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Original Article

A new classification system for pregnancy prognosis of tubal factor infertility

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Abstract: The aim of the present study was to assess the objectivity and accuracy of a new system to evaluate pregnancy prognosis in tubal factor infertility (TFI) patients. Retrospective study in 469 TFI patients were pre- and postoperatively scored using the new system as mild, moderate or severe TFI, based on tubal adhesions, patency, morphology and structure. Follow-up was assessed to determine pregnancy outcomes. Laparoscopic salpingoplasty and hydrotubation, hysteroscopic-laparoscopic salpingoplasty and hydrotubation, and laparoscopic hydrotubation all decreased TFI scores to a similar extent. The pre- and postoperative TFI classification was significantly associated with intrauterine pregnancy (mild: 43.6% vs. moderate: 34.0% vs. severe: 19.4%, $P < 0.0001$) and live births (mild: 35.9% and moderate: 31.5% vs. severe: 16.8%, $P = 0.0002$) rates. Multivariate analysis showed that the preoperative disease course ($P = 0.02$), preoperative TFI score ($P < 0.0001$), and postoperative TFI score ($P = 0.0007$) were independently associated with the rate of intrauterine pregnancy rate. Multivariate analysis also showed that the postoperative TFI score ($P = 0.001$), pelvic inflammatory disease ($P = 0.03$) and age ($P = 0.03$) were independently associated with the rate of live births. Conclusion: We devised a new classification system for TFI prognosis. Salpingoplasty improved these scores. Both pre- and postoperative TFI assessments using this new system are associated with pregnancy prognosis in TFI patients.

Keywords: Tubal factor infertility, salpingoplasty, follow-up, retrospective analysis, tubal classification system

Introduction

Tubal factor infertility (TFI) is one of the most common causes of female infertility, accounting for 30-35% of cases [1]. The use of tubal classification systems can help to better evaluate the effects of salpingoplasty and pregnancy outcomes. However, many systems exist for tubal scoring [2-10], the most popular ones being the pelvic adhesions classification in the revised American Fertility Society (AFS-r) [2], the Hulka tubal classification system [3], the Hull & Rutherford classification system [4], and falloposcopy [10].

However, these systems are known to have a number of limitations [11-14]. Indeed, AFS-r only evaluates pelvic adhesions, and the Hulka and the Hull & Rutherford systems are too general. Finally, falloposcopy is not widely used domestically, and it can only diagnose and treat the inner diseases of fallopian tubes, and cannot evaluate the conditions of the pelvic cavity. Nevertheless, there is an important need to be able to make a correct prognosis after tubal surgery in order to optimize the correct use of expensive resources [15-17]. Therefore, we devised a combined classification using the pelvic adhesions from the AFS-r, the observational items from the Hulka system, and the level descriptions from the Hull & Rutherford system, to which we added a new tubal classification system based on surgical records (**Table 1**). The aim of the present study was to assess the objectivity and accuracy of a new system to evaluate pregnancy prognosis in tubal factor infertility (TFI) patients. The ultimate aim was to assess the prognostic value of this new tubal classification using a system that is simple, logical and evidence-based.

Material and methods

Patients

This was a retrospective study performed in all TFI cases (n = 1290) from the Obstetrics and

Table 1. Our new tubal classification system

Nature of adhesion \ Adhesion range		Peritubal	Partial ovarian	Completely wrapped or extensive
	Membranous	1	2	4
	Dense	2	4	8
Patency	Patent	Passable	Sub-passable	Completely blocked
	0	4	6	8
Morphology	Soft	Partially narrowed or twisted	Stiffness or hydrosalpinx	
	0	4	8	
Fimbrial structure	Complete	Partially destroyed	Destroyed	
	0	4	8	

Mild: 0-7 points; Moderate: 8-15 points; Severe: more than 16 points.

