Original Article

Comparative Study of Satisfaction and Acceptability between Using Menstrual Cup versus Sanitary Pads in Health Care Personnel: A Randomized Crossover Trial

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Background: In the past decade, menstrual cups (MC) have become increasingly popular in many countries but there was no previous reporting on MC usage in Thailand.

Objective: To evaluate and compare the satisfaction and acceptability of using MC and sanitary pads (SP) in health care personnel (HCP).

Materials and Methods: Participants were HCP in Bhumibol Adulyadej Hospital who were willing to participate in the study between October 2019 and March 2020. They were randomly assigned into groups A and B. During the first three cycles of menstruation, participants in group A and B used SP and MC, respectively. In the later three cycles of menstruation, they were switched from SP to MC and vice versa. The demographic and menstrual characteristics were recorded. Satisfaction was evaluated by using the five-point Likert scale. Acceptability of MC usage was recorded on the sixth cycle questionnaire.

Results: Ninety-eight HCP were recruited and equally divided into two groups (A and B). Acceptability for MC was significantly lower than SP (89 versus 100 percent, respectively). Participants who had regular sexual intercourse had more acceptability with MC than those who had no regular intercourse (98.4 versus 68.7 percent, respectively). Participants reported more significant satisfaction for MC than SP in terms of leakage prevention, cleaning, odor prevention, land activity, daily activity, comfortable sleep, and overall satisfaction. Contact dermatitis associated with MC was less than with SP with a statistically significant difference.

Conclusion: Acceptability for MC was lower than SP. MC's acceptability was preferred among HCPs with regular sexual intercourse. MC had higher satisfaction and less side effects than SP.

Keywords: Acceptability, Menstrual cup, Menstruation, Sanitary pads, Satisfaction

Received 26 May 2020 | Revised 24 August 2020 | Accepted 25 August 2020

J Med Assoc Thai 2021;104(1):1-9

Website: http://www.jmatonline.com

Menstrual cups are a relatively new menstrual care product. The product was first manufactured from rubber by McGlasson and Perkins in 1932 to replace sanitary pads[1]. Sanitary pads in their commercial form have many pros and cons. Women need menstrual care but also want the solutions to fit changing lifestyles. Sanitary pads sometimes leak, may result in odor control problems, as well as some reported allergenic issues[2]. Menstrual cups have been designed to alleviate those problems. However, it took environmental issues to bring this 80+ years old invention into the public eye. The use of the menstrual cup could alleviate the waste management problem of non-reusable sanitary pads.

Menstrual cups were first produced for sale in the USA by Chalmers in 1937 but were unpopular[3]. In 2001, a company in England started to produce menstrual cups from silicone called thermoplastic elastomer. This new material met medical standards was durable and non-allergenic. The use of menstrual cup has been recently widespread, primarily in Canada, England, and South Africa[4-6].

Nowadays, menstrual cups are made from medical grade silicone. Its bell shape is designed for

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How to cite this article:

Weerawatsopon S, Luangdansakul W, Prommas S, Smanchat B, Bhamarapravatana K, Suwannarurk K. Comparative Study of Satisfaction and Acceptability between Using Menstrual Cup versus Sanitary Pads in Health Care Personnel: A Randomized Crossover Trial. J Med Assoc Thai 2021;104:1-9.

doi.org/10.35755/jmedassocthai.2021.01.11485

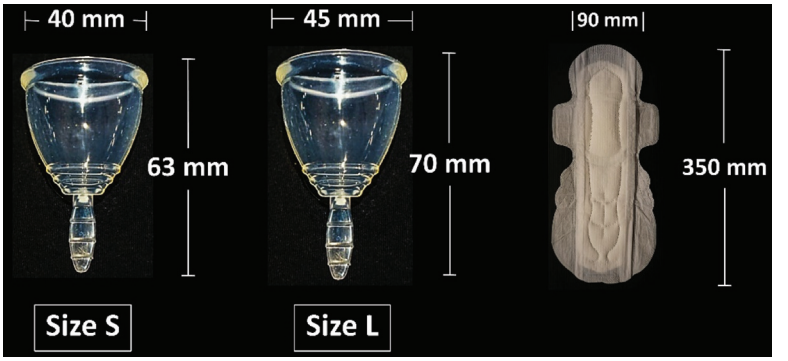

Figure 1. The JoyliveCY® menstrual cup (Shenzhen, China) size S, L and sanitary pads (Chachoengsao, Thailand).

