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ORIGINAL RESEARCH

A Preoperative Scoring System Based on Clinical Characteristics and Hematologic Parameters for Differentiating Uterine Leiomyosarcoma from Leiomyoma

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Purpose: Preoperative diagnosis of uterine leiomyosarcoma (ULMS) can be difficult due to its ability to mimic benign leiomyomas (LM). The current study aimed to investigate the influence of preoperative clinical characteristics and hematologic parameters on preoperative diagnosis and to design a scoring system.

Patients and Methods: We conducted a retrospective analysis of 288 patients with uterine tumors treated at the First Affiliated Hospital of Wenzhou Medical University between January 2006 and April 2022, including 64 with ULMS and 224 with LM. Preoperative clinical and laboratory variables were compared between groups. Logistic regression analysis was employed to identify predictors of ULMS, with receiver operating characteristic (ROC) curves used to evaluate diagnostic performance.

Results: Multivariate analysis identified four independent risk factors for ULMS: older age (>48 years), larger tumor size (>9.7 cm), elevated systemic immune-inflammation index (SII > 500), and higher controlling nutritional status score (CONUT ≥ 3) (all P<0.001). A preoperative scoring system was developed by assigning one point for each risk factor, yielding a total possible score of 0–4 points. A score ≥ 2 points demonstrated significant utility in differentiating ULMS from LM (AUC = 0.823, sensitivity 64.1%, specificity 85.3%).

Conclusion: This single-center retrospective study demonstrates that the integration of age, tumor size, SII, and CONUT score shows promising utility for preoperative differentiation between ULMS and LM. The constructed scoring system may provide valuable auxiliary support for identifying occult ULMS preoperatively. However, given the study's limitations, including its retrospective design and sample size, external validation through large-scale, multicenter prospective studies is necessary before clinical implementation.

Keywords: uterine leiomyosarcoma, systemic immune-inflammation index, SII, controlling nutritional status score, CONUT score, diagnosis, scoring system

Introduction

Globally, uterine myoma remains the leading cause of hysterectomy, affecting 40–60% of reproductive-aged women. Minimally invasive surgery, such as a myomectomy and hysterectomy, is associated with a low complication rate, mild pain, and quick recovery.[1] A morcellation procedure can also be used to treat giant uterine myoma minimally invasively. Moreover, it has been reported that up to 0.49% of women undergoing hysterectomy for presumed benign LM develop unexpected sarcomas.[2] The ULMS is a rare and aggressive tumor that arises from uterine smooth muscle cells, which makes it a serious concern for patients and healthcare providers alike.

Currently, despite the use of various suggested tools, there is no reliable preoperative diagnostic test for predicting ULMS. Some clinical studies have indicated that age, menopausal status, body mass index (BMI), and tumor size may be helpful, but

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they cannot provide a definitive diagnosis. There are no specific serum tumor markers. While MRI is slightly more effective, and 18-fluorine-fluorodeoxyglucose positron emission tomography/computed tomography (18F-FDG PET-CT) can be useful to distinguish between the two entities, these are not foolproof, and their high cost and limited accessibility make them less practical for diagnosing uterine tumors.[3] Cancer cachexia, which serves as an indicator of the general health of cancer patients, often compromises their nutritional status. Controlling nutritional status score (CONUT) consists of serum albumin concentration, lymphocyte count, and cholesterol concentration, and is a simple and validated objective data assessment method.[4] Multiple types of malignancies are initiated, developed, and progressed through the interplay between the systemic immune-inflammation index (SII) and the local immune response. Local immune responses and systemic inflammation are more accurately measured with the SII, which is not only a prognostic factor for mortality in patients with solid tumors, but also an independent risk indicator for developing a solid cancer.[5–7] However, there is currently no research on the clinical significance of the CONUT score and the SII in patients with ULMS.

Accordingly, the aim of our study was to examine the clinical importance of the pretreatment CONUT score and SII in patients diagnosed with ULMS. Additionally, we sought to create a scoring system based on preoperative clinical characteristics that could differentiate ULMS from LM.

