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EXPERT OPINION

Expulsion and continuation rates after postabortion insertion of framed IUDs versus frameless IUDs – review of the literature

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Background: Early intrauterine device (IUD) discontinuation after insertion immediately following aspiration abortion or after early medical abortion occurs as a consequence of expulsion of the IUD or removal due to side effects. These are often the consequence of the uterine forces impacting on the IUD due to spatial discrepancy with the uterine cavity causing pain, abnormal bleeding, and eventually, removal of the IUD. These women are candidates for repeat pregnancy as they often select less-effective methods or no contraception at all. Repeat abortion could be reduced by giving attention to these factors.

Study design: In order to have an indication on the magnitude of the problem of IUD expulsion or discontinuation, we searched the MEDLINE database for clinical trials, randomized controlled trials, and prospective observational studies related to immediate postaspiration termination of pregnancy (TOP) and early medical abortion IUD insertion studies that reported IUD expulsion and IUD continuation rates.

Results: The search identified 17 clinical trials that were suitable based on the data they presented. The majority concerned T-shape IUDs, inserted immediately following surgical (aspiration) pregnancy termination. Two studies were conducted after medical TOP, and four studies were conducted with the frameless IUD inserted after surgical (vacuum aspiration) TOP. The results showed expulsion rates between 0.8% and 17.3% at 8 weeks, up to 5 years after insertion, respectively. In four studies with the frameless IUD, totaling 553 insertions, the expulsion rate was 0.0% in three of them. Follow-up in the latter studies varied between 5 weeks and 54 months. Reported continuation rates with conventional (framed) IUDs were between 33.8% and 80% at 1 year for studies providing 1 year rates and between 68% and 94.1% for studies reporting continuation rates at 6 months. Studies utilizing frameless IUDs reported 1 year continuation rate over 95%.

Conclusion: Frameless IUDs, due to their attachment to the uterine fundus, appear to be better retained by the postabortal uterus when compared with conventional framed IUDs. The absence of a frame ensures compatibility with uterine cavity anatomical dimensions, and may therefore result in improved acceptability and continuation rates in comparison with framed IUDs. Both these characteristics of the frameless IUD could help reduce the number of repeat unwanted pregnancies and subsequent abortions in some cases.

Keywords: IUD, abortion, frameless IUD, expulsion, continuation, repeat abortion, unintended pregnancy

Introduction

In recent years, many attempts have been made to prevent induced and repeat abortion by greater access to long-acting reversible contraceptives such as IUDs and implants. Immediate intrauterine device (IUD) insertion after the termination of pregnancy (TOP) is a very convenient way to provide contraception and prevent repeat abortion

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as it is an opportune moment to carry out this very short, easy, and safe procedure. As the cervix is dilated, insertion is virtually painless. Following insertion, the woman is protected immediately, before ovulation returns, usually within 7–10 days after first-trimester abortion.[1]

Half of the women having induced abortion in the US (1.2 million) and many in Europe have already had a previous abortion indicating the need for effective, well-tolerated long-term contraception with a high continuation rate.[2,3] Prompt insertion following TOP has many advantages as many women do not return for delayed insertion.[4] Immediate, same-day postaspiration abortion IUD insertion has been associated with a decreased rate of repeat abortion.[5–7]

Medical abortion is increasingly being used when conventional contraceptive methodology fails or is not being used in countries where it is legalized. The close surveillance of medical TOP with mifepristone and misoprostol has confirmed the high safety of this regimen.[8] Medical abortion now comprises 22% of all abortions <9 weeks gestation in the US.[9]

Despite the demonstrated safety of both aspiration and medical TOPs, IUDs for post-TOP insertion are still underused. This may be due to provider concerns and fear of insertion caused by lack of training and insertion-related information. Concerns about infection and IUD expulsion may mistakenly influence providers as well as women not to choose post-termination IUD insertion. The added cost may also be a deterrent to many women despite the data that confirm that IUDs are the most cost-efficient contraception systems available to women.[10] Insertion training and counseling to dispel lingering misconceptions regarding IUD safety of postabortal insertion have increased IUD use dramatically.[6] Analysis of the situation in the US predicts that if 20% of US women would choose to use intrauterine contraception immediately after abortion, 20,000 repeat abortions would be prevented in the subsequent year.[11]

The current article, presented at the Fédération Internationale des Associés Professionels de l'Avortement et de la Contraception in Ljubljana in 2014, reviews the main determinants related to postabortion IUD use, which could lead to a reduction of repeat abortion rates. This review is designed to provide clear information for general gynecologists, abortion doctors, including primary health care physicians, and nurse practitioners who assist them in the management of providing immediate contraception.

