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Review

Application of Patient-Reported Outcomes in Back Pain in Adults: Part 1

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Abstract: The aim of the research is generalization of information about the most common foreign and domestic scales and questionnaires used in acute and chronic back pain (BP). The analysis of Russian-language and foreign literature was carried out with a search depth of 5 years (2016–2021) in the following databases: e-Library, PubMed, Oxford Press, Clinical Keys, Springer, Elsevier, Google Scholar. For the diagnosis of acute and chronic BP and the assessment of the characteristics of its course in dynamics, both a standardized study may be use: collection of complaints, anamnesis, objective examination, assessment of neurological status, as well as valid scales and questionnaires. For the timely diagnosis and monitoring of the development of BP in patients, a wide range of scales and questionnaires were proposed, which were conventionally ranked into 4 groups: scales for assessing the quality of life of patients with BP; scales for assessing the characteristics of pain in BP; scales for assessing the outcomes of the disease in BP; scales for assessing disability in BP. The first part of the thematic review presents an analysis of the advantages and disadvantages of scales for assessing the quality of life of patients with BP. These perspective scales for assessing the quality of life of patients with BP are popular in the world neurological practice. It is necessary to adapt to the use in domestic clinical practice the Stratford Functional Back Pain Scale, the Index of Disability Associated with Pain, The Patient Assessment for Low Back Pain–Impacts.

Keywords: *patient-reported outcomes; back pain; scale; questionnaire.*

Introduction

Back pain (BP) is one of the most important problems in clinical medicine due to the high prevalence of this pathological condition. In the course of BP, acute (lasting less than 6 weeks), subacute (from 6 to 12 weeks) and chronic (more than 12 weeks) forms are distinguished. Chronic BP, in turn, is classified as recurrent (occurs at least 1 month after the previous pain episode has subsided) and persistent [1]. Such systematization makes it possible to choose the optimal algorithm for managing a particular patient with BP [2]. In most cases, BP is acute, lasts several days, and is well relieved at the outpatient stage with non-steroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants. In 30% of patients, BP persists for 6 weeks (persistent pain) [3].

Chronic BP causes the patient to develop anxiety and depressive disorders, "pain behavior" is gradually formed, the perception of pain changes, fear, a feeling of expectation of pain, and irritability appear. There are known factors that can aggravate the course of BP: anxiety and depressive disorders, the patient's desire for social protection. The transformation of acute BP into chronic requires a different approach to managing the patient [4].

In recent years, chronic BP has received much attention both in domestic [5,6,7,8] and foreign [9,10,11,12] literature. The urgency of the problem is due not only to medical, but also to social factors. It is known that in 10–20% of patients of working age, acute BP is transformed into a chronic one. This group of patients is characterized by an unfavorable prognosis for recovery, and it accounts for up to 80% of all healthcare costs for the treatment of BP [13]. Chronic BP with a neuropathic component is more commonly associated with severe pain, decreased quality of life, and overall high healthcare costs compared to non-neuropathic BP. According to the results of the Russian epidemiological study, it was found that the occurrence of the neuropathic component of pain is noted in 35% of patients with BP [14].

Patient-reported outcomes (PRO) using standardized scales and questionnaires to be filled in has become a daily practice for clinical studies in many spinal surgery centers in Europe and a number of clinics in Russia in patients with BP [15].

By definition, PRO is an assessment of any aspect of a patient's health that comes directly from the patient without interpretation of their response by the clinician or anyone else [16]. PRO allows you to evaluate the symptoms of the disease, the patient's health status, its functionality in everyday life, psychological well-being, health-related quality of life, satisfaction with treatment, as well as track their dynamics [17]. Scales and questionnaires are typical tools for assessing these parameters.

The ultimate goal of using scales and questionnaires is to compare the results of conservative treatment, predict surgical outcomes, identify risk groups, and adequately select patients [18].

