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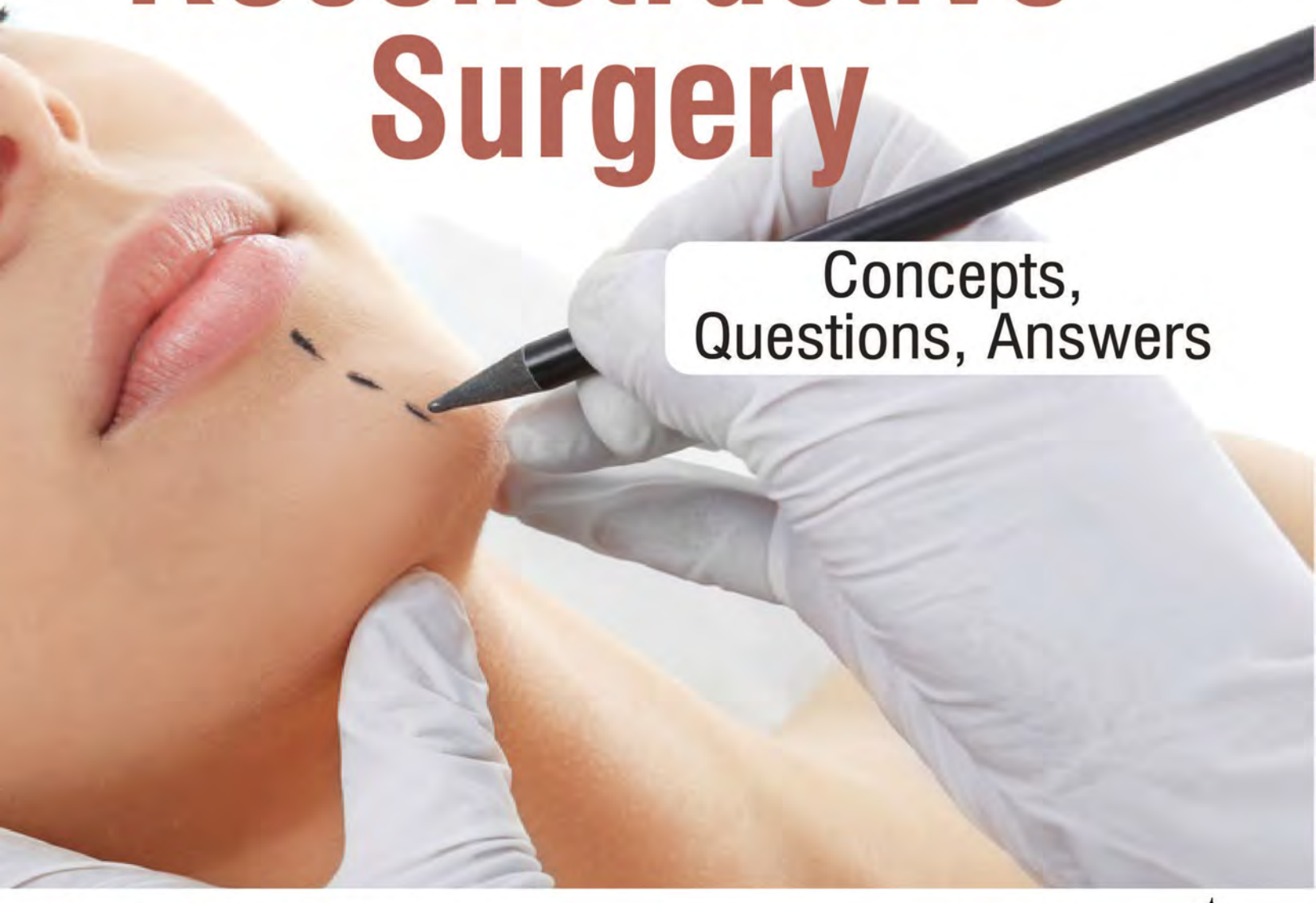
Concepts, Questions, Answers



Sami P Moubayed
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Chapter 3

Evidence-based Medicine

Dina Moubayed, Sami P Moubayed

INTRODUCTION

Before the beginning of evidence-base medicine (EBM), clinical decisions were based on personal experience and anecdotes. Evidence-based medicine is a concept that can be traced back as early as the 1850s, in the era of Florence Nightingale, where she applied statistical analysis and gathered evidence to help guide health care reform. Archie Cochrane, a British epidemiologist, set a precedent for EBM in the 1970s by highlighting the important of randomization in clinical trials.[1] However, it is in the 1990s that the term "evidence-based medicine" appeared in literature, and its origin can be traced back to McMaster University in Canada. It was introduced to the wide medical community in a 1992 JAMA article. Now, EBM is widespread and utilized throughout the medical community in multiple ways by legislators, policy makers, clinicians, and for teaching purposes.[2] Modern EBM is defined as "the conscientious, explicit and judicious use of current best evidence, combined with individual clinical expertise and patient preference values, in making decisions about the care of individual patients". It is composed of five steps (Table 1).[2] Evidence-based medicine integrates three critical elements: best research evidence, clinical expertise, and patient values.[8]

The levels of evidence vary according to the clinical question we are trying to answer. Therefore, there has been a classification created to modify the levels according to treatment, prognosis, diagnosis, and economic/decision analysis.[3,8]

The Oxford Centre for Evidence-Based Medicine (OCEBM) levels of evidence were redesigned in 2011. The levels of evidence for treatment are adapted and summarized in Table 2. This was adapted by the editorial board of JAMA facial plastic surgery for use in facial plastic and reconstructive surgery research. Another useful tool is the level of evidence pyramid. It helps visualize the quality of evidence and the amount of evidence available (Fig. 1).[10]

