Evaluation of the effect of 10% lidocaine spray on reducing the pain of intrauterine device insertion: A randomised controlled trial

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Background. The intrauterine device (IUD) is among the most efficient contraceptive methods. However, IUD insertion is accompanied by pain and discomfort.
Objectives. To evaluate the analgesic effects of 10% lidocaine spray in reducing pain during IUD insertion.
Method. In a randomised clinical trial, 80 volunteers attending two clinics for IUD insertion were selected for study, and randomly allocated to two groups. The intervention group received four puffs of 10% lidocaine spray on their cervix prior to IUD insertion. The routine procedure (without an analgesic) was followed in the control group. The intensity of perceived pain in both groups was measured using a visual analogue scale from 0 to 10.
Results. The two groups had significant differences in pain intensity at all stages of the procedure ($p<0.001$). The most painful stage of the procedure was tenaculum placement (mean (standard deviation) pain intensity 2.2 (1.34) in the intervention group; 4.25 (1.92) in the control group).
Conclusion. Based on our findings, 10% lidocaine spray can be applied as a non-invasive, inexpensive, easy-to-use and accessible method to decrease IUD insertion pain.

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Long-acting reversible contraception methods, such as intrauterine devices (IUDs), implants and injectable contraceptives, are associated with high effectiveness in preventing unintended pregnancies, and thereby their significant health and economic consequences.[1] International reports have demonstrated that IUDs are the second-most common contraceptive method worldwide, used by 14% of women of reproductive age who are married or in a union; the highest prevalences of IUD use in this demographic have been reported in China (over 40%), South Korea and Uzbekistan.[2] IUD prevalence in Iran was calculated as 8.1% in 2012.[2] IUD insertion is generally associated with fear, which may decrease its acceptability, and anticipated pain or discomfort at the time of insertion could be a major barrier to the acceptance of IUDs among both clients and healthcare providers.[3,4] Nulliparity, non-lactation and time since the last pregnancy have all been suggested as factors that increase the probability of pain and discomfort during the IUD insertion procedure.[5-7]

Previous studies have shown conflicting results regarding the effects of several pain-relief methods in IUD insertion.[8] Randomised controlled trials have shown neither ibuprofen[9] nor naproxen[10,11] to have beneficial effects on IUD insertion pain. Similarly, different doses of sublingual and vaginal misoprostol (also a nonsteroidal anti-inflammatory drug (NSAID) pain-relief methods) failed to reduce pain during IUD insertion.[6,12]

Widespread use of lidocaine gel has been reported from countries such as the UK,[13] where different forms of intracervical lidocaine have been applied to attempt to decrease IUD insertion pain. However, studies on the effect of lidocaine gel have had conflicting results. In one of these, the effect of intracervical application of 2% lignocaine (lidocaine gel) on pain and discomfort perception on IUD insertion was studied, and showed some promising results.[14] Two other randomised controlled trials, however, concluded that intracervical lidocaine gel did not decrease IUD insertion pain.[15,16] Using a 1% lidocaine solution for paracervical anaesthesia similarly had no effect on pain.[17]

Because of its rapid absorption and distribution over a wide area, it may be expected that lidocaine in spray form would result in better anaesthesia. A study by Aksoy *et al.*[18] in Turkey reported a significant decrease in IUD insertion pain when using lidocaine 10% spray. We therefore hypothesised that 10% lidocaine spray (the only available concentration) would reduce IUD insertion pain in our study sample. The present study was performed to assess the analgesic impact of cervical lidocaine spray on IUD insertion pain.

