Immediate post-partum insertion of intrauterine devices (Review)

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[Intervention Review]

Immediate post-partum insertion of intrauterine devices

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Editorial group: Cochrane Fertility Regulation Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 5, 2010.
Review content assessed as up-to-date: 31 March 2010.

Citation: Grimes DA, Lopez LM, Schulz KF, Van Vliet HAAM, Stanwood NL. Immediate post-partum insertion of intrauterine devices. *Cochrane Database of Systematic Reviews* 2010, Issue 5. Art. No.: CD003036. DOI: 10.1002/14651858.CD003036.pub2.

ABSTRACT

Background

Insertion of an intrauterine device (IUD) immediately after delivery is appealing for several reasons. The woman is known not to be pregnant, her motivation for contraception may be high, and the setting may be convenient for both the woman and her provider. However, the risk of spontaneous expulsion may be unacceptably high.

Objectives

To assess the efficacy and feasibility of IUD insertion immediately after expulsion of the placenta. Our a priori hypothesis was that this practice is safe but associated with higher expulsion rates than interval IUD insertion.

Search strategy

We searched MEDLINE, CENTRAL, POPLINE, EMBASE, ClinicalTrials.gov, and ICTRP. We also contacted investigators to identify other trials.

Selection criteria

We sought all randomized controlled trials (RCTs) with at least one treatment arm that involved immediate post-partum (within 10 minutes of placental expulsion) insertion of an IUD. Comparisons could include different IUDs, different insertion techniques, immediate versus delayed post-partum insertion, or immediate versus interval insertion (unrelated to pregnancy). Studies could include either vaginal or cesarean deliveries.

Data collection and analysis

We evaluated the methodological quality of each report and sought to identify duplicate reporting of data from multicenter trials. Two authors abstracted the data. Principal outcome measures were pregnancy, expulsion, and continuation rates. Because the trials did not have uniform interventions, we were unable to aggregate them in a meta-analysis.

Main results

We found nine RCTs; one directly compared immediate post-partum insertion with delayed insertion. Expulsion by six months was more likely for the immediate group than the delayed insertion group (OR 6.77; 95% CI 1.43 to 32.14). In trials of immediate insertion alone, modifications of existing devices, such as adding absorbable sutures or additional appendages, did not appear beneficial. Most studies showed no important differences between insertions done by hand or by instruments. Lippes Loop and Progestasert devices did not perform as well as did copper devices.

Authors' conclusions

Immediate post-partum insertion of IUDs appeared safe and effective, though direct comparisons with other insertion times were limited. Expulsion rates appear to be higher than with interval insertion. Advantages of immediate post-partum insertion include high motivation, assurance that the woman is not pregnant, and convenience. The popularity of immediate post-partum IUD insertion in countries as diverse as China, Mexico, and Egypt support the feasibility of this approach. Early follow up may be important in identifying spontaneous IUD expulsions.

PLAIN LANGUAGE SUMMARY

Inserting an IUD right after childbirth versus a later time

Inserting an intrauterine device (IUD) right after childbirth can be good for many reasons. The woman is not pregnant and may be thinking about birth control. The time and place are convenient for the woman. However, the IUD might be more likely to come out on its own if put in right after having a baby. This review looked how safe it was to insert an IUD right after childbirth. We also looked at whether the IUD stayed in.

We did computer searches for randomized trials of IUDs inserted right after the placenta (afterbirth) delivered. We also wrote to researchers to find more studies. Trials could compare types of IUDs, ways to insert the device, or times for insertion.

We found nine trials; one compared insertion right after childbirth with a later time. The IUD was more likely to come out when inserted right away. The other eight studies looked at types of IUDs put in right after childbirth. We compared those results with studies of IUDs inserted at other times. Inserting an IUD in this setting appeared safe. The IUDs came out more often when put in just after childbirth. Changing the IUD design did not help. Most studies showed no major difference when the IUD was inserted by hand or with a holding instrument.

Putting in an IUD right after childbirth is common in China, Mexico, and Egypt. The timing seems to work well in some countries. Early follow up may help in noting IUDs that come out.

BACKGROUND

Insertion of an intrauterine device (IUD) immediately after delivery is appealing for several reasons. The woman is known not to be pregnant, and her motivation for contraception may be high. For women with limited access to medical care, the delivery affords a unique opportunity to address the need for contraception. In contrast, women waiting for IUD may experience an unintended pregnancy or never return for the insertion (Allen 2009). In one study from Colombia, 95% of women expressing a desire for immediate post-partum IUD insertion had it done. Only 45% of those wishing later insertion ultimately had an IUD inserted. While some of the latter group may have been ambivalent and later decided against an IUD, the inconvenience and expense of a return visit probably deterred some women (Echeverry 1973).

