Reprinted from *The Journal of Reproductive Medicine®*
Vol.51 No.7, July 2006

Cost-Effectiveness of Treatments for Dysfunctional Uterine Bleeding

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OBJECTIVE: To compare the cost-effectiveness of treatments for dysfunctional uterine bleeding (DUB).

STUDY DESIGN: The decision analytic model used a third-party payer perspective and 18-month horizon to compare treatment of DUB patients ≥40 years old with no desire for fertility. Treatments were oral contraceptives (OCs) vs. surgery (first-/second-generation ablation or hysterectomy) after 3–9 months of OCs. Costs were based on publications and expert opinion. Efficacy measures were based on months with pictorial blood loss assessment chart (PBAC) score <100 and number of months of amenorrhea.

RESULTS: Treatment costs were estimated at $513 per patient per year (OCs), $3,500 (first-generation ablation), $3,000 (second-generation ablation) and $7,500 (hysterectomy). Adverse event costs ranged from $12 per year or episode (OCs, second-generation ablation) to $164 per episode (hysterectomy). To achieve PBAC <100, second-generation ablation after 3 months of OCs was the most cost-effective (7.6 additional DUB-free months vs. OCs, $215 per additional month). Second-generation ablation was less costly and more effective than first-generation ablation. Early treatment with hysterectomy was more effective than ablation, but at substantial cost. When using the end point of amenorrhea, hysterectomy was most cost-effective. Results were not sensitive to variations in costs, effectiveness or length of OC use.

A short treatment trial with OCs followed by second-generation endometrial ablation is the most cost-effective strategy for treating DUB....

CONCLUSION: A short OC trial followed by second-generation ablation is the most cost-effective strategy for women with DUB, although hysterectomy is more cost-effective to achieve amenorrhea. Hysterectomy cost-effectiveness might improve if evaluated over more time. Cost-effectiveness and patient preference must all play a role in treatment decisions. (J Reprod Med 2006; 51:553–562)

Keywords: bleeding, uterus, cost effectiveness.

Approximately 10% of reproductive-age women have objective evidence of menorrhagia (menstrual blood loss >80 mL).[1-3] Self-reported prevalence is much higher, with nearly one-third of women aged 35–59 years reporting heavy menstrual bleeding. Younger, nonwhite women who are single and

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Funded by Ethicon, Inc.

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Financial Disclosure: Mr. Magee is an employee of Ethicon, manufacturer of a second-generation endometrial ablation device.

have lower educational and income levels are especially at increased risk for such bleeding.[4,5]

Menorrhagia has both organic (fibroids, polyps) and nonorganic (functional) etiologies. Eighty percent of women who present with menorrhagia and have no identifiable pathology are typically diagnosed with dysfunctional uterine bleeding (DUB), which is thought to account for nearly half the abnormal bleeding episodes in women during their reproductive years.[6]

Common treatments for DUB include medical therapy using oral contraceptives (OCs) or progestin (and less commonly nonsteroidal antiinflammatory drugs and antifibrinolytics), endometrial destruction (via a variety of methods) and hysterectomy. Though guidelines suggest that medical treatment be used as first-line treatment, there are no well-accepted algorithms for treating DUB in the United States.[1] Rather than follow guidelines, physicians appear to choose the option that they feel best suits their patients. For example, up to 70% of patients who have hysterectomy for abnormal bleeding do not undergo trials of medical therapy.[7] Conversely, a number of women with DUB are treated for years with noninvasive methods, never progressing to more invasive treatment, despite lack of adequate symptom control.[8-10]

When presented with a variety of options to treat a condition, the physician typically selects 1 based on estimates of the likelihood of a successful outcome, the risks of treatment and the anticipated cost. In the case of DUB, lack of clarity about 1 or all of these factors may complicate decision making. As an example, even understanding the probability of success for any given treatment is difficult since trials of DUB treatments have reported outcomes in a variety of ways, including rates of patient satisfaction, amenorrhea, eumenorrhea and likelihood of retreatment.

Since the effectiveness, direct treatment costs and incidence of treatment-related adverse events vary considerably across the available therapeutic options, there is no simple way to assess the relative cost-effectiveness of each type of treatment. Therefore, we constructed a decision analytic model to assess whether second-generation ablation techniques offer any economic advantages over medical therapy, first-generation ablation or hysterectomy.

