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# Clinical value of four-dimensional hysterosalpingo-contrast sonography assisted by intrauterine pressure measurement for tubal patency evaluation.

Chunhong Lin<sup>1</sup>, Jianyong Chen<sup>2</sup>, Xianguo Li<sup>3</sup>, Linlin Wang<sup>1</sup>, Fengqin Yan<sup>1</sup>,  
Ye Chang<sup>4</sup>, and Xueniu Yang<sup>5</sup>

<sup>1</sup>Third Department of Ultrasound, Hengshui People's Hospital, Hengshui, Hebei Province, China.

<sup>2</sup>Department of Medical Medicine, Hubei College of Chinese Medicine, Jingzhou, Hubei Province.

<sup>3</sup>Medical Department, The Fifth People's Hospital of Hengshui, Hengshui, Hebei Province, China.

<sup>4</sup>First Department of Ultrasound, Hengshui People's Hospital, Hengshui, Hebei Province, China.

<sup>5</sup>NHC Key Laboratory of Birth Defects and Reproductive Health. Chongqing Population and Family Planning Science and Technology Research Institute, Chongqing, China.

**Keywords:** tubal patency; 4D hysterosalpingo-contrast sonography; intrauterine pressure.

**Abstract.** We aimed to explore the clinical value of four-dimensional hysterosalpingo-contrast sonography (4D-HyCoSy) assisted by intrauterine pressure measurement for evaluating tubal patency. One hundred and thirty-two patients diagnosed with tubal factor infertility from February 2018 to February 2021 were selected as subjects. With hysterosalpingography diagnosis results as the gold standard, 4D-HyCoSy was conducted for all patients, and the status of the fallopian tubes was classified into patency, occlusion, and partial occlusion. Based on the function of fallopian tubes, 4D-HyCoSy diagnosis results revealed that fallopian tubes showed bilateral patency, incomplete patency (including bilateral partial occlusion, unilateral patency, and unilateral partial occlusion, unilateral patency and unilateral occlusion), unilateral partial occlusion and unilateral occlusion, and bilateral occlusion. The cutoff value of peak intrauterine pressure was determined using the receiver operating characteristic curve (ROC), specificity, and the area under the ROC curve (AUC) between 4D-HyCoSy alone and 4D-HyCoSy assisted by intrauterine pressure measurements. There were significant differences in the peak intrauterine pressure among patients with bilateral patency, incomplete patency, unilateral partial

occlusion, and unilateral and bilateral occlusions ( $p < 0.05$ ). The corresponding cutoff values of peak intrauterine pressure were 24.42, 36.34, and 47.68 kPa; AUC values were 0.812, 0.836, and 0.827, respectively. The FSM model showed that the AUC of 4D-HyCoSy alone, assisted by peak intrauterine pressure was 0.85, with a higher sensitivity (88.13%) than that of 4D-HyCoSy ( $p < 0.05$ ). 4D-HyCoSy, assisted by intrauterine pressure measurement, has an excellent value for evaluating tubal patency.

### **Valor clínico de la histerosalpingo-sonografía 4D por contraste, asistida por medición de la presión intrauterina, para evaluar la permeabilidad tubárica.**

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**Palabras clave:** permeabilidad tubárica; ecografía con contraste de histerosalpingo en cuatro dimensiones; presión intrauterina.

**Resumen.** Nuestro objetivo fue explorar el valor clínico de la histerosalpingo-sonografía con contraste en cuatro dimensiones (4D-HyCoSy) asistida por la medición de la presión intrauterina para evaluar la permeabilidad tubárica. Se seleccionaron como sujetos un total de 132 pacientes diagnosticadas como infertilidad por factor tubárico desde febrero de 2018 hasta febrero de 2021. Con los resultados del diagnóstico de histerosalpingografía como estándar de oro, se realizó 4D-HyCoSy para todas las pacientes y el estado de las trompas de Falopio se clasificó como permeable, ocluída y parcialmente ocluída. Según la función de las trompas de Falopio, los resultados del diagnóstico 4D-HyCoSy revelaron que las trompas de Falopio mostraban permeabilidad bilateral, permeabilidad incompleta (incluida oclusión parcial bilateral, permeabilidad unilateral y oclusión parcial unilateral, permeabilidad unilateral y oclusión unilateral), oclusión parcial unilateral y oclusión unilateral, y oclusión bilateral. El valor de corte de la presión intrauterina máxima se determinó utilizando la curva característica operativa del receptor (ROC), la especificidad y el área bajo la curva ROC (AUC) entre 4D-HyCoSy sola y 4D-HyCoSy asistida por la medición de la presión intrauterina. Hubo diferencias significativas en la presión intrauterina máxima entre pacientes con permeabilidad bilateral, permeabilidad incompleta, oclusión parcial unilateral y oclusión unilateral y oclusión bilateral ( $p < 0,05$ ). Los valores de corte correspondientes de la presión intrauterina máxima fueron 24,42, 36,34 y 47,68 kPa, y los valores de AUC fueron 0,812, 0,836 y 0,827, respectivamente. El modelo FSM mostró que el AUC de 4D-HyCoSy asistida por la presión intrauterina máxima fue de 0,85, con una sensibilidad más alta (88,13%) que la de 4D-HyCoSy ( $p < 0,05$ ). 4D-HyCoSy asistido por la medición de la presión intrauterina tiene un valor diagnóstico significativo en la evaluación de la permeabilidad tubárica.

