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Factors affecting the success of fallopian tube recanalization in treatment of tubal obstructive infertility

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Abstract

Objective: To examine potential risk factors associated with the success rate following fallopian tube recanalization (FTR) in infertile women with obstruction of the proximal fallopian tube.

Methods: We retrospectively studied patients who underwent FTR for tubal obstructive infertility between January 2016 and December 2018 at the Third Affiliated Hospital of Guangzhou Medical University. FTR was performed using a catheter and guidewire system to clear tubal obstruction. Predictive factors potentially associated with the success rate were assessed by logistic regression.

Results: A total of 762 patients were included. Multivariable analysis showed that age (odds ratio [OR] = 2.38, 95% confidence interval [CI]: 1.24–4.58), infertility type (OR = 2.82, 95% CI: 1.36–6.21), history of ectopic pregnancy (OR = 7.87, 95% CI: 4.05–15.81), history of abdominal surgery (OR = 4.30, 95% CI: 2.22–8.60), history of artificial abortion curettage (OR = 4.08, 95% CI: 2.12–8.03), and duration of infertility (OR = 2.03, 95% CI: 1.06–3.85) were independently associated with postoperative tubal patency.

Conclusions: Our findings suggest that risk factors, such as age ≥35 years, secondary infertility, duration of infertility ≥5 years, and histories of ectopic pregnancy, abdominal surgery, and artificial abortion curettage, affect the success rate of FTR. These factors may also predict surgical success in treating tubal obstructive infertility.

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Introduction

Infertility is the inability to conceive after 1 year of appropriate, timed, and unprotected sexual intercourse.[1–4] Infertility occurs in approximately 15% of reproductive-aged couples worldwide and is more common in developing countries.[2,5] Infertility is multifactorial in nature and may be attributed to male factors (approximately 26% to 30%) or a combination of male and female factors (mixed infertility; approximately 40%). Infertility may be due female factors related to ovulation disorders (approximately 21% to 25%), tubal factors (approximately 14% to 20%), cervical, uterine, or peritoneal disorders (approximately 10% to 13%), and/or idiopathic or unexplained infertility (approximately 25% to 28%).[1–4] A recent study showed that approximately 25% of reproductive-aged couples in China were affected by infertility.[6]

Tubal obstruction is one of the most common causes of female infertility, accounting for approximately 14% to 45% of all female factor infertilities.[1–5] Tubal obstruction involves the proximal, mid, or distal portion. Infertility due to proximal fallopian tube obstruction occurs in approximately 10% to 25% of women with tubal disease.[7] A distinct variable anatomy of the proximal portion of the fallopian tube (straight or slightly curved or tortuous) makes it highly susceptible to muscular spasm, accumulation of viscous secretion, mucosal agglutination, and intrinsic luminal filling defects,[8,9] This leads to obstruction and infertility.[10]

Interventional tubal recanalization or fallopian tube recanalization (FTR) is an extremely effective procedure for treating proximal tubal obstruction with a technical success rate as high as 90%.[11–14] However, more than 20% of patients have poor outcomes at discharge following interventional recanalization.[14,15] The conception rate after this procedure is variable, with an average rate of 33%.[14] While a previous study showed that the pregnancy rates following FTR significantly varied,[16] the potential factors affecting the success rate of FTR remain unclear. Therefore, there is conflicting evidence regarding the technical success rate following FTR and a paucity of data on the factors that affect it. This retrospective study aimed to examine various risk factors that might affect tubal patency and in turn affect the success rate of FTR in treatment of tubal obstructive infertility.

Methods

Study design and patients

This was a retrospective study of consecutively selected patients who underwent FTR for tubal obstructive infertility between January 2016 and December 2018 at the Department of Interventional Radiology of the Third Affiliated Hospital of Guangzhou Medical University. This study was approved by the institutional review board and the Ethics Committee of

the Third Affiliated Hospital of Guangzhou Medical University, Guangzhou, Guangdong Province, China ([2019] No. 010). Written informed consent for treatment was obtained from all patients. The need for informed consent for research was waived by the committee owing to the retrospective design of the study and all data were de-identified.

