2.13 Bowel Dysfunctions

2.13.1 Constipation

The most common interventions for constipation include increasing fluid intake, increasing dietary fiber intake, and promoting bowel motility via abdominal massage. Based on a review of four studies, Muller concluded that there was no conclusive scientific evidence to support that constipation can be successfully treated by increasing fluids. Of the reviewed studies, one found fluid intake volume to be similar in constipated subjects and controls. Another study that examined whether constipation could be improved by increasing fluid intake reported no changes in subjects’ stool frequency, consistency, or ease of defecation. Finally, another study that examined the effect of increasing fluid intake in constipated patients reported increased stool frequency. However, subjects drank mineral water containing magnesium and other ions that may have acted as a light laxative.

Dietary fiber has been recommended for improved bowel function. The National Academy of Sciences Institute of Medicine recommends that female adults over 50 years of age have 20-25 g of fiber daily. Most Americans consume only 5-10 g daily. There are 2 types of dietary fiber. Soluble fiber is thought to be beneficial in lowering blood cholesterol and decreasing plaque-forming low density lipoprotein. Insoluble fiber increases fecal volume density by slowing digestion, colon distention, peristalsis, and increased water absorption. Women with constipation who supplemented their diet with high-fiber cereal reported significantly improved constipative symptoms, as well as significantly decreased use of laxatives, and the need for vaginal and/or perineal splintings to assist bowel movements. The 30 women in the study also significantly
decreased their caffeine intake compared to baseline which may have contributed to the favorable results. Muller cautioned that a diet low in fiber should not be assumed to be the cause of constipation, but may be a contributory factor.\textsuperscript{159} Patients with more severe constipation may experience gas production from fiber metabolism which limits effectiveness of fiber. Moreover, a review of four studies that examined dietary fiber intake by people with chronic constipation, found no differences compared to controls.\textsuperscript{159}

For patients with a specific type of constipation, slow-transit constipation, abdominal massage may be beneficial. Slow-transit constipation is due to decreased neuromuscular function of the colon; therefore, interventions are aimed at increasing gut mobility. Klauser and colleagues reported that abdominal massage performed three times per week for three weeks did not improve slow-transit constipation.\textsuperscript{161} However, a case study utilizing a more frequent approach yielded positive results. Harrington and Haskvitz instructed an 85-year old woman with slow-transit constipation in bowel management, as well as a 10-minute home abdominal massage program.\textsuperscript{40} After five visits over a 13 week period, the patient reported a return of normal bowel frequency without the need to strain or use digital evacuation.

2.13.2 Fecal Incontinence

Fiber intake also plays a role in the management of FI by promoting increased stool consistency. Subjects with FI that took fiber supplements for 31 days demonstrated a significant decrease in the percentage of incontinent stools, and an improvement in stool consistency compared to a placebo control group.\textsuperscript{162} However, fiber supplements
can potentially worsen diarrhea by increasing fermentation of inabsorbable fiber in the colon.\textsuperscript{45}

Physical therapy interventions for FI include PFM exercise, biofeedback, and electrical stimulation.\textsuperscript{41} PFM training is used to improve coordination of muscle contractions, improve muscular strength, and increase awareness and isolated contraction of the PFMs. The use of biofeedback and electrical stimulation augment such goals as discussed previously. In addition, biofeedback can be used for rectal sensitivity and coordination training.\textsuperscript{43} The rationale for rectal sensitivity training is to enhance detection of a lower stool volume in the rectum to promote earlier opportunity for a patient to find a toilet and/or contract their PFMs to delay or prevent FI. In rectal sensitivity training, a rectal balloon is filled with air or water to imitate rectal contents, and the patient is asked to report first sensation with rectal filling. Repeated re-inflations of the balloon are performed to the determined volume with the goal of teaching the patient to feel the distension at progressively lower volumes. In coordination training, typically a three balloon system is utilized: one situated in the rectum, and the second and third (recording balloons) are placed in the upper and lower anal canal. When the rectal balloon is distended, the patient is taught to counteract the momentary anal relaxation by voluntary squeezing the PFM until the relaxation period is over.\textsuperscript{43}

Norton and Kamm investigated PFM exercise and biofeedback in 100 patients with FI.\textsuperscript{163} Patients performed PFM exercise with biofeedback for a median of 4 sessions; and for those who demonstrated high stool threshold volumes, rectal sensitivity training was also included. Forty-three percent of subjects regarded themselves as “symptomatically cured” while 24% were “improved” after treatment. Patients with
structurally intact sphincters (as measured by anal endosonography) were most likely to benefit from treatment, although some with structural changes also improved. In a systematic review, Palsson and colleagues concluded that biofeedback for FI provides a significantly higher probability of successful outcome than standard medical care, and should be viewed as a valuable adjunct to medical management. On the contrary, the Cochrane review regarding biofeedback and/or PFM exercise for FI concluded that the limited number of clinical trials combined with their methodological weaknesses do not allow for a definitive assessment of the role of biofeedback and/or PFM exercise in the management of FI. However, there were suggestions that rectal sensitivity training improves FI more than sham training. As biofeedback and PFM exercises are safe and certainly more conservative compared to surgical options, the American College of Gastroenterology Practice Parameter Committee contends that biofeedback is an effective treatment in patients with weak sphincters and/or impaired rectal sensation.

A Cochrane review of electrical stimulation (ES) as an intervention for FI concluded a lack of evidence to judge whether ES is efficacious. Norton and colleagues found no differences regarding FI episodes, patient satisfaction, or manometric squeeze pressures following 8 weeks of daily anal ES compared to sham stimulation in 90 patients with FI. Ostenberg and colleagues compared surgery with ES in patients with FI. Electrical stimulation lasted 20 minutes for a total of 12 sessions over a period of 4-5 weeks. Compared to baseline status, those receiving ES demonstrated significantly improved incontinence scores on a condition-specific questionnaire and less absorbent pad use at 3, 12, and 24 months after treatment. However, manometric squeeze measures were unchanged. Surgery was superior to ES at
3 months but not at 12 or 24 months. Conclusions regarding the effectiveness of ES for FI are unclear. Recent practice guidelines by the American College of Gastroenterology suggest that ES should be considered experimental and merit controlled clinical trials.

2.14 Interventions for Chronic Pelvic Pain

Physical therapists use a variety of techniques for treatment of musculoskeletal causes of CPP. Treatment is aimed at reducing or eliminating the impairments found during the initial examination. Table 2.1 outlines common physical therapy interventions as well as the impairments that the intervention attempts to influence.
Table 2.1: Physical therapy interventions utilized in the treatment of CPP

<table>
<thead>
<tr>
<th>Physical Therapy Intervention</th>
<th>Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biofeedback</td>
<td>Weak PFM, Hypertonic PFM</td>
</tr>
<tr>
<td>Electrical Stimulation</td>
<td>Pain in hip, lumbar, or pelvic region; Hypertonic PFM, Weak PFM</td>
</tr>
<tr>
<td>Superficial Heat and Cold Modalities</td>
<td>Pain in hip, lumbar, or pelvic region</td>
</tr>
<tr>
<td>Joint mobilization or Muscle energy techniques</td>
<td>Restricted joint motion of the hip and/or pelvis</td>
</tr>
<tr>
<td>Soft tissue mobilization, Myofascial release, Trigger Point release externally or internally</td>
<td>Hypertonic PFM; Spasm of hip, lumbar, or pelvic musculature; Trigger points</td>
</tr>
<tr>
<td>Connective and scar tissue release</td>
<td>Hypomobile scars due to abdominal and/or pelvic surgery (i.e. episiotomy, cesarean section)</td>
</tr>
<tr>
<td>Vaginal dilation</td>
<td>Hypertonic PFM and/or introitus pain</td>
</tr>
<tr>
<td>Stretching / Range of motion techniques</td>
<td>Shortening of hip, low back, or pelvic muscles</td>
</tr>
<tr>
<td>Therapeutic Exercise which may include postural exercises</td>
<td>Weak muscles of the hip, low back, or pelvic region</td>
</tr>
</tbody>
</table>

2.15 Outcomes

To assess if interventions are effective, outcome questionnaires are needed to quantify patient perceptions of symptom improvement. Because the clinical presentation of women with UI is varied, it is necessary to utilize outcome measures that incorporate the myriad of co-existing pelvic symptoms.

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2.15.1 Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire

Generic health-related quality of life (QOL) instruments such as, the Medical Outcomes Survey Short-36 and the Sickness Impact Profile, have been used to examine the QOL in women with UI. Although generic health-related QOL measures have the advantage of comparing results among groups, such instruments may lack the sensitivity to measure the unique aspects of a specific disease and its impact on a patient’s QOL.

The Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFQI) are condition specific quality of life instruments that assess the impact of urinary, bowel, and prolapse symptoms on a woman’s QOL. Although there are several standardized quality of life instruments specific to UI symptoms, only the PFDI and PFIQ encompass the ability to assess co-existing disorders of UI, specifically, bowel dysfunction and POP. Because several pelvic floor disorders may co-exist in the same woman, the use of instruments that assess the whole spectrum of interrelated symptoms is essential when evaluating the efficacy of treatment interventions.

Both the PFDI and the PFIQ are based on the structure and content of two widely used condition-specific health related QOL instruments for women with lower urinary tract symptoms: the Urinary Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ). The UDI contains 19 symptom questions related to lower urinary tract dysfunction including urinary frequency, UI, nocturia, incomplete bladder emptying, and lower abdominal pressure. The UDI measures symptoms and the perceived degree of bother associated with each symptom. The IIQ is a 30-item questionnaire that measures the degree to which UI impacts social relationships, physical activities, travel, and...
emotional health. Data on the reliability, validity, and sensitivity to change of these measures demonstrate that they are psychometrically strong.\textsuperscript{166} Both the UDI and IIQ subscales demonstrate acceptable internal consistency reliability with Cronabach’s alpha coefficients for the UDI subscales ranging from 0.48-0.77; and for the IIQ ranging from 0.87-0.90. Only one subscale of the UDI, stress symptoms, demonstrated reliability (0.48) below the desired range recommend (0.7-0.95) by Portney and Watkins.\textsuperscript{167} When compared to well-validated generic health related QOL measures including the RAND-36 Health Survey, the Centers for Epidemiological Studies Depression Scale, the Medical Outcomes Study measure of Social Support 1992, and the Profile of Mood States, the UDI and IIQ scores generally correlated well with scores on these measures verifying convergent validity. For the IIQ, 15 of the 16 correlations between the four IIQ subscales and the four generic measures were significantly significant with correlations ranging from 0.37 to 0.52, mean = 0.37. For the UDI, 9 of the 12 correlations between the three UDI subscales and four generic measures were significant with correlations ranging from 0.09 to 0.40, mean = 0.22. Such moderate correlations demonstrate that the IIQ and UDI measure more than general health constructs. Moreover, the UDI and IIQ are responsive to change, and significantly correlate with clinical measures of condition severity including number of incontinent episodes and the amount of urine leakage as measured by a pad test.\textsuperscript{166}

All questions from the UDI and IIQ are included in the PFDI and PFIQ along with additional items regarding POP and bowel dysfunction.\textsuperscript{168} These additional items were included to ensure that the full range of QOL issues of women with pelvic floor dysfunction were addressed. The PFDI has 46 items and contains 3 subscales: the UDI,
Pelvic Organ Prolapse Distress Inventory (POPDI), and the Colorectal-anal Distress Inventory (CRADI). Respondents are asked if they experience symptoms and if so, to rate the degree on which they are bothersome on a scale from 1 (not at all) to 4 (quite a bit). The PFIQ has 93 items and contains 3 scales: the Urinary Impact Questionnaire (UIQ), the Pelvic Organ Prolapse Impact Questionnaire (POPIQ), and the Colorectal-anal Impact Questionnaire (CRAIQ). Each subscale contains 31 items with 30 of these items identical to the questions in the IIQ referring to the degree to which symptoms affect social relationships, physical activity, travel, and emotional health. One question was added to each subscale to assess the effect of bladder, bowel, or vaginal symptoms on the patient’s relationship with her husband or intimate partner. The psychometric properties of the PFDI and PFIQ were assessed in study of 100 women (mean age 56 years) with pelvic floor dysfunction who underwent a standard pelvic floor dysfunction evaluation including a structured interview, physical examination that included POP quantification, and urodynamic evaluation. Additionally, women kept a 1-week prospective bladder and bowel diary. Subjects completed the PFDI and PFIQ at their initial visit and completed it again 7 days later. The PFDI and PFIQ demonstrated good internal consistency, with Cronbach’s α reported as 0.88 for the overall PFDI score and 0.98 for the PFIQ. Test-retest reliability was good for both instruments with the ICCs of 0.87 and 0.86 for the PFDI and PFIQ respectively. Content validity was confirmed by an expert panel. Finally, content validity of the PFDI and PFIQ was tested by comparing objective data of symptom severity, responses to structured interviews, and final pelvic floor diagnoses with the appropriate scales of each instrument. POP subscales of the PFDI and PFIQ positively correlated with a validated measure of prolapse severity and two pelvic floor...
conditions associated with prolapse (voiding dysfunction and defecatory dysfunction). Colorectal subscales of the PFDI and PFIQ correlated with one measure of symptom severity (number of FI episodes per week), two symptoms associated with abnormal defecation (hard straining and perineal splinting), and three diagnoses of bowel dysfunction (FI, defecatory dysfunction, and rectal prolapse). Urinary subscales of the PFDI and PFIQ significantly correlated with three measures of symptom severity from the bladder diary including number of UI episodes per week, number of pads used per week, and the average daytime voiding interval. Thus, the PFDI and PFIQ are valid and reliable instruments for women with pelvic floor disorders.

