Texas Orthopedics
Sports & Rehabilitation Associates

Top spine papers of 2016

Ai Mukai, MD
Texas Orthopedics, Sports & Rehabilitation
University of Texas-Austin, PM&R Residency

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“Top papers in spine?”

YOU GOT C-SPINE?

WHY NOT A-SPINE?!
Top papers in Spine

How do you define “top”?

- Study that got a lot of press? (patients will be asking)
- Does it change what I do in practice?
- Could the insurance company and other payers use this information for or against me? 😊
- Trend towards value based care, cost effectiveness, quality initiatives, payment models emphasizing outcomes rather than quantity
Timing of Pre-surgical Steroid injections and risk of infection

- In early 2016 – a lot of press and change in practice surrounding the correlation of pre-operative cortisone injections with increased infection rate after THR and TKR. Specifically the hip study came out of HSS and presented at AAOS.
  - Preoperative Hip Injections Increase the Rate of Periprosthetic Infection After Total Hip Arthroplasty, Schaier et al. Journal of Arthroplasty, September 2016

DOES THIS APPLY TO THE SPINE?
Steroid injections and post operative infection risk

- Two studies in 2016 – one for the C spine, one for the L spine
- Does the Timing of Pre-Operative Epidural Steroid Injection Affect Infection Risk after ACDF or Posterior Cervical Fusion? By Cancienne et al. (Dept Ortho Surg UVa) SPINE 2016
- Is there an Association of Epidural Corticosteroid Injection with Postoperative Surgical Site Infection After Surgery for Lumbar Degenerative Spine Disease? By Hartveldt et al. (Dept Ortho Surg Harvard) SPINE 2016
Does the Timing of Pre-Operative ESI Affect Infection Risk after ACDF or PCF?

- Epidural Steroid Injections - One of the most commonly performed procedures in the U.S. with 2.3 million procedures per year for Medicare alone
- PCFs are known to have higher infection rate than ACDF
- Yang et al. – single level decompression infection risk increased within 3 months of ESI
Does the Timing of Pre-Operative ESI Affect Infection Risk after ACDF or PCF?

- Retrospective database analysis
  - National insurance database containing procedural volumes, patient demographics, ICD-9, CPT codes.
  - Medicare database within “pearldriver” which contains over 100 million records from 2005-12.
  - Identify those who underwent ACDF or PCF—exclude revision codes, then identify those who had cervical ESIs (64479 and 62310) – ILESI and TFESI
    - Injection within 3 months, 3-6 months, and 6-12 months
  - Infection within 90 days of ACDF/PCF (for early and late infections)
- Controlled for age, gender, obesity, diabetes, and smoking
Does the Timing of Pre-Operative ESI Affect Infection Risk after ACDF or PCF?

**PCF**

- 62870 patients had PCF after ESI → 420 PCF within 3 months of ESI, 586 within 3-6 months, and 629 within 6-12 months)
- 61253 patients had PCF without any ESI
- 3 months group had 4% infection rate vs control group 2.1%. 3-6 months had 3.2% and 6-12 months had 2.2%. (no difference after 6 months)
Does the Timing of Pre-Operative ESI Affect Infection Risk after ACDF or PCF?

ACDF

- 254863 patients had ACDF
- ACDF after ESI → 4354 within 3 months of ESI, 5183 within 3-6 months, and 3648 within 6-12 months)
- 241678 patients had ACDF without any ESI
- Patients who had ESIs prior to ACDF on average were significantly younger, more males, and much less healthy than controls based on co-morbidities.
- 3 months group had 0.8% infection rate vs control group 0.6%. (no difference after 3 months)
CONCLUSION

• ESI within 3 months before an ACDF and 6 months before a PCF appears to have an increased risk of post-operative infection
Does the Timing of Pre-Operative ESI Affect Infection Risk after ACDF or PCF?

