Original Article

The effect of preemptive pudendal nerve block on pain after anterior and posterior vaginal repair

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Abstract

Introduction: Anterior and posterior vaginal repair (APR) is a common surgery for women with prolapse of pelvic organs which creates post-operative pain because of damage of tissues that we should manage and control this pain. For this purpose, this study was conducted in order to evaluate the effect of preemptive pudendal nerve block on post-operative pain in anterior and posterior vaginal wall repair.

Materials and Methods: In a double-blinded clinical trial study, 60 women candidates of APR were randomly divided to two groups. In both of them was injected 0.3 cc/kg bupivacaine 0.25% for the intervention group or normal saline for the control group in pudendal nerve tract with the guide of nerve stimulator. A visual analog scale was used to measure pain during the first 48 h after the surgery. Data were analyzed by repeated measures analysis of variance (ANOVA).

Results: Compared with the intervention group, the control group experienced greater pain during rest and walking. There were significant differences between the two groups from the first post-operative hour ($P = 0.003$) until 48 h after the operation ($P = 0.021$). Furthermore, the mean ± SD values of pain in the sitting position was not significantly different between control and intervention groups at the same time ($P = 0.340$).

Conclusion: Preemptive pudendal nerve block can reduce post-operative pain score in anterior and posterior vaginal wall repair and this method was suggested in anterior and posterior vaginal wall repair.

Key Words: Anterior and posterior vaginal repair, pelvic organ prolapse, post-operative pain, pudendal nerve block

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INTRODUCTION

The surgery causes releasing of painful chemical mediators such as prostaglandin, histamine, bradykinin, serotonin, hydroxytryptophan and substance P. These mediators make pain impulses and transmit them to central nervous system by C and A delta neuron fibers. Body responses to pain are increasing of tonicity and spasm in skeletal muscles, rising of O_2 consumption and lactic acid production, rising of heart rate (HR) and cardiac output by stimulation of autonomic systems.[1,2]

Pelvic organ prolapse (pop) is a bulge or protrusion of pelvic organs and their associated vaginal segments into or through the vagina. Anterior and posterior vaginal repair (APR) is a surgical method

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that apply to treatment of patients with pelvic organs prolapse. Pop is a pelvic disorder that often need to surgery. Annually, approximately 200,000 American women undergo surgery due to pop.[3-5] 1.1% of women undergo surgery due to pop until 80 years.[5] The annual direct cost of treating pop, was estimated more than 1 billion dollars. With the aging population, this disorder has become a problem with increasing prevalence. It has been estimated that treatment of this disorder will increase until 45%, over the next 30 years, commensurate with the increase in the female population over 50 years old.[3-5]

Methods of treatment are non-surgical and surgical. Non-surgical treatment includes pelvic floor muscle training and usage of vaginal devices. The primary aims of surgery are to relieve symptoms, which may be caused by prolapse and in most cases, to restore vaginal anatomy so that sexual function may be maintained or improved without significant adverse effects. Approaches to surgery include vaginal surgery, laparotomy, laparoscopy routes or a combination of approaches.[3-5]

Post-operative pain managements are pain control (PC), narcotic, cryoanalgesia, non-steroidal anti-inflammatory drugs local anesthesia, glucocorticoids, preemptive pudendal nerve block. Post-operative pain has been treated with systemic analgesia and oral or intravenous (IV) opioids as well as epidural opioids and local anesthetics. Because of post-operative pain after APR is commonly localized to the perineum and discomfort may also originate from the sacrospinous ligament and pelvic floor, pudendal nerve block provides adequate and effective analgesia of the perineum.[1,2,6-13] Preemptive pudendal nerve block have some benefits safe and simple compared with other methods and without any systemic side-effects. A peripheral nerve stimulator, which is an excellent teaching method for regional anesthesia, helps the physition in this type of blockade due to location monitored by peripheral muscle contraction.[1,2] Complications are intravascular injection may cause severe systemic toxicity, there are risk of hematoma if patient has clotting disorder, infection at the injection site.[1,2]

Various studies on post-operative PC by preemptive analgesia, have conflicting results.[14-23] Someone have suggested that the effect of preemptive analgesia may vary and depends on the kind of surgery.[19] Because the so far studies on the effect of preemptive pudendal nerve block was not performed on women candidates for APR. This study was performed to determine the effect of preemptive pudendal nerve block on post-operative pain in APR and compare with the control group.

