

# Evidenz von Injektionen in der Schmerztherapie im nationalen und internationalen Vergleich



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28.10.2016 DKOU BERLIN



# Evidenzen national – Literaturrecherche

**Lumbales Facettensyndrom:  
Behandlung des zygoapophysalen  
Schmerzes zwischen Evidenz und  
Anekdote**

Schneider C, Kothbauer KF

*Journal für Neurologie*

*Neurochirurgie und Psychiatrie*

2013; 14 (2), 64-68

- ▶ Einmaliger Block nicht aussagekräftig
- ▶ Für diagnostischen 2maligen MBB besteht Level I bis II-1 Evidenz
- ▶ Mit Steroiden therapeutisch Level II-1 oder II-2

**Tabelle 1:** Qualität der Evidenz. Adaptiert nach United States Preventive Services Task Force (USPSTF) [15].

Level	Definition
I	Evidenz aus multiplen, sauber durchgeführten Studien zur diagnostischen Genauigkeit.
II-1	Evidenz aus mindestens einer sauber durchgeführten Studie suffizienter Größe zur diagnostischen Genauigkeit.
II-2	Evidenz aus mindestens einer kleinen, sauber durchgeführten Studie zur diagnostischen Genauigkeit.
II-3	Evidenz aus unsicheren diagnostischen Studien
III	Expertenmeinungen; deskriptive Studien, Fallberichte

# Leitlinien national?

- ▶ NVL Nationale Versorgungsleitlinie Rückenschmerz
- ▶ Cave: UNSPEZIFISCHER Rückenschmerz

## 7. Invasive Therapie

Für die Anwendung von **perkutanen Verfahren** bei akutem nichtspezifischem Kreuzschmerz liegen keine verlässlichen Daten vor. Für den chronischen Kreuzschmerz gibt es eine Vielzahl von Studien, die in Metaanalysen bzw. systematischen Reviews für die einzelnen Verfahren auch bei spezifischem Kreuzschmerz keine eindeutige Effektivität aufweisen.

Für die Anwendung **operativer Verfahren** bei akutem sowie chronischem nichtspezifischem Kreuzschmerz gibt es keine Studien.

Empfehlungen/Statements	Empfehlungsgrad
<b>7-1</b> Invasive Therapieverfahren sollen bei Patientinnen/Patienten mit nichtspezifischem Kreuzschmerz nicht eingesetzt werden.	↓↓↓



**Programm für Nationale VersorgungsLeitlinien**

Träger:  
Bundesärztekammer  
Kassenärztliche Bundesvereinigung  
Arbeitsgemeinschaft der Wissenschaftlichen  
Medizinischen Fachgesellschaften

Nationale VersorgungsLeitlinie

# Kreuzschmerz

## Langfassung

1. Auflage

Version 5  
November 2010  
Zuletzt geändert: Oktober 2015

# Ist Cochrane hilfreich?

[Cochrane Database Syst Rev.](#) 2008 Jul 16;(3):CD001824. doi: 10.1002/14651858.CD001824.pub3.

## **Injection therapy for subacute and chronic low-back pain.**

[Staal JB<sup>1</sup>](#), [de Bie R](#), [de Vet HC](#), [Hildebrandt J](#), [Nelemans P](#).

- **OBJECTIVE:** To determine if injection therapy is more effective than placebo or other treatments for patients with subacute or chronic low-back pain.
- **AUTHORS' CONCLUSIONS:** There is insufficient evidence to support the use of injection therapy in subacute and chronic low-back pain. However, it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy.

Kritik: keine Untergliederung in radikulär/nicht radikulär oder Facettenschmerz/unspezifischem Kreuzschmerz!

# Ist Cochrane hilfreich? Nein!

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## **Injection therapy for subacute and chronic low-back pain.**

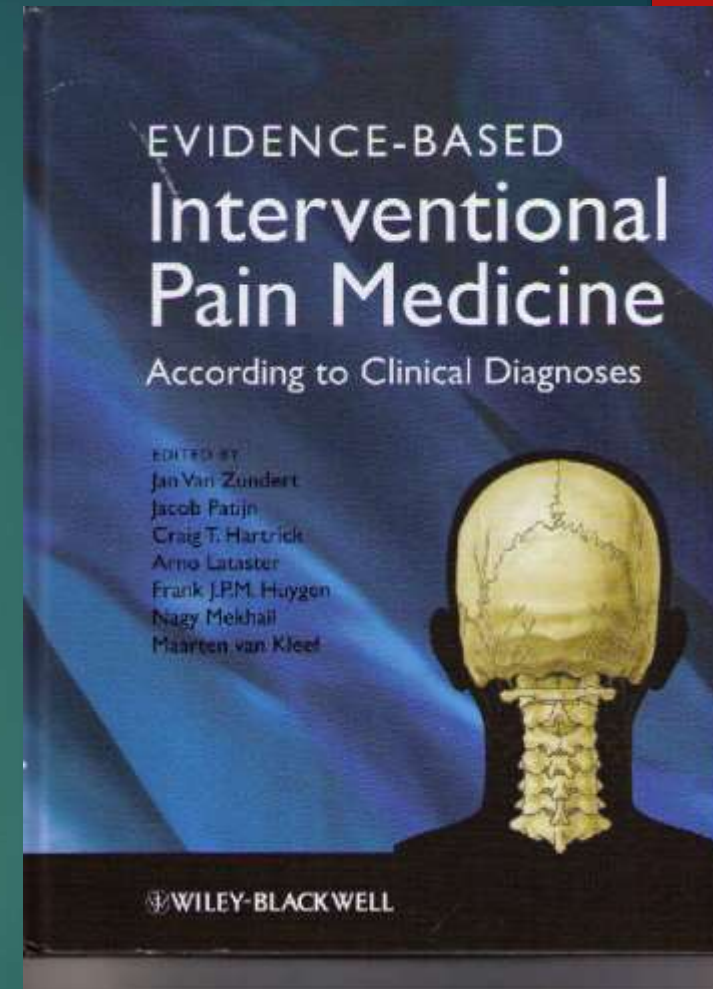
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Kritik: keine Untergliederung in radikulär/nicht radikulär oder Facettenschmerz/unspezifischem Kreuzschmerz!

# Evidenzen international

- ▶ Aus Manual in Niederländisch (2009) entstand mit angloamerikanischen Autoren ein Lehrbuch mit klaren Evidenzangaben, Algorithmen und Verfahrensanweisungen zu interventionellen Methoden (2012), europäische und angloamerikanische Literatur



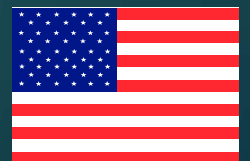
**Table 1.** Summary of Evidence Scores and Implications for Recommendation.

Score	Description	Implication
1 A +	Effectiveness demonstrated in various RCTs of good quality. The benefits clearly outweigh risk and burdens.	Positive recommendation
1 B +	One RCT or more RCTs with methodological weaknesses, demonstrate effectiveness. The benefits clearly outweigh risk and burdens.	
2 B +	One or more RCTs with methodological weaknesses, demonstrate effectiveness. Benefits closely balanced with risk and burdens.	
2 B ±	Multiple RCTs, with methodological weaknesses, yield contradictory results better or worse than the control treatment. Benefits closely balanced with risk and burdens, or uncertainty in the estimates of benefits, risk and burdens.	Considered, preferably study-related
2 C +	Effectiveness only demonstrated in observational studies. Given that there is no conclusive evidence of the effect, benefits closely balanced with risk and burdens.	
0	There is no literature or there are case reports available, but these are insufficient to prove effectiveness and/or safety. These treatments should only be applied in relation to studies.	Only study-related
2 C -	Observational studies indicate no or too short-lived effectiveness. Given that there is no positive clinical effect, risk and burdens outweigh the benefit.	Negative recommendation
2 B -	One or more RCTs with methodological weaknesses, or large observational studies that do not indicate any superiority to the control treatment. Given that there is no positive clinical effect, risk and burdens outweigh the benefit.	