Although the PFDI and PFIQ are psychometrically strong, the time it takes patients to complete the questionnaire (23 minutes (+11 minutes)) may limit their clinical utility. Barber and colleagues developed two short form versions of these questionnaires that are valid, reliable, and responsive to change. The short form versions (PFDI-20 and PFIQ-7) were tested in 45 women (mean age 59 years) having one or more pelvic floor disorders including UI, voiding dysfunction, ≥stage 2 pelvic organ prolapse, defecatory dysfunction, and/or rectal prolapse; and were scheduled for reconstructive pelvic surgery or continence surgery. Preoperatively, subjects underwent a standardized evaluation consisting of a structured urogynecologic history, physical examination with POP quantification; and they completed the Medical Outcomes Study Short Form-36 (SF-36) and the short and long forms of the PFDI and PFIQ. The short versions demonstrated significant correlations with the long versions for both the PFDI and PFIQ with ICCs ranging from 0.86-0.93 and 0.94-0.96, respectively. Additionally, each of the PFDI-20 and PFIQ-7 subscales demonstrated good to excellent test-retest
reliability with ICC values between 0.70 and 0.91. To assess the responsiveness of the PFDI and PFIQ, subjects completed the instruments and the SF-36 again 3 to 6 months after the surgery. The instruments were responsive to change as demonstrated by significant improvements pre- to post-surgery in PFDI-20 and PFIQ-7 scores. Additionally, the PFDI-20 demonstrated moderate to excellent responsiveness with an effect size and standardized response mean (SRM) values ranging from 0.70 to 1.28, respectively. The PFIQ had moderate responsiveness with an effect size of 0.67 and SRM of 0.63. For both the effect size and SRM, a value of 0.5 to 0.7 is considered moderate responsiveness, 0.80 to 1.00 is considered good, and more than 1.0 is considered excellent. In contrast, the majority of the scales of the SF-36 were not responsive to change. Moreover, the summary scores of PFDI-20 and PFIQ-7 significantly correlated with subjects’ global index of improvement score, indicating that the instruments are able to differentiate between those who got “better” from those who got “worse” (C-statistic 0.96 and 0.88, respectively, where 1 indicates a perfect test and 0.56 indicates a test with no discriminative ability). Based on comparisons to global index of improvement scores, Barber and colleagues determined that a ≥ 45 point change in the PFDI-20 summary score and a ≥36 point change in PFIQ-7 summary score were clinically meaningful changes in QOL life in patients undergoing surgery for pelvic floor dysfunction.

2.15.2 Patient Global Impression of Improvement

Global indices are utilized in order to obtain a very simple and direct appraisal of the patient perceptions of improvement. In contrast to QOL and symptom distress and/or
impact questionnaires, a global index usually contains one question that asks the patient to rate the severity of the condition or the response of the condition following therapy. The Patient Global Impression of Improvement (PGI-I) is a global index used in recent research trials to assess patient perception of treatment intervention.\textsuperscript{170-173} The PGI-I has been shown to have good construct validity in women with SUI.\textsuperscript{77} Yalcin and Bump demonstrated significant correlations between the PGI-I and frequency of UI episodes, urine leakage on pad test, and a validated condition-specific QOL questionnaire in a prospective study of women assigned to drug therapy or placebo for UI.\textsuperscript{77}

2.15.3 Constipation Scoring System

Although the PFDI-20 and PFIQ-7 are comprehensive instruments to evaluate women with pelvic floor dysfunction, the subscales assessing bowel dysfunction primarily refer to FI. Women with UI report often report co-existing constipation.\textsuperscript{33, 34} Inclusion of a questionnaire assessing constipation symptoms is necessary to determine the effectiveness of interventions. The Constipation Scoring System (CSS) is a valid instrument that correlates with objective physiologic findings in constipated patients. Agachan and colleagues reported that the CSS demonstrated convergent and divergent validity in 185 women and 47 men (mean age 65 years) with constipation confirmed via physiological tests.\textsuperscript{79} Subjects’ scores on the CSS were significantly correlated with anal and colorectal physiologic studies. Agachan and colleagues also demonstrated divergent validity of the CCS using 2 groups of subjects, those with and without constipation confirmed by physiologic studies. CSS scores differentiated between those that were constipated and were not constipated with 96% accuracy. Advantages to the CSS are that
it is valid, and that it includes only 8 items. The reliability, responsiveness, or sensitivity to change of the CSS has not been determined.

2.15.4 Female Sexual Function Index

The Female Sexual Function Index (FSFI) is a 19-item questionnaire that measures sexual function across 6 domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. FSFI items are rated on a 5 point Likert-type scale with higher scores indicating better sexual function.\(^8^0\) The maximum possible score for a domain is 6.0. A full scale score can range from 2.0 to 36.0, and is obtained by adding the 6 domain scores. The FSFI has been reported to have good internal consistency, reproducibility, and discriminative validity.\(^8^0\) Rosen and colleagues reported acceptable internal consistency reliability for all six FSFI domains with Cronbach’s \(\alpha\) values of 0.82 – 0.97 in women aged 21-69 years with and without Female Sexual Arousal Disorder. Test-retest reliability was also confirmed with significant Pearson product-moment correlation coefficients ranging from 0.69 – 0.91. Moreover, females with sexual function had significantly poorer scores when compared to healthy controls, indicating that the FSFI is able to differentiate between clinical and nonclinical populations.\(^8^0\) One domain, instead of the entire questionnaire, can be administered as Rosen reported the psychometrics for all of the specific domains. Because women with UI are at a higher risk for dyspareunia,\(^3^5\) it seems prudent to include an instrument assessing sexual pain when evaluating the efficacy of UI interventions.
2.16 Barriers to successful physical therapy outcomes

Women seeking physical therapy for treatment of UI are typically seen one time per week over a period of 4-8 weeks. An integral part of the patient’s intervention program is instruction and performance of pelvic floor muscle training at home to supplement the weekly physical therapy visits. A woman’s adherence or non-adherence to the prescribed home exercise program may logically impact the success of physical therapy for UI treatment.

For postpartum women, factors that may influence whether women perform PFM exercise include education, activity level, parity, smoking status, type of child delivery, UI status, and pelvic pain. Women who performed PFM at least once a week 6 months postpartum were significantly more educated, had more children (2 children OR 1.07; 95% CI 1.09-12.26 and 3 children OR 1.45; 95% CI 1.33-1.59) and were twice as likely to participate in a general fitness activities 3 or more times a week (OR 2.06; 95% CI 1.3-2.33) than women who performed PFM exercises less frequently or not at all. Additionally, women who were experiencing UI and/or pelvic pain were also more likely to do PFM exercises. On the contrary, women who smoked daily or had cesarean section were less likely to do PFM regularly. Rates of performance of PFM exercise at 6 months postpartum vary from 58%-67%. Reasons women gave for not initiating PFM or for stopping PFM exercise in the 6-month postpartum period include the rationale that exercise was unnecessary if the woman was not experiencing any UI, they forgot to perform the PFM exercise, or that they were too busy.
For women with UI, PFM exercise adherence rates at 5 years vary from 10% - 70%. Only one study investigated adherence after 15 year after cessation of PFM training and reported that 28% of women performed PFM exercise at least weekly. Those that do not regularly engage in PFM exercise after cessation of formal PFM training are at increased risk of frequency of UI episodes. Lagro-Janssen reported that those who performed PFM exercise at five years were over 8 times more likely to report a 50% or greater decrease in the frequency of UI episodes compared to UI episodes one year after cessation of physical therapy. Patients who did not perform PFM exercise at follow-up cited lack of discipline, interference with daily activities, lack of time, and disinterest as reasons for failure to perform PFM exercise at home.

Studies have reported an inconsistent relationship between patient characteristics and exercise adherence. Alewijnse and colleagues investigated predictors of long-term adherence to PFM exercise among women with UI who sought physical therapy treatment. The most striking association reported was that women who performed PFM exercise after cessation of physical therapy were more likely to continue adherence at one year follow-up. Additionally, women who had more frequent weekly UI episodes before physical therapy treatment and at one year follow-up had higher adherence levels one year after therapy than women with fewer weekly losses. Lagro-Janssen reported that age, parity, severity of incontinence, and patients’ psychological characteristics such as anxiety, did not predict successful urinary outcomes. On the contrary, Alewijnse reported that the amount of urine loss per incontinent episode as well as a women’s perception of their ability to do the exercises as recommended under various circumstances were significant predictors of the intention to adhere to PFM exercise.
The discrepancy regarding the severity of incontinence in Lagro-Janssen and Alewijnse’s studies could be explained in the fact that Lagro-Janssen defined severity as a function of frequency of urine loss, amount of urine loss, use of protective pads, and restriction in daily activities due to incontinence, while Alewijnse utilized a strict definition of urine loss per incontinent episode.
Chapter 3

Methods

3.1 Experimental Design & Setting

The first primary aim of this retrospective descriptive study was to determine the efficacy of physical therapy interventions provided within a pragmatic setting on global impression of improvement, pelvic symptoms, and health-related quality of life to women with a primary diagnosis of UI. Women’s post-intervention PGI-I scores were summarized to determine the subjects’ global impression of improvement with physical therapy intervention. To determine the efficacy of physical therapy intervention on pelvic symptoms, women’s pre-post intervention PFDI-20, CSS, and FSFI change scores were analyzed. In addition, women’s pre-post PFIQ-7 change scores were examined to determine the effectiveness of the physical therapy intervention on health-related quality of life. The second primary aim was to determine the relationship between selected patient-related characteristics (age, parity, race, number of comorbidities, carbonated beverage intake, current smoking status, presence of barriers to intervention recommendations, and number of physical therapy visits) and treatment success. Treatment success was defined as a post-intervention PGI-I score of “much better” or “very much better;” a reduction in pelvic symptoms (reduction in PFDI-20 score at discharge); and improvement in health-related quality of life (reduction in PFIQ-7 at discharge).

The secondary aim was to document the percentage of women who received 4 possible interventions. Because intervention selection may be determined by the constellation of symptoms a woman possesses, separate percentages were calculated for 4
symptom-based categories of women. The categories included: UI symptoms only, UI + bowel symptoms, UI + pelvic pain, or UI + bowel symptoms + pelvic pain. Interventions included patient education, modalities, manual physical therapy procedures, and exercise. (See Table 3.5 for delineation of interventions).

Data for this study were obtained from the Centers for Rehabilitation Services (CRS) Women’s Health Physical Therapy Database. Fifteen physical therapists (PTs) from 12 different CRS clinic locations managed the care of women referred to physical therapy services at the CRS for UI. Each physical therapist (PT) hand entered patient data into the Women’s Health Physical Therapy Database. The locations of the 12 clinics are delineated in Table 3.1.

Table 3.1: CRS Locations

<table>
<thead>
<tr>
<th>CRS Cranberry</th>
<th>CRS Harmarville</th>
<th>CRS Delmont</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rowan Towers</td>
<td>Alexander's Athletic Club</td>
<td>Salem Place</td>
</tr>
<tr>
<td>8050 Rowan Rd.</td>
<td>2585 Freeport Rd.</td>
<td>6530 Route 22</td>
</tr>
<tr>
<td>Suite 101</td>
<td>Suite 205</td>
<td>Suite 100</td>
</tr>
<tr>
<td>Cranberry, PA 16066</td>
<td>Pittsburgh, PA 15238</td>
<td>Delmont, PA 15626</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CRS Monroeville</th>
<th>CRS Moon Township</th>
<th>CRS Oakland</th>
</tr>
</thead>
<tbody>
<tr>
<td>UPMC at Oxford Drive</td>
<td>UPMC West</td>
<td>Kaufmann Medical Bldg.</td>
</tr>
<tr>
<td>600 Oxford Drive</td>
<td>1600 Coraopolis Heights Rd.</td>
<td>3471 Fifth Ave.</td>
</tr>
<tr>
<td>Suite 310</td>
<td>Coraopolis, PA 15108</td>
<td>Suite 1201</td>
</tr>
<tr>
<td>Monroeville, PA 15146</td>
<td></td>
<td>Pittsburgh, PA 15213</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CRS South Hills</th>
<th>CRS Squirrel Hill</th>
<th>CRS-UPMC St. Margaret</th>
</tr>
</thead>
<tbody>
<tr>
<td>1300 Oxford Dr.</td>
<td>2345 Murray Ave.</td>
<td>Park Place at Chapel Harbor</td>
</tr>
<tr>
<td>Suite 1F</td>
<td>Suite 300</td>
<td>300 Chapel Harbor Dr.</td>
</tr>
<tr>
<td>Bethel Park, PA 15102</td>
<td>Pittsburgh, PA 15217</td>
<td>Suite 200</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chippewa</th>
<th>CRS Gibsonia</th>
<th>CRS McCandless</th>
</tr>
</thead>
<tbody>
<tr>
<td>2580 Constitution Blvd.</td>
<td>Northtowne Square</td>
<td>9365 McKnight Rd.</td>
</tr>
<tr>
<td>Beaver Falls, PA 15010</td>
<td>5600 William Flynn Highway</td>
<td>Suite 300</td>
</tr>
<tr>
<td></td>
<td>Gibsonia, PA 15044</td>
<td>Pittsburgh, PA 15237</td>
</tr>
</tbody>
</table>
3.2 Subjects

Data from female patients with UI (of both neurogenic and non-neurogenic origin) managed by CRS PTs between November 1, 2009-November 15, 2010 were included for study analysis. Potential patient records were excluded from this study if the patient:

- was seen for less than 2 therapy visits;
- did not complete at least one of the three initial primary outcome measures (PGI-I, PFDI-20, and/or PFIQ-7); and/or
- reported pain with urination (indicating possible urinary infection).

In addition, women with neurogenic bladder symptoms (predominate etiology of multiple sclerosis), who indicated that they were currently experiencing a neurological relapse or a score of 8 (indicating a walking status of “bedridden”) on the Patient-Determined Disease Steps were not eligible for inclusion in the study. The Patient-Determined Disease Steps is a disease-specific measure for individuals with multiple sclerosis used to assess mobility based on the patient’s own perception of her walking ability. For patients with multiple sclerosis, this questionnaire was completed at baseline and discharge physical therapy visits. This measure was also used to define the level of disability for women with multiple sclerosis and to determine if a decline in function occurred over the course of physical therapy management.

