

# FLOW (finding lasting options for women)

## Multicentre randomized controlled trial comparing tampons with menstrual cups

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### Abstract

**Objective** To determine whether menstrual cups are a viable alternative to tampons.

**Design** Randomized controlled trial.

**Setting** Prince George, Victoria, and Vancouver, BC.

**Participants** A total of 110 women aged 19 to 40 years who had previously used tampons as their main method of menstrual management.

**Intervention** Participants were randomized into 2 groups, a tampon group and a menstrual cup group. Using online diaries, participants tracked 1 menstrual cycle using their regular method and 3 menstrual cycles using the method of their allocated group.

**Main outcome measures** Overall satisfaction; secondary outcomes included discomfort, urovaginal infection, cost, and waste.

**Results** Forty-seven women in each group completed the final survey, 5 of whom were subsequently excluded from analysis (3 from the tampon group and 2 from the menstrual cup group). Overall satisfaction on a 7-point Likert scale was higher for the menstrual cup group than for the tampon group (mean [standard deviation] score 5.4 [1.5] vs 5.0 [1.0], respectively;  $P=.04$ ). Approximately 91% of women in the menstrual cup group said they would continue to use the cup and recommend it to others. Women used a median of 13 menstrual products per cycle, or 169 products per year, which corresponds to approximately 771 248 400 products used annually in Canada. Estimated cost for tampon use was \$37.44 a year (similar to the retail cost of 1 menstrual cup). Subjective vaginal discomfort was initially higher in the menstrual cup group, but the discomfort decreased with continued use. There was no significant difference in physician-diagnosed urovaginal symptoms between the 2 groups.

**Conclusion** Both of the menstrual management methods evaluated were well tolerated by subjects. Menstrual cups are a satisfactory alternative to tampons and have the potential to be a sustainable solution to menstrual management, with moderate cost savings and much-reduced environmental effects compared with tampons.

**Trial registration number** C06-0478 (ClinicalTrials.gov).

This article has been peer reviewed.

Cet article a fait l'objet d'une révision par des pairs.

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### EDITOR'S KEY POINTS

- Patients are increasingly asking physicians about more environmentally friendly alternatives to disposable menstrual management products, particularly menstrual cups, and about their effectiveness compared with tampons. Although the safety and efficacy of menstrual cups have been studied previously, a randomized controlled trial comparing cups with tampons has never been done.
- This study compared the experiences of women using only tampons with women using only menstrual cups over a period of 3 menstrual cycles; in terms of overall satisfaction, study participants were as satisfied with menstrual cups as they were with tampons if not more satisfied, and 91% said they would continue to use the cup and recommend it to others.
- Although subjective vaginal discomfort was higher in menstrual cup users, this decreased with continued use and did not affect the prevalence of urovaginal symptoms. Women took advantage of the support offered in this study, suggesting that there is a role for primary care providers in providing counseling to help optimize menstrual management.
- Menstrual cups are a comparable alternative to tampons; over the long term, they are less costly and produce less environmental waste.
- The study was limited to a small group of mostly white women over a relatively short period of time; further long-term study in a more diverse population is required to confirm the generalizability of these results.

# Flux menstruel : à la recherche d'une alternative durable pour les femmes

## Essai clinique randomisé multicentrique comparant les tampons hygiéniques aux coupes menstruelles

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### Résumé

**Objectif** Déterminer si les coupes menstruelles constituent une solution de remplacement satisfaisante aux tampons hygiéniques.

**Type d'étude** Essai clinique randomisé.

**Contexte** Prince George, Victoria et Vancouver, BC.

**Participant** Un total de 110 femmes de 19 à 40 ans qui avaient antérieurement utilisé surtout des tampons pour leurs menstruations.

**Intervention** Les participantes ont été assignées au hasard à 2 groupes, un groupe tampons et un groupe coupes menstruelles. Elles ont utilisé un journal en ligne pour inscrire des commentaires sur un premier cycle menstruel avec leur méthode habituelle et 3 autres cycles avec la méthode choisie pour leur groupe.

