Higher discontinuation rate with a standard-sized compared to a small-sized 'gold standard' copper intrauterine device: a case-control review

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ABSTRACT

Background T-shaped intrauterine devices (IUDs) with a copper surface area of 380 mm^2 and copper bands on the transverse arms are the most effective types of copper-containing IUDs. A small-sized 'gold standard' IUD is available but there has been little research to compare the effects of this small-sized IUD to its standard-sized counterpart.

Aim To determine discontinuation rates and reasons for discontinuation at 1 year of the small-sized Mini TT380 Slimline IUD compared with the standard-sized TT380 Slimline.

Methods The clinical records of women fitted with Mini TT380 Slimline ('mini') IUDs were compared with those of women fitted with standard-sized TT380 Slimline ('standard') IUDs over a 3-year period (2013–2016).

Results Clinical records were available for 67 women fitted with a mini IUD (mean age 23 years, 64% nulliparous) and 63 women fitted with a standard IUD (mean age 25 years, 39% nulliparous). At 1 year, twice as many standard IUD users (32%, n=20) had discontinued their IUD use compared with mini IUD users (15%, n=10). Complaints of pain and bleeding were more than double (70%, n=14) in those women who discontinued standard IUD use compared with those who discontinued using the mini IUD (30%, n=3). These differences were statistically significant and were unrelated to parity.

Conclusions More women using a standard-sized 'gold standard' IUD rather than its smaller counterpart complained of pain and bleeding, leading to higher discontinuation at 1 year. More research on the association between size and discontinuation of these IUDs is needed.

Key messages

- A review of 130 clinical records showed that at 1 year twice as many women had discontinued using a standard-sized 'gold standard' intrauterine device (IUD) compared with its smaller counterpart.
- There were also more reports of pain and bleeding in standard-sized IUD users irrespective of age, uterine sounding length and parity.
- More research comparing these standard-sized IUDs with their smaller counterparts is needed.

BACKGROUND

The copper-containing intrauterine contraceptive device (IUD) is the most cost-effective long-acting reversible contraceptive (LARC) method. It is also the most effective emergency contraceptive and a popular choice for women wishing to avoid hormones.[1 2] Over 50 000 IUD insertions are estimated to take place each year in England.[3] However, the IUD's cost effectiveness is hindered by high method discontinuation.[1]

The most common reasons for IUD discontinuation are pain and bleeding, irrespective of parity.[4 5] On average, 30% of women have their IUDs removed in the first few months following insertion, with teenagers and young nulliparous women more likely to discontinue.[6–9] Many women repeatedly attend health services with complaints of pain and bleeding, requiring examination and investigations prior to IUD removal. This discourages women from using the IUD.[10]

Those IUDs containing at least 380 mm^2 of copper and with banded copper on the IUD's arms are the most efficacious

types of IUDs and are referred to as 'gold standard' IUDs.[11] The Faculty of Sexual & Reproductive Healthcare (FSRH) recommends gold standard IUDs with the longest duration of use to reduce the risk of complications associated with insertion.[12]Standard-sized IUDs measuring 32 mm in arm width and ≥33 mm in stem length are licensed for 10 years and are the most popular gold standard IUDs. The standard-sized TT380 Slimline is the the most common gold standard IUD used in our service. Its less frequently used smaller counterpart is the Mini TT380 Slimline, measuring 23.2 mm in width and 29.5 mm in height and has a 5-year licence. There is a paucity of research on the effects of IUD size on pain, bleeding and discontinuation.

This study compares user experiences and discontinuation rates in the first year following insertion of these two differently sized gold standard IUDs.

METHODS

A retrospective review was undertaken of the clinical records of women newly fitted with a Mini TT380 Slimline ('mini') and similarly-aged women newly fitted with a standard-sized TT380 Slimline ('standard') IUD in our service over a 3-year period, from 1 October 2013 to 30 September 2016. In this period, a total of 1743 IUD insertions were recorded to have taken place in the service, of which 1284 were Nova-T380, 333 were standard-sized TT380 Slimline and 84 were Mini TT380 Slimline IUDs. Other IUDs inserted by the service at the time were T-Safe 380A, T-Safe 380A QL, Flexi-T 300, Multiload Cu375 and GyneFix 330.

All retrievable clinical records of women who had had a mini IUD inserted in the 3-year study period were included. These clinical records were then randomly 1:1 matched based on age, or age group (15–19, 20–24, 25–29, 30–34, 35 years and over) if a same-age direct comparator was not available, with retrievable clinical records of women who had had a standard IUD inserted in the same year.

Users' experiences in the first year following IUD insertion including adverse events at the time of insertion and number of service attendances were obtained. Adverse and unwanted effects such as lower abdominal pain, dyspareunia, intermenstrual bleeding, postcoital bleeding, worse dysmenorrhea, heavier menstrual bleeding, expulsion and pregnancy were noted. Relevant clinical findings, results of investigations and IUD removals were also documented.

