



ACCEPTABILITY AND SAFETY OF THE MENSTRUAL CUP: A SYSTEMATIC REVIEW OF THE LITERATURE

Aceptabilidad y seguridad de la copa menstrual: revisión sistemática de la literatura

Camilo Arenas-Gallo, MD¹; Gabriela Ramírez-Rocha²; Laura González-Hakspiel³; Catalina Merlano-Alcendra³; Daniela Palomino-Suárez, MD⁴; Santiago Rueda-Espinel, MD⁵

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ABSTRACT

Objective: To conduct a systematic review of the literature and assess the acceptability and safety of the menstrual cup as a feminine hygiene product.

Materials and methods: A search was conducted in the PubMed, Cochrane Library, Scopus, PopLine and Google Scholar databases for publications between 1966 and July 2019. The terms (“Menstrual” AND “Cup”) OR (“Copa” AND “Menstrual”) were used. Quantitative, qualitative and mixed studies were included, as well as case series and case reports published in English and Spanish that assessed the menstrual cup in women in childbearing age. The studies were selected and the data extracted by

two reviewers working independently. Acceptability and safety were assessed as the primary result. The summary of the information is presented in narrative form.

Results: Overall, 737 titles were found for initial review and, in the end, 38 studies were included in this work. The acceptability of the menstrual cup ranges between 35% and 90%. Between 10 to 45% of women found it difficult to use. It was described as more comfortable when compared to tampons and pads. Continued use of the cup ranges between 48 and 94%. In terms of safety, there was one case of toxic shock syndrome, one case of mechanical entrapment, and another case of allergy. A higher risk of expulsion was found among intrauterine device users.

Conclusion: The menstrual cup appears to be a comfortable, safe and efficient option for menstrual hygiene. Randomized controlled studies and long-term prospective cohort studies are needed in order to determine the risk of complications due to excess bacterial colonization or retrograde menstruation.

Key words: Menstrual cycle; feminine hygiene products; menstrual hygiene products.

* Correspondence: Camilo Arenas-Gallo, carrera 21 # 158-80 Álamos Parque, Casa 83. Floridablanca, Santander (Colombia). camiloareg@hotmail.com

1 Surgeon, Universidad Industrial de Santander, Bucaramanga (Colombia).

2 Medical Student, Universidad Industrial de Santander, Bucaramanga (Colombia).

3 Medical Student, Universidad Autónoma de Bucaramanga, Bucaramanga (Colombia).

4 Physician, Universidad Autónoma de Bucaramanga, Bucaramanga (Colombia).

5 Obstetrics and Gynecology Resident, Universidad Autónoma de Bucaramanga, Bucaramanga (Colombia).

RESUMEN

Objetivo: realizar una búsqueda sistemática de la literatura para evaluar la aceptabilidad y seguridad de la copa menstrual como producto de higiene genital femenina.

Materiales y métodos: se realizó búsqueda en las bases de datos PubMed, Cochrane Library, Scopus, PopLine y Google Scholar, desde 1966 hasta julio de 2019. Se utilizaron los términos: “Menstrual” AND “Cup” OR “Copa” AND “Menstrual”. Se incluyeron estudios cuantitativos, cualitativos y mixtos, series y reportes de caso publicados en inglés y español que hubieran evaluado la copa menstrual en women en edad reproductiva. Los estudios fueron seleccionados y los datos fueron extraídos por dos evaluadores de manera independiente. Como resultado primario se evaluó la aceptabilidad y seguridad. La síntesis de información se presenta de manera narrativa. Resultados: se encontraron 737 títulos para revisión inicial. Finalmente, se incluyeron 38 estudios. La copa menstrual tiene una aceptabilidad que varía entre el 35 y el 90%. Del 10 al 45% la encontraron difícil de usar. Fue descrita como más cómoda comparada con el tampón y la toalla higiénica de fabricación industrial. La continuidad de su uso está entre el 48 y el 94%. En cuanto a la seguridad se presentó un caso de síndrome de choque tóxico, uno de atrapamiento mecánico, uno de alergia al producto y mayor riesgo de expulsión en usuarias del dispositivo intrauterino.

Conclusión: la copa menstrual es una alternativa cómoda, segura y eficiente para la higiene menstrual. Se requieren más estudios controlados aleatorizados y cohortes prospectivas a largo plazo para determinar el riesgo de complicaciones por una exagerada colonización bacteriana o menstruación retrógrada.

Palabras clave: ciclo menstrual; productos para la higiene femenina; productos para la higiene menstrual.

INTRODUCTION

Menstrual bleeding is the result of endometrial shedding at the end of the ovulation cycle in women in childbearing age. Around the world, this physiological event has been shrouded in all kinds of myths and superstitions, to the point that some cultures have created specific rules of behavior that must be followed during this period (1). Moreover, the process of civilization that led to adequate disposal of bodily fluids and waste has resulted, in the case of menstruation, in the manufacture of different materials and devices to retain or absorb the blood as a way to protect the female body against infections and discomfort, nurturing it for motherhood. As a result, there is currently a wide offering and selection of menstrual hygiene products (2).