The availability of generally accepted and accessible methods for assessing BP is very important, both in clinical practice and in research. Currently, there is no unified approach to the use of PRO in our country, although this would help to standardize and unify the study of various aspects of the problem of acute and chronic BP [19]. To determine the possibility of developing a standardized methodological approach to the diagnosis of BP in adult patients, the most commonly used domestic and foreign scales and questionnaires were summarized, and their advantages and disadvantages were highlighted. Unification of the criteria for research in the field of vertebroneurology according to the specified questionnaires and scales can make it possible to modify the existing standards for diagnosing and monitoring the dynamics of the course of BP, which can facilitate the continuity of patient management at the outpatient and inpatient levels of general medical and specialized neurological care [20].

Objective

The main purpose of the study to summarize information about the most common foreign and domestic scales and questionnaires used in acute and chronic VBS in adults.

Materials and Methods

We searched for full-text publications in Russian and English in the e-Library, PubMed, Oxford Press, Clinical Keys, Springer, Elsevier, Google Scholar databases using keywords and combined word search (patient outcome assessment, vertebrogenic pain syndrome, pain in back, scale, questionnaire) for 2016-2021 using "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA) standard. In addition, earlier publications of historical interest were included in the review. Despite our extensive search of these commonly used databases and search terms, it cannot be ruled out that some publications may have been overlooked.

Results

For the diagnosis of BS in patients and dynamic monitoring of its course, standardized methods are used, such as: collection of complaints, anamnesis, objective examination, assessment of neurological status, laboratory and instrumental methods. Also, at present, there are many valid scales and questionnaires (Table 1) that can help assess various aspects of the course of BS and its outcomes. However, at present there is no single protocol for using a wide range of diagnostic scales and questionnaires for adult patients with BS in Russia and abroad, which makes it difficult to manage continuity in the management of this category of patients at the hospital and outpatient stages of health care.

Table 1. PRO tools used and promising for use in back pain.

Group of scales and questionnaires	Names of scales and questionnaires
Scales and questionnaires for assessing the quality of life in patients with back pain	Oswestry Disability Index
	Roland-Morris Disability Questionary
	Quebek Back Pain Disability Scale
	The Back Pain Function Scale of Stratford
	The Short Form (36) Health Survey
	The West Haven-Yale Multidimensional Pain Inventory
	Chronic Low Back Pain Impact Questionnaire
	Brief Pain Inventory and Brief Pain Inventory Short Form
	The Pain Disability Index
	The Patient Assessment for Low Back Pain–Impacts

Scales for assessing the quality of life in patients with back pain

Oswestry Disability Index (ODI)

ODI is a widely used scale for assessing the degree of disability caused by spinal pathology [21,22]. ODI was developed in 1980 by Jeremy C.T. Fairbank while working at Agnes Hunt Orthopedic Hospital in Oswestry, UK [23,24].

Currently, a Russian adapted version of ODI 2.1a is available (E.A. Cherepanov, 2009, 2011) which consists of 10 sections (pain intensity, self-care, lifting objects, walking, sitting position, standing position, sleep, sexual life, leisure, travel). For each section, the maximum score is 5. If the first item is checked, this is 0 points, if the last one is 5 [25]. In the case when all 10 sections are completed, the Oswestry index is calculated as follows: 16 (sum of points scored) / 50 (maximum possible number of points) x 100 \u003d 32. If one of the sections is not completed or cannot be assessed, then the index is calculated as follows, for example: 16 (sum of points scored) / 45 (maximum points possible) x 100 = 35.5. The higher the score, the more severe the disability. For example, patients scoring 0-20 have minimal impairment, can carry out all types of life activities. Usually, no treatment is indicated other than advice on physical activity. Patients who score 81-100 are either bedridden or aggravate their symptoms.

ODI is included in the clinical guidelines of the Russian Interregional Society for the Study of Pain of 2021. and is used to assess the quality of inpatient care (improvement of impaired functions) in acute and subacute discogenic lumbosacral radiculopathy [26]. Evaluation is recommended before the start of treatment, at the end of treatment (at discharge), and after 1.3 and 6 months [27].