Methods

The present randomised controlled trial used a parallel design on women who were referred for IUD insertion to the Reproductive Health Research Center in Urmia, Iran. Study participants were selected between March 2013 and September 2014. According to a sample size calculation, based on a 10% dropout rate, with a one-sided α of 1%, and 80% power, a total of 40 women in each trial group was needed. Parous women between 18 and 45 years of age were recruited from two selected urban public health facilities. The ethics committee of Urmia Islamic Azad University of Medical Sciences approved the study protocol (ref. no P/05124284/92). The women were firstly counselled for a broad spectrum of reproductive

health services, including family planning. Those willing to have an IUD (copper-bearing Tcu380A) inserted, and gave informed consent, participated in the trial. The exclusion criteria were women with a history of allergic reaction to lidocaine, those who were pregnant or had had a pregnancy within the last 6 weeks, women with a history of pelvic inflammatory disease, abnormal uterine anatomy, uterine size <6 cm or >9 cm, Wilson's disease, unexplained vaginal bleeding or cervical malignancy, and those who had received analgesics or narcotic agents during the past 24 hours. Before insertion of the IUD, baseline sociodemographic characteristics and reproductive and obstetric and gynaecological histories of the women were recorded on a data sheet.

A researcher who was not involved in the trial protocol prepared envelopes containing either A (intervention group) or B (control group) markers using a block randomisation scheme in a 1:1 ratio, in blocks of four. The participants were then randomly allocated to the intervention group (in which 10% lidocaine spray was applied to the ectocervix) or the control group (routine IUD insertion with no analgesia). Based on previous studies, the two most probable confounders for IUD insertion pain are parity and previous obstetric experience (women who have only had caesarean sections may be viewed as nulliparous with respect to IUD placement).[19] In order to control these confounders, subjects were stratified by type of delivery (normal vaginal delivery or caesarean only) in random blocks.

The IUDs were inserted by four midwives with advanced training in family planning and >5 years' experience in IUD insertion, according to a standard IUD insertion protocol. The intervention group received local anaesthetic using four puffs of 10% lidocaine (each puff containing 10 mg lidocaine) at the cervical area. There was a standardised 3-minute waiting period between the administration of the lidocaine spray and IUD insertion. Fig. 1 shows the flow of participants through the trial.

In the control group, the IUD was inserted without local anaesthetic (the routine IUD insertion procedure at the health centre). While the midwives were not blinded, data on pain severity were collected by a research assistant not involved in the procedure. A visual analogue scale (VAS) was used to record

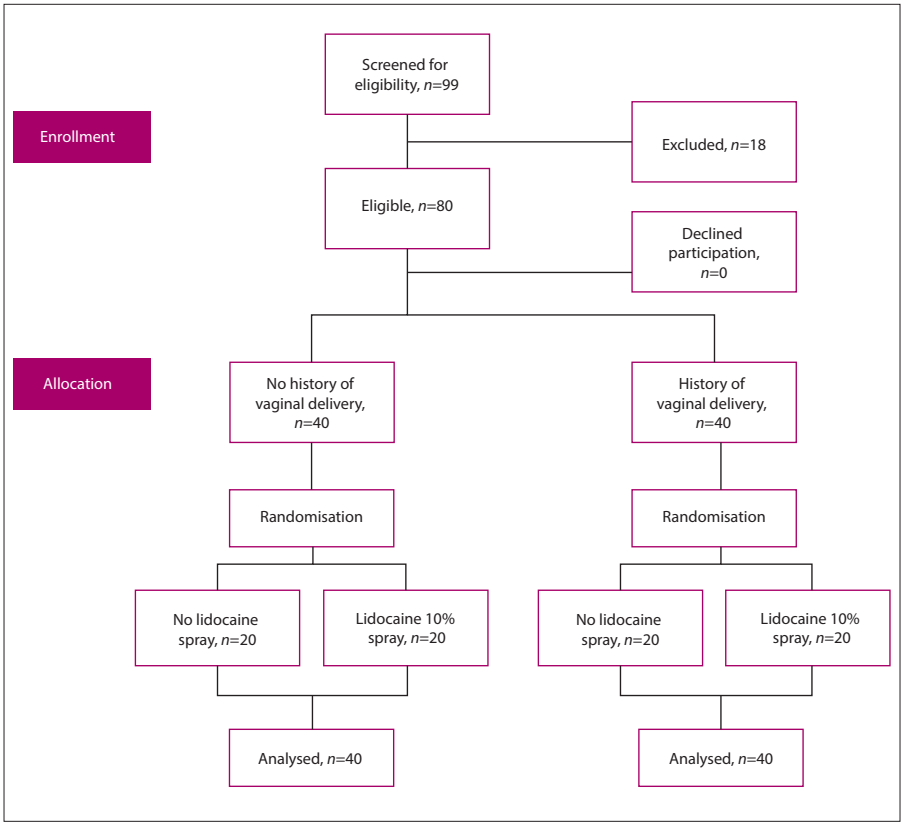

Fig.1. Consort diagram of flow of participants through the trial.

