Attitudes Toward Menstrual Suppression Among Cyclic and Continuous Contraceptive Vaginal Ring Users in Kenya

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Abstract

Objective: Multipurpose prevention technologies (MPTs) are developmental dual-purpose options that would provide women with a contraceptive as well as a prevention modality aimed at sexually transmitted infections. The contraceptive vaginal ring (CVR) has many properties that makes it an ideal MPT candidate. The objective of this study is to understand women's attitudes towards menstrual suppression, a potential side effect of using a CVR, and how to address these attitudes for MPT vaginal rings in development.

Materials and methods: We analyzed data derived from a subset of cohort study participants (n=45) in Thika, Kenya between January 2016- December 2018. The primary study enrolled 121 women 18-40 years with bacterial vaginosis and randomized them to cyclic or continuous CVR use for eight months. During the 6-month follow-up, a questionnaire eliciting attitudes towards menstrual suppression was administered. Responses to the menstrual suppression questionnaire between participants in the cyclic and continuous CVR use groups were compared. Likert-scale responses were summed to create a menstrual suppression attitude summary score, and a hierarchical cluster analysis was conducted to identify similarities in response patterns among all participants.

Results: Totally 81.8% of continuous CVR users believed that one was less likely to get pregnant after using hormonal medication to suppress menses, compared to 47.8% of cyclic CVR users (P=0.02), and were more worried it would cause long-term health effects (86.4% vs 60.9%, p = 0.05). The menstrual suppression attitude summary score ranged from 8 to 42, with lower scores indicating negative attitudes. The summary score identified three distinct clusters. When asked if menstrual suppression effects long-term health; 100% of Cluster 3 was worried compared to 80.8% of Cluster 2 and 46.2% of Cluster 1 (p = 0.03). The average summary score among Cluster 3 (Mean = 14.8, SD = 4.6) was lower



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This work is licensed under a Creative Commons Attribution-Noncommercial 4.0 International license (https://creativecommons.org/licenses/by-nc/4.0/). Noncommercial uses of the work are permitted, provided the original work is properly cited. (p < 0.001) and women were more worried about discomfort during sex (p=0.05) as well as their sexual partners feeling the ring (p=0.02).

Conclusion: Women are more likely to have negative attitudes if they believe menstrual suppression hinders future reproductive health. Education on cycle control and fertility could mitigate negative attitudes and improve uptake of CVRs.

Keywords: Contraceptive Vaginal Ring (CVR); Menstrual Suppression; HIV; Multipurpose Prevention Technologies

Introduction

Approximately 218 million women of reproductive age (15-49 years) are currently not using any form of modern contraceptive despite wanting to avoid pregnancy (1). This unmet contraceptive need is especially focused in lower- and middle-income countries (1, 2). Additionally, in 2020, 50% of incident HIV cases were among women and girls (3). To address unmet contraceptive need, as well as decrease the rate of HIV infection among women globally, the development of multipurpose prevention technologies (MPT) has become a priority for improving sexual and reproductive health options (4). MPTs provide options that typically include a hormonal contraceptive component and a prevention component aimed at sexually transmitted infections (STI), including HIV. One advantage of these options is their potential to be initiated and controlled by women themselves. For example, vaginal rings offer a potentially adaptable platform that can incorporate different pharmaceutical agents to deliver MPT agents.

The contraceptive vaginal ring (CVR) provides localized and sustained progestin and estrogen, thus decreasing the risk of side effects associated with systemic contraceptive methods (5). Previous studies have demonstrated high acceptability and improved control of the menstrual cycle (5). Currently available CVRs are intended for users to insert the ring for a 21-day period followed by a 7-day ring free period to allow for menses. This withdrawal bleeding was incorporated for the purpose of mimicking a 28-day menstrual cycle; however, it is not biologically necessary (6, 7). In fact, off-label continuous 28-day use is frequently used to mitigate or fully suppress menstruation (8, 9).

