

A RAND NOTE

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The research described in this report was supported by a grant from the U.S. Department of Health and Human Services.

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N-3363-HHS

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Sufficiency of Clinical Literature on the Appropriate Uses of Six Medical and Surgical Procedures

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We reviewed the English-language clinical literature on carotid endarterectomy, cholecystectomy, upper gastrointestinal endoscopy, colonoscopy, coronary angiography and coronary artery bypass graft procedure to identify the appropriateness of using these procedures in 1981. Most of the 803 relevant articles and textbooks were published after 1975; about 10% of the 571 research studies were randomized, controlled trials, while two thirds were retrospective studies. Incomplete or contradictory information was available on the indications for and efficacy of using the procedures; almost no data were available on costs and use; data on complications failed to specify patients' symptoms or the relationship between complications and reasons for doing the procedure.

(Fink A, Brook RH, Kosecoff J, et al: Sufficiency of clinical literature on the appropriate uses of six medical and surgical procedures. *West J Med* Nov; 147:609-614)

Contemporary methods of containing rising medical costs in the developed world have been based on economic rather than medical principles, and their focus has been on allocating health funds on a geographic basis, prepaying hospitals, setting limits on physicians' fees or changing health insurance plans and benefits. Such methods, we assert, are inadequate because of their failure to distinguish efficiently between effective and ineffective care.¹ Could a combined clinical-epidemiologic approach to cost containment produce better health at similar levels of cost?

The clinical-epidemiologic approach strives to separate, in medically meaningful ways, appropriate from inappropriate uses of diagnostic and therapeutic procedures. When a procedure is appropriately used, expected health benefits (increased life expectancy, relief of pain, reduction in anxiety and improved functional capacity) meaningfully exceed expected negative consequences (mortality, morbidity, anxiety of anticipating the procedure). An underlying assumption of this approach is that physicians can identify and subsequently eliminate inappropriate use, and this will result in a better use of health funds.

One purpose of the medical literature should be to help physicians distinguish between the appropriate and inappropriate use of procedures. In this article we attempt to evaluate the usefulness of the medical literature in providing information on the appropriateness of six frequently used medical and surgical procedures.^{2,3} We studied the literature through 1981 on carotid endarterectomy, cholecystectomy, upper gastrointestinal endoscopy, colonoscopy, coronary angiography and coronary artery bypass operation.

Methods

We located articles by searching the US National Library of Medicine's computerized bibliographic data base (MED-

LINE), by reviewing references in the articles uncovered by the MEDLINE search and in leading textbooks and by analyzing articles suggested by a 15-member advisory group. The results were reviewed by Stanley Cohen, MD, of the Veterans Administration, and Dennis M. Jensen, MD, and Ronald D. Tompkins, MD, of UCLA, Los Angeles. We assigned all publications to one of eight categories: controlled trials in which subjects are randomly assigned to one or more experimental and control groups and all data are collected prospectively; other prospective studies in which subjects are not randomly assigned to groups; retrospective studies in which the investigator defines clearly which existing source of information is used; probably retrospective studies with unspecified or unclear data sources; surveys of opinion and experience; editorials; reviews of research, and textbooks. We excluded case reports and articles on technical advances in doing a procedure. No attempt was made to qualitatively score the quality of journals, articles or their contents. Our concern was with uncovering the available literature's recommendations for the use of each procedure, the frequency of its use with specific groups of patients, the evidence for its efficacy compared with alternative diagnostic or therapeutic strategies, the types and rates of complications from its use and the costs of doing it.

Results

Characteristics of Articles and Textbooks

The six literature reviews uncovered 803 germane publications. Relatively little information was available on carotid endarterectomy or colonoscopy compared with coronary angiography or the coronary artery bypass procedure. Except for that on cholecystectomy, most of the literature appeared after 1975 (Table 1).

