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Original Article

Tubal Anastomosis Surgery in A Public Hospital Operating as A Secondary Care Facility: One-Year Experience

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ABSTRACT

Objective: To describe the characteristics, management and treatment options of patients with a history of tubal sterilization who wish to become pregnant again and prefer tubal anastomosis (TA) surgery for this purpose, examine the factors involved in deciding on treatment options, describe our surgical technique and review our results.

Methods: Between January 2020 and January 2021, all women who underwent TA surgery with the mini-laparotomy approach in a high-density public hospital were retrospectively examined. After describing the surgical technique, demographic data, medical characteristics, peri- and postoperative features including pregnancy rates and outcomes of participants were retrospectively reviewed.

Results: After excluding five patients with missing data, two patients who underwent concomitant myomectomy and endometriosis surgery and one patient who refused to participate, 13 participants were included in the study. Eleven of these women became pregnant after TA surgery, while the overall pregnancy and live birth rates were 84.6% and 53.8%, respectively. No woman older than 40 years had a live birth.

Conclusion: Parallel to the rise in divorce rates and subsequent new marriages in our country, we are increasingly facing with women who have undergone tubal sterilization and wish to become pregnant again. In vitro fertilization (IVF) should be considered as an option for this group of patients, especially for those over 40 years of age, as TA surgery carries some surgical and anesthesiologic risks. However, even in times of significant advances in assisted reproductive techniques, TA still plays an important role with satisfactory results in restoring fertility after tubal ligation. Tubal anastomosis via a mini-laparotomy with pure saline pertubation is a safe, inexpensive and effective option for such patients, especially for couples with limited financial resources or for couples who are planning more than one pregnancy and do not wish to undergo IVF for religious reasons.

INTRODUCTION

Bilateral tubal ligation is the most commonly preferred method for couples seeking permanent sterilization after their family is complete.[1] Traditionally, this procedure involves the occlusion of both fallopian tubes with clips, tape or electrocautery or even a bilateral partial or total salpingectomy, either by mini-laparotomy, laparoscopy or during a cesarean delivery.[2] On the other hand, the hysteroscopic method of tubal sterilization, which was not very popular in our country, was used for a limited time in some countries, but then abandoned due to some serious complications.[3] Recently, vaginal transluminal endoscopic surgery with natural orifice (vNOTES) has gained popularity in both benign and malignant gynecological surgery, even in elderly and obese patients, and seems to be one of the most commonly chosen methods for tubal sterilization in the near future.[4-6]

The 2021 Committee of the American Society of Reproductive Medicine stated that microsurgical anastomosis is the recommended technique for tubal ligation reversal.[7] In addition, tubal anastomosis (TA) has been shown to be a more cost-effective alternative to in vitro fertilization (IVF) in women under the age of 41.[8] Although tubal sterilization is a highly effective, easy to perform and well-tolerated method of contraception, about two to three out of 10 patients regret after the procedure.[9,10] Among young people, this rate is as high as 40%.[11] Many of these women come to the clinics with the desire to regain their

fertility. Alternative methods for future fertility after a previous tubal ligation or segmental resection include IVF and TA. To this end, studies have been conducted comparing TA surgery and IVF, but the ideal method has not yet been determined and there are no established guidelines for the treatment of these women.[12,13] As the regret rate after tubal sterilization is high, research on the most appropriate treatment methods for patients with a previous tubal sterilization who wish to regain their fertility continues to be of interest.

Despite recent advances in surgical techniques, including assisted reproductive technologies and minimally invasive principles, many questions about the side effects and efficacy of TA surgery remain unclear. Furthermore, it is not yet clear which route is the best for this surgery, as each route has advantages and disadvantages. To fill some of the gaps in this area and to share our experiences and findings, we have conducted this study in which we report on a single surgeon's experience of TA surgery by mini-laparotomy over a one-year period.

MATERIALS AND METHODS

Study Protocol

We conducted a retrospective cohort study of women with previous tubal sterilization who underwent TA surgery by mini-laparotomy between January 1, 2020, and January 1, 2021, in a public hospital that functions as a high-volume secondary care facility and admits patients from outside the city, mostly from neighboring provinces. After approval of the study protocol by the Medical Research Ethics Committee (Date: 13.09.2022, decision no: E-60116787-020-258614), the data were retrospectively examined by scanning the patient files and the hospital's information processing system.

