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Comparison of Lidocaine 1% and Normal Saline in Paracervical Anesthesia for Decreasing of Pain in Curettage

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Abstract: The objective of this study was to compare the efficiency of lidocaine with that of plain saline for paracervical pain relief during fractional curettage. The double-blind randomized clinical trial was performed on 150 patients presenting from 2004 to 2005 for curettage. The patients were assigned randomly in two groups to receive lidocaine 1% or normal saline. Number of patients at each group was 75 women. The pain intensity was assessed in four stages: 1) after speculum insertion, 2) during cervical dilatation, 3) during curettage and 4) 30 min after curettage completion. The pain intensity was graded as 0 to 100 according to the Likert Scale. The Mean±SD of pain intensity after speculum insertion, during dilatation, during curettage and 30 min after curettage in lidocaine group were 11.33±9.70, 24.93±15.36, 37.00±17.35, 6.47±6.42 and in normal saline group were 11.73±9.81, 28.20±13.19, 49.47±21.55 and 7.33±6.22, respectively. There was no significant difference between pain intensity after speculum insertion, during dilatation and during 30 min after curettage but there was a significant difference in pain intensity during curettage between lidocaine 1% group and normal saline group ($p<0.05$). Normal saline is as effective as lidocaine 1% in low pain in curettage (distention of nerve capsule) but when increase pain in curettage (third time point), lidocaine 1% is more effective than normal saline. Nerve capsule distention is not the only factor for pain control in paracervical block and analgesic agent is still an important factor.

Key words: Local anesthesia, paracervical block, lidocaine, normal saline, curettage

INTRODUCTION

The use of sharp curette has been described as being associated with pain in patients undergoing dilation and curettage. local anesthesia, less costly and with a lower risk of complications than general anesthesia, is feasible for pain control, especially if administered 2-5 min before the abortion procedure begins (Gómez *et al*., 2004; Phittayawechwiwat *et al*., 2007; Donati *et al*., 1996; Edelman *et al*., 2006; Api *et al*., 2009; Guney *et al*., 2007). The paracervical block has been used for minor gynecologic procedures since 1925. Although, use of general anesthetics provides analgesia, amnesia and a hypnotic effect, it carries a higher mortality risk than properly administered local anesthetics. Lidocaine, the amide-type agent, is used widely for local anesthesia. It has a rapid onset of action and is inexpensive. Although, lidocaine is a safe local anesthetic, an overdose carries an appreciable risk of toxic effects, particularly to the cardiovascular system and the central nervous system (Chanrachakul *et al*., 2001).

There was an idea that normal saline solution could be considered for the paracervical injection solution. The explanation for this was the local anesthetic mechanism may be from distension of nerve capsules rather than blockage of specific autonomic nerves (Titapant *et al*., 2003). Earlier observations during pain studies demonstrated that plain saline, used as a placebo, had a significant analgesic effect and some studies suggested a level of pain relief similar tothat achieved with lidocaine (Chanrachakul *et al*., 2001; Miller *et al*., 1996; Ader *et al*., 1990). The objective of this study was to compare the efficiency of lidocaine with that of plain saline for paracervical pain relief during fractional curettage.

MATERIALS AND METHODS

To comparison of lidocaine and normal saline for cervical anesthesia, the double-blind randomized clinical trial was performed on 150 patients presenting to Bandar-Abbass Sharyati Hospital from 2004 to 2005 for curettage. The age range of studied patients was 13 to

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43 years. The inclusion criteria were uterine size lesser than 14 weeks, patients who didn't have molar pregnancy, missed abortion, underlying painful condition and negative past history of allergic reactive to Ibuprofen. The exclusion criteria were allergic reaction to lidocaine, uterine perforation and severe bleeding during curettage. Variables including age, number of pregnancies, history of curettage, academic achievement and patients' anxiety were collected and recorded. Subjects gave written informed consent. All patients received 400 mg oral Ibuprofen 30 min before curettage. Then, the patients were assigned randomly in two groups to receive lidocaine 1% or normal saline. Number of patients at each group was 75 women. Twenty milliliter syringes were made up at the beginning of each session and were labeled with stickers preprinted with computer-generated random numbers. The appearance of the syringes, as well as that of the solutions, was identical in each group. The syringes were placed in the operative set and the stickers were removed before the procedure so that the gynecologist performing the operation and assisting nurses were blinded to the type of solution used. The patients were treated according to the departmental routine. The random-number key was not broken until data analysis. After patient preparation and under sterile condition, the physician injected 4 mL of the content of syringe with 23-gauge spinal needle in posterior or anterior part of cervix submucosa; this followed by 16 mL injections at 3 and 9 o'clock of cervicovaginal reflection. Total drug injected for each patient was 20 mL. The injections were made in depth of 1 cm.

