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RESEARCH ARTICLE

Real-world experience with the IUB Ballerine MIDI copper IUD: an observational study in the French-speaking region of Switzerland

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ABSTRACT

Objective: The aim of the study was to assess the acceptability of the intrauterine ball IUB Ballerine MIDI copper intrauterine device (IUD), using real-world data collected from users and physicians.

Methods: In this retrospective, observational study, conducted in the French-speaking region of Switzerland, healthy women ($n=207$) who had had an IUB Ballerine MIDI inserted $\geq$12 months before enrolment, and their physicians completed questionnaires relating to device insertion, user experience and outcome. Questions relating to current menstrual patterns, physical comfort and product satisfaction were only posed to women still using the device.

Results: The mean age at insertion was 30.8 ± 7.2 years, with an average 14.2 ± 2.9 month lapse from time of insertion until study commencement. At the time of the study, 140 (67.6%) women were still using the device. The expulsion rate was 5.3% ($n=11$) and the pregnancy rate was 1.4% ($n=3$). Most of the women still using the device reported no to moderate pain or cramps (80.7%). The majority of women reported moderate to high (65.7%) satisfaction with the device, with 81.4% claiming they would recommend it to friends and relatives. Over 84.8% of physicians reported that the device was easy to insert, with no difficulties encountered during the procedure.

Conclusions: The IUB Ballerine MIDI was demonstrated to be safe and acceptable in different clinical settings and risk groups among a socioeconomically and demographically diverse study population.

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Introduction

Unintended pregnancies [1,2], typically attributed to incorrect or inconsistent use of contraception, result in both personal and financial challenges that have immediate effects on the health of women and their offspring. The disproportionate incidence of unintended pregnancies among young adults, women from minority groups and women in developing and low-income countries [3], poses a particularly significant challenge to public health care systems across the globe. Increasing awareness and access to long-acting reversible contraception (LARC) have been strongly promoted in recent years by governments, health protection agencies and family planning organisations around the world and are believed to underlie the recent marked global decrease in the incidence of unintended pregnancies [1,4]. LARC methods provide long-term, reliable and cost-effective contraception, requiring a simple insertion procedure once in 3–10 years. LARC is fully independent of user adherence, which contributes to its higher effectiveness when compared to pills, patches and rings [4]. The levonorgestrel-releasing intrauterine system, copper intrauterine device (IUD) and subdermal levonorgestrel or etonogestrel implants are LARC methods with high efficacy and have been demonstrated to be safe in most female populations, including adolescents [5]. First-year failure rates among copper IUD users have been reported to range from 0.1% to 1.4%, depending on the device type and studied population [6], in sharp contrast to the 9% and 30% rates among combined oral contraceptive users and its high-risk subpopulation, respectively [7]. User satisfaction with intrauterine contraception is generally high, with reported 12 month continuation rates ranging from 74 % to 85% [8].

Copper IUDs have often been associated with increased cramping and menstrual bleeding in the first 3 months of use, as well as intermenstrual spotting during the first year of use, which have been reported as key factors leading to discontinuation within the first 2 years of use [9–11]. The reasons for these effects remain elusive. It has been suggested that disproportion between the device size and the dimensions of the uterine cavity, seen with the conventional T-shaped copper IUD, can elicit endo- or myometrial trauma, which may underlie the adverse effects and lead to malposition and embedment within the uterine tissue [12,13].

The IUB Ballerine MIDI (OCON Healthcare, Modiin, Israel) was designed to better adapt to the geometry of the intrauterine cavity, by adopting a spherical shape after insertion. This may reduce the risk of perforation and minimise endometrial irritation and, in turn, improve user comfort. This observational, multicentre study is the first to retrospectively collect real-world data relating to both physician and user experiences with the IUB Ballerine MIDI in the French-speaking region of Switzerland.

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Supplemental data for this article can be accessed here.

