Article

Validity of a Screening Tool for Patients with a Sub-Threshold Level of Lumbar Instability: A Cross-Sectional Study

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Abstract: Lumbar instability (LI) comprises one subgroup of those with chronic low back pain (CLBP); it indicates the impairment of at least one of the spinal stabilizing systems, and radiographic criteria of translation and rotation are used for its diagnosis. Previous studies have developed and tested a screening tool for LI where patients with sub-threshold lumbar instability (STLI) were detected in the initial stage of lumbar pathology using radiographs as a gold standard for diagnosis. The radiographic measurement in STLI lies between the range of translation and rotation of the LI and asymptomatic lumbar motion. However, there are no studies indicating the validity and cut-off points of the screening tool for STLI. The current study aimed to determine the validity of an LI screening tool to support the diagnostic process in patients with STLI. This study design was cross-sectional in nature. A total of 135 participants with CLBP, aged between 20 and 60 years, who had undergone flexion and extension radiographs, answered a screening tool with 14 questions. The cut-off score for identifying STLI using the screening tool was at least 6/14 positive responses to the LI questions. The findings suggested that the LI screening tool we tested is effective for the detection of STLI. The tool can be used in outpatient settings.

Keywords: sub-threshold lumbar instability; non-radiological lumbar instability; lumbar instability; radiography; lumbar translation; lumbar rotation; screening tool; X-ray; sensitivity; specificity

1. Introduction

Lumbar instability (LI) is defined as excessive translation and rotation motion values of each lumbar segment compared with normal values [1], and dysfunction of one of the spinal stabilizing systems, which consist of three subsystems: passive, active, and neural [2,3]. LI is considered to be a subgroup of mechanical low back pain (MLBP) [4]. Previous articles have demonstrated that 12–57% [1,5–9] of patients with CLBP have lumbar instability. Patients with LI report a number of symptoms, including: pain [10], muscle spasms [11,12], abnormal movement quality [13], functional disability [5,10,12], and diminished quality of life [12]. The severity of LI can evolve and may require surgical stabilization [14].

LI can be measured using a flexion–extension radiograph as the gold standard for diagnosis. Patients with LI were defined by White and Panjabi (1990) using flexion–extension radiographic characteristics. Their criteria were: a sagittal plane translation greater than 4.5 mm, or sagittal plane rotation of greater than 15° at L1/L2, L2/L3, or L3/L4, greater than 20° at L4/L5, or greater than 25° at L5/S1 [15].

Staub and colleagues reported that, for asymptomatic volunteers, with an age range of 18 to 82 years, the value of sagittal translation at each lumbar segment was: 1.9 mm

at L1/L2, 2.4 mm at L2/L3, 2.7 mm at L3/4, 2.8 mm at L4/L5, and 0.5 mm at L5/S1. The sagittal plane rotation ranges were 11.0° at L1/L2, 12.6° at L2/L3, 13.3° at L3/4, 14.7° at L4/L5, and 12.8° at L5/S1 [16]. However, there remains a gap in the current clinical knowledge about the range of segmental motion in asymptomatic participants and those with a diagnosis of LI which has not yet been studied. This was the reason for developing the new concept of the "sub-threshold level of lumbar instability (STLI)", defined as the sagittal translation and rotation of each lumbar segment that lies between the asymptomatic or normal range and the range leading to an X-ray diagnosis of LI. The STLI prevalence was reported as 78% amongst participants with CLBP in a previous study that was reported at an international conference on integrative medicine in 2019 at Mae Fah Luang University (Arisa Leungbootnak) [17]. This group of patients with STLI has not been reviewed, although a review is necessary as they are at risk of developing LI, as LI is rarely addressed by conservative treatment. The early detection of patients with STLI may facilitate early appropriate treatment and thereby slow the patient's progression to LI.

The gold-standard radiograph measurement has some limitations in terms of assessment, including the cost of radiograms, time required for examination and interpretation, and radiation exposure [18,19]. The detection of patients with STLI in the community remains difficult due to the limitations of X-ray assessment. Thus, a screening tool (questionnaire) for LI patients was developed. The signs and symptoms of LI were studied originally in 1982 by Kirkaldy-Willis and Farfan [20]. More recently, a specific lumbar instability screening tool was first reported by Cook et al. (2006), who performed a Delphi study with 168 physical therapists [21] and developed a screening tool based on subjective signs and symptoms. The screening was also associated with clinical lumbar instability, and was used to inform the diagnosis in many studies where the criteria related to LI were of interest [9,21–25]. A Thai version was subsequently created by a group of Thai physical therapists [26], who evaluated its construct validity; in 2020, the same group used the questionnaire as a tool for screening patients with LI among CLBP patients [23]. They found that a score of at least 7/14 correlated with having LI; this score was used as an inclusion criterion for participants with LI among patients with CLBP. The tool was also translated (from English into Brazilian-Portuguese) [22] and tested for reliability [9,21,22,24–26].

