Research Article

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Cost-Comparison Analysis of APEX M™ Pelvic Floor Therapy for the Treatment and Management of Female Urinary Incontinence

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Abstract

The primary objective of this study was to assess the efficacy of APEX M™ pelvic floor therapy, a pelvic stimulating device, for women with urinary incontinence (UI) from April 1, 2014 to January 31, 2018 at a tertiary medical center. Efficacy of the device was measured by daytime incontinence episodes; nighttime incontinence episodes (nocturia); number of female incontinence pads at study visits. A total of 47 women purchased the device and participated in a treatment protocol. A total of 71 women purchased the device online or over the counter and did not participate in the treatment protocol. A secondary objective was to assess health-related direct costs of UI including prescription medications, pelvic floor physical therapy sessions, surgical interventions, and female incontinence pads in patients who used APEX M™ and those who didn't use the device. Health care resource utilization and costs were calculated for women who purchased APEX M™ (47 women) and participated in a treatment protocol as well as for those who were eligible to benefit from the use of the pelvic stimulating device but chose not to purchase it (236 women). Wilcoxon signed-rank tests showed that daytime incontinence episodes, nocturia, and number of pads used had significant decreases from the initial to follow-up visits (day incontinence episodes $P<0.001$, episodes of nocturia $P<0.001$ and number of pads $P=0.014$). More cost-effective and conservative approaches are becoming more common in the treatment of UI. The results of this study may be useful in shared-decision making with your patients regarding the most appropriate, cost-effective and less-invasive treatment for female urinary incontinence.

Keywords: Female urinary incontinence; Pelvic stimulating device; Neuromuscular stimulation; Pelvic floor therapy; Electrical muscle stimulation; Pelvic floor electrical stimulator; Pelvic floor strengthening; Pelvic floor training

Abbreviations: UI: Urinary Incontinence; HrQoL: Health-Related Quality of Life; PFMT: Pelvic floor muscle training; ACOG ACOG: American Congress of Obstetricians and Gynecologists; AUGS: American Urogynecologic Society; PFES: Pelvic Floor Electrical Stimulators; AHRQ: Agency for Healthcare Research and Quality

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INTRODUCTION

Urinary incontinence (UI) is defined as the unintentional loss of urine. It is common, debilitating, distressing, and can affect a woman's health-related quality of life (HrQoL). UI affects ~38% of women in the United States [1] and is associated with significant medical and non-medical expenses. Most recent estimations of annual direct costs of incontinence in all ages in the US is over 19.5 billion dollars [2], which suggests that UI is an economic burden to the patient and the health system.

Pelvic floor muscle training (PFMT), also known as kegel exercises, is first-line treatment for stress, urge, and mixed UI. However, only ~30% of women perform the exercises effectively [3]. Electrical muscle stimulation and biofeedback became popular and are now often utilized as a non-invasive approach to pelvic floor strengthening. In the US, medical societies including the American Congress of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) support the use of pelvic floor electrical stimulators (PFES), inserted into the vaginal canal or rectum, as reasonable and appropriate treatment for stress and/or urge urinary incontinence [4].

Pharmacological agents for urgency

Pharmacotherapy (primarily anticholinergics) provides symptom management for urge incontinence and is widely covered by most commercial policies. The Agency for Healthcare Research and Quality (AHRQ) reported that over half of patients stop taking medications for UI after 1 year of use due to common adverse effects including dry mouth, constipation, and worsening cognitive function. No medication has been approved for the treatment of stress UI, although a few are underway. Costs for most of these medications are similar but cumulatively add up, indefinitely.

Pelvic floor physical therapy

Once patients have correctly identified their pelvic floor muscles, a well-trained physical therapist can enhance pelvic floor and abdominal wall exercises and help incorporate these into their daily activities. Unfortunately, most insurance policies don't provide coverage for such treatments and patients are often left with an out-of-pocket cost [5].

