

THE EFFECTS OF TUBAL SURFACE OR INTRATUBAL LIDOCAINE INJECTION ON POSTOPERATIVE PAIN AND OVARIAN RESERVE DURING LAPAROSCOPIC TUBAL LIGATION

LAPAROSKOPIK TÜP LİGASYONU SIRASINDA TUBA YÜZEYİ VEYA İNTRATUBAL LİDOKAİN ENJEKSİYONUNUN POSTOPERATİF AĞRI VE OVER REZERVİ ÜZERİNE ETKİSİ

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Abstract

Laparoscopic tubal ligation is a common procedure in the sterilization methods. Some methods and drugs applied for postoperative pain after tubal ligation. The aim of this study was to evaluate the effects of tubal surface (Group 2) or intratubal (Group 3) lidocaine injection on postoperative pain and ovarian reserve comparing with controlled group (Group 1) after laparoscopic tubal sterilization. Forty five women (30-45 age) was enrolled in this prospective, randomized, controlled, double blinded, clinical study. Preoperative and third-month postoperative ovarian reserve tests were compared. There was no difference in demographic characteristics among three groups. Pain scores (verbal rating score) were lower in the lidocaine superficial and intratubal injection group compared with control group after postoperative 15 and 60 minutes. In hormonal evaluation three months after operation, follicle stimulating hormone (FSH) levels slightly increased in all groups compared with preoperative values. Total ovarian volume and total antral follicle count which were the ultrasonographic indicators of ovarian reserve were not different between the groups. Topical lidocaine applied to the fallopian tubes during the laparoscopic tubal sterilization might decrease postoperative pain without affecting the ovarian reserve.

Key words: Laparoscopy; sterilization; lidocaine; postoperative pain; ovarian reserve.

Özet

Laparoskopik tüp ligasyonu sıklıkla uygulanan bir sterilizasyon yöntemidir. Tubal ligasyon sonrası postoperatif ağrı için bazı ilaçlar ve metotlar uygulanmıştır. Bu çalışmanın amacı laparoskopik tubal sterilizasyon sonrası tubanın yüzeyine (Grup 1) veya intratubal lidokain (Grup 2) enjeksiyonunun etkisini kontrol grubu ile kıyaslayarak araştırmaktır. Kırkbeş bayan (30-45 yaş) bu prospektif, randomize, kontrollü, çift kör, klinik çalışmaya dahil edildi. Operasyon öncesi ve operasyondan 3 ay sonrası ovarian rezerv testleri karşılaştırıldı. Üç grup arasında demografik özelliklerde fark görülmemiştir. Ağrı skorları (verbal derecelendirme skoru) postoperatif 15 ve 60. dakika lidokain yüzeysel ve intratubal enjeksiyon grubunda kontrol grubuna göre daha düşük bulunmuştur. Operasyondan üç ay sonrası hormonal değerlendirmede, folikül uyarıcı hormon (FSH) seviyeleri operasyon öncesi değerlerle kıyaslandığında tüm gruplarda hafif artış göstermiştir. Over rezervi belirteçlerinden toplam over volümü ve toplam antral folikül sayısı gruplar arasında fark izlenmemiştir. Laparoskopik tubal ligasyon sırasında fallop tüpüne topikal lidokain uygulanması over rezervini etkilemeksizin operasyon sonrası ağrıyı azaltabilmektedir.

Anahtar Kelimeler: Laparoscopi; sterilizasyon; lidokain; postoperatif ağrı; over rezervi.

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Introduction

Laparoscopic sterilization is the most common surgical method for interval sterilization due to the advantages of the outpatient setting and rapid recovery (1). Tubal ligation is associated with pain after the operation. Therefore, several local anesthetics including lidocaine, bupivacaine, lignocaine, etidocaine were applied to the fallopian tubes to relieve this pain (2-4). Application way and the efficiency of local anesthetics were found variable in laparoscopic sterilization method. They were injected into peritonea, tubal surface, tuba and mesosalpinx (4-7). All of the authors claimed that the methods were effective and reduced the postoperative pain. But, to the best our knowledge, there was no study to compare which technique was more effective and feasible previously.

