Evidence-Based Science

A Worthwhile Mode of Surgical Inquiry

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The randomized clinical trial (RCT) is a laudable and invaluable mode of surgical inquiry. It has been presented as the Holy Grail—responsible surgeons must base all patient-related therapies on level I evidence. In this article, we propose (1) to plumb the origins of evidence-based thought, (2) to explore the validity of programs that predigest the morass of surgical information provided to data-deluged surgeons, and (3) to examine the value of all 5 (I-V) levels of scientific inquiry in directing therapeutic surgical strategies.

ARE THERE REALLY “LEVELS” OF SCIENTIFIC INQUIRY?

The traditional levels of scientific investigation are presented in the Table, from the exalted RCT to the lowly case report and expert opinion. Perhaps predictably, if we review the reviews of RCTs and the RCT reviewers, patterns of reviewer confusion and conflict emerge. Equally predictable is the observation that we only publish our results if we are proud of them. This explains why we cannot extrapolate from retrospective reviews or morbidity and mortality reports to national/regional registry data. Additionally, by the time an RCT is published, the conclusions are often obsolete. As a conscientious surgical investigator, you must grow your idea on a foundation of expertise (expert opinion, level V). You then try it once (case report, level IV). If your idea works, you try it a couple more times (nonconsecutive, small population study, level III). At this point, you think that you are on to something, so you scrounge around collecting anyone else’s similar experience (retrospective review, level II). If you have been both persistent and lucky, you now talk your colleagues and patients into an RCT (level I). All levels of scientific inquiry enjoy an important place in the sequence of investigation leading to an advance in surgical therapy.

WHAT IS THE PROBLEM?

It is axiomatic that we derive data from the highest possible authority. So here goes: “God created man.” Adam, when he had lived for 130 years, had a son in his own likeness. Adam then lived another 800 years. Current-day astrophysicists note that a year is 365 days, 5 hours, 48 minutes, and 46 seconds. As faithful and trusting scientists, how should we react to these observations? At first blush, our ancestors clearly knew something about reproductive endocrinology that has been lost over the centuries and they certainly knew how to hold onto life.

Alternatively, when challenged by observations that we do not understand, most of us quibble with the scientific methods. Perhaps it was a “lunar” year (only a week or so shorter) or perhaps the translators have misinterpreted Moses and a “year” really means a “short period of time.” We can resort to character assassination and attack the author: perhaps Moses did not even write Genesis, as he (or the confused author) gives 2 contradictory accounts of this “creation of man” in Genesis 1:26 and 2:7. When pushed, we are always on comfortable ground when we sanctimoniously proclaim that Moses never subjected his manuscript to peer review.

As scientific surgeons, why are we so resistant to ideas that do not conform to our preconceived notions? Is recent personal experience (levels IV and V) unshakable? Is it more persuasive than 1000 similar patients collected in Rochester, Minnesota? Once we become “experts,” are we even more adamantly anti-intellectually dangerous? The problem is not that we cannot develop treatment strategies derived from prior inquiry, but that with frustrating frequency we do not seem to want to.

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IS EVIDENCE-BASED DECISION MAKING NEW?

Arguably, Aristotle first created the discipline of science by insisting on a rigorous delineation of evidence and a logic for the use of evidence to create theory. Several hundred years later, Lucretius (in On the Nature of Things) dissected evidence-based thinking into strict analytical precepts of axiom, terminology, and corollary. Evidence-based thinking then hibernated in cold storage for almost 1500 years.

Five hundred years ago, Francis Bacon wrote in “The Praise of Knowledge” that “…a man is but what he knoweth.” Evidence was reborn when the always practical Bacon declared that “Nature cannot be commanded except by being obeyed.” The following century witnessed a return to first principles, and our ability to even perceive evidence was challenged. Descartes was confident of his existence because he could think, and Hobbes and Spinoza envisioned the world as a mathematical system that could be deduced a priori from principles, and our ability to even perceive evidence was obeyed.

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WHOM WAS ARCHIBALD L. COCHRANE?

In 1909, Archie Cochrane was born to wealthy Scottish parents from whom he, much like King George III, inherited vast lands, a comfortable income, and porphyria. As a student, Archie’s dazzling intellect required periodic psychoanalytic quenching but he eventually qualified in medicine at age 29 years. World War II broke out and Archie enlisted, only to be taken prisoner in 1941. Archie initiated his critical review of medical practice from the unenviable perspective of a resource-poor (no library, no pharmacy, and no personal experience) medical officer in prisoner-of-war camps. At the end of the war, Archie continued his critical appraisal of medicine when he joined the Medical Research Council as a field epidemiologist in South Wales. For 25 years, Archie made some seminal epidemiological contributions involving typhoid fever and tuberculosis, which appropriately earned him the esteem of his colleagues. Although he never actually practiced medicine, he was favorably positioned to witness “how” it was practiced. Never shy, Archie observed conscientious physicians grapple with complex but recurring problems. As an epidemiologist, it struck him that standard therapies were incompletely tested and poorly analyzed, while innovations did not exist. In 1972, Archie Cochrane published his unabashedly critical (but surprisingly readable) observations in a monograph entitled Effectiveness and Efficiency: Random Reflections on Health Services. His thesis was simple: patients have a menu of recognizable problems on initial examination. Physicians have hearts of gold, and we try to do the right thing. Medical information is provided to us in an overwhelmingly haphazard and unfiltered fashion (with the advent of the Internet, it is now exponentially worse). Thus, even the good guys (us) are powerless to organize scientifically rigorous treatments for even common problems. Archie’s solution was characteristically logical: Why not institute a collaborative group that prepares, maintains, and disseminates systematic reviews of the effects of health care?

