Percutaneous Vertebroplasty: The Evidence Is Still Elusive

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A quarter of a century has passed since Galibert and Deramond published their first description of a new method for the treatment of painful vertebral hemangiomata [1], and the dispute over its indications is livelier than ever. Since its inception, this technique has gained extensive popularity worldwide, mainly for stabilization of the 1.4 million annual osteoporotic vertebral compression fractures occurring in the growing elderly population [2]. Other indications include stabilization of pathological vertebral fractures secondary to metastatic disease or multiple myeloma, and augmentation of pedicle screws in osteoporotic bone.

The surgical technique entails injection of polymethyl methacrylate into the fractured vertebra. PMMA is distributed as a powder that is mixed in the operating room with a monomer liquid accelerator to produce an acrylic bone cement similar in consistency to toothpaste. Once injected, the PMMA rapidly hardens inside the bone, thereby stabilizing the fragments. There are two ways of delivering the mixed PMMA into the vertebra. The first is by direct injection through a small cannulla, and is termed 'vertebroplasty'. The second method involves inserting a bone expansion device into the vertebral body, creating a cavity within, and then injecting the PMMA into the void. This method is termed 'kyphoplasty', implying an ability to correct the kyphotic deformity produced by the fracture, in addition to the stabilization and pain relief offered by both techniques.

Initially, vertebroplasty was limited to fractures refractory to 3 months of optimal conservative therapy. These guidelines were based on theoretical concerns over adverse events such as PMMA leakage into the spinal canal or emboli to the lungs. As experience mounted, two realizations emerged. The first was that vertebroplasty is a very safe procedure, and that although leakage and emboli do occur in up to 23% of patients, only rarely do they produce any measurable negative effect [3]. The second realization, based entirely on low level clinical evidence, is that vertebroplasty is much more effective in the earlier post-fracture period, and that as time from fracture increases, both conservative and surgical patients do similarly well [4].

Two clinical trials, published in the *New England Journal of Medicine* in August 2009, rocked the spine surgery community [5,6]. In these randomized, double-blinded, placebo-controlled multicenter trials, the authors compared percutaneous vertebroplasty with a sham procedure and found that the primary outcome measure – pain relief at 1 and 3 months – was the same for both groups.

As these results were in complete disagreement with all previously published data, but of far superior methodological quality, a hot debate ensued between opponents and proponents. Since vertebroplasty is mostly effective in the acute stage, the main critique points against this new insight were related to the inclusion criteria and clinical endpoint, which allowed patients with older fractures to be included, and measured pain relief too late for comparison.

In September 2010, the VERTOS II study was published in the *Lancet* [7]. In this prospective randomized controlled study, vertebroplasty for acute fractures (less than 6 weeks) was found to be significantly superior to conservative treatment regarding pain reduction after 1 month and 1 year. This study fuelled the debate once more, but since it did not include a placebo arm (sham surgery), it was convincing mainly for the convinced. Currently, VERTOS IV is recruiting [8]. In this study 180 patients with acute vertebral compression fractures will be prospectively randomized to receive either percutaneous vertebroplasty or a sham intervention, in the hope of settling the ongoing debate.

In their study published in this edition of *IMAJ*, Drs. Floman and Shabat [9] compare two Israeli developed systems – one for vertebroplasties and the other for kyphoplasties. They found little difference in the final outcome measures. While The Sky kyphoplasty system did correct the deformity better, both systems significantly and equally alleviated pain in acute fractures. They found the complication rate to be very low, in accordance with current knowledge [10]. It is assumed, although not proven clinically, that kyphoplasty will reduce the leakage and embolism rate since injecting the cement into a void requires lower cementation pressures. Although quite logical, this assumption

PMMA = polymethyl methacrylate

is not supported in the current literature, and this study is underpowered to address this issue.

While the debate in the literature remains open, percutaneous vertebroplasty is still an invaluable tool for the clinician. It provides rapid pain relief with minimal risk for complications. As most low grade compression fractures will do just as well with conservative therapy, the decision is currently based on clinical judgment rather than evidence-based medicine.

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