Based on previous behavioral training and physical therapy trials for women with UI, it is estimated that \(15\% \pm 144,182 - 18\% \pm 16\) will be treated < 2 visits or will not complete at least one of the three initial primary outcome measures and \(2\% \pm 16\) will report pain with urination indicating possible infection. Thus, data from approximately 20% of women managed by CRS PTs during the study period were expected to be excluded from
consideration. Data from 166 women were expected to be reviewed with the expectation that data from 138 women would eligible for study inclusion.

3.3 Procedures

3.3.1 Uniform Data Collection Procedures

Data were entered by the PT responsible for the patient’s care into an electronic database designed for quality improvement and research purposes. The database was developed based upon input from the CRS Director of Women’s Health Physical Therapy at CRS, the CRS Chief Operating Officer, and the 15 CRS PTs who specialized in women’s health physical therapy. The database had the capacity to store the following data: patient demographics; medical, surgical (including obstetric and gynecologic) and medication history; urinary symptoms; dietary intake (fiber, fluid, caffeine); musculoskeletal and neuromuscular impairments identified during the physical therapy examination; physical therapy interventions administered during the course of patient care; barriers to intervention recommendations; and study outcome scores (PGI-I, PFDI-20, PFIQ-7, CSS, FSFI).

To promote consistency and uniformity in data collection, the medical history form completed by the patient at the initial physical therapy examination was developed to parallel medical, surgical, and medication history database fields. Likewise, physical therapy examination and intervention forms were developed to ensure uniform and comprehensive documentation, adherence to CRS documentation standards, and concurrence with examination and intervention database fields. In addition, one in-person meeting between the CRS Women’s Health PTs and the primary study
investigators occurred to discuss and operationally define the tests and measures utilized during the physical therapy examination.

Finally, three in-person meetings were conducted between the CRS Women’s Health PTs and the primary study investigators to discuss and educate the PTs on existing valid and reliable pelvic-floor specific symptom and quality of life outcome measures. Based on input from the PTs, outcome measures were selected to assess the impact of physical therapy management on the patient’s global impression of improvement, pelvic symptoms, and patient’s health-related quality of life. The PTs were educated on procedures for administering and scoring these measures.

3.3.2 Selected Outcome measures/questionnaires

Study primary outcome measures included the PGI-I, PFDI-20, and PFIQ-7. Only the PGI-I score obtained at the discharge examination was collected. The PFDI-20 and PFIQ-7 questionnaires were completed by women at their initial (baseline) and discharge physical therapy examinations.

The PGI-I is a global index to assess the patient’s perception of improvement following treatment intervention.\textsuperscript{170-173} The PGI-I has been shown to have good construct validity for treatment response in women with SUI.\textsuperscript{77} It includes one question that asks the respondent to compare their current condition to how it was prior to starting treatment. The response range is 1-7, with 1 being “very much better” and 7 being “very much worse.” Thus, lower scores indicate an improvement in the condition, while higher scores indicate a worsening of the condition.
The PFDI-20 and PFIQ-7 are condition-specific instruments that assess urinary, bowel, and prolapse symptoms, and the impact of urinary, bowel, and prolapse symptoms on a woman’s quality of life, respectively. Because it is common for several pelvic floor disorders to co-exist in the same woman, the use of instruments that assess the whole spectrum of interrelated symptoms is essential when evaluating the efficacy of treatment interventions. The PFDI-20 has a total of 20 questions and contains 3 subscales: the Urinary Distress Inventory-6, the Pelvic Organ Prolapse Distress Inventory-6, and the Colorectal-anal Distress Inventory-8. Respondents are asked to endorse the presence of symptoms and the degree of bother on a scale from 1 (not at all) to 4 (quite a bit) associated with each symptom. The 3 subscales of the PFDI-20 are scored from 0 (least distress) to 100 (greatest distress), and the summary PFDI-20 score includes the sum of the 3 scales and ranges from 0 to 300. The PFIQ-7 has 21 items and contains 3 subscales: the Urinary Impact Questionnaire-7, the Pelvic Organ Prolapse Impact Questionnaire-7, and the Colorectal-anal Impact Questionnaire-7. On this questionnaire, respondents are asked to rate the degree their bladder, prolapse, and/or bowel symptoms affect their activities, relationships, and feelings on a scale from 0 (not at all) to 3 (quite a bit). Each of the subscales are scored from 0 (symptoms do not impact) to 100 (symptoms greatly impact) with an overall PFIQ-7 summary score ranging from 0 to 300. Both the PFDI-20 and PFIQ-7 are valid, reliable, and responsive to change, and demonstrate significant correlations with the long versions of the PFDI and PFIQ (ICCs ranging from 0.86-0.93 and 0.94-0.96 respectively).

Secondary study outcome measures included the CSS and FSFI. These questionnaires were completed at initial (baseline) and at discharge physical therapy
examinations. The CSS is a valid instrument that assesses the bowel habits and symptoms of constipated patients. The CSS contains 7 items that are scored from 0-4. A score of 0 indicates less distress and a score of 4 indicates greatest distress. An additional CSS item queries the type of assistance needed to produce a bowel movement. Score range on this item is from 0 (without assistance) to 2 (digital assistance or enema). Thus, the total CSS score ranges from 0-30, with a score greater than 15 indicating constipation. The brevity of CSS is advantageous. In addition, Agachan and colleagues reported that the CSS demonstrated convergent and divergent validity as well as significant correlation with anal and colorectal physiologic studies. However, the reliability, responsiveness, and sensitivity to change of the CSS have not been determined.

The FSFI is a 19-item questionnaire that measures sexual function across 6 domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. An advantage of the FSFI is that one domain, instead of the entire questionnaire, can be administered. This study utilized only the pain domain which includes 3 questions. The questions query how often the respondent experiences pain during vaginal penetration, after vaginal penetration, and the degree of discomfort during or following penetration. FSFI items are rated on a 5 point Likert-type scale with “1” indicating that the respondent “almost always” has pain and “5” indicating she “almost never” has pain. The respondent is also given the choice of “0” indicating “did not attempt intercourse” for each item yielding an overall score range of 0-6. Consequently, higher scores on the FSFI indicate better sexual function. The pain domain of the FSFI has high internal consistency (Cronbach’s
alpha 0.92-0.94), moderately high test-retest reliability (r=0.69-0.87), and discriminant validity.\textsuperscript{80}

3.3.3 Selected Patient Demographic, History Data

Based on the pathophysiology and risk factors for UI, the history review for a woman with UI should be multi-factorial taking into account the patient’s demographics; gynecologic/obstetric history; comorbid conditions (including presence of co-existing pelvic symptoms); medication use; dietary habits (fiber, fluid, and caffeine intake); and current smoking status. Table 3.2 identifies selected patient demographic and history information investigated for their possible impact on intervention outcomes. The table also includes the rationale for inclusion into the database. In addition, the number of physical therapy visits may also impact physical therapy outcomes. According to a recent systematic review, treatment effect may be greater in women with SUI who received a longer duration of PFM training (6 months versus 8 weeks).\textsuperscript{17} Subsequently, the association between the number of physical therapy visits and outcomes was also investigated. To describe the study sample, the following selected patient demographic and history data were used: marital status (married/living as married or not married), menopausal status (regular cycle, perimenopause, or menopause), medications (drug therapy for UI, diuretics, hormone replacement, psychotropic medications, and/or narcotics/analgesics), pelvic surgeries (hysterectomy, abdominal/anal-rectal/bladder surgery, and/or urethral dilation) types of urinary symptoms (difficulty emptying, urinary frequency, urinary urgency, nocturia, SUI symptoms, and/or UUI symptoms), duration of UI (years) and dietary habits including caffeine intake (< 2.5 cups per day or ≥ 2.5 cups
per day), water (< 3 or 3-6 or >6 glasses per day) and fiber intake (do or do not include fiber in diet). Both predictor variables and selected demographic/history data were extracted from the patient’s medical record and entered into the database.
Table 3.2: Components of the Demographic/History Review

<table>
<thead>
<tr>
<th>Demographic Factors</th>
<th>Obstetric History</th>
<th>Comorbidities that affect bladder function</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>Older age significant risk factor for UUI(^{48, 50, 57}) and increased severity of symptoms(^{47})</td>
<td>Possible injury to pudendal nerve, disruption of intravaginal attachments of vagina, stretching and tearing of PFM(^{9})</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td>Caucasian significant risk for UIC(^{55})</td>
<td></td>
</tr>
<tr>
<td>(Caucasian or non-Caucasian)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Obstetric History</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Parity (0,1,2,3,&gt;3)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Body Mass Index (kg/m(^{2}))</strong></td>
<td>BMI &gt; 30 significant risk for SUI(^{50, 57}) and increased severity of symptoms(^{48})</td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory disease, chronic coughing</strong></td>
<td>Increase bladder volume and pressure(^{184})</td>
<td></td>
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<tr>
<td><strong>Bowel dysfunction</strong></td>
<td></td>
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<tr>
<td>Constipation</td>
<td></td>
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<tr>
<td>Irritable Bowel Syndrome</td>
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<tr>
<td>Fecal incontinence</td>
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<tr>
<td><strong>Neurological conditions</strong> (Cerebrovascular accident, Multiple sclerosis, Other)</td>
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<tr>
<td><strong>Diabetes</strong></td>
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<tr>
<td><strong>Pelvic organ prolapse</strong></td>
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<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
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<tr>
<td>Pelvic pain</td>
<td>Urologic(^{116-118}) or musculoskeletal(^{116-118}) causes of pelvic pain may directly impact bladder function</td>
<td></td>
</tr>
<tr>
<td>Low back pain</td>
<td>May disrupt PFM function via pain inhibition or decreased muscle reaction(^{57})</td>
<td></td>
</tr>
<tr>
<td>Pelvic surgery</td>
<td>Cause possible tissue injury or impair neuromuscular function(^{184})</td>
<td></td>
</tr>
<tr>
<td><strong>Dietary and Lifestyle Habits</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbonated beverages (≥ 1 per week or &lt;1 per week)</td>
<td>Postulated that the ingredients in these beverages (sugar, artificial sweeteners, citric acid) may irritate the bladder(^{57})</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>Increase bladder volume and pressure(^{184})</td>
<td></td>
</tr>
</tbody>
</table>
3.3.4 Tests and Measures

Data obtained from the patient during the initial and discharge physical therapy examinations included the presence of pelvic organ prolapse, PFM strength, and PFM tension/pain. The examination data were entered into the database and utilized to describe the study sample.

3.3.4.1 Pelvic organ prolapse

To measure pelvic organ prolapse (POP) via vaginal palpation, patients were positioned in hook-lying. The PT inserted two lubricated fingers to the level of the PIP joint into the patient’s vagina. The examiner then pressed down on the patient’s posterior vaginal wall to enhance visualization of the anterior vaginal wall. The patient was then asked to bear down or cough. Bulging tissues on the anterior vaginal wall indicate a prolapse of the bladder (cystocele), urethra, or cervix, which were subsequently graded on a scale of 0-IV (Table 3.3). To examine the posterior vaginal wall, the examiner separated the examining fingers laterally and pressed against the posterior vaginal wall. The patient was then asked to bear down or cough. Bulging of the posterior wall indicates a rectocele which was subsequently graded on the 0-IV scale. If the patient had multiple pelvic organ prolapse (i.e. rectocele and cystocele), the PT entered the most severe prolapse grade into the database.
Table 3.3: Pelvic Organ Prolapse Grades

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No prolapse is demonstrated</td>
</tr>
<tr>
<td>Grade I</td>
<td>Deep prolapse; palpable only</td>
</tr>
<tr>
<td>Grade II</td>
<td>Prolapse half-way toward level of introitus; palpable and visualized</td>
</tr>
<tr>
<td>Grade III</td>
<td>Prolapse at level of introitus; visualized</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Prolapse outside level of introitus; visualized</td>
</tr>
</tbody>
</table>

3.3.4.2 Pelvic Floor Muscle Strength

Several methods have been described to examine and evaluate pelvic floor muscle (PFM) strength, including manual muscle testing via vaginal palpation and manometry.\textsuperscript{69} Correct contraction of the PFM includes both a squeeze around the pelvic openings and an upward lift. Measures to examine and evaluate strength should take into account both the squeeze and lift components. Most PTs utilize vaginal palpation and the modified Oxford scale to evaluate PFM strength because squeeze pressure and lift are included in the Oxford scale criteria.\textsuperscript{69}

To measure PFM strength via vaginal palpation, patients were positioned in hook-lying. The examiner inserted two lubricated fingers approximately 3.5 cm inward from the patient’s vaginal introitus to palpate the levator ani. The patient was then asked to “lift and squeeze” the PFM as tightly as possible around the examiner’s fingers. PFM strength was graded based on the modified Oxford Scale as detailed in Table 3.4.\textsuperscript{187}
Table 3.4: Modified Oxford Scale for PFM Strength

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No movement palpable</td>
</tr>
<tr>
<td>1</td>
<td>Minimal or very small muscle bulging on palpation</td>
</tr>
<tr>
<td>2</td>
<td>Small range of motion, weak with brief hold</td>
</tr>
<tr>
<td>3</td>
<td>Definite muscle movement, upward lift to half range</td>
</tr>
<tr>
<td>4</td>
<td>Firm muscle movement closing around finger, upward lift to half to three-quarter range</td>
</tr>
<tr>
<td>5</td>
<td>Very firm muscle pull that compresses finger, upward lift to full range and strong hold</td>
</tr>
</tbody>
</table>

The modified Oxford scale has good intra-tester and inter-tester reliability. Neumann investigated the intra- and inter-rater reliability of PTs performing the modified Oxford scale in a multi-site study. For intra-rater reliability, Neumann found complete agreement between test 1 and test 2 in 13 out of 14 tests, representing 93% overall agreement and 100% agreement to within one grade (Kappa coefficient 0.9, p<0.001: suggesting almost perfect agreement). Inter-tester reliability between 50 PTs at 6 different sites showed 56% inter-rater agreement (Kappa coefficient = 0.4, p<0.001), suggesting fair agreement between the PTs and Neumann. In 42% of the tests, there was a difference of one grade. Thus, there was 96% agreement within one grade between the PTs and Neumann. Similarly, Bo and Finckenhagen reported acceptable inter-test reliability (Kappa coefficient = 0.47) between PTs utilizing the modified Oxford scale. In 9 of the 10 cases of disagreement, one PT consistently rated subjects one grade lower than the other PT, indicating a systematic difference between the raters. It is recognized that PFM testing via vaginal palpation may not provide the sensitivity and responsiveness necessary for scientific investigations, while other measures may be more appropriate in measuring force. However, vaginal examination and rating the PFM
using the modified Oxford scale is a clinically accepted method by PTs for evaluating PFM function.

