Near-infrared mapping with indocyanine green is associated with an increase in oncological margin length in minimally invasive segmentectomy

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ABSTRACT

Background: Near-infrared fluorescence mapping with indocyanine green dye is a recent advancement in minimally invasive segmental resection. This technique has not yet been reproduced, validated, or objectively evaluated in a large prospective case series. We hypothesized that near-infrared fluorescence mapping is associated with an increased oncological margin distance from the tumor, over and above the best judgment of the surgeon.

Methods: This was a phase 2 prospective cohort trial in patients who are undergoing robotic segmentectomy for lung tumors <3 cm. The predicted intersegmental plane was first identified by consensus between 2 thoracic surgeons. The true plane was then mapped by indocyanine green injection. A 7-item binary rating scale was used for the evaluation of feasibility, reproducibility, and added oncological margin distance from the tumor. The margin distance between the tumor and the true plane was compared with the margin distance between the tumor and the predicted plane.

Results: Fifty-three patients were enrolled between September 2016 and May 2018 and 31 patients (58.4%) received the planned operation with indocyanine green mapping. In 74.2% of cases (23 out of 31), a score of 7 out of 7 was achieved, indicating the true intersegmental plane identified by indocyanine green mapping was different than the predicted plane identified by the surgeon. In 61.2% (19 out of 31) of those cases, the mean additional margin distance from the tumor to the staple line attributable to the indocyanine green mapping was 2.41 ± 1.6 cm. The overall complication rate was 18.5% (10 out of 53) and there were no deaths.

Conclusions: Near-infrared fluorescence mapping in robotic segmentectomy is associated with increased oncological margin length, over and above the best judgment of the surgeon, in the majority cases where it is used. (J Thorac Cardiovasc Surg 2019;157:2029-35)

Margin extension by ICG mapping.

Central Message

Near-infrared mapping with indocyanine green in robotic segmentectomy is associated with extended margins from the tumor to the staple line, over and above the best judgment of the operating surgeon.

Perspective

This trial demonstrates that near-infrared fluorescence mapping can extend margin length on segmental resection. With the growing need for segmentectomy, this technique may allow for extended oncological margins on the resected specimen.

See Commentary on page 2036.

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Near-infrared fluorescence (NIF) mapping with indocyanine green (ICG) dye is a recent advancement in minimally invasive segmental resection.¹ This technique involves the isolation of the target segment by ligation of the bronchus, vein, and artery within the hilum of the lung. ICG is then injected

Scanning this QR code will take you to the article title page to access supplementary information.

Abbreviations and Acronyms

CT	= computed tomography
Dp	= predicted intersegmental plane (by the surgeon)
Dt	= true intersegmental plane
ICG	= indocyanine green
NIF	= near-infrared fluorescence

into a peripheral vein and perfuses all lung tissue except for the isolated segment. A thoracoscope with a NIF light source is then used to visualize the lung, and the entire lung will appear to fluoresce in green, except for the target segment that was isolated from blood supply. This provides a clear delineation of the intersegmental plane between the green lung and the dark segment.

The initial description of this technique on the robotic platform by Pardolesi and colleagues² has demonstrated it to be safe and successful in 2 patients.² Since then, multiple other groups have successfully reproduced this work in isolated case reports and videos.³ However, the clinical utility of NIF mapping remains unknown, because this procedure has not yet been reproduced, validated, or objectively evaluated in a large prospective case series. We hypothesized that NIF mapping is safe, reproducible, and increases the oncological margin distance from the tumor to the staple line on the resected segmentectomy specimen. To test this hypothesis, we aimed to reproduce and validate the technique of NIF mapping in robotic segmental resection, and to objectively determine whether it allows for increased oncological margin distance from the tumor.

METHODS**Study Design**

This is a phase 2, single-centered, prospective cohort trial. Eligible patients were older than age 18 years, with suspected or confirmed clinical stage I non-small cell lung cancer or isolated metastases to the lung, and peripheral tumors ≤ 3 cm in diameter. Preoperative computed tomography (CT) was used to confirm that the tumor was isolated to 1 or more bronchopulmonary segments that are amenable to segmental resection. The exclusion criteria were hypersensitivity to contrast dye, pregnant or breastfeeding women, or women of child-bearing potential not taking adequate birth control. Patients were prospectively enrolled in the study before operation and were followed for 30 days postoperatively. Following enrollment, baseline data on patient demographic characteristics, medical history, social history, diagnosis, preoperative tests, and preoperative staging were collected. Before surgery, all imaging data were reviewed jointly by an expert chest radiologist and the operating thoracic surgeon to identify the bronchopulmonary segment where the lung nodule was located and its corresponding pulmonary vein and artery. Perioperative complications, duration of chest tubes in situ, duration of hospital stay, and 30-day morbidity and mortality were recorded.

