

## EFFECT OF PRE-INCISIONAL AND MESOSALPINX INFILTRATION OF LOCAL ANAESTHESIA FOR POST-OPERATIVE ANALGESIA IN BILATERAL ABDOMINAL TUBECTOMIES- A RANDOMISED PLACEBO-CONTROLLED STUDY

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### ABSTRACT

#### BACKGROUND

The aim of the study is to evaluate the effectiveness of subcutaneous pre-incisional and mesosalpinx infiltration of 0.5% bupivacaine in post-operative pain relief.

#### MATERIALS AND METHODS

This is a randomised placebo-controlled double-blind study conducted at Bangalore Medical College and Research Institute on 50 patients scheduled for elective tubal ligation by minilaparotomy under general anaesthesia from April to October 2014. Patients were randomised into 2 groups of 25 each by computer generated random list. Group A patients received 0.5% bupivacaine 10 cc pre-incisional subcutaneous and 5 cc in the mesosalpinx, while Group B patients received normal saline infiltration. In this study, the intensity of post-operative pain was assessed using Verbal Rating Scale (VRS). Data collection was done using questionnaire and collected data was analysed by Student's t-test, Chi-square and Fisher Exact test using SPSS software and descriptive statistical programme, p value < 0.01 was considered significant.

#### RESULTS

50 patients were studied in two groups. Age and weight of the patients were comparable between 2 groups. Pain score in recovery room 2, 4, 6, 8, 10 hours post-surgery were significantly less in bupivacaine group (p < 0.005). Time for rescue analgesia is 3.92 ± 1.07 hrs. in Group A compared to 1.32 ± 0.54 in Group B with p < 0.01.

#### CONCLUSION

Pre-incisional and mesosalpinx infiltration of 0.5% bupivacaine in abdominal tubectomies by minilaparotomy led to significant reduction of post-operative pain with prolonged period for rescue analgesia.

#### KEYWORDS

Bupivacaine, Local Infiltration, Analgesia, Mesosalpinx.

**HOW TO CITE THIS ARTICLE:** Shivanna P, Raghuram S. Effect of pre-incisional and mesosalpinx infiltration of local anaesthesia for post-operative analgesia in bilateral abdominal tubectomies- a randomised placebo-controlled study. J. Evid. Based Med. Healthc. 2017; 4(40), 2437-2442. DOI: 10.18410/jebmh/2017/481

#### BACKGROUND

Surgical tubal ligation is the most popular effective permanent sterilisation method with low rate of side effects.<sup>1</sup>

Tubal ligation in the postpartum period may be recommended as safe and effective method for women who desire permanent contraception.<sup>2</sup>

The uterine fundus is near the umbilicus permitting a small subumbilical incision and easy to access tubes.<sup>3,4</sup>

Postpartum tubal ligation is a brief surgical procedure with minimal tissue injury, yet post-operative recovery and analgesia requirements are often disproportionately large.<sup>5</sup>

*Financial or Other, Competing Interest: None.*

*Submission 23-04-2017, Peer Review 28-04-2017,*

*Acceptance 14-05-2017, Published 18-05-2017.*

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*DOI: 10.18410/jebmh/2017/481*



The relief of pain and suffering is and has always been one of the primary aims of medicine.<sup>6</sup> Post-operative pain is an unpleasant sensory and emotional experience and the most common cause of fear and anxiety in the perioperative period.

Several post-operative pain control methods are available including local anaesthesia infiltration, such as lidocaine and bupivacaine that causes pain relief without unwanted opioid side effects.

