

Original Article

A randomised clinical trial to assess satisfaction with the levonorgestrel-releasing intrauterine system inserted at caesarean section compared to postpartum placement

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Background: Insertion of levonorgestrel-releasing intrauterine system (LNG-IUS) at caesarean section (CS) provides contraception prior to resumption of ovulation or sexual activity. Patient satisfaction with insertion at CS has not previously been studied.

Aims: The aim of this study was to compare patient satisfaction with LNG-IUS inserted at the time of lower uterine segment CS to six weeks postpartum.

Materials and Methods: Open-label randomised controlled trial. Women booked for elective CS were randomised to LNG-IUS insertion either at the time of CS (study group) or at six weeks postpartum (control group). The primary outcome measure was patient satisfaction. Outcomes were measured at six weeks, three months and six months postpartum.

Results: Forty-eight women were randomised into two treatment groups. Twenty-five women were randomised to have LNG-IUS inserted at the time of CS, 23 of whom had the planned intervention and two had the LNG-IUS inserted postpartum. Twenty-three women were randomised to the control group, four of whom withdrew prior to treatment. The 44 remaining women contributed to data analysis. Patient satisfaction was high and similar in both groups. At six months postpartum, 90.5% of the study group were very satisfied or somewhat satisfied compared with 88.2% of the control group.

Conclusions: Patient satisfaction is high with LNG-IUS insertion at CS and not different to that with delayed insertion. LNG-IUS insertion may be an option for women who find postpartum contraception difficult to access.

Key words: caesarean section, intrauterine devices, medicated, levonorgestrel-releasing intrauterine system, patient satisfaction, postpartum period.

Introduction

The levonorgestrel intrauterine system (LNG-IUS Mirena[®]; Bayer Healthcare) provides long-acting reversible contraception with satisfaction rates over 90%.¹ Insertion of LNG-IUS at the time of caesarean section (CS) provides immediate long-acting reversible contraception with several advantages over device insertion at the usual time of six to eight weeks postpartum (postpuerperal or delayed insertion). These advantages include convenience, high patient motivation and immediate contraception prior to resumption of

ovulation.^{2,3} Uptake may also be higher with insertion at the time of delivery, as two studies of LNG-IUS insertion at the time of CS⁴ and vaginal delivery⁵ both found that the women in the delayed insertion group were less likely to have the device inserted. Another benefit of insertion at CS is that women who have LNG-IUS inserted at CS also have less bleeding postpartum than women who have a copper-containing intrauterine contraceptive device (IUCD) inserted or no IUCD inserted at the time of CS.⁶

Despite the possible advantages of insertion of LNG-IUS at CS, the procedure is not commonly done in Australia, perhaps due to concerns about the safety of the procedure, visibility of strings and risk of expulsion.

There is reassuring evidence that insertion of an IUCD at the time of CS does not increase the risk of infection or perforation,^{2,7} whereas insertion in lactating women is associated with increased risk of uterine perforation.⁸

Rates of visibility of the LNG-IUS or IUCD strings in the vagina depend on the technique of insertion at CS. Strings are visible in the vagina in only 25% of women

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when the strings are not directed through the cervix;⁹ however, directing the strings through the cervix increases the chance of visibility at follow-up to 92%,¹⁰ and elongating the strings and threading them through the cervix using the insertion tubing increase string visibility to 100%.¹¹

Expulsion rates of various IUCDs inserted at the time of CS generally seem to be higher than after delayed insertion, with expulsion rates of 0–10.9% at six months following IUCD insertion at CS,^{7,10–13} compared with 3–5% following delayed insertion.^{14,15} Less data exist for expulsion of LNG-IUS inserted at CS, and expulsion rates may be device specific. Reported rates of expulsion of LNG-IUS inserted at CS range from 0⁹ to 20%.⁴

Another issue with immediate insertion of LNG-IUS at CS is the possible effect of progestogen on the infant via the breast milk. There is no evidence that the use of progestogen-containing contraceptives affects the quantity or quality of breast milk and they appear to have no deleterious effects on infant health.^{16,17} Despite this, the 2010 WHO medical eligibility criteria categorised progestogen-containing contraceptives as medical eligibility criteria category 3 (the theoretical or proven risks usually outweigh the advantages of the method) in the first four postpartum weeks in breastfeeding women, due to lack of data on possible long-term health effects of neonatal exposure to progestogens.^{17,18}

There is a paucity of data on insertion of LNG-IUS at CS. Randomised controlled trials of LNG-IUS insertion at CS have assessed usage at one year (compared to LNG-IUS insertion six to eight weeks postpartum⁴) and bleeding patterns (compared to copper-containing IUCD inserted at CS or no device inserted at CS⁶). No studies have specifically examined uptake rates or patient satisfaction with LNG-IUS inserted at CS,³ and large studies are required to look at effectiveness and device expulsion.

