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# Laparoscopic sentinel lymph node mapping with indocyanine green in endometrial cancer: surgeon's learning curve (cumulative sum analysis)

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## ABSTRACT

**Objectives** To evaluate surgeons' learning curves for laparoscopic sentinel lymph node biopsy in endometrial cancer.

**Methods** A prospective observational study was performed at the Oncogynecology Center, Lithuanian University of Health Sciences Hospital, from March 2018 to October 2022. Participating surgeons had no previous experience of laparoscopic sentinel lymph node biopsy with indocyanine green tracer. Cumulative sum analysis was used to create learning curves for the performance of eight surgeons, based on a specific result over a time period. Two different cumulative sum plots were made for each surgeon: successful bilateral sentinel lymph node mapping and removal of sentinel lymph node specimens containing actual lymphatic tissue.

**Results** 190 patients were included. The overall rate of sentinel lymph node mapping was 89.5%: successful bilateral mapping was achieved in 134 (70.5%) patients, while in 36 (19%) patients sentinel lymph nodes were mapped unilaterally. The bilateral detection rate significantly improved in later study periods (from 59.3% in the first year to 85.0% in the last year;  $p=0.03$ ). Analysis of the performance of the surgeons for bilateral sentinel lymph node mapping showed that the cumulative sum plot crossed the  $H_0$  limit line after 13 consecutive successful bilateral sentinel lymph node biopsies, indicating an acceptable level of competence to achieve the bilateral detection rate of at least 75%. This was accomplished by only one surgeon after 30 surgeries. Analysis of the performance of the surgeons for identification and removal of specimens containing histologically confirmed lymphatic tissue showed that the cumulative sum plots crossed the  $H_0$  limit line after six consecutive successful sentinel lymph node removals. This was accomplished by most of the surgeons (5 of 8).

**Conclusion** At least 30 procedures of indocyanine green traced laparoscopic sentinel lymph node biopsy were needed to reach an acceptable level of competence for a bilateral sentinel lymph node detection rate of at least 75%.

**Trial registration number** ACTRN12619000979156.

## INTRODUCTION

Sentinel lymph node biopsy with indocyanine green as a tracer is becoming the standard method for lymph node evaluation in endometrial cancer, thus

## WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Sentinel lymph node biopsy in endometrial cancer patients was approved for surgical lymph node evaluation and is often included in management protocols.
- ⇒ Surgeons' competence to learn the procedure and to successfully implement it in clinical practice needs to be established.

## WHAT THIS STUDY ADDS

- ⇒ This study uses a cumulative sum method to evaluate surgeons' learning curves for sentinel lymph node biopsy in patients with endometrial cancer.
- ⇒ At least 30 procedures were needed to achieve competence for indocyanine green traced sentinel lymph node biopsy to reach a bilateral detection rate of at least 75%.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ We provide standards on the learning curve in sentinel lymph node mapping to implement in clinical practice.

allowing adjuvant treatment to be tailored to individuals.<sup>1,2</sup> The concept of sentinel lymph nodes enables more thorough histological lymph node evaluation, while omitting systemic pelvic lymphonodectomy and its associated complications.<sup>3–5</sup> However, these goals are achieved only when sentinel lymph nodes are detected bilaterally and appropriate specimens are removed for further evaluation.<sup>6</sup> While sentinel lymph node biopsy in endometrial cancer patients is being widely adopted into clinical practice, this raises concerns for the competence of the surgeon.

Cumulative sum analysis is a well established instrument for quality control in the healthcare domain, allowing learning curves to be created based on a specific result over a time period.<sup>7</sup> The aim of our study was to evaluate surgeons' learning curves for laparoscopic sentinel lymph node biopsy with indocyanine green in endometrial cancer patients in a center

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with no previous experience of laparoscopic sentinel lymph node biopsy.

### METHODS

A prospective observational study was performed in Lithuanian University of Health Sciences Hospital. During the period March 2018 to June 2022, patients with histologically confirmed endometrial carcinoma scheduled for minimally invasive surgery were included in the study. All participating patients provided written informed consent.

