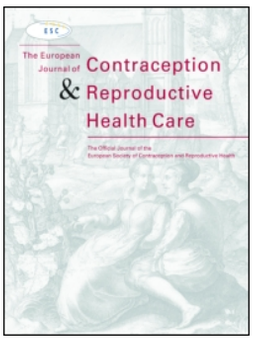

The European Journal of Contraception & Reproductive Health Care

ISSN: 1362-5187 (Print) 1473-0782 (Online) Journal homepage: http://www.tandfonline.com/loi/iejc20

Ultrasound-guided intrauterine device insertion: a step closer to painless insertion: a randomized control trial

Dina Mohamed Refaat Dakhly & Yasmin Ahmed Bassiouny

To cite this article: Dina Mohamed Refaat Dakhly & Yasmin Ahmed Bassiouny (2017): Ultrasound-guided intrauterine device insertion: a step closer to painless insertion: a randomized control trial, The European Journal of Contraception & Reproductive Health Care, DOI: 10.1080/13625187.2017.1381234

To link to this article: http://dx.doi.org/10.1080/13625187.2017.1381234

Published online: 05 Oct 2017.

THE EUROPEAN JOURNAL OF CONTRACEPTION & REPRODUCTIVE HEALTH CARE, 2017
https://doi.org/10.1080/13625187.2017.1381234

Taylor & Francis
Taylor & Francis Group

CLINICAL STUDY

Ultrasound-guided intrauterine device insertion: a step closer to painless insertion: a randomized control trial

Dina Mohamed Refaat Dakhly and Yasmin Ahmed Bassiouny

Department of Obstetrics and Gynecology, Cairo University, Cairo, Egypt

ABSTRACT

Aim of study: To reduce the pain and duration of the intrauterine device (IUD) insertion procedure through minimizing instrumentation and using trans-abdominal sonography (TAS).

Methods: This randomized control trial was conducted in a university hospital and included 102 eligible females, fulfilling the inclusion criteria. They were randomly assigned into two groups via 1:1 computer-based randomization program; the trans-abdominal guided IUD insertion group ($n = 51$), and the traditional IUD insertion group ($n = 51$). The main outcomes were the pain experienced during the procedure as scored by the visual analogue score and the duration of the procedure.

Results: The trans-abdominal guided IUD insertion was found to be statistically superior to the traditional technique for IUD insertion regarding the pain scores (according to the Visual Analogue Scale, from 0 to 10) recorded by the candidates (2.4 ± 2.1 vs. 5.0 ± 1.7, $p < .001$) as well as the time (in seconds) taken for IUD insertion procedure (32.2 ± 14.8 vs. 77.7 ± 30.6, $p < .001$).

Conclusions: Due to the decrease in pain and time taken for IUD insertion, the trans-abdominal guided technique can be used as a modified technique for IUD insertion.

ClinicalTrials.gov Identifier: NCT02582268.

ARTICLE HISTORY
Received 10 June 2017
Revised 19 August 2017
Accepted 13 September 2017
Published online 5 October 2017

KEYWORDS
Contraception; intrauterine device; painless insertion; trans-abdominal ultrasound

Introduction

The intrauterine device (IUD) has long been known to be an effective contraceptive method. Over the past years, no change has been noticed in the proportion of women using IUD (Globally, 14.3% of women of reproductive age use IUD, and it varies between <2% in some countries and reaching up to >40% in others [1]), despite its reputation as a cost effective long acting reversible contraception (LARC) [2], with high continuation and satisfaction rates among users [3–5].

IUD insertion can be quite painful as it involves the use of different instruments: speculum insertion, tenaculum use, manipulation of cervix and application of the uterine sound. In a study performed by Maguire et al., 2012, they demonstrated that the pain associated with uterine sounding can be similar or even worse than that of the mere IUD insertion [6]. Also, the pain may be related to the parity; nulliparous females and those with previous cesarean deliveries, are more likely to encounter difficult insertion [7,8].

To reduce the pain and discomfort associated with the procedure, studies were performed to develop more simplified methods for IUD insertion. Some authors tried a simple modification to the traditional IUD insertion procedure including omitting the step for bimanual examination and uterine sounding [9].

