Intraoperative Placement of the Non-Hormonal Copper Intrauterine Devices in Women Undergoing Cesarean Delivery

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Conflict of interest:

MNA, AAHA and MAASh conceived and supervised the study; MAE was responsible for data collection, analyzed and interpreted the data. All authors provided comments on the manuscript at various stages of development. All authors read and approved the final manuscript.

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Abstract

Background: Intrauterine devices (IUDs) are a popular contraceptive option for women worldwide. While traditionally inserted postpartum, there is growing interest in intraoperative placement during cesarean delivery as a convenient and effective strategy. This study aimed to evaluate the efficacy and safety of non-hormonal copper IUD insertion during cesarean sections and compare outcomes with postpartum insertion.

Methods: This prospective case-control study enrolled women aged 18-45 years undergoing cesarean section at Benha University's Obstetrics & Gynecology department from June 2021 to June 2023. Participants were divided into two groups: Group 1 (intrapartum) received IUD insertion during cesarean section, and Group 2 (postpartum) received insertion six weeks after discharge.

Results: Of the 130 women assessed, 104 met inclusion criteria and were included in the study (Group 1: n=50, Group 2: n=54). There were no failed insertions in either group. Hemoglobin levels were significantly lower in Group 1 compared to Group 2 after one week (9.3 vs. 10 g/dl, P=0.000) and six weeks (9.75 vs. 10.35 g/dl, P=0.0001). At six weeks, bleeding and IUD removal rates were 4% in Group 1 and 7.41% in Group 2 (P=0.457). Rates of expulsion were 2% in Group 1 and 3.7% in Group 2 (P=0.604). Displacement and removal rates were similar between groups (4% vs. 3.7%, P=0.937).

Conclusions: Intraoperative placement of non-hormonal copper IUDs during cesarean delivery is a safe and effective contraceptive option with comparable complication rates to postpartum insertion. While hemoglobin levels were lower in the intrapartum group, overall outcomes support the feasibility and utility of this approach in clinical practice.

Keywords: Intrauterine device, cesarean delivery, contraception, copper IUD, expulsion, complication rates.

Introduction

In recent years, intrauterine devices (IUDs) have gained considerable popularity as a highly favoured method of long-term reversible contraception. These devices, small in size, are inserted into the uterus by a healthcare professional through the vaginal canal. There exist two primary categories of IUDs – hormonal variants, which discharge progestin, and non-hormonal copper IUDs. Functionally, IUDs chiefly operate by impeding fertilization, boasting a remarkable efficacy rate of over 99% in preventing pregnancy[1]. Depending on the specific type, they offer continuous contraception for a span ranging from 3 to 10 years. The appeal of IUDs lies in their manifold benefits, including exceptional effectiveness, prolonged duration of action, prompt reversibility, freedom from adherence constraints, and minimal incidence of side effects [2].

Although IUDs offer notable advantages, their utilization rates persist below those of alternative contraceptive options in specific geographical areas. Several obstacles hinder broader acceptance, including initial out-of-pocket expenses, healthcare provider prejudice against women who have not given birth, and apprehensions regarding potential side effects. Nevertheless, initiatives are actively being pursued to encourage the use of IUDs, particularly among young and nulliparous individuals, through extensive counselling services and enhanced availability [3].

The practice of inserting intrauterine contraceptive devices during cesarean deliveries is increasingly being recognized as a viable means of offering efficient long-term contraception. Both hormonal and copper IUDs can be securely implanted during cesarean procedures. Immediate insertion addresses the barriers that many women encounter when scheduling a separate appointment for insertion at a later date, enabling them to depart from the hospital with their chosen contraceptive method already in place. This approach holds potential benefits, particularly for women undergoing planned cesarean sections. Nonetheless, uncertainties persist regarding the optimal timing for IUD insertion during the cesarean procedure. Furthermore, concerns linger regarding potential risks such as uterine perforation, expulsion, and bleeding [4].

We aimed to determine the efficacy of non-hormonal Cupper IUD insertion during a cesarean section, as well as the rate of expulsion and complication.

Patients and Methods

This prospective case-control study was conducted to determine the efficacy of non-hormonal Cu-IUD implantation during cesarean sections, as well as to assess the rates of expulsion and complications at the Obstetrics & Gynecology department of Faculty of Medicine of Benha University during the period from June 2021 to June 2023.

An informed written consent was obtained from the patient or relatives of the patients. The study was done after approval from the Ethical Committee Benha University Hospitals Inclusion criteria were age 18-45 years, absence of infectious diseases, no intranatal bleeding, hemoglobin (Hb) level ≥ 9 g/dl, full-term pregnancy without medical disorders, and singleton uncomplicated pregnancy.

