Published in final edited form as:
*Fertil Steril*. 2009 July ; 92(1): 205–216. doi:10.1016/j.fertnstert.2008.04.023.

# ABNORMAL UTERINE BLEEDING: A REVIEW OF PATIENT-BASED OUTCOME MEASURES

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## Abstract

**Objectives:** To summarize and evaluate the patient-based outcome measures (PBOMs) that have been used to study women with abnormal uterine bleeding (AUB)

**Design:** Systematic review

**Setting:** Original articles that used at least one PBOM and were conducted within a population of women with AUB

**Patients:** Women with AUB

**Interventions:** The titles, abstracts, and studies were systematically reviewed for eligibility. PBOMs used in eligible studies were summarized. Essential psychometric properties were identified and a list of criteria for each property was generated.

**Main Outcome Measures:** "Quality" of individual PBOMs as determined using the listed criteria for psychometric properties.

**Results:** Nine hundred eighty three studies referenced AUB and patient reported outcomes. Of these, eighty studies met the eligibility criteria. Fifty different instruments were used to evaluate amount of bleeding, bleeding related symptoms, or menstrual bleeding-specific quality of life. The "quality" of each of these instruments was evaluated on eight psychometric properties. The majority of instruments had no documentation of reliability, precision, or feasibility. There was not satisfactory evidence that any one instrument completely addressed all eight psychometric properties.



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**Author Conflicts of Interest:** Matteson: none Boardman: Merck Munro: Ethicon Women's Health, Covidien, Gynesonics Inc., Karl Storz Endoscopy, AMAG Pharmaceuticals, Impres Medical Clark: none

**Presentation at medical meeting:** This study was presented as an oral presentation at the First International Meeting on Abnormal Uterine Bleeding, The American Association of Gynecologic Laparoscopists and the Society for Endoscopic Gynecologists of Italy, Palermo, Italy, June 2007

**Conclusions:** Studies of women with AUB are increasingly utilizing PBOMs. Many different PBOMs were used; however no single instrument completely addressed eight important measurement properties

### Keywords

Patient-based outcome measures; abnormal uterine bleeding; questionnaires; menstrual bleeding

## INTRODUCTION

Abnormal uterine bleeding (AUB) is defined as any alteration in the pattern or volume of menstrual blood flow. Two main categories of AUB are heavy menstrual bleeding or irregular menstrual bleeding. Menstrual disorders are the most prevalent gynecologic health problems in the United States and heavy menstrual bleeding (HMB) affects up to 30% of women at some time during their reproductive years (1-3). The societal and personal burden of AUB lies in its major impact on quality of life, productivity, and healthcare utilization and costs (4-6).

Traditionally, research on AUB objectively measured menstrual blood loss as the main study outcome. In 1964, Hallberg and Nilsson described a method to objectively measure mean menstrual blood loss (MBL) from sanitary products, a method that is still used in many studies evaluating women who report heavy menstrual bleeding (7). Other methods have been proposed for the objective quantification of menstrual blood loss, including determining menstrual fluid volume (8). In these studies heavy menstrual bleeding, or menorrhagia, is often defined as at least 80 mls MBL per cycle. However, less than half of women seeking treatment for heavy menstrual periods have MBL greater than this defined 80 ml cut-off and almost half of all women reporting heavy menstrual periods have less than 40 mls MBL (9-11). This means that something other than the objectively measured amount of bleeding, such as bleeding pattern, patient perception of bleeding, or quality of life, is leading women to seek medical attention.

In clinical practice, the diagnosis and evaluation of AUB is based on a woman's personal assessment of her blood loss and its impact upon her quality of life. However, this instrumental outcome has not been measured in a consistent manner. Recent research in this area recognized the importance of the “patient experience” as an outcome that should be measured (12). Thus, patient-based outcome measures (PBOM) have been developed and utilized for clinical research in this area.

Patient-based outcome measures can be generic or disease-specific and include questionnaires, standardized interviews, and other varied methods that assess health and illness from the patient's perspective. They have been applied to research in the area of AUB to evaluate patient-determined blood loss (through pictorial blood loss assessment scales, such as the PBAC) (13), disease-specific symptoms (through menstrual questionnaires), and quality of life (through quality of life (QOL) instruments). The quality of PBOMs varies, however. To be the “standard of care” for evaluation of a condition or disease, a PBOM should be reliable, valid, responsive, precise, interpretable, acceptable, and feasible (14). In 2002, a systematic review evaluating the “quality” of all QOL instruments (both generic and disease-specific) used in studies on heavy menstrual bleeding found that although the QOL instruments were of good quality in terms of “measurement properties”; the validity of the instruments was not well established (12).

