



MINIMAL CLINICALLY IMPORTANT DIFFERENCE AS A METHOD FOR ASSESSING THE EFFECTIVENESS OF SPINAL SURGERY USING SCALES AND QUESTIONNAIRES: NON-SYSTEMATIC LITERATURE REVIEW

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Objective. To analyze the literature data and to present recommendations on the use of the minimum clinically important difference (MCID) in the practice of spinal surgeon-researcher.

Material and Methods. The article is a non-systematic review of the literature. A search was performed for sources, which describe the calculation and analysis of the MCID parameter on a cohort of patients with degenerative spinal diseases in the PubMed, Scopus and Web of Science databases. Further, the analysis of the literature was carried out on the application of MCID to assess the effectiveness of surgical treatment.

Results. The MCID parameter is illustrated for the most common clinical scales used to assess the effectiveness of treatment in spinal surgery, with their detailed description and discussion of their benefits and drawbacks. The specific MCID values for cervical and lumbar pathologies, first of all degenerative ones, and follow-up periods, which can be used in assessing the results of the treatment, as well as in planning prospective comparative studies are presented.

Conclusion. The MCID parameter is required for sample size calculation and for the analysis of treatment outcomes. The MCID reflects not just the change in the baseline indicator, but also the clinical significance for the patient.

Key Words: minimal clinically important difference, MCID, questionnaires, clinical scales, spinal surgery, surgical treatment.

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According to the guidelines of evidence-based medicine, the evaluation of treatment outcomes must be done in accordance with standards like significance, reliability, and reproducibility. In addition to objective metric indicators (degrees, centimeters, percentages, etc.), quantitative scales and questionnaires are frequently used in clinical practice to evaluate the efficacy of treatment. In these scales and questionnaires, the gradation of qualitative indicators is fulfilled in conditional numerical values (points) [1]. The link between objective and subjective indicators is not always present. For instance, the degree of pain or the improvement in the patient's functional status are not usually correlated with the maturity of the interbody bone block [2]. Additionally, statistically significant

increases in health as measured by clinical scales and questionnaires do not necessarily mean an improvement in the patients' quality of life. Such contradictions can be revealed both in common intergroup comparisons of results and intragroup comparisons (for example, before and after surgery or between visits of patients at different postoperative follow-up periods). This is particularly relevant when outcomes are discovered using limited samples or rates that are initially very low: a very small difference can become statistically significant while having no practical impact. This is just where the criteria of minimum clinically important difference (MCID) appeared, that gives differences between good and bad outcomes.

The concept of MCID is very rarely used in the domestic scientific community, including among spinal surgeons, and those who are familiar with it do not spread it to a large audience. The use of MCID can change the attitude toward the positive results of the study in exactly the opposite way. The MCID indicator should be used to calculate the sample size while planning prospective comparative research. This is essential to obtaining trustworthy results, which are frequently lacking in domestic scientific papers and present a considerable obstacle to the presentation of data in high-ranking foreign journals.

The objective is to present recommendations on the use of the MCID in the practice of spinal surgeons and in planning of prospective clinical researches.

Material and Methods

The article is a non-systematic review of the literature. A search was performed in the PubMed, Scopus, and Web of Science databases for sources that describe the calculation and analysis of the MCID parameter on a cohort of patients with degenerative spinal diseases. The following keywords were included in the search term: MCID, clinical outcomes, lumbar spine, and cervical spine. Additionally, the review of the scientific literature was done concerning use of the MCID parameter to evaluate the efficacy of surgical treatment. The following word combinations were used to search for publications in Russian using the eLibrary.ru database: minimal clinical importance, MCID, clinical outcomes, surgical treatment, and spine. Nevertheless, no Russian-language articles on this issue were found.

Inclusion criteria: 1) availability of full-text articles; 2) surgical treatment of patients with degenerative diseases of the spine; 3) assessment of the efficacy of the treatment using clinical questionnaires and scales; 4) indication of the MCID value used in the analysis of the efficacy of treatment. All the articles that did not comply with the requirements were excluded from the review. 45 papers contained the required data were found during the search.

Results

The MCID parameter was first defined in 1989 as “the smallest amount of change or difference that might be considered important by patients or clinicians” [3], in other words, a value that indicates a discernible change in the outcome. Over time the concept of the MCID underwent different changes and have the following meanings: “minimum important difference,” “minimum important change”, “minimum detectable difference” and etc. [3–6]. Despite the fact that it can be described as both a clinical improvement and a deterioration, the literature focuses on the calculation of the first one.

