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A quality-of-life questionnaire for heavy menstrual bleeding in Thai women receiving oral antithrombotics: Assessment of the translated Menstrual Bleeding Questionnaire

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Abstract

Background: Heavy menstrual bleeding (HMB) is common among reproductive-aged women receiving oral antithrombotics and frequently results in a negative impact on quality of life.

Methods: We translated the Menstrual Bleeding Questionnaire (MBQ) into Thai by forward translation, back-translation, pretesting, and cognitive interviewing. The translated questionnaire was content validated by a gynecologist. A validation study was conducted for the translated MBQ and defined the optimal score for the diagnosis of HMB. We then performed a cross-sectional study to determine the prevalence of HMB using the translated MBQ. Reproductive-aged Thai women who visited outpatient clinics receiving oral antithrombotics were asked to assess menstrual characteristics after receiving antithrombotics. The impact of menstruation on quality of life was assessed by using the MBQ.

Results: The translated MBQ had excellent reliability (intraclass correlation coefficient = 0.93) and discriminated between women with and without HMB (area under the receiver operating characteristic curve = 0.93). A score of 21.5 had 82.9% sensitivity and 83.1% specificity in the diagnosis of HMB. The mean (standard deviation) of the score was significantly higher in the HMB group than in the normal menstrual bleeding group (30.4 [9.4] vs 15.4 [5.6]; $P < .001$, respectively). Of the 49 women, the prevalence of HMB in patients receiving warfarin (n = 29), direct oral anticoagulants (n = 4), or antiplatelet agents (n = 16) was 27.6%, 25.0%, and 25.0%, respectively.

Conclusions: MBQ is a simple and valid tool that can be applied to screen women experiencing HMB. One-fourth of reproductive-aged women who received oral antithrombotics experienced HMB that impacted their quality of life.

KEYWORDS
anticoagulants, antiplatelet drugs, heavy menstrual bleeding, quality of life, questionnaires

Essentials

- Heavy menstrual bleeding (HMB) impacts quality of life in women receiving antithrombotics.
- A questionnaire evaluating quality of life was used to define HMB.
- The translated questionnaire is valid in diagnosing women with HMB.
- One-fourth of women receiving oral antithrombotics had HMB.

1 | INTRODUCTION

Oral anticoagulants are widely used for the prevention of systemic thromboembolism in patients with atrial fibrillation and in the treatment of venous thromboembolism. The increased risk of bleeding, especially intracerebral and gastrointestinal hemorrhage, is well documented. However, in reproductive-aged women, heavy menstrual bleeding (HMB) may occur in those receiving oral anticoagulants and is frequently underrecognized. Several studies have demonstrated that HMB has a profound negative impact on health-related quality of life (HRQoL) in affected women.[1-5] Women with HMB were more likely to have had negative feelings than women with normal menstruation, which could limit their social and professional activity.[6] In addition, the correction of anemia associated with HMB results in improvement in HRQoL.[7,8]

The reported prevalence of HMB in women receiving warfarin ranged from 20% to 65%.[9] As for direct oral anticoagulants (DOACs), the prevalence of abnormal uterine bleeding (AUB) associated with factor Xa inhibitors was higher compared to warfarin, while AUB was lower with the direct thrombin inhibitor dabigatran etexilate compared to warfarin.[10] Women treated with antiplatelet agents also reported having HMB.[11] The duration of menstruation also increased with the use of oral anticoagulants.[12] In these studies, the definition of HMB varied. One cohort study used clinical indicators including significant menstrual blood loss requiring hospitalization, documented iron deficiency anemia, more than two hourly changes of pad or tampon or nocturnal flooding, blood loss impacting psychosocial functioning, and heavy bleeding of >7 days per month.[13] In other studies, the definition of HMB was not explicitly defined.