MATERIALS AND METHODS

This is a randomized, double-blinded, clinical trial study that conducted in Shahid Beheshti Hospital in Isfahan at during the period from October 2011 to August 2012. Sixteen women who were schooled to undergo APR under spinal anesthesia were invited to enroll in the study. Inclusion criteria included women candidate APR under spinal anesthesia, American Society of Anesthesiology physical status Class I and II and consent to participate in the study, no history of allergy to local anesthetic agents and narcotics, no history of clotting problems, no history of major psychological disorders, no history of chronic pain syndrome, lack of long-term use of painkillers, no recent use of opioids, lake of diabetes mellitus type 1 and 2. Exclusion criteria included need to change the type of anesthesia during surgery (due to prolongation of the operation or failure to block).

A sample size of 60 patients was calculated to be required with standard errors 0.05, a power of 0.95 and d = 1.2 based on previous relevant clinical data.

All included participants were asked to participate in the study by the study personnel soon after admission to the ward and a written consent was obtained from each women. 60 women candidates APR in Beheshti Hospital were divided into two groups randomly.

Both groups received the same pre-operative care and same anesthesia too (spinal). All subjects received antibiotic prophylaxis with cephasolin 2 g intravenously within an hour before surgery. In the operating room, standard monitoring was applied (the lead II electrocardiogram, pulse oximetry and non-invasive blood pressure monitor). During the 15 min preceeding the spinal block, subjects were administered 10 cc/kg ringer lactate solution via an 18-gauge IV cannula. Spinal anesthesia was performed in all patients at L_3-L_4 interspace with patients in the sitting position using a 25-gauge quincke needle. The block was done with 3 cc bupivacaine 0.25% in 10-15 s. After 5 min, patient was placed in lithotomy position and surgery was performed on all patients with the same technique by Gynecologist. Vital sign was controlled before spinal anesthesia and after that in 15 min interval to end of surgery. A solution was injected in the pudendal nerve passage way by nerve stimulator in both groups at the same period of anesthesia. The solution was included 0.3 cc/kg

bupivacaine 0.25% for the intervention group and 0.3 cc/kg normal saline for the control group.[2,21] Both groups received the same post-operative care and were monitored for up to 48 h. Each patient visit at 0, 1, 2, 4, 6, 12, 24 and 48 h after surgery and data were recorded. On arrival in recovery room, pain intensity was educated to patients by visual analogs scale (VAS) ranging from 0 (no pain) to 10 (worst pain imaginable). If analgesia was considered inadequate at any stage, the anesthesiologist could give additional IV bulous of morphine 0.08 mg/kg until VAS was <3. The frequency of nausea and vomiting evaluated at the same time and at the ongoing visited. Nausea and vomiting was managed with metoclopramide 0.15 mg/kg as necessary.

Data were analyzed by SPSS version 20. Analysis of variance (ANOVA) with repeated measures was used to compare the changes in VAS, systolic blood pressure (SBP), diastolic blood pressure (DBP), HR and respiratory rate (RR). Chi-square test was used to assess the relationship between qualitative variables such as frequency of nausea, consumption of metoclopramide and morphine. A value of $P < 0.05$ was considered statistically significant.