The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent for the surgical procedure was obtained from all patients after they had been informed about the procedure, including its potential benefits, disadvantages and risks. All participants gave written informed consent for both participation and publication prior to their participation in the study.

Patient Selection, Participant Characteristics, Data Collection and Definitions

All women with a previous bilateral tubal ligation for permanent sterilization who wanted to become pregnant again and who preferred TA surgery to IVF were examined. Anatomic assessment and imaging of the uterus and adnexa was performed in all women using the same ultrasound machine [Voluson E6 (General Electric Medical Systems, Milwaukee, WI, USA) with a transvaginal imaging probe].

All participants underwent hysterosalpingography and bilateral tubal occlusion was confirmed prior to surgery. Women with a cause of infertility other than tubal factor, additional male infertility, contraindications to surgery and general anesthesia, suspected gynecologic malignancy, women who required concurrent gynecologic surgery, including surgery for uterine fibroids, ovarian cysts, endometriomas, and endometriosis that could affect the patient's fertility, and patients with missing data were excluded.

Demographic and medical data, including age, body mass index (BMI), comorbidities, obstetric and gynecologic history, previous intra-abdominal surgery, duration of surgery, peri- and/or postoperative complications, visual analog scale (VAS) pain scores at the 12th, and 24th postoperative hours were collected. Details about the functional tubal patency which was assessed by postoperative hysterosalpingography performed after the patients' 3rd menstrual cycle (Fig. 1), and about the subsequent pregnancy were obtained either during follow-up examinations or in a telephone interview. The data for subsequent pregnancies were recorded over a period of at least three years postoperatively.

The VAS is a numerical rating scale used to measure some non-categorical variables that cannot be quantified numerically. Participants rated their postoperative pain by giving a number corresponding to their pain intensity on a scale divided into 10 equal parts from zero (no pain) to 10 (intolerable pain). The duration of the operation was the time interval between the skin incision and the closure of this incision.

Surgical Procedure

All operations were performed with a mini-laparotomy approach in lithotomy position after general anesthesia with intratracheal intubation. For antibiotic prophylaxis, a single 1-g dose of cefazolin was administered intramuscularly within 60 minutes before the incision as standard. Antisepsis of the abdomen and vagina was achieved by applying a 1% povidone-iodine solution. The cervix was visualized by placing two vaginal retractors and grasped with a teneculum at 11 o'clock. First, a saline pertubation kit was prepared for tubal patency test. The kit consists of a 10 French silicone-coated latex Foley catheter (Hitec Medical, Minhang, Shangai, China), a three-way stopcock (Poly Medicure Ltd, Ballabhgarh, Faridabad, India), a Y-cannula (Plasti-med Medical, İstanbul, Türkiye) cut to a length of 50 cm, and a 60-mL syringe (Ayset Medical, İstanbul, Türkiye), all connected to each other (Fig. 2). The tubal patency test kit was inserted through the cervical canal and its balloon was filled with 5 mL of saline to prevent displacement from the uterine cavity. In accordance with the rules of antisepsis, the patient was placed in the supine position after the tubal patency test kit was passed upwards between the patient's legs and attached to the surgical sheets for ease of handling (Fig. 2). Once the proper location of the mini-laparotomy incision was determined, the skin and subcutaneous tissue were cut. The abdominal folds were properly crossed and the abdominal cavity was entered. After a general inspection of the pelvis and

