Using Outcomes Data to Justify Instituting New Technology: a Single Institution's Experience

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ABSTRACT:

BACKGROUND: The PILLAR II trial confirmed PINPOINT is safe and resulted in no anastomotic leaks as a result of PINPOINT's ability to intraoperatively assess tissue perfusion during colorectal resection. It is unknown if the cost savings associated with the reduction in anastomotic complications offset the cost of investing in PINPOINT.

METHODS: A retrospective analysis of 347 patients undergoing colectomy with primary anastomosis from January 2015 to April 2016 was performed. Clinical outcomes and direct hospital costs associated with the use of fluorescence imaging was assessed to determine if the decreased costs from averted anastomotic complications justified the upfront costs of purchasing PINPOINT.

RESULTS: Patients assessed with PINPOINT experienced a 0.84% (2/238 patients) anastomotic failure rate. Patients not assessed with PINPOINT experienced a 5.5% (6/109 patients) anastomotic failure rate. 4.6% (11/238) of patients in the PINPOINT group had a change in resection margin, and none of these patients experienced an anastomotic failure.

CONCLUSIONS: This study validates the findings of the PILLAR II trial and confirm the use of PINPOINT resulted in decreased costs as a result of reduction in anastomotic failures. The initial expense of PINPOINT was offset after 143 cases.

KEY POINTS:

1. This retrospective study validated PILLAR II trial results which state PINPOINT is safe and feasible to use as an intraoperative assessment tool during colorectal resection and may result in the decreased incidence of anastomotic leaks.

    a. PILLAR II results show PINPOINT contributed to a change in surgical plan related to planned anastomosis in 11 (8%) patients.

    b. The overall anastomotic leak rate in the PILLAR II study was 1.4% (N=2) with no leaks in the 11 patients who had a change in surgical plan based on the intraoperative fluorescence imaging assessment with PINPOINT.

2. Clinical outcomes of this study include postoperative (30 days from the procedure date) anastomotic outcomes, such as leaks and strictures.

    a. Leaks or disruption of the anastomosis was confirmed by radiographic imaging or by surgical intervention.

    b. Strictures were defined as anastomotic narrowing to ≤11 mm (identified endoscopically or on radiographic imaging) or narrowing that required endoscopic dilatation due to obstructive symptoms.

3. The intraoperative outcomes of this study include a change in resection margin, revision of anastomosis, and additional resection margin.

    a. Change in resection margin refers to the number of patients identified by PINPOINT to have insufficient perfusion of the bowel which was to be used for the anastomosis resulting in further resection.

    b. Revision on anastomosis refers to the number of patients who were identified by PINPOINT to have insufficient perfusion of the bowel after the anastomosis was completed resulting in further resection.

    c. Additional resection margin is the amount of intestine resected to obtain bowel margins, as assessed by PINPOINT, with appropriate perfusion to perform a reliable anastomosis.

4. Direct costs included supply costs, staff salaries, and operating room and hospital room charges as reported by Overlook Medical Center (OMC).

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5. Results show the use of PINPOINT Fluorescence Imaging System in laparoscopic surgery beginning in 2015 resulted in significant reductions in postoperative complications.

   a. There were no significant differences in abdominal abscess, wound infection, and ileus between the PINPOINT and non-PINPOINT groups.

   b. There was a significantly higher incidence of anastomotic complications in the non-PINPOINT user than in the PINPOINT user, specifically anastomotic leakage (3.7 vs. 0.84%, p=0.03) and anastomotic leakage and strictures in non-PINPOINT users (5.5 vs. 0.84%, p=0.004).

   c. The use of PINPOINT resulted in a change in resection margin in 4.6% (11/238) of the patients and resulted in a revision of an already completed anastomosis in 0.4%(1/238) of the patients. None of the patients who underwent an anastomotic revision or additional resection prior to anastomosis experienced a postoperative anastomotic leak or stricture.

6. Using PINPOINT resulted in cost savings during the study period.

   a. Postoperative costs for non-PINPOINT users were 9.1% more than the average postoperative costs associated with PINPOINT users ($16,086 vs. $14,745).

   b. With the cost of the ICG dye factored in this results in an average cost savings of $1,216 per case or to $121,600 in average cost savings for 100 cases.

7. Patients who underwent PINPOINT imaging during their surgery experienced significantly lower anastomotic failure rates and cost less to treat compared to those who were not treated with PINPOINT.

8. The cost of the equipment and the cost of the disposables to perform PINPOINT intraoperative imaging are offset by the improved quality and subsequent cost savings associated with the use of the PINPOINT system after just 143 colon resections.

9. Limitations of this study include the fact that strictures could not be adequately tracked as a result of being identified after discharge and could only be identified if patients were readmitted to OMC. This is also a retrospective study of a single institution; so selection bias may be present, and the results of this study may not be generalizable to other facilities.

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