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Original Research Article

How can a heavy menstrual bleeding scoring system be utilized in practice?

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ABSTRACT

Background: The objective of the study was to utilise a scoring system which aims to triage women with heavy menstrual bleeding (HMB) into hysterectomy or conservative options in practice. The design of the study was a retrospective study in a UK single centre.

Methods: A six-factor scoring tool to triage women with HMB was identified based on different published evidence. These factors are the presence of a uterine fibroid, chronic pelvic pain/endometriosis, adenomyosis, patient desire for hysterectomy, large uterine cavity and anaemia needing parental therapy. Each factor scores 1, apart from uterine cavity length which scores 2. Hysterectomy would be advised if the score is ≥ 3 , otherwise conservative options would be indicated. For this tool to be clinically recognised, it needed to be validated retrospectively over one year. In order to validate this scoring tool, 327 women aged 25-54 referred with HMB between January 2021 and December 2021 were identified and reviewed. Data was retrieved from patients' records, then divided by outcome. The score was applied to the collected data, patients followed for two years. Differences and associations between variables were examined. Sensitivity and specificity of the scoring system in triaging women with HMB was measured. The application of the validated scoring tool in practice was considered depending on the validation outcome.

Results: 38/327 (11.6%) of patients had hysterectomy. There was a significant association between having each factor of the score and hysterectomy and a significant association of having a total score of ≥ 3 and hysterectomy OR 6.23 (95% CI 4.80 – 7.67). The score has a calculated sensitivity of 0.84 (0.68-0.93), specificity of 0.99 (0.97-0.99) and positive predictive value of 0.91 (0.75-0.98). The strongest predictive factor for hysterectomy was large uterine cavity, followed by woman's desire for hysterectomy, then adenomyosis ($p < 0.001$). Other demographic and clinical variables did not predict hysterectomy as an outcome with the exception of dysmenorrhea which when added to the score, it decreased positive predictive value affecting performance. To apply this validated scoring tool in practice, a prospective feasibility trial needs to be conducted prior to a definitive randomised control trial which is on the way.

Conclusions: To use this scoring tool to triage women with HMB in practice, it needed to be validated. Validation has confirmed that this scoring system has high sensitivity and specificity in predicting outcome. Further evaluation of this validated tool in a randomised clinical feasibility trial prior to the definitive trial is needed so the scoring tool can be utilised in practice.

Keywords: Heavy, Menstrual, Bleeding, Validation, Scoring system, Practice

INTRODUCTION

Heavy menstrual bleeding (HMB), defined as excessive menstrual blood loss that interferes with a woman's physical, emotional, or social quality of life, is a common gynecological condition affecting at least a quarter of

premenopausal women and around a fifth of the referrals to gynaecological clinics are due to HMB.¹ While traditionally managed with surgical intervention, modern management focuses on a patient-centred approach that prioritizes fewer invasive methods before considering definitive surgery.¹⁻⁴

This typically begins with conservative options to avoid hysterectomy, including hormonal treatments (such as the Levonorgestrel-releasing intrauterine system (LNG-IUS), Mirena IUS, Bayer Healthcare pharmaceutical Inc, POBOX 1000 Montvale NJ, USA) and endometrial ablation (EA). They both proved to be very effective in managing the condition and controlling women's symptoms.⁵⁻⁸ These procedures represent a lower cost with a shorter recovery time compared to hysterectomy.

Hysterectomy, is highly effective in stopping bleeding. However, because it carries higher rates of surgical risks and longer recovery times compared to conservative methods, evidence-based guidelines generally recommend reserving it as the last option where other therapies have failed, are unsuitable, or have been declined by the patient.¹

Despite the effectiveness of the conservative options, several women fail to respond to them with reduced treatment efficacy and continuation of HMB and other symptoms for years before definitive management is offered.⁴⁻¹⁸ It has been reported that a post ablation hysterectomy rate could reach 21% in some studies and a similar failure rate reported with hormonal IUS on a longer-five year follow up.⁴⁻⁷

There is clearly a need for research to help identify in which women the hormonal IUS/EA and other conservative options are not likely to offer a long-term solution, and hysterectomy will be required. Identification of conditions lead to failure of these conservative options during the gynaecological consultation for HMB is important which can highlight the best available care plan to deal with these symptoms with significant cost saving.⁸

A six-factor scoring system has been introduced based on previous evidence.

