

Intraoperative Fluorescence Imaging for Detection of Sentinel Lymph Nodes and Lymphatic Vessels during Open Prostatectomy using Indocyanine Green

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Purpose: We investigated the feasibility and validity of intraoperative fluorescence imaging using indocyanine green for the detection of sentinel lymph nodes and lymphatic vessels during open prostatectomy.

Materials and Methods: Indocyanine green was injected into the prostate under transrectal ultrasound guidance just before surgery. Intraoperative fluorescence imaging was performed using a near-infrared camera system in 66 consecutive patients with clinically localized prostate cancer after a 10-patient pilot test to optimize indocyanine green dosing, observation timing and injection method. Lymphatic vessels were visualized and followed to identify the sentinel lymph nodes. Confirmatory pelvic lymph node dissection including all fluorescent nodes and open radical prostatectomy were performed in all patients.

Results: Lymphatic vessels were successfully visualized in 65 patients (98%) and sentinel lymph nodes in 64 patients (97%). Sentinel lymph nodes were located in the obturator fossa, internal and external iliac regions, and rarely in the common iliac and presacral regions. A median of 4 sentinel lymph nodes per patient was detected. Three lymphatic pathways, the paravesical, internal and lateral routes, were identified. Pathological examination revealed metastases to 9 sentinel lymph nodes in 6 patients (9%). All pathologically positive lymph nodes were detected as sentinel lymph nodes using this imaging. No adverse reactions due to the use of indocyanine green were observed.

Conclusions: Intraoperative fluorescence imaging using indocyanine green during open prostatectomy enables the detection of lymphatic vessels and sentinel lymph nodes with high sensitivity. This novel method is technically feasible, safe and easy to apply with minimal additional operative time.

Key Words: prostatic neoplasms, sentinel lymph node biopsy, indocyanine green, optical imaging

Abbreviations and Acronyms

CCD	= charge-coupled device
CT	= computerized tomography
EPLND	= extended pelvic lymph node dissection
FI	= fluorescence imaging
ICG	= indocyanine green
LED	= light-emitting diode
LN	= lymph node
LV	= lymphatic vessel
MRI	= magnetic resonance imaging
PLND	= pelvic LN dissection
PSA	= prostate specific antigen
SLN	= sentinel LN
SPECT	= single photon emission CT

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INFORMATION regarding the presence of LN metastases is important for the staging and management of prostate cancer. Imaging procedures such as CT and MRI have limited ability to predict LN involvement.¹ PLND during radical surgery remains the most accurate procedure for the detection

of occult LN involvement in clinically localized prostate cancer. The optimal area and survival benefit of PLND are still under debate. Recent data suggest that EPLND with radical prostatectomy enhances the accuracy of surgical staging compared to standard PLND.^{2,3} EPLND may be

necessary to provide accurate staging information and potential therapeutic benefit.^{4–6} However, meticulous EPLND is time-consuming, surgeon dependent and associated with an increased risk of complications.

SLN is defined as the first LN that receives lymphatic drainage from the primary tumor. In prostate cancer it has been reported that radio-tracer guided SLN mapping had high sensitivity in detecting positive nodes.^{7–10} Fluorescence imaging using ICG has been demonstrated to enable real-time transcutaneous detection of SLNs in breast cancer and malignant melanoma.^{11,12} ICG is a fluorescent dye administered by intravenous injection and used for examination of hepatic function. ICG has not been associated with any major adverse effects other than occasional allergic reactions. ICG has a characteristic fluorescence spectra when excited by near-infrared rays, which is advantageous for clinical applications due to the ability of near-infrared rays and fluorescence to penetrate into the tissue.^{11–13}

Novel FI using ICG in prostatectomy was recently reported. Van der Poel et al reported imaging using a hybrid tracer in robot-assisted laparoscopic prostatectomy.¹⁴ Jeschke et al reported a combined method of laparoscopic radio-tracer guided imaging and FI using ICG injected twice.¹⁵ They reported a strong correlation between radiotracer signals and fluorescent LNs, and a higher detection rate in fluorescence guided SLN dissection compared to radiotracer alone. We evaluated FI using ICG in the detection of SLNs and LVs during open prostatectomy using a near-infrared FI camera system suitable for open use, and compared this with the pathological results of confirmatory EPLND as a control.

