

Difficult Decisions in Surgery:
An Evidence-Based Approach

J. Michael Millis
Jeffrey B. Matthews *Editors*

Difficult Decisions in Hepatobiliary and Pancreatic Surgery

An Evidence-Based Approach

 Springer

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Editors

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Preface

We are excited to present to the hepatobiliary and pancreatic multidisciplinary community a new format in assessing and making decisions for our patients. This volume expands on the successful editions of *Difficult Decisions in Thoracic Surgery*. The success of those editions has stimulated the University of Chicago surgical faculty to develop a series of *Difficult Decisions in XXX Surgery*. The *Difficult Decisions in Hepatobiliary and Pancreatic Surgery* volume is the first of several to be published over the next several years. Given that many difficult decisions in this field required multidisciplinary input, we have asked a number of leaders from interventional radiology, intervention endoscopy, gastroenterology/hepatology, and diagnostic radiology to provide and analyze the strength of the data regarding the underlying diseases, diagnostics, and the nonoperative therapy.

The format of this book follows its predecessor. The table of contents was developed that reflects the difficult decisions faced by busy, thoughtful surgeons specializing in the field of hepatobiliary and pancreatic surgery on controversial issues. We invited authors with national and international reputations on the specific topics to examine the evidence that hope to inform us on the correct path. When possible, we asked the authors to suggested best practice approaches to these challenging topics. We asked the authors to develop a PICO table (patient population, intervention, comparator group, and outcomes measured) to crystallize the question and data relevant to the decision.

As this concept is new to hepatobiliary and pancreatic surgery, all of the chapters presented are new and up to date with recent literature searches. The literature search terms are provided so that new information relevant to the topic can be easily identified as time progresses.

We are grateful to our busy colleagues who agreed to contribute to this volume and the publisher for supporting this volume as well as the entire planned series. As we know many of these difficult questions are initially asked by our trainees and

students who stimulate us to think of different approaches and evaluate the evidence of our current decisions. Each of the authors in this volume epitomize the constant effort to evaluate all the current evidence to make the correct decisions and provide the best clinical care for our patients.

Chicago, IL, USA

J. Michael Millis
Jeffrey B. Matthews

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Chapter 1

Finding and Appraising the Evidence: EBM and GRADE

Sadeesh K. Srinathan

Abstract This chapter provides an overview of the principles of evidence based medicine (EBM) which will assist in making difficult decisions in the face of incomplete and inadequate evidence. The steps of searching for the evidence using the PICO format and an overview of the study design types which make up the body evidence will be discussed. A more detailed treatment of the GRADE system to make explicit the decisions on the quality of evidence and the nature of recommendations for interventions will be provided.

Keywords Evidence based medicine • EBM • GRADE • PICO

Introduction

Surgeons routinely make difficult decisions. In many cases, the difficulty lies in the need to make these decisions in the face of incomplete or unreliable information. An example of this in an individual patient is deciding to perform an exploratory laparotomy for an acute abdomen where the evidence from diagnostic studies may be incomplete or contradictory. Another example, in terms of policy, would be to decide on the appropriateness of screening for occult malignancies where the evidence for early detection may be closely matched by evidence for undesirable events such as overtreatment.

In this book, difficult scenarios commonly encountered by the hepatobiliary surgeon are presented. The authors lay out the available evidence and make a recommendation as to the appropriate responses in these scenarios. They have followed the principles of evidence based medicine in order to come to their recommendations

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and the purpose of this introductory chapter is to present an overview of the process which led their recommendations.

The phrase Evidence Based Medicine (EBM) came into widespread use after 1992 following a publication by Guyatt et al. [5], and is now commonly agreed to mean: ‘...the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research’ it also means that ‘... thoughtful identification and compassionate use of individual patients’ predicaments, rights, and preferences in making clinical decision...’ [13].

The practice of EBM can be carried out by using the following principles: (1) ask a clinical question, (2) locate the evidence, (3) appraise and synthesize the evidence, and (4) apply the evidence [12].

Ask the Clinical Question

On the face of it, asking the clinical question is straightforward. A patient problem is presented and a question arises. For example, Mrs. Smith is presenting with painless jaundice and a diagnosis of periampullary carcinoma. In considering the surgical options, you consider whether a pylorus preserving pancreaticoduodenectomy rather than a standard Whipple procedure should be performed.