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## INTRODUCTION

Infertility is a health concern worldwide. Among the total cases of female infertility, 54.7% of patients suffer from tubal factor infertility, and the cases show a year-by-year uptrend due to increased reproductive infections, sexually transmitted diseases, and endometriosis<sup>1-3</sup>. Therefore, effective diagnostic measures are essential for accurately evaluating the tubal patency of patients. Transvaginal hysterosalpingo-contrast sonography (TV HyCoSy) is a primary noninvasive method to assess the tubal patency of infertile patients. As technologies constantly progress, four-dimensional HyCoSy (4D-HyCoSy) has been widely applied in clinical diagnosis. Patients can still undergo missed diagnosis by this method despite of its advantages such as simple operation, low cost, and low risk<sup>4-8</sup>. In recent years, intrauterine pressure measurement is a new auxiliary means to examine fallopian tube pressure. It can be applied in combination with 4D-HyCoSy to examine the intrauterine pressure at a constant speed, improving the accuracy of the clinical diagnosis and ensuring the safety of patients<sup>9,10</sup>. In this study, the clinical data of 132 patients with tubal infertility were analyzed, and the diagnostic value of 4D-HyCoSy assisted by intrauterine pressure measurement was assessed for tubal patency.

## PATIENTS AND METHODS

### General data

One hundred and thirty-two outpatient infertile patients treated in our hospital's Department of Obstetrics and Gynecology from February 2018 to February 2021 were selected. They were 23-42 years old ( $28.69 \pm 4.32$ ) and examined at 3-7 d after menstruation, including 42 primary and 90 secondary infertile patients. This study was approved by the Ethics Committee of our hospital and performed following the Declaration of Helsinki. All the patients included in this study

and their families were informed of this study and signed an informed consent.

### Inclusion criteria

1) Patients with no pregnancy for more than one year, 2) those whose husbands had a normal reproductive function, and those who had sexual harmony with their husband and took no contraceptive measures, 3) those with indications confirmed by HyCoSy, 4) those suspected of primary or secondary tubal infertility, 5) those with negative hysterosalpingography (HSG) results, and 6) those whose family members signed the informed consent after communication.

### Exclusion criteria

1) Patients with serious gynecological diseases (vaginitis, pelvic inflammatory disease, adnexitis, etc.), 2) those complicated with malignant tumors, 3) those with ovulation failure caused by congenital malformations or other genetic factors, 4) those with heart, liver or kidney dysfunction, 5) those who were pregnant or suspected of pregnancy, 6) those who suffered from abortion within six months, 7) those who were allergic to contrast media, or 8) those with hysteromyoma >5 cm.

### Diagnosis methods

HSG is a safe method with high accuracy for checking tubal patency. This study applied HSG diagnosis results as the gold standard and compared them to 4D-HyCoSy diagnosis results, and statistical analysis was carried out.

### Apparatus and reagents

In this study, a Philips EPIQ5 color Doppler ultrasound diagnostic machine (Philips, Netherlands) was adopted for 4D-HyCoSy with a probe frequency of 5-9 MHz under low image quality; the volume angle of 100-120°, the volume frame angle of 179°, direction (Up/Down), the frame frequency of 0.6 and low threshold (20, adjusted according to different images). The contrast agent

used was SonoVue (59 mg/tube, NMPN: J20080052, Bracco, Italy). The antispasmodic and anti-inflammatory agents [gentamicin (80,000 units) + dexamethasone (2.5 mg) + atropine (0.25 mg) + lidocaine (50 mg)] were added into 20 mL of 0.9% normal saline, and mixed evenly to prepare a suspension. Later, 59 mg SonoVue was added into 5 mL of injectable normal saline and mixed evenly to form a microbubble suspension, which was diluted with 5 mL of normal saline before injection.

