

Diagnostic yield of endometrial biopsy following a normal outpatient hysteroscopy: a retrospective cohort study

Abstract

Introduction: Outpatient hysteroscopy permits direct visualisation of the endometrial cavity and is widely used in the investigation of abnormal uterine bleeding and postmenopausal bleeding. Endometrial biopsy is frequently performed during the same consultation, including when the hysteroscopic appearance is documented as normal. The additional diagnostic yield of routine biopsy in this setting remains clinically relevant, particularly given the possibility of inadequate sampling and additional procedural discomfort.

Objective: To determine the frequency of endometrial hyperplasia with atypia or carcinoma identified by endometrial sampling following a normal outpatient hysteroscopic impression, and to describe the histological yield and rate of insufficient sampling in this group.

Methods: We conducted a retrospective cohort study of patients attending a consultant-led outpatient hysteroscopy clinic at The Coombe Hospital, Dublin, between January and December 2024. Patients referred for assessment of abnormal uterine bleeding, postmenopausal bleeding, increased endometrial thickness or related indications were included. Hysteroscopic findings were classified according to the operating clinician's documented hysteroscopic impression. The primary outcome was histologically confirmed endometrial hyperplasia with atypia or endometrial carcinoma following a normal hysteroscopic impression. Histological samples were classified as normal, insufficient/non-diagnostic, or significant pathology.

Results: Of 709 patients attending the clinic during the study period, 442 were eligible for inclusion, and 267 were excluded. Hysteroscopy was performed in 358/442 (81.0%) patients. A good or excellent hysteroscopic view was documented in 327/358 (91.3%). The operating clinician documented a normal hysteroscopic impression in 207/358 (57.8%) patients. Among these 207 patients, 196 (94.7%) had a documented histology report. Of these, 171 (87.2%) had normal histology and 25 (12.8%) had an insufficient sample. No case of endometrial hyperplasia with atypia or carcinoma was identified among the 171 patients with diagnostic histology following a normal hysteroscopic impression.

Conclusions: In this retrospective cohort, no atypical hyperplasia or endometrial carcinoma was identified among patients with a normal outpatient hysteroscopic impression and diagnostic histology. More than one in eight histology reports in this subgroup was insufficient. These findings suggest that routine biopsy following a normal hysteroscopic impression may have limited additional diagnostic yield in appropriately selected patients. Prospective studies with predefined risk stratification and systematic follow-up are warranted to evaluate selective rather than routine endometrial sampling.

Keywords: Outpatient hysteroscopy, endometrial biopsy, abnormal uterine bleeding, postmenopausal bleeding, endometrial hyperplasia, endometrial carcinoma, histology

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Introduction

Abnormal uterine bleeding (AUB), including heavy menstrual bleeding, irregular bleeding and postmenopausal bleeding (PMB), is among the most common indications for assessment of the endometrial cavity.¹⁻⁵ Outpatient hysteroscopy permits direct visualisation of the endometrial cavity and facilitates identification of focal lesions such as endometrial polyps and submucosal fibroids, as well as endometrial appearances that warrant tissue sampling or further investigation.⁶⁻⁸

The diagnostic performance of hysteroscopy for endometrial pathology has been examined extensively. Previous systematic reviews have demonstrated good diagnostic performance for endometrial carcinoma and hyperplasia, and a normal hysteroscopic examination is associated with a low subsequent probability of endometrial carcinoma.⁹⁻¹²

Despite this, endometrial sampling is commonly performed routinely alongside hysteroscopy, including in patients in whom the operating clinician documents a normal-appearing cavity. Endometrial sampling remains appropriate where there is a visual abnormality or an independent clinical indication for tissue diagnosis. However, the incremental diagnostic value of routine sampling following a reassuring hysteroscopic examination is less clear.