All infertile women who met the diagnostic criteria for tubal obstructive infertility[1–4] and were diagnosed with tubal interstitial, isthmus, or proximal ampullary occlusion by X-ray hysterosalpingography or ultrasonography were included in this study. Infertile women who had pre-existing conditions, such as cardiovascular and cerebrovascular diseases or acute pelvic and abdominal infections, were excluded. Additionally, we excluded infertile women who showed the presence of the following: (i) an obstruction in the distal end of the ampulla, (ii) severe occlusion at the uterine horn, (iii) tubal ligation, or (iv) tubal tuberculosis.

Interventional tubal recanalization

All surgical procedures were performed under sterile conditions using standard aseptic techniques by the same chief physician with more than 30 years of experience in interventional radiology. All FTR procedures were performed in the angiography room (Integris 3000; Philips Medical Systems, Eindhoven, The Netherlands) using the Rösch-Thurmond Fallopian Tube Catheterization Set (FTC-900; Cook Medical Inc., Bloomington, IN, USA).

Acute infection of the reproductive system was ruled out before surgery. FTR was performed 3 to 7 days after the last menstruation. The patient was placed in the lithotomy position and the patient's genital area was routinely sterilized and draped. Initially, the cervix was cannulated with a 16-F balloon catheter through a vaginal speculum and was stabilized. A 5-F slightly curved polyethylene catheter was then advanced over a 0.035"-diameter (0.089 cm) hydrophilic, super-smooth guidewire to the uterine cornua followed by its placement into the ostium of the fallopian tube. The hydrophilic guidewire was used to gently probe the obstruction.[17] Subsequently, the guidewire was withdrawn, and 2 mL of contrast medium was injected through the 5-F catheter into the tubal ostium. During this procedure, we searched under fluoroscopy for spillage from the fimbrial portion of the tube to confirm tubal patency. If spillage was not observed, a 3-F catheter and 0.018" platinum guidewire were advanced through the 5-F catheter until the distal tip of the 3-F catheter was aligned with the tip of the 5-F catheter. Subsequently, the platinum guidewire was removed and 2 mL of contrast medium was injected to verify recanalization.

Observational index

The technical success rate was defined as successful catheterization followed by reopening of proximally blocked tubes. Successful FTR or tubal patency was confirmed when contrast agent that was injected through the catheter in the occluded tube was visualized.

Postoperative management

All patients underwent outpatient day surgery and were kept under observation for several hours for ambulatory management of pain. All patients were prescribed an oral antibiotic regimen of doxycycline and metronidazole, while a few of them were also provided antispasmodics and analgesics. All patients were advised to avoid strenuous exercise for 1 week and abstain from sexual intercourse for 1 month.

Statistical analyses

Continuous variables are expressed as mean $\pm$ standard deviation and categorical

variables are shown as frequency and percentage. Univariable logistic regression analysis was performed to determine the association of success rate with other variables. The results are presented as odds ratios (ORs) and 95% confidence intervals (CIs). We assessed the concurrent effect of potential risk factors (continuous and categorical, including age, infertility type, obstruction site, a history of ectopic pregnancy, abdominal surgery, abdominal disease, pelvic inflammation, dysmenorrhea, menstrual cycle disorder, artificial abortion curettage, and the duration of infertility) on postoperative tubal patency by multivariable logistic regression analysis (enter method). Finally, sensitivity analyses or post-hoc tests were carried out to validate the robustness of our results. Two-sided P values <0.05 were considered statistically significant.

Results

Patients' characteristics

Table 1 summarizes patients' characteristics that were included in the logistic regression model. A total of 762 infertile women were included in this study. The mean age of the women was 31.6 ± 5.6 years. Among them, approximately 38.8% of patients had primary infertility, while 61.1% of them had secondary infertility. The mean duration of infertility was 4.2 ± 2.7 years. Further, 60.9% of patients had interstitial obstruction, whereas only 39.1% of them had obstruction of the isthmus.

