Journal of Minimally Invasive Gynecology (2006) 13, 409–412

THE JOURNAL OF
MINIMALLY INVASIVE
GYNECOLOGY

Validation of hysteroscopic view in cases of endometrial hyperplasia and cancer in patients with abnormal uterine bleeding

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KEYWORDS:
Diagnosis;
Validation study;
Hysteroscopy;
Uterine bleeding;
Endometrial neoplasia

Abstract

STUDY OBJECTIVE: To validate hysteroscopic view with histology in cases of endometrial hyperplasia and cancer in patients with abnormal uterine bleeding (AUB)

DESIGN: Retrospective study (Canadian Task Force classification II-3).

SETTING: University teaching hospitals in Rio de Janeiro and São Paulo, and private office in Rio de Janeiro.

PATIENTS: Four thousand and fifty-four patients with AUB in whom hysteroscopic views were complete and the histologic result was conclusive.

INTERVENTION: Four thousand and fifty-four office hysteroscopies with complete views and conclusive histologic results. The material for histologic examination was obtained through biopsy of the lesion in an outpatient unit or through the resection of the entire lesion in patients who underwent surgery. Histology was considered the "gold standard" and compared with the hysteroscopic view.

MEASUREMENTS AND MAIN RESULTS: In the histology of the 4054 examinations, 613 (15.2%) were endometrial hyperplasia, and 105 (2.6%) were endometrial cancer. The most frequent hysteroscopic finding was endometrial polyps (31.2%). In endometrial hyperplasia, the sensitivity of the hysteroscopic view was 56.3% (95% CI 52.2%–60.2%), specificity was 89.1% (95% CI 88.0%–90.1%), positive predictive value (PPV) was 48.0% (95% CI 44.3%–51.7%), negative predictive value (NPV) was 92.0% (95% CI 90.1%–92.9%), and accuracy was 72.7% (95% CI 70.7%–74.7%). Accuracy was defined as the proportion of correct results among the hysteroscopic examinations. In endometrial cancer, the sensitivity of the hysteroscopic view was 80.0% (95% CI 71.1%–87.2%), specificity was 99.5% (95% CI 99.2%–99.7%), PPV was 81.5% (95% CI 72.7%–88.5%), NPV was 99.5% (95% CI 99.2%–99.7%), and accuracy was 89.8% (95% CI, 85.9%–93.6%). In the 814 patients (20.0%) in whom the hysteroscopic view was normal, there were no false negatives for endometrial cancer; however, there were 37 (4.5%) false negatives for endometrial hyperplasia. In the histologic cases of endometrial cancer, 101 (96.2%) hysteroscopic views were compatible with cancer or hyperplasia (80.0% and 16.2%, respectively). Ninety-seven out of 103 hysteroscopic views with cancer findings (94.2%) had histologic diagnosis of cancer or hyperplasia (81.5% and 12.6%, respectively).

CONCLUSION: It seems that even in face of good validity of hysteroscopic view for endometrial hyperplasia and cancer, histologic study is mandatory in the presence of any lesion as the hysteroscopic view cannot completely replace the histologic study in patients with AUB.

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Submitted March 13, 2006. Accepted for publication May 7, 2006.

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doi:10.1016/j.jmig.2006.05.002

Abnormal uterine bleeding (AUB) can be defined as any bleeding whose duration, frequency, and amount are excessive for a certain patient. It can be organic or functional.[1] Abnormal uterine bleeding makes the patient uncomfortable due to the limitations that it poses, such as the increased need to use tampons and the concern about the cause of bleeding and the possibility of a malignant disease.

In addition to the disturbance caused to women, AUB is viewed as a sign for possible uterine diseases, some of which are pre-malignant or malignant, confirming its relevance in scientific research.[2–5] Vaginal bleeding is also the most frequent sign of malignant uterine disease, particularly in the postmenopausal period.[6]

The incidence of endometrial cancer in the world population is 5.9 per 100 000 individuals with a mortality rate of 1.7 per 100 000 women. In South America, endometrial cancer incidence is higher than average and affects 7.85 per 100 000 people.[7] In the United States, the prediction for 2001 was of 38 300 new endometrial cancer diagnoses and 6600 deaths caused by the disease.[8] Abnormal uterine bleeding is the most frequent indication for hysteroscopy in patients with endometrial hyperplasia.[3]