**Principaux paramètres à l'étude** Satisfaction globale; les issues secondaires incluaient l'inconfort, les infections vaginales, le coût et la disposition des déchets.

**Résultats** Quarante-sept femmes de chaque groupe ont complété le questionnaire final, dont 5 ont été subséquemment exclus de l'analyse (3 du groupe tampons et 2 du groupe coupes menstruelles). Mesurée sur une échelle de Likert de 7 points, la satisfaction globale était plus élevée dans le groupe coupes menstruelles que dans le groupe tampons (moyenne [écart type] 5.4 [1.5] vs 5.0 [1.0] respectivement;  $P = .04$ ). Environ 91 % des femmes du groupe coupes menstruelles ont dit qu'elles continueraient à utiliser les coupes et à les recommander à d'autres. Les participantes ont utilisé une médiane de 13 produits menstruels par cycle, ou 169 produits par année, ce qui correspond à environ 771 248 400 produits par année au Canada. Le coût estimé pour utiliser des tampons était de 37,44 \$ par année (semblable au prix de détail d'une coupe menstruelle). Il y avait plus d'inconfort vaginal subjectif dans le groupe coupes menstruelles, mais ce problème diminuait avec l'usage. Il n'y avait pas de différence significative entre les 2 groupes quant au taux de symptômes uro-ginaux diagnostiqués par un médecin.

**Conclusion** Les 2 méthodes de gestion des menstruations évaluées étaient bien tolérées par les participantes. Les coupes menstruelles constituent une solution de rechange satisfaisante aux tampons et elles sont susceptibles de représenter une solution à long terme pour la gestion des menstruations, avec un coût un peu moindre et beaucoup moins d'effets sur l'environnement par rapport aux tampons.

**Numéro d'enregistrement de l'étude** C06-0478 (ClinicalTrials.gov).

### POINTS DE REPÈRE DU RÉDACTEUR

- Les médecins reçoivent de plus en plus de questions sur une façon de se débarrasser des produits de menstruation qui soit plus respectueuse de l'environnement, comme par exemple l'utilisation des coupes menstruelles et leur efficacité par rapport aux tampons hygiéniques. Même si l'efficacité et l'innocuité des coupes menstruelles ont déjà été étudiées, il n'y a jamais eu d'essai clinique randomisé comparant les coupes aux tampons.

- Cette étude a comparé l'expérience de femmes qui, sur une période de 3 cycles menstruels, ont utilisé uniquement des tampons à d'autres qui n'ont utilisé que des coupes; en termes de satisfaction globale, celles du groupe coupe menstruelle étaient aussi, sinon plus satisfaites que celles du groupe tampon hygiénique, et 91 % d'entre elles ont déclaré qu'elles continueraient à utiliser les coupes et à le recommander à d'autres.

- Quoique les utilisatrices des coupes rapportaient davantage d'inconfort vaginal, ce problème diminuait avec le temps et n'avait pas d'influence sur la prévalence des symptômes uro-vaginaux. Les femmes ont bénéficié du support offert dans cette étude, ce qui laisse croire que les intervenants de première ligne ont un rôle à jouer pour aider à optimiser la gestion des menstruations.

- Les coupes menstruelles représentent une solution de rechange à long terme aussi valable que les tampons; elles sont moins coûteuses et génèrent moins de déchets environnementaux.

- Cette étude portait sur un groupe limité de femmes caucasiennes et sur une période relativement courte; il faudra d'autres études à long terme sur une population plus diversifiée pour que ces résultats puissent être généralisés.

