



Evaluating the Non-invasive Screening Tools in Women with Abnormal Uterine Bleeding

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Abstract

Objectives: Today, few non-invasive diagnostic tests or biomarkers can diagnose the cause of abnormal uterine bleeding (AUB) for invasive procedures. Therefore, the present study considered the non-invasive scoring system in patients with endometrial disease leading to bleeding and compared it with the pathology results.

Methods and Materials: This study (cross-sectional, test-diagnosis) was conducted on all women with abnormal endometrial bleeding referred to the gynecology ward and clinic of Ayatollah Rouhani Hospital from 2018 to 2019. Patients underwent transvaginal ultrasound (TVS) examination by a sonographer after hospitalization. Patients' information, including age, menopausal status, history of underlying diseases such as diabetes, hypertension, obesity (body mass index $>30 \text{ kg/m}^2$), hormonal therapy, and use of tamoxifen, was recorded in a checklist by the responsible resident.

Results: There was good agreement between non-invasive screening tools and pathology to detect AUB (agreement coefficient=0.90 and $P<0.001$). There was an unfavorable agreement between screening tools with body mass index and pathology to detect AUB (agreement coefficient=0.68 and $P<0.001$). The cut-off point of the non-invasive screening tool was 9 in women with a normal pathologic diagnosis, giving it a sensitivity of 97% and a specificity of 98%. The cut-off point of the non-invasive screening tool was 11.5 in women diagnosed with benign pathology, giving it a sensitivity of 96% and a specificity of 97%. The cut-off point of the non-invasive screening tool was 16.5 in women with malignant pathology, giving it a sensitivity of 94% and a specificity of 98%.

Conclusions: The 90% agreement of screening tools with pathology indicates that these tools can be used to predict diagnostic features of pathology in women suffering from AUB.

Keywords: Abnormal uterine bleeding, Non-invasive screening tool, Gynecology, Pathology, Endometrium

Introduction

Abnormal uterine bleeding (AUB) is one of the major problems in women of childbearing age (1). Endometrial diseases account for a significant portion of the causes of abnormal bleeding. This disease includes normal endometrium, benign, premalignant, and variable malignant pathologies (2).

Uterine bleeding with abnormal volume and regularly or at regular intervals is defined as AUB (3), which occurs in 14 to 25% of women of reproductive age (4-6). However, for further clarification, the difference in frequency, duration, and bleeding pattern compared with the menstrual cycle describes abnormal bleeding (7,8).

AUB is an expression of a disturbance in the normal cycle pattern of ovulatory hormone stimulation and its effect on the endometrium. In general, endometrial tissue is needed for differential diagnosis in women <35 years of age with ovulatory bleeding and over 35 years of age with abnormal bleeding (9).

Endometrial cancer is the most common gynecologic cancer. Vaginal bleeding is one of the symptoms of

endometrial cancer in more than 90% of postmenopausal women. Clinical risk factors for endometrial cancer include age, obesity, progesterone-free estrogen, underlying diseases (diabetes type II and atypical glandular cells) in the Pap smear, and a family history of postmenopausal vaginal bleeding (1).

According to the PALM-COEIN classification, the causes of AUB include polyps, leiomyoma, adenomyosis, coagulopathy, hyperplasia, anovulation, endometrium, and idiopathic or unclassifiable causes (3). Endometrial disorders such as polyps, myomas, synechiae, septa, hyperplasia, and endometrial cancer are some of the conditions that can cause bleeding in postmenopausal women and AUB in women of reproductive age (10,11).

AUB, for whatever reason, negatively affects the quality of life in women, and examination of the uterus as a source of bleeding seems necessary. Methods such as transvaginal ultrasound (TVS), hysterosonography with two- and three-dimensional saline contrast, hysteroscopy, and uterine curettage are recommended to examine the uterine cavity (12-14). TVS is very accurate in diagnosing

