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Discontinuation rates and acceptability during one year of using the Intrauterine Ball (the SCu380A)

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Abstract

Objective—To characterize method-related discontinuation rates and acceptability over one year of SCu380A use

Study Design—Women enrolled into this prospective pilot study underwent SCu380A placement by a single clinician with follow-up at 6–8 weeks, 3, 6 9 and 12 months. Outcome measures included reasons for discontinuation and satisfaction.

Results—Fifty-one women had a 12 mm diameter intrauterine ball (IUB, SCu380A) inserted by a single clinician(EW). Post insertion ultrasonography showed all the devices to be correctly placed. By 8 weeks, there were 9 expulsions and two removals for symptoms. By 12 months there were 14 expulsions (27%), 8 removals for symptoms (16%), one pregnancy and 7 lost to follow-up. Of the remaining 21 women, 15 said they were satisfied.

Conclusion—The high rate of expulsions and removals for symptoms in the first year indicate that this device, as presently designed, is unacceptable as an alternative to the currently available copper IUDs.

Implications—More research is needed before we know if it is the spherical design, the size of the device or some other factor which led to the high expulsion rate. There are currently three different IUBs (12, 15 and 18 mm) approved and being investigated.

1 Introduction

Complications of intrauterine devices (IUDs) include perforation (1:1000), infection (1:100) and expulsion (1:20). [1] Expulsions are more common in the first month after insertion, and more common with copper than levonorgestrel IUDs; there is no difference with age or parity [2] Discontinuation rates are higher in women <20 years of age and most

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Competing Interests

None declared

discontinuations are for pain and bleeding.[2] Copper IUDs may also cause menorrhagia, discomfort and pain. [3] These side effects may be due to both the copper and to distortion of the uterus by the semi-rigid polymeric frame. Side effects lead to a discontinuation rate of about 15–20% in the first year. [1,2]The intrauterine ball (IUB) was designed to prevent some of these complications and side effects. [4][Figure 1] It is 1.2 cm in diameter and made of a shape memory alloy. When inserted into the uterus, the IUB takes a spherical shape. An important feature includes its downwards curving away from the uterine fundus as it emerges out of the tube, minimizing the risk of perforation. The three dimensional shape's elasticity allows it to conform to the uterus, a feature that may reduce expulsion, distortion and tissue irritation, possibly resulting in less bleeding, discomfort and pain, leading to lower discontinuation rates. The version of IUB reported in this study is the SCu380A. The purpose of this pilot study was to ensure that method-related discontinuation rates were acceptable in order to plan a larger trial with the SCu380A.

2. Materials and Methods

This was an observational pilot case series. We enrolled women aged 18–50 years requesting non-hormonal intrauterine contraception. Exclusions included recent pelvic inflammatory disease, genital malignancy, current pregnancy and anemia. One clinician (EW) inserted all the devices and performed a post insertion ultrasound to confirm correct placement. Women returned to the clinic for the first follow-up visit with an ultrasound 6–8 weeks later. We used a combination of phone calls and emails for follow-up at 3 months, 6 months and 9 months and did an in-clinic visit with ultrasound at 12 months. The main outcome measure was discontinuation for method-related reasons at each of the follow-up points during the first year. The secondary outcome measure was satisfaction. Data were entered into SPSS (V22) and descriptive statistics were prepared. The manufacturer, Ocon Medical Ltd, Israel, supplied the SCu380A devices but no funding. Approval was granted for this study from the University of British Columbia Clinical Research Ethics Board (H13-02707) and it was registered at clinicaltrials.gov (NCT01973777).

3. Results

Fifty-one women had an SCu380A inserted between January and May 2014 by a single clinician. Their mean age was 27 (range 18–39) years; 45 (88%) had no previous vaginal births and 16 (31%) had had previous IUDs (Table 1). Post-insertion ultrasounds showed all the devices to be correctly placed. By 8 weeks post insertion, there were 9 expulsions and two removals for symptoms of pain and bleeding. [Table 1] By 3 months, there had been 10 expulsions and three removals; by six months, 14 expulsions and five removals; by 9 months 14 expulsions and 8 removals (one woman was pregnant and the IUB was low); and by 12 months 14 expulsions and 9 removals (one woman wanted to conceive). The expulsions were confirmed by clinical and ultrasound examination and defined as partial if the device was in the cervix and complete if it was out of the uterus completely. Of the women who retained the devices, 21/35 (60%) said they were satisfied at 3 months, 16/26 (62%) at 6 months, 13/22 (59%) at 9 months, and 15/21 (71%) at 12 months. This means that 15/51 (29.4%) of all the women who had IUBs inserted retained and said they were satisfied at 12

months. The women who retained the devices and said they were not satisfied complained of bleeding, spotting and pain.

4. Discussion

CuT380 IUDs are common throughout the world and are the standard used for most comparisons [2]. It is important to continue to search for a better design which would cause less bleeding and pain than the CuT380. The high rate of expulsions (14/51, 27%) and removals for symptoms (8/51, 16%) in the first year and the low rate of satisfaction of known retained devices (15/21, 71%) would indicate that the design of this intrauterine device is not acceptable. We had a high number of seven women (14%) lost to follow-up. If all these women retained and were satisfied with the device, the satisfaction rate would be 22/51 (43.1%). The actual retained and satisfied rate may be even lower. Based on these results the design was modified and currently there are 12, 15 and 18 mm IUBs approved and under investigation.

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Figure 1.
Intrauterine Ball (SCu380A).

Table 1

Characteristics of women who had an SCu380A inserted (N=51)

Mean age (years)	27.7 ± 5.4 range 18–39
Mean worst period pain (0–10)	6.4 ± 2.5 range 1–10
No previous vaginal birth(s)	45/51 (88.2%)
Uterine sounding length (cm)	7.4±0.5 range 6–8
Previous IUD(s)	Copper 10 (19.6%) LNG 4 (7.8%) Both copper and LNG 2 (3.9%)

Table 2

Experience with SCu380A in the first year (N=51)

	6–8 weeks	3 months	6 months	9 months	1 year	Total
Complete expulsions	4	1	2	0	0	7/51 (14%)
Partial expulsions	5	0	2	0	0	7/51 (14%)
Removal for pregnancy	0	0	0	1	0	1/51 (2%)
Removals for symptoms	2	1	2	3	0	8/51 (16%)
Lost to follow up	2	1	3	0	1	7/51 (14%)
Retained IUB (known)	38	35	26	22	21	21/44 (48%)
Retained and satisfied with IUB	n/a	21	16	15	15	15/21 (71%)