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ORIGINAL RESEARCH ARTICLE

Effectiveness, safety and overall satisfaction of early postpartum placement of hormonal IUD compared with standard procedure: An open-label, randomized, multicenter study

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Abstract

Introduction: In this open-label, randomized controlled, non-inferiority, multicenter study we aimed to study the risk of termination of pregnancy within 1 year postpartum, the safety profile and patient acceptability after early postpartum insertion of a hormonal intrauterine device (LNG-IUS, Mirena®) compared with standard placement 6–8 weeks postpartum.

Material and methods: April 2018 to January 2020 women with uncomplicated vaginal delivery at four urban birth centers in Sweden, were randomized to either early placement within 48 h after delivery (early group) or standard placement 6–8 weeks postpartum (standard group) of a hormonal intrauterine device. The main outcome measure was the proportion of terminations of pregnancies in each group during the first year after placement of the intrauterine device. Registration EudraCT database no. 2017–001945-29.

Results: The study was prematurely stopped according to the protocol due to an expulsion rate >20% in the early group. No pregnancies occurred. Fifty-two women were randomized to early and 49 women to standard insertion. In the early group, 23/52 (44.2%) of the intrauterine devices were expelled. After expulsion, 10 women chose to have another hormonal intrauterine device placed but still significantly fewer women (39/52, 75%, $p = 0.22$) in the early group used the hormonal intrauterine device method at study completion. No expulsions occurred in the standard group, but 5/49 (10.2%) requested removal and 41/49 (83.7%, $p = 0.22$) had used the hormonal intrauterine device method continuously for 1 year.

Conclusions: Early hormonal intrauterine device insertion after vaginal delivery is associated with high expulsion rates. Despite this, a high continuation rate of the hormonal intrauterine device method is seen among women once choosing the method.

Abbreviations: Cu-IUD, copper intrauterine device; IUD, intrauterine device; IUS, intrauterine system; VAS, visual analogue scales.

In the light of high continuation rates, the advantages of early insertion could balance the risk of expulsion for well-informed women.

KEYWORDS
contraception, early and standard hormonal IUD placement, hormonal, intrauterine device, LNG-IUS, postpartum

1 | INTRODUCTION

Long-acting reversible contraception are modern, effective and highly accepted methods with well-known side effects. With one single intervention at the time of placement, the intrauterine devices provide a high contraceptive effectiveness over several years.[1] Additional health advantages such as reduced menstrual bleeding and reduced dysmenorrhea make hormonal intrauterine devices (IUDs) the contraceptive choice with the highest patient satisfaction and acceptability rates on the market.[2]

Contraception postpartum remains a challenge worldwide. Globally, up to 62% of all women have an unmet need of contraception in the period following childbirth.[3] In Sweden, contraceptive counseling and provision is currently not available during the hospital stay after delivery. The antenatal health care program instead recommends a follow-up visit 6–12 weeks postpartum for counseling and provision of contraception.[4] However, approximately 30% of women do not attend the follow-up visit.[5] Furthermore, approximately 50% of women report unprotected intercourse within 6 weeks postpartum.[6] The absence of effective contraception during this period of life puts women at risk for an unintended pregnancy[7] and it has been shown that 2.3% of women in Sweden have an abortion within 1–2 years of childbirth.[5]

There is evidence that placement of a copper intrauterine device (Cu-IUD) or an IUD-intrauterine system (IUS) within hours after vaginal delivery is safe.[8–10] The obvious advantage is uptake of a highly effective contraceptive method before fertility is restored. Additionally, placement of an intrauterine device at this time may cause women less pain and discomfort during the procedure. A Cochrane review in 2015 comparing immediate placement of an IUD/IUS (defined as placement within 10 min after placenta delivery) with early placement (defined as placement from 10 min after placenta delivery to 48 h after delivery) found immediate placement overall safe, with no higher risk of perforation or infection compared with standard placement (defined as placement during a postpartum visit).[9] A more recent systematic review and meta-analysis published in 2020 found the rate of expulsion after early placement to be higher than after standard placement, on average 13.3%, but with a reported wide variation between 3.5%–46.7%.[11]

Recently, several studies have investigated the time-points of IUD placement postpartum, but so far, no study has been designed to investigate whether the time point of insertion will affect the risk of an unintended pregnancy postpartum.

Key message

Early placement of an IUD after vaginal delivery is safe, with high overall satisfaction. Expulsion rate is high, but if IUD replacement is readily available, the continuation rate of the IUD method is comparable to that of standard placement postpartum.

