Sentinel Lymph Node Sampling in Robot-Assisted Staging of Endometrial Cancer

Erin Curcio, DO, Briana Miller, PA-C, Alexandra Giglio, DO, Arda Akoluk, MD, Brian Erler, MD, James Bosscher, MD, Mark Borowsky, MD, Verda Hicks, MD, and Karim ElSahwi, MD

Objective: Sentinel lymph node (SLN) sampling in endometrial cancer staging has become an acceptable standard. Indocyanine green dye injected into the cervix and detected by near-infrared light is technically simple and sensitive. We aimed to evaluate SLN sampling in robot-assisted surgical staging of endometrial cancer at a university-affiliated teaching hospital.

Methods: A retrospective chart review, from January 2016 to December 2017, of patients who underwent robot-assisted surgical staging with cervical injection of indocyanine green dye detected by near-infrared light. The map rate, sensitivity, false negatives, and negative predictive value were calculated.

Results: A total of 105 charts were reviewed; 79 patients met inclusion criteria. The mean age was 65 (range 38–93) and the mean body mass index was 33.3 (range 16–49). Most patients (72.2%) had stage I disease and grade 1 or 2 histology (77.1%). Eight (10.1%) patients had lymph node metastasis. Seventy-two (91.1%) patients had positive mapping to at least 1 SLN. Sixty-two (78.5%) patients had bilateral mapping. Forty-four patients had concurrent pelvic ± para-aortic lymph node dissection and were included in the sensitivity analysis. Five of 44 cases had LN metastasis. The sensitivity was 80%, and the negative predictive value of SLN sampling was 97.5%.

Conclusions: SLN mapping and sampling at a university-affiliated teaching hospital have comparable map rate, sensitivity, and negative predictive value as demonstrated in multiple trials. The technique has the potential to standardize endometrial cancer staging across different practice settings.

Key Words: endometrial cancer, robotic surgery, sentinel lymph nodes, staging

Endometrial cancer is the most common gynecologic malignancy in the United States, with an estimated 61,880 new cases diagnosed in 2019.[1] Most cases present early where the overall risk of lymph node (LN) spread is low[2]; however, LN metastasis is the most important factor that predicts prognosis and informs adjuvant therapy.[3] As such, the International Federation of Obstetrics and Gynecology classification for staging of endometrial cancer includes lymphadenectomy, in addition to hysterectomy and bilateral salpingo-oophorectomy.[4] Two randomized controlled trials have, however, shown no survival advantage associated with LN dissection (LND) in clinical stage 1 endometrial cancer.[5,6] In addition, patients who undergo lymphadenectomy have a higher incidence of complications than those who undergo hysterectomy alone, including lower extremity lymphedema.[7,8] Risk-based LND informed by intraoperative evaluation of the uterus has been practiced at some institutions as a strategy to balance the risk between unnecessary LND and overtreating with radiation therapy,[9] but it has not found universal adoption by gynecologic oncologists.[10–12]

Sentinel LN (SLN) sampling has been investigated as a less morbid alternative to systematic LND in endometrial cancer staging,[13–15] and multiple studies have documented the feasibility, accuracy, and safety of the technique.[16–18] An SLN sampling algorithm is an acceptable staging alternative under National Comprehensive Cancer Network (NCCN) guidelines.[19] Cervical injection of indocyanine green (ICG) dye and detection of SLN under near-infrared (NIR) light has emerged as an efficient and valid method of SLN mapping.[15,20–23]

Key Points

- Evaluation of the lymph nodes is a key component of the International Federation of Gynecology and Obstetrics staging system and informs adjuvant therapy decisions, but practice patterns of lymph node sampling vary widely.
- Sentinel lymph node sampling has been shown to decrease lymph node dissection–associated morbidity, but different techniques and methods have been reported.
- Detection of indocyanine green, when injected into the cervix, under near-infrared light is a reliable method that yields a high mapping rate of sentinel lymph nodes with a low false-negative rate for detecting lymph node metastasis.
- The robotic platform has been widely adopted by gynecologic oncologists and can be used successfully to complete this procedure where available.

From the Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, the Department of Medicine, and the Department of Pathology, Jersey Shore University Medical Center, Hackensack Meridian Health, Neptune, New Jersey.

Correspondence to Dr Karim ElSahwi, Hackensack Meridian Health, 1945 Route 33, Jersey Shore University Medical Center, HOPE Tower E7129, Neptune, NJ 07753. E-mail: karim.elsahwi@hmhn.org.

