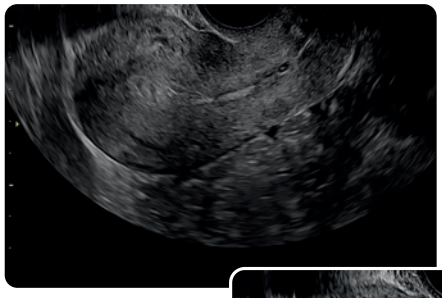
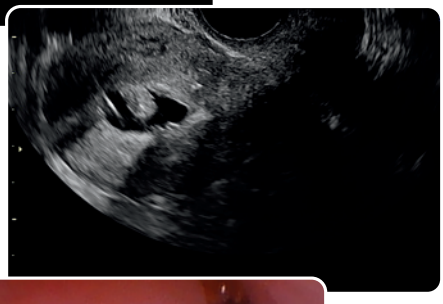
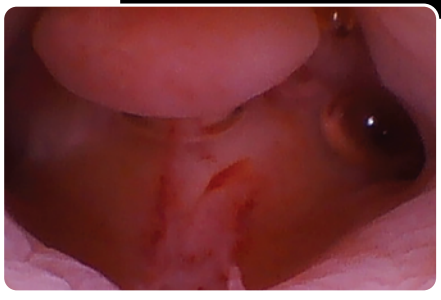
Endosee® Advance | by CooperSurgical®

A direct approach to evaluating uterine conditions







could have a dramatic effect on your patients and your practice.

> "The ability to look inside the uterus to diagnose anatomic abnormalities that affect reproductive health and underlying gynecologic disorders is an invaluable tool for the modern gynecologist. Doing that in the office not only offers the benefit of convenience for the patient and the surgeon, but also has the potential to contribute significantly to overall reduction in healthcare costs.[1]"
>
> – Anderson TL. Contemp ObGYN. 2016.

> "Many have seen hysteroscopy evolve...diagnostic and most operative hysteroscopies can be performed in an office.[2]"
>
> – Parry PJ, Isaccscon K. Fertil Steril. 2019;112:203-210.

AUB comprises

~33%

of all gynecology outpatient visits[1]

May account for

>70%

of consults among peri- and post-menopausal women[2]

The primary causes of AUB in patients between 35 years & menopause[3-5]

20-40%

Structural abnormalities[3-5]

60-80%

Non-structural dysfunctions[3-5]

Blind biopsy has limitations in diagnosing abnormalities within the uterine cavity[3]

> *"The primary role of endometrial sampling in patients with AUB is to determine whether carcinoma or premalignant lesions are present."*[3]

EMB has high overall accuracy in diagnosing endometrial cancer when:[3]

- an adequate specimen is obtained
- the endometrial process is global

If cancer occupies **less than 50%** of the surface area of the endometrial cavity, the cancer can be missed by a blind EMB[3]

ACOG guideline recommendations for AUB

- ACOG stated in a 2012 Practice Bulletin that an endometrial biopsy is ONLY an endpoint[3]
- Other evaluation methods, such as office hysteroscopy, may be necessary when the endometrial biopsy is insufficient, nondiagnostic, or cannot be performed[3]

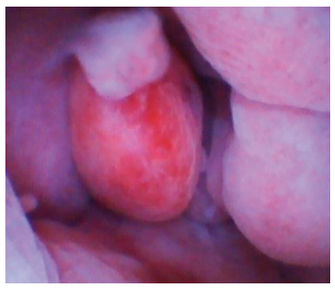
> *"A positive result is more accurate for ruling in disease than a negative test result is for ruling it out. Therefore, these tests are only an endpoint when they reveal cancer or atypical complex hyperplasia."*[3]
>
> – The American College of Obstetricians and Gynecologists

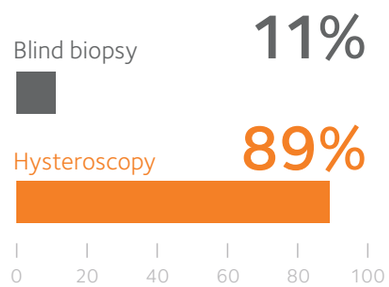
Diagnostic hysteroscopy may be more accurate than biopsy alone[4]

Diagnostic sensitivity of hysteroscopy vs blind biopsy*

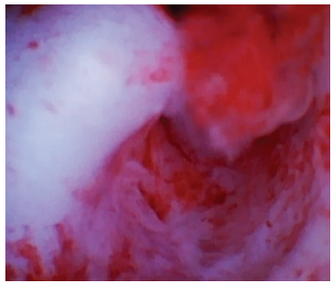
*n=319 women with AUB

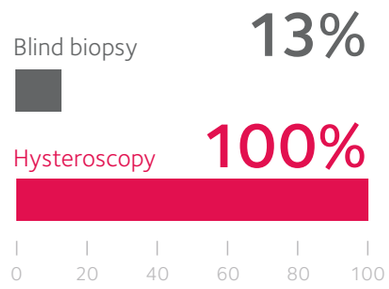
Polyps[4]



