Madrid , November 4 2017
Jan Willem Kallewaard, MD

Disclosures

- Scientific Advisory Board: NA
- Scientific Research: Abbott, Nevro, Boston, Medtronic, Saluda
- Speaker's Bureau: NA
- Stock Holder / Stock Options: NA
- Product Royalties: NA
- Employed by: NA

- Any off label uses of devices or products will be disclosed and discussed in a balanced manner
- No company or product names or logos will be used in the presentation

Effectiveness of DRG stimulation for treating discogenic low back pain: prospective study

J. Kallewaard, MD[1]; M. van Kleef, MD, PhD[2]; J. van Susante, MD[1]; C. Edelbroek[1]; J. Geurts[2]; W. Cusack, PhD[3]; J. Kramer, PhD[3]

[1]Rijnstate Ziekenhuis, Velp, The Netherlands; [2]Maastricht University Medical Center, Maastricht, The Netherlands; [3]Abbott, Sunnyvale, CA, USA.

International Neuromodulation Society 13th World Congress

May 30th, 2017

Post market observational study on the effect of DRG stimulation in patients with chronic pain following surgical lumbar discectomy (failed back surgery syndrome)

Jan Willem Kallewaard, MD[1]; Harold Nijhuis, MD[2]; Frank Huygen, MD, PhD[3]; Frank Wille, MD[4,5]; Xander Zuidema, MD[4,5]; Johan van de Minkelis, MD[6]; Christophe Perruchoud, MD[7]

[1]Rijnstate Ziekenhuis, Velp, The Netherlands; [2]St. Antonius Hospital, Nieuwegein, The Netherlands; [3]Erasmus University, Rotterdam, The Netherlands; [4]Diakonessenhuis Utrecht, Zeist, The Netherlands, [5]Academic Medical Centre Amsterdam, Amsterdam, The Netherlands; [6]St. Elisabeth Ziekenhuis, Tilburg, The Netherlands; [7]Hospital de Morges, Morges, Switzerland

This work was supported by Abbott.

BACKGROUND

Surgical lumbar discectomy is believed to be the most commonly performed routine spinal procedure; usually to alleviate lumbar radicular symptoms caused by a herniated intervertebral disc[1]. It has also been reported to be a surgical intervention that can lead to chronic post surgical leg and/or back pain (failed back surgery syndrome, FBSS)[2]. This condition is often refractory to pharmacological or other minimally invasive treatments[3]. The results for spinal cord stimulation (SCS) in this patient population are mixed[4]. Early clinical results on the use of dorsal root ganglion (DRG) stimulation for FBSS have supported the use of this treatment alternative[5]. The purpose of this study is to evaluate the effectiveness of DRG stimulation for the management of chronic pain in the back, groin, and/or lower extremities following surgical lumbar discectomy.

METHODS

Data were collected on pain (Numerical Pain Rating Score, NPRS, Brief Pain Inventory, BPI), quality of life (EuroQol Five Dimensions Questionnaire, EQ-5D), mood (Profile of Mood, POMS), and physical functioning (Oswestry Disability Index, ODI) in this prospective, single-arm, multi-center, post-market, observational study. In order to meet the inclusion criteria for the study, subjects must have chronic pain in the back, groin, and/or lower extremities following surgical lumbar discectomy for at least 6 months, failed conservative treatments, and minimum baseline pain rating of 60 mm in the primary area of pain. Clinical outcomes were compared between baseline and measurements made at the 1-week post-implant and 1, 3, 6, and 12-month follow-ups. A total of 25 subjects enrolled and screened for the study, with 13 qualifying for the study based on the inclusion/exclusion criteria. All 13 subjects moved forward into an external or intraoperative trial evaluation. Two-sample, two-tailed t-tests were used with α=0.05, adjusted with the Bonferroni correction for multiple comparisons.

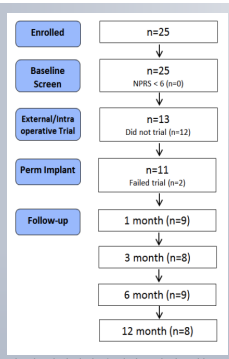


Figure 1: Consort diagram showing the inclusion/exclusion criteria, subject selection process and follow-up consistency for subjects receiving DRG stimulation.

