

Clinical Outcomes Research in Spine Surgery: What are Appropriate Follow-up Times

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Introduction

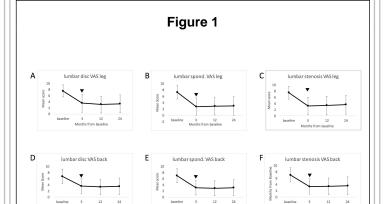
There has been a generic dictum in spine and musculoskeletal clinical research that 2 year follow-up is necessary for patient reported outcomes (PRO) to adequately assess the treatment effect of surgery; however, the rationale for this duration is not evidence based. The purpose of this study is to determine the PRO follow-up time necessary to ensure that the effectiveness of a lumbar surgical intervention is adequately captured.

Methods

Using the different dimensions of PROs from the Canadian Spine Outcomes and Research Network (CSORN) prospective database the time-course to recovery plateau after lumbar spine surgery was assessed for lumbar disc herniation, degenerative spondylolisthesis, and spinal stenosis. One-way ANOVAs with post-hoc testing were used to compare the following standardized PROs at baseline, 3, 12, and 24 months post-operatively: Disability Scale (DS), Visual Analogue Scale (VAS) leg and back pain, and Short form (SF-12) mental and physical component summary (MCS/PCS) scores.

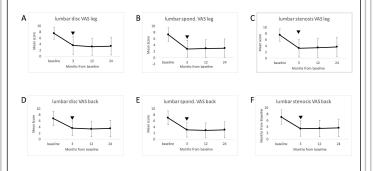
Results

There were significant differences determined by one-way ANOVAs for all spine pathologies and specific PROs (p<0.0001). Time to plateaued recovery after surgery for lumbar disc herniation (n=661), lumbar stenosis (n=913), and lumbar spondylolisthesis (n=563) followed the same course for the following PROs: VAS back and leg pain, 3 months; DS, 12 months; PCS, 12 months; and MCS,3 months. Beyond these time points no further significant improvements in PRO were seen.



Patient reported outcomes of physical function over time after surgery for lumbar disc herniation, lumbar degenerative spondylolisthesis, and lumbar spinal stenosis on the disability scale (A,B,C), and physical component summary (D,E,F). Recovery plateau indicated by .

Figure 2



Patient reported outcomes of the pain dimension over time after surgery for lumbar disc herniation, lumbar degenerative spondylolisthesis, and lumbar spinal stenosis on the visual analog scale leg (A,B,C), and back (D,E,F).

Recovery plateau indicated by .



Patient reported outcomes of Mental QOL over time after surgery for lumbar disc herniation, lumbar degenerative spondylolisthesis, and lumbar spinal stenosis on the mental component summary (A,B,C). Recovery plateau indicated by .

Conclusions

Specific health dimensions of PROs follow distinctly different recovery plateaus, indicating a two-year postoperative follow-up is not required for all PROs to accurately assess the treatment effect of lumbar spinal surgery. Ultimately the clinical research question should dictate follow-up time and the health dimension of the outcome measure utilized, however there is now evidence to guide the specific duration of follow-up for pain, function and mental quality of life dimensions.

Learning Objectives

-Two-year postoperative follow-up is not required for all PROs to accurately assess the treatment effect of lumbar spinal surgery -Ultimately the clinical research question should dictate follow-up time and the health dimension of the outcome measure utilized, however there is now evidence to guide the specific duration of follow-up for pain, function and mental quality of life dimensions.

References

Weinstein J. et al., Surgical vs Nonoperative Treatment for Lumbar Disk HerniationThe Spine Patient Outcomes Research Trial (SPORT): A Randomized Trial. JAMA. 2006;296(20):2441-2450.