As PBOMs are increasingly being utilized in clinical research, it is important that investigators constantly evaluate the quality of these PBOMs. For this study, our objectives were to (1) Summarize all patient-based outcomes measures that have been applied to research in the area

of AUB over the past 20 years; and (2) Evaluate whether or not PBOMs developed specifically for the population of women with AUB demonstrated eight psychometric properties experts consider important for PBOMs: appropriateness, reliability, validity, responsiveness, preciseness, interpretability, acceptability, and feasibility (14).

## MATERIALS AND METHODS

### Study identification

A search of the PubMed electronic database was performed. PubMed provides access to bibliographic information that includes MEDLINE, OLDMEDLINE, citations that precede the date that a journal was selected for MEDLINE indexing, and in-process citations. This database was chosen because of its comprehensive cataloguing of high-impact gynecologic and women's health journals and its universal accessibility by physicians and researchers. The search was limited to the years 1987-2007, English language, human, and female.

The search terms used to define and describe the population of interest were “menstrual bleeding, menorrhagia, menometrorrhagia, dysfunctional uterine bleeding, DUB, AUB, abnormal uterine bleeding, heavy periods, heavy menses, anovulatory bleeding, or irregular bleeding”. To identify studies that measured patient-based outcomes, the following search terms were used: “patient based outcome measure, patient reported outcome, patient based outcome, quality of life, scale, chart, diary, questionnaire, or survey”.

### Inclusion and Exclusion Criteria

Our intent was to review patient-based outcome measurement instruments that were specific for AUB, but not specific to any individual systemic or structural etiology, such as uterine leiomyomata. The inclusion criteria for this study were: (1) The population of interest was women with AUB; and (2) At least one patient based outcome measure was used in the study. Studies were excluded if: (1) The population was only women with AUB attributed to a specific etiology (such as fibroids or bleeding disorders) (2) The study was a review article and (3) The study only measured “satisfaction with treatment” as its patient-based outcome measure.

### Process of systematic review of articles and PBOMs

The titles, abstracts, and studies identified through the PubMed search were sequentially reviewed for eligibility by the first author (KAM). Additional studies were included if they were referenced in the “methods” section of eligible studies. The studies that met all inclusion and exclusion criteria were described in terms of study design, the study's independent variable, and number of instruments utilized. PBOMs were then described in terms of what types of outcomes they measured including amount of bleeding, menstrual symptoms, quality of life, depression, anxiety, body image, sexual functioning, or a combination of these listed outcomes.

Instruments that evaluated amount of menstrual bleeding, menstrual symptoms, or AUB-specific quality of life were evaluated for “quality”. The method of PBOM quality evaluation is described in detail in the following paragraph. General instruments (general health related quality of life instruments, psychiatric instruments, sexual functioning instruments) were reviewed and described. Previous studies have evaluated the quality of general instruments that have been used in a population of women with AUB and determined the need for a “condition-specific” instrument (12). We, therefore, evaluated the “quality” of all “condition-specific” instruments but reviewed and described all general instruments that were used to assess women with AUB.

### Method of PBOM quality evaluation

We identified important instrument properties using existing methodologic publications and other studies that reviewed the quality of PBOMs (12,14). Eight psychometric properties were identified as essential: appropriateness, reliability, validity, responsiveness, precision, interpretability, acceptability, and feasibility. We developed three criteria for each property. These properties and criteria are displayed in Table 1. Psychometric properties were assessed using the available information in the eligible study. If the eligible study provided additional references for the PBOM, the referenced study was reviewed to more comprehensively evaluate the PBOM's psychometric properties.

### Data collection and synthesis

A list of PBOMs that were AUB-specific and either quantified amount of menstrual bleeding, evaluated bleeding and menstrual symptoms, or assessed AUB-specific quality of life was generated by the first author (KAM). AUB-specific PBOMs were then systematically reviewed and rated, using the criteria listed in Table 1, separately by two independent reviewers (KAM, LAB).

For each psychometric property: (1) If the article provided information that 2 or more criteria were met, the instrument was given a score of “2” and we considered there to be “complete evidence” that the psychometric property was addressed; (2) If the article provided information that one criterion was met, the instrument was given a score of “1” and we considered there to be “some evidence” that the property was addressed; (3) If the article contained no information that any of the criteria were met, the instrument was given a score of “0” and we considered there to be “no evidence” that the property was addressed. Each instrument could receive a maximum of 16 points. Disagreements between raters were discussed, and consensus was reached after re-review of the instrument and associated article(s).

