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Research Article

The Learning Curve of Sentinel Lymph Node Mapping with Indocyanine Green in Endometrial Cancer Patients

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Abstract

Objective: The objective of this study was to evaluate the learning curve of Sentinel Lymph Node (SLN) mapping and to establish a minimum number of performed SLN mappings before proficiency with the procedure is achieved.

Methods: Patients who underwent SLN mapping for presumed low- and intermediate-risk EC as part of the SLIM study were included in the analysis. Four gynaecologists performed the procedures: two gynaecological oncologists and two general gynaecologists. All patients underwent SLN mapping with indocyanine green, a hysterectomy and a bilateral salpingo-oophorectomy. Successful SLN mapping was defined as bilateral SLN mapping with actual lymphatic tissue in the SLN specimen (pathologically confirmed). Patient demographics and surgical data were entered in a database. The cumulative summation test for learning curve (LC-CUSUM) was used to determine the learning curves per gynaecologist for bilateral SLN mapping, indicating when an individual has reached a predefined level of performance. The CUSUM was used to detect a shift from in control to out of control after reaching the learning curve.

Results: A total of 122 patients were included. The bilateral SLN detection rate was 91%. The overall detection rate was 72%. One gynaecological oncologist and one general gynaecologist reached proficiency with bilateral SLN mapping, after 22 and 45 cases, respectively.

Conclusion: Gynaecologists with and without experience in lymph node dissections are able to learn SLN mapping in EC, but the length of the learning curve before reaching proficiency is highly variable. This justifies a tailored training to learn for SLN mapping, related to the pre-existent level of oncological surgical experience.

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Keywords: Endometrial Cancer; Indocyanine Green; Learning Curves; Sentinel Lymph Node Mapping

Introduction

Performing Sentinel Lymph Node (SLN) mapping in women with presumed early-stage Endometrial Cancer (EC) increased enormously, as it is applied by 50.3% of physicians or consultants in gynaecologic oncology and recommended by multiple international groups. [1-5] The SLNs are the first lymph nodes that receive lymphatic fluid through the regional lymphatic drainage pathway from the uterus, and these lymph nodes are detected and removed in both hemipelvis. [6] By examining a SLN on metastasis, instead of assuming a chance of metastasis, over- and undertreatment of patients can be prevented: only patients with actual lymph node metastases require adjuvant treatment. SLN mapping in EC patients performed by experienced gynaecologists detects or excludes pelvic lymph node metastases, with a sensitivity over 90% and a false-negative rate below 5%. [7-9] In the Netherlands, a hysterectomy with bilateral salpingo-oophorectomy (BSO) is still standard for presumed low- and intermediate-risk EC, with adjuvant therapy based on a risk assessment including both tumour and patient characteristics, more commonly including molecular markers as well. [10] The actual lymph node status is no part of the risk assessment, even though lymph node metastases can be found in up to 15% of presumed low- and intermediate-risk EC patients. [10-12] If lymph node metastases are present, survival can be improved by treating patients adequately. The PORTEC-3 study showed 10% overall survival benefit for radiotherapy with chemotherapy as compared to radiotherapy alone in women with stage IIIC EC. [13] As SLN mapping in EC is not common practice in the Netherlands, it is important to acknowledge and establish a learning curve prior to the implementation of SLN mapping. The aim of this study was to evaluate the learning curve of gynaecologists with different levels of surgical oncological experience.

Methods

Since SLN mapping is no part of the standard treatment of EC in the Netherlands, all patients included in this learning curve analysis were patients who participated in a multicenter, intervention, prospective, cohort study (i.e. SLIM study; Sentinel node biopsy in Low- and Intermediate-risk EC Management, NL52051.091.15). [14] They were included in the SLIM study between March 2016 and December 2021 and underwent SLN mapping for histological confirmed, presumed early-stage, low- and intermediate-risk EC. All patients provided written informed consent. After reaching the required number of inclusions for the SLIM study, no more patients could be added to our learning curve analysis, as SLN mapping in grade 1 and 2 endometrioid EC is only performed in study context in the Netherlands. All patients underwent minimally invasive surgery: SLN mapping followed by a hysterectomy and BSO. A subsequent (side-specific) lymphadenectomy in case of mapping failure was not performed. SLN mapping was performed using indocyanine green (ICG, 1.25 mg/ml), injected superficial (1-2 mm) and deep (20-30 mm) at 3 and 9 o'clock in the cervix after induction of anesthesia and 15-30 minutes before surgery for a total of 4 ml. The dye was injected slowly, at a rate of 5-10 seconds per quadrant. ICG was chosen as marker because of its preferable status based on technical ease, high success rate and reliability. [2,8] The mapping procedure was performed with a near-infrared camera (laparoscopy: Olympus; robot-assisted: Da Vinci X or Xi). SLN mapping was performed conform the operation guideline as described by Moloney et al. [15] The mapped SLNs on both hemipelvis were dissected separately. Tracer re-injection was an option if the SLNs were not visualised upfront. If multiple draining pathways were seen then both draining lymph nodes were dissected. Removed ICG positive tissue was not palpated routinely to determine if nodal tissue was felt. Histological assessment was performed by experienced gynaecological pathologists and consisted of ultrastaging according to a standardised protocol, by 5-step paraffin sections, Haematoxylin And Eosin (H&E) staining and immunohistochemistry on all levels.

