Intraosseous Basivertebral Nerve Ablation for Chronic Vertebrogenic Pain: 6-Month Outcomes from the IMPROVE Study

Ramana Naidu[1], Gregory Moore[2], Ronald Boeding[3], Zachary McCormick[4], Adem Aktas[5], Nathan Swain[6], Shawn Milburn[7], John Smirniotopoulos[8], David Schneider[9], Maged Guirguis[10], Brian Durkin[11], Christine Haddad[12], Rajat Sekhar[13], Justin Davanzo[14], Kent Cochran[15], Brian Bruel[16]

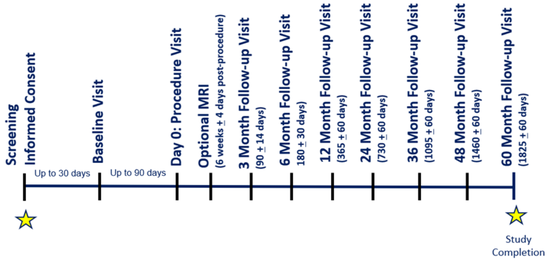
1. University of Chicago Medical Center, Anesthesia and Critical Care Medicine, Chicago, IL USA 2. Piedmont Comprehensive Pain Management Group, PCPMG Clinical Research Unit LLC, Greenville, SC USA 3. Carolinas Pain Institute and Center for Clinical Research, Winston-Salem, North Carolina, USA 4. Multidisciplinary Pain Program, Montefiore Medical Center, Bronx, NY USA 5. The Orthopaedic Institute, Gainesville, Florida, USA 6. Vitamed Research, Palm Desert, California, USA 7. The Denver Spine and Pain Institute, Denver, CO USA 8. Spine and Pain Specialists, Shreveport, LA USA 9. Pacific Sports and Spine, Eugene, Oregon, USA 10. Department of Sports & Spine, Evergreen Health Medical Group, Kirkland, WA USA 11. South Lake Pain Institute, Clermont, Florida, USA 12. Goodman Campbell Brain & Spine; Ascension St. Vincent's Carmel, IN, USA 13. Boston Scientific Neuromodulation, Valencia, CA, USA

BACKGROUND

The role of vertebral endplates and the basivertebral nerve (BVN) in generating chronic axial low back pain (CLBP) is supported with histopathological findings.1-2 When vertebrogenic CLBP is identified, a BVN ablation (BVNA) procedure can be considered. The effectiveness and safety of intraosseous BVNA for the treatment of vertebrogenic CLBP has been established in two level 1 randomized controlled trials and a single-arm cohort study to 5-years.3-6 The goal of this ongoing multicenter study is to compile real-world outcomes of a commercially approved BVNA system in the treatment of patients diagnosed with vertebrogenic CLBP. Here we disclose preliminary outcomes for the first 120 patients who received BVNA per standard practice across multiple sites in the United States, and who have completed their 3-month follow-up visit. We also present the prevalence of multi-factorial low back pain and explore differences in outcomes between patients with all levels of Modic I and/or II (L3-S1) treated with BVNA versus those without all levels treated.

METHODS

Study	IMPROVE (**I**ntracept™ **M**inimally-invasive **PRO**cedure for **VE**rtebrogenic back pain); Clinicaltrial.gov ID NCT06827262
Design	Prospective, multicenter, single-arm study out to 5-year follow-up
Study Device	Boston Scientific Intracept™ Intraosseous Nerve Ablation System
Primary Endpoint	Study visit assessments include pain intensity with Visual Analog Scale (VAS), EuroQOL Quality of Life (EQ-5D-5L), Oswestry Disability Index (ODI v2.1b), Short Form Health Survey (SF-36), patient satisfaction (PGIC), concomitant medications for chronic low back pain, and pain management and resource utilization for chronic low back pain.

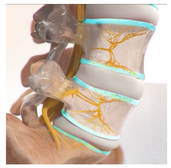


BASELINE CHARACTERISTICS

Age (yrs.) - Mean (SD) n	61.5 (14.2) 259
Gender (Female) - % (n/N)	51.7%
Main diagnosis associated with vertebrogenic CLBP (may have multiple) - %	
None	8.5%
Degenerative disc disease	48.1%
Radiculopathy	41.9%
Spondylolysis	35.8%
Lumbar spinal stenosis	29.6%
Average Low Back Pain (VAS) - Mean (SD) n	65.2 (19.5) 250
Disability (Oswestry Disability Index [ODI] - Mean (SD) n	38.3 (15.6) 253
MODIC changes (MRI-identified levels) - % (n/N)	
1 level	1.6% (4/245)
2 levels	44.9% (110/245)
3 levels	22.0% (54/245)
4 levels	31.4% (77/245)