Women having an IUD replaced were excluded from this review. However, past IUD users having a new IUD inserted were included. Women who had the IUD inserted for emergency contraception were also excluded, except where it was documented that the woman intended to retain the IUD for future contraception. Complete expulsion was defined as when the IUD was no longer in the uterus or cervix and partial when the IUD was found in the cervical canal.

Data analysis

All information including user demographics, attendances, adverse effects and IUD removal was collected from paper clinical records onto an Excel spreadsheet. Data obtained for users of the mini IUD was compared with that of standard IUD users.

All expulsion cases were recorded as 'no IUD at 1 year' and included in the analysis. Descriptive analysis of demographic characteristics and the variables associated with attendances, adverse effects and expulsion are presented as either mean (SD) for the continuous variables or median (IQR) for discreet or score variables. Characteristics of the two IUD groups were compared using Student's t-test, Mann–Whitney U test, Pearson's Chi-square test or Fisher's exact test as appropriate. A p value <0.05 was considered to be statistically significant. In addition, descriptive analysis of experiences of women who had discontinued IUD use at 1 year is presented. Analysis of data presented is for all available cases.

Ethics

This research was categorised as a service evaluation by the National Health Service (NHS) Health Research Authority and therefore exempt from Research Ethics Committee review. Local NHS Research and Development as well as Caldicott approvals were obtained from the Newcastle Joint Research Office, Newcastle on Tyne Hospitals NHS Foundation Trust.

Patient and public involvement

Patients (IUD users) and staff of our sexual health service were asked about how to increase the use of IUDs. Their suggestions included studying women's experiences with the IUD. Their responses influenced the research question, aims and design of this study.

RESULTS

Eighty-four mini IUD insertions were documented during the 3-year period, however the clinical records of only 67 of these were retrievable for the review. The clinical records of 63 standard IUD users were obtained for comparison with those of the 67 mini IUD users. A total of 130 IUD users' clinical records were therefore reviewed and the findings are depicted in table 1.

The age range of standard IUD users was 15 to 37 years while that of mini IUD users was 16 to 37 years. Pregnancy history was missing from the clinical record of one standard IUD user. There was a tendency for standard IUD users to be older and parous compared with mini IUD users. Uterine sounding length was not documented in the clinical records of two standard IUD users.

Four adverse events warranting additional care were reported at the time of IUD insertion, two in each IUD user group. In the standard user group, one woman had bradycardia and another had severe nausea. Both women had never been pregnant, were aged 27 and

Table 1 Summary of intrauterine device users' characteristics and experiences at 1 year

Characteristic	Total (N=130)	Standard IUD (N=63)	Mini IUD (N=67)	P value
Mean age (years) (SD)	24.8 (5.04)	25.9 (4.63)	23.9 (5.23)	0.021*
Uterine sounding length at insertion (cm)†				
Range	5.5–9.5	6–9	5.5–9.5	
Mean sounding length	7.6†	7.6†	7.5	
Sounding length median (IQR)	8 (7,8)†	8(7,8)†	7.5 (7,8)	0.636‡
	n (%)	n (%)	n (%)	
Pregnancy history§				
Never pregnant	67 (52)§	24 (39)§	43 (64)	0.004¶
Previously pregnant	62 (48)§	38 (61)§	24 (36)	
Parity§				
Nulliparous	80 (62)§	27 (44)§	53 (79)	<0.0001¶
Parous	49 (38)§	35 (56)§	14 (21)	
Attendances in first year following insertion				
Users who did not attend in first year	90 (69)	39 (62)	51 (76)	0.079¶
Users who attended in first year	40 (31)	24 (38)	16 (24)	
Users with no investigations required	103 (79)	49 (78)	54 (81)	0.692¶
Users for whom investigations were required	27 (21)	14 (22)	13 (19)	
Discontinuation at 1 year				
No record of IUD discontinuation	100 (77)	43 (68)	57 (85)	0.023¶
Record of IUD discontinuation	30 (23)	20 (32)	10 (15)	
IUD discontinuation at 1 year	**Total (N=30)**	**Standard IUD (N=20)**	**Mini IUD (N=10)**	**P value**
	n (%)	n (%)	n (%)	
IUD discontinuation based on parity				
IUD discontinuation in nulliparous users	16 (53)	9 (45)	7 (70)	0.260**
IUD discontinuation in parous users	14 (47)	11 (55)	3 (30)	
IUD discontinuation based on pain and/or bleeding				
Discontinuation for pain and/or bleeding	17 (57)	14 (70)	3 (30)	0.056**
Discontinuation unrelated to pain and/or bleeding	13 (43)	6 (30)	7 (70)	

*Student's T-test mean comparison
†Uterine sounding length not stated in the clinical records of 2 standard IUD users
‡Mann-Whitney U test
§Parity not stated in 1 clinical record of a standard size IUD user
¶Pearson's Chi-square test
**Fisher's exact test
IUD, intrauterine device.

