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Original article

Intra-rater and inter-rater reliability and minimum detectable change of visual analog scale and digital goniometer in patients with subacute unilateral lateral ankle sprain

Thongchai Suksri [a, b], Chitanongk Gaogasigam [a], Sujitra Boonyong [a,*]

[a] *Human Movement Performance Enhancement Research Unit, Department of Physical Therapy, Faculty of Allied Health Sciences, Chulalongkorn University, Bangkok, Thailand*
[b] *Department of Physical therapy, Medical Division of Armed Forces Academies Preparatory School, Nakhon – Nayok Province, Thailand*

Background: Patients with subacute unilateral lateral ankle sprain commonly experience pain and limited range of motion (ROM). Measurement reliability should be investigated before assessing treatment effectiveness.
Objective: To determine both intra-rater and inter-rater reliability and minimal detectable change (MDC) of visual analog scale (VAS) and digital goniometer in patients with subacute unilateral lateral ankle sprain.
Methods: Ten subjects (7 men, 3 women; aged 29.90 ± 12.81 years) with subacute unilateral lateral ankle sprain were recruited. Two investigators measured pain intensity and ROM using VAS and a digital goniometer, respectively, with a 30-minute break between measurements. The same protocol was repeated on the next day. Intra-rater and inter-rater reliability measurements were analyzed to determine intraclass correlation coefficients (ICC).
Results: Intra-rater and inter-rater reliability of VAS showed excellent reliability (ICC ranged from 0.97 to 0.99), whereas ankle and subtalar joint ROM showed good to excellent reliability (ICC ranged from 0.76 to 0.97). The MDC of VAS was 5.49 mm, while MDC of the ankle and subtalar joint ROMs ranged from 2.97º to 7.97º, respectively.
Conclusion: In individuals with subacute unilateral lateral ankle sprain, the VAS and digital goniometer demonstrated good to excellent reliability in pain intensity and ankle and subtalar joint ROM. Preliminary MDC data can be used to assess treatment efficacy.

Keywords: Ankle sprain, pain, ankle and subtalar joint, range of motion, reliability.

Ankle sprains result from damage caused by stretching the ligaments that support the ankles beyond their elastic limit. One in 10,000 people is diagnosed with an ankle sprain every hour. [1] Lateral ankle sprains frequently occur (85.0% of all cases), involving injury to the anterior talofibular ligament (ATFL) in about 70.0% of cases.[2] Patients with lateral ankle sprain visit the physical therapy department on average 2.3 days after injury. [3] The onset of the subacute phase is considered to develop between 4 and 14 days after injury.[4] Patients commonly complain of pain with limited range of ankle motion, while recurrence of ankle sprains often occurs.[4] Reliable tools are required to accurately assess and follow- up the symptoms of patients with ankle strains.

The reliability of the measurement tools should be determined before assessments are made in clinical practices or research.[5] Intraclass correlation coefficients (ICC) are used as one measure of the reliability of experimental research.[6] These involve a variety of methodological issues including sensitivity to assumptions regarding normality and homogeneous variance.[7] ICC have been widely used to evaluate intra-rater, inter-rater or test-retest reliability.[8] Intra-rater reliability is the degree of agreement

***Correspondence to: Sujitra Boonyong,** Department of Physical Therapy, Faculty of Allied Health Sciences, Chulalongkorn University, Bangkok 10330, Thailand.
E-mail: Sujitra.B@Chula.ac.th
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among repeated tests performed by an individual rater, and usually reported using the ICC between two occasions of the individual rater.[8] Inter-rater reliability is a measure of the reliability between two different raters when measuring the same participants. Excellent inter-rater reliability presents low standard error of measurement (SEM) values.[9] The SEM presents the error in the same units as the original measurement [10] to estimate minimal detectable change (MDC).[11] MDC is defined as the smallest amount of change that is higher than the SEM.[12] Therefore, MDC can detect statistically significant and clinically important improvements following physical therapy intervention. [8]

The severity of pain is represented by pain intensity and can be used to evaluate the effectiveness of the treatment intervention. Outcome measurements of pain intensity include the visual analog scale (VAS), verbal rating scales, numerical rating scales and graphical scales.[13] The VAS has been widely used in various musculoskeletal conditions in adult populations, with excellent reliability.[14] The VAS can be rapidly and easily completed by respondents, and shows high sensitivity to change.[15]

The range of motion (ROM) of the ankle and subtalar joints can be measured by a universal goniometer and a digital goniometer. A previous study reported moderate inter-rater reliability (ICC = 0.46 to 0.69) when using a universal goniometer and digital goniometer to measure shoulder and elbow joint ROMs. The study also reported that intra-rater reliability of the digital goniometer (ICC = 0.65 to 0.90) was higher than the universal goniometer (ICC = 0.34 to 0.81). The authors recommended using a digital goniometer to measure ROM because this reduced the reading errors, was easy to use and reduced training time. [16] However, no studies have assessed the reliability and MDC of the VAS for ankle and subtalar joint ROMs in patients with subacute unilateral lateral ankle sprain.

