Percutaneous Sacroiliac Joint Fusion

DEFINING APPROPRIATE COVERAGE POSITIONS
Introduction

North American Spine Society (NASS) coverage policy recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy.

Methodology

The coverage policies put forth by NASS use an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, policies reflect the multidisciplinary and non-conflicted experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States.

NASS Coverage Policy Methodology

Scope and Clinical Indications

While the reported incidence of pain arising from the sacroiliac joint (SIJ) varies depending on the diagnostic criteria utilized, the sacroiliac joint is an established source of chronic low back, buttock, groin, or lower extremity pain. Anatomic data has demonstrated nociceptive innervation of the sacroiliac joint by the dorsal rami of the distal lumbar nerve roots and the lateral branches of the sacral nerve roots. Pathologic conditions that may result in pain arising from the sacroiliac joint include degenerative and inflammatory arthritis, post-traumatic arthritis, post-partum instability, post-infectious arthritis, joint degeneration related to previous lumbar spinal fusion, joint damage from previous posterior iliac crest bone graft harvesting, and neoplastic processes affecting the sacroiliac joint.

Studies have reported the source of chronic lower back and buttock pain is from disorders of the sacroiliac joint in 10% to 26% of cases. Unfortunately, there is no single clinical, imaging, or provocative test that definitively confirms the sacroiliac joint as a primary source of pain. Physical examination should include a combination of several provocative maneuvers to help identify pain arising from the sacroiliac joint and exclude other sources of pain. Diagnostic imaging studies have not been shown to reliably predict pain arising from the SI joint, but are sometimes necessary to identify other...
pathologic conditions that may be the source of a patient’s back pain. A critical step in confirming the sacroiliac joint as the source of pain involves diagnostic intra-articular injection of the sacroiliac joint with local anesthetic. This must be performed under contrast-enhanced image guidance (fluoroscopy or CT) and with a relatively low volume (e.g. 2mls) of injectate to minimize leakage onto surrounding structures. Intraarticular confirmation of contrast spread should be confirmed and hard copies or digital images saved in the medical records. A positive response is one in which a patient experiences a substantial reduction in his or her pain, defined as at least 75 percent pain reduction, while the anesthetic is in effect. An hourly pain log should be kept by the patient and reviewed by the provider upon follow-up evaluation. The duration of pain relief should be consistent with the expected duration (i.e. long-acting or short-acting) of the anesthetic used. The pain log should also be stored in the medical records. A negative response excludes an intraarticular source of sacroiliac pain. Due to a potential placebo effect, a second diagnostic injection is required to further confirm the diagnosis in patients who report substantial (albeit temporary) pain reduction from an initial injection.

Previous work has evaluated the diagnostic validity of clusters of provocative maneuvers. One group recommended three specific criteria (developed by the International Association for the Study of Pain) for the diagnosis of SIJ pain (Szadek, 2009). From analysis of their data, one could reasonably support a diagnosis of SIJ-mediated pain in the presence of pain and tenderness with palpation of the sacral sulcus (Fortin’s point), positive findings to a thrust test, compression test or 3 or more provocative tests (additionally including the Gaenslen test, Patrick test, and compression test), and at least 50 percent pain reduction from diagnostic infiltration of the SIJ using contrast-enhanced anesthetic that lasts at least 1 to 4 hours on two separate occasions. Others have suggested that clusters of 3 or more different provocative maneuvers can be useful, but that the same 3 tests do not have to be used in all patients. From these and other data, it seems reasonable to recommend that positive responses to 3 or more provocative tests be used as one of the diagnostic criteria to support the potential diagnosis of SIJ related pain. This information is important in determining which patients should proceed with a confirmatory, diagnostic SIJ injection.

Traditional care for the treatment of pain arising from the sacroiliac joint not due to an infectious or neoplastic process begins with physical therapy and activity modification. Analgesic medication including NSAIDS, acetaminophen, or opioids could be considered depending on each patient’s medical history and symptom severity. Alternative treatments such as sacroiliac support belts and manual medicine may be considered as well. It is important to note that while these treatments are utilized routinely, no comparative effectiveness study has been published to establish their efficacy.