This project was exempt from review by the Institutional Review Board. Conflicts of interest are listed for both Dr. Boardman and Dr. Munro. Dr. Boardman is on the speakers' bureau for Merck. Dr. Munro is a consultant for Boston Scientific Inc, Ethicon Inc, Covidien INc, Gynesonics Inc, Karl Storz Endoscopy America, and AMAG Pharmaceuticals. He is a shareholder in Gynesonics Inc and Impres Medical.

## RESULTS

### Overview of articles reviewed

The PUBMED search as described in the “Materials and Methods” section generated 983 articles. Figure 1 outlines the study selection process.

Based on the inclusion and exclusion criteria, 80 articles were available and relevant for analyses. Of these studies, sixteen developed, tested, or validated at least one PBOM, 26 were descriptive or cohort studies, and 38 were randomized clinical trials. The following interventions were evaluated in the 64 descriptive or randomized clinical studies: Medical therapies [excluding the intrauterine device (IUD)] (n=7), endometrial ablation or resection (n=40), the IUD (n=9), other interventions including dilation and curettage, hysterectomy, and decision aids (n=16).

Of the 80 articles reviewed, 70 used PBOMs that were specifically designed to evaluate menstrual bleeding or AUB related quality of life. Thirty-eight articles used only PBOMs that were specifically designed to evaluate women with AUB. Twenty-three articles used both generic QOL instruments and AUB-specific instruments to measure outcomes. Several articles documented that the AUB-specific multidimensional PBOM contained items from previously

tested generic QOL questionnaires (15-20). Nine articles used only generic PBOMs that were not specifically designed for women with AUB. A median of 2 PBOMs (minimum=1, maximum=8) was employed by each article.

## Overview of the PBOMs

Fifty identified PBOMs were specifically designed to evaluate women with AUB and were subsequently evaluated for quality. These PBOMs are listed in Table 2. Of these instruments, 7 quantified the amount of bleeding and 23 evaluated menstrual or gynecologic symptoms.

Twenty instruments were multidimensional questionnaires that assessed both menstrual symptoms and AUB-related quality of life.

Twenty-seven PBOMs, not specifically designed to evaluate women with AUB, were used in the included studies. These instruments are listed in Table 3. Twelve instruments measured health-related quality of life and eight instruments measured anxiety and depression. Of the remaining instruments, five evaluated sexual functioning, one assessed body image, and one evaluated sleep.

### PBOMs specific for AUB

**Instruments that quantified menstrual bleeding:** Table 2 lists the 7 instruments which quantified the amount of menstrual bleeding by using a diary, chart, or questionnaire. Of these instruments, the Pictorial Bleeding Assessment Chart (PBAC) (13), by Higham et al, was used most frequently (n=19 studies).

**Instruments that evaluated bleeding and menstrual symptoms:** Twenty three instruments evaluated menstrual and gynecologic symptoms. (Table 2) The most frequently used questionnaire, a clinical questionnaire first utilized by Pinion et al (54), was used in 7 separate studies generated from the same institution. A menorrhagia questionnaire was used by two separate studies by Fernandez et al (57,58) and all other instruments that evaluated menstrual and gynecological symptoms were used by only one study.

**Instruments that evaluated both menstrual bleeding and AUB-related quality of life:** Twenty multidimensional questionnaires evaluated both menstrual bleeding and AUB-related quality of life. (Table 2) The Aberdeen Menorrhagia Severity Scale, by Ruta et al (69), was used by five studies. All other multidimensional questionnaires were used to measure outcomes in only one or two studies.

### PBOMs not specific for AUB

**Instruments that evaluated generic health-related quality of life:** Twelve general and health-related quality of life instruments were used by the eligible studies. These are listed in Table 3. The Medical Outcomes Study (MOS) Short-Form-36 (SF-36) (84-86,107,116) (used by 29 studies), the EQ5D (95,107) (used by 9 studies), and the MOS Short-Form-12 (SF-12) (121) (used by 3 studies), were the most frequently used instruments. All other instruments were used by one or two studies.

**Instruments that evaluated depression and anxiety:** Eight instruments specifically evaluated depression or anxiety. The Hospital Anxiety and Depression Scale (HADS) (124) was used by 9 studies, the State-Trait Anxiety Inventory (STAI) (130) was used by 5 studies, and the Beck's Depression Inventory (124) and the Mental Health Index (105) were each used by 3 studies. The remaining four instruments were each used by one study.

