Physical Therapy Outpatient Practice Patterns for Treatment Of Urinary Incontinence

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Urinary incontinence (UI) is a common pelvic floor dysfunction impairment that often prompts referral to physical therapy (PT) for treatment. Due to the significant burden of UI among adults, the use of best care practices is essential to maintain quality care. Yet physical therapists face challenges in the assessment of individuals referred to them for treatment of UI and in formulating plans of care within their scope of professional practice because little is known to guide efforts in standardizing PT-UI care. This study used real-world data to help illuminate the variability in PT practice patterns that create challenges for both researchers and practicing clinicians. These data provide a first step in determining optimal PT-UI care and in establishing practice standards and PT-UI clinical practice guidelines.

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Analysis of commercial urinary incontinence (UI) data provides useful information to examine physical therapy (PT) practice patterns. This report describes the frequency and duration of PT-UI care and patients' perception of urinary function over time among a national sample of adults receiving PT for treatment of UI. Additional research is needed to better inform our understanding of optimal PT-UI care.

Key Words: **Non-pharmacologic, pelvic floor training, patient-reported outcomes, physical therapy, patient-reported outcomes.**

Background

UI, defined as the involuntary loss of urine associated with a strong desire and/or urge to void, is a common debilitating condition, particularly among older women. The Centers for Disease Control and Prevention (CDC) reports that of non-institutionalized persons aged 65 years and over, 50.9% report urinary leakage (Gorina, Schappert, Bercovitz, Elgaddal, & Kramarow, 2014). As reported by the National Institutes of Health (NIH), the natural history of UI over several years is not well described in reported studies (NIH Consensus Development Program, 2007). The significance of UI among women was further highlighted by Dr. Tamara Bavendum during the 2014 NIH Summit on Urinary Incontinence in Women:

> There is a lack of interaction between physicians and both

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Research Summary

Introduction

Non-pharmacologic therapy options are recommended as first-line treatment for urinary incontinence (UI), and physical therapy (PT) is well-positioned to provide first-line pelvic floor and bladder training for UI disorders. Yet there are no established PT-UI practice guidelines to direct care. This study presents a first step toward efforts to determine optimal PT-UI care.

Purpose

This study examined the frequency and duration of PT-UI care and patients' perception of urinary function over time among a national sample of adults receiving PT for treatment of UI.

Methods

A retrospective, secondary analysis of data extracted from the Focus on Therapeutic Outcomes, Inc. (FOTO) database was conducted. The records for 19,459 patient observations were examined to determine PT practice patterns, change in urinary status measurement (urinary function), and insurance coverage at multiple time points across a 138-day period between January 2014 and July 2017.

Results

Across the predominantly female sample, the average number of PT visits per week decreased from 1.26 per week to 0.48. There was consistent improvement in urinary status (function) across the study period, with a notable plateau at approximately 65.3 days on average following baseline assessment. There was a high attrition rate; only 357 subjects continued with PT throughout the study period. Significant variability in type of insurance coverage was observed.

Conclusion

This study used real-world data to help illuminate the variability in PT practice patterns in PT-UI care. Further research is needed to better inform our understanding of optimal PT-UI care.

Level of Evidence – III-B

Source: Johns Hopkins Hospital/Johns Hopkins University, 2016.

continence nurse specialists and physical therapists to help patients with UI. Physical therapists and continence nurses design individualized treatments for their patients, discussing dietary management, exercise, weight loss, and pelvic floor muscle training. Behavioral therapy needs to be emphasized as a first-line therapy before considering surgery. This message has not reached enough physicians. Physicians rarely refer their patients to physical therapy or continence nurse specialists (National Institute of Diabetes and Digestive Kidney Diseases, 2014, p. 18).

