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Editorial

Evidence-based surgery: The obstacles and solutions

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A B S T R A C T

Surgeons are often accused of lagging behind their medical colleagues in embracing evidence based medicine and utilizing new research tools to conducting high quality randomized controlled trials. Although there has been a noticeable improvement in the quantity and quality of high quality studies in surgical journals, the widespread practice of evidence based surgery is still poor. Unlike evidence based medicine, the practice of evidence based surgery is hampered by inherent problems and obstacles. This article reviews these difficulties and the limitations of randomized controlled trials in surgical practice. It also outlines some solutions that may help remedy this ongoing problem.

1. Introduction

It was in the late eighties and early nineties of the last century, when the practice of evidence based medicine (EBM) was adopted; thanks to the pioneering work of Dr. David Sackett and colleagues who defined EBM as 'the conscientious, explicit and judicious use of current best evidence in making decision about treating individual patients'[1]. The aim of EBM is to encourage clinicians to critically appraise the available evidence in the current literature more thoroughly when treating their patients. In evidence based surgery (EBS), the aim is essentially to objectively evaluate the quality of clinical research by critically assessing surgical techniques reported by fellow researchers in the literature. Moreover, the 3 main components of EBM were identified as the clinical expertise of the individual surgeon, the best available external evidence from systematic research and the patient values, preference and expectation. These components can also be referred to as the 'triad of EBM'. It cannot be overemphasized that EBM places value on the clinical experience of the individual clinician practicing EBM. Sackett and colleague strongly believe that if these 3 components of the triad are integrated together, patients are destined to receive evidence-based treatments and improvements in patients' care and outcome are imminent [1].

2. The highest level of evidence in EBS

As available external evidence in the literature is one of the main components of EBM, the highest level of evidence should be obtained. It is the best available for estimating the beneficial as well as the harmful effects of an intervention; most commonly a surgical procedure. The effects are referred to as the '*effect estimates*'. In surgical practice, it is now accepted that the highest level of evidence (level I evidence) in surgical research are randomized controlled trials and systematic reviews preferably with meta-analyses [2]. The 4 key principles of EBS are also outlined as identification of the surgical problem and designing appropriate research question, then identification of the best available evidence by searching the literature specifically for RCTs and systematic reviews, then critical appraisal and evaluation of the gathered evidence. Finally, to use it in combination with clinical expertise to aid the treatment of patients on the basis of best evidence [3].

Researcher needs to recognize that high-quality studies must possess 5 main components. It must have clearly defined eligibility (inclusion and exclusion criteria), and a sufficient number of subjects to detect any subtle difference that may occur between the study arms. Moreover, it must have a sufficient follow-up time for '*effect*' to appear, a strong generalizability i.e. strong '*external validity*', and no or minimal missing data such as that concerning cost-effectiveness analysis and quality of life [4]. Searching the literature in the 70's and 80's through the hard copies of '*Index Medicus*' was a daunting, time-consuming and frustrating task. With the emergence of various electronic search engines, digital libraries and free-access journals, this task became much easier. Researchers can look up the literature on any research question at the 'touch of a button' of their smart phones. This can facilitate the dissemination of EBS among young surgeons.

3. Is EBS the surgeon's enemy

When Sackett introduced the term EBM in the early 90's, he probably intended to exclude the surgeons from the evidence-based approach. Surgeons on the other hand perhaps looked at EBM as a notion introduced by a physician and published in a medical rather than a surgical journal. Unfamiliar with this new research tool surgeons argued emergency and urgent surgery to save lives made application of EBS in these settings difficult.

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Consequently, it was not surprising to see surgeons failing to adopt this new research tool and to practice EBS. As a result, they have fallen behind the medical specialties in evaluating the treatments for their patients and the concept of EBS.

Surgical treatments are often costly, and it is more so if inappropriate surgical procedure is conducted. It is also hazardous to patient and costly for institutions. Hence, surgeons are under increasing pressures from professional bodies and the public to justify both the clinical benefits and cost-effectiveness of their operations and procedures; especially when compared to non-surgical treatments. Adopting EBS would help clarify treatment outcomes. But, are surgeons really resistant to adopting EBS and if so what are the reasons?

