

Long-term results with percutaneous interspinous process devices in the treatment of neurogenic intermittent claudication

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Background: Neurogenic intermittent claudication (NIC) is the main symptom of degenerative lumbar spinal stenosis. Percutaneous interspinous process decompression devices (IPDs) have been designed as an alternative therapy to conservative treatment and to open decompressive surgery for patients suffering from NIC. Initial short-term results were encouraging. We present the long-term results of a group of patients that we followed to provide insight on long-term outcomes and effectiveness of this technique compared to other decompression methods.

Methods: Fifteen patients operated for NIC by implantation of percutaneous IPDs have been prospectively monitored for reoperations or complications. Follow-up (FU) was interrupted if the patient was reoperated. Results were considered poor if the patient had to be reoperated at any stage of the FU or if the treatment failed to alleviate the pain after 6 months. Results were considered average if the patient still suffered some pain but did not require reoperation.

Results: The patients were followed up to 7 years after the initial surgery. The mean length of the FU was 3.53 years and all patients could be followed. At the end of the FU, the results were good in only 20.0% (3/15), average in 13.3% (2/15) and poor in 66.7% (10/15).

Conclusions: Despite initial satisfactory results, long-term FU is disappointing, with 80% poor or average results. The long-term reoperation rate is high (66.6%), increases over time and is higher than after implantation of IPDs for decompression augmentation. Although this technique is simple and safe, its effectiveness seems short-lived. We recommend cautious use and informing patients about the risk of relatively early failure and recurrence.

Keywords: Interspinous process device; spinal stenosis; minimally invasive surgery

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Introduction

The treatment of degenerative lumbar spinal stenosis has become a major challenge in modern spinal surgery, facing the ever-increasing number of patients suffering from this condition in an ageing population. Although its reported incidence was of 2–8% in the general population, the prevalence of relative and absolute acquired stenosis increases with age to 47.2% and 19.4%, with patients over 60 (1). The usual clinical presentation is neurogenic intermittent claudication (NIC) an association of numbness,

weakness, cramps pain and discomfort in the legs, increased by walking. These symptoms are often positional, relieved by bending or leaning forward, and by sitting (2), as extension decreases the diameter of both spinal canal and neuroforamens, triggering pain, whereas flexion does the opposite, creating space and relieving the pain (3–5).

Biomechanical studies have shown that these implants increase stability in extension and that their insertion between the spinous processes has a segmental distractive effect increasing the size of the spinal canal and foraminal canals without influencing the adjacent levels. Therefore,

interspinous nonfusion devices could provide an intermediate therapy between conservative treatment and open surgery (6,7), but although short-term results are published (8,9), long-term results have rarely been presented.

We present a single center experience with the use of percutaneous interspinous process decompression devices (IPDs), with a long follow-up (FU).

Methods

All 15 patients, eight men and seven women, aged between 42 and 77 years (mean age, 63.3 years), have been operated between October 2006 and September 2008, for neurogenic claudication caused by spinal canal stenosis, by percutaneous implantation of stand-alone interspinous process devices. Two different types of implants were used. The Aperius (Medtronic Inc, Tolochenaz, Switzerland) is a fully metallic titanium implant, and the Inspace (Synthes, Bettlach, Switzerland) is a polyetheretherketone (PEEK) implant, with metallic wings. In both systems, the implant is maintained in position by the expansion of wings on each side of the spinous process.

The technical aspects of this procedure have been described elsewhere (8,9).

To be initially included, the patients had to have a history of degenerative lumbar spinal stenosis, from L1 to L5, with exclusion of the L5/S1 level, confirmed by magnetic resonance imaging (MRI), with symptoms of NIC, including leg/buttock/groin pain, with or without back pain, relieved by flexion. If back pain was also present, it was to be partially relieved when flexed. Patients had to be able to sit for 50 min without pain and walk a distance of 20 m without pain.

All patients were contacted by telephone between January 1st, 2012 and March 31st, 2012. Two simple questions were asked to each patient. The first question enquired if they had had to be reoperated for recurrent neurogenic claudication, and in this case, what type of surgery had been performed. The second was only asked to the patients that had not been reoperated, and enquired about the evolution of their symptoms of NIC. The FU was stopped if the patient had been reoperated. The non reoperated patients were contacted again in 2014.