**Instruments that evaluated sexual functioning, body image, or sleep:** Five instruments evaluated sexual functioning, one instrument evaluated body image, and one instrument evaluated sleep problems. Of these, the McCoy Sex Scale (131,132), used in four studies, was the most frequently used. All others instruments were used by one or two studies.

### Quality assessment of the PBOMs specifically designed to evaluate women with AUB

Table 4 summarizes the available evidence about the psychometric properties of the PBOMs. "Complete evidence" that the PBOM satisfied the criteria for appropriateness was available for 92% (46/50) of PBOMs. In contrast, "complete evidence" that the PBOM was feasible was available for only 2% (1/50) of PBOMs. For over half of the PBOMs, "no evidence" was provided that the instrument was reliable (32/48, 64%), precise (25/50, 50%), or feasible (48/50, 96%).

The "scores" for quality were broken down by the type of PBOM and are displayed in Table 5. A total of 16 points translates into "complete evidence" that the instrument met all psychometric properties (appropriateness, reliability, validity, responsiveness, precision, interpretability, acceptability, and feasibility), and was therefore highest quality. No instrument had "complete evidence" available that all psychometric properties were addressed. Bleeding quantification instruments, menstrual and gynecological symptoms questionnaires, and multidimensional instruments received 56%, 31%, and 44%, respectively, of possible points for instrument quality.

## DISCUSSION

Abnormal Uterine Bleeding is a major health problem that adversely affects the lives of women. The clinical management of women with AUB aims to improve the patient's symptoms and quality of life. Because PBOMs allow clinicians and researchers to assess health and illness from the patient's perspective, they are increasingly being used to measure clinical outcomes. Researchers in the area of AUB have used PBOMs to evaluate patient-determined blood loss (through pictorial blood loss assessment scales), disease-specific symptoms (through menstrual questionnaires), and health related quality of life (through QOL instruments). We found that although some instruments were used more frequently than others, there was no one instrument that was considered the "standard of care" for evaluating women with AUB. Additionally, there was wide variation in the "quality" of PBOMs used to assess women with AUB.

Although heavy menstrual bleeding is clinically defined as greater than 80mls MBL per cycle, less than half of women seeking medical attention for their bleeding lose more than this defined amount (9,10). This means that something other than the amount of bleeding is driving women to seek medical attention. Quality of life (QOL) is likely one factor influencing women with AUB to request treatment. Health related quality of life (HRQOL) represents an individual's perceived physical and mental health and how it affects his or her day-to-day activities. HRQOL, often used by physicians and researchers to measure the effects of illness in patients, can be measured using general HRQOL instruments, such as the MOS SF36, or disease-specific instruments.

Disease-specific QOL instruments should be considered for the evaluation of women reporting AUB because symptoms are not generally constant and symptoms are disturbing but not necessarily life-threatening (12). Our review identified 20 different "AUB-specific instruments" that evaluated both menstrual bleeding and quality of life. Although the Aberdeen Menorrhagia Severity Scale, by Ruta et al (69), was the most frequently utilized multidimensional disease-specific questionnaire, it was used in only 5 of the 80 studies

reviewed. No one instrument was used consistently as the "standard of care" for the evaluation of AUB. .

The SF-36, a general HRQOL instrument which was used in 29 of the 80 articles that we reviewed, is a 36-item questionnaire that generates an overall "score" for HRQOL based on scores across 8 domains (Physical Functioning, Role Limitations due to physical health problems, Bodily Pain, Social Functioning, General Mental Health, Role Limitations due to emotional problems, Vitality, and General Health Perceptions). Although the SF-36 has been shown to be both reliable and responsive in women with AUB, women with AUB have reported difficulty answering some of its questions because of the intermittent nature of AUB and how that may affect perceptions of general health (117-120). Therefore, to evaluate outcomes in research, investigators have suggested either the use of disease-specific QOL instruments or the use of disease-specific instruments together with generic QOL instruments (12). Twenty three studies that we reviewed used generic instruments in combination with disease-specific instruments

For a PBOM to become the "standard of care" for evaluating a condition, it should be psychometrically sound. To be psychometrically sound, an instrument should be appropriate, reliable, valid, responsive, precise, interpretable, acceptable, and feasible. In our review of all instruments used to evaluate women with AUB, including bleeding quantification questionnaires, symptom questionnaires, and multidimensional questionnaires, we found that no instrument completely met all criteria for psychometric properties. Additionally, the majority of instruments lacked evidence that they were precise, reliable, or feasible.

