Full Length Article

Quality of life measurement tools for heavy menstrual bleeding: A systematic review and critical appraisal

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ABSTRACT

Objectives: Accurate and reliable heavy menstrual bleeding (HMB) specific quality of life (QoL) tools can offer a holistic assessment of HMB impact and response to treatment. We systematically reviewed published disease-specific QoL assessment tools for HBM to assess their methodological quality.
Methods: We searched PubMed and EMBASE until March 2024 complemented by a search of PROQOLID database and reference lists for studies reporting on the development or validation of HMB specific QoL instruments for adult women. We assessed them against the COSMIN checklist. We scored tools for their methodological quality to make recommendations for use in practice.
Results: We identified 2621 citations and included 17 studies reporting on the development and validation of 10 HMB specific QoL tools. All the studies were conducted in the USA and western Europe, and all were available in the English language except one. Three tools were in digital format, while seven were in paper format (7/10, 70 %). The median of QoL tool items was 21 (range 3–72) with a recall period of 1–3 months in 7/10 (70 %) tools. The overall quality was low to medium and none of the tools met all the COSMIN requirements to be recommended in clinical practice. The **UFS-QOL** and **SAMANTA** tools showed high quality for validity, responsiveness and interpretability but require further validation.
Conclusion: None of the available QoL tools for HMB are appropriate for use in practice. There is a need to invest in developing and validating reliable tools that offer high quality qualitative and quantitative assessment.

Introduction

Heavy menstrual bleeding (HMB), a condition that chronically affects otherwise healthy women at various life stages during reproductive age including adolescents, pre-pregnancy, and perimenopause, afflicts one in four women and leads to an impairment of their quality of life, wellbeing, and productivity [1]. The cause of HMB is often unknown with more than 20 % of women seeking specialist treatment at secondary gynaecology services [2,3]. HMB chronically affects women who are otherwise healthy at varied life stages (adolescents, pre-pregnancy, perimenopause) adversely impacting their wellbeing, quality of life, and productivity in society. As such, it is important to consider women's evolving health needs (e.g. need for contraception vs the desire to get

pregnant), their treatment preferences, and impact on their quality of life to inform treatment choice [4].

Women with HMB are treated based on the severity of their symptoms, and therefore their accurate and reliable assessment is key to selecting, initiating and monitoring treatment. However, most affected women experience significant delay to access timely treatment for HMB [5]. Specifically, there is poor correlation between quasi-objective measures of menorrhagia, e.g. self-reports of blood loss and patient-based health status measures [6]. HMB specific quality of life assessment tools can offer a holistic assessment of HMB impact and response to treatment [7]. The use of such tools can help to focus the treatment choice on improving women's quality of life (QoL) holistically rather than on selected objective outcomes which may have limited longterm

benefit such as mean blood loss and achieving amenorrhoea. Previous systematic reviews attempted to identify reliable QoL tools specific to HMB [8] but several tools have since been developed ([9 10 11]).

The aim of this study was to systematically review published HMB specific quality of life assessment tools, the domains they cover, and assess their methodological quality.

Material and methods

We conducted our review following a prospective public registration with OSF (OSF.IO/563TS) and reported it in line with established guidelines [12].

Literature search, and study selection

We searched electronic databases (MEDLINE, EMBASE) from inception to March 2024 for all studies that met our inclusion criteria. We developed a bespoke search strategy of combined MeSH terms and keywords using the Boolean operators AND/OR (*Appendix 1*). We performed complementary searches in Google Scholar and Scopus to identify any missed citations. We manually searched the PROQOLID database (https://www.proqolid.org) and reference lists of included studies and key articles on QoL in condition and population of interest. We also searched the bibliographies of potentially relevant articles for any missing articles. We did not apply any search filters or language restrictions.

