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Brief communication (Original)

Acceptability, tolerability, and satisfaction of a contraceptive vaginal ring (the NuvaRing) among Thai women

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Background: The NuvaRing has demonstrated efficacy and acceptability in a number of clinical studies mostly in western countries. Because of cultural differences and self-administration of the device, it may not be well-accepted by Thai women.
Objectives: To assess the acceptability, tolerability and satisfaction of Thai women who started to use the NuvaRing.
Methods: The levels of acceptance by 39 clients who began using the NuvaRing were reviewed in this retrospective observational cohort study of clients at a family planning clinic in Bangkok. Ring-related and other adverse events were recorded at the end of second, fourth, and sixth cycles.
Results: Included in this study were clients (38/39; 97%) who used the NuvaRing for six cycles consecutively. Difficulties in removing the NuvaRing were experienced by 13% of the participants and 49% felt transient vaginal discomfort; however, these problems resolved over time. Approximately one third of clients had asymptomatic watery discharges. Of the total of 229 cycles 95.1% were as usual with scheduled bleeding. Seventy-one percent of the clients were very satisfied. Before and after 6 cycles of using the NuvaRing, there were no significant clinical differences between body weight, blood pressure, duration of period, and amount of pads used per cycle found using paired 2-sample *t* tests.
Conclusions: NuvaRing has demonstrated no significant effects on regular cycle continuation and had very few clients experienced adverse events. The acceptability of this device and satisfaction of using it were partly owing to structural, comprehensive counseling, and support provided by the family planning staff.

Keywords: Acceptability, contraceptive vaginal ring, NuvaRing, satisfaction, tolerability

Combined oral contraceptives (COCs) are among the most commonly used contraceptive methods used by Thai women [1]. However, the required daily administration [2] is cumbersome. Studies conducted in Western countries have shown that up to one third of the women forgot to take at least one pill during three consecutive menstrual cycles [3]. In Thailand, 75% of COCs users forget to take at least one pill per cycle [4]. This can result in increased risk of unintended pregnancies and poor control of the menstrual cycle. An alternative method such as a vaginal ring with combined contraceptives may be a better solution for contraception.

Even though contraceptive vaginal rings have been available since the early 1970s [5], currently there is only one combined hormonal contraceptive vaginal ring, that releases 15 μg of ethinyl estradiol and 120 μg of etonogestrel, known as the NuvaRing (developed by NV Organon, Oss, The Netherlands, and marketed worldwide by Merck and Co, Whitehouse Station, NJ, USA) [6]. Previous studies [7-9] have shown that the NuvaRing is a novel contraceptive device that can effectively prevent pregnancy, has a high efficacy to control the cycle [8], and is well accepted by western women. Its qualities make it an extremely attractive choice for contraception for women with poor compliance. However, most of the data on

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the NuvaRing are from western countries [5, 10, 11]. We need to know whether this is also applicable to conservative Southeast Asian women. Thai women often believe that anything inserted into the vagina, such as medications, are undesirable. Another example is tampons, which are less popular among Thai women. This may also explain why there are only limited studies of the NuvaRing conducted in Asian women despite its availability over decades [12]. To our knowledge, there are no published data regarding the acceptability of the NuvaRing to Thai women. Thus, this study assessed the acceptability, tolerability, and satisfaction of using the NuvaRing in Thai women.

Methods

Study protocol and data collection

This retrospective observational cohort study assessed the initial use of a contraceptive vaginal ring (the NuvaRing) in clients who attended the Family Planning and Reproductive Health Clinic, Chulalongkorn Memorial Hospital, Bangkok, Thailand, in 2012. The medical records and menstrual diaries of the women were retrospectively reviewed by the authors after approval of the present study by the Institutional Research Ethical Committees of the Faculty of Medicine, Chulalongkorn University (certificate of approval No. 775/2015, Institutional Review Board No. 415/58). According to the procedures of the Clinic, family planning nurses first checked the clients' eligibility (excluding contraindications) for using combined hormonal contraceptives as per the World Health Organization (WHO)'s criteria for contraceptive use [13]. Then, they performed a standard physical examination. Subsequently, a structural and comprehensive counseling session regarding this method was conducted. Information about the efficacy, safety, side effects, and how to deal with them were provided. The clients were also taught how to insert and remove the ring using the three standard positions: squatting, standing with one leg, or in a supine position. Scheduled visits were made at the end of the second, fourth, and sixth cycles. During each visit, the menstrual diary was reviewed and the clients' concerns and questions were addressed. Additional information related to ring issues were recorded, such as the occurrence of adverse effects, and the effect of the ring on sexual intercourse. At the end of the sixth cycle, the clients' satisfaction with using the ring was recorded. Clients' medical records and menstrual diary were again reviewed.

