Abstract:

Background: Addressing insufficient menstrual care has been a prolonged and significant health concern. A rising number of women are embracing sanitary pads as a dependable and secure choice, as compared with menstrual cups. In contrast to menstrual cups, which collect fluids without absorption, sanitary pads provide an alternative that minimizes the risk of infection and other potential health issues.

Objectives: To compare the efficiency of menstrual cup vs sanitary napkins in healthy women. To compare the ease of daily activities with the use of menstrual cup vs sanitary napkins in healthy women. To compare the tolerability of menstrual cup vs sanitary napkins in healthy women. To compare the satisfaction score with the use of menstrual cup vs sanitary napkins in healthy women. To assess the acceptability and willingness to continue menstrual cup in healthy women.

Methods: A randomized two-way crossover study was conducted involving 100 women divided into two groups. One group, consisting of 50 participants, used a menstrual cup for at least six consecutive cycles followed by a sanitary pad, while the other group followed the reverse order. Participant data were collected through an online questionnaire utilizing a Likert scale.

Results: When compared between the two groups, the self-reported scores for the accessibility and ease of use of sanitary pads remained higher than the menstrual cup throughout the study period. The self-reported scores for comfort, leakage protection and discretion for the use of menstrual cups were initially lower than the sanitary pads, however, there was an improvement in the scores from the third cycle and at the end of the study period. When assessed in terms of overall improvement, the scores for menstrual cups were significantly better than the scores for sanitary pads, especially in the later cycles (with increase in use). Overall 66.04% of the cases preferred menstrual cups over sanitary pads at the end of the study period.

Conclusions: The overall improvement with each cycle for menstrual cups is significantly better than with sanitary pads. However, sanitary pads still remain as the preferred option in the initial cycles of menstrual cup. There is an improvement in all the scores with the learning period with menstrual cups.

Keywords: Menstrual Cup, Sanitary Pad, Menstrual Hygiene, Sanitary Products.
Despite the growing popularity of menstrual cups, sanitary pads continue to be widely used due to their convenience and familiarity. The comparative advantages and disadvantages of these two commonly used menstrual hygiene products are not yet fully understood, particularly in the context of user preferences, satisfaction, and environmental considerations.

This prospective, randomized, two-way crossover study aims to address this gap in knowledge by comprehensively evaluating the effectiveness, user satisfaction, and environmental impact of menstrual cups compared to sanitary pads. By adopting a two-way crossover design, we aim to provide a nuanced understanding of individual preferences and experiences, considering both objective metrics and subjective parameters.

Through this research, we aspire to contribute valuable insights that can inform healthcare professionals, educators, and policymakers about the benefits and challenges associated with menstrual cups and sanitary pads, promoting evidence-based decision-making and fostering a greater understanding of the implications of menstrual product choices.

Objectives
To compare the efficiency of menstrual cup vs sanitary napkins in healthy women. To compare the ease of daily activities with the use of menstrual cup vs sanitary napkins in healthy women. To compare the tolerability of menstrual cup vs sanitary napkins in healthy women. To compare the satisfaction score with the use of menstrual hygiene tool in healthy women. To assess the acceptability and willingness to continue menstrual cup in healthy women.

Materials & Methods
Prospective, randomized, comparative, two-way, cross-over study held at Gynecology OPD at the Department of Obstetrics and Gynecology of Dr D Y Patil Hospital for duration of 14-16 months. The sample size is not based on any calculations and assumptions. 100 women were enrolled in the study. Being a crossover study design, the total sample that will be available for analysis was 200.

Assessment Parameters
1. Efficiency of menstrual hygiene tool
   - Leakage Protection
   - Comfort
2. Ease of daily activities with the use of menstrual hygiene tool
   - Discretion
   - Ease of use
3. Tolerability of menstrual hygiene tool
   - Skin rash
   - Discomfort
4. Satisfaction score with the use of menstrual hygiene tool
   Likert Scale
   - Very Unsatisfied: 1
   - Unsatisfied: 2
   - Neutral: 3
   - Satisfied: 4
   - Very Satisfied: 5

Method
Demographic details were recorded. Detailed history of illnesses, if any, along with personal and past history were recorded. Detailed obstetric history was recorded.

Participants were randomly divided in two groups:
A. Menstrual Cup Group
B. Sanitary Pad Group

The participants were shown an audio-video clip explaining about the correct way of using the cup. A graphical hand-out was given to all participants about using, cleaning and storage of the cup.

The participants were switched over to the other group at the end of 6 cycles.

