Evidence Based Medicine in Spine Care

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• I hoped you enjoyed the talk!
Evidence Based Medicine is difficult to come by. It requires randomized controlled clinical trials to document efficacy.

Most EBM in spine is based on a lesser degree of scientific rigidity. Case controlled studies, retrospective review, series.

Some statistics knowledge is helpful. Industry studies can be prominent with spinal equipment. Payments to implant medical device makers are reimbursed at 2X rate of inflation and MDs have been flat X10 yrs. Government funding can be limited.
<table>
<thead>
<tr>
<th>Types of Studies</th>
<th>Therapeutic Studies – Investigating the results of treatment</th>
<th>Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease</th>
<th>Diagnostic Studies – Investigating a diagnostic test</th>
<th>Economic and Decision Analyses – Developing an economic or decision model</th>
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</thead>
<tbody>
<tr>
<td>Level I</td>
<td>• High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals</td>
<td>• High quality prospective study(^4) (all patients were enrolled at the same point in their disease with ( \geq 80% ) follow-up of enrolled patients)</td>
<td>• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)</td>
<td>• Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses</td>
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<td></td>
<td>• Systematic Review(^2) of Level I RCTs (and study results were homogenous(^3))</td>
<td>• Systematic review(^2) of Level I studies</td>
<td>• Systematic review(^2) of Level I studies</td>
<td>• Systematic review(^3) of Level I studies</td>
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<tr>
<td>Level II</td>
<td>• Lesser quality RCT (eg, (&lt; 80% ) follow-up, no blinding, or improper randomization)</td>
<td>• Retrospective(^4) study</td>
<td>• Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)</td>
<td>• Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses</td>
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<td></td>
<td>• Prospective(^4) comparative study(^3)</td>
<td>• Untreated controls from an RCT</td>
<td>• Systematic review(^2) of Level II studies</td>
<td>• Systematic review(^3) of Level II studies</td>
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<td></td>
<td>• Systematic review(^2) of Level II studies or Level I studies with inconsistent results</td>
<td>• Lesser quality prospective study (eg, patients enrolled at different points in their disease or (&lt; 80% ) follow-up.)</td>
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<td>Level III</td>
<td>• Case control study(^7)</td>
<td>• Case control study(^7)</td>
<td>• Study of non-consecutive patients; without consistently applied reference “gold” standard</td>
<td>• Analyses based on limited alternatives and costs; and poor estimates</td>
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<tr>
<td></td>
<td>• Retrospective(^4) comparative study(^3)</td>
<td></td>
<td>• Systematic review(^2) of Level III studies</td>
<td>• Systematic review(^3) of Level III studies</td>
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<td>Level IV</td>
<td>Case series(^8)</td>
<td>Case series</td>
<td>Case-control study</td>
<td>Analyses with no sensitivity analyses</td>
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<tr>
<td>Level V</td>
<td>Expert Opinion</td>
<td>Expert Opinion</td>
<td>Poor reference standard</td>
<td>Expert Opinion</td>
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</table>
• Many layers
  – Indications, validity of different surgical techniques, patient reported outcomes, cost, efficacy, effect of health, weight, socioeconomic status
    • QOD shows socioeconomic factors, depression and smoking are biggest drivers of outcome
    • 11-20% of patients in databases with PROs say they wouldn’t do it again.
Conservative Therapy

- Short term activity restriction – not bedrest - resume normal activities ASAP
- Chiropractic treatment, spinal manipulation are as effective as medical treatment for acute back pain. No evidence of long-term effectiveness or reduction of recurrence risk. PT of equal benefit in first six weeks, but can also be helpful for long term lifestyle changes.
- Acupuncture – safe, probably better for chronic than acute LBP
- Heat- may be, cold probably less effective.
- Medications
Mindfulness works as well as conservative therapy for low back pain
My doctor should have ordered an MRI!!

