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A STUDY ON EFFECTIVE STERILIZATION OF VAGINAL CONE USED FOR PELVIC FLOOR DYSFUNCTION PATIENTS.

G.DEEPTHI[1*], MANIPRIYA[1], DR.PRATHAP SUGANTHIRABABU[2], DR.HEPZIBAH KIRUBAIMANI[3], P.SANKARA KUMARAN[4], J. LAVANYA PRATHAP[5], AND HEMA SWAROOPA[6]

*[*1]Lecturer, Department of Urology & Obstetrics Physiotherapy, Saveetha College of physiotherapy,Saveetha University, Chennai.*
[1]Medical MSC second year, Department of Microbiology, Saveetha Medical college and hospital,Saveetha University, Chennai.
[2]Assistant professor, College of allied health sciences, Gulf medical university, Ajman, UAE.
[3]Professor, Department of Obstetrics & Gynaecology, Saveetha medical college & Hospital, Chennai.
[4]Lecturer, School of Physiotherapy, AIMST University, Malaysia.
[5]Adjunct Assistant Professor, Department of bio medical sciences, Gulf medical university, Ajman, UAE.
[6]MPT second year, Department of Urology and obstetrics physiotherapy, Saveetha college of physiotherapy, Saveetha University, Chennai

ABSTRACT

The vaginal cone is a medically designed device used as resistance for pelvic floor training. Resistance training is nothing but making the muscles to contract against an external resistance. It increases muscle strength, tone, mass, and/or endurance. Since this device is administered in genital tract it requires effective sterilization as it has high chances for spreading infections when the same cone is used for many patients in hospital set up and there are chances for recurrence of the infections in individuals if persists when it is used single handed. So the effective sterilization is mandatory. 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 patients were selected from Department of Obstetrics and Gynecology, Saveetha Medical College and Hospital, Chennai. The patient was given pelvic floor exercise with vaginal cone for fifteen minutes twice a day under the supervision of physiotherapists and the vaginal cone was taken out of the vagina and was washed in the running water with normal bathing soap, air dried and sample was taken with sterile cotton swab by swabbing it over the cone. Then the same procedure was repeated by putting the vaginal cone in boiling water for 5 minutes, surgical spirit and autoclave in consecutive sessions. The sample was given for culture using three different medias. Three out of the twenty samples which was collected after detergent washing showed growth and rest of the samples were inactive. Streptococcus pyogen were the predominant isolated bacteria found. The 20 samples done with boiling water, ethanol and autoclave did not show any growth at all. This study concludes that the boiling water, ethanol and autoclave can be used for vaginal cone sterilization. The detergent washing can also be used with precautions and combined with other methods for domiciliary sterilization and it needs further more research with large sample size.

KEYWORDS: *vaginal cone, boiling water, ethanol, autoclave, domiciliary sterilization, Institutional sterilization.*

G.DEEPTHI*

Lecturer, Department of Urology & Obstetrics Physiotherapy, Saveetha College of physiotherapy, Saveetha University, Chennai.

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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.

MATERIALS AND METHODS

Collection of Samples

After getting human ethical clearance (018/04/2016/IEC/SU) (sub study) comparative study was carried out. Using simple random sampling method 20 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 autoclaved121^{0}celsius for 15 minutes at 15 lbs as shown in Figure 2.

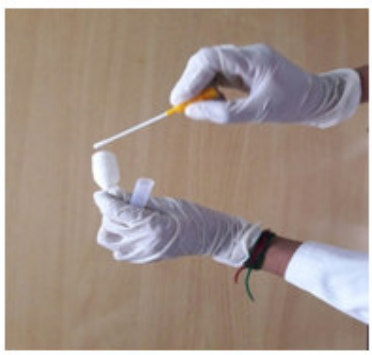

Figure 1
Swab collection from vaginal cone

Figure 2
Sterilizing vaginal cone in autoclave

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 as shown in Figure 3

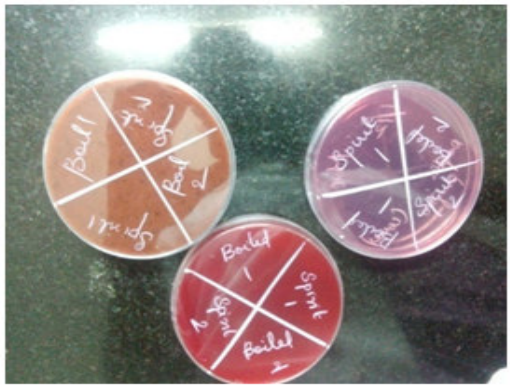

Figure 3
Bacterial Plates

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.

Findings

The result of the bacteriological examination for the twenty patients were described in Table: 1

Table 1
Bacteriological results

S.No	Patient sample	Observation			
		Detergent	Boiling water	95% ethanol	Autoclave
1.	Sample 1	No growth	No growth	No growth	No growth
2.	Sample 2	No growth	No growth	No growth	No growth
3.	Sample 3	No growth	No growth	No growth	No growth
4.	Sample 4	No growth	No growth	No growth	No growth
5.	Sample 5	No growth	No growth	No growth	No growth
6.	Sample 6	No growth	No growth	No growth	No growth
7.	Sample 7	No growth	No growth	No growth	No growth
8.	Sample 8	10^3 CFU/ml	No growth	No growth	No growth
9.	Sample 9	No growth	No growth	No growth	No growth
10.	Sample 10	No growth	No growth	No growth	No growth
11.	Sample 11	No growth	No growth	No growth	No growth
12.	Sample 12	No growth	No growth	No growth	No growth
13.	Sample 13	No growth	No growth	No growth	No growth
14.	Sample 14	10^2 CFU/ml	No growth	No growth	No growth
15.	Sample 15	No growth	No growth	No growth	No growth
16.	Sample 16	No growth	No growth	No growth	No growth
17.	Sample 17	No growth	No growth	No growth	No growth
18.	Sample 18	No growth	No growth	No growth	No growth
19.	Sample 19	No growth	No growth	No growth	No growth
20.	Sample 20	10^3 CFU/ml	No growth	No growth	No growth

The presence of streptococcus pyogen was found in all the three samples which have shown growth. The rest of the seventy seven samples do not shown any growth.

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[8-9]. The growth was found in three samples out of twenty 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.

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.

CONFLICT OF INTEREST

Conflict of interest declares none.

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