Efficacy and Safety of Ultrasound Guided versus Blind Technique for Office Insertion of Intrauterine Contraceptive Device: A Randomised Clinical Trial

Amro S. Elhoussieny, Ahmed M. Ibrahim, Alaa S. Hassanin, Shaimaa S. Abd El-Azeem

Department of Obstetrics and Gynecology, Faculty of Medicine, Ain-Shams University, Egypt

ABSTRACT

Background: Intrauterine devices are highly, if not the most effective method of contraception with typical use related failure rates of between 0.2-0.8%. Difficulties with IUD insertion, failure and complications can lead to decreasing utilization of such an effective method.

Objective: To compare between ultrasound guided and blind IUD insertion technique as regards proper fundal location of IUD, incidence of complications, time consumption and patient satisfaction.

Patients and Methods: A randomized clinical trial was conducted on 100 women at Ain-Shams University Maternity Hospital in Birth Control Clinic during the period from 1st of August 2016 till 30th of April 2017.

Results: Proper fundal distances after insertion were significantly more frequent among group U than among group B (p=0.009) and the overall complications were significantly less frequent in group U than in group B (p=0.016). Also pain perception (VAS-100), procedure duration and dissatisfaction were significantly lower among group U than among group B. These results point out that in women undergoing IUD insertion, ultrasound guided insertion is more effective, safe, less painful, less time consuming and result in better patient satisfaction.

Conclusion: This study suggests that ultrasound guided IUD insertion is more effective than blind technique with proper fundal position of IUD and lesser incidence of complications. It is also less painful with better patient satisfaction.

Key Words: Blind technique, office insertion intrauterine contraceptive device, ultrasound

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Corresponding Author: Shaimaa S. Abd El-Azeem, MSc., Department of Obstetrics and Gynecology, Faculty of Medicine, Ain-Shams University, Egypt, Tel: 01282339819, E-mail: shaimaasaad4@gmail.com

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INTRODUCTION

The intrauterine device (IUD) is the most widely used reversible method of contraception currently. The estimation is that 15% of the world’s women of reproductive age use it. IUDs provide a reversible and long-term method of contraception as a convenient, efficient, relatively safe and low-cost method(1).

Several investigators have examined the efficacy of various copper IUD devices. A Cochrane review published by Kulier et al.(2), The authors concluded that Copper T-380A was more effective in preventing pregnancy than the other devices including the Multiload 375, Multiload 250, Copper T-220 and Copper T-200.

Results from household surveys including the Pan Arab Project for Family Health (PAPFAM) and the Demographic and Health Survey (DHS) in six countries (Algeria, Lebanon, Morocco, Palestine, Syria, and Yemen) indicated that these countries have 1.2 million unintended births(3). It is estimated that 86 million unintended pregnancies every year are caused by inadequate access to family planning services(4).

Unwanted pregnancies may adversely affect maternal and fetal health due to unsafe abortion(5), delayed antenatal care(6), adverse life outcomes for offspring, or reduced educational opportunities and financial situation for the woman(7).

Difficulties with IUD insertion, failure and complications can lead to decreasing utilization of such an effective method(8). From the literature search one author identified that the incidence of IUD insertion failure was between 2.3 and 8.3 per 1000 insertions, and pain during the insertion procedure was associated with increased likelihood of IUD insertion failure. However, as this is a concomitant event it cannot be used to predict patients at high risk of an insertion failure(9).
In the first year after insertion, between 5 and 15% of women will have their IUD removed because of irregular uterine bleeding which have been attributed to the effect of contact between the device and the endometrium and even the pressure on the uterine muscle. The disharmonious relationship between the IUD and the uterus is the cause of most of the bleeding complaints, so bleeding is related to improper position rather than the contraceptive method itself which should be excluded before abandoning the IUD for any other method of birth control[10].

Ultrasonography of the pelvis and especially the transvaginal route, plays an essential role in evaluating the IUD position[11] and its potential complications, thus is considered the gold standard for this gynaecological condition[12]. Investigation of the symptomatic patient and even routine follow-up of asymptomatic women with IUDs include transvaginal ultrasonography to rule out IUD malposition and other complications such as perforation, expulsion and pregnancy[13].

