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Validation of a Scoring System to Triage Heavy Menstrual Bleeding into Hysterectomy or Conservative Options

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Abstract

Objective: To validate a scoring system aims to triage individuals with Heavy Menstrual Bleeding (HMB) into hysterectomy or uterine sparing options and inform the development of a prospective clinical trial.

Design: Retrospective study.

Methods: 327 women aged 25–54 referred with HMB between January 2021 and December 2021 were identified; data was retrieved from patients' records and divided by outcome. The score was applied to the collected data and patients were followed for two years. The score has 6 parameters (pelvic pain/endometriosis, adenomyosis, fibroid(s), large endometrial cavity, anemia needing parenteral therapy, desire for hysterectomy), each score 1, apart from uterine cavity length scores 2. Differences and associations between variables were examined. Sensitivity and specificity of the scoring tool was measured.

Results: 38/327 (11.6%) of patients had hysterectomy. Demographic and clinical variables were divided by outcome. 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]. A series of logistic regression models was constructed to determine which factors predict hysterectomy using the six members of the score (and to determine their combined effect). The strongest predictive factor for hysterectomy was large endometrial 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 alone. However, adding this to the score construct did not improve performance, resulting in reduction in the positive predictive value of the measure.

Conclusion: This scoring system as developed has high sensitivity and specificity in triaging women with HMB into hysterectomy and uterine sparing modalities. Further evaluation in a prospective clinical trial is warranted.

Keywords: Heavy menstrual bleeding, Validation, Scoring system

Introduction

Many women in their reproductive age suffer with Heavy Menstrual Bleeding (HMB), described as excessive menstrual blood loss affecting the woman's physical, social, and emotional quality of life [1–3]. It affects around 25% of women and around a fifth of the referrals to gynecological clinics are due to HMB [3,4].

Different medical and surgical interventions are usually offered prior to hysterectomy. These interventions might temporarily relieve some of the symptoms, however; several women continue with HMB & other symptoms for years before definitive management is offered.

The two most widely used uterine sparing medical and surgical interventions in modern gynecological practice for HMB are the Levonorgestrel IUS (Mirena IUS Bayer Healthcare pharmaceutical Inc, POBOX 1000 Montvale NJ, USA,) and endometrial ablation (EA)—such as the Novasure radiofrequency endometrial ablation (Hologic Inc, Massachusetts, USA & Mini touch 3.8 ERA system, MicroCube LLC, Fermont, USA). They both proved to be very effective in managing the condition and controlling symptoms [5–8]. These procedures represent a lower cost with a shorter recovery time compared to hysterectomy. However, the ECLIPSE Trial highlighted on a longer term that 1 in 5 women needed hysterectomy after 5 years of having the Levonorgestrel IUS [5]. The same applies to EA, where follow up showed reduced treatment efficacy and women's satisfaction with a post ablation hysterectomy rate reaching 21% in some series [7–9].

Utilizing these uterine sparing modalities prior to hysterectomy for women with HMB who have additional gynecological symptoms and pathologies, might result in failure of these interventions. This can negatively impact the individual's Quality of Life (QoL) and wellbeing by prolonging their treatment journey in addition to the procedure-related additional costs.

Certain conditions can result in failure of EA leading to hysterectomy. This includes fibroids, adenomyosis and endometriosis, uterine cavity length >10.5 cm, and woman's desire for complete amenorrhea [3,9,10]. There is no available scoring tool for HMB.

In this study, we have validated the use of a scoring tool which utilizes 6 factors to triage women with HMB into hysterectomy and uterine sparing modalities. This tool was applied retrospectively on patients who had hysterectomy for HMB and was found to be beneficial in predicting hysterectomy [11]. This scoring tool aims to shorten the time to hysterectomy when other modalities would fail and avoid hysterectomy when other options would be effective. This is intended to support the future counselling process and decision making. To use this score in practice, it needed to

be validated by applying it to all patients referred with HMB. The study has found the scoring tool to be highly sensitive and specific and recommends its use in a wider prospective randomized clinical trial.

