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Original research article

Fast-track vs. delayed insertion of the levonorgestrel-releasing intrauterine system after early medical abortion — a randomized trial

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Abstract

Objective: To compare levonorgestrel (LNG) 52-mg intrauterine system (IUS) expulsion rates with fast-track (≤3 days) or delayed (2–4 weeks) insertion following mifepristone and misoprostol medical abortion.

Study design: In this pilot trial, we randomized 108 women at ≤63 days' gestation to fast-track (n=55) or delayed (n=53) insertion. Follow-up visits occurred at 2–4 weeks, 3 months and 1 year. We assessed total and partial expulsion at 3 months and 1 year, adverse effects and bleeding profiles.

Results: We had follow-up data at 3 months and 1 year for 41 (74.5%) and 37 (69.8%) women in the fast-track group and 31 (56.4%) and 28 (52.8%) women in the delayed group. By 3 months, expulsion occurred in six (12.5%) women after fast-track and one (2.3%) woman after delayed insertion [risk ratio (RR) 5.50, 95% confidence interval (CI) 0.69–43.90]; most (n=5) of these were partial expulsions in the fast-track group. By 1 year, expulsion had occurred in seven (14.6%) and five (11.5%) women in the fast-track and delayed groups, respectively (RR 1.28, 95% CI 0.44–3.75). We found no differences in rates of vacuum aspiration, residual tissue, infection and bleeding or bleeding patterns within 3 months of insertion.

Conclusion: Fast-track insertion of the LNG 52-mg IUS after medical abortion is feasible but may result in higher expulsion rates compared to delayed insertion. Due to lack of statistical power and high lost-to-follow-up rates, we were unable to fully address this question.

Implications: Fast-tract initiation of LNG 52-mg IUS contraception after medical abortion is feasible. It results in higher expulsion rates than delayed insertion but may improve postabortal intrauterine contraception uptake.

Keywords: Medically induced abortion; Contraception; Contraceptive devices; Intrauterine devices

1. Introduction

The proportion of medical abortions varies from 23% in the United States to over 55% in England and Wales, 81% in Scotland, 91% in Sweden and 96% in Finland [1–4]. While long-acting reversible contraceptives, including intrauterine devices (IUDs) and contraceptive implants, are most effective in unwanted pregnancy prevention [5–8], the high prevalence of medical abortion use raises the question of the IUD insertion timing. IUD insertion immediately after surgical abortion is safe and effective [9–12]. IUDs are conventionally inserted a few weeks after medical abortion. However, up to half of the women do not attend follow-up appointments and are likely to miss effective contraception [13,14]. According to study conducted by Sääv et al., a shorter delay (approximately 1 week) between medical abortion and IUD insertion resulted in better IUD uptake compared to conventional delay (3–4 weeks) [15]. Moreover, as ovulation returns at approximately 3 weeks after medical abortion [16], early IUD insertion would ensure effective contraceptive initiation.

Early IUD insertion within approximately 1 week after first-trimester medical abortion shows 7%–12% expulsion rates [15,17,18], with no major complications related to early IUD insertion. However, there are no reports concerning quicker IUD insertion after early medical abortion or as regards use of the levonorgestrel-releasing intrauterine system (LNG-IUS) only.

The aim of our randomized pilot trial was to compare LNG 52-mg IUS expulsion rates at 3 months following

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fast-track (within 3 days) vs. delayed (2–4 weeks) insertion after medical abortion.

2. Material and methods

2.1. Study design

In this prospective randomized pilot trial, we compared the feasibility and outcomes of fast-track (≤3 days after misoprostol) and delayed (2–4 weeks after misoprostol) LNG 52-mg IUS (Mirena®; Bayer, Turku, Finland) insertion following medical abortion. We hypothesized that expulsion rates do not differ by more than 20% between the groups. Thus, the primary outcome was the total or partial expulsion rate of LNG-IUS within 3 months. The secondary outcomes were the expulsion rates within 1 year, infection and surgical completion rates, bleeding problems and bleeding patterns.

