



## A comparison of colorimetric versus fluorometric sentinel lymph node mapping during robotic surgery for endometrial cancer<sup>☆</sup>



Abdulrahman K. Sinno, Amanda Nickles Fader, Kara Long Roche, Robert L. Giuntoli II, Edward J. Tanner<sup>\*</sup>

The Kelly Gynecologic Oncology Service, Department of Gynecology and Obstetrics, Johns Hopkins Hospital, Baltimore, MD, USA

### HIGHLIGHTS

- Seventy one consecutive endometrial cancer sentinel lymph node (SLN) mapping cases utilizing isosulfan blue (ISB) or indocyanine green (ICG) are presented.
- Bilateral mapping was higher in the ICG group and BMI a significant predictor for successful mapping in the ISB group.
- Utilizing our institutional SLN protocol resulted in a 100% negative predictive value and 100% sensitivity for detecting metastatic lymph nodes.

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### ABSTRACT

**Objective.** The study objective was to compare the ability to detect sentinel lymph nodes (SLNs) in women with endometrial cancer (EC) or complex atypical hyperplasia (CAH) using fluorometric imaging with indocyanine green (ICG) versus colorimetric imaging with isosulfan blue (ISB).

**Methods.** Women underwent SLN mapping, with either ISB or ICG, during robotic-assisted total laparoscopic hysterectomy (RA-TLH) from September 2012 to March 2014. SLNs were submitted for permanent pathologic analysis. Completion lymphadenectomy and ultrastaging were performed according to institutional protocols.

**Results.** RA-TLH and SLN mapping was performed in 71 women; 64 had EC (64) and 7 had CAH. Age, body mass index (BMI), stage and tumor characteristics were similar in the ICG versus the ISB cohorts. Overall, SLNs were identified bilaterally (62.0%), unilaterally (21.1%), or neither (16.9%), and in 103 of 142 hemi-pelvises (72.5%). The mean number of SLNs retrieved per hemipelvis was 2.23 (SD 1.7). SLNs were identified in the hypo-gastric (76.8%), external iliac (14.2%), common iliac (4.5%) and paraaortic (4.5%) regions. ICG mapped bilaterally in 78.9% of women compared with 42.4% of those injected with ISB ( $p = 0.02$ ). Five women (7%) had positive lymph nodes, all identified by the SLN protocol (false negative rate: 0%). On multivariate analysis, BMI was negatively correlated with bilateral mapping success ( $p = 0.02$ ). When stratified by dye type, the association with BMI was only significant for ISB ( $p = 0.03$ ).

**Conclusions.** Fluorescence imaging with ICG may be superior to colorimetric imaging with ISB in women undergoing SLN mapping for endometrial cancer. SLN mapping success is negatively associated with increasing patient BMI only when ISB is used.

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### Introduction

Endometrial cancer is the most common gynecologic cancer in the United States (U.S.) with 49,560 cases expected in 2014 [1,2]. The standard treatment for women diagnosed with this malignancy is a total hysterectomy, bilateral salpingo-oophorectomy and lymph node assessment. Despite being a powerful predictor of recurrence and prognosis [3,4], the role and extent of the lymph node assessment remains

variable across institutions [5]. The spectrum of lymph node assessment spans from omitting a lymphadenectomy altogether, to perform a complete pelvic and para-aortic lymphadenectomy for all histologies and tumor grades. Some centers utilize intraoperative assessment criteria, based upon histologic and tumor characteristics, to triage patients for lymph node assessment [6–10]. Variability in lymph node assessment strategies reflects unresolved issues regarding the 1) therapeutic benefit (or lack thereof) of lymphadenectomy in women with endometrial cancer [11,12], 2) increased scrutiny regarding the potential morbidity of the procedure, and 3) shifting treatment paradigms for women at high risk for metastatic disease [13].

Given that greater than 75% of women with endometrial cancer will have an early-stage, low grade disease, with an inherently low risk of lymph node metastases [14], most will not benefit from

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<sup>\*</sup> Corresponding author at: 600 N Wolfe St, Phipps 281 Baltimore, MD 21287, USA.  
Fax: +1 410 614 8718.

E-mail address: [etanner4@jhmi.edu](mailto:etanner4@jhmi.edu) (E.J. Tanner).

lymphadenectomy. Sentinel lymph node (SLN) biopsy, a technique that has revolutionized the approach to lymph node assessment in many other cancer types [15,16], has been proposed for endometrial cancer surgery to minimize both the rate of unnecessary lymphadenectomy in low risk women, as well as the risk of under-staging and hence under-treatment [17]. Since first described by Burke et al. 15 years ago, SLN biopsy techniques for women with endometrial cancer have evolved [18]. Single institution data from the group at Memorial Sloan Kettering Cancer Center suggests that cervical injection with blue or green dye at the time of hysterectomy and staging results in reliable mapping of relevant lymph nodes that drain the uterus [19]. Select U.S. centers have recently adopted this technique, but there is a lack of prospective, multicenter data to validate it. Much remains to be learned about the optimal choice of dye, technique, and overall sensitivity of SLN detection of metastases in women with endometrial cancer.