IPM Guidelines

**An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part II: Guidance and Recommendations**

- systematischer Review der American Society of Interventional Pain Physicians (ASIPP)
- 283 Seiten, 2424 Literaturstellen, 51 Autoren
- Modifiziert nach cervical, thoracal, lumbal radikulär (epidural und transforaminal) oder Facettengelenk-bezogen, zusätzlich Interventionen am ISG
- Einteilung nach Cochrane in good, fair, limited (Staal 2008)



# ASIPP Guidelines 2013

## ▶ **Methoden:**

- ▶ Datenquellen: PubMed, EMBASE and manual searches from **1966 to 2012**
- ▶ Assessmentqualität und klinische Relevanzkriterien:
  - ▶ – Cochrane Musculoskeletal Review Group Kriterien für randomisierte Trials bei interventionellen Techniken
  - ▶ – Newcastle-Ottawa Scale Kriterien für fluoroskopische Beobachtungsstudien
- ▶ Evidenzqualität: U.S. Preventive Services Task Force (USPSTF)
- ▶ Outcome-Kriterien:
  - ▶ – **primär: Schmerzreduktion: Kurzzeit (KZ) < 6 Mon., Langzeit (LZ) > 6 Mon.**
  - ▶ – sekundäre: Verbesserung Funktionsstatus, psychologischer Status, Arbeitsfähigkeit, Reduktion Opiatsubstitution

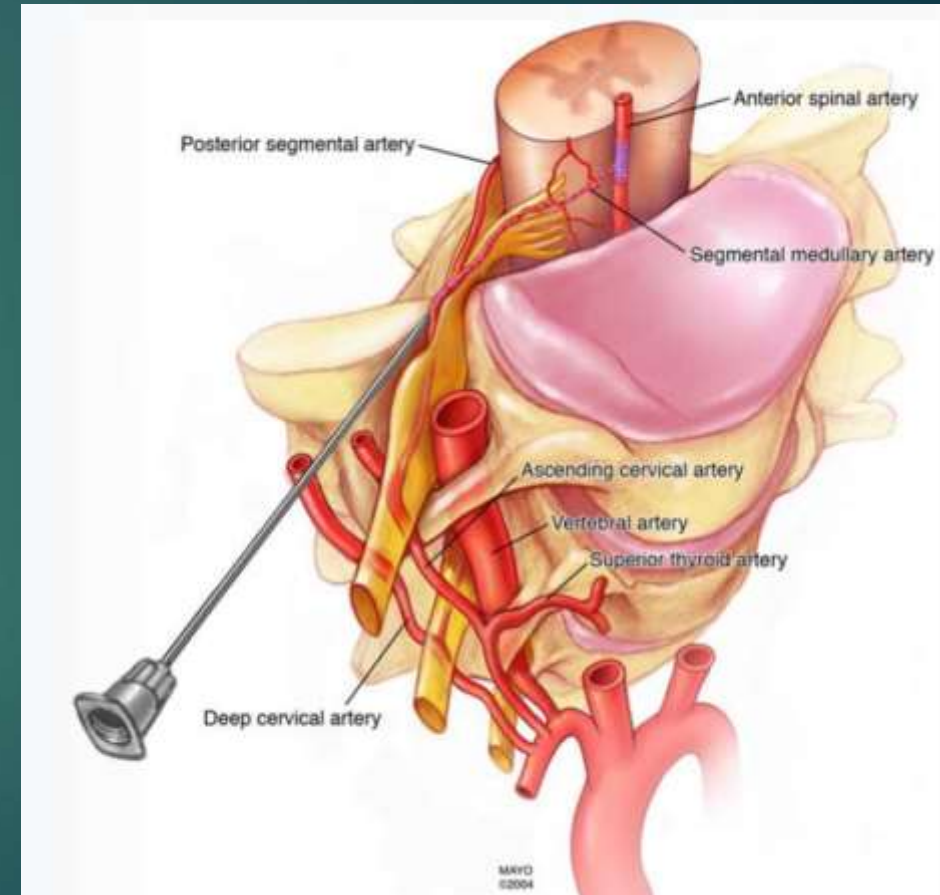
Neuere Studien, soweit vorhanden



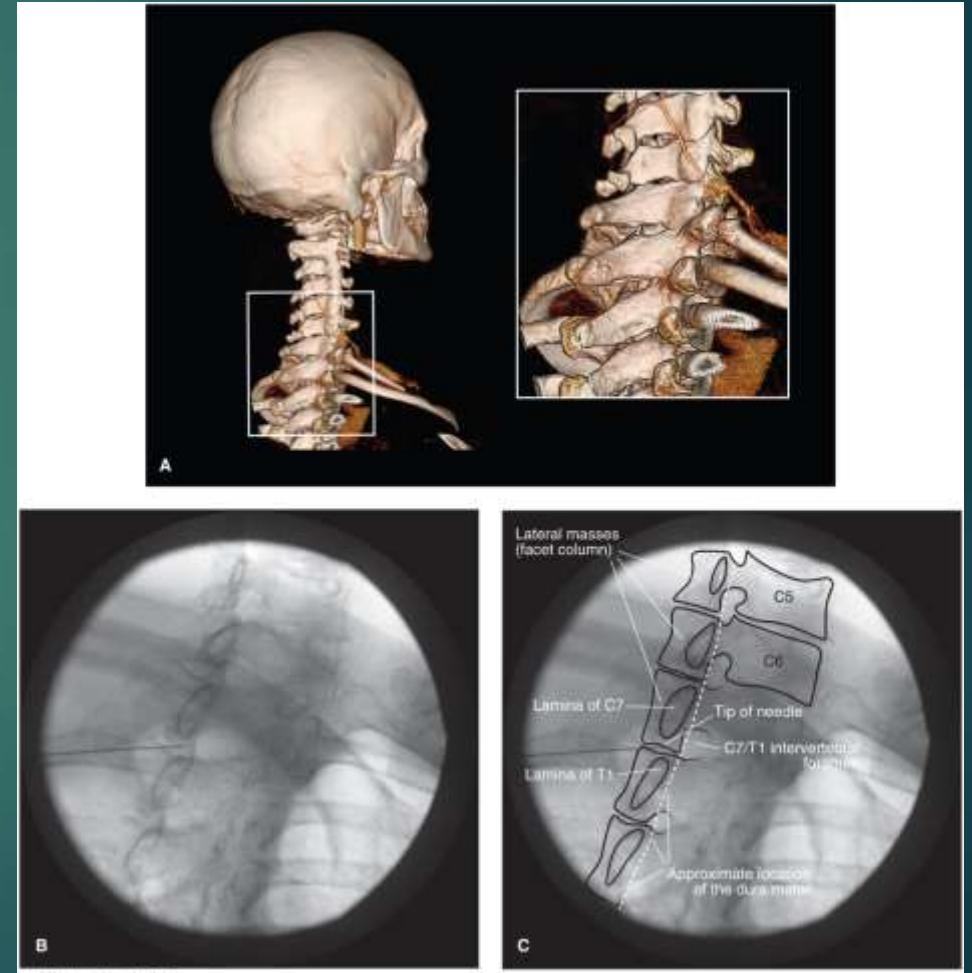
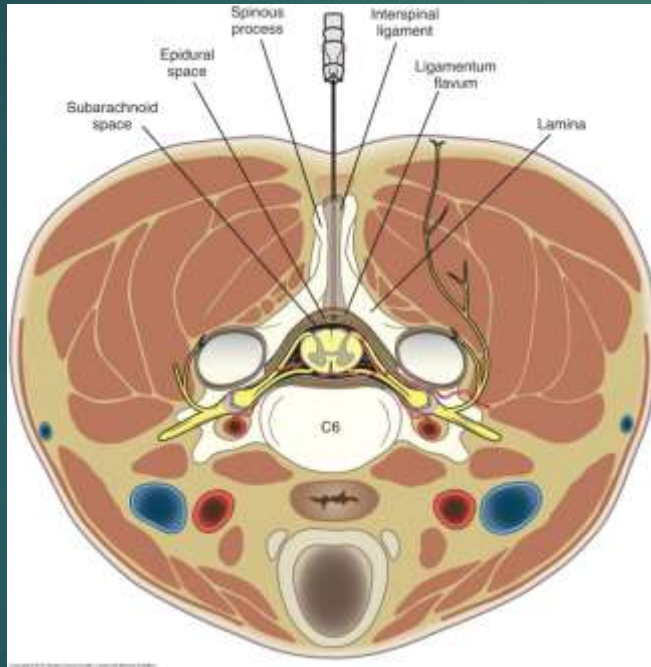
# Cervicale Injektionen epidural transforaminal