Two reviewers (SS and VM) independently screened the titles and abstracts to identify relevant citations. Then, we screened full-text articles against our inclusion criteria. Discrepancies were resolved through consultation with the senior author (BHA). We included all studies that reported on the development and/or evaluation of any measurement properties ('validation paper') of standardised tools to evaluate QoL or health-related quality of life in adult women who are suffering from HMB (as defined by the authors in each study) including those for specific condition like fibroids or coagulopathies. We did not include or assess diagnostic tools aimed to diagnose HMB in affected women. We excluded studies that evaluated measurement instruments not specifically used for HMB. We also excluded articles that reported on indirect evidence, for instance, by using data obtained within the context of a clinical trial. Articles assessing the measurement properties of generic health-related quality of life tools were excluded. Finally, we excluded systematic and narrative reviews and those reporting on animal or laboratory findings.

Quality assessment

We used the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist [13] to evaluate the methodological quality of included studies. In the COSMIN checklist (https://www.cosmin.nl), four domains are distinguished (reliability, validity, responsiveness, and interpretability) with related measurement properties and aspects of measurement properties. We assessed the methodological standards for each measurement property against the COSMIN checklist [13]. We scored each item in the checklist on a four-point rating scale ('poor', 'fair,' 'good,' 'excellent'). We also generated an overall quality score as low, medium, high quality for each measurement property separately after taking the lowest rating for each item in one box. We did not assess the criterion validity as no gold standard exists for QoL in HMB.

We conducted an adequacy assessment of the following measurement properties: internal consistency, measurement error, reliability, content validity, structural validity, hypothesis testing (convergent/divergent validity), hypothesis testing (discriminative validity), cross-cultural validity, responsiveness, and Interpretability.

Data extraction

Two reviewers extracted data in duplicate (SS and VM) using a bespoke electronic data extraction tool. Disagreements were resolved by consensus-seeking discussions within the research team. We extracted data on the studies: geographical location, language, setting, study type, key characteristics of study subjects, name of measurement instruments, domains measured, number of items and (sub)scales, number and type of response categories, recall period in the questions, scoring algorithm, time needed for administration, mode of administration, target population for whom the questionnaire was originally developed, how a full copy of the questionnaire can be obtained, the instructions given to those who complete the questionnaire, the results of the measurement properties. When general characteristics of an instrument could not be extracted from the studies included, the original development paper were consulted to obtain missing information. Where different version of the same tool exists in different languages, we considered those in English language only.

Statistical analysis

We reported using frequencies and natural percentages on ability for each of the included tools to meet COSMIN requirements to be recommended for use, or if the tool requires further validation work, and which tool if available is best (currently available) to assess QoL in women with heavy periods in clinical practice and future research work. Analyses were conducted using Microsoft Excel (Microsoft 360, Microsoft, Richmond, WA) and SPSS IBM(Version 19.0. Armonk, NY: IBM Corp).

Results

Characteristics of included studies and reported QoL tools

Our search results identified 2621 potentially relevant citations, of which we screened 27 in full against our inclusion criteria. In total, we included 17 studies on 10 unique HMB specific QoL tools (10 development studies and 7 validation studies) in our review reporting (Fig. 1).

All the included studies were conducted in the USA (5/10, 50 %) and western Europe (6/10, 60 %) (UK, Canada, Spain and Italy). All the included tools were available in the English language except one (Table 1, *Supplementary Table 1*). The median number of participants across included studies was 274 (range 111–499). Most included studies did not report the age range of included participants, two focused on participants aged 18–55 years old (2/10, 20 %)[14](9), one engaged those aged 18–50 (1/10, 10 %)(10) and one focused on age range 25–50 years (1/10, 10 %)(11) (Table 1). *Physical symptoms and general quality of life assessment were the comments two domains included in 60 % of tools (6/10), followed by cognitive and emotional, productivity and social, energy and mood domains in 5 tools (5/10, 50 %)(Supplementary Table 1, Supplementary* Fig. 1*).*

Of the 10 tools, three were in digital format (3/10, 30 %), six were in paper only format (6/10, 60 %), one was in both. The median number of items per tool was 21 (range 3–72) and the majority used more than 3 subscales (6/10, 60 %). Four tools had a recall period of less than one month (4/10, 40 %), three were for 3 months (3/10, 30 %), and only two tools covered a recall period of more than 6 months (2/10, 20 %) (Table 1, *Supplementary Table 1*).