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endometrial pathologies. TVS is an alternative method and the first approach to endometrial sampling. It is used to make judgments about postmenopausal women who experience a first bleeding episode (1,2). It is also very effective in determining endometrial thickness but cannot diagnose specialized endometrial lesions (3-5). TVS is the primary imaging study of the uterus to investigate AUB, but it is most commonly used as a key tool in the structural causes of AUB (15). However, research has shown that TVS is unreliable and may not detect half of the intrauterine pathologies (16,17). Nowadays, methods for early detection of endometrial lesions, such as Pipelle, dilatation and curettage, Tao brush, Vabra aspirator, and SAP-1 device, are widely used. Among all these methods, dilatation and curettage have been detected as standard methods for studying endogenous pathogenesis for a decade, apart from the need for anesthesia, high mortality, and risk of perforation (9). Pipelle sampling is currently the best biopsy instrument compared with other instruments (6). Pipelle is a simple, safe, and effective method of endometrial biopsy that does not require anesthesia (7). On the other hand, the hysteroscopic diagnostic method has been used to diagnose endometrial polyps and various causes of endometrial hyperplasia. The European Society of Embryology stated that hysteroscopy with gold biopsy is a standard method for diagnosing AUB (8,9). Saline contrast hysterosonography is one of the methods used to assess the uterine cavity and associated pathologies; it is less invasive and less expensive than hysteroscopy. Saline infusion sonohysterography evaluates the uterine cavity, adhesions, and focal pathological lesions (18). Generally, TVS is the first diagnostic method for patients with AUB, and the next step is invasive endometrial sampling (19). In the meantime, patients may not need a biopsy depending on individual circumstances, clinical examination findings, medical history, pelvic examination, and known risk factors. In addition, a scoring program or risk factor compilation system can be used to avoid risky work and additional costs (10).

Other diagnostic methods are costly and invasive and require expertise. To date, no non-invasive diagnostic test or biomarker can identify the cause of AUB without requiring invasive procedures (11). Therefore, the current research aims to evaluate the non-invasive scoring system in patients with endometrial disease leading to bleeding and compare it with pathology results.

Materials and Methods

This cross-sectional-analytical study (test-diagnosis) was conducted on all women with abnormal endometrial bleeding referred to the Gynecology Ward and Clinic of Ayatollah Rouhani Hospital from 2018 to 2019.

After admission, the patients underwent TVS by a sonographer. Moreover, TVS measured elements such as endometrial thickness, the endometrial-myometrial junction (EMJ), echotexture, polyps, and endometrial

accumulation. Then, the endometrial sample was taken from the patient whose pathology was read by a pathologist.

Patients' information, including age, menopausal status, history of underlying diseases such as diabetes, hypertension, obesity (body mass index $>30 \text{ kg/m}^2$), hormonal therapy, and use of tamoxifen, as well as TVS results like endometrial thickness, EMJ, echotexture, polyps, and endometrial accumulation, was recorded in a checklist by the responsible resident.

The screening methods utilized in this research were introduced by Deeksha Pandey in 2018, as indicated by Tables 1-3.

The researchers' assumption in this dissertation was to add body mass index as a variable to the scoring system, so in the scoring system, number 2, body mass index was added to the scoring system numbers 1 and 3, defined as normal, benign, and malignant.

Data were analyzed using SPSS version 22. The kappa agreement coefficient, chi-square, and one-way ANOVA were used. In addition, the CATmaker software was applied to determine the cut-off point, receiver operating characteristic (ROC) curve, sensitivity, specificity, positive predictive value, and negative predictive value ($P < 0.05$).

Results

This study selected 1066 women with abnormal endometrial bleeding who were referred to the gynecology

Table 1. Scoring System for Abnormal Uterine Bleeding and Risk Assessment Based on Demographic Characteristics

Demographic features	Scores
Age (y)	20-40 (1 score)
	41-55 (2 scores)
	>56 (5 scores)
Menopausal status	Premenopause (1 score)
	Postmenopause (4 scores)
Comorbidity (Diabetes mellitus, hypertension, etc)	Each 1 score
Hormone therapy	1 score
Taking tamoxifen	1 score
Body mass index	30-35 (1 score)
	$35 <$ (2 scores)

Table 2. Scoring System for Abnormal Uterine Bleeding and Risk Assessment Based on Transvaginal Ultrasound Results

Transvaginal Sonography Findings	Scores
Endometrial thickness (mm)	<5 (1 score)
	6-10 (2 scores)
	11-20 (3 scores)
	$21 <$ (4 scores)
EMJ	Distinct (1 score)
	Indistinct (5 scores)
Echotexture	Homogeneous (1 score)
	Cystic spaces (3 scores)
	Heterogeneous (3 scores)
Polyp	4 scores

Table 3. Total Scores of Demographic Characteristics and Transvaginal Ultrasound Results in Women With Abnormal Uterine Bleeding to Predict Endometrial Pathology

