Diagnostic accuracy of sonohysterography compared to endometrial biopsy in pre-menopausal women with abnormal uterine bleeding

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Abstract
Background: AUB is a common cause of women’s referring to gynecologists. Although hysteroscopy is known as the gold standard technique for diagnosing the cause of AUB, sonohysterography is less invasive, and it is performed by general gynecologists. The purpose of this study was to evaluate the diagnostic performance of sonohysterography compared to the results of the endometrial biopsy, guided by hysteroscopy in premenopausal women with AUB.

Methods: This cross-sectional Study was conducted at the gynecological clinic of Roointan-Arash women’s Hospital from February 2011 to February 2012. The study participants were 90 premenopausal female patients, who visited the clinic for AUB, for whom, hormonal, iatrogenic and systemic causes were ruled out. They underwent sonohysterography and hysteroscopy and endometrial biopsy. The results of sonohysterography and pathological reports of endometrial biopsy were compared, and the diagnostic accuracy of sonohysterography for normal endometrium, endometrial polyps, sub mucosal fibroids and endometrial hyperplasia was evaluated.

Results: The diagnostic accuracy of sonohysterography was found to be 89.1% for the normal endometrium, 90% for endometrial polyps, 99% for sub mucosal fibroids and 94.4% for endometrial hyperplasia.

Conclusion: Sonohysterography is an accurate, non-invasive and cost-effective method for diagnosing AUB causes compared to hysteroscopy and endometrial biopsy. Therefore, as an initial diagnostic step, it can replace the alternative and less accurate methods such as transvaginal ultrasound, blind endometrial curettage or more costly and invasive methods such as hysteroscopy requiring anesthesia.

Keywords: Sonohysterography, Hysteroscopy, Endometrial Biopsy, Abnormal Uterine Bleeding, Premenopausal.


Introduction
Sonohysterography of the uterine cavity is a diagnostic tool for Abnormal Uterine Bleeding (AUB), and its significance is due to the fact that AUB is the most common cause of women’s visit to the gynecological clinics in their pre-menopausal age (1). It affects approximately 15% of women (2).
Besides hormonal, iatrogenic and systemic causes, other pathologies such as endometrial polyps, sub mucosal fibroids, hyperplasia and endometrial carcinoma should always be considered as potential prognosis. Sonohysterography is a simple ultrasound-based technique that involves the slow infusion of sterile saline solution into a woman's uterus before the insertion of transvaginal ultrasound probe for evaluation. Although the procedure of office hysteroscopy and eye-directed biopsy is the gold-standard investigation, the technique of sonohysterography may be offered as a first line tool looking to the simplicity of the procedure and relative cost-effectiveness (3,4). It can also be easily performed by most gynecologists (5). Hysteroscopy, along with histological examination is now the golden standard for evaluation of abnormal uterine bleeding, which very few gynecologists perform in an outpatient setting. It often requires general anesthesia in the operating room (6). Studies have shown that sensitivity and specificity of the diagnosis of various intrauterine pathologies with sonohysterography is similar to hysteroscopy (7-9). Some studies have reported that patients with abnormal uterine bleeding did not need invasive medical diagnosis or invasive treatment, unless sonohysterography reports abnormal uterine cavity (4, 10). The purpose of this study was to evaluate the diagnostic performance of sonohysterography compared to the results of the endometrial biopsy, guided by hysteroscopy in premenopausal women with abnormal uterine bleeding in women who referred to Rooointan_ Arash Hospital.