In 2007, the National Institute for Health and Care Excellence (NICE) guideline established a new definition of HMB, namely, excessive menstrual blood loss that interferes with a woman's physical, social, emotional, and/or material quality of life.[14] This definition considers the impact of HMB on quality of life. The 36-Item Short Form Survey is a standard patient-reported health survey that includes physical and mental health summary measures.[15] However, it does not specifically measure HRQoL related to HMB.

The Menstrual Bleeding Questionnaire (MBQ) was developed and validated for measuring patient-reported outcomes for HMB.[16] The questionnaire specifically evaluates HRQoL related to HMB. We translated the MBQ, validated the translated questionnaire, and defined the optimal score for the diagnosis of HMB. We then performed a prevalence study to determine the prevalence of HMB among Thai women receiving antithrombotic drugs using the NICE definition of HMB, and to raise the awareness of HMB among women receiving antithrombotics.

2 | METHOD

2.1 | Part I: Translation and validation of the MBQ

The MBQ was developed and validated by Matteson (Appendix S1).[16] The objective of the questionnaire is to evaluate the effects of menstruation on HRQoL. The questionnaire comprises a total of 20 items, which include four domains: bleeding heaviness, bleeding irregularity, pain, and quality of life. Maximum and minimum scores are 75 and 0, respectively. In the original study, the average score was significantly different in women with HMB versus those with normal menstrual bleeding (30.8 vs 10.6, respectively). In addition, the mean scores of all domains were significantly higher in women with HMB than in those with normal menstrual bleeding.

With permission, the MBQ was translated into the Thai language (Appendix S1) according to the process of translation and adaptation of instruments by the World Health Organization (WHO) guideline,[17] which consists of forward translation, back-translation, pretesting, and cognitive interviewing. An expert panel including two hematologists, a gynecologist, and a general physician identified and resolved the unclear questions or responses after translation. Back-translation was performed by an independent translator who was proficient in the Thai and English languages and had no knowledge of the questionnaire. The translated questionnaire was content validated by a gynecologist. Reproductive-aged women working in the back office, medical personnel, and women visiting a gynecology clinic (irrespective of their chief complaint), were asked to participate in the study if they reported regular menstruation. The translated questionnaire was given to participants for pretesting and cognitive interviewing to identify unclear questions or responses. Reliability was tested by a test-retest method. Participants were asked to complete the MBQ twice, 1 week apart. The intraclass correlation coefficient (ICC) was calculated, and a value of ≥0.7 indicated good reliability. The subjective definition of HMB[14] was provided to participants. They were asked whether their menstrual bleeding met the subjective definition of HMB before the MBQ was administered in an outpatient setting. Sensitivity, specificity, and receiver operating characteristic (ROC) were calculated to determine the optimal score that could discriminate patients with HMB from subjects who reported normal menstrual bleeding. As a screening tool for HMB, we aimed to achieve a sensitivity and a specificity of >80%. For the sample size calculation, we aimed to include at least 100 respondents to achieve a 5:1 respondent-to-item ratio.[18]

2.2 | Part II: Prevalence of HMB among women receiving oral antithrombotics

2.2.1 | Study design

The cross-sectional study was conducted in an academic tertiary care hospital in Bangkok, Thailand, from January 2020 to January 2021. The study protocol was approved by the Institutional Review Board of Mahidol University. Women who received oral anticoagulants or antiplatelet agents who visited outpatient clinics were screened for eligibility criteria. Patients were included if all of the following conditions were present at the time of enrollment: (1) age 18 to 50 years; (2) receiving oral anticoagulants (including warfarin, dabigatran, rivaroxaban, apixaban, or edoxaban) or antiplatelet agents (including aspirin and clopidogrel); and (3) having regular menstruation or at least once in the past 3 months. Patients were excluded if at least one of the following conditions was present: (1) previously diagnosed with coagulopathy or platelet disorders including von Willebrand disease or hemophilia; (2) persistent thrombocytopenia (platelet count <50,000/μL; or (3) receiving nonsteroidal anti-inflammatory drugs continuously for >1 month. Patients who met the eligibility criteria were asked to sign an informed consent.

