

Sentinel Node Mapping in Cervical and Endometrial Cancer: Indocyanine Green Versus Other Conventional Dyes—A Meta-Analysis

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ABSTRACT

Background. Historically, blue dyes, ⁹⁹Tc or a combination of the two tracers have been used for sentinel lymph node (SLN) mapping in cervical and endometrial cancer patients. Indocyanine green (ICG), as a tracer, has been recently introduced in this setting. Our goal was to assess the differences in overall and bilateral detection rates as well as in false-negative rates among the different tracers. **Methods.** The electronic databases PubMed, MEDLINE, and Scopus were searched in January 2016 by searching the terms “sentinel lymph node” and “dye” and “indocyanine green,” and “cervical cancer” or “endometrial cancer.” Series comparing different tracers injected intracervically and reporting the detection rate and/or SLN false-negative rate were selected.

Results. Forty-five studies were retrieved. Six studies including 538 patients met selection criteria. Compared with blue dyes, ICG SLN mapping had higher overall (odds ratio [OR] 0.27; 95 % confidence interval [CI] 0.15–0.50; $p < 0.0001$) and bilateral detection rates (OR 0.27; 95 % CI 0.19–0.40; $p < 0.00001$). No differences were found

between ICG and ⁹⁹Tc, although these results are based on data of a single series. No differences in overall and bilateral detection rates were found between ICG and the combination of blue dyes and ⁹⁹Tc. The pooled analysis of false-negative rates data showed no difference in false-negative rates between tracers.

Conclusions. In cervical and endometrial cancer, ICG SLN mapping seems to be equivalent to the combination of blue dyes and ⁹⁹Tc in terms of overall and bilateral detection rates. Its safety profile and ease of use may favor its employment respect to conventional tracers.

Although sentinel lymph node (SLN) mapping has been investigated in gynecologic oncology for over a decade, it has gained widespread diffusion only recently.¹ Since 2014, SLN mapping has been recognized by NCCN guidelines as an appropriate surgical lymph node assessment in patients with cervical and endometrial cancer.^{2,3} When substituting a lymphadenectomy with a SLN mapping, an algorithm that includes the removal of any suspicious lymph node and a side-specific lymphadenectomy on every non-mapping hemipelvis in addition to the SLN biopsy is recommended.^{4,5} Because the uterus is a midline structure, its lymphatic flow involves the bilateral pelvic lymph nodes. Hence, the most successful SLN mapping is the one that detects at least a SLN on each hemipelvis. From an oncological perspective, it is crucial that a SLN mapping technique is characterized by low false-negative rates to minimize the risk to undertreat patients.

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Historically, SLN mapping has been performed with ^{99}Tc radiocolloid (^{99}Tc) alone or in combination with blue dyes. However, these tracers have some side effects. Blue dyes cause discoloration of the skin and urine, a decrease in pulse oximetry readings and occasionally severe allergic reactions. Mapping with ^{99}Tc is logistically complicated because of the coordination required between the injection in a controlled environment, the imaging acquisition and the surgery, making this technique more time-consuming and expensive.

Indocyanine green (ICG) is an intravascular confined fluorescent dye that has been used in ophthalmology to visualize the retinal and choroid vascularization for more than 40 years.⁶ Recently, ICG has been used for SLN detection in various tumors with promising. At present, it is still unclear how ICG performs as a tracer for SLN mapping in cervical and endometrial cancer compared with other conventional tracers.

The purpose of this meta-analysis was to compare the efficacy of ICG versus other conventional tracers (^{99}Tc , blue dyes or a combination of the two) in terms of overall and bilateral detection rates and false negative rates, in cervical and endometrial cancer patients undergoing SLN mapping.

METHODS

Data Identification and Selection

This meta-analysis was performed following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement and included all studies without any restriction on publication year. On January 2016, a systematic literature search was performed. Data were identified using the electronic databases PubMed, MEDLINE, and Scopus by searching the terms “sentinel lymph node” and “dye” and “indocyanine green,” and “cervical cancer” or “endometrial cancer.” All English-language original reports evaluating the efficacy of SLN mapping with ICG or other conventional dyes (^{99}Tc , blue dyes or a combination of these two) in patients affected by cervical or endometrial cancer were considered for inclusion. Studies reporting laparotomy, laparoscopic, or robotic surgery for SLN biopsy were all assessed for inclusion. The reference list of original reports and reviews already published also were analyzed to identify other potential studies.

