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RESEARCH ARTICLE

Real-world experience with the IUB Ballerine MIDI copper IUD: an observational, single-centre study in Israel

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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 in Israel.

Methods: In this retrospective, observational study, conducted in a single clinic in Israel, healthy women ($n = 175$) who had had the device inserted ≥12 months prior to enrolment, and their physician, completed questionnaires relating to device insertion, user experience and performance.

Results: The mean age at insertion was 32.8 ± 6.7 years; most women were married (80.6%) and multigravid (89.1%). At the time of the study, 131 (74.9%) women were still using the device; in 13 cases (7.4%), premature removal was due to desire to conceive. The 12 month continuation rate, excluding the women seeking to conceive, was 90.1%. The expulsion rate was 3.4% ($n = 6$) and the pregnancy rate was 0.57% ($n = 1$). Most of the women still using the device reported no to moderate pain or cramps (90.0%) and moderate to high (72.6%) satisfaction with the device; 76.3% said they would recommend it to friends and relatives. Most of the insertion procedures (86.9%) were uneventful and none required cervical dilation.

Conclusion: The IUB Ballerine MIDI raised no major safety concerns and was both effective and highly accepted in a cohort of women, covering a broad age range, treated in a gynaecology clinic in Israel.

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Introduction

Unintended pregnancies continue to pose a substantial challenge to public health systems, with close to 3 million cases occurring annually in the USA alone [1]. This incidence is generally ascribed to inconsistent and inaccurate use of effective contraception and is disproportionately high among low-income and minority groups [2–4]. Methods of long-acting reversible contraception (LARC), which include implants and intrauterine devices (IUDs), have benefited from increasing awareness and acceptance in recent years, with government programmes and professional committees recommending their use across the childbearing age range [5]. Their effectiveness is wholly user-independent, unlike non-LARC methods, which are highly reliant on user compliance, and they have been proven to be very safe [6]. Moreover, they are associated with low discontinuation rates, even among adolescents and young adults [7], and with superior effectiveness compared with non-LARC methods [8,9].

Despite their clinical virtues, IUDs are associated with irregular vaginal bleeding, cramping and pain [10], driving some women to have the device prematurely removed, ultimately leaving them vulnerable to unintended pregnancy. The underlying causes of these effects remain unknown but have been suggested to be rooted in incompatibility of the conventional T-shaped IUD with the uterine dimensions or in device malpositioning or embedment within the uterine tissue [11,12].

The intrauterine ball IUB Ballerine MIDI (OCON Medical [dba OCON Healthcare], Modiin, Israel) is a spherical copper IUD, designed to overcome uterine dimensional incompatibility, consequently minimising endometrial irritation and enhancing user comfort. In a recent retrospective multicentre clinical study performed in Switzerland, real-world data relating to user experience and the effectiveness and safety of the IUB Ballerine MIDI were collected from a diverse population ($n = 207$) that spanned broad socioeconomic and demographic ranges [13]. There were no reports of cervical damage or uterine perforation, and tolerability proved high, with most women reporting no/light or moderate cramping while using the device and high satisfaction. The present observational, single-centre retrospective study aimed to expand the surveillance dataset to include the Israeli market, which is largely covered by a national health insurance plan and is mostly characterised by high provider and user awareness of modern family planning options [14].

Methods

Study design

In this retrospective, single-arm, observational study, conducted between January and October 2018, 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, were contacted by phone and

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asked to participate in the study. A study staff member met with each participant in her home and presented her with a questionnaire which focussed on her experiences with the device. Participants were recruited by their physician (IB) at a single clinic affiliated with Maccabi Healthcare Services, the second largest health maintenance organisation in Israel, and provided their signed informed consent before completing the questionnaire. Questions related to IUB insertion, removal and expulsion and to pregnancy rates since insertion. Questions relating to current menstrual patterns (3 months preceding completion of the questionnaire), physical comfort and satisfaction with IUB use were only presented to women still using the device at the time of the study. 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 compared with pre-insertion (1 indicating 'much better' and 10 indicating 'much worse'), tolerability of the last three periods (1 indicating 'pleasant', 5 indicating 'acceptable' and 10 indicating 'unbearable') and satisfaction with the device (1 indicating 'very satisfied' and 10 indicating 'very dissatisfied'). In parallel, the physician provided clinical information documented in the woman's medical records relating to her medical history and to the insertion procedure, follow-up and removal. Devices that were even slightly within the cervical internal os on ultrasound follow-up were considered misplaced. The study protocol was approved by Maccabi Healthcare Service's ethical committee.

