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Can Meta-Analysis Save Vertebroplasty?

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Other variations of keyboards include those found in touch screens, which are becoming more popular with tablet computing. Touch screen keyboards are considered the natural evolution of “on-screen” keyboards, in which an image of the keyboard appears on the screen and keys are selected by clicking the mouse. Foldable or flexible keyboards are made of plastic or silicone and are great for traveling. They can be attached to computers and other devices such as cellular telephones.

Flexible keyboards are also ideal for hospitals and laboratories because they can be washed and disinfected, and the absence of crevices between keys makes them “cleaner.” Britain’s *Daily Mail* newspaper reported that computer keyboards have more than 150 times the acceptable number of germs and are 5 times dirtier than a toilet (a fact to keep in mind when you are eating your sandwich while typing or surfing the Web). In a study performed here at the University of North Carolina, computer keyboards housed in the Burn Unit were found to be uniformly infected with coagulase-negative *Staphylococcus* organisms, a common source of hospital-acquired sepsis.⁶ Diphtheroids were present on 80% of those keyboards, and are particularly dangerous for immunosuppressed individuals such as those with extensive burns. Commercial cleaners maintain keyboards bacteria-free for about 48 hours. A benefit of one of the most intriguing new keyboards, the holographic or projection keyboard, is that the flat surface used for its projection can be easily cleaned. A laser projects an image of a keyboard onto any flat surface, detects keystrokes, and even simulates the clicking noise of a conventional keyboard. These are truly virtual keyboards, and miniature versions that can be used with smart phones have just hit the market. It does not matter which keyboard you use or prefer as all contain some bewildering keys.

One of the most commonly used keys is the “at” symbol, @, which shares the number 2 key in the QWERTY arrangement. @ means simply “at,” “located at,” or “at the rate of.” @ has been present in keyboards since 1885 but became ubiquitous in the early 1970s when used in the first e-mail messages. In other languages, the @ symbol is more colorfully named (eg, “snail” in Italian, “monkey tail” in German, “dog” in Russian, and “little mouse” in Chinese).⁷ In Spanish, Portuguese, and French, @ denotes an old measure of weight (the arroba) and is called “arrobas” or “arrobases” (French). @ is probably of Italian origin and was initially used by Venetians to designate the amount of weight contained in an amphora. Currently, @ is most commonly used in e-mail addresses to separate the name of a person from the domain in which the address is located. In text messaging, @ may serve as a substitute for “at.” Recognizing the importance of @, in 2010 the Museum of Modern Art in New York City admitted this sign into its architectural and design collections.⁸

Although substituting @ for “at” does not save me many keystrokes, using “&” instead of “and” is more economical. The ampersand, &, means “and per se and” or more simply “and.” & dates back to the first century of the Common Era and its shape has been progressively changed by the Romans and French. The ampersand should not be used to mean “et,” which is generally symbolized by “7.” When handwritten, the ampersand looks a bit different: $\&$ (sometimes the vertical line is

left out). Regardless of its exact shape, I think the ampersand is one of the most elegant and practical symbols used in language.

The number sign, #, is probably used as commonly as @ and &. It is usually used to designate a numeric position such as the following: *AJNR* is the #1 journal in clinical neuroimaging. In the United States, # is called the “pound” sign, whereas in other countries, it is simply known as the “number” sign (scientists sometimes call it the “octothorpe”).⁹ Calling it a “pound” sign may lead to confusion in England, where the pound sign is £. Thus in England, # is called the “hash” sign. In Spanish-speaking regions, the number sign is generally “Nº.” In Spanish, # has many names (“almohadilla,” “cardinal,” and even “tic-tac-toe”). The musical symbol “sharp” is nearly identical to #, but its 2 horizontal bars are angled upwards from left to right. A fact that is interesting to editors is that in copyediting, ### means that more content will be added or that mistakes that need to be corrected are found in the text. ### at the end of a manuscript means no further information is forthcoming. Chess fans know that # after a move means “checkmate.”

Last, a few words about keyboards and health. I now spend more hours in front of my computer screen typing than ever before. Strain to your wrists, arms, back, and neck from typing may cause pain. Keep your shoulders in a relaxed position, your elbows at about a 90° flexion, and your wrists and back straight. Get to know your keyboard and play it like a piano: Do not rest your palms or wrists on anything. Take short and repetitive breaks throughout the day. They are good for the body and the mind.

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EDITORIAL

Can Meta-Analysis Save Vertebroplasty?

Last February, I was asked to testify in front of the California Technology Assessment Forum (CTAF), a public service forum composed of numerous California physicians and

health experts who assess new and emerging medical technology, on behalf of DePuy Spine regarding vertebroplasty as a treatment for osteoporotic compression fractures. The review was prompted by the publication of 2 randomized controlled trials in the *New England Journal of Medicine (NEJM)*,^{1,2} which questioned the efficacy of vertebroplasty. Blue Shield of California Foundation spearheads the CTAF, managing the technology assessment reviews and organizing all CTAF meetings and events.

