Diagnostic Performance and Agreement of Preoperative, Intraoperative Evaluations, and Final Pathology for Lymphadenectomy and Lymph Node Involvement in Endometrial Cancer

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Objective: *To determine the accuracy of clinical parameters examined by preoperative and intraoperative evaluations compared with final histological results in patients with endometrial cancer, and to evaluate the application of preoperative investigations, intraoperative evaluations, and final histological results in predicting lymph node involvement.*
Material and Method: *The medical records of the patients diagnosed with endometrial cancer who had surgical staging between January 1, 2006 and December 31, 2012 at Songklanagarind Hospital were retrospectively reviewed. The agreement of clinical parameters identified through preoperative investigations and intraoperative evaluations with the final histology findings were calculated using kappa statistics. The diagnostic performance of preoperative investigations, intraoperative evaluations, and final histological results to predict lymph node involvement were calculated in terms of sensitivity, specificity, positive predictive value, and negative predictive value.*
Results: *Preoperative investigations showed a slight to fair agreement whereas intraoperative evaluations had a fair to moderate agreement in detecting clinical parameters compared with the final histological results. Endocervical curettage and endometrial biopsy exhibited the highest sensitivity, pelvic ultrasonography the highest specificity, and intraoperative evaluations had a high-level sensitivity and specificity.*
Conclusion: *Preoperative investigations have role as an adjunctive evaluation, whereas intraoperative gross assessment remains the most accurate and useful method of detecting patients for lymphadenectomy.*

Keywords: *Accuracy, Endometrial cancer, Intraoperative evaluations, Lymphadenectomy, Lymph node involvement, Preoperative investigation*

Endometrial cancer is the most common gynecologic malignancy in developed countries[1,2]. It is the third most common in Thailand, and shows an increasing trend[3]. Its standard surgery involves total abdominal hysterectomy (TAH), bilateral salpingo-oophorectomy (BSO), and selective pelvic and paraaortic lymphadenectomy[2,4]. Selective pelvic and paraaortic lymphadenectomy are performed in patients with the following clinical parameters: non-endometrioid type, tumor grade 2 or 3, cervical invasion, tumor size larger than 2 cm, tumor invasion of more than 50% of myometrial thickness, and extrauterine lesion such as serosal or adnexal involvement. These clinical parameters present a high incidence of lymph node metastasis (15-66%), which affects prognosis and requires adjuvant treatment[1,2,4].

Since these clinical parameters are determined based on final histological results after a standard surgical operation, it may lead to either under- or over-performed lymphadenectomy and, subsequently, to re-exploration for lymphadenectomy or idiopathic surgical complications[1,2]. Majority of patients who suspected lymph node involvement were referred to tertiary hospital for surgery by gynecologic oncologists but some patients who were not suspected would be operated by gynecologists at secondary hospital. As a result, it would be useful if some investigation during the preoperative or intraoperative periods could help estimate these parameters. Preoperative investigations and intraoperative evaluations reported in previous studies include endocervical curettage[5], endometrial

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biopsy[6,7], pelvic ultrasonography[8,9], magnetic resonance imaging (MRI)[10] or positron emission tomography/computed tomography (PET/CT)[11], intraoperative evaluations[12,13], and frozen section[4]. Tumor grade and type can be identified via preoperative investigations. Cervical or myometrial invasion can be determined by both preoperative investigations and intraoperative evaluations.

The accuracy of preoperative investigations in determining the tumor type and grade varies from 35 to 98%. Although MRI, PET/CT, or frozen section have been shown to be slightly more accurate in detecting clinical parameters than other investigations[10,11], they are costly and not widely available in limited-resource settings. In contrast, endocervical curettage, endometrial sampling, pelvic ultrasonography, or intraoperative evaluations are practical and have an acceptable accuracy level[5-9,12,13]. However, previous studies that aimed to compare available investigations to determine these parameters have studied some parameters in one investigation. Therefore, the objectives of the present study were to determine the accuracy all of clinical parameters examined by preoperative investigations (endocervical curettage, endometrial biopsy, and pelvic ultra-sonography) and intraoperative evaluations compared with the final histological results, and to evaluate the application of preoperative investigations, intraoperative evaluations, and final histological results in predicting lymph node involvement.

