

---

## OBSTETRICS

---

# Lidocaine Injection in Mesosalpinx for Pain Relief during Post-partum Tubal Sterilization in Srinagarind Hospital: A randomized controlled trial

Vilasinee Songserm, M.D.\*,  
Yuthapong Werawatakul, M.D.\*,  
Jen Sothornwit, M.D.\*,  
Molruedee Prasit, RN.\*\*,  
Sompong Thongpha, PN.\*\*.

\* Department of Obstetrics and Gynecology, Faculty of Medicine, Srinagarind Hospital, Khon Kaen University, Khon Kaen, Thailand

\*\* Family Planning Unit, Nursing Division, Faculty of Medicine, Srinagarind Hospital, Khon Kaen University, Khon Kaen, Thailand

### ABSTRACT

**Objectives:** To evaluate the effectiveness of lidocaine injection in mesosalpinx for pain relief during, immediately after and one hour post-operative for post-partum tubal sterilization in Srinagarind Hospital.

**Materials and Methods:** 139 post-partum women participated, but 79 women were excluded. The remaining 60 women were recruited in this randomized, double-blinded, placebo controlled study. They undergoing postpartum tubal sterilization under local anesthesia performed by residents at the Department of Obstetrics and Gynecology. They were randomly assigned to one of two groups. They all received 4 ml solution injection in mesosalpinx divided for each side. Group one received 1% lidocaine 4 ml (40mg). And the other group received 0.9%NSS 4 ml. The intra-operative, immediately after and one hour post-operative pain was measured by using a numerical rating score (NRS) from 0 to 10.

**Result:** There was no significant difference in the mean of intra-operative, immediately after and one hour post-operative NRS between the lidocaine group and placebo group (mean difference -0.7, 95%CI, -1.65 to 0.25 (p-value 0.147))

**Conclusion:** Mesosalpinx injection of lidocaine was not effective for pain relief during and after post-partum tubal sterilization under local anesthesia.

**Keywords:** Lidocaine, Mesosalpinx, Post-partum tubal sterilization

**Correspondence to:** Vilasinee Songserm, M.D., Department of Obstetrics and Gynecology, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand, E-mail: rrvsinata@hotmail.com

---

## ผลของการฉีด Lidocaine เข้าเนื้อเยื่อใต้หลอดมดลูก เพื่อลดความเจ็บปวดขณะผ่าตัด ทำหมันหลังคลอดในโรงพยาบาลศรีนครินทร์

วิลาสินี ส่งเสริม, ยุทธพงศ์ วีระวัฒน์ตระกูล, เจน ไสธรวิทย์, มลฤดี ประสิทธิ์, สมปอง ทองผา

### บทคัดย่อ

**วัตถุประสงค์:** เพื่อศึกษาประสิทธิภาพของการฉีด Lidocaine เข้าเนื้อเยื่อใต้หลอดมดลูก เพื่อลดความเจ็บปวดขณะทำและ  
หลังทำหมันหลังคลอดในโรงพยาบาลศรีนครินทร์

**วัสดุและวิธีการ:** สตรีหลังคลอดจำนวน 139 ราย เข้าร่วมการศึกษา แต่ถูกคัดออก 79 ราย คงเหลือสตรีหลังคลอดที่มีสุขภาพ  
แข็งแรง และไม่มีข้อห้ามในการทำหมัน 60 ราย ได้รับการทำหมันหลังคลอดภายใต้การระงับปวด โดยใช้ยาชาเฉพาะที่โดย  
แพทย์ใช้ทุน และแพทย์ประจำบ้านภาควิชาสูติศาสตร์และนรีเวชวิทยา ทำการสุ่มโดยแบ่งออกเป็น 2 กลุ่ม แต่ละกลุ่มได้รับ  
สารละลายฉีดเข้าเนื้อเยื่อใต้หลอดมดลูก 4 มิลลิลิตร สำหรับสองข้าง กลุ่มที่ 1 ได้รับ 1% Lidocaine 40 มิลลิกรัม และกลุ่มที่  
2 ได้รับน้ำเกลือ (Normal saline) ทำการวัดระดับความเจ็บปวดโดยใช้ Numerical rating scale (NRS 0-10) ในระหว่างการทำ  
ทำหมัน หลังจากการทำหมันทันที และหลังจากการทำหมัน 1 ชั่วโมง

