Concordance and Discordance of Endometrial Biopsy vs Hysterectomy Specimen Findings for the Diagnosis of Endometrial Cancer

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Abstract: *Background*: Endometrial cancer (EC) is the most common malignancy of uterus in the Western World. The literature shows a varied association between biopsy versus hysterectomy specimen findings. The objective of the study is to describe the concordance and discordance between endometrial biopsy vs hysterectomy specimens for the detection and grading of EC.

Methods: This is a retrospective cross-sectional analytical study. Data were reviewed from 2018 to 2021 from the departmental archive.

Results: The mean±SD of age was 55.4±9.6 years. The most common clinical feature was postmenopausal bleeding (45.4%). The overall concordance for diagnosis of EC was 59.1% between biopsy and hysterectomy. The highest concordance found for endometrioid carcinoma-NOS was 67.6%. Concordance for overall grading of endometrial cancer was 52.3%, and it was maximum for G1 (78.6%). The strength of association was mild to moderate (C= 0.379 to 0.592) between biopsy vs hysterectomy was significant with the Chi^2 test. A biopsy had sensitivity, specificity, positive predictive value, and negative predictive value of 67.6%, 57.1%, 89.3%, and 25%, respectively, compared to hysterectomy for diagnosis of EC. Cohen's Kappa test showed agreement between biopsy and hysterectomy was significant and moderate for the diagnosis EC (59.1%, κ=0.1101) and for grading of EC (overall grading-52.2%, κ=0.2925, architectural grading- 45.5% κ=0.1156, nuclear grading 40.9%, κ=0.1746).

Conclusion: Concordance/agreement between endometrial biopsy and hysterectomy was moderate for the diagnosis and grading of EC. The accuracy of biopsy is moderate in diagnosis of EC. We recommend endometrial biopsy as a minimally invasive surgical and cost-effective approach in resource-poor countries.

Keywords: Concordance, Endometrial biopsy, Hysterectomy, Endometrial Cancer, Grading.

INTRODUCTION

Endometrial cancer is the most common malignancy of the uterus in Western countries [1]. It is the fourth most common malignancy in women in the developed world after breast, colorectal and lung cancer [2]. Approximately 8,000 deaths/per year occur in the USA due to endometrial cancer [2]. The worldwide incidence of occurrence and death of endometrial cancer was estimatedto be12.7 million new cancer cases and 7.6 million, respectively, in 2008 [3].

In India, the overall incidence rate of endometrial cancer was 105.5 per 100,000 women. It was low in some cities like Delhi (4.3), Bangalore (4.2) and Mumbai (2.8) [4]. The aetiology of endometrial cancer (EC)is related to multiple factors. The exact cause of EC is unknown.EC is mainly seen in women with diabetes, hypertension, and obesity, with 2 to 3 times more risk than the general population [5-6]. Abnormal uterine bleeding in perimeno pause or postmenopausal is the most frequent presentation of endometrial hyperplasia, and endometrial carcinoma [7]. Literature search revealed that progression of atypical endometrial hyperplasia to endometrial carcinoma was 13% to 23%, whereas endometrial hyperplasia without atypia progression rate was 1-2% [8].The detection rate of endometrial carcinoma is relatively high on hysterectomy specimens (up to 43%) in patients with atypical endometrial hyperplasia (AH) on biopsy [9].

There is a varied association between biopsy vs hysterectomy specimen findings. In this context, we aimed to describe the concordance and discordance between endometrial biopsy and hysterectomy specimens for detecting and grading endometrial carcinoma.