The ODI has been translated or adapted for use in patients of different nationalities, in addition to the original English version, there are the following versions: Russian [25], Spanish [28], Arabic [29], Nepalese [30], Indonesian [31], Hausa version in African languages (distributed in the territories of Niger and the northern half of Nigeria, as well as with significant minorities in Chad, Ghana and Cameroon) [32] and Yoruba (Nigeria, Togo, Benin, Ghana) [33], in Gujarati and Punjabi languages (one of the 23 official languages of India) [34,35], in Urdu (one of the two official languages of Pakistan) [36], etc.

The advantages of this diagnostic tool are that the worldwide prevalence and relevance after almost 40 years simplifies the analysis of the data obtained during the survey, because. they are often found in the literature, have high sensitivity and specificity in chronic BP, regardless of the race and ethnicity of patients.

One of the obvious shortcomings of ODI for a long time was that the study was conducted in outpatient clinics and inpatient clinics, which made the process costly and time consuming. However, a study by Christopher T. Martin et al. (2019) showed that completing the ODI questionnaire remotely (by phone) provided superior testing reliability compared to face-to-face communication [37]. Conducting a survey by telephone, or via the Internet, is a convenient and reliable way to obtain data on follow-up results, and its possibility is an additional advantage for this assessment tool.

Roland-Morris Disability Questionnaire (RDQ)

RDQ helps to assess the impact of BP on disability in adult patients [38]. The original version of the questionnaire was published by Professor Martin Roland and Professor Richard Morris in 1983. It provides a diagnostic tool to measure the level of functional impairment experienced by a person suffering from low BP. The questionnaire consists of 24 items related to physical activity (15), sleep and rest (3), psychosocial issues (2), housekeeping (2), food intake (1) and frequency of pain (1). It is designed to be completed in about 5 minutes without any outside help, i.e. The patient answers questions on his own. The doctor calculates the total number of points marked by the patient, receiving a sum from 0 to 24 points. The larger the amount, the more pronounced the violation of the patient's life. To control the dynamics of BP, the questionnaire is filled out again and it is calculated by how many points the improvement occurred, which is then expressed as a percentage [39]. The advantage of this questionnaire in BP is that the RDQ is the most validated [40]. It is also the second most popular and is proposed as the main criterion for the outcome of treatment for the pathology under consideration. The RDQ is approved by most experts and recommends its use in clinical trials [41].

Currently, RDQ has been translated and adapted for many languages and cultures of the world, for example, there is a version for the Hausa nation (Africa) [42,43] and other versions. The Russian-language adapted RDQ [44] is also included in the clinical guidelines of the Russian Interregional Society for the Study of Pain of 2021. and is used to assess the quality of medical care (improvement of impaired functions) in a hospital with acute and subacute discogenic lumbosacral radiculopathy [26].

The advantage of the RDQ is that the questionnaire is short, understandable and well perceived by ear; it is easy to fill out, can be used both in paper and electronic form, both in person, and in surveys by phone and the Internet. However, the RDQ is recommended in the group of patients with BP who have moderate to mild disability, in the groups with moderate to severe disability, the ODI is preferred [39,45].

The disadvantage of the RDQ is that for a group of patients with a predominance of the neuropathic component of BP, other scales and questionnaires are likely to be better suited.

