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Hang-up Technique versus Non-fixation Technique for Immediate Post-placental IUD Insertion during Cesarean Section: A Randomized Controlled Trial

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ABSTRACT

Background: Postpartum intrauterine device (IUD) insertion provides safe and extremely effective contraception, while women are receiving medical treatment.

Objective: To evaluate the expulsion rate of IUD implantation during caesarean section (CS) using the hang-up and non-fixation techniques.

Patients and Methods: This is a randomized controlled trial from the Women's Health Hospital, Assiut University, Egypt. Eligible women for inclusion were the pregnant women after age of viability (28 weeks) who were undergoing elective or emergency cesarean section (n = 118). Participants were divided into two groups; 59 participants in each study group. IUD was inserted using the hang-up technique in one group and using non-fixation technique in the other group.

Results: No cases of IUD expulsion were reported in the 1st group; however, the expulsion rate was high in the non-fixation group (0% Vs 12.5%, p = 0.013). Moreover, hang up technique showed higher continuation rate after 6 months of delivery than non-fixation technique (96.4 %, Vs 78.8 % P = 0.003). No significant differences were detected between both study groups regarding postpartum endometritis, heavy menstrual bleeding, pelvic infection, and dysmenorrhea.

Conclusion: The hang-up technique resulted in better IUD fixation with higher continuation rate and less expulsion rate than on –fixation technique. IUD fixation during cesarean section was safe easy and rapid learning curve.

Keywords: Intrauterine device, CS, Hang-up technique.

INTRODUCTION

Breastfeeding while pregnant increases the risk of an untimely, unexpected, and occasionally undesirable delivery. Unwanted pregnancies are a global issue. Up to 30% of pregnancies that result in births in the UK are thought to be unplanned [(1)].

Unintentional pregnancy is thought to be riskier throughout the postpartum period. In women who are not nursing, ovulation can restart as early as 2-4 weeks after giving birth, which increases the possibility of an unwanted pregnancy [(2)].

Postpartum family planning is advised by the WHO to promote appropriate birth spacing [(3)].

IUDs are incredibly successful in spacing out pregnancies, particularly in underdeveloped nations where women lack frequent access to medical facilities [(2)]. In less than ten minutes, an intra-cesarean post-placental IUD insertion offers a strong chance to provide reversible, long-term, safe, and affordable contraception with little to no discomfort for the patient [(4)]. The CDC and ACOG endorsed this strategy [(5)].

The immediate CU T 380A IUD insertion during CS without fixation has been the subject of several trials. The high risk of expulsion that occurs when an IUD is implanted after placental birth without fixation was the primary issue with immediate postpartum IUDs [(6–9)]. In 2014 was the first description of the hang-up method for IUD insertion after CS, and no expulsions were noted [(10)].

Till now there is no randomized controlled trial comparing IUD insertion using hang up technique versus non-fixation technique.

This study aimed to evaluate the expulsion rate of IUD implantation during caesarean section (CS) using the hang-up and non-fixation techniques.

PATIENTS AND METHODS

This is a single-blinded randomized controlled trial conducted in the Department of Obstetrics and Gynecology, Assiut University Hospital, Assiut, Egypt. All pregnant women after the age of viability (28 weeks), who were willing for immediate postpartum contraception, and were counseled during antenatal care; they were included in this study after signing written consents; either undergoing elective or emergency CS.

The exclusion criteria were intrauterine infection, intrauterine lesions such as submucous fibroid or uterine septum, bleeding disorders, genital tract malignancy, uterine atony, sexually-transmitted diseases, extensive adhesions that prevent uterus exteriorization, hypersensitivity to copper, bad general conditions such as cardiac diseases or diabetes with pregnancy.

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All the participants were divided into one of two groups at random (1:1):

Group A:

Non-fixation group and **Group B:** Fixation (hang-up) group. The allocation data were put in sequentially numbered sealed envelopes and a computer-generated random table was constructed by a statistician who was not otherwise involved in the study. A card with the group identifier was placed inside each envelope, which was sent to a designated nurse who opened them right before the CS. To prevent bias, the allocation was hidden from all patients.

