



**Pelvic Floor training with Vaginal Cone on Urinary Tract symptoms among Women  
with Stress urinary incontinence.**

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50 million men and women all over the world are distressed with urinary incontinence. Research studies proved that almost 10% of all women are suffering with incontinence issues. When a woman is having a urinary incontinence the results are worsened by misinterpretations such as UI is an inevitable because of aged or that once had UI the person must live throughout her lifetime Kang (2009) Gunnar (2005). Women troubled with UI develop tension and fear that they are not having control over their physical functions and that there is no cure Nygaard *et al* (2003).

**Aim:** Evaluate the effectiveness of Pelvic Floor training with Vaginal cone on urinary tract symptoms (UTS) among women with stress urinary incontinence.

**Methodology:** The research design adopted was Randomized control trial. The sample size was 250, 125 in each group.

**Results:** During post-test II, 99(92%) of the women in the treatment group and 38 (37%) of women in the control group had mild level of UTS, 9 (8%) of the women in the treatment and 66 (63%) of women in the control group had moderate level of UTS. Comparison of pre and post-test II results reveals between treatment and control group, in the treatment group there was a 90.4% reduction of UTS when comparing to control group 33% which is statistically significant at  $P < .001$

**Conclusion:** Pelvic floor muscle training with vaginal cone helps to reduce the urinary symptoms.

**Keywords:** Urinary Incontinence, Stress Urinary Incontinence, Pelvic Floor Training  
Vaginal cone

The advanced health care technology boosts up the life expectancy of people. DeLancey J O (2007) et.al predicted that the worldwide number of SUI are anticipated to rise by 10.4% to 152 million by 2013 and by 20.8% to 167 million by 2018, with the incidence expected to rise from 3.2% to 3.3% between 2008 and 2018. Women suffering with urgency urinary incontinence are estimated to surge from 49 million in 2008 to 55 million in 2013 11.1% increase and to 60 million in 2018 22.5% increase, which relates to an increase in incidence from 1.15% to 1.21%. About 11 million women in the United States may be regularly incontinent.

The pregnancy, child birth and increase in age play a major role in developing SUI. Trupti N. Bodhare, Sameer Valsangkar, and Samir D. Bele (2009) conducted a cross-sectional descriptive study in Karimnagar district India . In a research study among 552 women, 53 (10%) described episodes of urinary incontinence. The incidence of urinary incontinence presented important association with increasing age ( $P < 0.01$ ). 57% of them had stress incontinence, 23% had urge, and 20% mixed symptoms of UI.

The myth and wrong perception surrounding the SUI the treatment seeking behaviour is also reduced which may further lead in to complication it is also supported by the study conducted by Kumari S, Singh AJ, Jain V (2008) in Chandigarh among Indian women including 220 incontinent women, 20% (44) women consulted some health agency. 8.6% (19) women had overheard about pelvic floor muscle exercises. 72 % (158) cases had UI for more than one year. The most common reason mentioned for not seeking medical management was, 'UI was reflected as 'normal', 'did not take it serious' and feeling shy to discuss with any one.' Many of the 153 (70%) women stated that UI disturbing their everyday activities as well as social happenings like shopping and staying and spending time with their friends and relatives.

**Aim:** The aim of the study was to determine the effectiveness of Pelvic Floor training with Vaginal Cone on urinary tract symptoms among women with stress urinary incontinence

**Study design:** Randomized Control Trial is a type of methodical experimental studies which purpose is to decrease prejudice when testing a new treatment. Randomization reduces selection bias and the diverse evaluation groups allow the investigators to control any effects of the treatment when associated with the no treatment (control) group, while other variables are kept constant.

**Sample:** Samples were parous women in the age group of 25- 65 years and 250 samples were included in the study.

## **Urinary tract symptoms**

The symptoms experienced by the women with stress urinary incontinence for the past four weeks is assessed by the International Consultation on Incontinence Questionnaire at initial visit, 12<sup>th</sup> week and at 24 weeks.

