Organisation invasiver Behandlungsmethoden (epidurale/ intrathekale Medikamentenapplikation

Univ. Prof. Dr. Rudolf Likar, MSc

Vorstand der Abteilung für Anästhesiologie, allgemeine Intensivmedizin, Notfallmedizin, interdisziplinäre Schmerztherapie und Palliativmedizin
Klinikum Klagenfurt am Wörthersee
LKH Wolfsberg

Lehrabteilung der Medizinischen Universität Graz, Innsbruck, Wien

Lehrstuhl für Palliativmedizin SFU
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LKH Klagenfurt-schmerzchirurgische Eingriffe

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- **Orthopädie**
- **Radiologie**
- **Physikalische Medizin, klinische Psychologie, Onkologie, Chirurgie, Strahlentherapie, Nuklearmedizin**

Ambulanzzeiten: **MO – FR 07.00 – 14.00 Uhr**

Tel. ++43 463 538 23720
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McQuay/Moore: Effekt epiduraler Applikation von Corticoiden Metaanalyse nach EBM-Kriterien

- **Erneute Analyse der Daten der Metaanalyse von Watts/Silagy (1995) und der Studie von Carrete et al (1995)**

Studien	% SR	SR-Dauer	Steroide (Pat.)	Placebo (Pat.)	Stat. Sign. Studien	NNT	Gesamt-Signifikanz
11	>75	1-60 Tage	319	345	3	7.3 (4.7 -16/ 95% CI)	1.5 (1.2-1.9/ 95% CI)
6	>50	12 Wo – 1 Jahr	315	395	1	13 (66-314/ 95% CI)	1.3 (1.1-1.5/ 95% CI)

McQuay HJ, Moore A: An evidence-based resource for pain (1998)

Summary:

The consensus of this review evidences that caudal epidural steroid injection outclasses the interlaminar epidural injection but is equal to the transforaminal epidural injection.

Level 1 Evidence for caudal epidural steroid injection at disk herniation or radiculitis or disk conditioned pain, without disk herniation or radiculitis.

Evidence Level 2 a or 2 b for epidural caudal injections in case of post laminectomy syndromes and lumbar spinal stenosis.

High recommendation for 1 b or 1 c for caudal epidural steroid injections in case of pain, which are secondary caused by disk herniation or radiculitis or disk conditioned pain without herniation or radiculitis or post laminectomy syndrome or spinal stenosis.

Sukdeb Datta, MD, [a] Ramsin M. Benyamin, MD, [b] Laxmaiah Manchikanti, MD[c], Evidence-based practice of lumbar epidural injections. Techniques in Regional Anesthesia and Pain Management (2009) 13, 281-287

Epidurale Applikation von Corticoiden Klinische Studien - Probleme

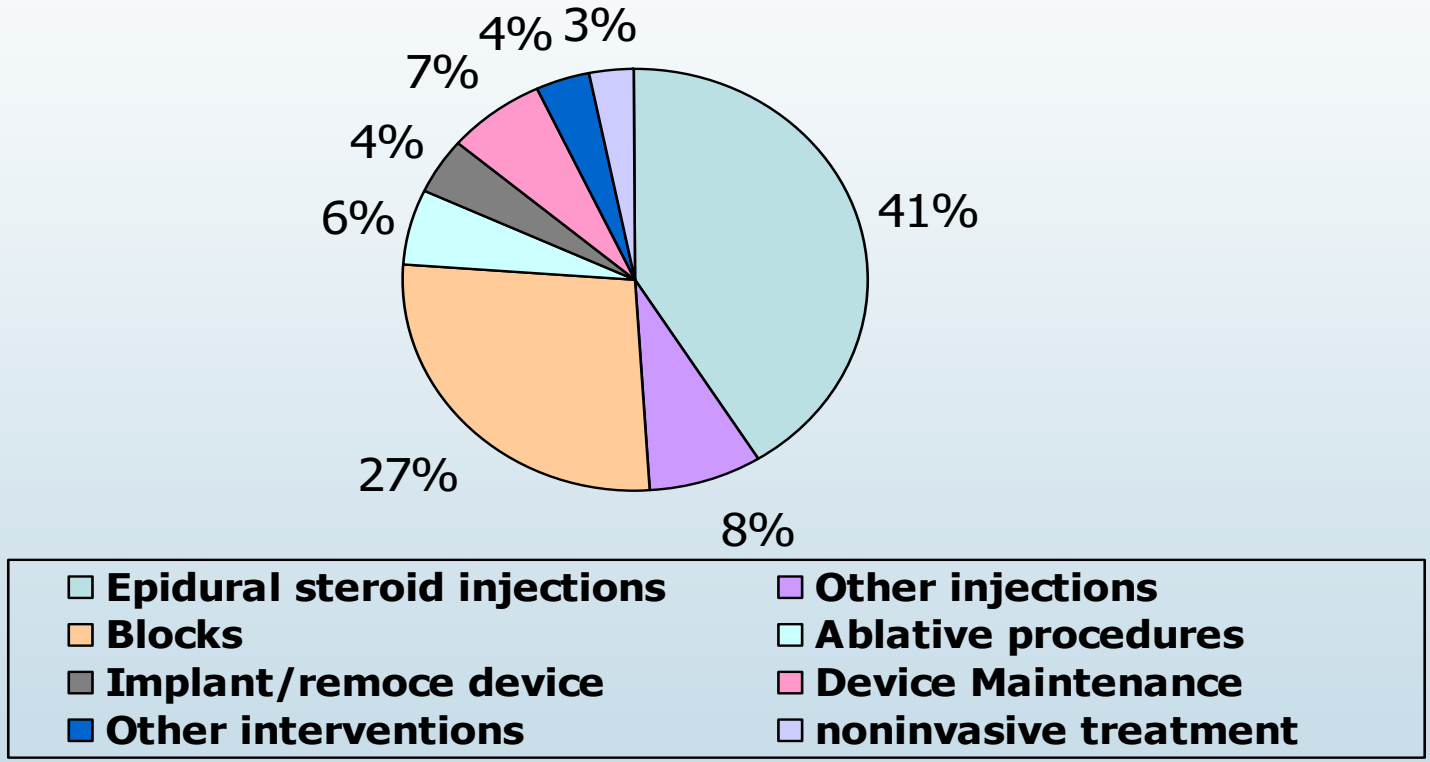
- **Studien nicht vergleichbar (Injektionsvolumen, Ort der Injektion, lösliches oder kristallines Präparat)**
- **Meist retrospektive Studien**
- **Meist geringe Patientenzahl**
- **Erhebliche Unterschiede in den Einschlußkriterien**
- **Keine Standardisierung von Diagnosen und diagnostischen Tests**
- **Keine einheitlichen Daten**
- **keine adäquaten Kontrollgruppen**
- **unzureichendes Follow-Up**
- **unzureichendes Outcome- Assessment**

Commonly used corticosteroid preparations for spinal injections

Corticosteroid	Brand Name	Description	Common Dose[a]
Methylprednisolone acetate	Depo-Medrol	Particles densely packed; smaller than red blood cells; not prone to aggregation; contains benzyl alcohol (potentially neurotoxic); may not completely dissolve	20–80 mg
Triamcinolone diacetate	Aristocort	Particles vary greatly in size; form aggregations	40–120 mg
Triamcinolone acetonide	Kenalog	Particles vary greatly in size; form aggregations	40–80 mg (ESI) 20–40 mg (other sites)
Triamcinolone hexacetonide	Aristospan	Similar to triamcinolone acetonide, with less intense but more sustained action	20–40 mg
Betamethasone acetate/ phosphate mixture	Celestone Soluspan	Particles vary greatly in size; form aggregations but is soluble	12–18 mg (ESI)
Dexamethasone	Decadron	Particles 5–10 times smaller than red blood cells; can aggregate	variable

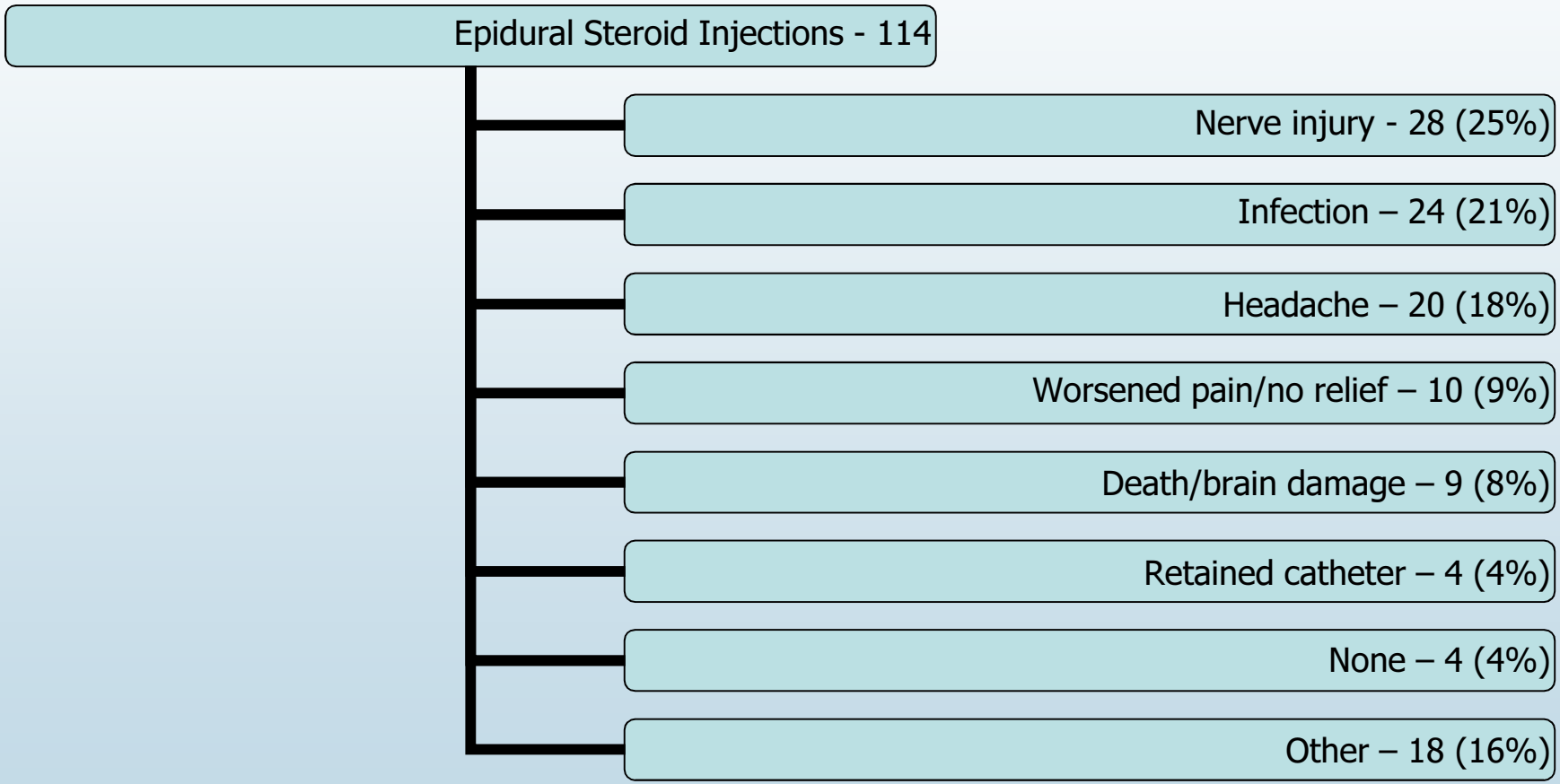
Manray K.S. Heran, MD, FRCPC, Andrew D. Smith, Gerald M. Legiehn, Spinal Injection Procedures: A Review of Concepts, Controversies, and Complications; Radiol Clin N Am 46 (2008) 487-514

Distribution of Chronic Pain Management Claims based on events occurring between 1970 and 1999 and collected through December of 2000 by Closed Claims Project.



Seth A. Waldman, MD, Abiona Berkely, MD, JD; Medicolegal aspects of epidural steroid injections; Techniques in Regional Anesthesia and Pain Management (2009) 13, 272-280

Percentage occurrence of alleged injuries stemming from ESIs based on events occurring between 1970 and 1999 and collected through December of 2000 by The Closed Claims Project.

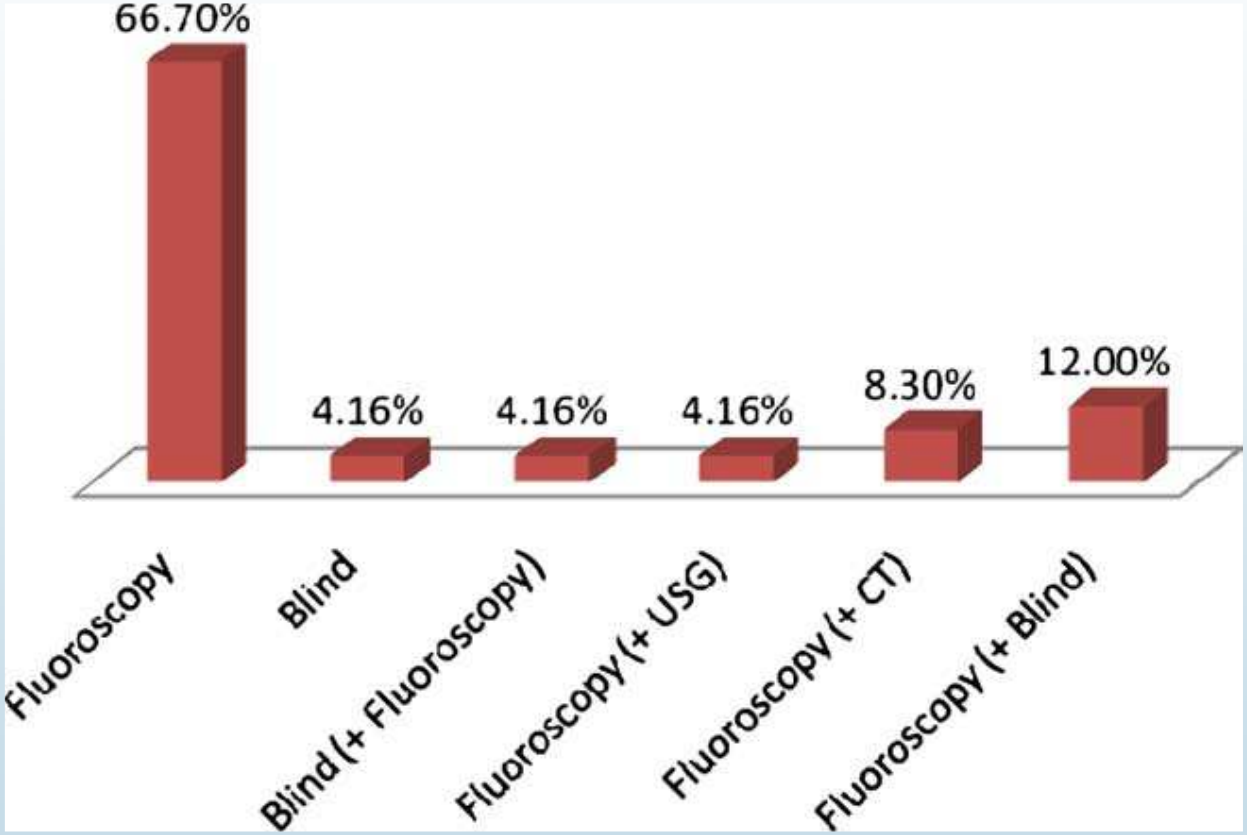


Seth A. Waldman, MD, Abiona Berkely, MD, JD; Medicolegal aspects of epidural steroid injections; Techniques in Regional Anesthesia and Pain Management (2009) 13, 272-280

Blind interlaminar ESI as practiced at many centers.

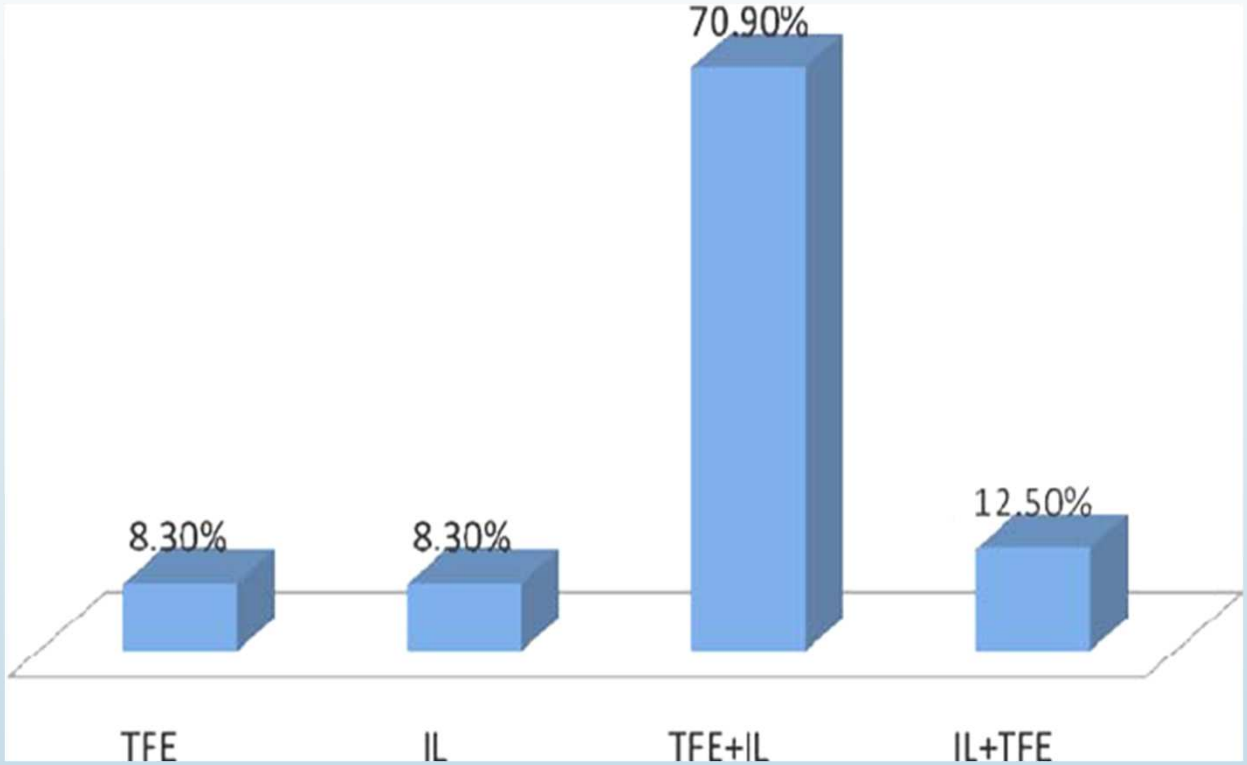
Preeti P. Doshi, MD, DA (UK), FRCA (II), FIPP, Jalpa D. Makwana, MBBS, DA; Practice of epidural steroid injections outside of the United States; Techniques in Regional Anesthesia and Pain Management (2009) 13, 258-265

Image guidance.



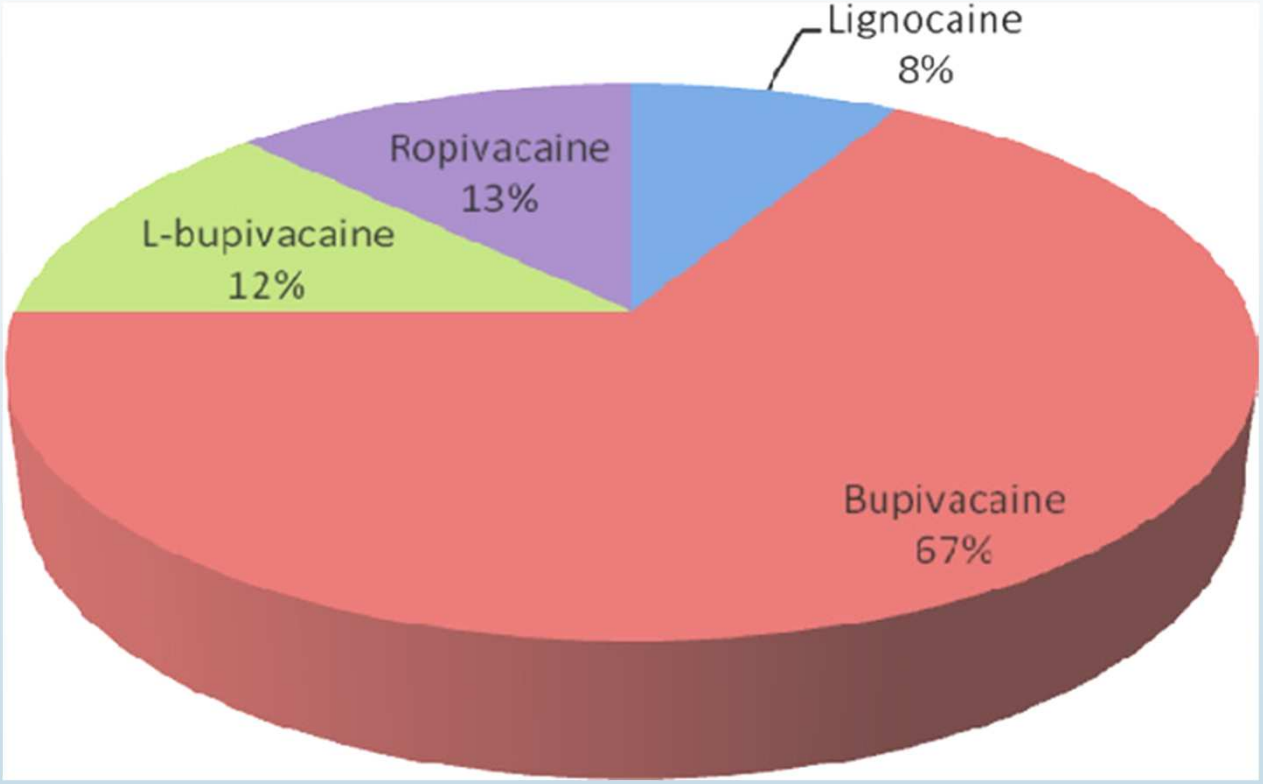
Preeti P. Doshi, MD, DA (UK), FRCA (II), FIPP, Jalpa D. Makwana, MBBS, DA; Practice of epidural steroid injections outside of the United States; Techniques in Regional Anesthesia and Pain Management (2009) 13, 258-265

Preferred approach to access epidural space.



Preeti P. Doshi, MD, DA (UK), FRCA (II), FIPP, Jalpa D. Makwana, MBBS, DA; Practice of epidural steroid injections outside of the United States; Techniques in Regional Anesthesia and Pain Management (2009) 13, 258-265

Choice for local anesthetic drug.



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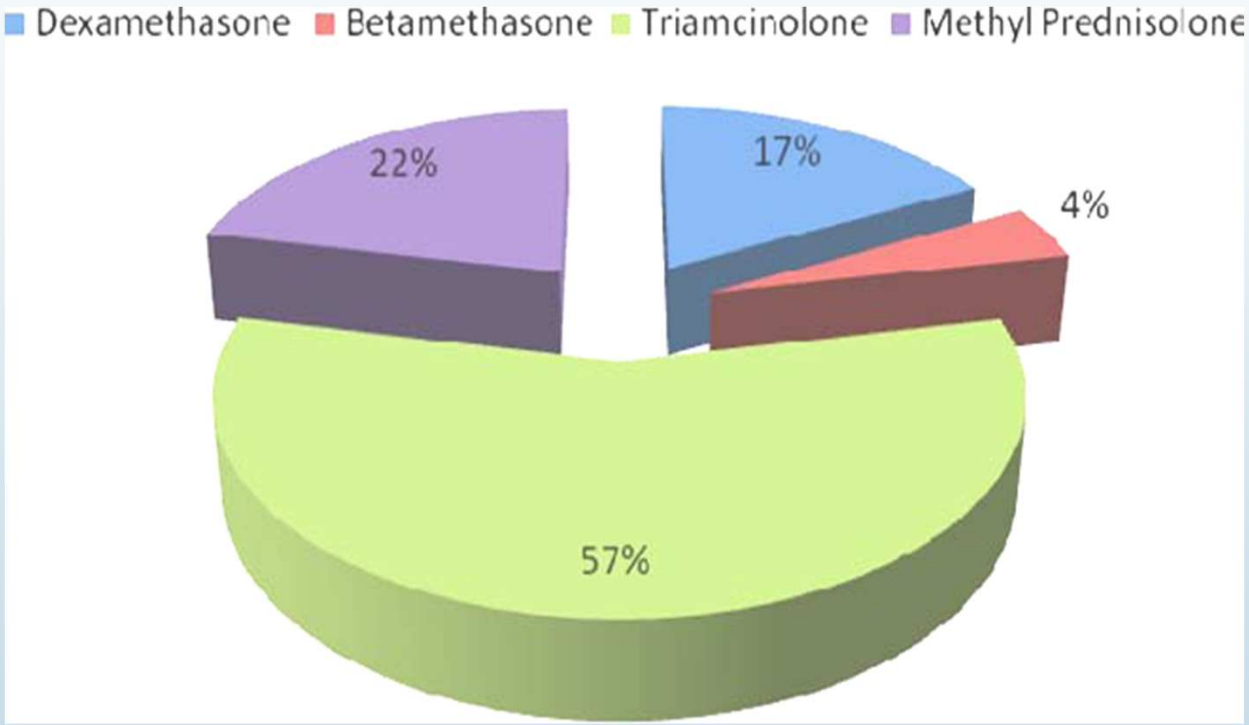
Type of steroid.



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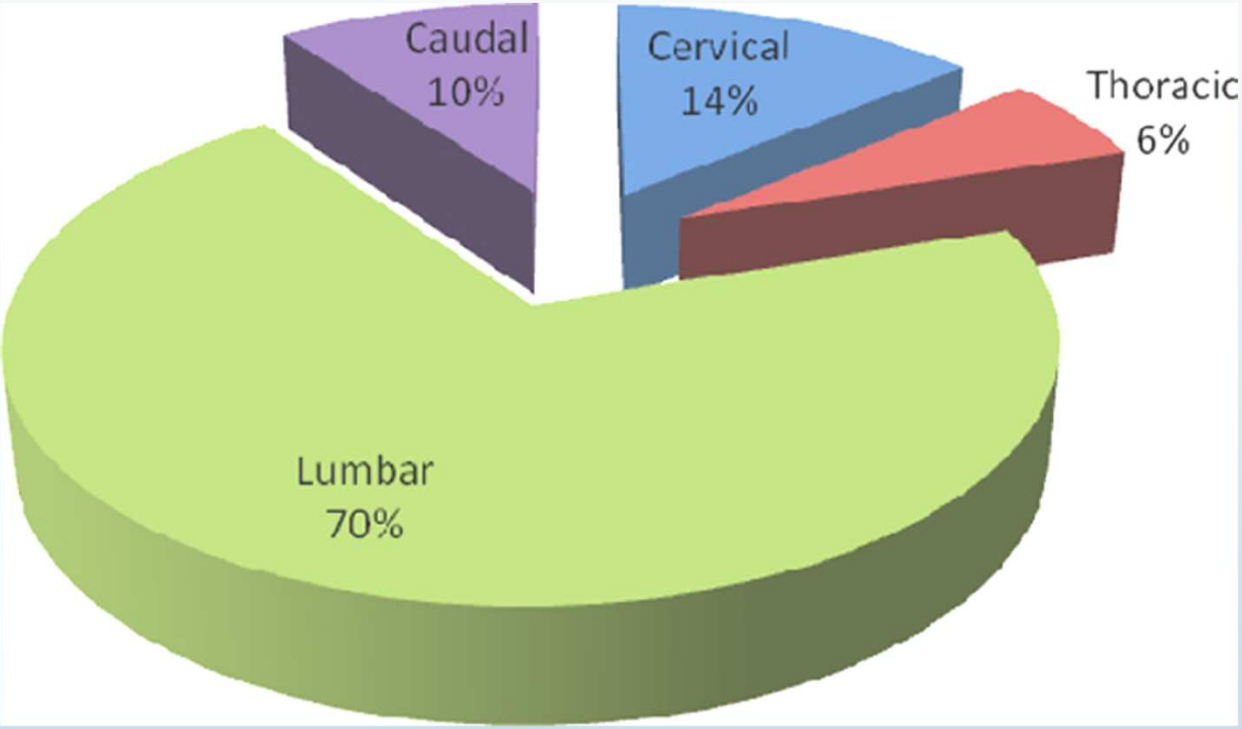
Anatomical distribution.



Preeti P. Doshi, MD, DA (UK), FRCA (II), FIPP, Jalpa D. Makwana, MBBS, DA; Practice of epidural steroid injections outside of the United States; Techniques in Regional Anesthesia and Pain Management (2009) 13, 258-265

Cortisonapplikation Indikation

Spez. Rückenschmerz (Low back pain)
Postlaminektomiesyndrom

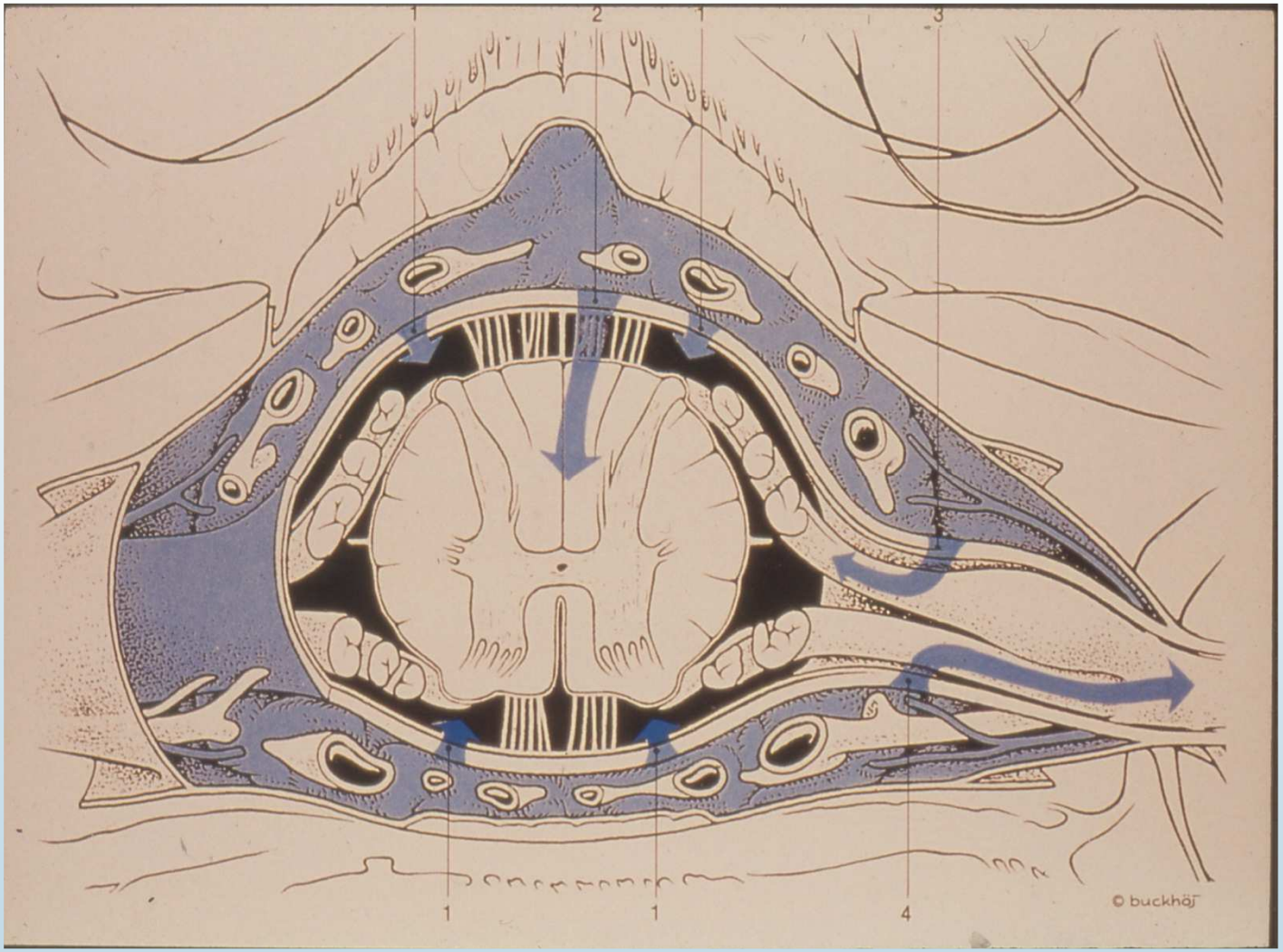
- **Methylprednisolon 80 – 120 mg**
- **Triamcinolon 20 – 40 mg**
- **Volumen (10 – 20 ml) LA**
- **Frequenz max. 3 / pro 6 Monate**

St.E. Abrom APS Journal 1994, 3(1) 28-30

Epidurale Applikation von Corticoiden Zusammenfassung

- **„.... Usefullness demonstrated by non-randomized trials..“**
- **Indikation: „radicular compression presumed“**
- **Kurzzeitige Reduktion von Beinschmerzen**
- **minimale Effekte bei unspezifischen Rückenschmerz**