Developed by the American College of Physicians (ACP), the clinical practice guideline *Nonsurgical Management of Urinary Incontinence in Women* (Qaseem et al., 2016) provides current standards of UI care. Key ACP recommendations include:

- First-line treatment with pelvic floor muscle training in women with stress UI (Grade: Strong recommendation, high-quality evidence).
- Bladder training in women with urgency UI (Grade: Strong recommendation, moderate-quality evidence).
- Pelvic floor muscle training with bladder training in women with mixed UI (Grade: Strong recommendation, moderate-quality evidence).
- Against treatment with systemic pharmacologic therapy for stress UI (Grade: Strong recommendation, low-quality evidence).
- Pharmacologic treatment in women with urgency UI if bladder training was unsuccessful. Clinicians should base the choice of pharmacologic agents on tolerability, adverse effect profile, ease of use, and cost of medication (Grade: Strong recommendation, high-quality evidence).
- Weight loss and exercise for obese women with UI (Grade: Strong recommendation, moderate-quality evidence).

These recommendations are based on the highest levels of evidence to support the usefulness of UI interventions.

The ACP guideline calls for non-pharmacologic therapy for UI as first-line treatment, and physical therapists are well positioned to provide first-line pelvic floor training and bladder training for UI disorders (Shamliyan, Kane, Wyman, & Wilt, 2008). PT methods used to treat UI include electrical stimulation (Schreiner, Santos, Souza, Nygaard, & Silva Filho, 2013), biofeedback (Anderson et al., 2015), Kegel exercises (Lamin, Parrillo, Newman, & Smith, 2016), relaxation exercises (Wyman, Burgio, & Newman, 2009), and exercises to improve abdominal and core muscle control (Di Benedetto, Coidessa, & Floris, 2008). Use of real-world data can help illuminate the variability in PT practice patterns faced by researchers and practitioners in efforts to standardize the approach to UI care.

Purpose

The purpose of this study was to determine the frequency and duration of PT-UI care and patients' perception of urinary function over time among a national sample of adults receiving PT for treatment of UI. This study builds on previous work of patients seeking rehabilitation for a variety of disorders in outpatient physical therapy clinics (Centers for Medicare & Medicaid Services [CMS], 2006; Hart, Wang, Cook, & Mioduski 2010; Hart, Werneke, Wang, Stratford, & Mioduski, 2010; Wang, Hart, Werneke, Stratford, & Mioduski, 2009).

Methodology

We conducted a retrospective, secondary analysis of real-world data extracted from the Focus on Therapeutic Outcomes, Inc. (FOTO) (Knoxville, TN) database (Swinkels et al., 2007) to examine PT practice patterns and the primary outcome measure of patient self-reported perception of urinary function over time. The FOTO dataset includes PT visits and outcomes data from patients referred to PT services for a variety of urinary impairments, such as incontinence/leakage, frequency, and urgency. The reliability of patient self-report of health status of PT rehabilitation has been reported by Hart (2003) and Wang, Hart, Deutscher, Yen, and Mioduski (2013).

FOTO developed state-of-the-art patient self-report outcome measures to assess patient and clinician encounters using a robust and sophisticated risk-adjusted analytical model. FOTO has amassed over 6.9 million rehabilitation episodes of care in the database. FOTO is being used by over 22,600 clinicians and over 4,700 clinics within all 50 of the United States. FOTO data include patient demographic variables (i.e., age, sex, symptom acuity, surgical history, number of comorbid conditions, exercise history, and payer source) and data on pelvic floor dysfunction. When pelvic floor dysfunction surveys are administered, patients completing the surveys are instructed to select disorders that might apply to them (i.e., urinary, bowel, and pelvic pain). The urinary function survey includes a total of 21 items: 17 leakage items, 2 frequency items, and 2 retention items. The bowel function survey includes a total of 20 items: 15 leakage items and 5 constipation items. Percentages of patients are calculated as the number of patients who selected a specific rating category divided by the total number of patients with that disorder (i.e., the denominator varies depending on how many patients answer a specific UI question).

The construct of the FOTO analytic file is composed of data on urinary disorders, bowel disorders, and pelvic pain. If a record contained data indicating the disorder as urinary, we extracted this information, which formed the basis for calculating the prevalence of urinary leakage, frequency, and retention. Second, if the disorder indicated bowel, we extracted this information, which formed the basis for calculating the prevalence of bowel leakage, constipation, or straining. Third, if the disorder was pelvic pain, we extracted this information, which formed the basis for calculating prevalence of anatomical location by abdominal, rectal, sacroiliac, and vaginal. This information then formed the basis for calculating the severity of pelvic floor dysfunction disorders by inspecting the frequency count for each response category for all questions in the urinary and bowel function surveys developed by FOTO.

