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The Safety, Acceptability and Continuation Rate of Immediate Versus Delayed Insertion of Levonorgestrel Releasing Intrauterine System Following First Trimester Surgical Abortion: An Observational Study

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Abstract

Objective: To assess the safety, acceptability and six-month continuation rate of immediate versus delayed insertion of the levonorgestrel releasing intrauterine system (LNG-IUS) following surgical termination of first trimester pregnancy.

Methods: This prospective observational study was conducted on 180 patients who underwent surgical abortion and opted for LNG-IUS and divided into two groups; immediate group=86 and delayed group=94. Pain scores, adverse effects, acceptability and continuation rate were recorded.

Results: More patients in the delayed insertion group exhibited higher perception of pain ($p<0.001$) and requested additional analgesia upon LNG-IUS insertion ($p<0.05$) with no significant difference between the two groups regarding other adverse effects (fainting, abnormal vaginal bleeding, expulsion and pelvic infection), request for removal and re-insertion of LNG-IUS ($p>0.05$). The continuation rate and patient acceptability in terms of overall satisfaction and recommendation to other women, were comparable between the two groups ($p>0.05$) while overall discomfort was higher in the delayed group at one, three and six months after insertion ($p<0.05$)

Conclusion: Although immediate insertion of LNG-IUS after first trimester surgical abortion has higher expulsion rate, yet it has lower pain intensity, request for additional analgesia and overall discomfort compared to delayed insertion of LNG-IUS with comparable continuation and acceptability rates at 6 months after insertion.

Keywords: levonorgestrel releasing intrauterine system; abortion; post abortive contraception

Introduction

Implementation of safe and effective method of contraception should be undertaken as a fundamental part of abortion care in order to prevent unwanted or unplanned pregnancy [1].

Return of fertility after a surgical abortion does not differ from that following a first-trimester spontaneous abortion with more than half of women having their sexual intercourse within 2 weeks after the procedure [2].

Post abortion contraception should fulfill two criteria; first to be received by the woman before leaving the hospital and second should be a Long-Acting Reversible Contraceptive (LARC) method [3].

Early insertion of the LNG-IUS reduced the number of days of heavy bleeding following a first trimester medical abortion [4].

The aim of this study was to assess the safety, acceptability and six-month continuation rate of immediate versus delayed insertion of the Levonorgestrel Releasing Intrauterine System (LNG-IUS) following surgical termination of first trimester pregnancy.

Materials and methods

This prospective observational study was conducted at the department of Obstetrics and Gynecology, King Abdul-Aziz Airbase hospital, Dhuhran, Saudi Arabia in the period between April 2016 and December 2017.

The institutional review board and the ethical committee have formally reviewed and approved the study protocol and all participants signed the informed consent form after thorough explanation of the study objectives.

Patients presented with first trimester missed, spontaneous or incomplete abortions were candidates for surgical termination of pregnancy and opting for LNG-IUS insertion, with gestational age between 8 and 12 weeks, were eligible to participate. Gestational age was determined by the last menstrual period when known in conjunction with Trans Vaginal Sonographic (TVS) measurements of crown-rump length or gestational sac.

Exclusion criteria included patients with septic abortion, molar pregnancy, any type of medical disorders, bleeding

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tendency, uterine abnormality as fibroids, any contraindication to LNG-IUS insertion or progestin therapy as well as those with failure of LNG-IUS insertion.

According to the hospital policy, surgical evacuation was accomplished via suction evacuation under general anesthesia. All patients received prophylactic Doxycycline 100 mg/12 hours during the entire period of termination. Trans vaginal sonography was performed for all patients after evacuation to assure endometrial thickness less than 15 mm with absence of any remaining products of conception prior to LNG-IUS insertion.

Sample size calculation was primarily based on the assumption of 5% difference between the two groups regarding the expulsion rate. Accordingly, 80 patients were needed in every single group for the study to have a power of 80% at 95% confidence interval and alpha level of 0.05. To compensate for possible drop out cases and non-evaluable data, we enrolled 189 patients.

After counseling, patients were divided into two groups based on their choices either immediate or delayed insertion of LNG-IUS as follows:

Group 1 (Immediate insertion group):

comprised 91 patients who requested immediate insertion of LNG-IUS (Mirena, Bayer HealthCare, Berlin, Germany) within 15 minutes after completion of the surgical procedure, and before discharge from the hospital. LNG-IUS failed insertion in two patients with three patients lost to follow so, 86 patients completed the study.

