

# Diagnostic Accuracy of Transvaginal Ultrasound in Diagnosis of Endometrial Carcinoma among Women with Post-Menopausal Bleeding Taking Histopathology as Gold Standard

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## ABSTRACT

**Background:** Endometrial carcinoma is a significant cause of morbidity among post-menopausal women. Early detection through non-invasive methods like transvaginal ultrasound (TVUS) is essential, but its diagnostic accuracy varies compared to histopathology, the gold standard.

**Objective:** To assess the diagnostic accuracy of transvaginal ultrasound (TVUS) in detecting endometrial carcinoma in postmenopausal women with bleeding, using histopathology as the gold standard.

**Study Design:** cross-sectional study

**Study Setting:** The study was carried out Gynaecology & Radiology Department of Lahore Medical and Dental College, Lahore from April 2023 to September 2023.

**Methodology:** A total of 120 postmenopausal women with bleeding were enrolled. Each underwent transvaginal ultrasound (TVUS) to assess endometrial thickness, followed by an endometrial biopsy. An endometrial thickness threshold of 4 mm was used on TVUS. Histopathological findings were compared with TVUS results to determine sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

**Results:** The mean endometrial thickness was  $7.6 \pm 3.2$  mm. TVUS demonstrated a sensitivity of 83.3%, specificity of 33.3%, PPV of 29.4%, NPV of 85.7%, and an overall diagnostic accuracy of 45.8%. While effective in excluding malignancy, TVUS exhibited a high false-positive rate.

**Practical Implication:** Transvaginal ultrasound can serve as a valuable non-invasive screening tool for early detection of endometrial carcinoma in women with postmenopausal bleeding, aiding in timely diagnosis and management.

**Conclusion:** TVUS is a valuable screening tool with high sensitivity in detecting endometrial carcinoma. However, its low specificity highlights the need for histopathological confirmation to ensure accurate diagnosis.

**Keywords:** Diagnostic accuracy, Endometrial carcinoma, Histopathology, Post-menopausal bleeding, Sensitivity, Specificity, Transvaginal ultrasound (TVUS).

## INTRODUCTION

Endometrial carcinoma predominantly impacts the endometrial lining of the uterus known as the endometrium, and manifests through abnormal uterine bleeding, particularly post-menopausal bleeding (PMB).<sup>1,2</sup> As such, post-menopausal bleeding is often considered a red flag, warranting prompt and thorough diagnostic evaluation to rule out the possibility of malignancy. Early detection and accurate diagnosis of endometrial carcinoma are crucial to improving treatment outcomes and survival rates.<sup>3</sup> Various diagnostic modalities have been employed in assessing women with postmenopausal bleeding (PMB), transvaginal ultrasound (TVUS) is one of the most commonly utilized initial diagnostic modalities.<sup>4</sup>

TVUS is a non-invasive, readily available, and cost-effective diagnostic tool that enables clinicians to assess the endometrial thickness and detect any abnormalities. It has emerged as a valuable first-line imaging modality in assessing endometrial pathologies, particularly in the context of post-menopausal bleeding.<sup>5</sup> The ability of TVUS to measure endometrial thickness and detect structural abnormalities makes it a preferred choice in clinical practice, especially as it provides immediate results without exposing patients to ionizing radiation.<sup>6</sup> Histopathological analysis of endometrial tissue is the definitive standard for identifying endometrial cancer. A biopsy of the endometrial tissue followed by histopathological analysis, provides definitive evidence of cancer presence or absence.<sup>7</sup> However, obtaining a biopsy can be invasive, costly, and may carry certain risks, particularly for elderly and fragile patients. Consequently, there is growing interest in finding non-invasive methods with high

diagnostic accuracy that could reduce the need for biopsies, particularly when the risk of malignancy is low.<sup>8</sup> The sensitivity and specificity of TVUS in predicting malignancy are influenced by several factors, including the cut-off value of endometrial thickness, the expertise of the operator, and patient characteristics such as body mass index and hormonal therapy history.<sup>9,10</sup>

The rationale behind this study lies in the need to establish a non-invasive, reliable diagnostic tool that can reduce unnecessary biopsies. TVUS has shown promise, but its accuracy compared to histopathology must be clarified to ensure the best diagnostic approach for patient care. This study's findings will enhance the existing body of information by offering insights into whether TVUS can reliably be used as a non-invasive diagnostic tool in cases of post-menopausal bleeding, potentially reducing the need for invasive procedures.

