The Journal of Obstetrics and Gynecology of India (March–April 2021) 71(2):150–155
https://doi.org/10.1007/s13224-020-01409-2

ORIGINAL ARTICLE

Postplacental Insertion of Levonorgestrel Intrauterine System Versus Copper Intrauterine Device: A Prospective Study

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Received: 15 May 2020 / Accepted: 27 November 2020 / Published online: 20 January 2021

Abstract

Purpose To compare between postplacental insertion of levonorgestrel intrauterine system versus copper intrauterine device regarding expulsion rates, patient satisfaction, complications, and continuation rates.

Methods This prospective observational study was conducted on 1100 participants divided in to two groups: group (1) CU-IUD group and group (2) LNG-IUS group where women were assigned for postplacental insertion of either CU-IUD or LNG-IUS, respectively. Follow-up at 6 weeks, 3 and 6 months postpartum and data were collected and analyzed to evaluate outcomes.

Results No statistical difference between both groups regarding patients' characteristics, the overall expulsion rate was higher in LNS-IUS group than CU-IUD group; 77 patients (14%) and 50 patients (9%), respectively, (P value < 0.05), odds ratio: 1.63 at CI: (1.12–2.37). No significant difference between the two groups regarding pain intensity, perforation, abnormal uterine bleeding, and clinical endometritis ($P > 0.05$). Overall satisfaction rate at six months was 478(87%) in the CU-IUD group and 472(85.8%) in the LNS-IUS group (P value > 0.05), odds ratio: 1.1 at CI: (0.78–1.55). Continuation rate at s6 months was comparable between the two groups 485 (88.2%) and 480 (87.3%) in CU-IUD group and LNS-IUS group respectively, (P value < 0.05), odds ratio: 1.09 at CI: (0.76–1.56).

Conclusion The rate of expulsion of LNG-IUS is higher than copper IUD when inserted postplacental, yet the continuation and acceptability rates were comparable between the two groups.

Keywords Postpartum contraception · Intrauterine device · Levonorgestrel intrauterine system · Long-acting reversible contraception · Postplacental IUD · IUD expulsion

Introduction

Variable methods of contraception should be explained to women during the antenatal visits and women should be counseled about the method and possibility of starting it immediately postpartum [1]. The use of long-acting reversible contraceptive method (LARC) such as copper intrauterine device (IUD) and levonorgestrel releasing intrauterine system (LNG-IUS) is highly effective, and sexual activity can be resumed any time with good patient satisfaction despite the high rate of expulsion [2–4]

The aim of this study was to compare between postplacental insertion of levonorgestrel intrauterine system and copper intrauterine device regarding expulsion rates, patient satisfaction, complications, and continuation rates.

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Materials and Methods

This prospective observational study was conducted in the department of Obstetrics & Gynecology, Faculty of Medicine Menoufia university Hospital, Menoufia Governorate, Egypt, in the period between January 2018 and December 2019. The local institutional review board in Menoufia University hospital and research ethical committee have formally approved the study protocol, and an informed consent had been signed by all participants after explanation of the study objectives. All women with normal vaginal delivery at term pregnancy willing for insertion of LARC and request insertion of CU-IUD or LNG_IUS were eligible to participate in the study. Women with primary postpartum hemorrhage, cervical tears, extended episiotomy, those delivered by CS, women with medical complications during pregnancy, and women refusing to participate at counseling were excluded from the study.