The menstrual cup is a silicone product placed inside the vagina under the uterine cervix in order to collect the menstrual discharge (3). The first models, known as “catamenial sacks” were patented in 1867 in the United States (4) and, years later, in 1937, Leona Chalmers patented the first commercial prototype (5). Although initial acceptance was not good, the cup had its comeback in the 1980s in the wake of the “tampon crisis” due to the toxic shock syndrome cases (2). At first they were made from latex (6) but frequent allergic reactions led to their removal from the market. Finally, with the advent of hypoallergenic medical silicone in 1998, this has been the material of choice for menstrual cups until now (7). It is interesting to note, that despite their long history in the market, many women are still unaware of their existence (8).

Cup sizes vary depending on the manufacturer. In average, they are 6 cm long, 4.2 cm in diameter in its widest portion and their storage capacity ranges between 10 and 38 cm³ (9). Manufacturers recommend emptying it every four to twelve hours and washing it with water for reuse (7). Adoption of the menstrual cup requires a prior phase during

which the woman becomes acquainted with its use with the support from peers (10). Three menstrual cycles in average are needed to go through the learning curve on how to insert, empty and clean the cup (11).

One of the advantages of the menstrual cup, as claimed by manufacturers and distributors, is its life cycle which, depending on the brand, may range between five and ten years because of the ability to reuse it with proper cleaning and hygiene (12). This sets the cup apart from manufactured tampons and sanitary pads in terms of the high burden of waste material that is difficult to recycle or use (8). It is estimated that a woman could use up to 17,000 pads or tampons over her life time (13).

Manufacturers claim that the cup can be used during the night and during vigorous physical activity (14). Other marketing claims include increased comfort, freedom, and environmental savings (2,15). Menstrual cups have also been used clinically in the management of vesicovaginal (16) and enterovaginal (17) fistulas and menses collection for *in vitro* studies (18). The prevalence of menstrual cup use in the world has not been clearly established and there is only one study in the United States that estimates a 10% prevalence (19).

It has been described that girls in South Africa may miss up to 25% of their total education due to menstruation-related issues (20). Because of cost effectiveness and comfort, the menstrual cup has been proposed as a method to reduce school attrition in the rural areas, in those countries where menstrual hygiene is still managed with home-made and unclean methods (21), and where there is a relationship between first menstruation and school dropout status (22). Several factors are involved, including difficult access to menses control products, cultural taboo and lack of education in schools (23).

The majority of the brands sold in the world are listed in the online Menstrual Cup Master List (24) and information of where to find the product in Latin America is available on the Toallas femeninas

ecológicas (“Eco-friendly menstrual pads”) website (25). In Latin America, the cup can only be purchased through small distributors, mainly on-line, in entrepreneurship fairs and through retailers (26). Its positioning in the Latin-American market is growing and it is constantly promoted through social media with a very high number of users such as Facebook (27) or Instagram (28), where postings about the menstrual cup can elicit thousands of comments and interactions.

Based on these considerations, the objective of this study was to conduct a systematic review of the literature on the acceptability and safety of this device for menstrual hygiene so that gynecologists and sexual and reproductive health workers can provide informed guidance regarding this option to women in Latin America and the Caribbean.

MATERIALS AND METHODS

Using the research question “What is the acceptability and safety of the menstrual cup as an alternative female hygiene method?” a systematic review was conducted in Medline via Pubmed, Cochrane Library, Scopus, PopLine and Google Scholar databases up until July 26, 2019 with no retrospective limitation. The terms “Menstrual” AND “Cup” OR “Copa” AND “Menstrual” were used, and no MeSH or DeCS terms were used considering that none are specifically available for the menstrual cup. Quantitative, qualitative and mixed studies, case reports and case series, scope reviews and narratives published in English and Spanish were included. The study population consisted of women in childbearing age. Acceptability and safety were assessed as the primary endpoints. Acceptability measures included intention to use in the future, ease of use, failed use, and comfort. Safety measurements were adverse events and effects on vaginal microbiota. Assessment of titles and abstracts, and data extraction, were carried out by two reviewers (CAG y GRR). In cases of disagreement, inclusion was decided by a third reviewer (SRE).

Publication quality was determined on the basis of the study design, clinical trials were evaluated based on the CONSORT statement (Consolidated Standards of Reporting Trials) (29), the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) tool (30) for observational studies and the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) statement for systematic reviews (31); reporting quality in qualitative studies, case reports and case series was evaluated.

The synthesis of the information is presented in narrative form, and design, reporting quality and reported acceptability and safety results are described.

RESULTS

Using the search strategy described above, 737 titles were found for initial review: 69 in Medline, 37 in Cochrane Library, 116 in Scopus, 15 in PopLine and 500 titles reviewed in Google Scholar. A total of 699 articles were discarded by title and abstract because they failed to meet the inclusion criteria or because of double referencing. Four articles were discarded because they were written in Portuguese. Finally, 38 articles were included in the review: 3 randomized clinical trials (21,32,33), a cluster-randomized trial (34), 13 prospective cohorts (6,11-13,18,35-42), 1 cross-sectional study with prospective follow-up (published in three references) (10,43,44), 1 cross-sectional study (38), 1 retrospective study (19), 2 qualitative studies (20,45), 1 in vitro study (46), 1 case series (47), 7 case reports (16,17,48-52), and 5 narrative reviews (2,7,15,23,53) (Figure 1, Table 1). The full texts for all the selected articles were obtained. No clinical trials or descriptive studies conducted in Latin America were found.

The publication quality of all the clinical trials supported by the CONSORT statement was found to be good. Cohort and cross-sectional studies were considered to be of poor quality when assessed with the STROBE tool. The quality of the systematic review with meta-analysis was good.