- Limitations
  - Rely on quality of data and accuracy of codes (national coding error rate of 3.9% reported in 2006)
  - Can’t specify exact level of injection, dose or type of medication for injections.
  - Can’t specify exact level of surgery, duration of operation time, or post-op drain use
  - No specific information about infection – organism, course of treatment, etc.
    - Was it a specific surgeon/facility?
Steroid injections and post operative infection risk

How about the lumbar spine?
ESI and lumbar surgery infection risk

- Previous studies –
  - Lowell et al found among 31 patients who received INTRAOPERATIVE epidural methylprednisolone – 3 got epidural abscess vs those that didn’t
  - Yang et al – case control study in 2015 – looked at Medicare data looking at 18931 patients older than 65 years old who underwent single level lumbar decompression compared to 106545 patients who did NOT have an ESI. Found a higher incidence of 90 day postoperative infection for patients who received an ESI within 1 months or between 1 and 3 months compared to controls.
ESI and lumbar surgery infection risk

- Retrospective database analysis
  - Two affiliated tertiary care referral centers between January 2005 and January 2015
  - CPT code for single or multilevel laminectomy with and without fusion used to search database
    - 18 years or older with at least 90 days of clinical follow up
    - Excluded spinal tumor, fracture/trauma, pseudoarthrosis, pre-existing infection
    - Only the first spine procedure included if patient had multiple spine procedures
  - 5311 Total eligible patients identified
- Post operative SSI (Surgical Site Infection) identified for symptoms requiring I&D in the OR
ESI and lumbar surgery infection risk

- Transforaminal and Interlaminar ESIs were identified within 90 days of surgery and up to 10 days after the surgery (to include delay in code processing)
- Out of 5311 patients 945 had ESIs (18%) within 90 days of surgery
  - (controlled for coding error by randomly selecting 100 patients without ESI code to make sure they did NOT have an ESI – 11 of them had history of ESI within 90 days of surgery at an outside institution.
- Looked at sex, age, race, tobacco use, obesity, diabetes, type of operation, operative approach, drain placement, comorbidity status
ESI and lumbar surgery infection risk

- 945 patients who received ESIs – mean number of injections was 1.33. Mean age was 57 +/- 16 years. 50% men
- ESI group patients were younger, had shorter duration of surgery, less blood loss, shorter hospital stay, and more comorbidities.
- ESI group also had more single level, laminectomy only, posterior approach, less often had drains placed
- Further classified into: 30days, 90 days, 30-90days before surgery group
- 134 out of 5311 patients (2.5%) developed surgical site infection requiring re-operation
- No association of exposure or dose response relationship was identified between ESI and Postoperative infection for any time periods (30, 90, and 30-90days ESI)
CONCLUSION

• No association of Epidural Steroid Injection and postoperative infection after lumbar spine laminectomy +/- fusion

• Did find that longer hospital stay, more blood loss, posterior approach, and drain placement associated with higher infection rates (conflicting evidence in other studies)
ESI and lumbar surgery infection risk

- Limitations
  - Limited to two facilities – couldn’t capture outside facility procedures
  - Use of CPT and ICD9 codes – always risk of miscoding
  - Infection rate was low (2.5%) so power was impacted
Bottomline for practice?

- Consider communication with spine surgeon if surgery is planned or appears inevitable.
- Consider NOT performing epidural steroid injections if surgery is planned within 3 months (6 months may be hard to predict).
- Consider counseling patients on infection risk with surgery.
- Practice as much infection risk reduction as possible.
  - Consider risk stratifying – smoking, diabetes, immunocompromise, etc.
I'M GOING TO WRITE YOU A PRESCRIPTION. IT'S CALLED: SUCK IT UP
Predictors of the efficacy of epidural steroid injections for structural lumbar degenerative pathology

Predictors of efficacy of lumbar ESIs

• Several recent studies challenged effectiveness of lumbar ESIs in the degenerative spine disease patient
  • SPORT trial – no difference in avoidance of surgery, complications, or reoperation rates between patients with ESI undergoing surgery vs non-ESI

• Several studies have shown short term efficacy in selected patients with select disease pathology but no predictive models

• “value based medicine” is pushing us to try to stratify patients based on predictive models
Predictors of efficacy of lumbar ESIs