There are several uses of the MCID parameter. Firstly, it can be used to assess the efficacy of treatment and determine whether a certain form of treatment would significantly alter the degree of pain or functional status evaluated with clinical scales and questionnaires used in vertebrology. This is essential in applied medicine to assess the chances and risks of a course of treatment, which is crucial for both the clinician and the patient. For instance, a clinician can forecast how much pain a patient will experience after receiving a certain treatment. The MCID parameter simultaneously has variable values depending on the follow-up period, the type of pathology and types of surgical techniques [7].

Secondly, the MCID parameter is also used in the scientific community to determine the patient sample size and formulate hypotheses for comparative clinical studies. Therefore, using the design of a study with equal efficiency as an example [8], the null and alternative hypotheses will be as follows: $H_0: \mu_S - \mu_T \geq \delta$ versus $H_a: \mu_S - \mu_T < \delta$, where H_0 – null-hypothesis; H_a – an alternative hypothesis; μ_S – the key characteristic's average value in routine treatment; μ_T – the average value of the key characteristic in the new treatment under investigation; δ – the difference of clinical importance between the two types of treatment, that is, the value of the MCID.

When planning prospective comparison studies with a design of equal efficiency, these hypothesis formulas with the provided value of the variable δ (=MCID) can be used.

Thus, the advantage of one type of treatment over another is determined by the value of this difference δ (=MCID), according to the selected characteristic, such as ODI, VAS, blood loss volume, and so on. For example, when choosing the main ODI characteristic for a period of 3 months after surgery (its MCID at this time is equal to 12 points), the formulation of the research hypothesis would read as follows: “according to ODI data, the difference in the values of functional capacity (between a minimally invasive intervention and a conventional open procedure) will be no more than

12 points at the follow-up period of 3 months after surgery” [9].

The MCID value is based on the results of clinician's own pilot study performed prior to the main study or on literature data. The closest value on the desired scale for pathology, therapy rendered and follow-up times is taken into consideration when choosing the MCID value from the literature. Next, we will specify the quantitative scales and questionnaires that have been used most frequently by spinal surgeons, along with their values for the MCID parameter.

The Oswestry Disability Index (ODI) is an index of functional disability due to back pain. It may be the most used questionnaire for determining the level of disability due to lumbar spine pathology. This questionnaire is used to evaluate results of both non-surgical and surgical treatment techniques, including different lumbar spine fusion techniques. It is referred to as the “gold standard” in numerous systematic studies [10–12] and spinal surgery guidelines [13]. Additionally, it is used in a number of prospective investigations [14, 15] for various follow-up periods. Version ODI 2.1 is approved for many languages, including validated Russian translation of the questionnaire (version 2.1a) [16]. The MCID value for patients who have had spinal fusion ranges from 6.8 to 15.0 points on the ODI questionnaire, where the highest recommended value belongs to FDA (15 points) [17]. Meanwhile, other criteria are also used for particular situations and terms of the study (Table).

The Neck Disability Index (NDI) is an index of disability due to neck pain. NDI is an analogue of ODI, focused on the evaluation of disorders associated with pathology of the cervical spine. It also consists of ten questions concerning pain-related disability. It includes questions such as headaches, trouble concentrating, reading, and sleep disorders. NDI has demonstrated consistency in cases of mechanical neck pain [4], cervical radiculopathy [18], mixed non-specific neck pain [19], and with various duration of symptoms. The MCID value for the NDI questionnaire is defined by the authors

as a range of points (4.2–7.5 points) and percentage (17.3 %; [Table](#)).

The Japanese Orthopaedic Association (JOA). It is widely used to evaluate the severity of clinical symptoms in patients with cervical myelopathy. This scale has a total of six points, which are used to measure the motor and sensory function of the upper and lower extremities, the trunk, as well as the bladder function. The original version of the questionnaire has a limitations for use, for example, it can be applied to people who routinely use chopsticks, making it difficult to determine the degree of motor dysfunction of people who don't use them [20].

There are currently a number of modified JOA scales (mJOA), in which writing, buttoning clothing [30], and using a knife and fork when eating [31] are given as an analogue to the use of chopsticks. According to Yonenobu et al. [32], the severity of myelopathy is classified as mild if the JOA score is more than 13 points, moderate if it is between 9 and 13 points, and severe if it is less than 9 points. The JOA questionnaire's MCID for selective groups ranged from 1.8 to 2.5 points ([Table](#)).

