



# MINIMALLY INVASIVE GYNECOLOGY

Understanding of abnormal uterine bleeding has been hampered by inconsistent use of terminology and a lack of classification of its causes, but expert bodies are tackling these problems



» Amy Garcia, MD

Dr. Garcia is Director, Center for Women's Surgery, Albuquerque, and Clinical Assistant Professor, Department of Obstetrics and Gynecology, University of New Mexico School of Medicine, Albuquerque, New Mexico.

*The author reports no financial relationships relevant to this article.*

The proliferation of terms to describe heavy menstrual bleeding sometimes seems never-ending. From “menometrorrhagia” to “uterine hemorrhage,” these terms pop up quickly and confuse discussion of one of the most widespread problems in gynecology.

Enter the International Federation of Gynecology and Obstetrics (FIGO), which decided to tackle the inconsistent terminology and lack of classification of causes of abnormal uterine bleeding (AUB) with an eye toward standardizing research, facilitating

discussion, and informing management decisions.

In this article, I focus on three aspects of this effort:

- FIGO's revamping of terminology and classification
- comparisons of outcomes of hysterectomy versus endometrial ablation and the levonorgestrel-releasing intrauterine system
- guidelines on management of AUB related to ovulatory disorders and endometrial hemostatic dysfunction.

## FIGO revamps nomenclature for abnormal uterine bleeding

*Munro MG, Critchley HO, Fraser IS. The FIGO systems for nomenclature and classification of causes of abnormal uterine bleeding in the reproductive years: who needs them? Am J Obstet Gynecol. 2012;207(4):259-265.*

As early as 2004, FIGO began a process to standardize the nomenclature for defining both normal and abnormal uterine

bleeding in reproductive-aged women who are not pregnant.<sup>1</sup> This process was a response to a lack of consistency and continuity in the design and interpretation of basic science and clinical investigation related to the problem of AUB. Inconsistent definitions of AUB, such as “menorrhagia,” “metrorrhagia,” and “dysfunctional uterine bleeding,” along with the absence of standard categorization of the

### IN THIS ARTICLE

**How hysterectomy compares with less invasive treatment options**

page 36

**What the data reveal about hysterectomy versus ablation**

page 38

**Guidelines clarify treatment or AUB related to ovulatory disorders**

page 39

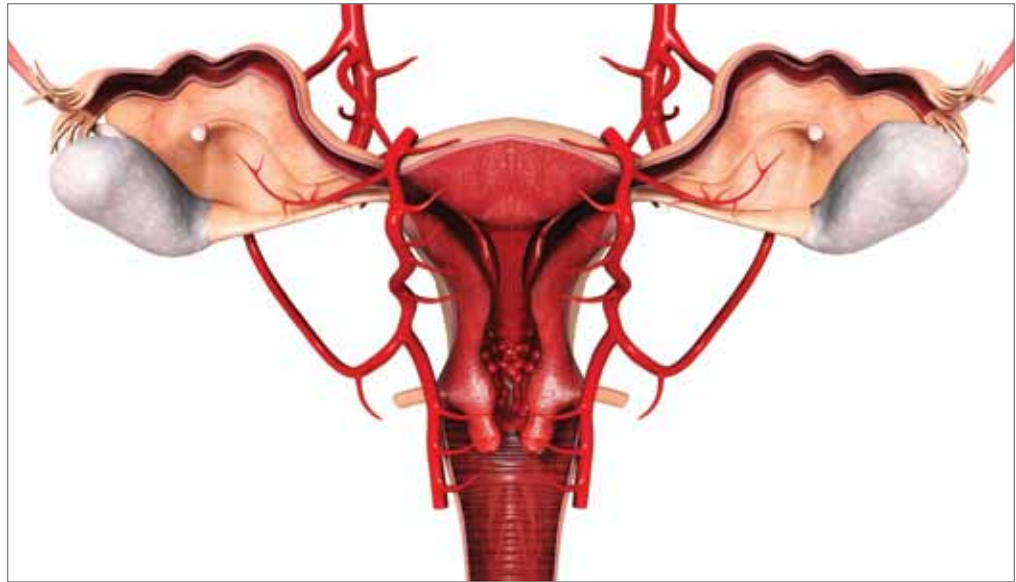


ILLUSTRATION: 3D4MEDICAL / SCIENCE SOURCE

## FAST TRACK

**AUB is the overarching term to describe any departure from normal bleeding**

causes of AUB, have led to confusion and difficulties in comparing clinical trials and in finding significant, relevant, and even meaningful correlations among investigations of AUB. Applying information from asynchronous and often incomplete investigations to evidence-based clinical practice then becomes a challenge for the gynecologist.