Materials and Methods

To validate the scoring tool, we had to review all gynecological referrals to gynecology clinics between January 2021 and December 2021 which were 44,225 referrals. There were 327 patients referred with HMB and included in the study. Those who were referred with HMB and had other gynecological indications for hysterectomy such as cervical intraepithelial neoplasia, malignant and premalignant uterine and ovarian conditions, uterine prolapse or those wanting to preserve fertility, were excluded from the study. Women with BMI >45 were also excluded as they are usually offered different uterine sparing modalities to avoid the complications of hysterectomy. Women with contraindications for hysterectomy such as those with significant anesthetic or surgical risk, were excluded. 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 proposed scoring system uses 6 clinical parameters: presence of uterine fibroid(s) of ≥ 3 cm, adenomyosis, uterine cavity length by sounding >10.5 cm, chronic pelvic pain/ endometriosis/ dysmenorrhea and dyspareunia, iron deficiency anemia needing iron infusion/ blood transfusion, and woman's desire for hysterectomy. Each parameter scores 1 apart from the uterine cavity length which scores 2. 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. [12]. 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.

Results

Thirty-eight out of 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. Six 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 IMD score (Index of Multiple Deprivation) 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 except for those women experiencing dysmenorrhea alone which was associated with hysterectomy as an outcome ($p<.001$) (**Table 1A**).

For all 6 members of the score there was a significant association between having this factor and hysterectomy and a significant association of having a total score of ≥ 3

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.

A.	No hysterectomy	Hysterectomy	p
N	289	38	
Age	42.89 (7.68)	43.13 (6.91)	.31
BMI	30.09 ()	30.41 (4.86)	.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	.37
Previous Tubal Ligation	No 263 (91.00%)	No 34 (89.47%)	.76
Duration HMB (months)	24.67 (35.74)	34.68 (36.55)	.12
Smoker	No 277 (95.85%)	No 36 (94.74%)	.75
IMD mean (SD), median	3.45 (2.33), 3.0	3.32 (2.00), 3.0	.97 (Mann-Whitney)
Ethnicity	WB 97.65%	WB 100%	-
PCOS	Yes 13 (4.51%)	Yes 3 (7.90%)	.37
Dysmenorrhea alone	Yes 44 (15.44%)	Yes 16 (42.11%)	<.001
B. SCORE			
CPP	Yes 58 (20.21%)	Yes 22 (57.90%)	<.001
Fibroid	Yes 29 (10.11%)	Yes 20 (52.63%)	<.001
Adenomyosis	Yes 16 (5.58%)	Yes 18 (47.39%)	<.001
Anaemia	Yes 12 (4.17%)	Yes 12 (31.58%)	<.001
Large uterine cavity	Yes 3 (1.05%)	Yes 18 (47.37%)	<.001
Desire	Yes 22 (7.61%)	Yes 25 (65.79%)	<.001
Score mean (SD) median	0.50 (0.71), 0.00	3.47 (1.20), 3.00	<.001
Number ≥ 3	2 (0.69%)	33 (86.84%)	<.001
C. Outcomes			
Score <3	287	5	292
Score ≥ 3	2	33	35
Totals	289	38	327

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 1B**). 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 $t(40.52) = 14.71, p < .001, d = 3.15$ [95% CI 2.24–3.90]. Number of women experiencing each outcome when classified by a score cutoff of ≥ 3 are shown in **Table 1C**.

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 2A**. $\chi^2(317) = 180.45, p < .001, R^2$ (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 ($p < .001$) followed by the woman's desire for hysterectomy ($p < .001$) and then the presence of adenomyosis. The remaining factors are then weaker but all significant ($p < .03$) (**Table 2A**).

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 2B**. $\chi^2(312) = 17.67, p = 0.05, R^2$ (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 2B**). 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 3A** with the ROC plot for this model is shown in **Figure 1B**.

Table 2. Coefficient 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.

