



Original Article

Clinical Practice Guideline for Abnormal Uterine Bleeding: Hysterectomy versus Alternative Therapy

Thomas L. Wheeler, II, MD, MSPH*, Miles Murphy, MD, MSPH, Rebecca G. Rogers, MD, Rajiv Gala, MD, Blair Washington, MD, Linda Bradley, MD, and Katrin Uhlig, MD, MS, for the Society of Gynecologic Surgeons Systematic Review Group

From the University Medical Group, Greenville Hospital Systems, Greenville, South Carolina (Dr. Wheeler), Institute for Female Pelvic Medicine and Reconstructive Surgery, Abington, Pennsylvania (Dr. Murphy), University of New Mexico Health Sciences Center, Albuquerque, New Mexico (Dr. Rogers), Ochsner Clinic Foundation, New Orleans, Louisiana (Dr. Gala), Women and Infant's Hospital, The Warren Alpert Medical School of Brown University, Providence, Rhode Island (Dr. Washington), Cleveland Clinic, Cleveland, Ohio (Dr. Bradley), and Tufts University School of Medicine, Tufts Medical Center, Boston, Massachusetts (Dr. Uhlig).

ABSTRACT Study Objective: To develop recommendations in selecting treatments for abnormal uterine bleeding (AUB).

Design: Clinical practice guidelines.

Setting: Randomized clinical trials compared bleeding, quality of life, pain, sexual health, satisfaction, the need for subsequent surgery, and adverse events between hysterectomy and less-invasive treatment options.

Patients: Women with AUB, predominantly from ovulatory disorders and endometrial causes.

Interventions: On the basis of findings from a systematic review, clinical practice guidelines were developed. Rating the quality of evidence and the strength of recommendations followed the Grades for Recommendation Assessment, Development, and Evaluation system.

Measurements and Main Results: This paper identified few high-quality studies that directly compared uterus-preserving treatments (endometrial ablation, levonorgestrel intrauterine system and systemically administered medications) with hysterectomy. The evidence from these randomized clinical trials demonstrated that there are trade-offs between hysterectomy and uterus-preserving treatments in terms of efficacy and adverse events.

Conclusion: Selecting an appropriate treatment for AUB requires identifying a woman's most burdensome symptoms and incorporating her values and preferences when weighing the relative benefits and harms of hysterectomy versus other treatment options. Journal of Minimally Invasive Gynecology (2012) 19, 81-88 © 2012 AAGL. All rights reserved.

Keywords:

Endometrial ablation; Guideline for uterine bleeding; Hysterectomy; Medical treatment; Levonorgestrel-releasing intrauterine system

DISCUSS

You can discuss this article with its authors and with other AAGL members at http://www.AAGL.org/jmig-19-1-11-00372



Use your Smartphone to scan this QR code and connect to the discussion forum for this article now*

Annually, 5% to 10% of women of reproductive age seek medical care for abnormal uterine bleeding (AUB), which negatively impacts quality of life (QoL) [1]. Most women with AUB report that their leisure activities are at least mod-

erately affected by their bleeding [2]. Compared with women without AUB, women with AUB work almost 4 fewer weeks per year in the United States [3]. Approximately 600 000 hysterectomies are performed annually in

Supported by the Society of Gynecologic Surgeons, who provided administrative and financial support for the Systematic Review Group's meetings and consultants (www.sgsonline.org).

Dr. Rogers' potential conflict of interest: American Medical Systems, consultant; NBC, consultant. Dr. Bradley's potential conflict of interest: Biosphere, consultant; Bayer, consultant. All other authors have no conflicts of interest to report.

Corresponding author: Thomas L. Wheeler, II, MD, MSPH, University Medical Group, Greenville Hospital Systems, 890 West Faris Rd, Greenville, SC 29605.

E-mail: twheeler@ghs.org

Submitted August 8, 2011. Accepted for publication October 6, 2011. Available at www.sciencedirect.com and www.jmig.org

1553-4650/\$ - see front matter © 2012 AAGL. All rights reserved. doi:10.1016/j.jmig.2011.10.001

Table 1

Categorization of quality of evidence and balance of potential benefits and harms

Quality of evidence

High Further research is unlikely to change the confidence in the estimate of the effect

Moderate Further research is likely to have an important impact on the confidence in the estimate of effect and may

change the estimate

Low Further research is very likely to have an important impact on the confidence in the estimate of effect and

is likely to change the estimate

Very low Any estimate of effect is very uncertain

Balance of potential benefits and harms

Trade-offs There are important trade-offs between the benefits and harms
Uncertain trade-offs It is not clear whether the intervention does more good than harm
No net benefits The intervention clearly does not do more good than harm

the United States, and many of these are performed to treat AUB [4]. AUB has several causes [5], but for patients with AUB caused by ovulatory disorders (AUB-O) or endometrial hemostatic disorders (AUB-E) uterine-preserving treatments include endometrial ablation, levonorgestrel releasing intrauterine system (LNG-IUS), and systemically administered medical management (which includes numerous medical therapy options).

