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ORIGINAL RESEARCH

Reproducibility and construct validity of three non-invasive instruments for assessing the trunk range of motion in patients with low back pain

Reprodutibilidade e validade do construto de três instrumentos não invasivos para a avaliação da amplitude de movimento da coluna em pacientes com dor lombar

Reproducibilidad y validad del constructo de tres instrumentos no invasivos para evaluar la amplitud de movimiento de la columna en pacientes con dolor lumbar

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ABSTRACT | Although there is a wide variety of methods and instruments aiming to assess the trunk range of motion, there is uncertainty regarding their construct validity and reproducibility. The objective of this study was to verify the construct validity and intra and inter-rater reproducibility of the goniometer, inclinometer and electrogoniometer in measuring the trunk range of motion in patients with history of low back pain. The measurement properties of reliability, agreement and construct validity were tested in 58 patients with low back pain using a test-retest design at baseline and after 24 to72 hours. All instruments showed good construct validity (r>0.60) as well as good levels of intra and inter-rater reliability with measurement errors ranging from 2.83 to 16.42 degrees. Among the assessed movements, the inclinometer, goniometer and electrogoniometer instruments can be considered as having good levels of construct validity and reproducibility for the assessment of trunk range of motion in patients with low back pain.

Keywords | Low Back Pain; Reproducibility of Results.

RESUMO | Apesar da grande variabilidade de métodos e instrumentos disponíveis para avaliar a amplitude de movimento da coluna, são escassos os métodos quantitativos precisos de mensuração. O objetivo do estudo foi verificar a reprodutibilidade intra e interexaminadores e a validade de construto entre as medidas de amplitude de movimento da coluna em pacientes com dor lombar, obtidas com os instrumentos goniômetro, inclinômetro e eletrogoniômetro. A reprodutibilidade e a validade do construto dos instrumentos foram testadas em 58 pacientes com dor lombar num delineamento de teste-reteste, na linha de base e após 24 a 72 horas. Todos os instrumentos apresentaram boa correlação entre si (r>0,60), refletindo boa validade do construto, e obtiveram bons níveis de confiabilidades inter e intraexaminadores. Entre todos os movimentos avaliados, o inclinômetro apresentou um erro absoluto inter e intraexaminador que variou de 6,20 a 7,52 e 6,75 a 11,89 graus respectivamente; o goniômetro mostrou um erro de 3,15 a 7,85 e 2,83 a 8,06 graus, respectivamente; e o eletrogoniômetro, entre 3,27 a 16,42 e 2,72 a 8,06 graus, respectivamente. Dessa forma, todos os instrumentos utilizados podem ser considerados com bons níveis de validade do construto e reprodutíveis para avaliação da amplitude de movimento em pacientes com dor lombar.

Descritores | Dor Lombar; Reprodutibilidade dos Testes.

RESUMEN | Mismo con una gran variabilidad de métodos e instrumentos disponibles para evaluar la amplitud de movimiento de la columna, son raros los métodos cuantitativos precisos de mensuración. El objetivo de eso estudio fue verificar la reproductibilidad intra- e interexaminadores y validad del constructo entre medidas de amplitud de movimiento de la columna en pacientes

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con dolor en la región lumbar, las cuales fueron obtenidas con los instrumentos goniómetro, inclinómetro y electrogoniómetro. La reproductibilidad y validad del constructo de instrumentos fueron testadas en 58 pacientes con dolor en la región lumbar en un diseño de test y re-test, en la línea de base y después de 24 a 72 horas. Todos los instrumentos presentaron buena correlación entre sí (r>0,60), lo que refleje buena validad del constructo, y tuvieron buenos niveles de confiabilidades inter- e intra-examinadores. Entre todos los movimientos evaluados, el inclinómetro presentó un error absoluto inter- e intra-examinador que varió del 6,20 al 7,52 y 6,75 al 11,89 grados; y lo goniómetro mostró uno del 15 al 7,85 y 2,83 al 8,06 grados; y lo electrogoniómetro con uno entre 3,27 al 16,42 y 2,72 al 8,06 grados. Por lo tanto, los instrumentos aplicados pueden ser considerados con buenos niveles de validad del constructo y reproducibles para evaluación de la amplitud de movimiento en pacientes con dolor en la región lumbar.

