NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain

Problems with the sacroiliac joints can cause lower back pain. These joints are at the bottom of the back where part of the spine called the sacrum joins part of the pelvis called the ilium. Minimally invasive sacroiliac joint fusion surgery is done through a small cut in the skin. It aims to stabilise the joint by fixing the sacrum to the ilium. It involves drilling small channels through the 2 bones, then fixing them together using 2 or 3 metal implants.

The National Institute for Health and Care Excellence (NICE) is examining minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.

- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 20 January 2017

Target date for publication of guidance: April 2017

1 Draft recommendations

1.1 Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

1.2 Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.

1.3 This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain.

2 Indications and current treatments

2.1 Chronic pain in the lower back triggered from the sacroiliac (SI) joint occurs in 15% to 30% of patients with low back pain. The causes of SI joint pain include degenerative sacroiliitis, osteoarthritis, SI joint disruptions from trauma or pregnancy, problems after lumbar spinal fixation techniques, anatomical abnormalities such as scoliosis, infection, gout, tumour or idiopathic causes.

2.2 Conservative treatments for SI joint pain include analgesics, non-steroidal anti-inflammatory drugs, physiotherapy, manipulative therapy, intra-articular SI joint corticosteroid injections, periarticular injections, botulinum toxin injections and radiofrequency denervation. Surgical treatment is considered for persistent chronic symptoms that are unresponsive to conservative treatment. Surgical techniques include open SI joint fusion surgery or minimally invasive SI joint fusion using percutaneous implants to stabilise the joint and treat joint pain.

3 The procedure

3.1 Minimally invasive surgical fusion of the sacroiliac (SI) joint is done with the patient under general or spinal anaesthesia and in a prone position. Fluoroscopic guidance is used. Using a lateral transarticular approach, the SI joint is accessed laterally through a

small incision made in the buttock to reach the ilium. A pin is passed through the ilium across the SI joint into the centre of the sacrum, avoiding the neural foramen. A drill is then used to create a pathway through the ilium to the sacrum. An implant is inserted (with the lateral portion of the implant sitting in the ilium and the medial end in the sacrum), spanning the SI joint. Typically, 3 implants are used.

3.2 Treatment of both SI joints can be done at the same time, or in staged procedures. After surgery, patients are advised to make a gradual return to full weight bearing over several weeks, using a walker for assistance, and then have physiotherapy.

4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 In a randomised controlled trial (RCT) of 148 patients with sacroiliac (SI) joint dysfunction comparing minimally invasive SI joint fusion (n=102) with non-surgical management (NSM, n=46), success rates at 6 months were higher in the minimally invasive SI joint fusion group (81% [83/102] versus 26% [12/46]; Bayesian posterior probability of superiority >0.9999). (Success was defined as a composite of pain reduction from baseline visual analogue scale [VAS] pain score by at least 20 mm, absence of device-related serious adverse events or neurological worsening, and absence of surgical re-intervention). In a prospective case series of 172 patients, intention-to-treat success rate was 80% (119/149) at 24 months (Bayesian posterior probability of superiority >0.9999).

4.2 In a systematic review of SI joint fusion of 430 patients, in those who had minimally invasive SI joint fusion (n=299), radiographically confirmed fusion rates (determined by CT or plain radiograph) were 13% to 100% (in 4 out of 9 studies) at a mean follow-up of 21 months. In the prospective case series of 172 patients, CT scan at 1-year follow-up showed 97% bone adherence to at least 2 implants on both the iliac and sacral sides, with moderate rates of bone growth across the SI joint.

4.3 In the RCT of 148 patients, in the SI joint fusion group (n=102), mean joint pain (measured using a 0–100 VAS) improved from 82.3 at baseline to 30.4 at 6-month follow-up ($p<0.001$), 28.3 at 12-month follow-up ($p<0.001$) and 26.7 at the 24-month follow-up ($p<0.001$). In the NSM group, mean SI joint pain improved from 82.2 at baseline to 70.3 at 6 months ($p=0.001$). Similarly, in the SI joint fusion group, mean Oswestry Disability Index (ODI) decreased from 57.2 at baseline to 29.9 at 6 months ($p<0.001$), 28.1 at 12 months ($p<0.001$) and 28.7 at 24 months ($p<0.001$). In the NSM group, mean ODI decreased from 56.0 at baseline to 51.6 at 6 months ($p=0.06$). There were clinically important improvements from baseline (VAS more than 20.0 points; ODI more than 15.0 points) and sustained clinical benefit ((VAS more than 25.0 or less than 35.0 points; ODI more than 18.8 points) in the SI joint fusion group compared with patients in the NSM group.

