Awaga *et al.*
Middle East Fertility Society Journal (2024) 29:32
https://doi.org/10.1186/s43043-024-00192-8

Middle East Fertility Society Journal

RESEARCH

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Clinical outcomes of post-placental insertion of Copper T380A and Multiload 375 contraceptive devices during cesarean section: a randomized clinical trial

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Abstract

Background To compare two types of intrauterine devices, namely Cu T380A IUD and Multiload 375 IUD, inserted immediately post-placental during cesarean section, with regard to expulsion rates and side effects.

Methods A randomized comparative clinical trial was carried out over 200 patients with 100 patients in each group. Transabdominal ultrasonography (US) was done on all patients before discharge to ensure the adequate position of the IUD in addition to casco speculum examination to assess the IUD threads, and then women were requested to attend a follow-up appointment at 6 weeks after delivery; gynecological examinations in addition to transvaginal sonography were done to measure the top-fundal distance that reflects the position of the IUD. The participants were instructed to report the pattern of bleeding during the puerperium, fever, or vaginal discharge.

Results The ultrasonographic assessment of IUD position before patient discharge (1st assessment) revealed that 18% of Cu T380A IUD users were displaced in comparison to 24% of Multiload 375 IUD, and such difference between both groups was not statistically significant ($P = 0.3$); furthermore, the ultrasonographic assessment of IUD position after 6 weeks (2nd assessment) revealed that 19% of Cu T380A IUD users were displaced in comparison to 30% of Multiload 375 IUD, and such difference between both groups was statistically significant ($P = 0.047$). In addition, none of the included patients in both groups suffered from fever after IUD insertion.

Conclusion The present study demonstrated that post-placental insertion of Multiload 375 IUCD results in significantly higher displacement compared to post-placental insertion of Cu T380A IUCD, as well as significantly more bleeding problems with Cu T380A IUCD as compared with Multiload 375 IUCD.

Trial registration The study was registered prospectively on clinical trial.gov with trial registeration number NCT05624411 (Registered 22-October-2022, https://clinicaltrials.gov/study/NCT05624411).

Keywords Cesarean section, Intrauterine contraceptive device, Cu T380A IUD and Multiload 375 IUD

Background

Contraception is defined as the intentional prevention of conception through the use of various devices, sexual practices, chemicals, drugs, or surgical procedures [1]

One of the best, most practical, and least expensive forms of contraception is the intrauterine device (IUD), and it has been endorsed as a first-line contraceptive

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choice by the American College of Obstetricians and Gynecologists [2, 3].

However, the use of IUD has been related to a number of issues, including irregular uterine bleeding, mal-positioning, pelvic discomfort, and unexpected pregnancy. Immediate postpartum IUD insertion, done within 10 min after placenta delivery, is one of the most secure, dependable, and practical methods for preventing future undesired pregnancies giving extremely effective contraception to new mothers shortly after birth has more positive effects than negative ones [4].

There are two main types of Cu-containing intrauterine contraceptive devices (IUCDS): the most common kind is Cu T380A IUCD, and another form, known as Multiload Cu 375 was also created to reduce expulsion. It is a horseshoe-shaped device with serrated fins and lateral flexible plastic end [5]. Data from the literature revealed that intrapartum IUD insertion was deemed to be equally safe to interval insertion except for the increased risk of expulsion especially when the insertion was performed after vaginal delivery [6, 7]. A previously well-designed study revealed that the lowest frequency of displacement was reported with Multiload 375; however, Cu T380A was associated with the worst bleeding pattern and the highest discontinuation rate [8].

Furthermore, there are various restrictions with post-placental IUD (PPIUCD) insertion such as the increased chance of expulsion of around 8–11%. Therefore, additional training of healthcare professionals is needed, and women must be followed up [9–11].

A wider range of contraceptive options will be available to postpartum women if the clinical outcome of postpartum IUD insertion is known. This should be a useful addition that will allow women to select their suitable postpartum contraceptive method [5].

Because of the currently available, very little information on the clinical results of PPIUCD implantation, the present study was conducted to compare two types of intrauterine devices, namely Cu T380A IUD and Multiload 375 IUD, inserted immediately post-placental during cesarean section, with regard to expulsion rates, side effects, and complications.

