Predictive value of a modified classification of fallopian tube status on prognosis of tubal factor infertility after laparoscopic surgery

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Abstract
Built on 2 existing classification systems, this study was to develop a new classification system to better predict the pregnancy prognosis after laparoscopic surgery in patients with tubal factor infertility and accordingly propose a management strategy.
We followed up 423 patients suffering from tubal factor infertility who had undergone hysteroscopic-laparoscopic surgery for 2 years without in vitro fertilization and embryo transfer (IVF/ET). Based on the operative reports, a new, modified classification of fallopian tube status (hereafter referred to as the modified classification) was developed with reference to the 2 existing classification systems (the r- r-AFS classification of pelvic adhesions and the scoring system of distal tubal obstruction). A score of 0 to 3 was assigned to each of the 4 factors (tubal wall consistency, hydrosalpinx, pelvic adhesions, and tubal patency) for each of the tubes with a total bilateral score of 0 to 24. The patients were classified for the abnormalities of the fallopian tubes into 3 groups: mild (<8), moderate (8–15) and severe (>15). By utilizing SPSS 20.0 Statistic Analysis Software, the data were analyzed with t test, Chi-Square test, ANOVA or ROC as appropriate.
Each of the 4 factors of the modified classification was independently and closely associated with post-surgical prognosis (P < .05). There was a statistically significant difference in postoperative pregnancy prognosis among the 3 groups of patients (P < .05). Patients with a score of <8 (mild) had the highest intrauterine pregnancy rate, reaching 60.1%. In contrast, patients with a score of 8 to 15 (moderate) had a significant increase in ectopic pregnancy (21.5%), while patients with a score of >15 (severe) had a significantly increased infertility rate of 89.5%. When the pregnancy outcomes were divided into intrauterine pregnancy and other outcomes, the modified classification had the largest area under the ROC curve (0.569) (P < .05). With the optimum cutoff of 4.5, the sensitivity was 88.6%, specificity was 74.5% and accuracy was 63.1%.
The modified classification of fallopian tube status is a simple and practical scoring system which can comprehensively and effectively evaluate the function of the fallopian tube and thus is more accurate than the other 2 systems in predicting the postoperative pregnancy outcomes.

Abbreviations: AUC = area under the curve, HSG = hysterosalpingography, IRB = Institutional Review Board, IVF/ET = in vitro fertilization and embryo transfer, r-AFS = revised American Fertility Society, ROC = receiver operating characteristic curve, TFI = tubal factor infertility.

Keywords: laparoscopic surgery, modified classification of fallopian tube status, postoperative prognosis, tubal infertility

1. Introduction
Tubal factor infertility (TFI) accounts for one third of female infertility. It is the most common cause of female infertility with an ever-increasing incidence in recent years.12 If the function of the fallopian tube can be successfully restored after laparoscopic surgery with adhesiolysis and re-establishment of tubal patency, a pregnancy rate of 28% to 53% can be achieved.13–11 Despite surgery, however, the optimal tubal function still cannot be obtained in a significant number of patients, resulting in continued infertility and an increased risk of ectopic pregnancy, while precious time is wasted in waiting for a natural conception. Therefore, how to effectively assess the tubal condition and accurately predict the therapeutic efficacy of operation during laparoscopic surgery is of paramount importance. The scoring systems that are currently used and have some value in predicting prognosis are the r-AFS (revised American Fertility Society) classification of pelvic adhesions and the scoring system of distal tubal obstruction. Besides the complexity in the scoring calculation, however, these 2 systems both emphasize the
evaluation of pelvic adhesions and pay inadequate attention to tubal condition itself. Not surprisingly, these systems are not widely used in clinical practice. The purpose of this study was to develop a new, easy-to-use and practical scoring system to more objectively describe the tubal condition as well as accurately assess the post-operative pregnancy outcome. The ultimate goal was to apply this new, modified classification of fallopian tube status (hereafter referred to as the modified classification) in the assessment of tubal condition and provide a guide to the management.

2. Materials and methods

2.1. Patients

This was a retrospective study on all patients of our hospital with TFI as principal diagnosis who had undergone hysteroscopic-laparoscopic surgery between December 2011 and December 2013. The patients were included in the study if they fulfilled the following criteria:

1. had regular menstrual periods and normal ovulation cycles with normal blood level of 6 hormones (FSH, LH, Estradiol, Progesterone, HCG, Testosterone);
2. had a desire for pregnancy but failed to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse;
3. had inadequate patency, hydrosalpinx, occlusion, or atresia of unilateral or bilateral fallopian tubes identified by preoperative hysterosalphingography (HSG), or had unilateral or bilateral hydrosalpinx found on ultrasound. Of note, all but 14 patients had HSG while all had ultrasound study.

