

ORIGINAL RESEARCH

Accuracy of the preoperative assessment of myometrial invasion with transvaginal ultrasound

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Abstract

Background: Myometrial invasion (MI) is an important prognostic factor in endometrial cancer. This study aimed to evaluate the diagnostic accuracy of transvaginal ultrasound (TVUS) in predicting preoperative MI compared to the postoperative histopathological diagnosis in clinical practice. Furthermore, we aimed to explore how comparable the accuracy of TVUS is between non-obese and obese patients. **Methods:** This was a hospital-based retrospective analysis of clinical data on patients with endometrioid endometrial cancer who were operatively treated between January 2019 and December 2020. **Results:** The final cohort size was 114 patients. Preoperative TVUS had 79.8% accuracy, 68.4% sensitivity, and 85.5% specificity in predicting MI. It was an even better MI predictor in patients with a higher body mass index (BMI; >30 kg/m²), with 84.2% accuracy, 80.0% sensitivity and 86.5% specificity. Moreover, the positive likelihood ratio is better among obese than non-obese patients. **Conclusions:** TVUS is an inexpensive and feasible method for assessing preoperative MI, especially in patients with a higher BMI.

Keywords

Endometrial cancer; Myometrial invasion; Transvaginal ultrasound

1. Introduction

Endometrial cancer (EC) is the most common gynecological malignancy in the Nordic countries and Europe as well as in the United States [1, 2]. Furthermore, its incidence is rising, mostly due to lifestyle factors, such as obesity [3]. Besides obesity, the risk factors of EC include increasing age, family history, genetic predisposition, type 2 diabetes, early menarche, late menopause, anovulation and nulliparity [4].

Myometrial invasion (MI) has been shown to be an important prognostic factor in EC, as it has been associated with recurrence, overall survival, and lymph node involvement [5]. Deep MI increases the risk of lymph node metastasis [6].

The leading techniques for determining MI are magnetic resonance imaging (MRI) and transvaginal ultrasound (TVUS) [6]. A newer technique is 3D-TVUS. MI can also be assessed intraoperatively using frozen sections or gross examinations of hysterectomy specimens [2]. However, these intraoperative methods are problematic in terms of surgery planning and on-site pathologist availability [2]. Studies have shown that in terms of sensitivity and specificity in preoperatively assessing MI, 3D-TVUS is comparable to MRI [7, 8].

Currently, the European Society of Gynecological Oncology, the European Society for Radiotherapy and Oncology, and the European Society of Pathology do not provide consistent recommendations for MI staging [8]. The aim of this study was to evaluate the diagnostic accuracy of TVUS in predicting

MI compared to the postoperative histopathological diagnosis in clinical practice. Furthermore, we aimed to explore how comparable the accuracy of TVUS is between non-obese and obese patients.

2. Materials and methods

2.1 Patient selection

Clinical data were collected from the hospital records of patients who were diagnosed with endometrioid EC and were admitted to Oulu University Hospital between January 2019 and December 2020. Endometrial biopsy was taken from all the patients before surgery either in primary/private healthcare, another hospital or the Oulu University Hospital.

Information was collected at five stages of the treatment chain: a referral to primary or private healthcare or another hospital, a preoperative visit to the gynecology department, an operation report, a postoperative stay in the ward, and pathologist's postoperative statement. From the postoperative histopathological diagnosis, information was collected on the EC stage according to 2009 International Federation of Gynecology and Obstetric (FIGO) staging [9], distance from the serosa, estrogen receptor status, p53 protein status, mismatch repair (MMR) status, and L1 cell adhesion molecule (L1CAM) status. The patients were followed up until the end of 2023 to determine whether the cancer had relapsed and whether the

patient had died.

2.2 Preoperative TVUS

Computed tomography was performed to all patients before the hospital visit. TVUS was used preoperatively to predict MI. TVUS was performed by specialists or doctors in training specializing in gynecologic oncology. MI was assessed subjectively ($<50\%$ or $\geq 50\%$) (Fig. 1). The accuracy, sensitivity, and specificity of TVUS was assessed in the entire study cohort and in two body mass index (BMI) groups: ≤ 30 and >30 kg/m².

