Self-rated evaluation of outcome of the implantation of interspinous process distraction (X-Stop) for neurogenic claudication

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Abstract The treatment of lumbar spinal stenosis is either conservative or surgical decompression. Recently, an interspinous decompression device (X-Stop) has been developed as an alternative. Patients treated with an X-Stop between 2003 and 2006 are subject of this study. The SF-36 Health Survey and Zürich Questionnaires are used. The data of pre- and post-operative self-rated questionnaires are collected and analysed by independent investigators. The data were statistically analysed. A good outcome was defined when the mean score at the ZQ for satisfaction was at maximal 2.0, and the mean improvement of the severity score was at least 0.5, and also for vitality score. For relations between outcome and gender, smoking, BMI, orthopaedic co-morbidity, number of implanted X-Stops were sought. The change in SF-36 scales was related to the outcome. Sixty-five patients did undergo implantation of an X-Stop. The mean age was 64.4 ± 10.0 years (range: 37.0–85.0 years). 31.1% Of the patients had a good outcome. A good outcome was not related

to smoking, BMI, number of implanted X-Stops. However, a good outcome was related to the absence of orthopaedic co-morbidity or male gender. Patients with a good outcome had significantly a better improvement of the scales of the SF-36 concerning physical pain or impairment. The X-Stop does improve the clinical situation. However, a good outcome is achieved less often than previously reported. Probable explanations are discussed.

Keywords Lumbar spinal stenosis · Surgery · Treatment · Interspinous distraction · Outcome

Introduction

Neurogenic claudication due to lumbar spinal stenosis has first been described by Verbiest [8]. Among two different therapies (surgical decompression, conservative treatment) a newer less invasive treatment has been proposed and investigated. An interspinous distracting device (X-Stop) has been developed in order to decompress indirectly the local stenotic lumbar segment. In relation to conservative treatment the device has proven its efficacy [2, 5, 9]. However, a randomised controlled study comparing the X-Stop with a surgical decompression has never been described. At this moment, lessons should be learned from cohorts of patients, and especially from the results of self-rated questionnaires. Therefore, this study was performed.

Patients and methods

Only patients with a classical neurogenic claudication due to lumbar spinal stenosis were surgically treated with a X-STOP. Classical neurogenic claudication does include:

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leg pain during walking with relief after sitting or squatting (flexion of the lumbar spine), standing does not relieve the pain, bicycling does not cause any leg pain, and neurological examination does not show any abnormalities. Spinal stenosis is caused by hypertrophic flaval ligaments, or hypertrophic facet joints. Disc degeneration may contribute to spinal stenosis due to the former causes. A minimal (less than grade 1) degenerative spondylolisthesis was not an exclusion criterium. In all cases radiological diagnosis was confirmed by magnetic resonance imaging (MRI). All patients have been operated by RD.

The patients were followed prospectively. Preoperatively, all patients had to fill in a SF-36 Health Survey questionnaire and a Zürich Questionnaire (ZQ). These questionnaires were also filled in at the last follow-up. Smoking habits, and orthopaedic co-morbidity were also registered. Orthopaedic co-morbidity is defined as all problems necessitating the consultation of an orthopaedic surgeon with the exception of lumbar spinal diseases, for example knee or hip problems.

The SF-36 Health Survey is the most widely used generic health status measure. It is composed of 36 questions organized in eight scales: physical functioning (PF), role limitations due to physical health problems (RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), and general mental health (MH) [1]. The ZQ is developed for neurogenic claudication [7]. It is divided in three domains: severity of symptoms, physical functions, and degree of satisfaction.

Independent investigators (P.B., J.H., and R.B.) retrieved all data, and performed statistical analysis. Some patients were visited and the questionnaires were filled in with the help of one of the independent investigators. The decision was based on the travelling distance. The other patients were asked to respond by mail. Statistical differences between these two groups were studied.

Outcome was measured based on the self administered ZQ score. First, outcome was related to the answer to the question how the overall situation was graded. A good result was present when the patient was very satisfied. Secondly, the method also applied by Zucherman [9] was used. A good result was achieved when the satisfaction score was at least moderately satisfied (mean score 2.0 or less), the severity score was at least improved 0.5 as was the vitality score. Until otherwise stated, outcome is the outcome considering all domains of the ZQ (second definition).

