## Clinical Outcome of a Randomized Controlled Trial for the Treatment of Lumbar Spinal Stenosis: The Uppsala Spinal Stenosis Trial (UppSten)

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INTRODUCTION:

Lumbar spinal stenosis (LSS) is the most common indication for spinal surgery. The aging global population increases the prevalence of LSS, which gains constantly socioeconomic attention. Previous studies have, due to methodological issues, left unanswered questions and until recently, there has been no clear consensus regarding LSS treatment.

The current study aimed to examine whether surgery with decompression for LSS leads to superior clinical outcome compared to structured physical therapy.

## METHODS:

We randomized 155 patients with symptomatic LSS, aged 50-85, years into two arms; surgery with decompression and structured physical therapy (PT). In the PT group, the patients could cross over (CO) to surgery at any time.

The primary outcome was the Oswestry Disability Index (ODI) which was obtained from the Swedish National Spine Registry (Swespine).

Secondary and tertiary outcomes included the six-minute walking test and patient reported outcome measures in terms of the quality of life according to EQ-5D, the Numeric Rate Scale for back and leg pain (NRS), the subjective walking ability, the patient satisfaction, and the global assessment (GA).

The latter represents a useful follow-up tool based on a single question: "how is your back/leg pain now compared to before surgery?" The possible answers are: 0-I did not have any leg/pain before, 1-completely relieved, 2-much better, 3-somewhat better, 4-not changed and 5-worse.

## RESULTS:

One year after the assigned treatments, the intention-to-treat (ITT) analysis found no differences between groups. However, this dataset included 32 patients (41%) from the PT group who underwent surgery within one year. In the per protocol (PP) dataset, the individuals from the PT group who were treated with surgery, and those who were randomized to surgery but not operated, were excluded. The PP analysis showed a difference favoring surgery for ODI [8.93, 95% CI -15.7; -2.18], NRS leg pain [OR 3.01 (95% CI 1.40; 6.51)] and GA for back [OR 2.88 (95% CI 1.29; 6.42)] and leg pain [OR 2.98 (95% CI 1.36; 6.55)].

Further, approximately 60% of the surgical patients achieved a decrease of 15 ODI units, which is above the minimal clinical important difference (MCID, 12.8), compared to 30% from the PT group.

## DISCUSSION AND CONCLUSION:

Our results showed that compared to PT, surgery led to superior outcome in ODI with 60% of the patients surpassing the MCID. Moreover, there was a difference in favor of surgery for leg pain and GA for back and leg pain.

The surgical treatment of LSS is reported to have up to 24% of side effects, whereas non-surgical regimes have none. Several studies have tried in the recent past to compare surgical and non-surgical treatment for LSS but without consensus. LSS is characterized by great variation in treatment modalities, making nowadays the need of an agreement on stepped and stratified care more than essential. In our trial, all the patients in the PT group underwent the same structured PT program on the static bicycle and thus, the treatment that they received was homogenous.

In conclusion, at one-year, surgery with decompression leads to superior outcome compared to PT in terms of ODI, NRS for leg pain and GA for back and leg pain.