Materials and Methods

Patients

This retrospective case-control study retrospectively enrolled 64 patients who were first diagnosed with ULMS and underwent surgery between January 2006 and April 2022 at the First Affiliated Hospital of Wenzhou Medical University. The inclusion criteria were: a) postoperative pathological confirmation of ULMS (for the case group) or LM (for the control group); b) initial treatment (no prior surgical intervention for uterine tumors); c) no evidence of tumor dissemination (eg, distant metastasis, lymph node involvement) before surgery; d) no history of inflammatory diseases (eg, rheumatoid arthritis, chronic bronchitis) or other malignant tumors; e) no evidence of endometriosis or adenomyosis (confirmed by preoperative ultrasonography and postoperative pathology); f) no major comorbidities affecting immune-inflammatory or nutritional status (eg, type 2 diabetes mellitus, chronic kidney disease [stage ≥3], chronic liver disease, or cardiovascular disease requiring long-term antiplatelet/anticoagulant therapy); and g) no use of drugs that may modulate immune-inflammatory status within 1 month before surgery (including hyperlipidemia treatment, systemic steroids, non-steroidal anti-inflammatory drugs [NSAIDs] used continuously for >2 weeks, or immunosuppressants). The exclusion criteria for the control group were consistent with those for the ULMS group, with additional confirmation of no pathological features suggestive of malignancy or borderline lesions. Preoperative data included patient age at the time of diagnosis, gravity, parity, BMI, menstrual status, blood test results and ultrasonography results of the largest diameter of myoma. Ultrasonography and laboratory tests were performed within one month prior to surgery. CONUT scores were calculated from the serum ALB concentration, total lymphocyte count, and total cholesterol concentration (Table 1). The SII was calculated with the formula SII = (P × N)/L, P, N, and L refer to the peripheral platelet, neutrophil, and lymphocyte counts, respectively.

This study was performed under the principles of the Declaration of Helsinki and got approval to use the registry data while maintaining confidentiality. All methods were performed under the relevant guidelines and regulations. This study was approved by the Ethical Committee of the First Affiliated Hospital of Wenzhou Medical University (number KY2023-R097), and written informed consent was obtained.

Statistical Analysis

Data analysis was conducted using R 4.4.2 (R Foundation for Statistical Computing, Vienna, Austria). Continuous variables with normal distribution were presented as mean ± standard deviation and compared using an independent sample Student's *t*-test. Non-normally distributed variables were described as median (interquartile range) and compared using the Wilcoxon rank sum test. Categorical variables were presented as frequencies (percentages) and compared using the chi-square test or Fisher's exact test as appropriate.

Table 1 Nutritional Status Assessment According to CONUT Scoring System

Parameters	Malnutrition Status			
	Normal	Light	Moderate	Severe
Serum albumin (g/L)	≥35.0	30.0–34.9	25.0–29.9	<25.0
Score	0	2	4	6
Total lymphocyte count (/µL)	≥1600	1200-1599	800-1199	<800
Score	0	1	2	3
Total cholesterol (mg/dL)	≥180	140-179	100-139	<100
Score	0	1	2	3
Total score	0-1	2-4	5-8	9-12

Variables showing significant differences in univariate analyses (P < 0.05) were selected for further analysis. Receiver operating characteristic (ROC) curve analysis, along with Youden's index, was employed to determine optimal cutoff values for continuous variables. These dichotomized variables were then entered into a multivariate logistic regression analysis using forward stepwise selection (Forward: LR) to identify independent risk factors for ULMS.

A weighted scoring system was developed based on the regression coefficients from the multivariate model. The performance of the scoring system was evaluated using ROC curve analysis, with sensitivity, specificity, positive predictive value, and negative predictive value calculated at the optimal cutoff determined by Youden's index. The Hosmer-Lemeshow test was used to assess model calibration. Statistical significance was set at P < 0.05 (two-tailed).

