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Original Article

Multiple Relationships Between Impairment, Activity and Participation-based Clinical Outcome Measures in 200 Low Back Pain

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Background: The International Classification of Functioning, Disability and Health (ICF) model, created by the World Health Organization, provides a theoretical framework that can be applied in the diagnosis and treatment of various disorders.

Objects: Our research purposed to ascertain the relationship between structure/function, activity, and participation domain variables of the ICF and pain, pain-associated disability, activities of daily living (ADL), and quality of life in patients with chronic low back pain (LBP).

Methods: Two-hundred patients with chronic LBP (mean age: 35.5 ± 8.8 years, females, n = 40) were recruited from hospital and community settings. We evaluated the body structure/function domain variable using the Numeric Pain Rating Scale (NPRS) and Roland–Morris disability (RMD) questionnaire. To evaluate the activity domain variable, we used the Oswestry Disability Index (ODI) and Quebec Back Pain Disability Scale (QBDS). For clinical outcome measures, we used Short-form 12 (SF-12). Pearson's correlation coefficient was used to ascertain the relationships among the variables ($p < 0.05$). All the participants with LBP received 30 minutes of conventional physical therapy 3 days/week for 4 weeks.

Results: There were significant correlations between the body structure/function domain (NPRS and RMD questionnaire), activity domain (ODI and QBDS), and participation domain variables (SF-12), rending from pre-intervention (r = –0.723 to 0.783) and postintervention (r = –0.742 to 0.757, $p < 0.05$).

Conclusion: The identification of a significant difference between these domain variables point to important relationships between pain, disability, performance of ADL, and quality in participants with LBP.

INTRODUCTION

Low back pain (LBP) with associated neuromuscular impairment and muscle weakness limits mobility and activities of daily living (ADL) and restricts social participation. The World Health Organization's International Classification of Functioning, Disability and Health (ICF) conceptualizes multiple associations between body function/structure impairment, activity limitation, and restricted participation [1,2]. It is used in many countries to classify LBP, which has impacts on ADL and various daily life disability factors [3]. According to recent research, patients with LBP experience pain, limited mobility, muscle weakness, limitations of ADL, and restricted participation in the workplace and the community [3,4].

According to several studies on recovery interventions, diverse factors cause LBP, suggesting that LBP rehabilitation preparation should focus on a wider set of issues, not just pain management. Research has been undertaken to recognize the relationship between pain and numerous commonly used clinical outcome measurements. A previous study that explored the correlation between limitation and pain intensity of ADL in 119 female patients with LBP reported that pain intensity was related to functional ADL performance (r = 0.522–0.890) [5]. Another study on LBP reported a relationship between disability, depression, and anxiety in 341 patients with chronic LBP [6]. Using the ICF, what can be classified into structure/function domains and activity domains [7]. Thus, the ICF model is useful, as it facilitates a broader consideration of the functional importance of individuals with LBP [8]. High-quality studies are needed to ascertain the relationships among variables in the ICF model and improve recovery following LBP interventions.

Clinically, information on what can aid LBT diagnosis and treatment, including physical therapy interventions. The aim of this study was to investigate the relationships between the body structure/function domain, body activity domain, and participation domain in patients (N = 200) with LBP. The clinical outcome measurements used comprised the Numeric Pain Rating Scale (NPRS) and Roland–Morris disability (RMD) questionnaire for the body structure/function domain variables and the Oswestry Disability Index (ODI) and Quebec Back Pain Disability Scale (QBDS) for the activity domain variable. Short-form 12 (SF-12) was used to assess the participation domain variable. Our hypothesis was that the body structure/function domain, activity domain, and participation domain would be positively correlated in the ICF model of LBP.

MATERIALS AND METHODS

1. Participants

This prospective research contained patients treated with conventional physical therapy at a hospital in Korea. In total, 200 patients with chronic LBT were recruited (mean age: 35.5 ± 8.8 years; females, n = 40). All the participants offered written informed consent, and the research was approved by the Institutional Review Board of Yonsei University Mirae campus (IRB no. 1041849-202106-BM-085-03).

