Interventional Pain Management for Musculoskeletal pain What is the Evidence?

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Disclosure

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This Talk

- Evidence, not technique nor subtleties
- Limitations
- Background
- Diagnostic Spinal interventions
- Therapeutic Spinal interventions
- An Algorithmic Approach

Limitations

- The limitations of this presentation include a paucity of literature and multiple conflicting systematic reviews that use different methodologies, inclusion and exclusion criteria.
  - Some SR include discredited research and exclude other papers.
  - Ambiguous conclusions.
- Cervical & thoracic discography, some intradiscal procedures and intrathecal drug delivery omitted due to limited data and time.

Pain is a Multidimensional Experience

"Treatment of only one element of the patient's pain may result in suboptimal outcome"

ANZCA PM3-2002

Shared Treatment Goals

- Improve ADLs, Sleep & Task Performance
- Reduce pain & distress
- Reduce Drug, Health Care Usage & Costs
- Minimise Adverse Effects
- Resume desired leisure & work activities
- Improve Quality of Life

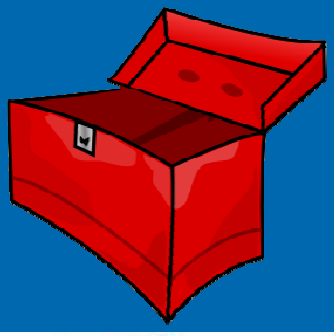
Non-Interventional Pain Medicine

- Drugs: Benefit ~ Multiple Adverse Effects ~ Unhelpful
  - Opioids- GIT, compartment syndrome, death
  - NSAIDs - multiple including death
  - Gabapentinoids - sedation, weight gain, $
- 3 CBT Pain Programs in Melbourne, n=462[1]
  - Markedly improved pain relief 15.3%
  - Much less distress, ~ less pain and disability 18.5%
  - Less disability & depression, worse pain 30.1%
  - Worse on all measures 36.1%

[1]Katz Poster 727 IASP 2005

If the only tool in the tool box is a hammer, everything looks like a nail

We Need A Full Toolbox



Pain Treatment Continuum

Multidisciplinary Assessment

- Simple Multimodal Therapy
  - Active Self-management
    - Heat/Cold, TENS, Educate
  - Reactivate & restore function
  - Medications
    - Simple Analgesics
    - Co-analgesics
    - Opioids (?)
      - Short or Long term
- Psychological
  - Cope, Relax, Distract etc
- CBT Pain Management
  - Individual or Group

- Corrective Surgery
- Interventional Pain Treatments
  - Focal injections
  - Nerve blocks & Epidurals
  - Radiofrequency (& Cryo) Tx
  - Sympathetic blocks
  - Neurolysis
  - Stimulation/Neuromodulation
    - Subcutaneous
    - Peripheral nerve
    - Spinal Cord
  - Spinal Drug Delivery
- Ablative surgery

Interventional Pain Medicine

Precision diagnostic blocks can clarify the pathophysiology, site of nociception, afferent pathway of neural signals and treatment options.

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Underlying Rationale

- Pain is arising from the target structure and is mediated by the target nerve(s), if complete pain relief & functional improvement is consistently obtained whenever the structure is anaesthetised.
  - Repeat blocks can increase the diagnostic accuracy
- Research Criteria
  - >80% pain relief and ability to perform previously painful tasks from **controlled diagnostic blocks** of target nerves
- Clinical Criteria
  - Ability to perform previously painful activities with lesser relief may be accepted depending on patient.

ISIS guidelines 2004, Datta 2009, Manchikanti 2009

Controlled Blocks

- 'Triple Block'
  - 1st block uses active agent to establish the target structure as the source of the pain
  - Active agent and placebo are then given in random double-blind order to confirm target as site of pain
- 'Comparative Block'
  - More commonly used & pragmatic approach
  - Two blocks are performed with lignocaine and bupivacaine on separate occasions
- Clinically, consistency of pain relief by active agent more important than relative duration.

Keep in mind

1. Research criteria tries to excludes false positive
2. Clinical criteria tries to include false negative
3. IPM palliative not curative in most cases

Intra-articular steroids

- Evidence of efficacy for use in shoulders is weak despite wide use[1]
  - Do any subgroups benefit?
  - Many studies are poor designed, compare different treatments & results

[1]McQuay & Moore 1998

Modified USPSTF criteria

- I: Evidence obtained from multiple properly conducted diagnostic accuracy studies.
- II-1: Evidence obtained from at least one properly conducted diagnostic accuracy study of adequate size
- II-2: Evidence obtained from at least one properly designed small diagnostic accuracy study.
- II-3: Evidence obtained from diagnostic studies of uncertainty.
- III: Opinions of respected authorities, based on clinical experience descriptive studies and case reports or reports of expert committees.

