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Journal of Obstetrics Gynecology and Reproductive Sciences

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Research Article

The Uterine Sound-Sparing Approach in the Insertion of Copper Intrauterine Device

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Received Date: July 25, 2021; **Accepted Date:** August 26, 2021; **Published Date:** October 09, 2021

Citation: Walaa E. Ahmed, Rania G. Elskaan, Heba M. Khattab, Mortada E. Ahmed, (2021), The Uterine Sound-Sparing Approach in the Insertion of Copper Intrauterine Device. *J. Obstetrics Gynecology and Reproductive Sciences*, 5(9) **DOI:10.31579/2578-8965/142**

Abstract

Background and aim: Insertion of an IUD is an invasive, painful procedure resembling a barrier among females to use IUDs as contraception. This study aimed to compare two different techniques of IUD insertion, either using uterine sound or an IUD plastic inserter, in the context of pain perception among patients.

Patients and methods: This randomized control trial included 70 women requesting IUD insertion. The study was conducted in the contraception clinics at Ain Shams University Hospital from. January to June 2021. We randomized the patients into 34 patients (group I), where women were subjected to a classic approach for copper IUD (T Cu 380A) insertion, and 36 patients (group II), where IUDs were inserted using a uterine inserter to assess the uterine cavity length and position without using uterine sound. We measured the VAS pain score during the uterus lengthening, IUD insertion, and vulsellum application. "The Ease score was used to calculate the easiness of uterine length measurement in both study groups, and the insertion duration was recorded.

Results:

There were no statistically significant differences regarding demographic characteristics between the two study groups. Group II showed significantly lower VAS pain scores during the lengthening of the uterus and the insertion of the IUD than group I (P=0.001). There were no statistically significant differences between the two groups regarding pain perception during the vulsellum application (P=0.146). No statistically significant difference was found between the two groups regarding the Ease score (P=0.855). The duration of insertion was significantly shorter in group II (P=0.001).

Conclusions: The classic uterine sound can be replaced by using an IUD inserter to define uterine position and length. This results in less pain, reduced time for IUD insertion, and easy application.

Keywords: intrauterine device, copper IUD, pain, sound-sparing, technique

Introduction

An intrauterine device (IUD) is a reliable and reversible long-acting method of contraception [1]. Insertion of an IUD is an invasive and painful procedure. Pain occurs due to manipulations of the genital tract by the instruments used. The cervix is grasped by the tenaculum, followed by cervical canal traction, and finally, the uterine sound and IUD introducer stretch the internal cervical os. Subsequently, an IUD is inserted, but it may cause endometrial irritation [2,3].

Pain associated with IUD insertion is a barrier for some patients to use an IUD for contraception [4,5]. Pharmacological and non-pharmacological strategies have been proposed to improve pain experience. Drugs, such as intracervical or intrauterine local anesthetic [6], local misoprostol [7], non-steroidal anti-inflammatory drugs [8], and paracervical block [9], have been tested to reduce pain during IUD insertion. Non-pharmacological strategies include music therapy [10], guided imagery, hypnosis, and distraction [11].

Insertion instructions for correctly placed IUDs include bimanual examination and the use of a uterine sound to define uterine size and position [12]. A metal uterine sound can cause pain during its passage into the cervical canal, internal os, and uterine cavity. Technique modifications to reduce pain as a uterine sound-sparing approach have been reported. In these studies,

ultrasonography was used to determine uterine position and length before insertion [13, 14].

This study aimed to compare two different techniques of IUD insertion, either using uterine sound or an IUD plastic inserter in the context of pain perception among patients. We hypothesize that a plastic IUD inserter could accurately estimate the uterine position and size during IUD insertion. As it is plastic, not metal, it may cause minimal or no pain. We also aimed to compare patients' pain perception when using an IUD inserter in a uterine sound-sparing approach compared to the classic approach.

Patients and methods

This randomized control trial included 70 women requesting IUD insertion. It was conducted in the contraception clinics at Ain Shams University Hospital from January 2021 to June 2021. Before enrollment, informed written consent was obtained from all patients. The study was performed following the Declaration of Helsinki and approved by the local ethical committee.

The study's primary outcome was VAS pain scores during uterine lengthening and IUD insertion.

The secondary outcomes were pain perception during the vulsellum application, the Ease score, and the duration of the IUD insertion.

Sample Size Justification: the sample size was calculated using the STATA program, a statistical software commonly used for data analysis. The type-1 error, which represents the probability of rejecting a true null hypothesis, was set at 0.05, and the power, which indicates the probability of rejecting a false null hypothesis, was set at 0.9. These values were chosen to ensure that the study had a high level of statistical significance. In addition, a previous study conducted by K Ali et al. [15] was used to determine the minimum sample size needed for this study. Their research indicated that a minimum of 80 cases in both groups was required to ensure sufficient power to detect meaningful differences between the studied groups.