RESULTS

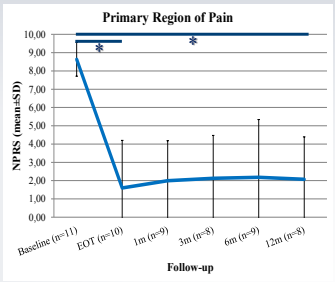


Figure 2: Pain ratings in the primary area of pain were reduced in responders to DRG stimulation. Compared to baseline, significant pain reduction was achieved at the end-of-trial follow-up (t(19)=8.41, p<0.001) and was sustained at the 12-month follow-up (t(17)=8.56, p<0.001).

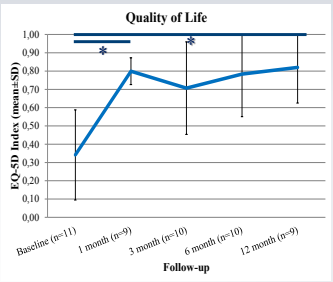


Figure 3: Overall quality of life ratings were increased in responders to DRG stimulation. Compared to baseline, significant quality increase was achieved at the 1-month follow-up (t(18)=-5.36, p<0.001) and was sustained at the 12-month follow-up (t(18)=-4.73, p<0.001).

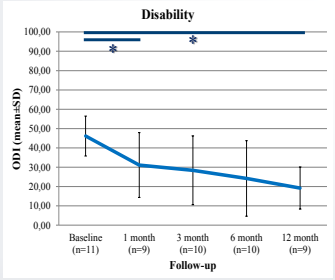


Figure 4: Overall disability ratings were decreased in responders to DRG stimulation. Compared to baseline, significant quality increase was achieved at the 1-month follow-up (t(18)=2.46, p<0.05) and was sustained at the 12-month follow-up (t(18)=5.66, p<0.001).

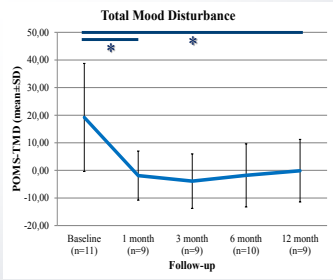


Figure 5: Total mood disturbance decreased in responders to DRG stimulation. Compared to baseline, significant quality increase was achieved at the 1-month follow-up (t(18)=2.98, p<0.01) and was sustained at the 12-month follow-up (t(18)=2.61, p<0.05).

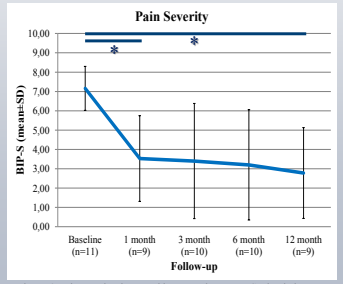


Figure 6: Pain severity decreased in responders to DRG stimulation. Compared to baseline, significant quality increase was achieved at the 1-month follow-up (t(18)=4.74, p<0.001) and was sustained at the 12-month follow-up (t(18)=5.45, p<0.001).

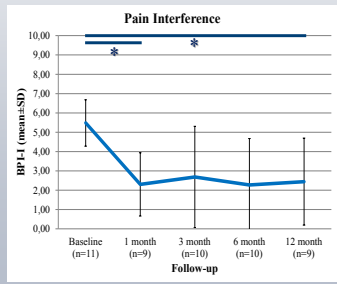


Figure 7: Pain interference decreased in responders to DRG stimulation. Compared to baseline, significant quality increase was achieved at the 1-month follow-up (t(18)=4.74, p<0.001) and was sustained at the 12-month follow-up (t(18)=3.87, p<0.001).

RESULTS

- 11/13 subjects (84.6%) experienced a successful trial and proceeded with a permanent implant.
- Baseline VAS in the primary area of pain was reduced from 8.64±0.92 to 1.60±2.61 (mean±SD) at the end-of-trial follow-up, for an average pain relief of 81.67%.
- This effect proved durable, as VAS at the 12-month follow-up in the 9 available subjects (2 lost to follow-up) remained low at 2.08±2.32, a pain reduction of 76.78%.
- Concomitant improvements were also reported in secondary clinical outcomes at the 1 month and 12 month follow-ups, respectively:
  - EQ-5D index increases of 134.3% and 140.2%
  - ODI decreases of 32.5% and 58.4%
  - POMS-TMD decreases of 109.8% and 100.6%
  - BPI-S decreases of 50.7% and 61.2%
  - BPI-I decreases of 58.0% and 55.4%

