The efficacy of BT/ PFMT in elderly women with any urinary incontinence refraining from surgery, prospective study

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ABSTRACT

Hypothesis / aims of study: ICS recommends pelvic floor muscle training to be first choice of treatment for stress and mixed urinary incontinence in women [1]. 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[2].
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
Study design, materials and methods: The study comprised women referred to voiding dysfunction unit during a period of six months. They were aged ≥ 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
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: 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. 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.
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). Interpretation of results: 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). 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 > 1gm 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). Concluding message: 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.

METHODS

The training program consisted of 6 sessions: **two educational** and **four training**, 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 instructions sheet, patients were asked to identify their muscles by tightening "vaginal muscles" while lying down. 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. 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:

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[1]. Postulating a 10% defaulter rate, sample size was estimated to be 50 patients; equally divided into two proportions (study and control) [2]. Data were analyzed using SPSS version 15. X^2 was used to test 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.

RESULTS

	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					(0.115)
With family	15	60.0	16	64.0	
With one of children	5	20.0	2	8.0	
Alone	5	20.0	7	28.0	

Diary (Mean± SD)	Study	Control	t Test
Pre program			
Fluid intake (ml)	1892±269.13	1794±266.3	(0.202)
Urine output (ml)	1826±270.46	1716±257.7	(0.147)
Incont. episodes	8.04±2.35	7.64 ± 1.93	(0.515)
After 2 months			
Fluid intake (ml)	1848±210.40	1716±223	(0.036)*
Urine output (ml)	1812±206.80	1672±218.5	(0.024)*
Incont. episodes	5.68 ± 2.84	8.64 ± 1.82	(0.000)*
After 4 months			
Fluid intake (ml)	1872±207.20	1700±223.2	(0.007)*
Urine output (ml)	1828± 199.00	1668±232.2	(0.012)*
Incont. episodes	5.08 ± 3.23	8.44 ± 1.96	(0.000)*
f Test (P)[1]	(0.001)*	(0.000)*	

Questionnaire	Study	Control	t Test (P)[a]
- UDI6 (Mean±SD)			
Pre program	56.44±15.8	47.56±17.1	(0.062)
After 2 months	42.44±19.7	54.67±14.5	(0.017)*
After 4 months	39.11±21.8	56.89±15.6	(0.002)*
f Test (P)[1]	(0.005)*	(0.101)	
- IIQ7 (Mean±SD)			
Pre program	75.81±18.5	69.52±18.8	(0.240)
After 2 months	46.29±23.1	71.43±19.0	(0.000)*
After 4 months	40.57±27.6	75.05±15.3	(0.000)*
f Test (P)[2]	(0.000)*	(0.539)	

CONCLUSIONS

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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