

## KLINIKINIAI TYRIMAI

### Health-related quality-of-life assessment in patients with low back pain using SF-36 questionnaire

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**Key words:** disc herniation; low back pain; health-related quality of life; preoperative SF-36 scores.

**Summary.** *Objective.* For complete assessment of benefits of the surgical intervention, it is essential to provide evidence of the impact on patients in terms of health status and health-related quality of life. In the present study, the preoperative 36-item Short Form (SF-36) Health Survey scores were determined in patients before lumbar microdiscectomy due to better preoperative screening likewise in the control group – almost healthy population taken into account any habitual ailments experienced in an appropriate age.

*Patients and methods.* In the present study, we investigated a cohort of 100 patients with disc herniation causing low back pain and another hundred of the control subjects, matched by age and gender. The short form 36 general health questionnaire (SF-36) was applied.

*Results.* Estimation of the SF-36 scores showed that (1) all of the domain values were considerably lower in the preoperative patient group than in the second one ( $P < 0.01$ ); (2) the bodily pain scores were closely correlated to the social function scores ( $R = 0.7$ ,  $P < 0.01$ ), whereas the physical function was less related to the bodily pain ( $R = 0.6$ ,  $P < 0.01$ ). The weakest correlation was observed between bodily pain and mental health and general health ( $R = 0.4$ ,  $P < 0.01$ ).

*Conclusion.* The present study showed that the generic instrument, SF-36 Health Survey, was optimized paraclinical method for patients predisposed to surgical treatment of the lumbar disc herniation disease likewise for normal population individuals, matched by age and sex, in the assessment of health-related quality of life.

#### Introduction

The lumbar disc herniation is the most frequent disease of the spinal degenerative processes, and they cause of 30% to 80% of the low back pain cases (1, 2). Along with the clinical examinations, computed tomography (CT), and magnetic resonance imaging (MRI), the paraclinical diagnostic techniques are frequently applied due to the additional standardized screening of patients for microdiscectomy surgical intervention (3–8). According to the recent publications, there is an increasing interest in the use of health-related quality-of-life measures for the assessment of outcomes of spinal surgery, because it might allow comparisons across studies using the standard questionnaires (3, 8–10). One of the most frequently applied questionnaires for the evaluation of health-related quality of life in spinal pathology is the 36-Item Short-Form Health Survey (SF-36) (11). The advanta-

ge of this questionnaire is that the SF-36 achieves the best balance between length, reliability, validity, responsiveness, and experience even in large populations of patients who complain of low back pain (10, 12). The SF-36 questionnaire is a multi-purpose, short-form health survey with 36 questions. It yields an 8-scale graph of functional health and well-being scores. They represent physical function, role physical, bodily pain, general health, vitality, social function, emotional role, and mental health. Two of the most interesting features of the SF-36 are the availability of the normative data and validation in many different languages and countries. These data usually include normal values for healthy persons as well as for series of common pathological conditions triggering low back pain.

Generic measurement, the SF-36, is broadly applicable, as it could be cheaply and lightly used for the

additional screening. The aim of our study was to define and compare results from the SF-36 domains in patients with disc herniation scheduled for surgery and in the relatively healthy patients – control group. Therefore, in the present study, the SF-36 scores were determined in patients before lumbar microdiscectomy for better preoperative screening, and these scores were compared to ones of control group.