4.4 In a systematic review and meta-analysis of 432 patients from 12 cohort studies on minimally invasive SI joint fusion using a lateral transarticular approach, the random effects meta-analysis (RMA) mean pain score decreased from a baseline of 8.1 (95% confidence interval [CI] 7.8 to 8.4) to 2.8 (95% CI 2.4 to 3.2) at 6 months, 2.7 (95% CI 2.1 to 3.3) at 12 months and 2.0 (95% CI

1.4 to 2.5) at 24 months. ODI decreased from a RMA mean score of 56.6 (95% CI 51.0 to 61.5) at baseline, 30.3 (95% CI 22.5 to 38.0) at 6 months and 25.1 (95% CI 12.3 to 37.9) at 12 months.

4.5 In an RCT of 103 patients, SI joint function ratings (measured using the active straight leg raise test on a scale of 0 to 6) decreased statistically significantly more ($p<0.0001$) in the SI joint fusion group (from 4.0 to 2.0) than in the conservative management group (from 3.8 to 3.7). The proportion of patients who could raise the leg with no difficulty at 6 months was 71% in SIJ fusion group and 32% in conservative management group ($p=0.0002$).

4.6 In the systematic review and meta-analysis of 432 patients, improvements in quality of life (measured on the SF-36 physical component score [PCS]) were consistent in 2 studies of triangular implants; scores increased from 30.2 and 30.7 at baseline to 42.8 and 37.0 at 6 months respectively. In the RCT of 148 patients, in the SI joint fusion group (n=102), quality of life (measured with an EQ-5D time trade off index utility of current health) improved from 0.44 at baseline to 0.72 at 6-month follow-up ($p<0.001$), 0.74 at 12-month follow-up ($p<0.001$) and 0.72 at the 24-month follow-up ($p<0.001$). The mean change was only 0.05 points in the NSM group at 6 months ($p=0.17$). For patients who crossed over (n=35), the change was small at 6 months (0.02; $p=0.66$) but, after crossover, improved from 0.47 at 6 months to 0.73 at 12 months (0.26 point increase, $p<0.001$). In those who did not cross over (n=11), the change from 6 to 12 months was little ($p=0.008$). Quality of life (measured using SF-36) showed that mean 6-month changes in PCS and mental health component summary scores (MCS) were statistically significant ($p<0.001$) in the fusion group compared with the NSM group. Patients who crossed over from

NSM after 6 months had larger improvements in PCS and MCS scores compared with those who did not cross over.

4.7 In the systematic review of SI joint fusion of 430 patients, clinical and patient satisfaction with surgery (determined by subjective questionnaires and judged by a patients' stated satisfaction with surgery) ranged from 56% to 100% in 299 patients (from 9 studies) who had minimally invasive SI joint fusion at a mean follow-up of 21 months. In the RCT of 103 patients, satisfaction levels were higher at 3 and 6 months in the SI joint fusion group compared with the conservative management group ($p<0.0001$ by proportional odds logistic regression). The proportion of patients reporting that they would have the procedure again was also higher in the SI joint fusion group ($p=0.0001$).

4.8 The specialist advisers listed key efficacy outcomes as improvement in pain and function, and reduced length of hospital stay.

5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 The overall complication rate was 4% (204/5,319) in a prospective database analysis of post-marketing complaints for patients having minimally invasive sacroiliac (SI) joint fusion for degenerative sacroiliitis and SI joint disruption. Pain was the most commonly reported event (2% [119/5,319]), followed by nerve impingement in

less than 1% (n=48) and recurrent SI joint pain in less than 1% (n=43).