This scoring tool was validated retrospectively over one year to test its ability to identify women who would benefit from receiving hysterectomy for HMB. The tool was found to be highly sensitive and specific in identifying outcome. This would support the future counselling process and decision making. To apply this validated scoring system in practice, a prospective randomised feasibility trial has been planned prior to a definitive randomised controlled trial.

METHODS

Gynaecological referrals to gynaecology clinics at South Tyneside and Sunderland Foundation trust between January 2021 and December 2021 were identified and 327 women referred with HMB met the inclusion criteria of the study and were included. Exclusion criteria included patients who had other gynaecological indications for hysterectomy such as cervical intraepithelial neoplasia, malignant and premalignant uterine and ovarian conditions, uterine prolapse or women declining

hysterectomy and wanting to preserve fertility, those with very high (body mass index) BMI >45 as we usually try to avoid hysterectomy due to high chance of complications and when there are contraindications for hysterectomy such as previous multiple laparotomies or significant anaesthetic risk. Patients' consent was not obtained or required being a retrospective case note review study.

Data including demographics, clinical presentation, investigations and treatment options was retrieved retrospectively from patient's notes via the local online information system (Meditech). Collected data was documented on an Excel spreadsheet. The scoring system was applied to the collected data. The scoring system uses 6 clinical parameters: presence of uterine fibroid of ≥ 3 cm, adenomyosis, uterine cavity length >10.5 cm, chronic pelvic pain/ endometriosis/ dysmenorrhoea and dyspareunia, iron deficiency anaemia needing iron infusion/blood transfusion and woman's desire for hysterectomy. Each parameter scores 1 apart from the uterine cavity length which scores 2 (Table 1). The score was measured following data collection on each patient. Patients were then followed for two years.

Core outcome sets: we calculated the number of patients who needed hysterectomy. We also divided the patients into those who scored <3 and those who scored ≥ 3 and followed them for two years. We measured the correlation between each factor in the scoring tool and the outcome of hysterectomy and measured the sensitivity and specificity of the scoring tool in predicting outcome.

Sample size estimation

This was calculated as suggested by Negida et al.¹¹ Based on clinical experience that between 10 and 15% of women in this clinical group proceeded to hysterectomy, an average prevalence of 12.5% was chosen and this yielded a total required sample size of 320 participants and 35 outcomes of hysterectomy to estimate sensitivity and specificity at 0.9.

Statistical analysis

All analysis was performed using JASP 0.19.3 with an alpha level of <.05 throughout. Differences between scale variables were examined using the Welch corrected t-test (except for IMD -Index of multiple deprivation) where the ordinal data needed the use of Mann-Whitney test for non-parametric data and associations between categorical variables using the Chi-squared test.

Associations with the binary outcome (hysterectomy or not) were assessed using a series of logistic regressions with hysterectomy as the outcome variable and the members of the score construct or other clinical and demographic variables as predictors. Depending on the validation outcome of the scoring tool, its applicability and utilisation in clinical practice was assessed.

RESULTS

38/327 of the patients who met the criteria (11.6%) had hysterectomy. Duration of HMB was converted into months. Where a range was given the midpoint was chosen. For one patient this was reported as since menarche and this was replaced as her age minus 13 expressed in months. 6 patients were reported as “years” or “many years” and these were replaced at approximately mean value + 3 SD or 10 years (120 months).

Postcode was converted to index of multiple deprivation (IMD) score to assess if there was any association between socio-economic status and having hysterectomy. There were no significant differences or associations between demographic variables and clinical variables outside the score construct and having a hysterectomy with the exception of those women experiencing dysmenorrhea alone which was associated with hysterectomy as an outcome ($p < 0.001$) (Table 1).

Table 1: Differences between those who did/did not have hysterectomy in (A) clinical and demographic variables, (B) members of the score construct, and (C) number of patients experiencing each outcome depending on score status.