Materials and methods

In order to have a view on the reasons that lead to IUD discontinuation following insertion after first-trimester abortion, we performed a search of the literature for prospective, randomized, and observational studies that studied immediate IUD insertion following aspiration and early insertion after medically induced first-trimester abortion using PubMed and MEDLINE, complemented by citations from review articles and personal contact with investigators. This meant including as yet unpublished work. The results are deliberately not reported as a systematic review in order to give a historical perspective of the development of this technique. The objective of this review was to focus on the main determinants of early discontinuation, IUD expulsion, and discontinuations for medical reasons. Current IUDs are highly effective to prevent pregnancy, and therefore, pregnancy rates were not taken into account in this review. We included studies that reported expulsion rates and also information on displacement of the IUD during use, embedment, and partial expulsion. In the majority of cases, the studies with conventional IUDs that did not report continuation rates were excluded in order to determine patient overall acceptability of the devices over time. The objective of this paper was not to compare immediate versus delayed IUD insertion as there are sufficient data available that indicate the advantage of immediate postaspiration TOP and early postmedical IUD insertion versus delayed insertion.

A total of 17 studies were identified, including both randomized and prospective observational studies, using conventional IUDs (eg, copper- and hormone-releasing IUDs) as well as the frameless copper-releasing IUD used immediately after uterine aspiration for TOP during the first trimester or within 7–10 days after medical abortion of <9 weeks gestation. Table 1 summarizes the studies.

The randomized and nonrandomized comparative studies are listed first, followed by prospective observational trials, and finally, the immediate post-TOP IUD insertion studies conducted with the frameless copper IUD. Several IUDs used in the studies were withdrawn from the market, Cu-7 and Lippes Loop. The T-shaped copper IUDs that were most often used in the studies included: TCu200, TCu220C, TCu380A or ParaGard® ([Duramed, now Teva] Pharmaceuticals, Petach Tikva, Israel), and Nova-T® (Levonova®; Leiras Pharmaceuticals, Turku, Finland). Multiload® IUDs (Organon [now MSD], Oss, the Netherlands) were used in two studies, and the frameless, GyneFix® IUD (Contrel Europe, Ghent, Belgium) in four studies. The studies are listed according to their year of publication. The table provides the names of the first author, the country where the study was conducted, the methods used, aspiration or medical abortion, comparison

Table 1 Randomized, nonrandomized comparative, and observational trials of immediate first-trimester postabortal insertion

