Effect of Vaginal Cone on Pelvic Floor Muscle Strength in Post- Menopausal Women With Stress Incontinence- Community Based Study

Lata D. Parmar*, Bhavi B. Patel**

* Phd, Principal, College Of Physiotherapy, .** M.P.T, Sumandeep University, Piparia, Waghodiya, Vadodara

Abstract: Context: SUI is defined as involuntary loss of urine during coughing, sneezing or physical exertion. This is common complaint in post menopausal women. Conservative physical treatments preferred as first choice. This study assessed the effect of vaginal cone on pelvic floor muscle strength in these women. Method: Total 32 subjects recruited. Participants randomly assigned to 2 groups. Control group-1(PFMT) and experimental group-2 (PFMT. + vaginal cone). Group-1, N=15 and group -2, N=17, treatment for 6 weeks was given. Result: Independent T-test between Group-I and Group-II showed both groups were homogenous. Paired T-test to compare pre – post difference of variables within the group was significant with p-value <0.01 for Brink score, water glasses per day, frequency of urine per day, leakage episodes. In group 2 majority women with vaginal cone for strength gain reached to 40gms (2-3 subjects progressed to 55gms cone). To check association between 2 variables between groups, chi-square test showed no significant difference, throughout the results significant level was set at 5%. Conclusion: Pelvic floor muscles' training is effective to improve SUI symptoms and improve quality of life, but effects of vaginal cones need to be studied on larger sample. [Lata P NJIRM 2017; 8(4):10-16]

Key Words: Post-menopausal women, Pelvic Floor Muscles Training, stress urinary incontinence, vaginal cone

Author for correspondence: Prof Lata Shroff Parmar PhD, Principal , College Of Physiotherapy, Sumandeep Vidyapeeth ,Piparia, Waghodia, Vadodara-391760(Gujarat) Ph : 02668245029, M: 9825825578
E-Mail: shrofflata1856@gmail.com

Introduction: Urinary incontinence is a common, debilitating, economical burden and a serious medical condition in that it can lead to negative self-perception, creating embarrassment, reduce social interaction & physical activities and it is associated with poor self rated health, also develops impaired sexual relationship, however which does not lead to death[1, 2, 3, 4, 5, 6, 7, 8] UI is more common in women, although it affects all ages, it increases with age,[1, 2], [3,4,9,10,11,15,21] in fact this is said to be more applicable to urge type rather than SUI.[15] This condition is however said to be under diagnosed & under reported.[3,4,9,17]

Prevalence of UI in women varies from 8.5% to 60%[1,2,3,4,5,9,12,13] Prevalence of incontinence in post menopause is 15% to 56 % [9,14]

The most common type of UI in women is SUI, defined as the involuntary loss of urine during coughing, sneezing or physical exertion such as heavy weight lifting, sports activities, or sudden change in position in the absence of detrusor contraction1,[2,3,6,7,9,10,11,15]

The prevalence of SUI varies from 12% to 40%,[3,5,7,9,15] the range given is between 29 % - 75%[13]. The reported prevalence of SUI in India is about 46% [17] Umasingh et al reported prevalence to be as high as 73.8 %(8). Prevalence of SUI during pregnancy is said to vary between 6% - 67%.[3,4,16]

Studies have shown that important risk factors for SUI are increasing age, increasing parity, obesity, smoking, chronic obstructive pulmonary disease, and prolonged second stage of labor. [3,4,16,6,8,15,11] Menopause is probably a contributory factor rather than cause.[6]

There are various management options for treatment of SUI such as medication, physiotherapy, and surgery. Physiotherapy includes electrical stimulation, pelvic floor exercises, biofeedback, and vaginal cones etc. These all are largely focused on providing symptom relief, maintenance of function & improve quality of life.

PFMT has been described in ancient Indian, Chinese & ancient Greece literature.[4,16] These are also said to improve sexual health, increase longevity, and promote spiritual development.3 According to Price N et al (2010) as early as 1936 PFMT is said to enter modern medicine, when Margaret Morris described tensing & relaxing of pelvic floor as treatment to prevent faecal incontinence.[3] There are studies which support and /or refute vaginal cones to be as or more effective as compared to pelvic floor exercises in management of SUI[1,2,3,9,18]

The aim of the present study was to study the effect of vaginal cone on PFM strength in post-menopausal women with SUI.