On analyzing the content of the 803 publications (Table 2),

TABLE 1.—Year of Publication of Articles and Textbooks Included in a Literature Review of the Use of 6 Surgical Procedures

| Procedure | Year of Publication | | | Number of Publications |
|--|---------------------|-----------|-----------|------------------------|
| | Before 1970 | 1970-1975 | 1976-1981 | |
| Carotid endarterectomy | 10 | 50 | 88 | 148 |
| Cholecystectomy | 29 | 31 | 51 | 111 |
| Upper gastrointestinal endoscopy | 4 | 29 | 79 | 112 |
| Colonoscopy | 0 | 35 | 57 | 92 |
| Coronary angiography | 8 | 53 | 131 | 192 |
| Coronary artery bypass graft procedure | 0 | 21 | 127 | 148 |
| Total* | 51(6) | 219(27) | 533(66) | 803(100) |

*Number in parentheses indicates percentage of total number of publications.

TABLE 2.—Content of 803 Publications on 6 Medical and Surgical Procedures

| Procedure | Indications | Content | | | |
|--|-------------|-----------------------|----------|---------------|-------|
| | | Population-Based Use* | Efficacy | Complications | Costs |
| Coronary angiography | 31 | 6 | 77 | 33 | 7 |
| Coronary artery bypass graft procedure | 29 | 7 | 116 | 73 | 6 |
| Carotid endarterectomy | 56 | 0 | 50 | 43 | 0 |
| Upper gastrointestinal endoscopy | 53 | 0 | 52 | 38 | 9 |
| Colonoscopy | 50 | 0 | 22 | 54 | 4 |
| Cholecystectomy | 57 | 32 | 19 | 39 | 5 |
| Total† | 276(34) | 45(6) | 336(42) | 280(35) | 31(4) |

*Refers to use in a defined area such as the residents of a state or county.
 †Number in parentheses indicates percentage of publications. One publication might contain data on more than one topic and so totals add up to more than 100%.

we found that 276 (34%) had information on the indications for using the procedure, 45 (6%) described the use of the procedure in a specified population such as that of a county or state, 336 (42%) reported the procedure's relative efficacy, 280 (35%) had information about the complications resulting from the procedure and 31 (4%) concerned the costs of doing the procedure.

Of 571 research studies—the rest were textbooks, surveys, reviews or editorials—10% reported the results of randomized, controlled trials (Table 3). Most knowledge about the six procedures originated in retrospective or presumably retrospective studies (66%), so it is not surprising that more than three fourths of the data on indications and two thirds of the information on efficacy were found in studies that used a retrospective research design (Table 4).

Indications

We assembled indications from the literature that were specific recommendations for physicians to act clinically. Statements of theoretic interest or concerns regarding the use of a procedure were not included.

We found that the indications for using all six procedures were characterized by disagreement and unanswered questions. For example, whereas many investigators agreed that endoscopy is indicated for patients with acute gastrointestinal bleeding,⁴⁻⁶ they disagreed on when to do the procedure. Some asserted an early endoscopy was not essential if results of an adequate upper gastrointestinal x-ray study were available⁷; others argued that massively bleeding patients would be at a disadvantage without early endoscopy. The definition of early varied from within 12 hours⁸ to no later than 24 hours^{9,10} to 48 hours.¹¹⁻¹³

For colonoscopy, the literature was unclear as to the

schedule for colonoscopic follow-up in patients who had a polypectomy¹⁴⁻¹⁶ or a colonic cancer resected.^{16,17} Controversy also persisted in the literature on cholecystectomy, particularly whether the procedure should be done for patients with asymptomatic gallstones.^{12,13,18}

The indications for the cardiovascular procedures were also characterized by uncertainty. The literature showed agreement that a coronary artery bypass procedure, for example, was indicated for patients with left main coronary artery obstruction or those with angina that does not respond to medical management. For all other clinical situations, we found much disagreement.¹⁹⁻²⁵