A. Members of Score Variable			
Factor	B (SEB)	OR [95% CI]	p
Intercept	-7.43 (1.24)		
Large cavity	5.90 (1.27)	360.87 [29.99–4342.51]	<.001
Desire	4.36 (0.98)	78.52 [11.53–534.59]	<.001
Adenomyosis	3.67 (0.94)	39.22 [6.24–243.49]	<.001
CPP	1.85 (0.81)	6.38 [1.32–30.89]	.021
Anaemia	1.98 (0.99)	7.22 [1.03–50.63]	.047
Fibroid	2.02 (0.89)	7.56 [1.31–43.55]	.024
$\chi^2(317) = 180.45, p < .001, R^2$ (McFadden) 0.77, R^2 (Nagelkerke) 0.83, R^2 (Tjur) 0.77, R^2 (Cox & Snell) 0.43			
B. Other demographic and clinical factors			
Factor	B (SEB)	OR [95% CI]	p
Intercept	-3.21 (1.47)		
Age	0.03 (0.03)	1.03 [0.98–1.08]	.29
Parity	0.13 (0.18)	0.87 [0.61–1.25]	.47
BMI	-0.006 (0.03)	0.99 [0.93–1.06]	.86
Number Prev CS	0.17 (0.25)	1.19 [0.73–1.92]	.49
Tubal ligation v not	-0.22 (0.67)	0.80 [0.22–3.01]	.75
Duration of HMB	0.006 (0.004)	1.01 [0.99–1.01]	.20
Smoker v not	0.33 (0.83)	1.40 [0.28–7.08]	.69
IMD decile	-0.04 (0.08)	0.96 [0.82–1.13]	.64
Dysmenorrhea	1.36 (0.38)	3.90 [1.85–8.19]	<.001
$\chi^2(312) = 17.67, p = .05, R^2$ (McFadden) 0.07, R^2 (Nagelkerke) 0.10, R^2 (Tjur) 0.06, R^2 (Cox & Snell) 0.05			

