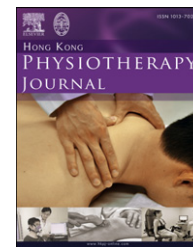


available at www.sciencedirect.comjournal homepage: www.hkpj-online.com

RESEARCH REPORT

Responsiveness of pain, active range of motion, and disability in patients with acute nonspecific low back pain

Prasert Sakulsriprasert, PhD^a, Roongtiwa Vachalathiti, PhD^{a,*},
Mantana Vongsirinavarat, PhD^a, Witchate Pichaisak, MD^b

^aFaculty of Physical Therapy, Mahidol University, Bangkok, Thailand

^bFaculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

KEYWORDS

back pain;
disability;
physical therapy;
responsiveness;
sensitivity

Abstract Many parameters are now used for investigations in clinical settings, such as pain, active range of motion (AROM), and disability, but it is not yet known which parameters are responsive in patients with acute nonspecific low back pain (LBP). This study aimed to investigate the responsiveness of pain, AROM, and disability in patients with acute nonspecific LBP. Fifty subjects were assessed for pain, AROM, and disability at baseline and after 6 weeks. The effect size (ES) was calculated for each parameter. Also, patient's perception of change was collected after 6 weeks for correlating it with change scores for each parameter. The most responsive parameter for detecting the change in patients with acute nonspecific LBP was pain (ES, 1.57) and disability (ES, 0.93). However, AROM was proved to be less responsive. This study indicated that pain and disability were responsive in detecting the changes in patients with acute nonspecific LBP over time.

Copyright © 2011, Elsevier. All rights reserved.

Introduction

Low back pain (LBP) is a major health problem in many countries [1], for which an appropriate intervention is needed to jettison or minimise the symptoms and its

consequences. According to diagnostic triage, LBP can be divided into nonspecific LBP, specific LBP, and sciatica/radicular LBP [1]. Nonspecific LBP is the biggest group, which indicates that no specific structure is determined as the source of pain [2]. Individuals with LBP have complaints, such as pain, restricted active range of motion (AROM), and restricted function or disability. However, each LBP parameter has different responsiveness to see the change in individuals.

Responsiveness or sensitivity is meaningful for clinical practice and clinical research because it represents an ability of each outcome measure that can detect the

* Corresponding author. Faculty of Physical Therapy, Mahidol University, 999 Phuttamonthon 4 Rd, Salaya, Phuttamonthon, Nakhon Pathom, 73170, Thailand.

E-mail address: ptrvc@mahidol.ac.th (R. Vachalathiti).

patient's recovery or health status from time to time [3]. Therefore, the responsiveness provides information for clinicians to make a decision for intervention planning and outcome investigations. Each outcome measure has its own responsiveness [4].

There are many methods for analysing responsiveness, such as change score, effect size (ES), correlation with gold standard of clinically relevant change, and receiver operating characteristic curve. However, change score, ES, and correlation with gold standard are frequently used, easy for interpretation, and clinically meaningful [3–6].

Change score is an absolute number of the difference in parameters before and after treatment that is easy to be calculated. It is, therefore, able to quantify the magnitude of change in each outcome measure [7]. However, the limitation of change score is that it represents only the change in parameter, but no statistical significance is provided. ES is another way to report responsiveness, allowing a comparison across different units providing a standardised score that is unit free [8]. Correlation with gold standard of clinically relevant change is also applicable for determining the responsiveness, which provides the correlation magnitude and the statistical significance [7]. Although there is no gold standard of clinically relevant change, patient's perception of change (PPC) has been used in a previous responsiveness study [4], and it is reliable and meaningful statistically and clinically. To understand the responsiveness of each parameter, correlation with gold standard is the most significant, whereas change score and ES should also be considered.

