USE OF GENERAL LIFE QUALITY QUESTIONNAIRES FOR ASSESSING THE EFFECTIVENESS OF TREATMENT OF CHILDREN WITH FRACTURES OF LONG BONES OF THE LOWER EXTREMITIES: A LITERATURE REVIEW

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WHO experts recommend including quality of life measures when evaluating the results of surgical treatment in the postoperative period. Quality of life measures help to determine not only the quality of treatment but also the completeness of medical and social rehabilitation. We reviewed the research of international authors, who had used general questionnaires to study quality of life of children with long bones fractures of the lower extremities. We suggest using general questionnaires—PedsQLTM 4.0 (for children aged 2–18 years) and QUALIN (for children aged between 3 months and 3 years) as tools to evaluate treatment results in this population. Presentation of the results of studies using international efficiency indicators, in particular the assessment of quality of life, provides the basis for reliable summary of the international clinical experience.

Keywords: quality of life; PedsQLTM 4.0, QUALIN, long bone fracture in children, the outcome of the treatment of fractures.

Accurate assessment of therapeutic measures aimed at providing specialized care to children with injuries of the long bones of the lower extremities is the main problem in children's traumatology and orthopedics.

Fractures of long bones in pediatric traumatology account for 53%–55% of all fractures [1]. Fractures of the tibia and femur in children are one of the most frequent injuries of the musculoskeletal system [2] and lead to hospitalization [3].

The severity of damage to bone structures and soft tissues at the fracture site as well as mistakes during the treatment period can lead to serious injury and subsequent child disabilities caused by post-traumatic shortening and deformity of extremities, abnormal consolidation between the fragments, formation of pseudoarthrosis, bone defects, and joint contractures. These problems often require surgical correction, and in some cases, multi-stage surgical treatment is required [4].

Increased demands of the quality of treatment and preventive measures necessitate the search for more effective medical technologies and criteria to measure the results of treatment and rehabilitation [5, 6]. Planning of rehabilitation measures and evaluation of their effectiveness require measurements of both the severity of pathological processes and impairment of bio-social adaptive capacities [7].

In domestic trauma, the treatment outcome of the fracture itself is most commonly assessed rather than the overall treatment outcome for the patient with all the possible consequences of injury. Often, only restoration of the bone anatomical integrity allows us to consider the patient outcomes as good or excellent, despite the presence of various residual effects leading to changes in physical and social activity [8].

Recently, however, this assessment of treatment method efficacy has been considered to be insufficient and ineffective. World Health Organization (WHO) specialists have proposed to assess the results of surgical treatment by quality of life (QOL) examination in the postoperative period, which has recently led to a great increase in interest in this approach, which includes assessment of patients with injuries for whom the treatment outcome may be known or those with only partial restoration of function during a long rehabilitation period [9, 10]. Assessment of health-related QOL provides a better determination of the treatment quality and thoroughness of medical and social rehabilitation.
[11], and the presentation of study results using international efficacy outcomes provides the basis for reliable compilation of the international clinical experience [12].

According to WHO, QOL is "a way of life as the result of the combined effects of the factors influencing health, happiness, individual well-being in the environment, a satisfactory job, education, social success, freedom, the possibility of free action, justice, and the absence of any oppression" [13].

In Russia, the concept of QOL studies in medicine, including pediatrics, was developed by the experts of the International Center for Quality of Life Study. The main elements of this concept are the definition and components of QOL concept, research methodology, and the main functional areas for this method in medicine [14, 15].

In foreign countries, individual monitoring of a patient's health-related QOL has been widely used in surgery and traumatology since 1980s. A standard principle of treatment evaluation by the patient himself helps to minimize the subjectivity of study outcome evaluations and enables comparison of findings of different authors on the basis of the standardization of the indicators used. This approach provides the possibility of quantifying the burden associated with the injury perceived by the patient and the course of the rehabilitation period [16], and a lot of information on a significant number of patients can be collected in standard form fairly quickly with minimal cost.

Valid and reliable tools for assessment of health QOL are the basis for treatment efficacy and rehabilitation program evaluations as well as for monitoring of patient status and identification of prognostic factors [17-20].