2.3 Statistical methods

The data were analyzed using R version 4.4.1. Means and standard deviations were calculated for variables with a symmetrical distribution, while medians and quartiles were calculated for variables with a skewed distribution. For numerical variables, p values were calculated using one-way analysis of variance (ANOVA) and the Kruskal-Wallis test for symmetrically and asymmetrically distributed variables, respectively. For categorical variables, p values were calculated using the chi-squared test or Fisher's exact test if the assumptions of the chi-squared test were not satisfied. Likelihood ratios and their confidence intervals were calculated by R package bootLR and its function diagCI.

3. Results

There were altogether 143 patients who were diagnosed with endometrioid EC and were admitted to Oulu University Hospital between January 2019 and December 2020 (Fig. 2). Twenty-one patients who did not receive surgical treatment and one patient who underwent surgery before the defined study period were excluded from the study. The most common reason for not receiving surgical treatment was a high risk of death or operative complications due to underlying conditions ($n = 13$). Other reasons were widely metastasized cancer, refusal to undergo surgery, and undergoing surgery in another hospital. Also, seven patients with unclear, unknown, or uncertain MI status were excluded from the analysis. Thus, the study population consisted of 114 patients who received

operative treatment during the study period. Operative treatment included at least hysterectomy and unilateral or bilateral oophorectomy, with or without sentinel node biopsy or lymphadenectomy.

The patients underwent traditional laparoscopic surgery ($n = 52$, 45.6%), robotic laparoscopy surgery ($n = 42$, 36.8%), or laparotomy ($n = 20$, 17.5%). The average age at EC diagnosis was 67.0 years (Table 1). The median BMI was 31.3 kg/m².

MI was determined to be superficial (less than 50% of the myometrium) in 67.5% of the patients and deep ($\geq 50\%$ of the myometrium) in 32.5% of the patients. As a method for assessing MI preoperatively, TVUS had 79.8% accuracy, 68.4% sensitivity, and 85.5% specificity. In the higher BMI group, it had 84.2% accuracy, 80.0% sensitivity, and 86.5% specificity. In the lower BMI group, it had 77.8% accuracy, 58.8% sensitivity, and 86.5% specificity.

Patients with preoperatively TVUS assessed deep MI were older (mean age: 70.2 years) than those with superficial MI (mean age: 65.4 years; Table 1). Patients with preoperatively assessed deep MI also had a higher median CA-125 value, although the difference was not clinically significant. Understandably, lymphadenectomy was more common among patients with preoperatively assessed deep MI. The postoperative histopathological assessment largely confirmed these differences between patients with superficial MI and those with deep MI (Table 2).

In addition, we assessed the likelihood ratios (LR) for TVUS in the prediction of MI. The results show that positive LR is 5.92 for patients with BMI >30 kg/m² and 4.35 for patients with BMI ≤ 30 kg/m² (Table 3).

The tumor characteristics of the patients with superficial and deep MI were quite similar (Tables 4 and 5). Patients with deep MI had more advanced cancer stages than patients with superficial MI, as the depth of MI impacts the EC stage (Tables 4 and 5). Furthermore, the distance from the serosa was clearly shorter in patients with deep MI (Table 5).

After the final histopathological diagnosis, follow-up visits or treatments were arranged for the patients according to cancer stage and grade and molecular findings. Specifically, 64.0% of the patients were assigned low-risk follow-up visits, 7.0% were assigned high-risk follow-up visits, 15.8% received postoperative radiotherapy, 3.5% received postoperative chemotherapy.