"I am using tampons right now, but I would like to try a menstrual cup. Do they work as well as tampons?" This patient query is becoming more common. Menstrual cups are flexible, reusable cups made of rubber or silicone that are worn intravaginally to collect menstrual flow.<sup>1</sup> Interest in their use is increasing, largely because of public desire for more environmentally friendly menstrual products.<sup>2</sup>

Studies on tampons show that they are well tolerated.<sup>3,4</sup> There is no conclusive evidence that tampons substantially affect rates of vaginitis or urinary tract infection (UTI).<sup>5-10</sup> Independent research in the 1980s found toxic shock syndrome to be associated with high absorbency tampons and the aerobic production of *Staphylococcus aureus*, which led to a change in tampon composition and instructions for use.<sup>11-15</sup>

The first studies on menstrual cups done in the 1960s showed that they were also well tolerated, with most women becoming comfortable with use after a 1- to 2-month adjustment period.<sup>16-19</sup> A 1995 study done in Toronto, Ont, asked participants to use the cup for 1 year and found that 62% of those who used the cup for 2 or more cycles found it acceptable.<sup>20</sup> A recent British study asking 53 medical students to record 3 baseline cycles then 3 cycles with the Mooncup menstrual cup found that 55% continued using the Mooncup at the end of the study.<sup>21</sup>

In terms of infection, an independent study showed that a menstrual cup did not amplify the *S aureus* toxin when tested in vitro,<sup>22</sup> and an older study found less bacterial growth obtained from cultures of the used cup than from cultures of used tampons or pads.<sup>17</sup> There have not been any published case reports of toxic shock syndrome associated with menstrual cup use. Cups have also been evaluated with generally encouraging results as tools for the collection of shed menstrual tissue for analysis<sup>20,23</sup>; control of and volume measurement in menorrhagia<sup>19,20,24</sup>; and management of urine leakage in 3 subjects with vesicovaginal fistula.<sup>18,19</sup>

A randomized controlled trial comparing tampons with menstrual cups has never been done. The primary objective of this study was to determine if a menstrual cup is an acceptable alternative to tampons in women aged 19 to 40 years, as measured by the participants' overall satisfaction after 3 months of use, and whether the women would continue using the product or recommend it to others. The secondary objectives were to track subjective vaginal irritation, physician-diagnosed UTI and vaginitis, and estimates of cost and waste.

## METHODS

### Participants

Women from Vancouver, Victoria, and Prince George, BC, were enrolled in this prospective randomized study

from November 2006 to September 2007. They were recruited via posters in family practice offices, e-mail lists, and stories in local media. Women between 19 and 40 years of age with monthly menstrual flow who used tampons as their primary method of menstrual management were eligible. Exclusion criteria were sensitivity or allergy to silicone, active vaginal or urogenital infection, pregnancy or plans to become pregnant before the end of the study, use of systemic antimicrobials within the previous 14 days, inability to understand the nature and purpose of the study, and inability to understand and express themselves in written and spoken English. All interested participants who fulfilled the study criteria were sent an electronic copy of the consent form and were scheduled for an information session.

### Study design, intervention, and measurements

Upon arrival at the information session, women were sequentially enrolled and randomized to the tampon group or the menstrual cup group using a computer-generated, site-specific block randomization scheme. Participants filled out a prestudy survey and received instruction regarding manufacturer-recommended use of tampons and menstrual cups.

Participants randomized to the menstrual cup group were each given a DivaCup, a Canadian-made silicone menstrual cup purchased with study funds, while women in the tampon group were reimbursed the equivalent value of a menstrual cup upon study completion. The first menstrual cycle was treated as a run-in cycle, during which both groups maintained their primary menstrual management strategy (ie, tampons). The menstrual cup intervention began in menstrual cycle 2 (study cycle 1), and continued for 2 more cycles (study cycles 2 and 3). At the end of each study cycle, participants completed an end-of-cycle survey, in which convenience, insertion, wear, removal, comfort, leakage, and overall satisfaction were rated on a 7-point Likert scale, with 1 being "terrible" and 7 being "fantastic." At the end of the 4 cycles, participants indicated their overall satisfaction with their assigned menstrual strategy in an online final survey.

During each study cycle, participants kept online daily diaries detailing the number of menstrual products used and tracked episodes of subjective vaginal irritation as well as physician diagnoses of UTI or vaginitis.<sup>25-32</sup> Use of additional products, such as pads, was at the discretion of the participants and was recorded in the diaries.

Diaries and surveys were based on those described in a previous study<sup>4</sup>; they have not been validated, owing to the novelty of the research, but were deemed the best option with which to prospectively collect data.