3.3.4.3 PFM Tension and Pain

Muscle tension testing via palpation is a test performed by PTs to assess the quality of the muscle. For example, if a muscle feels excessively “soft,” the PT may suspect muscle atrophy. Conversely, if a muscle feels excessively “hard,” the PT may suspect muscle spasm. There are no standard measures to evaluate muscle tension. Thus, we operationally defined muscle tension for the purpose of evaluating pelvic floor muscle tension. A grade of atrophy indicated low muscle bulk, a grade of normal indicated normal muscle bulk, and a grade of spasm indicated tissue restriction to palpation or stretch. In addition, pain noted upon palpation of muscle tension was rated by the patient on a 0-10 scale (0 = no pain and 10 = worst imaginable pain).

3.3.5 Intervention

3.3.5.1 Treatments Received

The PT evaluated data gathered from the initial examination and determined the patient’s plan of care. The plan of care was individualized for each patient and included standard physical therapy interventions. Standard physical therapy intervention for pelvic floor dysfunction may consist of standard physical therapy interventions used to treat other diagnoses. Such interventions include those to address pain (modalities), improve strength and coordination of the PFM (PFM exercise with or without biofeedback and/or electrical stimulation), improve strength of abdominal and/or lumbar
extensor muscles, and improve range of motion (flexibility exercises, soft tissue/joint mobilization). Patient education was also recorded including recommendations for bladder and/or bowel training, fluid management, and diet modification. PTs entered their interventions in their plan of care and in the database at the initial examination, monthly following the initial examination, and at the time of discharge from physical therapy. Intervention categories included in the database are outlined in Table 3.5.
Table 3.5: Intervention categories with evidence-based references of justification noted

<table>
<thead>
<tr>
<th>Modalities</th>
<th>Manual physical therapy procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heat\textsuperscript{129}</td>
<td>Soft tissue mobilization to decrease soft tissue restriction and improve range of motion\textsuperscript{125, 127}</td>
</tr>
<tr>
<td>Ice\textsuperscript{130}</td>
<td>Joint mobilization to improve range of motion\textsuperscript{128}</td>
</tr>
<tr>
<td>PFM Biofeedback\textsuperscript{18, 23-26, 76, 144, 145}</td>
<td></td>
</tr>
<tr>
<td>• To promote strength and endurance</td>
<td></td>
</tr>
<tr>
<td>• To increase coordination</td>
<td></td>
</tr>
<tr>
<td>• To promote muscle relaxation</td>
<td></td>
</tr>
<tr>
<td>PFM Electrical Stimulation\textsuperscript{16, 26}</td>
<td></td>
</tr>
<tr>
<td>• To improve PFM muscle strength (if &lt; 2/5 PFM strength)</td>
<td></td>
</tr>
<tr>
<td>• To promote sensory awareness due to sensory impairment</td>
<td></td>
</tr>
<tr>
<td>• To reduce pain</td>
<td></td>
</tr>
<tr>
<td>Exercises</td>
<td>Education</td>
</tr>
<tr>
<td>PFM\textsuperscript{11, 13-18, 20, 22, 23, 68, 70, 141}</td>
<td>Body mechanics/posture\textsuperscript{117, 128, 132}</td>
</tr>
<tr>
<td>• Manual facilitation</td>
<td>Bladder/bowel schedule\textsuperscript{75}</td>
</tr>
<tr>
<td>• Gravity eliminated</td>
<td>Diet modification</td>
</tr>
<tr>
<td>• Anti-gravity</td>
<td>• Caffeine reduction\textsuperscript{56}</td>
</tr>
<tr>
<td>• During functional tasks</td>
<td>• Carbonated beverage reduction\textsuperscript{56}</td>
</tr>
<tr>
<td>• Downtraining</td>
<td>• Increase water intake\textsuperscript{159}</td>
</tr>
<tr>
<td>Core Stabilization\textsuperscript{71, 72}</td>
<td>• Decrease water intake\textsuperscript{152, 153}</td>
</tr>
<tr>
<td>• Transverse Abdominus</td>
<td>• Fiber education\textsuperscript{159, 160}</td>
</tr>
<tr>
<td>• Other Abdominal</td>
<td>Relaxation techniques to decrease muscle tension\textsuperscript{132, 165}</td>
</tr>
<tr>
<td>• Multifidus</td>
<td>SUI strategies\textsuperscript{22, 73} (PFM contraction before increase in intra-abdominal pressure)</td>
</tr>
<tr>
<td>• Functional</td>
<td>UUI strategies\textsuperscript{74-76} (inhibition techniques to suppress bladder contractions)</td>
</tr>
<tr>
<td>Flexibility</td>
<td>Toilet strategies</td>
</tr>
<tr>
<td>• Hip\textsuperscript{130}</td>
<td>• Constipation (toilet posture to promote bowel movement)\textsuperscript{10, 189}</td>
</tr>
<tr>
<td>• Lumbopelvic\textsuperscript{67, 130}</td>
<td>• Voiding without straining</td>
</tr>
<tr>
<td></td>
<td>Soft tissue massage (abdominal massage,\textsuperscript{40} scar massage,\textsuperscript{130, 132} self-stretching for introitus\textsuperscript{127})</td>
</tr>
</tbody>
</table>
3.3.5.2 Barriers to Intervention Recommendations and Changes in Intervention

If a patient was not progressing with the plan of care, the PT recorded changes in the plan of care and barriers impacting outcomes during monthly re-evaluation visits. The presence or absence of barriers to intervention recommendation was utilized as a predictor variable for statistical analysis. The changes in plan of care were reported descriptively for the entire study sample. Table 3.6 defines the categories utilized in the database.

Table 3.6: Barriers to Intervention Recommendations and Changes in Plan of Care

<table>
<thead>
<tr>
<th>Barriers to Intervention Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient did not attend all recommended physical therapy visits</td>
</tr>
<tr>
<td>• Patient was not adherent to home exercise program</td>
</tr>
<tr>
<td>• Patient did not adhere to recommended lifestyle modifications (fluid</td>
</tr>
<tr>
<td>management, diet modification, urge/stress, strategy, etc)</td>
</tr>
<tr>
<td>• Cognitive impairments interfered with patient’s ability to follow through</td>
</tr>
<tr>
<td>with physical therapy recommendations</td>
</tr>
<tr>
<td>• Comorbidities contributed to UI or interfered with the patient’s ability to</td>
</tr>
<tr>
<td>follow the plan of care</td>
</tr>
<tr>
<td>• Medications contributed to UI, limiting outcomes</td>
</tr>
<tr>
<td>• Sensory loss limited patient’s ability to recognize correct muscle</td>
</tr>
<tr>
<td>contraction</td>
</tr>
<tr>
<td>• Profound muscle weakness/muscle denervation limited potential for increased</td>
</tr>
<tr>
<td>muscle function</td>
</tr>
</tbody>
</table>

| Changes in plan of care due to barriers encountered during physical therapy  |
| sessions                                                                    |
| • Patient education on importance of visit attendance                       |
| • Change in exercise intensity (increased intensity to promote strength,      |
| decreased intensity due to lack of patient adherence to home exercise program)|
| • Internal PFM facilitation due to lack of ability to contract PFM           |
| • Functional PFM activation (progression of PFM exercise in standing        |
| postures)                                                                   |
| • Further interdisciplinary or specialist consultation                       |
| • Increase in core (abdominal, lumbar extensor) exercises to promote PFM    |
| recruitment                                                                 |

3.4 Statistical Analysis

Statistical analysis was completed using a commercially available software package (SPSS; Chicago, IL). Descriptive statistics were calculated to describe the
selected demographic and history information, examination findings, and to describe primary (PGI-I, PFDI-20, PFIQ-7) and secondary (CSS, FSFI) outcome scores of women with UI following pragmatic physical therapy management. Demographic sample characteristics included: age, race/ethnicity, body mass index, and marital status. History sample characteristics included: parity; number of comorbidities; pelvic surgeries; menopausal status; medications; types of urinary symptoms; duration of UI; smoking status; and dietary habits including caffeine, carbonated beverage, water, and fiber intake. Examination findings described for the study sample included pelvic organ prolapse grade, PFM strength grade, and PFM tension/pain.

To determine if pelvic symptoms (PFDI-20) or health-related quality of life (PFIQ-7) was altered by physical therapy interventions, mean baseline and post-intervention scores for each dependent variable were compared with a paired t-test. To determine if constipation symptoms (CSS) or pain with sexual intercourse (FSFI) was altered by physical therapy interventions, mean rank baseline and post-intervention scores for each dependent variable were compared with a Wilcoxon signed-rank test. To determine women’s perception of improvement attributed to physical therapy interventions, the median post intervention PGI-I score was reported. No pre-post intervention on this outcome was performed as this measure was obtained only at discharge from physical therapy.

Correlation coefficients were calculated to determine if age, number of physical therapy visits, and number of comorbidities were related to PFDI-20 and PFIQ-7 outcomes. Correlations between PFDI-20 change scores (PFDI-20 postintervention – PFDI-7 baseline) and age (years) and number of physical therapy visits were
independently assessed using Pearson correlation coefficients. Correlations between
PFDI-20 change scores and number of comorbidities were assessed using Spearman’s
rho. In a similar fashion, PFIQ-7 change scores were assessed. Variables with
correlations with a p-value of $\leq 0.10$ were entered into a stepwise linear regression.

To examine the relationship between PFDI-20 change scores and the dichotomous
independent variables of parity (nulliparous or parous), presence of barriers to
intervention recommendations (none or $\geq 1$), race, (Caucasian or non-Caucasian),
carbonated beverage intake ($\geq 1$ per week or $< 1$ per week), and current smoking status
(smoker or non-smoker) a stepwise linear regression was used. To determine the
dichotomous variables to be included in the stepwise linear regression, the mean PFDI-20
change scores associated with both categories of a dichotomous variable were calculated
and compared using a two sample t-test. For example, the mean PFDI-20 change score
for Caucasian subjects was compared to that of non-Caucasian subjects. Should a
significant difference in mean score ($p \leq 0.10$) exist between the two categories of a
dichotomous variable; the dichotomous variable was included in the stepwise linear
regression. The same procedure was used to examine the relationship between PFIQ-7
change scores and dichotomous variables.

Two sample t-tests and chi-square analysis were used to determine if predictor
variables were related to treatment success or failure. For these analyses, post
intervention PGI-I scores were divided into 2 categories: scores indicating treatment
success and scores indicating treatment failure. Treatment success was defined by a post-
intervention PGI-I score of “much better” or “very much better” while treatment failure
was defined by the PGI-I scores of “a little better,” “no change,” “a little worse,” “much
worse,” and “very much worse.” Two sample t-tests were used to compare the mean age, number of comorbidities, and number of physical therapy visits between success and failure groups. Variables showing statistically significant differences between groups (p-value ≤0.10) were entered into a stepwise logistic regression. Finally, chi square analyses were utilized to determine if parity (nulliparous or parous), presence of barriers to intervention recommendations (none or ≥1), race (Caucasian or non-Caucasian), carbonated beverage intake (≥ 1 per week or <1 per week), and current smoking status (smoker or non-smoker) significantly influenced the distribution of women to the categories of success and failure. Variables resulting in a p-value of ≤0.10 were entered into a stepwise logistic regression.

Descriptive statistics were utilized to address the secondary aim of describing the types of interventions received by women. For these analyses, data from women were presented according to symptom constellation (UI symptoms only, UI + bowel symptoms, UI + pelvic pain, or UI + bowel symptoms + pelvic pain). However, for selected interventions, the proportion of women receiving the intervention was presented for specific subgroups. For example, education on the stress strategy was only applicable to women with SUI symptoms. Thus, the percentage of women who received education on the stress strategy was documented for women with SUI symptoms only.

3.5 Power Analysis

The minimum important difference (MID) is the smallest change in score associated with a clinically meaningful change in a questionnaire.\textsuperscript{81} Statistical tests are not responsive to practical or clinical implications of the data. Subsequently, statistical
differences may not be clinically meaningful changes and determining the MID is essential in interpreting questionnaire results. To date, there have been no trials investigating the impact of physical therapy interventions on concurrent urinary, bowel, pelvic organ prolapse, and sexual function symptoms in women utilizing the PFDI-20 and PFIQ-7. However, Barber and colleagues estimated the MID for the urinary subscales in the PFDI and PFIQ long questionnaires. Women with SUI were randomized into 1 of 3 interventions: an incontinence pessary, a 12-week behavioral therapy program, or both. The behavioral program consisted of 4 clinic visits at 2-week intervals and included PFM exercise and education in SUI strategies. Using both anchor- and distribution-based approaches to calculate the MID, Barber evaluated the change in score from baseline to 3 months after initiating treatment. Anchors used were the PGI-I, incontinence episodes from a urinary diary, and the Incontinence Severity Index. The MID for the urinary subscales of the PFDI and PFIQ were 11.1 and 16.0 respectively. Essentially, a change score of 11 on the PFDI urinary subscale differentiated those who were “about the same” from those who were “better.” Although this study utilized the long forms of the PFDI and PFIQ, the short forms (PFDI-20 and PFDI-7) have been shown to be significantly correlated with the long forms with ICC values between 0.70 and 0.91. Using a 99% CI, a MID of 11, and standard deviations from Barber’s trial, an initial sample size of 138 patients was determined based on the formula below. Taking into account that 20% of the available medical records will meet exclusion criteria, the sample size appropriate for this study is 166.
**PFDI-20**

$$((2.58*\text{standard deviation}) / \text{MID}))=n^2$$

$$((2.58*32)/11)^2=56$$

Based on the proportions reported in Barber, we would expect that approximately 10% of women would get worse (overestimate) \(n=6\), 10% would stay about the same \(n=6\), 30% would get better \(n=57\), and 50% would get much better \(n=69\) for a total of 138 patients.

