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Sentinel Lymph Node Biopsy versus Complete Lymphadenectomy in The Management of Endometrial Carcinoma

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ABSTRACT

Background: 320,000 new instances of endometrial cancer (EC) are thought to occur annually worldwide, making it the fifth most frequent malignancy in women. **Objective**: To assess the diagnostic accuracy and clinical impact of sentinel lymph node (LN) mapping in the management of EC. **Patients and Method:** This prospective study was conducted on 23 patients who attended the Gynecology and Obstetrics clinic in Menoufia University Hospital and were diagnosed to have endometrial carcinoma by histopathological examination, from September 2019 until July 2022. **Results:** Sentinel lymph node biopsy (SLNB) is an efficient diagnostic tool in the management of endometrial carcinoma with 9 (81.82%) TP, 9 (90%) TN, 1 (10%) FP, 2 (18.18%) FN, 85.7% diagnostic accuracy, 81.8% sensitivity, 90% specificity, 90% PPV and 81.8% NPP. SLN mapping (Number of SLNs, SLNs metastases, type of metastases) were insignificantly different between frozen section and permanent section. Hysterectomy type was simple in 21 (91.3%) patients and was radical in 2 (8.7%) patients. Regarding histologic subtype of the studied patients, 2 (8.7%) patients had serous subtype, 9 (39.13%) patients had grade III endometrioid subtype, 10 (43.5%) patients had grade II endometrioid subtype, 1 (4.35%) patient had carcinosarcoma subtype, 1 (4.35%) patient had clear cell subtype. **Conclusion:** SLNB is an effective diagnostic technique for the treatment of endometrial carcinoma. Retroperitoneal lymphadenectomy increases intraoperative and postoperative complications.

Keywords: Endometrial carcinoma, Endometrial intraepithelial neoplasia, SLNB.

INTRODUCTION

According to estimates, 320,000 new instances of EC are diagnosed worldwide each year, making it the fifth most frequent malignancy in women [1]. Ageing, obesity, diabetes, nulliparity, late menopause, unopposed estrogen replacement therapy, and tamoxifen usage are risk factors for end-stage cancer[2].

Surgery, which includes a complete hysterectomy and bilateral salpingo-oophorectomy with or without LN dissection, is the mainstay of care for the majority of women with EC [3].

Depending on risk factors for recurrence, including stage, age, grade, involvement of the lymphovascular space, myometrial invasion, and LN status, women may be offered adjuvant treatment following surgery, which might include radiation, chemotherapy, or a combination of these. LN metastases are one of the primary independent predictors of survival; hence, their diagnosis affects the adjuvant therapy that is administered, including chemotherapy, radiation therapy, or both [4].

In patients with apparent early-stage EC, a thorough dissection of the LNs was traditionally recommended to check for extra-uterine disease; however, new European guidelines recommend systematically removing the pelvic and para-aortic nodes in patients with high-risk EC [5].

Nonetheless, it has been demonstrated that performing a lymphadenectomy—either pelvic alone or pelvic plus para-aortic—reduces operating time, raises expenses, and has unfavorable effects like lower-extremity lymphedema. Furthermore, the available data does not support the notion that a total lymphadenectomy improves patient survival [6].

The goal of this study was to assess the diagnostic accuracy and clinical impact of SLN mapping in the management of EC.

PATIENTS AND METHODS

This prospective study was conducted on 23 patients who attended the Gynecology and Obstetrics clinic in Menoufia University Hospital and were diagnosed to have endometrial carcinoma by histopathological examination, from September 2019 until July 2022.

Inclusion criteria:

Patients diagnosed to have endometrial carcinoma by histopathological examination.

Exclusion criteria:

1. Patients with known allergy to the dye.
2. Those with grossly enlarged lymph node by radiological methods.
3. Patients diagnosed with stage IV endometrial carcinoma.

All patients were subjected to:

a) **Complete history taking of clinical importance including:**

- **Personal history:** Age, residence, occupation, marital status and special habits as smoking, alcohol, etc.
- **Menstrual history:** Date of menopause if postmenopausal.
- **Obstetric history:** Gravidity, parity, previous miscarriages or obstetric complications.
- **Contraceptive history:** Type, duration of use.
- **Medical history:** Medical comorbidities as hepatic, renal, cardiac, endocrinal.
- **Surgical history:** Previous operations.

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- **Family history** of similar conditions.

b) General and local examination with special emphasis on: Vital indicators, body mass index, pallor, indications of any related medical diseases, uterine bimanual examination, and sterile Cusco speculum inspection to rule out any unusual local issues.

c) Investigation: Routine investigations as CBP, liver and kidney function tests, coagulation profile "PT, PTT and INR", viral hepatitis markers: hepatitis B and C viruses, blood group (ABO) and Rh.