In the Netherlands, EC patients with presumed early-stage, low- and intermediate-risk disease are not centralised in the eight tertiary referral hospitals, unlike other gynaecological malignancies, but treated by general gynaecologists in all other hospitals, of whom some only treat less than ten patients per year. Implementation of SLN mapping to standard treatment requires new surgical skills for general gynaecologists and a high-volume of procedures. And although gynaecological oncologists are common with lymph node dissections, SLN mapping may be a relatively new skill for them as well. Therefore, we aimed to evaluate the learning curve of gynaecologists with different levels of surgical oncological experience. All surgeries were performed by general gynaecologists or gynaecological oncologists with experience in minimally invasive surgery, but without previous experience in SLN mapping. All surgeons had at least three years of experience in laparoscopic or robot-assisted hysterectomies, with a minimum of 50 minimally invasive hysterectomies performed; the gynaecological oncologists were also experienced in minimally invasive pelvic lymph node dissection. The first five cases of sentinel lymph node mapping were performed under direct supervision of an experienced proctor. The learning curve started from the first SLN mapping on. Participants in this study were two gynaecological oncologists (gynaecologist 1 and 2, working in different tertiary referral hospitals, both over ten years of experience in laparoscopic or robot-assisted hysterectomies) and two general gynaecologists (gynaecologist 3 and 4, working in a general hospital, respectively over three and over ten years of experience in laparoscopic or robot-assisted hysterectomies). The general gynaecologists did not have any experience with lymphadenectomies. The learning curve for bilateral SLN mapping was determined for each gynaecologist. Successful SLN mapping was defined as bilateral SLN mapping with actual lymphatic tissue in the SLN specimen (pathologically confirmed). By the use of this definition, unilateral and bilateral empty packets (i.e. SLN specimens without actual lymph nodes) were not considered as successful SLN mapping. The false negative rate of SLN mapping could not be determined, as a subsequent lymphadenectomy is not performed in the study population.

Statistics

Statistical analyses were performed using R (version 4.2.1; R Foundation for Statistical Computing, Vienna, Austria). Descriptive statistics were used to summarize the data. To determine when proficiency was reached [16], the cumulative summation test for learning curve (LC-CUSUM) was applied. The LC-CUSUM test is derived from the CUSUM test, which is a method used in statistical process control to monitor a process over time and to detect inadequate runs of performance. [17] Unlike other methods which can be used to determine a learning curve, the LC-CUSUM indicates when a process has reached a predefined level of performance, and allows to determine when proficiency is achieved. [18] The LC-CUSUM test presumes that the gynaecologist is not proficient at the start of monitoring and signals when the trainee has reached the acceptable predefined level of performance. Therefore, the Null Hypothesis (H_0) is that the process is out of control (gynaecologist's performance deviates from adequate performance, p_0, by at least delta), and an Alternative Hypothesis (H_1) is that process is in control (gynaecologist's performance is equal to the adequate performance). The gynaecologist is considered not proficient as long as the LC-CUSUM score remains below the limit h. When the LC-CUSUM score crosses this limit, the gynaecologist is considered to be proficient.