Although an initial sample size of 166 was calculated to determine efficacy of physical therapy treatment on the PFDI-20 and PFIQ-7 scores, a second power calculation was performed to determine the number of subjects necessary to perform the stepwise linear regression analysis using the 2-step rule-of-thumb based on Cohen’s power analytic approach. The calculations utilize a power of 0.80, alpha of 0.05, and an effect size \(f^2\) for regression analysis of 0.15 which indicates a medium effect size based on Cohen’s work.\(^{191}\)

Step 1: Compute lambda \((L)\): 

$$L = 6.4 + 1.65m - 0.05m^2$$

where \(m\) equals the number of independent variables.

Step 1 results: 

$$L = 6.4 + 1.65(8) - 0.05(8)^2 = 16.4$$

Step 2: Compute required minimum sample size: 

$$N = L / f^2$$

Step 2 results: 

$$N = 16.4 / 0.15 = 109.3 = 110$$

Since 138 > 110, the most appropriate sample calculation for this study was 166 taking into account that 20% of the medical records will meet exclusion criteria.
Chapter 4

Results

4.1 Subjects

Between November 1, 2009 and November 15, 2010, 500 physical therapy records were screened by the CRS honest broker. Data from 100 women met study inclusion criteria, were extracted from the database, and included for data analysis.

Ninety eight percent of the participants were Caucasian and their mean age was 54.4 ± 15.2 years. Most women (82%) were parous, 16% were nulliparous, and 2% did not report parity. Median parity of the sample was 2.0 (1st quartile value = 1.0 and 3rd quartile value = 3.0). Body mass index was reported for 70/100 subjects (mean 27.9 kg/m²± 7.1). Only one participant (1%) reported smoking. Participants reported a variety of urinary symptoms, with most women (49%) reporting more than one urinary symptom. Most of the women in the study complained of SUI (54%), while 37% described urgency symptoms and 35% noted UUI. The mean duration of UI and the mean number of physical therapy visits attended for all women in the study was 5.4 ± 7.0 years and 7.9 ± 4.9 visits, respectively. The remaining participant characteristics are presented in Table 4.1. Table 4.2 summarizes the participants’ history of pelvic surgeries and comorbid conditions and the use of medications that are known to impact bladder function. The most commonly reported comorbidities were pelvic pain, constipation, irritable bowel syndrome, and low back pain. Forty-three percent of women were taking medications known to impact urinary continence.
Table 4.1: Characteristics of participants

<table>
<thead>
<tr>
<th>Characteristic (n=100)</th>
<th>Values (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>54.4 (15.2)</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>98</td>
</tr>
<tr>
<td>Non-Caucasian</td>
<td>2</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>16</td>
</tr>
<tr>
<td>Parous</td>
<td>82</td>
</tr>
<tr>
<td>Unreported</td>
<td>2</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
</tr>
<tr>
<td>Married, living as married</td>
<td>75</td>
</tr>
<tr>
<td>Separated, divorced, widowed, single, or never married</td>
<td>25</td>
</tr>
<tr>
<td>Menopausal status</td>
<td></td>
</tr>
<tr>
<td>Regular cycle</td>
<td>27</td>
</tr>
<tr>
<td>Irregular cycle</td>
<td>4</td>
</tr>
<tr>
<td>Peri-menopause</td>
<td>4</td>
</tr>
<tr>
<td>Menopause</td>
<td>63</td>
</tr>
<tr>
<td>Unreported</td>
<td>2</td>
</tr>
<tr>
<td>Types of Urinary Symptoms</td>
<td></td>
</tr>
<tr>
<td>Difficulty emptying</td>
<td>13</td>
</tr>
<tr>
<td>Frequency</td>
<td>35</td>
</tr>
<tr>
<td>Urgency</td>
<td>37</td>
</tr>
<tr>
<td>Nocturia</td>
<td>15</td>
</tr>
<tr>
<td>Stress urinary incontinence</td>
<td>54</td>
</tr>
<tr>
<td>Urge urinary incontinence</td>
<td>35</td>
</tr>
<tr>
<td>Number of physical therapy visits attended, mean (SD)</td>
<td>7.9 (4.9)</td>
</tr>
<tr>
<td>Body mass index (kg/m²), mean (SD) (n=70)</td>
<td>25.9 (7.1)</td>
</tr>
</tbody>
</table>
Table 4.2: Medical history / medications of participants

<table>
<thead>
<tr>
<th>Characteristic (n=100)</th>
<th>Values (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic Surgeries</td>
<td></td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>26</td>
</tr>
<tr>
<td>Abdominal surgery</td>
<td>23</td>
</tr>
<tr>
<td>Anal/rectal surgery</td>
<td>11</td>
</tr>
<tr>
<td>Bladder surgery</td>
<td>15</td>
</tr>
<tr>
<td>Urethral dilation</td>
<td>4</td>
</tr>
<tr>
<td>None</td>
<td>21</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
</tr>
<tr>
<td>Lung disease</td>
<td>3</td>
</tr>
<tr>
<td>Diabetes</td>
<td>4</td>
</tr>
<tr>
<td>Irritable bowel syndrome</td>
<td>30</td>
</tr>
<tr>
<td>Constipation</td>
<td>38</td>
</tr>
<tr>
<td>Fecal incontinence</td>
<td>12</td>
</tr>
<tr>
<td>Stroke</td>
<td>4</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>1</td>
</tr>
<tr>
<td>Other neurological</td>
<td>4</td>
</tr>
<tr>
<td>Frequent UTI (&gt; 3 per year)</td>
<td>6</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>17</td>
</tr>
<tr>
<td>Low back pain</td>
<td>27</td>
</tr>
<tr>
<td>Pelvic pain</td>
<td>45</td>
</tr>
<tr>
<td>Medications that impact urinary continence</td>
<td></td>
</tr>
<tr>
<td>Drug therapy for urinary incontinence</td>
<td>8</td>
</tr>
<tr>
<td>Diuretics</td>
<td>3</td>
</tr>
<tr>
<td>Hormone replacement</td>
<td>7</td>
</tr>
<tr>
<td>Psychotropic</td>
<td>11</td>
</tr>
<tr>
<td>Narcotics / Analgesics</td>
<td>14</td>
</tr>
<tr>
<td>None</td>
<td>57</td>
</tr>
</tbody>
</table>

Table 4.3 summarizes selected physical therapy examination findings including presence of pelvic organ prolapse and PFM tension/pain; and reported dietary habits.

Less than half of the women (43%) presented with pelvic organ prolapse. Most women (78%) demonstrated abnormal pelvic floor muscle tension/pain upon vaginal palpation. Most participants reported intake of < 1 carbonated beverage/wk and ≤ 2.5 cups of caffeine per day. Forty-three percent of women were drinking fewer than 3 glasses of water per day. Less than half of women included fiber in their daily diet. In addition, the sample median Oxford muscle strength grade was 2, indicating the levator ani contraction
was weak and brief; and that the contraction resulted in a small range of pelvic floor motion.

Table 4.3: Examination findings of participants

<table>
<thead>
<tr>
<th>Characteristic (n=100)</th>
<th>Values (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic organ prolapse</td>
<td></td>
</tr>
<tr>
<td>Grade 0</td>
<td>53</td>
</tr>
<tr>
<td>Grade I</td>
<td>17</td>
</tr>
<tr>
<td>Grade II</td>
<td>18</td>
</tr>
<tr>
<td>Grade III</td>
<td>4</td>
</tr>
<tr>
<td>Grade IV</td>
<td>1</td>
</tr>
<tr>
<td>Unreported</td>
<td>7</td>
</tr>
<tr>
<td>PFM tension/pain</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>22</td>
</tr>
<tr>
<td>Abnormal</td>
<td>78</td>
</tr>
<tr>
<td>Atrophy</td>
<td>32</td>
</tr>
<tr>
<td>Spasm</td>
<td>56</td>
</tr>
<tr>
<td>Pain upon vaginal palpation</td>
<td>59</td>
</tr>
<tr>
<td>Dietary Habits</td>
<td></td>
</tr>
<tr>
<td>Caffeine intake ≥2.5 cups per day</td>
<td>27</td>
</tr>
<tr>
<td>Caffeine intake &lt; 2.5 cups per day</td>
<td>73</td>
</tr>
<tr>
<td>Carbonated beverage intake ≥ 1 beverage per week</td>
<td>16</td>
</tr>
<tr>
<td>Carbonated beverage intake &lt; 1 beverage per week</td>
<td>84</td>
</tr>
<tr>
<td>Fiber included in diet</td>
<td>43</td>
</tr>
<tr>
<td>Fiber not included in diet</td>
<td>57</td>
</tr>
<tr>
<td>Water intake</td>
<td></td>
</tr>
<tr>
<td>&lt;3 glasses per day</td>
<td>43</td>
</tr>
<tr>
<td>3-6 glasses per day</td>
<td>43</td>
</tr>
<tr>
<td>&gt;6 glasses per day</td>
<td>9</td>
</tr>
<tr>
<td>Unreported</td>
<td>5</td>
</tr>
</tbody>
</table>

4.2 Physical Therapy Outcomes

Fifty-four and 52 participants completed the initial and discharge PFDI-20 and PFIQ-7 questionnaires, respectively. In addition, 3 women did not complete either questionnaire at initial or discharge evaluations. All participants reported a PGI-I score post-intervention. Secondary outcomes including the CSS and FSFI were not administered routinely to study participants with only 10 participants and 5 participants
completing the CSS and FSFI, respectively. Consequently, CSS and FSFI scores were excluded from statistical analysis.

Baseline, post-intervention, and baseline-post-intervention change scores for the PFDI-20, PFIQ-7; and the distribution of post-intervention PGI-I scores are presented in Table 4.4. Baseline to post-intervention PFDI-20 and PFIQ-7 scores were significantly reduced (p<0.001) indicating that women’s pelvic symptoms and health-related quality of life improved following physical therapy intervention. The median value in the PGI-I frequency distribution was “2” indicating that women perceived their symptoms as “much better” following physical therapy. Sixty-six percent of women achieved the study criteria for PGI-I treatment success, with 28 women reporting a PGI-I score of “1” (symptoms are “very much better”) and 38 women reporting a PGI-I score of “2” (symptoms are “much better”).

Because only about half of the sample completed the PFDI-20 and PFIQ-7 at discharge, results of an intention-to-treat analysis (n=97) are presented. For these analyses, the initial PFDI-20 and PFIQ-7 scores were carried forward when the discharge outcome scores were missing. This intention-to-treat analysis supported the efficacy analysis that showed that both PFDI-20 and PFIQ-7 scores significantly improved following physical therapy intervention (p<0.001). The results of the intention-to-treat analysis may be found in Appendix Table A1.1.
Table 4.4: Outcome scores of study participants

<table>
<thead>
<tr>
<th></th>
<th>Mean Baseline Value (±SD)</th>
<th>Mean Post-intervention Value (±SD)</th>
<th>Baseline to post-intervention change score (±SD)</th>
<th>95% CI</th>
<th>t-statistic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFDI-20 (n=54)</td>
<td>88.69±49.19</td>
<td>50.80±46.25</td>
<td>37.89±48.97</td>
<td>24.52-51.25</td>
<td>5.686</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PFIQ-7 (n=52)</td>
<td>52.21±56.50</td>
<td>21.96±34.96</td>
<td>30.25±51.21</td>
<td>15.99-44.51</td>
<td>4.260</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PGI-I Score (n=100)</th>
<th>Frequency Count</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1=very much better</td>
<td>28</td>
<td>NA</td>
</tr>
<tr>
<td>2=much better</td>
<td>38</td>
<td>NA</td>
</tr>
<tr>
<td>3=a little better</td>
<td>26</td>
<td>NA</td>
</tr>
<tr>
<td>4=no change</td>
<td>7</td>
<td>NA</td>
</tr>
<tr>
<td>5=a little worse</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>6=much worse</td>
<td>0</td>
<td>NA</td>
</tr>
<tr>
<td>7=very much worse</td>
<td>0</td>
<td>NA</td>
</tr>
</tbody>
</table>

4.3 Factors associated with Physical Therapy Outcomes

Mean PFDI-20 and PFIQ-7 pre- to post-intervention change scores did not differ between women based on parity, presence of barriers to intervention recommendations, or carbonated beverage intake (p>0.10). In addition, age, the number of physical therapy visits, and the number of comorbidities were not statistically associated with PFDI-20 or PFIQ-7 scores (p >0.10). (See Appendix A1.2 and A1.3 for tables.)

Age and number of physical therapy visits differed between women who did and did not achieve PGI-I defined treatment success. Women who achieved treatment success had a lower mean age (51.86±15.59 vs. 59.29±13.15 years, p<0.019) and had
more physical therapy visits (9.05±5.51 vs. 5.74±2.55 visits, p<0.001) than those who did not perceive symptom improvement. (See Appendix A1.4 for table.) There was no difference in the mean number of comorbidities between women who perceived and did not perceive treatment success.

The distribution of the occurrence of barriers between women who did and did not perceive treatment success was different than would be expected by chance (Fisher’s exact test p-value<0.001; Table 4.5). Specifically, 56% of women perceiving treatment success reported no barriers to intervention recommendations and only 10% of women perceiving treatment failure reported no barriers to intervention. The distribution of the occurrence of parity and carbonated beverage intake was not significantly different between women perceiving and not perceiving treatment success. (See Appendix A1.5 for tables.)

