

## Editorial

### Treatment options for lumbar spinal stenosis

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Lumbar spinal stenosis (LSS) is one of the most common reasons why patients in their middle and later years seek a consultation with a neurosurgeon or spine surgeon. The surgical correction of LSS is also predictably satisfying, with consistent relief of symptoms of neurogenic claudication. The factors that most significantly affect the surgical outcome include patient selection and meticulous attention to technical detail.<sup>8</sup> First performed by Professor Victor Alexander Haden Horsley of University College London in 1887, spinal laminectomy has been a standard surgical practice for decades. Until the past decade, the primary alternatives to the use of laminectomy or variations such as laminotomies or laminoplasty were nonoperative, including a host of pharmaceutical alternatives, physiotherapy, and various types of spinal injection. With the advent of X-STOP and other types of interspinous spacers,<sup>14</sup> spine surgeons suddenly found themselves with a whole new “less-invasive” surgical alternative. The X-STOP was approved by the FDA in November 2005,<sup>11</sup> and the Centers for Medicare and Medicaid Services have approved a special add-on payment since October 2006.<sup>2</sup> Although the short- and medium-term results of the X-STOP have been made available,<sup>13–15</sup> the long-term results and outcome of similar interspinous spacers are still unknown, and longer-term clinical follow-up studies are needed to more clearly define the role of these devices in the management of lumbar spinal stenosis.<sup>3</sup> It is arguable that interspinous spacers might only be a temporary solution, delaying the eventuality of a laminectomy, which has been the “gold standard” for years.

The options for treating LSS span the spectrum of nonsurgical care and decompressive laminectomy/laminotomies with the X-STOP lodged in between—seemingly bridging the 2 extremes. It is therefore interesting to consider what it would mean for health care costs

when one chooses each option. Does new mean better, or does traditional open surgery triumph? Does the cost of interspinous spacers justify their use?

Given this background, Burnett et al.,<sup>1</sup> in this issue of the *Journal of Neurosurgery: Spine*, seek to identify the most cost-effective strategies to deal with LSS. With the escalating health care costs today in North America, their article reminds us to always consider the economic aspect and impact of the myriad treatment modalities available in medicine today.

Rising health care costs are a global phenomenon, especially in North America. The US spent approximately \$2.2 trillion on health care in 2007, or \$7421 per person.<sup>10</sup> This comes to 16.2% of the gross domestic product (GDP), nearly twice the average of other developed nations.<sup>6</sup> Health care costs doubled from 1996 to 2006, and are projected to rise to 25% of GDP in 2025 and 49% in 2082.<sup>7</sup> Canada spent approximately 10.1% of its GDP on health care in 2007, more than 1 percentage point higher than the average of 8.9% in OECD (Organisation for Economic Co-operation and Development) countries.<sup>4</sup>

Recently, the Spine Patient Outcomes Research Trial (SPORT)<sup>12</sup> reported favorable outcomes for surgical intervention of spinal stenosis over 2 years, and Tosteson et al.<sup>9</sup> used the same set of patients who suffered from LSS from the SPORT to compare nonoperative care versus surgery—primarily decompressive laminectomy for stenosis and decompressive laminectomy with fusion for stenosis associated with degenerative spondylolisthesis. They used cost per quality-adjusted life-year (QALY) gained as the outcome measure, and concluded that surgical treatment of spinal stenosis with laminectomy provided reasonable value over a 2-year time frame and compared favorably with many health care interventions.

In contrast, relatively little has been published related to the cost-effectiveness of X-STOP versus decompressive surgery. Kondrashov et al.<sup>4</sup> recently compared 4-year Oswestry Disability Index outcomes of X-STOP versus laminectomy and suggested that use of the X-STOP device for the treatment of LSS is clinically at least as effective as standard laminectomy at 4 years postoperatively and provides substantial direct cost savings compared with decompressive surgery.

In the article in this issue, Burnett et al.<sup>1</sup> conducted an in-depth systematic review of the literature related to

LSS, which included both surgical and nonsurgical approaches. They gathered information based on 3 treatment arms—nonsurgical management, laminectomy, and X-STOP. Because of the diversity of measurements used by the various studies, they faced the difficulty of digesting and harmonizing the barrage of objective outcome data. The data were analyzed using a complex mathematical outcome model to calculate each treatment arm's cost-effectiveness—even accounting for multiple-level surgeries. The authors had to make certain assumptions to accommodate their mathematical model. The primary outcome for the optimal management strategy was set at the 2-year mark, with a secondary outcome set at the 4-year mark.

The analysis by Burnett et al.<sup>1</sup> showed that at the 2-year mark, laminectomy was, on the whole, most effective, followed by X-STOP and conservative treatment. Decompressive surgical intervention was, however, more costly than nonoperative treatment. For single-level disease, laminectomy was more effective than X-STOP but it was also more expensive. Interestingly, for 2-level disease, laminectomy was more effective and less costly than the X-STOP.