Palabras clave | Dolor de la Región Lumbar; Reproducibilidad de Resultados.

INTRODUCTION

Low back pain (LBP) is a major health problem associated with disability and work absenteeism[1]. LBP is a very prevalent condition, which requires high cost for treatment[2]. During the clinical examination of patients with low back pain, one of the recommendations is the evaluation of range of movement (ROM) of the trunk[3]. Its measurement is used to facilitate the functional assessment as well as to analyze the evolution of the treatment of these patients[4]. There are several methods[3] that quantify ROM such as: observation[3,5], the Schober method[4,6], goniometer[3], electrogoniometers[3,7], inclinometer[4,8] and radiological analysis[9]. These methods vary in complexity of use and costs[3]. There are a small number of studies on the reproducibility of these instruments in patients with low back pain[10-12]. Most of the existing data deals with the measurement of ROM in healthy subjects[13-15] and, although providing important information regarding the normative values of the measures of ROM[16], they cannot be considered generalizable to patients with low back pain.

Therefore, this study aimed to: verify both reliability (relative error of measurement)[17] and agreement (absolute error of measurement)[17] intra- and inter raters of ROM measurements of the spine in patients with low back pain, obtained through the goniometer, inclinometer and electrogoniometers; and to measure the construct validity (correlation between measures that measure the same construct)[18] of these instruments.

METHODS

After approval by the Research Ethics Committee, 58 patients with history of low back pain were recruited. The sample size was based on the Guidelines of health-related questionnaires[18], that requires that at least 50 participants are needed to evaluate the reproducibility and construct validity. Eligible subjects should be aged between 18 and 80 years, of both sexes and with history of non-specific low back pain, (ie, pain between the 12th rib and the lower gluteal folds, with and without irradiation to the lower limbs, of mechanical origin)[1]. Participants were excluded if they had contraindications to physical exercise, underwent spine surgery, were pregnant, had serious spinal pathologies or cardiorespiratory diseases. The subjects were recruited from the waiting list of the Physiotherapy Clinic of the Universidade Cidade de São Paulo (UNICID). Previously, a pilot study with 10 subjects was conducted. Data from this pilot study were not incorporated into this study.

Procedures

Eligible patients were informed about the study objectives and procedures. Then the volunteers were instructed to sign the informed consent. We have used the following instruments: A questionnaire containing questions about socio-demographic and anthropometric data; Pain Numerical Rating Scale[19]; and the Roland Morris Disability Questionnaire[20]. After assessing the patients, we performed the ROM measurements for flexion, extension and lateral bending of the spine, using the goniometer, the electrogoniometer and the inclinometer.

Description of measurement instruments

The Pain Numerical Rating Scale [19] evaluates pain intensity through a 11-point scale, with 0 being classified as "no pain at all" and 10 "the worst pain possible"[19] in the last 7 days.

The Roland Morris Disability Questionnaire[21] is used to analyze the disability associated with back pain. It consists of 24 items that describe activities in which patients

may have difficulty in performing them due to low back pain. Higher scores mean high disability.

Goniometer

The goniometer[22] comprises a body (rotation axis) with two arms attached to it, one being fixed and the other movable. The measurement of the ROM is performed by direct reading of the angle between the axis of rotation at the end of the active ROM of the movement assessed. In this study, it was applied the goniometer of the manufacturer *Carci*® (Figure 1).

Inclinometer

The inclinometer[23] uses the gravity upon the pointers and fluid levels to evaluate ROM[23]. As a tool that does not contain joint vertices, but a self-adhesive strip (velcro) which is fixed in the joint of interest, it allows to isolate the various joint movements[24]. It was employed an inclinometer of the manufacturer *Fleximeter*®[24] (Figure 1).

