Original

Evaluation of Local Infiltration with Bupivacaine for Pain Management after Partial Bilateral Salpingectomy

(Evaluación de la infiltración local de bupivacaina en el manejo del dolor post salpingectomía parcial bilateral)

Mariella Fajardo-Arcia[1], Leonardo Orozco-Saborío[2], Gerardo Montiel-Larios[3]

1. Gynecology and Obstetrics Resident. Hospital de las Mujeres Dr. Adolfo Carit Eva (HOMACE).
2. Gynecologist, HOMACE.
3. Chief of the Gynecology Department, HOMACE. CCSS. Hospital de las Mujeres Dr. Adolfo Carit Eva. Gynecology Department.
Clinical Investigation Unit, Hospital de las Mujeres, Dr. Adolfo Carit Eva.
Abbreviations: VAS, Visual-Analog Scale.
Correspondence: Leonardo Orozco S. P.O. Box 11619-1000. San José, Costa Rica
E-mail: loscr@yahoo.com

Abstract

Objective: the efficacy of locally applied bupivacaine for decreasing postoperative pain was evaluated, in patients who underwent mini-laparotomy partial bilateral salpingectomy.

Methods: A total of 100 women, scheduled for surgical sterilization, were randomized to either an intervention group that received 2.5mg of bupivacaine in the mesosalpinx and 2.5 mg in the fallopian tube stump, or a control group that received no intervention. Postoperative pain was measured one and four hours after the procedure, using the visual analogue scale (VAS, 0-10 cm), and the need and quantity of postoperative analgesia was determined. The Student t-test was used to compare averages, and all analyses were made with the Stata 10.0 statistical software, a critical point of 0.05 (p≤ 0.05) was defined as statistically significant.

Results: Scores on the visual analogue scale (VAS cm) for the bupivacaine group were 4.7 and 2.6, compared to 5.3 and 2.6 for the control group, one and four hours after surgery respectively (p> 0.05). Application of bupivacaine significantly reduced the patients´ requests for a second dose of analgesics one hour after surgery (p<0.03). The control group had a greater need to use opioids (n=8) compared to the bupivacaine group (n=1).The application of bupivacaine in the fallopian tube stumps and mesosalpinx at the time of mini-laparotomy surgical sterilization does not produce differences in postoperative pain management, as measured by the visual analogue scale at one and four hours post-surgery.

Conclusions: Application of bupivacaine is effective in reducing the need for analgesics one hour after surgery and reduces the use of opioids.

Keywords: Bupivacaine, surgical sterilization, post operative pain.

Female sterilization, also known as tubal occlusion, has been one of the most used contraceptive methods worldwide.[1,2] More than one million reproductive age women have been sterilized, and it is estimated that since 1982, more than 100 million women, just in developing countries, will look for sterilization.[3]

Sterilization has evolved similarly to other surgical procedures; many techniques have been developed in an effort to simplify the procedure, from the performance through a mini-laparotomy, to laparoscopic sterilization techniques.[4]

In developed countries, laparoscopy is performed, based on its safety and effectiveness. However, in developing countries, mini-laparotomy is used because of low available resources, performing 696 procedures in 2006 for example, at the Gynecology Department of the Hospital de las Mujeres in San José, Costa Rica.[7]

Several studies have been performed to evaluate the improvement of postoperative pain with local anesthetics after partial bilateral salpingectomy. Most of them showed that these anesthetics diminish pain scale scores, besides decreasing the need for postoperative analgesia.[8-27] However, most of studies used laparoscopy as the approach method, which is why the objective of this study was to evaluate the efficacy of local bupivacaine infiltration to reduce postoperative pain in patients subject to mini-laparotomy partial bilateral salpingectomy.

Materials and methods

This was designed as a randomized, double blinded, study. Previously being approved by the Institutional Ethics Committee, the Informed Consent was obtained, and 100 patients were enrolled in this study. These patients were women who were programmed for surgical sterilization in the ambulatory surgery program of the Gynecology Department of the Hospital de las Mujeres. The inclusion criteria were: women older than 18 years old and who met the necessary paperwork for surgical sterilization. Women excluded were those with a history of tubal surgery, intra-abdominal adhesions, chronic pelvic pain, psychiatric disorders or mental

retardation, and a history of any type of allergic reactions to local anesthetics. This trial´s sample population was chosen based on another study,[28] which determined that 57 women were necessary to detect, with a 95% probability and 90% power, a 25% reduction in the visual analogue scale after 2 hours.

