USE OF INDOCYANINE GREEN (ICG) IN THE NOVADAQ PINPOINT/SPY-PHI PLATFORM TO DECREASE URETERAL STRICTURES IN URINARY DIVERSION DURING RADICAL CYSTECTOMY

Kevin Chan, MD
Associate Clinical Professor
Head, Reconstructive Urology
City of Hope Cancer Center
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Disclosures

• None
Ureteral Strictures in Urinary Diversion

• Reported rates 2.6-13%\(^1\)\(^2\)
  – Highly variable
• No differences despite variations in:
  – Bricker v. Wallace\(^3\)
  – Running v. Interrupted\(^4\)
  – Robotic v. Open\(^5\)

2. Anderson et al. 2013 Feb;189(2);541-7
3. Evangelidis et al. J Urol 2006 May;175(5):1755-8
4. Large et al. J Urol 2013 Sep;190(3):923-7
“Surgical technique remains an art, and any surgeon reporting benign ureteroenteric stricture rates of more than 3% needs to seriously reevaluate his or her technique and learn great respect for the ureter to avoid instrument trauma, ischemia, crushing or excessive manipulation”

- Donald G. Skinner, MD

The Cause of Benign Ureteroenteric Strictures in Urinary Diversion

• Ischemia
  – Beyond our gross vision, nothing before has allowed surgeons to accurately assess the perfusion of the ureter
  – Even in the best of hands: A stricture rate of 2.6% is acceptable
  – Is there technology that can allow us to improve upon this?
What is Indocyanine Green (ICG)?

- Iodide dye FDA approved in 1959
- Intravascularly, 98% binds to plasma proteins
  - Confines it to intravascular space
- Standard dose 2mg/kg
  - We use 3-5mg/dosing
  - No side effects
- Only contraindication: Iodine allergy
- Hepatic clearance (18-24%/min)
  - T½ is 3-4 min, cleared from the system 10-20 min
  - Allows for multiple injections
- Absorbs near infrared light at 780nm and provokes detectable photon emission at 820-830 nm
Near Infrared Fluorescence Imaging After Intravenous Indocyanine Green: Initial Clinical Experience With Open Partial Nephrectomy for Renal Cortical Tumors


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https://doi.org/10.1016/j.urology.2011.10.016

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ICG in Urology
ICG in Urology

- Robotic partial nephrectomy
- Robotic pyeloplasty (100% success)
- Robotic ureteral re-implant (100% success)
- Robotic ureteroureterostomy (100% success)
- Robotic ureterolysis (71% success)
ICG in Urology

- (a) Intraoperative spiral flap pyeloplasty under white light and (b) near-infrared fluorescence imaging showing a poorly perfused section of renal pelvis (dotted line) that required additional excision

• (a) Intraoperative ureteral stricture under white light and (b) near-infrared fluorescence imaging showing a poorly perfused section of ureter (dotted line)

ICG in Urology

V12-06 UTILIZATION OF INDOCYANINE GREEN FLUORESCENCE ANGIOGRAPHY DURING INTRACORPOREAL URETERO-ILEAL ANASTOMOSIS FOLLOWING ROBOTIC RADICAL CYSTECTOMY

Daniel Melecchi Freitas, Carlos Fay, Nariman Ahmadi, Andre Abreu, Toshitaka Shin, Inderbir Gill, Andre Berger, Mihir Desai, and Monish Aron

Proof of Concept Video at Presented at the AUA
• Utilized ICG and Firefly™ to evaluate distal ureteral vascularity
Novadaq/Stryker SPY v. Intuitive Firefly™
Novadaq/Stryker Spy Fluorescence Imaging

- Spy Elite

SPY ELITE
FLUORESCENCE IMAGING SYSTEM

SPY Elite is the first and most advanced fluorescence imaging system that enables surgeons performing open procedures, such as breast and other reconstruction, gastrointestinal and cardiothoracic surgery, to visualize microvascular blood flow and perfusion in tissue intraoperatively.
Novadaq/Stryker Spy Fluorescence Imaging

- PINPOINT
Novadaq/Stryker Spy Fluorescence Imaging

• SPY-PHI
Novadaq/Stryker Spy Fluorescence Imaging

Real Time Fluorescence ICG angiography
Spy Fluorescence Imaging Procedure

• PINPOINT – 1ST ASSESSMENT
  – Utilizes endoscope
  – All room lights must be off
  – 3 ml of ICG injected intravenously followed by 10 ml of saline
  – 3 Modes:
    • Fluorescence
    • Spy
    • Color segmented fluorescence
Spy Fluorescence Imaging Procedure

- PINPOINT – 1st ASSESSMENT
Spy Fluorescence Imaging Procedure

• PINPOINT – 1ST ASSESSMENT
Spy Fluorescence Imaging Procedure

- PINPOINT – 1ST ASSESSMENT
Spy Fluorescence Imaging Procedure

- PINPOINT – 1ST ASSESSMENT
Spy Fluorescence Imaging Procedure

• PINPOINT – 1ST ASSESSMENT
Spy Fluorescence Imaging Procedure

- PINPOINT – 2ND ASSESSMENT
  - Evaluation of the uretero-intestinal anastomoses
  - 2nd dose of ICG given (3 ml)
  - For ileal conduits and Indiana pouch: EXTRACORPOREAL
  - For neobladders: INTRACORPOREAL
Spy Fluorescence Imaging Procedure

• PINPOINT – 2ND ASSESSMENT
Spy Fluorescence Imaging Procedure

- PINPOINT – 2ND ASSESSMENT
Spy Fluorescence Imaging Procedure

- PINPOINT – 2ND ASSESSMENT
Spy Fluorescence Imaging Procedure

- PINPOINT – 2ND ASSESSMENT
Spy Fluorescence Imaging Procedure

• PINPOINT – 2ND ASSESSMENT
Spy Fluorescence Imaging Procedure

- **SPY-PHI – 1st ASSESSMENT**
  - 2 ml of ICG
  - Room lights can stay on but should be directed away
Spy Fluorescence Imaging Procedure