Questionnaires to evaluate the signs and symptoms of patients with lumbar instability are easy to use in clinical practice [21]; however, to date, no studies have used a specific LI screening tool for patients with STLI in the early STLI stages. The results of this study could be beneficial for the early detection of STLI in patients with CLBP using minimally invasive assessment methods; these patients may be at the pre-stage of LI.

2. Materials and Methods

2.1. Design and Setting

The study design was cross-sectional in nature. Participant testing was conducted at the Department of Associated Medical Science, Khon Kaen University, Thailand. The study was approved by the Ethics Committee for Human Research (HE582228) approved on 12 September 2018 at Khon Kaen University, Thailand. This study has been registered in Thai Clinical Trials at http://www.thaiclinicaltrials.org/show/TCTR20180920003 (accessed on 20 September 2019).

2.2. Participants

Participants with CLBP were recruited via poster and social media announcements. The inclusion criteria were: (1) having intermittent low back pain for at least 12 weeks, (2) participant age range 20 to 60 years, and (3) a pain numeric rating scale (NRS) score between 4 and 7 [27–29]. Participants were excluded if they had: (1) a contraindication to radiographic assessment, such as pregnancy, (2) acute fracture, tumor, or infection, (3) a history of serious neurological or psychiatric disease, (4) previous lumbar fusion surgery, or (5) a diagnosis of radiological lumbar instability (LI), spondylolisthesis, or lumbar disc

herniation [1,5,30]. The investigators gained informed written consent from the participants prior to assessment.

2.3. Sample Size Determination

This is the first study to specifically investigate STLI, so the rate of disease came from the results of our previous study, reported at an international conference on integrative medicine (Arisa Leungbootnak, 7 October 2019) in 2019 at Mae Fah Luang University, Thailand (prevalence of STLI = 78%) [17]. The sample size calculation was conducted based on a significance level (α) of 0.01 and a precision of estimation value (e) of 0.10. According to acceptable sensitivity in the physical therapy field, (P) was set as 80% [31], meaning 135 participants were required.

2.4. Instruments

2.4.1. Radiographic Assessment and Measurement

Flexion–extension radiography is the most common form of examination used in studies to provide an imaging diagnosis of lumbar intervertebral instability [32]. The method of measuring the sagittal translation and rotation in the radiographs was previously described by Iguchi [30]. The sagittal translation and rotation were measured during full flexion and extension, and calculated using the formula (sagittal rotation (degrees) = A − (−a) and translation (mm) = B − (−b)), as shown in Figures 1 and 2.
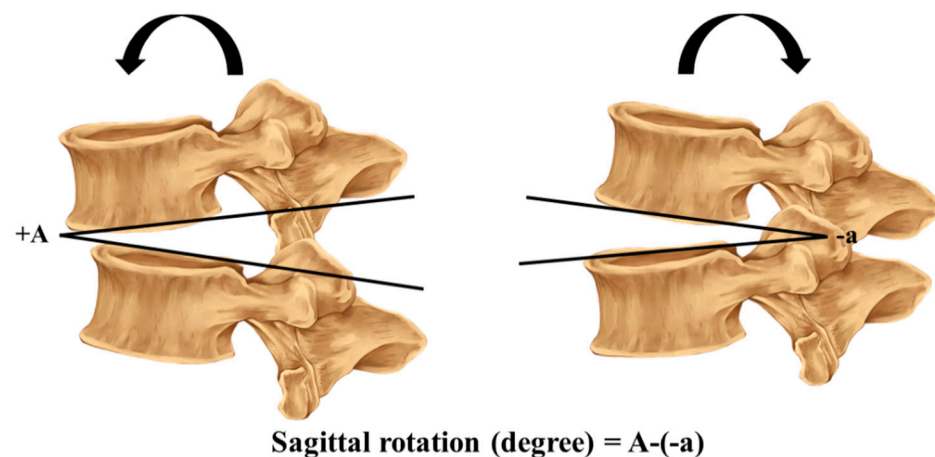

Sagittal rotation (degree) = A-(-a)

Figure 1. Sagittal rotation: a baseline is drawn passing the anterior and posterior endplate of the upper and lower vertebrae where the difference between the flexion and extension radiograph is measured and calculated.