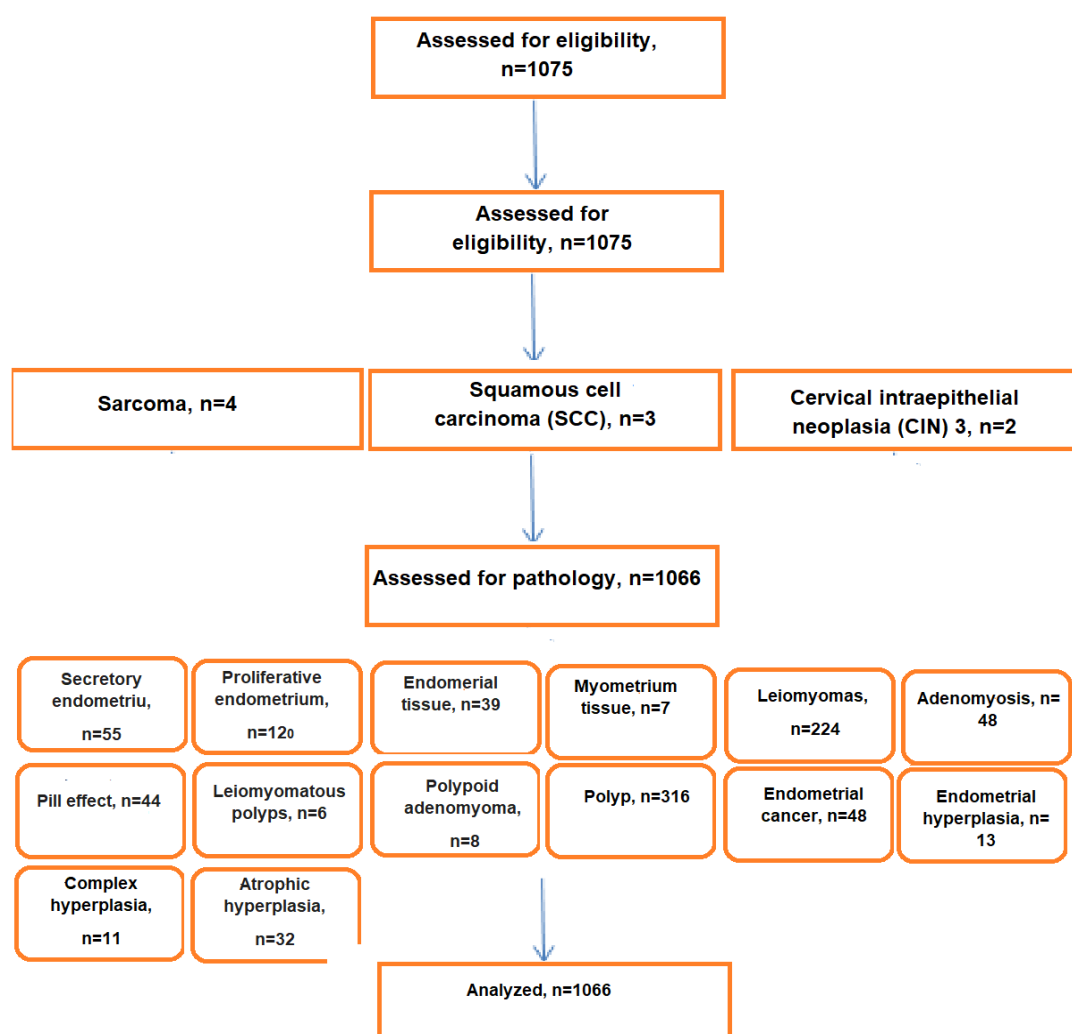
Endometrial Pathology	Total of Demographic Features and Transvaginal Sonography Findings
Normal endometrium (secretory or proliferative)	6-9
Benign pathology: polyps, submucosal myoma, Disordered proliferation, simple endometrial hyperplasia	10-15
Complex hyperplasia	16-25
Endometrial malignancy	26-35

ward and clinic of Ayatollah Rouhani Hospital in Babol from 2018 to 2019 using the available sampling method (Figure 1). The mean age of the women was 46.61 ± 8.39 years with a median of 46 years (minimum age=20 and maximum age=83 years).

On the classification of pathology obtained, 221 patients (20.7%) had normal endometrium, 791 patients (74.2%) had benign pathology, including polyps, submucosal myoma, disordered proliferation, and simple endometrial hyperplasia, and 54 patients (5.1%) had complex endometrium and endometrial malignancy.