Most of the included studies (7/10, 70 %) performed literature reviews and then consolidated the tool design using expert reviews or interviews with patient groups. The remaining tools used undisclosed focus groups or built upon previous questionnaires. Two thirds of included studies (7/10, 70 %) used a single development round, two employed two development rounds [15 16] and only one carried out three rounds [9] (Table 1). All except one tool were available in English, the remaining tool was only disclosed in Italian. Two tools were
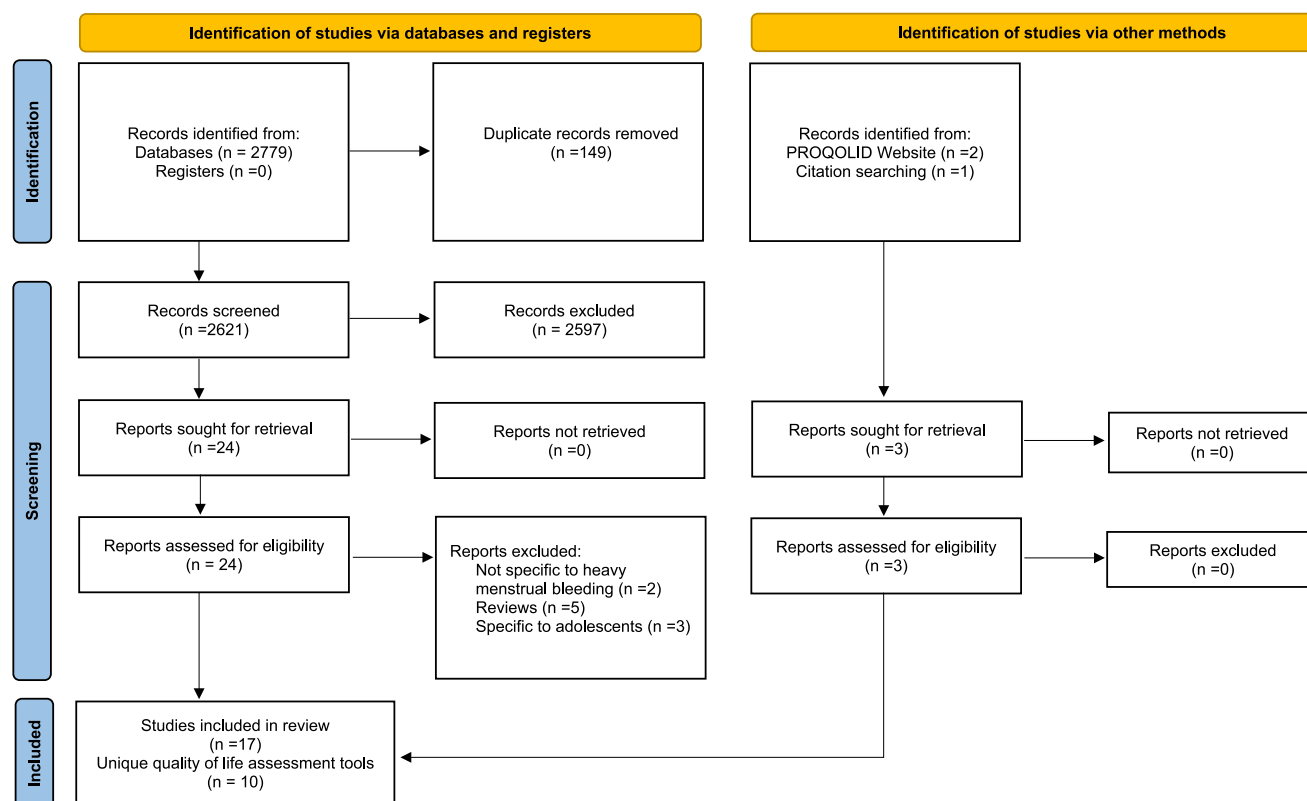
Fig. 1. Study screening and inclusion process for systematic review evaluating the quality of available quality of life assessment tools for women with heavy menstrual bleeding.

available in two languages: English and Spanish or English and Dutch (Table1).