The measurement of sagittal translation and rotation motion of each lumbar segment level from L1 to S1 was compared with ranges set for diagnosing STLI. Values for STLI were defined as: translation range from 1.9 to 4.5 mm at L1/L2, 2.4 to 4.5 mm at L2/L3, 2.7 to 4.5 mm at L3/4, 2.8 to 4.5 mm at L4/L5, and 0.5 to 4.5 mm at L5/S1, or a sagittal plane rotation range from 11.0° to 15° at L1/L2, 12.6° to 15° at L2/L3, 13.3° to 15° at L3/4, 14.7° to 20° at L4/L5, or 12.8° to 25° at L5/S1 [15,16]. The diagnosis of LI required showing either rotation or translation in two segments or rotation and translation in one segment to be classified as STLI [1]. This definition was used to reduce the false-positive rates from the X-ray measurement process [23].

A trained observer (researcher A.L.), who was blinded to other information, measured the translation and rotation of each lumbar segment in all participants using digitalized radiographs from a picture archive and communication (PACS) on a computer at Srinagarind Hospital, Khon Kaen, Thailand. The researcher (A.L.) was trained qualified to assess the radiographs by a radiologist with 30 years of experience. The evaluation practice of A.L.'s X-ray measurement consisted of using the program, pinpointing margins and spinal borders, and drawing the measurement line. The measurement process was practiced until

A.L.'s accuracy was rated as satisfactory by the radiologist. Next, A.L. measured each level of the lumbar spine three times. The mean of each of the three measurements was compared with the STLI diagnostic criteria. The intra-rater reliability of X-ray measures was assessed based on the radiographs of 10 participants selected at random. The within researcher ICC (A.L.), measured three times, was 0.998 (95%CI: 0.994–0.999) in translation and 0.994 (95%CI: 0.982–0.998) in rotation. The standard error of measurement (SEM) was 0.025 for translation and 0.058 for rotation. These were a lesser variation than the X-ray measurement [33].
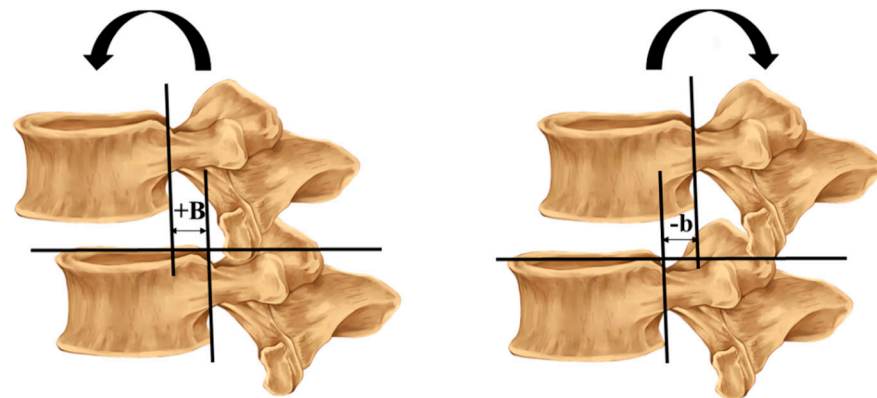
Sagittal translation (mm) = B-(-b)

Figure 2. Sagittal translation: a horizontal line is drawn passing the superior endplate of the lower vertebra. Two vertical lines are drawn passing the posterior edge of the upper vertebra and lower vertebra. The distance between the two vertical lines is considered during flexion and extension, and the difference between the two distances from flexion and extension is used in the formula to calculate the segmental translation.

2.4.2. Screening Tool

The specific lumbar instability screening tool had 14 questions and was written in English (Table 1) [23]. This tool was translated and tested for content validity, criteria-related validity, and rater reliability in relation to lumbar instability as reported in previous studies [23,26]. The possible total questionnaire scores ranged from 0 (not correlated with instability) to 14 (strongly correlated with instability). The questions relate to participants' pain characteristics, positional alteration, muscle spasms, and injury history.