B.E. has received compensation from Meridian Laboratory Physicians. V.H. has received compensation from Hackensack Meridian Health and the American College of Obstetricians and Gynecologists. The remaining authors did not report any financial relationships or conflicts of interest.

Accepted March 18, 2021.

0038-4348/0–2000/114-680

DOI: 10.14423/SMJ.0000000000001319

We recently published our experience with risk-based LND,[24] in which we found a significant discrepancy between intraoperative evaluation and the final pathology report prohibiting the use of this method at our institution.[24] The purpose of the present study was, therefore, to assess the map rate, sensitivity, and negative predictive value of SLN sampling in robot-assisted endometrial cancer staging using cervical injection of ICG in a university-affiliated teaching setting.

Methods

Institutional review board approval was obtained for a retrospective chart review of endometrial cancer patients treated at a university-affiliated teaching hospital with robot-assisted surgical staging by a single surgeon from January 2016 through December 2017. Included were patients with a diagnosis of endometrial cancer on preoperative biopsy or curettage specimen, who underwent cervical injection of ICG dye for SLN identification using NIR light (Firefly, Intuitive Surgical, Sunnyvale, CA). Patients were excluded if there was evidence of cancer outside the uterus.

All of the patients underwent robot-assisted total laparoscopic hysterectomy, bilateral salpingo-oopherectomy, and assessment of peritoneal cytology. ICG dye (1.25 mg/cm^3) was injected in the submucosa (2 mm depth) and at an intrastromal depth of 1 cm at 3 and 9 o'clock as previously described.[15] Patients were injected 1 cm^3 in each position, for a total of 4 cm^3.[15] The da Vinci robotic platform-mounted NIR light (Firefly) was used to visualize SLNs as previously described.[21] When identified, all of the SLNs were sampled. All suspiciously enlarged LNs also were removed. Complete LND was performed if there was negative mapping in one hemipelvis.[15] Systematic pelvic LND was performed in case of negative bilateral mapping, and for tumors >2 cm in greatest dimension or invading >50% of the myometrium. Pelvic and paraaortic LND up to the level of the renal veins was attempted for all grade 3 tumors, uterine serous cancer, clear cell carcinoma, and carcinosarcoma. Systematic LND was omitted in low-risk cases, based on intraoperative evaluation of the uterus,[25] and when impractical or unsafe because of morbid obesity or the presence of comorbidities. Adjuvant management was informed by LN status based on well-established guidelines.[3]

LNs were pathologically examined by hematoxylin and eosin staining of paraffin-embedded fixed specimens as well as by ultrastaging using immunohistochemistry staining for cytokeratin as previously described.[21] Macrometastases, micrometastases, and isolated tumor cells were defined as tumor burden >2 mm, <2 mm but >0.2 mm, or ≤ 0.2 mm, respectively.[21]

The primary outcome was SLN map rate, defined as detection of at least 1 SLN. Secondary outcomes included the sensitivity and negative predictive value and false-negative rate of SLN sampling. Variables abstracted included demographics, comorbidities, operative findings, and pathologic findings.

Statistical methods included descriptive statistics, as well as sensitivity, negative predictive value, and false-negative rate calculation. The following definitions were used as previously published[16]:

- Sensitivity: patients with positive SLNs divided by all metastatic patients.
- Negative predictive value: patients who are nonmetastatic with negative SLN divided by all patients without a positive SLN.
- False-negative rate: metastatic patients without a positive SLN divided by all metastatic patients.

Results

A total of 105 charts were reviewed. Seventy-nine cases met inclusion criteria (Fig. 1). The mean age was 65 years (range 38–93) and mean body mass index was 33.3 (range 16–49). Thirty-five patients (44%) had prior abdominal surgery and most patients (77%) had American Society of Anesthesiologists grade 2–3 (Table 1).

