Fluorescence-enhanced Robotic Radical Cystectomy Using Unconjugated Indocyanine Green for Pelvic Lymphangiography, Tumor Marking, and Mesenteric Angiography: The Initial Clinical Experience

Ted B. Manny and Ashok K. Hemal

OBJECTIVE To describe the initial feasibility of fluorescence-enhanced robotic radical cystectomy (FERRC) using real-time cystoscopic injection of unconjugated indocyanine green (ICG) for tumor marking and identification of sentinel lymphatic drainage with additional intravenous injection for mesenteric angiography.

METHODS Ten patients with clinically localized high-grade bladder cancer underwent FERRC. Before robot docking, rigid cystoscopy was performed, during which a 2.5-mg/mL ICG solution was injected in the bladder submucosa and detrusor circumferentially around the tumor. After robot docking, parameters describing the time course of tissue fluorescence and pelvic lymphangiography were systematically recorded. Lymphatic packets containing fluorescent lymph nodes were considered the sentinel drainage. Eight patients underwent intracorporeal ileal conduit urinary diversion, during which an additional 2-mL ICG solution was given intravenously for mesenteric angiography, allowing maximal preservation of bowel vascularity to the conduit and remaining bowel segments.

RESULTS Bladder tumor marking and identification of sentinel drainage were achieved in 9 of 10 (90%) patients. The area of bladder tumor was identified at a median of 15 minutes after injection, whereas sentinel drainage was visualized at a median of 30 minutes. Mesenteric angiography was successful in 8 of 8 (100%) patients at a median time of <1 minutes after intravenous injection and enabled identification of bowel arcades before intracorporeal bowel stapling.

CONCLUSION FERRC using combined cystoscopic and intravenous injection of ICG is safe and feasible. FERRC allows for reliable bladder tumor marking, identification of sentinel lymphatic drainage, and identification of mesenteric vasculature in most patients. UROLOGY 83: 824–830, 2014. © 2014 Elsevier Inc.

Radical cystectomy with pelvic lymphadenctomy and urinary diversion remains the gold standard for the treatment of clinically localized muscle-invasive bladder cancer.[1] Since its original description by Menon et al in 2003, robotic cystectomy techniques are becoming more widely studied and appear to offer similar oncologic outcomes with decreased morbidity.[2,3] Further advantages of the robotic approach may exist. In addition to providing magnified 3-dimensional vision of the operative field, the robotic platform has the ability to integrate and display additional information to the surgeon, including the recently introduced Firefly (Novadaq Technologies, Mississauga ON, Canada) near infrared fluorescence (NIRF) visualization system.

Potential benefits of fluorescence-guided cystectomy are 3 fold. First, direct cystoscopic injection of the tumor may allow for rapid confirmation of tumor location during the extirpative portions of the procedure. Second, dye taken up by lymphatic tissues could potentially identify sentential bladder drainage. Third, intravenous injection may allow better identification of mesenteric vasculature during intracorporeal diversion to help avoid ischemia.

Of the currently available Food and Drug Administration–approved fluorochromes, indocyanine green (ICG) boasts several properties, which may prove useful in pelvic surgery.[3,4] ICG is nontoxic, nonradioactive, and exhibits NIRF with deeper tissue penetration than visible light. The dye has been proved for both angiography with intravenous administration and tissue and lymphatic identification with interstitial injection. In addition, ICG

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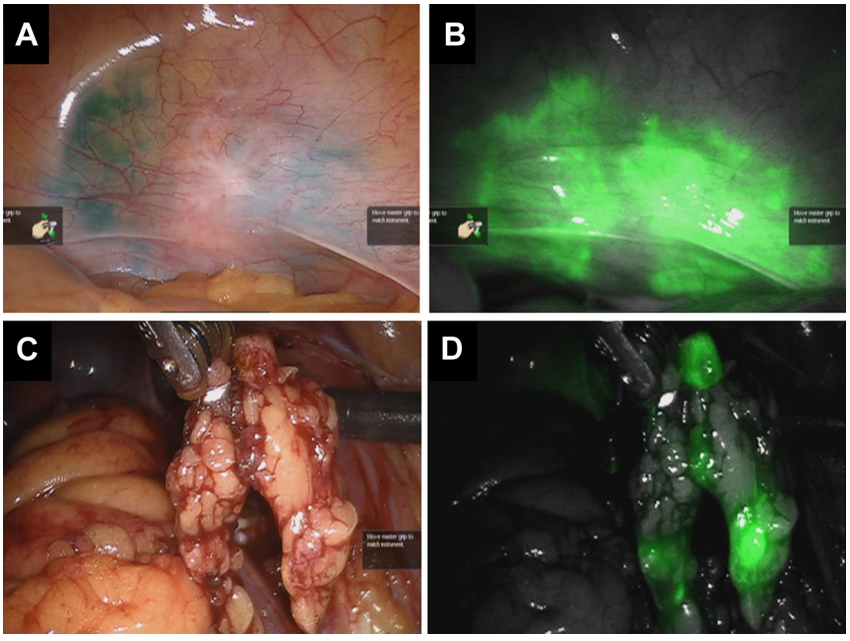

