Title: Disposable Stapler Use in Bowel Surgery: Incidence of Adverse Events

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Context and policy issues:

The ability to perform a safe bowel resection and anastomosis is an essential part of the bowel surgery.¹ The ideal anastomosis is one which does not leak, does not obstruct, does not get infected, and facilitates restoration of normal bowel function within a few days of reconstruction.¹ In recent years, there has been a large shift towards the use of intestinal stapling devices.¹ They offer potential reduction in operative time and are associated with a faster learning curve compared to hand-sewn techniques.² Given the incidence of adverse events reported following the use of staplers in bowel surgery, policy makers are reviewing the overall effectiveness of this technique. This report will discuss the rates of adverse events that the stapling technique may cause to patients undergoing bowel surgery.

Research questions:

1. Is there evidence that there is an increased rate of infection with the use of a disposable stapler in bowel surgery patients?

2. What are the guidelines for use of the stapler in bowel surgery patients? What patient population should it be used in?

Methods:

A limited literature search was conducted on key health technology assessment resources, including PubMed, the Cochrane Library (Issue 4, 2007), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2002 and the present, and are limited to English language publications only. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, randomized control trials, and observational studies.

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Summary of findings:

A meta-analysis in 2002 included nine randomized controlled trials that compared stapled versus hand-sewn methods for colorectal anastomosis surgery in 1233 patients. It looked at complication-related mortality, anastomosis dehiscence (i.e., a premature bursting open or splitting along surgical suture line), stricture, hemorrhage, reoperation, infection of the operative wound, time to perform the anastomosis and length of hospitalization. No statistical difference was found between the stapling and the hand-sewn groups regarding mortality (0.6% and 0.3%, respectively), anastomosis dehiscence (13% and 13.4%), hemorrhage from the anastomotic site (3.1% and 5.4%), reoperation of the patients after anastomotic complications (4.1% and 7.6%), wound infection (4.3% and 5.9%), and length of hospital stay (average of 2 days). Statistically significant differences were found in terms of anastomotic stricture in favor of the hand-sewn technique (p= 0.00001, rates not reported) and in terms of anastomosis time duration, favoring the stapling technique (p = 0.005). There was no limitation noted in this systematic review. The same results were published as a Cochrane review in 2001.

Another meta-analysis in 2006 included 21 studies that compared hand-sewn versus stapled ileal pouch-anal anastomosis following proctocolectomy (i.e., surgical removal of the rectum and part or the entire colon). It looked at postoperative complications, and functional and physiologic outcomes of 4183 patients. There were no statistical significant differences in the incidence of postoperative complications between the stapled and the hand-sewn groups, such as anastomotic leak (5.2% and 8.8%, respectively), stricture (12.5% and 18.2%), pouch-related fistula (2.2% and 5.9%), infection (rates not reported) and mortality (total 2.4%). The review also suggested guidelines for performing hand-sewn or stapled ileal pouch-anal anastomosis. It was suggested that patients with a grossly inflamed mucosa of the distal rectum despite aggressive medical therapy may not be ideal candidates for a stapled procedure, as opposed to patients with no dysplasia in colon or rectum and no risk factors for mucosa inflammation. There was no notable limitation to this systematic review.

A prospective randomized study on hand-sewn versus stapled anastomoses for gastroduodenostomy after distal gastrectomy examined anastomotic complications in 187 patients with gastric cancer. The study found no statistically significant differences between the stapled and the hand-sewn groups in terms of suture leak (1.1% and 2.1%, respectively), anastomotic bleeding (1.1% and 1.1%), stenosis (4.3% and 6.3%), and reoperation rate (1.1% and 2.1%).

A prospective multicenter study examined hand-sewn versus stapled anastomosis in penetrating colon injuries requiring resection and anastomosis in 217 patients. There was no colon-related death and no statistically significant difference found between the stapled and the hand-sewn groups in terms of abdominal complications such as infection, anastomosis dehiscence, and anastomotic leak.

Another prospective randomized study on stapled versus hand-sewn anastomoses in 201 patients undergoing emergency intestinal surgery looked at operation times, and complication rates in the two groups. No statistically significant differences were found between the stapled and the hand-sewn groups regarding these outcomes, such as anastomotic leak (6.3% and 7.8%, respectively), abdominal sepsis (26.6% and 20.3%) and mortality (no death) even though the operation times in the stapled group were significantly shorter.

Stapled technique was also found as a safe technique for hemorrhoidectomy. The stapled hemorrhoidectomy technique was also found to be a safe alternative to the traditional open
diathermy hemorrhoidectomy in a prospective study on 41 patients in a community hospital setting. There were no intraoperative complications in either group. A trial including 100 patients who were randomly selected to receive either stapled hemorrhoidectomy or open hemorrhoidectomy (Milligan-Morgan technique) compared post-operative and long-term complications (48 months after surgery) between the two groups. The stapled group experienced significantly less pain than the hand-sewn group (mean number of analgesic tablets used per patient 2.60 versus 15.9) ($p<0.001$). No stenosis or prolapse was found at long-term follow up in either group. Stapled technique was also compared to close hemorrhoidectomy (Ferguson technique) in 50 patients who were randomized to receive either technique in a prospective study. The number of analgesic tablets taken during the first two weeks was $10\pm3.0$ for the staple group and $22\pm8.7$ for the hand-sewn group. There was no significant difference in major complications between the two groups.

**Conclusions and implications for decision making:**

Stapling technique was found to be a safe technique in bowel surgery. There was limited evidence on long-term complication rates of the technique. There were no statistically significant differences found between hand-sewn and stapling techniques in terms of complications. Personal preference, experience, and available resources will dictate the surgical technique used. Irrespective of whether one uses hand-sewn or stapling devices, attention to detail is paramount to achieving a satisfactory outcome. There was one guideline found that suggested that patients with grossly inflamed rectal mucosa may not be ideal candidates for a stapled procedure.

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