Quebec Back Pain Disability Scale (QBPDQ)

The QBPDQ is a BP-specific quality of life scale published by a group of authors from Montreal, Toronto and London in 1995. The QBPDQ evaluates a patient's difficulty in performing 20 daily activities on a five-point scale. The scores are summed to give a score ranging from 0 to 100 points, where a higher value corresponds to a lower quality of life. The final set of questions for the QBPDQ is selected from a huge number of candidate questions in a factor analysis, assessment of the reliability, correlation and sensitivity of individual questions [46]. This questionnaire, designed for outpatients with various levels of functional impairment, is used to evaluate acute and chronic BP, sacroiliac joint dysfunction, lumbar spinal stenosis, and spinal surgery. The questionnaire takes approximately 5 minutes to complete, and the result can be delivered in person, electronically, or by telephone [47]. QBPDS was originally developed in English and French and translated and adapted to different cultures into several languages, including Dutch, Persian and Turkish [48]. Differences in measurements without direct comparison of scales in homogeneous groups are difficult to interpret. However, the Chiarotto et al. (2017) a systematic review of studies evaluating the validity or one-dimensionality of various measuring instruments showed that the RDQ has an advantage in assessing patients with BP compared to the QBPDQ scale, and the ODI version 2.1a is comparable to it (both research methods have moderate-quality evidence) [41].

The advantages of the scale are the simplicity and self-completion of the questionnaire form by the patient, its brevity and specificity in relation to BP.

The disadvantage is that caution is advised when using QBPDS in languages other than English and French because the evidence base for cross-cultural validity for all QBPDS translations is currently insufficient [48]. Also, the questionnaire does not reflect such an important area of activity for young people as sexual life.

The Stratford Back Pain Function Scale (BPFS)

The scale was developed by Canadian researcher Professor Paul Stratford and American professor Daniel L. Riddle in 2000 to assess changes in functional capabilities of patients with BP only [49]. On a 5-point scale, the 12 most frequent activities are examined: ordinary housework, outdoor activities / sports, heavy physical housework, hobbies, putting on socks / shoes, bending forward, lifting things from the floor, sleeping, 1 hour in a standing position, rising to the second floor, sitting position for an hour, driving a car for an hour. The results of this scale have a strong correlation with the RDQ.

Compared with QBPDQ and ODI, BPFS has advantages in evaluating patients with low back pain [50].

The disadvantage is that this scale is not widely used, which makes it difficult to collect and analyze data, despite the high specificity in BP. Also, the disadvantage of this scale is the lack of an adapted version in Russian.

Short Form (36) Health Survey (SF-36)

SF-36 refers to non-specific questionnaires for assessing the quality of life, was developed in the study of medical outcomes (Medical Outcome Study, MOS), performed by the RAND Corporation (Research and Development Corporation). It is widely used in the United States and European countries in quality-of-life studies. RAND-36 is the commercial version of SF-36. The SF-36 questionnaire was normalized for the general US population and representative samples in Australia, France, and Italy. In the United States and European countries, studies of individual populations were conducted and results were obtained according to the norms for a healthy population and for groups of patients with various chronic diseases [51]. The 36 items of the questionnaire are grouped into eight scales: physical functioning, role-playing, bodily pain, general health, vitality, social functioning, emotional state, and mental health. The scores of each scale range between 0 and 100 points, where 100 points represents overall health, all scales form two indicators: mental and physical well-being [52]. The results are presented in the form of scores on 8 scales, compiled in such a way that a higher score indicates a higher level of quality of life.

The advantages of SF-36 are a good match of specificity, accuracy, sensitivity, number of questions; there is a wealth of experience in its use in large groups of patients. SF-36 also has the advantage of a "normal" distribution (mean, standard deviation) over very large and varied series. This questionary translated into more than 40 languages, including Russian. The SF-36 questionnaire is applicable in studies of the cost effectiveness of treatment, monitoring and comparing the economic burden of various diseases. There are also short versions of it - SF-12 and SF-8 [53].

The disadvantages of this questionnaire are: the complexity of the calculations or the need to purchase special software for their implementation. The questionnaire is not specific for assessing the results of treatment in BP. Also, the SF-36 questionnaire has not been sufficiently studied among the population over 65 years of age; it is not applicable to representatives of different races and nationalities [54].

