Colonoscopy by a Family Physician: A 9-Year Experience of 1048 Procedures

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BACKGROUND. In the last 15 years, family physicians and general internists have adopted flexible fiberoptic endoscopy as a procedure to screen patients at risk of premature death from colorectal cancer. There has been controversy regarding the ability of non-fellowship-trained primary care physicians to extend this experience to full colonoscopy.

METHODS. The results of 1048 consecutive colonoscopy examinations performed by a family physician over a 9-year period were tabulated. Outcomes measured included the reach-the-cecum rate (RCR), use of medication, complication rate, and diagnostic yield. In a convenience sample of 110 cases, the effectiveness of the non-narcotic analgesic ketorolac was assessed by the RCR. Outcomes of cases in which ketorolac was used were compared with cases in which traditional sedation and analgesia were used.

RESULT. A high diagnostic yield without significant complications was noted. The RCR for nonmedicated patients was 36%. Among all medicated cases, the RCR was 93%. In patients who were given the non-narcotic analgesic ketorolac, the RCR was 96%, compared with 95% in patients not given ketorolac.

CONCLUSIONS. A family physician in rural practice was able to attain and sustain a state-of-the-art, reach-the-cecum rate over a 9-year period. This service resulted in a high diagnostic yield, high degree of safety, and satisfactory results for the community. Ketorolac is an effective alternative for patients who may be hypersensitive to narcotic analgesia/sedation.

KEY WORDS. Colorectal neoplasms; signmoidoscopy; colonoscopy; analgesics, non-narcotic; analgesics, narcotic. (*J Fam Pract 1996; 43:561-566*)

s early as 1986, some suggested that colonoscopy by family physicians might be useful in the early detection of colorectal cancer.¹³ Early detection has been verified as one means of preventing premature death from this cancer,⁴ but formal training was not generally available to family physicians.⁵ These isolated reports of colonoscopy⁶ in family medicine¹³ were interesting, but went largely unnoticed.

By 1989, the American Academy of Family

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Physicians expanded the the number of continuing medical education (CME) procedural courses offered at the Annual Scientific Assembly. In addition to flexible sigmoidoscopy, new course offerings included esophagogastroduodenoscopy (EGD) and colonoscopy. Despite these training efforts, several letters were published in 1994 criticizing the use of colonoscopy by family physicians. The focus of this criticism was a perceived inadequate standard of care as reflected by a less than desirable "reach-the-cecum" rate.

Although the definition of a complete colonoscopic examination is complex, the reach-the-cecum rate (RCR) is one standard for ascertaining completion of the examination. Letters and other published reports from subspecialists in tertiary care have suggested that an RCR of 90% is the standard of care for the 1990s. 7.8.10 A community-based survey reported rates of 82% to 93% in 1994.6

Previously published lower RCRs¹¹⁻¹³ may no longer be valid because of improved training, improved equipment, and continued clinical experience. 14,15 One of the authors (W.M.R.) noted an improvement in the RCR, from 85% to over 90%, after he traded in first-generation for second-generation equipment.

During his clinical practice, the index physician (W.H.) realized that many of the patients examined with the flexible sigmoidoscope actually required examination of the entire colon. For this reason, the physician started performing colonoscopy with sedation/analgesia in patients with above-average risk for colorectal carcinoma. Initially, a low RCR was explained by the lack of sedation/analgesia in the nonmedicated group. Since the original intent was to provide flexible sigmoidoscopy, medication was not administered for the first 335 procedures. To the best of our knowledge, no clinical experience of this size has been published by a family physician to date.

The purposes of this study were to tabulate the data from such a large series of colonoscopies to test the hypotheses of: whether colonoscopy examinations in a community-based family practice met the currently published standards of care, and whether the safety of this procedure as performed by a family physician could be substantiated. Another purpose of this study was to describe the use of the analgesic ketorolac without accompanying sedation in patients undergoing colonoscopy procedures, and the effect of this analgesia technique on the RCR.

METHODS

The study is a tabulation of the 9-year experience of a family physician who advanced from flexible sigmoidoscopy to full colonoscopy in his office and in a hospital-based outpatient endoscopy Endoscopic outcomes with and without intravenous sedation/analgesia were tabulated and analyzed.

