The test to retest reproducibility of walking test for intermittent claudication associated with lumbar spinal stenosis

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Abstract
Background The walking test is useful to evaluate leg numbness and pain caused by cauda equina symptoms in patients with lumbar spinal stenosis but there are few reports described about reproducibility. The study aim was to evaluate the reproducibility of the walking test for lumbar spinal stenosis.

Methods Seventy patients with lumbar spinal stenosis who had intermittent claudication symptoms at a multicenter outpatient clinic were examined prospectively. A walking test was performed at 0 and 4 weeks. We investigated walking distance and lower limb pain and numbness in this study. Pain and numbness were evaluated by using the Visual Analog Scale (VAS) immediately after the walking test for the hip and outside, inside, front, and posterior sides of the lower legs. Cohen’s kappa analysis and interphase correlation coefficients (ICCs) were used to evaluate reproducibility. The Swiss Spinal Stenosis Questionnaire (SSS) was used to evaluate stenosis severity.

Results The mean SSS was 30.2 ± 5.5 initially and 29.2 ± 5.2 at week 4, with no significant difference in severity (P = 0.10). The walking distance ICC between baseline and 4 weeks was 0.670. The interobserver reliabilities for lower limb ache and numbness in both legs were acceptable. The average VAS for lower leg pain was 23.2 ± 25.2 mm at baseline and 27.4 ± 28.8 mm at week 4. The ICC was 0.668. The average VAS for leg numbness was 23.4 ± 26.7 mm at baseline and 24.8 ± 25.2 mm at week 4. The ICC was 0.683.

Conclusions The walking test walking distance and symptomatic site results were reproducible.

Background
Intermittent claudication is a major symptom of lumbar spinal stenosis (LSS) [1–3]. Increasing lumbar lordosis with standing and walking affects the circumference of cauda equina nerve and can cause ischemia. As a result, patients with LSS complain of pain or numbness of the legs. The walking test is used to assess lower limb symptoms during actual walking. The treadmill test [4], bicycle test [5], and stoop test [6] are also used to detect ischemia in cauda equina. On the contrary, few studies have compared the reproducibility of assessments of intermittent claudication. A previous investigation showed the superior reproducibility of the walking test for leg symptoms during walking compared
with that of the treadmill test [7]. However, the walking test has some disadvantages. The walking test requires a huge space that is not required by other tests. Physicians cannot repeat this test easily, especially in an outpatient clinic. Therefore, the reproducibility of walking test results is important. However, reports on the reproducibility of the walking test are lacking. We therefore investigated the test-to-retest reproducibility of the walking test for intermittent claudication associated with LSS.

Methods
Study design
This was a multicenter analysis of patients with LSS. The study involved two types of patients with LSS: subjects who had not previously used any drugs and therapies for LSS, and subjects who had used some drugs and therapies for LSS before the study. All the subjects received vitamin B12 as treatment when the study began. For the subjects who had previously been treated for LSS, we preferred that they not continue receiving the original drugs and therapies during the study, but for those who chose to continue use, the original drugs or therapies, dosages, and frequency of drugs or treatment were not changed during the study. In addition, new drugs or therapies for LSS were forbidden. In total, 80 patients were recruited for the study. We enrolled patients who were diagnosed as having LSS and lumbar spondylolisthesis and had bilateral leg symptoms because of cauda equina. The exclusion criteria were as follows: 1) positive results for straight-leg-raising test; 2) a past history of surgery for LSS; 3) lower leg numbness from cerebral palsy, brain infarctions, or diabetes mellitus neuropathy; 4) disease affecting gait (e.g., Parkinson disease), mental disease (e.g., depression); and 5) inability to understand this investigation.

Demographic Data Variables
We investigated the following demographic variables: age (defined as the duration from birth to informed consent rounded to the nearest year), sex, height (first observation value), weight (first observation value), disease duration, comorbidity, medical history, symptom assessment (pain or numbness), and walking distance.