Intermittent aspiration was performed before and during injection to ensure that paracervical blood vessels were not punctured. All injections were made by one gynecologist. Oxygen and vasopressors were always available. The standard procedure for fractional curettage was performed after waiting 2 min for the onset of action of lidocaine.

The intensity of pain was graded as 0 to 100 according to the Likert Scale (0 indicates painlessness and 100 indicates maximum pain) (Eser *et al*., 2008). The pain intensity was assessed in four stages: 1) after speculum insertion, 2) during cervical dilatation, 3) during curettage and 4-30 min after curettage completion. If the pain was maximum at each stage, we injected 50 mg of fentanyl. Also, those requiring general anesthesia because of pain intensity, were considered as maximum pain and excluded.

SPSS-13 statistical software and Microsoft Office Excel 2003 were used for statistical analysis of collected data. Categorical (qualitative) variables were sorted in Contingency Tables and compared by Chi-square Test or Fishers Exact Test. Quantitative variables were assessed by Student t-test and One-way ANOVA. Results were considered to be statistically significant if there was ($p = 0.05$).

RESULTS

This study was performed on 150 patients as 75 patients in two groups. The patients in Normal Saline group had the age of 15 to 43 years with the mean age of 26.15±6.14 years. These figures for patients in lidocaine 1% group were 13 to 43 and 27.13±6.75 years, respectively. The difference between two groups was not significant.

Other demographic and clinical characteristics of patients in two groups are compared in Table 1.

As showed in Table 1, the difference of education level, history of labor and curettage and anxiety level was not significant between two groups. The pain severities in two groups at four stages have been compared on Table 2.

Variance analysis showed that the difference of pain intensity between two groups after speculum insertion, during cervical dilatation and 30 min after curettage was not significant ($p>0.05$) but it was significant During curettage ($p<0.05$).

Estimated gestational age, fentanyl used and need for general anesthesia did not differ significantly between the two groups (Table 3). A dilator was used in 91% of patients but the size of dilator used and difficulty of procedure was not documented. An observation was that most injections had blanching of the mucosa and some pain was commonly reported by the patient from the injections, even using distraction techniques (e.g., 8% coughing) when the needle was placed.

Table 1: Demographic and clinical characteristics of patients in two groups

	Groups		
Characteristics	Normal saline	Lidocain 1%	p-value
Education			
No education	16(21.03)	19(25.3)	>0.05
Sub diploma	53(70.7)	49(65.3)	>0.05
Diploma and higher	6(8)	7(9.33)	>0.05
History of labor			
Yes	56(74.7)	54(72)	>0.05
History of curettage			
Yes	19(25.3)	18(24)	>0.05
Anxiety level			
Mild	37(49.3)	30(40)	>0.05
Moderate	23(30.7)	25(33.3)	>0.05
Severe	15(20)	20(26.7)	>0.05

Values in brakets are in percentage

Table 2: The comparison of pain intensity in two groups at four stages

Groups	After speculum insertion	During cervical dilatation	During curettage	30 min after curettage
Lidocain 1%	11.33±9.70	24.93±15.36	37.00±17.35	6.47±6.24
Normal saline	11.73±9.81	28.20±13.19	49.47±21.55	7.33±6.22

Table 3: procedure characteristics

	Groups		
Characterristics	Normal saline	Lidocain 1%	p-value
History of NVD			
Yes	23(30.66)	25(33.33)	>0.05
History of D and C			
Yes	11(14.66)	8(10.66)	>0.05
Estimated Gestational age			
<8 week	60(45)		>0.05
8-12 week	30(40)	28(37.3)	>0.05
Need for additional drug (fentanyl)			
Yes	17(22.6)	14(18.66)	>0.05
Need for general anesthesia			
Yes	14(18.66)	9(12)	>0.05
Duration of operation			
<10 min	30(40)	34(45.3)	>0.05
≥10 min	41(54.6)	45(60)	>0.05

Values in brackets are in percentage

We did not have any side effect. Fourteen (18.66%) women requested addition drug (fentanyl) after they felt the dilation to be painful in lidocaine 1% group and 17 (22.6%) women in normal saline group. The difference between two groups was not significant (Table 3).