Deciding who may benefit from less-invasive options and who would benefit from an expeditious hysterectomy could optimize patient care and health care efficiency. The Society for Gynecologic Surgeons (SGS) Systematic Review Group (SRG) set out to develop a clinical practice guideline to assist health care providers in delivering evidence-based counseling about the relative advantages and disadvantages of various treatment options for women with AUB predominately from ovulatory disorders (AUB-O) or endometrial causes (AUB-E) who would consider having a hysterectomy. These clinical practice guidelines are based on a systematic review of the literature [6].

Materials and Methods

The SRG includes SGS members with clinical and surgical expertise and methods consultants with expertise in the conduct of systematic reviews and guideline development [7]. For recommendations on treatment of AUB, in women with either AUB-O or AUB-E, the SGS-SRG conducted a systematic review of trials for AUB that included hysterectomy as one of the treatment assignments. The full description of methods and findings of this systematic review can be found in the companion publication to this guideline [6]. Briefly, a literature search was performed in Medline (inception to January 14, 2011) for randomized controlled trials comparing hysterectomy with other treatments for premenopausal women with AUB. We included RCTs that compared hysterectomy (via any route) to endometrial ablation, LNG-IUS, or systemically administered medical therapies as treatments of AUB caused by presumed ovulatory disorders or disorders of endometrial hemostasis (AUB-O and AUB-E) and reported an outcome of interest. We excluded RCTs that included only participants with AUB attributed to fibroids (AUB-L).

In the process of reviewing eligible randomized trials for AUB-O and AUB-E, the SGS-SRG identified numerous reported clinical outcomes that were categorized into 7 groups: (1) bleeding; (2) quality of life; (3) pain; (4) sexual health; (5) patient satisfaction; (6) need for additional treatments; and (7) adverse events. The importance of each outcome for clinical decision making was determined by consensus in the SGS-SRG [8]. The systematic review for this guideline included only outcomes of critical or high importance. In each study, the methodologic quality of the data for each outcome was scored as good, fair, or poor.

To grade the overall quality of evidence and the strength of the recommendations, we followed the Grades for Recommendation, Assessment, Development and Evaluation system [9]. For each set of studies evaluating a given treatment comparison, we graded the quality of evidence for each specific outcome across studies, including methodologic quality, consistency across studies, directness of evidence, and other factors such as imprecision or sparseness of evidence. We then evaluated the balance between benefits and harms of the given treatments and assessed the overall quality of evidence across all outcomes of interest (Table 1).

Guideline recommendations were assigned a grade for the strength of the recommendation on the basis of the quality of the supporting evidence, the size of the net medical benefit, and other considerations including values and preferences applied in judgments.

The strength of a recommendation indicates the extent to which one can be confident that adherence to the recommendation will do more good than harm. For this guideline, we graded the strength of each recommendation as either "strong" or as "weak." The wording and its implications for patients, physicians, and policy makers are detailed in Table 2. This system differs from the 3-level system used in the previous SGS guideline on vaginal repair of pelvic

Table 2 Nomenclature and description for grading recommendations								
	Implications							
Grade	Patients	Clinicians	Policy					
Level 1 "We recommend"	Most people in the situation will want the recommended course of action and only a few will not	Most patients should receive the recommended course of action	The recommendation can be evaluated as a candidate for developing a policy or a performance measure					
Level 2 "We suggest"	Most people in the situation would want the recommended course of action, but many would not	Different choices will be appropriate for different patients. Each patient needs help to arrive at a management decision consistent with her (or his) values and preferences	The recommendation is likely to require substantial debate and involvement of stakeholders before policy can be determined					

organ prolapse [7] but adheres more closely to the Grades for Recommendation, Assessment, Development and Evaluation protocol.

For this study, recommendations about patient counseling were included but not graded, because they were not explicitly based on the evidence reviewed. We chose to include these ungraded recommendations because they provide a context with which to interpret and apply the available evidence to patient care.