Fusion of the sacroiliac joint was initially described as a treatment option in 1925 (Smith-Peterson 1926). Given the depth and anatomic location of the SI joint, significant morbidity was associated with open

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fusion approaches and limited usage of these procedures. Over the past few decades, techniques utilizing trans-iliac approaches to fuse the sacroiliac joint have been developed. Minimally invasive technology has been applied to these approaches and has resulted in the development of percutaneous SIJ fusion procedures in recent years.

**Percutaneous (also referred to as minimally invasive) SIJ fusion** (e.g. insertion of a metallic device across the SIJ that is intended to fuse to the bone or lead to fusion of the joint itself, in distinction from insertion of screws without bone graft across the SIJ which are intended to stabilize but not fuse the joint) is indicated for the treatment of SIJ pain for patients with low back/buttock pain who meet ALL of the following criteria:

- **a)** Have undergone and failed a minimum six months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program
- **b)** Patient’s report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain
- **c)** A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin’s point, i.e. at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (e.g. greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist
- **d)** Positive response to a cluster of 3 provocative tests (e.g. thigh thrust test, compression test, Gaenslen’s test, distraction test, Patrick’s sign, posterior provocation test). *Note that the thrust tests is not recommended in pregnant patients or those with connective tissue disorders*
- **e)** Absence of generalized pain behavior (e.g. somatoform disorder) or generalized pain disorders (e.g. fibromyalgia)
- **f)** Diagnostic imaging studies that include ALL of the following:
  1. Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (e.g. tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion
  2. Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology
  3. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain
- **g)** At least 75 percent reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on two separate occasions
- **h)** A trial of at least one therapeutic intra-articular SIJ injection (i.e. corticosteroid injection)

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Percutaneous SIJ fusion for SIJ pain is NOT indicated in ANY of the following scenarios:

- Any case that does not fulfill ALL of the above criteria
- Presence of systemic arthropathy such as ankylosing spondylitis or rheumatoid arthritis
- Presence of generalized pain behavior (e.g. somatoform disorder) or generalized pain disorder (e.g. fibromyalgia)
- Presence of infection, tumor, or fracture
- Presence of acute, traumatic instability of the SIJ
- Presence of neural compression as seen on an MRI or CT that correlates with the patient’s symptoms or other more likely source for their pain.

Coverage Recommendations

Within the limits of a moderate body of evidence, the Coverage Committee recommends coverage for percutaneous SIJ fusion when the criteria outlined above are met. Due to the relatively moderate evidence, it is particularly critical that inclusion criteria are scrutinized and patient selection is executed with vigilance. The procedure itself has proven to be relatively safe. There is a valid concern for bias in that the overwhelming majority of the data produced so far has been industry-sponsored and generally composed of case series. However there are some data on five-year outcomes that demonstrate sustained benefit that does not appear to degrade from 1 year to 5 year time-points. The committee will revisit the quality of forthcoming evidence as it is produced in re-evaluations of the indications and coverage of this procedure.