The idea caught on. The Cochrane collaboration is now an international organization addressing focused subjects like bronchodilators, glutamine, and volume expansion in preterm infants. Like the Beatles, Archie attracted legions of fans and his words are now glorified, revisited, and presented as gospel.

SO, HOW SHOULD WE SURGEONS DECIDE?

When a physician drops a brick out the window, it goes down—every time. When a cell biologist plates out endothelial cells, they grow to confluence—most of the time. When an aggressive surgical oncologist resects a hepatic metastasis, he or she cures the patient—some of the time. When a surgical intensivist infuses tumor necrosis factor–binding protein into a critically ill patient, he or she reverses multiple organ failure—almost never. As surgeons, it is our comprehensive goal to reverse metabolic dysfunction, repair the physiologic defect, energize our patient’s psychological conquest of his or her disease, and return our patient as a contributing member to his or her family and community.

Surely, evidence-based surgery can facilitate these laudable goals, but what is evidence-based surgery? As clinical surgeons we do not have the luxury of the physicist or even the cell biologist when we try to decipher surgical evidence. Evidence-based medicine has been variably defined as:

The conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients;

…an approach to practice and teaching that is based on knowledge of the evidence upon which practice is based, and the strength

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<th>Level</th>
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Levels of Evidence-Based Medicine
of that evidence. Although it focuses on the results of clinical reports of human experiments, it acknowledges that trials are built on the pivotal work of laboratory research and upon preliminary observational studies in animals and humans and finally

Evidence-based medicine is an information and learning strategy that seeks to integrate clinical expertise with best evidence available in order to make effective clinical decisions that will ultimately improve patient care.  

While our patients, Mr Johnson and Mr O’Flaherty, are 99.9% identical genetically and are even very similar metabolically and physiologically, Mr Johnson is a mercenary alcoholic trial lawyer who feeds off elementary school liability cases while Mr O’Flaherty has taught history and coached boys’ and girls’ basketball in those same elementary schools for 25 years. These patients have different values. As surgeons, once we have successfully returned these guys to textbook metabolism, have we finished our job? We must balance and incorporate sensitive clinical expertise with evidence-based medicine:

Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful and compassionate use of individual patient’s predicaments, rights and preferences in making clinical decisions about their care and Without clinical expertise, practice risks becoming tyrannized by evidence.  

SO, LET US PRACTICE EVIDENCE-BASED MEDICINE

If a patient’s well-being and happiness is our goal (and it should be), then we enthusiastically endorse the prescription of low-dose fluorouracil (or even vitamin B12) in a patient with widely metastatic gastric cancer when the alternative is to throw up our hands and acknowledge that there is “nothing we can do.” This is not evidence-based. Similarly, if only 10 studies are published daily on problems related to our patient’s disease (probably an underestimate), is it possible for us to read and digest this stuff and still have any time to practice surgery? The solution, of course, is to have some self-appointed meta-analyzer predigest this relevant evidence before serving it up to us. Yet, is it paternalism for the Cochrane crowd to edit the evidence prior to providing it to us? Is it then paternalism if we select the evidence that we provide to our patients to influence the treatment decision? Is bias (editorial influence) an obligate part of any review? As an egregious example, would the tobacco company lawyers be capable of developing a review and mega-analysis indicating that cigarettes are neither addictive nor carcinogenic? Is paternalism just feeding the hand that bites you?  

Cook, in a thoughtful analysis of the spectrum from patient autonomy to physician dictatorship, delineated 4 overlapping kinds of doctor-patient relationships:

1. Parental (or paternalistic) model: “Doc, you know what’s best. Just do what you think is right.”
2. Informative (or consumer) model: “Doc just give me all of the facts and I’ll decide.”
3. Interpretive model: “Doc, just give me some of the facts and we’ll decide together.”
4. Deliberative model: “Doc, let’s analyze and debate my predicament so that you can learn my values and I can trust yours; then you give me some facts and we’ll decide together.”

As we surf the crest of an information typhoon, let us agree that providing a patient (or a physician) “all of the facts” is delusionally unrealistic. However, as soon as we (or Cochrane’s cronies) begin filtering the facts, we are progressively paternalistic. We need help in managing this data glut. This is where Archie has and will continue to help.

We applaud the incorporation of the best available data (levels I through V) into clinical decisions. We appreciate the formidably subjective responsibility of the surgeon in relating our patient’s physiologic and social predicament to the available evidence. Services such as the International Cochrane collaborators, who assist us in sorting through the deluge of variably credible medical/surgical trials, can be helpful. It is ultimately the responsibility (and the gratifyingly rewarding joy) of the surgeons to match our patients’ predicaments with therapies that return these patients to their families and communities as contributing members, and that takes more than data.

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