In endometrial cancer, intracervical, hysteroscopic, and subserosal tracer injections for SLN mapping have been described. However, only series in which the tracer for the SLN mapping was injected intracervically were selected due to the overwhelming diffusion of this procedure and its proven correlation with higher detection rates.^{7–13}

Only studies comparing the efficacy of SLN mapping with ICG versus blue-dyes, ^{99}Tc or a combination of the two were included in the meta-analysis. Review articles, case reports, video articles, and letters were excluded. Two independent reviewers (IR and MLG) identified and selected the studies based on inclusion and exclusion criteria. Divergent opinions were resolved by consultation between the reviewers with the involvement of a third author (AP).

For each study included in the meta-analysis, the following data were recorded: first author’s information, publication year, study design, sample size, type of cancer, type of surgery (robotic, laparoscopy or laparotomy), SLN detection rate, and false-negative rate.

Endpoints

The primary endpoints were the overall and bilateral detection rates of the different mapping tracers (ICG vs. conventional dyes), expressed in terms of risk failure in detecting at least one SLN and at least one SLN per hemipelvis respectively. We assessed overall and bilateral detection rates of different SLN mapping tracers comparing ICG versus blue dyes only, ICG versus ^{99}Tc only, and ICG versus the combination of blue dyes and ^{99}Tc .

The secondary endpoint was the SLN false-negative rate using different mapping tracers. We assessed the SLN false-negative rate comparing ICG versus blue dyes only, ICG versus ^{99}Tc only, and ICG versus the combination of blue dyes and ^{99}Tc . For this purpose, only studies reporting SLN false-negative rates on fully staged patients were considered. Studies reporting SLN false-negative rates based on patients who were not subjected to both SLN biopsy and complete lymphadenectomy were excluded.

Statistical Analysis

Risk failure of overall and bilateral detection of SLNs using ICG versus the other conventional tracers was stratified by studies and the pooled odds ratio (OR) or risk ratio (RR) were calculated using a fixed- or a random-effects model. A χ^2 test for heterogeneity among proportions was performed to assess the presence of statistical heterogeneity between studies. A fixed-effects model was used if statistical heterogeneity was not significant (I^2 value $\leq 50\%$); differently, a random-effects model was adopted. Graphical representation of each study and pooled analysis was displayed by forest plots. The weight that each study provides in the meta-analysis was graphically reported as a square of different size. Confidence intervals (CIs) for each study were symbolized as a horizontal line passing through the square. The pooled OR or RR were represented as a

lozenge in the forest plot and its size corresponded to the 95 % CI of the OR. A *p* value ≤ 0.05 was considered significant. Statistical analysis was performed using Review Manager 5.3 (<http://www.cochrane.org>).

RESULTS

Overall, 45 studies were retrieved through the literature search. Among these, 13 (28.9 %) studies were removed as duplicates. Twenty-four (53.3 %) were excluded after title and abstract evaluation, because two (4.4 %) studies were not English-language original reports, three (6.7 %) studies regarded nongynecologic cancers, one (2.2 %) study was performed on animals, three (6.7 %) reports were reviews, three (6.7 %) were case reports, one (2.2 %) was a video article, one (2.2 %) was a letter, and ten (22.2 %) studies did not compare ICG with other conventional tracers. Two (4.4 %) further studies were excluded successively after full-text evaluation. In the first a nonintracervical tracer injection was used, whereas in the second a population that was later reported more extensively was presented.¹⁴⁻¹⁶ Six studies (13.4 %) remained for comparison at the end of the selection process. The PRISMA flow chart summarizing the process of evidence acquisition is presented in Fig. 1. The flow chart maps out the number of studies identified, screened, included, and excluded as well as the reasons for exclusions.

Overall, 538 patients were included. A total of 173 (32.2 %) patients underwent laparoscopic SLN mapping; 318 (59.1 %) of the patients underwent a robotic SLN mapping and 48 (8.9 %) patients underwent a SLN mapping via laparotomy.