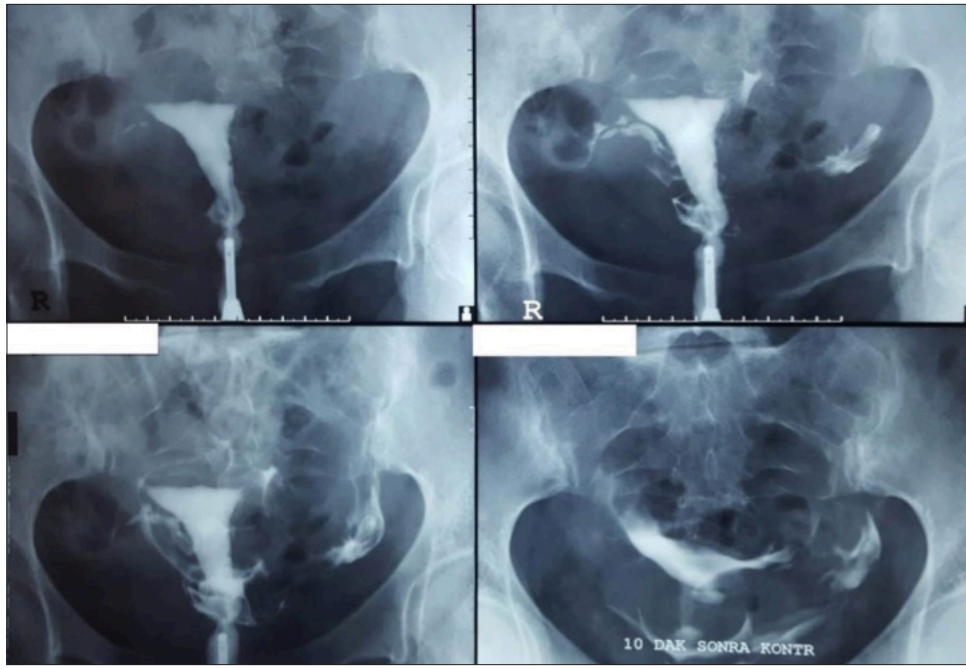

Figure 1. Postoperative hysterosalpingogram after the third menstrual cycle of the patient with bilateral functional tubal patency. There is no intracavitary filling defect or excessive filling. Bilateral tubal patency and normal distribution of the contrast medium in the pelvis are visible.

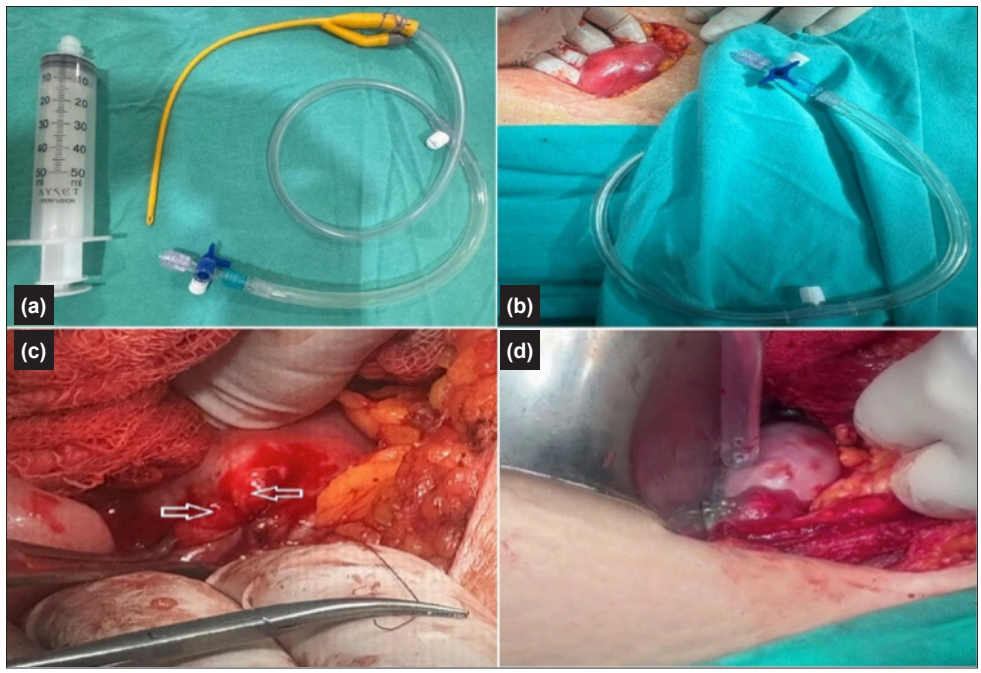

Figure 2. Preparation of the saline pertubation kit and steps of the procedure. **(a)** The components of the saline pertubation kit. **(b)** Placement of the kit near the surgical area. **(c)** Distal and proximal tubal ends after approximation by a continuous suture of the separated mesosalpinges. **(d)** Confirmation of patency of the fallopian tubes by saline with air bubbles flowing from the fimbriae.