IUB

The IUB Ballerine MIDI comprises 17 copper beads threaded on a flexible, polymer-coated nickel titanium wire frame, with a double-tailed monofilament removal thread attached to its distal tip. The IUB is provided preloaded into an insertion tube. After introduction into the uterus, the device is deployed via a push-rod, after which the frame forms two circles juxtaposed at a 90° angle, forming a 15 mm diameter sphere (Figure 1).

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 were calculated. Sub-analyses were performed with data collected from women aged 18–24. Women requiring IUB replacement with another device, for any reason, within the 12 month period, were not included in the analyses.

Results

Baseline characteristics of the study population

In total, 201 women had undergone IUB insertion at the participating clinic at least 12 months prior to initiation of the study. Of these, 175 women provided their consent and were deemed eligible to participate in the study. Of

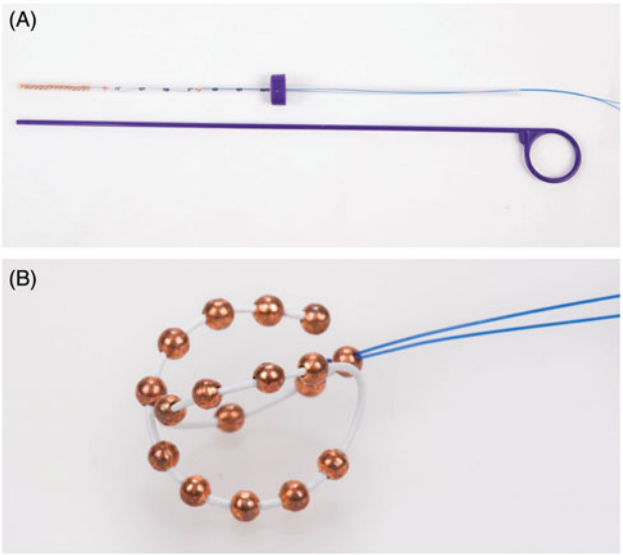

Figure 1. The IUB Ballerine MIDI. (A) The insertion tube with slider/flange, loaded with the device. (B) The device in its final 3D shape, with the 17 copper beads forming two circles juxtaposed at a 90° angle, resulting in an anatomically compliant 15 mm diameter sphere.

the remaining women contacted, 13 were not interested in participating, five were out of the country, three were not reachable, three had communication barriers, one was a cancer patient and one was participating in another study. Mean age at insertion was 32.8 ± 6.7 and duration of use averaged 18.1 ± 5.4 months. Most of the participants were married (80.6%) and multigravid (89.1%); 50.3% had had three or more pregnancies and 85.1% had experienced at least one term delivery. A relatively high percentage of women in the younger age group (18–24) were married (44.4%) and/or multigravid (48.1%); all women over the age of 34 ($n = 79$) were multigravid. The women were in good medical health; medical history records showed dysmenorrhoea as the most common gynaecological condition (18.9%) and depression as the most common medical condition (6.9%). Sociodemographic and baseline characteristics are summarised in Table 1.

IUB insertion and short-term follow-up

In most cases (86.9%), IUB deployment was uneventful (Table 2). Four cases of vagal reflex (2.3%), two cases of severe bleeding (1.1%) and 18 reports of severe pain during the procedure (10.3%) were documented; more than half of the women reporting these effects were nulliparous. Of the 18 incidents of severe pain, seven were reported by women below the age of 25. None of the insertion procedures required cervical dilation. Ultrasound assessments confirmed that all but one of the 175 inserted IUB devices were in place immediately after the procedure, as were 116 of the 118 (98.3%) devices assessed 1–3 months thereafter; the two displaced devices were removed.