After the acknowledge that with 57 women the above mentioned indicators were obtained, and taking into account the number of groups to be compared in this study, a sample of 100 randomized women was obtained, equally distributed to both treatment groups.

The making of the randomizing list was performed with the aid of computer software, assigning 50 participants to the intervention group and the other 50 to the control group (Figure 1). To hide this assignation, sealed envelopes were used, which were later opened by the operating room´s anesthesiologist once the patient was anesthetized. The participants and physicians who applied the visual analogue scale were blinded to the group assignations (Figure 1).

All proceedings were realized under a general anesthesia standardized regimen. Before anesthetic induction, patients were pre-medicated with 10mg of metoclopramide, 1mg of midazolam and 0.75 micrograms/kg of fentanyl, the latter was used as analgesia.

Standard anesthetic induction was performed with propofol at a 2mg/kg dose, 5mg of atracurium and 100mg of succinylcholine were applied to facilitate endotracheal intubation. All participants were subject to mechanical ventilation, and maintenance of anesthesia was performed with sevoflurane and oxygen. Intraoperative monitoring was made with clinical standards. Anesthesia was stopped at the end of the surgery, and the blocking was not reverted. Modified Pomeroy partial bilateral salpingectomy was the technique used for surgical sterilization. The intervention group received 5 cc of 0.5% bupivacaine (5mg/ml flask presentation) in each Fallopian tube as follows: 2.5 cc in the mesosalpinx
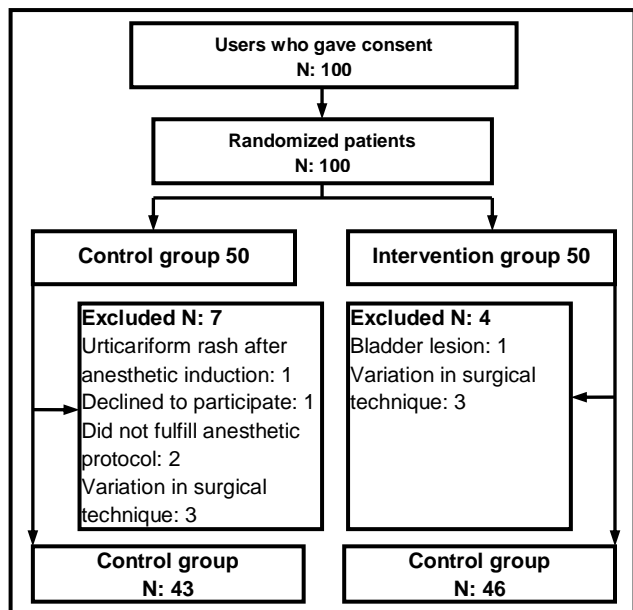
Figure 1. Randomizing and group assignment flowchart.

and 2.5 cc in the surgical stump. The control group did not receive any drug in the Fallopian tubes.

In the hospital room, the evaluation of the visual analogue scale (VAS, 0-10cm) began after 1 and 4 hours of the surgical intervention.

The applied regimen for those patients who requested analgesia in hospital room was, a 75mg dose of Intramuscular diclofenac was given. If a second request was made, 50mg of subcutaneous tramadol was applied, and in case a third request for analgesia was made, 15mg of subcutaneous morphine was given. Postoperative analgesia was applied by the nursery staff, previously prescribed by a physician and recorded in the patient´s file, and according to the expressed requirements for each patient. The time of application and the type of analgesia were recorded.

For the data analysis, patients were characterized by estimating the frequencies and proportions for the qualitative variables, and estimating the averages and standard deviations as descriptive measures for the quantitative variables for each group. Characteristics were compared with the Student t-test for the quantitative variables, and with the chi-square test for the qualitative variable distribution between groups.

A comparison of the visual analogue scale between groups after 1 and 4 hours was made, by comparing the averages using the Student t-test. All analyses were made with the Stata 10.0 statistical software, defining a statistically significant critical point of 0.05 ($p \leq 0.05$).

Results

From April 1st until September 9th, 2008, a total of 100 participants agreed the Informed Consent.

A total of eleven participants were excluded, seven of them were part of the control group, and their causes were: an urticarial eruption after the anesthetic induction, one patient declined to participate, two patients did not fulfill the anesthetic protocol, and three patients had variations in the surgical technique. For the intervention group, four patients were excluded: one had a bladder lesion, and three had variations in the surgical technique. This resulted in 43 patients in the control group and 46 in the intervention group.