Exclusion criteria were known copper allergy, history of pelvic infection, prenatal outflow of

amniotic fluid, uterine abnormalities, history of HIV, previous failed IUD, uterine fibroid, history of post-operative complications, hemorrhagic disorder, history of ectopic pregnancy. The participants were categorized into two groups:

Group 1 (intrapartum group): Comprising 50 cases, this group underwent cesarean sections with simultaneous non-hormonal Cu-IUD insertion.

Group 2 (postpartum group): Consisting of 54 participants, this group received postpartum IUD insertion during a postpartum visit 6 weeks after hospital discharge.

All participants were subjected to full history taking (During prenatal visits, detailed medical histories were obtained from each participant. This involved discussions about the participant's obstetric and gynecological history, including the number of previous pregnancies, history of cesarean sections, any medical conditions, and contraceptive preferences postpartum. This comprehensive history-taking process aimed to ensure that participants met the medical criteria for cesarean section and were suitable candidates for non-hormonal Cu-IUD insertion.

Clinical examination

Comprehensive clinical examinations were conducted during prenatal visits to assess the participants' overall health and ascertain their eligibility for cesarean section and subsequent IUD insertion. The clinical examination involved vital sign assessments, abdominal palpation, and pelvic examinations. Any potential contraindications, such as uterine anomalies or infections, were carefully identified and taken into consideration for patient selection.

IUD insertion

Cesarean section procedures were performed according to established protocols. Following the safe delivery of the baby and within 10 minutes of placental removal, a non-hormonal Cu-IUD was implanted in the uterine fundus in the study group. Implantation was done by experienced obstetricians using ring forceps through the hysterotomy incision, with IUD strings threaded into the cervix.

IUD insertion assessment

Before patients were discharged from the hospital, a thorough assessment of the inserted IUD was conducted. A speculum examination was performed to visually confirm the presence of the IUD strings, thus verifying that the device was in place within the uterine cavity. This step aimed to ensure proper IUD positioning and exclude any initial signs of IUD expulsion.

Follow-up visits

Participants were scheduled for follow-up visits at one week and six weeks postpartum. During these visits, participants were questioned about any symptoms, concerns, or complications. Physical and pelvic examinations were conducted to confirm IUD presence and assess symptoms like infection or heavy bleeding.

Clinical and ultrasonographic examinations

At the follow-up visits, thorough clinical and pelvic examinations were conducted by trained healthcare professionals. These examinations were designed to confirm the presence and positioning of the IUD, assess symptoms like pain or discomfort, and identify potential signs of infection or heavy bleeding. To enhance accuracy, transvaginal ultrasonography was employed to visualize the IUD and its location within the uterine cavity.

Expulsion confirmation

The occurrence of IUD expulsion was confirmed both clinically and through transvaginal

ultrasonography. Any cases of expulsion were documented and further investigated.

Patient management

Participants reporting pelvic discomfort, fever, heavy bleeding, unusual vaginal discharge, or other concerns were advised to seek medical attention at any time. In cases of bleeding, discomfort, expulsion, pregnancy, or patient requests, IUD removal was carried out according to hospital policy. Antibiotics were administered in alignment with the Maternity Hospital's Caesarean section policy.

Primary outcome

The primary outcome measure of this study was the efficacy of non-hormonal Cu-IUD implantation during cesarean section. Successful insertion of the IUD within the uterine cavity during the cesarean procedure was the key parameter to assess. The determination of successful insertion was based on postoperative imaging or direct observation during follow-up visits.

Secondary outcome

Rate of Expulsion

Statistical analysis

The data collected underwent analysis using Stata version 17 software. Continuous variables were depicted as mean ± standard deviation and median with interquartile ranges. Normality of the data was assessed through Skewness and Kurtosis tests. Categorical variables were presented as frequencies and percentages. Mean comparisons were conducted using independent samples t-tests, while median comparisons utilized the Mann–Whitney test (Wilcoxon rank sum test). Proportions were analyzed using the chi-square test or Fisher's exact test. Additionally, multiple logistic regression analysis was employed to evaluate the association between intrapartum IUCD insertion and the incidence of complications post-insertion, with adjustments made for potential confounding factors.

Results

A total of 130 women who were seeking IUD insertion were enrolled in the study and were assessed for the inclusion criteria. Among the 130 women enrolled, only 104 (80%) women met the inclusion criteria and were included in this study and divided into two cohorts; 50 patients (48.08%) in group 1 (intrapartum group) and 54 patients (51.92%) in group 2 (postpartum group), the 104 women were followed for up to 6 weeks after insertion of IUCD.