The learning curve was established for bilateral SLN mapping with actual lymph node tissue in the specimen during the pathological assessment. Based on available literature [2], we considered p_0 = 34% as the criterion for an acceptable failure rate (i.e. the bilateral SLN mapping rate should be at least 66%), p_1 = 45% as an unacceptable failure rate, and δ = 5% as the acceptable deviation from adequate performance for pathological bilateral SLN mapping. Based on these settings and using computer simulation (10,000 simulations of series of 100 procedures) a limit of h = 1.1 was chosen for LC-CUSUM test to provide a true discovery rate (TDR; i.e. the probability of an alarm being raised over 100 procedures if the true performance of the gynaecologist is 34% failure) of 79% and an false discovery rate (FDR; i.e. the probability of an alarm being raised over 100 procedures if the true performance of the gynaecologist is 45% failure) of 11%. A standard CUSUM test was applied once gynaecologists demonstrated competency to ensure retention of proficiency. A limit h = 3.75 was chosen for the CUSUM test to provide TDR of 81% and an FDR of 7%.

Ethical Approval

Ethical approval was obtained from the Radboudumc Committee for Ethics in Research (CMO) in the region Arnhem and Nijmegen (file number 2015-1783).

Results

A total of 122 SLN mappings were performed by the four participating gynaecologists. After 122 procedures, the inclusion of the SLIM study was completed and no more patients could be added in this the learning curve analysis. The patient and operative characteristics are presented in (Table 1). None of patients had prior lymphadenectomy or prior radiation therapy. The majority of patients (82%) underwent robot-assisted surgery. SLN mapping was deemed successful per operatively in both hemipelvis in 81% of patients (n=99). However, in 11 patients with apparent bilateral SLN mapping, the dissected SLN specimens on one or both hemipelvis did not contain actual lymph node tissue (empty packet dissection; Table 2). After pathological assessment, the actual bilateral detection rate of SLNs was 72% (n=88). The overall (bilateral and unilateral) SLN detection rate per operatively was 94% (n=115). Final pathological assessment showed a true overall detection rate of 91% (n=111). In seven patients (6%), no SLN at all was found in both hemipelvis. There were few complications: two patients developed a complication during the operative procedure (blood loss > 500 mL, vaginal vault lesion). Five patients developed postoperative complications: extensive skin haematoma (n=1), haematoma of vaginal vault (n=1), and wound infection (n=3). In none of the cases this could be directly linked to SLN mapping.

Characteristics	**All patients**	**Gynaecologist 1**	**Gynaecologist 2**	**Gynaecologist 3**	**Gynaecologist 4**
Inclusions	122	25	22	53	22
Age (range)	66.0 (30-81)	62.0 (30-78)	66.0 (41-80)	65.0 (46-81)	72.6 (48-81)
BMI (range)	29.1 (18-59)	27.1 (18-47)	29.9 (19-43)	28.0 (20-59)	32.4 (18-49)
Previous abdominal surgery (%)	32 (26%)	10 (40%)	10 (45%)	7 (13%)	5 (23%)
ASA classification (%)					
1	30 (24%)	10 (40%)	6 (27%)	11 (21%)	3 (14%)
2	64 (53%)	13 (52%)	13 (59%)	27 (51%)	11 (50%)
3	27 (22%)	2 (8%)	3 (14%)	14 (26%)	8 (36%)
4	1 (1%)	0	0	1 (2%)	0
Conversion rate	4 (3%)	2 (8%)	0	2 (4%)	0
Operation time * (minutes)	163 (88-310)	140 (88-270)	170 (126-243)	155 (107-245)	191 (137-310)
Blood loss (ml)	50 (0-500)	50 (20-500)	50 (10-250)	20 (0-400)	50 (0-500)
SLN detection rate, surgical (%)					
Bilateral detection	99 (81%)	23 (92%)	17 (77%)	44 (83%)	15 (68%)
Unilateral detection	16 (13%)	1 (4%)	1 (5%)	7 (13%)	7 (32%)
No detection	7 (6%)	1 (4%)	4 (18%)	2 (4%)	0
SLN detection rate, pathological (%)					
Bilateral detection	90 (74%)	21 (84%)	16 (73%)	40 (76%)	13 (59%)
Unilateral detection	21 (17%)	3 (12%)	2 (9%)	8 (15%)	8 (36%)
No detection **	11 (9%)	1 (4%)	4 (18%)	5 (9%)	1 (5%)

*Operation time was the time from start anaesthesia until end of anaesthesia

** Patients without SLN detection during surgery are included

Table 1: Patient characteristics and operative characteristics. Data presented as median (range in brackets) or count (percentage in brackets).

