Middle East Fertility Society Journal xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

Middle East Fertility Society Journal

journal homepage: www.sciencedirect.com

Original Article

Classic versus uterine sound-sparing approach for insertion of copper T380A intrauterine device: A randomized clinical trial

Mohammed K. Ali, Ahmed M. Abbas *, Osama S. Abdalmageed, Tarek A. Farghaly, Ali H. Yosef

Department of Obstetrics and Gynecology, Faculty of Medicine, Assiut University, Egypt

ARTICLE INFO

Article history:
Received 13 August 2017
Revised 19 October 2017
Accepted 24 October 2017
Available online xxxx

Keywords:
Intrauterine device
TV/US
Ultrasound
Contraception
Uterine sound

ABSTRACT

Objective: The current study compares the efficacy of the classic approach and the uterine sounding sparing approach (a new approach) for copper intrauterine device (Cu-IUD) insertion.
Study design: A randomized clinical trial.
Setting: Woman's Health Hospital, Assiut, Egypt.
Materials and methods: The current study was an open parallel randomized clinical study conducted in Assiut Woman's Health Hospital, Egypt included women requesting Copper IUD insertion. Enrolled women were randomized into 2 groups; group I included women subjected to classic approach for Cu-IUD insertion and group II included women had Cu-IUD insertion using the uterine sound-sparing approach (USSA). This approach utilized transvaginal ultrasound (TV/US) for assessment of the uterine cavity length and position before IUD insertion without using uterine sounding. The primary outcome was the successful Cu-IUD insertion.
Results: 46 women were analyzed in group I and 46 in group II. The pain during IUD insertion and 5 min post-insertion was significantly lower in group II than group I ($p < .001$). The Cu-IUD inserted easier in group I than group II ($p < .001$). Moreover; significant shorter duration of insertion was reported in group II ($p = .002$). More satisfied women were found in group II ($p = .0001$). At the 4 weeks follow-up; TV/US showed that all IUDs were in place in all women.
Conclusions: Cu-IUD can be inserted successfully without using uterine sound provided using TV/US prior to insertion. This method associated with less pain, greater women satisfaction during insertion with shorter duration.

1. Introduction

The intrauterine device (IUD) is a safe, reliable and long-acting reversible contraceptive method [1]. Instrumentation of lower genital mucosa during IUD application provokes pain because it is highly sensitive to touch. Fear of pain associated with IUD insertion is considered a barrier to use this contraception method [2,3].

The pain during IUD insertion could be attributed to cervical grasping by the tenaculum, traction on the cervical canal, stretching of the internal os by the uterine sound or the IUD inserter, and irritation of the endometrial lining by the IUD [4,5]. However; the most painful reported steps are those stretching the cervical internal os; uterine sounding and IUD insertion, followed by tenaculum placement [6].

Previous studies have investigated different pharmacological strategies to minimize the IUD insertion pain including pre-insertion non steroidal anti-inflammatory use, intracervical or intrauterine local anasthetics, vaginal misoprostol, and paracervical block [7–10]. On the other hand, technical modifications to achieve less pain during Cu-IUD insertion are scarce in literature.

The insertion instructions recommend performing bimanual examination and uterine sounding prior to IUD insertion in order to guarantee proper determination of uterine size and position [11]. Some uterine cavities could be small for correct IUD insertion and accommodation, so without this step the IUD may be incorrectly placed and lost [12]. However; sounding before IUD insertion could induce pain if passed from tight cervix or uterine perforation if the size or direction of the uterus has been incorrectly assessed [13].

So, the present work tested the hypothesis that trans-vaginal ultrasound (TV/US) prior to IUD insertion can estimate the uterine position and size correctly with no or minimal pain, so it could replace the essential painful step of uterine sounding.

Peer review under responsibility of Middle East Fertility Society.
* Corresponding author at: Department of Obstetrics and Gynecology, Assiut University, Women Health Hospital, 71511 Assiut, Egypt.
E-mail address: ahmedabbas@aun.edu.eg (A.M. Abbas).

https://doi.org/10.1016/j.mefs.2017.10.006
1110-5690/

Please cite this article in press as: M.K. Ali et al., Classic versus uterine sound-sparing approach for insertion of copper T380A intrauterine device: A randomized clinical trial, Middle East Fertil Soc J (2017), https://doi.org/10.1016/j.mefs.2017.10.006

Accordingly, the aim of the present study was to compare the classic approach with a uterine sound-sparing approach for Cu-IUD insertion as regard the efficacy, patients' perception of pain, duration of insertion beside the easiness and satisfaction of both methods. To our knowledge, no randomized clinical trials have been conducted or registered, to address this topic.

2. Material and methods

The current study was registered open, parallel, randomized, clinical study (NCT02842177 clinicaltrials.gov) comparing the efficacy and pain perception during Cu-IUD by classic approach with that of a novel approach (uterine sound-sparing approach). The Assiut University Medical Ethical Review Board approved the study. We considered all women attending the Outpatient Family Planning Clinic of Assiut Women's Health Hospital between January 2016 and August 2016 for enrollment. This trial was designed and reported according to the revised recommendations of ClinicalTrials.gov for improving the quality of reporting randomized clinical trials (RCTs).

