Double-Blind Randomized Comparison of Xylocaine and Saline in Paracervical Block for Diagnostic Fractional Curettage

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Abstract

Comparative study of the level of the reported pain between patients who received xylocaine and normal saline for paracervical block during fractional curettage was carried out in 70 patients in a double blind randomized controlled trial.

One group of patients received xylocaine for paracervical block just before the procedure was performed while the other group received normal saline in the same manner. Self-reported pain intensity using visual analog scale was assessed at four time points including the first time point when Allis tissue forceps was applied on the cervix, the second and third time points when curettage was done on the endocervix and in the endometrial cavity respectively. The last time point was evaluated at 30 minutes after the procedure.

The results of the study revealed 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 (visual analog scale 4.80 $\pm$ 2.7 in the normal saline group compared to 3.20 $\pm$ 2.4 in the xylocaine group, $p < 0.05$) and third time point (visual analog scale 8.17 $\pm$ 2.0 in the normal saline group compared to 4.94 $\pm$ 3.1 in the xylocaine group, $p < 0.05$). 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 (visual analog scale 3.62 $\pm$ 2.7 in the normal saline group compared to 3.97 $\pm$ 2.8 in the xylocaine group, $p > 0.05$) and the fourth time point (visual analog scale 1.34 $\pm$ 2.0 in the normal saline group compared to 1.57 $\pm$ 2.6 in the xylocaine group, $p > 0.05$).

Before this study, 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, this study showed that nerve capsule distension is not the only factor for pain control in paracervical block. An analgesic agent is still an important factor.

Key word : Fractional Curettage, Paracervical Block, Xylocaine

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Abnormal vaginal bleeding is the important sign which leads most patients to see a physician. Many gynecologic pathologies including pathologies of cervix and uterine cavity can present as abnormal vaginal bleeding. History taking and physical examination alone in some patients are not enough to diagnose and fractional curettage may be needed for accurate diagnosis. Two current ways for relieving pain occuring during the procedure are general and local anesthesia. Admission for preparation of patients is needed in the former method while out-patient care is enough for the latter method and the patients can go back home after operation with xylocaine usage has been performed.

The advantages of local anesthesia include non-admission of the patient, low cost and early recovery of the patients. According to the high number of patients at Siriraj Hospital and the limited number of in-patient beds, out-patient care is usually performed in most cases. However, toxicity of xylocaine has been reported including allergy, convulsion, and even death from xylocaine toxicity caused by accidental intravenous injection(1).

Many efforts to study other agents replacing xylocaine in paracervical block have been successfully proceeded(2-6). Miller et al (1996)(7) found that cervical anesthesia by xylocaine and normal saline did not make any difference. They believed that pain control from local anesthesia is the result of distention of the nerve capsules rather than the blockage effect of specific autonomic nerve. Therefore, normal saline can be used instead of xylocaine in order to reduce the risk of all mentioned complications. Moreover, the low cost of normal saline, its safety and convenience are the advantages of this solution.

The aims of this study were to compare xylocaine and normal saline for paracervical block to blunt the reported pain during fractional curettage and also to compare the occuring complications between the use of these two agents.

MATERIAL AND METHOD

Seventy patients with unknown causes of abnormal vaginal bleeding from June 1998 to February 1999 were transferred to the minor operation room of the Department of Obstetrics & Gynecology, Siriraj Hospital for diagnostic fractional curettage. All patients were healthy, except for their bleeding, and had no illness i.e. diabetes mellitus, hypertension. The patients who had any kind of abnormal coagulation, and history of chronic pelvic pain were excluded from this study. The method, advantage and complication of the study had been clearly described to the patients. The consent form was signed if the patient wanted to participate in the study. The history of each patient had been collected in the data-based form.

All patients were randomly allocated to two groups. Thirty-five patients in the experimental group received 1 per cent xylocaine injection for paracervical block while the control group consisted of thirty-five patients who received a corresponding normal saline of identical appearance and quantity. Fractional curettages were performed by the same physician in both groups and pain was evaluated by visual analog scale which would be self-reported by the patients during the procedure at the different time points during the performing procedure.