Patients were asked to complete the questionnaire at the time of enrollment. The questionnaire consists of two parts. The first part evaluates menstrual characteristics including changes in duration and intensity of menstrual bleeding before and after receiving oral antithrombotics. The second part of the questionnaire was to evaluate the impact of HMB on HRQoL using the translated MBQ.

2.2.2 | Data collection

Electronic medical records were reviewed by the researchers. Baseline characteristics including age and body mass index were collected. History of hormonal use, type and indications for antithrombotics, and treatment-related HMB were recorded.

2.2.3 | Statistical analyses

Continuous variables were reported as mean and standard deviation (SD) or median with interquartile range (IQR) as appropriate. Categorical variables were reported as frequency and percentage. The overall prevalence of HMB was reported as a percentage, as was the prevalence with each type of antithrombotic drug use. Continuous variables were compared using a t test for independent samples. Duration of menstrual bleeding before and after treatment was compared using a paired t test. The categorical variables were compared using the chi-square or Fisher's exact test as appropriate. A P value <.05 was considered statistically significant. All statistical analyses were performed using STATA version 16 (StataCorp, College Station, TX, USA). For the sample size calculation, we used the prevalence of HMB (22%) from a previous study.[13] The study

TABLE 1 Demographic characteristics of 118 Thai women in the validation study

Characteristics	N (%)
Median age, y (IQR)	29 (27-39)
Median BMI, kg/m^2 (IQR)	21.1 (19.5-24.5)
Hormonal use, n (%)	32 (27.1)

Abbreviations: BMI, body mass index; IQR, interquartile range.

required 66 women to estimate the prevalence, with an acceptable error of 10%.

3 | RESULTS

3.1 | Part I: Translation and validation of the MBQ

From July 2019 to December 2019, 34 Thai women completed the MBQ for test-retest reliability and were invited to participate in cognitive interviewing. The intraclass correlation coefficient was 0.93 (95% confidence interval [CI], 0.85-0.96), indicating good reliability. All participants reported clear understanding of the translated questionnaire.

A total of 118 Thai women completed the MBQ to define the optimal score for diagnosing HMB. The median age (IQR) of participants was 29 (27-39) years. Hormonal therapy was used in 32 (27.1%) participants. Other baseline characteristics are shown in Table 1. By the subjective NICE guideline definition of HMB, 83 (70.3%) participants reported having normal menstrual bleeding, and 35 (29.7%) participants reported having HMB. The mean (SD) of the MBQ score was significantly higher in the HMB group than in the normal menstrual bleeding group (30.4 [9.4] vs 15.4 [5.6]; $P < .001$, respectively). The mean scores of all domains in the HMB group were significantly higher than in the normal menstrual bleeding group (12.7 vs 5.9, $P < .001$ in bleeding heaviness; 9.7 vs 5.5, $P < .001$ in bleeding irregularity; 1.9 vs 1.2 in pain, $P = .002$; and 6.1 vs 2.7, $P < .001$ in the quality of life). The area under the ROC curve was 0.93 (Figure 1). A score of ≥21.5 had a sensitivity of 82.9% and a specificity of 83.1% in discriminating women with and without HMB. Therefore, we selected this score to define HMB in this study. A table showing the sensitivity and specificity is provided in the supplementary index.

3.2 | Part II: Prevalence of HMB among women receiving oral antithrombotics

From January 2020 to January 2021, 61 women were screened using the eligibility criteria. Ten women were excluded because of irregular menstruation. A total of 51 eligible patients gave their written informed consent to participate in the study. However, two women were excluded from the analysis because they received oral

antiplatelets or anticoagulants in combination with low-molecular-weight heparin. Therefore, a total of 49 patients were included in the analysis.

