Published in final edited form as:

Plast Reconstr Surg. 2009 April ; 123(4): 1385–1389. doi:10.1097/PRS.0b013e31819f25ff.

Introducing Evidence-based Medicine to Plastic and Reconstructive Surgery

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Abstract

An effective healthcare system is one in which healthcare spending provides acceptable returns in terms of health outcomes and broad coverage for its citizens. By this measure, the United States healthcare system unfortunately falls short. Tremendous pressure for improvement has given rise to several initiatives designed to decrease healthcare expenditure and improve outcomes, access, and quality of care. The outcomes movement, which is revolutionary in American medicine, has heightened awareness about the need to critically examine our treatment outcomes. However, the early euphoria surrounding the outcomes movement was met with restraint at the realization of its limitations. Although the outcomes movement has verified the effectiveness of many existing treatments in plastic surgery, most of the investments in these projects unfortunately have resulted in few, if any, positive changes for the patient, physician or healthcare system (1). US healthcare is now moving towards the adoption of evidence-based medicine (EBM), which may potentially be another revolution in American healthcare (2).

What is Evidence-Based Medicine?

In a nutshell, “Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values”(3). EBM integrates scientific principles and clinical care experiences in order to provide rational decision-making tools in the care of patients. In contrast with a long-adhered tradition of treating patients with practices based on rigidly-held protocols learned in residency training or opinions presented by leaders in the field, EBM challenges these unscientific methods of healthcare delivery and strives to remove the uncertainty of these “expert” opinions. It carefully scrutinizes existing treatments by identifying the best available evidence (4,5). Table 1 illustrates the five basic ideas of EBM. The genesis of EBM was credited to Archie Cochrane who advocated randomized controlled trials in the early 1900s to support treatment decisions made by clinicians (6). Cochrane was quite disturbed by the unscientific approaches for many of the treatment decisions of his time, which not only occasionally harmed patients but also promoted technology that was unproven.

The United States is a huge consumer of new technology with daily introduction of the newest diagnostic tests, cancer treatments, and implants. The marketing fervor for new technology overrides rational consideration about whether the latest innovation is supported by better

outcomes over the conventional treatment or justifies the higher costs for these new technologies. In the field of plastic surgery, which continuously strives for innovation, the increased cost must be backed by better outcomes. By bringing outcomes and cost into the equation, the new EBM model promotes economic analysis, an important component in evaluating the overall effectiveness of healthcare delivery (7).

Levels of Evidence and Evidence-Based Medicine

The lack of high level evidence in plastic surgery literature should be concerning to our specialty. As payers start demanding evidence that supports the use of expensive new products, such as the use of dermal substitutes for breast reconstruction or fillers for reconstructive purposes, the need for evidence clearly affects plastic surgeons' ability to justify the reimbursement for these essential devices. Although many may argue that the art of plastic surgery cannot be evaluated by the scientific method and certainly that the artistry of this specialty may not be captured by p-values or power analyses, it is important to remember that it will be difficult to differentiate plastic surgery from other wannabe specialties encroaching on this field when the broad research literature in plastic surgery is devoid of high level scientific content. Only through promotion of EMB and introspective scrutiny of our practices can plastic surgery lend a strong voice when advocating for patient welfare. Rather than having level 5 studies based on expert opinions, or level 4 studies, which rely on retrospective chart reviews of cases series, plastic surgeons must start performing level 3 retrospective studies with control groups. The vision of *Plastic and Reconstructive Surgery* is to think ahead and start planning level 2 prospective cohort studies, which follow cohorts of patients for long periods of time, or better yet, randomized controlled studies that can scientifically answer important questions in this specialty. Table 2 presents the levels of evidence chart, and Table 3 presents the grades of practice recommendations.

