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Original Article

Proximal Tubal Patency Demonstrated Through Air Infusion During Flexible Office Hysteroscopy Is Predictive of Whole Tubal Patency

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ABSTRACT **Study Objective:** To determine whether air bubbles infused into saline during flexible office hysteroscopy can accurately predict tubal patency.

Design: Diagnostic accuracy study (Canadian Task Force classification II-1).

Setting: An academic hospital.

Patients: Women undergoing office hysteroscopy and ultrasound.

Interventions: Air infusion into saline during office hysteroscopy.

Measurements and Main Results: The primary outcome measures were whether air bubbles traverse the ostia at hysteroscopy, whether there is patency at abdominal surgery, and the rate of cul-de-sac (CDS) fluid accumulation from office hysteroscopy. Four hundred thirty-five patients underwent office hysteroscopy with air infusion, 89 of whom also had abdominal surgery. Depending on interpretation, sensitivity to tubal occlusion was 98.3% to 100%, and specificity was 83.7% with standard chromopertubation pressures; 95.3% to 100% of the time proximal patency was observed, whole tubal patency was observed through chromopertubation for patients with surgical data. Changes in CDS fluid volume from before to after office hysteroscopy were also used as an indirect proxy for tubal patency. Patients with risk factors for occlusion such as known or suspected tubal disease, known or suspected adhesions, and sonographic identification of adhesions through the sliding sign were all less likely to demonstrate a change in CDS fluid volume after hysteroscopy than women without these risk factors ($p < .0001$). Bilateral dispersion of air bubbles during hysteroscopy better predicted shifts in CDS volume than these risk factors and demonstrated shifts comparable with bilateral patency at laparoscopy ($p < .001$).

Conclusion: Air-infused saline at office hysteroscopy can accurately assess tubal patency. Additionally, bilateral patency identified through office hysteroscopy may predict bilateral patency at surgery better than several commonly used historic and sonographic variables. Journal of Minimally Invasive Gynecology (2017) 24, 646–652 Published by Elsevier Inc. on behalf of AAGL.

Keywords: Fertility testing; Hysterosalpingogram; Hysterosalpingography; Hysteroscopy; Infertility; Office hysteroscopy; Parryscope; Sonosalpingrography; Tubal patency

After UMMC waived rights for patenting the described surgical technique, Dr. Parry followed advice to personally patent and trademark it. He has received no funding for the research, and does not have any funding from or associations with industry for other reasons. Also of note, a surgical technique patent cannot be used to obstruct a physician from performing a procedure under US patent law. None of the other authors have disclosures that relate to this publication.

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Gynecologists recognize that with hysteroscopy, although saline and other distention media may escape transcervically, they also often pass through patent fallopian tubes into the pelvis. Fluid traversing the fallopian tubes is readily recognized at laparoscopy after hysteroscopy. Several authors have used sonographic identification of new cul-de-sac (CDS) fluid after office hysteroscopy as a proxy for patency [1,2]. Limitations to this approach include hindered assessment when meaningful preexisting CDS fluid is present and difficulty in distinguishing unilateral from bilateral patency. The latter particularly matters for patients undergoing known or donor

insemination because they may not wish to undergo the cost of insemination if folliculogenesis is on the side of an occluded tube.

During office hysteroscopy, it can be difficult to observe saline directly traversing the ostia unless a nontranslucent substance contrasting with saline is present, such as mucus or blood. Many gynecologists have seen air accidentally mix with their distention media and disperse through the ostia and wondered whether this truly reflects tubal patency. With sonosalpingography, air and saline are deliberately mixed for assessing tubal patency. If one imagined viewing sonosalpingography while performing hysteroscopy (as though there were a camera at the tip of the sonosalpingography catheter), one would see air bubbles disperse through the ostia in the setting of patency while remaining in the cavity with occlusion.