- 239 consecutive patients undergoing lumbar ESI for degenerative pathology over a period of 2 years enrolled in web based registry
- Used Minimum Clinically Important Difference (MCID) of the Oswestry Disability Index (ODI) to differentiate between “responder” and “Non responder”. (threshold of 7.1%)
- Looked at variables including age, gender, employment, insurance, smoking status, preoperative ambulation, preinjection narcotic use, comorbidities, back vs leg location of pain, symptom duration, diagnosis, number of levels, prior surgery, type of stenosis, injection route, and number of injections
6 random patients per week with physical exam and imaging consistent with primary surgical pathology but who have chosen a non-surgical pathway screened

Inclusion criteria: age 18-70, radicular pain, correlative imaging findings

Exclusion criteria: pathological cause, active medical or work comp lawsuit, extraspinal cause of back pain, non-specific cause of back pain, unwillingness or inability to participate in follow up

Only those who completed 3 months follow up included
Predictors of efficacy of lumbar ESIs

- Outcomes measures:
  - Patient Reported Outcome (PRO) measures of pain
    - Numeric rating scale for back and leg pain
    - ODI
    - SF-12 physical and mental components
    - EQ-5D
    - NASS satisfactory questionnaire
    - Depressions defined as Zung depression index >33, anxiety defined as Modified Somatic Perception Questionnaire >12
  - Phone interview conducted by independent investigator not involved with clinical care
Predictors of efficacy of lumbar ESIs

- 239 patients included – 46 (19%) had listhesis, 41 (58.9%) had stenosis, and 52 (21.8%) had disc herniation
- 106 male, 133 female with mean age 60.6
- 63% symptoms greater than 12 months, 57% hx of prior surgery
- 13.8% (33) had motor deficits, 7 (2.9%) had neurogenic claudication
- 171 (71.5%) had pre-injection physical therapy
Predictors of efficacy of lumbar ESIs

- 72.8% (174) got TFESIs, 44 (18.4%) got ILESI, 21 (8.7%) got combined TF and IL routes or caudal. Mean number of injections per patient was 2.6. (105 or 44% of patients had additional injections following baseline injection)
- 52% of patients reached MCID following ESI
Predictors of efficacy of lumbar ESIs

- Factors identified that predict achievement of MCID in ODI 3 months after lumbar ESI:
  - Existence of central stenosis vs lateral recess/foraminal stenosis
  - TF or IL injection route vs caudal
  - Higher baseline ODI
  - Diagnosis of disc herniation

- Factors that decrease odds of achieving MCID
  - Symptom duration over a year
  - Prior surgery
  - Preoperative anxiety
Predictors of efficacy of lumbar ESIs

## Table 4
Hypothetical patients (A) and with differing baseline characteristics (B), demonstrating the predicted odds of achieving MCID for ODI at 3 months

<table>
<thead>
<tr>
<th></th>
<th>Patient A</th>
<th>Patient B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central stenosis</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Transforminal/interlaminar</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Baseline ODI</td>
<td>30</td>
<td>25</td>
</tr>
<tr>
<td>Symptom duration</td>
<td>&lt;3 months</td>
<td>3–12 months</td>
</tr>
<tr>
<td>Preoperative narcotic use (days)</td>
<td>30</td>
<td>100</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Disc herniation</td>
<td>Spondylolisthesis</td>
</tr>
<tr>
<td>Prior surgery</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Baseline MSPQ</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>Odds of 3 months MCID for ODI</td>
<td>95.77%</td>
<td>16.94%</td>
</tr>
</tbody>
</table>

MCID, minimum clinically important difference; MSPQ, Modified Somatic Perception Questionnaire; ODI, Oswestry Disability Index.
Predictors of efficacy of lumbar ESIs

**Limitations:**

- Number of patients enrolled in study is low
- MCID for ODI evaluated at 3 months (so not long term)
- Did not study patients that required crossover from injection to surgery
- Unclear their definition of central canal stenosis (mild – moderate severe – based on AP diameter?)
- Can have disc herniation and spondylosis – how was that differentiated?
Bottomline for practice?