2.5. Measurement Procedure

The 135 participants, all diagnosed with CLBP, were split into two groups: those with and without STLI based on X-ray findings. Data were collected from March 2019 through July 2019. The participants were assessed at one visit. On that day, participants signed an informed consent form before starting the study and were evaluated for LBP symptoms. Researcher R.P. asked participants for their demographic information: age, gender, BMI, duration of low back pain, pain scale rating, and smoking history, and then the 14 screening tool questions. Then, participants were evaluated by an orthopedic doctor who ordered an X-ray assessment. X-rays were taken in the full lateral flexion and extension positions, and were performed by a radiologist. The X-ray images were measured by the trained observer (A.L.) after data collection was completed. A.L. was blinded to all other information about the patients.

2.6. Statistical Analyses

The data were analyzed and grouped based on participants with and without STLI. Descriptive statistics were used, involving calculations of the mean, standard deviation, and percentage. Significance was set at a *p*-value of less than 0.05 when comparing between

groups. Intra-observer reliability was measured using the intraclass correlation coefficient (ICC) for the radiographic measurements.

The receiver operating characteristic (ROC) curve was used to determine the possible cut-off score of lumbar instability screening. Sensitivity, specificity, positive likelihood ratio (LR+), and negative likelihood ratio (LR-) for each cut-off score were calculated. The cut-off score that reached the maximum of sensitivity was taken as the maximum score. The area under the ROC curve (AUG) was used to evaluate the discriminatory ability of the 14 items of the screening tool. Statistical analysis was conducted using STATA ver. 10.0 (StataCorp, College Station, TX, USA).

Table 1. Lumbar instability screening tool.

Question 14 items	Yes (1)	No (0)
1. Patient reports his/her back has collapsed.		
2. Patient frequently self-manipulates to decrease their symptoms.		
3. Patient's back pain symptoms alternate periodically.		
4. Patient has a history of complaints of stiffness and sudden back pain when twisting or bending their back.		
5. Patient's back pain has been provoked by changing posture, for example standing up from sitting, etc.		
6. Patient has increased back pain when returning to upright after forward bending.		
7. Sudden or minor movements increase patient's back pain.		
8. Patient gets worse when sitting on a chair without a backrest and gets better when sitting on a chair with backrest.		
9. Patient reports being in a static posture for a long time has an effect on their back problem.		
10. Patient's back pain is worsening.		
11. Patient wears a brace or corset to temporarily alleviate back pain.		
12. Patient with back problems regularly experiences muscle spasms.		
13. Patient avoids or hesitates to move when they have back symptoms.		
14. Patient has a past history of back injury.		
Total score		

3. Results

3.1. Participant Characteristics

Of the 135 participants recruited, 113 participants (83.70%) had STLI. The mean age of all the participants was 35.58 ± 12.02 years. The participants' gender was 60.74% female. The average age of the participant groups with STLI and without STLI was 35.60 ± 12.46 and 35.45 ± 9.70 years old, respectively. All the continuous data were similar between the groups ($p > 0.05$), as shown in Table 2.

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Table 2. Demographic characteristics of participants.

Variable	Total (*n* = 135)	With STLI (*n* = 113)	Without STLI (*n* = 22)	*p*-Value
Age (years)	35.58 ± 12.02	35.60 ± 12.46	35.45 ± 9.70	0.95
Gender (%)				
Male	53 (39.26)	45 (39.82)	8 (36.36)	0.82
Female	82 (60.74)	68 (60.18)	14 (63.64)	
BMI (kg/m^2)	22.16 ± 2.10	22.29 ± 2.10	21.48 ± 2.04	0.10
Duration of current symptoms (months)	27.33 ± 27.07	26.40 ± 27.54	32.14 ± 24.57	0.37
NRS (pain)	4.63 ± 0.94	4.57 ± 0.88	4.95 ± 1.21	0.17
Smoking history (%)				
Yes	12 (8.89)	10 (8.85)	2 (9.09)	1.00
No	123 (91.11)	103 (91.15)	20 (90.91)	

Note: STLI: sub-threshold level of lumbar instability; BMI: body mass index; NRS: numeric rating scale.

3.2. The Screening Tool-Specific STLI Cut-Off Scores

The current study showed that the cut-off score for identifying STLI requires a total of at least six positive responses of a possible score of 14 from the screening tool-specific questions. The sensitivity, specificity, positive likelihood ratio, and negative likelihood ratio were 99.12%, 18.18%, 1.21, and 0.05, respectively, as shown in Table 3. The high sensitivity indicates the potential screening value because the measure rarely misses subjects who have the condition [34]. The area under the ROC curve was 0.73, reflecting sufficient diagnostic accuracy [35].