We presented a complete draft of the guideline at the 36th Annual Scientific Meeting of the Society of Gynecologic Surgeons in April 2010 in Tucson, Arizona. At that meeting, the guideline was publicly vetted, and attendees provided comments and suggestions for the guideline. After this scientific meeting, the guidelines were edited to reflect recommendations from the meeting. A draft of this manuscript was posted on the SGS website for 3 weeks in an effort to solicit input from members of SGS and other interested gynecologists. Members were encouraged to review the manuscript on the website, and a reminder email was sent to the SGS membership.

Results

The systematic review yielded 18 articles from 9 trials that directly compared hysterectomy with another intervention and met our eligibility criteria [10–27]. In women with predominately AUB-O or AUB-E, there were 7 studies comparing endometrial ablation against hysterectomy, 1 study comparing a variety of different systemically administered medical treatments versus hysterectomy, and 1 study comparing LNG-IUS versus hysterectomy. Other treatment alternatives to hysterectomy, though available, have not been studied directly against hysterectomy in RCTs for AUB-O or AUB-E and were, therefore, not considered for this guideline.

Recommendations and Rationale

Counseling Women With AUB

When counseling a woman with AUB-O or AUB-E about specific treatment choices (statements not graded),

determine the type and degree of burden and distress from AUB, other cycle-related symptoms and wishes for contraception; discuss benefits and harms of various appropriate treatments for AUB, other cycle related symptoms and contraception; consider patient factors that may modify the risks and benefits of different treatments; and explore the patient's values and preferences regarding specific treatment benefits and harms.

As is discussed in more detail below, different treatments have variable efficacy for different symptoms of AUB. The SGS SRG consensus was that severity and burden from AUB, as well as its impact on QoL and daily activities, needs to be elucidated to select a treatment with a high likelihood of addressing specific pretreatment AUB symptoms. Furthermore, trade-offs for different treatment alternatives need to be discussed. Although hysterectomy cures AUB regardless of cause, it is associated with higher operative risk and postoperative morbidity rates than other lessinvasive treatments. Thus a patient's values and preferences regarding the benefits and harms of different treatments need to be explored to determine how she appraises the net balance for each. Such a discussion should explore a patient's desire for future childbearing, proximity to menopause, and any relevant comorbid conditions that may impact on procedural risk or potential harms. To optimize decisionmaking, a patient needs to participate in a frank discussion so that she can choose a therapy that best fits her disease, her values, and her preferences, optimizes chances for treatment success, and minimizes risk for harms.

General Treatment Recommendations

In women with AUB presumed caused by predominately AUB-O or AUB-E, we suggest that any of the following treatment options may be chosen on the basis of patient values and preferences: hysterectomy, endometrial ablation, systemically administered medical therapies, or LNG IUS. (Weak).

Below we discuss the relative benefits and harms, on the basis of the available trial evidence, of each of the uterine preserving treatments (endometrial ablation, LNG IUS, or medical therapies) when compared directly with hysterectomy.

-		-
l o	h	- 4
10	.,	_ 7

Evidence profile: hysterectomy versus endometrial ablation

						Summary of Findings			
	No. of	Total	Methodologic			Other	Evidence		Outcome
Outcome	studies	No.	quality	Consistency	Directness	considerations	Quality	Effect	Importance
Bleeding	7	1167	6B, 1C (−1)	0	0	0	Moderate	Favor hyst	Critical
Quality of Life (general)	6	1116	1A, 2B, 3C (−1)	0	0	0	Moderate	No difference	Critical
Pain	5	818	1A, 1B, 3C (−2)	0	0	0	Low	Favor hyst	Critical
Sexual Health	5	879	2B, 3C (−2)	0	0	0	Low	No difference	High
Bulk-related Symptoms	2	404	2C (-2)	-1	0	0	Very low	No difference	High
Patient Satisfaction	5	935	5C (-2)	-1	0	0	Very low	No difference	High
Additional treatments	7	1167	1A, 6B (−1)	0	0	0	Moderate	Favor hyst	Moderate
Adverse events	7	1167	1A, 6B (−1)	0	0	0	Moderate	Favor ablation	Variable

0 = No limitation; -1 = some limitation; -2 = serious limitation.