The authors assessed the acceptability of the NuvaRing by calculating the percentage of discontinuation before their sixth cycle [8]. Tolerability was determined by the presence of ring-related adverse events such as problems during insertion and removal procedures, sensations of having a foreign body inserted into the vagina, negative feelings regarding the ring during sexual intercourse, and sexual impact for both the clients and their partners [8, 14], and other adverse events. Satisfaction was assessed by the clients' satisfaction and responses to using the ring at the end of their sixth cycle. The menstrual pattern [14] of the clients was also assessed. Normal intended bleeding was defined as having a withdrawal bleeding during one week of ring-free period. Early withdrawal bleeding was defined as having withdrawal bleeding before the ring-free period and continued withdrawal bleeding was defined as continuous bleeding after a new ring was inserted. Breakthrough bleeding was defined as using more than one pad per day during ring use. A breakthrough spotting was defined as using up to one pad per day during the ring use. Absent withdrawal bleeding was defined as no bleeding during the ring-free period.

Statistical analysis

Data analysis was performed using IBM SPSS for Windows, version 17 (IBM Corp, Armonk, NY) and Microsoft Excel for Mac 2011 version 14.5.2. Mean, standard deviation, and percentages were used to describe the demographic characteristics and bleeding pattern. A paired-sample *t* test was used to compare the body weight, blood pressure, duration of menstrual flow, and amount of pads used per cycle before and after using the ring. $P < 0.05$ was considered statistically significant.

Results

Data from a total of 39 clients who started to use the contraceptive vaginal rings were included in the study. Basic characteristics of all clients are shown in **Table 1**.

All of the clients were either married or cohabitated with someone, did not have any medical illnesses, did not have any contraindications for combined hormonal contraceptives [13], had a normal history of menstrual periods, and did not use any forms of hormonal contraceptives up to one month before starting the ring. Nearly all (38/39) continued using the ring until the end of their sixth cycle. One client

prematurely discontinued the ring during her second cycle because she considered that her vaginitis, leucorrhea and itching, was caused by the ring. Approximately one third of the clients had increased vaginal discharge, which was asymptomatic. There were no pregnancies during the 6 cycles while using the contraceptive vaginal ring. The incidence of adverse events is shown in **Table 2**.

One client had dizziness during the first few days after the first and second insertion of the ring. One client had mild dizziness and nausea during the first few days after inserting the ring at all cycles. One client had breakthrough bleeding and simultaneously experienced mild pelvic pain. Another client had mild dysmenorrhea during her first and second cycles. The incidence of ring-related events is shown in **Figure 1**.

Some difficulties inserting and removing the ring during their first and second cycles occurred in 12% of the clients, but with time, these issues disappeared. About half of the clients reported transient sensations of a foreign body in the vagina after inserting the new ring, but with time, these feelings gradually subsided. Some 40% of the clients and their partners could feel the ring in the vagina during sexual intercourse. However, this did not interfere with sexual activity. Only a few of the couples stated that the ring affected their sexual desire, which were owing to either positive and negative feelings.

