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Original Article

Safety profile of immediate post-partum intrauterine device insertion during caesarean delivery – a clinical trial with three years of follow up

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ABSTRACT

Background: Many countries recommend the use of long-acting reversible contraceptive intrauterine device immediately after cesarean delivery. The cesarean delivery rate in Iraqi public hospitals is 32.2% and may reach 85.8% in private hospitals. Immediate post-partum intrauterine device insertion at cesarean is rarely done in Iraq.
Objectives: To assess the safety and practicality of immediate post-partum intrauterine device insertion during cesarean delivery for family planning and pregnancy spacing in Iraqi women.
Subjects and Methods: A single arm clinical trial included 150 eligible women who attended Al-Elwiyah Maternity Teaching Hospital or Al Hayat Rahibat Hospital for term delivery. A copper intrauterine device was placed in the uterine cavity immediately after delivery of the placenta during cesarean delivery. The intrauterine device was fixed in place at the fundus using an absorbable suture. Patients were followed up at six weeks, then annually for three years.
Results: Expulsion of the intrauterine device was not reported by any of the participants. The most-reported complaints in the first twelve months of intrauterine device placement were abdominal pain, abnormal vaginal discharge, and heavy menstrual blood loss, however, none were statically significant (P= 0.256). After the first year, there was a significant reduction in the frequency of complaints (P= 0.002). Only 7.33% (95% CI: 6.92–7.75%) of the patient requested intrauterine device removal within the three years. The main reason was to plan a new pregnancy followed by recurrent infection associated with uncontrolled diabetes mellitus. Diabetes was a significant predictor for immediate post-partum intrauterine device removal, P= 0.049.
Conclusion: The intrauterine device placement during cesarean delivery with suture fixation is a safe procedure with a zero-expulsion rate and is an effective reversible long-term contraceptive method.

Introduction

In the developing countries, around 885 million women in reproductive age would like to avoid pregnancy, nonetheless, 25% experienced an unmet need for modern contraception. This is particularly true in the low- and middle-income countries. (1)
Pregnancy in the first year following birth can be as high as 10%–44%, too early pregnancy may associate with many adverse outcomes as fetal losses, premature labor, postpartum hemorrhage

and maternal deaths. Women are more likely to accept family planning advice soon after giving birth. Offering immediate postpartum contraception has a proven high impact practice in family planning since it encourages pregnancy spacing and reduce the likelihood of pregnancy in the first year postpartum. (2, 3)

Long-acting reversible contraception methods (LARC) have been used more widely in spacing pregnancies. Copper intrauterine device (IUD) can be an attractive option for postpartum women as it can be inserted immediately after delivery of the baby and the placenta, offering a one-stop approach service especially in countries where the institutional deliveries are considerably high. Immediate post-partum intrauterine device (IPPIUD) insertion is particularly important for women who want to space their pregnancies but have low opportunity to access family planning services in the postpartum period because of various socioeconomical factors. (4, 5) While IPPIUD is effective for family planning after both vaginal and cesarean delivery (CD), another benefit for women who deliver surgically is that it reduces the chance of aberrant placentation if an unexpected pregnancy occurs during the first 18 months. (6)

Zerzavy on 1967 had published the first study on the immediate placement of IUD after placental delivery whether during vaginal or CD using Birn berg Bow size 5 or 7 and sutured them during CD. Since then, sporadic studies have been published in the same context, till 1990s, when the fear from using this contraceptive approach was subside and at a later time in 2013 FIGO had started their project of IPPIUD in six countries where this practice became more popular. (7, 8) On August 2016, The American College of Obstetricians and Gynecologists recommended offering immediate LARC, following proper counselling. (9)

In a Cochrane review, researchers stated that an IPPIUD is not only safe and effective contraceptive method, but it can bend maternal and child mortality by more than 30% and 10%, respectively. The World Health Organization (WHO) had considered the IPPIUD as a category 1 rating in its medical eligibility criteria, which may avert the discomfort that had been linked to interval insertion. (10, 11) The higher expulsion rate that had been occasionally identified with the IPPIUD, compared to interval insertion, could be balanced with the high rate of non-insertion in the delayed postpartum period. As 40-75% of women who wanted to insert an IUD after puerperium, are not able to do that. (12, 13)

The number of CD is increased worldwide and in Iraq, with a CD rate of 32.2 % in public and may reach 85.8% in private hospitals. Repeated caesareans contribute much to increase maternal morbidity owing to the increase incidence of placenta previa, placenta accrete, postpartum hemorrhage and caesarean hysterectomy, which were much higher than what was encountered previously. Elevated number of early marriage in Iraq, high fertility rate and up to 96.9% institutional deliveries, (14) are all reasons made IPPIUD, especially during CD, an attractive option for pregnancy spacing and to prevent early repeated CDs.

This is study is aiming to investigate the safety of IPPIUD during CD and its acceptability and feasibility in spacing of pregnancy in Iraqi women.

