CLINICAL STUDY

Midterm Clinical and Radiologic Outcomes after Percutaneous Interspinous Spacer Treatment for Neurogenic Intermittent Claudication

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ABSTRACT

Purpose: To evaluate the midterm clinical and radiologic outcome of percutaneous interspinous process spacer (IPS) treatment for neurogenic intermittent claudication (NIC) in patients who fail conservative treatment.

Methods: Consecutive patients with NIC, lumbar spinal stenosis confirmed on magnetic resonance imaging, failure of conservative management for at least 6 months, and treatment with percutaneous IPS were included. Visual analog scale (VAS) and Oswestry Disability Index (ODI) scores were recorded at baseline, 1 month, 1 year and 3 years after treatment. Spinal canal and foraminal cross-sectional areas were calculated from multidetector computed tomography at baseline and 1 year.

Results: There were 80 patients treated with 94 IPS devices; 83% of patients received a single IPS; 78% of IPS devices were placed at L4-L5. An IPS dislocation was the single periprocedural major complication. VAS score of 8.1 ± 2 before treatment was reduced to 4.4 ± 2 at 1 month after treatment ($P = .0001$); ODI score of 23.3 ± 10 before treatment was reduced to 11.7 ± 8.5 at 1 month after treatment ($P = .0001$). These significant reductions were durable at 1-year and 3-year follow-up evaluations ($P < .01$). Spinal canal and foraminal cross-sectional area increased by 15% at 1 year ($P = .0001$).

Conclusions: Patients with NIC who failed conservative treatment and were treated with percutaneous IPS achieved significant gains in pain relief and reduced disability that remained durable at 3-year clinical follow-up evaluation. This outcome was accompanied by significant increases in spinal canal and foraminal cross-sectional areas at the treated level.

ABBREVIATIONS

IPS = interspinous process spacer, LSS = lumbar spinal stenosis, NIC = neurogenic intermittent claudication, ODI = Oswestry Disability Index, VAS = visual analog scale

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A Video is available online at *www.jvir.org*.

Figures E1 and E2 are available online at *www.jvir.org*.

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Lumbar spinal stenosis (LSS) with neurogenic intermittent claudication (NIC) is one of the most commonly treated spinal conditions (1,2). The prevalence of LSS increases with age (1), and symptomatic LSS causes significant disability and reduction in quality of life (2). Most patients with NIC are treated conservatively with nonsteroidal antiinflammatory drugs, physical therapy, brace support, and epidural corticosteroid injections. Conservative therapy results in a satisfactory outcome in many patients with mild to moderate symptoms after 3 months; on failure of conservative therapy, surgical decompression results in a similar outcome to earlier intervention (3). However, surgery typically requires general anesthesia, and it may not always be feasible in the growing elderly population with NIC.

An emerging minimally invasive alternative to surgical decompression is percutaneous implantation of an interspinous process spacer (IPS) that can be performed under local anesthesia and conscious sedation. Early small randomized controlled trials showed favorable outcomes in patients with NIC treated with the X-Stop IPS (Medtronic, Minneapolis, Minnesota) compared with conservative therapy with successful outcomes up to 4 years after treatment (4–6). Subsequent clinical series were characterized by more variable clinical outcome rates and higher reoperation rates (7). However, a more recent prospective randomized controlled trial revealed that percutaneous treatment with the X-Stop IPS achieved similar outcomes to open surgical decompression (8). Although there was a significantly higher reoperation rate in the IPS cohort, the overall clinical outcome was similar to open microsurgical decompression according to intention-to-treat analyses (8).

Although there are emerging data using the US Food and Drug Administration–approved X-Stop IPS (9), midterm clinical and radiologic outcome data using alternative IPS devices are sparse. The purpose of this study was to evaluate the midterm clinical and radiologic outcome of patients with NIC who failed conservative therapy and were treated with the percutaneous Kyphon Aperius PercLID IPS (Medtronic).

MATERIALS AND METHODS

Patient Selection

Between November 2009 and October 2010, 142 patients were assessed; 80 consecutive patients were included in this prospective single-center cohort study. The institutional review board approved this study, and written informed consent was obtained from all patients before participation, in accordance with national legislation and the Declaration of Helsinki.

Inclusion and Exclusion Criteria

For inclusion in the study, patients had to have a preoperative diagnosis of NIC based on clinical history of progressive low back pain associated with radicular pain exacerbated by prolonged standing or upright posture and relieved by flexion with an associated reduced walking distance. To confirm the clinical findings, all patients had to have degenerative narrowing of the lumbar spinal canal on magnetic resonance (MR) imaging. Initial conservative management included administration of nonsteroidal antiinflammatory medications, physical therapy, and epidural corticosteroid injections. Patients with NIC confirmed on MR imaging who failed 6 months of conservative management were included. The treatment level was decided using clinical examination findings, MR imaging results, and, in selected cases, electromyography. Patients with previous spine surgery, high-grade scoliosis, severe multilevel stenosis (three or more levels), stenosis at L5-S1, lumbar instability (spondylolisthesis greater than Meyerding grade I) (10), and a fixed neurologic motor deficit were excluded.

Percutaneous Procedure

All procedures were performed under moderate conscious sedation with sterile technique by one interventional radiologist (S.M.) with 11 years of experience. The patient was placed in a flexed prone position on the fluoroscopy table (Eleva; Philips Healthcare, Best, The Netherlands). Prophylactic antibiotics were administered (amoxicillin-clavulanic acid [Clavulin; GlaxoSmithKline S.p.A.,Verona, Italy]). After radiographic identification of the affected level, a subcutaneous injection of 10 mL of 2% lidocaine (Molteni Farmaceutici, Florence, Italy) and deeper injection of 7.5% ropivacaine (Molteni Farmaceutici) were performed. A bolus injection of 0.05 mg/kg intravenous midazolam (B. Braun Melsungen AG, Melsungen, Germany) or 1–4 mg/kg propofol (Giovanni Lorenzini S.p.A., Aprilia, Italy) was administered by an anesthesiologist. A small left paramedian (15-mm) incision was made 4–6 cm from the spinous process. Under fluoroscopic guidance, a trocar (8/10/12/14 mm) was introduced and advanced toward the interspinous space using anteroposterior and lateral projections. Increasing sized trocars (8/10/12/14 mm devices are available) were inserted percutaneously. When suitable access was available, the corresponding-sized IPS (Aperius PercLID) was introduced (**Fig E1** and **Video**, available online at *www.jvir.org*).

The titanium IPS was positioned through progressive wings deployment (**Fig 1a–e**) proximal and distal to the interspinous ligament to keep it fixed in place. It can be removed percutaneously before deployment of the distal wings. After final deployment, surgical removal is required. The optimal position for the IPS is posterior to the ligamentum flavum and adjacent to the facet joints. A suboptimal position may lead to overdistraction or underdistraction of the spinous processes.

Outcomes

Complications were divided into major and minor based on the Society of Interventional Radiology (SIR) classification system (11). Clinical assessment of pain was measured using the visual analog scale (VAS) score (12), and function was assessed with the Oswestry Disability Index (ODI) (13). Both assessments were performed - at baseline and at 1 month, 1 year, and 3 years after treatment.

The cross-sectional area of the lumbar spinal canal and neural foramina was measured on multidetector computed tomography (CT) (SOMATOM Sensation 40; Philips Healthcare). A radiologist (E.P.) blinded to the clinical information performed all measurements by hand at baseline and 1 year after treatment. Image