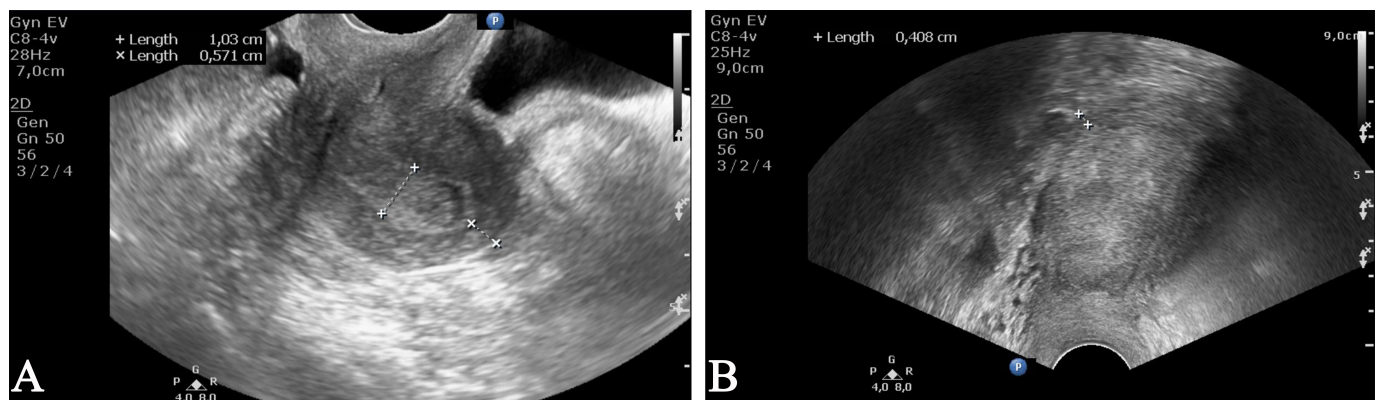


FIGURE 1. Examples of subjectively assessed (A) superficial and (B) deep myometrial invasion with transvaginal ultrasound.

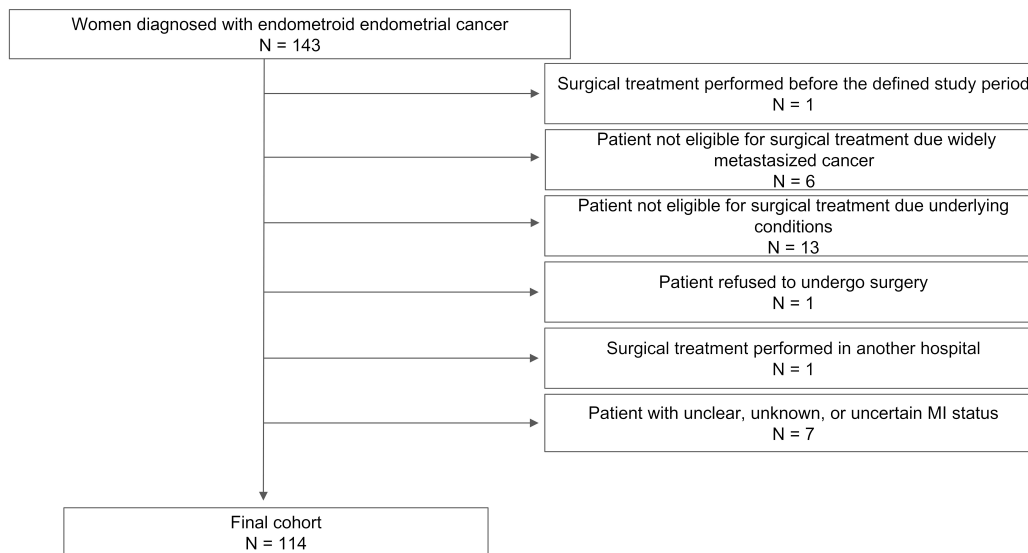


FIGURE 2. Flowchart. MI: myometrial invasion.

TABLE 1. Preoperative TVUS assessment of MI according to patient characteristics.

Parameter	Superficial MI (n = 77)	Deep MI (n = 37)	Total (n = 114)	p value
Age (yr)	65.4 (9.3)	70.2 (8.2)	67.0 (9.2)	0.008 ^a
Body mass index (kg/m ²)	30.6 (5.7)	32.8 (7.2)	31.3 (6.3)	0.095 ^a
CA-125 (kU/L)	11 [7.0–16.0]	16 [11.0–29.0]	12 [10.0–20.0]	<0.001 ^b
Parity				
0	61 (79%)	25 (67%)	86 (75%)	0.221 ^d
≥1	15 (20%)	12 (32%)	27 (24%)	
Unknown	1 (%)	0 (0%)	1 (1%)	
Number of removed lymph nodes				
0	40 (52%)	9 (24%)	49 (43%)	<0.001 ^c
1–3	26 (34%)	7 (19%)	33 (29%)	
≥4	11 (14%)	21 (57%)	32 (28%)	

The values are means (standard deviations) for symmetrical distributions and medians [25th percentiles–75th percentiles] for skewed distributions. ^aTwo-sample *t*-test. ^bMann-Whitney *U* test. ^cChi-squared test. ^dFisher's exact test. MI: myometrial invasion; TVUS: transvaginal ultrasonography; CA-125: carbohydrate antigen 125.