Material and Method

This retrospective study was conducted in Songklanagarind Hospital. It was approved by the Ethics Committee of the Faculty of Medicine at Prince of Songkla University, Hat Yai, Songkhla, Thailand. The medical records of all of the patients diagnosed with endometrial cancer who had surgery in this hospital between January 1, 2006 and December 31, 2012 were retrospectively reviewed. The medical records of the patients who had complete endometrial biopsy, pelvic ultrasonography, intraoperative gross assessment and postoperative results were included. Those whose endometrial biopsy showed a non-endometrial cancer or aggressive type of endometrial cancer, had a synchronous endometrial cancer with other gynecologic cancers or without residual lesions in the final histology were excluded.

The sample size was calculated by the one-group formula using an 80% sensitivity or specificity for preoperative investigations or intraoperative evaluations in identifying clinical parameters compared with the final histological results in patients with endometrial cancer[10] with a 95% confidence interval and a 10% level of precision. As a result, at least 230 patients were required to be included in the study.

In our hospital, patients diagnosed with endometrial cancer through endometrial biopsy did not routinely undergo pelvic ultrasonography. MRI and frozen sections were performed only in patients suspected of an advance in the disease. Surgical staging involved hysterectomy and bilateral salpingo-oophorectomy and peritoneal washing. Pelvic and paraaortic lymphadenectomy were performed in patients for whom it was indicated by the clinical parameters (non-endometrioid type, tumor grade 2 or 3, cervical invasion, tumor size larger than 2 cm, tumor invasion of more than 50% of myometrial thickness, or extrauterine lesion). Radical hysterectomy was performed in patients with cervical involvement. Pelvic lymph nodes comprised the external iliac, internal iliac, and obturator lymph node. The paraaortic ones were dissected below the inferior mesenteric artery.

The main outcomes of our study were the clinical parameters identified via the preoperative investigations, intraoperative evaluations, and final histological results. Preoperative investigations were defined as endocervical curettage, endometrial biopsy and pelvic ultrasonography, and intraoperative evaluations were defined as direct visual assessments that were recorded in the operative notes. Histology from endometrial biopsy and surgical staging were not reviewed. Clinical parameters comprised histological type, tumor grade, cervical invasion, tumor size, myometrial invasion, serosal involvement, and extrauterine involvement. The demographic characteristics consisted of age, menarche, menopausal age, body mass index (BMI), parity, reproductive status, chief complaint, Pap smear result, and staging. Staging was classified using the criteria of the 2009 International Federation of Gynecology and Obstetrics (FIGO)[14]. The procedure and pathological information involved method of endometrial biopsy and hysterectomy, result of endocervical curettage, adnexal involvement, lymph node involvement, and peritoneal cytology. All of the data were collected from medical record reviewed.

The data were double entered into EpiData 3.1 and analyzed using R software version 3.0.1 (the R Foundation for Statistical Computing 2008, Austria). The details of the main outcomes and independent variables were presented descriptively

using frequency and percentages. The clinical parameter accuracy examined by preoperative investigations (endocervical curettage, endometrial biopsy, and pelvic ultrasonography) and intraoperative evaluations compared with the final histological results were analyzed using kappa statistics[15]. The diagnostic performance of preoperative investigations, intraoperative evaluations, and final histological results to predict lymph node involvement were calculated using sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with 95% confidential interval (CI).

Results

Patients with no endometrial biopsy or pelvic ultrasonography results, were found to have a non-endometrial cancer or an aggressive type based on endometrial biopsy, and having a synchronous tumor or no residual tumor according to the final histological results were excluded. Two hundred thirty one patients were included in the present study. Their age at diagnosis ranged from 23 to 85 years (mean ± SD = 57±11), of whom 7.4% was diagnosed before the age of 40 years. A quarter of them were of a nulliparous status, and approximately 70% were in the menopausal state. Almost all of the patients presented with abnormal vaginal bleeding. Abnormal pap smears revealed atypical glandular cells, and adenocarcinoma were found in 29.5% to most of them were stage I (Table 1). The procedure and pathological information were shown in Table 2. The majority of patients had undergone fractional curettage and extrafascial hysterectomy. The mean interval time between endometrial biopsy and surgical staging was 58 days to within 1 month 19.5%, within 2 months 61.9%, and within 3 months 86.6% of the cases. Approximately 12% of patients had lymph node involvement.