From literature review, it was found that some studies have investigated about the responsiveness [4,5,9]. All of these studies focused on individuals with chronic LBP (CLBP), the onset of at least 6 weeks. The study conducted by Pengel et al [4] reported that the highest responsiveness goes to disability outcome measured by Patient-Specific Functional Scale (PSFS) with ES of 1.6, followed by pain measured by Numerical Pain Scale (ES = 1.3). This study stated that disability and pain are responsive for detecting the change in individuals with CLBP. However, it was found that the prognosis of acute LBP (ALBP) is better than CLBP, by which, pain, disability, return to work were noted in 1 month for improvement. Of which, 90% of all cases will recover within 9 weeks [1,6]. This study, therefore, aimed to investigate the responsiveness of pain, AROM, and disability in individuals with ALBP who got recovered.

Materials and methods

Subjects

A convenience sampling method was used. Fifty individuals (17 men and 33 women) with ALBP with the duration of their symptoms within 6 weeks were recruited from the clinic of Faculty of Physical Therapy, Mahidol University. Demographic data of the subjects are shown in Table 1, and baseline data of the subjects are provided in Table 2. All subjects were diagnosed by the researcher (P.S., a physiotherapist) as having nonspecific LBP, where the symptom was not seen lower than the gluteal folds. Exclusion criteria were as follows: prior episode of LBP within previous 6 months; pregnancy; prior spinal surgery; known herniated lumbar disc; diagnosed joint inflammatory disease; neurological involvement; cancer; or

Table 1 Demographic data of the subjects^a

Characteristics	
Female/male, <i>n</i>	33/17
Age (yr)	39.38 ± 6.25
Weight (kg)	62.11 ± 11.28
Height (cm)	161.14 ± 6.86
BMI (kg/m ²)	23.95 ± 4.40
Duration of symptom (d)	11.24 ± 5.17
Location of low back pain, %	
Left side	20
Right side	12
Both sides or centralised	68
Upper (L1–L3)	10
Lower (L4–L5)	24
Mixed (L1–L5)	66

^a Data are presented as *n*, mean ± SD or %. SD = standard deviation.

receiving other forms of treatment rather than physiotherapy, such as back pain injection, steroid use. Written informed consent was obtained from each subject before participation with the consideration of anonymity and privacy. The Ethics Committee, Faculty of Medicine Siriraj Hospital, Mahidol University, approved the study.

Clinical parameters

There are four clinical parameters used in the study.

Pain

Visual Analogue Scale (VAS) with 100-mm horizontal line described by “no pain” on the left end and “worst pain imaginable” on the right end was used [10]. The individuals expressed their pain with a mark on the line.

Active range of motion

The direction of lumbar movement mainly consists of flexion, extension, and right and left lateral flexion [11]. There are many methods to measure these movements, such as

Table 2 Baseline data of the subjects

Parameters	Mean ± SD
Pain	
Visual Analogue Scale (mm)	48.65 ± 24.1
Active range of motion (cm)	
MMST flexion	5.09 ± 1.40
MMST extension	1.59 ± 1.17
MMST right lateral flexion	19.32 ± 4.39
MMST left lateral flexion	19.57 ± 3.74
Disability	
MODQ total score (%)	22.36 ± 17.29

MMST = Modified-Modified Schober's test; MODQ = Modified Oswestry Disability Questionnaire; SD = standard deviation.

radiography, inclinometry, Schober's test, Modified-Modified Schober's test (MMST) [12], and many others. MMST is not only safe, easy, fast, and inexpensive, it is also proved to be excellently reliable (intratester Intraclass Correlation Coefficient (ICC) = 0.95, intertester ICC = 0.91) and valid ($r = 0.67$), with a minimum metrically detectable change of 1 cm [13]. The measurements are provided briefly here: the starting position of measurement for all directions was standing with hips and knees in neutral position and the distance between feet should be equal to the shoulder's width. For flexion and extension, the tape was aligned from baseline landmark (at the middle of spine in line between both sides of PSIS) to 15 cm above the baseline landmark. The subjects moved both hands down as far as possible while keeping knees extended. The investigator recorded the difference of distance between the superior and the baseline landmarks by subtracting from 15 cm while the subject fully flexed or extended. For right and left lateral flexion, the investigator marked the position of the tip of middle finger. Then the patients laterally flexed and moved hand downside of leg as far as possible. The difference between skin mark on thigh in erect standing and skin mark on thigh in full lateral flexion was recorded. The investigator was blinded from data record and data analysis. Before the study, the investigator practised for MMST and then underwent intratester reliability in flexion, extension, and right and left lateral flexion. The intratester ICC_(3,1) values were 0.96, 0.97, 0.96, and 0.94.