## MATERIALS AND METHODS

The research received approval from the institutional ethical review board, and all participants gave their written informed consent. This cross-sectional study took place at the Gynaecology & Radiology Department of Lahore Medical and Dental College, Lahore, spanning from April 2023 to September 2023. The privacy and confidentiality of all patient data were strictly maintained throughout the study. Women aged 45 and above who had experienced at least 12 consecutive months of amenorrhea and were suspected of having endometrial pathology were included in the study. Women with post-menopausal bleeding and women who provided informed consent to undergo both TVUS and endometrial biopsy people who had never had endometrial cancer before were enrolled in this research. Women with an established diagnosis of endometrial cancer were included in the study. Women who refused to participate or did not consent to an

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endometrial biopsy were excluded. Additionally, patients with incomplete data or those who were lost to follow-up were also excluded from the analysis. The sample size was calculated using a formula designed to estimate diagnostic accuracy based on sensitivity and specificity. With a presumed sensitivity of 80% and specificity of 85%, along with a confidence level of 95% and a margin of error of 10%, the minimum required sample size was determined to be 120 patients.<sup>13</sup>

After obtaining informed consent, all eligible participants underwent a detailed clinical assessment, followed by a transvaginal ultrasound (TVUS) to assess the endometrial thickness and any structural abnormalities. TVUS was performed using a high-resolution transvaginal probe, and endometrial thickness greater than 4 mm was considered suspicious for malignancy. Additional ultrasonographic findings, such as irregularity of the endometrium and heterogeneity, were also recorded. Following TVUS, all participants underwent an endometrial biopsy, which served as the reference standard for diagnosing endometrial carcinoma. The biopsy samples were sent to the pathology department for histopathological examination, and the results were used to confirm or rule out malignancy. The findings of TVUS were categorized as either positive or negative for endometrial carcinoma based on the pre-defined cut-off of endometrial thickness. Similarly, histopathological results were categorized as malignant or benign. A 2x2 contingency table was constructed to compare the TVUS results with the histopathology findings. Statistical analysis was conducted using SPSS version 25.0, with significance defined as a p-value < 0.05.

**RESULTS**

The study demographics (Table 1) revealed that the most patients belonged to the 56-65 age group (37.5%), with the 66-75 age group being the second most common (29.2%). The mean age was 62.4 ± 7.8 years. In terms of duration of post-menopausal bleeding, most patients (41.7%) experienced bleeding for 4-6 months. Additionally, 75% of the participants were multiparous, and 41.7% were overweight in table 1.

As shown in Table 2, 70.8% of patients exhibited an endometrial thickness exceeding 4 mm on TVUS, indicating suspicion for endometrial carcinoma, whereas 29.2% had a thickness of 4 mm or less in table 2.

The contingency table comparing TVUS results with histopathology (Table 3) showed that out of the 85 patients who tested positive on TVUS, 25 were confirmed to have endometrial carcinoma by histopathology. Among the 35 patients with negative TVUS findings, 30 had benign histopathology results in table 3.

Table 1: Study Demographics

Parameter	Category	Frequency (%)
Age Group (Years)	45-55	25 (20.8)
	56-65	45 (37.5)
	66-75	35 (29.2)
	> 75	15 (12.5)
Mean Age (± SD)		62.4 ± 7.8
Duration of Bleeding	1-3 months	40 (33.3)
	4-6 months	50 (41.7)
	7-12 months	30 (25.0)
Parity	Nulliparous	30 (25.0)
	Multiparous	90 (75.0)
Body Mass Index (BMI)	Normal	45 (37.5)
	Overweight	50 (41.7)
	Obese	25 (20.8)

Table 2: Distribution of Measurement of Endometrial Thickness Using Transvaginal Ultrasound (TVUS)

Endometrial Thickness	Frequency (n = 120)	Percentage (%)
> 4 mm (Positive)	85	70.8
≤ 4 mm (Negative)	35	29.2
Total	120	100

The diagnostic indices of TVUS (Table 4) indicated that the sensitivity of TVUS was 83.3%, meaning it correctly identified 83.3% of the true positive cases. However, the specificity was low at 33.3%, indicating that many false positives were recorded. The positive predictive value (PPV) was 29.4%, while the negative predictive value (NPV) was 85.7%, meaning TVUS was more reliable in ruling out malignancy. The overall diagnostic accuracy of TVUS was 45.8% in table 4.