With the recent approval of a contraceptive vaginal ring that can be used continuously for one

year by the FDA, the WHO recommendation of a dapivirine vaginal ring for prevention of HIV infection, as well as various multidrug vaginal rings in development, the importance of understanding women's responses to the vaginal ring as well as potential side effects experienced when using a vaginal ring is critical (5, 10). Many women consider withdrawal bleeding to be a form of cleansing and engage in other intravaginal practices (IVP) to maintain "cleanliness"(11). IVP include intravaginal washing as well as intravaginal insertion of products with the purpose of maintaining perceived hygiene or sexual health (11, 12). Women's decision to engage in IVP may strongly influence attitudes towards vaginal ring MPTs from the standpoints of potential menstrual suppression (a perceived benefit) and concerns of extended-use intravaginal products (a perceived concern) (13).

To optimize anti-infectious efficacy, continuous use of vaginal ring MPTs would likely be required. However, continuous delivery of such a product's hormonal component may also provide benefit in terms of menstrual suppression (8). For example, we conducted a study in Thika, Kenya, that randomized women previously treated for bacterial vaginosis (BV) to continuous vs. cyclic use of CVR and followed women for 8 months. We demonstrated that continuous CVR use was associated with lower concentrations of the vaginal bacteria that have been consistently associated with elevated risk of HIV acquisition (14). Recognizing that some of the continuous CVR users in this study would experience menstrual suppression, we systematically surveyed participants about their IVP habits as well as attitudes toward and knowledge of menstrual suppression. The objective of this secondary analysis is to examine influences on attitudes towards menstrual suppression among Kenyan women using a CVR.

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Materials and methods

The parent study was a prospective cohort study conducted in Thika, Kenya from April 2016 to November 2017 at the Thika Partners Study Clinic (University of Washington International Clinical Research Center) (14). Its main objective was to assess the benefits associated with cyclic and continuous CVR use among women (both HIV-infected and HIV-uninfected) with BV at enrollment. Participants were randomized to use the CVR cyclically or continuously for a 7-month period. Data collected at monthly follow up visit included sexual behaviors, genital examination, and vaginal ring acceptability. A questionnaire about menstrual suppression was administered to a subset of 45 women (37% of the total participants) at the 6-month follow-up visit.

Five hundred and seventy-six Kenyan women were screened for the parent study. Of the 546 who completed the screening visit, 151 were enrolled, and 122 randomized to cyclic or continuous CVR use. Women were eligible for the study it they were 18-40 years old, met Amsel's Criteria for BV (14), and did not have intentions of becoming pregnant during the study period. Exclusion criteria included women who are currently pregnant or intended on becoming pregnant at screening, had any contraindications for hormonal contraception use, or were older than 35 years and reported current smoking status.

Data Collection

Investigators collected demographic, sexual behavior, intravaginal practices, clinical outcomes, and ring acceptability at the enrollment visit. Subsequent sexual behaviors, clinical outcomes and ring acceptability were recorded by investigators at each follow up visit. Demographic variables included age, marital status, education, employment, HIV status, and past pregnancies. Sexual behavior variables were collected based on the previous month and included number of sexual partners, sexual frequency, and condom use per sexual encounter. Intravaginal practices included vaginal washing and vaginal insertions. Clinical genital exams were conducted at each monthly follow-up visit, where participants' menstruation status, Amsel criteria, and Nugent score were collected (15, 16).

The menstrual suppression questionnaire was administered to a subset of participants within the study from both cyclic and continuous CVR use groups at the 6-month follow-up visit. The questionnaire was developed by members of the Thika Study team using previous questions used in other research as a reference and reaching consensus. It included 15 questions and 3 sub questions for a total of 18 multiple choice items asking participants about their perceptions on menses and menstrual suppression, ranging from general opinion to personal experience (Figure 1).

- 1. Have you experienced a change in your menstrual cycle since you started using the ring? (Yes/No)
 - a. If yes, what was the change?
- 2. Women do not like having their monthly periods. (Strongly Agree/Strongly Disagree)*
- 3. Women are interested in not having any periods. (Strongly Agree/Strongly Disagree)
- 4. Most women would prefer less frequent periods. (Strongly Agree/Strongly Disagree)*
- In some ways, women enjoy their monthly periods. (Strongly Agree/Strongly Disagree)*
- 6. It does not seem natural for a woman not to have her monthly period. (Strongly Agree/Strongly Disagree) *
- 7. Women who use medication to stop their periods can get pregnant once they stop the medication. (Strongly Agree/Strongly Disagree)
- Women who use medication to stop their periods will be less likely to get pregnant after 8. they stop the medication. (Strongly Agree/Strongly Disagree)
- Do you know anyone who has missed work or school because of her period? (Yes/No)
- 10. Have you missed work or school because of your period? (Yes/No)
- 11. What products do most women in your community use during menstrual periods?)
 - (Commercially purchased towels/Other
 - Women have easy access to sanitary towels or other menstrual supplies. (Strongly a. Agree/Strongly Disagree)
- 12. What products do you use during menstrual periods? (Commercially purchased towels/ Other_
- a. I have easy access to sanitary towels or other menstrual supplies. 13. If it is possible to safely stop women from having menses, they would do better in school or at work. (Strongly Agree/Strongly Disagree)*
- 14. Menstrual suppression would affect my ability to have children in the future.
- (Worried/Not Worried)
- 15. Menstrual suppression would cause long-term health effects. (Worried/Not Worried)*

