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Combined Real-Time Three-Dimensional HyCoSy with B-Mode HyCoSy in the Evaluation of Fallopian Tube Patency in Patients Undergoing Infertility Investigations

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Introduction

Ultrasound techniques and the use of contrast media are the two essential aspects of evaluating tubal status by sono-hysterography. We used the second-generation ultrasound contrast agent, SonoVue® (Bracco, Italy). This is a suspension of stabilized sulfur hexafluoride (SF6) microbubbles which provide high resistance. The new generation of this technique, 4D HyCoSy (Hysterosalpingo-Contrast Sonography), uses multiple volumes under low mechanical indices and harmonic imaging, to reconstruct the dynamic observation of two-dimensional (2D) ultrasound and present this in a volume of three-dimensional (3D) ultrasound data. Using this technique, it is possible to show the uterine cavity morphology and entire fallopian tube, even if the tube is tortuous or angled; It is also possible to observe the movement of contrast media flowing through the fallopian tubes and the pelvis [1, 2]. In this study, we used 4D HyCoSy, with B-mode HyCoSy, to explore the clinical value of this technique for the evaluation of tubal patency. B-mode HyCoSy is a non-Doppler method which is capable of displaying fallopian tube lumen. The key aspect of our study is that 4D HyCoSy may readily visualize the entire fallopian tube, even it is tortuous or angled, while B-mode HyCoSy can observe tubal walls in a highly effective manner.

Materials and Methods

Research Subjects

This prospective study was undertaken in the First Affiliated Hospital of Shantou Medical College between January 2017 and July 2018 as part of our female infertility program. In total, 739 female patients were recruited; The age range was 21-44 years with mean infertility duration of 3.2 ± 2.1 years.

Instruments

All examinations were performed with a WS80A (SAMSUNG MEDISON, CO. LTD., Korea) and a transvaginal 5-9 MHz transducer with 2D, 3D, and 4D capabilities. SonoVue® was used as the ultrasonic contrast agent the dry powder contrast agent was diluted to 5.0ml with 0.9% chlorine sodium solution. After sufficient shaking, 2.5 mL of the microbubble suspension was extracted and dissolved in 17.5 mL of 0.9% sodium chloride solution.

Methods

Patients were positioned in the lithotomy position, a speculum was inserted, and the vagina and cervix were disinfected with a 10% povidone-iodine solution. Sterile draping was applied and a Foley catheter no. 12 (Jiangyang, Ltd., Yangzhou, Jiangsu, China) was inserted into the cervical canal. Then, 1.5mL of 0.9% sodium chloride solution was inserted into the balloon to ensure that the cervical canal was closed and the catheter located appropriately. Then, the speculum was removed and a transvaginal probe was inserted into the posterior vaginal fornix. Sterile saline was initially injected into the uterine cavity using 2D and 3D HyCoSy to evaluate any abnormal findings of the uterus and ovaries. We also attempted to recognize the uterine horn on the coronal plane using 3D HyCoSy. Then, the two diagnostic procedures in our study were performed sequentially. We switched to four-dimensional mode and prescan by using a 2D fan angle of 180° and a 4D sweep angle of 90°. We used this system to investigate the uterus, ovaries, and pelvic cavity; image quality was set to maximum. If the bilateral ovaries were too far from each other to be included in the max sweep angle, we would rescan the tubes separately to ensure that the entire fallopian tubes were included in our imaging. Then, we injected the SonoVue® slowly and evenly until the uterine cavity was fully expanded. Then, we observed the uterine cavity and the beginning of the bilateral tubes, which were filled with contrast agent and used to track the flow to the fimbria and pelvic cavity. The acquired data were stored by pressing P2 for offline analysis and reconstruction. When 4D HyCoSy completed, we immediately converted to the B-mode HyCoSy procedure. Two skilled sonographers independently analyzed the data; if a consensus was not reached, a third sonographer was consulted. The duration of the examination and pain score were evaluated during and after the examination. All patients were given antibiotic treatment for 2 days to prevent infection.