6 sets of questionnaires were handed over to both the groups, which were to be filled at the end of their every menstrual cycle.

All the data was recorded in excel and analyzed.

Statistical Analysis: The data was analyzed using statistical software (IBM SPSS, IBM Corporation, Armonk, NY, USA).

Descriptive statistics: The Numerical/Continuous data were expressed as Mean ± Standard Deviation and the Categorical data were expressed as Percentages.

Analytical statistics: The Numerical/Continuous data were analyzed by the ‘Paired/Unpaired t test’ and the Categorical data were analyzed by the Chi square test (Fischer’s exact test was used when more than 20% of the cells had value less than 5). P value of less than 0.05 was considered as “statistically significant” and indicated by “*” or “**” in the presentation of the data as applicable.

Results:
The present study was conducted to compare menstrual cups with sanitary pads for menstrual hygiene.

A total of 106 women aged 18 to 45 years were included in the present study after obtaining ethics approval and written informed consent. All the participants were demonstrated and counselled regarding the use of both the sanitary methods. They were followed up for a period of 6 cycles after which they were switched to the other method, shown in Figure 1 to 10.

At the end of every cycle, they had to fill up a questionnaire regarding the method used. All the responses were recorded as scores.

Figure 1: Inter-group comparison of accessibility in the two groups

Figure 2: Inter-group comparison of ease of use in the two groups

Figure 3: Inter-group comparison of comfort in the two groups
Figure 4: Inter-group comparison of leakage protection in the two groups

Figure 5: Inter-group comparison of capacity in the two groups

Figure 6: Inter-group comparison of frequency of change in the two groups

Figure 7: Inter-group comparison of discretion in the two groups
Discussion

In the present study, the mean age of the study population was 28.60 ± 6.29 years, range: 19 to 44 years. In the study by Beksinska M. et al [5], they included a total of 105 women aged 18 to 45 years. The mean age of the study population was 29 ± 6.0 years. This was similar to the present study.

In another study by Howard C. et al[6], the mean age of the cases in the tampon group was 28.9 ± 5.5 years and in the menstrual cup group was 26.6 ± 4.6 years. This was similar to the present study.

The self-reported scores for accessibility, ease of use, comfort, leakage protection, capacity of menstrual cup and discretion of use increased with each cycle of use; P value: less than 0.05. The frequency of change showed an increase in frequency from cycle 3 onwards; P value: less than 0.05. However, it remained lower than the baseline. In cycle 6 it became the same as the baseline/cycle 1; P value: 0.239. The score for self-reported skin rash increased with each cycle of use and remained higher than the baseline/cycle 1 throughout the study period; P value: less than 0.001. When assessed in terms of overall improvement, the scores were significantly higher in the cycles 4 to 6; P value: less than 0.05. This may be due to some practice - initial learning curve required for the use of a menstrual cup. Thus, there was an improvement in the individual scores as well as overall improvement in the later cycles.

In the sanitary pad group, accessibility was significantly lower in cycles 3 and 5; P value: less than 0.05. However, the accessibility was almost equal to the baseline/cycle 1 in the other cycles; P value: more than 0.05. There was a decrease in
self-reported scores for ease of use of sanitary pad over the cycles; P value: less than 0.05. Accordingly, there was also a decrease in the reported comfort level. The comfort levels remained significantly lower than the baseline/cycle 1; P value: less than 0.05. Similar trends were observed in the leakage protection and discretion of use of sanitary pads, with a significant decrease in scores over the cycles. The capacity of the sanitary pad was reported to be similar to the baseline/cycle 1; P value: more than 0.05. The reported frequency of change of sanitary pad was significantly lower in cycles 2 and 3. However, it was similar to the baseline/cycle 1 towards the end of the study; P value: more than 0.05. The trends in score of skin rash were similar throughout the study. In terms of overall improvement, the self-reported scores remained similar to the baseline; cycle 1; P value: more than 0.05.

When compared between the two groups, the self-reported scores for the accessibility and ease of use of sanitary pads remained higher than the menstrual cup throughout the study period. The self-reported scores for comfort, leakage protection and discretion for the use of menstrual cups were initially lower than the sanitary pads, however, there was an improvement in the scores with each cycle and at the end of the study period, the scores for menstrual cup were significantly better than the scores for sanitary pads; P value: less than 0.05. The scores for capacity of menstrual cups remained higher than the sanitary pads, throughout the study period; P value: less than 0.05. The scores for frequency of change and skin rash also remained higher for the menstrual cups than for sanitary pads; P value: less than 0.05. When assessed in terms of overall improvement, the scores for menstrual cups were significantly better than the scores for sanitary pads, especially in the later cycles (with increase in use); P value: less than 0.05.

