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Vaginal Cone Use in Passive and Active Phases in Patients with Stress Urinary Incontinence and a Study on Effective Sterilization of Vaginal Cone

B. Nivetha[1], R. Janani[2], M. K. Karthika[3]

[1, 2, 3]Bachelor of Physiotherapy, Department of Physiotherapy, Saveetha Institute of Medical and Technical Science, Chennai – 602105, India

Abstract: ***The present study was conducted to determine the effect of detergent washing, boiling water, surgical spirit and autoclave in sterilizing the vaginal cone which is used for the patients with pelvic floor dysfunction. Using simple random sampling method based on inclusion and exclusion criteria. Twenty four patients were selected from Department of Obstetrics and Gynecology, Saveetha Medical College and Hospital, Chennai. Twenty-four women with a clinical and urodynamic diagnosis of stress urinary incontinence were treated with sterile vaginal cones in a passive phase (without voluntary contractions of the pelvic floor) and an active phase (with voluntary contractions), each of which lasted three months. Clinical complaints, a functional evaluation of the pelvic floor, a pad test, and bladder neck mobility were analyzed before and after each phase. Three out of the twenty four samples which was collected after detergent washing showed growth and rest of the samples were inactive. Streptococcus pyogens were the predominant isolated bacteria found. The samples done with boiling water, ethanol and autoclave did not show any growth at all. This study also concludes that the boiling water, ethanol and autoclave can be used for vaginal cone sterilization. Twenty-one patients completed the treatment. The reduction in absolute risk with the pad test was 0.38 (p, 0.034) at the end of the passive phase and 0.67 (p, 0.0001) at the end of the active phase.***

Keywords: Vaginal cones, Sterilization, Detergent, Electromyography, Passive and Active phases

1. Introduction

Vaginal cone is a medically designed device, its outer shell is made up of Polypropylene (PP) and inner weights are made up of stainless steel. It is used in Obstetrics and Gynecology Physiotherapy set up for treating pelvic floor dysfunctions among women. It helps to restore the pelvic floor muscle strength and brings enhanced quality life to the patients. [1] This device is advised to use single handed. This device is costlier as it costs around INR 10000-/- It is not affordable for all women especially women from poor economical background at the same time they are more prone for pelvic floor dysfunction because of their occupation. So the single device is used for multiple patients in hospitals which is covered with male condom as we use vaginal probe in ultra sonogram. So that it does not come in contact with the skin directly thus prevents the spread of infections. Women those who can afford would buy it and use it at their home after consultation with physiotherapist. The effective domiciliary and institutional sterilization is mandatory as it is used in genitals where the crowding of microorganisms occurs. Knowledge about the vaginal normal bacterial flora is of paramount importance for the proper selection of sterilization measures. The genital tracts of women consist of residents' micro floras which are made of a wide variety of species some of which play useful roles to the healthy state of the vagina while others reside there as commensals but may become pathogenic if opportunity arises [2]. The normal microbial flora of the female reproductive tract is based on individual's development and age related. As the infant passes through the birth canal it picks up microorganisms representative from the mothers reproductive tract. The pH of the infant of about one month of age is about 7.0 and the microbial flora is quite diverse with no single organism being dominant. The most common organisms isolated are *staphylococcus epidermis, coryneform* bacteria and the species of *pepto streptococcus bacteriodes, clostridium, Eubacterium.* After puberty the lining of the vagina begins to secrete glycogen, a polysaccharide that favors the colonization and growth of lactobacilli. The Lactobacilli plays a major role in protecting the upper reproductive tract. It is typically dominant and present along with *Staphylococci, Coryneform bacteria Candida, Streptococcus spp. Gardnerellavaginalis, Ureaplasma spp., Bacteroides, Veillonella spp., Bifidobacterium spp., and Clostridium*. After menopause due to hormonal changes the pH varies and it will have microflora similar to infants and prone for more infections [3]. Martins *et al* reported that micro flora is usually harmless until presence of predisposing factors such as trauma or another infection which may be pathogenic and cause disease [4]. It has then also been reported that intravaginal devices constitute a predisposing factor for the vaginitis caused by opportunistic micro-organisms [5, 6]. Hence this study attempt to find out the effective sterilization of vaginal cones meticulously in order to prevent infections in patients.

