Use of Fluorescence Angiography and Imaging to “See More” during Bariatric Surgery

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Financial Disclosures

• Medtronic
• Novadaq
• Stryker
• W.L. Gore
• Teleflex
Multiple clinical applications

- Breast Reconstruction
- Tumor Margins in Robotic PN
- Ischemic Bowel
- Wound Care/Extremity
- Lymph Node * in Prostate Surgery
- Coronary Artery Bypass Graft

* Application not yet cleared by the FDA
How does it work and what do I need?
Function

- VASCULAR PERFUSION
- BILIARY MAPPING
- LYMPHATIC MAPPING
- ENHANCING LED LIGHT SOURCE
Once you have the laparoscopic system, then the cost of using this technology is just the cost of the ICG dye (~$100).
Indocyanine Green (ICG)

- Been around > 50 years
- T/2 = 3 min
- Binds to albumin / hepatic clearance
- Non-toxic
- May cause allergic reaction to patients allergic to iodide (but anaphylaxis reaction rare)

- Comes in 25mg aliquots. Typically reconstituted in 10ml normal saline for final concentration of 2.5mg/ml.
Fluorescence Imaging Technology in Action

SLIDE COURTESY OF Novadaq
How does ICG get around?

- **Injected IV.**
- **Circulates in blood vessels (immediately).**
- **Taken up by the liver (excreted into bile).**
How does ICG get around?

Goes into the gallbladder (as long as cystic duct is OPEN) ***
Current Status of this Technology
Status of fluorescence imaging technology in surgery in 2015?

- Reconstructive surgery (reduce wound complications)
- Colorectal surgery after low, left-sided resections (reduce leaks)
- Esophageal surgery after esophagectomy (reduce leaks)
- Gallbladder surgery???
- Cancer surgery???
Status of fluorescence imaging technology in surgery in 2016?

• Reconstructive surgery (reduce wound complications)

• Colorectal surgery after low, left-sided resections (reduce leaks)

• Esophageal surgery after esophagectomy (reduce leaks)

• Gallbladder surgery (accepted by SAGES and studies underway)

• Bariatric surgery (Duke ➔ ASMBS)

• Cancer surgery (sentinel lymph node, tumor localization)
Fluorescent assessment of proximal margin and anastomosis during left-sided colectomy

View of anastomosis (transanal view)

View of proximal margin (laparoscopic view)
PILLAR II Trial

- **Perfusion Assessment in Laparoscopic Left-sided / Anterior Resection**
- Prospective, multi-center (11), open label study
- N = 139 patients
- Mean level of anastomosis 10 ± 4 cm
- Splenic flexure mobilization 81%
- High IMA ligation 62%

- PINPOINT changed surgical plans in 8% (11 pts) with majority at transection of proximal margin (7%)
- Anastomotic leak rate 1.4% (2 pts) ➔ *none occurred* in the 11 patients who had margins revised due to PINPOINT
## Subjects with a Change Based on PINPOINT

<table>
<thead>
<tr>
<th>Subject Number</th>
<th>Location</th>
<th>Distance from Planned Transection</th>
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<td>0205</td>
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PILLAR III Trial

- **Perfusion Assessment in Laparoscopic Left-sided / Anterior Resection**

- RANDOMIZED, multi-center study

- GOAL ENROLLMENT: 400 – 800 patients
Why is this important for bariatric surgery?
Bariatric surgery in the U.S.

- 220,000 surgical procedures per year (* only 1% of the patient population that qualifies for surgery are getting surgery)

- Obesity is an epidemic that is steadily increasing

- Complication and death are substantially lower than other GI surgery, but they have to be. Because…
  - elective surgery
  - zero tolerance for complication or death
The Math

- Low anterior resection
  6% leak rate of 40,000 cases ➔ 2400 leaks

- Bariatric surgery
  1% leak rate of 220,000 cases ➔ 2200 leaks

- Even though leak rate is lower in bariatric surgery, due to the case volume, the impact is similar

- And obesity epidemic is on faster growth trajectory than rectal cancer
Roux-en-Y gastric bypass and Sleeve gastrectomy

- Similar complication profiles

<table>
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<th>Bypass</th>
<th>Sleeve</th>
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<tbody>
<tr>
<td>Leak</td>
<td>1-3%</td>
<td>1-3%</td>
</tr>
<tr>
<td>Stricture</td>
<td>1-15%</td>
<td>1-2%</td>
</tr>
<tr>
<td>Marginal ulcer</td>
<td>3-5%</td>
<td>N/A</td>
</tr>
</tbody>
</table>

5–23%  
2–5%

7 – 28% complication rate associated with ischemia at the time of surgery
Original article

Technical factors associated with anastomotic leak after Roux–en–Y gastric bypass

Mark D. Smith, M.B.Ch.B. a,⁎, Abidemi Adeniji, Ph.D. b, Abdus S. Wahed, Ph.D. c, Emma Patterson, M.D. a, William Chapman, M.D. d, Anita P. Courcoulas, M.D. M.P.H. F.A.C.S. e, Gregory Dakin, M.D. F.A.C.S. f, David Flum, M.D. M.P.H. F.A.C.S. g, Carol McCloskey, M.D. e, James E. Mitchell, M.D. h, Alfons Pomp, M.D. F.A.C.S. i, Mylene Staten, M.D. i, Bruce Wolfe, M.D. F.A.C.S. j

Background: Anastomotic leak is one of the most serious complications after Roux-en-Y gastric bypass (RYGB). Our objective was to examine the relationship between technical factors and incidence of clinically relevant anastomotic leak after RYGB in longitudinal assessment of bariatric surgery (LABS). The setting of the study was 11 bariatric centers in the United States, university, and private practice.