CONCLUSIONS

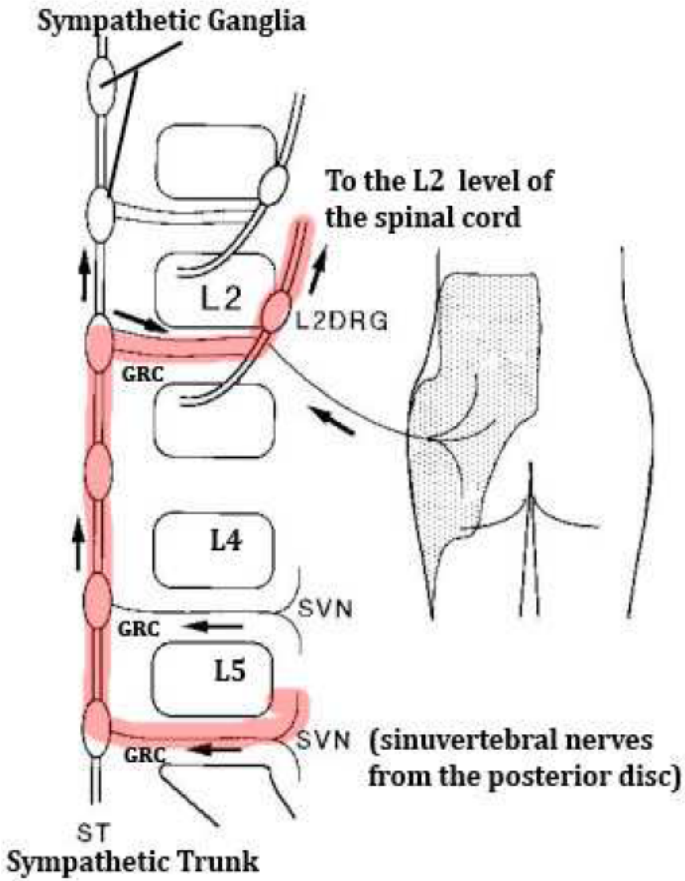
- These data suggest that DRG stimulation induces pain relief in subjects diagnosed with failed back surgery syndrome.
- These reductions in pain were also associated with improvements in quality of life, disability, total mood disturbance, pain severity and pain interference.
- Additional prospective studies are warranted to further investigate this application of DRG stimulation, as well as to optimize patient selection, lead placement and programming strategies.

REFERENCES

1. Deyo RA, Weinstein JN. Low back pain. N Engl J Med. 2001;344:363–370.
2. DePalma MJ, Ketchum JM, Saullo TR, Laplante BL. Is the history of a surgical discectomy related to the source of chronic low back pain? Pain Physician 2012;15:E53-E58.
3. Schofferman J, Reynolds J, Herzog R, Covington E, Dreyfuss P, O'Neill C. Failed back surgery: etiology and diagnostic evaluation. Spine J 2003; 3:400-403
4. Cameron, T., Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. J Neurosurg, 2004. 100(3 Suppl Spine): p. 254-67.
5. Deer T.R., Grigsby E., Weiner R.L., Wilcosky B., Kramer J.M. 2012. A Prospective Study of Dorsal Root Ganglion Stimulation for the Relief of Chronic Pain. Neuromodulation 2013; 16: 67–72

Chronic Low Back Pain

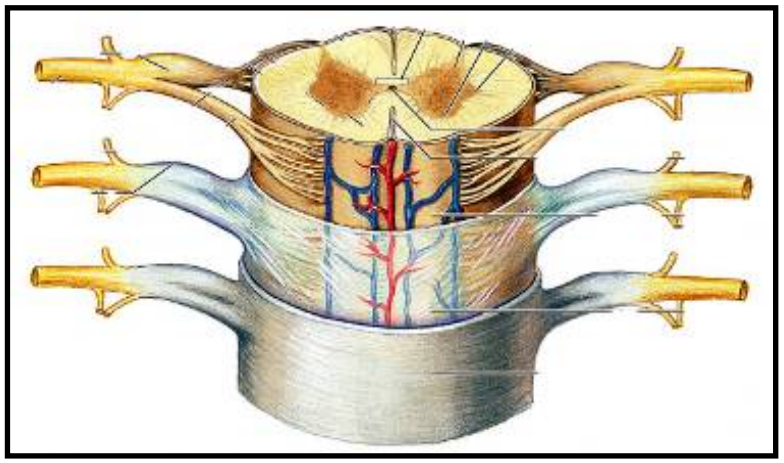
- Low back pain (LBP) has a lifetime prevalence of 70%[1]
- Chronic low back pain (CLBP) is generally defined by symptoms lasting for more than 3 months; often leading to a low quality of life due to pain, disability and loss of work productivity[2-3]
- Previous studies suggest that approximately 40% of CLBP is caused by internal disc disruption and involves vascularized granulation tissue containing sensitized nociceptive nerves[4]
- Lumbar disc is innervated by sinuvertebral nerves consisting of spinal sensory and postganglionic sympathetic fibers[5]