- Erhebliche Zunahme von schwerwiegenden Komplikationen 2005-2010 in USA wegen zunehmender Frequenz
- Hemi- und Paraplegien, Todesfälle
- Alle assoziiert mit kristallinem Kortikoid
- Daraus folgend Zurückhaltung gegenüber cervivaler transforaminaler Injektion in einigen Gesellschaften und Empfehlung des Gebrauchs nicht kristallinen Kortikoids

- ▶ **FDA Briefing Document**  
**Anesthetic and Analgesic Drug Products Advisory Committee Meeting**  
Epidural Steroid Injections (ESI) and the Risk of Serious Neurologic Adverse Reactions  
November 24-25, 2014



# Cervicale Injektionen epidural interlaminär



# Cervicale Injektionen

## Evidenz Injektionen IL -TF

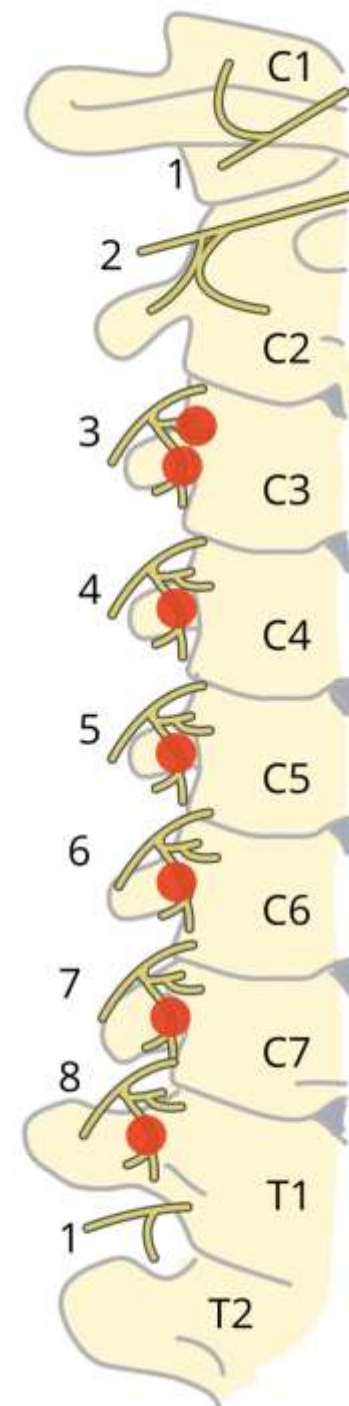
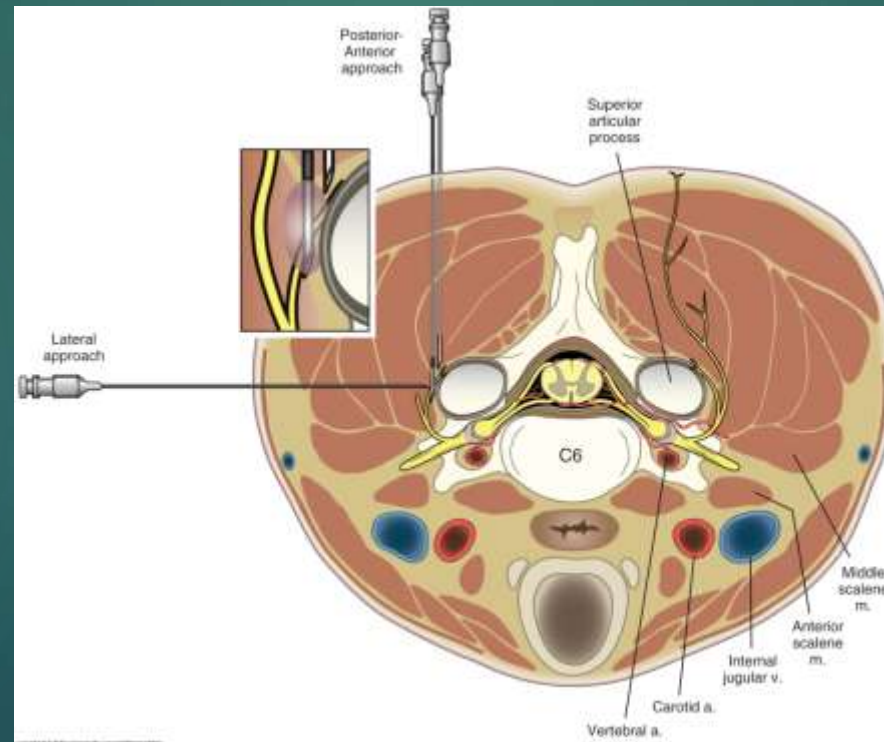
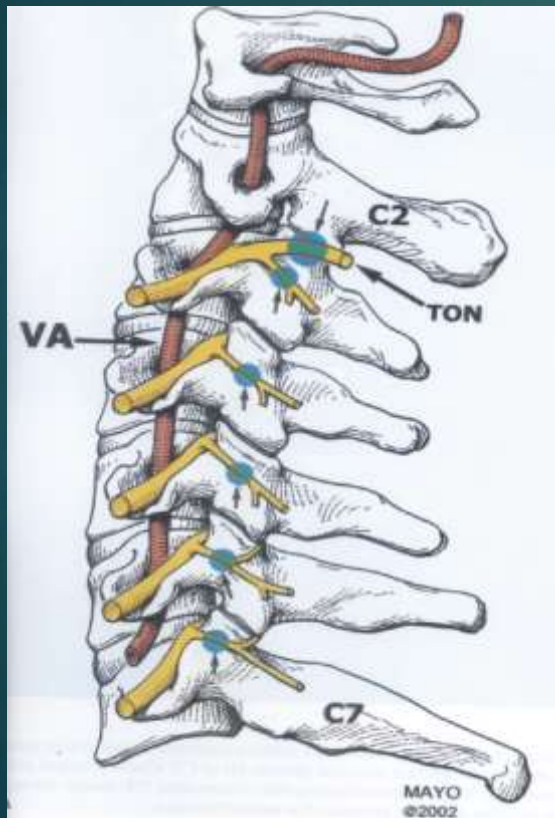


Evidenzen cerv.		
transforaminal	n/a (vor FDA-Briefing Doc.)	2B- neg. recomm.
interlaminär	Good	2 B+ recomm.