	No hysterectomy (%)	Hysterectomy (%)	P value
(A) Characteristics (N)	289	38	
Age (in years)	42.89 (7.68)	43.13 (6.91)	0.31
BMI	30.09 (4.290)	30.41 (4.86)	0.70
Previous CS	No 238 (82.35)	No 30 (78.95)	
Number of CS	1.67 (0.77) n=51	1.88 (0.64) n = 8	0.37
Previous tubal ligation	No 263 (91.00)	No 34 (89.47)	0.76
Duration HMB (months)	24.67 (35.74)	34.68 (36.55)	0.12
Smoker	No 277 (95.85)	No 36 (94.74)	0.75
IMD mean (SD), median	3.45 (2.33), 3.0	3.32 (2.00), 3.0	0.97 (Mann-Whitney)
Ethnicity	WB 97.65	WB 100	-
PCOS	Yes 13 (4.51)	Yes 3 (7.90)	0.37
Dysmenorrhea alone	Yes 44 (15.44)	Yes 16 (42.11)	<0.001
(B) Score			
CPP	Yes 58 (20.21)	Yes 22 (57/90)	<0.001
fibroid	Yes 29 (10.11)	Yes 20 (52.63)	<0.001
adenomyosis	Yes 16 (5.58)	Yes 18 (47.39)	<0.001
anaemia	Yes 12 (4.17)	Yes 12 (31.58)	<0.001
Large uterine cavity	Yes 3 (1.05)	Yes 18 (47.37)	<0.001
desire	Yes 22 (7.61)	Yes 25 (65.79)	<0.001
Score mean (SD) median	0.50 (0.71), 0.00	3.47 (1.20), 3.00	<0.001
Number ≥ 3	2 (0.69)	33 (86.84)	<0.001
(C) Outcomes			Total
Score < 3	287	5	292
Score ≥ 3	2	33	35
Total	289	38	327

Table 2: Coefficients for logistic regression model predicting outcome of hysterectomy (A) from the 6 members of the SCORE variable, and (B) from the other demographic and clinical variables measured.

Factor	B (SEB)	OR (95% CI)	P value
(A) Members of score variable			
Intercept	-7.43 (1.24)		
Large cavity	5.90(1.27)	360.87 (29.99 – 4342.51)	<0.001
Desire	4.36 (0.98)	78.52 (11.53 – 534.59)	<0.001
Adenomyosis	3.67 (0.94)	39.22 (6.24 – 243.49)	<0.001
CPP	1.85 (0.81)	6.38 (1.32 – 30.89)	0.021
Anaemia	1.98 (0.99)	7.22 (1.03 – 50.63)	0.047
Fibroid	2.02 (0.89)	7.56 (1.31– 43.55)	0.024
(B) Other demographic and clinical factors			
Factor			
Intercept	-3.21 (1.47)		

Continued.

Factor	B (SEB)	OR (95% CI)	P value
Age (in years)	0.03 (0.03)	1.03 (0.98 – 1.08)	0.29
Parity	0.13 (0.18)	0.87 (0.61 – 1.25)	0.47
BMI	-0.006(0.03)	0.99 (0.93 – 1.06)	0.86
Number prev CS	0.17 (0.25)	1.19 (0.73 – 1.92)	0.49
Tubal ligation v not	-0.22 (0.67)	0.80 (0.22– 3.01)	0.75
Duration of HMB	0.006 (0.004)	1.01 (0.99 – 1.01)	0.20
Smoker v not	0.33 (0.83)	1.40 (0.28– 7.08)	0.69
IMD decile	-0.04 (0.08)	0.96 (0.82 – 1.13)	0.64
Dysmenorrhea	1.36 (0.38)	3.90 (1.85 – 8.19)	<0.001

$\chi^2(317) = 180.45$, $p < 0.001$, R^2 (McFadden) 0.77, R^2 (Nagelkerke) 0.83, R^2 (Tjur) 0.77, R^2 (Cox & Snell) 0.43
 $\chi^2(312) = 17.67$, $p = 0.05$, R^2 (McFadden) 0.07, R^2 (Nagelkerke) 0.10, R^2 (Tjur) 0.06, R^2 (Cox & Snell) 0.05

For all 6 members of the score there was a significant association between having this factor and hysterectomy and also a significant association of having a total score of ≥ 3 and hysterectomy, OR 6.23 (95% CI 4.80-7.67). Each of the elements of the score system was independently associated with the outcome of hysterectomy (Table 1). The scoring system has a calculated sensitivity of 0.84 (95% CI 0.68-0.93), specificity of 0.99 (95% CI 0.97-0.99) and positive predictive value of 0.91 (95% CI 0.75-0.98). Women who ended up having hysterectomy had higher mean score than those who did not ($40.52 = 14.71$, $p < 0.001$, $d = 3.15$ (95% CI 2.24-3.90). Number of women experiencing each outcome when classified by a score cutoff of ≤ 3 is shown in Table 1.