Methods

Study design

This retrospective observational cohort study recruited healthy, nulliparous or multiparous women aged ≥ 18 years, who had had an IUB Ballerine MIDI inserted at least 12 months prior to the time of enrolment, between January and October 2018. All 207 women meeting these criteria provided their consent (either electronically or by signing an informed consent form). Participants were recruited by their medical providers at one of six private clinics, one hospital-affiliated family planning clinic and one operating theatre after an abortion, all in the French-speaking region of Switzerland. Participants were asked to complete a password-secured web-based questionnaire which presented questions relating to IUB insertion, removal and expulsion, as well as pregnancy since insertion (Supplementary File 1). Questions relating to current menstrual pattern, physical comfort and satisfaction associated with use of the IUB, were only presented to women using the device at the time of questionnaire completion. Blood loss and pain/cramp patterns were graded by selecting the text most accurately describing the user's last three menstrual periods. A 10-point Likert scale was used to rate change in menstrual pattern (1 indicating 'much better' and 10 indicating 'much worse') and satisfaction (1 indicating 'very satisfied' and 10 indicating 'very dissatisfied'). In parallel, physicians completed a short electronic case report documenting participant demographic data and gynaecological and obstetric history, as well as details relating to device insertion, follow-up and removal. The study protocol was approved by the Geneva University Hospitals ethics committee.

IUB

The IUB Ballerine MIDI, formerly marketed as the IUB SCu300B MIDI, comprises 17 copper beads, with a copper surface area of 300 mm^2, strung on a flexible, polymer-coated nickel titanium wire frame and with a double-tailed monofilament removal thread attached to its tip. The device is provided preloaded, in a linear form, in an insertion tube measuring 3.2 mm in diameter. After inserting the tube into the uterine cavity, the device is deployed using a push-rod, retrogradely curls to form a spherical shape composed of four perpendicular semicircular lobes, forming an anatomically compliant sphere with a diameter of 15 mm (Figure 1). The IUB Ballerine MIDI is commercially available within the European Union, Asia and Africa as a class III medical device.

Statistical analysis

Statistical analyses were conducted using R software version 3.3.3 (R Development Core Team, Vienna, Austria) and were descriptive in nature. For continuous variables, arithmetic means, standard deviation (SD), median, minimum and maximum values and 95% confidence intervals were calculated. A sub-analysis was performed for data collected from women aged 18–24 years.

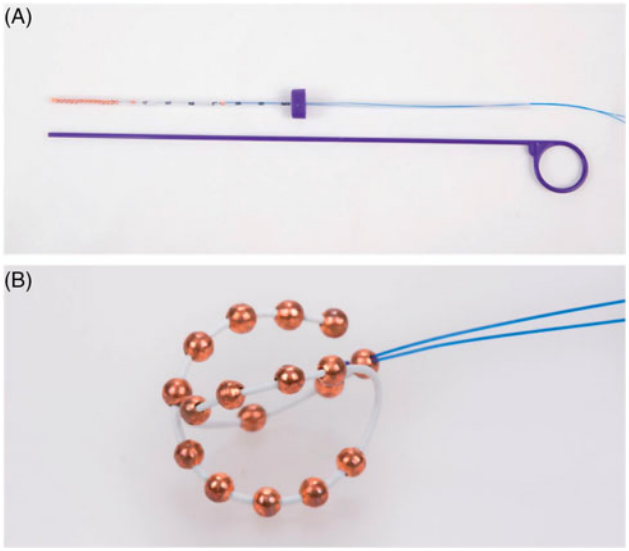

Figure 1. The IUB Ballerine MIDI. (A) The insertion tube with slider/flange, loaded with the device. (B) The device in its final 3D shape, with the 17 copper beads forming 2 circles juxtaposed at a 90° angle, resulting in an anatomically compliant 15 mm diameter sphere.