All patients underwent laparoscopic surgery: hysterectomy with bilateral salpingo-oophorectomy and pelvic lymph node evaluation. According to the preoperatively assessed risk (International Federation of Gynecology and Obstetrics (FIGO) risk stratification<sup>1</sup>), sentinel lymph node biopsy for low risk patients or sentinel lymph node biopsy and systemic pelvic lymphadenectomy for intermediate and high risk patients were performed. An indocyanine green tracer was used to map sentinel lymph nodes. Under general anesthesia, 1 mL of indocyanine green dye (Verdye, Diagnostic Green GmbH, Germany; dilution 2.5 mg/mL) was injected into four cervical quadrants and a uterine manipulator (RUMI, Cooper Surgical, USA) was then placed. After opening the avascular retroperitoneal spaces in the pelvis, near infrared mode was activated, and the pelvic lymphatic basement was inspected using the Olympus VISERA Elite II CLV-S2-IR system (Olympus, Tokyo, Japan). The mapped lymph nodes (at least one per hemipelvis) that were most proximal to the uterus were labeled as sentinel lymph nodes. These were removed separately and evaluated with near infrared mode on camera *ex vivo*, documenting the anatomical site. After removing the sentinel lymph nodes, surgery was continued, performing pelvic lymphadenectomy (if assigned) and hysterectomy. The detailed sentinel lymph node removal protocol is presented in the supplementary online file (Online Supplemental Appendix S1). The surgeries were performed by eight oncological gynecology surgeons with different levels of experience in laparoscopic surgery, but with no previous experience of sentinel lymph node biopsy with indocyanine green in laparoscopic surgery.

Statistical analysis was performed using the Statistical Package of Social Sciences, Mac V.27 (SPSS, IBM, Brøndby, Denmark). One way repeated measures ANOVA was used to evaluate the related continuous variables. A surgeon's learning curve was analyzed using the cumulative sum formula method described by Bolsin and Colson.<sup>8</sup> It is the statistical process control method used to monitor the quality of output and indicates when a process is out of control.<sup>9</sup> The principle of this method is that certain values are assigned to a successful or unsuccessful event, and those values are then summed and plotted graphically. The rise of the plotted line is linked with failure, while the descent of the line shows success. The null hypothesis for the test states that, for a given occurrence, the true failure rate is not different from the target value rate.<sup>10</sup> Significance is reached when the plotted line crosses the limit set by the sequential probability ratio test ( $H_0$  limit line).<sup>8,9,11</sup> This test depends on the type I error (or the false positive rate, meaning that the surgeon's performance is 'out of control' when it is not) and type II error (or false negative rate, leading to the conclusion that the surgeon is 'in control' when they are not). In the healthcare

system, calculations are normally based on the assumption that the type I error is 0.05 (false positive rate 5%) and the type II error is 0.2 (false negative rate 20%).<sup>7,8,10</sup>

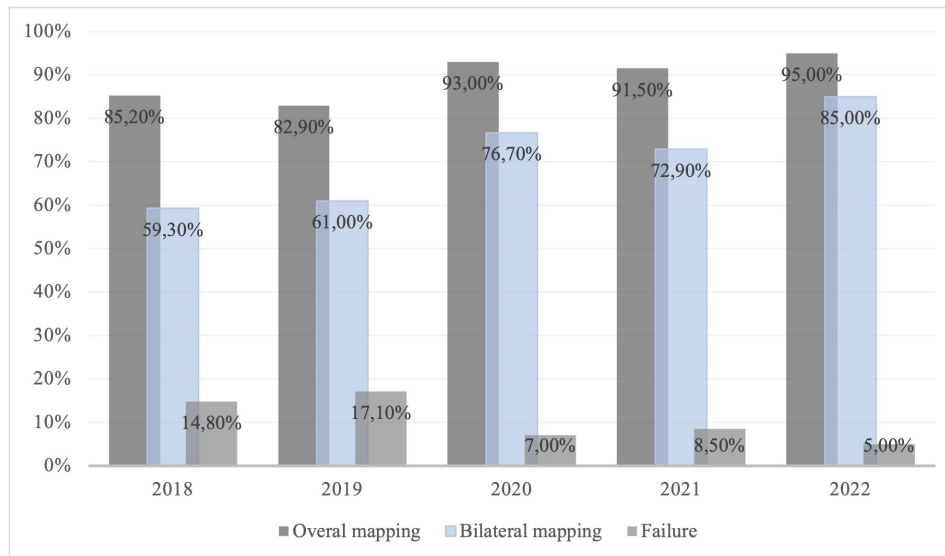
To evaluate the surgeon's performance in sentinel lymph node biopsy, two different cumulative sum plots were made for each surgeon: (1) successful bilateral sentinel lymph node mapping and (2) removal of sentinel lymph node specimens containing actual lymphatic tissue. Based on the reported bilateral mapping rates, varying from 52% to 96%,<sup>6,12,13</sup> for our cumulative sum analysis of surgeons' performances in bilateral sentinel lymph node mapping we chose an acceptable failure rate ( $p_0$ ) of 25% (meaning that the target bilateral mapping should be at least 75%) and an unacceptable failure rate ( $p_1$ ) of 40%. For cumulative sum analysis of specimens containing actual lymphatic tissue, the target was 90% (acceptable failure rate ( $p_0$ ) of 10%) and the unacceptable failure rate ( $p_1$ ) was 30%, assuming a type 1 error ( $\alpha$ ) of 0.05 and a type 2 error ( $\beta$ ) of 0.2 (in both plots).