Table 4.5: Distribution of the occurrence of barriers when women are divided by PGI-I success/failure

<table>
<thead>
<tr>
<th>No barriers</th>
<th>PGI-I Success</th>
<th>PGI-I Failure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presence of barriers</td>
<td>56 (56%)</td>
<td>13 (13%)</td>
<td>69 (69%)</td>
</tr>
<tr>
<td>Total</td>
<td>10 (10%)</td>
<td>21 (21%)</td>
<td>31 (31%)</td>
</tr>
</tbody>
</table>

Fisher’s exact test p-value<0.001

When age, presence of barriers to intervention recommendations, and number of physical therapy visits were entered into the logistic regression model, only barriers to intervention recommendations (p<0.001) and number of physical therapy visits (p=0.007) were influential in predicting PGI-I outcome (Table 4.6). The odds of success for women who did not report barriers to intervention recommendations were 12.8 times greater than those for women who reported barriers to intervention recommendations (OR 12.82; 95%
CI 4.05-40.55). In addition, as the number of physical therapy visits increased, a woman was more likely to attain treatment success. Specifically, for each additional treatment visit received, the odds for a woman to achieve treatment success increased 1.26 times (OR 1.26; 95% CI 1.07-1.50).

Table 4.6: PGI-I success logistic regression model

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Regression Coefficient</th>
<th>Standard Error</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>-1.105</td>
<td>1.362</td>
<td></td>
</tr>
<tr>
<td>Age in years</td>
<td>0.028</td>
<td>0.019</td>
<td>0.151</td>
</tr>
<tr>
<td>Presence of barriers</td>
<td>2.551</td>
<td>0.587</td>
<td>0.000</td>
</tr>
<tr>
<td>Number of PT visits</td>
<td>0.233</td>
<td>0.086</td>
<td>0.007</td>
</tr>
</tbody>
</table>

*The overall accuracy of predicting success is 80% based on this logistic regression model.

4.4 Treatments Received

4.4.1 Education

94% of women in this study received some type of patient education (see Table 4.7). Education in body mechanics, relaxation techniques to decrease muscle tension, and voiding without straining were most often prescribed for women with pelvic pain. Education in soft tissue massage was provided most often to women who reported all 3 types of pelvic symptoms, urinary, bowel and pelvic pain. Alternately, therapists provided education in bowel/bladder scheduling less often to women with concomitant urinary, bowel and pelvic pain symptoms.
Table 4.7: Education by category

<table>
<thead>
<tr>
<th>Categories</th>
<th>n</th>
<th>n (%)</th>
<th>n (%)</th>
<th>n (%)</th>
<th>n (%)</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UI only</td>
<td>10</td>
<td>2 (20)</td>
<td>2 (20)</td>
<td>1 (10)</td>
<td>2 (20)</td>
<td>2 (20)</td>
</tr>
<tr>
<td>UI + bowel</td>
<td>31</td>
<td>2 (6.5)</td>
<td>10 (32.2)</td>
<td>3 (9.6)</td>
<td>2 (6.5)</td>
<td>6 (19.4)</td>
</tr>
<tr>
<td>UI + pelvic pain</td>
<td>5</td>
<td>2 (40)</td>
<td>2 (40)</td>
<td>3 (60)</td>
<td>1 (20)</td>
<td>2 (40)</td>
</tr>
<tr>
<td>UI + bowel + pelvic pain</td>
<td>54</td>
<td>19 (35)</td>
<td>7 (13)</td>
<td>37 (68.5)</td>
<td>33 (61)</td>
<td>30 (55)</td>
</tr>
</tbody>
</table>

Fifty four women had SUI symptoms, 35 had UUI symptoms, and 38 women had symptoms of constipation. Education in strategies to prevent UI episodes (stress strategy for SUI and urge suppression strategy for UUI) was provided to 51.9% and 71.4% of the women with SUI and UUI, respectively. For women with constipation, 71.1% were educated in toileting strategies to promote bowel emptying.

Physical therapists educated 92.6% (25/27) of the women who indicated that they consumed excessive caffeine to reduce caffeine intake; and 50% (8/16) of the women who drank at least one carbonated beverage per week to reduce carbonated beverage intake. Seventy-two percent of women (31/43) who consumed <3 glasses of water per day received education on increasing water intake; and none of the 9 women drinking >6 glasses of water per day received education on decreasing water intake. In addition, education to increase fiber intake was provided to 26/38 (68.4%) of the women with symptoms of constipation.

4.4.2 Exercise

PFM training was included in the physical therapy plan of care for 98% of women (Table 4.8). Downtraining was most often prescribed for women with pelvic pain symptoms. Manual facilitation of the levator ani was included in the plan of care for 61%
of the women. Gravity-eliminated PFM exercise was prescribed for 52% of women. Finally, 75% of women performed PFM exercises in antigravity positions. In addition to PFM training, ≥50% of women in each symptom category received core stabilization training. Interestingly, women who received core stabilization training were significantly more likely to obtain treatment PGI-defined success (Fisher’s exact test p-value=0.031) than women who did not perform core stabilization exercises (see Table 4.9). Flexibility exercises of the lumbar spine and hip were incorporated into the treatment plans of 20 women with UI + bowel + pelvic pain (37%) and 1 woman with UI only (10%). Women in the other categories did not perform flexibility exercises.

Table 4.8: Exercise by category

<table>
<thead>
<tr>
<th>Categories</th>
<th>n</th>
<th>PFM manual facilitation</th>
<th>PFM gravity eliminated</th>
<th>PFM anti-gravity</th>
<th>PFM downtraining</th>
<th>Core stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>UI only</td>
<td>10</td>
<td>4 (40)</td>
<td>3 (30)</td>
<td>9 (90)</td>
<td>1 (10)</td>
<td>5 (50)</td>
</tr>
<tr>
<td>UI + bowel</td>
<td>31</td>
<td>21 (67.7)</td>
<td>18 (58)</td>
<td>28 (90)</td>
<td>4 (12.9)</td>
<td>19 (61.3)</td>
</tr>
<tr>
<td>UI + pelvic pain</td>
<td>5</td>
<td>2 (40)</td>
<td>3 (60)</td>
<td>1 (10)</td>
<td>4 (80)</td>
<td>3 (60)</td>
</tr>
<tr>
<td>UI + bowel + pelvic pain</td>
<td>54</td>
<td>34 (63)</td>
<td>28 (52)</td>
<td>37 (68.5)</td>
<td>43 (79.6)</td>
<td>33 (61.1)</td>
</tr>
</tbody>
</table>

Table 4.9: Performance of Core stabilization exercise and Treatment Success on PGI-I

<table>
<thead>
<tr>
<th></th>
<th>Treatment Success on PGI-I</th>
<th>Treatment Failure on PGI-I</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women who performed core stabilization</td>
<td>45 (45%)</td>
<td>15 (15%)</td>
<td>60 (60%)</td>
</tr>
<tr>
<td>Women who did not perform core stabilization</td>
<td>21 (21%)</td>
<td>19 (19%)</td>
<td>40 (40%)</td>
</tr>
<tr>
<td>Total</td>
<td>66 (66%)</td>
<td>34 (34%)</td>
<td>100 (100%)</td>
</tr>
</tbody>
</table>

*Fisher’s exact test p-value=0.031
4.4.3 Modalities

Physical therapists included modalities of hot/cold, biofeedback, and/or electrical stimulation in the plan of care for 42% of women (Table 4.10). Only women with all three pelvic symptoms received hot/cold modalities as part of their physical therapy intervention. 17% of the total sample of women received biofeedback, while 22% received electrical stimulation.

Table 4.10: Modalities and Manual Physical Therapy Procedures by category

<table>
<thead>
<tr>
<th>Categories</th>
<th>Hot /cold</th>
<th>Biofeedback</th>
<th>Electrical Stimulation</th>
<th>Joint mobilization</th>
<th>Soft tissue mobilization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>UI only</td>
<td>10</td>
<td>0 (0)</td>
<td>5 (50)</td>
<td>2 (20)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>UI + bowel</td>
<td>31</td>
<td>0 (0)</td>
<td>7 (22.6)</td>
<td>11 (35.5)</td>
<td>1 (3.2)</td>
</tr>
<tr>
<td>UI + pelvic pain</td>
<td>5</td>
<td>0 (0)</td>
<td>1 (20)</td>
<td>2 (40)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>UI + bowel + pelvic pain</td>
<td>54</td>
<td>14 (25.9)</td>
<td>4 (7.4)</td>
<td>7 (13)</td>
<td>16 (29.6)</td>
</tr>
</tbody>
</table>

4.4.4 Manual physical therapy procedures

72% of the sample received some type of manual physical therapy procedures (Table 4.10). Joint mobilization was predominantly prescribed for women with all 3 pelvic symptoms. Physical therapists performed soft tissue mobilization most often on women with pelvic pain.

4.4.5 Barriers to intervention recommendations and changes in intervention

Thirty one women in the study reported barriers to intervention recommendations. 71% (22/31) of the women reported 1 barrier, 22.6% (7/31) reported 2 barriers, and 6.5% (2/31) reported 3 barriers. The most common barriers noted were that the patient failed to attend all recommended physical therapy visits, that patient’s comorbidities contributed to UI or interfered with the patient’s ability to follow the plan of care, and the
patient did not adhere to the home exercise program (Table 4.11). In response to these barriers, physical therapists altered the plan of care of 87.1% (27/31) of the women. The most common change in treatment plan was a change in exercise intensity (Table 4.11). Functional PFM activation and introduction of core exercises to promote PFM recruitment were the most frequently endorsed changes in exercise recommendations.

Table 4.11: Barriers to Intervention Recommendations and Changes in Plan of Care

<table>
<thead>
<tr>
<th>Barrier to intervention recommendations (n=31)</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient did not attend all recommended physical therapy visits</td>
<td>10 (32.3)</td>
</tr>
<tr>
<td>Patient was not adherent to home exercise program</td>
<td>8 (25.8)</td>
</tr>
<tr>
<td>Patient did not adhere to recommended lifestyle modifications (fluid management, diet modification, urge/stress, strategy, etc)</td>
<td>6 (19.4)</td>
</tr>
<tr>
<td>Comorbidities contributed to UI or interfered with the patient’s ability to follow the plan of care</td>
<td>10 (32.3)</td>
</tr>
<tr>
<td>Medications contributed to UI, limiting outcomes</td>
<td>2 (6.5)</td>
</tr>
<tr>
<td>Sensory loss limited patient’s ability to recognize correct muscle contraction</td>
<td>1 (3.2)</td>
</tr>
<tr>
<td>Profound muscle weakness/muscle denervation limited potential for increased muscle function</td>
<td>5 (16.1)</td>
</tr>
<tr>
<td>Changes in plan of care due to barriers encountered during physical therapy sessions</td>
<td></td>
</tr>
<tr>
<td>Patient education on importance of visit attendance</td>
<td>10 (32.2)</td>
</tr>
<tr>
<td>Change in exercise intensity (increased intensity to promote strength, decreased intensity due to lack of patient adherence to home exercise program)</td>
<td>21 (67.7)</td>
</tr>
<tr>
<td>Internal PFM facilitation due to lack of ability to contract PFM</td>
<td>5 (16.1)</td>
</tr>
<tr>
<td>Functional PFM activation (progression of PFM exercise in standing postures)</td>
<td>13 (41.9)</td>
</tr>
<tr>
<td>Further interdisciplinary or specialist consultation</td>
<td>1 (3.2)</td>
</tr>
<tr>
<td>Increase in core (abdominal, lumbar extensor) exercises to promote PFM recruitment</td>
<td>11 (35.5)</td>
</tr>
<tr>
<td>Other</td>
<td>13 (41.9)</td>
</tr>
</tbody>
</table>
Chapter 5

Discussion

5.1 Patient Characteristics

Similar to other reports, this investigation found that women with UI seeking physical therapy services often complain of additional pelvic symptoms. Of the 100 community dwelling women seeking physical therapy for UI, nearly half (48%) reported other co-existing pelvic symptoms as indicated by their responses to the Colorectal-Anal and Pelvic Organ Prolapse subscale items of the PFDI-20. Co-existing bowel conditions reported by women included constipation (38%), irritable bowel syndrome (30%), and/or fecal incontinence (12%). The prevalence rates of bowel conditions in women with UI in the present study are similar to rates previously reported. Specifically, previous investigators have found the prevalence of constipation ranges from 31\(^{34}\)-36\(^{33}\); and the presence of fecal incontinence in women with UUI to be 18% (mean age = 57).\(^{64}\) The prevalence of irritable bowel syndrome in women with urinary symptoms has not been previously reported. The current study also found that more than half of the women (59%) reported PFM pain upon palpation. Questionnaires that address the whole spectrum of pelvic symptoms are prudent in understanding the various impairments women may possess when seeking physical therapy for UI.

5.2 Physical therapy outcome measures

This study found that physical therapy interventions provided within a pragmatic setting are effective in improving pelvic symptoms, including urinary, bowel, and
prolapse symptoms. It is well established that physical therapy interventions aimed toward improving urinary symptoms are effective. However, there are too few published data to conclude whether or not these physical therapy interventions can effectively manage women with urinary and concurrent bowel and/or pelvic organ prolapse symptoms. Even data to describe the types of interventions used by physical therapists to manage women with a myriad of pelvic symptoms are scarce. This study was unique in that it obtained data that described current physical therapy practice from a large group (15) of physical therapists within one outpatient physical therapy company (Centers for Rehab Services). It was not an aim of this study to discern which intervention(s) were most successful. Thus, study conclusions are limited toward the overall effectiveness of the physical therapy plan of care to reduce women’s pelvic symptoms. Within this sample of convenience, this study found evidence that Centers for Rehab Services physical therapists were very effective in reducing their client’s pelvic symptoms.

Pre- to post intervention PFDI-20 and PFIQ-7 scores improved significantly by 37.89 and 30.25, respectively. Such statistical improvements exceed the minimum important difference for both the PFDI-20 and PFIQ-7. Barber et al. reported minimum important differences of 11.1 and 16.0 points for the urinary subscales of the PFDI and PFIQ, respectively. Thus, women in the current study experienced a clinically significant improvement in their symptoms. This conclusion is further validated by the fact that 66% of women achieved at least or greater than a PGI-I score of 2, indicating that symptoms were “much better”.