Local anaesthetics have less side-effects and inexpensive, potent and available. Bupivacaine 0.25% and 0.5% solution have slow onset (15 mins.), a high potency and duration of effect equal to 4 - 8 hrs.<sup>7</sup>

Local anaesthetics have been applied topically as solutions to the fallopian tubes, in gel form to the clip/ring before application, injected into the mesosalpinx or instilled per cervix into the fallopian tubes. Local anaesthetics have also been instilled in relatively large volumes into the peritoneal cavity to reduce subdiaphragmatic and shoulder pain caused by residual pneumoperitoneum. Since the 1970s, there has been some enthusiasm in the gynaecologic

literature for the use of local anaesthetic solutions that are applied topically to the fallopian tubes at the time of occlusion. Large series of patients were thus successfully sterilised, while receiving local anaesthesia with minimal post-operative pain or other associated morbidity. As a technique it is easy to learn, is not likely to be associated with risks of mesosalpinx injection (bleeding, intravascular or visceral injection), and does not require cervical manipulation (which is itself painful, vagotonic and emetogenic) or the large volumes of local anaesthetic needed for intraperitoneal instillation.

The present study is to evaluate the effect of pre-incisional subcutaneous and mesosalpinx infiltration of 0.5% bupivacaine in the reduction of post tubal ligation pain and analgesics requirement.

### MATERIALS AND METHODS

Parturients for tubal ligation in Bowring and Lady Curzon Hospital of Bangalore Medical College and Research Institute were studied from April to October 2014 in a randomised double-blind placebo controlled study. Included women in this study were- (a) Who delivered within 72 hours before tubal sterilisation, (b) ASA 1 and 2, (c) Had given consent for the procedure, (d) No contraindication for the surgery. Exclusion criteria were women with- (a) BMI  $\geq 32$  kg/m<sup>2</sup>, (b) History of pelvic inflammatory disease or pelvic surgery, (c) Systemic illness and (d) Local anaesthetic allergy.

After approval by Institutional Ethical Committee and obtaining informed written consent from the parturients, 50 of them were randomised into 2 groups of 25 each by the computer generated random list as follows:

Group A: Bupivacaine group (n = 25)

Group B: Normal saline group (n = 25)

The sequence was delivered in a sealed envelope on the morning of surgery.

Sample size was 25 women in every group (with = 0.05 and power of 80%). Demographic parameters were recorded through questionnaire.

All parturients were kept fasting overnight. Upon arrival in the operating room, 20-gauge intravenous catheter secured and Ringer's lactate infusion started. Monitors for pulse oximetry, electrocardiogram and non-invasive blood pressure were attached and baseline readings noted. Both groups premedicated with Inj. midaz 0.02 mg/kg, Inj. glyco 0.001 mg/kg and Inj. Fentanyl 2 microgm/kg. Induced with Inj. propofol 2 mg/kg. Group A patients received 10 cc of

0.5% bupivacaine subcutaneous at the pre-incisional site (Fig. 1 (a)) and 5 cc in the mesosalpinx both sides (Figure 1 (b)) using No. 26 half-inch needle 1 cm below the tip of Babcock forceps. Group B patients received normal saline. The syringes were randomly selected and the type of drugs were identified only after decoding them at the time of data analysis. Anaesthesia was maintained with halothane 0.2 to 1% in oxygen nitrous mixture through mask ventilation.

Verbal rating score (0, no pain; 1, mild pain; 2, moderate pain; 3, severe pain; 4 intolerable pain)<sup>6</sup> was recorded for evaluation of post-operative analgesia every 2 hrs. for 10 hrs. and every 4 hrs. for 24 hours and time for rescue analgesia was recorded in both groups. In the post anaesthesia care unit, patients with VRS  $\geq 2$  were given Inj. diclofenac 75 mg IV as rescue analgesia. All the observations were made by an anaesthesiology resident who was unaware of the group allocation and blinded to the study drug.

### Statistical Analysis

Power analysis based on pilot case done prior to the study indicated that at least 25 patients in each group would be required to demonstrate a clinically important difference in post-operative analgesia score with an alpha= 0.05 and a power of 80%.

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean  $\pm$  SD (Min - Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance.

Student 't' test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Intergroup analysis) on metric parameters. Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

### Significant Figures

+ Suggestive significance (P value: 0.05 < P < 0.10).