The West Haven-Yale Multidimensional Pain Inventory (WHYMPI)

WHYMPI was developed to fill a widely recognized gap in the assessment of clinical pain. The original version of WHYMPI was developed by Robert Kearns and colleagues as a self-administered rating scale designed to assess cancer pain. WHYMPI consists of 52 items, contains 12 scales, divided into 3 parts, examining the impact of pain on patients' lives, the reaction of others to patients' reports of pain, and the degree of participation of patients in normal daily activities [55]. The tool is recommended for use in conjunction with behavioral and psychophysiological assessment strategies when evaluating patients with chronic pain in clinical settings [56].

The advantages of this questionnaire are its brevity and clarity, based on modern psychological theory, multifaceted focus and strong psychometric properties. The usefulness of WHYMPI in empirical studies of chronic BP is also discussed [57].

The disadvantage of this questionnaire is its non-specificity in relation to chronic BP.

Chronic Low Back Pain Impact Questionnaire (CLBP-IQ)

The CLBP-IQ questionnaire is a tool for evaluating and documenting the effectiveness of treatment for BP. Its development began with the involvement of patients with chronic BP in a concept elicitation survey to identify target measurement concepts. Based on data from patients taking pain medication daily for at least three months, 28 items were generated and tested on a sample of patients with chronic back pain. The questionnaire was later reduced to 26 items due to patient reports of item redundancy. The final version consists of 26 items (for example, “In the last 24 hours, how depressed have you felt because of lower back pain?” and “In the last 24 hours, how often did you need to find a resting position to relax your back?”) and uses two response scales: from "No difficulty" to "Extremely difficult" and from "Never" to "Very often" [58].

Ramasamy et al. (2017) compared the quality of the evidence for instruments that assess pain and pain-related exposure and their relevance to patients with chronic BP. However, the study found no published clinical studies that used CLBP-IQ. The development article is the only source of information about this questionnaire. CLBP-IQ has not been validated in any patient population [19].

Brief Pain Inventory and Brief Pain Inventory Short Form (BPI, BPI-SF)

The BPI is a self-administered questionnaire originally developed to assess cancer pain. It is now increasingly used as a general questionnaire for chronic non-cancer diseases and acute pain in epidemiological studies and clinical trials, including BP. It is available in abbreviated (9 elements) and full (17 elements) forms [59]. The short form BPI-SF is more commonly used and is the one usually referred to when BPI is cited in studies [60]. The first optional item is a follow-up question about the respondent's pain during the day. The questionnaire then consists of pain charts, four items on pain intensity (worst pain, least pain, moderate pain, pain right now), two items on pain management, and one item on the impact of pain on quality of life with seven sub-items: general activity, mood, ability to walk, normal gait, relationships with other people, sleep, life satisfaction, which are assessed on a 10-point scale. Completing the questionnaire takes about 5 minutes [61-62]. The BPI-SF differs from the BPI (full form) in that there are no additional questions about demographics (date of birth, marital status, education, employment), medical history, aggravating and mitigating factors, treatment and medications, quality of pain, and response to treatment.

The advantage of the BPI-SF is its brevity, which makes the questionnaire suitable for settings in which BP is assessed on a daily basis (for example, in a randomized control trial), while the long form of the BPI may be more appropriate as a baseline measure. Also, the study proved the validity and usefulness of the use of BPI-SF in emergency care, for example, in acute BP [60]. This questionnaire demonstrated good clinical-metric properties and is recommended by the international consensus of the mission of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) for the study of chronic pain [63]. BPI is free for unfunded academic research and clinical practice, but charges apply when used for funded academic or commercial research [59].

The disadvantage of this measuring tool is that, at present, a review that combines and translates the results of studies on measuring the psychometric properties of this questionnaire has not been conducted in patients with BP [64]. According to a review by Jumbo et al. (2021), the disadvantage of BPI is the lack of information on cross-cultural validity and measurement error indices (e.g., standard error of measurement). Therefore, more high-quality studies are needed on their repeated reliability, validity in known groups, cross-cultural validity, interpretability properties, and measurement error indices in different populations of patients with BP [65].