Table 2. Patients' baseline characteristics

Disease course	Level 1 of the preoperative scoring	Level 2 of the preoperative scoring	Level 3 of the preoperative scoring	All	*P*-value
N	78 (16.6)	159 (33.9)	232 (49.5)	469	
Age	30.00 ± 6.00	28.00 ± 6.00	30.00 ± 6.00	29.00 ± 5.00	0.0099
Disease course (duration of infertility)	3.00 ± 4.00	3.00 ± 2.00	3.00 ± 4.00	3.00 ± 4.00	0.0338
Number of pregnancies	1.00 ± 2.00	1.00 ± 2.00	1.00 ± 2.00	1.00 ± 2.00	0.5843
History of ectopic pregnancy					
Yes	18 (23.1)	8 (5.0)	10 (4.3)	36 (7.7)	< .0001
No	60 (76.9)	151 (95.0)	222 (95.7)	433 (92.3)	
History of operation					
Yes	12 (15.4)	14 (8.8)	28 (12.1)	54 (11.5)	0.3069
No	66 (84.6)	145 (91.2)	204 (87.9)	415 (88.5)	
Ovarian tumors					
With	3 (3.9)	0 (0.0)	3 (1.3)	6 (1.3)	0.0337
Without	75 (96.1)	159 (100.0)	229 (98.7)	463 (98.7)	
PID					
With	8 (10.3)	18 (11.3)	30 (12.9)	56 (11.9)	0.7847
Without	70 (89.7)	141 (88.7)	202 (87.1)	413 (88.1)	
Surgery					
Laparoscopic salpingoplasty + hydrotubation	66 (84.6)	134 (84.3)	199 (85.8)	399 (85.1)	
Hysteroscopic-laparoscopic salpingoplasty + hydrotubation	12 (15.4)	24 (15.1)	31 (13.4)	67 (14.3)	0.9123
Hydrotubation	0 (0.0)	1 (0.6)	2 (0.9)	3 (0.6)	

PID: pelvic inflammatory disease.

Gynecology Hospital of Fudan University (Shanghai, China) who underwent salpingoplasty between 2003 and 2007 and who had available follow-up data (final n = 469).

Scoring

All 469 patients were stratified using our new score (**Table 1**), both pre- and post-operatively, based on available data from the medical charts, and according to Mild (0-7 points), Moderate (8-15 points) or Severe (> 16 points) TFI. Pregnancy outcomes (intrauterine pregnancy, ectopic pregnancy, live birth and infertility rates) were compared across these scores.

Statistical analysis

Data were analyzed using Mann-Witney U tests, Wilcoxon rank sum tests, χ^2 tests and binary logistic regression analysis, as appropriate. SPSS 16.0 (SPSS Inc., Chicago, IL, USA) was used to perform all statistical analyses. A *P*-value < 0.05 was considered statistically significant.

Results

Baseline characteristics

Table 2 shows the baseline characteristics of the 469 included patients according to TFI

Table 3. Patients' preoperative and postoperative scorings (median ± interquartile). Comparison of the three surgical methods in the new tubal classification system (mean)

	Preoperative	Postoperative	*P*-value
Laparoscopic salpingoplasty + hydrotubation	15 ± 12	4 ± 5	< 0.0001
Hysteroscopic-laparoscopic salpingoplasty + hydrotubation	14 ± 10	4 ± 8	< 0.0001
Laparotomic hydrotubation	20 ± 10	5 ± 10	0.0424

Table 4. Pregnancy outcomes according to the preoperative TFI grading system

Outcome	All	Mild	Moderate	Severe	*P*-value
N	469	78 (16.6)	159 (33.9)	232 (49.5)	
Infertility within 2 years	278 (59.3)	36 (46.2)	78 (49.1)	164 (70.7)	<0.0001
Intrauterine pregnancy within 2 years	133 (28.4)	34 (43.6)	54 (34.0)	45 (19.4)	<0.0001
Ectopic pregnancy within 2 years	60 (12.8)	9 (11.5)	27 (17.0)	24 (10.3)	0.1454
Live birth	117 (24.9)	28 (35.9)	50 (31.5)	39 (16.8)	0.0002