**ผลการศึกษา:** ค่าเฉลี่ยความเจ็บปวดในกลุ่มที่ได้รับ Lidocaine และกลุ่มที่ได้รับน้ำเกลือ ไม่มีความแตกต่างกันอย่างมี  
นัยสำคัญทางสถิติ ทั้งในระหว่างการทำหมัน หลังจากการทำหมันทันที และหลังจากการทำหมัน 1 ชั่วโมง (mean difference  
-0.7, 95%CI, -1.65 to 0.25 (p-value 0.147))

**สรุป:** การฉีด Lidocaine เข้าเนื้อเยื่อใต้หลอดมดลูกขณะผ่าตัดทำหมันหลังคลอด ไม่มีประสิทธิภาพในการลดความเจ็บปวด  
ทั้งในระหว่างการทำหมัน หลังจากการทำหมันทันที หรือหลังจากการทำหมัน 1 ชั่วโมง

**คำสำคัญ:** ลิโดเคน, เนื้อเยื่อใต้หลอดมดลูก, การทำหมันหลังคลอด

---

## Introduction

Postpartum tubal sterilization may be recommended as a safe and effective for women who desire permanent contraception<sup>(1)</sup>. The procedure can be performed safely shortly after delivery and is suitable for a patient who has had uncomplicated labor, is hemodynamically stable and understands the risks and benefits of surgery and anesthesia<sup>(2)</sup>. The uterine fundus is near the umbilicus, permitting a small subumbilical incision and easy to access to the tubes<sup>(1-5)</sup>. It also requires only basic surgical instrument and training<sup>(1)</sup>. The anesthetic techniques for tubal sterilization vary from local anesthesia to epidural, spinal, or general anesthesia<sup>(3,6)</sup>. The most common approach in developing countries is local anesthesia<sup>(5)</sup>. While medically safe, it often provides inadequate pain relief<sup>(2,4,5,7-8)</sup>. The instillation of lidocaine intraperitoneally was reported to adequately control pain under local anesthesia<sup>(2,9-11)</sup>. However, direct mesosalpinx injection of lidocaine 40-200 mg has been reported to provide long-lasting analgesia in laparoscopic tubal sterilization<sup>(12-14)</sup>. The main objective of this study was to evaluate the effectiveness of lidocaine injection in mesosalpinx for pain relief during postpartum tubal sterilization.

## Materials and Methods

The authors performed a randomized, double blinded, placebo-controlled study. Included subjects in this study were healthy women who (a) delivered within 72 hours before tubal sterilization (b) completed childbearing (had at least 2 children) and needed permanent contraception (c) had American Society of Anesthesiologists (ASA) physical status of I<sup>(15)</sup> (d) had no contraindication for surgery, and (e) had given consent for post-partum tubal sterilization. All procedures were performed by residents in the Department of Obstetrics and Gynecology. Exclusion criteria were women with (a) BMI  $\geq 32$  kg/m<sup>2</sup> (b) history of pelvic inflammatory disease or pelvic surgery (c) liver disease (d) asthma, and (e) lidocaine allergy.

After the study was approved by the Office of The Khon Kaen University Ethics Committee in Human

Research (HE571180), the allocation was done by computer generated vary block randomization. Randomization sequence was concealed in sealed opaque envelopes. The randomization order was blinded to surgeon, patient and assistants. Informed consent was obtained from women who were randomly assigned to one of two groups. All two groups received a solution injected in mesosalpinx divided for each side (left and right) (a) Group 1: 0.9% NSS 4 ml (40 mg) and (b) Group 2: 1% lidocaine 4 ml. The solution was clear color fluid contained in 5 ml disposable syringes with needle. There was no label to identified type of solution. Only one nurse who knew randomization order prepared the solution just before the operation.