women's perceived pain at various points before, during and after the IUD insertion process. The scale was graded from 0 (no pain) to 10 (worst pain possible). Subjects rated their level of pain by making a mark on the VAS. Pain measurement was performed at baseline (when the woman's legs were positioned in stirrups), at three points during the procedure (tenaculum placement, uterine sounding and IUD insertion) and 15 minutes after the procedure.

Data were analysed using Statistical Package for Social Sciences 20.0 (SPSS Inc., USA). To evaluate differences between the two groups, Fisher's exact test and the independent sample *t*-test were used for categorical and normally distributed continuous variables, respectively. Statistical significance was set at $p \leq 0.05$. Repeated analysis of variance (ANOVA) measures were performed to identify intergroup differences in pain at baseline and during and after IUD insertion.

Results

We randomised a total sample of 80 women to receive Tcu380A IUDs either with or without 10% lidocaine spray as an intervention, at the Reproductive Health Research Center of Urmia University of Medical Sciences in Urmia, Iran. None of the approached women declined participation and all had successful IUD insertions. The mean ages of the participants in the control and intervention group were not statistically different [30.6 (6.8) v. 28.8 (7.5); $p=0.26$]. The majority (91.3%) of the participants did not have a high school diploma, and most were unemployed (95%). The mean (SD) body mass indexes (BMIs) of women in the control and intervention groups were very similar (27.3 (3.3) v. 27.0 (4.2); $p=0.68$). Randomisation was successful for most variables including age, education, BMI, occupation, gravidity, number of children living and abortion history. The two groups were also similar with regard to current breastfeeding status, history of previous IUD use and history of cryosurgery on the cervix (Table 1).

The IUD was inserted during the menstruation period in most cases, except for four women from the intervention group and six from the control group, owing to breastfeeding amenorrhoea. The most painful phase of IUD insertion in both groups was tenaculum placement. The mean (SD; range) score of pain at this stage was 4.25 (1.92; 1 - 8) in the control

Table 1. Distribution of study participants by selected demographic and reproductive characteristics (*N*=80)

Variable	Group		*p*-value
	Control (*n*=40)	Intervention (*n*=40)	
Age (years), mean (SD)	30.6 (6.8)	28.8 (7.5)	0.26
Education level, *n* (%)			
<12 grades completed	25 (62.5)	24 (60.0)	0.88*
12 grades completed	11 (27.5)	13 (32.5)	
University	4 (10.0)	3 (7.5)	
Occupation, *n* (%)			
Housewife	38 (95.0)	38 (95.0)	1.0*
Employed	2 (5.0)	2 (5.0)	
BMI, mean (SD)	27.3 (3.3)	27.0 (4.2)	0.68
Number of previous abortions, *n* (%)			
0	31 (77.5)	28 (70.0)	0.64*
1	7 (17.5)	8 (30.0)	
2	2 (5.0)	4 (10.0)	
Parity			
1	12 (30.0)	12 (30.0)	0.86
2	23 (57.5)	21 (52.5)	
3	5 (12.5)	7 (17.5)	
Number of previous deliveries, *n* (%)			
NVD, with or without CS			
0	20 (50.0)	20 (50.0)	0.92*
1	6 (15.0)	8 (20.0)	
2	11 (27.5)	9 (22.5)	
3	3 (7.5)	3 (7.5)	
Only CS			
0	18 (45.0)	16 (40.0)	0.73*
1	9 (22.5)	11 (27.5)	
2	12 (30.0)	10 (25.0)	
3	1 (2.5)	3 (7.5)	
Number of living children, *n* (%)			
1	11 (27.5)	13 (32.5)	0.87
2	23 (57.5)	21 (52.5)	
3	6 (15)	6 (15.0)	
Months since last pregnancy, mean (SD)	53.55 (41.22)	47.06 (37.32)	0.89
Months since last pregnancy, *n* (%)			
2	7 (17.5)	7 (17.5)	096*
3 - 6	7 (17.5)	6 (15.0)	
7 - 12	9 (22.5)	8 (20.0)	
13 - 24	3 (7.5)	5 (12.5)	
>25	14 (35)	14 (35)	
Currently lactating			
No	16 (40)	15 (37.5)	0.81*
Yes	24 (60)	25 (62.5)	
History of previous IUD use			
No	21 (52.5)	24 (60)	0.49*
Yes	19 (47.5)	16 (40)	
The last method of contraception			
Oral contraceptives	15 (37.5)	11 (27.5)	0.50*
Intrauterine device	4 (10)	7 (17.5)	
Natural	11 (27.5)	7 (17.5)	
Injection	1 (2.5)	2 (5)	
Condom	5 (12.5)	10 (25.0)	
Pregnancy	4 (10)	3 (7.5)	
Current menses, days			
No menstrual bleeding	6 (15)	4 (10)	0.62*
1	3 (7.5)	1 (2.5)	
2	14 (32)	12 (30)	
3	12 (30)	18 (45)	
>4	5 (12.5)	5 (12.5)	