Spitzer ea:
Scientific approach to the assessment and management of activity-related spinal disorders: A monograph for clinicians.
Report on the Quebec Task Force on Spinal Disorders. Spine 12: S1, 1987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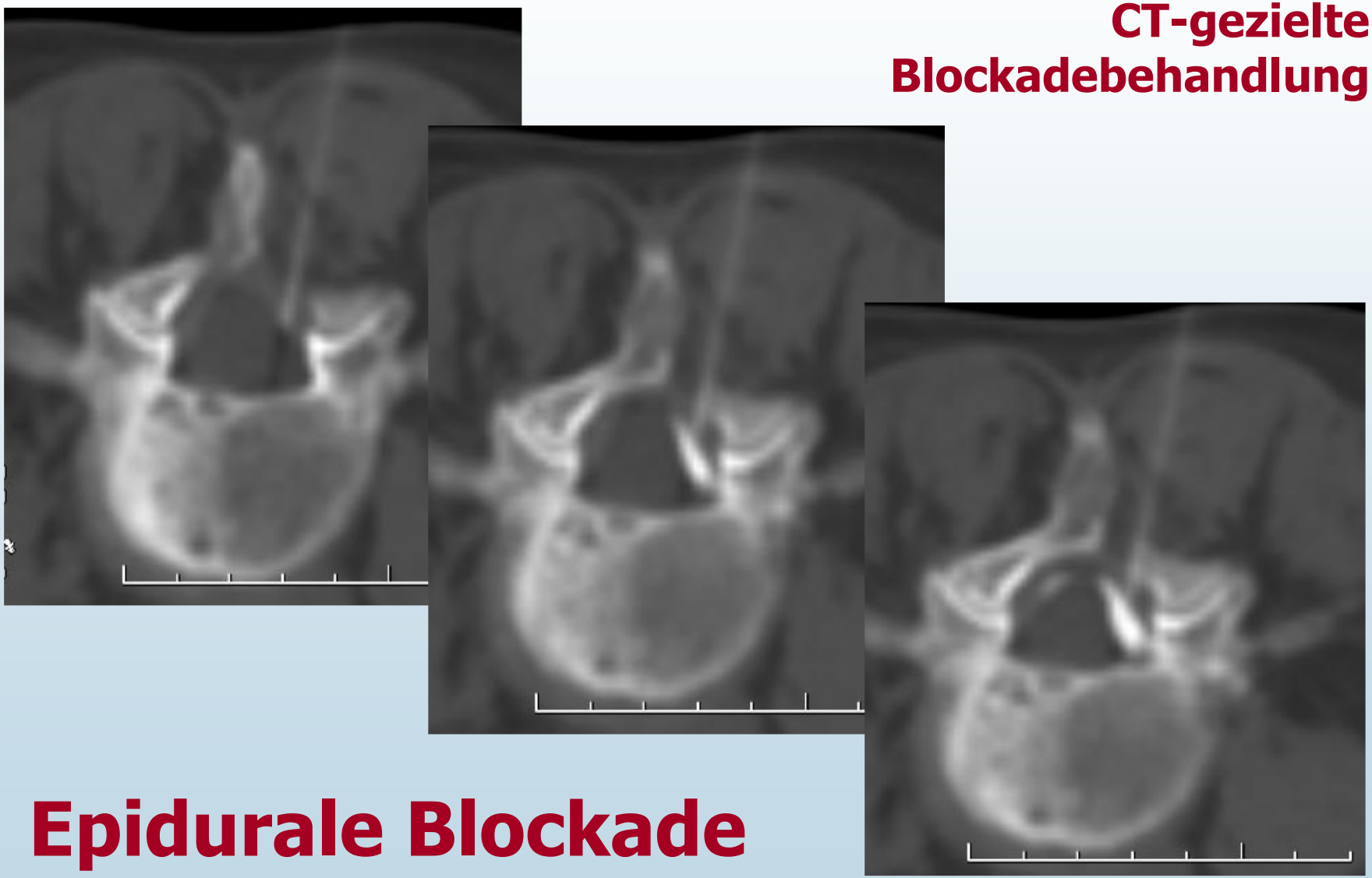
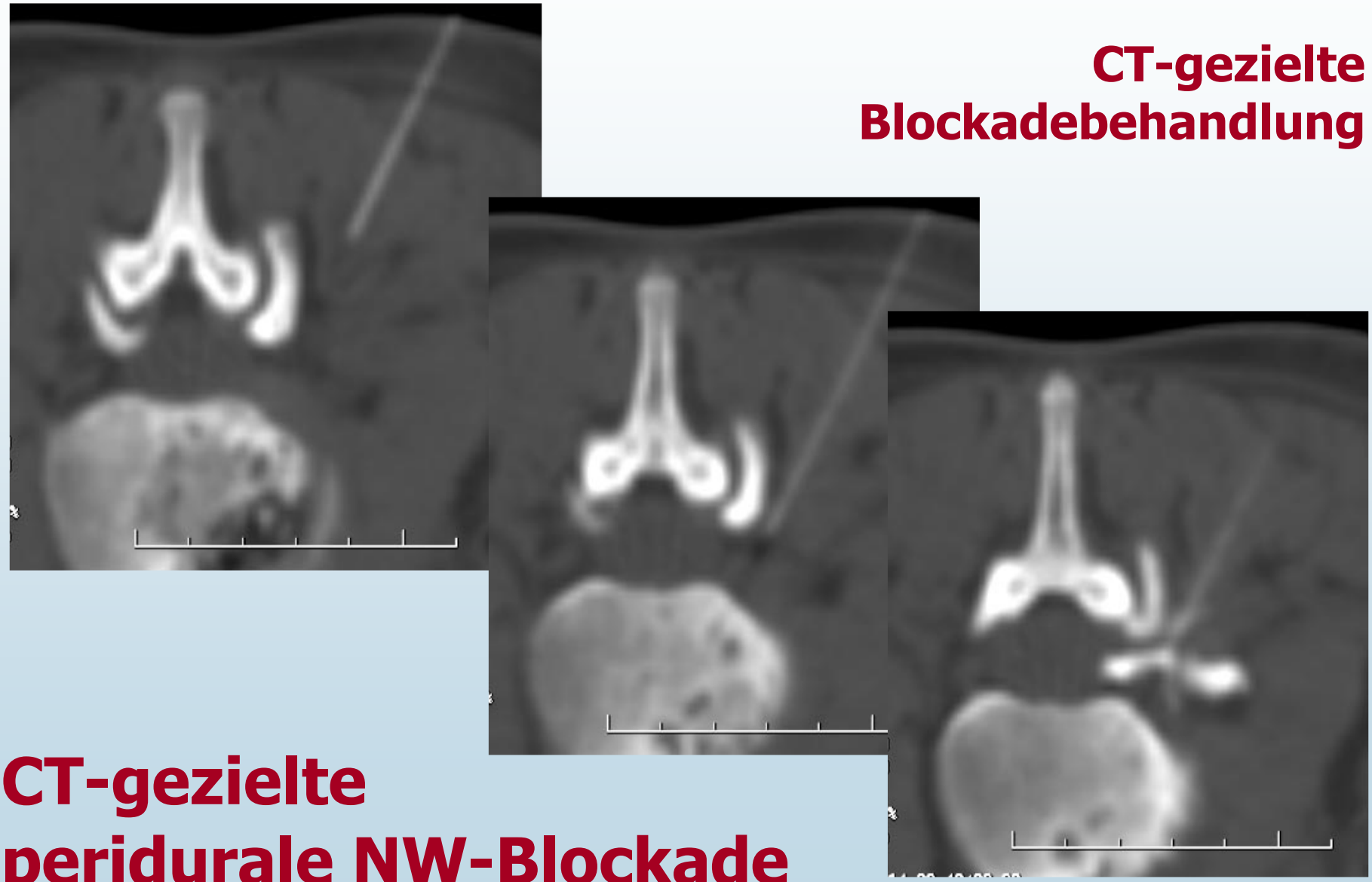
CT-gezielte Blockadebehandlung



Epidurale Blockade

CT-gezielte Blockadebehandlung



CT-gezielte peridurale NW-Blockade

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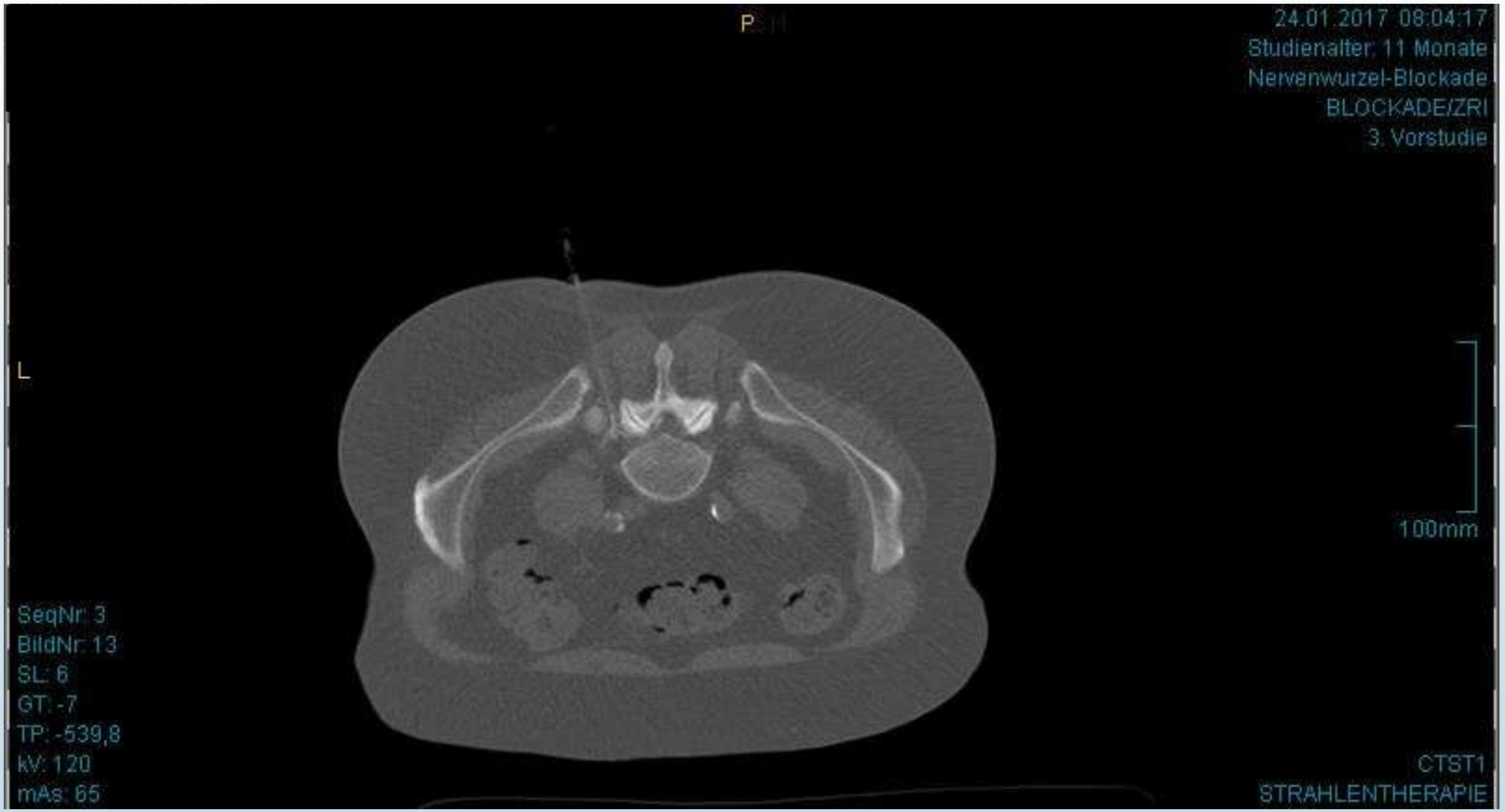

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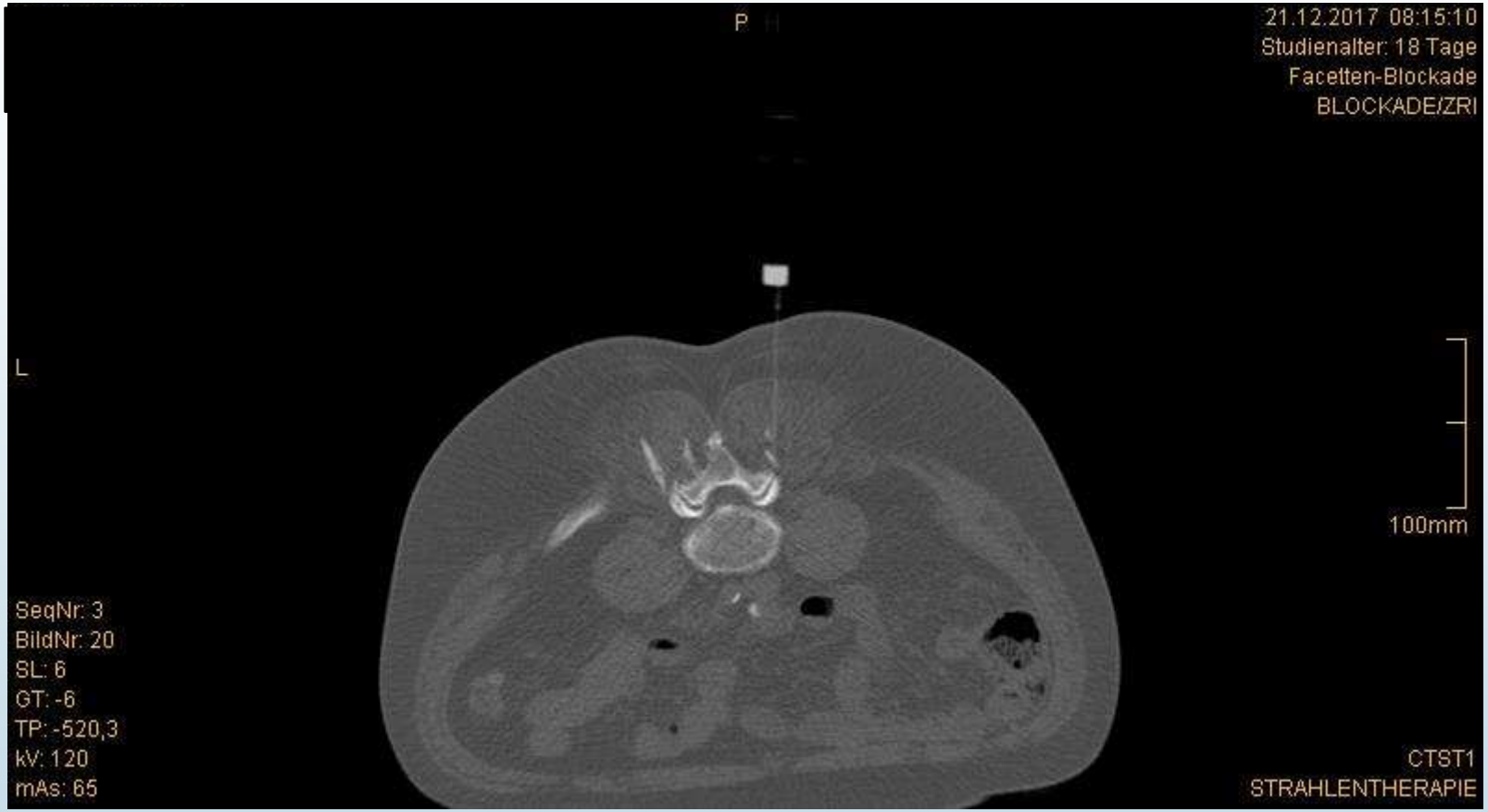

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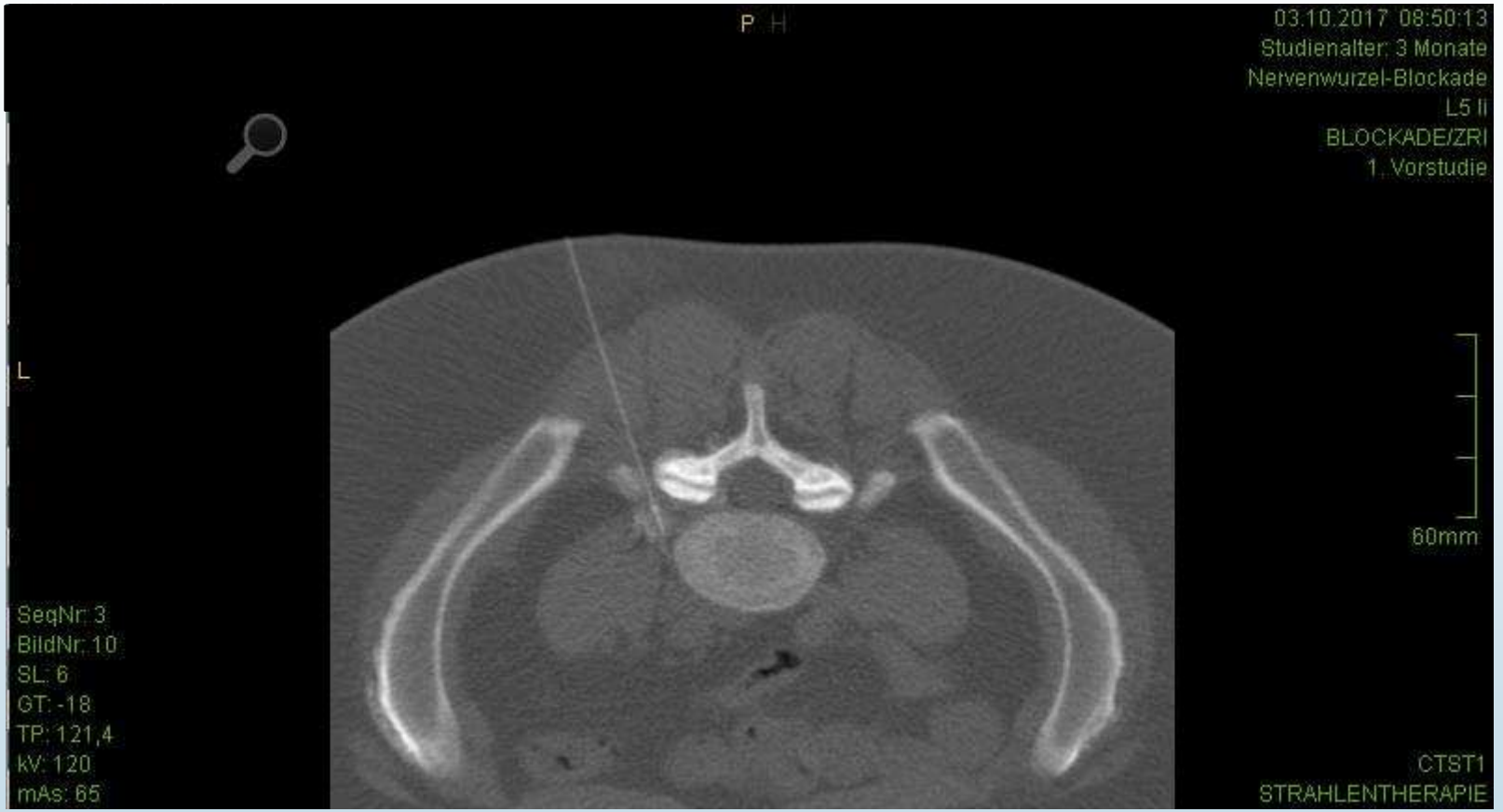

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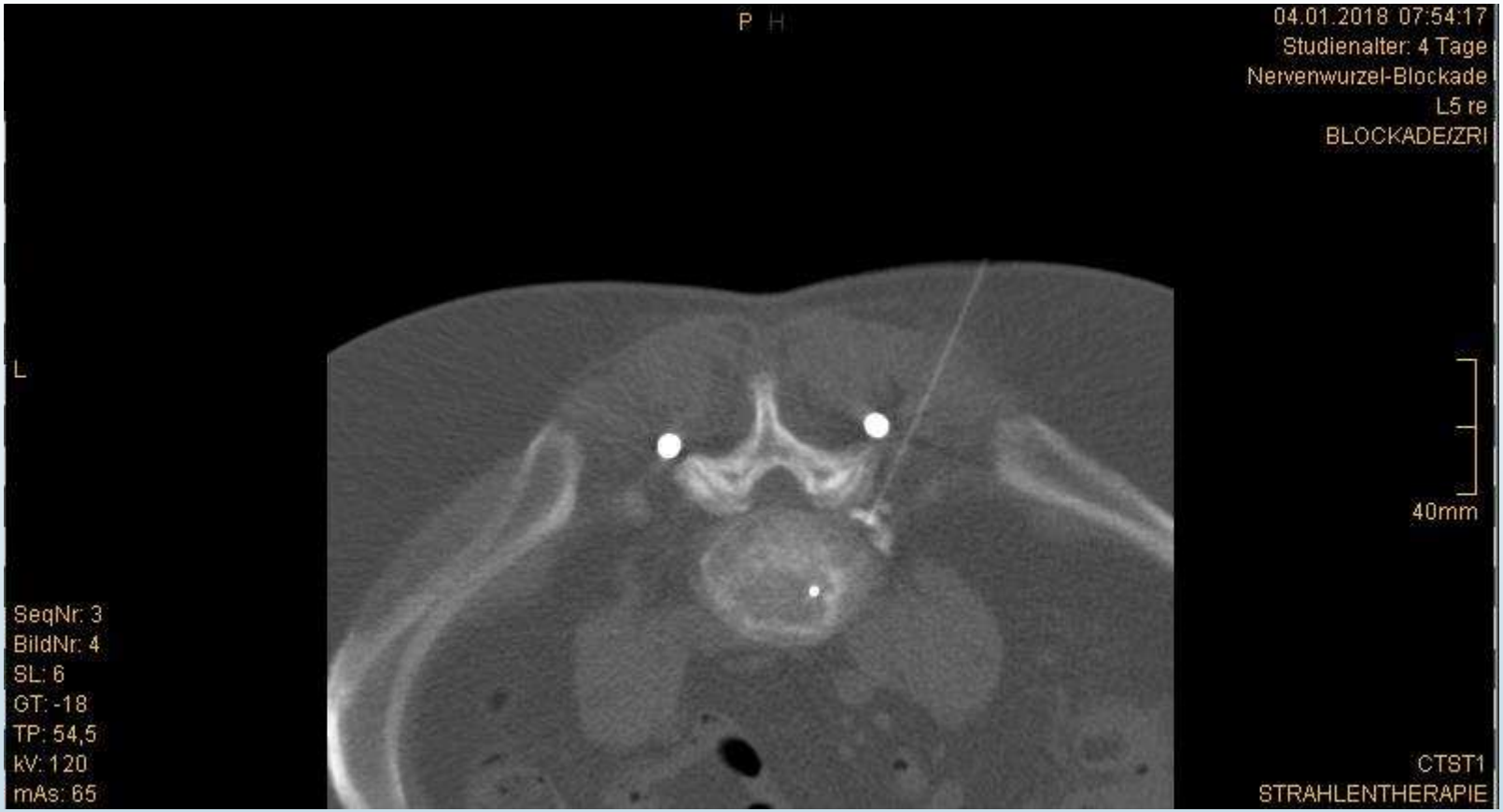

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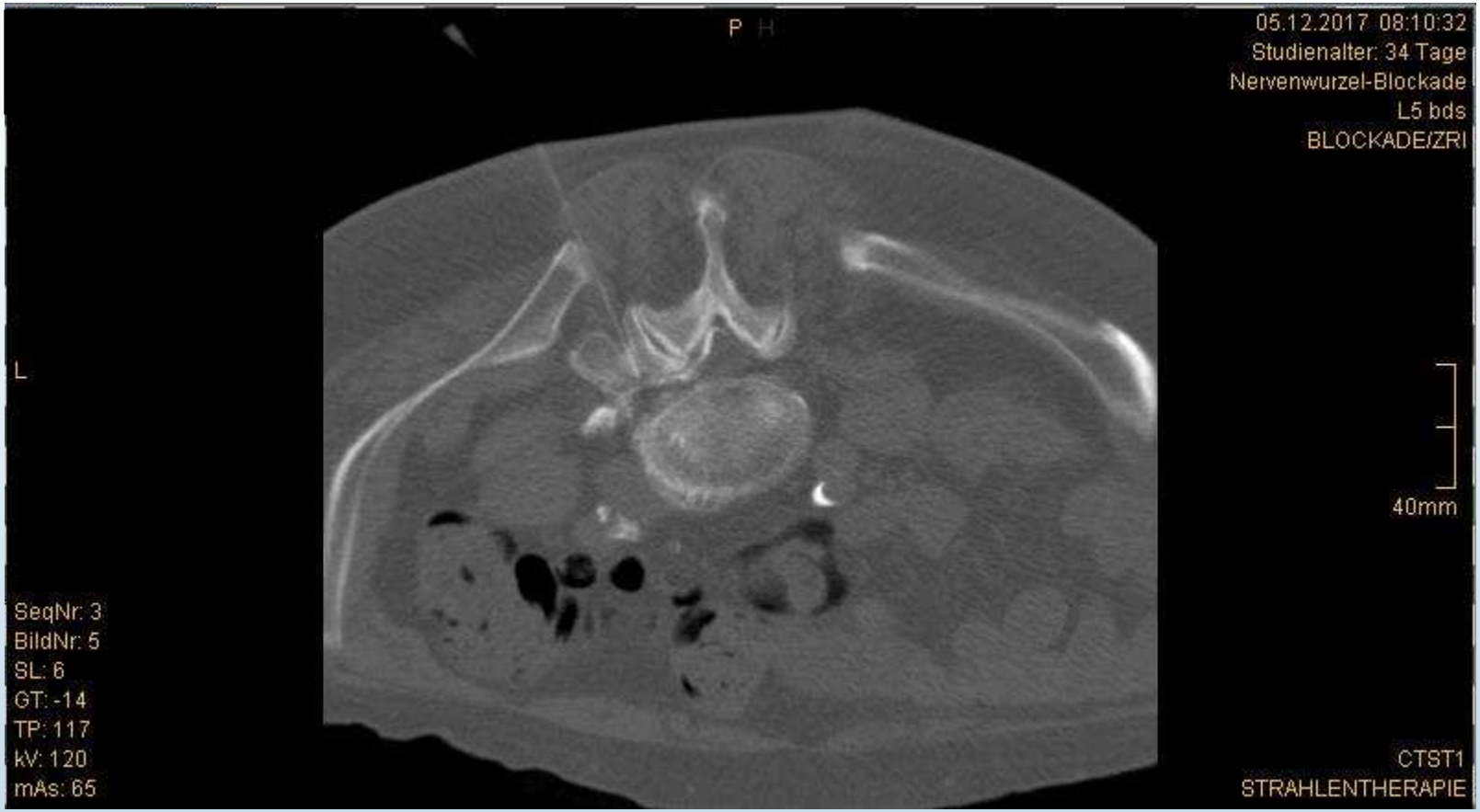

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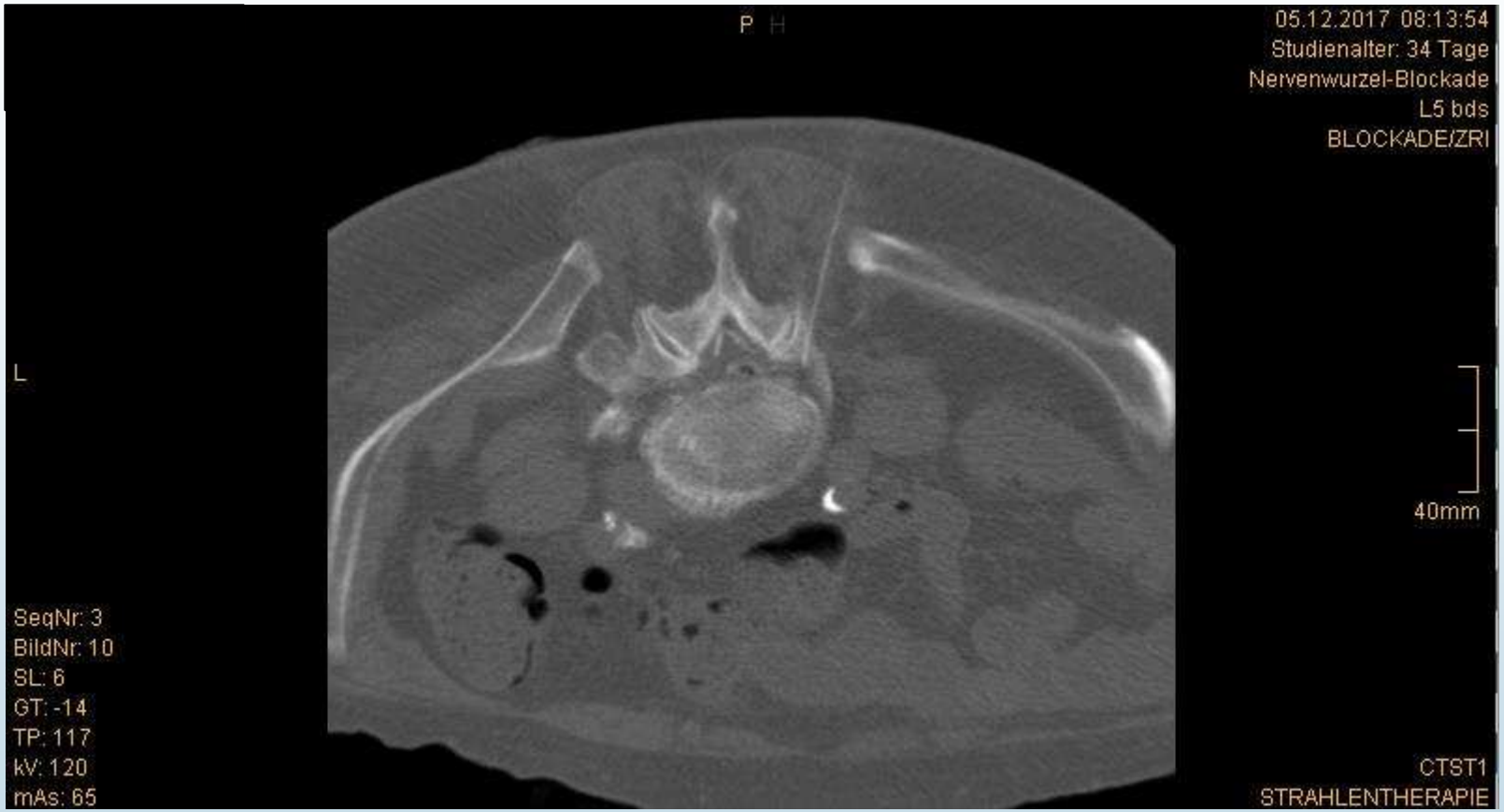

