Difficult Decisions in Thoracic Surgery

Mark K. Ferguson, Ed.

Difficult Decisions in Thoracic Surgery

An Evidence-Based Approach

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To Phyllis, a decision that has withstood the test of time.

Preface

Why do thoracic surgeons need training in decision making? Many of us who have weathered harrowing residencies in surgery feel that, after such experiences, decision making is a natural extension of our selves. While this is no doubt true, *correct* decision making is something that many of us have yet to master. The impetus to develop a text on evidence-based decision making in thoracic surgery was stimulated by a conference for cardiothoracic surgical trainees developed in 2004 and sponsored by the American College of Chest Physicians. During that conference it became clear that we as thoracic surgeons are operating from a very limited fund of true evidence-based information. What was also clear was the fact that many of the decisions we make in our everyday practices are not only uninformed by evidence-based medicine, but often are contradictory to existing guidelines or evidence-based recommendations.

The objectives of this book are to explain the process of decision making, both on the part of the physician and on the part of the patient, and to discuss specific clinical problems in thoracic surgery and provide recommendations regarding their management using evidence-based methodology. Producing a text that will purportedly guide experienced, practicing surgeons in the decision-making process that they are accustomed to observe on a daily basis is a daunting task. To accomplish this it was necessary to assemble a veritable army of authors who are widely considered to be experts in their fields. They were given the unusual (to many of them) task of critically evaluating evidence on a well-defined topic and provide two opinions regarding appropriate management of their topic: one based solely on the existing evidence, and another based on their prevailing practice, clinical experience, and teaching. Most authors found this to be an excellent learning experience. It is hoped that the readers of this book will be similarly enlightened by its contents.

How should a practicing surgeon use this text? As is mentioned in the book, wholesale adoption of the stated recommendations will serve neither physician nor patient well. The reader is asked to critically examine the material presented, assess it in the light of his or her own practice, and integrate the recommendations that are appropriate. The reader must have the understanding that surgery is a complex, individualized, and rapidly evolving specialty. Recommendations made today for one patient may not be appropriate for that same patient in the same situation several years hence. Similarly, one recommendation will not serve all patients well. The surgeon must use judgment and experience to adequately utilize the guidelines and recommendations presented herein.

To produce a text with timely recommendations about clinical situations in a world of rapidly evolving technology and information requires that the editor, authors, and publisher work in concert to provide a work that is relevant and up-to-date. To this end I am grateful to the authors for producing their chapters in an extraordinarily timely fashion. My special thanks go to Melissa Morton, Senior Editor at Springer, for her rapid processing and approval of the request to develop this book, and to Eva Senior, Senior Editorial Assistant at Springer, for her tireless work in keeping us all on schedule. My thanks go to Kevin Roggin, MD, for sharing the T.S. Eliot lines and the addendum to them. Finally, the residents with whom I have had the opportunity and privilege to work during the past two decades continually reinforce the conviction that quality information is the key to improved patient care and outcomes.

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Part 1
Background

1
Introduction

Mark K. Ferguson

Dorothy Smith, an elderly and somewhat portly woman, presented to her local emergency room with chest pain and shortness of breath. An extensive evaluation revealed no evidence for coronary artery disease, congestive heart failure, or pneumonia. A chest radiograph demonstrated a large air–fluid level posterior to her heart shadow, a finding that all thoracic surgeons recognize as being consistent with a large paraesophageal hiatal hernia. The patient had not had similar symptoms previously. Her discomfort was relieved after a large eructation, and she was discharged from the emergency room a few hours later. When seen several weeks later in an outpatient setting by an experienced surgeon, who reviewed her history and the data from her emergency room visit, she was told that surgery is sometimes necessary to repair such hernias. Her surgeon indicated that the objectives of such an intervention would include relief of symptoms such as chest pain, shortness of breath, and postprandial fullness, and prevention of catastrophic complications of giant paraesophageal hernia, including incarceration, strangulation, and perforation. Ms. Smith, having recovered completely from her episode of a few weeks earlier, declined intervention, despite her surgeon's strenuous encouragement.