Electrogoniometer

The goniometer[25] is an instrument consisted of a body (rotation axis) with two arms attached to it, being one fixed and the other movable. The measurement of ROM is performed by the electronic reading of the angle formed in the axis of rotation through the positioning of the fixed and mobile arms at the end of the ROM evaluated. It was used the electrogoniometer produced by *EMG Systems*® (Figure 1).

Data collection

Data collection was performed at two different times, by two evaluators. On the first day, both performed the measurements independently in order to verify the inter-rater reproducibility. On the second day (with a minimum interval of 24 hours), measurements were made only by the first evaluator to check the intra-rater reproducibility. In order to control a possible ordering bias, all movements were randomly selected. Before the start of each collection, the evaluator reported to the one that would be responsible for collecting the initial movement, so that she could position the patient and the instruments, as well as perform the calibration of the goniometer.

Stickers were set at specific anatomical points suggested by the manuals of the instruments, as follows: C7 and the midpoint between the two postero-superior iliac crest (to measure frontal plane movements) and the right side of the anterosuperior iliac crest and the axillary line (sagittal). The inclinometer was placed in the right axillary line at nipple height to measure the flexion and extension movements. To evaluate lateral bending, this instrument was placed in the posterior region of the midline of the body, at nipple height, directed to C7. The universal goniometer and the electrogoniometer were placed at the midpoint of the posterosuperior iliac crests for lateral bending movements. To measure the flexion and extension, the universal goniometer and the electrogoniometer were inserted into the right anterosuperior iliac crest (Figure 2). When patients reached the end of the ROM, the evaluator memorized the values obtained by the goniometer and inclinometer and gave a "can record" verbal command to a colleague who was processing the data on the computer.. Each movement was performed three times, and then the averaged was calculated.

Statistical analysis

Reproducibility is an umbrella term that encompasses two measurement properties, called reliability (relative measurement error) and agreement (absolute measurement