TABLE 2. Postoperative histopathological assessment of MI according to patient characteristics.

Parameter	Superficial MI (n = 76)	Deep MI (n = 38)	Total (n = 114)	p value
Age (yr)	65.2 (9.1)	70.4 (8.5)	67.0 (9.2)	0.004 ^a
Body mass index (kg/m ²)	31.0 (6.3)	31.9 (6.2)	31.3 (6.3)	0.458 ^a
CA-125 (kU/L)	11 [7–13]	18 [12–31]	12 [10–20]	<0.001 ^b
Parity				
0	58 (76%)	28 (74%)	86 (75%)	0.495 ^d
≥1	18 (24%)	9 (24%)	27 (24%)	
Unknown	0 (0%)	1 (3%)	1 (1%)	
Number of removed lymph nodes				
0	35 (46%)	14 (37%)	49 (43%)	0.057 ^c
1–3	25 (33%)	8 (21%)	33 (29%)	
≥4	16 (21%)	16 (42%)	32 (28%)	

The values are means (standard deviations) for symmetrical distributions and medians [25th percentiles–75th percentiles] for skewed distributions. ^aTwo-sample *t*-test. ^bMann-Whitney *U* test. ^cChi-squared test. ^dFisher's exact test. MI: myometrial invasion; CA-125: carbohydrate antigen 125.

TABLE 3. Likelihood ratios (LR) of transvaginal ultrasonography in the prediction of myometrial invasion.

Population	LR Positive (95% CI)	LR Negative (95% CI)
All patients (n = 114)	4.73 (2.63–8.51)	0.37 (0.23–0.60)
Patients with BMI ≤ 30 (n = 54)	4.35 (1.76–10.78)	0.48 (0.27–0.85)
Patients with BMI >30 (n = 57)	5.92 (2.55–13.77)	0.23 (0.10–0.56)

BMI: body mass index; LR: likelihood ratio; CI: confidence interval. BMI data was missing from three patients.

TABLE 4. Preoperative TVUS assessment of MI according to tumor characteristics.

Parameter	Superficial MI (n = 77)	Deep MI (n = 37)	Total (n = 114)	p value
Stage				
Ia	64 (83%)	9 (24%)	73 (64%)	<0.001 ^a
Ib–IVb	13 (17%)	28 (76%)	41 (36%)	
Distance from serosa (mm)				
≤ 5	14 (18%)	20 (54%)	34 (30%)	<0.001 ^a
6–10	19 (25%)	7 (19%)	26 (21%)	
≥ 11	23 (30%)	1 (3%)	24 (23%)	
Unknown	21 (27%)	9 (24%)	30 (26%)	
Estrogen receptor status				
Positive	34 (44%)	19 (51%)	53 (47%)	0.697 ^b
Negative	1 (1%)	0 (0%)	1 (1%)	
Unknown/unclear	42 (55%)	18 (49%)	60 (53%)	
p53 status				
Wild type	22 (29%)	19 (51%)	41 (36%)	0.029 ^b
Mutated	2 (3%)	2 (5%)	4 (4%)	
Unknown	53 (69%)	16 (43%)	69 (61%)	
MMR status				
Proficient	51 (66%)	25 (68%)	76 (67%)	0.453 ^b
Sporadic deficiency	15 (20%)	10 (27%)	25 (22%)	
Lynch syndrome	6 (8%)	1 (3%)	7 (6%)	
Unclear	1 (1%)	1 (3%)	2 (2%)	
Unknown	4 (5%)	0 (0%)	4 (4%)	
L1CAM status				
Negative	61 (79%)	27 (73%)	88 (77%)	0.698 ^a
Positive	6 (8%)	3 (8%)	9 (8%)	
Unknown	10 (13%)	7 (19%)	17 (15%)	

All values are numbers (percentages). ^aChi-squared test. ^bFisher's exact test. MI: myometrial invasion; TVUS: transvaginal ultrasonography; MMR: DNA mismatch repair; L1CAM: L1 cell adhesion molecule.

apy, 2.6% received postoperative high-dose-rate brachytherapy, and 6.1% received a combination of radiotherapy and chemotherapy. One patient (0.9%) who was diagnosed with a nongynecological malignancy was referred to the oncology department.