- No yield in chronic spine pain
- No yield in improving spine pain
- Appropriate with failure of improvement after six week trial of MD directed treatment and documentation of exam
- Red Flags on exam should prompt more rapid MRI
- Correlation of findings with clinical picture is key
  - 1200 asymptomatic patients
    - 88% disc bulge (% of patients & # of levels increased with age)
  - Dutch study with patients only referred after failure of conservative therapy showed 7/10 with relevant findings.
Pre-operative Considerations

• Modifiable Risk Factors
• Nonmodifiable Risk Factors
  – Age, Fragility Index
• Use of medical risk stratification
• Informed Consent
  – SRS – patients remembered <50% of risks discussed
• Shared Decision Making
Modifiable Risk Factors

- Smoking
- Obesity
- Opioid Use
- Uncontrolled Depression/anxiety
- Poorly controlled diabetes
- Osteoporosis, Vitamin D Deficiency
- Nutrition Status

It is not unethical to decline to offer surgery to people who will not modify risk factors.
Obesity

- Increased cost
  - Mayo clinic study showed cost increase extends out a year with one level lami
- Increased difficulty
  - OR equipment, all aspects of care
- Poorer outcomes
  - More difficult rehab, LOS longer
- Where to draw the line – 30, 40?
  - Joint replacement study showed 8.4Xhigher complication rate in BMI>30
• Smoking –
  – Greatly worsened risk of fusion failure
    • Henry Ford study showed 5X increased risk of reoperation for smokers
    • OHP requires carboxyhemoglobin on all patients prior to surgery including nonfusion pts and six months nicotine free for fusions
    • Other insurances vary
    • Data supports at least six weeks
  – Joint replacement study – 24X incr complication
  – Providence initiative to decrease fusions in smokers
    • Cessation Materials are available on Sharepoint
Opioid Dependence

• Benefits of Opioids
  – Modest in nonmalignant pain
    • 2010 Cochrane Review
      – Biggest drop was 2 on VAS
    • Annals of Int Med 2017
      – No benefit in acute LBP
      – 0-1 improvement in VAS
      – 10-20% in ODI
      » Best evidence was for Tramadol (still low-mod)
    • U of Mich – 8% of CTR still on after 90d
  • Recent data shows length of time on meds is more predictive of long term use than which med
Opioid Dependence

• Opioid use daily prior to surgery
  – 4X increase in mortality
  – 2X increase in complications
  – Increased LOS, decreased d/c to home
  – For every 10u inc in ME pre-op
    • % decrease in SF 32, increased ODI, NDI at 12 months post op
  – Saturated mu receptors limit ability to control post op pain
  – Joint replacement study shows 22% readmission rates for high pre/post op narc users
Depression/Anxiety

- ODI >58, VAS>7, on antidepressants
  - These patients have more spine surgery and do less well
  - Neuropsych evaluation may be helpful
  - Treating uncontrolled depression, anxiety is essential
  - Involving available support systems
Preoperative Clearance

- HgA1c <8
- Vitamin D in nl range for fusion
- Treated osteoporosis
- Optimized pulmonary, cardiac function
- Sufficient clotting factors
- Modify med regimen as needed
  - NSAID’s, steroids, etc.
- Use of risk stratification calculation
- Screening for MRSA/MSSA
Surgical Considerations

- Too numerous to address studies looking at benefits of various surgical procedures
  - Microdiscectomy
    - Surgery = better faster, everyone eventually gets better
  - Stenosis
    - Surgical outcomes are better than conservative for appropriate candidates
      - Laminectomy + fusion increases QALYs over lami starting at 6 months and increases to most effect @3-4 yrs, lower level of reop than lami alone
  - Cord Compression, Myelopathy
    - Surgery
  - Metastatic Disease
  - Deformity
    - QUALY benefits highest for those most debilitated
    - Minimally invasive – short term better, no difference in long term outcomes
Cervical Stenosis
Cervical Stenosis
Lumbar Stenosis
Discitis with Collapse

Surgical for failure of antibiotics, progressive deformity, cord compression
Indications for Treatment Of Spinal Mets

• Neurologic compromise
• Intractable pain
• Spinal instability and/or deformity
• Alter prognosis
• Relative:
  – Impending cord compression
  – Progression of lesion despite current treatment
Critical Issues

Can a feasible operation be performed?