Table 5. Pregnancy outcomes according to the postoperative TFI grading system

Outcome	All	Mild	Moderate	Severe	*P*-value
N	469	358 (76.3)	106 (22.6)	5 (1.1)	
Infertility within 2 years	278 (59.3)	195 (54.5)	78 (73.6)	5 (100.0)	0.0004
Intrauterine pregnancy within 2 years	133 (28.4)	116 (32.4)	17 (16.0)	0 (0.0)	0.0017
Ectopic pregnancy within 2 years	60 (12.8)	49 (13.7)	11 (10.4)	0 (0.0)	0.4620
Live birth	117 (24.9)	102 (28.5)	15 (14.2)	0 (0.0)	0.0048

grading according to our new scoring system. Patients in the moderate TFI group were slightly younger. The number of past pregnancies was the same, but patients in the mild TFI group had a higher number of ectopic pregnancies (mild: 23.1% vs. moderate: 5.0% and severe: 4.3%, P < 0.0001) and a higher frequency of ovarian tumors (mild: 3.9% vs. moderate: 0% and severe: 1.3%, P = 0.03).

Impact of surgery on TFI grade

Table 3 shows the effects of the three types of surgery used in our center to correct TFI. Using laparoscopic salpingoplasty and hydrotubation, the score decreased from 15 ± 12 to 4 ± 5 (P < 0.0001). Using hysteroscopic-laparoscopic salpingoplasty and hydrotubation, the score decreased from 14 ± 10 to 4 ± 8 (P < 0.0001). Finally, using laparoscopic hydrotubation, the score decreased from 20 ± 10 to 5 ± 10 (P = 0.04).

Pregnancy outcomes

Table 4 shows the 2-year pregnancy outcomes of the patients according to their preoperative TFI score. More patients in the severe TFI group were still infertile 2 years after surgery (severe: 70.7% vs. mild: 46.2% and moderate: 49.1%, P < 0.0001). Significantly more intrauterine pregnancies were observed in the mild and moderate TFI groups (mild: 43.6% vs. moderate: 34.0% vs. severe: 19.4%, P < 0.0001). No difference in the rate of ectopic pregnancies was observed (P = 0.15). Significantly more live births were obtained in patients with mild and moderate TFI (mild: 35.9% and moderate: 31.5% vs. severe: 16.8%, P = 0.0002).

Table 5 shows the same analysis, but according to postoperative TFI grade. More patients in the moderate and severe TFI groups were still infertile 2 years after surgery (moderate: 73.6% vs. severe: 100.0% vs. mild: 54.5%, P = 0.0004). Significantly more intrauterine pregnancies were observed in the mild and moderate TFI groups (mild: 32.4% vs. moderate: 16.0% vs. severe: 0%, P = 0.0002). No difference in the rate of ectopic pregnancies was observed (P = 0.46). Significantly more live births were obtained in patients with mild and moderate TFI (mild: 28.5% vs. moderate: 14.2% vs. severe: 0%, P = 0.005).

Table 6. Univariate analyses of factors affecting the rate of intrauterine pregnancies

Factors		HR (95% CI)	*P*-value
Age		0.96 (0.92-1.00)	0.0506
Preoperative disease course		0.87 (0.78-0.98)	0.0167
Number of pregnancies		1.02 (0.87-1.19)	0.8075
Ectopic pregnancy	Yes vs. No	0.61 (0.30-1.27)	0.1869
Other operations	Yes vs. No	0.95 (0.55-1.66)	0.8679
Ovarian tumors	Yes vs. No	1.43 (0.35-5.79)	0.6155
PID	Yes vs. No	1.55 (0.97-2.48)	0.0659
Surgery			
Laparoscopic salpingoplasty + hydrotubation		1.0	
Hysteroscopic-laparoscopic salpingoplasty + hydrotubation		1.01 (0.62-1.67)	0.9597
Hydrotubation		---	---
Preoperative scoring	Mild	1.0	
	Moderate	0.86 (0.55-1.33)	0.4888
	Severe	0.44 (0.28-0.68)	0.0003
Postoperative scoring	Mild	1.0	
	Moderate	0.41 (0.25-0.69)	0.0007
	Severe	---	---

PID: pelvic inflammatory disease.

Table 7. Multivariate analyses of factors affecting the rate of intrauterine pregnancies

Factors		HR (95% CI)	*P*-value
Preoperative scoring		0.75 (0.59-0.95)	0.0155
Postoperative scoring		0.53 (0.31-0.91)	0.0203
PID	Yes vs. No	1.64 (1.03-2.63)	0.0387
Preoperative disease course		0.88 (0.78-0.98)	0.0232

PID: pelvic inflammatory disease.