MATERIALS AND METHODS

A consecutive series of 76 patients with localized prostate cancer from January 2012 to June 2014 were enrolled in this study. This study was approved by the institutional review board and performed in accordance with the ethical standards of the Helsinki Declaration of 1975. All 76 patients gave written informed consent. The first 10 patients participated in an initial pilot study with direct injection of ICG (Diagnogreen, Daiichi Pharmaceutical, Tokyo, Japan) to the prostate after laparotomy to optimize ICG dosing, observation timing and injection method. In the first 20 cases blue dye (indigo carmine, Daiichi Pharmaceutical) was combined with ICG for evaluation of dye guided method. No patients underwent preoperative irradiation. Three patients had received hormone therapy, 1 had undergone transurethral microwave thermotherapy and 1 had undergone holmium laser enucleation of the prostate. Risk of LN metastasis was assessed using the D'Amico risk classification.¹⁶

FI was performed using a near-infrared FI camera system. In this study the 2 camera systems used were PDE and PDE-neo (Hamamatsu Photonics, Hamamatsu, Japan). The large aperture, CCD camera and focusing function of PDE-neo allows a clear display of the image on the monitor with a higher signal-to-noise ratio than its predecessor, PDE. The light source was a LED that emitted light at a wavelength of 760 nm. The high-pass filter was set to 820 nm. LEDs were aligned on a board and the CCD camera was set at the center (fig. 1). Images were observed on the monitor and recorded by video recorder.

The degree of ICG dilution was selected according to the results of an ex vivo phantom test using the camera systems described with consideration to avoid the quenching effect (fig. 2). Due to this effect the ICG concentration is not linearly related to the fluorescence intensity and it is necessary to find an optimal concentration for the best signal.

In the 10-patient pilot study we injected ICG into the prostate after laparotomy and increased the ICG dosing step by step. After exploration of the pelvic cavity 1 ml 0.05 mg/ml ICG was gently injected into each lobe of the prostate with a fine needle and observed for optimized visualization timing. Results of the initial pilot study showed that the best timing for observation was about 30 to 90 minutes after injection. The detection rate of SLNs in the pilot study was 60% and injection of ICG was then changed to before laparotomy under transrectal ultrasound guidance to obtain better timing of observation and to gain stable distribution of injected ICG in the prostate in the next 66 consecutive patients. After induction of general anesthesia, 0.05 mg/ml ICG was gently injected into each lobe of the prostate with a fine needle (22 gauge). Under transrectal ultrasound guidance the solution was injected while moving vertically into the apex and base of the bilateral lobes to obtain a homogeneous distribution.¹⁷ If the prostate was small 1 site in each lobe was injected. We minimized the number of punctures to the rectal wall to 2 to 4. Some of the injected ICG excreted directly into the urethra and the bladder,

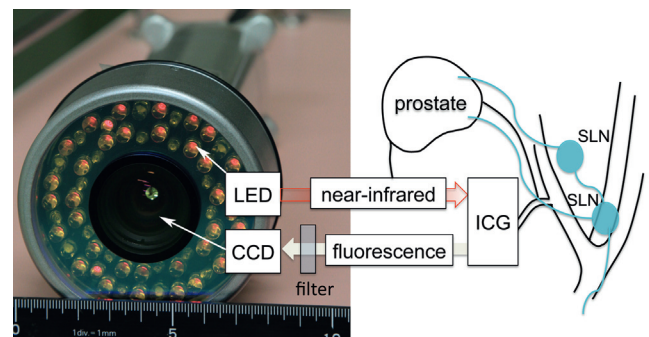


Figure 1. Near-infrared fluorescence imaging camera for open use. LEDs were aligned on board and CCD camera was set at center of camera head. Red colored LEDs emitted near-infrared ray at wavelength of 760 nm and other LEDs emitted white light.

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