### II. CERVICAL SPINE

- The evidence for **cervical provocation discography** is limited; whereas the evidence for **diagnostic cervical facet joint nerve blocks** is good with a criterion standard of 75% or greater relief with controlled diagnostic blocks.
- The evidence is good for **cervical interlaminar epidural injections** for cervical disc herniation or radiculitis, fair for axial or discogenic pain, spinal stenosis, and post cervical surgery syndrome.
- The evidence for therapeutic cervical facet joint interventions is fair for **conventional cervical radiofrequency neurotomy** and **cervical medial branch blocks**, and limited for **cervical intraarticular injections**.

# Cervicale Injektionen Facette medial branch



# Cervicaler radikulärer Schmerz – Evidenz Injektionen MBB/i.a.



Evidenzen cerv.		
MBB	Good (diagn.) Fair (therap.)	2B+ recomm.
i.a.	limited	0 study related.

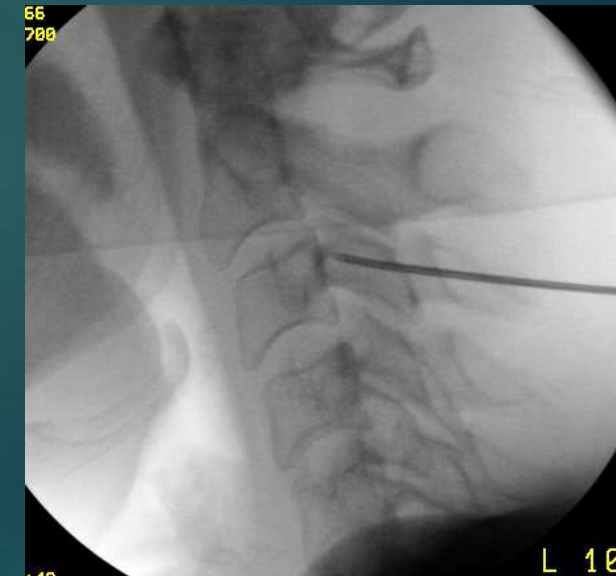
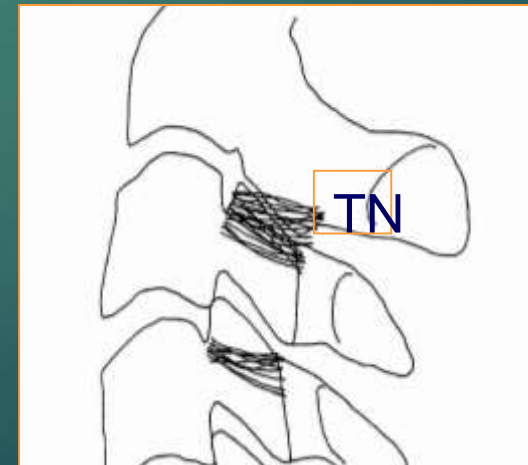
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# Cervicaler nicht-radikulärer Schmerz – Radiofrequenz off topic



Evidenzen cerv.		
MBB	Good (diagn.) Fair (therap.)	2B+ recomm. (therap.!)
i.a.	limited	0 study related.
RF	fair	2C +(to be cons.)



# Exkurs MB RF

Review Article

The Effectiveness and Risks of  
Fluoroscopically-Guided Cervical  
Medial Branch

Thermal Radiofrequency  
Neurotomy: A

Systematic Review with  
Comprehensive

Analysis of the Published Data

Engel et al.

Pain Medicine 2016; 17: 658–669

doi: 10.1111/pme.12928

- Aber hohe Effektivität nur bei doppeltem Block nach Guidelines ISIS
- Keine permanente Heilung
- Hohe return-to-work-rate

## Beschwerdefrei 6 Monate

**Table 1** Reported rates of success (defined as abolition of pain) 6 months after CMBTRFN of patients selected by analgesic responses to comparative medial branch blocks

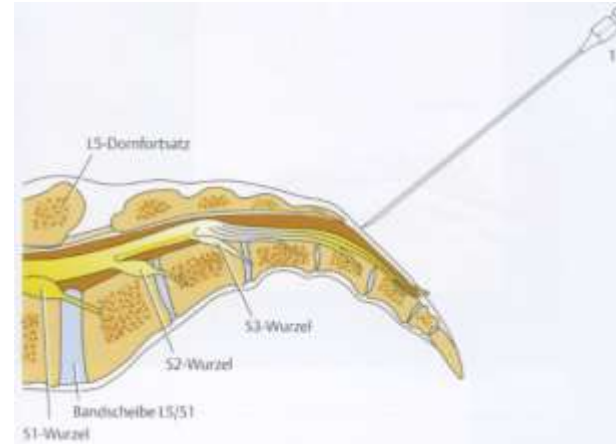
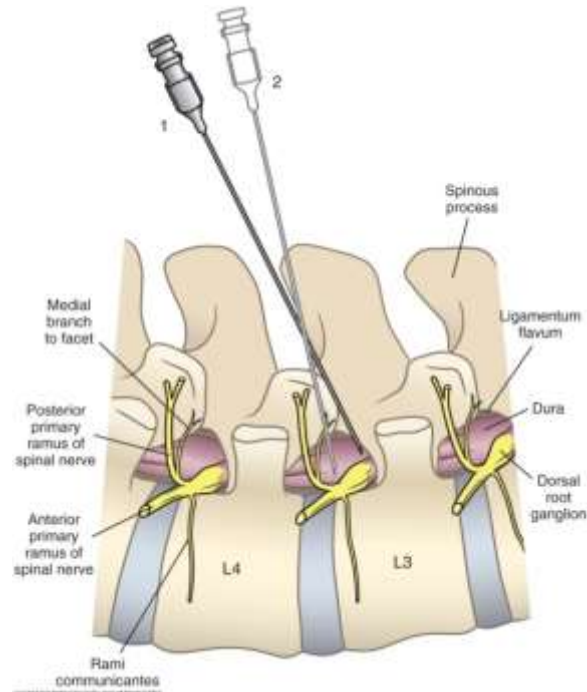
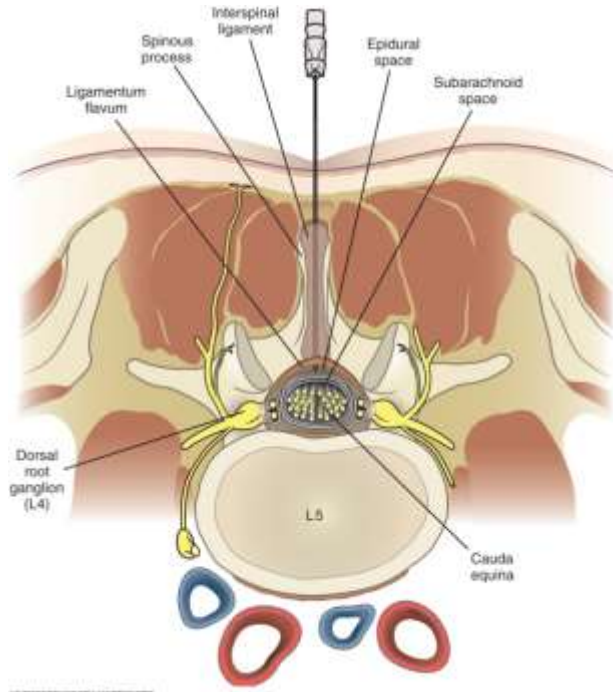
Study	Design	Levels	Pain Completely Relieved	
Lord [1995]	Observational	C5-7	7/10	70% (CI <sub>95</sub> 42–98%)
Lord [1996]	Explanatory	C3-7	7/12	58% (CI <sub>95</sub> 30–86%)
McDonald [1999]	Observational	C3-7	16/28	57% (CI <sub>95</sub> 39–75%)
Govind [2003]	Observational	C2-3	32/49	65% (CI <sub>95</sub> 52–78%)
Barnsley [2005]	Observational	C2-7	16/35	46% (CI <sub>95</sub> 29–63%)
MacVicar [2012]	Observational	C2-7	71/104	68% (CI <sub>95</sub> 59–77%)