Observation Variables
Subjects with LSS underwent the walking test performed according to the procedure detailed in a
previous report [7]. The investigator walked in parallel with the subject away from the visual field without talking to the subject. Each subject continued walking until he or she became unable to walk because of pain or numbness of the lower extremities. We determined the walking distance and subjective symptoms (lower limb ache and numbness) in the walking test at baseline and at week 4. We divided the lower leg into five parts as symptom areas: the front, back, outside, inside, and hips of the right and left legs (Fig. 1). The subjects were tested to determine in which parts of the lower leg pain or numbness was felt. We administered the Swiss Spinal Stenosis Questionnaire (SSS) at baseline and week 4 and compared both the baseline data and week 4 data to determine the reproducibility of the walking test results. Table 1 shows the schedule of this investigation.

|                          | Baseline | Week 4 (28 ± 3 days) |
|--------------------------|----------|----------------------|
| Informed consent signed  | ●        | ●                    |
| Patient registration     | ●        | ●                    |
| Distance of intermittent claudication | ●            | ●                    |
| Numbness of lower limb while walking | ●        | ●                    |
| Ache of lower limb while walking | ●        | ●                    |
| SSS                      | ●        | ●                    |

SSS: Swiss Spinal Stenosis Questionnaire.

Statistical analysis

Three statistical tests were used to assess the test-to-retest reproducibility: The intraclass correlation coefficient (ICC) was used to measure interobserver agreement for walking distance to assess intermittent claudication. Cohen’s kappa analysis was used to assess reproducibility of pain and numbness of the lower legs after walking. The chi-squared test was used to compare the changing severity assessed by the SSS over a 4-week period. The data analysis was performed using IBM SPSS Statistics software, Version 25.0 (IBM Corp., Armonk, NY, USA).

Results

1) Subject enrollment and follow-up

A total of 80 subjects were recruited in this study. Of these subjects, 10 stopped participating after the baseline trial (one subject did not meet the inclusion criteria, one subject was not available, two subjects were lost to follow-up, and six subjects planned to stop participation before study completion). Finally, 70 patients were registered and investigated in this study. Table 2 summarizes
the baseline characteristics.

Table 2
Demographic variables

| Variable                               | Lumbar spinal stenosis subjects (n=70) |
|----------------------------------------|----------------------------------------|
| Age (years)                            | 62.7 ± 7.20                            |
| Sex, n (%)                             |                                        |
| Male                                   | 27 (32.9)                              |
| Female                                 | 43 (67.1)                              |
| Height (cm)                            | 162.5 ± 8.2                            |
| Weight (kg)                            | 65.4 ± 8.7                             |
| Type of disease, n (%)                 |                                        |
| Central stenosis                       | 46 (65.7)                              |
| Degenerative spondylolisthesis         | 24 (34.3)                              |
| Duration of disease (month)            | 42.3 ± 66.8                            |
| Comorbidity, n (%)                     |                                        |
| Yes                                    | 42 (53.2)                              |
| No                                     | 37 (46.8)                              |
| Past medical history for lumbar spinal stenosis, n (%) |                      |
| Yes                                    | 3 (4.3)                                |
| No                                     | 67 (95.7)                              |

Mean ± standard deviation

2) SSS Results At Baseline And At Week 4

The average SSS was 30.2 ± 5.2 at baseline and 29.2 ± 5.2 at week 4. There were no significant differences in the SSS results between baseline and week 4 (chi-square test: P = 0.10). The severity of LSS did not deteriorate during the investigation period.

3) Reproducibility of the walking test

A. Walking distance

The average walking distance was 467.8 ± 551.3 m at baseline and 500.0 ± 543.5 m at week 4. The ICC of walking distance between baseline and week 4 was 0.67 (95% Confident interval (CI), 0.519-0.782), which indicated high reproducibility. Figure 2 presents the walking distance of each subject at baseline and at week 4.