Studies of the QOL of patients with traumas are also conducted in our country, but most studies have been conducted in adult patients [7, 21-26].

To obtain complete health characteristics of traumatized children that are similar to those of adult patients, it is recommended to assess the parameters of health-related QOL [27].

Conceptually, the methods of QOL assessment for children are designed to accommodate a wider range of children's daily activity than that assessed by clinical scales. Empirical evidence suggests that parameters of QOL provide unique information beyond clinical symptoms. Accordingly, a means for QOL assessment in children can be used in clinical studies in addition to conventional clinical parameters. The combination of health-related QOL assessment and clinical parameters can provide a complete description of disease and its treatment impact on the overall health of a child [28].

QOL questionnaires are divided into two groups: general and specialized. General QOL questionnaires are developed for different populations and have the advantage of allowing comparisons of the findings of individual researchers. Specialized questionnaires are used in special groups of patients [14, 15].

During development of tools for assessment of children's QOL, it is important that questions should be applicable to the experience, activity, and other factors directly related to the patients’ age [28]. According to Novik A. A. and Ionova T.I., in children < 5 years of age, it is recommended that questionnaires for QOL assessment be used with the help of the parents. At the age of 5–7 years, the assessment should be performed by using individual interviews with the child, a survey in a format appropriate to the age (scales with pictures), and a questionnaire for QOL tailored to the child's nearest environment. In children > 8 years old, a questionnaire for child's QOL assessment is used as well as a questionnaire for QOL assessment using the child's nearest environment [15].

Methods of QOL evaluation have been successfully used in pediatrics in developed countries over the last 10–15 years and are highly informative, sensitive, and reliable methods of children's health status and measurement of QOL as well as being effective for assessment of medical and social programs for children.

The International Society for Quality of Life Research works on implementation of QOL questionnaires and on creation of knowledge and common approaches in QOL studies for specialists. The following general questionnaires are the most popular: PedsQL™ 4.0 [29], CHQ [30], TACQOL [31], WCHMP [32], QUALIN [33], CHIP-AE [34], 17D and 16D [35], KINDL [36], and KIDSCREEN-52, 27 [37].

In our country, a Multinational Center for Quality of Life Study was created. In Russia, the effective application of international questionnaires for QOL studies in children and adolescents is possible when the following conditions are met: translation into Russian language in accordance with generally accepted requirements, cultural and
linguistic adaptation, and validation (adaptation and reliability) of the Russian version [15]. The following general questionnaires for QOL assessment have been translated, adapted, and widely used in scientific studies in Russia: the SF-36 (adolescents > 14 years of age and adults), TACQOL TNO-AZL (children and adolescents from 6–15 years old), PedsQL™ 4.0 (children and adolescents from 2–8 years old), and QUALIN (children from 3 months to 3 years old).

In national studies, the SF-36 questionnaire is most commonly used and was originally developed for adults but can be used in adolescents > 14 years old [38, 14]. The Russified version of the SF-36, which was created and recommended by the Multinational Center for QOL Study (MCQLS), consists of 36 questions with various choices for answers. The results are presented in the form of scores (0–100) and are distributed among eight scales, with a higher number indicating a higher QOL. The result is a quantitative evaluation of the following categories: physical functioning, influence of physical status on functional roles, intensity of pain and its impact on the ability to perform daily activities, general health, vitality, social functioning, influence of emotional status on functional roles, and mental health assessment. All scales of the questionnaire are combined in two summary measures: a physical component of health (1–4 scales) and a mental or psychosocial component of health (5–8 scales). However, age restrictions do not allow the use of this questionnaire in children.

Among general questionnaires adapted for Russian children, the PedsQL™ 4.0 is the most popular QOL questionnaire [29] and is recommended for healthy children and patients, including those with orthopedic pathologies. The Russian version was developed by the MCQLS (forms for children and parents) for age groups of 2–4 years, 5–7 years, 8–12 years, and 13–18 years. This questionnaire consists of 23 (21) questions grouped into the following scales: physical functioning (8 questions), emotional functioning (5 questions), social functioning (5 questions), and role functioning (3-5 questions). The total score and psychosocial health are evaluated. The questionnaire is divided into blocks by age: 2–4 years (filled by parents), 5–7 years, 8–12 years, and 13–18 years (forms for children and parents). The total number of points is calculated according to a 100-point scale [15].