According to the results of Table 4, factors such as age, postmenopausal status, lack of hormone therapy, history of underlying disease, endometrial thickness >11 mm, presence of polyps, heterogeneous echotexture, and indistinct EMJ are significantly associated with complex hyperplasia + endometrial malignancy.

When the obtained scores were examined, 229 (21.6%), 762 (71.8%), 67 (6.3%), and 3 (0.3%) subjects had scores of 6-9, 10-15, 16-25, and 26 to 35, respectively. Because the frequency of scores from 26 to 35 was low, scores from 26 to 35 were added to the scores from 16 to 25.

**Figure 1.** Flowchart of Selection of Women With Abnormal Uterine Bleeding

The researchers' assumption in this dissertation was to add body mass index as a variable to the screening tool. Therefore, in the screening tool with body mass index, the body mass index score was added to the score, and three categories of normal, benign, and malignant were defined.

The results showed good agreement between non-invasive screening tools and pathology to detect AUB (agreement coefficient=0.90 and $P<0.001$). Based on the results, there was an unfavorable agreement between

screening tools with body mass index and pathology to diagnose AUB (agreement coefficient=0.68 and $P<0.001$) (Table 5).

The cut-off point of the non-invasive screening tool for a normal diagnosis was 9, with an area under the curve of 0.97 and a confidence interval of 0.96-0.99 ($P<0.001$) (Figure 2A).

The cut-off point of the non-invasive screening tool for a benign diagnosis was 11.5, with an area under the curve

Table 4. Relationship Between Effective Factors and Pathologies Obtained From Women With Abnormal Uterine Bleeding

Variables	Total No. (%)	Normal Endometrium No. (%)	Benign Pathology No. (%)	Complex hyperplasia+ Endometrial Malignancy No. (%)	P Value
Menopausal status					
Premenopause	88 (100)	215 (24.2)	657 (74)	16 (1.8)	<0.001*
Postmenopause	178 (100)	6 (3.4)	134 (75.3)	38 (21.3)	
Hormone therapy					
No	631 (100)	125 (19.8)	463 (73.4)	43 (6.8)	0.006*
Yes	435 (100)	96 (22.1)	328 (75.4)	11 (2.5)	
Taking tamoxifen					
No	1056 (100)	219 (20.7)	784 (74.20)	53 (5)	0.77*
Yes	10 (100)	2 (20)	7 (70)	1 (10)	
Number of underlying diseases					
0	562 (100)	126 (22.4)	429 (76.3)	7 (1.2)	<0.001*
1	287 (100)	63 (22)	206 (71.8)	18 (6.3)	
2	152 (100)	29 (19.1)	107 (70.4)	16 (10.5)	
3	48 (100)	2 (4.2)	40 (83.3)	6 (12.5)	
4	16 (100)	1 (6.3)	9 (56.3)	6 (37.5)	
5	1 (100)	-	-	1 (100)	
Diabetes					
No	878 (100)	202 (23)	643 (73.2)	33 (3.8)	<0.001*
Yes	183 (100)	27 (14.8)	119 (65)	37 (20.2)	
Hypertension					
No	820 (100)	185 (22.6)	604 (73.7)	31 (3.8)	<0.001*
Yes	241 (100)	44 (18.3)	158 (65.6)	39 (16.2)	
Hypothyroidism					
No	936 (100)	201 (21.5)	374 (72)	61 (6.5)	0.92*
Yes	125 (100)	28 (22.4)	88 (70.4)	9 (7.2)	
Endometrial thickness (mm)					
Less than 5	284 (100)	62 (21.8)	211 (74.3)	11 (3.9)	<0.001*
6-10	441 (100)	101 (22.9)	338 (76.6)	2 (0.5)	
11-21	284 (100) 57	55 (19.4)	206 (72.5)	23 (8.1)	
More than 21	(100)	3 (5.4)	36 (62.5)	18 (32.1)	
Polyps					
No	884 (100)	216 (21.4)	625 (70.7)	43 (4.9)	<0.001*
Yes	182 (100)	5 (2.8)	166 (91)	11 (6.2)	
Echotexture					
Homogenous	530 (100)	215 (40.6)	312 (58.9)	3 (0.6)	<0.001*
Cystic spaces	14 (100)	1 (7.1)	13 (92.9)	-	
Heterogeneous	522 (100)	5 (1)	466 (89.3)	51 (9.8)	
EMJ					
Distinct	1003 (100)	221 (22)	758 (75.6)	24 (2.4)	<0.001*
Indistinct	63 (100)	-	33 (52.4)	30 (47.6)	
Age (y), mean (SD)	46.61 (8.39)	43.87 (6.19)	47.65 (29.17)	56.52 (11.22)	0.004**
Body mass index (kg/m ²), mean (SD)	31.32 (5.59)	30.92 (5.54)	31.19 (5.74)	32.05	0.420**
Sonography score, mean (SD)	7 (2.51)	4.18 (0.99) ^a	7.47 (1.92) ^b	11.70 (2.92) ^c	<0.001**
Demographic profile score, mean (SD)	4.82 (2.56)	3.87 (1.28) ^a	4.82 (2.51) ^b	8.79 (3.33) ^c	<0.001**
Overall score, mean (SD)	20.50 (3.46)	8.06 (1.57) ^a	12.29 (2.03) ^b	20.50 (3.46) ^c	<0.001**

