Reassessment of Intraoperative Decisions:

Why Operations for Cancer of the Large Bowel Fail

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A program developed for the intraoperative judgment decisions commonly faced in cancer of the colon and rectum has been published and has been found to correlate frequently with the management carried out in a cancer hospital and on the ward services of university programs in city/county and Veterans Administration hospitals. Those patients whose management varies with the recommendations of the program are subject to statistically significant excess risk of dying in the hospital and excess risk of failure of ultimate control of their malignant process. It is our opinion that this program is not only useful in demonstrating the explicit nature of surgical judgment but is also useful to the operating surgeon as an indication for the need for consultation or reassessment of his observations.

FEW MORE PERSISTENT PROBLEMS exist than the control of cancer of the large bowel. It perenially ranks among the two most frequent killers among neoplastic diseases in the adult North American population and is the source of substantial morbidity. Indeed, there are few other problems that are at once so familiar and yet so persistently vexing. Periodically one will note proposals advocated as major advances in the control of such neoplasms. More often than not, however, when subjected to further scrutiny, comparison and analysis, these proposals have been disappointing. By reviewing trends and results in the management of cancer of the colon and rectum over several decades rather than shorter periods of time, one can better perceive the truly significant patterns. As a result of such studies, Ederer[2] and others[6,7] pointed out that the only real progress made in the management of cancer of the colon and rectum in the first half of this century was due to: 1) a substantial increase in the operability and resectability, and 2) a very sharp decrease in the risk of treatment, *i.e.*, death in the hospital after operation.

Reports concerning special operative technics and adjunctive systemic or local chemotherapy or radiotherapy have been enthusiastically received. Each of these modalities have produced equivocal improvement and represent observations of which the majority have not been confirmed by further investigation. Most assuredly, an approach to cancer of the colon and rectum which would truly increase patient survival and decrease morbidity, both from the illness and from treatment thereof, is a genuine need.

As part of a continuing analysis of cancer of the colon and rectum and the associated results of diagnostic and therapeutic manuevers, a special programmatic approach was envisioned and developed.[4] This approach (CAMEO) emphasized 1) identification of those characteristics of patients which would facilitate favorable definitive surgical therapy, and 2) meticulous definition of the nature of the operative procedure. The former project, obviously a more complicated proposition, is in the process of development and refinement. The latter process, which was developed as a potential aid to intraoperative management of colorectal carcinoma, defines operative judgment, intraoperative therapeutic decisions and other technical considerations. By utilizing a computer management protocol in this endeavor, the surgeon is provided appropriate treatment alternatives based on objective input of observations at the time of operation. The data input consists of 1) the anatomic location of the primary lesion, 2) the presence or absence of distant metastases, 3) the involvement of contiguous structures by the pri-

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TABLE 1. *Consecutive Operated Cases Analyzed*

Private community hospital	(A)	171
City-County teaching hospital	(B)	97
Veterans administration hospital	(C)	93
		361

mary lesion, and 4) the presence or absence of perforation or obstruction. From these observations, treatment alternatives based on the most currently accepted surgical information are provided by the computer logic scheme. Factors applicable to treatment alternatives are the extent of colonic resection, advisability of primary anastomosis, and other adjunctive measures (*i.e.*, drains and/or delayed primary closure of the incision itself).

Utilizing the investigational and clinical skills of individuals with a particular interest in cancer of the colon, the scheme was tested against actual practices in a hospital with a patient base representing predominantly referred problems in neoplastic disease. A 96% correlation was identified. This emphasized the program's usefulness as an explicit example of proper intraoperative surgical judgment: perhaps as a guideline for peer review process for young surgeons and possibly as a "pilot's checklist" for more experienced surgeons.

Ravitch[8] and others[3] have formally and informally criticized both the concept and the system, emphasizing primarily that judgments involved in the program were simple and within the capability of virtually all certified, practicing surgeons. Furthermore, the problem of obtaining appropriately accurate descriptions of operative findings for input and cumbersome technology represented other criticisms. Ravitch also questioned whether the initial high correlation was related to overlapping responsibilities and identities between the program developers and the operating surgeons at the hospital in question. He furthermore suggested testing of the program in an unrelated clinical setting.

