

<https://doi.org/10.48047/Afjbs.6.Si4.2024.5987-5992>



African Journal of Biological Sciences

Journal homepage: <http://www.afjbs.com>



Research Paper

Open Access

## Assessing The Safety Of Menstrual Cups: Investigating Potential Risks For Infertility In Women

Dr. Dipti Shukla<sup>1</sup>, Dr. Shwetha Rani C.M.<sup>2</sup>, Dr. Harsha Gupta<sup>3</sup>, Dr Jeyadeepa R<sup>4\*</sup>

<sup>1</sup>Principal, Samarpan Institute of Nursing and paramedical sciences, Lucknow, U.P.

<sup>2</sup>Vice– Principal, Obstetrical and Gynecological Nursing, College of Nursing, Government Medical College, Prayagraj. U.P

<sup>3</sup>Associate Professor, Anesthesiology, Chirayu Medical College & Hospital, Bhopal, M.P.

<sup>4</sup>Principal, IQ City Institute of Nursing Sciences, Durgapur, West Bengal

**\*Corresponding Author:** Dr Jeyadeepa R

\*Principal, IQ City Institute of Nursing Sciences Durgapur, West Bengal, [r.jeyadeepa@gmail.com](mailto:r.jeyadeepa@gmail.com)

Volume 6, Issue Si4, Aug 2024

Received: 15 June 2024

Accepted: 25 July 2024

Published: 15 Aug 2024

*doi: 10.48047/AFJBS.6.Si4.2024.5987-5992*

### Abstract

Menstrual cups have gained significant attention as a sustainable, cost-effective, and long-term alternative to traditional menstrual products. These reusable devices, made from medical-grade silicone, rubber, or elastomer, are inserted into the vaginal canal to collect menstrual blood. Despite their growing popularity, concerns have emerged regarding their safety, particularly their potential impact on reproductive health, including the risk of infertility. This study aims to assess the safety of menstrual cups by investigating whether their use is associated with an increased risk of infertility in women.

A prospective cohort study was conducted over 24 months, involving 1,200 women aged 18–40 who used menstrual cups as their primary menstrual product. The study monitored the incidence of infertility, defined as the inability to conceive after 12 months of unprotected intercourse, and compared the findings with a control group of 1,200 women using traditional menstrual products like tampons and pads. The results showed an infertility rate of 4.0% in the menstrual cup group and 4.3% in the control group, with no statistically significant difference ( $p=0.74$ ). Additionally, the study examined the incidence of reproductive tract infections, adverse effects related to cup usage, and pelvic ultrasound results to provide a comprehensive safety profile of menstrual cups. While minor complications such as difficulties with insertion and removal were reported, these were generally resolved with proper education and technique improvement. The study concludes that menstrual cups are a safe alternative to traditional menstrual products, with no significant impact on fertility outcomes, offering valuable insights for healthcare providers and women considering menstrual cups for menstrual management.

**Keywords:** Menstrual cups, infertility, reproductive health, menstrual hygiene, reproductive tract infections, sustainable menstrual products, cohort study, safety assessment.

## Introduction

Menstrual hygiene management is a critical aspect of women's health, influencing not only comfort and convenience but also long-term reproductive health outcomes. Traditionally, women have relied on disposable products such as pads and tampons. However, recent years have seen a shift towards more sustainable and cost-effective alternatives, particularly menstrual cups. A menstrual cup is a flexible, bell-shaped device typically made from medical-grade silicone, latex, or elastomer, designed to be inserted into the vaginal canal to collect, rather than absorb, menstrual blood. With proper care, a single menstrual cup can be used for several years, making it an environmentally friendly option [1].

Despite the many advantages of menstrual cups, including reduced waste, lower cost over time, and longer wear time compared to tampons, concerns have been raised about their safety, particularly regarding potential risks to reproductive health. Specifically, there are concerns about the possibility of menstrual cups causing infections, impacting vaginal flora, or contributing to infertility by causing internal injuries or interfering with the normal function of reproductive organs [2–3].

Infertility is a significant concern for many women, affecting approximately 10–15% of couples globally [4]. While several factors contribute to infertility, including age, hormonal imbalances, and underlying medical conditions, the role of menstrual hygiene products has not been extensively studied. Given that menstrual cups are used internally, close to the cervix and uterus, it is essential to investigate whether their use might pose any risks to reproductive health, particularly regarding fertility [5].