Logistic regression analysis

Univariable analysis showed that age (OR = 3.44, 95% CI: 2.06–5.77, $P<0.001$), infertility type (OR = 2.53, 95% CI: 1.41–4.82, $P = 0.003$), a history of ectopic pregnancy (OR = 8.70, 95% CI: 5.93–14.32, $P < 0.001$), a history of abdominal surgery (OR = 9.52, 95% CI: 5.40–17.66, $P < 0.001$), a history of artificial abortion curettage (OR = 5.67, 95% CI: 3.33–9.94, $P < 0.001$), and the duration of infertility (OR = 3.29, 95% CI: 1.97–5.52, $P < 0.001$) were associated with the success rate of tubal recanalization (Table 2).

Multivariable analysis showed that age (OR = 2.38, 95% CI: 1.24–4.58, $P = 0.009$), infertility type (OR = 2.82, 95% CI: 1.36–6.21, $P = 0.01$), a history of ectopic pregnancy (OR = 7.87, 95% CI: 4.05–15.81, $P < 0.001$), a history of abdominal surgery (OR = 4.30, 95% CI: 2.22–8.60, $P < 0.001$), a history of artificial abortion curettage

Table 1. Variable encoding for logistic regression and characteristics of the patients.

Variable	Type/presence	n (%)	Type/presence	n (%)
Postoperative tubal patency	Tubal patency	696 (91.3)	Tubal occlusion	66 (8.7)
Age (years)	<35	555 (72.8)	≥35	207 (27.2)
Infertility type	Primary infertility	296 (38.8)	Secondary infertility	466 (61.1)
Obstruction site	Interstitial	464 (60.9)	Isthmus	298 (39.1)
History of ectopic pregnancy	No	596 (78.2)	Yes	166 (21.8)
History of abdominal operation	No	540 (70.9)	Yes	222 (29.1)
History of abdominal disease	No	515 (67.6)	Yes	247 (32.4)
History of pelvic inflammation	No	287 (36.1)	Yes	487 (63.9)
History of artificial abortion curettage	No	526 (69.0)	Yes	236 (31.0)
Course of disease	<5 years	540 (70.9)	≥5 years	222 (29.1)
Menstrual cycle disorder	No	488 (64.0)	Yes	274 (36.0)
History of dysmenorrhea	No	526 (69.0)	Yes	236 (31.0)

Table 2. Univariable and multivariable analyses for identifying potential risk factors associated with tubal recanalization.

	Univariable analysis		Multivariable analysis	
Variable	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Age	**3.44 (2.06–5.77)**	***<0.001****	**2.38 (1.24–4.58)**	***0.009****
Infertility type	**2.53 (1.41–4.82)**	***0.003****	**2.82 (1.36–6.21)**	***0.01****
Obstruction site	0.71 (0.40–1.20)	0.210	0.52 (0.23–1.15)	0.120
History of ectopic pregnancy	**8.7 (5.93–14.32)**	***<0.001****	**7.87 (4.05–15.81)**	***<0.001****
History of abdominal surgery	**9.52 (5.40–17.66)**	***<0.001****	**4.30 (2.22–8.60)**	***<0.001****
History of abdominal disease	0.76 (0.42–1.32)	0.350	0.85 (0.37–1.91)	0.710
History of pelvic inflammation	1.06 (0.63–1.83)	0.830	1.35 (0.63–2.96)	0.440
History of artificial abortion curettage	**5.67 (3.33–9.94)**	***<0.001****	**4.08 (2.12–8.03)**	***<0.001****
Duration of infertility	**3.29 (1.97–5.52)**	***<0.001****	**2.03 (1.06–3.85)**	***0.031****
Menstrual cycle disorder	1.4 4 (0.86–2.40)	0.159	1.35 (0.66–2.73)	0.410
History of dysmenorrhea	1.21 (0.70,2.04)	0.480	1.32 (0.62,2.77)	0.460

*$P < 0.05$ is considered significant.
OR, odds ratio; CI, confidence interval.

(OR = 4.08, 95% CI: 2.12–8.03, $P < 0.001$), and the duration of infertility (OR = 2.03, 95% CI: 1.06–3.85, $P = 0.031$) were independently associated with postoperative tubal patency (Table 2). Therefore, factors such as age ≥35 years, secondary infertility, duration of infertility ≥5 years, and histories of ectopic pregnancy, abdominal surgery, and artificial abortion curettage were potential risk factors for tubal patency. These factors might strongly affect the success rate following the procedure.

