

# The Effect of Bupivacaine Infiltration on Postoperative Tubal-Ligation Pain

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## Abstract

Infiltration of Bupivacaine 0.5% in postpartum tubal ligation minilaparotomy cases under spinal anesthesia led to significant reduction of postoperative pain and analgesic requirement and increased satisfaction during the first 24 hours and 7th postoperative day.

Objective: To evaluate the effectiveness of subcutaneous and intratubal infiltration of bupivacaine 0.5% in postoperative pain relief.

Materials and Methods: Parturients for minilaparotomy tubal ligation under spinal anesthesia in the Fatemeh Hospital of Hamadan who met the necessary criteria and signed written consent to be studied, took part in a double blind randomized clinical trial. After tubal ligation, bupivacaine 0.5% in 25 women (intervention group) and normal saline in another 25 cases (placebo group) was injected in subcutaneous tissue of the abdominal wall and fallopian tubes. Pain (with visual analog scale), analgesic requirement, nausea, vomiting, headache and abdominal cramps were measured in two groups immediately after surgery (recovery room), 2, 8, 16 and 24 hours and 7 days after surgery. The patients were asked to voice their satisfaction on the seventh day after the operation. The comparison of the two groups was done by  $\chi^2$ , Fisher's exact and T test with the significance level of  $\alpha = 0.05$

Results: Fifty patients were studied in two groups. Age, education, place of living and number of children were similar in the two groups. Pain score and analgesic requirement in the recovery room 2, 16, 24 hours and 7 days after surgery were significantly less in the intervention group ( $P < 0.005$ ). The two groups were similar regarding pain and analgesic consumption 8 hours after the surgery. Nausea, vomiting and headache were similar in the two groups in all scheduled evaluation times. Abdominal cramping was significantly less in the intervention group only 8 hours after the operation. All patients of intervention group were satisfied from the surgery in comparison to 60% satisfied patients in the placebo group ( $P = 0.001$ ).

Conclusion: Infiltration of Bupivacaine 0.5% in postpartum tubal ligation minilaparotomy under spinal anesthesia led to a significant reduction of postoperative pain and analgesic requirement and increased satisfaction of pain management during the first 24 hours and 7th postoperative day.

## INTRODUCTION

Surgical tubal ligation is the most popular and effective permanent sterilization method [1] with a low rate of side effects (1.7%). [2] The postpartum period is a suitable time for tubal ligation [1] and it can be immediately done under spinal anesthesia. [3] Postoperative pain is an unpleasant sensory and emotional experience and the most common

cause of fear and anxiety in perioperative period. [3]

Several postoperative pain control methods are available including local anesthesia infiltration such as lidocaine and bupivacaine that causes pain relief without unwanted opioid side effects.[3]

Bupivacaine 0.25% and 0.5% solution have slow onset (15

minutes), a high potency, and a duration of effect equal to 240-480 minutes (4-8 hours). [3]

Local anesthetics have less side-effects and are inexpensive, potent and available. A double blind randomized placebo-controlled trial in Thailand in post partum tubal ligation minilaparotomy confirmed the significance postoperative pain relief with intraperitoneal lidocaine.[4]

In another study of 105 cases in Massachusetts, pain relief 30 minutes after laparoscopic tubal ligation in the bupivacaine group was significantly better than in the placebo group. However, analgesic consumption, vomiting, recovery stay and pain on the next day were not different in the groups.[5]

In another study in Chicago, twenty parturients scheduled for tubal-ligation minilaparotomy, were randomized into two groups. Bupivacaine 0.5% was injected subcutaneous, bilateral intratubal and intramesosalpangeal in the intervention group and normal saline injections were administered in the placebo group.

Pain score at 30, 45, 60, 75, 90 minutes and on the seventh postoperative day were significantly less in the bupivacaine group compared to the placebo group. [6]

The present study is to evaluate the effects of subcutaneous and intratubal infiltration of bupivacaine in the reduction of post tubal-ligation pain, analgesic requirement, side effects and increasing personal satisfaction in Iranian parturients undergoing tubal ligation.

### **MATERIALS AND METHODS**

Parturients for tubal ligation in Fatemieh Hospital of Hamadan were studied from April to September 2001 in a randomized double blind clinical trial. Women without drug sensitivity, systemic painful disease and contraindication to spinal anesthesia were included in the study.

After approval by the ethics committee of the Hamadan University of Medical Sciences and obtaining written consent by the patients, the candidates were educated about the visual analoge scale and were included in this randomised study. Primary demographic characteristics were recorded using questionnaires. Sample size was 25 women in every group (with = 0.05 and power of 80%).