Table 3 demonstrated the agreement of clinical parameters determined by a pair of final histological results to the results of either endocervical curettage, endometrial biopsy, pelvic ultrasonography, or intraoperative evaluations. Endocervical curettage showed a slight agreement in detecting cervical invasion (kappa = 0.07, 95% CI = -0.08 to 0.22) Endometrial biopsy had a slight agreement in detecting histological type (kappa = 0.13, 95% CI = 0.02-0.24), but a fair agreement in detecting tumor grade (kappa = 0.31, 95% CI = 0.20-0.42). Pelvic ultrasonography revealed a slight agreement in detecting all of the clinical parameters (kappa = 0.06-0.19). Intraoperative

Table 1. Demographic data

Characteristics	n = 231 mean ± SD or n (%)
Age	57±11
Menarche	14±2
Menopausal age	50±4
Body mass index	28±5
Parity	3±2
Reproductivity	
Premenopause	67 (29.0)
Postmenopause	164 (71.0)
Chief complaint	
Bleeding	226 (97.8)
Pain and mass	5 (2.2)
Pap smear	
Normal	145 (62.8)
Glandular cell abnormality	22 (9.5)
Adenocarcinoma	23 (10.0)
Squamous cell abnormality	6 (2.6)
Squamous cell carcinoma	2 (0.9)
No data	33 (14.3)
Stage	
I	182 (78.8)
II	4 (1.7)
III	35 (15.2)
IV	10 (4.3)

Table 2. Procedure and pathological information

Characteristics	n = 231, n (%)
Endometrial biopsy	
Fractional curettage	169 (73.2)
Office endometrial sampling	62 (26.8)
Hysterectomy	
Extrafascial	225 (97.4)
Radical	6 (2.6)
Endocervical curettage	
Negative	36 (15.6)
Positive	44 (19.0)
Not done	151 (65.4)
Adnexal involvement	
No	213 (92.2)
Yes	18 (7.8)
Lymph node involvement	
No	181 (78.4)
Yes	28 (12.1)
Not done	22 (9.5)
Peritoneal cytology	
Negative	216 (93.5)
Positive	8 (3.5)
Not done	7 (3.0)

evaluations had a moderate agreement in detecting cervical invasion (kappa = 0.48, 95% CI = 0.35-0.61),

Table 3. Agreement of endocervical curettage, endometrial biopsy, pelvic ultrasonography, and intraoperative evaluations compared to final histological results by clinical parameter

Factor	Final histological results		Agreement (%)		*p*-value
			Observed	Kappa (95% CI)	
Histological type	Non-endometriod	Endometrioid			
Endometrial biopsy			85.3	0.13 (0.02 to 0.24)	0.02
- Non-endometrioid	4	26			
- Endometrioid	8	193			
Tumor grade	2+3	1			
Endometrial biopsy			62.3	0.31 (0.20 to 0.42)	<0.001
- 2+3	49	23			
- 1	37	94			
Tumor size	>2 cm	≤2 cm			
Ultrasonography			58.0	0.17 (0.04 to 0.30)	0.004
- >2 cm	71	36			
- ≤2 cm	61	63			
Intraoperative evaluations			66.7	0.33 (0.20 to 0.46)	<0.001
- >2 cm	90	35			
- ≤2 cm	42	64			
Cervical invasion	Yes	No			
Endocervical curettage			50.0	0.07 (-0.08 to 0.22)	0.189
- Yes	8	36			
- No	4	32			
Ultrasonography			86.6	0.09 (0.02 to 0.16)	0.004
- Yes	2	1			
- No	30	198			
Intraoperative evaluations			89.6	0.48 (0.35 to 0.61)	<0.001
- Yes	14	6			
- No	18	193			
Myometrial invasion	>50%	≤50%			
Ultrasonography			66.2	0.19 (0.06 to 0.32)	0.002
- >50%	28	28			
- ≤50%	50	125			
Intraoperative evaluations			72.7	0.38 (0.25 to 0.51)	<0.001
- >50%	43	28			
- ≤50%	35	125			
Serosal involvement	Yes	No			
Ultrasonography			91.8	0.06 (-0.06 to 0.18)	0.18
- Yes	1	6			
- No	13	211			
Intraoperative evaluations			93.5	0.37 (0.24 to 0.50)	<0.001
- Yes	5	6			
- No	9	211			
Extrauterine involvement	Yes	No			
Intraoperative evaluations			91.3	0.37 (0.24 to 0.50)	<0.001
- Yes	7	9			
- No	11	204			
Lymph node metastasis	Yes	No			
Intraoperative evaluations			87.6	0.37 (0.24 to 0.50)	<0.001
- Yes	10	10			
- No	18	173			