Results

Baseline characteristics of the study population

A total of 207 women were enrolled, 140 (67.6%) of whom were still using the IUB. Questionnaires were completed 14.2 ± 2.9 months after device insertion (range 12.9–27.5 months), after an average 11.9 ± 4.6 (range 0.9–27.5) months of use (Table 1); 153 women (73.9%) had used the device for at least 12 months. Participants' mean age was 32.0 ± 7.2 years at the time of questionnaire completion, and the device was inserted at a mean age of 30.8 ± 7.2 years. Among the participants, 44 (21.3%) were below the age of 25. Most women in the full-cohort analysis reported being single (47.8%) or married (36.7%) and multigravid (78.7%), while most women in the younger subset were single (86.4%) and had never been pregnant (52.3%). Eighty-nine women (43.0%) had a history of at least one abortion, with most recent abortions typically being medically induced (20.3%), while 17.4% had been surgically induced and 5.3% were spontaneous. This finding was in contrast to that in the younger subset of women, among whom only 16 of 44 (36.4%) had a history of at least one abortion, all of which were either surgically (56.3%) or medically (43.8%) induced. A minority of women reported a history of gynaecological conditions, including dysmenorrhoea (11.9%), dyspareunia (3.7%), known endometriosis/adenomyosis (2.75%) and pelvic inflammatory disease (<1%); none reported the presence of uterine fibromas or polyps. Most women were generally healthy, although almost 5% reported depression. Sociodemographic details and baseline characteristics are summarised in Table 1.

Clinical settings of IUB insertion

Device insertion settings were private gynaecological practices (47.3%), a hospital outpatient family planning clinic (38.7%) and an operating theatre (14.0%) (Table 2). Devices were inserted by one of 12 hospital physicians or one of 6 private practice physicians. The 29 devices

Table 1. Sociodemographic and baseline characteristics of the study participants.

Characteristic	Entire cohort (age ≥ 18) *n*= 207	Younger subset (age 18–24) *n*= 44
Age at insertion, years		
Mean (SD)	30.8 (7.2)	21 (2.3)
Minimum, maximum	15.9, 51.2	15.9, 24.0
Age at survey, years		
Mean (SD)	32.0 (7.2)	22.5 (2.3)
Minimum, maximum	17.0, 53.0	17.0, 25.0
Time from insertion, months		
Mean (SD)	14.2 (2.9)	14.7 (3.5)
Minimum, maximum	12.9, 27.5	12.0, 27.5
Marital status, *n* (%)		
Single	99 (47.8)	38 (86.4)
Married	76 (36.7)	3 (6.8)
Divorced	17 (8.2)	–
Other	13 (6.3)	3 (6.8)
Unknown	2 (1.0)	–
Gravidity, *n* (%)		
Multigravid	163 (78.7)	21 (47.7)
Nulligravid	44 (21.3)	23 (52.3)
Previous abortion, *n* (%)		
1	53 (25.6)	11 (25.0)
2	24 (11.6)	3 (6.8)
3	10 (4.8)	2 (4.5)
4	2 (1.0)	–
Any	89 (43.0)	16 (36.4)
Most recent abortion, *n* (%)		
Spontaneous	11 (5.3)	–
Surgically induced	36 (17.4)	9 (20.5)
Medically induced	42 (20.3)	7 (15.9)

(14.0%) inserted in an operating theatre, were placed immediately after a surgical abortion. Most of the younger women had the device inserted in a hospital outpatient family planning clinic (47.7%) or in a private gynaecological practice (40.9%).

Aspects of IUB insertion and short-term follow-up

According to physician reports, in most cases (87.0%), device insertion was uneventful and elicited no pain. Among the 178 women undergoing IUB insertion in a private or outpatient clinic, cervical dilation was necessary in 16 cases (9.0%), and vagal reflex and severe pain were reported by 6 (3.4%) and 4 (2.3%) women, respectively. Post-insertion ultrasound-based confirmation of device positioning was performed in 196 of the 207 (94.7%) enrolled women; all but one showed correct intracavitary placement (Table 2). Of the 153 ultrasound assessments performed 1–3 months after placement, 140 (91.5%) showed correct device positioning and 13 (8.5%) were found to be displaced, 10 of which were removed, while no intervention was undertaken for the remaining 3. A higher rate of displacement was documented among the younger subset of women (13.8%) (Table 2).