FOTO measures patient urinary function using Computer Adaptive Testing (CAT) to assesses the patient's perception of his/her urinary function and pelvic floor dysfunction, and is based on sound psychometric properties (Wang et al., 2013). The CAT was developed using item response theory methods and produces a precise estimate of function. By tailoring each question to the individual patient, patient response burden is reduced. The resulting urinary status score is continuous and linear. Scores range from 0 to 100, with higher scores indicating better urinary function. The survey is standardized, and scores are validated for the measurement of function for this population (Rogers, Coates, Kammerer-Doak, Khalsa, & Qualls, 2003).

FOTO data included the following patient factors that could be evaluated for inclusion in a model for risk-adjustment: urinary status at admission (continuous), age (continuous), sex (male/female), acuity as number of days from onset of the treated condition (6 categories), type of payer (10 categories), number of related surgeries (4 categories), exercise history (3 categories), use of medication at intake for the treatment of UI (yes/no), previous treatment for UI (yes/no), and 31 comorbidities.

This report describes PT-UI visits through descriptive statistics and urinary status score changes. We define urinary status (i.e., the physical therapist evaluates the urinary status of a patient through use of the CAT scoring system, whose scores would indicate what, if any, additional assessments are necessary) as an individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being. This description parallels previously reported urinary status studies (Leidy, 1994; Testa, 2015; Wilson & Cleary 1995). PT practice patterns were defined by 1) lapsed time (days) from baseline urinary status measurement to the next follow-up urinary status measurement, 2) lapsed days between urinary status measurements,

and 3) change in average number of PT visits from previous measurement.

Results

During the study period of January 2014 and July 2017, the FOTO national sample collected data for 6,904,893 PT visits for all conditions and for 40,961 (0.6%) PT-UI visits (observations). UI services were rendered in PT clinics located in 50 states (and the District of Columbia), in 479 cities, within 321 PT organizations, at 628 PT clinics, by 918 physical therapists. All PT-UI treatment observations were retrieved and reviewed. Fifty-two percent of the PT-UI observations had missing outcomes data at data collection time point 1 (T1), which occurred approximately 6 weeks after the initiation of PT therapy (baseline). This left a total of 19,459 observations with complete records of services that met sample selection criteria (reported one or more PT visits, treatment episode of greater than 6 days, and at least one urinary status measure taken after the baseline urinary status assessment).

The sample was predominately female (86.7%) with an average age of 56.3 years, height of 65.3 cm, weight of 168.8 Kg, and body mass index (BMI) of 27.8. At the initial (baseline) PT intake assessment, patients could report up to 30 comorbidities (see Table 1). The most reported comorbidities were prior history of incontinence (11.5%), kidney (10%), back pain (9.1%), pre-surgical (8.2%), arthritis (7.0%), and high blood pressure (6.1%).

Table 2 displays PT practice patterns, urinary status scores, and mean number of comorbidities at baseline and at five subsequent data collection time points (T1 to T5). Approximately 6 PT-UI visits occurred between each urinary status measurement. However, we also found a significant drop off in patient counts from the initial baseline 19,459 count down to 367 count by the T5 urinary status measurement. Over the observation period, the average number of PT visits started at 1.26 visits per week (during the first 43-day period) and there was a consistent decrease in the number of PT visits from T1 through T5. T2 occurred on average at 65.3 days following baseline, T3 at 88.2 days, T4 at 112.2 days, and T5 at 138.2 days on average following baseline data measurement.