Table 1. Baseline characteristics of the clients

Variable	Mean (SD)/Number of clients (%)[1]
Age (years)	29.2 (4.9)
Parity (%)	
0	3 (7.7%)
1	28 (71.8%)
2	5 (12.8%)
>2	3 (7.7%)
Occupation	
Housewife	8 (20.5%)
Employee	19 (48.7%)
Bureaucrat	4 (10.3%)
Business	3 (7.7%)
Others	5 (12.5%)
Dysmenorrhea	
No	9 (23.0%)
Mild	25 (64.1%)
Moderate	5 (12.8%)
Recent method of contraception	
Combined oral contraceptives	8 (20.5%)
DMPA	1 (2.6%)
Condom	20 (51.3%)
None	10 (25.6%)

[1]Continuous variables are presented as mean (SD), and categorical variables are presented as n (%)

Table 2. Adverse events reported during the study period

Adverse events	Number of clients (%)
Dizziness	2 (5.12)
Nausea	1 (2.56)
Pelvic pain	2 (2.5)
Back pain	1 (2.5)

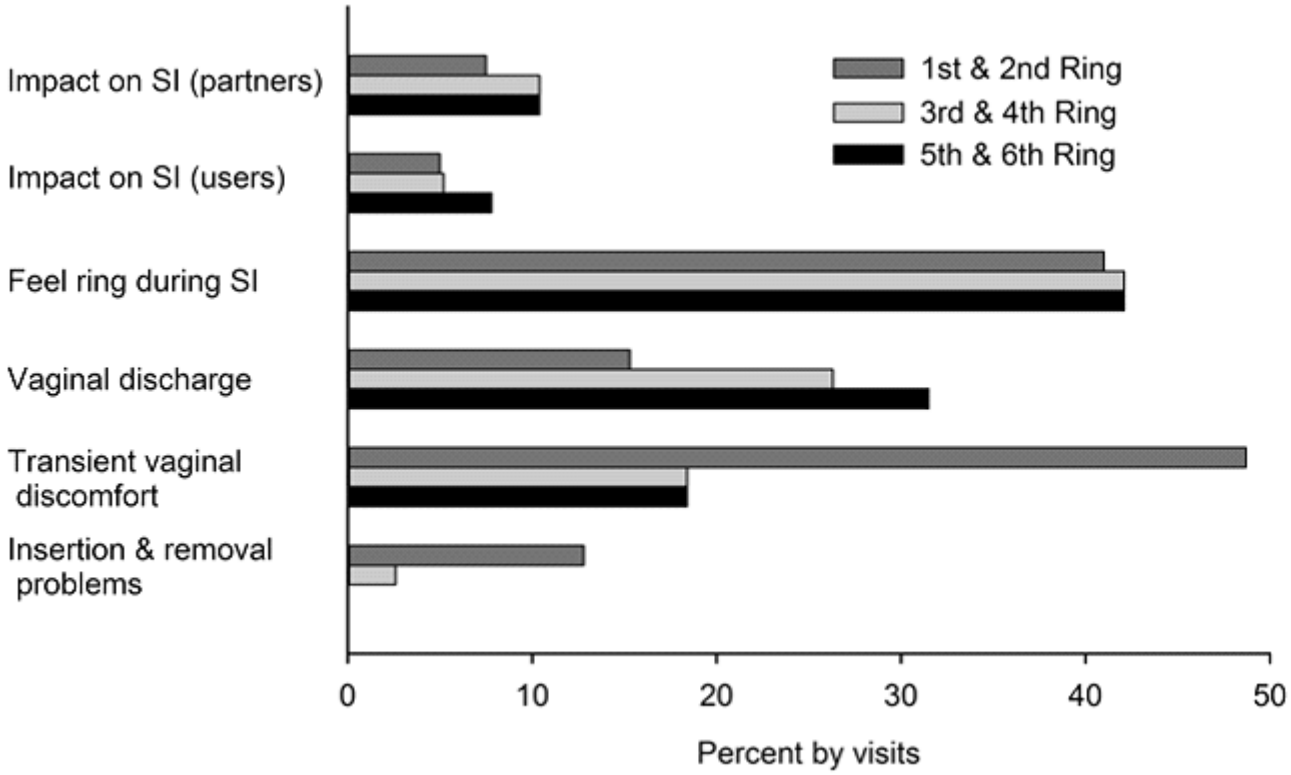

Figure 1. Ring-related adverse events by visits

A total of 229 menstrual cycles were analyzed in **Table 3** and **Figure 2** and 95.1% (218/229) of the cycles had normal intended bleeding that lasted for an average of 4-5 days. Early and continued bleeding, which lasted for 11 days occurred in one cycle. Breakthrough bleeding and spotting occurred in 3% (7/229) of the cycles of which lasted up to 9 days. Absence of withdrawal bleeding occurred in 3% (7/229) of the cycles. Urine pregnancy tests were all negative for 7 cycles for women with amenorrhea.