Exclusion criteria were:
1. male factor infertility;
2. infertility caused by endocrine, immunological or hereditary abnormality;
3. congenital anomaly of internal or external genitalia;
4. complication with ovarian tumor, pelvic tuberculosis, endometriosis, endometrial polyps, intrauterine adhesions, or multiple uterine leiomyomas.

This study was approved by Institutional Review Board (IRB) of our hospital.

A total of 632 patients met the above criteria, with an age range of 19 to 43 years (mean 29.05 ± 4.46). Postoperatively, the pregnancy outcomes of the patients were followed for 24 months by clinic visits or telephone calls on a regular basis. Of all, 569 patients were followed successfully while the remaining 63 were lost to follow-up, achieving a follow-up rate of 90%. After excluding 121 patients who immediately underwent in vitro fertilization and embryo transfer (IVF/ET) and 23 patients who had no immediate desire for pregnancy, 423 patients who had attempted for 24 months postoperatively to get pregnant were included in the final analysis, with a total of 831 fallopian tubes (419 left and 412 right).

2.2. Tubal classification systems

The r-AFS classification of pelvic adhesions[21]: this system was developed and revised by the American Fertility Society in 1980s, in an effort to evaluate the condition of pelvis and fallopian tubes.[11,12] Focusing on the extent and severity of adnexal adhesions and the cul-de-sac obliteration, it attempts to indirectly evaluate the fallopian tubes. With a score of 0, 1, 2, 4, 6, 16, 20 or 40 assigned to each of individual factors evaluated and a potential total score of 0 to 104, the tubal abnormalities are classified as mild (0–7), moderate (8–19) and severe (≥20).

The AFS classification of distal tubal occlusion[13]: this was developed by AFS in 1988. The evaluation factors are distal ampullary diameter (reflecting the severity of hydrosalpinx), tubal wall thickness, mucosal folds at neostomy site, extent of adhesions, and type (nature) of adhesions. With a score of 0, 1, 2, 3, 4, 6 assigned to each of the factors and a potential total score of 0 to 56, the abnormalities of the fallopian tubes are classified as normal (0), mild (1–3), moderate (3–10) and severe (≥10).

The modified classification: Based on the r-AFS classification of pelvic adhesions and the scoring system of distal tubal obstruction, we developed a new, modified scoring system of fallopian tube status (Table 1). According to the intra-operative findings, the fallopian tubes were evaluated based on 4 factors: tubal wall consistency, diameter of hydrosalpinx, adnexal adhesions, and tubal patency. A score of 0, 1, 2, 3 was assigned to each factor depending on the severity of their respective abnormalities. Then the scores were summed, with a potential total score of 0 to 24.

Laparoscopic hydrotubation with methylene blue solution test was performed to classify the tubal patency as follows:

1. fully patent: when 5 to 10 ml of the solution was infused into the fallopian tube, there was immediate spillage of methylene blue through the fimbrial end without focal enlargement of the tube;

By clinic visits or telephone calls on a regular basis. Of all, 569 patients were followed successfully while the remaining 63 were lost to follow-up, achieving a follow-up rate of 90%. After excluding 121 patients who immediately underwent in vitro fertilization and embryo transfer (IVF/ET) and 23 patients who had no immediate desire for pregnancy, 423 patients who had attempted for 24 months postoperatively to get pregnant were included in the final analysis, with a total of 831 fallopian tubes (419 left and 412 right).

| Factors | Tubal wall consistency | Diameter of hydrosalpinx (cm) | Adnexal adhesions | Tubal patency |
|---------|------------------------|-------------------------------|-------------------|--------------|
| Scores  |                        |                               |                   |              |
| 0       | Supple                 | none                          | None              | Fully patent |
| 1       | Supple, mildly thickened or edematous, or focally distorted | <1.5                        | Focally filmy     | Mildly occluded |
| 2       | Moderately thickened or edematous | 1.5–3.0                    | Focally dense, or extensively filmy, or filmy encapsulating | Severely occluded |
| 3       | Thick and rigid         | >3.0                          | Extensively dense, or densely encapsulating | Completely occluded |
| Left    | Right                  | Total score                  |                   |              |

*Abnormalities based on the total score: mild <8; moderate, 8–15; severe: >15.