Ethical considerations:

Patients who were willing to participate completed informed written permission forms after being fully told about the nature and goals of the present investigation. Individuals were free to leave the research at any time without fear of losing their access to proper medical treatment. Menoufia University Faculty of Medicine's Ethical Research Committee gave its approval to the study plan. The Helsinki Declaration was adhered to at every stage of the investigation.

Statistical analysis

With SPSS v. 26.0, statistical analysis was carried out. A quantitative variable's mean±SD or median and interquartile range (IQR) were displayed. Qualitative factors were shown as percentages (%) and frequencies. SLNB was validated by measuring its sensitivity, specificity, PPV, NPV, and diagnostic accuracy in the treatment of endometrial cancer. P value < 0.05 was considered significant.

RESULTS

Regarding baseline characteristics of the studied patients, mean age was 58.3 ± 12.58 years. Mean BMI was 29.3 ± 4.31 Kg/m^2. Regarding menopausal status, most (82.61%) of the patients were postmenopausal **(Table 1)**.

Table (1): Baseline characteristics of the studied patients

		N=23
Age (years)	**Mean ± SD**	58.3 ± 12.58
	Range	37 – 80
Weight (Kg)	**Mean ± SD**	82.7 ± 10.38
	Range	62 - 100
Height (m)	**Mean ± SD**	1.7 ± 0.06
	Range	1.59 - 1.77
BMI (Kg/m^2)	**Mean ± SD**	29.3 ± 4.31
	Range	21.45 - 35.38
Menopausal status	**Postmenopausal**	19 (82.61%)
	Premenopausal	4 (17.39%)

Hysterectomy type was mostly simple in 21 (91.3%) patients. Regarding histologic subtype of the studied patients, 9 (39.13%) patients had grade III endometrioid subtype and 10 (43.4%) patients had grade II endometrioid subtype **(Table 2)**.

Table (2): Hysterectomy type and histologic subtype of the surgical specimens

		N= 23
Hysterectomy type	**Simple**	21 (91.3%)
	Radical	2 (8.7%)
Histologic subtype	**Serous**	2 (8.7%)
	Grade 3 endometrioid	9 (39.13%)
	Grade 2 endometrioid	10 (43.5%)
	Carcinosarcoma	1 (4.35%)
	Mixed	0 (0%)
	Clear cell	1 (4.35%)

All patients underwent the SLNB, with a detection rate of 91.3% per patient, and 66.6% bilaterally and the sentinel LN which were resected per each patient was with a median (IQR) 3 (2-4). Patients subsequently underwent lymphadenectomy; all patients 23 (100%) underwent pelvic lymphadenectomy, and 4 (17.3%) with high-grade EC also underwent para-aortic lymphadenectomy. The average pelvic LN resected was 17 (73.91%). 11 (52.4%) patients underwent laparoscope and frozen section and 10 (47.6%) underwent open technique (permanent section) **(Table 3)**.

Table (3): Operative findings of enrolled Patients

		N= 23
SLN detection	Sidal	21 (91.3%)
	Bilateral	14 (66.67%)
Pelvic lymphadenectomy		23 (100%)
Para-aortic lymphadenectomy		4 (17.3%)
Number of Lymph nodes removed	Sentinel	3 (13.04%)
	Pelvic	17 (73.91%)
	Para-aortic	3 (13.04%)
Laparoscope and frozen section		11 (52.4%)
Open technique (permanent section)		10 (47.6%)

SLNB is an efficient diagnostic tool in the management of endometrial carcinoma with 85.7% diagnostic accuracy, 81.8% sensitivity, and 90% specificity **(Table 4)**.

Table (4): The diagnostic accuracy of SLNB in the management of endometrial carcinoma

	TP	TN	FP	FN	Accuracy	Sensitivity	Specificity	PPV	NPP
SLNB	9 (81.82%)	9 (90%)	1 (10%)	2 (18.18%	87.7%	81.8%	90.0%	90.0%	81.8%

TP: True positive, TN: True negative, AUC: area under the curve, PPV: positive predictive value, NPP: negative predictive value.

SLN mapping (Number of SLNs, SLNs metastases, type of metastases) were insignificantly different between frozen section and permanent section **(Table 5)**.

Table (5): SLN mapping: frozen versus permanent section from 13 cases

		Frozen section (%)	Permanent section (%)	P value
Number of SLNs		6 (54.5%)	5(45.5%)	0.669
SLNs metastases		5(83.3%)	4(80%)	0.886
Type of metastases	Macro metastases	2(40%)	2 (50%)	0.764
	Micro metastases	2 (40%)	1 (25%)	0.635
	ITC	1 (20%)	1 (25%)	0.857

SLN: sentinel lymph node, ITC: Isolated tumor cells.