AIM OF THE WORK

To compare between ultrasound guided and blind IUD insertion technique as regards proper fundal location of IUD, incidence of complications, time consumption and patient satisfaction.

PATIENTS AND METHODS

Study Design:
Randomized clinical trial.

Study Setting:
The study was conducted at Ain-Shams University Maternity Hospital in Birth Control Clinic.

Time of The Study:
The study started from 1st of August 2016 till 30th of April 2017.

Population Of The Study:

Sample Size Justification:
EpiInfo® version 6.0 program was used for calculations of sample size, statistical calculator based on 95% confidence interval and power of the study 80% with α error 5%, According to a previous study by Elsedeek[14] showed that the rates of successful device insertion (80%) and (98%) in non-guided device insertion group and ultrasonography-guided device insertion group women, respectively, based on this assumption, sample size was calculated according to these values produced a minimal samples size of 95 cases were enough to find such a difference between successful device insertion. Assuming a drop-out ratio of 5%, the sample size was 50 women in each group.

The participants included in the study met the following inclusion and exclusion criteria:

Inclusion Criteria:
- Age: from 18 years to 40 years.
- Females desiring contraception with the use of IUD.
- Timing: postmenstrual.

Exclusion Criteria:
- Was pregnant.
- Had unexplained abnormal vaginal bleeding.
- Had untreated cervical cancer, uterine cancer or ovarian cancer.
- Had benign or malignant gestational trophoblastic disease.
- Had uterine abnormalities.
- Had or may have had a pelvic infection within the past three months. History of fever, purulent vaginal discharge, Laboratory documentation of cervical infection with Neisseria gonorrhoeae or Chlamydia trachomatis, evidence of salpingitis or tubo-ovarian complex.
- Was postpartum between 48 hours and 6 weeks.

Then the study population was distributed randomly in 2 groups (50) patient in each group using computer generated program.

For both groups, the same IUD type Copper TCU-380A (Pregna) and the same insertion technique (withdrawal technique) was used.

Group B: Using the blind technique for IUD insertion.

Group U: Using ultrasound guided technique for IUD insertion.

Allocation and Concealment:

One hundred opaque envelopes were numbered serially and in each envelope the corresponding letter which denotes the allocated group was put according to randomization table. Then all envelopes were closed and put in one box. When the first patient arrived, the first envelope was opened and the patient was allocated according to the letter inside.

Randomization:

Was done using computer generated randomization sheet using MedCalc© version 13.
**Methodology:**

1- Ain-Shams University Hospital Ethical Broad Approval.

2- Written informed consent was obtained from all participants after explaining the nature and scope of the study.

3- Clinical evaluation by:

**A- History taking:**

*Personal History:* name, age, occupation, address, special habits.

*Menstrual History:* LMP, Regularity, Duration, Amount of blood loss.

*Contraceptive History:* Asked about the previous used methods, if there were any complications from any used method, if yes; what were these complications?

*CURRENT History:* Asked if there was pregnancy. Asked about unexplained abnormal vaginal bleeding. Asked about symptoms of pelvic infection or STDs as vaginal or urethral discharge.

*Obstetric History:* parity, mode of delivery, date of the last delivery, complications following delivery or abortion if present eg. sepsis.

*Surgical History:* Asked about previous operations.

*Medical History:* Asked about chronic diseases eg. diabetes, cardiac diseases, hypertension, bleeding disorders, history of medications.

*Past History:* Untreated cervical cancer, uterine cancer or ovarian cancer. Pelvic infection within the past three months.

**B- Clinical Examination:**

1- **General Examination:** General appearance, weight, height, pallor, vital signs (temperature, pulse and blood pressure).

2- **Abdominal Examination:** Pelvi-abdominal mass, enlarged liver or spleen.

3- **Local Pelvic Examination:** Inspection: vulva, vagina and cervix for any abnormal discharge.