A series of logistic regression models was constructed to determine which factors predict hysterectomy using initially the six members of the score (and to determine their combined effect). A significant model is found with coefficients as in Table 2. $\chi^2(317) = 180.45$, $p < 0.001$, R^2 (McFadden) 0.77, R^2 (Nagelkerke) 0.83, R^2 (Tjur) 0.77, R^2 (Cox & Snell) 0.43.

When considered as a group of 6, the strongest predictive factor is the presence of a large uterine cavity ($p < 0.001$) followed by the woman's desire for hysterectomy ($p < 0.001$) and then the presence of adenomyosis. The remaining factors are then weaker but all significant ($p < 0.03$) (Table 2).

A second series of logistic regression models was constructed to determine if any of the other clinical or demographic factors predict hysterectomy using the other measured variables (and to determine their combined effect). A borderline significant model is found with coefficients as in Table 2. $\chi^2(312) = 17.67$, $p = 0.05$, R^2 (McFadden) 0.07, R^2 (Nagelkerke) 0.10, R^2 (Tjur) 0.06, R^2 (Cox & Snell) 0.05.

None of the demographic or other factors were significantly related to the outcome of having a hysterectomy at two years with the exception of dysmenorrhea alone which is a significant predictor (Table 2). In a combined logistic regression model once the members of the score variable were entered, none of the

other clinical or demographic factors were significant predictors of hysterectomy as an outcome.

Distribution of scores calculated for each woman divided by outcome is shown in Figure 1a. Taking estimated prevalence of hysterectomy (from data) calculated as 0.12 (95% CI 0.08–0.16) then the sensitivity and specificity of the cut off of 3 on this scoring system is as shown in Table 3 with the ROC plot for this model is shown in Figure 1b.

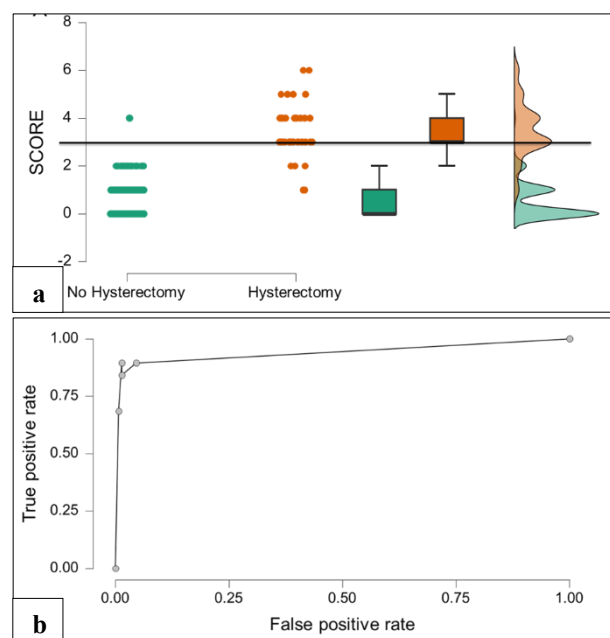


Figure 1: (a) Distribution of the score variable between those who did/did not have hysterectomy. Heavy black line indicates cut off of 3, and (b) ROC plot showing performance of logistic model including the 6 factors of the SCORE.

Even though dysmenorrhea alone did not add significantly to the combined logistic model, its significance as an independent predictor of hysterectomy suggested it should be considered as a member of the score construct. Scoring was repeated including this factor. There was a significant association between scoring above/below the threshold with the outcome of having a hysterectomy $\chi^2(1) = 243.07$, $p < 0.001$ with sensitivity and specificity as shown in Table 3. Adding dysmenorrhoea as a member of the scoring

system leads to an increase in sensitivity but a considerable reduction in positive predictive value suggesting it should not be retained as a predictive factor and the original

members of the score construct should be retained unchanged. Confirming that this scoring system is valid, facilitates its application and utilisation in practice.