Methods: This was Interventional study, Community based (villages around the institute)

Inclusion Criteria: Post-menopausal women with SUI

Exclusion Criteria:

- Having any gynaecological or any other pelvic surgery
- Patient suffering from neurological condition affecting bladder function
- Urinary tract infections
- Bed ridden patients

Methodology: After getting approval from Institutional ethical committee, Sarpanches of nearby villages were approached and explained about the study, with the help of village health worker, the post-menopausal women with urinary problems were identified. The women for diagnosis for SUI were confirmed from answers given to the question; this was by one to one interview method.

Table 1
The Questionnaire for female Stress and Urge Urinary Incontinence Diagnosis
Do you leak urine (even small drops), wet yourself, or wet your pads or undergarments...
1. When you cough or sneeze?
2. When you bend down or lift something up?
3. When you walk quickly, jog or exercise?
4. While you are undressing in order to use the toilet?
5. Do you get such a strong and uncomfortable need to urinate that you leak urine (even small drops) or wet yourself before reaching the toilet?
6. Do you have to rush to the bathroom because you get a sudden, strong need to urinate?
Scoring: each item scoring
0 = (None of the time),
1 = (rarely)
2 = (once in a while)
3 = (often)
4 = (most of the time)

Participants identified were explained about the study in detail and on agreement written informed consent was taken. Following this participants from one village were included in either of the groups: 1) PFM training 2) PFM training + vaginal cones. Total of six villages were visited. Before starting the intervention pre-training assessment of PFM strength was done with the use of brink score.

After assessment of strength of pelvic floor muscles, examiner explained conservative treatment (kegel's exercise) to both the groups and women were told to practice daily for 6 weeks and twice/week exercise was given under supervision of the investigator to both groups. Standard procedure i.e. examiner instructed the participant that bladder should be empty and in crook lying position (distance between both feet shoulder width apart), the instructor inserted a finger with sterile precaution, i.e. use of gloves, into participant's vagina, and gave command to tighten the muscles as if you are holding in your urine, examiner felt the muscles tighten and finger move up and in and gave instructions 'Don't hold your breath, Don't tighten the tummy, thigh or buttock muscles, Don't squeeze your legs'.

Once the examiner find that they can hold the contraction for one or two seconds, they were asked to concentrate on gradually increasing the contraction time until you reach 10 second and then relax your muscles and rest for 10 seconds. Repeat the contractions up to 10 times in 1 set (10 seconds contraction 10 seconds relax). So this type of 10 sets had to be repeated daily. Six weeks training was in the said position, although the patients were asked to practice as and when they could in sitting or standing too.

For second group, subjects were instructed on the use of vaginal cones in addition to above. A set of 6 cones of identical shape but of increasing weight (25, 40, 55, 70, 85, 100 gm) (pic) were used. Starting with the lightest weight the subjects were taught to place vaginal cone in to vagina while in lithotomic position. The same exercise protocol for same duration was followed. The selected cone could be retained in place for 10 seconds while voluntary contracting the pelvic floor and after that 10 seconds relax. And this was continued for 6 weeks.

Women were told to practice daily for 6 weeks kegel's exercise and twice/week exercise with vaginal cone was given under supervision of the investigator. A set of 10 seconds contract and 10 seconds relax with vaginal cone was continued for 15 minutes. In the next session heavier weight vaginal cone was used but only after assurance that required a voluntary contraction

was strong enough to prevent the cone from slipping out of vagina and continue for 6 weeks.

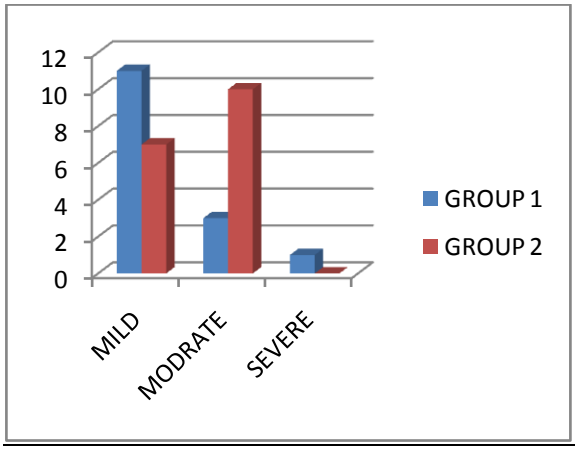
Participants were also instructed to maintain daily records through bladder diary method.