A randomised controlled clinical study was conducted to assess and compare patient satisfaction after six months in women with LNG-IUS inserted at the time of CS (study group) with those who had LNG-IUS inserted six weeks postpartum (control group). We also collected data on some safety aspects (pelvic infection and uterine perforation), visibility of strings in the vagina, device position within the uterine cavity, expulsion, vaginal bleeding, breastfeeding rates and infant weight gain.

Materials and Methods

All consecutive women who were planning to have an elective CS at Mackay Base Hospital in regional North Queensland between 1 January 2011 and 31 December 2012 were invited to take part in the study in the antenatal clinic. The only exclusion criteria were prolonged rupture of membranes, suspected chorioamnionitis, uterine anomalies, cervical dysplasia, age under 18 years and inability to give informed consent.

After informed consent was obtained, women were randomised to have the LNG-IUS inserted at the time of

CS (study group) or at the usual time six weeks later (control group). Randomisation was done in blocks of 10 using a computer-generated list. Allocation forms were in sequentially numbered sealed opaque envelopes.

The nature of the intervention made blinding impossible; thus, the study was conducted as open label, with both patients and clinicians aware of the treatment allocation.

LNG-IUS insertion in the experimental group was performed using the technique described by Puzey,⁹ the only published method identified at the time of the study. The LNG-IUS was inserted by an obstetrician or an obstetric registrar experienced in the normal method of insertion of the LNG-IUS. The device was inserted through the uterine incision to the fundus of the uterus using the normal applicator. The strings were cut at the level of the uterine incision and gently pushed up against the posterior wall of the uterus, and not pushed through the cervix. The device was not sutured into the cavity, and the uterine muscle closure was performed as per normal practice. All women had prophylactic antibiotics at the time of CS as per normal practice. LNG-IUS insertion in the control group was performed in the usual way by an experienced obstetrician or obstetric registrar.

Follow-up visits were performed by doctors in the women's health clinic six weeks, three months and six months after delivery. At each follow-up visit, women were asked to rate their satisfaction with LNG-IUS on a five-point scale (ranging from very dissatisfied to very satisfied). They were also asked about breastfeeding behaviour and difficulties, and recent bleeding pattern. At each visit speculum, vaginal and pelvic ultrasound examinations were performed and baby weights were recorded. As per the study protocol, LNG-IUS that were low or oblique within the uterine cavity were removed and a replacement LNG-IUS offered.

The primary outcome was patient satisfaction at six months postpartum. Secondary outcomes were safety aspects (pelvic infection and perforation), string visibility, correct device position (including expulsion), vaginal bleeding, breastfeeding, breastfeeding difficulties and infant weight gain.

Sample size calculations revealed that a sample size of 16 (in each group) provided power in excess of 80% to detect a difference of 0.5 on the satisfaction scale (the smallest difference deemed clinically relevant) from the expected mean in the control group of 4.5 (with a standard deviation of 0.5) as significant at an alpha level of 5%. The targeted initial sample size was increased to 25 women per group to account for patient attrition (such as loss to follow-up).

All statistical analyses follow the intention-to-treat principle. Descriptive statistics were based on percentages (categorical variables) or mean (SD)/median (interquartile range), depending on normality assumptions of the underlying numerical variables.

Bivariate tests for categorical variables between the groups were conducted using exact binomial tests

(standard for nominal variables; trend tests for ordinal variables). Bivariate tests for numerical variables employed were *t*-tests when normality assumptions held or exact versions of Wilcoxon tests otherwise.

The main outcome (dichotomised to positive/indifferent or negative responses) was also checked by multivariate logistic regression modelling for potential confounding. Crude and adjusted odds ratios, together with their 95% confidence limits, were calculated.

All statistical analyses were conducted using STATA version 12 (StataCorp LP, College Station, TX, USA) at a *P*-level of 5%.

Results

Forty-eight women were recruited to the study and randomised. Twenty-five women were randomised to have LNG-IUS inserted at CS (study group). Twenty-three of these women had the planned intervention; two women did not have the LNG-IUS inserted at the time of CS because the device was forgotten or not available at the time of surgery. Both of these women had it inserted six weeks postpartum and were analysed with the study group according to intention-to-treat principles. Twenty-three women were randomised to have the LNG-IUS inserted at the usual time six weeks postpartum (control group). Four of these women withdrew from the study prior to treatment and were excluded from the statistical analysis. Of the 44 women remaining in the trial, 100% attended at least one follow-up visit, 41 (93%) attended at least two follow-up visits, and 37 (84%) of women attended all three follow-up visits.

Table 1 displays the demographic data of the women in the two randomised groups. Since patients in the control group were slightly younger, additional multivariate checks for potential confounding were conducted with respect to the main outcome (see below).

