

Basivertebral Nerve Ablation

Procedure Overview

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Disclosures:

NASS: All money received represent reimbursements for expenses related to NASS activities

Presentation Overview

- Chronic Vertebrogenic Low Back Pain Overview
- BVN Ablation Procedure Overview & Patient Selection
- Clinical Evidence Overview
- Program Integration Best Practices

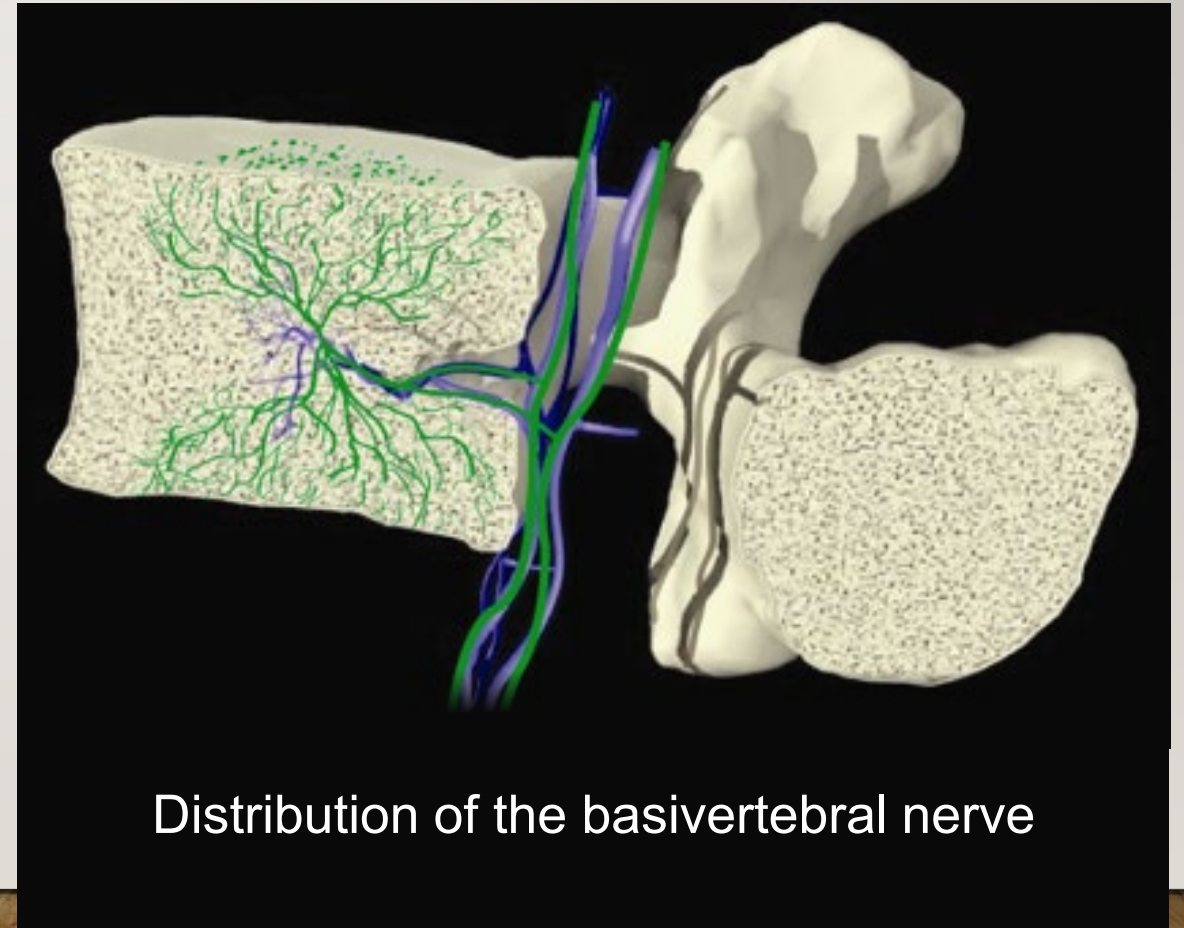
Chronic Vertebroprogenic Low Back Pain Overview



For decades, treatments focused on the disc and ignored the endplates.