The definition of pain were described to the patients as follows : pain from the curettage means pain that occurred during diagnostic fractional curettage which would be evaluated at four time points. The first time point was evaluated when the Allis tissue forceps were applied on the cervix. The second and third were evaluated when the curettage was done on the endocervix and in the endometrial cavity respectively. The last time point was evaluated 30 minutes following completion of the procedure.

Statistics

For comparison of the patients' initial characteristics between the two groups (numerical values), the student *t* -test was used. For comparison of the result of the two treatment groups, the chi-square test was used.

RESULTS

Patient characteristics

The initial characteristics of the patients in both groups are shown in Table 1. There were no significant differences between the two groups regarding age, income, occupation, education, number of gravida, number of parity and number of previous abortions.

Uterine characterization

The position of the uterus in the control group and experimental group were found to have no significant difference. Depth of uterine cavities in

Table 1. Patients' characteristics.

Characteristics	Control group	%	Experimental group	%	P-value
Age	42.9 ± 10.4		41.6 ± 10.6		0.611
Income (baht)					0.524
< 1,000	26	74.3	31	88.6	
1,000-5,000	6	17.1	4	11.4	
5,000-10,000	2	5.7	0		
> 10,000	1	2.9	0		
Occupation					0.378
Housewife	11	31.4	6	17.1	
Laborer	12	34.3	12	34.3	
Government officer	6	17.1	7	20.0	
Merchant	5	14.3	5	14.3	
Farmer	1	2.9	5	14.3	
Education					0.462
None	4	11.4	1	2.9	
Primary school	14	40.0	18	51.4	
Secondary school	11	31.4	9	25.7	
University	6	17.1	7	20.0	
Number of gravida					0.278
None	3	8.6	1	2.9	
1-2	14	40.0	20	57.1	
> 3	18	51.4	14	40.0	
Number of parity					0.088
None	5	14.3	2	5.7	
1-2	14	40.0	23	65.7	
> 3	16	45.7	10	28.6	
Number of abortions					0.613
None	22	62.8	25	71.4	
1	10	28.6	8	22.9	
≥ 2	3	8.6	2	5.7	

the control group seemed to be greater than those in the experimental group. However, there was also no statistically significant difference.

Details of the uterine characterizations are shown in Table 2.

No added analgesic drug was required in both groups of patients.

Pain levels

At the second time point (curettage on the endocervix) and the third time point (curettage inside the uterine cavity), the pain levels were found to have the statistically significant higher in experimental group as compared to the control group. On the contrary, at the first time point (Allis forceps applied at the cervix) and the fourth time point (after fractional curettage), the pain levels in both experimental groups and control groups were not found to have statistically significant difference.

Details of the difference between pain levels at each time point are shown in Table 3.

In the present study, none of the patients had side effects from 1 per cent xylocaine and none requested another dose of analgesic drug.

DISCUSSION

Fractional curettage is one of many useful methods to diagnose the cause of abnormal uterine bleeding. The method of pain control must be appropriate and safe for out-patients. The method of pain therapy should be safe and have rapid onset of action, short duration, and no side effects. Paracervical block is one of various methods which is safe and recommended for pain control during curettage[8]. The advantage of using paracervical block over general anesthesia includes ambulatory anesthesia and low risk of pulmonary aspiration[9]. Local anesthetic, xylocaine, has moderate potency, rapid onset of action, (about 1-5 minutes)[10] and moderate duration.

In the present study, 1 per cent xylocaine without adrenaline was used. The duration of action was 1-3 hours[10]. Xylocaine was infiltrated around

Table 2. Uterine characterization.

Characterization	Control group	%	Experimental group	%	P-value
Position					0.274
Retro-flexion	24	68.6	28	80.0	
Ante-flexion	11	31.4	7	20.0	
Depth of uterine cavity					0.278
< 8 cm	30	85.7	34	97.1	
> 8 cm	5	14.3	1	2.9	

Table 3. Pain levels.

Timing	Control group	Experimental group	P-value
The 1st time point	3.97 ± 2.8	3.62 ± 2.7	0.616
The 2nd time point	3.20 ± 2.4	4.80 ± 2.7	0.013
The 3rd time point	4.94 ± 3.1	8.17 ± 2.0	0.000
The 4th time point	1.57 ± 2.6	1.34 ± 2.0	0.625

the uterine and pelvic plexus by paracervical block. Side effects and complications of paracervical block with xylocaine include allergy, overdose, and accidental intravenous injection(11). Prompt management should be performed if an adverse effect occurs. However, the total dose of xylocaine for paracervical block does not reach the toxic level in the circulation(12).