Table 1: Changes in DBP and SBP in both groups

Time (*P* value)		Time (*P* value)		Time (*P* value)
Pudendal group±SD	Control group±SD	Pudendal group±SD	Control group±SD	
0 min	0 min	0 min	0 min	0 min
15 min	15 min	15 min	15 min	15 min
30 min	30 min	30 min	30 min	30 min
60 min	60 min	60 min	60 min	60 min
2 h	2 h	2 h	2 h	2 h
4 h	4 h	4 h	4 h	4 h
6 h	6 h	6 h	6 h	6 h
12 h	12 h	12 h	12 h	12 h
24 h	24 h	24 h	24 h	24 h
48 h	48 h	48 h	48 h	48 h

SD: Standard deviation, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

RESULTS

In this study, 60 women candidates APR were selected and were divided into two groups randomly. Thirty patients were in the intervention group and 30 patients were in the control group. During the study, two patients were excluded due to prolonged surgical procedure (1 patient from each group). A solution was injected in the pudendal nerve passage way by nerve stimulator in both groups at the same period of anesthesia. The solution was included 0.3 cc/kg bupivacaine 0.25% for the intervention group and 0.3 cc/kg normal saline for the control group.

The mean age of the patients in the intervention and control groups, respectively, were 41.9 ± 7.1 and 41.6 ± 10 that there was no significant difference between the two groups according to *t*-test ($P = 0.92$).

Mean systolic and DBP in both groups of patients from 0 h to 48 h after surgery are shown in Table 1. According to this table, changes in systolic and DBP were equal in the intervention and control groups and there was no significant differences between two groups according to ANOVA with repeated measures ($P = 0.2$) and ($P = 0.15$).

Mean changes in HR and RR in both groups of patients from 0 h to 48 h after surgery are shown in Table 2. According to this table, changes in HR and RR were equal in the intervention and control groups and there was no significant differences between two groups according to ANOVA with repeated measures ($P = 0.47$) and ($P = 0.81$).

Mean changes in pain intensity at rest; sitting and walking in both groups of patients from 0 h to 48 h

Table 2: Changes in RR and RR in both groups

Time	RR		HR		RR		HR		Time
	Pudendal group±SD	Control group±SD	Pudendal group±SD	Control group±SD	Pudendal group±SD	Control group±SD	Pudendal group±SD	Control group±SD	
0 min	16±1.9	16±1.9	76±8	76.2±10.7	16±1.9	16±1.9	76±8	76.2±10.7	0 min
15 min	16±1.9	16.1±1.8	76.7±8	75.3±13.6	16±1.9	16.1±1.8	76.7±8	75.3±13.6	15 min
30 min	16±1.9	16.1±1.7	78.7±8.6	76.2±11.2	16±1.9	16.1±1.7	78.7±8.6	76.2±11.2	30 min
60 min	15.9±1.8	16±1.8	80.9±7.9	77.3±11	15.9±1.8	16±1.8	80.9±7.9	77.3±11	60 min
2 h	16.1±2.2	16.3±1.7	82.7±8.2	78.1±8.5	16.1±2.2	16.3±1.7	82.7±8.2	78.1±8.5	2 h
4 h	16.4±2.5	16.7±2	83.5±7	80.3±10.4	16.4±2.5	16.7±2	83.5±7	80.3±10.4	4 h
6 h	16.3±2.5	16.6±2.1	85.5±7.6	80.4±7.7	16.3±2.5	16.6±2.1	85.5±7.6	80.4±7.7	6 h
12 h	16.3±2.4	16.2±3	85.4±6.7	78.6±8.5	16.3±2.4	16.2±3	85.4±6.7	78.6±8.5	12 h
24 h	16.1±2.3	16.3±2.2	83.9±6.4	78.9±7.4	16.1±2.3	16.3±2.2	83.9±6.4	78.9±7.4	24 h
48 h	16.1±2.1	16.1±2	82.2±7.7	77.7±6.5	16.1±2.1	16.1±2	82.2±7.7	77.7±6.5	48 h
P value	0.81		0.47		0.81		0.47		*P* value

RR: Respiratory rate, HR: Heart rate, HR: Heart rate, RR: Respiratory rate, SD: Standard deviation

after surgery are shown in Table 3. According to this table, changes in pain intensity at rest in the control group were more than intervention group and this difference was significant according to ANOVA with repeated measures (P = 0. 003). Changes in pain intensity at sitting and walking were analyzed at 12, 24 and 48 h after surgery. According to ANOVA with repeated measures, there was no significant differences between two group at sitting position (P = 0.34) while the difference was significant at walking (P = 0.021).

