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Symposium integrating evidence-based medicine into clinical practice

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THE ORTHOPAEDIC FORUM



THE AMERICAN ORTHOPAEDIC ASSOCIATION

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Symposium

Integrating Evidence-Based Medicine into Clinical Practice*

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Evidence-based medicine represents the combination of the best available clinical research evidence with clinical experience and expertise and the needs and expectations of patients. Evidence-based medicine as a concept has been available for years, but it has become increasingly important over the last decade. Some evidence has suggested that it began as early as the ancient Chinese medicine practices, while other evidence has indicated its origins were in postrevolutionary France with the systematic patient observations of Pierre

**Presented at the Annual Meeting of the American Orthopaedic Association, Huntington Beach, California, June 25, 2005.*

Louis¹. Gordon Guyatt led a group at McMaster University in the early 1990s that introduced many of the current concepts of evidence-based medicine. This led to a major increase in interest in the area. One paper had been published in the literature in 1992, but by 1998 over a thousand manuscripts had been published in the field¹.

Evidence-based medicine utilizes the best available research evidence. In the hierarchy of medical evidence, systematic reviews including meta-analyses represent the highest form of evidence if inclusion is limited to Level-I or II studies (Table I). Systematic reviews of Level-III or IV observational studies can be performed, but they rep-

resent Level-III or IV evidence. Frequently, in orthopaedics, systematic reviews or meta-analyses may not be available and clinicians may need to rely upon randomized controlled trials, cohorts, case-control studies, case series, or, in some areas, expert opinion. Orthopaedists may not yet recognize this hierarchy. During the 2005 Annual Meeting of the American Orthopaedic Association (AOA), the audience was asked the question: "Findings from which type of study design are most likely to influence your clinical practice?" The responses indicated that a randomized controlled study design was used by 49%; a systematic review and/or meta-analysis of Level-I studies,

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TABLE I Medical Evidence Hierarchy

Meta-analysis and/or systematic review (if performed on Level-I or II studies)
Randomized clinical trials
Clinical trials
Cohort studies
Case-control studies
Case series
Case reports
Expert opinion

by 44%; expert opinion, by 5%; and case series, by 3%.

At a symposium at the 2005 Annual Meeting of the AOA, a series of eleven systematic reviews was presented. The series involved more than fifty randomized controlled trials performed to determine the best available evidence in the literature to address a series of clinical questions on the treatment of injuries in sports medicine involving the shoulder, knee, foot, and ankle. The symposium demonstrated the ability to use the highest form of evidence available in a practical manner to assist in clinical decision-making. In the present review of that symposium, we use selected examples of systematic reviews of major clinical questions to reveal the strength of evidence-based medicine in routine clinical practice. Areas that can be clarified through the use of systematic reviews include challenging previously held dogma, assessing the efficacy of new technology compared with previous methods, and improving decision making in the face of studies with a limited or low level of evidence.

The steps of performing a systematic review are reasonably straightforward and can be performed by most researchers (Table II). The systematic reviews in this symposium were developed with use of these methods. Each clinical question was assessed with a rigorous review of the literature, including a search of MEDLINE, EMBASE, and the Cochrane Controlled

Trials Register. The bibliographies of the appropriate manuscripts identified by this search were also reviewed for additional relevant studies. To ensure that no recently published articles were missed, a hand search of journals published in the previous six months was performed and included a search of *The Journal of Bone and Joint Surgery* (American and British Volumes), *Clinical Orthopaedics and Related Research*, and appropriate subspecialty journals in the areas of sports medicine, shoulder, knee, and foot and ankle. The search was limited to English-language journals. Studies identified by this search were reviewed with use of a standardized worksheet as a method of quality appraisal. Biases were identified, and the study was included or excluded on the basis of the specific evidence available with each question that is outlined throughout the present article.

The Shoulder

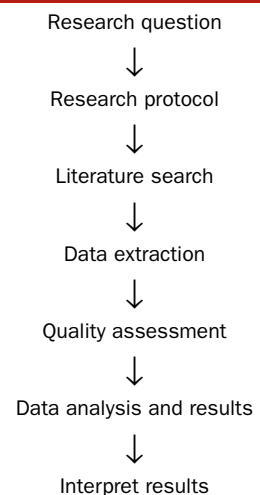
There are a number of questions in the current treatment of shoulder disorders that can be addressed with use of an evidence-based medicine approach. The shoulder represents a clinical area where systematic reviews can assess the efficacy of recently introduced technology or methods and can help the clinician to determine whether the data supports changing his or her practice. The example presented is a systematic review regarding the success of arthroscopic compared with open shoulder stabilization procedures.

