The Vermont Colorectal Cancer Project

Self-portrait

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Hypothesis: A prospective statewide quality assessment and improvement project requiring active participation and case entry by surgeons is feasible provided that confidentiality and peer review protection are provided.

Design: Inception cohort.

Setting: Acute-care hospitals in Vermont.

Patients: Consecutive series of 364 patients undergoing elective surgery for colorectal cancer between April 1, 1999, and March 31, 2001, who were prospectively entered into a database created by the Vermont Chapter of the American College of Surgeons under peer review protection from the Vermont Program for Quality Health Care.

Intervention: Surgery for invasive colorectal cancer.

Main Outcome Measures: Case entry compliance, surgical complications, length of stay, demographics, cancer-specific characteristics, and use of adjuvant therapy.

Results: The calculated case entry compliance rate was 78%. There were 7 deaths (2%) and 45 major complications in 39 patients (12.3%). All patients were offered referral for adjuvant therapy when appropriate based on National Institutes of Health Consensus Conference standards. Mean age was 68.7 years, and 52% of cancers occurred in women. The most common site of cancer was the right colon (36.6% of patients), and only 47.9% of malignancies were in the rectum or sigmoid. Eighty-two percent of patients had symptoms on presentation.

Conclusions: Elective colorectal cancer surgery in Vermont is reasonably safe, and adherence to national standards for the use of adjuvant therapy is outstanding. Surgeons will provide outcome data if confidentiality and peer review protection are provided. The predominance of right-sided lesions and the low incidence of asymptomatic detection have significant implications for screening efforts in Vermont.

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Colorectal cancer is the second most common cause of cancer-related mortality in the United States1 and in Vermont.2 Colon resections for cancer are performed by many different surgeons in most hospitals in the United States,3 including all acute-care hospitals in Vermont. Considerable variation in outcome measures have been reported, suggesting improvement in high-volume hospitals4,5 or in the hands of specialty-trained surgeons.6,7 However, these studies4-7 are typically retrospective in nature, are not always population based, and may be subject to considerable reporting bias.

The purpose of this study was to assess the feasibility of performing a quality study of the surgical management of colorectal cancer in Vermont using a surgeon-initiated, prospective database. A secondary aim was to assess the implications of cancer demographics for colorectal cancer screening in a defined population.
MATERIALS AND METHODS

The project was conceived and implemented by the Vermont Chapter of the American College of Surgeons in conjunction with the Vermont Program for Quality Health Care. Input and participation were requested from all surgeons who operate on Vermont residents with colorectal cancer. An initial data form to be filled out by the operating surgeon at the time of the index procedure included patient demographics, tumor location, procedure performed, method of detection (ie, symptomatic vs screening), American Society of Anesthesiologists (ASA) classification, length of surgery, and need for blood transfusion. Only patients undergoing elective resection were included in the study. Patients presenting emergently with overt large-bowel obstruction, hemorrhage, or perforation were excluded to provide for a homogeneous cohort.

Approximately 30 days after receipt of the initial data, a follow-up form was sent requesting information on length of hospital stay, complications, TNM cancer stage, whether oncology consultation was requested, and whether adjuvant therapy was administered. A copy of the pathology report was also returned with the second data form.

All data were submitted voluntarily under the peer review protection of the Vermont Program for Quality Health Care. A single colon and rectal surgeon not involved in this study (S.B.L.) reviewed all of the data forms and pathology reports to ensure standardization of the data end points. Once the data were entered into the registry, the forms were returned to the surgeon to verify accuracy. Progress of the study was monitored by a steering committee of broad geographic representation, and all were asked to encourage colleagues to maintain active participation. Interval reports were provided to individual surgeons, and aggregate data updates were presented at meetings of the Vermont Chapter of the American College of Surgeons. Reporting occurred between April 1, 1999, and March 31, 2001.

The Vermont Tumor Registry was queried to determine the expected number of colorectal malignancies occurring annually in Vermont. The expected number of emergency cases was then subtracted from the overall cancer incidence to assess surgeon compliance with patient registration.

There were 7 deaths (2%) and 45 complications in 39 patients (12.3%). Reported complications included 17 wound infections, 8 intra-abdominal infections (including anastomotic leaks), 3 deep vein thromboses, and 10 miscellaneous complications. Mean length of hospital stay was 7.2 days. All patients with stage III colon cancer and stage II or III rectal cancer were offered referral for adjuvant therapy.