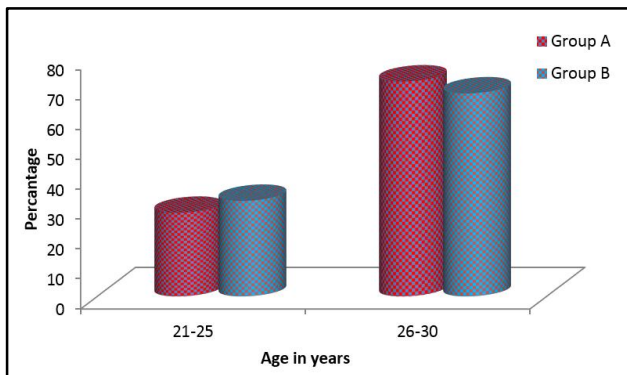
\* Moderately significant (P value: 0.01 < P  $\leq$  0.05).

\*\* Strongly significant (P value: P  $\leq$  0.01).

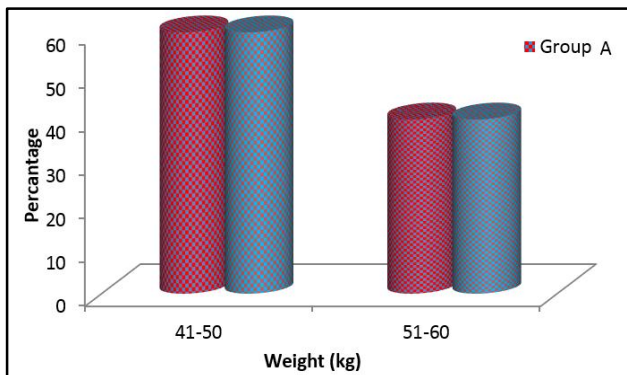


**RESULTS**

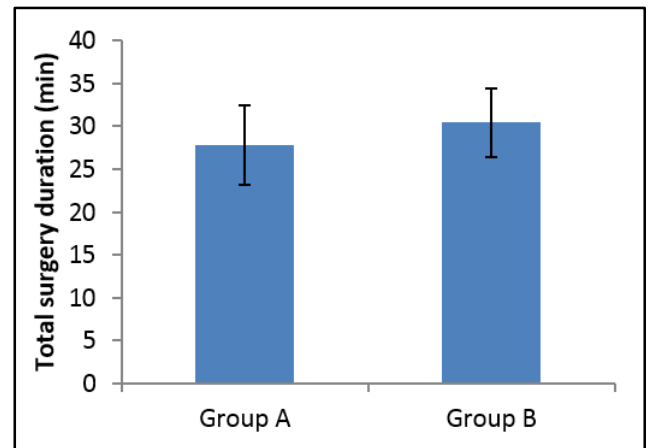
Both groups were comparable with regard to age (Figure 2) and weight (Figure 3). The duration of surgery was approximately 30 mins. (Figure 4).