Calculation of the sample size was based on the rate of expulsion of CU-IUD after postplacental insertion of 8% from the literature [5], a total of 967 participants were required for the study to have a power of 80% at one-tailed alpha level of 0.05. For compensation of possible drop out cases, 1134 women were enrolled and randomly allocated into two groups generated by the study statistician (using online research randomizer software program: group (1) CU-IUD group: 566 participants were assigned for postplacental insertion of CU-IUD (copper T-380 IUD, DPK, Egypt). and group (2) LNG-IUS group: 568 participants were assigned for postplacental LNG-IUS (Mirena, Bayer HealthCare, Berlin, Germany) insertion and finally a total of 1100 participants (550 in each group) were analyzed after exclusion of 34 women due to failed insertion in some and loss of follow-up in others) Fig. 1: Flow diagram (postplacental insertion means insertion within 10 min after delivery of the placenta [6]. Follow-up at 6 weeks postpartum, this was done routinely for all deliveries according to hospital policy. Then women were given appointments at 3 and 6 months to assess and to record outcome measures. Primary outcome was expulsion rates. Expulsion was defined as the presence of the device within the cervical canal or the vagina or failure to detect device by both transvaginal ultrasound and abdominopelvic x ray. Secondary outcomes included side effects, acceptability and continuation rates. Clinical endometritis was diagnosed by fever greater than 38 °C for two consecutive days (excluding the first 24 h) during the first 10 days postpartum, leukocytosis, lochia with foul odor associated with spontaneous pain or tenderness over the uterus and/or uterine subinvolution. Women were given menstrual calendars recommended by the WHO to record bleeding episodes and bleeding-free intervals during the follow-up period. Very slight bleeding not requiring sanitary protection was considered vaginal spotting, whereas bleeding requiring sanitary protection was considered heavy bleeding. Women acceptability in terms of overall satisfaction and recommendation of the method of contraception to another woman was assessed at 6-month follow-up visit via a pre-designed questionnaire.

Statistical Analysis

Statistical analysis was done by computer using SPSS version 22 (SPSS Inc, Chicago, IL, USA). Quantitative data was expressed as means and standard deviations with student t-test was used to compare between the two groups, while qualitative data was expressed as number and percent with Chi-squared test was used to compare categorical outcome. Odds ratio with 95% confidence interval (CI) was evaluated for the outcome measures of both groups. P value ≤ 0.05 was considered to indicate significance and $p \leq 0.001$ was considered to indicate strong significance.

Results

There was no statistically significant difference between both groups regarding patients' characteristics in terms of age, parity, body mass index, gestational weeks at delivery and the use of episiotomy during vaginal delivery ($p > 0.05$) as depicted in Table 1.

There was a statistically significant higher rate of IUD expulsion in the LNG-IUS group notably at three months and total expulsion rate at six months after insertion compared to the copper IUD ($p < 0.05$) as revealed in Table 2.

There was no significant statistical difference between the two groups regarding side effects and complication in terms of pain intensity, perforation, abnormal uterine bleeding and clinical endometritis ($p > 0.05$) as shown in Table 3.

Continuation rate and patients' satisfaction at 6 months post-insertion was statistically comparable between the two groups as depicted in Table 4.

Discussion

Most of participants in the current study were multiparous who delivered at term with average body weight.

There current study revealed statistically significant higher rate of IUD expulsion in the LNG-IUS group notably at three months and total expulsion rate at six months after insertion. A little bit increase in parity in LNG-IUS group may, partially, justify the higher rate of IUD expulsion. However, the actual mechanism is unclear.

