

Pelvic floor rehabilitation with biofeedback and electrical stimulation with Urostym[®] for treatment of urinary incontinence

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Abstract

Objective: To show that supervised pelvic floor rehabilitation with biofeedback and electrostimulation using the Urostym[®] system is an effective treatment for urinary incontinence.

Methods: A retrospective case series of women who underwent pelvic floor rehabilitation program using the Urostym[®] system at our institution. The Urostym[®] program includes supervised biofeedback and electrostimulation for pelvic floor muscle weakness. Charts were reviewed for demographics, prior treatment, completion of program, number of leaks pre- and post-treatment, patient satisfaction, and need for treatment at six months' post-treatment.

Results: There was a significant decrease in the number of leaks after undergoing the pelvic floor rehabilitation program. The mean (SD) number of leaks decreased from 2.4 ± 2.1 to 1.1 ± 2.2 ($p < 0.0005$) after treatment. There was a trend towards an association between patient satisfaction and treatment success. 71.4% of those with complete or partial satisfaction required no further treatment, whereas only 20% of those who were unsatisfied required no further treatment, ($p = 0.55$).

Conclusions: Pelvic floor rehabilitation with biofeedback and electrostimulation using the Urostym[®] system is an effective therapy for urinary incontinence and significantly decreases the number of urinary accidents.

Introduction

Urinary incontinence is a prevalent and significant problem worldwide. In the United States, a large study has shown up to 37% prevalence with at least one diagnosis of pelvic floor disorders [1]. Urinary incontinence has been shown to be present in 51.4% of women in the United States [2].

Successful management and treatment of incontinence could significantly affect a large population who has been left untreated or undertreated in the past. Non-surgical treatment options offer less risk and morbidity to the patient population by avoiding surgical interventions.

There is currently a wide array of treatment modalities ranging from conservative management and medical therapy to surgical methods. Conservative management with pelvic floor muscle therapy has been shown to be effective as a first line treatment for urinary incontinence when comparing to placebo or other treatment modalities such as advice, general education, and exercises aimed at weight loss [3]. Supervised pelvic floor therapy by health professionals showed increased satisfaction and reports of overall improvement by patients when compared with individual non-supervised therapy [4]. Biofeedback is an adjunct therapy modality, in addition to pelvic floor muscle therapy. Biofeedback provides patients with either audible or visual cues on proper use and strength of contractions of the pelvic floor during therapy. In a randomized control study of postmenopausal women with stress urinary incontinence, biofeedback versus therapy without biofeedback shows increased patient satisfaction and rate of cure and improvement of stress incontinence [5]. However,

another randomized control study showed that adjunct outpatient biofeedback showed no difference in subjective or objective cure [6]. In our institution, the Urostym[®] system is utilized for our pelvic floor rehabilitation program. Urostym[®] by Laborie uses not only biofeedback but also electrical muscle stimulation via a vaginal probe as well as an intensive supervised program by healthcare professionals. Patients undergo weekly sessions in the office with assigned home therapy throughout the week, for a total of 4-6 sessions.

There are studies using electrostimulation but within specific populations (i.e. multiple sclerosis) [7]. These studies show supervision by health professionals as well as biofeedback can significantly improve outcomes for patients undergoing pelvic floor muscle therapy. A study by Erekson *et al.* also showed the cumulative factors of pelvic floor muscle therapy with supervision, biofeedback, and electrical stimulation to demonstrate a significant improvement in symptoms for mixed urinary incontinence [8]. Urostym[®] was not used in that study. Our study investigated patients who underwent our institution's pelvic floor muscle therapy program via Urostym[®] with weekly supervised sessions using biofeedback and with the primary endpoint as a decrease in the number of accidents post-treatment. While there have been studies on pelvic floor physical therapy and urinary incontinence, to

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our knowledge, this is the first study using UroStym® for pelvic floor rehabilitation in adult women with urinary incontinence.

Materials and methods

This is a retrospective case series. We conducted a retrospective chart review using electronic charts from St. John Hospital and Medical Center in Detroit, MI from June 2015 to April 2017 of all patients diagnosed with urinary and/or fecal incontinence and treated who underwent pelvic floor physical therapy with the UroStym® program. Patients were females of any age with urinary stress, urge, or mixed incontinence with or without fecal incontinence. Patients underwent at least one full session of the pelvic floor rehabilitation program which includes supervised biofeedback therapy by a medical health professional followed by electrostimulation with the UroStym® system. We conducted a chart review for age, race, ethnicity, type of incontinence, parity, mode of delivery, comorbidities, BMI, smoking status, pelvic organ prolapse, concurrent medical therapy, prior treatment (including medications and Kegel exercises), number of leaks (pre- and post-treatment program), completion of program to be defined as at least four sessions, total number of sessions, and overall patient satisfaction. Our primary outcome was to evaluate the number of leaks pre- and post-treatment. Number of leaks were measured on a voiding diary. Secondary outcomes included success of treatment (defined as lack of need for further treatment) and correlation of satisfaction with success. Complete satisfaction was defined as at least 80% or more satisfied by a subjective standard at the termination of the program, whereas partial satisfaction was defined as anything less than 80% but had some subjective satisfaction with the program. Success was indicated if there was no need for any further treatment at six months or failure if there was need for treatment at six months or less. Descriptive statistics for all variables were calculated. Associations between categorical variables were made with Fisher’s exact tests. Differences between groups on continuous variables were measured using the Wilcoxon signed rank test. P values <0.05 were considered significant. Analyses were performed with SPSS version 22.