assessment of the bilateral relationships between the ovaries, the fallopian tubes and uterus were examined. The proximal and distal ligated ends of the tubes were identified, transected and the lumens were exposed and prepared for anastomosis. Proximal patency was confirmed by direct observation of the saline injected through the kit flowing through the proximal tubal ends. Hemostasis was achieved, if necessary, by bipolar cauterization. The separated mesosalpinx ends were sutured continuously with a 5-0 poliglactin suture attached to a 16-mm semicircular

needle with a round body and pointed tip [Vicryl (Ethicon, Somerville, New Jersey, USA)] until the separated distal and proximal lumens were close together (Fig. 2). Mucosal and muscular anastomoses were created by interrupted sutures with a blunt Vicryl suture 5-0 at the 12, 3, 6 and 9 o'clock positions. The serosal layers were approximated with a number of interrupted sutures. Finally, tubal patency was confirmed when saline and air bubbles was seen flowing out of the fimbriae (Fig. 2).

Statistical Analysis

The variables were analyzed using visual (histogram, probability plots) and analytical methods (Kolmogrov-Simirnov/Shapiro-Wilk test) to determine whether they were normally distributed or not. Descriptive analyzes were presented using means and standard deviations for normally distributed variables. For the non-normally distributed numerical data, descriptive analyzes were presented using medians and quartiles (first quartile-third quartile).

RESULTS

In this retrospective study, 18 patients were identified in order to collect data. However, a total of five patients were excluded for whom data was missing and who could not be contacted (2), who underwent concurrent myomectomy and endometriosis surgery (2) and who had not consented to participate in the study (1). Finally, 13 participants were included in the study.

The surgical techniques used for tubal sterilization were Pomeroy's method in 10 participants and laparoscopic tubal electrocoagulation in three women. Participants' age at TA and BMI ranged from 33 to 42 years and 25 to 38.2 kg/m2 with a mean of 38 (33-42) years and 30.9±4.71 kg/m2. The reasons for regretting tubal ligation were: 15.4% (2/13) the desire to have children again, 15.4% (2/13) the death of a child and 69.2% (9/13) the desire for children from a new marriage after a divorce. The reasons for choosing TA over IVF were 76.9% (10/13) high cost and 23.1% (3/13) religious beliefs. All participants had already undergone intra-abdominal surgery, including cesarean section (10/13), laparoscopic tubal electrocoagulation (3/13), appendectomy (3/13) and cholecystectomy (1/13). The mean duration of surgery was 51±4.9 minutes. Bilateral TA could be performed in all patients. There were no intra- and/or postoperative complications. The median VAS score at postoperative 12 hour was 5 (5-6), while the mean VAS score at postoperative 24 hour was 4.5±0.78. The demographic and clinical characteristics of the study population are summarized in Table 1.

Overall, 84.6% (11/13) of women had bilateral and 15.4% (2/13) of women had unilateral functional tubal patency at hysterosalpingography three months after surgery, while 84.6% (11/13) of women were able to conceive during the follow-up period after TA surgery. Of these, 9/13 of the first pregnancies were intrauterine pregnancies, 1/13 were ectopic pregnancies and 1/13 were biochemical pregnan-

Table 1. Demographic data, intra- and postoperative characteristics and pregnancy outcomes of the participants