Study (year of publication)	Centers (surgical/ medical)	Comparison	N	Follow-up (months)	Expulsion rates (%)	Continuation rates (months, %)
Randomized and nonrandomized comparative trials						
1. WHO (1983)[12] Prospective	Multicenter study in different countries (surgical)	TCu220C Lippes Loop D Cu-7	2,340	24	4.4 9.6 8.4	61 (at 12 months) 56 (at 12 months) 54 (at 12 months)
2. WHO (1983)[13] Prospective	Multicenter study in different countries (surgical)	TCu220C Lippes Loop D Cu-7	1,364	24	9.2 13.2 12.7	55 (at 12 months) 60 (at 12 months) 63 (at 12 months)
3. Nielsen et al (1984)[14] Prospective	Finland (surgical)	Nova-T Copper-T	331	36	17.3 11.9	38.8 (at 12 months) 37.5 (at 12 months)
4. Lim et al (1985)[15] Prospective	Singapore (surgical)	MLCu250 MLCu375	549	24	1.4 1.8	80 (at 12 months) 71 (at 12 months)
5. McCarthy et al (1985)[16] Prospective	Singapore (surgical)	Nova-T MLCu250	400	24	6.5 6.3	NR
6. Pakarinen et al (2003)[17] Prospective	Finland (surgical)	Mirena Nova-T	305 133	60	10.5 15.4	10.1 (at 60 months) 36.7 (at 60 months)
7. Goodman et al (2008)[5] Retrospective	USA (surgical)	Mirena ParaGard	679	9 (mean follow-up time)	3.8	88 (at ~9 months) (underreporting)
8. Drey et al (2009)[18] Prospective	USA (surgical)	Mirena (75%) ParaGard (25%)	123	8 weeks (7–544 days)	0.8	93.5 (at ~8 weeks)
9. Bednarek et al (2011)[19] Prospective	USA (surgical)	Mirena (77%) ParaGard (23%)	258	6	5.5 3.2	94.1 (at 6 months) 85.7 (at 6 months)
10. Shimoni et al (2011)[20] Prospective	USA (medical)	ParaGard	69	6	12.0	69 (at 6 months)
11. Sääv et al (2012)[21] Prospective	Sweden (medical)	Mirena T-shaped Cu	62	6	9.7	68 (at 6 months)
Prospective observational trials with no IUD comparator						
12. Timonen and Luukkainen (1974)[22] Prospective	Finland (surgical)	TCu200	154	18	3.3	81.5 (at 18 months)
13. Betstadt et al (2011)[23] Prospective	USA (medical)	Mirena (75%) ParaGard (25%)	118	3	4.1	~80% (at 3 months)
Frameless IUD trials						
14. Batár et al (1998)[24] Prospective	Hungary, Belgium (surgical)	GyneFix 330	112	12	0	~95 (at 12 months)
15. Gbolade (1999)[25] Prospective	UK (surgical)	GyneFix 330	44	4–8 weeks	0	NR (follow-up in 30 women)
16. Cao et al (2000)[26] Prospective	People's Republic of China (surgical)	GyneFix 330	175	5 weeks up to 54 months	0	~97
17. Wiebe et al (unpublished data, 2013) Prospective	Canada (surgical)	GyneFix 200	152	6–8 weeks	4.1	92 (at 6–8 weeks)

Notes: Surgical means induced abortion by vacuum aspiration. Medical means abortion by the mifepristone-misoprostol regimen.
Abbreviations: NR, not reported; WHO, World Health Organization; IUD, intrauterine device; ML, multiload.

group(s), number of insertions, months of follow-up, expulsion rate(s), and continuation rate(s).

Results

Randomized and nonrandomized comparative clinical trials

Nine among the eleven randomized and nonrandomized clinical trials were conducted in women fitted with IUDs immediately after surgical TOP. Two studies were done after medical abortion, either 7–10 days following complete abortion or later. The results of immediate insertion after surgical TOP and within 7–10 days following medical TOP are given below.

World Health Organization (WHO)-Human Reproduction Program:[12,13] two large (n=3,704) WHO studies were conducted, the first related to immediate IUD insertion after first-trimester surgical TOP and the second after dilatation and curettage for miscarriage. For both the trials, the expulsion rates at 24 months varied from 4.4% to 13.2% and the continuation rates at 12 months from 54% to 63%.

Nielsen et al:[14] they studied 331 women who were fitted with two different copper IUDs immediately following

vacuum aspiration during the first trimester. Expulsions at 36 months occurred in 17.3% (Nova-T) and in 11.9% (Copper-T), respectively. Continuation rates at 12 months were 38.8% and 37.5%, respectively.

Lim et al:[15] they inserted 549 Multiload (ML) Cu250 and MLCu375 IUDs in the first trimester after suction curettage abortion and observed low expulsion rates of 1.4%–1.8% for both devices at 24 months. The 12-month continuation rate was 80% for MLCu250 and 71% for MLCu375.

McCarthy et al:[16] they performed 400 insertions immediately following first-trimester abortion using Nova-T and MLCu250. Expulsions at 24 months were similar (6.3%–6.5%) for both the devices.

Pakarinen et al:[17] they compared 305 Mirena levonorgestrel intrauterine system (LNG-IUS) and 133 Nova-T first-trimester insertions immediately after TOP with follow-up up to 60 months. The cumulative gross expulsion rate at 60 months was 15.4% for Nova-T and 10.5% for Mirena. Cumulative discontinuation rates at 60 months were 89.9% for Nova-T and 63.3% for Mirena.