The mean differences in body weight, blood pressure, duration of menstrual bleeding, and amount of pads used per cycle before and after using the ring are shown in **Table 4**.

There were no significant clinical differences between these parameters. At the end of the sixth cycle, 71% of the clients stated that they were very satisfied with the use of the NuvaRing. Most of clients (94%) opted to extend the use of the ring, and all of the clients stated that they would recommend the NuvaRing to their friends.

Table 3. Bleeding patterns from a total of 229 cycles

Outcome	Number of cycles (%)
Normal expected bleeding	218 (95.1)
Early and continued withdrawal bleeding	1 (0.43)
Breakthrough bleeding/spotting	7 (3.0)
Breakthrough bleeding	5 (2.1)
Breakthrough spotting	2 (0.9)
No withdrawal bleeding	7 (3.0)

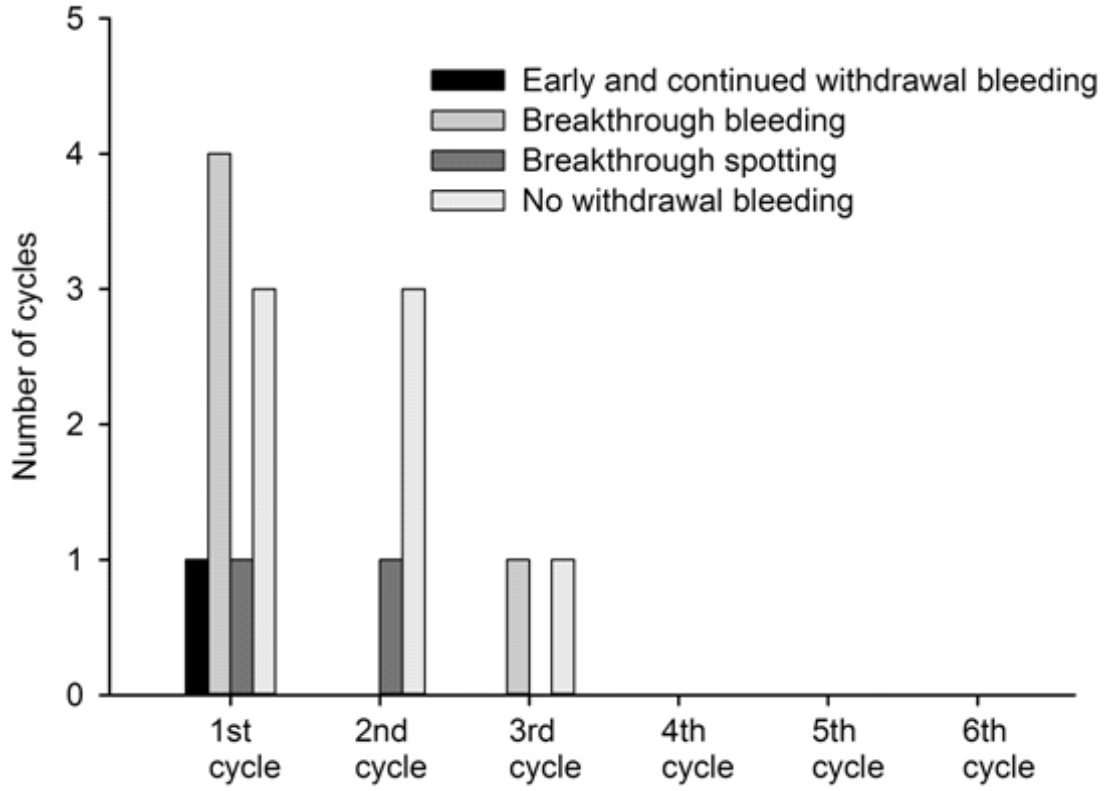

Figure 2. Number of cycles with at least one abnormal bleeding pattern

Table 4. Statistical analysis comparing before and after using the NuvaRing

Variables	Baseline Mean (SD)	After 6th cycle Mean (SD)	Mean difference	*P*
Body weight (kg)	56.49 (6.85)	56.49 (6.72)	0.002 (1.11)	0.998
Systolic BP (mmHg)	111.92 (7.30)	111.07 (7.84)	-1.13 (5.7)	0.23
Diastolic BP (mmHg)	69.60 (5.78)	72.10 (4.13)	2.5 (6.16)	0.017
Duration of menstrual flow (days)	4.61 (1.22)	4.15 (1.00)	-0.44 (1.00)	0.009
Amount of pads/cycle (pads)	14.42 (4.57)	13.71 (4.17)	-0.71 (2.76)	0.12

Discussion

This study showed that the acceptability, continuous use of, and satisfaction with the NuvaRing in Thai women was high. The authors were surprised that the continuation rate of using the contraceptive ring in the women was high because of cultural conservatism of Thai women. These results are consistent with previous clinical studies conducted in western countries that found this contraceptive vaginal ring was well accepted [5, 8, 15]. It should be noted that structural, comprehensive counseling, and great support by the family planning staff also contributed to the high rates of acceptability and continuous use of the ring in the present study.

Despite the high acceptability and continuous use of the ring, some adverse events were detected. Some women reported experiencing dizziness and nausea after a few days of inserting of the ring, which may have been associated with the estrogen use even though its levels are much lower than in the COCs. However, the serum concentration of ethinyl estradiol is at its highest level a few days after the ring is inserted [16]. This may explain why some clients experienced adverse events during that period. Ring administration issues and transient vaginal discomfort decreased over time. The clients felt more comfortable with the method after its extensive use.