Should We Use an Open or Arthroscopic Approach for Bankart Repairs? An Example of the Use of

Evidence-Based Medicine to Decide Whether to Change Your Practice

Historically, the surgical treatment of recurrent traumatic anterior shoulder instability included a variety of open surgical repairs. With the advent of arthroscopy, surgeons in the 1980s began to approach patients who had recurrent traumatic anterior shoulder instability with new, minimally invasive techniques. Early repairs were complicated by a lack of technology, and a number of case series in the literature (Level-IV studies) presented very high failure rates. In the 1990s, arthroscopic suture anchor and suture management techniques evolved to the point where arthroscopic surgery for recurrent traumatic anterior shoulder instability closely approximated the open repair techniques and the results that were reported appeared to be promising. At this point, the clinician can ask: On the basis of the recurrence rate as an outcome measure, should I now adopt the arthroscopic approach?

This clinical question was assessed with a rigorous review of the literature. A search of MEDLINE, EMBASE, and the Cochrane Controlled Trials Register was performed with the terms "Bankart,"

TABLE II Steps in Performing a Systematic Review

“shoulder,” “anterior,” “reconstruction,” “clinical trial,” and “randomized trial” in combinations with use of the Boolean operators “and” and “or.” The bibliographies of the appropriate manuscripts identified by this search were also reviewed for additional relevant studies. To ensure that no recently published articles were missed, a hand search of journals published in the previous six months was performed and included a search of *The Journal of Bone and Joint Surgery* (American and British Volumes), *Clinical Orthopaedics and Related Research*, *The American Journal of Sports Medicine*, *Arthroscopy*, and *Journal of Shoulder and Elbow Surgery*. The search was limited to English-language journals. Exclusion criteria included case series or nonrandomized trials. Studies identified by this search were reviewed with use of a standardized worksheet as a method of quality appraisal, and biases were identified. This review of the literature identified three prospective, appropriately randomized, and controlled Level-I studies that could be reviewed to answer this question²⁻⁴. In each of these studies, the populations were small (forty-one to sixty subjects), yet the follow-up was 100% and the patients were followed for two years or more. The recurrence rates were not significantly different in any of the studies (the recurrence rate ranged from 0% to 12% for open surgery and from 0% to 23% for arthroscopic procedures; $p > 0.6$).

While it is difficult to demonstrate statistically that two procedures are identical, statistics can determine whether two procedures differ. In this instance, none of the studies demonstrated a significantly higher recurrence rate with the arthroscopic approach. While none of the authors addressed the statistical power of their studies (clearly a flaw when the two groups in a trial do not show a difference) and the use of 95% confidence intervals would have provided more information and allowed for stronger conclusions, the evidence suggests that the recurrence rates are not significantly different and that, in the hands of those investigators, for their patient population, the

arthroscopic approach had recurrence rates that were not different from those obtained with a traditional open approach. This is not yet a commonly held belief as demonstrated by the results of a survey at the 2005 Annual Meeting of the AOA in which 70% of the responders indicated that they believed that the results are not equivalent. The clinician who is considering changing from a traditional open procedure to an arthroscopic approach for the treatment of shoulder instability can now do so with the support of a very high level of evidence demonstrated in this systematic review.

In summary, any question regarding the treatment of patients with disorders of the shoulder can be addressed with use of this approach. In some cases, the data are very strong and, if our experience and patient population is represented in the studies, the Level-I evidence can guide our treatment decisions. In other cases, the Level-I evidence may be less persuasive than we had thought, or there may be no Level-I evidence and we are forced to rely on lower levels of evidence as is demonstrated below. Use of an evidence-based medicine approach is helpful, even in these situations, and hopefully it will direct our research efforts toward higher-level studies.

Foot and Ankle

Not infrequently, there may be no Level-I or Level-II evidence with regard to a clinical problem in orthopaedics. As pointed out in the introduction, evidence-based medicine is the use of the best available evidence in combination with patient needs and clinical experience. Thus, when no Level-I or II evidence is available, then lower levels of evidence will have to suffice for decision making, but researchers should be stimulated to perform higher levels of studies in these areas.