## Beschwerdefrei 12 Monate

**Table 2** Reported rates of success (defined as abolition of pain) 12 months after CMBTRFN of patients selected by analgesic responses to comparative medial branch blocks

Study	Design	Levels	Pain Completely Relieved	
Lord [1995]	Observational	C5-7	4/10	40% (CI <sub>95</sub> 10–70%)
McDonald [1999]	Observational	C3-7	10/28	36% (CI <sub>95</sub> 18–54%)
Govind [2003]	Observational	C2-3	10/49	20% (CI <sub>95</sub> 9–31%)
Barnsley [2005]	Observational	C2-7	9/35	26% (CI <sub>95</sub> 11–41%)
MacVicar [2012]	Observational	C2-7	53/104	51% (CI <sub>95</sub> 41–61%)

63% (CI<sub>95</sub> 57–69%) of patients being pain free at 6 months and  
38% (CI<sub>95</sub> 32–44%) free at 1 year



Lumbaler epidurale Injektionen  
 Zugangswege caudal, interlaminär, transforaminal

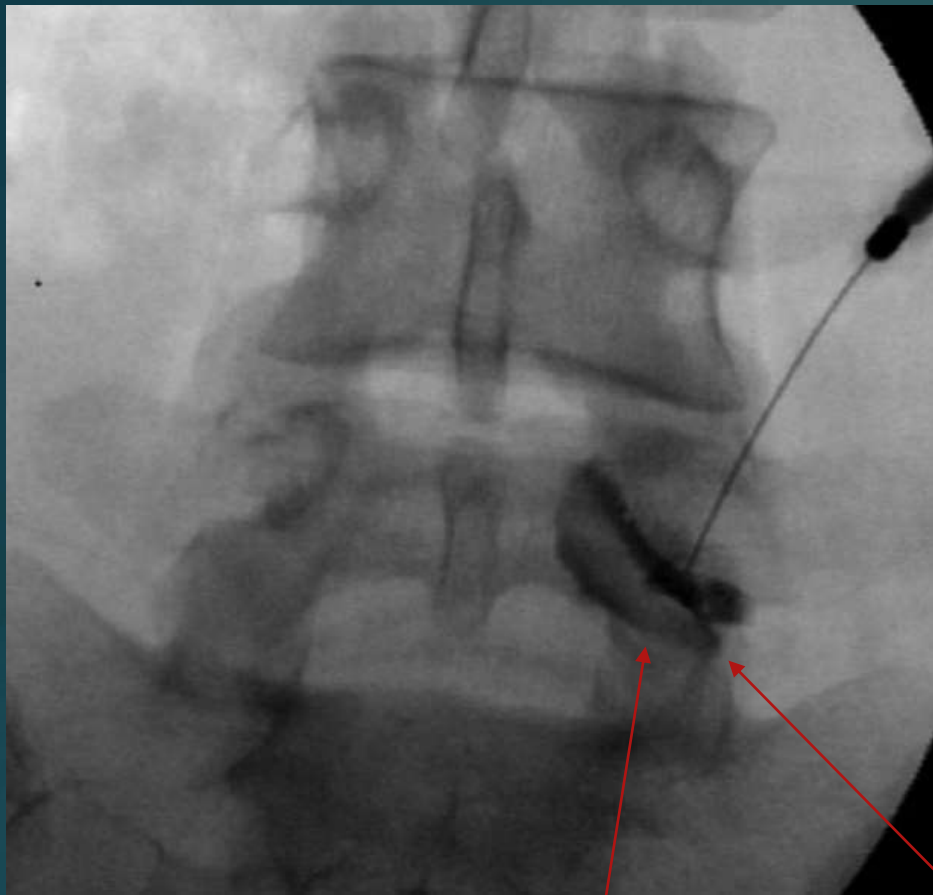


# Lumbale epidurale Injektionen -

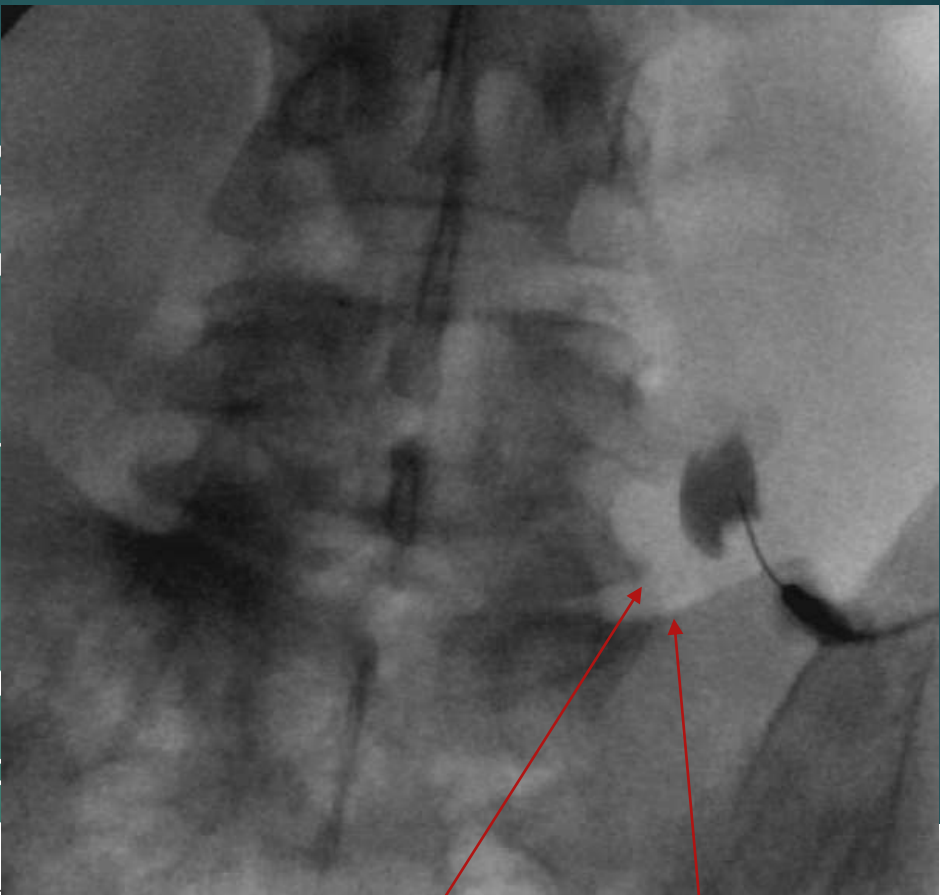


Evidenzen lumb.		
transforaminal	Good	2B+ recomm.
interlaminär	Good	2B +/- t.b. consid.
sacral	Good	n/a