Surgical interventions for stress incontinence

The surgical approach including implantation of a mid-urethral sling is costly with varied subjective cure rates. Patients report only a 55-62% subjective cure [6]. Additionally, adverse events including infection, neurological symptoms, vascular events, and wound-related issues have been reported [6].

Pelvic floor electrical simulator

APEX M™, an over the counter battery powered inflatable probe and muscle stimulating device is an at-home device for pelvic floor training that ensures exercises are done correctly and effectively (Figure 1). There is, however, a lack of reliable data on the performance of pelvic stimulating devices in the real-world setting, both for short and long-term management.

Figure 1

With the high out-of-pocket and limited insurance coverage for UI interventions, an over-the counter pelvic stimulating device that treats stress incontinence, urge incontinence and mixed incontinence is of medico-economic interest for patients and the healthcare system. Understanding the effectiveness of such a device will help fill an existing gap in the management of UI.

METHODS

Study design and data source and patient selection

This is a retrospective, quantitative, cohort study of women presenting with UI to a tertiary medical facility between April 1, 2014 to January 31, 2018. Institutional review board approval for medical records research or chart review was obtained for this study.

Forty-seven women who purchased the APEX M™ device participated in a treatment protocol, including home practice sessions 6x/week for 3 months. Patient subjective responses about their current incontinence status, specifically the number of incontinence episodes (daytime and night) in addition to the number of female incontinence pads were documented at their initial and follow-up visits scheduled within the study period.

Healthcare resource utilization and costs were calculated for women who purchased APEX M (47 women) and participated in a treatment protocol as well as for those who were eligible to benefit from the use of pelvic stimulating device but chose not to purchase it (236). All health care utilization, including prescription medications relating to UI documented within the electronic medical record after purchase/refusal of the device were abstracted

from each patient's chart. A cost was assigned to each utilization category based on average costs for pelvic floor physical therapy and common surgical procedures according to the Cleveland Clinic Women's Health Institute cost analysis. Prescription medication costs were assigned as wholesale acquisition costs according to Rx Price Verify [7].

Outcome measures

The use of surgical interventions and pharmacotherapy, as identified by the Cleveland Clinic Women's Health Institute administrative claims and the data from the Agency for Healthcare Research and Quality (AHRQ), were evaluated in the four-year period following the diagnosis of urinary incontinence. The ICD-10-CM codes for stress, urge, overactive bladder, and mixed urinary incontinence include N32.81, N39.41, N39.46, N39.46, and N39.3. The ICD-9-CM codes for stress, urge, overactive bladder, and mixed urinary incontinence include 596.51, 788.31, 788.33, and 625.6. The CPT code for the tension-free vaginal tape sling includes 57288. The most common surgical interventions include intradetrusor Botox injections, sacral nerve stimulation (Interstim™), periurethral bulking, burches, and monarch slings. The cost of pelvic floor physical therapy was estimated for six sessions. For the primary cost analysis, the number of incontinence episodes (daytime and night) documented in the office visits with the healthcare provider during the reporting period was measured in the intervention group. For the secondary cost analysis, health-related direct costs of UI including prescription medications, pelvic floor physical therapy sessions, surgical interventions, and female incontinence pads in patients who used APEX M™ compared to those who didn't use the device were calculated. Categorical and continuous variables including parity, history of pelvic floor surgeries, history of hysterectomy, use of estrogen therapy were not reported.

Statistical method

Age was summarized using means and standard deviations. Ordinal measures were summarized using medians and quartiles or frequencies and percentages. Categorical factors were summarized using frequencies and percentages. Wilcoxon signed-rank tests were performed for paired before and after follow-up outcomes. All analyses were done using SAS (version 9.4, The SAS Institute, Cary, NC) and a $p < 0.05$ was considered statistically significant.

RESULTS

Baseline characteristics of participants

47 APEX M™ patients had a mean age of 58. 217. Those in the non- APEX M™ group had a mean age of 57. As depicted in the table below, the baseline characteristics between the two groups were dissimilar, providing the inability to compare study populations (Table 1).