### Patients and methods

Within the randomized controlled clinical trial, the population of patients with low back pain was reviewed at the Clinic of Neurosurgery of Kaunas University of Medicine Hospital. Only one spinal surgeon with adequate training and experienced in performing microdiscectomies participated, and the examination of randomized study sample was taken between June 2005 and December 2006 under permission of our local Ethics Committee (No. BE-2-31). One hundred patients with disc herniation were recruited in the present study according to the following criteria: 1) chronic pain occurring daily for at least three months and at least 20 hours per day; 2) chief complaint of pain and/or numbness in the lumbar spine, buttock, and/or lower extremity; 3) age greater than 21 years and less than 76 years; 4) duration of current episode less than 16 days (judged from the patient's self-report); 5) symptoms extending distal to the knee (judged from the pain diagram); 6) stiffness in the lumbar spine (judged from segmental mobility testing); 7) signs consistent with nerve root compression, including any one of the following: a) reproduction of low back pain or leg pain with straight leg raise less than 45°; b) muscle weakness involving a major muscle group of the lower extremity; c) diminished muscle stretch reflex in the lower extremity (quadriceps and Achilles tendon); d) diminished or absent sensation to pinprick in any dermatome of the lower extremity; 8) magnetic resonance imaging or computed tomography demonstrating anatomical intervertebral disc disease correlating with the patient's symptoms. The next hundred of subjects, the majority of which were nursing personnel of Kaunas University of Medicine Hospital, experiencing mild low back pain, were involved into the present study according to the following criteria: 1) nonspecific chronic pain occurring after physical chores for at least three months; 2) chief complaint of pain and/or numbness in the lumbar spine; 3) age greater than 20 years and less than 65 years; 4) no symptoms extending distal to the knee (judged from the pain diagram); 5) reproduction of low back pain or leg pain with straight leg

raise more than 45°. According to the one-way ANOVA test, both groups were matched for age and sex. The patients were ineligible when meeting of further specification: prior lumbar surgery, other degenerative spinal diseases, traumatic segmental instability, vertebral fractures, spine infections, tumors, and pregnancy.

*Assessment methods.* Subjects were asked to complete the basic questionnaire, which combined demographic characteristics with information about previous and present history and current medication. Physical examinations of the preoperative patients and subjects from the control group included motor, sensation, reflexes, degree of pain-onset by the straight leg raise test (Laseque symptom) and computed tomography imaging, included consecutive criteria: asymmetric protruding disc, obliteration of the epidural fat, compression or displacement of the nerve root, indentation of the dural sac. Strength of motor function was determined by using a manual muscle test, and results were classified as normal, good, fair, poor, trace, and zero. Sensation was judged according to whether or not there were some hypoaesthetic or hypalgesic changes.

*Specific outcome tools.* The short form-36 (SF-36) health survey questionnaire is typically used for the assessment of health-related quality of life and includes 36 items summarized in two measures related to physical and mental health. The physical health is represented by four domains – physical function, physical role, bodily pain, and general health – and the emotional one includes emotional role, social function, mental health, and vitality domains. Each scale ranges from 0 (worst health state) to 100 (best health state).

*Pain measure.* The primary measure of pain in this study was bodily pain intensity item on the SF-36 quality-of-life instrument. Patients responded to the question, "How much bodily pain did you have during the past 4 weeks?" by choosing from "very severe," "severe," "moderate," "mild," "very mild," and "none."

*Depression and anxiety measures.* The mood measure was the mental health subscale of the SF-36 health survey. This subscale includes three Likert-scale items about the frequency of depressed vs. happy moods in the previous month and two items about the frequency of anxious vs. peaceful moods, each with six possible responses ranging from "all of the time" to "none of the time." Because depression and anxiety commonly coexist in this category of patients, the developers of the scale combined the items into a single score, which correlates closely with psychiatric diagnoses.

### Statistical methods

Data were expressed as mean  $\pm$  standard error. The statistical significance of the difference between the means was performed with Student's independent test, along with nonparametric tests (Mann-Whitney) due to assumption of abnormal variables. The statistical analysis was performed using SPSS version 10.0, and significance was accepted at  $P < 0.05$ .