During the follow-up period, six (5.3%) patients relapsed. Two of these patients were preoperatively determined to have superficial MI, and four were determined to have deep MI. All six patients had undergone either a successful sentinel node procedure or a full lymphadenectomy. One of those patients with preoperative assessment of deep MI had, after

all, superficial MI according to histopathological examination. In contrast, preoperatively assessed MI matched the MI in the histopathological evaluation with the rest of the patients.

A total of seven patients died. One of them had been preoperatively determined to have superficial MI, and six had been determined to have deep MI. Postoperatively, all these patients were determined to have deep MI.

TABLE 5. Postoperative histopathological assessment of MI according to tumor characteristics.

Parameter	Superficial MI (n = 76)	Deep MI (n = 38)	Total (n = 114)	<i>p</i> value
Preoperative MI assessment				
<50%	65 (86%)	12 (32%)	77 (68%)	<0.001 ^a
≥50% or more	11 (14%)	26 (68%)	37 (32%)	
Stage				
Ia	71 (93%)	2 (5%)	73 (64%)	<0.001 ^a
Ib–IVb	5 (7%)	36 (95%)	41 (36%)	
Distance from serosa (mm)				
≤5	8 (11%)	26 (68%)	34 (30%)	<0.001 ^a
6–10	18 (24%)	8 (21%)	26 (23%)	
≥11	23 (30%)	1 (3%)	24 (21%)	
Unknown	27 (36%)	3 (8%)	30 (26%)	
Estrogen receptor status				
Positive	31 (41%)	22 (58%)	53 (46%)	0.151 ^b
Negative	1 (1%)	0 (0%)	1 (1%)	
Unknown/unclear	44 (58%)	16 (42%)	60 (53%)	
p53 status				
Wild type	22 (29%)	19 (50%)	41 (36%)	0.036 ^b
Mutated	2 (3%)	2 (5%)	4 (4%)	
Unknown	52 (68%)	17 (45%)	69 (61%)	
MMR status				
Proficient	49 (64%)	27 (71%)	76 (67%)	0.137 ^b
Sporadic deficiency	15 (20%)	10 (26%)	25 (22%)	
Lynch syndrome	7 (9%)	0 (0%)	7 (6%)	
Unclear	1 (1%)	1 (3%)	2 (2%)	
Unknown	4 (5%)	0 (0%)	4 (4%)	
L1CAM status				
Negative	60 (79%)	28 (74%)	88 (77%)	0.733 ^a
Positive	5 (7%)	4 (11%)	9 (8%)	
Unknown	11 (14%)	6 (16%)	17 (15%)	

All values are numbers (percentages). ^aChi-squared test. ^bFisher's exact test. MI: myometrial invasion; MMR: DNA mismatch repair; L1CAM: L1 cell adhesion molecule.

4. Discussion

In this study, preoperative TVUS had 79.8% accuracy, 68.4% sensitivity, and 85.5% specificity in predicting MI. It was an even better MI predictor in patients with a higher BMI, with 84.2% accuracy, 80.0% sensitivity, and 86.5% specificity. This finding was confirmed by better positive LR among obese patients.

Our results are in line with previous studies. A large meta-analysis reported a sensitivity of 82% for TVUS (based on 184 studies) and a sensitivity of 81% for MRI (based on 50 studies). Thus, MRI was not found to be more advantageous than TVUS [6]. However, in a recent Swedish prospective study MRI had a higher specificity than TVUS for assessing deep MI and cervical stroma infiltration in low-grade EC, but

MRI and TVUS had similar sensitivities [10]. Furthermore, a Czech prospective study and a Swedish retrospective study found that BMI did not influence the assessment of MI using TVUS, even though a higher BMI appeared to negatively affect image quality [11, 12]. Overall, TVUS is an inexpensive and time-saving method for determining the depth of MI when operated by experienced specialists [6].