Consistency refers to treatments showing similar effect for each outcome across all or most studies. Directness refers to applicability of the results to the population of interest. Other considerations refer to issues besides quality, consistency, and directness of the evidence that may affect interpretation of the evidence. (eg, imprecision or sparseness of the evidence). The quality of overall evidence was low to moderate. The balance of potential benefits and harms included important trade-offs.

Choosing Between Endometrial Ablation and Hysterectomy for the Treatment of Gbnormal Uterine Bleeding from Predominately AUB-O or AUB-E

If the patient's main preference is for amenorrhea or avoiding additional therapy or experiencing less pain, we suggest hysterectomy rather than endometrial ablation (Weak). If the patient's main preference is for shorter hospitalization and for lower operative and postoperative procedural risk, we suggest endometrial ablation rather than hysterectomy (Weak). If the patient's main preference is for improvement in overall quality of life or sexual health, we suggest that either hysterectomy or endometrial ablation may be chosen and that the selection of treatment be based on additional patient preferences (Weak).

There were 7 studies comparing hysterectomy with endometrial ablation for predominately AUB-O or AUB-E [10–19]. Overall quality of the evidence for these studies was low to moderate for each outcome domain. Of note, all trials used resectoscopic methods of endometrial ablation, and 3 trials offered laser ablation, rollerball ablation, or thermal balloon ablation in addition to resection. No RCTs were available specifically comparing newer nonresectoscopic ablation techniques to hysterectomy (Table 3).

Choosing Between Levonorgestrel-Releasing IUS and Hysterectomy for the Treatment of Abnormal Uterine Bleeding from Predominately AUB-O or AUB-E

If the patient's main preference is for amenorrhea or avoiding additional therapy, we suggest hysterectomy rather than LNG-IUS (Weak). If the patient's main preference is to avoid adverse events, we suggest LNG-IUS rather than hysterectomy (Weak). If the patient's main preference is improvement in overall QOL or sexual health, we suggest that either hysterectomy or LNG-IUS is appropriate and that the choice of treatment be based on additional patient preferences (Weak).

One randomized trial of 236 women with heavy menstrual bleeding compared LNG-IUS and hysterectomy for patients with AUB without intrauterine pathology (presumed AUB-O or AUB-E) [20–25]. This study has resulted in a series of publications including a 10-year follow-up report (Table 4).

Choosing Between Systemically Administered Medications and Hysterectomy for the Treatment of Abnormal Uterine Bleeding from Predominately AUB-O or AUB-E

If the patient's main preference is for amenorrhea or avoiding additional therapy, we suggest hysterectomy rather than systemically administered medications (Weak). If the patient's main preference is to avoid adverse events, we suggest systemically administered medications rather than hysterectomy (Weak). If the patient's main preference is long-term improvement in QOL, pain or sexual health, we suggest that either hysterectomy or systemically administered medications is appropriate and that the choice of treatment be based on additional patient preferences (Weak).

One randomized trial with 63 women evaluated the effect of hysterectomy versus medical treatment on patient outcomes for presumed dysfunctional uterine bleeding [26,27]. The overall quality of evidence from this study was low. Notably, the trial did not mandate a specific medication regimen. Although the investigators recommended the use of a combination of 21 days of low-dose oral contraceptives with a placebo week during each 4-week cycle and use of a prostaglandin synthetase inhibitor (such as nonsteroidal antiinflammatory drugs) for the first 5 cycle days, several other regimens were used in the medical treatment arm of this study and included continuous oral contraceptive use, oral or intramuscular progestins, and cyclic estrogen-progestin use. This study evaluated pain, health-related QoL, and sexual function (Table 5).

т	w.			- 4
	я	п	ю	4

Evidence profile: hysterectomy versus LNG-IUS

							Summary of findings		
	No.		Methodologic			Other	Evidence		Outcome
	studies	Total N	quality	Consistency	Directness	considerations	quality	Effect	Importance
Bleeding	1	63	NA	NA	NA	NA	NA	Favor Hyst*	Critical
Quality of Life (general)	1	63	1A (-1)	NA	0	0	Low	No difference	Critical
Pain	1	63	1C (-2)	NA	0	-1	Very low	No difference	Critical
Sexual Health	1	63	1A (-1)	NA	0	-1	Low	No difference	High
Bulk-related Symptoms	0	0	NA	NA	NA	NA	NA	NA	High
Patient Satisfaction	1	63	1B (-1)	NA	0	-1	Low	No difference	High
Additional treatments	0	0	NA	NA	NA	NA	NA	NA	Moderate
Adverse events	1	63	1B (-1)	NA	0	-1	Low	Favor alt.	Variable

 $^{0 = \}text{No limitation}$; -1 = some limitation; -2 = serious limitation.