### Results

In the present study, preoperative group of the patients with disc herniation and control group were examined by using the SF-36 questionnaire (Table). A total of 200 participants were divided into two groups ( $n=100$  preoperative group and  $n=100$  the second group). The mean age of the first group of patients was  $43 \pm 1$  years and ranged from 21 to 76 years, whereas the mean age of the second group of patients was  $41 \pm 1$  years and ranged from 20 to 65 years (Table). In the present study, we clinically investigated patients with  $L_2-L_3$ ,  $L_3-L_4$ ,  $L_4-L_5$ , and  $L_5-S_1$  disc herniation medial and lateral subtypes (Table). The neurological examination of the preoperative patients with disc herniation showed weaker muscle function of the lower extremity, reduced reflex (such as patellar or Achilles tendon) as well as sensory function, and Laseque symptom ranged from  $10^\circ$  to  $70^\circ$  compared to another group. In turn, the physical function domain correlated weakly with muscle function ( $R=0.2$  and  $P < 0.01$ ).

The SF-36 profiles were compared between two quantitatively predominant subgroups ( $L_4-L_5$  and  $L_5-S_1$  disc herniation) of the patients, and the differences

between mean scores were statistically significant ( $P < 0.01$ ) despite quite weak correlation (correlation coefficient ranged from  $R=0.1$  to  $0.2$ ). However, the statistical analysis showed substantially lower mean scores in both patient subgroups compared to maximal score values (except for the social function and the mental health domains, where the observed differences were less sharp).

The mean SF-36 scores and standard errors were estimated in both the groups (Fig. 1). According to the data from Fig. 1, all of the domain values were considerably lower in the first group than in the second, and the differences were statistically significant ( $P < 0.01$ ). However, in the social function and mental health domains, the differences remained trivial in both groups, though statistically significant ( $P < 0.01$ ) (Fig. 1). All domain mean values of the control group were nearly corresponding to maximal score values (Fig. 1).

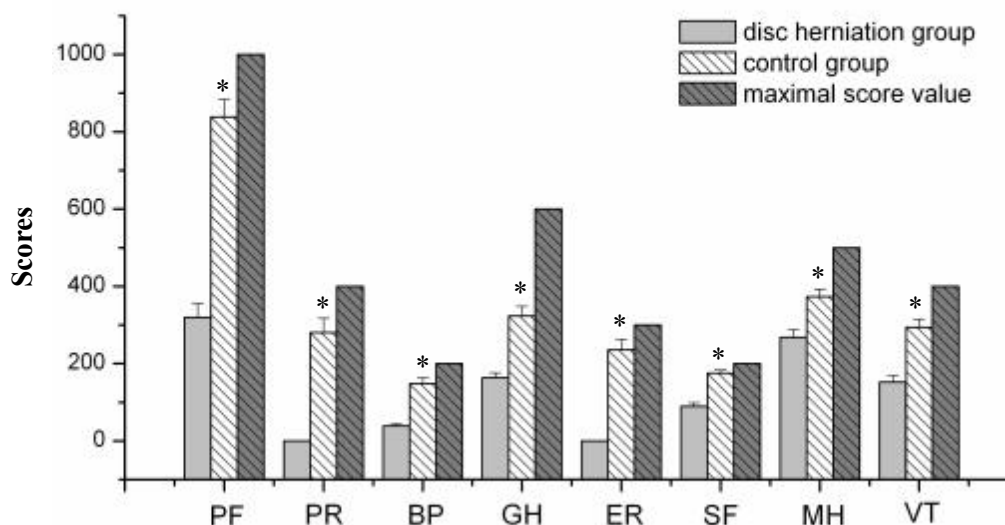
The SF-36 scores were tested regarding to correlation between the bodily pain and other domains (Fig. 2). According to the data shown in Fig. 2, correlation analysis showed the statistically significant ratios ( $P < 0.01$ ) between the bodily pain and the mental health (Fig. 2a), likewise among the social function (Fig. 2b), physical function (Fig. 2c), and general health domains (Fig. 2d) (correlation coefficient ranged from  $0.4$  to  $0.7$ ). The bodily pain scores were closely correlated with the social function scores ( $R=0.7$ ,  $P < 0.01$ ), whereas the physical function was less related to the bodily pain ( $R=0.6$ ,  $P < 0.01$ ) (Fig. 2b, c). However, the bodily pain at least correlated to the mental health and the general health, and correlation coefficient was  $R=0.4$ ,  $P < 0.01$  (Fig. 2a, d).