She presented to her local emergency room several months later with symptoms of an incarcerated hernia and underwent emergency surgery to correct the problem. The surgeon found a somewhat ischemic stomach and had to decide whether to resect the stomach or just repair the hernia. If resection was to be performed, an additional decision was whether to reconstruct immediately or at the time of a subsequent operation. If resection was not performed, the surgeon needed to consider a variety of options as part of any planned hernia repair: whether to perform a gastric lengthening procedure; whether a fundoplication should be constructed; and whether to reinforce the hiatal closure with nonautologous materials. Each of these intraoperative decisions could importantly affect the need for a subsequent reoperation, the patient's immediate survival, and her long-term quality of life. Given the dire circumstances that the surgeon was presented with during the emergency operation, perhaps it would have been optimal if the emergent nature of the operation could have been avoided entirely. In retrospect, which was correct in this hypothetical situation, the recommendation of the surgeon or the decision of the patient?

Decisions are the stuff of everyday life for all physicians; for surgeons, life-altering decisions often must be made on the spot, frequently without what many might consider to be necessary data. The ability to make such decisions confidently is the hallmark of the surgeon. However, decisions made under such circumstances are often not correct or even well reasoned. All surgeons (and many of their spouses) are familiar with the saying "...often wrong, but never in doubt." As early as the 14th century, physicians were cautioned never to admit uncertainty. Arnauld of Villanova wrote that, even when in doubt, physicians should look and act authoritative and confident.[1] In fact, useful data do exist that impact on many of the individual decisions regarding elective and emergent management of giant paraesophageal hernia outlined above. Despite the existence of these data, surgeons tend to make decisions based on their own personal experience, anecdotal tales of good or bad outcomes, and unquestioned adherence to dictums from their mentors or other respected leaders in the field, often to the exclusion of objective data. It is believed that only 15% of medical decisions are scientifically based,[2] and it is possible that an even lower percentage of thoracic surgical decisions are so founded. With all of our modern technological, data processing, and communication skills, why do we still find ourselves in this situation?

1.1. Early Surgical Decision Making

Physicians' diagnostic capabilities, not to mention their therapeutic armamentarium, were quite limited until the middle to late 19th century. Drainage of empyema, cutting for stone, amputation for open fractures of the extremities, and mastectomy for cancer were relatively common procedures, but few such conditions were diagnostic dilemmas. Surgery, when it was performed, was generally indicated for clearly identified problems that could not be otherwise remedied. Some surgeons were all too mindful of the warnings of Hippocrates: "…physicians, when they treat men who have no serious illness,…may commit great mistakes without producing any formidable mischief…under these circumstances, when they commit mistakes, they do not expose themselves to ordinary men; but when they fall in with a great, a strong, and a dangerous disease, then their mistakes and want of skill are made apparent to all. Their punishment is not far off, but is swift in overtaking both the one and the other."[3] Others took a less considered approach to their craft, leading Hunter to liken a surgeon to "an armed savage who attempts to get that by force which a civilized man would get by stratagem."[4]

Based on small numbers of procedures, lack of a true understanding of pathophysiology, frequently mistaken diagnoses, and the absence of technology to communicate information quickly, surgical therapy until the middle of the 19th century was largely empirical. For example, by this time fewer than 90 diaphragmatic hernias had been reported in the literature, most of them having been diagnosed postmortem as a result of gastric or bowel strangulation and perforation.[5] Decisions were based on dogma promulgated by word of mouth. This has been termed the "ancient era" of evidence-based medicine.[6]

An exception to the empirical nature of surgery was the approach espoused by Hunter in the mid-18th century, who suggested to Jenner, his favorite pupil, "I think your solution is just, but why think? Why not try the experiment?"[4] Hunter challenged the established practices of bleeding, purging, and mercury administration, believing them to be useless and often harmful. Theses views were so heretical that, 50 years later, editors added footnotes to his collected works insisting that these were still valuable treatments. Hunter and others were the progenitors of the "renaissance era" of evidence-based medicine, in which personal journals, textbooks, and some medical journal publications were becoming prominent.[6]

The discovery of X rays in 1895 and the subsequent rapid development of radiology in the following years made the diagnosis and surgical therapy of a large paraesophageal hernia, such as that described at the beginning of this chapter, commonplace. By 1908, the X ray was accepted as a reliable means for diagnosing diaphragmatic hernia, and by the late 1920s surgery had been performed for this condition on almost 400 patients in one large medical center.[7,8] Thus, the ability to diagnose a condition was becoming a prerequisite to instituting proper therapy.