Currently, the PedsQL general questionnaire is widely used by Russian researchers not only for population studies but also for determination of health-related QOL in children with various diseases [39-42]. The advantages of this questionnaire include: good psychometric quality; simplicity and convenience for filling, statistical processing and interpretation of results, wide age range (2–18 years), availability of parallel forms for children and parents, possibility of using combined with the special modules of the PedsQL in various diseases, and wide application in pediatrics in all countries in scientific and clinical studies. However, this questionnaire is not intended to assess the QOL in children < 2 years of age.

One of the most well-known international tools for QOL assessment in young children is the QUALIN general questionnaire. It has been validated in a multicenter European study (Belgium, France, Italy, Luxembourg, Spain, and Switzerland), which confirmed its good psychometric properties (reliability, validity, and sensitivity) [33]. A Russian version of the QUALIN questionnaire for QOL assessment in children aged from 3 months to 3 years has been developed, and its applicability for QOL assessment in young children has been confirmed. The questionnaire consists of two blocks: for children from 3 months to 1 year old and for children from 1–3 years old. Each block consists of two forms: one for parents and one for pediatricians. Four main aspects of a child's functioning are examined: behavior and communication (13 questions), ability to be alone (5 questions), family environment (4 questions), psychological development and physical health (11 questions in one block for children < 1 year, and 12 questions for children from 1–3 years old) [43, 44].

The TACQOL TNO-AZL Child QOL has been translated into Russian. The original is in Dutch. This tool was designed for children from 8–15 years old and for parents of children from 6–15 years old to assess QOL and functional status. Physical complaints for physical disorders are self-evaluated and include motor functioning, autonomy, cognitive skills, social function, and positive/negative emotions [30].

The Child Health Questionnaire (CHQ) was designed to assess and compare health status in a population of healthy children and in groups of

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children with various diseases. It has three models: PF50, PF28, and CF87 (the PF is filled in by parents; the CF is filled in by children). The original version is in English [15]. The CHQ assesses QOL by using 14 scales: physical functioning, physical pain/discomfort, social limitations due to physical problems, social limitations due to emotional problems, social limitations due to behavior, perception of overall health, self-esteem, psychological health, behavior, family life, family stability, personal time dependence of parents on the state of health of the child, dependence of emotional well-being of parents on health status of the child, and changes in health status. The CHQ questionnaire has two types of forms: filled in by the child, and changes in health status. The CHQ measures the emotional well-being of parents on health status of the state of health of the child, dependence of stability, personal time dependence of parents on psychological health, behavior, family life, family relationships, and duties (school and work). The CHQ consists of 66 questions (CH1P–CE(PR), and the standard form consists of 25 questions (Parent Form 25). On the basis of the 10 scales, two integral indicators are calculated: the total physical score and total psychosocial score. The total number of points after the transcoding procedure is finally calculated according to a 100-point scale, with higher values indicating worse QOL of the child [30]. The disadvantages of the CHQ questionnaire include the cumbersome format of the children’s forms and the limited age range.

The Child Health and Illness Profile (CHIP) is a profile of health and diseases in children that was designed to assess the QOL of children/adolescents from 6–17 years. The profile includes the following scales: self-satisfaction with health and appearance, comfort (physical and emotional), resistance (family involvement, physical activity, ability to resolve problems, calm at home), stress levels (obstacles in the performance of duties, conflicts in interpersonal relationships), and duties (school and work). The form of the questionnaire for children from 6–11 years consists of 45 questions (CHIP-CE), and the form for children/adolescents from 11–17 years consists of 108 questions (CHIP-AE). Forms to be filled by parents also exist for children from 6–11 years old: the full version includes 76 questions (CHIP-CE(PR), and the standard form consists of 45 questions. A text format is used in the children's forms of the questionnaire to assess the QOL of children/adolescents from 11–17 years old and in the parent forms of the questionnaire to assess the QOL in children from 6–11 years old. The questionnaire to be filled by children from 6–11 years old has the form of illustrations accompanying each question. After scaling, the data are presented as scores on each scale of the questionnaire: higher scores indicate better QOL [31].