Discontinuation rates

Overall, 11 (5.3%) IUBs were spontaneously or partially (partially or fully within the cervix) expelled. When considering the clinical setting of device insertion, expulsion rates among all women and younger women treated in a private clinic were 4.0% and 4.8%, respectively, while devices inserted immediately after an abortion, were expelled among 6.9% of the entire cohort and among 17% of those

Table 2. IUB clinical insertion settings and follow-up.

Variable	Entire cohort (age ≥ 18) *n*= 207	Younger subset (age 18–24) *n*= 44
Insertion setting		
Private gynaecological clinic	98 (47.3)	18 (40.9)
Hospital operating theatre	29 (14.0)	5 (11.4)
Hospital family planning clinic	80 (38.7)	21 (47.7)
Insertion immediately after surgical abortion procedure	29 (14.0)	6 (13.6)
Difficulty during insertion[a]		
None	180 (87.0)	33 (84.6)
Need to dilate cervix	16 (7.7)	1 (2.6)
Need to use more than one IUB	1 (0.5)	–
Vagal reflex	6 (2.9)	3 (7.7)
Severe pain	4 (1.9)	1 (2.6)
Other	7 (3.4)	3 (7.7)
Use of pozzi forceps for dilation	4	1
Need to anesthetise cervix	2	2
Insertion under nitrous oxide	1	–
Ultrasound immediately after insertion[b]		
Ultrasound performed	196 (94.7)	42 (95.5)
In place	195 (99.5)	41 (97.6)
Displaced	1 (0.5)	1 (2.4)
Ultrasound 1–3 months after insertion[a]		
Ultrasound performed	153 (73.9)	29 (65.9)
In place	140 (91.5)	25 (86.2)
Displaced	13 (8.5)	4 (13.8)
IUB removed	10 (6.5)	3 (10.3)
No action taken	3 (2.0)	1 (3.4)

Data are presented as *n* (%).
[a]Physicians were allowed to indicate more than one difficulty in the insertion procedure; percentages were calculated in relation to the total number of women undergoing IUB insertion in a private or outpatient clinic (entire cohort, *n*= 178; younger cohort, *n*= 39).
[b]Percentages were calculated in relation to the total number of ultrasound scans performed.

Table 3. Duration of use of IUB and reasons for early removal.

Variable	Entire cohort (age ≥ 18) *n*= 207	Younger subset (age 18–24) *n*= 44
Duration of IUB use		
>12 months	153 (73.9)	30 (68.2)
<12 months	54 (26.1)	14 (31.8)
Reason for removal[a]		
Spontaneous expulsion	8 (3.9)	3 (6.8)
Partial expulsion	3 (1.4)	1 (2.3)
Intentional removal[b]	8 (3.9)	1 (2.3)
Heavy menstrual bleeding	33 (16.0)	6 (13.6)
Severe cramps	20 (9.7)	6 (13.6)
Interested in other form of contraception	4 (1.9)	1 (2.3)
Desire to conceive	7 (3.4)	1 (2.3)
Pregnancy	3 (1.4)	2 (4.5)
Other	35 (16.9)	7 (15.9)

Data are presented as *n* (%).
[a]Women were allowed to indicate more than one reason for removal.
[b]As per physician's discretion based on ultrasound demonstrating that the device was within the uterus but somewhat lower than the fundus.

aged < 25 years. Fifty-six women (27.1%) asked to have the device removed, primarily because of heavy menstrual bleeding (*n*= 33), severe cramps (*n*= 20), desire for another form of contraception (*n*= 4) or desire to conceive (*n*= 7) and/or for other reasons (*n*= 35) (Table 3). Thus, after excluding women seeking to become pregnant, the >12 month IUB removal rate was 22.7%. In 3 cases, the IUB was removed due to pregnancy, giving a 1.4% pregnancy rate over the mean 11.9 month follow-up period. Of the seven women discontinuing IUB use because they wished to become pregnant, four became pregnant within 2.8 ± 2.0 months of removal. In the younger women, 4 (9.1%) IUBs were spontaneously or partially expelled and 12 women (27.3%) asked to have the device removed, primarily because

Table 4. Menstrual patterns and satisfaction with the IUB.