The trial was granted a no objection letter from Health Canada authorizing the off-label use of ICG (#184323), received full approval by the Hamilton Integrated Research Ethics Board, and was conducted in full compliance with the Canadian Tri-Council Policy Statement on Ethical Conduct for Research Involving Human Subjects. Participants provided

full informed consent for the surgical procedure and the use of ICG in an experimental trial. The trial was registered on www.ClinicalTrials.gov (#NCT02570815).

Intraoperative Outcome Measures

A 7-item binary rating scale (Figure 1) was used for the evaluation of feasibility, reproducibility, and added oncological margin distance from the tumor associated with NIF mapping in robotic segmental resection. This scale was developed by consensus specifically for this operation. A panel of 4 thoracic surgeons evaluated the scale and confirmed face validity of the 7 items. No additional items were recommended for inclusion by the panel. The feasibility of NIF mapping was evaluated using questions 1, 2, and 3 on the rating scale. Reproducibility was assessed using questions 4, 5, and 6 on the rating scale. Added oncological margin distance from the tumor was evaluated by question 7. An aggregate score of 7 out of 7 was mandated to consider the procedure successfully completed. Safety was evaluated by measuring the rates of adverse reactions to ICG dye, intraoperative complications, and perioperative complications using the Ottawa Thoracic Morbidity and Mortality Classification.⁴ Other measured outcomes included operative time, rate of conversion to lobectomy, and rate of conversion to thoracotomy.

Operative Technique

All operations were conducted by 1 surgeon on the DaVinci Si (Intuitive Surgical, Sunnyvale, Calif) robotic platform, using the Completely Portal 4-Arm approach,⁵ and Firefly Fluorescence Imaging camera (Intuitive Surgical) as a NIF light source. Conversions to lobectomy were mandated when N1 disease was suspected or confirmed on intraoperative frozen section, when positive margins were suspected on the resection specimen, or when the tumor was not found in the resection specimen. Conversions to thoracotomy occurred due to intraoperative complications or failure to progress robotically.

Following ligation of the corresponding segmental artery, vein, and bronchus, an independent experienced thoracic surgeon was called into the operating room to examine the lung parenchyma and identify the predicted intersegmental plane, where stapler division would have occurred if NIF mapping was not used. The predicted plane was identified with the inflation method. The predicted plane was then marked by cautery for future reference (Figure 2, A). The identification of the predicted plane by an independent surgeon was done to eliminate the possibility of any bias that the operating surgeon might have toward or against the ICG mapping technique (Video 1). ICG was reconstituted into distilled water to produce a 2.5 mg/mL solution, and a volume of 6 to 10 mL (dose of 15-20 mg) was injected in a peripheral intravenous catheter, followed by a 10-mL flush of sterile normal saline. The optimal ICG doses and concentrations for fluorescence were selected based on previous case reports.² After injection, the surgical field was visualized with the integrated fluorescence imaging capability of the Firefly camera. The target segment, which was now isolated from the pulmonary vasculature (and therefore not perfused with ICG), exhibited no fluorescence and remained dark. The remainder of the lung, which was perfused with ICG, became fluorescent green. The true intersegmental plane was then identified as the line separating the dark lung parenchyma from the green lung parenchyma (Figure 2, B). The true plane was then marked by cautery and stapled across to complete the division of the lung parenchyma (Video 2). The shortest distance between the tumor and the predicted intersegmental plane (Dp) was measured on the resection specimen, and this was compared with the shortest distance between the tumor and the true intersegmental plane (Dt). The difference (Dt-Dp) was then considered to be the added distance from the tumor to the resection edge of the specimen (Figure 3). If Dt-Dp was > 0 , NIF mapping was considered to have increased the length of the oncological margin distance from the tumor. The reverse was true if Dt-Dp < 0 . If Dt-Dp = 0, it was considered that the NIF mapping did not alter oncological margin distance from tumor to the staple line.