Intervention:

All women underwent CS and received cefazolin sodium (zinol) (1 gm) (1st generation cephalosporin, Pharco B International, Egypt) before skin incision as antibiotic prophylaxis against postpartum infection according to the Department's protocol.

After placental delivery and ensuring complete evacuation of uterine cavity, good uterine contraction, and no bleeding from the placental site, CU T 380A IUD (PREGNA Safeload, DKT, India) was immediately inserted by the surgeon through uterine incision where the transverse limbs of IUD were placed in fundus and threads were cut, and so IUD was placed without fixation.

In group (B), ring forceps was entered into the uterine cavity through the uterine incision, then the ring forceps was opened and pushed to tap on the wall of uterine fundus and press on it. Then, the surgeon used the tip of index finger to tap on the outside of uterine fundus, forming a basin between the two ends of ring forceps.

A straight needle (48 mm length) was prepared with rapidly absorbable suture 0 (EGYCRYL Fast, Braided Degraded polyglactin PGLA, TAISEIER MED, EGYPT) and needle puncture on the concave wall. Once the needle penetrated the wall of uterine fundus, it was clamped with ring forceps, then the ring is pulled out the uterine cavity, Cu T380A postpartum IUD and anchor knot in the branching limbs of IUD were prepared, the anchor knot was strengthened with another slip knot, the IUD was then pulled such that the thread was at the uterine cavity entrance and the IUD was hanging in the centre of the fundus. A slip knot was then tied on the outer retaining wall of the uterine fundus, and IUD strands were cut and transmitted through the cervix **Figure (1).**