### RESULTS

A total of 190 patients were included in the study. Median age was 64 years (range 31–88), and median body mass index was 30.1 kg/m<sup>2</sup> (range 19.2–48.1). Most patients (108, 56.8%) were in the intermediate preoperative risk group (FIGO risk assessment using the primary histology report and the depth of myometrial invasion defined by transvaginal ultrasound examination), 72 (37.9%) patients were in the low risk group and 10 (5.3%) patients were in the high risk group. Systematic pelvic lymphadenectomy was performed in 98 (51.6%) patients, with a median number of 7 (range 2–22) lymph nodes removed. Overall, 305 sentinel lymph node specimens were removed during sentinel lymph node biopsies. After final histological evaluation, in 10.5% (32/305) of the sentinel lymph node samples no lymphoid tissue was found. The rate of sentinel lymph nodes containing lymphatic tissue was 89.5%. Lymph node metastases (FIGO stage III C1) were confirmed in 10 (5.3%) cases, and eight were found in sentinel lymph nodes. The sensitivity of sentinel lymph node biopsy was 80.0% and the negative predictive value was 97.8%. After ultrastaging, two false negative sentinel lymph node cases were confirmed with tumor micrometastasis, increasing the sensitivity of sentinel lymph node biopsy to 100%.

All surgeries were performed by eight surgeons. Their performance characteristics are presented in the online supplementary file (Online Supplemental Appendix S2). The overall rate of sentinel lymph node mapping was 89.5%: bilateral mapping was achieved in 134 (70.5%) patients, while in 36 (19%) patients, sentinel lymph nodes were mapped unilaterally. In 20 (10.5%) patients, no sentinel lymph nodes were identified. The most common anatomical sites for sentinel lymph nodes were the external iliac (47.5% on the right and 49.3% on the left) and obturator region (20.4% on the right and 24.6% on the left). The sentinel lymph node anatomical sites are detailed in the supplementary online file (Online Supplemental Appendix S3). The rates of bilateral and overall sentinel lymph node mapping, together with the failure rate according to the study period, are presented in [Figure 1](#).

A one way repeated measures ANOVA was conducted to compare the rate of bilateral sentinel lymph node detection during different



**Figure 1** Sentinel lymph node mapping rates over the course of the study.

study years. The bilateral detection rate significantly improved in later study periods (from 59.3% in the first year of the study to 85.0% in the last year;  $p=0.03$ ). The individual cumulative success rates for bilateral mapping are presented in Figure 2. The cumulative sum formula was applied to each surgeon's results and used to create their individual learning curves. The cumulative sum plots for successful bilateral sentinel lymph node mapping are presented in Figure 3. The primary  $H_0$  limit was crossed by only one surgeon (surgeon 1) after 13 consecutive successfully mapped sentinel lymph node biopsies. This result was achieved after 30 surgeries. The tendency to reach the primary limit could be seen in the plots of three other surgeons (Nos 2, 5, and 8) but statistically significant results were not reached due to insufficient numbers of surgeries performed. The cumulative sum plots for removal of sentinel lymph nodes containing lymphatic tissue are presented in Figure 4.