The median age (IQR) was 40 (34-46). Hormonal therapy was used in 6 (12.2%) patients. All patients received hormonal therapy before they participated in the study. Twenty-nine (59.2%) were on warfarin, 4 (8.2%) were on DOACs (2 rivaroxaban, 2 apixaban), and 16 (32.7%) were on antiplatelet agents (15 aspirin 81 mg, 1 clopidogrel 75 mg). Other patient characteristics are presented in Table 2.

Overall, the prevalence of HMB in the reproductive-aged women receiving oral antithrombotics was 26.5% (13/49) (95% CI, 14.9-41.1). The prevalence of HMB in patients receiving warfarin, DOACs, and antiplatelets was 27.6% (95% CI, 12.7-47.0), 25.0% (95% CI, 0.6-80.0), and 25.0% (95% CI, 7.0-52.0), respectively. The mean (SD) MBQ score in patients with HMB versus no HMB was 29.5 (2.3) and 13.9 (0.7) (P < .001), respectively.

The mean (SD) duration of menstruation before and after treatment was 4.5 (2.0) versus 5.2 (2.4) days in patients receiving warfarin, 2.8 (1.7) versus 4 (1.2) days in patients receiving DOACs, and 4.6 (1.9) and 4.6 (1.9) days in patients receiving antiplatelets, respectively. Patients reported having an increase in menstrual intensity compared with before treatment in 19 (65.5%), 3 (75%), and 6 (37.5%) of patients receiving warfarin, DOACs, and antiplatelet agents, respectively. Patients reported an increased duration of menstruation from before treatment in 12 (41.1%), 2 (50%), and 2 (12.5%) patients, respectively (Figures 2 and 3).

Of the 13 patients who met the definition of HMB, 4 (30.8%) required HMB-related treatment. One patient received tranexamic acid. One patient received an iron supplement, and 2 patients were referred to the gynecology clinic. Of the 36 patients with normal menstruation, 4 (11.1%) had documented HMB treatment. One patient received an iron supplement, and 2 patients received surgical intervention (one, uterine arterial embolization; and one, fractional curettage). Most patients had HMB treatment before they participated in the study.
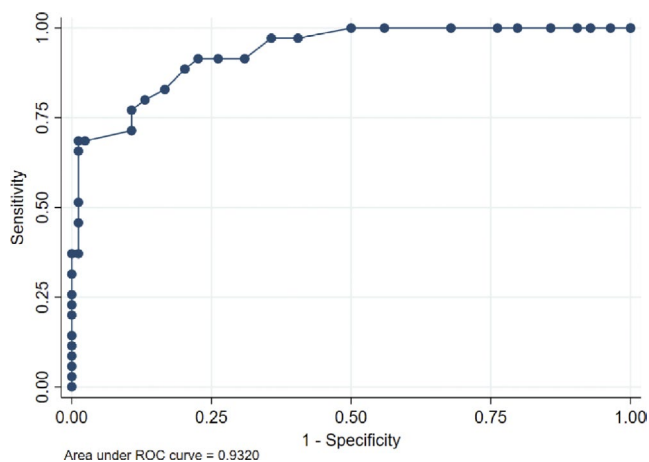

FIGURE 1 Receiver operating characteristic (ROC) of the Menstrual Bleeding Questionnaire in discriminating women with heavy menstrual bleeding (HMB) and no HMB

4 | DISCUSSION

The MBQ, which specifically measures the impact of HMB on HRQoL, was developed and validated to improve the evaluation of women with self-reported HMB in research and clinical practice. To our knowledge, this is the first study that translates the MBQ into the Thai language. We demonstrated that the Thai version of the MBQ had excellent reliability and validity. In addition, the translated MBQ is clearly able to distinguish women with HMB from those with normal menstrual bleeding.