easy vaginal insertion. Cup capacity ranges from 10 to 38 mL, which is enough for an average menstrual cycle (86.7 mL with range 15 to 271 mL per cycle[7,8]). For sanitary reasons, a used cup should be cleaned every 4 to 12 hours depending on the amount of secreted blood[9]. The cup should be cleaned by placing in rapid boiling water for a 5 to 10 minutes sterilization after each period cessation. It can be reused for up to 10 years until the silicone degrades[9].

There are several studies concerning the satisfaction and side effects of menstrual cup usage[7,10,11]. Until now, there has been no study of menstrual cup usage in Thailand. The primary objective of the present study was conducted to evaluate the acceptability of the use of menstrual cup in health care personnel (HCP). The secondary objectives were to evaluate satisfaction of insertion, removal, leakage and odor prevention, cleaning, on land, in water, and daily activities, sleep comfort, and overall satisfaction. In addition, frequency of changing sanitary pads or menstrual cup per day and side effects were also evaluated.

Materials and Methods

The present study was a single-blinded randomized crossover-controlled trial conducted at Bhumibol Adulyadej Hospital (BAH), Thailand, between October 2019 and March 2020. The study was ethically approved by the BAH Institutional Review Board (IRB No.55/62) on August 2, 2019 and registered with the Thai Clinical Trial Registry (TCTR20190908003).

Participants were female HCP ranging from 18 to 50 years of age and willing to participate in the present study. Exclusion criteria were women currently using long-acting reversible contraception, with no menstruation, who were unavailable for follow up, who had irregular menstrual bleeding, with a history of hypersensitivity to silicone, with an immunocompromised status, with autoimmune diseases, and with a history of steroid intake.

A pilot study was done. From 20 subjects, the acceptability of the use of a menstrual cup was 80%. The sample size for the investigation was calculated using the acceptability to the use of a menstrual cup from the pilot study with two dependent proportions formula. With a power of 90% and a 2-sided type I error of 0.01, at least 70 participants were required. With a 40% addition for possible data loss, the number of participants required was 98.

All eligible participants were informed in detail about the research study and all signed written informed consents prior to the study enrollment. Participants were randomly assigned to group A (using sanitary pads during the first to the third cycles and using the menstrual cup during the fourth to the sixth cycles), and group B (using the menstrual cup during the first to the third cycles and using sanitary pads during the fourth to the sixth cycles), using a block size of 4 with a 1:1 fashion. The demographic data including age, body mass index (BMI), medical diseases, education, parity, history of normal delivery, and sexual activity, and clinical characteristics including the history of using menstrual product were recorded. Self-filling questionnaires were used in the present study.

After randomization, menstrual cups (JoyliveCY®, Shenzhen, Republic of China) and sanitary pads (Figure 1), were provided to all participants. Menstrual cups employed in the present study were of two sizes. Size S and L cup had 25 mL and 28 mL capacity, respectively. The participants could freely choose the appropriate cup and change to another size for comfortable application. Instruction manual was given to all participants as brochures and an instructional YouTube video in Thai[12]. Sanitary