Upon analysis, there was no significant difference between the women in the two groups regarding most of the basic characteristics and obstetric history. The mean age of the women in group 1 (intrapartum) and group 2 (postpartum group) were 28.72 (±4.67) and 28.72 (±3.98) respectively with no significant difference (P value= 0.998), median hemoglobin level before insertion of the IUCD in group 1 (intrapartum) and group 2 (postpartum group) were10 g/dl (9.8-11), 10 g/dl (9.7-10.6) respectively with no significant difference (P value= 0.209). Table 1

Table 1: Comparison between the two groups regarding patients' basic characteristics and obstetric history

Characteristics	Group 1 Intrapartum group (n=50)	Group 2 Postpartum group (n= 54)	Significance P value	Test value
Maternal age, mean (SD), (years)	28.72 (±4.67)	28.72 (±3.98)	0.998	t= 0.0026
Gravidity (median)	2 (1-3)	2 (1-3)	0.6918	z= -0.400
Parity (median)	1 (0-2)	1 (0-2)	0.8182	z = -0.240

Blood group **A□** **B□** **O□** **AB□** **A^-** **B^-** **O^-** **AB^-**	 13 (26%) 6 (12%) 16 (32%) 4 (8%) 4 (8%) 5 (10%) 2 (4%) 0 (0%)	 9 (16.67%) 11 (20.37%) 22 (40.74%) 1 (1.85%) 5 (9.26%) 1 (1.85%) 3 (5.55%) 2 (3.70%)	0.9320	z = 0.087
Hemoglobin level before insertion (median) (g/dl)	10 (9.8-11)	10 (9.7-10.6)	0.209	z = -1.260

Primary analysis:

The complications after insertion of the IUCD as failed insertion, hemoglobin level, post insertion pain, bleeding & IUCD removal, displacement & IUCD removal, expulsion and perforation in the two groups were followed for up to 6 weeks and were compared as shown in **Table 2.**

Table 2: Comparison between groups regarding patients' complications

Complications	Group 1 Intrapartum group (n=50)	Group 2 Postpartum group (n= 54)	Significance P value	
Failed insertion	0 (0%)	0 (0%)	----	----
Hemoglobin level after 1 week of insertion	9.3 (9-9.9)	10 (9.6-10.5)	0.000	z = 4.488
Hemoglobin level after 6 weeks of insertion	9.75 (9.2 -10.2)	10.35 (9.9-10.8)	0.0001	z = 3.836
Post insertion pain 1 week	0 (0%)	0 (0%)	----	----
Post insertion pain 6 week	2 (4%)	3 (5.56 %)	0.711	0.1373
Bleeding & Removed 1 week	1 (2%)	0 (0%)	0.296	1.0905
Bleeding & Removed 6 week	2 (4%)	4 (7.41%)	0.457	0.5545
Displaced & Removed 1 week	0 (0%)	0 (0%)	----	----
Displaced & Removed 6 week	2 (4%)	2 (3.7%)	0.937	0.0062
Expulsion 1 week	1 (2%)	0 (0%)	0.296	1.0905
Expulsion 6 week	1 (2%)	2 (3.7%)	0.604	0.2690
Perforation 1 week	0 (0%)	1 (1.85%)	0.334	0.9349
Perforation 6 week	0 (0%)	0 (0%)	----	----
Missed threads	3 (6%)	0 (0%)	0.068	3.3362
Vaginal infection 1 week	0 (0%)	2 (3.7%)	0.169	1.8882
Vaginal infection 6 wk	0 (0%)	1 (1.85%)	0.334	0.9349
Unintended pregnancy	0 (0%)	0 (0%)	----	----

There was no failure in the insertion of the IUCD in the two groups. After analysis, the hemoglobin level was higher in group 2 (postpartum) compared to group 1(intrapartum) after one and six weeks of follow-up with significant difference (P value= 0.000). There was one case of Bleeding and removal of the IUCD after one week in group 1 (intrapartum) and no case in group 2 (postpartum) with no significant difference (P value=0.296), there was a higher rate of bleeding and IUCD removal after six weeks of follow up, there were 4 cases of bleeding and IUCD removal in group 2 (postpartum) and 2 cases in group 1(intrapartum), but with no significant difference (P value=0.457). After one week no cases of IUCD displacement and removal were noted in the two groups but after six weeks there were 2 cases of displacement and removal of IUCD in each group with no significant differences (P value= 0.937).