Materials and methods

Study population and eligibility criteria

The current study is a clinical trial that included 200 patients, 18–45 years in age, and presented to the emergency unit of the Department of Obstetrics and Gynecology at Sohag University Hospital (Egyptian tertiary referral hospital) who were requesting immediate postpartum contraception between November 2022 and September 2023. Furthermore, all patients with chorioamnionitis, postpartum hemorrhage, uterine anomalies (distorted uterine cavity), multiple pregnancy, macrosomia, polyhydramnios, history of previous IUD expulsion, history of previous ectopic pregnancy, anemic patients with hemoglobin less than 10 g/dl, pre-labor rupture of membranes for more than 18 h, and patients suffering from placenta previa were excluded.

Ethical considerations

The current study was approved by the ethical committee of the Faculty of Medicine, Sohag University, and all included patients signed an informed consent. The study was registered with clinicaltrials.gov (number NCT05624411).

The attending physician had explained the nature of the study, and all included patients were asked to sign an informed consent.

Randomization process

Randomization was done using the IBM SPSS program version 26. A list of 200 was entered into the program then an exact random sample of 100 was ordered, and then we obtained two groups each containing 100 patients. The randomization list was ready before patients' recruitment, and patients were assigned to either group one or two according to their date of admission to the emergency unit. One hundred patients were assigned to each group. In the first group, 100 Cu T380A (Pregna International Ltd) had been inserted, while in the second group, 100 Multiload 375 (Pregna International Ltd) had been inserted. Furthermore, the study was an open-label trial, in which researchers and participants were not masked to the type of IUCD inserted.

As regards the technique of CS, the procedure was performed in all cases according to the international recommendations of the National Institute of Clinical Excellence (NICE) guidelines [12] that were adopted by our department. Sohag University Hospital is a tertiary care unit, and the structure of the emergency team is well constructed for many years including residents, assistant lecturers, lecturers, and supervisors, and all steps starting from patients' assessment to surgical interventions are done by all team members with strict supervision. Before patients' recruitment, a training course was given to all residents and assistant lecturers in our department including the recent changes in the technique of cesarean section and the technique of intrapartum IUD insertion. IUCDs were inserted high at the fundus through the lower uterine segment incision immediately after delivery of the placenta using the cylinder provided within the sterile packaging; the IUCD pushing rod was not used. Before placement in the uterine cavity, both IUCD strings were lengthened using 10 cm of Vicryl sutures (polyglactin 910) number 0 which was then threaded through the

cylinder to appear at the other end. Following insertion adjacent to the fundus, the cylinder was gradually moved downwards across the threads, passed through the cervix, and then removed vaginally after delivery; this technique ensures that the threads are located within the vagina immediately after the operation and prevents their entanglement within the cervical canal or uterine cavity. The uterine incision will then be closed in two layers.

Transabdominal US was done to all patients before discharge to ensure adequate position of the IUD in addition to casco speculum examination to assess the IUD threads, and then women were requested to attend follow-up appointment at 6 weeks after delivery; gynecological examinations in addition to transvaginal sonography were done to measure the top-fundal distance that reflects the position of the IUD. The participants were instructed to report the pattern of bleeding during the puerperium, fever, or vaginal discharge. They were shown how to find the threads and informed to urgently seek medical care if they could not feel the threads. During the follow-up visit (after 6 weeks), the Vicryl suture knot appeared below the cervix; the threads were shortened to a length of 2 cm from the cervix. Transabdominal and transvaginal two-dimensional (2D) ultrasonography were used to evaluate the IUCD position. Complete expulsion was recorded when the longitudinal arm of the IUCD was partially or totally inside the cervix or vagina. Partial expulsion or displacement was recorded when the IUCD was more than 10 mm away from the fundus but still totally within the uterine cavity [13]. Women with severe pelvic inflammatory disease (PID) who did not respond to treatment and/or had severe vaginal bleeding were candidates for IUCD discontinuation and were prescribed another contraception method if required.

Statistical analysis

The primary outcome in the current study was the expulsion rate of Multiload IUCD versus Copper T380A after post-placental insertion. The secondary outcomes were the visibility of strings, pattern of bleeding, fever, and vaginal discharge. Data was analyzed using STATA version 17.0 (Stata Statistical Software: Release 17.0 College Station, TX: StataCorp LP.). Quantitative data was represented as mean, standard deviation, median, and range. Data was analyzed using Student's *t*-test to compare the means of two groups. When the data was not normally distributed, the Mann-Whitney test was used. Qualitative data was presented as number and percentage and compared using either the chi-square test or Fisher's exact test. Graphs were produced by using Excel or STATA program. *P* value was considered significant if it was less than 0.05.