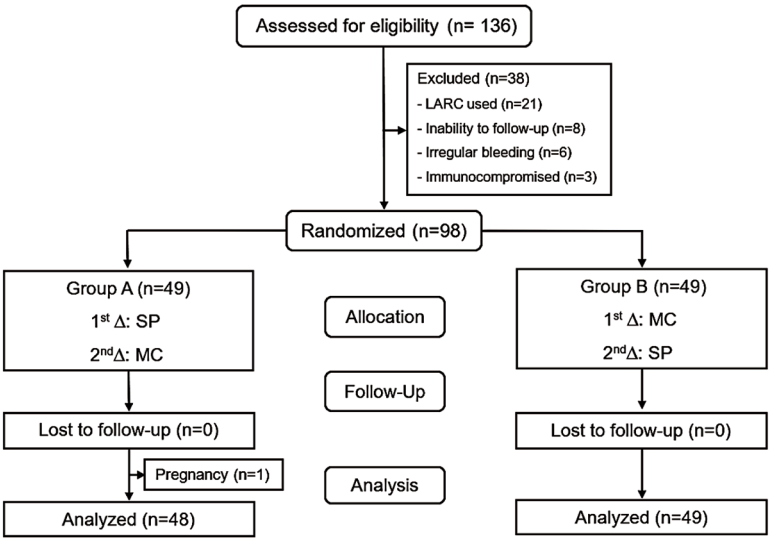

Figure 2. Consort flow chart of randomization.

LARC=long-acting reversible contraception, 1stΔ=first three cycles, 2ndΔ=later three cycles, SP=sanitary pads, MC=menstrual cup

pads were 35 cm in length and 9 cm in width with wings (SOFY®, Chachoengsao, Thailand). After using sanitary pads or menstrual cups for three consecutive menstrual cycles, participants were asked to answer the first set of questionnaires then continue to follow-up for a total of six menstrual cycles. After the sixth cycle usage period, participants were asked to answer the second set of questionnaires.

Satisfaction scores were assessed using the five-point Likert scale. In this scale, 5 indicated 'extremely satisfied' and 1 indicated 'unsatisfied'. Satisfaction for insertion, removal, leakage prevention, cleaning, odor prevention, on land activity, in water activity, daily activity, sleep comfort, overall satisfaction score, frequency for changing or removal for cleaning (per day), and any adverse reaction were also recorded. Acceptability of menstrual cup usage was recorded at the sixth cycle questionnaire. The outcome evaluator was blinded from the methods.

The construct validity was used for the questionnaire validity by using the cut-off value of 0.7 or above Cronbach's alpha coefficient[13]. This validated the questionnaire. Reliability was 0.884.

Statistical analysis

A per-protocol analysis was performed using PASW Statistics, version 18.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were reported using the mean ± standard deviation (SD) or median (interquartile range [IQR]) for continuous data and the number with percentages reported for categorical data. The acceptability of the use of menstrual cup and sanitary pads in HCP were calculated based on binomial distribution and compared using Mc-Nemar test. For outcome comparisons in each period, the continuous variables were tested for normal distributions using the Kolmogorov-Smirnov test. Independent student t-tests were used for parametric data analysis and the Wilcoxon rank sum test was used for nonparametric data. Pearson chi-square or Fisher's exact test were used for categorical variables. A p-value of less than 0.05 was considered to be statistically significant.

Results

One hundred thirty-six BAH HCP were recruited for the present study. Ninety-eight cases were enrolled into the study. During the period of the present study, one case in group A became pregnant and dropped out. The consort flow diagram is shown in Figure 2. Completion of questionnaires was one hundred percent.

Average age of the participants was 32 years old. Two-third of the cases had a bachelor's degree or higher. Vaginal tampon using experience was found in one-sixth of the participants. Others clinical characteristics of the participants between both groups were comparable as presented in Table 1.