DISCUSSION

A comprehensive LND can assist define prognosis and help customize the most appropriate adjuvant therapy, even if it does not appear to have a direct impact on survival [7]. It's interesting to note that individuals whose lymph node status was unclear had the lowest survival rates in a sizable multicenter retrospective analysis on patients with high-intermediate and high-risk EC [8].

Adjuvant radiation is administered less frequently to individuals whose lymph node status is uncertain than to those whose lymph node status is pathologically negative [9]. As a result, a number of prospective studies were conducted with the goal of comparing the sensitivity of SLN mapping to the reference standard of total lymphadenectomy. One of the first prospective trials to investigate the reliability of SLN in EC was the SENTIENDO experiment, in which the enrolled patients had pelvic lymphadenectomy as the gold standard after an SLN assessment [10]**.** They reported an 89% detection rate, a 97% NPV, and an 84% sensitivity for each patient using a cervical injection of Tc-99 and blue dye. This work made a significant contribution to our knowledge of the SLN mapping technique's accuracy. Also, 87% of the patients had low grade EC, which made extrapolating the findings to the high-grade population challenging.

Our study reported that, SLNB is an efficient diagnostic tool in the management of endometrial carcinoma with 85.7% diagnostic accuracy, 81.8% sensitivity, 90% specificity, 90% PPV and 81.8% NPP.

Tanaka *et al.* [11] concurred with us and stated that, out of 951 identified sentinel nodes, 51 nodes were determined to be positive in the final pathological diagnosis. This comparison of the diagnostic accuracy of intraoperative frozen section analysis and imprint cytology was made with the final pathological diagnosis. Frozen section analysis, imprint cytology, and the combination of the two modalities had sensitivity values of 76.5%, 72.6%, and 92.2%, in that order. Imprint cytology and frozen section analysis both had 100% specificity. Frozen section analysis and imprint cytology had negative predictive values of 98.7% and 98.5%, respectively. The sensitivity of the combined technique was better than when a frozen section analysis or imprint cytology was conducted alone. In these situations, the accuracy of the frozen section analysis and imprint cytology in the evaluation of SNB specimens was deemed satisfactory.

Bellaminutti *et al.* [12] concurred with us and reported that the intraoperative evaluation of SLN in EC accurately identifies patients with macrometastases. Fifty-eight patients met the inclusion criteria, and clinical-pathologic characteristics of the patients and surgical data were analyzed. Overall, 100% (58/58), 89.7% (52/58), and 10.3% (6/58), respectively, were found for bilateral and unilateral detection rates; eight patients had a stage IIIC disease at permanent section; four of the eight patients had SLN metastases, two of which were micrometastases, and two of which were macrometastases; no macrometastases were misdiagnosed at the frozen section of the SLNs.

Recent research by **Renz *et al.*** [13] showed that instantaneous SLN mapping with FS has a high negative predictive value of 98.7% and a high sensitivity of 83.3%. However, ultrastaging at the permanent segment was not part of their procedure.

In a large multicenter prospective experiment, the NPV and SLN mapping sensitivity in clinical stage 1 EC using ICG were compared to complete lymphadenectomy (pelvic with or without para-aortic lymphadenectomy) [14]. The results of this experiment showed that the NPV was 99.6%, the sensitivity was 97.2%, and the detection rate was 86%. More data supporting the use of the SLN approach in EC staging

was provided by the large multicenter prospective study, which showed that only 28% of the cohort had high-grade histology.

SLN mapping has been investigated in several prospective trials including individuals with high-risk EC. In a prospective study conducted by the MD Anderson Cancer Center team, patients with a high-grade histologic subtype, cervical involvement, or FIGO grade 1/2 with probable deep myometrial invasion on imaging were enrolled in SLN mapping [15]. Following SLN mapping, all patients had pelvic and para-aortic lymphadenectomy. The bilateral detection rate was 47.8%, and the detection rate per patient was 69.5%. By using SLN biopsy alone, 95% of those with positive lymph nodes were appropriately identified. Only one patient had bilaterally negative SLN and positive non- SLN, according to final pathology. These findings suggest that SLN mapping was accurate in patients with high-grade histology, who constituted just over 50% of the cohort and were more likely to have nodal involvement.

To evaluate the diagnostic effectiveness of pelvic SLN in high-risk EC, prospective research was designed in Sweden and named the Pelvic SLN identification in High-Risk EC trial [16]. Patients with clinical stage I-II EC were included into the study if they satisfied one or more of the subsequent preoperative high-risk criteria: non-diploid cytometry, deep myometrial invasion, high-grade histology, or cervical stromal invasion. The identification process included looking for any prospective studies including patients with clinical stage 1 high-grade EC undergoing SLN mapping with cervical IGC injection and at least bilateral pelvic LND as the reference standard. This showed a bilateral detection rate of 64% (50–81%) and an overall SLN detection rate of 91% per subject. Each patient had an NPV of 97% and an SLN sensitivity of 92%. Since the majority of the included research did not have this as their primary goal, this study was unable to evaluate the SLN algorithm's performance. However, the results added to the body of data in favor of SLN mapping in patients with high-grade EC [17].