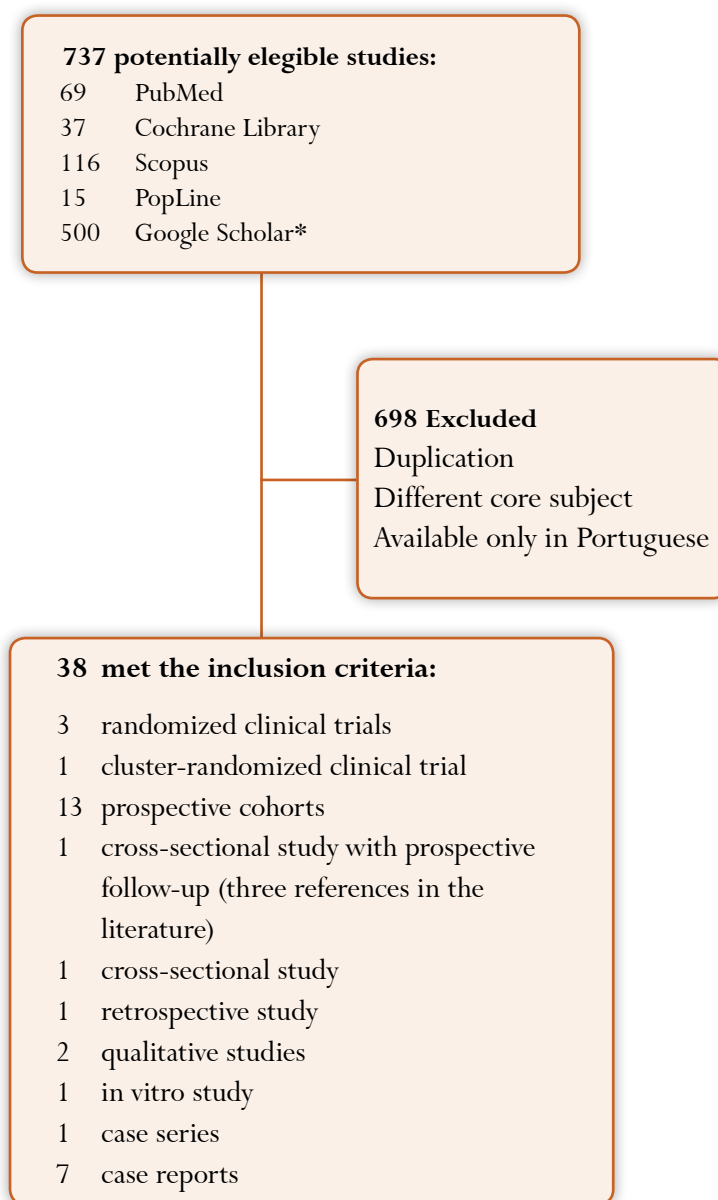
Acceptability: As far as intention to use is concerned, a cross-sectional study conducted in 2009 with 69 women attending a menstrual disorder clinic in the United Kingdom reported that only 20% of that population was aware of the menstrual cup. After providing education, 52% reported interest in using it (8). In a prospective cohort with focus groups including 43 women between 18 and 35 years of age, Averbach et al. reported that 100% of the women showed interest in using the cup. However, the authors describe a cultural barrier in the form of the concern voiced by some women of “losing their virginity” or exhibiting inappropriate sexual behaviors (37).

Regarding ease of use and comfort, a prospective cohort of 51 Canadian women in 1995 assessed a rubber cup during two to three cycles. Of them, 45% reported difficulty with insertion, 65% found it uncomfortable and 55% had accidental leakage (42). Oster and Thornton, in a prospective follow-up of 99 adolescents, identified that 30% found it difficult to use and 10% had failed at inserting it (10,43,44). In another prospective study carried out in the United States with 125 participants, up to 4.8% were unable to introduce the cup (13). It was also found that the insertion process was painful for some women and there were doubts on whether it could be used in women who had not had intercourse (13,20).

A randomized clinical trial carried out in South Africa in 2013 with women between 18 and 45 years of age divided 110 women into two groups: women in the first group used the menstrual cup for three months followed by another three months of pad/tampon use, while the second group started with three cycles of pad/tampon use followed by three cycles of menstrual cup use. Results showed that by the end of the third cycle using the cup, 91% of the participants rated the cup as being better than their usual product in terms of comfort, and 92% preferred it overall; 10 patients (9%) experienced pain and issues at the time of insertion (33).

Figure 1.

Flow diagram of selected studies on menstrual cup acceptability and safety



* By titles, the search included eligible elements that did not appear in the other databases.

In a survey conducted in 2014 in San Diego, California, among 125 respondents between 18 and 40 years of age who used the cup during three menstrual cycles, 85% considered it to be better than their previous menstrual hygiene product; however, six women (4.8%) were unable to insert it (13).

In a prospective cohort of 54 women between 19 and 45 years of age and low socioeconomic status in Zimbabwe, 100% of the participants reported no discomfort during insertion or accidental leakage (11).