Figure 1. Tumor marking and identification of sentinel pelvic lymph nodes after interstitial bladder injection of indocyanine green. **(A)** Robotic view of bladder immediately after docking under white light, **(B)** robotic view of bladder under near infrared fluorescence, **(C)** right common iliac group under white light, **(D)** right common iliac group under near infrared fluorescence.

has a long record of safety with adverse reactions estimated to occur in 1:300,000 patients.[5-7]

On the basis of our experience in over 150 robotic cystectomies with intracorporeal diversion and familiarity with ICG fluorescence guidance in renal, adrenal, and prostatic disease, we formulated a technique of robotic cystectomy incorporating functional and anatomic properties of real-time tissue fluorescence.[8,9]

MATERIALS AND METHODS

Ten patients with clinically localized high-grade transitional cell carcinoma undergoing curative intent robotic cystectomy from November 2012 to April 2013 were included for analysis. An institutional review board approved all aspects of the study.

After induction of anesthesia, patients were placed in a low-lithotomy position, and rigid cystoscopy was performed. An 18-gauge cystoscopic injection needle was used to inject a total of 2 mL of 2.5 mg/mL of ICG (IC-Green, Akorn Pharmaceuticals, Lake Forest, IL) circumferentially around the tumor. Injection was aimed at the submucosa and superficial detrusor to avoid perforation. Foley catheter was then inserted to gravity drainage and the patient placed in steep Trendelenburg for port placement.

A 4-armed DaVinci Si (Intuitive Surgical, Sunnyvale Ca) robot with Firefly (Novadaq Technologies, Mississauga ON, Canada) NIRF scopes, lightsource, and software was used for all procedures. The fourth robotic arm was positioned on the right side was used for all procedures. A 15-mm assist port was placed in the right lower quadrant at the predefined location for the ileal conduit with an additional 10-mm assist port above the left anterior superior iliac spine. All other aspects were as previously decribed.[2]

Initial inspection was performed under NIRF and white light to assess ability of ICG to successfully mark the area of tumor (Fig. 1). Dissection then commenced lateral to the bladder on both sides from the anterior abdominal wall inferior-superior to expose the surface of the iliac vessels from the deep pelvis to the level of the aortic bifurcation so that areas of node fluorescence could be seen. During the remainder of the procedure, systematic examination of the operative field under NIRF was performed every 5 minutes to document the flow of ICG through the lymphatics (Fig. 1).

Meanwhile, the extirpative aspects proceeded as follows: mobilization of ureters, transposition of right ureter behind sigmoid mesentery, posterior dissection, vascular pedicle control with endoscopic staplers, and anterior and apical dissection.

Lymphadenectomy was then performed from the aortic bifurcation distally to the endopelvic fascia (Fig. 2). Node packets were separately sent for permanent pathologic examination with packets containing fluorescent nodal material by NIRF considered the sentential drainage. Lymphostasis was achieved with Lapro-Clips (Covidian Medical, Mansfield MA).

In female patients, the bladder specimen was then placed into an endoscopic retrieval bag and removed vaginally with double-layered reconstruction. In male patients, the specimen was retrieved just before maturation of the stoma.

