

The safety of menstrual cups in women of low socio-economic status in Zimbabwe: a pilot study

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Abstract

Background: Poor women in Zimbabwe struggle to find appropriate affordable menstrual care products and often use pieces of blankets, cloths and toilet paper. Menstrual cups are a re-usable alternative which can be kept for many years.

Objectives: To assess the safety of menstrual cups when used by women in the poor socio-economic stratum.

Design: This was a prospective interventional study where 52 sexually active women from Epworth district in Zimbabwe aged 18-45 years who had been experiencing monthly periods and who had no intention of falling pregnant within 1 year were given and trained in use of menstrual cups and followed up for 12 months.

Results: Fifty one (94%) were still using the cup at 12 months follow up and they all wished to continue using the cup. Eighty three percent (43) of participants would recommend the cup to another woman. The majority (92%) did not experience a change in menstrual cycle length or volume of flow while none of the women sought treatment for a pelvic infection. There was no onset or worsening of dysmenorrhoea in 83%, dyspareunia in 94%, pelvic pain in 92% and vaginal discharge in 92% of the participants during the 12 months of cup use.

Conclusion: This study shows that the menstrual cup is acceptable, safe and a convenient menstrual care management device which can be used by women of low socio-economic status in Zimbabwe.

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Introduction

Menstrual cups (Figure I) are re-usable bell shaped devices made of silicone, rubber, or thermo plastic elastomer worn in the vagina to collect menstrual discharge, which are emptied, cleaned and reinserted during menses and sterilised at the end of the menstrual period. They are available as a small or medium size and collect 3 times as much fluid as the average tampon. They are inserted in a squatting position or with one leg raised on a step after folding them to the size and shape of a tampon and pushed inside until the pulling tip is in the vaginal canal (Figure II). Women with heavy flow are advised to use the large cup. They open up once in the vagina to form an air tight seal with vaginal walls. They have a tip to pull them out for emptying. Like tampons they don't require the vagina to be cleaned. They can be lubricated with ordinary tap water but generally don't require lubrication during insertion. They are heat treated with boiling water or disinfectant after the menstrual cycle and stored for the next cycle. The same cup can be used up to 10 years. They were patented for general use in 1937 and subsequently got

the United States Food and Drug Administration licensing.^{1,2} They don't have official approval in Zimbabwe though they are sold or distributed alongside other menstrual care products by private pharmacies and non-governmental organisations.

Poor Zimbabwean women struggle to find affordable menstrual care products with majority resorting to pieces of worn out clothes or blankets and toilet paper.³ This predisposes them to poor menstrual hygiene, absenteeism from school, poor performance in sports and other social activities.⁴ Even the re-usable menstrual pads sometimes distributed by non-governmental organizations to rural girls require frequent changing and this is hampered by lack of public facilities offering privacy and good hygiene.³ Menstrual cups are comfortable after the first cycle of use, don't disturb day to day activities, can be worn during the whole day and are acceptable amongst poor women and girls in Zimbabwe.^{5,6}

However the safety of menstrual cups use by women in the low socio-economic stratum remains questionable. There are concerns with issues of the ability to clean, store and properly use the device. If not

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used properly then there is the potential of causing infections or bruising in the genital tract. Menstrual cups can potentially cause retrograde menstruation, which is associated with endometriosis although this association has not been proven.⁷⁻⁸ There is therefore need for continued vigilance and monitoring of all women using menstrual cups. A study in the US has not shown toxic effects or mutagenicity amongst 406 women using menstrual cups and likewise a pilot study in Kampala, Uganda did not report any adverse effects.^{5,9} We therefore sought to evaluate the safety of menstrual cups after 12 months of usage by women in the low socio-economic stratum.