Factors affecting the rate of intrauterine pregnancy

Table 6 shows the univariate analysis of factors involved in the rate of intrauterine pregnancies. Preoperative disease course (HR = 0.89, 95% CI: 0.78-0.98, P = 0.02), preoperative TFI score (severe TFI: HR = 0.44, 95% CI: 0.28-0.68, P < 0.0001) and postoperative TFI score (moderate TFI: HR = 0.41, 95% CI: 0.25-0.69, P = 0.0007) had an impact on the rate of intrauterine pregnancies.

The factors identified using univariate analyses with a *P*-value < 0.10 were added to a multivariate model. Results showed that preoperative score (P = 0.02), postoperative score (P = 0.02), pelvic inflammatory disease (PID) (P = 0.04) and preoperative disease course (P = 0.02) were all independently involved in the rate of intrauterine pregnancies (**Table 7**).

Table 8 shows the univariate analysis of factors involved in the rate of live births. Age (HR = 0.95, 95% CI: 0.91-1.00, P = 0.03), PID (HR = 1.71, 95% CI: 1.05-2.78, P = 0.03), preoperative TFI score (severe TFI: HR = 0.49, 95% CI: 0.30-0.80, P = 0.004) and postoperative TFI score (moderate TFI: HR = 0.44, 95% CI: 0.26-0.76, P = 0.003) had an impact on the rate of live births.

The factors identified using univariate analyses with a *P*-value < 0.10 were added to a multivariate model. Results show that postoperative score (P = 0.001), PID (P = 0.03) and age (P = 0.03) were all independently involved in the rate of live births (**Table 9**).

Discussion

The present study was motivated by the need for a better prognosis system for TFI patients who undergo tubal surgery. Our results showed that all three surgical approaches used in our centre (laparoscopic salpingoplasty and hydrotubation, hysteroscopic-laparoscopic salpingoplasty and hydrotubation, and laparoscopic

Table 8. Univariate analyses of factors affecting the rate of live births

Factors		HR (95% CI)	*P*-value
Age		0.95 (0.91-1.00)	0.0333
Preoperative disease course		0.90 (0.80-1.00)	0.0573
Number of pregnancies		0.94 (0.79-1.12)	0.4915
Ectopic pregnancy	Yes vs. No	0.56 (0.25-1.22)	0.1453
Other operations	Yes vs. No	1.12 (0.64-1.96)	0.6910
Ovarian tumors	Yes vs. No	0.75 (0.10-5.35)	0.7714
PID	Yes vs. No	1.71 (1.05-2.78)	0.0301
Surgery			
Laparoscopic salpingoplasty + hydrotubation		1.0	
Hysteroscopic-laparoscopic salpingoplasty + hydrotubation		1.10 (0.66-1.85)	0.7078
Hydrotubation		---	---
Preoperative scoring	Mild	1.0	
	Moderate	0.99 (0.62-1.60	0.9788
	Severe	0.49 (0.30-0.80)	0.0044
Postoperative scoring	Mild	1.0	
	Moderate	0.44 (0.26-0.76)	0.0032
	Severe	---	---

PID: pelvic inflammatory disease.

Table 9. Multivariate analysis of factors affecting the rate of live births

Factors		HR (95% CI)	*P*-value
Postoperative scoring		0.41 (0.24-0.70)	0.0012
PID	Yes vs. No	1.74 (1.07-2.83)	0.0255
Age		0.95 (0.90-0.99)	0.0311

PID: pelvic inflammatory disease.

hydrotubation) improved the TFI score. Our results also showed that the preoperative and postoperative TFI score classifications were significantly associated with pregnancy outcomes. Multivariate analysis showed that the preoperative disease course, the preoperative TFI score and the postoperative TFI score were independently associated with the rate of intrauterine pregnancies. Multivariate analysis also showed that the postoperative TFI score, PID and age were independently associated with the rate of live births.