Results

Patient Characteristics

64 patients in the ULMS group and 224 patients in the control group were enrolled in this study. The preoperative clinical characteristics of the two groups are shown in Table 2. Patients in the ULMS group tended to be older (median age 51 vs 45 years old, P < 0.001), with a greater percentage of postmenopausal patients (39.0% vs 5.0%, P < 0.001). Patients in two groups had the same median parity of 2, but the mean number of children was higher in the ULMS group (2.08 vs 1.64), and the Wilcoxon rank sum test showed a significant difference (Z=3.795, P < 0.001). There were no notable variances in BMI or gravidity between the two groups. The ultrasonographic examination findings revealed that the ULMS group displayed a significantly larger myoma diameter compared to the control group (8.5 vs 6.8 cm, P < 0.001). For laboratory tests, significant differences were observed between the ULMS and LM groups for the following variables: white blood cell count, neutrophil count, the SII, the serum ALB concentration, and the CONUT score. However, there were no significant differences in the CA 125 level, hemoglobin, lymphocyte, platelet, or cholesterol concentrations.

Identification of Independent Risk Factors and ROC Analysis

To identify potential predictors for ULMS, we first performed univariate analyses on preoperative clinical and hematologic parameters (Table 2). Variables showing significant association (P < 0.05) were selected for further investigation. Receiver operating characteristic (ROC) curve analysis was then employed for these significant continuous variables to determine optimal cutoff values for differentiating ULMS from LM. The results were as follows: age (>48 years, AUC=0.771, P<0.001), tumor size (>9.7 cm, AUC=0.655, P<0.001), SII (>500, AUC=0.625, P=0.001), and CONUT score (≥3, AUC=0.694, P<0.001).

Subsequently, these dichotomized variables, along with other significant univariate factors, were entered into a multivariate logistic regression model to identify independent risk factors. As detailed in Table 3, four factors retained independent significance: age >48 years (OR 8.411, 95% CI 4.087–17.312; P<0.001), tumor size >9.7 cm (OR 6.151, 95% CI 2.411–15.693; P<0.001), SII >500 (OR 4.078, 95% CI 1.850–8.991; P<0.001), and CONUT score ≥ 3 (OR 9.700, 95% CI 2.902–32.428; P<0.001).

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Table 2 The Preoperative Clinical Characteristics of ULMS Group and Control Group

Characteristics	ULMS (n=64)	Uterine Leiomyoma (n=224)	P-value
Age (years)	50.47±8.69	44.13±5.91	<0.001
Postmenopausal, n (%)	25(39.06%)	11(4.91%)	<0.001
Gravidity	3.12±1.48	2.97±1.40	0.420
BMI (kg/m2)	23.36±3.08	23.29±2.95	0.858
Tumor size (cm)	8.43±3.32	6.79±2.10	<0.001
>9.7cm, n (%)	26(40.63%)	13(5.80%)	<0.001
CA125 (IU/L)	17.40(11.90,27.60)	15.45(11.50,24.60)	0.382
White blood cell (×10^9/L)	6.82(5.37,8.10)	5.99(4.86,7.11)	0.002
Hemoglobin (g/L)	113.13±26.21	116.17±19.49	0.273
Lymphocyte (×10^9/L)	1.74±0.52	1.76±0.48	0.755
Neutrophil (×10^9/L)	5.16±5.17	3.79±1.40	<0.001
Platelet (×10^9/L)	295.89±82.52	295.42±82.18	0.965
SII	693.75(502.44,1109.22)	557.79(407.16,785.39)	0.001
Serum albumin (g/L)	41.15±4.37	43.37±3.90	<0.001
Total cholesterol (mmol/L)	5.15±1.37	5.03±0.96	0.390
CONUT	1.37±1.63	0.75±0.90	<0.001

Notes: Data given as mean ± SD or n (%) or median (interquartile range). Bold text indicates a statistically significant difference (P < 0.05).
Abbreviations: BMI, body mass index; CONUT, the controlling nutritional status score; SII, systemic immune-inflammation index.

