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Size of Sentinel Node Metastasis Predicts Non-sentinel Node Involvement in Endometrial Cancer

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ABSTRACT

Purpose. To analyze the relationship between the size of metastatic sentinel lymph nodes (SLNs) and the risk of non-sentinel lymph node (non-SLN) metastasis in endometrial cancer.

Patients and Methods. From a total of 328 patients with endometrial cancer who underwent SLN mapping from January 2013 to April 2019, 142 patients also underwent systematic completion pelvic ± paraaortic node dissections, and they form the basis of this study. The SLNs were examined by immunohistochemistry (IHC) when the hematoxylin–eosin stain was negative.

Results. The median age was 60 years. The overall detection rate for SLNs was 87.5%, and bilateral SLNs were observed in 66.2%, with a median of 2 SLNs resected (range 1–8). Twenty-nine (20.4%) cases had positive SLNs, with a median of one positive SLN. Regarding the size of SLN metastasis, 5 (3.5%) cases had isolated tumor cells (ITCs), 13 (9.2%) had micrometastases, and 11 (7.7%) had macrometastases. Notably, 14/29 (48.3%) had node metastases that were detected after IHC. Eight (27.6%) patients had positive non-SLNs, with a median count of 7 positive nodes (range 2–23). Regarding the size of SLN metastasis, non-SLN involvement was not present in cases with ITC (0/5) but was present in 15.4% (2/13) of cases with micrometastases and 54.5% (6/11) of cases with macrometastases. The only risk factor for positive non-SLNs was the size of SLN metastasis.

Conclusions. Our data suggest that size of SLN metastasis is associated with the risk of non-SLN metastasis. No patients with ITCs in SLNs had another metastatic lymph node in this study.

Recently, sentinel lymph node (SLN) mapping has emerged as an acceptable surgical strategy when deciding between complete lymphadenectomy and no node dissection, even for high-risk patients.[1] This approach can help avoid morbidities that are associated with complete lymphadenectomy, such as lymphocyst formation, neurovascular injury, and lymphedema.[2] Additionally, SLN mapping allows detection of unusual drainage sites that may be overlooked by standard lymph node dissection, another benefit being the detection of micrometastases and ITCs, because they might be the only sites of extrauterine spread.[3]

Growing evidence supports SLN mapping in endometrial cancer, in which SLN status can accurately predict the status of the regional lymphatic basin and eventually become the standard of care for staging. However, some issues have not been solved, such as the risk factors for non-SLN metastasis, the role of systematic lymph node dissection in SLN-positive patients, and the prognostic value of ITCs and micrometastases.

There is limited information in literature that evaluates the risk factors for presence of non-SLN metastasis in case of positive SLN. Therefore, the aim of the present work is

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to identify the predictive factors of the presence of non-SLN metastasis after a diagnosed metastatic SLN in endometrial cancer.

PATIENTS AND METHODS

We analyzed a series of 328 patients who were treated for endometrial cancer from January 2013 to April 2019 at the Department of Gynecologic Oncology, AC Camargo Cancer Center. All patients underwent sentinel lymph node mapping as part of surgical staging. Of these subjects, 287 had at least one SLN that was detected, with overall and bilateral detection rates of 87.5% and 66.2%, respectively. Of the cohort, 269 (82%) had patent blue dye and 59 (18%) had indocyanine green, with bilateral detection rates of 60.8% and 91.5%, respectively. Further, 145 (50.5%) underwent SLN mapping without systematic lymphadenectomy, and 142 (49.5%) did so with pelvic ± paraaortic lymphadenectomy. Ultimately, patients with systematic lymphadenectomy were included in the analysis of non-SLN metastasis. This study was approved by the institutional review board (#120563).

There were 106 (74.6%) high-risk-tumor patients. The criterion for high-risk tumors was the presence of one of the following: high-grade tumor (endometrioid grade 3 and nonendometrioid histologies—serous, clear cell, or carcinosarcoma), deep myometrial invasion (MI) (≥ 50%), lymphovascular space invasion (LVSI), or cervical stromal invasion.

In the sentinel lymph node protocol, all patients received patent blue dye or indocyanine green (ICG), at 1.25 mg/ml dilution. These compounds were given only by cervical injection—a total of 4 ml of patent blue dye or ICG—1 ml superficially and 1 ml deep (1 cm) at 3 and 9 o'clock. All blue or green lymph nodes were resected.