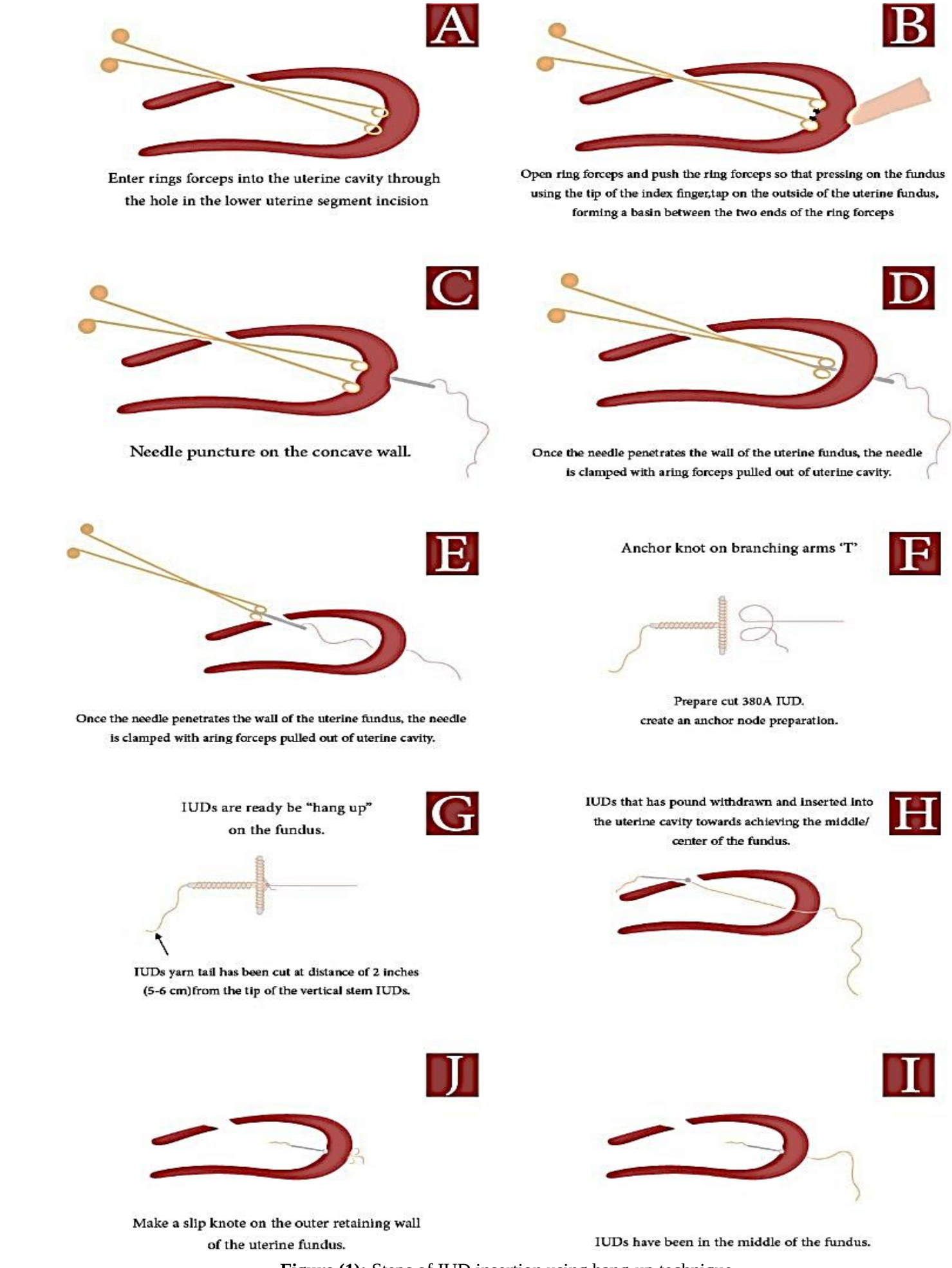

Figure (1): Steps of IUD insertion using hang-up technique.

Follow-up schedule:

Follow-up visits were conducted in the postpartum period (after 2 weeks, 6 weeks, 3 months, and 6 months of delivery).

1st visit (2 weeks postpartum): The following items were checked:

- IUD threads using sterile Cusco speculum.
- Ultrasound (type of 2D transvaginal US) examination to check the site and position of IUD.

The IUD was classified as 'in place' when it was visualised in close proximity to the uterine fundus and the distances between the uterine wall and the body of the IUD were identical [(11)].

Complete expulsion was defined as the patient reporting seeing the IUD come out and there being no IUD visible on the ultrasound [(12)].

Partial expulsion was defined as a space of more than 10 mm between the IUD's vertical arm and the endometrium of the uterine fundus [(4)].

Displacement was described as the IUD rotating from its typical transverse position or being placed distant from the fundus and into the lower uterine segment or cervix [(13)].

Wound infections were characterized by the presence of purulent discharge, erythema, and induration of the incision site [(14)].

2nd visit (6 weeks postpartum): The IUD threads were checked and ultrasound examination was performed to check the IUD's site and position.

3rd visit (12 weeks postpartum)

The IUD threads were checked and ultrasound examination was performed to check the IUD's site and position.

4th Visit (6 months postpartum)

The IUD threads were checked and ultrasound examination was performed to check the IUD's site and position and estimate the following:

Menstrual pattern (Amenorrhea: absence of menstruation, normal pattern of the patient, or menorrhagia, which refers to regular and prolonged menstrual bleeding that is viewed as excessive [(15)].

Dysmenorrhea is defined as severe uterine pain during menstruation [(16)].

Continuation rate after 6 months (The percentage of contraceptive method acceptors who continue to use any contraceptive method supplied by the programme after a certain length of time) [(17)].

Pelvic infection symptoms: include fever, rigours, lower abdomen discomfort, soreness, and foul vaginal discharge [(7)].

If the patient does not arrive on time, they were reached by mobile numbers or home visits. If they could not be reached or found by the conclusion of the study, they were counted in the category of "lost at the follow-up".

Primary outcome of this study was the difference in expulsion rate between both groups (complete or partial) utilising 2D transvaginal US.

Secondary outcomes included 6-month continuation rate, displacement, postpartum endometritis, dysmenorrhea, and pelvic pain.