Some IUDs, such as the TCu 380A (UN 1997), confer contraceptive protection similar to that achieved with tubal sterilization (Peterson 1996). Compared with sterilization, however, use of an IUD is simpler, less expensive, and immediately reversible. Insertion of an IUD after delivery may avoid the discomfort related to interval insertion, and any bleeding from insertion will be disguised by lochia. However, immediate post-partum IUD insertion may have disadvantages as well. The risk of spontaneous expulsion may be unacceptably high (WHO 1980). The risk of uterine

perforation is unclear.

OBJECTIVES

This review assesses the safety and efficacy of immediate post-partum IUD insertion. Our a priori hypothesis was that this practice is safe but associated with a higher expulsion rate than interval insertion.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomized controlled trials having at least one arm with immediate post-partum IUD insertion, defined as within ten minutes of passage of the placenta (Cole 1984).

Types of participants

We included studies of post-partum women of any age.

Types of interventions

Insertion of any type of IUD within ten minutes of passing the placenta was eligible for inclusion. Comparisons could include different devices, different insertion techniques, immediate post-partum (within ten minutes of delivery of the placenta) versus delayed post-partum insertion, and immediate post-partum versus interval insertion (more than six weeks after delivery).

Types of outcome measures

Principal outcome measures included pregnancy, spontaneous expulsion, and continuation with the method.

Search methods for identification of studies

Electronic searches

We searched MEDLINE, Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, POPLINE, and LILACS. We also searched for current trials via ClinicalTrials.gov and International Clinical Trials Registry Program (ICTRP). The search strategies are given below.

MEDLINE via PubMed

(postpartum OR puerperium OR postcesarean OR delivery OR cesarean section) AND (iud* OR iucd* OR intrauterine devices OR intrauterine device) AND insert*

EMBASE

(iud? (3n)insertion? OR iucd? (3n)insertion) AND (postpartum OR puerperium) AND (trial? OR study).

POPLINE

1) IUD(kw) AND insertion(kw) AND (postpartum(tw) OR puerperium(tw) OR postcesarean(tw))
2) iud(kw) AND (clinical trials(kw) OR clinical research(kw)) AND (postpartum(tw) OR puerperium(tw) OR postcesarean(tw)).

LILACS

intrauterine devices or dispositivos intrauterinos or dispositivos intra-uterinos [Words] and childbirth or parto or delivery, obstetric or parto obstetrico or postpartum or posparto or pos-parto or puerperium or puerperio or cesarian section or cesarean [Words] and insertion or insertions or inserted or insert [Words].

CENTRAL

1) postpartum OR post-partum in Title, Abstract or Keywords AND IUD* OR intrauterine device* in Title, Abstract or Keywords
2) intrauterine device OR IUD) AND ((delayed OR immediate) AND insertion) in Title, Abstract or Keywords

ClinicalTrials.gov

(intrauterine device OR IUD) AND ((delayed OR immediate) AND insertion)

ICTRP

(intrauterine device OR IUD) AND ((delayed OR immediate) AND insertion)

Searching other resources

For the initial review, we used several comprehensive review articles to begin our search (Chi 1984; Chi 1994; Pop Info Prog 1995; WHO 1987; Xu 1994). We also contacted other investigators in the field to find studies we might have missed, including unpublished reports.

Data collection and analysis

For the initial review, two co-authors read the titles and abstracts of all the citations identified. We then obtained photocopies of those that appeared relevant. Two co-authors examined each article for possible inclusion and assessed the methodological quality of each. When necessary, we corresponded with the researchers to supplement information provided in the reports. Two co-authors independently abstracted data from each included article, and we resolved any discrepancies by discussion. Because the studies did not have uniform interventions, we were unable to aggregate the studies in a meta-analysis. Results are primarily expressed as gross cumulative event rates per 100 women unless otherwise stated.
Where only the crude number of events was published for dichotomous outcomes, the Mantel-Haenszel odds ratio (OR) with 95% CI was calculated using a fixed-effect model. An example is the proportion of women with spontaneous expulsion. Fixed and random effects give the same result if no heterogeneity exists, as when a comparison includes only one study. The Peto OR was used when a study arm had no events, e.g., pregnancy. The Peto OR does not require correction for zero events (Higgins 2009).
Most studies had insufficient sample sizes to assess rare events, such as uterine perforation.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Included studies

We included nine trials in this review. A recent study used the levonorgestrel-releasing intrauterine system (IUS), containing 52 mg levonorgestrel (Chen 2009). Women were randomized to immediate insertion (within 10 minutes of passing the placenta) or delayed insertion (6 to 8 weeks post-partum).
The other eight studies are 15 to 30 years old and examined immediate insertion.