We analysed data after 12 months follow up from a pilot study on Zimbabwean women in Epworth district using the menstrual cup. An interim analysis of this pilot group at 3 months follow up assessing correct use and acceptability of menstrual cups as an alternative reusable menstrual care product is reported elsewhere.⁶

Materials and Methods

Participants

Fifty two sexually active women aged 19-45 years who had been experiencing monthly periods and who had no intention of becoming pregnant within 1 year were successively recruited after consenting. These had been identified by a community health worker in Epworth district as they came for family planning at the local clinic. Women who were allergic to silicone, pregnant or planning to become pregnant within 1 year, never been sexually active and had symptoms of active genital infections were excluded from the study.

The minimum age of 18 years was chosen, as it is the legal age of consent in Zimbabwe. The majority of participants (74%) did not have monetary income. Forty six (85%) were educated up to secondary school level. The majority (87%) were married (See Table I).

Setting

Epworth is a poor peri-urban under serviced residential area bordering the eastern side of Harare and is densely populated. It has a population of about 30 000 people living in shacks and only about 15% of adults are employed.¹⁰

Materials

A questionnaire was designed by the investigators to capture experiences with the menstrual cup, after 12 months of use. Safety was assessed by the continuity rate of cup use, presence of adverse effects such as vaginal bruising, onset or worsening of vaginal discharge, dysmenorrhoea, dyspareunia and pelvic pain during the 12 months of cup use. Participants also reported whether they would recommend it to other women. Convenience of cup use was assessed by the number of times the cup needed to be emptied per day, method of sterilisation and overall experience with cup after 1 year of use.

Procedure

Permission to conduct the study was granted by the Medical Research Council of Zimbabwe (A/2111). Permission was also sought and granted by the Epworth local board and the Provincial Medical Director of Mashonaland East.

The pilot group was recruited by community health workers in Epworth. This was a prospective interventional study which assessed participants after 12 months of follow up. A training workshop was held at Epworth local board hall to train the study participants about menstrual cups. Training emphasized hygienic handling, such as hand washing and sterilization of the menstrual cups during and after a menstrual period. Those who met the inclusion criteria were asked to provide consent; baseline characteristics were recorded, and were supplied with a butterfly menstrual cup. The cups were bought from a local pharmacy by the researchers. There was no preference for this cup other than that it was the brand in stock. The participants were contacted by phone or home visits in November 2017, after the whole cohort had experienced 12 months of cup use and questionnaires completed. Consistency in cup use was recorded. No compensation, monetary or otherwise was given to participants. The questionnaires were checked for completeness and were entered into Microsoft Excel and frequency tables and graphs produced.

Results

Figure 1: Menstrual cup.



Figure II: Insertion method.

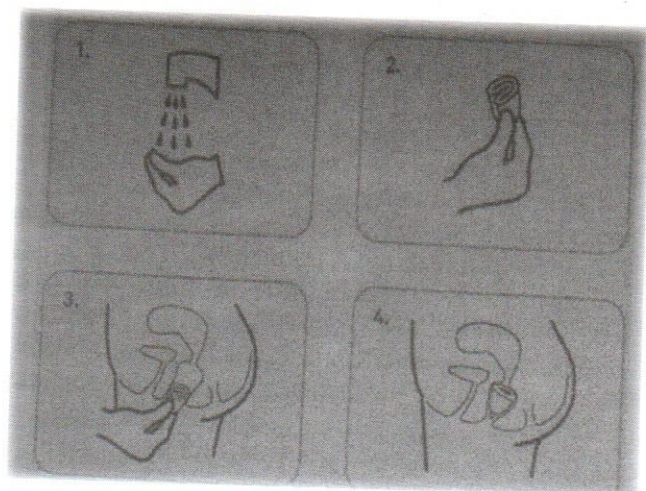


Table I: Table I: Socio-demographic characteristics of women who used the menstrual cup.

Category	n	%
Age:		
18-24	7	13
25-31	12	22
32-38	18	33
39-45	17	32
Marital status:		
Single	6	11
Married	47	87
Cohabiting	0	0
Other	1	2
Education:		
Primary	8	15
Secondary	45	83
Tertiary	1	2
Income (US\$):		
0	40	74
<100	12	22
100-200	0	0
Other	2	4

Out of the 54 participants enrolled 52 were followed up for 1 year. Two participants had dropped out after the first two cycles of cup use. The first participant who dropped out had wished to continue but her husband did not agree to use of the cup. The second participant went to a rural area to farm and was lost to follow up.