Ovarian reserve after tubal sterilization that local anesthetic was applied for pain was not investigated in the literature. Additionally only one preliminary study was designed to evaluate the effect of laparoscopic tubal sterilization on ovarian reserves (8). In this recently published study, a slight but non-significant change in the ovarian reserve markers was found due to reduced utero-ovarian arterial blood flow in the mesosalpinx, leading to tissue damage in the ovaries after tubal sterilization. Currently ovarian reserve tests were composed of baseline hormone measurements, such as follicle stimulating hormone (FSH), estradiol (E2), inhibin B and anti-Mullerian hormone (AMH); dynamic tests, such as the clomiphene citrate challenge and GnRHa tests; and biophysical tests such as ovarian volume, ovarian peak stromal blood-flow velocity, and antral follicle counts (AFC) (9). Even though, there are multiple ovarian reserve tests available in clinical use none is ideal (10).

The aim of this prospective, randomized, controlled, clinical study was to determine

the effects of tubal surface and intratubal lidocaine injection on postoperative pain and ovarian reserve comparing with placebo-controlled group after laparoscopic tubal sterilization.

Material and methods

Fifty-five healthy patients who voluntarily requested elective surgical sterilization in 2012 and 2013 were enrolled in this prospective study. The effects of tubal surface (group 2) intratubal (group 3) lidocaine injection on postoperative pain and ovarian reserve compared with placebo-controlled group (Group 1) after laparoscopic tubal sterilization. The study was approved by ethics committee of Erciyes University, and all women who gave informed consent for participation before enrolling in the study.

The inclusion criteria were menstruating regularly, being sexually active between the ages of 30 and 45. The exclusion criteria were smoking, being pregnant, history of abortion or elective termination, any drug usage, delivery within the last 3 months, gynecologic disorders (e.g. endometriosis, pelvic inflammatory disease, pelvic mass), history of systemic disease (i.e., hepatic, pulmonary, renal, hematological or endocrine diseases such as diabetes mellitus, prolactinoma, thyroid dysfunction), history of infertility treatment, previous tubal and/or ovarian surgery, and perimenopausal symptoms.

Pain was assessed using a 4-point verbal rating score (VRS) (0 = no pain, 1 = minimal, 2 = mild, 3 = moderate and 4 = severe) (11). VRS was measured 15 minutes and 1 hour after the procedure by an operator blinded to the groups. The patients were asked to visit the hospital on early follicular phase (the 2nd to 5th days of their menstrual cycle) before the sterilization procedure and three months later following sterilization procedure for the evaluation of the hormonal and sonographic markers of ovarian reserve.

The women blindly underwent venipuncture at approximately eight hours after overnight fasting. Serum samples were stored at -20°C and assayed for LH, FSH, and E2. In the same morning of the

blood tests, the total numbers of antral follicles measuring 2–10 mm in diameter were counted by the same operator blinded to the groups. A 7.5 MHz transvaginal probe was used in all examinations, and both ovaries were presented on transvaginal ultrasound scan. Ovarian volume was calculated with the equation of an ellipsoid ($0.526 \times \text{length} \times \text{height} \times \text{width}$).