A Swedish large retrospective cohort study reported 65.6% sensitivity, 80.3% specificity, and 75.8% accuracy for TVUS and 76.9% sensitivity, 71.9% specificity, and 73.8% accuracy for MRI [2]. Another small prospective study compared the effectiveness of TVUS, MRI and frozen section examinations in detecting MI in EC preoperatively and reported 88.6% sensitivity and 90.5% specificity for TVUS and 63.6% sensitivity and 95.2% specificity for MRI [6].

The possible effect of obesity on the assessment of MI with TVUS was not previously studied. Our goal was to explore how comparable is the accuracy of TVUS between non-obese and obese patients. One of our main findings is that TVUS is even a better MI predictor in obese patients (BMI >30 kg/m²) in terms of accuracy, sensitivity, specificity and LR_s.

The major strength of our study is that it was based on extensive and reliable patient data. All patients had access to the same resources and were treated according to national guidelines, which remained the same during the study period. The main limitation of our study is its small cohort size. Moreover, because of the retrospective nature of the study, it was not possible to categorize all patients into deep and superficial MI groups based on preoperative evaluations. Thus, seven patients were excluded from the study. Also, the study cohort is quite old (2019–2020) due to a few years follow-up period of the patients. As this study was conducted retrospectively, the 3D-TVUS and MRI were not available in the routine clinical practice, and therefore it is not possible to compare these imaging modalities in the study. Also, the endometrial features along with the endometrial thickness and the use of color doppler were not collected from the patient records, although much likely that both were used in subjective MI assessment.

The standards for TVUS remain inconsistent. Both objective and subjective TVUS methods are used to assess MI [13]. Subjective ultrasound assessment of MI seems to be comparable with objective TVUS methods [14]. Also, color Doppler blood flow mapping is known to be an effective diagnostic tool for the differential diagnosis of intrauterine focal lesions, but it seems to be beneficial in assessing MI [13]. As only subjective assessment is routine in our clinical practice, it is not possible to compare different TVUS methods in this study.

Finally, the Cancer Genome Atlas (TCGA) changed the landscape of EC completing a genome-wide analysis of endometrial carcinomas in 2013 [15]. TCGA defined tumors into four distinct subgroups: polymerase epsilon (POLE) ultramutated, microsatellite unstable (MMR deficient) hypermutated, copy-number low, and copy-number high (p53 mutated) [15]. These molecular subgroups are associated with different prognoses as the POLE ultramutated have remarkably good and copy number high extremely poor prognosis [16]. Molecular subgroups associate with different clinical factors, for example, POLE ultramutated correlates with younger age and lower BMI [16]. In the current study, the MMR status was quite comprehensively available and did not differ between the two study groups. Unfortunately, the p53 data were lacking from most patients, which leads to an imbalance between the study groups. Furthermore, POLE mutations were not available at all. Therefore, it was not possible to categorize the patients according to all TCGA criteria. In addition, due to the lack of full molecular profiling, we were not able to categorize our cohort according to the updated and current 2023 FIGO staging [17]. However, although molecular profiling has a significant impact on the prognosis of the patients, it is not known whether it influences the preoperative TVUS assessment.

5. Conclusions

TVUS is an accurate method for preoperatively assessing MI, especially in patients with a higher BMI. Therefore, TVUS remains to be an inexpensive and feasible method for assessing preoperative MI. However, due to the small cohort size, the reproducibility of the results needs further verification and studies.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

AUTHOR CONTRIBUTIONS

EH and EU—designed the research study. EH—collected the research data. EU—provided help and advice on data collection and the structure of the article. HH—analyzed the data. EH, HH and EU—wrote the manuscript. ST and UP—revised the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was granted ethics approval (48/2021; 16 March 2021) and a separate permit for the use of registry data (date: 09 March 2021) by Oulu University Hospital. The ethics committee of Oulu University Hospital waived the requirement to obtain informed consent.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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