ECAP-CONTROLLED CLOSED-LOOP SCS WITH A SINGLE LEAD

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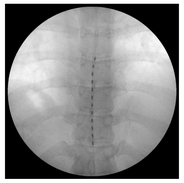
Background and Aims

Evoked compound action potential (ECAP)-controlled closed-loop spinal cord stimulation (SCS) has been proven to show superior pain relief compared to traditional 'open-loop' SCS due to its ability to maintain consistent and accurate activation of the spinal cord (1,2). Here, we present a single-center case-series in which ECAP-controlled closed-loop SCS was delivered using a single percutaneous lead to treat chronic pain.

Materials and Methods

N=8 patients with persistent spinal pain syndrome (PSPS) type 2 (5F; 3M; 55.3 years (mean)) were implanted with a single-percutaneous 12-contact lead (Fig. 1) guided by intraoperative paresthesia-based testing and coupled to an ECAP-controlled closed-loop SCS system. Pain relief was assessed using the visual analogue scale (VAS) and objective neurophysiology was collected at the follow-up visits after 1, 3, 6 and 12 months.



In addition, scores for average pain, worst pain, the interference of pain on general activity, walking ability, relationships, work, mood, life and sleep (ascertained by numerical rating scale, NRS) and health-related quality of life (assessed by the EQ-5D-3L) prior to implant and at the latest follow-up were collected.

Figure 1: Lead placement. To cover low back and leg pain the lead tip was placed at T7. For patients suffering from predominant leg pain the lead tip was placed at T8.

Results

At 3, 6 and 12 months all patients achieved a pain relief of at least 50% (responder) and the rate of high responder (pain relief of at least 80%) increased over time (Fig. 2).

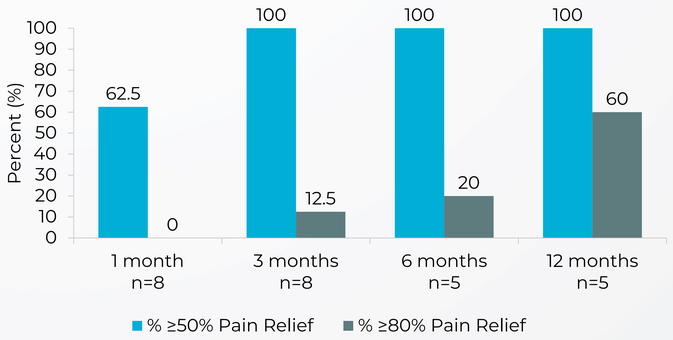


Figure 2: Responder rate over time. Patients achieving pain relief of at least 50% were defined as responder, whereas pain relief of 80% or higher was defined as high responder. Pain relief was assessed at each follow-up visit.

Results

At 1-year post-permanent implant, patients achieved an average of 84% pain relief (Fig. 3). Pain relief is consistent with the Evoke and Avalon multicenter prospective studies (1,2).

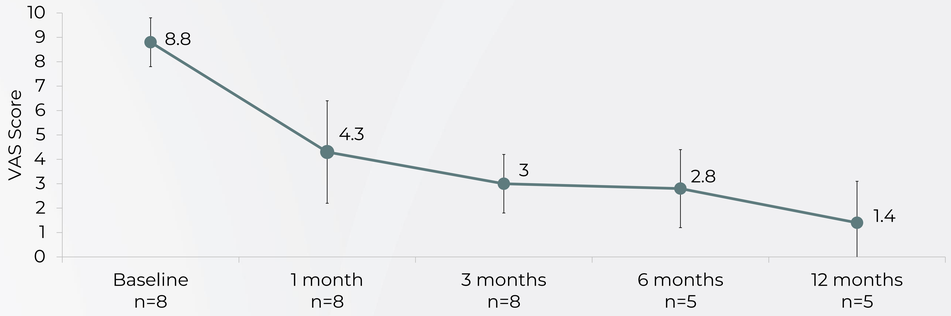


Figure 3: Mean VAS score. Mean (±SD) VAS at baseline, 1, 3, 6 and 12 month permanent implantation.

In addition, measurements of quality of life appeared to improve when comparing pre-implant to latest follow-up visit.

For instance, health-related quality of life scores (ascertained by the EQ-5D-3L) increased at follow-up compared to pre-implant (Fig. 4).