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A major limitation of the study is the small sample size. In order to determine statistical difference in the baseline to post-intervention PFDI-20 and PFIQ-7 scores, the power analysis revealed a sample size of 138. Although we had a large pool of medical records in the database (500), only 100 subjects met the inclusion criteria. Of these 100 subjects, just over half of the patients completed both baseline and post-intervention PFDI-20 (54 patients) and PFIQ-7 (52 patients) questionnaires. When smaller sample sizes are used, true statistical differences are less likely to be recognized. Even with this smaller sample size, we were able to detect a true difference between baseline and post-treatment PFDI-20 and PFIQ-7 scores. The differences also exceeded the minimum important difference as reported by Barber. Because women who did not complete the questionnaires at discharge may have had poorer outcomes, intention-to-treat analyses including these women were performed. The results of the intention to treat analyses were congruent with the results of the efficacy analyses. That is both PFDI-20 and PFIQ-7 scores significantly improved following physical therapy intervention.

We chose a global impression of improvement as a primary outcome measure in order to obtain a very simple and direct appraisal of the patient perception of improvement. The PGI-I is a global index used in recent research trials to assess patient perception of treatment intervention. The PGI-I has been shown to have good construct validity. Sixty-six percent of the women in our study achieved treatment success as defined by the PGI-I. This is a slightly higher success rate than reported by Richter et al. who also used the PGI-I. Richter et al. reported a per-protocol success rate of 61.6% and an intention-to treat success rate of 49% for women who received physical therapy management for SUI. In Richter’s study, treatment consisted of interventions
aimed only at UI (PFM exercise and additional skills and strategies for active use of muscles to prevent SUI and UUI). The present study included additional interventions that may have contributed to the higher percentage of women attaining success. Our 66% success rate is similar to the 60%-85% range for reduction in incontinence episodes reported in other behavioral intervention trials.11, 16, 17, 24, 70, 141, 196, 197

5.3 Factors associated with Physical Therapy Outcomes

This study explored a number of variables that were thought to have potential for influencing physical therapy outcomes. Regression analysis revealed that only two variables influenced treatment success as defined by the PGI-I score. Patients without barriers to intervention recommendations and patients who attended more physical therapy visits were more likely to attain PGI-I defined success.

An absence of barriers to intervention recommendations was a strong predictor of patient defined success. The odds of success for women who did not report barriers were 12.8 times greater than those for women who reported barriers. Our finding is similar to Grindley et al. who reported a negative correlation between the total number of barriers and treatment efficacy (r=−0.380) for patients of various diagnoses receiving outpatient physical therapy for 4-8 weeks.198 In addition, Borello-France et al. reported that the total number of barriers was significantly associated with a lower number of PFM exercises performed by women with predominant UUI (p<0.05).199 One of the most common barriers in the present study was non-adherence to the prescribed home exercise program. Eight percent of all women in the study (8/100) reported not adhering to the home exercise program during the intervention period. This rate is similar to non-
adherence rates (7%-13%)\textsuperscript{11,199} to behavioral therapy previously reported. Additionally, patient non-attendance was another common barrier. It is generally believed that the failure of a patient to attend therapy sessions can interfere with rehabilitation process and potentially impact outcomes. In our study, 10% of the women did not attend physical therapy regularly which may have impacted their outcomes. Forkan et al. reported that barriers, and not motivators, predicted adherence to physical therapists’ recommendations following discharge.\textsuperscript{200} The evidence from this and other cited studies strongly support the need for physical therapists to engage their patients in order to identify and resolve barriers to intervention recommendations.

The number of physical therapy visits received was associated with PGI-I defined treatment success. The odds of success for a woman receiving one additional physical therapy visit increased 1.26 times. This finding confirms that of Hay-Smith who reported treatment effect may be greater in women with SUI who receive a longer duration of PFM training (6 months versus 8 weeks).\textsuperscript{17} Yet, research investigating a relationship between number of physical therapy visits and treatment outcome is lacking. Trials exploring predictors of physical therapy outcomes routinely have little variability in the number of physical therapy visits administered.\textsuperscript{13,201-203} The pragmatic design of the present study captured a large variance of physical therapy visits (2-29 visits) and subsequently, statistical analysis was possible.

Most of study variables identified as possible predictors of outcomes were not confirmed statistically as such. Parity which is a known risk factor for UI\textsuperscript{48,51-54} was unrelated to physical therapy outcomes. Our finding is similar to Theofrastous et al. who found no relationship between parity and reduction of incontinent episodes per week in
community-dwelling women (mean age 60.6±10 years) with SUI, UUI, or mixed incontinence following treatment that included biofeedback-assisted pelvic floor muscle exercise training or bladder training. Similarly, Burgio et al. reported no relationship between parity and reduction of incontinent episodes in ambulatory, community-dwelling women with UI that were managed with behavioral treatment. Burgio’s conclusion was based on pooled data from 3 prospective randomized clinical trials that tested behavioral therapy (PFM exercise, stress/urge strategies, and self-monitoring with bladder diaries) in women with UUI, urge-predominant mixed incontinence, or SUI.

Although comorbidities may influence the complexity of the intervention, they did not relate to treatment outcomes in this study. This finding is similar to those of McDowell et al. and Burgio et al. McDowell reported no relationship between the number of medical diagnoses and degree of improvement in incontinent episodes per week in persons with UI and multiple comorbidities (mean 6.0 problems) receiving behavioral intervention (PFM exercise and stress/urge suppression strategies). Similarly, Burgio reported that treatment outcomes did not associate with medical history (including arthritis, bladder infections, constipation, age at menopause, duration of menopause, hysterectomy, and use of alcohol). The influence of comorbidities may have been minimized in our study due to the selection and categorization procedure used. For example, the comorbidities selected for exploration in our study included only those identified as documented risk factors for UI (body mass index >30, lung disease, diabetes, bowel/constipation/irritable bowel syndrome/fecal incontinence, neurological diseases, pain [lumbar or pelvic pain], pelvic surgery [hysterectomy, abdominal, rectal, bladder, urethral dilation], and pelvic organ prolapse). Yet, results of the present study,
along with results of previous investigations, suggest that the complexity of a
woman’s medical history does not relate to treatment outcomes. Consequently, a woman
may be able to respond favorably to physical therapy interventions despite a complex
medical history.

In univariate analysis, women who achieved treatment success had a lower mean age than those who did not perceive symptom improvement. Previous investigations have found that age was not related to reduction of incontinence. However, unlike studies that explored age within a restricted range (minimum 40 to maximum 97 years), the age range of women in our study was not restricted (minimum 20 to 89 yrs) which may have contributed to our significant findings. The only other trial with a similar age range (range 25 to 81 years, mean age 54 years), conducted by Smith et al, found a significant difference in improvement noted on bladder diaries between those <40 years and those >60 years of age. Younger women reported more improvement than older women with SUI, UUI, and mixed UI in episodes of incontinence per day following behavioral therapy.

Although significant in the univariate analysis, age was not a significant predictor of treatment success in the logistic regression model. The advantage of multivariable analysis is the ability to examine several variables within a single study and account for their potential interrelationship in the analysis of data. Using multivariable analysis, we found that barriers to intervention recommendations and number of physical therapy visits were most influential in predicting treatment success when age was held constant. Our result is similar to Burgio who also found no relationship between age and
treatment success using multivariable analysis. Consequently, age may not be a barrier to a woman’s ability to respond to physical therapy.

Consumption of carbonated beverages is a risk factor for development of OAB. Dallosso and colleagues found that women who consumed 2-6 carbonated beverages per week had nearly a 50% increased risk for onset OAB (OR 1.44; 95% CI 1.12-1.185) compared to those consuming <1 carbonated beverage per week. Thus, it is reasonable to predict that women who consume more carbonated beverages may not achieve favorable outcomes. The present study did not find a relationship between consumption of carbonated beverages and outcomes. The manner that data were recorded may have biased this result. The database was designed to require therapists to check a box for patients who consumed ≥ 1 carbonated beverage weekly (database value of 1). If this item was not completed, the database defaulted to a value of 0, indicating consumption of <1 beverage weekly. Based on database design, there was no way to delineate if the value was truly 0 (consumption of <1 carbonated beverage weekly) or if the value was missing. In addition, the patient’s consumption of carbonated drinks was taken at baseline. If the patient received education on carbonated beverage reduction, then the patient may have decreased consumption by the end of treatment. Consequently, since the risk factor (excessive consumption of carbonated beverages) was addressed during treatment, it may not relate to treatment outcomes post-intervention. In future research studies, it is important to consider if this item should be dropped or reprogrammed so data will be valid and reliable.
5.4 Treatments Received

This study is the first to describe treatment interventions for women with UI and concomitant bowel symptoms, prolapse symptoms, and/or pelvic pain. Using a pragmatic study design, we were able to obtain treatment information from 15 physical therapists to capture what interventions women were receiving in true clinical situations. The information will be presented to Centers for Rehab physical therapists and administration for their interpretation and their decision on how they would use this information for program quality improvement.

Nearly all (94%) of the women in this study received some type of patient education. There was a trend for physical therapists to provide education on body mechanics and relaxation techniques to women with pelvic pain. Patients with lumbopelvic pain may demonstrate faulty posture and/or lifting techniques which, if not corrected, may cause further injury to inert structures. Lifting with a neutral spine posture provides greater stability of the spine and uses both the ligamentous and muscular system for stabilization and control. Subsequently, education of body mechanics to women with pelvic pain may help reduce chronic strain on the pelvic floor muscles which may improve pain symptoms. In addition, women with pelvic pain may demonstrate pain and/or spasm of the pelvic floor muscles and relaxation training may increase patient awareness and tension control over these muscles. In this study, nearly 90% of women with pelvic pain (53/59) demonstrated spasm and pain of the levator ani upon vaginal palpation. Of the women with levator ani muscle spasm, 71.7% (38/53) received education in relaxation techniques. In a systematic review, relaxation techniques, in combination with other interventions, were found to reduce pain for
patients with chronic musculoskeletal pain. In addition, several case studies reported decreased pain and levator ani tenderness for patients with pelvic pain receiving multimodal interventions of relaxation techniques, manual physical therapy, and exercise. Thus, it appears that education of relaxation techniques, in combination with other interventions, seems to be a reasonable way to address pain due to muscle spasm. Centers for Rehab Services physical therapists included the education of relaxation techniques for the majority of women with levator ani spasm and pain. Physical therapists who did not incorporate education of relaxation techniques for women with levator ani spasm may have instead selected equally effective interventions including: education of soft tissue techniques, PFM downtraining, biofeedback for PFM relaxation, or soft tissue mobilization.

We also examined if the distribution of selected treatment interventions was consistent with evidence in the literature. Physical therapists indicated that they provided education on the stress strategy for 51.9% of the women with SUI. The stress strategy, as a single intervention, has been shown to be highly effective in reducing urine leakage in women with mild SUI. Miller et al. reported a 98.2% reduction in urinary leakage for a medium cough, and a 73.3% reduction for a deep cough when women with mild SUI used the stress strategy. Moreover, behavioral therapy including PFM exercise and the stress strategy has been shown to reduce episodes of incontinence and improve quality of life. Thus, it is surprising that the stress strategy was not included for a larger proportion of women with SUI. However, out of the 26 women in the study that did not receive education on the stress strategy, 9 women had spasm of the levator ani noted on initial examination, and an additional 15 had symptoms of UUI. It is possible that
physical therapists did not utilize the stress strategy for women with spasm of the levator ani because contracting an already tightened muscle quickly and forcefully may actually perpetuate the spasm. Of the 15 women with mixed UI (symptoms of SUI and UUI) who did not receive education on stress strategy, 8 received urge suppression strategy education. A common element of both urge and stress suppression techniques is instructing the patient to contract her pelvic floor muscles to prevent UI when the precipitating event occurs. The 8 patients who received urge suppression strategy education may have automatically applied the PFM contraction to their stress symptoms and consequently did indirectly receive education in preventing SUI episodes. However, 17% (9/54) of women with SUI did not receive any stress strategy education. Because the stress strategy has been shown to be effective by itself or as a component of multimodal intervention trials, a quality improvement initiative regarding this discrepancy is recommended.

Seventy one percent of women included in this study that had UUI were taught urge suppression strategies. Urge suppression strategies along with PFM exercise has been shown to decrease UI episodes. Out of the 10 women with UUI that did not receive education on urge suppression strategies, 2 had mixed UI and received education on the stress strategy. Consequently, these 2 women may have applied the stress strategy to automatically address their UUI symptoms and indirectly received education on urge suppression techniques. Thus, 23% (8/35) of women with UUI did not receive education on the urge suppression strategy. Because the urge suppression strategy has been shown to be effective as part of a comprehensive treatment plan, a quality improvement initiative regarding this discrepancy is recommended. However, it must be noted that 6 of
the 8 women who did not receive education on urge suppression strategies were treated with PFM downtraining. Physical therapists may have focused on downtraining in these women, rather than repeated PFM contraction as in urge suppression, to promote relaxation of PFM in an attempt to decrease urgency.

Sixty-eight percent (26/38) of women with constipation were educated to increase fiber intake. Of the 32% (12/38) of women who did not receive this education, half indicated at the initial examination they already included fiber in their diet. Subsequently, it is possible that the physical therapist decided further fiber education was not necessary. Evidence for increasing fiber intake to reduce constipation in women with constipation is divided. One study found favorable results with supplementing participants’ diets with high-fiber cereal.\textsuperscript{160} Alternately, a review of four studies that examined dietary fiber intake by people with chronic constipation, found no differences compared to controls.\textsuperscript{159} In the present study, it appears that physical therapists are educating the majority of women who lack appropriate fiber intake. Although evidence on increasing fiber intake for constipation is inconclusive, it seems reasonable to suggest that women consume 20-25 g of fiber daily as recommended by the National Academy of Sciences Institute of Medicine to promote bowel health.\textsuperscript{160}

Most (92.6%) of the women who indicated that they consumed excessive caffeine were educated by physical therapists to reduce caffeine intake. This finding was expected because of the common belief that caffeine worsens UI symptoms; however little evidence exists to support this assumption. Although the stimulatory effect of caffeine has been shown to directly influence the bladder by increasing bladder pressure during filling,\textsuperscript{155} altering caffeine intake does not necessarily decrease UI symptoms.\textsuperscript{152}
For example, Dowd found no association between caffeine intake and UI episodes in 32 women >50 years.\textsuperscript{154} Conversely, Ayra and colleagues reported a significant association between high caffeine intake (>400mg) and OAB.\textsuperscript{56} Despite conflicting evidence to support caffeine restriction, it is clinically reasonable to educate patients to decrease caffeine since excessive caffeine is a risk factor for OAB.