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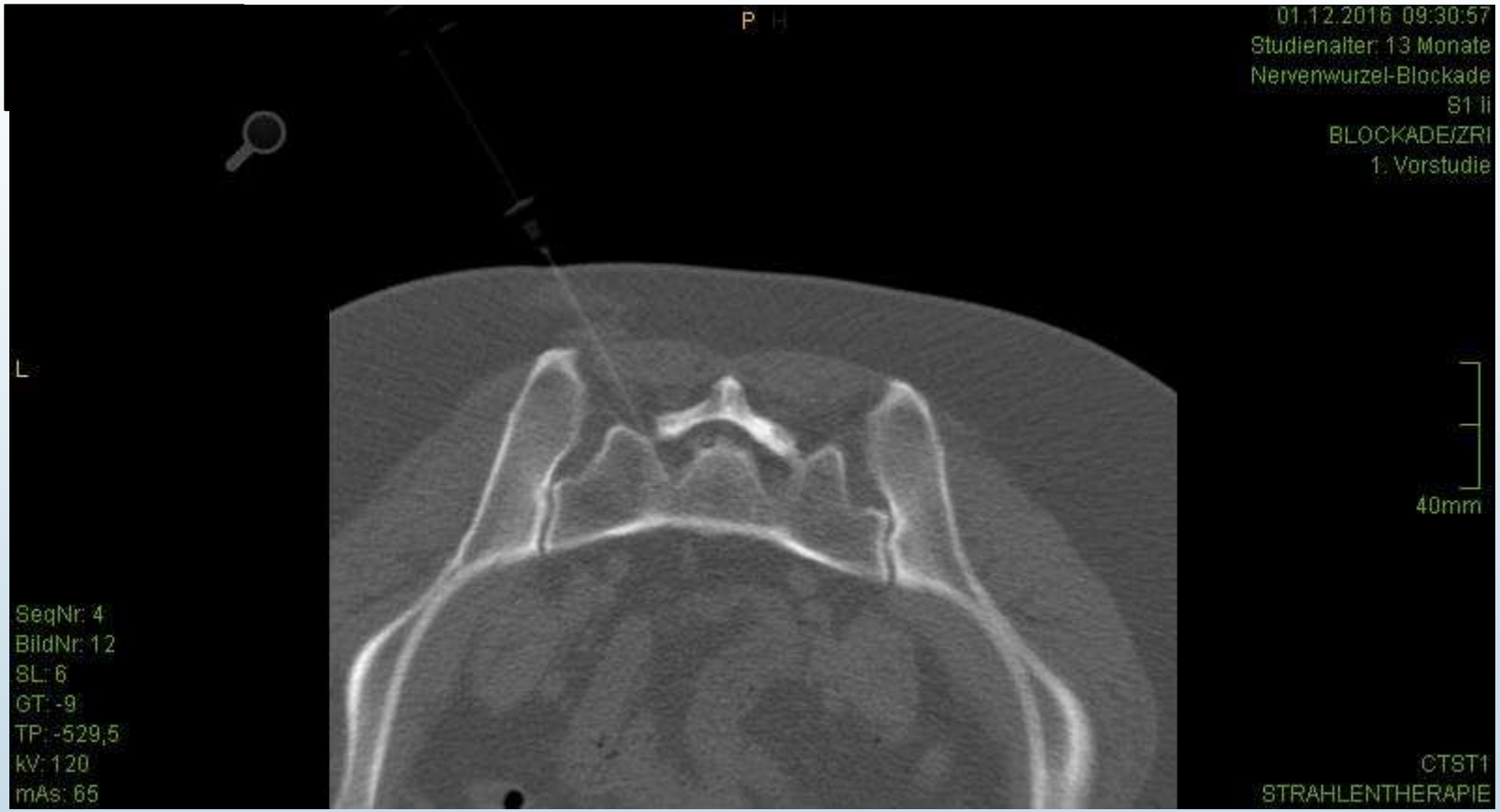
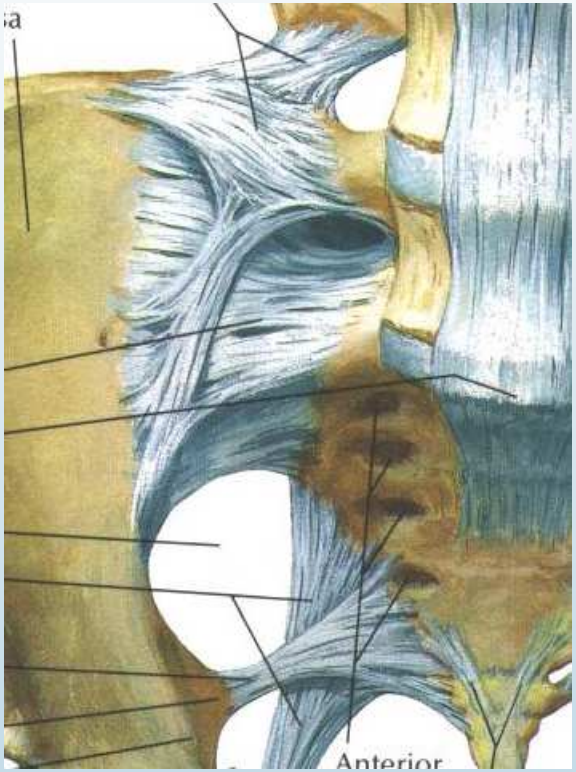
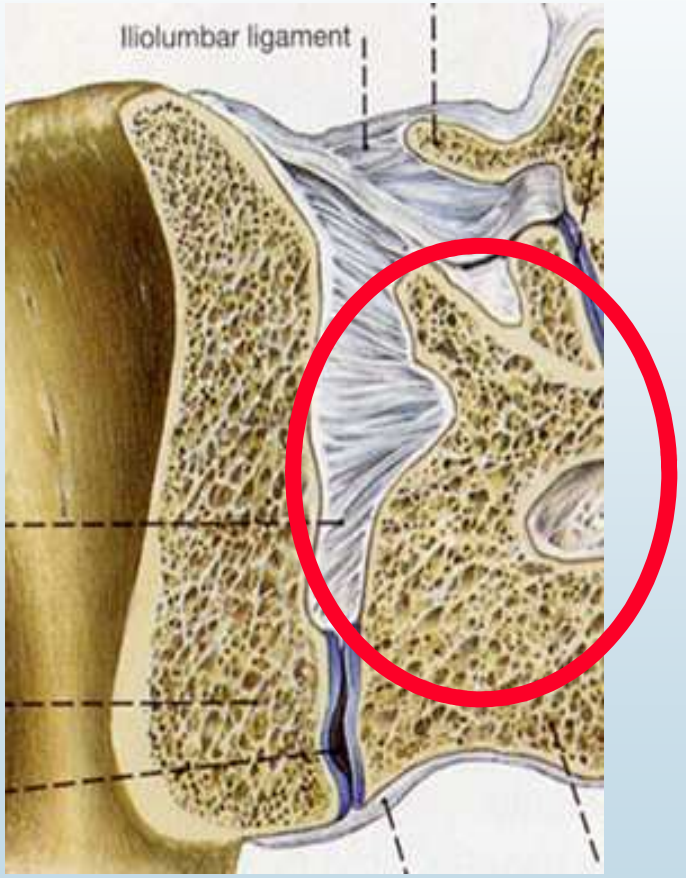
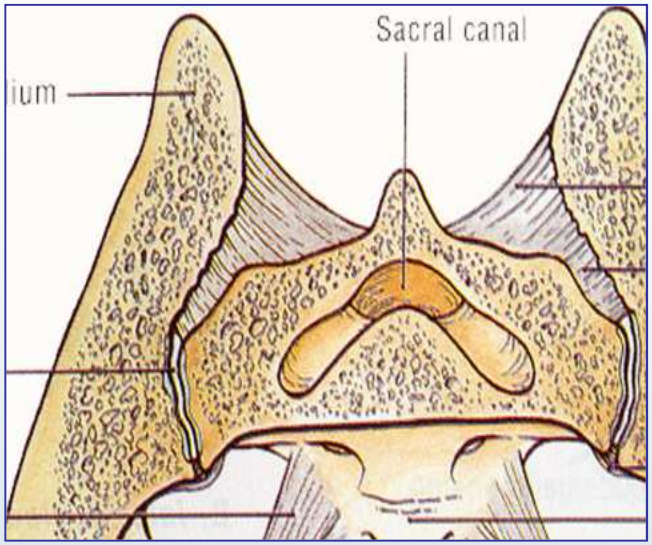


Iliosakralgelenke (ISG)






Sacral canal
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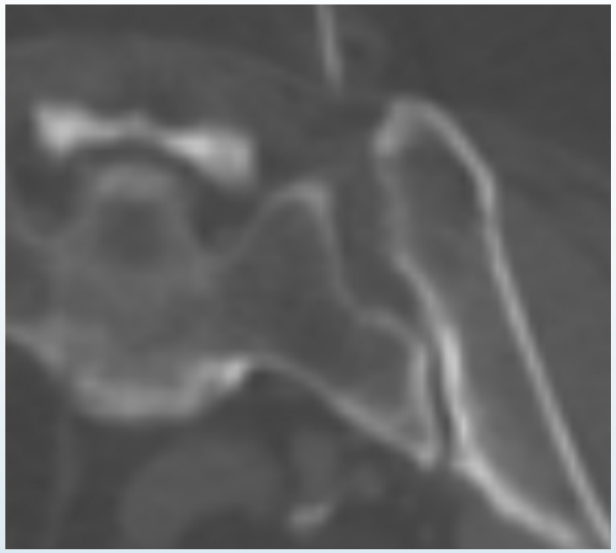
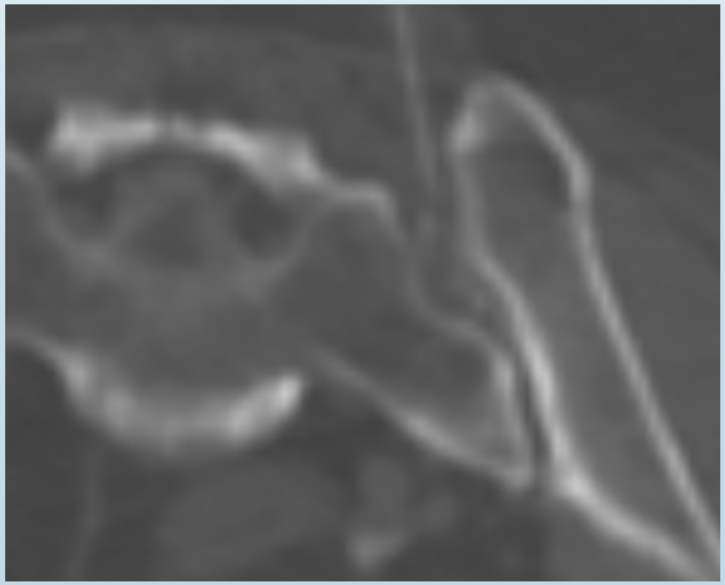
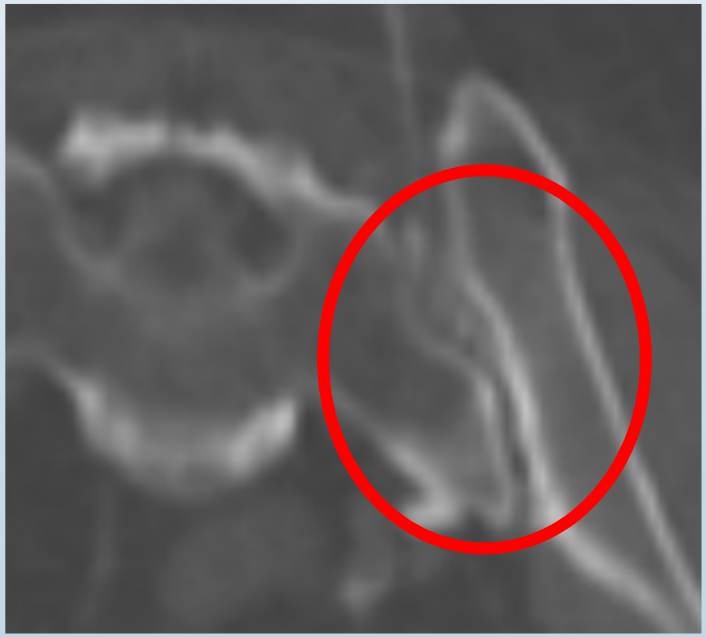
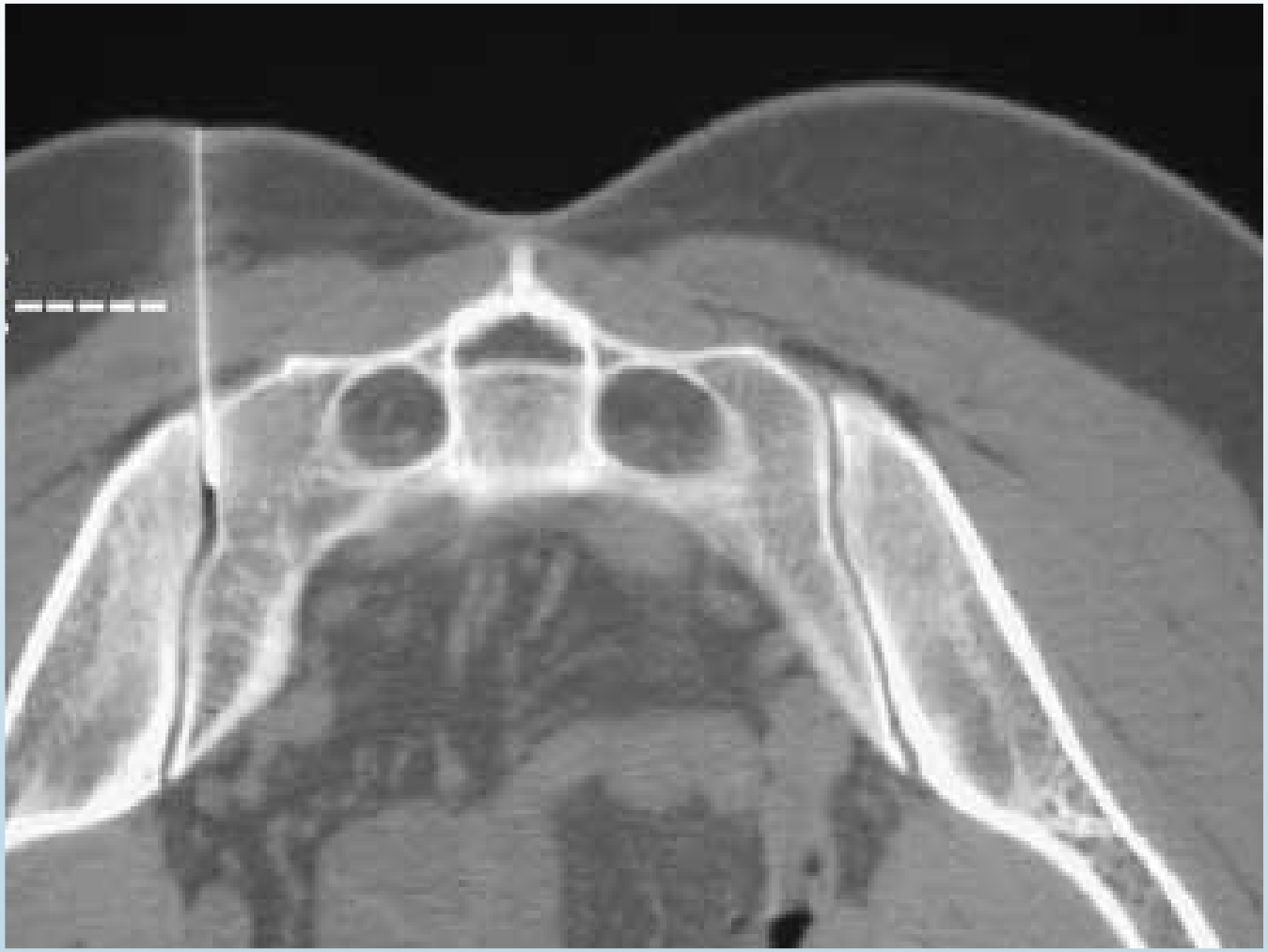






Iliosakralgelenks-Blockade links



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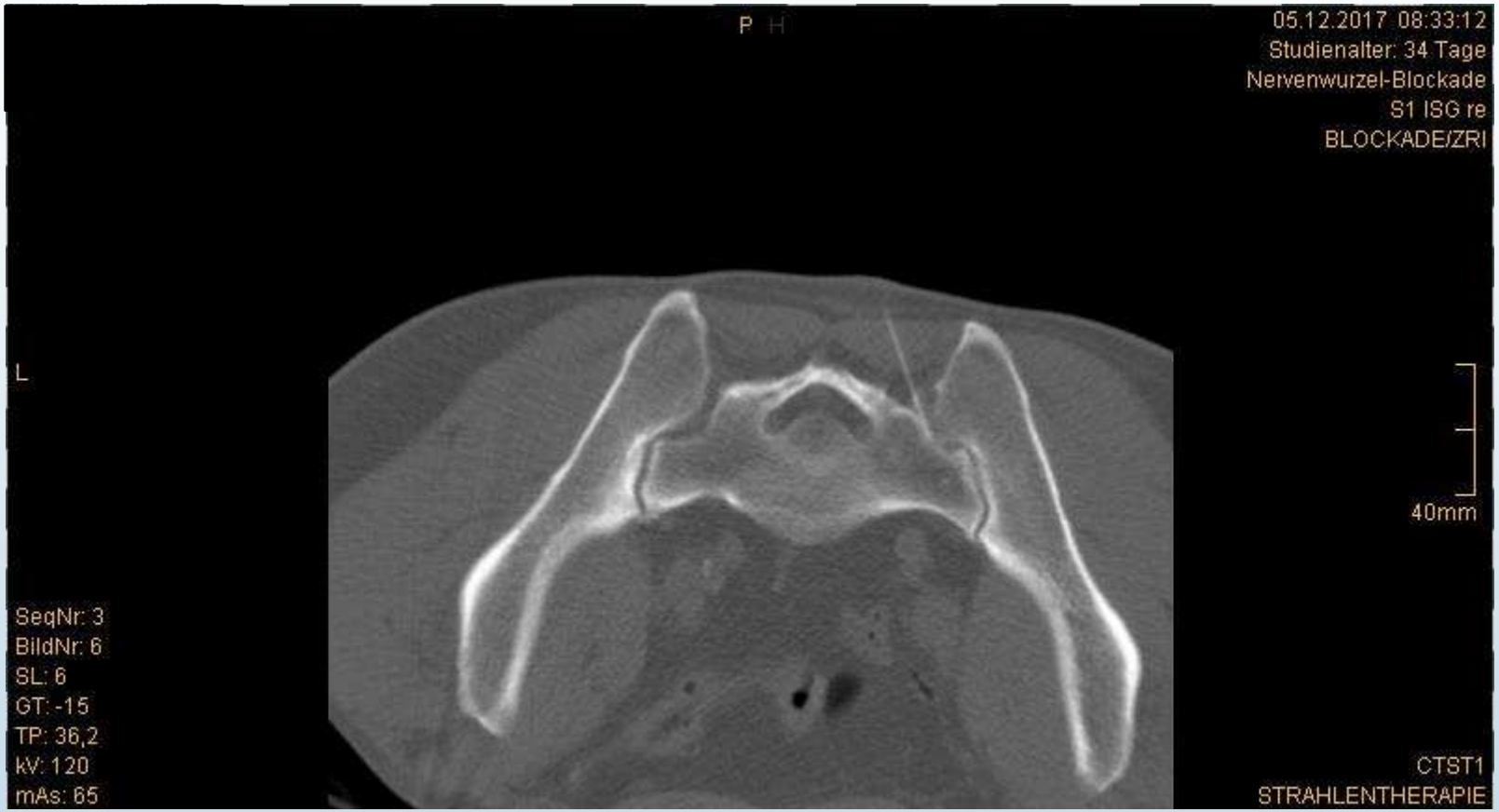

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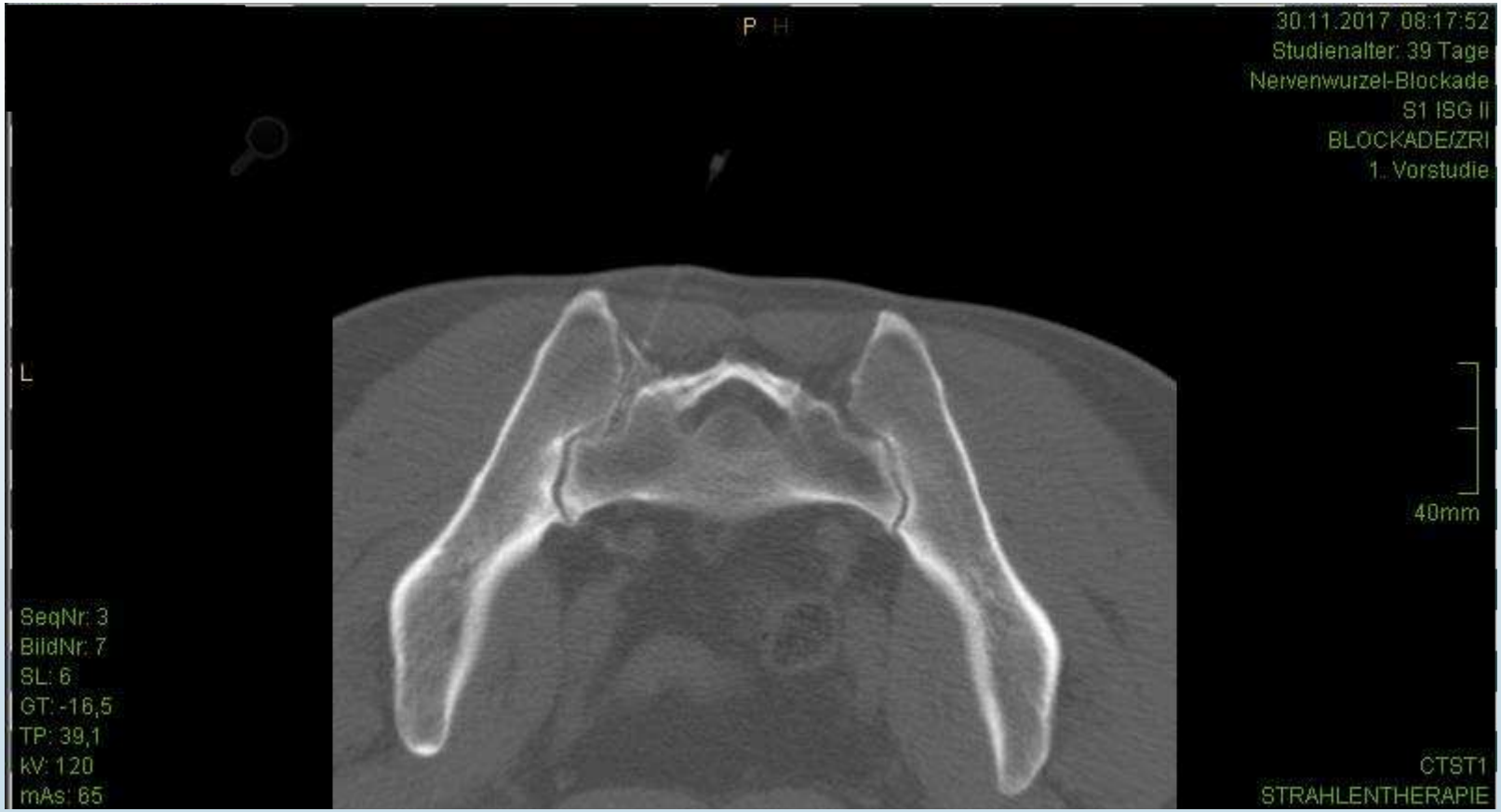

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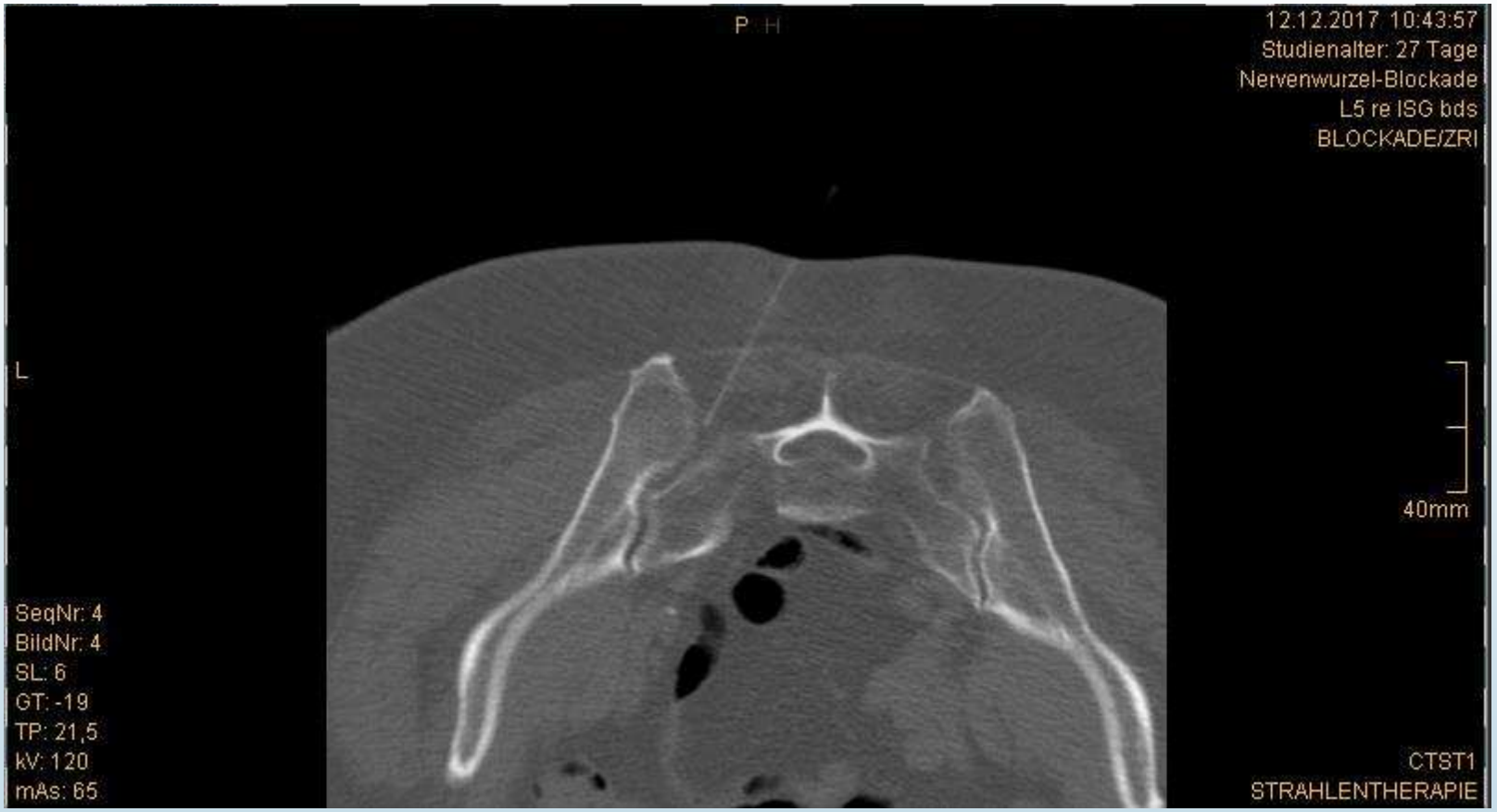
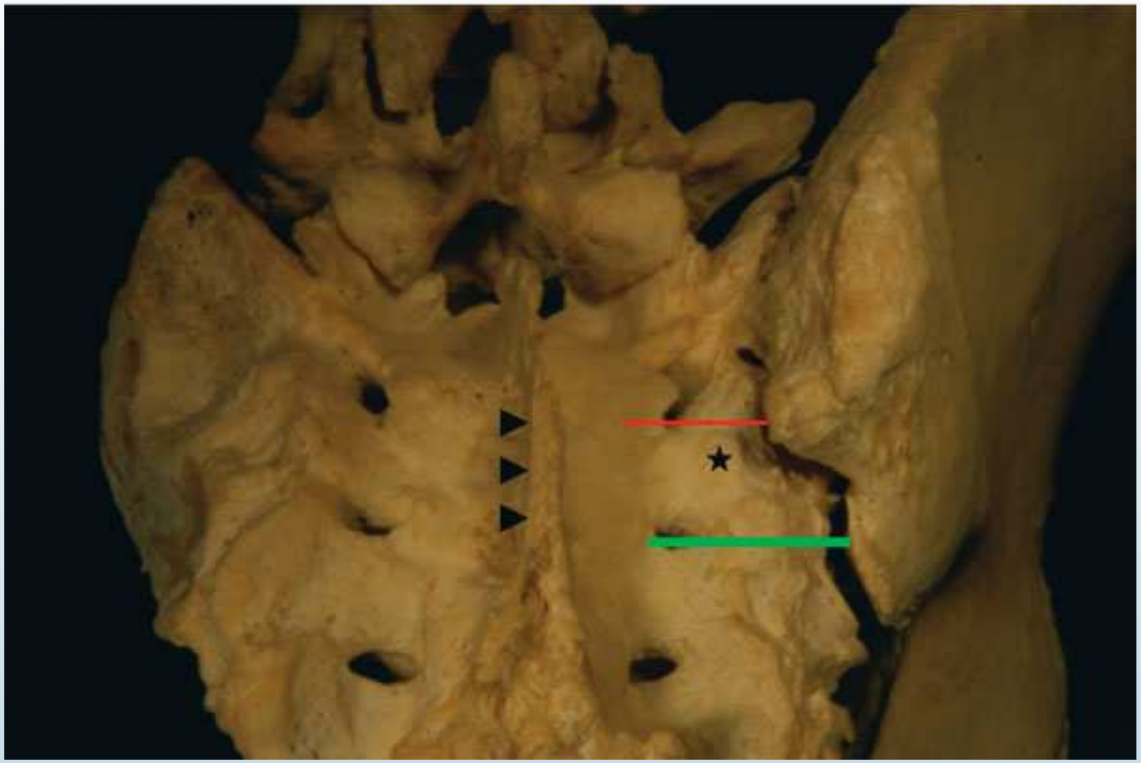
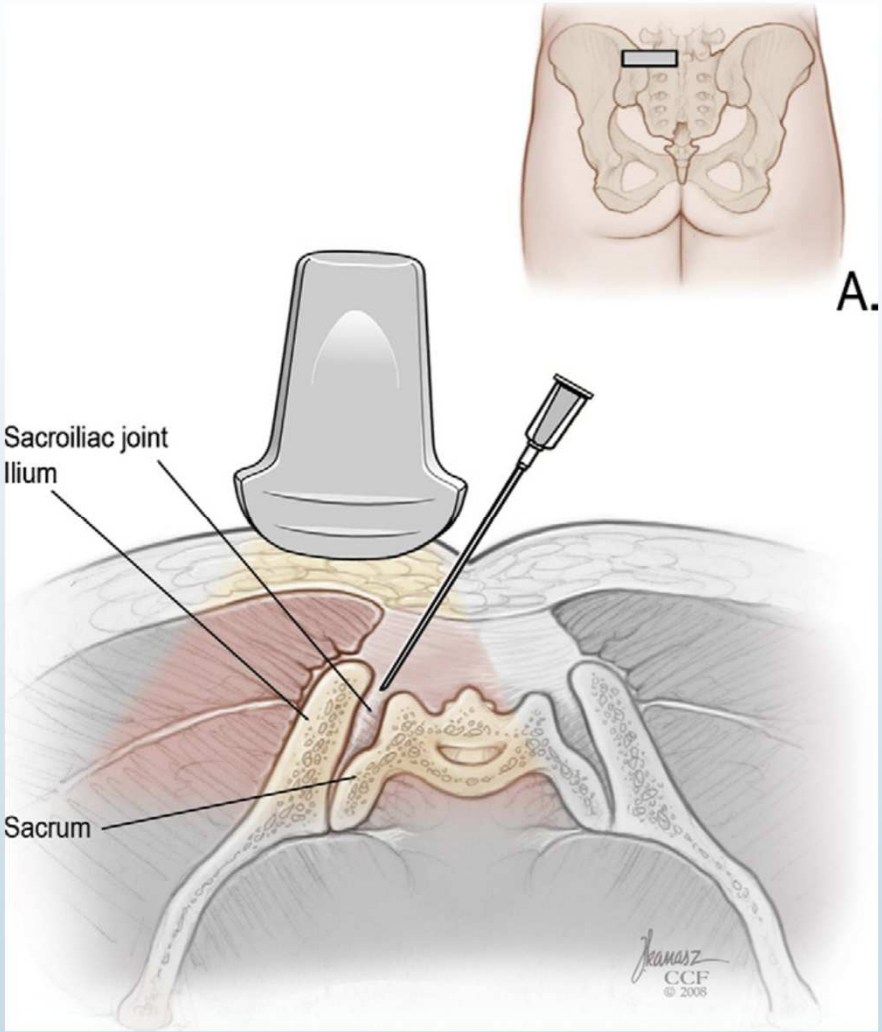




A.KLAUSER,T. DE ZORDO, G. FEUCHTNER, P. SÖGNER, M. SCHIRMER, J. GRUBER, N. SEPP AND B. MORIGGL; Feasibility of Ultrasound-Guided Sacroiliac Joint Injection Considering Sonoanatomic Landmarks at Two Different Levels in Cadavers and Patients; 2008, American College of Rheumatology, Arthritis & Rheumatism (Arthritis Care & Research) Vol. 59, No. 11, November 15, 2008, 1618–1624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Sacroiliac joint
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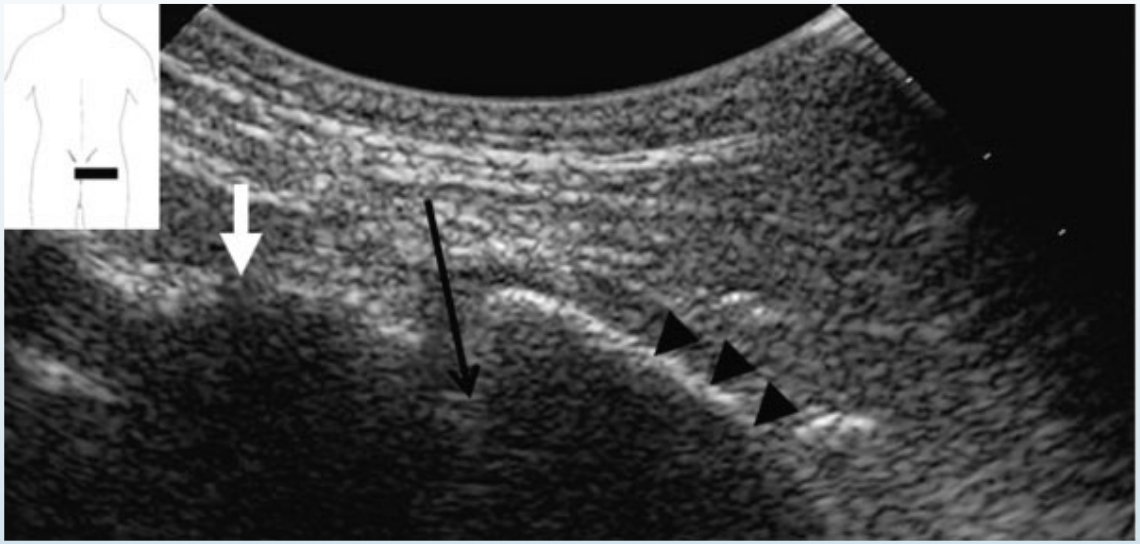