U.S. Preventive Services Task Force (USPSTF) 2001

Diagnostic Interventions for Pain of Spinal Origin

Diagnostic Lumbar Facet Joint Blocks

- 5 systematic reviews[1-5],
  - 7 studies met inclusion criteria >80% relief and ability to perform tasks previously limited by pain[3]
- Prevalence facetogenic low back pain
  - 31% (95%CI; 28–33%)
- Cost-effectiveness: no studies
- False positive single block 30% (95%CI 27-33%)
- False negative ~8% due to unrecognised intravascular injection & faulty needle placement[6]

[1,2]Sehgal etal 2005, 2007, [3]Datta etal 2009, [4]Boswell etal 2003, [5]Hancock etal 2007, [6]Dreyfuss etal 1997

Diagnostic Cervical Facet Joint Blocks

- 4 systematic reviews[1-4]
  - 9 studies met inclusion criteria >80% relief and ability to perform tasks previously limited by pain[3]
- Prevalence of cervical facet joint pain
  - 49% (95%CI, 45-52%)
- Cost-effectiveness: no studies
- False positive
  - Single block 49% (95%CI 44-54%)
- False negative
  - unknown

[1,2]Sehgal etal 2005, 2007, [3]Falco etal 2009, [4]Boswell etal 2003

Diagnostic Thoracic Facet Joint Blocks

- 4 systematic reviews[1-4]
  - 3 studies met inclusion criteria >80% relief and ability to perform tasks previously limited by pain[3]
- Prevalence of thoracic facet joint pain
  - 34-42% with (95%CI 22-53%).
- False positive
  - Single block 42-55% with (95%CI 26-78%)
- False negatives
  - unknown

[1,2]Sehgal etal 2005, 2007, [3]Atluri etal 2008, [4]Boswell etal 2003

Sacroiliac Joint Blocks

- 1 systematic review
  - 5 studies met inclusion criteria >80% relief and ability to perform tasks previously limited by pain[1]
- Prevalence: 10-38% (95%CI 0-51%)
- Cost-effectiveness: no studies
- False Positive 20-54% (95%CI 3-64%)
- False Negatives
  - unknown

Rupert 2009

Evidence

- Lumbar & cervical facet blocks
  - Strong Level I or Level II-1 on USPSTF criteria
- Thoracic facet blocks
  - Moderate Level II-1 on USPSTF criteria
- Sacroiliac joint blocks
  - Moderate Level II-2 on USPSTF criteria

Rubinstein & Van Tulder 2008

Recommendations

- Controlled diagnostic facet or sacroiliac joint blocks are recommended for suspected facet or sacroiliac joint pain >3m
- Somatic or non-radicular extremity pain
  - Pain ≥ 6/10 and causing disability
  - Unimproved by physio, chiro, NSAIDs or C/I
  - Disc or radicular pain unlikely
  - No block contraindications (C/I)

Provocation Discography

- Concordant pain with discography, 7+/10 (severe), pressure <50psi & low volume, adjacent control discs not painful & grade3+ annular tear
  - Discography is Controversial
  - Gold standard to protagonists[1],
    - 2/3 asymptomatic subjects have abnormal MRI scans[2]
  - Antagonists question significance and validity[3]
- Complete pain relief from injection of local anaesthetic
- Negative discogram excludes, but positive discography alone doesn't establish diagnosis

Cohen 2005, Jensen 1994, Carragee 2002, ISIS Practice Guidelines 2004

Discogenic low back pain

- 5 systematic reviews[1-5]
  - 9 studies met IASP & ISIS criteria
- Prevalence: 26 - 39%
- Cost-effectiveness: no studies
- Discography False Positive
  - 9.3% (95%CI, 3 -16%)[4]
  - May be 40 - 83%[6,7]

[1]Buenaventura etal 2007, [2,3]Manchikanti 2008, 2009, [4]Wolfer etal 2008, [5]Shah 2005
[6,7]Carragee etal 2006a&b

Evidence & Recommendation

- Lumbar Discography
  - Moderate Level II-2 on USPSTF criteria
- To prove pain is discogenic after excluding other sources of pain and
  - identifying target disc(s) to treat,
  - to establish that no disc is painful
  - too many discs hurt & that percutaneous Tx or lumbar surgery may be unhelpful

Diagnostic Intervention Complications

- hematoma formation,
- dural puncture,
- epidural, subdural, or subarachnoid spread
- infective
- haemorrhage,
- intravascular injection
- chemical meningitis,
- facet capsule rupture,
- pneumothorax (thoracic)
- neural trauma,
- spinal cord trauma or paralysis
- steroid side effects,
- discitis (discography)
- damage to adjoining tissue
- radiation exposure,