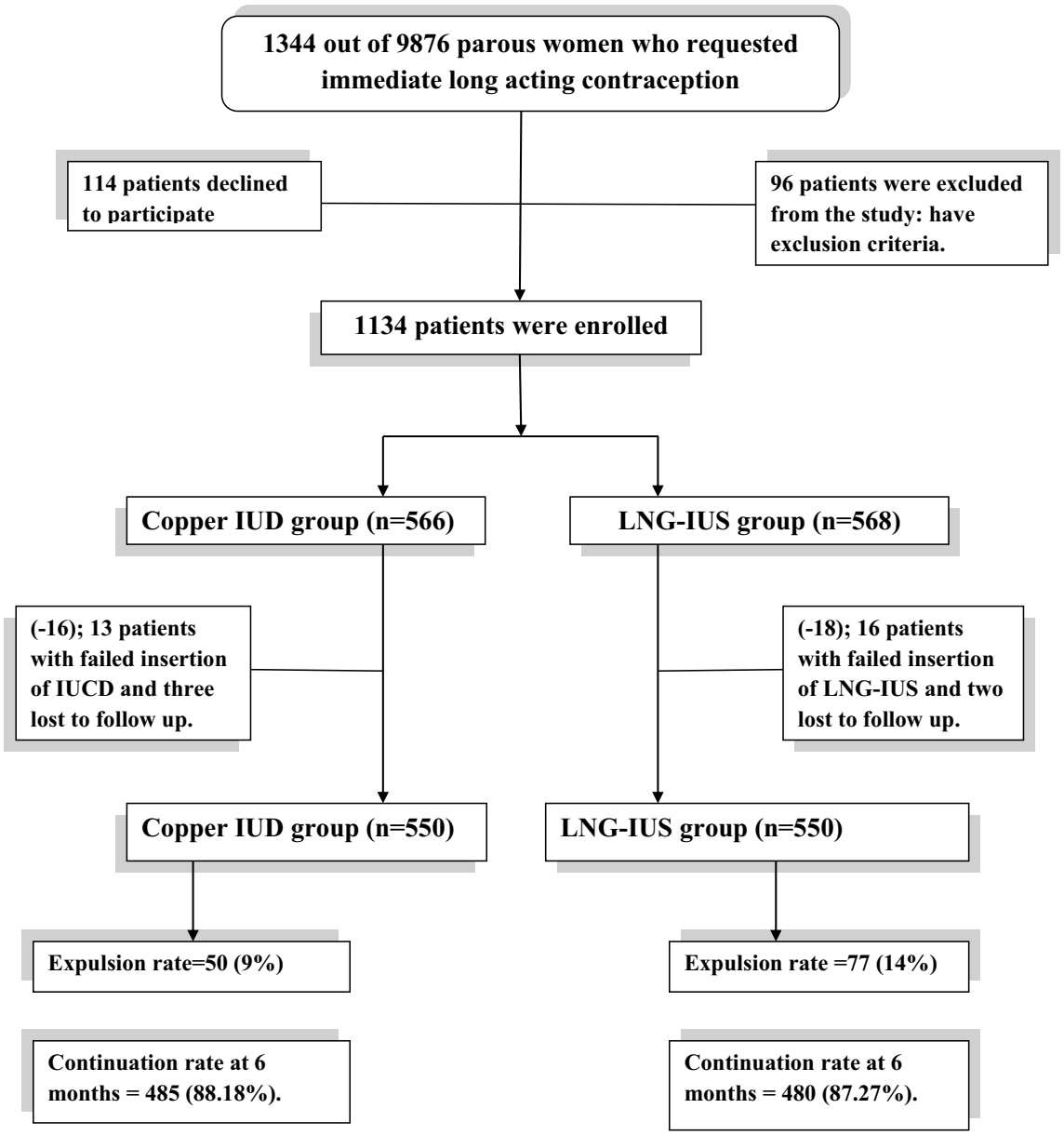

Fig. 1 Flow diagram of recruitment and retention of patients in the study

Table 1 Patient characteristics

Characteristic	CU-IUD (N:550)	LNS-IUS (N:550)	Student *t*-test	*P* value
Age (years)	29.2 ± 3.4	29.5 ± 3.3	1.49	0.14
Parity	2.6 ± 1.5	2.7 ± 1.8	1	0.32
Body mass index (kg/m^2)	24.9 ± 4.4	25.1 ± 4.9	0.7	0.48
Gestational age (weeks)	39.1 ± 1.6	389 ± 2	1.1	0.07
The presence of episiotomy (No & %)	310 (56%)	318 (48%)	0.37*	0.54

*Chi-square

Table 2 Expulsion rates

Expulsion rate		CU-IUD (N:550)	LNS-IUS (N:550)	Chi-square	P value	Odd's ratio at 95% CI
Partial	3 m	8 (1.5%)	11 (2%)	0.16	0.69	1.38(0.55–3.46)
	6 m	6 (1%)	6 (1%)	0.09	0.76	1 (0.32–3.12)
complete	3 m	25 (4.5%)	41 (7.5%)	3.87	0.049	1.69(1.01–2.82)
	6 m	11 (2%)	19 (3.5%)	1.79	0.18	1.75(0.8–3.72)
total		50 (9%)	77 (14%)	6.27	0.012	1.63(1.12–2.37)

Table 3 Side effects and complications

	CU-IUD (N:550)	LNS-IUS (N:550)	Chi-square	*P* value	Odd's ratio at 95% CI
Pain intensity VAS	4.64 ± 0.80	4.68 ± 0.81	0.82*	0.4	–
Perforation	0	0	–	–	–
Abnormal uterine bleeding	49(9%)	38(7%)	1.25	0.26	1.32 (0.85–2.05)
Clinical endometritis	14 (2.5%)	13 (2.4%)	0.008	1	1.08(0.5–2.32)