Numeric Pain Rating Score (NPRS). It is a one-dimensional eleven-point numerical scale that has been extensively studied across a wide range of patients and pathologies. NPRS data are easily documented, intuitively interpretable, and comply with regulatory requirements for pain assessment and documentation [33]. Even though there are other one-dimensional scales for measuring the intensity of pain (visual analogue scale (VAS) and the verbal rating scale (VRS), the strengths of the NPRS, compared to the VAS, are the ability to register patient data not only in writing but also orally (including by phone) and the simplicity of this scale's evaluation [34]. In contrast to the VAS scale, the NPRS can be applied to any patient group. The original source for the use of this scale clearly states that NPRS can only have integer values, although the medical community and the authors of the papers do not follow this straightforward interpretation. They more often use an average version of pain scales (such as

the VAS, NPRS, VRS, and others), which allows for both integer and fractional values and does not interfere with clinicians' ability to understand patients and interact with relevant specialists. The range of MCID values for the NPRS scale is large, running from 0.5 to 3.5 points ([Table](#)).

EQ-5D (EuroQOL-5 Dimension). It's a standardized non-specific set of questions to assess general health condition of a patient with any diagnosis. Additionally, the EQ-5D questionnaire was tested in patients with back pain and in the context of spine surgery [35, 36], demonstrating its reliability, validity, and responsiveness [37]. EQ-5D consists of five aspects: mobility, self-care, daily activities, pain or discomfort, and anxiety or depression. There are three types of responses for each aspect. The responses are converted and indexed to evaluate the non-specific quality of life of patients and see how it relates to their health, as well as to investigate the effects of treatment. The MCID value for the EQ-5D scale was 0.2400–0.0485 points ([Table](#)).

The presence and evolution of pain syndrome are influenced by nociceptive and neuropathic components, which necessitate accurate diagnosis before and throughout treatment as well as various pain management techniques. When using MCID, it is possibly misleading to underestimate the complexity of the pain syndrome. Thus, neuropathy cannot currently be quantified; only binary data is used to determine it (yes or no). The two questionnaires most widely used clinician to determine neuropathic pain are DN4 (Douleur Neuropathique 4 Questions) and PainDetect. A clinician fills out the first one while a patient fills out the second one. The researcher can suspect and identify the neuropathic origin of pain with appropriate sensitivity and specificity by defining the characteristics of the pain syndrome [38, 39]. However, only the likelihood that the patient may have neuropathic pain is identified by both scales. The fact that the MCID values for the scales used to measure neuropathic pain have not been established may be because the neuropathic component is entirely undefined. The inability to use adequate scales and

questionnaires for degenerative spinal pathology as well as the unavailability of large-scale studies on the investigation of neuropathic pain with high subjectivity make it difficult to evaluate the data.

Several scales can be used to evaluate patient satisfaction with treatment: the Likert scale, the HTI (Health Transition Item) section of the SF-36 questionnaire, and the Patient Satisfaction Index (PSI). They are rating scales with a set number of predetermined conditions or responses. Patients rate the degree of satisfaction with the procedure [41] as well as the change in their health status over time compared to the present [23, 40].

Global Impression of Change (GIC) scale requires the respondent to determine whether significant changes have occurred in the time before retesting by comparing the condition before treatment with the condition after treatment. The assessment can be performed both by the patient (Patient Global Impression of Change – PGIC) and by the clinician (Clinician Global Impression of Change – CGIC). This kind of scale is advised for use in clinical trials of chronic pain as the primary criterion for assessing overall therapy improvement [42], including back pain [43].

Scales assessing patient satisfaction is necessary to calculate the MCID values by the rank technique [44]. However, the MCID values obtained for each of them are singular, wildly inconsistent (as a result of the diverse range of responses), and of little interest. It should also be considered that there are two common methods of calculating MCID: category-based (rank-based) and distribution-based. Unfortunately, there is no agreement on which approach is better since both have advantages and disadvantages in particular circumstances. Additionally, the rank can be an objective (assessed by a clinician) or subjective (assessed by a patient) value in the form of a satisfaction scale. In turn, the distribution-based method is affected by the significance of statistical differences in the assessments received from patients [3].

Medical researchers can use the information in the [Table](#) for both practical purposes, such as assessing treatment