Is There a Best Evidence Method for the Treatment of a Syndesmosis Sprain?
How to Use Evidence-Based Medicine
When There Is No High Level of Evidence
Syndesmosis sprains remain a challeng-

ing injury for physicians. Despite improved identification and assessment with magnetic resonance imaging, the time lost from participation in sports following this ankle injury remains long. Traditionally, treatment has been nonoperative, but the prolonged recovery time requires analysis of this and other options.

This clinical question was assessed with a rigorous review of the literature. A search of MEDLINE, EMBASE, and the Cochrane Controlled Trials Register was performed with use of the terms “syndesmosis,” “syndesmotic,” and “high ankle” (connected with the Boolean operator “or”). The bibliographies of the appropriate manuscripts identified by this search were also reviewed for additional relevant studies. To ensure that no recently published articles were missed, a hand search of journals published in the previous six months was performed and included a search of *The Journal of Bone and Joint Surgery* (American and British Volumes), *Clinical Orthopaedics and Related Research*, *American Journal of Sports Medicine*, *Arthroscopy*, *Foot and Ankle International*, and *The Journal of Foot Surgery*. The search was limited to English-language journals. Exclusion criteria included injuries sustained in high-energy situations outside of sports and injuries involving fractures of the ankle.

Our literature search did not identify any Level-I or II randomized, controlled trials, and the highest level of evidence available was Level IV, or case series. Series were excluded unless they collected data on consecutive patients and included only athletically active patients. In addition, only studies dealing with isolated syndesmosis sprains without radiographic evidence of widening of the mortise or an associated ankle fracture were included for review. Six studies met the criteria for review (see Appendix)⁵⁻¹⁰.

All studies were case series that were Level-IV evidence. All of the series reported included professional or college athletes. The diagnosis in all studies was clinical. Radiographs were made,

but the diagnosis was not based on the findings of radiographs or magnetic resonance imaging. There was a large variation in the time lost from sports and return to play, with a range of 6.3 practices and 1.4 games for professional football players, forty-five days for professional hockey players, and fifty-two days for army cadets involved in a variety of sports.

Homogeneous outcome measures were not used in these studies. In addition, functional outcome was not reported in every study. In four of the six studies, a functional outcome measure was used and most of the patients returned to good or excellent function once they had recovered from the injury. In terms of surgery, one of fourteen patients in the study by Wright et al. and one of fifteen patients in the study by Hopkinson et al. were managed operatively^{7,10}. In general, surgery was not required and conservative treatment was employed. A number of nonoperative modalities were used, and they included removal from activity, immobilization, ice, and anti-inflammatory medication. Once the patients became pain-free and were able to function, they were allowed to return to sports as tolerated.

Syndesmotic, or high ankle, sprains continue to be a common injury that results in substantial time lost from sports. The lower level of evidence (a Level-IV case series) in this systematic review does not give solid or high-level scientific evidence for the best treatment and management. The conclusion to be made from this type of evidence is that the diagnosis does not allow accurate assessment of the severity of the injury and, thus, the ability to predict the time lost from sports. This can be an injury with a considerable period of time lost from sports, but there are also some instances with very few days lost. This suggests that current diagnostic methods are not prognostic. In addition, conservative (nonoperative) treatment may not be appropriate in these various degrees of injuries in which several weeks are missed from the sport. Operative treatment for se-

vere injuries may improve the ability of the patient to return to sports sooner and needs consideration. Clearly, this systematic review highlights the need for further research, such as prospective cohort studies, Level-I prognostic studies, or treatment studies (Level-I or II clinical trials) to answer the hypotheses generated by this systematic review of Level-IV case series.

Knee

Orthopaedic surgeons who perform anterior cruciate ligament reconstruction frequently have very strong beliefs regarding their choice of grafts for the reconstructed knee. Currently, hamstring and patellar tendon are the most common autograft choices used by surgeons. Different groups have proposed that each graft offers a superior outcome compared with the other graft. Evidence-based medicine can be used to systematically review the literature to determine whether a significant difference truly exists and thus challenge surgeons' beliefs.