#### **4D-HyCoSy diagnosis**

1) Thirty min before diagnosis, atropine was injected. 2) Upon bladder filling, the patients were placed in the bladder lithotomy position. Then the shape of the patient's uterus and ovary, relative cross-section position, and pelvic cavity effusion were observed. Next, the injection pressure for bilateral ovaries was slightly increased, and the ovarian activity was evaluated. 3) Perineum and vagina were disinfected using complex iodine; a double-cavity Foley catheter was placed into the uterine cavity under the guidance of the abdominal probe, and 1.5-2 mL of normal saline was injected into the balloon using a syringe. 4) After the size and position of the balloon were adjusted, 5 mL of normal saline was slowly injected through the Foley catheter and then pumped back. After that, the tubal patency was preliminarily evaluated according to the resistance and the amount of liquid pumped back. 5) The probe was continuously adjusted to turn on the four-dimensional mode, and the contrast agent was injected slowly. Next, the solvent data were recorded in real-time following the optimization of the sampling frame, and the data of liquid pumped back were recorded. Afterward, the speed and pressure of the injection were adjusted at any time based on patients' adverse reactions. 6) The Foley catheter was removed, and the uterine cavity was observed under the radiography mode.

#### **HSG diagnosis**

The patients were placed in the supine bladder lithotomy position, and the first slice was taken. A vaginal speculum was put after disinfection. Then the cervical side wall was fixed with cervical forceps, the second slice was taken after contrast agent iohexol was slowly added, and the shape of the uterus was observed. Subsequently, the angle was adjusted for photography of the third slice, after which the development of fallopian tubes and uteri were observed. If the development effect was unsatisfactory, the medicine could be increased appropriately.

HSG diagnostic criteria were displayed below: 1) Patency: the fallopian tubes on both sides were completely developed, showing a natural shape. The contrast agent overflowed normally at the umbrella end and diffused in the pelvic cavity. There was almost no contrast agent left in the fallopian tubes. 2) Partial occlusion: fallopian tubes had poor morphology, and a small amount of contrast agent was left. 3) Occlusion: the contrast agent gathered in the occlusion site and did not enter the pelvic cavity.

#### **Combined diagnosis**

The receiver operating characteristic (ROC) curve was plotted to calculate the cutoff value of intrauterine pressure measurement, and the sensitivity, specificity, and area under ROC curve (AUC) of 4D-HyCoSy and combined diagnosis were determined based on 4D-HyCoSy diagnosis results, which coincided with the peak intrauterine pressure interval, with HSG diagnosis results as the gold standard.

#### **Diagnostic criteria of 4D-HyCoSy**

1) Patency: there was no resistance when the contrast agent was injected, the fallopian tubes ran smoothly and softly, and a large amount of contrast agent overflowed from the umbrella end and diffused in the pelvic cavity. 2) Partial occlusion: there was positive resistance during the injection of contrast

agent, fallopian tubes were stiff and twisted, the thickness of the lumen was uneven, and a small amount of contrast agent overflowed from the umbrella end. 3) Occlusion: during the injection of the contrast agent, there was significant resistance, no development in the whole or distal end of fallopian tubes, and no diffusion of the contrast agent in the pelvic cavity.

#### Observation of adverse reactions

Adverse reactions included adverse drug reactions, which were determined according to SonoVue instructions, and adverse non-drug reactions, such as pain, pale complexion, dizziness, profuse sweating, hypotension, arrhythmia, nausea, vomiting, and fainting.

#### Statistical analysis

The IBM® SPSS23.0 software was utilized for statistical analysis. Measurement data were expressed as mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ) and compared between groups using the *t*-test. Numerical data were expressed as percentages (%) and compared between groups *via* the  $\chi^2$  test. Dichotomous logistic regression analysis was conducted to analyze diagnostic factors, and the finite state machine (FSM) diagnostic model was established and verified using the ROC curve.  $p < 0.05$  represented a statistically significant difference.

## RESULTS

#### Detection results of tubal patency by 4D-HyCoSy

All 132 patients completed the 4D-HyCoSy examination, and their images were clear. Among 264 fallopian tubes, 145 were open, 42 were occluded entirely, and 77 were partially occluded. Among them, there were

- 53 cases of bilateral patency (106 fallopian tubes),
- 13 cases of bilateral occlusion (26 fallopian tubes),

- 20 cases of bilateral partial occlusion (40 fallopian tubes),
- Nine cases of unilateral patency and unilateral occlusion (9/9 fallopian tubes),
- 30 cases of unilateral patency and unilateral partial occlusion (30/30 fallopian tubes), and
- Seven cases of unilateral occlusion and unilateral partial occlusion (7/7 fallopian tubes).