To assess leakage with the use of the menstrual cup, a meta-analysis was published in 2019 includ-

Table 1.
Menstrual cup acceptability, systematic review up to July 26, 2019

Author	Country	Year	Design	Sample	Results		Quality evaluation
					Acceptability	Safety	
Clinical trials							Consort
Howard (32)	United States	2011	Randomized clinical trial	110 women	Continuity and intent to use		20/22
Beksinska (33)	Africa	2015	Cross-over randomized clinical trial	110 women	Ease of use, comfort, continuity of use		21/22
Phillips (21)	Africa	2016	Randomized clinical trial	644 adolescents between 14 and 16 years	Comfort, school attrition	STDs, vaginal infections, vaginal or cervical lesions	22/22
Juma (34)	Africa	2017	Cluster-randomized trial	604 adolescents between 14 and 16 years		E. coli isolates in cups	22/22
Prospective cohorts							Strobe
Peña (35)	USA	1961	Prospective cohort	125 women between 20 and 45 years	Ease of use, leakage, cost and comfort		3/22
Karnaky (6)	USA	1962	Prospective cohort	150 women		Altered vaginal pH, vaginal or cervical lesions	5/22
Parker (36)	USA	1964	Prospective cohort	46 women with menorrhagia and 19 with normal menses	Continuity of use		16/22
Cheng (42)	Canada	1995	Prospective cohort	51 women	Continuity of use, leakage, comfort		17/22
Koks (18)	Belgium	1997	Prospective cohort	9 women between 26 and 34 years	Comfort, continuity of use, removal difficulty		15/22
Oster (10,43, 44)	Nepal	2009	Cross-sectional cohort with prospective follow-up	99 adolescents and 99 mothers	Continuity of use, insertion failure. Comfort		10/22

Author	Country	Year	Design	Sample	Results		Quality evaluation
					Acceptability	Safety	
Stewart (38)	United Kingdom	2010	Prospective cohort	54 women	Continuity of use, leakage		1/22
North (39)	USA	2011	Prospective cohort	406 women	Ease of use, comfort, leakage	Effects on vaginal flora, irritation, toxicity, mutagenicity	11/22
Tellier (12)	Uganda	2012	Prospective cohort	31 women	Ease of use, comfort, continuity of use		8/22
Shihata (13)	USA	2014	Prospective cohort	125 women	Ease of use, leakage		10/22
Kakani (40)	India	2017	Prospective cohort	158 women	Continuity of use	Allergy	14/22
Chintan (41)	India	2017	Prospective cohort	100 women	Continuity of use		1/22
Madziyire (11)	Africa	2018	Prospective cohort	54 women	Comfort, leakage, continuity of use		11/22
Meta-analysis							Prisma
van Eijk (9)	United Kingdom	2019	Systematic review and meta-analysis	43 studies	Leakage, continuity of use	Effects on vaginal flora, pain, allergy, hydronephrosis, toxic shock, IUD expulsion	27/27
Observational studies							Strobe
Stewart (8)	United Kingdom	2009	Cross-sectional study	69 women	Intention to use		4/22
Wiebe (19)	Canada	2012	Retrospective study	135 women		IUD expulsion	13/22
Johansson (20)	Africa	2018	Qualitative study	20 adolescents	Ease of use, cost, comfort		N/A
Nonfoux (46)	France	2018	In vitro study	4 cups	In vitro <i>S. aureus</i> isolate and TSST-1 in cups		14/22

Author	Country	Year	Design	Sample	Results		Quality evaluation
					Acceptability	Safety	
Serie de casos y reportes de caso							N/A
Seale (47)	USA	2019	Case series	7 women		IUD expulsion	
Spechler (48)	USA	2003	Case report	1 woman		Association with adenomyosis and endometriosis	-
Spechler (49)	England	2012	Case report	1 woman		Vaginal retention	-
Mitchell (50)	Canada	2015	Case report	1 woman		Toxic shock syndrome	-
Goldberg (16)	Canada	2016	Case report	1 woman		Management of vesicouterine fistula	-
Russell (17)	USA	2016	Case report	1 woman		Management of enterovaginal fistula	-
Nunes-Carneiro (51)	Portugal	2018	Case report	1 woman		Renal colic and secondary hydronephrosis	-
Stolz (52)	Switzerland	2019	Case report	1 woman		Secondary hydronephrosis	-

ing 43 studies published between 1960 and 2018 comparing the menstrual cup and the cervical diaphragm. The proportion of occasional leakage ranged between 2 and 31% of 3319 participants. (9). North and Oldham (39) did not find differences in leakage in the comparison between the menstrual cup and pads and tampons. In contrast, Stewart et al. identified lower rates of leakage in medical students with the use of the cup during three menstrual cycles when compared to three cycles using the regular method (pads or tampons) (38). A prospective cohort study that included 406 participants showed no difference in leakage after three cycles of cup use. For 37% of the participants, the cup was better than their usual menstrual hygiene method and was preferred based on comfort, dryness, irritation, odor, length of use and interference with

daily activities (39). In 2011, a multi-center randomized clinical trial of 110 women between 19 and 40 years of age compared the tampon and the cup vs. the usual menstrual hygiene method during four cycles. In the study, each participant was her own control. Overall acceptability was assessed using a 7-point Likert scale and it was found to be higher for the menstrual cup compared with the tampon: 5.4 (standard deviation [SD] \pm 1.5) vs. 5.0 (SD \pm 1.0), respectively ($p = 0.04$) (32).

In a qualitative focus groups study carried out in 2015 including 101 adolescents 14 to 16 years of age and 64 parents, perceptions and experiences were evaluated after six months of menstrual cup use. The authors concluded that the cup is acceptable, comfortable, low-cost and easy to use among adolescents in rural areas where, many times, napkins,

cloths and even mattress foam trimmings are used as menstrual hygiene items (45). Another qualitative study carried out the same year among students in Africa identified the menstrual cup as a tool that reduces costs for adolescents and represents an efficient option for most users (20).