Intracorporeal ileal conduit urinary diversion was performed in 8 patients. A 15- to 20-cm segment of distal ileum at least 15 cm proximal to the ileocecal valve was identified. Before division of the bowel, an additional 2 mL of 2.5 mg/mL ICG solution was given intravenously for mesenteric angiography (Fig. 2). This allowed successful identification of mesenteric arcades as to maximally preserve blood supply to the conduit and anastamotic segments. The bowel was taken out of continuity with bowel-load 60 mm motorized endoscopic stapler (Ethicon, Somerville NJ). Additional vascular load stapling was performed at surgeon discretion to provide further mesenteric

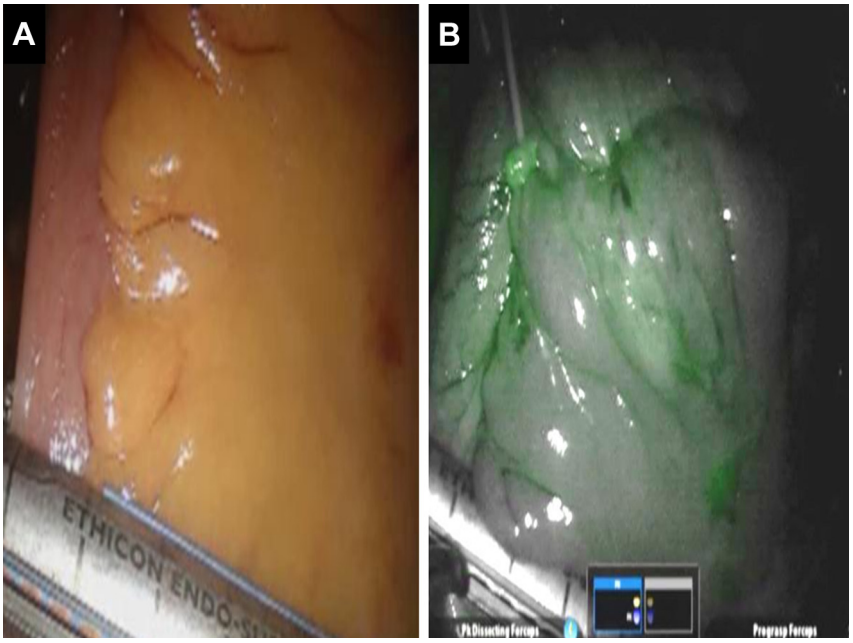

Figure 2. Mesenteric angiography after intravenous injection of indocyanine green. **(A)** Distal ileum under white light, **(B)** distal ileum under near infrared fluorescence. (Color version available online.)

mobilization, again relying on real-time mesenteric ICG angiography to aid in positioning of the staplers. Bowel was brought back in continuity in a side-to-side fashion with overstapling of the free end. Ureteroileal anastamosis was performed with running 5-0 poliglecaprone over robotically placed JJ stents.

RESULTS

Fluorescence-enhanced robotic radical cystectomy was successfully performed in 6 men and 4 women with a median age of 71 years (range, 54-77). Five of 10 (50%) patients harbored locally advanced disease (T3 or more), whereas 3 had nodal metastasis. One patient, patient 4, had multifocal positive surgical margins and peritoneal carcinomatosis on final pathology. The remaining 9 of 10 (90%) of patients had negative margins, including 4 with locally advanced disease. Lymph node yield was median 16 nodes per patient (range, 12-25). Two of 10 patients did not undergo intracorporeal urinary diversion, one of which had a planned right-sided cutaneous ureterostomy for solitary kidney, whereas another had open diversion at the intraoperative request of anesthesia to decrease ventilatory pressures despite reductions in pneumoperitoneum and Trendelenburg positioning angle.

Follow-up is a median of 5.45 months (range, 3-10). No complications relating to the use of ICG were encountered. One patient, patient 3, died of infectious complications during adjuvant chemotherapy 6 months postoperatively. Patient 2, a gentleman with known chronic obstructive pulmonary disease (COPD) and coal miner's lung, experienced a hospital-acquired pneumonia that resolved with intravenous vancomycin.

In terms of tumor marking, cystoscopic injection of ICG allowed robotic identification of the region of tumor in 9 of 10 (90%) patients. The sole patient in whom tumor marking was not successful, patient 4, had a severely hypertrophic bladder over 2 cm thick.

Identification of sentinel drainage by ICG lymphangiography was also successful in 9 of 10 (90%) of patients, all of whom had multiple areas of nodal drainage (Fig. 3). Bilateral sentential drainage was seen in 8 of 9 (89%) patients, with the external iliac group being the most common.

