Design and Development of Vaginal Cone to reduce Urinary Tract Symptoms and Pelvic Floor Muscle Strength among Women with Stress Urinary Incontinence (SUI)

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Abstract

Background: Urinary Incontinence (UI) is perceived as a debilitating condition which affects the quality of life of numerous women. The worldwide prevalence of UI ranges from 10% to 40% among women. In developed countries such as UK, nearly 50% adult females in primary care settings have reported of UI, yet few seek for health care support. Little is known about effectiveness of various interventions that could reduce burden of UI at resource limited countries.

Aims: To evaluate the effectiveness of Pelvic Floor Rehabilitation with Vaginal cone on the urinary tract symptoms and pelvic floor muscle strength among women with stress urinary incontinence.

Materials and methods: A randomized control trial with teaching on SUI and Pelvic Floor Muscle Training with Vaginal Cone was adopted as an intervention that was provided by the investigator for the women with stress urinary incontinence in the study group apart from the routine care. 250 subjects with parous in the age group of 25- 65 years were included in the study.

Results: Comparison of pre and post-test II data, results reveals that there was a 90% reduction of urinary tract symptoms in the study group when compared to control group (33%) which was statistically significant at $p<0.001$ level.

Conclusion: We conclude that the pelvic floor rehabilitation, with vaginal cone, is proven to reduce urinary tract symptoms and improve pelvic floor muscle strength among women with stress urinary incontinence. Further studies are needed to examine the cost effectiveness of vaginal cone in order to alleviate the burden of UI among women in resource limited countries.

Key words. Urinary incontinence, vaginal cone, Pelvic floor Rehabilitation

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INTRODUCTION

Stress Urinary Incontinence (SUI) is the symptomatic complaint of involuntary leakage on effort or exertion, or on sneezing or coughing (Abrams P et al 2009). The advanced health care technology boosts up the life expectancy of people. Miller, D (2007) predicted that the worldwide number of SUI are projected to increase by 10.4%to 152 million by 2013 and by 20.8% to 167 million by 2018, with the overall prevalence anticipated to increase from 3.2% to 3.3% between 2008 and 2018. In India, the questionnaire based survey was conducted by Guna et al (2013) found that among 2,000 women in the 30 – 50 age group, 37% complained of urge incontinence. While 31% thought that their condition was indeed bothersome and required help and 38% seemed to be aware of the availability of treatment, only 13% were not averse to approaching a doctor. The main reason for hesitating to consult a doctor ranged from shyness (22%), the notion that incontinence was a passing problem (31%) of being unsure of which specialist they needed to consult (34%). 40% knew that help was available and only one in four actually consulted. Stavros Charalambous (2009) reported that co morbid conditions such as urinary tract infections (UTIs), skin problems such as rashes, infections, and sores occur due to constantly wet skin. Economic burden due to increased costs and efforts for linen washing and healthcare adds to the consequences of this condition.

Dougherty et al, (1993) stated that the goal of Pelvic Floor Muscle Training is to isolate the pelvic floor muscle, specifically the Levator Ani. The pelvic floor muscle exercises (PFMs) comprise a striated, skeletal muscle group, that is under voluntary control and is important in maintaining urinary and faecal continence as well as in providing support to the pelvic organs (bladder, rectum and the uterus). Vaginal cones are in practice in developed countries since four decades but utilization of vaginal cones and practice of pelvic floor exercises is an emerging concept in India.

AIMS:

The aim of this study were to 1)To find out the effectiveness of Pelvic Floor Rehabilitation with Vaginal cone on urinary tract symptoms among women with stress urinary incontinence and 2) Evaluate the effectiveness of Pelvic Floor Rehabilitation with Vaginal cone on pelvic floor muscle strength among women with stress urinary incontinence.

