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Original Research Article

Effect of Pelvic Floor Muscle Training Based on Severity of Incontinence on Incontinence Episodes in Women with Stress Urinary Incontinence

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ABSTRACT

Background: Urinary Incontinence is widely prevalent in females but poorly diagnosed. Several studies all around the world have already proven the effect of physiotherapy management in females with stress urinary incontinence. In India, since last 10 years the awareness and education regarding physiotherapy in SUI has increased. Still limited evidences in India, and acceptance of this problem by majority of females lead to low level of evidence based practice. The cultural, economic and religious scenario of Indian women is very different than that of western or other developed countries. So there is immense need to work on these areas, define a protocol of exercise for them and to see the efficacy of this protocol on incontinence episodes in women with SUI.
Aim: To evaluate the effect of Pelvic Floor Muscle Training (PFMT) based on severity of incontinence on incontinence episodes in women with Stress Urinary Incontinence.
Materials and Methods: Total 65 subjects were recruited according to inclusion criteria for an experimental study which was set up at SBB College of Physiotherapy, V.S.General Hospital Campus and Shruti nursing home, Naranpura, Ahmedabad. Each subject received 6 weeks of home based PFMT based on severity of incontinence which was decided by Incontinence Severity Index. Pre and post data were taken and further analysis was done using SPSS 21.0. The outcome measure used was voiding diary (Number of incontinence episodes per week and frequency of micturition per day).
Results and Discussion: Level of significance was set at 5%. Wilcoxon test was used to compare the pre and post data for all the subjects. The hypothesis is proven with Z = -5.566 and Z = -6.167 for frequency and number of leakages respectively. $p < 0.001$ shows highly significant difference between two groups.
Conclusions: Six weeks home based PFMT based on severity of incontinence is effective in reducing no. of leakages per week and frequency of micturition per day in female with SUI.

Key words: Pelvic Floor Muscle Training, No. of leakages, Frequency of micturition, voiding diary, Stress Urinary Incontinence.

INTRODUCTION

Stress Urinary Incontinence (SUI) is the non-volitional leakage of urine on effort or exertion, sneezing, coughing, or laughing. [1] These activities increase the intra-abdominal pressure. This overcomes the sphincter closure mechanism when a bladder contraction is not present. Weak pelvic floor muscles (PFM) are frequently the cause behind the leakage of urine in such condition.

According to most of the studies, the prevalence of urinary incontinence in women varies between 10 to 40%. [2] Approximately 50 million people worldwide suffer from UI wherein a woman to man ratio is 2:1. [3] In a survey done in Asia, prevalence of UI in India was 12%. [4] A

study done in Tamil Nadu in 2009 has estimated that amongst 197 women surveyed about 41(20.8%) were found to have UI. [5] Out of these 41 women more than 50% had SUI.

Pelvic Floor Muscle Training (PFMT) should be the first line treatment for stress incontinence, as it has no serious adverse effects. However, the training needs proper instruction and close follow-up to be effective. [6]

Several studies all around the world have already proven the effect of physiotherapy management in females with SUI. In India, since last 10 years the awareness and education regarding physiotherapy in SUI has increased. Still limited evidences in India, and acceptance of this problem by majority of females lead to low level of evidence based practice. The cultural, economic and religious scenario of Indian women is very different than that of western or other developed countries. So there is immense need to work on these areas, define a protocol of exercise for them and to see the efficacy of this protocol on females with SUI. So, the objective of the study was to see the effect of PFMT based on severity of incontinence on incontinence episodes in women with SUI.

It has been hypothesised that the PFMT given in this study is effective in reducing the no of leakages per week and frequency of micturition per day in female with SUI.

METHODOLOGY

It was an experimental clinical trial where source of data was department of Obstetrics and Gynaecology, Sheth Chinai maternity home, V.S.General Hospital and menopause health club of Ahmedabad. Apart from this, several awareness programs were conducted by the principal investigator to get maximum subjects from different parts of Ahmedabad. Many private gynaecologists also referred patients with SUI. The data was primary which was collected by the principal investigator. This study was conducted from January 2013 to Dec 2015.The intervention period was of 6 weeks. Subjects were asked to perform the exercises at home for one to three times in a day depending on severity of incontinence which was decided by Incontinence Severity Index. [7,8]

The females with confirm case of stress urinary incontinence (confirmation of diagnosis was made by cough stress test either by gynaecologist or principal investigator) and having slight, moderate and severe incontinence as per Incontinence Severity Impact scale [7,8] were included. Female with prolapsed perineal organs, neurogenic bladder, pregnancy, Acute Urinary Tract Infection and Incontinence Severity Index score 0 (No incontinence) or 12 (very severe incontinence) were excluded.