Sample size:

The sample size was calculated using Epi- Info7. Based on past investigations, the continuation rate (after 6 months of delivery) in the group of IUD conventional insertion (group A) was 81.6%, while the continuation rate in the group of IUD insertion with the hang-up technique (group B) was 97.2% [(6,10)]. So, the expectant difference between study groups was 16%, with a confidence level of 90% and power of 85%. The required sample size needed for the study is 112 cases. If the drop-out was hypothesized to be 5%, so 118 cases in total were enrolled in the study to compensate the people who may be lost at follow up.

Ethical approval:

Assiut Medical Ethics Committee of the Assiut Faculty of Medicine gave its approval to this study. The trial was planned and reported in accordance with Clinical Trials.Gov for improve the quality of reporting RCTs (registered trial; NCT03780985). All participants gave written consent after receiving all information. The Helsinki Declaration was followed throughout the study's conduct.

Statistical analysis

SPSS 22.0 was used. The data were shown as mean±standard deviation (SD), number and percentage. Fisher's exact test and Chi-squared were used to compare different qualitative variables. Quantitative factors were compared between groups using the independent samples t-test. P-values less than 0.05 were regarded as statistically significant.

RESULTS

Figure 2 shows the participant recruitment process. In total, 180 women were assessed for eligibility, of whom 16 had a contraindication for IUD insertion, 46 refused to participate and causes of refusal are shown in **Table (1)**, leaving 118 women randomized to one of the two groups. Fifty-nine women received a post-placental IUD using non-fixation technique and fifty-nine women were randomized to receive a post-placental IUD using hang up technique. All patients were followed for 6 months after delivery; in non-fixation IUD group, three patients lost to follow up while in the hang up group four patients lost. Analysis has been done for patients who completed the study (56 in the non-fixed group and 55 in fixed group)