Participants were contacted by telephone by an investigator 1 month after enrolment, and reminded monthly via e-mail to complete the online diaries. A designated

paper was carried by an investigator who was available at all times in case of urgent questions.

This trial was approved by the Clinical Research Ethics Board at the University of British Columbia in Vancouver (identifier number H06-70478) and was registered with ClinicalTrials.gov (identifier number C06-0478).

### Statistical analysis

Sample size calculations were performed for the primary outcome of overall satisfaction. Sixty-seven participants in each group were required in order to have 80% power to detect a difference in effect size of 0.50 using a 2-sided Mann-Whitney test. To account for a 10% loss to follow-up, we attempted to recruit 74 participants into each arm of the study.

Data were analyzed as intention-to-treat. Categorical and numerical variables were compared between groups using  $\chi^2$  and Mann-Whitney tests, respectively. Satisfaction scores were reported as means and standard deviations for final survey and end-of-cycle satisfaction outcomes, and comparisons between groups were calculated using Mann-Whitney tests. The proportion of participants in the menstrual cup group who would continue to use menstrual cups or would recommend use to someone else was reported. Urovaginal irritation variables were compared between groups.

To calculate product waste, we averaged the number of tampons, pads, and pantliners used per subject in the run-in cycle. To estimate the monetary cost of menstrual management strategies, the average waste per cycle was multiplied by an averaged product cost (Table 1).

All analyses were performed using SAS (Statistical Analysis System, version 9.1). Significance was set at  $P < .05$ .

## RESULTS

A total of 110 subjects were enrolled in the study (Figure 1), with 47 subjects in each group completing the final survey (13 were lost to follow-up, 3 discontinued the intervention); 5 were subsequently excluded from the analysis after data revealed that they had taken antibiotics within 2 weeks of the start date of the study. At baseline, the tampon group was older and more likely to have given birth (Table 2). More than half of the women had a history of urovaginal symptoms (60 of 89).

### Final survey results

Although the targeted sample size was not achieved, a statistically significant difference in overall satisfaction was still found: the mean (standard deviation) satisfaction score was higher for the menstrual cup

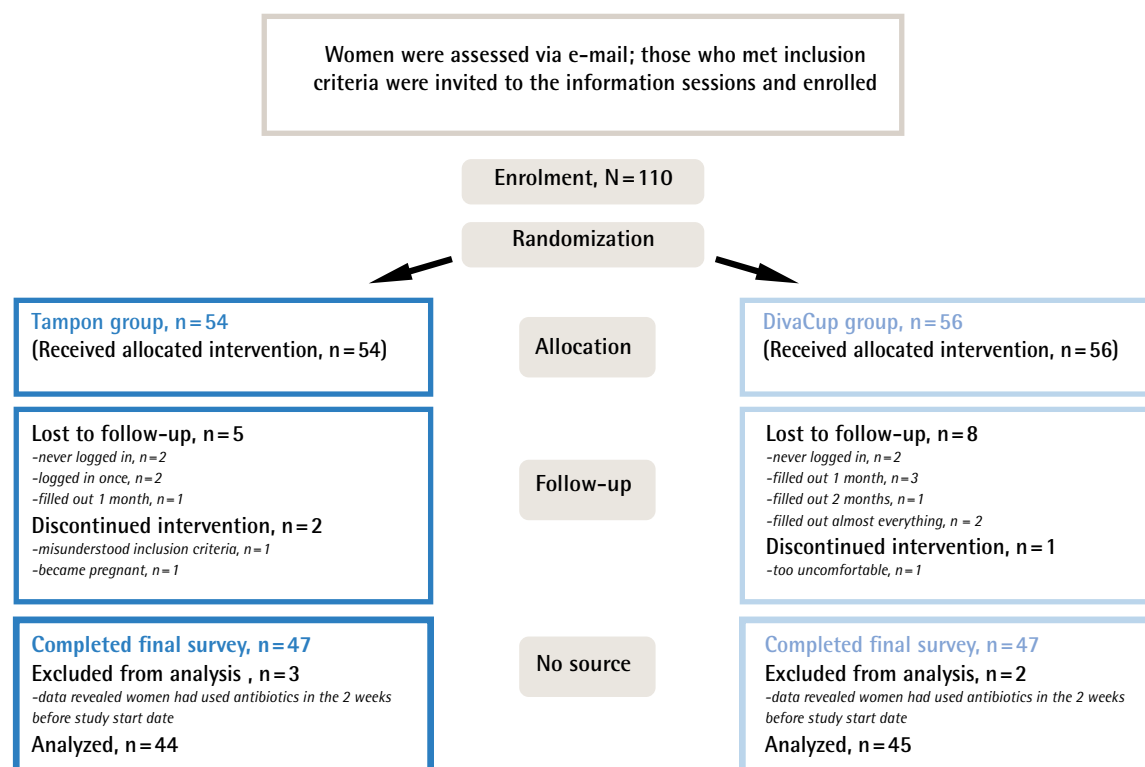
**Table 1. Cost calculations for menstrual products, by brand: Prices gathered on September 18, 2009, from London Drugs in West Vancouver, BC.\***