The time course to node fluorescence after cystoscopic injection was rapid (Fig. 4) and persisted throughout the procedure in all patients.

Three patients (30%) harbored node positive disease (Fig. 3). In patients in whom sentinel drainage was identified, nodal fluorescence was 100% sensitive, but only 47% specific for the identification of node positivity. In an intention to treat analysis, ICG node fluorescence had 75% sensitivity and 52% specificity as a predictor of nodal malignancy.

Mesenteric angiography with ICG successfully identified mesenteric arcades in all patients undergoing intracorporeal diversion (8 of 8). Real-time visualization of the bowel vasculature guided all aspects of intracorporeal stapling. No ischemic complications such as anastamotic stricture or stomal stenosis were noted on short follow-up.

COMMENT

Tumor marking is potentially useful for several reasons. First, during radical cystectomy, it allows precise identification of the area of tumor during the extirpative portions of the procedure. This may allow for wider excision around the perivesical fat or other adjacent structures in this area. If this area is seen to be grossly adherent to other viscera or sidewall, it may prompt more precise tissue sampling to

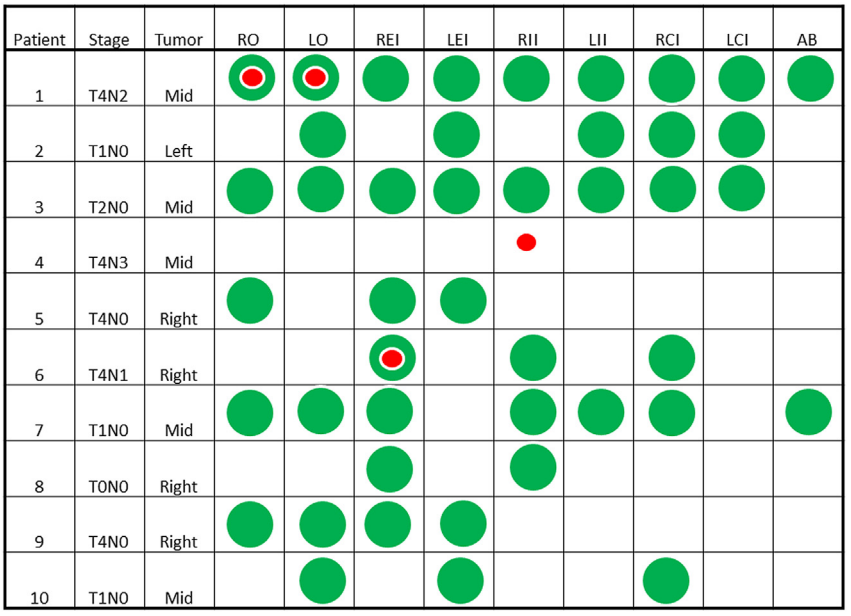

Figure 3. Sentinel lymph nodes identified by indocyanine green lymphangiography for each patient undergoing fluorescence-enhanced robotic radical cystectomy. Large circles, fluorescent sentinel nodes; small circles, pathologically positive nodes; small circles within large circles, fluorescent sentinel nodes that are pathologically positive for carcinoma. AB, aortic bifurcation; LCI, left common iliac; LEI, left external iliac; LII, left internal iliac; LO, left obturator; RCI, right common iliac; REI, right external iliac; RII, right internal iliac; RO, right obturator. (Color version available online.)