*Copper T380A IUD Insertion (Withdrawal technique)*

The copper T380A packaging is opened by an assistant, taking care to maintain the sterility of the package contents. Load the IUD into the insertion tubing. This is accomplished by slightly withdrawing the insertion tubing and folding the horizontal arms of the IUD down along the vertical arm using your thumb and index finger. The insertion tubing is then advanced so that the horizontal arms sit securely within the insertion tubing. See the images below. Next, the solid white rod is introduced into the bottom of the insertion tubing and advanced to the point that it touches the bottom of the IUD (see the image below). The insertion tube is grasped at the open end and the blue flange is set to the level which the uterus sounds. The insertion tubing is then rotated so that the horizontal arms of the IUD are parallel to the long axis of the blue flange. See the image below. The loaded insertion tube is passed through the cervical canal until resistance is met at the uterine fundus and the blue flange should be at the external cervical os, as shown in the image below. With the solid white rod steady, the insertion tubing is withdrawn approximately 1 cm, releasing the IUD. The insertion tube is then gently moved up to the fundus of the uterus, ensuring placement of the IUD at the level of the fundus. Holding the insertion tubing steady, withdraw the white rod. Then, gently withdraw the insertion tubing. See the image below. Following removal of insertion device, the IUD strings will be readily visualized in vagina. Using long-handled scissors, the strings are then trimmed so that approximately 3 cm are visible extending, from the external cervical os (Paraguard T380A package insert, 2003). See the image below.

**Group B:** Using the blind technique for IUD insertion.

In this group bimanual examination was done to assess the uterus as regard position and size before device insertion to assist the practitioner in planning the procedure. A Cusco speculum was introduced by the most senior doctor to visualize the cervix, which was then wiped using a povidone–iodine swab before tenaculum application on the cervix, then attempted to introduce uterine sound. The shoulder of the IUD applicator was adjusted, based on the measured uterine length. The device applicator was introduced and the device was released inside the uterine cavity.

**Group U:** Using ultrasound guided technique for IUD insertion.

In this group transabdominal pelvic ultrasonography was used to visualize the uterus using Medison Sonoace abdominal transducer, the transducer was held longitudinally in suprapubic area to view the uterus in sagittal plain by an assistant. A Cusco speculum was introduced to visualize the cervix, which was wiped with a povidone-iodine swab before attempting to introduce uterine sound; the procedure was completed using the same approach as the non-guided technique. The principle difference is that the device was visualized during introduction and was adjusted accordingly.

Upon cusco opening and visualization of the cervix in both groups, a stopwatch was started. The stopwatch was stopped once the practitioner completed the procedure with cusco removal.
Trans-vaginal ultrasonography was done for every patient in both groups at ultrasound unit-Ain Shams Maternity Hospital to assess the IUD position post-insertion using Samsung H60. Vaginal transducer was inserted through vaginal showing the uterus sagittal plain with IUD echo inside. Patients were instructed to return to the study institution after the next menstruation and device positioning was confirmed by another transvaginal ultrasonography.

**Primary Outcome:**

Measure proper fundal device placement post-insertion and after the next menstruation.

To assess the proper position ultrasound scanning of the uterus was done including a true longitudinal section to visualize the entire length of the endometrial cavity. The distance from the superior edge of IUD to the internal uterine wall in sagittal plane was calculated (D=Fundal distance)

\[ D = A - B \]

where:

- A = the distance from the superior edge of IUD to the outer edge of the uterine fundus
- B = the myometrial thickness

The fundal distance (D) was calculated again in the second visit after one month.

Definition of the IUD misplacement was D > 3 mm at immediate post insertion.

The downward displacement was defined as an increase of more than 5 mm of the D from the initial location after the following menstruation (15). Transvaginal ultrasound was done after the following menses and D distance (fundal distance) was calculated. Then the new D distance was subtracted from the D distance at time of insertion to calculate the degree of displacement. It was considered downward displacement when the difference was more than 5 mm.

The IUD was defined as cervically located when the vertical stem was found to lie completely in the cervical canal (15).

**Secondary Outcome:**

1- Measured the incidence of complications including:

**1-Perforation:** detected clinically by sharp pain and bleeding on device insertion, and by the ultrasound showing either extraterine position of IUD with complete perforation, or partial perforation of the myometrium.

**2-Expulsion:** Expulsion was defined as visible protrusion of the stem of IUD through the external cervical os (15).

**3-Cervical problems:** including initial difficulty in passing the sound and difficulty in passing the IUD through the cervix each was graded from easy, normal, mild difficulty, moderate difficulty to severe difficulty.