Rationale

As percutaneous fusion techniques addressing the SIJ have become available, multiple clinical studies have evaluated the results of these procedures. A prospective study by Al-Khayer in 2008 reported results of nine patients undergoing percutaneous sacroiliac fusion using a hollow modular anchorage screw filled with demineralized bone matrix and local bone that was obtained during drilling. The mean follow up was 40 months (range, 24 – 70 months). The mean ODI value dropped from 59 (range: 34 to 70) preoperatively to 45 (range: 28 to 60) postoperatively (P<0.005), which we would interpret as a modest clinical improvement. The mean VAS value also modestly dropped from 8.1 (range: 7 to 9) preoperatively to 4.6 (range: 3 to 7) postoperatively (P<0.002). All of the patients reported that they would have the procedure again given the same circumstances. The average estimated blood loss was less than 50 ml. There was one complication consisting of a deep wound infection that healed with
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large buttock hematoma that gradually resolved. Two patients had implant penetration of the sacral foramen discovered on post-operative CT scan associated with nerve root irritation and radicular pain without neurological deficits. In both cases the implants were retracted surgically with complete resolution of symptoms. In one patient an implant had been placed too cephalad resulting in L5 nerve compression. The implant was retracted surgically with complete resolution of symptoms. One patient had a non-displaced fracture of the ilium adjacent to the sciatic notch at the edge of the lowest implant. The fracture healed without implant loosening. One late complication was reported. This involved recurrence of SI joint pain three years after surgery. CT scan identified that the two caudal implants were showing signs of motion and had been misplaced too posteriorly. Two additional implants were able to be placed anterior to the loosened implants with complete pain resolution.

Rudolf and Capobianco (2014) reported five-year outcomes of 17 patients. It is unclear if these patients were part of the 2012 publication. In addition, it should be noted that there were a total of 21 consecutive patients, though only 17 were available for follow-up. One of these patients was truly lost to follow-up, two had passed away and one had become quadriplegic after cervical trauma. The percentages of patients who achieved substantial clinical benefit were 77%, 82%, and 88% at the 12, 24, and 60 month time points. The authors used an unvalidated outcome score (termed SI joint survey instrument) which was comprised of parts of both the ODI and SF-36. Improvement was seen in 6 of 8 domains at final follow-up. Patient satisfaction was 82 percent at 1 and 5 years. Fusion was noted in 87% of cases. No intraoperative complications were noted, though the authors did report a case of hematoma, wound infection, and two cases of cellulitis.

In 2012, McGuire retrospectively reviewed and reported on 37 consecutive patients treated with 38 minimally invasive elective SIJ fusions using dual fibular allografts filled with local autograft obtained during drilling. Patients were followed-up for a mean of 52 months (range, 24–62 months). Visual Analog Scale (VAS) was used to monitor clinical pain improvement and fusion was deemed to be present when bone bridging trabeculae could be seen crossing the SIJ on either oblique x-rays or by computed tomographic scan. Thirty-four patients (89.5%) achieved a solid arthrodesis; this group had substantial improvement in mean VAS pain scores from preoperative 9.1 to postoperative 3.4 (P < .001). This improvement in VAS occurred over a 6-month period and was sustained with subsequent follow-up. Nonunion occurred in four patients (10.5%). All four nonunions were successfully treated by secondary autogenous bone grafting and compression screw fixation.

A retrospective study by Sachs and Capobianco in 2012 reported on 11 consecutive patients treated by a single surgeon with a percutaneous SI joint using triangular, porous, plasma-coated, titanium implants. The baseline VAS pain score average was 7.9 (± 2.2) and the mean pain score average at the 12 month follow-up interval was 2.3 (±3.1), resulting in an average improvement of 6.2 points from baseline.
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(p=0.000). Patient satisfaction was very high with 100% of patients indicating that they would have the same surgery again for the same result. The estimated blood loss was less than 50ml, there were no operative complications reported, and no revision surgeries were needed.

In 2013, this same group published one year outcomes of 40 patients undergoing percutaneous SIJ fusion. Again, it is unclear if this included patients from the 2012 report. The indications and inclusion criteria of this study resemble those outlined in the coverage recommendation above. All patients indicated they would have the surgery again. A clinically significant improvement in pain was noted in all but one patient.

To our knowledge, the largest series of patients undergoing percutaneous SIJ fusions was recently published in 2014 by Sachs et al. This was a review of 144 patients who underwent the procedure with a mean follow-up of 16 months. Mean pain scores improved from 8.6 preoperatively to 2.7 postoperatively. Though there were no intraoperative complications noted, one patient presented with nerve root impingement from implant malposition that required revision surgery. It should be noted that the authors of this study had previously published multiple other case series on this subject in prior years. Although it not clearly defined, it is likely that some of the patients in this study were included in the other published studies. It should also be noted that this study, as well as many of the studies listed above, have been co-authored by industry employees and paid consultant. This underscores the need to consider both industry and non-industry sponsored studies on this topic as well as reserve the right to amend recommendations as future data evolves.