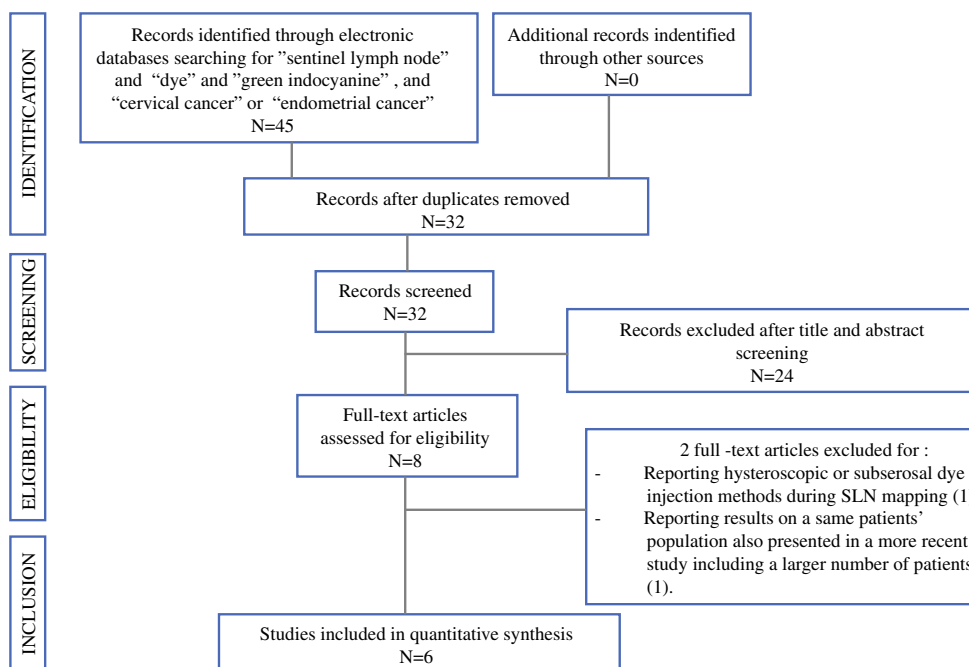
In two series, a combination of tracers was used in the same patient; however, detection rates were reported separately for each tracer, thus allowing extrapolation of the data for each tracer or a combination thereof in each case. In one series, 100 (18.6 %) patients underwent SLN with all the three tracers.¹² In another series, 35 (6.5 %) patients underwent SLN mapping with both ICG and blue dye.¹⁷ In the other four series, different groups were mapped with different tracers. In these series, SLN mapping was performed as follows: 165 (30.7 %) patients underwent ICG SLN mapping, whereas 113 (21 %) patients underwent SLN mapping with a combination of blue-dyes and ⁹⁹Tc and 131 (24.3 %) patients underwent SLN mapping with blue dyes only.^{10,13,16,18} From one of the selected series comparing SLN mapping with ICG versus blue-dyes, only data on bilateral and not on overall detection rates could be extrapolated.¹⁸

All six studies included in the meta-analysis reported the number of false-negative cases, but in two studies, data on false-negative rates per tracer used could not be extrapolated.^{12,18} Consequently, these two studies were excluded from the false-negative rate analysis. Furthermore, one study reported the false-negative rate on a SLN algorithm and therefore was excluded from the analysis as well.¹⁰ The characteristics of the selected studies are listed in Table 1.

Overall and Bilateral Detection Rates

ICG Versus Blue-Dyes When comparing ICG with blue dyes for SLN mapping, the pooled analysis data showed a significant increase in overall detection rate for ICG SLN