Doctor was asked to determine the degree of difficulty in passing the sound and the IUD using the following score: Easy (1-2) Normal (3-4) Mild difficulty (5-6), Severe difficulty (9-10).

**4-Bradycardia:** assessed by pulse rate measured during insertion.

**5-Syncope:**

1- Measured the time needed for the procedure in each group using a stopwatch started with cusco opening and visualization of the cervix in both groups, and stopped when the procedure ended with cusco removal in each group.

2- Measured pain during IUD insertion by visual analogue scale (VAS), which is a unidimensional measure of pain intensity.

A horizontal VAS 10 centimeters (100 mm) in length was used, it was anchored by 2 verbal descriptors, one for each symptom extreme.

The scale is anchored by “no pain” (score of 0) and “worst imaginable pain” (score of 100) [100-mm scale].

**Method of administration:**

The VAS is administered as a paper and pencil measure. It is self-completed by the respondent. The respondent was asked to place a line perpendicular to the VAS line at the point that represents their pain intensity.

**Scoring:**

Using a ruler, the score was determined by measuring the distance (mm) on the 10-cm line between the “no pain” anchor and the patient's mark, providing a range of scores from 0-100.

**Score interpretation:**

A higher score indicates greater pain intensity. The following cut points on the pain VAS had been used:

- No pain (0-4 mm),
- Mild pain (5-44 mm),
- Moderate pain (45-74 mm),
- And severe pain (75-100 mm).

The VAS is administered as a paper and pencil measure.

4- Measured patient satisfaction (reported as crude satisfaction scores). Patient satisfaction was assessed in a separate office after completion of the procedure. Satisfaction was scored on a three-point scale measured using one question. Patients was asked to rate the procedure as having been more difficult than expected, as expected, or easier than expected, assigning scores of one, two, or three, respectively.

RESULTS

The current study was conducted at Ain-Shams University Maternity Hospital during the period between August 2016 and April 2017.

A total number of 118 patients assessed for eligibility. 18 were excluded from the study due to:
- Did not meet inclusion criteria (n=14)
- Refused to participate (n=2)
- Abort the procedure due to:
  - Severe pain with cusco opening and refusal to continue the procedure (n=1)
  - Accidentally discovered cervical polyp (n=1)

Randomization started after cusco opening into two groups.

The investigated groups described as follows:

Group U: 50 women who underwent ultrasound guided technique for IUD insertion. Group B: 50 women who underwent the blind technique for IUD insertion. No significant statistical difference between study and control groups regarding demographic characteristics. No significant difference between group U and group B regarding sounding status (Tables 1, 2).

Table 3 shows that proper fundal distances after insertion were significantly more frequent among group U than among group B.

Three cases with fundal distance <0.0 in group B had partial perforation and the IUD was extracted immediately after insertion.

Three cases of fundal distance more than 10 mm: one was cervical IUD and two were lowlying IUD. All were extracted immediately after insertion.

Table 4 shows that fundal distance at follow up was non-significantly lower among group U than among group B.

Displacement was non-significantly different among the studied groups.

Displacement was calculated by subtracting fundal distance (D) after one month from fundal distance at time of insertion.

The three cases of downward displacement had to extract the IUD at follow up visit due to low fundal position after one month postmenstrual.

Table 6 shows that over all complications were significantly less frequent in group U than in group B.

Table 7 shows that pain perception (VAS-100), procedure duration and unsatisfaction were significantly lower among group U than among group B.

Table 1: Demographic characteristics among the studied groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group U (N=50)</th>
<th>Group B (N=50)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Mean±SD Range</td>
<td>30.0±5.4</td>
<td>28.7±5.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21.0–39.0</td>
<td>21.0–40.0</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>Mean±SD Range</td>
<td>27.1±2.1</td>
<td>27.3±2.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>22.7–32.2</td>
<td>23.2–30.8</td>
</tr>
<tr>
<td>Parity</td>
<td>Mean±SD Range</td>
<td>3.0±1.6</td>
<td>2.8±1.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.0–7.0</td>
<td>1.0–6.0</td>
</tr>
<tr>
<td>Previous vaginal delivery</td>
<td>Mean±SD Range</td>
<td>2.0±2.1</td>
<td>1.6±1.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.0–7.0</td>
<td>0.0–6.0</td>
</tr>
<tr>
<td>Previous CS</td>
<td>Mean±SD Range</td>
<td>1.0±1.1</td>
<td>1.3±1.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.0–4.0</td>
<td>0.0–4.0</td>
</tr>
</tbody>
</table>