Pain Disability Index (PDI)

PDI (C. Alec Pollard, CA, 1984) is a widely used tool to measure impairment in various aspects of life associated with pain, including BS. It can be used in various patient groups, for example, in chronic low back pain, fibromyalgia, cancer, and other chronic pain conditions [66]. For each of the 7 categories of life activities listed (household duties; recreation; social activity; professional activities; sexual life; self-care; basic needs such as food, sleep, breathing), the patient circles a number on a scale that describes the level of impairment that he usually experiences. A score of 0 means no impairment at all, and a score of 10 means that all activities in which he is involved were completely impaired due to the pain syndrome [67]. McKillop et al. (2017) studied the validity of a modified PDI questionnaire (devoid of the last two items) in a group of patients with chronic BP. The results showed that this simple and short measuring tool can be used in clinical practice and research [68].

The advantages of PDI are validity, reliability, it is intuitive and does not require much time and outside help to complete [66]. Free online PDI calculators have been developed that are easy and convenient to use during remote counseling [69]. The advantages of PDI also include the high specificity of the questionnaire for use in BP. The disadvantages include the lack of an adapted translation into Russian. The brevity of the questionnaire makes it primarily a screening method. The main disadvantage of PDI is that other tools, such as ODI or RDQ, are preferred for a deep and complete study of the impact of BP on life dysfunctions (in the absence of the need to save time).

Patient Assessment for Low Back Pain–Impacts (PAL-I)

The PAL-I questionnaire was designed to include patient perspectives on treatment efficacy in studies of chronic BP. The questionnaire contains 9 items describing the impact of chronic BP on various activities (walking, sitting, standing, lifting weights, sleeping, social activity, travel, lifting and moving the body in space). It gives a single overall assessment of the consequences of pain syndrome on a scale of 0 to 3 points, where higher scores indicate a greater impact of BP on aspects of life. Patient's rate each of the 9 items with response options of "Not at all limited" (score = 0 points), "Slightly limited" (score = 1 point), "Severely limited" (score = 2 points) or "Did not because of my pain" (score = 3 points), or patients may refuse to participate in the study ("Did not do for other reasons"). The mean score for all assessed items (excluding withdrawal items) is a single overall assessment of the effect of pain on quality of life. PAL-I has demonstrated validity and potential utility for evaluating the efficacy of treating chronic BP in clinical trials [70]. In a multicenter observational study by Bushnell et al. (2020) he also showed very robust estimates with substantial evidence of validity [71].

The strength of the questionnaire is that due to the recruitment of patients with chronic low BP across the spectrum of pain severity, as well as demographics in the development of PAL-I, this measurement tool is intended for use in global clinical trials. Its versatility, along with high specificity, gives PAL-I an advantage in research in a variety of chronic BP populations. In addition, PAL-I is currently the only tool for the subjective assessment of the effectiveness of drug therapy by a patient that fully complies with the recommendations of the US Food and Drug Administration (FDA) [70].

The disadvantage is that this questionnaire was not designed specifically for use in clinical practice. We did not find information on the possibility of using PAL-I in the practice of a doctor. Another disadvantage is the lack of an adapted Russian version of this questionnaire.

Conclusion

The main aspect of the patient with BP, for the study of changes in which scales and questionnaires are used, is the "quality of life". This aspect can be the subject of study in almost any pathology. Therefore, there are both universal scales that are appropriate to use for various diseases, and specialized ones that have been developed to assess certain conditions. The scales and questionnaires described above are currently used or may be used in the future in patients with BP.

The lack of a review that integrates and translates the results of studies on measuring the psychometric properties of scales and questionnaires leaves clinicians and researchers no choice but to make decisions about the choice of measuring instrument in BP based on their personal observation, the availability of the questionnaire, recommendations from colleagues, etc. A systematic synthesis of a group of individual studies will provide information on the measurement properties of questionnaires in a wide range of chronic BP conditions. This would provide a more reliable and evidence-based choice and use of these tools in practical and research settings in clinical vertebroneurology.

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