Figure 1 shows pre- and post-intervention images of tubal patency.

Stratification sensitivity analysis

We empirically performed multivariate stratification-based sensitivity analysis to determine whether the identified independent risk factors that affected postoperative tubal patency (age, infertility type, history of ectopic pregnancy, history of abdominal surgery, history of artificial abortion curettage, and duration of infertility) affect the variables of age, infertility type, duration of infertility, and tubal obstruction site. For this analysis, we dichotomously stratified these variables as follows: age < 35 years and ≥35 years, infertility type (primary infertility and secondary infertility), duration of infertility (< 5 years and ≥5 years), and the site of tubal obstruction (interstitial and isthmus). Figure 2 shows the results of multivariate stratification-based sensitivity analysis. We found that estimates significantly varied between strata for age, infertility type, a history of ectopic pregnancy, a history of abdominal surgery, a history of artificial abortion curettage, and the duration of infertility. These findings suggested that age, infertility type, and the duration of infertility were strongly associated with the success rate of tubal recanalization, further validating the robustness of our results.

Discussion

In this study, we examined various risk factors that might affect tubal patency and in turn affect the success rate of FTR in treatment of tubal obstructive infertility. We found that age ≥35 years, secondary infertility, a duration of infertility ≥5 years, and

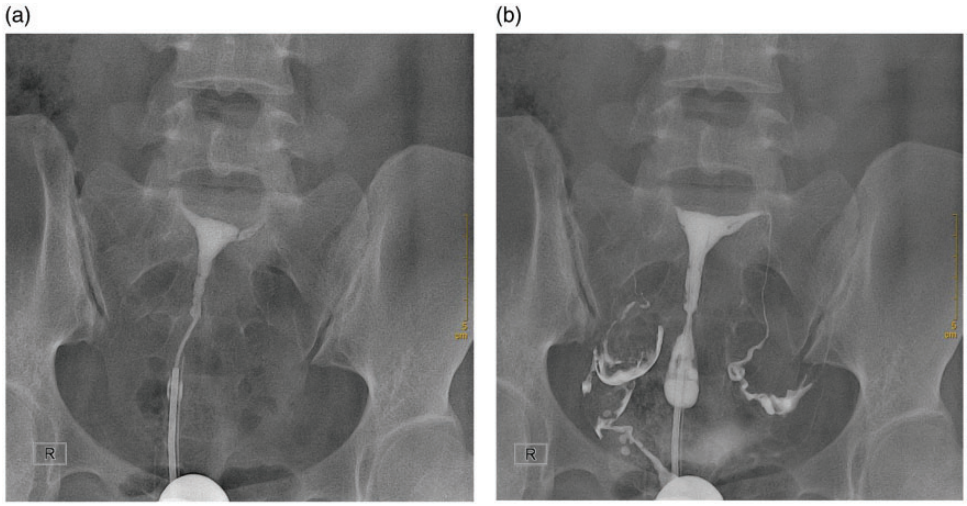

Figure 1. (a) Hysterosalpingogram shows occlusion of both tubes. (b) Post-intervention image showing spillage of contrast medium after successful recanalization with a guidewire in the same patient. The right and left tubes were successfully recanalized and a salpingogram shows widely patent tubes.

histories of ectopic pregnancy, abdominal surgery, and artificial abortion curettage were potential risk factors that might strongly affect the success of FTR. These factors may also predict the surgical success rate in treatment of tubal obstructive infertility.

We retrospectively analyzed 762 patients who underwent FTR for tubal obstructive infertility over a study period of 3 years. Univariable analysis showed that six factors were associated with the success rate of tubal recanalization, including age, infertility type, a history of ectopic pregnancy, a history of abdominal surgery, a history of artificial abortion curettage, and the duration of infertility. Further, multivariable analysis showed that same factors found in univariable analysis were independently associated with the prognosis of tubal recanalization.