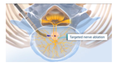
BVNA PROCEDURE

Number of levels treated		
1 level	4%	9/260
2 levels	68%	117/260
3 levels	18%	46/260
4 levels	10%	25/260



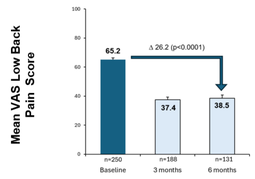
68% (117/260) had 2 levels treated

BVNA Treatment Parameters	
Standard (15-min)*	30.0% (78/260)
Targeted (7-min)**	43.5% (113/260)
Mixed	24.6% (64/260)



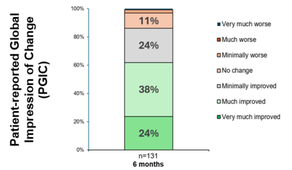
* 15-min, 85°C
** 7-min, 75°C

LOW BACK PAIN



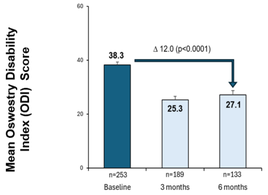
61% have ≥ 20-point reduction in low back pain at 6-month follow-up

PATIENT SATISFACTION



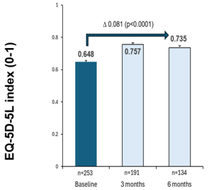
62% of the patients reported being "much" or "very much" improved at 6-months

FUNCTIONAL DISABILITY OUTCOMES



42% have minimal disability at 6-months versus 13% at baseline

HEALTH-RELATED QoL

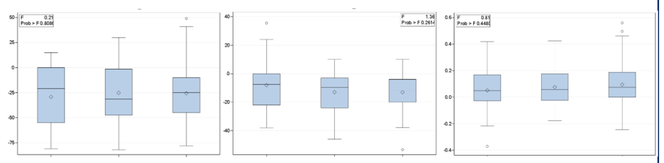


EQ5D-5L index improvement was superior to the MCID[7]

IMPACT OF TREATMENT COVERAGE

2-Level treatment in the presence of 2-Level versus 4-Level Modic Changes

Change in **VAS** p=0.8086 | Change in **ODI** p=0.2614 | Change in **EQ-5D-5L index** p=0.4480



No statistical differences were found in VAS, ODI, and EQ5D-5L when comparing ablation parameters (standard, targeted, mixed)

CONCLUSIONS

Early clinical outcomes from this ongoing prospective real-world, observational study show improvements in pain, function, patient satisfaction and quality of life by 6-months post-BVNA:

- **≥ 20-point reduction in low back VAS for 61% of the patients**
- **42% of the patients had minimal disability (versus 13% pre-BVNA)**
- **62% of the patients reported being "much" or "very much improved"**
- **The improvement in EQ-5D-5L index exceeded the MCID**

Results suggest that patients limited to treatment at only 2-levels in presence of 4-level Modic had less improvement in clinical

REFERENCES

1. Lotz JC, Fields AJ, Liebenberg EC. The role of the vertebral endplate in low back pain. Global Spine J. 2013;3(3):153-164.
2. Dudli S, Fields AJ, Samartzis D, et al. Pathobiology of Modic changes. Eur Spine J. 2016;25(11):3723-3734.
3. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2018;27(5):1146-1156.
4. Khalil J, Smuck M, Koreckij T, et al.; INTRACEPT Trial Investigators A prospective, randomized, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. Spine J. 2019;19(10):1620-1632. https://doi.org/10.1016/j.spinee.2019.05.598
5. Smuck M, Khalil JG, Barrett K, et al.; INTRACEPT Trial Investigators A prospective, randomized, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. Reg Anesth Pain Med. 2021;46(8):683-693.
6. Khalil JG et al. Intraosseous basivertebral nerve ablation: A 5-year pooled analysis from three prospective clinical trials. Interv Pain Med. 2024 Dec 13;3(4):100529.
7. McClure NS, Sayah FA, Xie F, Luo N, Johnson JA. Instrument-Defined Estimates of the Minimally Important Difference for EQ-5D-5L Index Scores. Value Health. 2017 Apr;20(4):644-650. doi: 10.1016/j.jval.2016.11.015. Epub 2017 Jan 10. PMID: 28408007.

DISCLOSURES

Study Sponsored by Boston Scientific.

November 5-7, 2026
JW Marriott Tampa Water Street | Tampa, Florida
#ASRAFALL26