A review of the indications for carotid endarterectomy also revealed controversy. Relatively strong support existed for the use of the procedure in treating patients who had a combination of classic carotid transient ischemic attacks and a surgically amenable lesion on the side appropriate to the symptoms. But disagreement was plentiful over the use of the procedure in patients who had a completed stroke,²⁶⁻²⁹ were asymptomatic³⁰⁻³³ or had an evolving stroke³⁴⁻³⁶; even the issue of what is meant by surgically amenable stenosis was unresolved.³⁷⁻³⁹

Frequency

No information could be found in the literature that described the use in a specific population (such as residents of a city or region) of fiber-optic colonoscopy, upper gastrointestinal endoscopy or carotid endarterectomy. A few population-based studies could be found for the use of coronary artery bypass graft procedure. These showed that the procedure was frequently used, for example, in the United States—at least 70,000 done in each year studied by the researchers—its use increased for a time, but may have leveled

TABLE 3.—The Research Methods Used in Published Studies of 6 Medical and Surgical Procedures

| Procedure | Methods* | | | | Total Number of Research Articles |
|--|------------------------------|---------------------------|---|--|-----------------------------------|
| | Randomized Controlled Trials | Other Prospective Studies | Retrospective Studies, Clear Data Sources | Probably Retrospective Studies, Unclear Data Sources | |
| Carotid endarterectomy | 1 | 17 | 20 | 25 | 63 |
| Cholecystectomy | 11 | 1 | 77 | 4 | 93 |
| Upper gastrointestinal endoscopy for diagnosis | 10 | 20 | 13 | 33 | 74 |
| Colonoscopy | 0 | 6 | 8 | 38 | 52 |
| Coronary angiography | 19 | 55 | 84 | 7 | 163 |
| Coronary artery bypass graft procedure | 18 | 41 | 62 | 5 | 126 |
| Total† | 59(10) | 140(25) | 264(46) | 112(20) | 571(100) |

*See text for definitions.
†Number in parentheses indicates percentage of total number of research articles (571) for all procedures.

TABLE 4.—Relationship of Research Design to Type of Information Produced for 6 Medical or Surgical Procedures

| Research Design* | Type of Information | | | | |
|--|-----------------------------|-------------------------------------|--------------------------|-------------------------------|----------------------|
| | Indications, N=171, No. (%) | Population-Based Use, N=74, No. (%) | Efficacy, N=284, No. (%) | Complications, N=197, No. (%) | Costs, N=16, No. (%) |
| Randomized, controlled trials | 13 (8) | 0 (0) | 59 (21) | 17 (9) | 1 (6) |
| Other prospective studies | 23 (13) | 1 (1) | 47 (17) | 24 (12) | 2 (13) |
| Retrospective studies, clear sources of data | 70 (41) | 72 (97) | 116 (41) | 103 (52) | 8 (50) |
| Probably retrospective studies or unclear data sources | 65 (38) | 1 (1) | 62 (22) | 53 (27) | 5 (31) |

*See text for definitions.

off by 1980.^{4,40-43} Some US population-based use rates were also available for coronary angiography.^{40,44-48} In the United States, this procedure is characterized by a steady growth in use, with the number of angiograms per year estimated to be between 300,000 and 400,000; often they are carried out in facilities whose cardiac catheterization rates are low; fewer than 300 per year. Population-based use rates were also found for cholecystectomy and included rates for different years, geographic regions and patient characteristics.⁴⁹⁻⁵⁶ In 1980 a cholecystectomy was done on more than 20 persons out of every 10,000 in the United States. The procedure was used twice as often for women as for men. In certain census regions cholecystectomy was done more often than in others, with a ratio of high to low use of 1:3.

Efficacy

The efficacy of a procedure must be assessed by the benefit it confers on patients relative to its risks. The randomized, controlled trial is one accepted way to show a procedure's benefits and risks and to compare them with those of possibly competing techniques.