Table 3: Performance of the score system with a cut off of ≥ 3 for predicting hysterectomy (A) based on original members of the score system, and (B) also including the predictor “dysmenorrhea alone” as a possible predictive factor.

Scores	(A) Initial score		(B) Score including dysmenorrhea	
Measure	Value	95% CI	Value	95% CI
Sensitivity	0.87	0.71 – 0.95	0.92	0.78 – 0.98
Specificity	0.99	0.97 – 1.00	0.98	0.95 – 0.99
For any particular positive test result the probability that it is a				
True positive (positive predictive value)	0.94	0.79 – 0.99	0.85	0.70 – 0.94
False positive	0.06	0.01 – 0.20	0.15	0.06 – 0.30
For any particular negative test result the probability that it is a				
True negative (negative predictive value)	0.98	0.96 – 0.99	0.99	0.97– 0.99
False negative	0.02	0.01 – 0.04	0.01	0.002– 0.03
Likelihood ratios conventional				
Positive	125.49	31.36 – 502.12	44.36	19.99 – 98.46
Negative	0.13	0.06 – 0.30	0.08	0.02 – 0.24
Likelihood ratios weighted by prevalence				
Positive	16.50	4.29 – 63.53	5.83	2.76 – 12.35
Negative	0.02	0.007 – 0.04	0.01	0.003– 0.03

DISCUSSION

HMB, a common gynaecological condition which may affect the individual's wellbeing. Despite that the majority of cases are idiopathic, different pathologies can be associated with HMB including uterine fibroids, adenomyosis and endometriosis.⁴⁻¹⁷

Conservative options are typically offered as the first line treatment to women with HMB leaving hysterectomy as the last option.¹ These options frequently fail resulting in prolongation of suffering for the women in addition to the additional cost to the health service until definitive surgery is offered.¹⁵

Several research have shown reduced treatment efficacy and satisfaction over time from conservative options.⁴⁻⁷ The ECLIPSE Trial has highlighted that 1 in 5 women needed hysterectomy after 5 years of having the Levonorgestrel IUS5. These failures could have been related to different gynaecological conditions such as uterine fibroids, adenomyosis, large uterine cavity and endometriosis which can predispose to additional symptoms such as pelvic pain, dysmenorrhoea, dyspareunia, anaemia, fatigue and pressure symptoms.⁴⁻¹⁷

In this study, we have validated the use of a scoring tool which utilises six factors associated with HMB identified from previously published data, which could lead to the failure of conservative options. When calculated together and the score is ≥ 3 , conservative measures might fail leading to hysterectomy.⁴⁻²³ This scoring system aims to shorten the time to hysterectomy when other modalities

would fail and avoid hysterectomy when other medical and surgical interventions would usually work.

Husu et al, reported a 7.1% hysterectomy rate following Novasure EA and suggested preoperative imaging to detect submucous myomas, large myomas, polyps and adenomyosis to optimise patient's selection and reduce the need for subsequent hysterectomy.¹⁶ Stevens et al in 2019 predicted the likelihood of failed EA for HMB. This was based on woman's age, parity, duration of HMB, associated dysmenorrhoea and previous caesarean section.⁴

EA was reported to be associated with post ablation pelvic pain in 20.8% in one series especially in women with pre ablation dysmenorrhoea and endometriosis. It recommended properly counselling women regarding this expected surgical outcome.^{17,18} Late-onset endometrial ablation failure (LOEAF) was recently identified to be associated with hysterectomy in 25% of women regardless of the type of EA used and an unknown number of women in this series, have less than satisfactory results.²⁰ In order to reduce LOEAF, proper understanding of factors which lead to LOEAF with good patient selection can improve patient's satisfaction.¹⁹ Recurrence of HMB post EA was found to be due to inadequate destruction of the endometrium or its regrowth following ablation, chronic pelvic pain, leiomyomas and adenomyosis.¹⁷⁻²¹