This enormous leap in physicians' abilities to render appropriate ministrations to their patients was based on substantial new and valuable objective data. In contrast, however, the memorable anecdotal case presented by a master (or at least an influential) surgeon continued to dominate the surgical landscape. Prior to World War II, it was common for surgeons throughout the world with high career aspirations to travel Europe for a year or two, visiting renowned surgical centers to gain insight into surgical techniques, indications, and outcomes. In the early 20th century, Murphy attracted a similar group of surgeons to his busy clinic at Mercy Hospital in Chicago. His publication of case reports and other observations evolved into the Surgical Clinics of North America. Seeing individual cases and drawing conclusions based upon such limited exposure no doubt reinforced the concept of empiricism in decision making in these visitors. True, compared to the strict empiricism of the 19th century there were more data available upon which to base surgical decisions in the early 20th century, but information regarding objective short-term and long-term outcomes still was not readily available in the surgical literature or at surgical meetings.

Reinforcing the imperative of empiricism in decision making, surgeons often disregarded valuable techniques that might have greatly improved their efforts. It took many years for anesthetic methods to be accepted. The slow adoption of endotracheal intubation combined with positive pressure ventilation prevented safe thoracotomy for decades after their introduction into animal research. Wholesale denial of germ theory by U.S. physicians for decades resulted in continued unacceptable infection rates for years after preventive measures were identified. These are just a few examples of how ignorance and its bedfellow, recalcitrance, delayed progress in thoracic surgery in the late 19th and early 20th centuries.

1.2. Evidence-based Surgical Decisions

There were important exceptions in the late 19th and early 20th centuries to the empirical nature of surgical decision making. Among the first were the demonstration of antiseptic methods in surgery and the optimal therapy for pleural empyema. Similar evidence-based approaches to managing global health problems were developing in nonsurgical fields. Reed's important work in the prevention of yellow fever led to the virtual elimination of this historically endemic problem in Central America, an accomplishment that permitted construction of the Panama Canal. The connection between the pancreas and diabetes that had been identified decades earlier was formalized by the discovery and subsequent clinical application of insulin in 1922, leading to the awarding of a Nobel prize to Banting and Macleod in 1923. Fleming's rediscovery of the antibacterial properties of penicillin in 1928 led to its development as an antibiotic for humans in 1939, and it received widespread use during World War II. The emergency use of penicillin, as well as new techniques for fluid resuscitation, were said to account for the unexpectedly high rate of survival among burn victims of the Coconut Grove nightclub fire in Boston in 1942. Similar stories can be told for the development of evidence in the management of polio and tuberculosis in the mid-20th century. As a result, the first half of the 20th century has been referred to as the "transitional era" of evidence-based medicine, in which information was shared easily through textbooks and peer-reviewed journals.[6]

Among the first important examples of the used of evidence-based medicine is the work of Semmelweiss, who in 1861 demonstrated that careful attention to antiseptic principles could reduce mortality associated with puerperal fever from over 18% to just over 1%. The effective use of such principles in surgery was investigated during that same decade by Lister, who noted a decrease in mortality on his trauma ward from 45% to 15% with the use of carbolic acid as an antiseptic agent during operations. However, both the germ theory of infection and the ability of an antiseptic such as carbolic acid to decrease the risk of infection were not generally accepted, particularly in the United States, for another decade. In 1877, Lister performed an elective wiring of a patellar fracture using aseptic techniques, essentially converting a closed fracture to an open one in the process. Under practice patterns of the day, such an operation would almost certainly lead to infection and possible death, but the success of Lister's approach secured his place in history. It is interesting to note that a single case such as this, rather than prior reports of his extensive experience with the use of antiseptic agents, helped Lister turn the tide towards universal use of antiseptic techniques in surgery thereafter.

The second example developed over 40 years after the landmark demonstration of antiseptic techniques and also involved surgical infectious problems. Hippocrates described open drainage for empyema in 229 B.C.E., indicating that "when empyema are opened by the cautery or by the knife, and the pus flows pale and white, the patient survives, but if it is mixed with blood and muddy and foul smelling, he will die."[3] There was little change in the management of this problem until the introduction of thoracentesis by Trusseau in 1843. The mortality rate for empyema remained at 50% to 75% well into the 20th century.[9] The confluence of two important events, the flu pandemic of 1918 and the Great War, stimulated the formation of the U.S. Army Empyema Commission in 1918. Led by Graham and Bell, this commission's recommendations for management included three basic principles: drainage, with avoidance of open pneumothorax; obliteration of the empyema cavity; and nutritional maintenance for the patient. Employing these simples principles led to a decrease in mortality rates associated with empyema to 10% to 15%.

