RESPONSIVENESS OF OUTCOME MEASURES IN NON-SURGICAL PATIENTS WITH LUMBAR SPINAL STENOSIS: A SECONDARY ANALYSIS FROM A RANDOMIZED CONTROLLED TRIAL

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INTRODUCTION

• Lumbar Spinal Stenosis (LSS) is a common condition, condition highly associated with disability.
• It occurs mostly as result of degenerative changes, being prevalent in older adults.
• LSS is characterized by poor physical function and limited walking capacity.
• Physical function is frequently assessed by patient reported outcomes (PROs) such as the Oswestry Disability Index (ODI) and Swedish Spinal Stenosis Questionnaire (SSS).
• Walking capacity is commonly assessed by performance-based tests such as the Self-Paced Walking Test (SPWT).
• However, there is limited evidence about the responsiveness and Minimal Clinically Important Difference (MCID) values of the ODI, SSS, and SPWT in non-surgical patients with LSS.

OBJECTIVES

• To assess the responsiveness of the SPWT, SSS and ODI in patients undergoing non-surgical interventions for LSS.
• To provide Minimal Clinically Important Difference (MCID) values for each of these outcome measures.

MATERIALS & METHODS

• This is a secondary analysis from a randomized clinical trial comparing 3 different non-surgical interventions for 263 patients with lumbar spinal stenosis (LSS).
• Patients were ≥ 60 years old, with clinical history and diagnostic imaging evidence of LSS, neurogenic claudication and ability to engage in mild exercise.
• Patients were excluded if history of metastatic cancer, cauda equina, lumbar decompressive surgery, severe peripheral artery disease and inability to complete the performance-based test without an assistive device were present.
• A total of 180 participants completed the SPWT, SSS and ODI at baseline, 2 and 6 months at the Physical Therapy - Clinical and Translation Research Center at the University of Pittsburgh.

• The responsiveness of the outcome measures was assessed by two methods.
• Distribution-based method calculated effect sizes and standardized response mean.
• Anchor-based method, using the patient global index of change (PGIC) as the external anchor to distinguish responders and non-responders.
• Areas under the curve (AUC) were calculated along with MCIDs for each outcome measure in 2 categories of responders: the "minimal improvement" (PGIC ≥1) and the "moderate improvement" (PGIC ≥2) subgroups.
• The MCIDs for each outcome measure were calculated by two methods for each subgroup.
• MCID Method 1 is the mean change of the responders from baseline.
• MCID Method 2 is the difference between responders and non-responders.

RESULTS

The following values represent the 2- and 6-month analyses of each outcome measure, respectively.
• Standard effect sizes: 0.48 and 0.50 for SPWT, -0.42 and -0.36 for SSS, -0.29 and -0.25 for ODI.
• Spearman’s correlation coefficients between PGIC and outcomes: 0.44 and 0.39 for SPWT, -0.53 and -0.55 for SSS, -0.46 and -0.54 for ODI.
• MCIDs for the “minimal improvement” subgroup: 375.9 and 319.3 meters for SPWT, -5.3 and -5.8 points for SSS, -9.3 and -10.6 points for ODI.
• MCIDs for the “moderate improvement” subgroup: 344.2 and 353.2 meters for SPWT, -5.5 and -7.5 points for SSS, -9.1 and -13.6 points for ODI.
• AUCs ranged from 0.68 to 0.76.

CONCLUSIONS

• The ODI, SSS and the SPWT are similarly responsive outcome measures in non-surgical patients with LSS.
• This study presents for the first time MCID values for the ODI, SSS and the SPWT in this population.
• Clinicians may use the MCID values as estimates of clinical progress and to support shared decision-making with their LSS patients.
• Researchers may use the MCID values and the effect sizes as reference points for sample size and power calculations for future studies in the same field.

REFERENCES

• Tomkins-Lane CC, Battle MC, Macedo LG. Longitudinal construct validity and responsiveness of measures of walking capacity in individuals with lumbar spinal stenosis. Spine J. 2014.

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