Discontinuation rates

At the time of the survey, 131 women (74.9%) were still using the device; their average age was 34.6 ± 7.0 years and most were married (74.0%) and multigravid (86.3%). The average duration of use among current users was 17.3 ± 5.1 months. In total, 38 devices (21.7%) had been

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

Characteristic	Entire cohort (age ≥18) $n = 175$	Younger subset (age 18–24) $n = 27$
Age at insertion, years		
Mean (SD)	32.8 (6.7)	22.9 (1.7)
Minimum, maximum	17.4, 45.6	17.4, 24.9
Age at survey, years		
Mean (SD)	34.4 (6.8)	24.2 (1.8)
Minimum, maximum	18.6, 47.8	18.6, 26.0
Time from insertion, months		
Mean (SD)	18.1 (5.4)	16.0 (4.9)
Minimum, maximum	11.7, 33.4	12.1, 28.8
Marital status, *n* (%)		
Single	15 (8.6)	9 (33.3)
Married	141 (80.6)	12 (44.4)
Divorced	8 (4.6)	–
Other	11 (6.3)	6 (22.2)
Gravidity, *n* (%)		
Multigravid	156 (89.1)	13 (48.1)
Nulligravid	19 (10.9)	14 (51.9)
Number of previous term deliveries, *n* (%)		
1	8 (4.6)	–
2	52 (29.7)	9 (33.3)
3	41 (23.4)	1 (3.7)
4	25 (14.3)	–
5	8 (4.6)	–
6	7 (4.0)	–
7	4 (2.3)	–
8	3 (1.7)	–
9	1 (0.6)	–
Any	149 (85.1)	10 (37.0)
Previous abortion, *n* (%)		
1	45 (25.7)	4 (14.8)
2	22 (12.6)	–
3	5 (2.9)	–
4	1 (0.6)	–
5	1 (0.6)	–
Any	74 (42.3)	4 (14.8)
Most recent abortion[a], *n* (%)		
Spontaneous	46 (26.3)	1 (3.7)
Surgically induced	11 (6.3)	2 (7.4)
Medically induced	22 (12.6)	1 (3.7)

[a]Multiple choice item with more than one possible answer.

Table 2. IUB insertion data and follow-up.

Variable	Entire cohort (age ≥18) $n = 175$	Younger subset (age 18–24) $n = 27$
Difficulty during insertion		
None	152 (86.9)	18 (66.7)
Severe pain	18 (10.3)	7 (25.9)
Vagal reflex	4 (2.3)	3 (11.1)
Severe bleeding	2 (1.1)	–
Other[a]	2 (1.1)	2 (7.4)
Ultrasound immediately after insertion		
Ultrasound performed	175 (100)	27 (100)
In place	174 (99.4)	27 (100)
Displaced	1 (0.6)	–
Ultrasound 1–3 months after insertion		
Ultrasound performed	118 (67.8)	22 (81.5)
In place[b]	116 (98.3)	22 (100)
Displaced[b]	2 (1.7)	–
IUB removed	2 (1.7)	–

Data are presented as *n* (%).
[a]One woman vomited and another suffered from hypotension/vomiting/diarrhoea immediately after the procedure.
[b]Percentages were calculated in relation to the total number of ultrasound scans performed 1–3 months post-insertion (entire cohort, $n = 118$; younger cohort, $n = 22$).

intentionally removed, with removal rates relatively similar across age groups. The average age at the time of insertion of women no longer carrying the device, was 31.6 ± 6.1 years and the request for early removal of the IUB was

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

Variable	Entire cohort (age ≥18) $n = 175$	Younger subset (age 18–24) $n = 27$
Duration of IUB use[a]		
>12 months	146 (83.9)	23 (88.5)
≤12 months	28 (16.1)	3 (11.5)
Reason for removal[b]		
Spontaneous expulsion	6 (3.4)	1 (3.7)
Heavy menstrual bleeding[c]	14 (36.8)	1 (50.0)
Severe cramps[c]	1 (2.6)	–
Desire to conceive[c]	13 (34.2)	–
Pregnancy[c]	1 (2.6)	–
Other[c]	9 (23.7)	1 (50.0)