* Chi-square test; ** One-way ANOVA test.

Note: Different letters in each line indicate a significant difference between the two groups has existed.

of 0.79 and a confidence interval of 0.74-0.83 ($P < 0.001$) (Figure 2B).

The cut-off point of the non-invasive screening tool for a malignant diagnosis was 16.5, with an area under the curve of 0.97 and a confidence interval of 0.95-0.99 ($P < 0.001$) (Figure 2C).

The sensitivity and specificity of the scoring scale compared to pathology in diagnosing normal, benign, and malignant cases of AUB are given in Table 6.

Discussion

It should be noted that because in the young age of women with endometrial cancer, the frequency of scores from 26 to 35 was low, the scores from 26 to 35 were added to the scores from 16 to 25, and in general, malignancy was diagnosed for these scores. The notable point of this article was the rate of young women who have endometrial cancer, which was also included in the study by Kadkhodayan et al. They found that the prevalence of endometrial cancer in young women under 40 years of age in Iran was higher than that in developed countries (20).

One of the strengths of this study was the addition of body mass index as a variable to the screening tool and the examination of the screening tool in agreement with body mass index with pathology results in women with abnormal bleeding, which was performed along with sub-targets. The correlation rate of the screening tools with body mass index with pathology results was 68%, which was statistically unfavorable and inconsistent.

In explaining the unfavorable agreement between the screening tool and body mass index, it should be noted that patients with a body mass index $>30 \text{ kg/m}^2$ were included in the scoring system so that of 1066 individuals, 445 patients had a body mass index <30 and did not receive a score.

On the other hand, the allocation of points was agreed in such a way that the body mass index between 30 and 35 kg/m^2 received 1 point and $>35 \text{ kg/m}^2$ received 2 points, which was consistent with the opinion of the researchers.

In these interpretations, the body mass index of 42% of patients received no score, and the values of 1 and 2 assigned in other patients were insufficient to change the screening tool's score. Therefore, the inconsistency of the