The oldest study found in the literature on continuous use was conducted in 1962 in the United States to assess comfort using a rubber cup during three menstrual cycles in a prospective cohort of women between 20 and 45 years of age. At the completion of the study, all the participants found the cup to be practical, low-cost, hygienic and easy to use, and 100% reported that they would continue to use it in the future (35). Later, Parker et al. (36) reported on a prospective cohort of 65 women, 46 of them with heavy menses. The use of a rubber menstrual cup was assessed during a period of two to six months. At the end of the study, 63% of the participants with heavy bleeding and 74% of women with normal bleeding would continue to use the cup as they considered it better than their usual method (36).

Up until the time of this review, multiple studies have reported varying percentages of continued use after participation in clinical studies: Cheng et al. reported 15% (42); Tellier et al., 48% (12); Stewart et al., 55% (38); Chintan et al., 57% (41); Shihata et al., 58% (13); Parker et al., 63% (36); Kakani et al., 85% (40); Howard, et al., 91% (32), and Madziyire et al., 94% (11).

In a prospective cohort of 150 women who used a rubber menstrual cup, Karnaky et al. (6), using cultures and speculoscopy determined that the cup did not alter vaginal pH or injure the walls of the vagina or the cervix, and that the amount of bacterial contamination was higher with pads, followed by tampons, and was lowest with the cup (6). North et al., in a prospective cohort study with 406 participants, concluded that the silicone cup does not cause vaginal or cervical epithelial disruption, as determined by colposcopic assessment and cytology (39).

In a cluster-randomized study, Phillips et al. (21) assessed the use of menstrual cups and sanitary pads in school girls living in rural Kenya in terms of reduction in sexually transmitted infections. Three groups were compared: cup, sanitary pads and the usual menstrual hygiene method. The results included 644 adolescents. Genital tract infections were found in 21.5, 28.7 and 26.9% of the participants in the menstrual cup, pad and control groups, respectively. *S. aureus* was reported in 9.6% of the menstrual cup group, 11.2% in the sanitary pad group, and 11.3% in the control group. Toxic shock syndrome toxin (TSST-1) was detected in 2 out of 10 cultures from *S. aureus*-positive cups. *E. coli* grew in 37% of the cups, 53% in new cups (less than 6 months of use), 22.2% in cups which had been used for over 6 months, while there was no evidence of growth in the 6 cups that were used for more than 9 months. No serious adverse events were reported (21).

A clinical trial measured vaginal *S. aureus* colonization and *E. coli* growth in 188 participants assigned to the menstrual cup group. No serious adverse effects were reported and no direct association was found with *S. aureus* colonization however, *E. coli* growth was detected in 25% of the sampled cups (34).

There was one published case of vaginal retention (49), two cases of hydronephrosis secondary to mechanical ureteric entrapment which resolved as soon as the cup was removed (51,52), and one confirmed case of severe toxic shock syndrome (50). One study found the use of the menstrual cup as a risk factor for toxic syndrome given the in vitro isolation of the toxic shock syndrome toxin 1 (TSST-1) in three of the four cups assessed (46). In 2017, in Dharapur, India, in a prospective cohort of 158 women between 21 and 50 years, one participant reported allergy to the product (40).

The potential increase in the risk of intra-uterine device (IUD) expulsion with the use of the cup has also been studied. An observational study carried

out in Canada in 135 menstrual cup and IUD users did not find a significant association (19); however, a series of seven cases of accidental removal during manual extraction of the cup was recently described in a population in the United States (47). It is important to highlight that accidental removal was recognized by all the women. Subsequent management of the women who decided to continue using the menstrual cup consisted of changing the contraceptive method or reinserting the IUD, cutting the threads close to the cervix. Tables 2 and 3 show a summary of the reported advantages and disadvantages of menstrual cup use.

DISCUSSION

In general terms, the menstrual cup is considered an acceptable menstrual hygiene device. In average, three menstrual cycles are required to achieve a learning curve for cup introduction, emptying and cleaning (11). This is a disadvantage when compared to the manufactured sanitary pad which is easier to use and does not require genital manipulation. In some women, cup insertion is not feasible and it may be associated with women with no prior intercourse (13,20).

The cup is claimed to be safe although associated adverse effects have been reported, mainly limited to local symptoms such as irritation and pain, especially with initial use. However, there is a low probability of developing major complications such as toxic shock syndrome, which may have serious health implications (34). The assessment of safety, adverse effects and risks is limited by short follow-up, not longer than four months, in the studies.

It is worth noting that in low and middle income countries, lack of water, sanitation and hygiene, inadequate education and deficient disposal facilities did not prevent women from using the menstrual cup, with no significant increase in adverse reactions.