Table 1:

Variable	APEX M™ (n=47)	Control (n=236)
	N (%)	N (%)
Mean age	58.1±8.4	57.7±7.7
Vaginal Parity	Yes: 12	Unknown
	No: 11	
	Unknown: 24	
History of Hysterectomy	14 (30.4)	Unknown
History of Pelvic Floor Surgery	11 (23.4)	46 (18.7)
History of Pelvic Floor Therapy	0 (0)	5 (2.0)
On Hormone Therapy	44 (95.7)	Unknown
On Anticholinergic Medication	1 (2.1)	23 (9.7)

Descriptive results with APEX M™ intervention

Subsequent tables shown below demonstrate subjective responses indicating each patient's incontinence status. This specifically includes the number of incontinence episodes as well as the number of female incontinence pads that were documented at the initial and follow-up visits.

Wilcoxon signed-rank tests showed that all three outcomes had significant decreases from the initial visit to follow-up (day incontinence episodes P<0.001, episodes of nocturia P<0.001 and number of pads P=0.014).

Daytime incontinence episodes in the APEX M™ group

Patients in the APEX M™ group had a median of 7 (IQR: 5-10) incontinence episodes per day at the initial visit and 5 (IQR: 3-7) at follow-up. There was a median decrease of 2 (IQR: 0-4.5) episodes per day from the initial to follow-up visits (Table 2).

Table 2:

	Day Incontinence Episodes at Initial Visit	Day Incontinence Episodes at Follow-Up Visit	Decrease in Number of Day Incontinence Episodes	
Median number of episodes (IQR)	7 (5, 10)	5 (3, 7)	2 (0, 5)	p<0.001

Nocturia episodes in the APEX M™ group

Most patients in the APEX M™ group had one N=12 (31.6%) or two N=11 (28.9%) episodes at initial visit and zero N=16 (39.0%) or one N=18 (43.9%) episode at the last follow up. Overall, the majority had one episode decrease N=18 (47.4%) (Table 3).

Female incontinence pads in the APEX M™ group

Majority of APEX M™ patients (75%) did not have a change (increase or decrease) in the number of pads used per day. However, 12.5% of patients had a 1 pad decrease, 7.5% had a 2 pad decrease and 2.5% had a 6-pad decrease (Table 4).

Table 3:

	Nocturia Episodes at Initial Visit	Nocturia Episodes at Follow-Up Visit	Decrease in Number of Nocturia Episodes	
Median number of episodes (IQR)	2 (1, 3)	1 (0, 1)	1 (0, 1)	p<0.001

Table 4:

Number of Pads at Initial Visit (N=41)	(Frequency, %)	Number of Pads at Follow-Up Visit (N=46)	(Frequency, %)	Decrease of Number of Pads (N=40)	(Frequency, %)
0	26 (63.4)	0	39 (84.8)	-1	1 (2.5)
1	7 (17.1)	1	4 (8.7)	0	30 (75.0)
2	4 (9.8)	2	1 (2.2)	1	5 (12.5)
4	2 (4.9)	4	1 (2.2)	2	3 (7.5)
5	1 (2.4)	5	1 (2.2)	6	1 (2.5)
8	1 (2.4)				

Prescription medication utilization (1 year)

8.5% more in non-APEX M™ group used medication at baseline compared to the APEX M™ group, with 2.3% more at 1 year. 6.2% more patients in non-APEX M™ group saw a change in medication compared to APEX M™ (Table 5).

The median cost of medications for the APEX M™ group was $2286.00 and $4114.80 for that of the non-APEX M™ group (Table 6).

Total cost utilization (1 year)

Surgical rates were similar in both groups with the most common procedure being the TVT sling. No patients in the APEX M™ group had PFPT versus 5 in the control group (Table 7).