Regarding the use of the different pharmacological agents, to reduce the pain, many recent studies investigated the use of misoprostol [10–13] in different doses and routes of administration. They found out that it facilitated the insertion but with no impact on the associated pain. Lignocaine, a promising agent in past trials [14,15], recent data show that it did not decrease the pain scores during IUD insertion [6]. Prophylactic ibuprofen and other NSAIDs have also been tried and were found to decrease the post-insertion pain rather than the insertion pain [8,16,17]. Researchers even went a step further towards the use of nitroprusside [18] and inhaled nitrous oxide (Entonox®22) [19].

The aim of this study was to minimize the pain and duration of IUD insertion procedure by conducting trans-abdominal sonographic-guided technique for IUD insertion.

Methods

A parallel, randomized controlled trial was conducted in Kasr Al Aini hospital, Cairo University, Cairo, Egypt, from October 2015 to March 2016. The University outpatient clinic provides a daily walk-in service for over 120 female patients. These services include IUD insertion, with an average of 6 cases daily. As the study was performed by two authors each one attended the gynecologic clinic once weekly, the sample size was calculated and participants were recruited over a period of 6 months.

Participants

All females desiring IUD as a method of contraception and attending the University outpatient clinic were included in the study. While, those refusing to participate, females

CONTACT Dina Mohamed Refaat Dakhly dinadakhly@gmail.com 60 Mosadak Street, Dokki, Giza 12311, Egypt

defined as category 3 and 4 of the World Health Organization's (2015) medical eligibility criteria for contraceptive use, [20] or females who desired an immediate replacement for a removed IUD (which is against the clinic policy) were excluded from the study.

In all included participants, TCu 380A IUD was inserted, immediately postmenstrual (day 7–10 of the cycle). Before starting the study, the institutional review board of Cairo University approved the study.

Procedure

As a part of our clinic protocol, all females desiring IUD insertion undergo full history taking and gynaecological examination as well as trans-vaginal sonography (TVS) using SonoAce R5 apparatus (Samsung Medison, Seoul, Korea) to exclude the presence of any contraindications. Cases who were found eligible to participate in the study were asked to sign a written informed consent, with all the details included and verbally explained. So, the participants only required a single visit to get recruited in the study and have their IUD inserted.

Randomization was carried out by a specific computer scheme, which performed a 1:1 simple randomization method and contained sequential numbers from 1 to 102 (the number of females to be randomized). Accordingly, the participants were allocated into two main groups: TAS-guided IUD insertion (A) and the traditional method control group (B). Random assignments were concealed in sealed opaque envelopes until the time of enrollment.

After being allocated in one of the two study groups. The female was asked to lie in lithotomy position. A speculum was inserted in the vagina and adjusted to view the cervix. A multiple toothed tenaculum is used to swab the cervix using cotton ball dipped in povidine iodine for disinfection. In both groups, an assistant was present placing the abdominal probe on the female's suprapubic region. The ultrasound monitor was only visualized by the physician and blinded for the participants.

Then an IUD was inserted by one of the two studied methods:

In the TAS-guided IUD insertion group (group A): the participant was asked to have a full bladder. Full bladder helps to displace the bowel out of the pelvis and acts as an acoustic window for high frequency sound waves and to straighten the angle between the uterine body and cervix in anteverted uterus [21,22], performing the function of the tenaculum. Participants, who did not have full bladder, were asked to return after 30–60 minutes, but their exact number was not recorded. In this group, the assistant applied the TAS probe (operating at 2.5–3.5 MHz) to the suprapubic region to view the bladder and the longitudinal section of the uterine body cervix and vagina. Then the IUD was introduced vaginally under TAS vision directly passing through the cervical canal and entering the uterine cavity, till it was placed safely (under vision) in its proper position.

The traditional method of IUD insertion (group B) was done as following:

The tenaculum was used to grasp the anterior lip of the cervix, and then a uterine sound passed through the cervical canal to reach the fundus and estimate the appropriate length for IUD insertion. Then the IUD was inserted in a traditional way. In this group, the TAS probe was applied but not functioning. It was used to nullify the placebo effect of the presence of the assistant or the probe that can affect the perception of pain by the participants.

To ensure successful insertion, a TVS was done following the procedure, which was not included in the recorded procedure time.

Assessment and outcome variables

The duration of the procedure was recorded in seconds (from the step after application of povidine iodine to the cervix) in both groups, by a stopwatch, until the speculum was removed. The participant was then asked to report the level of pain she felt during the procedure using the Visual Analog Scale (VAS) (from 0 to 10, in which '0' is no pain and '10' is the worst possible pain) [10].