A gynecological pathologist prospectively viewed the pathological specimens. The SLNs were examined by IHC when the hematoxylin–eosin (H&E) stain was negative. Briefly, SLNs were serially sectioned every 2 mm and stained with H&E at three levels of the tissue block. If the sample was negative, a pan-cytokeratin stain was performed at each of the three levels. SLNs were classified as: (1) macrometastases: tumor ≥ 2.0 mm; (2) micrometastases: tumor cell aggregates between 0.2 and 2.0 mm; (3) ITCs: individual tumor cells or aggregates ≤ 0.2 mm; or (4) negative. When ≥ 2 positive SLNs were found, we grouped the cases based on the largest SLN metastasis.

All lymph nodes with ITCs, microscopic or macroscopic metastases were considered to be positive. Non-SLNs were reported as positive or negative for metastasis, based on routine sectioning and examination of a single H&E-stained slide per a standard protocol.

A database was constructed using SPSS, version 20.0 for Mac (SPSS; Inc., Chicago, IL). Chi square, Fisher's exact, and Student *t*-tests were used to analyze the correlations between categories and clinicopathological variables. For all tests, $p < 0.05$ was considered to be significant. Due to the total number of non-SLN metastases being 8, multivariate analysis could not be performed.

RESULTS

The 142 patients with at least one SLN mapped who had undergone systematic pelvic ± paraaortic lymph node dissection were included in the present work. Median age was 60 years (range 28–83 years), and 73.9% of patients had undergone minimally invasive surgeries. For the 65 (45.8%) patients with only pelvic lymph node dissection, the median pelvic lymph node count was 19; and for the 77 (54.2%) patients with pelvic and paraaortic lymph node dissection, the median pelvic and paraaortic lymph node counts were 27 and 13.5, respectively.

Fifty-three (37.3%) cases had deep myometrial invasion (≥ 50%), 100 (70.4%) had endometrioid histology, 20 (14.1%) were endometrioid grade 3 tumors, 42 (29.6%) non-endometrioid histologies, 46 (32.4%) had LVSI, and 15 (10.6%) showed cervical invasion. Regarding the number of high-risk factors, 63 (44.3%), 27 (19%), 10 (7%), and 6 (4.2%) cases had one, two, three, and four high-risk factors, respectively. The clinical and pathological data are summarized in Table 1.

A median of 2 SLNs was resected (range 1–8), and we noted 2 false negatives—1 with a unilateral negative SLN and a positive ipsilateral non-SLN positive lymph node, and 1 with bilateral negative SLNs and positive pelvic non-SLNs. These patients were excluded from the non-SLN analysis. We recorded an overall sensitivity of 93.5%, a negative predictive value (NPV) of 98.2%, a false-negative rate (FNR) of 6.4% (2/31), and a false-negative predictive value (FNPV) of 1.8%.

Twenty-nine (20.4%) cases had positive SLNs, with a median of 1 positive SLN (range 1–8). Regarding the size of SLN metastasis, 5 (3.5%) cases had ITCs, 13 (9.2%) had micrometastases, and 11 (7.7%) had macrometastases. Notably, 14 (48.3%) cases had ≥ 2 positive SLNs, and 14/29 (48.3%) had lymph node (LN) metastases that were detected only after IHC. In 21 (72.4%) patients, the SLN was the only positive lymph node.

Nevertheless, 8 (27.6%) patients had positive non-SLNs, the median count of which was 7 (range 2–23). Of the eight patients with positive non-SLN, four (50%) had suspicious enlarged lymph nodes. However, of the remaining 21 patients with positive SLN and negative non-SLN, 3 (14.3%) also had suspicious lymph nodes.