Goodman et al:[6] they inserted 679 ParaGard and Mirena IUDs immediately after aspiration TOP. The mean follow-up rate was 9 months (range unknown): 3.8% of IUDs expelled and 12% were removed for medical reasons. The authors commented that expulsion and removal may have been underreported due to nonfollow-up.

Drey et al:[18] in the group of women who had IUD insertions (~75% Mirena and ~25% ParaGard), 123 were inserted at <14 weeks of gestational age. The median time to follow-up was 8 weeks (mean 90.4 days, range 7–544 days). Five expulsions occurred (0.8%) and 19 discontinuations (6.5%) occurred, resulting in an 8-week continuation rate of 93.5%. Removal rates according to IUD type were not specified.

Bednarek et al:[19] two hundred and fifty-eight Mirena (77%) and ParaGard (23%) insertions were performed after first-trimester uterine aspiration. At 6 months, 5.5% expulsions had occurred with Mirena and 3.2% with ParaGard. Continuation at 6 months was 94.1% and 85.7%, respectively.

Shimoni et al:[20] they inserted 69 ParaGard IUDs 1 week after medical abortion. A total of 12% of the IUDs had been expelled after 6 months. The number of the IUDs in place at 6 months was 49, giving a continuation rate of 69%.

Sääv et al:[21] sixty-two women received either a hormonal or copper IUD early after medical abortion. At 6 months, 9.7% expulsions were reported. Forty-two (68%) continued the intrauterine contraceptive at 6 months.

Prospective observational trials

Two studies are reported, one conducted in Finland and the other in the US.

Timonen and Luukkainen:[22] one hundred and fifty-four CuT200 IUDs were inserted immediately after first-trimester aspiration TOP. At 18 months, the expulsion rate was 3.3% and the rate of medical removal was 13.1%. The continuation rate at 18 months was 81.5%, which included two removals for planned pregnancy.

Betstadt et al:[23] of the 118 subjects included in the study, 78 women had a LNG-IUS (Mirena) placed, whereas 41 women received copper IUDs (ParaGard). Of the 97 subjects who completed the study, there were four spontaneous expulsions (4.1%) after 3 months of follow-up. The continuation rate at 3 months was 80%.

Frameless IUDs

Four studies were performed with the frameless GyneFix 330 (3) and the GyneFix 200 IUDs (1). The IUDs were inserted immediately after vacuum aspiration TOP up to 13 weeks gestation. Studies focused mainly on the expulsion rate to evaluate retention. These studies were the first to be conducted in postabortal women with frameless, anchored IUDs.

Batár et al:[24] in this preliminary GyneFix 330 study conducted in Hungary and Belgium, 112 immediate TOP insertions were performed in women <10 weeks gestation. Follow-up was done up to 38 months (961 woman-months of experience). There were no expulsions, and six IUDs were removed for abnormal bleeding. At 12 months, 95% of IUDs were still in place.

Gbolade:[25] a GyneFix 330 pilot study was conducted in the UK in 44 women after first-trimester TOP up to 13 weeks gestation. Of these 44 women, 30 were followed-up after 1–2 months. There were no expulsions.

Cao et al:[26] GyneFix 330 insertions were done immediately after TOP of <10 weeks amenorrhea in 175 women. The longest follow-up was 54 months and the shortest 5 weeks. There were no expulsions. Three removals were done for abnormal bleeding, one for nonmedical reasons, giving a continuation rate of 97%. The total woman-months of experience were 1,616.

Wiebe et al (unpublished data, 2014): a group in Canada performed 152 immediate insertions after first-trimester TOP by vacuum aspiration. Follow-up data were available in 80% of these women after 6–8 weeks. There were five expulsions (4.1%). Continuation at 6–8 weeks was 92%.