Patients were scheduled for surgery in the follicular phase of their menstrual cycles. Under general anesthesia the laparoscope was inserted and the pelvis was examined for pelvic pathology. Then a suprapubic 5 mm operative trocar was introduced and both tubes were grasped with bipolar forceps approximately 2–3 cm from the uterine cornu and placed on tension. Current was applied with a PlasmakineticTM (GYRUS Medical, Maple Grove, MN, USA) using pulsed bipolar energy for coagulation until complete desiccation was understood by an audible alert and/or visual inspection that electrical current could no longer be transmitted and the tube was transected. The tube was then regrasped, and the cut edges were re-coagulated. The procedure was repeated on the opposite side. The groups were randomized with a computer randomization system. In the placebo group (Group 1), normal saline were administered. In group 2, 5 ml of lidocaine 1 % was dripped on each tube. Five ml of lidocaine 1 % was injected into each fallopian tube in group 3. One ml intramuscular diclofenac (75 mg) were administered to all of the patients one hour after the procedure, and the patients were discharged on the first postoperative day at the latest.

Numerical variables were presented as means \pm SD. Non-normally distributed metric variables were analyzed by Kruskal–Wallis test and Mann–Whitney U test. After the confirmation of normal distribution, paired-t tests were used to compare the values of the groups. $p \leq 0.05$

was considered statistically significant. All other analyses were performed using the Statistical Package for the Social Sciences, version 15.0 (SPSS, Chicago, IL, USA).

Results

All patients were enrolled and completed the study without any complications and side effects. There was no statistically significant demographic difference among the three groups of patients (Table 1). As shown in Table 1, the preoperative and third-month postoperative LH and E2 hormonal levels did not reveal statistically significant differences between the groups, but FSH levels slightly increased in all groups compared with preoperative values. There was no statistically significant difference between the groups regarding the FSH, LH, and E2 levels. Moreover, the ultrasonographic indicators of ovarian reserve did not change in terms of total ovarian volume and total AFC before and after the sterilization procedure.

According to the VRS, there was a statistically significant difference between the study groups and control group (Table 2). Minimal pain feeling rates in postoperative 15. and 60. minute were higher in group 2 and 3 comparing with

control group. Furthermore, control group had higher moderate and severe pain feeling. Five patients in the control group required additional analgesia in the form of 1 ml intramuscular diclofenac (75 mg). In the study, there was no moderate and severe pain in lidocaine administered group.

	Group 1		Group 2		Group 3	
	Before procedure	After procedure	Before procedure	After procedure	Before procedure	After procedure
Age	35.46 ± 4.17 ^a		35.06 ± 4.16 ^a		35.40 ± 4.08 ^a	
Gravida	3.86 ± 1.24 ^a		4.40 ± 1.12 ^a		4.26 ± 1.10 ^a	
Live births	3.20 ± 0.86 ^a		3.86 ± 0.83 ^a		3.80 ± 0.94 ^a	
FSH	7.46 ± 1.84 ^a	9.64 ± 2.24 ^b	8.13 ± 2.29 ^a	10.42 ± 2.3 ^b	8.00 ± 2.07 ^a	10.09 ± 2.0 ^b
LH	9.60 ± 1.35 ^a	9.00 ± 1.84 ^a	9.66 ± 1.87 ^a	9.85 ± 2.4 ^a	9.33 ± 1.75 ^a	9.14 ± 2.03 ^a
E2	50.86 ± 6.36 ^a	49.78 ± 6.6 ^a	53.86 ± 9.45 ^a	50.07 ± 7.35 ^a	54.93 ± 8.49 ^a	51.57 ± 8.82 ^a
AFC	10.26 ± 1.87 ^a	9.78 ± 1.52 ^a	10.13 ± 1.45 ^a	9.42 ± 1.15 ^a	9.86 ± 1.84 ^a	9.14 ± 0.94 ^a
OV	6.53 ± 1.55 ^a	6.21 ± 0.89 ^a	6.60 ± 1.45 ^a	6.35 ± 1.08 ^a	7.33 ± 1.34 ^a	7.42 ± 1.01 ^a

Table 1. Demographic and ovarian reserve characteristics of the groups.

AFC: Antral follicle counts, OV: ovarian volume, E2: Estradiol
Statistically significant difference is not present in groups sharing the same letter (P > 0.05). All data sets of power of performed test with alpha = 0,050; 0,998–1.000.