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Therapeutic Interventions for Pain of Spinal Origin

Evidence Scoring System for Therapeutic Interventions

- Complications
  - 1: Benefit greater than risk/burden of side-effects
  - 2: Benefit closely balances risk/burden of side-effects
- Power of evidence

  A: Multiple good quality RCTs,

  B: Questionable RCT or large cohort studies

  C: Observational studies and Case series
- Effect: + positive, - negative or ± **inconclusive**
- Duration: Short term <6 months, long term >6months

Guyat et al Chest 2006, Van Kleef PainPract 2009

Acupuncture

- Acupuncture is widely practised
- Numerous studies, equivocal results
- Little evidence that acupuncture is effective for either acute or chronic back pain[1]
- Possible short term benefit up to 3 months[2]

[1]NIH Consensus Panel on Acupuncture, 1999; [2]Furlan 2008

Therapeutic Facet Joint Interventions

- Intraarticular injections
- Medial branch blocks
- Medial branch radiofrequency neurotomy

Intraarticular facet joint injections

- 9 systematic reviews
  - Staal 2009 used <6w short term, >6w long term
  - Others used <6m short term, >6m long term
- Staal concluded moderate evidence that i/a steroids were no better than placebo for short term pain relief & functional improvement
- Datta 2009 looked at 5 SR and 15 studies and concluded none met inclusion criteria of controlled blocks and follow-up

Boswell 2007, Atluri 2008, Datta 2009, Falco 2009, Manchikanti 2008, Nelemans 2001, Staal 2009, Boswell 2005, Slipman 2003, Bogduk 2004, 2005

Therapeutic Medial branch blocks

- 6 SR, 6 RCT and 2 case series[1-6]
  - Criterion: Controlled diagnostic blocks, <6m short term, >6m long term relief
- All studies showed positive short-term and 71-92% long-term relief (>6m)[7-10]
  - But single centre, non-academic, no placebo
- Cost effectiveness: 1-year improvement of quality of life (QOL) at $3,461.

[1]Boswell 2007, [2]Atluri 2008, [3]Datta 2009, [4]Falco 2009, [5]Staal 2009, [6]Boswell 2005, [7-10]Manchikanti 2001, 2008a,b,c

Medial Branch Neurotomy Systematic Reviews

- Geurts 2001 moderate evidence lumbar RFN better than placebo for low back pain limited evidence for cervical RFN
- Niemesto 2003 & Staal 2009, Chou 2009 (& UpToDate)
  - Limited evidence cervical RFN short term
  - Conflicting lumbar RFN
    - Included discredited studies
- Slipman 2003 level 3 limited evidence
- Boswell 2007 & Manchikanti 2009
  - moderate to strong evidence for cervical and lumbar RFN
  - Of 9 RCTs and 21 case studies, only 2 RCT and 7CS met inclusion criteria

Medial Branch Neurotomy Studies

- Nath et al n=40 1:1 DBPRCT
  - active significantly reduced pain and less analgesia use
  - Only short term benefit shown as 6m study
- Lord n=24, 1:1 DBPRCT
  - at 27 weeks 7 active & 1 control remained pain free.
  - Median time for pain to return to 50% of baseline was 263 days in active and 8 days in control.
- Barnsley 2005, McDonald 1999 & Govind 2003 all showed positive short & long term results
- Dreyfuss 87% had 60% pain relief at 12m
- Gofeld 68.4% long term relief

Sacroiliac Joint RFN

- SIJ has variable dorsal & anterior innervation[1]
- L4-5 DR RFN & S1-3 DR Cooled RFN better than 'Sham' at 1, 3 and 6m[2]
  - Also showed conventional L4-S2 RFN effective.
- Several techniques described, don't know which is best

[1]Yin, W 2003, [2]Cohen et al 2008

Pulsed Radiofrequency Treatment

- Tekin n=60 3x20 DBRCT lumbar facet pain
  - All showed improved pain & Oswestry scores
    - Continuous RF > Pulsed RF > Control
    - CRF better than PRF = LA at 6 months
    - CRF improvement maintained at 12months
- VanZundert n=23 DBRCT cervical radicular pain
  - Significant global perceived improvement > 50% and > 20/100 pain reduction achieved in pulsed RF group at 3m, but not at 6m compared to sham.
  - Non-significant reduction in medication
- Conclusion: Pulsed RF works 3-6m

[1]Tekin 2007, [2]VanZundert 2007

Evidence & Recommendation

- Therapeutic intraarticular facet joint injections
  - Limited USPSTF: Level III against i/a facet joint injection
  - very weak 2C- recommendation
- Therapeutic medial branch blocks
  - Strong USPSTF: Level II-1 or II-2 that therapeutic medial branch blocks give short-term & long-term pain relief
  - Strong (1B+ or 1C+) recommendation