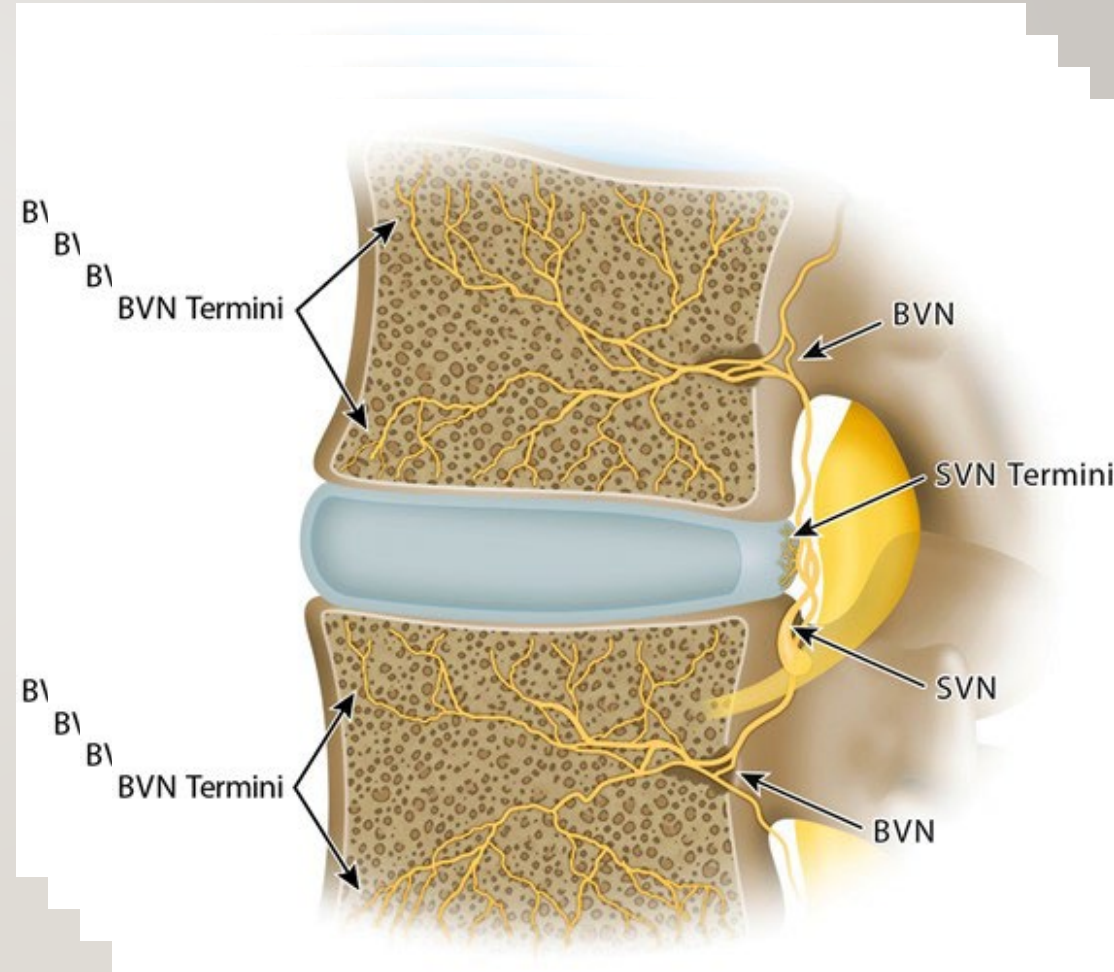
- Vertebral endplates are more innervated than intervertebral discs¹
- Basivertebral nerve (BVN) innervates the endplates and transmits pain signals from the vertebral endplates to the CNS²
- September 2021 – CMS designated an ICD-10 diagnosis code specifically for vertebrogenic low back pain (M54.51)

Vertebrogenic Pain is a Paradigm Shift in the Science of CLBP



Emerging Concept: Discovertebral Pain

- Discs and vertebral endplates (VEPs) are one functional unit
- Traditionally, discogenic and vertebrogenic pain have been seen as clinically distinct with treatments focused on the disc, despite VEPs being more innervated^{3,4}
- Disc vs. endplate pain source is less important than nociception pathway— direct to SVN or via BVN