Table 5:

Variable	Control N (%)	APEX M™ N (%)	Incremental Difference (%) Control vs APEX M™
Medication at baseline	23 (10.6)	1 (2.1)	8.5
Medication at 1 year	14 (6.5)	2 (4.2)	2.3
Δ in Medication use	9 (4.1)	-1 (-2.1)	6.2

Table 6:

Cost of Medication ($)	APEX M™ N (%)	Control N (%)
0-599	46 (98)	196 (90)
600-999	0 (0)	4 (2)
1000-1999	0 (0)	3 (1)
2000-3999	1 (2)	1 (0.46)
4000-5999	0 (0)	8 (4)
6000 +	0 (0)	5 (2)

DISCUSSION

Many females assume that urinary incontinence is a normal consequence of aging and a chronic burden that one must live with. They tend to cope with their symptoms by using female incontinence pads and other over-the-counter products. UI is a condition that most are not comfortable talking about, causing shame and depressive feelings which lead to lack of medical help.

What the affected population and majority of medical professionals don't know is that there have been improvements in the management of female urinary incontinence that are attainable and non-invasive. Evidence-based treatment options including electrical muscle stimulation and biofeedback continue to be underutilized despite rising annual direct and indirect costs of incontinence in all ages.

Table 7:

Variable	Control		APEX M™		Incremental Difference Control vs APEX M™	
	N (%)	Median cost (IQR)	N (%)	Median cost (IQR)	(%)	Cost
Medication	14	4115	2	2286	2.3	1829
	-6.5	(932 -4639)	-4.2	(N/A)		
Surgery	2	23017	3	23017	-1	0
	-0.9	(23017-23017)	-6.4	(1356-23017)		
Pelvic Floor PT	2	14270	0	0	2	14270
	-0.9	(11416-17124)	0	(N/A)		
Total Cost	18	41402	5	25303	13	16099
Utilization	-8.3	(N/A)	-10.6	(N/A)		

Electrical muscle stimulation is achieved by stimulating a passive contraction of the pelvic floor muscles through the transmission of low-grade electrical impulses to the nerves that supply these muscles, as well as the bladder and bowel. This stimulation works to heighten the patient's perception and awareness of the pelvic muscle activity especially in those who have very weak pelvic muscles. The small electrical impulses are delivered to the pelvic structures through an internal vaginal electrode.

Typically, the participant is advised to use the device 1 to 2 times per week after demonstrating subjective improvement following the treatment protocol designed in our study and after a detailed assessment by a healthcare provider at follow-up visits. This will enhance the transition to a more independent, unassisted pelvic floor muscle- strengthening program.

Our cost-comparison study revealed that those who used APEX M™ had improvement in descriptive costs including daytime incontinence episodes, episodes of nocturia, and number of female incontinence pads ($p<0.05$). Compared to other means of management for female urinary incontinence, the results of this study may be useful in shared-decision making with your patients regarding a less-invasive treatment for female urinary incontinence.

STUDY LIMITATIONS

In regards with the patient population studied, it was a single institution experience involving a small cohort of participants who used APEX MTM and participated in the treatment protocol. There was also a significant proportion of participants who purchased the device online or over the counter and did not participate in the treatment protocol. There was incomplete data extraction that may contribute to selection bias as it relates to other baseline characteristics of the study population such as parity, body mass index (BMI), history of pelvic floor surgeries, history of hysterectomy, use of estrogen therapy, and severity of urinary incontinence. Also, patient subjective responses varied in regards with documentation in the medical chart despite using a standard template. Furthermore, objective measurements including weight of incontinence pads used would eliminate any subjective confounding variables and further identify the severity of urinary incontinence.

Future directions of this project would include measuring patient satisfaction in the form of scores or questionnaires.

CONCLUSION

With the high out of pocket and limited insurance coverage for UI interventions, an over-the counter pelvic stimulating device that treats stress incontinence, urge incontinence and mixed incontinence is of medico-economic interest for patients and the healthcare system. Based on our study, the one-time cost of APEX M™ pelvic floor therapy is a non-invasive treatment option for female urinary incontinence that reduces disease burden.

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