MINI tab software was used to decide the sample size. Difference of means of pre and post no. of leakages (17 - 6 = 11) taken from pilot study and keeping 80% power of study sample size was calculated and found to be 33. Sample size recorded in the study is 73 by purposive sampling.

Procedure

Ethical clearance from the local ethics committee of S.B.B. College of physiotherapy was taken in Dec, 2012 (PTC/IEC/59/2012–13) under a broad titled study "Efficacy of Physiotherapy Management in women with SUI".

The study has passed through Institutional Review Board of RK University, Rajkot and has been approved.

The study is part of a broad study "Efficacy of Physiotherapy Management in women with SUI" which has been registered under CTRI. The registration no. of the trial is CTRI/2016/12/007614.

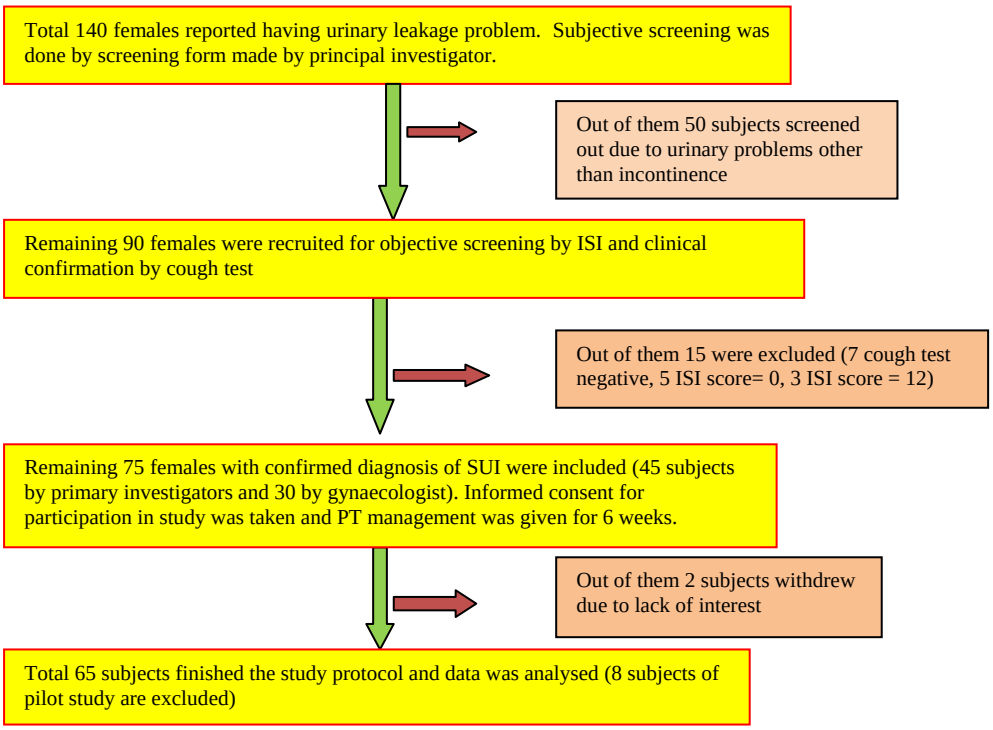

Fig 1: Flow chart of procedure

The ISI is an ordinal scale having two questions regarding the frequency of leakage and quantity of leakage. The scale was translated in Gujarati by principal investigator. According to the answers by patients, the score is calculated by multiplying two scores of two questions. The score ranges from 0 to 12, 0 meaning no incontinence and 12 meaning very severe incontinence. 1 – 2 score means slight, 3 – 4 means moderate and 6 – 8 means severe incontinence. Sandvik et al in 1993 have validated the scale to measure severity of incontinence in women with urinary incontinence. [7,8] Subjects with score 0 and score 12 on ISI were excluded.

The screened subjects were then made to perform cough test. Cough test was done with full bladder. Subjects were asked to cough in crook lying position and urine leakage was observed. Leakage of urine while coughing indicates positive cough test. The cough test has shown good sensitivity and specificity in the diagnosis of SUI. [9-11] The clinically confirmed cases of SUI (positive cough test) were then explained and asked to sign the consent form and then included in the study and were given 6 weeks home based physiotherapy management which included pelvic floor muscle training and life style modification.