The efficacy of the coronary artery bypass graft operation was the focus of 11 randomized, controlled trials. Six investigated the efficacy of the procedure for patients with chronic stable angina.⁵⁷⁻⁶² The researchers concluded that the procedure is effective for those patients in whom angina is inadequately controlled by medical management. It also prolongs life in patients with left main coronary artery stenosis and in some patients with three-vessel disease. Four randomized, controlled trials were done to test the efficacy of a coronary artery bypass graft procedure for patients with unstable angina.

na.⁶³⁻⁶⁶ These studies showed that the incidence of anginal pain is reduced with surgical treatment, but the operation's effect on survival is less certain. Two randomized, controlled trials were done to research the efficacy of a coronary artery bypass graft procedure after an acute myocardial infarction.^{58,67} The trials were unable to confirm the operation's effectiveness in prolonging life in myocardial infarction survivors in whom angina did not develop.

Many patient groups on whom a coronary artery bypass procedure could be done were excluded from these studies, however. Very few women or patients older than 65 were included in research on the use of the operation in patients with chronic stable angina. Even fewer patients with ejection fractions under 30% were studied. Patients with severe concomitant illnesses were usually systematically excluded. No randomized, controlled trials of the efficacy of a coronary artery bypass graft operation could be found for patients who were in the acute phase of myocardial infarction; who received a second bypass operation; who survived sudden cardiac death, or who had variant angina, chest pain of uncertain origin or were asymptomatic.

We found just one randomized, controlled trial to evaluate if carotid endarterectomy prevents stroke,⁶⁸ and it failed to show the operation's efficacy. The current applicability of the study is uncertain, however, because it was done between 1961 and 1965 and medical and surgical therapies have changed since then. Also, the research concerned patients with a limited number of neurologic presentations.

Eight randomized, controlled trials provided data to support the efficacy of endoscopy for patients with acute upper gastrointestinal bleeding (for instance, Dronfield and co-

workers and Morris and associates^{7,69}); only one⁷⁰ studied patients who were endoscoped for other reasons, and it confirmed the diagnostic accuracy of the procedure when compared with radiography.

No randomized, controlled trial could be found that compared a surgical approach (either early or delayed) with a conservative medical approach (avoiding surgical treatment unless forced to operate because of a complication) in patients with acute cholecystitis. Four randomized, controlled trials were available,⁷¹⁻⁷⁴ however, on the timing of a surgical procedure (early versus delayed) for patients with acute cholecystitis; these supported an early procedure.

No randomized, controlled trials of coronary angiography were available, but a large body of literature compared one or more noninvasive cardiac studies with coronary angiography and, assuming that the angiography provided the correct diagnosis, gave data on the diagnostic accuracy of the noninvasive test. These investigations did not randomly allocate patients to differing diagnostic methods, one of which included angiography, nor did they assess outcomes for clinically homogeneous patient groups. Therefore, we could not assess the implications for the patient's health of using methods other than angiography for the diagnosis of coronary artery disease in patients with specific symptoms such as chest pain of uncertain origin or chronic stable angina.

No randomized, controlled trial was found to study the efficacy of colonoscopy, nor were data from any kind of prospectively done research available for review.

Complications

For all six procedures, data on complications were available primarily from retrospective studies or from physician surveys that tallied complication rates rather than from more rigorous research. The use of surveys probably was dictated by practical necessity. A large number of patients needs to be observed for a researcher to be confident that a low frequency of complication has occurred. The costs of obtaining large samples for prospective research are considerable; surveys and retrospective studies are less expensive. Despite this possible justification, the literature revealed many inadequacies in presenting information on the complications of a procedure.

Research on the complications from endoscopy and colonoscopy basically ceased to be reported after 1977. Because of this, our estimates of the incidence of complications from these procedures may have been inflated; improvements in instrumentation and physicians' experience may have resulted in decreased complication rates.

