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Vaginal Weight Cone For Stress Urinary Incontinence (SUI): What's The Impact On Women's Health?

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ABSTRACT: Background: Stress Urinary Incontinence(SUI) largely affect the physical,psychologicaland social welfare of the patients especially the women. The pelvic floor muscles strength training by natural boost treatment such as Pelvic Floor Muscle Training (PFMT)is a measure to those women subjected to SUI.
Aim: Assist the women in training pelvic floor muscles and by utilising weighted vaginal cones. A weighed device was developed to increase the pelvic floor muscle strength amongst those women's who get affected due to stress urinary incontinence.
Design and setting: Randomized control trial was the performed research design. Assigning stress urinary incontinence subjected patients was done by a method termed of block randomization (BR) and the size of sample utilized in every group was observed as250and 125.The was conducted at selected hospital in Chennai.
Results: The pad weight reduction was the major findings observed in this study with the mean score from 5.86 to 3.62 during the stages pretest and posttest, respectively having a Standard Deviation (SD) of 2.24. Comparatively, the pad weight mean score of the control group has decreased from 5.90 to 4.97 in the juncture of pre-test and post-test II respectively with the SD is 0.93and the same is viewed as exceedingly substantial at the level of p<0.01.
Conclusion: Women subjected to SUI are bestowed with a superior life qualityand less complications by undergoing PFMT using vaginalcone.

Keywords: Urinary Incontinence, SUI, PFMT,vaginal cone, Pad weight.

1. INTRODUCTION

Stress Urinary Incontinence (SUI) largely affect the physical, psychological and social welfare of the patients especially the women. There are 200 million women affected by SUI

and it has been observed that the occurrence of SUI is identified from nearly 50% of the patients diagnosed with urinary incontinence and the same corresponds to women's population of around 4% to 35%. The universal number of SUI gets escalated and it is estimated to catapult by 10.4% and 20.8% to 152 million and 167 million respectively from the current value. The overall incidence is projected to surge from 3.2% in 2008 to 3.3% during 2018. In relation to the women subjected to urgency UI, the statistics portrays a growth of 11.1% and 25% by the year 2013 and 2018 which equates to 55 million and 65 million respectively from the number of 49 million prevailing during the year 2008. This depicts that the frequency will be enhanced to 1.21% from 1.15% (De Lancey et.al 2013, 2018).

Spontaneous urine leakage commonly occursduring the period of physical activity which leads to abdominal pressure rise while cough, sneezing, giggling, exertion, exercise, or an exerted effort is known as SUI. The women's age group of between 45 and 49 years seem to have profound type of urinary incontinence and are diagnosed to have SUI of the young women category(Herbison2013).However, an essential association with increasing age ($P < 0.01$) is exhibited due to the incidence of UI. Studies shows that Stress Incontinence (SI) is developed with 57% women, urinary urge was at 23% of the women and other combination symptoms of UI to the tune of 20%. As examined by Sharma (2010) Asian Society of Female Urology, 12% of UI occurrence rate is observed (Kumari and Jain, 2008) and around 30 to 40 percentages of the women are suffering due to UI as depicted in the latest report. This related to solemn psychological and socioeconomic issues which very much affect the women's health.

The economic and social burden of the women are grossly affected with improper identification of risk factors pertaining to UI, this mitigates them to avoid their normal social living (Danforth 2006). The association between UI and age is viewed as vague and unclear and it is observed that the incidence of UI surges in relation to the progression in age. Decrease in contractility, advancing muscle tone loss, recurring injuries that occurs at the time of labor and hormonal stimulation changes are few of the symptoms that are evident in the case of UI.

Recounted occurrence of UI are in progression with age and the renowned risk factor related to UI is witnessed as motherhood, pelvic floor dysfunction may cause during the delivery and labor process owing to muscular and nerve damage, and direct tissue disruption and stretching(Luber 2004). It has to be noted that a minimum of two children are delivered in the obstetrical career by sixty-four percent of the women having UI. It was observed that due to UI, a higher percentage ofwomen are opting for caesarean delivery amongst all the other delivery methods (Danforth 2006).

2. THE NEED: STRESS URINARY INCONTINENCE (SUI)

Owing to the nominal costs and adverse consequences, the severity of the riskbeing very low, the most preferred treatment among all the other typesare the techniqueswhich have beenused for strengthening themuscles of pelvic floor. The initialdefence in conservative management of women that are subjected to SI, Pelvic floor muscle exercises should be the prime techniqueincorporated in it. Originally during the year 1985 Plevnik suggestedpreliminarily that for the purpose of strengthening the pelvic floor muscles, Vagical Cones (VC) was

utilized. Thewomen's life standards and welfareareaffected because of SUI and appears to enhance the outcome by non-surgical treatment, even though it may not be the decisive option available amongst women. It was observed that the life expectancy of the people could be improved by deploying advanced technology in the field of health care.Though SUI can be treated by various choices of treatment made available and the same can be managed by adopting either conservative methods comprising of the usage of vaginal cones (VC), pelvic floor exercises and also by means of undergoing surgery are altering the lifestyle practices(Malallah, Al-Shaiji 2015).