The treatment was given at different places according to the convenience of subjects. These places include S.B.B. college of Physiotherapy and other private set ups of gynaecologists.

Before starting the main study a pilot study was done on 8 subjects. These subjects were asked to keep records of frequency of micturition and no. of leakages on a self-made voiding diary. It was observed that self-made diaries were very different for all subjects and so to maintain uniformity and objectivity, voiding diaries were provided to all subjects after the pilot study. These 8 pilot study subjects were not included in the study.

Subjects were given 7 days voiding diary prepared in Gujarati language and were asked to record their no. of leakages and frequency of micturition at first and last week of treatment.

The physiotherapy management based on severity of incontinence was given in the

form of pelvic floor muscle training and lifestyle modification as follows:

- Life style modification:
  - Educating women with severe (ISI = 6–8) incontinence to wear diapers.
  - Avoiding caffeine, and excessive fluid intake.
  - Weight control exercises like walking or jogging.
  - Asking them to go to void for every 2 hours.
  - Ergonomic advices of lifting heavy weight (>5 kg) so that intra abdominal pressure does not increase much and thus avoiding instances of incontinence.
  - Performing Pelvic Floor Muscle Training (PFMT) whenever they find time e.g. waiting at traffic signal.
- Pelvic floor muscle training protocol
  - 5 repetitions of general stretching and warm up for pelvic floor muscles and hip adductors (butterfly posture).
  - 10 repetition of voluntary pelvic floor muscle contraction with 5 second hold and 10 second rest, progress at 2 weeks to 10 second hold and 20 second rest.
  - 10 repetitions of isometrics of hip adductors and irradiation to pelvic floor muscle with 5 sec hold and 10 sec rest, progress to 10 sec hold and 20 sec rest.
  - 5 repetitions of transverse abdominis muscle contraction and pelvic floor muscle contraction simultaneously, 5 sec hold and 10 sec rest.
  - Cool down with slow stretching of adductors and perineal muscles.

This treatment was properly explained and given under supervision on the very first day. The subjects were asked to carry out the treatment at home. The subjects who were slight incontinent (ISI = 1 – 2) were asked to perform one session a day, moderate incontinent (ISI 3 – 4) two sessions a day and severe incontinent (ISI 6 – 8) three sessions a day. Pre-treatment readings were taken at first day whereas post treatment readings were taken after 6 weeks. Though the subjects were asked to carry out regular exercises every day for 6 weeks, exercises for 5 to 6 days a week were considered.

The pelvic floor muscle contractions were first taught in crook lying position. On the very first day, the physiotherapist exposed the part and checked for proper contraction. The patients were explained well how to contract the pelvic floor muscles. Once mastered, subject was asked to practice this in sitting position.

Figure 2: Pelvic floor muscle contraction

Figure 3: Transverse abdominis contraction and pelvic floor muscle contraction simultaneously

The pelvic floor muscle contraction along with transverse abdominis contraction was performed first in lying and then in sitting. It is believed that there is co-contraction of transverses abdominis muscle during PFM contraction. [12] So, transverses

abdominis muscle contraction with PFM contraction is now incorporated into treatment protocols. [13] For this reason, transverses abdominis contraction exercise was added with PFM exercise.

Figure 4: Hip adductor isometric and pelvic floor muscle contraction

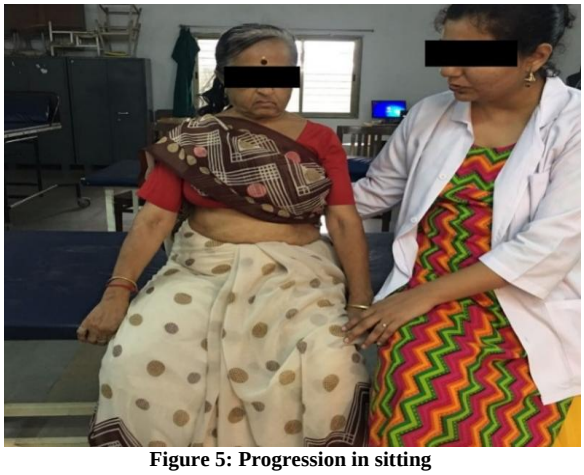

Figure 5: Progression in sitting

The isometric exercises for hip adductor muscles were given in crook lying. Subjects were asked to press pillow between the two knees. It is believed that isometric hip adductors irradiate the contraction to pelvic floor muscles and pelvic floor muscles also contract along with it due to their biomechanical relationship. Though very less evidences are available for this, Hulme and colleagues have introduced Kegel plus hip muscle exercises including obturator muscle resisted exercise in Beyond Kegels protocol for incontinence and have proven them to be effective. [14-16]