- Multicenter trials (Cole 1984; Kisnisci 1985) studied the addition of absorbable chromic sutures tied around the superior arms of conventional IUDs. For example, investigators tied two chromic sutures (size No. 2) to the lateral arms of a Copper T 220 C (TCu 220C) with the free ends of the sutures left 0.5 cm long and projecting caudad at a 45-degree angle. This modification of the TCu 220C was termed the Delta T. Similarly, investigators tied three chromic sutures to the superior bar of a Lippes Loop D, thereafter termed the Delta Loop. Each of these modifications was compared to the conventional device without sutures. The other interventions examined in these two reports (Cole 1984; Kisnisci 1985) were hand versus instrument insertion of the various devices.
- Progesterone-releasing IUDs were the subjects of two trials. Lavin 1983 compared the conventional Progestasert IUD, containing 38 mg of crystalline progesterone released into the uterus over a year, with the Copper T 200 (TCu 200). A prototype of a longer-acting Progestasert contained 52 mg of progesterone (ICPS-52), designed to provide three years of protection. This was compared with the TCu 200 in Apelo 1985.
- The Population Council modified a Nova T device to have two flexible arms 2 cm in length added to the base of the vertical stem; the arms pointed superiorly at a 45-degree angle. This Nova T Postpartum (Nova-T-PP) and standard Nova T were otherwise identical. Van Kets 1987 compared the modified and standard Nova T, and WHO 1980 compared the Nova-T-PP with the Lippes Loop D and Copper 7 (Gravigard).
- Other interventions compared included the standard Multiload 250 (MLCu 250) versus TCu 200 (Thiery 1980) and hand versus ring-forceps insertion of a standard copper T 380A (TCu 380A) (Xu 1996).

Excluded studies

We excluded several trials from the review. Tatum 1996, despite its title, proved not to be a randomized controlled trial. Data from Thiery 1983 were included in a larger report (Cole 1984). Similarly, some data from an included study (Apelo 1985) were covered in the multicenter report of Cole 1984. We also excluded another subgroup analysis (Chi 1985) of the Cole 1984 data. Shikary 1987 examined delayed post-partum insertions.

Risk of bias in included studies

Although quality varied, several trials had good methods. Most used an appropriate method of generating the randomization sequence, and many attempted to conceal the upcoming assignment from those involved with the trials, usually by using sequentially-numbered, sealed, opaque envelopes. On the other hand, only Xu 1996 described an a priori hypothesis and provided a sample size calculation. Communication with researchers was necessary to supplement most of the published reports (Apelo 1985; Cole 1984; Kisnisci 1985; Lavin 1983; Xu 1996; WHO 1980). A recent trial had an abstract from a conference presentation; additional information was extracted from ClinicalTrials.gov (Chen 2009). The final report was in progress at this writing.

Effects of interventions

Immediate versus delayed insertion

Chen 2009 examined immediate post-partum versus delayed insertion of the levonorgestrel-releasing IUS. Expulsion by six months was more likely for the immediate group than the delayed insertion group (23.5% vs 4.4%) (OR 6.77; 95% CI 1.43 to 32.14) (Analysis 11.2). The groups were similar in pregnancy (none found) and in use at six months (84% and 77%, respectively).

Immediate insertion

The addition of chromic sutures to conventional IUDs had little impact on clinical outcomes (Cole 1984). Among more than 1300 women randomized to either a Delta Loop or Lippes Loop D, the only significant finding the researchers reported was a lower rate of expulsion with the Delta Loop at six months (15.7 versus 21.5 per 100 women). Gross six-month continuation rates with the two devices were 73.8 and 78.5 per 100 women, respectively. Among more than 1400 women randomized to either the Delta T or TCu 220C, the rates of expulsion at six months were 11.6 and 11.5 per 100 women, respectively. Six-month continuation rates were 81.8 per 100 women for both groups. The technique of insertion (hand versus inserter or forceps) had no significant impact on expulsion or continuation rates with the Delta Loop device (Cole 1984).

One center involved in the Cole 1984 multicenter trial reported its comparison of the Delta Loop and Delta T separately (Kisnisci 1985). Expulsion rates per 100 women at 12 months were 3.7 for the Delta Loop and 7.6 for the Delta T. The 12-month pregnancy rates were 2.1 and 0, respectively. The two devices had similar 12-month rates of removals for pain or bleeding: 1.1 and 1.0 per 100 women. Likewise, continuation rates were comparable: 93.3 and 90.7 per 100 women, respectively. No testing of statistical significance was reported.