Munro and colleagues summarize the process by which FIGO developed both a nomenclature system and a classification system of the causes of AUB, which were formally adopted by FIGO in 2010 and endorsed in 2012 by the American College of Obstetricians and Gynecologists (ACOG).<sup>1-6</sup> The arduous process led to:

- a refined definition of chronic AUB
- a new category called acute AUB
- a method for describing the clinical dimensions of menstruation and the menstrual cycle according to the following parameters:
  - regularity of onset
  - frequency of onset
  - duration of menstrual flow
  - heaviness, or volume, of menstrual flow.

Wherever appropriate, the definitions of normal for these parameters were based on statistics from large population studies that used medians and 5th and 95th percentiles.

The term “heavy menstrual bleeding” (HMB) is used to describe a woman’s perception of increased menstrual volume,

regardless of regularity, frequency, or duration. AUB is the overarching term to describe any departure from normal menstruation, as defined by the parameters listed above. A group of misleading terms commonly used to describe AUB were eliminated from the FIGO nomenclature system, including “dysfunctional uterine bleeding,” “menorrhagia,” “hypermenorrhea,” “menometrorrhagia,” “polymenorrhagia,” and “metrorrhagia.”

The causes of AUB are classified in nine categories that are arranged according to the acronym PALM-COEIN:

- **P**olyp
- **A**domyosis
- **L**eiomyoma
- **M**alignancy and hyperplasia
- **C**oagulopathy
- **O**vulatory disorders
- **E**ndometrial dysfunction
- **I**atrogenic
- **N**ot otherwise classified.

Leiomyoma are subclassified as submucous or other, with tertiary subcategorization for intramural, subserosal, and transmural lesions.

In general, the components of the PALM group are discrete (structural) entities that are measurable visually via imaging or histopathology, or both, while the COEI (of the COEIN group) includes women for whom the AUB is unrelated to structural abnormalities.

CONTINUED ON PAGE 36



The classification system provides the infrastructure for a thorough investigative process and a means to characterize AUB for an individual who may have one or more potential causes or contributors. Such a comprehensive assessment allows the basic scientist to identify pure populations for tissue and molecular studies, the clinical scientist to identify potential confounders when defining populations for clinical investigation, and the clinician, educator, and trainee to consider the multidimensional nature of AUB where asymptomatic “red herrings” may coexist with otherwise invisible disorders of menstrual function.

The FIGO Menstrual Disorders Working Group anticipates that widespread, international acceptance of the recommended

### WHAT THIS EVIDENCE MEANS FOR PRACTICE

Use of the FIGO-recommended terms, definitions, and classification of AUB will lead to higher-quality clinical research and thorough clinical investigation into the causes of AUB, with improved management of patients.

terms, definitions, and classification for AUB will lead to improved and more meaningful communication in clinical trials and published research and will enhance communication between health-care providers and patients, leading to better management of AUB.

## How hysterectomy for AUB compares with less invasive treatment options

*Matteson KA, Abed H, Wheeler TL II, et al; Society of Gynecologic Surgeons Systematic Review Group. A systematic review comparing hysterectomy with less invasive treatments for abnormal uterine bleeding. J Minim Invasive Gynecol. 2012;19(1):13-28.*

To create reliable treatment recommendations for AUB, as defined by the FIGO classification system just described, in women with ovulatory disorders, endometrial hemostatic dysfunction, and concomitant leiomyoma, the Systematic Review Group (SRG) of the Society of Gynecologic Surgeons performed a systematic review of treatments. The analysis was intended to compare hysterectomy with less invasive treatment modalities. The SRG reviewed randomized, controlled trials of AUB treatment that compared hysterectomy with:

- endometrial ablation by resectoscopic loop, rollerball, or thermal balloon

- the LNG-IUS
- medical therapy.

This comprehensive review of literature published between 1950 and January 14, 2011 led the SRG to create seven categories of clinical outcomes:

- bleeding control
- quality of life
- pain
- sexual health
- patient satisfaction
- need for additional treatment
- adverse events.