- SPY-PHI – 1st ASSESSMENT
Spy Fluorescence Imaging Procedure

- **SPY-PHI – 1st ASSESSMENT**
Spy Fluorescence Imaging Procedure

- SPY-PHI – 1\textsuperscript{st} ASSESSMENT
Spy Fluorescence Imaging Procedure

- SPY-PHI – 2nd ASSESSMENT
  - 2ml ICG
  - Need to switch to PINPOINT if doing neobladder
Spy Fluorescence Imaging Procedure

- SPY-PHI – 2nd ASSESSMENT
Outcomes

- Retrospective comparison of 47 Consecutive Cases (93 using PINPOINT vs. 47 previous consecutive cases (93 ureters) without PINPOINT
  - 93 ureters in each group
  - Mean f/u: 12 months

<table>
<thead>
<tr>
<th></th>
<th>Non-PINPOINT (n=93)</th>
<th>PINPOINT (n=93)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age</td>
<td>74 (IQR 62-80)</td>
<td>69 (IQR 65-76)</td>
<td>0.3</td>
</tr>
<tr>
<td>Median body mass index (kg/m$^2$)</td>
<td>25.9 (IQR 24.6-28.8)</td>
<td>24.7 (IQR 23.9-30.3)</td>
<td>0.2</td>
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<tr>
<td>Gender</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Female</td>
<td>18 (19.4%)</td>
<td>17 (18.3%)</td>
<td>0.9</td>
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<tr>
<td>Male</td>
<td>75 (80.7%)</td>
<td>76 (81.7%)</td>
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</tr>
<tr>
<td>Laterality of ureteroenteric anastomosis</td>
<td></td>
<td></td>
<td>1.0</td>
</tr>
<tr>
<td>Left</td>
<td>47 (50.5%)</td>
<td>47 (50.5%)</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>46 (49.5%)</td>
<td>46 (49.5%)</td>
<td></td>
</tr>
<tr>
<td>Diversion type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ileal conduit</td>
<td>56 (60.2%)</td>
<td>51 (54.8%)</td>
<td>0.2</td>
</tr>
<tr>
<td>Indiana pouch</td>
<td>5 (5.4%)</td>
<td>12 (12.9%)</td>
<td></td>
</tr>
<tr>
<td>Studer neobladder</td>
<td>32 (34.4%)</td>
<td>30 (32.3%)</td>
<td></td>
</tr>
</tbody>
</table>
Outcomes

• Retrospective comparison of 47 Consecutive Cases (93 using PINPOINT vs. 47 previous consecutive cases without PINPOINT
  – Follow up
    • 6 week ultrasound and CT q 6 months
    • If hydronephrosis seen:
      – Pouch/loopogram
      – Renal scan with Lasix Washout
    • If Obstruction
      – Nephrostomy tube → Open revision
Outcomes

• Retrospective comparison of 47 Consecutive Cases (93 using PINPOINT vs. 47 previous consecutive cases without PINPOINT
  – 0% (0/93) vs. 7.5% (7/93) ureteroenteric strictures: PINPOINT vs. no PINPOINT
  – Perfusion not identified to the clip v. Perfusion to the clip: 3.8 cm ureter excised v. 2.2 cm ureter excised (p < 0.0001)
  – No complications attributable to ICG
Cost of Novadaq/Stryker Spy Technology

• PINPOINT/SPY-PHI Tower: $150-175K
• ICG: $125/case
• SPY-PHI Drape/ICG: $495/case
Cost of Novadaq/Stryker Spy Technology

Key Applications – U.S. Market

<table>
<thead>
<tr>
<th>Applications</th>
<th>Existing Procedures</th>
<th>Annual Opportunity</th>
<th>Emerging Procedures*</th>
<th>Annual Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer and Reconstructive Surgeries</td>
<td>Breast Reconstruction</td>
<td>100,000</td>
<td>GYN Onc</td>
<td>200,000</td>
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<tr>
<td></td>
<td>Head and Neck Reconstruction</td>
<td>150,000</td>
<td>Breast Surgery</td>
<td>250,000</td>
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<tr>
<td></td>
<td>Gastrointestinal Surgery</td>
<td>450,000</td>
<td>Lymphedema</td>
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<td></td>
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<td>Melanoma</td>
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<td></td>
<td>Gastric Cancer</td>
<td>100,000</td>
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<tr>
<td>Non-Cancer Surgeries</td>
<td>Vascular Surgery</td>
<td>600,000+</td>
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<tr>
<td></td>
<td>Laparoscopic Cholecystectomy</td>
<td>900,000+</td>
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<td></td>
<td>Coronary Artery Bypass Surgery</td>
<td>350,000</td>
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<tr>
<td>Wound Care</td>
<td>Diabetic, Arterial and Venous</td>
<td>600,000</td>
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<td></td>
<td>Stasis Ulcers</td>
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</tbody>
</table>

*not yet cleared for market by the U.S. FDA
Other Uses for Spy Technology

- Transureteroureterostomy
Other Uses for Spy Technology

• Transureteroureterostomy
Other Uses for Spy Technology

• Lacerated psoas hitched ureter
Other Uses for Spy Technology

• Lacerated psoas hitched ureter
Other Uses for Spy Technology

- Lacerated psoas-hitched ureter
Conclusions

• Novadaq/Stryker Spy technology allows surgeons to evaluate viability of delicate urinary tract tissue in a objective and quantifiable fashion.