Anterior cruciate ligament reconstruction is the current standard of care in athletically active patients on the basis of Level-I evidence (randomized controlled trials) demonstrating improved stability, increased activity, and a reduced rate of meniscal tears¹¹⁻¹³. Disruption of the anterior cruciate ligament is the most frequent ligament injury in the body¹⁴⁻¹⁶. There may be as many as 200,000 anterior cruciate ligament reconstructions annually, with a cost in excess of \$2 billion, and there is evidence that the number of these procedures is increasing¹⁷⁻¹⁹. The orthopaedic surgeon contemplating the choice of autograft tissue as an anterior cruciate ligament graft is confronted with several hundred articles expressing different opinions. Most of these articles are case series lacking a representative control group and are usually retrospective. This review focuses on the most common choice facing a surgeon deciding to reconstruct an anterior cruciate ligament, that is, the choice between hamstring or bone-patellar tendon-bone graft as the autograft tissue.

Therefore, an evidence-based medicine review was conducted to determine whether there is evidence to address this specific question. The result is a systematic review of ten Level-I randomized controlled trials on the choice of autograft (hamstring graft or bone-patellar tendon-bone graft).

Does the Choice of a Hamstring or Bone-Patellar Tendon-Bone Graft Offer an Advantage for Patients?

How to Use Evidence-Based Medicine to Challenge or Confirm Commonly Held Beliefs

In *The American Journal of Sports Medicine* in 2004, a systematic review was published on the choice of autograft for anterior cruciate ligament reconstruction²⁰. That article contained nine Level-I randomized controlled trials designed to compare autograft types (hamstring grafts and bone-patellar tendon-bone grafts)²¹⁻²⁹. The objectives were to identify reproducible, clinically important differences in objective measures (stability, range of motion, and strength) and subjective measures (questionnaire results) to determine whether the choice of autograft is an important variable in the outcome after anterior cruciate ligament reconstruction. The results were presented in tabular form, and the absolute differences between outcome measures for the different grafts were evaluated and presented such that the reader could interpret the reproducibility and clinical importance of the results. The goal was to provide orthopaedic surgeons with the data on which to base their decisions on the highest level of evidence for their practice. The presentation of a systematic review in tabular form was deemed to be complementary to, not a substitute for, formal statistical combining of data as in a meta-analysis. This review builds on these nine randomized controlled trials and adds a tenth trial by Laxdal et al., which appeared in January 2005 in *Arthroscopy*³⁰. Thus, this systematic review on autograft choice contains ten randomized controlled trials, all with Level-I evidence.

The studies were identified with a

rigorous review of the literature. A search of MEDLINE, EMBASE, and the Cochrane Controlled Trials Register was performed with use of the terms “ACL,” “anterior cruciate ligament,” “reconstruction,” “autograft,” “clinical trial,” and “randomized controlled trial” in combinations (connected with the Boolean operators “and” and “or”). The bibliographies of the appropriate manuscripts identified by this search were also reviewed for additional relevant studies. To ensure that no recently published articles were missed, a hand search of journals published in the previous six months was performed and included a search of *The Journal of Bone and Joint Surgery* (American and British Volumes), *Clinical Orthopaedics and Related Research*, *The American Journal of Sports Medicine*, *Arthroscopy*, and *The Journal of Knee Surgery*. The search was limited to English-language journals. Exclusion criteria included inadequate or lack of randomization (alternating sequence or consecutive series), or series using allografts.

These studies were conducted in five countries by a total of twenty-seven surgeons and consisted of a sample size with follow-up of 890 (91%) of a possible 974 patients. Eight of the studies used an endoscopic arthroscopic approach to bone-patellar tendon-bone grafts, and two of the studies used a rear-entry approach. With regard to the hamstring constructs, a similar distribution of endoscopic and rear-entry approach was compared. In all studies, the fixation points, whether interference screws, EndoButtons (Smith and Nephew, Andover, Massachusetts), screw and post, or staple, were thought to be satisfactory, thus eliminating differences in fixation technique between grafts. The hamstring studies were either three or four-graft constructs in seven of the ten studies. When the demographic data or rehabilitation protocols were evaluated, no differences were found between groups.

Instrumented laxity at the time of the final follow-up was usually the primary outcome measure to determine the results between the autograft

groups. The results of the ten studies, including the method of measuring instrumented laxity, the force, the percentage with force of <3 mm, the actual millimeters of force, degree of variation, and p value are reported in a table in the Appendix. Seven of the ten studies demonstrated no significant difference between grafts with respect to instrumented laxity at the time of final follow-up. Three of the ten studies demonstrated a significant difference ($p = 0.05$ in two studies, and $p = 0.004$ in one), with the patellar tendon group being more stable in each study. However, the differences between the bone-patellar tendon-bone and hamstring grafts were 1 mm in two studies and 3.3 mm in another study. It should be noted that, in two of the three studies, a two-strand hamstring construct was used and not the typical three or four-bundle construct used most commonly today. It should also be noted that the follow-up periods reported by the authors were, in the majority, two years and up to three years in some studies.