TABLE 1 Clinical and pathological characteristics of the 142 patients with endometrial cancer submitted to sentinel node mapping ± pelvic and paraaortic lymphadenectomy with at least one sentinel node detected

Variable	No. of patients	(%)
Age, median (range), years	60 (28–83)	
Body mass index, median (range), kg/m^2	27 (26.9–46.9)	
Type of surgery		
Open	37	26.1
Laparoscopy	67	47.2
Robotic assisted	38	26.8
Type of lymphadenectomy		
Pelvic	66	46.5
Pelvic and paraaortic	76	53.5
Histologic type		
Endometrioid	100	70.4
Serous	13	9.2
Clear cell	5	3.5
Mixed[a]	12	8.4
Carcinosarcoma	10	7.0
Dedifferentiated	2	1.4
Histologic grade		
Grade 1 + 2	80	56.3
Grade 3[b]	62	43.7
Presence of LVSI		
No	96	67.6
Yes	46	32.4
Myometrial invasion		
< 50%	89	62.7
≥ 50%	53	37.3
Parametrial invasion		
No	136	95.7
Yes	6	4.3
Cervical invasion		
No	127	89.4
Yes	15	10.6
Adnexal metastasis		
No	136	95.8
Yes	6	4.2
Number of positive SLN		
0	113	79.6
1	15	10.6
≥ 2	14	9.9
Positive non-SLN		
No	21	72.4
Yes	8	27.6

LVSI Lymphovascular space invasion, *SLN* Sentinel lymph node

[a]Mixed: endometrioid + clear cell or serous histologies

[b]Includes endometrioid G3, clear cell and serous histologies

The only risk factor for positive non-SLNs was the size of the SLN metastasis. Positive non-SLNs were detected in 15.4% of cases with SLN micrometastases, and 54.5% of cases where the SLN had macrometastases. Conversely, no case with ITCs had positive non-SLNs. Non-SLN positivity did not correlate with the number of positive SLNs, high-grade histology, nonendometrioid histology, deep myometrial invasion, cervical invasion, or LVSI (Table 2). Of note, the two patients with micrometastases and positive non-SLNs had adverse prognostic factors of deep myometrial invasion, high-grade tumors, and LVSI.

DISCUSSION

Since 2014, the National Comprehensive Cancer Network (NCCN) guidelines have recommended SLN mapping as an alternative option for lymph node staging in endometrial cancer.[4] One of the main benefits of SLN mapping is increasing lymph node positivity due to ultra-staging. Similar to previous data, we found that 48.3% of cases had positive SLN detected after IHC. Kim et al.[5] found 39.6% (23/58) of positive lymph nodes after ultra-staging in a large series that included low-risk tumors. Moreover, for high-risk tumors, Holloway et al.[6] found that 61% (22/36) of cases had ITCs and micrometastases, compared with 43% (12/28) for Soliman et al.[7] Of note, we found an FNR of 6.4% and FNPV of 1.8%, similar to other series on this topic that evaluated high-risk tumor.[6,7]

Nevertheless, one of the remaining uncertainties in SLN mapping is the value of performing a second surgery for systematic lymph node dissection when an SLN is positive. Theoretically, adjuvant treatment with chemotherapy or radiotherapy can be administered to patients with remaining microscopic lymph node metastases. Further, the therapeutic value of lymph node dissection has not been proven in randomized trials,[8,9] and retrospective data in high-risk patients have not demonstrated any differences in survival when comparing SLN alone with systematic lymph node dissection, despite reporting patients with a relatively short follow-up time in these series.[10–12]

Schiavone et al.[10] published a series of 136 patients with uterine carcinosarcoma who had undergone a lymph node evaluation (48 SLNs mapped and 88 systematic lymphadenectomies), reporting no difference in progression-free survival between groups after adjuvant therapy. The same group published similar results for 248 patients (153 SLNs mapped and 95 lymphadenectomies) for serous endometrial cancer. Although metastatic SLNs were observed in 23% of cases (4 micrometastases and 12 ITCs), the incorporation of SLN mapping did not compromise the prognosis, suggesting a central role of adjuvant therapy in the treatment of microscopic disease.[11] Further, Ducie

TABLE 2 Association between clinical-pathological variables and presence of non-sentinel lymph node metastases for the 142 patients with endometrial cancer

Variable	Non-SLN metastases (no. of patients)			
	Category	Negative	Positive	*p* value
Myometrial invasion	< 50%	9	1 (10%)	0.20
	≥ 50%	12	7 (36.8%)	
Histologic type	Endometrioid	17	5 (22.7%)	0.35
	Nonendometrioid	4	3 (42.9%)	
Histologic grade	Grade 1 + 2	13	4 (23.5%)	0.68
	Grade 3[a]	8	4 (33.3%)	
LVSI	No	7	0 (0%)	0.14
	Yes	14	8 (36.4%)	
Cervical invasion	No	15	4 (21.1%)	0.37
	Yes	5	4 (44.4%)	
Number of positive SLN	1	13	2 (13.3%)	0.10
	≥ 2	8	6 (42.9%)	
	Continuous			0.18
Size of positive SLN	Isolated tumor cells	5	0 (0%)	0.032
	Micrometastases	11	2 (15.4%)	
	Macrometastases	5	6 (54.5%)	

