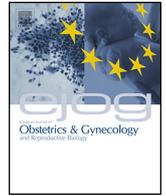




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Full length article

## The pregnancy rate of infertile patients with proximal tubal obstruction 12 months following selective salpingography and tubal catheterization



Krzysztof Pyra<sup>a</sup>, Maciej Szmygin<sup>b,\*</sup>, Weronika Dymara-Konopka<sup>c</sup>, Anna Zych<sup>d</sup>, Michał Sojka<sup>e</sup>, Tomasz Jargiełło<sup>f</sup>, Bożena Leszczyńska-Gorzelałak<sup>g</sup>

<sup>a</sup> Department of Interventional Radiology and Neuroradiology, Medical University of Lublin, Jaczewskiego 8 Str., 20-954, Lublin, Poland

<sup>b</sup> Department of Interventional Radiology and Neuroradiology, Medical University of Lublin, Jaczewskiego 8 Str., 20-954, Lublin, Poland

<sup>c</sup> Department of Obstetrics and Perinatology, Medical University of Lublin, Jaczewskiego 8 Str., 20-954, Lublin, Poland

<sup>d</sup> Student's Scientific Association at the Chair and Department of Obstetrics and Perinatology, Medical University of Lublin, Jaczewskiego 8 Str., 20-954, Lublin, Poland

<sup>e</sup> Department of Interventional Radiology and Neuroradiology, Medical University of Lublin, Jaczewskiego 8 Str., 20-954, Lublin, Poland

<sup>f</sup> Department of Interventional Radiology and Neuroradiology, Medical University of Lublin, Jaczewskiego 8 Str., 20-954, Lublin, Poland

<sup>g</sup> Department of Obstetrics and Perinatology, Medical University of Lublin, Jaczewskiego 8 Str., 20-954, Lublin, Poland

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### ABSTRACT

**Objective:** To assess the efficacy of selective salpingography (SSG) with additional tubal catheterization (TC) among infertile patients diagnosed with PTO and analysis of reproductive outcome.

**Study Design:** Retrospective cohort study.

**Results:** Of a total of 399 tubes with confirmed proximal tubal occlusion, 383 successfully restored their patency resulting in 96 % technical success rate. Thirty-five percent of oviducts that had their patency restored was treated with SSG and 65% required additional TC.

Reproductive outcomes at minimum 12 months following the treatment were collected by a telephone survey. 21/221 women were lost to follow up. Out of remaining 200 patients with at least one patent tube, 80 patients conceived which resulted in 40 % overall pregnancy rate.

**Conclusion:** Selective salpingography and tubal canalization offer patient-friendly, minimally invasive and cost-effective alternatives to tubal microsurgery and IVF-ET in women with tubal occlusion with very high technical success rate and promising clinical results which depend also on the complexity of couple infertility. Specific indications and limitations make a careful assessment of fallopian tubes and comprehensive evaluation of partners' reproductive situation prior to therapy an absolute requirement.

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### Introduction

Tubal factor is credited with up to 30 % of the etiology of female infertility [1]. From this group about 10–25 % of women are diagnosed with proximal tubal occlusion (PTO) [2]. Most common causes of PTO include pelvic inflammatory disease, endometriosis and salpingitis isthmica nodosa [3]. Moreover, several anatomical and histological conditions (small caliber of the tube, its prominent

muscle layer or disrupted ciliated cells proportion in the epithelium) may lead to PTO [4]. Finally, hormonal factors resulting in dysfunction of utero-tubal junction inducing mechanical blockage of the fallopian tubes [5]. Therefore, assessment of the nature of tubal disease remains crucial in treatment of PTO.

Hysterosalpingography (HSG) and laparoscopic chromoperturbation are well established methods in evaluation of tubal patency. Due to high false positive rates after the HSG, the surgical option became a gold standard, especially due to its comprehensive assessment of the pelvis and intrauterine cavity [6]. However, costs of the procedure as well as risks of anesthesia and surgery cause many patients to choose HSG as a first-line approach [7]. Selective salpingography (SSG) is another useful and low-invasive method used for assessment of tubal patency. According to Woolcott et al. it is a better diagnostic test of PTO than laparoscopic means [8].