A more serious problem with the data in the literature on complication rates was the failure of many researchers to describe carefully the symptoms for which they did a procedure. About 98% of the data on the complications from endoscopy, for example, came from surveys of physicians in which the symptoms—including the presence or absence of bleeding—for which the procedure was done were not specified.⁷⁵⁻⁷⁷ When reviewing the complications of cholecystectomy, we encountered a similar problem. In several articles, the complications for cholecystectomy were described, but the clinical presentations were not.⁷⁸⁻⁸⁰ As a result, we could not tell if relatively low rates of infection and short hospital stays reported in certain papers accurately reflected good care or if they might have resulted from a preponderance of elec-

tive operations or those carried out mainly in relatively healthy, young patients.

Finally, data on complications in most studies of carotid endarterectomy, coronary artery bypass procedure and cholecystectomy came from research that was conducted in major medical centers and teaching hospitals. We could not infer the applicability of the results to the care provided by typical physicians in typical hospitals.

Cost

Few sources of data could be found on the charges or cost of cholecystectomy,⁸⁶ coronary artery bypass grafting⁴³ or coronary angiography,⁸¹ and none were available on carotid endarterectomy. Information on charges or potential savings in the United States from using colonoscopy as opposed to a surgical procedure to remove polyps could only be obtained from four articles published between 1973 and 1975.⁸²⁻⁸⁵ Nine studies (one a randomized, controlled trial) addressed the costs of upper gastrointestinal endoscopy (see, for example, Holdsworth, Merion and Peterson and their colleagues⁸⁶⁻⁸⁸).

Discussion

Considered as a whole, the clinical literature is a helpful but not a sufficient source of information on the appropriate uses of these six procedures. The most useful were the results of randomized, controlled trials on carefully selected groups of patients. The research methods and data collection activities in other studies were sometimes unsound or explained poorly. The number of persons who participated in some investigations was often not given, and essential characteristics of patients, such as their symptoms, were also omitted. Additionally, we could not always infer from a researcher's explanation whether a study's design was retrospective or not and even where and how data were gathered.

The information we sought was often unavailable, inconclusive or contradictory. With the exception of cholecystectomy, little could be found on the costs and use of the six procedures. We found scant data on how the cardiac procedures were actually being used and contrary views on the indications for doing a carotid endarterectomy.

We are aware that our work may not contain all that is known about a procedure. We relied on published data, and some researchers may not have reported everything they did or found.⁸⁹ Also, we may have failed to uncover some published articles even though we had others check our bibliography for comprehensiveness. Despite these caveats, we have concluded that the patterns of inadequacy in the clinical literature for all six procedures are pervasive.

How might the clinical-epidemiologic approach to cost containment work best when it cannot rely on literature alone? First, vigilance is needed in interpreting the findings of reported research, a stance requiring careful screening of a study's methods. Although it is unrealistic to expect all physicians to become experts in research methods, familiarity with the available standards for conducting and reporting the results of clinical investigations^{90,91} unquestionably is desirable. Publication does not automatically guarantee the soundness of a study's finding.^{92,93}

Second, clinicians, using their experience, may be able to extrapolate findings that pertain to the appropriateness of a procedure's use in patients who have participated in a randomized, controlled trial or another rigorously done study to

patients who have not. They can also judge the appropriateness of indications for a procedure's use, although unanimity must not be expected. In one study, three separate panels of physicians used a modified Delphi approach^{94,95} to evaluate the appropriateness of hundreds of specific indications for coronary angiography, coronary artery bypass graft procedure, carotid endarterectomy, colonoscopy or upper gastrointestinal endoscopy.⁹⁶ Although agreement among panelists was enhanced by using a highly structured consensus method, disagreement on appropriateness was found for as many as 30% of the indications. Among the explanations for this relatively high level of disagreement was the scarcity of experimentally derived data about the risks and benefits of a procedure's use.

Clinical researchers can be of great assistance in assuring that health funds are wisely spent. The long-run success of the clinical-epidemiologic approach depends on such researchers targeting their efforts to the need for information revealed by this study of the inadequacies in the literature. If published information were more complete, it might be easier for clinicians to recommend cuts in inappropriate services while fighting to maintain an increased access to the appropriate ones.

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