Outcome Measure: Brink score recorded pre and post intervention, also a record of maximum weight of cone used was noted.

- Bladder diary analysis:
- Water Glasses per day,
- Urine Frequency per day
- Urine leakage episodes

Results: In six villages total numbers of menopausal women were - 382. The number of menopausal women with complaints of SUI (many self reporting and some referred from Primary Health Centre) was 32 (8.37%). Range varied between 5.61% & 14.28%. SUI Grade v/s Group is as shown in Fig. 1

The average BMI of both the groups was as 24.908 & 26.309 of group 1& 2 resp.



SUI grade v/s group

Table 1: - Independent T-Test to compare mean values between two groups (Inter group comparison)

	Group	N	Mean	Std. Deviation	Std. Error Mean	Mean Difference	t-value	p-value
Age	Group-1	15	58.00	7.783	2.010	3.529	1.320	.197
	Group-2	17	54.47	7.332	1.778			
WEIGHT(KG)	Group-1	15	58.67	6.779	1.750	-3.922	-1.630	.114
	Group-2	17	62.59	6.801	1.650			
HEIGHT(CM)	Group-1	15	155.07	4.131	1.067	.773	.461	.648
	Group-2	17	154.29	5.205	1.262			
No of vaginal delivery	Group-1	15	3.80	1.424	.368	.682	1.665	.106
	Group-2	17	3.12	.857	.208			

Paired T-Test was done to compare pre – post difference of different variables within the group

Table 2: shows comparison of pre and post scores of group 1

Total Score -Brink	Mean	N	Std. Deviation	Mean Difference	t-value	p-value
Pre brink	6.00	13	.816	-3.231	-16.067	.000
Post brink	9.23	13	.439			
Water Glasses per day Pre	7.23	13	1.739	-.462	-2.144	.053
Post	7.69	13	1.377			
Urine Frequency per day Pre	8.77	13	2.166	1.846	4.951	.000
Post	6.92	13	1.188			

Urine Leakage /month Pre	19.38	13	39.589	19.077	1.773	.000
Post	.31	13	.855			

Table 3: shows comparison of pre and post scores of group 2

Total Score	Mean	N	Std. Deviation	Mean Difference	t-value	p-value
Pre Brink	6.12	17	1.05	3.294	9.998	.000
Post Brink	9.41	17	0.87			

Water Glasses per day Pre	6.06	17	1.391	-1.471	-6.934	.000
Post	7.53	17	1.179			

Urine Frequency per day Pre	8.12	17	1.536	2.176	7.572	.000
Post	5.94	17	1.144			

Urine Leakage per month Pre	11.65	17	8.624	11.000	5.692	.000
Post	.65	17	1.272			

For Group-2 majority with resistance for strength gain reached to 40gms (2-3 subjects progressed to 55gms cone)

Table 4: shows pre and post mean difference in total Brink Score between the groups

Total Score	Group	N	Mean	Std. Deviation	Std. Error Mean	Mean Difference	t-value	p-value
Pre	Group-1	15	6.13	0.834	0.215	0.016	0.046	0.963
	Group-2	17	6.12	1.05	0.256			
Post	Group-1	13	9.23	0.439	0.122	-0.181	-0.684	0.499
	Group-2	17	9.41	0.87	0.211			

Similarly Pre to Post mean difference of Urine Leakage per month, Urine frequency & mean of water glass / day between group 1&2 was insignificant i.e. p value >0.05

Discussion: Urinary incontinence is a common health problem among women. The most common type of UI in women is stress urinary incontinence. The study was conducted in the six villages (within 8-10 km radius) surrounding the institute, 382 post-menopausal women were identified with help of village health worker. The mean age of participants' in the two groups was 58 ± 7.9 and 54.5 ± 7.3. The questionnaire for female UI (QUID) was administered directly on one to one basis and therefore ensures reliability. According to Karolina Chmaj-Wierzchowska et al [11] thoroughly collected history taking is usually sufficient to make a correct diagnosis of SUI.