- Start identifying patients who may not respond as well to ESIs – chronic pain (over 12 months), baseline anxiety, etc.
- May want to consider intervention for anxiety prior to injection therapy
- Set up expectation of patient – let them know if they have poor predictive factors for improvement with ESI
BACK PAIN

IS YOUTH LEAVING THE BODY.
Spine surgery literature
Spine surgery

- Trend towards value based medicine and quality and cost effectiveness.

- Report in 2014 showed spinal fusion accounted for highest aggregate hospital costs ($12.8 billion in 2011) of any surgical procedure performed in US hospitals (Weiss et al. HCUP statistical brief #170, Feb 2014)

- SPORT trial showed that surgery was superior to nonoperative care for management of lumbar degenerative spondylolisthesis – most patients in that study got laminectomy with fusion (Weinstein et al. NEJM 2007;356:2257-70)
Spine surgery

- Herkowitz et al. did a nonrandomized prospective comparative study that found that laminectomy with fusion was superior to laminectomy alone (JBJS 1991)

- No class 1 evidence that laminectomy plus fusion is superior

- Half of patients in the U.S. who received surgery for lumbar spinal stenosis had fusion with laminectomy. 96% of those with spinal listhesis undergo fusion and decompression.
Fusion for lumbar spinal stenosis

- 2 studies in NEJM same issue April 2016 different conclusions:
  - A Randomized Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis by Forsth et al. NEJM 2016 374:15 - Results of the Swedish Spinal Stenosis Study (SSSS)
  - Laminectomy plus Fusion versus Laminectomy Alone for Lumbar Spondylolisthesis by Ghogawala et al. NEJM 2016 374:15 (Dept of Neurosurgery, MGH – results of the SLIP trial (Spinal Laminectomy vs Instrumented Pedicle Screw))
Swedish Study

- Multi-center open label clinical superiority trial
- 247 patients between 50-80 years old with lumbar spinal stenosis at one or two adjacent levels to undergo decompression only or decompression plus fusion
- Outcomes measures: ODI, 6 minute walk test, health economic evaluation, patient reported outcome measures (ZCQ – Zurich Claudication Questionnaire, National Swedish Register for Spine Surgery or Swespine)
- Primary outcome was ODI 2 years after surgery
Inclusion criteria: pseudoclaudication in one or both legs and back pain, 1 or 2 adjacent stenosis btwn L2 through S1 (defined as less than 75mm cross section area on MRI), duration of symptoms >6 months

Exclusion criteria: spondylolysis, degenerative scoliosis with cobb angle >20 degrees, history of lumbar spine surgery, stenosis not caused by spondylosis (including HNP), hx of Fx, psychological disorders

Assess for degenerative spondylolisthesis with lateral xray. Flexion-extension views were NOT obtained. Defined as more than 3mm movement – average was 7.4mm (range 3-14.3mm)
Swedish Study

- No significant difference between the two groups in primary outcome. Mean score of ODI was 27 in fusion group and 24 in decompression alone group.

- No difference between listhesis vs no listhesis group.
  - Further stratification for listhesis less than 7.4 mm and greater than 7.4 mm showed no difference in ODI (25 in both groups).

- No difference in 6 minute walk test at 2 years (397m in fusion, 405m in no fusion group).
Swedish Study

- 153 patients were enrolled early enough to have a 5 year follow up
  - 7 died, 1 had stroke, 1 had severe dementia
- At 5 years, no significant difference in any of the seven patient reported outcome measures and no difference between listhesis no listehsis group
- Mean direct cost was $6800 higher in fusion group due to additional OR time, extended hospitalization, cost of implant. Indirect cost was similar
- Fusion group stayed mean of 7.4 days in hospital vs 4.1 days for decompression only group
Swedish Study

- Complications:
  - Dural tears in 11% in fusion group and 11% in decompression group
  - Post op infection treated with Abx but no surgery 10% in fusion (11) and 4% in decompression group (5)
  - MI, stroke, thromboembolic events in 3% in fusion group (3) and 4% in decompression alone group (5)
  - Additional surgeries before end of Oct 2015 (end of follow up period) – 22% in fusion group, 21% in decompression only group
Swedish Study