There were no significant differences in the sociodemographic characteristics or clinical history between both groups (Table 1; Table2). The surgery length was 17.5 ± 6.1 minutes for the bupivacaine group, and 18.5 ± 5.9 for the control group (Table 1 and Table 2).

The VAS score one hour after surgery was 4.7 ± 2.7 for the bupivacaine group and 5.3 ± 3.2 for the control group (p= 0.30). Four hours after surgery, the scores were 2.6 ± 2.2 for the bupivacaine group and 2.6 ± 2.3 for the control group (Figure 2).

An exploratory analysis was made, comparing the VAS for the interventional and control groups one and four hours after surgery for those patients who did not request analgesia after surgery, without finding significant differences: 35.7 ± 24.8 for the intervention group and 38.0 ± 29.8 for the control group after one group (p= 0.79); 23.9 ± 5.3 and 17.2 ± 2.8, after four hours, respectively (p= 0.29). When comparing the magnitude of decrease in the VAS for patients who did not request analgesia, a significant difference was seen for the control group when comparing one to four hours after surgery, 38.0 ± 29.8 and 17.2 ± 2.8 respectively (p= 0.01), not so in the bupivacaine group, 35.7 ± 24.8 after one hour and

Table 1: Comparison of the general characteristics for patients subject to surgical sterilization. Hospital de las Mujeres, 2008							
	Control Group			Bupivacaine Group			P
	N	Mean	SD	N	Mean	SD	
Age	43	30.7	7.5	46	30.3	5.8	0.74
Weight	43	62.6	12.4	46	65.6	11.4	0.24
Height	43	154.6	16.4	46	157.4	6.5	0.28
BMI	43	25.8	3.5	46	26.4	4.3	0.52
Gynecoobstetrical history							
Pregnancies	43	2.9	1.6	46	2.7	1.3	0.52
Deliveries	43	2.6	1.3	46	2.3	1.2	0.21
Cesarean Delivery	43	0.3	0.7	46	0.1	0.3	0.17
Abortions	43	0.3	0.6	46	0.4	0.6	0.45

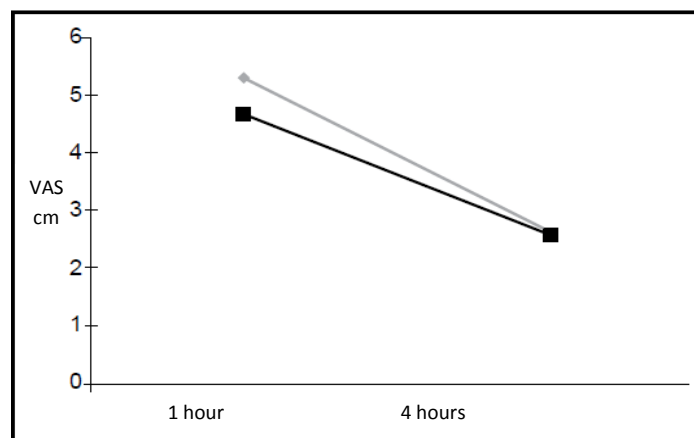| Table 2: Surgical history according to each group, for patients subject to surgical sterilization				
	Non-Exposed		Bupivacaine	
	N	%	N	%
Cesarean Delivery	5	31.2	6	35.3
Curettage	4	25.0	5	29.4
Cholecistectomy	3	18.7	0	0.0
Appendectomy	2	12.5	4	23.5
Two or more cesarean deliveries	2	12.5	0	0.0
Hernioplasty	1	6.2	1	5.9
Cystectomy	0	0.0	1	5.9
Laparotomy	0	0.0	1	5.9

Figure 2. Comparison of the visual analogue scale according to the evaluation time between groups, for patients subject to surgical sterilization. Hospital de las Mujeres, 2008

23.9 ± 5.3 after four hours (p=0.13).

In the control group, 15.9% of participants requested a second dose of analgesia compared with 2.2% in the bupivacaine group (p< 0.03). Furthermore, the control group had a larger use of opioids (n=8) compared to the bupivacaine group (n=1). No patient needed a third dose of analgesia (Figure 3).

Regarding the elapsed time from surgery to the first dose of analgesia, there was no difference between the groups (p= 0.76). No adverse effects were reported because of the intervention, and intraoperative complications or variations in the surgical technique were not related to the use of bupivacaine.