Method

To examine the system in light of these thoughtful critiques, we then set out to compare the intraoperative management of patients with carcinoma of the colon and rectum within our university affiliated system and to determine the applicability of the principles and of the concept. Accordingly, we examined the operative records in 361 consecutive operations performed in university affiliated hospitals of somewhat different characteristics. The cases studied were characterized by: 1) the presence of only one primary colorectal cancer; 2) the ability to tolerate any appropriate surgical procedure; 3) the surgeon being capable of performing any appropriate operative procedure.

The institutions which have been further defined in prior publications[1,6] regarding overall care of carcinoma of the colon, may be characterized as follows: Hospital A is a private hospital with a formal affiliation with the Department of Surgery at the university. Its entire surgical staff are Fellows of the American College of Surgeons and 90% of that staff have been certified by the American Board of Surgery. In every case, the individual operating surgeon was solely responsible for intraoperative decisions; no protocol of any sort was under study or in effect at the time. Hospital B is a city/county 350 bed hospital with a population that represents primarily the medically indigent of the city and county, plus some complicated, referred "teaching" cases. Hospital C is a 450 bed Veterans Administration Hospital affiliated through a Dean's Committee with the University of Louisville. Its patient population is representative of such regional institutions and therefore may be commonly recognized as predominantly male with a past history of military service. Operations performed at Hospitals B and C were performed by residents directed and usually assisted by University surgical faculty. Because of the retrospective nature of the study, the operative decisions in Hospitals B and C were not determined by protocol or the CAMEO concept.

The 361 cases from the three hospitals were reviewed: 171 cases from Hospital A, 97 cases from Hospital B and 93 cases from Hospital C (Table 1). The cases were analyzed in view of preoperative and operative findings and were tabulated according to the CAMEO protocol. The operative judgments and treatment options carried out were correlated with the expected choice(s) determined by the computerized logic flow diagrams. If two or more treatment alternatives were listed in the logic flow diagram, the case was considered correlated if the operation performed matched with *any* of the choices.

Data from correlating and noncorrelating cases were then analyzed for postoperative morbidity, operative (hospital) mortality, and long-term patient survival. Chi square statistical analysis was utilized to evaluate differences between correlating and noncorrelating groups. Probability values of less than 0.05 were considered statistically significant and analysis of the power of the test having values greater than 90% were considered reproducible.

The flexibility of the program may be best exemplified by a hypothetical patient with a curable obstructing carcinoma of the sigmoid colon. Program suggested management for that patient is: 1) diverting colostomy with subsequent resection, anastomosis, and later

TABLE 2. *Comparison of Postoperative Morbidity, Mortality and Survival Between Cases in Which CAMEO Could and Could Not Evaluate*

	Total	Postoperative Morbidity	Operative Mortality	Survival 5 years	P	PT
Postoperative Morbidity						
CAMEO could evaluate (++;+0)	347	84 (24%)				
CAMEO could not evaluate (00)	14	7 (50%)			.06*	.70†
Operative (Hospital) Mortality						
CAMEO could evaluate	347		31 (9%)			
CAMEO could not evaluate	14		6 (43%)		.0006	.90
Long-term Survival (5 years or more)						
CAMEO could evaluate	347			134 (39%)		
CAMEO could not evaluate	14			0	.008	.95

* Probability.
† Power of the test.

colostomy closure, or 2) resection with proximal colostomy and either exterization of the distal colon through a mucous fistula or closure as a Hartmann pouch, or 3) resection and anastomosis with a proximal diverting colostomy.

Results

Three major categories in terms of correlation were identified. The first is that there was correlation between what was actually done and what was program-recommended (++), the surgeon in question following in general the recommendations reflected in the program. The second category is a group of patients whose intraoperative findings were so complex as to not be suitable for analysis within the constraints of the existing program (00). The third category represents those patients in which the intraoperative management deviated from the program-recommended care (+0). The basic results of this comparison are displayed in Tables 2–6. These tables may be summarized narratively as follows: those patients in whom operative findings were so complex as to not be suitable for comparison with the programmatic recommendations obviously represented extraordinarily unusual and perplexing situations and, not surprisingly, this particular combination of events eventuated in a 43% hospital mortality rate, a postoperative complication rate of 50%, and no patient was cured of his colorectal cancer (Table 2). Those patients whose treatment correlated precisely with the program-recommended operative procedures, whether examined within each institution or the groups as a whole, bore the lowest treatment mortality rate, the lowest complication rate and the highest five-year survival rate of any of the subgroups eligible for analysis (Table 3). To the contrary, those patients whose operative management deviated from the protocol were associated with statistically significant increases in hospital mortality rates and decreases in five year survival. The increase in complication rate noted in these patients was impressive but did not reach a level of statistical significance.