\* Corresponding author.

E-mail addresses: [k.pyra@poczta.fm](mailto:k.pyra@poczta.fm) (K. Pyra), [mszmygin@gmail.com](mailto:mszmygin@gmail.com) (M. Szmygin), [weronika.dymara@gmail.com](mailto:weronika.dymara@gmail.com) (W. Dymara-Konopka), [annazych93@gmail.com](mailto:annazych93@gmail.com) (A. Zych), [michalsojka@op.pl](mailto:michalsojka@op.pl) (M. Sojka), [mst@radiology.com.pl](mailto:mst@radiology.com.pl) (T. Jargiełło), [b.leszczyńska@umlub.pl](mailto:b.leszczyńska@umlub.pl) (B. Leszczyńska-Gorzelałak).

Several methods (microsurgical, radiological and hormonal treatments, IVF techniques) have been described to overcome PTO [9–11]. All of them have their advantages and limitations therefore final decision concerning the treatment should always be made after taking many different variables under consideration when counseling patients with respect for their individual preferences.

The aim of the study was to evaluate the efficacy of selective salpingography (SSG) with additional tubal catheterization (TC) among infertile patients diagnosed with PTO and analysis of reproductive outcome.

## Materials and methods

In this single-center prospective study we analyzed records of patients referred for SSG and TC between January 2012 and January 2019. On admission, fertility and medical history of both patient and her partner were collected. They gave informed consent and asseverated that they had restrained from sexual intercourse since the date of menstruation until the procedure, in order to avoid pregnancy. All procedures were carried out in the proliferative phase of the menstrual cycle. All patients received antispasmodic drug (Papaverine) together with analgesic treatment (Ketoprofen and/or Paracetamol and/or Morphine) before or additionally during the procedure, as well as they were undergoing a course of antibiotics (Doxycycline 100 mg orally twice a day for 5 days). Before discharge, patients completed the visual analogue score of pain (VAS 1–10) to evaluate discomfort level during the procedure and answered a question about possible repetition if needed.

Information regarding the reproductive outcome at minimum 12 months following the procedure was collected by a telephone survey or direct contact with the patient. The institutional review board approved the study. Consent for publication was obtained for every individual person's data included in the study.

### Inclusion criteria

Exclusively patients with obstruction of both fallopian tubes or the only tube they possessed after having undergone a salpingectomy, diagnosed with HSG and/or laparoscopy were eligible for further investigation. Minimal duration of infertility was 12 months prior to the procedure. Only patients between 18 and 45 years of age were enrolled.

### Exclusion criteria

Women with unilateral tubal obstruction but the other tube being patent, diagnosed prior or during the procedure were excluded from the study to avoid false positive clinical outcome with pregnancy coming from primarily patent oviduct. Patients with incomplete data, unwilling to respond to reproductive survey and patients lost in the follow-up were also excluded from the study. Patients with partners diagnosed with severe oligospermia (concentration of less than  $5 \times 10^6$  sperm/mL) were excluded from the study. Patients in whom infertility was also due to other causes were excluded from the study.

## Procedures

### Hysterosalpingography

Following the disinfection procedure, the vagina was dilated, the external cervical os was localized and the 12 Fr catheter was introduced into cervical canal and uterine cavity. Afterwards, the balloon was filled with contrast in order to ensure uterine cavity tightness and achieve appropriate pressure. Then the catheter and

gynecological forceps were pulled simultaneously and contrast medium injected under the fluoroscopy control.

### Selective salpingography

SSG was performed with the 5 F Kumpe catheter (Cook, Bloomington, IN) directed to and abutted against the inner fallopian tube ostia by tactile sensation. Its position was controlled under fluoroscopy and if correct, contrast medium was injected and its passage with peritoneal spill or evidence of either proximal or distal occlusion were assessed by at least two independent observers.

