



Technical Notes & Surgical Techniques

A pilot study to propose a treatment-based classification for subgrouping patients with surgically treated degenerative lumbar spine with focus on comparing decompression versus decompression with fusion



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ABSTRACT

Objective and background: Degenerative lumbar spine and chronic back pain is a heterogeneous disorder with controversies over the correlation of degenerative image findings to pain generation. This resulted in variable treatment response and the risk of overdoing unnecessary surgery and instrumentation. The current pilot study is an initial work suggesting a new sub-classification for a heterogeneous disorder of degenerative spine diseases and chronic back pain into 6 homogeneous sub-classes. Addressing all subclasses need at least 3 articles so we presented a pilot data for two of these six subclasses and presented the comparison just as a method for future comparison once we have data for all 6 subclasses from our or other centers research.

Methods: A retrospective cohort study reporting health related quality of life outcome (HRQoL), demographics, surgery indications, surgical type, procedural data. The rationale of reporting functional patient outcome is to stress that the ultimate goal is not only the surgical procedure success but the return of the patients to daily and working life. Example outcome comparison is included to guide future treatment effectiveness comparison once TBC groups 1–6 are available.

Results: A total of 32 patients underwent decompression alone and 30 patient's decompressions plus instrumental fusion. The mean scores for all SF-12 domains and the summary measures of pain, social, physical and mental components are reported.

Conclusion: In the current study we report HRQoL for two degenerative spine presentations; lumbar spinal stenosis with and without significant back pain with two treatments; decompression with and without fusion. Owing to the complexity of degenerative spine, the current paper proposes reporting treatment effectiveness and outcome for 6 TBC groups surgically treated patient's subgroups with the aim of building a database from reported outcome studies that can use the TBC subgrouping model for guiding therapeutic selection for each individual patient.

1. Introduction

Degenerative spine disease (DSD) or spondylosis is an increasingly prevalent diagnosis with a negative impact on health-related quality of life (HR-QoL) [1]. The degenerative process is thought to be initiated by the disc resulting in a facet joint degeneration, ligament flavum thickening, spinal stenosis and possible vertebral displacement (degenerative spondylolisthesis) [2]. Though the majority of DSD are asymptomatic, narrowing of the spinal canal and neural foramina associated with diminished space for the neural and vascular elements can present with neurogenic claudication and decreasing walking

distance in extended posture [3], whereas, irritation of the sino-vertebral and medial dorsal branches can present with nociceptive localized or referred chronic pain [4]. Pain in DSD is nonspecific and cannot be definitively attributed to a specific pathology specially with the discrepancy between image findings and symptoms (asymptomatic, pain or stenosis). Consequently, addressing and classification DSD as heterogeneous subgroups is mandatory.

Image based classification among other suboptimal subgrouping failed to establish relationships between pathology and clinical symptoms [5]. Treatment-based classification (TBC) where clinical presentation utilized to distribute patients to appropriate treatment

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subgroup can improve the effectiveness of care provided to symptomatic patients [6,7]. Identifying the clinical prediction rules (CPR) which predict better treatment response is vital for validation of TBC model [8,9]. However, with the numerous available and newly arising therapeutic options for each presentation, obtaining enough sample size can be difficult in a heterogeneous disorder like DSD. Consequently, in the absence of large multicenter collaboration, reporting of therapeutic outcome and responses for different presentations and therapeutic procedures can form an alternative method providing database building blocks for identification of CPR and utilizing TBC model in surgical interventions before final validation.

The surgical methods for degenerative lumbar canal stenosis are decompressive surgery with or without fusion. Both techniques include partial removal of posterior osseous tissue with excision of the compressing ligamentum flavum spinal fusion is added to avoid or to treat spinal instability [10,11]. However, adding instrumental fusion can be associated with higher complication risk. Even in the presence of low-grade spondylolisthesis, the fusion benefit is being challenged [12,13].

There is a lack of consensus in the literature around the weather surgical treatment outweigh conservative treatment and if adding instrumental fusion in DSD can improve or worsen quality of life. In light of this reporting quality of life outcome can add the data available for CPR selection in the different DSD presentations with the aim of expanding TBC model. The shortened questionnaire, known as the SF-12 [14] was shown to be reliable and valid for use as their SF-36 counterparts [15] and required only one-third of the usual time for completion.