Group 2 (Delayed insertion group):

comprised 98 patients who requested delayed insertion of LNG-IUS (Mirena, Bayer HealthCare, Berlin, Germany) after 10-14 days following discharge from the hospital after instruction to abstain from sexual intercourse until insertion of the LNG-IUS. LNG-IUS failed insertion in two patients with two patients lost to follow so, 94 patients completed the study. (Figure 1: The flow diagram).

Follow up visits in the outpatient clinic were scheduled after one month, 3 months and 6 months following insertion of LNG-IUS. Patients were contacted via phone calls and electronic mails to attend the visits.

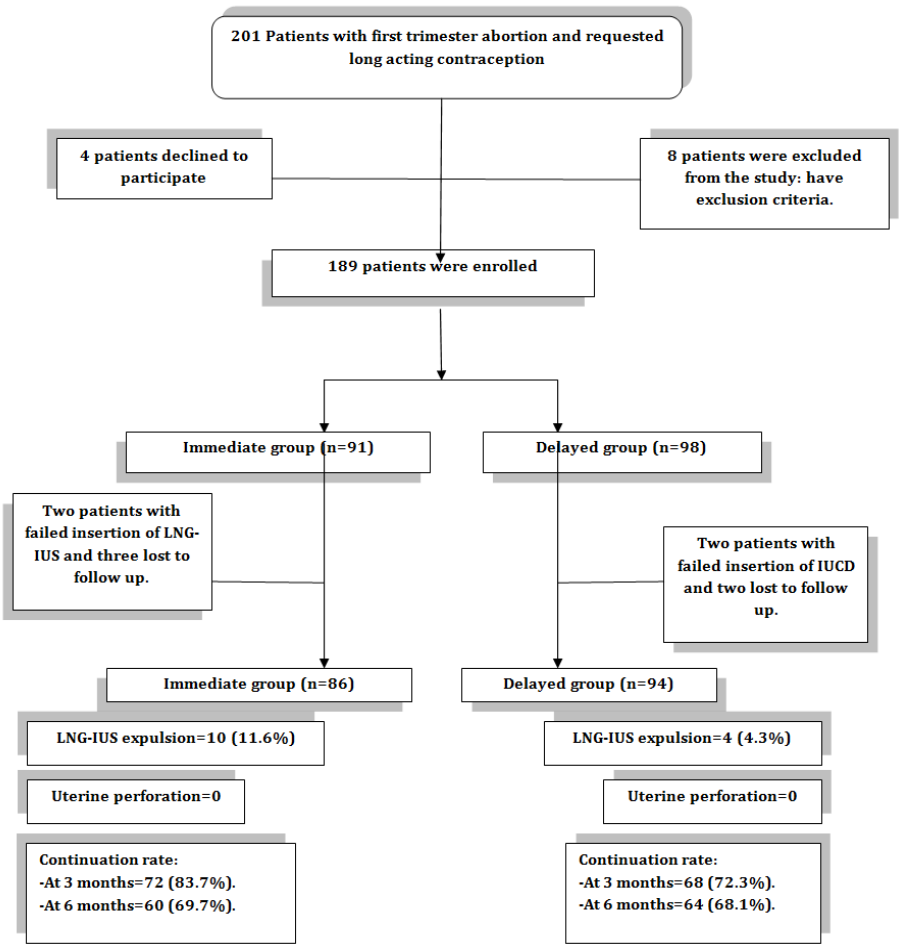

Figure 1: Flow diagram of recruitment and retention of patients in the study

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Outcome Measures

- Pain intensity was assessed on the Visual Analogue Scale (VAS) with range from zero to ten directly with points of 0 = no pain at all and 10 = the most distressing pain, after insertion of the LNG-IUS before administration of analgesics.

- Adverse effects of LNG-IUS as fainting, abnormal bleeding, expulsion, pelvic pain, pelvic infections, perforation and request for removal were recorded. Menstrual calendars were used to record the days on which women suffered bleeding as recommended by the World Health Organization (WHO) with participants recorded bleeding in a diary for 4 weeks. Expulsion was defined as the presence of the LNG-IUS within the cervical canal (partial) or the passage of the LNG-IUS out of the cervix (complete). Pelvic infection was considered to be present in women with purulent vaginal discharge, cervical or uterine tenderness, a tender adnexal mass, with other features of infection as fever or leucocytosis. Patients diagnosed with perforation or pelvic infection received the appropriate management at the hospital.