Diagnostic Criteria for 4D HyCoSy

(1) Tube patent: 4D reconstruction revealed no resistance and reflux. The contrast agent flowed from the uterinecavity into the uterine cornu and through the Fallopian tube and finally arrived at the fimbriae end of the tube. The passage of the tube was natural and smooth. An annular high echoic area was evident around the ovaries, and micro bubbles were dispersed evenly within the pelvic cavity.

(2) Tube patent but not smooth: 4D reconstruction revealed mild resistance and reflux. Pressurized infusion was needed. Contrast agent revealed fallopian tubes of uneven thickness, partially slim. In addition, a semiannual high echoic area was observed around the ovaries, and a small number ofmicro-bubbles were dispersed within the pelvic cavity.

(3) Tube blocked: the patient was obviously in pain following pressurized infusion. We were unable to see the entire passage of the tube or spillage at the fimbria end. There was a lack of high echoic areas around the ovaries. There was also a lack of microbubble echo within the pelvic cavity.

Diagnostic Criteria for B-Mode HyCoSy

(1) Tube patent: B-mode revealed abrightbandwithinthe tube. High echoic micro bubblesspread rapidly and evenly and repeatedly flowed from the uterus horn to the fimbria end of the tube. We referred to this sign as “turbulent flow.” The wall of the tube was displayed clearly and was smooth. High echoic microbubbles dispersed in the end of the fimbria.

(2) Oviduct passable but not smooth: B-mode revealed small amounts of high echoic microbubbles flowing slowly. The full or sectional oviduct presented with a defective and heterogenous filling. In addition, a small number of high echoic microbubbles were dispersed in the end of the tube.

(3) Oviduct occlusion: failure to display a full or partial bright band and no microbubble echo dispersed at the fimbria end of the tube.

Diagnostic Criteria for Laparoscopy and Dye Test

(1) Tube patent: no resistance during injection and overflow of methylene blue from the fallopian fimbria.

(2) Tube obstruction: apparent resistance during injection, obvious reflux, and the absence of methylene blue overflowing from the fallopian fimbria.

Results and Discussion

In total, 739 female patients were recruited. The age range was 21-44 years and the duration of infertility was 3.2 ± 2.1 years. The examination was conducted during days 5-12 of the menstrual cycle. The patients recruited did not have any history of serious diseases and contraindications. All tests were performed with SonoVue® successfully [739 of 739 (100%)]. Six of the 739 women had only one fallopian tube; 145 had pathological findings in their fallopian tubes during HyCoSy. Overall, 34 of these 145 cases (62 tubes) were verified using the gold standard laparoscopy and dye test. We defined the segment which was more than 3cm distal from the uterus as the distal part of the fallopian tube [3].

Compared with the laparoscopy and dye test, tubal occlusion diagnostic accordance rates for 4D HyCoSy was 88.7% (23+32)/62 (Table 1). Distal occlusion diagnostic accordance rates for 4D HyCoSy was 100% (8/8) (Table 2). The sensitivity, specificity, PPV (Positive Predictive Value), and NPV (Negative Predictive Value) of 4D HyCoSy compared to laparoscopywere 88.4%, 88.8% 85.1%, and 91.4%, respectively (Figure 1).

Twenty tubes were diagnosed as "patent" by 4D HyCoSy although the B-mode HyCoSy procedure showed these tubes as passable but not smooth (Figure 2). Four tubes were misdiagnosed as proximal partial obstruction by 4D HyCoSy, while subsequent B-mode HyCoSy indicated that these tubes were "patent".

Table 1. Agreement between HyCoSy and the laparoscopic dye (LD) test. (Kappa:0.769)

HyCoSy	LD		
	patent	occlusion	total
patent	32	3	35
occlusion	4	23	27
total	36	26	62

Table 2. Agreement of distal occlusion between HyCoSy and the laparoscopic dye (LD) test. (Kappa:1.000)

HyCoSy	LD		
	patent	distal occlusion	total
patent	8	0	8
distal occlusion	0	8	8
total	8	8	16

The mean total examination time was 26.2 ± 10 min (range, 9-47 min), and the time taken for the 4D procedure (examination time after intubation) was 5.6 ± 3.5 min (range, 2-18 min), with 42 ± 26 s (range, 12-51 s) for the 4D HyCoSy examination. Examination time was 11.8 ± 3.5 min (range 3.5-28.5 min) for B- mode. The most important factors affecting the length of the examination was likely to be the proficiency of the sonographer and the time taken to insert the catheter.