Discussion

Applicability

For this guideline we included only evidence from randomized trials directly comparing hysterectomy to uterine-preserving treatments. This specific inclusion criterion could be considered both an asset and a limitation for our guideline. Study populations, treatments used, and outcomes measured varied from study to study. Having the "constant" of a hysterectomy comparator group helped limit the clinical heterogeneity and selection bias that could result from recruitment for trials including treatments with varying interventional risks. However, because the evidence base for our guideline included only studies that included a "hysterectomy" arm, the target population for the guideline is

limited to women with AUB predominately from AUB-O or AUB-E, who a priori would not exclude hysterectomy as a treatment option—women who do not place a high value on preserving their uterus per se and who would otherwise be candidates for hysterectomy. Of note, trials that randomize to a nonsurgical versus surgical group may not fully capture differences in outcomes when patients self-select treatment in clinical practice.

Although other guidelines for the treatment of women with AUB have been published, this SRG guideline provides a concise reference for evidence-based counseling on hysterectomy versus all other treatments. The National Institute of Health and Clinical Excellence (NICE) in the United Kingdom provided a guideline in 2007 for the evaluation and treatment of AUB based on a systematic review of all

Evidence profile: hysterectomy vs. systemically administered medications

							Summary of findings		
	No. of	Total	Methodologic			Other	Evidence		Outcome
Outcome	studies	No.	quality	Consistency	Directness	considerations	quality	Effect	importance
Bleeding	1	63	NA	NA	NA	NA	NA	Favor Hyst*	Critical
Quality of life (general)	1	63	1A (-1)	NA	0	0	Low	No difference	Critical
Pain	1	63	1C (-2)	NA	0	-1	Very low	No difference	Critical
Sexual Health	1	63	1A (-1)	NA	0	-1	Low	No difference	High
Bulk-related Symptoms	0	0	NA	NA	NA	NA	NA	NA	High
Patient Satisfaction	1	63	1B (-1)	NA	0	-1	Low	No difference	High
Additional treatments	0	0	NA	NA	NA	NA	NA	NA	Moderate
Adverse events	1	63	1B (-1)	NA	0	-1	Low	Favor alt.	Variable

 $^{0 = \}text{No limitation}; -1 = \text{some limitation}; -2 = \text{Serious limitation}.$

Consistency refers to treatments showing similar effect for each outcome across all or most studies. Directness refers to applicability of the results to the population of interest. Other considerations refer to issues besides quality, consistency, and directness of the evidence that may affect interpretation of the evidence (eg, imprecision or sparseness of the evidence). The quality of overall evidence was low. The balance of potential benefits and harms included important trade-offs.

Consistency refers to treatments showing similar effect for each outcome across all or most studies. Directness refers to applicability of the results to the population of interest. Other considerations refer to issues besides quality, consistency, and directness of the evidence that may affect interpretation of the evidence. (e.g., imprecision or sparseness of the evidence). The quality of overall evidence was low. The balance of potential benefits and harms included important trade-offs.

^{*} Data were not reported to make conclusions on control of bleeding in the medical treatment arm; however, 16 of 30 (53%) crossed over to the hysterectomy group.

^{*} Data were not reported to make conclusions on control of bleeding in the medical treatment arm; however, 16 of 30 (53%) crossed over to the hysterectomy group.

randomized trials of evaluation procedures and treatments for AUB [28]. In comparing hysterectomy with uterus-preserving options the guideline development group of NICE stated that "in their interpretation of the evidence, the guideline development group placed a high value on women avoiding hysterectomy" [28]. The SRG did not place any inherent value on uterine preservation. Despite this variation in values, the 2 guidelines were similar in that they both suggest hysterectomy for patients who desire amenor-rhea or specifically request hysterectomy. The guidelines differ in that in this guideline we suggest hysterectomy may be the better option for patients who wish to minimize the possibility of needing subsequent treatments to achieve satisfactory symptom control.

Limitations of the Evidence Base

We encountered several challenges in review and synthesis of the evidence on this topic. First, although AUB is highly prevalent, leading to hundreds of thousands of hysterectomies annually, there is only a disappointingly small number of RCTs with head-to-head comparisons of hysterectomy to uterine sparing treatments. Our guideline is based on our systematic review [6] of RCTs and is therefore limited to the treatments and outcomes evaluated within the specific studies included in our review. Though available, other treatment alternatives, like tranexamic acid, nonsteroidal antiinflammatory drugs or different interventional modalities were, therefore, not considered for this guideline.