Several studies have validated the safety and efficacy of FTR for treating proximal fallopian tube obstruction.[16,18,19] However, there is considerable variation in the reported technical success rates following FTR. These variations may be partially attributed to the clinician's experience, tools, equipment, and diversity of patient populations, in addition to the presence of multiple contributing factors.[16,20] A study by Al-Omari et al.[16] showed that all women who underwent FTR of one or both proximally obstructed tubes were successfully recanalized. Therefore, there was a 100% technical success rate, although only 41% of women conceived. Further, this previous study suggested an association of multiple contributing factors in affecting the pregnancy rate following FTR. However, because the technical success rate of the study was 100%, factors associated with conception failure could not be explored. In this study, infertility type and a history of ectopic pregnancy were the strongest risk factors potentially affecting the success rate after FTR. In a review by Thurmond et al.,[18] the presence of uterine leiomyomas or polyps, or fibrotic scarring caused by salpingitis, endometriosis, or

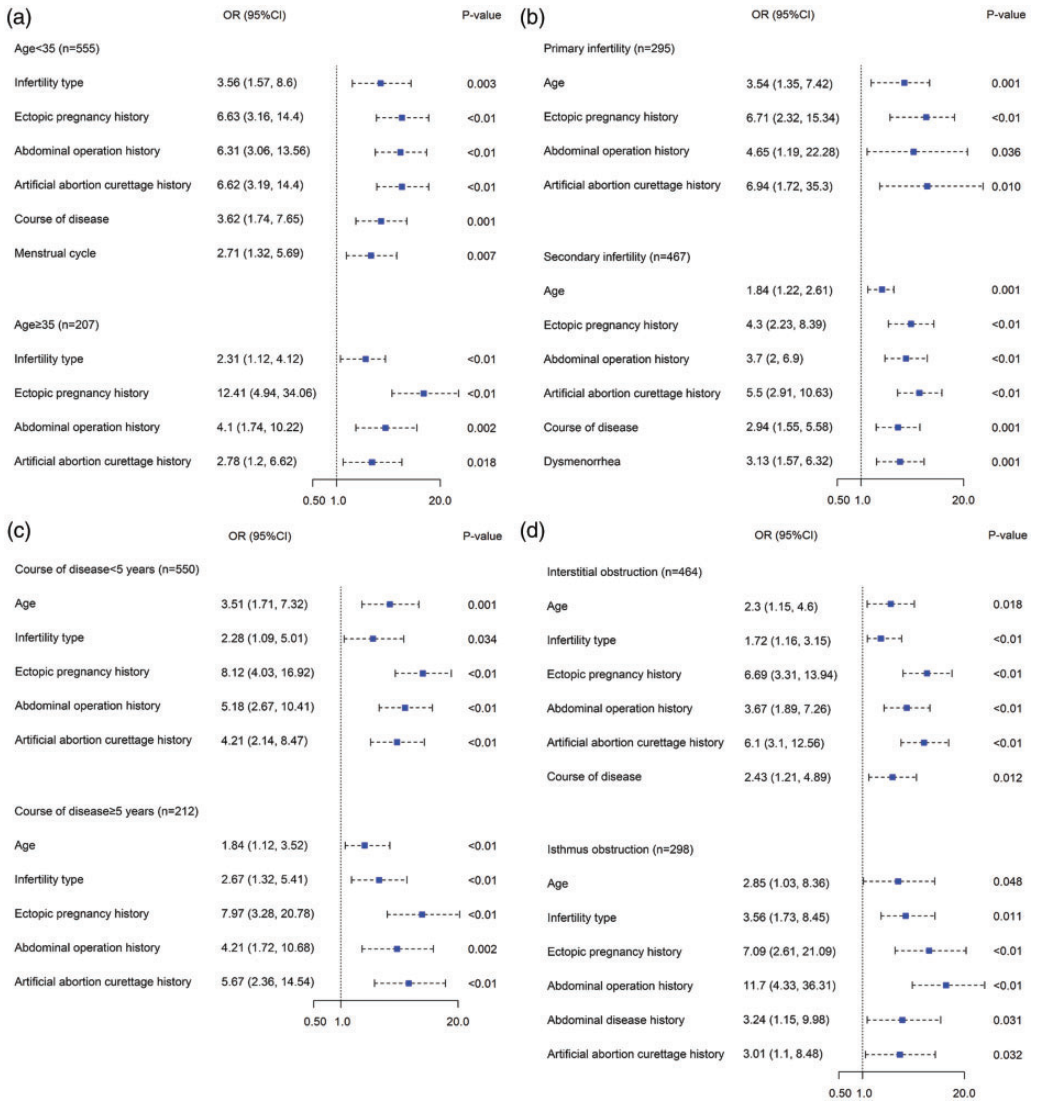

Figure 2. Multivariate stratification-based analyses of (a) age (<35 years and ≥35 years), (b) infertility type (primary infertility and secondary infertility), (c) duration of infertility (<5 years and ≥5 years), and (d) the site of tubal obstruction (interstitial and isthmus).
OR, odds ratio; CI, confidence interval.