For removal of sentinel lymph node samples containing lymphatic tissue, cumulative sum plots showed that the  $H_0$  line was crossed by five surgeons after at least six consecutive lymphatic tissue containing sentinel lymph node removals. Two other surgeons crossed the  $H_0$  limit after successfully removing 13 and 25 sentinel lymph node samples containing lymphatic tissue.

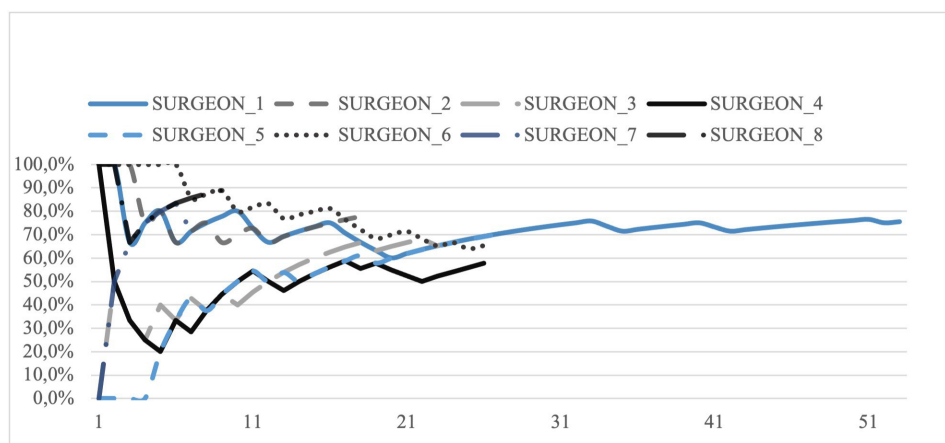
## DISCUSSION

### Summary of Main Results

The rate of bilateral sentinel lymph node mapping increased with time and most surgeons achieved competence after six consecutive successful sentinel lymph node removals. This might suggest that the surgeon's willingness to find the mapped nodes could lead to misinterpretation and removal of specimens that are not actually the intended sentinel lymph nodes.

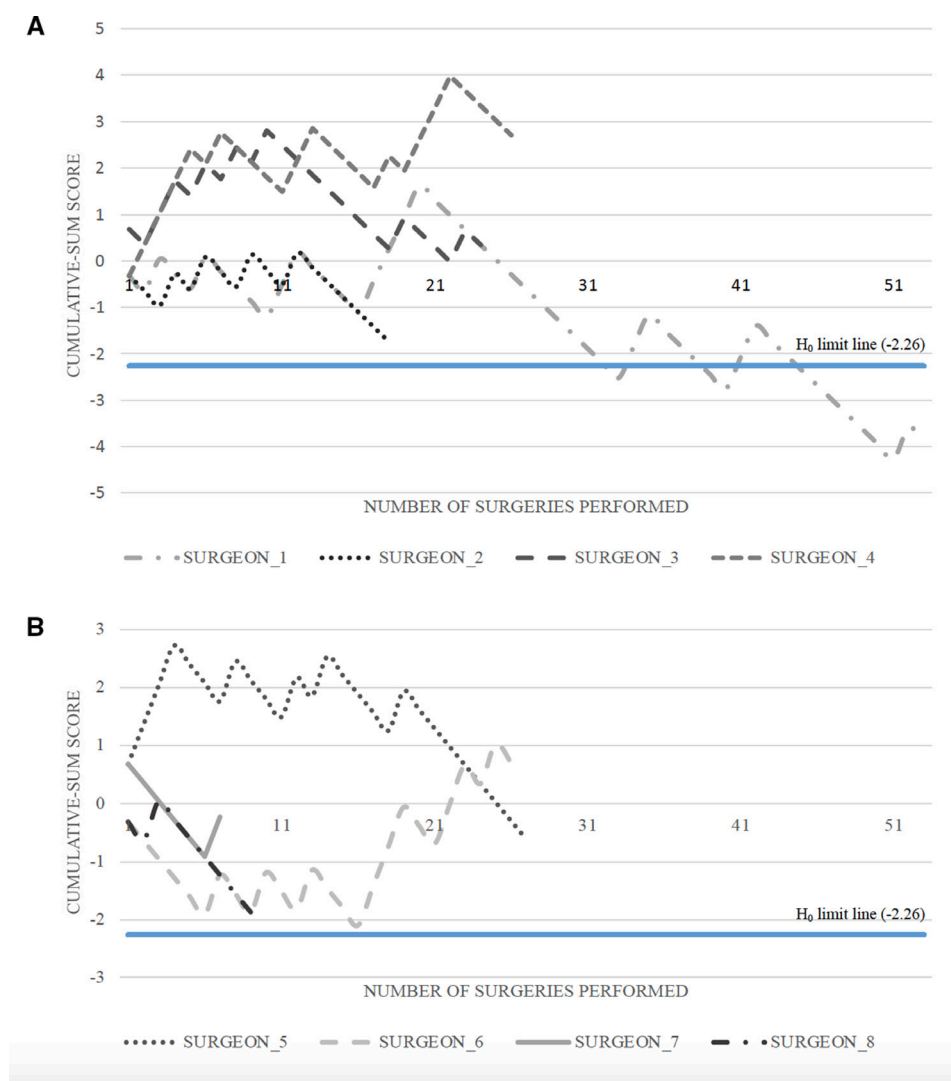
### Results in the Context of Published Literature