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Evidence & Recommendation

- Cervical radiofrequency neurotomy
  - USPSTF: Level II-1 or II-2
  - 1B+ strong recommendation short & long term relief
- Lumbar radiofrequency neurotomy
  - USPSTF: Level II-2 or II-3
  - 1C+ strong recommendation short & long term relief
- Thoracic radiofrequency neurotomy
  - No evidence available
- Pulsed radiofrequency treatment
  - USPSTF: Level II-2 or II-3,
    - Pulsed RF works 3-6months
    - Continuous RF is better if appropriate to use
  - 1B+ short term relief

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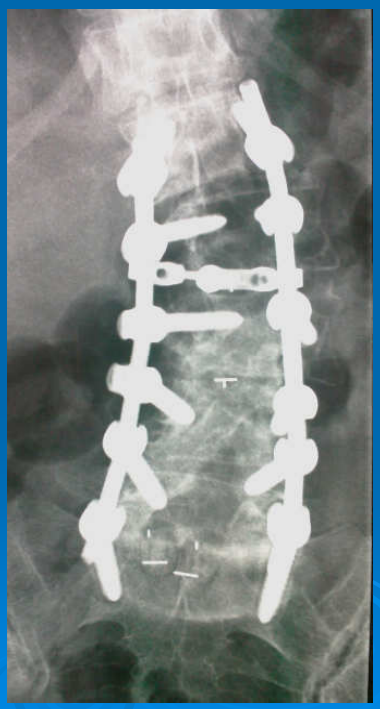
Epidural Adhesions and fibrosis

Obtained from Epimed International



Blind Lumbar Epidural Steroids

- Blind Lumbar interlaminar epidural steroid[1]
  - HNP USPSTF: Level II-2 **Short Term** (< 6m) benefit
    - 1C+ strong recommendation
  - HNP USPSTF: Level III **No Long Term** (> 6m) benefit
    - 2B- weak recommendation
  - Spinal Stenosis or Axial back pain Level III **No Effect**
    - 2C- weak recommendation
- Bogduk recommended against lumbar ESI for sciatica[2,3]
- Koes reported conflicting evidence, but reanalysis showed 5 of 7 lumbar ESI studies were negative[4,5]

[1]Parr et al 2009, [2,3]Bogduk 1994, 1999; [4,5]Koes 1995, 1999

Epidural Interventions

- Blind vs. Fluoroscopy
  - No data on benefit or harm …
  - Target specificity & confirmation requires X-ray[1,2]

[1,2]Botwin 2004a, 2004b,

Caudal Epidural Injections

- HNP & Axial LBP [1,6]
  - USPSTF: Level I for < 6m & > 6m relief
  - 1A+ or 1B+ : strong recommendation, good evidence
- Spinal Stenosis & Post Surgery Syndrome[1,6]
  - USPSTF: Level II-1 or II-2 short & long term relief
  - 1B+ or 1C+: strong recommendation, weaker evidence
- Conclusion:
  - Caudal Epidurals are effective short and long term[1-6]

[1]Conn et al 2009, [2,3]Bogduk 1994, 1999; [4,5]Koes 1995, 1999, [6]Manchikanti 2008a,b,c,d

Transforaminal Epidurals

- HNP and Radicular pain[1,2]
  - USPSTF: Level II-1 for short-term (< 6m) relief
  - USPSTF: Level II-2 for long-term (> 6m) relief
  - 2C+ strong recommend, weaker evidence
- Bupivacaine + Steroid significantly reduces operation rate[3,4]

[1]Buenaventura 2009; [2]Jeong 2008; [3,4]Riew 2000, 2006

Epidural Adhesiolysis

- Epidural adhesiolysis is effective
  - 4 Randomised Control Studies[1-4]
  - 2 Prospective Evaluations[5-6]
    - Adhesiolysis superior to epidural steroid injection[3-6]
    - Adhesiolysis superior to standard care[4]
    - Hypertonic saline use unproven & controversial[1,3]
    - No evidence that hyaluronidase improves outcome[1]
- Epidural adhesiolysis Trescot 2007& Epter 2009
  - USPSTF: Level I or II-1 short (<6m) and long term (>6m) relief
  - 1A+ or 1B+ strong recommendation

[1]Heavner 1999; [2,3]Manchikanti 2001, 2004; [4]Veihelmann 2006, [5,6]Gerdesmyer 2003, 2005