In lidocaine 1% group, the relation of pain intensity with uterus size, education level and duration of curettage at four stages was not significant ($p>0.05$), but the relation of pain intensity with history of curettage and history of vaginal birth was significant ($p<0.05$). In normal saline group, the relation of pain intensity with uterus size and education level at four stages was not significant ($p>0.05$), but the relation of pain intensity with history of curettage, history of vaginal birth and duration of curettage was significant ($p<0.05$).

DISCUSSION

The various procedures used during fractional curettage such as placement of the tenaculum, traction of the cervixand dilation of the cervical os, as well as curettage itself can cause discomfort. Pain sensation transmits by sensory and sympathetic pathways from the posterolateral aspect of the cervix to the lateral spinothalamic tracts of the spina l cord (Chanrachakul *et al*., 2001; Güney *et al*., 2006). Paracervical anesthetics block transmission of pain through sympathetic and parasympathetic sensory fibers before these fibers enter the uterus at the level of the internal cervical os (Chanrachakul *et al*., 2001). Paracervical block is a convenient, safe, simple and effective anesthetic technique for curettage (Chanrachakul *et al*., 2001; Miller *et al*., 1996; Rattanachaiyanont *et al*., 2005) and first-trimester abortions (Wong *et al*., 2002; Edelman *et al*., 2004). Lidocaine is used widely because of its effectiveness and rapid onset of action. It blocks the movement of sodium across the nerve membrane by binding to a specific receptor located at the internal opening of sodium channels.

Lidocaine can be associated with adverse effects that range from mild toxicity such as numbness around the mouth and dizziness to convulsion and respiratory arrest (Chanrachakul *et al*., 2001; Miller *et al*., 1996; Rattanachaiyanont *et al*., 2005). Grimes and Cates reported five deaths from use of lidocaine to induce paracervical anesthesia (Chanrachakul *et al*., 2001). In this study, we did not see any adverse effect for lidocaine. It probably was due the fact that our injections were not deeper than 1 cm. This study showed that the difference of pain intensity between two groups when the speculum was inserted, during cervical dilatation and 30 min after curettage was not significant but it was significant during curettage. So, lidocaine is more effective during curettage.

Fourteen women (18%) in normal saline group and 9 women (12%) in lidocaine group dropped out (requested general anesthesia) and 17 women (22%) in normal saline group and 14 women (18%) in lidocaine group requested fentanyl; so, in comparison with Miller *et al*. (1996) and Chanrachakul *et al*. (2001) studies, these differences were not significant. There was an idea that normal saline solution could be considered for the paracervical injection solution. The explanation for this was the local anesthetic mechanism may be from distension of nerve capsules rather than blockage of specific autonomic nerves. However, as concluded from the present study, lidocaine is more effective than normal saline during curettage.The nerve capsule distension is not the only factor for pain control in paracervical block. An analgesic agent is still an important factor (Titapant *et al*., 2003).

A study on 1,055 women to determine which factors predict pain perception in women undergoing first-trimester abortion under local anesthesia. Factors that were not found to be related to pain were the operating physician, maximal amount of cervical dilatation, size of the suction cannula, prior abortion and prior pelvic examination. Gestational age did not show a consistent relationship to pain. Longer procedures tended to have higher pain scores. Prior vaginal delivery was the most consistent predictor of decreased pain perception during first-trimester abortion (Borgatta and Nickinovich, 1997). Their findings are compatible with this study results. The majority of abortions are performed using a paracervical block (without general anaesthesia) and involve a significant amount of pain. If fentanyl was given with the lidocaine in the paracervical block, it potentially could improve pain control, while decreasing side effects (Wiebe *et al*., 2005). There was no drug side effect in this study, indicating the safeness of local anesthetic drugs in paracervical blocking. However, if the pain was maximum at each stage, we injected 50 mg of fentanyl.