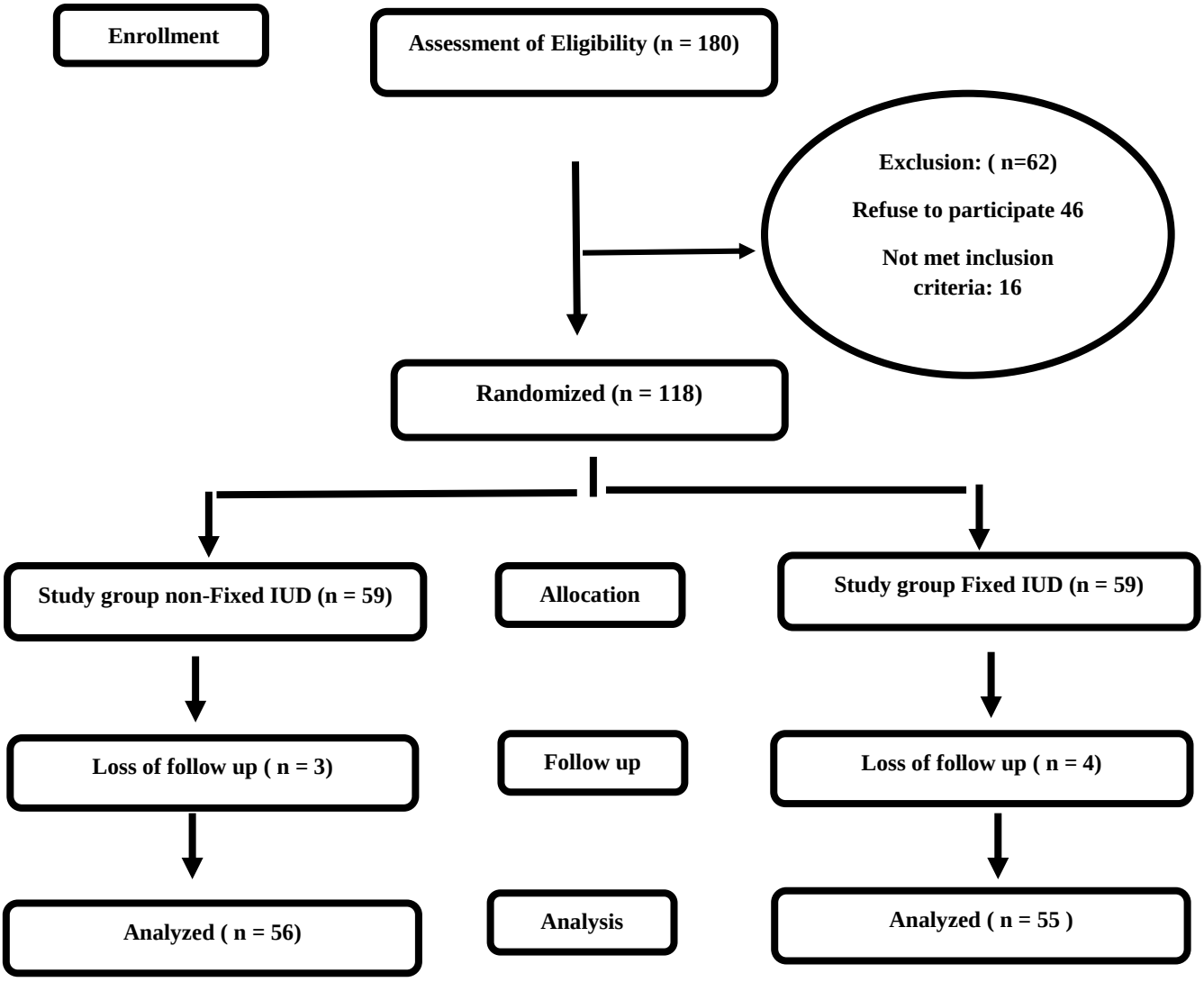

Figure (2) Consort flow diagram

Table (1): Causes of refusal to participate in the study

Causes	**No**	**%**
Prefer to use another method	14	30.4 %
Fear of pain and heavy bleeding	16	34.8%
Partner refusal	3	6.5%
Interfere with sexual intercourse	6	13.1%
Not need contraception	4	8.7%
Not enough knowledge about IUD insertion during CS	3	6.5%
Total	46	100 %

The baseline characteristics of the study participants are shown in **Table (2).** Both groups had similar baseline characteristics.

Table (2): Baseline characteristics of the studied groups

	Group A (n= 56)	**Group B (n= 55)**	**P-value**
Age: (years)			
< 30	22 (39.3%)	18 (32.7%)	0.566
30 – 35	25 (44.6%)	24 (43.6%)	
> 35	9 (16.1%)	13 (23.6%)	
Mean ± SD	30.64 ± 4.92	31.73 ± 4.56	0.231
Range	21.0-40.0	20.0-40.0	
BMI: (Kg/m^2)			
Normal	33 (58.9%)	36 (65.5%)	0.742
Overweight	12 (21.4%)	9 (16.4%)	
Obese	11 (19.6%)	10 (18.2%)	
Parity:			
PG	1 (1.8%)	0 (0.0%)	0.332
Para 1	7 (12.5%)	2 (3.6%)	
Para 2	15 (26.8%)	13 (23.6%)	
Para 3	14 (25.0%)	19 (34.5%)	
Para 4	12 (21.4%)	10 (18.2%)	
Para 5 or more	7 (12.5%)	11 (20.0%)	
Mean ± SD	2.98 ± 1.48	3.44 ± 1.50	0.112
Range	0 – 7	1 - 8	
No. of previous CS:			
Mean ± SD	2.21 ± 1.17	2.38 ± 1.06	0.432
Range	0 – 5	0 - 5	
Gestational age: (weeks)			
Mean ± SD	37.77 ± 1.35	37.31 ± 1.60	0.105
Range	32.0-40.0	30.0-40.0	

Table 3 shows no differences between the study groups regarding types or indications of cesarean section.y