METHODS

The present study was a retrospective cross-sectional analytical study. We collected data from histopathology reports and demographic details from 2018 to 2021 from the departmental archives. All biopsies with a diagnosis of atypical hyperplasia and endometrial cancer diagnosed and corresponding hysterectomy specimens were selected for the study. Slides of biopsy and hysterectomy were retrieved for review, and we compared the diagnosis and grading of endometrial cancer between biopsy vs hysterectomy

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ISSN: 1927-7210 / E-ISSN: 1927-7229/25

specimens to see concordance and discordance. All cases with endometrial atypical hyperplasia and endometrial carcinoma were included in the study. All patients with endometrial hyperplasia without atypia and endometrial dating biopsy were excluded. The grading was performed as per recommendations of the most recent WHO and FIGO classification based on the architectural and nuclear features, which follows as [10]:

1. Architectural grading of endometrial carcinoma:

   Grade 1- <5% or less of nonsquamous, non-nodular solid pattern

   Grade 2- 6-50% tumour is solid

   Grade 3- > 50% tumour is solid

2. Nuclear grading of endometrial carcinoma:

   Grade 1- Mildly enlarged oval nuclei with evenly dispersed chromatin

   Grade 2- Features intermediate to 1 and 3

   Grade 3- Markedly enlarged nuclei, pleomorphic, irregular coarse chromatin and prominent eosinophilic

3. All endometrial carcinoma type II (serous, clear cell, undifferentiated carcinomas and carcinosarcomas) were considered high grades G3.

Further, this grading was gradedas G1- well-differentiated carcinoma, G2- moderately differentiated carcinoma and G3- poorly differentiated carcinoma.

Statistical Analysis

Continuous data were reported as mean±SD for normally distributed variables. Categorical data were reported as percentages. Comparison between the two groups' type of diagnosis, architectural grading, nuclear grading, and overall grading between endometrial biopsy and hysterectomy specimens was done with the chi^2 test (association) and Kappa statistics (agreement/ concordance or discordance/disagreement). "C" is the contingency coefficient, and it was calculated as values from 0 to 1, where 0 means no association and 1 is a very strong association, which shows the strength of the relationship between variables. Cohen's Kappa statistics (linear κ) was used to see agreement/ disagreement between biopsy vs hysterectomy specimen. The sensitivity and specificity of the endometrial biopsy were calculated to detect endometrial carcinoma against hysterectomy specimens diagnosis, which was considered the gold standard. A p-value of <0.05 was considered statistically significant. We used STATA 14 software for statistical analysis.

RESULTS

A total of 83 cases of atypical endometrial hyperplasia and endometrial cancer were reported on endometrial biopsy during the study period. Only 44 cases had hysterectomies for endometrial cancer and atypical hyperplasia as per treatment protocol. Therefore, we included 44 patients in this study. All 44 cases were of endometrial carcinoma on hysterectomy. The patient's clinical, radiological, operative findings (gross), myometrial involvement, lymph node metastasis and TNM staging for endometrial carcinoma are listed in Table **1**.

The association between endometrial biopsy diagnosis and hysterectomy specimens diagnosis is shown in Table **2**.

On endometrial biopsy, the most common cancer was endometroid-NOS (not other specific)at 63.64% (n=28/44), and on hysterectomy specimens, the most common endometrial cancer was also endometroid-NOS type 84.0% (n=37/44).The overall concordance for diagnosis was 59.1% (n=26/44) between biopsy and hysterectomy. The association of biopsy and hysterectomy specimens for histological diagnosis was significant (p=0.0001), and the value of $Chi^2(20) =48.1523$, the strength of association (C=0.379) was mild. The highest concordance was found for endometroid carcinoma-NOS of 67.6% (n=25/37) between biopsy and hysterectomy specimens. The discordance (40.9%) was found mainly for AH 22.7%(10 cases) diagnosed on biopsy, and they turned out as endometrial carcinoma-NOS in (09) cases andas endometrioid carcinoma special type in one on hysterectomy specimens. Two cases of endometrial cancer special type(one papillary type, other one villoglandular type)and one mixed type turned out as endometrioid cancer -NOS type on hysterectomy specimens. Mismatch on biopsy and hysterectomy included: endometrioid carcinoma and mixed-type carcinoma; AH and endometroid cancer-special type; special type endometrioid and undifferentiated carcinoma.