Figure 1. Tubal patency diagnosed with 4D HyCoSy: (a) bilateral patent oviducts; (b) bilateral obstructed oviduct.

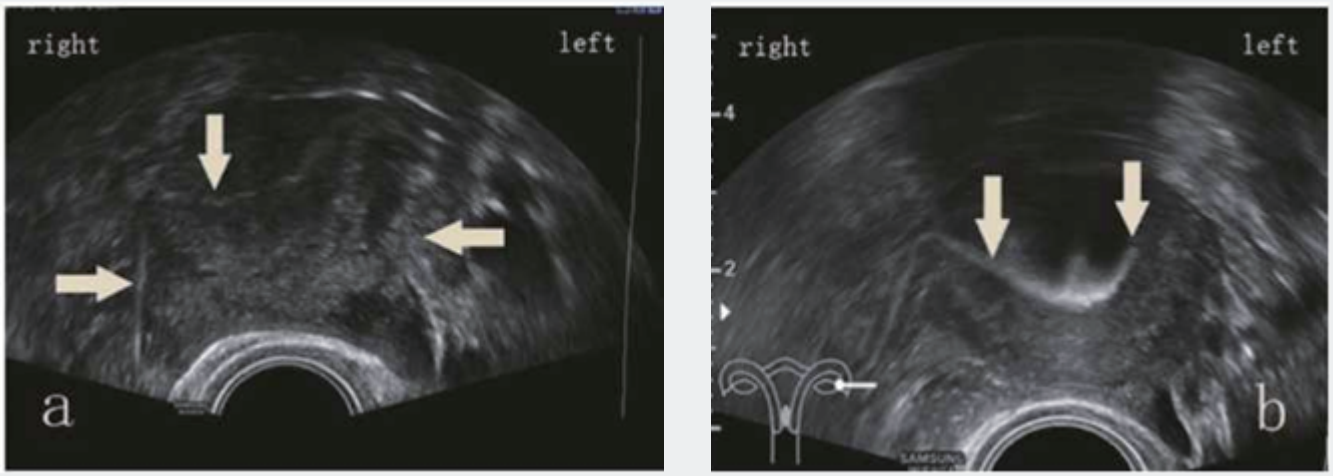

Figure 2. Tubal patency diagnosed with B-mode HyCoSy: (a) right patent oviduct; left patent but not smooth; (b) right patent oviduct; left obstructed oviduct.

Conclusion

B-mode HyCoSy may be used as an additional technique to 4D HyCoSy and the combination of both methods may improve diagnostic accuracy. These procedures should be understood as being complementary rather than competitive. The drawback of our study was that because we did not perform laparoscopic dye testing in normal fallopian tubes, we could not presume that HyCoSy was an accurate test for evaluating the overall health of the fallopian tube. All patients had very low pain scores during the test, and only 2 patients (2/739, 0.002%) developed complications while undergoing HyCoSy and required resuscitation.

References

[1] Y. He, Q. Geng, H. Liu, and X. Han, "First experience using4-dimensionalhysterosalpingo-contrastsonographywith SonoVue for assessing fallopian tube patency," Journal of Ultra sound in Medicine, vol. 32, no. 7, pp. 1233-1243, 2013.

[2] D. Kong, X. Dong, Z. Wang, L. Zhang, X. Shao, and Y. Qi, "Four-dimensional hysterosalpingo-contrast sonography with auxiliary hydrogen peroxide examination for the diagnosis of fallopian tube patency following interventional treatment of ovarian ectopic cysts," Archives of Gynecology and Obstetrics, vol. 295, no. 2, pp. 519-526, 2017.

[3] A. Kleinkauf-Houcken, B. Huneke, C. Lindner, and W. Braen- dle, "Combining B-mode ultrasound with pulsed wave Doppler for the assessment of tubal patency," Human Reproduction, vol. 12, no. 11, pp. 2457-2460,1997.

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