7-Item Scale

Item #1 - Visualization of fluoresced lung by NIF imaging

☐ The lung fluoresces with a green hue at the time of exposure to near infrared light

☐ The lung does NOT fluoresce with a green hue at the time of exposure to near infrared light

Item #2 - Demarcation of a dark segment and inter-segmental plane

☐ A dark segment is demarcated from the rest of the lung

☐ A dark segment is NOT demarcated from the rest of the lung

Item #3 - Completion of a dark segment and inter-segmental plane

☐ The dark segment is successfully resected along the dark inter-segmental plane

☐ The dark segment is NOT successfully resected along the dark inter-segmental plane

Item #4 - Ex-vivo localization of lesion

☐ The lesion is found in the resected lung tissue as confirmed by on-site pathologist

☐ The lesion is NOT found in the resected lung tissue as confirmed by on-site pathologist

Item #5 - Ex-vivo confirmation of tumour-free margins around lesion

☐ Tumour-free margins are confirmed by on-site pathologist

☐ Tumour-free margins are NOT confirmed by on-site pathologist

Item #6 - Ex-vivo confirmation of adequate anatomical inter-segmental planes

☐ Confirmation of the presence of the segmental vein within the specimen

☐ NO confirmation of the presence of the segmental vein within the specimen

Item #7 - Added value of NIF-guidance

☐ The cautery marked ischemic inter-segmental line is different than the staple line

☐ The cautery marked ischemic inter-segmental line is NOT different than the staple line

FIGURE 1. This 7-item binary rating scale was used for objective evaluation of feasibility, accuracy, and added margin length. An aggregate score of 7 out of 7 was mandated to consider the procedure successfully completed score of 7 out of 7. *NIF*, Near-infrared fluorescence.

Statistical Analysis

Per-protocol analysis was used. The percentage of successful cases was calculated as the number of cases scoring 7 out of 7 on the rating scale,

divided by the total number of procedures where ICG was used. Descriptive statistics for each of the proposed outcome variables were generated. Continuous variables were compared using the Student *t* test, and

FIGURE 2. A, After ligation of the vasculature, the predicted intersegmental plane is marked with cautery by the surgeon. B, After intravascular injection of indocyanine green, near-infrared fluorescence mapping delineates the actual intersegmental plane between the excluded segment (*dark*) and remaining lung (*green*). *Red arrows* demonstrate the difference between the predicted plane (control) and the true plane (after mapping).

VIDEO 1. Control marking of the predicted intersegmental plane (Dp). This video demonstrates the surgeon marking the predicted intersegmental plane (Dp), based on their best judgment, before indocyanine green mapping. Video available at: [https://www.jtcvs.org/article/S0022-5223\(19\)30061-3/fulltext](https://www.jtcvs.org/article/S0022-5223(19)30061-3/fulltext).

categorical variables were compared using χ^2 or Fisher exact test. Paired t test analysis was used to compare Dt and Dp.

RESULTS

Fifty-three patients were enrolled in the trial between September 2016 and May 2018. The majority (31 out of 53 [58.4%]) received the planned operation with ICG injection. The remainder (22 out of 53 [41.5%]) did not receive a segmental resection because of conversion to thoracotomy, lobectomy, or wedge resection (Figure 4). Conversions to

VIDEO 2. Indocyanine green mapping of the true intersegmental plane (Dt). This video demonstrates the surgeon marking the true intersegmental plane (Dt), after indocyanine green injection under near-infrared fluorescence. The dark lung parenchyma demarcates the segment to be resected, whereas the green lung parenchyma demarcates viable lung that should be left behind. The plane between the dark and green lung parenchyma is the true intersegmental plane. Video available at: [https://www.jtcvs.org/article/S0022-5223\(19\)30061-3/fulltext](https://www.jtcvs.org/article/S0022-5223(19)30061-3/fulltext).

FIGURE 3. The pathologic specimen demonstrates the location of tumor (black circle). The white double arrow demonstrates the distance from the tumor to the predicted plane (Dp) (by the surgeon, before mapping with indocyanine green). The black double arrow demonstrates the distance from the tumor to the true plane (Dt) that was identified by near-infrared fluorescence mapping (after injection of indocyanine green). Dt-Dp is the difference in oncological margin between the tumor and staple line; in this particular case, an added margin of 1.5 cm.

thoracotomy (4 out of 53 [7.54%]) occurred due to dense adhesions. Conversions to robotic lobectomy (12 out of 53 [22.6%]) occurred due to N1 disease that was suspected or confirmed on intraoperative frozen section (3 out of 12 [25.0%]), when positive resection margins were suspected or confirmed on frozen section (8 out of 12 [66.7%]), or when the tumor was not found in the resection specimen

FIGURE 4. Consolidated Standards of Reporting Trials diagram. ICG, Indocyanine green.