There is a distinction to make between a systematic review and a meta-analysis. Although systematic reviews and meta-analysis both combine data from multiples studies, a meta-analysis is a statistical technique that combines the results of independent studies, as if the data was collected from one large study, and analyzes it in a quantitative synthesis.[1,4] Therefore, it does not take into account the quality of the data or the distinctive characteristics of the study. A systematic review may or may not include a meta-analysis, whereas a meta-analysis is always based on a systematic review of quantitative data.[4] A systematic review is thus a powerful tool for evidence-based medical practice since it takes into account the quality of the data and the distinctive characteristic of a study, and can also include a meta-analysis of quantitative data, if necessary.[4]

Table 1: Steps in evidence-based medicine (EBM) reasoning.[1,2]

Step 1	*What is the question?* Identify the clinical problem or need for information in an answerable question
Step 2	*Search for answers* Tracking down the best evidence with which to answer the question
Step 3	*Appraise the evidence* According to its validity, impact, and applicability
Step 4	*Apply the results* Integrating the results of step 3 with our clinical experience and the patient's uniqueness
Step 5	*Assess the outcome* Evaluating our effectiveness and efficiency in executing steps 1 to 4 and seeking ways to improve next time

Table 2: Level of evidence [Oxford Centre for Evidence-Based Medicine (OCEBM)].[9]

Level 1	Properly powered and conducted randomized controlled trial (RCT), and systematic review or meta-analysis of RCTs
Level 2	Well-designed controlled trial without randomization; prospective comparative cohort trial
Level 3	Case-control studies; retrospective cohort study
Level 4	Case series with or without intervention; cross-sectional study
Level 5	Opinion of respected authorities; case reports

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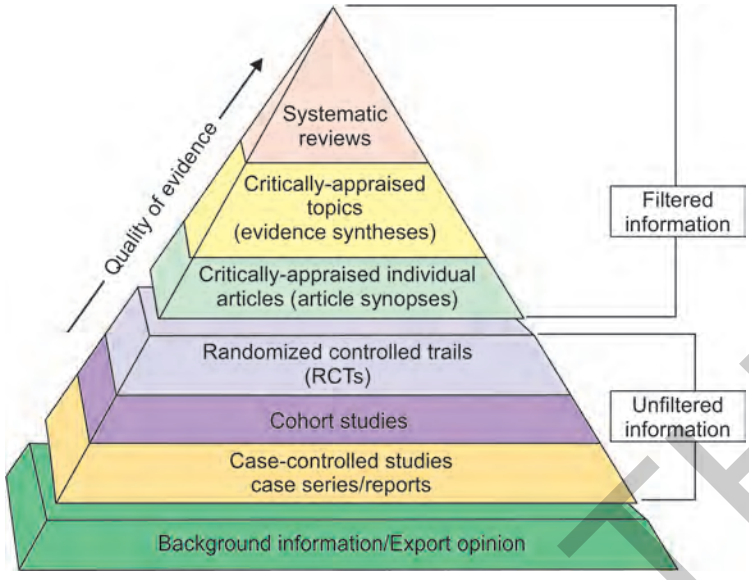

Fig. 1: Level of evidence pyramid.[10]

Table 3: Determining strength of action for key guideline statements.[9]

Statement	*Definition*
Strong recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms and that the quality of the supporting evidence is excellent
Recommendation	A recommendation means the benefits exceed the harms, but the quality of evidence is not as strong
Option	An option means that either the quality of evidence is suspect or that well-done studies show little clear advantage to one approach versus another.

Distinct from levels of evidence are recommendation grades, which are of particular interest in guideline development. The commonly used recommendation scheme in the guidelines put out by the American Academy of Otolaryngology—Head and Neck Surgery is explained in Table 3 and is based on aggregate evidence levels.[9]

Because EBM is based on the clinical use of well-constructed studies, it is important to address how to formulate a research study using the PICO method and the gold-standard research methodology, which is the randomized controlled trial (RCT). First, PICO is a tool to express the clinical problem in a focused, answerable question.[1] It contains four essential parts: patient/problem of interest, intervention, control or alternative treatment and outcome of interest. The more parts are answered, the more focused the clinical question will be.[5] Moreover, an RCT, which involves assigning patients to either an experimental group or a control group using a non-human distribution tool, is the gold-standard research methodology because it provides the most rigorous way of determining whether cause-effect relationship exists between treatment and outcome.[6] It does so by ruling out the confounding variables or associations caused by a third factor by using randomization.[1,7]

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Self-Assessment Exercise

Q 1. What is the modern definition of evidence-based medicine?

Ans:

The conscientious, explicit and judicious use of current best evidence, combined with individual clinical expertise and patient preference values, in making decisions about the care of individual patients.

Q 2. Name the 5 levels of evidence according to OCEBM 2011.

Ans:

Level 1 Systematic review of randomized trials or n-of-1 trials
Level 2 Randomized trial or observational study with dramatic effect
Level 3 Nonrandomized controlled cohort/follow-up study*
Level 4 Case-series, case-control studies, or historically controlled studies*
Level 5 Mechanism-based reasoning.

Q 3. What does PICO stand for?

Ans:

Patient/Problem of interest, Intervention, Control or alternative treatment and Outcome of interest.

Q 4. What two components does the level of evidence pyramid help visualize?

Ans: It helps visualize the quality of evidence and the amount of evidence available

Q 5. What are the three levels of recommendation in guidelines?

Ans:

Strong recommendation
Recommendation
Option.

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