

Official Title of the Study: The Use of Fluorescent Imaging for Intraoperative Cholangiogram during Laparoscopic Cholecystectomy

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NEAR INFRARED FLUORESCENT CHOLANGIOGRAPHY: A RANDOMIZED CONTROL TRIAL

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Abstract

BACKGROUND: Bile duct injury (BDI) is the most feared complication encountered during laparoscopic cholecystectomy. Intraoperative cholangiography (IOC) has been shown to decrease the incidence of BDI yet has failed to become routine in the US. Fluorescent cholangiography using near infrared (NIR) imaging provides similar anatomic detail to radiographic cholangiography without some of the drawbacks.

METHODS: 50 patients undergoing laparoscopic cholecystectomy were randomized. 25 acted as the control group while the other 25 received 1cc of indocyanine green (ICG) intravenously prior to the procedure. Operative time, time to identification of the major structures and the surgeon's assessment of visualization, safety, teaching value and resident autonomy were evaluated.

RESULTS: No difference in mean operative times was noted between the control and ICG groups (46.1 and 52.4 minutes respectively) but mean time to identification of the key anatomical structures (19.7 and 14.2 minutes respectively) was significantly reduced. NIRC did not significantly improve the safety of the procedure or the ability of the surgeon to identify important structures but did allow the surgeon to give trainees

greater operative autonomy. Operative management was altered based on pinpoint imaging (4%) in 2 cases. There were no complications or leaks in this series.

CONCLUSION: The results of this study are encouraging and indicate that although NIRC does not supplant the critical view of safety technique it speeds recognition of key structures. It may be especially helpful for surgeons early in the learning curve to help in identifying anatomy and preventing injury and in teaching centers.

Methods: 50 consecutive patients undergoing laparoscopic cholecystectomy were enrolled in this study. Patients were randomized to either the study or control group using a sealed envelope system.

Prospectively collected data included demographics, indications for surgery, operative time, adequacy of cholangiographic images and any change in operative plan based on the NIR images.

Student's t test was used to compare groups and a difference considered statistically significant when $P < 0.05$. This study was approved by the ethics review board of our institution and registered with clinicaltrials.gov (Identifier#NCT01424215).

Underweight, normal weight overweight, obesity and severe obesity were defined using WHO guidelines¹. Patients were considered to have acute cholecystitis based on imaging (ultrasound or CT scan indicated a thickened wall and or pericholecystic fluid), elevated WBC count, physical exam (murphy's sign) and intraoperative findings.

Cholangiographic imaging was considered successful only in one of two scenarios:

- a. the common hepatic duct (CHD) and common bile ducts (CBD)
- b. the cystic duct (CD) and CBD/CHD fluoresced

and were readily distinguishable from the surrounding areolar tissue. Dissection continued until this result was achieved.

Fluorophore - Indocyanine Green (Akorn, Lake Forest, IL): Intravenous ICG binds to plasma proteins, is taken up almost exclusively by the liver and is rapidly excreted in the bile². When exposed to near infrared light ICG fluoresces at a peak

wavelength of approximately 830 nm and can be imaged using a NIR camera. 1-3ml (2.5-7.5mg reconstituted) of ICG was injected via a peripheral IV catheter concomitant with induction of anesthesia. ICG can be seen in bile within minutes following intravenous injection and will continue to be evident even after a prolonged period of time.

NIR Fluorescent imaging system - Pinpoint™ (Novadaq, Ontario, Canada) :

The Pinpoint system consists of a specialized endoscopic camera and light source capable of acquiring both high definition (HD) white light images and NIRC images simultaneously. These images can be displayed separately or as a composite of the NIRC image superimposed on the visible light HD image. This mode is especially useful because it provides context for the ICG cholangiogram thus allowing the user to more readily interpret the data (Figure 1).



Figure 1. Combined mode NIRC view (Cystic artery = arrow, Cystic Duct = arrowhead)

Of the 50 patients undergoing laparoscopic cholecystectomy 25 were randomized to receive indocyanine green (ICG) and 25 were randomized to the control group.

A standardized technique was used in all cases³. In summary, a 4 trocar technique was used, which includes a 12mm trocar placed in the supraumbilical region, an 11mm trocar in the subxiphoid region and 2 lateral 5mm trocars (Kii, Applied Medical, Rancho Santa Margarita, CA) for retraction. The camera was placed at the 12mm site and dissection carried out using the subxiphoid trocar. The combined imaging mode –which displays a composite image made up of the HD white light image and the superimposed real-time NIRC – was used as the sole imaging system in all cases (Video 1).

Operative time was calculated based on time from incision to skin closure. Time to identification of the structures was calculated from procedure start time until either the CHD and CBD or the CD and CBD/CHD were identified by the attending surgeon. Dissection in all cases was performed by a surgical resident, while retraction and direction was provided by the attending surgeon.

In all cases the critical view of safety (CVS) as described by Strasberg⁴ was obtained prior to clipping and dividing any structure. Using electrocautery the gall bladder was separated from the gall bladder fossa and removed through the umbilicus using a specimen retrieval bag (Inzii, Applied Medical). An absorbable stitch was placed to close the fascial defect at the umbilicus followed by skin closure.

At the completion of the cases, the operative surgeon was asked to assess visualization, safety, teaching value of the case and resident autonomy on a five-point Likert Scale (Figure 2).

Postoperative Assessment

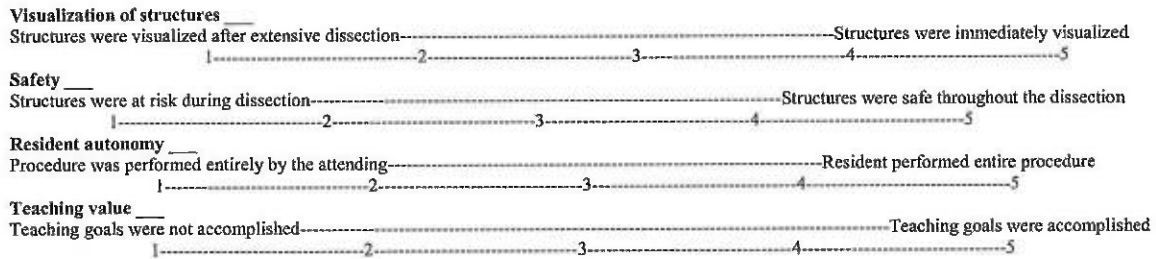


Figure 2. Subjective postoperative assessment

All patients were followed up at least twice postoperatively, at one week and one month post discharge.

cial disclosures related to this study.

¹ World Health Organization. Report of a WHO Consultation on Obesity. Obesity: preventing and managing the global epidemic. Geneva: World Health Organization, 2000.

² Mordon S, Devoisselle JM, Soulie-Begu S, Desmettre T. Microvasc Res. Indocyanine green: physicochemical factors affecting its fluorescence in vivo. 1998;55(2):146-52

³ <http://emedicine.medscape.com/article/1582292-overview> Last accessed 1/15/2016

⁴ Strasberg SM, Brunt LM. Rationale and use of the critical view of safety in laparoscopic cholecystectomy. Journal of the American College of Surgeons 2010; 211:132-8.