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Selective salpingography: preliminary experience of an office operative option for proximal tubal recanalization

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ABSTRACT

Objective: To evaluate treatment efficacy and patient acceptability of the new Radiographic Tubal Assessment Set (RTAS) (Cook Ireland Ltd., Limerick, Ireland) for selective salpingography (SSG).
Study design: 33 women, between 23 and 38 years old, referred to the Fertility Centre of the Department of Obstetrics, Gynecology and Reproductive Science, Second University of Naples, for sterility problems, underwent an office operative SSG with the RTAS. Of the 33 women, 12 had bilateral tubal obstruction (Group A) and 21 had unilateral tubal obstruction (Group B). Patients who did not regain tubal patency were referred for laparoscopic surgery. To verify patient acceptability, a visual analogue score (VAS 1-10) of pain was completed immediately after the procedure.
Results: From a total of 45 obstructed fallopian tubes, 34 were recanalized, giving a success rate for the procedure of 75.6% ($p < 0.001$). Nine patients with bilateral tubal obstruction (Group A) had the tubes recanalized and five obtained a spontaneous pregnancy. Sixteen patients with monolateral tubal obstruction (Group B) had the tubes recanalized and nine obtained a spontaneous pregnancy. A total of seven patients were sent for operative laparoscopy: four of them had the tubes recanalized and two obtained a spontaneous pregnancy. One patient was lost to follow-up. The evaluation of the level of pain felt during the procedure on the 10 cm VAS showed mean pelvic pain 2.9 ± 2.2, and an incidence of no discomfort $\pm$ low pain significantly higher than moderate $\pm$ severe pain ($p < 0.0001$).
Conclusion: The RTAS can be considered a safe and effective tool to perform this office operative procedure for tubal recanalization, with a high acceptability for the patient. The "see and treat" approach in patients with proximal tubal obstruction (PTO) suggests for the future the use of this device under sonographic guidance, taking into account accurate patient selection.

1. Introduction

Tubal disease is the cause of subfertility in approximately 30% of women, and 10–25% of these cases are due to proximal tubal obstruction (PTO) [1]. In the past hysterosalpingography (HSG) has represented the most accurate diagnostic tool to obtain information about both the uterine cavity and tubal patency. A high incidence of false-positive diagnosis of PTO (ranging from 16% to 40%) is reported, with no correlation between radiological and pathological findings in approximately two-thirds of the Fallopian tubes resected [2,3]. Moreover, Woolcott has reported that when bilateral proximal blockage was diagnosed by both HSG and laparoscopy, about 35% of tubes showed patency at selective salpingography [4].

In the last 10 years selective tubal catheterization has been evaluated as an option in patients with hysterosalpingographic findings of PTO [5]. In fact since 1993 the American Society for Reproductive Medicine has recommended that patients who have PTO undergo selective salpingography (SSG) and tubal recanalization before considering the more invasive and costly treatments [6].

SSG, a procedure in which the fallopian tube is directly opacified through a catheter placed in the tubal ostium, has been used since the late 1980s [7]. Since the first descriptions, there have been numerous reports of successful cannulation using different devices (ureteral stents or catheters, epidural catheters, guidewires, etc.) [8–10]. The key point is to obtain, if possible, an accurate distinction between true pathologic occlusion, spasm or mucosa abnormalities, crucial to determining therapy and further infertility approach [8].

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The indications for, and limitations of, Fallopian tube recanalization require an accurate and exhaustive evaluation of the tube, because PTO is a not a standardized condition, and there are differences in the pathogenesis and between patients [11,12].

The aim of this study is to evaluate and report the preliminary results of the feasibility, treatment efficacy and patient acceptability of the new Radiographic Tubal Assessment Set (RTAS) (Cook Ireland Ltd., Limerick, Ireland) for SSG.

2. Materials and methods

The study involved 33 infertile women (age range 23–38 years), referred to the Fertility Centre of the Department of Obstetrics, Gynecology and Reproductive Science of the Second University of Naples. All patients were enrolled with a previous hysterosalpingographic diagnosis of PTO, monolateral or bilateral. All of them gave informed consent at study inclusion.

The study protocol, informed consent, and test product(s) information received institutional review board (IRB) approval before the beginning of the study, in accordance with The Code of Ethics of the Declaration of Helsinki.

The characteristic of the patients is depicted in Table 1. All the patients received a careful evaluation, in order to achieve an optimal and complete fertility assessment. Of the 33 women, 12 had bilateral tubal obstruction (Group A); 21 had monolateral proximal tubal obstruction (Group B). All the patients were sent for an office SSG with the RTAS (Fig. 1).