- If Lesion is approachable and decompressible
  - Amenable to reconstruction/stabilization
  - Provides a durable benefit
- If Patient is medically stable and can endure anesthesia
  - Adequate blood counts (WBC, Hct, Platelets)
  - Adequate clotting factors
  - Reasonable predicted survival (mortality not imminent)
Surgery + RT: median 126 days
RT-alone: median 35 days

RR=0.55 (95%CI, 0.35-0.86)
P=0.006, log rank
OVERALL SURVIVAL

Surgery + RT: median 129 days
RT-alone: median 100 days

RR=0.69 (95%CI, 0.45-1.04)
P=0.08, log rank
Cauda Equina Syndrome

- Rare condition, requiring emergency surgery within 6-12 hours
- Leg weakness and pain often bilateral, bowel/bladder dysfunction, urinary retention, sexual dysfunction, saddle anesthesia
- Large disc herniation, tumor, infection

**NOT A RADIOGRAPHIC DIAGNOSIS!!!**
Artificial Disc Replacement

• Cervical – 7 yr f/u shows equally good outcome
  – Decreased reop in 1 and 2 level CDA vs ACDF

• Lumbar – no difference in long term outcome with current technology
  – NY study, equal satisfaction in blinded pts until broke blind – LDA pts satisfaction increased and fusion patients went down
Outcome of carpal tunnel surgery in 6263 operations

- Cured: 49%
- Much better: 28%
- Slightly better: 10%
- Unchanged: 6%
- Worse: 7%
Ulnar Decompression (Guyon’s Canal)

Data varies significantly, all show a majority of patients improve
Kyphoplasty & Vertebroplasty

• Medicare data – 40% of >80 yo get VCF
  – Vertebroplasty vs sham – similar outcomes
  – Kyphoplasty – EVOLVE Trial
    • 1-3 levels, < 4months pain
    • Statistical improvement in pain out to 12 months on SF36 and ODI
    • Decreased narcotic use
    • Kypho improves QOL, pain with effects >24 months and some improvement in kyphosis
I should have thought this through...
Are you going to do that with a laser?

2016 study

Percutaneous endoscopic laser diskectomy (PELD) vs percutaneous lumbar disc decompression (PLDD) and target percutaneous laser disc decompression (T-PLDD) in patients with minimal/mild disc herniations.

The study found that not only were lasers significantly less effective than minimally invasive microdiscectomy, but that they also resulted in a near doubling of the need for a subsequent surgery.
No, I am not.

- Traditional spine surgery has been tested in numerous clinical trials and proved to be effective. Studies have shown that discectomy reduces pain and other symptoms in about 85 percent of people who have a herniated disk. In elderly patients who have radiating pain due to spinal stenosis, laminectomy effectively reduces symptoms in about 80 percent of patients. Very few neurosurgeons regard laser spine surgery as a viable alternative to conventional spine surgery techniques. At Mayo Clinic, we don’t use or recommend laser spine surgery.
Spine Care Continuum
Sept 2013-present

- Partnership w/ 26 PMG PCP clinics in Northern Oregon.
- Criteria: PHP commercial & Medicare plans & Medicare A&B pts w/ back/neck pain with or w/o radicular pain who have had an MRI or CT of spine.
- Spine surgeons review detailed spine histories, correlate symptoms to imaging. Document impression and make recommendations to PCP.
- RN navigator provides education and support to pt on the journey.
- Measure outcomes at designated intervals.
- PHP Claims Analysis for cost data*

6 surgeon reviewers
3 RNs + 1 RN manager
2 intake specialists
Project Participation

• Live at 27 Clinics
  
  – 3 RN navigators, 2 intake specialists, 6 spine surgeons
  – Reviewing about 60-80 patients each month.
  – Planning to expand to remaining Northern Oregon PMG clinics in 2017
SCC Claims: Surgical Rate

Percent of Patients Who Had Surgery

- Baseline PHP Medicare (n=403): 20.6%
- SCC Enrolled PHP Medicare (n=247): 12.6%
- Baseline Commercial PHP (n=610): 19.2%
- SCC Enrolled Commercial PHP (n=234): 16.2%

% Lower CI Upper CI
SCC Claims Analysis: Mean Overall Spend

![Chart showing mean overall spend for different groups, including Baseline PHP Medicare (n=435), SCC Enrolled PHP Medicare (n=247), Baseline Commercial PHP (n=614), and SCC Enrolled Commercial PHP (n=234). The chart includes mean values and confidence intervals for each group.](image-url)
Failed Back/Neck Syndrome