The TCu 200 proved superior to the Progestasert for immediate post-partum insertions (Lavin 1983). The Progestasert had significantly higher expulsion rates than the T Cu 200, and the differences were independent of whether the devices had been introduced by hand or with an inserter. The 12-month rates for hand insertion and instrument insertion were 9.0 and 8.1 for the T Cu 200, while they were 35.8 and 35.2 for the Progestasert. The 12-month continuation rates were significantly higher for the TCu 200 groups (86.3 when introduced by hand and 86.1 for inserter) than for the Progestasert groups (59.9 and 57.2, respectively).

The TCu 200 also performed significantly better than the prototype three-year progesterone device (IPCS-52) (Apelo 1985). The 12-month rates for expulsion when hand-introduced were 39.0 for IPCS-52 and 19.9 TCu 200. The comparable rates for the inserter-introduced devices were 14.2 for the IPCS-52 and 10.3 for the TCu 200. The 12-month continuation rates per 100 women for the TCu 200 were 73.8 for hand inserted and 84.9 for instrument inserted. For the IPCS-52, the continuation rates were 57.3 for hand insertion and 77.1 for instrument insertion. The researchers tested for statistical significance after 36 months. The life-table rates of expulsion at 36 months were 39.0 for the hand-introduced IPCS-52, 24.2 for the inserter-introduced IPCS-52, 19.9 for the hand-introduced TCu 200, and 13.1 for the inserter-introduced TCu 200. Expulsion for the hand-inserted IPCS-52 was significantly greater than the hand- or instrument-inserted TCu 200. Removals for bleeding and pain were uncommon with both devices and did not change between 12 and 36 months. For pooled data, the researchers reported that the TCu 200 had a significantly lower expulsion rate than did the IPCS-52, and instrument insertions had a significantly lower expulsion rate than hand insertions.

Both trials of the modified Nova T found it to be no better than the standard Nova T (Van Kets 1987; WHO 1980). In the WHO multicenter trial (WHO 1980), spontaneous expulsion rates at six months for all three IUDs exceeded the predetermined stopping rules, so the trial terminated early. In this comparison of the Nova-T-PP, Lippes Loop D, and Copper 7, the Lippes Loop seemed inferior to the other two devices. The 12-month discontinuation rates per 100 women for expulsion were 41.3 for the Nova-T-PP, 44.1 for the Lippes Loop, and 34.8 for the Copper 7. Corresponding 12-month pregnancy rates were 5.6, 12.1, and 7.2 per 100 women. Total 12-month discontinuation rates were high with all devices: 53.1, 60.9, and 47.7 per 100 women. The discontinuation rate at 12 months was significantly higher for the Lippes Loop (60.9) than for the Copper 7 (47.7).

Outcomes with the modified and standard Nova T were more favorable in a single-center trial from Belgium (Van Kets 1987) than in the multicenter WHO trial (WHO 1980). Twelve-month spontaneous expulsion rates per 100 women were low with both the Nova-T-PP (6.2) and standard Nova T (6.6). The 12-month pregnancy rates were also low with both devices: 0.6 and 0.0, respectively. Continuation rates at 12 months were 87.4 for the Nova-T-PP and 78.2 for the Nova T. None of these differences was statistically significant.

The trial comparing immediate insertion of the MLCu 250 and TCu 200 found the two to be similar (Thiery 1980). Twelve-month rates of expulsion per 100 women were 9.9 for the MLCu 250 and 11.2 for the TCu 200. Corresponding pregnancy rates were 2.4 and 0.5. The 12-month continuation rates were 77.3 and 77.2, respectively. At 24 months, the differences between the devices in pregnancy and expulsion rates reportedly showed "borderline" significance.

The trial comparing hand with instrument insertion of TCu 380A IUDs found both techniques to be comparable (Xu 1996). Six-month expulsion rates per 100 women were 13.3 for hand insertion and 12.7 for instrument insertion. No pregnancies, perforations, or infections occurred.

DISCUSSION

We found one recently completed trial (Chen 2009) that directly compared immediate post-partum insertion with delayed insertion of the levonorgestrel-releasing IUS. Expulsion was higher in the immediate-insertion group. However, because of re-insertion of new devices after expulsion, the proportions of women using the device at six months were similar in the two groups. Many of the other IUDs in this review are no longer widely used. Good comparative evidence concerning timing may come from Thiery 1980, in which women requesting interval (N=1394) or immediate post-partum insertions (N=562) were randomized to two copper devices. Both IUDs had higher expulsion rates when inserted immediately post-partum than when inserted at times unrelated to pregnancy. In contrast, the expulsion rates in trials of immediate post-partum insertion generally appear lower than those reported with delayed post-partum insertions (Chi 1989).