1.3. The Age of Information

These surgical efforts in the late 19th and early 20th centuries ushered in the beginning of an era of scientific investigation of surgical problems. This was a period of true surgical research characterized by both laboratory and clinical efforts. It paralleled similar efforts in nonsurgical medical disciplines. Such research led to the publication of hundreds of thousands of papers on surgical management. This growth of medical information is not a new phenomenon, however. The increase in published manuscripts, and the increase in medical journals, has been exponential over a period of more than two centuries, with a compound annual growth rate of almost 4% per year (Figure 1.1).[10] In addition, the quality and utility of currently published information is substantially better than that of publications in centuries past.

Currently, there are more than 2000 publishers producing works in the general field of science, technology, and medicine. The field comprises more than 1800 journals containing 1.4 million peer-reviewed articles annually. The annual growth rate of health science articles during the past two decades is about 3%, continuing the trend of the past two centuries and adding to the difficulty of identifying useful information (Figure 1.2).[10] When confronting this large amount of published information, separating the wheat from the chaff is a daunting task. The work of assessing such information has been assumed to some extent by experts in the field who perform structured reviews of information on important issues and meta-analyses of high quality, controlled, randomized trials. These techniques have the potential to summarize results from multiple studies and, in some instances, crystallize findings into a simple, coherent statement.

An early proponent of such processes was Cochrane, who in the 1970s and 1980s suggested that increasingly limited medical resources should be equitably distributed and consist of interventions that have been shown in properly designed evaluations to be effective. He stressed the importance of using evidence from randomized, controlled trials, which were likely to provide much more reliable information than other sources of evidence.[11] These efforts ushered in an era of high-quality medical and surgical research. Cochrane was posthumously honored with the development of the Cochrane Collabora-

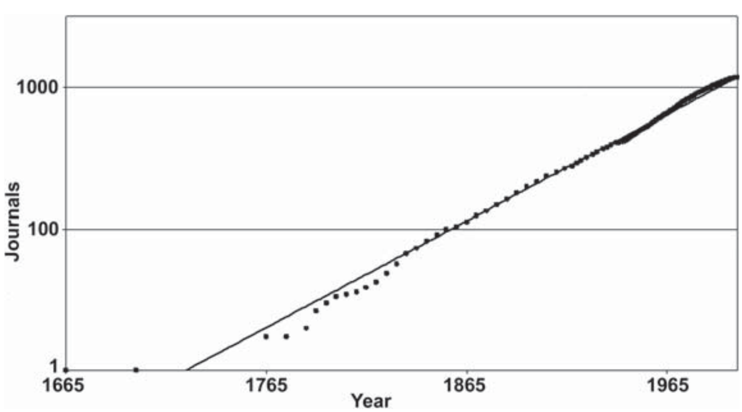

FIGURE 1.1. The total number of active refereed journals published annually. (Data from Mabe.[10])

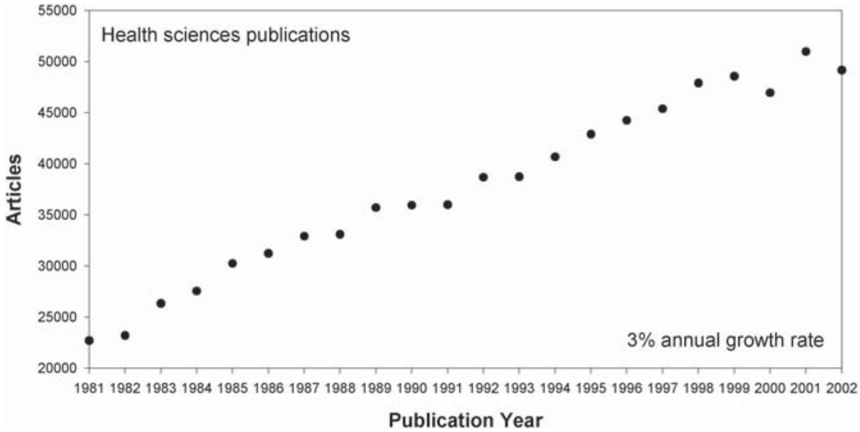

FIGURE 1.2. Growth in the number of published health science articles published annually. (Data from Mabe.[10])

tion in 1993, encompassing multiple centers in North America and Europe, which "produces and disseminates systematic reviews of healthcare interventions, and promotes the search for evidence in the form of clinical trials and other studies of the effects of interventions."[12]

Methods originally espoused by Cochrane and others have been codified into techniques for rating the quality of evidence in a publication and for grading the strength of a recommendation based on the preponderance of available evidence. This methodology is described in detail in Chapter 2. The clinical problems addressed in this book have been assessed using one of two commonly employed rating systems, one from the Scottish Intercollegiate Guidelines Network (Table 1.1) and the other from the Oxford Centre for Evidence-Based Medicine (Table 1.2).[13,14] Each has its own advantages and disadvantages, and each has been shown to function well in a variety of settings, providing consistent results that are reproducible. The latter system is explained in detail in Chapter 2.

