The Efficacy of BT/PFMT in Elderly Women with Urinary Incontinence Refraining from Surgery, a Prospective Study

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Abstract

Purpose: PFMT is 1st line treatment in women with stress incontinence particularly in the elderly. The aim of this study is to evaluate the value of a structured program of BT/PFMT in treatment of any incontinence among elderly women.

Methods: A quasi-experimental study conducted in a tertiary care urologic facility, included women above 60 with no neurological disorders who refrain from surgery. Those in the study group received 6 sessions: Two educational and 4 instructed PFMT and BT, including biofeedback. Women were evaluated at baseline, 2 and 4 months after the program ended. History, examination, voiding diary, pad test and Standard Arabic UDI-6 and IIQ-7 were collected.

Results: Improvement of incontinence based on pad weight and symptom scores were primary outcome measures. No statistically significant difference was observed between the study and control group regarding socio-demographics. Number of incontinence episodes among study group significantly decreased at 2 and 4 month (p = 0.001). Sixteen and 13 patients in study and control group had pad weight > 1 gm. At 2 months, numbers significantly decreased in the study but not in the control group at 2 and 4 months. UDI-6 and IIQ-7 showed significant improvement in the study group at 2 months that was maintained at 4 months.

Conclusions: A structured PFMT/BT program is helpful in elderly women with any type of incontinence at short term. Long term evaluation is underway.

Keywords: Elderly; Incontinence; PFMT

Abbreviations

BT: Bladder Training; PFMT: Pelvic Floor Muscle Training; SUI: Stress Urinary Incontinence; UI: Urinary Incontinence

Introduction

Coyne., *et al.* [1] reported a prevalence of UI of 67.6% in a cross-sectional internet –based survey on women over 40 years from 3 countries. Hannestad., *et al.* [2] reported a prevalence of 25% among women 20 – 90 years; half had SUI. Using UDI 6 and IIQ 7 others [3] found the prevalence of SUI in women 30 to 50 to be 37.5%. SUI is the predominant type in younger and middle aged while urge and mixed UI increases in older women [4].

ICS recommends pelvic floor muscle training to be first choice of treatment for stress and mixed urinary incontinence in women [5]. Based on the report presented by the 4th ICI, there is Level 1 evidence that pelvic floor muscle training programs effectively treat stress and mixed urinary incontinence [6].

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This study is a prospective one, looking into the value of structured BT/PFMT in treating UI in elderly women who are refraining from surgery.

Patients and Methods

The study comprised women referred to voiding dysfunction unit during a period of six months. They were aged \geq 60 years, having stress, urge or mixed UI for at least 1 year with free neuro-urological examination, unwilling to undergo surgery for their UI. They should be able to cooperate in the program able to provide an informed consent.

Data collected included socio-demographic and UI risk factors. The type and onset of UI, number of pads, stress test and 1-hour pad test were also recorded.

Evaluation

Women responded to a standard Arabic short forms of (UDI-6) and (IIQ-7). These questionnaires were developed by Uebersax., *et al* [7]. An Arabic version that was used earlier [8] continued to be used in this study. Standard 1-hour pad test [9] was used for quantification of UI. Pad weight gain of 1 gm or less was considered normal [10].

The training program consisted of 6 sessions: two educational and four training, spanning over 3 weeks. Each session was 30 to 45 minutes. Educational sessions entailed information on anatomy and physiology of lower urinary tract (First session) and personal hygiene and lifestyle modifications (Second session). Training sessions: included PFMT (1st and 2nd sessions). With the aid of an instructions sheet, patients were asked to identify their pubococcygeus muscles by tightening "vaginal muscles" while lying down. A trained nurse put 2 fingers in the vagina of the patient to assist her identifying the muscles. Women were asked to perform around 60 contractions per day for the treatment period. In the 3rd session, patients were trained to prolong the interval between urinations gradually. Intervals were increased by 15 to 30 minutes each week. Then, in the 4th session, biofeedback was added. Surface patch electrode applied to perineal skin so that patient would recognize her pelvic floor muscles.

Control group were given only diaries and were asked to attend the same follow up visits as did the study group.

Endpoints

Two and 4 months from the start of the program, evaluation of both study and control groups was carried out using the same tools used earlier.

Statistical analysis

This is a quasi-experimental prospective non-randomized study. Sample size was calculated assuming α level to be 0.2 and the β level 0.2. Symptom improvement rate was expected to be 44% (48% for control group and 78% for study group) based on reviewed literature [11. Postulating a 10% defaulter rate, sample size was estimated to be 50 patients; equally divided into two proportions (study and control) [12].

Data were analyzed using SPSS (Statistical Package for Social Sciences) version 15. (p) was significant when less than or equal to 0.05. Data are presented as arithmetic mean (X) \pm Standard deviation (SD). Chi square (X²) was used to test the association between qualitative variables. Wilcoxon singed rank test for comparison within group, Kolmogorov-Smirnov test for normality, Paired t-test for comparison within groups, Student t-test for comparison between two groups and One-Way Anova for comparison between more than two groups. Pearson's correlation coefficient was used to test correlation.