Subjects and Methods

This a single arm clinical trial that was carried out at Al-Elwiyah Maternity Teaching Public Hospital and Al Hayat Rahibat Private Hospital from September 2015 to June 2019. A total of 150 women who completed 36 weeks of pregnancy and were undergoing CD have been recruited after giving an informed written consent including a full description of the procedure, advantages and the frequency of occurrence of any possible complications. Women who were planned for elective CD approached in the antenatal period and women with emergency caesarean were counselled when they before entering the labour theatre.

Exclusion criteria included women who tested positive for sexually transmitted diseases in this pregnancy, uterine anomalies and pathologies, intrapartum fever, a history of ruptured membranes for more than 24 hours before delivery, diagnosed chorioamnionitis, placenta previa or accrete, anaemia during pregnancy (Hb < 10 g/dl), or intrapartum haemorrhage.

*Primary outcome*s measured were the expulsion rate and the percentage of immediate and late complications of IPPIUD, namely heavy menstrual blood loss, abdominal pain, abnormal vaginal discharge, absent threads, perforation. *Secondary outcomes* were to determine IUD removal predictors, how frequent the involved women would recommend this method of contraception for others, and the feasibility of IPPIUD insertion concerning the extra cost and time that will be added.

Interventions

The copper IUD (Cu-T 380A) was prepared and removed from the applicator tube and left on the sterile field, after delivery of the placenta (within 10 minutes), ensuring haemostasis and starting the uterine incision closure, an absorbable suture: vicryl 0 is introduce through the fundus to the uterine cavity, cutting the needle and wrapped the suture around the IUD arm, pulling the thread out to place the IUD at the fundus and make a knob outside the fundus to keep the IUD in place. The IUD threads were placed in the lower uterine segment, and then proceeds with completing the closure of the uterine incision, ensuring not to incorporate the IUD threads with uterine suture. All IUDs were inserted by the same investigators, one consultant obstetrician, and two specialists in obstetrics, who received training about the procedure. The extra cost for the copper IUD (Cu-T 380A) was $2.5 / per case, and the average extra time of the procedure for the insertion of the device was 3.5 min.

Follow-up

Women were assessed before hospital discharge and were provided with a mobile number for follow-up. subsequent visit was at six weeks postpartum, where speculum examination was performed to check IUD threads, when seen, it was trimmed at two cm from external cervical os. when not seen, a pelvic ultrasonography was performed to ensure accurate location of IUD. Then, women

were reassessed at yearly intervals for three years, looking for the occurrence of .the conserned complications

McNemar test was used to assess the change in complaint frequency at each time period (paired data). The odd ratio and its 95% confidence interval (CI) were calculated using the binary logistic analysis. To categorise the parameters, affect, the Wald test was used for this purpose (Wald basically is t^2 which is Chi-Square distributed with df = 1). GraphPad Prism version 8.3.0 was used to produce the statistical analysis, and the p-value was considered when appropriate to be significant if less than 0.05.

The study was approved by the Scientific Affairs Unit and Medical Ethics committee at Al Kindy College of Medicine (reference:123/June 29th, 2015) and the hospitals administrative boards. The trial was registered at clinicaltrials.gov (NCT04136613) under the name of Utility of Immediate Post Placental Insertion of Intrauterine Device During Cesarean Delivery. It was conducted according to Good Clinical Trial practice and the principles of the Declaration of Helsinki.

Results

Recruitment was started at September 2015. The participant's flowchart is demonstrated in Figure 1. Approximately 72% of invited women were eligible for the study, 63 women were further excluded; 40 of them became ineligible at the time of CD, and 23 women delivered in other health facilities. After three years of follow-up, only 150 women continued from the initial sample, while 13 women (7.8 %) didn't attend their follow up visits and could not be reached through mobile calls.

The mean age (SD) of participants was 32.7 ± 4.3 years, ranged between 23–42 years. The majority of them were from urban residency and have intermediate education levels, only 29.7% were working. 67.3% the women were offered the procedure in public health services. Both abdominal pain and heavy menstruation were reported by few participants and were not significant over the period of follow up. Abnormal vaginal discharge reported in 10.7% of the participants at 12-month visit, however, this was significantly reduced at 3rd year visit (P=0.004). the thread of the IUD was absent in 32% of the patients at the 6th week visit and this was significantly reduced in 1st and 3rd year visits. Patients' minor complaints were reported in the 6th week and 12-month visits, but the IUD was well tolerated at the 3rd year visit with only 5% complaint as illustrated in Table 1 and Figure 2.

IUD removal predictors:

IUD removal was requested by 7.33% within the three years (95% CI: 6.92–7.75) and the most frequent reason was the intention to conceive (4.0%) as illustrated in Table 2 and Figure 3. Overall, participants were satisfied with IPPIUD and 97.3% recommended the procedure to a friend or relative.

Diabetes Mellitus was the only significant predictor of IUD removal, and its presence increased the risk of IUD removal by 5.956 folds. Other parameters such as not working, elective CD and numerous CD showed lower likelihood to get their IUD removed, yet statistically were not significant as illustrated in Table 3.