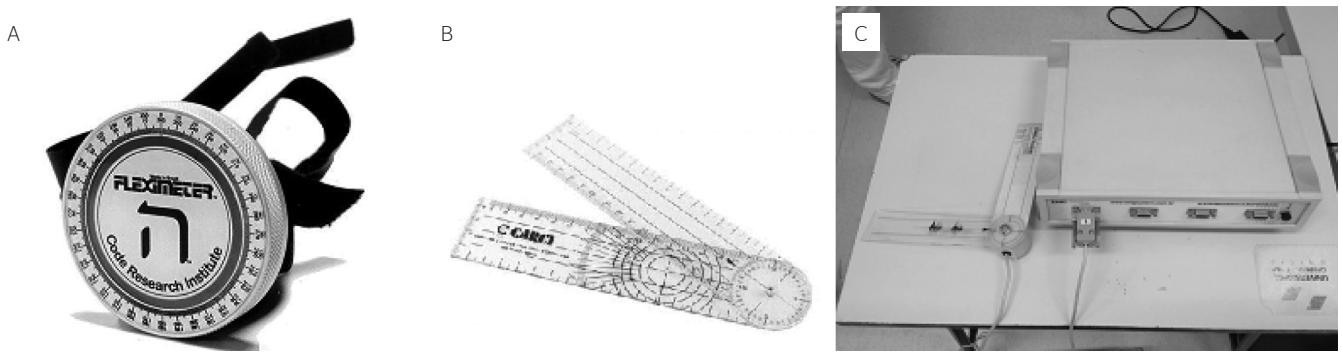

Figure 1. Instruments: (A) inclinometer; (B) goniometer; (C) electrogoniomete

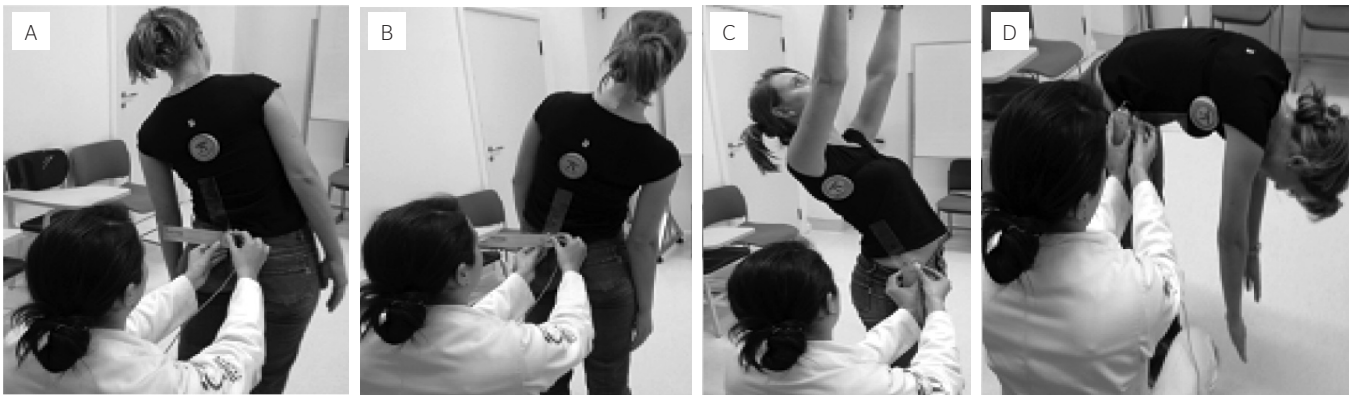

Figure 2. Positioning of the instruments: (A) bending to the left; (B) bending to the right; (C) extension and (D) flexion

error)[26]. Reliability was assessed by intraclass correlation coefficient (ICC, type 2,3), which was interpreted as follows: less than 0.40 indicates low reliability; between 0.40 and 0.75, moderate; between 0.75 and 0.90, substantial and greater than 0.90, excellent[26].

To evaluate the agreement, we used the standard error of measurement (SEM) and at minimum detectable change with 90% confidence (MDC90). The SEM was calculated by dividing the standard deviation of the differences and the square root of two. MDC90 (minimal change in which a score can be interpreted as real) was calculated using the formula MDC=1.645 x √2 x SEM. The smaller the value of SEM and of MDC90, the greater is the agreement[27]. We also used Bland and Altman plots. In this case, it was found that the observations of the examiners were contained within the "limits of agreement", which was established in 1.96 times the standard deviation of the observations[26].

The construct validity refers to the extent to which the values of a particular instrument correlate with other similar measures[26]. Construct validity was estimated using Pearson's correlation coefficients (r) between the instruments, provided that when $p<0.30$, it is considered poor; $0.30\leq r<0.60$, moderate; and $r\geq 0,60$, good[28]. For this analysis, we used the measures of the examiner 1 and was also performed a sensitive analysis, with the data from examiner 2.

RESULTS

Table 1 shows the demographic and clinical characteristics of the participants. Of the 58 patients initially recruited, eight did not attend to the retest.

Table 1. Clinical and demographic characteristics of the study patients at baseline (n=58)

Variables	
Gender	
Female	50 (86.20)
Age (years)	45.02 (18.25)
Duration of symptoms (months)*	36 (66)
Weight (kg)	70.21 (15.84)
Height (m)	1.62 (0.86)
Body Mass Index	
Normal	33 (60.3)
Overweight	11 (17.3)
Obese	14 (22.4)
Marital status	
Single	27 (46.6)
Married	24 (41.4)
Divorced	7 (12.0)
Education status	
Elementary school	14 (24.6)
High school	17 (29.8)
Higher education	26 (45.6)
Use of pain killers	34 (58.6)
Physical exercise	16 (27.6)
Smoker	13 (23.2)
Recent episode of low back pain	45 (77.6)
Pain intensity (0 to 10)	5.81 (2.65)
Disability (0 to 24)	9.47 (5.54)

The variables were expressed as numbers and percentages. Continuous variables are presented as mean and standard deviation. *Variable expressed as median and (interquartile range)

Inter-rater reliability

The inclinometer showed excellent reliability for flexion, substantial for extension and bending to the right and moderate for bending to the left. The goniometer demonstrated excellent reliability for flexion and bending to the right, and substantial for bending to the left. The eletrogoniometer had excellent reliability for flexion and bending to right and substantial for bending to the left (Table 2).