Finally, the outcome was correlated with the initial values, and an eventual improvement noticed. Through univariate analysis a search for predictive factors was done. For statistical analysis SPSS 11.5 (Lead Technologies) was used. Chi-square, Fisher's exact test, or unpaired Student's

t tests were used. Statistical significance was reached when $p < 0.05$. Unless otherwise written, data are given as mean $\pm$ standard deviation (SD), range between brackets, or with 95% confidence intervals (95% CI).

Results

Between July 2003 and August 2006, 65 patients meeting the criteria for classical neurogenic claudication due to a lumbar spinal stenosis were surgically treated with a X-Stop. Males slightly outnumbered females: 34 versus 31. The mean age at surgery was 64.4 ± 10.0 years (range: 37.0–85.0 years). A difference in age was not found between the sexes ($p = 0.562$). Three patients did not respond. So, data of 62 patients could be gathered completely. The mean follow up was 1.0 ± 0.75 years. Intra- or post-operative complications did not occur.

However, one patient had recurrent complaints after a X-Stop implantation. The interspinous distance was decreased, and recurrence of spinal stenosis was seen at MRI. Because this male patient was satisfied about the previous procedure, he preferred removal of the device and implantation of a bigger one instead of microsurgical decompression. Five patients were offered decompressive surgery and fusion because of persistent symptoms. After this procedure, three patients were completely free of signs and symptoms, one patients had still the same complaints, and one patient has a cauda syndrome due to a post-operative hemorrhage. Thus, 9.2% had a reoperation because of persistent or recurrent symptoms.

Based solely on the question inquiring the degree of satisfaction about the overall result, a good result was achieved in 30.6% of the patients. Statistically, a difference was not found in this outcome between sexes. On the other hand, 46 (74.2%) patients did report to be very or moderately satisfied. Again, statistical significance comparing sexes was not reached ($p = 0.148$). However, a good outcome considering all three domains of the ZQ was reached in 31.1% with a clear difference between males and females ($p = 0.012$). About 14.3% of the female patients had a good outcome, whereas 45.5% of the males had a good outcome. Age did neither influence outcome ($p = 0.908$). Nor did the time between surgery and follow-up influence the outcome ($p = 0.155$).

Fifty patients returned the questionnaires by mail. Twelve patients were visited at home, and together with one of the investigators the questionnaires were filled. Between these two groups any statistical differences did not exist.

The self-rated walking distance according to one question of the physical function scale of the ZQ is depicted in Table 1. All patients with a post-operative walking

Table 1 Self-rated walking distance preoperatively and after implantation of X-Stop at last follow up according to question of ZQ

Preoperative	Post-operative				Total
	A	B	C	D	
A	0	0	0	0	0
B	8	10	3	0	21
C	2	17	14	2	35
D	0	1	2	3	6
Total	10	28	19	5	62

Walking distance: more than 3 km (A), more than 250 m and less than 3 km (B), more than 15 m and less than 250 m (C), and less than 15 m (D)

distance less than 15 m reported a bad outcome. Actually, two of them rated their post-operative walking distance worse than before implantation of the X-Stop: before surgery they were able to walk more than 15 m and less than 250 m.

Nine males received two X-Stops as did 11 females. The remaining patients received one X-Stop ($p = 0.591$). Overall satisfaction was not influenced by the amount of implanted X-Stops ($p = 0.771$). Five times a X-Stop is implanted at level L2–L3, in 29 at L3–L4, and 51 at L4–L5. Implanted sizes were: three times a 10 mm, six times a 12 mm, 56 times a 14 mm, and 20 times a 16 mm device.

The body mass index (BMI) was calculated and related to the outcome. The mean BMI was 27.3 ± 3.7 . After dichotomising BMI in more than 25 (obese), and BMI between 20 and 25 (normal stature), a difference in good outcome did not reach statistical difference ($p = 0.143$).

The absence of orthopaedic co-morbidity was noticed in 57.7% patients, and was statistical significantly related to a good outcome ($p = 0.025$).

The relation of a good outcome was also related to the relative difference of the eight items of the preoperative SF-36 and that one of the last follow-up (Table 2).