LVSI lymphovascular space invasion, *SLN* sentinel lymph node

[a]Includes endometrioid G3, clear cell and serous histologies

et al.[12] compared series of cases ($n = 82$) with endometrioid tumors and deep myometrial invasion to whom an SLN mapping algorithm was applied and who were treated at Memorial Sloan Kettering Cancer Center (MSKCC) with patients ($n = 94$) who received systematic pelvic and paraaortic lymphadenectomy at Mayo Clinic. They also found that oncological outcomes were not impaired by the SLN algorithm.

Notably, Aloisi et al.[13] assessed a large series from MSKCC ($n = 207$) in regard to patterns of first recurrence in pelvic node-positive patients who did not undergo paraaortic lymph node dissection at primary staging. Sixty-two (30.1%) cases recurred, and 17 (8.3%) had isolated nodal recurrences, 8 (3.9%) of which were paraaortic. Micro- and macrometastases were associated with twice the recurrence rate compared with ITCs (37% vs. 17%). Of the eight patients with isolated paraaortic nodal recurrence, five women had endometrioid cancer and three had nonendometrioid tumors. Of these patients, two had ITCs in pelvic lymph nodes, while the remaining patients had macrometastases. Notably, nearly all patients (97%) with ITCs received adjuvant treatment. On multivariate analysis, nonendometrioid type was the only independent factor that maintained its association with a higher risk of recurrence.

Moreover, it seems important to correlate the risk of having non-SLN metastases to the size of the SLN metastasis. Yet, only three studies have addressed this issue. Touhami et al.[14] evaluated a series of 268 patients who underwent SLN mapping, followed by lymph node dissection, among whom 43 (16%) had SLN metastasis—24 macrometastases, 7 micrometastases, and 12 ITCs. Fifteen (34.8%) had non-SLN metastases, and the size of SLN metastasis was the only risk factor for non-SLN metastasis. The risk of positive non-SLNs when the SLN metastases were ≤ 2 mm and > 2 mm was 5% and 60.8%, respectively. Notably, nearly all (14/15) had macrometastases; only one had ITCs. This group showed unusually good results with frozen SLN sections and suggests it to help avoid a second surgery. They analyzed 49 samples (18.2%) by frozen sectioning and correctly identified lymph node metastasis in 12 (85.7%) of 14 cases, with a sensitivity of 85.7%. The two that were missed were one ITCs and one macrometastasis.

Although it can be argued that frozen sectioning should be completed for all SLNs to discriminate patients in whom systematic lymph node dissection should be performed, its accuracy remains controversial. Results from the Senti–Endo study[15] showed that intraoperative examinations had low sensitivity overall (56.3%) and a false-negative rate of 43.7% (all micrometastases and ITCs). Moreover, colleagues from Italy[16] recently evaluated 141 cases that had SLNs that were examined transoperatively using a novel technique, called one-step nucleic acid amplification assay (OSNA), and found positive SLNs in 24 (17%) cases: 22 macrometastases and 2 micrometastases. Subsequently, full lymph node dissection was performed in 14 cases, and non-SLN metastases were found in only 2 cases, all with

macrometastases in SLNs. Despite a correlation existing between the size of SLN metastasis and the presence of non-SLN metastases, non-SLN metastases were observed in only 2 of 22 macrometastases, in contrast to the present study and other reports.[14,17]

Ultimately, Kennard et al.[17] published a series that included 414 patients with SLN mapping and lymph node dissection and found that 31.5% of positive SLN cases had pelvic non-SLN metastases (n = 28/89), compared with 8.3% of ITCs—33.3% micro and 56.3% macro. In the case of ITCs, presence of deep myometrial invasion was predictive of non-SLNs. Table 3 summarizes the articles that addressed the size of metastatic SLNs as a risk factor for non-SLN involvement.

