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AN AOA CRITICAL ISSUE

HOW TO READ THE LITERATURE TO CHANGE YOUR PRACTICE: AN EVIDENCE-BASED MEDICINE APPROACH*

BY SHEPARD R. HURWITZ, MD, PAUL TORNETTA III, MD, AND JAMES G. WRIGHT, MD

"... To fix a health care system distorted by spiraling costs ... true reform needs to go farther. Certainly any far-reaching reform must make greater use of evidence-based medicine ..."

—"Healing Health Care"
The Washington Post, May 15, 2004

What is this "evidence-based medicine" that the editorial staff of *The Washington Post* feels is a cornerstone of health-care reform, and what, if anything, does it have to do with the current practice of orthopaedic surgery? Does the application of evidence-based medicine offer a way to reduce public expenditure on health care? The short answer is that evidence-based medicine is a process that uses truthful clinical information in addition to the practical experience of the surgeon to make medical decisions[1]. Also, in theory, the practice guidelines that are generated by scientific clinical studies can reduce the complications and bad surgical outcomes that drive health-care costs higher[2].

The long answer with regard to how evidence-based medicine works requires some rigorous learning about statistics, probability, clinical research, guided inquiry, systematic reviews, and levels of evidence. Fortunately, the short answer is enough to get started, and orthopaedic surgeons can get up to speed by reading about levels of evidence in peer-reviewed journals.

The editors of peer-reviewed clinical journals have adopted a rating system that simplifies the process of rating articles for content[3]. Levels of evidence have been created to help clinicians to understand that evidence is created by scientific research that answers questions or solves problems. The application of journal articles into practice is the fourth stage of a problem-solving algorithm that starts with (1) formulating answerable questions, (2) gathering evidence, (3) evaluating the evidence, (4) putting evidence into practice, and (5) evaluating the results of putting evidence into practice. Surgeon-scientists have their articles published in journals that rate the level of evidence, and the individual surgeon learns to apply the knowledge that is the best evidence. If the clinical results are not acceptable, then the events must all be reviewed, looking for errors in the first

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four stages. Journals aid in the use of best evidence because they are making the results of clinical trials available and are assigning a level of importance[4].

The goals of this presentation are to acquaint the reader with some of the terminology, demonstrate some of the principles of evidence-based medicine, and help orthopaedists to locate the requisite evidence. Some of the learning comes from self-directed effort at reading the literature critically after raising questions of relevance to patient care, while other examples come from working with experts in data analysis and decision-making. These experts, termed YODAs (your own data analyzer) by David Slawson[5], can teach others to be their own data analyzers and decision makers.

Medical Evidence and Errors: Statistical Considerations

Clinical specialists in orthopaedics do not fully understand and are somewhat skeptical of statistics used in the literature. Statistics are commonly viewed as a complex method of supporting incorrect information by 'massaging' data and manipulating results to support anything an author decides is significant. In other words, statistics are the tool of the devil that gives the answer intended by the author, which may vary from 'the truth.' Better education of clinicians in the use and meaning of statistics and outcomes measurements will allow them to gain an increased understanding of what is being presented in the clinical literature, and, to a certain degree, will allow the reader to arrive at a more correct conclusion on the basis of the data presented in a manuscript. The purpose of this section is to discuss some common sources of error in the clinical literature and to show how dealing with error is an important step in creating evidence.

The first educational issue is error. All studies have some error, and a critical analysis of the manuscript for the means that are used to assess, minimize, and outline error is necessary. The most important thing that the clinician should know is how relevant is the question being asked in the manuscript to his or her own patient population. Several questions arise: Is this question an appropriate question? Was the study performed in an appropriate population? Was there selection bias? Was there technique bias? Were the outcomes measures ones that the reader deems to be important? Just as an orthopaedist evaluates a radiograph in a standardized fashion, similar methodology should be used to evaluate a scientific article. A systematic approach works best and has been outlined in several manuscripts and used for orthopaedic journal clubs[6].