*Fisher's exact test.
SD = standard deviation; BMI = body mass index; NVD = normal vaginal delivery; CS = caesarean section; IUD = intrauterine device.

group and 2.20 (1.96; 0 - 6) in the intervention group. During the hysterometer insertion, the mean (SD; range) scores for pain in the control and intervention groups were 3.45 (1.95; 0 - 8) and 1.92 (1.40; 0 - 5), respectively. During the IUD insertion, the mean (SD; range) pain score was 2.45 (2.10; 0 - 8) in the control and 1.30 (1.5; 0 - 5) in the intervention group ($p<0.001$).

There was also a significant difference in pain score at 15 minutes after IUD insertion between the control and intervention groups (1.70 (1.75) v. 0.87 (1.04); $p=0.03$). The intervention and control groups had no significant differences in background pain score (dysmenorrhoea) at IUD insertion time (0.55 (0.98) v. 0.47 (0.98); $p=0.38$) or anticipated pain before IUD insertion (5.02 (1.82) v. 4.35 (1.91); $p=0.6$).

The results of repeated measures of ANOVA suggested a significant difference in total scores of IUD insertion pain between the two groups ($p<0.001$; F=26.94). Systemic adverse effects of 10% lidocaine spray are very rare and are seen only at high doses (>20 puffs). As four puffs were used in the present study, no systemic adverse effects were observed (Table 2).

Discussion

The findings of the present study demonstrated that pain was felt in different phases of IUD insertion, including tenaculum placement and measurement of the uterine cavity with a hysterometer. Although pain during IUD insertion cannot be easily evaluated, as it is a subjective sensation and a combination of sensational, affective and cognitive elements, several studies on IUD insertion have reported pain of various levels, and noted that pain tolerance is also dependant on women's cultural background.[3,4]

The results showed tenaculum placement to be the most painful phase. While similar findings were reported by Seamark,[20] Maguire *et al.*[15] found hysterometer placement and uterine depth measurement to be the most painful phase. This inconsistency can be partly explained by differences in participant characteristics and time of IUD insertion between the two studies: while our participants had a history of previous delivery, and IUDs were inserted during the menstruation period, Maguire *et al.*[15] recruited nulliparous women, and inserted IUDs on non-menstrual days (a dilator was even used to open the cervical os in some cases). Since the internal os is believed to be softest and most open during menstrual days, inserting the hysterometer would be easier and less painful during this period.