FIG. 1 PRISMA flow diagram on the meta-analysis process



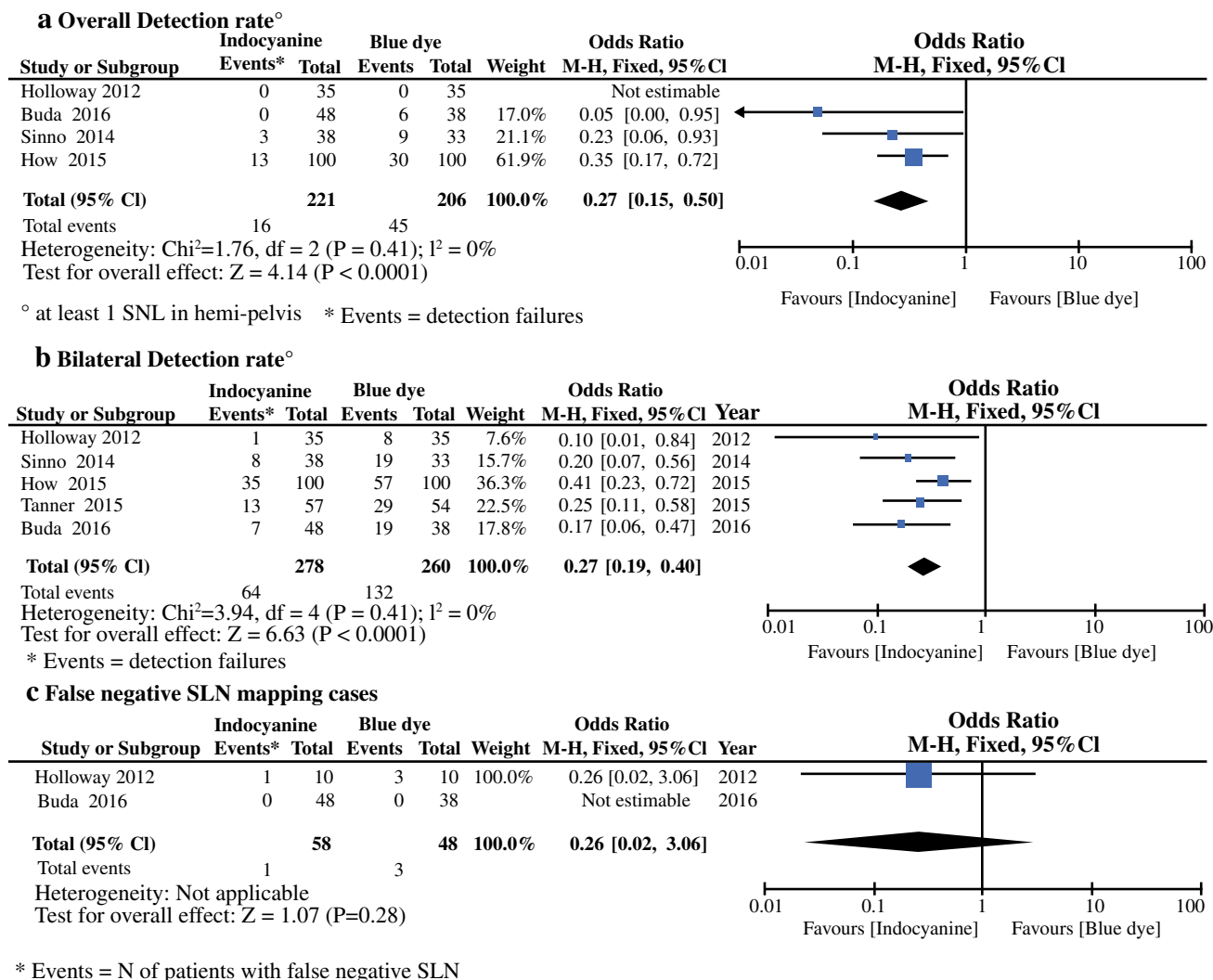


FIG. 2 SLN mapping: ICG versus blue dyes. **a** Overall detection rate. **b** Bilateral detection rate. **c** False-negative SLN mapping rates

mapping (OR 0.27; 95 % CI 0.15–0.50; $p < 0.0001$, fixed-effect model; Fig. 2a). For bilateral detection rates, the pooled analysis data showed a significant increase for ICG SLN mapping (OR 0.27; 95 % CI 0.19–0.40; $p < 0.00001$, fixed-effect model; Fig. 2b).