During the translation and psychometric properties testing procedure, the principles of good practice for the translation and cultural adaptation process for patient-reported outcomes measures were strictly followed (16). We performed forward and back-translation by native Thais who are proficient in both English and Thai languages. Native translators understand the context and culture of the Thai people and can properly adapt words and contexts of the questionnaire accordingly. The quality criteria for measurement properties of health status questionnaires, including reliability by test-retest variability and content validity, were used.[19]

TABLE 2 Baseline characteristics of 49 patients in the prevalence study

Characteristics	N (%)
Median age, y (IQR)	40 (34-46)
Median BMI, kg/m^2 (IQR)	23.5 (20.7-28.3)
Hormonal used	6 (12.2)
Combined oral contraceptive pill	4 (8.2)
Progestin only pill	1 (2.0)
Depot medroxyprogesterone acetate	1 (2.0)
Type of antithrombotic drug	
Warfarin	29 (59.2)
Direct oral anticoagulants	4 (8.2)
Antiplatelets	16 (32.7)
Indications	
Warfarin (n = 29)	
VTE	9 (31)
APS	7 (24.1)
VHD	10 (34.5)
Cardiac arrhythmia	2 (6.9)
Stroke	1 (3.4)
Direct oral anticoagulants (n = 4)	
VTE	2 (50)
Cardiac arrhythmia	2 (50)
Antiplatelets (n = 16)	
Primary prevention	10 (62.5)
Secondary prevention	6 (37.5)

Abbreviations: APS, antiphospholipid syndrome; BMI, body mass index; IQR, interquartile range; VHD, valvular heart disease; VTE, venous thromboembolism.

FIGURE 2 Menstrual intensity among women receiving oral antithrombotics. DOACs, direct oral anticoagulants
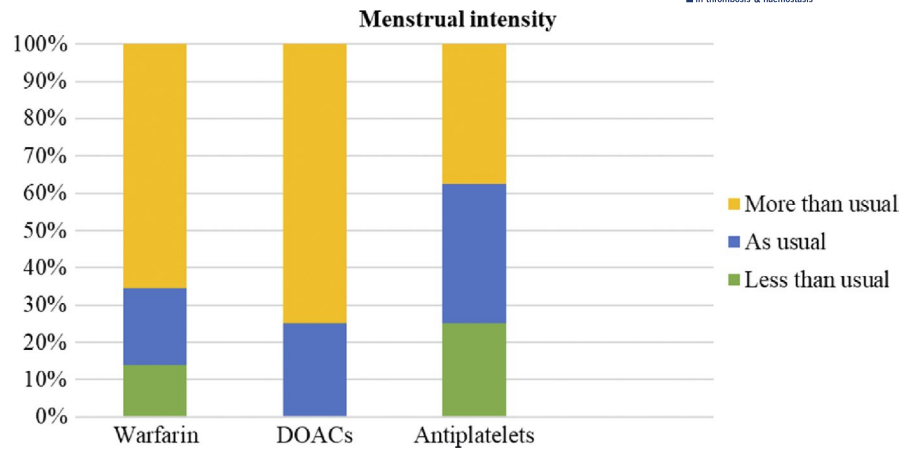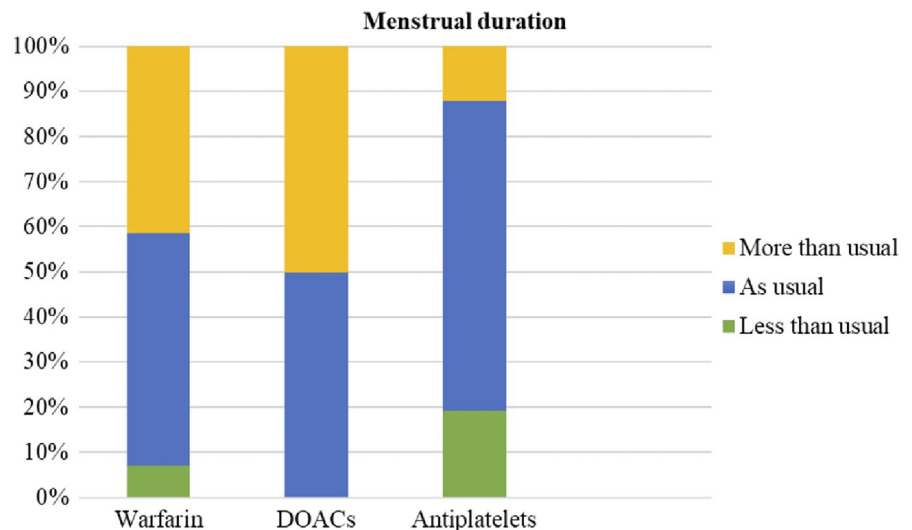