STUDY SITE

The index physician graduated from medical school in 1970 and was first certified by the American Board of Family Practice in 1976. He entered practice at his current location in 1974 and became certified in Advanced Cardiac Life Support (ACLS) in 1982. In 1984, the physician completed a short continuing medical education course in lower endoscopy. He has practiced in a town of approximately 7500, and

the nearest hospital was 15 miles away from his office. The practice averaged 20 patients per day in the office, with 50% female and 5% pediatric patients. Approximately 15% of his practice included patients over the age of 60.

Over two thirds of these cases were done in an outpatient endoscopy laboratory affiliated with a hospital. The results were peer-reviewed on a regular basis as required by the Joint Commission on Health Care Organizations (JCAHO). Procedures were ordered for indications accepted in the medical literature, and data were extracted from permanent medical records.

USE OF COLONOSCOPY

Between March 1985 and July 1994, 1048 colonoscopy procedures were performed by a board-certified family physician in a manner similar to the methods of Dervin¹ and Rodney. ¹⁶ Three hundred thirty-five nonmedicated procedures were performed as flexible sigmoidoscopies, although colonoscopy equipment was used. The colonoscope was inserted to the point at which the patient reported pain.

DATA COLLECTION AND ANALYSIS

Patient demographics (name, sex, age) were recorded for each procedure. Patients were selected on the basis of risk for colorectal cancer. These risks included age greater than 50, personal history of polyps, family history of colorectal cancer, and/or unexplained symptoms greater than 2 weeks' duration. Symptoms included, but were not limited to, anemia, rectal bleeding, positive fecal occult blood test, change in bowel habit, weight loss, and abdominal pain.

The following data were collected about each procedure: date of procedure, instrument, indication, name of medication, anatomical depth, maximum insertion (cm), insertion time, total time of procedure, and complications. Diagnostic findings were recorded. Data were collected for greater than 99% of the procedures for all of the above categories. All procedures were prospectively entered into a log and a chart audit was performed retrospectively to collect data. All data analysis was done by researchers other than the index physician.

Colonoscopies were divided into two groups: a nonmedicated group, and an analgesia/sedation group. The procedures were analyzed by calculating the percentage rate of the physician's ability to perform a complete examination. A complete examination was defined as one in which the physician was able to reach the cecum. The RCR, rate of complications, insertion depth, procedure time, age, sex, and indications were compared for the two groups of procedures. The diagnostic yield was also tabulated.

USE OF SEDATION/ANALGESIA

The sedation/analgesia regimen most often employed was a combination of

midazolam and meperidine. Exact dosage data were not available. Using a convenience sample of 65 procedures, the mean dosage for midazolam was 3.5 mg intravenously with a range of 2.0 to 9.0 mg. Using a convenience sample of 44 procedures, the mean dosage for meperidine was 43 mg with a range of 25 to 100 mg. During colonoscopy procedures in which ketorolac was administered, a dosage of 60 mg intramuscularly was used in each case.

USE OF KETOROLAC

In October 1990, the index physician began administering ketorolac without sedation on a convenience sample of colonoscopy patients. Patients did not differ in age, sex, or indication when compared with patients not receiving ketorolac. Colonoscopy procedures in which ketorolac was used were compared with those in which the traditional analgesia medications (midazolam/meperidine) were used. Ketorolac was given by intramuscular injection in the deltoid or gluteal muscle, 30 to 60 minutes before the start of the procedure. The RCR of patients undergoing colonoscopy with ketorolac was compared with that of patients receiving the traditional sedation regimen during the same period (October 1990 to July 1994). This second comparison was performed to discover any potential bias caused by a change in the physician's skill level.

TABLE 1

| Reach-the-Cecum Rates for Various | Types of Sedation/Analgesia vs No Medication |
|-----------------------------------|--|
|-----------------------------------|--|

| Procedural Medication | No. of Cases of RCR/Total | RCR (%) |
|---|------------------------------|---------|
| No medication, 1985-1994 | 121/335 | 36 |
| All medicated (analgesia/sedation), 1985-1994 | 662/713 | 93 |
| Sedation/analgesia (meperidine/midazolam), all cases 1985-1994* | 556/603 | 92 |
| Analgesic (ketorolac) only (Oct 1990 to July 1994) | 106/110 | 96 |
| Sedated non-ketorolac cases (Oct 1990 to July 1994)† | 190/200 | 95 |
| | | |

^{*}Excludes cases in which ketorolac was used.