Disability

Modified Oswestry Disability Questionnaire (MODQ), Thai version, was used to assess the physical function. It was cross-culturally translated into Thai and was proved to be highly reliable [14]. MODQ is composed of 10 items—pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, travelling, and employment/home making, which are categorised into six levels of each item starting from 0 (no disability) to 5 (highest disability). MODQ provides a percentage score of disability (total scores), and it can imply how pain affects various activities of daily living [14–16].

Patient's perception of change

PPC was used as a gold standard for correlation with each clinical parameter. The PPC is a three-point VAS horizontal line with 100-mm length (–50, 0, and 50), in which the left end was anchored by "worst change," the middle "unchanged," and the right end "completely recovered" [4]. Individuals expressed their change with a mark on the PPC line at the end of the treatment programme.

Treatments

All individuals with ALBP underwent physiotherapy programme lasting 6 weeks maximally. The interventions used in the treatment programme mainly included manual therapy; therapeutic exercise, such as stretching and strengthening; and ultrasound therapy.

Procedures

Baseline assessments were recorded as pre-test data. The assessments included pain (VAS), AROM (MMST), and disability

(MODQ). Then, all subjects underwent physiotherapy treatment programme. At the end of the treatment programme, they were assessed again for post-test data, including all aforementioned assessments plus PPC.

Statistical analysis

Change scores

Change score is the outcome difference between pre-test and post-test values, calculated by subtracting post-test value with pre-test value; the greater the difference, the greater the responsiveness (change). However, there is no gold standard of change score for each parameter. Physiotherapists can determine if the parameter is responsive or not by observing whether there is any difference occurring from calculation. In addition, minimal clinically important difference (MCID) is frequently used clinically for helping physiotherapists in decision making [3].

Effect size

ES was to compare pre-test and post-test values in each parameter. ES is defined as the mean change divided by standard deviation of the baseline score [7]. According to Cohen's suggestion, ES value less than 0.4 is considered small, 0.5 moderate, and 0.8 large [8].

Correlation with gold standard

A previous study [4] mentioned PPC as a gold standard; this method, therefore, correlated the change score of each parameter with PPC. Before correlation, the distribution of data has been considered with Kolmogorov–Smirnov goodness-of-fit test. The result indicated that the data were normally distributed. Therefore, Pearson's correlation would be used with p value set at less than 0.05.

Results

Demographic and baseline data of all subjects who participated in this study are shown in Tables 1 and 2, respectively. The results of change score, ES, and correlation are reported in Table 3. The change score of pain intensity was –37.85 mm. The change score of AROM in flexion, extension, and right and left lateral flexion were 0.37 cm, 0.76 cm, 1.48 cm, and 1.40 cm respectively. The change score of disability was –16.20%.

The responsiveness determined by ES, the most responsive parameter, was pain (ES = 1.57), followed by disability (ES = 0.93). Although AROM parameters were less responsive than pain and disability, the most responsive AROM was in extension direction (ES = 0.64). The correlation with PPC, the significant correlation went to disability ($r = 0.306$, $p = 0.03$). Other parameters did not significantly correlate with PPC.

Discussion

The aim of this study was to investigate the responsiveness of each clinical parameter, such as pain, AROM, and disability. The change or prognosis of these parameters can be expected especially in individuals with ALBP [6].

Table 3 Absolute values of change score, effect size, and Pearson's correlation of each parameter

Parameters	Change score	Effect size	Pearson <i>r</i>	<i>p</i> Value for Pearson <i>r</i>
Visual Analogue Scale	37.85	1.57	0.200	0.163
MMST flexion	0.37	0.26	0.240	0.094
MMST extension	0.76	0.64	0.039	0.788
MMST right lateral flexion	1.48	0.33	0.274	0.054
MMST left lateral flexion	1.40	0.37	0.267	0.061
Disability, MODQ	16.20	0.93	0.306	0.030 ^a

MMST = Modified-Modified Schober's test; MODQ = Modified Oswestry Disability Questionnaire.