**Materials and methods:** Tools used for the study were demographic variables, obstetric variables and clinical variables, International Consultation on Incontinence Questionnaire - Female Lower Urinary Tract Symptoms Long Form (ICIQ-FLUTS Long Form)

**Ethical considerations:** Permission was obtained from the Head of the department of Obstetrics and Gynaecology and Institutional Ethics Committee prior to the commencement of the study. The investigator has developed vaginal cones in collaboration with the department of Prosthodontics, faculty of Dental Sciences of the attached Medical University.

## **Data collection procedure**

Step I: Teaching was given. The 20 gm vaginal cone was washed with soap solution in a running water and it was cleaned with sterile gauze piece.

Step II - It was lubricated with 2% Xylocaine jelly and introduced into the vagina for about 3 cm where the levator ani muscles forms.

Step III-During the 1st day of the 12th week Pelvic Floor Training was given with 40 gm vaginal cone. Last day of 12th and 24th week the urinary tract symptoms were assessed

## **Data analysis**

Data Analysis has enabled the investigator to reduce, organize, summarize, appraise and understand the collected data .The data composed were analysed using descriptive and inferential statistics. Frequency, percentage and chi square were used to calculate the background and obstetrical variables of experimental and control group. Percentage and chi square were used to calculate the level of urinary incontinence for both the groups. Paired t and student t test was used to compare the values between study and the control groups.

**Results:** Majority of them, 65 (52%), in the treatment group 60 (48%) women in the control group were in the age group of 36 – 45 years , 25 (20%) of the women in the treatment group and 20 (16%) of the women in the control group belonged to the age of 26 – 35 years 20 (16%) women in the treatment group and 24 (19.2%) women in the control group were aged 46 – 55 years. 15 (12%) of the women in the treatment group and 21 (16.8%) of the women in the control group belongs to the age of 55 – 65 years of age.

While considering the educational status, 40 (32%) women in the treatment group and 32 (26%) women in the control group had completed their graduate education, 107 (86%) of them in the control group lived with their husband, 5 (4%) women in the treatment group and 3 (2%) of the women in the control group are widows, 4 (3%) of women in the treatment group and 15 (12%) of women in the control group lived separately.

While considering the duration of the problem, 60 (48%) of women in the treatment group and 49 (39%) of them in the control group had the problem for 6 – 8 years, 27 (22%) of the women in the treatment group and 36 (29%) of them in the control group had the problem for 3 – 5 years, 23 (18%) of the women in the treatment group and 20 (16%) in the control group had the problem for 1 – 2 years and 15 (12%) of them in the treatment group and 20 (16%) of them in the control group had the problem for 9 – 10 years.