We were unable to find any completed trials that examined IUD insertion at the time of cesarean delivery. However, an ongoing trial is comparing immediate insertion at cesarean delivery versus delayed insertion (NCT00635362). A cohort study from China (Chi 1984) found a significantly lower expulsion rate with IUD insertion at the time of cesarean delivery than with insertion immediately after vaginal birth. Case-series reports (Chi 1986; Ruiz-Velasco 1982) also suggest that insertions at cesarean delivery have a lower expulsion rate than do insertions after vaginal birth. Whether this relates to assurance of high fundal placement or to less cervical dilation is unclear.

Overall, immediate post-partum insertion of IUDs appears safe and effective. Another systematic review of immediate insertion included study designs other than RCTs (Kapp 2009). From their examination of copper IUD studies, the authors reached similar conclusions to ours. Decades ago, WHO 1980 judged expulsion and pregnancy rates to be excessive. IUD performance varied substantially by site in that study, suggesting that variable clinical experience, rather than patient characteristics, may have been responsible. Small sample sizes in these trials limited the precision of the outcome estimates, especially for rare outcomes such as infection or perforation. Other studies also suggest clinician experience may influence expulsion rates. A further analysis of Cole 1984 showed that insertions done in the first half of the trial were associated with significantly higher expulsion rates than were insertions in the second half (Chi 1985). The observational data of Thiery 1985 also showed that skilled clinicians were associated with lower expulsions rates of copper IUDs than were unskilled clinicians, though no definition of skill was provided.

Modifications of existing IUDs for immediate post-partum insertion were not helpful. These included the addition of absorbable sutures to the superior arms of T-shaped IUDs and Lippes Loops and addition of plastic arms to the vertical stem of a Nova T. The choice of insertion technique (hand versus instrument) also appeared to be clinically unimportant. Only one trial noted a significant difference (Apelo 1985), and recent trials with better methods have found no substantial differences (Xu 1996).

Immediate post-partum insertion of IUDs inevitably involves trade-offs. Expulsion rates appear higher in this setting than with interval insertions (Chen 2009; Chi 1989; Thiery 1980). The net effect of these expulsions is not clear from published studies; for example, if detected and another contraceptive begun, accidental pregnancies might not have resulted. Rates of perforation and infection appear similar to those reported in the literature (Cole 1984). Insertion of an IUD immediately after delivery is convenient for both the woman and clinician. Resumption of ovulation can be unpredictable after delivery, and an IUD provides highly effective contraception during the puerperium. Studies to date have not shown that IUDs interfere with lactation (Diaz 1993; Diaz 1997; Zacharias 1986).

Immediate post-partum IUD insertion is common in a number of countries (Moran 1992; Morrison 1996; Xu 1994). These include China, Mexico, and Egypt, where intrauterine contraception is popular. Clinical experience in these diverse settings confirms the practicality of this approach.

AUTHORS' CONCLUSIONS

Implications for practice

The evidence suggests that immediate post-partum insertion of IUDs is generally safe and effective. We found one recent trial that randomized women to time of insertion. Expulsion was higher for immediate versus delayed insertion. Other trials also showed expulsion rates after post-partum IUD insertions that were higher than those reported in the literature after interval insertions. Modifications of existing IUD designs have not been helpful in reducing expulsion rates. Insertions of IUDs by hand or by instruments appear to be equally successful.

Counseling women is difficult when evidence from randomized controlled trials is limited. The benefit of providing highly effective contraception immediately after delivery may outweigh the disadvantage of increased risk for expulsion. Early follow up, combined with self-examination for the presence of the strings, may be important in detecting early spontaneous expulsions (Thiery 1980).

Implications for research

Newer data are becoming available on this topic, although the studies are small. One examined post-placental insertion after vaginal delivery. An ongoing trial is examining insertion at the time of cesarean delivery versus interval insertion. Trials of adequate power are needed to compare immediate post-partum insertion with delayed post-partum and interval insertion.

ACKNOWLEDGEMENTS

Carol Manion of Family Health International assisted with the literature searches.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Apelo 1985

Methods	Randomized controlled trial comparing four devices and two insertion techniques. Computer-generated random number sequence, and sealed, sequentially-numbered opaque envelopes for allocation concealment.
Participants	400 women in Manila, Philippines, who had an IUD inserted within ten minutes of placental expulsion
Interventions	ICPS-52 (Intrauterine Contraceptive Progestasert System) with a 52 mg reservoir of progesterone designed for three years of use versus Copper TCu 200 IUD.
Outcomes	Principal outcomes included pregnancy, terminations for expulsion and bleeding/pain, and continuation.
Notes	The ICPS-52 was a modification of the original Progestasert IUD, which has a reservoir of 38 mg of progesterone, designed for one year of use. Delta Loop versus Lippes Loop D data are included in Cole (1984) and, hence, are not included here.