The success of sentinel lymph node biopsy in endometrial cancer relies on two principal aspects: bilateral sentinel lymph node detection rate and removal of sentinel lymph node specimens containing actual lymphatic tissue. In a recent retrospective study by Bizzarri et al, it was reported that successful bilateral sentinel lymph node mapping was associated with significantly improved 3 year disease free survival compared with unilaterally mapped sentinel lymph node or mapping failure. However, there was no difference in overall survival.<sup>14</sup> As sentinel lymph node biopsy with indocyanine green has been approved by the National Comprehensive Cancer Network<sup>2</sup> and the European Society of Gynaecological Oncology<sup>1</sup>



**Figure 2** Trend of individual cumulative success rates for bilateral sentinel lymph node mapping.

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**Figure 3** Cumulative sum plots for successful bilateral sentinel lymph node mapping. (A) Cumulative sum plots for surgeons 1–4. (B) Cumulative sum plots for surgeons 5–8.

and adopted into clinical practice, we evaluated procedure limitations associated with its success rates and the surgeon's ability to implement it into clinical practice.

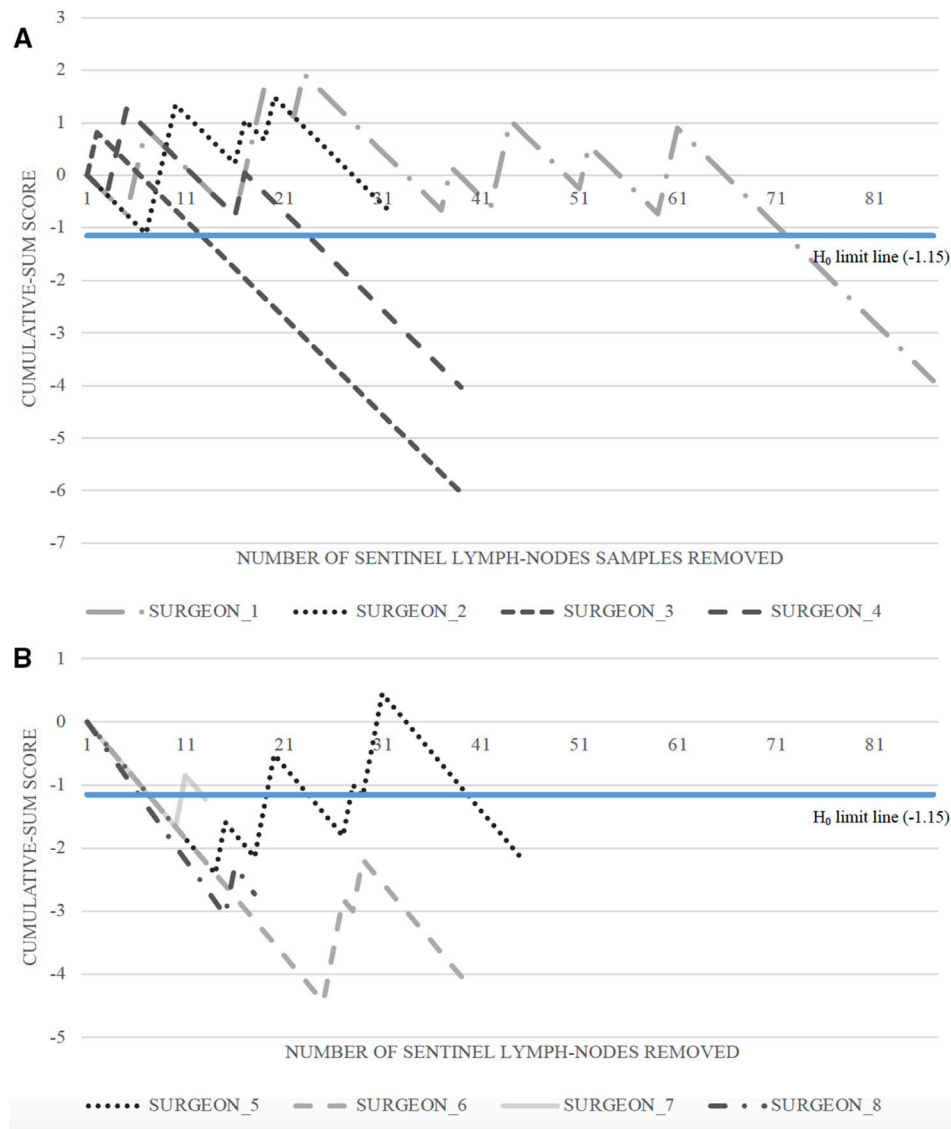
The number of studies concerning the learning curve of laparoscopic indocyanine green mapped sentinel lymph node biopsy in endometrial cancer is low. While the importance of the learning process is a well established paradigm in all fields of medicine, the minimal number of procedures needed to reach a stable outcomes is one indicator of successful implementation of a surgical method into daily clinical practice. There are several studies evaluating other non-surgeon related factors that might influence the bilateral sentinel lymph node detection rate in endometrial cancer. However, their results are controversial.