Therefore, the purpose of this study was to determine the reliability and MDC of the VAS for ankle and subtalar joint ROMs measured using a digital goniometer in patients with subacute unilateral lateral ankle sprain.

Materials and methods

Study design

A test-retest research design was used to determine the reliability and MDC of the VAS and digital goniometer measurements in patients with subacute unilateral lateral ankle sprain. Subjects were recruited from local physical therapy clinics between April and June 2020. The study protocols have been approved by the Institutional Ethics Committee (no. 079/2020), and all subjects were informed about the purposes of the study and testing protocol before providing written informed consent.

Subjects

Ten subjects were diagnosed by physician with subacute unilateral lateral ankle sprain (grade 1 - 2) at least 4 days and up to 14 days after injury.[17] Patients with lateral ankle sprain grade 1 present no loss of function, with decrease of ankle ROM at 5 degrees or less and swelling 0.5 cm or less, whereas grade 2 patients show some loss of function, tenderness point, decrease of ankle ROM of more than 5 degrees but less than 10 degrees and swelling more than 0.5 cm but less than 2 cm. [3] All subjects experienced pain during weight-bearing of at least 30 mm of 100 mm of VAS and ability to use a VAS for pain. Exclusion criteria were redness and warmth at the ankle sprain area.

The sample size was calculated by the formula for ICC, [18] with minimal reliability accepted (P0) at 0.50, expected reliability (P1) at 0.90, significance level at 0.05 and desired power at 0.80. The estimated required sample size was at least 9 subjects.

Procedures

Two investigators with three and ten years of experience as physical therapists were blinded and involved in this study. One physical therapist read and recorded the goniometer measurements. Both investigators underwent standardized training before data collection by measuring pain intensity and ankle dorsiflexion, plantarflexion, eversion and inversion ROM. Each subject was assessed for pain intensity and ROM by the two investigators on the same day, with a 30-minute interval between each investigation. A similar protocol was followed on the next day. For pain intensity assessment, subjects were asked to take two steps down a ladder, alternately using the affected side as the leading limb. Pain that occurred during weight-bearing was measured by VAS. The VAS in this study was a straight horizontal 100 mm line, where 100 mm represented the most intense level of pain and 0 mm gave no pain. [13, 14]

Dorsiflexion, plantar flexion, eversion and inversion ROM were randomly measured with a calibrated digital goniometer (2-in-1 Digital Angle Ruler, OEM, China). For dorsiflexion and plantar flexion, the subjects were placed in a supine position with a foam roll support under the knee joint. The foot was set at zero degrees of inversion and eversion and the lower leg was stabilized to prevent knee and hip rotation. The goniometer axis was placed inferior to the lateral malleolus, and the stationary arm was kept parallel to the longitudinal axis of the fibula. The movable arm was kept parallel to the longitudinal axis of the fifth metatarsal. The subjects were asked to perform maximal ankle dorsiflexion and plantarflexion within pain limitation. For eversion and inversion, subjects were asked to sit on the side of the bed with 90-degree knee flexion. The goniometer axis was placed over the anterior aspect of the ankle at the midpoint between the malleolus, and the stationary arm was kept anterior to the midline of the lower leg, using the tibia tuberosity for reference. The movable arm was kept anterior to the midline of the second metatarsal. [19] The subjects were asked to perform maximal subtalar joint eversion and inversion within pain limitation. Patients were allowed to rest for one minute between each direction. Each measurement was recorded for three trials, with the averaged value used for data analysis.

Statistical analysis

All data were analyzed using the SPSS program version 22.0 for Windows. Both intra-rater and inter-rater reliabilities were calculated by the ICC. The intra-rater reliabilities were used in the $ICC_{(3, 1)}$ model, whereas inter-rater reliability was used in the $ICC_{(2, 1)}$ model for measurements of pain intensity and ROM. $P < 0.05$ was considered to indicate statistical significance.

ICC values less than 0.50 indicated poor reliability, 0.50 to 0.75 indicated moderate reliability, 0.75 to 0.90 indicated good reliability and more than 0.90 indicated excellent reliability. [5]

The standard error of measurement (SEM) was used to present the error in units of measurements and calculated as standard deviation (SD) pooled variance × √1-ICC.[20] The minimal detectable change (MDC) is the minimal change that falls outside the measurement error of an instrument used to measure a symptom. [21] MDC was calculated at 1.96 × SEM or 2.77 × SEM. [22]

Results

Table 1. Demographic data and baseline clinical characteristics.

