Natural Evolution of Lumbar Spinal Stenosis

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MUST KNOW

- An understanding of the natural evolution of lumbar spinal stenosis (LSS) is important when considering the optimal treatment for a patient presenting with this condition.
- Cross-sectional population studies have shown:
    - That the prevalence of *radiologic* lumbar spinal stenosis is relatively high, with one large study finding MRI evidence of moderate or severe radiologic stenosis in approximately two-thirds of individuals in their fifties and rising to over 90% in individuals aged 80-years or more.
    - However*, radiologic* LSS is substantially more common than *clinical* LSS. In the study above, only 17.5% of those identified as having severe radiologic stenosis were symptomatic.
- Clinical longitudinal studies of conservative management have shown:
    - Between one-third and one-half of patients with clinical LSS are likely to improve and a similar percentage may become worse when managed conservatively.
    - Approximately 30% of patients, initially managed conservatively, cross-over to surgical management

SHOULD KNOW

- To date, clinical studies have not found clear or consistent prognostic indicators regarding which patients are likely to fail conservative management. Several studies have found that those with more severe radiologic stenosis or clinical symptoms are likely to fail conservative management.

1. Introduction

- Lumbar spinal stenosis (LSS) was first described as a clinical entity by Verbiest in 1949 [1], and probably even earlier by Van Gelderen in 1948 [2]. Verbiest described a syndrome, in which narrowing of the lumbar spinal canal was associated with disturbance of cauda equina function on standing or walking (bilateral radicular pain, disturbance of sensory and motor power in the legs), and relieved when recumbent.
- LSS is now one of the most commonly diagnosed conditions affecting the lumbar spine and rates of surgery for LSS are increasing rapidly. Between 1979 and 1992, rates of surgery increased eightfold for patients aged 65 and older [3] and it is likely that as the population ages, the societal burden of treating patients with LSS will grow.
- A decision on the optimal treatment for a patient presenting with LSS should be based on a knowledge and understanding of the natural evolution of the condition.
    - How prevalent is LSS in the community?
    - What is the likely outcome of conservative treatment?
        - Will the clinical condition deteriorate as the patient ages?
        - How often does conservative treatment give an acceptable result?
        - What are the risks of conservative treatment?
        - Can successful conservative management be predicted?
        - How often do patients switch to surgical management?
        - Could conservative treatment and delayed surgical intervention ultimately lead to worse outcomes?
- In 1996, Herno et al [4] commented that, "*the prevailing opinion seems to accept that the natural course of lumbar spinal stenosis is one of progressive worsening*". However, their study and other investigations into the natural history of the condition have indicated that contrary to that 'prevailing opinion', symptoms may improve or remain unchanged in the majority of patients treated conservatively [4,5,6].
- Our current knowledge of the prevalence and natural evolution of LSS has come from both cross-sectional and longitudinal studies:
    - Cross-sectional, population studies have provided information regarding the prevalence of both *radiologic* LSS and *clinical* LSS. They have provided an opportunity to correlate the occurrence of radiologic LSS with clinical symptoms. These studies have also provided clues to the natural evolution of LSS by studying correlations between the prevalence or severity of LSS and demographic factors – particularly age.
    - The longitudinal studies have included single cohort studies, non-randomized trials of conservative versus surgical management and more recently, the non-operative control arms of randomised control trials (RCTs). To date, the information provided by longitudinal studies has mainly involved patients with

symptomatic LSS and generally in the context of non-operative, active intervention such as physical therapy, oral medication or spinal injections.

2. Prevalence of Lumbar Spinal Stenosis (LSS):

In 1990, Boden et al[7] reported on the MRI findings in 67 asymptomatic individuals, assessed by 3 'blinded' neuro-radiologists. They identified LSS in one individual aged under 60-years and in 21% of the group aged 60-years or more.

More recently, two comprehensive, cross-sectional, population studies of LSS have been published – one involved a sub-group of the Framingham Heart Study in Massachusetts, USA [8] and one was from Japan [9].

The Framingham study [8] was an ancillary study, based on a sub-group drawn from the Offspring and Third Generation cohorts, of the (longitudinal) Framingham Heart Study. 191 consecutive participants with a mean age of 53 years, living in Framingham, Massachusetts, underwent a CT scan of their lumbar spine and completed a modified Nordic Low Back Questionnaire. In addition to congenital and acquired variants of LSS, the study defined two radiologic thresholds for LSS – 'relative' (sagittal canal diameter ≤12 mm) and 'absolute' stenosis (sagittal canal diameter ≤10 mm). Of note, they found that:

- The prevalence of acquired 'relative' and 'absolute' radiologic LSS increased with age. Between <40 years and ≥60 years, the prevalence of 'relative' LSS increased from 16% to 39% and the prevalence of 'absolute' LSS increased from 4% to 14%.
- The prevalence of congenital or acquired radiologic LSS was:
    - For *asymptomatic* participants – 22.5% 'relative' and 6% 'absolute' LSS.
    - For individuals *with low back pain* – 30% 'relative' and 19% 'absolute' LSS.
- A positive association was observed between relative acquired LSS and BMI (p=0.02).