**Table. Description of the patients' population**

Initial data of patients		Number of patients
Gender	Male	53
	Female	47
Age		$43 \pm 1$ (min 21 – max 76)* and $41 \pm 1$ (min 20 – max 65)**
Diagnosis		
$L_2-L_3$ disc herniation disease	Left sided	2.4%* – 0%**
$L_3-L_4$ disc herniation disease	Right sided	3.4%* – 0%**
$L_4-L_5$ disc herniation disease	Right sided	12.6%* – 13.8%**
$L_4-L_5$ disc herniation disease	Left sided	23%* – 20.1%**
$L_4-L_5$ disc herniation disease	Medial	9.2%* – 3.6%**
$L_5-S_1$ disc herniation disease	Right sided	27.6%* – 37.4%*
$L_5-S_1$ disc herniation disease	Left sided	21.8%* – 25.1%**

\*Preoperative patients with disc herniation.

\*\*Nonoperated patients.



**Fig. 1. Maximal score value and mean score values of disc herniation and control group subjects**

Score values of each domain are expressed as mean plus/minus standard error and compared with maximal ones.

PF – physical function; PR – physical role; BP – bodily pain; GH – general health; ER – emotional role; SF – social function; MH – mental health; VT – vitality.

\*P<0.01.

### Discussion

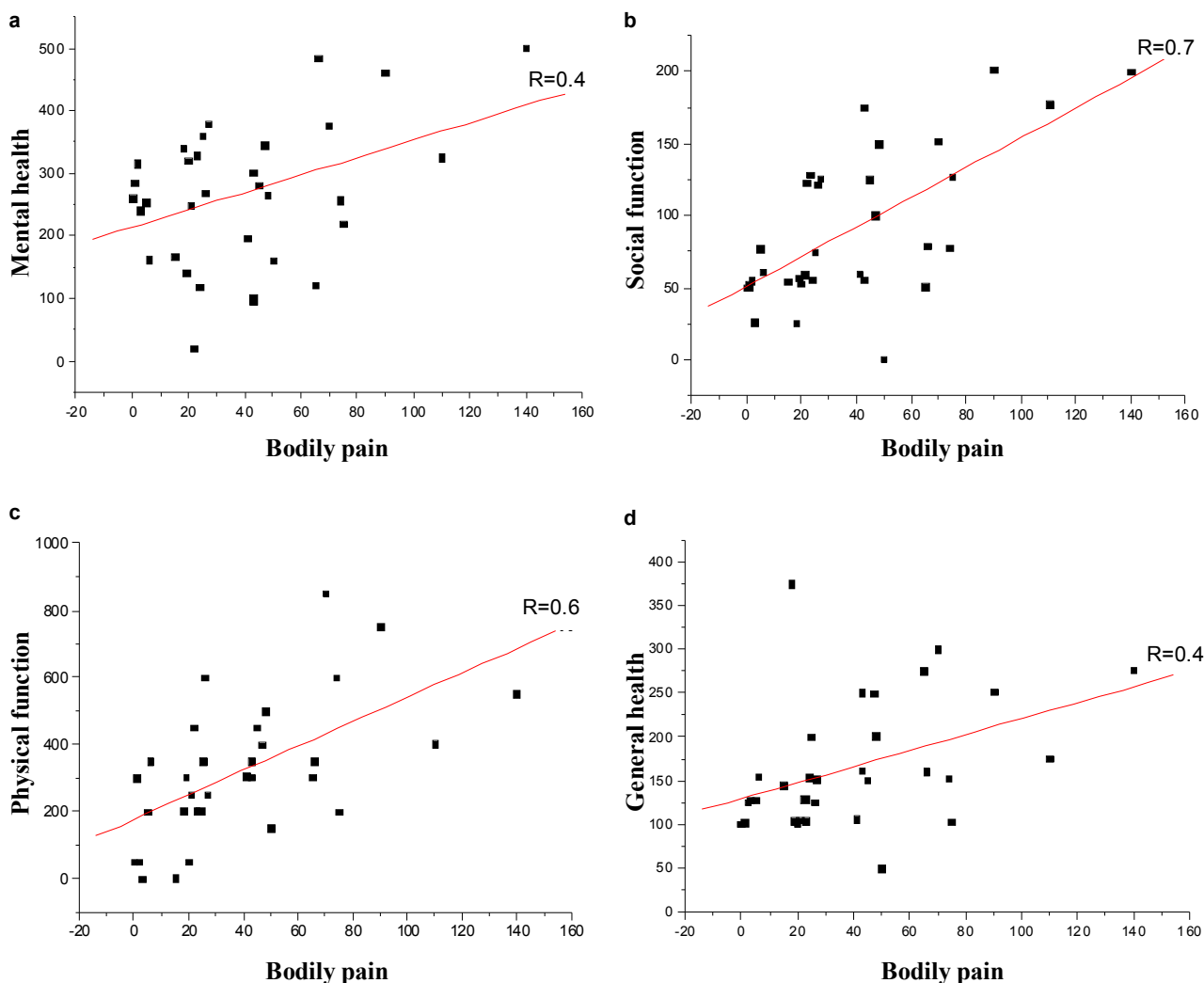
The present study was performed on the preoperative group with disc herniation and the control group subjects using a generic health-related quality-of-life instrument, the SF-36 (11). For the complete assessment of benefits of a surgical intervention, it is essential to provide evidence of the influence over the patient in terms of health status and health-related quality of life (13, 14). These terms refer to experiences of illness such as pain, fatigue, and broader aspects of the individual's physical, emotional, and social well-being (15). Unlike conventional medical indicators, these larger impacts of illness and treatment need to be assessed and reported by the patient (16, 17). Therefore, the application of patient-assessed measures of health outcome has become increasingly important for evaluation of health care (13). The measurement of quality of life provides objective estimations of how and how much the disease influences patients' life and how they cope with it. These evaluations may be used as a baseline and outcome measures and should provide framework to determine the impact of any change on patients' life quality (18).