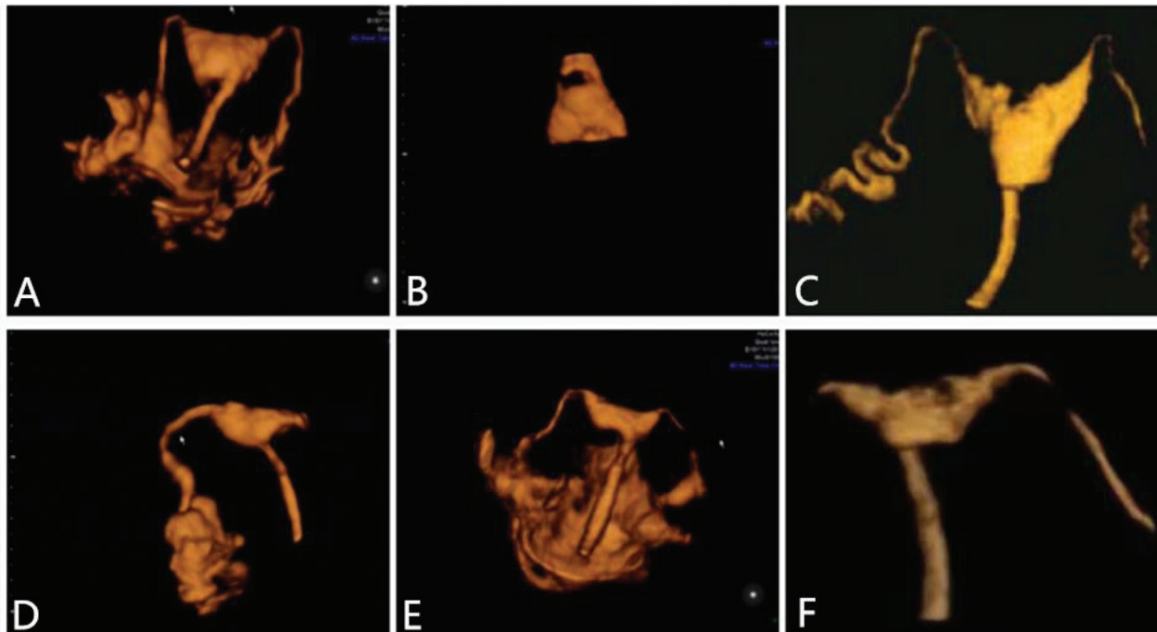
Besides, there were nine cases of arcuate uterus, five incomplete mediastinal uterus cases, three intrauterine adhesions, and two intrauterine polyps (Fig. 1).

#### 4D-HyCoSy and HSG diagnosis results

Within two weeks after the 4D-HyCoSy diagnosis, 132 patients underwent HSG diagnosis. The results showed that among 264 fallopian tubes, 132 were open, 55 were occluded entirely, and 77 were partially occluded. In the 4D-HyCoSy diagnosis, the patency of 212 fallopian tubes conformed to the HSG examination results, with a diagnostic coincidence rate of 86.18% (212/264). With HSG diagnosis results as the gold standard, the diagnostic coincidence rate of tubal patency was the highest [84.83% (123/145)], and that of tubal occlusion and partial occlusion was 80.95% (34/42) and 76.62% (59/77), respectively (Table 1).

*Bilateral patency* was defined as open fallopian tubes on both sides. Incomplete patency included partially occluded fallopian tubes on both sides, an open fallopian tube on one side, a partially occluded fallopian tube on the other, an open fallopian tube, and an occluded fallopian tube on the other. Unilateral partial occlusion and unilateral occlusion referred to a partially occluded fallopian tube on one side and an occluded fallopian tube on the other side. *Bilateral occlusion* was defined as occluded fallopian tubes on both sides. The diagnostic coincidence rate of the 4D-HyCoSy diagnosis in





**Fig. 1.** Fallopian tube images obtained after 4D-HyCoSy diagnosis. A. Bilateral patency, B. Bilateral occlusion, C. Bilateral partial occlusion, D. Unilateral partial occlusion, and unilateral occlusion. E. Unilateral patency and unilateral partial occlusion, and F. Unilateral patency and unilateral occlusion.