The first thing in a standard evaluation is to decide what type of study has been performed. Is it a case series? Is it a randomized clinical trial? Is it a prospective cohort series?

Case series are extremely helpful for some specific problems. If, for instance, an author, a center, or a group of centers reported on a large population of patients with a particular problem that was treated with a specific intervention or an algorithm of interventions, had a high percentage of follow-up, and used important outcomes measures, this type of series can provide important information to the clinician about his or her patients. This is most helpful when the series includes a patient population that is the same as that seen by the clinician and the intervention is reproducible by the clinician. The best examples may be the series of acetabular fractures described by Letournel and Judet[7] and by Matta[8]. In both series, the acetabular fractures were classified in the same manner, which is a reproducible classification scheme. The value of expanding upon a case series by inductive reasoning requires a case sample that is large enough, rigorous entry, and unbiased follow-up with the appropriate statistical analysis. In each instance, the surgeon was an expert in reconstructing the acetabulum and the postoperative reduction was graded in the same manner. Finally, the outcomes measures that were used, that is, radiographic signs of arthritis and a consistent clinical scoring system, are appropriate and applicable for all patients with these injuries. This is an example of a specific problem in which the information given in these large case series is likely the best information that will ever be obtained. Acetabular fractures, being as unique as they are, do not lend themselves well to any kind of randomized trial. It is also unethical to not treat an acetabular fracture when one knows the outcome will likely be poor. Therefore, the best information that can possibly be obtained is a large, prospective cohort study that describes the outcomes for the patient with use of current interventions. These results can be communicated to patients prior to surgery in the preoperative discussion to allow for the best possible knowledge to be transmitted and an informed consent obtained. The patients, on the basis of this information, which is the best available, will have a better understanding of their chances of doing well and what problems they may encounter in the future.

Finally, the clinician must be objective and fair when comparing his or her own skills with those of the authors of a published series. Not all surgeons are able to reconstruct a complex acetabular fracture. Specialty training is often necessary to acquire sufficient skill and judgment, and, even after additional experience, the ability to reduce the fracture may not be the same for each surgeon. It has been demonstrated that patient volumes may have a positive effect on the clinical outcome, with improvement seen as a surgeon gains greater experience with difficult acetabular fractures[9]. Even given this fact, the correlation of the reduction of the articular surface with the development of arthritis would be appropriate for all surgeons to use as a criterion postoperatively in explaining to a patient what his or her risk of arthritis is. Thus, large case series for specific problems may provide the ultimate information available.

What if there are multiple treatment options available and one would like to develop the best possible evidence for deciding among these treat-

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ment methods? In this situation, a randomized clinical trial is clearly the best possible method of evaluating the treatment options. The ultimate planning of randomized clinical trials is beyond the scope of this review; however, certain things that are apparent in reading through orthopaedic randomized clinical trials should be highlighted such that readers can be more cognizant of the problems that exist in these trials. The first thing is to understand what a "p" value is. The p value is simply a probability test. Thus, when we compare two methods of treating a problem, such as reamed and unreamed nailing of a tibial fracture, the standard p value of "significance" is 0.05. Essentially, this sets a standard so that, in order to state that one treatment is better than another, one must be 95% sure that this is the case. To understand this further, the reader needs to appreciate that a study is made up of a sampling of a population. By definition, a population is all patients with a particular problem. Thus, the population of tibial fractures that would be relevant for a study such as this would be all patients in the known universe with a tibial fracture. The study, however, includes what is referred to as the sample, which is only a portion of these patients. Thus, a sample is just a small portion of the overall population and may occur anywhere underneath the population curve. In other words, a random sample could occur more to the extreme left or right of the actual population mean.