Isokinetic strength at the time of final follow-up was also measured in seven studies. No differences were reported in quadriceps strength and in strength between the grafts. However, in three of the seven studies, there was a weakness in knee flexion with the hamstring graft. This weakness ranged between 7% and 11%, and averaged between those values.

Patellofemoral pain at the time of final follow-up should be divided into anterior knee pain and kneeling pain. All studies measured some component of patellofemoral pain, but their scales were not consistent. In eight of the ten studies, there was no significant difference in anterior knee pain between the groups. However, two of the studies demonstrated a significant difference, with less pain in the hamstring group ($p = 0.007$ and $p = 0.05$). The results of kneeling pain, defined as a knee walking test in two studies, as a visual analog scale score in two others, and as measured by a subjective scale in one, consistently showed that the patients with bone-patellar tendon-bone grafts had

more kneeling pain than did those with hamstring tendon constructs. These two topics were thought to be the most important with regard to the graft decision, as shown by the results of the survey at the 2005 Annual Meeting of the AOA, in which kneeling pain and patellofemoral pain were thought by 31% and 32% of the responders, respectively, to be the most critical reproducible factors. Instrumented laxity and isokinetic strength at the time of final follow-up were thought to be the most critical factors by 19% and 18% of the responders, respectively.

Activity level and functional assessment were also obtained postoperatively in nearly every study. When activity levels were compared, by non-validated means in the majority of the studies, nine of the ten studies showed that there was no difference between groups. However, O'Neill²⁸ demonstrated a significantly higher return to activity in the bone-patellar tendon-bone graft group compared with the hamstring construct group ($p < 0.02$), whereas a comparison with the preinjury activity level demonstrated a difference of only six percentage points. Furthermore, in a comparison of various clinical outcome assessments, in every case, no significant difference was observed between the autograft groups.

The present large, prospective cohort of ten randomized trials demonstrated that the failure rate of the anterior cruciate ligament reconstruction graft was 3.6% (95% confidence interval, 2.3% to 5.3%). No significant differences were found with regard to increased failure of the hamstring graft compared with the bone-patellar tendon-bone graft in any individual study, and, when the data of all of the studies were combined, no difference was found in the overall prevalence of failure of the bone-patellar tendon-bone graft compared with that of the hamstring graft. The rate of deep intra-articular infection ranged from 0% to 2.9%. When the data in the studies that noted infection were averaged, the frequency of infection was 1.0% (seven of 733 knees).


In conclusion, this systematic review did not find consistent reproducible differences between autograft patellar tendon and hamstring grafts that would separate or recommend a particular graft choice. How these graft choices may affect patient-centered outcomes or longer-term (i.e., five to ten-year) follow-up is unknown. However, the data and reviews suggest that the choice of autograft may not be the primary determinant of successful results in the short term after anterior cruciate ligament reconstruction. We hypothesize, given the excellent success rates of both surgical techniques and graft choices, that injury to and treatment of the meniscus and articular cartilage may have a more profound influence on anterior cruciate ligament reconstruction results and patient-centered outcomes than the specific graft selected.

Overview

As demonstrated by this symposium, the application of evidence-based medicine principles, highlighted by systematic reviews of the literature to determine the best available evidence, provides readers with guidance in patient-care decisions. Sometimes with systematic reviews, the available evidence is excellent. However, systematic reviews more frequently can use only Level-III or IV studies on which to base decisions and, thus, should lead to further studies in these areas.

We believe that, in the future, these principles should be applied to narrative reviews and current concept articles. In contrast to a current concepts narrative review, a systematic review answers a clinically relevant question in a scientific manner on the basis of evidence-based medicine principles. Thus, unlike the studies in a current concepts review that are self-selected by the authors, a systematic review includes or excludes studies on the basis of a transparent, defined set of criteria. This practice will elevate the level of evidence presented for review purposes in the orthopaedic literature.

Appendix

 Tables listing the specific studies evaluated in these analyses are available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM).

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