ICG Versus ⁹⁹Tc When comparing ICG with ⁹⁹Tc for SLN mapping, the pooled analysis data showed no differences in overall detection rates between the two methods (OR 1.08; 95 % CI 0.52–2.26; $p = 0.83$, fixed-effect model; Fig. 3a). For bilateral detection rates, the pooled analysis data showed no difference between the two methods (OR 1.21; 95 % CI 0.80–1.81; $p = 0.36$, fixed-effect model; Fig. 3b).

ICG Versus Blue-Dyes and ⁹⁹Tc Combined When comparing ICG with ⁹⁹Tc for SLN mapping, the pooled

analysis data showed no differences in overall detection rates between the two methods (OR 0.96; 95 % CI 0.45–2.02; $p = 0.91$, fixed-effect model; Fig. 4a). For bilateral detection rates, the pooled analysis data showed a nonsignificant increase for ICG SLN mapping (OR 0.37; 95 % CI 0.07–2.12; $p = 0.27$ random-effect model; Fig. 4b).

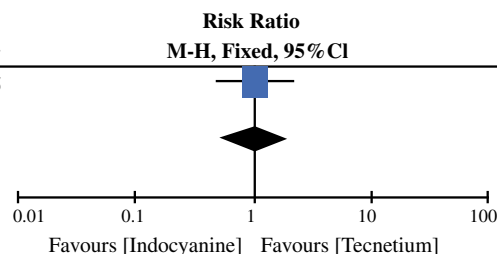
False-Negative Rates When comparing ICG with blue-dyes for SLN mapping, the pooled analysis data showed no difference in false-negative rates between the two groups (OR 0.26; 95 % CI 0.02–3.06; $p = 0.28$, fixed-effect model; Fig. 2c).^{16,17}

Study comparing ICG versus blue-dyes + ⁹⁹Tc reported no cases of false-negative SLNs in both groups.^{13,16} When comparing ICG versus ⁹⁹Tc alone, it is not possible to establish the number of false-negative cases per each group, because the only study comparing these two tracers

a Overall Detection rate^o

Study or Subgroup	Indocyanine		Tcnetium		Weight	Risk Ratio	Year
	Events*	Total	Events	Total		M-H, Fixed, 95% CI	
How 2015	13	100	12	100	100.0%	1.08 [0.52, 2.26]	2015
Total (95% CI)		100		100	100.0%	1.08 [0.52, 2.26]	
Total events	13		12				
Heterogeneity: Not applicable							
Test for overall effect: Z = 0.21 (P=0.83)							

^o at least 1 SNL in hemi-pelvis * Events = detection failures

**b Bilateral Detection**

Study or Subgroup	Indocyanine		Tcnetium		Weight	Risk Ratio	Year
	Events*	Total	Events	Total		M-H, Fixed, 95% CI	
How 2015	35	100	29	100	100.0%	1.21 [0.80, 1.81]	2015
Total (95% CI)		100		100	100.0%	1.21 [0.80, 1.81]	
Total events	35		29				
Heterogeneity: Not applicable							
Test for overall effect: Z = 0.91 (P=0.36)							

* Events = detection failures

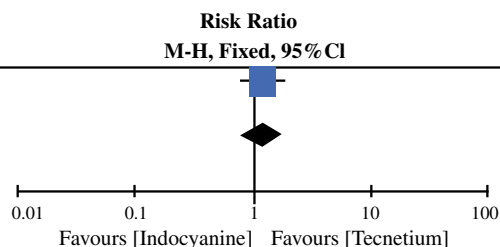


FIG. 3 SLN mapping detection rates: ICG versus ⁹⁹Tc. **a** Overall detection rate. **b** Bilateral detection rate

did not specify the type of tracer per reported false-negative SLN.¹²

DISCUSSION

Different tracers for SLN mapping have been used in cervical and endometrial cancer. The most commonly used are blue dyes and ⁹⁹Tc, with detection rates that range between 70 and 100 %; however, these data mainly relate to overall detection rates, whereas bilateral detection rates are significantly lower.^{19,20} It has been demonstrated that the combination of blue dyes and ⁹⁹Tc yields higher detection rates than any of the two tracers alone, with values that are as high as 90 %.^{21,22}

Recently, encouraging results with the use of ICG as a tracer for SLN mapping have been reported.^{8,9,23} However, whether ICG is superior to the other conventional tracers alone or in combination for the SLN mapping in uterine malignancies is still an unanswered question.