Stress urinary incontinence (SUI) is defined as the involuntary leakage of urine during effort.[17] It produces serious social and psychological problems that have a significant impact on a woman's health. Normally, the bladder and urethra are supported by endopelvic fascia as well as by ligamentous and pelvic floor muscles. [18] Descent of the bladder and urethra has been observed in women with SUI, and this hypermobility may result from denervation of the levator ani muscle. Thus, pelvic floor musculature, composed of both type I (slow) and type II (fast) muscle fibers, is important in the urinary continence mechanism.[9] Several treatment options are available for managing SUI. Techniques aimed at strengthening the pelvic floor muscles are often considered the first-choice treatment

because of their noninvasive character, the possibility of combining them with other treatments, the low risk of side effects and the moderate-to-low costs.[10] According to a review by Cochrane, pelvic floor muscle exercises must be included in the first line of conservative management programs for women with SUI. [11] The first technique was *described in 1948 by Kegel, 6 who prescribed rapid voluntary contractions of the pelvic floor muscles. The author observed that 70% of the patients improved or were cured. However, even when provided with information on the anatomy and function of these muscles, 30% of the patients were unable to perform adequate voluntary contraction, instead eliciting contraction of the rectus-abdominal, thigh adductor, or gluteus maximus muscles—some patients performed the Valsalva maneuver.[12] The use of vaginal cones to strengthen pelvic floor muscles was initially proposed by Plevnik in 1985. The patients were instructed to walk for 15 minutes twice a day with a cone in the vagina, without making a voluntary contraction despite the sensation of losing the cone. This sensation, however, produced an involuntary contraction of the pelvic floor musculature, as shown by electromyography of the pelvic floor during the use of a vaginal cone. [13] In a study with rats, analysis of the functional and histological effects of intravaginal electrical stimulation [14] revealed that 5-second contractions increased type II fibers but not type I fibers. In terms of the SUI treatment, some authors were equally successful with both the vaginal cone therapy recommended by Plevnik, which involves slow fibers, and with the pelvic floor muscle exercises, which involve fast fibers.[15] Thus, we wanted to evaluate the utilization of vaginal cones in associated passive and active phases; such use might produce an additional recruitment of type I and II fibers in the pelvic floor.

2. Materials and Methods

Using simple random sampling method 24 married women between 18-65 years diagnosed as having pelvic floor dysfunction (Urinary/fecal incontinence, second degree pelvic organ prolapse, and sexual dysfunction) by gynecologist were taken from Department of Obstetrics and Gynecology, Saveetha medical college and Hospital, Chennai. Those who have intra uterine devices, active menstrual cycle, clinically diagnosed active/ recurrent Vaginal infections, Urinary tract infections, warts, antenatal and post natal women within two months, were excluded from the study. After briefing them the procedure, informed consent was taken. The patient was given pelvic floor exercise with bare vaginal cone two times a day for fifteen minutes. Under the supervision of physiotherapists the vaginal cone was taken out of the vagina and was washed with bathing soap by the patient and air dried then the sterile cotton swabs were swabbed gently on the surface of vaginal cones for bacteriological studies The pelvic floor exercise was given in evening session and the vaginal cone was put into the boiling water for 5 minutes. Then the cone was taken out, air dried and sample was taken with as shown in Figure 1. The next day the same exercise protocol was followed and the sample was taken after soaking the cone in 70% of ethanol (surgical spirit) and autoclaved1210celsius for 15 minutes at 15 lbs.

Figure 1: Swab collection from vaginal cone

The sample was noted. Four samples were collected from single patient at different timings through different procedures and swab was taken from the surface of the sterilized vaginal cone of different cleansing, disinfectant and sterilization procedure. Each swab was cultured immediately or stored in a transport medium until cultured.

Bacteriological study

For all types of samples usually Blood agar, MacConkey agar and chocolate agar is used as culture media because of its cost effectiveness and suitable for gram positive and negative organism whereas new Granada medium is costlier and the nutrient agar will allow all the organisms to grow and it will be hard to differentiate the organisms. So we have used these three standard agars. Blood agar is a solid culture medium consists of agar, peptone and sheep blood. It is enriched, non selective medium use for general purpose medium as it supports the growth of both aerobic and anaerobic bacteria. It is used to culture those bacteria or microbes such as *Haemophilus Influenza, Streptococcus and neisseria* species that do not grow easily. Chocolate agar is also a solid culture medium made by heating the mixture of sheep blood and nutrient agar. During the process red blood cells are disrupted and it contents such as haemoglobin, hemin, nictoniamide adenine dinucleotide. The species that require this medium for growth includes *Neisseria gonorrhoeae, Neisseria meningitidis* and *Haemophilus spp.* Mac conkey agar is used to differentiate between various gram negative rod shaped organisms. It also used to inhibit the growth of gram positive organisms. It is differential and as well as selective. It is primarily used for isolation of members of enterobacteriaceae and Pseudomonas spp. All the plates were prepared and are streaked using inoculation loop.

