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Clinical Study

Interspinous process devices versus standard conventional surgical decompression for lumbar spinal stenosis: cost-utility analysis

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Abstract **BACKGROUND CONTEXT:** In the 1980s, a new implant was developed to treat patients with intermittent neurogenic claudication caused by lumbar spinal stenosis (LSS). This implant is now widely used.

FDA device/drug status: Not applicable.

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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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PURPOSE: The objective of this study is to determine whether a favorable cost-effectiveness for interspinous process devices (IPDs) compared with conventional bony decompression is attained.
STUDY DESIGN/SETTING: Cost-utility analysis was performed alongside a double-blind randomized controlled trial. Five neurosurgical centers (including one academic and four secondary level care centers) included participants for this study.
PATIENT SAMPLE: One hundred fifty-nine patients with LSS were treated with the implantation of IPD and with bony decompression. Eighty participants received an IPD, and seventy-nine participants underwent spinal bony decompression.
OUTCOME MEASURES: Outcome measures were quality-adjusted life-years (QALYs) and societal costs in the first year (estimated per quarter), estimated from patient-reported utilities (US and The Netherlands EuroQol 5D [EQ-5D] and EuroQol visual analog scale) and diaries on costs (health-care costs, patient costs, and productivity costs).
METHODS: All analyses followed the intention-to-treat principle. Given the statistical uncertainty of differences between costs and QALYs, cost-effectiveness acceptability curves graph the probability that a strategy is cost effective, as a function of willingness to pay. Paradigm Spine funded this trial but did not have any part in data analysis or the design and preparation of this article.
RESULTS: According to the EQ-5D, the valuation of quality of life after IPD and decompression was not different. Mean utilities during all four quarters were, not significantly, less favorable after IPD according to the EQ-5D with a decrease in QALYs according to the US EQ-5D of 0.024 (95% confidence interval, −0.031 to 0.079). From a health-care perspective, the costs of IPD treatment were higher (difference €3,030 per patient, 95% confidence interval, €561–€5,498). This significant difference is mainly because of additional cost of implants of €2,350 apiece. From a societal perspective, a nonsignificant difference of €2,762 (95% confidence interval, −€1,572 to €7,095) in favor of conventional bony decompression was found.
CONCLUSIONS: Implantation of IPD as indirect decompressing device is highly unlikely to be cost effective compared with bony decompression for patients with intermittent neurogenic claudication caused by LSS.
TRIAL REGISTRATION: Dutch Trial Register Number: NTR1307.

Keywords: Lumbar spinal stenosis; Spinal implants; Degenerative disease; Cost-utility; Societal costs; Health-care costs

Introduction

The average increase in age of the general population results in a growing older population, and thus to an increase in incidence of patients with intermittent neurogenic claudication (INC) caused by lumbar spinal stenosis (LSS) [1–3]. Intermittent neurogenic claudication is a complex of symptoms including pain in, frequently, both legs provoked by prolonged walking and standing and diminishes by flexion of the lumbar spine (such as in sitting position or when cycling) [1–3]. Accompanying back pain is also associated with INC [4]. The number of surgical interventions for lumbar stenosis increases concomitantly with the increase in age of the general population, and eventually this can lead to an increase in the use of implants [5–7]. In the beginning of the 21st century, a 15-fold increase of spinal surgeries with fusion techniques was reported [5–7]. One of the possible explanations for this dramatic increase of fusion procedures was the development of new devices in the end of the 20th century.

In 1984, an implant to indirectly decompress the lumbar spinal canal was developed [8,9]. The implant is placed between the spinous processes and is therefore called interspinous process device (IPD). The operation time was proposed to be shorter with less bony destruction, and the technique was meant to accustom day surgery protocols, resulting in a shorter rehabilitation period after surgery. The implant was believed to be ideal for the old and even octogeneric patients with LSS. Despite the high costs of the implants and the high rate of implantations of IPDs, clinical trials comparing IPDs with the golden standard (bony decompression) were not performed [10,11]. The scientific evidence published until 2004 showed that the use of IPDs was superior compared—only—with conservative (no intervention) treatment [12,13].

A lot of different IPDs have been introduced since 1984 [14–17]. Since 1984, no good estimation of the total costs for society of these IPDs has been performed. In the systematic review published in 2011, at least 20 different IPDs were identified [18]. The two most studied implants are the Coflex implant (Paradigm Spine, New York, NY, USA) and the X-stop (Kyphon, Inc., Neuchatel, Switzerland and Medtronic, Minneapolis, MN, USA) [12–17,19–27]. The Coflex implant—like the other IPDs—was used as a stand alone and subjected to our protocol as such. Currently, the Coflex is in the US-only approved for add-on to decompression. However, little is known about the costs of these regularly used implants. In 2007, worldwide sale of the X-stop implant