The frequency distribution of incidence of nausea and consumption of metoclopramide and morphine has been shown in Table 4. According to this table, morphine consumption had significant difference between two groups at 4 and 12 h after surgery and it was higher in the control group. It had no significant difference between two groups at other times. There was no significant difference between two groups in the frequency distribution of incidence of nausea and thus metoclopramide consumption.

The incidence of complication was shown in Table 5. According to this table, there was no significant difference between the two groups in complication for 48 h post-operatively.

The mean of sedation score in patient at 0 up to 48 h after surgery in both groups has been shown in Table 6. According to this table, there was no significant differences in changes of sedation score between two groups (P = 0.41).

DISCUSSION

The general objective of this study was to determine the effect of preemptive pudendal nerve block on post-operative pain in APR and comparison with the control group.

According to results of this study, preemptive pudendal nerve block had no effect on unexpected changes in the intervention group. Vital variables (SBP, DBP, HR and RR) were not different in both groups at 0 up to 48 h after surgery. Therefore, this method can be used to APR. Post-operative pain was significantly lower in the intervention group than the control group. Morphine consumption in the intervention group was

Table 3: Changing in pain intensity in both groups

Time (*P* value)		Time (*P* value)		Time (*P* value)		Time (*P* value)
Pudendal group±SD (h)	Control group±SD (h)	Pudendal group±SD (h)	Control group±SD (h)	Pudendal group±SD (h)	Control group±SD (h)	
1	1	1	1	1	1	1
2	2	2	2	2	2	2
4	4	4	4	4	4	4
6	6	6	6	6	6	6
12	12	12	12	12	12	12
24	24	24	24	24	24	24
48	48	48	48	48	48	48

SD: Standard deviation

Table 4: The frequency distribution of incidence of nausea and consumption of metoclopramid and morphin in both groups

Time	Level	*P* value	Metoclopramid consumption and nausea incidence		*P* value	Morphin consumption	
			Pudendal group number (%)	Control group number (%)		Pudendal group number (%)	Control group number (%)
Hour 1	Yes	0.33	1 (3.4)	3 (10.3)	0.25	2 (6.9)	6 (20.7)
	No		28 (96.6)	26 (89.7)		27 (93.1)	23 (79.3)
Hour 2	Yes	0.49	0 (0)	2 (6.9)	0.99	6 (20.7)	7 (24.1)
	No		29 (100)	27 (93.1)		23 (79.3)	22 (75.9)
Hour 4	Yes	1	1 (3.4)	1 (3.4)	0.028	6 (20.7)	15 (51.7)
	No		28 (96.6)	28 (96.6)		23 (79.3)	14 (48.3)
Hour 6	Yes	1	0 (0)	0 (0)	0.79	16 (55.2)	14 (48.3)
	No		29 (100)	29 (100)		13 (44.8)	15 (51.7)
Hour 12	Yes	0.33	1 (3.4)	3 (10.3)	0.008	11 (37.9)	21 (72.4)
	No		28 (96.6)	26 (89.7)		18 (62.1)	8 (27.6)
Hour 24	Yes	0.49	0 (0)	2 (6.9)	0.24	6 (20.7)	10 (34.5)
	No		29 (100)	27 (93.1)		23 (79.3)	19 (65.5)
Hour 48	Yes	0.99	0 (0)	1 (3.4)	0.71	3 (10.3)	5 (17.2)
	No		29 (100)	28 (96.6)		26 (89.7)	24 (82.8)