Of the initial 5,503 titles identified, only 18 articles, representing nine clinical trials, contained data of adequate quality to meet criteria for review. Seven of the trials compared hysterectomy with ablation, one compared hysterectomy with the LNG-IUS, and one compared hysterectomy with medical therapy. As FIGO has pointed out, the lack of homogeneity of terminology used to

### FAST TRACK

The SRG created 7 categories of clinical outcomes of AUB: bleeding control, quality of life, pain, sexual health, patient satisfaction, need for additional treatment, and adverse events



**TABLE 1** What the data reveal about hysterectomy versus ablation

Parameter	Strength of evidence (comparison)	
	Hysterectomy	Ablation
Bleeding control	Moderate (F)	—
Quality of life	Moderate (S)	Moderate (S)
Lower pain	Low (F)	—
Sexual health	Low (S)	Low (S)
Patient satisfaction	Very low (S)	Very low (S)
Need for additional treatment	Moderate (F)	—
Adverse events	—	Moderate (F)

F = Evidence favors comparator; S = no difference between comparators

**TABLE 2** What the data reveal about hysterectomy versus the levonorgestrel-releasing intrauterine system (LNG-IUS)

Parameter	Strength of evidence (comparison)	
	Hysterectomy	LNG-IUS
Bleeding control	Moderate (F)	—
Quality of life	Moderate (S)	Moderate (S)
Lower pain	Moderate (S)	Moderate (S)
Sexual health	Moderate (S)	Moderate (S)
Patient satisfaction	Moderate (S)	Moderate (S)
Need for additional treatment	Moderate (F)	—
Adverse events	—	Moderate (F)

F = Evidence favors comparator; S = no difference between comparators

### FAST TRACK

#### Bleeding appears to be better controlled after hysterectomy, compared with endometrial ablation

describe AUB and classification of its causes prevented clinically applicable comparative analyses of treatment outcomes.

Here are some of the SRG's findings:

- **Control of bleeding.** Only data regarding amenorrhea were sufficient for comparative analysis. The SRG was able to conclude only that there was moderate strength of evidence supporting the statement that bleeding is better controlled following hysterectomy than following ablation.
- **Quality of life.** Overall, studies that evaluated quality of life showed improvement after ablation and hysterectomy. The strength of evidence demonstrating no difference between hysterectomy and ablation in postoperative quality of life was moderate.
- **Pain, general health, vitality, and social function.** Three studies found statistically significant differences in validated

dimensions of the SF-36 questionnaire favoring hysterectomy for pain, general health, vitality, and social function. Two of these three studies evaluated minimally invasive hysterectomy by the laparoscopic supracervical or vaginal approach. The strength of evidence on pain beyond the postoperative time period was low and favored hysterectomy over ablation.

- **Sexual health.** The strength of evidence related to sexual health was low and revealed no differences between hysterectomy and ablation.
- **Patient satisfaction.** Overall, the quality of evidence was very low, showing no difference between hysterectomy and ablation.
- **Need for additional treatment.** The quality of evidence was moderate and favored hysterectomy over ablation.
- **Adverse events.** Evidence of moderate quality favored ablation and the LNG-IUS

over hysterectomy, and low-quality evidence favored medical therapy over hysterectomy (TABLES 1, 2).

The SRG concluded that there are trade-offs between treatment effectiveness and the risk of serious adverse events between hysterectomy, ablation, and the LNG-IUS. It recommended that clinicians be educated about the relative advantages and disadvantages of each option so that they can discuss them with patients.

The SRG developed clinical practice

#### WHAT THIS EVIDENCE MEANS FOR PRACTICE

Gynecologists should educate each patient about the efficacy and risks of options available for the management of AUB in the context of specific symptoms to facilitate an informed choice.

guidelines for the treatment of ovulatory disorders and endometrial hemostatic dysfunction associated with AUB (see below).

## Group issues guidelines for treatment of AUB related to ovulatory disorders, endometrial hemostatic dysfunction

*Wheeler TL II, Murphy M, Rogers RG, et al; Society of Gynecologic Surgeons Systematic Review Group. Clinical practice guidelines for abnormal uterine bleeding: hysterectomy versus alternative therapy. J Minim Invasive Gynecol. 2012;19(1):81-87.*

The SRG used the results of the systematic review just summarized to formulate clinical guidelines for the treatment of AUB related to ovulatory disorders and endometrial hemostatic dysfunction. Recommendations were assigned a grade for their strength on the basis of the quality of supporting evidence, the size of the net medical benefit, and other considerations, including values and preferences applied in judgments. The strength of the clinical recommendation is either “strong” or “weak” and indicates the degree to which one can be confident that adherence to the recommendation will do more good than harm. **All of the clinical recommendations described below received a grade of “weak.”**

One primary suggestion from the study group is patient counseling that must first determine the type of AUB and the degree of

burden or distress for the patient, as well as the presence of any additional cycle-related symptoms. Consideration should be given to variables that may modify the inherent risks or benefits of each intervention for the particular patient, as well as her values and preferences regarding treatment harms, benefits, and potential outcomes. Counseling should assess the patient’s need for contraception, desire for future childbearing, and proximity to menopause, as well as any cultural preferences for management.