Materials and Methods

The study population comprised premenopausal women who were at least 40 years old, had diagnosed DUB due to benign causes and who did not desire future fertility. The model examined cost-effectiveness from the third-party payer perspective during an 18-month period. We chose this period to allow enough time to capture the costs associated with short-term complications and retreatment and because of the paucity of long-term data on the use of OCs; to treat abnormal bleeding. Three primary treatment strategies were identified by the authors, one of whom (M.S.B.) is a board-certified obstetrician-gynecologist with significant clinical and research expertise. These strategies, confirmed as appropriate choices by the American College of Obstetrics and Gynecology practice bulletin on the management of anovulatory bleeding, were OCs, hysterectomy and endometrial destruction or ablation.[1] Ablation techniques were grouped to reflect the different cost, resource use and adverse event profiles of the techniques. Techniques that require hysteroscopic visualization of the endometrial cavity were considered "first-generation" techniques (e.g., rollerball and endometrial resection), while those that do not require such visualization (e.g., thermal balloon or microwave endometrial ablation) were considered "second-generation" techniques.

Several variations on these 3 primary strategies were also modeled to better reflect the diversity of clinical opinion for managing DUB. There is no general agreement on the proper length of a treatment trial with OCs, therefore, the model compared 10 different treatment scenarios, each of which begins with a course of OC therapy. Based on the availability of outcome data, the reference case is OC therapy for 18 months regardless of clinical improvement. The remaining treatment scenarios examined the use of surgical interventions (ablation or hysterectomy) for patients who did not improve with OC therapy. The cost-effectiveness of each of these surgical treatments was assessed in combination with 3, 6 or 9 months of initial OC therapy. Those patients who did not improve after ablation were treated with a second ablation or hysterectomy. The probability of repeat ablation or progression to hysterectomy was estimated using available published literature and clinical expertise (Figure 1).

In common clinical practice, objective measures of dysfunctional bleeding are rarely used, but such measures are standard in clinical trials. Different trials used different efficacy measures, but a score >100 on the pictorial blood loss assessment chart (PBAC) is one of the most commonly reported ob-

1) In the reference case, it is assumed that all patients use OCs for the full 18 months regardless of whether or not their DUB responds to therapy. In this group, those patients who do not respond to OC therapy will still remain on OCs and will not progress to any of the surgical interventions.

2) Patients who improve after at least 3 months of OC therapy remain in the improved health state throughout the remaining months.

3) Treatment success rates for OCs are the same for 3, 6 and 9 months of therapy.

4) Treatment with ablation or hysterectomy immediately follows treatment failure on OCs when failure occurs after 3, 6 or 9 months of OC therapy, depending on the scenario.

5) Patients are not prescribed OCs after ablation to prevent pregnancy.

6) All patients who experience treatment failure from initial surgical treatment would seek further surgical treatment.

7) The probability of further surgery after ablation (repeat ablation or hysterectomy) remains constant over time within the 18-month model time frame.

8) Further surgery occurs within 6 months after the initial surgical treatment failure.

9) All postoperative adverse events occur within the 18-month model time frame.

10) Repeat ablation has the same rate of perioperative complications as primary ablation does.

11) For repeat surgery, the adverse events related to both operations are counted. For example, if ablation is followed by repeat ablation, then the adverse events associated with ablation are counted twice.

Figure 1 Key model assumptions.

jective measures of menorrhagia.[11] We began, therefore, by defining successful treatment as PBAC < 100.

In order to determine the cost and efficacy of the procedures being reviewed, we searched the PubMed bibliographic database to identify English-language, randomized clinical trials, nonrandomized controlled trials and case series reporting outcomes, adverse events or costs associated with DUB treatments published from 1966 to 2003. The PubMed search began with 3 separate searches: (1) *dysfunctional uterine bleeding* in all searchable fields; (2) *dysfunctional* and *uterine* and *bleeding* in the abstract field; and (3) *menorrhagia* in the PubMed MeSH heading and title. Each search was restricted to papers that reported treatment outcome or costs in English only. Search terms and strategies were developed by the authors, who include clinicians (M.S.B., L.M.) and health services researchers. Additional relevant articles were identified by hand searching the bibliographies of key review articles.