The results of this review are consistent with the meta-analysis by van Eijk et al. (9), which assessed the safety of the menstrual cup and the cervical

Table 2.
Advantages reported by menstrual cup users, clinical studies and manufacturer claims

User-reported advantages
Durable (up to 10 years) (12)
Environmentally friendly (2,15,38)
Comfortable (2,10,12,15,39,45)
Acceptable (11-13,32,33,36,40,42,45)
Practical (35)
Low cost (2,15,35,38,45)
Hygienic (35)
Easy to use (18,35,45)
Low probability of leakage (9,11,13,35,38,39)
Can be used during intercourse (39)
Advantages reported by clinical studies and manufacturers
Does not alter vaginal pH (6)
No vaginal wall or cervical injuries (6)
No threat to life* (39)
No disruption of the vaginal or cervical epithelium (39)
Potential clinical uses (vesicovaginal and enterovaginal fistulas) (16-18)
Reduces menses-related school attrition (21,33)

* Debatable due to case related with toxic shock syndrome reported in the literature.

diaphragm which reviewed 43 studies, 25 of which coincided with this work; the main difference being the inclusion of the cervical diaphragm in the analysis, which was not included in this review because of low product availability in Latin America. In terms of adverse effects, 7 case reports, 1 cohort study, 1 retrospective study and 1 in vitro study (10 articles) coincided. However, there was a higher number (5 cases) of patients with toxic shock syndrome, one of which was described in this review (50), while the remaining four studies were reported by

Table 3.
Disadvantages and adverse events reported by menstrual cup users, clinical studies and manufacturers

User-reported disadvantages and adverse events
Increased menstrual cramps (33)
Difficulty introducing or removing the cup (10,13,18)
Vaginal irritation (33,34,39)
Learning curve required (11)
Fear of painful insertion (13,45)
Stigmatization of use in women who have not initiated sexual activity (8,13,37)
Little product availability (7,19)
Disadvantages and adverse events reported by clinical studies and manufacturers
E. coli colonization (34)
Toxic shock syndrome (9, 46,50)
In vitro production of toxic shock syndrome toxin (46,50)
Retrograde menstruation (48)
Vaginal retention (49)
Hydronephrosis and renal colic (51,52)
Accidental IUD removal (19,47)
Allergy to the material (40)

the United States Food and Drug Administration (FDA). Likewise, the authors estimated a low rate of toxic shock syndrome of approximately 2.25 cases per 100,000 users per year.

The majority of the articles included in this review are descriptive, retrospective or case series that do not report association measures. This constitutes a limitation and it is consistent with the meta-analysis by van Eijk et al. which only identified three good quality studies (9). No data on inflammatory pelvic disease or endometriosis secondary to the use of the cup were identified.

Another limitation was the potential selection bias in studies published in languages other than Spanish or English. Four studies published in Portugal were excluded, and the search did not include studies in other languages.

CONCLUSION

The menstrual cup is a comfortable, safe and efficient alternative for menstrual hygiene when compared to sanitary pads and tampons. Further randomized controlled and long-term prospective cohort studies are required to determine the risk of complications due to excessive bacterial colonization or retrograde menstruation.

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REFERENCES

1. Liswood R. Internal menstrual protection. Use of a safe and sanitary menstrual cup. *Obstet Gynecol.* 1959;13(5):539-43.
2. Felitti K. El ciclo menstrual en el siglo XXI. *Rev Latinoam Sex Salud y Soc.* 2016;(22):175-206. <https://doi.org/10.1590/1984-6487.sess.2016.22.08.a>
3. Organic Cup. Cómo usar una copa menstrual. La guía paso a paso de OrganiCup; 2020. Available at: <https://www.organicup.com/es/como-usar/>
4. Hockert S. Catamenial Sack. US Patent and Trademark Office; Patent No. 70843, 1867.
5. Chalmers L. Catamenial Appliance. US Patent and Trademark Office; Patent No. 2089113, 1937.