#Independent t-test

Table 2: Sounding status among the studied groups

<table>
<thead>
<tr>
<th>Measures</th>
<th>Group U (N=50)</th>
<th>Group B (N=50)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success</td>
<td>49 (98.0%)</td>
<td>48 (96.0%)</td>
<td>#1.000</td>
</tr>
<tr>
<td>Failure</td>
<td>1 (2.0%)</td>
<td>2 (4.0%)</td>
<td></td>
</tr>
</tbody>
</table>

#Fisher's Exact test

Table 3: Fundal Distance (D) immediately after insertion among the studied groups

<table>
<thead>
<tr>
<th>Measures</th>
<th>group U (N=49)</th>
<th>group B (N=48)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fundal distance (mm)</td>
<td>Mean±SD Range</td>
<td>3.3±0.6</td>
<td>4.4±4.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.7–5.0</td>
<td>-0.4–30.0</td>
</tr>
<tr>
<td>&lt;0.0</td>
<td>0 (0.0%)</td>
<td>3 (6.3%)</td>
<td></td>
</tr>
<tr>
<td>Fundal distance grades (mm)</td>
<td>Mean±SD</td>
<td>3.1±10.0</td>
<td>8 (36.7%)</td>
</tr>
<tr>
<td></td>
<td>(mm)</td>
<td>18 (36.7%)</td>
<td>24(50.0%)</td>
</tr>
<tr>
<td>≥10.0 mm</td>
<td>0 (0.0%)</td>
<td>3 (6.3%)</td>
<td></td>
</tr>
</tbody>
</table>

#Independent t-test, #Fisher's Exact test, *Significant, CI: Confidence interval
Intrauterine contraceptive devices (IUDs) represents a significant proportion of long-acting most effective reversible contraceptives, which demonstrates higher continuation rates than contraceptive methods that are not long acting.[16]

Difficulties with application, failure and complications can result in decreasing utilization, as well as the propagation of myths, fear, and negative attitudes towards these methods, not only among users and potential users, but also among different groups of health care professionals.[8]

The intrauterine position of IUD is thought to be closely related to its contraceptive power. IUD located more cervically may prevent conception to a lesser degree compared to adequately localized IUD.[10]

In the first year after insertion, between 5 and 15% of women will have their IUD removed because of irregular uterine bleeding. The disharmonious relationship between the IUD and the uterus is the cause of most of the bleeding complaints, so bleeding is related to improper position rather than the contraceptive method itself which will be excluded before abandoning the IUD for any other method of

| Table 4: Fundal distance (D) at follow up postmenstrual after one month among the studied groups |
|-----------------------------|---------|---------|------|
| Measures                  | Group U (N=46) | Group B (N=40) | P    |
| Fundal distance (mm)      | Mean±SD       | 3.6±1.1        | 4.4±1.9 | 0.032 |
|                           | Range         | 2.9–10.0       | 2.9–12.0 |
| Fundal distance grades (mm) | 0.0–3.0 mm | 17(37.0%)        | 8 (20.0%) |
|                            | 3.1–9.9 mm | 29(63.0%)        | 30 (75.0%) |
|                            | ≥10.0 mm     | 0 (0.0%)        | 2 (5.0%) |

*Independent t-test, #Fisher's Exact test

| Table 5: Follow up downward displacement (mm) postmenstrual after one month among the studied groups |
|-----------------------------|---------|---------|------|
| Complications              | Group U (N=46) | Group B (N=40) | P    |
| Displacement               | Mean±SD       | 0.4±0.8        | 0.4±1.4 | 0.741 |
|                           | Range         | -0.3–5.5       | -1.5–6.0 |
| Displacement > 5 mm        | 1 (2.1%)      | 2 (4.8%)       | #0.600 |