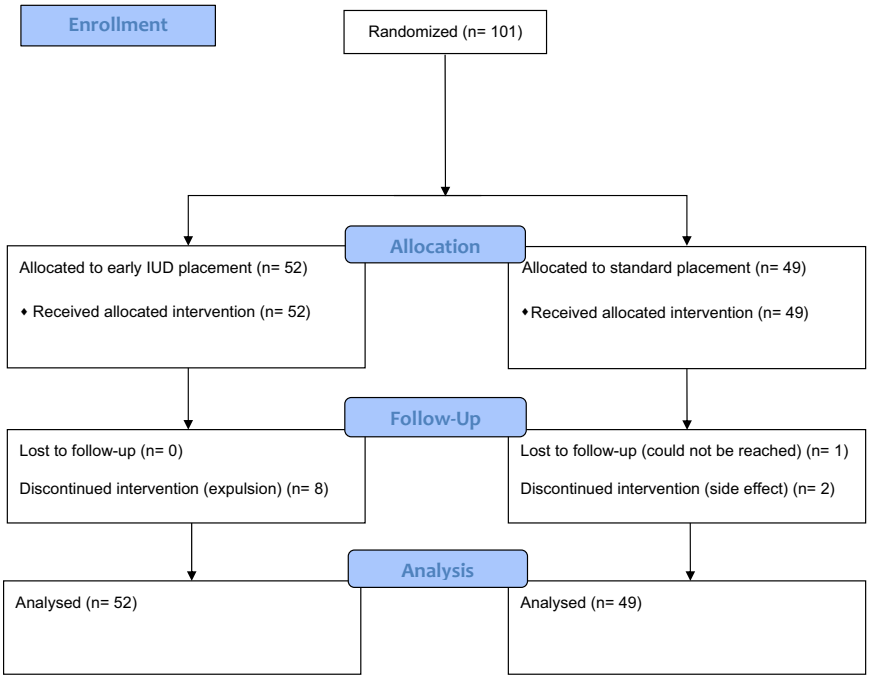
We aimed to investigate the effects of early postpartum placement of a hormonal IUD compared with standard placement regarding the risk of termination of pregnancy 1 year postpartum, safety and patient acceptability. We hypothesized that placement of a hormonal IUD within 48 h postpartum was non-inferior to placement at 6–8 weeks postpartum.

2 | MATERIAL AND METHODS

The present study was designed as an open-label, randomized controlled, non-inferiority, multicenter study (phase 3). From April 2018 to January 2020 women with uncomplicated vaginal delivery who fulfilled the inclusion but not the exclusion criteria were recruited at the urban delivery clinics of Danderyd, Linköping, Norrköping and Jönköping Hospitals in Sweden. Written information about the study was available antenatally for pregnant women at the Maternity Care units and at the delivery wards, and women were again informed of the study prior to delivery or within hours after delivery. Informed consent was obtained by a designated medical doctor within the first day postpartum. Included women were then randomized 1:1 after delivery in consecutive order and parallel groups, to placement of a hormonal IUD (Mirena®, Bayer AB) either early within 48 h after delivery (early group) or at standard time 6–8 weeks postpartum (standard group). All included women participated in the study for 12 months, with follow-up at 2, 4 and 8 weeks after IUD placement, and at 6 and 12 months postpartum. The standard group had a final follow-up at 12 months after IUD placement (Figure 1).

Nurse midwives and obstetrician gynecologists were highly experienced in placement of hormonal IUD at the regular timepoint postpartum but had no previous experience in early IUD placement when the study started. The same staff placed all the devices regardless of the timepoint postpartum and all insertions were made at

FIGURE 1 Consort flowchart



the hospital clinic. The early insertions were conducted at the postpartum ward 24–48 h after delivery.

We used a standardized protocol for hormonal IUD placement according to the recommendations for standard placement. All devices were inserted by the same midwives/gynecologists at each center, all having long experience of IUD insertions. We decided to use the inserter of the hormonal IUD to place the device in both the early and the standard group. No sounding was performed. During the early placement, the device was placed in a fundal position as judged by the healthcare personnel performing the insertion. The device was placed without pulling the T-shaped arms into the insertion tube. The placement of the hormonal IUD in the standard group was performed according to the manufacturer's instructions. No ultrasound examination was performed. Immediately after the IUD placement, women were asked to estimate the worst pain experienced during the placement procedure, using the visual analog scale (VAS) ranging from 0–100, where 0 is equal to no pain and 100 is equal to the worst possible pain. Bleeding patterns were determined by descriptions of how many continuous days after delivery, and after IUD placement, the woman experienced fresh and/or brown bleeding and/or spottings, including the pattern of menstrual bleeding during the 12 months of follow-up.