In terms of the oncologic result after SLN mapping, it is known that this method may properly identify lymphatic spread; however, it is uncertain if this procedure compromises overall survival and the absence of recurrence when compared to total lymphadenectomy [18].

Although prospective data comparing the oncologic outcomes of lymphadenectomy and SLN mapping are lacking, investigations have not demonstrated a statistically significant difference in survival between the two procedures for patients with confirmed nodal metastases [19].

Since a non-SLN or a portion of the lymphatic channels that remain in situ may be implicated in metastatic illness, one may argue that eliminating only the mapped SLNs would have a negative impact on oncologic outcomes. Adjuvant therapy, which treats occult metastases, will eventually be given to most patients who have been identified with nodal metastasis using SLN mapping [20].

Furthermore, in more than half of the patients with high-grade EC, the excised SLN is the sole site of illness, and low-volume metastases are frequently seen in this SLN [14].

An investigation that compared the results of individuals receiving SLN sampling followed by a full lymphadenectomy with those receiving lymphadenectomy alone discovered that the inclusion of SLNB led to better overall and progression-free survival as well as decreased rates of pelvic recurrence. These results imply that SLNB increased diagnostic precision and supplied more information to support adjuvant therapy decisions that may lead to better results [21].

In research by **Barlin *et al.*** [22] with 498 patients, the detection rate was 81%. Following the application of the SLN method, the NPV climbed from 98.1% to 99.8%, the sensitivity increased from 85.1% to 98.1%, and the false negative results significantly decreased from 14.9% to 1.9%. NPV rose from 95% to 99.2% when the MSKCC algorithm was retrospectively applied to 14 trials, including SENTI-ENDO [23].

385 patients with EC from 19 surgeons across 10 institutions were involved in the FIRES research. Both the bilateral and overall detection rates were 52% and 86%, respectively. The results showed a sensitivity of 97.2%, an NPV of 99.6%, and a false negative rate of 2.8%. There are currently no RCTs, and the majority of these investigations are prospective or retrospective in nature [14].

Numerous studies have carefully assessed the diagnostic value of SLN; the detection rate ranged from 80% to 100%, the percentage of false negative findings varied from 0% to 15%, and the sensitivity ranged from 86 to 100%. According to **Kang *et al.*'s**[24] meta-analysis of 26 trials, the sensitivity and detection rate were 93% and 78%, respectively. The detection rate and sensitivity with fewer than 30 patients were 82% and 88%, respectively, whereas with more than 30 cases, they were 78% and 93%, when learning curve deviation was taken into account.

A comprehensive evaluation of 17 research was carried out by **Cormier *et al.*** [25]**,** who omitted the studies that included fewer than 30 patients. The detection rate ranged from 60% to 100%; in a subset with more than 100 cases, the detection rate was higher than 80%. Following the SLN algorithm's retrospective application, the sensitivity, net present value, and false negative outcomes were 95%, 99%, and 5%, respectively. These findings demonstrate the beneficial effects of conventional surgical techniques and surgeon experience on SLN diagnostic accuracy.

A meta-analysis of 55 trials including 4,915 individuals was reported by **Smith *et al.* [26]**. 81% and 50%, respectively, were the detection rate and bilateral detection rate. The paraaortic lymph nodes were seen in 17% of cases. The NPV was 99.7%, while the sensitivity was 96%. The detection rate may be raised by ICG and cervical injection ($p < 0.05$).

How *et al.* [27] conducted a new meta-analysis that comprised 48 studies and 5,348 patients, examining the paraaortic lymph nodes, bilateral detection rate, and detection rate. The corresponding detection rates were 87%, 61%, and 6%. It is said that the study demonstrated that SLN mapping did not decrease the diagnostic value in high-risk histological types, nor did it raise the risk of recurrence or influence survival result when compared to lymphadenectomy.

Due to the wide-spread COVID-19 epidemic at the time of research conduct, which interferes with patient interaction, and the relatively small sample size for accuracy of study results, the current study has limitations.

CONCLUSION

A useful diagnostic technique for endometrial cancer treatment is SLNB. The risk of both intraoperative and postoperative complications is higher with retroperitoneal lymphadenectomy. Costs are reduced and quality adjusted survival is greater using SLN mapping. Furthermore, when it comes to managing low-risk ECs, SLN is the most economical approach. When compared to women who had systemic lymphadenectomy, those who underwent SLN mapping staging were more likely to get adjuvant therapy.

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