For this study, we reviewed 50 different PBOMs specific for the evaluation of women with AUB. Although no one instrument was used consistently as the "standard of care" and no instrument addressed all important psychometric properties, we identified several good quality instruments. Of the instruments that quantified bleeding, both the Higham PBAC (13) and the Janssen pictorial scale (18,39) were good quality based on meeting the criteria for addressing eight psychometric properties. A limitation to using these instruments, however, is that they estimate only one dimension of AUB, the quantity of menstrual blood lost. Of the 20 multidimensional instruments reviewed, the AMSS (69), the MS questionnaire (99,100), the Patient Generated Index (102), and the Post-operative Menorrhagia Outcomes Questionnaire were the best quality (103,104).

This article has several strengths. First, it is a comprehensive review of PBOMs used to evaluate women with AUB in studies published over the past 20 years. The expansive list of articles reviewed was generated using broad search terms in widely used databases to maximize the number of articles captured. Second, two investigators independently reviewed each eligible article and PBOM for information on the psychometric properties to determine the "quality" of the instrument. One limitation of this study is that the exact list of criteria (Table 1) we used to assess the quality of PBOMs has not been validated. However, it was developed by experts in the field and was based carefully upon previous literature (12,14). An additional limitation of this study is that the assessment of the quality of the PBOMs was based on the information provided by the studies in which they were used. It is possible that instruments may have been psychometrically evaluated but it was not discussed or referenced in the article. We would urge researchers to mention whether or not these psychometric properties were addressed or reference appropriate articles in which the properties were addressed. This would allow readers and other researchers to evaluate for themselves the validity of outcomes that the PBOMs generated. If researchers and clinicians are to consider altering their clinical practice based upon study results, they should be able to evaluate the quality with which the study results were obtained.

The quality of research on AUB is adversely affected by the lack of an accepted, validated, high quality patient-based outcome measure. Future research is necessary to develop a PBOM that satisfies the eight psychometric properties; Such a PBOM is currently being designed by the authors of this paper. We plan to develop and test a comprehensive PBOM for women with AUB which will become the standard of care for evaluating women with AUB. The diagnosis and evaluation of AUB is largely based upon “patient experience”, the woman's personal assessment of her blood loss and its impact upon her quality of life. Many AUB-specific PBOMs have been used over the past 20 years to evaluate women reporting AUB; However, our ability to perform research on AUB could be greatly improved with the development and utilization of a high quality standardized PBOM that provides a global assessment of the “patient experience” for women reporting AUB.

## Acknowledgments

**Financial Support:** This research is made possible through the National Institutes of Health-funded K12 - HD050108-02 WIH/Brown Women's Reproductive Health Research (WRHR) Grant (PI: Donald R. Coustan, MD