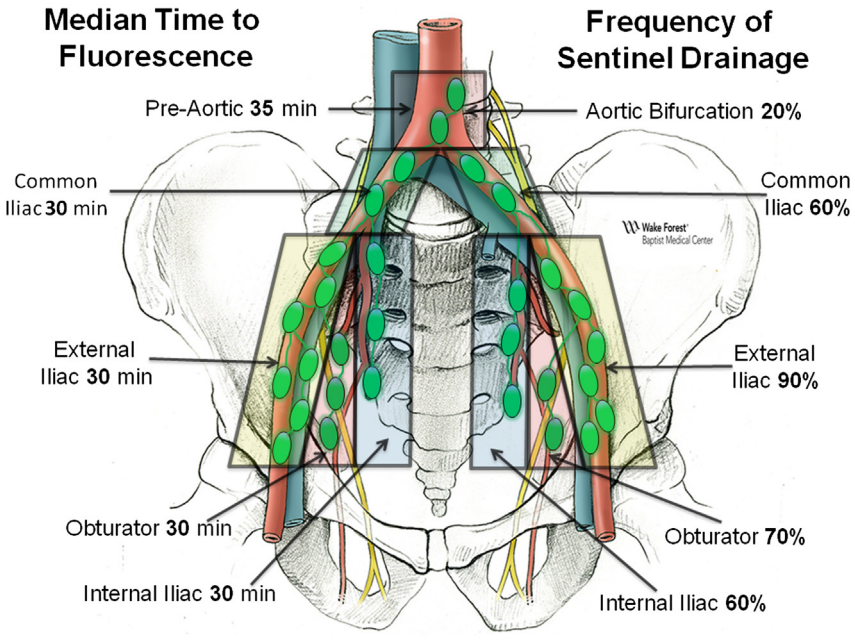

Figure 4. Time course and frequency of sentinel drainage of pelvic lymph nodes after interstitial bladder injection of indocyanine green.

verify advanced disease or change intraoperative determination of resectability. Second, this technique is likely applicable to partial cystectomy in which the periphery of the tumor could be similarly marked to allow for precise robotic identification and removal.

The concept of sentinel nodes in bladder cancer is relatively unexplored and usually met with appropriate skepticism. It is well known on the basis of anatomic and pathologic correlation studies that the bladder is very rich in lymphatic tissue making lymphatic spread of tumor highly variable.[10-12] Bilateral disease is seen in over 40% of node positive patients in large series.[11]

Previous work investigating the use of radiotracer combined with colored dyes has shown promise, but is

cumbersome and costly in its requirement of preoperative lymphoscintigraphy, intraoperative gamma counters, and separate anesthetics for injection.[10,12] Nevertheless, such studies have demonstrated ability to detect sentinel regions in over 80% of patients, often at sites beyond limited templates.

Inoue et al[13] first described ICG lymphangiography during cystectomy but injection technique, dosing, operative, and NIRF visualization techniques were not described. This study found ICG a relatively poor lymphangiography agent with identification of sentinel drainage in only 58% of patients and a 100% false negative rate for detection of nodal malignancy.

The present study is the first clinical description of the use of real-time interstitial injection of ICG for identification of sentinel drainage using the robotic platform. In contrast to previous work with bladder ICG, but similar to investigations using radiotracer + visual dye, we were able to identify sentinel nodal drainage in 9 of 10 (90%) of patients. The solitary patient in whom sentinel lymphangioraphy was unsuccessful, patient 4, also had failure of tissue marking and a detrusor >2 cm thick, possibly signifying a technical limitation to this technique in patients with a very thick-walled bladder.

Similar to previous studies, we found sentinel bladder drainage to be highly variable with bilateral drainage in over 80% of patients and sentinel regions extending to at least the level of the aortic bifurcation (Fig. 3).

In terms of ability to correctly identify nodal metastasis, we found ICG lymphangiography to be highly sensitive, but nonspecific. The utility of the technique in terms of lymphnode dissection may therefore be minimal for surgeons who routinely perform extended pelvic lymphadenectomy. However, the high sensitivity of ICG lymphangiography is potentially useful in algorithms involving bilateral limited templates, with extended dissection of groups that are only fluorescent. Such a strategy may offer improved staging while minimizing potential complications of more extensive dissection such as lymphocele, nerve injury, vascular injury, or excessive operative time.

Identification of bowel vascularity is one of the earliest and most studied applications of ICG and was first explored during robotic cystectomy by Goh et al.[14-16]

Gastrointestinal and ureteral complications are the most common and potentially some of the most problematic after robotic cystectomy.[3,17-20] Precise bowel work with preservation of maximal vascularity to all bowel segments is paramount in minimizing such risks. Intracorporeal robotic urinary diversion is potentially more prone to such problems because of the difficulty in visualization of the mesenteric arcades, as the common backlight technique used in open surgery is not readily available. The outlined technique of intravenous ICG injection for real-time mesenteric angiography is reliable and was subjectively useful in all diversions. It is reasonable that this technique may decrease future ischemic complications of the bowel and ureters.

Potential pitfalls of the study include the small sample size and very short follow-up of a pilot study with results that may not be generalizable. In terms of sentinel node identification, our present study was designed to detect disease up to the aortic bifurcation, and we did not routinely examine potential lymphatics superior to this or in the retrocolic area around the sacrum.