Recommendations to increase water intake was provided to 72% (31/43) of women who consumed <3 glasses of water per day. It is recommend that adults consume 0.5 oz of water per lb of body weight/day.\textsuperscript{62} Drinking less than the recommended amount may lead to concentrated and low-volume urine production. Subsequently, inadequate water intake may lead to bladder irritation, urgency and frequency, urinary tract infection and/or fecal impaction. Thus, it is surprising that 28% of women drinking <3 glasses were not educated to increase water intake. However, the manner that data were recorded may have biased this result. The database was designed to require physical therapists to check a box for patients who consumed 3-6 or >6 glasses of water per day. If this item was not completed, the database defaulted to the selection of <3 glasses of water per day and based on database design, there was no way to delineate if the value was truly <3 glasses of water per day or if the value was missing. In future research studies, it is important to consider reprogramming this item so data will be valid and reliable.

Nearly all women in the study (98%) were prescribed PFM training. Because PFM exercise has been shown to decrease UI episodes,\textsuperscript{11, 16-18, 23, 25, 70, 142-144} improve quality of life,\textsuperscript{11, 18, 70, 144} and increase PFM strength for women with UI;\textsuperscript{11, 25, 70} it appears that Centers for Rehab Services physical therapists were consistent with the evidence in
prescribing PFM exercise. There was more of a trend for physical therapists to elicit PFM contraction with manual facilitation for women with bowel symptoms. Since 71% (27/38) of women with constipation demonstrated PFM spasm upon vaginal palpation, manual facilitation may have been used to confirm relaxation of the PFM after contraction. In addition, it is possible that women with dual incontinence (urinary incontinence and fecal incontinence) demonstrated weaker pelvic floor muscles. In the present study, 50% (6/12) of women with dual incontinence demonstrated PFM atrophy during vaginal palpation. Consequently, physical therapists may have decided that manual facilitation was the most appropriate intervention to promote awareness of PFM activity.

Over half of all women in the study (60%) were prescribed core stabilization exercises. Because the percentages of women prescribed core stabilization were similar across pelvic floor diagnoses, a Chi-square analysis was performed to determine if there were differences in PGI-I defined success between women who were and were not prescribed core stabilization exercises. Interestingly, women who received core training were significantly more likely to obtain treatment success than woman who did not perform core stabilization exercises. There is a growing body of evidence that suggests a relationship between the function of the pelvic floor muscles and transverse abdominus muscle. One study that included 6 healthy women and 1 man found that PFM EMG rose above the resting level when a voluntary transverse abdominus contraction was performed in the supine position. Interestingly, when these same subjects were asked to perform a strong transverse abdominus contraction, levels of synergistic PFM activity were similar to that observed when subjects were asked to perform a strong isolated
Neumann and Gill and Sapsford also observed a synergistic activation of the levator ani when healthy women performed a transverse abdominus contraction in supine. In addition, the relationship between weak abdominal muscles and the development of SUI has been discussed. Sapsford noted that during coughing and nose-blowing, the abdominal wall of women with SUI bulges forward, especially when they assume poor posture and fail to contract their abdominal muscles. In comparison, healthy women pull their abdomen inward and contract their pelvic floor muscles during a cough to increase intra-abdominal pressure to maintain continence. The inclusion of core strengthening or transverse abdominus exercises in the plan of care may have contributed to women achieving PGI-I defined success. However, because the intervention plans for women in our study were multimodal, conclusions regarding the effectiveness of core stabilization exercises are limited. Women who achieved PGI-I success may have received a different intervention other than core stabilization or a combination of interventions that influenced PGI-I success.

Biofeedback and electrical stimulation to augment PFM exercises were prescribed for only 13% and 12% of women, respectively. Based on the literature, PFM exercise with biofeedback is not more efficacious than PFM exercise alone for women with SUI or UUI. Likewise, investigations that compared electrical stimulation to PFM exercise, or combined electrical stimulation and PFM exercise, have not shown superior results to PFM exercise used alone. The use of adjunctive modalities for PFM strengthening by physical therapists in this study was consistent with the scientific evidence. Only a small percentage of women received biofeedback and electrical stimulation. In some cases, the physical therapist may have only used these modalities
for women who demonstrated difficulty performing PFM exercise due to very extreme muscle weakness. Of the 13 women who received biofeedback for PFM strengthening, over half (7/13) demonstrated levator ani atrophy upon physical therapy examination. Similarly, 83% (10/13) of women who received electrical stimulation for PFM strengthening demonstrated levator ani atrophy at initial examination.

Flexibility exercises of the lumbar spine and hip, joint mobilization, and soft tissue mobilization were provided mostly to women with all 3 pelvic symptoms (urinary, bowel, and pelvic pain). Physical therapists may have decided to utilize manual therapy interventions to address common impairments that women with pelvic pain possess including restricted joint motion of the hip and/or pelvis;\textsuperscript{128} hypertonic PFM and/or spasm of hip, lumbar or pelvic musculature;\textsuperscript{127,130} and/or shortening of hip, low back or pelvic muscles.\textsuperscript{132} In fact, 90.5% (49/54) and 31.5% (17/54) of women with all 3 pelvic symptoms demonstrated levator ani muscle spasm and low back pain, respectively. However, women with all 3 pelvic symptoms also received a significantly higher number of mean physical therapy visits (8.92±5.72) compared to women without all 3 pelvic symptoms (6.69±3.51) (p<0.020). Thus, because women with all 3 pelvic symptoms had more visits, physical therapists may have had additional time/opportunity to implement manual physical therapy and flexibility exercise interventions.

A major limitation of the study is that data entry may have been inconsistently performed across physical therapists. In addition, it was assumed that physical therapists entered information accurately. However, there is a chance that they did not enter the data accurately. Additionally, they may have recorded an intervention(s) in the plan of care but were not able to administer it because the patient did not return for follow-up visits.
5.5 Conclusion

In our sample of convenience, physical therapy interventions provided within a pragmatic setting significantly improved the pelvic symptoms and health-related quality of life of women with a primary diagnosis of UI. Women’s global impression of improvement was favorable, with sixty-six percent of women achieving the study criteria for PGI-I treatment success. Patients without barriers to intervention recommendations and patients who attended more physical therapy visits were more likely to attain PGI-I defined success. Commonly used interventions for women in the study included patient education on diet modification and relaxation techniques, PFM training, core stabilization exercises, and manual physical therapy procedures.
REFERENCES

17. Hay-Smith E, Dumoulin C. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database of Systematic Reviews. 2006.


APPENDIX

Table A1.1: PFDI-20 and PFIQ-7 scores of study participants (Intention-to-treat analysis)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Post-Intervention</th>
<th>Change Score ±SD</th>
<th>95% CI</th>
<th>t-statistic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFDI-20</td>
<td>87.95±45.99</td>
<td>67.77±48.15</td>
<td>20.18±41.12</td>
<td>11.89-28.46</td>
<td>4.833</td>
<td>0.000</td>
</tr>
<tr>
<td>(n=97)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFIQ-7</td>
<td>56.54±59.57</td>
<td>40.46±53.52</td>
<td>16.07±40.47</td>
<td>7.93-24.21</td>
<td>3.921</td>
<td>0.000</td>
</tr>
<tr>
<td>(n=97)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table A1.2 (a-c): Relationships between dichotomous independent variables and PFDI-20 and PFIQ-7 mean change scores

Table A1.2a: Comparison of mean PFDI-20 and PFIQ-7 change scores when subjects are divided based on parity

<table>
<thead>
<tr>
<th></th>
<th>Parity=No deliveries</th>
<th>Parity=1 or more deliveries</th>
<th>Mean difference ±SD</th>
<th>95% CI</th>
<th>t-statistic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFDI-20</td>
<td>-18.43±19.38 (n=7)</td>
<td>-41.30±51.90 (n=46)</td>
<td>-22.88±19.96</td>
<td>-17.20-62.95</td>
<td>1.146</td>
<td>0.257</td>
</tr>
<tr>
<td>change score (n=53)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFIQ-7</td>
<td>-39.14±28.41 (n=7)</td>
<td>-29.73±54.30 (n=44)</td>
<td>-9.42±21.09</td>
<td>-51.80-32.97</td>
<td>-0.466</td>
<td>0.657</td>
</tr>
<tr>
<td>change score (n=51)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table A1.2b: Comparison of mean PFDI-20 and PFIQ-7 change scores when subjects are divided based on presence of barriers

<table>
<thead>
<tr>
<th></th>
<th>No barriers</th>
<th>1 or more barriers</th>
<th>Mean difference ±SD</th>
<th>95% CI</th>
<th>t-statistic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFDI-20</td>
<td>-41.00±44.08 (n=44)</td>
<td>-24.20±67.69 (n=10)</td>
<td>-16.80±17.16</td>
<td>-51.24-17.64</td>
<td>-0.979</td>
<td>0.332</td>
</tr>
<tr>
<td>change score (n=54)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFIQ-7</td>
<td>-29.14±48.46 (n=42)</td>
<td>-34.90±64.65 (n=10)</td>
<td>5.76±18.18</td>
<td>-30.76-42.27</td>
<td>0.317</td>
<td>0.753</td>
</tr>
<tr>
<td>change score (n=52)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tbody>
</table>
Table A1.2c: Comparison of mean PFDI-20 and PFIQ-7 change scores when subjects are divided based on parity consumption of carbonated beverages

<table>
<thead>
<tr>
<th></th>
<th>&lt;1 carbonated beverage / week</th>
<th>≥ 1 carbonated beverage / week</th>
<th>Mean difference ±SD</th>
<th>95% CI</th>
<th>t-statistic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFDI-20 change score (n=54)</td>
<td>-39.80±51.37 (n=46)</td>
<td>-26.88±32.09 (n=8)</td>
<td>-12.93±18.85</td>
<td>-50.76-24.90</td>
<td>-0.686</td>
<td>0.316</td>
</tr>
<tr>
<td>PFIQ-7 change score (n=52)</td>
<td>-30.93±54.28 (n=81)</td>
<td>-25.86±25.73 (n=16)</td>
<td>-5.08±21.00</td>
<td>-47.26-37.11</td>
<td>-0.242</td>
<td>0.810</td>
</tr>
</tbody>
</table>

Table A1.3: Correlations between independent variables of age, number of physical therapy visits and number of comorbidities and PFDI-20/PFIQ-7 change scores

<table>
<thead>
<tr>
<th>Age</th>
<th>Number of physical therapy visits</th>
<th>Number of comorbidities</th>
</tr>
</thead>
<tbody>
<tr>
<td>r</td>
<td>p-value</td>
<td>r</td>
</tr>
<tr>
<td>PFDI-20 change score (n=54)</td>
<td>0.167</td>
<td>0.227</td>
</tr>
<tr>
<td>PFIQ-7 change score (n=52)</td>
<td>-0.005</td>
<td>0.975</td>
</tr>
<tr>
<td> </td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table A1.4: Comparison of mean age, number of physical therapy visits and number of comorbidities when subjects are divided based on PGI-I success/failure

<table>
<thead>
<tr>
<th></th>
<th>PGI-I Success (n=66)</th>
<th>PGI-I Failure (n=34)</th>
<th>Mean difference ±SD</th>
<th>95% CI</th>
<th>t-statistic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>51.86±15.59</td>
<td>59.29±13.15</td>
<td>7.43±3.127</td>
<td>1.22-13.64</td>
<td>2.376</td>
<td>0.019*</td>
</tr>
<tr>
<td>Number of physical therapy visits</td>
<td>9.05±5.51</td>
<td>5.74±2.55</td>
<td>-3.31±0.82</td>
<td>-4.93-1.69</td>
<td>-4.06</td>
<td>0.000*</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>2.25±1.23</td>
<td>2.18±1.11</td>
<td>-0.066±.251</td>
<td>-0.565-0.433</td>
<td>-0.262</td>
<td>0.794</td>
</tr>
</tbody>
</table>

*p<0.10

Table A1.5 (a-b): Relationships between dichotomous variables and PGI-I success/failure

Table A1.5a: Parity

<table>
<thead>
<tr>
<th></th>
<th>PGI-I Success</th>
<th>PGI Failure</th>
<th>Total</th>
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<tbody>
<tr>
<td>Nulliparous</td>
<td>10 (10.2%)</td>
<td>6 (6.1%)</td>
<td>16 (16.3%)</td>
</tr>
<tr>
<td>Parous</td>
<td>54 (55.1%)</td>
<td>28 (28.6%)</td>
<td>82 (83.7%)</td>
</tr>
<tr>
<td>Total</td>
<td>64 (65.3%)</td>
<td>34 (34.7%)</td>
<td>100 (100%)</td>
</tr>
</tbody>
</table>

Fisher’s Exact Test p-value=0.782

Table A1.5b: Carbonated Beverage

<table>
<thead>
<tr>
<th></th>
<th>PGI-I Success</th>
<th>PGI-I Failure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 carbonated beverage / week</td>
<td>56 (56%)</td>
<td>28 (28%)</td>
<td>84 (84%)</td>
</tr>
<tr>
<td>≥1 carbonated beverage / week</td>
<td>10 (10%)</td>
<td>6 (6%)</td>
<td>16 (16%)</td>
</tr>
<tr>
<td>Total</td>
<td>66 (66%)</td>
<td>34 (34%)</td>
<td>100 (100%)</td>
</tr>
</tbody>
</table>

Fisher’s Exact Test p-value=0.778