We conducted the trial at the Department of Obstetrics and Gynecology, Helsinki University Hospital, Finland, and obtained approval from the Ethics Committee and the Hospital District of Helsinki and Uusimaa. We followed the Declaration of Helsinki principles and registered the study at www.clinicaltrials.gov on December 13, 2012 (NCT01755715).

2.2. Participants

We recruited ≥18-year old women requesting medical abortion, having ≤63 days of gestation and planning postabortal LNG-IUS. We excluded women with uterine abnormalities, uterine or cervical neoplasias, or acute pelvic infection. Other contraindications for the LNG-IUS, such as acute liver diseases or prior breast cancer, did not exist among the women assessed for eligibility. We obtained a written informed consent before enrolment. Recruitment occurred from January 30, 2013, to May 17, 2013.

2.3. Randomization and masking

We randomized the participants in a 1:1 allocation ratio to fast-track or delayed LNG-IUS insertion at the time of abortion after the determination of gestational age and postabortal contraception planning. We used a computer-generated block randomization list with block sizes of 4 and 6 and sequentially numbered opaque envelopes. The personnel responsible for generating the randomization list and sealing the envelopes did not take part in patient enrolment.

2.4. Procedures

All procedures were performed according to Finnish National guidelines on induced abortion [19]. Gestational age was determined by ultrasonography. The women received mifepristone (Mifepristone Linepharma®; Linepharma, France), 200 mg orally, and all women self-administered misoprostol 800 mcg vaginally at home (Cytotec®; Pfizer, Great Britain) 24–72 h later. A follow-up visit at 2–4 weeks was scheduled.

Fast-track LNG-IUS insertion occurred within 3 days (i.e., on the next working day) after misoprostol administration. Vaginal ultrasonography was performed to ensure gestational sac expulsion and to measure endometrial thickness to exclude clear signs of remaining products of conception. Also, uterine sound measure was recorded. We used the insertion technique recommended by the manufacturer and verified a fundal location using ultrasonography. We asked for insertion pain immediately after the insertion using a numeric rating scale of 0 (no pain) to 10 (the most severe pain imaginable). If vacuum aspiration was performed according to clinical judgment (no predefined criteria) in the fast-track-insertion group, the LNG-IUS was inserted during the procedure.

At the 2–4-week follow-up visit, we confirmed the LNG-IUS location in the fast-track-insertion group and measured fundal endometrial thickness in both groups by ultrasonography. At this follow-up, we inserted the LNG-IUS in the delayed-insertion group. If vacuum aspiration was performed at the time of follow-up, the LNG-IUS was inserted during the procedure. The three investigators performed all insertions. Our experience in LNG-IUS insertion is more than 10 (R.K.) or 20 years (M.M. and O.H.).

The women recorded their uterine bleeding during a 90-day period after abortion. A three-point-scale bleeding chart was used (heavy bleeding, bleeding or spotting). Heavy bleeding was described as a need for the largest sanitary towels during the day, or overflow at night; bleeding as a need of a normal sanitary towel or tampon; and spotting as the need of a panty liner or small tampon, or no need for sanitary protection.

The next follow-up visit was 3 months after insertion. At this visit, the research nurse checked for the presence and appropriate length of the LNG-IUS threads. A researcher performed ultrasonography if LNG-IUS strings were not visible or appeared to be too long.

At the last follow-up visit 1 year after abortion, we performed a pelvic examination and vaginal ultrasonography to verify the LNG-IUS location. We recorded possible complications at every follow-up visit. In cases of no show, the research nurse tried to contact the woman by calling or text messaging two to three times. We reviewed the electronic patient files to compensate for the dropout rate and maximize the information.

We defined LNG-IUS expulsion as “total” when it was spontaneously and completely expelled from the uterus and “partial” if part of the LNG-IUS was visible in the cervix or if the LNG-IUS stem was seen in the cervix in ultrasonography. If LNG-IUS was totally expelled, a new LNG-IUS was offered and inserted free of charge. Also, partial expulsion resulted in removal and new LNG-IUS insertion free of charge. Infection diagnosis was based on clinical judgment only and defined as antibiotics treatment because of uterine tenderness noted in clinical examination, and/or purulent cervical discharge or fever.