**Figure 2. Age Distribution of Patients**

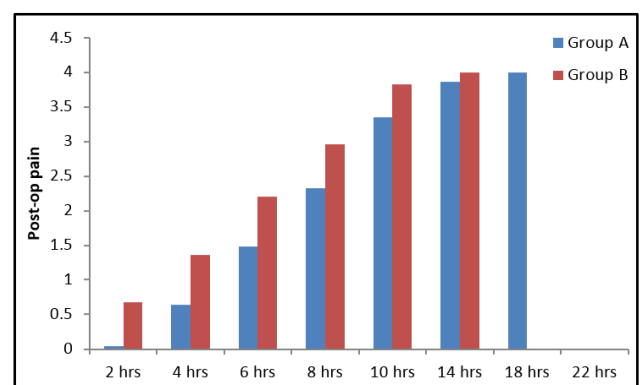


**Figure 3. Weight Distribution between Two Groups**

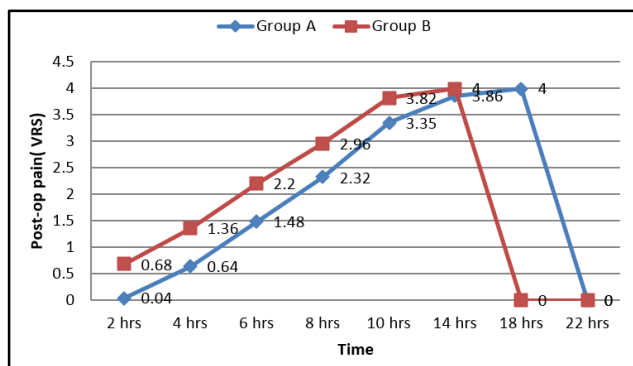


**Figure 4. Total Duration of Surgery between 2 Groups**

The results indicated that the incidence of post-surgical pain for up to 10 hrs. was significantly low in Group A compared to Group B ( $p < 0.001$ ) assessed through Verbal Rating Scale (VRS). After 10 hrs., no statistically significant difference in analgesia was found between two groups (Figure 5).

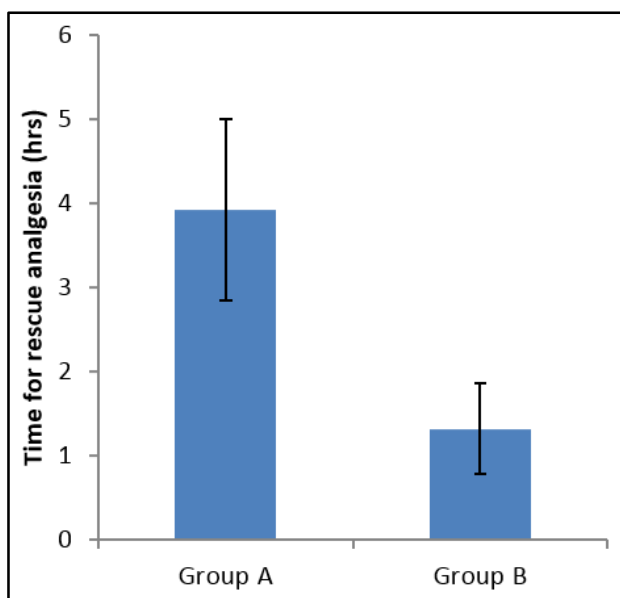


**Figure 5 (a). Bar Graph of Comparison of Post-operative Pain between Two Groups**



**Figure 5 (b). Line graph showing Comparison of Mean VRS (Verbal Rating Scale) between Two Groups**

It is noteworthy that in the present study, time for rescue analgesia is  $3.92 \pm 1.07$  hrs. in Group A compared to  $1.32 \pm 0.54$  in Group B with P value ( $< 0.001$ ). The patients in Group B asked for rescue analgesia in the first early hours (Figure 6).



**Figure 6. Comparison between Duration for Rescue Analgesia between 2 Groups**

**DISCUSSION**

The present study shows that the parturients who received bupivacaine infiltration revealed significantly less pain and longer duration for rescue analgesia post-operatively compared to placebo group.

When local anaesthetic is administered into mesosalpinx, it initially halts afferent visceral nociceptive input, inhibiting the development of central sensitisation.<sup>8</sup> Central sensitisation is thought to be dependent on painful stimuli acting on N-methyl-D-aspartic acid (NMDA) receptors located within the central neuraxis.<sup>6</sup>

It is evidenced that intense noxious stimulation can sensitise portions of system to subsequent input. Such stimulation in the form of surgical incision may lead to functional changes in the dorsal horn of spinal cord and other consequences that later cause post-operative pain

more painful than it would otherwise have been (wind up phenomenon).

On the other hand, local anaesthesia such as bupivacaine infiltration, spinal anaesthesia, opioids and other analgesic can neutralise the sensitising effects of surgical stimulation. In addition, chronic and pathological pain can be prevented in 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.<sup>7</sup>

Pain increases skeletal muscle tone in the surgical site. This reduction of post-operative muscle function can lead to physical immobility and delay of normal performance recovery. Insufficient pain control may cause anxiety, anosmia and helplessness. These psychiatric factors in addition to immobility due to increased muscle tone provides a fearful post-operative condition for most of the patients.<sup>9</sup>

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.<sup>7</sup>

Hence, pain relief in the first post-operative hours help in total comfort and rapid recovery.

