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# ROLE OF ULTRASOUND TECHNIQUE IN WOMAN SATISFACTION DURING PLACEMENT OF INTRAUTERINE CONTRACEPTION

# (A RANDOMIZED CLINICAL TRIAL)

By

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## ABSTRACT

**Background:** Intra uterine contraception methods are long-acting reversible contraceptives (LARC) with licensed durations of use ranging between 3 and 10 years. Fear of pain at placing can be an obstacle to IUD selection leading to women's counseling on other, less effective methods.

**Objective:** To evaluate the use of US-guided IUD insertion for increasing patient satisfaction and minimizing the pain and duration of the procedure and compared with the IUD traditional insertion method.

**Patients and Methods:** A randomized, comparative, trial was performed on 200 women scheduled to undergo IUD insertion at the outpatient clinics of Obstetrics and Gynecology Department of Sinbillawin General Hospital from(1st of April2020 till30thDecember2020) .Women received Copper T380A(pregna) by withdrawal technique and Mirena IUD insertion. Patients were classified into two equal groups: Group (A): were scheduled for trans abdominal ultrasound-guided IUD insertion; and Group (B): were scheduled for Non Guided method of IUD insertion.

**Results:** Patient's pain during IUD insertion in Group (A) was statistically significantly lower than group (B) (P<0.001). Patient's duration of the IUD insertion procedure (seconds) in Group (A) was statistically significantly lower than group (B) (P<0.001). Patient's failed insertion in Group (A) show that 3% of the women had failed insertion and 96% of them had IUD insertion in place, while in Group B, 6% of the women had failed insertion, 80% of the women had IUD insertion in place, and 14% had IUD insertion misplaced. There were statistically significant differences between groups (p<0.001). There was high statistically significant differences between groups as regard to patient's satisfaction (P<0.001).

**Conclusion:** US technique insertion is more effective, less painful and more client satisfaction.

**Key words:** Intrauterine Devices; Ultrasound; Satisfaction; Pain.

## INTRODUCTION

The intrauterine device (IUD) is one of the most commonly used contraception methods, which provides reversible, low cost, and long-term contraception *(Ahmadi et al., 2015).*

The insertion of an IUD can be very painful because of the use of multiple instruments such as speculum insertion, manipulation of the cervix, tissue forceps (vollesellum) and uterine sound application. The uterine sounding-related pain may be comparable or even worse

than mere IUD insertion *(Maguire et al., 2012)*. In addition, patients with prior cesarean delivery were found to be more likely to have difficult insertion *(Micks et al., 2014)*. The experienced pain is mild to moderate and less than expected for most women; however, some women remain worried about the potential for discomfort or more likely to be affected by many factors, including anatomical and psychological elements, nulliparity, or long time period since delivery *(Gemzell-Danielsson et al., 2019)*.

Fear of pain at placing can be an obstacle to IUD selection *(Lopez et al., 2015)*, leading to women's counseling on other, less effective methods *(Buhling et al., 2014)*. Therefore, many studies were conducted to establish a proper IUD insertion method to minimize the associated pain.

In terms of assessing the IUD position and its possible complications, pelvic ultrasound (US) plays an important role as a gold standard of this gynecological condition *(Maged et al., 2020)*. Transvaginal ultrasound is applied before Insertion routinely to exclude uterine abnormalities and applied after Insertion to exclude malposition and other complications, including perforation, expulsion, and pregnancy in asymptomatic women with IUDs *(Nowitzki et al., 2015)*.

**In this study, we aimed to** evaluate the use of US-guided IUD insertion in minimizing the pain and duration of the procedure and increasing patient satisfaction compared with the IUD traditional insertion method.

## PATIENTS AND METHODS

A written informed consent was taken from every participant after proper explanation of the study.

**Inclusion Criteria:**

- She has not had intercourse since last normal menses.
- She has been correctly and consistently using a reliable method of contraception.
- She was within the first 7 days of the onset of a normal menstrual period.
- She was not breastfeeding and less than 4 weeks from giving birth.
- She was fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months' postpartum.
- She was within the first 7 days post-abortion or miscarriage.

**Exclusion criteria:**

- Unexplained abnormal vaginal bleeding.
- Untreated cervical cancer, uterine cancer or ovarian cancer.
- Uterine abnormalities.
- Pelvic infection within the past three months.

A randomized, comparative, trial was performed on 200 women scheduled to undergo IUD insertion at the outpatient clinics of Obstetrics and Gynecology Department of Sinbillawin General Hospital. Women received Copper T380A (pregna) by withdrawal technique and Mirena IUD insertion. Patients were classified into two equal groups: Group (A): including were scheduled for trans

abdominal ultrasound-guided IUD insertion; and Group (B) including were scheduled for non-guided method of IUD insertion. Selection of type of IUD according to age and patient complaint.