Groups	Min.	VRS				
		0 n (%)	1 n (%)	2 n (%)	3 n (%)	4 n (%)
Group 1 (Control)	15.	1 (% 6)	1 (% 6)	6 (%40)	5 (%33.3) ^a	2 (% 13.3) ^a
	60.	1 (% 6)	2 (% 13.3)	7 (% 46.7)	4 (% 26.6) ^a	1 (% 6) ^a
Group 2 (Superficial)	15.	3 (% 20)	7 (% 46.7) ^a	5 (% 33.3)	0 (% 0)	0 (% 0)
	60.	4 (% 26.6)	8 (% 53.3) ^a	3 (% 20)	0 (% 0)	0 (% 0)
Group 3 (Intratubal)	15.	4 (% 26.6)	8 (% 53.3) ^a	3 (% 20)	0 (% 0)	0 (% 0)
	60.	5 (% 33.3)	8 (% 53.3) ^a	2 (% 13.3)	0 (% 0)	0 (% 0)

Table 2. Pain scoring with VRS between the groups. VRS: verbal rating score Min: Minute n: number Statistically significant difference is not present in groups sharing the same letter (P > 0.05).

Discussion

The local anesthetic agents to reduce postoperative pain have been used in many studies. The previous studies used different local anesthetics in a different way (4-7). FSH, LH, E2, OV, and AFC were the preferential methods for evaluation of ovarian reserve (12, 13). However, the postoperative effects of ovarian reserve were not studied in the literature. To the best of our knowledge, the current study was the first study to evaluate the effects of postoperative ovarian reserve of the patients that local anesthetics were administered during laparoscopic sterilization.

Tubal sterilization destroys not only the fallopian tube but also the adjacent vascular structures, such as the tubal branch or ovarian branch of the uterine artery in the mesosalpinx, causing an altered blood supply to the ovaries (14, 15). We hypothesized that additionally local anesthetic application might increase the tissue damage and also affect ovarian supply. In the literature, a recently published study revealed that sterilization with laparoscopic tubal bipolar electrodesiccation and transaction method did not alter the ovarian reserve (8). According to the study of Ercan et al., ovarian reserve markers did not significantly change. In another study, tubal sterilization by laparoscopic electrocoagulation did not cause any decrease in ovarian reserve tests except an early postoperative increase in FSH.¹⁶ In our study, FSH levels were slightly elevated, and this change was shown in all groups including control group. The current study showed that local anesthetic administration did not affect the ovarian reserves in women who underwent laparoscopic tubal sterilization.

Several studies have looked at local anesthesia in conjunction with general anesthesia for pain relief after laparoscopic

sterilization (4, 5, 17). It is also an inexpensive, safe, easy-to-use, and effective method for pain control after laparoscopic tubal sterilization (18). In our study, we administered local anesthetic both superficial and intratubal. Both of methods were comparable for postoperative pain relief. The various reasons in the previous reports can be different clinical settings, methodology, type of anesthesia (under general anesthesia vs local anesthesia), use of multimodal analgesia, type and duration of surgery, amount of dissection and experience of the surgeon (19). Moreover, it has been described various techniques using various drugs in different dosages and volumes, at different sites and at different timing of the procedure (20). In our study, patients sterilized with laparoscopy under general anesthesia and lidocaine applied as local anesthetic to the superficial and intratubal area of the fallopian tube before sterilization with electrocautery. Additionally, pain was found to be worst with tubal rings and intermediate with spring loaded clips, but least with electrocautery (21, 22). We used electrocautery method due to cost factors and less pain. However, some patients in control group had severe and intermediate pain and needed extra analgesia.

In conclusion, this prospective randomized, double blinded, controlled study revealed that the local applied lidocaine significantly reduced postoperative pain after laparoscopic sterilization without any change of ovarian reserve tests comparing with control group. Further studies should investigate the same topic with more participants in the long term.

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