*Student t test

Table 4 Continuation rate and satisfaction rate at 6 months

	CU-IUD (N:550)	LNS-IUS (N:550)	Chi-square	P value	Odd's ratio at 95% CI
Continuation rate	485(88.2%)	480(87.3%)	0.14	0.71	1.09 (0.76–1.56)
Overall discomfort	92(16.7%)	78(14.2%)	1.18	0.27	1.22(0.88–1.69)
Overall satisfaction	478(87%)	472(85.8%)	0.19	0.66	1.1(0.78–1.55)
Recommendation to others	452(82.2%)	474(86.2%)	3.01	0.08	0.74(0.53–1.02)

There was also no significant difference between the two groups regarding patient characteristics: pain intensity, perforation, abnormal uterine bleeding and clinical endometritis. Overall satisfaction rate at 6 months was 478 patients in the CU-IUD group and 472 patients in the LNS-IUS group. Continuation rate at 6 months was comparable between the two groups 485 patients and 480 patients in CU-IUD group and LNS-IUS group, respectively.

In the current study, postplacental insertion of either CU-IUD or LNG-IUS was safe without increased risks of adverse outcomes and this is consistent with previous reports [7].

Considerable number of women who experienced vaginal delivery in Egypt requested long acting reversible contraception preferably intrauterine contraception as reported in previous studies [8–10].

The current study revealed a higher rate of IUD expulsion following the insertion of LNG-IUS versus copper IUD (14% versus 9%, respectively).

Earlier study reported a higher expulsion rate (38%) of LNG-IUS when inserted 6 h after delivery among 40 women. However, all participants reported that they would recommend this method of contraception to a friend [11].

A previous Cochrane review failed to address the rate of IUD expulsion rate in women using LNG-IUS compared to copper IUD following delivery, secondary to lack of large sample size trials [3].

A recent prospective study enrolled 325 women who received copper IUD (88, 27%), LNG-IUS(123, 38%), and implant (114, 35%) immediately after delivery before discharge from the hospital; revealed among LNG-IUS users 17% reported expulsions relative to 4% of copper IUD users. The adjusted hazard ratio for expulsion was 5.8 (confidence interval, 1.3–26.4) with the 6-month device continuation was ≥ 80% for all device types [12].

Another prospective cohort study on 123 women who were designated to receive postplacental intrauterine device; with 68 (55%) initiated LNG-IUS and 55 (45%) initiated copper IUD revealed unexpectedly higher expulsion rate in the LNG-IUS versus copper IUD at the 12th week follow-up visit (38% vs. 20%) [13]. A previous randomized trial conducted on 259 women who were randomly allocated for immediate ($n = 132$) or delayed ($n = 127$) insertion of LNG-IUS after vaginal delivery reported a significantly higher expulsion rate in the immediate insertion group compared to delayed insertion (19% versus 2%,

respectively). The authors concluded that this disadvantage may be outweighed by the advantages of immediate initiation of contraception [14]. This variability in expulsion rates could be attributed to different populations studied different follow-up intervals or endometrial status at the time of IUD insertion. However, a previous randomized trial was conducted on 112 women to address the best timing of LNG-IUS insertion in relation to the menstrual cycle, reported absence of any significant difference in pain perception throughout the cycle [15]. Two-week postpartum LNG-IUS insertion was associated with an expulsion rate of only 4%, which is far lower than the rate of immediate postplacental insertion as previously reported [16]. Reduced bleeding was associated with high overall satisfaction and continuation rates among LNG-IUS users when followed for up to 5 years as previously reported [17].

In this study, the continuation and acceptability rates were comparable between the two groups, which are consistent with previous trials.

The large cohort with low dropout rate constitutes the main strength of this study.

Inability to conduct a randomized trial and to prolong the period of follow-up was unintended limitations of the current study.

Multicenter randomized trials are needed to address the actual expulsion rate of LNG-IUS when inserted immediately postplacental and to draw other advantages of early initiation of contraception.

Conclusion

Although the rate of expulsion of LNG-IUS is higher than copper IUD when inserted postplacental, yet the continuation and acceptability rates were comparable between the two groups. Regarding side effects and complications, the two groups were comparable in the occurrence of pain, perforation, abnormal uterine bleeding and clinical endometritis.

Author contributions Elsayed Elshamy contributed to project development, manuscript writing, and editing. Ahmed Nofal contributed to project development, data collection, and data analysis. Dalia Ibrahim contributed to project development, data collection, and data analysis.