Females from 18 to 40 years received Copper T380A (pregna). Females above 40 years who complain peri menopausal bleeding received Mirena IUD. Before insertion, each female took one tablet of misoprostol sublingually for softening the cervix and ease the insertion and Instructed to return after one month (post menstrual) to check up the inserted IUD.

**Levonorgestrel-Releasing Intrauterine System (Mirena) Insertion:**

The packaging was opened by an assistant, taking care to maintain the sterility of the package contents. Care was taken to ensure the arms of the IUD were in a horizontal position. The threads on the handle of the IUD insertion device were released from the groove in the handle of the insertion device.

The slider was pushed toward the insertion tubing, the strings at the base of the IUD handle should be pulled, which was retracted the IUD arms into the insertion tubing. This was accomplished by sliding the flange over the marked increments on the IUD insertion tube. While continued upward pressure is applied to the green slider on the IUD handle, the insertion tubing was placed into the vagina at the level of the external cervical os. The insertion tubing was then gently advanced until the flange was approximately 1.5-2 cm from the external cervical os. Next, the slider on the handle was pulled backward to the level of the raised mark on the insertion handle, expelling the IUD arms from the insertion tubing, and waiting 10 seconds to allow the arms to open completely. The insertion tubing was then advanced until the flange is at the external cervical os, thereby advancing the IUD to the level of the uterine fundus.

While holding the insertion device steady, the slider was pulled all the way down to release the IUD. The IUD handle and insertion tubing were then gently retracted from the uterus and cervix. The strings remain in place. Following removal of the insertion device, the IUD strings were readily visualized in vagina. Using long-handled scissor, the strings were then trimmed so that approximately 3 cm were visible, extending from the external cervical os.

**Group A:** Ultra sound technique for insertion IUC: In this group, Each women was instructed to have full bladder to ease the insertion. The woman was in lithotomy position. Acuso speculum (plastic disposable cusco to reduce pain and Infection) was introduced to visualise the cervix. The cervix was wiped by povidone Iodine. Lignocaine gel was applied on the cervix to reduce pain during the insertion. Uterine sound (plastic disposaple sound) was applied to measure the length from the fundus to the cervical canal under vision through trans abdominal ultra sound. Then, the insertion tubing was advanced until the flange was at the external cervical os, advancing the IUD to the level of the uterine fundus, hold the insertion device steady. The slider was pulled all the way down to release the IUD. The IUD handles and insertion tubing was then gently retracted from the uterus and cervix. This technique

under vision through trans abdominal ultra sound (Edan Dp10).

**Group B:** Non Guided Method for insertion IUC: Application of the tissue forceps (vollesellum) on the cervix to straight the angle of flexion of the uterus and uterine sound to was used to measure the proper length from the uterine fundus to the internal os. IUD was inserted by withdrawal technique. Women were instructed to return after one month (post menstrual) to assess the proper position and exclude complication of the inserted IUD.

**Primary outcome:** Assessment of proper length from the fundus to internal os, lower time consumption, less instruments.

**Secondary outcomes:** included incidence of complication as displacement, expulsions, perforation and patient satisfaction (reported as crude satisfaction scores).

**Statistical Analysis:**

Data were collected, revised, coded and entered to the Statistical Package for the Social Sciences (IBM SPSS) version 23. The distribution of quantitative data was tested by Kolmogorov-Smirnov test of normality. So, the quantitative data were presented as mean, standard deviations and ranges when parametric. Also, qualitative variables were presented as number and percentages.

The comparison between groups regarding qualitative data was done by using Chi-square test. The comparison between two independent groups with quantitative data and parametric distribution was done by using Independent t-test or Mann-Whitney test. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, p-value was considered significant when $P \leq 0.05$.

## RESULTS

Patients were classified into two groups: Group (A): including 100 women who were scheduled for trans abdominal ultrasound-guided IUD insertion; and Group (B) including 100 women who were scheduled for traditional method of IUD insertion. The mean age in Group (A) was 32.1 ±3.7 years while in Group (B) 31.7 ±4.4 years; there was no statistically significant difference between groups where P= 0.486. Similarly, there were no statistically significant differences between groups in terms of weight (P=0.159), Height (P=0.412), and BMI (P=0.882).

Patient's previous delivery type in Group (A) show that 40% of the women had a history of vaginal delivery type and 60% had a history of CS delivery. While in Group (B), 47% of the women had a history of vaginal delivery type and 53% of the women had a history of CS delivery. There was no statistically significant difference between groups where P=0.559 **(Table 1)**.