Given the potential advantages of SLN mapping, including reduction of lymphedema and intraoperative complications [5] and improved detection of positive lymph nodes with ultrastaging techniques [20], it is critical that this approach be rigorously studied and optimized to ensure patient safety without oncologic compromise. In addition to a variety of locations proposed for injection, the optimal dye to perform SLN mapping is unclear. Two dyes are currently available. Isosulfan blue (Lymphazurin, Covidien LP, Mansfield MA) has been used in sentinel lymph node mapping for many different cancers. It relies on the surgeon's ability to visualize blue lymph nodes and lymphatic channels and differentiate them from the surrounding tissues (Fig. 1a). This colorimetric technique maybe challenging in cases where visceral fat can impair the surgeons ability to adequately visualize blue lymph nodes and poses a technical challenge in endometrial cancer, given its association with obesity. Indocyanine green (IC-Green, Novadaq Technologies Inc. Mississauga, ON Canada) has been proposed as an alternative to ISB [21,22] (Fig. 1b). This fluorescent dye relies on a fluorometrically capable camera and appears green when excited by light in the near infrared

range (NIR). It has the potential advantage of being readily visible through visceral fat. Therefore, our study objective was to compare the sentinel lymph node detection rate of indocyanine green (ICG) versus isosulfan blue (ISB) in women with EC and CAH in a new sentinel lymph program. A secondary objective was to assess whether the ICG dye performed better than ISB in women with increasing body mass index.

## Materials and methods

The Kelly Gynecologic Oncology Service at Johns Hopkins Hospital, Baltimore MD adopted a sentinel lymph node mapping program in September 2012. Four gynecologic oncology surgeons with expertise in sentinel lymph node techniques have participated in this program and contributed patients to this prospectively collected database. The study, which was approved by the institutional review board at Johns Hopkins Hospital, occurred during the period of September 2012 to March 2014. All patients with complex atypical hyperplasia or endometrial cancer undergoing a planned robotic-assisted total laparoscopic hysterectomy with SLN mapping during this time were evaluated. Patients with complex atypical hyperplasia were included due to their risk of concurrent endometrial carcinoma, which has been found to up to 42% in some studies [23].

### Sentinel lymph node mapping algorithm (Fig. 2)

Upon induction of anesthesia, the cervix is injected with either ISB or ICG at the time of EUA (ISB) or at the time of uterine manipulator placement (ICG). One 50 mg vial of ISB is reconstituted according to package instructions in 5 mL of normal saline (10 mg/mL). One 25 mg vial of ICG is reconstituted in 10 mL of aqueous solvent and further diluted in 10 mL of normal saline (1.25 mg/mL). The solution is injected at the 3 and 9 o'clock positions of the cervical stroma. One mL is injected superficially (submucosa) and 1 mL is injected deep (~8 mm) in the cervical

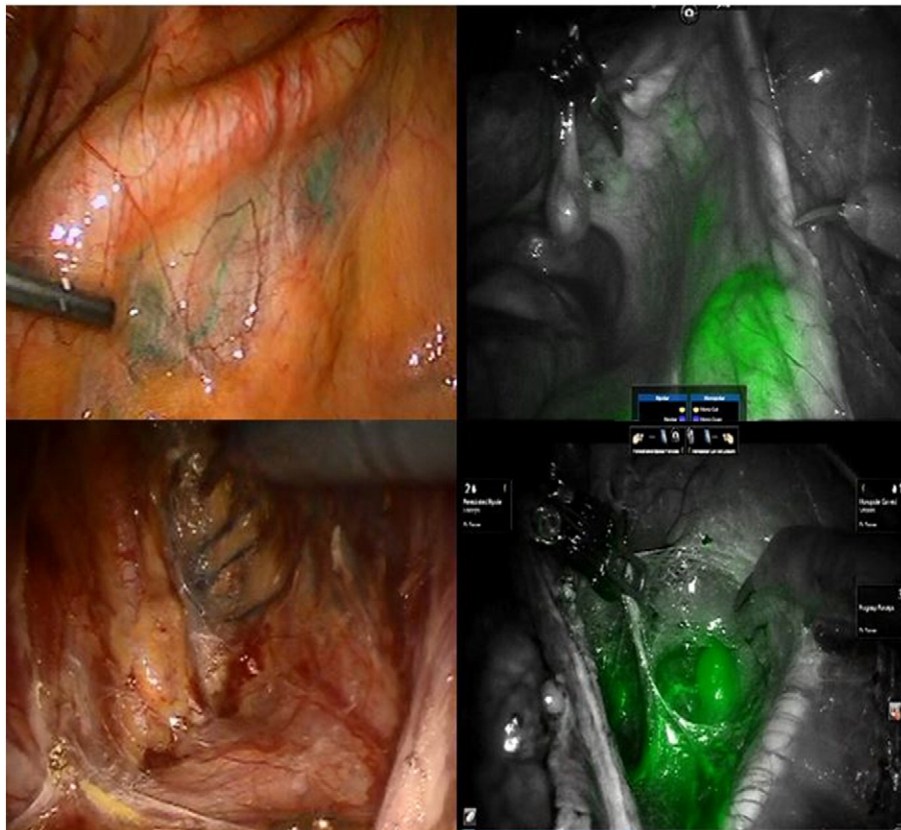


Fig. 1. (Left) Sentinel lymph node with ISB. (Right) Sentinel lymph node with ICG.

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