Techniques such as those described above for synthesizing large amounts of quality information were introduced for the development guidelines for clinical activity in thoracic surgery, most commonly for the management of lung cancer, beginning in the mid-1990s. An example of these is a set of guidelines based on current standards of care sponsored by the Society of Surgical Oncology for managing lung cancer. It was written by experts in the field without a formal process of evidence collection.[15] A better technique for arriving at guidelines is the consensus statement, usually derived during a consensus conference in which guidelines based on published medical evidence are revised until members of the conference agree by a substantial majority in the final statement. The problem with this technique is that the strength of recommendations, at times, is sometimes diluted until there is little content to them. The American College of Chest Physicians recently has issued over 20 guideline summaries in a recent supplement to their journal that appear to have avoided this drawback.[16] Similar sets of guidelines have recently been published for appropriate selection of patients for lung cancer surgery,[17] for multimodality management of lung cancer,[18] and for appropriate follow-up of lung cancer patients having received potentially curative therapy,[19] to name but a few. In addition to lung cancer management, guidelines have been developed for other areas of interest to the thoracic surgeon.

Despite the enormous efforts expended by professional societies in providing evidence-based algorithms for appropriate management of patients, adherence to these published guidelines, based on practice pattern reports, is disappointing. Focusing again on surgical management of lung cancer, there is strong evidence that standard procedures incorporated into surgical guidelines for lung cancer are widely ignored. For example, fewer than 50% of patients undergoing mediastinoscopy for nodal staging have lymph node biopsies performed. In patients undergoing major resection for lung cancer, fewer than 60% have mediastinal lymph nodes biopsied or dissected.[20] There are also important regional variations in the use of standard staging techniques and in the use of surgery for stage I lung cancer patients, patterns of activity that are also related to race and socioeconomic status.[21–23] Failure to adhere to accepted standards of care for surgical lung cancer patients results in higher postoperative mortality rates; whether long-term survival is adversely affected has yet to be determined.[24,25]

Table 1.1. Scottish Intercollegiate Guidelines Network evidence levels and grades of recommendations.

Level	Description
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias.
1–	Meta-analyses, systematic reviews or RCTs, or RCTs with a high risk of bias
2++	High-quality systematic reviews of case-control or cohort studies or High-quality case-control of cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2–	Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion
GradeH	**Description**
A	At least one meta-analysis, systematic review, or RCT rated as 1++ and directly applicable to the target population or A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results or Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results or Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4 or Extrapolated evidence from studies rated as 2+

Abbreviation: RCT, randomized, controlled trial.
Source: Harbour and Miller.[13]

Table 1.2. Oxford Centre for Evidence-Based Medicine levels of evidence and grades of recommendations for therapeutic interventions.

Level	Description
1a	SR (with homogeneity) of RCTs
1b	Individual RCT (with narrow confidence interval)
1c	All or none
2a	SR (with homogeneity) of cohort studies
2b	Individual cohort study (including low quality RCT; e.g., < 80% follow-up)
2c	"Outcomes" research; ecological studies
3a	SR (with homogeneity) of case-control studies
3b	Individual case-control studies
4	Case series (and poor quality cohort and case-control studies)
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"
Grade	**Description**
A	Consistent level 1 studies
B	Consistent level 2 or 3 studies or extrapolations from level 1 studies
C	Level 4 studies or extrapolations from level 2 or 3 studies
D	Level 5 evidence or troublingly inconsistent or inconclusive studies at any level

Abbreviations: RCT, randomized, controlled trials; SR, systematic review.
Source: Oxford Centre for Evidence-Based Medicine.[14]

The importance of adherence to accepted standards of care, particular those espoused by major professional societies, such as the American College of Surgeons, The Society of Surgical Oncology, the American Society of Clinical Oncology, the American Cancer Society, the National Comprehensive Cancer Network, is becoming clear as the United States Centers for Medicare and Medicaid Services develops processes for rewarding adherence to standards of clinical care.[26] This underscores the need for surgeons to become familiar with evidence-based practices and to adopt them as part of their daily routines. What is not known is whether surgeons should be rewarded for their efforts in following recommended standards of care, or for the outcomes of such care. Do we measure the process, the immediate success, or the long-term outcomes? If outcomes are to be the determining factor, what outcomes are important? Is operative mortality an adequate surrogate for quality of care and good results? Whose perspective is most important in determining success, that of the patient, or that of the medical establishment?