The inclusion criteria were: (1) aged older than 18 years; (2) having self-reported complaints of LBP for at least 3 months; (3) ability to perform simple activities at home; (4) willing and able to complete therapeutic exercises following verbal and visual instructions; (5) appropriate knowledge of the Korean language to realize the instructions; and (6) who work 5 days a week for a total of 40 hours. The exclusion criteria were: (1) spinal surgery or significant trauma in the past 3 months; (2) use of crutches or a walking aid; (3) structural deformities, such as scoliosis, spinal tumor, ankylosing spondylitis, or spondylolisthesis; (4) neurological and cognitive disorders; (5) congenital asthma; or (6) psychiatric diagnosis.

2. Clinical Outcome Measurement

We used standardized clinical measurements of LBP and applied the NPRS to assess the body structure/function domain, RMD questionnaire to assess the body structure/function domain, ODI and QBDS to assess the activity domain, and SF-12 to assess the participation domain.

1) NPRS (body structure/function domain)

We used the NPRS to determine unidimensional measures of pain intensity in LBP. The NPRS is a graphical self-completed scale where the participant selects the number on the scale that best captures the severity of their suffering. The 11-point numeric scale ranges from 0 (no pain) to 10 (the worse pain imaginable). The reliability and validity of the scale have been demonstrated (intraclass correlation coefficient [ICC] = 3, k = 0.89, and r = 0.94, respectively) [9,10].

2) RMD questionnaire (body structure/function domain)

The RMD questionnaire evaluates disability and is self-administered. On the questionnaire, higher scores on a 24-point scale represent higher levels of impairment. To track changes in time, the patient is asked to tick each statement that applies on a given day. The scores are from zero (no impairment) to 24 (major disability). The reliability and validity of the questionnaire have been established (ICC = 3, k = 0.83, and r = 0.89, respectively) [11].

3) ODI (activity domain)

We administered the ODI to investigate LBP symptoms and severity in terms of disability and how much radiating pain or LBP affected daily activities. The ODI contains 10 questions about pain severity, self-care, lifting, walking, sitting, standing, sleeping, sex, socializing, and travel. Each question has six statements that correspond to scores ranging from 0 to 5, and the patient selects the statement that best fits their level of activity. On the ODI, a score of 0 denotes the lowest level of disability, and a score of 5 denotes the highest level of disability. The reliability and validity of the ODI have been reported (ICC = 3, k = 0.97, and r = 0.82, respectively) [12,13].

4) QBDS (activity domain)

We employed the QBDS to gauge the severity of functional impairment due to LBP. One key question serves as the scale's foundation: "Do you have difficulty today with...?," followed by a list of 20 ADL. Getting out of bed and taking something from the refrigerator are examples of daily activities. Each task has six answer options that are rated on a Likert scale from 0 to

5 (0 being no effort and 5 being unable to). The patient rates an activity with a 5 if the activity causes a lot of pain that day and a 0 if it does not. The final score is calculated by adding the scores for the 20 listed daily ADL. The functional disability level is determined by these outcomes, which are scored on a scale from 0 to 100, with higher scores indicating higher levels of disability. The reliability and validity of the QBDS have been reported (ICC = 3, k = 0.85, and r = 0.86, respectively) [14].

5) SF-12 (participation domain)

The 12 questions items on SF-12 measure eight different aspects of health to evaluate both physical and mental well-being. General health, physical functioning, physical problem, and body pain are among the domains associated with physical health. Vitality, social functioning, emotional problem, and mental health are all metrics that are connected to mental health. The reliability and validity of SF-12 have been published previously (ICC = 3, k = 0.78, and r = 0.61, respectively) [15].