The most recent complete study on the incidence of colorectal cancer in Vermont reveals an incidence of...
335 new cases per year. Population-based studies have shown that 30% of colorectal cancers present as emergencies (obstruction, perforation, or bleeding) and would have been excluded from our database. As such, the expected number of cases that should have been reported to our registry is approximately 235, or 470 during the 2-year period. We have no estimate of the number of patients who colon cancer who did not undergo surgery or who underwent surgery outside our geographic area. The number of "expected" cases in the database is therefore likely to be less than 470. As such, the calculated surgeon compliance rate of 78% (364 actual/470 expected) is probably higher in reality.

Eleven of 13 acute-care hospitals submitted cases to the database, including a tertiary care hospital in New Hampshire that borders Vermont. Two small community hospitals with 2 or fewer surgeons did not submit cases. Half of the patients (n = 182) underwent surgery at Vermont’s tertiary care hospital, and almost 40% of the patients underwent surgery at 3 other regional medical centers throughout the state.

The most important finding from this study is that surgeons will provide data, report their outcomes, and generally work together on a quality improvement project under peer review protection. The surgeon is in the best position to provide reliable and accurate data regarding tumor characteristics, surgical technique, and the nature of complications. This provides an opportunity for collecting data prospectively and potentially with great detail if desired. Previous outcome studies have typically used retrospective medical chart reviews, often based on International Classification of Diseases, Ninth Revision, codes, that inevitably include reporting errors or bias (eg, “If it is not in the chart, it did not happen.”) or Medicare databases that rely on hospital coders whose differing abilities to generate complex codes may determine the extent of reimbursement to their hospital.

However, our database has several limitations. Reporting was voluntary, and surgeons may have chosen not to enter certain patients (eg, those at higher risk) who developed complications. Because the initial data form requested only demographic and tumor-specific information (complications were reported on the follow-up form), this was probably not a major problem. However, inaccurate reporting of certain events (eg, length of hospital stay, need for blood transfusion, and technical errors) is a concern. Ideally, a parallel independent review of the medical records and tumor registry would minimize this risk. We have not yet chosen to pursue this to maintain the collegial spirit that allowed the project to be successful. Now that the feasibility of this type of quality improvement project has been demonstrated, this issue will need to be addressed to ensure accuracy and completion of the data.

Despite these drawbacks, the ability to obtain population-based, statewide data from all hospitals and have them entered prospectively by the operating surgeon may represent an important opportunity for advancement over retrospective medical chart reviews. Data abstracted by ancillary personnel who never participated in the patient’s care, limited by the documentation in the medical chart and potentially motivated by other factors, is less than ideal. As such, many surgeons have been skeptical of the conclusions drawn by these studies. Nonetheless, systematic medical chart review will likely be a necessary adjunct to verify and complete even a prospective database and to provide a precise assessment of surgeon compliance with case entry.

The quality of surgical care for Vermonters with colorectal cancer seems to be good. Surgical mortality and morbidity (1.9% and 12.3%, respectively) compare favorably to the published literature. However, only specific complications were sought, and the actual complication rate was almost certainly higher. All patients with stage III colon cancer or stage II/III rectal cancer were reported to have been offered or considered for adjuvant therapy, in accordance with National Institutes of Health Consensus Conference Guidelines.

This study also documents the continuing shift of colorectal cancer to the right side. Almost 37% of the cancers were in the right colon, and less than half were in the rectum or sigmoid colon. The implications of these findings for screening are obvious and seem to further the case for primary screening colonoscopy. The finding that 82% of cancers were symptomatic on presentation suggests that much work needs to be done in our state to improve compliance with colorectal cancer screening guidelines.

In summary, the Vermont Colorectal Cancer Project showed that a statewide quality assessment and improvement effort requiring the participation of surgeons from all acute-care hospitals is feasible. Methodologic improvements need to be made to ensure the completeness and reliability of the data. However, the potential benefits of this “model” over retrospective medical chart reviews performed by medical surrogates seem obvious. We plan to use this database to identify variability and “best practices” that can be used to identify and remediate deficiencies in care. Even in the often hostile medicolegal arena that surgeons must deal with, they will provide data and report complications under peer review protection in an effort to improve quality of care for the patients they treat.