### Tubal catheterization

TC was performed subsequently during the same procedure by radiologically guided tubal catheterization and guidewire (Terumo, Tokyo, Japan) recanalization. Control contrast injection confirming tubal patency was performed (Fig. 1).

## Results

### Demographic results

The final group included 248 women without any patent tube diagnosed with HSG in 38 % (94/248) and HSG and laparoscopy in 62 % (154/248). The average age of patients was  $34.4 \pm 4.7$  years and the mean duration time of infertility  $3.6 \pm 2.2$  years. Fifty-six percent were diagnosed with primary infertility. A large group of patients had medical history of comorbidities: endocrinopathies and endometriosis being most common ones (44.8 % and 27.4 % respectively). Over 30 % of patients had history of pelvic surgical procedures. Eighteen patients (7%) reported infrequent ovulations and 6 (2%) anovulation. Male factor (oligospermia) was reported in 20 % of cases (50 patients' partners). It ranged from mild (10–15 million sperm/mL in 12 patients) to moderate (5–10 million sperm/mL in 38). Additional 10 men were diagnosed with varicoceles. Demographic information is presented in Table 1.

### Technical results

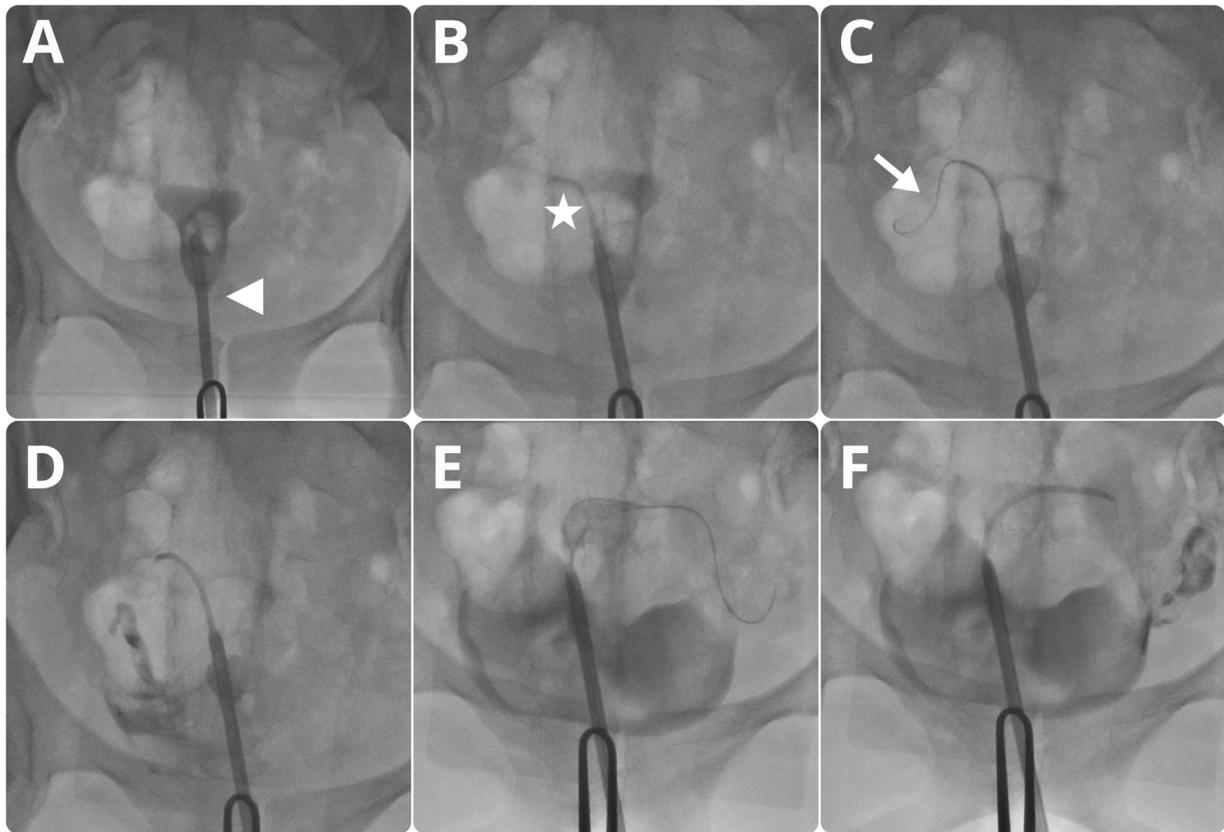
Two hundred seven patients (83 %) had bilateral (BTO - first group) and 41 patients (17 %) unilateral tubal occlusion (UTO - second group) in the only tube they possessed.