Participants reported more satisfaction with the menstrual cup than the sanitary pads, with respect to leakage and odor prevention, cleaning, on land and daily activities, comfortable sleep, and overall

Table 1. Clinical characteristics and demographic data

	Group A (n=48); n (%)	Group B (n=49); n (%)	p-value
Age (year); mean±SD	32.9±7.4	32.5±7.9	0.807
BMI (kg/m^2); median (P_{25}, P_{75})	22.1 (20.2, 24.5)	21.6 (20.3, 24.6)	0.954
Medical diseases*	10 (20.8)	7 (14.3)	0.396
Bachelor degree or higher	29 (60.4)	35 (71.4)	0.252
Alcohol use	8 (16.7)	6 (12.2)	0.536
Non-smoker	48 (100)	46 (93.9)	0.242
Duration (days); mean±SD	4.2±1.2	4.4±1.1	0.253
Amount of pads per day; median (P_{25}, P_{75})	3.5 (3, 4)	3.5 (3, 4.5)	0.657
Single	26 (54.2)	27 (55.1)	0.926
Nulliparity	30 (62.5)	33 (67.3)	0.617
History of normal delivery	6 (12.5)	9 (18.4)	0.424
No SI in 1 year	15 (31.3)	17 (34.7)	0.718
Age of coitarche (years); mean±SD	21.2±3.6	22.7±4.2	0.120
History of contraception			
Oral contraceptive pills	21 (43.8)	18 (36.7)	0.481
Condom	16 (33.3)	19 (38.8)	0.577
Tampons usage experience	9 (18.8)	8 (16.3)	0.754

BMI=body mass index; SI=sexual intercourse

Group A: use sanitary pads (SP) in first three cycles, menstrual cup (MC) in later three cycles; Group B: use MC in first three cycles, SP in later three cycles; * diabetic mellitus, hypertension, hyperlipidemia

p-value calculated by two sample independent t-test (mean), Wilcoxon rank sum test (median), and chi-square or Fisher's exact test (categorical variables)

Table 2. Satisfaction outcomes after each trimester

Five-point Likert scale	First; median (P_{25}, P_{75})		p-value	Second; median (P_{25}, P_{75})		p-value
	MC	SP		MC	SP	
Satisfaction						
Insertion	4 (4, 5)	4 (3, 4)	0.263	4 (4, 4.5)	4 (3, 4)	0.28
Removal	4 (4, 5)	4 (3, 4)	0.24	4 (3, 5)	4 (3, 4)	0.625
Leakage prevention	4 (3, 4)	3 (2, 3)	<0.001	5 (4, 5)	3 (2, 4)	<0.001
Cleaning	5 (4, 5)	3 (2, 3.5)	<0.001	5 (4, 5)	3 (2, 3)	<0.001
Odor prevention	5 (4, 5)	3 (2, 3)	<0.001	5 (4, 5)	2 (1, 3)	<0.001
Land activity	5 (4, 5)	2 (2, 3)	<0.001	5 (4, 5)	1 (1, 2)	<0.001
Water activity	5 (4, 5)	NA	NA	5 (4, 5)	NA	NA
Daily activity	5 (4, 5)	2.5 (2, 3)	<0.001	5 (4, 5)	3 (2, 3)	<0.001
Sleep	5 (4, 5)	3 (2, 3)	<0.001	5 (4, 5)	3 (2, 3)	<0.001
Overall satisfaction	4 (4, 5)	3 (3, 3)	<0.001	4 (4, 5)	3 (3, 3)	<0.001
FCD; mean±SD	3.37±0.97	3.6±1.13	0.17	3.35±0.97	3.78±0.77	0.02

First=first trimester; Second=second trimester; MC=menstrual cup; SP=sanitary pads; NA=not available; FCD=frequency for changing per day

p-value calculated by Wilcoxon rank sum test (median) and two samples independent t-test (mean)

satisfaction with statistical significance as shown in Table 2. Since none of the participants participated in water activities while using the sanitary pads, the satisfaction score in this issue was not available. In contrast to the sanitary pads, all participants with the menstrual cup participated in water activities, such as swimming or showering at least one time while wearing the cup. The changing frequency per day

Table 3. Participants' side effects (n=97)