One study reported that analgesia resulting from mesosalpinx blocks along with mesosalpinx instillation in laparoscopic tubal sterilisation lasted 8 - 12 hours.<sup>10</sup>

The study done by Fiddes et al<sup>11</sup> reported that lignocaine infiltration at the cornual end of the fallopian tubes during laparoscopic Filshie clip application is highly effective in producing post-operative pain relief.

Our findings were consistent with the study done by Mahile Arab et al,<sup>1</sup> which showed that injection of bupivacaine 0.5% in the subcutaneous and intratubal tissues in minilap tubal ligation led to significant reduction of pain and consumption of analgesics and increased patient satisfaction 24 hrs. and 7 days after operation. Mean VAS of pain 2, 16 and 24 hours after surgery was significantly decreased in bupivacaine group in comparison to the placebo ( $p < 0.001$ ), same way analgesic requirement was significantly less in the interventional group 24 hours and 16 hours after surgery ( $p < 0.001$ ).

A study on 20 parturients scheduled for elective tubal ligation by minilaparotomy by Wittles B. et al<sup>5</sup> inferred that infiltration of uterine tubes and mesosalpinx with 0.5% bupivacaine significantly enhanced analgesia both immediately and on 7<sup>th</sup> post-operative day compared to infiltration with sodium chloride. The total amount of meperidine administered in PACU (Post Anaesthesia Care Unit) was significantly larger in saline group than in bupivacaine group. Pain scores at 30, 45, 60, 75 and 90 minutes post-operatively and on 7<sup>th</sup> post-operative day was less in bupivacaine group.

M. R. Afhami et al<sup>6</sup> studied on effect of pre-incisional infiltration of lidocaine as a local anaesthetic in different concentrations on post-operative pain in tubectomy patients; three groups of 20 patients each received lidocaine infiltration before skin incision with different concentrations

(0.5%, 1%, 1.5%) were examined for pain intensity and duration of analgesia in comparison to the fourth placebo group in which normal saline infiltration was used. Average duration of analgesia was 5 hours in Group 1 (0.5%), 3.30 hours in Group 2 (1%) and 20 hours in Group 3 (1.5%), in the control group however it was only an hour.

A randomised controlled trial done by Tool AL<sup>12</sup> and colleagues reported that topical bupivacaine decreased post-operative pain scores significantly compared to placebo in women undergoing laparoscopic tubal sterilisation with silastic bands. Only topical bupivacaine was found to decrease post-operative pain scores significantly over those with placebo at 30 minutes post-operatively (median score 2 compared with 4,  $p = 0.002$ ) and at discharge from recovery room (median score 2 compared with 3,  $p = 0.03$ ).

Bordahl PE<sup>13</sup> in their study concluded that infiltration of bupivacaine to uterine tubes and lignocaine adrenaline infraumbilically at pre-incisional site led to less post-operative abdominal pain and less need of analgesics to that compared with general anaesthesia. In the local anaesthesia group operation time was shorter, perioperative discomfort was modest and the costs of equipment were lower than in the general anaesthesia group.

Similar to our study, Harrison MS et al reported that use of local anaesthetic during laparoscopic tubal ligation substantially reduced post-operative pain up to 8 hours after surgery.

Wheatley<sup>14</sup> and co-authors from their study demonstrated that in group receiving bupivacaine 0.5% to fallopian tubes time to first analgesia was significantly longer ( $p = 0.03$ ) and significantly fewer patients requested escape analgesia before 1 hour assessment ( $p = 0.01$ ). They even had less pain on VAS ( $p = 0.04$ ) and significantly lower VRS ( $P = 0.01$ ) at 1 hr assessment compared to placebo or normal saline group.

The study on evaluation of local infiltration with bupivacaine 0.25% for pain management after partial bilateral salpingectomy on 100 women by Mariella Fajardo Arcia<sup>15</sup> and co-authors reported that bupivacaine is effective in reducing the need for analgesics 1 hr after surgery and reduced the use of opioids.