Identification of bacterial isolates

The initial examination of colonies was made by naked eye and using a dissecting microscope. The colonies seen were described in terms of their morphological characters such as size, elevation, outline, color and their effect on the medium and these were recorded.

Colonies were presumptively identified by these characters and their identity confirmed by further tests. Smears were made from colonies of interest, fixed and stained by Gram's Method. Morphology and the staining reactions were recorded. The combination of colonial morphology, growth conditions, bacterial morphology and reaction to gram stain were used to reach a presumptive identification. The

biochemical tests were performed as catalase, oxidase. IMVC test (indole production, methyl red, vogasproskauer and citrate utilization), TSI (triple sugar iron). The culture media prepare depended to routine methods.

Patient Description

Twenty-four women with SUI, according to clinical and urodynamic evaluations, were consecutively selected for study at the Gynecology Division, Department of Obstetrics and Gynecology, Saveetha medical college and Hospital. This study was approved by the Internal Review Board of the institution and all patients signed an informed consent form prior to the study. The mean age of the patients was 34 years (28–40). Nineteen women were multiparous, with at least two vaginal deliveries each; three reported only one vaginal delivery; one had undergone two cesarean sections; and one was nulliparous. The average number of vaginal deliveries per patient was 2.3. All patients were white, and the body mass index (BMI) mean was 25.5 kg (mean weight, 66 kg). The diagnosis of SUI was based on clinical history, a urogynecological examination, and a urodynamic evaluation.

Pelvic floor strengthening methods

During the urogynecological examination, the patients were assessed and classified according to the pelvic organ prolapse quantification (POPQ):12 17 patients were in stage II, while 7 were in stage I. The exclusion criteria comprised surgical treatment for SUI, clinical treatment for SUI in the 6 months prior to the study, use of medication affecting the lower urinary tract, inability to contract the pelvic floor muscles voluntarily, inability to keep cone number 1 (the lightest) in the vagina, pregnancy, menopause, diabetes mellitus, chronic pulmonary obstructive disease, genital prolapse stage III or IV, 12 neurological abnormalities of the perineal region, cervical infection, urinary tract infection, pelvic tumors, overactive bladder, or intrinsic sphincteric deficiency. Vaginal cones are stainless steel devices with a plastic coating and a nylon thread at their apex to facilitate their removal. A set of 5 cones of similar shape and volume was used, numbered from 1 to 5 and weighing 20.0, 32.5, 45.0, 57.5, and 70.0 grams, respectively.

Prior to the treatment, the patients were taught how to contract their pelvic floor muscles correctly. The treatment consisted of two 3-month phases. The first was the passive phase, and the second, the active phase. In the passive phase, as recommended by the majority of authors, 2 while in a standing position, the patient introduced the heaviest cone she could keep in her vagina with the apex pointing toward the pelvic floor. The sensation of losing the cone produced involuntary contractions of the pelvic floor musculature. The patient initially introduced cone number 1; if she did not feel the sensation that it was slipping out, cone number 2 was then inserted; the replacements continued with consecutively heavier weights until a sensation of loss was perceived. The patient was then instructed to walk and not to contract her pelvic floor musculature for one minute and to report any sensation of losing the device. We thus identified the initial ‘‘passive cone.’’ The subject was instructed to walk for 15 minutes twice a day with the passive cone in her vagina without voluntarily contracting her pelvic floor muscles. When the patient no longer felt the cone was falling from her vagina, the next heaviest cone was used. This procedure was continued for three months. The active phase was initially performed with the heaviest cone the patient was able to retain in the vagina in a standing position for one minute via voluntary contraction of the pelvic floor muscles. To find the correct cone, the patient started by introducing the next heaviest device used at the end of the passive phase. If she was able to retain it in the vagina easily, she tried to use the next heaviest cone. Replacements continued until the cone fell from the vagina, in which case, the subject would begin the active phase with the previous cone. If the patient ended the passive phase with cone number 5, she would start the active phase with the same number device. After identifying the ‘‘active cone, ’’ the patient was instructed to perform 30 voluntary contractions of 5 seconds each, alternating with 5 seconds of relaxation, twice a day, in a standing position. When she was able to retain the cone easily, the next heaviest device was used. The patients were evaluated once a week by the author, and he determined whether they were using the vaginal cones correctly. Three patients abandoned the study after completing the passive phase and were excluded from the study. One moved from the city, and the other two preferred to seek surgical treatment. Clinical and ultrasonographic evaluations were performed before and after each of the two phases. The clinical assessment consisted of an analysis of clinical complaints, a functional pelvic floor evaluation, and a pad test. Ultrasound was used to estimate bladder neck mobility and thus to indirectly evaluate pelvic floor muscle strengthening. The severity of incontinence was subjectively determined through the patient’s report of her clinical response to the treatment and her satisfaction with it. For analytical purposes, the patients were divided in four groups as follows: a) unchanged; b) improved but unsatisfied with the treatment; c) improved and satisfied with the treatment; d) completely dry. Satisfaction with the treatment meant the patient did not want another treatment option; therefore, she was analyzed only at the end of the study.[23]