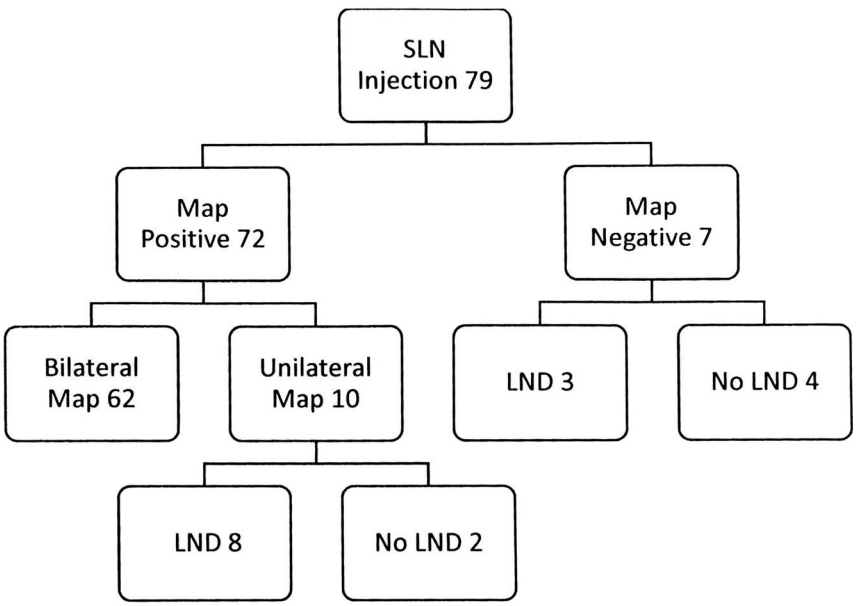

Fig. 1. **Sentinel lymph node dissection cohort. LND, lymph node dissection; SLN, sentinel lymph node.**

Table 1. Patient characteristics (N = 79)

Age, y	
Mean	65 (10.03)
Range	38–93
BMI, kg/m^2	
Mean (SD)	33 (7.73)
Range	16-49
Had prior abdominal surgery, n (%)	35 (44)
Operative time mean (SD)	212.4 (72.1)
EBL, mL, mean (SD)	112.1 (88.6)
ASA grade, n (%)	
1	2 (2.5)
2	42 (53.2)
3	35 (44)
Postoperative grade, n (%)	
1	36 (45.5)
2	25 (31.6)
3	18 (22.8)
Postoperative stage, n (%)	
1	61 (77.2)
2	9 (11.4)
3	9 (11.4)

ASA, American Society of Anesthesiologists; BMI, body mass index; EBL, estimated blood loss; SD, standard deviation.

Mean operative time was 212 minutes and mean estimated blood loss was 112 mL. On postoperative pathology, 61 (77.1%) patients had low-grade cancer, and 66 (83.6%) patients had stage 1 or 2 disease (Table 1).

ICG dye was injected in all of the patients (Fig. 1). SLN sampling was performed in 72 (91.1%) cases, systematic pelvic LND was performed in 44 (55.7%) cases, and paraaortic LND was performed in 26 (32.9%) cases (Fig. 1). The total number of LNS dissected was 889 (mean 11.2), and the total number of SLNs sampled was 274 (mean 3.5; Table 2).

Overall, 72 of 79 (91.1%) patients had successful mapping, in which at least 1 SLN was identified (Fig. 1). Sixty-two (78.5%) patients had bilateral mapping and 10 (12.6%) had unilateral mapping (Table 2). Of the 10 cases with unilateral mapping, 5 had pelvic LND, 3 had pelvic and paraaortic LND, and 2 had only contralateral SLN sampling. In one of the latter two cases, LND was omitted based on intraoperative evaluation of the uterus by frozen section; in the other it was omitted because of poor exposure secondary to morbid obesity. None of the 10 cases with unilateral mapping had LN metastasis.

Table 2. Lymph node dissection (N = 79)

LND, n (%)	79 (100)
Any LND performed	75 (94.9)
SLND (map rate)	72 (91.1)
Pelvic LND	44 (55.7)
Paraaortic LND	26 (32.9)
Bilateral SLN mapping (%)	62 (78.5)
Unilateral SLN mapping (%)	10 (12.6)
LN dissected, N (mean)	889 (11.2)
SLN sampled, n (mean)	274 (3.5)

LN, lymph node; LND, lymph node dissection; SLN, sentinel lymph node.

Table 3. SLN location

LN location	Cases, n	Percentage
External iliac	63	79.7
Obturator	31	39.2
Common iliac	19	24.1
Internal iliac	5	6.3
Presacral	3	3.8
Parametrial	3	3.8
Paraaortic	1	1.3
Unidentified	4	5.1

LN, lymph node; SLN, sentinel lymph node.

Seven cases had negative mapping bilaterally (Fig. 1). All but one had intraoperative frozen section evaluation of the uterus. Two cases had pelvic LND and 1 case had pelvic and paraaortic LND. Four cases had no LND: two because of low risk on intraoperative evaluation of the uterus and two because of morbid obesity and/or severe comorbidities. The 1 case without intraoperative evaluation received LND. None of the 3 cases with LND had LN metastasis.