Table 1 Baseline characteristics of included patients in both groups

Variable	Cu T380A IUD user *N* = 100	Multiload 375 IUD user *N* = 100	*P* value
Age/year			
Mean ± SD	30.67 ± 5.65	31.73 ± 6.45	0.21
Median (range)	32 (19:45)	32 (20:43)	NS
Age group			
≤ 20	4 (4.00%)	4 (4.00%)	0.60
> 20:26	26 (26.00%)	20 (20.00%)	NS
> 26	70 (70.00%)	76 (76.00%)	
Parity			
Mean ± SD	1.99 ± 1.51	2.31 ± 1.41	0.14
Median (range)	2 (0:6)	2 (0:5)	NS.
Gestational age			
Mean ± SD	36.14 ± 3.90	36.54 ± 3.68	0.46
Median (range)	37 (15:40)	37.64 (18:40)	NS
Number of previous deliveries (CS)			
Mean ± SD	2.19 ± 1.29	2.24 ± 1.33	0.71
Median (range)	2 (0:5)	2 (0:5)	NS

Sample size estimation

The sample size was calculated on the basis of a previously reported randomized clinical trial that showed expulsion rates with different IUCDs (9–15% with Cu T380A and Multiload 375) [14]. A total of 180 participants were needed to statistically demonstrate this difference with 80% power and a type I error rate of 5%. To compensate for a 10% dropout rate, a sample size of 200 was planned with 100 patients in each group.

Sample size calculation was performed through a web site "Sealed envelope" ,"Power (sample size) calculators", the study is a non-inferiority trial with a significance level of (5%), power (80%), percentage of success in the control group (9%), percentage of success in the experimental group (15%) and non-inferiority limit of (6%) [15].

Results

The current study was conducted on 200 women who were randomly allocated into two groups, the Cu T380A group and the Multiload-375 group with 100 women in each group.

There was no statistically significant difference in the socio-demographic characteristics of included patients such as age and parity between the two groups as shown in Table 1.

In addition, the gestational age among the Cu T380A IUD user group was 36.1 ± 3.9; however, it was 36.5 ± 3.6 among the Multiload 375 IUD user group (Fig. 1).

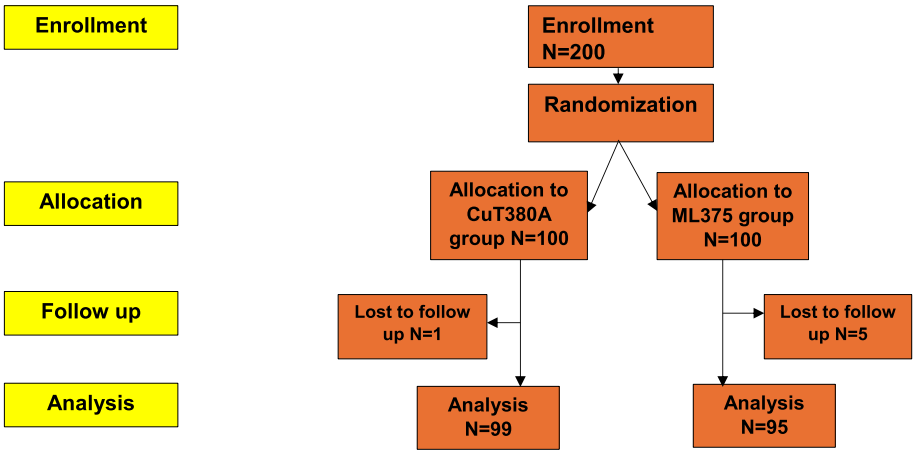

Fig. 1 The RCT flow chart of this study comparing between Cu T380A group and Multiload IUD group (CONSORT flow chart)

Table 2 Ultrasonographic assessment of IUD position and clinical assessment of IUD threads in both groups (1st assessment)

Variable	Cu T380 A IUD user *N* = 100 *N* (percent)	Multiload 375 IUD user *N* = 100 *N* (percent)	*P* value
Site of IUD by US on discharge			
In place	82 (82.00%)	76 (76.00%)	0.30
Displaced	18 (18.00%)	24 (24.00%)	NS
Threads of IUD by examination on discharge			
Felt	21 (21.00%)	90 (90.00%)	**< 0.0001**
Not felt	79 (79.00%)	10 (10.00%)	**Sig.**

Furthermore, the mean number of previous cesarean section (CS) was 2.1 ± 1.2 for the Cu T380A IUD user group; however, it was 2.24 ± 1.33 among the Multiload 375 IUD user group (Table 1).

Out of the 200 included patients, 194 patients were assessed in the follow-up visit after 6 weeks (2nd assessment), 99 patients were Cu T380A IUD users, and 95 patients were Multiload 375 IUD users as shown in the flow chart (Fig. 1).