The age, parity, number of miscarriages, and number of previous cesarean sections (CS) were recorded for all patients. Different items of the patients' history were obtained from all patients. We included all patients requesting IUDs as a contraceptive method. Excluded conditions for the study: postpartum <4 weeks, postpartum sepsis, post-abortive sepsis, unexplained vaginal bleeding, gestational trophoblastic disease, cervical/endometrial cancer, uterine anatomical abnormalities, cervicitis, PID, HIV with CD4 count <200, pelvic TB, complicated organ transplantation, or long QT syndrome.

Women who met the eligibility criteria and gave their informed consent were randomly assigned to one of two groups: the uterine sound or the IUD plastic applicator (uterine sound-sparing technique). Randomization was done using the computer and using serially numbered concealed opaque envelopes.

Copper IUD (T Cu 380A) was inserted during menstruation. To avoid any potential bias in the application technique, the same gynecologist performed IUD insertion on patients who were then randomized into two groups: I and II. Group I underwent the classic technique of IUD insertion using uterine sound, while group II underwent a uterine sound-sparing technique using an IUD inserter. This was done to measure uterine length.

In Group I, the cervix was viewed using a Cusco's speculum and cleaned with an antiseptic solution. The uterus was straightened and normalized by applying gentle traction with a vulsellum. Uterine sounds were used to measure the length and position of the uterus, and the copper IUD was inserted according to the manufacturer's instructions with the help of an assistant who maintained gentle traction of the vulsellum.

In Group II, the IUD insertion process was similar to that of Group I. The IUD inserter was slightly curved and was carefully inserted into the uterine cavity until the proximal end touched the fundus. The corresponding number on the centimeter scale of the insertion tube indicated the length of the uterus. After that, the insertion tube was withdrawn by 2 cm, and the flange was slid down the insertion tube to the corresponding number on the centimeter scale. The insertion tube was pushed through the cervical canal into the uterus until the flange touched the external cervical os. Throughout the process, gentle traction was maintained by the vulsellum with the help of an assistant.

Pain perception was measured using VAS, with 0 indicating no pain and 10 indicating the worst possible pain. Patients recorded pain during vulsellum placement, uterine length measurement, and IUD insertion. Correct IUD placement was confirmed with abdominal ultrasonography.

The two groups were evaluated based on ease of uterine length measurement using the Ease scale [7,18] and complications during IUD insertion were recorded. Patients returned for a sonographic check in the following cycle to ensure proper IUD positioning.

SPSS software (version 21.0; IBM Corp, Armonk, NY, USA) was used for statistical analyses. Numerical parametric variables were described as means and standard deviations, and categorical variables as numbers and percentages. Independent t-test was used to compare quantitative variables, whereas paired Student’s t-test was used to analyze differences between two independent groups. For parametric data (SD < 50% mean), the significance level was set at 0.05.

Results

Eighty women were included in this study. Five women were excluded due to the presence of abnormal uterine bleeding (2 cases), uterine fibroids (2 cases), and cervicitis (1 case). During the study, IUD insertion failed in five cases due to cervical stenosis (3 cases) and vaginismus (2 cases). Thus, the study was completed by 70 women: 34 patients in Group I and 36 patients in Group II (Figure. 1).