6. Karnaky KJ. Internal menstrual protection with the rubber menstrual cup. *Obstet Gynecol.* 1962;19(5):688-91. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/14454013>
7. Caballero A. La copa menstrual: un nuevo método de higiene femenina. *Rev Hoj Bosq.* 2016;2(4):62-9.
8. Stewart K, Powell M, Greer R. An alternative to conventional sanitary protection: Would women use a menstrual cup? *J Obstet Gynaecol.* 2009;29(1):49-52. <https://doi.org/10.1080/01443610802628841>
9. van Eijk AM, Zulaika G, Lenchner M, Mason L, Sivakami M, Nyothach E, et al. Menstrual cup use, leakage, acceptability, safety, and availability: A systematic review and meta-analysis. *Lancet Public Health.* 2019;2667(19). [https://doi.org/10.1016/S2468-2667\(19\)30111-2](https://doi.org/10.1016/S2468-2667(19)30111-2)
10. Oster EF, Thornton RL. Determinants of technology adoption: Peer effects in menstrual cup take-up. *J Eur Econ Assoc.* 2012;10(6):1263-93. <https://doi.org/10.1111/j.1542-4774.2012.01090.x>
11. Madziyire MG, Magure TM, Madziwa CF. Menstrual cups as a menstrual management method for low socioeconomic status women and girls in Zimbabwe: A pilot study. *Women's Reprod Heal.* 2018;5(1):59-65. <https://doi.org/10.1080/23293691.2018.1429371>
12. Tellier M, Hyttel M, Gad M. Assessing acceptability and hygienic safety of menstrual cups as a menstrual management method for vulnerable young women in Uganda Red Cross Society's Life Planning Skills Project. Kampala, Uganda: WoMena; 2012. Available at: http://womens.dk/wp-content/uploads/2012/12/Menstrual-Cups_-_WoMena_-_Uganda-Pilot-Study-Report-Dec-2012-new-version.pdf
13. Shihata A, Brody S. An innovative, reusable menstrual cup that enhances the quality of women's lives during menstruation. *Br J Med Med Research.* 2014;4(19):3581-90. <https://doi.org/10.9734/BJMMR/2014/9640>
14. Organic Cup - Official Website. 2020. Available at: <https://www.organiccup.com/>
15. Felitti K. Cíclica y la copa menstrual argentina. *Historia, propuestas y desafíos del movimiento Maggacup.* *RevIISE.* 2017;1(1):37-50.
16. Goldberg L, Elsamra S, Hutchinson-Colas J, Segal S. Delayed diagnosis of vesicouterine fistula after treatment for mixed urinary incontinence: Menstrual cup management and diagnosis. *Female Pelvic Med Reconstr Surg.* 2016;22(4):29-31. <https://doi.org/10.1097/SPV.0000000000000301>
17. Russell KW, Robinson RE, Mone MC, Scaife CL. Enterovaginal or vesicovaginal fistula control using a silicone cup. *Obstet Gynecol.* 2016;128(6):1365-8. <https://doi.org/10.1097/AOG.0000000000001745>
18. Koks CAM, Arends JW, Dunselman GAJ, Evers JLH, De Goeij AFPM. Evaluation of a menstrual cup to collect shed endometrium for in vitro studies. *Fertil Steril.* 1997;68(3):560-4. [https://doi.org/10.1016/S0015-0282\(97\)00250-1](https://doi.org/10.1016/S0015-0282(97)00250-1)
19. Wiebe ER, Trouton KJ. Does using tampons or menstrual cups increase early IUD expulsion rates? *Contraception.* 2012;86(2):119-21. <https://doi.org/10.1016/j.contraception.2011.12.002>
20. Johansson L, Hellström H. Is the menstrual cup filled with capabilities?: A qualitative case study of a menstrual hygiene program in the North West province of South Africa with focus on female students. (Bachelor's thesis) School of Natural sciences, technology and environmental studies Södertörn University; 2018. Available at: <http://www.diva-portal.org/smash/get/diva2:1218307/FULLTEXT01.pdf>
21. Phillips-Howard PA, Nyothach E, Ter Kuile FO, Omoto J, Wang D, Zeh C, et al. Menstrual cups and sanitary pads to reduce school attrition, and sexually transmitted and reproductive tract infections: A cluster randomised controlled feasibility study in rural Western Kenya. *BMJ Open.* 2016;6(11):e013229. <https://doi.org/10.1136/bmjopen-2016-013229>
22. Beksinska ME, Smit J, Greener R, Maphumulo V, Mabude Z. Better menstrual management options for adolescents needed in South Africa: What about the menstrual cup? Correspondence. *South African Med J.* 2015;105(5):331. <https://doi.org/10.7196/SAMJ.9205>
23. Sommer M, Caruso BA, Sahin M, Calderon T, Cavill S, Mahon T, et al. A time for global action: Addressing girls' menstrual hygiene management needs in

- schools. *PLOS Med.* 2016;13(2):e1001962. <https://doi.org/10.1371/journal.pmed.1001962>
24. Menstrual Cup Master List 2017. 2017. Available at: <https://menstrualcups.wordpress.com/menstrual-cup-master-list/>
 25. Colombia | Toallas Femeninas Ecológicas. 2019. Available at: <https://toallasfemeninasecológicas.wordpress.com/donde-conseguirlas/colombia/>
 26. Felitti K. Cíclica y la copa menstrual argentina. *Rev Ciencias Soc y Humanas del Inst Investig Socio- Económicas.* 2017;10(1):37-50.
 27. Eva Copa Menstrual - Facebook. 2020. Available at: <https://www.facebook.com/EvaCopaMenstrual>
 28. #CopaMenstrual - Instagram. 2020. Available at: <https://www.instagram.com/explore/tags/copamenstrual/?hl=es-la>
 29. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomized trials. *Open Med.* 2010;4(1). <https://doi.org/10.1186/1745-6215-11-32>
 30. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for reporting observational studies. *Lancet.* 2007;370(1):1453-7. [https://doi.org/10.1016/S0140-6736\(07\)61602-X](https://doi.org/10.1016/S0140-6736(07)61602-X)
 31. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *Int J Surg.* 2010;8(5):336-41. <https://doi.org/10.1016/j.ijso.2010.02.007>
 32. Howard C, Rose CL, Trouton KJ, Stamm H, Marenthette D, Kirkpatrick N, et al. FLOW (finding lasting options for women): Multicentre randomized controlled trial comparing tampons with menstrual cups. *Can Fam Physician.* 2011;57(6):208-15.
 33. Beksinska ME, Smit J, Greener R, Todd CS, Lee MT, Maphumulo V, et al. Acceptability and performance of the menstrual cup in South Africa: A randomized cross-over trial comparing the menstrual cup to tampons or sanitary pads. *J Women's Heal.* 2015;24(2):151-8. <https://doi.org/10.1089/jwh.2014.5021>
 34. Juma J, Nyothach E, Laserson KF, Oduor C, Arita L, Ouma C, et al. Examining the safety of menstrual cups among rural primary school girls in western Kenya: Observational studies nested in a randomised controlled feasibility study. *BMJ Open.* 2017;7(4):e015429. <https://doi.org/10.1136/bmjopen-2016-015429>
 35. Peña EF. Menstrual Protection. Advantages of the menstrual cup. *Obstet Gynecol.* 1962;19(5):684-7.
 36. Parker J, Bushell R, Behrman S. Hygienic control of menorrhagia: Use of rubber menstrual cup. *Int J Fertil.* 1964;9:619-21.
 37. Averbach S, Sahin-Hodoglugil N, Musara P, Chipato T, van der Straten A. Duet® for menstrual protection: A feasibility study in Zimbabwe. *Contraception.* 2009;79(6):463-8. <https://doi.org/10.1016/j.contraception.2008.12.002>
 38. Stewart K, Greer R, Powell M. Women's experience of using the mooncup. *J Obstet Gynaecol.* 2010;30(3):285-7. <https://doi.org/10.3109/01443610903572117>
 39. North BB, Oldham MJ. Preclinical, clinical, and over-the-counter postmarketing experience with a new vaginal cup: Menstrual collection. *J Women's Health.* 2011;20(2):303-11. <https://doi.org/10.1089/jwh.2009.1929>
 40. Kakani CR, Bhatt JK. Study of adaptability and efficacy of menstrual cup in managing menstrual health and hygiene. *Int J Reprod Contraception, Obstet Gynecol.* 2017;6(7):3045. <https://doi.org/10.18203/2320-1770.ijrcog20172932>
 41. Chintan S, Dipesh P, Maitri P. Use of flow care menstrual cups over conventional menstrual products in India. *Int J Adv Res Dev.* 2017;2(8):78-82.
 42. Cheng M, Kung R, Hannah M, Wilansky D, Shime J. Menses Cup* evaluation study. *Fertil Steril.* 1995;64(3):661-3. [https://doi.org/10.1016/S0015-0282\(16\)57812-1](https://doi.org/10.1016/S0015-0282(16)57812-1)
 43. Oster EF, Tharnton R. Determinants of technology adoption: Private value and peer effects in menstrual cup take-up. *NBER Work Pap;* 2009. <https://doi.org/10.3386/w14828>