• Limitations:
  • No flexion extension films – the authors state that this method has been questioned because of measurement errors, lack of definition of normal movements and low repeatability unless the observed vertebral slip > 5mm
    • They claim that the lack of difference between the less than 7.4mm and greater than 7.4mm slippage group indicate that there is no bias
  • Different grading system – we typically use grade 1-4 for listhesis. The absolute mm doesn’t matter as much as relative
  • Didn’t look at BMI – which may be more of an issue in the U.S. where obesity rates are higher
SLIP trial

WHAT IF I TOLD YOU...

DISCS DON'T SLIP.
SLIP trial

• Comparative Effectiveness Study of laminectomy alone vs laminectomy plus instrumented fusion for symptomatic grade 1 degenerative spondylolisthesis with spinal stenosis

• Randomized controlled trial of 66 patients 50-80 years old with listhesis 3-14mm and symptomatic spinal stenosis between 2002 through 2009 at five centers

• Primary outcome measure was change in SF-36 after 2 years. Secondary measure was ODI.
Inclusion criteria: grade 1 listhesis (3-14mm) with lumbar stenosis and neurogenic claudication, with or without lumbar radiculopathy.

Exclusion criteria: lumbar instability (flexion extension x-ray showing motion >3mm or hx mechanical LBP with axial loading), previous spine surgery, or ASA class 4 or higher.

Panel of 10 expert spine surgeons review brief clinical vignette plus 4 standardized radiographic and MR images (images reviewed by 2 neuroradiologists and 1 neurosurgeon) for each patient to assess suitability for randomization.
Patients underwent decompression alone (complete laminectomy with partial removal of medial facet joint) or decompression with posterolateral instrumented fusion (PLIF) with iliac crest bone graft at the single level of listhesis. (no BMP, interbody devices or minimally invasive techniques)

Outcome measures: at least 5 points difference in SF-36 and 10 points difference in ODI defined as minimal clinically important difference
SLIP trial

- Results: mean age 87 years old, 80% women (consistent with previous reports on patients with degenerative spondylolisthesis)
- Baseline SF-36 scores were 3.2 points lower in the fusion group, listhesis average was 5.6mm in the fusion group and 6.5mm in the decompression only group
SLIP trial

- 2 years post-op through 4 yrs—fusion group had significantly greater increase in SF-36 physical component summary score than decompression only
- Difference in ODI scores was NOT significant.
- Fusion group had lower rate of reoperation over 4 years than decompression alone
  - All the reoperation in decompression group was at the “index level” of the original surgery
  - All the reoperation performed in the fusion group was at adjacent levels
  - Obesity was NOT a risk factor for reoperation
- Surgical complications, blood loss, length of stay, and length of procedure significantly greater in fusion group
SLIP trial

A SF-36 Physical-Component Summary

Score
0 30 40 45 50 55 60

Fusion group
Decompression-alone group

Postoperative Month
0 1.5 3 6 12 36 48
SLIP trial

- Limitation:
  - Size of study not powered to see if reoperation rate is an indicator of instability after decompression alone
  - Only studied one way of doing decompression/fusion surgery (PLIF with pedicle screws) - There are newer techniques of unilateral laminotomy with bilateral decompression. There’s also different bone graft options (BMP – controversial, cadaver bone, etc.)
  - No difference in the ODI vs SF-36 – clinical significance?
  - 4 year follow up – so don’t know what happens long term
Bottomline for practice

- Weigh risks of fusion – bigger surgery, higher cost, complication rate, and hospital stay – with benefits of fusion – possibly less reoperation rate, possibly more quality of life
- If patient with milder listhesis (grade 1 or less) with no movement on flexion/extension – could consider decompression only
- We don’t perform surgeries but we refer our patients to surgeons. We know which surgeons tend to do what – which ones are more aggressive? Which ones fuse more? Consider patient factors when deciding when and to whom we refer our patients for surgery.
- “yo mama rule”