Fifty one (94%) were still using the cup at 12 months follow up and they all wished to continue using the cup. One participant used the cup for 5 months but it was thrown away by husband during a domestic scuffle. She was included in the analysis as she responded to the questions in the questionnaire.

Eighty three percent (43) of participants would recommend the cup to another woman. Sixty nine percent (36) preferred the small cup size. Seventy seven percent (40) emptied the cup twice a day with 13 and 12% emptying once and 3 or more times respectively.

The majority [92% (47)] did not experience a change in menstrual cycle lengthy or volume of flow while none of the women sought treatment for a pelvic infection.

The majority of women did not experience onset or worsening of dysmenorrhoea in 43 (83%), onset or worsening of dyspareunia 49 (94%), onset or worsening of pelvic pain in 48 (92%) and onset or worsening of vaginal discharge in 48 (92%) during the 12 months of cup use.

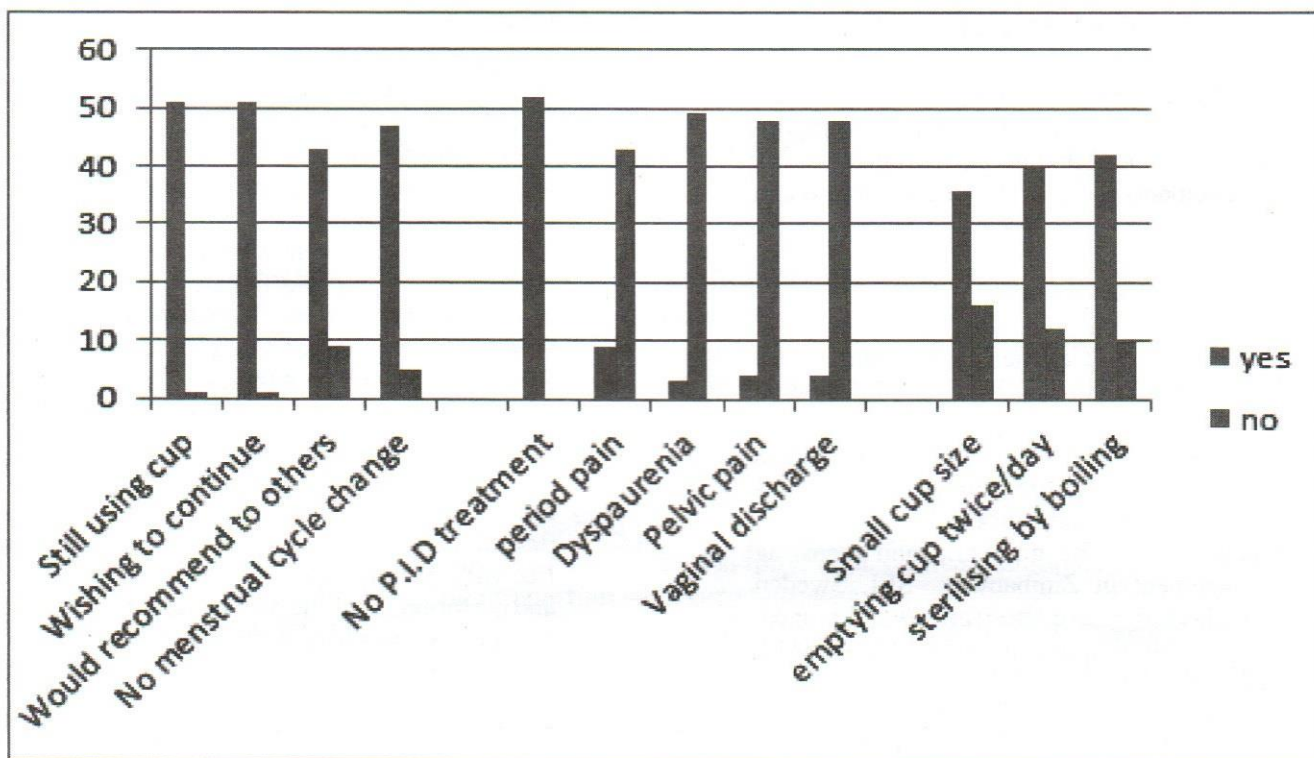
After 1 year of follow up 81% (42) preferred boiling the cup as compared to immersing in sterilising solution as means of sterilisation (Table II, Figure III).

