Reoperative Surgery: What Can We Learn from a Large Randomized Prospective Trial?

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ABSTRACT

Several recent large prospective trials and surveys of colon and rectal surgery patients have been conducted. Reviewing these studies can provide insight into current colorectal surgery practices.

KEYWORDS: Prospective trials, colon and rectal surgery practice

Objectives: Upon completion of this article, the reader should have a greater understanding of aspects of colorectal surgery practice.

Several recent large prospective trials and surveys of colon and rectal surgery patients have been conducted. Reviewing these studies can provide insight into current colorectal surgery practices.

METHODS

A PubMed search of large prospective trials or surveys of colorectal patients for the previous 5 years was performed. Studies that focused on one operative procedure such as restorative proctocolectomies or laparoscopy were eliminated. Each of the studies reviewed can provide a perspective on colorectal surgery practice, but each has limitations related to selection of patients and methods of data collection.

The Septrafilm[®] Outcome Study¹ was a large, prospective, randomized controlled trial that looked at the effect of an antiadhesive product (Septrafilm[®]) in preventing small bowel obstruction (SBO). Inclusion criteria included patients undergoing large bowel resection or adhesiolysis for SBO. Cancer patients were excluded. The study was conducted at 22 centers, and 83 surgeons were involved. Patients were randomly allocated to receive Septrafilm[®] to adhesiogenic areas in the abdomen or nothing (control) at the completion of

the study. Patients' demographics and intraoperative information provide an accurate summary or "snapshot" of the colorectal surgery practice at many of the busiest colorectal surgery centers. Patients were followed up for a mean of 3.5 years (range 2 to 5 years) to assess the safety and long-term clinical benefit of Septrafilm[®], specifically the incidence and types of subsequent bowel obstruction.

The Opening Time study² was a prospective consecutive case series from 11 colorectal surgeons at three referral centers (Ochsner Clinic, Washington University in St Louis, and Cleveland Clinic Florida). The study evaluated the differences in opening time between patients with and without previous abdominal operations. Opening time was defined to start at skin incision and end when the surgeon's usual abdominal retractor was placed.

The Adhesiotomy Study³ was a retrospective review of reoperative patients to evaluate risk factors for inadvertent enterotomy. Records of consecutive patients who underwent abdominal reoperation at which adhesions were divided at a large referral hospital in the Netherlands were reviewed for preoperative and perioperative data. The retrospective nature of the data collection limits its value.

The COST Study⁴ was a prospective randomized controlled noninferiority trial from 48 institutions of

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patients with adenocarcinoma of the colon to compare open or laparoscopy-assisted colectomy. Surgeons participating in the study had their laparoscopic techniques evaluated by videotape. Patients were followed up a median of 4.4 years to assess time to tumor recurrence. The study was limited to patients with cancer, those willing to participate in such a study, and those thought to be candidates for either a laparoscopic or open procedure.

The Care Survey Study⁵ was a prospective survey of postoperative care in the United States and Europe. Data from U.S. patients (39 hospitals) undergoing elective abdominal operations were used for this review article. Emergency operations as well as patients with inflammatory bowel disease or stoma were excluded. Details of perioperative care and postoperative recovery were recorded to assess practice patterns that might improve recovery and reduce complications. The retrospective data collection limits its accuracy.

PATIENTS' DEMOGRAPHICS

Patients' demographics from each of the selected studies are summarized in Table 1. In these studies, the mean

ages varied from 45 to 70 years with a range of 18 to 96 years. Female patients constituted 46 to 66% of patients and a large percentage of patients had previous abdominopelvic surgery (43 to 100%). The disease processes and operations performed varied with the inclusion and exclusion criteria of each study. Comorbid conditions were common.

OPERATIVE ASPECTS

The types of cases performed also vary with inclusion and exclusion criteria of the studies. Adhesions clearly represent a major problem. They add additional time, cost, and morbidity to operative cases.^{2,3} Previous studies have demonstrated that Seprafilm[®] is effective in reducing adhesions.⁶ Adhesions lengthen operations by increasing the time required to open an abdomen and the time required to divide the adhesions (Table 2). In the Opening Time study by Beck and colleagues, adhesions increased the opening time by an average of 16 minutes. Another study by Coleman and colleagues found a median increase in "incision time" of 5 minutes and an additional 15 minutes to divide adhesions if

Table 1 Patients' Demographics

Variable	Seprafilm [®] Outcome Study ¹	Opening Time Study ²	Adhesiotomy Study ³	COST Study ⁴ Laparotomy Laparoscopy		Care Survey ⁵ United States
Type of study	Prospective randomized	Prospective	Retrospective	Prospective randomized	Prospective randomized	Prospective survey
Number of patients	1701	198	270	428	428	232
Date entered	June 1998– November 2000	October– December 1998	July 1995– September 1997	August 1994– August 2001	August 1994– August 2001	September 2003– October 2004
Age, mean/ median (range)	45.5 years	58 years (18–91)	55 years (16–80)	69 year (29–94)	70 years (28–96)	56 years
Sex (% female)	51.9%	56%	66%	51%	49%	46%
BMI (kg/m ²) (mean + SD)	26.1 + 5.6	NS	22.6	NS	NS	NS
Prior abdominopelvic surgery	66.2%	55%	100%	46%	43%	45%
Number of previous operations (mean)	0.6	1 (0–6)	3.3 (1–17)	NS	NS	NS
History of diabetes	5.2%	NS	NS	NS	NS	NS
ASA class						
1 or 2	78%	NS	NS	86%	86%	82%
3 or 4	22%			14%	14%	
Diagnosis						
Inflammatory						
bowel disease	73%	NS	23%	0%	0%	0%
Diverticulosis	13%		7%	0%	0%	26%
Cancer	0%		19%	100%	100%	48%
Other	14%		51%	0%	0%	27%

ASA, American Society of Anesthesiologists; BMI, body mass index; NS, not specified.