Efficacy of Steroids

- Fluoroscopic Caudal with 10cc lignocaine 0.5% ± non-particulate betamethasone had similar outcomes
  - N=236 DBRCT equivalence studies[1-4]
    - Axial back, HNP, spinal stenosis. Post Surgery
    - ≥50% pain relief 55-79% @12m
    - Oswestry reduction ≥40% in 55-91% @12m
- Rat study showed bupivacaine ± dexamethasone reduced mechanical allodynia similarly[5]
- Transforaminal Steroid with Bupivacaine significantly reduced operation rate[6]
  - 18/27 bupivacaine alone proceeded to surgery
  - 8/28 bupivacaine+betamethasone had surgery

Conclusion: corticosteroid may be unnecessary

[1-4]Manchikanti 2008a,b,c,d; [5]Tachihara 2008; [6]Riew 2001, 2006;

Cost Effectiveness

➢ Epidural adhesiolysis	$2080+	per QALY
➢ Fluoroscopic Caudal	$2550+	per QALY
➢ Transforaminal ESI	$2927	per QALY
➢ Interlaminar lumbar ESI	$6024	per QALY
➢ Epiduroscopic lysis	$7020	per QALY
Comparison		
➢ Spine surgery	$24752	per QALY
➢ Outpatient pain program	$7000+	per QALY
➢ Inpatient pain program	$17000+	per QALY

Manchikanti 1999, Boswell 2007

Therapeutic Intervention for Discogenic Pain

- Steroid – 1 RCT: ineffective[1]
- Intradiscal Unipolar RF lesions, 1 RCT: ineffective[2]
- Chymopapain works, but discectomy better
- Ozone – lots of poor quality literature[3]
- Regenerative therapy – contradictory[4,5]
- IDET – Unproven after 3 conflicting RCTs[6-7]
- Dual Electrode Intradiscal RF lesions case series suggest benefit[8]
- Nucleoplasty 1 RCT+ for limb pain, but no evidence for axial pain[9]
- Percutaneous Gray Rami RFN 1RCT+[10]

[1]Simmons 1992; [2]Barendese 2001; [3]Bogduk 2003, [4]Derby 2003, [5]Linetsky 2002, [6]Pauza 2004, [7]Freeman 2005, [8]Bogduk ?; [8]Kapural 2008, [9]Gerszten 2010, [10]Oh 2004

Peng et al 2009

PAIN® 149 (2010) 124–129

PAIN®

www.elsevier.com/locate/pain

A randomized placebo-controlled trial of intradiscal methylene blue injection for the treatment of chronic discogenic low back pain

Baogan Peng[a,b,*], Xiaodong Pang[a], Ye Wu[b], Changcheng Zhao[c], Xinghua Song[d]

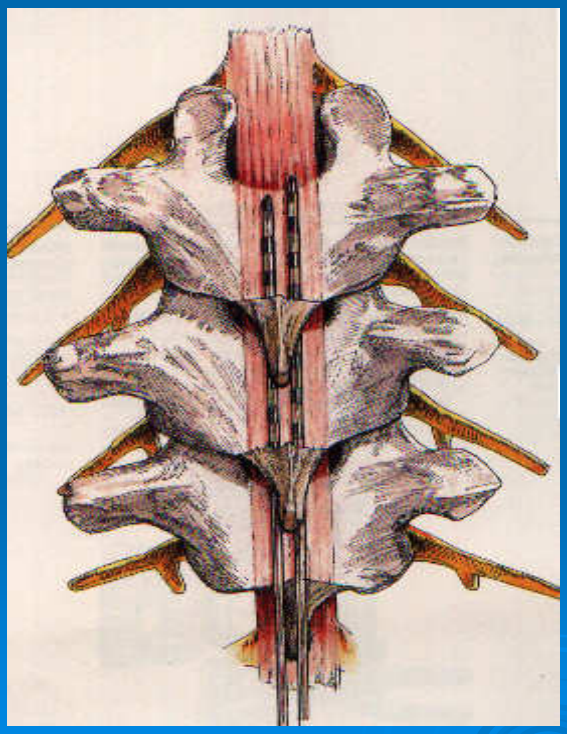
[a] Department of Spinal Surgery, General Hospital of Armed Police Force, Beijing 100039, China
[b] Department of Orthopaedics, 304th Hospital, Beijing, China
[c] Department of Orthopaedics, Sanhe People Hospital, Hebei, China
[d] Department of Orthopaedics, Shengli Hospital, Shandong, China