44. Oster EF, Thornton RL. Menstruation, sanitary products, and school attendance: Evidence from a randomized evaluation. *NBER Work Paper Ser.* 2010;3(1):91-100. <https://doi.org/10.1257/app.3.1.91>
45. Mason L, Laserson KF, Oruko K, Nyothach E, Alexander KT, Odhiambo FO, et al. Adolescent school-girls' experiences of menstrual cups and pads in rural western Kenya: A qualitative study. *Waterlines.* 2015;34(1):15-30. <https://doi.org/10.3362/1756-3488.2015.003>
46. Nonfoux L, Chiaruzzi M, Badiou C, Baude J, Tristan A, Thioulouse J, et al. Impact of currently marketed tampons and menstrual cups on staphylococcus aureus growth and toxic shock syndrome toxin 1 production in vitro. *Appl Environ Microbiol.* 2018;84(12):1-12. <https://doi.org/10.1128/AEM.00351-18>
47. Seale R, Powers L, Guiahi M, Coleman-Minahan K. Unintentional IUD expulsion with concomitant menstrual cup use: A case series. *Contraception.* 2019;100(1):85-87. <https://doi.org/10.1016/j.contraception.2019.03.047>
48. Spechler S, Nieman LK, Premkumar A, Stratton P. The keeper, a menstrual collection device, as a potential cause of endometriosis and adenomyosis. *Gynecol Obstet Invest.* 2003;56(1):35-7. <https://doi.org/10.1159/000072329>
49. Day S. A retained menstrual cup. *Int J STD AIDS.* 2012;23(5):367-8. <https://doi.org/10.1258/ijsa.2011.011277>
50. Mitchell MA, Bisch S, Arntfield S, Hosseini-Moghadam SM. A confirmed case of toxic shock syndrome associated with the use of a menstrual cup. *Can J Infect Dis Med Microbiol.* 2015;26(4):218-20. <https://doi.org/10.1155/2015/560959>
51. Nunes-Carneiro D, Couto T, Cavadas V. Is the menstrual cup harmless? A case report of an unusual cause of renal colic. *Int J Surg Case Rep.* 2018;46(1):28-30. <https://doi.org/10.1016/j.ijscr.2018.04.002>
52. Stolz A, Meuwly JY, Roussel A, Nicodème Paulin E. An improperly positioned menstrual cup complicated by hydronephrosis: A case report. *Case Reports Women's Heal.* 2019;22:e00108. <https://doi.org/10.1016/j.crwh.2019.e00108>
53. Liswood R. Internal menstrual protection. Use of a safe and sanitary menstrual cup. *Obstet Gynecol.* 1959;13(5):539-43.

AUTHORS' CONTRIBUTIONS

Camilo Arenas-Gallo: Conception, design of the review, database assessment, data analysis and interpretation, planning of the article and review of important intellectual content, and final approval of the version for publication.

Gabriela Ramírez-Rocha: Conception and design of the review, database assessment, data analysis and interpretation, planning of the article and review of important intellectual content, and final approval of the version for publication.

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Catalina Merlano-Alcendra: Conception and design of the review, data analysis and interpretation, planning of the article and review of important intellectual content, and final approval of the version for publication.

Daniela Palomino-Suárez: Conception and design of the review, data analysis and interpretation, planning of the article and review of important intellectual content, and final approval of the version for publication.

Santiago Rueda-Espinel: Conception, design of the review, database assessment, data analysis and interpretation, planning of the article and review of important intellectual content, and final approval of the version for publication.

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