The primary outcome was the proportion of terminations of pregnancies in each group within 1 year after IUD placement. The secondary outcomes were the rate of expulsions, assessment of reasons for discontinuation of the hormonal IUD method, rate of continuation with the method, successful placements of the hormonal IUD, assessment of reasons for non-application of the hormonal IUD as planned, pain reported at the time of placement, number of days and amount of postpartum and menstrual bleeding, and questions of acceptability. Furthermore, we compared safety parameters by studying the number of complications as well as infant growth and duration of breastfeeding.

We hypothesized that the proportion of terminations in the early group would not be higher than in the standard group. The sample size was calculated based on the results of a pilot study of medical records from 350 women postpartum which revealed that 6% had an appointment for termination of pregnancy within the following 1–2 years after childbirth. We expected 50% fewer terminations than in the pilot study among women using the levonorgestrel intrauterine system (LNG-IUS) with standard placement time and made the assumption that early placement most probably would lead to fewer terminations of pregnancy compared with the standard group. Based on that theory, we predicted approximately 1% terminations of pregnancy in the early group and 3% in the standard group. Given a non-inferiority limit of 1% (Δ), 80% power ($1-\beta$) and 5% significance level (α) we had to include 259 women in each group. To compensate for an estimated 15% drop-out rate, we decided to include 300 women in each group.

According to the study protocol we planned to perform a safety analysis after inclusion of 100 women with the predefined decision to prematurely stop the study if the rate of expulsion were to exceed 20% within 28 days after application in either of the two groups.

2.1 | Statistical analyses

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 25.0 (IBM). The analyses used the full dataset, and all the results were based on observed outcomes without imputation of missing data. Non-parametric continuous variables are presented as medians with minimum and maximum values; differences between groups were analyzed by the Mann–Whitney *U*-test. Dichotomous variables are presented as proportions with differences between groups analyzed by the χ^2 test or Fisher's exact test,

as appropriate. All differences between groups were considered statistically significant if they had a $p \leq 0.05$.

2.2 | Ethics statement

The study was approved by the Regional Ethical Review Board in Linköping, Sweden (No 2017/339–31, September 20, 2017) and by the Medical Products Agency in Sweden, EudraCT-no 2017–001945-29.

3 | RESULTS

Fifty-two women were randomized to early and 49 women to standard placement.

The study was prematurely stopped after we performed a safety analysis after inclusion of 100 women which was predefined in the protocol. The safety analysis showed a higher expulsion rate in the early placement group than the stopping criteria (>20%). In the early group 23/52 (44.2%) of hormonal IUDs were expelled, 12/52 (23.1%) partial and 11/52 (21.1%) complete expulsions. The expulsion rate was highest 12/52 (23.1%) during the first 2 weeks after placement. No expulsions were detected in the standard group.

There were no statistically significant differences between the groups regarding baseline characteristics (Table 1). Regarding earlier contraception, 26/101 (25.7%) of women had used an IUD for contraception before the current pregnancy, of which 10/101 (9.9%) had used a Cu-IUD and 16/101 (15.8%) had used a hormonal IUD.

All hormonal IUDs were placed according to the allocated plan. No pregnancies occurred during the 1-year of follow-up after IUD placement.

TABLE 1 Baseline characteristics of included women

	Early insertion *N* = 52 Median IQR min-max	Standard insertion *N* = 49 Median IQR min-max	*p*-value
Age (years)	30 28–32 22–36	30 27–32 20–35	0.85
Parity (Nr)	2 1.25–3.0 1–4	2 2.0–2.0 1–4	0.48
Vaginal deliveries (Nr)	2 1–2 1–4	2 1–2 1–4	0.59
Cesarean sections (Nr)	0 0–0 0–1	0 0–0 0–1	0.76

IQR, interquartile range.

In the early group there were three removals (3/52, 5.8%) on patient request due to perceived side effects (coital bleeding, mood changes and itching). In the standard group there were five removals 5/49 (10.2%) on patient request, in two cases due to pregnancy intention and three removals due to perceived side effect (daily spottings, frequent spottings and mood changes). There were two perforations (2/49, 4.1%) in the standard group, both diagnosed more than a year after application and after completion of the study. One was a partial perforation diagnosed due to pregnancy intention, and one was a complete perforation diagnosed during a check-up due to unintended early pregnancy.