Table (3): Type and indication of CS in the studied groups

	Group A (n= 56)		**Group B (n= 55)**		**P-value**
	No.	**%**	**No.**	**%**	
Type of CS:					
Elective	17	30.4	20	36.4	0.502
Emergency	39	69.6	35	63.6	
Indication of CS:					
Repeated CS	38	67.9	44	80.0	0.145
Fetal distress	5	8.9	3	5.5	0.716
Macrosomia	1	1.8	2	3.6	0.618
Severe preeclampsia	3	5.4	2	3.6	1.000
Failure of progress	3	5.4	1	1.8	0.618
Malpresentation	4	7.1	2	3.6	0.679
Cephalopelvic disproportion	2	3.6	1	1.8	1.000

Table 4 shows no differences between the study groups regarding postpartum endometritis, postpartum bleeding days, wound infections, and postpartum pelvic pain**.**

Table (4): Follow-up findings, after 2 weeks of delivery in the studied groups

		Group A (n= 56)		Group B (n= 55)		P-value
		No.	%	No.	%	
Evidence of endometritis:	Yes	0	0	0	0	--
	No	56	100	55	100	
Fever:	Yes	2	3.6	1	1.8	1
	No	54	96.4	54	98.2	
Abdominal tenderness:	Yes	5	8.9	2	3.6	0.438
	No	51	91.1	53	96.4	
Offensive vaginal discharge:	Yes	0	0	0	0	--
	No	56	100	55	100	
Leukocytosis:	Yes	4	7.1	3	5.5	1
	No	52	92.9	52	94.5	
Postpartum bleeding duration: (days)	Mean ± SD	20.54 ± 7.15		19.18 ± 5.11		0.254
	Range	9.0-40.0		10.0-35.0		
Superficial wound infection:	Yes	0	0	1	1.8	1
	No	56	100	54	98.2	

Table 5 shows that after six months of delivery, the fixation (hang-up) group had a greater continuation rate than the non-fixation group. Additionally, there were no documented occurrences of expulsion in the fixation group, but the expulsion rate was significant in the non-fixation group. Regarding pelvic infections, excessive uterine bleeding, pelvic discomfort and dysmenorrhea, pregnancy on top of an IUD, and IUD displacements, there were no differences found between the two research groups.

Table (5): Follow-up findings, after 6 months of delivery in the studied groups

	Group A (n= 56)		Group B (n= 55)		P-value
	No.	%	No.	%	
Continuation:					
Yes	43	76.8	53	96.4	0.004*
No	13	23.2	2	3.6	
Menstrual pattern:					
Normal	29	51.8	25	45.5	0.564
Menorrhagia	9	16.1	7	12.7	
Amenorrhea	18	32.1	23	41.8	
Pregnancy on top of IUD:					
Yes	1	1.8	0	0.0	1.000
No	55	98.2	55	100.0	
Dysmenorrhea:					
Yes	7	12.5	10	18.2	0.406
No	49	87.5	45	81.8	
Pelvic infection:					
Yes	0	0.0	1	1.8	1.000
No	56	100.0	54	98.2	
Displacement:					
Yes	1	1.8	0	0.0	1.000
No	55	98.2	55	100.0	
Expulsion:					
Yes	7	12.5	0	0.0	0.013*
No	49	87.5	55	100.0	
Expulsion type:					
Partial	5	71.4	--	--	--
Complete	2	28.6	--	--	

*: Statistically significant

Table (6) shows that fifteen patients not continued to use IUD as a contraception method after 6 months of IUD insertion during CS, 13 patients in non-fixation group and 2 patients in hang up group. There were 7 cases with IUD expulsion and all these cases was reported in non-fixation group and one case of IUD displacement in non-fixation group. Also, there were 4 cases of IUD removal due to abnormal uterine bleeding (menorrhagia) one case in hang up group and 3 cases in non-fixation group. There were 2 other cases of IUD removal due to pelvic pain and dysmenorrhea one in each group.

Table (6): Causes of discontinuation of IUD in the studied groups

Cause	Group A	Group B	total
Number of cases	13	2	15
Expulsion	7	0	7
Rotational displacement	1	0	1
Pelvic infection	0	1	1
Abnormal uterine Bleeding	3	1	4
Pelvic pain	1	0	1
Failure/pregnancy	1	0	1

DISCUSSION

Placement of a postpartum IUD offers women who are seeking medical care, safe and very effective contraception at that time [18]. The ACOG, among other professional associations, and the US Medical Eligibility Criteria for Contraceptive Use endorse the safety of placing an IUD right away after giving birth [19].