Patient Number	Age at TA (years)	Age at TL (years)	BMI (kg/m²)	Obstetric History	Stated reason for TL regret	Reason for choosing TA over IVF	Previous Intra-abdominal Surgery	Duration of Surgery (minutes)	VAS at 12th hour	VAS at 24th hour	Tubal patency*	Subsequent obstetric information#
1	35	32	27.4	$G_3P_2A_1$	Loss of children	Cost	Appendectomy, C/S	48	5	4	Bilateral	One live birth
2	42	36	35.4	$G_3P_3A_0$	Remarriage	Cost	C/S	55	5	4	Unilateral	No pregnancy
3	36	35	26.6	$G_1P_1A_0$	Desire for another pregnancy	Religious	L/S BTL	50	6	5	Bilateral	Two live births
4	33	30	25.0	$G_3P_2A_1$	Remarriage	Cost	C/S	45	5	5	Bilateral	Two live births
5	42	35	38.0	$G_3P_3A_0$	Remarriage	Religious	C/S	48	7	4	Bilateral	One miscarriage
6	34	30	25.6	$G2P_2A_0$	Loss of children	Cost	L/S BTL	55	5	4	Bilateral	One live birth
7	37	33	28.4	$G4P_3A_1$	Remarriage	Cost	C/S	50	5	3	Bilateral	One live birth
8	39	35	30.2	$G_3P_3A_0$	Remarriage	Religious	L/S BTL	52	5	5	Bilateral	One biochemical pregnancy
9	38	33	28.2	$G_3P_3A_0$	Remarriage	Cost	C/S	48	6	6	Bilateral	One live birth
10	40	36	33.5	$G2P_2A_0$	Remarriage	Cost	Cholecystectomy	60	7	5	Unilateral	No pregnancy
11	35	30	37.2	$G_3P_3A_0$	Remarriage	Cost	Appendectomy, C/S	60	6	4	Bilateral	Two miscarriages
12	39	36	29.4	$G_3P_2A_1$	Desire for another pregnancy	Cost	C/S	45	5	5	Bilateral	One tubal pregnancy
13	38	34	37.2	$G_3P_2A_1$	Remarriage	Cost	Appendectomy, C/S	52	5	4	Bilateral	One live birth

A: Abortus; BMI: Body-mass index; C/S, cesarean section; G, gravidity; IVF: In vitro fertilization; kg/m², kilograms/square meter; L/S BTL: Laparoscopic bilateral tubal ligation; P: Parity; TA, tubal anastomosis; TL: Tubal ligation; VAS: Visual analogue scale; *: A postoperative hysterosalpingogram was performed after the 3rd menstrual cycle to determine the status of tubal patency. #: Pregnancy information was available for at least 36 months.

cies. While 7/9 of the intrauterine pregnancies resulted in a live birth, 2/9 ended in a miscarriage. In addition, three of the patients had two live births each. In the analysis using age 40 as a cut-off point, which is an important factor in fertility studies, pregnancy and live birth rates were 100% (10/10) and 70% (7/10) for women under 40 and 33.3% (1/3) and 0% (0/3) for women aged 40 and over.

DISCUSSION

The history of tubal sterilization is quite old and the first modern tubal ligation was performed by Lungren in 1880.[14] Since its introduction, bilateral tubal ligation has been one of the most preferred methods for couples who want a simple, safe, convenient and highly effective permanent contraceptive method that can be performed at the same time as a cesarean section or at any time by minimally invasive surgical approaches. Although many couples are satisfied with the method, the regret rate after the procedure is quite high.[9-11] Many confounding factors and reasons for regret after tubal ligation have been reported, such as young age at surgery, marriage after divorce, loss of a child, a range of false religious or cultural beliefs, menstrual disorders, female sexual dysfunction, anxiety and depression.[15-17] The relationship between menstrual disorders and regret appears to be contradictory. One study found that women who experienced regret were more likely to complain of menstrual disorders.[17] Another study found no difference, while another study found no link between regret and menstrual disorders.[18,19] The correlation between regret for post tubal sterilization and menstrual disorders can be influenced by various components such as psychological state, culture, geographical region, ethnicity and even religion. As for the relationship between regret and sexual dysfunction, one study found an association between regret and sexual dysfunction, while another study showed that tubal ligation had an enhancing effect on sexual function when those who regretted not being able to have children were excluded.[20,21] Therefore, when women present to our clinic for TA, we first ask about the reason or reasons for the regret, and if the reason is other than the desire to have children, we first implement solutions for the reason or reasons (e.g., a psychiatric evaluation for anxiety or depression or planning for the diagnosis and treatment of menstrual disorders). In our study, the main reason for regret in all participants was a second marriage and the other reasons were the loss of a child and the desire for a new pregnancy. In addition, studies have shown that having a tubal ligation at a young age is the most important factor for regret, which is consistent with our findings.[15,22]