STATISTICAL ANALYSIS

Statistical analysis was performed by computer with Statview 4.01 (Abacus Concepts, Inc), a statistics program. Continuous variables were analyzed using the Student's t test. Categorical variables were compared using a chi-square comparison. An alpha level of .05 or less was used for denoting significance.

RESULTS

For the 1048 procedures, the patient mean age was 57 years, with a standard deviation of 15 years and a range of 14 to 91 years; 41% (433) of the patients were female.

The earlier procedures (n=335) were performed without medication (Table 1), and 36% (121) of these reached the cecum. Of the 713 colonoscopies in which medication was used, 93% (662) reached the cecum. The RCR for the ketorolac procedures was 96% (106), and 92% (556) for all procedures in which IV sedation/analgesia was used. A head-to-head comparison of procedures in which patients were medicated revealed that the RCR was 95% (190) for the same period (October 1990 to July 1994). There was no significant difference in the RCR between the two groups.

There were no significant differences in age and sex when sedated patients were compared with nonsedated patients. Slightly more nonsedated

[†]Comparison group controlled for similar period (ie, ketororac compared with traditional IV sedation/analgesia cases).

| TABLE 2 | | | | |
|------------------------------------|------------------|--|--|--|
| Diagnostic Yield of 1048 Cases | | | | |
| Type of Finding | No. (%) of Cases | | | |
| Significant findings* | 514 (49.0) | | | |
| Neoplastic polyp/lesion | 459 (43.8) | | | |
| Proctitis/colitis | 44 (4.2) | | | |
| Mucosal abnormality, miscellaneous | 11 (1.0) | | | |
| Nonsignificant findings | 190 (18.1) | | | |
| Hyperplastic polyps** | 151 (14.4) | | | |

*Significant was defined as a neoplastic polyp or a mucosal abnormality. When a mass lesion was accompanied by mucosal abnormality or proctitis/colitis, it was counted as a mass/lesion case (n=29)

39 (3.7)

Miscellaneous findings/other†

†Although encountered, hyperplastic polyps, lipomas, and other miscellaneous findings such as melanosis coli ere not tabulated as findings with a substantial clinical significance.

patients were receiving the examination for screening when compared with the sedated group. The diagnostic yield was substantial, with at least one clinically significant finding in 49% (514) of procedures (Table 2). Medicare assignment was accepted for reimbursement of charges (Table 3).

During the 9-year experience, no perforations, no transfusions, and no deaths occurred in association with colonoscopies. There was one hospitalization caused by the scope being incarcerated in a patient's inguinal hernia. Anesthesia was administered to relax the patient, and the scope was removed. The patient was hospitalized for less than 24 hours. No surgery was required and no further complications occurred.

DISCUSSION

The study evaluated three main issues. First, will a larger than previously published series of colonoscopies by a family physician continue to substantiate the safety of this procedure when performed by a generalist? Second, were colonoscopy outcomes comparable to literature standards when these procedures were performed by a board-certified family physician? After beginning the study, the use of analgesia without sedation (ketorolac) was introduced and became an issue of study within the larger series of colonoscopy procedures.

The study provides additional reassurance regarding the safety of colonoscopies performed by FPs in that there were no perforations in 1048 procedures. This is comparable to low perforation rates reported in the literature. 17,18 No transfusions and no required surgery were reported. The one hospitalization was not a serious medical problem, and the utilization of one hospital day among 1048 cases sunports the safety of the procedures as performed in this series.

In this series, the diagnostic yield of significant findings was 49% (Table 2). A similar series of 1842 colonoscopies performed on patients with indications yielded 35% neoplastic polyps with an additional 5% significant inflammatory findings.19

In a series of 97 patients with persistent largebowel symptoms, the diagnostic yield for neoplastic lesions was 26%.20 Although the study did not report any data on inflammatory bowel disease, it concluded that colonoscopy rather than radiology studies should be the first line of investigation for persistent large bowel symptoms.

In another study of 76 consecutive patients with symptoms, a colonic abnormality was identified in 65%.21 Others have also commented on the diagnostic yield in this range for patients with suspected lesions of the lower intestinal tract.²² Thus, the diagnostic yield of this study is within the range of other studies reported in the medical literature. This suggests validity from external sources.