This work is the first RCT to compare the hang-up technique with the non-fixation technique in the placement of CU T 380A IUCD during CS.

Finding and interpretations

IUCD expulsion is an important factor that affects the device efficacy [20]. Nonetheless, a great deal of variation in expulsion rates among research indicates the existence of variables that may lower expulsion rate [21].

The non-fixation group in the current randomised clinical trial had a higher expulsion rate (12.5%), whereas there were no recorded expulsion instances in the group using the hang-up approach. The likelihood of expulsion and/or displacement after postpartum implantation may be influenced by a number of variables besides the form and surface area of IUCDs. The degree of cervical dilatation during insertion (with a higher risk if the cervix dilates by 2 cm or more), and the distance between the uterine fundus and IUCD during insertion (with a lower risk if the IUD is closer to the fundus) are two examples of these variables [22-23]. Since the IUD's horizontal arm is affixed to the fundus by the hang-up procedure, no movement or malposition is anticipated [10].

Similar to our study, in a large study, which included 245 patients and assessed IUD insertion using the non-fixation technique, the expulsion rate was reported to be 10.6% after 6 months of IUCD insertion and 17.6 % after 1 year of IUCD insertion [6]. In 2015, a multicentric study including 120 patients (with only one patient underwent elective CS) assessed 3 different types of IUCDs, Nova T380, Multiload CU 375, and CU T 380A, where they were inserted with the non-fixation technique during CS. The total expulsion rate after 1 year was 10.8%; the expulsion rate was 15% in the CU T 380A group [9]. In 2018, another study comparing innovative frameless copper-releasing IUD (Gyn-CS®) versus Cu T 380A insertion during CS found that the expulsion rate after 3 months in the arm of CU T 380A placement with the non-fixation technique was 11.4% [8].

In 2014, the hang-up technique was described by **Tjahjanto and Haryuni**[10] in the placement of C T380A IUCD during CS and no cases of expulsion were reported in the study group after 12 months of delivery**.** Similarly, our study reported no cases of expulsion after 6 months in the women group with IUD inserted with the fixation technique. Accordingly, the expulsion rate markedly decreased with the fixation of IUCD during CS.

In contrast of our study, a large observational study reported low expulsion rate of 5.3% after 1 year of IUD insertion**;** this study included 300 primiparous patients and assessed IUCD insertion during CS with the non-fixation technique [20].

In this trial, only one case was reported with IUD displacement (rotational) in the non-fixation group where the transverse limbs of IUD were moved towards cervix (1.8%) but no cases reported in hang up technique group. In agreement with our study, **Elsokary *et al.*** [24] compared IUD placement during CS and IUD placement 3 months postpartum found that IUD displacement in the intracesarean IUD insertion group was 1.9%**.** In contrast to our study, **Ragab *et al.*** [9] found that the displacement rate was 28%, but this study used 3 different types of IUDs.

Regarding the continuation rate after 6 months, our study reported that the continuation rate was higher in the fixation group (96.4%) than the non-fixation group (76.5 %). Total number of cases with IUD removal was 15 patients in both groups; 13 patients in the non-fixation group and 2 patients in the fixation group. Seven cases with IUD expulsion were reported; all of them were in the non-fixation group and there was one case of IUD displacement also in non-fixation group. Also, there were 4 cases who removed the IUD because of abnormal uterine bleeding; one case in the fixation group and 3 cases in the non-fixation group. Other 2 patients removed IUD due to pelvic pain and dysmenorrhea; one case in each group. High expulsion rate, which reported in non-fixation group is a major cause of IUD discontinuation, and IUD placement

using hang up technique increased continuation rate of postpartum IUD.