<sup>13–15</sup> All of these studies reported that the bilateral detection rate improves with experience gained during the study period. Moreover, in the study of Ianieri et al, the only independent factor associated with successful bilateral mapping was the experience of the surgeon.<sup>12</sup>

The importance of the case load was also emphasized by studies in other gynecological malignancies with a well established use of sentinel lymph node biopsy. According to the recent report of the European Vulvar Cancer Expert Panel, experience is gained

with case load and, taking into account the rarity of vulvar cancer, these types of surgeries should only be performed by experienced gynecologic oncologists with at least 10 successful cases per year and no false negative results.<sup>16</sup> The importance of the case load was also reported for cervical cancer: analyzing the results of the SENTICOL-I and SENTICOL-II trials of sentinel lymph node biopsy in early stage cervical cancer, it was concluded that higher sentinel lymph node mapping rates for patients were achieved in high volume sentinel lymph node biopsy centers (>5 patients per year), compared with low volume center ( $\leq 1$  patient per year). The experience the surgeon gained during the trial period was also associated with higher success rates compared with the results of patients included in the SENTICOL-I (2005–07) and SENTICOL-II (2009–12) trials.<sup>17–19</sup> A significant increase in bilateral mapping success rates in sentinel lymph node biopsy in cervical cancer (51% in the first 28 cases vs 93% in the last 15 cases,  $p < 0.01$ ) was reported by Plante et al.<sup>20</sup>

Our results in endometrial cancer patients demonstrated the increase in bilateral sentinel lymph node mapping rates over the study period. Similarly, improved rates of bilateral sentinel lymph node mapping and decreased surgery time over the 2 year study