Results

There were 27 women who underwent pelvic floor rehabilitation program. One woman was excluded due to her inability to tolerate the vaginal probe and was unable to complete her first session, and we included 26 women in the final analysis. Demographics and characteristics of our cohort are shown in table 1. The mean (SD) age at initiation of the program was 49.7 +/- 10.7 years with a mean (SD) BMI of 33.8 +/- 6.6. There was an even distribution of race, with 46% Caucasian (n=12) and 54% African-American (n=14). Almost half of patients had mixed incontinence, 46% (n=12), while the remaining had either pure stress incontinence, 27% (n=7), or pure urge incontinence, 27% (n=7). Patients that had a fecal incontinence component to their incontinence made up 23% (n=6). Parity ranged from nulliparity to grand multiparity, with a mean (SD) parity of 2.4 +/- 1.9. Spontaneous vaginal deliveries were the most common mode at 67% (n=14), while operative vaginal deliveries also accounted for an additional 23% (n=5). Most (85%) of the cohort had no prolapse (n=22), while the remaining 15% had asymptomatic prolapse at stage 2 (n=4). Over half of the patients had not tried any prior treatment (62%, n=14) while the remaining patients tried either Kegel exercises, 27% (n=7) or medications, 8% (n=2), and one patient tried a urinary incontinence ring pessary. There was a significant reduction of incontinence accidents after finishing the program, from 2.4 (standard deviation (sd)=2.1) accidents a day to 1.11 (sd= 2.2) accidents a day (p<0.0005) regardless of the number of sessions in which the patient participated (Figure 1).

Table 1. Demographics & Clinical Characteristics of Patients Who Underwent UroStym® Program

	n = 26 Mean ± SD or n (%)
Age (yrs.)	49.7 ± 10.7
BMI	33.8 ± 6.6
Race:	
Caucasian	12 (46)
African-American	14 (54)
Smoking status:	
Never	14 (54)
Former	9 (35)
Current	3 (11)
Comorbidities:	
HTN	11 (42)
None	11 (42)
Other	6 (23)
Parity	2.4 ± 1.9
Delivery type:	
Standard vaginal	14 (64)
Cesarean	3
Operative	(613)
	(23)
Urinary incontinence:	
Stress	7
Urge	(127)
Mixed	(127)(46)
Fecal incontinence	6
	(23)
POP stage:	
0	21 (81)
1	1 (4)
2	4
	(15)
Prior treatment:	
None	16 (61)
Kegel exercises	7
Medication	(27)(8)
Urinary incontinence ring	1 (4)

Completion of the program was defined as participating in at least four sessions, and 80% (n=21) of patients completed the program (Table 2). Success was defined as the lack of further treatment at six months after finishing pelvic floor rehabilitation program. 61.5% of patients (n=16) had success after pelvic floor rehabilitation. Of the patients who had success with pelvic floor rehabilitation, 31% (n=5) suffered from pure stress incontinence, 19% (n=3) from pure urge incontinence, and 50% (n=8) from mixed incontinence. Patients suffering from stress incontinence and mixed incontinence had the highest rate of success (71% [n=5] and 67% [n=8], respectively). The remaining 10 patients needed treatment within the first six months such as Botox injections with or without medications (n=3 without, n=1 with medications; 12% and 4% respectively), surgery (n=3, 12%) (tension free vaginal tape sling), PTNS (posterior tibial nerve stimulation) with medications (n=1, 4%), Interstim sacral neuromodulation (n=1, 4%), and medications alone (n=1, 4%). The association between satisfaction and success was close to significance (p=0.055). The pelvic floor rehabilitation program was successful for 71% (n=15) of patients who had at least partial to complete satisfaction at termination of the program, while 29% (n=6) needed further treatment (Figure 2). 80% (n=4) of patients who were unsatisfied by the program needed further treatment.

Table 2. Number of treatment cycles per patient

Treatments	n = 26 n (%)
No. of treatments	
1	2 (8)
2	3 (12)
3	0 (0)
4	5 (19)
5	5 (19)
6	6 (23)
7	1 (4)
8	4 (15)