PRODUCT	UNITS PER PACKAGE, N	COST PER PACKAGE, \$	AVERAGE UNIT COST, \$	AVERAGE UNIT COST OF PRODUCT, \$
DivaCup	1	39.99	39.99	39.99
Tampons				0.24
• Tampax	20	4.69	0.23	
	40	8.29	0.21	
• o.b.	18	4.69	0.26	
	40	7.99	0.20	
• Playtex	18	4.99	0.28	
	36	8.99	0.25	
Pantliners <sup>†</sup>				0.10
• Always	40	4.99	0.124	
	72	7.99	0.11	
• Kotex	45	4.29	0.10	
	96	7.99	0.08	
• Carefree	46	4.49	0.10	
Pads <sup>†</sup>				0.23
• Always	18	4.49	0.25	
	36	8.99	0.25	
• Stayfree	14	4.49	0.32	
	48	7.99	0.17	
• Kotex	24	4.99	0.21	
Maxi	44	7.99	0.18	

\*Previous cost estimates done by FLOW investigators over the past 2 years were as follows: \$0.24 per tampon and \$0.09 per pantliner in a Victoria survey; \$0.37 per tampon and \$0.24 per pad in a Vancouver survey; and \$38.99 per DivaCup at [well.ca](http://well.ca), \$37.67 per DivaCup at [lunapad.com](http://lunapad.com), and \$39.99 per DivaCup at [londondrugs.com](http://londondrugs.com) in an online survey of DivaCup prices. Our current estimate is in the same range as previous estimates; given that our methodology is more clearly laid out, we use our current estimate in our official cost calculations. <sup>†</sup>The prospectively gathered diary data from the run-in month, upon which the tampon and pad number estimates are based, do not differentiate between pads and pantliners, yet there is a substantial difference in cost between them. We have therefore gone through the presurvey data regarding subjects' retrospective estimates of the tampons, pads, or pantliners used per day to get an estimate of the average proportion of pads to pantliners used in this population. The results were as follows: ratio of pads to pantliners of 77 to 90; cost per pad or pantliner, in dollars:  $[(0.77)[0.23] + [0.90][0.10]] / 1.67 = (0.177 + 0.09) / 1.67 = 0.16$ .

group than for the tampon group (5.4 [1.5] vs 5.0 [1.0],  $P = .04$ ; Figure 2). The menstrual cup group appeared to be more satisfied with respect to convenience (5.7 [1.3] vs 5.2 [1.1],  $P = .02$ ) and leakage (5.4 [1.4] vs 4.8 [1.5],  $P = .04$ ), but might have been less satisfied with removal (5.0 [1.4] vs 5.5 [1.1],  $P = .06$ ). Most women in