Discussion

IUD expulsion

An IUD should be classified as "expelled" if it has been expelled spontaneously from the uterus or if any portion of the IUD is visible in the cervix or vagina at any follow-up visit. In the study by Betstadt et al, 4.1% of expulsions were reported. However, on further evaluation by vaginal ultrasound, the authors found an additional 6.2% of IUDs that were displaced in the lower uterine segment with the top of the IUD closer to the cervix than to the fundus.[23] As the uterus involutes and the uterine cavity shrinks, the IUD may become compressed and pushed downward toward the cervix due to uterine contractions.

The largest published clinical trial of IUD insertion following first-trimester surgical pregnancy termination was conducted by WHO. All three IUDs used in this trial are no longer available. However, since the TCu220C IUD has an identical T-shape design as the currently widely available TCu380A IUD (ParaGard), it may be assumed that the results would not have been much different. Expulsion rates were 4.4% at 2 years in women <9 weeks of gestation. In the group between 9 weeks and 12 weeks, the figure increased significantly (9.2% at 2 years). Thus, the shorter the period of gestation, the lower the risk of expulsion is. If the cavity is too big for the IUD, the IUD may translocate and become prone to expulsion.

The IUD expulsion rates in the WHO study after spontaneous abortion were much higher (9.2%) with the TCu220C IUD after 24 months. The other studies listed in Table 1 with TCu380A and Mirena used after first-trimester surgical abortion reported expulsion rates at 8 weeks up to 36 months between 0.8% and 17.3%, respectively. It is assumed that these figures include partial expulsions but not displaced IUDs.

Expulsion rates at 6 months after insertion, inserted within 7–10 days following medical abortion, appear to be higher than the expulsion rates observed after surgical abortion by vacuum aspiration and are very similar to the expulsion rates observed in the large WHO study conducted in women fitted with IUD after spontaneous abortion. There is no explanation for this difference.

Several studies after surgical abortion were conducted with ML IUDs.[15,16] The expulsion rate at 24 months was between 1.4% and 6.3% for MLCu250 according to the study site. These rates are similar to those observed with T-shaped IUDs.

The low expulsion rates reported in the studies conducted with the frameless IUD are attributed to the anchoring of the device in the fundus of the uterus to maintain retention. Consequently, very low rates of expulsions have been observed.

As the uterus is regaining its original size after the abortion, the size of the uterine cavity could actually become significantly smaller than the IUD itself, particularly in women who already had a small uterus prior to the pregnancy, as is the case in many among them (see below). These IUDs will likely cause side effects, particularly in young women who have already smaller uterine cavities, and become embedded, if not expelled, as a consequence of severe uterine pressure.[27,28] In addition, dislocated IUDs result in higher pregnancy rates.[29] Also, expulsion rates are expected to increase significantly when the IUDs are misplaced or have moved away from the fundus.[30] When the distance between the upper end of the IUD to the serosal surface of the uterus is >2 cm, as measured by ultrasound in the beginning of the menstrual cycle, the IUD should be removed to protect the woman from an unintended pregnancy. Removals for downward displacement of MLCu375 and TCu380A IUDs were 12.7% and 6.0%, respectively, in a study conducted in People's Republic of China, reported by Wu et al.[31] Hubacher's review of copper IUDs revealed that nulliparous women experience higher rates of expulsion and removals for bleeding and/or pain compared with parous women.[32] Higher pain and expulsion rates were also found in studies with the LNG-IUS (Mirena) conducted in nulliparous and adolescent women.[33,34] The few expulsions noted with the frameless IUD occurred within a few weeks following insertion and are likely caused by unfamiliarity with the new insertion technique. Insertion difficulties are often seen in the beginning of the learning curve and are usually overcome with experience with the insertion technique.[35,36] Following insertion, the position of an IUD can be verified by ultrasound. The position of the anchor in the uterine fundus of the frameless IUD can be located precisely by abdominal or vaginal ultrasound, thereby providing assurance about the correct placement of the IUD.[37]

IUD continuation

Unintended pregnancies due to contraceptive failure are frequent and result often in repeat abortions. The incidence of repeat abortion varies from 30% in Finland to 47% in the US.[38] In the context of reducing the number of repeat abortions, low IUD expulsion rate has a great merit but high continuation of use is paramount. Continuation of use is the most important determinant of performance of any contraceptive method. Continuation rates with conventional IUD after