**Table 1**  
4D-HyCoSy diagnosis results

4D-HyCoSy	HSG			Total
	Patency	Partial occlusion	Occlusion	
Patency	123 (84.83%)	12 (8.28%)	10 (6.90%)	145 (58.94%)
Partial occlusion	7 (9.09%)	59 (76.62%)	11 (14.29%)	77 (31.30%)
Occlusion	2 (4.76%)	6 (1.43%)	34 (80.95%)	42 (17.07%)
Total	132 (53.66%)	77 (31.30%)	55 (22.36%)	264 (100%)
4D-HyCoSy diagnostic coincidence rate	123/132 (93.18%)	59/77 (76.62%)	34/55 (61.82%)	212/264 (80.30%)

Values n= 132 are expressed in n (%).

132 patients was 87.12% (115/132), with HSG diagnosis results as the gold standard (Table 2).

#### **Intrauterine pressure measurement results**

Seventy out of 132 patients underwent intrauterine pressure measurement through the connection with a pressure measurement device before the 4D-HyCoSy

diagnosis, and their intrauterine pressure results were obtained. Pairwise comparisons of the pressure values were carried out in six groups. The results revealed no significant differences in the peak intrauterine pressure among patients in the unilateral patency and the unilateral occlusion group, unilateral patency and unilateral partial occlusion group, and the bilateral partial occlusion group ( $p < 0.05$ ). The patients

**Table 2**  
Diagnostic results of 4D-HyCoSy [n=132, n (%)]

4D-HyCoSy	HSG				Total
	Bilateral patency	Partial occlusion	Unilateral partial occlusion and unilateral occlusion	Bilateral occlusion	
Bilateral patency	43 (89.58%)	3 (5.00%)	0 (0.00%)	0 (0.00%)	46 (34.85%)
Partial occlusion	5 (1.04%)	50 (84.75%)	0 (0.00%)	1 (6.67%)	60 (45.45%)
Unilateral partial occlusion					
Unilateral occlusion	0 (0.00%)	7 (11.86%)	3 (33.33%)	3 (20.00%)	13 (9.85%)
Bilateral occlusion	0 (0.00%)	0 (0.00%)	6 (66.67%)	11 (73.33%)	17 (12.88%)
Total	48 (40.15%)	60 (45.45%)	9 (6.82%)	15 (11.36%)	132 (100%)
4D-HyCoSy diagnostic coincidence rate	48 (90.57%)	50 (84.75%)	6 (66.67%)	11 (73.33%)	115 (87.12%)

in these three groups were included in the incomplete patency group (Group A), and the differences between the bilateral patency group (Group B), bilateral occlusion group (Group C), unilateral occlusion, and unilateral occlusion group (Group D) and the other groups were significant ( $p < 0.05$ ). Besides, severer occlusion had higher intrauterine pressure (Table 3).

The ROC curve of the peak intrauterine pressure was plotted. The cutoff value between Group B and Group A was 25.42 kPa, with a sensitivity of 81% and a specificity of 85%. AUC was 0.812 (Fig. 2). The cutoff value between Group A and Group D was 36.34 kPa, with a sensitivity of 73% and a specificity of 89%; AUC was 0.836 (Fig. 3). Moreover, the cutoff value between Group D and Group C was 47.68 kPa, with a sensitivity of 79% and a specificity of 87%; AUC was 0.827 (Fig. 4).

#### Establishment of the combined diagnosis model

Dichotomous logistic regression analysis was conducted for the 4D-HyCoSy diagnosis (A) and intrauterine pressure measurement (B), to evaluate the efficacy of the combined diagnosis. The results demonstrated a significant difference between the

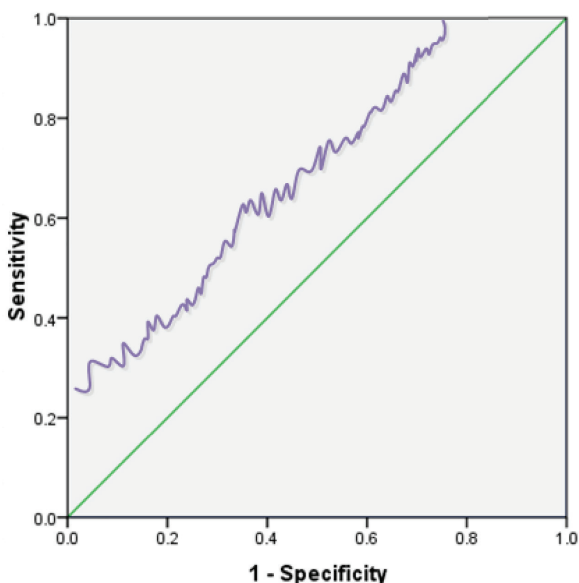
two diagnosis methods ( $p < 0.05$ ), so both could be used as predictive diagnostic indicators. According to the regression coefficient of the two variables, the mathematical diagnosis model of FSM was established as follows:  $FSM = 1.083 \ln(A) + 1.275 \ln(B) - 8.23$  (Table 4).