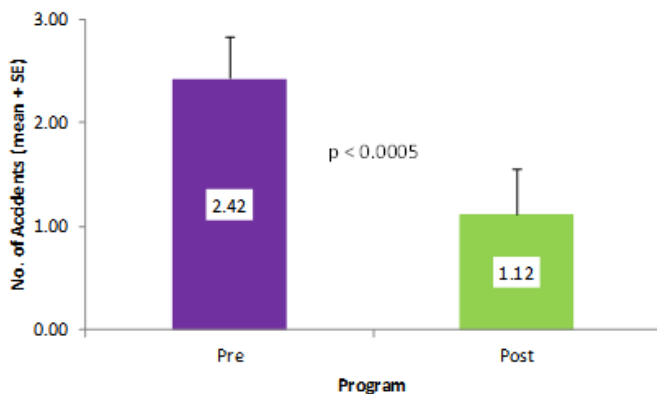


Figure 1. Number of accidents pre and post program

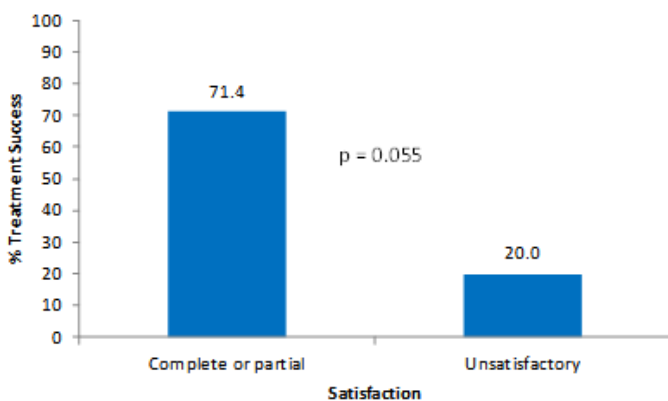


Figure 2. Treatment success and patient satisfaction

Discussion

Our study shows that pelvic floor rehabilitation was successful in 71% of patients with urinary incontinence and they did not need any further treatment after 6 months of follow up. While there have been studies on pelvic floor physical therapy and urinary incontinence, our study is the first to assess Urostym® for pelvic floor rehabilitation in adult women with urinary incontinence. Studies have already confirmed that a supervised pelvic floor rehabilitation program with electrostimulation is a valuable and effective therapy for incontinence [5,8,9]. We confirmed that pelvic floor rehabilitation via biofeedback and electrostimulation can significantly decrease the number of leaks after termination of the program regardless of type of incontinence. The relationship between subjective satisfaction with the pelvic floor rehabilitation program and success neared significance as well.

Another retrospective chart review explored the long-term effectiveness of pelvic floor rehabilitation with the elderly population

[10], but there is an overall paucity of data and studies to show long-term effectiveness of pelvic floor rehabilitation. More studies are needed to explore the long-term effectiveness of therapy and the relationship between success and patient satisfaction. Our study's use of a 6 month follow up for confirmation of treatment success is an introduction to the long-term success of pelvic floor rehabilitation with biofeedback and electrostimulation for the general population. Another area that would be of interest for further investigation is the use of pelvic floor rehabilitation for fecal incontinence. A literature review by Scott in 2014 confirms that rehabilitation is an important therapy for fecal incontinence, but the literature is limited to case reports and non-randomized prospective studies [8].

Urinary incontinence is a problem not only affecting quality of life for a significant number of patients but also a substantial onus economically. A systematic review of 7 studies reporting the economic burden of urinary incontinence in the United States estimated the annual cost in 2007 to be \$65.9 billion with projected annual costs to be \$82.6 billion by 2020 [11]. This highlights the importance of conservative treatments like pelvic floor rehabilitation for incontinence not only to decrease the risk of morbidity from surgical or more invasive modalities but also to help ebb the ever-rising healthcare costs in the United States.

Limitations of our study included our small sample size and lack of a control group but given the dearth of data on this subject it will help providers taking care of women with urinary incontinence. Our study also provides a spring board for future studies. There was also most likely selection bias as not all patients with incontinence underwent pelvic floor rehabilitation and likely women with more severe symptoms opted for more aggressive initial interventions; however, we offer this modality to all our patients. This is true for most clinical practices, as only some patients choose to undergo pelvic floor rehabilitation. This is a good predictor of success in women who decide to undergo this modality of treatment. Another factor that could be considered is number of sessions needed to reach a therapeutic level and be considered satisfactory for patients subjectively. Most of our patients completed 4 sessions of treatment and this seems to be an appropriate number to be considered for the least number of treatments needed. Further studies can look into the least number of sessions needed for successful pelvic floor rehabilitation. Another limitation of the study is that we did not use validated questionnaires, however the number of leaks were asked verbally and measured by voiding diaries. Mean BMI in our study high at 33.8 and therefore the results may differ in the normal BMI population, however this reflects the patient population in our part of the Midwest United States. Strengths of our study include our use of 6 month follow up to determine long-term success as well as our use of the Urostym® system in treatment of urinary incontinence in the adult population which is to our knowledge, an unprecedented study. Finally, we have shown that using objective measures such as number of leaks and patient satisfaction are effective and significant parameters to use in treating urinary incontinence with pelvic floor rehabilitation.

In conclusion, pelvic floor rehabilitation with Urostym® is a useful modality of treatment for urinary incontinence in women desiring non-surgical treatment options. Our study establishes the use of the Urostym® system for pelvic floor rehabilitation as a highly effective and non-surgical treatment for urinary incontinence which significantly decreased leaks and showed long-term success. Pelvic floor rehabilitation should be considered before any invasive treatment modality for patients presenting with urinary incontinence.

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