Figure 1: CONSORT Flow Diagram

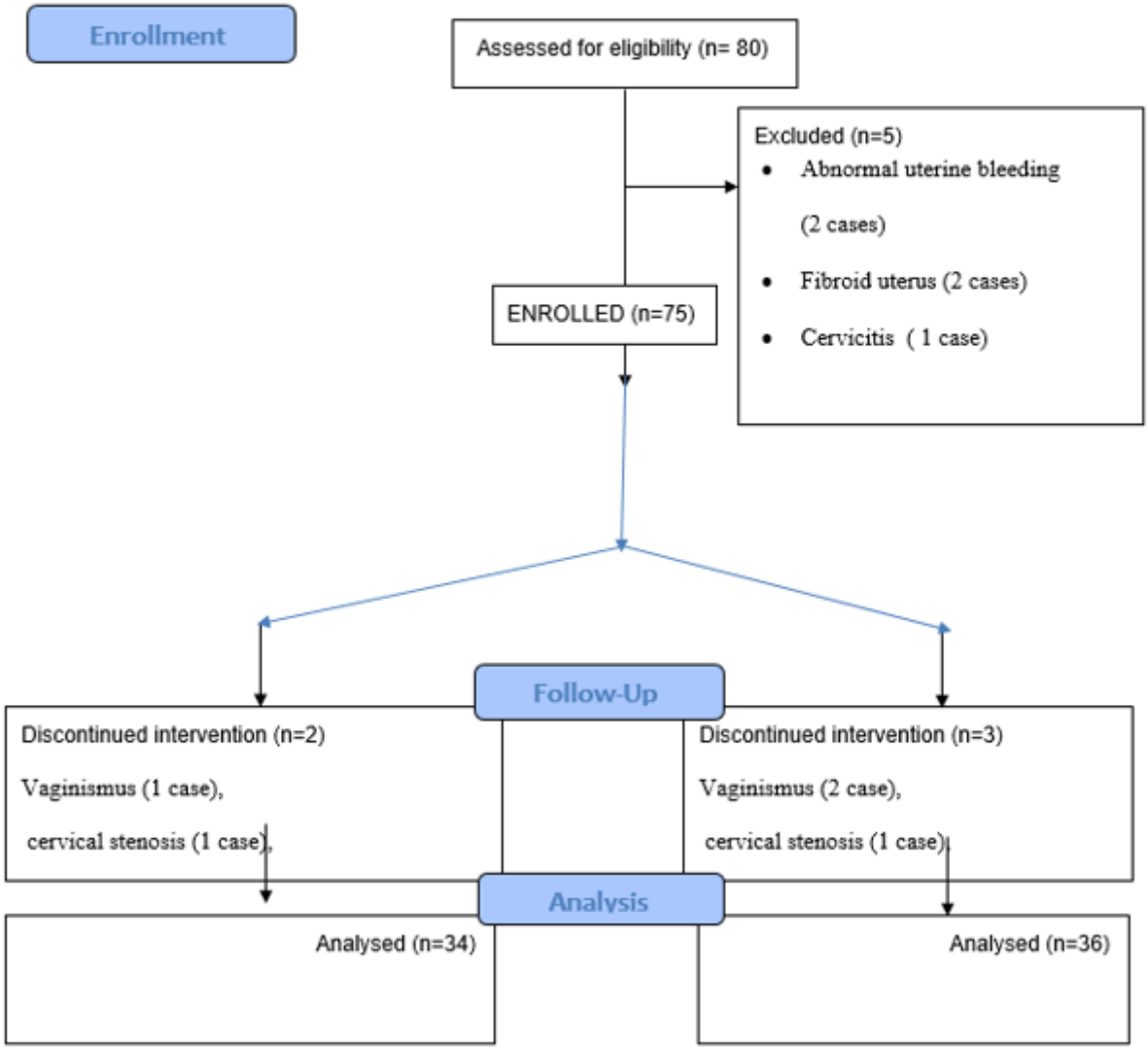

Table 1: The demographic characteristics of the two study groups

	Group I (n=34)	**Group II (n=36)**	**P value**
Age (years)	25.5±2.65	26.42±2.86	0.168
Parity	2.24±1.22	2.35±1.53	0.741
Miscarriage	1.73±1.63	1.22±1.12	0.074
Previous CS	2.24±0.71	2.35±1.43	0.688
BMI (kg/m2)	29.27 ± 7.55	28.76 ± 5.81	0.752

All data are presented as mean ± standard deviation. BMI: Body mass index CS: cesarean section

Table 1 shows no statistically significant difference between the two groups regarding demographic criteria.

Table 2: shows no statistically significant difference between the two groups regarding VAS pain during Vulsellum placement on the cervix and IUD insertion (P>0.05). However, Group II had a statistically significant decrease in VAS score during the Uterine length measurement step and post-IUD insertion (overall pain perception).

Table 2: VAS score in group I and II

VAS score	**Group I (n=34)**	**Group II (n=36)**	**P value**

Vulsellum placement	2.14±1.22	2.55±1.43	0.203
Uterine length measurement step	1.33±1.12	0.61±0.41	<0.001
During IUD insertion	2.96±1.63	2.86±1.84	0.811
Over-all pain after IUD insertion	3.67±0.82	1.94±1.22	<0.001

All data are presented as mean ± standard deviation, VAS: visual analogue scale,

Table 3: indicates no statistically significant difference (P>0.5) when comparing The Ease score of the uterine length measurement step. Group II had a significantly shorter duration of insertion (p=0.001). No complications arose during the insertion of the IUD. All patients had a correctly positioned IUD on transabdominal ultrasound conducted after the insertion and in the subsequent follow-up visits.