The pelvic floor muscles contraction is performed by contracting and relaxing the muscles of the pelvic floor. A correct contraction consists of a squeeze around the pelvic opening followed by an inward cranial lift. Many patients cannot perform PFM contraction easily at first time. Evidences also report difficulty in pelvic floor muscle contraction at 1st consultation. [17,18] For such patients, vaginal palpation method was used by per vaginal finger insertion and was taught proper contractions. They were also asked to palpate their perineum while performing the exercises. The following outcome measures were taken:

1. Frequency of micturition per day
2. No. of leakages per week

RESULTS

Statistical analysis was done using SPSS 21.0 version. The parameters used in the study are ordinal data and so, non-parametric tests were used to analyse these data. Wilcoxon test was applied to see the pre-post difference.

Table 1: Demographic details of the subjects

Parameter	Mean / Median	SD
Age	46.92 (years)	1.17
BMI	26.76 kg/m^2	5.25
Number of deliveries	2 (median)	
ISI score	3 (median)	

Table 2: Difference within the group

Outcome measures	No. of subjects	Pre treatment (Mean/ Median)	Post treatment (Mean/ Median)	Z value	p value
Frequency of micturition	65	10	8	-5.566	<0.001
No. of leakages	65	3	1	-6.167	<0.001

Table 3: Comparison between different severity groups for pre treatment-post treatment difference

Outcome measure	Group	no. of subjects	Mean/ Median	SD	p value	Significance
Frequency of micturition	1	35	1	1.5	0.143	No
	2	34	2	1.8		
	3	4	3.5	2.1		
No. of leakages	1	35	1	4.4	0.003	Yes
	2	34	3	6.3		
	3	4	8.5	4.3		

(Group 1 – Slight, Group 2 – Moderate and Group 3 – Severe)

Table 4 : Comparison between different age groups for pre-post treatment difference.

Outcome measure	Group	no. of subjects	Mean	SD	p value	Significance
Frequency of micturition	1	14	1.5	1.6	0.813	No
	2	48	2	1.7		
	3	11	1	2.0		
No. of leakages	1	14	3	3.3	0.749	No
	2	48	2	6.3		
	3	11	4	3.9		

(Group 1: 20–39 years, Group 2: 40–59 years, Group 3: 60–70 year)

Table 5: Comparison between different BMI groups for pre-post treatment difference.

Outcome measure	Group	no. of subjects	Mean	SD	p value	Significance
Frequency of micturition	1	4	1.5	0.9	0.687	No
	2	10	0.5	1.3		
	3	59	2	1.8		
No. of leakages	1	4	1.5	2.4	0.259	No
	2	10	2	1.4		
	3	59	3	6.0		

(Group 1 – Underweight, Group 2 – Normal, Group 3 – Overweight)

Table 6: Comparison between different parity groups for pre-post treatment difference.

Outcome measure	Group	no. of subjects	Mean	SD	p value	Significance
Frequency of micturition	1	60	1	1.8	0.281	No
	2	13	2	1.4		
No. of leakages	1	60	2	5.8	0.816	No
	2	13	3	4.3		

(Group 1: 0–2 deliveries, Group 2: >2 deliveries)

DISCUSSION

The present study aimed to prove the effectiveness of Pelvic Floor Muscle Training based on severity of incontinence on incontinence episodes in females with SUI. Total 65 females with SUI were included in the study. These 65 females were clinically confirmed cases of SUI. Urodynamic testing was not done due to financial reasons. The subjects were given 6 weeks home based pelvic floor exercises as taught along with tips of lifestyle modifications as mentioned in methodology.

The median frequency of micturition per day was 10 pre treatment and was 8 post treatment. This showed 20% improvement in frequency of micturition post treatment. The median no. of leakages per week was 3 pre-treatment, which was reduced to 1 episode per week after 6 weeks of physiotherapy. This shows 67% improvement in no. of leakages per week. This shows that leakage episodes decrease with physiotherapy management of 6 weeks.