The HEALTH trial; one of the largest randomised controlled trials to date in benign gynaecology; compared laparoscopic supracervical hysterectomy (LASH) with EA for HMB. It found that women allocated to LASH were more satisfied with their treatment with improved quality

of life (QoL) compared to the EA group with no difference in serious adverse events between the two groups over 15 months follow up.³ The trial excluded women with fibroids and large endometrial cavities and patients were only followed for 15 months which might not be sufficient to assess EA failure.²² Society guidelines describe hysterectomy as a last resort in the context of providing less invasive options for gynaecological conditions. However, methodologically sound evaluation is required to test the status quo.¹⁹

Adenomyosis is a common cause of chronic pelvic pain and HMB. Deep adenomyosis was identified in hysterectomy specimens in a significant number of patients following failed Novasure endometrial ablation.²¹⁻²⁴

On the other hand, the Levonorgestrel IUS was found to be associated with failure in women with a uterine fibroid ≥ 2.5 cm or a uterine size of >12 cm.^{24,25}

Large uterine cavity >10.5 cm was identified as a risk factor for failed EA and LOEAF and it can also be associated with a failed Levonorgestrel IUS.²⁰⁻²⁵

Large uterine cavity, chronic pelvic pain/dysmenorrhoea and dyspareunia or known endometriosis/adenomyosis were identified when present together and the score is ≥ 3 , a hysterectomy could be the preferred option.¹⁷

One of the causes of Iron deficiency anaemia is HMB which can be life-threatening, requiring urgent treatment.²⁶ A consensus guidance covering screening and diagnosis of iron deficiency anaemia in women with HMB has been suggested to improve health outcomes in those individuals.²⁷ We considered HMB leading to iron deficiency anaemia needing parenteral therapy as a factor which can predict hysterectomy if other factors also existed.¹⁷

Women's desire for definitive treatment was identified as a factor which would eventually lead to hysterectomy when present with other factors in a previous series.¹⁷ This was especially identified in women aiming for complete amenorrhoea. In this study, individual's desire for definitive surgery was found to have a strong predictive value for hysterectomy.

Hysterectomy is the most commonly performed major gynaecological surgical procedure.²⁹ Despite its invasive nature, it represents the most definitive treatment for HMB when future fertility is not desired.²⁹

Due to its invasive nature with longer recovery time and complications, hysterectomy is thought to be only considered when other treatment options have failed or are contraindicated.^{1,29}

There is no available scoring system to triage women with HMB into hysterectomy and uterine sparing modalities.

This study has validated a scoring tool and found a significant association between scoring \geq the threshold of 3 with the outcome of having a hysterectomy. Each member of the scoring system was significantly associated with the outcome of hysterectomy. This scoring system was found to be highly sensitive and specific in triaging women with HMB into hysterectomy and uterine sparing options. The strongest predictive factor in this scoring tool was found to be the presence of a large uterine cavity followed by woman's desire for hysterectomy then the presence of adenomyosis. No other clinical or demographic factors were found to be significant predictors. Dysmenorrhoea, which was found to be significantly associated with the outcome of hysterectomy, was not added to the final scoring tool as this would result in improving sensitivity, albeit a reduction in specificity, hence reducing the performance of the scoring system. This study has assisted us to consider utilizing this tool in practice by testing it first in a prospective randomised clinical trial. A feasibility study to gauge recruitment, retention in the trial and follow-up is on the way.

Strengths

This study has validated a scoring tool which utilised different evidence-based factors which usually lead to failed conservative measures and measured its sensitivity and specificity so that the tool could be utilised in clinical practice. It correctly excluded factors which reduced the score performance. It also identified which factors in the tool predicted hysterectomy most. It reviewed and summarised recent evidence on failed conservative management for HMB. To our knowledge, this is the only available scoring system to triage women with HMB. This study would lead to further testing of this tool in a prospective clinical randomised trial for wider use in practice.

Limitations

This study is a retrospective study over one year with a small sample size in one UK centre. It only followed women for two years which could have missed some of the LOEAF.

CONCLUSION

This scoring system as developed has high sensitivity and specificity with positive predictive value in triaging women with HMB into hysterectomy and conservative options with logistic regression confirming the validity of the scoring tool in differentiating outcomes. We can now further assess this validated tool in a prospective randomised clinical trial prior to its application in practice.

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