**Figure 1. Selection process for study participants**



**Table 2. Participant demographics: N = 89.**

CHARACTERISTIC	TAMPON GROUP (N = 44)	MENSTRUAL CUP GROUP (N = 45)	P VALUE*
Mean (SD) age, <sup>†</sup> y	28.9 (5.5)	26.6 (4.6)	.05
Race, <sup>†</sup> n (%)			.58
• White	37 (90.2)	38 (86.4)	
• Other	4 (9.8)	6 (13.6)	
Mean (SD) BMI, <sup>‡</sup> kg/m <sup>2</sup>	23.9 (3.5)	24.0 (6.3)	.12
≥ 1 child, n (%)	8 (18.2)	2 (4.4)	.04
Mean (SD) age of menarche, <sup>‡</sup> y	13.0 (1.3)	13.0 (1.3)	.80
Regular flow, n (%)	34 (82.9)	41 (95.3)	.14
Flow, <sup>‡</sup> n (%)			.06
• Light	4 (9.8)	11 (25.6)	
• Medium	35 (85.3)	27 (62.8)	
• Heavy	2 (4.9)	5 (11.6)	
Sexually active, n (%)	40 (97.6)	41 (93.2)	.34

BMI—body mass index, SD—standard deviation.

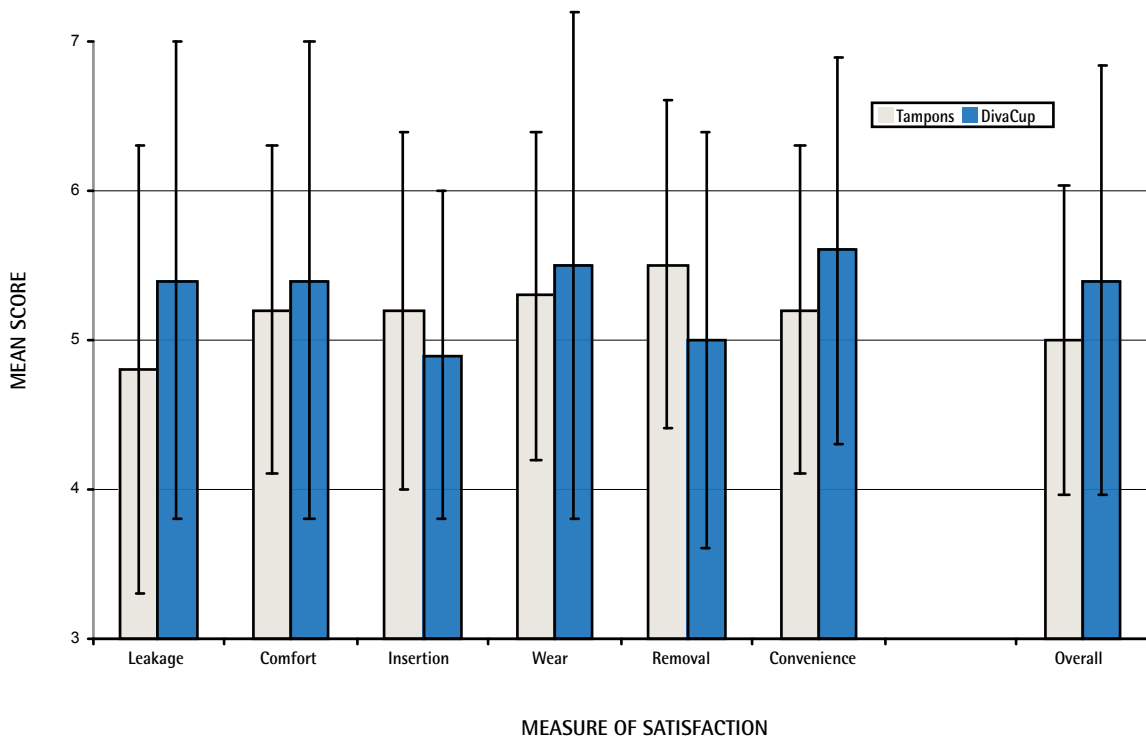
\*Significance was set at P < .05.

<sup>†</sup>Data missing for 4 participants.

<sup>‡</sup>Data missing for 5 participants.



**Figure 2.** Final survey results: Median scores on a 7-point Likert scale with error bars representing interquartile ranges; N=89.



