



Use of Flow care Menstrual Cups over Conventional Menstrual Products in India

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ABSTRACT

There are a number of options available in the market to tackle with menses i.e. tampons, sanitary pads made by polymers, locally made sanitary pads. Many people use unhygienic methods like untreated cotton rags, grass, husk, wood ash. Existing sanitary products possess substantial threat from Toxic Shock Syndrome (TSS), Toxic Shock like Syndrome (TSLs), Bacterial Vaginosis (BV) and other forms of infections due to its contents. 65% of the user's experience staining or leaking with existing methods. Flowcare menstrual cup is ergonomically designed to handle voluminous flow for an extended period of time without the aforementioned risks. It is manufactured from medical grade silicone copolymer and is safe for use. Also, Flowcare menstrual cup condenses the environmental hazards like incineration and landfill making it one stop solution for the problem.

Keyword: Sanitary Pad, Tampons, Toxic Shock Syndrome, Menstrual Cup.

1. INTRODUCTION

Vaginal devices have a long and intriguing history. In the US, the first device was patented in 1867. These devices have been intended for menstrual collection, contraception, uterine pelvic support, drug delivery, and as a conception aid for retention of semen over the cervix [1]. Menstrual management is a vital part of human existence and if not managed properly it has an adverse effect on the lives of women. Even though the human race is developing and adapting at an astonishing pace there are various taboos associated with menstruation. It is common for menstruating women to be confined at home or is considered too impure and spurned [2]. Many developed countries have started using disposable sanitary pads, cups, and tampons. But even though it is considered to be the hygienic approach to tackle menses its aftermath is highly precarious, as there arises another problem of disposal of these products. In context to population, the world number two has the population over 1,33,61,91,444 and is rising at a staggering rate of 1.26% per year. Out of which 356 million females lie in the menstruating category, and menstruate every month. Mere 12% of the menstruating females in India have access to disposable sanitary pads or tampons; whereas the rest resort to impromptu items like old cotton cloth or wool, ash, grass, husk or even using minimum number of pads which leak, smell and chafe, causing them stigma shame and discomfort [3]. Using this unhygienic approach can cause TSS, TSLs, BV and other vaginal bacterial infections. Due to increased efforts of Indian Government and NGO's slowly and steadily people are educated and gradually shifting their interest to a more civilized alternative. Approximately a female use 15-20 pads a month, computing we can deduce that in her lifetime she would use 8,000-14,000 pads [4]. Computing the data and tabulating, it is clear that each year due to growing population and literacy rate in India usage of pads will increase, but along with it, the need to dispose of pads according to WHO guidelines is also necessary.

Table 1: Estimated Number of Sanitary Pads to Be Disposed Between 2017-21

Year	Estimated Percentage of female having access to pads	Number of menstruating females each year	Women using pads each year	Avg. Number of Pads used each year	Number of Pads to be disposed of each year
	(%)				
2017	12	356 million	42.72 million	216	9227.52 million
2018	14	358.17 million	50.14 million	216	10831.06 million
2019	16	360.35 million	57.65 million	216	12453.69 million
2020	18	362.54 million	65.25 million	216	14095.55 million
20		364.75 million	72.95 million	216	15757.20 million

According to the official guidelines, pads cannot be disposed of without proper disinfectant. Or else they can be incinerated at 800°C in an electric incinerator, which in turn will convert pollution from one form to another. Sanitary pads and tampons take 500-800 years to decompose completely in a natural environment. The top weave sheet is made of polypropylene, middle sheet is made up of wood pulp and super absorbent polymers (SAP's). Whereas the leak proof layer is made up of polyethylene polymer. 90% of the material used are non-biodegradable. Since company made sanitary pads are expensive for females in India and to cope with the prices they use local made sanitary pads which often contains potential life threatening chemicals such as Bisphenol A and Bisphenol S which complicate embryonic development. In order to give proper flexibility to pads, various plasticizers are added which can damage organs. Fibers in the absorbent pads can also be the cause of cervical cancer. Dioxin present in the menstrual pads can be the reason for ovarian cancer. Likewise, while growing cotton in the fields farmers spray Furan; a toxic biocide which stays in the cotton fibers for a long period of time. Another option to tackle menstrual flow are tampons. Tampons are super adsorbent sticks made of a compressed polymer which can absorb high flows. Tampons are intravaginal devices and often increase the risk of infection if not used properly. Also the risk of TSS, TSLS exponentially increases if tampons are used for more than 3-4 hours. The normal pH of the vagina is 3.8-4.5 and bacteria's present are Lactobacillus acidophilus, Lactobacillus crispatus, Lactobacillus gasseri, Lactobacillus prevotella, Ureaplasma urealyticum, mycoplasma hominis etc. aforementioned bacteria's are considered to be healthy bacteria which help maintain the pH of the vagina and also prevents it from other vaginal infections [5]. But during the menstrual period the pH of the vagina changes substantially and reaches up to 7.4 due to a sudden change in pH various bacteria's such as E. coli salmonella, Staphylococcus aureus tend to develop [6].