3. Intervention

All the participants accepted 30 minutes of conventional physical therapy 3 days/week for 4 weeks. The physical therapy intervention comprised therapeutic modalities (heat, ultrasound, and electrical therapy), mobilization, manipulation, and therapeutic exercises (stretching, sling exercise, and core stability training). Two licensed, experienced physical therapists (6–12 years in practice) delivered the program according to standardized intervention protocols. Heat therapy was applied to the patient covered with a cotton towel after it was kept in the hydrocollator tank (Fizyopack 7000; Fizyomed®) at 75–80 degrees for 5 minutes. An ultrasound (Bio sonic; Hani Medical Co., Ltd.) was applied at a frequency of 1 MHz and an average spatial and temporal intensity of 120 mW/cm^2 was applied for 2 minutes. Electrical therapy was applied with constant frequency (182 Hz), constant pulse (50 microseconds) and constant current for 10 minutes with the number of electrodes selected according to the trigger point number and distribution [16]. Mobilization and manipulation were performed to improve joint mobility by finding the patient's hypomobility [17]. Stretching exercise was applied at the tightness muscles such as back muscles and gluteus muscles [18]. Sling exercise was conducted for 10 minutes per time, 2 times per week using the following the methods: First, a weight load exercise was performed under the Sling system. Second, passive fluctuation or mechanical vibration was selectively applied to body parts by using a stimulator. Third, the load was gradually increased. Fourth, treatment was adjusted so that pain was not triggered [19]. For core stability exercise, the patient was first asked to lie in supine with one hand placing on the upper thorax and the other hand on the abdominal area and performed the inward abdominal movement during expiration and outward abdominal movement during inspiration [20].

4. Statistical Analysis

The results are expressed as mean ± standard deviation. A paired t-test was used to compare the clinical outcome measures (NPRS, RMD questionnaire, ODI, QBDS, and SF-12 score) pre- versus post rehabilitation in the LBP patient population. As a parametric test, Pearson's correlation coefficients were calculated to determine the relationships between the body structure/function domain (NPRS and RMD questionnaire), activity domain (ODI and QBDS), and participation domain (SF-12) variables pre- and postintervention. IBM SPSS for Windows (ver. 26.0; IBM Co.) was used for data analysis, with the significance level set at $\alpha = 0.05$.

RESULTS

1. Clinical and Demographic Characteristics of the LBP Patient Population (N = 200)

Table 1 presents the characteristics of the patients with chronic LBP.

2. Comparison of Pre- and Postintervention Data

The results of the paired t-test showed that the mean postintervention NPRS, RMD, ODI, and QBDS scores were significantly decreased as compared to the pre-intervention scores. The paired t-test revealed that the mean post-SF-12 score was significantly increased as compared to the mean pre-SF-12 score (Table 2).

Table 1. Participants' demographic and clinical characteristics

Variable	Value
Sex (Male, female)	200 (160, 40)
Age (y)	44.83 ± 17.42
Height (cm)	157.83 ± 18.88
Weight (kg)	68.42 ± 19.23
Onset month	6.52 ± 2.18

Values are presented as number only or mean ± standard deviation.

3. Relationships Between Domains Pre-treatments

Pearson's correlation analysis revealed strong correlations between the RMD questionnaire and QBDS (r = 0.783, p < 0.001) and between the QBDS and SF-12 (r = –0.723, p < 0.001). It revealed a moderate correlation between the NPRS and RMD questionnaire (r = 0.641, p < 0.001), RMD questionnaire and ODI (r = 0.611, p < 0.05), NPRS and ODI (r = 0.587, p < 0.001), NPRS and QBDS (r = 0.598, p < 0.05), ODI and QBDS (r = 0.671, p < 0.05), RMD questionnaire and SF-12 (r = –0.648, p < 0.05), and ODI and SF-12 (r = –0.513, p < 0.05) (Table 3).