The need for a thorough investigation of the uterine cavity led to the development of hysteroscopy with instruments of smaller diameter, which enabled investigation in outpatient units and allowed for the enlarged in vivo view of the cervical canal and uterine cavity.[9] Additionally, instruments with smaller diameter also enabled the physician to obtain more accurate data that were previously provided only by hysterosalpingography, histologic studies of curettage, or post-hysterectomy specimens.[10–13] Hysteroscopy allows one to see the uterine cavity and to take targeted biopsies simultaneously in an outpatient setting.[3] It is a safe examination with low incidence of complications. The accuracy of the hysteroscopic diagnosis is high for endometrial cancer, but only moderate for benign endometrial diseases.[12]

Hysteroscopy with directed biopsy presents advantages over uterine dilatation and curettage (D&C) in the diagnosis of intracavity diseases, particularly focal ones. Therefore, it is the chosen method for patients with AUB who have not achieved an accurate diagnosis by D&C.[13] Hysteroscopy is regarded as the "gold-standard" for diagnosing endometrial diseases, especially when it is associated with directed biopsy performed under the hysteroscopic view.[9]

This work aimed at assessing the validity of the hysteroscopic view in the diagnosis of endometrial hyperplasia and cancer in patients with AUB. We intended to learn when the hysteroscopic view alone would be able to exclude the existence of malignant and pre-malignant diseases and determine which lesions were more likely to be confirmed by histology as the gold-standard.

Materials and methods

A retrospective study was conducted from June 1993 through December 2004. Ten thousand and twenty charts of patients from two Endoscopic Study Centers—the Gynecological Endoscopic Sector of the Botucatu School of Medicine and Ginecologia Endoscópica do Rio de Janeiro—were analyzed. The patients underwent office hysteroscopy performed in an outpatient unit, and the following inclusion criteria were used: women with AUB (47.9% of the total) who underwent hysteroscopy and who had a medical report for intrauterine lesion (by directed biopsy, by hysteroscopic resection of the lesion, or on the hysterectomy piece). Of the 4804 examinations performed in patients with AUB, 4054 (84.4%) met the inclusion criteria. Seven hundred and fifty (15.6%) examinations were excluded for the following reasons: incomplete or inconclusive hysteroscopic examinations and impaired histologic examinations. Therefore, the sample used in this study comprised 4054 cases (40.5% of the total).

Wolf and Storz hysteroscopies delivered CO_2 or 0.9% saline solution through a 3.5- or 5-mm outer-diameter sheath, with a 2.7-, 2.9-, or 4-mm telescope. Intrauterine pressure varied from 30 to 70 mm Hg. Patients used one tablet of bromide of N-butilscopolamine 30 minutes before the examination. All hysteroscopies were performed without anesthesia.

The hysteroscopic view criteria for hyperplasia were: (1) corrugated endometrial hypertrophy without vascularization and decrease in interglandular space; or (2) hypertrophy with an irregular surface, abundant and anomalous vascularization, hematic collection, and necrosis. For endometrial cancer, the criteria were: irregular and shiny, micropapillary, cerebroid or polypoid hypertrophy, with somewhat softened and friable consistency, irregular vascularization, and necrotic areas. Standard histopathologic criteria were used for the diagnosis of endometrial hyperplasia and cancer.

Due to the large number of hysteroscopic findings and histopathologic diagnoses, the data were grouped in entities with similar characteristics and separately classified into six groups: I: normal; II: endometrial cancer; III: hyperplasia or endometrial hyperplastic polyps; IV: uterine cavity benign disease; V: cervical and cervical canal benign disease; and VI: cervical and cervical canal cancer. Such groupings were necessary for calculation of sensitivity, specificity, accuracy, and predictive values.

The data were transferred to an Excel spreadsheet (Microsoft Corp., Redmond, WA), precodified in numbers and analyzed by using Stata software, version 7.0 (Stata Corporation, College Station, TX). For descriptive data, we used the observed numbers and percentage. Sensitivity was calculated as the proportion of positive cases (hyperplasia and cancer) that were correctly identified by hysteroscopic view. Specificity was calculated as the proportion of negative cases (hyperplasia and cancer) that were correctly identified by hysteroscopic view. Accuracy was calculated by as the proportion of correct results among the hysteroscopic examinations. Positive predictive value (PPV) and negative predictive value (NPV) were defined as the patient's probability to have hyperplasia/cancer given that hysteroscopy was positive (PPV) and not to have hyperplasia/cancer given that hysteroscopy was negative