Table 3 Independent Risk Factors for ULMS in Multivariate Logistic Regression Analysis

Variables	β	SE	Wald	P-value	OR	95% CI
Age >48 years	2.130	0.421	25.584	<0.001	8.411	3.692–19.162
Tumor size >9.7 cm	1.817	0.456	15.867	<0.001	6.151	2.518–15.026
SII >500	1.405	0.403	12.143	<0.001	4.078	1.850–8.991
CONUT ≥3	2.272	0.584	15.126	<0.001	9.700	3.089–30.462
Constant	−4.215	0.512	67.732	<0.001	0.015	–

Abbreviations: CONUT, the controlling nutritional status score; SII, systemic immune-inflammation index; SE, Standard Error.

Development and Performance of the Preoperative Scoring System

A simple preoperative clinical characteristics scoring system was developed by assigning one point for each of the four independent risk factors identified above, yielding a total possible score of 0 to 4 points. The diagnostic performance of this cumulative score was evaluated using ROC curve analysis (Figure 1 and Supplementary Table). The area under the curve (AUC) for the scoring system was 0.823 (95% CI, 0.586–1.000; P<0.001). The optimal cutoff value, determined by maximizing Youden's index, was ≥2 points. At this threshold, the scoring system demonstrated a sensitivity of 64.1% (41/64), a specificity of 85.3% (191/224), a positive predictive value of 55.4%, and a negative predictive value of 89.3%. The Hosmer-Lemeshow test indicated a good model fit (P = 0.430).

Novelty and Key Findings

Our scoring system is novel in its unique integration of clinical characteristics (age, tumor size) with immune-nutritional indicators (SII, CONUT score). No prior study has simultaneously utilized the SII (calculated from platelet, neutrophil, and lymphocyte counts) and the CONUT score (based on albumin, lymphocyte, and cholesterol) for preoperative ULMS/LM differentiation, and all components are derived from routine, low-cost tests.

In univariate analysis, WBC count (P=0.002) showed statistical differences between groups (Table 2). However, it was excluded from the final multivariate model. WBC count was redundant due to significant collinearity with the SII,

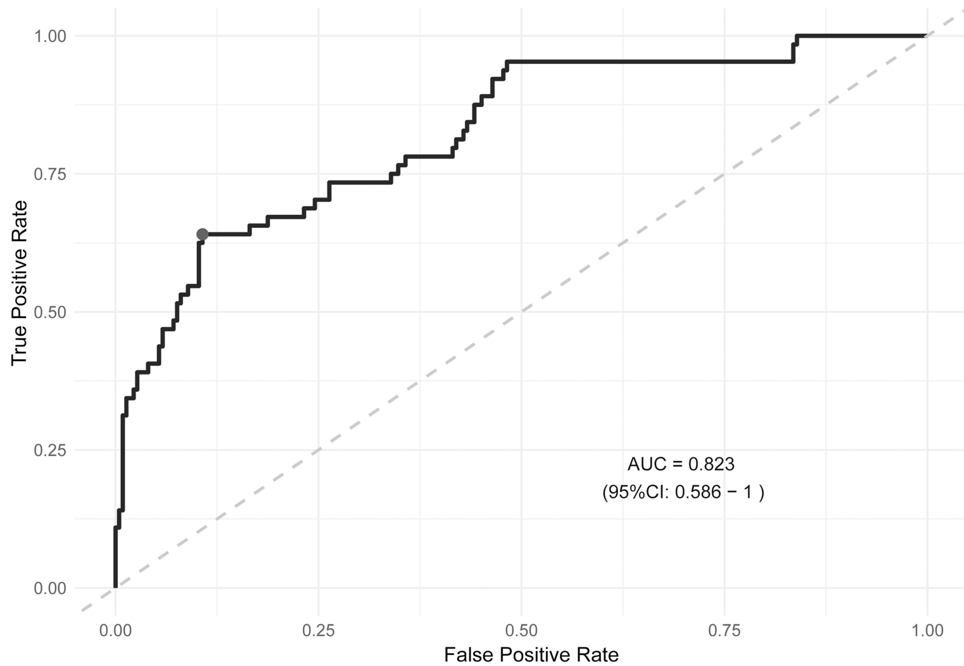

Figure 1 Receiver operating characteristic (ROC) curve of the preoperative scoring system for differentiating uterine leiomyosarcoma (ULMS) from leiomyoma (LM).