- 62 yo female with previous ACDF C4-5 2015
- L4-S1 fusion 2013, ESIs 2016
- Right sided neck and scapular pain extending to the shoulder, aching in triceps
  - Failed conservative management
  - MRI without obvious etiology
  - Spinal stimulator trial with 80% pain relief
Spinal Cord Stimulation

- For chronic radiculopathy, intercostal neuralgia, peripheral neuropathy (e.g. failed ulnar decompression).
- Angina and peripheral vascular disease (improves pain and blood flow).
- Cervical, thoracic or lumbar.
- Percutaneous trial, then limited laminectomy (if trial successful) and placement of permanent lead.
- Requires high degree of patient cooperation, motivation to succeed.
Spinal Cord Stimulation

**Indications**

- Pain of neuropathic or ischemic origin
  - Failed back is most common indication
- Reasonably well-defined pain generator
- Nonoperative methods must have been exhausted
- Surgery is considered a last resort therapy
- Other treatable painful conditions include peripheral nerve injury, multiple sclerosis, post-herpetic neuralgia, post-amputation pain, complex regional pain syndrome
Spinal Cord Stimulation
Spinal Cord Stimulation
Failed back

- 63 yo female with two levels of previous disc arthroplasty with LBP, left leg pain in approximately L4, painful sex, worse with activity
- Failed PT, inconsistent response to injections
EMG normal

No response to L4 injection where there was minimal narrowing

Positive response to L3 injection where there is no narrowing

Presented at Complex spine conference – spinal cord stimulator, pt declined.
L4 fracture

- 52 yo morbidly obese osteopenic patient with GLF
  - to ED 2 d later (5/12/2017) with progressive LB and LE pain limiting ambulation
    - 300cc residual with normal rectal tone
    - Normal motor exam
  - PMH
    - s/p gastric bypass, DM, immune DO, thyroid disease, esophageal scleroderma
    - Hysterectomy
    - 4 weeks post rotator cuff surgery
Severe stenosis L3-4 d/t burst fracture
• Hospitalized, clearance from Immunologist
  – HOB Flat, fitted with TLSO
• Significant narcotic requirement d/t chronic opioid use
• 5/15 L3-4 decompression, open reduction of fracture with instrumented arthrodesis L2-S1 with O-arm
• Discharged POD#7 to SNF
And then.....

• The patient d/c’d herself from SNF
• On 5/31 office appt
  – To ED on 5/30 with c/o several days drainage from wound unreported to us
Post op fluid collection
• Returned to OR 6/1 – seroma, no infection
• Closed over drain
• Spent further 5 days in hospital watching drain output and wound
9/8 xray ?screw lucency
Modifiable risk factors?

- 11/1 will return to OR for revision instrumentation, extension of fusion
- +MSSA nasal colonization – mupiricin
- Caught double dipping narcotics with us & PCP
- BMI 41.45
- On Calcium, Vitamin D
Spine Care Continuum

• 73 yo female with h/o breast CA with one year h/o worsening right shoulder pain
  – Sharp pain post neck to scapula, axilla, elbow
  – Feels weak
  – Tried medical management
  – Ortho doctor recommended MRI of neck
  – Enrolled in SCC
Expected disc or foraminal stenosis
H&P

- Weak in right grip, bilateral R>L intrinsics, right triceps weakness
- No improvement with steroids
- OR for resection with nerve monitoring
Post-op lami and tumor resection
Lumbar HNP

- 37 yo attorney with 4.5 months of LBP and left leg pain radiating to the calf.
  - Subjective weakness, none on exam
  - Has reached a plateau with activity
  - Still going to PT
  - Self employed
  - Active, athletic, yoga participant
Cervical Myelopathy

- 53 yo several yr h/o peripheral neuropathy with numb hands and feet
- Severe viral infection with coughing X 3 weeks
- Balance, gait, driving issues
- Right hemiparesis, T7 sensory level
- Seen in office
- 2/5 grip, 3/5 triceps, intrinsics 1/5, wrist extension 2/5 4 to 4-/5 on right LE
- 3/5-4/5 on left with spastic gait and hyperreflexia
Cervical Myelopathy

• Calcification extending behind the body – corpectomy rather than ACDF
Cervical Myelopathy
Cervical Myelopathy
Cervical Myelopathy

- 4 months post op, strength and gait improved, back to driving, ongoing OT
Finally over!!!

Thanks for your attention.