Difficult Decisions in Surgery:
An Evidence-Based Approach 1

Mark K. Ferguson *Editor*

Difficult Decisions in Thoracic Surgery

An Evidence-Based Approach

Third Edition

Springer

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To Phyllis – I could not have hoped for a better partner on this journey.

Preface

I am pleased to offer readers Edition 3 of *Difficult Decisions in Thoracic Surgery*. The series was planned to include new editions every 3–4 years, and this volume follows on the heels of two successful prior editions. I am grateful for the positive feedback from many readers who use the information in these books to help guide their clinical practices and for the compliments from educators who found the data and discussions valuable for their trainees.

The format of this volume is similar to that of the past two editions. A table of contents was developed that focused on current areas of controversy in general thoracic surgery, and authors with recognized expertise were invited to examine evidence relevant to the controversies. Their charge was to develop best practice recommendations based on published evidence, and to also provide a statement as to their personal approaches to these challenging clinical topics. One change for this edition was that authors were asked to construct their reviews based on PICO (patient population, intervention, comparator group, and outcomes measured) formatting, helping to clarify the question for the author/reader and to direct the appropriate literature search and analysis.

The authors were asked to work within a very tight timetable to ensure that the content was as up-to-date as possible. In fact, the author list and table of contents were developed less than a year before the publication date of this volume. Creating a print publication that involves so many moving parts in such a short time frame speaks to the dedication of the authors and the publisher to the concept of evidence-based medicine. They recognize the need for timely and accurate information to inform practicing physicians. I am grateful for their invaluable contributions.

Overall, 35 of the 55 clinical chapters in this volume are new compared to Edition 2, and all of the remaining 20 chapters were written by new authors. When viewed collectively, the three editions comprise over 100 unique clinical topics authored by over 140 senior authors, which makes the series a great resource for surgeons and trainees.

The success of these editions has engendered a plan to publish similar volumes in a newly developed series titled “Difficult Decisions in Surgery”. The current volume is the first of the series. We hope to publish 3–4 volumes annually,

ultimately covering a dozen subspecialty areas in great general surgery. The volumes will be edited by recognized authorities in their fields and new editions of each volume will be published every 3–4 years with updated information and new clinical topics. This will result in an entire library of up-to-date information of immediate use to specialty surgeons around the world. I envision that the series will serve as a teaching aid, an invaluable clinical tool, and as a source of inspiration for clinical research.

As always, I am grateful to my colleagues nationally and internationally for their friendship and cooperation. I am indebted to our trainees, who continue to ask important questions that illustrate the wide gaps that exist in our clinical knowledge. The ongoing pursuit by these esteemed professionals of evidence fostering excellence is the inspiration for this work.

Chicago, IL, USA
May, 2014

Mark K. Ferguson, MD

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Chapter 1
Introduction

Mark K. Ferguson

Introduction

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

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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 non-autologous 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, it would have been optimal if the emergent nature of the operation could have been avoided entirely. In retrospect, which was more 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 fourteenth 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 could have an impact on many of the individual decisions regarding elective and emergent management of the giant paraesophageal hernia scenario 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?

Early Surgical Decision Making

Physicians' diagnostic capabilities, not to mention their therapeutic armamentarium, were quite limited until the middle to late nineteenth 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 nineteenth century was largely empiric. For example, by that 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 empiric nature of surgery was the approach espoused by Hunter in the mid-eighteenth 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. These 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 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 to Europe for a year or two, visiting renowned surgical centers to gain insight into surgical techniques, indications, and outcomes. In the early twentieth 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 nineteenth century there were more data available upon which to base surgical decisions in the early twentieth 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 US 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 nineteenth and early twentieth centuries.

Evidence-Based Surgical Decisions

There were important exceptions in the late nineteenth and early twentieth centuries to the empiric 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 non-surgical 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-twentieth century. As a result, the first half of the twentieth 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 BC, 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 is 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 50–75 % well into the twentieth century [9]. The confluence of two important events, the flu pandemic of 1918 and the Great War, stimulated the formation of the US 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 simple principles led to a decrease in mortality rates associated with empyema to 10–15 %.

The Age of Information

These surgical efforts in the late nineteenth and early twentieth 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 non-surgical 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 (Fig. 1.1) [10]. In addition, the quality and utility of currently published information is substantially better than that of publications in centuries past.