With so many studies using different patient pools, methodologies, and outcome measurements, Burnett and his coauthors are to be congratulated for their efforts to reconcile the complex data from these studies and to make intelligible conclusions. There are, however, a number of caveats that readers should recognize when reading the article by Burnett et al.<sup>1</sup> It is inevitable that certain assumptions had to be made (some of which have been pointed out in the article itself) in order that the data sources could be compared. First, patient groups from different studies were assumed to be similar, which may not be the case. Moreover, the diagnostic and treatment algorithms in different centers likely differed substantially also. For instance, the number of postoperative or preoperative radiological investigations was arbitrarily assumed. Moreover, there are numerous variations on decompressive procedures used—ranging from microsurgical or minimally invasive laminotomies or laminoplasty to laminectomy with variable sparing of facets.

Importantly, in the Burnett et al.<sup>1</sup> paper, all forms of “decompression” were lumped together as “laminectomies.” In the same vein, because of the variants of laminectomies today, some of these procedures are less invasive than others, and there are centers that perform “laminectomies” as a day-surgery procedure. Burnett et al., however, assumed that all laminectomies are performed as inpatient cases. Moreover, the use of laminectomy was also assumed to be the “rescue” treatment of all failed X-STOP procedures. In reality, laminectomy is but one of the revision options. Finally, there is not much mentioned about nonsurgical treatment. In our outpatient practice, we are well aware that all patients undergo different experiences with regard to “nonsurgical treatment.” Some may have tried nothing at all, others may have undergone varying amounts of physiotherapy, chiropractic treatment, acupuncture sessions, and spinal injections and possibly performed varying amounts of core strengthening exercises. There is also no mention of the use of pharmaceutical products, which can be a significant cost-driver.

Overall, Burnett and his coauthors are to be congratulated for their scholarly and thought-provoking article that attempts to systematically combine data from a large number of studies. Lumbar spinal stenosis is a common condition for which surgical treatment has a clear role. Surgeons now have the option of choosing from an array of options ranging from interspinous spacers to more formal decompressive procedures. Readers are encouraged to carefully review the article by Burnett et al. to make a more informed choice regarding the most cost-effective options to treat LSS.

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## Response

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We would like to thank Drs. Fehlings and Chua for their insightful comments regarding this investigation. As with many clinical questions in our discipline, there is need for a well-designed randomized clinical trial comparing treatment strategies for lumbar stenosis. It is often the case that when new technologies are introduced, initial reports are published in the form of case studies and case series demonstrating safe and effective usage rather than comparative effectiveness. Randomized trials tend to follow years later, if at all. Such is the case with X-STOP. The device was introduced in 1995 and is used widely by surgeons, but we are still waiting for a comparative randomized trial to emerge.

In the absence of a trial, clinicians need to have some reasonable measuring stick by which they can judge the merit of a new technology or technique. We have found that decision analytic modeling can provide such a tool.

No methodology is immune to criticism. As Drs.

Fehlings and Chua correctly point out, we pool data from several sources (for example, all lumbar decompressions were pooled as “laminectomy” without note of the number of levels decompressed). We also decided that all initial treatment failures would be treated with laminectomy despite the fact that some patients might need a more comprehensive surgery such as a fusion. Pooling permits us to use larger numbers of cases for better statistical power, but at the cost of introducing heterogeneity.

Given the high price of the X-STOP device, we were concerned at the outset of this analysis that its cost alone would cause it to perform poorly in a cost-effectiveness analysis. We decided that our “virtual trial” should be designed to give the benefit of the doubt to X-STOP where possible. As an example, for cost comparison we decided to classify all X-STOP procedures as “outpatient and local anesthesia” cases but all laminectomy procedures as “inpatient and general anesthesia” cases, despite the fact that some laminectomies can be done in the lower-cost outpatient setting.

There is at least one randomized clinical trial currently underway that compares the use of an interspinous decompression device with laminectomy, and we are anxiously awaiting the results. However, clinical effectiveness alone is not enough to judge a medical advancement. Cost to society must also be considered. Given our analysis, X-STOP would need to be significantly more effective clinically than the current literature seems to indicate in order for it to outperform laminectomy in a cost-effectiveness analysis.

Whether it is the artificial disc, the X-STOP, or the absorbable cervical plate, advancements in spinal device technology tend to come with a steep price tag. It is unfortunate that proof of comparative clinical effectiveness and cost-effectiveness tends to be determined years after a product’s introduction. Perhaps practitioners and patients would be better served if comparative trials were conducted in addition to safety studies before a new spinal implant is released. Until this occurs, we feel that decision analytic evaluations like this one are necessary and useful. (DOI: 10.3171/2009.11.SPINE09853)