

Single incision-two port laparoscopic tubal ligation versus conventional three port laparoscopic tubal ligation: A prospective comparative study

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Ethics Committee Approval

This study was approved by İstanbul Medipol University Faculty of Medicine Ethic Committee (01/2019/51-605).

All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest

No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Most women who have completed childbearing request tubal ligation, as it is an effective and irreversible form of contraception. Single incision laparoscopic surgery (SILS) which is currently standard in most surgical specialties, eliminates multiple port incisions and provides faster recovery with better cosmesis. However, there is less data about single incision laparoscopic bilateral tubal ligation. We aimed to compare the results of single-incision-two port laparoscopic tubal ligation and conventional three port laparoscopic tubal ligation.

Methods: Patients who desired tubal ligation procedure as a contraceptive method were randomly allocated to two groups as single-incision-two port laparoscopic tubal ligation (Group 1) and conventional three port laparoscopic tubal ligation (Group 2) between April 2015 to January 2020 in the Obstetrics and Gynecology clinics of two university hospitals. A prospective comparative study was conducted, and sixty patients were included in each group, which were compared in terms of operation time, blood loss, length of hospital stay, complications, port site hernia, postoperative pain score, conversion rate, cosmesis and failure of sterilization.

Results: There was no need to convert to open surgery in either group. Average blood loss was similar between the groups (107.6 ml vs 98.4 ml, $P=0.14$). Operating time was significantly longer in group 2 compared to group 1 (38 minutes vs. 26 minutes, $P=0.02$). Higher pain scores were observed in group 2 compared to group 1 at the 24th postoperative hour (2.21 vs 3.82, $P=0.012$). Patients in group 1 were more satisfied with the single incision in the umbilicus based on cosmetic outcome scores (4.88 vs 3.16, $P=0.018$). There were no reported intraoperative complications in either group. No port site hernias and failure of sterilization were observed in any of the patients. All patients were followed up for a mean of 19 months (range: 12–60 months).

Conclusion: Single incision two port laparoscopic tubal ligation does not increase the risk of complications and appears safe. It provides better cosmetic outcomes and lower pain scores compared to conventional laparoscopy.

Keywords: Single incision laparoscopy, Tubal ligation, Conventional laparoscopy

Introduction

Minimally invasive approaches are currently standard in most surgical specialties. Single incision laparoscopic surgery (SILS) is the most recently developed method. It eliminates multiple port incisions and provides faster recovery with better cosmesis [1,2]. The first single incision laparoscopy was performed in gynecology for tubal ligation as a contraception method in the 1970s [2]. Then, ovarian cystectomies, myomectomies, even hysterectomy procedures were successfully performed with SILS all over the world [3-6]. Although less postoperative pain, better cosmesis and faster recovery are its main advantages over conventional laparoscopy and millions of women undergo tubal ligation for contraception worldwide each year, there is limited data on single incision-two port laparoscopic tubal ligation procedure in the literature. In Turkey, Taşdemir et al. [3] reported their experience of single incision two port laparoscopic tubal ligations on three patients. Our aim in this study was to compare the results of single-incision-two port laparoscopic tubal ligation and conventional three port laparoscopic tubal ligation.

Materials and methods

In this prospective study, 120 patients who wanted tubal ligation procedure as a contraceptive method were randomly allocated to single-incision-two port laparoscopic tubal ligation (Group 1) or three port conventional laparoscopic tubal ligation (Group 2) at two tertiary centers from April 2015 to January 2020. This study was approved by İstanbul Medipol University Faculty of Medicine Ethic Committee (01/2019/51-605). Written and signed informed consent was obtained from each patient. Demographic features of patients, operation time, blood loss, length of hospital stay, complications, postoperative pain score, conversion rate, satisfaction of cosmetic outcome, port site hernia and failure of sterilization were recorded and compared. All procedures were performed by two surgeons experienced in minimally invasive endoscopic surgery, who perform two hundred laparoscopic cases annually.

One hundred and twenty patients aged 31 to 49 years (mean: 41.5 (4.16) years) were randomly assigned to undergo single-incision-two port laparoscopic tubal ligation (group 1, n=60) or three port conventional laparoscopic tubal ligation (group 2, n=60) according to a computer-generated table of random numbers. First, power analysis was conducted with definitive measurements to determine the size of the ideal sampling. The effect size was calculated according to VAS score, as $d=0.80$. The sample size was calculated as thirty-nine for both groups with an error level of 5% and a power of 95%. The number of patient populations reached a minimum of sixty for each subgroup. Patients for whom anesthesia would pose a high risk (score > III, according to an American Society of Anesthesiologists [ASA] score), those with histories of abdominal surgery, diagnosed with endometriosis and who underwent laparoscopic tubal ligation procedures concomitant with other gynecologic procedures like ovarian cystectomies, myomectomies, or ectopic pregnancies were excluded from the study.