Data are presented as *n* (%).
[a]Percentages were calculated in relation to the total number of women for whom duration of use was available (entire cohort: $n = 174$; younger subset: $n = 26$); one woman was unaware of the fact that the device had been expelled.
[b]Women were allowed to indicate more than one reason for removal.
[c]Percentages were calculated in relation to the total number of devices intentionally removed (entire cohort: $n = 38$; younger subset: $n = 2$).

after a mean 12.0 ± 5.4 months of use. All the women were married and all but one were multigravid. Six devices (3.4%) were spontaneously expelled, within a mean of 5.6 ± 5.0 months (range 2–14 months) of insertion, all in women with history of pregnancy; five of the devices were expelled in women over the age of 24 (Table 3). Primary reasons for requested removal were heavy menstrual bleeding (36.8%) and desire to conceive (34.2%). The mean duration of use among women still using the device was 17.3 ± 5.1 months. When excluding the women seeking to conceive, the 12 month continuation rate was 90.1%. The return to fertility following removal was rapid: most women who desired to become pregnant conceived within 2 months (12/13; 92.3%). Only one woman (0.57%) became pregnant while using the IUB.

Menstrual patterns and user satisfaction

Women still using the IUB reported light (3.8%) or moderate (56.9%) menstrual flow, typically lasting 5–7 days (Table 4). Women generally reported no to light (71.5%) or moderate (18.5%) menstrual cramps/pain and overall tolerable menstruation (mean score 5.5 ± 2.3). The younger age group (ages 18–24) also reported light or moderate menstrual flow (50%) and no/light (50%) or moderate pain/cramps (20%). User satisfaction was high, with most women (76.3%) reporting that they would recommend the device to friends and family (Table 4).

Discussion

Findings and interpretation

In the current study, which questioned IUB users in Israel with respect to their experiences with the device, most women reported light to moderate periods (61%), with either no/light to moderate cramps or pains (90%). User product acceptability was positive and most women claimed they would recommend the device to friends and family (76%). Moreover, the physician reported a simple and straightforward insertion procedure, which required no cervical manipulation and did not elicit cervical damage, uterine perforation, cervicitis or pelvic inflammatory

Table 4. Menstrual patterns and user satisfaction with the IUB.

Variable	Entire cohort (age ≥18) $n = 131$	Younger subset (age 18–24) $n = 20$
Blood flow[a]		
Light	5 (3.8)	–
Moderate	74 (56.9)	10 (50.0)
Heavy	51 (39.2)	10 (50.0)
Menstrual pain/cramps[a]		
None	52 (40.0)	3 (15.0)
Light	41 (31.5)	7 (35.0)
Moderate	24 (18.5)	4 (20.0)
Severe	9 (6.9)	6 (30.0)
Unbearable	4 (3.1)	–
Tolerability of menstruation[a]		
1–3	24 (18.5)	2 (10.0)
4–5	54 (41.5)	7 (35.0)
6–7	26 (20.0)	7 (35.0)
8–10	26 (20.0)	4 (20.0)
Change in menstrual pattern[b]		
1–3	6 (4.7)	1 (5.0)
4–5	37 (28.7)	5 (25.0)
6–7	42 (32.6)	5 (25.0)
8–10	44 (34.1)	9 (45.0)
Satisfaction[c]		
1–3	72 (55.0)	10 (50.0)
4–5	23 (17.6)	4 (20.0)
6–7	20 (15.3)	4 (20.0)
8–10	16 (12.2)	2 (10.0)
Recommend to friends and family		
Yes	100 (76.3)	15 (75.0)
No	16 (12.2)	2 (10.0)
Prefer not to respond	15 (11.5)	3 (15.0)

Data are presented as *n* (%).

[a]Calculated as percent of women who answered these questions (entire cohort: $n = 130$); one participant was still using the device but was not menstruating because she was breastfeeding.

[b]Calculated as percent of women who answered these questions (entire cohort: $n = 129$); one participant was still using the device but was not menstruating because she was breastfeeding, and one participant did not remember.

