Sacroiliac Joint Pain: Evidence Based Diagnosis and Treatment Options

Raj Sureja M.D.
Interventional Pain Management
Orthopaedic & Spine Center

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Program Overview

• What is the sacroiliac joint?
• Prevalence of sacroiliac joint pain
• How to establish the diagnosis?
• What are the treatment options?
The Sacroiliac Joint

• Lies next to the bottom of the spine, below the lumbar spine and above the tailbone (coccyx)
• Connects sacrum (sacro-) with the pelvis (-iliac)
• Characteristics:
  – Small and very strong, reinforced by strong ligaments that surround it
  – Minimal motion
  – Transmits forces of the upper body to the pelvis (hips) and legs
  – Shock-absorbing structure
SIJ pain symptoms

• May be characterized by the following:
  – Pain in the thigh and/or buttock, and possibly pain that radiates down the sciatic nerve, although it rarely radiates into the foot
  – More commonly experienced on one side of the body, but may occur on both sides
  – Typically characterized by “stabbing” pain
Prevalence of SI Joint Pain

- 13 - 30% incidence of SIJ pain in LBP patients
  - Schwarzer AC. Spine 1995

- 18.5% incidence of SIJ pain in LBP patients
  - Maigne JY. Spine 1996

- 15-25% of patients with axial LBP have SI joint pain
  - Cohen SP. Anesth Analg 2005

- 27% incidence of SIJ pain in LBP patients

Bernard
Clinical Orthopedic & Related Research 1987
(N=1,293 pts)
Prevalence of SI Joint Pain

Post-Fusion\(^1\)  
- 43%

Failed Back Surgery\(^2\)  
- 29%

Diagnosing SI Joint Pain
SI Joint Diagnostic Challenges

• Presenting complaints mimic other causes of chronic LBP
  – Evaluate all possible pain generators for the lumbar spine, the hip, and the SI Joint
  ▪ Imaging studies often inconclusive
  ▪ Referral pain patterns for the three conditions overlap
Who Are the SIJ Patients?

• Is there clinical evidence for how to diagnosis?
Diagnosing Overview

- History
- Physical exam
- Differential diagnosis
- Current reference standard
History: Potential Causes

**TRAUMATIC**
- Fall
- Motor vehicle collision
- Lifting
- Pregnancy

**ATRAUMATIC**
- Adjacent Segment Disorder
  - Prior Lumbar Fusion
- Cumulative Injury
- Arthritis
- Obesity
- Scoliosis
- Inflammatory Arthropathy
- Infection
The SI Joint in Adjacent Segment Disease

Fusion of the spine has an effect on adjacent segments because there are changes in the motion required of these segments and in the stress they receive. The SI joint is located at the base of the spine and its movements are influenced by the motion of the spine.

PREVALENCE

- **SI Joint Degeneration**
  - Radiographic Evidence 5 years Post-Fusion
  - 75%

- **Symptomatic SI Joint**
  - 1-year Median Duration Post-Lumbar Fusion
  - 43%

“The sacroiliac joint may be a contributing factor in 29% to 40% of cases of failed back surgery syndrome.”
Sacroiliac Joint Disruptions Due to Minor Trauma

During the physical exam, one of the most common findings of patients with sacroiliac (SI) joint pain is a history of minor trauma. Trauma to the SI joint may occur from one incident (fall to the buttocks, motor vehicle accident, pregnancy) or from repeated stress over time (sports related, heavy lifting, torsional strain).

**PREVALENCE**

- **Prevalence of SI Joint Injury**
  - Minor Trauma: 21%
  - Cumulative Injury: 44%

- **Work Related Injury**
  - 42%
Physical Exam: Pain Localization

Fortin Finger Test\(^1\)

- Point to pain while standing
  1. Able to localize pain with one finger
  2. Within 1 cm of PSIS (inferomedial)
  3. Consistent over at least 2 trials

- Ask patient to point to location of primary pain
  - **Below L5**: Consider SIJ
  - **Above L5**: Consider lumbar spine etiologies


SI Joint Pain Referred Patterns

SIJ-related pain patterns can be similar to the L5 and S1 dermatome areas.