Based on the clinical evidence related to **hysterectomy versus endometrial ablation**, the SRG made the following recommendations:

- If the patient desires amenorrhea and less pain and wants to avoid additional therapy, hysterectomy is preferred
- If the patient wants to avoid adverse events and seeks a shorter hospital stay, endometrial ablation is preferred
- If the patient’s main desire is for improvement in overall quality of life or sexual health, either intervention is appropriate, depending on patient preferences.

There were no data available in the systematic review concerning newer technologies



**If a patient desires amenorrhea and less pain and wants to avoid additional therapy, hysterectomy is preferred**



for nonhysteroscopic endometrial ablation versus hysterectomy.

Based on the clinical evidence related to **hysterectomy versus the LNG-IUS**, the SRG made the following recommendations:

- If the patient desires amenorrhea or seeks to avoid additional therapy, hysterectomy is preferred
- If the patient's main preference is to avoid adverse events, the LNG-IUS is preferred
- If her preference is for improved quality of life or sexual health, either treatment can be offered.

Based on the clinical evidence related to **hysterectomy versus systemic medication**, the SRG made the following recommendations:

- If the patient wants to become amenorrheic or hopes to avoid further intervention, hysterectomy is recommended
- If she wants to avoid adverse events, medications are recommended
- If her main preference is overall improvement in quality of life, less pain, or improvement in sexual health, either hysterectomy or medication is appropriate.

Note that no standard therapy was given; medical agents included combined oral contraceptive pills, cyclic or continuous progestin, conjugated estrogen with or without progestin, and prostaglandin synthetase inhibitors, usually with hormonal therapy. There are no randomized, controlled trials of other medications such as nonsteroidal anti-inflammatory drugs or tranexamic acid versus hysterectomy.

The SRG cited three main difficulties in

### WHAT THIS EVIDENCE MEANS FOR PRACTICE

“Decision-making about treatments of AUB requires discussion so a patient can choose a therapy that best fits her disease, her values, and her preferences and optimizes her chance for treatment success while minimizing risks,” the SRG concluded.

the development of clinical guidelines:

- a lack of well-developed randomized, controlled trials of alternative management versus hysterectomy, as well as inconsistent measurement and reporting among the few trials that exist
- a lack of uniformity in AUB diagnoses among the randomized, controlled trials evaluated
- inconsistent use of terminology related to AUB within the trials.

All of these challenges were addressed by the FIGO nomenclature and AUB classification recommendations. Adherence to the FIGO guidelines for future clinical research would eliminate the difficulties faced by this study group and lead to higher-quality clinical evidence that could form the basis of solid clinical recommendations for the treatment of AUB related to ovulatory disorders or endometrial hemostatic dysfunction. 📌

### Acknowledgment

Thank you to Dr. Malcolm Munro and Dr. Anita Lee Sloan for their thoughtful reviews of this manuscript.

### FAST TRACK

**If a patient's main desire is to avoid adverse events, the LNG-IUS is preferred**

### References

1. Munro MG, Critchley HO, Broder MS, Fraser IS; FIGO Working Group on Menstrual Disorders. FIGO classification system (PALM-COIN) for causes of abnormal uterine bleeding in nongravid women of reproductive age. *Int J Gynaecol Obstet.* 2011;113(1):3-13.
2. Munro MG, Critchley HO, Broder MS, Fraser IS; FIGO Working Group on Menstrual Disorders. The FIGO classification of causes of abnormal bleeding in the reproductive years. *Fertil Steril.* 2011;95(7):2204-2208.
3. Critchley HO, Munro MG, Broder M, Fraser IS. A five-year international review process concerning terminologies and definitions for normal and abnormal uterine bleeding. *Semin Reprod Med.* 2011;29(5):377-382.
4. Fraser IS, Critchley HO, Broder M, Munro MG. The FIGO recommendations on terminologies and definitions for normal and abnormal uterine bleeding. *Semin Reprod Med.* 2011;29(5):383-390.
5. Munro MG, Critchley HO, Fraser IS. The flexible FIGO classification concept for underlying causes of abnormal uterine bleeding. *Semin Reprod Med.* 2011;29(5):391-399.
6. American College of Obstetricians and Gynecologists. Practice bulletin #128: Diagnosis of abnormal uterine bleeding in reproductive-aged women. *Obstet Gynecol.* 2012;120(1):207-211.