The SF-36 contains such domains as physical function, physical role, bodily pain, and general health that reflect physical state and vitality, emotional role, and mental health reflecting the psychological status of the patients; social function represents the socioeconomic status of the responders.

### Quality of life and somatosensory SF-36 domains.

The present study provides the evidence of relation between quality of life and clinical variables (reflecting severity of disease) in population with disc herniation. The physical function, the physical role, and the bodily pain are the domains that represent the physical sphere of quality of life. According to our study, in the population of low back pain sufferers, considerably lower mean scores of all physical SF-36 domains were determined, and these findings coincide with acquired data of the neurological examination. Decrease in scores of the physical function and the physical role domains should be explained by motor dysfunction of the lower extremity, reducing of the reflex function. The bodily pain scores might be reduced regarding to the mechanical compression of sensory radices of spinal nerves by herniated disc.

*Quality of life and psychological and sensory SF-36 domains.* The present investigation reveals relations among either psychological domains – the emotional role, the mental health and sensory domain as the bodily pain. Regarding our data, a quite weak correlation was observed between the mental health and the bodily pain, and this could be clarified by many other essential factors that influenced the mental health of participants (for example, socioeconomic status). According to the recent reports, depression and anxiety were linked to bodily pain and these results concur with our findings (19). However, neither depression nor anxiety plays a very important role in the patho-



**Fig. 2. Correlation between the various SF-36 domains**

(a) mental health, (b) social function, (c) physical function, and (d) general health *versus* bodily pain ( $P < 0.01$ ).

genesis of disc herniation, as it was previously reported by Coelho and co-authors (2005), who investigated health-related life quality of patients with congestive heart failure (20). The physical function, physical role, bodily pain, emotional role, and mental health in turn influenced general health status, which was definitely reflected by the SF-36 general health domain. Regarding to the current investigation, the general health scores were related to the bodily pain ones, but this relation was not very strong enough because general health status of patients is usually related to other concomitant pathology. Whereas both the vitality and the general health SF-36 domains are determined mostly by psychological factors (20–22).

