

The Promise of an Effective Treatment for Sacroiliac-related Low Back Pain

BACK pain is the most frequent type of pain reported by adults, with more than one fourth of adults in the United States having had at least one episode of back pain within the past 3 months.¹ In 2002, office visits for back pain in the United States totaled 890 million, comprising 2.3% of all office visits.¹ The economic impact of low back pain is large and seems to be growing.² Sacroiliac joint dysfunction is estimated to be the underlying cause in 15-25% of patients who have persistent low back pain.³ Diagnosing pain related to sacroiliac dysfunction is difficult, because findings on history and physical examination⁴ and diagnostic radiography^{5,6} are unreliable; placement of intraarticular local anesthetic has become the gold standard, but this too is plagued by a frequent placebo response that decreases the diagnostic specificity.³ Even more problematic has been the search for an effective treatment for sacroiliac-related pain. Treatments currently in use range from targeted exercise programs⁷ to surgical fusion,⁸ and none of these have proven effective. Pain related to sacroiliac joint dysfunction is common, and a safe and effective treatment would address a major unmet medical need. In this issue of ANESTHESIOLOGY, Cohen *et al.*⁹ have tested a new type of radiofrequency neurolysis for treatment of sacroiliac joint pain.

The use of radiofrequency neurolysis of the medial branch nerves has shown modest success in reducing low back pain associated with lumbar facet arthropathy.¹⁰ Based on the technique used for treating the lumbar facets, a number of investigators have developed strategies for applying radiofrequency neurolysis to the sacroiliac joints.¹¹⁻¹³ However, the effectiveness of this approach has been limited, typically producing significant pain reduction (50% or more) lasting for several months in less than half of carefully selected patients. Investigators believe that these limited treatment effects may stem, in part, from limitations inherent to the radiofrequency technology and our limited knowledge of the anatomy of the innervation of the sacroiliac joint. The morphology of radiofrequency lesions is well known. The extent of the lesion anterior to the active tip of the treatment cannula is limited, therefore, the cannulae

must be placed in such a way that the nerve that is targeted lies along the side or shaft of the cannula, where the size of the resulting lesion is largest.¹⁴ This does not present a problem when treating the lumbar facets, because the needle can be advanced over the transverse process to bring the entire length of the active tip of the radiofrequency cannula in to close apposition to the medial branch nerve. However, placement of lesions over the posterior sacrum is more problematic, because the tip of the cannula is perpendicular to the plane of the sacrum where the sacral lateral branch nerves supplying sensory innervation to the sacroiliac joint are accessible for treatment, limiting the volume of the lesion placed adjacent to each nerve, and likely leading to treatment failure simply because the lesion did not encompass the targeted nerves. When difficulties related to the treatment cannulae are coupled with a heretofore poor understanding of the anatomy of the sensory innervation to the sacroiliac joints, it is not surprising that previous studies have demonstrated limited success.

Cohen *et al.*⁹ have tested the effectiveness of a new adaptation of radiofrequency technology called *cooled-probe technology* in treating sacroiliac joint pain. Cooled radiofrequency was designed to overcome some of the limitations of conventional radiofrequency technology. This new technology uses a treatment cannula that is cooled by a continuous flow of water within the shaft of the cannula itself, thus limiting the rate of heating at the tip of the cannula. This leads to delivery of significantly greater energy to the tissue surrounding the cannula and results in a lesion that extends anterior to the active tip. Therefore, using cooled radiofrequency, the cannula can be placed perpendicular to the course of the nerve to be treated and, in this position, can be expected to incorporate the nerve within the resulting lesion. Recent study of the innervation of the sacroiliac joints demonstrates that the sensory nerves supplying the posterior sacroiliac joint lie in a predictable location relative to the sacral foramina.¹³ Combining this new technology with a better understanding of the anatomy has led directly to the new treatment detailed in the study of Cohen *et al.*⁹

The results of Cohen *et al.* demonstrate greater than 50% pain relief and significant functional improvement in the majority of patients receiving active radiofrequency treatment, and these improvements are sustained in the majority of patients for 6 months after treatment, in comparison to only 14% of patients receiving sham treatment, who had significant improvement at 1-month follow-up and none beyond that time. It is exciting to think that we might well have a new and effective treatment for sacroiliac-related pain, but caution is in order. This is a very small randomized con-

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trolled trial with significant heterogeneity in the two treatment groups that could well have biased the findings. The randomization resulted in unbalanced groups with more serious illness markers in the placebo group, including more frequent previous surgery, worse function/disability, and greater narcotic use in those randomly assigned to the placebo group. In a study of such small sample size, the confounding effects of unequal treatment groups can lead to erroneous conclusions about the actual treatment effect. The more frequent previous surgery (4 of 14 [29%] *vs.* 2 of 14 [14%]), worse functional status (Oswestry disability index 47.9 *vs.* 37.1), and greater narcotic usage (7 of 14 [50%] *vs.* 6 of 14 [43%]) in the placebo *versus* the active treatment group, respectively, all suggest that the severity of the disease alone could explain the poor outcomes in the placebo group. Although the investigators made significant efforts to assure that true blinding was maintained, the sequelae of conventional radiofrequency treatment are likely to result in loss of blinding soon after the local anesthetic effects dissipate. The majority of patients receiving conventional radiofrequency treatment for lumbar facet-related pain will experience a significant flare in pain related to the procedure itself that would cue patients to the treatment received.¹⁵ Therefore, true blinding in this study is unlikely. Indeed, the investigators conducted an audit to assure that blinding had been maintained by asking patients which treatment they thought they had received; this audit suggests that patients could not determine the actual treatment delivered. However, this audit was conducted before the local anesthetic used for the procedure had worn off; therefore, the usual sequelae would not yet have appeared. Finally, as expected from our understanding of radiofrequency treatment of the lumbar facets, the duration of the treatment effect is limited in duration to between 6 and 12 months after treatment. By 1 yr after treatment, only 12% of patients receiving active treatment showed persistent pain relief. Despite these limi-

tations, Cohen *et al.* should be congratulated for their attempts to address a major unmet medical need. They have conducted a well-designed study to provide early and scientifically rigorous evidence regarding the efficacy of this novel treatment; their promising results should encourage others to construct a large, multi-center trial to confirm these preliminary findings.

James P. Rathmell, M.D., Center for Pain Medicine, Massachusetts General Hospital, Department of Anesthesia and Critical Care; Harvard Medical School, Boston, Massachusetts. jrathmell@partners.org

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