Table 1: Patient's Attributes of Endometrial Cancer Based on Hysterectomy (n=44)

S.N.	Patients attribute	Value
1	Age on hysterectomy, mean±SD (range), years	55.4±9.6 (49.5- 62)
2	Clinical menifestations	
	Postmenopausal bleeding	20 (45.4%)
	Postmenopausal bleeding along with diabetes mellitus and hypertension	16 (36.4 %)
	Abnormal uterine bleeding in perimenopause	8 (18.2%)
3	Parity	
	Nulliparous (P0)	05 (11.4%)
	P3 and P4	11 (25.2%) each
	P2 and P5	7 (15.3%) each
	P1, P8, and P10	1 (2.7%) each
4	Perioperative findings (gross)	
	Enlarged uterus with single growth intrauterine cavity	22 (55%)
	Irregular multiple growth intrauterine cavity	12 (30%)
	Patchy discoloration intrauterine cavity	4 (10%)
	Massively enlarged uterus with mass in cavity	2 (5%)
5	Radiological details (n=27)	
	Increased endometrial thickness	6 (22.2%)
	Enlarged uterus	9 (33.3%),
	Polypoidal growth in the uterus	6 (22.2%),
	Heterogenous mass in the uterus	3 (11.1%)
	Hyperplasia with the fibroid	3 (11.1%)
6	Myometrial Invasion on Hysterectomy specimens	
	<50% myometrial invasion with EC	23 (57.3%)
	>50% myometrial invasion with EC	18 (40.9%)
	Full thickness myometrial invasion with EC	3 (6.8%)
7	Lymph node metastasis	
	No lymph node involvement (N0)	39 (88.6%)
	N1	3 (6.8%)
	N2	2 (4.6 %)
8	TNM staging of AJCC (8th edition)	
	pTla	25 (56.8%)
	pTlb	17 (38.6%)
	pT2	1 (2.3%)
	pT2M1	1 (2.3%)
EC-endometrial carcinoma, AJCC-American joint cancer control.		

Table 2: The Frequency and Association of the Diagnosis of Endometrial Carcinoma Between Biopsy vs Hysterectomy Specimen

Hysterectomy specimen Diag n=(%)	Endometrial biopsy diagnosis n= (%)					
	Endometroid ca-NOS	AH	Endometroid Ca special type	Clear cell Ca	Mixed Ca	Total
Endometroid ca-NOS	25 (67.6)	9 (20.5)	2 (4.5)	0	1	37 (84)
Serous Ca	1(2.3)	0	0	0	0	1 (2.3)
Clear cell Ca	1(2.3)	0	0	1 (2.3)	0	2 (4.5)
Endometroid Ca special type	0	1	0	0	1	2 (4.5)
Mixed Ca	1 (2.3)	0	0	0	0	1 (2.3)
Undifferenced Ca	0	0	1	0	0	1 (2.3)
Total	28 (63.6)	10 (27.7)	3 (6.8)	1 (2.3)	2 (4.5)	44
AH-Atypical Hyperplasia, Diag.-diagnosis, NOS- not otherwise specified, Ca-cancer						

We also determined the association between endometrial biopsy and hysterectomy specimens for architectural, nuclear, and overall/final grading (Table **3**).

On architectural grading and nuclear grading, G1 [40.9% (18/44)] and G3 [56.8% (25/44)] respectively, were most frequent. On overall/ final grading, G3 [36.4% (16/44)] was most commonly followed by G1 and G2 at 31.8% (14/44)each. The type of carcinoma, based on differentiation, was poorly differentiated endometrioid carcinoma-NOS in 36.6% (16/44) and moderately and well-differentiated cancers in 31.8% (14/44) patients each.