*See text for description of patency.
2. mildly occluded: there was mild resistance to the infusion of 5–10 ml solution, with tubal enlargement and distortion, followed by spillage of methylene blue through the fimbrial end, which indicated mild fimbrial stenosis;

3. severely occluded: similar to (b), except there was severe resistance to the infusion, which indicated severe fimbrial stenosis;

4. completely occluded: there was severe resistance to the infusion of even only 5 ml solution, with no spillage of methylene blue at fimbria.

2.3. Statistical analysis

All data were analyzed using SPSS 20.0 Statistic Analysis Software. Continuous variables were presented as mean ± SD, while the significant difference between means was tested using independent samples t test or multivariate analysis of variance (MANOVA). For categorical variables, Chi-Square Test was utilized to analyze the sample frequency and composition ratio. Receiver Operating Characteristic (ROC) curve was applied to evaluate the prognostic value of different classification systems. A P value of <.05 was considered statistically significant.

3. Results

3.1. Post-operative pregnancy outcomes

Of the 423 patients who had attempted for 24 months after hysteroscopic-laparoscopic surgery to get pregnant, 233 patients achieved a pregnancy with a pregnancy rate of 55.1% (233/423) and an infertility rate of 44.9% (190/423). Among the 233 pregnant patients, 163 patients (38.5%, 163/423) had intrauterine pregnancy and 70 patients (16.5%, 70/423) had ectopic pregnancy. The outcomes of intrauterine pregnancy in the 163 patients were as follows: live birth in 123 patients (29.1%, 123/423) including premature birth in 15 patients (3.5%, 15/423), miscarriage in 16 patients (3.8%, 16/423), and ongoing pregnancy in 24 patients at last follow-up (of whom, 21 patients were beyond 12 weeks of pregnancy).

Postoperatively, the cumulative pregnancy rate was 14.2% at 3 months, 33.3% at 6 months, 49.7% at 12 months, 52.7% at 18 months, and 55.1% at 24 months of follow-up, respectively.

3.2. The development of the modified classification

The relationship between the individual factors of the modified classification and the postoperative prognosis was examined. When the postoperative outcomes were divided into intrauterine pregnancy and all other outcomes, the increasing combined score (from 0 to 6) of bilateral fallopian tubes for each of the factors (tubal wall consistency, diameter of hydrosalpinx, pelvic adhesions, tubal patency) was independently associated with the prognosis (P < .05 for each of the 4 factors, data not shown). Chi-Square Test showed that each factor affected intrauterine pregnancy rates. Therefore we chose these 4 factors for the modified classification.

Using descriptive statistics, with the total bilateral scores of the modified classification arranged from the lowest to the highest, linear curves for cumulative pregnancy outcomes were created (Fig. 1). It showed the trend of 3 different outcomes (intrauterine pregnancy, ectopic pregnancy or infertility) according to the different scores of fallopian tubes. Of note, there was an inflection point at the score of 8 and 15, respectively, for each curve. Using the score of 8 and 15 as cutoff, the classification criterion of the modified classification was established, classifying the abnormalities of fallopian tube status into 3 groups: mild (<8), moderate (8–15) and severe (>15).

The postoperative pregnancy outcomes among the 3 groups of patients with different severity of tubal abnormalities were statistically significant (P < .01), suggesting the total scores based on the modified classification were associated with postoperative pregnancy outcomes (Table 2).

The intrauterine pregnancy rates in TFI patients progressively declined with the increasing scores of the fallopian tubes by the modified classification (Table 1), indicating that the classification has prognostic value for postoperative pregnancy and infertility. Patients with scores of <8 (mild) had the highest intrauterine pregnancy rate, reaching 60.1%. In contrast, patients with scores

![Figure 1. The trend of three different pregnancy outcomes with regard to the different scores of the fallopian tube status.](image-url)
of 8 to 15 (moderate) had a significant increase in ectopic pregnancy (21.5%) while intrauterine pregnancy rate decreased to 26.8%. Further, patients with scores of >15 (severe) had a significantly increased infertility rate of 89.5%, with pregnancy occurring in only 2 patients.

3.3. The diagnostic value of the other 2 classification systems

3.3.1. The r-AFS classification of pelvic adhesions. Based on the scores of pelvic adhesions of r-AFS classification, all patients were divided into 3 groups according to tubal abnormalities: mild (0–7), moderate (8–19) and severe (>20). There was a significant difference in the prognosis among the 3 groups (P < .05, Table 3). With decreasing scores, there was an increase in the intrauterine pregnancy rate. Interestingly, infertility rate tended to be higher in mild abnormality group (43.9%) than that of moderate abnormality group (38.7%), while the infertility rate was the highest (51%) in severe abnormality group. These results suggested r-AFS classification of pelvic adhesions may have some value in predicting the postoperative prognosis, but it is not a good tool in predicting infertility.