Morphin in both groups

Table 5: The frequency distribution of incidence of complications in both groups

Time	Time	Time	Time	Time
1 h	1 h	1 h	1 h	1 h
	29 (100)	27 (93.1)	No	
2 h	2 h	2 h	2 h	2 h
	29 (100)	28 (96.6)	No	
4 h	4 h	4 h	4 h	4 h
	29 (100)	28 (96.6)	No	
6 h	6 h	6 h	6 h	6 h
	29 (100)	29 (100)	No	
12 h	12 h	12 h	12 h	12 h
	29 (100)	26 (89.7)	No	
24 h	24 h	24 h	24 h	24 h
	28 (96.6)	27 (93.1)	No	
48 h	48 h	48 h	48 h	48 h
	29 (100)	29 (100)	No	

Table 6: changes of sedation score in two groups

Time (*P* value)	Time	Time (*P* value)
0 min	0 min	0 min
15 min	15 min	15 min
30 min	30 min	30 min
60 min	60 min	60 min
2 h	2 h	2 h
4 h	4 h	4 h
6 h	6 h	6 h
12 h	12 h	12 h
24 h	24 h	24 h
48 h	48 h	48 h

less than the control group at all mentioned times. However, this different was significant at 4 and 12 h after surgery according to statistical tests and there were no significant differencesbetween two groups at other times.

In another study, in 2003, in a randomized, double-blind clinical trial study, O'Neal *et al*. were injected 20 mL bupivacaine 0.5% or 20 mL normal saline paracervical into intervention and control groups and obtained results similar to our results. They found that post-operative pain in the intervention group was less than the control group.[20] In 2005, in a randomized, double blind clinical trial study, Abramov *et al*. have studied the effect of preemptive pudendal nerve block on post-operative pain on 102 women candidate trans vaginal pelvic repair under spinal anesthesia. They were injected 10 mL bupivacaine 0.25% or normal saline in each side of pudendal nerve passageway and found that there were no significant differences between two groups in PC and narcotic consumption.[21] In 2008, in a randomized, double-blind study, Aissaoui *et al*. were found that preemptive pudendal nerve block can decrease post-operative pain at rest and during activity and need for additional analgesics. They were injected 15 mL ropivacaine 7.5 mg/mL or normal saline after repair of episiotomy in 40 women. Their result was similar to our results.[22] In 2009, in a randomized, double-blind clinical trial study, Long *et al*. were injected 20 mL bupivacaine 0.5% into 45 women of the intervention group from 90 women candidate vaginal hysterectomy under general anesthesia and found that post-operative pain and use of additional narcotic in the intervention group were less than the control group.[23] Ismail *et al*.[24] found that preemptive analgesia by bilateral nerve stimulator with 10 ml of 0.25% bupivacaine, reduce post-operative pain and shorten the time to return to normal activity.

Although the fewer patients in the intervention group were nausea and received metoclopramide, there was no significant difference between two groups in incidence of nausea and metoclopramide consumption after surgery according to statistical tests. Also, there were no significant difference between two groups in the frequency distribution of incidence of complications and changes of sedation score after surgery. Therefore, preemptive pudendal nerve block is a relatively safe and simple method for providing analgesia after surgery. The lack of systemic side-effects is another benefit for this method.[1,2] Complications of this method are similar to other methods of local anesthesia. Intravascular injection may cause severe systemic toxicity. There is a risk of hematoma if patient has clotting disorder infection at the injection site. However, we did not have any complication in this study. Preemptive pudendal nerve block can reduce post-operative pain and need to additional narcotic in patients undergoing APR. Therefore, this method is suggested for reducing of post-operative pain in APR.

Some limitations and problems of our study is that this study was conducted on women undergoing APR who received spinal anesthesia. Therefore, suggestion of this method for other methods of surgery and anesthesia need to further studied. This study was prolonged due to less patients with inclusion criteria. Data collection at different times required cooperation of personnel in the operation room and section. Therefore, we suggest altering of the study design and further investigation.

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