The prevalence of SUI in the menopausal women in these villages was 8.37% [5.61%-14.28%], the possibility however, of many not reporting cannot be excluded. According to Santosh Kumari & others[17] the problem is more pronounced in India where treatment seeking for reproductive health problems may not even be vocalized. The prevalence of SUI was 46% [17] among north Indian women & Uma Singh et al (2013)[8] also recorded prevalence of SUI relatively high i.e. 16.1 % as compared to urge UI (2.07%) & mixed UI (3.67%).[8] In the age group > 50 years, women being post-menopausal, SUI is more prevalent. The age of menopause is unchangeably assessed to be approximately 50.[11]

Hundley, Wu, and Visco (2005),[20] compared Brink scores with Perineometer and found high degree of correlations between the two methods of evaluation suggesting both have similar levels of reproducibility and are measuring comparable parameters i.e. the pelvic floor muscle strength. A number of studies have demonstrated considerably reduced PFM strength,[5, 7,15,21] and decreased tension & relaxation of the muscles[7,11] in women with incontinence.

The International Continence Society by consensus has defined that although quantification may be problem the vaginal digital palpation method is easy to perform[21] According to authors[6] bimanual examination can assess the function of levator ani by asking the patient to tighten her vaginal muscles and hold the contraction as long as possible and normally this is in range of 5-10 seconds. The digital assessment of pelvic floor is said to be essential before PFMT[6]

In the present study Brink score analysis showed that there was statistically significant improvement in strength pre to post intervention of six weeks within both groups 1 & 2. In 1948 a first time cure rate of 84% was reported by Kegel following training of the PFM in various types of UI, since then number of studies advocated benefits of PFMT.[1, 2,3,5,7] A single blind RCT[1] employed 8-12 high intensity (almost to maximum) 3 times a day with additional of group exercises once a week, participants held the contractions for 6-8 seconds. Significant improvement in strength was recorded in the experimental group compared to control.

Different regimens are used by different studies.[1,3,4,5,12,16] the number of contractions reported in different studies vary from 8-12 done 3 times per day to 20 contractions for 4 times per day, for hold range from 4-40 seconds.[5] The postures in which exercises are recommended also varies. Many studies support the PFMT intervention to be successful[1,9, 3,4,5,16,12,10] PFMT is graded at level 1 evidence by systematic reviews of the randomised control trials.[2] The improvement is said to be evident across the age groups.[3] long term effects of PFMT in those who continuously adhere needs to be studied. Physiotherapy with minimal / no risk however, is said to play a key role in the management of SUI. One study[5] found that supervised PFMT increased muscle volume, reduced the hiatus in the levator ani, elevating the resting position of pelvic organs i.e. the bladder & rectum.

The literature suggests that women with SUI who undergo PFMT were 8 times more likely than the controls (no any treatment given) to report that they were cured and the active treatment was reported as more satisfying. According to Bo K, Herbert RD (2013) "there is not yet strong evidence that exercise regimen other than pelvic floor muscle training can reduce stress urinary incontinence in women."[2] Cammu et al concluded that pelvic floor training comprising of pelvic exercise for stress incontinence is not only initially successful but there is 66% chance that favorable results will persist for at least 10 years[16] Dosage for strength training of the PFM as extrapolated from exercise physiology principles for normal skeletal muscle, slow velocity near maximal contractions is suggested as 6-8 seconds hold, with 3 sets of 8-12 contractions repeated 2-4 days a week for 5-6 months.[10]

In the present study too in agreement to literature[1], the progress in the experimental group in the majority with resistance for strength gain reached to vaginal cones of 40gms (2-3 subjects progressed to 55gms cone). In some studies[1,] the progression was to 70 gm depending on their ability to hold. Use of vaginal cones are said to be better than no treatment.[5, 10,12, 18,22,] Herbison GP & Dean N[18] report that there is little difference between the cones & PFMT the present study also noted no significant difference between the groups. One study reported vaginal cones to be equally effective to PFMT.[22] Vaginal cones may be held inside the vagina with contraction of muscles for 20 minutes at a time, progression on to heavy weights can be made as the strength improves.[3,9]

