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Detection of Sentinel Lymph Nodes in Minimally Invasive Surgery Using Indocyanine Green and Near-Infrared Fluorescence Imaging for Uterine and Cervical Malignancies

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Abstract

Objectives—Our primary objective was to assess the detection rate of sentinel lymph nodes (SLNs) using indocyanine green (ICG) and near-infrared (NIR) fluorescence imaging for uterine and cervical malignancies.

Methods—NIR fluorescence imaging for the robotic platform was obtained at our institution in 12/2011. We identified all cases planned for SLN mapping using fluorescence imaging from 12/2011-4/2013. Intracervical ICG was the fluorophore in all cases. Four cc (1.25 mg/mL) of ICG was injected into the cervix alone divided into the 3- and 9-o'clock positions, with 1 cc deep into the stroma and 1cc submucosally before initiating laparoscopic entry. Blue dye was concurrently injected in some cases.

Results—Two hundred twenty-seven cases were performed. Median age was 60 years (range, 28-90). Median BMI was 30.2 kg/m² (range, 18-60). The median SLN count was 3 (range, 1-23). An SLN was identified in 216 cases (95%), with bilateral pelvic mapping in 179 (79%). An aortic SLN was identified in 21 (10%) of the 216 mapped cases. When ICG alone was used to map cases, 188/197 patients mapped, for a 95% detection rate compared to 93% (28/30) in cases in which both dyes were used (P=NS). Bilateral mapping was seen in 156/197 (79%) ICG-only cases and 23/30 (77%) ICG and blue dye cases (P=NS).

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Conclusions—NIR fluorescence imaging with intracervical ICG injection using the robotic platform has a high bilateral SLN detection rate and appears favorable to using blue dye alone and/or other modalities. Combined use of ICG and blue dye appears unnecessary.

Keywords

indocyanine green; sentinel lymph node; sentinel lymph node mapping; near-infrared fluorescence imaging; uterine cancer; cervical cancer

Background

The importance of sentinel lymph node (SLN) mapping in the prognostication of cancer was first described over a half century ago and has since been incorporated into the routine management of various solid tumor types [1-4]. In gynecologic cancer, the SLN concept is most accepted for vulvar carcinomas, as seen with the publication of Gynecologic Oncology Group (GOG) protocol 174 and the Groningen international study on sentinel nodes in vulvar cancer (GROINSS V-1) [5-7]. Its use in cervical and uterine cancers is being increasingly investigated [8-25]. The accuracy of SLN mapping in uterine cancer remains to be determined and needs to be addressed in a prospective fashion. However, efforts to continue to improve the detection of SLNs are important.

Since 1996, blue dye, with or without technetium, has been the predominate dye used to identify SLNs [26]. More recently, SLN detection rates of approximately 80% have been reported [27-31]. However, these rates do not reflect bilateral detection. Bilateral detection rates of the SLN are the most clinically relevant as the lymphatic drainage in the pelvis is not unilateral [20]. “Successful” SLN mapping for cervical and uterine cancers, therefore, must reflect bilateral mapping. When specifically looking at the bilateral rates in minimally invasive surgery at our institution, bilateral mapping occurred in approximately half of patients (61%) [14]. In robotic-assisted cases, bilateral mapping was achieved in 40% of cases using blue dyes such as isosulfan blue or methylene blue [32]. This is consistent with other published reports suggesting that bilateral mapping using blue dyes alone can only be achieved in approximately 50% of cases [14,32]. This translates into approximately half of patients requiring some form of lymphadenectomy (LND), and improvement in detection rates is needed.

Near-infrared (NIR) fluorescence imaging with indocyanine green (ICG) has been described for SLN mapping in various malignancies. ICG is the only FDA-approved fluorophore in use for many years, but it has not yet been approved specifically for SLN mapping in the United States. NIR imaging appears to provide a beneficial technique for SLN mapping of gynecologic malignancies. NIR imaging capabilities are now available for the da Vinci Si robotic platforms (Intuitive Surgical®, Sunnyvale, CA) as well as for laparoscopic and open approaches (PINPOINT® and SPY Elite®)(Novadaq Technologies, Bonita Springs, FL). Small single series have been recently published [33-35]. The primary objective of this study was to assess the detection rate of SLNs for uterine and cervical malignancies using ICG and NIR fluorescent imaging with the robotic platform at Memorial Sloan-Kettering Cancer Center.

Methods

Institutional Review Board approval was obtained for this retrospective study. All consecutive cases planned for SLN mapping using fluorescence imaging from 12/2011 to 4/2013 were identified and prospectively entered into our database, which is maintained for quality assurance purposes for all our robotic cases. Intracervical ICG was the fluorophore used in all cases. The concentration used was 1.25 mg/mL. For each patient, a 25 mg vial with ICG powder was diluted in 20 cc of aqueous sterile water. Four cc of this ICG solution was injected into the cervix alone divided into the 3- and 9-o'clock positions, with 1 cc deep into the stroma and 1 cc submucosally on the right and the left of the cervix, usually prior to initiating laparoscopic entry. Isosulfan blue was concurrently injected in some cases using the same method as described for ICG. Isosulfan blue was our preferred blue dye at the time these cases were performed. The cervix was injected after the patient was prepped and draped but prior to the insertion of any uterine manipulator or the docking of the robot. Once the cervix was injected, the robotic platform was docked as per surgeon preference. Our previously published SLN algorithm (Figure 1) [36], which included pelvic washings for endometrial cancers, the evaluation of the retroperitoneum, and the removal of SLNs and any grossly enlarged nodes regardless of mapping, was followed by all surgeons.