The left and right-sided tubo-ovarian adhesions and cul-de-sac obliterations are the factors of r-AFS classification of pelvic adhesions. Based on the scores of each of these factors, we analyzed the relationship between the r-AFS scores and the 3 pregnancy outcomes (intrauterine pregnancy, ectopic pregnancy, infertility) by using ANOVA (Tables 4–6).

The nature (type) and extent of tubo-ovarian adhesions of either side (left or right) were associated with postoperative pregnancy outcomes (P = .000). With increasing scores of tubo-ovarian adhesions, there was a progressively increase in the likelihood of infertility. The r-AFS classification puts relatively large weight on the scores of cul-de-sac. However, our results showed the severity of cul-de-sac obliteration was not associated with pregnancy outcomes (P = .493). Accordingly, the obliteration of cul-de-sac was excluded as a factor in our modified classification.

3.4. The scoring system of distal tubal obstruction

Based on the scores of distal tubal occlusion, all patients were divided into 4 groups according to tubal abnormalities: normal (0), mild (1–3), moderate (3–10) and severe (>10). The postoperative pregnancy outcomes were not statistically different among the 4 groups (P > .05), which suggested this scoring
system was not sufficient in predicting postoperative intrauterine pregnancy or infertility (Table 7).

3.5. The comparison of the prognostic values of the 3 classification systems

ROC curve, with its characteristics shown in Table 8, was utilized to compare the prognostic values of the 3 classification systems. The ROC for r-AFS classification of pelvic adhesions had a $P$ value of >.05, suggesting it basically has no value in predicting the postoperative prognosis. In contrast, the $P$ value of ROC was <.05 for both the AFS classification of distal tubal occlusion and the modified classification. However, the AUC (area under the curve) for the AFS classification of distal tubal occlusion was only 0.411, suggesting that it has no prognostic value for postoperative outcomes. In comparison, the modified classification had the largest AUC and thus had prognostic value. When compared with the other 2 systems, the modified classification had the highest sensitivity and accuracy.

4. Discussion

The tubal scoring systems that are currently used and have some value in predicting prognosis are the r-AFS classification of pelvic adhesions and the scoring system of distal tubal obstruction. The present study analyzed the predictive values of these 2 systems and suggested the r-AFS classification of pelvic adhesions may have some value in predicting the postoperative prognosis, but it is not a good tool in predicting infertility. Similarly, the r-AFS classification of distal tubal obstruction is not sufficient in predicting postoperative outcomes.

We further investigated the relationship between each of the individual factors of the 2 systems and the prognosis. We found that the r-AFS classification of pelvic adhesions is mainly designed to evaluate the status of pelvis and fallopian tubes in endometriosis, focusing on the adhesions of bilateral adnexa and the obliteration of cul-de-sac. Of a total score of 0 to 104, a significant portion (0–40) is assigned to the cul-de-sac. However, we found that the obliteration status of cul-de-sac was not associated with postoperative outcomes. Therefore, we elected not to include cul-de-sac obliteration as a factor in scoring. Likewise, the scores assigned for pelvic adhesions by the scoring system of distal tubal obstruction are 0–20. Of 423 patients, 311 patients were classified as having severe abnormalities by this classification system. Of note, 116 of these 311 patients achieved intrauterine pregnancy postoperatively. The results suggested this classification puts a relatively large weight on the pelvic adhesions, causing subjective bias in scoring. In addition, both of the 2 systems do not include the tubal patency as a factor, limiting their power in evaluation of the tubal status. Therefore, their value in predicting postoperative outcomes is limited.

Based on the above observations, we adjusted the scoring system as follows:

1. eliminated the obliteration of cul-de-sac;
2. reduced the scores assigned for pelvic adhesions;
3. added the tubal patency as a new factor;
4. gave a detailed description of tubal wall consistency and patency.

Then we built a modified classification for tubal factor infertility. The 4 factors selected for the evaluation were tubal wall consistency, diameter of hydrosalpinx, pelvic adhesions and tubal patency. Each of the factors was independently associated with the prognosis. A score of 0 to 3 was assigned for each factor, with a total score of 0 to 24. With the scores assigned for pelvic adhesions reduced and the tubal patency added, the subjective bias was greatly reduced and hence little variation in the scoring by different surgeons. The system is easy to remember and thus is more likely to be applied in routine clinical practice. The modified classification comprehensively described the tubal condition, accurately revealed the tubal status, and therefore, could effectively evaluate the fertility potential of the fallopian tubes.