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Results

Fifty women were included; 25 in each group. No significant differences were observed between the study and control group as regards age, marital status, education and living arrangements. Table 1 shows socio- demographic characteristics of both groups. Diabetes mellitus was more common among the study group while hypertension and musculo-skeletal diseases were similarly affecting both groups. Figure 1 shows co-morbid conditions.

	Study group		Control group		P value
	N= (25)	%	N= (25)	%	
Age (in years)					
60 < 65	13	52.0	11	44.0	(0.840)
65 < 70	10	40.0	12	48.0	
70 +	2	8.0	2	8.0	
Marital status					
Married	14	56.0	16	64.0	(0.564)
Widowed	11	44.0	9	36.0	
Level of education					
Illiterate	17	68.0	17	68.0	
Read and write	2	8.0	5	20.0	(0.063)
Primary school	1	4.0	3	12.0	
Secondary school	5	20.0	0	0	
Occupation					
House wife	14	56.0	18	72.0	
Employee	3	12.0	1	4.0	(0.619)
Worker	4	16.0	3	12.0	
Trader	4	16.0	3	12.0	
Living arrangement					
With family	15	60.0	16	64.0	
With one of children	5	20.0	2	8.0	(0.115)
Alone	5	20.0	7	28.0	

 Table 1: Socio-demographic characteristics of the study and control groups.

*Significant, at $P \leq 0.05$, using Chi-Square (X²)



Gravidity and parity were similar in both groups. Median pregnancy was 6 and 7 in the study and control group respectively (p= 0.15). Likewise, median normal delivery was 5 in the two groups (p = 0.47).

Two thirds (68%) of the study and 72% of the control group had UI for 1-5 years, 24% of each group had UI for 5 -10 years while the remaining had incontinence for over 10 years. Over half of the study and control groups (56.0%, 52.0% respectively) had mixed incontinence, 32.0% of study group and 40.0% of control group had urge. The rest (12.0% of study, 8.0% of control) had SUI. Difference between the groups remained insignificant (p=0.795). Table 2 shows type and duration of UI.

	Study group		Control group		P value
	N = (25)	%	N = (25)	%	
Duration in years					
1 - 5	17	68.0	18	72.0	
5 - 10	6	24.0	6	24.0	(0.834)
≥ 10	2	8.0	1	4.0	
Timing of incontinence					
Diurnal	3	12.0	9	36.0	
Nocturnal	1	4.0	2	8.0	(0.094)
During day and night	21	84.0	14	56.0	
Types of incontinence					
Urge	8	32.0	10	40.0	
Stress	3	12.0	2	8.0	(0.795)
Mixed	14	56.0	13	52.0	

Table 2: Duration and type of urinary incontinence of the study and control groups.

*Significant, at $P \le 0.05$, using Chi-Square (X²)

Forty four percent of both groups were using pads, while 32.0% of study and 16.0% of control group decreased their fluid intake, 12% decreased caffeine intake. Nevertheless, difference between the two groups were insignificant (p = 0.158 and 0.074 respectively). The number of incontinence episodes among study group significantly decreased at 2 and 4 month follow- ups. (p = 0.001). Table 3 shows the Voiding diary in study and control groups before and after behavioral intervention program.

Voiding diary (Mean ± SD)	Study	Control	t Test (P) ^a
Pre program			
- Fluid intake (ml)	1892.00 ± 269.13	1794.00 ± 266.27	(0.202)
- Urine output (ml)	1826.00 ± 270.46	1716.00 ± 257.68	(0.147)
- Incontinence episodes	8.04 ± 2.35	7.64 ± 1.93	(0.515)
After 2 months			
- Fluid intake (ml)	1848.00 ± 210.40	1716.00 ± 223.01	(0.036)*
- Urine output (ml)	1812.00 ± 206.80	1672.00 ± 218.94	(0.024)*
- Incontinence episode s	5.68 ± 2.84	8.64 ± 1.82	(0.000)*
After 4 months			
- Fluid intake (ml)	1872.00 ± 207.20	1700.00 ± 223.61	
- Urine output (ml)	1828.00 ± 199.00	1668.00 ± 232.24	(0.007)*
- Incontinence episodes	5.08 ± 3.23	8.44 ± 1.96	(0.012)*
f Test (P) ¹	(0.001)*	(0.000)*	(0.000)*

Table 3: Voiding diary of the study and control groups before and after behavioral intervention program.

 p^{a} : using t test; p1: using Anova test; *Significant, at P \leq 0.05.

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At baseline, 9 and 12 patients in the study and control group had insignificant (≤ 1 gm) pad weight increase respectively whereas 16 and 13 in the study and control groups had pad weight increase > 1 gm. After 2 months, 14 and 15 had pad weight gain > 1 gm in the study and control group. At 4 months, the numbers of women with pad weight gain of > 1 gm decreased to 12 in the study group and remained at 15 in the control.