[c]Measured on a 10 point Likert scale (ranging from 1 'very satisfied' to 10 'very dissatisfied').

disease. These favourable experiences translated to a high 12 month continuation rate of 90.1%, which is similar to that reported for conventional IUDs (87%) and considerably higher than the continuation rates of non-LARC methods (57%) [9]

Differences and similarities in relation to other studies

Similar participant menstruation patterns and feedback were reported by Swiss IUB users, although the 12 month continuation rate was slightly lower (77.3%), likely influenced by the diversity of clinical settings and user obstetric history [13]. While many surveys worldwide have identified clinician reluctance to provide LARC methods to women seeking contraception, particularly to young, nulliparous and single women [15–18], LARC is highly promoted in Israel, where approximately 30% of contraceptive users choose an IUD [14]. Well-informed users, together with positive provider attitudes and high-quality family planning counselling are likely to have influenced the sustainability of LARC use reported in this study and may explain discrepancies between discontinuation rates reported in other countries.

Spontaneous IUB expulsion (3.4%) occurred in six women, all of whom were multigravid and five of whom were over the age of 24, a trend inconsistent with reports of heightened expulsion risk among young users [19]. Failure was rare, with one woman (0.57%) conceiving while using the device, and aligned with the pregnancy rates reported for other intrauterine contraceptives [20].

Strengths and weaknesses of the study

Because of the study's relatively small sample size, detection of statistically significant differences between subsets of participants was limited. Furthermore, reliance on subjective, retrospective user ratings is a key limiting element in the study design. Additionally, the user population in this study was from a single geographical area, which may not parallel populations in other geographical regions. However, when considering the trends reported in the current survey, which was characterised by a high percentage of women with a history of pregnancy (89.1%) and women over the age of 34 (45%), compared with those reported in a Swiss population surveyed in an earlier study [13] which included a high percentage of women under the age of 35 (72.9%), nulligravid (21.3%) or women fitted immediately after an abortion (14%), the IUB Ballerine raised no major safety concerns and proved effective in a wide age range of contraceptive seekers.

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

Reducing the high incidence of unintended pregnancies, which account for nearly half of all pregnancies in the USA [21], has been a chief focus of family planning and sexual health programmes and policies worldwide. In light of the central impact of incorrect or inconsistent contraceptive use on these statistics, alongside the trends showing longer durations of time between first intercourse and first birth, LARC methods are being increasingly promoted by health care providers and have been classified by the American Congress of Obstetricians and Gynaecologists as preferred first-line methods [5]. Yet these shifting trends are not always translated into matching practice patterns, often resulting from misconceptions and inadequate provider training [16]. Current efforts are focussing on raising global accessibility to LARC methods and uptake by young women, as well as on addressing the determinants leading to early discontinuation. Intensified menstrual flow and cramps/pain have been repeatedly reported to be a key trigger for premature IUD removal and are often thought to be the result of incompatibility between the conventional T shape of IUDs and the anatomy of the uterus, an aspect addressed by the unique spherical shape of the IUB. The results of this report of 1 year real-world experience with the IUB Ballerine MIDI corroborate earlier IUB user experience reports [13,22]. Apart from pregnancy and discontinuation rates that fell within the range reported for other copper IUDs, user feedback suggested that the device was well tolerated by women of all age groups, likely because of its improved uterine conformity. This, in turn, is expected to expand its acceptance by clinicians and potential users alike, and extend its duration of use, subsequently reducing unintended pregnancy rates.

Unanswered questions and future research

Further analysis will include larger cohorts and longer follow-up of efficacy and user quality-of-life variables, to assess the durability of the benefits provided by the IUB Ballerine MIDI.

Conclusion

Overall, the IUB Ballerine MIDI proved simple to deploy, raised no significant safety issues and was both effective and highly accepted by users. The high user-reported tolerability, likely due to improved conformity of the device shape with the uterine anatomy, is expected to extend the duration of use, compared with other LARC methods, subsequently reducing unintended pregnancy rates. Future longer-term (3–5 years), prospective analyses of larger cohorts will be necessary to further characterise the device's performance and to expand its acceptance, with the long-term goal of promoting global efforts to reduce unintended pregnancy rates.

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Disclosure statement

IB is the founder of OCON Healthcare, inventor of the IUB and current chief medical officer at OCON Healthcare. KS serves as vice president of clinical affairs at OCON Healthcare. RK is a senior clinical project manager and AA a clinical consultant at OCON Healthcare.

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