Primary
Below L5
Pain over PSIS

14% Groin
28% Lower Leg
94% Buttock
48% Thigh
12% Ankle

Sacroiliac Provocation Tests

- Compression
- Thigh thrust
- Distraction
- FABER
- Gaenslen’s
Sacroiliac Provocation Tests

Provocative Tests
1. Distraction*
2. Thigh Thrust*
3. Compression
4. FABER
5. Gaenslen’s Maneuver

* most sensitive of the tests

Diagnostic Criteria:
- 3 of 5 must be positive
  - At least 1 of 3 being Compression or Thigh Thrust

Laslett (2) | Szadek (1)
---|---
Sensitivity | 91% | 85%
Specificity  | 78% | 76%

1. Diagnostic Validity of Criteria for Sacroiliac Joint Pain: A Systematic Review

2. Evidence Based Diagnosis and treatment of the painful Sacroiliac Joint - Journal of Manual & Manipulative Therapy, 2008, Mark Laslett
Conservative Treatment Options
Treatment Options

• Drugs
  – NSAIDS
  – Oral steroid taper
  – Opioids (acute pain)

• Physical Rehabilitation
  – 6-8 weeks duration
  – Manual Therapy
  – SIJ Belt
  – Postural modifications

• Therapeutic Injection
  – 1-4 per year

• Radiofrequency Ablation
2 year outcomes:
• Physical therapy exercise produced good long-term results
• Chronic or Disability due to LBP saw no to modest improvements
• This subset could be due to an underlying disruption

Diagnostic SIJ Injections

Current Gold Standard

- 22 gauge 5” styletted needle
- 0.25ml contrast medium
- 1.25ml local anesthetic
- Pain Reduction
  - ≥75% test is positive
  - 50-75% May be considered a major contributor to the patient’s pain
SI Joint Injections

Maugars 1996
- Only randomized control study
- Spondylarthropathy patients diagnosed with sacroiliitis

SI Joint Injections

Hawkins 2009

SIJ corticosteroid injections appear to be an effective palliative treatment for selected patients with SIJ pain. Most patients whose pain is responsive to SIJ steroid injections improved sufficiently and remained well after 1 to 3 injections, but some required frequent injections on a long-term basis (duration between injections: 8.5 months)

RF for SI Joint Pain

Patel, et al. 2011
- 51 Patients randomized 2:1
- True RF group had greater decrease in pain at 3 months (2.4 points vs. 0.8 points), and also had greater improvement on Oswestry (decrease of 11 points vs. increase of 2 points) than the sham RF

* P < 0.05 comparing means between treatment and sham groups

RF for SI Joint Pain

Cheng et al. 2012
- 88 patients
  - 30 traditional RF
  - 58 cooled RF

Cohen et al. 2008
- 28 patients

“...benefit constrained by nerve regeneration to between 6 months and 1 yr.”
Treatment Options

Recurrent Pain?
– May have underlying disruptions

• Disruptions can cause instability through:¹
  – ligamentous laxity
  – tearing of the joint capsule
  – up to 61% of patients had capsular tears²,³

• Is there another option?

Sacroiliac Joint Fusion
SI Joint Fusion

- Minimally Invasive iFuse Implant System

- Vs. Open SI Fusion:
  - Small incision
  - Reduced blood loss
- Short procedure length
  ~ 1 hour
- No need for bone grafting
SI Joint Fusion: iFuse Implant System®

Why the unique triangular design?

• Cannulated screw may loosen\textsuperscript{1,2,3}

Design: Triangle vs. Round

• Porous titanium plasma coating allows for biologic fixation

• Larger surface area designed to stabilize and fuse the heavily loaded SI joint

• 3X stronger than screw\textsuperscript{4}

1. The Effects of Cyclic Loading on Pull-Out Strength of Sacral Screw Fixation: An In Vitro Biomechanical Study
iFuse Clinical Results

- Clinical Publications (10)
- Outcome Measures
  - Pain – Visual Analog Scale (VAS)
  - Back Function – Oswestry Disability Index (ODI)
  - Quality of life – SF-12, SF-36, EQ-5D, RDQ
  - Patient Satisfaction
  - Perioperative – EBL, OR time, LOS
  - Complaints / Complications
iFuse Procedure Outcomes

3 year: Early and Sustained

Pain Scores
How much pain are you in at this time?
(0=No pain; 10=Worst pain imaginable)