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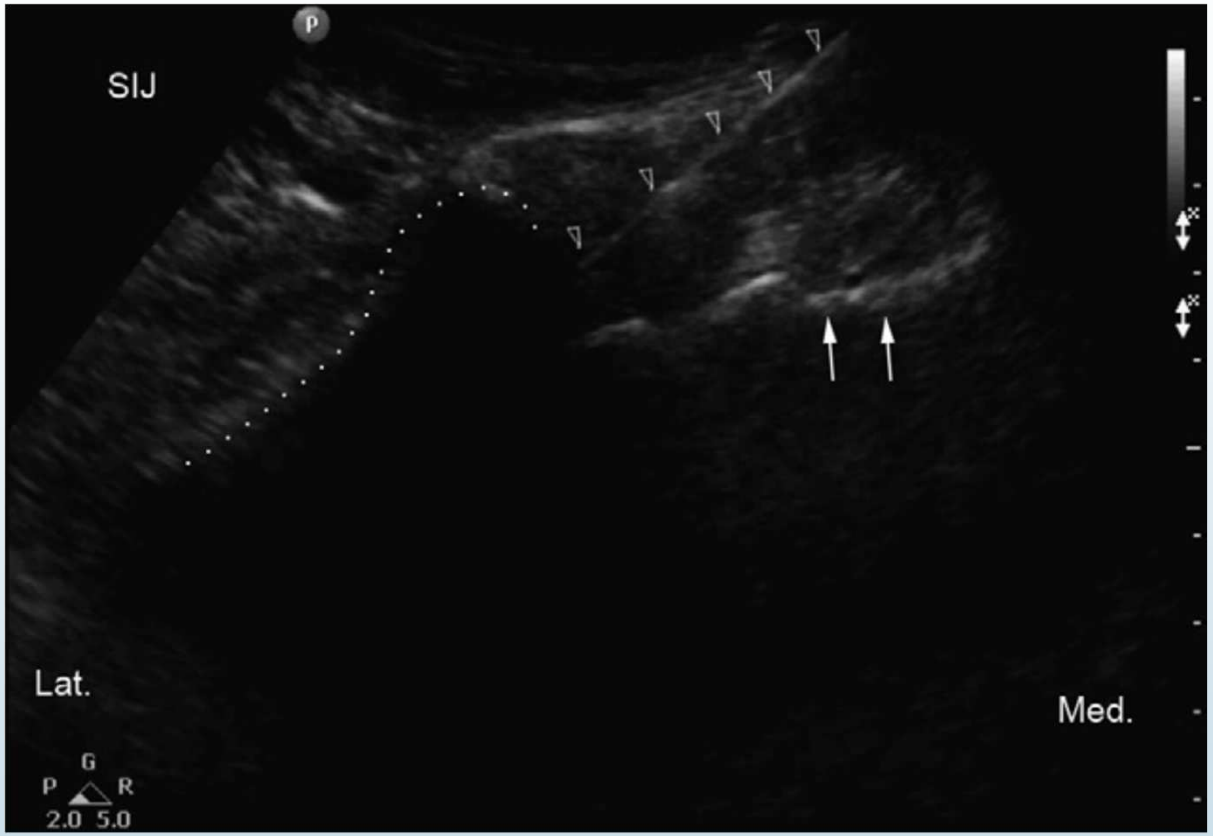
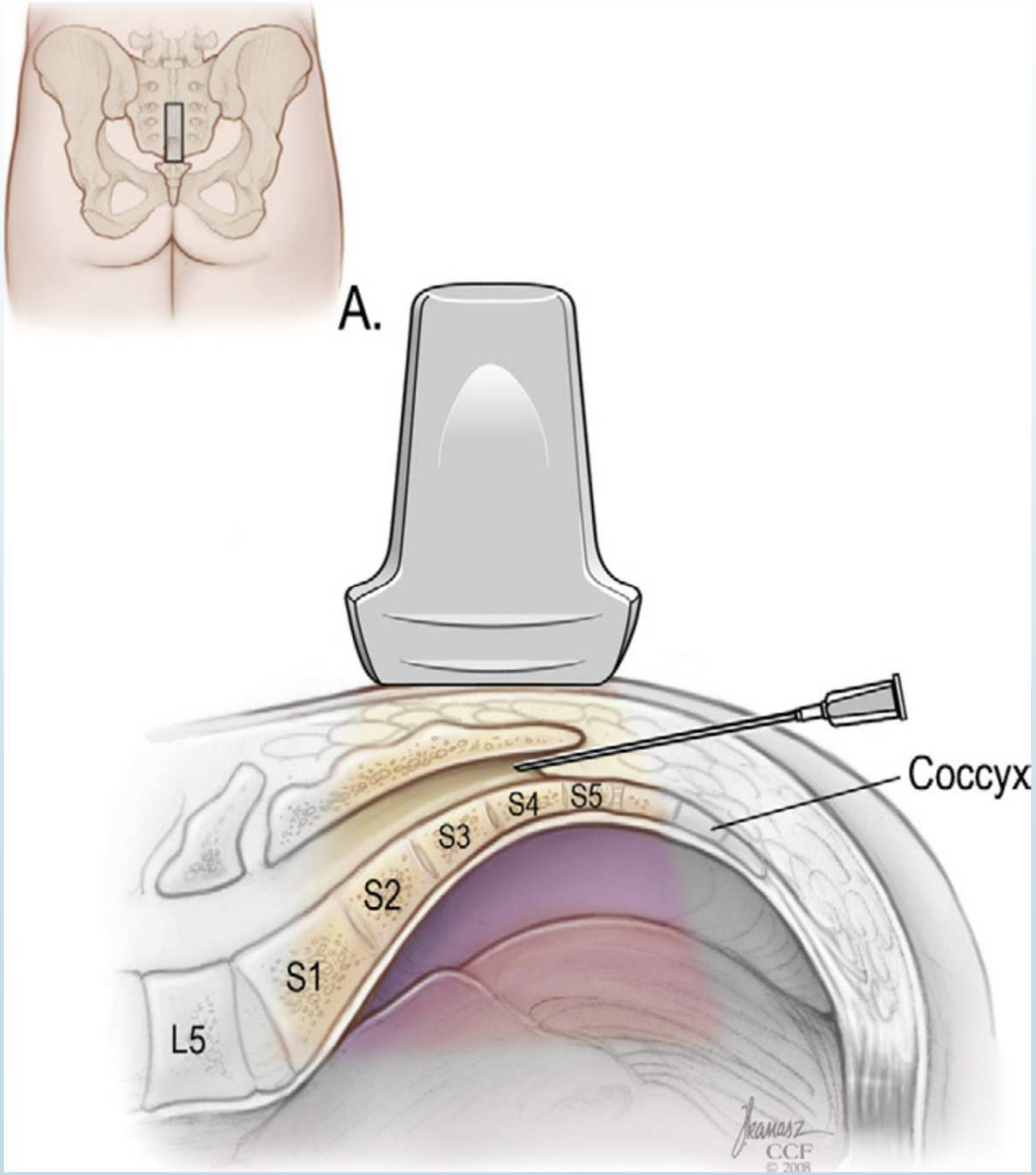


Klauser A, De Zordo T, Feuchtner G, et al. Feasibility of ultrasound-guided sacroiliac joint injection considering sonoanatomic landmarks at two different levels in cadavers and patients. Arthritis Rheum. 2008;59:1618Y1624

Harmon D, O'Sullivan M. Ultrasound-guided sacroiliac joint injection technique. Pain Physician. 2008;11:543Y547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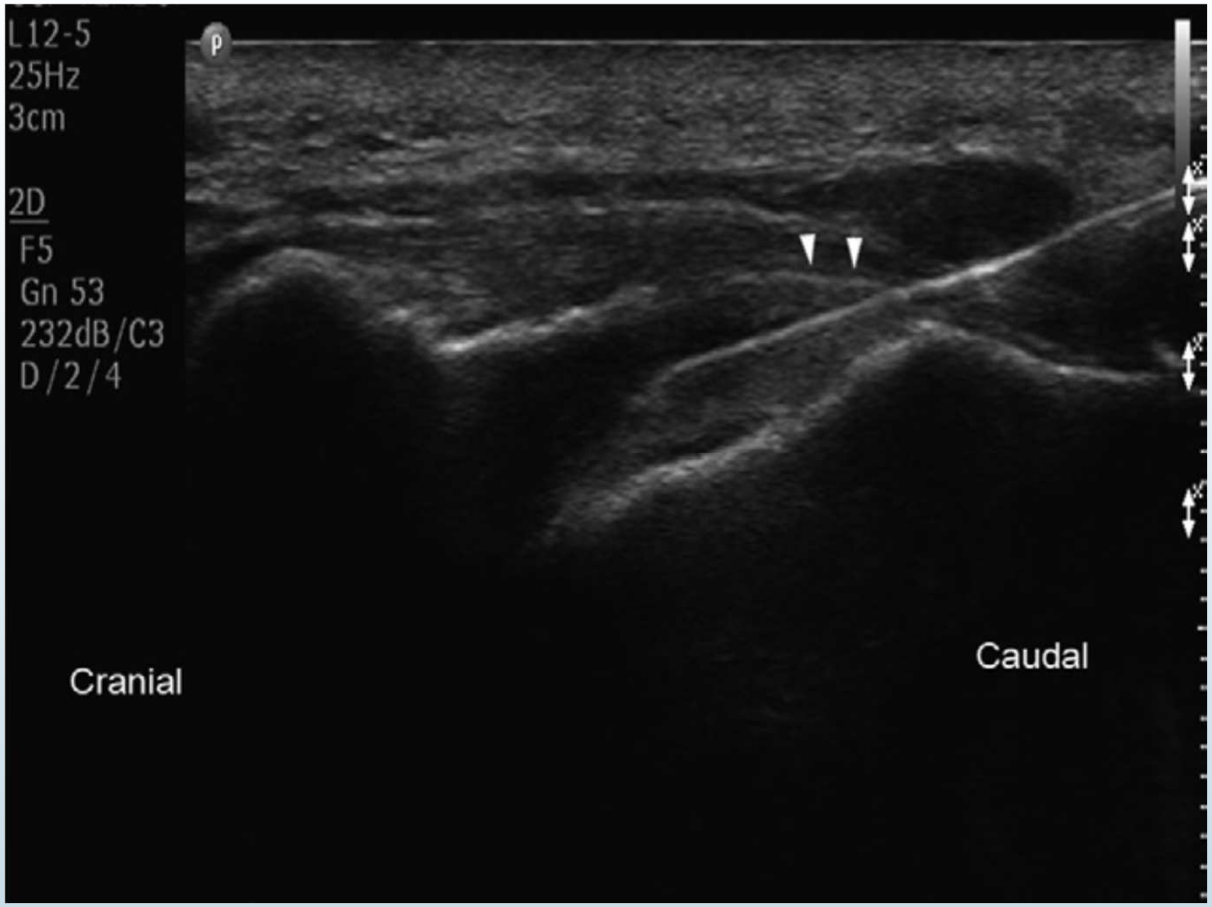


Sekiguchi M, Yabuki S, Satoh K, Kikuchi S. An anatomic study of the sacral hiatus: a basis for successful caudal epidural block. Clin J Pain. 2004;20:51Y54

Klocke R, Jenkinson T, Glew D. Sonographically guided caudal epidural steroid injections. J Ultrasound Med. 2003;22:1229Y1232

Chen CP, Tang SF, Hsu TC, et al. Ultrasound guidance in caudal epidural needle placement. Anesthesiology. 2004;101:181Y184

Low back pain

Facettensydrom

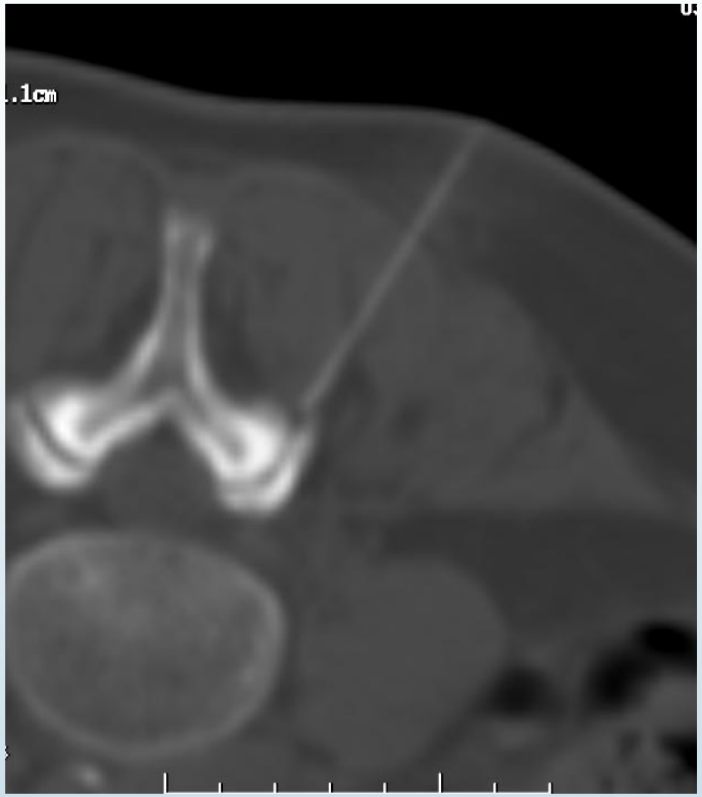
- **Diffuse Rückenschmerzen durch Bewegung verstärkt, ausstrahlend zum Beckenkamm und zur Leiste, Gesäß, Oberschenkel**
- **Blockierung und Fehlbelastung der kleinen Wirbelgelenke**
- **pseudoradikulär**

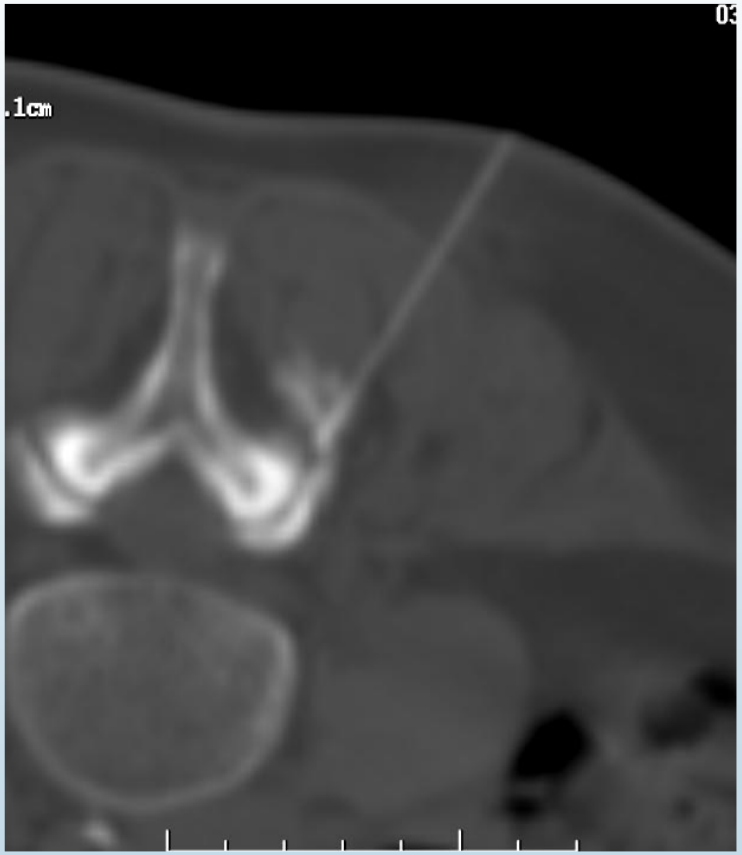
Low back pain

Indikationen zur Facettenblockade oder Facettendenervierung

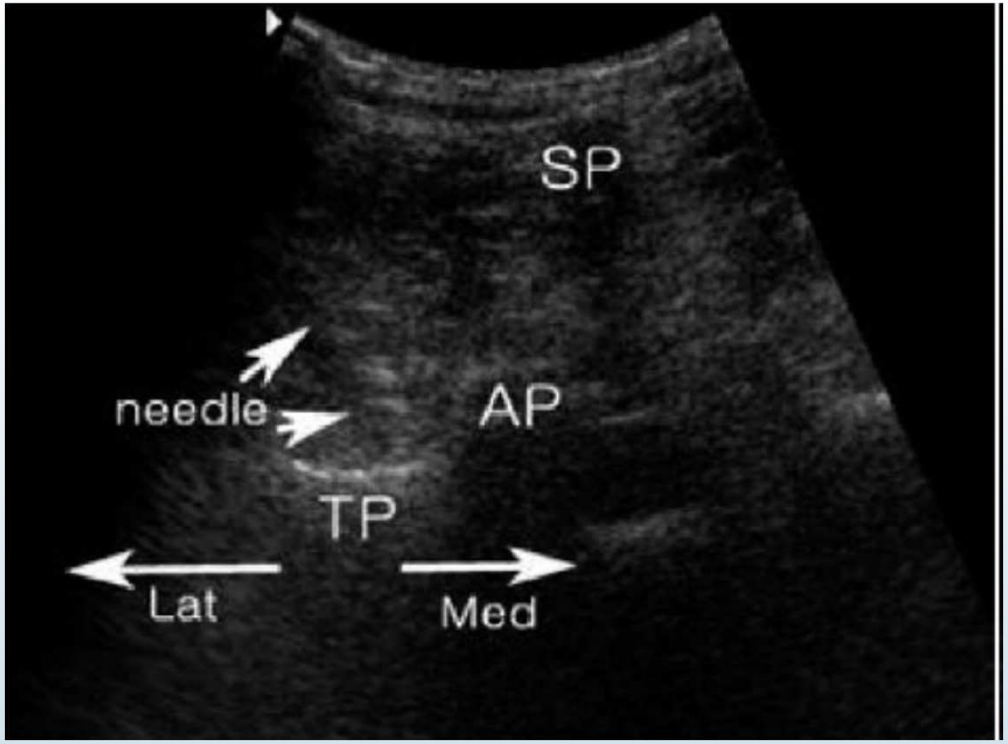
- **Pseudoradikulärer Schmerz in HWS, BWS, LWS**
- **Blockierung und Fehlbelastung der kleinen Wirbelgelenke**
- **Degenerative Veränderungen der Facettengelenke**
- **Addition zur periradikulären Therapie**

CT-gezielte Blockadebehandlung



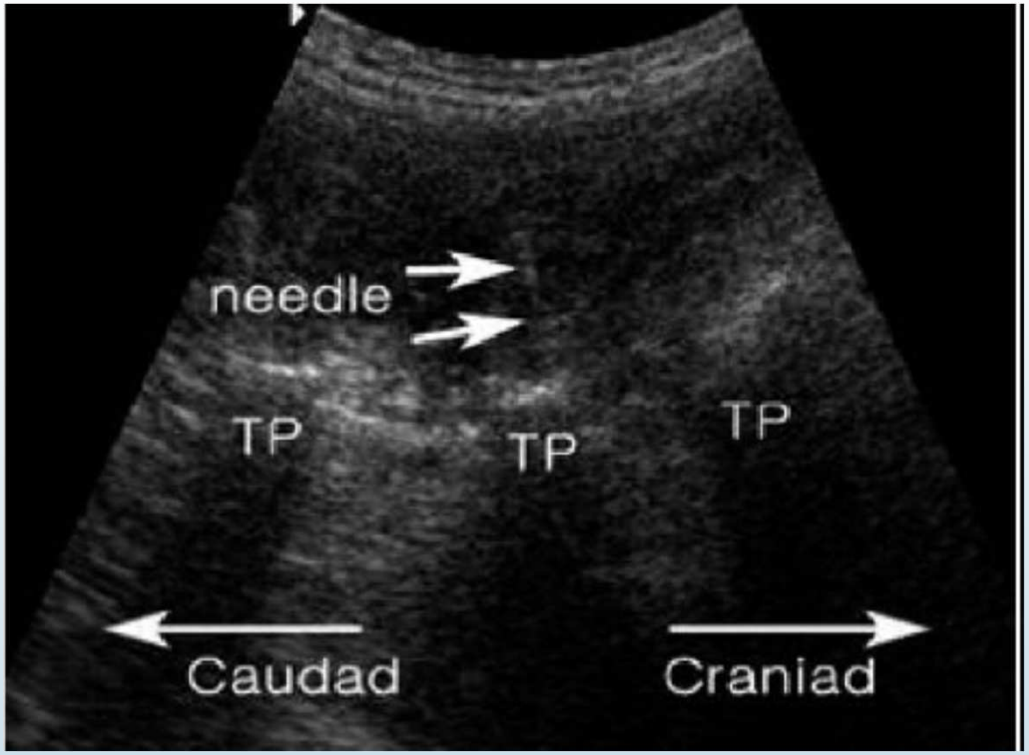


Facettengelenks-Blockade



Ultrasonographic cross-axis view with the needle at the groove of the transverse process adjacent to the superior articular process. SP, spinous process; TP,trans-verse process; AP, articular process; Lat,lateral; Med, medial

Shim JK, Moon JC, Yoon KB, Kim WO,Yoon DM. Ultrasound-Guided Lumbar Medial-Branch Block: A Clinical Study With Fluoroscopy Control . Regional Anesthesia and Pain Medicine 2006; Vol. 31 No. 5 September – October 2006



Ultrasonographic longitudinal paravertebral view with the needle at the cephalad margin of the transverse process. TP, transverse process.

Shim JK, Moon JC, Yoon KB, Kim WO,Yoon DM. Ultrasound-Guided Lumbar Medial-Branch Block: A Clinical Study With Fluoroscopy Control . Regional Anesthesia and Pain Medicine 2006; Vol. 31 No. 5 September – October 2006

Liebe Kolleginnen und Kollegen!

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WICHTIG !! Im Auftrag von Prof. Likar gibt es folgende Änderung:

Bitte ab sofort bei Epiduralblockaden und CT-gezielten Blockaden anstelle von Urbason „Dexabene" verwenden.

Folgende Dosierung:

HWS-Blockade:

Statt Urbason 64 mg Dexabene 12 mg

Bucain 0,25 % 2,5 ml + Dexabene 12 mg (3 ml) + 4,5 ml NaCl 0,9 %

LWS-Blockade:

Statt Urbason 64 mg Dexabene 12 mg

Bucian 0,25 % 5 ml + Dexabene 12 mg (3 ml) + 2 ml NaCl ,9 %

CT-Blockaden:

Statt Volon-A-KS 40 mg Dexabene 4 mg

Bucain 0,25 % 2,5 ml + Dexabene 4 mg (1 ml) + KM, insgesamt ca. 3,5 ml.

Die restlichen Interventionen können weiterhin mit Urbason durchgeführt werden.

Danke!

Mit lieben Grüßen

Dr. Markus Egger

Toxicity and glucocorticoids

• The chances of neurotoxicity are extremely small when the corticosteroids correctly enter the epidural space

• It is still unclear whether leaving out preservatives and solvents for the purposes of preventing arachnoiditis or vascular complications outweighs the infection risk in the event of accidental contamination

• There are currently no indications that one type of particulate corticosteroid is safer

• It is recommended to inject a local anesthetic prior to a transforaminal corticosteroid injection. Pay attention to any neurological symptoms occurring within a minute after the injection. The exact value in tracking down an accidental intravascular or intrathecal injection at the lumbar level is unclear

• It is recommended to use the lowest possible dose of a glucocorticosteroid for the epidural injection. Considering effectiveness, this amounts to 40 mg for methylprednisolone acetate, 10 to 20 mg for triamcinolone acetate, and 10 mg (10 mg/mL) for dexamethasone phosphate

Van Boxem K. et al.; Safe Use of Epidural Corticosteroid Injections: Recommendations of the WIP Benelux Work Group; Pain Practice; 2018.

Place of dexamethasone

• In the event of contrast allergy or above the L3 level, transforaminal corticosteroid injections should always be done with dexamethasone.

• **Both particulate corticosteroids and dexamethasone are permitted for lumbar transforaminal infiltrations at level L3 or lower. As we currently have too little information on the long-term safety of dexamethasone and the availability of safe formulations is limited (in the Benelux), this cannot be required at the moment**

•There are currently no arguments in favor of switching to dexamethasone for interlaminar epidural infiltration

Van Boxem K. et al.; Safe Use of Epidural Corticosteroid Injections: Recommendations of the WIP Benelux Work Group; Pain Practice; 2018.

Cervical subacute cervico-brachialgia

•**Cervical Interlaminar level: preferably at C7–T1, and no higher than C6–7**
• A radiological assessment must be performed, including MRI (or CT as a second option) to rule out any red flags before conducting a cervical epidural infiltration. It is also recommended to assess the available cervical epidural space at the cervical level first
• **Negative recommendation for cervical transforaminal injection of particulate corticosteroids. Although not recommended, there are currently no counterarguments for the cervical transforaminal administration of dexamethasone**
• For the interlaminar injection, no vascular complications are reported and a particulate corticosteroid (or dexamethasone 10 mg) can be used. If required, 0.9% NaCl or lidocaine 1% to 2% can be used for dilution
•**Limit the total volume to be injected to no more than 4 mL**

Van Boxem K. et al.; Safe Use of Epidural Corticosteroid Injections: Recommendations of the WIP Benelux Work Group; Pain Practice; 2018.

Place of radiology

• **Fluoroscopy with contrast is compulsory for the interlaminar technique at the cervical level and recommended at the lumbar level. At the very least, a latero-lateral recording must be done; there are arguments to perform this procedure in the prone position as the visualization of the course of the contrast medium is better in an anteroposterior recording. No superior safety has been determined for any one technique (seated vs. prone)**

• With the transforaminal technique, fluoroscopy with contrast under real-time imaging is also compulsory. Digital subtraction angiography is optional

• Despite fluoroscopy with contrast administration/digital subtraction angiography, an accidental intravascular injection cannot be fully ruled out

Lumbar subacute lumbosacral radicular syndrome

• The transforaminal approach is recommended via the “safe triangle,” with a clear preference to keep the needle tip posterior in the neuroforamen. Particulate corticosteroids may only be transforaminally injected at level L3 or lower; this limitation does not apply for dexamethasone

• After an accidental intrathecal puncture, the needle must be placed in a different location. Once correct epidural positioning has been confirmed, a glucocorticosteroid may be injected

Van Boxem K. et al.; Safe Use of Epidural Corticosteroid Injections: Recommendations of the WIP Benelux Work Group; Pain Practice; 2018.

Epidural volume

• Limit the cervical interlaminar and (lumbar) transforaminal volume to 4 mL (or less if it is too painful) and inject sufficiently slowly

Sterility

• Chlorhexidine/alcohol is the first choice as skin disinfectant for neuro-axial procedures. Allow sufficient time for the skin to dry and avoid contact with sterile material such as needles, syringes, or medication

What to do in the event of a suspected neurological complication

•In case of unexpectedly prolonged sensory or motor block, the reappearance of sensory or motor symptoms after an initial disappearance or the occurrence of a nerve block outside the expected distribution area, an MRI is recommended within 3 hours:

- MRI negative: new MRI after 24 hours
- MRI shows epidural hematoma or abscess: urgent decompression
- MRI shows spinal cord ischemia: maintain high-normal blood pressure and normoglycemia, consider drainage of cerebrospinal fluid

Van Boxem K. et al.; Safe Use of Epidural Corticosteroid Injections: Recommendations of the WIP Benelux Work Group; Pain Practice; 2018.

It is therefore recommended to use short-acting and low-dose local anesthetics in epidural mixtures to enable a rapid neurological evaluation. Lidocaine is therefore preferred

Miscellaneous

• The use of needles with extension lines is recommended for transforaminal injections. It is recommended rinsing with a fluid to avoid any unnecessary air

• Excessive sedation must be avoided. Preferably a patient should be able to respond appropriately during a procedure

• The routine use of prophylactic antibiotics in case of (accidental) disc puncture is not recommended; however, this may be considered for high-risk patients

• Collaborations: establish agreements with emergency services, the radiology and neurology departments, and back surgeons as to what is to be done in the event of a suspected neurological complication after epidural corticosteroids

Van Boxem K. et al.; Safe Use of Epidural Corticosteroid Injections: Recommendations of the WIP Benelux Work Group; Pain Practice; 2018.

Table 4. Summary of Positive Recommendations for the Prevention of Neurological Complications

Transforaminal lumbar
• Evaluate MRI or CT to determine the level and to rule out red flags
• Use needles with extension lines and flush these beforehand with contrast (or lidocaine)
• Under fluoroscopic control, enter the needle tip into the posterior part of the neuroforamen
• Anteroposterior image: control contrast pattern under real-time imaging. Consider digital subtraction angiography if the image is unclear
• Inject lidocaine 1 mL 1% to 2% Wait 1 minute
• Particulate corticosteroids (only L3 or lower) or dexamethasone 10 mg
Interlaminar cervical
• Evaluate MRI (CT) beforehand
• Infiltration level: preferably at C7–T1, and no higher than C6–7
• Always use fluoroscopy with at least 1 latero-lateral view or contralateral oblique and contrast (except in the event of contrast allergy)
• Use lidocaine 1% to 2% as local anesthetic
• Limit the volume to 4 mL
Contrast allergy
• Interlaminar: carry out infiltration without contrast
• Transforaminal: only use dexamethasone 10 mg

Van Boxem K. et al.; Safe Use of Epidural Corticosteroid Injections: Recommendations of the WIP Benelux Work Group; Pain Practice; 2018.

Table 2. 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	

Jan Van Zundert et at, Editorial Evidence-Based Interventional Pain Medicine According to Clinical Diagnoses; Pain Practice 2011 Volume 11, Issue 5, 2011 423-429

Sacroiliac joint pain		
Therapeutic intra-articular injections with corticosteroids and local anesthetic	1 B +	Recommended
RF treatment of rami dorsales and rami laterales	2 C +	To be considered
Pulsed RF treatment of rami dorsales and rami laterales	2 C +	To be considered
Cooled RF treatment of the rami laterales	2 B +	Recommended
Coccygodynia		
Local injections corticosteroids/local anesthetic	2 C +	To be considered
Intradiscal corticosteroid injections, ganglion impar block, RF ganglion impar, caudal block	0	Study related
Neurostimulation	0	Study related
Discogenic low back pain		
Intradiscal corticosteroid administration	2 B –	Negative recommendation
RF treatment of the discus intervertebralis	2 B ±	To be considered
Intradiscal electrothermal therapy	2 B ±	To be considered
Biacuplasty	0	Study related
Disctrode	0	Study related
RF of the ramus communicans	2 B +	Recommended
Complex regional pain syndrome		
Intravenous regional block guanethidine	2 A –	Negative recommendation
Ganglion stellatum (stellate ganglion) block	2 B +	Recommended
Lumbar sympathetic block	2 B +	Recommended
Plexus brachialis block	2 C +	To be considered
Epidural infusion analgesia	2 C +	To be considered
Spinal cord stimulation	2 B +	Recommended in specialized centers
Peripheral nerve stimulation	2 C +	To be considered in specialized centers

Jan Van Zundert et at, Editorial Evidence-Based Interventional Pain Medicine According to Clinical Diagnoses; Pain Practice 2011 Volume 11, Issue 5, 2011 423-429

Visceral pain due to pelvic tumors		
Neurolytic plexus hypogastricus block	2 C +	Recommended
Perineal pain due to pelvic tumors		
Intrathecal phenolization of lower sacral roots of cauda equina	0	Study related
Spinal pain due to vertebral compression fractures		
Vertebroplasty	2 B +	Recommended
Kyphoplasty	2 B +	Recommended
Chronic refractory angina pectoris		
Spinal cord stimulation	2 B +	Recommended in specialized centers
Ischemic pain in the extremities and Raynaud's phenomenon		
Ischemic vascular disease		
Sympathectomy	2 B ±	To be considered
Spinal cord stimulation	2 B ±	To be considered in specialized centers
Raynaud's phenomenon		
Sympathectomy	2 C +	To be considered
Pain in chronic pancreatitis		
RF nervus splanchnicus block	2 C +	To be considered
Spinal cord stimulation	2 C +	To be considered in specialized centers

Jan Van Zundert et at, Editorial Evidence-Based Interventional Pain Medicine According to Clinical Diagnoses; Pain Practice 2011 Volume 11, Issue 5, 2011 423-429

Stellenwert der intrathekalen Schmerztherapie – Konsensuspapier

R. Likar[7], W. Ilias[6], H. Kloimstein[5], A. Kofler[4], HG Kress[3], J. Neuhold[2], MM Pinter[1] und MC Spendel[7]

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DER SCHMERZ 2007

Indikation für intrathekale Applikation

Consensus Statement

Wirkungen

Nebenwirkungen

Indikationen für intrathekale Therapie

SCS

Pumpen

Rückenschmerz
Arachnoiditis
Plexusläsion

Radikolopathien
Neuralgien
Periphere Ischämie
Angina pectoris
CRPS
Postzosterneuralgien
Phantomschmerz
Neuropathien

diffuser Tumorschmerz
Osteoporose
viszerale Schmerzen
Kopfschmerz
Neuropathischer Schmerz


Das Stufenschema der Schmerztherapie
Körperliches Training
Meditation und Entspannungstechniken
Nichtopioide Analgetika
Adjuvante Medikation (Antidepressiva, Antikonvulsiva)
Physikalische Rehabilitation
Somatische und sympathische Nervenblockade
Kognitive und Verhaltens-Therapien
Orale Opioidmedikation
Epidurale Elektrostimulation (SCS)
Intrathekale Analgesie
Neurodestruktive Verfahren

Schmerzbehandlungsplan

- Übungsprogramme
- Biofeedback
- Entspannungsverfahren
- Nicht-Opioid-Analgetika
- Co-Analgetika
- Physiotherapie
- Rehabilitationstraining
- Kognitive Verhaltenstherapie
- somatische, sympathische Nervenblockaden
- Orale Opioide/subkutan
- Rückenmarksnahe Stimulation
- intraspinale Infusionsanalgesie
- neurodestruktive Verfahren

Generelle Einschlusskriterien für die intrathekale Schmerztherapie

- **Therapieresistenz trotz ausgereizter medikamentöser Therapie**
- **Nebenwirkungen der oralen/systemischen medikamentösen Therapie nicht vertretbar**
- **Chirurgische Sanierung der Schmerzursache ist nicht möglich**
- **Multimorbidität ?**
- **Schlechte Lebensqualität: dazu gehören Schmerz, Angst, gastrointestinale Probleme, Müdigkeit, Bewegungseinschränkungen, Depression, die durch die Therapie verbesserbar ist**
- **hohe medikamentöse Therapiekosten**

RECOMMENDATIONS OF THE PACC TO REDUCE MORBIDITY AND MORTALITY

General Recommendations

1. The use of IDDS to treat chronic pain should be part of a treatment algorithm that involves the failure of more conservative attempts at treatment. IDDS should be considered prior to other options when unacceptable side-effects or lack of efficacy is established.

2. The use of IDDS should be based on an analysis of safety, efficacy, a goal of economic neutrality and appropriateness for the individual patient. These factors have been described as the S.A.F.E. principles.(safety,appropriateness,fiscal neutrality,efficacy)

3. Spinal cord stimulation (SCS), peripheral nerve stimulation (PNS), and hybrids of both SCS and PNS should be considered inappropriate candidates prior to considering an IDDS.

