Interspinous spacers: update summary 2012

Background and Purpose

Claims for interspinous spacer devices (ISDs) to treat neurogenic claudication as a result of lumbar spinal stenosis decreased by more than 50% between 2010 (n=36) and 2011 (n=15), with 14 claims in 2012 to date. The popularity of the devices has decreased amidst concerns over their long-term clinical benefit and higher than expected rates of device removal and other complications, with other surgical options becoming a more attractive option. In 2009 under purchasing guidance the ACC decided to purchase ISDs on a case by case basis. It has become evident that more surgery is now being performed to remove ISDs than to implant them. The purpose of this report is to update the 2009 Brief Report on the effectiveness and safety of ISDs and the suitability of ISDs as a treatment option for lumbar spinal stenosis.

Methodology

A systematic search of the literature from 2009 – July 2012 yielded 176 relevant references and it was decided to focus primarily on the highest level evidence, namely guidelines and systematic reviews. Three guidelines (Chou, Baisden et al. 2009; National Institute for Health and Clinical Excellence 2010; North American Spine Society 2011), one health technology assessment (Stordeur, Gerkens et al. 2009), two systematic reviews (Kabir, Gupta et al. 2010; Kovacs, Urrutia et al. 2011) and one meta-analysis (Moojen, Arts et al. 2011) met the criteria for inclusion in this evidence update.

Summary of Findings

Quality of the evidence

The guidelines and systematic reviews included in this update were generally well-conducted and well-reported. They were limited however by a lack of high quality evidence upon which to base conclusions, with many reviews concluding that the evidence base remains weak and of low quality. There remains a lack of data regarding long-term outcomes (post two years) following the insertion of an ISD. Of the higher level evidence, most centres on the X-STOP device, with some lower level studies of the Coflex and Wallis devices. The most widely cited randomised controlled trials (Anderson, Tribus et al. 2006; Hsu, Zucherman et al. 2006) compared the X-STOP device with nonsurgical treatment, rather than other surgical options such as laminecotomy or fusion. These studies were also included in the 2009 ACC brief report on the safety and effectiveness of interspinous spacers. Methodological flaws in these studies include potential recruitment bias, a lack of consistency in the treatment offered to the control group, and a high drop-out rate in the treatment group which was neither explained nor accounted for in analyses. The four year follow-up included only 18 of the original 100 patients treated with an ISD.
Effectiveness

Most of the guidelines and systematic reviews grouped all ISDs together and based findings primarily on the same randomised trials of the X-STOP device. Where authors attempted to report separately for each of the devices they reported a lack of sufficient evidence regarding the Cofflex and DIAM devices. Most of the measures utilised were patient-centred self-report measures of pain and disability, such as the SF-36, the Zurich Claudication Questionnaire (ZCQ) and the Visual Analogue Scale (VAS). Patients in the randomised trials were carefully selected, aged 50 years and over, with radiologically-confirmed lumbar canal stenosis whose symptoms improve on flexion. In general, the reviews reported some evidence of an improvement in pain, physical function and quality of life or satisfaction measures for up to two years following the implantation of an ISD (most often the X-STOP device) but commented that there was a lack of long-term follow-up data and that the quality of the evidence was low. This corroborates reports received by ACC in the three years since the last decision to purchase ISDs on a case by case basis, indicating that specialists have begun to notice problems with the devices and that many have been removed.

Safety

In the NICE guideline (National Institute for Health and Clinical Excellence 2010), which included randomised trials, controlled trials, case series and unpublished abstracts, the authors noted a 6.5% rate of subsequent laminectomy within 2 years of initial treatment with an ISD, removal of the device in 5 – 27% of cases (case series and unpublished abstracts) and rates of 1- 5% of device malpositioning or migration. A Belgian report (Stordeur, Gerkens et al. 2009) also noted that before-and-after studies reported an improvement in pain, physical function and walking distance with the use of interspinous devices. However, the authors noted that ~60% of patients showed these improvements, 30 – 60% required further analgesics, and 4.6% - 9.2% needed subsequent surgery. Kovacs et al (2011) reported that the rate of subsequent laminectomy rose to 11.9% in a subgroup of patients with lumbar stenosis and grade 1 spondylolisthesis.

Moojen et al (2011) compared the effectiveness and safety of interspinous spacer devices for neurogenic claudication caused by lumbar stenosis compared with conservative treatment or bony decompression. Meta-analysis was not possible for most outcomes because of a lack of RCTs and heterogeneity in the patient populations. The authors utilised a best-evidence synthesis approach for safety data and reported an overall device failure rate of 6%, where the device either had to be replaced or reoperation and further stabilization with bony decompression was required. The authors further concluded that because studies often did not report complications beyond thirty days post-implantation, it was likely that those rates were underestimated. Kabir et al (2010) reported similar rates of complication and noted one case series indicated up to 10.1% device failure and revision surgery.

Conclusions

- There is low quality evidence that interspinous spacer devices may be effective in improving symptoms in the short- to medium-term in carefully selected patients (aged 50 years and over with radiologically confirmed lumbar canal stenosis whose symptoms improve on flexion)
- There is little evidence for the long-term efficacy of these devices and further long-term studies are required comparing the devices to other treatment options such as laminectomy or fusion
- There is conflicting evidence for the benefit of using interspinous spacer devices in patients with spondylolisthesis
- Device failure rates were high considering the short-term follow-up of many studies. There was some variation in the rates reported depending on the types of studies included in the reviews, however further decompressive surgery was required in approximately 5-10% of patients within two years of receiving an interspinous spacer device.
The NICE guideline reported that removal of the device occurred in 5 – 27% of cases with rates of 1- 5% for device malpositioning or migration. Reviewers noted that these figures may be underestimated because many studies did not report this data beyond thirty days postsurgery. Again, there is a lack of data regarding longer-term failure rates or subsequent surgery following an interspinous spacer implantation.

References