All patients were prepared similarly in a lithotomy position under general anesthesia. No prophylactic antibiotic was administered. Patients in Group 1 were operated as first published by Taşdemir et al. [3]. A one cm vertical skin incision was made in the umbilicus with a scalpel. Then, a five-millimeter trocar was inserted through the abdominal cavity with a five-millimeter 30-degree camera. The 30-degree Trendelenburg position was maintained; pneumoperitoneum up to 15 mm Hg pressure with carbon dioxide insufflation was assured. Afterwards, a second five-millimeter accessory port was introduced through the same skin incision on a different fascial plane, one centimeter away from the first trocar (Figure 1). A five-millimeter endoscopic monopolar scissor was introduced into this accessory trocar; the proximal and mid-portion of the tubes were coagulated and cut with monopolar diathermy bilaterally. After trocars were removed, fascia was sutured with an interrupted 1-0 Vicryl (Ethicon, Istanbul, Turkey) suture. Umbilical skin was restored subcutaneously with 3-0 Rapid Vicryl (Ethicon, Istanbul, Turkey) suture. Patients in Group 2 were operated with conventional three port laparoscopy. Similarly, a 30-degree camera port was inserted into the umbilicus and two five-millimeter accessory ports were inserted above the inguinal crest. The mid portion of the tubes were retracted with a forceps through accessory port and the proximal and mid-portion of the tubes were coagulated and cut bilaterally with monopolar diathermy through the other accessory port.

Figure 1: The view of two 5-mm trocars inserted into single umbilical incision



Patients' demographic features, body mass index (BMI), operation time (calculating from the first umbilical skin incision to the end of suturing the umbilical skin), amount of blood aspirated from the operation field to the suction machine with excluded intraperitoneal washing liquid, number of accessory ports needed, intraoperative complications, length of hospital stay, pain score and cosmetic outcomes were analyzed and compared. Postoperative pain was assessed according to a visual analogue scale (VAS) from 0 (no pain) to 10 (worst pain imaginable) on the postoperative sixth and twenty-fourth hours [8]. A standard analgesic protocol was implemented with the use of an intravenous nonsteroidal anti-inflammatory drug (tenoxicam, 20 mg) twice a day. An opioid analgesic (tramadol, 50 mg) was added when patients experienced no relief from pain. Satisfaction with cosmetic outcomes was evaluated through face-to-face interviews with all patients, assessed on a scale from 1 (lowest satisfaction) to 5 (highest satisfaction) three months after the operation.

Statistical analysis

We used SPSS® software, version 20.0 (IBM Corp;2011; Armonk, NY) to analyze the collected data, which

were summarized as mean (range) or median (range). Patient demographic data, operating times, and hospital stays were compared using the parametric t-test. A nonparametric Mann-Whitney U test was used to compare pain scores and cosmetic outcomes, and a Fisher exact test was used for comparing complications. A *P*-value of 0.05 was considered statistically significant.

Results

A total of 120 patients were enrolled in this study from April 2015 to January 2020. The patients' characteristics are presented in Table 1. The two groups were similar in terms of age, caesarean section histories, ASA scores, and BMI. Sixty single-incision-two port laparoscopic tubal ligation (group 1, *n*=60) and sixty conventional three port laparoscopic tubal ligation (group 2, *n*=60) procedures were successfully completed; there was no need to convert to open surgery in either groups. Two cases in group 1 and one case in group 2 required one extra port due to severe intraabdominal adhesions. However, it was not statistically significant (*P*=0.24).

Table 1: Patients' characteristics

Characteristic	Group 1	Group 2	<i>P</i> -value*
Age(years)	41.5(2.16)	40.5(3.12)	0.23
BMI (kg/m ²)	27.6(5.16)	28.4(4.58)	0.22
C/S (n)	2.1(2.26)	2.4(2.66)	0.31
ASA score	1.88(0.56)	1.76(0.48)	0.24

Values are presented as mean (standard deviation). * Paired t test was used, ASA: American Society of Anesthesiology, BMI: Body Mass Index

There were no complications during surgery such as bleeding, vessel, or bowel injury in either of the groups. Average blood loss was similar between the groups. Operating data are shown in Table 2. Operating time was significantly longer in group 2 compared with group 1 (38.5 minutes vs. 26.5 minutes; *P*=0.02). Higher pain scores were observed in group 2 versus group 1 at the 24th postoperative hours (*P*<0.05). Two umbilical port site infections in group 2 were treated with antibiotherapy. Port site hernia and failure of sterilization was not observed in any of the groups during a mean follow-up of 19 months (range, 12–60 months). Cosmetic outcome scores showed statistically significant differences between the groups (*P*<0.05). Patients in group 1 were more satisfied with the single incision into the umbilicus (Table 3).

Table 2: Operation data

Variable	Group 1	Group 2	<i>P</i> -value*
Operating time(min)	26.5 (2.16)	38.5(3.12)	0.02
Blood loss(ml)	107.6(5.16)	98.4(8.58)	0.14
Conversion	0	0	1.00
Need to extra port(n)	2	1	0.24

Values are presented as mean (standard deviation). *Paired t test was used.