Table

Specific features of MCID values of different questionnaires and scales

Authors	Pathology	Evaluation period	MCID value, points
<i>Oswestry Disability Index (ODI)</i>			
Parker et al. [21]	Spinal fusion extention for “adjacent segment disease”	2 years	6.80
Försth et al. [22]	Lumbar stenosis	2 years	12.00
Parker et al. [5]	Degenerative low-grade spondylolisthesis	2 years	14.19
Carreon et al. [23]	Lumbar stenosis	1 year	12.54
Copay et al. [24]	Surgical treatment of the lumbar spine	1 year	12.80
Roland et al. [17]	Spinal fusion	1 year	15.00
<i>Neck Disability Index (NDI)</i>			
Young et al. [4]	Mechanical pain in the neck after non-surgical treatment	20 months	5.50
Kato et al. [25]	Myelopathy in the cervical spine after laminoplasty	12 months	4.20
Sorocanu et al. [26]	Correction of deformity in the cervical spine	1 year	7.00
Carreon et al. [27]	Spinal fusion for degenerative diseases in the cervical spine	1 year	7.50
Parker et al. [6]	Anterior interbody fusion in the cervical spine	3 months	17.3 %
<i>Japanese Orthopaedic Association (JOA)</i>			
Sorocanu et al. [26]	Correction of deformity in the cervical spine	1 year	1.80
Tetreault et al. [28]	Myelopathy in the cervical spine after surgical decompression	1 year	~2.00 (depends on the calculation method)
Kato et al. [25]	Myelopathy in the cervical spine after laminoplasty	1 year	2.50
<i>Numerical Pain Rating Scale (NPRS)</i>			
Copay et al. [24]	Surgical treatment of the lumbar spine	1 year	1.20 – for back pain, 1.60 – for leg pain
Vanhorn et al. [29]	Microdecompression in the lumbar spine	1 year	2.50–3.50 – for back pain, 0.50 – for leg pain
Carreon et al. [27]	Spinal fusion for degenerative diseases in the cervical spine	1 year	2.50 – for arm pain and neck pain
Young et al. [4]	Non-surgical treatment of the cervical spine pathology	20 months	1.50 – for neck pain
<i>EQ-5D (EuroQOL-5 Dimension)</i>			
Kato et al. [25]	Vertebrogenic myelopathy	More than 12 months	0.0485
Parker et al. [6]	Anterior interbody fusion in the cervical spine	3 months	0.24

outcomes, and planning of scientific research when constructing a hypothesis. To achieve this, the literature data are chosen that is close to own study parameters: the primary parameter, nosology, patient cohort, follow-up period, and treatment strategy. desired MCID value for the key parameter according to the literature should preferably match the criteria of our investigation.

Discussion

When conducting this study, we made the assumption that the spinal surgeon

community would be aware of the MCID parameter used in the application of scales and questionnaires as a threshold for evaluating the significant efficacy of the treatment technique. Planning a comparative clinical trial and conducting an accurate analysis of the treatment's effects are both challenging without the use of the MCID parameter. Each clinician involved in science must comprehend this parameter's nature and function. In addition, the determination of the computed MCID value depends on the objectives of the study and the clinical scales used. It could be affected

by the initial characteristics of the patient cohort, the type of therapy, the follow-up period, the study's design, and other factors. Due to this, when selecting a good MCID value from literary sources, one should consider the wide range of their values and apply the one that perfectly matches each unique situation. The variation in MCID values for each questionnaire can be attributed to the lack of placebo-controlled randomized clinical trials, the significant heterogeneity of the study populations and follow-up periods, as well as the use of methods to

calculate the MCID parameter: ranked or distribution-based [2].

The most crucial determinant of the outcome of clinical trials is the patient's perception of their own health, whether it is improving, declining, or remaining stable. Sometimes, the subjective satisfaction of the patient with the outcomes of surgical treatment is just as significant as the favorable trends of objective indicators. Since the two indicators do not necessarily represent the same issue, there is not always a correlation between patient satisfaction levels and objective evaluations of the outcomes of surgical intervention [45, 46].

When analyzing the findings of clinical trials, it is important to understand whether the obtained result has clinical relevance for patients and whether the method of evaluating the outcomes comply with current standards. For instance, although the term of MCID is not used in the study by M.A. Mushkin [47], the concept itself is used frequently.

As a result, there were statistically significant differences between study groups in term of patients' body temperatures at the time of hospital admission – 36.7 °C and 37.2 °C ($p < 0.001$). However, the research revealed no clinically significant findings, indicating that the patients were unable to tell this difference apart in any way! The relevance of the parameter under study may be misrepresented if a statistically significant difference between the groups is obtained but the MCID threshold value is not exceeded.

In contemporary clinical research, the concept of the MCID parameter is crucial. The clinical questionnaires and scales used in surgical vertebrology as the primary indicators for evaluating the clinical outcomes of treatment of pathology, particularly degenerative conditions of the cervical and lumbar spine, are used as an example to explain and provide precise values for the MCID parameter. The MCID value, range, and follow-up periods are provided for each scale, which

are frequently used when evaluating the efficiency of surgical treatment. The formula for determining the required sample size for prospective randomized trials is also included.

Conclusion

This effort produced a concentration of MCID values for clinical scales and questionnaires for use in a spinal surgeon's everyday practice as well as for the design of research. Not enough research has been done in this field of knowledge. The MCID concept can be used as a foundation for explaining treatment outcomes and taking a close look at published research findings.

The study had no sponsors. The authors declare that they have no conflict of interest. The study was approved by the institution's local ethics committee. All authors contributed significantly to the research and preparation of the article, read and approved the final version before publication.

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