Bupivacaine 0.5% infiltration of mesosalpinx was compared to lidocaine 1%, normal saline or no injection for pain relief in women with elective laparoscopic tubal sterilisation by Alexander et al<sup>16</sup> found that bupivacaine was most effective in providing analgesia and also those patients received significantly less fentanyl in post-anaesthesia care unit ( $p < 0.05$ ).

Study done by Binil Issac Mathew<sup>17</sup> and co-workers on the efficacy of intraperitoneal bupivacaine for post-operative analgesia after laparoscopic tubal ligation versus diclofenac administration per rectum showed that 10 mL of 0.125% intraperitoneal bupivacaine is safe and effective method for pain relief in immediate post-operative period.

Similarly, a study by Shushee Visalyaputra et al<sup>18</sup> on 80 post-partum patients in Thailand concluded that intraperitoneal instillation of 0.5% lidocaine and pre-incisional local infiltration with 15 mL of 1% lidocaine

decreased intraoperative pain effectively compared to intramuscular morphine and normal saline.

63 women undergoing laparoscopic tubal sterilisation with Filshie clips were studied by Matthew C Brennan<sup>19</sup> et al to evaluate post-operative pain after topical bupivacaine administration compared with placebo and found that topical bupivacaine reduced the incidence ( $p = 0.005$ ) and intensity ( $p = 0.028$ ) of pain at 30 minutes.

The instillation of lignocaine intraperitoneally was reported to adequately control pain under local anaesthesia. However, direct mesosalpinx injection of lidocaine 40 – 200 mg has been reported to provide long-lasting analgesia in laparoscopic tubal sterilisation.<sup>20,21</sup>

Manjunath<sup>22</sup> and co-workers studied the effect of laparoscopic tubal ligation using intraperitoneal lignocaine 0.5% 20 mL compared to 20 mL of isotonic saline and found lignocaine instillation is safe and effective method for post-operative pain relief.

Moiniche et al<sup>23</sup> evaluated Randomised Controlled Trials (RCTs) of peripheral local anaesthetics (LA) compared with placebo or no treatment in the control of post-operative pain after laparoscopic surgery. All RCTs of mesosalpinx or fallopian tube block after sterilisation showed improved pain relief with a statistically significant weighted mean difference of -19 mm of VAS (95% CI -25 to -14) in favour of treatment groups. There was evidence for a significant, but short-lasting effect of mesosalpinx/fallopian tube block after sterilisation, but there was a lack of evidence for any important effect of port-site infiltration.

## CONCLUSION

In conclusion, we have demonstrated that pre-incisional subcutaneous and mesosalpinx infiltration of 0.5% bupivacaine in minilaparotomy tubal ligation provided good post-operative analgesia and prolonged the duration of rescue analgesia.

Hence, we recommend routine usage of this safe, feasible and cost effective technique for relieving post-tubectomy pain.

## REFERENCES

- [1] Arab M, Manocherian N, Mehrangiz Z. The effect of Bupivacaine infiltration on postoperative tubal ligation pain. *Internet Journal of Pain, Symptom Control and Palliative Care* 2003;3(1):1-6.
- [2] American College of Obstetricians and Gynecologists. ACOG Practice bulletin no. 133: benefits and risks of sterilization. *Obstet Gynecol* 2013;121(2 Pt 1):392-404.
- [3] Werawatakul Y, Sakondhavit C, Kuchaisit C, et al. Evaluation of female sterilization at Srinagarind hospital. *J Med Assoc Thai* 2005;88(8):1028-1034.
- [4] Pati S, Cullins V. Female sterilization. Evidence. *Obstet Gynecol Clin North Am* 2000;27(4):859-899.
- [5] Wittles B, Faure EA, Chavez R, et al. Effective analgesia after bilateral tubal ligation. *Anesth Analg* 1998;87(3):619-623.