Figure 1: Menstrual Suppression Questionnaire

*Included in the menstrual suppression questionnaire summary score

Questions ranged from general opinion to personal experience and responses were collected as yes/no, worried/not worried, and strongly agree/strongly disagree on a 5-point Likert scale. Participants were asked about CVR-related menstrual cycle changes during the study period, and those who reported changes were asked about their sexual partners' response to these changes. Additionally, the questionnaire inquired about participants missing school or work due to their period and whether participants were worried about menstrual suppression affecting future pregnancies or long-term health.

Statistical Methods: Menstrual suppression questionnaire 5-point Likert scale responses were combined into two response options (agree/disagree) based on sample size. Bivariate analysis was completed comparing demographics, baseline IVP and sexual behaviors, and questionnaire responses between participants randomized to cyclic CVR use and participants randomized to continuous CVR use. Participants overall attitude towards menstrual suppression was assessed by creating a menstrual suppression summary score from relevant questionnaire responses (Figure 1). Linear regression models were used to report associations of menstrual suppression attitudes with age, treatment group, partner status, HIV status, and IVP.

Hierarchical cluster analysis is a statistical method used to identify clusters of records or participants based on a variable (17, 18). We used hierarchical cluster analysis determine similarities in menstrual suppression responses. The agglomerative method of clustering repeatedly combined individual participants based on their summary score, with a complete linkage distance function. Responses to individual questions and covariates were then compared between clusters using Fisher exact tests. All tests were considered statistically significant at $\alpha \leq 0.05$ (2-tailed). Univariate and bivariate analysis was conducted with SAS Version 9.4 (SAS Institute, Inc., Cary, NC, USA), cluster analysis was conducted with R.

Results

Of the 122 participants randomized in the parent study, a subset of 45 (37%) were randomly selected to complete a menstrual suppression questionnaire. At their 6-month follow-up visit 22 participants randomized to cyclic CVR use and 23 participants randomized to continuous CVR use completed the questionnaire (Figure 2). Demographic and sociodemographic characteristics by study arm were not different (Table 1). The average age of participants was 30.2 years, they had similar socioeconomic status, and more than half of participants had 2 or more children. Overall, 46.7% of the participants were living with HIV, and of those, 45% did not know the HIV status of their long-term sexual partner.



Figure 2: Flow Diagram of Menstrual Suppression Questionnaire Respondents

Sexual behaviors and intravaginal practices were also similar between groups (Table 2). During the enrolment visit most participants reported one sexual partner in the past month (79.6%) and less than 30% of participants reported a new sexual partner within the same time frame. In the continuous CVR use arm sexual frequency trended toward increased frequency with 50% reporting intercourse 5 or more times in the past month compared to 18.2% among cyclic CVR users (p=0.08). Condom use was low for both groups with 65.9% of participants reported no condom use within the past month. Intravaginal washing was common (79.6%) and all participants that reported they washed inside the vagina indicated it was a daily occurrence. Sensitivity analyses of sexual behavior and intravaginal washing throughout the study period and at the time of questionnaire administration resulted in similar findings.