1.4. The Age of Data

We have now entered into an era in which the number of data available for studying problems and outcomes in surgery is truly overwhelming. Large clinical trials involving thousands of subjects render databases measured in megabytes. As an example, for the National Emphysema Treatment Trial (NETT), which entered over 1200 patients, initial data collection prior to randomization consisted of over 50 pages of data for each patient.[27] Patients were subsequently followed for up to 5 years after randomization, creating an enormous research database. The size of the NETT database is dwarfed by other databases in which surgical information is stored, including the National Medicare Database, the Surveillance Epidemiology and End Results (SEER; 170,000 new patients annually), Nationwide Inpatient Sample (NIS; 7 million hospital stays annually), and the Society of Thoracic Surgeons (STS) database (1.5 million patients).

Medical databases are of two basic types: those that contain information that is primarily clinical in nature, especially those that are developed specifically for a particular research project such as the NETT, and administrative databases that are maintained for other than clinical purposes but that can be used in some instances to assess clinical information and outcomes, an example of which is the National Medicare Database. Information is organized in databases in a hierarchical structure. An individual unit of data is a field; a patient's name, address, and age are each individual fields. Fields are grouped into records, such that all of one patient's fields constitute a record. Data in a record have a one-to-one relationship with each other. Records are complied in relations, or files. Relations can be as simple as a spreadsheet, or flat file, in which there is a one-to-one relationship between each field. More complex relations contain many-to-one, or one-to-many, relationships among fields, relationships that must be accessed through queries rather than through simple inspection. Examples are multiple diagnoses for a single patient or multiple patients with a single diagnosis.

In addition to collection of data such as those above that are routinely generated in the process of standard patient care, new technological advances are providing an exponential increase in the amount of data generated by standard studies. An example is the new 64-slice computed tomography (CT) scanner, which has quadrupled the amount of information collected in each of the *x*–*y*–*z*-axes as well as providing temporal information during a routine CT scan. The vast amount of additional information provided by this technology has created a revolutionary, rather than evolutionary, change in diagnostic radiology. Using this technology, virtual angiograms can be performed, three-dimensional reconstruction of isolated anatomical entities is possible, and radiologists are discovering more abnormalities than clinicians know what to do with.

A case in point is the use of CT as a screening test for lung cancer. Rapid low-dose CT scans were introduced in the late 1990s and were quickly adopted as a means for screening high-risk patients for lung cancer. The results of this screening have been mixed. Several reports suggest that the number of radiographic abnormalities identified is high compared to the number of clinically important findings. For example, in the early experience at the Mayo Clinic, over 1500 patients were enrolled in an annual CT screening trial, and in the 4 years of the trial, over 3100 indeterminate nodules were identified, only 45 of which were found to be malignant.[28] Many additional radiographic abnormalities other than lung nodules were also identified.

1.5. What Lies in the Future?

What do we now do with the plethora of information that is being collected on patients? How do we make sense of these gigabytes of data? It may be that we now have more information than we can use or that we even want. Regardless, the trend is clearly in the direction of collecting more, rather than less, data, and it behooves us to make some sense of the situation. In the case of additional radiographic findings resulting from improved technology, new algorithms have already been refined for evaluating nodules and for managing their follow-up over time, and have yielded impressive results in the ability of these approaches to identify which patients should be observed and which patients should undergo biopsy or surgery.[29] What, though, of the reams of numerical and other data that pour in daily and populate large databases? When confronting this dilemma, it useful to remember that we are dealing with an evolutionary problem, the extent of which has been recognized for decades. Eliot aptly described this predicament in *The Rock* (1934), lamenting:[30]

Where is the wisdom we have lost in knowledge?
Where is the knowledge we have lost in information?

To those lines one might add:

Where is the information we have lost in data?