VAS pain scores of patients in group 2 was significantly higher compared to group 1 at the sixth and twenty-fourth postoperative hours.

Correlation between operative time and VAS score was assessed. Pearson correlation test showed that the pain score correlated with operative time (*P*<0.001). Postoperative data are shown in Table 3.

Table 3: Postoperative data

Variable	Group 1	Group 2	<i>P</i> -value*
VAS**	3.25(1.16)	4.52(1.12)	0.031
VAS***	2.21(1.08)	3.82(2.14)	0.012
Narcotic analgesic use(n)	0	4	0.001
Hospitalization(day)	1.1(0.26)	1.4(0.66)	0.320
Cosmetic result	4.88(1.56)	3.16(0.98)	0.018

Values are presented as mean (standard deviation). * Mann Whitney U test was used, ** Sixth postoperative hour visual analogue scale, *** First postoperative day (24th hour) visual analogue scale

Discussion

Tubal ligation procedure accounts for about 10-40% of all contraceptive methods worldwide [7]. We performed at least one hundred laparoscopic tubal ligation procedures with three ports annually up to mid-2015 in our hospital. In this study, we tried to compare safety and efficacy of single incision two port laparoscopic tubal ligation with conventional three port laparoscopic tubal ligation. SILS provides better cosmesis, less trauma, less blood loss and less pain [4,6]. A single incision laparoscopic tubal ligation is an easier and less technically challenging procedure when compared with ovarian cystectomy, myomectomy, and hysterectomy procedures performed with single incision laparoscopy. The rapid development in medical technology has enabled surgeons to adopt laparoscopy rapidly. Even tubal ligation procedures are performed under local anesthesia with microlaparoscopy or office laparoscopy in some centers [7]. Laparoscopic tubal ligation is an effective birth control method. However, physicians should inform all couples about the rates of failure. We try to pay attention to coagulate and cut especially two portions of the tubes (the proximal and mid portion) bilaterally in both techniques. During a mean of 19 months follow up, we did not encounter failure of sterilization with either of the two methods. In a series of 1000 laparoscopic sterilizations performed with only one incision and electrocoagulation without cutting, the total failure rate was 1.6% [8]. The probable reason of failure after laparoscopic tubal ligation is incomplete transection, which causes recanalization after a while [8]. Studies showed that electrocoagulation offers slightly less failures when a substantial part of the tube or two segments are destroyed by experienced hands [9]. The mean age of the study population was 45 years with the range of 35 to 52 years in our study. Age is important for deciding on the contraceptive method as some young patients may regret this decision later. The methods for laparoscopic sterilization include silicone rubber rings, silastic band, spring clip and Filshie clip application, all of which offer a better chance of reversal comparative to laparoscopic electrocoagulation [9,10]. No patients regretted their decision in our study population. A significant concern about SILS is the risk of trocar site hernia [11]. It was reported as 2.2% in a randomized controlled trial including 1705 patients, while this rate was 0.7% in the conventional laparoscopic surgery group (odds ratio 2.26, 95 % confidence interval 1.00–5.08, *P*=0.05) [11]. The main advantage of single incision two port laparoscopic technique as performed in group 1 is that there is no need of using an access device like SILS port™ (Covidien, Mansfield, Massachusetts), R- Port™ (Advanced Surgical Concepts, Wicklow, United Kingdom), Octoport™ (Dalim, Seoul, Korea) and GelPort™ (Applied Medical, USA). Although the marketing of these new access devices allowed surgeons to use more than two instruments and an endoscope through the umbilical port only, the total cost of surgery and risk of umbilical site hernia increased significantly. In addition, single port laparoscopic surgery is more challenging due to limitations of triangulation and frequent collisions between instruments [12]. However, insertion of a second trocar 1 cm away from the optic trocar through a different fascial plane facilitates the triangulation of instrument in this technique. It also improves cosmetic outcomes,

as documented in Table 3. Deviation of the uterus contralaterally by an assistant with manual manipulation into the vagina will facilitate the visualization of the tubes. Hence, there is no need of inserting the third trocar for retraction of the tuba. If significant difficulty is encountered at any time during the surgery, an additional port should always be considered. Although less data is currently available about the single incision two port laparoscopic tubal ligation in the literature, the overall complication rate is low and the technique seems safe. Like gynecologists, general surgeons have used this technique since 1997 for cholecystectomy and appendectomy procedures [14-16]. Their studies also support the feasibility and safety of the procedure with no major complications reported.

Limitations

Our limitations include reflecting the experience of two centers only, and small number of cases. Also, feasibility and safety of the procedure depends on physician experience and skill in laparoscopy. SILS surgery may need more experience compared to conventional laparoscopic three port surgery.

Conclusion

Single incision two port laparoscopic tubal ligation does not increase the risk of complications and appears safe. It provides better cosmetic outcomes, which may be important for female patients. When it is performed by experienced surgeons, it is as successful and safe as conventional laparoscopic tubal ligation. However, further, multicenter, comparative studies with larger series are necessary to evaluate the safety and feasibility of this technique.

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