This question is clinically relevant because endometrial biopsy can cause additional discomfort and may produce an insufficient or non-diagnostic specimen, potentially resulting in repeat investigation and additional healthcare utilisation. Previous studies have reported substantial rates of inadequate sampling in selected postmenopausal populations and have examined the discomfort associated with biopsy during outpatient hysteroscopy.¹³⁻¹⁵

The present study therefore examined the histological findings obtained following a normal hysteroscopic impression as documented by the operating clinician in a large, real-world outpatient hysteroscopy service.

Objectives

The primary objective was to determine the frequency of endometrial hyperplasia with atypia or endometrial carcinoma identified by histological sampling following a normal outpatient hysteroscopic impression. Secondary objectives were to describe:

- 1) The proportion of patients with a normal hysteroscopic impression who underwent sampling
- 2) The distribution of histological findings in this group, and
- 3) The proportion of samples reported as insufficient or non-diagnostic

Methodology

Study design and setting

This was a retrospective observational cohort study conducted at The Coombe Hospital, Dublin, Ireland. The study was undertaken within a consultant-led outpatient hysteroscopy clinic in the hospital's ambulatory gynaecology service. Clinical records for patients attending the clinic between 1 January and 31 December 2024 were reviewed. The study was designed and reported in accordance with principles of transparent reporting for observational research.

Study population

A total of 709 patients attended the outpatient hysteroscopy clinic during the study period. Patients were eligible if they were assessed for AUB, PMB, increased endometrial thickness on ultrasound or another clinically related indication and underwent, or were assessed for, outpatient hysteroscopy and/or endometrial biopsy. A total of 442 patients fulfilled the study eligibility criteria. Two hundred sixty-seven patients were excluded because of one or more of the following:

- a) Referral indication outside the predefined target clinical group
- b) Hysteroscopy and/or biopsy was considered not indicated, including patients with a thin endometrium where invasive investigation was not considered clinically indicated
- c) Inability to tolerate outpatient assessment or request for assessment under general anaesthesia, or
- d) Insufficient clinical information for reliable data extraction

Data collection

Eligible patients were identified from the hospital electronic database. Electronic medical records were examined by two members of the research team, and data were entered into a standardised Microsoft Excel spreadsheet. Variables collected included:

- a) Referral indication
- b) Age
- c) BMI
- d) Parity
- e) Menopausal status
- f) Ultrasound/endometrial thickness findings
- g) Pre-procedure analgesia

- h) Local anaesthesia
- i) Whether hysteroscopy was performed
- j) Reason for non-performance of hysteroscopy
- k) Quality of hysteroscopic visualisation
- l) Hysteroscopic impression
- m) Whether endometrial biopsy was performed
- n) Whether a see-and-treat procedure was undertaken, and
- o) Histological diagnosis

No patient names, medical record numbers, addresses, dates of birth or other direct patient identifiers were collected or retained.

Definition of normal hysteroscopy

The primary exposure of interest was a normal hysteroscopic impression. A hysteroscopy was classified as normal when the operating clinician documented the hysteroscopic impression as normal in the clinical record. Thus, the study evaluates the clinical performance of the clinician's documented visual assessment as it occurred in routine practice.

Histological classification

Histology was classified according to the final pathology report as:

- 1) Normal
- 2) Insufficient/non-diagnostic
- 3) Hyperplasia without atypia
- 4) Hyperplasia with atypia, or
- 5) Carcinoma

The primary histological endpoint was defined a priori as endometrial hyperplasia with atypia or endometrial carcinoma. Insufficient samples were not considered equivalent to normal histology and were retained as a separate category.

Statistical analysis

Descriptive statistics were used to summarise the study population. Continuous variables are reported as median and range. Categorical variables are presented as numbers and percentages. For the primary analysis of patients with a normal hysteroscopic impression, histological outcomes were reported separately according to whether the specimen was diagnostic or insufficient.