Before the operation, the participants were asked to practice scoring their pain using a numerical rating score (NRS, 0 = no pain; 10 = the most severe pain). Non-invasive monitoring of blood pressure and pulse oximeter was used before, during and after the operation. Every woman received 20 ml of 1% lidocaine with adrenaline (1:100,000) infiltration of the skin and beneath the rectus sheath. Numbness was checked prior to do the subumbilical skin incision. After approaching the intraperitoneum, the surgeon began searching for the fallopian tube and held the fallopian tubes using Babcock forceps. The 2 ml solution was injected in mesosalpinx (1 cm below the tip of Babcock forceps), using a no. 26 half inch needle before tubal resection was done by Pomeroy technique. When the first side of fallopian tube was resected, participants were asked to rate their pain. The same procedure was done on the other fallopian tube and participants were asked to rate the pain again. Intravenous meperidine with or without diazepam was given if the pain score was more than 4. Rescue drugs were given when the surgeon could not perform the operation due to the patient's feeling severe pain (NRS=10). Immediately after surgery, the participants were given paracetamol administered every 6 hour (2 x 500 mg tablets) for pain relief as required. Pain assessment was done by nurses who were blind to the random sequence. At 1 hour after surgery, the participants were asked to rate her pain. The side effects of

lidocaine (i.e. tinnitus, dizziness, perioral numbness) were observed and recorded post-operatively for 1-2 hours.

The results of the study by Rattanalappaiboon D. et al<sup>(11)</sup> were used to estimate the sample size for the current study (n=60) based on a power of 0.8 and a type I error probability of 0.05 (two-tailed) to detect a 3 point difference in pain intensity between two

groups. The continuous data are presented as a mean±SD and the differences among groups were tested using generalized estimating equation. A p<0.05 was considered statistically significant. The results are presented as a mean and 95% confidence interval (95% CI). All analyses were completed using STATA version 10. The trial was registered at the Thai Clinical Trials Registry (TCTR20150306001).