Hysteroscopically visualizing what happens during sonosalpingography should work in theory, but the core concern with clinical accuracy relates to when there is proximal patency with distal occlusion. A hydrosalpinx with fimbrial agglutination could allow air to enter the fallopian tubes if saline infusion pressure did not pre-equilibrate before air introduction. Seeking perspective, we were unable to find literature describing others' experience with air infusion into saline during hysteroscopy, nor could we find data describing the accuracy of such an approach. This led to our pilot study with 4 main goals: (1) to describe a hysteroscopic technique for air-infused saline to assess tubal patency; (2) to assess safety; (3) to compare hysteroscopic proximal patency with the gold standard of laparoscopic chromopertubation; and (4) to determine how hysteroscopic proximal patency, whole tubal patency at surgery, and risk factors are associated with rates of CDS fluid accumulation from before to after flexible office hysteroscopy as an indirect proxy for patency.

Methods

Study Oversight

This study was designed by University of Mississippi Medical Center faculty, including epidemiologic and statistical design. The study was not funded, receiving no financial support from grants or industry. The Clinicaltrials.gov identifier is NCT02005263, and it was institutional review board approved with protocol number 2013-0230. All authors contributed to this study and agree to its submission for publication. Dr. Parry oversaw adherence to the study protocol, and Dr. Parry and Dr. Riche oversaw accuracy of the data and validity of the analysis.

Study Design and Participants

A diagnostic accuracy study following Standards for Reporting Diagnostic Accuracy Studies guidelines was performed in which patients with indications for concurrent flexible office hysteroscopy and ultrasound were invited to participate. All consecutive participants presented to the Reproductive Endocrinology and Infertility Division in the Department of Obstetrics and Gynecology at the University of Mississippi Medical Center, Jackson, MS, between December 16, 2013, and April 8, 2016. Inclusion criteria were women between 18 and 50 years old, the ability to provide consent, a present uterus, and negative testing for gonorrhea and chlamydia. Exclusion criteria included pregnancy, active lower or upper genital tract infection, premenarchal or postmenopausal status, inability to read and understand English at the sixth grade level or above, prior endometrial ablation, or greater than stage I Asherman syndrome (or other conditions meaningfully fractionating the uterine cavity, such as uterus didelphys). Additionally, some patients were excluded after consent if they were found to have anatomy (such as numerous large myomas) precluding office hysteroscopy. Patients with a history of sexually transmitted infection (other than trichomoniasis, herpes simplex, or human papilloma virus) or suspected hydrosalpinges were pretreated with doxycycline 100 mg orally every 12 hours for 5 days beginning 2 days before hysteroscopy.

For clinical workflow, after obtaining informed consent and a negative urine pregnancy test, patients underwent transvaginal sonography, with the identification of pathology and measurement of uterine and ovarian dimensions as well as the antral follicle count and CDS fluid volume (measured as the largest 2-dimensional pocket visualized). The sliding of tissue planes in the posterior CDS and for the ovaries was assessed as a sonographic proxy for adhesions that would reflect risk for tubal agglutination and occlusion. All sonographic assessments were performed transvaginally using the Voluson i BT11 (GE, Fairfield, CT) by an attending physician with over 10 years of sonography experience (J.P.P.). Flexible office hysteroscopy was then performed as described later. After the completion of hysteroscopy, the CDS volume was reassessed, with the net change equal to the postprocedure volume minus the preprocedure volume. To control for the effect of the procedural duration on CDS volume, the volume was divided by time as measured from speculum placement to removal.

For the subset of patients participating in operative distal tubal assessment, prospective surgical data regarding tubal patency were preferred, but retrospective data were used if they were deemed unlikely to have changed. For example, partial salpingectomy was considered a persistent occlusive condition, whereas laparoscopic chromopertubation showing patency 3 months before hysteroscopy was considered acceptable providing the patient did not have endometriosis, interval peritonitis, or abdominal surgery deemed likely to result in meaningful adhesions. Of note, and as addressed in the Discussion section, patients were prospectively enrolled in the study without necessarily knowing whether an operating room assessment of tubal patency would be indicated. All participants provided normative data for safety and procedural duration as well as for