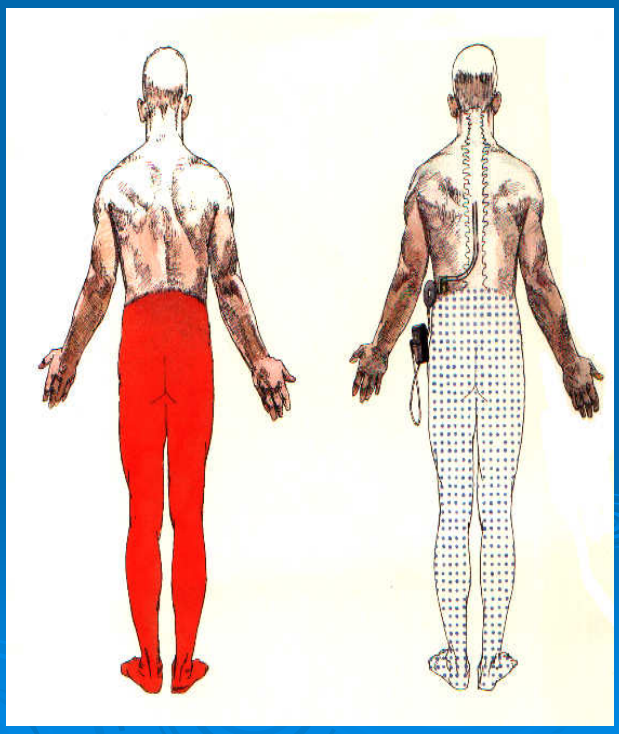
N=72	T0 VAS	T24 VAS	T0 ODI	T24 ODI
Placebo	67	60	49	47
1%MB	72	20*	48	12*

Evidence & Recommendation

- Percutaneous Gray Rami RFN
  - USPSTF Level I or II-1 & recommendation 2A+
- Intradiscal Methylene Blue
  - USPSTF Level I or II-1 & recommendation 2A+
- IDET
  - USPSTF level II-1 & recommendation 2A±
- Dual Electrode intradiscal RF lesioning
  - USPSTF level III, & recommendation 2C±

Neurostimulation - Masking Pain





Effect of SCS in post laminectomy syndrome

- SCS versus repeat lumbosacral spine op[1]
  - SCS successful 9/19 (47%)* p<0.01
  - Re-operation successful 3/26 (11.5%)
- PROCESS study, n=100 post back surgery[2]
  - SCS 24/52 (48%) > 50% pain relief at 2 years
    - 32% device complication 1st 12m
  - Conventional Tx 4/48 (9%) >50% relief
- Evidence – 2A+ based on 2 RCTs

North RB etal 2005, Kumar etal 2007

SCS is Cost Effective

- Consistent reduction in pain, improved QOL and function
- 4 studies, same conclusion
  - SCS is more effective than reoperation & maximal medial therapy
  - Less cost long term, despite high init $
    - Cheaper at 30months

North etal 2005,Bala 2008, Kumar etal 2002, Mekhail etal 2004

NTT – Number To Treat

- North 2005
  - 47% SCS 'successful' for PLS
  - 11.5% reoperation 'successful'
- Kumar 2007
  - 60% SCS 'successful PLS
- NTT SCS ~ 2
  - Treat 2 get one SCS success
- NTT reoperate ~ 8
  - Treat 8 get one success

Therapeutic Intervention Complications

- Haematoma or bleeding
- cellulitis, discitis, deep abscess or meningitis
- dysaesthesias ± pain
- anaesthesia dolorosa,
- intravascular injection & embolic events
- dural puncture
- pneumothorax (thoracic)
- spinal anaesthesia,
- High epidural pressure, retinal, brain damage etc
- drug related allergy or meningeal irritation
- catheter shearing or device breakage
- disc space collapse, disc space collapse
- vertebral endplate osteonecrosis
- spinal instability
- nerve injury
- spinal cord trauma,
- radiation exposure,