\* $P < .05$

the menstrual cup group said they would continue to use the cup (91%) and that they would recommend the menstrual cup to others (91%).

### End-of-cycle surveys

End-of-cycle survey results are shown in **Figure 3**. **Figure 3A** shows that the tampon group had a small decline in overall satisfaction over time, whereas the menstrual cup group had a noticeable drop in the first cycle of cup use but then an increase to study end. **Figures 3B** and **3C** show changes over time in each satisfaction variable.

### Urovaginal symptoms

The prevalence of physician-diagnosed urovaginal symptoms was low and did not differ between groups. Subjective vaginal discomfort was reported on at least 1 day during the run-in cycle by 9 (20%) and 12 (27%) women in the tampon and menstrual cup groups, respectively ( $P = .49$ ). Over the course of the 3 study cycles, 12 (27%) women in the tampon group and 23 (51%) women in the menstrual cup group experienced discomfort on at least 1 day ( $P = .02$ ). In the menstrual

cup group, the number of women reporting vaginal discomfort on at least 1 day per cycle decreased from 42% in study cycle 1 to 16% in study cycle 3.

### Cost and waste

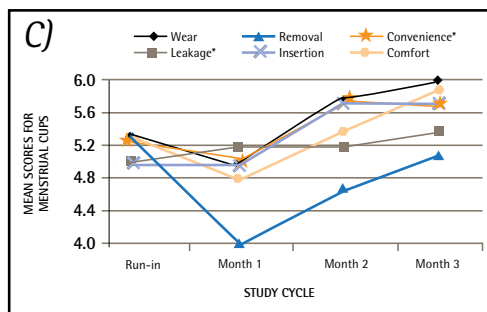
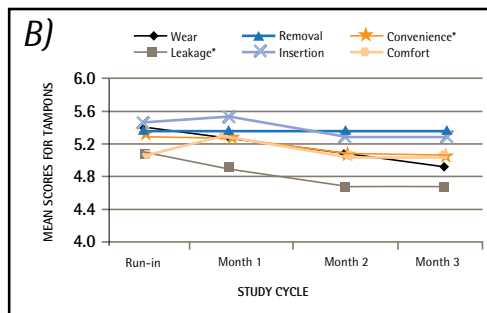
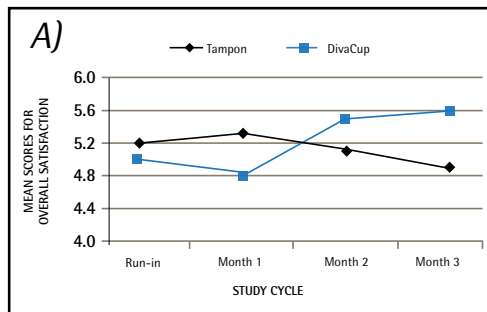
The median (first and third quartiles) number of tampons used per subject in the run-in cycle was 10 (5 and 16) and the median (first and third quartiles) number of pads or pantliners used per subject was 3 (0 and 7). Based on an average cost of 24 cents per tampon and 16 cents per pad or pantliner, this represents a cost of \$2.88/cycle and \$37.44/year (**Table 1**). This is similar to the retail cost of 1 DivaCup. There was a negligible number of pads or pantliners used during the study cycles in the menstrual cup group; cost was not affected.

## DISCUSSION

In this population of women who normally used tampons, we have shown that women who used a menstrual cup for 3 cycles were at least as satisfied with the new menstrual

management strategy as women who continued with tampon use. Cup users also found that their menstrual management was more convenient, and they appeared to be more satisfied with regard to leakage. Most (91%) would continue to use the cup and recommend it to others.

**Figure 3. End-of-cycle results, by month, as measured by mean scores on a 7-point Likert scale: A) Overall satisfaction, by study cycle; N=89. B) Tampon satisfaction data, by study cycle; N=44. C) Menstrual cup satisfaction data, by study cycle; N=45.**



\*P<.05

### Learning curve

Consistent with previous studies,<sup>11,15</sup> we found a trend toward increased satisfaction with duration of menstrual cup use. Comments from the women included the following: “My comfort level with the DivaCup increased a lot over the 3 months. It just took a bit of practice to easily insert and remove it!” and “I just recently trimmed the tip of the cup and that helped with comfort as well.”