which provides a more comprehensive reflection of systemic immune-inflammation. Excluding this variable improved model parsimony, with the Hosmer-Lemeshow test confirming good calibration (P=0.430).

The scoring system's modest sensitivity (0.641 at cutoff ≥2 points) should be interpreted alongside its high specificity (0.853). This profile is strategically valuable for a screening tool in a condition where the benign entity (LM) is far more prevalent. High specificity effectively rules out non-ULMS cases, reducing unnecessary invasive evaluations for low-risk patients. The system is designed for preliminary risk stratification, not definitive diagnosis. Patients with scores <2 (low risk) still undergo standard preoperative monitoring and postoperative pathological evaluation, ensuring that occult ULMS is ultimately identified, while those with scores ≥2 (high risk) warrant more intensive preoperative assessment.

Furthermore, although postmenopausal status was significantly associated with ULMS in univariate analysis (Table 2), it was not included as an independent variable in the multivariate model alongside age. This decision was made due to the significant clinical and statistical collinearity between advanced age and menopausal status. Including both would have introduced redundancy and potential multicollinearity, compromising the model's stability. Age was selected for the final model as it is an objective, continuously measurable variable that effectively captures the risk profile associated with both increasing age and the likelihood of being postmenopausal, thereby contributing to a more parsimonious and clinically applicable scoring system.

Discussion

Our study developed and validated a novel preoperative scoring system that integrates clinical characteristics with immune-nutritional indices, as age, tumor size, SII, and CONUT score, to differentiate uterine leiomyosarcoma (ULMS) from leiomyoma (LM). The system achieved an AUC of 0.823, with a high specificity of 85.3% at a cutoff of ≥2 points. This work directly addresses a critical unmet need in gynecologic oncology: the reliable preoperative identification of occult ULMS, thereby mitigating the risk of unintended morcellation.[2,8] In contrast to advanced imaging techniques like MRI, which are not universally accessible due to cost and availability,[3] our model leverages routine, low-cost parameters, offering a practical and complementary risk-stratification tool for widespread clinical use.

Consistent with prior literature,[9–11] we confirmed that advanced age and larger tumor size are robust predictors of ULMS. Our cohort demonstrated a significant age disparity (51 vs 45 years, p<0.001) and a higher prevalence of postmenopausal status in the ULMS group (39% vs 5%, p<0.001). While menopausal status was significant in univariate analysis, it was not included in the final multivariate model alongside age due to significant collinearity, and age was selected for its objectivity and greater utility in a clinical scoring system. Similarly, our findings align with ESGO guidelines and other studies that identify larger tumor size (>8 cm) as a risk factor.[12,13] Furthermore, the result of this study highlighted that the tumor size in ULMS patients was larger compared to those with LM, while ULMS tumors measuring on average 8.5 cm vs 6.8 cm for LM ($P < 0.001$). Notably, a tumor size larger than 9.7 cm was identified as a strong independent predictor of ULMS, further emphasizing the importance of tumor size in identifying this condition.