Because insufficient histology does not establish the absence of endometrial pathology, the primary estimate of the frequency of atypical hyperplasia or carcinoma among patients with diagnostic histology was calculated using the number of patients with diagnostic histology as the denominator. For the observed proportion of atypical hyperplasia/carcinoma in patients with diagnostic histology, an exact binomial 95% confidence interval was calculated.

Institutional approval

The study received approval from the hospital's Audit and Quality Advisory (AQUA) Committee at The Coombe Hospital before data extraction began (AQUA-2025-02-06). Given the retrospective nature of the study and use of anonymised routinely collected clinical data, individual patient consent was not required. Access to the dataset was restricted to members of the research team.

Results

Study cohort

A total of 709 patients attended the outpatient hysteroscopy clinic during 2024. Of these, 442 patients were included in the study, and 267 were excluded. Of the 442 included patients,

358/442 (81.0%) underwent hysteroscopy. Among the 84 patients in whom hysteroscopy was not performed, 73/84 (86.9%) were documented as not requiring hysteroscopy, and 11/84 (13.1%) did not tolerate the outpatient procedure. Among the 358 patients who underwent hysteroscopy, the operating clinician documented a normal hysteroscopic impression in 207 (57.8%) (Figure 1).

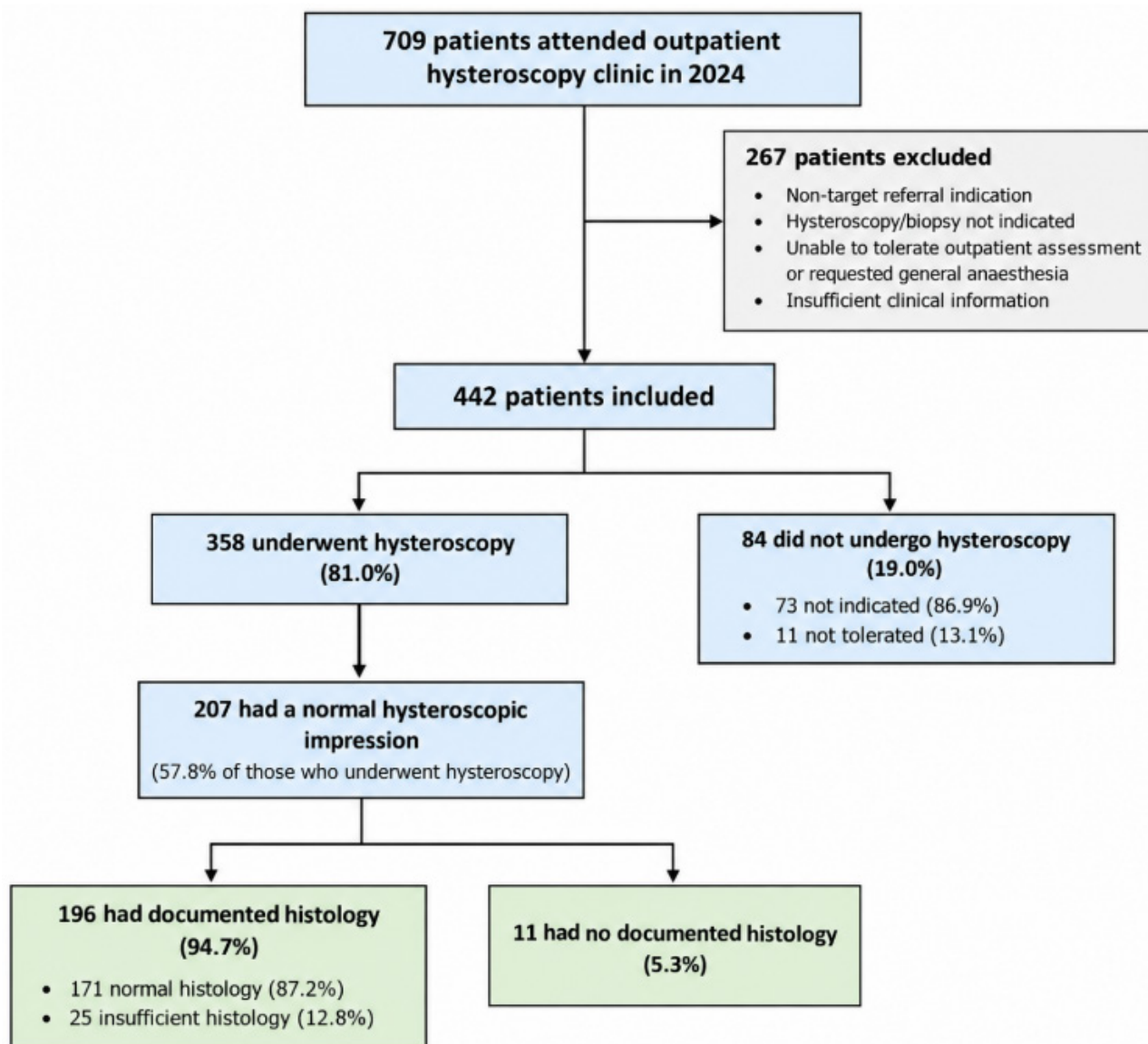


Figure 1 Flow chart of the study population.

Baseline characteristics

The median age of the 442 patients was 52 years (range 31–89 years), and the median BMI was 28 kg/m² (range 19–54 kg/m²). The majority of patients were multiparous (388/442; 87.8%) and 292/442 (66.1%) were postmenopausal. Pre-procedure analgesia was documented in 152 patients (34.4%), while paracervical or intracervical local anaesthesia was used in 250 patients (56.6%). Baseline characteristics are summarised in Table 1.

Table 1 Baseline characteristics of the study population (n=442)

Characteristic	N (%) or Median (Range)