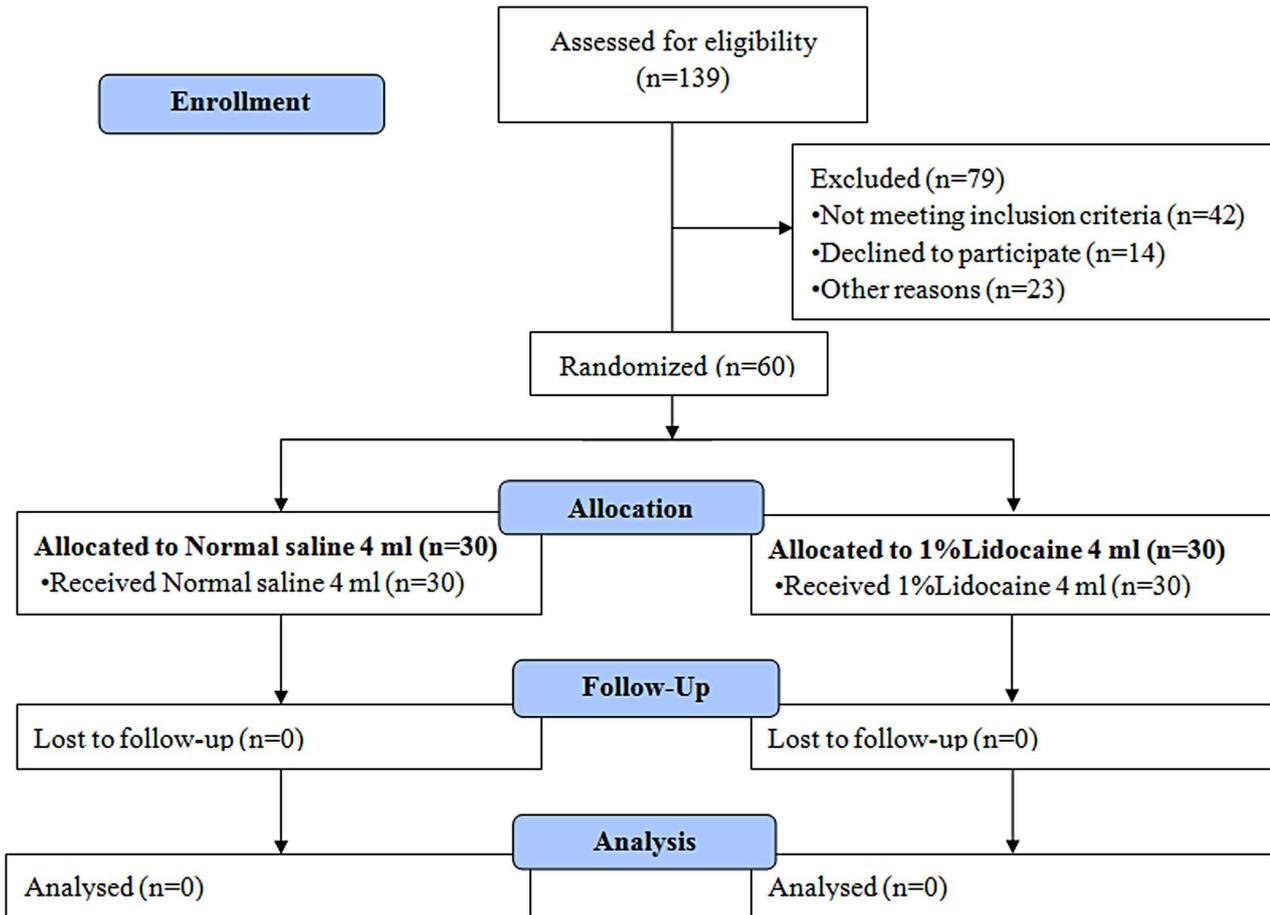


Fig. 1. Flow diagram

## Results

There were 139 eligible women, but 79 women were excluded. Of those who were excluded; 42 were not meeting inclusion criteria, 14 declined to participate, 20 had previous pelvic surgery and 3 had BMI ≥ 32 kg/m<sup>2</sup>. The remaining 60 participants

were recruited in the study. No one lost to follow-up. Data from all 60 participants were analyzed. The demographic data and duration of surgery between two groups were not statistically significant (p>0.05) (Table 1). The mean blood pressure and oxygen saturation were not significant difference between the

two groups either before, during or after operation (Table 2). Although the mean oxygen saturation before operation was statistically significant ( $p=0.048$ ) but there was no clinically significant between the group. The mean intra-operative, immediately after and 1 hour post-operative NRS were not significant different between the two groups (mean difference  $-0.7$ , 95%CI,  $-1.65$  to  $0.25$  ( $p$ -value  $0.147$ )) (Table 3). The intra-operative and post-operative NRS in lidocaine groups were lower than in NSS group around 1 point; however they were not statistically

significant (Table 3).

There were ten women who required meperidine as a rescue drug to treat severe pain and difficulty in performing the operation (viz., six patients in the normal saline group and four in the lidocaine group,  $p = 0.488$ ). Two of six patients in the normal saline group needed 10 mg of diazepam to achieve the procedure ( $p = 0.150$ ).

Neither serious side-effect from lidocaine or operative complications was observed in any of the women.

**Table 1.** Demographic data and duration of surgery.

Characteristics	Group 1 (Normal Saline) (n=30)		Group 2 (Lidocaine 40 mg) (n=30)		P
	Mean	SD	Mean	SD	
	Age (years)	31.93	2.97	31.40	
Weight (kg)	59.79	9.81	64.21	8.34	0.065
Height (cm)	159.13	4.70	160.46	5.28	0.087
BMI (kg/m <sup>2</sup> )	23.55	3.26	24.95	3.20	0.097
Duration of surgery (min)	35.80	13.52	34.26	10.86	0.630