The most common deviations from the protocol by the operating surgeon or surgeons were two-fold (Table 4). The tendency to treat partial or complete colonic obstruction with less than optimum respect resulted in compromise: the avoidance of colostomy and diversion in favor of primary anastomosis even though partial or complete colonic obstruction was *recognized* (Table 5). The second major area of disagreement was associated

TABLE 3. *Three Hundred Forty-seven Cases CAMEO Program Could Evaluate: Correlation Between Actual and Program-suggested Operative Treatments*

	Treatments correlated	Total	Postoperative Morbidity	Operative Mortality	Survival 5 or more years	P	PT
Postoperative Morbidity	Yes (++)	307	70 (23%)			0.13*	0.50†
	No (+0)		14 (35%)				
Operative (Hospital) Mortality	Yes (++)	307		23 (7%)		0.02	0.85
	No (+0)			8 (20%)			
Long-term Survival (5 years or more)	Yes (++)	307			126 (41%)	0.02	0.85
	No (+0)	40			8 (20%)		

* Probability.
† Power of the test.

TABLE 4. *Cases Deviating from CAMEO (+0) in 40 Patients*

Reasons for Deviation from CAMEO			
Anastomosis associated with partial/complete obstruction	21/40	(53%)	73%
Palliative rather than curative procedure	8/40	(20%)	
Significantly more colon removed than required	1/40	(2%)	
Other reasons (includes tumor transection)	10/40	(25%)	

with failure to adequately excise a clinically curable colon cancer—the tendency being to leave possible tumor extension on adjacent organs or sites rather than expand the scope of the operation (Table 5). Thus one sees the peculiar paradox of a relatively radical (*i.e.* aggressive) surgical approach for obstructing lesions and an overly conservative approach with respect to those occasional colon cancers which show some signs of local extension but no real signs of incurability.[5] The former error contributes to increased hospital morbidity and mortality and the latter reduces opportunity for long-term cure.

One may readily see that digressions from the recommended intraoperative management occurred significantly more commonly in the private affiliated hospital than in the city/county and Veterans Hospital (Table 6). One patient in six undergoing operative management of a cancer of the colon or rectum in Hospital A was subjected to an operative procedure at significant variance with that which was program-recommended.

Discussion

In respect to the medical welfare of the North American population, few lesions by virtue of prevalence, morbidity, or intrinsic death rate are more worthy of attention and improvement than adenocarcinoma of the colon and rectum. We must continue to evaluate all adjunctive modalities, in addition to each new technical innovation, with care and precision. However, reconsideration of the basic principles of colon surgery enable us to determine how often significant deviations from the time-honored and *proven* treatment modalities occur. Thus the study in questions indicates that there is both need and opportunity for improvement. Perhaps as many as 15% of operations, even when performed by Board certified surgeons who are also Fellows of the American College of Surgeons, represent significant digression from what is deemed optimum treatment under the circumstance. The clinical significance of these deviations is profound. The observations closely correlate with the short and long-term results which are the appropriate parameters for the assessment of any chronic illness. Furthermore, there is direct correlation between overly aggressive management of the obstructed colon and postoperative morbidity and mortality. On the other hand, inadequately aggressive management of the biologically favorable tumor which is locally extensive increases the probability of an uncomplicated postoperative recovery but significantly decreases the change for long-term cure. These observations vary with those principles expounded in the course of surgical meetings or through other contacts with certified surgeons. In such relaxed settings, one rarely encounters a surgeon who is not very conservative about the management of the totally or partially obstructed colon. It seems that surgeons don't always practice the principles they recognize. On the contrary, one does on occasion note surgeons who have not appreciated the unusually favorable characteristics of some extensive colorectal carcinomas. As a result of analysis of these records, we propose that during the course of the operation some surgeons subconsciously de-emphasize the significance of colonic obstruction and local extension of a curable tumor and find themselves justifying an operative procedure hopefully aimed at a live, happy patient with no colostomy. The data indicate that this practice is an expensive compromise.

