

Op-Ed

## **Evidence-Based Surgery: a Growing Need for a Limited Enterprise**

**The gap between surgeons' professional idealism and clinical reality is widening because surgeons fail to keep up with the growing demand for evidence-based surgery.**

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The call for rigorous scientific testing of surgical therapies is not new[1, 2], but has seen a steady increase in volume. About a decade ago a surgery textbook observed that:

When large numbers of innovative treatments are being continuously introduced into clinical practice, rigorous testing is mandatory for the protection of individual patients and the just use of limited resources. This holds true with even greater force in light of the evidence that many innovations show no advantage over existing treatments when they are subjected to properly controlled study [3].

The latter observation came painfully true for cardiac ventriculotomy and arthroscopic knee surgery[4,5].

Concurrently, the push to innovate is greater than ever. Surgery professional meetings encourage the presentation of "new approaches" specifically selected by their program committees, and most surgery journals have a section especially reserved for innovations and new techniques. New is hot, old is not. Academic and private surgeons alike feel this unrelenting push to innovate, not only for the sake of their patients, but also to safeguard their status, their reputation and, ultimately, their income. Yesterday's procedures are old news, and surgeons may be reluctant to continue using old-fashioned techniques, regardless of the fact that these may have been proven safe and effective unlike their innovative counterparts. While ideally these "new and improved" procedures should have been scientifically tested for safety and efficacy, this is not often the case. Though most surgeons' awareness of the importance of evidence-based therapy is deepening, as a profession, surgeons fail to keep up with the growing demand for evidence-based surgery (EBS) [6-14]. The gap between surgeons' professional idealism and clinical reality is widening.

It needs to be stated up front that surgeons are not alone in using therapies that are essentially untried and unproven. Other physicians are at liberty to employ medical therapies at their discretion, may opt for off-label use of drugs, and can choose dosages, medication combinations, and strategies as they see fit. But unlike innovative surgeries, (conventional) drugs have generally been tested before entering the market and have been determined to be safe and effective (for specific conditions) in FDA-monitored trials and studies. Surgeons have, in essence, carte blanche to introduce untested new procedures. In the absence of any overseeing entity [15-19], it currently is the sole responsibility of the surgical profession to ensure the use of evidence-based techniques [20]. Individual surgeons have brought this point to light, and have sought ways to stimulate others to innovate responsibly [19, 21-36], and the American College of Surgeons has made it its goal to improve the use of EBS [37].

Regardless, it remains a formidable challenge for surgeons to embrace EBS. Within evidence-based therapy, there is a hierarchy of evidence according to strength [38,39]. The best evidence is ranked Level 1: (meta-analysis of) prospective randomized clinical trials and Level 2: cohort studies or outcomes research. Evidence of lesser strength is

ranked Level 3 (case-control studies), 4 (case series) or 5 (expert opinion and bench research). Modern-day surgical literature still consists mainly of reported Level 4 and 5 evidence, sometimes Level 3, and rarely Level 2 or 1 [34]. The reported declining engagement of surgeons in research adds to this troublesome situation [40]. Moreover, as Rangler et al. reported recently, surgeons are less likely to receive federal funding for research, they often receive smaller awards when they do, fewer surgeons participate in the National Institutes of Health (NIH) reviewing process, and, most surprisingly, surgeons were in the minority in the Surgery Study Sections [41].

Why is the occurrence of evidence-based therapy so limited in surgery? Several explanations that are more or less related have been given for this apparent discrepancy between surgery and the rest of medicine. First, the very definition of surgical innovation and, related to that, clinical surgical research, is vague. The boundaries between clinical care and clinical experimentation are not always clear in the surgical situation. It is difficult for surgeons to determine when routine modifications in operations become extensive enough to warrant formal study and a patient's informed consent for participation in research. This elusive definition of surgical research is the very core of this problem [34, 42].

Second, and related to this, is the notion of surgical exceptionalism [43]. This is the view that the somewhat exceptional ethical or regulatory status of surgery and surgical research is justified by the exceptional differences between surgeries and pharmaceutical interventions [44-46]. Comparing 2 pills appears more straightforward than comparing 2 surgical procedures. Whether this comes down to substantial differences between the 2 forms of therapy or is due, perhaps, to psychological differences between physicians and surgeons is not wholly understood.

Third, and indirectly flowing from the above notion; to produce Level 1 evidence, one has to conduct randomized controlled clinical trials (RCTs) or meta-analyze existing RCTs. Implementing RCTs can be problematic for the surgical situation, and incorporating sham surgery as a placebo into such trials even more so. Sham surgery is ethically contentious at best [47], and although it has proven effective in certain scenarios [5] and its ethical permissibility has been defended effectively [48], it has not gained wide acceptance yet. It deserves attention that while the RCT is widely regarded as the gold standard of evidence-based therapy, it is not always necessary, feasible, or appropriate in the surgical situation [11, 49-52].

Finally, and perhaps the most worrisome reason why EBS has not taken off, is the alleged insufficiency of knowledge and research skills among surgeons [18, 53]. In his 2004 American College of Surgeons presidential address, surgeon R. Scott Jones paints a dismal picture of the current research climate in surgery [40]. Most alarmingly, Jones stipulates that the mainstream surgery community actually devalues research, and is neither well-informed about nor respectful of the scientific method. Jones goes on to state that it is enormously difficult to incorporate research into a surgeon's professional life, not in the least because other demands are increasingly taking away time and energy from potential research efforts. Understandably, Jones urges his professional community to address this problem and dedicate more time and attention towards EBS and to the education of future surgeons about this matter. Indeed, it appears necessary and timely for surgeons to realize they are lagging behind in the quest for evidence-based therapy, and to increase their efforts to embrace, produce, and implement EBS into their professional lives and in every day clinical practice, for the protection of themselves, their patients, and the public interest [54].

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