RECOMMENDATION BASE FOR THE DELIVERY OF SPECIALIZED MEDICAL CARE TO PATIENTS WITH SPINE AND SPINAL CORD INJURY IN RUSSIA: SCOPING REVIEW

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Objective. To evaluate the composition and content of the recommendation base for delivery of specialized medical care to patients with spine and spinal cord injury on the territory of the Russian Federation.
Material and Methods. The published recommendations specifying the content of the diagnostic, therapeutic, rehabilitation and preventive components of the provision of medical care to patients with spine and spinal cord injury were reviewed. The search for information was carried out in the eLibrary.ru bibliographic resource, documents of the Ministry of Health of the Russian Federation, publications of specialized medical professional non-profit organizations, and other manuals. The depth of information selection was 18 years (since 2003). The review was prepared following the PRISMA-ScR and PRISMA-S guidelines.
Results. The current Russian recommendation base in the field under consideration includes articles in peer-reviewed scientific journals, practical guidelines, regulatory documents and eight clinical guidelines prepared by the Association of Traumatologists and Orthopedists of Russia and by the Association of Neurosurgeons of Russia approved or submitted for approval by the Ministry of Health. A significant degree of cross-use of information has been established, in general covering a wide range of diagnostic, therapeutic, rehabilitation and preventive issues.
Conclusion. Most of the Russian recommendations on the provision of medical care to patients with spine and spinal cord injury do not have high strength, are not based on high-certainty evidence, are general in nature, especially in terms of diagnostic and therapeutic tactics, and are created without consideration of the medical care delivery setting. The methodology for their development is reported extremely poorly.
Key Words: spine and spinal cord injuries, clinical guidelines, specialized medical care, diagnostics, surgical treatment, Russian Federation, scoping review, systematic review.

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In view of the active discussion devoted to the development and improvement of domestic clinical guidelines, it becomes relevant not only to use them as practical manuals, but also as quality assessment tools for medical care and control over its funding [1, 2]. Considering the gained, primarily international, experience, attention is being paid to the methodology for development of clinical guidelines [3]. This is especially true when assessing the certainty of evidence and strength of recommendations from the health management authorities [4–6], bearing in mind regulatory framework reform [7]. The discussion of domestic clinical guidelines on various specialties has already found a place in the academic literature. Nevertheless, it is not applied to spine and spinal cord injury (SSCI). Moreover, it is not in the form of a scoping review. The term "scoping review", well-established in Russian academic literature in 2019–2020 [8, 9] and widely used abroad [10], reflects the difference between the study design from a systematic review. It is used when the purpose of the review is to systematically study the composition and content of documentary sources on a certain topic (scope), but nothing more (for example, there are no plans to conduct a meta-analysis; the researchers are not going to evaluate the certainty of evidence; there is no goal to formulate clinical guidelines, etc.) [11, 12]. Nowadays, there are five clinical guidelines on the territory of the Russian Federation dedicated to the provision of medical care to patients with SSCI. They have been developed by three medical professional non-profit organizations: the Association of Traumatologists and Orthopedists of Russia (ATOR), the Association of Neurosurgeons of Russia (ANR) and the Russian Association of Spine Surgeons (RASS). In 2016, they were approved by the Ministry of Health of the Russian Federation (clinical guidelines KP442 [13], KP443 [14], KP444 [15], KP448 [16], KP521 [17] respectively). They should

be revised by December 31, 2021 in accordance with Federal Law No. 489-FZ as of December 25, 2018 [18]. Therefore, we considered it essential for the first time to review the scope of existing recommendations for medical care provided to such patients.

The objective is to evaluate the composition and content of the recommendation base for delivery of specialized medical care to patients with spine and spinal cord injury in Russia.

Material and Methods

The published to date recommendations specifying the content of the diagnostic, therapeutic, rehabilitation and preventive components of the provision of medical care to patients with spine and spinal cord injury (SSCI) were reviewed. They are defined by sections VI–IX of the standard form of clinical guidelines, introduced by the order of the Ministry of Health of the Russian Federation No. 103n as of February 28, 2019 [19].

The article was prepared following the PRISMA-ScR [20] and PRISMA-S [21] guidelines. The search for documents was performed during 2018–2020, the depth of selection was 18 years (since 2003); a detailed description of the search and processing of the discovered materials is given in the repository of this review on the Open Science Framework (OSF) platform at: https://doi.org/10.17605/OSF.IO/7VX5N. The inclusion and exclusion of documents was performed according to the following criteria.