The current paper is an initial work suggesting a new sub-classification for a heterogeneous disorder of degenerative spine diseases and chronic back pain into 6 homogeneous sub-groups. Addressing all subgroups need at least 3 articles so we presented a pilot data for two of these six subgroups and presented the comparison just as a method for future comparison once we have data for all 6 subclasses from our or other centers research. Regarding the CT and MRI images classifications, it is not part of the current study aim. However, the issues of the image findings and classifications need to be addressed in a separate future study due to the scientific debate about the correlation of degenerative disc findings to back pain generation. Regarding Cronbach value and other statistical analysis and comparison methods, it is not applicable to the current initial study as the aim is proposing a skeleton for a new classification to fragment the heterogeneous degenerative spine and back pain into subclasses that can be comparable so we are not on the stage to compare as our data is a pilot and only for two different groups.

2. Methods and materials

2.1. Study design and patients

Treatment-based classification (TBC) where clinical presentation utilized to distribute patients to appropriate treatment subgroups as described [6,7]. The proposed TBC 1–6 in the present article as follow: back pain treated with and without fusion, stenosis in the absence of back pain treated with and without fusion, spinal stenosis and back pain treated with and without fusion. Though treating back pain in the absence of neurogenic claudication with decompression alone is uncommon, it is included as one of the subgroups due to the possible mechanisms of soft structures (i.e. dura sleeves, ligamentum flavum) distortion and adhesions in the absence of previous surgery (possibly due to micro-venous bleedings). These mechanisms are being emphasized with the new treatment techniques of percutaneous epidural adhesiolysis. We analyzed two groups of patients (decompression alone versus decompression with instrumental fusion). All patients who underwent surgical treatment for degenerative lumbar canal stenosis without spondylolisthesis (as documented by lateral flexion-extension radiographs) between May 2015 and April 2016 at were identified from

the electronic file data base. To limit the bias and heterogeneity with retrospective recruitment, only elective planned patients who their surgery were performed by senior spine-orthopedic or spine-neurosurgeon were recruited. Other inclusion criteria were: age \geq 18 years, no complicating chronic diseases (rheumatoid arthritis, ankylosing spondylitis, renal failure). Eligible patients were contacted and the SF-12 and HADS questionnaire were completed with the senior resident after average 12 months from the procedure.

Data collection included patient demographics, procedural data and quality of life, outcome measured by the Arabic validated version of Short-Form Health Survey (SF-12) and Hospital Anxiety and Depression Scale (HADS) questionnaires [16]. Eligible patients were contacted and completed SF-12 and HADS questionnaires with the senior resident's doctors. The study was approved by the Hospital Ethics and the Department Scientific Committees.

2.1.1. Surgical indication

Patients undergoing decompression alone are those with neurogenic claudication improved by bending forward, affecting patient daily life and failed conservative treatment. Whereas, patients undergoing decompression with fusion are those meeting the above indication but in addition with significant chronic or recurrent back pain with positive response of symptoms to image guided facet joint injection.

2.2. Intervention procedure

In summary the surgical procedures were as follow: midline posterior approach to the lumbar spine with exposure to the medial aspect of the facet in the decompression alone group and extended laterally to the transverse process in the fusion group where pedicle screws were inserted before decompression. For both groups, the laminectomy of the affected levels with ligamentum flavum removal laterally to the roof of nerve canal was done. In decompression alone group facet were preserved and decompression laterally performed via undermining, whereas, in the fusion group nearly one-half of the facet were removed. The rods were positioned and connected to the pedicle screws with distraction on the affected levels. The instrumentation in all patients was augmented with a local bone graft from the lamina and demineralized bone matrix placed along the lateral gutters following de-ortifications.

2.3. Outcome measures

Primary outcomes included quality of life, symptoms of anxiety or depression.

1. The SF-12 health status questionnaire is derived from the SF-36 questionnaire [16], it is used to assess overall health status and measures eight domains and two components (PCS-12 and MCS-12). General health, vitality and social functioning domains are shared by PCS and MCS whereas, PCS encompass physical functioning, role-physical, and bodily pain, whereas, MCS encompasses social functioning, role-emotional, and mental health. The SF-12 summary scores (PCS-12 and MCS-12) range from 0 to 100, with higher scores representing better self-reported health, and they were calculated using standard SF-12 interpretation manual.
2. The HADS is a self-assessment scale consisting of 14 items that measure the presence and severity of anxiety and depression separately. While the seven odd number items reflect the anxiety, the even number items reflect the depression. A score greater than or equal to 8 is regarded as the clinical cutoff [17].
3. Symptoms of anxiety or depression assessed by the Hospital Anxiety and Depression Scale (HADS). Normal 0–7, borderline abnormal 8–10, abnormal 11–21.
4. Demographic and procedural parameters from the electronic medical records: age, gender, smoking habits, method of treatment,

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