#### Model validation results

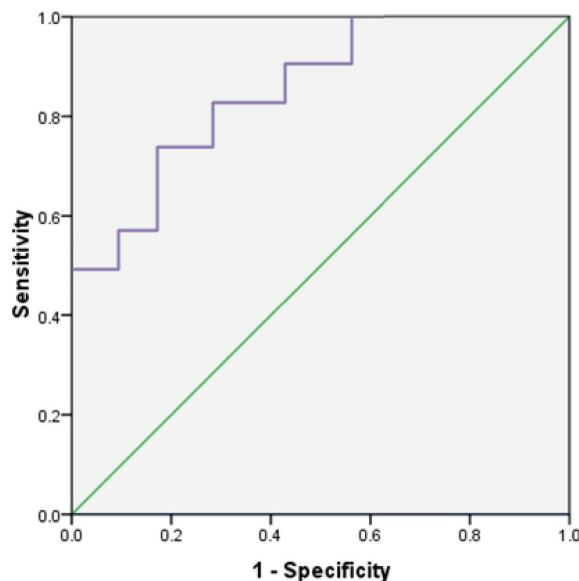
The diagnostic efficiency of the FSM diagnostic model was assessed using the ROC curve. It was discovered that the combined diagnosis model had a high diagnostic value, with an AUC of 0.85. When  $FSM = 11.3$ , the model had a high sensitivity (89.36%), which meant that only three of 70 patients undergoing combined diagnosis were misdiagnosed due to a  $FSM < 11.3$ . When the  $FSM = 13.8$ , the model had a high specificity (92.55%). Besides, the model was still particularly valuable in the diagnosis of other patients. The diagnostic efficiency was compared between the 4D-HyCoSy diagnosis and the combined diagnosis. The ROC curve illustrated that the diagnostic value of the 4D-HyCoSy diagnosis was lower than that of the combined diagnosis. With the maximum value of the Youden index (YI) as a threshold, the AUC of 4D-HyCoSy diagnosis was

**Table 3**  
Intrauterine pressure measurement results.

Group	Radiography results	n (number of fallopian tubes)	Pressure (kPa)	Peak intrauterine pressure (kPa)	Comparison group	<i>p</i>
A	Unilateral patency and unilateral occlusion	5 (10)	17.9~42.6	36.42±3.15	B, C, D	<0.05
A	Unilateral patency and unilateral partial occlusion	11 (22)	15.2~34.8	25.47±2.51	B, C, D	<0.05
A	Bilateral partial occlusion	6 (12)	17.2~37.6	32.17±2.74	B, C, D	<0.05
B	Bilateral patency	35 (70)	13.2~28.4	19.43±1.68	A, C, D	<0.001
C	Bilateral occlusion	6 (12)	42.0~63.2	54.35±2.30	A, B, D	<0.001
D	Unilateral partial occlusion and unilateral occlusion	7 (14)	25.7~52.3	43.42±1.70	A, B, C	<0.05



**Fig. 2.** ROC curves of Group B and Group C.



**Fig. 3.** ROC curves of Group A and Group D.

0.82, with a sensitivity of 78.04%, which was markedly lower than that of the combined diagnosis (sensitivity: 70.13%). However, the specificity displayed no significant difference between the two diagnosis methods ( $p>0.05$ ) (Fig. 5). Comparative evaluation indicators for diagnostic efficiency are shown in Table 5.

#### Adverse reactions

Among the 132 patients, the majority had pain during the examination, and the

minority suffered from dizziness and nausea without adverse reactions such as arrhythmia, vomiting, hypotension, and fainting. Patients' adverse reactions were all within the tolerable range, and no allergic reactions or vaginal bleeding occurred. In addition, 41 cases (31.06%) had grade 0 adverse reactions, 65 cases (49.24%) had grade I adverse reactions, 19 cases (14.39%) had grade II adverse reactions, and seven cases (5.30%) had grade III adverse reactions (Fig. 6).