Table 2. Reproducibility (reliability and intra- and inter- agreement)

Moviments	Reliability		Agreement *			
	Inter-rater $ICC_{2,3}$ (95%CI) (n=58)	Intra-rater $ICC_{2,3}$ (95%CI) (n=50)	SEM inter-rater (n=58)	SEM intra-rater (n=50)	MDC90 inter-rater (n=58)	MDC90 intra-rater (n=50)
Flexion						
Inclinometer	0.95 (0.91-0.97)	0.88 (0.79-0.93)	7.52	11.89	17.50	27.65
Goniometer	0.94 (0.90-0.96)	0.93 (0.86-0.96)	7.85	8.06	18.26	18.75
Eletrogoniometer	0.94 (0.89-0.96)	0.93 (0.86-0.96)	8.07	8.06	18.77	18.75
Extension						
Inclinometer	0.78 (0.58-0.88)	0.73 (0.53-0.85)	6.43	7.21	14.95	16.76
Goniometer	0.67 (-0.21-0.89)	0.92 (0.85-0.95)	3.32	2.83	7.72	6.58
Eletrogoniometer	0.65 (-0.22-0.88)	0.91 (0.84-0.95)	3.27	2.95	7.60	6.86
Tilt to the right						
Inclinometer	0.82 (0.70-0.90)	0.79 (0.63-0.88)	6.20	6.75	14.43	15.71
Goniometer	0.72 (0.46-0.85)	0.92 (0.86-0.95)	3.82	2.69	8.88	6.25
Eletrogoniometer	0.73 (0.48-0.85)	0.92 (0.86-0.96)	16.42	2.72	38.20	6.33
Tilt to the left						
Inclinometer	0.74 (0.56-0.85)	0.74 (0.54-0.85)	7.09	7.83	16.50	18.21
Goniometer	0.88 (0.79-0.93)	0.92 (0.85-0.95)	3.15	3.15	7.34	7.34
Eletrogoniometer	0.87 (0.77-0.92)	0.92 (0.85-0.95)	3.47	3.25	8.06	7.55

$ICC_{2,3}$: intraclass correlation coefficient, types 2, 3; CI: confidence interval; SEM: standard error of measurement; MDC: minimum detectable change; *unit of measurement of values is expressed in degrees

Intra-rater reliability

The inclinometer showed substantial reliability for flexion, moderate to extension and bending to the left and substantial for bending to the right. The goniometer and eletrogoniometer demonstrated excellent reliability for all movements. Again, the flexion movement had better reliability for the three instruments (Table 2).

Inter- and intra-raters agreement

Among all evaluated movements, the goniometer showed the lowest agreement followed by the electrogoniometer. The agreement estimates measured by Bland and Altman plots confirmed the findings of SEM and MDC, so the graphics have been omitted from this manuscript.

Construct validity

All instruments indicated good correlation for all movements (r>0.60 – Table 3). A secondary analysis using the data from examiner 2 showed no differences between the correlation estimates, so this data was also omitted from this manuscript.

DISCUSSION

It was observed that all instruments have good correlation with each other, meaning that they are capable of measuring the same construct, reflecting good construct validity. In addition, we found that they had good levels of reliability, however, with a high absolute error of measurement for some movements (i.e. inter-raters bending to the right and flexion measured by the eletrogoniometer and intra-raters flexion measured by the inclinometer).

The main sources of error in measurements in this study were: verbal commands of the examiner, the performance of motor tasks by the patient and the errors inherent in the use of equipment, such as identification of anatomical structures, positioning the subjects and calibration of the equipment. All sources of measurement errors were minimized by long periods of training and calibration of the instruments, but it is expected that they will always be present in such kinds of measurement. Therefore, it can be assumed that the possibility of different training levels may lead to different reproducibility estimates.