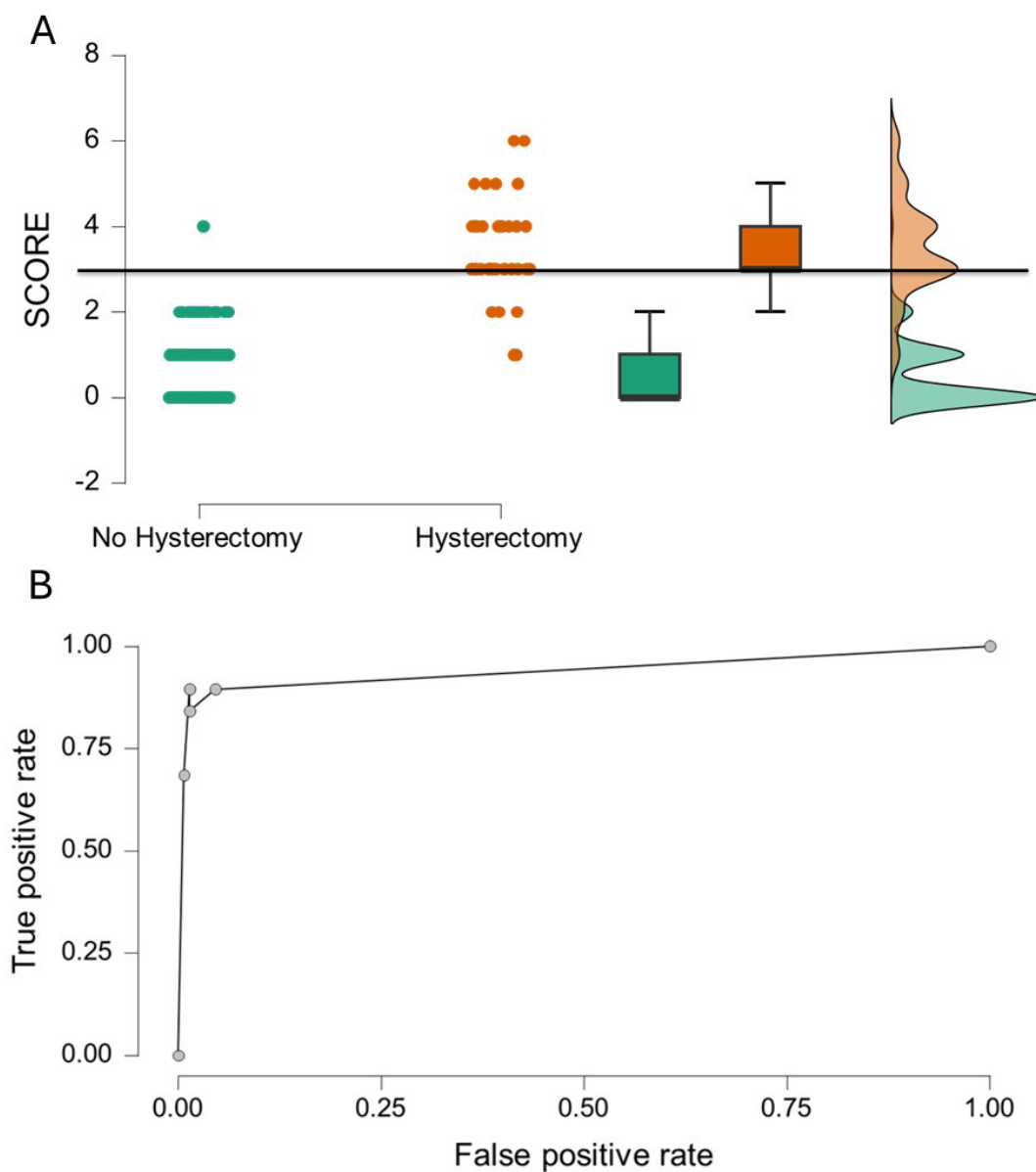


Figure 1. A. Distribution of the score variable between those who did / did not have hysterectomy. Heavy black line indicates cut off of 3 and **B.** Roc plot showing performance of logistic model including the 6 factors of the SCORE.

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 $\chi^2(1) = 243.07$, $p < .001$

with sensitivity and specificity as shown in **Table 3B**. Adding dysmenorrhea 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.

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.

Measure	A. Initial SCORE		B. SCORE including Dysmenorrhea	
	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
<i>For any particular positive test result the probability that it is a:</i>				
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
<i>For any particular negative test result the probability that it is a:</i>				
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
<i>Likelihood ratios Conventional:</i>				
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
<i>Likelihood ratios Weighted by prevalence</i>				
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

Heavy menstrual bleeding (HMB) is a common gynecological condition affecting at least a quarter of women during their reproductive life and has several implications on women's quality of life by affecting their physical and mental health, as well as their emotional and social wellbeing [8–10]. It can also be associated with significant pelvic pain, anemia and fatigue [13–15].

Different pathologies can be associated with HMB, including uterine fibroids, adenomyosis and endometriosis, which can predispose to additional symptoms of chronic pelvic pain, dysmenorrhea, dyspareunia, anemia, fatigue, and pressure symptoms [9,10].

Several medical options are usually offered to individuals with HMB and if failed or declined, EA would be offered if family is deemed complete. Hysterectomy is usually reserved as last option if all options fail [1].

Individuals who have tried different medical and surgical interventions but continue with HMB and its associated symptoms of pain, tiredness, anemia and fatigue, are usually less satisfied with their received treatment until hysterectomy is offered which can lead to additional costs [16].

Main findings

In this study, we have validated the use of a scoring tool which utilizes six factors identified from previous studies

and are associated with HMB. When calculated together and the score is ≥ 3 , conservative measures might fail leading to hysterectomy [4,6,9,11,15–24]. 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.

Several researchers have identified the correlation between different factors and failed EA. 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 optimize patient's selection and reduce the need for subsequent hysterectomy [17].

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 dysmenorrhea, 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 dysmenorrhea and endometriosis. It recommended properly counselling women regarding this expected surgical outcome [18,19]. 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 [19]. Understanding factors which lead to LOEAF with good patient selection would reduce LOEAF and improve patient's satisfaction [19]. The commonest causes of post ablation hysterectomy in different series were

found to be recurrence of HMB due to inadequate destruction of the endometrium or its regrowth following ablation, chronic pelvic pain, leiomyomas and adenomyosis [18–21].

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 [22].

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 cavity length by sounding of >10 cm (>12 weeks size) [23,24].

Large endometrial cavity measured by sounding of >10.5 cm was identified as a risk factor for failed EA and LOEAF [19,25,26], hence EA is relatively contraindicated in uterine cavity sounding length of >11 cm [26]. Measured uterine cavity depth by sounding is usually affected by different factors such as the presence of leiomyoma or adenomyosis which could make the endometrial cavity larger.

Large endometrial cavity, chronic pelvic pain/dysmenorrhea and dyspareunia or known endometriosis/adenomyosis were identified when present together, a hysterectomy could be the preferred option [11].