By PICO parameters: Patient or Population, Intervention, Comparison, Outcomes. Inclusion criteria: mechanical injury to the spine, including against the background of metabolic disorders of bone tissue, with a low impact injury mechanism or low bone mineral density; closed or open injury; injury complicated or uncomplicated by damage to the spinal cord or its roots; any level of the spine; in the multiple injury structure or not; any injury morphology; any intervention; any outcomes. Exclusion criteria: only children; only sequelae of SSCI; only revision surgery; indications of the presence of a background spinal pathology, which in fact excludes a clinical case from the category of "injury" (infectious or tumorous).

By medical care types. Inclusion criterion: specialized medical care. Exclusion criterion: only primary medical care by non-physician and/or physician providers.

By document content. Inclusion criteria: contains recommendations for medical care to patients with SSCI in general or with any of its variants, expressed in the form of a statement directly calling for the use or against the use of a specific intervention in a particular category of patients, or in the form of a scheme. Exclusion criteria: studies of various types analyzing the experience in treating patients, but not formulating direct recommendations to apply or not to apply certain medical procedures in practice.

By document format. Inclusion criteria: any publication date; any publication language. Exclusion criteria: publications in collections of abstracts of reports and conference proceedings, articles such as "case report", "commentary", "editorial", etc., which are not reports on a complete study.

The following sources of information on the Russian recommendation base were:

– peer-reviewed academic journals registered in eLibrary.ru;

– state documents of the Ministry of Health of the Russian Federation;

– official publications (including electronic ones) of ATOR, ANR and RASS;

– editions of the series "National Guides", published by "GEOTAR-Media";

– relevant sources found when viewing previously discovered papers ("snowballing" method).

A total of 169 bibliographic records were found in Russian information sources: eLibrary.ru (n = 110); Ministry of Health of Russia (n = 13); ATOR, ANR, RASS (n = 40); "National Guides" (n = 3); others (n = 3). After the duplicates were removed, 168 bibliographic records were accepted for the screening stage, for which an evaluation was performed for compliance with the specified inclusion and exclusion criteria. As a result, 81 records were excluded. Full texts were requested for the remaining 87. Full texts, with the exception of unavailable ones (n = 5), were also assessed according to the above criteria. As a result, 34 more documents were excluded. Eventually, 48 documents were accepted for detailed examination within the scope of this study.

PubMed was used to search for international publications required for a comparative assessment of the domestic recommendation base. We also viewed the related sources for the discovered relevant papers ("snowballing" method): references, as well as the lists of "Similar articles" and "Cited by" of PubMed and PubMed Central, respectively.

From the documents included in the review, the recommendations for medical care (statements or schemes) themselves were isolated, as well as information on the methodology for formulating these recommendations. Meanwhile, the study of the AGREE II manual [22] allowed to separate the terms "clinical guidelines" and "recommendations for medical care" in this review. According to this manual, clinical guidelines are understood as documents of a certain format (actually "clinical practice guidelines"), while recommendations for medical care (management recommendations in the terminology of the AGREE II; "recommendation statements" in the terminology of the Order of the Ministry of Health of the Russian Federation as of February 28, 2019 No.103n) [19] – statements in the structure of clinical guidelines having an advisory nature. Therefore, in this article an overview of recommendations for medical care (recommendation statements), both presented in clinical guidelines and found in publications of other formats, is performed.

According to paragraph 6 of the above-mentioned Order [19], a number of additional requirements must be fulfilled when forming recommendation statements. The essential of which were the requirements arising from the semantic essence of the recommendation statements in clinical guidelines. It is required to have an answer to the questions: "What should be done?", "For

whom should it be done?", "To what end should it be done?"; an indication that medical intervention is "recommended" or "not recommended"; the presence of explanatory comments and references to literature sources indicating the reliability of evidence (similar to the English concept of level/quality/certainty of evidence) and the credibility of the recommendation (similar to the English concept of strength of recommendation) of this recommendation statement according to the evaluation scales attached to the Order. Regarding the latter requirement, it should be pointed out that the scales proposed in the above-mentioned Order are evaluated as rather controversial in the context of contemporary world practice [4]. Therefore, under the present study, we have decided to use a different terminology to provide an accurate translation of the English formulations, the most relevant, in our opinion, in the world literature [23, 24]: "certainty of evidence" and "strength of recommendation". Due to the difference in the evaluation scales in the reviewed documents, we were forced to use a simple descriptive terminology, denoting the certainty of evidence and strength of the recommendation as the lowest, low, medium, high or highest, relative to each specific scale used by the authors of a particular article.

Results

The structure of the Russian recommendation base for the treatment of patients with SSCI. Within the framework of the research, various types of documents were considered: articles published in peer-reviewed academic journals, editions of the "National Guides" series, proper clinical guidelines, regulatory and other documentation.