Among this national sample, we found consistency in improvement between the baseline and follow up (T1 through T5) urinary status measures during the 138-day follow-up period in

Table 1.
Self-Reported Comorbidities and Distribution at Initial (Baseline) Physical Therapy Intake Assessment (*N*=19,420)

Comorbidity	Count	%
Arthritis	7,042	7.0
Osteoporosis	2,218	2.2
Asthma	2,343	2.3
Chronic	606	0.6
Angina	241	0.2
Congest heart failure	807	0.8
Heart attack	383	0.4
High blood pressure	6,072	6.1
Neurological disorder	566	0.6
Stroke	661	0.7
Pace maker	169	0.2
Seizure	160	0.2
Peripheral vascular disease	307	0.3
Headache	4,698	4.7
Diabetes	1,932	1.9
Gastrological	5,052	5.0
Visual	2,498	2.5
Hearing	1,205	1.2
Back pain	9,087	9.1
Kidney	10,032	10.0
Previous accidents – Auto, work, other	2,091	2.1
Allergic	6,908	6.9
Incontinence[a]	11,552	11.5
Anxiety	4,196	4.2
Depression	4,316	4.3
Other	1,333	1.3
Hepatitis	194	0.2
Pre-surgical	8,216	8.2
Prosthesis	1,214	1.2
Sleep dysfunction	4,045	4.0

[a] History of incontinence prior to initial intake.

patients who underwent PT visits for UI conditions. Wilcoxon Signed-Ranks tests for paired samples were calculated to examine the relationships between the baseline urinary status and each subsequent urinary-status assessment measurements (T1 to T5). All analyses yielded *p* values less than 0.0001. Urinary status scores increased +7.97 on average from T1 to T2 and appeared to plateau after the T2 urinary status measurement.

Data revealed variation in the type of insurance coverage as PT-UI patients proceeded from the T1 urinary status measure observation through subsequent urinary status measurements (see Table 3). The greatest change was among patients covered by indemnity insurance, and the least change was for patients covered by Medicare Part C. The average age of the sample decreased from 56.3 years at T1 to 52.2 years at T5.

Discussion

The purpose of this study was to determine the frequency and duration of PT-UI care and patients' perception of urinary function over time among a national sample of adults receiving PT for treatment of UI. The FOTO dataset provided real-world data to explore the relationship between outpatient PT-UI visits (observations) and change in urinary status measurements over time. This report provides a fist-step in determining optimal PT-UI care and will support efforts toward the development of PT-UI clinical practice guidelines. The importance of establishing PT-UI metrics is further driven by the reliance of such information by third-party payers in establishing pay-for-performance and quality guidance. For example, FOTO participates in the CMS Quality Payment Program – Merit-Based Incentive Payment System 2017 Qualified Registries and complies with the Qualified Registry Data Validation Plan.

The patient demographics of our cohort were similar to those reported by Wang, Hart, and Mioduski (2012). The incidence of male UI in this sample was scarce. The average of the female patient group who proceeded from the first urinary status measure (T1) to subsequent urinary status measures decreased from 56.3 years to 52.2 years by the T5 measure. This may reflect a disproportionate share of Medicare-eligible patients who did not require further PT UI visits over time, exhausted their PT coverage, or did not find benefit in continuing care.

Over the study period, the average number of PT visits started at 1.26 visits per week (week = intake day/discharge day-interruption days/7) administered over the first 6-week period and then dropped to 0.48 visits per week by the fifth urinary status measurement, which was administered in the last three weeks of the study period. PT-UI caregivers provide interventions, such as biofeedback, and instructions, such as Kegel exercises, relaxation exercises, and exercises to improve abdominal and core muscle control. In addition, patients are instructed and encouraged to complete these exercises at home between scheduled PT visits. Some patients in this sample could have achieved early success in achieving their personal care goals, while others could have dropped out due to a lack of success. Due to the severity of UI and/or the presence of comorbid conditions, some patients may require longer-term PT-UI care to achieve their personal care goals. For those patients, it seems PT-UI non-pharmacologic treatments could contribute to improved outcomes as called for by the ACP.