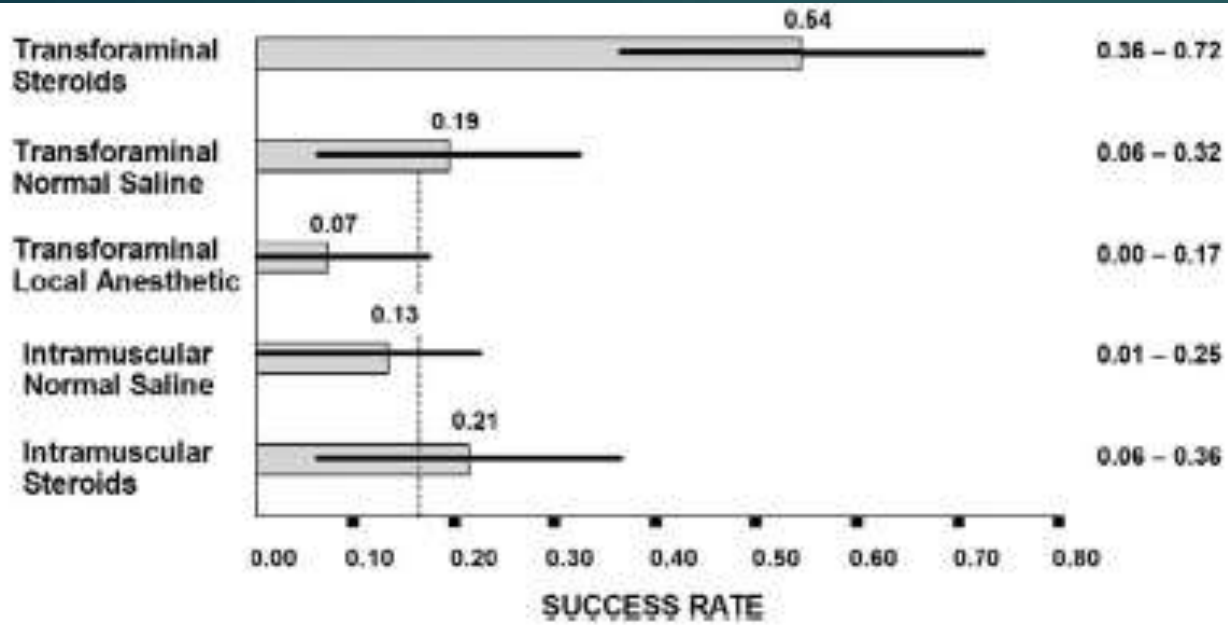
The evidence is good in managing disc herniation or radiculitis for **caudal, interlaminar, and transforaminal epidural injections**; fair for axial or discogenic pain without disc herniation, radiculitis or facet joint pain with **caudal, and interlaminar epidural injections**, and limited for **transforaminal epidural injections**; fair for spinal stenosis with **caudal, interlaminar, and transforaminal epidural injections**; and fair for post surgery syndrome with **caudal epidural injections** and limited with **transforaminal epidural injections**.



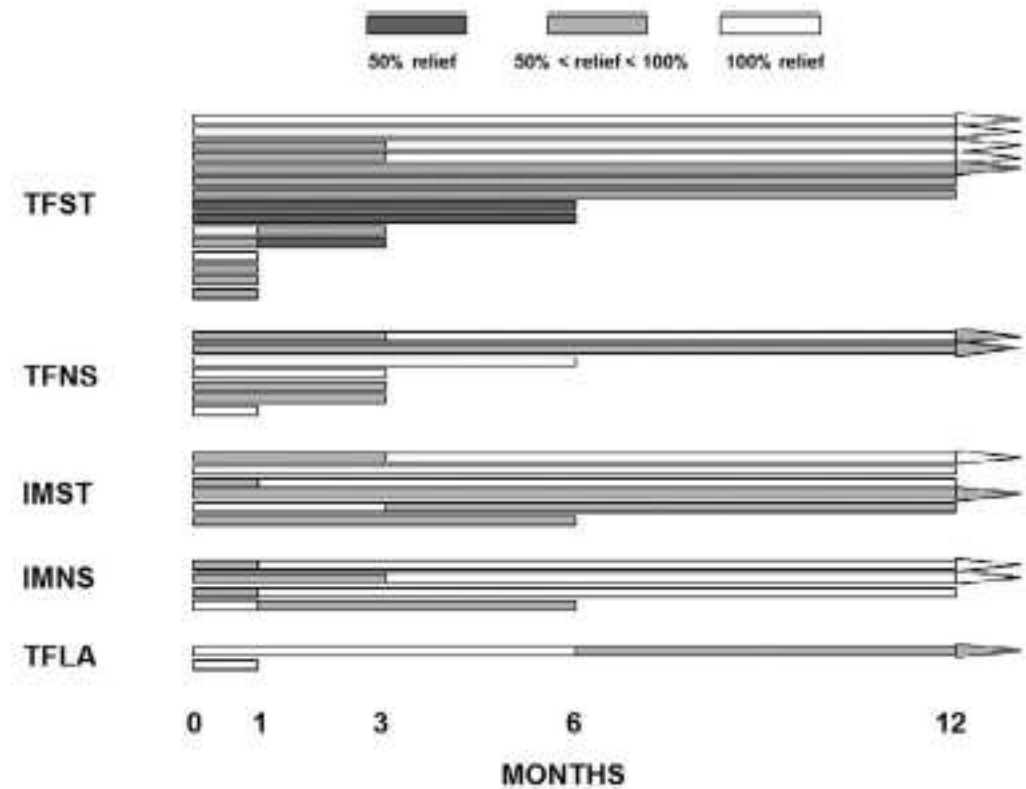
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Feature	TFST	TFNS	TFLA	IMST	IMNS	<i>P</i>
Male	17	19	17	15	21	0.567
Female	11	18	10	13	9	
Age						
Median	49	44	43	49	46	
IQR	39–61	33–54	35–66	38–62	37–64	
Acute	19	21	13	12	15	0.379
Chronic	9	16	14	16	15	



Dauer und prozentuale Verbesserung nach erfolgreicher Injektion

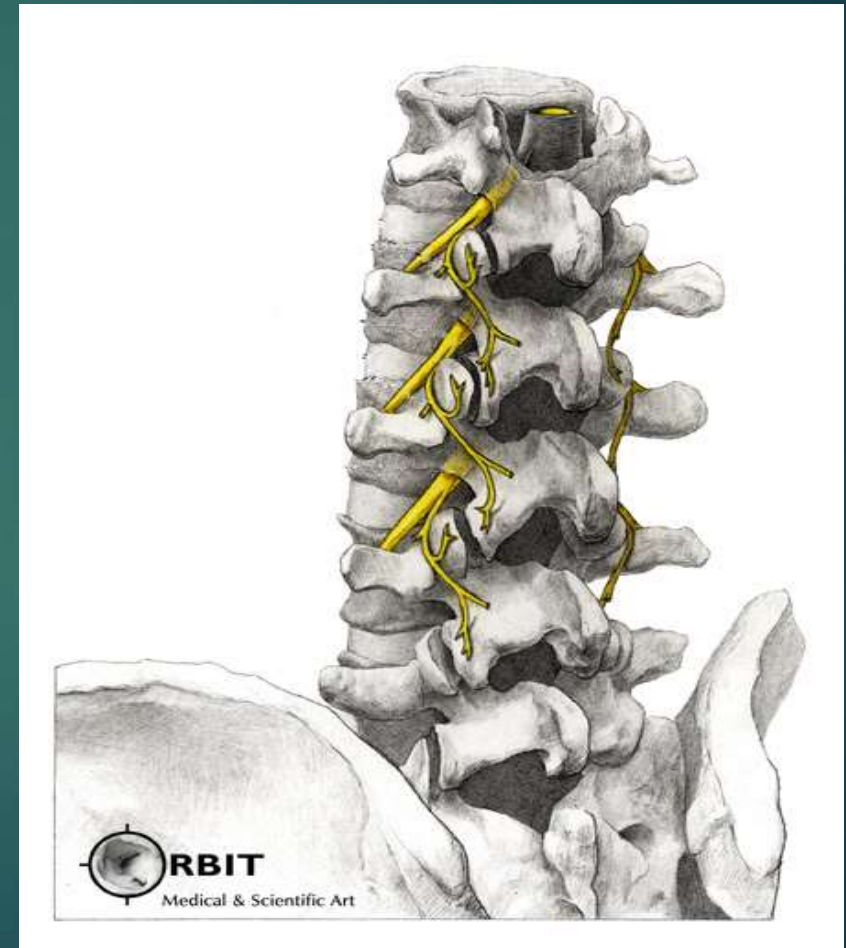


# Lumbale Facetteninterventionen – MBB – i.a. – RF MBB



Evidenzen lumb.		
MBB	Good	n/a ★
i.a.	limited	2B +/- t.b. consid.
RF MBB	Good	1 B+ recomm.