4. Relationship Between the Body Structure/Function Domain, Activities Domain, and Participation Domain Pre-intervention

The correlations between the body structure/function domain and activity domain variables were all significant. The NPRS scores showed a moderate correlation with the RMD scores in the structure domain (r = 0.641, p < 0.001). In the activity domain, a moderate correlation was found between the NPRS and ODI (r = 0.587, p < 0.001) and between the NPRS and QBDS (r = 0.598, p < 0.05). The NPRS showed a weak correlation with SF-12 in the participation domain (r = –0.334, p < 0.05) (Table 3).

The RMD scores showed a strong correlation with the QBDS scores in the activity domain (r = 0.783, p < 0.001). A moderate correlation was found between the RMD questionnaire and ODI score in the activity domain (r = 0.611, p < 0.05) and between the RMD questionnaire and SF-12 score in the participation domain (r = –0.648, p < 0.05) (Table 3). The ODI scores showed a moderate correlation with the QBDS score in the activity domain (r = 0.671, p < 0.05) and the SF-12 score in the participation domain (r = –0.513, p < 0.05) (Table 3). The QBDS scores exhibited a strong correlation with the SF-12 score in the participation domain (r = –0.723, p < 0.001) (Table 3).

5. Relationships Between Domains Postintervention

Pearson's correlation analysis showed strong correlations between the ODI and QBDS (r = 0.757, p < 0.001) and between the ODI and SF-12 (r = –0.742, p < 0.05). A moderate correlation was observed between the NPRS and RMD questionnaire (r = 0.687, p < 0.05), RMD questionnaire and ODI (r = 0.518, p < 0.05), NPRS and ODI (r = 0.693, p < 0.001), NPRS and QBDS (r = 0.543, p < 0.05), RMD questionnaire and QBDS (r = 0.668, p < 0.001), RMD questionnaire and SF-12 (r = –0.593, p < 0.05), and QBDS and SF-12 (r = –0.581, p < 0.001) (Table 4).

6. Relationship Between the Body Structure/Function Domain, Activities Domain, and Participation Domain Variables Postintervention

The correlations between the body structure/function domain and activity domain variables were all significant. The NPRS scores showed a moderate correlation with the RMD questionnaire score in the structure domain (r = 0.687, p < 0.05). In the activity domain, a moderate correlation was found between the NPRS and ODI (r = 0.693, p < 0.001) and between the NPRS and QBDS (r = 0.543, p < 0.05). The NPRS showed a weak correlation with SF-12 in the participation domain (r = –0.287, p < 0.05) (Table 4).

The RMD scores showed a strong correlation with the QBDS score in the activity domain (r = 0.668, p < 0.001). A moder-

Table 2. Comparison of pre- and postintervention values

Variable	Pre-intervention	Postintervention	p-value***
NPRS	6.76 ± 1.38	3.50 ± 2.14	0.001
RMD	14.72 ± 2.48	8.38 ± 2.09	0.001
ODI	45.51 ± 8.76	26.48 ± 8.48	0.001
QBDS	28.38 ± 10.28	18.34 ± 6.11	0.001
SF-12	58.34 ± 8.13	71.28 ± 7.73	0.001

Values are presented as mean ± standard deviation. NPRS, Numeric Pain Rating Scale; RMD, Roland–Morris disability; ODI, Oswestry Disability Index; QBDS, Quebec Back Pain Disability Scale; SF-12, Short-form 12. ***p < 0.001.

Table 3. Correlations between clinical outcome variables pre-intervention

Variable	NPRS	RMD	ODI	QBDS	SF-12
NPRS	-	-	-	-	-
RMD	0.641***	-	-	-	-
ODI	0.587***	0.611*	-	-	-
QBDS	0.598*	0.783***	0.671*	-	-
SF-12	–0.334*	–0.648*	–0.513*	–0.723***	-

NPRS, Numeric Pain Rating Scale; RMD, Roland–Morris disability; ODI, Oswestry Disability Index; QBDS, Quebec Back Pain Disability Scale; SF-12, Short-form 12; –, not available. *p < 0.05, ***p < 0.001.