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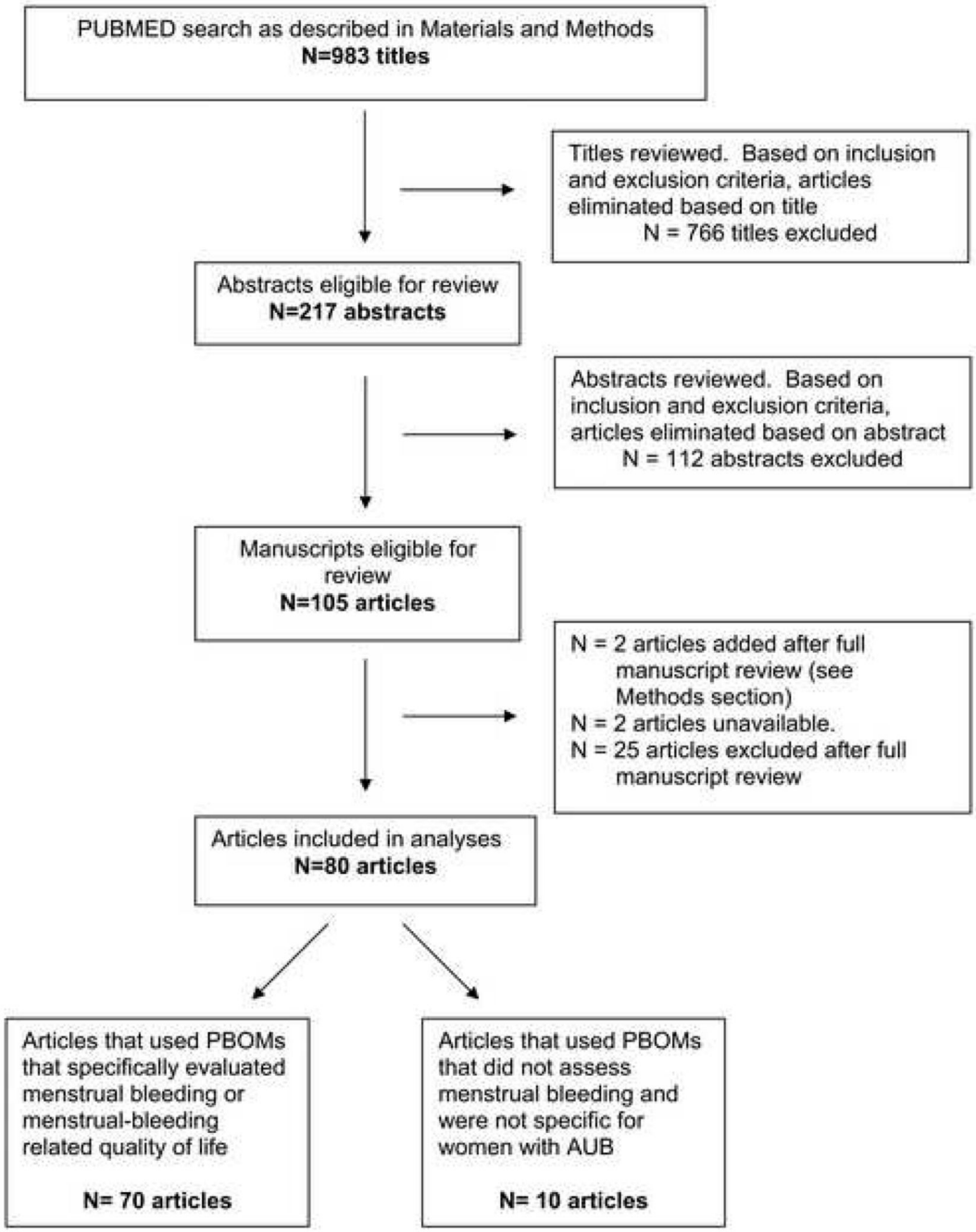


**Figure 1.**
The PUBMED search as described in the "Materials and Methods" section generated 983 articles. Figure 1 outlines the study selection process.

**Table 1**

Evaluation of "quality" of patient based outcome measures: Description of criteria for psychometric properties

| Psychometric Property | Criteria |
|---|---|
| **Appropriateness** | (1) Outcomes are justified: evidence that aspects of patients' lives that they are known to value are being measured;(2) Outcomes have been shown as important in previous studies; (3) Outcome appears important/appropriate to the purpose of the trial |
| **Reliability** | (1) More than one item is used to measure a construct; (2) Calculated Cronbach's alpha, compared item responses to the scale as a whole, or test-retest performed; (3) Any mention of "reliability" of the outcome |
| **Validity** | (1) Criterion validity: how this "new" measure correlates with some other accepted measure was described; (2) Content validity or face validity was described: Did individuals with AUB or individuals with health status methodology expertise participate in the preparation of the measurement tool?; (3) Construct validity: Was the relationships between sets of variables within the measure described? (For example: the relationship between menstrual symptoms and quality of life OR the relationship between menstrual symptoms and subjectively recorded amount of bleeding) |
| **Responsiveness** | (1) Any evidence that this was addressed? Requires evidence that changes in measurement over time are seen when there is good reason to think that changes have occurred that are of importance to patients; (2) Scores of the instrument converted into categorical data and the sensitivity or specificity of the categories were tested OR sensitivity or specificity plotted as ROCs; (3) Change scores: changes in different measured variables correlated |
| **Precision** | (1)Precision of response categories or numeric values: At least 5 response categories used to generate scores(if seven used, give an extra point) OR evidence that the instrument used metrics that were capable of reflecting changes; (2) Any evidence that the instrument was able to measure items across the full range of experience (the sickest and the healthiest, the most affected and the least affected); (3) Evidence that items in the instrument measured only one dimension (for example one question aiming to address depression did not address both depression and physical functioning) or that scale bias was addressed |
| **Interpretability** | (1) Were the instruments used considered somewhat "familiar" to a clinician-researcher?; (2) Is the "score" obtained meaningful to a clinician-researcher?; (3) Is it possible to determine at which point of a scale or what difference seen in a scale would identify a clinically important finding? |
| **Acceptability** | (1) Any evidence that the acceptability of the instrument to patients was addressed; (2) Response rates reported; (3) Time to complete the forms were reported |
| **Feasibility** | (1) Time or resources required to collect the measure were reported; (2)Time or resources required to process the measure were reported; (3)Time or resources required to analyze the measure were reported |