- Method acceptability in terms of overall discomfort, overall satisfaction and recommendation to other women. Acceptability was measured at the follow up visits.

Statistical analysis

Data was statistically analyzed by computer using SPSS version 22(SPSS Inc, Chicago, IL, USA). Parametric data was expressed as means and standard deviations with student t-test was used to compare between the two groups, while non-parametric data was expressed as number and percent with Chi-squared and Fischer's exact tests were used to compare categorical outcome where appropriate. P value ≤ 0.05 was considered to indicate significance and p ≤ 0.001 was considered to indicate strong significance.

Results

There was no significant difference between the two groups regarding age, parity, body mass index, gestational age, previous history of abortion or pelvic infection and endometrial thickness before LNG-IUS insertion (p>0.05) as depicted in (table 1).

More patients in the delayed insertion group exhibited higher perception of pain (p<0.001) and requested additional analgesia upon LNG-IUS insertion (p < 0.05) with no significant difference between the two groups regarding other adverse effects (fainting, abnormal vaginal bleeding, expulsion and pelvic infection), request for removal and re-insertion of LNG-IUS (p > 0.05) as revealed in (table 2).

(Figure 2) shows the adverse effects of LNG-IUS insertion in both groups.

The continuation rate and patient acceptability in terms of overall satisfaction and recommendation to other women, were comparable between the two groups (p>0.05) while overall discomfort was higher in the delayed group at one, three and six months after insertion (p<0.05) as shown in (table 3).

Table 1: Patients characteristics

	Immediate group (n=86)	Delayed group (n=94)	Student t-test	P-value
Age (years)	30.1±3.3	29.9±3.3	0.41	>0.05
Parity	2.4±1.6	2.8±1.2	1.91	>0.05
Body mass index (Kg/m^2)	25.8±4.3	26.1±4.7	0.45	>0.05
Gestational age (weeks)	7.6±4.3	7.7±4.1	0.16	>0.05
History of pelvic infection	7 (8.1%)	10 (10.6%)	0.1†	>0.05
Previous abortion	18 (20.9%)	24 (25.5%)	0.31†	>0.05
Endometrial thickness before LNG-IUS insertion	9.4±3.5	9.2±3.6	0.38	>0.05

†Chi square test

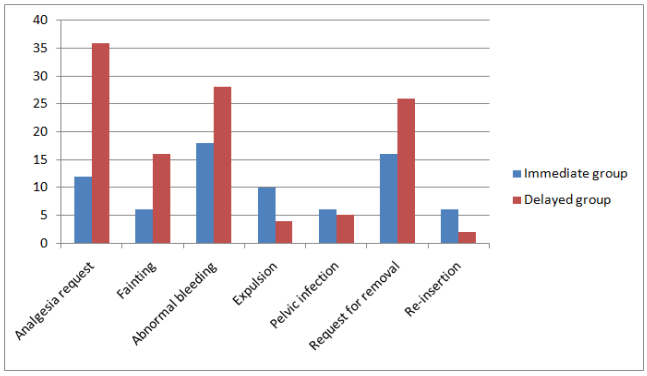

Figure 2: Adverse effects of LNG-IUS

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Table 2: Adverse effects of LNG-IUS

	Immediate group (n=86)	Delayed group (n=94)	Chi square test	P-value	Odd's ratio at 95% CI
Pain intensity (VAS)	5.3±0.82	6.6±1.5	7.12*	<0.001	-
Request for analgesia	12 (13.9%)	36 (38.3%)	12.39	<0.001	0.26 (0.12-0.55)
Fainting	6 (6.9%)	16 (17.1%)	3.55	>0.05	3.66 (1.12-11.99)
Perforation	0	0	-	-	-
Abnormal bleeding	18 (20.9%)	28 (29.8%)	1.42	>0.05	0.62 (0.32-1.23)
LNG-IUS expulsion:	10 (11.6%)	4 (4.3%)	2.45†	>0.05	2.96 (0.89-9.82)
Partial	6	3	-	-	
Complete	4	1	-	-	
Pelvic infection:					
At one month	6 (6.9%)	5 (5.3%)	0.02	>0.05	1.34 (0.39-4.54)
3 months	0	0	-	-	
6 months	0	0	-	-	
Request for removal:	16 (18.6%)	26 (27.6%)	1.58	>0.05	0.6 (0.29-1.21)
At one month	10	12	-	-	
3months	4	9	-	-	
6 months	2	5	-	-	
Re-insertion:	6 (6.9%)	2 (2.1%)	1.48†	>0.05	3.45 (0.68-17.58)
After expulsion	2	1	-	-	
After removal	4	1	-	-	
Pregnancy rate at 6 months	0	0	-	-	-

VAS=Visual analogue scale, *Student t-test, †Fischer's exact test.