The lack of evidence in medicine was recently demonstrated in an article by Gina Kolata, health columnist for the *New York Times*, discussing the evidence surrounding beta carotene and its use as a dietary supplement to protect against cancer. It seems rather intuitive that eating more fruits and vegetables containing beta carotene, an orange-red organic compound that is a precursor to vitamin A, should make one healthier. After all, our mothers have known all along the wonderful antioxidant effect of beta carotene, and they have been encouraging us to eat more carrots and broccoli because these vegetables are healthful foods that can make us stronger and run faster, and potentially protect us against ailments. To demonstrate this point, several promising observational studies have shown that people who eat more fruits and vegetables have lower cancer risk (8-10), and laboratory studies have demonstrated the positive effects of beta carotene on the immune system of rats (11). Therefore, not only does eating more beta-carotene-containing foods or consuming beta-carotene supplements appear logical, this belief is also supported by level 2 and level 3 studies that corroborated the beneficial effects of beta carotene.

“Well, not so fast,” as stated by one of the football gurus in the college pre-game show. Two randomized controlled trials (RCTs) in which study subjects took beta-carotene pills or placebos failed to demonstrate a protective effect against cancer and heart disease. In fact, these studies showed a statistically significant increase in lung cancer mortality of subjects taking high levels of beta-carotene over the subjects receiving placebo pills (12-14). Results of these trials dashed the hopes of millions of people who swore by this supplement. So how can this be, when all the cumulative evidence supports the effectiveness of this magic pill in protecting one from disastrous health problems? Additionally, how valid is the evidence from the multiple observational and animal studies that showed the efficacy of beta carotene?

The answer lies in the basic epidemiology concept of confounding variables and biases. In these observational studies, the study subjects who took beta carotene were very different from the subjects who did not take this dietary supplement. The subjects who took beta carotene were potentially more motivated to be healthy; perhaps they exercised more, refrained from smoking or ate less fatty food. Although an epidemiologist can usually account for potential confounding variables, unknown confounders can contribute to differences between the two study groups. Because it is impossible for a statistician to control for unknown confounders and selection biases that can be introduced into the study unbeknownst to the investigators, observational studies are categorized as level 2 (prospective) or level 3 (retrospective) evidence studies. By contrast, in clinical trials, the study subjects are allocated randomly to either intervention or no intervention groups (15). For example, the intervention group that underwent a surgical treatment or took a medication is compared to the control group that received an alternative surgical treatment or took the placebo pill. Therefore, the random allocation of intervention, provided that the sample size is sufficiently large, should balance out known and unknown confounders. Thus, in this strict experimental situation, level 1 evidence is produced that can potentially define whether the intervention is truly effective.

Despite the allure of RCTs, there are certain perils with clinical trials (Table 4). For example, the results may not be generalizable to the entire population because they often are conducted in large academic settings under strict inclusion and exclusion criteria. Patients in these academic centers may be quite different from those in the general population, and the level of expertise in these centers may be higher than some community hospitals. Therefore, RCTs are often considered as efficacy studies that are conducted under ideal situations, when compared to effectiveness studies that are conducted without the randomization designs. In an effort to achieve generalizable results, the National Institutes of Health (NIH) put forth a conscious effort to request inclusion of minority groups in NIH-funded clinical trials to ensure that the results can be applicable to all racial groups and for various socioeconomic strata.

EBM, ASPS and PRS: A New Initiative

It is distressing when a long-held belief regarding a treatment's effectiveness is dispelled by a more rigorous study design. However, striving for the highest level of evidence in clinical research is essential and will guide the decision-making process, to allow us to provide the best treatment for our patients. It is unnerving to challenge a long established practice. For example, Dextran is routinely used after a free flap operation, and its use may be justified if evidence shows that it can prevent free flap failure. However, because the risk of flap failure in high volume centers is quite low, it will require the recruitment of thousands of subjects to reach adequate statistical power. The cost and effort associated with a Dextran study may be too prohibitive. Therefore, RCTs should be designed when the study question is so important that the results derived from level 1 evidence can have an important impact in changing practice patterns. *Plastic and Reconstructive Surgery* is embarking on an exciting initiative to promote EBM. With more effort by researchers to conduct RCTs, we may witness the walls coming down on many of the sacrosanct practices that we have cherished. The demise of the beta-carotene mirage may serve as a guide, compelling us to seek high level evidence in our own practices.