The patients were not allowed to eat or drink for at least 8 hours before surgery. Just before the operation, 10 mg metoclopramide and 20 mg hyoscine and 500 mg ringer

solution was administered. In both groups, spinal anesthesia with 60 mg of hyperbaric lidocaine 5%, 3-4 cm infraumbilical incision, and Parkland tubal ligation with chromic 0 suture was performed.

After randomization, 5 ml of bupivacaine 0.5% was injected in the intervention group in each fallopian tube and mesosalpynx and another 5 ml was subcutaneously injected. In the placebo group, similar injections including normal saline were administered. The syringes were randomly selected. The types of drugs were identified only after decoding them at the time of data analysis.

Immediately after surgery (in therecovery room) and 2, 8, 16 and 24 hours after surgery the patients were evaluated regarding vital signs, headache, abdominal cramps, nausea, vomiting, pain (visual analog scale) and analgesic requirement. Data were recorded using questionnaires. In patients who needed analgesia, 25 mg Pethidine was intravenously injected in the recovery room and 75 mg Diclofenac (IM) was intramuscularly injected in the post recovery period.

Hospital stay after postpartum tubal ligation was 24 hours. They were followed up until 7 days by phone and/or house call. Necessity of medical appointment, analgesic consumption, pain score and total satisfaction were collected 7 days after the surgery. Data analysis was done using SPSS and EPI inf 6 software and fisher's exact, x2 and t test with the significance level of  $\alpha = 0.05$ .

### **RESULTS**

Fifty parturients were randomly divided in to placebo and intervention groups ( $n = 25$ ). Age, education, living place and number of children were the same in the two groups. Mean age of patients in both groups was 32 years. Patients not holding a high school diploma were 96% in the intervention and 88% in the placebo group. Urban women were 24% in the intervention and 36% in the placebo group. Seventy six percent of the intervention and 52% of the placebo group had less than 5 children. Mean VAS of pain during recovery was 1 (SD = 1.8) in the intervention and 4 (SD = 3.2) in the placebo group ( $P = 0.0001$ ).

Mean VAS of pain 2, 16 and 24 hours after surgery was significantly decreased in the bupivacaine group in comparison to the placebo ( $P < 0.001$ ) (Table 1 and Figure 1). In the eighth hour evaluation, two groups suffered from the pain similarly. On the seventh day. the intervention group experienced less pain ( $0.3 \pm 0.7$ ) in comparison to

the placebo group ( $1.7 \pm 1.4$ ) ( $P = 0.00009$ ). In the recovery room, 12% of the intervention and 56% of the placebo group needed analgesics ( $P = 0.002$ ). Analgesic requirement was significantly less in the interventional group 24 and 16 hours after surgery ( $p < 0.001$ ).