UDI-6 did not show any statistically significant differences between the groups at baseline (p = 0.062). However, difference between groups became statistically significant at 2-month and the improvement continued till 4 months (p= 0.005). This was the same regarding IIQ-7, where no significant differences between groups were noted at baseline. However, differences turned to be statistically significant at both 2 and 4 months (p=0.000). Table 4 reflects changes in UDI-6 and IIQ-7 scores.

Questionnaire	Study	Control	t Test (P) ^a
- UDI6 (Mean ± SD)			
- Pre program	56.44 ± 15.77	47.56 ± 17.05	(0.062)
- After 2 months	42.44 ± 19.76	54.67 ± 14.84	(0.017)*
- After 4 months	39.11 ± 21.78	56.89 ± 15.57	(0.002)*
f Test (P) ¹	(0.005)*	(0.101)	
- IIQ7 (Mean ± SD)			
- Pre program	75.81 ± 18.54	69.52 ± 18.80	(0.240)
- After 2 months	46.29 ± 23.02	71.43 ± 19.00	(0.000)*
- After 4 months	40.57 ± 27.63	75.05 ± 15.26	(0.000)*
f Test (P) ²	(0.000)*	(0.539)	

Table 4: UDI-6 and IIQ- 7 for the study and control groups before and after behavioral intervention program

P^a: Comparing the study and control group pre, 2 months, and 4 months after the program using t test.

(P)¹: comparing UDI6 pre, 2 months and 4 months post program in the study and control group using Anova test.

 $(P)^2$: comparing IIQ-7 pre, 2 months and 4 months post program in the study and control group using Anova test. *Significant, at P \leq 0.05

Discussion

Supervised PFMT attested grade A recommendation as a first line management of stress and mixed incontinence in guidelines [13] after many reports showed their efficacy [14-16]. BT enables women to accommodate greater volumes of urine and gradually extend the interval between voiding. The combination of both was found more effective than PFMT alone [17].

It seems that low educational level was associated with higher prevalence of incontinence in our patients. Less educated women are less knowledgeable of body anatomy and healthy life style and probably this makes them at higher risk for UI. Melville., *et al.* [18] reported that incontinent women had lower educational attainment and lower income. Likewise, Kumari., *et al.* [19] reported that women with UI had a high illiteracy rate of 60%.

Fifty two of the study and 44% of control group had > 5 deliveries. This is similar to other studies [20-22] confirming potential causal effect of vaginal delivery on UI. The present study shows that women from both groups have morbid obesity (BMI was 34.58 ± 8.61 and 33.77 ± 4.90). Others have proven that obesity is a major risk factor for all types of incontinence [23].

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Mixed incontinence is the major type in our cohort; affecting more than half. This is similar to the prevalence of UI reported by Diokno., *et al.* [24] in a cross-sectional study involving 1955 females, aged 60 years and above. They found that 61% had mixed, 29% had SUI, and 10% had urge incontinence. However, other studies maintained that stress incontinence was the most prevalent, accounting for approximately 33% of all cases of UI in one study [25] and between 20 and 36% in a recent meta- analysis [26].

Items of voiding diary did not show statistically significant difference between groups at baseline but differences became statistically significant at 2 and 4 months after the program. Number of incontinence episodes of study group significantly decreased at 2 and 4 months (p = 0.001). At baseline, pad weight increase was similar in both groups but at 2 months, 2 (12.5%) women of the study group had pad weight < 1 gm. Two more patients turned to have < 1 gm increase at 4 months. To the contrary, the control group showed worsening of their pad test results. Both UDI- 6 and IIQ-7 were similar at baseline. However, differences turned statistically significant at 2 and 4 months (Table 4). Wyman., *et al.* [27] conducted a 12-week randomized trial of intervention program for incontinent women, adopting BT, PFMT with biofeedback and a combination of both as 3 treatment arms. A combination of BT and biofeedback PFMT resulted in the greatest immediate efficacy. Nevertheless, this efficacy was not maintained at 3 months, where the three interventions resulted in similar effect. However, Subak., *et al.* [28] in a randomized trial on women over 55 years reported a 40% decrease in mean weekly incontinent episodes which was maintained over 6 months. Burgio., *et al.* [29] reported high cure rates and reduction of incontinence episodes in patients who received BT in conjunction with biofeedback, compared to those receiving verbal feedback or just instructions manual. Mean reduction in frequency of episodes was 63.1%, 69.4% and 58.6% respectively.

Conclusion

Elderly women in our locality have predominantly mixed incontinence. The combination of BT with instructed PFMT had positive effect on any incontinence. The effect is maintained at 4 months and it involved quality of life, voiding diary variables and pad test. More extended follow up of those women is underway, to confirm durability of results.

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