Overall 66.04% of the cases preferred menstrual cups over sanitary pads at the end of the study period. When assessed according to the type of method first used (menstrual cup vs sanitary pad), there was no significant difference in the preferential choice of the study population; P value: 0.415.

In the study by Bekinska M. et al[6], they included 150 participants to evaluate the acceptability and efficacy of menstrual cups. They observed that more than 80% of participants found the menstrual cup improved over the three cycles. However, they also reported an increased incidence of problems related to the use and adverse events with menstrual cups than with sanitary pads. They also reported an increase in percentage of women that were likely or highly likely to recommend menstrual cups, and those that were likely or highly likely to purchase the menstrual cup. They concluded that the acceptance of menstrual cups in a population of novice users was good, indicating potential users in the low-resource settings. The initial cost of the cup may be prohibitive, however, cost savings would be realised within one year of continued use.

In another study by Howard C. et al[6], they included a total of 89 cases. They studied the participants for three menstrual cycles. They observed an increased satisfaction with the duration of use of the menstrual cup, in terms of convenience and leakage. They also observed that the tampon group had a small decline in overall satisfaction over time, whereas the menstrual cup group had a noticeable drop in the first cycle of cup use but then an increase to study end. With progressive use, there was also a drop in the percentage of women reporting vaginal discomfort on at least one day per cycle (42% in cycle 1 vs 16% in cycle 3). These findings were almost similar to the present study.

In the meta-analysis by van Eijk A. et al[7], they included a total of 43 studies with 3319 participants. They observed that 4 studies with 293 participants compared leakage for menstrual cups with the usual products. The proportion of leakage for menstrual cups ranged from 2 to 31% and was associated with factors like menorrhagia, unusual anatomy of the uterus, incorrect placement of cup, etc. The leakage was similar or lower for cups than for disposable pads or tampons. They also reported user familiarization with menstrual cups over time and with training as a key to success, leading to greater acceptability and increased use over the cycles. The studies reported a positive effect of use of the menstrual cup on participants’ lives, decreased stress concerning staining and leakage, and improvements in mobility. In the studies involving school children, there was an improvement in the school attendance, concentration and performance of the students with the use of menstrual cups. Challenges described included difficulties with cleaning and storage of the menstrual cup in low-income and middle-income countries. Other challenges were associated with emptying the menstrual cup in school or public toilets.

In the study by Kakani C. and Bhatt J.[8], they included 150 participants to evaluate the acceptability and efficacy of menstrual cups. They observed that more than 80% of participants found
menstrual cup insertion easy with increasing comfort in the second and third cycle. There was minimal problem of leakage and it was similar to that as with the previous method. The menstrual cup was acceptable to most users in relation to comfort, ease of use, and effectiveness in menstrual collection. Cited advantages include overall convenience, portability and easy storage, extended wear time, and greater freedom of movement.[5] When reusable, menstrual cups are easy to clean and, therefore, more hygienic than cloth pads, and they require less water for cleansing. Internal placement of cups avoids the odor and discomfort of an external pad.[9]

**Limitations:** The present study is limited by the OPD attendance of the patients. Therefore, the results may not be generalized. The effects of the use of products/methods were not assessed for different subgroups, like those having IUD, those having menorrhagia, etc., as it was not a part of study protocol. Therefore, further studies may be needed in this regard. As the menstrual cup is a less popular and less widely available method of use as compared to sanitary pads, therefore, a demonstration and counseling regarding the use of menstrual cup was made at the start of the study. This may have led to bias towards the use of menstrual cups. More awareness campaigns and better availability of cup should be there in the community.[10]

**Conclusion**

It can be effectively concluded from the present study that; Menstrual cups are more effective than sanitary pads in terms of comfort, leakage protection, capacity and discretion. Accessibility and ease of use of menstrual cups are equally comparable with sanitary pads. The scores for skin rash and frequency of change are higher for menstrual cups than sanitary pads.

The overall improvement with each cycle for menstrual cups is significantly better than with sanitary pads. However, sanitary pads still remain as the preferred option in the initial cycles of menstrual cup. There is an improvement in all the scores with the learning period with menstrual cups. Further studies need to be conducted to assess the cost-effectiveness and its efficacy in other subgroups like those with menorrhagia, etc. Imparting awareness and educating masses with environment friendliness as well as the initial learning curve of the menstrual cup is necessary.

**References**