FIGURE 3 Menstrual duration among women receiving oral antithrombotics. DOACs, direct oral anticoagulants

The original English version of MBQ is effective in evaluating and discriminating between women with and without HMB (15). The findings of our present study similarly confirmed its benefit in Thai-speaking women. Though participants included in the original validation study[16] were almost all White, the mean MBQ scores in both the validation and prevalence parts in our study were comparable (mean score in HMB vs no HMB, 30.8 vs 10.6 in the original study, and 30.4 vs 15.6, and 29.5 vs. 13.9 in the validation and prevalence parts of our study, respectively). The mean scores of all domains in the MBQ were significantly higher in women with HMB compared with women with normal bleeding.

Since the definition of HMB used in a research setting varied, we also studied the optimal score of the translated MBQ for diagnosing women with HMB. Traditionally, HMB is objectively defined as menstrual blood loss of >80 mL by the alkaline hematin method.[5] However, the complexity of the method has limited its use in clinical practice. Alternatively, a Pictorial Blood Assessment Chart (PBAC) is a semiquantitative tool that calculates a score from the number of tampons or towels used and the degree of soiling.[20] It has been validated to correlate with the defined loss, and has been widely used for the diagnosis of HMB.[21] However, the use of the PBAC in routine clinical care or even in the research setting is precluded due to the variety of towel or tampon products available.[22] In addition, it

does not incorporate the impact of HMB on HRQoL. Using the MBQ, which specifically evaluates impact of HMB on HRQoL, as a diagnostic tool would provide a comprehensive evaluation according to the NICE guideline definition of HMB. The proposed optimal score in our study demonstrated high sensitivity and specificity. However, the use of the MBQ and the proposed score in the diagnosis of HMB in a research setting needs further validation in a larger cohort study.

The prevalence of HMB, as defined by the NICE definition of HMB, was 26.5% among reproductive-aged Thai women receiving oral antithrombotic therapy. There was no difference in the prevalence of HMB among each drug class, although the prevalence was slightly higher in women receiving warfarin compared to those receiving DOACs or antiplatelet agents. Our prevalence of HMB is comparable to that in other studies of anticoagulated women.[13] In addition, we demonstrated a comparable prevalence of HMB in women receiving antiplatelet and anticoagulant therapy. This finding aligns with a previous study that reported a high frequency of menstrual problems in those receiving antiplatelets and anticoagulants.[11] However, this number was almost twofold higher than in the general population which is estimated at 9% to 18%.[23-25] This indicates that physicians should be aware of HMB as a prevalent and morbid bleeding complication in women receiving anticoagulant and antiplatelet therapy.

The strengths of our study were that (i) the MBQ was translated according to the WHO guidance and validated in the general population; (ii) the optimal score in the diagnosis of HMB was proposed with high sensitivity and specificity; (iii) no previous study has focused on the prevalence of HMB using a subjective definition that included specific HMB-related HRQoL; and (iv) in the prevalence study, we included patients receiving a variety of anticoagulant and antiplatelet therapies, and demonstrated the effect of various drugs on the menstrual bleeding pattern.