SLN detection during surgery	**Actual SLN tissue during pathological assessment**			
	Bilateral	Unilateral	No detection	
Bilateral	88	9	2	99
Unilateral	2	12	2	16
No detection	0	0	7	7
	90	21	11	122

Table 2: Overview of surgical versus pathological SLN detection. Data presented as counts.

Learning Curve of SLN Mapping

The LC-CUSUM and CUSUM plots of bilateral SLN mapping are shown in Figure 1. The h-limit was crossed by gynaecologists 1 and 3 after 22 and 45 cases, respectively, meaning they reached proficiency in SLN mapping (pathologically confirmed). During their short maintenance period, there were no signs of progressing from an in-control to an out-of-control state, and they maintained the performance at an acceptable success rate there onwards, based on the CUSUM curve. Gynaecologists 2 and 4 did not reach proficiency for bilateral SLN mapping after the 22 cases that they performed (after which no more patients could be included). But a tendency to reach the h-limit is seen, especially in gynaecologist 2.

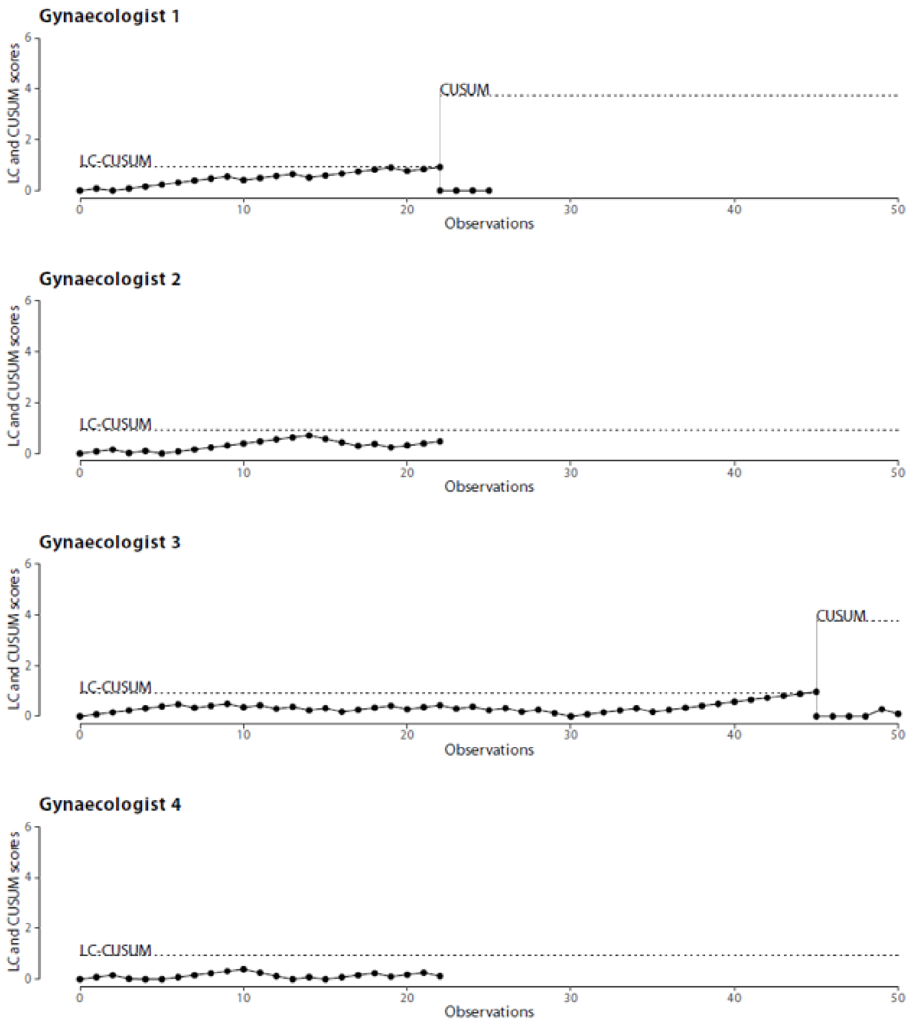

Figure 1: LC-CUSUM and CUSUM curve for bilateral SLN mapping.

LC-CUSUM is applied until acceptable performance has been reached and CUSUM is used thereafter to ensure that adequate level is maintained. For the LC-CUSUM, as long as the score remains below the h-limit (dotted line), the gynaecologist is not considered as proficient; when the LC-CUSUM score crosses this limit, the gynaecologist is considered to have learned the procedure. For the CUSUM, as long as the score remains under the limit, the gynaecologist is considered to maintain an acceptable performance.