A total of 10 women in the early group chose to have a new hormonal IUD placed after the first one was partially or completely expelled. Thus, 39/52 (75%) of the women in the early group had used the hormonal intrauterine device method continuously at study completion compared with 41/49 (83.7%, $p = 0.22$) in the standard group. In the early group one woman chose to have an implant inserted, resulting in use of long-acting reversible contraception in 40/52 women (76.9%) at the closure of the study. In the standard group, one woman chose to have an implant inserted and one chose to have a Cu-IUD placed after removal of the hormonal IUD, resulting in continued use of long-acting reversible contraception in 43/49 (87.8%, $p = 0.11$) women at study closure 1 year after IUD placement.

There was no significant difference in reported pain during application of the hormonal IUD measured by the VAS between the groups. Women reported a median pain level of 20 (20/100; min-max 0–70) VAS in the early group and a median pain level of 24.5 (24.5/100; min-max 0–84, $p = 0.77$) VAS in the standard group.

All women in both groups would choose to have a hormonal IUD placed again when asked directly after placement.

The period of bleeding after delivery was significantly shorter in the early group (21 vs 30 days, $p < 0.01$).

The proportion of women in the early group preferring early placement was 31/41 (75.6%) and the proportion of women in the standard group preferring standard placement was 30/45 (66.7%) ($p = 0.48$). Furthermore, at the 6-month follow-up, 37/41 (90.2%) of women in the early group would choose the hormonal IUD method again compared with 42/45 (93.3, $p = 0.70$) of women in the standard group. At the 12-month follow-up, all women were asked if they would recommend the hormonal IUD method to a friend based on the current experience. In the early group 36/43, (83.7%) of women would recommend the method to a friend compared with 42/44 (95.5%, $p = 0.089$) of women in the standard group.

At the 6-month follow-up, 27/41 (65.9%) in the early group and 24/46 (52.2%) in the standard group were partially or exclusively breastfeeding. There were no significant differences in breastfeeding length ($p = 0.34$) or the proportion of women who exclusively breastfed ($p = 0.14$). At the 12-month follow-up, two women continued exclusive breastfeeding in the early group and two women in each group partially breastfed. There were no differences in infant growth in terms of weight ($p = 0.97$), length ($p = 0.19$) or head circumference ($p = 0.07$) at the age of 12 months.

Detected treatment emergent adverse events did not differ between groups.

4 | DISCUSSION

This study was prematurely discontinued due to the high expulsion rate, reaching 44% in the early placement group. The setting of the study was influenced by the promising results of Cu-IUD placement postpartum and was initiated because studies on hormonal IUDs were few and lacked sufficient power.[12–14] There are now recently published studies with high expulsion rates of up to approximately 46% after IUD/IUS placement within 48 h after vaginal delivery[11] but with a wide range of variation.[9] In contrast, studies of IUD/IUS placement during an elective cesarean section consistently reports low expulsion rates.[11]

In a randomized trial by Marangoni et al., a vaginal ultrasound was performed at three timepoints during the first year following post-placental IUD placement after vaginal delivery. The expulsion rate reached 43.8% within the first year. Most expulsions were detected within the first 42 days after placement but cases occurred from 3 months up to a year after placement.[15] Laporte et al. reported similar results detecting most expulsions within the first 42 days after placement, but follow-up ended 3 months after placement.[16] Our findings are consistent with the findings of Marangoni et al., highlighting that the final evaluation of true expulsion rates are most accurately based on a long-term follow-up and can only cautiously be evaluated within the first months following IUD placement.

Our primary outcome for the original power calculation was the proportion of pregnancies as a measure of method failure. We note that no pregnancies occurred before the study was prematurely closed, but due to the premature stop of inclusion and subsequent lack of power, we cannot draw any conclusion regarding our primary outcome.

Cooper and co-workers reported a similar high expulsion rate, but their protocol included an offer of a re-insertion which was accepted by 87.6% of the women. In their study, the method continuation 1 year later reached almost 80%.[17] In the present study, 10 of 23 women who experienced expulsion, chose placement of another hormonal IUD or Cu-IUD before the study was closed. There was no defined process for IUD replacement in the study protocol. None of the replaced IUD/IUS was expelled, and thus 75% of women in the early group continued to use the hormonal IUD method at the 1-year follow-up.