The study also had limitations. We did not use the standard objective measurement (the PBAC) along with the MBQ. Therefore, we did not demonstrate the correlation between the objective and subjective measurement. However, we measured the HMB-specific HRQoL that incorporates the impact on the physical, emotional, social, and material quality of life. The number of patients in the prevalence study was lower than the calculated sample size. Therefore, the results should be interpreted with caution since it is underpowered to report the incidence. In addition, a robust comparison of HMB among the various types of antithrombotic agents was not plausible. Furthermore, we included women who had definitive treatment for HMB before the study that could minimize the risk of HMB. Finally, most patients had been on antithrombotics for a length of time, and imprecise recall could have been an issue.

5 | CONCLUSIONS

The MBQ is a simple, noninvasive, and valid tool to screen for the impact of menstruation on HRQoL. Using the translated MBQ, one-fourth of Thai women of reproductive age who received oral antithrombotic therapy experienced HMB that met the subjective NICE guideline definition. This approach thus reflected the impact of HMB on HRQoL. Reproductive-aged women who were treated with antithrombotics should be alerted to the effect of antithrombotics on menstruation.

RELATIONSHIP DISCLOSURE

All authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

TR designed the method of study, performed a forward translation of the questionnaire, enrolled patients in the validation and prevalence study, reviewed and analyzed the data, and wrote the manuscript. JM designed and led the study and provided critical revision to the manuscript. PA wrote and revised the manuscript. KB designed and led the study, analyzed the data, and edited the manuscript.

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REFERENCES

1. Bushnell DM, Martin ML, Moore KA, Richter HE, Rubin A, Patrick DL. Menorrhagia Impact Questionnaire: assessing the influence of heavy menstrual bleeding on quality of life. *Curr Med Res Opin*. 2010;26:2745-2755. https://doi.org/10.1185/03007995.2010.532200
2. Shankar M, Chi C, Kadir RA. Review of quality of life: menorrhagia in women with or without inherited bleeding disorders. *Haemophilia*. 2008;14:15-20. https://doi.org/10.1111/j.1365-2516.2007.01586.x
3. Liu Z, Doan QV, Blumenthal P, Dubois RW. A systematic review evaluating health-related quality of life, work impairment, and health-care costs and utilization in abnormal uterine bleeding. *Value Health*. 2007;10:183-194. https://doi.org/10.1111/j.1524-4733.2007.00168.x
4. Beyer-Westendorf J, Michalski F, Tittl L, Hauswald-Dorschel S, Marten S. Management and outcomes of vaginal bleeding and heavy menstrual bleeding in women of reproductive age on direct oral anti-factor Xa inhibitor therapy: a case series. *Lancet Haematol*. 2016;3:e480-e488. https://doi.org/10.1016/s2352-3026(16)30111-9
5. Hallberg L, Hôgdahl A-M, Nilsson L, Rybo G. Menstrual blood loss–a population study. *Acta Obstet Gynecol Scand*. 1966;45:320-351. https://doi.org/10.3109/00016346609158455
6. Karlsson TS, Marions LB, Edlund MG. Heavy menstrual bleeding significantly affects quality of life. *Acta Obstet Gynecol Scand*. 2014;93:52-57. https://doi.org/10.1111/aogs.12292
7. Peuranpaa P, Heliovaara-Peippo S, Fraser I, Paavonen J, Hurskainen R. Effects of anemia and iron deficiency on quality of life in women with heavy menstrual bleeding. *Acta Obstet Gynecol Scand*. 2014;93:654-660. https://doi.org/10.1111/aogs.12394
8. de Souza SS, Camargos AF, Ferreira MCF, et al. Hemoglobin levels predict quality of life in women with heavy menstrual bleeding. *Arch Gynecol Obstet*. 2010;281:895-900. https://doi.org/10.1007/s00404-009-1207-9
9. Boonyawat K, O'Brien SH, Bates SM. How I treat heavy menstrual bleeding associated with anticoagulants. *Blood*. 2017;130:2603-2609. https://doi.org/10.1182/blood-2017-07-797423
10. Huisman MV, Ferreira M, Feuring M, Fraessdorf M, Klok FA. Less abnormal uterine bleeding with dabigatran than warfarin in women treated for acute venous thromboembolism. *J Thromb Haemost*. 2018;16:1775-1778. https://doi.org/10.1111/jth.14226
11. Devabhaktuni P, Thomas P, Kapadia A, et al. Menstrual abnormalities and gynaecological problems in women on anticoagulant and antiplatelet therapy: management options. *Open J Obstet Gynecol*. 2017;7:581-599. https://doi.org/10.4236/ojog.2017.75061
12. Sjalander A, Friberg B, Svensson P, Stigendal L, Lethagen S. Menorrhagia and minor bleeding symptoms in women on oral anticoagulation. *J Thromb Thrombolysis*. 2007;24:39-41. https://doi.org/10.1007/s11239-006-0003-7
13. Peake LJ, Grover SR, Monagle PT, Kennedy AD. Effect of warfarin on menstruation and menstrual management of the adolescent on warfarin. *J Paediatr Child Health*. 2011;47:893-897. https://doi.org/10.1111/j.1440-1754.2011.02101.x
14. National Guideline A. National Institute for Health and Care Excellence: Clinical Guidelines. In *Heavy Menstrual Bleeding (update)*.