B. Locations of lower limb aches

The analysis of intraobserver reproducibility for the locations of lower limb aches revealed Cohen’s κ values of 0.470, 0.204, 0.480, 0.485, and 0.580 for the front, back, outside, inside, and hip of the right leg, respectively. Similarly, Cohen’s κ values for the front, back, outside, inside, and hip of the left leg were 0.550, 0.446, 0.208, 0.660, and 0.558, respectively (Table 3).
Table 3
Reproductivity analysis for lower limb ache after walking

| Part of leg | 95% CI       | \( \kappa \) coefficient |
|------------|--------------|---------------------------|
| **Right side** |              |                           |
| Front      | 0.114–0.782  | 0.470                     |
| Back       | −0.0003–0.410 | 0.204                     |
| Outside    | 0.176–0.633  | 0.480                     |
| Inside     | 0.075–0.852  | 0.485                     |
| Hip        | 0.359–0.729  | 0.580                     |
| **Left side** |              |                           |
| Front      | 0.154–0.788  | 0.550                     |
| Back       | 0.169–0.558  | 0.446                     |
| Outside    | −0.012–0.518 | 0.208                     |
| Inside     | 0.132–0.66   | 0.660                     |
| Hip        | 0.331–0.714  | 0.558                     |

C. Locations of lower limb numbness

The analysis of intraobserver reproducibility for the locations of lower limb numbness revealed Cohen’s \( \kappa \) values of 0.325, 0.639, 0.530, 0.480, and 0.400 for the front, back, outside, inside, and hip of the right leg, respectively. Similarly, Cohen’s \( \kappa \) values for the front, back, outside, inside, and hip of the left leg were 0.339, 0.533, 0.433, 0.478, and −0.027, respectively (Table 4).

Table 4
Reproductivity analysis for lower limb numbness after walking

| Part of leg | 95% CI       | \( \kappa \) coefficient |
|------------|--------------|---------------------------|
| **Right side** |              |                           |
| Front      | 0.022–0.579  | 0.325                     |
| Back       | 0.379–0.723  | 0.639                     |
| Outside    | 0.266–0.701  | 0.530                     |
| Inside     | 0.089–0.489  | 0.489                     |
| Hip        | 0.119–0.635  | 0.400                     |
| **Left side** |              |                           |
| Front      | 0.084–0.581  | 0.339                     |
| Back       | 0.257–0.719  | 0.533                     |
| Outside    | 0.169–0.621  | 0.433                     |
| Inside     | 0.145–0.478  | 0.478                     |
| Hip        | −0.026–0.177 | −0.027                    |

D. Magnitude of lower limb pain

The average VAS score was 23.2 ± 25.2 mm at baseline and 27.4 ± 28.8 mm at week 4. The ICC of the VAS scores between baseline and week 4 was 0.668 (95% CI, 0.515–0.780). The magnitude of lower limb pain showed high reliability between baseline and week 4. Figure 3 details the walking distance of each subject at baseline and week 4.

E. Magnitude of lower limb numbness

The average VAS score was 23.4 ± 26.7 mm at baseline and 24.8 ± 25.2 mm at week 4. The ICC of VAS between baseline and week 4 was 0.683 (95% CI, 0.535–0.790). The magnitude of lower limb pain showed high reliability between baseline and week 4. Figure 4 details the walking distance of each subject at baseline and week 4.

Discussion

Neurogenic intermittent claudication is caused by epidural pressure while walking [8]. Takahashi et al.
used an epidural transducer to investigate the epidural space pressure in patients with LSS. They concluded that epidural space pressure was higher in patients with LSS than in normal individuals and that it increased during walking [9]. Amundsen reported that 95 of 100 patients with LSS showed intermittent claudication, which is a major symptom of LSS [10]. We believe that it is highly important for physicians to check intermittent claudication associated with LSS to confirm the patients’ symptoms.

The walking test, stoop test, cycling test, and treadmill test are used to detect neurological intermittent claudication [4–6, 11–21]. However, no studies have compared these tests to show how well they can assess the symptoms of LSS. Previous studies have compared the walking test and treadmill test for intermittent claudication in patients with LSS and assessed their leg symptoms [7, 22]. Rainville et al. performed the self-paced walking test and treadmill test for patients with LSS before and after treatment. They reported that the self-paced walking test was superior to the treadmill test for assessing the efficacy of LSS therapy [22]. Tanishima et al. performed the walking test and treadmill test to assess LSS symptoms (root pain, cauda equina symptoms, and mixed symptoms). They concluded that significantly more symptoms were detected by the walking test than by the treadmill test [7].