From the first group, in 52/207 patients SSG was sufficient to restore patency in both tubes, while 144/207 patients required SSG followed by active TC in at least one tube. The SSG and SSG + TC procedure resulted in bilateral open tubes in 162 (78.3 %) patients and unilateral open tube in 34 (16.4 %) patients making 196/207 from this group eligible for conception. There were 11/207 patients in whom we did not restore patency in any tube - in 8 due to bilateral distal occlusion/hydrosalpinx, in 3 technical problems occurred. In the group which resulted in unilateral patency only, 27 presented distal occlusion or hydrosalpinx of one tube and in 7 technical difficulties were encountered.

In the second group, 3/41 (7.3 %) got their unique fallopian tube patent with SSG alone and 22/41 (53.7 %) patients required TC. Thirteen patients (31.7 %) revealed blockage at fimbrial end or hydrosalpinx and in 3 cases (7.3 %) procedural failure was observed.

Detailed technical outcome in both groups is presented in Table 2.

A total of 399 tubes with confirmed proximal tubal occlusion - fallopian tubes with fimbrial blockage/hydrosalpinx were excluded from this analysis (43 in BTO-group and 13 in UTO-group) - were treated. From this 383 successfully restored their patency



**Fig. 1.** A – initial on-table HSG performed from 12 F catheter (white triangle) showing bilateral proximal tubal occlusion in a 31-year old female patient with primary infertility. B – selective salpingography of the right fallopian tube performed with the 5 F catheter (white star) directed to and abutted against the inner fallopian tube ostia. C – catheterization of the right fallopian tube with 0.035" guide wire (white arrow). D – control contrast injection confirming patency of the right tube (peritoneal contrast spill). E – selective catheterization of the left fallopian tube. F – control contrast injection confirming patency of the left tube.

**Table 1**  
Demographic data of patients.

Patients	N = 248	%
Mean age (years)	34.4 ± 4.7	
Duration of infertility	3.6 ± 2.2	
Type of infertility		
Primary	139/248	56 %
Secondary	109/248	44 %
Diagnostic method		
HSG	94/248	38 %
HSG and Laparoscopy	154/248	62 %
Medical history		
Endocrinopathies		
Hypothyroidism (including Hashimoto disease)	62/248	25 %
Diabetes mellitus	36/248	15 %
Hiperprolactinemia	13/248	5 %
Endometriosis	68/248	27 %
Fibroids	29/248	12 %
Uterine Congenital Malformation	7/248	3 %
Infrequent ovulation	18/248	7 %
Anovulation	6/248	2 %
History of pelvic surgical procedure		
Ectopic pregnancy	52/248	21 %
Other	25/248	10 %
Male factor		
Oligospermia	50/248	20 %
Mild (10–15 million sperm/mL)	12/50	24 %
Moderate (5–10 million sperm/mL)	38/50	76 %
Varicocele	10/248	4 %

resulting in 96 % technical success rate. Thirty-five percent of oviducts that had their patency restored was treated with SSG (135/383) and 65 % required additional TC (248/383). Technical

problems included: unvisualised ostium, mechanical obstacle constituted by myoma or endometrial polyp and unsuccessful catheterization. There was one case of vasovagal response. We observed intramural position of the catheter and intravasation of contrast medium to uterine venous plexus in two patients. One patient refused to cooperate after recanalization of the first tube. In one case oviduct perforation occurred. Overall outcome of SSG and TC and reasons of technical failure are presented in Table 3.