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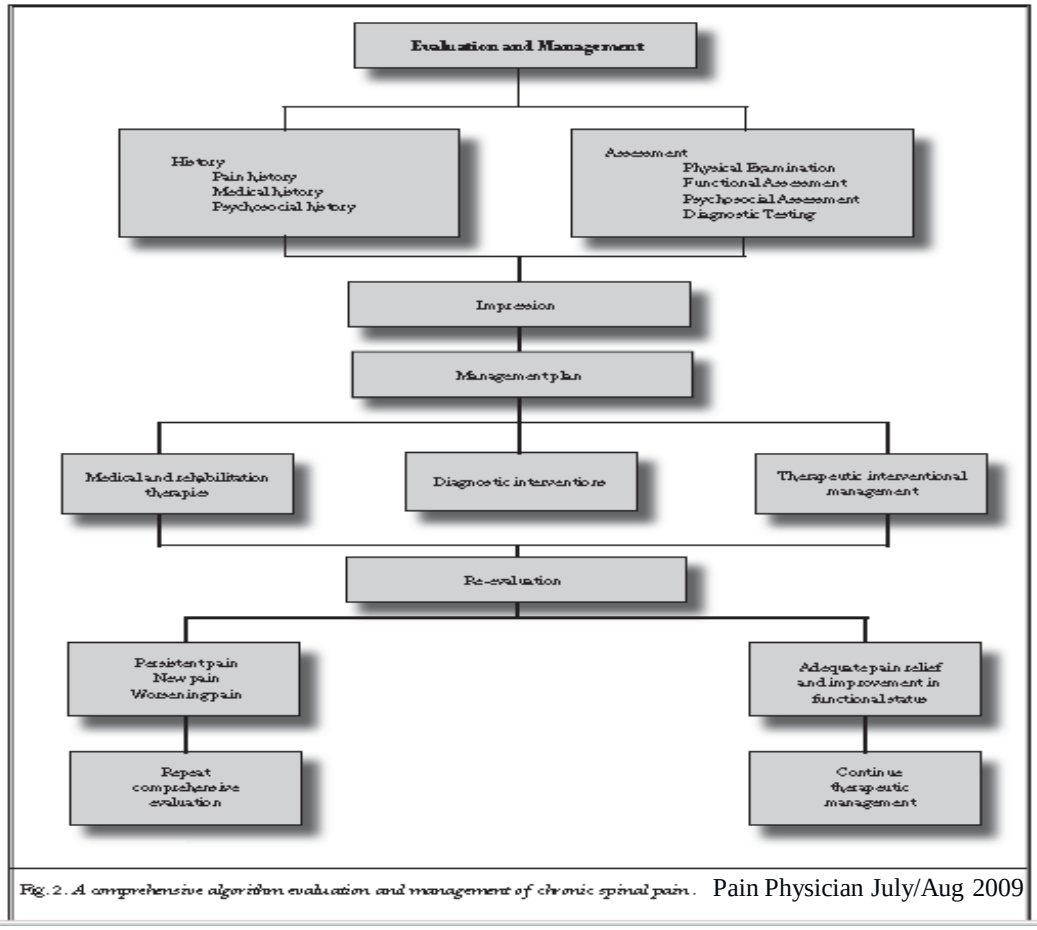

Fig. 2. A comprehensive algorithm evaluation and management of chronic spinal pain. Pain Physician July/Aug 2009