Another important point to consider before deciding to undergo a TA is the fact that this procedure, like any surgical intervention, carries some risks. Therefore, IVF should be offered as an option and its effectiveness as well as its advantages and disadvantages should be explained. In a study of patients who wished to have a child after tubal sterilization, live birth rates were significantly higher in the TA group than in the IVF group.[13] Malacova et al.[23] found that women undergoing IVF after tubal sterilization and age-matched, subfertile IVF control patients had similar live birth rates. Similarly, Chua et al.[24] found that pregnancy and live birth rates were significantly higher in the TA group than in the IVF group. According to a recent review, pregnancy rates after TA varied in a wide range between 42 and 69%, which could be due to the different methods used.[25] Compared to IVF, TA surgery offers higher live birth rates and is much more cost-effective, especially when performed via mini-laparotomy. On the other hand, there is an increased risk of multiple pregnancy with IVF and a risk of ectopic pregnancy with TA.[26] In addition, IVF offers the possibility of one-time pregnancy in one cycle, while TA offers the possibility of more than once.[25] In our study, six of the participants chose TA instead of IVF because they could not afford IVF, while seven of them wanted to conceive more than once and three of them refused IVF for religious reasons. On the other hand, pregnancy and live birth rates were found to be lower with TA than with IVF in women aged 40 and over, the age at which fertility declines.[8,24] Therefore, IVF should be preferred in this age group.

There are currently three approaches available for TA: laparotomic, laparoscopic and robot-assisted surgery. A recent review of several studies comparing these methods found no statistically significant difference, with pooled pregnancy rates of 62.4%, 67.1% and 66.6% for laparotomy, laparoscopic and robotic surgery, respectively.[27] Rates for ectopic pregnancies were also similar.[27] According to the results of this study, the overall pregnancy rate after TA surgery was 65.3% regardless of the type of procedure, which is a very good rate for those who prefer TA surgery.[27] The general trend is to perform tubal anastomosis by laparoscopy or robot-assisted surgery, as both procedures promise a shorter recovery time, less postoperative pain and better cosmetic results. But these two methods also have disadvantages. Firstly, both techniques require a high level of expertise, particularly in endoscopic suturing. Besides, these two methods, especially robot-assisted surgery, are more expensive than laparotomy. Since this procedure uses sutures with very thin and small needles, we think that the possibility of losing this needle during endoscopic surgery in the pelvic area is higher than with the mini-laparotomy method, which can complicate the surgical procedure.

On the other hand, methylene blue is a frequently used dye in chromopertubation. Rare but serious complications such as inflammatory peritonitis, anaphylaxis, pulmonary edema and methemoglobinemia due to extravasation into lymphatic vessels during chromopertubation have been reported in case reports.[28-30] Studies have shown that these complications occur especially when methylene blue is used in high concentrations and/or in cases with increased pelvic inflammation, such as chronic pelvic inflammatory disease and pelvic tuberculosis.[30] Since the passage of pure saline through the fimbrial ends is already

visible enough, unlike other studies, we used a method called pure saline pertubation, which allows us to avoid the complications of using color pigments, as opposed to chromopertubation, which uses color pigments such as methylene blue to assess tubal patency.

Tubal anastomosis surgery can achieve satisfactory results with high fertility rates in young women, while IVF may be more effective in older women. The surgical approach chosen for reversal of sterilization can be laparotomic, laparoscopic or robotic. The patient's age is very important in the decision-making process, but the risks of the procedure, the risk of an ectopic pregnancy, the costs, the type of previous tubal sterilization and the expected length of the remaining fallopian tube should also be considered and discussed with the patient.

The main limitations of the present study are its retrospective nature and small sample size, which is mainly due to the limited time period covered by the study. The major strengths are the fact that the study was conducted in a single referral hospital where such operations were performed by the same experienced surgeon and the relatively long postoperative follow-up period for pregnancy outcomes.