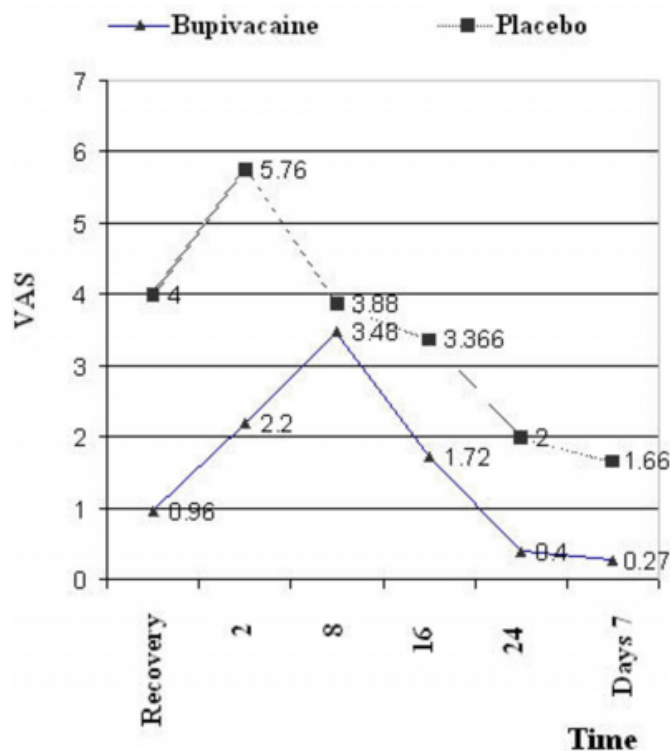
**Figure 1**

Table 1: Comparison of post operative mean pain score in the two groups

| Time                  | Intervention Group |                | Placebo Group (n=25) |                | Meanfulness Based on t Test |
|-----------------------|--------------------|----------------|----------------------|----------------|-----------------------------|
|                       | Mean ( $\pm$ SD)   | Median (Range) | Mean ( $\pm$ SD)     | Median (Range) |                             |
| Recovery              | 1 ( $\pm 1.8$ )    | 0 (0-6)        | 4 ( $\pm 3.2$ )      | 3 (0-9)        | 0.0001                      |
| 2 <sup>nd</sup> Hour  | 2.2 ( $\pm 2.1$ )  | 2 (0-8)        | 5.8 ( $\pm 2.4$ )    | 6 (2-9)        | 0.00002                     |
| 8 <sup>th</sup> Hour  | 3.5 ( $\pm 1.8$ )  | 3 (0-7)        | 3.9 ( $\pm 2.5$ )    | 4 (0-8)        | 0.51                        |
| 16 <sup>th</sup> Hour | 1.7 ( $\pm 1.7$ )  | 1 (0-6)        | 3.4 ( $\pm 1.5$ )    | 3 (0-5)        | 0.001                       |
| 24 <sup>th</sup> Hour | 0.4 ( $\pm 1$ )    | 0 (0-4)        | 2 ( $\pm 1.3$ )      | 2 (0-4)        | 0.00006                     |
| 7 <sup>th</sup> Day   | 0.3 ( $\pm 0.7$ )  | 0 (0-3)        | 1.7 ( $\pm 1.4$ )    | 1.5 (0-4)      | 0.00009                     |

**Figure 2**

Figure 1: Comparison of post tubal ligation VAS in the two groups



In the eighth hour evaluation, the two groups were similar

regarding analgesic requirements. Although, 24 hours after surgery the placebo group needed more analgesic in comparison to the intervention group (20% and 4%), the difference was not significant on the level of 0.05 ( $P = 0.095$ ). Seven days after the operation less analgesic requirement was reported in the bupivacaine group (4% and 48%) ( $P = 0.001$ ) (Table 2 and Figure 2).

**Figure 3**

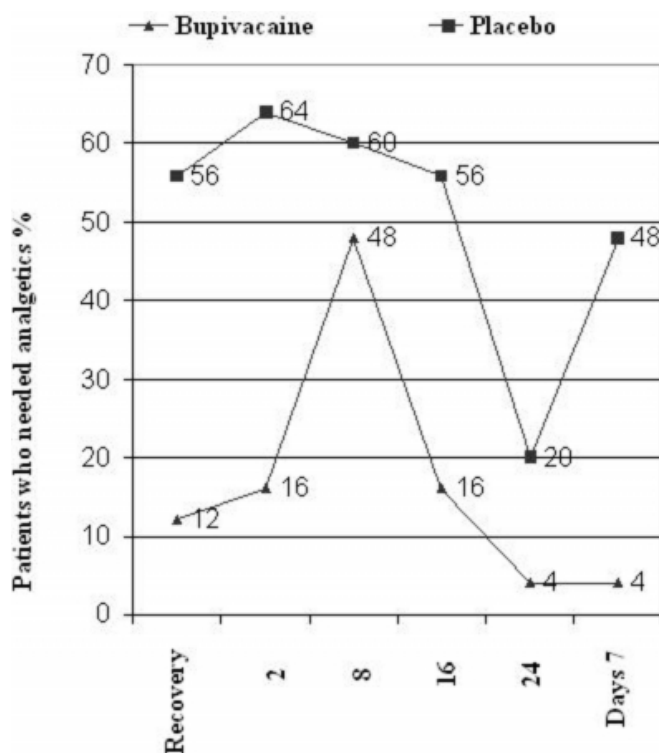
Table 2: Comparison of postoperative analgesic requirement in the two groups

| Time                  | Intervention Group % | Placebo Group % | Meanfulness Based on $\chi^2$ Test |
|-----------------------|----------------------|-----------------|------------------------------------|
| Recovery              | 12                   | 56              | 0.002                              |
| 2 <sup>nd</sup> Hour  | 16                   | 64              | 0.001                              |
| 8 <sup>th</sup> Hour  | 48                   | 60              | 0.57                               |
| 16 <sup>th</sup> Hour | 16                   | 56              | 0.008                              |
| 24 <sup>th</sup> Hour | 4                    | 20              | 0.18 ( $P = 0.095$ )*              |
| 7 <sup>th</sup> Day   | 4                    | 48              | 0.001                              |

\* Based on Fisher's Exact Test

**Figure 4**

Figure 2: Comparison of post tubal ligation analgesic requirements in the two groups



One out of 25 women in the placebo and no one in the bupivacaine group, needed a medical visit due to pain. In the recovery room, one patient (4%) in the intervention group suffered from nausea and vomiting and one case (4%) in the placebo group experienced nausea and no one had vomiting. One patient (4%) in the intervention group and 2 (8%) in the placebo group experienced headache. These differences were not significant.