The ultrasonographic assessment of IUD position before patient discharge (1st assessment) revealed that 18% of Cu T380A IUD users were displaced in comparison to 24% of Multiload 375 IUD, and such difference between both groups was not statistically significant ($P = 0.3$) (Table 2, Fig. 2). Furthermore, IUD threads were felt by examination on patient discharge in 21% of Cu T380A IUD users in comparison to 90% of Multiload 375

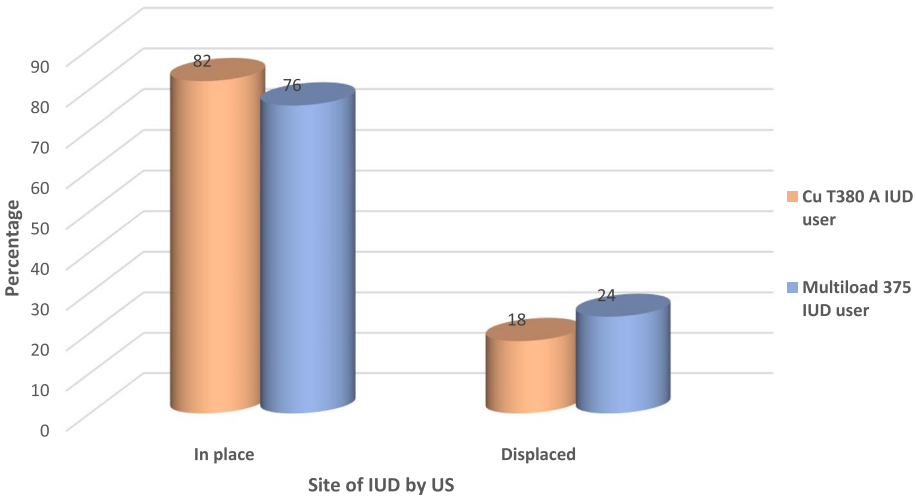

Fig. 2 The ultrasonographic assessment of IUD position (1st assessment)

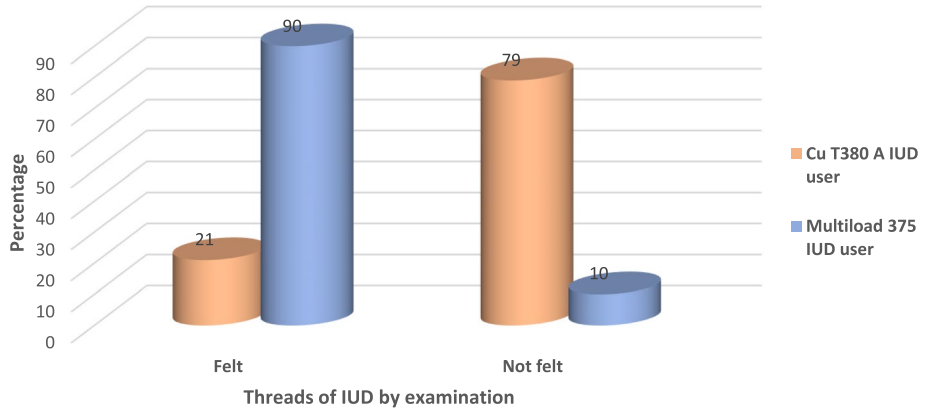

Fig. 3 The clinical assessment of IUD threads (1st assessment)

IUD, and such difference was statistically significant ($P = 0.0001$) (Table 2, Fig. 3).

The ultrasonographic assessment of IUD position after 6 weeks (2nd assessment) revealed that 19% of Cu T380A IUD users were displaced in comparison to 30% of Multiload 375 IUD, and such difference between both groups was statistically significant ($P = 0.047$). Furthermore, IUD expulsion was reported in 4% of Cu T380A IUD users in comparison to 10% of Multiload 375 IUD users, and such difference was statistically insignificant (Table 3, Fig. 4). Furthermore, IUD threads were felt by examination (2nd assessment) in 37% of Cu T380A IUD users in comparison to 93% of Multiload 375 IUD users, and such difference was statistically significant ($P = 0.0001$) (Table 3, Fig. 5).