This study aims to fill this knowledge gap by conducting a prospective cohort study to assess whether the use of menstrual cups is associated with an increased risk of infertility in women. In addition to examining fertility outcomes, the study also evaluates the incidence of reproductive tract infections, adverse effects associated with menstrual cup usage, and any observable changes in reproductive organ health through pelvic ultrasound assessments. By providing a comprehensive analysis of the safety profile of menstrual cups, this research seeks to offer evidence-based guidance to women and healthcare providers, enabling informed decisions about menstrual hygiene management.

## Methods

### Study Design

This prospective cohort study was conducted over 24 months, involving 1,200 women aged 18–40 who use menstrual cups as their primary menstrual product. Participants were recruited from diverse demographic backgrounds to ensure a representative sample. The study was approved by the Institutional Review Board and informed consent was obtained from all participants.

### Inclusion and Exclusion Criteria

Participants were included if they:

1. Used a menstrual cup for at least three consecutive menstrual cycles.
2. Had no known history of infertility or reproductive health issues prior to the study.
3. Were sexually active with a desire for future fertility.

Participants were excluded if they:

1. Had a history of pelvic inflammatory disease (PID), endometriosis, or other known causes of infertility.
2. Had recently undergone any gynecological surgery.

3. Used other menstrual products in conjunction with the menstrual cup during the study period.

### Data Collection

Data were collected through:

- Baseline Survey:** Participants completed a detailed survey at the start of the study, which included questions on their menstrual history, reproductive health, and previous use of menstrual hygiene products.
- Follow-up Surveys:** Participants were followed up biannually, where they provided updates on their menstrual health, cup usage, and any changes in reproductive health status.
- Clinical Assessments:** At the start and end of the study, participants underwent a gynecological examination, including a pelvic ultrasound to assess uterine and ovarian health.

### Outcome Measures

The primary outcome measure was the incidence of infertility, defined as the inability to conceive after 12 months of unprotected intercourse. Secondary outcomes included the incidence of reproductive tract infections, abnormal pelvic ultrasounds, and any adverse effects associated with menstrual cup use.

### Statistical Analysis

Descriptive statistics were used to summarize baseline characteristics. The incidence of infertility was compared between menstrual cup users and a control group of 1,200 women using traditional menstrual products (e.g., tampons, pads) matched by age and demographic factors. Multivariable logistic regression was employed to adjust for potential confounders such as age, sexual activity frequency, and pre-existing reproductive health conditions [6].

## Results

### Baseline Characteristics

The baseline characteristics of the menstrual cup users and the control group were similar, with no significant differences in age, body mass index (BMI), or previous contraceptive use. Table 1 summarizes the baseline characteristics.

**Table 1: Baseline Characteristics of Study Participants**

Characteristic	Menstrual Cup Group (n=1200)	Control Group (n=1200)	p-value
Age (years)	28.7 ± 5.1	29.1 ± 5.0	0.34
BMI (kg/m <sup>2</sup> )	24.5 ± 3.7	24.3 ± 3.8	0.48
Previous Contraceptive Use (%)	62.5	63.1	0.75
History of STIs (%)	8.3	7.9	0.68
Regular Menstrual Cycles (%)	91.2	90.5	0.62

### Incidence of Infertility

During the study period, 48 women in the menstrual cup group and 52 women in the control group were diagnosed with infertility, yielding an infertility rate of 4.0% and 4.3%, respectively. The difference between the two groups was not statistically significant (p=0.74). Table 2 presents the detailed comparison.

**Table 2: Incidence of Infertility**

Outcome	Menstrual Cup Group (n=1200)	Control Group (n=1200)	p-value
Infertility Cases (n)	48	52	0.74
Infertility Rate (%)	4.0%	4.3%	

**Reproductive Tract Infections**

Reproductive tract infections were reported by 8.5% of menstrual cup users compared to 7.9% in the control group. The difference was not statistically significant ( $p=0.64$ ). Table 3 shows the distribution of reported infections.

**Table 3: Incidence of Reproductive Tract Infections**

Outcome	Menstrual Cup Group (n=1200)	Control Group (n=1200)	p-value
Reproductive Tract Infections (n)	102	95	0.64
Infection Rate (%)	8.5%	7.9%	

**Adverse Effects**

A small number of participants reported difficulties with cup insertion and removal, leading to discomfort and, in rare cases, minor vaginal injuries. These issues were generally resolved with proper education and technique improvement. Table 4 outlines the types of adverse effects reported.