1. Itz CJ, Geurts JW, van Kleef M, et al. Clinical course of non-specific low back pain: a systematic review of prospective cohort studies set in primary care. Eur J Pain 2013;17:5-15.
2. Becker A, Held H, Redaelli M, et al. Implementation of a guideline for low back pain management in primary care: a cost-effectiveness analysis. Spine (Phila Pa 1976) 2012;37:701-10.
3. Kuslich SD, Ulstrom CL, Michael CJ. The tissue origin of low back pain and sciatica: a report of pain response to tissue stimulation during operations on the lumbar spine using local anesthesia. Ortho Clin Nor Am 1991;22:181-7.
4. Bogduk N, Aprill C, Derby R. Lumbar Discogenic Pain: State-of-the-Art Review. Pain Med 2013.
5. H.V. Luschka. Die Nerven des menschlichen Wirbelkanales. H. Laupp , Tubingen, Germany, 1850 (image)

Dorsal Root Ganglion Stimulation

- Despite promising results in anti-inflammatory and ablation methods, the ideal interventional treatment for treating chronic discogenic low back pain has yet to be found[5-6]
- Stimulation of the dorsal root ganglia (DRG) is a safe and effective treatment for a variety of chronic pain conditions including failed back surgery syndrome (FBSS) and general CLBP[7]
- The purpose of this study is to evaluate the effectiveness of DRG stimulation in a population consisting of those with confirmed discogenic CLBP



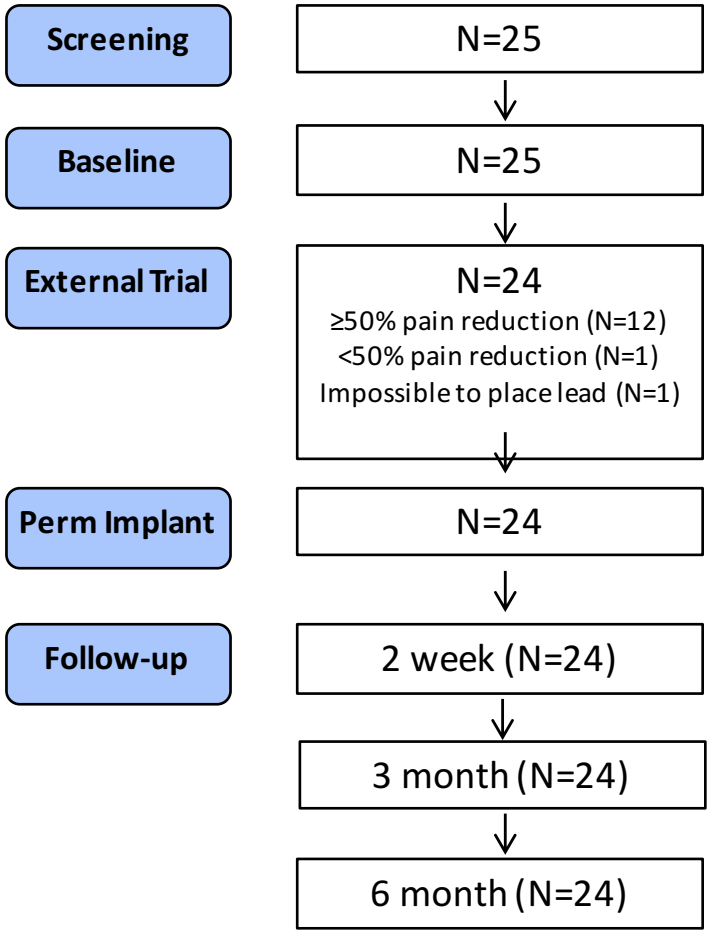
5. Kallewaard JW, Terheggen MA, Groen GJ, et al. 15. Discogenic low back pain. Pain Pract 2010;10:560-79.
6. Singh K, Ledet E, Carl A. Intradiscal therapy: a review of current treatment modalities. Spine (Phila Pa 1976) 2005;30:S20-6.
7. Deer T.R., Grigsby E., Weiner R.L., Wilcosky B., Kramer J.M. 2012. A Prospective Study of Dorsal Root Ganglion Stimulation for the Relief of Chronic Pain. Neuromodulation 2013; 16: 67–72.
http://iws.collin.edu/cdoumen/histocccd/labslides/dorsalganglion.html