Variable	Entire cohort (age ≥ 18) *n*= 140	Younger subset (age 18–24) *n*= 28
Blood flow		
Light	3 (2.1)	–
Moderate	78 (55.7)	14 (50.0)
Heavy	59 (42.1)	14 (50.0)
Menstrual pain/cramps		
None	31 (22.1)	5 (17.9)
Light	52 (37.1)	8 (28.6)
Moderate	30 (21.4)	7 (25.0)
Severe	27 (19.3)	8 (28.6)
Change in menstrual pattern[a]		
1–3	23 (16.4)	6 (21.4)
4–5	19 (13.6)	3 (10.7)
6–7	42 (30.0)	10 (35.7)
8–10	56 (40.0)	9 (32.1)
Satisfaction[a]		
1–3	62 (44.3)	15 (53.6)
4–5	30 (21.4)	4 (14.3)
6–7	21 (15.0)	6 (21.4)
8–10	27 (19.3)	3 (10.7)
Recommend to friends and family		
Yes	114 (81.4)	27 (96.4)
No	10 (7.1)	1 (3.6)
Prefer not to respond	16 (11.4)	–

Data are presented as *n* (%).
[a]Measured on a 10-point Likert scale (ranging from 1 'very satisfied' to 10 'very dissatisfied').

of heavy menstrual bleeding (*n*= 6), severe cramps (*n*= 6), desire for another form of contraception (*n*= 1), desire to conceive (*n*= 1) or for another reason (*n*= 7).

User satisfaction and side effects

In total, 140 women were still using the device at the time of questionnaire completion, which was an average of 13.9 months (range 12.9–27.5) after insertion. The women were an average age of 32.5 years at the time of enrolment and most were multigravid (78.7%) and either single (47.1%) or married (35.0%). Questions relating to menstrual bleeding pattern, pain and cramps and overall satisfaction were posed to these 140 women only (Table 4). Slightly more than 50% reported menstrual bleeding lasting ≤5 d and 81.4% reported menstrual bleeding lasting ≤7 d in the 3 months preceding completion of the questionnaire. Menstruation flow was typically rated moderate (55.7%) to heavy (42.1%), and heavier than bleeding patterns experienced prior to insertion. No to light pain or cramps during menstruation was reported by 59.2% of women, while 21.4% reported moderate and 19.3% severe pain/cramps. While similar bleeding patterns were reported by the younger women still using the IUB (*n*= 28), a higher percentage suffered from moderate or severe pain or cramps (25.0% and 28.6%, respectively). Multigravid women still using the IUB (*n*= 111) were more likely to report no or mild pain or cramps (64.9%), whereas nulligravid women were more likely to report moderate to severe cramps (63.3%).

Overall, 67.9% of women <25 years and 65.7% of all women still using the device described themselves as satisfied or very satisfied (Table 4). Satisfaction was further reflected by the high percentage (81.4%) of women claiming they would recommend the IUB to friends and relatives. Despite the seemingly worsened menstrual symptoms among younger women, 96.4% indicated that they would recommend the device to friends and relatives.

Discussion

Findings and interpretation

This study aimed to collect real-world data regarding the IUB Ballerine MIDI (15 mm diameter), uniquely designed to enhance uterine compatibility and user comfort. The study included a wide variety of participants, comprising a socio-economically and demographically diverse population in the French-speaking region of Switzerland. All participants had chosen the IUB as a means of contraception at least 1 year earlier and the device had been inserted in a private clinic or at the Geneva University Hospitals outpatient family planning clinic or operating theatre after an abortion. The device proved safe, with no reports of cervical damage, uterine perforation, cervicitis or pelvic inflammatory disease after insertion. Physicians reported a simple and straightforward insertion procedure, regardless of women's parity, which generally required no cervical manipulation. Two-thirds (68.1%) of users were satisfied with the IUB, and the vast majority (81.4%) reported they would highly recommend it to their friends and family. In addition, while the sample size of women seeking to become pregnant was small, return to fertility was rapid, as expected.