Pelvic floor muscle function was evaluated according to the grading system proposed by Ortiz et al., 1994. The patients were put into the gynecological position and instructed to contract the pelvic floor muscles for five seconds. The following scores were used to report the results of this procedure:

0: Neither visual sign nor digital perception of vaginal muscle contraction
1: No visual sign of muscle contraction, but perception of a weak contraction upon vaginal palpation
2: Weak muscle contraction upon both visual survey and vaginal palpation
3: Good muscle contraction at both visual survey and vaginal palpation but with no resistance to palpation
4: Strong muscle contraction at both visual survey and vaginal palpation but with less than 5 seconds of resistance to palpation
5: Strong muscle contraction at both visual survey and vaginal palpation with 5 seconds of resistance to palpation

Musculature was considered weak if the score of the functional pelvic floor evaluation was less than 3.15 Urine loss was evaluated using the 1-hour pad test with a standardized bladder volume13, 16 when 250 ml were

introduced by catheter into the bladder. Pad weights were measured in grams, and a weight of less than 2 g was considered normal. Bladder neck mobility was assessed by introital ultrasound with the patient in a standing position and with an intravesical volume of 200 to 250 ml, as defined by transabdominal ultrasonography (Sonochrome, General Electric) using a 5 MHZ vaginal transducer. The distance between the bladder neck and the pubic symphysis was measured at rest and during stress maneuvers (Valsalva). Measurements were made according to an orthogonal system of Cartesian coordinates, using the inferior limit of the pubis symphysis as the point of origin. Bladder neck mobility from rest to stress was measured in millimeters.

Less than 10 mm of bladder neck mobility was considered normal. In the statistical analysis, Pearson's chi-square test, Fisher's exact test and Student's t-test were used to analyze the pad test, the bladder neck mobility, and the functional pelvic floor evaluation at the end of each of the two phases. P, 0.05% was considered statistically significant. An intention- to-treat analysis was also performed.

3. Results

The result of the bacteriological examination for the twenty four patients. The presence of streptococcus pyogens was found in all the three samples which have shown growth. The rest of the twenty one samples do not shown any growth.

Then the results showed that 21 (87.5%) patients completed the treatment. Three women (13.5%) withdrew from the study: one moved from the city and the other two requested surgical treatment The absolute risk of the pad test (.2 g) at baseline was 1. At the end of the passive phase, the reduction in absolute risk was 0.38 (p = 0.0034); at the end of the active phase, this value was 0.67 (p, 0.0001). In the intention-to-treat analysis (24 patients), the absolute risk at baseline was 1 (.2 g), while the reduction in absolute risk at the end of the passive phase was 0.33 (p = 0.0039); at the end of the active phase, this value was 0.58 (p, 0.0001). When comparing the variation in mean values between the passive phase endpoint and the baseline (16.11 g) with that between the active phase endpoint and the baseline (18.39 g), the difference was 2.28 g (p = 0.61). The absolute risk of the functional evaluation of the pelvic floor (#3) at baseline was 0.81. At the end of the passive phase, the reduction in absolute risk was 0.62 (p, 0.0001); at the end of the active phase, this value was 0.77 (p, 0.0001). In the intention-to-treat analysis (24 patients), the absolute risk at baseline was 0.83 (#3), while the reduction in absolute risk at the end of the passive phase was 0.65 (p = 0.0004); at the end of the active phase, this value was 0.66 (p, 0.0001). When comparing the variation in mean values between the passive-phase endpoint and the baseline (1.09) with that between the active-phase endpoint and the baseline (1.61), the difference was 0.52 (p = 0.01). The absolute risk of bladder neck mobility (.10 mm) at the baseline was 0.95. At the end of the passive phase, the reduction in absolute risk was 0.38 (p = 0.0089); at the end of the active phase, this value was 0.52 (p = 0.0005). In the intention-to-treat analysis (24 patients), the absolute risk at baseline was 0.95 (.10 mm), while the reduction in absolute risk at the end of the passive phase was 0.33 (p = 0.01) and 0.45 (p = 0.0007) at the end of the active phase. Comparing the variation in mean values between the passive-phase endpoint and the baseline (4.80 mm) with that between the active-phase endpoint and the baseline (6.55 mm), the difference was 1.75 mm (p = 0.12). With respect to the clinical questionnaire, 12 (57.1%) patients reported complete recovery; 7 (33.3%) reported improvement and satisfaction; and 1 (4.8%) reported no change. Thus, 19 (90.4%) patients were satisfied with the treatment, and 10 (47.6%) patients, who showed improvement at the end of the passive phase, were found to be cured at the end of the active phase. These results were statistically significant (p = 0.0002).