TABLE 5. *Hospital Morbidity Among Cases Deviating From CAMEO (+0)*

	Postoperative (Hospital) Morbidity			
	No Morbidity (26)		Morbidity (14)	
Reason for Deviation	No. of Patients	%	No. of Patients	%
Anastomosis associated with partial/complete bowel obstruction	10	38%	11	79%
Palliative rather than curative procedure	8	31%	0	
Significantly more colon removed than required	1	4%	0	
Other reasons (includes tumor, transection)	7	27%	3	21%
	26		14	

TABLE 6. *Correlation with CAMEO in Three Differing Hospital Settings*

		Correlated	
Hospital	Total	Yes	No
A	166	83%	17%
B	90	93%	7%
C	91	95%	5%
	347	88%	12%

It seems that this analysis has, to the extent possible in a retrospective study, refuted some of the criticisms of the CAMEO concept. In the course of an operation for colon or rectal cancer, a portion of certified surgeons will make inappropriate decisions that would not be justifiable before their peers nor probably in the light of their own analysis at some other less pressured time and place.

The ability of the CAMEO program to deal with the operative findings in some 96% of these cases is evidence of its applicability and further suggests that the program might be very useful as an analogy to the "pilot's checklist." One could simply enter the operative observations into the program, thereby making certain that the treatment about to be provided was consistent with the best analysis resulting from the program. We feel that a noncorrelating response would be an indication for intraoperative consultation with another surgeon, suggesting either that the case exceeds the program's present stage of development, and therefore is not suitable for comparison, or that the operating surgeon has made an error in his observations or judgments.

This program, we feel, is not only useful in demonstrating the explicit nature of surgical judgment but is also useful to the operating surgeon as an indication for the need for consultation or reassessment of his observations.

Further real advances in the management of the patient with cancer of the colon and rectum are going to be hard fought and hard won. It appears that this is an area in which some patients could have their care improved tomorrow.

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Discussion

Dr. Branham B. Baughman (Frankfort, Kentucky): When Dr. Polk asked me to discuss this paper, I was reluctant, because I don't like to discuss my unsuccessful cases, and about all I can add to this is some of the things which I did years ago which Dr. Polk says not to do now.

As most of you know, since 1905, when William Ernest Miles did his work on cancer of the rectum, we have had 70 years in which, as Dr. Polk said, we have not improved too much in the five and ten year survival, except for certain unusual and excessively fine reports by men like Dr. Turnbull and our own Drs. Beahrs and McSwain and others who have reported good results.

Now, Mr. Miles was a very courageous man. In 1908, when he reported his first series of cases, his hospital mortality was 44%. That would certainly discourage me, and, I think, a good many of us. But he had what Dr. Byrd said the other day—patience, with a "c-e", and persistence—and we have made some improvements, shown by many of these men.

Despite all these good reports, a year ago the National Institutes of Health reported that overall in the United States the survival for cancer of the colon and rectum was between 45 and 50%, which is still not good. It's the second killer of cancer, as you know, second to lung cancer.

Now, a good many of you here, I see, were in what I like to call "our war," World War II, in the military service, as I was, in the Army, and prior to World War II there was one gentleman who had written and spoken and done, probably, more about cancer of the colon than anybody else. He was a former member and President of this society, Dr. Fred Rankin.

During the war he became the surgical consultant to the Surgeon General of the Army. He became General Rankin, and prior to the war he devised a very unique, safe operation, before antibiotics and intestinal antiseptics. He called it obstructive resection. He devised a very unique three-bladed clamp. It was actually a modification of the old Block-Paul-Mikulicz exteriorization, but it was safe. It was an improvement.

So I had the occasion in the Army hospital where I was situated to see two patients under the age of 30 within about a year of each other with intestinal obstruction, proven to be tumor of the left colon. Now, I guess every Army hospital then had a Rankin clamp, and I was not about to do anything else, for two reasons. First, it was a good, safe operation. Secondly, when General Rankin came around to inspect us, if I had done anything else, in about 24 hours I would have had orders to China, Burma, or as far away as the Army could send me, because General Rankin didn't brook much disagreement, as Coleman Johnston well knows, and Mel Bernhard, and others who knew him.

So I did his operation on these two soldiers. Of course, you could not resect a very wide mesentery, one of the things that Dr. Polk and his colleagues talk about. But I did these boys, and finally closed their colostomies. They were discharged from the hospital, given CDD's from the Army, and their pockets were full of self-addressed cards to me.

One of them I never heard from. The other one I did hear over a period of about a year and a half, and, unfortunately, he died in Veterans Hospital of metastasis, which was not totally unexpected. But I did what I thought then was a safe operation, although it's not done today. We think we have improved a good deal.

Now, I have three other cases which are also not all successful. (Slide) This is an old gentleman who came in with obstruction of the