After one week there was one case of expulsion in group 1(intrapartum) and no case of expulsion in group 2 (postpartum) with no significant difference (P value=0.296), after 6 weeks there were 2 cases of expulsion in group 2 (postpartum) and one case in group 1 (intrapartum) with no significant difference (P value=0.604). No significant difference regarding perforation after one and six weeks. there were only 3 cases of missed threads in group 1 (intrapartum) and no case of missed thread in group 2 (postpartum) but with no significant difference(P value=0.068), the rate of vaginal infection was higher in group 2 (postpartum), after one week 2 cases of vaginal infection in group 2 (postpartum) and no case in group 1 (intrapartum) with no significant difference (P value=0.169), after six weeks 1 case of vaginal infection in group 2 (postpartum) and no case of vaginal infection in group 1 (intrapartum) (P value=0.334), no cases of unintended pregnancy were noted in the two groups.

We used a multiple regression model to compare the two groups and rate of complications after six weeks; in the model we use all the following variables: age, parity, gravity and hemoglobin level before the CS to adjust for all the possible confounders. Using the multiple logistic regression model, the adjusted odds ratio for bleeding and IUCD removal after 6 weeks were 0.24 (95% CI: 0.02-2.30, P-value 0.217), the adjusted odds ratio for displacement and IUCD removal after 6 weeks were 0.54 (95% CI: 0.05-6.34, P-value 0.628), the adjusted odds ratio for expulsion after 6 weeks were 0.53 (95% CI: 0.04-6.63, P-value 0.620) as shown in **Table 3**.

Table 3: Multivariable analysis of predictors of outcomes regarding the studied groups

Complication	Group 1 Intrapartum group (n=50)	Group 2 Postpartum group (n= 54)	Adjusted Odds ratio	Confi-dence interval	P value
Bleeding & Removed 6 week	2 (4%)	4 (7.41%)	0.24	0.02-2.30	0.217
Displaced & Removed 6 week	2 (4%)	2 (3.7%)	0.54	0.05-6.34	0.628
Expulsion 6 week	1 (2%)	2 (3.7%)	0.53	0.04-6.63	0.620

Discussion

The utilization of intrauterine devices (IUDs) as a reliable method of contraception has witnessed a significant surge, owing to their effectiveness and long-term benefits [5]. However, the ideal timing for IUD insertion, especially during or immediately after a cesarean section, remained a subject of interest and clinical investigation [6]. Non-hormonal Copper IUDs (Cu-IUDs) have gained prominence due to their non-hormonal nature and durability, making them an appealing choice for postpartum contraception [7].

These collective findings, including our own, indicate a robust pattern of similarity in baseline characteristics among participants across various studies and settings. This consistency reinforces the notion that the timing of Cu-IUD insertion, whether during cesarean section or postpartum, does not substantially influence these baseline characteristics. Therefore, healthcare providers can confidently base their decisions on clinical appropriateness and patient preferences, with less concern about introducing variations in these fundamental factors. This not only enhances the generalizability of our results but also underscores the importance of personalized patient care in the domain of contraceptive decision-making.

This study meticulously examined various complications associated with Cu-IUD insertion, including bleeding and IUD removal, displacement, expulsion, perforation, missed threads, vaginal infection, and unintended pregnancy.

This study found no cases of failed IUD insertion in either the intrapartum or postpartum group. This result demonstrates that both methods of Cu-IUD insertion, whether during cesarean section or postpartum, were technically successful, and this finding is consistent with previous research in the field. Aligned with our findings, a randomized controlled trial revealed that immediate postplacental insertion of intrauterine Cu IUD is not linked to failed insertion when compared to standard insertion in postpartum women [8]. This consistency between our study and theirs supports the notion that immediate intrapartum insertion is a viable and technically successful option for Cu-IUD placement.

We observed significant differences in hemoglobin levels between the two groups. Specifically, participants in the postpartum group had higher hemoglobin levels after both one and six weeks. This difference suggests that postpartum Cu-IUD insertion may result in less immediate blood loss, or a quicker recovery of hemoglobin levels compared to intrapartum insertion. Conversely, immediate postplacental insertion of intrauterine Cu IUD is not associated with different hemoglobin levels compared to standard insertion in women who are postpartum at a Brazilian University Hospital [9]. The clinical significance of this finding merits further investigation.

Our analysis showed no significant differences in post-insertion pain between the two groups at both one and six weeks. This indicates that the timing of Cu-IUD insertion, whether during cesarean section or postpartum, did not significantly affect the experience of pain. The lack of a substantial pain difference is reassuring for both clinical practice and patient comfort.

In line with our results, another study also found no substantial differences between the two groups regarding post-insertion pain or bleeding [10].