Quality of included tools

Most of the included tools demonstrated low to medium quality when assessed against the COSMIN checklist (Fig. 2). Only two tools (2/10, 20 %) showed high quality for content validity and three for structural validity (3/10, 30 %). Reliability was poor in four tools (4/10, 40 %) and unclear in seven tools (7/10, 70 %). Similarly, measurement error was poorly tested across most included tool with eight showing unclear quality (8/10, 80 %). Four tools had high quality hypothesis testing (4/10, 40 %) and three had high quality for responsiveness (3/10, 30 %) (Fig. 2).

Performance

Overall, none of the included tools met all COSMIN requirements and could be recommended for use in clinical practice. The **UFS-QOL** [15] and **SAMANTA** [16] **tools** showed high quality for validity, responsiveness and interpretability of the four domains (reliability, validity, responsiveness, and interpretability) but still requires further validation before they can be adopted in practice (Fig. 2, *Supplementary Table 2*).

Discussion

Summary of main findings

In this systematic review we assessed ten tools which aimed to quantitatively assess the impact of HMB on the QoL of affected women. All the included tools were developed and validated in Europe and the United States and majority were in paper format using long questionnaires. Against the COSMIN criteria, none of these tools satisfactorily

met the standards to recommend their use in clinical and research practice.

Strength and limitations

The strengths of this systematic review include the use of clear prospective registration, employing a robust search strategy including both established databases and the grey literature. We followed a standard methodology and performed a multi-domain quality assessment using the COSMIN checklist to standardise the assessment of included tools and their suitability for use in clinical practice. We compared the overall quality of available tools and suggested those that are likely to offer most value in clinical practice.

Still, our work may suffer from some limitations. First, we were unable to assess criterion validity due to the absence of an agreed golden standard to compare against. We were able to assess only tools that were published in English or had an English translation. All the included studies were conducted in the USA or western Europe which may limit the generalizability of evaluated tools and the findings of our review. There was limited reporting of overall validity and reliability values of each tools which limited out ability to conduct any meaningful data pooling. Several of the evaluated tools pre-dates the COSMIN checklist which may limit its applicability by default. Finally, we were unable to examine the actual questionnaires/format of some of the included tools as they were not freely available online. As an up-to-date, comprehensive review our work merits consideration.

Implications for practice and/or policy

HMB is a prevalent health condition that affects millions of women worldwide. Measured objectively, HMB affects between 9 % and 14 % of women, yet when measured qualitatively, its prevalence can be as high as 52 % [17]. This discrepancy highlights the importance of systematic

Table 1
Characteristics of included quality of life assessment tools for heavy menstrual bleeding.