SLN location is summarized in Table 3. Most were found in the external iliac (79.7%) chain followed by the obturator (39.2%) and the common iliac (24.1%) LN chains. Three (3.8%) cases had presacral SLNs, and 3 (3.8%) cases had a parametrial SLN. One

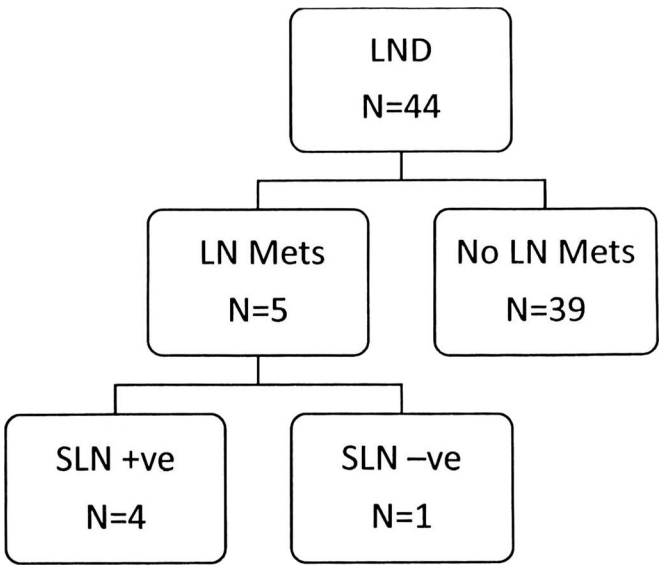

Fig. 2. Lymph node metastases. LN, lymph node; LND, lymph node dissection; SLN, sentinel lymph node.

Table 4. Sensitivity and NPV

	LN+	LN−	Total
SLN+	4	0	
SLN−	1	39	
			44

Sensitivity: 4/(4 + 1) × 100 = 80%; NPV: 39/(39 + 1) × 100 = 97.5%; false-negative rate: 1/5 × 10 0 = 20%. LN, lymph node; NPV, negative predictive value; SLN, sentinel lymph node.

(1.3%) case had a paraaortic SLN (Table 3). There were no isolated sentinel paraaortic LNs.

Eight (10.1%) cases had LN metastasis. Three had grade 2 endometrioid cancer and 5 had high-grade disease. Three received only bilateral SLN sampling and were excluded from the sensitivity analysis. One case had unilateral mapping and systematic pelvic LND. Four cases had bilateral mapping and systematic pelvic and paraaortic LND. An SLN was the only positive node in 1 case. One case with clear cell carcinoma had a positive nonsentinel paraaortic LN and negative bilateral SLNs. All metastatic LNs were classified as macrometastases (>2 mm).

Forty-four patients had both SLN sampling and systematic pelvic ± paraaortic LND and were included in the sensitivity analysis (Fig. 2). Five of the 44 cases had LN metastasis. An SLN was the only positive LN in 1 case. Three cases had both positive sentinel and other LN metastasis, whereas 1 case of clear cell carcinoma had negative SLNs and metastasis in one paraaortic lymph node. This yielded a sensitivity of 80%, a negative predictive value of 97.5%, and a false-negative rate of 20% (Table 4).

Discussion

This was a retrospective single-institution study that showed that SLN sampling using cervical injection of ICG dye in robotically staged endometrial cancer has a high map rate, sensitivity, and negative predictive value, comparable to the reported literature. We chose cervical injection of ICG dye with the da Vinci robotic platform–mounted NIR light (Firefly) camera detection because of the availability of the technology at our institution and the validity of the technique.[21] Our blood loss, complication, and readmission rates were comparable to the literature and are reported in a separate manuscript. Two recent surveys indicate that more gynecologic oncologists chose cervical injection of ICG dye and SLN sampling via a minimally invasive approach.[26,27] The Society of Gynecologic Oncology Consensus Recommendations[28] favor cervical rather than uterine injection of dye because of its simplicity and high map rate, and a recent meta-analysis found a significantly higher bilateral SLN detection rate with cervical versus uterine injection of dye (56% vs 33%, $P = 0.003$).[29]

The superiority of ICG over blue dye when injected in the cervix and detected by NIR has been documented in multiple large retrospective series and prospective trials.[15,20,21,29] Two recent prospective trials by Frumovitz et al[22] and Backes et al[30] found a significantly higher map rate of ICG versus isosulfan blue (97% vs 47% and 83% vs 64%, respectively).[22,30] Using the contralateral pelvis as the control, Rozenholc et al randomized cases to either blue dye or ICG and found a significantly higher map rate of ICG (90.9% vs 64.4%; Table 5).[23]