Ng *et al.* (1999) studied 135 patients undergoing egg collection in their first IVF cycle were randomized to receive 10 mL of 1.5% lignocaine (group A) or normal saline (group B) in the paracervical block and no local injection (group C). All patients experienced similar pain scores for vaginal puncture but patients in group A experienced significantly less abdominal pain during egg collection, compared with those in group B and group C. When lignocaine was used, the abdominal pain scores were reduced by 38.9 and 51.4% compared with placebo and no local injection respectively (Ng *et al.*, 1999). Earlier studies have suggested that normal saline also has an analgesic effect (Chanrachakul *et al.*, 2001; Miller *et al.*, 1996). Chanrachakul *et al.* (2001) compared the efficiency of lidocaine with that of plain saline for paracervical pain relief during fractional curettage. The intensity of pain was significantly lower in the lidocaine group than in the plain saline group over the course of the procedure, especially during fractional curettage. There were no serious adverse effects in this study. They concluded that lidocaine is more effective than plain saline for paracervical pain relief during fractional curettage. The anesthetic mechanisms of lidocaine are mechanical distention of tissue and peripheral nerve block (Chanrachakul *et al.*, 2001).

The pain intensity between patients who received xylocaine and normal saline for paracervical block during fractional curettage in 70 patients. The study revealed that the pain occurring in patients in the normal saline group was more severe than those in the xylocaine group with statistically significant difference at the second time point (curettage on the endocervix) and third time point (curettage on the endometrial cavity). On the contrary, pain occurring in patients in the normal saline group and xylocaine group was not statistically significantly different at the first time point (when Allis tissue forceps was applied on the cervix) and the fourth time point (30 min after the procedure) (Titapant *et al.*, 2003).

Miller *et al.* (1996) conducted a clinical trial on 52 women presenting for pregnancy termination procedures. Participants received paracervical submucosal injections of bacteriostatic saline (saline containing 0.9% benzyl alcohol) or lidocaine 1% just before cervical dilation. They compared lidocaine and bacteriostatic saline containing 0.9% benzyl alcohol. Benzyl alcohol is an active anesthetic agent that has been used as a local anesthetic. It is unclear whether an analgesic effect from bacteriostatic saline was due to tissue distention causing disruption of neuronal impulses or to the effect of benzyl alcohol. They proposed that the local anesthetic mechanism might be due to distention rather than blockage of a specific nerve, because there was no waiting time after paracervical block to perform the procedure (Chanrachakul *et al.*, 2001). We used plain saline in this study to prevent the anesthetic effect of benzyl alcohol that might have influenced the findings of Miller *et al.* (1996) study. However, a few min pass before lidocaine begins to take effect (Chanrachakul *et al.*, 2001). We had 2 min waiting time for onset of lidocaine action before performing curettage. The analgesic effect of plain saline was due to mechanical pressure on the nerve to stimulate the fast-conducting A fibers producing pain inhibition, the same principle found in acupuncture and transcutaneous electrical nerve stimulation (Chanrachakul *et al.*, 2001). However, mechanical pressure on the nerve is not the only factor for pain relief and analgesic effect of lidocaine is still an important factor especially during the more painful phases.

Cetin designed, a study on 66 women undergoing legal abortion to investigate whether deep injections of local anesthetics provide better pain control than regular injections of local anesthetics. The mean pain score during 1) cervical dilatation and 2) curettage was less for the deep injection versus the regular injection group (Cetin and Cetin, 1997). In conclusion, deep injection of local anesthetics is a safe adjunct in the management of abortion. However, because of the risk of drug entrance in blood vessels and toxicity (Lau *et al.*, 1999), the regular injection was preferred.

Further studies should be conducted to evaluate the benefit of a waiting period. We did not evaluate the pain of injection and future studies should assess the pain with injections.

CONCLUSION

Although, normal saline is not local anesthetic but it is as effectives as lidocaine 1% in low pain in curettage (distention of nerve capsule) but when increase pain in curettage (third time point), lidocaine 1% is more effective than normal saline. This study show that nerve capsule distention is not the only factor for pain control in paracervical block and analgesic agent is still an important factor.

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