	MC; n (%)	SP; n (%)	p-value
No	89 (91.8)	62 (63.9)	<0.001
Contact dermatitis	0 (0.0)	30 (30.9)	<0.001
Genital abrasion	1 (1.0)	2 (2.1)	0.56
Abdominal pain	3 (3.1)	4 (4.1)	0.65
Leukorrhea	4 (4.1)	3 (3.1)	0.71

MC=menstrual cup; SP=sanitary pads

p-value calculated by MC-Nemar test

between menstrual cup and sanitary pads use was not statistically significant different in the first trimester. However, in the second trimester, the frequency for daily changing of menstrual cup usage was significantly less than sanitary pads usage (Table 2).

Overall acceptability for menstrual cup and sanitary pads group were 88.7 and 100% (p=0.001), respectively. Participants who had regular sexual intercourse had higher acceptance to menstrual cups than those who reported no sexual intercourse in more than one year (98.4 versus 68.7% (p<0.001), respectively).

Around 91.8 and 63.9% of the participants during the period of menstrual cup and sanitary pads usage reported no side effect, respectively. Major complaint of sanitary pad usage side effect was contact dermatitis at around one-third with statistical significance (Table 3).

Comparisons between previous menstrual cup studies in different countries including Canada, USA, Sweden, Mexico, Brazil, Colombia, South Africa, India, Uganda, and Zimbabwe are summarized and presented in Table 4[4 6,14-17]. The present study had a higher number of participants who had no current or

Table 4. Comparison of menstrual cup usage

Author	Howard, et al.[4]	Shihata and Brody[14]	Beksinska, et al.[6]	Kakani and Bhatt[15]	Care-U[16]	Madziyire, et al.[17]	Present study
Years	2011	2014	2015	2017	2018	2018	2020
Country	Canada	Multiple	South Africa	India	Uganda	Zimbabwe	Thailand
Type	R	C	RC	R	C	C	RC
Age (years)	26.6	18 to 40	29	20 to 50	15 to 30	18 to 45	32.7
Case (n)	45	146	110	150	80	54	98
Comparison	TP	UP	UP	No	UP	No	SP
Menstrual cup brand	Divacup	FemmyCycle	Mcup	NA	Ruby cup	Butterfly	JoyliveCY
Follow-up (cycles)	4	3	6 (3 each)	3	3 months	3	6 (3 each)
Loss to follow-up (%)	11.8	28.1	4-5	0	53.8	3.7	0
ASI (%)	93.2		91.8			87	67
Satisfaction	7-PLS	%	%	%	%	%	5-PLS
Insertion	5.7			90	96	100	4
Removal	5.1			94			4
Leakage prevention	5.4*	84	92	97		98	5*
Cleaning			97	91	88		5*
Odor prevention		92					5*
Land activity							5*
Water activity						94	5
Daily activity	5.7*	96	91	93	94		5*
Sleep	5.9	84					5*
Price			69				
Dermatitis (%)				0.2			0*
Genital abrasion (%)				0.4			1
Infection (%)				0.4	0	0	0
Acceptability (%)	91	84			87	83	89

Care-U=Care International in Uganda; Multiple=USA, Sweden, Mexico, Brazil, Colombia; R=randomized; C=cohort; RC=randomized crossover; TP=tampons; UP=usual products; SP=sanitary pads; m=months; ASI=active sexual intercourse; PLS=point Likert scale

* p-value less than 0.05

regular sexual intercourse in one year than Howard et al's[4], Beksinska et al's[6], and Madziyire et al's[17] studies. Satisfaction level of the menstrual cup usage in the present study finding was compared to the level reported in previous studies between 2011 to 2020[4 6,14-17] (Table 4). Side effects of the menstrual cup usage in the present study were relatively low compared to reported side effects from the use of sanitary pads or tampons[15-17].

Discussion

The present study was conducted in the tertiary care hospital setting. The participants were health care providers in BAH.