Statistical analysis

Data were statistically described in terms of mean ± standard deviation (± SD), median and range or frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using Student *t* test for independent samples in comparing two groups when normally distributed and Mann Whitney *U* test for independent samples when not normally distributed. For comparing categorical data, Chi square (c^2) test was performed. Exact test was used instead when the expected frequency is less than 5. *p* Values less than .05 was considered statistically significant. All statistical calculations were done using computer program SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL) release 15 for Microsoft Windows (2006).

Sample size calculation

It was done using the comparison of occurrence of moderate to severe pain during IUD insertion between cases in which IUD will be placed under trans-abdominal sonographic guidance and those in which IUD will be placed in a traditional way. Calculation was done based on comparing 2 proportions from independent samples using Fisher Exact test, α-error level was fixed at .05 and the power was set at 80%. As previously published [11], moderate to severe pain occurred in 37.2% of cases pretreatment with misoprostol while 66.7% of non-treated cases experienced such pain. Accordingly, the optimum sample size should be 51 cases in each arm. Sample size calculation was done using PS Power and Sample Size Calculations software, version 3.0.11 for MS Windows (William D. Dupont and Walton D. Vanderbilt, Nashville, TN).

Results

IUD was initially offered to 124 females (as shown in Figure 1); 19 eligible females refused to participate in the study; 3 participants did not meet the inclusion criteria of (undiagnosed vaginal bleeding, purulent cervicitis). Therefore, 102 patients were randomized into two groups;