Discussion

To our knowledge, this is the first Iraqi study evaluating the IPPIUD as a method of contraception during CD. We were able to recruit 163 women who fulfilled the inclusion criteria, and 150 completed three years follow up. The main outcome was zero expulsion rate and the overall complaints from IPPIUD were rather low. Uterine perforation rate was zero, since the IUD was inserted under direct vision during CD.

One of the major advantages of IPPIUD insertion, is lower discomfort than an interval insertion, it also does not interfere with breast feeding.(15) Interestingly, patient received IPPIUD did not report an increase of postpartum bleeding, infection, or uterine subinvolution consistent with other studies.(16) By contrast, our participants had reported a decrease in blood loss in the first postpartum days in comparison with their previous deliveries, however, this was an incidental finding and has not been assessed statistically.

The main early problems with any immediate IPPIUD insertion are; first is the expulsion rate which could be linked to personal operative experiences. Previous studies reported around (5%–17%) expulsion rate when the IUD is inserted during caesarean within the first six weeks.(17, 18) Şevki Çelen et al in their study that include 245 women shown that IPPIUD insertion can give reasonable protection against pregnancy, however, greater than 25% have discontinued IUD use because of spontaneous expulsion or some other reasons. (17) A Cochrane Database showed higher expulsion rates with immediate insertion of IUDs than later insertion even when modifications as putting a stich had been practiced, but other studies later showed reasonable justification for using fixation suture in various countries such as Egypt, China, Mexico and others.(10, 19) Several other studies have optimizing other anchoring procedures that can bring the expulsion rate close to zero.(7) Taking all these studies in consideration, and to reduce the expulsion rate to minimum we used absorbable suture (vicryl 0) to stabilize the IUD in place at the uterine fundus. This type of suture holds its tensile strength for approximately two to three weeks in tissue then it will be absorbed completely by the time when the uterine involution process will be completed. This fixation approach had a minimum negligible impact on the procedure time and required only simple extra training. The second important early finding with IPPIUD was absent threads, which was the most prominent finding in our study when the women wereexamined at the sixth week. It was observed in 32% of participants which was resolved significantly (6.7%) by the third years. Missing thread is higher after IPPIUD insertion during Caesarean delivery 44%–79% versus 5% after vaginal delivery.(12) Similar results were described by Sunita et.al who reported string visibility in 61.87% at the first visit versus 84.62% at 12 months.(18)

The IPPIUD did add very little extra time to the CD procedure, which was only 3.5 minutes and a small extra cost which was only

$2.5 per case. In a study evaluated the cost–benefit of IUD programme in the immediate postpartum period in Oregon between 2001 and 2006, results showed that for every dollar spent in the programme, $2.94 was saved. Similarly, Washington CI et. al found that there was a cost savings of $282,540 with a gain of 10 quality adjusted life year for each 1,000 women who desired IPPIUD.(20, 21) Further studies are needed to examine the cost effectiveness of this intervention in our hospitals.

While the frequency of IUD removal within the three years was 7.33%, Diabetes Mellitus was the only significant predictor of IUD removal. This is expected as diabetes associates with increased risk for persistent infection therefore, removal of the IUD was requested in two of the cases, one of which was as early as six weeks. The most common cause of IUD removal was the will to conceive (4.0%). Three of the removed IUD were due to heavy menstrual blood loss which was not responding to medical treatment. Otherwise all other participants were happy to continue with their IUD and 97.3% did recommended the procedure to other women which indicate reasonable satisfaction. Singal et al, had same removal rate of 7%, although they were for different reasons as psychological causes, menstrual irregularity and pelvic pain.(18)

Counselling of the participants for immediate IPPIUD insertion whether antenatally or at the time of admission had no significant contribution to the IUD removal, so absent antenatal counselling for IPPIUD was not a barrier for providing this services immediately at the time of delivery, this was also described by Alberto Moreno Zaconeta et al.(22) That will add to the advantage of this contraception services type especially in a country like Iraq where contraception counselling is not usually offered during the antenatal period.

Taking in consideration that by the sixth week postpartum, most women will be sexually active; the immediate postpartum period would be an ideal time to begin contraception. It is the time when the women will be much motivated to delay their pregnancies.(15, 16, 23) Leaving the hospital with an effective long method of contraception would be an appropriate choice to a country with socioeconomic and demographic factors like Iraq particularly when knowing that 63% of our participants were having less than one-year interpregnancy interval before their last pregnancy and considerable numbers of them having three previous CD scars which make them at risk of further complications.

Conclusion

This work showed that IPPIUD placement during CD is safe, feasible; contribute to a negligible prolongation in the operation time and add no extra cost if compared with cost and complication of unplanned pregnancy. Using fixation suture is a safe and efficient method to prevent the IUD expulsion. These results can be taken further to implement the FIGO project that started in 2013 in other countries in order to institutionalise the provision of IPPIUD services into the daily maternity care.

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Conflict of Interest

No conflict of interest

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