Table 3. The screening tool-specific STLI cut-off scores.

Cut-Off Value	Sensitivity (%)	Specificity (%)	LR+	LR−	AUG (95%CI)
≥5	100.00	0.00	1.00		
≥6	99.12	18.18	1.21	0.05	
≥7	90.27	31.82	1.32	0.31	
≥8	69.91	68.18	2.20	0.44	
≥9	46.02	72.73	1.69	0.74	0.73 (0.61–0.84)
≥10	31.86	95.45	7.01	0.71	
≥11	17.70	100.00		0.82	
≥12	5.31	100.00		0.95	
≥13	2.65	100.00		0.97	
≥14	0.88	100.00		0.99	
14	0.00	100.00		1.00	

4. Discussion

The impairment or dysfunction of the active, passive, or neural control subsystems in CLBP patients causes LI. Delayed detection of patients with LI can lead to more structural degeneration, which is challenging to improve with conservative treatment. The early-stage detection of LI by physical therapists may help the patient by preventing further structural damage early on; for example, exercise stabilization, which focuses on deep trunk muscle training, can improve or delay the development of lumbar instability [36–38]. In the present study, a subjective questionnaire cut-off score for identifying STLI was found to be 6/14.

The Delphi survey results from Cook et al. (2006) listed 14 screening questions to determine the clinical lumbar instability in the CLBP participants [21]. The current study results showed that at least six positive answers to the fourteen listed lumbar instability questions among the CLBP participants led to a diagnosis of STLI. This result was similar to Kumar (2018) and Puntumetakul et al. (2014), who selected 7/13 positive responses to similar screening questions that could act as the criteria for diagnosing lumbar segmental instability [9,24]. However, when compared with the study by Chatprem et al. in 2020, our result was lower than their cutoff score (7/14) [23]. This may be because the participants in this study had less translation and rotation (STLI) than those in their (LI) study.

In the current study, three key symptoms were frequently reported by the participants with CLBP, that led to a positive diagnosis of STLI: (1) back pain alternating occasionally (97.35%); (2) worsening pain when sitting on a chair without a backrest and less pain when sitting on a chair with a backrest (96.46%); and (3) increasing back pain when maintaining prolonged static postures (95.58%) (Figure 3). The symptom of back pain alternating periodically may arise from the spinal unit moving together while the passive subsystem is in fixed alignment. During spinal movement, the passive subsystem is unable to restrain shear forces that arise from muscle contraction and gravity. A possible reason underlying this symptom is that one or more of the spinal subsystems that cause instability may be dysfunctional due to injury or degeneration [6]. In the sitting position, many people experience musculoskeletal discomfort, principally in the lower back and buttock areas, where the discomfort increases significantly during prolonged sitting [39]. The responses in the current study differed from some of those reported in a farming population by Puntumetakul et al. (2014) [9]. The responses in that study consisted of: (1) frequent episodes of muscle spasm (93%); (2) worsening symptoms with sustained postures (90%); and (3) frequent episodes of symptoms (88%). The differences between these two studies included: the participant occupation, number and age of participants, and use of different criteria to determine the presence of lumbar instability (clinical symptoms in the former study but X-ray evaluation in the current study). Nevertheless, the characteristic of worsening symptoms with sustained postures was the same in both studies.

An optimal cut-off point for LI patients of at least 7 of 14 scores was reported by Chatprem et al. in 2020 [23]. The 7/14 score was based on the maximum summation of sensitivity and specificity, which differed by one point from the current study in choosing the highest sensitivity for screening [34]. However, they reported three items as receiving 100% positive responses in LI, and two out of their three fit with the top responses in our study. These symptoms were prolonged sitting and sustained posture. The possible reasons for the lower score in the STLI participants may be twofold. First, the number of lumbar instability participants (STLI, 113 or 83.70%) was higher in the current study than the number of patients with LI in Chatprem's study. Second, the STLI criteria in the current study required less translation and rotation compared with LI. Less severe LI may lead to a lower score when comparing LI and STLI. However, considering their study in terms of the highest sensitivity for screening, a score of at least 7 of 14 remains the cut-off point.

Our participant demographic characteristics, particularly gender, have no difference between those with chronic low back pain with STLI and without STLI. Therefore, this minimizes other factors that may influence our results. The current study demonstrated that a screening tool specific for LI is beneficial in accurately identifying STLI among CLBP participants. In a clinical setting, choosing the cut-off scores of at least 6/14 positive points can be used to screen patients with CLBP for STLI responses. Interestingly, patients with positive STLI also had positive results on items 3, 8, and 9 of the screening tool questionnaire. Moreover, the effect size was large [40].