Others have commented on the benefits of expanding the procedural skills of generalist physicians. 23-25 Some of these benefits are that the fragmentation of health care is reduced; patient care access is improved; patient compliance with cancer screening improves²⁶; and costs to the patient are less, even though physician charges are substantial. Because Medicare reimbursement levels have been less than charges (Table 3), family physicians must analyze their individual practices to determine the feasibility of purchasing equipment. The experience of the index physician, however, suggests that family physicians can afford equipment based on these charges.

Beyond the diagnostic yield, intangible benefits may contribute to the care of the patient. The authors observed that continuity of treatment by the patient's own family physician was of positive value to the patient receiving colonoscopy. The personal relationship seemed to decrease the anxiety of such a procedure. A familiar office and staff also seemed to diminish apprehension. These observations deserve further systematic study.

Opportunities for training within family medicine

for these procedural skills have been limited by a variety of factors. Bredfeldt et al27 noted that community hospital-based programs were perceived as less restrictive than academic residency programs in providing opportunities for procedural skills training. Kruse et al28 noted that family physicians received less favorable treatment for the assessment of their obstetrical skills when evaluated by nonfamily physicians. Geyman²⁹ predicted that there would continue to be controversy as these boundary issues between generalists and specialists were studied. Nevertheless, these procedural skills, particularly lower GI endoscopy training, continue to grow in generalist residencies. 30-33

Another purpose of this study was to evaluate the use of ketorolac without accompanying sedation in patients undergoing colonoscopy. Ketorolac was used alone in 110 cases, and endoscopic outcomes were compared with cases in which a combination of sedation and analgesia was used. The high rate of completed examinations (RCRs 96%) suggests that ketorolac could be a valid alternative to sedation. Ketorolac may diminish the risk of respiratory depression present with traditional sedation and/or analgesia. Ketorolac could be an alternative for those patients with known hypersensitivity to sedatives. It also offers an alternative medication for those medical offices that cannot keep narcotics on site.

A recent study concluded that there is little or no risk of bleeding associated with parenteral ketorolac dosages as used in this study.³⁴ No bleeding complications were associated with any colonoscopy. The results of this study of ketorolac use in colonoscopy appear promising, and this area will require further study.³⁵

The uncontrolled nature of the ketorolac portion of the study and the small convenience sample have limited the generalizability of this study. Other small published studies, however, have subsequently confirmed ketorolac as a valid option.^{36,37}

The data reported in our study describe the largest series of colonoscopy examinations by a family physician in the world's literature. The number of cases, the diagnostic findings, and the low complication rate support the ability of family physicians to effectively advance from flexible sigmoidoscopy (60-cm short colonoscopy) to full diagnostic

TABLE 3

Colonoscopy with

polypectomy

| In-office Colonoscopy Charges | | | |
|-------------------------------|-------------------------|--------------------------------|--|
| Procedure* | Physician's Charge (\$) | Medicare Reimbursement (\$) | |
| Colonoscopy | 725 | 261 | |
| Colonoscopy with biopsy | 792 | 292 | |

*These charges and reimbursements represent one physician's experience, but do not necessarily represent national Medicare policy. Local policies vary. There are additional charges for the medication, IV tubing, pulse oximetry, and other monitoring.

colonoscopy. Recently published studies have indicated that identification and removal of benign neoplastic lesions such as adenomatous polyps will lower mortality from colorectal cancer.^{4,38} Despite the limited generalizability of one person's experience to others, these data provide additional evidence supporting the effectiveness of colonoscopy by community-based family physicians.

These data address some of the concerns regarding "training numbers" as an arbitrary standard for credentialing of physicians. A recent study of gastroenterology fellows documented an 86% RCR despite 149 to 328 training cases. The authors suggest that fellowship training be lengthened and minimum numbers be increased. Description that other hand, a recently published study acknowledges the acceptability of an overall 85% RCR.

SUMMARY

Our study provides further evidence that increasing proficiency in reaching the cecum can occur with experience in practice. A reasonable RCR is probably a range of acceptable values. In this study, the family physician documented an acceptable level of skill when his outcomes were compared with other published data.

This is the largest series of consecutive colonoscopies performed by a board-certified family physician. Complications and procedure-related morbidity were not encountered. The diagnostic yield was high and the rate of complete examination as noted by the RCR met standards of care published in the subspecialist literature.

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