We suppose that the walking test is excellent for assessing LSS symptoms. Tomkins et al. [21] performed a self-paced walking test in patients with LSS to investigate the test–retest reliability for walking distance. The patients were required to walk until their LSS symptoms required them to sit down and rest. The test–retest ICC of 0.98 for distance walked was reported. Another study reported an ICC of 0.65 for walking distance in the walking test [23].

There are some problems with using the walking test to assess the leg symptoms of LSS. There have been no reports on the test’s responsiveness without measuring the walking distance, which is the reason we attempted to show the test-to-retest reproducibility of the walking test for intermittent claudication associated with LSS. To confirm reproducibility, we performed the walking test at baseline, at the first visit, and at week 4. The SSS results between baseline and week 4 were not significantly different, indicating no change in the severity of LSS. Our study showed that the ICC for
walking distance in the walking test was 0.67. This result was not inferior to those of previous investigations despite the 4-week interval. The reproducibilities of the magnitudes of pain and numbness in the lower leg assessed by the walking test were 0.688 and 0.683 for ICC, and the reproducibilities for the locations of lower leg numbness and pain were 0.2 to 0.6 determined by the κ coefficient. Although this is by no means a high correlation, most of the κ coefficients were approximately 0.5. The leg pain and numbness caused by LSS are often affected by standing and walking posture or other factors, not all of which are known. Considering the characteristics of LSS, which symptoms vary depending on several factors, we think the reproducibility of the walking test has acceptable accuracy. It is possible to derive the symptoms experienced by the patient to a certain extent by conducting the walking test at any time when clinical symptoms do not improve. We set the interval to investigate Test-to-retest reproducibility of this test with 4 weeks in this study. This interval may be too long to assess the reproducibility to any tests in physical examinations in statistics. Physicians always assess the efficacy of drug therapy or other treatments for 4 weeks or more. We think that to clarify the test-to retest Test-to-retest reproducibility of this test with 4 weeks will indicate possibility this test being excellent tool to investigate the treatment outcomes with any procedures such as drug therapy, rehabilitation or surgery.

A limitation of this study was that we did not compare lower limb symptoms assessed by an imaging modality, such as magnetic resonance imaging, computed tomography, or X-ray radiography.

Conclusion

The walking test showed acceptable reproducibility of the walking distance and lower leg symptomatic sites.

Abbreviations

CI: Confident interval; ICC: interphase correlation coefficient; LSS: lumbar spinal stenosis; VAS: Visual analog scale; SSS: Swiss Spinal Stenosis Questionnaire

Declarations

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Authors’ contributions
ST designed the study, participated in this study, conducted acquisition, analysis, and interpretation of data, and drafted the manuscript. HN contributed to draft the manuscript. LW, HJ, ZJ and YH helped the design of the study and participated in this study, and did the acquisition of data of the work. All authors read and approved the final version of the manuscript.

Consent for publication
Written informed consent was acquired from each of the residents. The patients consented to the publication of their data.

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Availability of data and materials
The datasets generated and analyzed during the current study are not publicly available due professional discretion, as they were part of patient’s records, but are available as de-identified data sheet from the corresponding author on reasonable request.

Ethics approval and consent to participate
All of participants provided written informed consent, and the study was approved by the local ethics committee of the Peking Union Medical College Hospital (No.S-653), Peking University Third Hospital (No.2014-32-II-GK), Military general hospital; command general hospital; pla general hospital (No.2014-056), The First Affiliated Hospital of Soochou University (No.2014909126), Xiangya Hospital Central South University (No.201404035), Qilu Hospital of Shandong University (No.2014-001),
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Competing interests

The following authors declare that they have no competing interests: HG, ZJ, YH and HN

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Figures

The schema of lower limb a: in front of leg b: back of leg c: outside of leg d: inner of leg e: hip
Figure 2

This graph shows the distance of walking at baseline and week 4 with each subject.
This graph shows the magnitudes of lower limb pain at baseline and week 4 using a visual analog scale.
Figure 4

This graph shows the magnitudes of lower limb numbness at baseline and week 4 using with Visual analog scale.