| Characteristic	Target Population	Mode of administration	Number of items	Number of subscales	Number/ type of response categories	Scoring algorithm	Recall Period in the items	Available Translations	Development Method	Development Rounds	Age range
MEDI-Q	Healthy women aged 18–50 years without diagnosed uterine or psychiatric disorders	Digital	25	3	4 Categories: 0–3 scale	Calculation of domain scores, then total score	12 months	Italian only	Reviewed research on the topic, followed COSMIN standards for content validity then consulted a panel of specialists in gynaecology and psychiatry	1	18–50 years
MBQ	Women aged 18—55 years with +/- without self-reported heavy menstrual bleeding	Digital	20	5	3 Categories: 0–5 scale	Score assigned to each answer, then totalled	1 month or daily for 1 months	English only	Literature review, a patient focus group sessions and a national survey of US gynaecologists for expert review	1	18–55 years
PERIOD-QOL	Women aged 18–55	Paper and Digital	10	6	5 Categories: 0–5 scale	Score assigned to each answer, then totalled	6 months	English only	3 pilot studies for PERIOD-QOL development and a cross-sectional survey	3	18–55 years
MOQ	Women undergoing hysterectomy due to benign disease	Paper	26	None mentioned	2 Categories: Numerical scale	Score assigned to each answer, then totalled	3 months	English only	Interviews, expert opinion and review of literature and existing questionnaires	1	Not stated
MAQ	US College students (both Women and Men) and also adolescent girls	Paper	33	7	7 Categories: 1–7 Likert scale	Average score calculated: Sum of items divided by number of factors within	1 month	English only	Put together by the two authors, with consideration of the findings of other unnamed questionnaire publications.	1	Not stated
UFS-QOL	Women with +/- without leiomyomata	Paper	72	5	5 Categories: Likert scale: 1–4	Scores converted to a 0–100 scale	3 months	English and Dutch	Focus groups held then questionnaire reviewed by three gynaecologists	2	Not stated
UFS-QOL-Hysterectomy	US women: scheduled for hysterectomy, myomectomy or uterine artery embolisation	Digital	29	6	5 Categories: 1–5 Likert scale and 1–2 scale	Scores totalled: higher value = greater severity, higher HRQOL score = better quality of life	3 months	English only	Used tool already developed, then adapted question phrasing to be inclusive of women who had undergone a hysterectomy	1	Not stated
SAMANTA	Spanish women with known HMB + those without	Paper	21	None Mentioned	2 Categories: Dichotomous (Yes/No)	Score assigned to each answer, then totalled	1 month	Spanish and unvalidated English version	Literature review, cognitive debriefing interviews and expert review	2	Not stated
MMAS	Women aged 25–50 years with menorrhagia	Unclear	6	None Mentioned	4 Categories: Likert Scale 1–4	Different domains have different weightings (unclear which) then added: 0–100	1 month	English only	Not clear	Unclear	25–50 years
MIQ	Women diagnosed with menorrhagia + those without	Paper	6	3	2 separate scales: Likert scale 1–4 and Likert scale 1–5, a open descriptive response	Not openly described	Not stated	English only	Literature review, cognitive interviewing of patients	1	Not stated
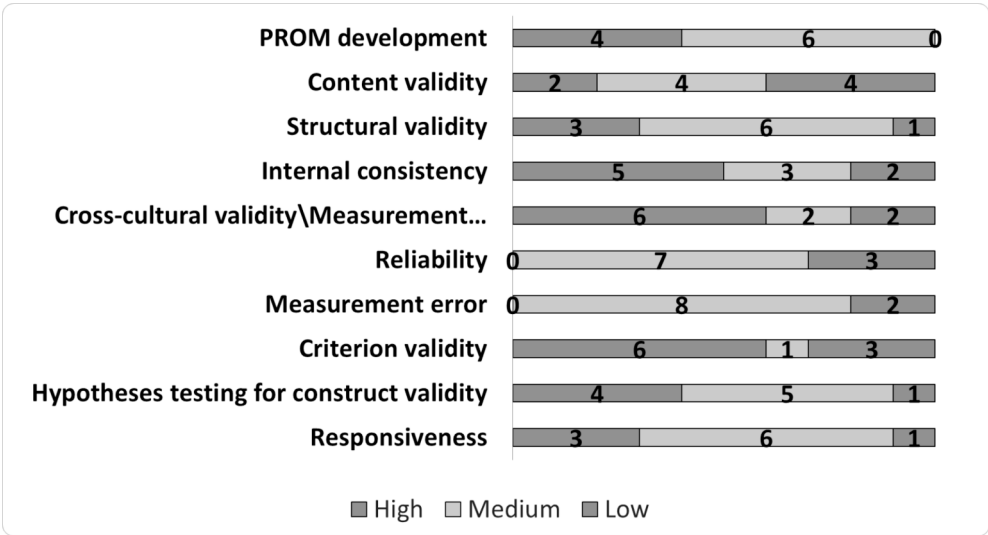
Fig. 2. Summary of quality assessment of the included quality of life measurement tools for heavy menstrual bleeding using the COSMIN Tool.

assessment of the qualitative impact of HMB on women's health and wellbeing as part of routine clinical practice.