but a fair agreement in detecting tumor size, myometrial invasion, serosal involvement, extrauterine involvement and lymph node metastasis (kappa = 0.33-0.38).

Table 4 demonstrated the diagnostic performance of clinical parameters for lymph node involvement based on final histological results

Table 4. Diagnostic performance of clinical parameters in endocervical curettage, endometrial biopsy, pelvic ultrasonography, intraoperative evaluations, and final histological results for lymph node involvement

Indication for lymphadenectomy		Lymph node involvement		Diagnostic performance (%)			
		Yes	No	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Final histological results	Yes	23	110	82.1	39.2	17.3	93.4
	No	5	71	(63.1-93.9)	(32.1-46.7)	(11.3-24.8)	(85.3-97.8)
Single							
ECC & EB	Yes	22	88	100.0	18.5	20.0	100.0
	No	0	20	(84.6-100.0)	(11.7-27.1)	(13.0-28.7)	(83.2-100.0)
USG	Yes	9	43	32.1	76.2	17.3	87.9
	No	19	138	(15.9-52.4)	(69.4-82.2)	(8.2-30.3)	(81.8-92.6)
IOE	Yes	17	62	60.7	65.8	21.5	91.5
	No	11	119	(40.6-78.5)	(58.3-72.6)	(13.1-32.2)	(85.4-95.7)
Combination							
ECC & EB + USG	Yes	24	107	100.0	13.7	18.3	100.0
	No	0	17	(85.8-100.0)	(8.2-21.0)	(12.1-26.0)	(80.5-100.0)
ECC & EB + IOE	Yes	25	114	100.0	11.6	18.0	100.0
	No	0	15	(86.3-100.0)	(6.7-18.5)	(12.0-25.4)	(78.2-100.0)
USG + IOE	Yes	20	82	71.4	54.7	19.6	92.5
	No	8	99	(51.3-86.8)	(47.1-62.1)	(12.4-28.7)	(85.8-96.7)
ECC & EB + USG + IOE	Yes	25	126	100.0	10.0	16.6	100.0
	No	0	14	(86.3-100.0)	(5.6-16.2)	(11.0-23.5)	(76.8-100.0)

ECC = endocervical curettage; EB = endometrial biopsy; USG = pelvic ultrasonography; IOE = intraoperative evaluation; PPV = positive predictive value; NPV = negative predictive value

(histological type, tumor grade, tumor size, cervical, myometrial, serosal, and extrauterine involvement), endocervical curettage and endometrial biopsy (histological type, tumor grade, cervical invasion), pelvic ultrasonography (tumor size, cervical, myometrial, and serosal involvement), and intraoperative evaluations (tumor size, cervical, myometrial, serosal, and extrauterine involvement). The final histological results showed a high sensitivity and low specificity in detecting lymph node involvement. Endocervical curettage and endometrial biopsy revealed the highest sensitivity, pelvic ultrasonography the highest specificity, and intraoperative evaluations showed high sensitivity and specificity.

Discussion

Intraoperative evaluations were the most accurate in determining the clinical parameters when comparing them to the final histological results. A slight-to-moderate kappa agreement and accuracy between intraoperative evaluations and final histological results in detecting cervical invasion, tumor size, myometrial invasion, serosal involvement, extrauterine involvement, and lymph node involvement were seen.