If the study met: None of the criteria, it got a "0" (no evidence that the property was addressed), one of the criteria, it got a "1" (Some evidence that the property was addressed), two or three of the criteria, it got a "2" (Complete evidence that the property was addressed). Criteria based on "Evaluating patient-based outcome measures for use in clinical trials", by Fitzpatrick et al. (14)

**Table 2**

Summary of the PBOMS that were reviewed for overall quality: Instruments that quantified bleeding, evaluated menstrual and gynecological symptoms, or evaluated AUB-related quality of life

| Name of the Instrument | Background studies*, instrument development, or instrument testing | Studies which utilized the instrument to measure study outcome |
|---|---|---|
| Instruments that quantified bleeding (n=7) | | |
| Barr pictoral chart | -------- | (21) |
| Higham PBAC | (13) | (18,19,22-38) |
| Janssen pictoral | (13,39) | (40,41) |
| Mansfield-Voda-Jorgensen Menstrual bleeding scale | (42) | -------- |
| Menstrual pictogram (paper and computerized) | (37,38) | -------- |
| Pad and tampon count | -------- | (43,44) |
| Unspecified Pictoral bleeding | -------- | (45) |
| Menstrual and Gynecological symptoms (n= 23) | | |
| Bleeding Diary and bleeding patterns | (46) | (18) |
| Categorical bleeding questionnaire | -------- | (47) |
| Clinical Questionnaire | -------- | (48-54) |
| Detailed menstrual questionnaire | -------- | (55) |
| Follow-up menstrual bleeding and gynecologic questionnaire | -------- | (29) |
| Gynecologic symptoms questionnaire | -------- | (56) |
| Individual subjective change in menstrual loss | -------- | (23) |
| Menorrhagia questionnaire | -------- | (57,58) |
| Menstrual and gynecologic questionnaire | -------- | (59) |
| Menstrual bleeding questionnaire | -------- | (60) |
| Menstrual pattern chart and questionnaire | -------- | (61) |
| Menstrual pattern questionnaire | -------- | (62) |
| Menstrual symptoms and bleeding days | -------- | (44) |
| Menstrual symptoms and gynecologic questionnaire | -------- | (30) |
| Menstrual symptoms questionnaire | -------- | (63) |
| Menstrual symptoms questionnaire | -------- | (64) |
| Menstrual symptoms questionnaire | -------- | (65) |
| Menstrual symptoms questionnaire | -------- | (32) |
| Menstrual symptoms score | -------- | (66) |
| Menstrual variations questionnaire | -------- | (36) |
| Numeric scale rating of bleeding and symptoms | -------- | (67) |
| Questionnaire including menstrual symptoms | -------- | (45) |
| Structured clinical history questionnaire for menorrhagia | -------- | (68) |
| Multidimensional questionnaires (both menstrual symptoms and quality of life) (n=20) | | |
| Aberdeen Menorrhagia Severity Scale | (69) | (40,41,69-71) |

| Name of the Instrument | Background studies*, instrument development, or instrument testing | Studies which utilized the instrument to measure study outcome |
|---|---|---|
| Dartmouth COOP QOL questionnaire supplemented with questions about menstrual bleeding | (72) | (19) |
| Follow-up questionnaire that addressed menstrual symptoms, daily activities, and sexual functioning | -------- | (73,74) |
| Follow-up questionnaire that assessed gynecologic symptoms, satisfaction, anxiety, and depression, sexual activity | (75) | (15) |
| General questionnaire (patterns of menstrual bleeding, gynecologic and unrelated symptoms, time to resume sexual activity, return to normal activity | -------- | (76) |
| Menstrual and quality of life questionnaire | -------- | (43) |
| Menstrual bleeding and quality of life | -------- | (77) |
| Menstrual bleeding and Quality of life questionnaire | -------- | (78) |
| Menstrual Bleeding-related quality of life | (79) | (20) |
| Menstrual Experience Questionnaire (MEQ) | (10) | (10,80) |
| Menstrual symptoms and associated quality of life | (81) | (16) |
| Menstrual symptoms and perceived inconvenience | (82) | (83) |
| Menstrual symptoms and quality of life | -------- | (31) |
| MS questionnaire | (81,84-99) | (99,100) |
| Multiattribute utility assessment | (101) | (60,101) |
| Patient Generated Index | (102) | -------- |
| Post-operative menorrhagia outcomes questionnaire | (103,104) | -------- |
| Social impact score | -------- | (66) |
| Subjective change in menstrual bleeding, quality of life, and sexual functioning | (87,88,97,105, 106) | (18) |
| VAS menstrual symptoms and quality of life | -------- | (28) |

* "Background information": Many questionnaires incorporated validated scales or portions of validated questionnaires. References containing background information for questionnaire development or information on the original validated scales or questionnaires are included in this part of the table.