4. Psychological evaluation and stability should be confirmed prior to proceeding with an IDDS in noncancer patients.

Portenoy RK, Hassenbusch SJ. Polyanalgesic Consensus Conference 2000. J Pain Symptom Manage 2000;20:S3; Krames E, Poree L, Deer T, Levy R. Implementing the SAFE principles for the development of pain medicine therapeutic algorithms that include neuromodulation techniques. Neuromodulation 2009;12:104–113;Deer TR.A critical time for practice change in the treatment continuum:we need to reconsider the role of pumps in the patient care algorithm. Pain Med 2010;11:987– 989; Deer TR, Smith HS, Cousins M et al. Consensus guidelines for the selection and implantation of patients with non-cancer pain for intrathecal drug delivery. Pain Physician 2010; 13:E175–E213.

Vorbereitung auf die Wirksamkeitsprüfung:

- **Schmerzanamnese, bisherige Medikation**
- **Funktionsbeurteilung (subjektiv und objektiv)**
- **Psychologische/psychiatrische Evaluierung**
- **Lokalbefund am geplanten Insertionsort (WS, Abdomen, eventl. Röntgen, CT/MRI)**
- **Ausschluss von Kontraindikationen (Infektion, Gerinnung etc.)**

Schmerzpumpenplan

- **Neurologische, neurophysiologische, neurochirurgische und radiologische Abklärung**
- **Psychiatrische, psychologische und soziökonomische Evaluierung**
- **Multiinterdisziplinäre Entscheidung für spinale Testphase**
- **Durchführung einer einfach blinden Testphase (Singleshot bzw. kontinuierlich mit intrathekalen Katheter und Port). In Ausnahmefällen placebokontrollierte Testphase.**

Prager JP. Spine 2002; 27(22);2593-2605

Table 1. Hierarchy of Studies by the Type of Design (U.S. Preventive Services Task Force, Ref [7]).

Evidence level	Study type
I	At least one controlled and randomized clinical trial, properly designed
II-1	Well-designed, controlled, nonrandomized clinical trials
II-2	Cohort or case studies and well designed-controls, preferably multicenter
II-3	Multiple series compared over time, with or without intervention, and surprising results in noncontrolled experiences
III	Clinical experience-based opinions, descriptive studies, clinical observations or reports of expert committees.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks, International Neuromodulation Society, 2017, 20:155-176.

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Table 2. Meaning of Recommendation Degrees (U.S. Preventive Services Task Force, Ref [7]).

Degree of recommendation	Meaning
A	Highly recommended (good evidence that the measure is effective and benefits outweigh the harms)
B	Recommended (at least, moderate evidence that the measure is effective and benefits exceed harms)
C	Neither recommend nor advise (at least moderate evidence that the measure is effective, but benefits are similar to harms and a general recommendation cannot be justified)
D	Not advisable (at least moderate evidence that the measure is ineffective or that the harms exceed the benefits)
I	Insufficient, low quality, or contradictory evidence; the balance between benefit and harms cannot be determined.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks, International Neuromodulation Society, 2017, 20:155-176.

Table 3. Strength of Consensus.

Strength of consensus	Definition*
Strong	>80% consensus
Moderate	50–79% consensus
Weak	<50% consensus

*Quorum defined as 80% of participants available for vote.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks, International Neuromodulation Society, 2017, 20:155-176.

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Table 4. Polyanalgesic Consensus Conference (PACC) Evidence and Recommendations on Intrathecal Therapy (3).

Statement	Evidence level	Recommendation grade	Consensus strength
Intrathecal therapy should be utilized for active cancer-related pain.	I for opioids; I for ziconotide	A	Strong
Intrathecal therapy should be utilized for noncancer-related pain.	III-2 for opioids; II-3 for opioids in combination with bupivacaine; I for ziconotide	B	Strong

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks, International Neuromodulation Society, 2017, 20:155-176.

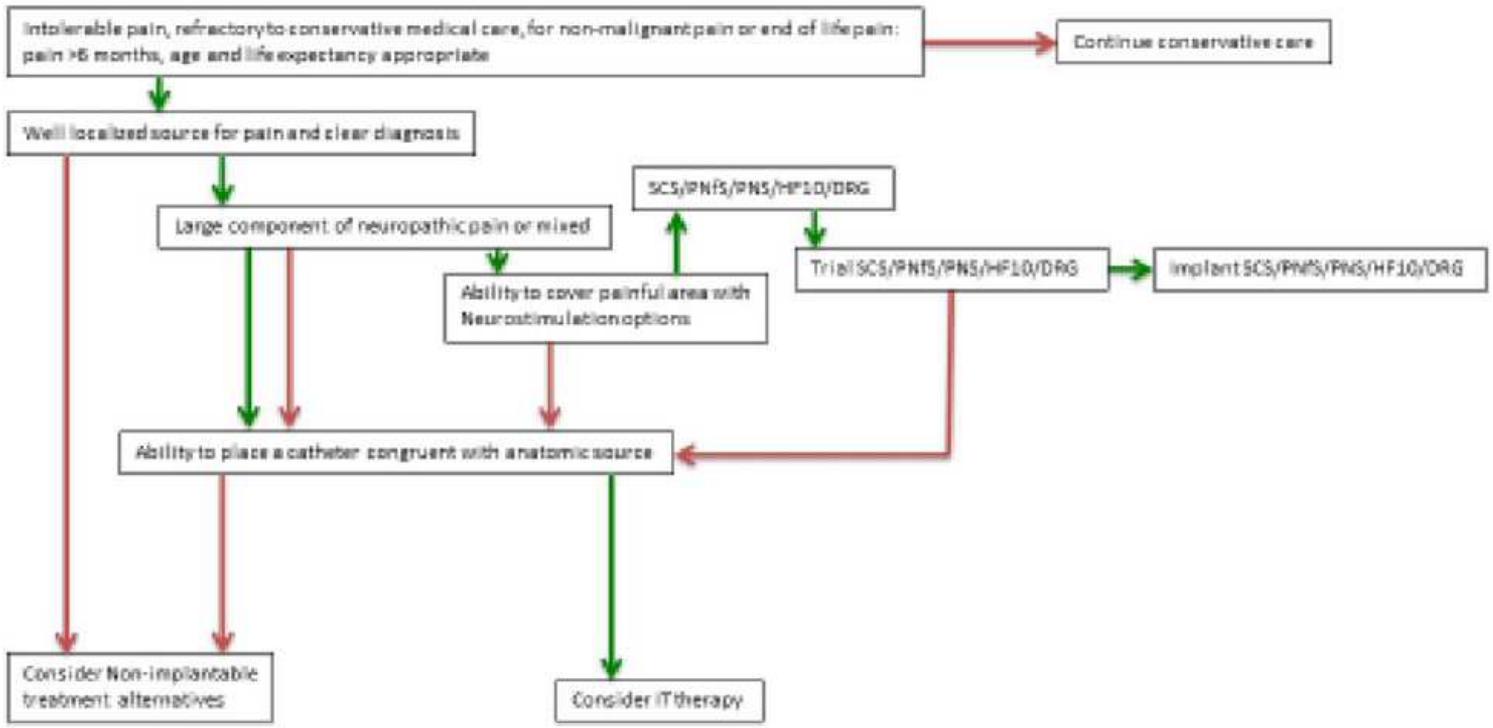

Figure 2. Algorithm for placement within the pain care algorithm for noncancer or non-end-of-life pain. DRG, dorsal root ganglion; HF10, high frequency stimulation; PNfS, peripheral nerve field stimulation; PNS, peripheral nerve stimulation; SCS, spinal cord stimulation. Green arrows indicate affirmation or positive response; red arrows signify negative response.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practice and Guidelines, International Neuromodulation Society, 2017, 20:96-132

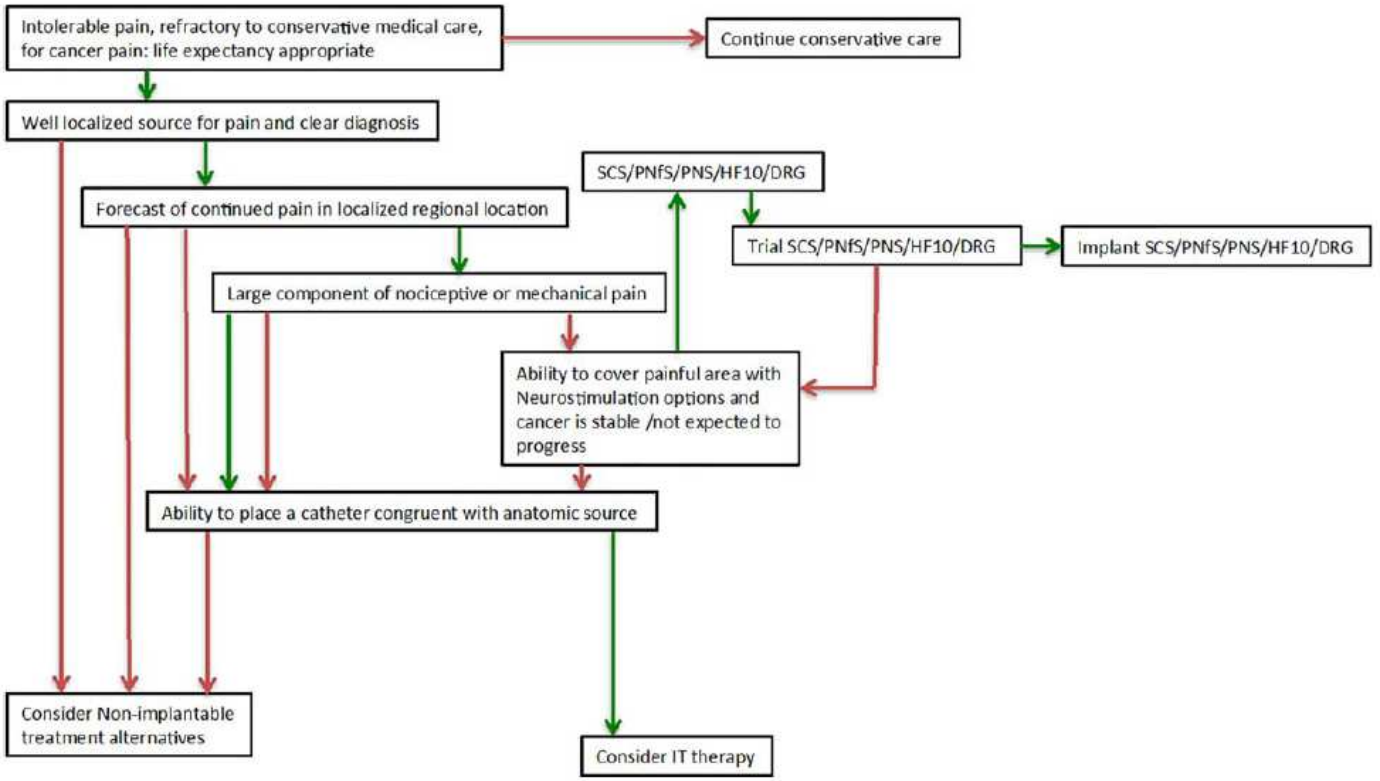

Figure 3. Pain care algorithm for cancer-related pain. DRG, dorsal root ganglion; HF10, high frequency stimulation; PNfS, peripheral nerve field stimulation; PNS, peripheral nerve stimulation; SCS, spinal cord stimulation. Green arrows indicate affirmation or positive response; red arrows signify negative response.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practice and Guidelines, International Neuromodulation Society, 2017, 20:96-132

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Table 6. Disease Indications for Intrathecal Drug Delivery.

- Axial neck or back pain; not a surgical candidate
  - Multiple compression fractures
  - Discogenic pain
  - Spinal stenosis
  - Diffuse multiple-level spondylosis
- Failed back surgery syndrome
- Abdominal/pelvic pain
  - Visceral
  - Somatic
- Extremity pain
  - Radicular pain
  - Joint pain
- Complex regional pain syndrome (CRPS)
- Trunk pain
  - Postherpetic neuralgia
  - Post-thoracotomy syndromes
- Cancer pain, direct invasion and chemotherapy related
- Analgesic efficacy with systemic opioid delivery complicated by intolerable side effects

Persistent spinal pain syndrome (failed back surgery syndrome)

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practice and Guidelines, International Neuromodulation Society, 2017, 20:96-132

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Table 5. Polyanalgesic Consensus Conference (PACC) Evidence and Recommendations for Intrathecal Opioid Therapy and Risk Mitigation.

Statement	Evidence level	Recommendation grade	Consensus strength
Intrathecal opioid delivery is a relatively safe and effective method for chronic infusion to treat cancer and noncancer-related pain.	II-2	A	Strong
Respiratory depression can occur with intrathecal opioid administration, and careful dosing is critical to avoid this complication.	II-3	B	Strong
Concurrent use of sedative medications in patients receiving opioids should be minimized or avoided.	II-2	A	Strong
Single-shot trialing with intrathecal opioids is a safe strategy, with an observation period of at least six hours, in an outpatient or inpatient site of service. Outpatients should have continued observation after discharge with a responsible adult.	II-3	B	Moderate
Endocrinopathic side effects are a consequence of intrathecal opioids, and preoperative surveillance and monitoring is recommended.	II-3	A	Strong
Lower extremity edema can occur by an unknown mechanism and can be mitigated by transition to a more lipophilic opioid.	III	C	Strong
Urinary retention is a complication that may be mitigated by the administration of parasympathomimetic medications.	III	C	Moderate
Nausea, vomiting, and pruritus are consequences of intrathecal delivery of opioids and, although they typically resolve with time, should be considered when employing opioids for chronic infusion.	III	C	Moderate
Consideration of patient candidacy for intrathecal opioid therapy is crucial, and evaluation should consider the pain generator(s), patient age, location and type of pain, previous opioid exposure, and patient comorbidities (3).	II-2	B	Strong

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks, International Neuromodulation Society, 2017, 20:155-176.

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Table 7. Polyanalgesic Consensus Conference (PACC) Evidence and Recommendations on Intrathecal Clonidine Therapy and Risk Mitigation.

Statement	Evidence level	Recommendation grade	Consensus strength
Clonidine is recommended as an adjuvant for both nociceptive and neuropathic pain management with intrathecal infusion.	II-3	B	Strong
Clonidine dosing can cause cardiac effects and patients should be monitored during titration.	II-2	A	Strong
Withdrawal from intrathecal clonidine can cause hypertensive crisis, and reinitiating therapy or systemic dosing is critical for treatment and supportive care.	II-3	B	Strong

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks, International Neuromodulation Society, 2017, 20:155-176.

Table 24. Recommendations Regarding Intrathecal Clonidine Treatment by the PACC Using USPSTF Criteria.

Statements	Evidence levels	Recommendation strength	Consensus strength
Intrathecal clonidine in CRPS patients decreases pain scores over time as well as allodynia, hyperalgesia, and mean arterial blood pressure.	I	A	Strong
Clonidine increases analgesia duration and decreases morphine use in the acute postoperative setting.	II-2	B	Strong
Clonidine may precipitate hypotension in patients with baseline hypertension.	II-3	B	Strong
Ziconotide concentration decreases over time when mixed with clonidine.	II-3	B	Strong

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practice and Guidelines, International Neuromodulation Society, 2017, 20:96-132

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Table 25. Recommendations Regarding Intrathecal Baclofen Treatment by the PACC Using USPSTF Criteria.

Statement	Evidence level	Recommendation grade	Consensus strength
Baclofen should be considered an intrathecal medication for use to treat spasticity.	II-2	A	Strong
Baclofen can be used as an adjuvant to treat pain.	II-3	B	Moderate
Care regarding mitigating withdrawal from baclofen is suggested.	II-2	A	Strong
Ancillary resources regarding physical therapy to aid in titration and assessment when employing baclofen is recommended.	III	C	Moderate
Using bolus or flex dosing strategies to improve spasticity demonstrates promise.	II-3	B	Moderate

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practice and Guidelines, International Neuromodulation Society, 2017, 20:96-132

PACC - Trailing

Table 4. Does Trialing Predict Therapy Outcome? Recommendations by the Polyanalgesic Consensus Conference (PACC).

Statements	Evidence level	Recommendation strength	Consensus level
A trial should be considered before initiating IT drug delivery for noncancer pain.	II-3	B	moderate
A trial is not a necessity before initiating IT drug delivery for cancer pain.	III	I	moderate
If a trial is performed, delivery of the medication within the IT space is an acceptable method.	II	C	strong
IT trials should be monitored in a safe setting, with due vigilance, appropriate monitoring of the patient, and appreciation for patient comorbidities.	II-3	B	strong
IT ziconotide trials should be monitored in a safe setting, with due vigilance, and appropriate monitoring of the patient.	II-3	B	strong

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Trailing of Intrathecal Drug Delivery Infusion Therapy, International Neuromodulation Society, 2017, 20:133-154.

Table 10. Possible Outcomes of Bolus IT Trials.

Outcome	Consideration
Relief without side effects	Successful trial, medication and dose considered for chronic delivery
Relief with side effects	May be appropriate IT medication; consider reduction in medication dose for retrial or medication switch
No relief, side effects noted	Medication switch recommended for retrial
No relief, no side effects	Consider retrial with higher dose or medication switch

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Trailing of Intrathecal Drug Delivery Infusion Therapy, International Neuromodulation Society, 2017, 20:133-154.

Table 5. Recommendations for Application of Intrathecal Therapy vs. Neurostimulation by the NACC Using USPSTF Criteria.

Statement	Evidence level	Recommendation grade	Consensus level
Intrathecal therapy should be considered within the same line as neurostimulation strategies to treat noncancer-related pain.	III	C	Moderate
Intrathecal therapy should be considered after neurostimulation strategies to treat noncancer-related pain if the pain is isolated and unlikely to spread.	III	I	Strong
Intrathecal therapy should be considered before neurostimulation therapy for active cancer-related pain that is mechanical and likely to spread.	III	C	Strong

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practice and Guidelines, International Neuromodulation Society, 2017, 20:96-132

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Non-cancer related pain with localized nociceptive and neuropathic pain

Table 16. Noncancer-Related Pain With Localized Nociceptive or Neuropathic Pain.

Line 1A	Ziconotide		Morphine	
Line 1B	Fentanyl		Fentanyl + bupivacaine	
Line 2	Fentanyl + clonidine	Hydromorphone or morphine + bupivacaine	Fentanyl + bupivacaine + clonidine	Bupivacaine
Line 3	Fentanyl + ziconotide + bupivacaine	Morphine or hydromorphone + clonidine	Ziconotide + clonidine or bupivacaine or both	Bupivacaine + clonidine
Line 4	Sufentanil + bupivacaine or clonidine	Baclofen	Bupivacaine + clonidine + ziconotide	
Line 5	Sufentanil + bupivacaine + clonidine		Sufentanil + ziconotide	

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practice and Guidelines, International Neuromodulation Society, 2017, 20:96-132

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Non-cancer pain with diffuse nociceptive and neuropathic pain

Table 18. Noncancer-Related Pain With Diffuse Nociceptive or Neuropathic Pain.

Line 1A	Morphine		Ziconotide*	
Line 1B	Hydromorphone		Morphine or hydromorphone + bupivacaine	
Line 3	Hydromorphone or morphine + clonidine		Fentanyl + bupivacaine	Ziconotide + morphine or hydromorphone
Line 4	Hydromorphone or morphine + bupivacaine + clonidine	Fentanyl + ziconotide	Sufentanil + bupivacaine or clonidine	Ziconotide + clonidine or bupivacaine or both
Line 5	Fentanyl or sufentanil + bupivacaine + clonidine		Sufentanil + ziconotide	Baclofen
Line 6	Opioid + ziconotide + bupivacaine or clonidine			

*Ziconotide should be first choice in patients with >120 morphine equivalents or fast systemic dose escalation, in the absence of history of psychosis.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practice and Guidelines, International Neuromodulation Society, 2017, 20:96-132

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Cancer Pain with localized nociceptive and neuropathic pain

Table 12. Cancer or Other Terminal Condition-Related Pain With Localized Nociceptive or Neuropathic Pain.

Line 1A	Ziconotide			Morphine		
Line 1B	Fentanyl			Morphine or fentanyl + bupivacaine		
Line 2	Hydromorphone	Hydromorphone + bupivacaine		Hydromorphone or fentanyl or morphine + clonidine	Morphine or hydromorphone or fentanyl + ziconotide	
Line 3	Hydromorphone or morphine or fentanyl + bupivacaine + clonidine	Ziconotide + bupivacaine		Ziconotide + clonidine	Hydromorphone or morphine or fentanyl + bupivacaine + ziconotide	Sufentanil
Line 4	Sufentanil + ziconotide	Sufentanil + bupivacaine	Baclofen	Sufentanil + clonidine	Bupivacaine + clonidine + ziconotide	Bupivacaine + clonidine
Line 5	Sufentanil + bupivacaine + clonidine					
Line 6	Opioid* + bupivacaine + clonidine + adjuvants†					

*Opioid (all known intrathecal opioids).
†Adjuvants include midazolam, ketamine, octreotide.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practice and Guidelines, International Neuromodulation Society, 2017, 20:96-132

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Cancer Pain with diffuse nociceptive and neuropathic pain

Table 14. Cancer or Other Terminal Condition-Related Pain With Diffuse Nociceptive or Neuropathic Pain.

Line 1A	Ziconotide			Morphine		
Line 1B	Hydromorphone			Morphine or hydromorphone + bupivacaine		
Line 2	Hydromorphone or morphine + clonidine			Morphine or hydromorphone + ziconotide		
Line 3	Hydromorphone or morphine or fentanyl + bupivacaine + clonidine	Ziconotide + bupivacaine		Ziconotide + clonidine	Hydromorphone or morphine or fentanyl + bupivacaine + ziconotide	Sufentanil
Line 4	Sufentanil + ziconotide	Baclofen	Sufentanil + bupivacaine	Sufentanil + clonidine	Bupivacaine + clonidine + ziconotide	Bupivacaine + clonidine
Line 5	Sufentanil + bupivacaine + clonidine		Sufentanil + bupivacaine + ziconotide		Sufentanil + clonidine + ziconotide	
Line 6	Opioid* + bupivacaine + clonidine + adjuvants†					

*Opioid (all known intrathecal opioids).
†Adjuvants include midazolam, ketamine, octreotide.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practice and Guidelines, International Neuromodulation Society, 2017, 20:96-132

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Table 12. Doses Ranges for IT Bolus Trialing Recommended by the Polyanalgesic Consensus Conference (PACC).

Drug	Recommended dose*
Morphine	0.1–0.5 mg
Hydromorphone	0.025–0.1 mg
Ziconotide	1–5 mcg
Fentanyl	15–75 mcg
Bupivacaine	0.5–2.5 mg
Clonidine	5–20 mcg
Sufentanil	5–20 mcg

*Starting dose of medication in the opioid-naive patient for outpatient bolus delivery should not exceed 0.15 mg morphine, 0.04 mg hydromorphone, or 25 mcg fentanyl.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Trailing of Intrathecal Drug Delivery Infusion Therapy, International Neuromodulation Society, 2017, 20:133-154.

Table 11. Starting Infusion Trial Dosage Ranges for Single Medications Intended for Long-Term IT Delivery Recommended by the Polyanalgesic Consensus Conference (PACC).

Drug	Recommended starting dose*
Morphine	0.1–0.5 mg/day
Hydromorphone	0.01–0.15 mg/day
Ziconotide	0.5–2.4 mcg/day
Fentanyl	25–75 mcg/day
Bupivacaine	0.01–4 mg/day
Clonidine	20–100 mcg/day
Sufentanil	10–20 mcg/day

*Starting doses of continuous IT delivery should be half of the trial dose for opioid-based medications.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Trailing of Intrathecal Drug Delivery Infusion Therapy, International Neuromodulation Society, 2017, 20:133-154.

Table 22. Maximum Concentrations and Daily Doses of Intrathecal Agents as Recommended by PACC 2012 (8) and 2016.

Drug	Maximum concentration	Maximum dose per day
Morphine	20 mg/mL	15 mg
Hydromorphone	15 mg/mL	10 mg
Fentanyl	10 mg/mL	1000 mcg
Sufentanil	5 mg/mL	500 mcg
Bupivacaine	30 mg/mL	15–20 mg*
Clonidine	1000 mcg/mL	600 mcg
Ziconotide	100 mcg/mL	19.2 mcg

*May be exceeded in end-of-life care and complicated cases as determined by medical necessity.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practice and Guidelines, International Neuromodulation Society, 2017, 20:96-132

Intrathekale Analgesie

- **Ziconotid**
  - **N – type VSCC (voltage sensitive calcium –channel) antagonist**
  - **dosisabhängige antihyperalgetische Wirkung**
  - **lineare spinale Pharmakokinetik**
  - **Wirkung reversibel und Fehlen der Organtoxizität**
  - **Tolerabilität wird verbessert mit langsamer Titration**
  - **Keine kumulative Toxizität bei langer Anwendung**
  - **KEINE Toleranz, KEINE Abhängigkeit**
  - **Synergetische Wirkung mit Morphin (KEINE Cross Toleranz)**
  - **Clonidin hat additive Analgesie (Baclofen ?)**

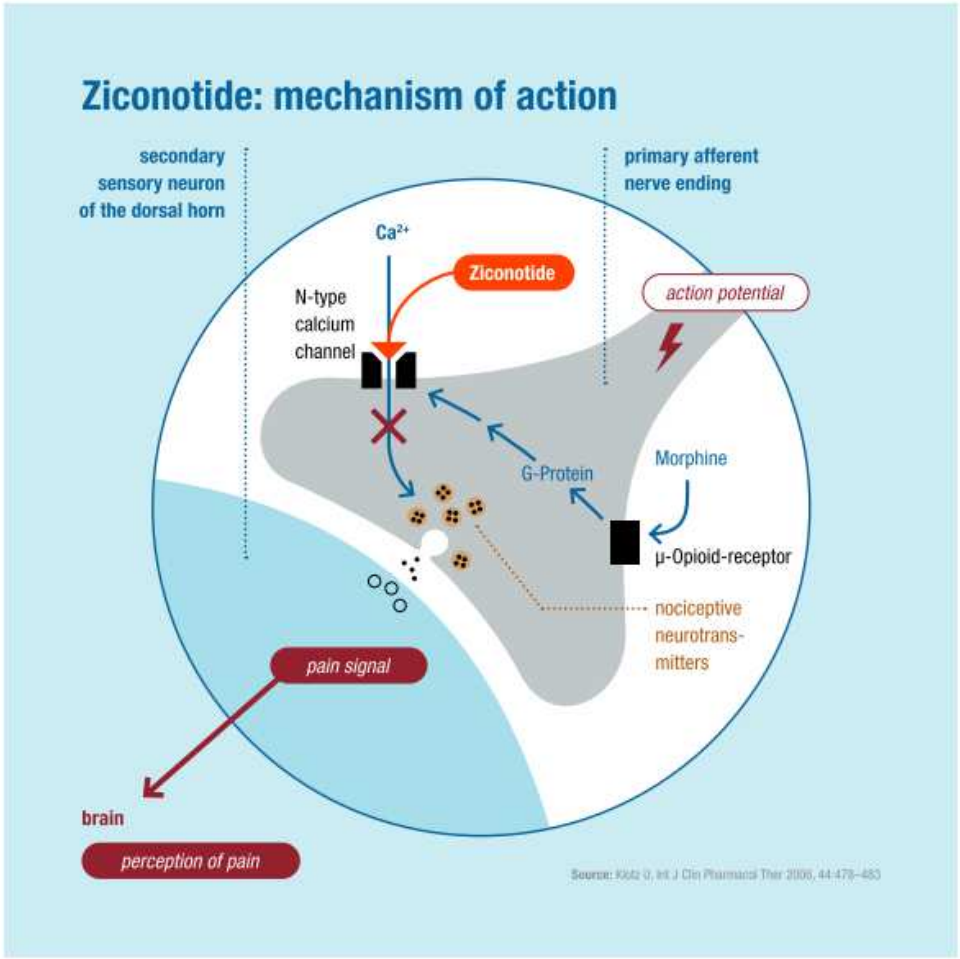

FIGURE 2 Mechanisms of action of ziconotide, a nonopioid analgesic administered intrathecally for chronic, refractory cancer- or noncancer-related pain (modified from Klotz, 2006, with permission)

Matis G. et al.; Intrathecal pain management with ziconotide: Time for consensus?. Brain and Behavior. 2021;11.

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Table 6. Polyanalgesic Consensus Conference (PACC) Evidence and Recommendations on Intrathecal Ziconotide Therapy and Risk Mitigation.

Statement	Evidence level	Recommendation grade	Consensus strength
Ziconotide has no cardiopulmonary side effects when delivered intrathecally.	I	A	Strong
Ziconotide use is contraindicated in patients with a history of psychosis.	I	A	Strong
Ziconotide can cause predictable increases in creatinine kinase and it is recommended to perform baseline laboratory testing prior to initiation, and repeat testing if muscle-related symptoms occur.	I	B	Strong
It is recommended that ziconotide therapy be introduced initially if appropriate (or "first in pump") and not as an adjuvant therapy.	I	A	Strong
Ziconotide needs to be titrated slowly with recommended amounts of less than 1 mcg/day each week.	II	B	Moderate
If side effects occur, and depending on their severity, titration to half the dose with continued infusion may be helpful.	III	C	Strong

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks, International Neuromodulation Society, 2017, 20:155-176.

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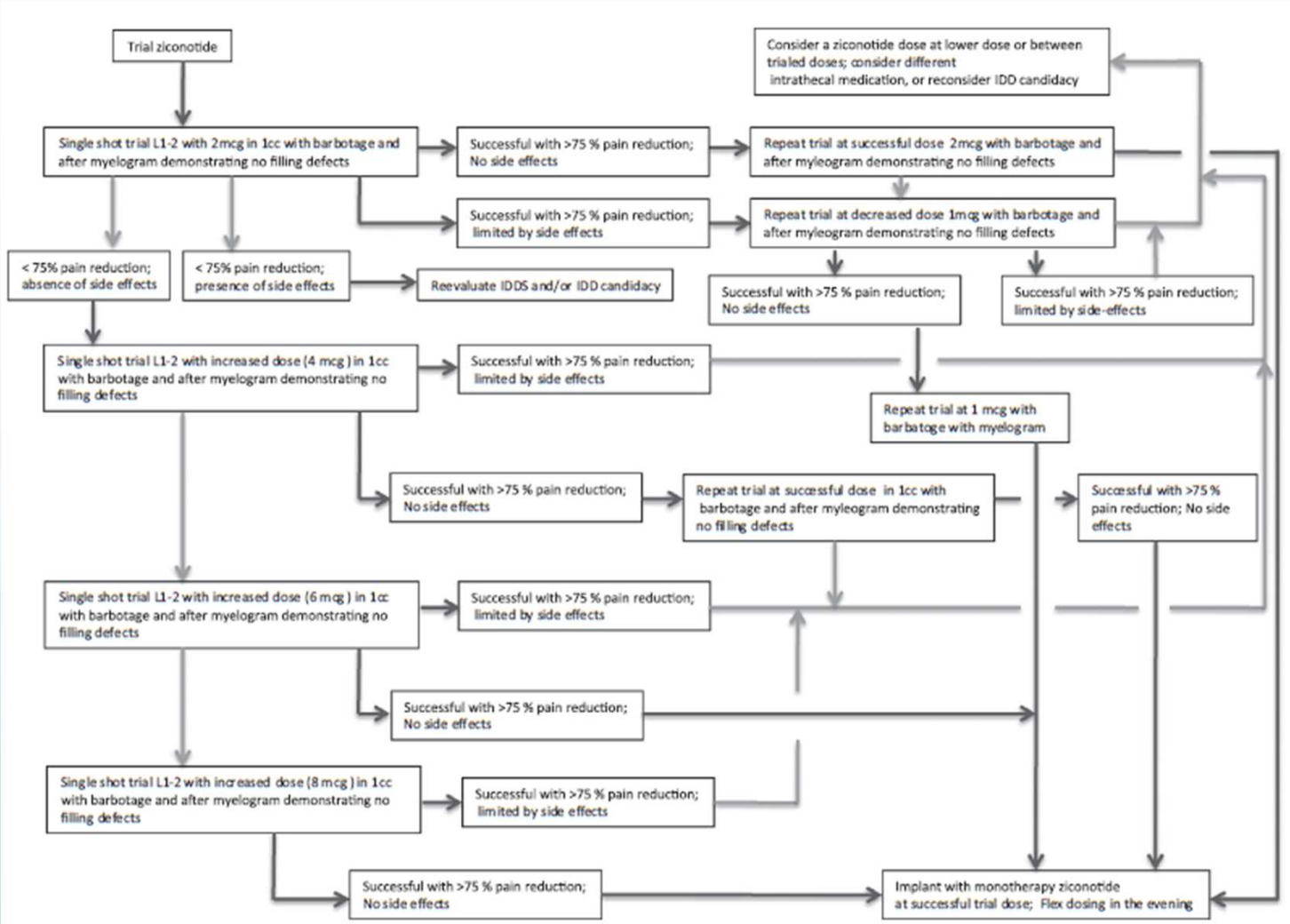

Figure 1. Flow diagram for methodology of trialing ziconotide and subsequent long-term dosing. Dark grey arrows: desired outcome achieved. Light grey arrows signify failure.

Pope Je, Deer TR. Intrathecal Pharmacology Update: Novel Dosing Strategy for Intrathecal Monotherapy Ziconotide on Efficacy and Sustainability. Neuromodulation 2015 Jul;18(5):414-20.