One might ask, in the presence of all this information, are we collecting the correct data? Evidence-based guidelines regarding indications for surgery, surgical techniques, and postoperative management are often lacking. We successfully track surgical outcomes of a limited sort, and often only in retrospect: complications, operative mortality, and survival. We do not successfully track patient's satisfaction with their experience, the quality of life they are left with as a result of surgery, and whether they would make the same decision regarding surgery if they had to do things over again. Perhaps these are important questions upon which physicians should focus. In addition to migrating towards patient-focused rather than institutionally focused data, are we prepared to take the greater leap of addressing more important issues requiring data from a societal perspective, including cost effectiveness and appropriate resource distribution (human and otherwise) and utilization? This would likely result in redeployment of resources towards health prevention and maintenance rather than intervention. Such efforts are already underway, sponsored not by medical societies and other professional organizations, but by those paying the increasingly unaffordable costs of medical care.

Insurance companies have long been involved, through their actuarial functions, in identifying populations who are at high risk for medical problems, and it is likely that they will extend this actuarial methodology into evaluating the success of surgical care on an institutional and individual surgeon basis as more relevant data become available. The Leapfrog Group, representing a consortium of large commercial enterprises that covers insurance costs for millions of workers, was founded to differentiate levels of quality of outcomes for common or very expensive diseases, thereby potentially limiting costs of care by directing patients to better outcome centers. These efforts have three potential drawbacks from the perspective of the surgeon. First, decisions made in this way are primarily fiscally based, and are not patient focused. Second, policies put in place by payers will undoubtedly lead to regionalization of health care, effectively resulting in de facto restraint of trade affecting those surgeons with low individual case volumes or comparatively poor outcomes for a procedure, or who work in low volume centers. Finally, decisions about point of care will be taken from the hands of the patients and their physicians. The next phase of this process will be requirements on the part of payers regarding practice patterns, in which penalties are incurred if proscribed patterns are not followed, and rewards are provided for following such patterns, even if they lead to worse outcomes in an individual patient.

Physicians can retain control of the care of their patients in a variety of ways. First, they must make decisions based on evidence and in accordance with accepted guidelines and recommendations. This text serves to provide an outline for only a fraction of the decisions that are made in a thoracic surgical practice. For many of the topics in this book there are preciously few data that can be used to formulate a rational basis for a recommendation. Practicing physicians must therefore become actively involved in the process of developing useful evidence upon which decisions can be made. There are a variety of means for doing this, including participation in randomized clinical trials, entry of their patient data (appropriately anonymized) into large databases for study, and participation in consensus conferences aimed at providing useful management guidelines for problems in which they have a special interest. Critical evaluation of new technology and procedures, rather than merely adopting what is new to appear to the public and referring physicians that one's practice is cutting edge, may help reduce the wholesale adoption of what is new into patterns of practice before its value is proven.

1.6. Conclusion

Decisions are the life blood of surgeons. How we make decisions affects the immediate and long-term outcomes of care of individual patients. Such decisions will also, in the near future, affect our reimbursement, our referral patterns, and possibly our privileges to perform certain operations. Most of the decisions that we currently make in our surgical practices are insufficiently grounded in adequate evidence. In addition, we tend to ignore published evidence and guidelines, preferring to base our decisions on prior training, anecdotal experience, and intuition as to what is best for an individual patient.

Improving the process of decision making is vital to our patients' welfare, to the health of our specialty, and to our own careers. To do this we must thoughtfully embrace the culture of evidence-based medicine. This requires critical appraisal of reported evidence, interpretation of the evidence with regards to the surgeon's target population, and integration of appropriate information and guidelines into daily practice. Constant review of practice patterns, updating management algorithms, and critical assessment of results is necessary to maintain optimal quality care. Documentation of these processes must become second nature. Unless individual surgeons adopt leadership roles in this process and thoracic surgeons as a group buy into this concept, we will find ourselves marginalized by outside forces that will distance us from our patients and discount our expertise in making vital decisions.

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2
Evidence-Based Medicine: Levels of Evidence and Grades of Recommendation

Andrew J. Graham and Sean C. Grondin

Evidenced-based medicine (EMB) is a philosophical approach to clinical problems introduced in the 1980s by a group of clinicians with an interest in clinical epidemiology at McMaster University in Canada. The concepts associated with this approach have been widely disseminated and described by many as a paradigm shift. Others, however, have debated the usefulness of this approach.