Table 3: Ease score, duration of insertion, complications, follow-up results

	Group I (n=34)	Group II (n=36)	P value
Ease score (ES)	7.14±1.22	752±1.09	0.173
Duration of insertion (min)	4.59±0.31	4.08±0.61	<0.001
Complications at time of insertion	0	0	-
IUD in place (by US)	34 (100%)	36 (100%)	-

All data are presented as mean ± standard deviation or n (%), ES=Easiness of uterine length measurement step

Discussion

Our results and their interpretation

Our results show that Group II (IUD plastic applicator) experienced significantly less pain during the uterine length measurement step compared to Group I (p=0.001). No significant difference in pain was observed during vulsellum application and IUD insertion between the two groups. After IUD insertion, the overall pain perception was attributed to vulsellum application, IUD insertion, and sounding using the classic uterine sound in group I and IUD inserter in group II, which could explain the significantly lower overall pain perception after IUD insertion when the IUD inserter was used instead of the classic sound.

We have developed another method for IUD insertion that spares the use of a uterine sound. By using the IUD inserter alone, the size and position of the uterus can be accurately estimated. Our findings indicate that this approach is less uncomfortable than the traditional method, shortens the time required for the procedure, and is simple to implement. As far as we know, no clinical trials have been conducted on this technique yet.

During the insertion of an intrauterine device (IUD), stretching of the cervical internal os is the most painful step. The second most painful steps are the placement of the vulsellum, uterine sounding, and IUD insertion [16]. The classic approach to IUD insertion involves stretching the cervical os twice by introducing the uterine sound and then the IUD inserter, which increases the pain. However, in our study, we introduced the IUD inserter into the uterine cavity only once, which may result in less pain. Additionally, the plastic nature of the IUD inserter, when compared to the metal sound, exerts lesser tissue trauma, which could also cause less or no pain.

Our study found that measuring the uterus length was equally easy in both groups. This could be because the vulsellum, which is used to apply cervical traction, straightens the uterine cavity. The insertion tube may also become slightly curved, similar to a traditional uterine sound.

The time required to insert the IUD was significantly reduced in group II as compared to group I. This could be attributed to omitting the traditional step of using a uterine sound, introducing the IUD inserter only once into the uterine cavity throughout the procedure and Ease scores recorded during the measurement of uterine length by IUD inserter.

Comparison of our results to different studies

It is important for a copper IUD to be placed correctly in order to be effective [17]. In a study by Christenson et al. [18], the IUD was inserted without prior pelvic examination or sounding. Insertion was not guided by ultrasonography. This study's 6% expulsion rate may be due to incorrect placement. The use of uterine sound or sonography to define uterine length and position can ensure safe and proper IUD placement [15]. In our study, we used the IUD inserter to sound instead of the classic metal uterine sound, which resulted in correct placement confirmed by ultrasound in all patients.

In a study conducted by Mohamed et al. [14], it was discovered that trans-abdominal ultrasound-guided IUD insertion was statistically more effective than the conventional technique regarding VAS pain scores (p<0.001) as well as time taken (in seconds) for IUD insertion (p<0.001). A different research study showed that the VAS pain score in women in the ultrasound-guided group was significantly lower (p<0.001), the insertion was easier (p<0.001), and the time required for the procedure was significantly shorter (p<0.001) when compared to the control group [13].

The study observed lesser pain scores and a shorter insertion duration than the studies mentioned earlier. The placement of the IUD was confirmed using ultrasound both before and during insertion, followed by another round of imaging after insertion. However, patients may experience distress due to multiple rounds of imaging, leading to increased pain perception. Our study, on the other hand, used ultrasonography only after IUD insertion.

A study [19] linked the use of traditional uterine sounds to a high risk of uterine perforation. Our study found that avoiding these sounds may have prevented complications related to perforation.

Strengths and limitations of our study

The strength point of our study is that it was done in a university hospital, and the IUD application was made by a single gynecologist in the contraception clinic. Our study has a few limitations, including a small sample size, which could be why complications were absent and correct placement rates were 100%. Although the data we presented demonstrate that the technique is safe and easy, it is advisable to have the procedure carried out by experienced physicians only.

Clinical Implications of our study

we should encourage junior residents to use the plastic IUD applicator during the sounding of the uterus, and the IUD application.

Recommendation for further studies

Multicentric studies are needed to study the effect of using uterine sound or an IUD plastic inserter using an IUD inserter in the context of pain perception among patients.

Conclusion

Using an IUD inserter to define uterine position and size can replace the classic uterine sound. This novel method is associated with less pain, reduces the time required for IUD insertion, and is easily applied.

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DOI:10.31579/2578-8965/142