Similarly, **Çelen *et al.*** [6] reported that the continuation rate after 6 months and 1 year of IUD insertion using non-fixation technique was 81.6% and 62%, respectively. **Ragab *et al.*** [9] reported that the continuation rate after 1 year using the non-fixation technique was 81.7 but they used 3 types of IUDs. Also, **Sucak *et al.*** [4] reported that the continuation rate after 1 year using the non-fixation technique was about 84 % in the patients who underwent CS and were in labour, while the continuation rate in patients who underwent elective CS was 87%. In 2018, another study comparing innovative frameless copper-releasing IUD (Gyn-CS®) with the Cu T 380A insertion during CS reported that the continuation rate after 3 months in the arm of CU T 380A placement with the non-fixation technique was 79% [8].

On the other hand, our study reported that the continuation rate after 6 months of IUD insertion using the fixation technique was 96.4%. Similarly, **Tjahjanto and Haryuni**[10] reported that the continuation rate after 6 months of delivery was 97%**.**

In the present study, no cases of postpartum endometritis or puerperal infections were reported in both study groups. This related to strict antiseptic conditions and good antibiotic prophylaxis administration before CS. Another study including 300 patients reported only 1 case of puerperal infection (0.33%) [20]**.** Moreover, **Ragab *et al.***[9] reported only 1 case of puerperal infection with post-placental IUD insertion during CS (0.8%).

In the present study, dysmenorrhea and pelvic pain was higher in the fixation group (18.5%) than the non-fixation group (12.5%) but this was not statistically significant. **Ragab *et al.***[9] found that dysmenorrhea and persistent pelvic pain after 1 year in the patient group, where TCU380A was inserted with the non-fixation technique, was 20%**.** Another study was performed using the non-fixation technique in TCU380A IUD insertion during CS, where dysmenorrhea and persistent pelvic pain were reported to be 47% [25].

The risk of pelvic infection following intra-cesarean implantation was minimal in our study and did not differ significantly between the two groups. These findings align with the randomised studies, which found no evidence of an infection difference related to the date or technique of insertion [20].

In our study, no significant difference was reported between both study groups regarding menorrhagia over 6 months after IUD insertion. Average percentage of menorrhagia was about 14%. **Salem *et al.***[7] reported that the percentage of patients with menorrhagia after 6 months was 19%. In 2015, **Ragab *et al.***[9] found that the percentage of menorrhagia after 1 year in the patient group where CU T 380A was inserted during CS was 15 %. Another study, where CU T 380A insertion was done with the non-fixation technique during CS, revealed that about 10.6 % of patients had menorrhagia after 1 year [20]. A study by **Elsokary *et al.*** [24] reported that the percentage of patients with abnormal uterine bleeding after 1 year of IUD insertion during CS was 9.8%. **Tjahjanto and Haryuni**[10] reported that abnormal uterine bleeding after 1 year was detected in 5.6% of the included patients**.**

The visibility of strings is an indicator for IUD users and healthcare workers of IUD proper positioning. Also, it facilitates IUDs removal. In this study, visible threads after 6 months were detected using Cusco speculum in about 66% of the non-fixation group of patients and about 54% of the fixation group of patients. There were no significant differences between both groups regarding the visibility of threads.

Strength and limitations:

Points of strength in our study were:

- A double-blind RCT wherein the sonographer and subjects were blinded to the group assignment.
- High follow up rate was reported in our study.

However, our study is not without limitations:

- Short period of follow up did not give us the opportunity to know continuation rate and expulsion after 1 year and there were no data regarding the presence of a problem with removal of fixed IUD or residual intrauterine adhesions due to this maneuver.
- Sample size was relatively small, which was not adequately powered to detect the differences between both techniques.

Future research:

1. Future studies to follow up patients with IUD fixation regarding removal of IUD and adverse outcomes as intrauterine adhesions.
2. Future studies with a bigger sample size and longer follow-up.
3. Future studies with using Levonorgestrel IUD (Mirena) instead of copper T 380A IUCD to decrease adverse effects of copper IUCD.

CONCLUSION

The hang-up technique resulted in better IUD fixation with higher continuation rate and less expulsion rate than in fixation technique. IUD fixation during CS was safe easy and rapid learning curve.

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