Table 2 Operative Parameters

Variable	Seprafilm Outcome ¹	Opening Time Study ²	Adhesiotomy ³	COST Study ⁴		Care Survey ⁵ United States
				Laparotomy	Laparoscopy	
Duration of surgery	164 minutes + 72	NS	NS	95 minutes (27–435)	150 (35–450)	150 minutes
Blood loss	381 mL + 444	NS	NS	NS	NS	NS
Incision length		22 cm (8–45)	NS	18 cm (3–35)	6 cm (2–35)	NS
Procedures			NS			
Right colectomy	41%	29%		54%	54%	83%
Left, sigmoid colectomy	53%	36%		45%	45%	12%
IPAA, APR	6%	16%		0%	100%	0%
Other	0%	19%				5%
Laparoscopic		0%				19%

APR, abdominoperineal resection; IPAA, ileal pouch–anal anastomosis; NS, not specified.

patients had previous surgery.⁷ In the Seprafilm Outcome study, adhesiolysis added 25.2 minutes. If operating room time has an estimated cost of \$30 per minute, adhesions add \$480 to \$756 to each case.

Enterotomies are another major intraoperative consequence or complication of adhesions. They occur in 8 to 19% of patients with adhesions.^{3,8} In addition to lengthening operating room time and increasing the stress on the surgeon, enterotomies result in significantly more complications (leaks, fistulas, sepsis, etc.), higher use of intensive care units, and longer hospital stays.^{4,9}

As expected, incision length was greater in the open cases than in the laparoscopic cases, but there is wide variability and overlap. The open procedures averaged over 2 hours in duration, but as multiple studies have shown that open procedures are faster than laparoscopic cases. The incidence of cases that are performed with laparoscopic technique is difficult to document accurately. Most current estimates suggest that 15 to 20% of cases are laparoscopy assisted.

POSTOPERATIVE ASPECTS AND OUTCOMES

Several outcomes were evaluated in the reviewed articles (Table 3). The Seprafilm Outcome study demonstrated that Seprafilm[®] was safe with respect to abdominal abscess, pelvic abscess, and pulmonary embolism in patients undergoing abdominopelvic surgery.⁷ Foreign

body reaction was not reported for any patient. However, wrapping the suture or staple line of a fresh bowel anastomosis or enterotomy repair with Seprafilm[®] was discouraged, as the data suggest that this practice might increase the risk of sequelae associated with anastomotic leak.⁷ This study revealed a surprisingly low incidence of overall and adhesive SBO after intestinal resection and anastomosis (12%). There was no significant difference between treatment and control groups in the overall rate of SBO. However, Seprafilm[®] adhesion barrier did reduce adhesive SBO (1.8 versus 3.4%, $p < 0.05$) and was the only factor that predicted this outcome. The clinical relevance of this reduction along with the advantages and disadvantages of adhesive prevention products must be individually determined. Unfortunately, a single adhesion can cause an SBO and a gross reduction of adhesions does not eliminate that possibility. Patients who have a high likelihood of recurrence of disease requiring operation (e.g., Crohn's disease) or develop functional problems after major procedures (ileoanal pouch procedures) that require reoperation will benefit from the use of antiadhesive therapy for the previously mentioned reasons. Although minimally invasive procedures may produce less adhesions than traditional open cases, as discussed in other articles in this issue, patients undergoing laparoscopic procedures do produce adhesions and experience SBOs. Each surgeon must weigh the value of these advantages against the cost of the antiadhesive product.

Table 3 Outcome Measures

Variable	Seprafilm Outcome ¹	Opening Time Study ²	Adhesiotomy ³	COST Study ⁴		Care Survey ⁵ United States
				Laparotomy	Laparoscopy	
Morbidity		NS	38.5%			NS
Intraoperative	NS			2%	4%	
Postoperative	26.4%			19%	19%	
Mortality (30 day)	0.4%	NS	8.5%	1%	< 1%	NS
Enterotomy	4.7%	NS	19%			
Length of stay mean/median	9.95 days	NS	10.6 days (5–173)	6 days	5 days	7.0 days

NS, not specified.

Length of hospital stay is dependent on several factors. These include patient-related and cultural factors as well as postoperative management. The mean reported length of stay varied from 5 to 10 days in the reviewed studies, and a Medicare data review documented an average postoperative stay of 10 days. Perioperative care measures that have been shown to reduce postoperative stay include avoidance of nasogastric tubes and drains, early feeding and ambulation, pain management, and minimally invasive techniques.¹⁰⁻¹⁴ Many of these activities have been put together into "care paths" or "fast track" programs. The survey by Kehlet and Dahl suggests that few of these measures have yet gained widespread acceptance outside major training institutions.¹¹

Mortality was low in the mostly elective cases reviewed, but morbidity remains significant (20 to 38%). Morbidity is higher in reoperative surgery, and many of the articles in this issue address this aspect.

SUMMARY

Review of large series of colon and rectal surgery patients provides insight into current practice patterns. Colorectal surgeons operate on challenging patients with overall good results.

DISCLOSURE

The author of this article was the author of several articles reviewed and has been a consultant for Genzyme.

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