5.2 The overall complication rate was 13% (57/432) in a systematic review and meta-analysis of 432 patients from 12 cohort studies on minimally invasive SI joint fusion using a lateral transarticular approach. The most common events were surgical wound problems (4% 17/432), trochanteric bursitis (2% (8/432), facet pain (less than 1%, 3/432), recurrent SI pain (less than 1%, 3/432), toe and foot numbness (less than 1%, 2/432), and nerve root impingement needing revision in 2% (9/432) patients. In a systematic review on SI joint fusion including 430 patients, for those having minimally invasive SI joint fusion (n=299 in 9 studies), Complications reported were new-onset facet joint pain, trochanteric bursitis, deep wound infections, new onset of low back or buttock pain, worsening knee or leg pain, superficial cellulitis, radiculopathy, large haematomas, vascular necrosis of the hip, piriformis syndrome, implant penetration into the sacral neural foramen, peripheral neuropathy, a nondisplaced fracture, pulmonary embolism and deep vein thrombosis.

5.3 The device-related adverse event rate was 1% (75/5,319) in the prospective database analysis of post-marketing complaints. These were related to issues with binding, bending or breakage of the Steinmann pin (n=43), pin advancement difficulties (n=14), radiographic halo (n=13) and device migration (n=4). In a randomised controlled trial (RCT) of 148 patients, device-related events were reported in 3% (3/102) in the SI joint fusion group at 6-month follow-up. Two events (1 implant-related impingement on a sacral nerve causing pain and needing immediate revision and 1 hairline ilium fracture adjacent to implant causing pain resolved

after revision surgery) were definitely related to the device and 1 event (SI joint pain because of suboptimal placement of implants, which needed revision surgery) was deemed probably related to the device.

5.4 The procedure-related adverse event rate was 2% (108/5,319) in the prospective database analysis of post-marketing complaints. Improper implant placement was reported in 1% (n=72) of patients. Improper device length was reported in less than 1% (n=36) of patients, with most implants deemed to be too short (n=30). In the RCT of 148 patients, 19% (19/102) of the events were probably or definitely related to the SI joint fusion and 11% (/46) of the events were related to non-surgical management (NSM) at 6-month follow-up. Events related to surgical procedure included neuropathic symptoms (n=1), postoperative medical problems (n=4; urinary retention, nausea/vomiting, atrial fibrillation), SI joint pain or trochanteric bursitis (n=7), surgical wound problems (n=5), iliac fracture (n=1) and asymptomatic physical examination findings (n=1). With NSM, 3 patients reported SI joint pain after treatment; 1 had flushing and shortness of breath after SI joint injection and 1 had worsening SI joint pain related to physiotherapy.

5.5 The revision rate was 2% (9/432) in the systematic review and meta-analysis of 432 patients. Reoperation rate ranged from 0% to 17% (mean 6%) in the 299 patients who had minimally invasive SI joint fusion surgery in the systematic review of 430 patients (in 9 studies; mean follow-up of 21 months). In the prospective database analysis of post-marketing complaints, the reoperation rate was 2% (n=96/5,319) at a median follow-up of 4 months. Revisions were typically done in the early postoperative period (median 19 days) for treatment of a symptomatic wrongly

positioned implant (less than 1%, n=46), or to correct an improperly sized implant in an asymptomatic patient (less than 1%, n=10). Revisions in the late postoperative period were done (at a median of 297 days) to treat symptom recurrence (n=34) or for continued pain of undetermined aetiology (n=6). Revision outcomes and management of these patients were not reported.

5.6 Postoperative infection rate was 4% (n=19) at 6 months in a retrospective analysis of 469 patients treated by minimally invasive SI joint fusion.

5.7 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: non-union and implant loosening, which would be similar to pseudoarthrosis. They considered that the following were theoretical adverse events: residual pain and injury to L5 or sacral nerve roots by wrong positioning of the screw (implant).

6 Committee comments

6.1 The committee noted that the evidence reviewed by the committee was mainly from 1 device, but that there is more than 1 device available. The committee also noted that there was a lack of evidence beyond 3 years of follow-up.

6.2 The committee encourages data submission to registers, for example to the British Spine Registry.

6.3 The committee noted that, while this procedure achieves stabilisation of the joint, there was evidence that fusion of the joint does not occur in many patients.

7 Further information

7.1 For related NICE guidance, see the NICE website.

7.2 Patient commentary was sought but none was received.

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