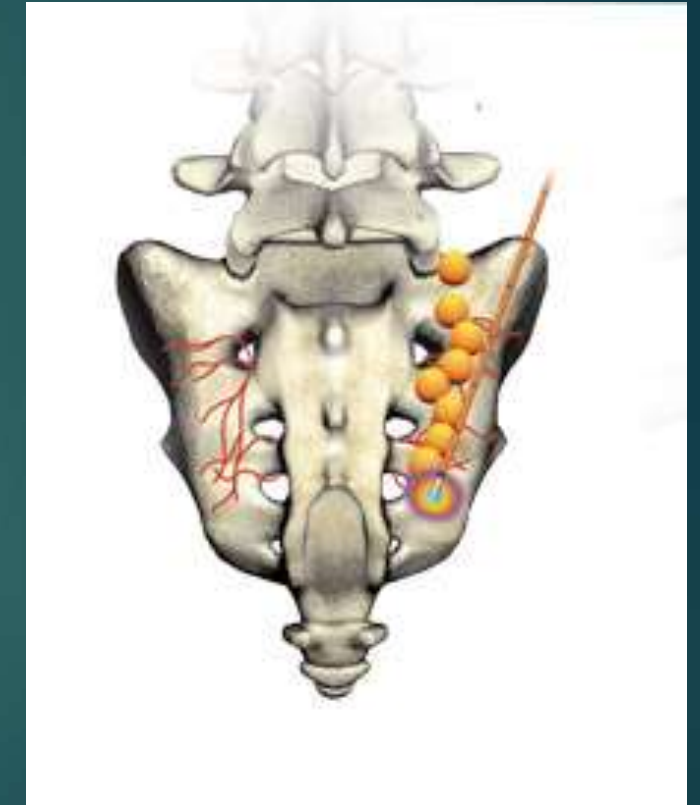
★ Keine Beurteilung, da keine  
therapeutische Indikation, nur  
diagnostisch



# Interventionen am ISG



Evidenzen ISG		
i.a. Injektion	Good	1B+ recomm.
RF Rami dorsales	limited	2C + t.b. consid.
RF watercooled	Good	2B+ recomm.



*Appendix Table 6. Level of Evidence and Summary Grades for Noninvasive Interventions in Patients with Chronic or Subacute Low Back Pain\**

Intervention	Level of Evidence	Net Benefit	Grade
Acetaminophen	Fair	Small (no significant harms)	B
Acupuncture	Fair (some inconsistency vs. sham acupuncture)	Moderate	B
Psychological therapy (cognitive-behavioral therapy or progressive relaxation)	Good for cognitive-behavioral, fair for progressive relaxation	Moderate (cognitive-behavioral) to substantial (progressive relaxation)	B
Exercise therapy	Good	Moderate	B
Interdisciplinary rehabilitation	Good	Moderate	B
Nonsteroidal anti-inflammatory drugs	Good	Moderate	B
Spinal manipulation	Good	Moderate	B
Opioids and tramadol	Fair (primarily indirect evidence from trials of patients with other pain conditions)	Moderate	B
Brief individualized educational interventions	Fair	Moderate	B
Benzodiazepines	Fair	Moderate	B
Massage	Fair	Moderate	B
Yoga	Fair (for Vinyoga) to poor (for Hatha yoga)	Moderate (Vinyoga), unable to estimate (Hatha yoga)	B (Vinyoga)
Tricyclic antidepressants	Good	Small to moderate	B/C
Antiepileptic drugs	Fair (for gabapentin) to poor (for topiramate)	Small (gabapentin in patients with radiculopathy), unable to estimate (topiramate)	C (gabapentin), I (topiramate)
Back schools	Fair (some inconsistency)	Small	C
Firm mattresses	Fair	No benefit or harm	D
Traction	Fair	No benefit (continuous or intermittent traction), small to moderate (autotraction for sciatica)	D (continuous or intermittent traction), C (autotraction for sciatica)
Aspirin	Poor	Unable to estimate	I
Biofeedback	Poor	Unable to estimate	I
Interferential therapy	Poor	Unable to estimate	I
Low-level laser	Poor	Unable to estimate	I
Lumbar supports	Poor	Unable to estimate	I
Shortwave diathermy	Poor	Unable to estimate	I
Skeletal muscle relaxants	Poor	Unable to estimate	I
Transcutaneous electrical nerve stimulation	Poor	Unable to estimate	I
Ultrasonography	Poor	Unable to estimate	I

**CLINICAL GUIDELINE FOR THE EVALUATION AND MANAGEMENT OF LOW BACK PAIN** Evidence Review  
 American Pain Society 2007

S 193ff von 492

# Zusammenfassung der Evidenzen



Von 14 Interventionen 9 (ASIPP; USA) bzw. 7 (NL) gut bzw. Empfehlung, 5 limited oder fair (USA) bzw. zu erwägen. Cervical transforaminal als einzige Methode ausdrücklich nicht empfohlen! (NL)

Evidenzen cerv.		
transforaminal	n/a (vor FDA-Briefing Doc.)	2B- neg. <b>recomm.</b>
interlaminär	Good	2 B+ <b>recomm.</b>

Evidenzen cerv.		
MBB	Good (diagn.) Fair (therap.)	2B+ <b>recomm.</b> (therap.!)
i.a.	limited	0 <b>study related.</b>
RF	fair	2C + (to be cons.)

Evidenzen lumb.		
transforaminal	Good	2B+ <b>recomm.</b>
interlaminär	Good	2B +/- t.b. <b>consid.</b>
sacral	Good	n/a