4. Discussion

There are three types of decontaminations. First is cleansing- the physical removal of microbes contamination using detergent in running water or 40- 55 degree Celsius water. Researchers say that there is a chance for growth even in 80 degree Celsius heating. Second is Disinfection – removal of bacteria or reduction of bacterial count by chemical disinfectant such as ethanol or temperature of 90 degree Celsius. It may kill all the microbes but spores will remain the same. Third is sterilization- the name itself says it's sterile. Removal or destruction of all microorganisms including spores. It is done using the chemical sterilization such as glutraldehyde, 70% of ethanolor 6% of hydrogen peroxide or using steam heat at 121 degree Celsius or 136 degree Celsius. In our study we have found the lower percentage growth of streptococcus pyogen from the vagina of pelvic floor dysfunction patients[28-29]. The growth was found in three samples out of twenty four samples cleansing done with soap wash in running water. This might be due to the soap used by the patient might not be that effective in killing the microbes and we have not prescribed the specific brand of soaps because practically we cannot do that when we advise sterilization. Because when it comes to soap washing people use different soaps and if we prescribe specific soaps the constraints such as easy availability of the product, acceptability of the product by the patient and affordability all matters. Birmingham women's foundation NHS foundation trust given instructions for the use of vaginal cones to their patients and they suggested washing the cone with soap and keeping it dried. The twenty samples cleansed with boiling water, surgical spirit and autoclave did not show any culture of microbes. The weight and dimensions of the cone remained the same. These disinfectant methods are quite reliable in this case. Heat is considered to be most reliable method of sterilization. Heat acts by oxidative effects as well as denaturation and coagulation of proteins. Those articles that cannot withstand high temperatures can still be sterilized at lower temperature by prolonging the duration of exposure 9. In the warm water there is a chance for spores to get multiplied. So boiling water is recommended as the boiling point of water is 100 degree Celsius. Autoclave can be used if the need of more heat and long exposure is necessary.

The majority of authors recommend only passive use of this technique.[18, 15, 19, 20] In our study, cones were used in two different phases, passive and active, to stimulate the use of muscle fiber types I (slow) and II (fast). In the passive

phase, type I fibers were stimulated when the contractions were prolonged.[21] However, in the active phase and during the exercises proposed by Kegel, there was an increase in the use of type II fibers. With reference to the objective evaluation of this therapy, most investigators recommend the pad test, as suggested by the International Continence Society (ICS). However, one may claim that improvement was possibly due to the variation in intravesical volume.[26] We chose to use the pad test indicated by the ICS, but we adopted an intravesical volume of 250 ml, which was perfectly well tolerated by the patients. We found a significant reduction in the absolute risk at the end of the passive and active phases, including in an intention-to-treat analysis, perhaps owing to the complementary recruitment of type I and II muscle fibers during muscular contraction of the pelvic floor.

5. Conclusion

From this study it is concluded that the boiling water and soap washing can be used economically for domestic sterilization of vaginal cone which was handled by single person. It's better to use the boiling water which is proven to be more effective compared to soap washing. 70% ethanol (surgical spirit) and autoclave was recommended for institutional (hospital) sterilization. Though vaginal cones were washed with soap and boiling water minimized or eliminated bacterial growth there is a chance of opportunistic pathogen due to the presence of spores. Autoclave gives sterility to the vaginal cone. Otherwise based on Food and Drug administration recommendation the chemical sterilization with 2% of gluteraldyhyde, 70% of ethyl alcohol or 6% of hydrogen peroxide could be done to achieve sterility. In conclusion, using vaginal cones in the passive phase, as other researchers have done, was effective. Inclusion of the active phase induced additional improvement in all of the study parameters for women with stress urinary incontinence. Randomized studies are needed, however, to confirm these results.

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