Approximately 3%-5% of the participants experienced leukorrhea or vaginitis [5, 17, 18]. However, in this study, asymptomatic watery discharge occurred in about a third of clients. It is possible that because there are no unfavorable cytological or bacteriological changes of the cervicovaginal epithelium [19], this may explain why few of the clients did not experience any symptoms. It is also possible that some clients, who had asymptomatic vaginal discharge, may not have found these symptoms significant and did not report them in their diary.

Other effects of the ring, such as during sexual intercourse, showed that nearly 40% of clients and their partners could sense the ring during sex, but this did not interfere with their sexual activity. Similarly, previous studies noted that 15% of the women and 30% of their partners occasionally felt the ring during intercourse, and that were comfortable having sex with the ring in situ [19].

Aside from the noted effects, the ring produced excellent cycle control. The normal intended bleeding occurred in nearly all analyzed cycles. There were a few abnormal uterine bleeds and only in the first few cycles after using NuvaRing. This finding is consistent with previous reports that the incidence of abnormal bleeding in NuvaRing was low [8, 14, 15]. It is possible that the exceptional cycle control may have been the result of the combined hormonal contraceptive agents in the NuvaRing and the high compliance achieved by the users. This cycle control of the ring may also be a reason for the clients' satisfaction.

One of the limitations of this study is that the results cannot be generalized to other settings that do not provide extended counseling and comprehensive family planning services. Thus, it is imperative to provide such services to achieve high rates of acceptability and continuous use of the ring. It is also possible that other safety profiles were not detected because of the small sample size. Finally, the design of this study was limited to gathering information only from medical records and menstrual diaries of the clients. However, it is highly unlikely to affect the results of the study because the medical records and menstrual diaries were well recorded at the family planning unit. The authors had all of the information needed for analyzing the main outcomes of the study.

Conclusion

The NuvaRing was found to be well accepted by the Thai women in the present study. The ring demonstrated its excellent cycle control and produced very few adverse events. The ring did not negatively impact on sexual intercourse significantly. The high rates of acceptability, continuous use, and satisfaction of the ring is attributed to the structural, comprehensive counseling, and great support provided by the family planning staff.

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Conflict of interest statement

The manufacturer of the NuvaRing played no part in this project and the authors have no conflicts of interest to report.

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