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Parameter	FDA SmPC	EMA SmPC	Other recommendations
Maximum daily dose	19.2 μg/day (0.8 μg/h)	21.6 μg/day	19.2 μg/day (0.8 μg/h)[a]
Starting dose	≤2.4 μg/day (0.1 μg/h)	2.4 μg/day	0.5–1.2 μg/day (0.02–0.05 μg/h)[a]; initiation with ≤ 0.5 μg/day (0.02 μg/h) may be preferred[b]
Dose increments	≤2.4 μg/day (0.1 μg/h)	≤2.4 μg/day	≤0.5 μg/day (≤0.02 μg/h) on a no more than weekly basis[b], according to individual patient's pain reduction and tolerability (Fisher; Prager[b])
Minimum interval between dose increases	≤2–3/week (56–84 h)	24 hr	Titration slow and not more than once weekly[b]
Recommended interval (safety)	≤2.4 μg/day and ≤2–3/week	≥48 hr	Not more than once weekly[b]
Minimum concentration, external pump reservoir	5 μg/ml; change dose rate by adjusting flow rate or solution concentration	5 μg/ml	–
Minimum concentration, internal pump reservoir	25 μg/ml	25 μg/ml	–

Note: **Sources:** (FDA SmPC, 2019); (EMA SmPC, 2019).

[a](Deer, Hayek, Pope, et al., 2017; Deer, Pope, Hayek, Bux, et al., 2017; Deer, Pope, Hayek, Lamer, Veizi, et al., 2017).

[b](Fisher et al., 2005; McDowell & Pope, 2016; Prager et al., 2014).

Matis G. et al.; Intrathecal pain management with ziconotide: Time for consensus?. Brain and Behavior. 2021;11.

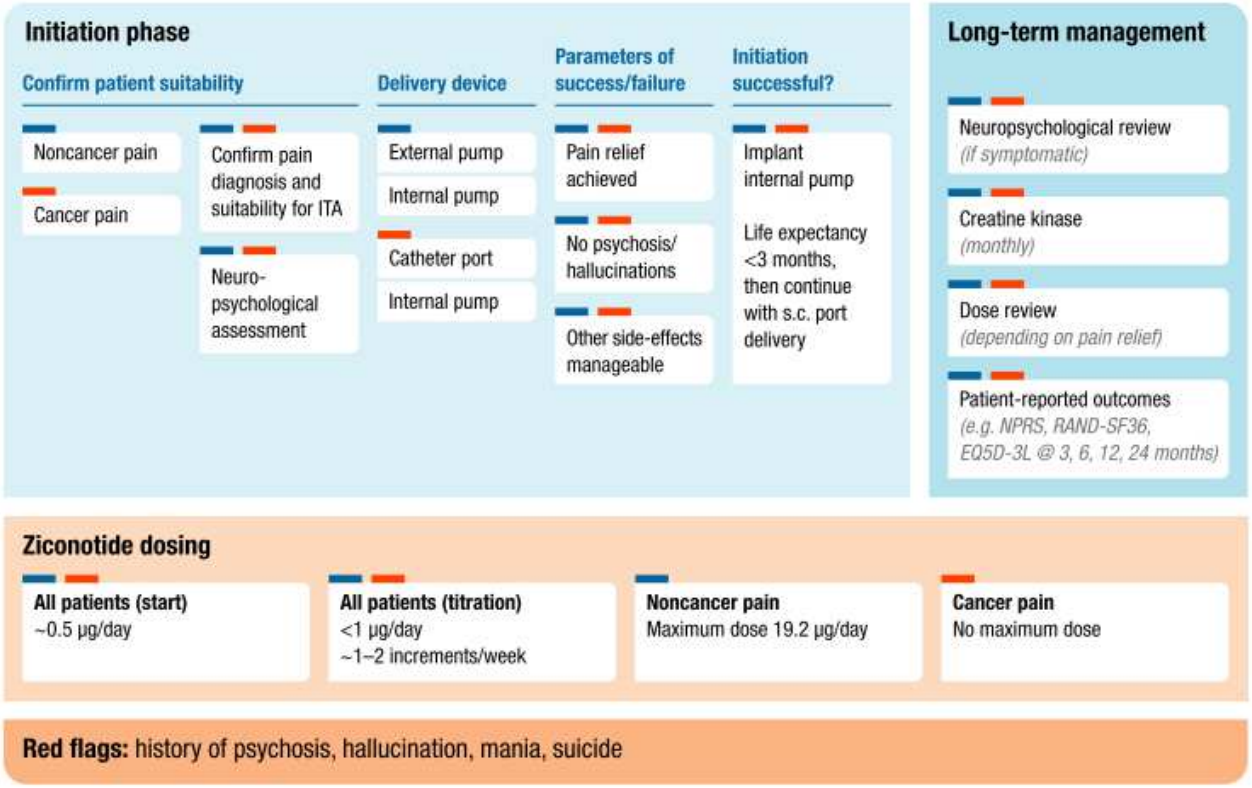


FIGURE 3 Infographic summarizing the key requirements for consideration in of any European Consensus Statement for initiation and long-term management phases of ziconotide intrathecal analgesia (continuous infusion) (ITA). s.c., spinal catheter; NPRS, numeric pain rating scale; RAND-SF36, Research and Development Corporation short-form 36; EQ5D-3L, EuroQol five-dimension three-level

Matis G. et al.; Intrathecal pain management with ziconotide: Time for consensus?. Brain and Behavior. 2021;11.

Empfehlung: Dosierschema Ziconotid		
Dosierschritte	**Empfohlene Dosiserhöhung pro Woche [µg/w]**	**Empfohlene Tagesdosis [µg/d]**
1. Woche	Initialdosis	1,2-2,4
2. Woche	0,6	1,8-3,0
3. Woche	0,6	2,4-3,6
4. Woche	0,6	3-4,2
5. Woche	0,6	3,6-4,8
6. Woche	0,6	4,2-5,4
……	…..	…..
		Max. empf. Tagesdosis 21,6

Die häufigsten aufgetretenen Nebenwirkungen während der Behandlungsdauer (Inzidenz mehr als 10% in jeder Behandlungsgruppe)

Nebenwirkung	Patienten in % Ziconitid (n = 112)	Patienten in % Placebo (n = 108)
Alle Nebenwirkungen	104 (92,9)	89 (82,4)
Schwindel	53 (47,3)	14 (13,0)
Übelkeit	46 (41,1)	33 (30,6)
Körperliche Schwäche	25 (22,3)	13 (12,0)
Schläfrigkeit	25 (22,3)	16 (14,8)
Durchfall	21 (18,8)	18 (16,7)
Verwirrtheit	20 (17,9)	5 (4,6)
Ataxie	18 (16,1)	2 (1,9)
Kopfschmerzen	17 (15,2)	13 (12,0)
Erbrechen	17 (15,2)	14 (13,0)
Abnormer Gang	17 (15,2)	2 (1,9)
Beeinträchtigung der Denkleistung	13 (11,6)	1 (0,9)
Schmerzen	12 (10,7)	8 (7,4)
CK Anstieg	12 (10,7)	4 (3,7)
Juckreiz	9 (8,0)	11 (10,2)
Schlaflosigkeit	7 (6,3)	13 (12,0)

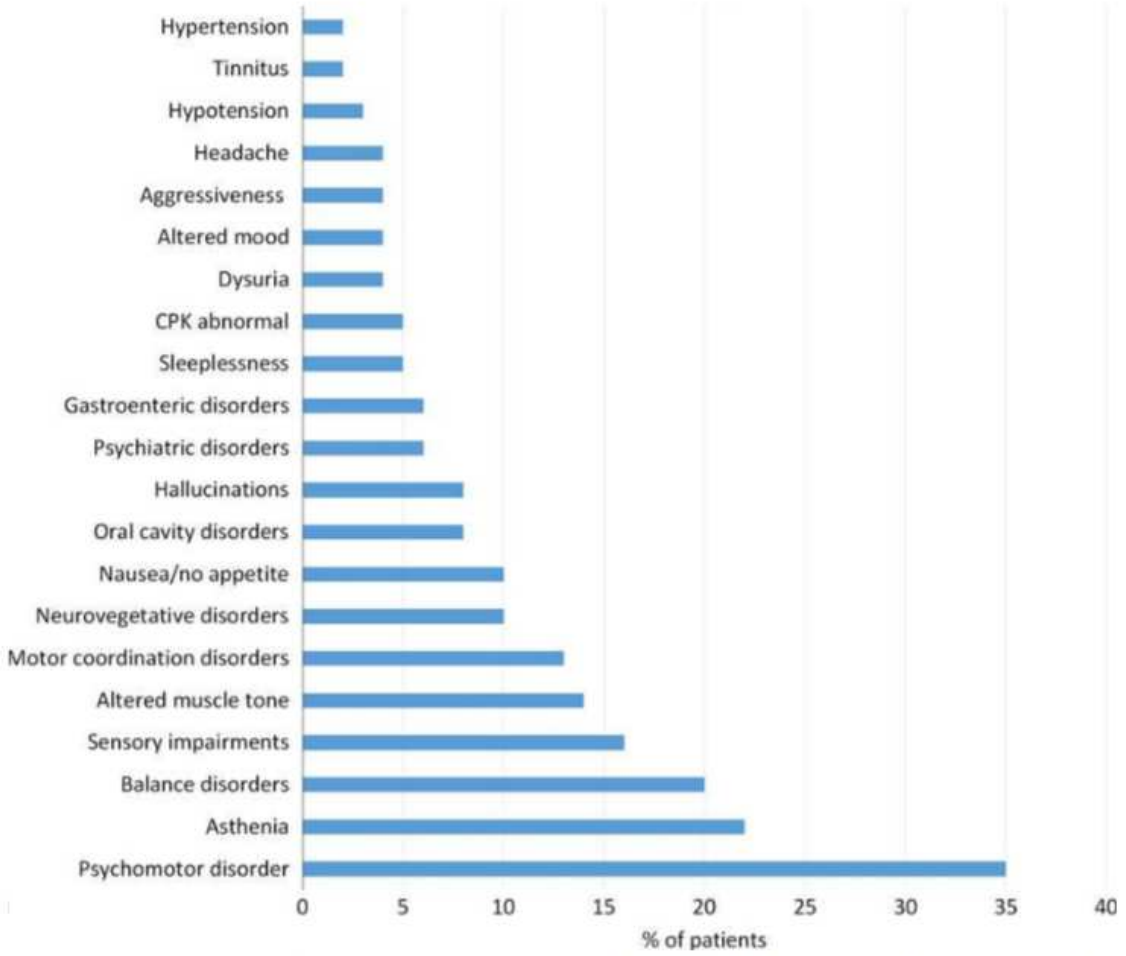


Figure 2 Ziconotide-related adverse events recorded in the Italian registry of ziconotide. Based on tabulated data in (Raffaeli et al., 2011).

Bäckryd E. et al.; Do the potential benefits outweigh the risks? An update on the use of ziconotide in clinical practice; European Journal of Pain; 2018.

Zeit des Auftretens der ersten Nebenwirkungen (nur Ziconotid – behandelte Patienten)

Nebenwirkung	Inzidenz (%)	Tagesmittelwert	Durchschnittsdosis/h
Abnormer Gang (inkl. Ataxie)	34 (30,4)	4,5 (0-24)	0,20 (0,1-4,0)
Abnormes Sehen (inkl. Sehschwäche)	11 (9,8)	8,0 (0-30)	0,20 (0,1-0,6)
Aphasie bzw. Sprachstörung	19 (17,0)	16,0 (4-24)	0,30 (0,1-0,6)
Körperliche Schwäche (inkl. Myasthenie)	27 (24,1)	3,0 (0-30)	0,15 (0,1-0,6)
Verwirrtheit	20 (17,9)	9,5 (0-24)	0,28 (0,1-0,6)
Schwindel	53 (47,3)	3,0 (0-24)	0,15 (0,1-0,6)
Kognitive Beeinträchtigung oder Amnesie	16 (14,3)	7,5 (2-29)	0,16 (0,1-0,6)
Übelkeit (inkl. Erbrechen)	53 (47,3)	4,0 (0,32)	0,13 (0,1-0,4)
Nystagmus	9 (8,0)	8,0 (4-16)	0,16 (0,1-0,7)
Somnolenz	25 (22,3)	4,0 (0-24)	0,11 (0,1-0,5)
Abnormes Denken (inkl. Denkschwierigkeiten)	8 (7,1)	4,0 (0-18)	0,12 (0,1-0,5)
Harnretention	10 (8,9)	7,5 (1-24)	0,15 (0,0-0,6)

Rauck RL et al: A randomized, double-blind, placebo-controlled study of intrathecal ziconotide in adults with severe chronic pain; J Pain Symptom Manage, 2006; 31(5): 393-406

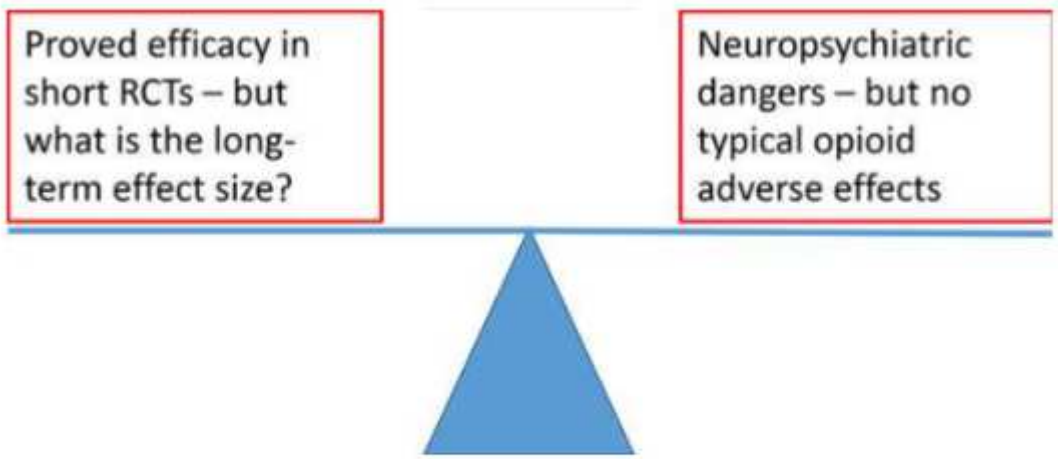


Figure 3 Balancing potential benefits and risks when considering intrathecal ziconotide. RCT, randomized controlled trial.

Bäckryd E. et al.; Do the potential benefits outweigh the risks? An update on the use of ziconotide in clinical practice; European Journal of Pain; 2018.

13-jähriges Mädchen, CRPS Typ 1 – brennender, einschießender, stechender Schmerz; Schmerzskala VAS 5

Allodynie untere Extremität/Fuß

Therapie:

Epiduralkatheter mit Bupivacain und Fentanyl; mit Physikotherapie konnte eine gute Besserung erzielt werden.

10 Monate später neue Verletzung: Verletzung des Sprunggelenks beim Mountainbiken.

Die Patientin entwickelt eine massive Allodynie vom Fuß bis zur Hüfte. Es wurde eine SCS Sonde ohne Erfolg implantiert.

Intrathekaler Katheter für Single Shot Bupivacain Injektionen. Es wurde dann Ziconotid beigefügt (6 µg/Tag).

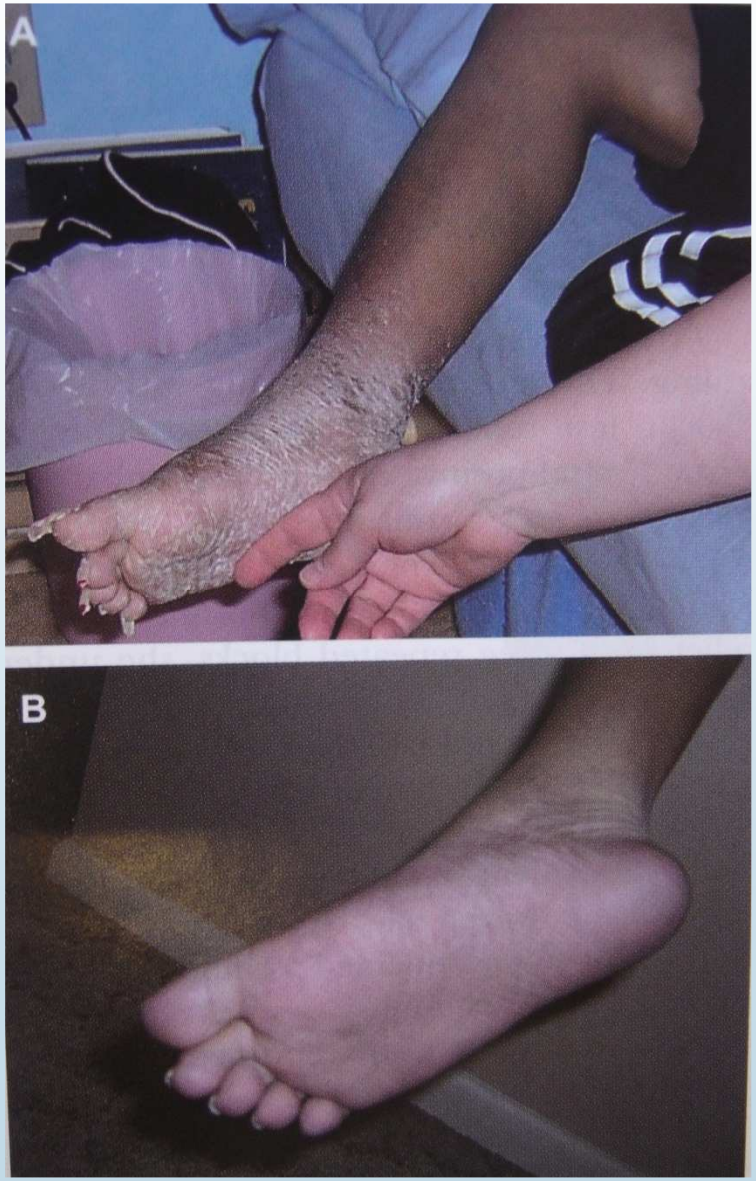
Stanton-Hicks M, Kapural L. An Effective Treatment of Severe Complex Regional Pain Syndrome Type I in a Child Using High Doses of Intrathecal Ziconotide. Letters. Journal of Pain and Symptom Management 2006; 32(6):509-511

Zwei Monate später 24 µg/Tag Ziconotid. Die Patientin konnte wieder gehen, fast kompletter Rückgang der Allodynie und Hyperalgesie.

Zusammenfassung:

Diese Beobachtung lässt vermuten, dass Ziconotid eine effektive Therapie bei CRPS Typ I im Kindesalter.

Stanton-Hicks M, Kapural L. An Effective Treatment of Severe Complex Regional Pain Syndrome Type I in a Child Using High Doses of Intrathecal Ziconotide. Letters. Journal of Pain and Symptom Management 2006; 32(6):509-511



CRPS – angegriffener Fuß vor und nach der Titration von intrathekalem Ziconotid

Stanton-Hicks M, Kapural L. An Effective Treatment of Severe Complex Regional Pain Syndrome Type I in a Child Using High Doses of Intrathecal Ziconotide. Letters. Journal of Pain and Symptom Management 2006; 32(6):509-511

23-jährige Patientin, Kompressionsfraktur Th4

Konstanter, bandförmiger, stechender Schmerz thorakal, einschießender heftiger Schmerz in die Hüfte/Leiste ausstrahlend.

Die Patientin wurde 14 Jahren nach dem Trauma vorgestellt mit einer Therapie mit Oxycodon 300-400 mg täglich. Es wurde ein intrathekaler Versuch mit Hydromorphon bis 1100 µg/d durchgeführt. Die Patientin berichtet über eine partielle Schmerzlinderung im Bereich des Levels der Läsion, aber nicht unterhalb des Levels.

Der Patientin wurde eine intrathekale Pumpe mit Hydromorphon 500 µg/Tag implantiert. Die beste Schmerzlinderung wurde mit Hydromorphon 8,5 mg/Tag in der Kombination mit 400 µg Baclofen erzielt. Es konnte in dieser Zeit keine zufrieden stellende Schmerzlinderung unterhalb des Levels der Läsion erreicht werden.

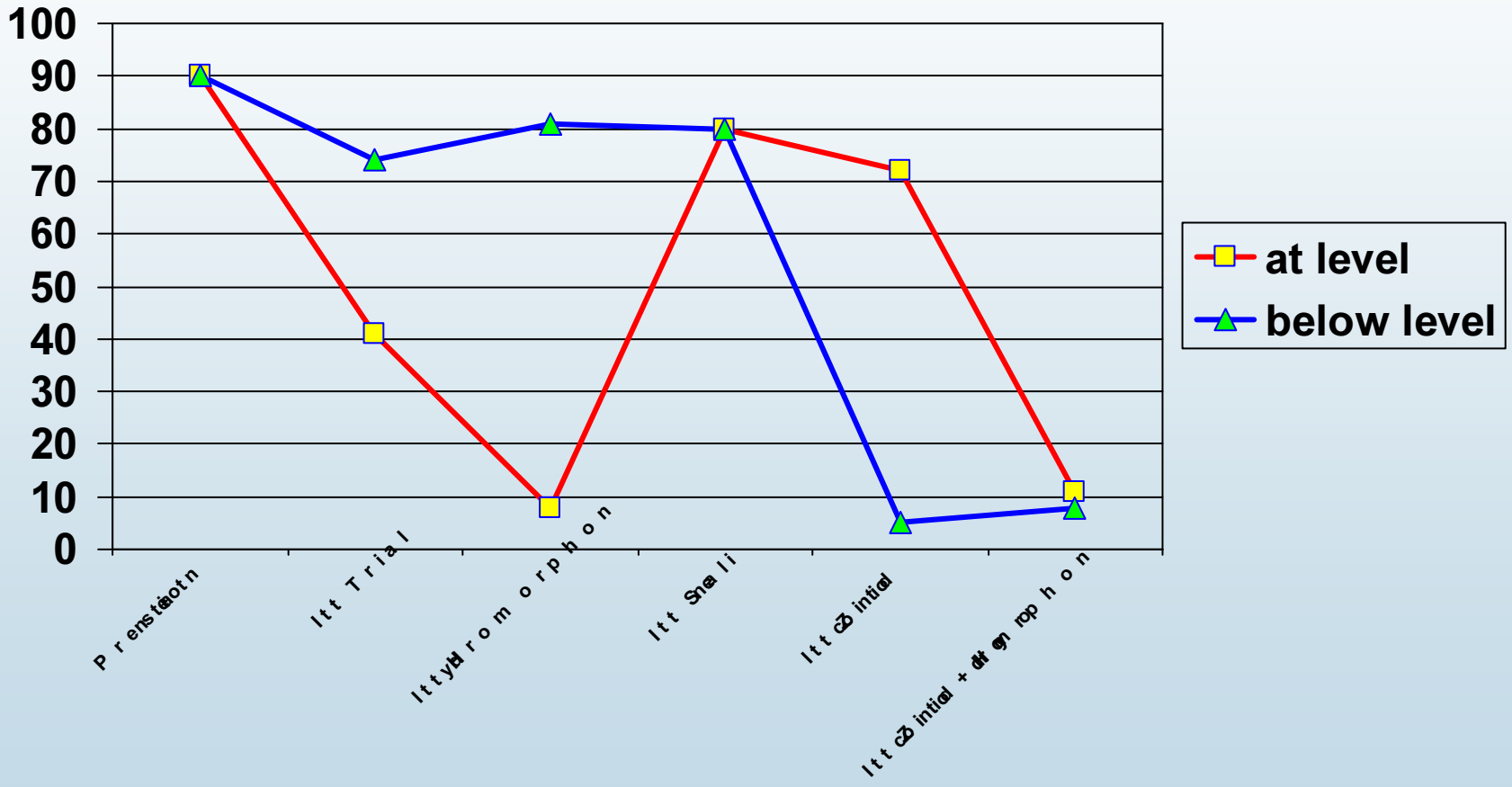
Saulino M. Successful reduction of neuropathic pain associated with spinal cord injury via of a combination of intrathecal hydromorphone and ziconotide: a case report. Spinal Cord 2007; 07:1-4

Die Patientin wurde auf Ziconotid 2,4 µg/Tag ausgetestet. Patientin hat eine gute Schmerzlinderung – im Endeffekt mit 11 µg/Tag Ziconotid und 1,2 mg Hydromorphon täglich.

Schlussfolgerung:

Mit der Kombination Hydromorphon und Ziconotid konnte bei der Patientin mit traumatischer Rückenmarksläsion eine gute Schmerzlinderung erzielt werden.

Saulino M. Successful reduction of neuropathic pain associated with spinal cord injury via of a combination of intrathecal hydromorphone and ziconotide: a case report. Spinal Cord 2007; 07:1-4



Saulino M. Successful reduction of neuropathic pain associated with spinal cord injury via of a combination of intrathecal hydromorphone and ziconotide: a case report. Spinal Cord 2007; 07:1-4

Wechseln von intrathekalen Medikamenten zu Ziconotid

- Die Pat. sollten unbedingt geweant werden von intrathekalen Therapien bevor sie durch Ziconotid ersetzt werden.
- Der Pat. sollte in einem stabilen Zustand sein.
- Clonidin kann stufenweise um ein Zehntel reduziert werden, alle 10 Tage ist dies ohne große Nebenwirkungen möglich.
- Das Weaning von spinalen Opioiden kann in einem Zeitraum von 1 bis 2 Wochen erfolgen bei Ersetzen der intrathekalen Opioide mit oralen Opioiden oder transdermalem System.
- Der Wechsel zu Ziconotid sollte stationär erfolgen oder unter enger Kontrolle als ambulanter Patient.

Kress H. G., Simpson K. H., Marchettini P., Donck A. V., Varrassi G. Intrathecal Therapy: What Has Changed With the Introduction of Ziconotide Pain Pactrice, Volume 9, Issue 5, 2009 338-347

Diese Fälle verdächtigen einen kausale Zusammenhang zwischen Ziconotid und Suizid, Suizidalität bei symptomfreien Patienten mit einer Anamnese der Depression. Deswegen ist eine psychiatrische Evaluierung unvermeidbar vor der und während der Ziconotid-Behandlung.

(EU keine Restriktion – US nicht zugelassen bei Psychosen)

Christoph Maier, Hans-Helmut Gockel; Increased risk of suicide under intrathecal ziconotide treatment? – A warning; Pain 152 (2011) 235-237

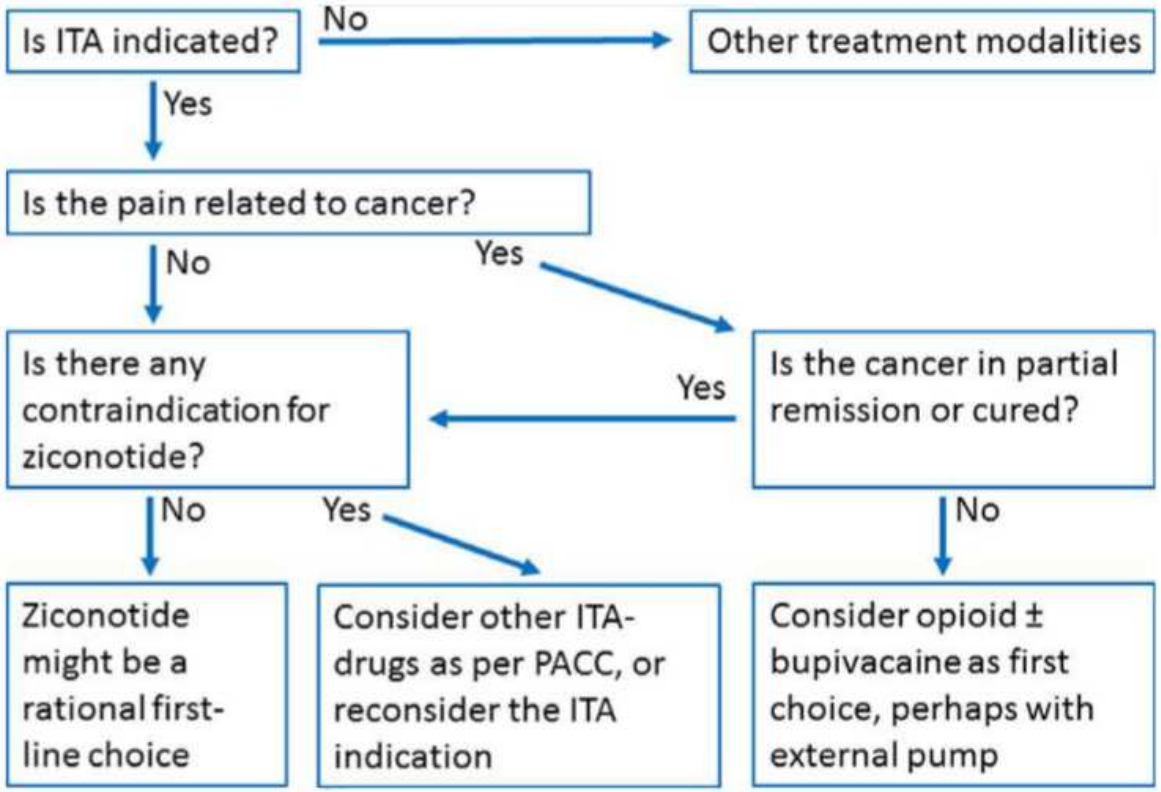


Figure 4 Overall decision-making algorithm focusing on ziconotide. ITA, intrathecal analgesia; PACC, polyanalgesic consensus conference (Deer et al., 2017b).

Bäckryd E. et al.; Do the potential benefits outweigh the risks? An update on the use of ziconotide in clinical practice; European Journal of Pain; 2018.

Intrathekale Analgesie

- **Intrathekale Infusion 1,2 – 8, 3 mg /h (30 –200 mg/d)**
- **Paradoxer Schmerz, Hyperalgesie oder Allodynie**
  - **Symptome verschwinden bei Dosisreduktion**
- **Neuropathische Schmerzen 1/3 höhere Opioiddosen als Nozizeptor – Schmerz**
  - **Beinödeme (3Pat) Wechsel Morphin > Sufentanil**

Hassenbusch SJ, Stanton-Hicks M, Covington EC, Walsh JG, Guthrey DS. Long-term intraspinal Infusions of opioids in the treatment of neuropathic pain. J Pain Symptom Manage. 1995 Oct; 10(7):527-43.

Intrathekale Analgesie

- **Nebenwirkungen**
  - **Übelkeit, Erbrechen 25,2%**
  - **Pruritus 13,3%**
  - **Ödeme 11,7%**
  - **Schwitzen 7,2%**
  - **Müdigkeit 7,2%**
  - **Gewichtszunahme 5,4%**
  - **Libidoverlust 4,9 %**

Paice JA, Penn RD, Shott S. Intraspinal morphine for cronic pain: a retrospective, multicenter study. J Pain Symptom Manage. 1996 11(2):71-80
Supanz S, Likar R, Liebmann PM, Wintersteiger R, Sittl R, Sadjak A. On the role of the kidneys in the pathogenesis of edema formation during permanent morphine application/an experimental study in rats. Arzneimittelforschung. 2004;54(5):259-64

Intrathekale Analgesie

- **Intraspinale Opioide**
  - **80 % hypogonadotropischer Hypogonadismus**
  - **20 % Wachstumshormondefizit**
  - **20 % zentraler Hypocorticismus**
  - **50 % hyporeniner Hypoaldosterinismus**
- **Keine Korrelation zwischen hormoneller Störung und Dauer der Opioidtherapie**
- **Wenn Defizit : Androgene, Östrogene, Corticosteroide und eventuell Wachstumshormon substituieren**

Abs R, Verhelst J, Maeyaert J, Van Buyten JP, Opsomer F, Adriaensen H, Verlooy J, Van Havenbergh T, Smet M, Van Acker K. Endocrine consequences of long-term intrathecal administration of opioids. J Clin Endochrinol Metab. 2000 Jun; 85(6):2215-22.

Table 5. Common* AEs Associated with IT Ziconotide Therapy

Ziconotide[23–25]	Ziconotide[23–25]
• Abnormal gait	• Headache
• Asthenia	• Nausea
• Ataxia	• Nystagmus
• Confusion	• Pain
• Constipation	• Postural hypotension
• Diarrhea	• Somnolence
• Dizziness	• Urinary retention
• Fever	• Vomiting

* Occuring in ≥15% of patients in any study.
AEs, adverse events; IT, intrathecal.

Table 6. Common* AEs Associated with IT Morphine Therapy

Morphine[59]	Morphine[59]
• Constipation	• Insomnia
• Depression	• Loss of appetite
• Disturbance of libido	• Myoclonic jerk/spasm
• Disturbance of micturition	• Nausea
• Dizziness	• Nightmare
• Dry mouth	• Provocation of asthma
• Edema	• Pruritus
• Fatigue	• Sweating
• Hallucinations	

* Occuring in ≥15% of patients.
AEs, adverse events; IT, intrathecal.

Rauck R.L., Wallace M. S., Burton A. W., Kapural L., North J. M. Intrathecal Ziconotide for Neuropathic Pain: A Review Pain Practice, Volume 9, Issue 5, 2009 327-337

KABEG
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Results: Thirty-six patients (21 m/15 f, mean age 62.9 years, range 30.5–83.9 years, SD 11.0 years) were studied. **Mean duration of intrathecal therapy at time of study was 11.8 years. Thirty-two patients had gas-driven pumps and four patients had programmable pumps.** The mean actual dose in those patients receiving morphine sulfate was 4.6 mg/day (range 0.2–11.1 mg, SD 2.63 mg).
Pain levels prior to pump implantation were 7.98 (NRS) (range 4–10, SD 1.62). Pain levels directly after pump implantation were 4.87 (range 2–7, SD 1.86) and at time of follow-up 4.44 (range 0–9, SD 2.03).
The most common unwanted side-effects reported by the patients were fatigue, obstipation, urinary retention, and sexual dysfunction. There was no life-threatening complication or permanent neurological deficit.

Conclusions: IOT seems to be effective also for long-term application. Clinically unwanted side-effects are relatively frequent but not the limiting factor for patient satisfaction.