31 years and had uterine sounding lengths of 7.5 and 8 cm, respectively. In the mini IUD insertion group, dizziness was experienced by two women. Both women had never been pregnant, were aged 17 and 19 years and had uterine sounding lengths of 6.5 and 7 cm, respectively.

Fifty-seven investigations were requested during the first year of IUD use, 25 for standard IUD users and 32 for mini IUD users. Thirty-three women had attended with complaints of pain and bleeding in their first year, 22 of whom were standard IUD users while 11 were mini IUD users.

Of the 130 clinical records reviewed, there was no significant difference in IUD discontinuation at 1 year based on parity (p=0.260). Further analyses based on pregnancy history and parity showed that IUD users who had never been pregnant (n=67) and those IUD users with previous pregnancies but no births (n=13) had similar uterine sounding lengths (ranges of 5.5–9.5 and 6–9 cm and means of 7.7 and 7.4 cm, respectively) to parous IUD users (n=48, range of 6–9 cm and mean of 7.8 cm) in the study sample. There were no statistically significant differences observed between these three IUD user groups related to attendances, investigations requested or discontinuation at 1 year (p values of 0.699, 0.697 and 0.510, respectively).

However, standard IUD discontinuation (n=20) was twice that of mini IUD discontinuation (n=10)

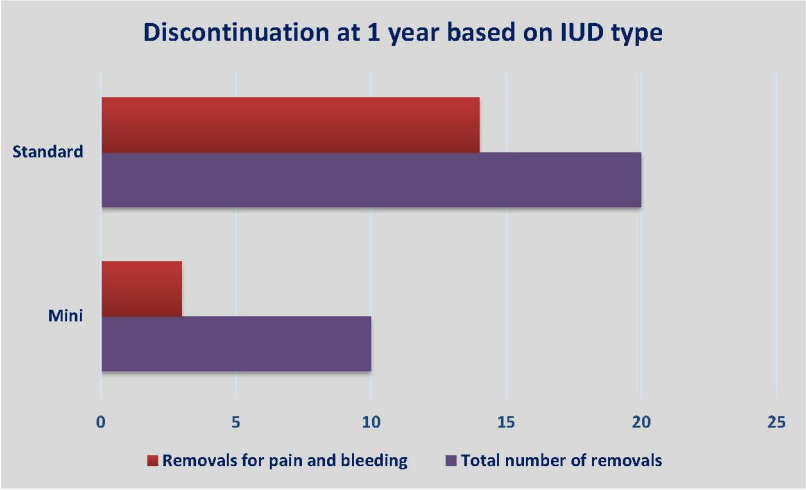

Figure 1 Main reason for intrauterine device (IUD) discontinuation at 1 year based on IUD type

in the sample. Standard IUD discontinuation specified to have been for complaints of pain and bleeding (70%, n=14) was more than twice that of mini IUD discontinuation for the same symptoms (30%, n=3) (figure 1). Expulsions were also double in the standard IUD users group (n=4) compared with the mini IUD users group (n=2). All parous IUD users (n=3) who had experienced expulsions had had a standard IUD. The experiences of those IUD users who had discontinued at 1 year are summarised in table 2. A pregnancy was reported in a 30-year-old parous standard IUD user 4 months after IUD insertion. The IUD had been inserted 8 months after the woman's third vaginal delivery. There had been no issues with the IUD prior to pregnancy detection.

DISCUSSION

Our results show a striking difference in discontinuation rates, particularly for pain and bleeding, between the two gold standard IUDs. Twice as many standard IUD users discontinued compared with mini IUD users at 1 year. Complaints of pain and bleeding were more likely to be reported in those requesting removal of the standard IUD compared with those discontinuing mini IUD use. These differences were statistically significant and unrelated to parity. Attendances in the first year for IUD-related problems were also higher in standard IUD users than in mini IUD users. There was no significant difference between the standard IUD and mini IUD user groups based on age and uterine sounding length.

There is little available evidence of any benefit in the use of smaller IUDs. Differences in IUD performance based on IUD size in a randomised controlled trial (RCT) reported by Petersen *et al* were not statistically significant.[13] They compared standard and shorter versions of the non-gold standard Multiload 250 and Gravigard Cu-7 IUDs. Another RCT involving only nulliparous IUD users reported significantly higher rates of pain, bleeding and IUD discontinuation at 1 year in the group of standard-sized TCu380A IUD users compared with the smaller and shorter-stemmed TCu380Nul and Multiload 375.[8] However the findings of that RCT were heavily criticised as being inaccurate.[14] Available evidence on current commonly used framed and frameless IUDs is that they all have similar effects of pain, bleeding and discontinuation.[15 16]

The small sample size from a single service, the short follow-up period, and the tendency for standard IUD users to be older and of higher parity than their mini IUD-using counterparts may be limitations of this retrospective comparison and limit the applicability of its findings to other settings.