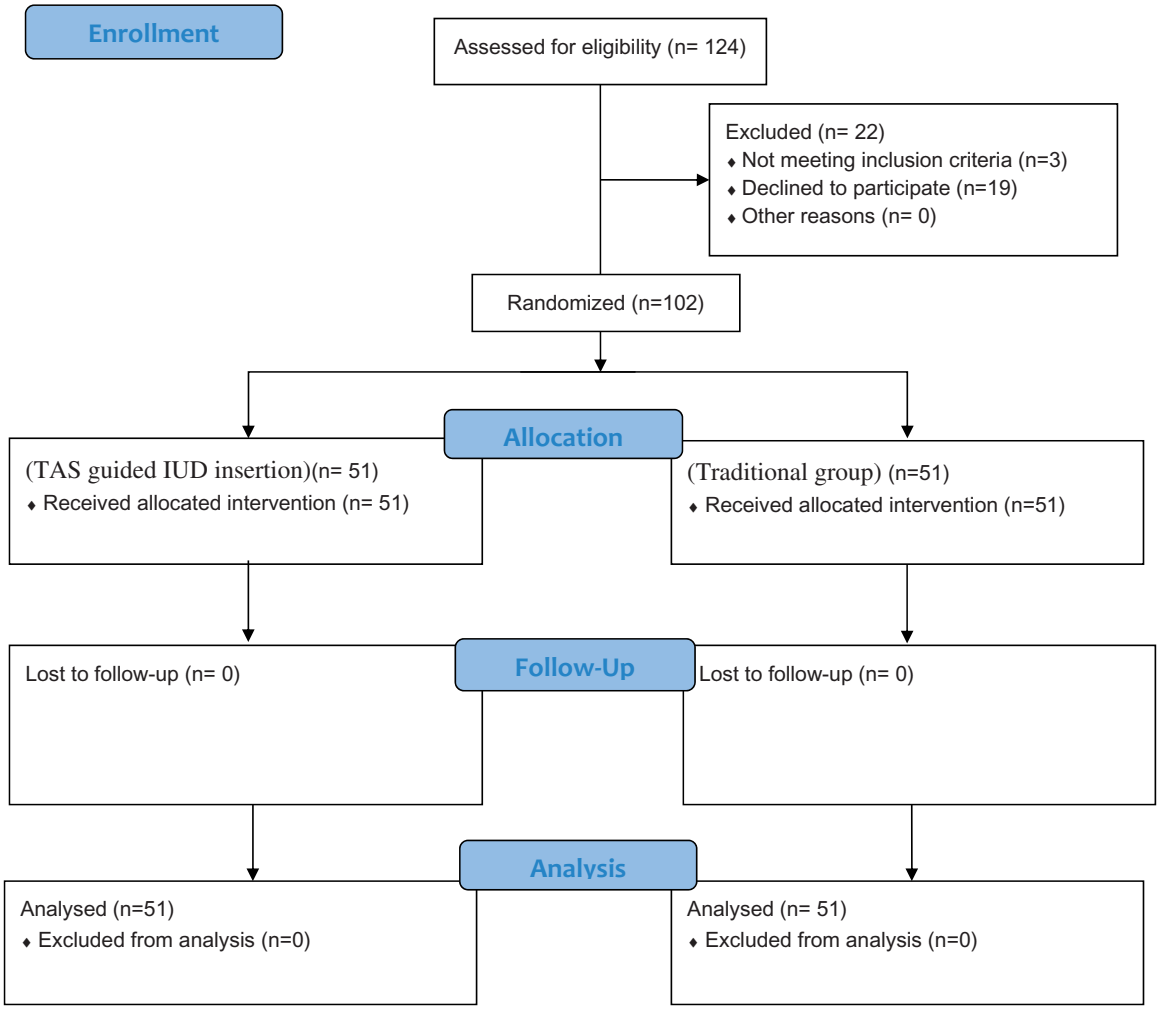

Figure 1. CONSORT 2010 flow diagram.

Table 1. The demographic criteria of the two groups.

Criteria	TAS-guided IUD insertion ($n = 51$)	Traditional IUD insertion ($n = 51$)	p Value
Age (years)	31.3 ± 5.8	31.5 ± 5.0	.87
Gravidity	2 (1–5)	2 (1–5)	.30
Parity	2 (1–6)	2 (1–4)	.07
BMI (kg/m^2)	28.7 ± 3.5	28.5 ± 3.6	.78
Nulligravida	2 (3.9%)	1 (1.9%)	1.00
Previous vaginal delivery	26 (50.9%)	21 (52.9%)	.42
Previous 1 CS	14 (27.5%)	24 (47.1%)	.06
Previous 2 or more CS	9 (17.6%)	5 (9.8%)	.39
History of previous IUD insertion (times)	1 (0–3)	0 (0–3)	.39
Number of females with previous IUD use	25 (49%)	17 (33.3%)	.16
Duration of previous IUD insertion (years)	2.4 ± 2.8	1.6 ± 2.2	.15
Previous IUD-associated complication:			
Bleeding[a]	8 (15.7%)	11 (21.6%)	.61
Colics[b]	7 (13.7%)	8 (15.7%)	>.99
Pregnancy	0 (0%)	2 (3.9%)	.49

BMI: body mass index, CS: caesarean section, IUD: intrauterine device, TAS: trans-abdominal sonography.
All values are expressed in mean ± SD; or in n (percentage), median (range).
p Value is significant if <.05.
[a]Excessive menstrual flow, intermenstrual bleeding or spotting.
[b]IUD associated dysmenorrhea, or intermenstrual colics.

the TAS-guided IUD insertion group (51) and the traditional IUD insertion group (51).

The demographic criteria of both groups are shown in Table 1. No evidence of statistical significance was detected when comparing age, gravidity, parity, body mass index (BMI), previous deliveries, past history and duration of IUD use and previous IUD-associated complications.

Table 2 expressed comparison between the two studied interventions; this showed a statistically significant difference in favour of the TAS-guided IUD insertion technique regarding the pain score recorded by the participating females and the duration of the process of IUD insertion. Table 2 also expressed the complications of the procedures as:

- Failed IUD insertion, represents failure of passage of the uterine sound in the traditional group (group B), or failure of the passage of the IUD itself through the internal os in Group A.

Table 2. The difference between the two interventions.

Criteria	TAS-guided IUD insertion ($n = 51$)	Traditional IUD insertion ($n = 51$)	p Value
Pain during IUD insertion (scale from 0 to 10)	2.4 ± 2.1	5.0 ± 1.7	<.001*
The duration of the IUD insertion procedure (seconds)	32.2 ± 14.8	77.7 ± 30.6	<.001*
Failed insertion	1 (1.9%)	2 (3.9%)	>.99
TVS following insertion			
IUD in place	50 (98%)	46 (90.2)	.20
Misplaced	0 (0%)	3 (5.9%)	.24

IUD: intrauterine device, n: number, TAS: trans-abdominal sonography, TVS: trans-vaginal sonography.
Values are expressed in mean ± SD; or in n (percentage).
*p Value is significant if <.05.