surgery were shown to adversely affect the outcome of FTR. Nonetheless, these authors suggested a plausible association of various factors with the technical success rate of tubal recanalization.

In our study, the effect of FTR was significantly better in patients with secondary tubal infertility compared with those with primary infertility. This finding could be attributed to the differences in pathological

aspects of the fallopian tubes, as shown by hysterosalpingography, between women with primary infertility and those with secondary infertility. Further strengthening this hypothesis, previous studies have shown that women with secondary infertility have a higher likelihood of having unilateral fallopian tube obstruction on hysterosalpingography than those with primary infertility.[21–24] Taken together, these findings indicate that success rates might vary with the type of infertility. Additionally, these findings suggest that accurately identifying and treating the underlying cause of secondary infertility with simultaneous initialization of intervention could significantly improve the technical success rate of FTR.

Notably, in our study, the recanalization rate was significantly lower in older women (age $\geq$35 years) and in those with a longer duration of fertility ($\geq$5 years). Our findings are supported by a previous study that showed an increased incidence of secondary infertility in women older than 35 years with an increased duration of infertility.[25]

Studies have reported that more than 60% of women have an increased risk of developing adhesions after pelvic and abdominal surgeries.[26] Anatomical and functional blockages occur when these adhesions lead to closure of the abdominal orifice of the fallopian tubes and cause retraction of the ovary and/or tube, thus hampering oocyte pick up, leading to infertility.[27] Peri-tubal adhesions due to intra-abdominal or pelvic surgery account for approximately 15% to 20% of all cases of secondary infertility.[28] Repeated suction curettage for abortion can result in development of intrauterine and cervical adhesions, thus causing proximal tubal obstruction.[29] Further, curettage and other surgeries could lead to profound changes in the intrauterine environment, leading to neuroendocrine abnormalities,[30] and this could negatively affect the chances of conception. Significant associations of tubal occlusion with previous histories of pelvic infection and abdominopelvic surgeries, especially dilatation and curettage for termination of pregnancy, have been observed.[27,31] Consistent with these findings, our study showed that previous histories of abdominal surgery and artificial abortion curettage were independent prognostic factors for tubal recanalization, and further demonstrated that they might affect the success rate of FTR. Because of the inevitable occurrence of peritoneal adhesions in infertile women, a previous history of intra-abdominal or pelvic surgery or artificial abortion curettage might predict poor surgical success following FTR.

Different factors, such as uterine curettage, pelvic inflammatory disease, endometritis, infections after childbirth or abortions, and intraabdominal infections, including appendicitis and peritonitis, may influence proximal tubal obstruction. However, surgical intervention will not always be the preferred choice for treating an infection/inflammation or repairing tubal damage related to tubal obstruction. Therefore, opting for surgery in these cases might contribute to poor postoperative outcomes.

This study has some limitations. As a consequence of the retrospective nature of our study, the analyzable data were limited to those available in the medical charts. Therefore, in addition to the inherent biases, the results may have been prone to selection bias or information bias. Further, the single-center study design may limit the generalizability of the findings in this study. Additionally, the association of inflammatory markers with the success rate of FTR was not evaluated.

Conclusions

Factors such as age $\geq$35 years, secondary infertility, a duration of infertility $\geq$5 years,

and histories of ectopic pregnancy, abdominal surgery, and artificial abortion curettage are potential risk factors and are strongly associated with tubal patency. Further, these factors might affect the success rate of FTR in the treatment of tubal obstructive infertility. Therefore, additional supplementary interventions targeting high-risk patients might improve the surgical success rates of this procedure.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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