**Figure 4** Cumulative sum plots for removal of sentinel lymph nodes containing lymphatic tissue. (A) Cumulative sum plots for surgeons 1–4. (B) Cumulative sum plots for surgeons 5–8.

period were reported by Tortorella et al. However, most surgeries (91.1%) in the latter trial were performed by the robotic approach.<sup>15</sup> In agreement with our results, the minimal number of 30 procedures was also suggested by Khoury Collado et al but their study was conducted using a combination of blue dye with radiolabelled technetium-99m.<sup>21</sup> According to the most recent systematic review by Nagar et al, indocyanine green tracer has a better detection rate (sentinel lymph node mapping rate of 92.4%, range 88.7–96.2%; pooled sensitivity 92.5%) compared with a combination of technetium-99m with blue dye (86.3%, range 80.7–91.9%; pooled sensitivity 91.9%).<sup>22</sup> A similar trend in improving the bilateral mapping rate in robotic endometrial cancer surgery with indocyanine green tracer was also reported by Tucker et al but the authors concluded that rates stabilized after 40 cases. The authors also addressed another important issue, the rate of removed specimens containing lymphatic tissue. They reported that the odds ratio for successful procedure increased with each 10 additional procedures.<sup>13</sup> In our study, most surgeons reached a stable result after six successfully removed sentinel lymph node specimens.

### Strengths and Weaknesses

In this study, we used the cumulative sum method to investigate a surgeon's learning curve in sentinel lymph node biopsy using indocyanine green tracer in endometrial cancer. However, the interpretation of cumulative sum results depends on acceptable and unacceptable failure rates, as well as type 1 and type 2 errors. As mentioned before, our failure rates were chosen based on bilateral sentinel lymph node mapping rates reported by other authors.<sup>6 12 13</sup> We reported that 30 surgeries were needed to achieve significant competence with a rate of at least 75% for bilateral sentinel lymph node mapping and six sentinel lymph node biopsies to achieve the rate of 90% for appropriate specimens. However, choosing different rates might produce different results. This concern was addressed by Sivaprakasam et al in their cumulative sum analysis for evaluation of labor epidural, concluding that different failure rates produced different results, leading to potential confusion when comparing cumulative sum results.<sup>23</sup> In the study by East et al analyzing the learning curve for sentinel lymph node biopsy in breast cancer, the cumulative sum analysis showed that the

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competence of the surgeon to perform sentinel lymph node biopsy was achieved after eight consecutive positively identified sentinel lymph node when the type 2 error was set at 0.2, and after 12 identified sentinel lymph nodes if the type 2 error was 0.1 (acceptable and unacceptable failure rates were equal for both calculations, but the standard for the surgeon's competence was set higher, avoiding false positive results).<sup>9</sup> Both authors expressed the need for expert organizations or conventions to provide uniform failure rates in order to gain competence.<sup>9,23</sup>

While it may be suggested that the weakness of our study might be an insufficient number of surgeries performed by surgeons for the interpretation of bilateral mapping results to achieve significant results, it should be noted that the cumulative sum method can be applied without the need for a specific sample size and can provide guidance with every new case included.<sup>7</sup>

### Implications for Practice and Future Research

In our study, we demonstrated a significant improvement in bilateral sentinel lymph node detection rates over the study period implementing indocyanine green guided laparoscopic sentinel lymph node biopsy in a center with no previous experience. The cumulative sum method allowed evaluation of each surgeon's learning curves, suggesting that at least 30 procedures were needed to achieve competence when seeking a detection rate of at least 75%. As reported, detection rates differ between studies, and we also raise the need for guidelines to suggest the acceptable failure rates for this procedure, as sentinel lymph node biopsy in endometrial cancer is becoming the standard method for surgical lymph node evaluation.

### CONCLUSIONS

The bilateral indocyanine green mapped sentinel lymph node detection rates in endometrial cancer patients significantly improved over the study period. The cumulative sum analysis showed that 30 surgeries were needed to achieve the rate of at least 75% in bilateral sentinel lymph node mapping, and six consecutive sentinel lymph node biopsies should be performed to remove actual lymphatic tissue with a success rate of at least 90%.

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**Patient consent for publication** Not applicable.

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