The patients suffered from nausea, vomiting and headache similarly at 2, 8, 16, 24 hours and 7 days after surgery. The placebo group significantly suffered more abdominal cramps only until 8 hours after the operation and then, the two groups showed similar patterns.

Abdominal cramps in the intervention group during recovery, 2 and 8 hours after the surgery were 2 (8%), 2 (8%) and 3 (12%) and they were 10 (40%), 12 (48%) and 13 (52%) in the placebo group ( $p < 0.05$ ). Seven days after the surgery all of bupivacaine cases and 15 cases (60%) of placebo group were satisfied with their surgery. ( $P = 0.001$ )

## DISCUSSION

In the present study recovery and 2 hours after surgery evaluation revealed significantly less pain and analgesic

requirement in the bupivacaine group. In the study in Massachusetts, USA in 105 laparoscopic tubal ligated women, local bupivacaine significantly decreased postoperative pain after 30 minutes and recovery discharge time in comparison to intramuscular Ketorolac and placebo. This confirms our study. However, in that survey analgesic requirement was not changed.[5]

In the Chicago study on 20 minilaparotomy tubal ligations, VAS and analgesic requirement in 30, 45, 60, 75 and 90 minutes after surgery in the bupivacaine group was significantly less than in the normal saline group.[6]

Eight hours after surgery the mean pain score was 3.48 in the bupivacaine and 3.88 in the placebo group. Forty eight percent of the bupivacaine and 60% of the placebo group needed analgesics. Pain and analgesic requirement 8 hours after the surgery was not significantly different in the two groups.

We should keep in mind that the half-life of bupivacaine is 4-8 hours. [3] It means that after 8 hours the patients are not directly influenced by the drug anymore. On the other hand, the placebo group using more analgesics in the previous 8 hours had experienced pain relief. 16 and 24 hours after the surgery, the pain was less in the bupivacaine group. Analgesic requirement was less in the intervention group 16 hours after the operation. However, in the 24<sup>th</sup> hour evaluation, one case in the drug group and 5 out of 25 in the placebo group needed analgesics ( $P = 0.095$ )

It should be mentioned that although 16-24 hours after the surgery patients were not under direct bupivacaine medication, they experienced pain differently. It might be due to more primary pain episodes experienced by the placebo group leading to more discomfort in the next hours.

It is evidenced that intense noxious stimulation can sensitize portions of system to subsequent input. Such stimulation in the form of surgical incision may lead to functional changes in the dorsal horn of the spinal cord and other consequences that later cause postoperative pain more painful than it would otherwise have been (wind up phenomenon).

On the other hand, local anesthesia such as bupivacaine infiltration, spinal anesthesia, opioids and other analgesics can neutralize the sensitizing effects of surgical stimulation. In addition, chronic and pathologic pain can be prevented in the future. It is observed that the amount of acute pain experienced immediately after thoracotomy appears to predict the probability of subsequent chronic post

thoracotomy pain.[3]

In the Massachusetts study in 105 laparoscopic tubal ligation women, local bupivacaine did not reduce pain as analgesic requirements which is completely different from our study.[3]

In the present study in the seventh day evaluation significantly less pain was reported in the bupivacaine group. On the other hand, oral analgesic consumption (self treatment) was different in the two groups. (Tables 1 and 2)

Pain increases skeletal muscle tone in the surgical site. This reduction of postoperative muscle function can lead to physical immobility and delay of normal performance recovery. Insufficient pain control may cause anosmia, anxiety and helplessness. These psychiatric factors, in addition to immobility due to increased muscle tone, provides a fearful postoperative condition for most of the patients.[7]

The main cause of fear and anxiety in hospitalized patients is postoperative pain. Anxiety is one of the most common psychiatric consequences of acute pain. However, other problems such as depression irritability, sleep disorders, hypersensitivity to environmental stimuli, agitation, delirium and acute psychiatric responses are observed.[3]

It seems that pain relief in the first postoperative hours help in total comfort and rapid recovery.

In the Chicago study tubal ligated women under bupivacaine infiltration experienced significantly less pain in seven days after the surgery, which confirms our results.[6]

More abdominal cramps until the 8<sup>th</sup> hour in the placebo group may be due to pain. Pain can increase skeletal muscle tone.[7] In 20 tubal ligation in the Chicago study, less cramping in the bupivacaine group was experienced.

### **CONCLUSION**

In the present study the injection of bupivacaine 0.5% in subcutaneous and intratubal tissues in minilaparotomy tubal ligation led to significant reduction of pain and consumption of analgesics and increased the satisfaction 24 hours and 7 days after the operation.

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