The American Society of Plastic Surgery (ASPS) has been spearheading EBM through the work of three important committees: Quality and Performance Measurement committee, Health Policy Committee, and Patient Safety Committee. The premier journal of this specialty—*Plastic and Reconstructive Surgery*—plans to partner with the ASPS in this movement. The designation of Kevin C. Chung, MD, MS as sectional editor for outcomes and evidence-based medicine will strive to introduce the concept of EBM to our contributing authors and readers. Of course, presenting this concept cannot occur overnight, and will require a major shift in

how the specialty approaches scientific literature and how it applies evidence in decision-making and clinical care. Several of the proposed EBM initiatives aim to:

1. Critically appraise clinical studies with a preference to accept papers with higher levels of evidence.
2. Highlight a key article in each issue of Plastic and Reconstructive Surgery that can serve as a model for an EBM-type paper.
3. Provide tutorial guides on various aspects of EBM such as how to craft practice guidelines, how to distill evidence based on statistical principles, and how to perform economic analysis projects.
4. Invite discussions of selected EBM articles by experts who are able to evaluate whether recommendations for new treatments have sufficient evidence to support adoption.
5. Publish systematic reviews and if possible, meta-analyses, that summarize data from the literature and provide the readers with an unbiased scientific critique of evidence for plastic surgery technologies and treatments.
6. Collaborate with ASPS in promoting high level evidence studies, e.g., deriving evidence for DVT prophylaxis and analyzing outcomes of reconstruction for lower leg injuries.

These are ambitious goals that may take several years to complete and involve several simultaneous and intense efforts. Plastic surgery must be more methodical in designing and conducting research, and even more critical in evaluating research publications; therefore, PRS will look for opportunities to capitalize on initiatives already underway that address these issues. For example, the PSEF is partnering with the Research Council to hold an inaugural symposium, on May 30 and 31, 2009, following the Research Council meeting in Pittsburgh, which will include topics on how to conduct clinical studies. We will encourage organized plastic surgery to support high impact research questions and grant applications that will attract a critical mass of clinical researchers who are capable of conducting EBM research studies. These efforts will result in publication of higher level scientific evidence, thereby promoting the mission of plastic surgery to ensure the safety and best possible outcomes for our patients.

The EBM movement in plastic surgery is synergistic with advocacy efforts by the ASPS, which depend on sound scientific data that justify fair insurance-coverage criteria and adequate third-party payer reimbursement for plastic surgery procedures. Unless plastic surgery can provide rich data to support the global scope of plastic surgery practices, payers will continue to use imperfect and often skewed data to their advantage, and therefore continue to decrease reimbursement. Plastic surgery should lead in the evidence movement or others will be more than happy to lead us. Plastic surgery is a specialty of innovation and the challenge has been presented to us—we must engage and energize our specialty to produce publications of highest levels of evidence, thereby promoting plastic surgeons as the leading scientists in the surgical disciplines.

Acknowledgments

We would like to thank DeLaine Schmitz and Jennifer Swanson, ASPS staff, for their invaluable input in this paper

Supported in part by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (R01 AR047328) and a Midcareer Investigator Award in Patient-Oriented Research (K24 AR053120) (to Dr. Kevin C. Chung)

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Table 1
The Five Basic Ideas of Evidence-Based Medicine

1	Gathering evidence
2	Integrating evidence with experience to arrive at a clinical decision
3	Implementing of this decision at bedside
4	Assessing performance
5	Staying current with research

Table 2**Levels of Evidence****Evidence Rating Scale for Therapeutic Studies**

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies
III	Retrospective comparative study; case-control study; or systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research or “first principles”

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Table 3
Scale for Grading Practice Recommendations

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong Recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences.
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V evidence: Little or no systematic empirical evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

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Table 4
Randomized Controlled Studies

Advantages

- Unbiased distribution of confounders

Disadvantages

- Time consuming
 - Expensive
 - Subject to volunteer bias
 - Can be ethically problematic
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