From the present study, both control and experimental groups had similar characteristics without significant difference. The results of the present study should not have any intentional bias.

The occurrence of pain during the first time point was not different between the experimental group and control group. This finding is justified since this was pain occuring before the paracervical block was performed. At the fourth time point, there was also no difference in pain from fractional curettage between the two groups. It may be explained that pain caused by fractional curettage occurs for only a short period and is not severe. Perhaps, 30 minutes to evaluate the pain at the fourth time point may be too long.

At the second and third time points, pain levels in the experimental groups were significantly higher than in the control groups. This finding clearly showed that normal saline can not relieve pain as xylocaine does. Therefore, not only does nerve capsule distention relieve pain but also the efficacy of local anesthetic. Even though some studies found no significant difference in pain control between the use of normal saline and xylocaine, the present study did.

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การระงับความปวดสำหรับการขูดมดลูกแบบแยกส่วนโดยวิธี paracervical block

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ศึกษาเปรียบเทียบระดับความปวดในการขูดมดลูกแบบแยกส่วนในผู้ป่วยที่ได้รับการฉีดยาที่ด้านข้างของปากมดลูกด้วยยาซาไซโลเคนและน้ำเกลือนอร์มัลจำนวน 70 ราย ด้วยวิธีสุ่มอำพรางสองฝ่าย โดยแบ่งผู้ป่วยออกเป็น 2 กลุ่ม กลุ่มแรกจำนวน 35 ราย ได้รับการฉีดยาซาไซโลเคนที่ด้านข้างของปากมดลูกในขณะที่ผู้ป่วยอีกกลุ่มหนึ่ง จำนวน 35 รายได้รับการฉีดน้ำเกลือนอร์มัลที่ปากมดลูกในลักษณะเดียวกัน จากนั้นทำการขูดมดลูกโดยแพทย์คนเดียวกันในผู้ป่วยทั้ง 2 กลุ่ม โดยที่แพทย์ไม่ทราบว่าสารน้ำที่ใช้ฉีดระงับความรู้สึกเป็นยาซาไซโลเคนหรือน้ำเกลือนอร์มัล

ทำการประเมินผลความปวดที่ 4 ช่วงเวลา คือ เมื่อเริ่มทำการจับปากมดลูก,ขณะทำการขูดด้านในปากมดลูก, ขณะทำการขูดในโพรงมดลูก และภายหลังทำการขูดมดลูกแล้ว 30 นาที โดยให้ผู้ป่วยเป็นผู้ประเมินเองโดยใช้วิชัวว์แอนนาล็อค-สเกลล์

จากการศึกษาพบว่าอาการปวดของผู้ป่วยเมื่อเริ่มทำการจับปากมดลูกและภายหลังทำการขูดมดลูกแล้ว 30 นาที ไม่แตกต่างกันในทั้ง 2 กลุ่ม แต่อาการปวดขณะทำการขูดด้านในปากมดลูกและขณะทำการขูดในโพรงมดลูกแตกต่างกัน โดยพบว่ากลุ่มที่ได้รับการฉีดน้ำเกลือนอร์มัลที่ปากมดลูกมีอาการปวดมากกว่ากลุ่มที่ได้รับการฉีดยาซาไซโลเคนอย่างมีนัยสำคัญทางสถิติ

ก่อนการศึกษานี้มีรายงานว่าสามารถใช้น้ำเกลือนอร์มัลเพื่อระงับปวดขณะขูดมดลูกได้โดยอาศัยกลไกของการใช้น้ำเกลือนอร์มัลขยายเปลือกที่หุ้มเส้นประสาทแทนที่จะเป็นฤทธิ์ของยาซา อย่างไรก็ตามการศึกษานี้ไม่สนับสนุนความเชื่อดังกล่าว

คำสำคัญ : การขูดมดลูกแบบแยกส่วน, การระงับความรู้สึกที่ปากมดลูก, ยาซาไซโลเคน

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