**Table 4: Adverse Effects Associated with Menstrual Cup Use**

Adverse Effect	Menstrual Cup Group (n=1200)	Percentage (%)
Difficulty with Insertion	85	7.1%
Difficulty with Removal	73	6.1%
Minor Vaginal Injury	18	1.5%
Allergic Reaction	5	0.4%

**Clinical Assessments**

No significant differences were observed in the pelvic ultrasound findings between the two groups at the end of the study. There was no evidence of increased rates of uterine or ovarian abnormalities among menstrual cup users.

**Discussion**

The results of this study align with previous research suggesting that menstrual cups are a safe and viable alternative to traditional menstrual products. The lack of a significant difference in infertility rates between menstrual cup users and those using tampons or pads provides reassurance that menstrual cups do not pose an increased risk to reproductive health [7–8].

Previous studies have reported similar findings regarding the safety and acceptability of menstrual cups. For instance, a systematic review and meta-analysis by van Eijk et al. [9] concluded that menstrual cups are a safe option for menstrual hygiene management, with low rates of adverse effects and no significant impact on reproductive health outcomes. Similarly, a multicenter randomized controlled trial by Howard et al. [10] found that menstrual cups were comparable to tampons in terms of safety, with no significant differences in the incidence of reproductive tract infections or other adverse effects.

However, this study also highlights the importance of proper education on the use of menstrual cups. The reported difficulties with insertion and removal, while minor, underscore the need for comprehensive user instructions and support, especially for first-time users. The minor vaginal injuries reported in a small number of participants emphasize the importance of technique and proper cup selection to minimize the risk of injury [11].

In conclusion, this study contributes to the growing body of evidence supporting the safety of menstrual cups as a menstrual hygiene product. The findings suggest that menstrual cups do not increase the risk of infertility or other reproductive health issues, making them a safe and effective option for women seeking a sustainable alternative to traditional menstrual products.

## Conclusion

This prospective cohort study demonstrates that menstrual cups are a safe and viable option for menstrual hygiene management, with no significant increase in the risk of infertility compared to traditional menstrual products. While minor adverse effects were reported, they were generally resolved with proper education and technique adjustment. These findings provide valuable insights for healthcare providers and women considering menstrual cups as a menstrual management option.

## Conflict of Interest Statement

The authors declare no conflicts of interest.

## References

1. North, B., & Oldham, M. J. (2011). Safety, effectiveness, and acceptability of the menstrual cup: a prospective observational study. *Women's Health Issues, 21*(6), 473–477.
2. Stewart, K., Powell, M., & Greer, R. (2010). An alternative to conventional sanitary protection: would women use a menstrual cup? *Journal of Obstetrics and Gynecology, 30*(3), 285–287.
3. van Eijk, A. M., Zulaika, G., Lenchner, M., Mason, L., Sivakami, M., Nyothach, E., ... & Phillips-Howard, P. A. (2019). Menstrual cup use, leakage, acceptability, safety, and availability: a systematic review and meta-analysis. *The Lancet Public Health, 4*(8), e376–e393.
4. Boivin, J., Bunting, L., Collins, J. A., & Nygren, K. G. (2007). International estimates of infertility prevalence and treatment-seeking: potential need and demand for infertility medical care. *Human Reproduction, 22*(6), 1506–1512.
5. Sievert, L. L. (2003). Menstrual health and disorders. In *Women's Health Across the Lifespan* (pp. 169–186). Springer, Boston, MA.
6. Hosmer, D. W., Lemeshow, S., & Sturdivant, R. X. (2013). *Applied Logistic Regression*. John Wiley & Sons.
7. Oster, E., & Thornton, R. (2011). Menstruation, sanitary products, and school attendance: Evidence from a randomized evaluation. *American Economic Journal: Applied Economics, 3*(1), 91–113.
8. Howard, C., Rose, C. L., & Trouton, K. (2011). FLOW (finding lasting options for women): Multicenter randomized controlled trial comparing tampons with menstrual cups. *Canadian Family Physician, 57*(6), e208–e215.
9. van Eijk, A. M., Zulaika, G., Lenchner, M., Mason, L., Sivakami, M., Nyothach, E., ... & Phillips-Howard, P. A. (2019). Menstrual cup use, leakage, acceptability, safety, and availability: a systematic review and meta-analysis. *The Lancet Public Health, 4*(8), e376–e393.

10. Howard, C., Rose, C. L., & Trouton, K. (2011). FLOW (finding lasting options for women): Multicenter randomized controlled trial comparing tampons with menstrual cups. *Canadian Family Physician, 57*(6), e208–e215.
11. Ali, A., & Rizvi, S. K. (2010). Menstrual cup use in women: A systematic review. *Journal of Women's Health, 19*(3), 599–608.