Possible factors influencing on the effect of minimally invasive sacroiliac joint fusion – a call for further research and discussion

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We thank Kampkuiper et al., and Dr Capel, for their comments and questions regarding our double-blind randomized placebo-controlled trial comparing minimally invasive sacroiliac joint fusion to sham surgery. Our response focuses on five main points: bilateralism of SIJ symptoms; individual response to SIJ fusion; diagnostic procedures; per-protocol treatment and post-intervention care procedures; and bias and generalizability.

Bilateralism of sacroiliac joint (SIJ) pain can complicate the evaluation of improvement in SIJ pain and disability. To our knowledge no international consensus, definition of, or "diagnosis" of bilateralism of SIJ pain exists, especially based on reported pain or disability outcomes. Our trial was not designed nor powered to evaluate the impact of bilateralism on MIS SIJ fusion. When defining bilateral pain as NRS >2 in the contralateral SIJ our trial reported a larger population with bilateral complaints than the two former RCTs from Europe and the United States.[1,2] No criteria for defining bilateral complaints were provided in either two former RCTs.[1,2] In the European RCT, 35% of patients in the fusion group received a diagnosis of bilateral complaints.[2] An indication for bilateral SIJ fusion was found in only 13%, indicating only 39% of patients with bilateral complaints were candidates for bilateral fusion.[2] In the American RCT, 25.5% of patients received a same-day or staged bilateral procedure, the total amount of patients with bilateral complaints was not reported.[1] The actual proportion of patients with bilateral complaints could be suspected to be much higher when considering the numbers from the European RCT.[2] Based on the numbers presented in the European RCT, it appears that not all patients with bilateral symptoms are candidates for bilateral surgery, meaning that not all bilateralism of symptoms will influence the end result after SIJ fusion.

The threshold SIJ pain for inclusion of patients, NRS ≥5 (or VAS ≥50), was similar in all three RCTs.[1–3] Altering the NRS threshold needed to "diagnose" bilateral complaints in our trial alters the percentage with bilateral complaints, exemplified as follows; using NRS ≥5.43% had bilateral complaints, with NRS ≥7.17% had bilateral complaints. Considering the lack of reported numbers, alteration in percentages related to different thresholds and the lack of a diagnostic definition, the percentage of bilateral complaints between the three RCTs may be less different than initially observed.

Our trial was not powered to evaluate individual response and strict adherence to the predefined statistical analysis plan is highly recommended to avoid non-preplanned analyses producing misleading data.[4] As more granular data may increase the understanding of the effect of SIJ fusion, individual level data for the primary outcome of our trial are presented in Fig. 1.

All diagnostic procedures and diagnostic blocks in Norway were performed and evaluated collectively by two spine surgeons (first and last author) with more than 5 years' experience on diagnosing SIJ pain. All patients in Sweden underwent CT-guided diagnostic blocks performed by a radiologist. Patients in Sweden were clinically evaluated by the Swedish surgeon (second author). Pain relief of the diagnostic blocks were evaluated with patient reported pain (NRS 0–10) levels and clinical examination before, and 1 h after injection.

Treatment and postoperative care were performed according to protocol. Intraoperative CT was not available for the first 12 trial cases in Norway. It was used for the remaining cases on both trial sites. Sham procedures between trial sites differed only on the use of an endotracheal tube in Norway compared to a laryngeal mask in Sweden.

Postoperatively, per-protocol SIJ injection on the operating table and postoperative pain medication was

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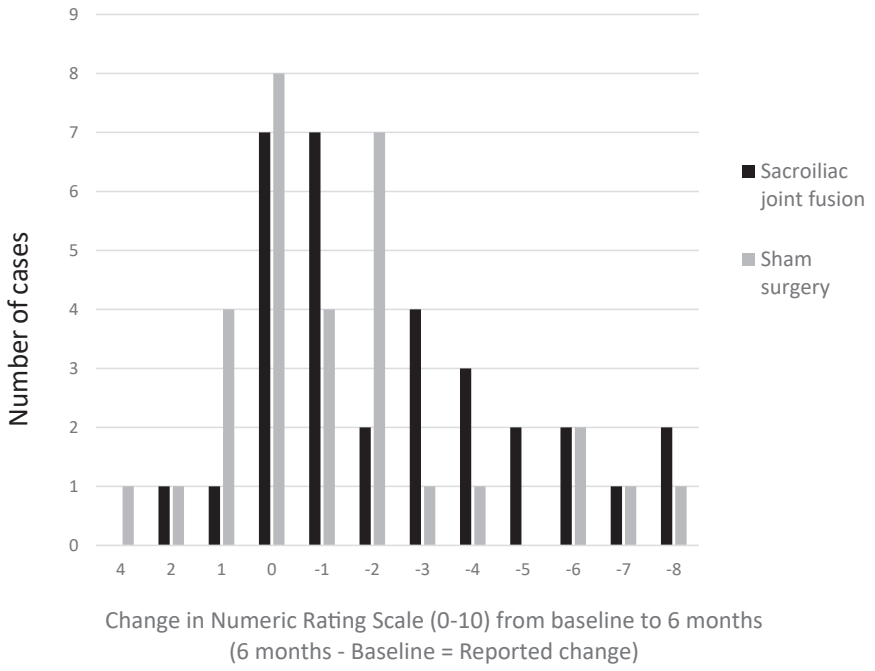

Fig. 1: Individual change in sacroiliac joint pain from baseline to 6 months. Figure 1 demonstrates individual change in sacroiliac joint pain measured by change in Numeric Rating Scale (NRS; 0 = no pain, 10 = worst possible pain) from baseline to 6 months follow-up.

administered. Further pain medication was administered and controlled through the general practitioner in Norway, or by a physician unaware of the treatment allocation in Sweden. Patients were allowed to use physiotherapy at their own discretion. No specialized physiotherapy program was recommended to exclude bias.

The generalizability of the trial due to differences in study population regarding sick leave and disability leave introducing bias have been raised. The social welfare system in Scandinavia is state funded, differing from the United States. All patients with a social security number are entitled to compensatory sick leave for 1 year, and thereafter disability leave for a time period. There are no financial benefits for patients receiving sick or disability leave compared to working wages. Patients can undergo trial periods back to work if desirable whilst on welfare. Reporting truthfully on perceived improvement does not provide economic advantage or disadvantage to patients. A recent registry-based cohort study based on the Swedish spine registry showed similar results and baseline characteristics as our RCT.[5]

In conclusion, our view is that there is a need for a broad discussion on the effect of and indications for SIJ fusion in patients with long lasting severe SIJ pain.

Contributors

All authors (ER, PG, BS, ED, LN, SMR, TJK) contributed to the writing, editing and approval of the final article.

Declaration of interests

Engelke Randers, Britt Stuge, Elias Diarbakerli and Lars Nordsletten have no conflicts of interest. Paul Gerdhem has received grants from the Swedish Research council, Stockholm County council and Karolinska Institutet funding his research time and received lecture fees from DePuySynthes paid to him. He is also a member of the steering committees for the Swedish spine register and Swedish Fracture register (unpaid). Thomas Johan Kibsgård has received consulting fees from Stryker, and support covering travel costs for attending spinal deformity meetings through SMAIO and SI-BONE. Stephan M. Röhrl is on the advisory board of the Norwegian arthroplasty registry and vice president of the International RSA society.

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