In the Western countries, draining the muscles of pelvic floor and developingVC is performed for the last 50 years. However, the significance of utilizing VC to lessen SUI is oblivious amongst the women in India are not popular. In respect to the treatment rendered to SUI, a key role is made on the specific pelvic floor muscles identification.The acceptance and utilization of VCneed to be improved amongst the women. Since this process involves an introduction of a foreign particle into the vagina, certain amount of reluctance is shown by the women.

In plight of the socio-economic burden faced by the women in India, the investigatorshad made a remarkable effort in the preparation of the VCin a most reasonable and economic rate. The investigator hasdeveloped the VCs for the women in a manner which can be used easily, harmless and quite simple during itspractice.Thus, the ultimate aim of the study was to identify the efficiency of pelvic floor training in conjunction with the usage of vaginal cone on pad weight during the treatment for women's who get affected by SUI.

3. MATERIALS AND METHODS

Research design: Randomized Control Trailwas the research design embraced for this studyand tools such as randomization,manipulation, and control were utilized.
Setting- Sri Ramachandra Hospital, Porur, Chennai, Tamilnadu is the venue in which the study was undertaken.
Sampling technique - Block Randomization
Sample size -Total samples included – 250 Nos, Study group – 125 Nos, Control group – 125 Nos.
Inclusion criteria: Women with stress urinary incontinence:

- Willingness to participate
- Understand Tamil or/and English
- Post voidal urine volume less than 50 ml
- Porous women aged 25- 65 years

Exclusion criteria: Women with:

- Fibroid uterus
- Pregnancy
- Neurological disease
- Cancer bladder
- 2^{nd}, 3rd, 4^{th} degree uterine prolapsed
- Previous participation in PFMT program
- Underwent surgery for SUI

4. TOOLS USED FOR THE STUDY

1. Demographic variables
2. Clinical variables
3. Pad weight

1.Demographic variables - Age, marital status, residence, education, occupation, family type income per month, social supportand duration of the problem is incorporated using this tool. Other variables such as mode of delivery, age at first delivery, place of delivery, no of abortions, birth weight of the baby, Para is also utilized.

2. Clinical variablesencompassesCo morbid conditions such as hypertension, Diabetes, chronic cough (6 months),constipation (6 months), body Mass Index & attained menopause

3. The Gynaecology outpatient department is utilized for performing the test and Incontinence Society Guidelines 1983 is utilized for assessing the Pad weight.

5. PILOT STUDY

The Gynaecology outpatient department located at "G" block of Sri Ramachandra Hospital, Chennaiis utilized for performing the pilot study. There is no alteration made in the tools deployed as they are viable for the study, keeping in view of the pilot study results.

Ethical clearance -The Ethical committee of the author's institution has granted the Official Permission (IEC-NL/08/Aug/05/30).

6. SCORING AND INTERPRETATION

Mild incontinence - 1gm/1 hour leak of urine
Moderate incontinence -1gm < span> 1hr <10 gm leakage
Severe incontinence - 10 gm > 1 hr < 50 gm
By conducting the test and retest method, the assessment of the tool was done and itsreliability of r =0.78 was found.

7. DATA COLLECTION PROCEDURE

The investigation set forthindividual teaching to the population present for the study by making use of the booklet/pamphlet made available on SUI and briefing themduring the initial 20 minutes related tothe treatment,types, investigations, symptoms, causes, medications, pelvic floor exercises, surgery and apath for leading a wet free healthy life. In addition to the above, any queries or clarifications arising out of the aforesaid topic need to be raised by the participants and they are motivated accordingly. Hence, the participantsarebriefed in entirety of the procedure independentlywith regards to the types in which the exercisesneed to be carried out.

The procedure carried out during the study is listed out methodically as follows:

1. In prior to the training, the participants are advised to empty their bladder.
2. The privacy of the participants is assured, as theyarekept at a separate roomand the knees of the women are flexed since they are subjected to a dorsal position.
3. By utilizing an antiseptic soap in runningwater, VCs (20 gm.) of the participants are cleansed.