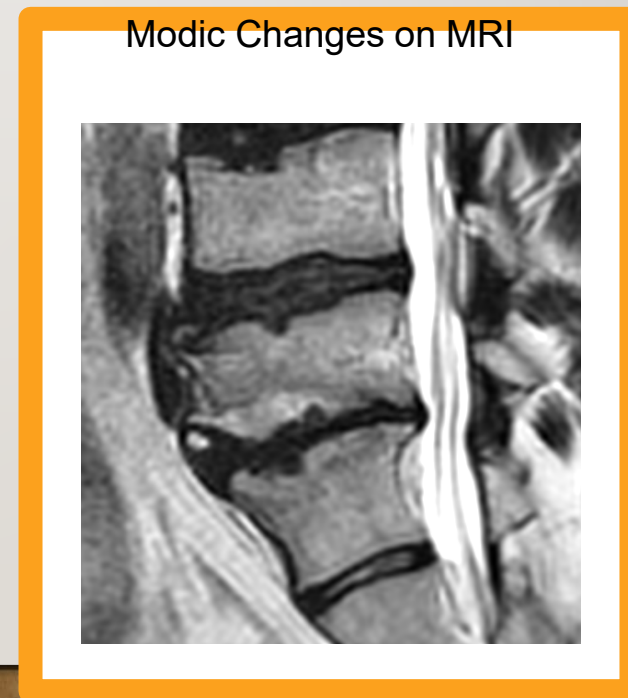
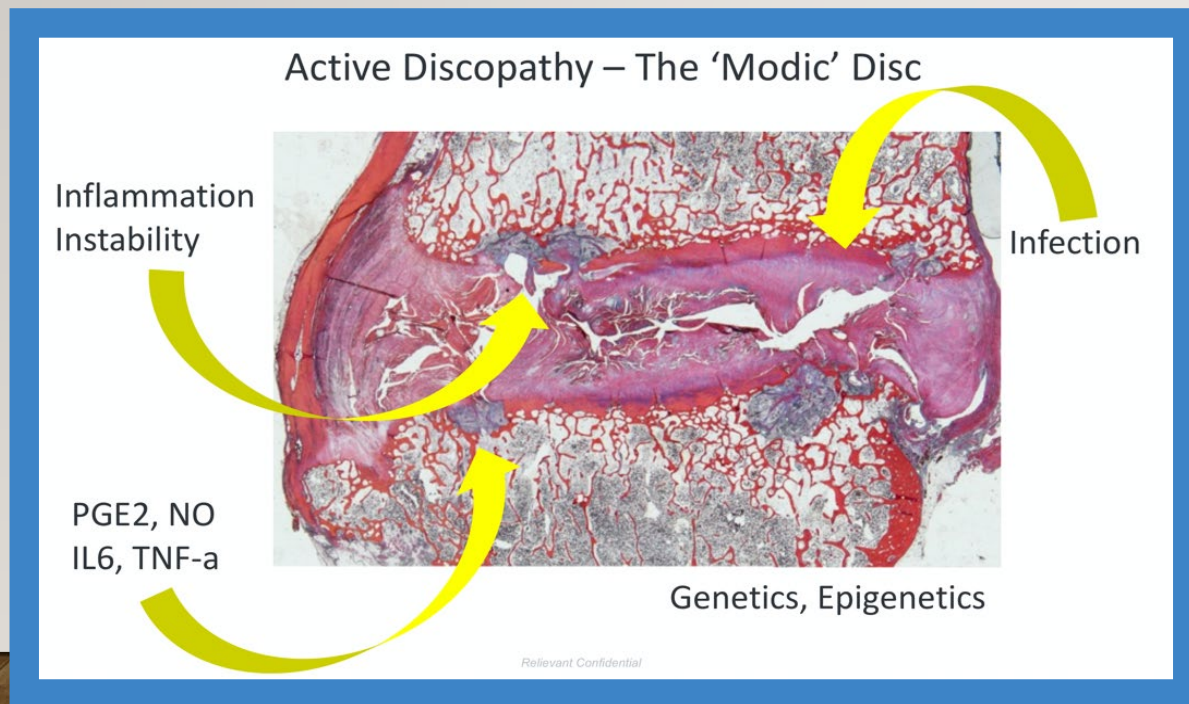


Endplate Defects Lead to Modic Changes

- Biomarker for Vertebroprogenic Pain

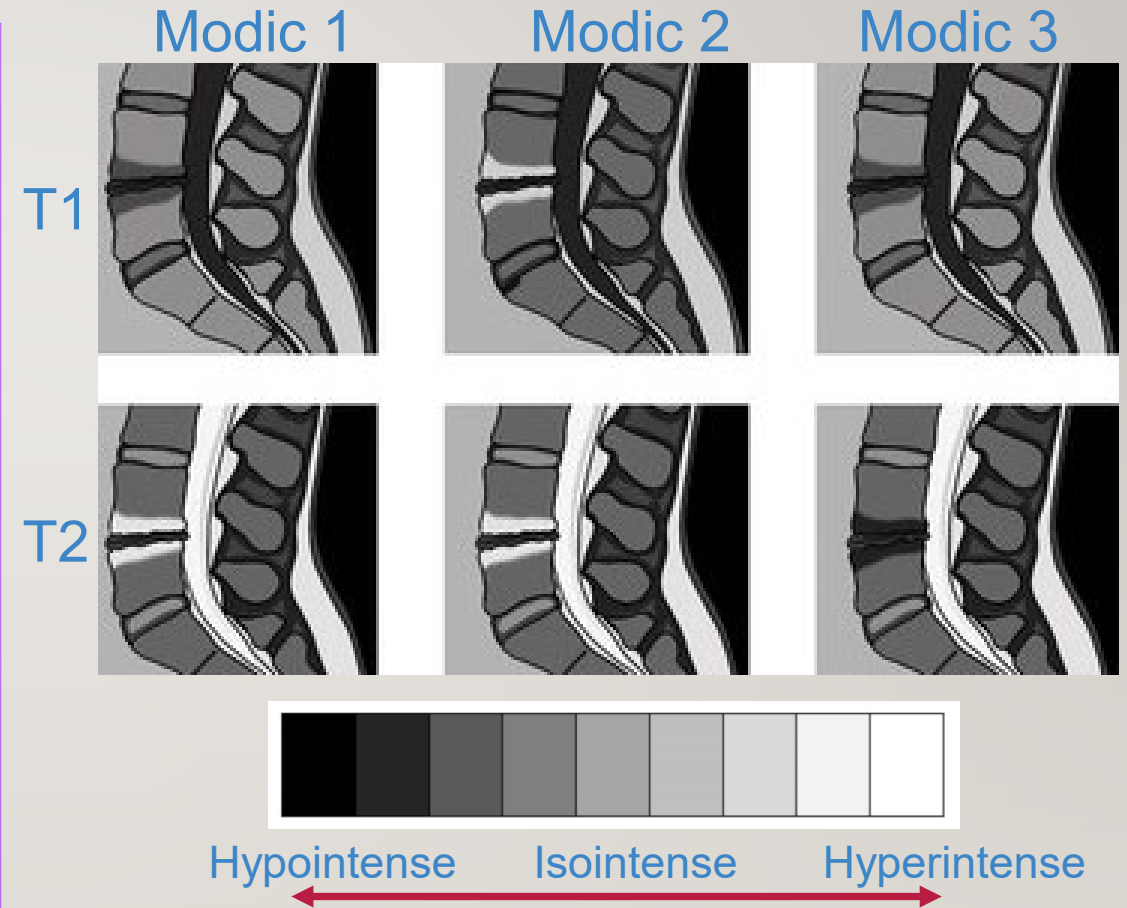
Endplate defects allow proinflammatory disc tissue to leak into the bone marrow, inciting an inflammatory response