**Table 2.** Demographic and clinical characteristics of the participants.

		Group 1 (Normal Saline) (n=30)		Group 2 (Lidocaine 40 mg) (n=30)		P
		Mean	SD	Mean	SD	
		<b>Before operation</b>	Systolic BP (mmHg)	116.2	13.47	
	Diastolic BP (mmHg)	74.56	9.16	77.3	7.76	0.217
	Oxygen saturation (%)	99.63	1.24	98.24	1.05	0.048
<b>During operation</b>	Systolic BP (mmHg)	114	11.41	114.4	8.34	0.877
	Diastolic BP (mmHg)	73.0	10.18	74.6	6.54	0.481
	Oxygen saturation (%)	99.8	1.32	99.6	2.01	0.650
<b>After operation</b>	Systolic BP (mmHg)	113.7	9.62	112.89	8.24	0.732
	Diastolic BP (mmHg)	72.26	7.64	72.06	4.83	0.906
	Oxygen saturation (%)	99.6	1.35	99.72	1.27	0.718

**Table 3.** Intra-operative and post-operative NRS.

	Group 1 (Normal Saline) (n=30)		Group 2 (Lidocaine 40 mg) (n=30)		Mean difference (95% CI)	P
	Mean	SD	Mean	SD		
Intra-operative NRS	7.15	2.70	6.28	2.60	- 0.7	0.147
Immediate post-operative NRS	7.23	2.44	6.36	2.53	(- 1.65, 0.25)	
1 hour post-operative NRS	2.90	1.84	2.53	1.87		

NRS = Numerical rating score

**Table 4.** Total meperidine and diazepam requirements during the operation.

	Group 1 (Normal Saline)	Group 2 (Lidocaine 40 mg)	P
NRS $\geq$ 4	25	24	0.739
NRS $\geq$ 4 + Meperidine	6	4	0.488
NRS $\geq$ 4 + Meperidine + Diazepam	2	0	0.150

NRS = Numerical rating score

## Discussion

The rationale for this route of administration is that when fallopian tubes and mesosalpinx are disrupted, lidocaine initially halts afferent visceral nociceptive input, inhibiting the development of central sensitization. Lidocaine is an intermediate potency anesthetic agent, has rapid onset of action and provides a 30-60 minute duration of action<sup>(16)</sup>. Although optimal concentration, volume and duration of action of mesosalpinx blockage using lidocaine is inconclusive, one study<sup>(17)</sup> reported that analgesia resulting from mesosalpinx blocks along with mesosalpinx instillation laparoscopic tubal sterilization lasted 8-12 hours. Theoretically, a mesosalpinx block would provide long-lasting analgesia. Nociceptive impulses from disrupted fallopian tubes are conducted along fine, predominantly nonmodulated visceral afferents, and analgesia generated by blocking such nerves in others parts of the body usually outlasts the duration of the blockage. The authors selected lidocaine 40 mg in 4 ml volume because the authors wanted to use the smallest dose that would provide pain relief as well as the smallest dosage to minimize the

side effects and/or complications due to the procedure. The result of the present study demonstrated that mesosalpinx injection of lidocaine did not provide effective pain relief during and after postpartum tubal sterilization under local anesthesia. The intra-operative and immediate post-operative NRS of two groups reached 6-7 point, this may be because the solution caused peritoneum at mesosalpinx distended, then stimulated visceral pain input before onset of lidocaine's action. Pain also occurred from traction on peritoneum and skin, therefore discontinued operation caused the pain ceased. This can be explained that the post-operative NRS of two groups decreased from intra-operative. The results in Table 4 showed that this procedure could not reduce the use of additional intravenous drugs i.e. meperidine and diazepam.

Since there was no previous study with similar methodology to assess intraoperative pain, comparison our results with other studies was imprecise. The difference in anesthetic technique i.e. regional, general or local anesthesia made it difficult to compare other studies to our study.

The strength of the current study was the

randomization, blinding and placebo-control. The limitation of this study was that the pain score depended on many subjective, individually-based factors.