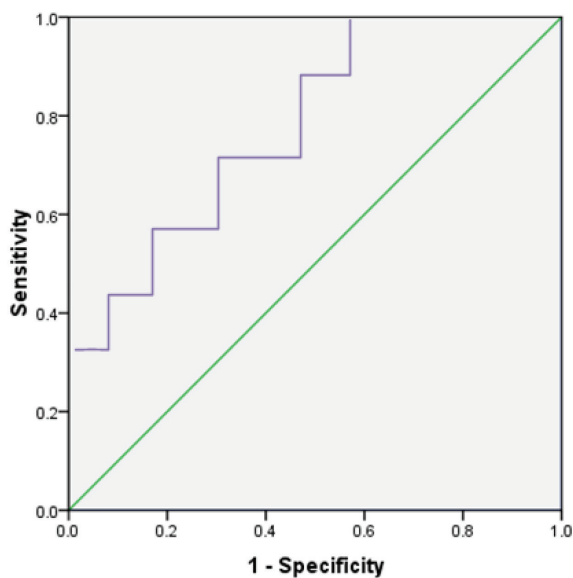


Fig. 4. ROC curves of Group D and Group C.

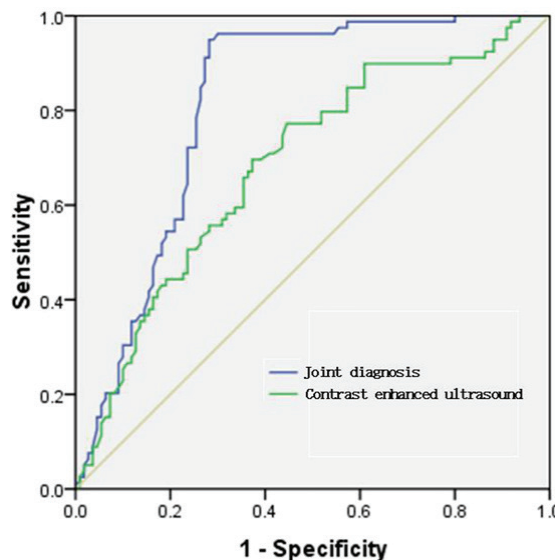


Fig. 5. ROC curves of combined diagnosis and 4D-HyCoSy diagnosis.

**Table 4**  
Results of dichotomous logistic regression analysis.

Indicator	Regression coefficient	Standard error	Wald value	Odds ratio (OR)	95%CI	p
4D-HyCoSy	1.083	0.531	4.16	2.953	1.009~12.937	0.017
Peak intrauterine pressure	1.275	0.414	9.485	3.579	1.105~13.564	0.015

**Table 5**  
Evaluation results of combined diagnosis and 4D-HyCoSy diagnosis efficiency.

Indicator	AUC (95% CI)	YI	Threshold value	Sen (%)	Spe (%)	DA (%)	Positive predictive value	Negative predictive value
4D-HyCoSy diagnosis	0.82(0.78-0.88)	0.43	69.57	78.04%	70.13%	78.27%	80.36%	53.14%
Combined diagnosis	0.85(0.81-0.92)	0.56	20.93	88.13%	79.46%	87.97%	94.64%	69.23%

### DISCUSSION

Infertility is a common disease in females, severely damaging patients' lives and mental health. It has now become a prevalent disease needing treatment in the medical field. Tubal patency makes the proportion of infertile females exceed 50%, so it is a critical basis for treating infertility to explore efficient methods for diagnosing fallopian tubes at a general degree, contributing to early diagnosis and early treatment<sup>11</sup>.

In clinical practice, diagnosis methods commonly used for tubal patency include hydrotubation under the ascites (laparoscopic chromopertubation (LC)), uterine hydrotubation, HSG, hysterolaparoscopy, contrast-enhanced ultrasonography of fallopian tubes and X-ray HSG. Among them, traditional hydrotubation is a blind operation with a low diagnostic accuracy rate. Laparoscopy is an operation causing trauma, which is harmful to patients. LC diagnosis requires general

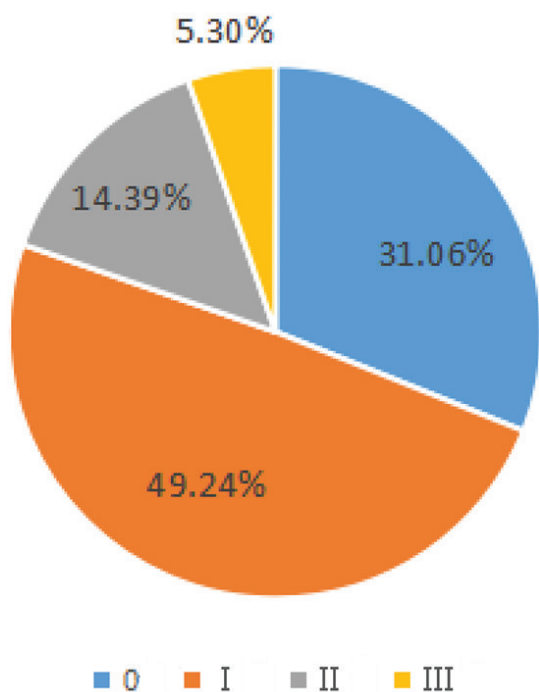


Fig. 6. Adverse reactions of patients.