Conclusion

At a time when there have been significant advances in assisted reproductive techniques, tubal anastomosis still has an important place in restoring fertility after tubal ligation. Tubal anastomosis via a mini-laparotomy with pure saline pertubation is a safe and effective surgical approach for patients with a history of bilateral tubal ligation who wish to conceive again.

Ethics Committee Approval

The study was approved by the Pamukkale University Ethics Committee Ethics Committee (Date: 13.09.2022, Decision No: E-60116787-020-258614).

Informed Consent

Retrospective study.

Peer-review

Externally peer-reviewed.

Authorship Contributions

Concept: M.I.D.; Design: M.I.D.; Supervision: M.I.D.; Materials: B.S., O.K.; Data collection &/or processing: M.I.D., B.S.; Analysis and/or interpretation: P.Y.; Literature search: M.I.D., P.Y., O.K.; Writing: M.I.D.; Critical review: P.Y.

Conflict of Interest

None declared.

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İkinci Basamak Sağlık Kurumu Olarak Çalışan Bir Devlet Hastanesinde Tubal Anastomoz Cerrahisi: Bir Yıllık Deneyimlerimiz

Amaç: Çalışmanın amacı, tubal sterilizasyon öyküsü olup tekrar çocuk sahibi olmak isteyen ve bunun için tubal anastomoz (TA) cerrahisini tercih eden hastaların özelliklerini, yönetim ve tedavi seçeneklerini tanımlamak, tedavi seçiminde etkili faktörleri irdelemek ve cerrahi tekniğimizi tanımlayarak, sonuçlarmızı gözden geçirmekti.

Gereç ve Yöntem: Ocak 2020 ile Ocak 2021 tarihleri arasında, hasta yoğunluğunun fazla olduğu ikinci basamak olarak çalışan bir devlet hastanesinde mini lapatoromi yöntemiyle TA cerrahisi yapılan tüm kadınlar geriye yönelik olarak incelendi. Cerrahi teknik tanımlandıktan sonra katılımcıların demografik özellikleri, tıbbi özellikleri, gebelik oranları ve sonuçları da dahil olmak üzere ameliyat öncesi ve sonrası özellikleri retrospektif olarak analiz edildi.

Bulgular: Verileri eksik olan beş hasta, myomektomi ve endometriozis cerrahisinin birlikte uygulandığı iki hasta ve katılmayı reddeden bir hasta dışlandıktan sonra, 13 katılımcı çalışmaya dahil edildi. Tubal anastomoz sonrası süreçte katılımcılardan 11'inde gebelik elde edilebilirken, genel gebelik ve canlı doğum oranları sırasıyla %84.6 ve %53.8 olarak bulundu. Kırk yaş ve üzerindeki hiçbir kadında canlı doğum elde edilemedi.

Sonuç: Ülkemizdeki boşanma oranlarının ve buna bağlı olarak da yeniden evliliklerin artışına paralel olarak, tubal sterilizasyon yaptırmış olup sonra yeniden çocuk sahibi olmak isteyen kadınların sayısı giderek artmaktadır. Tubal anastomoz bazı cerrahi ve anesteziyolojik riskler taşıdığından, özellikle 40 yaşın üzerindeki hasta grubu için *in vitro* fertilizasyon (İVF) bir seçenek olarak düşünülmelidir. Bununla birlikte, yardımcı üreme tekniklerinde önemli gelişmelerin yaşandığı günümüzde bile TA, tüp ligasyonu sonrası doğurganlığın geri kazanılmasında tatmin edici sonuçlarla hala önemli bir rol oynamaktadır. Mini-laparotomi yoluyla salin pertubasyonlu tubal anastomoz, bu tür hastalar için, özellikle de birden fazla gebelik planlayan, bazı inançlar nedeniyle İVF'yi istemeyen ve sınırlı mali kaynaklara sahip çiftler için güvenli, ucuz ve etkin bir seçenektir.

Anahtar Sözcükler: Bilateral tubal ligasyon; in vitro fertilizasyon; tubal anastomoz; tubal desterilizasyon; tubal rekanalizasyon; tüplerin açılması.