In addition, there was less interference of pain on general activity, walking ability, relationships, work, mood, life and sleep at follow-up compared to pre-implant (Fig. 5).

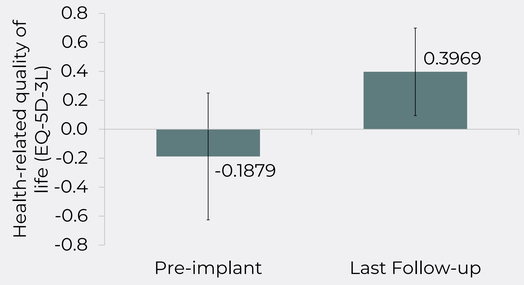


Figure 4: Health-related quality of life. Mean (±SEM) EQ-5D-3L at pre-implant and follow-up.

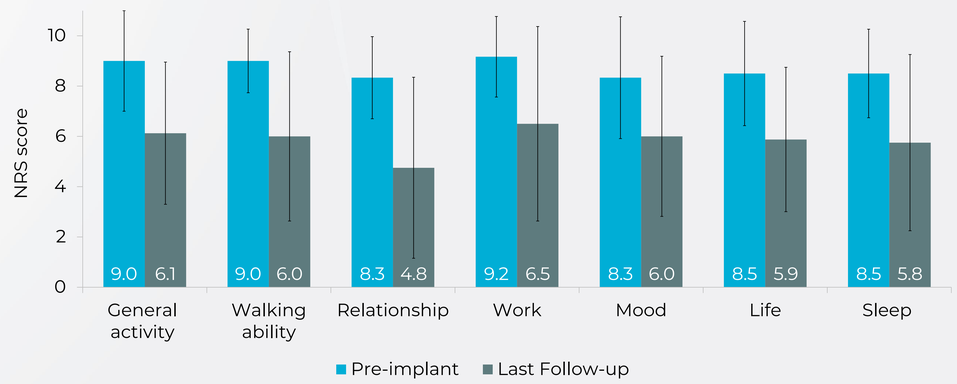


Figure 5: The interference of pain in daily life. Mean (±SD) NRS difference between pre-implant and follow-up.

Results

In addition to patient reported outcomes objective neurophysiological measurements were collected (Fig. 6). All patients received a closed loop stimulation and neural activation could be measured.

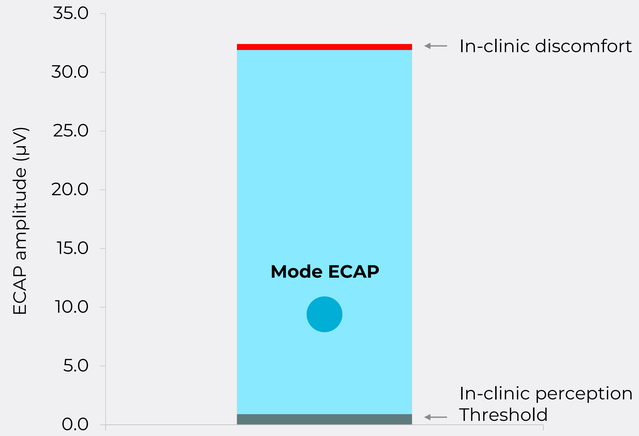


Figure 6: Example of neurophysiological measurements from one patient. From the bottom, first is the Neural Activation (ECAP amplitude) at the patients' report of 'In-Clinic Perception Threshold' (0.9 µV). The patients used their closed-loop SCS above perception threshold (Neural Activation Level; mode ECAP: 9.4 µV) identified in-clinic.

Discussion and Conclusion

Initial data from this single-center case-series indicated the feasibility of using single-lead placements for treating PSPS type 2 with the ECAP-controlled closed-loop SCS system. Neurophysiology-based programming and accurate neural activation enabled by pulse-pulse monitoring and control have shown to provide superior, effective, and durable pain relief (1,2). Further research is required to validate and build on these preliminary findings using single-lead placements.

References

1. Mekhail N et al. Long-term safety, and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. Lancet Neurol. 2020.
2. Russo M et al. Sustained Long-Term Outcomes with Closed-Loop Spinal Cord Stimulation: 12-Month Results of the Prospective, Multicenter, Open-Label Avalon Study. Neurosurgery. 2020.