TOP at 1 year are between ~50% and ~80%. Precise calculations are difficult as follow-up is often poor in postabortal women. Studies comparing immediate versus delayed IUD insertion show that same-day IUD insertion increases IUD use when compared with delayed IUD insertion and significantly reduces repeat abortion.[5,10] Irregular bleeding and pain are the most common reasons stated for the discontinuation of IUD use. The higher expulsion and lower continuation rates after medical abortion, compared to the rates after surgical abortion, may be due to more cramping and bleeding, which occur more often after medical abortion, causing downward displacement of the IUD. Fundal placement is essential for proper performance of any IUD, including framed LNG-IUS, as an IUD that has moved away from the fundus will result in a higher incidence of side effects. Thus, reducing expulsion rates and enhancing continuation is the challenge. This may be accomplished by the use of a more effective intrauterine contraception that minimizes expulsion, downward displacement, and embedment as this will enhance the continuation of use.

Due to its unidimensional design and anchoring to the uterine fundus, the frameless IUD may have several distinct advantages over conventional IUDs. Expulsion, downward displacement, and embedment, which are the consequences of spatial discrepancy between the size of the IUD and the size, particularly the narrow transverse diameter of the uterine cavity, are avoided when utilizing a frameless IUD. The low expulsion rates and high continuation rates in the studies presented in this review with the frameless IUD may be due to the optimal relationship between the device and the narrow cavity of many women.[39] The small diameter (<2.5 mm) and its flexible design allow for use in women with all shape and varied size uteri with a high degree of uterine compatibility being achieved. As a consequence, high continuation rates >90% were recorded similar to the high continuation rates reported during interval insertion at 3 years. The continuation rates remained high during subsequent years as women do not or rarely develop side effects.[35] The studies also suggested that adolescent and nulliparous women tolerate the small GyneFix 200 IUD.[36] Due to the absence of a frame, copper ions are released from both the outside and the inside of the copper cylinders. This design is beneficial for women as the IUD could be reduced in size, which enhances tolerability. The impact on bleeding is also minimized by reducing the total surface area of the IUD.[40]

Conclusion

In 1993, an article that appeared in the *Lancet* by McLaurin et al made a plea "to bridge the gap to deal more realistically with the urgent need of postabortion family planning".[41] This review suggests that the reduction in expulsion rates of IUDs inserted postabortion is technically possible. It can be assumed that optimal retention and absence of spatial discrepancy will result in high continuation of use, which is the ultimate goal to reduce repeat abortions. There are several limitations of this review, mainly the small size and the duration of the studies. Few IUD studies are conducted for immediate postabortal insertion and for insertion in medical abortion patients. The frameless IUD studies have small numbers and are not directly compared with other IUDs. However, based on the published information in this paper, one can conclude that IUD insertion postabortion appears to be possible with many available IUDs; however, anchored IUDs have superior overall retention with lower expulsion rates, when inserted properly, and a better acceptability profile. We realize that continuation rates are multifactorial and only related to the contraceptive method used. Therefore, comparing data from different studies has limitations. In addition, the studies reviewed using different methodologies and follow-up periods were different. Further studies should be conducted to add more data, especially related to the immediate postabortal use of the frameless IUDs.

Taking these limitations into account, it can, however, be assumed that IUD insertion immediately postabortion could significantly reduce the frequency of abortions worldwide while also providing women with safe and effective long-term contraception. IUD insertion postabortion should, therefore, be advocated. Besides, immediate postabortion IUD insertion has been shown to be cost-effective.[42] Among other practical implications are simple interventions to remove barriers to IUD insertion such as staff and clinician training in IUD insertion and simplified protocols for IUD insertion, as Goodman et al suggested.[6]

Disclosure

Dirk Wildemeersch is the developer of the frameless GyneFix IUD. He has also been involved in the development and optimization of new, innovative, drug delivery systems for use in the uterus. Currently, he acts as a trainer in the insertion procedure of GyneFix during training sessions organized by the commercial companies distributing the product. He is also an advisor in devising new concepts in controlled release for contraception and gynecological treatment, and sometimes receives compensation for these activities. He is the last Belgian doctor who has been jailed in 1986 for helping a 13-year-old girl. The authors report no other conflicts of interest in this work.

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