We derived treatment costs by examining published scientific literature and using publicly available fee and coding guides. Medication and device costs were obtained from the 2003 *Drug Topics® Red Book* of average wholesale prices. Costs of physician services and procedures were obtained from the 2003 *American Medical Association Current Procedural Terminology* codebook and the 2003 *Medicare Reimbursement Fee Schedule*. Cost estimates for hysterectomy were derived from diagnosis-related group (DRG) rather than a calculation of number of hospital days. Ablation does not require hospitalization. Hospital costs, including facility fees, anesthesiology service, and laboratory fees, were obtained from Medstat's 2002 DRG guidelines. Services used for treatment of adverse events were defined by clinical experts. We did not address costs or convenience for women after menstrual products were no longer needed.

The cost of OCs was estimated to be $513 per patient per year.[12,13] Published estimates of first-generation ablation costs were approximately $3,500 per episode.[14-16] Based on expert opinion, costs of second-generation ablation were $3,000, reflecting the lesser complexity and shorter operating time associated with the new technique. Hysterectomy cost estimates varied between $6,868 and $7,721.[17,18] Incorporating the adverse event cost of $164, we used $7,500 as the base case cost (Table I).

In the model, we included adverse events that would be expected to result in substantial use of medical services. Adverse events such as cervical laceration, fluid deficit without further treatment, nausea and headache, were not included in the model as they typically are not associated with either long-term sequelae or significant use of medical services. The average total cost associated with adverse events for each treatment technique was summed over the costs of each adverse event weighted by the incidence or probability of occurrence of the adverse event (Table I).

Estimates and sources of information for the probabilities of specific events in the model are presented in Table II. On average, first-generation and second-generation ablation appear to offer similar benefits to patients in terms of improvement in DUB, with the second-generation ablation techniques having slightly lower rates of further invasive surgery.

The decision analytic model was constructed with DATA 4.0 (TreeAge, Williamstown, Massachusetts) to determine the relative cost-effectiveness of medical and surgical treatments and

Table I *Cost of Direct Treatment and Adverse Events*

Cost component	OCs (12 mo)	Ablation (per episode)	Hysterectomy (per episode)
Drug	$437	$336	$165
Pretreatment		$321–340	
Physician procedure fee		$354–722	$861–1,507
Facility fee, anesthesiology, pathology/laboratory		$539	$5,487–5,694
General practitioner visit/home care	$76	$1,972	$191
Total treatment costs	$513	$3,540–3,749	$6,868–7,721
Adverse event costs	$12	$12 (Second-generation) $118 (First-generation)	$164
Source	12, 13, expert opinion	14, 15, 16	14, 17, 18, 31, 32

whether changes in the duration of medical therapy have an impact on cost-effectiveness (Figure 2).

The model results are summarized in terms of incremental cost-effectiveness ratios (ICERs). In calculating the ICER, each treatment scenario is compared to the next-more-expensive treatment scenario. If the next-more-expensive treatment scenario is also more effective, then the ICER is calculated as the difference between the costs of the 2 scenarios divided by the difference between the effectiveness measures. However, if the next-more-expensive scenario is less effective, then it is "dominated" by the less expensive scenario. Once a scenario has been dominated, it cannot be used as the reference scenario. The reference scenario is always the next-most-expensive nondominated strategy.

Several 1-way sensitivity analyses (changing 1 variable at a time) were conducted to test the model's robustness when varying the input parameters, including the average direct treatment costs and adverse event costs, as well as the threshold defining improvement in DUB.

Results

We searched PubMed using keywords *dysfunctional, uterine, bleeding* and *menorrhagia*. We also hand searched bibliographies of key articles. These searches yielded 318 citations, of which 133 included relevant data (e.g., estimates of treatment success rates, adverse event frequencies or costs). Two reviewers trained in health services research and the principles of critical appraisal abstracted relevant data from these papers. Except for studies of medical treatment and cost, for which there are limited data, we used data from randomized trials. If we found no randomized trial data, we used estimates from large (> 300 patients) case series or cohort studies. Table III shows the types of studies included.