MATERIALS AND METHODS:

Study design: Randomized Control Trial is a type of scientific experiment which aims to reduce bias when testing a new treatment. The people participating in the trial are randomly allocated to either the group receiving the treatment under investigation or to a group receiving standard treatment (or placebo treatment) as the control. Randomization minimises selection bias and the different comparison groups allow the researchers to determine any effects of the treatment when compared with the no treatment (control) group, while other variables are kept constant. The RCT is often considered the gold standard for a clinical trial. RCTs are often used to test the efficacy or effectiveness of various types of medical intervention and may provide information about adverse effects, such as drug reactions. Random assignment of intervention is done after subjects have been assessed for eligibility and recruited, but before the intervention to be studied (*Schulz KF 2010)*

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

Sampling criteria: The sampling strategy used will determine whether the sample actually studied is representative of the target population. For the findings of the study to be generalizable to the population as a whole, the sample must be representative of the population from which it is drawn.

Inclusion Criteria	Exclusion Criteria
Women who are having post voidal urine volumes less than 50 ml	Women who have neurological disease
Women who are Able to understand Tamil or/and English	Women who have cancer bladder
Women who are Willing to participate	Women who have pregnancy
Women who are With telephone facility	Women who have Underwent surgery for stress urinary incontinence
	Women who have Previous participation in PFMT program
	Women who have fibroid uterus
	Women who have 2nd, 3rd and 4th degree uterine prolapsed.

Instruments 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 1996 and Pelvic floor muscle strength was assessed using Modified Oxford Grading Scale (6 point scale) (Laycock and Chiarelli, 1989).

Ethical considerations: Permission was obtained from the Head of the department of Obstetrics and Gynecology and Institutional Ethics Committee prior to the commencement of the study.

Intervention

The investigator has developed vaginal cones in collaboration with the department of Prosthodontics, faculty of Dental Sciences of the attached Medical University. The Vaginal cones are made up of poly Methyl Metacrylate. This material has proved to be safe with unreported major side- effects. The size of the vaginal cones varies from 20gm to 100gm.

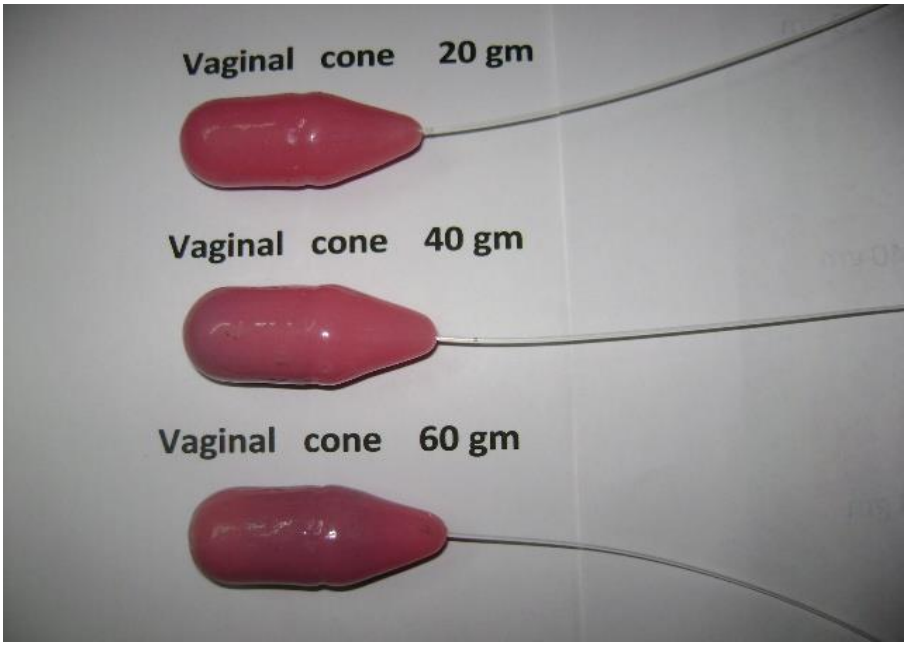
Data collection procedure

Step I: Teaching was given**.** Before insertion of vaginal cone, 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 week the urinary tract symptoms, Pelvic floor strength and Quality of life was assessed. The subjects in both the group were given reminder three days prior to their date of visit. If in case they did not turn up on the due date they were given additional reminders two days prior to the due day of visit. The following week, maximum of three reminders were given for each due visit. If the woman did not turn up with three reminders, it was accounted as missed visit. During the 24th week the urinary tract symptoms, pelvic floor strength, pad weight, and Quality of life was assessed using the same instruments. In study group 108 samples and 104 in control group were analyzed.