Our intraoperative evaluations' accuracy level for detecting cervical invasion is consistent with that of previous studies[12,16,17] that it can be done via direct visual tumor assessment, but it is dependent on surgeon experience. However, the detection of cervical invasion by pelvic ultrasonography showed a poor kappa agreement but a high accuracy, which was better than in previous studies[11,18]. In contrast, the detection accuracy by ECC was lower than the previous studies[5,19]. This may be due to the prevalence of invasion leading to a low power of detection. The detection of cervical involvement by uterine specimen visualization after a hysterectomy is not meaningful for clinical applications on the type of hysterectomy, but it is useful for decision making on additional lymphadenectomies.

The tumor size accuracy was found to be in slight agreement based on pelvic ultrasonography and in fair agreement based on intraoperative evaluations. Previous studies have reported that the combination of tumor size and myometrial invasion suggested that tumors less than 2 cm with less than a half of myometrial thickness involvement were more associated with the final pathology[16,17]. The accuracy of myometrial invasion detection using pelvic

ultrasonography and intraoperative evaluations in the present study was less than those of previous studies, 67-81% and 79-91%, respectively[8,9,12,13,16,17,20,21]. This difference may be explained by differences in study design, study subjects, and methodology. Their clinical parameter information was obtained in a prospective study rather than a retrospective one. Moreover, endometrioid-type lesions are difficult to differentiate from normal endometrial tissue, which is different from the aggressive types of tumors. Preoperative investigations for serosal, extrauterine and lymph node involvement have not been reported in previous studies.

Our study included only endometrioid types because the findings of aggressive histological type from the endometrial biopsy definitely indicated for lymphadenectomy with the reason of high lymph node metastasis[2]. Fractional curettage was performed in two-thirds of the patients and our study resulted in a greater accuracy in detecting histological types, and for tumor grades, when compared to previous studies where endometrial sampling was usually used[6,7,22,23].

The incidence of lymph node metastasis detected in our study was 12.1%; that concurred with the finding of a previous study (10%)[9]. Endocervical curettage and endometrial biopsy had a high sensitivity and low specificity in detecting lymph node involvement. This was in contrast to pelvic ultrasonography, which had high specificity but low sensitivity. Intraoperative evaluations had a high sensitivity and specificity in detecting lymph node involvement. Endocervical curettage and endometrial biopsy had 100% of sensitivity, but low specificity in detecting lymph node. In case of no indication for lymphadenectomy, the possibility of lymph node involvement is low. Thus, histology should be reviewed before surgery in order to plan the operation, and notify or refer to the oncologist for lymph node dissection. Pelvic ultrasonography had a low sensitivity, but a high specificity in detecting lymph node involvement. When there is an indication for lymphadenectomy, the possibility of lymph node involvement is high. Pelvic ultrasonography can increase the accuracy of decision for lymphadenectomy. Intraoperative evaluations had high sensitivity and specificity in detecting lymph node involvement. They can confirm and support the true decision of lymphadenectomy.

Surgical staging is considered crucial in endometrial cancer surgery either with or without lymphadenectomy. Decision making is important for the patient's survival and any further operations. Therefore, the information of preoperative and intraoperative evaluations, which is relevant to clinical judgment, are useful in actual clinical practice and help to decide about referring to gynecologic oncologist. All of the clinical parameters that have been suggested as prognostic factors were included in our study. This is different from previous studies where only some of them were assessed. There were some limitations in the present study. First, this was a retrospective study, which excluded some patients due to incomplete procedure or clinical parameter data. Second, the histological review was not performed since all of the pathologists who reported the pathological findings in our study are well-experienced. Lastly, MRI, PET/CT, or frozen sections were not performed due to limitations concerning costs, limited resources, and lack of experienced physicians.

In conclusion, histological type and tumor grade should confirm the diagnosis; pelvic ultrasonography had a role as an adjunctive method for the selection of patients for lymphadenectomy. Additional preoperative investigations had benefit for gynecologists' decision to refer patients to gynecologic oncologists, whereas, intraoperative gross assessment was the most accurate and useful method in selecting patients for lymphadenectomy, so the intraoperative gross assessment is the important skill for every gynecologist and gynecologic oncologists.