Kleinman B, Wolter T. Intrathecal Opioid Therapy for Non-Malignant Chronic Pain: A Long-Term Perspective. Neuromodulation 2017; 20: 719–726

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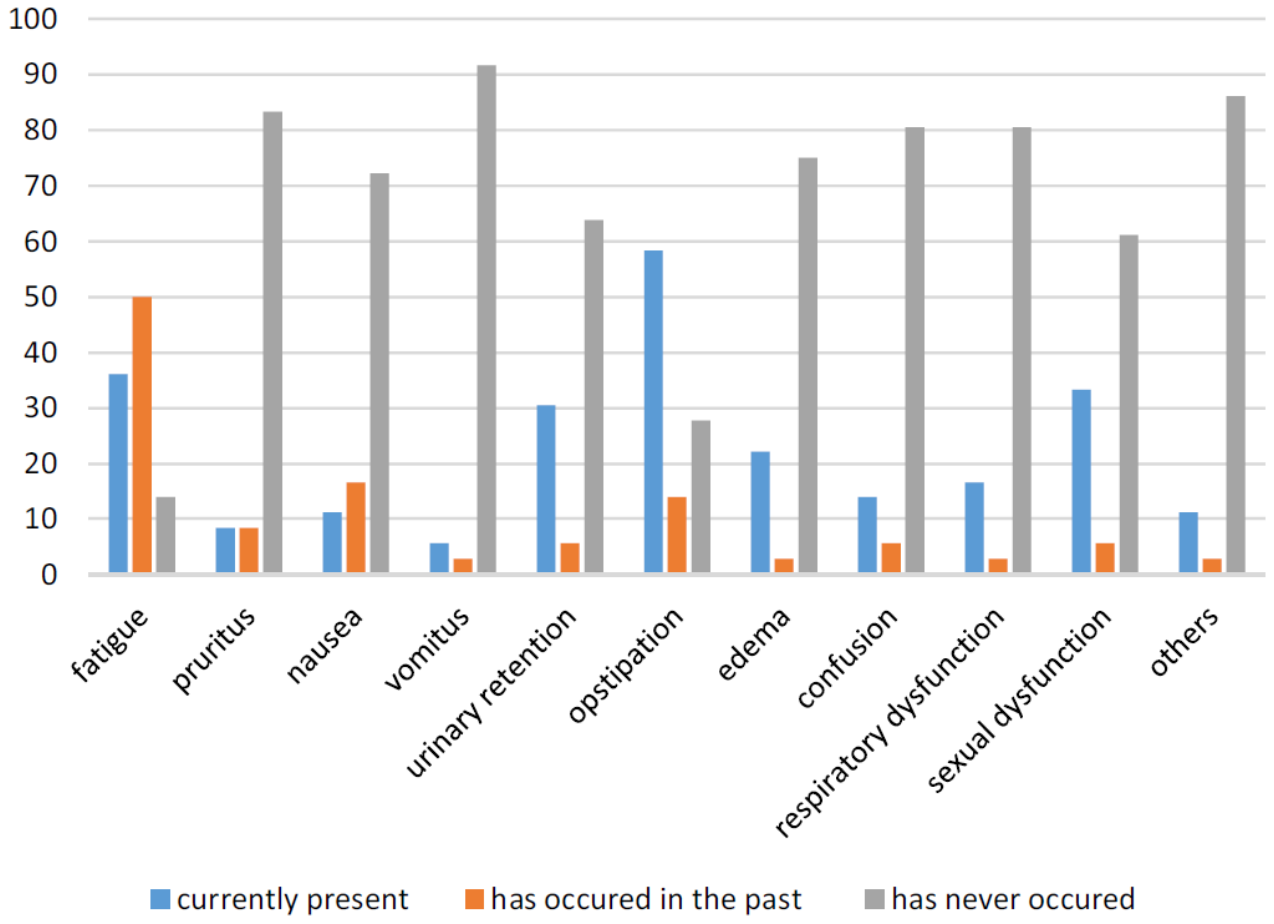
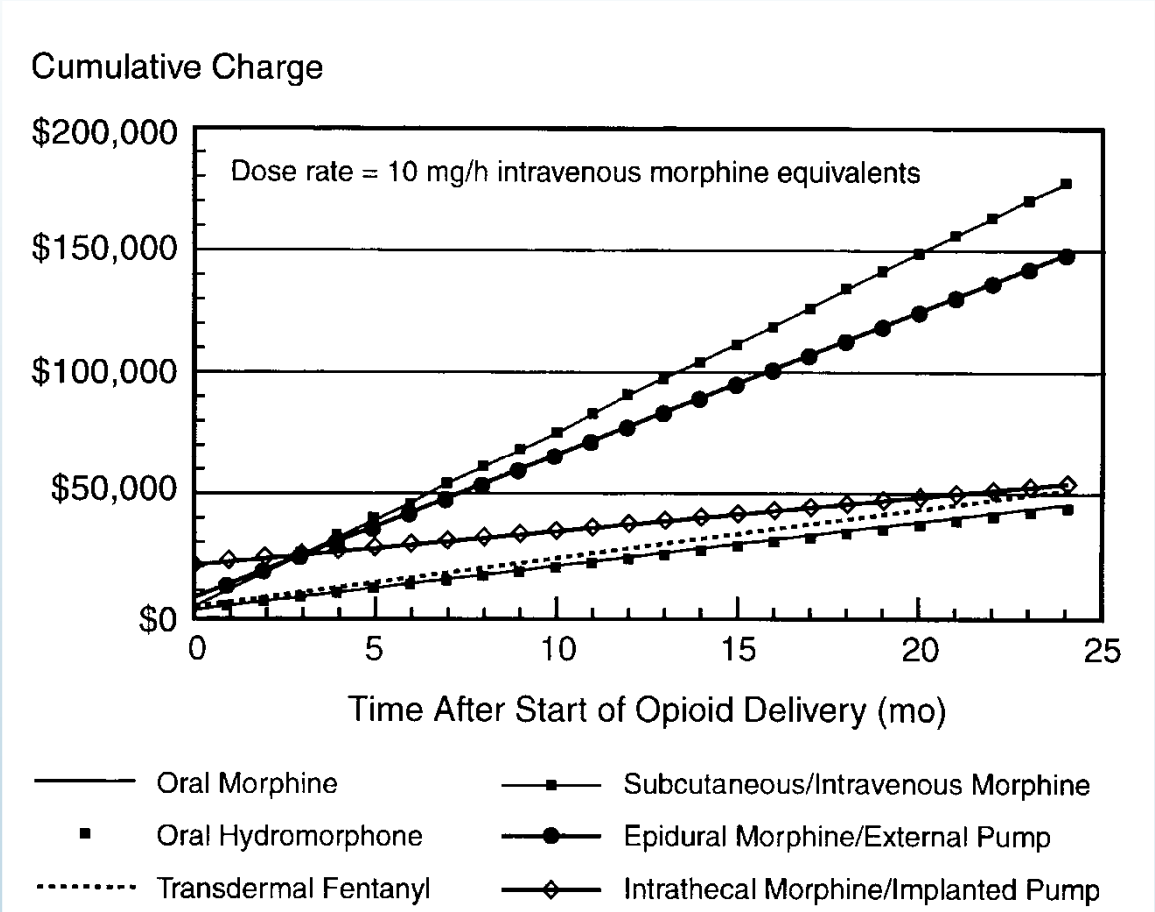
AM WÖRTHERSEE



Percentage of patients with unwanted side-effects. [Color figure can be viewed at wileyonlinelibrary.com]

Kleinman B, Wolter T. Intrathecal Opioid Therapy for Non-Malignant Chronic Pain: A Long-Term Perspective. Neuromodulation 2017; 20: 719–726

Kosten der Morphintherapie
Vergleichsanalyse break-even-points je Applikationsweg



Mueller-Schwefe G, Hassenbusch SJ, Reig E. Cost effectiveness of intrathecal therapy for pain. Neuromodulation; 1999 Apr. 2(2):77-84

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AM WÖRTHERSEE

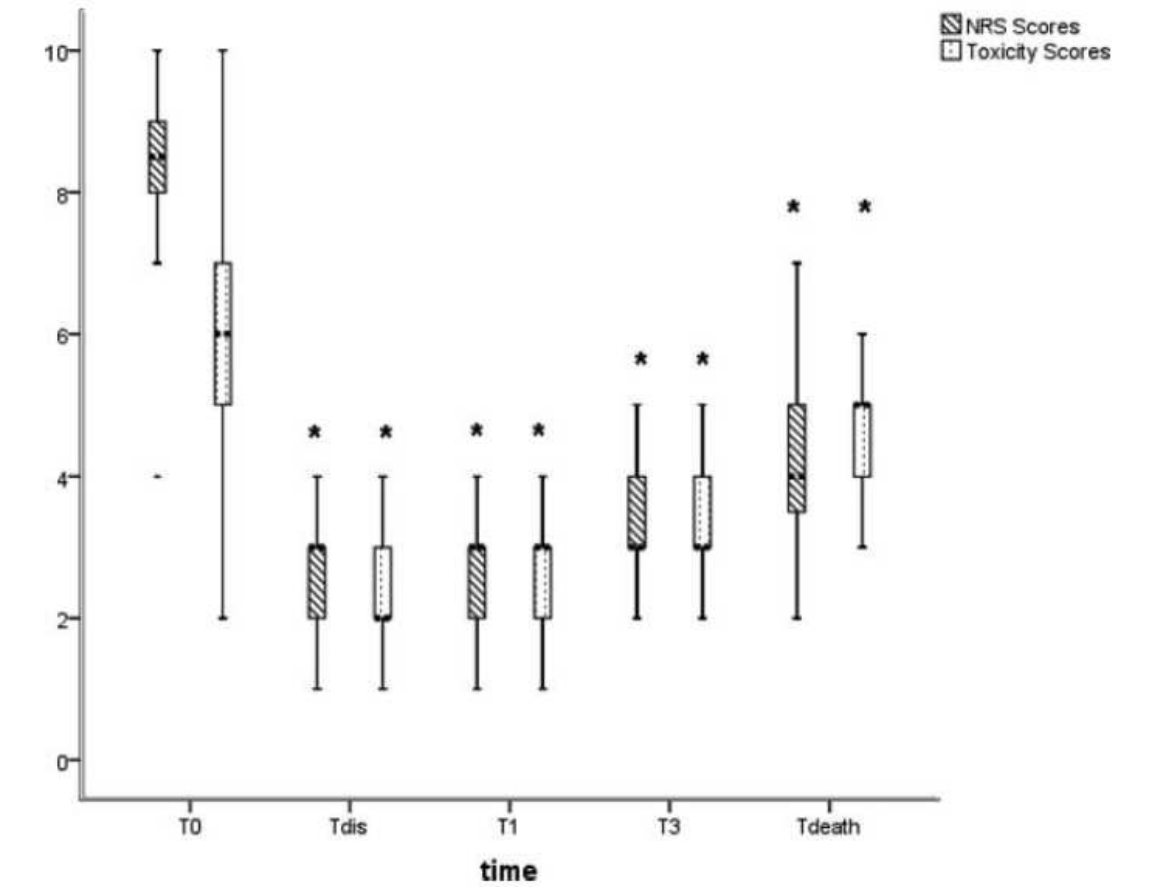

Figure 2. A boxplot of pain NRS scores and toxicity scores at baseline and different follow-up visits after procedure. (*) A significant difference compared with baseline value ($P < 0.05$). NRS = numeric rating scale; T death = 1 week before death; T dis = the time of discharge, T0 = baseline, T1 = 1 month after procedure, T3 = 3 months after procedure.

Zheng et al., Evaluation of intrathecal drug delivery system for intractable pain in advanced malignancies- A prospective cohort study, Medicine, 2017, 96:11

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KLINIKUM KLAGENFURT
AM WÖRTHERSEE

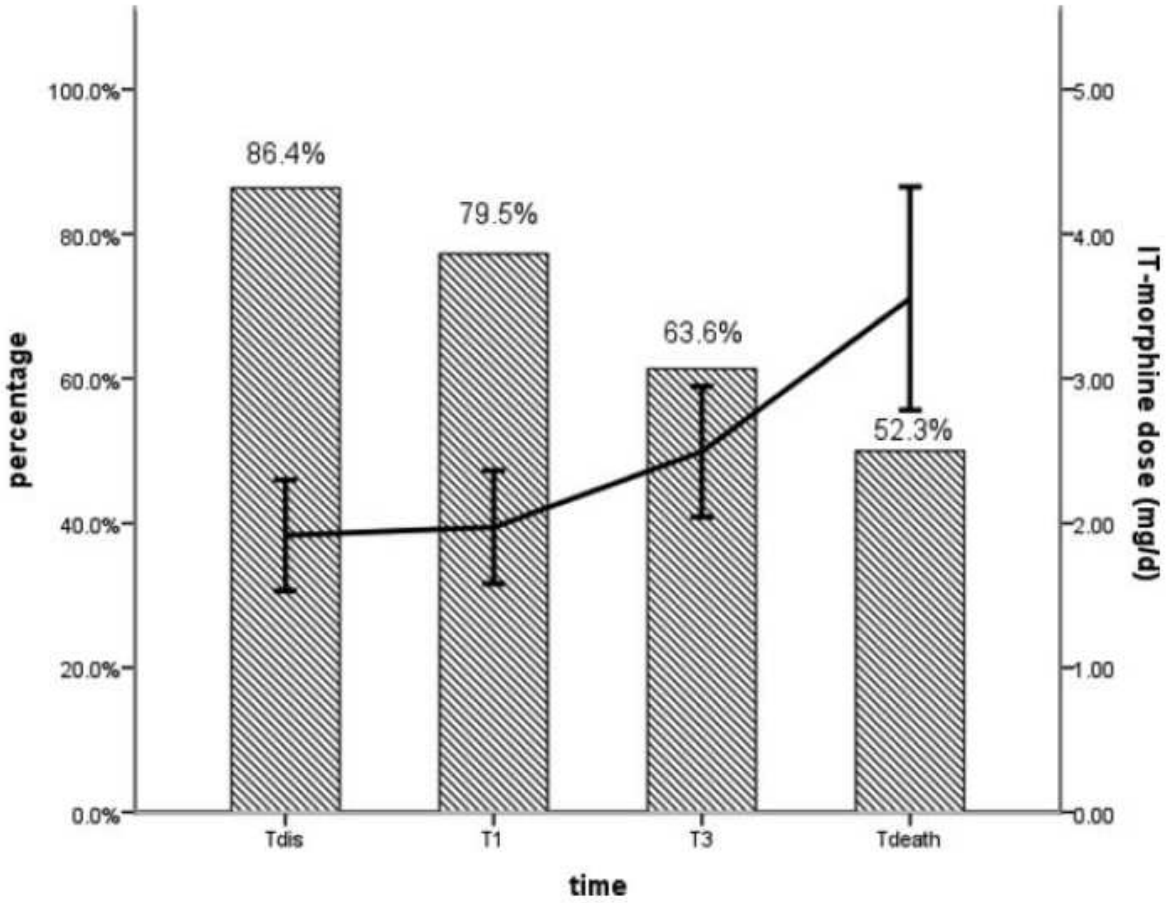
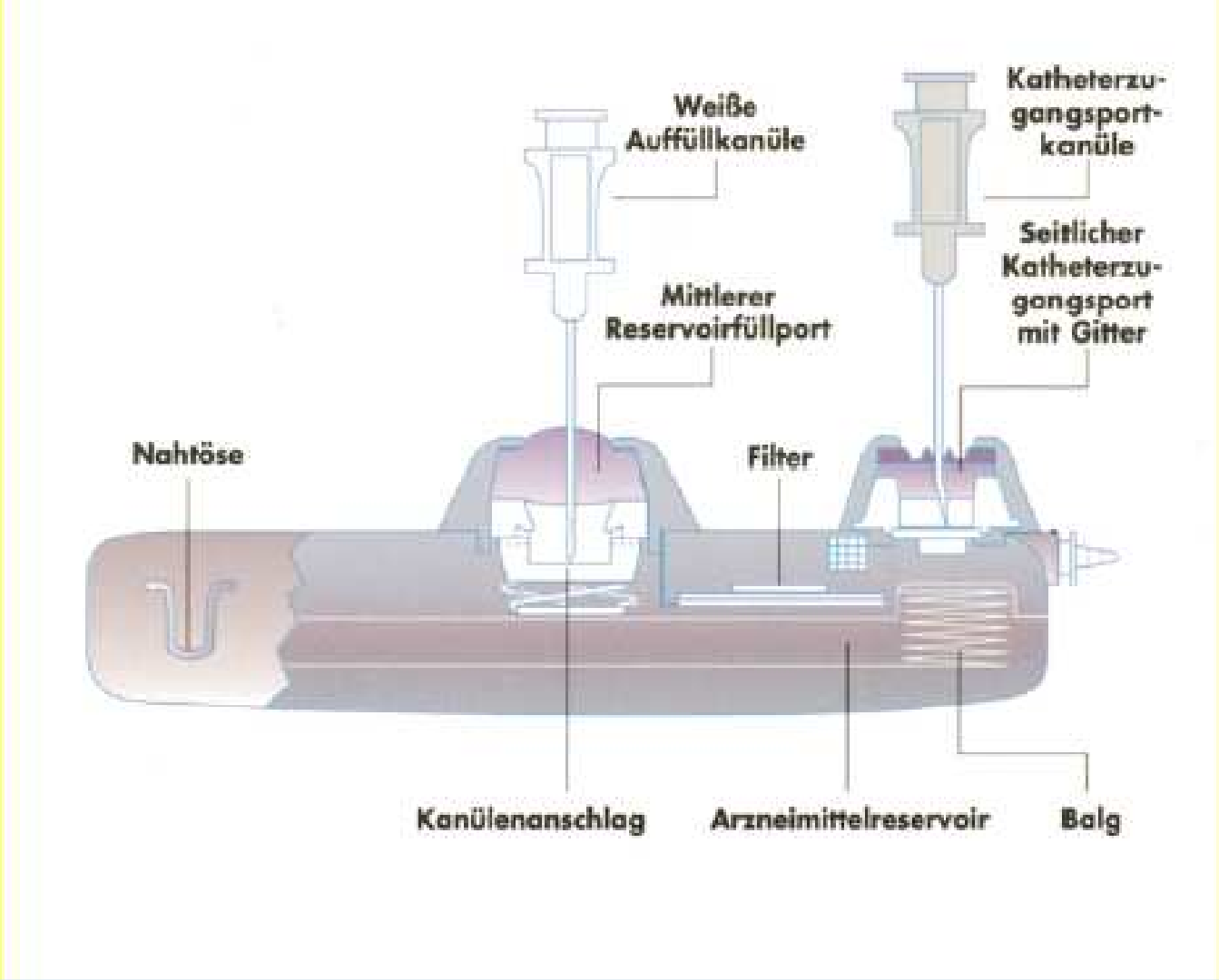


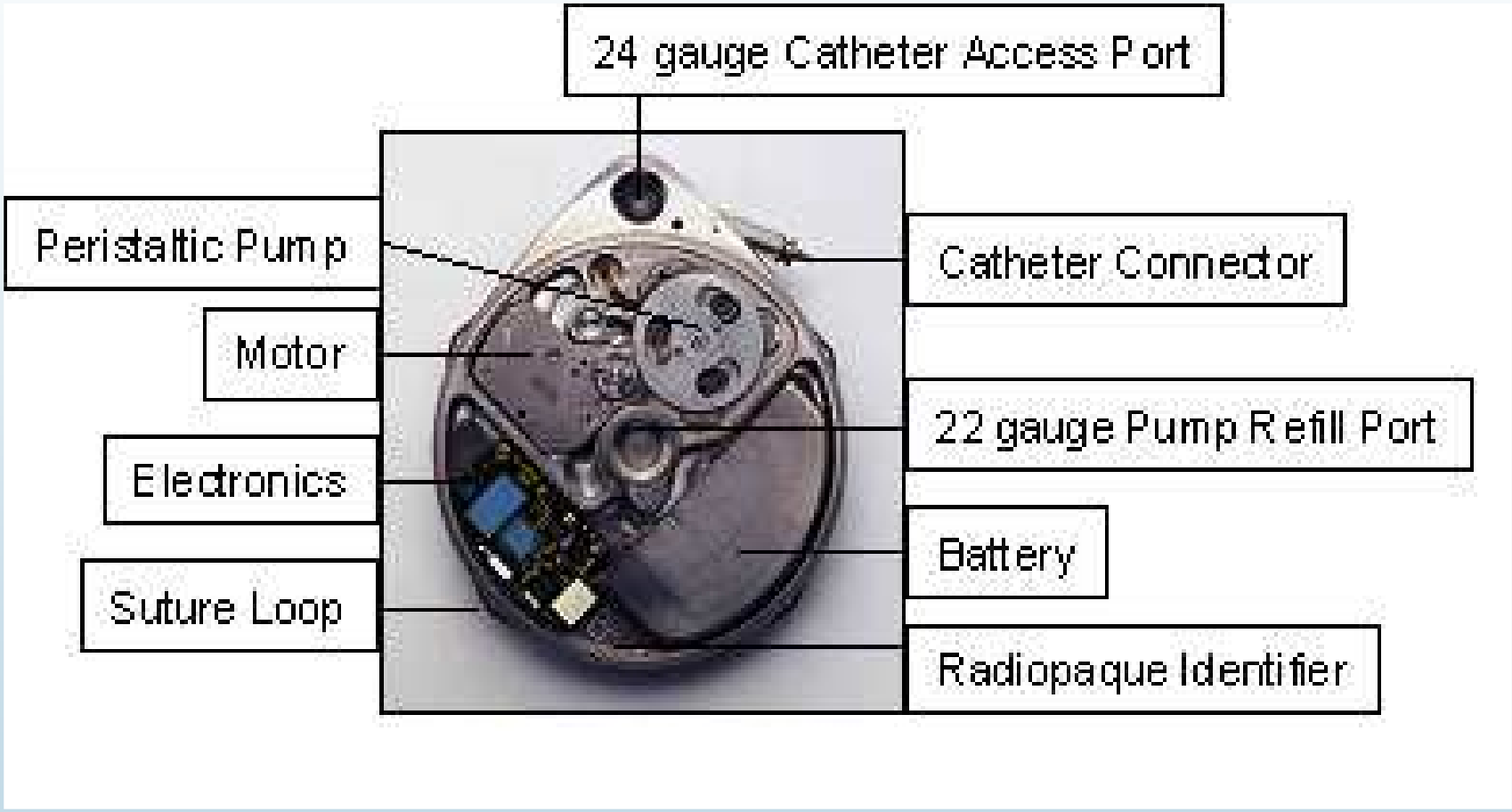
Figure 3. The proportion of patients with significant pain relief (≥50%) and intrathecal morphine dose over the follow-up period. Error bars represent 95% CI for the mean. CI = confidence interval, IT = intrathecal; T death = 1 week before death; T dis = the time of discharge, T0 = baseline, T1 = 1 month after procedure, T3 = 3 months after procedure.

Zheng et al., Evaluation of intrathecal drug delivery system for intractable pain in advanced malignancies- A prospective cohort study, Medicine, 2017, 96:11

Gasdruckpumpe



elektronische Pumpe



SynchroMed EL vs SynchroMed II

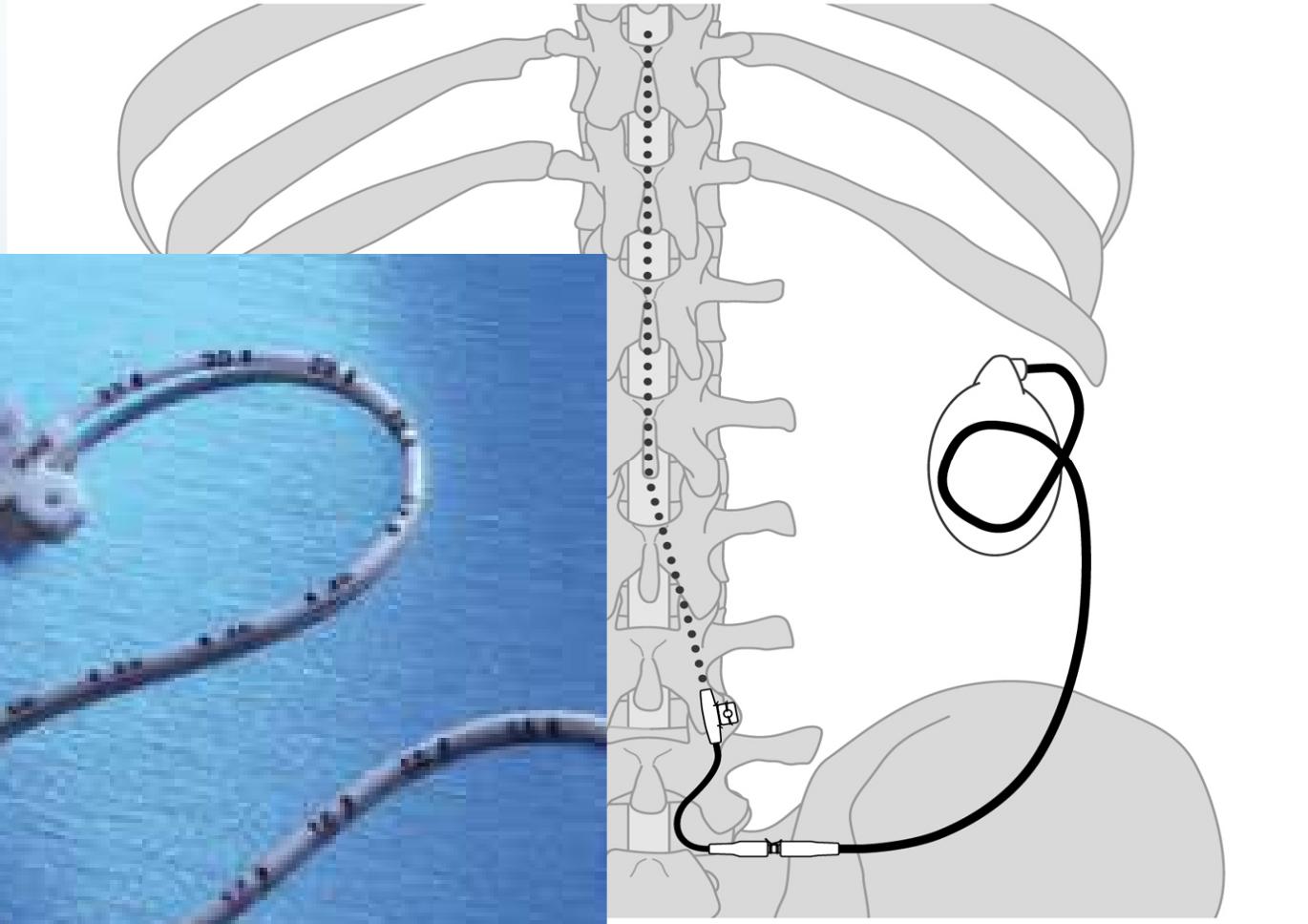
	SMEL 10	SMEL 18	SMII 20	SMII 40
				
SynchroMed Pump Models				
Total Reservoir Volume	10 ml	18 ml	20 ml	40 ml
Usable Reservoir Volume	8 ml	16 ml	19 ml	39 ml
Device Displacement Volume	105 cc	125 cc	87.3 cc	117.5 cc
Device Weight (full)	185 g	223 g	165 g	215 g
Drug Stability Labeling - Morphine - Baclofen	90 days	90 days	180 days	180 days

Gegenüberstellung Gasdruckpumpen und elektronische Pumpen

	batteriebetriebene, programmierbare Pumpen	gasbetriebene Pumpen
Nachteile	**kleineres Reservoirvolumen**	**Dosisänderung nur über Konzentrationsänderung**
	begrenzte Batterielebensdauer (ca. 7 Jahre)	**Titration nur über Neubefüllung**
	mehrfacher Austausch im Verlauf einer Therapie (Kosten)	**kein Tagesprofil**
	hohe Konzentration an Katheterspitze (Granulombildung)	**keine PCA**
		Einfluss von Umgebungsdruck und Temperatur auf die Flussrate
		hohe Konzentration an Katheterspitze (Granulombildung)

konstante Flussrate vs. variabler Substanzfluss

konstante Flussrate	programmierbarer Fluss
stabiler Dauerschmerz	variable Schmerzstärke
Durchbruchschmerz selten	Durchbruchschmerz häufig
Standardmedikation (First Line)	zirkadiane Rhythmik
ökonomische Aspekte	Schmerzprogression
	komplexe Medikation (Second oder Third Line)



Was ist der N'Vision Programmer?

Postoperatives Management

- **Antibiotikaprophylaxe**
- **Dokumentation der Katheterlage**
- **Dokumentation der Dosierung**
- **QOL-Score, MPQ, BPI, VAS**
- **Patienten- und Angehörigenschulung**
- **postoperative Schmerztherapie**
- **Weaning der oralen Dosierung**
- **Graduelle orale Reduktion über 48h**
- **Dosisanpassung intrathekal**
- **3-5 Tage stationär postoperativ**

Antibiotische Prophylaxe der Wahl während der Implantation eines Spinal Cord Stimulators oder eines spinalen Drug-Delivery Systems

Medikament	präoperative Dosis	Anmerkungen
Cefazolin	**1-2 g i.v. 30 Min. vor Inzision**	
Clindamycin	**600 mg i.v. 30 Min. vor Inzision**	**bei Patienten mit β – Lactam Allergie**
Vancomycin	**1 g i.v. über 60 Min. vor Inzision**	**bei Patienten, die Träger eines methicillin – resistenten Staphylococcus aureus sind**

Evidence level 1a, Empfehlungsgrad A

Rathmell JP, Lake T, Ramundo MB. Infectious risks of chronic pain treatments: Injection Therapy, Surgical Implants, and Intradiscal Techniques. Reg Anesth Pain Med. 31(4);2006:346-352

Intrathekale Morphine und Granulome Ursachen

- **Effekt ideopathisch ?** **nein**
- **Medikamentenkonzentration versus Dosis?** **ja**
- **Rezeptor verursacht ?** **unsicher**
- **Rolle der Mastzellen?**
  - **Ursprung des Granuloms in der Dura/Arachnoidea**
  - **die Anwesenheit von Mastzellen in der Dura**
  - **die Fähigkeit von Opioiden einige aber nicht alle Arten von Mastzellen zu degranulieren**
  - **Opioidrezeptoren spielen eine fragliche Rolle**

Morphin > Hydromorphin > Fentanyl

Intrathekales Granulom

- ***North R, et al , Neurosurgery 29; 778-784, 1991***
- ***Blount JP, et al, Journal of Neurosurgery, 84: 272-6, 1996***
- ***Bejjani GK, et al, 48: 288-91, 1997***
- ***Cabbell KL, et al, Neurosurgery, 42: 1176-80, 1998***
- ***Langsam A, Neurosurgery, 44: 689-91, 1999***
- ***Coffey R, Burchiel K (Review) Neurosurgery, 50: 78-86, 2002***
- ***McMillan, M. et al, Anesth Analg 96: 186-90, 2003***

0,1 % Prävalenz von intrathekalen Veränderungen bei Patienten

More than 95,000 IT drug-delivery systems have been implanted worldwide since the 1980s, and the incidence of catheter-tip granuloma has generally been estimated at <3%, although estimates in select populations have been as high as 43%.

Timothy R. Deer, Joshua Prager et al; Polyanalgesic Consensus Conference—2012: Consensus on Diagnosis, Detection, and Treatment of Catheter-Tip Granulomas (Inflammatory Masses); Neuromodulation 2012

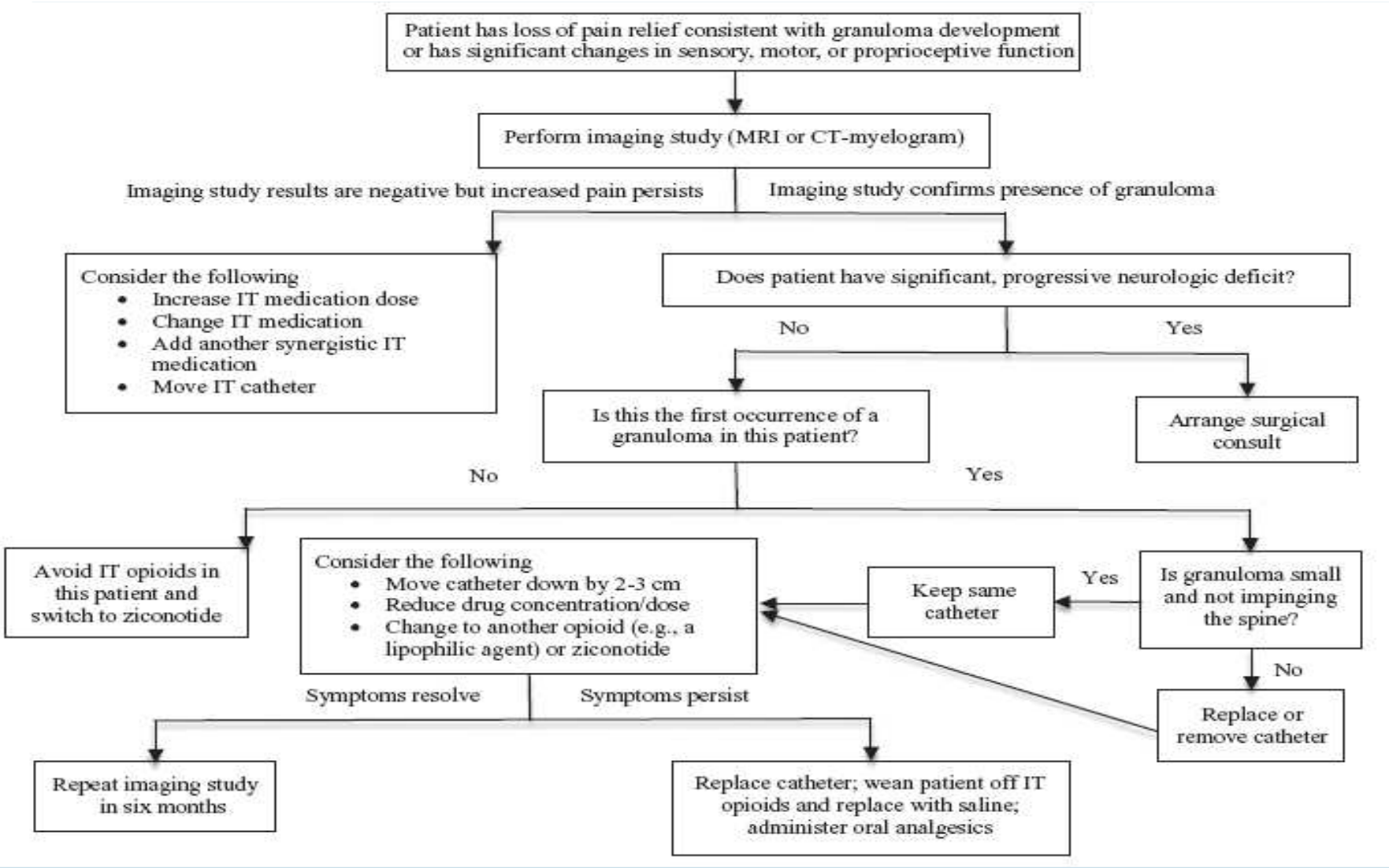
McMillan MR, Doud T, Nugent W. Catheter-associated masses in patients receiving intrathecal analgesic therapy. *Anesth Analg* 2003;96:186–190.