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	Cyclic CVR use	Continuous CVR use	P-Value
Age, Mean (SD)	29.8 (6.1)	30.5 (6.0)	0.71
Education (Years), Median (IQR)	8 (6-8)	9 (7-12)	0.23
Monthly Income, Mean (SD)	5,684 (6,765)	7,181 (6,357)	0.45
(Kenyan Shillings)			
Current Occupation			
No Income	5 (21.7)	1 (4.6)	
Laborer	9 (39.1)	15 (68.2)	
Trade/Sales	6 (26.1)	4 (18.2)	
Student	2 (8.7)	0 (0)	
Farming	1 (4.4)	2 (9.1)	
Partner	9 (39.1)	11 (50.0)	0.55
HIV Status			
Positive	9 (39.1)	12 (54.6)	0.30
Negative	14 (60.9)	10 (45.5)	
Partner HIV Status ($n = 20$)			0.33
Positive	0 (0)	3 (27.2)	
Negative	4 (44.4)	4 (36.4)	
Don't Know	5 (55.6)	4 (36.4)	
Previous Pregnancies			
0	2 (8.7)	0 (0)	0.49
1	5 (21.7)	6 (27.3)	
2	6 (26.1)	5 (22.7)	
3+	10 (43.5)	11 (50.0)	

 Table 1: Demographic Characteristics of Cyclic CVR Users vs. Continuous CVR Users

Participant's opinion of the CVR throughout the study period were also reported, overall acceptability was high, and worry was similar between cyclic and continuous CVR users (Table 3).

At the 6-month follow up visit, 22 (48.9%) of all participants experienced changes to their menstrual cycle while using the CVR. Of those participants, 4 (18.2%) of cyclic CVR users and 5 (21.7%) reported menstrual suppression (Table 4). Majority of participants disagreed that women do not like having their monthly periods (60%) and that women are not interested in having periods (64.4%). However, more than half of cyclic (73.9%) and continuous (54.6%) users alike agreed that women would prefer to have their periods less frequently. More participants in the continuous CVR use group agreed that future pregnancies would be less likely once stopping CVR use (81.8% vs. 47.8%, p =0.02). The continuous CVR use group was also more worried that menstrual suppression would cause long-term health effects (86.4% vs. 60.9%, p = 0.05).

The menstrual suppression summary score ranged from 8 to 42 with higher scores indicating a more positive attitude toward menstrual suppression. Results of the hierarchical cluster analysis identified three distinct clusters of participants based on their menstrual suppression attitude summary score, Cluster 1 (n=13), Cluster 2 (n=26), and Cluster 3 (n=6) (Figure 3). The median score for clusters were 28, 25.5, and 13.5 respectively. Average summary score was 24.2 (SD: 5.0), participants in Cluster 3 had lower summary scores than Clusters 1 and 2 (Mean (SD) = 14.1(4.6), p < 0.001), and 83.3% of Cluster 3 are in the continuous CVR use group (Figure 2). Participants in each cluster had similar demographic characteristics as well as sexual behaviors and intravaginal practices. Cluster 3 participants were defined by their opinions of the ring and were more likely to report worry about the CVR causing pain during sex (p = 0.05) and their partners feeling the CVR during sex (p = 0.02).

Discussion

Continuous CVR use has the potential to suppress menstruation thus eliminating or reducing the withdrawal bleeding many women using hormonal contraceptives experience. That said, our data highlight some of the nuances associated with women's perception of menstrual suppression, and social constructs surrounding menstruation (13).

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Sexual partners in the past month 0	Total (N=45) 4 (9.1)	Cyclic CVR (N=22)	Continuous CVR (N=23)	P-value
Sexual partners in the past month 0	4 (9.1)			
0	4 (9.1)	· · · · · · ·		
		2 (9.1)	2(9.1)	1.00
1	35 (79.6)	17 (77.3)	18 (81.8)	
2+	5 (11.4)	3 (13.4)	2 (9.1)	
New sexual partners in the past month				
0	31 (70.5)	13 (59.1)	18 (81.8)	0.29
1	9 (20.5)	6 (27.3)	3 (13.6)	
2+	4 (9.1)	3 (13.6)	1 (4.6)	
Intercourse in the past month				
0	5 (11.4)	3(13.6)	2 (9.1)	0.08
1	7 (15.9)	6 (27.3)	1 (4.6)	
2	8 (18.2)	5 (22.7)	3 (13.6)	
3	2 (4.6)	0 (0)	2 (9.1)	
4	7 (15.9)	4 (18.2)	3 (13.6)	
≥5	15 (34.1)	4 (18.2)	11(50.0)	
Condom use in the past month				
0	29 (65.9)	16 (72.7)	13 (59.1)	0.13
1	0 (0)	0 (0)	0 (0)	
2	6 (13.6)	4(18.2)	2(9.1)	
3+	9 (18.2)	2(9.1)	7(31.8)	
Contraception in the past 6 months				
Oral contraceptive	3 (6.7)	1 (4.4)	2 (9.1)	0.39
Injectable	2 (4.4)	2 (9.1)	0(0)	
Condoms	7 (15.6)	2 (9.1)	5 (21.7)	
Sponge	1 (2.2)	1 (4.4)	0(0)	
None	32 (71.1)	16 (72.7)	16 (69.6)	
Ever wash inside the vagina				
Yes	35 (79.6)	15 (68.2)	20 (90.1)	0.13
No	9 (20.5)	7 (31.8)	2 (9.1)	