The study’s e-mail account and pager line received numerous requests for advice during the first 2 cycles of cup use; this support, as well as the shorter study period, might in part account for the lower dropout rate and higher acceptance rate than those of the Mooncup study,<sup>21</sup> whose participants collected data for 6 months and had e-mail but not pager access to the investigators.

### Vaginitis, vaginal irritation, and UTI

Our study was not powered to find a statistically significant difference in rates of physician-diagnosed UTI or vaginitis, but overall rates were low in both groups. More women in the menstrual cup group reported subjective vaginal irritation. This decreased throughout the study. Additional studies with larger sample sizes and longer follow-up are required to compare comfort and clinical urovaginal infection rates between tampon and menstrual cup users.

### Cost and waste


The DivaCup is guaranteed for 1 year under its licensure with Health Canada, but it is expected to last for several years. Taking into account this 1-year minimum, the costs between the 2 strategies are comparable. If the cup were to be used for more than a year, it would begin to represent a substantial cost savings. Perhaps more important, during the run-in month the women used 13 menstrual products per cycle, or 169 disposable menstrual products per year. To generate a rough estimate, if we were to assume that the 4563 600 Canadian women between the ages of 20 and 39 years<sup>33</sup> all menstruate regularly (assuming 13 cycles/woman each year) and use products at this rate, then 771 248 400 disposable menstrual products are being used every year in Canada. Using menstrual cups would effectively reduce this waste.

### Limitations

In addition to the limitations of a small study size and short duration, as described above, we attempted to sample a cross-section of the population through multisite recruiting, but still had a mostly nulliparous and overwhelmingly white population. This limits the generalizability of the study results.

## Conclusion

Studies with more subjects, longer follow-up, and more diverse populations in terms of parity, ethnicity, and culture should be undertaken. In particular, the utility of menstrual cups in underresourced environments with limited access to clean water and in women with vesicovaginal fistula needs to be assessed.<sup>34-37</sup>

The menstrual cup is a satisfactory alternative to tampons in women who have previously used tampons as their primary method of menstrual management. Physician-diagnosed urinary tract infections and vaginitis comparisons between groups were inconclusive owing to limited sample size. Menstrual cups have the potential to be a sustainable solution to menstrual management with moderate cost savings and much-reduced environmental effects compared with tampons. 

**Dr Howard** is an emergency room physician practising in the Northwest Territories and Ontario and a board member of the Canadian Association of Physicians for the Environment. **Ms Rose** is a doctoral candidate at the University of British Columbia (UBC) in Vancouver and a statistician in the Department of Medicine at UBC. **Dr Trouton** is Director of the Vancouver Island Women's Health Clinic in View Royal, BC, Clinical Associate Professor in the Department of Medicine at UBC, and cofounder of the Canadian Association of Physicians for the Environment. **Dr Stamm** is a family physician practising in Vancouver. **Dr Marentette** is a family physician practising in Powell River, BC. **Dr Kirkpatrick** is an emergency room physician practising in Nanaimo, BC. **Drs Karalic** and **Fernandez** are family physicians practising in Vancouver. **Dr Paget** is a family physician practising in Prince George, BC.

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### Contributors

**Dr Howard** contributed to the study conception and design, literature review, submission for ethics approval, building of the team and coordination of collaborators, data collection and interpretation, writing of the first draft, and manuscript revisions. **Ms Rose** contributed to the study design, data analysis and interpretation, writing of the first draft, and manuscript revisions. **Dr Trouton** was the principal investigator on this study and contributed to the study design, submission for ethics approval, submissions for funding, interpretation of data, and manuscript revisions. **Dr Stamm** contributed to data collection, interpretation of results, and manuscript revisions. **Drs Marentette, Kirkpatrick, Karalic, Fernandez, and Paget** all contributed to the study design, collection of data, and manuscript revisions.

### Competing interests

None declared

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