A combination of the service's electronic records (Sexual and Reproductive Health Activity Dataset - SRHAD) and paper clinical records was used to identify all eligible cases for inclusion in this study. There is the possibility that some eligible cases may have been missed due to coding errors, although this is minimised by the additional input of the service's system administrators, or because some IUD users attended other services with their complaints or requests for IUD removal.

The Mini TT380 Slimline is the only small gold standard IUD available in the UK. Its price and copper content are the same as for the standard-sized TT380 Slimline, but it has a 5-year licence instead of the 10-year licence of the standard-sized TT380 Slimline.[17] The authors have reviewed the published literature and have been unable to find any information to justify the Mini TT380 Slimline's shorter 5-year licence.

More research on the different types and sizes of IUDs is needed to enable provision of the right IUD to the right patient. This could improve user experience, method cost-effectiveness and reduce the adverse effects and discontinuation rates of IUDs. This research should focus on gold standard IUDs and include those

Table 2 Summary of experiences of women who discontinued intrauterine device use at 1 year

Standard IUD users				Mini IUD users			
Issues reported	**Atts**	**Investigations**	**Reason for discontinuation**	**Issues reported**	**Atts**	**Investigations**	**Reason for discontinuation**
HMB, prolonged periods	1	PT, CT/GC, TVS	Prolonged periods, IMB	–	0	–	Acne
–	1	–	HMB, longer periods	HMB, pain	3	PT, urinalysis, CT/GC	HMB, pain
Dyspareunia, LAP, discharge	1	Microscopy, CT/GC	Pain	–	0	–	IMB, dyspareunia
Prolonged bleeding	1	PT, CT/GC	Prolonged bleeding	–	0	–	Patient's choice, not required
Expelled IUD	0	–	Expulsion	–	0	–	Discharge, recurrent BV
HMB, painful periods	0	–	HMB, painful periods	Threads not felt	2	PT	To conceive
Pain	1	CT/GC	Pain	HMB, pain	2	PT, CT/GC	HMB, pain, partial expulsion
HMB	1	–	HMB	–	0	–	To conceive
HMB, pain	1	PT, CT/GC	HMB, partial expulsion	–	0	–	To conceive
HMB, longer periods	1	–	HMB, longer periods	–	0	–	Expulsion
–	0	–	Not stated				
Pain	1	PT, CT/GC	Pain				
HMB, PCB	1	CT/GC	HMB, PCB				
Pain	1	–	HMB				
Pain	1	–	Partial expulsion				
Pain, prolonged bleeding	1	–	Pain, prolonged bleeding				
–	1	–	Pregnancy. TOP referral				
PID, HMB, pain	1	CT/GC	Pain, prolonged bleeding				
HMB, prolonged bleeding	0	–	Prolonged bleeding				
Expulsion	1	TVS	Expulsion				

Atts, number of additional attendances prior to IUD discontinuation; BV, bacterial vaginosis; CT/GC, vaginal swab for chlamydia and gonorrhoea testing; HMB, heavy menstrual bleeding; IMB, intermenstrual bleeding; IUD, intrauterine device ; LAP, lower abdominal pain; PCB, postcoital bleeding; PID, pelvic inflammatory disease; PT, pregnancy test; TOP, termination of pregnancy; TVS, transvaginal ultrasound scan.

user groups currently known to have higher IUD discontinuation rates, for example, teenagers and nulliparous women.

Further research is required to confirm our study findings. We suggest an RCT to determine the effect of gold standard IUD size on discontinuation rates, as well as larger cohort and multicentre studies on gold standard IUDs of different sizes.

CONCLUSIONS

This retrospective review of two gold standard IUDs suggests that irrespective of parity, a higher proportion of women using a standard-sized IUD rather than a small-sized IUD complain of pain and bleeding and experience expulsion, leading to a greater risk of discontinuation by 1 year after insertion. We suggest the need for further studies looking at the association between gold standard IUD size and user discontinuation, especially for pain and bleeding.

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Contributors HA undertook the planning of the study (including patient and public involvement and obtaining approvals), data collection and initial data analysis, literature searches, writing and revision of the manuscript. PB was involved in initial data analysis, literature searches and writing and revision of the manuscript. NB performed data analysis, and writing and revision of the manuscript. DM was involved in the planning of the study (including obtaining approvals), and writing and revising the manuscript.

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