Original Article

Uterine sound-sparing approach in insertion of Nova T-380 intrauterine device

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ABSTRACT

Objectives: Insertion of IUD is an invasive painful procedure. Pain associated with IUD insertion is a barrier among females to use IUD for contraception. This study aims to compare using IUD inserter as a uterine sound-sparing approach to classic approach using uterine sound in context of pain perception among patients.

Study design: This prospective study included women requesting IUD insertion. In group (I) women were subjected to classic approach for NOVA T-380 insertion and in group (II) IUD was inserted using uterine inserter for assessment of the uterine cavity length and position without using uterine sound.

Results: 70 women were analysed in group (I) and 68 in group (II). Pain associated with uterine length measurement and overall pain perception in group (II) were significantly lower than group (I) (p =0 .001). Ease of uterine length measurement step was statistically comparable in both groups. Significant short duration of insertion was reported in group (II) (p = 0.001).Ultrasound showed that IUD was in place in all women.

Conclusions: Using IUD inserter in defining uterine position and length can replace the classic uterine sound. Less pain, reduction in time taken in IUD insertion and easy application were reported.

Key Words: Intrauterine device, IUD, NOVA T- 380, pain, sound-sparing.

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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 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 prior to insertion[13-16].

We hypothesize that IUD inserter could be utilized for accurate estimation of 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 pain perception among patients when using an IUD inserter in a uterine sound-sparing approach, compared to the classic approach.

PATIENTS AND METHODS

This prospective study was conducted in obstetrics and gynecology clinics at the Galaa Military Hospital (Cairo, Egypt), Badr University Hospital-Helwan University (Cairo, Egypt), and Al-Khafji National Hospital (Al-Khafji, Saudi Arabia) from February 2016 to October 2020. Women who underwent IUD insertion were included in the study, and informed written consent was obtained from all patients before enrollment. The study was performed in accordance with the Declaration of Helsinki and approved by the local ethical committees.

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Demographic characteristics and medical and reproductive histories were recorded. According to the medical eligibility criteria of the Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines[17], women were excluded from the study for the following conditions: postpartum (from 48 hours to <4 weeks), postpartum sepsis, post-abortive sepsis, unexplained vaginal bleeding, gestational trophoblastic disease (with either decreasing β-HCG levels , persistently elevated β-HCG levels, or malignant disease), cervical cancer, endometrial cancer, fibroid or uterine anatomical abnormalities causing distortion of the uterine cavity, cervicitis, current pelvic inflammatory disease , HIV infection with CD4 count <200 cells/mm3, pelvic tuberculosis, complicated organ transplantation, or cardiac arrhythmias (known long QT syndrome).

The IUD was inserted during menstruation using a copper T-380 IUD (NOVA T-380; Bayer Oy, Turku, Finland). Anti-inflammatory drugs, analgesics, misoprostol, and local anesthetics were not administered prior to the procedure. IUD insertion was performed by the same gynecologist to avoid inter-personal bias in the application technique, and patients were randomized to either group I (classic technique of IUD insertion using uterine sound) or group II (uterine sound-sparing technique using an IUD inserter) to measure uterine length. Randomization was performed using a computer-generated random table.

In group I, a Cusco's speculum was placed in the vagina to visualize the cervix, and then an antiseptic solution (povidone iodine) was applied to cleanse it. The anterior cervical lip was grasped by the vulsellum, and gentle traction was performed to reduce the angle between the cervical canal and uterine cavity (to straighten the uterus and normalize its position). Uterine sounds were then introduced to determine the uterine length and position. The NOVA T-380 was inserted according to the manufacturer's instructions. The gentle traction made by the vulsellum was maintained throughout the procedure by a helping nurse.

In group II, steps were performed as in group I until the uterine length was measured. The IUD inserter (insertion tube) was slightly bent, making it curved like a classic uterine sound to conform to the position of the uterus. The flange used for marking on the centimeter scale, printed on the insertion tube, was moved towards the distal end of the insertion tube. The inserter was then cautiously introduced into the uterine cavity until the proximal end touched the fundus. Uterine length was indicated by the corresponding number on the centimeter scale of the insertion tube. It was identified visually (i.e., the number seen at the level of the external cervical os) and rechecked by the distal mark of blood or povidone-iodine traces staining the inserter (Figure 1).The insertion tube was then withdrawn 2 cm, and the flange was slid using artery forceps along the insertion tube until its lower edge reached the mark on the centimeter scale. The insertion tube was then pushed through the cervical canal into the uterus until the flange touched the external cervical os and insertion was completed according to the manufacturer's instructions. Throughout the procedure, gentle traction made by the vulsellum was maintained by a helping nurse.

