

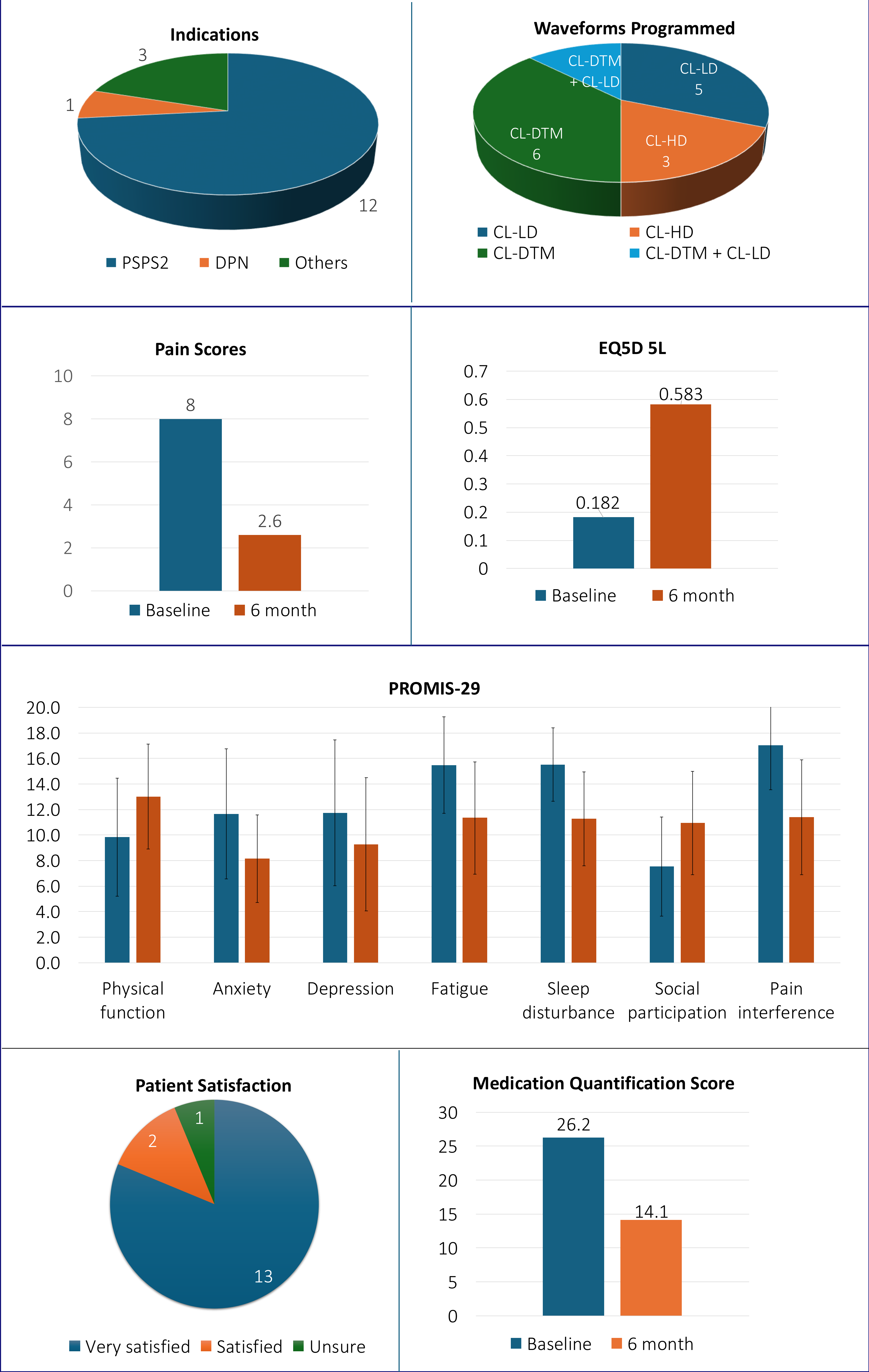
Real-World Patient Reported Outcomes of Closed Loop Multi-Waveform Spinal Cord Stimulation

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Introduction

- A major challenge in spinal cord stimulation is variation in the intensity of paraesthesia perception and uncomfortable stimulation or electric shocks or jolts.
- Even with programming intended to be sub-paraesthesia, changes to stimulation occur because the relative distance between a spinal cord stimulator electrode and the spinal cord changes with everyday movement, including the cardiorespiratory cycle, coughing, or changes in body position.
- The manual adjustments are not quick enough for the patients to avoid these. Patients may respond to inconsistent dose delivery by limiting the activities³ or change to sub-effective therapy settings², or stop using therapy⁴ and discontinue programming adjustments^{1,2}. This compromises pain relief and functional improvement over longer term.
- The spinal evoked compound action potential (ECAP) is a biopotential resulting from the synchronized activation of dorsal column fibres in response to spinal cord stimulation (SCS).
- The ECAP is therefore a direct measure of spinal cord activation and provides information on the fibres activated by SCS, contributing to the therapeutic effect of stimulation.
- One currently marketed ECAP sensing SCS system is constrained to deliver only low-rate programs (LRP) when sensing⁵.
- A newly launched Inceptiv™ system can also deliver concurrent high-rate programs (HRP). Thus, the new ECAP sensing SCS system is capable of multiple waveforms; Differential Target Multiplexed (DTM™), High Dose, Low Dose as well as all other types of programming /cycling which gives the broadest options for the patients.
- In this prospective case series, we assessed patient reported outcome measures in terms pain relief and patient satisfaction with Inceptiv™ ECAP sensing SCS system.



Materials and Methods

- 16 patients with NICE approved indications⁷ for spinal cord stimulation were implanted with Inceptiv™ spinal cord stimulator.
- After implantation, patients were programmed with the most suitable program for their pain distribution.
- We collected outcome measures in the form of pain scores, EQ5D, Promis-29, burden of programming, charging, comfort of stimulation and patient satisfaction at baseline and 6 months.

Main Results

- The average baseline numerical rating pain score of 8 ± 1.203 dropped to 2.6 ± 2 at 6 months.
- The quality of life as measured by EQ5D-5L improved by 0.401.
- The average reduction in the MQS was 12.1
- Significant improvement across all the domains of Promis-29.
- None of the patients reported unwanted tingling, jolting or shocks
- None of the patients have to limit any activities of daily living due to overstimulation.

Conclusion

- This is the first 'real-world' prospective case series of Inceptiv ECAP-controlled CL-SCS system.
- It shows clinically significant pain relief across low-rate and high-rate programs, significant improvement in the quality of life and function along with reduction in medication.
- None of the patients reported therapy-related side effects in the form of electric shocks, jolts or had to limit any activities.

References

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