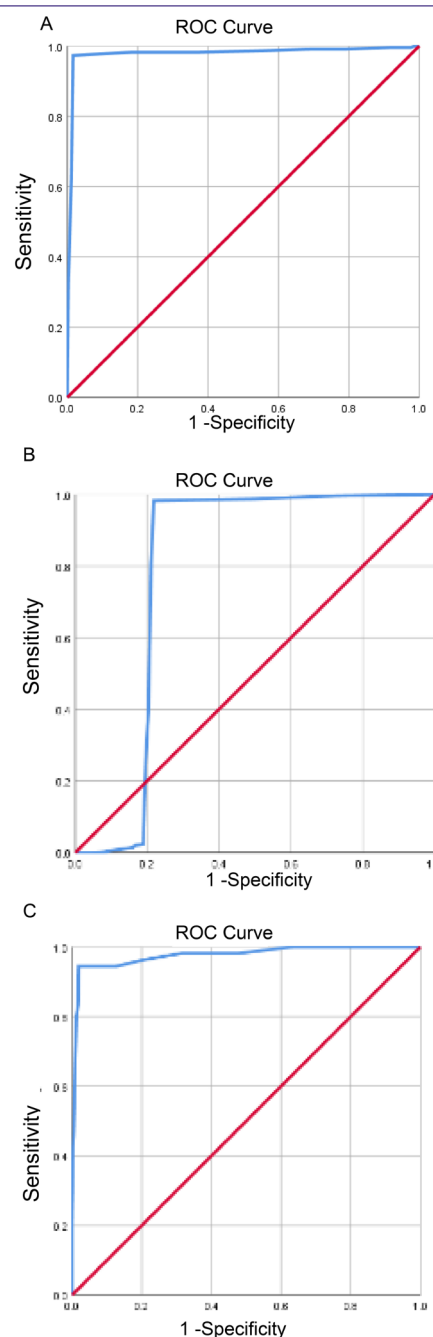


Figure 2. ROC Curve Indicating The Relationship Between the Specificity and Sensitivity of Screening Tools in Women With AUB With a Diagnosis of Normal (A), Benign (B), and Malignant (C) Pathology.

Table 5. Evaluation of the Compatibility of Non-invasive Screening Tools (With and Without Body Mass Index) With Pathology Results in Women With Abnormal Uterine Bleeding

Pathology Non-invasive Screening Tools	Normal Endometrium No. (%)	Benign Pathology No. (%)	Complex Hyperplasia + Endometrial Malignancy No. (%)	Coefficient of Agreement	P Value
Normal	215 (97.3)	14 (1.8)	-	0.90	<0.001*
Benign	5 (2.3)	754 (95.9)	3 (5.6)		
Malignant	1 (0.5)	18 (2.3)	51 (94.4)		
Body mass index (kg/m^2)					
Normal (≤ 10)	201 (91.0)	77 (9.8)	-	.068	<0.001*
Benign (11-16)	18 (8.1)	653 (83.3)	6 (11.3)		
Malignant (≥ 17)	2 (0.9)	54 (6.9)	47 (88.7)		

* Chi-square test.

Table 6. Evaluation of the Diagnostic Value of the Scoring Scale Compared to Pathology in the Diagnosis of Normal, Benign, and Malignant Cases in Women With Abnormal Uterine Bleeding

Pathology	Sensitivity 95% CI	Specificity 95% CI	Positive Predictive Value 95% CI	Negative Predictive Value 95% CI	Positive Likelihood Ratio 95% CI	Negative Likelihood Ratio 95% CI	Accuracy
Normal	97 % 95-99 %	98 % 97-99 %	94 % 91-97 %	99 % 99-100 %	58.37 34.71-98.17	0.03 0.01-0.06	98.1 %
Benign	96 % 95-97 %	97 % 95-99 %	99 % 98-100 %	89 % 86-93 %	32.98 16.66-65.28	0.04 0.03-0.06	96.2 %
Malignant	94 % 88-100 %	98 % 97-99%	73.5 62-83 %	100 % 99-100 %	50.06 31.91-78.51	0.06 0.02-0.17	97.9 %

agreement between the screening tool and the body mass index about the pathology results can be justified.

Since this was one of the researchers' premises, no published articles on this topic were found after numerous searches. It is impossible to compare the results of screening tools with those of other studies on body mass index and pathology.

Since the addition of body mass index to the scores of invasive screening tools is based on a hypothesis, and this study is one of the first studies in Iran and abroad, it is impossible to reconcile the results of the current study with those of others.

The purpose of the present study was to evaluate the agreement between the *results* of non-invasive screening tools and pathology in 3 diagnoses: normal, benign, and malignant. The non-invasive screening tools' finding was consistent with pathology results in 90%. In other words, this tool can be helpful to identify the pathology of women with AUB.

In 2018, Pandey et al conducted a study as a non-invasive screening tool for endometrial pathology at AUB. They reported that this screening tool showed a sensitivity of 72.2%, specificity of 92.1%, positive predictive value of 44.1%, and negative predictive value of 97.5% (18), similar to the current study.

Mirzaeian et al reported significant agreement in the assessment of concordance of ultrasound findings with dilation and curettage results in both abnormal and normal groups (21). Because the present study examined the compatibility of screening tools with pathology results and the survey by Mirzaeian et al examined ultrasound findings and pathology results, it was not possible to compare the results, and this study was used only due to the lack of a similar study.

In this study, the tool score's cut-off points were determined in 3 diagnoses of normal, benign, and malignant pathology to increase the screening tool's validity. Subsequently, the diagnostic value indices for the obtained cut-off points were determined.

In the normal diagnosis based on pathology, the cut-off point of the screening tool was set at a score of 9. Based on the cut-off point determined, women with AUB and a score <9 were considered to have a normal diagnosis.