Patient satisfaction at six months was the primary outcome. Satisfaction at six months (and during the whole of the follow-up period) was not significantly different between the two groups. At six months, 90.5% (19/21) in the study group were very or somewhat satisfied, compared with 88.2% (15/17) in the control group ($P > 0.99$). The mean satisfaction rating at six months was 4.52/5 for the study group and 4.47/5 for the control group ($P = 0.87$; Table 2). The alternative hypothesis that satisfaction in the study group differs by at least 0.5 points on the assessed scale when compared with the control group thus is rejected. Adjusting for potential confounders (age, marital status, ethnicity, parity and number of prior vaginal deliveries) validates the above-stated bivariate findings with no significant results for the treatment effect in the adjusted model ($P = 0.90$), thus disproving any relevant confounding originating from the assessed variables.

There were no pelvic infections or uterine perforations due to insertion of LNG-IUS in either group.

Table 1 Baseline characteristics of the study population

	LNG-IUS postpartum (<i>n</i> = 19)	LNG-IUS at caesarean (<i>n</i> = 25)	<i>P</i> -value
Age (mean (SD), years)	28.4 (4.8)	31.0 (4.9)	0.08
Ethnicity, % (<i>n</i>)			
White	89.5 (17)	84.0 (21)	0.68
Aboriginal/Torres Strait	10.6 (2)	4.0 (1)	
Other	0	12.0 (3)	
Marital status, % (<i>n</i>)			
Married	63.2 (12)	72.0 (18)	0.75
De facto	36.8 (7)	24.0 (6)	
Separated	0	4.0 (1)	
Parity, % (<i>n</i>)			
1	5.3 (1)	8.0 (2)	0.80
2	52.6 (10)	40.0 (10)	
3 or more	42.1 (8)	52.0 (13)	
No of vaginal deliveries, % (<i>n</i>)			
0	84.2 (16)	88.0 (22)	>0.99
1	10.5 (2)	8.0 (2)	
2 or more	5.3 (1)	4.0 (1)	
Infant birth weight (mean (SD), g)	3553 (665)	3673 (605)	0.53

LNG-IUS strings were significantly more likely to be visible in the control group compared with the experimental group at six months (82.4% versus 31.6%, $P = 0.03$; Table 3).

There were no cases of LNG-IUS expulsion during the study although two LNG-IUS inserted at CS were subsequently found to be low or oblique within the uterine cavity on ultrasound examination, and two inserted postpartum were initially correctly positioned but found to be low in the uterine cavity on follow-up ultrasound examination (Table 3). According to the study protocol, these were removed. Three women had new devices inserted, and one woman whose LNG-IUS had been inserted six weeks postpartum declined insertion of a second device at six months postpartum. Neither of the two women who had LNG-IUS inserted at CS and subsequently found to be low or oblique within the uterine cavity had strings visible in the vagina. One of these women had her device removed easily using an Emmett thread retriever, and the other woman had her device changed under general anaesthesia.

Frequent vaginal bleeding was more common at six-week follow-up in the study group (50% versus 10.5%, $P = 0.009$) but not statistically different at three months or six months (Table 3).

Rates of breastfeeding were consistently higher in the group who had LNG-IUS inserted at the time of CS (52.4% versus 11.8% at six months postpartum, $P = 0.015$). Rates of difficulty with breastfeeding were low and not different between the two groups. There was no

Table 2 Patient satisfaction at six weeks, three months and six months postpartum following insertion of LNG-IUS at caesarean section or postpartum

	Six weeks		Three months		Six months	
	LNG-IUS Postpartum (<i>n</i> = 18)	LNG-IUS at CS (<i>n</i> = 22)	LNG-IUS Postpartum (<i>n</i> = 18)	LNG-IUS at CS (<i>n</i> = 23)	LNG-IUS Postpartum (<i>n</i> = 17)	LNG-IUS at CS (<i>n</i> = 21)
Very satisfied, % (<i>n</i>)	72.2 (13)	50.0 (11)	61.1 (11)	65.2 (15)	76.5 (13)	66.7 (14)
Somewhat satisfied, % (<i>n</i>)	11.1 (2)	30.9 (9)	22.2 (4)	13.0 (3)	11.8 (2)	23.8 (5)
Neither satisfied/dissatisfied, % (<i>n</i>)	16.7 (3)	9.1 (2)	16.7 (3)	17.4 (4)	0	4.8 (1)
Somewhat dissatisfied, % (<i>n</i>)	0	0	0	0	5.9 (1)	4.8 (1)
Very dissatisfied, % (<i>n</i>)	0	0	0	4.3 (1)	5.9 (1)	0
Mean (SD)	4.56 (0.78)	4.41 (0.67)	4.44 (0.78)	4.35 (1.07)	4.47 (1.18)	4.52 (0.81)
<i>P</i> -value (exact trend test)	0.66		0.87		0.99	