National Institute for Health and Care Excellence (UK). Copyright (c) NICE 2018, 2018.

15. Ware J. SF-36 health survey update. *Spine*. 2001;25:3130-3139. https://doi.org/10.1097/00007632-200012150-00008

16. Matteson KA, Scott DM, Raker CA, Clark MA. The menstrual bleeding questionnaire: development and validation of a comprehensive patient-reported outcome instrument for heavy menstrual bleeding. *BJOG*. 2015;122:681-689. https://doi.org/10.1111/1471-0528.13273

17. Process of translation and adaptation of instruments.

18. Tsang S, Royse CF, Terkawi AS. Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine. *Saudi J Anaesth*. 2017;11:S80-S89. https://doi.org/10.4103/sja.SJA_203_17

19. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol*. 2007;60:34-42. https://doi.org/10.1016/j.jclinepi.2006.03.012

20. Halimeh S, Rott H, Kappert G. PBAC score: an easy-to-use tool to predict coagulation disorders in women with idiopathic heavy menstrual bleeding. *Haemophilia*. 2016;22:e217-e220. https://doi.org/10.1111/hae.12886

21. Zakherah MS, Sayed GH, El-Nashar SA, Shaaban MM. Pictorial Blood Loss Assessment Chart in the evaluation of heavy menstrual bleeding: diagnostic accuracy compared to alkaline hematin. *Gynecol Obstet Invest*. 2011;71:281-284. https://doi.org/10.1159/000320336

22. Magnay JL, O'Brien S, Gerlinger C, Seitz C. Pictorial methods to assess heavy menstrual bleeding in research and clinical practice: a systematic literature review. *BMC Womens Health*. 2020;20:24. https://doi.org/10.1186/s12905-020-0887-y

23. Ding C, Wang J, Cao Y, et al. Heavy menstrual bleeding among women aged 18–50 years living in Beijing, China: prevalence, risk factors, and impact on daily life. *BMC Womens Health*. 2019;19:27. https://doi.org/10.1186/s12905-019-0726-1

24. Harlow SD, Campbell OM. Epidemiology of menstrual disorders in developing countries: a systematic review. *BJOG*. 2004;111:6-16. https://doi.org/10.1111/j.1471-0528.2004.00012.x

25. Harlow SD, Campbell OM. Menstrual dysfunction: a missed opportunity for improving reproductive health in developing countries. *Reprod Health Matters*. 2000;8:142-147. https://doi.org/10.1016/s0968-8080(00)90016-8

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