The 17-dimension health-related measure (17D) is another questionnaire. The original version is written in Finnish and English and is designed for children from 8–11 years old. The assessment consists of 17 items (with illustrations). The studied parameters include mobility, vision, hearing, breathing, sleeping, appetite, speech, bowel and bladder habits, school activities, circle of acquaintances, physical and mental development, depression, anxiety, ability to concentrate, learning/memorization, and energy level. The level of functioning is assessed according to a 5-point scale [35].

Questionnaire 16D is a 16-dimension questionnaire originally written in Finnish and English that was designed for children from 12–15 years. The individual assessment consists of 16 points for the following items: mobility, vision, hearing, breathing, sleeping, appetite, speech, physiological administration, daily activities, circle of acquaintances, physical and mental development, discomfort, depression, distress, and energy level. The level of functioning is assessed on a scale from 1 to 5 [35].

The Warwick Child Health and Morbidity Profile (WCHMP Warwick graphics is used to assess health and morbidity of children (Spencer & Coe, 1996). The original version is written in English. Parents of preschoolers assess the child’s general condition, presence of acute illness, behavior, accidents, severe acute diseases, hospitalization, vaccinations, surgical diseases, and functional status for HR-QOL according to 10 parameters [32].

The KINDL is a German generic QOL instrument for children that is written in German. Children from 8–16 years and one of the parents together assess psychological well-being, social relationships, physical condition, and daily activities according to 40 items. Currently, a shortened version of the questionnaire (KINDLR, 24 questions) is also used. The KINDL is widely used in Germany when conducting epidemiological studies to examine the
The KINDL and CHQ questionnaires for health of the child and the YQOL questionnaire for QOL in adolescents have been selected as the basis for development of a new general tool for QOL assessment in children living in Europe (project KIDSCREEN). KIDSCREEN-52 consists of 52 questions that represent 10 domains of QOL: physical well-being, psychological well-being, mood and emotions, self-perception, parents and home life, independence, financial well-being, successful relationships with peers and social support, school environment, and problems in contacts with peers. On average, it takes 15–20 minutes to fill out the KIDSCREEN-52. The KIDSCREEN-27 is a shortened version that consists of 27 questions divided into five scales.

Physical and psychological functioning after injury is quite quickly recovered in the majority of patients, but in some cases of post-traumatic stress disorder, QOL can be significantly affected [45, 46]. In this regard, the assessment of health-related QOL in children after trauma is included in the standards of medical care in foreign countries [47].

Review of the foreign literature along with specialized sources showed widespread use of common questionnaires for assessment of QOL in children with injuries of lower extremities [48, 49, 50].

A short-term study of QOL (TACQOL questionnaire) in children immediately, 3 months, and 6 months after injury showed that decline in physical functioning was associated with a subtle change in psychosocial functioning, and QOL was found to be lower in children with fractures of the lower extremities than of the upper extremities [45].

The timing of recovery of indicators for QOL parameters after injury of the lower extremities in children ranges from 1–2 years or more according to different authors; these indicators reflect varying degrees of severity and have been obtained from different sample size and ages of the patients as well as from different variants of the questionnaires.

According to C. S. Sabatini et al. in a study in patients assessed 6 months after injury, it was found that the QOL in children was significantly reduced; however, complete recovery was observed by 12 months [50].

R. Ding et al. noted that in children admitted for fractures of the extremities, there was a decrease in physical and psychological well-being (PedsQL questionnaire) in the first 3 months. After 12 months, most of the children showed recovery in the QOL assessment; however, in those with fractures of the lower extremities, there was a decrease in physical functioning even at later stages of the study [48], which is confirmed by data of other authors obtained using the CHQ-PF50 questionnaire [39] and PIFOS functional scale [51].

In another study, complete recovery of physical activity in children after injury of lower extremities was found only at 18 months [49].

Holbrook T. L. et al. performed a QOL assessment after extremity injury in adolescents by using the scale of well-being and found that injuries had long-term effects on QOL in adolescents even after 2 years and that the well-being of traumatized adolescents was lower than that of their peers [52]. Similar results were obtained by Davey T. M. et al., who found that 2 years after injury, the QOL (according to CHQ) parameters remained below the population standard values [53].