**Table(1): Baseline characteristics of the studied groups**

| Parameters \ Groups | | Group (A) (n=100) | | Group (B) (n=100) | | P Value |
|---|---|---|---|---|---|---|
| **Age** | Mean ± S.D | 32.11±3.657 | | 31.71±4.404 | | 0.486 |
| **Parity (No)** | Median (IQR) | 1(1-2) | | 1(1-2) | | 0.633 |
| **Weight** | Mean ± S.D | 64.64±5.800 | | 65.80±5.790 | | 0.159 |
| **Height** | Mean ± S.D | 161.96±7.983 | | 162.89±8.029 | | 0.412 |
| **BMI** | Mean ± S.D | 20.15±32.89 | | 19.47±31.62 | | 0.882 |
| **Previous Delivery Type** | Vaginal Delivery | 40 | 40 | 47 | 47 | 0.559 |
| | 1 CS | 26 | 26 | 25 | 25 | |
| | 2 or More CS | 34 | 34 | 28 | 28 | |

*IUD: Intrauterine Device; BMI: Body Mass Index

Selection of IUD type according to Age & patient complaint. In Group (A):91% received Copper T380A by withdrawal technique and 9% received hormonal type (Mirena).while In Group (B): 98% received Copper T380A by withdrawal technique and 2% received Mirena **(Table 2)**.

**Table(2): Selection of IUD type**

| Selection of IUD type \ Groups | Group (A) (n=100) | | Group (B) (n=100) | | P Value |
|---|---|---|---|---|---|
| Copper T 380 A | 91 | 91 | 98 | 98 | 0.029 |
| Mirena | 9 | 9 | 2 | 2 | |

Concerning the study's outcomes, patient's failed insertion in Group (A) showed that 3% of the women had failed insertion and 96% of them had IUD insertion in place, while in Group B, 6% of the women had failed insertion, 80% of the women had IUD insertion in place, and 14% had IUD insertion low lying. There were high statistically significant differences between group (P<0.001). There was statistically significant differences between groups as regard to patient's satisfaction (P<0.001).

Patient's duration of the IUD insertion procedure (seconds) in Group (A) ranged between 25-45 with mean ±S.D. 35.56 ±6.323, while in Group (B) ranged between 56-110 with mean ±S.D. 82.44±17.545. There were statistically significant differences between groups (P<0.001).

Patient's pain during IUD insertion in Group (A) ranged between 1-5 with Median (IQR). 4 (3 – 5); while in Group (B) ranged between 3-8 with Median (IQR). 7 (6 – 8). There was statistically significant difference between groups (P<0.001) **(Table 3)**.

**Table (3): Comparison between two groups as regard to study's outcomes**

| Parameters \ Groups | | Group (A) (n=100) | | Group (B) (n=100) | | P Value |
|---|---|---|---|---|---|---|
| **TVS after Insertion** | Failed insertion | 3 | 3 | 6 | 6 | <0.001 |
| | IUD in place | 96 | 96 | 80 | 80 | |
| | Low lying | 1 | 1 | 14 | 14 | |
| **Time consumed during insertion (seconds)** | Mean± S.D | 35.56±6.323 | | 82.44±17.545 | | <0.001 |
| **Pain score (scales from 0 to 10)** | Median (IQR) | 4(3-5) | | 7(6-8) | | <0.001 |
| **Patient satisfaction** | Satisfied | 51 | 51 | 15 | 15 | <0.001 |
| | Un-satisfied | 3 | 3 | 53 | 53 | |
| | Indifferent | 46 | 46 | 32 | 32 | |

*IUD: Intrauterine Device
*TVS: trans vaginal ultrasound

TVS after one month (post menstrual), 81 % percent of the women in group (A) had IUD in place, 9% had low lying IUD and 3% displaced while in Group (B) 58% of the women had IUD in place 32% had low lying IUD and 10% displaced. There was high statistically significant difference between groups (P< 0.001). IUD Inserted IUD associated complication in Group (A) showed that 71% of the women had no complication, 16 % had bleeding complication, 7% pelvic pain, and 6% backache. In Group (B), 69% of the women had no complication, 20% bleeding 9% had pelvic pain and 2% had backache. There was no statistically significant difference between groups (P=0.436) according patient satisfaction, 89% satisfied, and 11% unsatisfied in group (A), while in Group (B) 41% satisfied, and 59% unsatisfied **(Table 4)**.