Table 3 Visibility of strings, LNG-IUS position and vaginal bleeding patterns in patients who received LNG-IUS at caesarean and postpartum

	LNG-IUS postpartum	LNG-IUS at caesarean	<i>P</i> -value
Strings visible, %			
Six weeks	100.0 (19/19)	29.2 (7/24)	<0.001
Three months	94.4 (17/18)	30.4 (7/23)	<0.001
Six months	82.4 (14/17)	31.6 (6/19)	0.003
Correct LNG-IUS position, %			
Six weeks	88.9 (16/18)	91.7 (22/24)	>0.99
Three months	94.4 (17/18)	91.3 (21/23)	>0.99
Six months	88.2 (15/17)	95.2 (20/21)	0.58
Frequent vaginal bleeding, %			
Six weeks	10.5 (2/19)	50.0 (12/24)	0.009
Three months	55.6 (10/18)	26.1 (6/23)	0.11
Six months	17.6 (3/17)	9.5 (2/21)	0.64

significant difference in infant weight gain between the two groups (Table 4).

Discussion

Insertion of LNG-IUS at the time of CS provides long-acting reversible contraception prior to resumption of ovulation and avoids the need for insertion six to eight weeks postpartum. There have been no large or long-term randomised controlled trials of LNG-IUS insertion at CS. This is the first study designed to assess patient satisfaction with insertion of LNG-IUS at CS compared to postpartum insertion. High follow-up was achieved with all women attending at least one follow-up visit. Analysis of the two groups by intention-to-treat principle showed that patient satisfaction with insertion of LNG-IUS at the time of CS was high and not different to satisfaction with insertion six weeks after delivery.

One finding of note is that all women randomised to have a LNG-IUS inserted at CS had the device inserted (though two insertions were performed six weeks postpartum). The four women who withdrew from the

Table 4 Breastfeeding practices, breastfeeding difficulties and mean infant weight gain in patients

	LNG-IUS postpartum	LNG-IUS at caesarean	<i>P</i> -value
Breastfeeding, %			
Six weeks	36.8 (7/19)	70.8 (17/24)	0.034
Three months	22.2 (4/18)	56.5 (13/23)	0.054
Six months	11.8 (2/17)	52.4 (11/21)	0.015
Breastfeeding difficulties, %			
Six weeks	5.3 (1/19)	12.5 (3/24)	0.62
Three months	0	0	
Six months	0	0	
Mean infant weight gain			
Six weeks	1496 g (510 g)	1399 g (612 g)	0.62
Mean (SD)	<i>n</i> = 15	<i>n</i> = 20	
Three months	2472 g (757 g)	2719 g (651 g)	0.32
Mean (SD)	<i>n</i> = 13	<i>n</i> = 21	
Six months	4361 g (792 g)	4163 g (1560 g)	0.69
Mean (SD)	<i>n</i> = 13	<i>n</i> = 14	

study had all been randomised to have LNG-IUS inserted postpartum. This finding is similar to the findings from other studies that women are less likely to have LNG-IUS inserted four to eight weeks postpartum than at the time of CS⁴ or vaginal delivery.⁵ It is plausible that women are less likely to attend to have LNG-IUS inserted six weeks postpartum due to difficulty or inconvenience of accessing postpartum care, or fear of an outpatient procedure.

One problem with LNG-IUS insertion at CS was that the strings were visible in the vagina in only 31.6% of women. This low rate was due to the insertion technique chosen, and modification of the insertion technique is likely to overcome this problem as two recent studies have shown that threading the strings through the cervix at the time of insertion results in much higher rates of strings being visible at follow-up.^{10,11}

Expulsion rates may be higher when LNG-IUS is inserted at CS (0–20%^{4,9}) compared with insertion six weeks later (3–5%), and larger studies are required to

address this issue. In this study, no LNG-IUS was expelled and there were two LNG-IUS low or oblique within the uterine cavity in each group. Ultrasound follow-up to check the position of the LNG-IUS in the cavity may be prudent regardless of the timing of insertion.

The women who had LNG-IUS inserted at CS were more likely to breastfeed their babies at six weeks, three months and six months postpartum (52.4% versus 11.8% at six months). There were no differences in the rates of breastfeeding difficulties or infant weight gain. The difference in breastfeeding rates was unexpected and may warrant further study, although the current controversial nature of progestogen-containing contraception in the neonatal period is acknowledged.¹⁸

Insertion of LNG-IUS at CS has a high rate of patient satisfaction and may have a role for women who desire effective reversible contraception and who have difficulty accessing care or who are reluctant to have postnatal insertion of a contraceptive device.

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Ethics Approval

Ethics approval for all parts of this study was obtained from The Human Research Ethics Committee of the Townsville Health Service District (HREC Reference number HREC/10/QTHS/50).

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. CONSORT 2010 flow diagram.