Peripheral Nerve Stimulation: Evidence

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Disclosures

- Abbott – consultant, advisory board member, funded research
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- This presentation does not contain off-label or investigational use of drugs or products.

Learning Objectives

- After participating in this session, attendees should be able to:
  1. Describe appropriate peripheral nerve stimulation targets to treat appropriate pain pathologies.
  2. Understand appropriate peripheral nerve stimulation candidates and where the best evidence exists.

Head and Neck

- Chronic Migraine
  - Multiple RCTs have shown evidence for PNS in CM
  - In a recent randomized, double blind, controlled trial, 20 patients were implanted with occipital nerve PNS.
    - They randomized to an active or control group for 12 weeks, and received open-label treatment for an additional 40 weeks.
    - In the PNS arm at one year, headache days per month were reduced by 8.51 (±9.81) days ($P < 0.0001$).
    - The proportion of patients who achieved a 30% and 50% reduction in headache days and/or pain intensity was 60% and 35%, respectively.

Upper Extremities

- Currently three randomized controlled trials (hemiplegic shoulder pain) have been performed evaluating the utility of peripheral nerve stimulation for chronic upper extremity pain demonstrating a safe, effective, and practical application.
- Significant opportunity, but understudied and underutilized at this time.

Low Back

- One multicenter randomized controlled trial compared 38 patients with FBSS who received subcutaneous nerve stimulation plus CMM versus 36 patients with FBSS who received CMM only.
- Interventional arm – two leads implanted in area of pain
- Primary endpoint – percentage of patients who reported greater than 50% improvement at 6 months and greater than 30% at 9 months
- Results:
  - 33.9% of PNS/CMM arm versus 1.7% of CMM only were responders at 9 months.

Mixed Etiologies

- Deer et al. performed the initial prospective, multicenter, randomized, double-blind, partial crossover RCT studying the use of PNS for peripheral nerve chronic pain of a variety of anatomical regions (lower extremity was largest cohort).
- Patients were randomized 1:1 and a total of 94 patients were randomized to the study (45 treatment group and 49 control group).
- Primary outcomes included pain relief, measured by average pain at rest using NRS followed for 3 months, and safety determined by assessment of adverse events during the one-year study period.
  - Responder was defined as >30% pain relief compared to baseline.

Mixed Etiologies

- The treatment group received electrical stimulation and stable pain medication dosing, while the control group received no stimulation and a stable dose of pain medications, both for 90 days.
- Results:
  - In the lower extremity at 3 months, there was a 38% responder rate in the treatment group versus 14% in the placebo group.
  - Average pain reduction at 3 months was 21% in the treatment group versus 1.2% in the control group. These results were similar to the overall cohort ($p<0.0001$).
  - The secondary outcomes showed the treatment group had better improvement than the control group in multiple domains, including worst pain score, BPI scores, quality of life, and PGIC.

Conclusion

- Strong evidence exists for occipital nerve PNS for treatment of chronic migraine.
  - 60-day device is FDA approved for head, neck, and torso.
- The most understudied area is the upper extremities (besides hemiplegic shoulder pain).
- Subcutaneous PNS for FBSS provides relief, but results were not impressive.
- Better evidence exists for shoulder and knee (including post-amputation pain) – more to come on this!