Figure 3 depicts the results of the model in terms of total cost, DUB-free months and ICER. ICER estimates the incremental cost of each additional DUB-free month relative to the next least costly scenario (excluding dominated scenarios). The bars represent scenarios in which OCs are used for 3–9

Table II *Efficacy Data Used in Model*

Event	Probability estimate	Source
Improvement in DUB after		
OCs	47%	25
Hysterectomy	100%	33
First-generation ablation	90% (range, 81–95%)	10, 12, 35–41
Second-generation ablation	90% (range, 85–99%)	35, 37, 40–43
Requiring/requesting hysterectomy after		
First-generation ablation	5.6% (range, 1.77–14.7%)	36, 37, 39–46
Second-generation ablation	3.5% (range, 0–9%)	37, 39–41, 47
Requiring/requesting repeat ablation after		
First-generation ablation	5.0% (range, 0–11%)	38–40, 42, 43, 45, 46, 48
Second-generation ablation	1% (range, 0–1.9%)	39, 40, 45

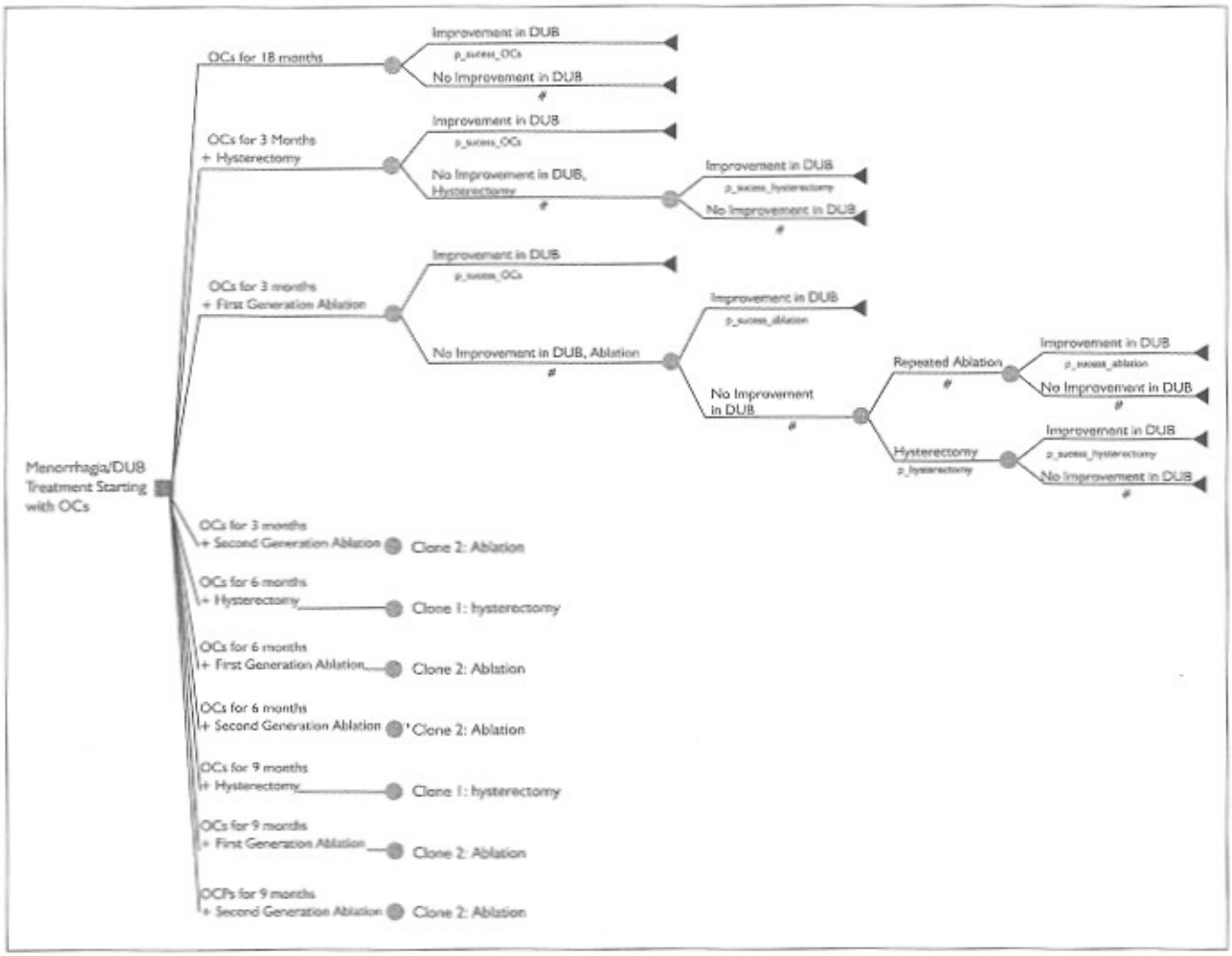

Figure 2 Decision analytic tree structure.