Demographic and clinical characteristics	Subjects (n = 10)
Gender	
Male [n (%)]	7 (70.00)
Female [n (%)]	3 (30.00)
Age (years) [a]	29.90 ± 12.81
Height (cm) [a]	169.00 ± 7.03
Weight (kg) [a]	65.00 ± 5.85
BMI (kg/m^2) [a]	22.82 ± 2.52
Duration of injury (days) [a]	7.80 ± 3.52
Side of injury	
Right [n (%)]	6 (60.00)
Left (n (%))	4 (40.0)
Severity of injury	
Grade 1 [n (%)]	1 (10.00)
Grade 2 [n (%)]	9 (90.00)
VAS scores	
Resting (mm)	9.00 ± 11.00
Weight-bearing (mm) [a]	43.00 ± 14.18

[a] = Mean ± SD; VAS = visual analog scale; BMI = body mass index.

Ten participants (7 men, 3 women; average age 29.90 ± 12.81 years) diagnosed with subacute unilateral lateral ankle sprain were enrolled in this study. Their demographics and clinical characteristic data were recorded as mean value, standard deviation (SD) and percent (Table 1).

Both investigators showed excellent intra-rater reliability for the measurement of pain intensity, whereas ankle and subtalar joint ROM presented good to excellent reliability. The $ICC_{(3, 1)}$ values of pain intensity ranged from 0.986 to 0.994, whereas the $ICC_{(3, 1)}$ values of ROMs ranged from 0.843 to 0.977, as shown in Table 2. Inter-rater reliabilities for pain intensity showed excellent reliability, with ankle and subtalar joint ROMs giving good to excellent reliability. The $ICC_{(2, 1)}$ values of pain intensity ranged from 0.97 to 0.98, whereas the $ICC_{(2, 1)}$ values of ROMs ranged from 0.755 to 0.905, as shown in Table 3. The VAS determined the SEM and MDC as 1.58 mm and 5.49 mm, respectively. The ankle and subtalar joint ROMs showed that the SEM and MDC ranged from 1.07° to 2.88° and from 2.97° to 7.97°, respectively (Table 4).

Table 2. Intraclass correlation coefficients (ICC) of intra-rater reliability $ICC_{(3, 1)}$ for two outcome measurements by VAS and digital goniometer.

Outcome measurements	Intra-rater reliability			
	Rater I	*P*-value	Rater II	*P*-value
Pain intensity (VAS)	0.986	0.001	0.994	0.001
Ankle dorsiflexion	0.843	0.007	0.977	0.001
Ankle plantarflexion	0.900	0.001	0.928	0.001
Ankle eversion	0.851	0.005	0.886	0.002
Ankle inversion	0.944	0.001	0.869	0.003

Table 3. Intraclass correlation coefficients (ICC) of inter-rater reliability $ICC_{(2, 1)}$ for outcome measurements on two occasions by VAS and digital goniometer.

Variables	Trial 1				Trial 2			
	Rater 1	Rater 2	$ICC_{(2,1)}$	*P*-value	Rater 1	Rater 2	$ICC_{(2,1)}$	*P*-value
Pain intensity								
VAS (mm)	42.15 ± 8.65	41.95 ± 8.29	0.978	0.001	41.25 ± 8.81	41.55 ± 7.32	0.974	0.001
Range of motion								
Dorsiflexion (°)	11.42 ± 5.55	12.40 ± 6.26	0.895	0.001	10.73 ± 4.35	12.36 ± 5.92	0.755	0.024
Plantarflexion (°)	34.48 ± 13.97	33.35 ± 11.72	0.781	0.017	35.23 ± 12.92	33.64 ± 12.54	0.894	0.001
Eversion (°)	9.24 ± 5.41	11.54 ± 3.90	0.783	0.016	10.39 ± 4.64	12.54 ± 4.75	0.905	0.001
In version (°)	20.88 ± 5.94	19.43 ± 8.30	0.851	0.005	21.35 ± 7.56	18.31 ± 7.63	0.898	0.001

Table 4. Standard error of measurement (SEM) and minimal detectable change (MDC) of visual analog scale and digital goniometer.