The overall concordance for grading was 52.3% (n=23/44) between biopsy vs hysterectomy. The concordance for the overall grading was maximum for G1 (11/14=78.6%), followed by G2 (6/14= 42.8%) and G3 (6/16=37.5%) between biopsy vs hysterectomy. For architectural grading, the maximum concordance was for G1 (17/18= 94.4%), followed by G2 (02/14= 14.3%) and G3 (01/12= 8.3%).On nuclear grading, concordance was maximum for G1(06/7= 85.7%), followed by G2 (04/12= 33.3%) and G3 (08/25= 32%).

The overall discordance for grading was 47.7 % (21/44) between endometrial biopsy vs hysterectomy. The discordance in overall grading for G1, G2, and G3 was 21.4%, 57.1% and 62.5%, respectively, between biopsy vs hysterectomy. In architectural grading, the discordance for G1, G2, and G3 was 5.5%, 85.7% and 91.6%, respectively. Nuclear grading revealed discordance for G1, G2 and G3 as 14.3%, 66.6% and 68%, respectively.

There was a significant association between biopsy and hysterectomy for architectural grading [Chi^2 (4) =9.679 with C=0.371 and p value=0.046]. For nuclear grading [Chi2 (4) = 10.9931, C= 0.480 and P= 0.027] and overall/final grading [chi2(4) = 16.5284, C= 0.592 and p = 0.002] also, there was a significant association between biopsy and hysterectomy.

Histological gradingbased on histomorphology is shown in Figure **1**.

Diagnostic Agreement

The diagnostic agreement between biopsy and hysterectomy specimens is shown in Table **4**.

Cohen's Kappastatistics showed agreement in 59.1% (26/44) cases for type of endometrial carcinoma between biopsies and hysterectomy that was significant (p-value0.049) agreement. Similarly, overall grading and nuclear grading also had a considerable agreement between biopsy and hysterectomy (Table **4**).

Sensitivity and Specificity of Endometrial Biopsy

We analyzed the sensitivity and specificity of endometrial biopsy in comparison to hysterectomy (considered as gold standard), and it was 67.6% (95% CI 50.2% to 82%) and 57.1% (95% CI 18.4% to 90.1%) respectively. The positive predictive value (PPV) and

Table 3: Comparison between Architectural, Nuclear and overall Grading of Endometrial Carcinoma by Biopsy and Hysterectomy Specimen

Hysterectomy Specimen Grading		Endometrial Biopsy Grading									
		Architectural			Nuclear			Final/Overall			Total
		G1	G2	G3	G1	G2	G3	G1	G2	G3	
Architectural Grading	G1	17	1	0							18
	G2	10	2	2							14
	G3	6	5	1							12
Nuclear Grading	G1				6	1	0				7
	G2				7	4	1				12
	G3				6	11	8				25
Final /overall Grading	G1							11	3	0	14
	G2							7	6	1	14
	G3							2	8	6	16
		33	8	3	19	16	9	20	17	7	