Table 2 Relative difference (Δ , relative improvement) of eight items of the SF-36 related to outcome, and p values

SF-36 item	Good outcome (%)	Not good outcome (%)	p Value
Δ PF	29.3 ± 23.4	4.8 ± 19.4	0.000
Δ SF	1.3 ± 16.0	1.6 ± 17.3	0.966
Δ RP	33.4 ± 37.8	3.0 ± 18.0	0.004
Δ BP	39.8 ± 23.7	8.8 ± 25.2	0.000
Δ GH	1.8 ± 14.3	13.4 ± 23.0	0.024
Δ MH	4.6 ± 10.6	4.6 ± 14.6	0.997
Δ RE	7.4 ± 16.4	9.2 ± 23.6	0.775
Δ VT	7.3 ± 10.0	3.1 ± 17.4	0.254

The relative difference is calculated as: (value at the last follow up minus the preoperative value) divided by preoperative value multiplied by 100%

Irrespective of the outcome on all scores except for the SF ($p = 0.497$) a significant relative improvement was noticed. Especially the relative improvement of PF, RP, and BP was statistically ($p < 0.001$, $p = 0.004$, respectively, $p < 0.001$) greater in patients with a good outcome. Instead, the relative improvement of GH was greater in patients without a good outcome. For the other items, the differences among the two outcomes did not differ statistically.

Discussion

Stenosis secondary to degenerative lumbar spondylosis may be a cause of low back and leg symptoms, particularly in older patients. Lumbar spinal stenosis is probably now the most common and fastest growing reason for spinal surgery in adults over 65 years of age [3]. Conservative treatment as well as surgery may be applied. Mostly surgery was surgical decompression with or without some form of fusion. Despite many methodological flaws, a preference for surgical decompression exist. It still remains a question whether a fusion is needed, and what sort of fusion [3].

In a recent study [9] 10% of the conservatively treated patients rated their result as successful one year after the start of the treatment. Although success is variably defined, the success rate for surgical decompression is between 64 and 95% [4].

A novel alternative therapy to conservative treatment and conservative decompression has been developed. Through distraction of the spinous processes narrowing of the spinal canal and foramina at symptomatic level are prevented, and the symptoms relieved [6].

In this study only 31.1% of the patients had a good result. This is not as good a success rate of 59% at one year published in a recent study [9]. We can think of two possible explanations.

First, in our study the grade of satisfaction in the ZQ was indeed at least moderately. Relating to the scores on satisfaction, the sum of scores of the six questions should be maximally 12 or a maximal mean of two. Instead Zucherman described that a good satisfaction score was reached with an average score of 2.5 [9]. Less than moderately satisfied or not satisfied patients are also included. In this way, the success rate is artificially increased.

However, if the patients were asked if they were satisfied without taking into account the other domains, our success rate would increase to 74.2%. We realize that its clinical relevance is doubtful.

Secondly, our patient selection could differ from that one of Zucherman [9]. However, the patients are carefully selected with a clear history of neurogenic claudication and

a radiological examination disclosing a spinal stenosis at one or two levels. Neurologic examination was always done by a neurologist. Therefore, if our selection is a problem, the external validity of other studies can also be discussed.

We can not explain the difference in outcome between males and females. We did not construct our study to resolve this question. It was more explorative design. Similarly, smoking, BMI, and the number of implanted X-Stops was not related to outcome. However, the absence of orthopaedic co-morbidity is strongly related with a good outcome. Although not investigated but easily imaginable, older people will have more problems with joints (orthopaedic co-morbidity) prohibiting a successful overall outcome.

As expected, the scales relating to physical pain and functioning improved statistical significantly more in the patients with a good outcome. We can not explain why the patients without a good outcome did improve more on the general health perceptions.

Finally, a major drawback is the lack of a control group. On the other hand, description of a case series with a less favorable outcome than previous studies is also important. First, the enthusiasm of newer techniques can be tempered. Secondly, this knowledge can contribute to a more reasonable calculation of sample sizes, if a randomized controlled study is designed comparing implantation of the X-Stop versus surgical decompression. This will be the most ideal design for testing whether this device will contribute to a better or equal outcome compared to the surgical decompression.

In conclusion, the X-Stop does improve the self rated clinical situation. However, a good outcome is achieved less often than previously reported. Probable causes are discussed. Adequate controlled studies comparing X-Stop

and surgical decompression are needed. It is imaginable that X-Stop is suitable for patients that can not undergo or refuse more extensive surgery.

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