Table 3 Ultrasonographic assessment of IUD position and clinical assessment of IUD threads in both groups at follow-up visit

Variable	Cu T380A IUD user *N* = 99 *N* (percent)	Multiload 375 IUD user *N* = 95 *N* (percent)	*P* value
Site of IUD by US on follow-up visit after 6 weeks			
In place	76 (76.77%)	55 (57.89%)	**0.047**
Displaced	19 (19.19%)	30 (31.58%)	**Sig.**
Expulsion	4 (4.04%)	10 (10.53%)	0.08 NS
Threads of IUD by examination on follow-up visit after 6 weeks			
Felt	37 (37.37%)	89 (93.68%)	**< 0.0001**
Not felt	62 (62.63%)	6 (6.3%)	**Sig.**

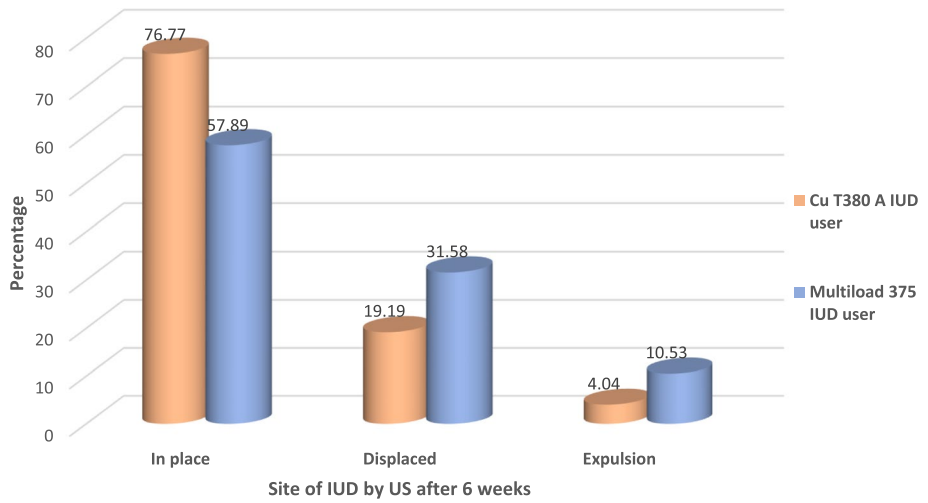

Fig. 4 The ultrasonographic assessment of IUD position (2nd assessment)

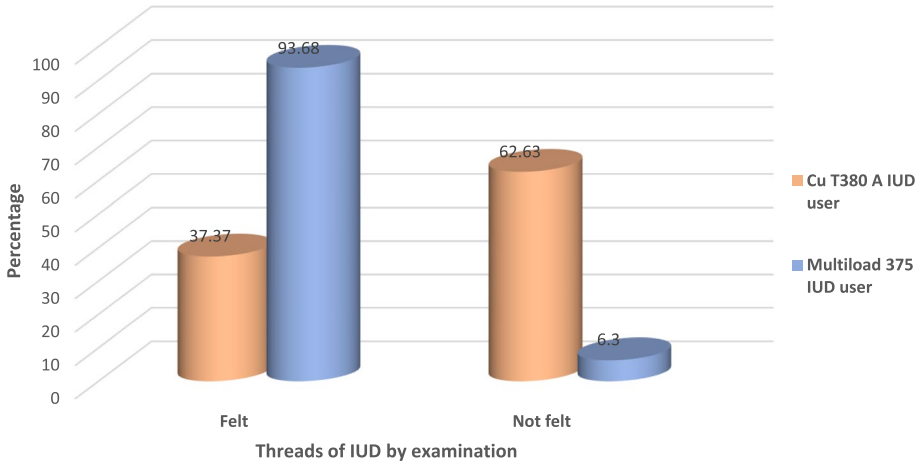

Fig. 5 The clinical assessment of IUD threads (2nd assessment)

As regards complications after IUD insertion in both groups, around 27% of Cu T380A IUD users suffered from irregular uterine bleeding; however, only 10% of Multiload 375 IUD users suffered such problems, and the difference was statistically significant ($P = 0.003$) (Table 4, Fig. 6). Furthermore, none of the included patients in both groups suffered from fever after IUD insertion.

In addition, around 13% of Cu T380A IUD users suffered from vaginal discharge in comparison to 10% of Multiload 375 IUD users and that difference was statistically insignificant ($P = 0.57$) (Table 4)

Out of 194 women analyzed in both groups at follow-up visit. IUD removal was performed in 33 patients (17%) in total, 13 patients (13%) were in the Cu T380A

Table 4 Complications of IUD in both groups

Variable	Cu T380A IUD user *N* = 99 *N* (percent)	Multiload 375 IUD user *N* = 95 *N* (percent)	*P* value
Pattern of bleeding during puerperium			
Normal	72 (72.73%)	85 (89.47%)	**0.003**
Irregular uterine bleeding	27 (27.27%)	10 (10.53%)	**Sig.**
Fever			
No	99 (100%)	95 (100%)	
Vaginal discharge			
No	86 (86.87%)	85 (89.47%)	0.57
Yes	13 (13.13%)	10 (10.53%)	NS