To investigate the impact on prognosis of the modified classification, we started with analyzing the impact of individual factors. When the postoperative outcomes were divided into intrauterine pregnancy and all other outcomes, each of the 4 factors was independently associated with the prognosis, suggesting each factor can affect the intrauterine pregnancy rate postoperatively.

This classification system semi-quantitatively evaluated bilateral fallopian tubes by assigning and then summing numeric scores. With

| TABLE 7 |
| The postoperative prognosis according to the scores of AFS distal tubal occlusion. |

| Abnormalities (Scores) | Intrauterine pregnancy | Ectopic pregnancy | Infertility |
|------------------------|------------------------|-------------------|------------|
| Normal (0)             | 5 (62.50%)             | 0 (0.00%)         | 3 (37.50%) |
| Mild (1–3)             | 4 (44.4%)              | 0 (0.00%)         | 5 (55.6%)  |
| Moderate (3–10)        | 38 (40.0%)             | 8 (8.4%)          | 49 (51.6%) |
| Severe (>10)           | 116 (37.3%)            | 62 (19.9%)        | 133 (42.8%)|
| Total                  | 163                    | 70                | 190        |

| TABLE 8 |
| The ROC characteristics of the 3 classification systems. |

| Classification system | ROC area | Standard error | $P$ value | Optimal cutoff | Sensitivity | Specificity | Accuracy |
|-----------------------|----------|----------------|-----------|----------------|-------------|-------------|----------|
| Modified†             | 0.569    | 0.032          | .045      | 4.5            | 0.886       | 0.745       | 0.631    |
| r-AFS‡                 | 0.538    | 0.035          | .319      | 9.5            | 0.829       | 0.728       | 0.557    |
| AFS distal§            | 0.411    | 0.028          | .002      | 10.5           | 0.712       | 0.760       | 0.544    |

† The modified classification of the fallopian tube status.
‡ The r-AFS classification of pelvic adhesions.
§ The AFS classification of distal tubal occlusion.
a total score of 8 and 15 as cutoff, the patients were classified into 3 groups for the abnormalities of fallopian tubes: mild (<8), moderate (8–15), and severe (>15). There was a statistically significant difference of postoperative prognosis among the 3 groups of patients. In general, the intrauterine pregnancy rate in TFI patients progressively declined with increasing scores of the fallopian tube abnormalities. On the other hand, the ectopic pregnancy rate progressively increased with rising scores. Specifically, patients with scores of <8 had the highest intrauterine pregnancy rate, reaching 60.1%. Meanwhile, patients with scores of 8 to 15 had a significant increase in ectopic pregnancy (21.5%) while patients with scores of >15 had the highest infertility rate (89.5%). These results indicated the prognostic value of the modified classification in predicting postoperative pregnancy outcomes.

Compared with the 2 existing referenced classification systems, the modified classification is more closely associated with postoperative prognosis, especially in predicting intrauterine pregnancy vs other pregnancy outcomes. The patients with a score of <15, awaiting a spontaneous pregnancy is, of course, the best choice, while the patients with a score of 8 to 15 should be warned of the increased risk of ectopic pregnancy. For patients with a score of >15, whether waiting for a spontaneous pregnancy is an individual choice.

In addition, we used ROC curve to compare the prognostic values of the 3 classification systems. When the postoperative outcomes were divided into intrauterine pregnancy and all other outcomes, the modified classification had the largest AUC and thus had prognostic value. When compared with the other 2 systems, the modified classification system had the highest sensitivity and accuracy. Therefore, the modified classification is more accurate and practical than the other 2 systems in predicting postoperative prognosis.

Finally, our data showed that the vast majority of pregnancy occurred within 1 year after surgery, which was consistent with the results of others. Thus, women who fail to conceive spontaneously after 1 year of trying, especially those with a score of >15, should be advised to choose IVF-ET. Although the modified classification had the highest accuracy in predicting the prognosis among the 3 classification systems, its accuracy was still somewhat limited. Therefore, a large-scale prospective study is warranted to evaluate the factors of the modified classification in predicting postoperative pregnancy outcomes.

Key limitation of this study is that it is retrospective and depends on the operative reports. Patients’ classifications are based on operative reports, therefore, it may be misplaced classification. An additional limitation is different assessment of the pelvis and the stage of the disease, different surgical approach to TFI patients may all affect our results. Further studies should be carried out to address these issues.

In conclusion, the modified classification of fallopian tube status is a simple and practical scoring system which can comprehensively and effectively evaluate the function of the fallopian tube and thus is more accurate than the other 2 systems in predicting the postoperative pregnancy outcomes.

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