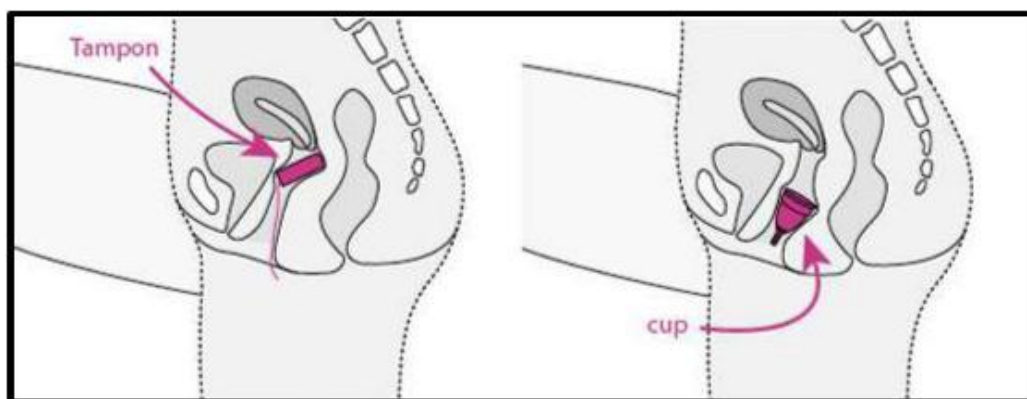


Fig 1: Position of Flowcare menstrual in the vagina

Also *Gardnerella vaginalis* creates a biofilm which allows other opportunistic bacteria's to grow on the epithelial tissue's and cervical walls which can cause Bacterial vaginosis; characterized by fishy smell. *Trichomonas vaginalis*; are a type of parasites that should be treated with proper medication [7]. Therefore, if tampons are used they absorb the menstrual blood but also absorb all the bacteria's making the vaginal pH unstable and thus further increasing the risk of above-mentioned infections along with TSS. Also if the flow is high then pads, cloth, and tampons become soggy thus leaving a squishy feeling about it and leaving the user in an inappropriate condition. Also if they are not replaced at the earliest there are chances of clothes getting stained and making it a public embarrassment in front of the society [8]. In various remote areas of India, females tend to use cotton rags which contain phthalates which harm their reproductive system. Also, people are reported using grass which may have fungicides and also contain bacteria's and fungi which can prove fatal. Husk is another material that women use to absorb flow, but since the skin of the husk is very rough it can scratch the internal walls and tissues leaving it vulnerable to bacteria's and yeast [9][10].

1.1 Description about Flowcare menstrual cup

Flowcare menstrual cups are an ergonomically designed bell shaped cup to hold the menstrual blood without leaving the user squishy and free from stains [11]. Also, these cups are premeditated to handle more volume of secretion as compare to other products. Flowcare menstrual cup is built from medical grade silicone free from latex and are inert with the human body and does not possess any threat from chemicals [12]. Cups also provide a reduced risk of TSS, TSLS and other bacterial infections as compared to other marketed products. Flowcare menstrual cup is available in two sizes which are classified on a volume basis. 10 ml cups are intended to be used by teenage females whereas 15 ml cups should be used by females who are above the age of 20. Physical specifications of the cups are disclosed in table – 2.

Table 2: Specification of the Menstrual Cups

Capacity	Diameter	Length	Weight
10 ml	39.96 mm	51.1 mm	12 gm
15 ml	45.46 mm	58.5 mm	15 gm

The rim of the cup is pliable and hence it can be squeezed in a C shape form to facilitate smooth insertion. Once inserted, flow care menstrual cup opens in an oval shape and positions itself between the posterior fornix and the notch behind the pubic bone, covering the cervix [13]. All day to day activities can be performed without the risk of cup becoming soggy as in the case of other menstrual products. Removal of the cup is accomplished by inserting a finger and pulling the stem below the menstrual cup to facilitate easy and hassle free removal [14]. Menstrual cups are an Intrauterine device (IUD) compatible and do not have created any interference in its functioning.