The next thing to understand about how samples work is the 95% confidence limits. This means that 95% of the time (the 95% confidence limit) the sample overlaps with the actual mean of the population. Once the concept of a study sample is understood, the errors that can occur from sampling error become self-evident. When two treatment methods are compared, there are two sample populations. Both of these samples, having come from the general overall population of tibial fractures in this case, would have to be underneath that curve. Assuming that the outcomes from these two treatments are equal, they may occur close together or, by chance, they may occur farther apart. If the two treatment methods are, in fact, the same and, by random chance, one encountered the samples from the main population, which do not overlap, one could conclude that these two treatments were different on the basis of the data seen in these random samples. By choosing $p = 0.05$, we accept that there is a 5% (five-in-100) chance of this occurring. Thus, in this particular case, two treatment methods would seem to be different when, in fact, they are the same. This is called an alpha error. Alpha error occurs when the populations for treatments A and B are actually the same, but the two samples, by chance, do not overlap. In other words, we incorrectly conclude that there is a difference between the treatments when, in fact, there is no difference. A true difference in study populations would be reflected in a difference between two sample populations treated with different methods. The sample groups would not overlap, but this would be a true difference in outcomes, supporting the conclusion that there is a difference between treatments.

Alpha error is increased when studies include multiple variables. In reviewing forty peer-reviewed orthopaedic studies, Bhandari et al.[10], in 2005, reported that 37% of randomized clinical trials were at risk for a Type-I error, or alpha error, concluding that there was a difference when, in fact, there may not have been a difference. This is primarily due to the fact that multiple evaluations were performed without correcting for these variables. If we accept that there is a 5% chance that random sampling could create a difference where one does not exist, then it is easy to understand that, if twenty variables were evaluated, there is a very good chance that one of the variables would meet those standards purely by chance. Thus, when multiple evaluations are performed in a study, a Bonferroni[11] correction must be performed. The reader can use a general guideline, which is simply to divide the p value by the number of evaluations done. Then, if an author reports on ten different outcome variables, one divides the standard value of $p = 0.05$ by ten, and the new p value that would clearly demonstrate that a difference exists between two treatment methods with respect to that specific variable would be 0.005. Thus, not all differences reported in the literature are properly proven statistically.

In addition to looking for an alpha error, the surgeon decides whether a difference that is true and proven is actually clinically useful. This is referred to as the effect size. In other words, the difference between treatments has a measurable difference, but that difference may not matter to the surgeon or the patient. For example, we may refer back to our study comparing two techniques of fixing tibial fractures and assume that the mean time to union is 250 days with one treatment and 260 days with another treatment and that the standard deviation is sixty days. There may be a true difference in this scenario, for instance, if $p = 0.03$; however, in the grand scheme of the treatment of tibial fractures, ten days with a standard deviation of sixty days in the treatment groups is probably not very important. The effect size here would be 10/60 or only 0.16. In general, an effect size of ≥0.8 is considered important enough that one might change practice, given similar patient risk profiles and other factors. Similarly, a biomechanical study comparing one fixation method or one prosthesis with another might have a very tight set of data; however, the difference may be clinically negligible. Does a surgeon really need to care if there is 1 mm more motion at a proximal tibial metaphyseal fracture as long as the method of fixation provides enough biomechanical stability and rigidity to allow the fracture to heal in that position? The answer is quite clearly, no. For studies with dichotomous variables, the use of relative risk reduction is an excellent method of evaluating clinical importance. Absolute risk reduction or the number of cases that are affected by

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treatment is another useful tool for the evaluation of clinical importance. If a prevalent condition such as nonunion decreases by 5% with a given treatment, then five of 100 patients have a reduced risk of nonunion with that treatment.

It is also important to look at the differences in the clinical parameters reported. If the study finds that there is a 95% chance that a treatment would provide a 4-point improvement in the score on a 100-point scale, this may not be very important to the surgeon or the patient. In particular, what risks would be worth taking to gain an average of 4 points on a 100-point scale? These are some of the clinical decisions that need to be made by the surgeon, and these decisions are influenced by reading scientific articles and texts. Risk is a topic for another discussion, but the relative value of an outcome to a patient is greatly influenced by how the information is presented by the surgeon. This is one of the dangers of clinicians relying on review articles with less utilization of the primary literature[12]. If one reads only review articles or general textbooks, opinions would be shaded toward conclusions made by an author that may not actually be supported by the data presented in the relevant studies.