Going directly to Google with the key words “pylorus preserving pancreaticoduodenectomy”, we obtain 47,900 hits, while Wikipedia results in 2 hits. Clearly, neither of these extremes is satisfactory in determining a surgical approach. A useful step is to convert this specific clinical question about Mrs. Smith to a form that will allow us to search for the relevant evidence. The **PICO** format, which is used throughout this book, is a useful tool for this purpose.

The **P** stands for Patient or Population and specifies the patient group to which the question refers, in this case it may be: (a) all patients undergoing a pancreaticoduodenectomy, (b) women over the age of 50, (c) Caucasian women over 50, or (d) Caucasian women over 50 who have previously undergone a cholecystectomy. It is apparent that each iteration of the definition of the population is more and more specific. These details are important, but we may limit the information available to us if we define our population of interest too narrowly.

The **I** is for the Intervention or exposure of interest, and specifies what has happened to a group of patients such as an operation, or a diagnostic test. In our example the intervention we are considering is a pylorus preserving pancreaticoduodenectomy. However, there could also be specific issues that are considered important such as the specific method of reconstruction used or the use of drains.

The **C** refers to the comparator that we are interested in. In this case it is a standard Whipple procedure, but again we should be mindful of specific details of the standard procedure that may be important for our specific question.

O stands for the Outcome of interest. It is very important to be specific about the outcome of interest as it is likely that various studies may have used different outcomes in the study design than the one you are interested in. One study may have been focused on gastric emptying, whereas another may have been focused on blood loss during the procedure. It is worthwhile to identify each outcome of interest in the specific clinical scenario and to order them in order of importance to the patient and surgeon so that an overall assessment of the utility of an intervention can be made.

Taking these features of the clinical question into account, we can frame the scenario for Mrs. Smith in the following PICO question:

In patients with periampullary carcinoma or carcinoma of the pancreatic head, does a pylorus preserving pancreaticoduodenectomy result in 1) less blood loss 2) lower incidence of delayed gastric emptying 3) lower operative mortality than a standard Whipple procedure?

P: Patients with a periampullary carcinoma or carcinoma of the pancreatic head

I: pylorus preserving pancreaticoduodenectomy with the use of drains

C: standard Whipple operation with the use of drains

O: (1) operative mortality, (2) delayed emptying, (3) blood loss

It is worth considering when reviewing the chapters in this book, whether the PICO questions chosen by the authors are sufficiently similar to your own formulation of the question for their findings and recommendations to apply to your specific case.

Find the Evidence

Often the first step in a literature search is to go to PubMed, the interface to access the Medline database of citations in the National Library of Medicine in the United States. However, a search of “pylorus preserving pancreaticoduodenectomy” produces 781 citations. This is more than we can reasonably go through for the purposes of answering a specific question for a patient. But, if we use the Clinical Queries page in PubMed which uses an algorithm to deliver focused studies relevant to clinical practice, [10] we obtain citations for 35 systematic reviews and 45 clinical studies, much better. Alternative search engines include TRIPdatabase (<http://www.tripdatabase.com/>) and SUMsearch (<http://sumsearch.org/>), which use multiple databases including Medline, EMBASE, and databases of guidelines and technology may also be used. Last, but certainly not least is the expertise available through your local medical librarian who will be well versed in the methods of constructing a PICO question and finding the relevant information from the medical literature.

Appraise the Studies

Once we have found the studies of interest, the next step is to identify the “best evidence”. The concept of “best evidence” assumes a hierarchy of evidence. But in order to apply a hierarchy, it is important to understand the types of study designs and their use in answering specific types of clinical questions. Grimes et al. [7] provide a useful taxonomy of study designs (Fig. 1.1). In general, questions related to the superiority of one intervention over another (or no intervention) are best answered by experimental studies where one group of patients are assigned to the intervention by a bias free method, while another receive a comparison intervention. The gold standard for the experimental study is a well-designed randomized trial. Other types of clinical questions such as that of prognosis are appropriately answered using cohort studies, while questions of diagnosis rely on comparing the performance of a diagnostic test to a gold standard.