This study has useful implications for clinicians; however, there are some limitations. First, the participants experiencing pain while the flexion–extension radiographs were taken may have shown a lower range of instability than they actually had. Second, the sample size was small. Third, our participants had a wide age range, meaning they may have had a varied state of disc degeneration. Fourth, there may have been an overlap with

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the upper range of normal asymptomatic participants with those in the STLI group. Future studies could consider using a magnetic resonance image assessment to determine the stage of disc degeneration, to help improve the strength of the results.
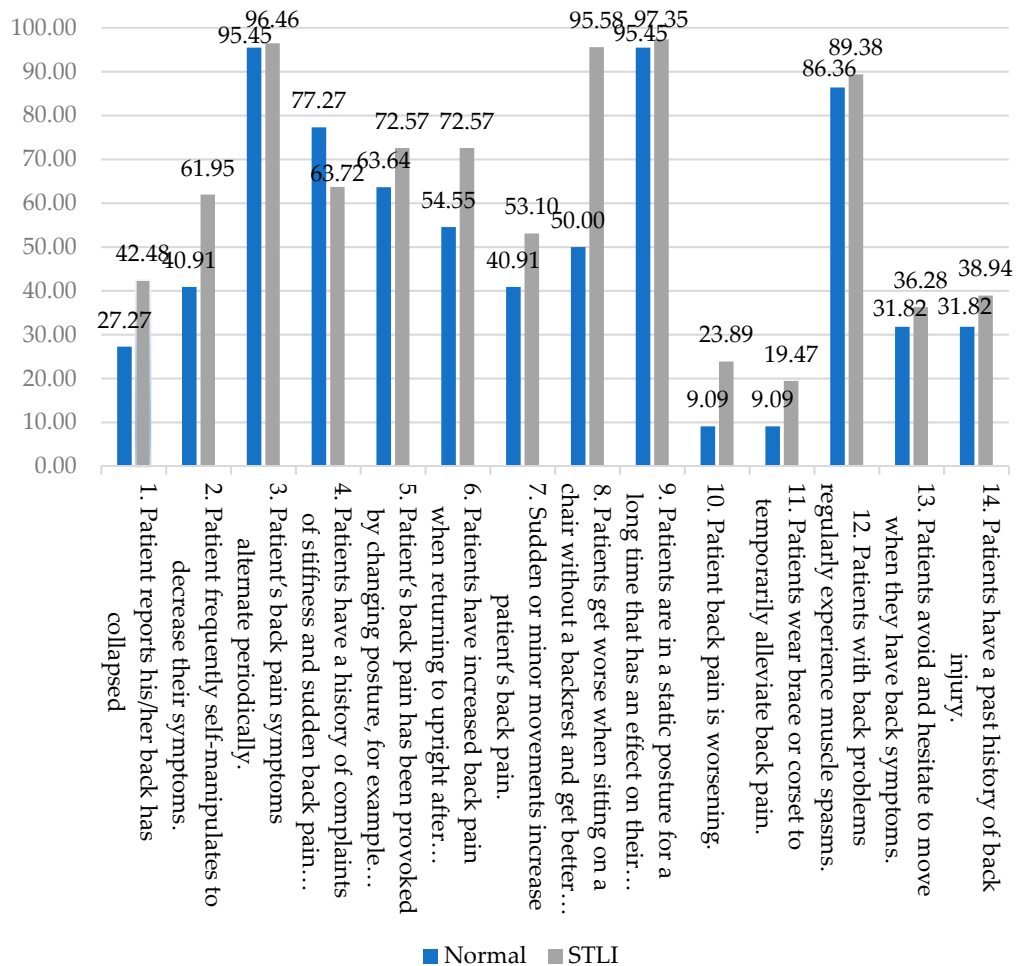

Figure 3. Comparison of the percentage of positive answers to the lumbar instability screening tool questions in chronic low back pain patients with and without the sub-threshold level of lumbar instability.

5. Conclusions

The findings of the current study revealed useful information for identifying STLI using a specific screening tool for patients with LI. Although this screening tool is effective for assessing the lumbar spinal instability in an outpatient clinic without the need for sophisticated and expensive equipment, high specificity tests, such as the passive lumbar extension test (PLE), are still recommended to confirm the diagnosis of STLI.

Conflicts of Interest: The authors declare no conflict of interest.

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