Differences and similarities in relation to other studies

Women using the IUB reported menstrual bleeding lasting up to 7 d. At the same time, tolerability in the full-cohort analysis was high, with 80.7% of women reporting no, light or moderate cramping; reports of moderate or severe cramping were higher among the younger subset of women compared with the overall study group (53.6% *vs.* 40.7%, respectively). Despite this, as seen with other copper IUDs, 10–16% of participants in this study, with variations by age group, requested its removal because of exacerbated bleeding and cramping. While these findings align with reports of the impact of copper IUDs on menstrual bleeding patterns, they are likely grossly influenced by the bias to recommend copper IUDs to women with lighter and less painful menses. Moreover, subjective impressions of changes in menstrual blood loss and tolerability have been shown to contradict objective measures and are likely greatly impacted by user expectations [14].

Overall, 11 of the 207 inserted devices were spontaneously or partially expelled (5.3%), which is comparative to the 6–8% expulsion rates reported by others [15–17]. Of the 11 expelled devices, 4 had been used by women under the age of 25 years (9.1%), demonstrating a correlation between expulsion rate and younger age, particularly immediately after an abortion, a time associated with heightened incidence of copper IUD expulsion [18]. Similarly, a secondary analysis of the contraceptive CHOICE project data relating only to first-time copper IUD users, demonstrated a twofold increase (18.8% *vs.* 9.3%) in expulsion rates among young (ages 14–19) *vs.* older women, with an adjusted hazard ratio of 3.1 for young copper IUD users [17]. The increased expulsion rates reported in young users of intrauterine contraception is a clinical concern that

should be taken into account during counselling [7,19,20]. The first-year IUB failure rate (1.4%), which aligned with those reported for other intrauterine contraceptives [6,21], will require further assessment due to the relatively small sample size in this study.

Strengths and weaknesses of the study

The diversity of the study population, which included a broad age range, gravidity status and abortion history, renders the collected data applicable to other geographical regions. In addition, the study involved 18 physicians who inserted the device in a range of clinical settings.

Limitations of this study were its retrospective, non-controlled nature and small sample size, as well as its reliance on subjective reports relating to menstrual patterns after device insertion, which have often been demonstrated to fail to reflect objective measures of blood loss [14]. In addition, devices positioned low in the uterus might have been reported as partial expulsions, leading to an overestimation of this variable and to unnecessary removal.

Relevance of the findings: implications for clinicians and policy-makers

The results of this first report of 1-year real-world experience with the IUB Ballerine MIDI are similar to those of a small-scale study ($n = 15$) assessing the safety and 12-month effectiveness of a smaller device model (12 mm diameter IUB SCu300A MINI, OCON Healthcare, Modiin, Israel) [22]. The evaluation demonstrated its safety and acceptability in a broad range of subpopulations and clinical settings. Apart from pregnancy and discontinuation rates similar to those reported for other copper IUDs, these early findings suggest that the device was well tolerated, likely due to improved conformity of the device shape with the uterine anatomy. Heightened user comfort, a key determinant of continuation rates, is expected to extend duration of use, subsequently reducing unintended pregnancy rates.

Unanswered questions and future research

Further analysis will include larger cohorts and longer follow-up of clinical outcomes and user quality-of-life variables.

Conclusion

Overall, the IUB Ballerine MIDI proved simple to insert and was suitable for use in a diverse female population. Participants' high overall satisfaction further supports its acceptance as a safe and effective LARC method. Future longer-term (3–5 years), prospective analyses of larger cohorts will be necessary to further characterise the device's performance over time. Such studies will increase awareness and acceptance of LARC methods in general, and of IUB Ballerine MIDI in particular, further promoting global efforts to reduce unintended pregnancy rates.

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KS serves as vice president of Clinical Affairs at OCON Healthcare. AA is a clinical consultant at OCON Healthcare. MY, MV and CG declare no conflict of interest.

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