Chronic endplate inflammation leads to Modic changes (MC) on MRI



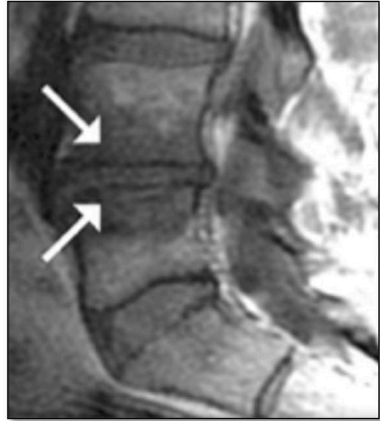
Modic Changes – Anatomical Changes & Imaging

Modic Change	1	2	3
MRI T1	Low	High	Low
MRI T2	High	High-intermediate	Low
Implication	Marrow inflammation and edema	Fatty replacement of marrow	Trabecular micro-fracture and sclerosis

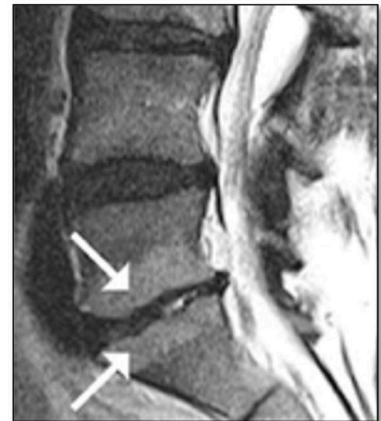


Imaging Modic Changes

MRI T1 (fat)



MRI T2 (fat and water)



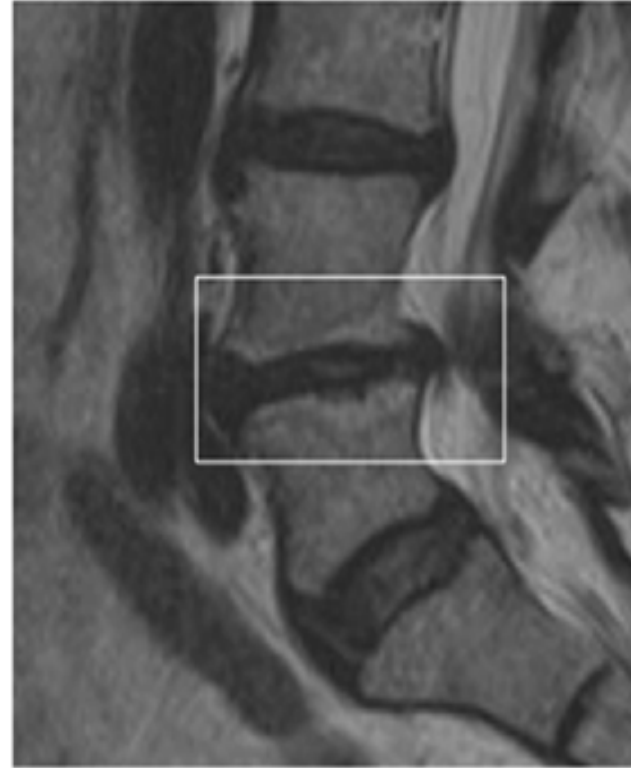
Modic Type 1 (1 tissue hyper-intense):

- Hypointense T1W
- Hyperintense T2W MR images

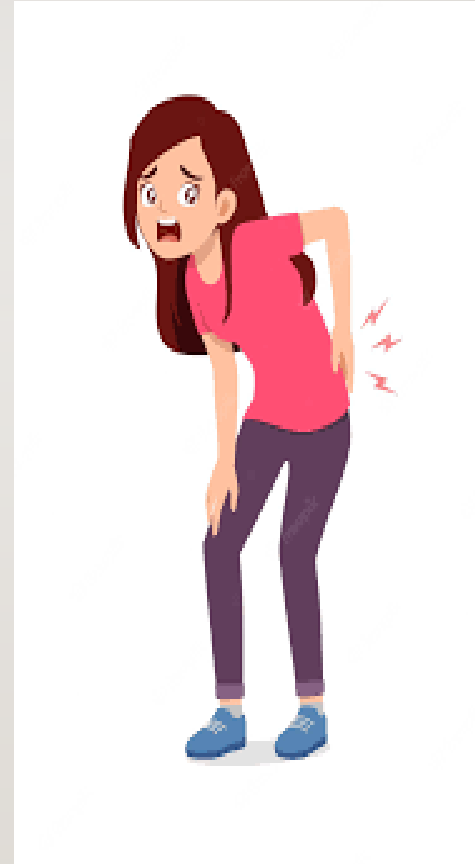
Modic Type 2 (2 tissues hyper-intense):