Table 4. Multiple correlations between clinical outcome variables postintervention

Variable	NPRS	RMD	ODI	QBDS	SF-12
NPRS	-	-	-	-	-
RMD	0.687*	-	-	-	-
ODI	0.693***	0.518*	-	-	-
QBDS	0.543*	0.668***	0.757*	-	-
SF-12	–0.287*	–0.593*	–0.742*	–0.581***	-

NPRS, Numeric Pain Rating Scale; RMD, Roland–Morris disability; ODI, Oswestry Disability Index; QBDS, Quebec Back Pain Disability Scale; SF-12, Short-form 12; –, not available. *$p < 0.05$, ***$p < 0.001$.

ate correlation was found between the RMD questionnaire and ODI score in the activity domain (r = 0.518, $p < 0.05$) and the RMD questionnaire and SF-12 score in the participation domain (r = –0.593, $p < 0.05$) (Table 4).

There was a strong correlation between the ODI scores and QBDS score in the activity domain (r = 0.757, $p < 0.05$). The ODI score also showed a strong correlation with the SF-12 score in the participation domain (r = –0.742, $p < 0.05$) (Table 4).

The QBDS scores showed a moderate correlation with the SF-12 score in the participation domain (r = –0.581, $p < 0.001$) (Table 4).

DISCUSSION

This clinical study investigated the relationships between impairment, activity, and participation using the NPRS, RMD questionnaire, ODI, QBDS, and SF-12 in 200 patients with chronic LBP. Our results revealed meaningful relationships among the body structure/function, activities, and participation domains. These relationships are of therapeutic importance in LBP physical therapy rehabilitation programs.

The relationship analysis showed strong correlations between the RMD and QBDS (r = 0.783, $p < 0.001$), QBDS and SF-12 (r = –0.723, $p < 0.001$), RMD and QBDS (r = 0.668, $p < 0.001$), ODI and QBDS (r = 0.757, $p < 0.05$), and ODI and SF-12 score (r = –0.742, $p < 0.05$), all of which belong to the domain, and demonstrated an adjacent relationship between these variables. A previous correlation study including 341 individuals with LBP described moderate-to-strong correlations between psychological beliefs and anxiety (r = 0.26–0.58) [6]. Another LBP study supported moderate-to-strong correlations between pain and disability (r = 0.94–2.12) in 681 LBP patients [21]. A study involving 195 patients with LBP reported strong correlations between the RMD questionnaire and visual analog scale (VAS) score (r = 0.798, $p < 0.05$) [22]. These findings are consistent with the fact that trunk stabilization is closely related to the ability to perform ADL. The activity of the muscles that control the trunk are impaired in patients with LBP, resulting in an absence of proximal and distal stabilization. The trunk instability increases distal spasms in compensation for gravity, producing it difficult to control posture and perform daily activities due to increased pain intensity. These outcomes encourage this study's findings, and it can be assumed that movements have a clinically crucial relationship in LBP [23]. They point to clinically important relationships between clinical outcome measurement and movements [23].

The correlation analysis revealed a moderate positive relationship between the NPRS and RMD questionnaire (r = 0.687, $p < 0.05$), RMD questionnaire and ODI (r = 0.518, $p < 0.05$), NPRS and ODI (r = 0.693, $p < 0.001$), NPRS and QBDS (r = 0.543, $p < 0.05$), RMD questionnaire and QBDS (r = 0.668, $p < 0.001$), RMD questionnaire and SF-12 (r = –0.593, $p < 0.05$), QBDS and SF-12 (r = –0.581, $p < 0.001$) NPRS and ODI (r = 0.693, $p < 0.001$), and NPRS and QBDS (r = 0.543, $p < 0.05$). A previous correlation study on 195 patients with LBP reported a moderate correlation between the RMD questionnaire and ODI (r = 0.570, $p < 0.001$) [22]. Quality of life and the RMD questionnaire (r = –0.637) and quality of life and the VAS (r = –0.672) showed a moderate negative correlation in 195 patients with LBP [22]. Another correlation study documented a moderate-to-strong correlation between exercise frequency and pain and between pain education and pain in 772 patients with LBP [24]. Hasegawa et al. reported a difference in the range of motion and moments during standing of 64 subjects with and without LBP [25]. In their study, among low back load indications, the intervertebral disc compressive over-force and low back hyper-moment were considerably higher in the LBP group compared to no-LBP group. The upper body's weight is taken into account when calculating the compressive force acting on the intervertebral disc, which has an impact on the force's magnitude. Their results implied that changed posture was the basis of the elevated intervertebral disc compressive force in the LBP group. The arrangement of the trunk and pelvis, as well as the joint angles and joint moments of the lower limbs, did not change significantly in either group, making it impossible to determine the cause of the higher intervertebral disc compressive force.