## Conclusion

The result of the present study demonstrated that intra-operative mesosalpinx injection of lidocaine was not effective for pain relief during and after postpartum tubal sterilization under local anesthesia. This technique should be carefully performed to avoid complications and/or side effects from the procedure.

## Acknowledgement

The authors are grateful to the women for their participation. The authors would like to thank you to (a) the residents, (b) the nursing staffs and (c) the Department of Obstetrics and Gynecology, Faculty of Medicine at Khon Kaen University for their cooperation and support.

## Potential conflicts of interest

The authors declare no conflict of interest.

## References

1. American College of Obstetricians and Gynecologists. ACOG Practice bulletin no. 133: benefits and risks of sterilization. *Obstet Gynecol* 2013;121:392-404.
2. Huffnagle S, Huffnagle HJ. Anesthesia for postpartum tubal ligation. *Tech Reg Anesth Pain Manag* 2003;7:222-8.
3. Werawatakul Y, Sakondhvat C, Kuchaisit C, Kukiattikool P, Tharnprisan P, Ngoksin U, et al. Evaluation of female sterilization at Srinagarind Hospital. *J Med Assoc Thai* 2005;88:1028-34.
4. Pati S, Cullins V. Female sterilization. Evidence. *Obstet Gynecol Clin North Am* 2000;27:859-99.
5. Chi IC, Gates D, Thapa S. Performing tubal sterilizations during women's postpartum hospitalization: a review of the United States and international experiences. *Obstet Gynecol Surv* 1992;47:71-9.
6. Nisanian A. Outpatient minilaparotomy sterilization with local anesthesia. *J Reprod Med* 1990;35:380-3.
7. Bucklin BA, Smith CV. Postpartum tubal ligation: safety, timing, and other implications for anesthesia. *Anesth Analg* 1999;89:1269-74.
8. Visalyaputra S, Lertakyamanee J, Pethpaisit N, Somprakit P, Parakkamodom S, Suwanapeum P. Intraperitoneal lidocaine decreases intraoperative pain during postpartum tubal ligation. *Anesth Analg* 1999;88:1077-80.
9. Cruikshank DP, Laube DW, De Backer LJ. Intraperitoneal lidocaine anesthesia for postpartum tubal ligation. *Obstet Gynecol* 1973;42:127-30.
10. Visalyaputra S, Pethpaisit N, Ariyanon P, Parakkamodom S, Permpolprasert L, Apidechakul P, et al. EMLA cream and intraperitoneal lidocaine decrease intraoperative pain during postpartum tubal sterilization. *J Med Assoc Thai* 2002;85 Suppl 3:S942-7.
11. Rattanalappaiboon D, Werawatakul Y, Tharnprisan P, Prasit M. Intraperitoneal lidocaine for decreasing intraoperative pain during postpartum tubal resection in Srinagarind Hospital. *J Med Assoc Thai* 2012;95:477-81.
12. Alexander CD, Wetchler BV, Thompson RE. Bupivacaine infiltration of the mesosalpinx in ambulatory surgical laparoscopic tubal sterilization. *Can J Anaesth* 1987;34:362-5.
13. Benhamou D, Narchi P, Mazoit JX, Fernandez H. Postoperative pain after local anesthetics for laparoscopic sterilization. *Obstet Gynecol* 1994;84:877-80.
14. Fiddes TM, Williams HW, Herbison GP. Evaluation of post-operative analgesia following laparoscopic application of Filshie clips. *Br J Obstet Gynaecol* 1996;103:1143-7.
15. American Society of Anesthesiologists. ASA Physical Status Classification System [Internet]. 1995 [cited 2014 Feb 17]; Available from: <http://goo.gl/z9fG3D>
16. Berde CB, Strichartz GR. Local anesthetics. In: Miller RD, Eriksson LI, editors. *Miller's anesthesia*. 7th ed. Philadelphia: Livingstone; 2010. p 913-40.
17. Benhamou D, Narchi P, Mazoit JX, Fernandez H. Postoperative pain after local anesthetics for laparoscopic