In this chapter, we will provide a definition and rationale for an evidence-based approach to clinical practice. The central role of systems that grade clinical recommendations and levels of evidence will be outlined. Readers interested in a more in-depth review are advised to consult the *Users' Guide to the Medical Literature: A Manual for Evidence-Based Clinical Practice.*[1]

2.1. What Is Evidence-Based Medicine

Evidence-based medicine is a philosophical approach to clinical problems that has arisen from the physician's need to offer proven therapies to patients. In 1996, Sackett and colleagues more formally defined EBM as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."[2] The goal of this approach is to be aware of the evidence supporting a particular approach to a clinical problem, its soundness, and the strength of its inferences. More recently, the term *evidence-based clinical practice* (EBCP) has been used instead of EBM to indicate that this approach is useful in a variety of disciplines. In this chapter the terms are used interchangeably.

Two fundamental principles of EBM have been proposed.[1] The first is that evidence alone is never enough to guide clinical decision making. Clinical expertise is required to place the evidence in context and advise individual patients while considering their unique values and preferences. The second principle is that a hierarchy of evidence exists that is determined by the soundness of the evidence and the strength of the inferences that can be drawn from it.

It has been recognized that clinicians can embrace the philosophy of EBM either as practitioners of EBM or as evidence users.

A practitioner would adhere to the following five steps:

1. Form clinical questions so that they can be answered.
2. Search for the best external evidence for its validity and importance.
3. Clinically appraise that evidence for its validity and importance.
4. Apply it to clinical practice.
5. Self-evaluate performance as a practitioner of evidence-based medicine.

The evidence user searches for pre-appraised or preprocessed evidence in order to use bottom-line summaries to assist patients in making decisions about clinical care.

2.2. Why Use an Evidence-Based Approach?

Proponents of EBCP report that the advantages to the physician who use an EBCP approach are that the practitioner acquires the ability to obtain current information, is able to perform a direct review of the evidence, and utilizes a interactive form of continuing medical education.[3]

2.2.1. Obtain Current Evidence

The traditional method of acquiring information has been the review of textbooks and ongoing review of medical journals. Traditional texts have been shown to go out of date quickly. In one study, for example, the delay in the recommendation of thrombolytic therapy for myocardial infarction was up to 10 years from when the published literature suggested it was advisable.[4] Due to the huge number and variety of journals, however, it is challenging even for the most diligent practitioner to stay current. With the development of modern technology that allows easy and rapid access to Medline and other full-text rapid internet access sites, an increasing number of busy practitioners have been able to obtain current evidence.

2.2.2. Direct Review of Evidence

Developing and maintaining critical assessment skills is essential in order to have an EBCP. The ability to perform a direct review of the evidence by the individual practitioner is felt to be a superior method for appraising the literature compared to traditional review articles by experts.[5] In many instances, reviews by experts have been revealed to be of low scientific quality and felt to be influenced unfavorably by potentially unsystematic hierarchal authority. Given the time required to critically appraise the literature, however, preprocessed sources of EBM have been necessary for most surgeons to incorporate EBM into their practice.

2.2.3. Interactive Learning

Many consider an evidence-based approach to clinical practice an interactive form of learning designed to improve physician performance. Studies designed to examine the effectiveness of continuing medical education have found that traditional didactic approaches are inferior to interactive forms of learning at changing physician performance.[6] Once the learner has acquired the necessary skills for EBCP, interactions with students and fellow learners reinforces the active process of learning and becomes the starting point for self-appraisal.[7]

Ironically, the evidence that EBM works is from observational studies that have suggested that recommendations arising from an evidence-based approach are more consistent with the actual evidence than traditional approaches.[4] The second piece of evidence suggested to demonstrate the effectiveness of EBM is gathered from studies that show that those patients who get the treatment supported by high-quality evidence have better outcomes than those who do not.[8,9]

2.3. What Is the Role of Grades of Recommendation and Levels of Evidence?

An evidence-based approach to clinical practice is said to have two fundamental principles. First, evidence alone is never enough to make a clinical decision, and, second, a hierarchy of evidence exists to guide decision making.

The proponents of an evidence-based approach define evidence very broadly as any empirical observation about the apparent relation between events. Thus, evidence can come from unsystematic clinical observations of individual clinicians to systematic reviews of multiple randomized clinical trials. The different forms of evidence may each provide recommendations that result in good outcomes for patients but it is clear that some forms of evidence are more reliable than others in giving guidance to surgeons and their patients. It is for this reason that a hierarchy of the strength of evidence has been proposed to further guide decision making. The assumption is that the stronger the evidence the more likely the proposed treatment or diagnostic test will lead to the predicted result.