Some studies have highlighted failure of the surgical community to adopt EBS. In the early 1990s, surgical RCTs accounted for only 7% of the published articles, and most of the surgical studies were either retrospective studies or case series [5]. By 2003, a similar study found RCTs accounted for only 3.4% of all publications in the leading surgical journals [6]. In one leading surgical journal, the British journal of surgery (*BJS*), the number of RCTs in research articles has declined from 14% in 1985 to 5% in 1992 [7,8]. Similarly, the number of RCTs in orthopaedic journals fell from 6% in 2006 to 4% in 2010 [9]. Also, three quarters of surgical trials were actually of medical treatments in surgical patients, and only a small number of the RCTs have a surgeon as their first author [7,8]. Moreover, adequate blinding was evident in only third of surgical trials [5]. In 2005, Slim reviewed articles in 4 leading surgical journals (*BJS, Surgery, Annals Surgery, Archives Surgery*) and 4 leading medical journal (*British Medical Journal, Lancet, NEJM, JAMA*) [10]. Over a 2 year period (2002–2003), there were only 113 RCTS in the leading surgical journals *vs.* 551 RCTs in the medical journals [10]. Furthermore, a search of the April 2003 issue of the Cochrane library (the main database for EBM) yielded only 5.3% systematic reviews and less than 3.5% surgical RCTs [10]. Hence, it has been concluded that most of the available evidence in surgery is of poor quality and comes from non-randomized studies (case–control or cohort studies), and reviews were qualitative (descriptive) rather than quantitative (systematic) ones, leading to a lower level of evidence on the EBM scale [10]. Further evidence that surgeons are lagging behind their medical colleagues in adopting EBM has come from the USA and the Netherlands both reporting that up to 40% of surgical patients do not receive evidence-based care [11,12]. An Australian survey of colorectal Surgeons ($n = 195$) on the management of colorectal cancer patients showed 40% of surveyed surgeons in Australia were unaware of the current best-practice evidence [13]. Similarly, 50% of the routine gastrointestinal surgery procedures were not evidence based when 379 members of the French Society of Digestive Surgery were surveyed [14].

A glimmer of hope was reported in the specialties of both plastic and orthopaedic surgery which indicated a slow but progressive increase in the quantity and quality of level I evidence over the past 30 years [15,16]. A recent review of 5 leading plastic surgery journals (*Plastic and Reconstructive Surgery*, *Annals of Plastic Surgery*, *British Journal of Plastic Surgery*, *Aesthetic Plastic Surgery*, and *Journal of Plastic, Reconstructive &Aesthetic Surgery*), included 309 publications for analysis [16]. It was evident that from 1978 to 2009, there has been a steady increase in the number of level I studies, which was welcome and encouraging news. However, over 50% of these studies were either single-blinded (31%) or not blinded (20%) at all, and only 8% were meta-analyses. Randomization technique was reported in only 39% of the studies, cost and efficiency were primary outcomes in only 2.6% and 4.2%, respectively and power analysis was performed only 15.5% of the time [16]. A recommendation was made for future studies to be designed to produce high-quality evidence and studies should address cost and comparative effectiveness [16].

Based on the above, it is clear that surgeons have been slow to embrace EBS although some improvement in the number of RCTs in some surgical specialties has been recently evident. It is therefore wise to try and identify the underlying reasons and hopefully be able to outline appropriate solutions to promote EBS among surgeons. One encouraging development is the recent introduction of EBM sections in most of the leading surgical journals and the emergence of publications that are dedicated to and specialized in EBM. Also, there has been an increase in the number of courses and workshops on research methodology, bio-statistics and epidemiology. Despite this slow but progressive improvement in promoting and adopting EBS, more intensive effort is needed to make EBS part of the junior and senior surgeons' daily practice and one of their strategies to plan their patients' surgical care and management.

4. Problems and obstacles for EBS

Individual approaches to treatment has resulted in a wide range of therapies to patients with the same surgical condition e.g. management of appendiceal mass, surgery for pilonidal sinus and laparoscopic vs. open repair of hernia. To overcome such obstacles, groups such as the National Institute of Clinical Excellence (NICE) in UK and similar bodies in other countries carry out evaluation of various therapies (medical and surgical) and issue recommendations of the best evidence-based therapy. This has made decisions easier for surgeons and relieved them from carrying out their own costly evaluations or research.

Two cornerstones of good clinical research are randomization reducing selection bias and blinding reducing other biases (e.g. performance and detection bias) during the trial [17]. In surgical trials, randomization can be difficult due to patients or surgeon preference. Blinding of patients, health care providers and outcome assessors is not only difficult, but often impossible [18]. The surgeon who performed the operation is wrongly often the outcome assessor as well. This problem with blinding can be partially solved by allowing another surgeon, a nurse or research assistant to undertake postoperative assessment.

Any bias in RCT can over or underestimate the true benefits or harms of a surgical intervention i.e. deviation from the true "*effect estimate*" [19] and this adversely affects the '*internal validity*' of the study. Blinding of patients and the surgical team remains a major challenge in conducting surgical RCTs [18] and may help explain why only third of surgical trials have adequate blinding [5].

5. Limitations of surgical RCTs

The obstacles and problems facing EBS already outlined are only the tip of the iceberg. Many other factors contribute to hamper the widespread adoption of RCTs by the surgical community. Some of these are surgeon-related and others are related to the surgical technique or to the study design itself. RCTs may themselves be the main obstacle [18]. Other contributory factors may be patient-related or surround ethical issues or publication bias.

5.1. The surgeon as an obstacle

Many surgeons are lacking the basic training, expertise and possibly even the desire to perform RCTs. Often this is due to lack of core knowledge of epidemiology and statistics. Moreover, the final results of RCTs which are often lengthy can affect the surgeon who may be impatient and under publication pressure [17]. Surgeons may be biased towards their own patients, and their judgement and choice of surgical treatment are often influenced by