In the present study, we performed a meta-analysis on series evaluating overall and bilateral detection rates for SLN mapping in uterine cancer using different tracers. We observed that ICG SLN mapping increases both overall and bilateral detection rates by 27 % compared with blue dyes. No differences were recorded in overall and bilateral detection rates between ICG and ⁹⁹Tc; however, these results are based on data from a single series. When comparing ICG with the combination of blue dyes and

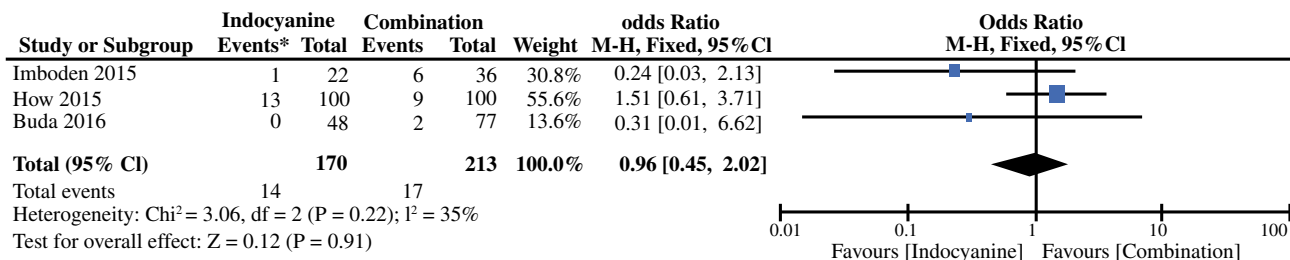
⁹⁹Tc, no differences in overall detection rate between the two groups were recorded. Although nonsignificant, an improvement in bilateral detection rate for ICG was noted. As far as false-negative rates, no differences were recorded between ICG and other conventional tracers.

When adopting the SLN mapping algorithms for cervical and endometrial cancer proposed by the MSKCC, higher overall and bilateral detection rates will lead to a lower number of side-specific lymphadenectomies on nonmapping hemipelvises.^{4,5} This may ultimately result in a reduction in lymphadenectomy-related surgical morbidity, which has been reported to be as high as 20 %.²⁴

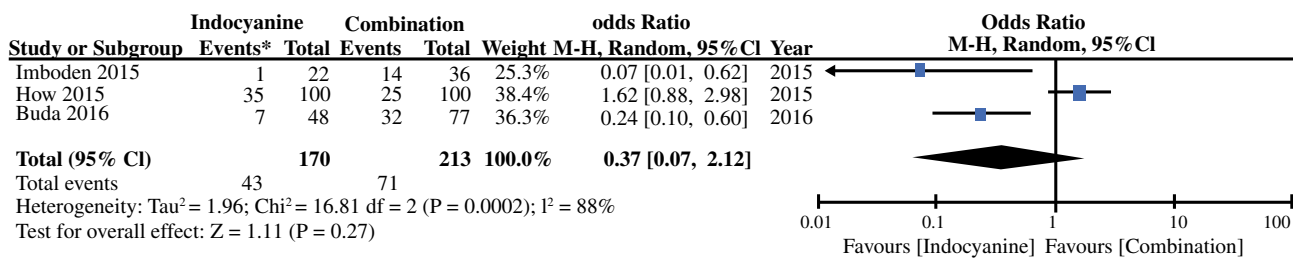
Cervical and endometrial cancer patients without lymph nodal metastases often do not undergo any adjuvant treatment. In this setting, low to virtually absent false-negative rates are crucial for oncological safety.²⁵ Furthermore, it has been demonstrated that the highest NPV for the SLN mapping in early stage cervical cancer is reached in patients with bilateral negative SLN mapping.²⁶

In this view, our results are clinically relevant, because they may help physicians to choose which SLN mapping strategy to adopt and to counsel patients with regards to the oncological safety of the procedure and their risk of still undergoing a full lymphadenectomy despite undergoing SLN mapping for their uterine malignancies.