There are little data on the number of positive non-SLNs and its prognostic value. Of the series cited herein, only the Italian study[16] recorded the number of non-SLNs. It found two non-SLN lymph nodes in the only two positive non-SLN cases. Kennard et al.[17] did not directly report the number of positive non-SLN nodes but noted a median number of 2 positive lymph nodes (1–3) per patient in the bilateral positive cases. Conversely, we found positive non-SLNs in 27% of cases, with a high median positive non-SLN count of seven, raising concerns over omitting complete lymph node dissection for these patients. Notably, we reported higher rates of high-risk factors compared with the other series.[14,16,17] High-risk factors were present in 74.6% of the cases investigated in the current study, with 30.3% presenting more than one. In our series, 29.6% of the studied cases presented nonendometrioid histologies, whereas Monterossi's, Touhami's, and Kennard's series recorded 7.1%, 13.1%, and 14.2% of nonendometrioid histologies, respectively.

Furthermore, in the work presented herein, 50% of patients with positive non-SLN had suspicious lymph nodes that should also have been dissected. Presumably, lymph nodes without bulky metastases are controlled by adjuvant therapies. In contrast, the recent results of GOG 258[18] demonstrated increased locoregional failure in patients who received chemotherapy alone, warranting a discussion over whether remaining non-SLNs negatively impact recurrence and whether radiation is essential for such cases.

To determine the value of the addition of systematic lymphadenectomy to sentinel lymph node mapping, we are conducting a multicenter prospective clinical trial (ALICE trial—NCT03366051). High-risk endometrial cancer (high-grade histologies or deep myometrial invasion) patients will be randomized in a noninferiority, controlled trial into two groups: SLN mapping algorithm and SLN mapping that is followed by systematic lymphadenectomy. The primary endpoint is 3-year recurrence-free survival.

TABLE 3 Published series that addressed non-sentinel lymph node metastases in endometrial cancer

Study	n	Positive SLN (%)	Size of SLN (%)		Positive non-SLN (%)	Number of non-SLN (%)	
1. Touhami et al.[14]	268	43 (16%)	ITCs	12 (27.9%)	15 (34.8%)	ITCs (n = 12)	1 (8.3%)
			Micro	7 (16.2%)		Micro (n = 7)	0 (0%)
			Macro	24 (55.8%)		Macro (n = 24)	14 (58.3%)
2. Kennard et al.[17]	414	89 (21.5%)	ITCs	36 (40.4%)	28 (31.5%)	ITCs (n = 36)	1 (8.3%)
			Micro	21 (23.6%)		Micro (n = 21)	7 (33.3%)
			Macro	32 (36%)		Macro (n = 32)	18 (56.3%)
3. Monterrosi et al.[16a]	141	24 (17%)	ITCs	0 (0%)	2 (8.3%)	ITCs (n = 0)	–
			Micro	2 (8.3%)		Micro (n = 2)	0 (0%)
			Macro	22 (91.6%)		Macro (n = 22)	2 (9.1%)
4. Present series	142	29 (20.4%)	ITCs	5 (17.2%)	8 (27.6%)	ITCs (n = 5)	0 (0%)
			Micro	13 (44.8%)		Micro (n = 13)	2 (15.4%)
			Macro	11 (38%)		Macro (n = 11)	6 (54.5%)
Total	965	185 (19.2%)	ITCs	53 (28.6%)	53 (28.6%)	ITCs (n = 53)	2 (3.8%)
			Micro	43 (23.3%)		Micro (n = 43)	9 (20.9%)
			Macro	89 (48.1%)		Macro (n = 89)	40 (44.9%)

SLN sentinel lymph node, *ITCs* isolated tumor cells, *Micro* micrometastases, *Macro* macrometastases

[a]Sentinel lymph nodes had intraoperative analysis by one-step nucleic acid amplification assay (OSNA)

Overall, our series is comparable in size to the most recent studies on this topic and contributes valuable data. Our data suggest that the size of the metastasis in SLNs correlates with the risk of non-SLN metastasis. No patients with ITCs in SLNs had other metastatic lymph nodes.

AUTHOR CONTRIBUTIONS Study concept and design: GB, HM, LBF; data acquisition: CCF, GB, HM, BTG; quality control of data: GB, LYK, LDB, BTG; data analysis and interpretation: GB, LDB, LBF; statistical analysis: GB; manuscript preparation and editing: GB, HM, LYK, AABAC; manuscript review: all authors.

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