The reported map rate and sensitivity of ICG/NIR detection of SLNs after cervical injection in endometrial cancer range from 86% to 97%[15,20–23,28,29,31,33] and 94% to 100%,[21,30–32] respectively (Table 5). The higher overall (91% vs 86%) and bilateral (78.5% vs 52%) map rate documented in this study as compared with the largest prospective published trial, namely the fluorescence imaging for robotic endometrial sentinel lymph nodebiopsy (FIRES) trial,[21] most likely reflects the learning curve of surgeons with different levels of experience in the FIRES trial. This study does not represent the learning curve of this single surgeon whose experience in SLN mapping predates the study period. The lower sensitivity

Table 5. Studies with cervical injection of dye

Study	No.	Study design	Map rate, %		Sensitivity, %	NPV, %	False negative, %
			Total	Bilateral			
Jewell et al, 2014[15]	237	Retrospective	95	79	NA	NA	NA
Sinno et al, 2014[29]	71	Prospective	92.1	78.9	NA	NA	NA
Eriksson, 2017[20]	472	Retrospective	95	85	NA	NA	NA
Paley et al, 2016[31]	123	Prospective	96.7	80	100	NA	NA
Rossi et al, 2017[21]	385	Prospective	86	86	97.2	99.6	2.8
Holloway et al, 2016[32]	180	Prospective	96.1	83.9	97.5	99.3	2.5
Frumovitz et al, 2018[22]	180	Prospective	97	81	NA	NA	NA
Rozenholc et al, 2019[23]	132	Prospective	90.9	NA	NA	NA	NA
Backes et al, 2019[30]	204	Prospective	90.2	68	94	99	6
Tortorella et al, 2019[33]	327	Retrospective	93.3	78.3	NA	NA	NA
Curcio, 2021	79	Retrospective	91.1	78.5	80	97.5	20

NA, not applicable; NPV, negative predictive value.

(80% vs 97%) reported in this study likely reflects the large sample size and prospective design of the multicenter FIRES trial, however.[21]

The depth of cervical injection in this study following NCCN guidelines[19] was 2 mm and 1 cm. Consistent with other studies,[16] this led to a paraaortic SLN detection rate of appoximately 1.3%. Deeper cervical injection was associated with higher sentinel paraaortic LN detection rate in the literature,[16] but it is not clear that it increased the sensitivity of the technique.

We reported a 10% incidence of LN metastasis, which correlates with the reported literature.[18,21] Although all of the LN metastases found in this study were > 2 mm (macrometastases), we followed NCCN ultra-staging guidelines[19] of serial sectioning and staining with hematoxylin and eosin as well as immunohistochemistry for cytokeratin. Ultra-staging has been found to improve the sensitivity of SLN sampling[18,34] and the results are reportable.[35] Although more prospective data are needed, a recent review of the literature suggests that micrometastasis should receive adjuvant treatment, whereas isolated tumor cells should be managed based on uterine risk factors.[18]

One (1.3%) isolated paraaortic LN metastasis was found in this study in a patient with clear cell cancer and negative bilateral sentinel pelvic LNs. In a large prospective study, a Mayo Clinic group reported that the rate of isolated paraaortic lymph node metastasis was 3%, and that it was clustered in high-grade deeply invasive tumors.[25]

Finally, we were unable to assess the sensitivity of the NCCN SLN algorithm[19] because 4 of the 7 map-negative cases and 2 of the 10 unilateral map cases did not had pelvic LND (Fig. 1). This algorithm, proposed by Barlin et al[36] and endorsed by the Society of Gynecologic Oncology Consensus Recommendations[28] stipulates that all suspicious LNs be removed and systematic LND be performed in the hemipelvis where mapping has failed. Paraaortic LND also may be performed for high-risk cancers. This was shown to enhance the sensitivity of SLN sampling in endometrial cancer,[36] and a recent study suggests that this algorithm compares favorably with comprehensive surgical staging in cases with nonbulky LN metastases in terms of recurrence and survival.[37]

In conclusion, although limited by its small sample size and retrospective nature, our study has demonstrated that SLN mapping and sampling at our university-affiliated teaching hospital has comparable map rate, sensitivity, and negative predictive value as demonstrated in multiple trials. The technique has the potential to standardize endometrial cancer staging across different practice settings.

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