**Table (4): Assessment of Inserted IUD after one month (post menstrual)**

| Parameters \ Groups | | Group (A) (n=100) | | Group (B) (n=100) | | P Value |
|---|---|---|---|---|---|---|
| **TVS after one month (post menstrual)** | **In place** | 88 | 88 | 58 | 58 | <0.001 |
| | **Low lying** | 9 | 9 | 32 | 32 | |
| | **Displaced** | 3 | 3 | 10 | 10 | |
| **Inserted IUD associated complication** | No | 71 | 71 | 69 | 69 | 0.436 |
| | Bleeding | 16 | 16 | 20 | 20 | |
| | Pelvic pain | 7 | 7 | 9 | 9 | |
| | Backache | 6 | 6 | 2 | 2 | |
| **Client satisfaction** | Satisfied | 89 | 89 | 41 | 41 | <0.001 |
| | Unsatisfied | 11 | 11 | 59 | 59 | |

*IUD: Intrauterine Device
*TVS: trans vaginal ultra sound.

## DISCUSSION

IUDs provide a long-term contraception method as a convenient, efficient, relatively safe, and low-cost method *(Maged et al., 2020)*. Placing of IUD is a major challenge, which requires considerable skills due to the relatively invasive insertion procedure *(Gemzell-Danielsson et al., 2019)*. In improper placement, there are many complications, including failure of the device associated with an unplanned pregnancy, perforation, and penetration *(Elsedeek et al., 2016)*. During insertion, the experienced pain may be an obstacle to IUD selection, resulting in searching for different unsafe methods *(Ali et al., 2019)*. Studies have been carried out to develop easier methods of IUD insertion to minimize the pain and discomfort involved in the process by omitting bi-manual and uterine assessments, using different pharmacological agents, and using ultrasound-guided IUD insertion *(Gemzell-Danielsson et al., 2019)*. Many studies were conducted to evaluate pharmaceutical agents' use in reducing the pain, either before, during, or after the insertion. However, they showed insufficient evidence that supports their routine use *(Lopez et al., 2015)*.

**Patients were classified into two equal groups:** Group (A): were scheduled for trans abdominal ultrasound-guided IUD insertion; and Group (B) were scheduled for traditional method of IUD insertion. Selection of IUD type according to age and patient complaint. Females from 18 to 40 years received Copper T380A (pregna). Females above 40 years who complain peri menopausal bleeding received Mirena IUD.

There was a harmony between both groups regarding participants' age, parity, and BMI, with no statistically significant differences. Our finding demonstrated that using US-guided IUD insertion was associated with a significant reduction in the pain score (VAS), with a statistically significant difference between the two groups. The US-guided procedure was completed quicker than the traditional technique in our study, as duration of the IUD insertion procedure in the US-guided group ranged between 25-45 seconds with a mean of 35.56±6.32 sec, compared to 82.44±17.5 sec in the traditional technique.

There were differences between our study and the study of *Dakhly et al. (2017)* and *Elhoussieny et al. (2019)* and who insert copper T380 A by withdrawal technique While in our study insert IUS (Mirena) and copper T380 A according to Age and patient complaint. In our study lignocaine Gel was applied on the cervix to reduce pain during the insertion *(McNicholas et al., 2012)*.

The trans-abdominal guidance with IUD and found a significant reduction in pain scores evaluated by VAS. *Maged et al. (2020)* conducted a randomized control trial on 400 women with the retroverted flexed uterus (RVF) to evaluate the role of US guidance during IUD insertion. They reported that the VAS score was significantly lower in the US group than the control group. Moreover, they showed that the insertion was easier in the same group with a significant reduction in the procedure time. In terms of the procedure complication, the proportion of overall complications, bleeding, failure, and abdominal cramps were much lower in the

US group compared with the controls .The estimation of IUD insertion time has also been measured in many studies as one of the key findings *(Lopez et al., 2015)* The fact that a trained physician and more steps are required in the conventional approach led to a substantial difference between the two methods that favored the new technique *(Ouyang et al., 2019).* Although the gap appears to be minor, it is considered to be massive for patients. Furthermore, the more pain the patient experiences, the more they move, leading to the greater difficulty and longer duration of the procedure. Similar to our findings, *Elsedeek et al. (2016)* demonstrated that the procedure time was significantly shorter in the US-guided group, which was also confirmed by *Dakhly et al. (2017)* and *Elhoussieny et al. (2019)* On the other hand, *Ali et al. (2019).* Compared trans-abdominal US-guided IUD insertion and Uterine Sounding Sparing Approach (USSA) in terms of IUD insertion pain and duration. Their findings indicated that USSA is a more advanced technique with much higher patient satisfaction and less procedure pain and duration.