Median age, years	52 (31–89)
Median BMI, kg/m ²	28 (19–54)
Postmenopausal	292 (66.1%)
Multiparous	388 (87.8%)
Pre-procedure analgesia	152 (34.4%)
Paracervical/intracervical block	250 (56.6%)

Referral indications

The most common referral indication was PMB, including PMB in women receiving HRT, accounting for 226/442 patients (51.1%) (Table 2).

Table 2 Reasons for referral to the outpatient hysteroscopy clinic (n = 442)

Referral reason	N (%)
PMB	125 (28.3%)
PMB on HRT	101 (22.9%)
Heavy menstrual bleeding	106 (24.0%)
Irregular or intermenstrual bleeding	54 (12.2%)
Increased endometrial thickness on ultrasound	11 (2.5%)
Postcoital bleeding	11 (2.5%)
Prolonged uterine bleeding	4 (0.9%)
Others	30 (6.8%)

Hysteroscopic visualisation

Among the 358 patients who underwent hysteroscopy, the view was documented as good or excellent in 327/358 (91.3%), while poor hysteroscopic view was recorded in 10 (2.8%) patients. The quality of the visualisation was not documented/not applicable in 4 (1.1%) of patients. The high proportion of good or excellent visualisation is relevant when interpreting a normal hysteroscopic impression, although it does not eliminate the possibility of occult disease.

Normal hysteroscopic impression

The operating clinician documented a normal hysteroscopic impression in 207/358 (57.8%) of patients undergoing hysteroscopy. These 207 patients constituted the primary subgroup for this study. The definition was based exclusively on the contemporaneous documented impression of the operating clinician, rather than retrospective reinterpretation of hysteroscopic findings.

Histological findings following normal hysteroscopy

Of the 207 patients with a normal hysteroscopic impression, 196 (94.7%) had a documented histology report. Of these 196, 171 (87.2%) had normal histology while 25 (12.8%) had insufficient histology. Among the 171 patients with diagnostic histology following a normal hysteroscopic impression, no patient had atypical hyperplasia or carcinoma. Thus, the observed rate was 0/171 (0%) with an exact 95% confidence interval of 0–2.1% (Table 3).