- Misplaced IUD, occurs when the distance between the upper end of the IUD to the external uterine fundus is >2 cm, as identified by ultrasonography [23].

Discussion

In this study, TAS-guided IUD insertion was introduced to help in reducing the pain associated with the IUD insertion procedure. It was used and compared with the traditional technique for IUD insertion.

Findings and interpretations

We recruited 102 candidates fulfilling the inclusion criteria. It was found that there was significantly less pain sensation and shorter duration in favour of the TAS-guided IUD insertion.

We attribute those findings to the fact that we did not use a tenaculum to grasp the cervix nor sound the uterus. An important point to be mentioned is that some experienced gynaecologist practice blind IUD insertion in which they insert the IUD in a traditional way but without grasping the cervix to reduce the pain. However, this procedure was not verified by scientific researches, needs good experience and carries the risk of uterine perforation, which can be avoided using ultrasound guidance.

It is believed that pain can be one of the reasons that hold back the further increase in the use of IUD as a method of contraception. Many studies involve the use of pharmaceutical agents to reduce the pain, either before the insertion (oral analgesia, cervical ripening/priming and local anesthesia), during the insertion procedure (local anesthesia administered reactively) or after the end of the procedure (non-steroidal anti-inflammatory drugs [NSAIDs] and opioid analgesia), and were found to lack the sufficient evidence that support their routine use [24,25].

Psychological preparation of the female for the procedure was tried by Newton and Reading. They found out that explaining the procedure to the female helped to decrease the anxiety towards the procedure and subsequently the perception of pain [25].

Estimation of the duration of IUD insertion is one of the main outcomes of this study; this also has not been assessed in previous studies. The fact that the traditional method required more steps and instrumentations, led to the significant difference between the two procedures favoring the new technique. Although the difference seems minor, but to the female patients, it is considered huge. Furthermore, the more the pain the patient experiences, the more they move and consequently the more increased difficulty and the duration of the procedure.

Certainly, the nulliparous females are considered as a challenge to the introduced technique. It is doubtful that IUD applicator could be successfully inserted without a tenaculum and prior sounding due to their extremely flexed uterus, unfortunately there was a small number of nulliparous females recruited, as in Egypt, IUDs are scarcely used as their method of contraception due to the absence of the desire to delay pregnancy after marriage, in fact getting pregnant becomes the main concern of the newly married couples, and also due to the delay in the age of marriage.

Strengths and weakness of the study

The strength of the study is attributed to being a randomized controlled trial. However, this introduced technique has some limitations: (i) it requires the presence of a full bladder, which may add pain during speculum insertion and it can be time consuming as well, (ii) the need for presence of an assistant with sonographic knowledge to place the TAS probe, however by our experience through this study, it was easy to direct the regular attending nurse to place the probe on the suprapubic region, and finally, (iii) the need for the presence of an ultrasound device in the setting which may not be feasible in some developing countries' clinics due to the limited resources.

This was not a limitation in our study, as there is usually an ultrasound machine present in every gynecology clinic. So consequently, in this study there was no increase in the cost neither on the patients nor the doctors. Also, this study did not aim to analyze the cost-effectiveness of the procedure and its further applicability in different settings.

This study is not the first trial conducted by our team. There was a previous pilot study conducted to test the feasibility of such technique (ClinicalTrials.gov Identifier: NCT02393495).

Unanswered questions and future research

Proper assessment of the TAS-guided IUD insertion in nulliparous females and those with more than two previous cesarean deliveries, as well as analyzing the cost-effectiveness of the procedure in the different settings.

Conclusion

The TAS-guided IUD insertion technique can be used as a new modality for IUD insertion reducing the pain and duration of procedure.

Acknowledgements

We thank all the female participants for their collaboration towards accomplishing this study.

Disclosure statement

The authors report no conflict of interest.

Funding

There was no source of funding for this study.