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

Chen 2009

Methods	Randomized controlled trial
Participants	102 women, 18 years or older. Inclusion criteria: >= 24 0/7 weeks pregnant at enrollment, anticipates undergoing a vaginal delivery, desires levonorgestrel-releasing system for postpartum contraception. Exclusion criteria: scheduled cesarean section; allergy to polyethylene or levonorgestrel or other contraindication to use of levonorgestrel-releasing system; exposure to or treatment for gonorrhea, chlamydia, or trichomoniasis during the pregnancy; leiomyomata > 3 cm diameter; uterine anomaly (other than a repaired septate uterus); current cervical cancer or carcinoma in-situ; desires repeat pregnancy within one year of delivery
Interventions	Levonorgestrel-releasing intrauterine system, containing 52 mg levonorgestrel: inserted after vaginal delivery (within 10 minutes of passing the placenta) versus delayed placement at 6 to 8 weeks postpartum
Outcomes	Primary: use at 6 months Secondary: expulsion, pregnancy, safety (infection and perforation), acceptability, attitudes towards contraception at 6 months Outcome data collected by phone interviews at 3 and 6 months
Notes	

Chen 2009 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	Not specified in abstract or in ClinicalTrials.gov posting

Cole 1984

Methods	Randomized controlled trial with three different comparisons. Computer-generated random number sequence, and sealed, sequentially-numbered opaque envelopes for allocation concealment.
Participants	3791 women participating in Family Health International trial of post-partum IUD insertions at 15 sites in 13 countries.
Interventions	Delta T (a TCu 220 with two chromic catgut sutures tied to the transverse arms; the free ends were 0.5 cm in length and pointed inferiorly) vs. TCu 220; Delta Loop (a Lippes Loop D with three similar sutures tied to the top of the device) versus the Lippes Loop D; and hand versus mechanical insertion of the Delta Loop.
Outcomes	Principal outcomes included pregnancy, terminations for expulsion, and continuation.
Notes	This report summarizes observational data and a series of multicenter trials conducted by Family Health International on modifications of existing IUDs. Only randomized controlled trial data are included in the review.

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

Kisnisci 1985

Methods	Randomized controlled trial comparing two modifications of existing IUDs. Computer-generated randomization sequence and sealed, sequentially-numbered opaque envelopes for allocation concealment.
Participants	246 women in Ankara, Turkey, participating in Family Health International trials of post-partum IUD insertions. Years of study: 1979-1980.
Interventions	Delta Loop versus Delta T
Outcomes	Principal outcomes included pregnancy, expulsion, removal for bleeding/pain, and continuation rates.
Notes	No a priori hypothesis or sample size calculation. Small sample size limited power.

Risk of bias

Kisnisci 1985 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Lavin 1983

Methods	Randomized controlled trial comparing two standard IUDs. Computer-generated randomization sequence and sealed, opaque, sequentially-numbered envelopes for allocation concealment.
Participants	400 women in Santiago, Chile, who had IUD insertions within 10 minutes of delivery of the placenta. Years of study: 1978-1980.
Interventions	Progestasert versus Copper T 200
Outcomes	Principal outcomes included pregnancy, expulsion, and continuation rates.
Notes	No a priori hypothesis or sample size calculation.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Thiery 1980

Methods	Randomized controlled trial with unclear masking. "List of randomized numbers" was used; method of allocation concealment not specified.
Participants	562 women in Gent, Belgium, "immediately after delivery of the placenta."
Interventions	Multiload 250 versus TCu 200 IUD.
Outcomes	Principal outcomes included pregnancy, expulsion, removal for bleeding/pain, removal for other medical reasons, and continuation.
Notes	One of a series of studies in a center with extensive experience with post-partum IUD insertions.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Van Kets 1987

Methods	Randomized controlled trial. Method of randomization and allocation concealment not specified.
Participants	408 women in Gent, Belgium, who had an IUD inserted within 10 minutes of delivery of the placenta.
Interventions	Postpartum Nova T versus Nova T
Outcomes	Principal outcomes included pregnancy, expulsion, and continuation rates.
Notes	No a priori hypothesis or sample size calculation provided. Limited details about methods of trial.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