The Wakayama Spine Study [9] examined a cohort of 938 participants, said to resemble the general Japanese population. Older and with a lower mean BMI than the Framingham participants (mean age: 67 *vs.* 53 years and mean BMI:23 *vs.* 28, respectively), the Wakayama study evaluated the prevalence of radiographic LSS and clarified its association with clinical symptoms. The authors used MRI scans to rate the stenosis as mild, moderate or severe and discriminated between central, lateral, and foraminal stenosis. They found that:

- The prevalence of moderate or severe radiographic central stenosis was 64% for participants aged in their 50s and 93% for those in their 80s.

- Although many participants had radiographic LSS, few had clinical symptoms and only 17.5% of the participants with severe central stenosis were symptomatic.
- the prevalence of clinical symptoms increased with increasing severity of radiographic LSS. Logistic regression analysis, adjusted for age, sex, body mass index, and severity of radiographic LSS showed that severe central stenosis was related to clinical symptoms.

3. Natural evolution:

Knowledge of the natural evolution of LSS has come in part, from cross-sectional studies (such as Framingham and Wakayama [8,9]), which examined the radiographic, clinical and demographic factors in both asymptomatic and symptomatic volunteers. While the current data from these two studies is cross-sectional in nature, the studies are ongoing and longitudinal data should emerge.

By following the progress of individual patients, longitudinal studies provide a further perspective. The information currently available from longitudinal studies is mostly derived from cohorts of symptomatic individuals who underwent non-operative management. Such management has usually often some form of active intervention such as physical or exercise therapy, oral medication or spinal injections. Historically, early single cohort reports tended to be retrospective and lacked objective measures of pain and disability [4,5,10]. The more recently reported studies have tended to include surgical and conservative treatment (control) arms [11,6,12,13,14,15]. Treatment allocation may be non-randomized (observational), randomized or a combination of the two. The combined studies have attempted to address the issue of equipoise where the investigators felt it would be unethical to subject patients with mild symptoms to surgery or patients with severe symptoms to conservative management [11,15].

a. Results of conservative management:

i. Clinical Outcomes:

The published results of eight clinical trials, which included conservative management of LSS are summarized in Table 1. [11-18]. These trials reported the conservative management clinical outcomes of almost 700 patients from prospective, observational, single cohort trials as well as the observational (subjects who chose not to be randomized) and randomized cohorts of prospective, randomized, controlled trials (RCTs). Unfortunately, despite the large total number of participants, the reported studies have not used a uniform methodology when assessing and describing the pain and disability associated of their study populations. This and the frequent lack of reported measures of baseline and final disability create difficulty when attempting to compare the

reported treatment outcomes. For the prospective, observational cohorts, some authors stated that the pain and disability of the study participants was relatively 'mild or moderate' [10,11]. The percentage of patients reported to have 'improved' over the study period ranged from 31% to 56%. 29% to 39% were noted to be 'worse' with conservative management.

It is uncertain from the published material as to whether the baseline disability of patients undergoing non-operative treatment in the single cohort, observational trials was generally different to that of patients in the randomized controlled trials but it is noteworthy that the authors of these RCTs, mostly noted that symptom severity among study participants was sufficiently severe to justify surgery but not sufficient to necessitate surgery. In the SPORT trial [15], the baseline health status measures of both the observational and randomized cohorts were similar (mean Oswestry Disability Index (ODI) scores of 42.1 and 42.7, respectively) but it is evident that baseline disability severity differed between trials. The mean baseline ODI in the 44 patients of the Malmivaara et al study [14] was 34.7 compared with 42.7 for the 151 patients randomized to non-operative treatment in the SPORT trial.

ii. Cross-over to surgery:

One measure of non-operative treatment failure is the conversion or cross-over rate to surgical intervention. The rate varied considerably among the trials. It was 49% for the randomized, control cohort of the SPORT trial [15] and 26% for the non-randomized, control cohort of the same trial. The baseline demographics and health summary status of these two control cohorts were similar. For the randomized, control patients in the Malmivaara et al RCT [14], the cross-over rate was only 11%.