months (months indicated on bar) followed by the technique identified on the x-axis. Early treatment with second-generation ablation is the most cost-effective alternative treatment. When compared to OC treatment for 18 months, an additional 7.6 DUB-free months are gained by using second-generation ablation after 3 months of OC therapy, with each additional DUB-free month costing $215. Second-generation ablation dominated first-generation ablation, meaning that it is both less costly and more effective. Early treatment with hysterectomy is more effective than "long-term" OC use but provides only an average of 10 more DUB-free days than ablation does over 18 months. With hysterectomy, each additional DUB-free month cost $6,318. The cost of achieving a DUB-free month using ablation or hysterectomy would decrease if examined over a longer time horizon since surgical costs are incurred up front, but benefits (DUB-free months) continue over time.

To test the robustness of the model, we varied the definition of a successful outcome. Redefining the primary efficacy measure as PBAC score <75 (the definition of treatment success used by the U.S. Food and Drug Administration to approve ablation devices) did not change the cost-effectiveness ranking of the various scenarios. When we used amenorrhea as the desired outcome with a 40% success rate for first-generation ablation and a 31% success rate for second-generation ablation, hysterectomy became the most cost-effective treatment.

Additional analyses showed that the overall results are not sensitive to most variations in treatment success rates and assumptions about the use