**Methods**

After obtaining approval from the Medical Ethics Committee, 90 premenopausal women with abnormal uterine bleeding, for whom hormonal, iatrogenic and systemic causes were ruled out were enrolled in a prospective observational study at Rooointan- Arash women 's hospital of Tehran University of Medical Sciences from February 2011 to February 2012. The patients underwent an outpatient evaluation. A complete medical, surgical and reproductive history was taken. General physical and gynecological examinations including cervical Pap smear were performed. Signed informed consent forms were obtained from all participants before each intervention. Exclusion criteria were as follows: virginity, cervical stenosis, neoplasia and cervical polyps, exogenous hormone use, systemic diseases including coagulopathy, thyroid disorders, hyperprolactinemia, use of coagulant medications and cervicovaginal infections, pelvic inflammation disease and pregnancy. The study participants underwent sonohysterography. In women with regular cycles, sonohysterography was performed in follicular phase; and in others, who had irregular cycles, it was performed arbitrary. There were no complications in any of the study participants. They were laid in the lithotomy position before sonohysterography, and after preparation and drape, a sterile speculum was used for each individual. After viewing the cervix, the foley catheter was inserted into the uterus through the cervix and fixed with two milliliters of sterile normal saline. Then speculum was removed and transvaginal ultrasound probe was inserted. After a slow infusion of 8 to 15 milliliters of sterile saline solution, the endometrial cavity was observed. The ultrasound and frequencies used were the Accuvix V20's ultrasound imaging system made in Japan, and 6-9 Megahertz, respectively. Uterus was viewed in a horizontal plane from corner to corner and in the vertical plane from fundus to isthmus area. Findings have been divided into two categories:

1. Without focal lesion of uterus: Single-layer endometrial thickness of less than six millimeters, the double-layer thickness less than 12 millimeters and the thickened abnormal endometrial containing cystic, irregular and heterogeneous areas were defined.

2. With focal lesion of uterus: Fibroid with round and regular shapes and polyp lesions with bases that are raised from the
endometrial cavity floor.

All patients underwent hysteroscopy and biopsy, under general anesthesia. If focal lesions were observed, directed biopsy was performed. Otherwise, at the end of hysteroscopy, curettage of the anterior and posterior wall of endometrium was performed and samples were sent to the lab for pathological examination. Acquired data were recorded on prepared questionnaires. Ultimately, the diagnostic accuracy of sonohysterography to assess normal endometrium, abnormal endometrium, and endometrial polyps and sub mucosal fibroids was calculated.

**Results**

In this study, 90 premenopausal women in the age range of 35-55 years with an average age of 42.6±5.2 with abnormal uterine bleeding pattern were examined. Endometrial thickness was 7-22 mm with an average of 10.4 ± 3.8, parity status from null parity to multiparity from seven times and the average 2.8 ± 1.5 respectively. Sonohysterography results revealed that 39 participants (43.3%) had normal endometrial thickness. Later, hysteroscopy and biopsy results indicated that three participants had polyps, four had hyperplasia and one had endometritis, which were incorrectly reported to have normal endometrial thickness. Thirty three cases (36.7%) were reported to have polyps in sonohysterography. Hysteroscopy and endometrial biopsy showed that two of the participants had a normal endometrial cavity, one had sub mucosal fibroids, one had hyperplasia and one had endometritis that were incorrectly reported as polyps. In sonohysterography, 10 cases (11.1%) were reported as sub mucosal fibroid. Hysteroscopy and biopsy confirmed 9 cases, and one was diagnosed as polyp, 8 patients (8.8%) were reported to have abnormal endometrium (hyperplasia), and the biopsy results reported 13 cases of simple and complex hyperplasia, one case was incorrectly reported as polyp and four were incorrectly reported as normal endometrium. This was a significant miss rate, which may have been due to the small sample size. Sensitivity and Specificity of sonohysterography method has been shown in Table 1.

**Discussion**

In this research, 90 premenopausal women with AUB, who had referred to the gynecological clinic of Rooiintan- Arash Women's Hospital were entered into the study and were evaluated though sonohysterography and hysteroscopy with biopsy. The diagnostic accuracy of sonohysterography was compared with hysteroscopy and biopsy. As presented in Table 1, the results revealed that sonohysterography is very accurate in evaluating the endometrial cavity; its accuracy is 90% for endometrial polyps, 99% for submusosal fibroids and 94.4% for endometrial hyperplasia; its sensitivity and specificity were calculated to be 87.5% and 91.3% for endometrial polyps, 90% and 98% for submusosal fibroids and 100% and 93% for endometrial hyperplasia. Sonohysterography can replace conventional and less accurate alternative methods such as transvaginal ultrasound and blind endometrial curettage which have 69% (11) and 40.5% (12) diagnostic accuracy, respectively and it can also replace the inva-