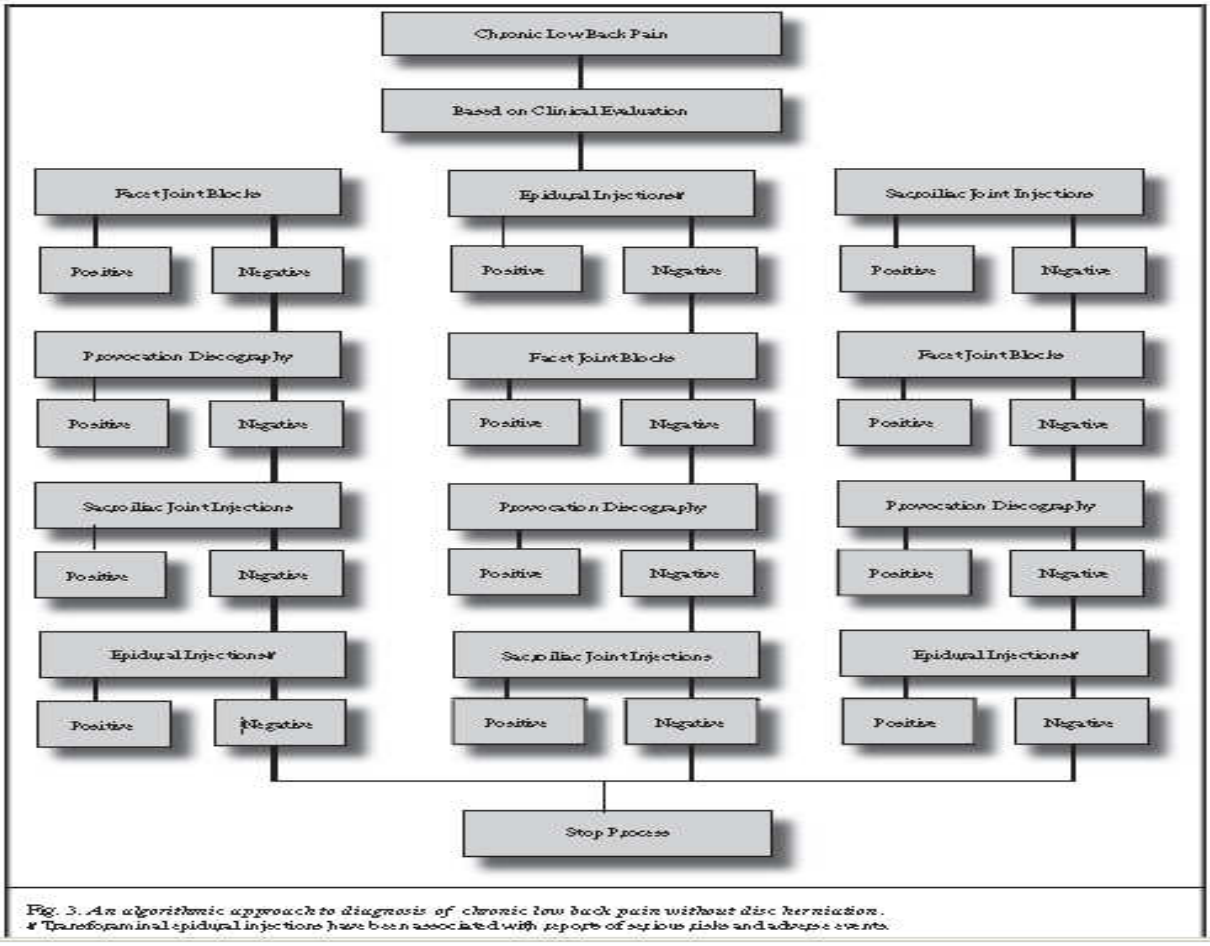

Fig. 3. *An algorithmic approach to diagnosis of chronic low back pain without disc herniation.*
Transforaminal epidural injections have been associated with reports of serious risks and adverse events.

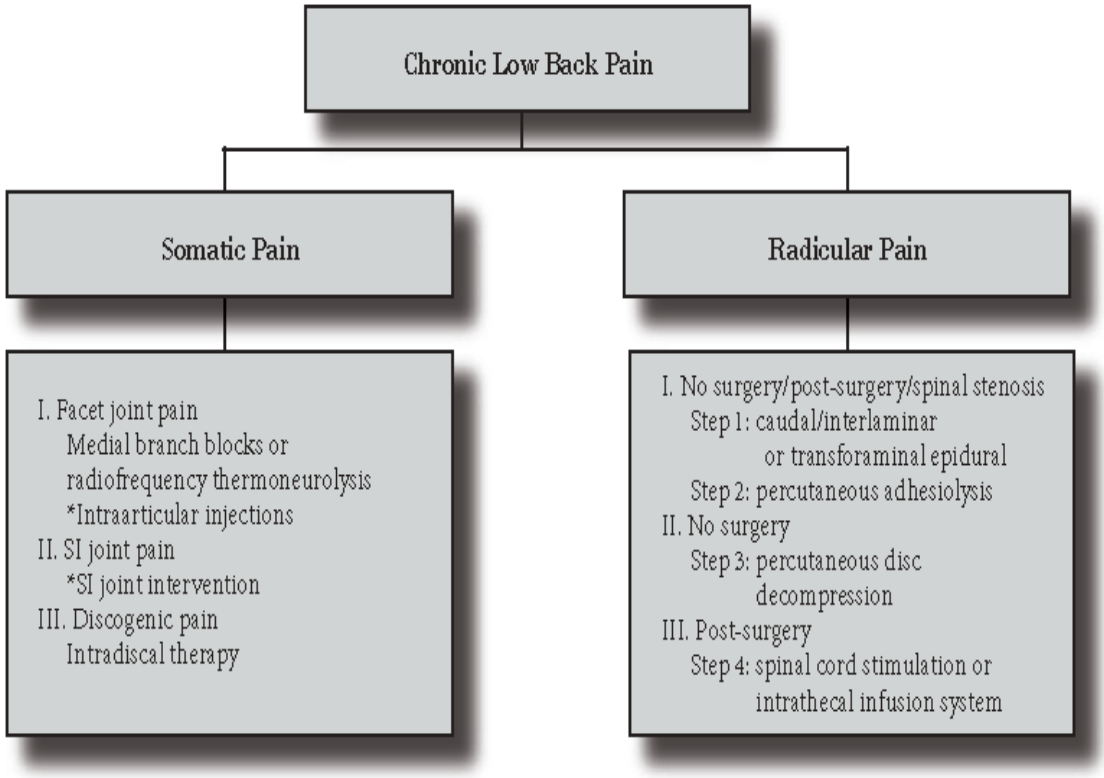

Fig. 4. *A suggested algorithm for therapeutic interventional techniques in management of chronic low back pain.*
* Not based on evidence

Final Remarks

- There is moderate to strong evidence supporting the use of precision diagnostic blocks and therapeutic procedures improve function, reduce suffering and pain.
- Interventional Pain Techniques should be part of the “Pain Management Toolbox”