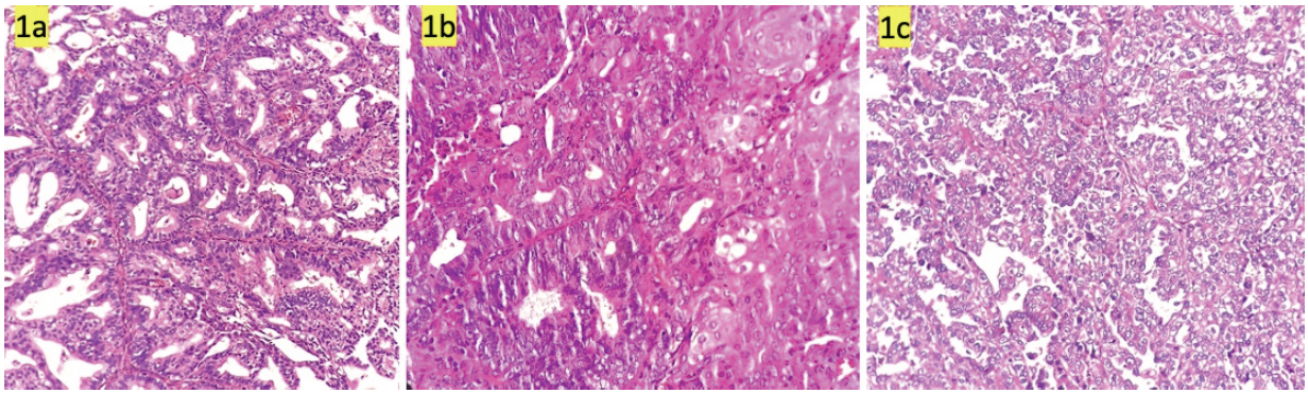

Figure 1: A Panel of micro images of endometrial carcinoma with architectural and nuclear grading; (**a**) Architectural grade 1 and nuclear grade 1, (**b**) Architectural grade 2 and nuclear grade 2, (**c**) Architectural grade 3 and nuclear grade 3, (All figures are H & E stain, x40).

Table 4: Comparison of Diagnostic Agreement between Biopsy and Hysterectomy Specimen for the Type and Grading of Endometrial Carcinoma

Comparison Biopsy vs Hysterectomy	Agreement (%)	Linear κ	Standard Error 95% CI	P-value
Type of EC	59.1	0.1101	0.0666	0.049
Architectural grading	45.5	0.1156	0.0912	0.103
Nuclear grading	40.9	0.1746	0.0872	0.023
Overall grading	52.3	0.2925	0.1006	0.002

negative predictive value (NPV) of the biopsy were 89.3% (95% CI 71.8% to 97.7%) and 25% (95% CI 7.3% to 52.4%), respectively.

DISCUSSION

Endometrial cancer is the most reported cancer in hysterectomy specimens [11]. The hysterectomy is the primary treatment for AUB or postmenopausal bleeding due to atypical hyperplasia (AH) and suspicion of cancer diagnosed on biopsy. There is always a need that laboratory services should be precise and cost-effective [12-14] Both endometrial biopsy and hysterectomy are acceptable for diagnosing endometrial cancer, but hysterectomy is a major surgical procedure, and biopsy is a minimally invasive procedure. So, establishing diagnostic accuracy, sensitivity and specificity of biopsy is needed for better patient care.

In this study, we found a diagnostic agreement/association of 59.1%between biopsy and hysterectomy specimen for the type of endometrial cancer, which was lower than the study by Kisielewski *et al*. which reported an 85% association between both [15]. Bryant *et al*. reported a diagnostic agreement of 96% between selective sampling and a complete sampling of the endometrium, which was very high compared to our study [16]. Other studies reported diagnostic agreement between endometrial biopsy and hysterectomy specimens varying from 30% to 60% [17-18]. It suggestsa highly variable agreement between biopsy and hysterectomy specimens among various centers, and it should be evaluated for each centre. Further, there is a need to improve the agreement where it is on the lower side. The discordance was reported from 4% to 40% in different studies to diagnose endometrial cancer between biopsy bs hysterectomy specimens [15-17]. In the present study, we had 40.9% discordance.

The strength of the agreement between biopsy vs hysterectomy diagnosis was mild but significant in our study (C=0.379, and κ =0.1101). Few studies showed moderate strength of association between biopsy vs hysterectomy Chi^2 (C= 0.509) and linear κ = 0.7697 [15-16]. The association between biopsy vs hysterectomy was mild for diagnosis of EC in our study might be related to inter observer variability of different experienced persons reported biopsies. It might be related to the sampling error of biopsies, atypical hyperplasia presented in the uterus and endometrial cancer, where the biopsy needle did not hit. That's why atypical hyperplasia was diagnosed on biopsy but not on the hysterectomy specimen. All symptomatic patients with atypical hyperplasia were followed radiologically to see invasion and extension in the

endometrium. The clinician manages these patients by both biopsies and radiologically. The radiological opinion, along with an endometrial biopsy, is also essential for managing atypical hyperplasia of the endometrium. There were few studies described discordance enables surgeons to anticipate potential management differences and adjust surgical plans, informing patients about potential risks or unwanted outcomes and fostering more realistic expectations, eventually improving informed conscent and patient satisfication [19,20].