WHO 1980

Methods	Randomized controlled trial without masking. Communication with authors indicated randomization by computer-generated table of numbers and allocation concealment by use of sealed, opaque, sequentially-numbered envelopes with a method indicator card.
Participants	841 women aged 16 to 40 yr having vaginal deliveries at 6 participating centers. Study sites included Hungary, Belgium, Brazil, United Kingdom, Chile, and Germany.
Interventions	One of three different devices was inserted immediately after expulsion of the placenta: Copper 7 (Gravigard), Lippes Loop D, or Post-partum T. The last device was a T-shaped IUD with two 2-cm long extra arms extending up and out from the lower end of the vertical stem. Insertions were done with either a standard or modified IUD inserter or by manual placement at the fundus.
Outcomes	Partial or complete expulsion, pregnancy, removal for bleeding or pain, and other medical removal.
Notes	The trial was stopped prematurely because the expulsion rates with all devices exceeded the predetermined limit of 20%. Women who experienced an expulsion within 48 hours after insertion were dropped from the analysis after randomization.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Xu 1996

Methods	Multicenter randomized controlled trial. Computer-generated random number sequence and sealed, sequentially-numbered opaque envelopes for allocation concealment.
Participants	910 women at 13 centers in Shanghai, China. Years of study: 1993-1994.
Interventions	Insertion by hand versus insertion with ring forceps.
Outcomes	Principal outcomes included pregnancy, expulsion, and continuation rates.
Notes	Sample size calculations based on an unstated a priori hypothesis.

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

Characteristics of excluded studies *[ordered by study ID]*

Chi 1985	Subgroup analysis of Cole (1984).
Eroglu 2006	Not an RCT; women chose the timing for insertion.
Lara Ricalde 2006	Participants were randomly assigned to type of IUD but not to timeframe for insertion.
Letti Müller 2005	Not an RCT. Assignment was based on type of delivery (vaginal or cesarean).
Shikary 1987	Although a randomized controlled trial, IUD insertions took place 4 to 6 weeks postpartum.
Tatum 1996	Although the title states this was a randomized controlled trial, women were allocated by alternate assignment, a non-random technique that precluded allocation concealment.
Thiery 1983	Data included in Cole (1984).

Characteristics of ongoing studies *[ordered by study ID]*

NCT00635362

Trial name or title	Postplacental insertion of levonorgestrel-releasing intrauterine system (LNG-IUS) after cesarean vs. interval insertion
Methods	Randomized, single blind (Investigator), active control, parallel assignment, safety/efficacy study

NCT00635362 (*Continued*)

Participants	120 healthy women, 18 years or older. Inclusion criteria: pregnant, planning a scheduled cesarean delivery, desires to use LNG-IUS for contraception, speaks English. Exclusion criteria: allergy to either polyethylene or levonorgestrel or other contraindications to use of the LNG-IUS; positive test for gonorrhea, chlamydia, or trichomoniasis during the pregnancy without treatment and a subsequent test of cure confirming negative result; leiomyomata distorting uterine cavity, uterine anomaly precluding IUS placement, current cervical cancer or carcinoma in-situ, desires repeat pregnancy within 12 months, history of postabortal or postpartum sepsis
Interventions	Immediate post-placental insertion of the levonorgestrel-releasing intrauterine system (LNG-IUS) vs. interval insertion of the LNG-IUS performed 4-8 weeks after delivery for patients undergoing scheduled cesarean delivery
Outcomes	Primary: use Secondary: expulsion, proportion able to have IUS inserted, pregnancy, infection, perforation, side effects and satisfaction, quality of life
Starting date	May 2007; estimated completion Dec 2009
Contact information	Melissa Gilliam, MD MPH; mgilliam@babies.bsd.uchicago.edu; 773-834-0840 Amy K Whitaker, MD; amy.whitaker@uchospitals.edu; 773-834-4129
Notes	

DATA AND ANALYSES

Comparison 1. Immediate post-partum insertion: Delta Loop versus Lippes Loop D

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Life-table rates per 100 women for expulsion (6-month)			Other data	No numeric data
2 Life-table rates per 100 women for continuation (6-month)			Other data	No numeric data

Comparison 2. Immediate post-partum insertion: Delta T versus TCu 220 C

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Life-table rates per 100 women for expulsion (6-month)			Other data	No numeric data
2 Life-table rates per 100 women for continuation (6-month)			Other data	No numeric data

Comparison 3. Immediate post-partum insertion: Delta Loop (hand versus instrument insertion)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Life-table rates per 100 women for expulsion (6-month)			Other data	No numeric data
2 Life-table rates per 100 women for continuation (6-month)			Other data	No numeric data

Comparison 4. Immediate post-partum insertion: Delta T versus Delta Loop

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Life-table rates per 100 women for expulsion (12-month)			Other data	No numeric data
2 Life-table rates per 100 women for pregnancy (12-month)			Other data	No numeric data