2.1. Eligible participants

We evaluated all women requesting Cu-IUD for contraception in accordance with WHO guidelines [14], and counseled them to participate in the study. Included women were aged between 20 and 45 years, received neither analgesics nor anxiolytics in the 24 h prior to insertion. Also misoprostol was not used by any subject prior to IUD insertion.

We excluded women with any uterine abnormalities as congenital anomalies, endometrial lesions, adenomyosis, fibroids and intrauterine adhesions. We obtained an informed consent from all eligible participants included in the study before participation after explaining the nature of the study.

2.2. Randomization

Randomization was done by computer-generated random table using Excel 2010. Eligible women who gave their informed consent were randomized to either group I: Classic approach or group II: uterine sound-sparing approach (USSA). Allocation concealment was performed using serially numbered closed opaque envelopes. Each envelope was labeled with a serial number and had a card noting the type of intervention. Allocation never changed after opening the closed envelopes.

2.3. Intervention

All women were approached by one of our researchers and the following data were collected: age, parity, body mass index (BMI), previous children and abortions, residency, education level, working status, duration from the last pregnancy and previous use of contraceptive methods. All participating woman had copper T380A IUD (Paragard®T380A; Teva Pharmaceuticals USA, Inc. North Wales) fitted. They were asked to empty their bladder and were menstruating at the time of insertion.

In group I (classic method); bimanual examination was done firstly. The speculum was placed into the vagina and the cervix was cleansed with povidone iodine. After placement of single toothed vulsellum on the anterior lip of the cervix, for traction and fixation of the uterus, the uterine sound was inserted for determination of uterine length and uterine position followed by Cu-IUD insertion. The duration of IUD insertion were reported. A single experienced physician inserts the IUDs to avoid any inter-observer bias during technique of application.

In group II (USSA); after bimanual examination, the same sonographer (Level II experience) performed TV/US using a SonoAce X6 machine (Medison, Korea) with transvaginal probe (4–8 MHz frequency, using an average 6.5 MHz). Firstly, he evaluated the uterine position. Then, he measured the endometrial and cervical stripe lengths in the sagittal view of the uterus and summed to have the actual length of the uterus; by which the IUD tube was adjusted before insertion. The same speculum and vulsellum were used and the IUD was inserted directly into the uterine cavity.

We asked the women in both groups to rate their pain 3 times; immediately following vulsellum placement, during IUD insertion and lastly; 5 min after IUD insertion. We utilized the Visual Analogue Scale (VAS) to measure the pain perception at those time points. It is a 10 points instrument with 0 point indicating no pain and 10 indicating the worst pain. The VAS was explained to the participants before entry to the study [15].

The physician assessed the ease of IUD insertion using the ease of insertion score (ES). The ES was calculated at a graduated VAS-like scale from zero to 10, in which 10 means terribly difficult insertion and zero means very easy insertion. The ES is a validated score used before in many trials for evaluation of use of analgesia during IUD insertion [7,16].

All participants expressed their level of satisfaction with IUD insertion approach using a 10-cm VAS (with 0 = no satisfaction and 10 = maximum satisfaction). After insertions, all women were subjected to TV/US to assess the IUD place and to ensure that the IUD was located in the uterine cavity correctly. Immediate adverse events of IUD insertion such as uterine perforation, failure of insertion, and vasovagal reaction were recorded.

2.4. Study outcomes

The primary outcome was the ideal IUD insertion as defined when IUD was clearly visualized by ultrasonography in a sagittal view and the upper end located in the fundus and the lower end at the internal os [17]. The secondary outcomes included the difference in pain VAS scores during IUD insertion; the ease of IUD insertion; the duration of insertion; the difference in women's satisfaction score.

2.5. Follow-up schedule

A follow-up visit was scheduled after the next menses to detect late complications of IUD (displacement, expulsion, and perforation). IUD placement was checked by TV/US and the distance between IUD and the end of endometrial line was measured. Finally, the patients were categorized into two categories; completed follow up schedules or lost for follow up.

2.6. Sample size

The required sample size was calculated based on previous study of Elsedeek, 2016 in which the ideal IUD insertion was achieved in 68% of the study participants using the classic approach [17]. Using 80% power with α error of 0.05, a sample size of 92 women (46 in each group) to detect 25% difference in the ideal IUD insertion with the uterine-sound sparing technique (OpenEpi, Version 3, open source calculator-SSMean).

2.7. Statistical analysis

We analyzed all data using SPSS software Chicago, IL, USA, version 21. Testing the normality of data distribution was done by Kolmogorov Smironov test. Qualitative data were expressed as frequency and percentage. Chi-square test was used to examine the relation between qualitative variables. Quantitative data were

Please cite this article in press as: M.K. Ali et al., Classic versus uterine sound-sparing approach for insertion of copper T380A intrauterine device: A randomized clinical trial, Middle East Fertil Soc J (2017), https://doi.org/10.1016/j.mefs.2017.10.006