Another systemic type of error seen in clinical trials is called beta error. This is a more common problem than alpha error. A beta error occurs when one concludes that there is no difference between two treatments when, in fact, a difference might exist. For example, two populations may have a true difference, but two random samples from the similar populations are not different. Beta error is related to the number of patients in the sample. This is so-called underpowering of a study. The power of a study is essentially its ability to demonstrate that two things are the same. Thus, a comparison of three tibial fractures treated with one method and three tibial fractures treated with another method would not be very convincing information. If, however, 600 patients treated with one method were compared with 600 treated with another, this would be very compelling information.

Randomized surgical trials frequently do not state the power of the study or their ability to demonstrate differences. In a review of orthopaedic trauma studies, Lochner et al.[13] found that, for primary outcomes in 117 studies that reported "no significant difference," the potential beta error rate was 92% for primary outcomes and 97% for secondary outcomes. The reason for this becomes quite apparent when one looks at the amount of difference that would be clinically relevant. For example, in a study of the healing time for tibial fractures, if the time for healing in a control situation was an average of 150 days and one wanted to see a 20% difference to bring it to an average of 120 days, this may require only sixteen patients for a group; however, if one expected only a 5% difference, it would require 289 patients per group. This is even more evident in problems that have dichotomous variables such as deep venous thrombosis. In this type of a situation, the patient either has or does not have a clot and one has to compare percentages. If the actual rate of pulmonary embolism is 0.1% for a specific procedure and one wanted to demonstrate a difference of as much as 20%, it would be necessary to have 353,000 patients in each arm of a randomized trial.

This raises the question of how negative results should be reported, because the beta error may mask a true difference. There are two ways in which authors can help the reader to understand "negative" findings. First, when a study comparing two outcomes is done and no difference is found, the p value and the range of p values can be reported, thus giving a probability of how likely these two outcomes are to be different. Additionally, the author can report the number of patients that might be required to demonstrate a difference if, in fact, the actual number of patients in the study and the number required to show a difference were different. For instance, it might be that a study conclusion is that no difference was found with the data available; however, if an additional number of patients were included in the study, a difference would be possible. This would give the reader an idea of exactly how big the difference in these two treatment methods may be. Stated differently, with 80% power, how much of a difference would have been detected in outcomes between two groups? For example, a study of two different treatments of tibial fractures might conclude that, with 80% power, a difference of six weeks in the time to union could have been detected. Then the reader sees more clearly that, if these two treatments have different outcomes, the likely difference in time to healing would be six weeks.

Improvements are now appearing in the quality of articles being published in peer-reviewed orthopaedic journals, as authors better understand statistics and reviewers hold them accountable for their proper use. In the past, clinical reports were found to have errors that likely produced less than optimal management of patients with orthopaedic problems. It is now clear that the reader of our literature must have some level of sophistication and understanding of the statistical methods used in clinical studies. As a greater number of evidence-based reviews by investigators who are more knowledgeable in these areas are published, treatment patterns of orthopaedic conditions will likely be more convergent. However, even evidence-based reviews and levels of evidence do not take into account all things. As stated in the beginning of this section, sometimes the best evidence is a simple case series demonstrating the results of a particular treatment method for a particular patient population. As surgeons, we should become, to a certain degree, expert in the critical analysis of the orthopaedic literature.

Where to Find Orthopaedic Evidence

One finds evidence in peer-reviewed journals and medical search engines (see below) that have expert reviewers interpreting clinical information and assembling evidence. Journals publish

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the outcomes of clinical trials and systematic reviews of trials, while search engines gather these and other similar publications to give a more complete picture of the evidence. Rarely, evidence is presented directly to the orthopaedic community in a scientific presentation or educational forum. Topic reviewers and the expert surgeons who write and speak in their area of expertise are content experts but not necessarily purveyors of the best evidence.