Results

The first evaluation was systematically done after 6 months.

At that time, the results were good for 66.6% of patients (less pain and/or increased walking perimeter), average for 6.6% and poor for 26.6% (status quo or worsening of the symptoms).

The patients were followed up to 7 years after the initial surgery. The mean length of the FU was 3.53 years and all patients could be followed. At the end of the FU, the results were good in only 20.0% (3/15), average in 13.3% (2/15) and poor in 66.7% (10/15).

One patient showed no improvement immediately after surgery and one patient had early postoperative failure following spinous process fracture. At the 2012 FU, an additional 8 of the initial 15 patients (8/15) had been reoperated, between 6 months and 7 years after surgery. Overall, two thirds of the patients had been reoperated.

Two patients had only moderate symptom relief, treated conservatively but were considering surgery.

One patient reported no more back related symptoms but died of colon cancer 4 years after surgery. Two patients (2/15) were suffering from minimal and progressively recurrent NIC, and were still treated conservatively.

Discussion

There may be some confusion in the literature regarding the results of IPDs. A distinction should be made between IPDs used as an augmentation method in addition to decompression, and percutaneous IPDs. In the latter technique, the decompression is purely indirect and relies only on the increase of the spinal canal and neuroforamen diameter caused by the implant. This would explain some apparently contradictory results.

Looking at IPDs used for lumbar decompression augmentation, Nicholson *et al.* (10) recently published a 4.5-year mean FU survival analysis of the Wallis implant, reporting 21% recurrent stenosis and only a 10% rate of reoperation. Also, he concluded that the use of interspinous spacers did not appear to significantly change the clinical result of the surgery from that expected from decompression alone. Similar results are drawn from a metanalysis by Phan *et al.* (11) finding no superiority for IPDs compared with traditional decompression, but higher reoperation rates and costs.

Without looking into the question of their cost/efficiency ratio, the reoperation rate for IPDs used for decompression augmentation seems lower than in both this study and the percutaneous IPDs literature.

Short-term results have been reported for treatment of

NIC by the implantation of percutaneous interspinous process devices. Van Meirhaeghe *et al.* (9) presented the results of a 12-month FU, showing that symptom and physical function were improved in 60% of patients assessed by the Zurich Claudication Questionnaire (ZCQ). In this study, only 9% of the patients had to be reoperated during the FU period, because of complications or lack of effectiveness.

Similar results have been reported by Surace *et al.* (12), describing an improvement in Oswestry Disability Index (ODI) and ZCQ scores over an 18-month FU period, and by Nunley *et al.* (13) and by Patel *et al.* over a 3-year FU period (14).

Overall, these few short-term studies concluded that indirect decompression by the use of percutaneous IPDs was safe and effective although the right indications for this technique remained to be determined.

Although these initial results were encouraging, the present study shows that patients treated with percutaneous IPDs for NIC present disappointing long-term results, with 80% of poor or average results, including 66.6% reoperations. Our results confirm the conclusions of Moojen *et al.* (15) who reported in a double blinded study no significant advantage of IPD without bony decompression over conventional decompression, 2 years after surgery. Their lower reoperation rate of 33% could be attributed to a shorter FU. Similarly, Beyer *et al.* (16) reported 41.6% therapeutic failure and reoperation after 2 years.

This study reports the longest FU and clinical results of indirect decompression for NIC using percutaneous interspinous process devices. Despite initial satisfactory results having been reported, the reoperation rate is high, increases over time and is higher than after implantation of IPDs for decompression augmentation. Although this technique is simple and safe, its effectiveness is short. It is unclear whether it fills a gap between conservative treatment and decompressive surgery or if it only adds a low benefit and potentially costly treatment to the armamentarium. We recommend cautious use and informing patients about the risk of relatively early failure and recurrence.

Acknowledgements

None.

Footnote

Conflicts of Interest: The author has no conflicts of interest to declare.

Ethical Statement: This research article was done with the approval of the local Ethics committees, and there was no study ID number filed (classically, this is only done in our country for the prospective studies involving surgery and or randomization).

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