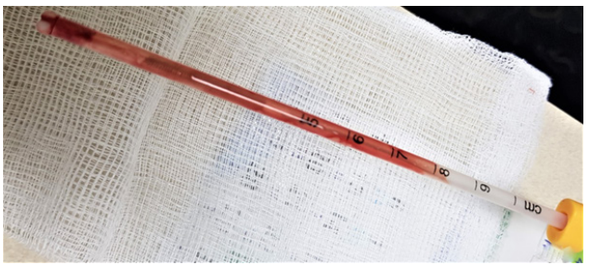

Fig. 1: Uterine length identified by distal mark of blood trace on the inserter

The visual analog scale (VAS) was used to measure pain perception. Patients marked a point along a continuous line from 0 to 10. The VAS score was determined by the distance, measured in centimeters to the nearest 0.1 cm marked point from the 0 edge. A score of 0 indicates no pain, and a score of 10 indicates the worst pain possible. Patients in both groups were asked to record the pain experienced during vulsellum placement and uterine length measurement utilizing either uterine sound or an inserter tube. After the procedure, overall pain perception during IUD insertion was also recorded. Abdominal ultrasonography was performed to confirm correct IUD placement.

The ease of uterine length measurement in both groups was assessed using the Ease score. A score from 0 to 10 was given, where 0 = very easy insertion and 10 = extremely difficult insertion[7,18]. The time taken for IUD insertion was measured in both study groups. Complications that occurred at the time of IUD insertion included uterine perforation, failure of insertion, and vasovagal attacks were reported. Patients were instructed to return to the clinic during their next menstrual cycle to check IUD position sonographically.

Statistical analyses were performed using SPSS version 21 (Chicago, IL, USA). Categorical variables are expressed as numbers and percentages. Numerical parametric variables are described as means and standard deviations. Quantitative data were compared using independent t-tests. *P-value* was evaluated and values <.05 were considered significant.

RESULTS

Hundred sixty-four women were included in this study. Eleven women were excluded due to the presence of unevaluated abnormal uterine bleeding (5 cases), history of submucous fibroids (3 cases), and cervicitis or PID

(3 cases). During the study, IUD insertion failed in seven cases due to cervical stenosis (four cases) and vaginismus (three cases). Eight patients did not attend the follow-up consultation. Thus, the study was completed by 138 women: 70 patients in Group I and 68 patients in Group II.

No significant differences were found in the demographic characteristics between the two study groups, as shown in (Table 1). The mean age of the participants in group I was 26±3.6 years and group II was 26.9±5.1 years. In group I, the mean values of parity, miscarriages, and previous cesarean sections were 2.1±1.1, 1.6±1.5 and 0.4±0.7, respectively. In group II, the mean parity, miscarriage, and number of previous cesarean sections done were 2.29±1.4, 1.1±1.1 and 0.6±1.4, respectively. Body mass index (BMI) was of an average 22.7±7.4 kg/m^2 in group I and 22.2±5.7 kg/m^2 in group II.

Table 1: The demographic characteristics of the two study groups

	Group I (n=70)	Group II (n=68)	*P value*
Age (years)	26±3.6	26.9±5.1	0.52
Parity	2.1±1.1	2.29±1.4	0.67
Miscarriage	1.6±1.5	1.1±1.1	0.9
Previous CS	0.4±0.7	0.6±1.4	0.43
BMI(kg/m^2)	22.7 ± 7.4	22.2 ± 5.7	0.58

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

Group II showed significantly lower pain scores in the uterine length measurement step and overall pain perception after IUD insertion than group I (0.3±0.5, versus 1.2±1; p=0.001) (1.8±1.3, versus 3.5±0.9; p=0.001) ,respectively. Pain experience was comparable in the 2 study arms during vulsellum placement (group I = 2±1.1 versus group II = 2.4±1.3; p=0.095) and during IUD insertion (group I = 2.8±1.5 versus group II = 2.9±1.7; p=0.146) (Table 2).

Table 2: VAS score in group I and II

VAS score	Group I (n=70)	Group II (n=68)	*P value*
Vulsellum placement	2±1.1	2.4±1.3	0.095
Uterine length measurement step	1.2±1	0.3±0.5	0.001
During IUD insertion	2.8±1.5	2.9±1.7	0.146
Post-IUD insertion (over-all pain perception)	3.5±0.9	1.8±1.3	0.001

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

The Ease score of the uterine length measurement step was 7±1.2 and 7±1.1 in groups I and II, respectively, with no statistically significant difference (p=0.855). The duration of insertion was significantly shorter in group II (1±0.6 min) than in group I (1.5±0.3 min, p=0.001). No complications were recorded during IUD insertion. All patients showed correctly placed IUD on transabdominal ultrasound, performed after insertion and in the subsequent follow-up visits (Table 3).

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

	Group I (n=70)	Group II (n=68)	*P value*
Ease score (ES)	7±1.2	7±1.1	0.855
Duration of insertion (min)	1.5±0.3	1±0.6	0.001
Complications at time of insertion	0	0	-
IUD correctly placed			
• post insertion	70 (100%)	68 (100%)	-
• Follow-up visit	70 (100%)	68 (100%)	-

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

DISCUSSION

We present a new uterine sound-sparing approach during IUD insertion. The IUD inserter can correctly estimate the uterine position and size by replacing the classic uterine sound. The results showed that this method was less painful than the classic approach, reduced the time required for IUD insertion, and was easily applied. To the best of our knowledge, no clinical trials have yet addressed this technique.