Our results may be accompanied by some limitations. First, surgical approach in the selected studies differed from a laparoscopic, robotically assisted laparotomy. This

a Overall Detection °

° at least 1 SNL in hemi-pelvis * Events = detection failures

b Bilateral Detection

* Events = detection failures

FIG. 4 SLN mapping detection rates: ICG versus blue dyes and ⁹⁹Tc combined. **a** Overall detection rate. **b** Bilateral detection rate

TABLE 1 Characteristics of the studies included in the meta-analysis

Author (ref.)	Study design	N of patients included	Type of cancer	Type of surgery	Type of tracers	Volume of tracer injected	SLN count	Mean/median Pelvic NSLN count
Holloway et al. ^{17a}	Retrospective	35	Endometrial	Robotic	ICG (35) + BD (35)	2 ml (ICG), 4 ml (BD)	n.a.	22.6 (±10.9)
Sinno et al. ¹⁰	Retrospective	71	Endometrial	Robotic	ICG (38); BD (33)	4 ml (ICG), 4 ml (BD)	2.23 (0–9)	n.a.
Tanner et al. ¹⁸	Retrospective	111	Endometrial	Robotic	ICG (57); BD (54)	4 ml (ICG), 4 ml (BD)	2.9 (0–12)	n.a.
How et al. ^{12a}	Prospective	100	Endometrial	Robotic	ICG (100) + TC (100) + BD (100)	0.4 ml (ICG), 0.4 ml (TC), 3.6 ml (BD)	2.9	6.9 (n.a.)
Imboden et al. ¹³	Retrospective	58	Cervical	Laparoscopy	ICG (22); TC + BD (36)	8–10 ml (ICG), 120 mBq (TC), 5 ml (BD)	2.1–3.7	39 (n.a.)
Buda et al. ¹⁶	Retrospective	163	Endometrial (118) Cervical (45)	Laparoscopy (115) Laparotomy (48)	ICG (48); BD (38); TC + BD (77)	4–5 ml (BD), 4 ml (BD), 0.2–0.3 ml (TC)	2 (0–9)	Endometrium 29 (4–54) Cervix 25 (6–58)

BD blue dye, ICG indocyanine green, TC ⁹⁹Tc, n.a. not available

^a All the patients in the series underwent SLN mapping with the same tracers but overall and bilateral detection rates were reported separately for each tracer

may have influenced the detection rates, because the platforms for the ICG-NIR technology are different based on surgical approach. However, the high detection rates recorded in every series suggest that the tracer, rather than the platform, is responsible for the results. Second, both cervical and endometrial cancer patients are included. Although the neoplastic involvement of the cervix may

affect the lymphatic uptake of the tracer in patients with cervical cancer, leading to differences in SLN mapping among these and endometrial cancer patients, series including both groups of patients have been published. There does not seem to be a substantial difference among the two scenarios. Additionally, the uterus has a complex lymphatic drainage system based on three anatomical

pathways: one (the most commonly involved in the lymphatic spread of the disease) draining to the iliac nodes, one draining the fundus mainly via the gonadal vessels to the high paraaortic area, and one draining to the inguinal lymph nodes through the round ligament.²⁷ The cervical injection of the tracer therefore may not always represent the best choice for proper mapping in patients with endometrial cancer, especially if this is located in the fundal area. Therefore, some authors recommend a hysteroscopic intratumoral injection of the tracer.²⁸ Although a matter of debate, because of the documented marginal risk of isolated para-aortic lymph nodes and because of its “user friendliness,” the cervix remains the preferred and most commonly adopted site of injection of the tracer for SLN mapping in endometrial cancer.²⁹

CONCLUSIONS

This meta-analysis demonstrated that ICG SLN seems to be equivalent to the combination of blue dyes and ⁹⁹Tc with in terms of overall and bilateral detection rates in uterine malignancies. The good toxicity profile and ease of use of ICG, which does not require the injection in a controlled environment and an image acquisition before surgery, along with the availability of integrated platforms for minimally invasive approaches that make the SLN mapping easy and intuitive, may favor the choice of this tracer over the combination of blue dyes and ⁹⁹Tc.

CONFLICT OF INTEREST All authors declare no conflict of interest.

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