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Using Science to Market Questionable Technology

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The Dell Medical School Orthopedic Surgery Residency Journal Club reviewed this article by Dengler et al. in our latest meeting. This research addresses a product that we have seen heavily marketed and promoted in our area. Local use of this product has been both spotty and questionable. This is an industry-funded trial. We have substantial concerns about the concept, the product, the marketing, and this trial specifically. We are disappointed that JBJS decided to publish it.

Sacroiliac (SI) joint pain is not easily distinguished from other forms of back pain (1, 2, 3). The basis of diagnosis appears to be radiographically guided injection of local anesthetic, which is subject to the placebo effect and not felt to be reliable or accurate. There is notable variation in the diagnosis of sacroiliac joint pain. The clinicians in our group who treat back pain rarely diagnose sacroiliac joint pain.

At the same time, low back pain is an attractive market. It's nearly universal and very bothersome. Commercial interests stand to benefit from confusion between SI joint pain and low back pain, because it could vastly expand their market. Scientists and clinicians should insist on reliable and accurate diagnosis of SI joint pain before considering invasive treatments. We are not there yet.

Given that the primary outcomes in the Dengler et al. study were all subjective, the only adequate experimental design would be a sham-surgery controlled trial. Invasive treatments always outperform noninvasive treatments due to a greater placebo effect. The results of this trial could have been predicted a priori. We are confident that the company funding this trial was fully aware of this. It's misleading to declare a "winner" in a comparison of an invasive and a noninvasive treatment. This trial amounts to marketing.

The procedure does not achieve SI joint arthrodesis, which is understandable given that the articular cartilage was not removed. The authors noted that "intra-articular fusion with bridging of trabeculae from ilium to sacrum was not commonly observed." The rationale seems flawed, and the goals of the procedure were not met. The claim of success based on subjective improvement with essentially universal lack of arthrodesis is quite remarkable. Judged on objective criteria, this procedure does not work.

Objectively verifiable SI joint pathology is typically treated by fracture surgeons. Fracture surgeons are not using this device. In addition, it would be extremely difficult to get these implants out if they were associated with infection, nerve damage, risk of vascular injury, or other pressing matters.

This trial supports the use of an expensive device and procedure for a questionable diagnosis. The procedure does not achieve arthrodesis, probably provides relief through the placebo effect, and would be very difficult to salvage. We therefore urge JBJS and the orthopedic community to regard the treatment strategies embodied in this paper with great skepticism, caution, and concern. We felt compelled on behalf of people with low back pain worldwide to speak up and try to avoid what could become a major problem.

References

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Conflict of Interest: None Declared