(1 out of 12 [8.3%]). Patient characteristics and differences between those who received ICG and those who did not are shown in Table 1. There was a statistically significant difference in the value of forced expiratory volume in 1 second (% predicted) between the 2 groups. Of patients who received ICG mapping followed by segmental resection (n = 31), the most frequently resected segments were the apical-posterior and anterior segments (S1, S2, and S3) of the left upper lobe (11 out of 31 [35.5%]). The second most frequently resected segments were the basilar (S7, S8, S9, and S10) and superior (S6) segments of the lower lobes (8 out of 32 [25.8%] each). The rest of the resections were in the lingular (S4 and S5) segments (4 out of 31 [12.9%]). There were no segmental resections performed on tumors of the right upper lobe.

The evaluation of feasibility, reproducibility, and oncological margin distance from the tumor, based on the 7-item binary rating scale is shown in Table 2. In the whole cohort where ICG mapping was used (n = 31), there appeared to be a slight, but not statistically significant increase, in the oncological margin distance between the tumor and the staple line (mean Dt–Dp, 0.49 cm; *P* = .42). A subgroup analysis of the effects of ICG mapping on segmental resection revealed 3 possible scenarios. In 25.9% of cases (8 out of 31), there was no alteration in the oncological margin distance because the score achieved was < 7 out of 7. In 4 out of 31 cases (12.9%), a score of 7 out of 7 was achieved and the margin distance from the tumor to the staple line was altered negatively by a mean ± standard deviation distance of -1.2 ± -0.72 cm from the tumor, indicating that ICG mapping shortened the oncological resection margin (*P* = .72). In 19 out of 31 cases (61.2%), a score of 7 out of 7 was achieved, and the margin distance from the tumor to the staple line was altered positively by a mean ± standard deviation distance

TABLE 1. Patient characteristics and differences between patients who received indocyanine green (ICG) and those who did not

Characteristic	ICG (n = 31)	No ICG (n = 22)	<i>P</i> value
Women	14 (45.2)	9 (40.9)	.094
Age (y)	67.6 ± 8.26	65.2 ± 6.5	.261
FEV1 (%)	93.13 ± 20.1	79.5 ± 19.6	.019
DLCO (%)	80.2 ± 16.4	76.5 ± 15.1	.431
Operative time (min)	133.7 ± 27.4	117.3 ± 36.5	.061
Nodule diameter (cm)	1.80 ± 1.0	1.53 ± 0.79	.329
Number of lymph nodes	6 (0-18)	4 (0-13)	.250
Conversion to thoracotomy	1 (3.2)	4 (18.2)	.066
Left lung lesions	21 (67.8)	15 (68.2)	.412

Data are presented as mean ± standard deviation, n (%), or median (range). *Bold* type indicates statistically significant results. ICG, Indocyanine green; FEV1, forced expiratory volume in 1 second; DLCO, diffusion capacity of the lungs for carbon monoxide.

TABLE 2. Feasibility, reproducibility, and effect on oncological margin distance from the tumor to the staple line based on the 7-item rating scale

n	%	Score*	Dt–Dp (cm)†	Notes
1	3.3	5	–	Tumor was not palpable in specimen
7	22.6	6	0	Predicted plane identified by surgeons is no different than real plane identified by indocyanine green injection
4	12.9	7	-1.2 ± 0.7	Predicted plane identified by surgeon was further from the tumor than the true plane identified by indocyanine green mapping
19	61.2	7	2.41 ± 1.6	True plane identified by indocyanine green mapping was further from the tumor than the predicted plane identified by the surgeon

Dt, True intersegmental plane; Dp, predicted intersegmental plane. *Out of possible 7. †Values are presented as mean ± standard deviation.

of 2.41 ± 1.4 cm, indicating that ICG mapping lengthened the oncological resection margin (*P* = .041).