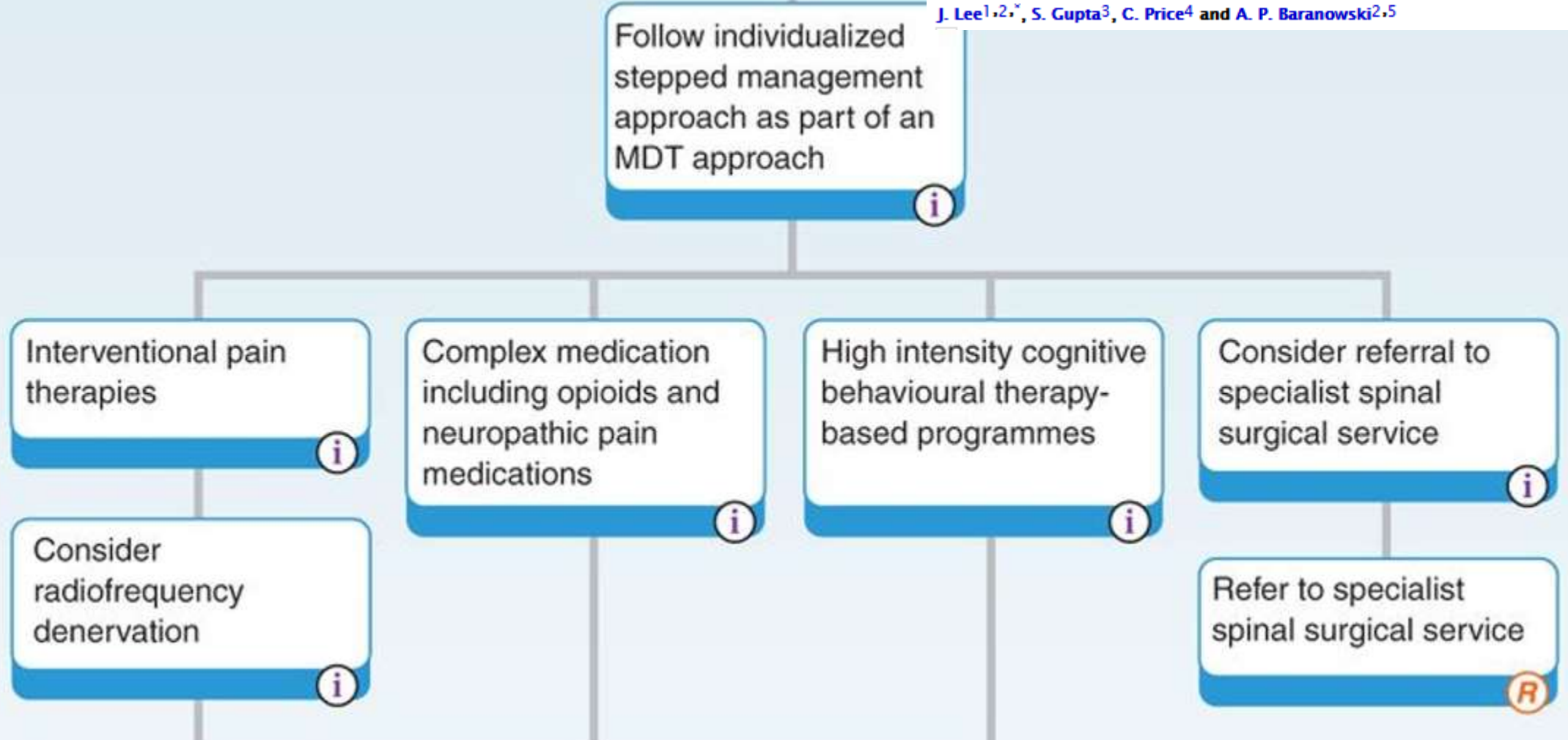
Evidenzen lumb.		
MBB	Good	n/a
i.a.	limited	2B +/- t.b. <b>consid.</b>
RF MBB	Good	1 B+ <b>recomm.</b>

Evidenzen ISG		
i.a. Injektion	Good	1B+ <b>recomm.</b>
RF Rami dorsales	limited	2C + t.b. <b>consid.</b>
RF watercooled	Good	2B+ <b>recomm.</b>

# Interventionen im multimodalen Ansatz im UK

## Low back and radicular pain: a pathway for care developed by the British Pain Society

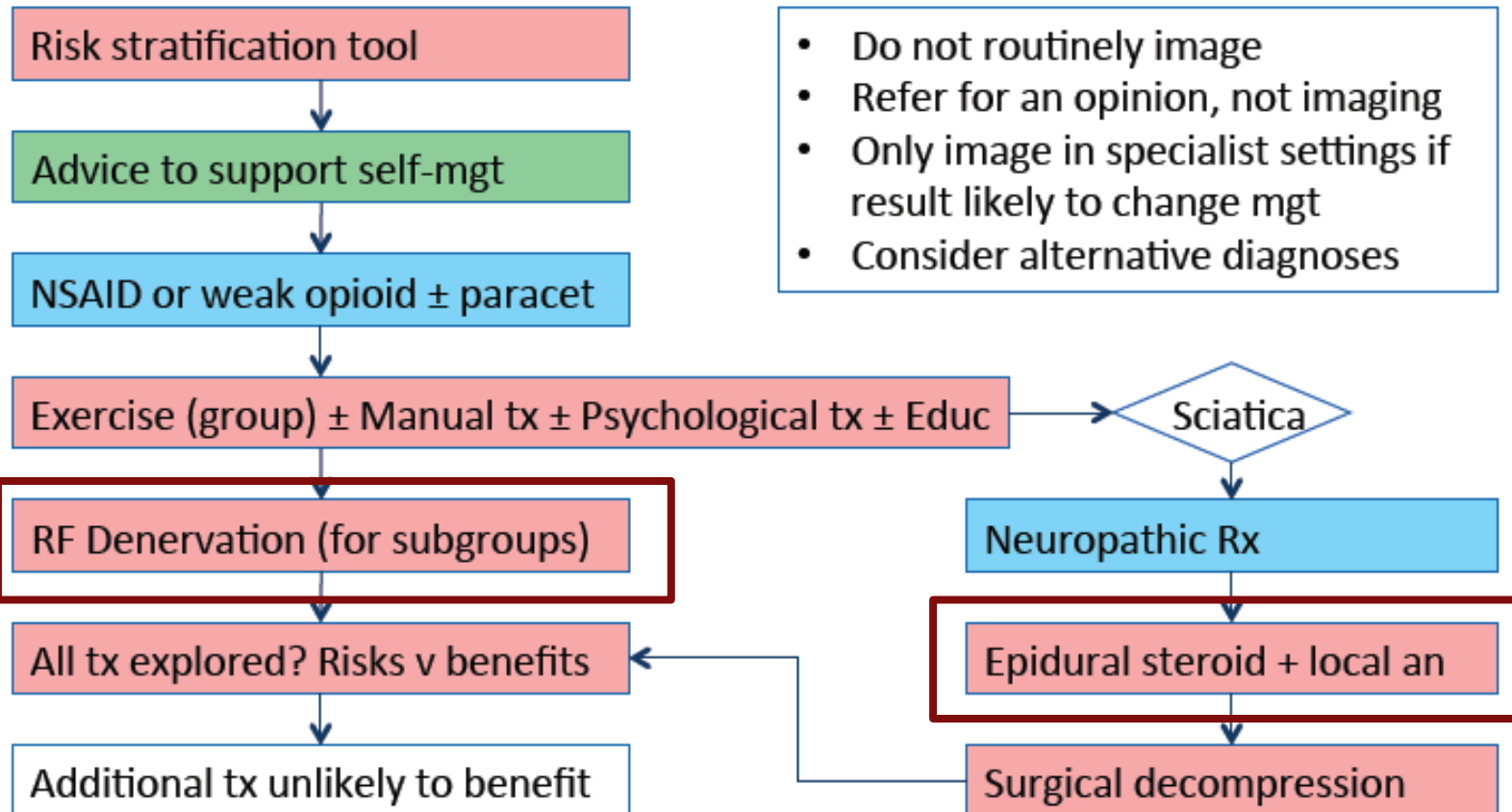
J. Lee<sup>1,2,\*</sup>, S. Gupta<sup>3</sup>, C. Price<sup>4</sup> and A. P. Baranowski<sup>2,5</sup>





# Treatment algorithm for non-specific LBP and sciatica

NICE



## Gesundheitspolitische Situation:

-in D Beschluss 290 zum 1.4.2013 = massiver Rückgang der Interventionen, besonders RF, neg. Bewertung NVL

-In NL derzeit aktuell Streichung der RF aus dem Leistungskatalog aufgrund einer unveröffentlichten Studie (3 mal zu Veröffentlichung abgelehnt!)

-in BE Wiederaufnahme der RF auch ISG wegen guter Studienlage

-in USA (Washington State) Wiederaufnahme der RF In Leistungskatalog (Arbeit SIS) nach 4 Jahren Nichtvergütung

-in UK Aufnahme RF und epidurale transforaminale Steroidinjektion in nationale Guidelines