- Hyperintense T1W and T2W MR images

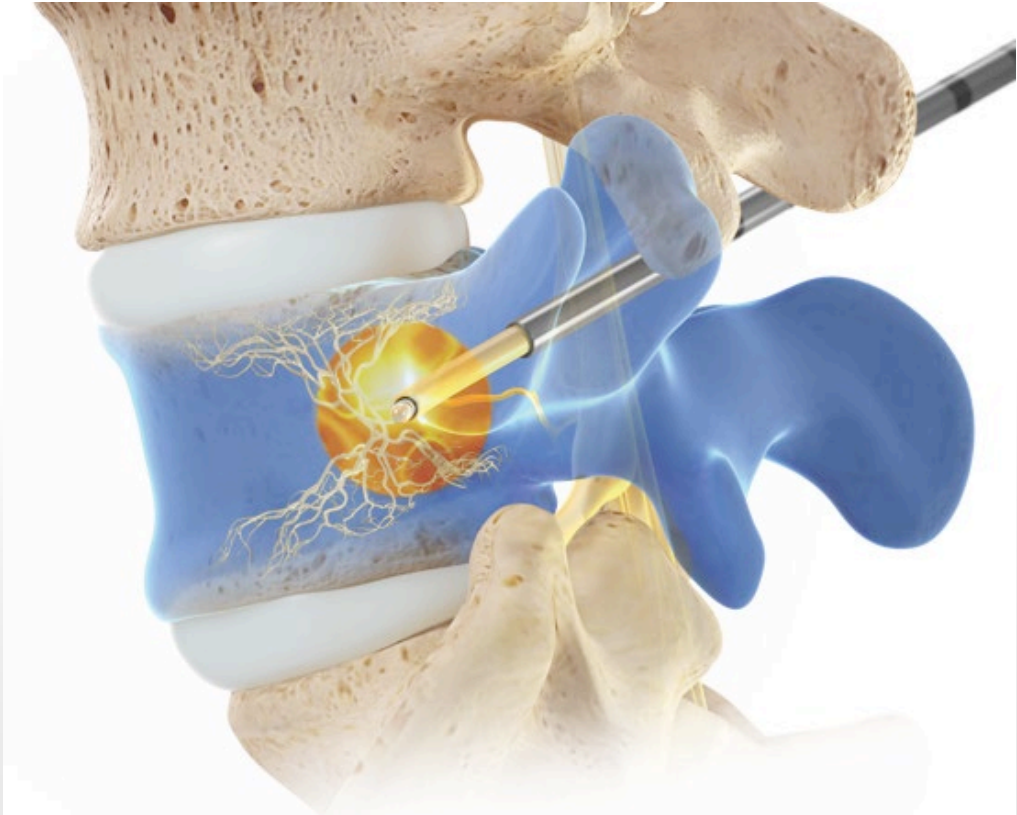
Modic Changes are Binary – Minimal Modic Reflects Endplate Damage



Procedure Overview and Patient Selection

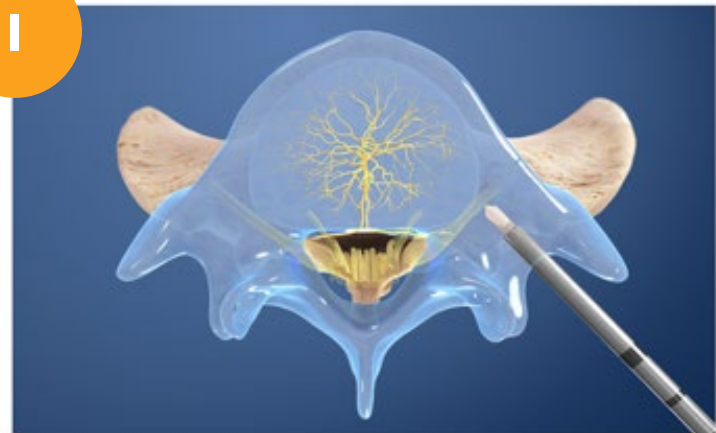


BASIVERTEBRAL NERVE (BVN) ABLATION PROCEDURE OVERVIEW

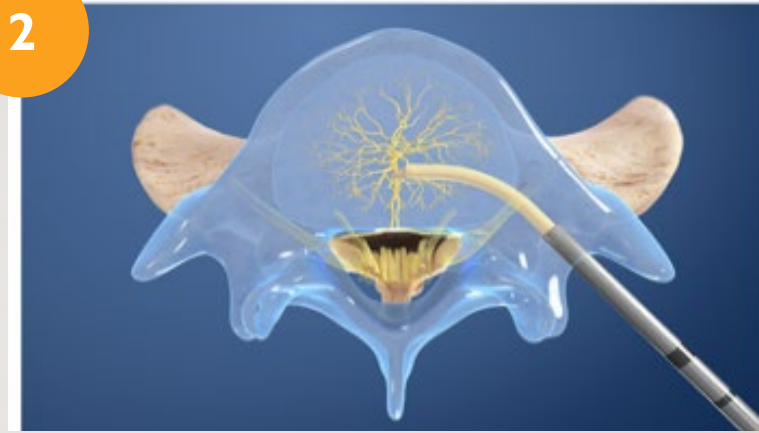


- Minimally invasive
- Brief recovery, same-day procedure
- Implant-free
- Preserves overall spine structure
- Long-term¹ pain relief after a single procedure
- Proven safety profile