Methods: Patient characteristics, technical factors of surgery, and postoperative outcomes were assessed by trained researchers using standardized protocols. Correlation of surgical factors of patients undergoing RYGB (n = 4444) with the incidence of postoperative anastomotic leak was assessed by univariate χ² analysis.

Results: Forty-four participants (1.0%, 95% CI .7%–1.3%) experienced a clinically relevant anastomotic leak. Of these, 39 (89%) underwent abdominal reoperation and 3 (7%) died. Technical factors associated with anastomotic leak were open surgery (P < .0001), revision surgery (P < .0001), and use of an abdominal drain (P = .02). Provocative leak testing, method of gastrojejunostomy, and use of fibrin sealant were not associated with anastomotic leak.

Conclusions: Anastomotic leak after RYGB was rare (1.0%). Most cases required reoperation; however, the majority (93%) recovered from this event. Open surgery, revision surgery, and routine drain placement were associated with increased leak rate. Some of these findings may be due to differences in preoperative patient risk. (Surg Obes Relat Dis 2015;11:313–320.) © 2015 American Society for Metabolic and Bariatric Surgery. Published by Elsevier Inc. All rights reserved.
Majority of leaks occur after negative leak test

So, these other leaks are likely due to:
- Insufficient blood supply
- Late staple line failure

*Some were tested by multiple methods
**1 was tested positive by both air and endoscopy
***This person was tested positive for anastomotic leak by air
Why is this important?

- Good for patient care / safety
- “But how much will this cost me?”
- Right now, complications don’t cost the hospital much
- In the near future, with bundled payment model, complications will cost the hospital (eat into their bottom line)
“I don’t need this to tell me if something is ischemic, I can SEE when a tissue is not going to survive…”

- THE CRITIC
In-vivo model of eye-balling “ischemia” vs using fluorescence-based imaging (VIDEO)
TIME POINT ZERO
TIME POINT = 2 seconds
TIME POINT = 10-12 seconds
TIME POINT = 20-22 seconds

Non-viable Ischemic zone not visible to naked eye
So, where can this technology be helpful in bariatric surgery?
Revisional bariatric surgery

• Revisional bariatric cases are on the rise

• **Higher complication rate than primary procedures (at least 2x higher)**

• FIT is even more important for revisional than primary procedures, BUT…

• You need to establish the norms in primary procedures so that you can interpret the data obtained from revisional cases
#1 To check for vascular perfusion of the conduits PRIOR to (and AFTER) an anastomosis.
• If abnormal, *prior* to anastomosis... consider resection

• If abnormal, *after* the anastomosis... consider redo and/or careful surveillance
#2 Aid in dissection of potential watershed area near GE junction -and- check staple line perfusion.
I noticed three different pattern of perfusion to the proximal GE junction area:

1) L-side dominant (L inferior phrenic artery)
2) R-side dominant (R inferior phrenic artery)
3) R-side dominant (accessory hepatic artery?)
LEFT inferior phrenic artery
Dominant L inferior phrenic artery
Dominant R inferior phrenic artery
Dominant accessory *hepatic* artery
Accessory left hepatic artery (VIDEO)

Example significant blood flow and flowing TO STOMACH
Post-sleeve exam of blood supply to stomach
#3 Aid in performing a precise, producible sleeve gastrectomy.
Sleeve resection with “PINPOINT” precision using GastriSail™

Not hugging the Bougie, but leaving a little space

After the Sail is passed back down
And the suction is on
Avoiding potential complication (narrowing GE junction) by being able visualize the esophagus
#4 Check status of gallbladder.
Concurrent cholecystectomy at time of bariatric surgery

- Not routinely done for many reasons (i.e. may not be necessary, reimbursement, safety, etc)

- But post-op gallbladder problems is common after bariatric surgery (20-30% in our series)

- CURRENT APPROACH: REACTIVE

- Can we identify the abnormal gallbladders before they become problematic? (PROACTIVE)
Gallbladder check (30 min after ICG injection)

NORMAL

ABNORMAL
Lap repair of perforated duodenal ulcer with Graham’s patch
Lap inguinal hernia repair

Checking testicular artery and seminiferous vessels
“The value of this technology is not in ONE procedure or even in ONE specialty... the true value lies in the impact it will have on the entire field of surgery as whole.”
Summary of its use during bariatric surgery

- Check for vascular perfusion of conduits before and after anastomosis
- Check variant blood supply to GE junction
- Check for staple line perfusion (or tissue near it)
- Better visualization of LED lighted devices (EGD and lighted bougies)
- Check for gallbladder disease at time of surgery
“It’s nice to have additional information, but how often does it impact what I do?”
Future direction

• Clinical studies are needed to measure outcome
  - Reduce complications (or help identify Cx earlier?)
  - Better weight loss due to better technique?
  - Save cost to the hospital?
  - ???
Which one of these statements is FALSE regarding fluorescence imaging technology (FIT) and bariatric surgery?

A) In addition to looking at tissue perfusion, FIT can also be used to enhance visualization of LED light sources and check cystic duct patency.

B) The use of FIT has been shown in clinical studies to decrease the incidence of leak rates in gastric bypass procedure.

C) Ischemic complications after GI anastomosis include leaks, strictures, and ulcerations.