Table 2: Sexual Behaviors & IVP at Enrollment of Cyclic CVR Users vs Continuous CVR Users

The majority of participants, regardless of which group of CVR use they were randomized to, agreed that women do not want to completely get rid of menses, and 82.2% also agreed that the absence of a monthly period is unnatural. More women among those who used the CVR continuously agreed that hormonal menstrual suppression makes it less likely for women to become pregnant following cessation of the contraceptive, and worried that menstrual suppression would affect long-term health. Similar themes have emerged in other qualitative studies, which have reported that women believed that natural menstruation or withdrawal bleeding were healthier than menstrual suppression and reported stopping or changing contraception methods if menstrual suppression was experienced (19). Our findings support reactions that can occur when women are unaware or do not understand the possibility of menstrual suppression until they begin using a hormonal contraceptive, which can conflict with

psycho-social beliefs about menstruation.

Overall, most women in our study reported a primary sexual partner and 1-2 new sexual partners monthly. Although there were no observed differences in behavior between arms, consistent condom use at each intercourse was low, about 34% condom use at baseline and 26% throughout the study duration. IVP, specifically vaginal washing was common among this cohort and was engaged in daily. Despite unobserved impact on attitudes toward menstrual suppression, the observed frequency of IVP among participants likely increases their risk of reproductive adverse effects and STI transmission (20).

Women within Cluster 3 had the most distinct responses to the questionnaire and an overall negative attitude towards menstrual suppression compared to Clusters 1 and 2. More than half agreed that women enjoy menstruating monthly, and all disagreed that women would want to menstruate less frequently.

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	Total	Cyclic CVR	Continuous CVR	P-value
Worried about vaginal ring inside every day	18 (40.0)	9 (39.1)	9 (40.9)	1.00
Worried about being dirty	1 (2.2)	0 (0.0)	1 (4.6)	0.49
Worried about accidental removal	12 (26.7)	6 (26.1)	6 (27.3)	1.00
Worried about not staying in place	13 (28.9)	5 (21.7)	8 (36.4)	0.34
Worried about getting stuck inside body	5 (11.1)	2 (8.7)	3 (13.6)	0.67
Worried about coming out during sex	10 (22.2)	4 (17.4)	6 (27.3)	0.49
Worried about causing pain during sex	7 (15.6)	3 (13.0)	4 (18.2)	0.70
Worried sex partner will feel ring during sex	6 (13.3)	2 (8.7)	4 (18.2)	0.41

Table 3: Vaginal Ring Acceptability by CVR Use Group*

*Responses were collapsed into ever or never because of small sample size.

Changes in menstrual bleeding from contraceptives are less preferred in other African countries, emphasizing the geographical and cultural influences that also contribute to perceptions of menstruation and concerns associated with changes to what is 'normal'(21).



Figure 3: Hierarchical cluster analysis of Menstrual Suppression Summary Score. A. Hierarchical cluster analysis dendrogram (complete linkage) of attitudes toward menstrual suppression. B. Responses to Menstrual Suppression Questionnaire and Covariates among Clusters.