According to the recent reports, the SF-36 is widely applied for the evaluation health-related quality of life in patients with different diseases and health states

(20, 21, 23–25). Also, the SF-36 was administered to patients with degenerative lumbar spinal disorders and chronic low back pain (10, 26–29). The data of our study coincide with Zanolini and co-authors (10), as they have reported quite low values of correlation coefficients between SF-36 domains too. In consequence, these authors would have expected stronger correlation between the bodily pain domain and assessment of back and leg pain on Visual Analogical Scale (VAS) or the consumption of analgesics, such as the one between physical function and walking ability too. Furthermore, score values of most domains in our study were similar to Zanolini and co-authors ones (10). For example, in the present investigation, the score values of such domains as the physical function, bodily pain, vitality, and mental health completely coincide with scores in patients with disc

herniation reported by Zanolis and co-authors. Whereas, we determined the lower score values than Zanolis and co-authors in the physical role, general health, social function, and emotional role domains (10). These discrepancies might occur due to the socioeconomic differences that exist between Lithuanian and Swedish populations. According to the recent reports, perceptions of living conditions and quality of life must be interpreted in the light of cultural differences between single European countries (23).

In conclusion, the SF-36 scores reported by patients

scheduled for appropriate lumbar spine surgery were much lower than control patients, collectively there were determined slight restrictions of health-related quality of life among L<sub>4</sub>-L<sub>5</sub> and L<sub>5</sub>-S<sub>1</sub> preoperative patients, as the results were more favorable to the latter.

It is obvious that a generic health-related quality-of-life instrument, the SF-36, may be applied to preoperative patients with disc herniation, because it could be cheaply and lightly used as an additional screening method in the Clinic of Neurosurgery or in other health center.

## Pacientų, besiskundžiančių juosmens skausmu, gyvenimo kokybės įvertinimas naudojant SF-36 anketą

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**Raktažodžiai:** tarpšlankstelių diskų išvaržos, juosmens skausmas, gyvenimo kokybė, ikioperacinis gydymo kokybės vertinimas, SF-36 anketa.

**Santrauka.** Atliekant chirurgines intervencijas bei taikant konservatyvų gydymą, ypač svarbi pacientų sveikatos būklė ir su sveikata susijusi gyvenimo kokybė.

*Darbo tikslas.* Pacientų, kuriems indikuotinas tarpšlankstelių diskų chirurginis gydymas, ir kontrolinės grupės tiriamųjų gyvenimo kokybės įvertinimas ir palyginimas.

*Tyrimo metodai ir pacientai.* Naudojant gyvenimo kokybės SF-36 anketą, ištirti pacientai, kuriems diagnozuotos tarpšlankstelių diskų išvaržos, 100 iš jų buvo indikuotinas chirurginis gydymas, 100 pacientų, turinčių jų amžiui būdingų nežymių negalavimų, sudarė kontrolinę grupę.

*Rezultatai.* Susumavus anketos duomenis, nustatyta: (1) visų sričių vertinimai buvo mažesni, bet statistiškai reikšmingi pirmos grupės pacientų ( $p < 0,01$ ) lyginant su kontroline grupe; (2) kūno skausmo balai koreliavo su socialinės funkcijos balais ( $R = 0,7$ ,  $p < 0,01$ ), o fizinės funkcijos balai buvo mažiau susiję su kūno skausmo balais ( $R = 0,6$ ,  $p < 0,01$ ); silpniausias koreliacinis ryšys nustatytas tarp kūno skausmo ir psichinės sveikatos bei bendrosios sveikatos sričių ( $R = 0,4$ ,  $p < 0,01$ ).

Tyrimas parodė, kad SF-36 anketa yra optimalus paraklininis gydymo vertinimo kokybės metodas sveikiems pacientams, kuriems indikuotinas tarpšlankstelių diskų chirurginis gydymas, ir to paties amžiaus ir lyties asmenims.

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