The continuation rate 1 year after early IUD placement is thereby similar to standard placement. Country, local and personal specific issues such as economic resources, insurance systems, and individual costs has been deemed important.[18] Immediate and early IUD-placement postpartum may entail advantages also in a high resource setting as close to 30% of women in Sweden abstain from the postpartum visit. Importantly, women should be informed about the advantages and disadvantages with early placement of an IUD. Considering the superior advantage of early initiation of postpartum contraception, the method can be recommended when followed by routine check-ups and an offer of IUD replacement in the case of expulsion.

Previous studies of postpartum hormonal IUD placement have not reported a comparison of the length of bleeding after early and standard placement after vaginal delivery. Women in the present study receiving an early placed hormonal IUD reported significantly fewer bleeding days postpartum compared with women with standard placement. Shorter post-abortion bleeding has been reported after hormonal IUD placement after medical abortion,[19] which may support that this is a consistent finding and that timing of placement of hormonal IUDs influences length of post-pregnancy bleeding.

The overall satisfaction with the hormonal IUD method including placement at allocated time was high in the present study. More than 90% of women in both groups would choose the hormonal IUD method including the placement procedure again, and up to 95% would recommend the method to a friend. The additional health benefits of hormonal IUD and the feeling of being "taken care of" in the present study might explain the high percentage of satisfaction. Additionally, 26% of all women in the study had used a Cu-IUD/hormonal IUD as the contraceptive method closest to the last pregnancy, and thus had experience of using the method before.

We found no statistically significant difference regarding the length of breastfeeding or the proportion of women who exclusively breastfed at the 6-month follow-up. Dahlke et al. reported the same results when comparing breastfeeding after hormonal IUD placement at three time points (immediately, early and standard) after vaginal delivery.[12] Furthermore, we found no differences regarding infant growth, supporting the safety of the method of early hormonal IUD placement after delivery for breastfed neonates.

The standard for early postpartum placement of IUDs has so far been using Kelly's placental forceps. We instead chose to use the inserter supplied by the manufacturer for the early group as well, to simplify the procedure. All staff engaged in the study had long experience in IUD placement. Before the start of the study all staff agreed on the standardized insertion procedure, but no formal training was undertaken. This can be considered as a weakness of the design, as there might be a learning curve for postpartum insertions.[17] However, we found no differences in the number of expulsions between early and late study periods, and the rate of expulsions is equal to that of Cooper et al., who practiced the procedure through a training period preceding their study.[17]

No immediate post-placental insertion was included, and we consider the length of the inserter sufficient for fundal placement. We did not, however, perform any ultrasound examinations to confirm fundal placement to make the methods and results transferable to settings without this resource.

We failed to find any study comparing the standard inserter with insertion using forceps and there are only few studies comparing different methods used for placement of an IUD postpartum. None of these studies, however, has found any major differences between different methods used.[9,20,21]

All staff engaged in the study were experienced in IUD placement, but despite this, two perforations were found in the standard placement group. This once again highlights the importance of carefulness when performing IUD placement at the standard time point during breast feeding.

The long 1-year follow-up period is one of the major strengths of the present study. Only a few randomized controlled trials have the corresponding long-term follow-up. The study was prematurely closed because of a high proportion of IUD expulsions why only 101 women were included instead of intended 600 women. The smaller sample size has affected the possibility to explore our primary outcome as we by far did not reach the estimated power, which is a main limitation of the present study. However, we were able to demonstrate that the women in the present study receiving an early placed levonorgestrel intrauterine system (LNG-IUS) reported significantly fewer bleeding days.

Advantages with early placement may be difficult to show in a randomized trial of highly motivated women. In "real life" a substantial proportion of women probably abstain from the visit of planned IUD/IUS placement.

5 | CONCLUSION

Because the study was prematurely stopped, data remain inconclusive as to whether early hormonal IUD placement is non-inferior to standard placement after vaginal delivery in terms of preventing unintended pregnancies and termination of pregnancy. However, our findings support the evidence that placement of an intrauterine device within the first 48 h of vaginal delivery is safe, with few complications, a shorter duration of bleeding and with a high patient satisfaction. The proportion of hormonal IUD expulsion is high after early placement, but in a setting where quick IUD replacement is possible, the continuation rate of the hormonal IUD 1 year after delivery is comparable to that of standard placement.

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CONFLICT OF INTEREST

None.

AUTHOR CONTRIBUTIONS

KLL and JB: conception and design. All authors contributed to the analysis and interpretation of data and drafting the article, and approved the final version to be published.

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