Concerns regarding sham-controlled trial of SI joint fusion procedure

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I congratulate Randers et al. on completing their sham-controlled study on SI joint fusion.[1] However, several points warrant further discussion.

The authors did not fully describe the diagnostic algorithm used to identify patients with SI joint pain. Critical details omitted were: how were examiners trained in performing physical examination tests? Were diagnostic blocks intra-articular? Were invalid blocks (those with major leakage) excluded? What volume of anesthetic was used? Larger volumes can cause false positive results. Was the same algorithm used at each study site? The study's small effects suggest patients without SI joint pain were included.

The authors describe the potential impact of patient expectations on study outcomes. However, how such expectations were managed is not described. Pre-procedural patient counseling can reduce placebo effects in sham-controlled studies.[2]

Successful joint fusion requires at least two implants placed across the joint with sufficient implant engagement into the sacrum to prevent joint motion with daily activities. The study used CT but did not describe device placement quality.

Authors admitted variation in the sham procedure across study sites. This needs explication.

The generalizability of the study is in question. Many patients included in the study were seeking or on disability leave (65% in the surgery group and 87% in the sham group). The study's small reported effects could reflect participants' lack of motivation to report improvement. The proportion of trial participants with pregnancy-related SI joint pain was far higher than the comparator study (iMIA). Both groups received an intervention (local anesthetic in the SI joint and the surgical wound following the procedure) that is not common clinical practice and not reported in other studies. Additionally, participants did not receive post-operative rehabilitation, which may aid postoperative recovery. The proportion of subjects with bilateral SI joint pain who underwent bilateral treatment is unclear. These study considerations could have blurred the difference between surgery and sham.

Because the published study protocol did not define adverse events, it is difficult to judge their occurrence rate. A surprisingly high proportion of participants, including the sham group, reported worse global health status after the procedure. This is surprising as the overall rate of adverse events from SI joint fusion is low.[3]

Running a blinded, sham-controlled study is challenging. However, deficits in study design and execution may have introduced substantial limitations. Real-world randomized trials against non-surgical treatment[4,5] and other experiences[3] have shown that SI joint fusion produces consistent improvements in pain and pain-related disability that exceed those of non-surgical treatment. The experience of Randers et al. differs markedly from my experience (over 300 cases), in which most patients derive substantial benefit.

Contributors

WTC authored the letter.

Declaration of interests

I declare no competing interests.

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