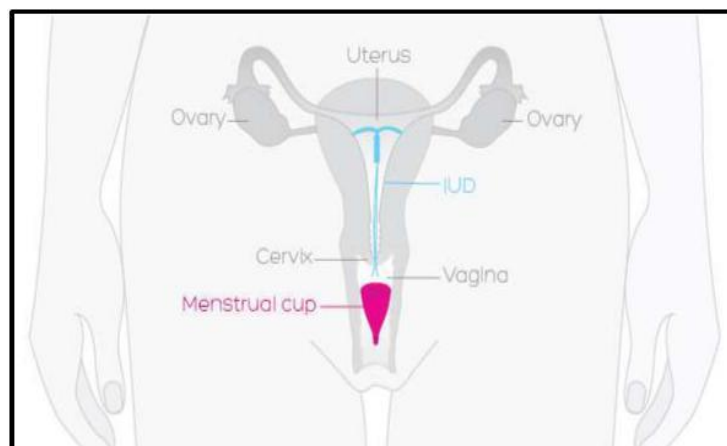


Fig 2: Compatibility of menstrual cup with IUD's

2. MATERIALS AND METHODOLOGY

Flowcare menstrual cups were tested for skin irritation also known as Draize test carried as per the section IP 2014/SPECIFICATIONS/IS 4011-1997. 25 menstrual cups were randomly selected and tested for the same. Six albino rabbits were clipped free from hair on the back on the day prior to the test. Four areas on the back spaced approximately 2-3 cm apart were designed for the position of the patches and three products and one positive control simultaneously tested on each animal. Patch measuring on approximately 10cm² consisting of 12 ply surgical gauze was placed on thin polythene sheet which in turn was placed on a suitable surgical adhesive plaster tape. 0.5 gm of preparation was applied on the surgical gauze. 5% sodium lauryl sulphate was applied as a positive control. The entire trunk of the rabbits was wrapped with canvas bandage. The patches were removed after 24 hours and the skin sites were scored then for 0 hour and 48 hours. The product surpassed the standards and achieved the score of 6.67 against the standard which states that the score should be more than 5 for positive control of primary irritation index.

3. PREMARKET HUMAN SURVEY

A multicenter study was conducted to establish the safety, efficacy, and adequacy of the flow care menstrual cup. Initially, one hundred females participated in this study and filled out an anonymous questionnaire after reading an information leaflet. Both were available in the waiting area of the clinic. 7% percent of the women stated that they use tampons as their menstrual tool where as an astonishing 82% women use sanitary pads both that are branded as well as locally made. While 11% of the females use both tampons as well as sanitary pads. Only 31% females were satisfied with their existing products. On speaking with a medical practitioner, women and teenage girls complained about soggy feel after the flow, potential fear from stains in public and also school girls admitted dropping out from school during their menstruating days. 60% females confessed of changing pads and tampons only once a day; which increases the risk of TSS substantially. The age of the participants ranged from 14-55 years and was in good health. After watching a short awareness video and consulting with doctor patients started using flow care menstrual cups. After 8 weeks the same subjects were asked to complete the study and out of which 43% females rated the cup as better than pads, tampons, cloth. 36% subjects rated cup as equal to pads or tampons whereas 21% thought that they are not as good as pads and tampons. 57% females would consider using a menstrual cup in future. Out of all the females who used menstrual cups 64%, women found the insertion of cup difficult for the first time, whereas almost all women had no issues removing the cup. The difficulty with insertion reduced from 65% to 18% over the period of time along with its usage. 76% women who previously had complained about staining were satisfied with the overall performance of the cup since no staining was observed. 12% women suggested using flow care menstrual cup overnight for heavy flow. Whereas, 3% of the overall users found the cup to misfit.

4. CONCLUSIONS

Evaluating the study undertaken it was deduced that most of the women would use the menstrual cup as a tool to tackle messes. And the number of users showed affirmative signs to use cups in future as they get acquainted with it. Also, the flow care menstrual cup is economically feasible to use as compared to other menstrual products and 85% women were willing to purchase menstrual cup as it was economical for them as one menstrual cup can be used for 3 years. Out of our test subjects, 16% were office going women and were satisfied with the performance of the cup as there was no sign of messiness as in case of pads and tampons. Since the cups could hold more volume the need to change them was considerably reduced making it suitable for working women. Pyrogen testing and premarket study indicated no adverse health issues. Flowcare menstrual cup was acceptable to most users in relation to comfort, ease of use, and effectiveness in menstrual flow collection. A heavy flow can be tackled with changing the cup more frequently. The acceptability and safety of the flow care used as a menstrual collection device have been well appreciated by the users of the menstrual cup. Cup is a better and safe alternative towards menses and also helps reduce the environmental risk.

5. ACKNOWLEDGEMENT

We thank Dr. Gayatri Kulali, B.M.S, and Mumbai, India for her continued support for conducting the premarket study and guiding subjects to use cup as an alternative to other menstrual products. Also, she did not charge patients using a menstrual cup in order to assist them with their problems.

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