In developing this guideline, we were faced with inconsistent measurement and reporting of a great number of outcomes [8]. We addressed this by categorizing outcomes and ranking their relative importance to weigh results when determining the net balance of benefits and harms. "Bleeding" was rated as a critically important outcome. However, we could not consider bleeding outcomes such as "reduction in bleeding," "improvement in bleeding symptoms," or "normalization of menses" in the non-hysterectomy arms because changes in bleeding patterns were not consistently assessed or measured across studies. Another limitation is that most of these studies defined AUB as heavy menstrual bleeding when it is not necessary to have heavy menstrual bleeding to have AUB. Because hysterectomy resolves bleeding completely, the alternative modality was judged to be inferior to hysterectomy in the bleeding domain. These challenges highlight the importance of measuring outcomes which may more meaningfully capture satisfaction with any procedure regarding improvement in the bleeding domain. Furthermore, dysmenorrhea, which may be an important factor in decision making, was included in the pain domain as it was not consistently reported or distinguished from pelvic pain. Other cycle-related symptoms, such as migraines or premenstrual syndromes, were not specifically examined as outcomes except possibly through their impact on quality of life. Yet, these symptoms, along with the need for contraception, may be important factors

for decision-making in individual patients. Also, cost considerations, both from the patient's and the society's perspective, can affect the strength of a recommendation. However, we did not assess costs for different treatment alternatives because costs are prone to perspective and assumptions and vary highly by context.

Second, there are multiple causes of AUB, which have been newly classified by the International Federation of Gynecology and Obstetrics (FIGO) Menstrual Disorders Group [29,30]. Under this system, causes of AUB are classified as polyps (AUB-P), adenomyosis (AUB-A), leiomyomas (AUB-L), malignancy and premalignant conditions (AUB-M), coagulopathy (AUB-C), ovulatory disorders (AUB-O), endometrial disorders (AUB-E), iatrogenic (AUB-I), and "not classified" (AUB-N). These conditions may coexist in the same patient, but they may also be present without being the cause of the AUB; For example, leiomyoma (AUB-L) may be found during the evaluation process but may not actually be the cause of the bleeding problem. Determining the most likely cause of the AUB is essential to planning treatment, because effectiveness often varies depending on the underlying cause of the bleeding. For example, the old term dysfunction uterine bleeding could refer to AUB-O, AUB-E or AUB-C. The NICE guideline for heavy menstrual bleeding provides good evidence-based recommendations for evaluating the etiology of AUB. For the trials we reviewed, we used the details provided within the papers, which was often limited, to categorize the cause of the AUB as "presumed AUB-E or AUB-O." However, the methods studies used to determine the cause of the AUB were often unclear.

The third challenge was the inconsistent use of terminology related to AUB. Recent studies have highlighted major variations in how clinicians and researchers use the commonly accepted terminologies used to describe the clinical signs and causes of menstrual disorders, which prompted the FIGO Menstrual Disorders working group to generate the new classification system listed above [30]. These studies found that even AUB experts did not universally agree on the definition of AUB, dysfunctional uterine bleeding (DUB), and menorrhagia, in terms of whether they referred to either a symptom/sign or a diagnosis or both. An international group of experts, using a Delphi process, recommended a simple set of terminology for the description and definition of symptoms and signs of AUB and agreed that the terms DUB, menorrhagia, and menometrorrhagia should no longer be used [29]. Specifically, they suggested assessing and documenting, in clinical encounters, the regularity, duration, frequency, and volume of menstrual bleeding with standard terminologies and conducting a structured menstrual history for patients reporting abnormal uterine bleeding [29]. Because of confusion surrounding the term "dysfunctional uterine bleeding" or "DUB," this term is not included in the naming system, and women who were formerly described as having "DUB" generally fit into the ovulatory disorders and endometrial hemostatic disorders categories if coagulopathy has been excluded. To be

consistent with this new classification system, we have described our population as having ovulatory disorders (AUB-O) or endometrial hemostatic disorders (AUB-E) throughout this manuscript; however, "DUB" and "dysfunctional uterine bleeding" were the terms used throughout the studies included in our systematic review. In future research, use of more-specific terminology, as described by this FIGO group, will, it is hoped, more clearly define study populations. Consistent and clear terminologies for the causes of AUB could facilitate systematic review and guideline development in the future.