INVESTIGATOR PREPARED VAGINAL CONE



Data analysis –

Data Analysis has enabled the investigator to reduce, summarize, organize, evaluate and interpret the numerical information .The data collected were analyzed using descriptive and inferential statistics. Frequency, percentage and chi square were used to calculate the demographic 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

In this study, in total of 250 women with SUI participated. Both in control group and study group, majority women were in the age group of 26-45 years. 48% in study group and 39% in control group had the duration of the problem at least for 6-8 years. Majority (80% in study group and 78% in control group) has had their first delivery at the age between 19-30 years (See Table 2)

Table 2: Demographic characteristics

Demographic variables	N0	%	Demographic variables	N0	%
Age (yrs.) 26 - 45	65	52	Age (yrs.) 26 - 45	60	48
25-35	25	20	25 -35	20	16
Duration of the problem 6-8 yrs.	60	48	Duration of the problem 6-8 yrs.	49	39
Age of first delivery 19-30 yrs.	100	80	Age of first delivery 19-30 yrs.	97	78
No of children-2	98	78	No of children-2	79	63
No of children-3	17	14	No of children-3	23	18

Results 1: Level of UTS among women with SUI and control group

Comparison of pre and post-test II results, reveals between the study and the control groups, in the study 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 rehabilitation with vaginal cone is very effective in reducing the urinary tract symptoms (See Figure 2)

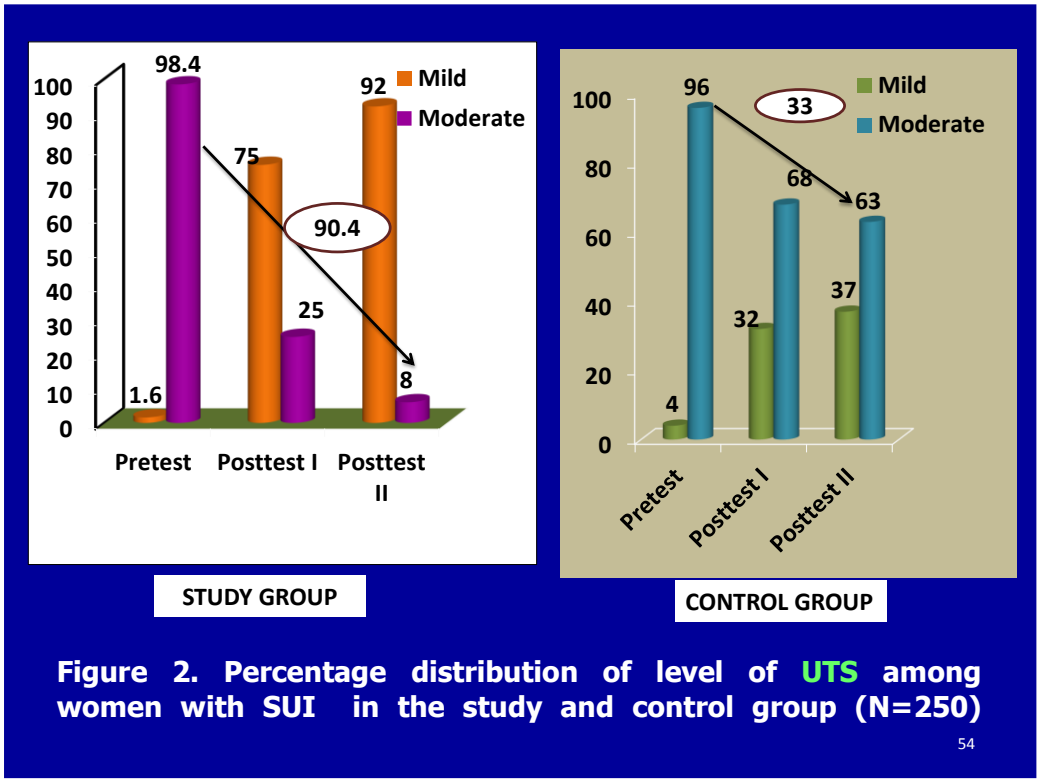


Figure 2. Percentage distribution of level of UTS among women with SUI in the study and control group (N=250)