There were no 30-day complications directly related to the injection of ICG. The overall complication rate was 18.5% (10 out of 53). The most frequent complications were an air leak longer than 5 days (7 out of 53 [13.5%]) and atrial fibrillation (2 out of 53 [3.7%]). There were no mortalities or any complications beyond Grade II on the Ottawa Thoracic Morbidity and Mortality Scale.⁴

DISCUSSION

Anatomic segmental resection is emerging as an alternative to lobectomy as the standard surgical treatment for small non–small cell lung cancer tumors.^{6,7} With the advent of low-dose CT screening, subcentimeter pulmonary nodules are being frequently detected and the demand for pulmonary segmentectomy is rising rapidly.⁸ The main advantage of segmentectomy over lobectomy is the preservation of healthy lung tissue in patients with compromised lung function, or in patients with evolving bilateral pulmonary nodules who will require multiple resections over time.⁹ Minimally invasive segmentectomy is a technically challenging operation that requires a higher level of dissection into the lung parenchyma and the correct identification and isolation of segmental bronchi and blood vessels.¹⁰ Moreover, the surgeon’s inability to reliably and objectively identify intersegmental parenchymal planes with the naked eye adds another layer of complexity to this operation. This a critical step in the operation because division of the lung

parenchyma in the incorrect plane may leave behind devascularized nonviable lung tissue. Currently, most surgeons rely on their best judgment to identify intersegmental planes, although some may use adjuncts such as preoperative 3-dimensional CT planning, lung inflation after division of the bronchus, or injection of dye at the divided bronchial stump.¹¹

We specifically aimed to study the reproducibility of NIF mapping in robotic segmental resection, and to determine whether it provides any added oncological margin distance from the tumor to the staple line, when compared with the best judgment of the surgeon. We devised a novel 7-item rating scale to objectively evaluate various steps of the operation. We were able to demonstrate in all cases, with the exception of 1 case, that the operation was reproducible. We chose to define added margin distance from the tumor to the staple line as a surrogate for better oncological margins,¹² and a more complete removal of all nonvascularized lung tissue. We were able to demonstrate that NIF mapping with ICG allows for added length on the oncological margin distance from the tumor to the staple line in more than half of cases in which it was used, with the paired *t* test showing a statistically significant difference in the oncological margin length before and after ICG injection. Although in some cases, ICG mapping resulted in shortening the oncological margin, the difference in margin length did not reach statistical significance when the margin was shortened.

Our control scenario, where an independent consultant surgeon defines the intersegmental plane based on his or her best judgment according to the inflation method, provides a high-fidelity simulation of what would happened if NIF mapping with ICG was not used. Furthermore, our case-control experiment, in which each patient served as his or her own control, affords us the opportunity to eliminate many of the possible biases related to nonmeasured confounding factors. The technique of ligating both the venous and arterial supply to the segment resulted in much spillage of dye at the time of peak ICG fluorescence. Some spillage was seen in a delayed fashion, after marking of the parenchymal plane, and was associated with very faint fluorescence, in such a way that it did not influence the identification of the intersegmental plane.

This study has multiple shortcomings. First, we note the absence of right upper lobe segmental resections. It is possible that our patient population had tumors in the right upper lobe that did not fit our inclusion criteria. Although the operating surgeon has extensive experience in robotic anatomic lung resection (more than 250 cases), it is theoretically possible that right upper lobe cases were not selected due to concerns of technical challenges or compromising oncologic resection. As such, this study was unable to evaluate the role of NIF mapping with ICG in the setting of right upper lobe segmentectomies. Another notable finding is the

large proportion of patients who were planned for segmental resections but ultimately underwent lobectomy. This is not an uncommon phenomenon in programs with nascent experience in segmental resection. The learning curve for robotic anatomic lung resection is reported to be between 25 and 40 cases,¹³ and in the early part of this curve, conversions to lobectomy are expected. It is also expected that with growing experience in segmental resection, surgeons will become more adept at evaluating preoperative imaging with respect to N1 disease and tumor location, and the rate of conversion to lobectomy will likely decrease with time. We also present a novel 7-item rating scale to objectively evaluate the steps of NIF mapping during segmental resection. Although face validity of the scale was confirmed by an expert panel of surgeons, additional reliability and validity testing should be performed to ensure generalizability in the case that this scale is to be used by other groups. Finally, although we report a positive correlation between ICG mapping and an increase in the length of the oncological margin distance between the tumor and the staple line, it is possible that this finding was due to other unmeasured variables or selection bias.

CONCLUSIONS

This phase 2 trial demonstrated that NIF mapping with ICG for robotic segmental resection is safe, feasible, and reproducible. It is also associated with an increased oncological margin distance from the tumor to the staple line, over and above the judgment of the surgeon, in the majority of cases where it is used.

Conflict of Interest Statement

Dr Hanna discloses being the recipient of a peer-reviewed research grant, awarded by Intuitive Surgical, which was used to fund this study. The other authors have nothing to disclose with regard to commercial support.

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Key Words: segmental resection, targeted lung surgery, image-guided lung resection, near-infrared fluorescence

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