The correlation between the goniometer and electrogoniometer was the highest, which means that both actually measure the same construct. Despite the other correlations being also high, the data indicate that the inclinometer does not have such a linear relationship with the other equipment.

A study on reliability and validity of the inclinometer in patients with chronic low back pain[29] found a similar result: good levels of reliability and validity for measuring spinal ROM for flexion (r=0.88) and extension (r=0.42). However, unlike this study, the authors used two inclinometers in an attempt to isolate the motion of the lumbar spine. If, in one hand, these authors monitored

Table 3. Correlation matrix of range of movement measures

	Flexion inclin	Flexion gonio	Flexion eletrog	Extension inclin	Extension gonio	Extension eletrog	Tilt right inclin	Tilt right gonio	Tilt right eletrog	Tilt left inclin	Tilt left gonio	Tilt left eletrog
Flexion inclin	1	0.85*	0.84*									
Flexion gonio	0.85*	1	0.99*									
Flexion eletrog	0.84*	0.99*	1									
Extension inclin				1	0.70*	0.72*						
Extension gonio				0.70*	1	0.99*						
Extension eletrog				0.72*	0.99*	1						
Tilt right inclin							1	0.75*	0.75*			
Tilt right gonio							0.75*	1	0.99*			
Tilt right eletrog							0.74*	0.99*	1			
Tilt left inclin										1	0,75*	0,73*
Tilt left gonio										0.75*	1	0,99*
Tilt left eletrog										0.73*	0,99*	1

*p<0.05; gonio: goniometer; inclin: inclinometer; eletrog: electrogoniometer. Note: only correlations for the same movements are displayed, for example bending with flexion or extension with extension

the movement variations compared to this study; on the other hand, the pragmatism of these ROM measurements is potentially reduced, since physical therapists do not use more than one inclinometer in daily clinical routine.

Considering the inter-rater reliability, the same study[29] concluded that the inclinometer was reliable (r=0.94), corroborating with our findings. Another study with 10 participants[30], which aimed to verify the validity and reliability of the electrogoniometer to the movements of lateral bending, found good correlation (r=0.97), which is similar to the present study. Regarding the use of the goniometer, a study[13] conducted in healthy individuals showed an ICC of 0.85 and 0.75 for the flexion and extension, respectively.

An important finding of this study was the highest absolute error of the measurement for most of the measures, for example, the inter-rater minimum detectable change for flexion was 27.65°, meaning that that a patient would need to improve at least 27.65° of flexion for this change to be considered true[17]. Such information may have occurred by chance (due to the high number of statistical comparisons in this study) or because the instruments really have a high absolute error. Unfortunately, there is no published data for a direct comparison with our results.

As this study included only a sample of patients with low back pain, we believe that our results are closer to measurements performed in clinical practice, assisting in the decision making in clinical setting. Another strength of this study was that evaluators have undergone previous training to the data collection. Finally, the random allocation of movements for each patient prevented the risk of ordering bias.

We did not collected pain intensity during the retest. Once the pain can influence the ROM, we believe that this constitutes a limitation to this study. In addition, participants had high variation in body mass index, and the identification of bone structures due to the variation may have influenced the results. The subjects were recruited from the waiting list of the UNICID Physiotherapy Clinic thus it is possible that these patients have the same characteristics in relation to economic status, level of education and accessibility, which can characterize a possible selection bias. Finally, the evaluation of movements was not simultaneous, the authors were unable to isolate the intrinsic variability of movement of the intra- and inter-raters reliability.

It is recommended in clinical practice[14] that the instruments for measuring spinal ROM are valid and reliable, have low cost and are easy to use[14]. It was possible to identify that the three instruments measure, in fact, the spinal ROM We recommend, with this study, the use of instruments with lower costs and easier handling, as the goniometer or inclinometer.

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