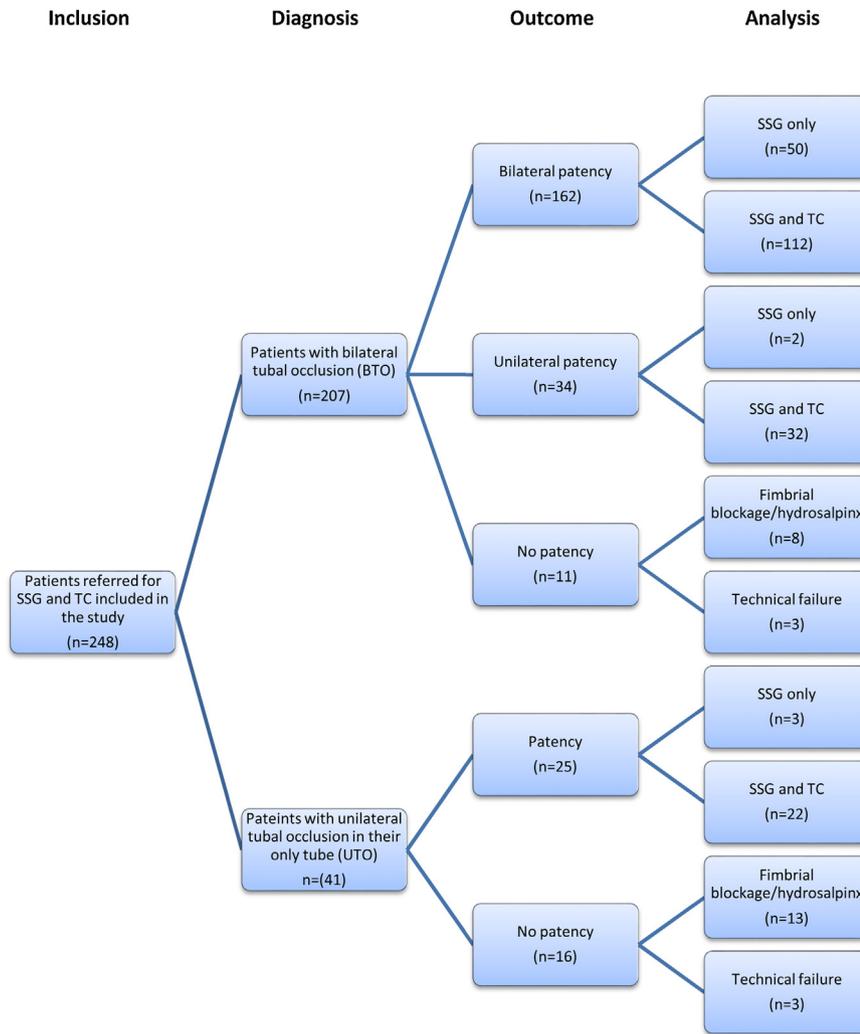
There were no major complications. Minor vaginal bleeding, nausea and uterine cramping or pelvic pain were frequent complaints. All women were asked to complete a visual analogue score of pain (VAS: 1- no discomfort, 10-severe pain) with an average  $6.4 \pm 2.6$  points. Significantly, almost all of them (99 %) declared themselves willing to repeat the procedure besides experiencing transient pain, given that there is a 30 % risk of reocclusion described in the literature [12].

#### Clinical outcome

After SSG and SSG + TC, 196/207 patients from the BTO group and 25/41 from UTO group were eligible for conceiving and involved in further investigation. Reproductive outcomes at minimum 12 months following the treatment were collected by a telephone survey. 21/221 women were lost to follow up. Among 200 patients left, 49 had undergone SSG and 151 SSG followed by TC in one or both tubes.