Table 3 Histological outcome following a normal hysteroscopic impression (n=207)

Histological outcome	N (%)
Documented histology (n=196)	
Normal	171 (87.2%)*
Insufficient	25 (12.8%)*
Hyperplasia or carcinoma	0
No documented histology (n=11)	11 (5.3%)

*Percentage of the 196 patients with documented histology

Discussion

In this retrospective cohort, a normal hysteroscopic impression was associated with a very low observed frequency of atypical hyperplasia or endometrial carcinoma. This finding is consistent with previous studies reporting an extremely low risk of endometrial carcinoma, generally less than 1%, among patients with a hysteroscopically normal or atrophic endometrium.^{12,13,17,16} However, the diagnostic

performance of hysteroscopy varies according to the pathology being assessed. A systematic review reported high diagnostic accuracy for endometrial carcinoma, while performance for endometrial hyperplasia was less consistent.¹² Similarly, a meta-analysis reported a pooled sensitivity of 82.6% for endometrial carcinoma and 75.2% for hyperplasia, with high specificity for carcinoma.⁹ These findings support the diagnostic value of hysteroscopy in identifying patients with a visually reassuring endometrial cavity, while also demonstrating that a normal appearance cannot completely exclude microscopic pathology. In our cohort, no cases of atypical hyperplasia or carcinoma were identified among the 171 patients with both a normal hysteroscopic impression and diagnostic normal histology.

The relatively high proportion of insufficient histological samples is another important finding. Previous studies have reported inadequate or insufficient endometrial sampling in patients with a visually normal or atrophic cavity, with rates of up to 28%.^{13,18} In our cohort, 25 of 196 patients (12.8%) with a normal hysteroscopic impression and documented histology had insufficient samples. This finding is particularly relevant because 67.1% of patients in the normal hysteroscopy group were postmenopausal, in whom insufficient sampling is commonly associated with paucity of endometrial tissue and mucosal thinning rather than sampling error or missed lesions.^{13,19–21} Importantly, an insufficient sample should not be considered equivalent to a negative histological result. Repeat sampling may also remain inconclusive. In one study, 43.5% of repeat samples following an initial insufficient biopsy were again inadequate, while the remainder showed benign findings.¹³ Thus, although insufficient sampling may not necessarily be of any concern, it may lead to repeat investigations, additional healthcare utilisation and procedural discomfort.^{13,22–25}

The potential additional value of routine biopsy following a visually reassuring hysteroscopy therefore requires careful consideration. Previous studies have demonstrated limitations of blind endometrial sampling, particularly for focal intrauterine lesions, supporting the diagnostic advantage of direct hysteroscopic visualisation.^{1,2,7,22} More recent evidence has specifically examined whether biopsy adds diagnostic information when the hysteroscopic cavity appears normal or atrophic. In a recent study of patients with postmenopausal bleeding and a visually atrophic endometrium, the prevalence of precancerous pathology was low and no endometrial cancers were identified; however, 21.8% of biopsies were inadequate.¹³ A randomised trial comparing biopsy with no biopsy following a normal-appearing cavity during outpatient hysteroscopy for postmenopausal bleeding found greater post-procedure pain among women undergoing biopsy, without a significant difference in subsequent clinical management.¹⁵ These findings suggest that the potential benefit of routine sampling should be considered alongside the possibility of inadequate sampling and the procedural burden associated with biopsy.