In the present study, pain associated with the uterine length measurement step was significantly lower in group II than in group I (0.3±0.5 versus 1.2±1; p=0.001). During vulsellum application and IUD insertion, pain was not significantly different between the study arms. After IUD insertion, the overall perceived pain was due 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.

Cervical internal os stretching is the most painful step during IUD insertion. Second is uterine sounding, IUD insertion, and vulsellum placement[19]. In the classic approach of IUD insertion, pain is aggravated by stretching the cervical os twice by introducing the uterine sound and then the IUD inserter. In our study, the IUD inserter was introduced only once into the uterine cavity throughout the procedure. In addition, the plastic nature of the IUD inserter may be less traumatic than the metal classic sound, consequently causing less or no pain.

It was found that ease of uterine length measurement step was statistically comparable in both study arms (7±1.2 versus 7±1.1 in groups I and II respectively). These results could be attributed to cervical traction by the vulsellum

straightening the uterine cavity. In addition, a slight bending of the insertion tube rendered it curved just as a classic uterine sound.

The time taken to insert the IUD was significantly shorter in group II than in group I. This could be attributed to omitting the classic uterine sound step, introducing the IUD inserter only once into the uterine cavity throughout the procedure, and Ease scores recorded in the measurement of uterine length by IUD inserter.

A copper IUD must be correctly placed to work effectively[20]. In a study by Christenson et al.[15], the IUD was inserted blindly without prior pelvic examination or sounding. Insertion was not guided by ultrasonography. The expulsion rate of 6% reported in this study may be due to incorrect placement. The use of sounding or sonography to define uterine length and position can guarantee safe and proper IUD placement[16]. In our study, using the IUD inserter in sounding instead of the classic metal uterine sound gave correct placement by ultrasound in all patients.

To assess uterine position, cavity length, or monitor IUD during insertion, other studies have used ultrasound. Ali et al.[16] proposed that transvaginal sonography (TVS) could replace uterine sounding and significantly ameliorate insertion pain. In a study by Mohamed et al.[14], trans-abdominal ultrasound-guided IUD insertion was found to be statistically superior to the traditional technique in terms of VAS pain scores (2.4±2.1 vs. 5.0±1.7, p<0.001) as well as time taken (in seconds) for IUD insertion (32.2±14.8 vs. 77.7±30.6, p<0.001). Another research showed that VAS pain score in women in the ultrasound-guided group was significantly lower (2.36±1.77 vs. 4.74 ± 2.35, p<0.001), insertion was easier (score 4.0 ± 0.9 vs. 2.5±1.27, p<0.001), and the time needed for the procedure was significantly shorter (5.82±2.56 vs. 9.4±4.99 min, p<0.001) when compared to the control group[13].

The present study had lower pain scores and a shorter insertion duration than aforementioned studies. Ultrasound was used before or during insertion and then after insertion to confirm placement. This course of multiple rounds of imaging may cause distress to patients, thus increasing their pain perception. In our study, ultrasonography was performed only after IUD insertion.

Use of classic uterine sounds is associated with a high risk of uterine perforation[21]. In our study, omitting classic uterine sounds may have caused the absence of complications related to perforation. Moreover, knobs at the end of the horizontal arms of the IUD cover the edges of the proximal end of the inserter tube when the IUD is withdrawn in the insertion tube. This made the proximal end of the inserter blunt and smooth, adding safety to the procedure (Figure 2).

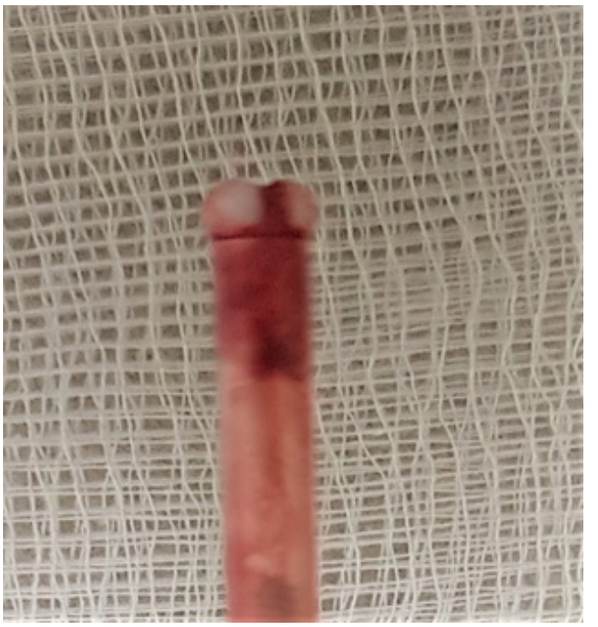

Fig. 2: Inserter proximal blunt and smooth end

The limitations of our study include the small sample size, which may also explain the absence of complications and 100% correct placement rates. In addition, the NOVA T-380 application requires special steps compared to traditional copper IUDs. Although the data presented show that the technique is safe and easy, it is recommended to be performed only by experienced physicians.

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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CONFLICT OF INTERESTS

There are no conflicts of interest.

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