4. Sterile gauze piece is used for cleansing the cone and 2% Xylocaine jelly is made use of forthe lubricating the cone.
5. Subsequently, the vagina is injected by the insertion of cone for a depth of around 3cm with the string lingeringexternally.
6. Guidelinesare given to the woman and are insisted to take deep breathes and easeout.
7. It gets directed for introducing the pelvic floor upward and holds the cone. Similarly, the sphincters gets stiffened and the inside passage has becomes slender and stressed which is squeeze by the virtue of holding the cone.
8. Later, the participantsare forbidden to contract their gluteal and abdominal muscles.
9. Directionsare given to the participants to relax by contracting their perineal muscles and to hold the cone for 10 seconds.
10. Considering 10 contractions for each session, the aforesaid procedureis instructed to be carried out for 5 sessions;nearly 30 minutes is consumed during theentirety of the procedure.
11. For a period of 3 minutes, the participants are asked to walk with the vagical cone held at the similar position. The cone is discardedat the end and subsequentlytoaid training of pelvic floor muscle, a distinct cone is used on every occasion.
12. In addition to the above, instructions were given to participants for practising pelvic floor exercises to be carried out at their respective houses without the use of vaginal cone.

Above mentioned procedure is continued during the 2^{nd} visit (2^{nd} day) as well akin to the one mentioned above and PFMT is provided consuming 40gms during the 3^{rd} visit (2^{nd} week). Furthermore 40gms and 60gms were consumedin the course of4th visit (4^{th} week) and 5^{th} visit (12^{th} week's first day) respectively.
VC-Poly Methyl Metacrylate is the material utilized for makingVCs.In order to trainpelvic floor muscles, the size of the vaginal cones used diverges from 20gm to 60gm.

In this study, without emptying the bladder, the evaluation of the pad weight is carried out during the commencement of 1st hour. Instructionsare given to the participants for drinkingwater of quantity 0.5 litre and are made to sit in a separate room situated at the outpatient department. On the woman's perineum, the pre weighed cotton pad is applied.

Afterthe completion of 30 minutes, the below mentionedexercisesare enforced on them and listed as follows:

1. **Repetition for 5 times**
   - standinguprightfrom a sitting position
   - cleansing the hands in running water
   - running at the similar position
   - climbing stairs

2. **Repetition for 10 times**
   - 10 times vigorous coughing

The pad is detached and the variation in weight has been observed using the electronic weighing machine after the completion of one hour. From the total weight of the pre pad, the variation found between the pad weights isdeducted and urine leak is considerefor those cases

of the surge in weight is more than 1 gm. Else, the rest of the cases is not taken into the consideration, sweat and vaginal secretions might be the probable cause of it.

Table: 1 Frequency, percentage and chi square distribution of obstetric variables amid women having stress urinary incontinence in control and study group. (N=250)

In reference to the women that fit to the age group of 55 – 65 years, 15 women (12%) and 21 women (16.8%) are found in the category of control group and study groupcorrespondingly. Notably, the majority were found to be falling under the age group of 36 – 45 years, i.e. 60 women (48%) and 65 women (52%) in the control group &study group.A swift decline of strength &muscle tone is attributed to the surge of age factor; however there is a high possibility of occurrence of SUI due to the decline in the oestrogen level.

Taking into consideration of the extent of the problem, most of the women were affected by SUI, 49 (39%) are in control group&60 (48%) pertaining to study groupare experiencing the problem for a duration of 6 – 8 years. Nevertheless, physiotherapists or doctors needed for the treatment of SUI are not approached by both the groups. First delivery at the age of 19 - 30 years is experienced by 97 women (78%) and 100 (80%) women in the control group & study group respectively. Thus, the women in the study group and control group corresponds to 13 (10%) and 15 (12%) has first delivery withinthe age of 18 years, muscle weakness exists which could potentially result in SUI due to the deliveries experienced at early age.

Table: 2Paired t and p value, SD and meanbased on pad weight ofSUIaffected women in study group (n=125).

Table 2– A comparison of pad weight pertaining to women subjected to SUI in the study groupareperformed. It is observed that the pre-test and post-test I mean score with a standard deviation of 2.21 was found to be 5.86 and 3.62 respectively; this was substantialat $p<0.01$. It portrays that for study group concerningpost-testI&pre-test, the pad weight had declined substantially. The pelvic floor rehabilitation in conjunction with vaginal cone was instrumental in decreasing the pad weight as compared to the routine pelvic floor exercises group;this has been established on basis of these findings.

Table:3 Comparison of protest - post-testI, protest - post-testII , post-testI – Mean of post-testII, SD, paired t and p value of pad weight among those women subjected to SUI inControl group (n=125).