Patient satisfaction 82% at 40 Months

Average Pain Scores


*Dr. Rudolf is a paid consultant and has an ownership interest in SI-BONE, Inc.
Pain Relief: Rapid & Sustained

Disclosures:
Rudolf – Paid consultant of, ownership interest in, and conducts clinical research for SI-BONE Inc.
Sachs – Paid consultant of and conducts clinical research for SI-BONE Inc.
Cummings – Paid consultant of and conducts clinical research for SI-BONE Inc.
Duhon – Paid consultant of and conducts clinical research for SI-BONE Inc.
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Oswestry Disability Index (ODI)

- Questionnaire used by clinicians and researchers to quantify disability for low back pain
- Questionnaire contains topics concerning:
  - intensity of pain
  - lifting,
  - ability to care for oneself
  - ability to walk
  - ability to sit
  - sexual function
  - ability to stand
  - social life
  - sleep quality
  - ability to travel

- Each question is scored on a scale of 0-5:
  - zero indicates the least amount of disability
  - 5 indicates most severe disability

- The index is scored from 0 to 100. Zero is equated with no disability and 100 being maximum disability
ODI (continued)

- 0% to 20%: Minimal disability
- 21%-40%: Moderate Disability
- 41%-60%: Severe Disability
- 61%-80%: Crippling back pain
- 81%-100%: These patients are either bed-bound or have an exaggeration of their symptoms
Back Function: Clinical Improvement

Oswestry Disability Index (ODI)

Cummings 2013 (n=18)
ODI Drop from BL to 12mo
-37.5 pts*† (p<0.001)

Gaetani 2013 (n=10)
ODI Drop from BL to mean 10mo
-19.4 pts*† (p<0.001)

Duhon 2013 (n=26)
ODI Drop from BL to 6mo
-15.8 pts* (p<0.0001)

Clinically & Statistically Significant Improvement

Clinical Improvement Definitions
*MCID: ≥ 12.8 point drop [1]
†SCB: ≥ 18.8 point drop or final score of < 31.3 [2]

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iFuse Procedure Outcomes

Multiple Studies: High patient satisfaction


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Satisfaction & Quality of Life

Patient Satisfaction

- Rudolf 2012 (avg 40mo): 82%
- Sachs 2013 (12mo): 100%
- Cummings 2013 (12mo): 95%
- Gaetani 2013 (8-18mo): 100%
- Duhon 2013 (6mo): 85%

QOL Improvement from Baseline

- SF-12 PCS
  - Cummings 2013
  - 12 mo, p<0.005
- SF-36 PCS
  - Duhon 2013
  - 6 mo, p=0.003
- EQ-5D
  - Duhon 2013
  - 6 mo, P=0.0006
- RDQ
  - Gaetani 2013
  - 10 mo, p<0.01

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SF-12 PCS = Short-Form 12 patient questionnaire, Physical Component Summary
SF-36 PCS = Short-Form 36 patient questionnaire, Physical Component Summary
EQ-5D = EuroQOL-5 Dimension questionnaire
RDQ = Roland-Morris Questionnaire
Perioperative Measures & Complaints

Operative Process Measures Significantly Less in MIS Compared to Open Surgery¹

- Less estimated blood loss (EBL)
- Shorter OR Time
- Shorter Length of Stay (LOS)

Low Complaint and Revision Rates

< 5% overall complaint rate  
(as of Feb 2014)²

Miller – Med Device Evid Res 2013³
5319 patients (~16,000 implants) in the US and Europe from Apr 2009-Jan 2013, performed by 487 different surgeons.

- 3.8% overall complaint rate
- 1.8% revision rate

2. Complaint Handling Database (SI-BONE, Inc. Data on file.)
Indications & Risk Statement

Indications:
• The iFuse Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Risk Statement:
• As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the iFuse Implant. Contraindications, warnings, precautions, risks, and alternative treatments should be discussed with the patient.
Summary

• Prevalence – 15 to 30% of all LBP
• Diagnosis – Battery of tests and SI joint injection
• Treatment options:
  – Conservative care:
    1. Physical Therapy/ Bracing
    2. SI joint injections
    3. RF Ablations
  – MIS SI Joint Fusion:
    1. iFuse Implant System