Recommendations for Future Research

The shortcomings in the current body of literature on treatment for AUB presumed caused by ovulatory disorders and endometrial hemostatic disorders highlight an important research agenda. Recommendations are listed below:

- Validated outcome measures specific for AUB type (AUB-O, AUB-P, AUB-A, AUB-L, AUB-C, and AUB-E) that are valid and feasible to use so that they can be consistently incorporated into studies on this condition in the future should be developed.
- 2. Because two thirds of women seeking medical attention for heavy menstrual bleeding do not meet the objective criteria for heavy menstrual bleeding based on blood loss alone, studies looking at outcomes of treatment for women with AUB should be powered to detect a meaningful difference in symptoms related to bleeding and disease-specific QOL and not solely to a difference in objectively quantified amount of menstrual blood loss.
- 3. The evaluation of women recruited into the studies should be transparently described. Because the onset of menopause usually results in cessation of bleeding symptoms and this can affect the apparent treatment success from nonhysterectomy treatments, there is a need to present detailed data about the ages of participants and how age affects effectiveness.

In summary, 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.

Acknowledgments

We would like to acknowledge the work and contributions of the following Society for Gynecologic Surgeons Systematic Review Group Members: Kristen A. Matteson, MD, MPH, Ethan M. Balk, MD, MPH, Husam Abed, MD, Oz Harmanli, MD, Matthew Barber, MD, MHS, Karl Tamussino, MD, Scott Smilen, MD, Joseph Schaffer, MD, Vivian W. Sung, MD, MPH

References

- Kjerulff KH, Erickson BA, Langenberg PW. Chronic gynecological conditions reported by US women: findings from the National Health Interview Survey, 1984 to 1992. Am J Public Health. 1996;86:195–199.
- Frick KD, Clark MA, Steinwachs DM, et al., STOP-DUB Research Group. Financial and quality-of-life burden of dysfunctional uterine bleeding among women agreeing to obtain surgical treatment. Womens Health Issues. 2009;19:70–78.
- 3. Cote I, Jacobs P, Cumming D. Work loss associated with increased menstrual loss in the United States. *Obstet Gynecol.* 2002;100:683–687.
- Farquhar CM, Steiner CA. Hysterectomy rates in the United States 1990–1997. Obstet Gynecol. 2002;99:229–234.
- Munro MG, Critchley HO, Broder MS, Fraser IS, FIGO Working Group on Menstrual Disorders. FIGO classification system (PALM-COEIN) for causes of abnormal uterine bleeding in nongravid women of reproductive age. *Int J Gynaecol Obstet*. 2011;113:3–13.
- Matteson KA, Abed H, Wheeler TL, et al. A systematic review comparing hysterectomy to less invasive treatments for abnormal uterine bleeding. *J Minim Invasive Gynecol*. 2011;19:13–28.
- Murphy M, for the Society of Gynecologic Surgeons Systematic Review Group. Clinical Practice Guidelines on Vaginal Graft Use From the Society of Gynecologic Surgeons. *Obstet Gynecol*. 2008;112: 1123–1130.
- Rahn DD, Abed H, Sung VW, et al. Systematic review highlights difficulty interpreting diverse clinical outcomes in abnormal uterine bleeding trials. J Clin Epidemiol. 2011;64:293–300.
- 9. Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328:1490.
- Gannon MJ, Holt EM, Fairbank J, Fitzgerald M, Milne MA, Crystal AM, et al. A randomised trial comparing endometrial resection and abdominal hysterectomy for the treatment of menorrhagia. *BMJ*. 1991;303:1362–1364.
- Dwyer N, Hutton J, Stirrat GM. Randomised controlled trial comparing endometrial resection with abdominal hysterectomy for the surgical treatment of menorrhagia. Br J Obstet Gynaecol. 1993;100:237–243.
- Sculpher MJ, Dwyer N, Byford S, Stirrat GM. Randomised trial comparing hysterectomy and transcervical endometrial resection: effect on health related quality of life and costs two years after surgery. Br J Obstet Gynaecol. 1996;103:142–149.
- Pinion SB, Parkin DE, Abramovich DR, et al. Randomised trial of hysterectomy, endometrial laser ablation, and transcervical endometrial resection for dysfunctional uterine bleeding. *BMJ*. 1994;309:979–983.
- Alexander DA, Naji AA, Pinion SB, et al. Randomised trial comparing hysterectomy with endometrial ablation for dysfunctional uterine bleeding: psychiatric and psychosocial aspects. *BMJ*. 1996;12:280–284.
- Aberdeen Endometrial Ablation Trials Group. A randomised trial of endometrial ablation versus hysterectomy for the treatment of dysfunctional uterine bleeding: outcome at four years. Br J Obstet Gynaecol. 1999;106:360–366.
- Crosignani PG, Vercellini P, Apolone G, De Giorgi O, Cortesi I, Meschia M. Endometrial resection versus vaginal hysterectomy for menorrhagia: long-term clinical and quality-of-life outcomes. Am J Obstet Gynecol. 1997;177:95–101.
- Zupi E, Zullo F, Marconi D, et al. Hysteroscopic endometrial resection versus laparoscopic supracervical hysterectomy for menorrhagia: a prospective randomized trial. Am J Obstet Gynecol. 2003;188:7–12.
- Dickersin K, Munro MG, Clark M, et al., Surgical Treatments Outcomes Project for Dysfunctional Uterine Bleeding (STOP-DUB) Research Group. Hysterectomy compared with endometrial ablation for dysfunctional uterine bleeding: a randomized controlled trial. *Obstet Gynecol.* 2007;110:1279–1289.
- O'Connor H, Broadbent JA, Magos AL, McPherson K. Medical Research Council randomised trial of endometrial resection versus hysterectomy in management of menorrhagia. *Lancet*. 1997;349:897–901.
- 20. Hurskainen R, Teperi J, Rissanen P, et al. Quality of life and costeffectiveness of levonorgestrel-releasing intrauterine system versus