In the present research, spraying the cervix with 10% lidocaine 3 minutes before IUD insertion was found to decrease pain in all phases of the procedure. There were, in fact, significant differences in pain intensity during tenaculum placement, hysterometer insertion and IUD insertion between the intervention and control groups. The difference remained significant at 15 minutes after IUD insertion. The mean (SD) pain intensity during the most painful stage (tenaculum insertion) was 2.20 (1.96) in the lidocaine spray group and 4.25 (1.92) in the control group. Aksoy *et al.*[18] reported a mean (SD) pain intensity of 1.01 (1.20) in the lidocaine spray group and 3.23 (1.60) in the placebo group. The difference between their study and ours can be attributed to the fact that all their subjects had a history of vaginal delivery, in contrast with the present study. Furthermore, they measured pain at only one stage, immediately after inserting the IUD. By contrast, half of our subjects had no history of vaginal delivery but only of caesarean section, and we assessed the intensity of pain in several stages, including immediately after inserting the IUD. Despite these differences, our finding of a significant decrease in pain intensity during IUD insertion using lidocaine 10% spray concurs with that of Aksoy *et al.*[18]

Although only one previous study confirmed the efficacy of lidocaine spray in decreasing IUD insertion pain, 10% lidocaine spray has been shown to be effective in reducing hysterosalpingography pain,[21] hysteroscopy pain[22] and first-trimester abortion pain.[23]

Vanichtantikul and Charoenkwan[24] recommend lidocaine spraying as a practical and effective method to decrease pain during the loop electrosurgical excision procedure. In a clinical trial, Olad-Saheb-Madarek *et al.*[25] concluded that the use of lidocaine solution in the uterus was effective in reducing endometrial biopsy pain; however, combining this method with 10% lidocaine spray to the cervix did not have any additional effects on pain reduction. It seems that different neural pain transmission pathways might be responsible in the cervix v. the uterus: while nerve impulses in the uterine body are transmitted through the 11th and 12th thoracic nerves, the pudendal nerve (derived from anterior roots of the 2nd to 4th sacral nerves) carries sensations from the cervix.[26,27]

Various methods to decrease IUD insertion pain have been tested. Some methods, such as NSAIDs and cervix-softener drugs, including misoprostol, have not been effective in decreasing IUD insertion pain.[9,12,28] Local anaesthesia has also been administered, for example by Maguire *et al.*[15] Mohammad-Alizadeh-Charandabi *et al.*[29] and McNicholas *et al.*[16] applied lidocaine gel to the cervix before IUD insertion and found the method to be ineffective in decreasing IUD insertion pain. Mody *et al.*[31] used paracervical anaesthesia to decrease IUD insertion pain, but although this invasive method did decrease the insertion pain, it was found to be painful itself. In addition, with this method the injectable substance may be absorbed into the circulation, and in lower doses may be accompanied by side-effects such as flushing, tachycardia and dysphoria.[30]

The strength of the present study, in comparison with the similar study by Aksoy *et al.*,[18] was in the measurement of pain and the

Table 2. Patient pain perception at IUD insertion (0 - 10 point scale)

Variable	Control group, mean (SD)	Intervention group, mean (SD)	*p*-value*
Background pain (dysmenorrhoea)	0.47 (0.98)	0.55 (0.81)	0.38*
Anticipated pain	4.35 (1.91)	5.02 (1.82)	0.06*
Tenaculum placement	4.25 (1.92)	2.20 (1.34)	<0.001*
Hysterometer placement (uterine sounding)	3.45 (1.95)	1.92 (1.40)	<0.001*
Intrauterine device insertion	2.95 (2.10)	1.30 (1.50)	<0.001*
Pain after 15 minutes	1.70 (1.74)	0.87 (1.04)	0.03*
ANOVA measures (repeated)	-	-	<0.001

*Mann-Whitney U test.
ANOVA = analysis of variance.

assessment of the effect of lidocaine spray at several stages of the procedure. However, a limitation was the allocation of participants to intervention (receiving lidocaine spray) and control (routine IUD insertion) groups; perhaps it would have been more reliable to have a third group receiving a placebo instead of lidocaine spray, which should be considered in future studies.

Using lidocaine spray for anaesthesia is non-invasive, cheap, easy and accessible for all medical centres. Despite the benefits observed in the current study, further surveys in different centres and populations should be performed before recommending the application of this method as a part of routine care before IUD insertion in all centres.

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