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We compared the pre-test - post-test I, pre-test - post-test II , post-test I - post-test II Mean, SD, paired t and p value of UTS among women with SUI in the study group (n=125). The below table 3 interprets the comparison of pre-test - post-test II reveals that the urinary tract symptoms had significantly reduced from mean score 23.15 to score 04.89 during the post-test II, which was highly significant at p <0.001 (See Table 3)

Urinary tract symptoms	Mean	SD	Paired t & p value
Pretest [a]	38.69	04.41	29.57
Posttest I [b]	23.15	05.36	.0002***
Pretest	38.69	04.36	35.64
Posttest I	23.15	4.26	29.15
Posttest II	10.85		.0001***

***p <0.001, a-SG (n=125), b- SG (n=120), c- SG (n=108)

In study group there was 21% improvement in pelvic floor muscle strength, whereas in control group only 8% (see below figure 7 and 8)

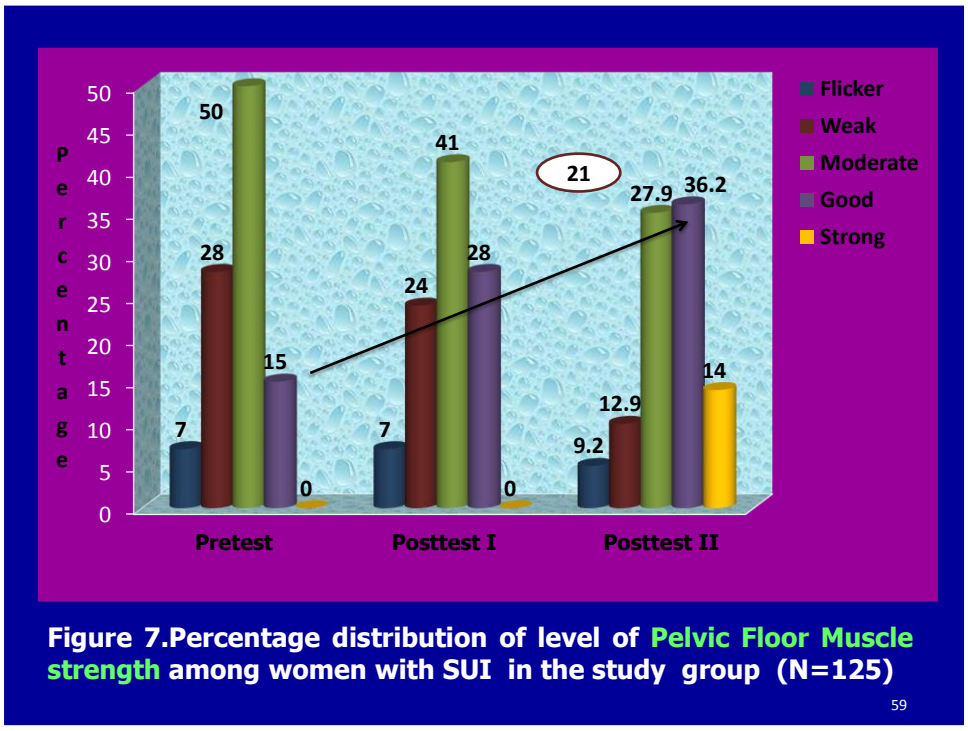

Figure 7.Percentage distribution of level of Pelvic Floor Muscle strength among women with SUI in the study group (N=125)