In studies performed by I. O. Pankov, the author obtained data on the correlation of treatment outcomes in articular fractures of the proximal tibia epimetaphysis in 32 patients by performing QOL assessment using the MOS SF-36 questionnaire. Treatment outcomes were evaluated from 1–5 years after transosseous osteosynthesis surgery with devices for external fixation. He found that personal data of the questionnaire in patients with a high QOL was associated with excellent and good results obtained from long-term clinical examinations. According to the author, results from a comprehensive clinical and radiological evaluation of the treatment outcomes in patients and from QOL assessment using the MOS SF-36 questionnaire did not conflict with each other but complemented one another in qualitative and quantitative respects and provided a higher level and more objective assessment of treatment outcomes [54].

It is clear that any injury and its treatment affect the patient’s QOL, which is an integral characteristic of physical, psychological, emotional, and social functioning according to the definition of A. A. Novik and T. I. Ionova [14]. Research concerning these changes for analysis of the efficacy of treatment and rehabilitation has become an increasingly urgent need, and reporting of study results by using international efficacy outcomes
will contribute to a better compilation of the international clinical experience. Implementation of “quantitative methods of outcome assessment with known and proven accuracy that allow conduct of all necessary statistical tests in accordance with the principles of evidence-based medicine” has particular importance [10, 55, 56].

Many reports in foreign publications have described age–sex standards, assessed the efficacy of particular importance [10, 55, 56]. The principles of evidence-based medicine” has become a specialized area of medicine with the development of international clinical experience. Implementation of “quantitative methods of outcome assessment with proven accuracy that allow conduct of all necessary statistical tests in accordance with the principles of evidence-based medicine” has particular importance [10, 55, 56].

Valid and reliable tools for health-related QOL assessments that have proven efficacy both in foreign and national studies enable more complete determinations of the treatment quality and thoroughness of medical and social rehabilitation. The methods used for QOL assessment in children can be used in clinical studies in addition to assessments of conventional clinical parameters. Changes in psychological, emotional, and social functioning identified by using general QOL questionnaires can show the need for a more detailed examination by a psychologist using special psychological questionnaires, which provide more complete descriptions of identified impairments.

Analysis of national and foreign literature has shown that the general PedsQL for children in the 2–4-year, 5–7-year, 8–12-year, and 13–18-year age groups and the QUALIN for children in the 3 months-to-3-years age group, questionnaires that are in accordance with international standards, can be used as tools for evaluation of treatment outcomes of long bone fractures of the lower extremities that have used general questionnaires.

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ИСПОЛЬЗОВАНИЕ ОБЩИХ ОПРОСНИКОВ КАЧЕСТВА ЖИЗНИ ДЛЯ ОЦЕНКИ ЭФФЕКТИВНОСТИ ЛЕЧЕНИЯ ДЕТЕЙ С ПЕРЕЛОМАМИ ДЛИННЫХ КОСТЕЙ НИЖНИХ КОНЕЧНОСТЕЙ (ОБЗОР ЛИТЕРАТУРЫ)

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В статье проведен краткий обзор современных данных об использовании общих опросников качества жизни в медицинских исследованиях для оценки эффективности лечения. Экспертами ВОЗ предложено оценивать результаты оперативного лечения путем изучения качества жизни в послеоперационном периоде, что позволяет более полно определить качество лечения и полноту медицинской и социальной реабилитации. Приводятся данные зарубежных авторов, изучавших качество жизни детей с переломами конечностей при помощи общих опросников. Высказывается мотивированное мнение о возможности использования общих опросников качества жизни PedsQL (для возрастных групп 2–4 года, 5–7 лет, 8–12 и 13–18 лет) и QUALIN (для детей от 3 месяцев до 3 лет) в качестве одного из инструментов для оценки результатов лечения переломов длинных костей нижних конечностей у детей. Представление результатов исследования с использованием международных показателей эффективности, в частности оценки качества жизни, создает базу для достоверного обобщения международного клинического опыта.

Ключевые слова: качество жизни, PedsQL, QUALIN, переломы у детей, исход лечения переломов.

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