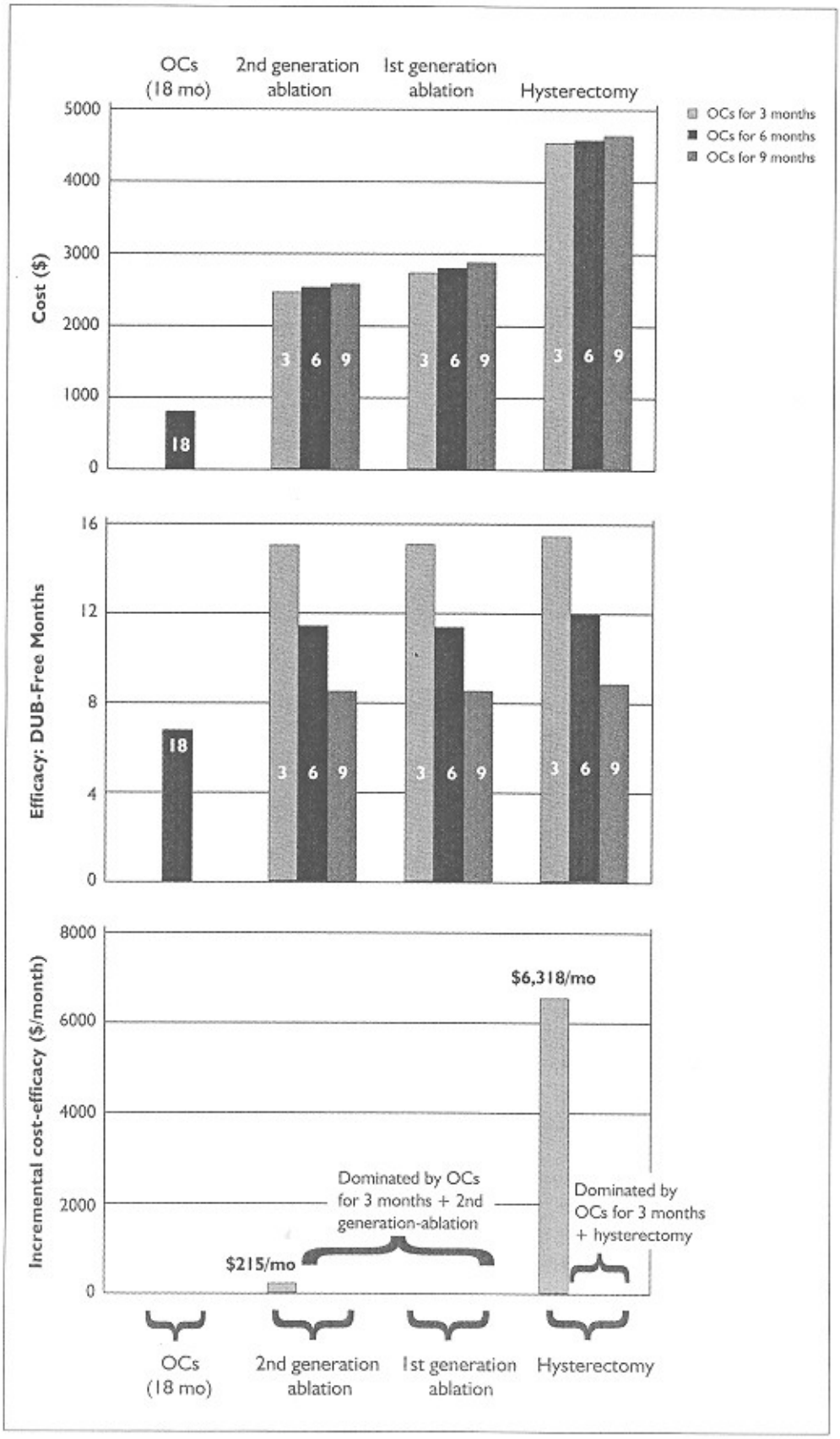

Figure 3 Summary of cost-effectiveness results. The incremental cost-efficacy ratio estimates the incremental cost of each additional DUB-free month relative to the next-least-costly scenario. The bars represent scenarios in which OCs are used for 3–9 months (months indicated on bar), with the technique identified on the x-axis.

Table III *Studies, by Treatment Strategy, Study Design and Country*

Treatment alternative	Study design			Country of study			
	Randomized, controlled trial	Cohort/ case-control	Case series	United States	United Kingdom	Canada	Others
OCs	1			1			
Progestin	5				5		
Dilation and curettage							
Ablation	42	16	65	33	30	15	32
Hysterectomy	10	19	6	7	11	1	7

The number of studies is listed in the columns.

of OCs after ablation. To illustrate, first-generation ablation became more cost-effective than second-generation ablation only when we assumed that it had a >92% probability of success, an assumption at odds with the clinical literature. We also examined the effect of increasing the success rate of OCs. Until they are assumed to achieve regular menses in 80% of patients (as compared to the literature-based estimate of 47%), second-generation ablation remained more cost-effective. Finally, we assumed that patients were prescribed OCs after ablation; this assumption increases the cost of each additional DUB-free month to $256 but does not change the ranking of the various treatment options.

Discussion

Between 10% and 30% of premenopausal women experience DUB, and a substantial number of these women are either untreated or undertreated. In a European study, 19% of women referred to obstetric/gynecology clinics with menorrhagia reported not having received treatment after 2 years.[19] In another study, over 16% of women aged 30–49 years who were diagnosed with menorrhagia did not receive any treatment during the 4-year study period.[6]

Not only is DUB common, but it has a broad impact on health status, quality of life and productivity. A recent study estimated that heavy menstrual blood loss resulted in a 6.9% workforce reduction, which translated to $1,692 in annual work-loss costs per case.[20] Studies have reported significant improvements along psychiatric morbidity scales following treatment for menorrhagia.[21,22] Jones et al reported that menorrhagia can adversely affect nearly all domains of quality-of-life measures, though it most substantially alters social functioning, mood and irritability subscales.[23] Women with menorrhagia surveyed by Shaw et al reported that it negatively affected many aspects of their lives, but most notably family life, physical health, work life, psychologic well-being, activities of daily living and social functioning.[24] Among women with objective evidence of menorrhagia, 20% reported having missed work due to menorrhagia during the previous 6 months vs. 12% among women complaining of menorrhagia but with menstrual blood loss within normal ranges.[25]

National and regional best-practice guidelines for the treatment of DUB, including those issued by the American College of Obstetricians and Gynecologists, agree that an appropriate treatment path starts with the least invasive and moves to more invasive options if earlier ones fail.[1] However, these guidelines do not specify how soon or at what symptom level doctors should recommend proceeding with more invasive treatment.

