Lumbar Spinal Stenosis Treatment with APERIUS® Percutaneous Interspinous Device (INCA Trial)

J.K. van Meirhaeghe, S. Lauwagie, P. Fransen, D. Morelli, N. Craig, F. Collignon
AZ Sint-Jan Brugge, Dienst Orthopedie en Traumatologie, Brugge, Belgium, Clinique du Parc Leopold, Centre Neurochirurgical, Brussels, Belgium, CHU Tivoli, Service de Neurochirurgie, La Louviere, Belgium, Woodend Hospital, Orthopedic Suite, Aberdeen, United Kingdom

Introduction: Degenerative lumbar spinal stenosis (DLSS) is a debilitating disease with cardinal symptom being Neurogenic Intermittent Claudication (NIC), a position-dependant syndrome. Patients presenting with leg pain and possibly back and/or buttock groin pain, have exacerbated complaints in extension (walking, standing) and symptom-relief during flexion. Interspinous devices (IPD) will induce slight flexion and limit extension at the symptomatic level with increase in the dimensions of the spinal canal and neural foramina size and thus induce symptom relief. The APERIUS® Percutaneous Interspinous Spacer is the first percutaneous IPD.

Material and methods: The INCA trial was designed as a multicenter single arm post-marketing study to evaluate the safety and effectiveness of the APERIUS® in patients with degenerative lumbar stenosis with symptomatic NIC. 156 patients with a history of DLSS (L1-L5) at one or maximum 2 levels with symptoms of NIC with or without back pain were included. All patients were followed for 12 months with visits at 48 hours, 7 days, 6 weeks, 6 and 12 months. General anesthesia was chosen in 97% of procedures. Primary effectiveness endpoint was assessed as the mean % change from baseline in ZCQ Symptom Severity at 6 weeks. Other effectiveness outcomes were % change in ZCQ, EQ-5D, VAS pain score (back, leg and buttock groin pain), pain medication and changes in walking distance from baseline to follow-up. Procedure and device related SAE were assessed throughout the complete 12 month follow-up period.

Results: A total of 128 patients completed the study up to 12 months follow-up. Mean age of patients was 65 years (range 19 to 84) with mean complaint duration 41.3 months. Stenosis surgery was done at 1 level in 72 patients, 2 levels in 74 patients and 10 patients received 3 levels which gives a total of 250 devices implanted. Mean total procedure time was 15.5 minutes for 1 level, 24.6 minutes for 2 levels and 39.1 minutes for 3 levels. Primary endpoint, % change from baseline in ZCQ symptom severity score at 6 weeks, was statistically significant (mean change 29%, p< 0.001). Results were evident at 7 days and maintained for up to 12 months. At 6 weeks post procedure, 77% of patients had reached the clinically important improvement with a decrease of at least 0.5 points Improvement in ZCQ Physical function was highly significant from 6 weeks onward (p< 0.001). VAS scores for leg pain decreased significantly from baseline at all time points (p< 0.001) as did back pain and buttock/groin pain scores. A total of 12 SAE were reported during the course of the study. Three were considered procedure related and 9 were considered device related. Return of back pain (4 patients) and spinal claudication symptoms (3 patients) being the most common complaints. At 12 months, 14 (9.3%) devices had been removed.

Conclusion: The results of this pilot study indicate the use of the percutaneous APERIUS® spacer is safe and effective for the relief of NIC complaints in patients with symptomatic DLSS over a period of 12 months. Patients experience immediate pain relief and physical functional improvement is evident shortly after surgery.