Discussion

Unlike previous studies; which showed an improvement in pain scales after partial bilateral salpingectomy; [10, 28, 30] this study, showed no significant differences in postoperative pain scores (using the visual analogue scale, one and four hours after surgery), after applying bupivacaine in the tubal stumps and mesosalpinx, when performing mini-laparotomy surgical sterilization.
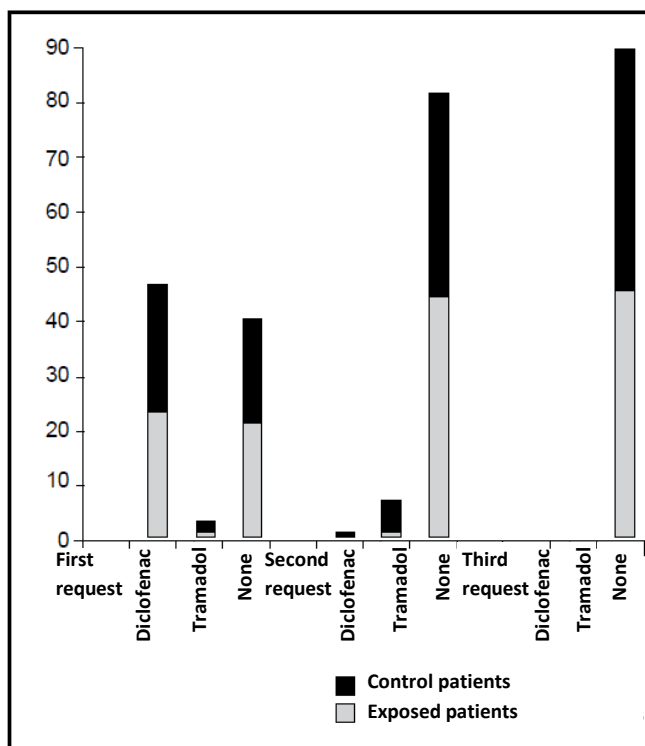

Figure 3. Postoperative analgesic drugs comparison, according to each group, for patients subject to surgical sterilization. Hospital de las Mujeres, 2008.

Remarkably, most studies which proved the effectiveness of a local anesthetic had a laparoscopic surgical approach, suggesting that dissection with mini-laparotomy of larger amounts of abdominal wall tissues (during pelvic access), highly influences postoperative pain.

However, applying bupivacaine was effective in reducing the needs for postsurgical analgesia and opioid use one hour after surgery, agreeing with a large number of studies which showed a variable decrease in analgesia consumption and the need for opioids for those patients with a local anesthetic. [17-10, 16,17,20] This shows that applying bupivacaine has a short term benefit after surgery, even though it is not reflected in the VAS score, as the control group had a similar reduction in the VAS score to that of the intervention group (Figure 2). This could be explained if pain´s amount, perception or tolerance is differentiated.

Pain is an emotive personal experience; its magnitude can only be subjectively described by the affected person. It is known that pain perception for any given subject greatly varies according to emotional and mood factors; [28,31] in this context it is known that psychological, cognitive and behavioral factors have become determinant factors in pain management. [32-37] This situation has been previously described, where a lower use of morphine one hour after surgery was described, although VAS scores in the study period were similar for both groups. [38]

There are some limitations for this trial. Firstly, although the applied dose was already used in other studies, [7-10] in Costa Rica it is difficult to measure drug concentrations, and it depends only on the surgeon to achieve a homogeneous drug dose. Secondly, the amount of analgesics taken by the participants after discharge was not recorded, because this self-report could represent an increased work for the patient. It might be conceivable that there was a difference in the amount of analgesia taken between both groups. However, since patients with more pain would take more analgesics, the difference in pain levels should decrease instead of

growing, and it would not be ethical to deny analgesia to a person in pain.

In conclusion, the fact that mini-laparotomy partial bilateral salpingectomy is an ambulatory procedure and that in some cases patients are not discharged due to pain, it is extremely important to seek for an improvement in postoperative pain relief. The use of bupivacaine by this surgical approach does not seem to benefit the achievement of this goal. However, it seems effective for diminishing the need for postoperative analgesia and the use of opioids.

The short effect duration of this treatment could postpone, but not eliminate the need for other analgesics; therefore bupivacaine should be seen as an add-on to therapy, not as a replacement of traditional analgesic therapy.

Acknowledgements

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Translated by: Dr. Javier Estrada Zeledón