OCs offer inexpensive, noninvasive first-line therapy for DUB. However, estimating efficacy of OCs is challenging given the paucity of literature on the ability of OCs to produce regular menses in women with menorrhagia. A 1999 Cochrane review found no high-quality studies on this topic.[15] In 2000, Davis et al compared the effectiveness of oral contraceptives and placebo in women with a variety of menstrual disorders. Women with oligomenorrhea constituted over half the sample. In order to use results from Davis' full study population in our model, we assumed that OC treatment produced regular menses at the same rate in patients presenting with menorrhagia and oligomenorrhea. This assumption is conservative because oral contraceptives are less likely to produce regular menses in women with menorrhagia than in women with oligomenorrhea. Davis reported that treatment produced regular menses in 46.7% of OC–treated women.[9] In sensitivity testing, we increased this estimate to 68.3% to include all women who, after

treatment with OCs, had eumenorrhea (46.7%), hypomenorrhea (8.3%), amenorrhea (0.0%) and "irregular bleeding" (13.3%). Even this assumption did not change the relative outcomes; second-generation ablation remained more cost-effective than continued treatment with OCs.

Among the surgical DUB treatments, hysterectomy has the greatest efficacy. However, it is also associated with much higher costs, longer hospitalization and recovery times, and greater risk of complications. Although endometrial ablation is the newest treatment option for DUB, its efficacy and safety profile over a 10-year period suggests that it should receive greater consideration relative to current medical therapy, at least from the clinical perspective.[27-29] Studies have demonstrated that early ablation can help achieve higher levels of patient satisfaction, better menstrual status and greater improvement in health-related quality of life than medical treatment can in women who have no desire for future fertility. It is possible that the cost-effectiveness of hysterectomy might improve if studied over more time.

Given the current health care environment, treatment decisions must be examined not only from the perspective of clinical and patient outcome, but also from that of cost-effectiveness. By combining the available data on treatment efficacy and costs (including costs of treatment-related adverse events), the model described above demonstrates that second-generation ablation is the most cost-effective therapy for DUB, even when compared to long-term OC use. The model suggests that OCs would have to achieve regular menses in 80% of patients by 6 months and 95% by 9 months in order to be more cost-effective than use of ablation at 3 months.

The profile for hysterectomy is essentially the inverse of that for OCs—it is an exceptionally effective therapy but comes at a high cost. These results demonstrate that although early hysterectomy offers additional DUB-free months, over an 18-month period each of those months costs $6,318. Furthermore, hysterectomy is superior to ablation only if amenorrhea is the therapeutic goal.

The model results and its lack of sensitivity to variations in treatment success rates and costs assumptions show that second-generation ablation is more cost effective than either long-term OC use or hysterectomy if the goal is simply an improvement in DUB. Since current medical treatment provides sufficient relief for only about half of DUB patients, many women are left with only surgical alternatives. Even if ablation did not offer greater cost-effectiveness, many women may be willing to trade the absolute efficacy of hysterectomy for a less invasive procedure that can be performed in an outpatient facility and has a shorter recovery time.[13,28-30] In a recent study, >50% of British women who underwent endometrial ablation as therapy for menorrhagia reported that they would rate ablation as acceptable even if there were only a 40% likelihood of reducing their menstrual blood loss and if amenorrhea was not achieved.[30]

This study had certain limitations. First, cost and efficacy data for DUB treatments are not widely reported in the published literature. This may affect the validity of comparisons made using data from different studies in at least 3 ways. There is considerable overlap in the literature between menorrhagia and DUB; thus, the study populations may lack true homogeneity. To prevent heterogeneity from skewing the results, we selected variable estimates for our model from patients with comparable characteristics. Second, no head-to-head clinical trial for all treatment strategies included in this model was available. Third, most evaluations of DUB treatments were conducted outside the United States; that may limit generalization to U.S. experience.

Despite these limitations, this study showed that a short treatment trial with OCs followed by second-generation endometrial ablation is the most cost-effective strategy for treating DUB when PBAC <100 is the desired outcome. Cost-effectiveness, along with safety and patient preferences, should be an important determinant of treatment decisions.

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