PFMT, Vaginal cones, electrical stimulations, Biofeedback etc are known therapies that have been utilized till date, and it is recommended to initiate these without referral for specialized testing[6,9,15,] These treatments improve the contractile force, recruitment speed & resting tone of the muscles of the pelvic floor and motivated patients of SUI if follow the education religiously of the PFMT for three months than 38% are expected to experience cure from SUI[9] The best results are said to be obtained by supervised training.[2, 16,15,6]

Studies encourage bladder diaries additionally as these help determine the functional bladder capacity with episodes of leakage during the daily activities.[6,7,15] In the present study there was 100% compliance with regards to the maintenance of the diary, analysis according to bladder diary analysis water glasses/day was significantly increase from pre to post within both the groups. And fear leading to urine frequency was significantly decreased from pre to post and urine leakage also was significantly reduced compared to baseline. This is well in agreement with some studies[7] Water Glasses per day

were increased; Urine Frequency per day within the groups was significant decreased[7] Urine leakage/day also showed significant improvement within the groups.

Some studies have analyzed the bladder diaries. One of the study[1]apart from reporting significant strength gains in the PFMT group compared to the electrical stimulation or the vaginal cone group also report significant reduction in the leakage on the pad test in the PFMT group as compared to others.[1] Miller et al also similarly report that PFMT could reduce urinary leakage as early as after one week of training to almost 98.2% with medium cough and 73.3% with deep cough[3,16]

The average BMI of group I & II in this study was 24.91 & 26.31 resp. (≥ 25) indicating overweight as per WHO (2004) classification. Several studies have reported BMI to be higher in the women who have SUI, however no relationship has been established between the obesity & SUI[23,24] In obesity increased intra abdominal pressure could be the reason of chronic stress on the pelvic floor resulting in the SUI.[23] Weight reduction in SUI has shown reduced number of leakage episode assessed by diaries and also had lesser volume of urine loss as determined by pad tests.[23] These women also reported satisfaction. This could be an important adjunct in treatment for SUI With increased longevity and ageing UI will become more prevalent and continue to increasingly affect the quality of life. This study shows that in our villages too, the women could be convinced and be trained of this simple & effective measure to help themselves

The present study well supported by literature that PFMT exercises are highly effective in SUI women and that vaginal cones provide no additional benefit. This is of importance to our country especially so in rural settings.

Acknowledgement: Authors acknowledge the immense help received from the scholars whose articles are cited and included in references of this manuscript.

The authors are also grateful to Sumandeep University trust for all the support provided.

References:

1. Kari Bø, Trygve Talseth, Ingar Holme Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress urinary incontinence in women. BMJ 1999; Volume 318: issue 7182, 487-937.
2. Kari Bø and Robert D Herbert. There is not yet strong evidence that exercise regimens other than pelvic floor muscle training can reduce stress urinary incontinence in women: A systematic review. 2013 Journal of Physiotherapy; Volume 59: Issue 3. 159 – 168. DOI 10.1016/s1836-9553(13)70180-2
3. Price N, et al. Pelvic floor exercises for urinary incontinence. A systematic literature review. Maturitas (2010), doi: 10.1016/j.maturitas.2010.08.004
4. Vjollca Ndreu, Fatjona Kamberi, Enkeleda Sinaj, Anila Sula, Pelvic Floor Muscle Training Versus No Treatment For Urinary Incontinence in Women. European Scientific Journal February 2015 /SPECIAL/ edition vol.2 ISSN: 1857 – 7881 (Print) e - ISSN 1857- 7431
5. Silva Filho et al. Analysis of the resources for rehabilitation of pelvic floor muscles in women with prolapse and urinary incontinence Fisioter Pesq. 2013;20(1):90-96
6. Management of urinary incontinence in primary care A national clinical guideline. Scottish Intercollegiate Guidelines Network. December 2014ISBN 1 899893 14 8. WWW.SIGN.AC.UK
7. Maria V. Capelini; Cassio L. Riccetto; Miriam Dambros; Jose T. Tamanini; Viviane Herrmann; Virginia Muller. Pelvic floor exercises with biofeedback for stress urinary incontinence. International Braz J Urol Vol. 32 (4): 462-469, July - August, 2006. http://dx.doi.org/10.1590/S1677-55382006000400015
8. Singh U, Agarwal P, Verma ML, Dalela D, Singh N, Shankhwar P. Prevalence and risk factors of urinary incontinence in Indian women: A hospital-baseD survey. Indian J Urol. 2013; 29; 31-6.
9. Culligan PJ, Heat M. Urinary incontinence in women: evaluation and management. Am Fam Physician. 2000 Dec 1;62(11):2433-44, 2447, 2452.
10. Patricia B Neumann, Karen A Grim and Yamini Deenadayalan. Pelvic floor muscle training and adjunctive therapies for the treatment of stress urinary incontinence in women: a