**Table 3**

Summary of PBOMs that did not evaluate symptoms or quality of life specific to the condition of interest, AUB. Either portions of these instruments or the full instrument was used in the studies reviewed.

| Name of the Instrument | Background studies*, instrument development, or instrument testing | Studies which utilized the instrument to measure study outcome |
|---|---|---|
| Instruments that evaluate Quality of life and Health-Related Quality of Life (n =12) | | |
| A General health questionnaire | ---------- | (37,38) |
| EQ5D | (95,107) | (30,45,60,70,77, 108-110) |
| General Quality of Life | ---------- | (26) |
| Health Distress Scale | (90) | (99,100) |
| Scale of overall health | (84-91,95,107) | (99,100) |
| The Activity Index | (111) | (16,17) |
| The General Health Index | (112,113) | (16,17) |
| The General Health Questionnaire | (114) | (76) |
| The Medical Outcomes Study (MOS) Short-Form-36 (SF36) | (84-91,107,115) | (1,24,27,35,38,48-53,65,66,68-70,77, 83,99,100,102, 108-110,116-120) |
| The MOS Short From -12 (SF12) | (121) | (25,30,45) |
| The Rotterdam symptoms checklist | (122) | (68) |
| The VAS for perceived health | ---------- | (83) |
| Instruments that evaluate Depression or Anxiety ( n= 8 ) | | |
| Beck's Depression Inventory | (123) | (108-110) |
| Hospital Anxiety and Depression Scale HADS | (124) | (15,35,48-53,116) |
| Mental Health Index | (105) | (17,99,100) |
| The Finnish Psychosomatic questionnaire | (125) | (83) |
| The modified social adjustment scale | (126) | (76) |
| The outpatient mood scale | (127) | (76) |
| The self-rating depression scale | (128,129) | (68) |
| The State-Trait Anxiety Inventory | (130) | (68,83,108-110) |
| Instruments that evaluate sexual functioning, body image, or sleep (n=7) | | |
| Body Image scale (adapted from Body Attitudes Questionnaire) | (92) | (99,100) |
| McCoy sex scale | (131,132) | (83,108-110) |
| Psychosexual function | ---------- | (133) |
| Sabbatsberg Sexual rating scale | (94) | (116) |
| Sexual activity questionnaire | (135) | (30,45) |
| Sexual functioning scale | (93,94,96-98) | (99,100) |
| Sleep Problems Scale | (89) | (99,100) |

* "Background information": Many questionnaires incorporated validated scales or portions of validated questionnaires. References containing background information for questionnaire development or information on the original validated scales or questionnaires are included in this part of the table

**Table 4**

Summary of available evidence that the specified psychometric properties were addressed.

| Psychometric Property | Complete Evidence[a] n ( row %) | Some evidence[b] n ( row %) | No evidence[c] n (row %) |
|---|---|---|---|
| **Appropriateness** | 46 (92.0) | 4 (8.0) | 0 (0.0) |
| **Reliability** | 6 (12.0) | 12 (24.0) | 32 (64.0) |
| **Validity** | 13 (26.0) | 18 (36.0) | 19 (38.0) |
| **Responsiveness** | 6 (12.0) | 32 (64.0) | 12 (24.0) |
| **Precision** | 8 (16.0) | 17 (34.0) | 25 (50.0) |
| **Interpretability** | 8 (16.0) | 37 (74.0) | 5 (10.0) |
| **Acceptability** | 4 (8.0) | 36 (72.0) | 10 (20.0) |
| **Feasibility** | 1 (2.0) | 1 (2.0) | 48 (96.0) |

[a] "Complete evidence" = a score of "2" for the property

[b] "Some evidence" = a score of "1" for the property

[c] "No evidence" = a score of "0" for the property

**Table 5**

Summary of overall “quality” scores for individual PBOMs, by type of PBOM

| Instrument | Number of instruments | Median Score ( 95% CI) | Min Score | Max Score |
|---|---|---|---|---|
| All instruments | 50 | 6 (5,7) | 2 | 15 |
| Bleeding quantification | 7 | 9 (4,12) | 4 | 12 |
| Menstrual/gynecologic symptoms | 23 | 5 (4,5) | 2 | 11 |
| Multidimensional instrument | 20 | 7 (6,10) | 5 | 15 |