Study Design Overview

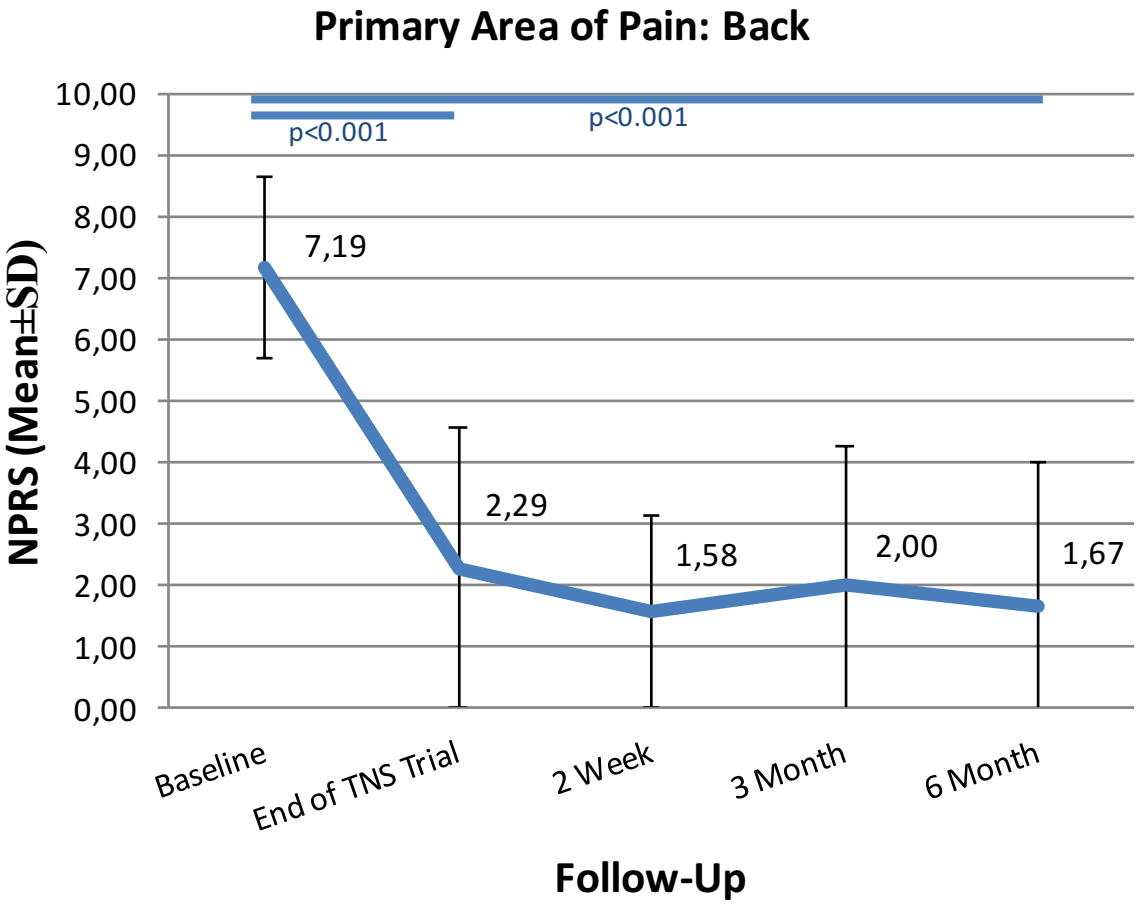
- Prospective, single-arm, multi-center, post-market pilot study in The Netherlands with approved indication for intractable chronic pain