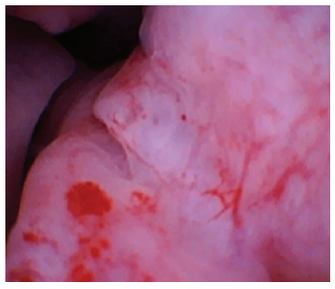


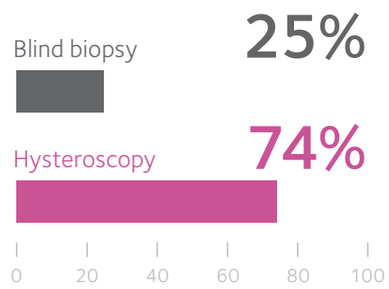
Myomas[4]





Hyperplasia[4]





> *"Hysteroscopy may be performed in an office setting or in the operating room, with office hysteroscopy being less expensive, more convenient for the physician and patient, and offering faster recovery and less time off work for the patient."*[3]
>
> – The American College of Obstetricians and Gynecologists

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Direct visualization is more accurate than SIS *and* TVUS in assessing endometrial pathology[5,6*]

Results of a prospective comparison of the diagnostic performance of TVUS, SIS, and DH in the detection of endometrial lesions[5]

	TVUS	SIS	DH
Any Uterine Abnormality			
Sensitivity (%)	89	92	**97**
Specificity (%)	56	60	**92**

N=105 symptomatic women with menorrhagia, postmenopausal bleeding and infertility.

*Each patient had a TVUS, SIS and DH

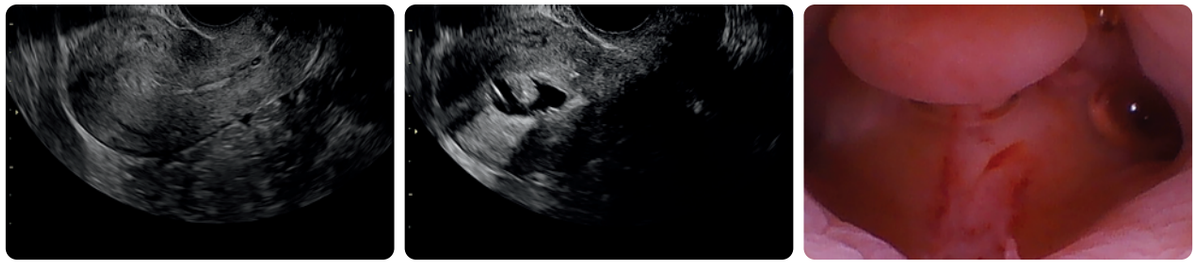
TVUS Transvaginal Ultrasound **SIS** Saline Infusion Sonohysterography **DH** Diagnostic Hysteroscopy

Transvaginal ultrasonography (TVUS) alone fails to diagnose endometrial polyps or leiomyomas in **1/6 patients** with intracavitary lesions and a thin endometrial stripe.

> *"Diseases of the endometrium such as endometrial hyperplasia and cancer cannot be distinguished by TVUS or SIS.[5]"*
>
> – Grimbizis GF, et al. *Fertil Steril.* 2016;94(7):2720-2725.

> *"Sonography is more effective in evaluating intramural and extramural uterine disease such as type III–VII myomas and ovarian abnormalities, but it is more limited with cornual disease, sessile polyps, intrauterine adhesions, and endometritis.[2]"*
>
> – Parry PJ, Isaccscon K. *Fertil Steril.* 2019;112:203-210.

Diagnostic hysteroscopy is considered the gold standard in evaluating intrauterine abnormalities[6]



TVUS **SIS** **Endosee® Advance**

Three imaging modalities in the same patient.

> *"Hysteroscopy provides direct visualization of the uterine cavity and, combined with histopathologic evaluation, is the criterion standard in the diagnosis of intrauterine abnormalities.[6]"*
>
> – Maheux-Lacroix S, et al. *Obstet Gynecol.* 2016;128(6):1425-1436.

A systematic review evaluating the accuracy of SIS vs TVUS for diagnosing polyps and submucosal leiomyomas in women with AUB found[6]:

	SIS	TVUS
Sensitivity (%)	92	64
Specificity (%)	89	90

(*P*<0.001)

	SIS	DH
Sensitivity (%)	93	**95**
Specificity (%)	83	**90**

(*P*=0.007)

> *"TVUS lacks sensitivity to be used alone to exclude the presence of polyps and leiomyomas in women with AUB.[6]"*
>
> – Maheux-Lacroix S, et al. *Obstet Gynecol.* 2016;128(6):1425-1436.

Office hysteroscopy provides convenience and cost-savings benefits

Avoiding OR intervention **may save approximately**

$3,500 per patient[7]

Estimated calculation of savings in procedure charges of patients undergoing diagnostic office hysteroscopy who did not need to undergo OR hysteroscopy.