Our findings should nevertheless be interpreted within the limitations of the study design. Biopsy was performed according to routine clinical practice rather than a predefined protocol, and the study therefore cannot establish that omission of biopsy is equivalent to routine sampling or that biopsy can safely be omitted in all patients with visually normal hysteroscopy. Furthermore, the study was retrospective and based on a clinician-documented hysteroscopic impression, without a standardised prospective classification system or systematic longitudinal follow-up. The 25 insufficient samples and 11 patients without documented histology also limit the ability to determine the true prevalence of occult pathology following a normal hysteroscopic examination. These limitations are particularly relevant when considering the reported sensitivity, specificity and predictive

values of hysteroscopy, which vary by patient population, disease prevalence and definition of a positive hysteroscopic finding.^{9–12}

Taken together, our findings raise the possibility that endometrial sampling following a visually reassuring hysteroscopic examination may be selectively avoided in some patients rather than performed universally in every case. However, any selective-biopsy pathway would need to incorporate factors beyond hysteroscopic appearance, including menopausal status, indication for referral, persistence or recurrence of bleeding, endometrial thickness and ultrasound findings, individual endometrial cancer risk factors, adequacy of hysteroscopic visualisation and the overall clinical assessment.^{13,15,26} Recent guidance supporting visually directed hysteroscopic biopsy also emphasises obtaining tissue from areas that are visually abnormal rather than relying solely on blind sampling.⁶ Our study was not designed to determine which combination of these factors could reliably identify patients in whom biopsy might be omitted. Prospective studies using predefined hysteroscopic criteria, standardised sampling protocols and systematic follow-up are therefore warranted to determine whether a risk-stratified selective-sampling pathway can safely reduce unnecessary biopsy while maintaining detection of clinically significant endometrial pathology.

Strengths

The study represents real-world clinical practice in a high-volume outpatient hysteroscopy service, with 442 patients included and 358 hysteroscopies performed. Hysteroscopic visualisation was documented as good or excellent in 91.3% of procedures, providing an important indicator of procedural quality. The definition of a normal hysteroscopy was based on the operating clinician's contemporaneous documented impression, rather than retrospective reinterpretation by the research team. This reflects the clinical decision-making process that would be used in routine practice. Finally, histological outcomes were explicitly separated into diagnostic normal histology and insufficient histology, avoiding the inappropriate assumption that an insufficient specimen represents a negative histological result.

Limitations

The retrospective design creates the possibility of selection and information bias, and the study depended on the accuracy and completeness of clinical documentation. The study was conducted within a single consultant-led service at one hospital. The findings may therefore not be generalisable to units with different patient populations, hysteroscopy expertise, equipment or clinical pathways. The study did not include systematic longitudinal follow-up to determine whether patients with insufficient histology or no histology subsequently underwent repeat investigation or were later diagnosed with endometrial pathology. This limits the ability of the study to assess the long-term clinical significance of an insufficient or absent histological result following a normal hysteroscopic examination.

Patients unable to tolerate outpatient hysteroscopy or who requested assessment under general anaesthesia were excluded. The results therefore apply primarily to patients who can undergo outpatient assessment. Finally, the decision to perform or withhold a biopsy was at the discretion of individual clinicians rather than following a standardised protocol, introducing potential variation in patient selection for biopsy and limiting the ability to determine the independent contribution of hysteroscopic appearance to the decision to sample.

Conclusion

In this retrospective cohort of 442 patients attending an outpatient hysteroscopy service, the observed additional diagnostic yield of endometrial sampling following a normal hysteroscopic impression was low. However, the study does not establish that biopsy can safely be omitted in all patients, particularly because some patients had insufficient or unavailable histology and systematic follow-up was not undertaken. The findings support prospective evaluation of a selective, risk-stratified approach to endometrial sampling following a normal outpatient hysteroscopic examination, rather than routine sampling in every patient.

Acknowledgments

None.

Institutional approval

The study received approval from the Audit and Quality Advisory Committee at The Coombe Hospital (AQUA-2025-02-06).

Consent

Individual patient consent was not required because this was a retrospective study using anonymised routinely collected clinical data.

Data availability

The dataset used for this study is not publicly available because of patient confidentiality and institutional data-governance requirements. Appropriate anonymised data may be available from the corresponding author subject to institutional approval.

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Conflicts of interest

The authors declare no conflicts of interest.

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