^a Denotes statistically significant difference.

Therefore, it would be beneficial to know which parameter is responsive to better understand the individuals with ALBP. This study has investigated the responsiveness in three ways: change scores, ES, and correlation with PPC.

In this study, it was found that all individuals recovered from ALBP within 1 month; of these, more than 90% recovered in 2 weeks. The most responsive parameters proved to be pain and disability according to change scores, ES, and correlation with PPC, whereas AROM seemed to be less responsive. From all AROM directions, extension was the most responsive to the change from time to time.

For pain intensity, this study reported the change score of 37.84 mm. This value was greater than the proposed MCID by Bird and Dickson [17]. They found that 19 mm indicated the MCID in VAS pain intensity for patients with wide range of pain intensity. Additionally, patients with pain intensity of 67–100 mm should have a difference of 28 mm minimum considered for a perceptible change in pain. Hence, the finding in this study was consistent with those of previous MCID studies regarding pain intensity [17,18]. The present study's pain intensity corresponds to that by Pengel et al; the ES for pain in this study is 1.57 and that in Pengel et al's study is 1.3. Thus, this finding suggests that individuals with ALBP have greater responsiveness in pain than the ones with CLBP.

For disability, this study used MODQ, Thai version [14], for disability measure that was culturally adapted concerning the understanding of Thai person to administer. The change score of 16.20 was noted. Fritz and Irrgang [16] reported that the MCID for MODQ to best distinguish between individuals with LBP who have recovered and those remaining stable was approximately 6 points. The correlation with PPC is also statistically significant ($p = 0.03$). Therefore, the significant correlation with PPC and the change score of 16.20 proved that disability parameter is responsive for individuals with ALBP. The results provide the magnitude of change in individuals with ALBP and can be used as a guideline in the future. ES for disability in this study is 0.93, whereas Pengel et al's value was 0.8 for ES of Roland Morris—24 items. The previous study also used PSFS for disability outcome, and the ES was high, 1.6 [4]. PSFS is appropriate for measuring change in individuals by reporting particular activities; however, its limitation is that the comparison of disability among individuals is less meaningful [19].

Low responsiveness in AROM is noted corresponding to the previous study. The most responsive direction is back extension according to ES of 0.64. The previous study also reported that back extension was more responsive than other directions, with an ES of 0.6 [4]. ESs of other directions of AROM

in this study are very low, ranging from 0.26 to 0.37. The low responsiveness of AROM gives physiotherapists a caution for using AROM as an indicator for LBP recovery. The techniques of measurement in this study differ from those of the previous study [4]. This study used MMST because of its excellent reliability, validity, and minimum metrically detectable change of only 1 cm. MMST measures AROM according to spinal elongation because a tape is attached closely to the spine for back flexion and extension; for this reason, MMST was valid when the correlation with radiography was made [13]. Although MMST is practical and easy for any investigators, even novices, the present study suggests that the future investigators who will use MMST should practice it beforehand for reliability of measurement. The previous study used fingertip-to-floor technique for back flexion and lateral flexion, and used an inclinometer for back extension. It has been reported that the reliability and validity of fingertip-to-floor technique are good as well [20]. However, for the fingertip-to-floor technique to be reliable, a control of shoulders, arms, fingers, and knees is required. In addition, for both fingertip-to-floor technique and inclinometer method, investigators must be experienced [20,21].

The finding in this study reported the similarity in responsiveness of clinical parameters in individuals with ALBP compared with ones with subacute LBP or CLBP [4]. Therefore, the findings affirm that more emphasis should be given on change in pain (VAS) and disability (MODQ) over time in individuals with ALBP. AROM (MMST) extension is also a responsive direction for clinicians in routine investigations. However, this study did not include individuals with radicular syndrome or symptoms below gluteal folds. Caution should be added for uses in acute cases with radicular syndrome. Further research may investigate the responsiveness in acute cases with radicular syndrome for more clinical comprehension.