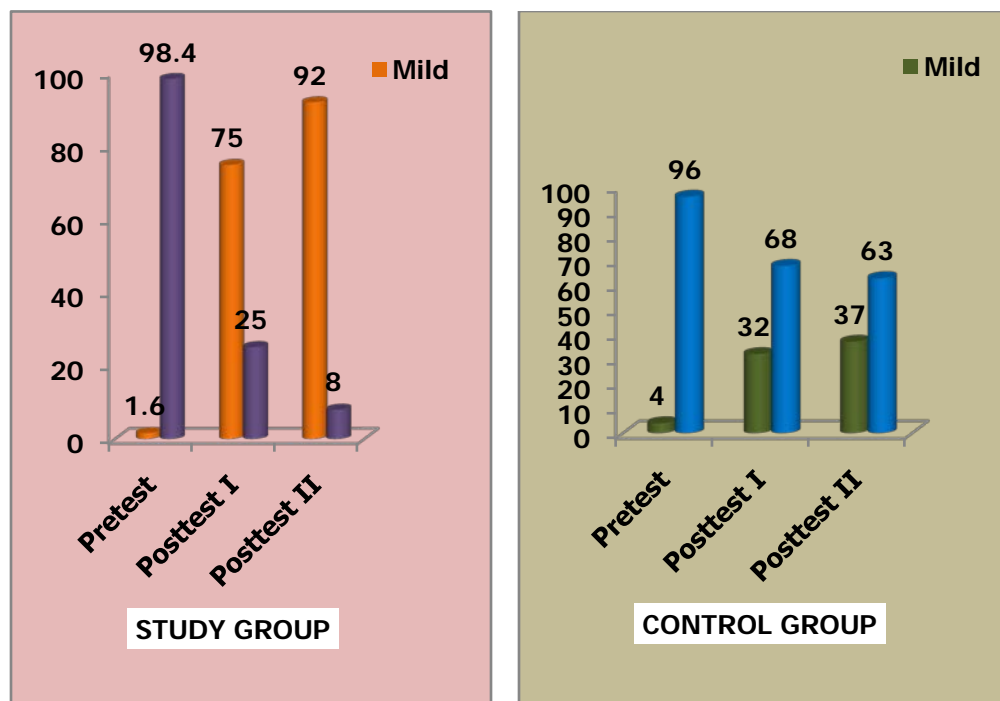


Figure 1: Percentage distribution of level of UTS among women with SUI in the study and control group (N=250)

Figure : 1 depicts that during the pre-test 2 (1.6%) of the women in the treatment group and 5 (4%) of the women in the control group had mild level of UTS, 123 (98.4%) of the women in the treatment group and 120 (96%) of women in the control group had a moderate level of UTS, While in the post test II, 99(92%) of the women in the treatment group and 38 (37%)

women in the control group had a mild level of UTS, 9 (8%) of the women in the treatment group and 66 (63%) women in the control group had a moderate level of UTS. Comparison of pre and post-test II results, reveals between the treatment and the control groups, in the treatment groups there was 90.4% reduction of UTS when compared to control group 33% which was statistically significant at  $p < 0.001$  level. It revealed that the pelvic floor training with vaginal cone is very effective in reducing the urinary tract symptoms.

**Table 1:** Comparison of percentage and chi square distribution of level of frequency among women with SUI in the study and the control group (N=250)

Level of frequency	Study group (n=125)		Control group (n=125)		$\chi^2$ & p value
	No.	%	No.	%	
<b>Pretest<sup>a</sup></b>					
Mild	23	18	29	23	0.87 0.349 NS
Moderate	102	82	96	77	
<b>Posttest I<sup>b</sup></b>					
Mild	62	52	29	25	18.09
Moderate	58	48	88	75	0.001**
<b>Posttest II<sup>c</sup></b>					
Mild	99	92	34	33	78.82
Moderate	9	8	70	67	0.001**

\*\*\*  $p < 0.001$ , NS- Non Significant, a-SG(n=125),CG(n=125),b-SG(n=120),

CG (n=117), c- SG (n=108), CG (n=104)

Table 2 depicts that during the pre-test 23 (18%) of the women in the treatment group and 29 (23%) of the women in the control group had a mild level of frequency among women with SUI, 102 (82%) of the women in the treatment group and 96 (77%) of the women in the control group had a moderate level of frequency among women with SUI. While in the post test II, 99 (92%) of the women in the treatment group and 34 (33%) of the women in the control group had a mild level of frequency among women with SUI, 9 (8%) of the women in the treatment group and 70 (67%) of the women in the control group had a moderate level of frequency among women with SUI. There was a 74 % reduction in frequency symptoms when compared to the control group (10%) which was significant at the level of  $p < 0.001$ .