CONCLUSION

Fluorescence-enhanced robotic radical cystectomy using cystoscopic injection of ICG for tumor marking and lymphangiography with intravenous injection for mesenteric angiography is safe and feasible. The described technique allows reliable identification of bowel vascularity, marking of the bladder tumor, and identification of potential sentinel lymphatic drainage in most patients with a high sensitivity for the detection of nodal metastasis.

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APPENDIX

Supplementary Data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.urology.2013.11.042.

EDITORIAL COMMENT

The use of real-time near infrared fluorescence (NIRF) image guidance with the aim to improve surgical precision has been increasingly investigated.[1-3] The computer-based robotic platform is particularly suitable for the integration of other technologies that could potentially enhance surgeons' performance. Although it is still early to have a clear idea of how meaningful these techniques will be for clinical outcomes, preliminary studies such as this one are extremely important to help define such a role.

The authors of this work demonstrated in 10 patients with clinically localized high-grade bladder cancer that indocyanine green (ICG) helped in the identification of anatomic structures during radical cystectomy using the surgical robotic system equipped with a NIRF detection scope. When injected around the tumor in the bladder submucosa through rigid cystoscopy, ICG allowed intraoperative identification of the tumor and lymphatic drainage. After intravenous injection, it helped in the identification of mesenteric arcades to assist intracorporeal urinary diversion.

Perhaps, the most promising feature of their technique is its potential to help surgeons to improve lymph node dissection for bladder cancer. Identification of sentinel lymph nodes using ICG NIRF demonstrated high sensitivity but low specificity to predict lymph node metastasis. Further study is required with detailed nodal mapping to ensure adequate sampling by only dissecting nodes that fluoresce. Frozen section analysis of NIRF nodes may potentially guide limited vs extended lymph node dissection. Ultimately, trials are required assessing recurrence and survival for limited NIRF-guided sentinel node biopsy vs extended lymph node dissection.

ICG is one of the few Food and Drug Administration—approved fluorophores, and it has a well-documented safety profile. However, it does not bind specifically to any target. In the future, we might see the clinical use of fluorophores conjugated to molecules or antibodies, which would bind specifically to certain targets in cancer cells. This could potentially increase the specificity of real-time detection of cancer during image-guided surgery.

Despite several limitations correctly acknowledged, the authors must be congratulated for their innovative work investigating potential new applications of real-time NIRF image-guided robotic surgery in the treatment of urologic cancers. Their contribution is certainly welcomed by other surgeons and basic scientists who are developing this emerging field.

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REPLY

The authors appreciate the interest in our technique of real-time lymphangiography to identify sentinel nodes and mesenteric angiography to help identify bowel vascularity during robotic cystectomy with intracorporeal urinary diversion. We certainly agree that the present study is "proof of concept" of 2 important themes; use of the robotic platform as an information integration tool and the clinical application of molecular-targeted surgery.

With applications such as integrated near infrared fluorescence and Tile-Pro, the surgeon is able to integrate new levels of anatomic and physiological information in real time at the robotic console.[1] The authors foresee this as the infancy of our ability to further apply the vast amounts of data obtained in modern imaging studies to the intraoperative care of the patient.

As the editors have astutely pointed out, indocyanine green is not in itself specific in binding to target tissues but can serve as a marker of physiology such as in the identification of lymphatics and varying tissue types depending on injection technique. Our group has tried to push the envelope conceptually in this regard using intravenous injection to directly identify renal and mesenteric blood vessels, intravenous injection to highlight renal tissue subtypes, tissue injection to "tattoo" target tissue, and identify sentinel lymphatics with applications in bladder cancer, prostate cancer, kidney cancer, ureteral cancer, and adrenal tumors.[2-5] The concept can surely be refined exponentially with targeting of fluophores to monoclonal antibodies or compounds to truly make near infrared fluorescence molecularly targeted. The applications would be myriad in the world of all

surgical oncology with respect to targeting primary cancer tissue and metastasis in sentinel lymphnodes or other distant sites.

We must, however, enter this arena with caution. These themes of improved precision through integration of new information may also lead to "information overload" for surgeons. Investigators and clinicians must always be cognizant of the fallacy that more information is better, when in fact better information is better. We must strive to bring better information to the operating room in the simplest and most usable formats so we can avoid distractions and use technology to improve patient outcomes.

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