Participants in the present study had an average age of 32. Around seventeen percent of sanitary pad and menstrual cup users reported tampon use experience. That was a relatively lower percentage than in the literature[6,18]. Nearly fifty percent of women in South Africa and thirty percent of American women reported tampon usage experience[6,18]. Women in Thai culture, similar to women in other Asian countries, considered looking or touching genital area as a shaming behavior and such practices were prohibited[19]. Thai and Asian women lived in the society that considered virginity is very important before marriage. People believe that tampon insertion might create tearing of the hymen[20]. Sixty percent of participants in the present study had post bachelor education. Western culture had more influence on women with bachelor and post bachelor education than those with lesser education, which is the majority population of Thailand[21]. The idea of tampon usage, which is a western practice, was higher in women with bachelor and post bachelor education[22]. However, there was no report of the prevalence of tampon usage in Thai women[23].

Results from the present study showed that participants in the menstrual cup group reported higher satisfaction rate with statistical difference in leakage prevention, cleaning, odor prevention, on land activity, daily activity, comfortable sleep, and overall satisfaction than the sanitary pad group. After receiving detailed instructions and watching the educational menstrual cup video, menstrual cup insertion and removal did not present any problems for participants. All of them could insert and remove the menstrual cup in the first cycle with a median satisfaction score of 4 (IQR 3 to 4), which was not different from the median score of sanitary pad usage as shown in Table 2.

This study reported levels of leakage prevention, daily activity, and sleep comfort in using a menstrual cup at 4 to 5 on 5-point Likert scale (Table 2). Satisfaction in using the menstrual cup was supported by the study of Howard et al[4], which was conducted in Canada. The authors reported the satisfaction with leakage prevention, daily activity, and sleep comfort with scores of 5.4, 5.7, and 5.9 on a 7-point Likert scale, respectively. The menstrual cup creates a tight seal around the edges and creates an effective vacuum that prevents menstrual leakage and odor. Because of the tight seal, participants could participate in water activities, such as swimming or showering safely without water leaking into the cup. Because of the insensitivity to the menstrual cup in the vagina, the satisfaction score of menstrual cup usage in terms of comfortable sleep, on land and daily activities were higher than for the sanitary pad usage.

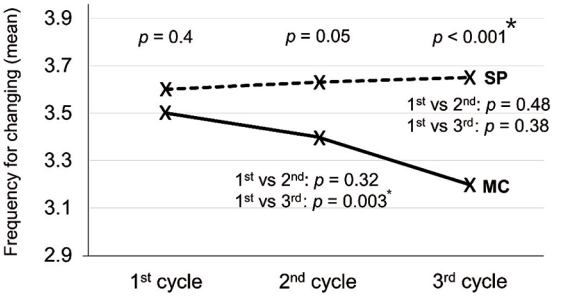

Figure 3. Frequency (times) for changing per day between MC and SP at each cycle.

MC=menstrual cup, SP=sanitary pads, p-value calculated by paired t-test

The frequency of menstrual cup removal for cleaning and reinsertion was 3.3 times per day. This result was different from Stewart et al's study in the United Kingdom[24]. The menstrual cup capacity in that study was comparable to the current study[25], but the frequency of menstrual cup changing was 2.3 times per day, which was more frequent than sanitary pad changing[24] due to the participants used sanitary pads for longer time and they decided how often they wanted to change their pads.

The result of personal interviews with participants after their first cycle revealed that participants were afraid of premature menstrual leakage. They changed their menstrual cup earlier than the 12 hours as recommended period. After participants received reassurance about menstrual cup efficacy during the interview, they reduced changing frequency in the next cycles without any leakage problem reported. The result is shown in Figure 3. Because of less frequency for changing per day for menstrual cup usage, the frequency of touching used menstrual

products was less. This process may result in a better satisfaction score with respect to cleaning of menstrual cup usage.