Discussion

This study shows the learning curve for bilateral SLN mapping in EC for four gynaecologists with different levels of surgical experience. Our learning curves show that the learning period is highly variable and might take longer for an individual. However, not all participating gynaecologists were able to reach proficiency. This was due to the fact that after 122 procedures no more patients could be added to this learning curve analysis as the SLIM study, in which all patients participated, completed its inclusions. We did include their learning curves into our analyses to show its trend, as a LC-CUSUM can be applied without the need for a specific sample size. It can provide guidance with every extra patient included. Empty packets occurred in 11% of patients, resulting in patients without adequate bilateral SLN detection. We defined successful SLN mapping as 'true lymph node specimen found at final histological assessment'. Unilateral SLN mapping or SLN mapping with empty packets on one or both hemipelvis were not considered successful, as in many countries this would result in a side-specific lymph node dissection with a higher complication risk. [8,19] The empty packet rate is comparable to a previous learning curve study, and is previously described by Thomaier et al. in 2019, showing that fewer empty packets are dissected with more experience, with a stabilization after 30 procedures. [20,21] SLN mapping in EC is considered as a feasible, safe and cost-effective technique. [3,22-24] So far, only a few papers about the learning curve of SLN mapping in EC with ICG have been published.

The overall consensus is that the bilateral SLN detection rate increases with more experience, and that at least 27 to 40 procedures are needed before reaching an acceptable level of competence with SLN mapping. [20, 21, 25, 26] The results of our study differ from previous studies. We applied a strict deduction in the LC-CUSUM for SLN mapping failure in one or both hemipelvis, as in many countries SLN mapping failure will result in a side-specific lymphadenectomy. In the Netherlands, however, standard-of-care does not include any kind of lymph node sampling in low- and intermediate-risk EC, and therefore a side-specific pelvic lymphadenectomy was not performed in patients with failed SLN mapping. [10] We expect that the management of patients in whom SLN mapping failure occurs, will be guided on the nowadays used risk classification to determine adjuvant treatment. Furthermore, the studies by Thomaier et al. and Tucker et al. defined the learning curve by using logistic regression analyses. [21,26] Various methods can be used to determine whether a trainee has reached proficiency. Although standard practice is to perform a recommended number of procedures under supervision, this approach is not well tailored to the individual. The LC-CUSUM method indicates when an individual has reached a predefined level of performance. By using the LC-CUSUM, the probabilities of false positive (declaring adequate while not adequate) and false negative (declaring inadequate while adequate) are taken into account when reaching the learning curve, making the results more reliable.

Also, not all studies present information on empty packet dissection. [25] Presenting the SLN detection rate during surgery, instead of the SLN detection rate after pathological assessment, might underestimate the length of the learning curve. This learning curve study started from the first procedure performed. A supervising proctor was available during the first five cases, but in more cases as it deemed necessary by the proctor or the gynaecologist. In some other studies, surgeons already had prior experience with SLN mapping. [21] All patients included in this study underwent minimally invasive surgery. Both conventional laparoscopy and robot-assisted laparoscopy were performed, in contrary to some other studies in which only robot-assisted procedures were performed. [25, 26] The combination makes our results more applicable to the Dutch situation, as not all Dutch hospitals own a robot platform, and robot-assisted procedures come with much higher costs. The combination of both conventional and robot-assisted laparoscopy may have an impact on the results. Although all gynaecologists were experienced and competent in performing conventional laparoscopy surgery as well as robot-assisted surgery, SLN mapping is considered easier with the three-dimensional vision in robotic surgery. However, a previous study on the laparoscopic versus robot approach of SLN mapping showed that this effect seems to be less than expected: no differences in SLN mapping and the bilateral SLN detection with ICG were found. [27]

Conclusion

This study shows that a learning period is prerequisite to perform adequate SLN mapping in low- and intermediate-risk EC. The length of the learning curve before reaching proficiency is highly variable, justifying a tailored training to learn the procedure. Since empty packet SLN dissection is common during the learning curve of SLN mapping, it is important to examine the true SLN detection rate as confirmed by the pathologist. Both gynaecological oncologists and general gynaecologists are able to learn SLN mapping, making it possible to implement SLN mapping both in tertiary referral hospitals and larger general hospitals, as long as gynaecologists treat sufficient numbers of EC patients and an experienced proctor is available.

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