58% avoided the OR

In a study of 130 AUB patients at two outpatient clinics in academic university settings:[7]

- 55 patients underwent office and OR hysteroscopy
- 75 patients underwent office hysteroscopy and did not need OR intervention

This represented an estimated savings of $1,498 per patient (95% confidence interval, $1,051–$1,923) in procedure charges.

Cost Breakdown[7]

Item	Office Hysteroscopy	OR Hysteroscopy
Physician fee	$1,356	$1,356
Anesthesia fee	$0	$1,190
Hospital fee	$0	$2,400
Total	$1,356	$4,946

The procedure cost for patients requiring both the inpatient procedure and the OR procedure could be up to $6,302.

> *Minimal to no pain has proved to be a benefit.*[7]

> *Office hysteroscopy helps prepare the physician for pathology that will be encountered in the OR.*

– Moawad N, Santamaria E, Johnson M, Shuster J. JSLS. 2014;18:1-5.

> *Technologic advances allow many opportunities for better diagnosis and treatment through office hysteroscopy.*[2]

– Parry P., Isaacson K. *Fertil Steril.* 2019;112:203-210.

> *Potential benefits of office hysteroscopy include patient and physician convenience, avoidance of general anesthesia, less patient anxiety related to familiarity with the office setting, cost effectiveness, and more efficient use of the operating room for more complex hysteroscopic cases.*[8]

– ACOG Committee Opinion, 2020.

Endosee® Advance | by CooperSurgical®

In-office hysteroscopy. It's time for a new standard of patient care.[10]

Can be performed prior to your endometrial biopsy in same visit

Average procedure completed in 3 minutes or less[11]*

*Based on 2019 Internal survey of Diagnostic only procedures, n= 69, conducted by one paid provider.

Increase your speed and accuracy of diagnosis and help provide your patient answers the same day with one exam[12]

Scan the QR code, visit Endosee.com or call 800.243.2974 to learn more

IMPORTANT SAFETY INFORMATION

Endosee® Advance Direct Visualization System is indicated for viewing the cervical canal, uterine cavity, or female urinary tract, for the purpose of performing diagnostic and therapeutic procedures. Hysteroscopy is contraindicated in patients with known or suspected pelvic inflammatory disease. Hysteroscopy may be contraindicated in patients with inability to distend the uterus, cervical stenosis, cervical/vaginal infection, uterine bleeding, or menses, known pregnancy, invasive carcinoma of the cervix, recent uterine perforation, or intolerance to anesthesia. Cystoscopy is contraindicated in patients with severe coagulopathy or febrile patients with urinary tract infection. Please refer to Instructions for Use for more information.

*Based on 2019 Internal survey of Diagnostic only procedures, n= 69, conducted by one paid provider.

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1. Anderson TL. Hand-held digital hysteroscopy system a game-changer. Contemp ObGyn. https://www.contemporaryobgyn.net/contemporary-obgyn/news/hand-held-digital-hysteroscopy-system-game-changer?page=0,3&trendmdshared=1. Updated September 13, 2016. Accessed May 8, 2019. 2. Parry PJ, Isaacson K. Hysteroscopy and why macroscopic uterine factors matter for fertility. Fertil Steril. 2019;112:203-210. 3. ACOG Practice Bulletin Number 128. Diagnosis of Abnormal Uterine Bleeding in Reproductive Aged Women. July 2012. 4. Angioni S, Loddo, A, Milano F, Piras B Minerba L, Melis GB. Detection of benign intracavitary lesions in postmenopausal women with abnormal uterine bleeding: a prospective comparative study on outpatient hysteroscopy and blind biopsy. J Minim Invasive Gynecol. 2008;15:87-91. 5. Grimbizis GF, Tsolakidis D, Mikos T, et al. A prospective comparison of transvaginal ultrasound and saline infusion sonohysterography and diagnostic hysteroscopy in the evaluation of endometrial pathology. Fertil Steril. 2016;94(7):2720-2725. 6. Maheux-Lacroix S, Li F, Laberge PY, Abbott J. Imaging for polyps and leiomyomas in women with abnormal uterine bleeding. Obstet Gynecol. 2016;128(6):1425-1436. 7. Moawad N, Santamaria E, Johnson M, Shuster J. Cost effectiveness of office hysteroscopy for abnormal bleeding. JSLS. 2014;18:1-5. 8. The use of hysteroscopy for the diagnosis and treatment of intrauterine pathology: ACOG Committee Opinion Summary, Number 800. Obstet Gynecol. 2020;135(3):754-756. doi: 10.1097/AOG.0000000000003713. 9. Goldstein SR. Finding a better approach to diagnosing abnormal uterine bleeding. OBG management. (suppl)Nov 2016. 10. Loffer, F. (2019). The time has come to quit relying on a blind endometrial biopsy or dilation and curettage to rule out malignant endometrial changes. 11. Based on Endosee Advance case study 2019 data on file. 12. ACOG Practice Bulletin, Diagnosis of Abnormal Uterine Bleeding in Reproductive-Aged Women, Number 128. July 2012.