Table 3: Continuation rate and acceptability of LNG-IUS

	Immediate group (n=86)	Delayed group (n=94)	Chi square test	P-value	Odd's ratio at 95% CI
Continuation rate:					
At one month	80 (93.1%)	82 (87.2%)	1.09	>0.05	1.95 (0.7-5.45)
3 months	72 (83.7%)	68 (72.3%)	2.74	>0.05	1.97 (0.95-4.08)
6 months	60 (69.7%)	64 (68.1%)	0.01	>0.05	1.08 (0.57-2.04)
Overall discomfort:					
At one month	8 (9.3%)	22 (23.4%)	5.46	<0.05	0.34 (0.14-0.8)
3 months	14 (16.3%)	28 (29.8%)	3.86	<0.05	0.46 (0.22-0.94)

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6 months	18 (20.9%)	34 (36.2%)	4.36	<0.05	0.47 (0.24-0.91)
Overall satisfaction:					
At one month	78 (90.7%)	78 (82.9%)	1.7	>0.05	2 (0.81-4.94)
3 months	70 (81.4%)	66 (70.2%)	0.07	>0.05	1.19 (0.56-2.53)
6 months	60 (69.7%)	60 (63.8%)	0.47	>0.05	1.31 (0.7-2.44)
Recommendation to others:					
At one month	76 (88.4%)	76 (80.9%)	1.4	>0.05	1.8 (0.78-4.15)
3 months	66 (76.7%)	62 (65.9%)	2.05	>0.05	1.7 (0.88-3.29)
6 months	58 (67.4%)	56 (59.6%)	0.88	>0.05	1.41(0.76-2.59)

Discussion

The current study confirmed that immediate insertion of LNG-IUS is safe and effective with comparable expulsion rate, acceptability and continuation rate at 6 months after surgical abortion when compared to delayed insertion with the advantage of lesser pain during insertion and lesser overall discomfort at 3 and 6 months.

In a recent prospective controlled study, 128 women have received counseling to adopt LNG-IUS contraception after termination of pregnancy with recording of pain scores, sexual function and quality of life (QoL) at 6 months following insertion. 62 women opted for LNG-IUS and 66 did not with positive changes in QoL and sexual function during LNG-IUS use [5].

Another recent multicenter, prospective, observational cohort study enrolled 512 women healthy women to whom intrauterine contraception were undertaken (LNG-IUS=312 and Cu-IUD=200) immediately after first-trimester surgical abortion and followed up to 6 months and concluded that LNG-IUS post-abortion shows better bleeding patterns, reduced dysmenorrheal and bleeding amount, but with a similar safety profile when compared with Cu-IUD [6].

In this study, the rate of LNG-IUS expulsion was higher in the immediate group (11.6%) compared to delayed insertion (4.3%) but did not reach to a significant difference.

In a recent pilot trial, randomized 108 women at ≤63 days' gestation, were randomized either to fast-track (n=55) or delayed (n=53) insertion of LNG-IUS after medical abortion. By 3 months, expulsion occurred in six (12.5%) women after fast-track and one (2.3%) woman after delayed insertion [7].

In our series, the continuation rate at 3 and 6 months was comparable between immediate and delayed insertion of LNG-IUS.

This is in contrast to the results of a recent randomized controlled trial conducted on 267 women who requested LNG-IUS insertion after medical termination of pregnancy up to 20 weeks with higher 1-year continuation rates in the early versus delayed insertion of LNG-IUS [8].

However, a previous Cochrane review has concluded that immediate insertion of an IUD after abortion is safe and practical but with higher expulsion rates. However, at six months post abortion, IUD use is higher following immediate insertion compared to delayed insertion [9].

LARC as LNG-IUS, Copper IUD and implants are more effective in preventing unwanted pregnancy and repeat abortion than short-acting methods like pills and barrier methods [10-12].

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

Future research should explore the expulsion and continuation rates in a larger multicenter study.

Conclusion

Although immediate insertion of LNG-IUS after first trimester surgical abortion has higher expulsion rate, yet it has lower pain intensity, request for additional analgesia and overall discomfort compared to delayed insertion of LNG-IUS with comparable continuation and acceptability rates at 6 months after insertion.

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