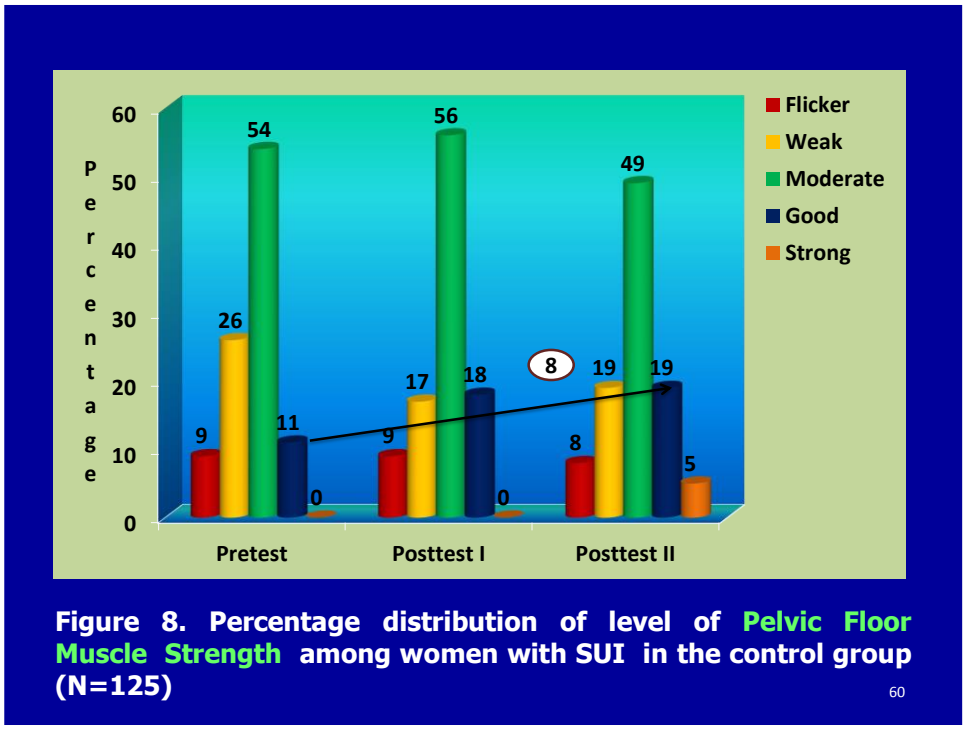

Figure 8. Percentage distribution of level of Pelvic Floor Muscle Strength among women with SUI in the control group (N=125)

Results 2: Comparison of pre-test, post-test I , post-test II Mean difference ,SD , t p value of pelvic floor muscle strength between the study and the control group (N=250)

There was an increase in pelvic floor muscles strength in the study group which was highly significant at the level of p< 0.001. The investigator telephonic reminders and clarification of their thoughts and counselling regarding diet, life style modification and tips to reduce weight could have been contributed to the better results. Regarding Urinary tract symptoms when comparing pre and post-test II results, reveals between the study and the control groups, in the study 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 rehabilitation with vaginal cone is very effective in reducing the symptoms. Considering the frequency of symptoms 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.In respect to voiding symptoms the results showed that the pelvic floor muscle training with vaginal cone had effective in reducing the symptoms when comparing the control group routine pelvic floor exercises. It is evident that the pelvic floor rehabilitation with vaginal cone the supervised training enabled the women to cope up and the urinary tract symptoms IMPACT also reduced (See Table 4)

Duration of Study	Study group (n=125)		Control group (n=125)		Independent t & p-value
	M D	SD	MD	SD	
Pre-test [a] Post-test I [b]	0.41	0.57	0.11	0.39	6.68 0.00**
Pre-test Post-test II [c]	1.05	0.41	0.15	0.54	3.59 0.001**
Post-test I Post-test II	0.64	0.64	0.03	0.69	11.93 0.002**