The incontinent patients had more complaints of leakage episodes than frequency. Increase in frequency does not bother them much but leakage caused several issues like wet clothes, restriction for social activities, interference in day to day life and participation restriction in society. Many women in developed countries manage to attend social gatherings wearing diapers or sanitary pads. This is not common in Indian cultural set up and so, advice to wear diaper or sanitary pad while going out was given as a part of life style modification in this study so the quality of life does not compromise.

The frequency and leakage episodes were noted in voiding diary provided by the investigator to the subjects. The subjects were properly explained how to fill in the diary. Many subjects reported no leakage in a day and one or two episodes in a week and so 7 days voiding diary was chosen. The 1 week voiding diary has high test-retest reliability for micturition frequency and incontinence episodes (r = 0.91). [19] Four subjects were found to have 0 leakages per week on voiding diary but the complaint was there. It is highly possible that these subjects might not have leaked in the week when they recorded but may have leaked in some other weeks or they might have forgotten to tick in voiding diary. Other possibility of no leak may be due to the instructions to go for void every 2 hourly (timed voiding) which may have reduced their leakage episodes.

33 out of 65 subjects had zero leakages in voiding diary after 6 weeks and so we considered them as 100% cured of incontinence. 51% such subjects have been cured of incontinence episodes after 6 weeks of physiotherapy management. We can say that 51% subjects became continent. The hypothesis is proven with Z = -5.566 and Z = -6.167 for frequency and number of leakages respectively. p <0.001 shows highly significant difference between two groups.

There was an improvement in the frequency of micturition after the physiotherapy intervention which is in accordance to the findings of Pages et al [20] and Kafri et al. Pages et al concluded that 4 weeks of group Physical Therapy in the form of pelvic floor exercises resulted in reduced daytime and nocturnal urinary frequency. Kafri [21] et al too reported the same after comparing the residual effects of a 3 month rehabilitation program and a standardized drug regime for Urge Urinary Incontinence 21 months after the intervention. In the long rehabilitation, patients maintained and also improved what achievements they had made in the intervention period while the patients on drug therapy deteriorated to initial pre-intervention values in urinary frequency. The improvement in the frequency of micturition can be attributed to the increase in strength of the PFM. Also, the lifestyle modifications that were taught like avoiding excessive caffeine and fluid intake may cause the improvement.

However, this is contradictory to the findings of Yoon HS [22] et al who concluded bladder training to be more effective than pelvic muscle exercises in reducing urinary frequency and in increasing voided volume. However, the pelvic muscles exercise group showed greater improvement in increasing the peak and average pressures of pelvic muscle contraction.

A Cochrane review done in 2010 by Dumoulin C [23] concluded that PFMT is more beneficial compared to no treatment, placebo drug, or inactive control treatments for females with SUI, MUI or UUI. Females given PFMT were more probable at reporting resolution or improvement, better QOL, lesser leakage episodes in a day and have less urine leakage on short pad tests than controls. The trials recommended that efficacy of the treatment (especially self-reported resolution/improvement) may be higher in females with SUI who have participated in a supervised PFMT program for a minimum of three months.

The PFMs are helpful in maintaining continence. Activities like coughing, sneezing or laughing affect the continence system, and cause the intra-abdominal pressure to rise. This pressure is then transferred to the urethra to increase closure. But this happens only when the urethra maintains its position between the pubic symphysis (PS) and the pelvic floor. Measurements of urethral trajectory and acceleration during functional tasks such as coughing have concluded that women with SUI demonstrate a larger excursion of the urethra and/or anorectal angle (ARA) during coughing manoeuvres than their continent counterparts. So, it may be stated that the urethra is not held at its normal position posterior to the pubic symphysis to safeguard its compression against the pelvic floor during times of an increased intra-abdominal pressure, which also suggests that females with SUI do not have effective endopelvic fascia (pubourethral ligaments) and/or have PFMs that are not fast enough or incapable to offer urethral support so as to press it close.

A study by McLean L et al [24] in 2013 demonstrated that PFMT under supervision decreases mobility of the urethra during coughing and leads to an increase in the urethral cross-sectional area, but does not decrease the capacity of the bladder neck to extend during maximal effort valsalva manoeuvres. This shows that PFMT effectively reduces urethral excursion and enhances urethral sphincter cross-sectional area in women with SUI.

This probably contributes to a decline in the number of leakage episodes.

CONCLUSION

Six weeks home based PFMT based on severity of incontinence is effective in reducing no. of leakages per week and frequency of micturition per day in female with SUI.

Future scopes for research:

- Subjects should be given adherence diaries and treatment adherence should be added as one of the parameter.

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