The procedure was performed in the proliferative menstrual phase, which facilitates better image interpretation. The patients were asked to refrain from unprotected sexual intercourse from the date of her period until after the investigation to be certain there is no risk of pregnancy.

SSG with the RTAS was performed with the following procedure. The patient was placed on the fluoroscopic machine in a gynaecologic examination position. After the external genital area had been cleaned with antiseptic solution, the vagina was dilated by a gynaecologic dilator. The cervix was localized and cleansed with iodine solution. Next, the external cervical ostium was catheterized. The catheter was pushed through the vagina and the cervix to the uterine cavity, and the balloon was inflated. The vaginal dilator was removed after catheterization and before administration of the contrast medium. Instillation of 5–10 ml of a water-soluble contrast agent into uterus let us perform standard hysterosalpingography. At this point, after verifying the presence of a tubal obstruction (Fig. 2a) the SSG Catheter was introduced through the working channel of the Intrauterine Access Balloon Catheter until the SSG Catheter marker ink enters the Check Flo Adapter located on the proximal end of the Intrauterine Access Balloon. While scanning with fluoroscopy, the catheter was rotated to address the appropriate fallopian tube. Since the distal tip of the SSG Catheter was radiopaque, it was visible under fluoroscopy (Fig. 2b). An appropriate quantity of contrast medium was injected through the SSG Catheter to better define tubal patency and perform tubal recanalization. If the obstruction was overcome the tubal contour was outlined with contrast (Fig. 2c). If it persisted, a guide-wire was threaded through the inner cannula and was advanced towards the obstruction. A gentle push was applied to

Table 1
Demographics, success at cannulation and pregnancy outcomes of the 33 women recruited at Second University of Naples.

Parameter	Value
Mean age in years (range)	27 (23–38)
Bilateral block (Group A)	12/33 (36.4%)
Both successfully cannulated	8/12 (66.6%)
One tube successfully cannulated	2/12 (16.7%)
Neither side cannulated	2/12 (16.7%)
Unilateral block (Group B)	21/33 (64.6%)
Tube successfully cannulated	16/33 (48.9%)
Success rate	
Per tube cannulated	34/45 (75.6%)
Per patient	25/33 (75.7%)
Pregnancy outcomes[a]	16/33 (48.5%)
Live birth	15/16 (93.8%)
Ectopic pregnancy	0 (0%)
Miscarriage	1/16 (6.2%)
Unknown	1/33 (3.0%)
Failed to conceive	17/33 (51.5%)
Other fertility treatment	
Ovulation induction	5
Intrauterine insemination	2
IVF	3
Outcome information missing	1/33 (3.0%)

[a] After a 6 month follow-up.

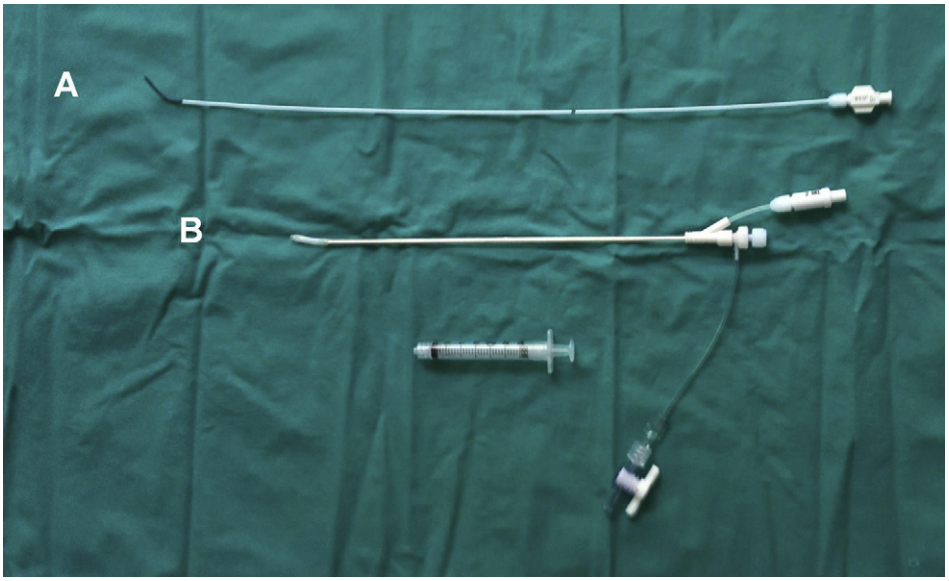

Fig. 1. The Radiographic Tubal Assessment Set (RTAS): (A) catheter used for standard HSG with operative channel, where the (B) Selective Salpingography (SSG) Catheter passes through.