While the majority of the evaluated QoL assessment tools in this review adopted standard methodology and a holistic approach to HMB assessment, their adoption in clinical practice is likely to be hampered by several factors. First, most of these tools were in paper format and included more than 20 questions. As such, using these tools in everyday clinical practice can be very time consuming to both the patient and the physician. Switching to a digital format that allows for automated analysis, archiving, and illustration of the results can significantly reduce the barrier to using these tools in everyday clinical practice [18]. There were wide variations in the domains covered across evaluated tools including physical health, mental wellbeing, productivity, ability to socialise, in addition to more objective measures like blood loss and days missed of work. However, there is still no consensus on the full length of domains that should be assess in HMB specific QoL tools which likely requires further qualitative research involving patients with lived experience and key stakeholders.

Furthermore, most of the evaluated tools adopted a snapshot assessment with a limited recall period between one to three months. HMB impact on QoL can vary significantly from one cycle to the other, also pre and post menstruation [19]. Offering a recurrent cumulative assessment of HMB impact is likely to offer more sensitive results and help clinicians to refine the treatment selection as well as assess treatment response.

HMB is a symptom of several pathologies that could contribute to this outcome as defined by the recent FIGO classification [20]. Several of these pathologies (e.g. adenomyosis) could also be contributing to worse QoL compounded with the HMB impact. Treatment side effects can also have a negative impact on QoL even though they may reduce mean blood loss. For example, using GnRH agonists may suppress menstrual bleeding but provoke menopause-like symptoms that could be very distressing to affected women. Therefore, there is a need to test the validity and reliability of HMB QoL tools across different subgroups depending on the underlying pathology, as well as other confounders such as age group, ethnicity, and treatment response.

Future research need

The mobile technological revolution simplified menstrual monitoring with millions of women using mobile apps to track periods worldwide [18]. Leveraging this technology to enable robust, concurrent, and user-friendly comprehensive assessment of menstrual symptoms could significantly reduce the barrier to access treatment and empower patients to take control of their menstrual health. Several mobile apps now offer tracking of menstrual symptoms with a built-in simplistic qualitative assessment of QoL [21], however, a validated technological HMB QoL tool that could be adopted at mass remains missing.

Effective management of HMB depends on rapid access to appropriate treatment methods across different care settings (primary, secondary, and tertiary) [2]. HMB specific QoL assessment tools can help to triage and facilitate onward referrals of more severe cases who may need more specialised treatment like surgical resection of fibroids. This, however, requires careful effectiveness evaluation within an established referral pathway using a standardised and validated QoL assessment tool. As the treatment priority switches to optimising QoL as well as reducing mean blood loss, there is a need for more evolved assessment tools that allow accurate and holistic objective and qualitative assessment. Several novel objective assessment tools are now proposed to enable a more accurate assessment of blood loss during menstruation [22] often combined with novel mobile technology to capture and analyse data. Embedding reliable QoL assessment tools can maximise the value of such diagnostic tools and help women to gain and communicate deeper insight on their menstrual health month to month.

In conclusion, none of the available quality of life assessment tools for HMB are appropriate for use in clinical and research practice. There is a need to invest in developing and validating reliable tools that offer high-quality qualitative and quantitative assessment of the symptoms associated with HMB.

CRediT authorship contribution statement

Bassel H. Al Wattar: Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Sophie Schofield:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Victoria Minns:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation, Conceptualization. **Khalid S. Khan:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation, Conceptualization.

Appendix 1. Search strategy for identifying quality of life assessment tools for women with heavy menstrual bleeding

1menorrhagia/ OR menorrhag$.tw. OR (menstrua$ adj5 (bleed$ or blood)).tw. OR (heavy adj5 menstrua$).tw. OR (dysfunctional adj5 uter

$).tw. OR hypermenorrh$.tw. OR heavy menstrual bleeding.ab,ti.OR heavy period$.ab,ti.

AND

2(quality of life mh. OR quality of life tw. OR health status .mh. OR health status tw. OR life quality* OR daily life tw. OR patient reported outcome tw.)

AND

3(instrument tw. OR tool tw. OR questionnaire tw. Question* tw. OR measurement tw. OR test tw OR

AND

4(develop* tw. OR validat* tw. OR production tw OR evaluation tw OR)

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.srhc.2025.101102.

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