- Major study inclusion criteria included:
  - Confirmed diagnosis of discogenic low back pain
  - Chronic low back pain for at least 6 months
  - Baseline pain rating in the primary pain region ≥6 on the Numerical Pain Rating Scale (NPRS)
  - Not suitable candidate for lumbar spinal surgery
  - Failed conservative treatments

- Outcome measures included:
  - Pain relief measured using a Numerical Pain Rating Scale (NPRS)
  - Quality of life (EQ-5D)
  - Oswestry Disability Index (ODI)
  - Profile of Mood States (POMS)
  - Subject Satisfaction (PGIC)



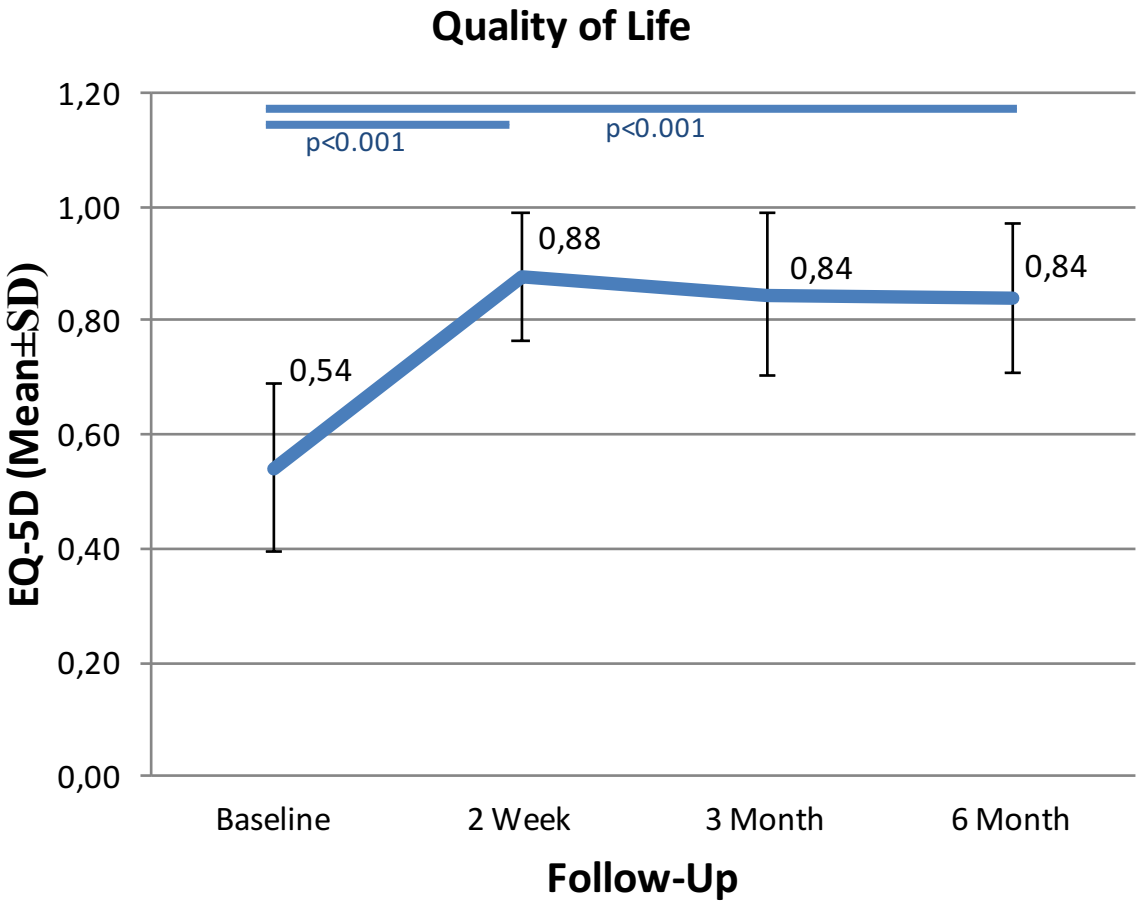
Results – Primary Outcome



Baseline pain reduced from 7.19 ± 1.47 to:

- 2.29 ± 2.27 at end of trial (68.2%)
- 1.67 ± 2.34 at 6 m follow-up (76.8%)

