

# Perfusion Assessment in Laparoscopic Left Sided/ Anterior Resection (PILLAR) II: A Multi-Institutional Study

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## ABSTRACT:

**Objective:** Our primary objective was to demonstrate the utility and feasibility of the intra-operative assessment of colon and rectal perfusion using fluorescence angiography (FA) during left-sided colectomies/anterior resections (LC/LAR).

**Background:** Anastomotic leak (AL) following colorectal resection increases morbidity, mortality and, in cancer cases, recurrence rates. Perfusion of a colorectal anastomosis is essential and inadequate perfusion may contribute to AL. The PINPOINT® Endoscopic Fluorescence Imaging System [PINPOINT®] (Novadaq Technologies Inc., Ontario, Canada) allows for intra-operative assessment of anastomotic perfusion.

**Methods:** This is a prospective, multicenter, open label, clinical study that assessed the feasibility and utility of FA for intra-operative perfusion assessment in patients undergoing LC/LAR in the elective setting at 11 centers in the United States.

**Results:** There were 147 patients enrolled, of whom 139 were eligible for final analysis. Diverticulitis (44%), rectal cancer (25%) and colon cancer (21%) were the most prevalent pre-operative diagnoses. The mean level of anastomosis was 10±4cm from the anal verge. Splenic flexure mobilization was performed in 81% and high inferior mesenteric artery ligation in 61.9% of patients. There was a 99% successful rate of imaging. FA changed surgical plans in 11 (8%) patients, with the majority of changes occurring at time of transection of proximal margin (7%). Overall morbidity rates were 17% with 12% associated with the surgical procedure and 1.4% recorded as severe in nature. AL rate was 1.4% (N=2). There were no anastomotic leaks in the 11 patients who had a change in surgical plan based on intra-operative perfusion assessment.

**Conclusions:** The PINPOINT system is a safe and feasible tool for intra-operative assessment of tissue perfusion during colorectal resection and it may lead to a decreased incidence of AL.

## KEY POINTS:

1. This was a prospective, multi-center feasibility study analysing 139 patients who underwent LAR (between 5 and 15cm).
  - a. < 8cm = 36
  - b. 8-9cm = 16
  - c. > 10cm = 87
2. For the initial "baseline image" assessment, the optimal point of transection was marked by the surgeon, typically with a clip, under white/visible light prior to imaging with PINPOINT®.
  - a. Perfusion of the colon was visualized and assessed via fluorescence angiography, and the line of demarcation between perfused and non-perfused tissue was noted and compared to the initial planned transection point.
3. Following the air leak test, perfusion of the completed anastomosis was assessed with fluorescence angiography.
  - a. The PINPOINT® endoscope was inserted into the anus using a disposable introducer and advanced to the staple line of the anastomosis under visible/white light guidance.

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4. Fluorescence angiography changed the surgical plan in 11 (7.9%) patients.
  - a. This included revision of the point of proximal colon transection as indicated by perfusion assessment in 9 patients (6.5%);
  - b. takedown and revision of anastomosis after transanal perfusion assessment in one patient;
  - c. and confirmation of viability of anastomosis where there was concern based on white light imaging in one patient.
5. There were no anastomotic leaks in the 11 patients in whom a change in the surgical plan occurred based on fluorescence angiography findings.
6. There were 2 (1.4%) anastomotic leaks reported, both diagnosed clinically and confirmed via radiological findings.
  - a. The anastomotic leak rate (1.4%) in this trial was lower than the reported rates in multiple recent large prospective randomized and cohort comparison studies in the literature.
7. This study demonstrates that the use of this technology may result in revisions of bowel transection point and can provide confirmation of a well-perfused anastomosis.
  - a. The alteration to a more well-perfused segment of bowel may in fact decrease the rates of anastomotic leak and thereby improve patient outcomes.

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