All study types have the potential for any number of biases which may lead to a finding which deviates from the “truth” [8]. The tools of critical appraisal are used

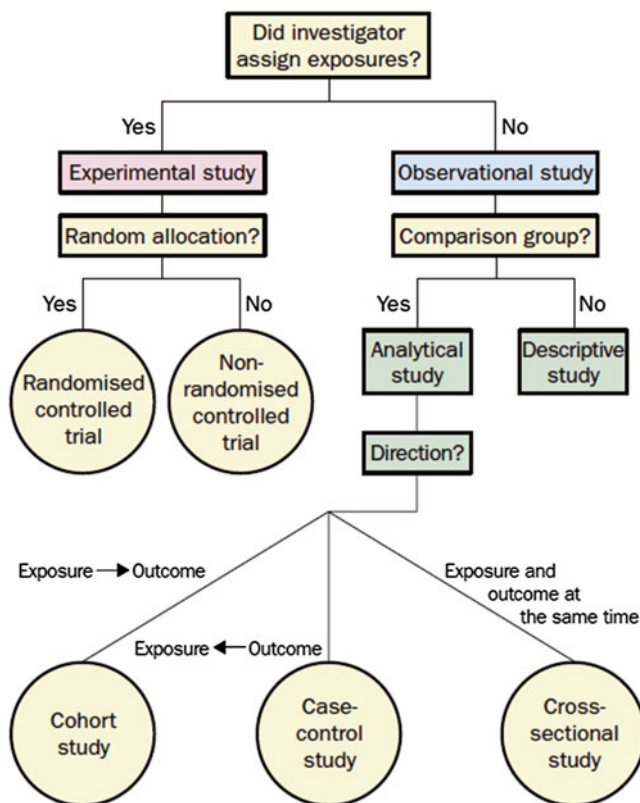


Fig. 1.1 Algorithm for classification of types of clinical research (Grimes and Schulz [7], Reprinted with permission from Elsevier)

determine the type and extent of these biases in the design and conduct of the study, and make a judgment of how it may have affected the findings of the study and the extent to which it undermines our confidence in the validity of the findings.

There are many excellent resources and tools to guide us in the specifics of appraising the medical literature and practicing EBM and these are listed in the recommended readings.

What happens when despite the best formulation of a question and literature search we are unable to find the high quality systematic review or randomized trial to guide us? Do we abandon the principles of EBM? Again from Sackett: “Evidence based medicine is not restricted to randomized trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions.... However, some questions about therapy do not require randomized trials (successful interventions for otherwise fatal conditions) or cannot wait for the trials to be conducted. And if no randomized trial has been carried out for our patient's predicament, we must follow the trail to the next best external evidence and work from there” [13].

Although we can approach each problem we face by formulating a question and finding the best available evidence, individual clinicians are unlikely to have the time or resources to do this for all possible scenarios. To illustrate: our example PICO question generated 171 results using PubMed. There were 50 reviews, 74 relevant trials or studies, 3 guidelines and 44 other possibly relevant titles. This took an experienced medical librarian about 2.5 h to identify these studies, and does not include the time necessary to actually read these documents and appraise them.

The alternative to searching for each question has been standard textbooks, which seek to distill the evidence and guide clinical practice. The authors of these textbooks have always made decisions about which studies to consider and judgments about their confidence in making recommendation based on this evidence. However, these judgments and decisions have not been transparent. And although there are many schemes in use which grade the level of evidence and have been increasingly used in textbooks, it is not clear on what basis these decisions of grade were specifically arrived at [2]. A good systematic review makes transparent the question, the search strategy, and the rules for inclusion of studies and on what basis the quality of the study is determined. However, the final assessment of the overall quality of evidence and the subsequent recommendation arising from this evidence is often obscure.

In order to address this deficiency this book has adopted the GRADE system to make transparent the decision-making about the quality of evidence and the factors considered in making a recommendation and a statement about the strength of this recommendation. The reader may disagree with certain judgments made by the authors, but the reason for disagreement will hopefully be clear with the GRADE system and the reader can make up their own minds whether the conclusions drawn by the authors are on the whole reasonable or valid. The key component of GRADE is that it explicitly separates the process of evaluating the quality of the evidence for an intervention from the process of making a recommendation for its adoption (or not).