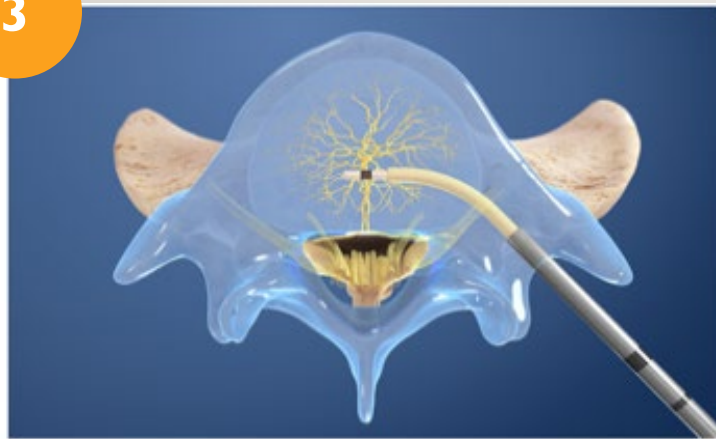
Straightforward Procedure Steps



Access the Pedicle



Create the Channel



Place the Radiofrequency Probe



Ablate the BVN

BVN Ablation Procedure Indications

- Chronic Low Back Pain of at least 6 months duration; and
- Failure to respond to at least 6 months of conservative care; and
- MRI changes consistent with Modic Type 1 or Type 2 at one or more levels from L3 to S1
- Features consistent with Type 1 or Type 2 Modic changes (MC) on an MRI:
 - Type 1 MC: Inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals
 - Type 2 MC: Changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals

BVN Ablation Patient Contraindications (Summary)

- Severe cardiac or pulmonary compromise
- Where the targeted ablation zone is <10mm away from a sensitive structure not intended to be ablated
- With active systemic infection or local infection in the treatment area
- Pregnancy
- Skeletally immature (≤ 18)
- With Implantable Pulse Generators (e.g. pacemakers, defibrillators)
- Where unintended tissue damage may result
- With instruments not tested / specified for use with RFG

Patient Characteristics of Vertebrogenic Pain

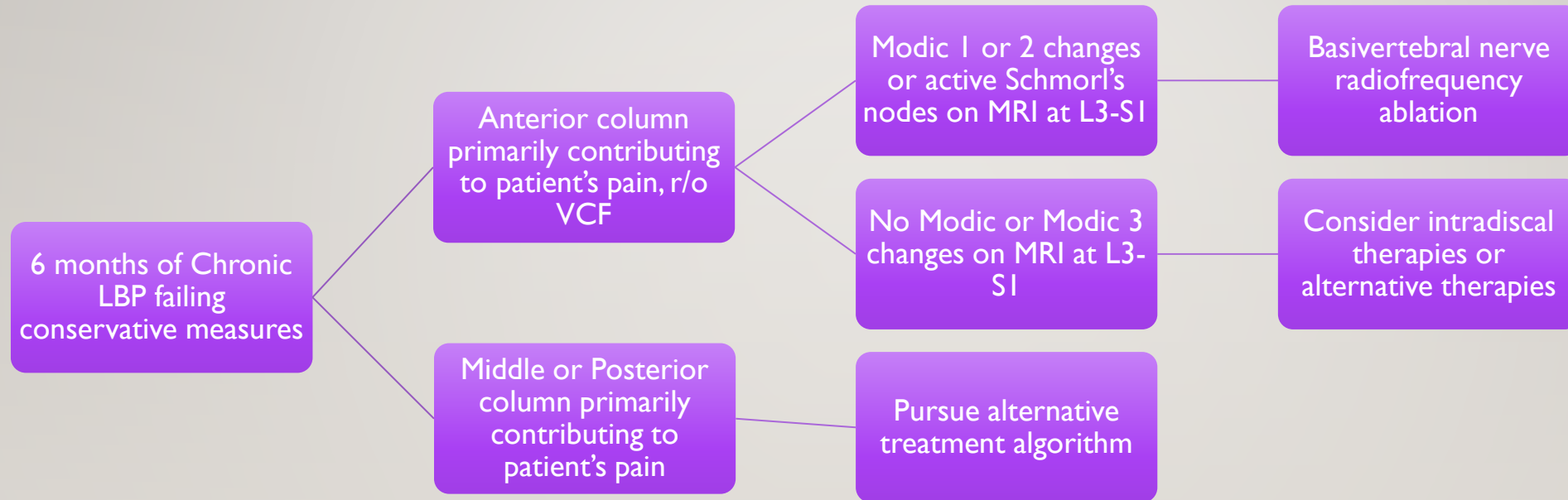
Vertebrogenic pain patients often describe their pain as:

- In the middle of their low back
- Pain that is worse during physical activity, prolonged sitting, and by
- Bending forward, or bending and lifting