Compliance with ethical standard

Conflict of interest The authors declare that there is no conflict of interest associated with this manuscript.

Ethical statement State that the manuscript has not been published and is not under consideration for publication elsewhere. All the authors have contributed significantly, and are in agreement with the content of the manuscript. Declare that the study does not violate the policies and/or procedures established by the journal.

References

1. American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. Guidelines for Perinatal Care. 7th ed. Washington: AAP Publications; 2012. p. 580.
2. Braniff K, Gomez E, Muller R. A randomised clinical trial to assess satisfaction with the levonorgestrel- releasing intrauterine system inserted at caesarean section compared to postpartum placement. Aust N Z J Obstet Gynaecol. 2015;55(3):279–83.
3. Lopez LM, Bernholc A, Hubacher D, Stuart G, et al. Immediate postpartum insertion of intrauterine device for contraception. Cochrane Database Syst Rev. 2015. https://doi.org/10.1002/14651858.CD003036.pub3.
4. Gurney EP, Sonalkar S, McAllister A, Sammel MD, et al. Six-month expulsion of postplacental copper intrauterine devices placed after vaginal delivery. Am J Obstet Gynecol. 2018;219(2):183-e1.
5. Sucak A, Ozcan S, Çelen Ş, Çağlar T, et al. Immediate postplacental insertion of a copper intrauterine device: a pilot study to evaluate expulsion rate by mode of delivery. BMC Pregnancy Childbirth. 2015;15(1):202.
6. World Health Organization. Intrauterine devices: their role in family planning care. WHO. 1983;75:1–53 (**Evidence Grade: III**).
7. Whitaker AK, Chen BA. Society of family planning guidelines: postplacental insertion of intrauterine devices. Contraception. 2018;97(1):2–13.
8. Rezk M, Al-Halaby A, Emarh M, Shawky M. Correlation between uterine artery Doppler indices and menstrual irregularities among levonorgestrel releasing intrauterine system and depot medroxyprogesterone acetate users: a prospective observational study. Eur J Contracept Reprod Health Care. 2017;22(4):316–20.
9. Rezk M, Elshamy E, Shaheen AE, Shawky M, et al. Effects of a levonorgestrel intrauterine system versus a copper intrauterine device on menstrual changes and uterine artery Doppler. Int J Gynaecol Obstet. 2019;145(1):18–22.
10. Khalifa M, Abdelaziz W, Metwally S, Sakr E. The recent increase in contraceptive discontinuation in Egypt. J Biosoc Sci. 2020;52(1):154–7.
11. Stuart GS, Bryant AG, O'Neill E, Doherty IA. Feasibility of postpartum placement of the levonorgestrel intrauterine system more than 6 h after vaginal birth. Contraception. 2012;85(4):359–62.
12. Eggebroten JL, Sanders JN, Turok DK. Immediate postpartum intrauterine device and implant program outcomes: a prospective analysis. Am J Obstet Gynecol. 2017;217(1):51.e1-51.e7.
13. Goldthwaite LM, Sheeder J, Hyer J, Tocce K, et al. Postplacental intrauterine device expulsion by 12 weeks: a prospective cohort study. Am J Obstet Gynecol. 2017;217(6):674.e1-674.e8.
14. Turok DK, Leeman L, Sanders JN, Thaxton L, et al. Immediate postpartum levonorgestrel intrauterine device insertion and breast-feeding outcomes: a noninferiority randomized controlled trial. Am J Obstet Gynecol. 2017;217(6):665.e1-665.e8.

15. Van der Heijden P, Geomini P, Herman MC, Veersema S, Bongers MY. Timing of insertion of levonorgestrel-releasing intrauterine system: a randomised controlled trial. BJOG. 2017;124(2):299–305.
16. Zerden ML, Stuart GS, Charm S, Bryant A, et al. Two-week postpartum intrauterine contraception insertion: a study of feasibility, patient acceptability and short-term outcomes. Contraception. 2017;95(1):65–70.
17. Heikinheimo O, Inki P, Schmelter T, Gemzell-Danielsson K. Bleeding pattern and user satisfaction in second consecutive levonorgestrel-releasing intrauterine system users: results of a prospective 5-year study. Human Reprod. 2014;29(6):1182–8.

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