Because my flight was delayed by the thick slow-rolling fog, which blankets San Francisco during that time of year, I was able to arrive just a few moments before the start of the session. I was on a panel of 5 physicians, each of whom was given 5 minutes to talk. Dr Leah Karliner, Assistant Professor of Medicine at the University of California, San Francisco, opened the talks by discussing that on the basis of the *NEJM* articles, vertebroplasty does not meet the CTAF criteria 3–5 for safety, effectiveness, and improvement in health outcomes for the treatment of osteoporotic vertebral compression fractures. These criteria are namely the following: 1) the technology must improve the net health outcome, 2) the technology must be as beneficial as any established alternatives, and 3) the improvement must be attainable outside the investigational settings.

Most interesting, the same author and forum had concluded last year that kyphoplasty meets criteria 3–5 on the basis of the Fracture Reduction Evaluation (FREE) trial.³ Kyphoplasty is at least 3 times more expensive than vertebroplasty, and to our knowledge, as yet no report has provided evidence for better clinical outcomes with kyphoplasty compared with vertebroplasty. The forum also ignored the fact that the 2 *NEJM* articles in question represented a subgroup of patients who were presented as outpatients, even though the Medicare data suggest that approximately 40% of vertebroplasty procedures are performed for inpatients who are admitted to the hospitals due to pain resulting from compression fractures (AMA resource-based relative value scale data manager 2009).

The US Food and Drug Administration notes that for clinical trials that show small effect sizes “it [is] informative to examine the cumulative distribution function (CDF) of responses between treatment groups to characterize the treatment effect.”⁴ In this light, responder analysis should be considered as a means to evaluate disparities in measures of pain in the *NEJM* randomized controlled trials. Although both *NEJM* studies conducted a responder analysis, neither was powered to detect differences by using this approach. Kallmes et al² considered patients to have experienced clinically meaningful pain relief if a decrease in pain of >30% was observed at 1 month. In this study, there was a trend toward a higher rate of clinically meaningful improvement in pain in the vertebroplasty group (64% versus 48%, $P = .06$) or a relative risk (RR) of 1.33 (95% confidence interval [CI], 0.97–1.82). Buchbinder et al¹ measured patient response by using a 7-point ordinal scale, ranging from “a great deal worse” to “a great deal better.” At 1 month, 34% of patients having undergone vertebroplasty versus 24% of control patients classified their pain as “moderately better” or “a great deal better,” for an RR of 1.45 (95% CI, 0.7–3.01) of experiencing a clinically meaningful response. Although distinct response definitions were used, re-

ductions in pain of $\geq 30\%$ have previously been shown to reflect much improved pain, allowing pooling of these response data.

Indeed, a pooled analysis of responders from both studies (completed by DePuy Spine) addresses inadequate power in each individual study and reveals that subjects in the vertebroplasty groups were 35% more likely than control subjects to experience clinically meaningful reductions in pain at 1 month ($P = .04$).⁵ Meta-analysis, by using the DerSimonian Laird random effects model, indicates that subjects with vertebroplasty had a pooled RR of 1.35 (95% CI, 1.01–1.80) versus controls for experiencing a clinically meaningful reduction in pain ($P = .04$).

These results illustrate that larger studies are required before rushing to a premature conclusion. Noridian Administrative Services, a Medicare intermediary for 11 Western states, has issued a draft of a local noncoverage decision for both percutaneous vertebroplasty and percutaneous vertebral augmentation, proposing to deny reimbursement for these procedures for all indications. On the international level, the Ontario Health Technology Advisory Committee in Ontario, Canada, is considering a similar position.

The Vertebroplasty versus Conservative Treatment in Acute Osteoporotic Vertebral Compression Fractures II trial was recently published, in August 2010.⁶ The study was a prospective randomized trial of vertebroplasty and conservative treatment for 202 patients. In this study, vertebroplasty resulted in greater pain relief than did conservative treatment; the difference in mean visual analog scale (VAS) score between baseline and 1 month was -5.2 (95% CI, -5.88 to -4.72) after vertebroplasty and -2.7 (95% CI, -3.22 to -1.98) after conservative treatment. Between baseline and 1 year, it was -5.7 (95% CI, -6.22 to -4.98) after vertebroplasty and -3.7 (95% CI, -4.35 to -3.05) after conservative treatment. The difference between groups in reduction of the mean VAS score from baseline was 2.6 (95% CI, 1.74–3.37; $P < .0001$) at 1 month and 2.0 (95% CI, 1.13–2.80, $P < .0001$) at 1 year. The study concluded that in a subgroup of patients with acute osteoporotic vertebral compression fractures and persistent pain, percutaneous vertebroplasty is both effective and safe. Pain relief after vertebroplasty is immediate, is sustained for at least 1 year, and significantly exceeds the relief achieved with conservative treatment, at an acceptable cost. Most interesting, although this study was every bit as well-implemented as the FREE trial,³ it received none of the media and insurance carrier attention given to the *NEJM* articles.

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