- [6] Afhami MR, Salmasi PH. Studying analgesic effect of preincisional infiltration of lidocaine as a local anaesthetic with different concentrations on postoperative pain. *Pak J Med Sci* 2009;25(5):821-824.
- [7] Miller RD, Cucchiara RF, Miller ED, et al. *Anesthesia*. 5th edn. New York: Churchill Livingstone 2000; p. 2877.
- [8] Songserm V, Werawatakul Y, Sothornwit J, et al. Lidocaine injection in mesosalpinx for pain relief during post-partum tubal sterilization in Srinagarind Hospital: A randomized controlled trial. *Thai Journal of Obstetrics and Gynaecology* 2017;25(1):11.
- [9] Barash PG, Cullen BF, Stoelting RK. *Clinical Anaesthesia*. 3rd edn. Philadelphia, New York: Lippincott-Raven 1997;p. 1483.
- [10] Benhamou D, Narchi P, Mazoit JX, et al. Postoperative pain after local anesthetics for laparoscopic sterilization. *Obstet Gynecol* 1994;84(5):877-880.
- [11] Fiddes TM, Williams HW, Herbison GP. Evaluation of post-operative analgesia following laparoscopic application of filshie clips. *J Obstet Gynaecol* 1996;103(11):1143-1147.
- [12] Tool AI, Kammerer-Doak DN, Nguyen CM, et al. Postoperative pain relief following laparoscopic tubal sterilization with silastic bands. *Obstet Gynecol* 1997;90(5):731-734.
- [13] Bordahl PE, Raeder JC, Nordentoft J, et al. Laparoscopic sterilization under local or general anesthesia? A randomized study. *Obstet Gynecol* 1993;81(1):137-141.
- [14] Wheatley SA, Millar JM, Jadad AR. Reduction of pain after laparoscopic sterilisation with local bupivacaine: a randomised, parallel, double-blind trial. *Br J Obstet Gynaecol* 1994;101(5):443-446.
- [15] Fajardo-Arcia M, Orozco-Saborio L, Montiel-Larios G. Evaluation of local infiltration with bupivacaine for pain management after partial bilateral salpingectomy. *Acta Med Costarric* 2011;53(4):199-204.
- [16] Alexander CD, Wetchler BV, Thompson RE. Bupivacaine infiltration of the mesosalpinx in ambulatory surgical laparoscopic tubal sterilization. *Can J Anaesth* 1987;34(4):362-365.
- [17] Mathew BI, Thasleem AK, Venugopal V. Efficacy of intraperitoneal bupivacaine for postoperative analgesia. *Int J Health Sci Res* 2016;6(10):63-67.
- [18] Visalyaputra S, Pethpaisit N, Ariyanon P, et al. EMLA cream and intraperitoneal lidocaine decrease intraoperative pain during postpartum tubal sterilization. *J Med Assoc Thai* 2002;85(Suppl 3):S942-947.
- [19] Brennan MC, Ogburn T, Hernandez CJ, et al. Effect of topical bupivacaine on postoperative pain after laparoscopic tubal sterilization with filshie clips. Randomized controlled trial. *Am J Obstet Gynecol* 2004;190(5):1411-1413.
- [20] Cruikshank DP, Laube DW, De Backer LJ. Intraperitoneal lidocaine anesthesia for postpartum tubal ligation. *Obstet Gynecol* 1973;42(1):127-130.
- [21] Rattanalappaiboon D, Werawatakul Y, Tharnprisan P, et al. Intraperitoneal lidocaine for decreasing intraoperative pain during postpartum tubal resection in Srinagarind hospital. *J Med Assoc Thai* 2012;95(4):477-481.
- [22] Manjunath AP, Chhabra N, Girija S, et al. Pain relief in laparoscopic tubal ligation using intraperitoneal lignocaine: a double masked randomized controlled trial. *Eur J Obstet Gynecol Reprod Biol* 2012;165(1):110-114.
- [23] Moiniche S, Jorgensen H, Wetterslev J, et al. Local anaesthesia infiltration for postoperative pain relief after laparoscopy: a quantitative and qualitative systematic review of intraperitoneal, port site infiltration and mesosalpinx block. *Anesth Analg* 2000;90(4):899-912.