Indocyanine Green (ICG) Enhanced Flourescence Guided Minimally Invasive Surgery - Full Clinical Guideline

Reference no.: CG-SURGEN/2024/012

1. Introduction

Fluorescence is the property of certain molecules to emit fluorescence radiation when exposed to light of a specific wavelength. Once the light is absorbed, the fluorescence reaches the observers eye at the aforementioned wavelength. In ICG, this appears green.

2. History of ICG

ICG dye was originally developed for near-infrared (NIR) photography by *Kodak Research Laboratories*® in 1955 and was introduced into clinical practice in 1956. Initially, it was used to measure cardiac output however its recent application is its use in improving visualisation and providing detailed anatomical information in laparoscopic surgery.

3. Scientific Background

ICG is a sterile, water-soluble molecule. Following intravenous injection, ICG is rapidly bound to plasma proteins with minimal leakage into the interstitium. The time of administration of ICG is procedural dependent.

4. Use at Royal Derby Hospital (RDH)

At RDH, the main use of ICG-enhanced fluorescence technology will be for assessment of tissue perfusion and identification of vital anatomical structures, especially in the context of minimally invasive GI surgery.

Application in Upper gastrointestinal (UGI) Surgery

- **Bariatric** – primary and revisional cases for perfusion assessment
- **UGI Cancer** – assessing perfusion of gastric conduit, identification of lymph nodes and to identify the thoracic duct during laparoscopic Ivor-Lewis oesophagectomy

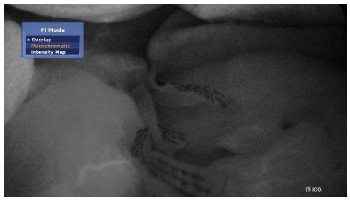
Application in Hepatopancreatico-biliary (HPB) Surgery

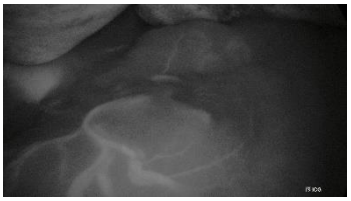
- Identification of common bile duct (CBD)
- Assessment of liver bed during difficult gallbladder dissection

Application in Colorectal Surgery

- To check perfusion of colorectal/colonic anastomosis
- Helps guide appropriate resection in splenic flexure tumours – extended right hemicolectomy vs left hemicolectomy based on identification of dominant blood supply to the area of interest
- Identification of ureter during difficult mobilisation of colon

Images of ICG-enhanced Fluorescence Angiography during Bariatric Surgery



Administration of ICG – the RDH Protocol – See Appendix 1 for Monograph

Perfusion Assessment

Preparation of ICG for administration

Under sterile conditions, reconstitute one (1) 25 mg vial of Indocyanine Green for Injection, using one (1) 10 mL Sterile Water for Injection vial located in the ICG for Injection Set. Shake the ICG vial gently to dissolve. After reconstitution, a 25 mg vial of ICG contains 2.5 mg of dye per mL of solution, so a 1.0 mL injection contains a 2.5 mg dose of ICG.

Indocyanine Green for Injection must be used within 6 hours after reconstitution. If a precipitate is present, discard the solution.

Dosage

A 3 mL (7.5 mg) dose followed by a 10 mL bolus of sodium chloride 0.9% is recommended. Multiple doses can be administered as required, up to the maximum recommended dose.

Maximum Recommended Dose

The total dose of dye injected should be kept below 2 mg/kg*

**No studies have made reference to this being actual or ideal body weight. Clinicians judgement should be used in this instance.*

Timing of ICG Administration

	Blood Vessels	Organs (Kidney, Liver, Adrenal Glands, Small Bowel)
See within:	5 – 30 seconds	1 – 2 minutes
Visibility lasts:	20 – 30 seconds	20 – 120 minutes

For fluorescence imaging of **PERFUSION** in blood vessels, administration of the ICG should be performed at the time fluorescence imaging is requested by the physician. Multiple imaging sequences may be performed as necessary [up to the maximum dose (2 mg/kg of patient

body weight)], so it is recommended to withdraw the desired dosage of ICG solution for each planned imaging sequence into separate syringes ahead of time.