Table 3: 2x2 Contingency Table (TVUS vs. Histopathology)

TVUS Result	Histopathology Positive (n = 30)	Histopathology Negative (n = 90)	Total (n = 120)
Positive (> 4 mm)	25	60	85
Negative (≤ 4 mm)	5	30	35
Total	30	90	120

Table 4: Diagnostic Indices of TVUS

Parameter	Formula	Calculation	Value (%)
Sensitivity	TP / (TP + FN) × 100	25 / 30 × 100	83.3
Specificity	TN / (TN + FP) × 100	30 / 90 × 100	33.3
Positive Predictive Value	TP / (TP + FP) × 100	25 / 85 × 100	29.4
Negative Predictive Value	TN / (TN + FN) × 100	30 / 35 × 100	85.7
Overall Accuracy	(TP + TN) / Total × 100	55 / 120 × 100	45.8

**DISCUSSION**

Endometrial carcinoma is a significant concern among women with post-menopausal bleeding, necessitating prompt and accurate diagnosis. Transvaginal ultrasound (TVS) is a widely used, non-invasive diagnostic tool for evaluating endometrial abnormalities in such patients.<sup>11</sup> However, the diagnostic accuracy of TVS in detecting endometrial carcinoma remains a critical area of research.<sup>12</sup> This study aims to assess the sensitivity, specificity, and overall diagnostic accuracy of transvaginal ultrasound in diagnosing endometrial carcinoma, with histopathology serving as the gold standard for confirmation. Understanding the reliability of TVS can help refine diagnostic protocols for early detection and management.

For instance, Iqbal et al. (2018) reported a sensitivity of 86.3% and specificity of 93.0%, indicating a high sensitivity similar to our results. However, our specificity was lower, suggesting a need to enhance differentiation between malignant and benign conditions. Zafar et al. (2020) presented a higher sensitivity of 95.1% and specificity of 87.4%. This discrepancy could be attributed to differences in patient demographics, such as age and menopause duration, or variations in the criteria for a positive ultrasound result.<sup>15,16</sup>

Our findings also resonate with Qurrat-Ul-Ain et al. (2018), who noted a specificity of 60%, indicating a trend of lower specificity in certain studies. This suggests a potential for a higher rate of false positives in our sample, raising questions about the contributing factors to these discrepancies.<sup>18</sup> Gupta et al. (2023) highlighted the performance of TVS compared to hysteroscopy, noting a sensitivity of 91.6% for TVS in malignancy diagnosis, which is comparable to our results. This reinforces TVS's effectiveness as a screening tool, but it also highlights the necessity of confirmatory procedures like hysteroscopy when malignancy is suspected. Their findings about increased diagnostic accuracy when combining modalities further emphasize the need for an integrated diagnostic approach.<sup>14</sup>

Khanum et al. (2022) reported a sensitivity of 90% and specificity of 87.06% using a 4 mm cutoff for endometrial thickness, which supports the idea that establishing standardized cutoff values could enhance diagnostic performance across studies.<sup>17</sup> Contrastingly, Nazim et al. (2013) reported a sensitivity of 100%, which highlights the importance of considering sample

selection and methodological differences. These variances underscore the value of multicenter studies in establishing robust guidelines for TVS use in clinical practice.<sup>20</sup> Lastly, Bibi et al. (2023) showed a sensitivity of 89.36% and specificity of 83.56%, which are close to our findings. This convergence reinforces the consensus regarding the effectiveness of TVS while indicating the need for further studies to refine diagnostic accuracy through improvements in technique and patient selection.<sup>21</sup>

One strength of our study is the histopathology as the reference standard, ensuring robust validation of transvaginal ultrasound findings. Additionally, the study involved a diverse patient population, enhancing the generalizability of the results. A limitation of the study is the relatively small sample size, which could impact statistical power and the reliability of the results. Additionally, the retrospective design may introduce biases in patient selection and data collection. Lastly, variations in ultrasound technique and interpretation among practitioners could impact the consistency of the results.

## CONCLUSION

In conclusion, transvaginal ultrasound (TVUS) demonstrated high sensitivity in sensing endometrial carcinoma among women using post-menopausal bleeding, making it a useful screening tool. However, due to its low specificity, histopathological confirmation remains essential for accurate diagnosis.

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