- hysterectomy for treatment of menorrhagia: a randomised trial. *Lancet*. 2001;357:273–277.
- Hurskainen R, Teperi J, Aalto AM, Grenman S, Kivelä A, Kujansuu E, et al. Levonorgestrel-releasing intrauterine system or hysterectomy in the treatment of essential menorrhagia: predictors of outcome. *Acta Obstet Gynecol Scand.* 2004:83:401–403.
- Hurskainen R, Teperi J, Rissanen P, et al. Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system or hysterectomy for treatment of menorrhagia: randomized trial 5-year follow-up. *JAMA*. 2004;291:1456–1463.
- Halmesmäki K, Hurskainen R, Teperi J, et al. The effect of hysterectomy or levonorgestrel-releasing intrauterine system on sexual functioning among women with menorrhagia: a 5-year randomised controlled trial. *BJOG*. 2007;114:563–568.
- 24. Heliövaara-Peippo S, Halmesmäki K, Hurskainen R, et al. The effect of hysterectomy or levonorgestrel-releasing intrauterine system on lower abdominal pain and back pain among women treated for menorrhagia: a five-year randomized controlled trial. Acta Obstet Gynecol Scand. 2009;88:1389–1396.
- Heliövaara-Peippo S, Halmesmäki K, Hurskainen R, et al. The effect of hysterectomy or levonorgestrel-releasing intrauterine system on lower

- urinary tract symptoms: a 10-year follow-up study of a randomised trial. *BJOG*. 2010;117:602–609.
- Kuppermann M, Varner RE, Summitt RL Jr, et al., Ms Research Group. Effect of hysterectomy vs medical treatment on health-related quality of life and sexual functioning: the medicine or surgery (Ms) randomized trial. *JAMA*. 2004;291:1447–1455.
- Learman LA, Summitt RL Jr, Varner RE, et al. Medicine or Surgery Research Group. Hysterectomy versus expanded medical treatment for abnormal uterine bleeding: clinical outcomes in the medicine or surgery trial. Obstet Gynecol. 2004;103(Pt 1):824–833.
- National Institute of Health and Clinical Excellence (NICE). Clinical Guideline CG 44: Heavy Menstrual Bleeding. London: National Institute for Health and Clinical Excellence; 2007.
- Fraser IS, Critchley HO, Munro MG, Broder M. A process designed to lead to international agreement on terminologies and definition to describe abnormalities of menstrual bleeding. *Fert Steril*. 2007;87: 466–467.
- Munro MG, Critchley HO, Broder MS, Fraser IS, FIGO Working Group on Menstrual Disorders. FIGO classification system (PALM-COEIN) for causes of abnormal uterine bleeding in nongravid women of reproductive age. *Int J Gynaecol Obstet*. 2011;113:3–13.