Method of Administration

ICG administration is to be performed via a central or peripheral venous line. Inject the prepared dose of ICG solution into the central or peripheral line as a tight bolus and immediately followed by a bolus of 10-12 mL of sodium chloride 0.9%.

Contra-indications

Indocyanine Green contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides because of the risk of anaphylaxis.

5. References

Karl Storz Endoscopy-America Inc. (2020) ICG for Injection Set. Available from: https://www.drugs.com/pro/icg-for-injection-set.html *[Accessed: 20/05/2021]*

6. Documentation Controls

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Approved By:	*Surgery DQRG – 15/02/2024* *Confirmed as cross -site 14/3/2024*
Review Date:	March 2027
Key Contact:	Mr. Altaf Awan

7. Appendices

Appendix 1: Indocyanine Green (ICG) Monograph

<table>
<tr><td>Indication</td><td>Assessment of tissue perfusion and identification of vital anatomical structures, especially in the context of minimally invasive GI surgery.</td></tr>
<tr><td>Dose</td><td>7.5 mg (3 mL). Multiple doses can be administered, up to the max. recommended dose (2 mg/kg).</td></tr>
<tr><td>Preparation</td><td>Reconstitute one 25 mg vial of Indocyanine Green for Injection using one 10 mL Sterile Water for Injection vial located in the ICG for Injection Set. Shake the ICG vial gently to dissolve. After reconstitution, a 25 mg vial of ICG contains 2.5 mg of dye per mL of solution.

Draw up 3 mL of the 25 mg/1 mL solution into a 5ml Luer Lock syringe to provide a dose of 7.5 mg.</td></tr>
<tr><td>Route</td><td>Intravenous</td></tr>
<tr><td>Administration</td><td>Via a central or peripheral venous line as a tight bolus and immediately followed by a bolus of 10-12 mL of sodium chloride 0.9%.</td></tr>
<tr><td>Shelf-life</td><td>Use within 6 hours after reconstitution. If a precipitate is present, discard the solution.</td></tr>
<tr><td>Compatibility Issues</td><td>Preparations containing sodium bisulfate, including some heparin products reduce the absorption peak of ICG for injection in blood.</td></tr>
<tr><td>Additional information</td><td>Timing of ICG Administration
<table>
<tr><th></th><th>Blood Vessels</th><th>Organs (Kidney, Liver, Adrenal Glands, Small Bowel)</th></tr>
<tr><td>See within:</td><td>5 – 30 seconds</td><td>1 – 2 minutes</td></tr>
<tr><td>Visibility lasts:</td><td>20 – 30 seconds</td><td>20 – 120 minutes</td></tr>
</table>
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</table>

<table>
<tr><td>Contra-indications</td><td>Indocyanine Green contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides because of the risk of anaphylaxis.</td></tr>
<tr><td>Sample Label</td><td>
<table>
<tr><td colspan="4">DRUGS ADDED TO THIS INFUSION</td></tr>
<tr><td colspan="3">PATIENT
A. Patient (A. Number)</td><td>WARD
General
Theatre 1</td></tr>
<tr><td>DRUG
Indocyanine Green
In
3 mL Water for Injections</td><td>AMOUNT
7.5 mg</td><td>ADD BY</td><td>CHECKED BY</td></tr>
<tr><td>DATE ADDED
TIME ADDED</td><td colspan="2">EXP. DATE
EXP. TIME</td><td>BATCH No.</td></tr>
<tr><td colspan="4">DISCONTINUE IF CLOUDINESS OR PRECIPITATE DEVELOPS</td></tr>
</table>
</td></tr>
</table>