However, in the study conducted at a municipal public maternity hospital in Porto Velho, Brazil, it was found that the main side effect in the first days of use, still in the puerperium, was pelvic pain in 20.36% of all IUDs inserted immediate postplacental [11].

After one week, there was one case of bleeding and IUCD removal in the intrapartum

group and none in the postpartum group. Although this difference was not statistically significant, it suggests a potential trend toward lower early complications in the postpartum group. However, after six weeks, the rates of bleeding and IUCD removal were higher in the postpartum group, though not significantly so. The longer-term data indicate that both groups had similar rates of this complication, suggesting that the timing of insertion may not be a critical factor.

In alignment with our findings, studies by [8, 12, 13] all yielded results indicating no significant impact on bleeding patterns following immediate post-placental IUD placement.

Both groups had similar rates of IUCD displacement and removal after one week, with no cases noted. However, after six weeks, there were two cases in each group. The lack of significant differences in both early and late complications suggests that Cu-IUD displacement and removal may be unrelated to the timing of insertion. While there was one case of expulsion in the intrapartum group after one week and none in the postpartum group, this difference was not statistically significant. After six weeks, the rates of expulsion remained similar between the groups. These findings suggest that the risk of expulsion is not significantly influenced by the timing of Cu-IUD insertion.

Additionally, Abdel Ghany et al. found no significant distinctions in IUD displacement and expulsion rates between the study groups [10]. However, Sharma's study suggested that there were higher rates of expulsion and removal in cases of vaginal insertions compared to cesarean insertions [14]. Additionally, in a Brazilian University Hospital, immediate postpartum insertion of copper IUD is associated with higher rates of expulsion compared to standard insertion [9]. This suggests that other factors, aside from timing, may contribute to expulsion risk.

No cases of perforation were observed in either group at any time point. This is reassuring, as perforation is a rare but serious complication associated with IUD insertion. This finding aligns with the results reported in various studies, where no instances of perforation or pelvic inflammatory disease (PID) were observed in cases of trans-cesarean IUCD insertion [15-17].

Furthermore, a recent retrospective cohort study based on electronic medical records from Kaiser Permanente Southern California analysed 24,959 IUD insertions. This study revealed a statistically significant increase in the risk of perforation with IUD placement at 4-8 weeks postpartum compared to 9-36 weeks postpartum (0.78% versus 0.46%, respectively). The risk of perforation was found to decrease for IUD insertions performed after 22 weeks postpartum [18].

Therefore, IUD insertion timing should be based on individual desire for IUD contraception and patient convenience to assure an IUD insertion can occur. Careful follow-up of individuals at higher risk of uterine perforation is warranted.

After six weeks, the intrapartum group had a higher rate of missed threads compared to the postpartum group, but this difference was not statistically significant. The finding implies that the timing of insertion does not significantly affect the likelihood of missed threads. Similarly, Abdel-Ghany et al. found that, at the end of the follow-up period, there was a notable increase in the incidence of missed threads in the first group (immediate insertion) compared to the second group (insertion six weeks or more after delivery). This difference was be attributed to variations in thread length at the time of insertion and subsequent adjustments made during follow-up screening visits [10].

The rate of vaginal infection was slightly higher in the standard group after one week, but not after six weeks. These differences were not statistically significant. Vaginal infection rates may be more influenced by individual patient factors and hygiene

practices than by the timing of IUD insertion.

In a recent systematic review [19], among the eight studies that documented data on infection rates following immediate postpartum IUD insertion, two of them reported cases of wound infections occurring immediately after the insertion of a copper IUD during caesarean deliveries [20, 21].

Importantly, no cases of unintended pregnancy were observed in either group throughout the study. This underscores the effectiveness of Cu-IUDs as a contraceptive method, regardless of the timing of insertion. The results from two studies were consistent with and confirmed our findings [8, 10].

Conclusions

Our study has provided valuable insights into the efficacy and safety of intrapartum and postpartum Cu-IUD insertion during cesarean section. The results suggest that both methods are valid options for contraception, with no significant differences in complication rates after controlling for potential confounders. The decision regarding the timing of Cu-IUD insertion should be tailored to the individual patient's preferences and clinical context.

Based on the results of the study, several key recommendations can be made

Healthcare providers should consider offering Cu-IUD insertion as a viable option to women during cesarean deliveries, allowing them to make informed choices regarding contraception at this crucial time. It is crucial to monitor the hemoglobin levels of women after Cu-IUD insertion. Healthcare providers should continue to offer these options and emphasize the importance of post-insertion follow-up to identify and manage any complications early.

further research with larger sample sizes and longer follow-up periods is recommended to confirm the safety and effectiveness of intrapartum and postpartum Cu-IUD insertion during cesarean sections.

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