Systemic inflammation plays a critical role in cancer progression, mediated by cytokines, immune cells, and various inflammatory mediators.[14,15] The systemic immune-inflammation index (SII), integrating platelet, neutrophil, and lymphocyte counts, has emerged as a valuable prognostic tool in several malignancies, including ovarian, cervical, and breast cancers.[7,16] The rationale for its utility lies in the biological roles of its components: neutrophils can remodel the tumor microenvironment and promote tumor growth and metastasis,[17,18] activated platelets may act as chemoattractants facilitating metastatic niche formation and epithelial-mesenchymal transition,[19,20] and lymphopenia is often associated with impaired cytotoxic T-cell function, enabling tumor immune evasion.[21] Collectively, an elevated SII reflects a pro-tumorigenic milieu conducive to cancer initiation and spread. While SII has proven prognostic in soft tissue sarcomas and other solid tumors,[22] its diagnostic value for uterine leiomyosarcoma (ULMS) remained unexplored. Our study establishes that an SII >500 is a significant independent predictor for ULMS (OR 4.078, 95% CI 1.850–8.991), underscoring its relevance in preoperative differentiation from benign leiomyoma.

The Controlling Nutritional Status (CONUT) score offers an integrated assessment of a patient's immune-nutritional status using serum albumin, total lymphocyte count (TLC), and total cholesterol (TC).[23] Its components are mechanistically linked to cancer outcomes: serum albumin reflects both nutritional status and systemic inflammation; lymphocytes are crucial for antitumor immunity,[24] and cholesterol serves as a marker of energy reserves and a component of cell membranes, potentially influencing cancer cell behavior.[25,26] Consequently, malnutrition, as captured by an elevated CONUT score, is linked to tumor progression, potentially due to cancer-induced metabolic alterations, diminished immune competence, and reduced tolerance to therapy.[27,28] This score has demonstrated prognostic value across various cancers, including ovarian, colorectal, and renal cell carcinomas,[29–35] and is associated with poorer outcomes in soft tissue sarcomas.[36–38]

To improve upon individual variables, others have proposed multi-parameter models. Our scoring system is designed not to replace but to complement existing diagnostic pathways. As advanced imaging like MRI provides definitive anatomical assessment,[39] our tool serves as a preliminary filter. Patients scoring ≥2 can be prioritized for definitive MRI, preventing inappropriate morcellation, while those scoring <2 can avoid unnecessary, costly imaging, optimizing resource allocation.

The high specificity (85.3%) of our system is its principal clinical strength, effectively ruling out ULMS in the vast majority of benign cases and reducing unnecessary interventions. While the sensitivity is modest (64.1%), meaning some ULMS cases may be missed, this risk is mitigated by standard clinical safeguards: all patients with uterine masses undergo preoperative ultrasonography, and definitive postoperative pathology remains the gold standard. Thus, the scoring system introduces a valuable triage step without eliminating existing safety nets.

Our study has limitations. Its single-center, retrospective nature necessitates validation in larger, multicenter prospective cohorts. The sensitivity may be improved in the future by integrating preoperative LDH or specific ultrasound features (eg, tumor border irregularity).[13] In conclusion, we present a practical, cost-effective scoring system that shows significant promise for preoperative ULMS risk stratification. Pending external validation, this tool has the potential to enhance clinical decision-making and improve patient safety by identifying high-risk cases before surgery.

Conclusion

In summary, this single-center retrospective study demonstrates that integrating age, tumor size, CONUT score, and SII has preliminary utility for differentiating ULMS from LM. These indicators are readily measurable, cost-effective, and widely accessible in clinical practice, making the proposed scoring system a potential auxiliary tool for preoperative assessment. However, due to limitations including the retrospective single-center design, relatively small sample size, and potential residual confounding, the system cannot be recommended for routine clinical use at this stage. Future validation in large-scale, multicenter prospective studies with diverse cohorts is mandatory to confirm its generalizability and robustness before clinical adoption.

Abbreviations

ULMS, uterine leiomyosarcoma; LM, leiomyoma; ROC, receiver operating characteristic; SII, systemic immune-inflammation index; CONUT, controlling nutritional status score; BMI, body mass index; ALB, albumin; ESGE, European Society of Gastrointestinal Endoscopy; NLR, Neutrophil-lymphocyte ratio; PLR, platelet-lymphocyte ratio; TLC, total lymphocyte count; TC, total cholesterol.

Data Sharing Statement

All data generated or analysed during this study are included in this published article and its supplementary information file.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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