anesthesia, after which patients have a risk of massive hemorrhage. HSG exhibits high accuracy, but some patients are allergic to iodine. Moreover, X-ray HSG is radioactive to some extent, and also it cannot be applied in patients allergic to iodine<sup>12,13</sup>. Hence, a simple diagnostic method that is easy to operate with low risk and low cost becomes a hot spot in the medical field<sup>14-16</sup>. HyCoSy diagnostic technology is increasingly recognized by doctors and patients since it is safe and non-invasive, with high accuracy, high operability, and good repeatability. The 4D-HyCoSy is a new type of contrast-enhanced ultrasound technology following 2D and 3D, during which the entire fallopian tubes can be visually displayed through imaging, and some fallopian tubes with unique positions or those in twisted and complicated shapes can also be well displayed. Through 4D-HyCoSy diagnosis, there remain cases of missed diagnosis though it is simple and efficient, so there is a necessity to find suitable auxiliary means to improve the accuracy of diagnosis.

In 2016, Kong checked the tubal patency using 4D-HyCoSy assisted by hydrogen peroxide, and its diagnostic coincidence rate (91.8%) was much higher than that of 4D-HyCoSy alone. Nevertheless, during 4D-HyCoSy diagnosis, scanning in a large fan-shaped angle can display the occlusion position of fallopian tubes and the variations of shape, and the injection pressure can be appropriately increased according to the occlusion of fallopian tubes for dredging the slightly adhesive fallopian tubes. Therefore, determining pressure using the traditional hand-pushing method is greatly affected by subjective factors, so a more intuitive auxiliary means is needed for evaluation. In the present study, 132 patients with tubal factor infertility were selected, and the tubal patency was detected by 4D-HyCoSy. Through comparison, it was found that the patency of 212 fallopian tubes conformed to HSG diagnosis results (gold standard), with a diagnostic coincidence rate of 86.18%. Besides, the fractional analysis based on the function of fallopian tubes revealed that the diagnostic coincidence rate of 4D-HyCoSy was 87.12%. Besides, the intrauterine pressure measurement demonstrated that the pressure was lower when the fallopian tubes were open, and the more severe the occlusion, the higher the pressure.

Subsequently, the cutoff value in each group was determined using the ROC curve. It was discovered that the cutoff value among bilateral patency, incomplete patency, unilateral partial occlusion, unilateral occlusion, and bilateral occlusion was 25.42 kPa, 36.34 kPa, and 47.86 kPa, respectively, and the AUC was 0.812, 0.836 and 0.827 respectively. Therefore, intrauterine pressure measurement can be applied as an effective means to assist the 4D-HyCoSy diagnosis to improve the accuracy of diagnosis. Furthermore, to investigate the clinical value of 4D-HyCoSy assisted by intrauterine pressure measurement in the evaluation of tubal patency, dichotomous logistic regression analysis was conducted for diagnosis factors, and the FSM diagnostic

model was established, which was verified by the ROC curve. The results showed that the AUC of combined diagnosis was 0.85, with a higher sensitivity (88.13%) than that of 4D-HyCoSy alone ( $p < 0.05$ ) and a specificity (79.46%) showing no significant difference in comparison with that of 4D-HyCoSy alone, confirming the extremely high diagnostic value of 4D-HyCoSy assisted by intrauterine pressure measurement in the evaluation of tubal patency.

In summary, 4D-HyCoSy, assisted by intrauterine pressure measurement, has high diagnostic value in evaluating tubal patency. Regardless, this study had a small sample size so the results may be biased. In the future, we will conduct multicenter studies with larger sample sizes to validate our findings.

#### Conflict of interest

The authors declare that they have no competing interests.

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#### ORCID numbers

- Chunhong Lin: 0000-0002-1576-6936
- Jianyong Chen: 0000-0001-8207-5433
- Xianguo Li: 0000-0002-2116-8692
- Linlin Wang: 0000-0002-3098-3226
- Fengqin Yan: 0000-0002-3505-5429
- Ye Chang: 0000-0003-2062-469X
- Xueniu Yang: 0000-0002-4370-2104

#### Authors contribution

The first two authors contributed equally to this study.

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