Demographics and surgical data were collected. Final pathology results were examined. The median age, body mass index (BMI), estimated blood loss (EBL), time to find the SLN, number of SLNs identified, and anatomic location of the SLN were recorded. The time to perform the SLN mapping was defined as the time from the initial development of the retroperitoneal space until the surgeon felt that SLNs were or were not identified. Overall detection rates and bilateral detection rates to find the SLN were calculated. Chi-square and Fisher's exact tests were used, as appropriate, to compare SLN detection rates and the dye used. The Mann-Whitney U test and Kruskal-Wallis test were performed to assess the impact of BMI on SLN detection. SPSS version 21.0 statistical software was used to perform all statistical tests.

Results

Two hundred twenty-seven patients with endometrial or cervical cancer were identified. The median age of the patients was 60 years (range, 28-90 years), median BMI was 30.2 kg/m² (range, 18-60 kg/m²), and median EBL was 50 cc (range, 5-1000 cc). The majority of patients (138/227, 61%) were diagnosed with grade 1 or 2 endometrioid adenocarcinoma of the uterus. The median surgical time to complete the SLN mapping was 30 minutes with some cases being mapped within 3 minutes (range, 3-84). The median number of SLNs removed was 3 (range, 1-23) (Table 1). ICG dye alone was used in 87% of cases (n=197), and ICG and blue dye was used in 13% of cases (n=30) (Table 2).

The overall detection rate of the SLN (uni- or bilateral) for this cohort of patients was 95% (216/227). An SLN was not identified in 11 cases. In cases in which ICG only was used, 95% (188/197) mapped either unilaterally or bilaterally compared to 93% (28/30) of cases in which both the ICG and blue dyes were used (P=NS) (Table 2). The bilateral detection rate

was (179/227) 79% overall. The bilateral SLN detection rate for ICG alone was 79% (156/197) compared to 77% (23/30) for ICG and blue dye (P=NS) (Table 3).

The median BMI of patients who mapped was 30.1 kg/m² (range, 17.7-59.6 kg/m²) compared to 41.2 kg/m² (range, 25.1-60.4 kg/m²) for patients who did not map (P=0.01). Median BMI appeared to impact bilateral mapping, with the median BMI of unilaterally and bilaterally mapped cases being 34 kg/m² (range, 17.9-49 kg/m²) and 29.6 kg/m² (range, 17.7-59.6 kg/m²), respectively (P=0.02).

Figure 2 depicts the anatomic distribution of where the SLNs were identified. A total of 868 SLNs were located in 216 cases. The most common sites were the internal and external iliac nodal basins. Notably, SLN mapping to the aortic nodal basins was seen in 10% of the 216 cases that mapped. Presacral localization was also noted.

Discussion

The use of SLN mapping in the management of melanoma and breast cancers has become the standard of care [1-4]. SLN mapping for uterine and cervical malignancies has been gaining acceptance and may offer a potential alternative to full LND in the future [8-32]. Optimization of detection techniques and rates, with a goal toward convenience, safety and lower cost, is important as we continue to assess accuracy rates. To date, overall SLN mapping of the pelvis has been adequate, with detection rates of approximately 80% [27-31]. Various combinations of blue dye and radioactive tracers have been described with various methods of injection used. Ballester et al described the detection and false-negative rates of SLN mapping and its contribution to staging women with endometrial cancers. They reported an SLN detection rate of 87% [31]. Van de Lande et al published a review of the literature involving more than 800 patients with cervical cancer in which they described detection rates of 84%, 88%, and 97% using blue dye alone, 99mTc alone, or both blue dye and 99mTc, respectively. This was not statistically different from the use of blue dye alone, with its pooled sensitivity of 82% and range of 67-92% [30]. Abu-Rustum et al reported on a large series of endometrial cancer patients in which 78% of the patients received blue dye alone to detect the SLN, and the overall detection rate was 84% [23]. The key to a more widespread adoption of SLN mapping is to provide techniques that can be easily taught and reproduced without incurring excess inconvenience or cost.

It is important to recognize that the above detection rates have been based on the finding of any SLN in a patient, either unilaterally or bilaterally. Bilateral SLN detection is the more clinically relevant “success” rate of SLN detection. The reported bilateral SLN mapping rate is 75% using blue dye and 99mTC, and only 61% using blue dye alone [14]. When using a robotic only platform with blue dye alone, bilateral mapping rates were 40% [32].