Out of remaining 200 patients with at least one patent tube, 80 patients conceived which resulted in 40 % overall pregnancy rate. Pregnancy rate in the SSG group was 41 % (21/51) and in the SSG + TC group 40 % (59/149). Mean time interval from procedure to

**Table 2**  
Technical outcomes in both groups.



**Table 3**  
Overall outcome and reasons for technical failure.

	N	%
Obstructed fallopian tubes	455	
Distal blockage or hydrosalpinx	56/455	12 %
Proximal tube obstruction (PTO)	399/455	88 %
Restored patency	383/399	96 %
SSG	135/383	35 %
SSG and TC	248/383	65 %
Reasons of recanalization fail in PTO	16/399	4 %
Unsuccessful catheterisation, not visualised ostium	10/16	63 %
Mechanical obstacle (myoma and endometrial polyp)	2/16	13 %
Intramural position and contrast intravasation	2/16	13 %
Tube perforation	1/16	5.5 %
Patients will to stop the procedure	1/16	5.5 %

pregnancy was 12.2 ± 14.1 months (2–60). Successful delivery was reported in 58 patients and there were 7 ongoing pregnancies. There were two patients with multiple, twin pregnancies and one patient who conceived and delivered twice, all from BTO group. Miscarriage was reported in 8/80 patients (10 %), and there were 7/80 ectopic pregnancies (9%). Out of 80 women, 68 conceived spontaneously (85 %) and 12 after COH (15 %). Detailed clinical outcome in particular groups of patients is presented in Table 4.

**Discussion**

Infertility is a common problem, with recent publications quoting up to 18 % prevalence in the general population [13]. Female infertility is believed to induce overall health implications including higher rates of psychiatric disorders and endometrial cancer [14]. Impaired tubal function caused by proximal tubal occlusion (PTO) is credited with up to 30 % of the etiology of female infertility [1]. In this study, authors presented the role of selective salpingography (SSG) followed by tubal catheterization (TC) in the treatment of PTO in population of infertile women.

The mechanisms resulting in PTO are variable therefore, investigation for potential tubal disease is an essential step in the assessment of infertility [15]. Appropriate evaluation of tubal patency is fundamental to determine correct treatment options. Hysterosalpingography (HSG) as the standard first-line test because of diagnostic, as well as therapeutic benefits is usually performed [16] although laparoscopy (LSC) persists a gold standard in pelvic anatomy evaluation [6,17]. However, both of these methods are not perfect, as around 60 % of patients in whom HSG showed proximal tubal blockage, repeat HSG 1 month later showed tubal patency [18] and similar percentage of patent tubes was revealed on subsequent laparoscopy [19]. Laparoscopy is neither an ideal method, as it was reported that 3% of patients with

**Table 4**  
Clinical outcomes. BTO-BTP Patients with bilateral tubal occlusion who achieved patency in both tubes; BTO-UTP Patients with bilateral tubal occlusion who achieved patency in one tube; UTO-UTP Patients with only one tube with restored patency.

	TOTAL	%	BTO- BTP	%	BTO-UTP	%	UTO-UTP	%
<b>ELEGIBLE PATIENTS</b>	221		162		34		25	
SSG	55		50		2		3	
SSG + TC	166		112		32		22	
<b>FOLLOW UP</b>	200	100 %	152/200	76 %	27/200	14%	21/200	10 %
SSG	51		48		1		2	
SSG + TC	149		104		26		19	
<b>PREGNANCY</b>	80/200	40 %	64/152	42%	6/27	22 %	10/21	48 %
SSG	21/51	41 %	17/48		1/1		2/2	
SSG + TC	59/149	40 %	47/104		5/26		8/19	
DELIVERY	58/80	72 %	48/64	75%	3/6	50 %	7/10	70%
ONGOING PREGNANCY	7/80	9%	4/64	6%	3/6	50 %	0	0%
ECTOPIC	7/80	9%	4/64	6%	0	0%	3	30 %
MISCARRIAGE	8/80	10 %	8/64	13%	0	0%	0	0%

bilateral tubal occlusion according to LSC subsequently conceived spontaneously [17]. SSG enables investigation of individual fallopian tube and helps to minimize the risk of false positive results. It could therefore be useful as a primary tubal assessment tool in the investigation of infertility [8,20].