systematic review. BMC Women's Health 2006; 6:11 DOI: 10.1186/1472-6874-6-11

11. Karolina Chmaj-Wierzchowska1, Beata Pięta1, Magdalena Kotecka1, Michał Michalak2 Stefan Sajdak3, Tomasz Opala1. Three most important etiological factors of occurrence of stress urinary incontinence in nulliparous pre-and postmenopausal Polish women Ann Agric Environ Med. 2012; 19(3): 581-585.
12. Daksha Trivedi. Cochrane Review Summary: Pelvic floor muscle training added to another active treatment versus the same active treatment alone for urinary incontinence in women.Primary Health Care Research & Development 2015; 16: 545–547 doi:10.1017/S1463423615000419https:/www.cambridge.org/core/terms.https://doi.org/10.1017/S1463423615000419
13. Victor W Nitti, MD. The Prevalence of Urinary Incontinence. Rev Urol. 2001; 3(Suppl 1): S2–S6
14. Grady D, Brown JS, Vittinghoff E, Applegate W, Varner E, Snyder T; HERS Research Group. Postmenopausal hormones and incontinence: the Heart and Estrogen/Progestin Replacement Study. Obstet Gynecol. 2001 Jan;97 (1):116-20.
15. Deborah J. Lightner, MD, Nancy M.B. Itano, MD. Treatment Options for Women With Stress Urinary Incontinence. Mayo Clinic Proceedings, Volume 74, Issue 11, November 1999, Pages 1149–1156
16. K Abdulaziz, T Hasan. Role of Pelvic Floor Muscle Therapy In Obese Perimenopausal Females With Stress Incontinence: A Randomized Control Trial The Internet Journal of Radiology Volume 14 Number 2. ISPUB.COM
17. Kumari, Santosh, A. J. Singh, and Vanita Jain. "Treatment seeking behavior for urinary incontinence among north Indian women." Indian journal of medical sciences 62.9 (2008): p 352.
18. Herbison GP, Dean N. Weighted vaginal cones for urinary incontinence. Cochrane Database Syst Rev. 2013 Jul 8;(7):CD002114. doi: 10.1002/14651858.CD002114.pub2
19. Bradley et al.The Questionnaire for Urinary Incontinence Diagnosis (QUID):Validity and Responsiveness to Change in Women Undergoing. Non-Surgical Therapies for Treatment of Stress Predominant Urinary Incontinence. Neurourol Urodyn. 2010 June; 29(5): 727–734. doi:10.1002/nau.20818.
20. Andrew F. Hundley, Jennifer M. Wu, Anthony G. Visco, A comparison of perineometer to brink score for assessment of pelvic floor muscle strength. American Journal of Obstetrics and Gynecology. Volume 192, Issue 5, May 2005, Pages 1583–1591
21. Sartori et al. Reliability of pelvic floor muscle strength assessment in healthy continent women. BMC Urology (2015) 15:29 DOI 10.1186/s12894-015-0017-6
22. Cammu H, Van Nylen M. Pelvic floor exercises versus vaginal weight cones in genuine stress incontinence Eur J Obstet Gynecol Reprod Biol. 1998 Mar;77(1):89-93.
23. Christina Aye, Natalia Price and Simon R Jackson. Weight Loss to Treat Urinary incontinence in Overweight and Obese Women. A commentary on the original article by Leslee L Subak et al., NEJM 2009;360:481-490
24. Bai SW , Kang JY , Rha KH , Lee MS , Kim JY , Park KH. Relationship of urodynamic parameters and obesity in women with stress urinary incontinence.The Journal of Reproductive Medicine 2002, 47(7):559-563

Conflict of interest: None
Funding: None
Cite this Article as: Lata P, Bhavi P. Effect of Vaginal Cone on Pelvic Floor Muscle Strength . Natl J Integr Res Med 2017; 8(4):10-16