EDITORIAL

Laparoscopic Restorative Proctocolectomy: Does the National Surgical Quality Improvement Program Tell the Whole Story?

It is generally agreed on that patients recover more quickly after a laparoscopic colectomy than after an open colectomy. However, measuring the true clinical short-term and long-term benefits of laparoscopic colon resection is often difficult. Multiple prospective randomized trials have consistently demonstrated the short-term benefits of shorter length of stay and faster return of bowel function, and more recently, fewer complications associated with laparoscopic segmental colectomies.[1,2] Several observational studies have concluded that patients undergoing laparoscopic colon resections have a higher rate of independent living, fewer ventral hernias, and fewer adhesive bowel obstructions.[3,4] Yet, for a complex procedure such as restorative proctocolectomy, a significant benefit to the laparoscopic approach has not been clearly demonstrated.

The morbidity associated with an open proctocolectomy and IPAA has been reported to be as high at 60%.[5] The high morbidity rate is due to the complexity of the procedure, the physiologic state of a patient with colitis, and the impact of immunomodulating medicines. Therefore, surgeons readily applied minimally invasive techniques in attempts to improve outcomes and minimize morbidity. However, the literature has been unable to clearly demonstrate the short-term benefits of laparoscopy over the open procedure in this group of patients. A recently published Cochrane review of open vs laparoscopic restorative proctocolectomy examined 11 studies that included a total of 607 patients (41% laparoscopy).[6] There was no difference in the complication, reoperation, or readmission rates. There was an improvement in cosmesis with the laparoscopic approach, but quality-of-life measures were found to be equivalent. Return of bowel function and length of stay were the only parameters to be consistently improved in the laparoscopic patients. The available literature is limited by observational study designs, small sample sizes, and single institutional experiences. The most important aspects of clinical studies are the accurate and complete collection of data and an unbiased patient selection, which are limited or nonexistent in a retrospective study design. in addition, limited sample sizes and single-institutional studies may not have the statistical power to truly demonstrate the benefit of one approach over the other.

In this edition of *Diseases of the Colon & Rectum*, Fleming et al[7] makes a very strong case that the laparoscopic approach leads to a significant reduction in minor and major postoperative complications. They reviewed the American College of Surgeons' National Surgical Quality Improvement Program (NSQIP) database for open and laparoscopic restorative proctocolectomy and identified 676 patients (50.1% were laparoscopic). Multivariate analysis demonstrated that the open approach, diagnosis of ulcerative colitis (vs familial adenomatous polyposis), intraoperative transfusion, and cardiac disease were independently associated with a higher risk of complications and the open approach, and the laparoscopic approach was the only factor associated with a decrease in minor complications. The strengths of this study are the sample size and the quality of the data points captured by the NSQIP database. In brief, the NSQIP collects 136 preoperative, intraoperative, and 30-day postoperative variables to quantify 30-day risk-adjusted surgical outcomes. This is a prospective, peer-controlled, and validated database that successfully captures 95% of the data points. The major limitations of the NSQIP database as a source of clinical outcomes data are the fact that hospital participation is voluntary and that only 20% of the eligible cases are randomly entered into the database. Therefore, the captured data may not tell the whole story. This can manifest itself in several areas within this study. First, it may introduce selection bias. Given that only 20% of general surgery cases with eligible Current Procedural Terminology codes are selected for the database, it is impossible to know the true denominator for open and laparoscopic restorative

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proctocolectomies. Also, there is the potential for hidden selection bias that will not be captured by a database. There are factors not in NSQIP that are impossible to identify (body habitus, prior abdominal surgery, surgeon preference), which impact a surgeon's decision to perform the procedure laparoscopically or open. Second, the data that are made available for analysis are not hierarchical. The researcher does not know from which institutions the data came. They do not know who the surgeons are: are they colorectal trained, do they perform pouch procedures laparoscopically, what is their criteria for selecting a particular approach, and what is the pouch volume of the surgeon. Therefore, a surgeon's experience and skill sets can not be controlled. Finally, the database does not capture conversion data because conversion does not have a Current Procedural Terminology code. Therefore, the conversion rate and clinical impact of conversion are unknown. Statistical modeling can be performed to help minimize many of these shortcomings.

The study by Fleming et al does well to control for many of the inherent limitations of observational studies using large-scale databases. I am a firm believer that laparoscopy does provide significant benefit to patients so I agree with their findings. However, because NSQIP data are being mined more and more frequently to publish outcomes data, the reader must be aware of its limitations and realize that it may not be telling the entire story.

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