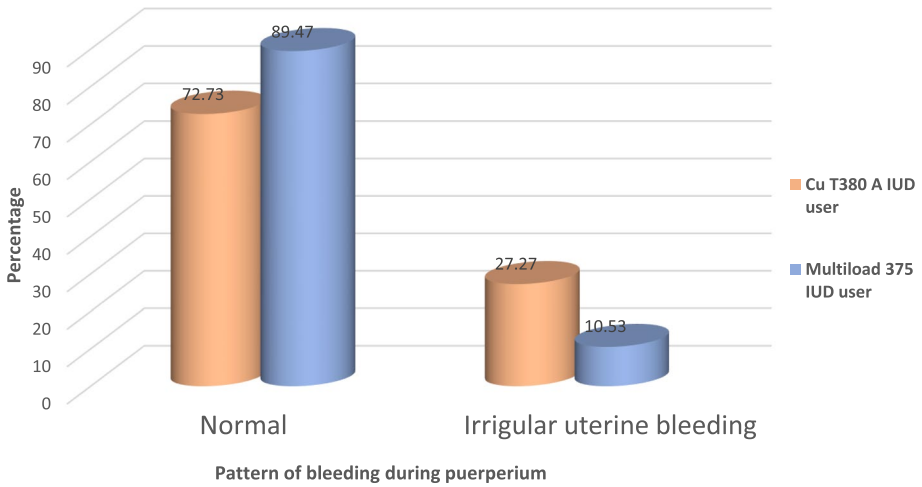

Fig. 6 The pattern of bleeding among included patients

Table 5 IUD removal in both groups

Variable	Cu T380A IUD user *N* = 95 *N* (percent)	Multiload 375 IUD user *N* = 85 *N* (percent)	*P* value
Removal	13 (13.7%)	20 (23.5%)	0.14 NS
Causes of IUD removal			
Displacement	7 (7.07%)	16 (16.84%)	**0.04 Sig.**
Bleeding	6 (6.06%)	2 (2.11%)	0.28 NS
Patient request	0	2 (2.11%)	0.06 NS

IUD users group and 20 patients (23%) were in the Multiload 375 IUD user group with no significant difference between both groups ($P = 0.14$) (Table 4). In addition, the indication of IUD removal varied in both groups, 7% was due to displacement in the Cu T380A IUD users in comparison to 16% of Multiload 375 IUD users, and such difference was statistically significant ($P = 0.04$), and 6% was due to bleeding in the Cu T380A IUD users in comparison to 2% of Multiload 375 IUD users, and only 2% of patients in the Multiload 375 IUD users requested IUD removal (Table 5 and Figs. 7 and 8).

Discussion

To our knowledge, the current study with such design is the most suitable one to answer our research question regarding the difference between Cu T380A IUD and Multiload 375 IUD inserted immediately post-placental during cesarean section.

Although such problem has been investigated before but because of its high significance in communities with huge population count such as Egypt, it deserves to be