*Independent t-test, #Fisher's Exact test

| Table 6: Complications among the studied groups |
|-----------------------------|---------|---------|------|
| Complications              | Group U (N=50) | Group B (N=50) | P    |
| Bradycardia                | 1 (2.0%)    | 2 (4.0%)    | 0.617 |
| Syncope                    | 0 (0.0%)    | 0 (0.0%)    | --    |
| Partial perforation        | 0 (0.0%)    | 3 (6.0%)    | 0.242 |
| Low lying IUD              | 0 (0.0%)    | 2 (4.0%)    | 0.495 |
| Cervical displacement of IUD | 0 (0.0%) | 1 (2.0%)        | 1.000 |
| Expulsion                  | 0 (0.0%)    | 1 (2.0%)    | 1.000 |
| Over all complications     | 1 (2.0%)    | 8 (16.0%)   | 0.016* |

#Fisher's Exact test

| Table 7: Evaluation of insertion the studied groups |
|-----------------------------|---------|---------|------|
| Measures                  | Group U (N=50) | Group B (N=50) | P    |
| Time (minutes)            | Mean±SD       | 5.6±0.8        | 7.0±0.6 | <0.001 |
|                           | Range         | 4.0–7.8       | 6.0–9.0 |
| Sounding difficulty (/10) | Mean±SD       | 4.7±1.3        | 5.2±1.5 | 0.091 |
|                           | Range         | 3.0–10.0     | 3.0–10.0 |
| Pain (/100mm)             | Mean±SD       | 44.8±11.7      | 57.5±9.2 | <0.001 |
|                           | Range         | 20.0–72.0    | 35.0–80.0 |
| Patient satisfaction (n, %) | 3 (6.0%) | 13 (26.0%)     | #0.001 |
| Unsatisfied               | 26 (52.0%)   | 32 (64.0%)    | 5 (10.0%) |
| Satisfied                 | 21 (42.0%)   | 5 (10.0%)    | --    |

#Chi square test, *Independent t-test, #Significant, CI: Confidence interval

DISCUSSION

Intrauterine contraceptive devices (IUDs) represents a significant proportion of long-acting most effective reversible contraceptives, which demonstrates higher continuation rates than contraceptive methods that are not long acting[16].

Difficulties with application, failure and complications can result in decreasing utilization, as well as the propagation of myths, fear, and negative attitudes towards these methods, not only among users and potential users, but also among different groups of health care professionals[8].

The intrauterine position of IUD is thought to be closely related to its contraceptive power. IUD located more cervically may prevent conception to a lesser degree compared to adequately localized IUD[10].

In the first year after insertion, between 5 and 15% of women will have their IUD removed because of irregular uterine bleeding. The disharmonious relationship between the IUD and the uterus is the cause of most of the bleeding complaints, so bleeding is related to improper position rather than the contraceptive method itself which will be excluded before abandoning the IUD for any other method of
birth control[10]. So, the proper fundal position will help to decrease early discontinuation of IUD which represent an economic burden and loss of one of highly effective contraceptive method. Without the proper use of effective contraceptive method after IUD discontinuation, the incidence of unwanted pregnancy is increased.

In the present study, we aim to evaluate the safety and efficacy of ultrasound guided versus blind technique for office insertion of intrauterine contraceptive device.

One hundred patients were considered for inclusion in the study were randomly distributed in two groups 50 in each; group U used the ultrasound guided IUD insertion and group B used the traditional technique. Following IUD insertion, transvaginal ultrasonography was done and the fundal distance was calculated. Then the patients was asked to retune for follow up after the next menses and re-evaluated by transvaginal ultrasound.

No significant difference was observed in the age, parity, number of cesarean section and body mass index between both groups. Sounding failure due to inability to pass the sound through external os as a result of cervical stenosis was seen in both groups with no significant difference between the two groups.

It was found that fundal distance (distance between the IUD and inner uterine wall) 0.0 -0.3 mm was significantly more frequent among the group U than group B \( (P=0.009) \) immediately after insertion.

There were 6 cases with complication during insertion (3 partial perforation 2 lowlying 1 cervical IUD) and ended with IUD removal at the same session. These six patients refused to re-insert the IUD again at the same day and asked for another contraceptive method.