In our study, we found both moderate and strong relationships among the variables and a distinct link between the body structure/function and body activity domains of the ICF model. Our findings imply that when planning therapy for LBP patients, the ICF framework is helpful in offering useful suggestions from a variety of aspects and viewpoints. The American Physical Therapy Association has approved the Nagi framework as a leading impairment framework for physical rehabilitation diagnosis and intervention [26]. For physical therapy diagnosis and intervention, the Nagi model is a crucial component of the Guide to Physical Therapist Practice (the Guide) in its earlier iteration. As a result, in this study, we modified the ICF model to include physical therapy diagnosis and treatments [27].

Understanding the connections between disability, pain, and activity variables within the ICF framework can provide crucial clinical evidence about the use of specific assessment tools to more thoroughly assess impairment, activity limitation, and restricted participation, which in turn can help to create effective therapeutic interventions [24]. As shown in Tables 3 and 4, there were multiple correlations between the clinical outcome variables pre- and postintervention. For each category of the ICF intervention framework, the outcome assessment tools were consistently related among the outcome variables pre- and postintervention. Thus, there were consistently strong relationships between the ICF domain variables between the impairments, activity limitation, and participation, supporting the idea of a bi-directional, interactive model of associations across elements in the ICF [27]. In addition, the application of the ICF framework (i.e., using the mutual diagnostic and intervention coding system offered by the ICF) in clinical rehabilitation practice may improve the effectiveness of communication between medical professionals in interdisciplinary rehabilitation teams (physical therapists, occupational therapists, doctors, rehab nurses, speech therapists, social workers as well as psychologists) and individuals with LBP, as well as their family members or caregivers [3]. As a result, the findings are very applicable and may help with even more successful rehabilitation.

A few limitations of the present study should be considered. One limitation is that depending on the varied LBP prevalence, the measurements of each clinical evaluation instrument might influence the results. Second limitation is that the present study concentrated mainly on quality of life, pain, disability, and ADL. It would be interesting to focus on trunk mobility and strength of the lower extremities in further studies on patients with LBP. Last limitation is that participants' job cannot be homogenized and variety of activities outside of work can be mixed with the effectiveness of our treatment.

CONCLUSIONS

Our research can help shed light on the connections between the ICF domains (body structure/function, activity, and participation) by determining relationships between the measured variables. The outcome measures used showed statistically significant differences in patients with LBP. This implies that pain-related structural and functional impairment, pain-associated disability, limited ADL, restricted participation in social activities, and poor quality of life are significantly associated in LBP. Our research offers crucial knowledge for creating a comprehensive clinical assessment instrument that properly addresses the variables in the body structure/function, activity, and involvement domains. Our research improves therapeutic efficiency by reducing the measurement time of clinical outcome measurement variables through each outcome measurement variable in patients with LBP. We found that the ICF domain variables' pre- and postintervention correlation comparisons consistently revealed changes linked to the intervention, as well as connections between the impairment, limitation, and restriction variables to take into account the multi-directional interaction. Our findings are extremely useful at a practical level and may potentially enable more effective treatments for LBP.

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CONFLICTS OF INTEREST

No potential conflicts of interest relevant to this article was reported.

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