On average, the plateauing of the change in urinary status by the T2 measurement is notable (see Table 2). It seems many patients in this cohort either completed a short-term course of PT or discontinued PT (due to the lack of benefit or other reasons) before reaching the point in time (or PT-visit) where the T2 urinary status measurement would have been obtained. This cohort started with 19,459 patients who completed an initial (baseline) urinary status assessment. Urinary status improved by an average of +6.47 by TD1. However, over 12,400 were lost to attrition by T2. These individuals, perhaps those who had greater severity of UI or more comorbidities, could have attained an acceptable improvement in urinary function and required no further PT care by T2. Conversely, limitations of their health insurance benefit could also have influenced their decision to continue with additional PT-UI care. For those 6,999 patients who continued with PT-UI care to T2, an improvement in urinary status of +7.97 above baseline measurement was observed. By the end of the study period (T5), the sample had a mean improvement of +8.00 above baseline urinary status, while patient observations decreased from 19,459 at baseline to 367.

Limitations

Despite the strength a significant sample, both in size and scope across the United States, there were several limitations of this study that impact interpretation of our findings. First, additional unmeasured clinical and secular confounders/covariates could have effected changes in urinary status values over the study period. A few possible examples include a lack of compliance with PT-recommended take-home instructions (e.g., exercises to improve abdominal and core muscle control), the presence and severity of comorbidities, lack of sufficient insurance coverage to complete a course of therapy, and lack of a home support system to reinforce take-home instructions.

Table 2.
Physical Therapy Practice Patterns, Urinary Status, and Comorbidities Across Time Points[a]

Variable	Baseline	T1	T2	T3	T4	T5
Patient count	19,459	19,459	6,999	2,375	920	367
Mean number physical therapy visits/week	—	1.26	0.81	0.66	0.56	0.48
Mean urinary status (US) score	55.47	61.94	63.44	63.86	64.05	63.46
Mean change in US score from baseline measure	—	+ 6.47	+ 7.97	+ 8.39	+ 8.58	+ 8.00
Mean number days lapsed between baseline US score and time-point US	—	42.9	65.3	88.2	112.2	138.2
Mean number of days since previous US score measure	—	4.2	22.4	22.9	24.0	26.0
Mean number of comorbidities[b]	5.38	5.56	5.70	5.82	5.82	5.98

[a] T1 = first 43-day period following baseline; T2 = at 65.3 days on average after baseline; T3 = at 88.2 days on average after baseline; T4 = at 112.2 days on average after baseline; T5 = at 138.2 days on average after baseline.

[b] Patients have the opportunity to amend the number of their comorbidities between baseline and the first follow-up urinary-status measure.

Second, the temporal relationship between the times that each subsequent urinary status assessment was measured to the time the PT service was rendered during the subsequent PT visit is unclear. Urinary status assessments can be measured either before or after the treatment rendered during the PT visit (FOTO staff, personal communication, February 7, 2017). This circumstance could confound modeling of outcomes.

Third, insurance coverage could have had a significant influence over the duration of PT-UI care. It seems that Medicaid beneficiaries may be covered for less time than individuals who are covered by other forms of insurance. Commercial indemnity (or "fee-for-service") plans appear to have the greatest retention of coverage and thus may allow for longer continuation of PT-UI therapy. Medicare limits annually how much outpatient therapy it will cover, although coverage is allowed for medically necessary therapy beyond the annual cap. Preferred provider plans, such as Blue Cross-Blue Shield preferred provider organization (PPO), typically cover individuals for longer durations of care episodes. Regardless of insurance coverage, any patient who does not perceive further benefit from continuing the services being delivered may be inclined to discontinue services prematurely.

Fourth, the presence of comorbid conditions may also have had a significant bearing on our results. Individuals with a high number of comorbid conditions could have had difficulties in completing their prescribed course of UI therapy.

Fifth, as this study was a secondary analysis of data prospectively collected via the proprietary FOTO database, the researchers were not in control of the data collection procedure or in control of a standardized sequence as to when an individual underwent a urinary status assessment. Missing data were also common.

Sixth, generalization of results could be limited because there may be differences between participating and non-participating clinics in the FOTO collect data collection system. However, use of proprietary database offers timely information based on large samples and provides insight that could not be obtained through a conventional analysis of a healthcare claims database.