3 Life-table rates per 100 women for removal due to bleeding / pain (12-month)		Other data	No numeric data
4 Life-table rates per 100 women for continuation (12-month)		Other data	No numeric data

Comparison 5. Immediate post-partum insertion: T Cu 200 versus Progestasert

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Hand insertion: Life-table rates per 100 women for expulsion (12-month)			Other data	No numeric data
2 Instrument insertion: Life-table rates per 100 women for expulsion (12-month)			Other data	No numeric data
3 Hand insertion: Life-table rates per 100 women for continuation (12-month)			Other data	No numeric data
4 Instrument insertion: Life-table rates per 100 women for continuation (12-month)			Other data	No numeric data

Comparison 6. Immediate post-partum insertion: T Cu 200 versus IPCS-52 mg

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Life-table rates per 100 women for expulsion (12-month) by device and insertion method			Other data	No numeric data
2 Life-table rates per 100 women for removal due to bleeding / pain (12-month) by device and insertion method			Other data	No numeric data
3 Life-table rates per 100 women for continuation (12-month) by device and insertion method			Other data	No numeric data
4 Life-table rates per 100 women for expulsion (36-month) by device and insertion method			Other data	No numeric data
5 Life-table rates per 100 women for continuation (36-month) by device and insertion method			Other data	No numeric data

6 Life-table rates per 100 women for expulsion (36-month) by device pooled		Other data	No numeric data
7 Life-table rates per 100 women for expulsion (36-month) by method pooled		Other data	No numeric data

Comparison 7. Immediate post-partum insertion: Nova-T-PP versus Lippes Loop versus Copper 7

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Life-table rates per 100 women for expulsion (12-month)			Other data	No numeric data
2 Life-table rates per 100 women for pregnancy (12-month)			Other data	No numeric data
3 Life-table rates per 100 women for discontinuation (12-month)			Other data	No numeric data

Comparison 8. Immediate post-partum insertion: Nova-T-PP versus Nova-T

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Life-table rates per 100 women for expulsion (12-month)			Other data	No numeric data
2 Life-table rates per 100 women for pregnancy (12-month)			Other data	No numeric data
3 Life-table rates per 100 women for continuation (12-month)			Other data	No numeric data

Comparison 9. Immediate post-partum insertion: T Cu 200 versus ML Cu 250

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Life-table rates per 100 women for expulsion (12-month)			Other data	No numeric data
2 Life-table rates per 100 women for pregnancy (12-month)			Other data	No numeric data
3 Life-table rates per 100 women for continuation (12-month)			Other data	No numeric data

Comparison 10. Immediate post-partum insertion: TCu 380A (hand versus instrument insertion)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Life-table rates per 100 women for expulsion (6-month)			Other data	No numeric data
2 Life-table rates per 100 women for removal for bleeding / pain (6-month)			Other data	No numeric data

Comparison 11. Immediate postplacental insertion versus delayed insertion of LNG IUD after vaginal delivery

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pregnancy by 6 months	1	102	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
2 Expulsion by 6 months	1	97	Odds Ratio (M-H, Fixed, 95% CI)	6.77 [1.43, 32.14]
3 Use at 6 months	1	102	Odds Ratio (M-H, Fixed, 95% CI)	1.65 [0.61, 4.47]

WHAT'S NEW

Last assessed as up-to-date: 31 March 2010.

17 February 2010	New citation required but conclusions have not changed	Preliminary results from a new trial were added (Chen 2009). Also, a trial in progress was identified (NCT00635362).
16 February 2010	New search has been performed	Searches were updated

HISTORY

Protocol first published: Issue 2, 2000

Review first published: Issue 2, 2001

15 April 2008	Amended	Converted to new review format.
30 January 2001	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Drs Grimes and Schulz developed the proposal, conducted the initial literature search, abstracted the data, and performed the analysis. Dr Lopez drafted the plain language summary and entered the original data into tables. Dr Lopez reviewed the literature searches for the 2007 and 2010 updates, incorporated new data, and drafted the revised review. All authors contributed to writing and revising the review.

DECLARATIONS OF INTEREST

Dr Grimes has consulted with the pharmaceutical companies Bayer Healthcare Pharmaceuticals and Merck & Co, Inc.

Two trials (Cole 1984; Kisnisci 1985) were conducted by Family Health International, where the authors of this review are employed. However, the review authors were not involved in those trials.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- National Institute of Child Health and Human Development, USA.
- U.S. Agency for International Development, USA.

INDEX TERMS

Medical Subject Headings (MeSH)

*Intrauterine Devices; *Postpartum Period; Feasibility Studies; Randomized Controlled Trials as Topic; Time Factors

MeSH check words

Female; Humans; Pregnancy