Overall, in the observational studies, 91 of 391 or 23% of patients crossed-over to surgery, having initially chosen non-operative treatment. This compared with 111 of 304 or 36.5% of the patients randomized to non-operative treatment in the RCTs.

iii. Risks of conservative management:

Kovacs et al [19] in their 2011 systematic review of RCTs of surgery versus conservative management were unable to find evidence of serious adverse or catastrophic events among patients receiving conservative treatment. In particular, no patients were reported to develop serious neurologic deficit. In the X-STOP RCT [13], in the group randomized to non-operative care (n=91), 4 epidural injection patients experienced post-injection flare up of symptoms. In a randomized, controlled trial of exercise based treatment Goran et al [20], no adverse events were noted within either the exercise or no treatment groups.

While the single cohort, prospective trials were generally positive regarding the risks of non-operative management; Simotas et al [16] reported that 2/40 (5%), who did not undergo any surgery, suffered significant motor deterioration.

iv. Delay in instituting surgical management:

It is controversial as to whether initial non-operative treatment and the resulting delay in instituting surgical management may ultimately lead to worse clinical outcomes. The published literature provides conflicting evidence:

- Ng et al. [21] in a well conducted prospective study of 100 consecutive patients undergoing surgery for LSS found a statistically significant association between symptom duration and the improvement in ODI (P=0.001), Low Back Outcome Scores (P <0.001) and VAS pain scores(P=0.001). Subgroup analyses showed that patients with symptom duration of less than 33 months had a more favourable result.
- However, perhaps a higher level of evidence comes from the cross-over patients in the initial control arms of the RCTs. The clinical outcomes in patients from the Amundsen and SPORT randomized controlled studies were similar in those patients who initially underwent operative treatment and those who crossed over to surgery following failed conservative treatment [11,15]. This would suggest that final outcome is not adversely affected by a delay in surgery.

b. Predicting the outcome of conservative management:

The literature is unclear as to whether or how the success or failure of conservative management may be predicted. Both the observational trials and the conservative control arms of the larger RCTs have all provided different conclusions on this important issue: some have found no pre-treatment prognostic factors while others have found that either the initial imaging, neurophysiologic abnormalities or clinical severity are related to final outcomes.

Some observational, single cohort trials found no imaging predictors among their cohorts [18], while others have disagreed [10,17,22]. Minamide et al [17] found that patients who crossed-over to surgery during the trial period had severe narrowing (<40 mm2) of the area at the initial examination. Mariconda et al [22] found that the baseline dural sac cross-sectional area positively predicted walking capacity in non-surgically treated patients at 1 and 2 years. However, the controversy surrounding imaging is not surprising given the difficulty of predicting clinical symptom severity or disability, based on initial radiological findings. Some authors have found no correlation between radiological findings and symptoms [7,23, 24, 25] whereas others, including the large Wakayama Spine Study, have [9,10].

Micankova Adamova et al [18] found neurophysiological studies helpful while Haig et al did not [25].

Haig et al [25] found that the best predictor of future functional ability was current function, measured by ambulation velocity or the more global Pain

Disability Index. Similarly, the SPORT study [15] found that patients who were assigned to non-operative treatment but underwent surgery within 4years had higher ODI scores – 46 vs. 39.3 (p=0.02). The X-STOP RCT though, in a univariate analysis, did not find any pre-treatment variables (baseline scores, patient demographics such as age or gender, or the presence of comorbid conditions) to be significantly associated with 'successful treatment' in the group randomized to non-operative care (n=91) [13].

4. Conclusions:

As the population ages, the frequency of patients presenting with symptomatic LSS will rise and create an increasing societal burden. Large, cross-sectional, population studies have found a high prevalence of moderate or severe radiologic stenosis. The Wakayama study noted that approximately two-thirds of individuals in their fifties had radiologic evidence of stenosis and that this rose to over 90% for individuals aged 80-years or more. However, only 17.5% of those identified as having severe radiologic stenosis are symptomatic.

Numerous longitudinal studies of patients presenting with clinical LSS have shown that symptoms will often improve or remain stable with conservative management. Among the almost 700 patients shown in Table 1, between one-third and one-half of patients were reported to have improved and a similar percentage became worse over a three to ten-year follow-up period, when managed conservatively.

Approximately 30% of patients, initially managed conservatively, were found to cross-over to surgical management. However, to date, no clear or consistent prognostic indicators have emerged from these studies regarding which patients are likely to fail conservative management. Several studies have found that those with more severe radiologic stenosis or clinical symptoms failed conservative management.

In the future, further well-controlled, prospective studies of baseline demographic, clinical and radiologic variables may help to clarify questions regarding the likely natural evolution of LSS in the case of an individual.