Evidence comes from clinical trials that demonstrate the effectiveness of a diagnostic test or treatment. Inasmuch as diagnosis affects treatment decisions, accuracy of diagnosis is where the search for evidence begins. Once a diagnosis has been established with near certainty, then treatment is agreed on by the surgeon and the patient in order to solve a clinical problem, which is most commonly pain or a lack of function in those with a musculoskeletal condition. Decisions are made throughout this process, but the most sharing between patient and surgeon comes with treatment decisions. Treatment decisions are often swayed by the information presented by the surgeon, who usually includes a brief list of options, and a choice is made by the patient.

In order to present information concerning treatment in a prioritized manner, the surgeon needs to have knowledge of the probability of success for each treatment in that particular patient. Evidence-based practice attempts to provide the surgeon with the probability of success based on clinical trials that have compared the alternative treatments. In the past, most surgeons took the view that randomized controlled trials were not possible or were not applicable to orthopaedic surgical procedures. Today the pendulum is swinging toward the necessity of clinical trials to give orthopaedic surgeons the evidence they need to practice in an evidence-based medicine world.

Surgical decision-making is sometimes easy but often difficult because of, among other factors, the lack of evidence and the preponderance of opinions and information that are not accurate. It is far easier for a busy surgeon to call a colleague and ask for an expert opinion and get answers to tough questions than to formulate answerable questions and search the body of orthopaedic literature. It is easier to read a textbook or a review article and do what the "expert" recommends than to wrestle with the full clinical question and search for relevant clinical trials and explain the results to a skeptical patient. This is where evidence-based medicine becomes useful and relevant—thanks largely to electronic search engines and the increasing availability of levels of evidence. In addition, the trend toward outcome measurements in all clinical medicine is a reaffirmation of the century-old concept of E.A. Codman, who observed that the end result is that empirical outcomes matter most to patients[14].

How to Apply Evidence

Surgeons want to do what is best for their patients. However, surgeons across the country, across town, or even across the hall commonly disagree on how best to treat clinical problems. The culture of orthopaedics is one of acceptance or even promotion of this divergence in opinion[15]. This variation in opinion can be attributed to many factors, including a reliance on uncontrolled case series and the unquestioning acceptance of the opinion of senior colleagues, who disagree on many clinical issues just like everyone else. Because not everyone can be right, the variation in surgeons' opinions almost certainly impacts negatively on overall clinical care. The costs of poor clinical decisions, both diagnostic and treatment, are borne by the patient and society.

Evidence-based practice provides an alternative paradigm to opinion-based practice[16]. Evidence-based practice means applying high-quality evidence from randomized trials to the care of patients. Pediatric oncology provides one of the most striking examples of the power of randomized trials[17]. If a child had cancer thirty years ago, the chosen chemotherapeutic regimen would have depended largely on the personal opinion of the individual oncologist. About that time, pediatric hematologists began to perform multicenter, collaborative clinical trials. The mortality rate of children with a malignant tumor since that time has decreased from 90% to 30% largely because of those multicenter randomized trials. This dramatic improvement in clinical outcome provides a compelling example of the power of randomized trials and evidence-based practice.