Treatment Guidelines: Vertebroprogenic Pain

Treatment Algorithm



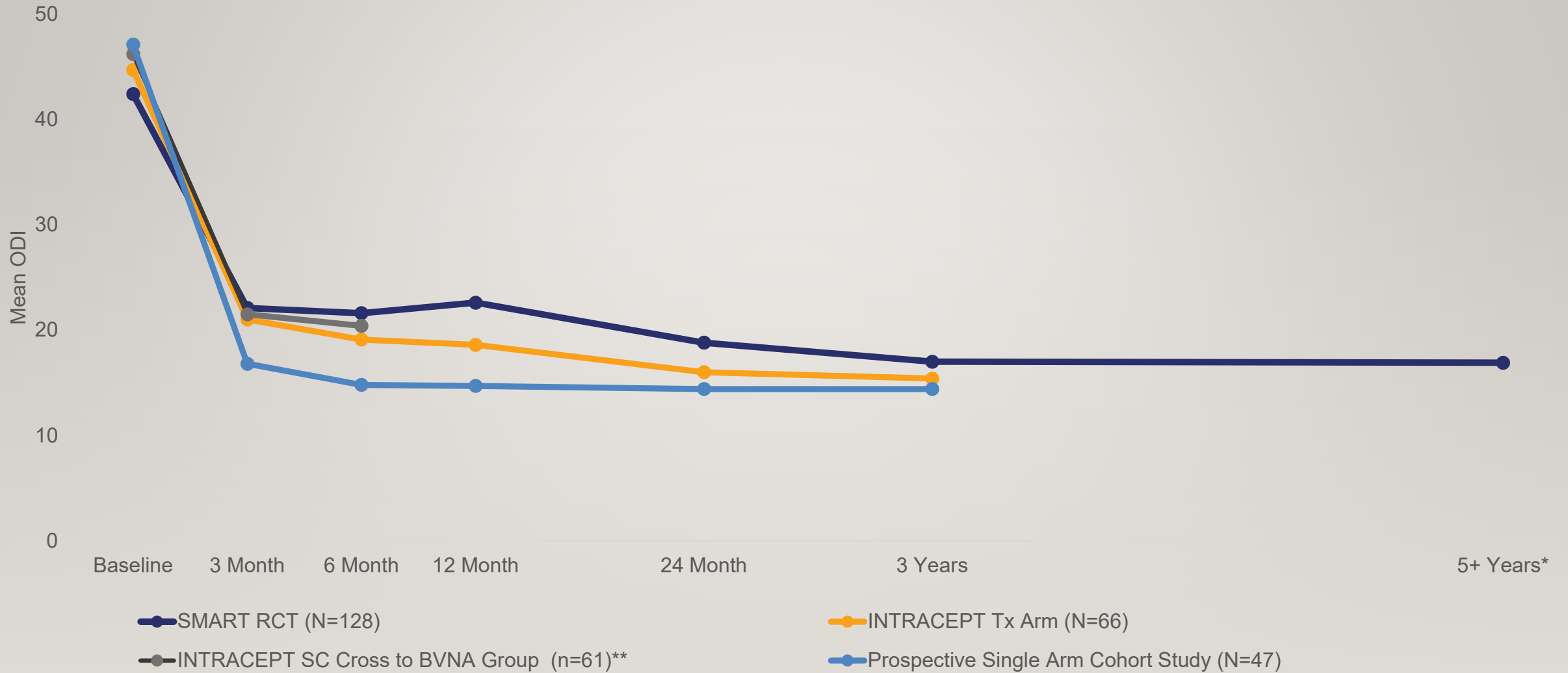
Clinical Evidence Overview:

Most of the published literature has been done with the support of Relivant, the company responsible for the development of this procedure which they market under the brand name “Intracept”