Table 3– Pad weight comparison of those women having stress urinary incontinence related to control groupiscarried out, a mean score of pre-testwith a standard deviation of 2.04 was found to be 5.43 and later declined during the post-test I to 5.28, this is quitesubstantial at $p < 0.05$. Adecreaseof pad weightassociated withcontrol group is observedamidpre-test&post-test Ias portrayed by this study.

Rodrigo A. Castroet al (2008) supports the present study results and the efficacy pertaining to vaginal cones, Pelvic Floor Exercises, no treatment in women suffering from urodynamic SUI and electrical stimulation (ES) is assessed. For the purpose of this study, Vaginal cones (n=27), Pelvic Floor Exercises (n=31), no treatment (untreated control) (n=30)and ES (n=30)accounting to One hundred and eighteen subjects were arbitrarily chosen for this

purpose. The assessment of women prior to and subsequent to the six months of treatment is carried out using a Survey on Life quality (I-LQS) and pad test.

As compared to control group and as per the statistics pertaining to the women who utilized vaginal cones, pelvic floor exercises and electrical stimulation, asignificant progress in LQS ($p<0.001$) and a substantialdecline of pad test (p-0.003) of stress urinary episodevalue($p<0.001$) isobserved.As per the assessment of the studies, women who were found to be satisfied with the treatment of SUI is witnessed as women which utilized vaginal cones – 54%, pelvic floor exercises -58% and 55% - electrical stimulation

In relation to the treatment rendered for SUI, only a meagre number ofwomen belonging to control group, which means 21% isperceived as pleased. Hence, for the women experiencing stress urinary incontinence, the researchers was keen and captivatedin the design, modelling and development of vaginal cone for training the pelvic floor muscles.

8. CONCLUSION

Training pelvic floor muscles with vaginal cone waswitnessed to be instrumental in decreasing the pad weight and enhancing the muscle strength of pelvic floor on the basis of current study.

Limitations

- For practicing at home, vaginal cone is not delivered.
- Oral response had stimulated adherence to practice

Recommendations

- To explore the perspective of Indian women related to SUI, a Qualitative study can be undertaken.
- In order to train Pelvic floor muscles, sameform of study can be carried out usingvaginal cone, electrical stimulation, & biofeedback.
- In a community setting, similar sort of studies could be performed.
- Parameters such as anxiety and depression can be examined through thestudy.
- An assessment of the knowledge, attitude and beliefs among women in relation to PFRand SUI could be carried out.

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Table: 1Frequency, percentage and chi square distribution of obstetric variables amid women having stress urinary incontinence in control and study group.
(N=250)

Obstetric Variable	Control Group (N -125)		Study Group (N -125)		χ^2 &p
	Nos	%	Nos	%	value
Age of first delivery					

Obstetric Variable	Control Group (N -125)		Study Group (N -125)		χ^2 &p
<18 years	15	12	13	10	0.552
19-30 years	97	78	100	80	0.759NS
> 30 years	13	10	12	10	
Mode of delivery					
Normal vaginal delivery	98	78.4	112	89.6	2.99
Forceps delivery	6	4.8	2	1.6	0.392NS
Vacuum delivery	10	8	3	2.4	
Lower segment caesarean section	11	8.8	8	6.4	
No of children					
One	17	14	7	6	8.11
Two	79	63	98	78	0.044*
Three	23	18	17	14	
Four	6	5	3	2	
Birth weight					
< 2.5 kg	19	8	10	8	1
2.5-3.5 kg	97	82.4	103	82.4	0.873NS
> 3.5 kg	9	9.6	12	9.6	
No. of abortions					
None	51	41	60	48	4.55
One	58	46	42	34	0.103NS
Two	16	13	23	18	
Place of delivery					
Hospital	80	64	73	58	0.825
Home	45	36	52	42	0.364NS
Para					
One	17	13.6	7	5.6	8.11
Two	79	63.2	98	78.4	0 .44NS
Three	23	18.4	17	13.6	
Four	6	4.8	3	2.4	

Table: 2 Paired t and p value, SD and mean based on pad weight of SUI affected women in study group (n=125).

Pad weight	"Mean"	"SD"	"Paired t & p value"
Pretest [a]	5.86	2.12	4.88
Posttest I [b]	3.62	2.21	.001**

**p < 0.01, a-SG (n=125) b- (n=120),c- SG, (n=108)

Table:3 Comparison of protest - post-test I, protest - post-test II , post-test I – Mean of post-test II, SD, paired t and p value of pad weight among those women subjected to SUI in Control group (n=125).

Pad weight	**"Mean"**	**"SD"**	**"Paired t & p value"**
Pretest [a]	5.43	2.1	2.57
Posttest I [b]	5.28	2.04	.030*

*p< 0.05, a-CG (n=125), b- , C G (n=117), c- CG (n=104)

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