This cut-off had a sensitivity and specificity of 97% and 98%, respectively. On the other hand, the area under the curve of this score was 97%, which is desirable because it shows the accuracy of the screening tool in detecting normal cases.

Based on the above results, it can be concluded that the non-invasive screening tool at cut-off point 9 can be an alternative to invasive diagnostic methods in diagnosing normal pathology.

In women with a diagnosis of benign pathology, the cut-off point of the non-invasive screening tool was 11.5 with a sensitivity of 96%, specificity of 97%, and area under the curve of 79%. Based on this, it could be predicted that women with a score <11.5 had benign pathology results. The cut-off point of the non-invasive screening tool in women diagnosed with malignant pathology was 16.5, with a sensitivity of 94%, specificity of 98%, and area under the curve of 97%.

Based on the cut-off points and diagnostic value indices obtained for all three diagnoses, it can be concluded that non-invasive screening tools have high diagnostic accuracy in diagnosing the cause of abnormal bleeding in women and can be used to predict pathology results.

Salehi Aali et al reported that the sensitivity and specificity of TVS in distinguishing normal from AUB were 59.5% and 65.4%, respectively. The positive and negative predictive values were 12.4% and 84.58%, respectively. Moreover, they have stated that because of the sensitivity and specificity of TVS in correctly diagnosing abnormal individuals (with abnormal bleeding) and its low cost and non-invasive nature, the present method is recommended in the first stage of evaluating patients suffering from abnormal bleeding (19). Salehi Aali et al compared the results of TVS with those of pathology and did not evaluate the invasive screening tools. Since this is the first study in this field, it is impossible to compare the results in agreement and disagreement (19).

The current study examined demographic characteristics, TVS scores, total scores, and pathology results. The results showed that the average scores of all three scales were higher in women with malignant pathology compared with benign and normal diagnoses. In addition, the score in all three scales was higher for

diagnoses of benign pathology than for typical diagnoses. This significant difference in scores may help predict pathology outcomes.

Yela et al have concluded that TVS in postmenopausal women is more effective for diagnosing endometrial disease (22). However, in our study, screening tools were an effective method in diagnosing AUB because the screening tools were not evaluated in their research.

One of the strong points of this study was examining the relationship between clinical variables and pathological diagnosis. The results indicated that postmenopausal status, absence of hormonal therapy, increase in underlying diseases, diabetes, and hypertension, endometrial thickness >11 mm, polyps, echo-heterogeneity, indistinct EMJ, and old age were associated with the diagnosis of malignant pathology. Investigating risk factors for malignancy in women with AUB is not one of the objectives of this study, as many others have already explored this area. The current study investigated only the relationship between baseline data and clinical variables with three pathological diagnoses in these women.

In the study by Yazdani et al, factors such as menopause, bleeding rate, body mass index, and history of internal diseases were among those that were more prevalent in women with endometrial cancer (23). The study mentioned above centered on variables associated with an increased risk for endometrial cancer, whereas the present study evaluated the diagnostic value of screening tools versus pathology.

Mirzaeian et al noted that major and malignant pathologies such as carcinoma metaplasia could present a size limit of <8 mm and even close to 5 mm. Therefore, even when the size is less than 8 mm, dilatation and curettage with TVS appear necessary (21). However, in our findings, endometrial thickness greater than 11 mm has a prognostic role in malignant pathology. Mirzaeian et al (21) examined TVS and pathology, and since they did not use screening tools, it is impossible to compare their results with ours.

In conclusion, 90% agreement of screening tools with pathology has indicated that these tools can be used to predict the pathological discernment in women suffering from AUB.

Limitations of the study

Due to time and space constraints, this study was conducted over a period of one year on patients referred to a hospital. Also, the treatment process of the patients was not followed up on. Therefore, it is better to conduct more extensive studies within the province and also compare different geographical locations. Treatment of patients should also be followed up according to the type of diagnosis. Gender and the number of children born were also not examined in this study. These factors can also be considered as variables in future studies.

Authors' Contribution

Conceptualization: Simin Asadollahi, Zinatosaadat Bouzari.

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Writing—review & editing: Simin Asadollahi, Mohammad Ranaee.

Conflict of Interests

Authors declare that they have no conflict of interests.

Ethical Issues

This study was approved by the Ethics Committee of Babol University of Medical Sciences (Ethics code: IR.MUBABOL.REC.1399.127). Informed consent was obtained from the patients to participate in the study.

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