What is already known on this topic?

Clinical parameters for lymphadenectomy in patient with endometrial cancer, histological type, tumor grade, tumor size, cervical, and myometrial invasion were established. Previous studies that aimed to compare available investigations to determine these parameters have studied on some parameters in one investigation.

What this study adds?

This study compared accuracy of all of clinical parameters examined by preoperative investigations and intraoperative evaluations with the final histological results. In addition, diagnostic performance of clinical parameters in endocervical curettage, endometrial biopsy, pelvic ultrasonography, intraoperative evaluations, and final histological results for lymph node involvement were determined.

Acknowledgments

Potential conflicts of interest

None.

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ความแม่นยำของตัวแปรทางคลินิกของการเลาะต่อมน้ำเหลืองและการแพร่กระจายไปยังต่อมน้ำเหลืองจากการประเมินก่อนการผ่าตัด ระหว่างการผ่าตัด และผลชิ้นเนื้อหลังการผ่าตัด ในผู้ป่วยมะเร็งมดลูก

หนึ่งฤทัย แซ่เอี๊ยบ, สาธนา บุณยพิพัฒน์, ทิพวรรณ เลียบสื่อตระกูล, สายบัว ชี้เจริญ, วิรัช วุฒิภูมิ, รักชาย บุหงาชาติ, จิตติ หาญประเสริฐพงษ์, ยุทธศักดิ์ ศุภสินธุ์

วัตถุประสงค์: ศึกษาความแม่นยำของตัวแปรทางคลินิกจากการประเมินก่อนการผ่าตัดและระหว่างผ่าตัดโดยเปรียบเทียบกับผลชิ้นเนื้อหลังการผ่าตัดและประเมินความสัมพันธ์ของผลการประเมินก่อนการผ่าตัด ระหว่างการผ่าตัด และผลชิ้นเนื้อหลังการผ่าตัด กับการทำนายการแพร่กระจายของมะเร็งไปยังต่อมน้ำเหลือง

วัสดุและวิธีการ: รวบรวมข้อมูลจากแฟ้มเวชระเบียนผู้ป่วยในของผู้ป่วยมะเร็งมดลูกที่ได้รับการวินิจฉัยและผ่าตัดในโรงพยาบาลสงขลานครินทร์ ระหว่างวันที่ 1 มกราคม พ.ศ. 2549 ถึง 31 ธันวาคม พ.ศ. 2555 เปรียบเทียบความแม่นยำของตัวแปรทางคลินิกจากการประเมินก่อนผ่าตัดและระหว่างผ่าตัดกับผลชิ้นเนื้อหลังการผ่าตัดโดยใช้ค่า *kappa* และประเมินความสัมพันธ์ของผลการประเมินก่อนการผ่าตัด ระหว่างการผ่าตัด และผลชิ้นเนื้อหลังการผ่าตัดกับการทำนายการแพร่กระจายของมะเร็งไปยังต่อมน้ำเหลืองโดยใช้ความไว ความจำเพาะ ค่าทำนายผลบวก และค่าทำนายผลลบ

ผลการศึกษา: ตัวแปรทางคลินิกจากการประเมินก่อนการผ่าตัดมีความแม่นยำเล็กน้อยแต่จากการประเมินระหว่างผ่าตัดมีความแม่นยำปานกลางเมื่อเทียบกับผลชิ้นเนื้อหลังการผ่าตัด ผลจากการขูดคอมดลูกและการขูดมดลูกมีความไวสูงที่สุดในขณะที่ผลจากการตรวจคลื่นเสียงความถี่สูงในอุ้งเชิงกรานมีความจำเพาะสูงที่สุดในการทำนายการแพร่กระจายของมะเร็งไปยังต่อมน้ำเหลือง

สรุป: ผลจากการประเมินก่อนการผ่าตัดยังคงมีบทบาทสำคัญ และการประเมินระหว่างการผ่าตัดมีความแม่นยำที่สุดในการวางแผนการเลาะต่อมน้ำเหลืองในผู้ป่วยมะเร็งมดลูก