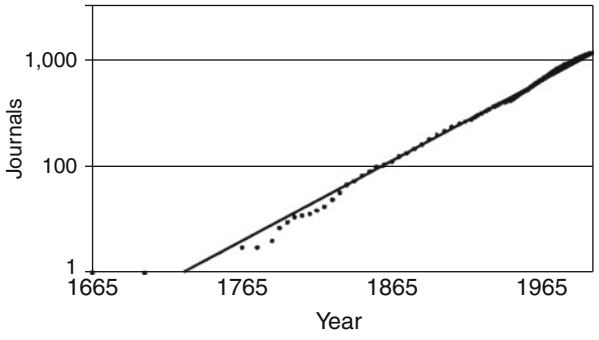

Fig. 1.1 The total number of active refereed journals published annually (Data from Mabe [10])

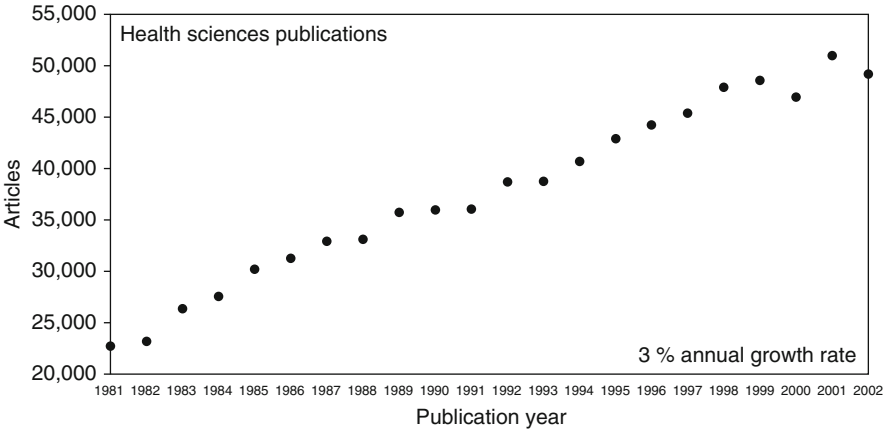

Fig. 1.2 Growth in the number of published health science articles published annually (Data from Mabe [10])

Currently there are more than 2,000 publishers producing works in the general field of science, technology, and medicine. The field comprises more than 1,800 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 (Fig. 1.2) [10]. There is also a trend towards decentralization of publication of biomedical data, which offers challenges to identifying useful information that is published outside of what are considered traditional journals [11]. For example, publication rates of clinical trials relevant to certain specialties vary from one to seven trials *per day* [12]. 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 [13]. These efforts ushered in an era of high quality medical and surgical research. Cochrane was posthumously honored with the development of the Cochrane Collaboration in 1993, encompassing multiple centers in North America and Europe, with the purpose of "helping healthcare providers, policy makers, patients, their advocates and carers, make well-informed decisions

about human health care by preparing, updating and promoting the accessibility of Cochrane Reviews [14]."

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. In accord with this, the clinical problems addressed in this book have been assessed using a modification of a single rating system (GRADE) that is outlined and updated in Chap. 2 [15].

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 what were then 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 [16]. A better technique for arriving at guidelines is the consensus statement, usually derived during a consensus process in which guidelines based on published medical evidence are revised until members of the conference agree by a substantial majority in the final statement. An example of this iterative structure is the Delphi process [17]. The problem with this technique is that the strength of recommendations, at times, is sometimes diluted until there is little content to them. Some organizations that appear to have avoided this pitfall in the general of guidelines of interest to thoracic surgeons include The American College of Chest Physicians, the Society of Thoracic Surgeons, the European Society of Thoracic Surgeons, the European Respiratory Society, the American Thoracic Society, the National Comprehensive Cancer Network, the Society of Clinical Oncology, the British Thoracic Society, and the Society of Surgical Oncology, to name but a few.

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 [18]. Only one-third of physicians routinely assess diffusing capacity in lung cancer patients who are candidates for lung resection in Europe, and in the United States fewer than 60 % of patients who undergo major lung resection for cancer have diffusing capacity measured [19, 20]. Even at centers with expertise in preoperative evaluation adherence to evaluation algorithms can be challenging, especially for higher risk patients [21]. 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 [22, 23]. Failure to adhere to accepted standards of care for surgical lung cancer patients results in higher postoperative mortality rates [24, 25], and the

selection of super specialists for one's lung cancer surgery confers an overall long-term survival advantage [26].

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. 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?

The Age of Data

We have now entered into an era in which the amount 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 1,200 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), Nationwide Inpatient Sample (NIS), the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), and the Society of Thoracic Surgeons (STS) database. Other foreign national and international databases contain similar large amounts of information.

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 compiled 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.