The essential elements of evidence-based practice are the formulation of a clinical question, identification and evaluation of the evidence, and application of the evidence to the clinical decision. Thus, surgeons need to recognize the need for evidence, look for and recognize evidence, and use the evidence. To practice evidence-based orthopaedics, the first step for surgeons, when confronted with a clinical dilemma, is either to admit they do not know the answer (if they don't) and look for the best answer, or to admit there is a best answer when one is known. A description of evidence popularized by Sackett et al. formalizes this step by articulating the problem and specifying the task[16]. For example, when confronted with an eight-year-old boy with an isolated mid-shaft transverse femoral fracture, the specific task for an evidence prescription would be to determine what form of treatment provides the lowest rates of malunion. The prescription would be filled by indicating what was found, how it was found, assessing the validity and/or applicability of the information, and then deciding how the information will affect management. Identifying the best evidence, however, is not always straightforward. Textbooks are most accessible to surgeons but are frequently out of date and are usually opinion-based. The surgical literature is the source of the most definitive evidence, but the number of publications is overwhelming. For example, a Medline search to determine treatment for a child with a femoral fracture yields more than 2000 articles! To narrow the search, Medline has provided a recent addition called

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"Clinical Queries" found under "PubMed Services" on the left-hand column of the PubMed home page. "Clinical Queries" refines the search, which can be narrow or broad, for a specific clinical condition to one of therapy, diagnosis, etiology, or prognosis. Narrow searches have the highest probability of identifying only randomized trials, whereas broader searches are more likely to identify all clinical trials. Peer-reviewed orthopaedic journals, such as *The Journal of Bone and Joint Surgery,* also aid surgeons by providing levels-of-evidence ratings at the end of the abstract. Levels of evidence categorize individual studies into one of four types: therapeutic, prognostic, diagnostic, or economic and decision analyses. Studies are graded according to the design into five levels, whereby randomized trials are the highest or Level-I evidence and expert opinion is the lowest or Level-V evidence. However, a practical problem for surgeons using both a literature search and "Clinical Queries" or refining the search by levels of evidence is to identify the best evidence fast enough for most clinical situations.

What surgeons really need is for someone to systematically review the literature to identify the best evidence. Practice guidelines, a kind of systematic overview, may provide useful information for surgeons. Practice guidelines, if evidence-based, review the literature and use grades of recommendations to evaluate the overall quality of the evidence. For example, a Grade-A recommendation indicates high quality and consistent evidence, whereas a Grade-C recommendation indicates poor quality or inconsistent evidence. To return to the example of a pediatric femoral fracture, the Evidence-Based Analysis Working Group of the Pediatric Orthopaedic Society of North America systematically reviewed the literature but was unable to provide any clear recommendations on the best treatment for pediatric femoral fractures; thus, their recommendations for treatment could be graded C (or uncertain). Other sources of systematic reviews are the *British Medical Journal's* "Clinical Evidence" web site (www.clinicalevidence.org/ceweb/conditions/index.jsp) and the Cochrane databases (www.cochrange.org/index.htm). Although there are costs associated with accessing these databases through their web sites, they address one of the key issues for surgeons, namely, timely access to a comprehensive review on a clinical topic. For many clinical questions, randomized trials will be lacking, but this is changing.

To bring systematic reviews to the clinical setting or the patient's bedside requires access to the Internet. For many clinical questions, if surgeons do not have access to the Internet in the clinic, they may answer the question when they next get access to the web. In the future, handheld devices may provide surgeons with real-time access to the Internet in "hot zones." The final step in evidence-based practice requires surgeons to adopt better evidence by changing their opinions and, more importantly, their practice, when confronted with good evidence. This step may be the most difficult because not all surgical therapy when subjected to randomized trials may be found to be beneficial[18]. For the patient's sake, such procedures should be refined or abandoned.

Conclusion

One of the changes in orthopaedic decision-making that comes with the implementation of evidence-based medicine is the belief that evidence trumps experience. Evidence, for the purpose of this discussion, comes from a rigorously designed research plan with an adequately powered study population demonstrating significant results. Thus, a commonly referenced definition is: "Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."[19] The decisions that an orthopaedist encounters are diagnosis, treatment outcome, disease outcome, and financial burden. Ideally, in the future, there will be evidence to help the surgeon and patient to arrive at shared decisions for all treatable conditions.

In conclusion, evidence-based practice has the potential to change the culture of orthopaedics for the better and improve the quality of care for patients.

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