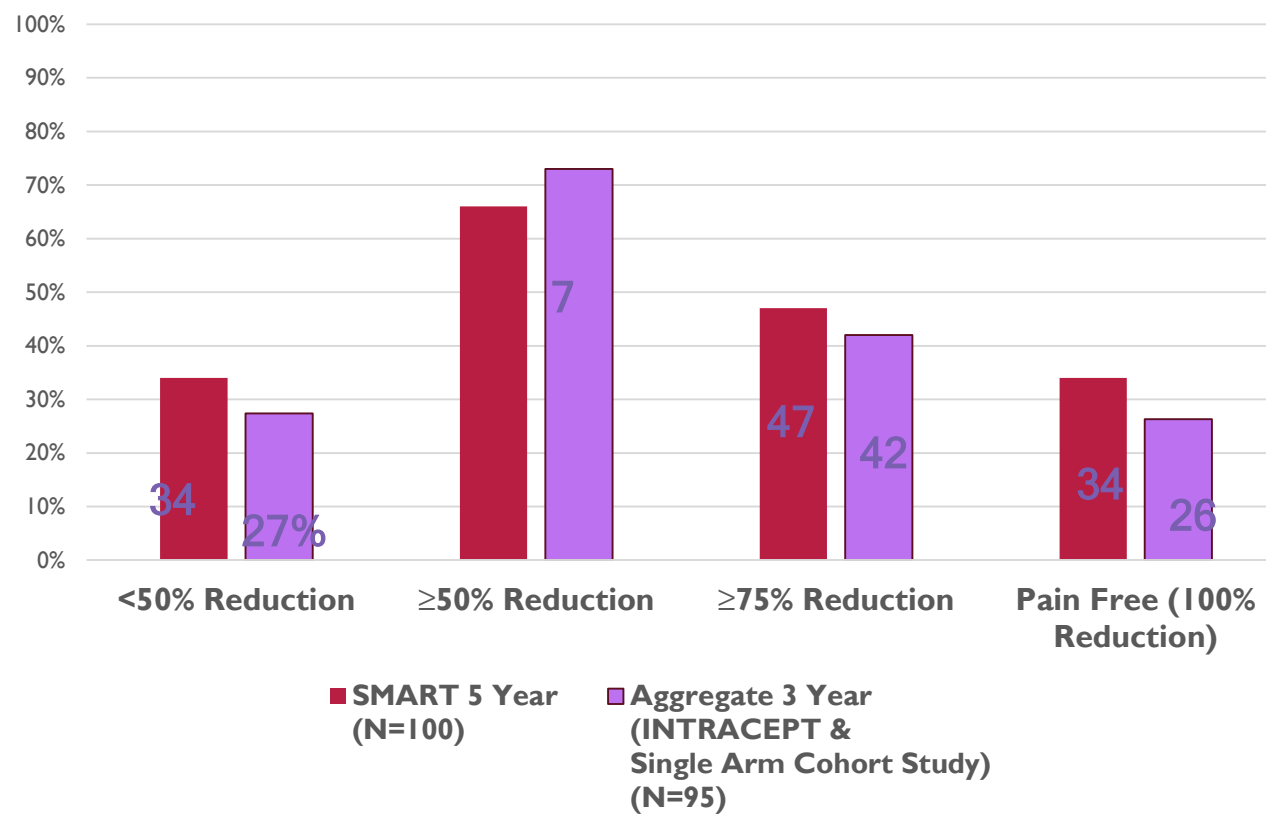
BVN Ablation Procedure Clinical Evidence

SMART RCT	SMART Pivotal RCT BVNA vs Sham	Fischgrund	N=225 (147 BVNA; 78 Sham)	European Spine Journal
	SMART 2-Year Outcomes	Fischgrund	N=106 (PP BVNA arm)	Int'l Journal of Spine Surgery
	SMART 5-Year Outcomes	Fischgrund	N=100 (US PP BVNA arm)	European Spine Journal
INTRACEPT RCT	INTRACEPT RCT BVNA vs Standard Care (SC)	Khalil	<i>Interim Analysis</i> N=104 (51 BVNA; 53 SC)	The Spine Journal
	INTRACEPT RCT - 1 Year Outcomes BVNA vs SC and SC crossover	Smuck	Full Cohort N=140 (66 BVNA; 74 SC) Total BVNA N=127 61 SC Crossover	Regional Anesthesia and Pain Management
	INTRACEPT - 2-Year Outcomes	Koreckij	N=58 BVNA arm	NASSJ
Prospective, Single-Arm Cohort Study	Prospective, Single-Arm Cohort Study - 3 Month Outcomes	Truumees	<i>Interim Analysis</i> N=28 BVNA	European Spine Journal
	Prospective, Single-Arm Cohort Study - 12 Month Outcomes	Macadaeg	N=47 BVNA	NASSJ
Aggregate INTRACEPT & Single Arm Cohort	Aggregate 3-Year Outcomes	Beall	N=95 INTRACEPT BVNA arm N=53 Prospective Single Arm N=42	ASPN 2022

Functional Improvement (ODI) Across Studies



VAS Reductions: SMART5 And Aggregate 3- year Data



Tips And Suggestions



Assessing Imaging Is Critical To Making The Right Diagnosis

- It is important to read all MRIs as many patient reports do not mention Modic changes
 - Modic Type I or II changes = objective biomarker for diagnosing vertebrogenic CLBP
 - Modic changes are more common than you may think
 - You may already be managing Intrasept Procedure candidates
- **DO NOT** rely exclusively on patient reports



Gather The Story: Write A Strong Office Note

- **Subjective:**

- The duration of the problem (not just that it's ≥ 6 months)
- Location of pain
- Include VAS and possibly ODI (best, worst, average)
- The impact upon ADLs (e.g. sleep, sex, work and/or recreational activities)
- Document specific treatments attempted (e.g. Meds, PT, Chiro, ESIs, RFAs)

- **Imaging:**

- Document specific vertebral bodies with endplate changes.
- Document type of endplate change: Modic Type I and/or Type 2
- Clip a picture of the actual image in the note

- **Impression:**

- Document diagnosis: Vertebrogenic CLBP with Modic changes at specific vertebral bodies

- **Plan:**

- BVN Ablation - Levels



Post Operative Care

- **Wound closure:** derma-bond or steri-strips
- **Pain control:** varies between oral Acetaminophen to a short course of oral opioids
- **Patient activity & limitations:**
 - Most physicians endorse avoiding any heavy lifting / repetitive bending for two weeks
 - Gradual return to full activities over the following four weeks
- **Patient follow-up:**
 - Most offices call patients 24-48 hours post procedure and perform a wound check after 1-2 weeks
 - If suspicious of anything more than transient radiculitis or LBP flare up, see patient for a follow-up examination





Thank you