Also, the use of ultrasound results in significant reduction in over all complications with IUD insertion including perforation, cervical position, low-lying IUD, bradycardia, syncope and expulsion \( (P=0.016) \).

Using ultrasound guided technique result in significant reduction in procedure duration \( (P<0.001) \), pain perception \( (P<0.001) \) and patient un-satisfaction \( (P<0.001) \).

The ultrasound guide technique for IUD insertion was previously studied by Elsedeek[14]. The ultrasound guided IUD insertion technique was evaluated and used both IUD and IUS, in the present study we use only the copper T 380 contraceptive device as IUS has a little bit different insertion steps.

In both studies, it was found that the use of ultrasound guided IUD insertion was associated with lesser time consumption \( (P<0.001) \).

The failure rate to insert the IUD was 20% by Elsedeck[14] study in the blind technique and 3% in ultrasound guided technique.

In our study, it was 16% in the blind technique and 2% in ultrasound guided technique.

Insertion failure was due to failure to insert the uterine sound or the IUD through the cervix or complication with insertion ended with misplacement of IUD and its removal immediately.

In Elsedeek[14] study, the inability to introduce the sound was the cause of failure in 10% and 3% in blind and US guided groups respectively. In our study it was 4% and 2% in blind and US guided groups, respectively. The cervical stenosis is more common in cesarean delivery than vaginal delivery. Also, it is not affected by the use of ultrasound as the problem is at the level of external os before the uterine sounding or IUD insertion process. In our study no significant difference between group U and group B regarding sounding status \( (p=1.000) \).

In Elsedeek[14] study, 10% of blind technique IUD was removed after insertion due to cervical placement or myometrial penetration. In our study it was 12% of cases.

Using the ultrasound will not help in cases of cervical stenosis but it will be of great importance to decrease the misplacement and decrease the failure rate with a very effective long acting contraceptive method as IUD.

In the previous study, the ideal device position was roughly determined by clear visualization of the IUD in a sagittal view by ultrasound with the upper end located in the fundus and the lower end at the internal os. In the present study the fundal distance was calculated by transvaginal ultrasound as described by Tangtongpet et al.[15]

All the patients were examined in the present study postmenstrual according to recommendation of Faundes et al.[17] who suggested that the IUD position in the uterine cavity is influenced by the growth and
thinning of the endometrium and this information should be considered when evaluating the IUD position by sonography. In Elsedeek\textsuperscript{[14]} study the follow up visit was after one week.

By Elsedeek\textsuperscript{[14]}, pain was assessed in previous study by a questionnaire, in the present study it was assessed by VAS which provide more accurate measure of pain\textsuperscript{[18]}. In both studies pain was significantly lower in the ultrasound guided group.

In both studies, patient satisfaction with IUD insertion using ultrasound guided technique is significantly more than that in the blind technique.

Most of IUD complications is related to its position e.g. contraceptive failure, perforation, bleeding and expulsion. So, inserting the IUD in the most fundal position will avoid many complications and decrease the 1st year discontinuation rate. This will encourage the patient and health care providers to use IUD.

Visualization of the uterine cavity and its relation to cervical canal determine the degree of cervical traction needed to straightened the utero-cervical angle to avoid periprocedural complications.

Following the direction of uterine cavity seen during IUD insertion with adjustment of cervical traction and visualization of IUD position by ultrasound before completion of the procedure give the chance to ensure fundal position of the IUD.

These results point out that In women undergoing IUD insertion, ultrasound guided insertion is more effective, safe, less painful, less time consuming and result in better patient satisfaction.

CONCLUSION AND RECOMMENDATION

This study suggests that ultrasound guided IUD insertion is more effective than blind technique with proper fundal position of IUD and lesser incidence of complications. It is also less painful with better patient satisfaction.

Further studies with a wider scale including more clinical centers and more IUD users is recommended for more evaluation of ultrasound guided technique in IUD insertion.

Evaluation of other types of different IUDs and comparison between them as regard usage of ultrasound guided technique to encourage women to use IUD as a highly effective and safe contraceptive method.

CONFLICT OF INTEREST

There are no conflicts of interest.

REFERENCES