Outcome measurements	SEM	MDC
Pain intensity	1.58	5.49
Ankle dorsiflexion	1.07	2.97
Ankle plantarflexion	2.81	7.79
Ankle eversion	1.24	3.43
Ankle inversion	2.88	7.97

Discussion

This study investigated intra-rater and inter-rater reliability of pain intensity measurements during weight-bearing and active ROMs of the ankle and subtalar joints in patients diagnosed with subacute unilateral lateral ankle sprain. Results reported excellent intra-rater and inter-rater reliability of VAS, and good to excellent intra-rater and inter-rater reliability of the digital goniometer. The study also measured minimal detectable change (MDC) when using both the VAS and digital goniometer.

Intra-rater reliability of the VAS was excellent (ICC ranged from 0.98 to 0.99). A previous study of the intra-rater reliability for VAS of pain limitation measurements in patients in other areas also reported good reliability (ICC = 0.90).[23] This study was conducted with a one-day interval between sessions, similar to the current study. A previous study of inter-rater reliability for VAS measurements in patients with knee osteoarthritis also reported excellent results (ICC ranged from 0.96 to 0.98).[24] This range of ICC values was similar to our study (ICC = 0.97). Moreover, the VAS in our study had an MDC of 5.49 mm. A previous study reported that the VAS in patients with knee osteoarthritis had a lower MDC value of = 0.08 mm.[24] Hence, the MDC was specific to each condition.

In our study, ankle dorsiflexion ROM measured by a digital goniometer showed good to excellent intra-rater and inter-rater reliability. A previous study assessing intra-rater reliability of a digital goniometer in a normal population presented that ankle dorsiflexion showed excellent reliability (ICC ranged from 0.96 to 0.97) [25] when performed in a weight-bearing position to reflect available ROMs during functional abilities such as walking and running. [25] Ankle dorsiflexion ROMs measured during either weight or non-weight bearing condition yielded high intra-rater reliability. Therefore, ankle dorsiflexion ROM did not require measurement in a weight-bearing position, especially in patients with ankle pain.

Ankle plantar flexion ROM, as well as subtalar joint inversion and eversion ROM were measured by a digital goniometer and demonstrated good to excellent intra-rater and inter-rater reliability. These findings were consistent with earlier universal goniometer research. A study of plantarflexion ROM showed good to excellent intra-rater and inter-rater reliability (ICC ranged from 0.79 to 0.97). [26] Furthermore, previous research of subtalar joint inversion and eversion ROM in patients with various ankle conditions reported good to excellent intra-rater reliability (ICC ranged from 0.91 to 0.96 and 0.82 to 0.93, respectively) and moderate inter-rater reliability (ICC 0.73 and 0.62, respectively).[27] Our study recorded high intra- and inter-rater reliability of subtalar joint ROM since subtalar joint orientation and bony landmarks for measurement were both considered. In a non-weight bearing position, the ankle was in plantar flexion. When measuring subtalar joint inversion and eversion, movements were performed in combination with plantarflexion and adduction, and dorsiflexion and abduction, respectively. Therefore, the investigator should accurately align the goniometry axis to cover the entire range of the subtalar joint axis. [27] Our study evaluated the second measurement one day apart, related to physical therapy treatment follow up commonly conducted one or two days apart. Pain intensity in patients with subacute unilateral lateral ankle sprain did not change in one day without treatment intervention. [28] Investigators also advised all participants to avoid putting weight on the affected foot or any activity that could aggravate the symptoms.

Our study reported excellent intra-rater and inter-rater reliability of VAS, with good to excellent intra-rater and inter-rater reliability of the digital goniometer, and also provided MDC in patients with subacute unilateral lateral ankle sprain. Results gave MDC of the VAS during weight-bearing for ankle dorsiflexion, ankle plantarflexion, subtalar joint eversion and inversion ROM at 2.97º, 7.79º, 3.43º and 7.79º, respectively. [25- 27] MDC values in this study were lowest for scores of VAS and digital goniometer used to measure pain intensity and ROM, and not due to measurement error. The results suggested that the MDC can be used as a preliminary assessment for patients with subacute unilateral lateral ankle sprain.

One limitation of this study was that a minimal clinically important difference (MCID) value was not determined. Future studies should investigated the MCID value, and follow up improvements in patients with subacute unilateral lateral ankle sprain. Our findings can increase the confidence of clinicians when using the VAS and a digital goniometer to evaluate the treatment of patients with subacute unilateral lateral ankle sprain.

Conclusions

Intra-rater and inter-rater reliability of the VAS and digital goniometer in patients with subacute

unilateral lateral ankle sprain were good to excellent. The MDC of pain intensity and ROM measured by the VAS and a digital goniometer can be used to assess treatment efficacy for patients suffering from subacute unilateral lateral ankle sprain.

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Conflict of interest

The authors, hereby, declare no conflict of interest.

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