Using the AFS-r system, patients classified with the worst adhesions had no pregnancy at all, while the pregnancy rate was 42.9% in the best adhesion level [18]. The Hulka tubal classification system is a system assessing the tubal conditions according to the degrees of adnexal adhesions [3]. The evaluation is based on: 1) extent of ovarian involvement in adhesive disease, 2) nature of the adhesions, 3) fimbrial patency, and 4) isthmic patency. This system was used in 177 patients undergoing laparoscopic salpingoplasty: the postoperative pregnancy rate was 13.6% and live birth rate was only 9%, while the ectopic pregnancy rate was 3.4%; however, this study favored patients with relatively severe tubal diseases [19]. A retrospective cohort study using the Hull & Rutherford system classified tubal injuries into three levels: level I was mild tubal adhesions; level II was unilateral severe tubal injuries; and level III was bilateral severe tubal injuries. The study revealed that ectopic pregnancy rate was associated with the injury level, but not infertility; the postoperative live birth rates of the three levels were 69%, 48% and 9%, respectively [20]. Their multivariate analysis showed that the hazard ratios between levels III and I, and between levels III and II were 13.7 and 6.54, respectively. Therefore, this system could be used to determine the prognosis of tubal surgery into good, general or poor [21]. These study showed that the Hull & Rutherford system was effective, but that it also subjective in the assessment of the three levels.

Falloposcopy allows the direct observation of the inner tubal condition and to classify it using evaluations of mucosal adhesions between the folds, extensive adhesions between mucosa

layers, appearance of scattered smooth regions and complete losses of mucosal structures. Marana et al. [10] observed in 51 patients with adnexal adhesions (24 cases) or hydrosalpinxes (27 cases) who had undergone laparoscopic tubo-ovarian adhesiolysis or salpingoplasties/falloposcopy that, based on AFS, the full-term birth rates of patients with normal fallopian mucosa in tubo-ovarian adhesiolysis was 71% and 64% in salpingoplasty patients, and that there were no intrauterine pregnancies in patients with severe intrafallopian injuries. Comparing the falloposcopic results with AFS assessments, it could be seen that AFS was not clearly related with postoperative outcomes.

In the present study, salpingoplasty significantly decreased the postoperative TFI scores. Furthermore, the postoperative TFI score was associated with both the intrauterine pregnancy and live births rates. Using this system, both pre- and postoperatively could improve the prognosis determination. However, TFI prognosis was most closely related with the postoperative scores.

In the present study, all three surgical approaches decreased TFI scores to a similar extent. Turjacanin-Pantelic et al [21] retrospectively analyzed 66 patients who had undergone salpingoplasty and observed that the prognosis of the laparotomic approach was not significantly different from the laparoscopic approach. Mossa et al [22] randomly assigned 224 patients with distal tubal occlusions to laparotomic microsurgery or laparoscopic surgery. After 24 months, the pregnancy rates between the two approaches were similar (43.7% vs. 41.6%). Ahmad et al [23] compared laparoscopy and laparotomy for distal tubal surgeries using a meta-analysis and found that there was no difference between the two approaches.

Based on the relationships between the preoperative TFI scores and prognosis, postoperative pregnancy outcomes in mild TFI patients were obviously higher than those of moderate and severe TFI patients, and that the infertility rate of severe TFI patients was obviously higher than in moderate TFI patients. Therefore, these results indicate that the scoring system can preliminarily evaluate prognosis. However, according to our observation, discrepancies between scores and prognosis could be due to differences in surgeons' skills, and to different improvements in tubal conditions resulting from different surgical approaches. The long-term significance of the postoperative score will be presented in the prospective part of our studies.

At present, the new tubal classification system is unable to estimate the rate ectopic pregnancy. In addition, the present study may suffer from some limitations, which are mainly due to the retrospective nature of the study. Indeed, we had to work with the data already collected in the medical charts, but a prospective trial could allow us determining new factors that could be associated with prognosis. Furthermore, our sample size was small. Multicentre studies could allow us to strengthen the observed associations.

Conclusion

We devised a new classification system for TFI prognosis. Salpingoplasty improved these scores. Both pre- and post-operative TFI assessment using this new system associated with pregnancy prognosis.

Disclosure of conflict of interest

None.

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