The grading of endometrial cancer we assessed in all cases (100%) of the present study, whereas different studies were evaluated from 67% to 83.7% cases of EC [15,17-18].

In our study, the most common cancer was poorly differentiated endometrioid carcinoma-NOS 36.6% (16/44), followed by well and moderately differentiated endometroid carcinoma, 31.8% (14/44) each. Whereas other studies reported moderately [G2 (75.8%)] cancer and poorly differentiated [G3 (73.3%)] cancer, higher than our results [9,15]. A study reported higher agreement for grading for moderately differentiated carcinoma 87% than poorly differentiated carcinoma (44.4%) [15]. We found the highest agreement for G1 (78.6%), followed by G2 (48.5%) and G3 (37.2%). Few studies reported higher concordance in high-grade cancers [18,21]. This might be due to biopsy sampling being focal/limited areas of the endometrium sampled; sampling error always affects the biopsy reporting.

We found a significant association between biopsy vs hysterectomy for architectural, nuclear and overall grading. These findings were similar to the results of Kisielewski's that reported a significant association between biopsy and hysterectomy for grading (contingency coefficient, C = 0.5445) [15]. Petersen *et al*. reported a poor correlation between pre-operative grading of endometrial cancer and grading done on the resected uterus [18]. They hada poor correlation (30%) for endometrial cancer grade 1 (G1) [18].In contrast, we had the highest correlation (78.6%) for G1 of endometrial cancer between biopsy vs hysterectomy. On Kappa statistics, we had mild to moderate significant agreement for architectural, nuclear and overall grading (k=0.1156, 0.1746 and 0.2925, respectively) between biopsy vs hysterectomy specimens.

Vorgias *et al*. reported 67.3% concordance for endometrial cancer (EC) diagnosis and 55.5% concordance for final tumour grade between pre-hysterectomy curettage and final histological diagnosis [21]. We had a concordance of 59.1% for the diagnosis of EC and 52.3% for final grading.

Bryant *et al*. reported a sensitivity of 92% and specificity of 100% of selective sampling (SS) in comparison to complete sampling [16]. We founda sensitivity of 67.6% and a specificity of 57.1% of biopsy in comparison to hysterectomy. Nemer *et al*. reported 53.8% sensitivity, 90% specificity, 70% positive predictive values and 81.8% negative predictive values for pre-operative histological examination compared to postoperative (hysterectomy) histological examination [20]. The study also reported moderate agreement between pre-operative and postoperative histologic diagnoses (79.1%, k=0.469) [22].

Limitations: This is a retrospective study with a small sample size. Further, we didn't correlate with immunohisto chemistry/molecular technique. Finally, we didn't have follow-up data.

We concluded that the concordance/ association and agreement between endometrial biopsy and hysterectomy was moderate for diagnosing and grading endometrial cancers. We recommended that endometrial biopsy is helpful for the diagnosis of endometrial carcinoma, especially in young females. The biopsy may be a cost-effective approach in resource-poor countries.

FUNDING INFORMATION

None.

CONFLICT OF INTEREST

No financial or non-financial competing interests.

AVAILABILITY OF DATA AND MATERIAL

Data available on request

ACKNOWLEDGEMENTS

Nil.

AUTHOR CONTRIBUTION

Dr Anju Khairwa did data collection and data analysis and wrote the manuscript, Dr Pooja helped with data collection, and Prof. Sonal Sharma suggested the title and edited the manuscript.

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Received on 02-08-2025 Accepted on 07-09-2025 Published on 07-10-2025

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