Table II: Experience after 12 months of cup use.

Experience	Yes n	%	No n	%	Total n	%
Still using cup	51	94	3	6	*54	100
Wishing to continue	51	94	3	6	*54	100
Would recommend to others	43	83	9	17	52	100
No menstrual cycle change	47	92	5	8	52	100
No pelvic inflammatory disease treatment	52	100	0	0	52	100
Period pain	9	17	43	83	52	100
Dyspareunia	3	6	49	94	52	100
Pelvic pain	4	8	48	92	52	100
Vaginal discharge	4	8	48	92	52	100
Small cup size	36	69	16	31	52	100
Emptying cup twice/day	40	67	12	33	52	100
Sterilising by boiling	42	81	10	19	52	100

*the experience of 'still using' and 'wishing to continue' with cup use was measured against the original cohort of 54 women enrolled while experience with the cup was against 52 women who continued cup use and were followed up to 1 year. Two women dropped out after the first two cycles of cup use.

Figure III: Experience after 12 months of cup use.



Discussion

Of the original cohort of 54 participants who had been trained to use the menstrual cup, 51 (94%) were still using it after 12 months and all wishing to continue using it. This shows continued acceptability of the cup which had been found at the 3 months interim analysis of this cohort.⁶ The high continuity rate of cup use has been shown in another study in Kenya amongst 35 women and 55 school girls which showed that 95% of them wished to continue using the cup despite initial anxiety about its size.¹¹ However despite all the participants followed up to 12 months of cup use wishing to continue using the cup only 43 (83%) would recommend it for use by others. The misgivings for not recommending use of the cup to others included fears of disturbing virginity (not shown) in sexually naïve girls which is a contentious issue in the local culture and can affect a girl's bride price at marriage.¹²

The cup did not cause changes in the pattern, flow and length of menses. This is expected as the cup is made of inert materials unlikely to induce reactions in the vagina or upper genital tract. Safety of the menstrual cups was assessed by experiences which would suggest infection or endometriosis. None of the participants sought care for a possible genital tract infection. Onset or worsening of dysmenorrhoea, dyspareunia, pelvic pain and vaginal discharge which can suggest infection or endometriosis were experienced by a minority of the women. The fact that all the women wished to continue using the cup suggest that even in the few who experienced the symptoms they considered them trivial.

Majority of participants emptied the cup twice a day.

This supports the convenience of the cup as it can be worn during the working hours and thereby removing the inconvenience of changing it while away from home. There is lack of public facilities in poor communities that ensure privacy and good hygiene for women and girls to change their menstrual care product when away from home.³

The participants preferred sterilising the cup by boiling over use of a sterilising solution. This is likely because participants perceive boiling to be cheaper and easier to use compared to the sterilising solution which requires a dilution formula and soaking the cup for a certain period of time before its deemed sterile.

This study relied on self-reported experience without confirmatory clinical evaluation and hence might fail to pick some adverse effects due to menstrual cup usage. Recall bias might also have made some participants fail to report certain experiences with cup use.

There is therefore need for continued surveillance of menstrual cups as some adverse events take time to build up and might become apparent after years of use. The pilot included girls who were sexually active and above the age of 18. While the cups is being used in school going girls in South Africa¹³ and Kenya^{11,14} there is need to assess its' acceptability in sexual naïve girls and women in a Zimbabwean cultural context.^{11,13-14}

Conclusion

This study shows that menstrual cups are acceptable, safe and convenient menstrual care management devices which can be used by women of low socio-

Acknowledgements

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