In our study, we report an improvement in both overall SLN detection rates and bilateral SLN detection rates using ICG. The overall detection rate was 95%, with bilateral mapping in 79% of cases. This seems to be an improvement over the reported detection rates for blue dye alone and comparable to the combined blue dye and technetium methods. Additional studies should be performed to confirm this suggested improvement. The clinical relevance

of this finding is that fewer patients may need hemi-pelvic LNDs to assess nodal status, especially if SLN mapping is ultimately validated as an acceptable alternative to lymphadenectomy. In our series, several cases recorded a large number of SLNs identified. Removal of a large numbers of nodes has the potential to defeat the benefit of an SLN surgical approach. These cases may have been related to a learning curve, and such information is important to adapt and improve upon an SLN program.

Interestingly, in this study, 10% of patients had an SLN identified in the aortic region. Another 2 patients had SLNs identified in the presacral space. Such areas are unlikely to be explored using the traditional approach to lymphadenectomy in the staging of uterine or cervical cancer. SLN mapping using ICG, as well as other techniques, has the potential added benefit of assessing lymph nodes and lymphatic drainage from the uterus that potentially would not be assessed by standard lymphadenectomy procedures.

The detection of SLNs appeared to be more feasible in patients with a lower BMI. The detection rate appeared to be influenced by BMI, with heavier patients having a lower likelihood of mapping and less mapping bilaterally. It appears that patients with BMIs greater than 34 are less likely to undergo bilateral SLN mapping. Such information may be informative when counseling patients about the risk of undergoing a full lymph node dissection.

The use of NIR fluorescence imaging and ICG with the robotic platform in gynecologic cancers has been reported in 3 small series. The number of cases in these series ranged from 12-35, with reported detection rates of 83-100% [33-35]. These studies reported on the combined use of green and blue dye to detect the SLN. We did not find added value in using both blue dyes and ICG. We abandoned the use of blue dye in conjunction with ICG after our initial experience with 30 cases of combined blue and green dyes, finding that the ICG dye alone simplified the identification of the SLN. Additionally, in the cases in which both dyes were used, we did not identify an SLN that was blue only and not also green.

NIR fluorescence imaging using ICG has the potential to improve SLN technology for cervical and endometrial cancers by improving the rate of bilateral SLN mapping without the added cost and inconvenience of technetium. Based on our experience with all SLN mapping modalities, fluorescence imaging provides a much simpler technique to more confidently and readily recognize and identify SLNs. Fluorescence imaging is available for both robotic and laparoscopic platforms as well as for an open laparotomy imaging system. Additional studies are needed to further assess this novel approach to SLN detection as well as to confirm and validate the accuracy of SLN mapping in general in patients with uterine and cervical malignancies.

In conclusion, NIR fluorescence imaging with intracervical ICG using this robotic platform has a high bilateral SLN detection rate and appears more favorable than using blue dye alone, as reported in the published literature. Additionally, the use of blue dye in combination with ICG appears unnecessary based on these data.

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Research Highlights

- The use of indocyanine green is associated with a high detection of sentinel lymph nodes
- The use of indocyanine green is associated with a high sentinel lymph node bilateral detection rate

Figure 1. Sentinel lymph node mapping algorithm

Figure 2. Anatomic locations of sentinel lymph nodes
868 SLNs were identified in 216 cases. The majority of SLNs were found in the internal and external iliac basins: 28% and 35%, respectively.

Table 1
Clinicopathologic demographics of the entire cohort

	Median (range)
Age (years)	60 (28-90)
Body Mass Index (kg/m ²)	30.2 (18-60)
Estimated Blood Loss (mL)	50 (5-1000)
OR time (min)	240 (146-440)
	Frequency (%)
Postoperative Diagnosis	N=227
Complex Hyperplasia with Atypia	11 (5%)
Endometrioid Adenocarcinoma of the Uterus	168 (74%)
Serous Carcinoma of the Uterus	15 (7%)
Carcinosarcoma of the Uterus	13 (6%)
Clear Cell of the Uterus	1 (0.04%)
Leiomyosarcoma of the Uterus	1 (0.04%)
Cervical Cancer	18 (8%)
Grade	N=168
1	100 (60%)*
2	38 (23%)*
3	30 (18%)*

* Grade assessment in 168 cases of endometrioid adenocarcinoma

Table 2
Sentinel lymph node detection rates in the entire cohort (N=227)

Variable	Patients
SLN Mapping Time (min)	30 (3-84)
Median (range)	
SLN Identified Per Patient	3 (1-23)
Median (range)	
	Frequency (%)
Dye Used	
ICG Alone	197 (87%)
ICG and Blue	30 (13%)
Overall Detection Rate	216 (95%)
Mapping By Pelvis	
None	11/227 (5%)
Unilateral	37/227 (16%)
Bilateral	179/227 (79%)

SLN, sentinel lymph node; ICG, indocyanine green

Table 3
Sentinel lymph node mapping according to dye used

	ICG Only N=197	ICG and Blue N=30	P
Mapped by Patient			
No Mapping	9 (5%)	2 (7%)	
Mapped	188 (95%)	28 (93%)	0.64
Mapped by Hemi-Pelvis			
No Mapping	9/197 (5%)	2/30 (7%)	0.80
Unilateral	32/197 (16%)	5/30(17%)	
Bilateral	156/197 (79%)	23/30 (77%)	

ICG, indocyanine green