Acknowledgement

The authors would like to thank all subjects who participated in this study from Physical Therapy Clinic of Faculty of Physical Therapy, Mahidol University. Also, the authors declare no conflict of interest.

References

- [1] Koes B, van Tulder M, Ostelo R. Clinical guidelines for the management of low back pain in primary care. *Spine* 2001;26: 2504–14.

- [2] Deyo R, Weinstein J. Low back pain. *N Engl J Med* 2001;344:363–70.
- [3] Portney L, Watkins M. *Foundations of clinical research: applications to practice*. 2nd ed. Upper Saddle River, NJ: Prentice-Hall, Inc.; 2000.
- [4] Pengel L, Refshauge K, Maher C. Responsiveness of pain, disability, and physical impairment outcomes in patients with low back pain. *Spine* 2004;29(8):879–83.
- [5] Beurskens A, de Vet H, Koke A. Responsiveness of functional status in low back pain: a comparison of different instruments. *Pain* 1996;65:71–6.
- [6] Pengel L, Herbert R, Maher C, Refshauge K. Acute low back pain: systematic review of its prognosis. *BMJ* 2003;327(323):1–5.
- [7] Stratford P, Binkley J, Riddle D. Health status measures: strategies and analytic methods for assessing change scores. *Phys Ther* 1996;76:1109–23.
- [8] Knobloch H, Stevens F, Malone A. *Manual of developmental diagnosis: the administration and interpretation of the revised Gesell and Amtruda developmental and neurological examination*. Hagerstown, MD: Harper & Row; 1980.
- [9] Beurskens A, de Vet H, Koke A. A patient-specific approach for measuring functional status in low back pain. *J Manipulative Physiol Ther* 1999;22:144–8.
- [10] Huskisson E. Visual analogue scales. In: Melzack R, editor. *Pain measurement and assessment*. New York: Raven Press; 1983. p. 33–7.
- [11] Lindh M. Biomechanics of the lumbar spine. In: Nordin M, Frankel V, editors. *Basic biomechanics of the musculoskeletal system*. Philadelphia, PA: Lea & Febiger; 1989. p. 323.
- [12] Reese N, Bandy W. *Joint range of motion and muscle length testing*. St. Louis, MO: W.B. Saunders Company; 2002.
- [13] Tousignant M, Poulin L, Marchand S, Viau A, Place C. The Modified-Modified Schober Test for range of motion assessment of lumbar flexion in patients with low back pain: a study of criterion validity, intra- and inter-rater reliability and minimum metrically detectable change. *Disabil Rehabil* 2005;27(10):553–9.
- [14] Sakulsriprasert P, Vachalathiti R, Vongsirinavarat M, Kantasorn J. Cross-cultural adaptation of modified Oswestry low back pain disability questionnaire to Thai and its reliability. *J Med Assoc Thai* 2006;89(10):1694–701.
- [15] Fairbanks J, Couper J, Davies J, O'Brien J. The Oswestry low back pain disability questionnaire. *Physiotherapy* 1980;66:271–3.
- [16] Fritz J, Irrgang J. A comparison of a modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. *Phys Ther* 2001;81:776–88.
- [17] Bird S, Dickson E. Clinically significant changes in pain along the visual analog scale. *Ann Emerg Med* 2001;38:639–43.
- [18] Salaffi F, Stancati A, Silvestri C, Ciapetti A, Grassi W. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. *Eur J Pain* 2004;8:283–91.
- [19] Westaway M, Stratford P, Binkley J. The patient-specific functional scale: validation of its use in persons with neck dysfunction. *J Orthop Sports Phys Ther* 1998;27:331–8.
- [20] Perret C, Poiraudreau S, Fermanian J, Colau M, Benhamou M, Revel M. Validity, reliability, and responsiveness of the fingertip-to-floor test. *Arch Phys Med Rehabil* 2001;82(11):1566–70.
- [21] Mayer T, Kondraske G, Beals S, Gatchel R. Spinal range of motion. Accuracy and sources of error with inclinometric measurement. *Spine* 1997;22:1976–84.