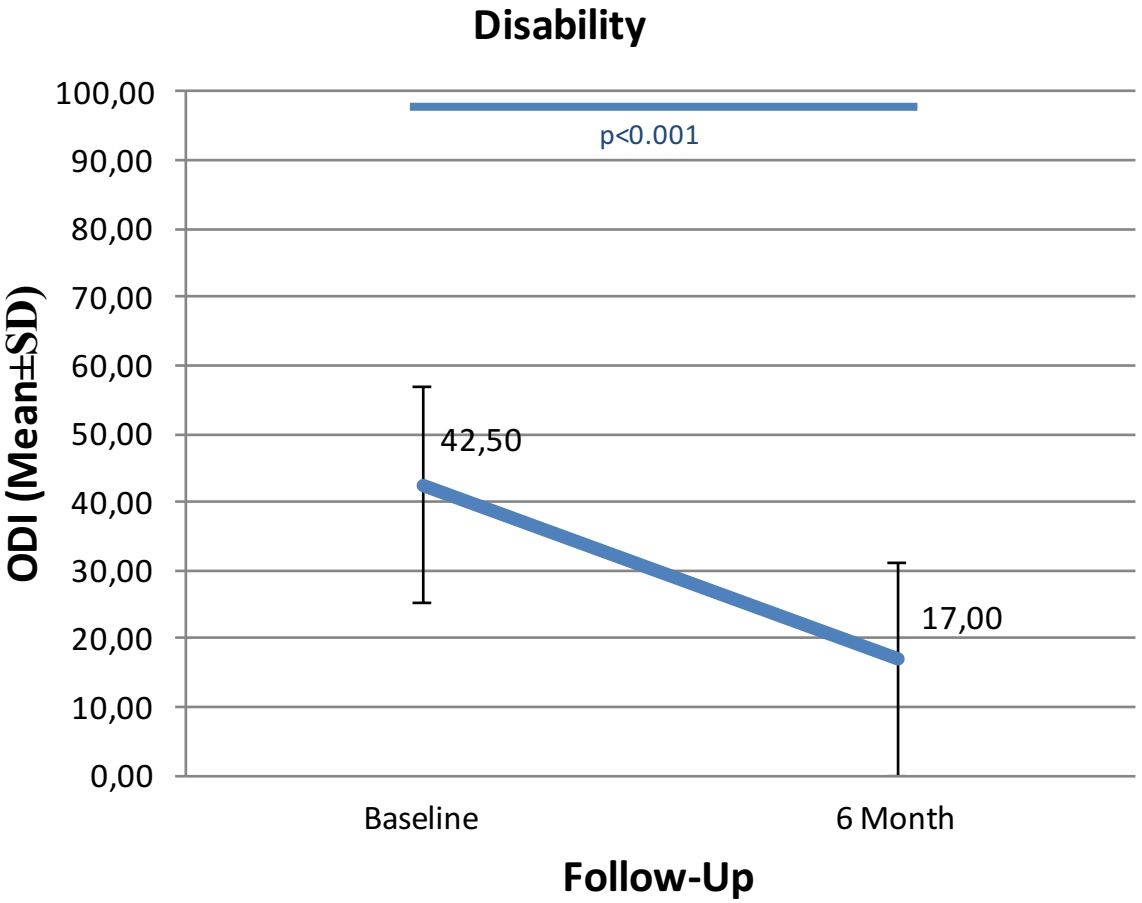
Results – Secondary Outcomes



Average quality of life was increased:

- 61.79% at 2 week follow-up
- 54.57%% at 6 m follow-up

Results – Secondary Outcomes



Average disability was decreased:

- 60.00% at 6 month follow-up

Discussion

- DRG stimulation at the L2 level may be an effective treatment option for discogenic low back pain
- Dorsal aspects of the lower lumbar (L4-L5) intervertebral discs known to be a source of discogenic low back pain
- These areas are innervated by sensory afferents that project through somatic spinal nerves, as well as by sympathetic nerves; both of which converge in the L2-L3 DRGs
- DRG stimulation at these levels may be effective for low back pain by recruiting both segmental and non-segmental neural pathways that are not otherwise accessible via traditional SCS

Conclusion

- Primary region pain was decreased by 68.20% and 76.81% at the end of trial (n=24) and 6 month follow-ups (n=24), respectively
- At the 2 week follow-up, 24/25 (91.67%) reported ≥50% reduction in primary region pain
- Concomitant secondary outcome improvements observed
- Further research is required to determine the position of this modality in the discogenic low back pain treatment algorithm