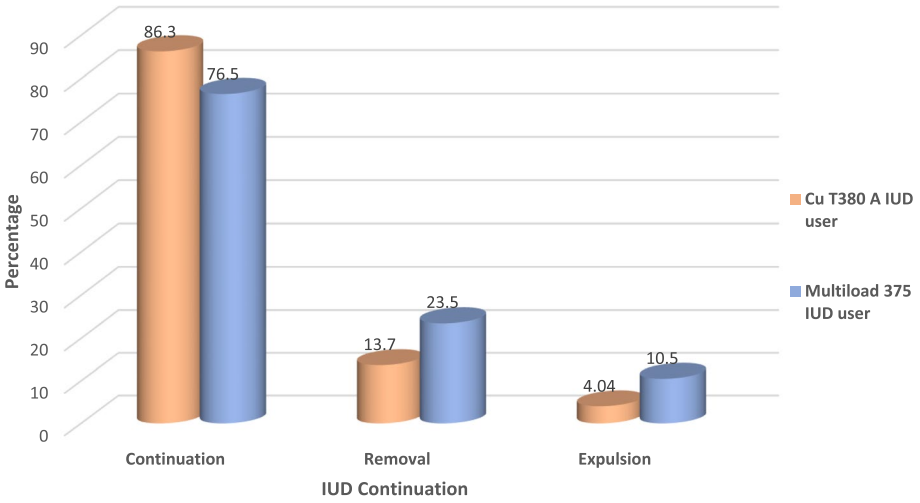

Fig. 7 The continuation, expulsion, and IUD removal among included patients

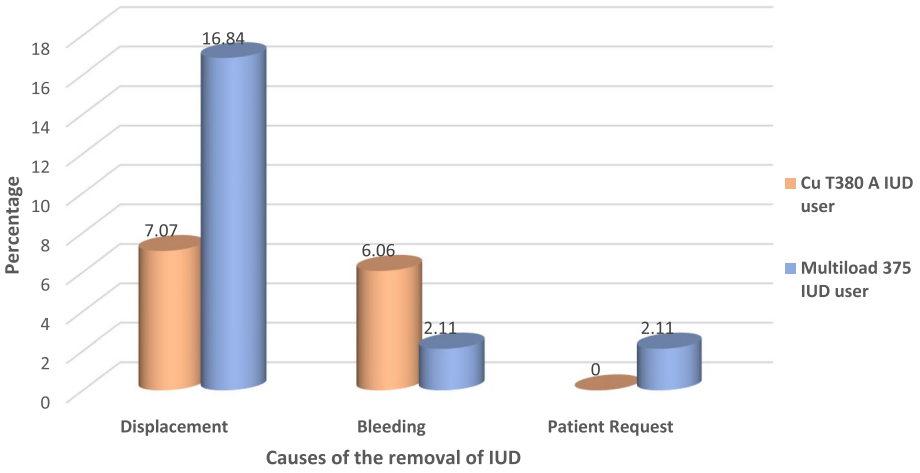

Fig. 8 The causes of IUD removal among included patients

studied again in different geographical areas to prove or disprove its efficacy in reducing the rapid increase in population count in Egypt.

Despite a World Health Organization (WHO) sponsored multicenter trial reporting that immediate post-placental insertion of IUCDs has "unacceptable high pregnancy and expulsion rates" [16], recent studies have reported an improved performance and reliability of this method [13, 17, 18].

The current study has shown that post-placental IUD insertion is an easy, reliable, long lasting, and reversible method of contraception with high compliance rate; however, there was no statistically significant difference between both groups in displacement rate during the first ultrasonographic assessment before patient discharge, and such evaluation was not reported in any previous studies.

During the 2nd assessment after 6 weeks in the current study, there were more IUD displacements in the Multiload 375 IUD user group in comparison to Cu T380A IUD users which is not in line with a previous study by Ragab et al. [8] who reported more displacements in Cu T380A IUDs (22%) in comparison to ML375 IUD (5%) after 6 weeks, and this is probably due to differences in study design and sample size, as well as eligibility criteria, as they were recruiting only elective cesarean deliveries; however, in the current study, both elective and emergent cesarean deliveries were recruited.

In addition, the current study has shown that ML375 IUCD users have statistically insignificant higher expulsion rate in comparison to Cu T380A IUCD users which was in line with the previous study by Divya et al. [19], but such results are not in line with the previous study by Ragab et al. [8] who reported more expulsion in Cu T380A IUDs than ML375 IUD after 6 weeks, and this is also probably due to differences in study design, sample size as well as eligibility criteria.

One of the new findings that was first reported in our study that spontaneous correction of IUD position may occurs in some patients as in Cu T380A IUCD users ,IUD was displaced in 18 patients (18%) during the 1st assessment and spontaneous correction occurred in 12 patients (12%), *P* value (0.24) , while in 24 patients (24%) of the ML375 IUCD users, IUD was displaced during the 1st assessment and spontaneous correction occurred in 10 patients (10%) P value (0.008)

As regards the evaluation of IUD threads during the 1st assessment before patient discharge and during 2nd assessment after 6 weeks, there were significantly higher missed threads in the Cu T380A IUD users in comparison to Multiload 375 IUD users, and these results are in line with the previous study by Divya et al. [19].

The reason for this could be that the length of the nylon thread in Multiload 375 was 19.4 cm, whereas the length of the thread in Cu T380A was 11.5 cm [20]. This could be the reason for the early visibility of the strings in the majority of subjects in whom Multiload 375 IUCDS were inserted immediately after the expulsion of the placenta. Furthermore, the fundus of the uterus corresponds to a 5-month pregnant uterus size; hence, IUD strings were not visible in Cu T380A group and some women in the Multiload 375 group. Non-visibility of strings in Cu T380A at the time of insertions reassures the provider about the fundal placement of the IUD.

However, visibility of strings is also important as it provides ease of removal of IUCD. In order to solve the problem, Nelson et al. reported a study where they provided tail strings of sufficient length and strength so that if at any time a complication developed (infection, bleeding, etc.), the device could easily be removed [13].