Therapeutic approaches for tubal infertility depend on type and degree of dysfunction and vary from a minimally invasive procedure - transcervical tubal catheterization, through rather historical surgical option - tubocornual anastomosis, and IVF-ET. Firstly described in 1985 transvaginal fluoroscopic recanalization of a proximally occluded oviduct has largely replaced surgical methods of treatment of PTO [21]. In our study group consisting of 248 patients, SSG with additional TC was effective in 96 % patients with PTO. In terms of technical effectiveness our results support previous publications and compare favorably with other studies performed within the last decade, in which technical success rate ranged between 67–100 % [22–26].

In general, the procedure is well tolerated by the patients and the risk of complications is very low. Tubal spasm may result in temporary proximal tubal obstruction during the test [27,28]. To minimize the risk of uterotubal ostium spasm together with analgesic treatment they were also given an antispasmodic drug. There were two critical moments in terms of pain: traction of the cervix with concurrent injection of contrast agent generating pressure in the beginning and during attempts to recanalize the tube with guidewire which could lead to peritoneum irritation. Pain evaluation directly after the procedure with VAS was performed with an average result of  $6.4 \pm 2.6$  points reflecting a moderate pain, which almost all patients interpreted as acceptable. We used a water-soluble contrast medium to lower the risk in case of vascular intravasation which in our study group occurred twice (2/399). Tube perforation that occurred in one woman is described in the literature as a mild complication in 3–11 % of cases, that heals spontaneously and does not require any further treatment [12,26]. Verma et al. [29] raised the concern of ectopic implantation after TC with guiding wire. Indeed, in our study the ectopic pregnancy rate is high (9%) but meta-analysis showed that the pooled ectopic pregnancy rate was 4% [30].

We lost 9.5 % of patients in the follow-up. We observed overall 40 % clinical pregnancy rate (CPR). Majority of women conceived spontaneously (85 %). Live birth rate (LBR) was 72 % with additional 9% of women being pregnant at the time of the survey. Highest CPR was noted in patients with only one tube with restored patency (48 %) and the lowest among patients with bilateral tubal occlusion who achieved patency in one tube (22 %). Lazer reported 43.4 % CPR but only 30 % in a group limited to bilateral occlusion, and 65 % live birth. Anil described 3684 % CPR in bilateral tubal blockage and in his study included only active

recanalisation group whereas Al-Omari established 41 % CPR and successful delivery in 84 %. Highest results were demonstrated by Cobellis after only 6 months long follow up with 56 % pregnancy rate and El Fekih - 50 % in a very small group including both SSG and TC. According to the authors of meta-analysis the pooled clinical pregnancy rate was lower (27 %).

Eight pregnancies (10 %) ended with a miscarriage. This result is higher than pooled miscarriage rate of meta-analysis (6%) but significantly lower than this achieved by Al-Omari (16 %) and Lazer (26 %).

Major drawback of this study is lack of statistical analysis of the results. Detailed analysis might help define predictors of favorable clinical outcome in order to identify patients likely to benefit the most from this treatment. However, two major strengths of this study are: its prospective nature and relatively large group of patients which enables to gain strong conclusions and to define a role of SSG and TC as the treatment of PTO.

## Conclusion

SSG and TC offer patient-friendly, minimally invasive and cost-effective alternatives to tubal microsurgery and IVF-ET in women with tubal occlusion with very high technical success rate and promising clinical results which depend also on the complexity of couple infertility. Specific indications and limitations make a careful assessment of fallopian tubes and comprehensive evaluation of partners' reproductive situation prior to therapy an absolute requirement.

## Declaration of Competing Interest

The authors report no declarations of interest.

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