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Assessment of bowel end perfusion after mesenteric division: eye *versus* SPY

Joseph E. Bornstein, MD, MBA,[a] *Jordan A. Munger, BS,*[a] *Juan R. Deliz, BA,*[a] *Alex Mui, BS,*[a] *Cheng S. Chen, PhD,*[b] *Sanghyun Kim, MD,*[a] *Sergey Khaitov, MD,*[a] *David B. Chessin, MD,*[a] *T. Bruce Ferguson, MD,*[b] *and Joel J. Bauer, MD*[a,*]

[a] *Department of Surgery, Icahn School of Medicine at Mount Sinai, New York, New York*
[b] *East Carolina Heart Institute Department of CV Sciences, Brody School of Medicine at East Carolina University, Greenville, North Carolina*

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ABSTRACT

Background: Anastomotic complications related to tissue ischemia cause morbidity in gastrointestinal (GI) surgery. Surgeons' standard practice to predict bowel perfusion is inspection of mesenteric perfusion before anastomosing bowel ends. Augmenting this assessment with fluorescent imaging is under study. A standardized system to evaluate this imaging has not yet been developed. This study compared the surgeon's intraoperative assessment to a novel GI-specific imaging analysis method.

Materials and methods: Forty-nine consecutive patients undergoing open or laparoscopic-assisted bowel resections were enrolled. After mesenteric division, the surgeon marked the site for bowel transection. Near-infrared fluorescence imaging was performed on the marked bowel ends. Imaging analysis identified theoretical transection sites based on the quantification of arterial and microvascular inflow (Perfusion) and venous outflow (Timing). The primary outcome was the measured disparity between the site marked by the surgeon using current standard of care parameters and the imaging-determined site. No clinical outcomes were assessed.

Results: Seventy-two bowel end segments from 46 patients were analyzed. Disparity was found in 11 of 72 (15%) bowel end segments. In five (7%), the disparity was due to either Perfusion or Timing (single), and in six (8%), due to both Perfusion and Timing (combined). In the single disparity group, the median disparity distance was 2.0 cm by Perfusion and 4.0 cm by Timing, and in the combined group, 3.8 cm by Perfusion and 3.5 cm by Timing. Disparity (either single or combined) was in 25% of colon and 11.5% of small bowel ($P = NS$). Combined and single disparity had equivalent lengths of disparity distance ($P = NS$).

Conclusions: Imaging coupled with this GI-specific analysis provides objective, real-time, and interpretable data of intramural blood supply. A 15% disparity rate from current clinical practice was observed.

* *Corresponding author.* Icahn School of Medicine at Mount Sinai, Department of Surgery, Laparoscopic Surgical Center of New York, 1010 5th Avenue, New York, NY 10028. Tel.: (646) 952 9898; fax: (212) 650 9981.
E-mail address: jjb.msh@gmail.com (J.J. Bauer).
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Introduction

Ischemia of the bowel tissue at anastomotic sites continues to contribute to the morbidity of gastrointestinal (GI) surgery. Macro- or micro-vascular ischemia can lead to either early or delayed complications of anastomotic dehiscence and stricture. The reported rate of anastomotic dehiscence in colorectal surgery remains between 3% and 7% for all bowel types, resulting in significant patient morbidity, mortality, unplanned hospital re-admissions, and significant health care costs.[1-4]

For decades, colorectal surgeons' intraoperative clinical assessment has been the standard for evaluation of bowel perfusion and ischemia before creating an anastomosis or stoma. This assessment relies on qualitative factors such as the color of the serosa, peristalsis of the bowel, palpation or Doppler flow evaluation of a mesenteric pulse, or bleeding from cut edges of the bowel. None of these current techniques are objective or directly assess GI intramural perfusion.

The SPY Elite (SPY) (Novadaq Technologies, Toronto, CA) system is a mobile imaging technology for intraoperative near infrared perfusion assessment of GI intramural tissue in real time. Experience with this technology has been predominant for qualitative assessment of tissue flap perfusion.[5-12] Further experience with this technology in off-pump coronary bypass grafting led to the development of the Comprehensive Angiographic and Perfusion Analysis (CAPA) platform to quantify flow and tissue perfusion.[13,14]

The application of this technology in colorectal surgery represents an opportunity to add real-time quantification of blood flow and perfusion in bowel tissues to the existing anatomic information already used by surgeons for decision-making. Mesenteric division can impact both arterial and venous blood flow at a site of bowel transection, and can subsequently affect GI intramural perfusion at the site of anastomosis. Bowel end segments with insufficient arterial and microvascular inflow (Perfusion) or venous outflow congestion (Timing) may potentially lead to bowel tissue ischemia at the site of the anastomosis. These Perfusion and Timing data are not discernible by visual assessment alone. Without this knowledge, a surgeon may anastomose bowel ends with deficits in tissue blood supply, which can lead to tissue ischemia and anastomotic dehiscence.

Although there have been studies with the SPY technology in a GI setting,[15-17] to date none have evaluated the SPY technology with the CAPA platform to assess the arterial and microvascular perfusion and venous outflow timing parameters in bowel ends after mesenteric division compared it with standard clinical assessment by the operating surgeon. The primary outcome was disparity between the surgeon-determined assessment *versus* the imaging-determined assessment of blood flow and perfusion. This blinded pilot study was not powered or designed to evaluate surgical complications associated with Perfusion or Timing abnormalities, and no clinical outcomes data were considered.

Materials and Methods

Setting

This study was performed on 49 consecutive patients undergoing open or laparoscopic-assisted small and large bowel resections at the Mount Sinai Hospital, the principal teaching hospital of the Icahn School of Medicine in New York City. The study was approved by the Institutional Review Board at the Mount Sinai Hospital and each subject provided informed consent. The SPY kit and all disposables, including indocyanine green dye (ICG), were provided at no cost by the LifeCell Corporation (Branchburg, NJ). Neither LifeCell Corporation nor Novadaq Technologies, Inc (Toronto, CA), the maker of the SPY technology, had influence over or took part in the design or analysis of this study.

Operative technique

In all operations, the procedure followed a standardized sequence of (1) mesenteric division followed by a 5 min surgical pause; (2) surgeon visual assessment and documentation of the planned transection site with a radio-opaque marker (clamp or forceps); (3) Near-infrared imaging assessment; and (4) bowel transection and completion of the operative procedure. Because mesenteric division includes ligation of the mesenteric arteries and veins to the bowel ends, potentially disrupting GI intramural blood supply, care was taken to ensure complete mesenteric division before perfusion assessment. The imaging protocol described below was then completed by an independent operator. The surgeon proceeded with the operation as planned without seeing or being influenced by any imaging data or imaging analyses.

SPY image data acquisition protocol

The imaging protocol began with positioning the SPY Elite imaging system above the bowel. ICG dye was injected in a peripheral venous access site. After 45-60 s of circulation through the cardiovascular system, the SPY system began recording video for another 68 s to account for patient differences in cardiovascular status, cardiac output, and blood circulation time. These patient-specific differences can influence imaging and data quality in the modified CAPA platform.

Modified CAPA of Perfusion and Timing

The modified CAPA platform used in this study does not alter or manipulate the raw digital imaging data. Rather, this platform analyzes the data according to physiologic parameters of flow and perfusion, and then presents a quantitative analysis in an image-based format for immediate interpretation. These analyses are based on individual pixel data.[13,14]

Prior work with SPY and the CAPA platform documented that the three phases of blood flow can be observed by a dose-response curve of increasing fluorescence intensity to a maximum followed by a washout period with non–ICG-containing blood.[13,14] Similar to previous work with the CAPA