**p <0.01, a-SG(n=125),CG(n=125),b- SG (n=120),CG (n=117),c- SG (n=108) ,CG (n=104)

Discussion

Even though they were suffering with this condition for long period the social situation arise due to women's participation in family functions, social gatherings, parties, shopping, spending leisure time, travelling has a positive influence to perform the pelvic floor exercises which make the women to become continent. The study supported by Mc Lennan MT et.al (2006) determined the patients received information about possible pelvic floor complications of pregnancy/delivery. Day 1 post-partum women completed a 52-item questionnaire assessing information given during routine antenatal care. Pelvic floor and general questions were intermixed. Of the 232

patients, the mean age was 26.9 years, with 59.5% white, 32.8% African-American and 7.7% other. Most (84.5%) had at least grade 12 education. The following percentage of patients reported receiving no information about Kegel exercises (46.1%); episiotomy (51.3%); urinary incontinence (46.6%); faecal incontinence (80.6%). Counselling on all of these issues occurred significantly less frequent than education on general pregnancy topics. Our results suggest that knowledge and instruction of pelvic floor risks is very much lacking and provides us with an impetus to develop educational tools.

Harbison GP (2012) explored the randomised controlled trials comparing weighted vaginal cones with alternative treatments or no treatment. The study included 23 trials involving 1806 women, among 717 who received cones. Cones than no active treatment (rate ratio (RR) for failure to cure incontinence 0.84, 95% confidence interval (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.

Peattie et al (1988) stated that the sensory feedback from the feeling of the weight on the pelvic floor and the need to increase PFM activity to retain the cone. Bo (1995) studies reported the improvement rate of 70–90%. Goldstein (2010) studied 119 women, aged 55–99, and reported that 27% of these incontinent women believed that incontinence was normal following childbirth. Women who have had children leak more than women who have never had children. In the present study the study group had better results because of the sensory feedback of vaginal cone when comparing to routine care.

Dmochowski (2005) expressed that many women treat their symptoms in private, withdrawing from society, restricting activities, experiencing a decreased quality of life along with an increase in depression and anxiety, years before seeking medical help. As the population continues to age and increasing numbers of patients and clinicians become more familiar with and more comfortable reporting and discussing SUI, it is anticipated that efforts to educate the public about the condition will grow and treatment options will continue to evolve, becoming more available, less invasive and economic.

CONCLUSION

We conclude that the pelvic floor rehabilitation, with vaginal cone, is proven to reduce urinary tract symptoms and improve pelvic floor muscle strength among women with stress urinary incontinence. In this present study, the investigator has identified that usage of vaginal cones and proceeding with the pelvic floor exercises has a more positive significance than in performing the pelvic floor exercises alone. It is evident that performing pelvic floor exercises by using vaginal cones reduced SUI symptoms, urinary tract symptoms impact, increased the pelvic floor strength. Further studies are needed to examine the cost effectiveness of vaginal cone in order to alleviate the burden of UI among women in resource limited countries.

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LIMITATIONS

Vaginal cone is a new concept, duration and pattern of practice was new. Cost effective, intervention based on evidence based practice. Yet, the limitations of the study are highly considered while interpreting the results.

1) Observation of practice at home

The investigator insisted the women to do pelvic floor exercises at home daily, without vaginal cone. But the investigator was unable to observe the practices done by the women, the performance of these exercises was ensured by giving them a daily performance sheet to code their practice of pelvic floor exercises.

2) Vaginal cone was not used for practice at home

The investigator used the vaginal cones only for training the pelvic floor muscles at the time of hospital visits. The investigator had not handed over the cone to practice the pelvic floor exercises at home because she had used separate cone for training the pelvic floor muscles eachtime, as these cones were given had to be cleaned everyday with soap and water before and after using it. It should be placed in a container with water which has to be closed and water should be changed daily and the hands should also be washed every time before and after placing it. If these precautions were not followed it may lead to infections and so the investigator had avoided further complications.

3) Uro dynamic parameters were unperformed

As these parametric measurements are of high cost, the investigator has not included them in this study. Conscription of samples had certain limitations. It included women who had telephone or residential address facilities so that regular follow up was improved. One of the unavoidable limitations is attrition of the samples. Women were lost for follow up to the hospitals, or loss of contact details in both the groups. Although reminders were given there was no response from some of the samples from both the groups.

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