Signs and Symptoms Associated With Granuloma.

- New or different sensory symptoms (e.g., numbness, tingling, burning, hyperesthesia, hyperalgesia, hypothesia, anesthesia)
- New, occasional, or intermittent bowel or bladder sphincter dysfunction
- New motor weakness, change in gait, or difficulty walking
- Any neurologic symptoms or signs that differ from baseline (e.g., reflex changes, clonus)
- Change in the character, quality, or intensity of pain
- The need for frequent or large escalations of the daily drug dose to maintain the analgesic effect
- Only temporary alleviation of increasing pain after rapid dose escalations
- Reports of new radicular pain, especially at or near the dermatomal level of the catheter tip

Timothy R. Deer, Joshua Prager et al; Polyanalgesic Consensus Conference—2012: Consensus on Diagnosis, Detection, and Treatment of Catheter-Tip Granulomas (Inflammatory Masses) Neuromodulation 2012

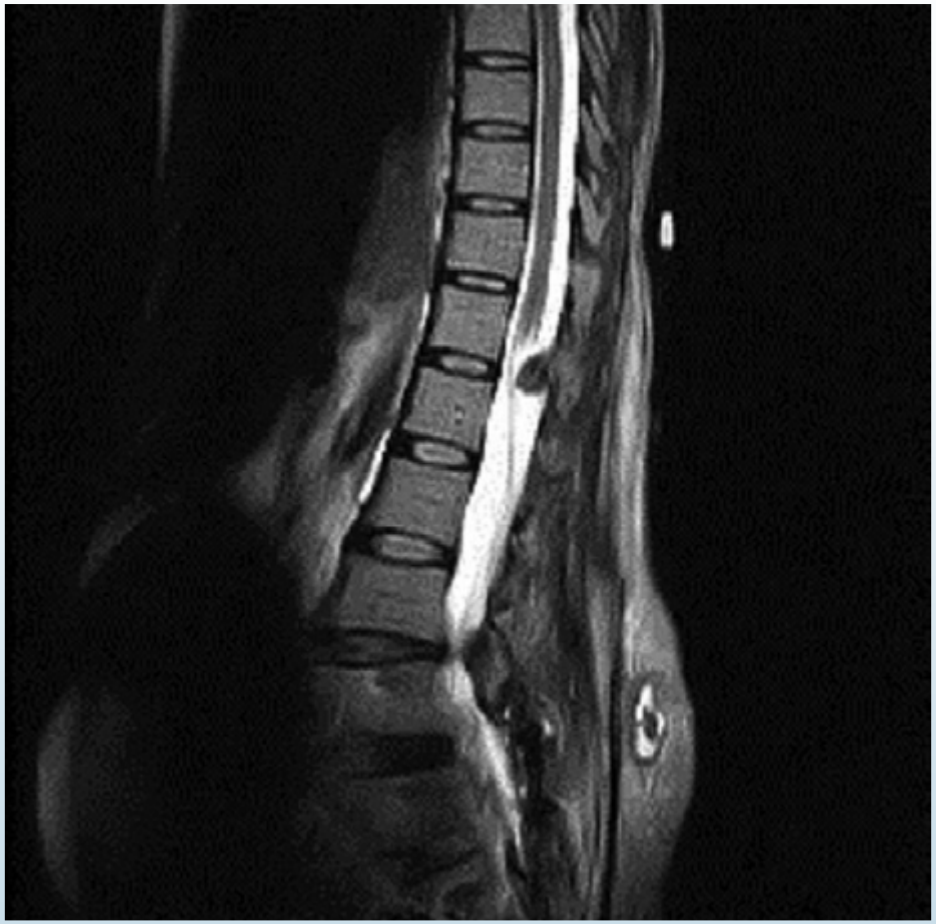
McMillan MR, Doud T, Nugent W. Catheter-associated masses in patients receiving intrathecal analgesic therapy. *Anesth Analg* 2003;96:186–190.



Algorithm for treatment of granuloma. MRI, magnetic resonance imaging; CT, computed tomography; IT, intrathecal.

Timothy R. Deer, Joshua Prager et al; Polyanalgesic Consensus Conference—2012: Consensus on Diagnosis, Detection, and Treatment of Catheter-Tip Granulomas (Inflammatory Masses) Neuromodulation 2012

McMillan MR, Doud T, Nugent W. Catheter-associated masses in patients receiving intrathecal analgesic therapy. *Anesth Analg* 2003;96:186–190.



Granuloma at T1-T2 as seen on magnetic resonance imaging.

Timothy R. Deer, Joshua Prager et al; Polyanalgesic Consensus Conference—2012: Consensus on Diagnosis, Detection, and Treatment of Catheter-Tip Granulomas (Inflammatory Masses) Neuromodulation 2012

McMillan MR, Doud T, Nugent W. Catheter-associated masses in patients receiving intrathecal analgesic therapy. *Anesth Analg* 2003;96:186–190.

Komplikationen können in zwei Gruppen eingeteilt werden, nämlich in systembezogene und medikamentenbezogene Komplikationen.

- **Systembezogene Komplikationen sind Wundinfektionen, Katheterbruch, Kathetermigration, Katheterspitzen – Granulom. Es besteht ein Konsensus darüber, dass das Katheterspitzen – Granulom in Beziehung zu hochkonzentrierten Opioiden steht, speziell zu Morphin.**

  Bei auftretendem neuen Schmerz im Rücken und den Beinen, im Bereich des Dermatoms sollte der Verdacht hoch sein.
- **Pumpentechnische Komplikationen sind sehr selten.**
- **Medikamentenbezogenen Komplikationen sind Dosierung, Programmierungsfehler, Fehlfüllungen und das Spektrum der opioidspezifischen Nebenwirkungen (Übelkeit, Erbrechen, Sedierung, Harnretention, Juckreiz, Atemdepression.**

Raj PP. Leland L, Erdine S, Staats PS. Radiographic Imaging for Regional Anesthesia and Pain Management. New York: Churchill Livingstone; 2003. Reproduced with permission of P. Prithvi Raj, MD.

Phan PC, Are M, Burton AW. Neuraxial Infusions. Techniques in Regional Anesthesia and Pain Management, 2005;9:152-160

Follett KA et al. Prevention and management of intrathecal drug delivery and spinal cord stimulation infections. Anesthesiology 2004;100:1582-1594.

Follet KA et al. analysierten vier prospektive Untersuchungen, 36 Infektionen bei 35 Patienten wurden berichtet (Gesamtzahl 700 Patienten), das ergibt eine Infektionsrate von 5 Prozent (Range in den vier Studien von 2,5 – 9%).

Die Infektionen betreffend die Pumpentasche machten 57 – 80% der Infektionen aus.

Infektionen im Lumbalbereich 13 – 33% und Meningitis in 0 – 14% der Patienten.

In 55 – 80% der Patienten wurde das System total explantiert.

Die Autoren empfehlen antibiotische Therapie plus Systementfernung.

Nur eine geringe Anzahl der Infektionen konnte erfolgreich behandelt werden, ohne dass das System entfernt wurde.

Follett KA et al. Prevention and management of intrathecal drug delivery and spinal cord stimulation infections. Anesthesiology 2004;100:1582-1594.

Schlussfolgerung

Behandlung muss individuell erfolgen unter Bedachtnahme, dass sich eine Infektion von der Pumpentasche bis zum Rückenmark ausbreiten kann.

Infektionsrisiko mit implantierten Systemen

- **Management der Patienten mit Infektionen des Implantationssystems (Pumpensystems)**
- **Pumpentascheninfektionen können durch konservatives Management ansprechen (lokale Revision, Drainage, orale Antibiotika) – Evidence level 2b, Empfehlungsgrad B.**
- **In den meisten Fällen sollte das System entfernt werden.**
- **Tiefer gehende Infektionen entlang der subkutanen Katheter können sich bis zum Epiduralraum ausbreiten. Die Entfernung des Systems und auch antibiotische Therapie sind hier anzuraten (Evidence Level 2b, Empfehlungsgrad B)**

Rathmell JP, Lake T, Ramundo MB. Infectious risks of chronic pain treatments: Injection Therapy, Surgical Implants, and Intradiscal Techniques. Reg Anesth Pain Med. 31(4);2006:346-352

Nebenwirkungen und Substanzen

- **Implantation und Nachsorge durch ein erfahrenes Zentrum**
- **standardisiertes Nachsorgeprogramm**
- **klarer Algorithmus zum Management von Nebenwirkungen und Komplikationen (Risk Management)**

Table 2. Survey of Recent Studies and Case Reports on Complications Associated With Intrathecal Therapies, Including Causes and Outcomes Where Available.

Author(s) and reference no.	Year of publication	Type of study	Number of patients	Population age (years)	Indication	Pump model	Catheter type	Complications (number of patients/% of those in study)	Procedure-related complications	Catheter-related complications	Pump-related complications	Therapy-related complications	Notes/insights
Penn et al. (19)	1995	Prospective	102	12–77	40 MS, 42 SCI, 20 SPA	_	Medtronic 8703, Medtronic 8704, other custom device etc.	42/41.2%	_	Hole, kink, disconnect, dislodgment, fibrosis, other	_	_	8703 performed better than 8704
Follett and Naumann (20)	2000	Prospective	209	>18	72.7% NPP, 4.8 % CDP, 22.5% SPA	SynchroMed	Medtronic 8709	37/17.7%	15 infection, 10 catheter migration, 5 catheter kink, 4 CFS leak, 8 other	3 leakage, 2 catheter migration; 2 pump disconnection	_	_	9 month complication-free survival was 78.9%
Kamran and Wright (21)	2001	Retrospective	97	28–85	15 FBSS, 10 CS/LS, 5 CRPS, 8 CF, 4 RPY, 6 PN, 2 SPA	_	_	43/44.3%	5 infection	1 distal occlusion, 2 shearing, 4 kink, 7 leakage, 3 spinal headache	1 failure,1 positional flip, misprograming	33 acute, 42 chronic	_
Ordia et al. (22)	2002	Prospective	131	17–53	63 MS, 53 SCI, 10 MISC, 5 FSP	SynchroMed	Medtronic 8703 W, Medtronic 8709, other unspecified device	31/23.6% (also 34 adverse responses to medication)	2 pocket erosion; 1 pocket infection; 1 CSF leak	12 occlusion & kink, 8 fracture; 2 puncture, 2 dislodgment	2 positional flip, 1 stuck valve	12 constipation, 7 muscular hypotonia, 6 headache, 4 urinary retention 5 other	Most complications were with "earlier model catheter"
Harney and Victor (47)	2004	Case report	1	n/a	FBSS	SynchroMed	Medtronic 8709 IP	_	_	Traumatic syrinx	_	_	_
Dvorak et al. (29)	2010	Retrospective	167	8–69	55 SCI, 37 CP, 31 MS, 19 TBI, 7 STR, 6 FSP, 3 ABI, 3 PLS, 6 MISC	SynchroMed	_	33/19.8%	_	14 occlusion & kink, 7 disconnection, 7 subdural placement, 4 fracture, 4 dislodgment	1 failure	_	_
Maugans (31)	2010	Case report	1	16	CP	SyncroMed I	Medtronic 8709	_	_	Catheter fracture and migration to ventricular system	_	_	Caudocranial CSF flow possible mechanism for migration
Awaad et al. (38)	2012	Retrospective	44	24 children 24 Adults	29 CP, 3 TBI, 3 MS, 2 DY, 4 CS, 2 ICH, 2 SPA	_	_	22/50%	4 infection	1 catheter dislocation, 1 pump-connection defect, 2 fracture, 1 occlusion, 3 dye leakage, 1 occult CSF	_	_	33 additional revisions were performed on 22 of 44 patients
Tomycz et al. (44)	2012	Case series	13	40–70	11 FBSS, 1 CRPS, 1 STR	_	_	_	None	_	None	None	Mass resection via laminectomy a reasonable treatment strategy
Varhabhatla and Zuo (27)	2012	Retrospective	2843	12 (median)	NPP, MS, CP, SCI, PAR, MISC (No numerical breakdowns given)	_	_	514/18%	_	_	_	_	Complications rate increased between 1997 and 2006

Nagel S. J. et al.; Intrathecal Therapeutics: Device Design, Access Methods, and Complication Mitigation. Neuromodulation. 2018; 21:625-640.

Table 2. *Continued*

Author(s) and reference no.	Year of publication	Type of study	Number of patients	Population age (years)	Indication	Pump model	Catheter type	Complications (number of patients/% of those in study)	Procedure-related complications	Catheter-related complications	Pump-related complications	Therapy-related complications	Notes/insights
Dardashti et al. (63)	2013	Case report	1	41	MS	SynchroMed II	_	_	_	1 occlusion at catheter & pump attachment	_	_	Catheter found to have arachnoid adhesion
Draulens et al. (30)	2013	Retrospective	130	49 for MS 38 for SCI (means)	81 MS, 49 SCI	SynchroMed EL SynchroMed II	_	104 over a mean of 5.25 years	4 infection, 1 perforation, 6 CSF leak, 3 wound rupture	9 occlusion, 6 kink, 7 migration, 9 tear, 7 disconnection, 6 fracture, 34 other	5 malfunction, 1 pump tilting, 2 volume discrepancy	2 overdose-related respiratory distress	_
Kochany et al. (46)	2013	Case report	1	40	NPP	SynchroMed II	_	_	_	Arachnoiditis, radicular pain related to catheter	_	_	A retained Tuohy needle was found in the patient
Perruchoud et al. (40)	2013	Case report	1	84	NPP	SynchroMed EL	_	_	_	_	Fluid leakage in the silicone septum	_	_
Borrini et al. (34)	2014	Prospective	158	17–87	67 SCI, 45 MS, 22 CP, 8 STR, 3 TBI, 13 MISC	SynchroMed II	_	38/24.1%	4 pump pocket hematoma, 10 infection, 2 CSF leak, 2 scar dehiscence, 2 other	94 migration, 1 disconnection, 4 other	1 pump malfunction, 1 pump pressure ulcer	2 serious, 5 mild	_
Ghosh et al. (32)	2014	Retrospective	119	3–21	113 SPA, 5 DY	_	_	49/41.2%	26 infection, 8 skin erosion over pump, 1 CSF leak	10 displacement or disconnection, 4 fracture	None	_	_
Motta and Antonello (25)	2014	Retrospective	430*	1–14	383 CP, 47 MISC	SynchroMed EL SynchroMed II	Medtronic 8709 SC, Medtronic Ascenda	137/25%	40 infection, 21 CSF leak	65 total	3 positional flip, 1 peritoneal migration	_	Subfascial pump implant reduced the risk of infection
Bolash et al. (42)	2015	Retrospective	365	52.2 (mean)	145 FBSS, 52 SPA, 49 SS, 48 CRPS, 20 CDP, 49 MISC	SynchroMed II SynchroMed EL	_	50/13%	41 infection, 3 pocket-related complication	2 catheter-related surgical complication, 2 granuloma	2 pump-related surgical complication	_	_
Hnenny et al. (33)	2015	Case report	1	70	FBSS	_	_	_	_	Catheter Fracture & subarachnoidal hemorrhage	_	_	Catheter migrated to the prepontine area causing hemorrhage
Kratzsch et al. (54)	2015	Retrospective	159	52.6 (mean)	30 NPP, 24 SPA	_	_	13/8.2%	_	Catheter tip granuloma	_	_	Morphine dosage and concentration were associated with granuloma
Manix et al. (37)	2015	Case report	1	58	SCI	_	_	1	None	1 drain catheter guidewire fracture	_	_	Endovascular retrieval tool was used the intrathecal space
Riordan and Murphy (41)	2015	Case report	1	37	SPA	SynchroMed II	_	_	_	_	Failure	_	Pump failed at 64 months

Nagel S. J. et al.; Intrathecal Therapeutics: Device Design, Access Methods, and Complication Mitigation. Neuromodulation. 2018; 21:625-640.

Table 2. *Continued*

Author(s) and reference no.	Year of publication	Type of study	Number of patients	Population age (years)	Indication	Pump model	Catheter type	Complications (number of patients/% of those in study)	Procedure-related complications	Catheter-related complications	Pump-related complications	Therapy-related complications	Notes/insights
Yue et al. (36)	2015	Case report	1	82	NPP/AAA	_	Medtronic EDM Lumbar Drain	_	None	Entrapments of nerve rootlets	None	None	Procedure led to increased perfusion pressure on the spinal cord
Zinboon-yahgoon et al. (48)	2015	Case series	2	37, 57	CDP	_	_	_	2 hemifacial flushing	_	_	_	Harlequin Syndrome, probably related intrathecal medication
Han et al. (35)	2016	Case report	1	60	NPP	_	_	_	None	1	None	None	Catheter formed a coil around the left T10 nerve root
Morgalla et al. (39)	2016	Retrospective	51	18–78	28 SPA, 2 DY, 21 NPP	_	_	22/24%	2 pump infection	1 pump disconnection, 3spinal catheter disconnection, 3 dislocations, 1 minor catheter leak, 2 occlusion	6 malfunction, 2 positional changes	1 baclofen intoxication	_
Motta and Antonello (28)	2016	Retrospective	508*	1–16	451 CP, 57 MISC	SynchroMed EL SynchroMed II	Medtronic 8709SC, Medtronic Ascenda	120 in Indura group (29%) 1 in Ascenda group (1.1%)	43 infection 24 CSF leak	75 total; 5 occlusion; 27 breaking; 18 dislodgment, 8 disconnec-tion; 24 other	_	_	Ascenda catheter can reduce the major catheter-related complications
Padalia et al. (45)	2016	Case report	1	38	CDP	_	_	_	_	1 (bradycardia and asystolic episodes)	_	_	Catheter tip could cause of autonomic dysfunction
Thakur et al. (43)	2016	Retrospective	43	3–50	33 CP, 3 MS, 2 TBI, 2 RS, 3 MISC	_	_	12/27%	3 infection 2 lumbar dehiscence	1 low flow, 2 loop migration, 1 disconnection	1 known malfunction, 1 uncertain malfunction	1 poor response	No CSF leak detected or catheter migration more than 3-year median follow-up

*Includes patients from the same population.

AAA, Abdominal aortic aneurysm; ABI, Anoxic brain injury; CDP, Cancer-derived pain; CF, Compression fracture; CP, Cerebral palsy; CRPS, Complex regional pain syndrome; CS, Cervical spondylosis; DY, Dystonia; FBSS, Failed back surgery syndrome; FSP, Familial spastic paresis; ICH, Intracranial hemorrhage; LS, Lumbar spondylosis; MISC, Miscellaneous causes; MS, Multiple sclerosis; NPP, Neuropathic pain; PAR, Paralysis (all types); PLS, Primary lateral sclerosis; PN, Peripheral neuropathy; RPY, Radiculopathy; RS, Rhett syndrome; SPA, Spasticity; SCI, Spinal cord injury; SS, Spinal stenosis; STR, Stroke; TBI, Traumatic brain injury.

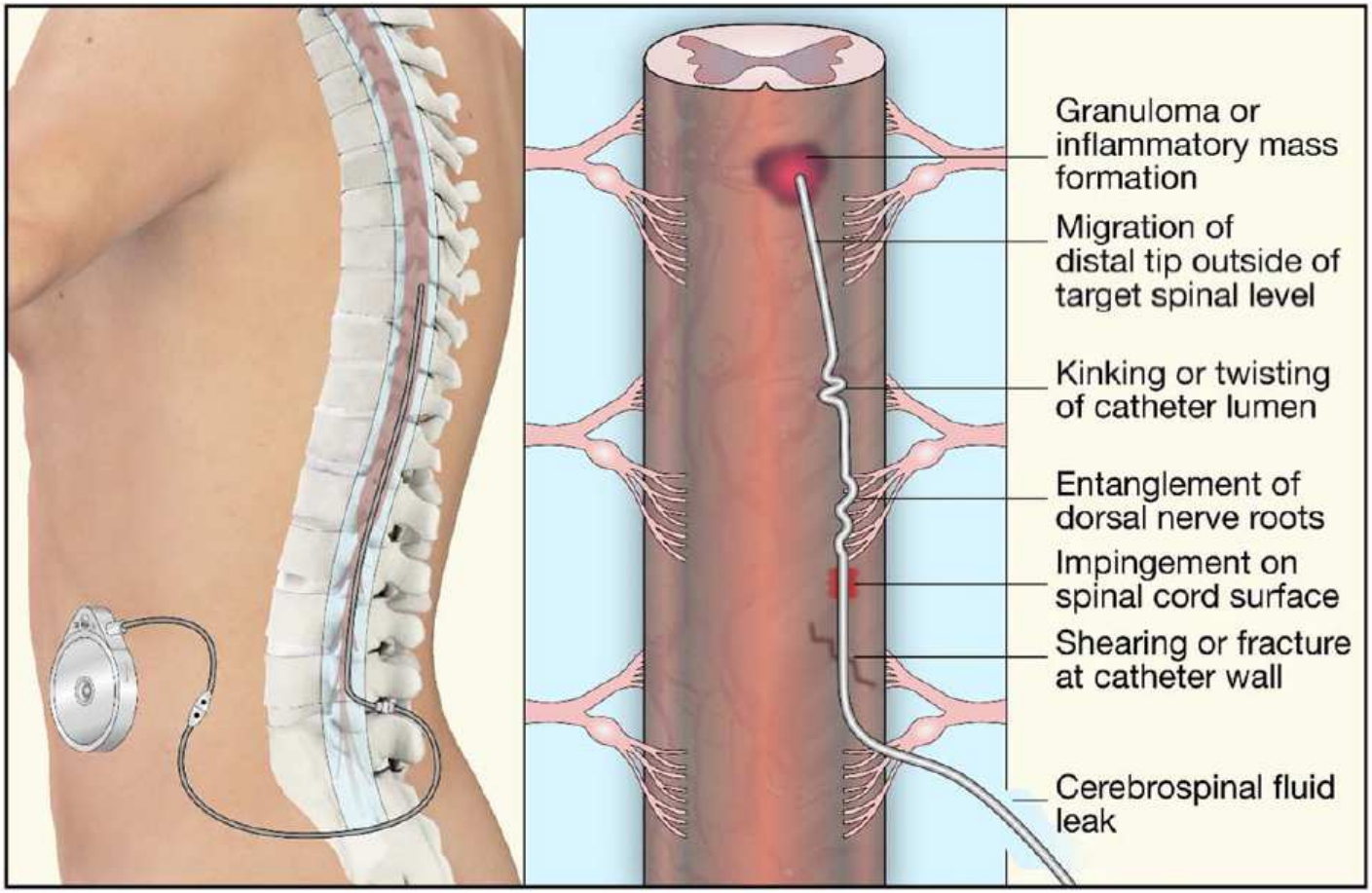


Figure 5. Schematic illustration of a drug delivery catheter within the intrathecal space, with representations of the most typical types of device malfunctions. [Color figure can be viewed at wileyonlinelibrary.com]

Nagel S. J. et al.; Intrathecal Therapeutics: Device Design, Access Methods, and Complication Mitigation. Neuromodulation. 2018; 21:625-640.

Schlussfolgerung:

- **Intrathekale Infusion für die Behandlung von chron. intrathekalen Schmerz bewirkt positives Langzeit-Outcome und spielt eine Rolle im fortgeschrittenen Stadium von refraktären Schmerzen.**

- **Review Level 2/3 oder Level 3 Evidenz für intrathekale Infusionen zur Langzeitschmerzlinderung bei chronischen Nichttumorschmerzen.**

Patel V. B., Manchikanti L., Singh V., Schultz D. M., Hayek S. M., Smith H. S. Systematic Review of Intrathecal Infusion, Systems for Long-Term Management of Chronic, Non-Cancer Pain Physician 2009; 12:345-360 . ISSN 1533-3159

Kress H. G., Simpson K. H., Marchettini P., Donck A. V., Varrassi G. Intrathecal Therapy: What Has Changed With the Introduction of Ziconotide Pain Pactrice, Volume 9, Issue 5, 2009 338-347

Table 3. Quality of evidence developed by AHRQ.

I:	Evidence obtained from at least one properly randomized controlled trial.
II-1:	Evidence obtained from well-designed controlled trials without randomization.
II-2:	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
II-3:	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
III:	Opinions of respected authorities, based on clinical experience descriptive studies and case reports or reports of expert committees.

Adapted from the Agency for Healthcare Research and Quality, U.S. Preventive Services Task Force (USPSTF) (65).

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Methods: Literature search through EMBASE, Medline, Cochrane databases, and systematic reviews as well as peer-reviewed non-indexed journals from 1980 to December 2010. Studies are assessed using the Agency for Healthcare Research and Quality (AHRQ) criteria for observational studies and the Cochrane Musculoskeletal Review Group criteria for randomized trials. **The level of evidence was determined using 5 levels of evidence, ranging from Level I to III with 3 subcategories in Level II, based on the quality of evidence developed by the U.S. Preventive Services Task Force (USPSTF).**

Outcome Measures: The primary outcome measure for chronic non-cancer is pain relief (short-term relief ≤ one-year and long-term > one-year), whereas it is 3 months for cancer. Secondary outcome measures of improvement in functional status, psychological status, return to work, and reduction in opioid intake.

Hayek S.M.; Intrathecal Therapy for Cancer and Non-Cancer Pain. Pain Physician 2011; 14:219-248.

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Results: The level of evidence for this systematic review of non-cancer pain studies meeting the inclusion criteria of continuous use of an intrathecal drug delivery system (IDDS) for at least 12 months duration with at least 25 patients in the cohort, **is Level II-3 based on USPSTF criteria. The level of evidence for this systemic review for cancer-related pain studies meeting the inclusion criteria of continuous use of IDDS for at least 3 months duration with at least 25 patients in the cohort is Level II-2 based on USPSTF criteria.**

Conclusion: Based on the available evidence, the recommendation for intrathecal infusion systems for cancer-related pain is moderate recommendation based on the high quality of evidence and the recommendation is limited to moderate based on the moderate quality of evidence from nonrandomized studies for non-cancer related pain.

Hayek S.M.; Intrathecal Therapy for Cancer and Non-Cancer Pain. Pain Physician 2011; 14:219-248.

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Abstract

The intrathecal drug-delivery system (IDDS) is one mode of infusing analgesic medications directly into the cerebrospinal fluid in close proximity to their site of action. This modality has been employed in patients with refractory pain either due to malignant or non-malignant causes for over 30 years. Unfortunately, and despite the number of years it has been in use, there is still a scarcity of rigorous evidence to guide its integration into clinical practice. **Current best evidence is inconclusive as to the comparative effectiveness and harms of the IDDS relative to routine medical care of patients. There are far more systematic reviews than high-quality primary comparative studies of the IDDS vs. conventional pain treatment.**

Smyth C. et al.; Intrathecal Analgesia for Chronic Refractory Pain: Current and Future Prospects. Drugs (2015).

Key Points
Intrathecal delivery of analgesics may benefit patients with refractory malignant and non-malignant pain as one component of a comprehensive treatment plan informed by the biopsychosocial model and supported by an interdisciplinary team of healthcare providers.
Multiple systematic reviews of intrathecal drug delivery have been published with many citing lack of high-quality evidence such as randomized controlled trials.
The state of evidence necessitates a collaborative approach between patient and healthcare team, as they weigh the potential for analgesia against the risk of serious complications with an intrathecal drug-delivery system.

Smyth C. et al.; Intrathecal Analgesia for Chronic Refractory Pain: Current and Future Prospects. Drugs (2015).

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There are substantial limitations in existing evidence addressing benefits, harms, and cost effectiveness of IDDS:

- **Lack of comparative studies;**
- **Inadequate sample size;**
- **Insufficient follow-up duration;**
- **Lack of explicit criteria for refractory pain;**
- **Risk of confounding indication;**
- **Lack of blinding to outcomes;**
- **Risk of selection bias through post-randomization trialing or attrition;**
- **Risk for selective reporting/non-reporting of outcome and analyses;**
- **Passive surveillance for drug, procedure, and device related harms**

Smyth C. et al.; Intrathecal Analgesia for Chronic Refractory Pain: Current and Future Prospects. Drugs (2015).

Die Vorteile der intrathekalen Schmerztherapie:

- **effektive Schmerzlinderung - hohe Wirksamkeit**
- **verringerte Nebenwirkungen**
- **signifikante Reduktion der oralen Medikation**
- **bessere Beweglichkeit und Funktionalität**
- **bessere Lebensqualität**
- **grundsätzlich längerfristige Kostenersparnis, allerdings abhängig vom Finanzierungssystem**

Schmerztherapie
Möglichkeiten einer symptomatischen Therapie

- Physikalische Therapie
- Medikamentöse Schmerztherapie
- Physiotherapeutische-Maßnahmen
- Psychologische Therapie
- Neurochirurgische/invasive Verfahren
- TENS Akupunktur

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Was sind Nebenwirkungen der CT gezielten Nervenwurzelblockaden im Lumbalbereich?

1) Blutung
2) Infektion
3) Hämatom
4) Pneumothorax

Non Votes : ## 000

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Eine permanente Ausschaltung der Nerven kann durchgeführt werden mit folgenden Methoden

- Phenol
- Alkohol
- Thermisch
- Kryotherapie

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Eine permanente Ausschaltung der Nerven kann durchgeführt werden mit folgenden Methoden?

1) Phenol
2) Alkohol
3) Thermisch
4) Kryotherapie

Non Votes : ## 000

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Was trifft zu?

Eine Neurolyse mit Phenol wirkt

1) eine Woche
2) drei Monate
3) drei bis sechs Monate
4) ein Jahr

Non Votes : ## 000

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Was trifft zu?

Epiduralblockaden sollen

1) immer blind durchgeführt werden — 25%

2) mit einem bildgebenden Verfahren durchgeführt werden, bei Unwirksamkeit — 25%

3) mehr als dreimal gemacht werden — 25%

4) wenn drei Blockaden keinen Erfolg bringen, nachdenken über ein anderes Therapieverfahren — 25%

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Was trifft zu?

Intrathekale Verfahren sind Therapieverfahren, die

1) nach der Gabe von oralen Opioiden durchgeführt werden sollen — 25%
2) vor der Gabe von oralen Opioiden durchgeführt werden sollen — 25%
3) bei Therapieresistenz trotz ausgereizter medikamentöser Therapie durchgeführt werden sollen — 25%
4) durchgeführt werden sollen, wenn eine chirurgische Sanierung möglich ist — 25%

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Non Votes : ## 000

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Welche der folgenden Medikamente sind für Intrathekal zugelassen?

1) Morphin — 20%
2) Fentanyl — 20%
3) Baclofen — 20%
4) Ziconotid — 20%
5) Clonidin — 20%

Non Votes : ## 000

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Was sind die Nebenwirkungen von Ziconotid?

1) Schwindel — 20%
2) Übelkeit — 20%
3) Schläfrigkeit — 20%
4) Durchfall — 20%
5) Verwirrtheit — 20%

Non Votes : ## 000

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Was sind die Nebenwirkungen von Opioiden?

1) Übelkeit — 16%
2) Erbrechen — 16%
3) Diarrhoe — 16%
4) Ödeme — 16%
5) Schwitzen — 16%
6) Gewichtsabnahme — 16%

Non Votes : ## 000

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Was sind Vorteile der intrathekalen Schmerztherapie?

1) effektive Schmerzlinderung 25%
2) verringerte Nebenwirkungen 25%
3) signifikante Reduktion der oralen Medikation 25%
4) bessere Beweglichkeit und Funktionalität 25%

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Non Votes : ## 000

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Welche Medikamente sind first-line Medikamente bei intrathekaler Austestung?

1) Morphin — 25%
2) Clonidin — 25%
3) Bupivacain — 25%
4) Ketamin — 25%

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Falls Entzugserscheinungen bei Opioiden auftreten, welche Symptome treffen zu?

1) Frösteln 14%
2) Schlafstörungen 14%
3) Mydriasis 14%
4) Tränen 14%
5) Nasenfluß 14%
6) Übelkeit 14%
7) Erbrechen 14%

Non Votes : ## 000

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Was trifft zu?

1) Bei intrathekalen Opioiden sind die Höchstdosierungsangaben zu beachten

25%

2) Es kann bei Höherdosierung von Morphin Hyperalgesie auftreten

25%

3) Morphin und Clonidin kann kombiniert werden

25%

4) Morphin und Baclofen kann kombiniert werden

25%

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Non Votes : ## 000

Danke für Ihre Aufmerksamkeit

Bei Fragen zu dieser Präsentation wenden Sie sich bitte per e-mail an sabine.grill@kabeg.at