

Accuracy of hysterosalpingo-foam sonography in comparison to hysterosalpingo-contrast sonography with air/saline and to laparoscopy with dye.

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Abstract

STUDY QUESTION: What is the diagnostic accuracy of 2D/3D hysterosalpingo-foam sonography (HyFoSy) and 2D/3D-high-definition flow Doppler (HDF)-HyFoSy in comparison to laparoscopy with dye chromotubation (as the reference method) and 2D air/saline-enhanced hysterosalpingo-contrast sonography (HyCoSy) (as the initial index test)?

SUMMARY ANSWER: 2D/3D-HDF-HyFoSy had the best diagnostic accuracy and was the only method that did not significantly differ from the reference method, while both 2D/3D-HyFoSy and 2D/3D-HDF-HyFoSy had significantly higher accuracy than 2D-air/saline-HyCoSy.

WHAT IS KNOWN ALREADY: Previous studies on X-ray hysterosalpingography and laparoscopy and dye as the reference standard have undermined the impact of older commercial contrast agents on the accuracy of ultrasound tubal patency tests. Recently, HyFoSy was reported to have very high accuracy in a small pilot study in comparison to laparoscopy and dye, and had a very high positive predictive value (PPV) for medical tubal occlusion. A new Doppler sonographic technique, known as HDF imaging with better axial resolution, fewer blooming artifacts and higher sensitivity than color and power Doppler imaging, has been introduced.

STUDY DESIGN, SIZE, DURATION: A prospective observational study was performed on 132 women (259 Fallopian tubes) consecutively enrolled between 2013 and 2015.

PARTICIPANTS/MATERIALS, SETTING, METHODS: This study included infertile women of reproductive age who previously had not been examined for tubal patency and who presented for the evaluation to the university hospital, private hospital and clinic at which this study was conducted. 2D-Air/saline-HyCoSy, 2D/3D-HyFoSy and 2D/3D-HDF-HyFoSy and laparoscopy were performed independently by experienced readers. During HyFoSy, the 3D mode was used for standardization of pelvic scanning and observations of contrast flow without diagnosis after volume acquisition. Sensitivity, specificity, negative and positive predictive value (NPV and PPV), negative and positive-likelihood ratio (LR- and LR+) and 95% CI were calculated. McNemar's test and relative predictive values (a comparison of NPV and PPV) were used to compare all the

index tests.

MAIN RESULTS AND THE ROLE OF CHANCE: 2D-Air/saline-HyCoSy, 2D/3D-HyFoSy and 2D/3D-HDF-HyFoSy indicated that 46 (17.8%), 27 (10.4%) and 24 (9.2%) of the 259 tubes were occluded, respectively; additionally, inconclusive results were obtained for 8 (3%), 5 (1.9%) and 3 (1.2%) tubes, respectively. The reference method revealed 18 (6.9%) occluded Fallopian tubes. 2D-Air/saline-HyCoSy had a high NPV (99.5%) that was similar to that of 2D/3D-HyFoSy (99%) and 2D/3D-HDF-HyFoSy (99.6%) ($P > 0.05$), but had a very low PPV (30.4%). The use of 2D/3D-HyFoSy, especially 2D/3D-HDF-HyFoSy, which had a significantly higher PPV (48% and 71%, $P < 0.05$ and $P < 0.01$; respectively), resulted in fewer false positive and inconclusive findings than the use of 2D-air/saline-HyCoSy. The LR- and LR+ was 0.14 and 14.8, respectively, for 2D/3D-HyFoSy, 0.06 and 32.1, respectively, for 2D/3D-HDF-HyFoSy, and 0.08 and 6.9, respectively, for 2D-air/saline-HyCoSy. The number of inconclusive or positive results per patient was significantly fewer with 2D/3D-HyFoSy (odds ratio, OR = 0.5, CI = 0.3-0.95, $P < 0.05$) and 2D/3D-HDF-HyFoSy (OR = 0.4, 95% CI = 0.2-0.8, $P < 0.01$) than with 2D-air/saline-HyCoSy.

LIMITATIONS, REASONS FOR CAUTION: An unselected infertile population with a low prevalence of tubal occlusion is suitable for estimating the diagnostic accuracy of imaging tests only as a screening tool.

WIDER IMPLICATIONS OF THE FINDINGS: These findings can be used to establish a diagnostic strategy with high accuracy but minimum invasiveness and limited use of contrast agents and sophisticated technology. 2D-Air/saline-HyCoSy, which has a high NPV, is suitable as an initial test and basic screening method, but 2D/3D-HDF-HyFoSy, which has a significantly higher PPV, can be used as a standard to verify any questionable or positive results obtained with 2D HyCoSy. This strategy may significantly reduce the need for laparoscopy as a reference standard.

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