In the present study, the plastic disposable Cusco was less painful and more satisfied for every participant compared by control group, while the previous studies the metal Cusco was used which was very painful and exposed the patient for infection. One tablet of misoprostol 200 mg sublingually before the procedure result in softening the cervical condition especially cesarean section delivery which lowers the failure rate of insertion. *(bednarek et al., 2013)* The US-guided technique resulted in a successful procedure completion and ideal device placement, as it showed successful insertion among the US-guided group and 80% in the control group .Likewise, devices were inserted successfully in 97% of the US-guided patients and 80% patients in the non-guided group in *Elsedeek et al. (2016),* with a significant difference. In addition, *Elhoussieny et al. (2019)* showed that the failure rate was reported in 16% of the blind technique and 2% in US-guided technique.

According to *Dakhly et al. (2017),* there was no significant difference between both groups regarding successful insertion. Regarding patients' satisfaction, our study showed statistically significant difference between both groups, as more than half of participants who had US-guided, were satisfied, compared to 10% in the control group, in accordance with *Elsedeek et al. (2016)* and *Elhoussieny et al. (2019).*

On the other hand, all the participants returned after one month (post menstrual) to assess the inserted IUD by ultrasound, 88% in group (A) successful insertion IUD comparative of the control group.

## CONCLUSION

In women undergoing IUD insertion, US-guided insertion is more effective, safe, less painful, less time consuming and result in better patient satisfaction.

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# إستخدام الموجات الصوتية فى إدراج اللولب داخل الرحم: وسيلة فعالة فى إرضاء المنتفعة (تجربه تحكم عشوائيه)

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**خلفيــة البحــث:** اللولــب الرحمــى هــي وســيلة فعالــة للغايــة لمنــع الحمــل مــع فتــرة صــلاحيه وفعاليــه تمتــد مــن 3 ســنوات الــى 10ســنوات. يمكــن أن تــؤدي الصــعوبات فــي إدخــال اللولــب والالــم والمضــاعفات إلــى تقليــل اســتخدام مثــل هذه الطريقة الفعالة.

**الهــدف مــن البحــث:** تقيــيم اســتخدام اللولــب الموجــه بالموجــات الصــوتيه فــي تقليــل الألــم، ومــدة الإجــراء، وزيــادة رضــا المنتفعــه مقارنــة بطريقــة الإدراج التقليدية للولب.

**المريضــات وطــرق البحــث :** تــم إجــراء تجربــة عشــوائية مقارنــة علــى مــائتين مــن الســيدات المقــرر أن يخضــعن لإدخــال اللولــب فــي العيــادات الخارجيــة لقســم التوليــد وأمــراض النســاء فــي مستشــفي الســنبلاوين العــام. وتــم ادخــال اللولــب الهرمــوني لــبعض الحــالات واللولــب النحاســي لبــاقي الحــالات T380A بتقنيــة الانســحاب. و تــم تصــنيف المرضــى إلــى مجمــوعتين متســاويتين: المجموعــة (أ): تــم إدخــال اللولــب الموجــه بالموجــات فــوق الصــوتية. والمجموعــة (ب) تــم جــدولتها بالطريقــة التقليديــة لإدخال اللولب.

**نتــائج البحــث:** كانــت شــدة الألــم أثنــاء إدخــال اللولــب فــي المجموعــة (أ) أقــل إحصــائيًا مــن المجموعــة (ب) كانــت مــدة إجــراء إدخــال اللولــب (بــالثواني)

في المجموعة (أ) أقل إحصائيًا من المجموعة (ب). واثناء ادخال اللولب بالموجات فوق الصوتيه وجد في المجموعة (أ) أن 3٪ من النساء فشلن في الإدخال 96٪ من النساء وجد اللولب في مكانه، 1% اللولب فى غير مكانه، بينما في المجموعة ب، 6٪ من النساء فشلن في الإدخال، و 80٪ من النساء تم ادخال اللولب في مكانه، و 14٪ كان اللولب في غير مكانه حيث كانت هناك فروق ذات دلالة إحصائية بين المجموعات، و كانت هناك فروق ذات دلالة إحصائية عالية بين المجموعات فيما يتعلق برضا المنتفعة.

**الإستنتاج:** يعتبر الإدخال الموجه بالموجات الصوتيه أكثر فعالية وأمانًا وأقل إيلامًا واستهلاكًا للوقت ويؤدي إلى إرضاء أفضل للمنتفعة.

**الكلمات الدالة:** اللولب الرحمي، الموجات فوق الصوتية، إرضاء المنتفعة.