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The following surgeons participated in the study: Lori Arviso Alvord, MD; David Angstreih, MD; Frederick H. Bagley, MD; Richard Barth, MD; Robert Baska, MD; David Kenneth Burchard, MD; David W. Butsch, MD; John L. Carmody, MD; Peter Cataldo, MD; Mathew Conway, MD; Michael Curran, MD; Christopher Danielson, MD; Eric Scott Frost, MD; Bradbury Fuller, MD; Gregory Gadowski, MD; Eugene Grabowski, MD; John Hartong, MD; Horace Henriques, MD; Neil Hyman, MD; John Louras, MD; Frederick P. Loy, MD; Michael Mason, MD; Stephen Payne, MD; Carl Petri, MD; Robert Pizzullich, MD; Patricia Pisanelli, MD; Victor Pisanelli, MD; Jerry Rankin, MD; Joseph Rosen, MD; Charles Salem, MD; William Segel, MD; Laurie Spaulding, MD; and John Sutton, MD.

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Vermont surgeons are at the top of their game. for such a large group, and the participating physicians are to surgeons operating for colorectal cancer. The authors are to be con-
cluded, which would, of course, favorably skew the morbidity
and mortality, length of stay, and the use of adjuvant therapy.

Eliminating emergency cases would skew these results as well as the complications data.

There are potential problems with voluntary reporting sur-
geons, which cannot be “blinded.” High-risk patients might not have been enrolled. Complications were reported only on a follow-up form, but surgeons can often recognize a bad situation from the outset, so there could be a conscious or unconscious bias not to report the more unfavorable cases. Also, a surgeon might not consider a given event a complication, whereas an independent observer might do so.

Despite my quibbles, the results here probably are, as Jack Nicholson said, “as good as it gets” for data reporting by surgeons. Vermont is a relatively small and homogeneous state, with motivated and capable physicians. Independent retrospective systematic chart review has accuracy problems too, as the authors pointed out. The most reliable data would probably come with a combination of both physician reporting and independent chart review. Nevertheless, this would inevitably increase the complexity and cost of a project and might erode the “collegial spirit” that characterized the Vermont study. Such a comprehensive undertaking would be a particular challenge in a larger and more diverse population. Our litigious society, shrinking budgets, and professional ambivalence about sub-specialization and quality measurements would be other obstacles.

I have a question for Drs Hyman and Labow. You stated that 100% of patients were offered referral for adjuvant treatment when appropriate. I got the impression that this was a postoperative referral, although it was not perfectly clear. For rectal cancer patients, did you ever give preoperative chemoradiation, and, if so, how did you decide when to give it pre-
operatively vs postoperatively?

Dr Hyman: We acknowledge the obvious weaknesses of having no concomitant chart review. As such, your concerns about the completeness and accuracy of the data are legitimate. We inten-
ted this in large part to be a feasibility study. That is, we think the real value of this study is that surgeons actually will do it. Whether we are doing it well or as well as we could be is another issue, and I think that is the next iteration.

You asked about cancer-specific survival. Obviously, the time period is from April 1999 to March 2001; it is too early to look at cancer survival, but we definitely intend to look at that. We think that is probably the most important end point: Is there variability in oncologic outcomes?

With respect to sphincter salvage rates, I did not share that, but there are differences in the sphincter salvage rates, and that is something that we plan on looking at but I did not show that data here.

Regarding your last point about chemoradiation, that is largely surgeon preference. For example, at our institution, for stage II and III rectal cancers, we routinely give preoperative chemoradiation. Some other surgeons in this series prefer to give postoperative chemoradiation. The form asked, “Did you give adjuvant therapy and what adjuvant therapy and was it given preoperative and postoperative?”

REFERENCES

Paul Shellito, MD, Boston, Mass: This is a nice study of elec-
tive procedures and complications for a statewide group of sur-
geons operating for colorectal cancer. The authors are to be con-
gratulated for eliciting the cooperation of and collating the data for such a large group, and the participating physicians are to be congratulated for their favorable results. As reported here, Vermont surgeons are at the top of their game.

There were, however, flaws in the study, most of which the authors pointed out. Only elective operations were included, which would, of course, favorably skew the morbidity and mortality results.

The authors estimated that 78% of cases were reported and speculated that compliance might have been even higher in reality. I doubt this, since the estimate of 30% of colorectal cancers presenting as emergencies seems high to me (and whether bleed-

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