References

[1] Buhling KJ, Zite NB, Lotke P, et al. INTRA Writing Group. Worldwide use of intrauterine contraception: a review. Contraception. 2014;89:162–173.
[2] National Collaborating Centre for Women's and Children's Health (UK). Long-acting reversible contraception: the effective and appropriate use of long-acting reversible contraception. London (UK): RCOG Press; 2005.
[3] Bayer LL, Jensen JT, Li H, et al. Adolescent experience with intrauterine device insertion and use: a retrospective cohort study. Contraception. 2012;86:443–451.
[4] Peipert JF, Zhao Q, Allsworth JE, et al. Continuation and satisfaction of reversible contraception. Obstet Gynecol. 2011;117: 1105–1113.
[5] Brockmeyer A, Kishen M, Webb A. Experience of IUD/IUS insertions and clinical performance in nulliparous women – a pilot study. Eur J Contracept Reprod Health Care. 2008;13:248–254.
[6] Maguire K, Davis A, Rosario Tejeda L, et al. Intracervical lidocaine gel for intrauterine device insertion: a randomized controlled trial. Contraception. 2012;86:214–219.
[7] McNicholas CP, Madden T, Zhao Q, et al. Cervical lidocaine for IUD insertional pain: a randomized controlled trial. Am J Obstet Gynecol. 2012;207:384.e1–386.
[8] Bednarek PH, Creinin MD, Reeves MF, Post-Aspiration IUD Randomization (PAIR) Study Trial Group, et al. Prophylactic ibuprofen does not improve pain with IUD insertion: a randomized trial. Contraception. 2015;91:193–197.
[9] Christenson K, Lerma K, Shaw KA, et al. Assessment of a simplified insertion technique for intrauterine devices. Int J Gynaecol Obstet. 2016;134:29–32.
[10] Sääv I, Aronsson A, Marions L, et al. Cervical priming with sublingual misoprostol prior to insertion of an intrauterine device in nulliparous women: a randomized controlled trial. Hum Reprod. 2007;22:2647–2652.
[11] Scavuzzi A, Souza AS, Costa AA, et al. Misoprostol prior to inserting an intrauterine device in nulligravidas: a randomized clinical trial. Hum Reprod. 2013;28:2118–2125.
[12] Dijkhuizen K, Dekkers OM, Holleboom CA, et al. Vaginal misoprostol prior to insertion of an intrauterine device: an RCT. Hum Reprod. 2011;26:323–329.
[13] Lathrop E, Haddad L, McWhorter CP, et al. Self-administration of misoprostol prior to intrauterine device insertion among nulliparous women: a randomized controlled trial. Contraception. 2013;88:725–729.
[14] Mody SK, Kiley J, Rademaker A, et al. Pain control for intrauterine device insertion: a randomized trial of 1% lidocaine paracervical block. Contraception. 2012;86:704–709.
[15] Allen RH, Raker C, Goyal V, Higher dose cervical 2% lidocaine gel for I2 insertion: a randomized controlled trial. Contraception. 2013;88:730–736.
[16] Buttram V, Izu A, Henzl MR. Naproxen sodium in uterine pain following intrauterine contraceptive device insertion. Am J Obstet Gynecol. 1979;134:575–578.
[17] Massey SE, Varady JC, Henzl MR. Pain relief with naproxen following insertion of an intrauterine device. J Reprod Med. 1974;13:226–231.
[18] Bednarek P, Micks E, Jensen J. The effect of nitroprusside on the IUD insertion experience in nulligravid women: a pilot study. Contraception. 2012;86:320.
[19] Vincent LC, Sewell E. Entonox® analgesia for IUD insertions and removals. J Fam Plann Reprod Health Care. 2012;38:270.
[20] World Health Organization. Medical eligibility criteria for contraceptive use. Geneva: World Health Organization; 2015.
[21] Sundström P, Wramsby H, Persson PH, et al. Filled bladder simplifies human embryo transfer. Br J Obstet Gynaecol. 1984;91: 506–507.
[22] Lewin A, Schenker JG, Avrech O, et al. The role of uterine straightening by passive bladder distension before embryo transfer in IVF cycles. J Assist Reprod Genet. 1997;14:32–34.
[23] Liang H, Li L, Yuan W, et al. Dimensions of the endometrial cavity and intrauterine device expulsion or removal for displacement: a nested case-control study. BJOG. 2014;121:997–1004.
[24] Lopez LM, Bernholc A, Zeng Y, et al. Interventions for pain with intrauterine device insertion. Cochrane Database Syst Rev. 2015;29:CD007373.
[25] Gemzell-Danielsson K, Mansour D, Fiala C, et al. Management of pain associated with the insertion of intrauterine contraceptives. Hum Reprod Update. 2013;19:419–427.