One of the causes of Iron deficiency anemia in women and individuals with a uterus is HMB which can be life-threatening, requiring urgent treatment [27]. A consensus guidance covering screening and diagnosis of iron deficiency anemia in individuals with HMB has been suggested to improve health outcomes [27]. We considered HMB leading to iron deficiency anemia needing parenteral therapy (iron infusion/blood transfusion) as a factor which could predict hysterectomy if other factors existed making the score ≥ 3 [11].

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 [11]. This was especially identified in women aiming for complete amenorrhea where other conservative options such as the Levonorgestrel IUS and EA might not guarantee.

Hysterectomy is the most performed major gynecological surgical procedure [28]. Despite its invasive nature, it represents the most definitive treatment option for HMB when future fertility is not desired [28].

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 [1,28].

The HEALTH Trial; one of the largest randomized controlled

trials to date in benign gynecology, which compared laparoscopic supracervical hysterectomy (LASH) with EA for HMB. It found that women allocated to LASH were more satisfied with their treatment with improved QoL compared to the EA group with no difference in serious adverse events between the two groups over 15 months follow up [3]. This trial has excluded women with endometrial cavity >11 cm due to high EA failure rate. In this trial, patient's decision making preference was eliminated by being in the trial which could have led to lower satisfaction [29]. 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.

A QoL questionnaire in women with HMB was suggested to identify individuals when HMB interferes with their QoL which was found to be valid [30]. However, a recent systematic review of QoL measurement tools for HMB highlighted that none of the available QoL tools for HMB are appropriate for use in practice. It also suggested the need to invest in developing and validating reliable tools that offer high qualitative and quantitative assessment [31]. We are planning to introduce and validate a QoL HMB specific questionnaire during the planned prospective clinical trial.

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

This study has validated a scoring tool for HMB and has 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 as it is, was found to be highly sensitive and specific in triaging women with HMB into hysterectomy and uterine sparing options. The strongest predictive factor was found to be the presence of a large uterine cavity length by sounding followed by woman's desire for hysterectomy then the presence of adenomyosis. No other clinical or demographic factors were found to be significant predictors. Dysmenorrhea, which was found to be significantly associated with the outcome of hysterectomy, was not added to the final scoring system as this would result in improving sensitivity, albeit with a reduction in specificity, hence reducing the performance of the scoring tool.

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. Further evaluation of this scoring system in a prospective clinical trial is now warranted prior to be used in practice.

Conflicts of Interest

The authors declare no conflicts of interest.

Funding Statement

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Disclosure

The word women is used as a collective term in this paper, but we acknowledge those that identify by other terms including the transgender population.

Ethical Approval

The study did not require ethics approval from the regional or institutional ethics committees as it is a retrospective study which reviewed the online medical records of the patients. The privacy rights of human subjects have been observed. All procedures were performed in compliance with relevant laws and institutional guidelines which did not require approval by the appropriate institutional committee(s) being a retrospective study.

Authors Contribution

Shamma Al-Inizi identified the concept of introducing a scoring system to triage women with HMB following publishing three articles on the subject. She planned this validation study with the support of the methodologist and statistician. She planned and obtained the final list of patients with the help of the coding department at the organization. She finalized the data collection excel sheet. She reviewed 55% of the cases and collected their data. She wrote the first, second, and final draft of the paper including its conclusions based on the statistical analysis. She also completed the Medline search.

Dr Jon Rees has advised on planning the validation study, the sample size and duration required to validate the scoring system. He has reviewed the data collection form and adjusted it and advised adding post codes to the demographics. He also advised converting each answer on the spreadsheet into numbers to facilitate the statistical analysis which led to the conclusions of the study. He has performed all the statistical

analysis required for the study which led to its outcome. He has reviewed the first, second, and final draft of the paper and has finalized it.

Dr. Laura Hewitt helped in around 37% of the data collection and finalizing the data collection spreadsheet.

Dr. Humaira Ali helped in around 8% of the data collection and reviewing the paper.

Safa Kindawi helped in converting results into numbers on the data collection spreadsheet as well as converting post codes into numbers. She also helped in the correction/writing of the paper including proof reading and Medline search.

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