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Endometrium</td>
<td>81% (CI 69 to 93)%</td>
<td>94.4% (CI 87 to 100)%</td>
<td>91% (CI 81 to 100)%</td>
<td>87% (CI 87 to 96)%</td>
<td>89.1%</td>
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<tr>
<td>Endometrial Polyp</td>
<td>87.5% (CI 76 To 98)%</td>
<td>91.3% (CI 84 to 98)%</td>
<td>84% (CI 72 to 97)%</td>
<td>92% (CI 86 to 98)%</td>
<td>90%</td>
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<tr>
<td>Submucosal Fibroid</td>
<td>90% (CI 71 to 100)%</td>
<td>98% (CI 71 to 100)%</td>
<td>98% (CI 96 to 100)%</td>
<td>99% (CI 100 to 100)%</td>
<td>99%</td>
</tr>
<tr>
<td>Endometrial Hyperplasia</td>
<td>100% (CI 100 to 100)%</td>
<td>93% (CI 88 to 99)%</td>
<td>61% (CI 71 to 100)%</td>
<td>100% (CI 96 to 100)%</td>
<td>94.4%</td>
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Sive, costly and time-consuming method of hysteroscopy. Our study was consistent with the 2008 study conducted in Turkey by Gunes. In that study, the results of sonohysterography and uterine biopsy for 83 women were compared, and the diagnostic accuracy of sonohysterography was assessed; its sensitivity for polyps was 80% and the specificity was 87%; its sensitivity was 81% for submucosal fibroids, and the specific was 89% (13). Our results were also somewhat consistent with a 2008 study by Verrotti of Norway, in which the results of the evaluation of abnormal endometrium revealed a sensitivity and specificity of sonohysterography to be 33.3% and 92.4%, respectively. The sensitivity and specificity of diagnostic focal pathology were 94.1% and 84.5%, respectively (2). In a 2001 study by Krampi of Norway, which was conducted as a conventional and futuristic comparative study, sonohysterography was identified to be very accurate in detecting intrauterine pathology, and to increase the diagnostic accuracy of ultrasound (3). Overall, our results seem to be comparable and consistent with other studies. The observed minor differences in some numbers were not statistically significant, and may be addressed in future studies with a larger sample size. Undoubtedly, outpatient hysteroscopy is an appropriate and useful tool for the evaluation of uterine cavity, but many gynecologists do not have enough facilities and expertise to use it, especially in our country. Therefore, sonohysterography is a simple technique that can be performed easily outside the hospital, with lower costs and is better tolerated than outpatient hysteroscopy (14, 15). Based on the results and comparison with other studies, it is concluded that instead of hysteroscopy, sonohysterography can be utilized as a safe, accurate, easy and affordable initial diagnostic tool for premenopausal AUB patients. Due to the explicit emphasis of the various articles on the cost-effectiveness of this approach, we decided to compare the cost of sonohysterography with that of hysteroscopy and biopsy. The cost of this procedure in Iranian public hospitals is estimated to be IRR 260000 Rials (~$7) with social insurance, and IRR 430000 Rials (~$12) without insurance, while hysteroscopy biopsy procedure costs 2 million IRR (~$57) with social insurance, and 5 million IRR (~$142) without insurance. There is a dramatic and significant cost difference between these two procedures; therefore, sonohysterography is certainly more affordable for patients.

Therefore, our results revealed that saline infusion sonohysterography can replace hysteroscopy with endometrial biopsy. Also, for women with normal sonohysterography reports of the uterine cavity, other invasive, expensive and time-consuming measures can be eliminated. Likewise, in the presence of endometrial abnormalities, appropriate medical or surgical treatment can be planned based on the patient’s condition and her desire to plan for pregnancy.

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Conflict of interest

The Authors declare that there is no conflict of interest.

References

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