Contact dermatitis was the common problem in participants who used sanitary pads in the present study and reported more side effects compared to the group using menstrual cups with a statistically significant difference. This finding was supported by data from Mason et al's study[26] reported that girls in Kenya preferred the menstrual cup to the sanitary pads. The advantages of menstrual cups from the Kenya study were reduced skin contact lesion and less allergic response. Unlike the studies by Nunes-Carneiro et al's and Athiel et al's, which reported renal colic or ureterohydronephrosis after using a menstrual cup with improper positioning, there was no such adverse event in the present study[27,28].

Eighty nine percent of the participants in the present study accepted to use the menstrual cup for their daily life in the future due to more satisfaction and fewer side effects. These findings were supported by previous studies[24,29,30]. In the current study, participants with regular sexual intercourse during the 12 months prior to the study were more accepting to the menstrual cup. Reducing waste products for earth saving was the major reason for menstrual cup preference reported by the Shihata et al's and Borowski's studies[14,31]. Moreover, the current situation in 2020 AC., the authors' world has been facing the pandemic COVID-19 (Coronavirus disease 2019) which is a potentially lethal infection. Social distancing and home quarantine are promoted to reduce the infection rate. Shopping, even for necessities, increases the rate of infection. Reusable goods such as menstrual cups could become a very appealing choice[32,33].

The effective lifetime of a menstrual cup is around five years. An average cost of menstrual cup usage per year ranged between 3 to 5 USD per year[6,34]. The cost of sanitary pads for one person in Thailand ranged from 34 to 48 USD per year[35]. Two-thirds of the participants in Beksinska et al's study reported good and excellent satisfaction in cost saving using a menstrual cup compared to tampons or sanitary pads[6]. The authors expect menstrual cup cost saving to be of advantage for Thai women in the near future.

The present study was the first randomized crossover-controlled menstrual cup usage trial report in Thailand, with an adequate number of participants and no-missing data. Teaching material for menstrual cup usage was provided with easy access using brochures and social media (YouTube channel). Higher educated Thai women could access all media in both English and Thai while the lower educated ones could access only Thai media. There were fewer Thai educational materials on the menstrual cup. As a result, very few Thai women have appropriate knowledge and acceptability to menstrual cups. Appropriate Thai resources in both social media and medical personnel contact were proposed as solutions to increase acceptability, knowledge, and menstrual cup usage percentage.

Future study of the usage of menstrual cups with more participants focusing on all non- HCP women is suggested. Adequacy and easy accessibility of teaching material should be of concern. Contact person in case of menstrual cup problem was one of the most important factors for encouraging the usage among Thai women.

Conclusion

Acceptability for the menstrual cup was significantly lower than sanitary pads. Participants who had regular sexual intercourse had more acceptability with the menstrual cup than those who had no regular intercourse. Menstrual cups were associated with significantly higher satisfaction in leakage and odor prevention, cleaning, on land and daily activities, comfortable sleep, overall satisfaction, and lower rates of contact dermatitis than sanitary pads. These differences were studied only in HCP who may have more knowledge of sanitation than the general population.

What is already known on this topic?

Menstrual care is needed for active reproductive women every month. Sanitary pads are widely used around the world. However, it creates an environmental issue with the amount of waste product. Menstrual cups were introduced more than 80 years ago. It has become increasingly popular in the past decade with an advantage in reusability and activity comfort. The limitation of menstrual cups was a dilemma for Thai women.

What this study adds?

To the best of the authors' knowledge, this is the first academic report of menstrual cup usage in Thai women. Leakage prevention, cleaning, odor prevention, on land activity, daily activity, comfortable sleep, overall satisfaction, and less contact dermatitis were advantages of menstrual cups when compared with sanitary pads. Menstrual cups

were widely accepted among women who had regular sexual intercourse. However, overall acceptability for menstrual cup was significantly lower than sanitary pads.

Acknowledgement

The present study was funded and supported by Bhumibol Adulyadej Hospital Research Fund and the authors would like to thank all BAH personnel who participated in the present study.

Conflicts of interest

The authors declare no conflict of interest.

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