As regards adverse effects, there was a significantly higher pattern of abnormal uterine bleeding among Cu T380A IUD users in comparison to ML375 IUD users, and such results are in line with the previously published trials [8, 19].

In the current study, none of the included patients suffered from an infection after IUD insertion, and only vaginal discharge was observed in 10–13% of included patients in both groups which was not associated with fever. Divya et al. reported more cases of vaginal discharge especially with Cu T380A users and reported only one case of PID with ML375 IUD [19]. Ragab et al. also reported no cases of puerperal infection in both groups after 6 weeks of post-placental insertion during cesarean section [8].

The previously mentioned data provides enough evidence that post-placental IUCD insertion affords adequate protection against pregnancy with no increased risk of infection. However, it could not be attributed to insertion procedure or IUCD type. The patient selection, strict antiseptic conditions, and the use of prophylactic surgical antibiotics might explain such low infection rates.

Furthermore, it is worthy to mention that the IUCD removal rate in our study was higher than previously published trial [19], especially in the Multiload 375 IUD users due to more displacement and patient request for removal.

The commonest reason for the removal of IUCD in our study was medical (displacement and bleeding), and it accounted for 93.9% of total removals in the present study. Removal for abnormal uterine bleeding accounted for 6% of IUCD removals in Cu T380A users and 2% of IUCD removals in ML375 IUD users, while displacement accounted for removal of 7% in Cu T380A users and 16%

in ML375 users. Patient request accounted for 2% of removals in ML375 IUD users. This was in accordance with the study by Lara R et al. in which the removal rates for bleeding and pain were 4.9 and 4.8 and the removal rates for nonmedical reason were 3.7 and 4.9 respectively for Multiload 375 and Cu T380A users, respectively [21].

In the present study, abnormal uterine bleeding, high expulsion, and displacement rates represented the leading causes of high discontinuation rate observed with both groups and none of those patients needed hysteroscopy for IUD removal as in most of the cases threads were visible in the vagina and if not, a long artery forceps was used to extract the IUD without need for anesthesia.

One of the limitations of the current study is its small sample size that does not allow for subgroup analysis of included patients according to the number of previous cesarean deliveries, in addition to recruiting patients from a single tertiary care unit that is usually dealing with complicated cases and not simple ones that may have better outcomes with intrapartum IUD insertion.

The current study is a well-designed study that ensured the safety and tolerability of post-placental Cu T380A and Multiload 375 IUCD insertion and added new information to the available literature by ensuring the possibility of spontaneous correction of IUD position, and so any decision regarding IUD malposition should be postponed till at least 6 weeks postpartum.

Conclusions

Finally, it could be concluded that post-placental IUD insertion is one of the most secure, dependable, and practical methods for preventing future undesired pregnancies especially in communities with high population count and high cesarean section rates after proper counselling regarding the side effects, displacements, and expulsion rates. The current study compared the two most popular IUDS and clarified that post-placental insertion of Multiload 375 IUCD results in significantly higher displacement rates compared to post-placental insertion of Cu T380A IUCD, as well as significantly more bleeding problems with Cu T380A IUCD as compared with Multiload 375 IUCD.

Abbreviations

IUCD	Intrauterine contraceptive device
PPIUCD	Post-placental intrauterine contraceptive device
IUD	Intrauterine device
PID	Pelvic inflammatory disease
WHO	World Health Organization
CS	Cesarean section
US	Ultrasonography
2D	Two dimensional
RCT	Randomized controlled trial

Acknowledgements

Special thanks to all patients who accepted to participate in our study and the Department of Obstetrics and Gynecology at Sohag University where the research was conducted.

Authors' contributions

All authors participated in the delivery of the final form of the manuscript. H.A: study design, protocol revision, data analysis, manuscript writing, and submission of final version of the manuscript. M.A: literature search, protocol writing, data collection, data analysis. M.I: data collection, data analysis, and manuscript writing. S.A: study design, protocol revision, data analysis, and revision of final version of the manuscript.

Funding

No fund.

Availability of data and material

The data that support the findings of this study are available from the authors, but restrictions apply to the availability of these data, which were used under license from Sohag University, medical research committee, Egypt, for the current study, and so are not publicly available. Data are, however, available from the authors upon reasonable request and with permission from Sohag University, medical research committee, Egypt.

Declarations

Ethics approval and consent to participate

The current study was approved by the ethical committee of Faculty of Medicine, Sohag University, with committee's reference number (sohMed-22-11-03), and all included patients signed an informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Received: 4 April 2024 Accepted: 6 June 2024
Published online: 15 June 2024

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