Vertebroplasty, evidence, and health care reform: What is quality care?

Recently, two clinical trials[1,2] reported that, compared with a sham intervention, vertebroplasty had little if any efficacy at reducing the short- and long-term pain of patients with vertebral compression fractures. Previously this common procedure had scant rigorous evidence of efficacy, but many clinicians and some of my patients felt it to be effective at reducing pain. I wondered what effect the new reports would or should have on how often vertebroplasty (injection of polymethylmethacrylate into a fractured vertebral body) is performed, and on its reimbursement. The more I thought about it, the more issues I realized need to be considered.

Should only evidence-based medicine be reimbursed?

In this time of intense discussion about ways to reduce health costs, and of President Obama's desire to include efficacy and safety outcome data in the dialogue of how to deliver health services to everyone (although perhaps not *every possible* health service to everyone), the practical and philosophical implications of studies like these are worth pondering. Like it or not, the concept that all health care services will be paid for on demand by third-party payers is not a sustainable model of health care.

Randomized placebo-controlled trials are the cornerstone of evidence-based medicine. But at their best they provide only an approximation of the truth. Sample size is always a limitation. Patients and physicians in the office or operating suite do not always behave exactly like those in clinical trials. Yet, well-designed clinical trials are often considered to be the best we can do. Practice guidelines and US Food and Drug Administration approvals are based more on the results of randomized clinical trials and less on information from clinical registries and real-world observational outcome studies (which have technical foibles of their own). Approval for devices and procedures does not historically get the same type of regulatory scrutiny, but health care payers in the future may be less likely to cover the cost of procedures that lack proof of efficacy from rigorously conducted outcome studies. The development of quality care measures also depends on appropriate conduct and application of these trials.

The deadly sins and decision-making

We physicians generally take umbrage with external oversight of our decision-making. It is *our* job and *our* responsibility to balance the science (evidence-based medicine) and the art (experience and gestalt) of clinical care for the benefit of our patients. But as I thought about the impact these new studies may exert on vertebroplasty utilization, I also wondered about the factors that influence our decision-making process. For example, we have long had solid data on the value of treating systolic hypertension (we undertreat), and of treating uncomplicated urinary tract infections with only 3 days of antibiotics (we overtreat). Performance indicators suggest that this solid evidence has only a modest influence on practice patterns. Why?

I recently heard Dr. Louis B. Rice, Professor of Medicine at Case Western Reserve University and Chief of the Medical Service at the Louis Stokes Cleveland VA Medical Center, discuss the possible impact of some of the seven deadly sins on clinical decision-making. A similar analysis applies when thinking about why some treatments continue to be offered despite good evidence of only limited efficacy.

Pride plays a role. We believe that our own clinical skills will permit us to select the ideal patient to undergo a procedure or therapy, whereas such cherry-picking of patients does not generally occur in large

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clinical trials. This argument (and others of "external validity," in the lingo of evidence-based medicine) has been put forth to defend the continued use of some procedures that may not have fared well against sham controls in clinical trials, and these procedures continue to flourish.

Pride may also apply to the feeling we physicians have for doing something right for our patients. This feeling may push us to believe we can succeed where an impersonal clinical trial failed. I suspect this is most keenly felt when the therapy is a procedure that depends on our own individual skills. I suspect that internists and subspecialists with special interest in osteoporosis will interpret these trials differently than surgeons and interventional radiologists who are routinely performing these procedures.

Avarice must be considered, and regulatory controls in the future may limit financial gain from these therapies. But I am not convinced that monetary greed drives all clinical decisions that go against the grain of evidence-based medicine.

And then there is *gluttony*: we and our patients want it all. We do not want to hear that our patient cannot be provided the most recent therapeutic advance—it might work.

Placebo effect, other issues in 'negative' studies

A number of factors in these trials of vertebroplasty need to be dissected and discussed. Not the least is the apparent salubrious effect of the sham procedure. This was documented previously with intra-articular injections of saline (placebo) in studies of hyaluronate joint injections for the pain of knee osteoarthritis,[3] in which either type of injection provided significant pain relief. Are these truly markedly positive effects of the sham but invasive maneuvers in the vertebroplasty studies, or are we witnessing the natural history of pain resolution in these disorders (in the absence of a true nonintervention control group that could help make this distinction)?

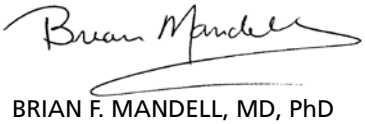
Crossover issues in one of the vertebroplasty papers will certainly generate letters to the editor. Were patients really blinded to their procedure throughout? Which subsets of patients might have responded better or worse? What about balloon kyphoplasty?

We plan to publish commentaries from proceduralists and medical experts in osteoporosis to critique these key clinical trials for us and to put these issues into clinical perspective.

What role for evidence-based medicine?

In the meantime, I urge you to peruse these papers along with the op-ed pieces in your local newspapers as catalysts to reconsider the role evidence-based medicine should play in our daily one-on-one routine with patients, as well as in the redesign of our health care delivery and reimbursement systems. I don't think that clinical conundrums can be resolved with a simple look at *P* values and confidence intervals; clinical trials are not the total story. As physicians, we always need to put the trial results into a clinical perspective. Nonetheless, our personal belief of efficacy (or lack of efficacy) also should not be the total story as we make decisions with individual patients and allocate resources within the health care system.

In the end, it should be all about giving high-quality care to the patient sitting in front of us. A question to be addressed is how well we can assess the quality of a given treatment prior to its administration.



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