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1. Have you experienced a change in your menstrul cycle since you started using the ring? 1 Yes 22 (48.9) 12 (54.6) 10 (45.5) 0.65 No 23 (51.1) 11 (47.8) 12 (52.2) 1 Ia. If yes, what was the change? 9 4 (33.3) 5 (50.0) 1 Intermenstrual bleeding 4 3 (25.0) 1 (10.0) Heavier or prolonged bleeding 6 4 (33.3) 2 (20.0) Other 3 1 (8.3) 2 (20.0) 2 2 0.00 14 (60.9) 13 (59.1) 0.90 Agree 18 (40.0 9 (31.4) 9 (40.9) 3 3 (59.1) 0.90 Agree 16 (35.6) 8 (34.8) 8 (36.4) 4 4 Agree 16 (35.6) 6 (26.1) 10 (45.5) 0.17 Agree 16 (35.6) 6 (26.1) 10 (45.5) 0.17 Agree 16 (35.6) 6 (26.1) 10 (45.5) 0.47 Sinsgree 29 (64.4) 17 (7.3.9) 12 (54.6) 1 Sinsgree 15 (65.7) 1 (4.6) 3 3 (6.7) 2 (8.7) 1 (4.6)<		Total (N=45)	Cyclic CVR	Continuous CVR	P-value
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Not Worried $Q(20.0)$ $f(10.0)$ $f(20.1)$ $Q(12.6)$	Worried	36 (80 0)	17 (73 Q)	19 (86 4)	0.46*
	Not Worried	9 (20 0)	6(261)	3(136)	0.40
15 Menstrual suppression would cause long-term health effects					
Worried $33(733)$ 14(609) 19(864) 0.05	Worried	33 (73 3)	14 (60.9)	19 (86 4)	0.05
Not Worried $12(26.7)$ $9(39.1)$ $3(13.6)$	Not Worried	12 (26.7)	9 (39.1)	3(13.6)	0.05

Table 4: Menstrual Suppression Questionnaire Responses by CVR Use Group

Column N(%) reported, *Fisher Exact Test for responses with expected values < 5

Additionally, a third of women in Cluster 3 conveyed concerns about experiencing discomfort during sexual intercourse while using the CVR, supporting previous ring studies that perceived or actual interruptions in sexual experiences increases the likelihood of discontinuation (5, 22). Consequently, half of women were also worried about their sexual partners feeling the CVR during sexual intercourse, suggesting partner perception of the CVR not only influences ring acceptability, but also how women perceive changes to their menstrual cycle. Partner perceptions of contraceptive methods is especially prevalent in low- and middle- income countries and could become another barrier in uptake of MPTs (6).

Vaginal ring MPTs currently range from preclinical development to Phase 2 clinical trials, reinforcing the importance of assessing women's preferences and perceptions related to continuous CVR use and potential side effects. Women in many parts of sub-Saharan Africa, including our participants, are at especially high risk of STI transmission and unintended pregnancy given the low condom use, limited use of a secondary contraceptive method, history of BV, and high prevalence of HIV-serodiscordant relationships, and are one of the primary targets for MPT implementation. Misunderstandings surrounding menstrual cycles, withdrawal bleeding, and negative opinions about menstrual suppression could potentially interfere with uptake of vaginal ring MPTs among similar populations that are at increased need for protection. The findings from our study confirm women's beliefs that menstrual suppression is unnatural and contraceptive induced suppression of menses can decrease fertility.

To our knowledge, this is the first study to assess attitudes toward menstrual suppression specifically among women who experienced continuous use of a CVR. Most previous studies about perceptions of menstrual suppression have been qualitative in design, thus our quantitative findings further expand understanding in the literature, however, there are important limitations that should be taken into consideration. Our sample size may have contributed to our observations of limited differences in sexual behaviors and IVP. Furthermore, women in the primary study were randomized to CVR regimen, optimally future research should consider changes in attitudes based on whether women choose to use the CVR on a cyclic or continuous regimen.

Participants included in our analyses were a randomized subset of women from the primary study, there were no statistically significant differences in demographics or sexual behaviors when compared to the entire cohort. However, the cohort identified in this study was specific and may limit the generalizability of results to other populations of women. Future studies with larger sample size among women from diverse backgrounds will further improve our understanding of attitudes towards menstrual suppression in the context of hormonal contraceptive use.

Conclusion

Our study suggests that menstrual suppression may not be fully understood by women prior to using contraceptive methods that have the potential to cause menstrual suppression. Education about menstrual suppression and its impact on fertility may be integral in increasing its acceptability. Especially for the implementation of developmental MPTs and other reproductive or sexual health options where menstrual suppression is a potential side effect.

Conflict of Interests

Authors declare no conflict of interests.

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