In a post-market analysis performed by one of the manufacturers (SI Bone, San Jose, CA, USA), co-authored by company employees (Miller et al, 2013), the safety profile of 5319 patients who underwent the procedure was analyzed. They noted complaints reported in 3.8 percent of patients. Pain, nerve impingement, and recurrent SIJ pain were the most common. Improper device placement occurred in 72 cases (1.4 percent). There were 96 revision surgeries performed in 94 patients. Various other parameters were listed. What is unclear from the study is a comparison to a benchmark of safety and complication rates of other surgical procedures.

Comparison to Open SIJ fusion

While current interest is clearly focused on percutaneous SI fusion techniques, in 2005 Buchowski et al reported a retrospective review of 20 patients undergoing open sacroiliac joint arthrodesis using a modified Smith Peterson approach with direct curettage of the joint. 19 Internal fixation was then applied using plates and screws. Preoperative and postoperative general health and function were assessed via the 36-item Short-Form (SF-36) Health Survey and the American Academy of Orthopaedic
Surgeons (AAOS) Modems Instrument, which were collected prospectively. Medical records and plain radiographs were reviewed retrospectively to determine the clinical and radiographic outcome. The average estimated blood loss was 290ml and seventeen patients (85%) achieved a solid fusion. The three non-unions required treatment with an open anterior sacroiliac joint fusion procedure. Fifteen patients (75%) completed preoperative and postoperative SF-36 forms. Significant (p<.05) improvement occurred in the following categories: physical functioning, role physical, bodily pain, vitality, social functioning, role emotional, and neurogenic and pain indices. Improvement (not statistically significant) was also noted in general and mental health. Most patients (60%) indicated they would choose to have the surgery again, and only one patient definitely would choose not to have the surgery again.

Smith et al (2013) compared results of open versus percutaneous SIJ fusions. Importantly, the open fusions were performed at different centers and by different surgeons than the percutaneous procedures. Though both groups seemed to improve, there was reportedly an average of 3.5 points less pain in the percutaneous group. With an attempt to match the patients for age, gender and other parameters, this difference decreased to 3 points.

Comparison to Nonoperative Care

Six month outcomes of an industry-sponsored, prospective, randomized controlled trial comparing minimally invasive SIJ fusion using triangular titanium implants to nonoperative care has been recently published by Whang et al (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4360612/). Success, as measured by a composite of pain reduction, absence of serious adverse events or neurological worsening, and absence of repeat surgery, was found in 81.4% of operative patients and 24% of nonoperative patients. At least 15 point improvement in the ODI scores were found in 75% of operative patients and 27% of nonoperative patients. One and two year follow-up reports are planned.

In summary, the outcomes of SIJ fusion for non-infectious, non-traumatic related pain appear to be relatively consistent. Both open and percutaneous SIJ fusions seem to produce improvement in pain scores. Considering that percutaneous SIJ fusions seem to be associated with less blood loss and fewer complications than open fusions, which has been a previously covered procedure, it seems reasonable to extend coverage to percutaneous or minimally invasive procedures. The most contentious part of the procedure admitted by each of the papers reviewed is the reliability and accuracy of diagnosing SIJ mediated pain. Thus, in reviewing a number of source recommendations and evaluative study of the criteria for the diagnosis, we propose the above listed criteria for coverage. Currently, a diagnostic contrast-enhanced, image-guided (fluoroscopy or CT) intra-articular SIJ injection with a local anesthetic is standard to exclude and/or confirm whether or not the SIJ is a source of the patient’s pain. As data continues to emerge with longer follow-up from prospective, randomized controlled trials, it will be
important to maintain scrupulous adherence to strict indications for surgical management of these patients. Future research and analysis must continue in order to further understand and refine the indications for this procedure.

References


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