Finally, selection bias limits interpretation and generalizability of our findings. Selection bias results from the way subjects are selected for inclusion in the study population. This bias may result when a provider has a special focus on a particular malady, and therefore, attracts a large number of a particular type of patients. For example, if a facility is known for treatment of UI, it is reasonable to posit that such a clinic would serve a larger population of individuals for the condition, compared to other facilities. Thus, patients in one clinic may be different for a variety of reasons from patients treated in another clinic. The high attrition rate over the study period may be partially explained through selection bias. Hence, the improvement in urinary functionality reported herein is more likely to be conservative, as those who continued treatment tended to report the least amount of improvement.

Recommendations

Consistently conducting a urinary status assessment at the initial PT encounter would improve the ability to structure appropriate outcomes analysis. A more frequent first follow-up uri-

Table 3.
Comparison of Number of Urinary Status Observations and Patient Age at Each Time Point by Type of Insurance

Variable	Time 1	Time 2		Time 3		Time 4		Time 5	
	N	*N*	% Change	*N*	% Change	*N*	% Change	*N*	% Change
TOTAL COUNT	19,420	6,982		2,367		916		366	
Payer									
HMO	1,745	579	33.2	175	10.0	71	4.1	27	1.5
Indemnity insurance	1,052	428	40.7	177	16.8	81	7.7	38	3.6
Medicaid	591	160	27.1	48	8.1	15	2.5	5	0.8
Medicare A	236	93	39.4	33	14.0	12	5.1	4	1.7
Medicare B	6,249	2,175	34.8	673	10.8	239	3.8	90	1.4
Medicare C	69	18	26.1	5	7.2	1	1.4	0	0.0
Other	1,871	640	34.2	230	12.3	91	4.9	39	2.1
Patient	156	57	36.5	16	10.3	4	2.6	0	0.0
Preferred provider	7,451	2,832	38.0	1,010	13.6	402	5.4	163	2.2
	Time 1	Time 2		Time 3		Time 4		Time 5	
Mean Age	56.3	55.4		53.9		52.6		52.2	

Note. There was a loss of 39 (19,459 to 19,420) urinary status (US) observations due to a lack of reporting the of the urinary status measure at time point 1.

nary status assessment (e.g., third to fourth week vs. sixth week) would help more fully understand the impact of PT-UI visits.

Patients with UI who received PT care through the first urinary status measure time point had, on average, 1.26 PT-UI visits/week over the first six-week period. This care was associated with an average 6.47 points improvement in urinary status. More frequent urinary status measurements during the first six-week period could provide greater insight into optimal PT-UI practice patterns. Earlier assessments could provide the treating therapist with valuable patient feedback. Such feedback could provide the therapist with opportunities to change treatment plans, as indicated, at an earlier point in the PT-UI care plan, improve care delivery, and possibly impact outcomes sooner. In addition, insurance type and coverage limitations may play a significant role in patient compliance with follow-up care. Studies should be conducted to further elucidate the effect of insurance coverage.

Future research on PT practice patterns would be helpful to better inform our understanding of the optimal number of visits for a given UI condition. The FOTO measurement system provides risk-adjusted modeling and could be used in studies to gauge the value of PT-UI services in the context of the overall healthcare delivery process. Future analysis should also be directed toward establishing a UI standard of care and pay-for-performance incentives.

Nursing Implications

Nurses across all levels (licensed practical nurses, registered nurses, advanced practice nurses) and all settings have the capacity to help patients with UI learn about and engage in evidence-based treatment options. Physical therapists employ a variety of methods in UI treat-

ment and are well positioned to provide first-line, non-pharmacologic therapies as recommended by the ACP guidelines.

Conclusions

Current ACP guidelines for UI call for non-pharmacologic therapy as first-line treatment. While physical therapists are well-positioned to provide first-line pelvic floor training and bladder training for UI disorders, they face challenges in formulating plans of care because little is known to guide efforts in standardizing PT-UI care. This study used real-world data to help illuminate the variability in PT practice patterns that create challenges for both researchers and practicing clinicians. This report provides a first step in efforts to determine optimal PT-UI care practice standards.

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