Table 2: Comparison of percentage and chi square distribution of level of voiding symptoms among women with SUI in the study and the control group (N=250)

Level of voiding symptoms	Study group (n=125)		Control group (n=125)		$\chi^2$ & p value
	No.	%	No.	%	
<b>Pretest <sup>a</sup></b>					
Mild	27	22	16	13	3.39
Moderate	98	78	109	87	0.065NS
<b>Posttest I <sup>b</sup></b>					
Mild	98	82	40	34	53.91
Moderate	22	18	77	66	0.001***
<b>Posttest II <sup>c</sup></b>					
Mild	101	94	47	45	54.48
Moderate	07	06	57	55	0.001***

\*\*\* p< 0.001,NS- Non Significant, a-SG(n=125),CG(n=125),b-SG(n=120),

CG (n=117),c- SG (n=108),CG (n=104)

Table 2: depicts that during the pre-test 27 (22%) of the women in the treatment group and 16 (13%) women in the control group had mild level of voiding symptoms, 98 (78%) of the women in the treatment group and 109 (87%) women in the control group had a moderate level of voiding symptoms. During the post-test I, 98 (82%) of the women in the treatment group and 38 (32%) of women in the control group had a mild level of voiding symptoms, 22 (18%) of the women in the treatment group and 77 (66%) women in the control group had a moderate level of voiding symptoms. While in the post test II, 101(94%) of the women in the treatment group and 47 (45%) women in the control group had a mild level of voiding symptoms, 7 (6%) of the women in the treatment group and 57 (55%) of the women in the control group had a moderate level of voiding symptoms at p < 0.001. This results showed that the pelvic floor muscle training with vaginal cone had effective in reducing the symptoms of voiding symptoms when comparing the control group routine pelvic floor exercises.

## Discussion

The stress urinary incontinence is a distressing condition which conveys a huge humiliation. This stigma and lack of information on stress urinary incontinence and the

significance of performing pelvic floor exercises badly disturbs the health related Quality of life in women. Due to this embarrassing condition women are not ready to discuss this to even with health care professionals, thinking that it will subside on its own, nothing can be done, and surgery is the only treatment option. Incontinence can influence all aspects of a women's life like physical activities, social communications, sexual role life, work performance, travel, and sports activities and contribute in public life and they feel powerlessness. It is related with a deprived self-rated health, negative impact in quality of life, social segregation, and indications of hopelessness and anxious.

The present study outcomes were supported by Herbison GP (2012) explored the randomised controlled trials associating weighted vaginal cones with alternate methods or no treatment. The study comprised of 23 research trials comprising 1806 women, among 717 who received cones. Cones than no active treatment (rate ratio (RR) for failure to cure incontinence 0.84, 95% (CI) 0.76 to 0.94). There was little evidence of difference for a subjective cure between cones and PFMT (RR 1.01, 95% CI 0.91 to 1.13), or between cones and electro stimulation (RR 1.26, 95% CI 0.85 to 1.87), but the confidence intervals were wide. There was not enough evidence to show that cones plus PFMT was different to either cones alone or PFMT alone. Only seven trials used a quality of life measures and no study looked at economic outcomes. This review provides evidence that weighted vaginal cones are better than no active treatment in women with SUI.

Haslam, J. (2008) observed the vaginal cones training in stress incontinence management with the women (n=39) of whom only 30 completed the one-month cone therapy with weights from 20–100g (Peattie et al, 1988). The women were trained to practise the passive weight for 15 minutes twice per day. When they were able to retain the cone on two repeated instances, they were instructed to start using the next heaviest weight of cone, out of 30 women completing the on month treatment, 70% reported a cure or an improvement.

**Conclusion:** The vaginal cones prepared by the investigator were cost effective, and keeping in mind about the economic burden of Indian women, she has prepared cones which the women will be able to afford and use them. The vaginal cones prepared by the investigator are simple, easy and harmless for the women to use.

### **Recommendations for further study**

- A similar study can be conducted using electrical stimulation, Vaginal cone & biofeedback for training the Pelvic floor muscles

- A study can be conducted in the community setting.
- A study can be conducted to including the antenatal women and follow up for five years.
- A similar study can be conducted including sports women

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