The proper clinical guidelines selected during the preparation of this review can be divided into two categories according to the professional organization responsible for their preparation: ATOR (n = 11) or ANR (n = 2). Due to partial duplication of documents, their total number (n = 13) does not reflect the actual amount of individual clinical guidelines. Thus, it is essential to summarize these data according to the available updated information. ATOR (2016) developed 5 clinical guidelines for the following variants of pathology: uncomplicated SSCI of the thoracic spine (TS) and lumbar spine (LS) [16]; complicated SSCI of TS and LS [17]; uncomplicated SSCI of the lower cervical spine (LCS) [15]; complicated SSCI of LCS [14]; SSCI of the upper cervical spine (UCS) [13]. The ANR has developed 2 clinical guidelines. One of them is devoted to uncomplicated and complicated SSCI of CS, TS and LS (2013) [25] and one (in the form of a project awaiting approval) – dislocations in CS (2019) [26]. Since 2013, ATOR clinical guidelines have been published on the official website of the RASS. In 2016, they were listed as approved in the "List of Headings of Clinical Guidelines of the Ministry of Health of Russia" (http://cr.rosminzdrav.ru/). Currently they are not available in the List of Headings for reasons unknown to us. In 2013-2015, the clinical guidelines of ANR were published on the official website of this organization and in a series of peer-reviewed publications [27-29]. The draft of the national clinical guidelines on dislocations in CS, in turn, is published on ANR website. Until 2013, the clinical guidelines could be found in the editions of the "National Guides" series [30-32]. Clinical guidelines for pathological fractures complicating osteoporosis were also considered. They were developed by ATOR together with the Russian Association of Endocrinologists and the Association of Rheumatologists of Russia, approved by the Ministry of Health of Russia and published in the "List of Headings of Clinical Guidelines" in 2018 [33]. It should be mentioned that, despite the large number of clinical guidelines actually analyzed in the review, there is a considerable degree of cross-use of the information reported in them. Thus, to simplify the data acquisition, it was decided not to refer to duplicate sources in the text.

The regulatory and legal documentation concerning medical care to patients with SSCI was compiled by the procedures for provision (n = 3) and standards of medical care (n = 5). The procedures for provision of medical care include recommendations for its organization. Nevertheless, since our study design did not assume the examination of this kind of information, these documents were excluded from detailed consideration. The standards of medical care investigated in detail under this study regulate the provision of specialized urgent and emergency medical care for injury to spine, spinal cord and spinal cord nerves (Order of the Ministry of Health of the Russian Federation as of December 21, 2012 No.639n) [34], as well as similar elective care for injuries of the thoracic and lumbosacral spine (Orders of the Ministry of Health of the Russian Federation as of July 01, 2015 No. 407abn [35] and No. 407an [36]). The two remaining standards define the scope of emergency medical services outside the medical organization in case of spine injury (Order of the Ministry of Health of the Russian Federation No. 1457n as of December 24, 2012) and in case of multiple injuries (Order of the Ministry of Health of the Russian Federation No. 1394n as of December 24, 2012). For this reason, they are excluded from detailed consideration when writing this review.

Finally, it is essential to mention one more type of documents reviewed during the implementation of this study. It is registration documentation. When studying the archived version of RASS website, permits for the use of a number of medical technologies were found. They are concerned with the provision of specialized medical care for SSCI. The permits represent diagnostic algorithms and surgical treatment techniques (n = 9). They were issued by the Federal State Budgetary Institution "Novosibirsk Research Institute of Traumatology and Orthopaedics n. a. Ya.L. Tsivyan" (Novosibirsk) and the Federal State Budgetary Institution "Russian Scientific Research Institute of Traumatology and Orthopedics n.a. R.R. Vreden" (St. Petersburg) in 2006–2011. Nevertheless, these documents were excluded from detailed consideration because, for their purpose (permission to use medical technology), they cannot be a source of recommendations for medical care. In other words, if

a medical technology is approved for use, this should not imply it is recommended for use. Additionally, it should be mentioned that the issuance of permission for medical technology use in Russia has stopped since January 1, 2012 with the introduction of Federal Law No. 323-FZ as of November 21, 2011 [37].

Content of the Russian recommendation base for the provision of specialized medical care to patients with SSCI. While analyzing the recommendations for examination of patients with SSCI, it seems that they do not have substantial features in comparison with traditional approaches to subjective examination and history-taking in general and in patients with trauma in particular. Thus, it is recommended to conduct a full survey of the patient, finding out the history of trauma and the nature of the existing neurological abnormalities, especially by clarifying the time of their development and the prescription of the injury. In the case of an initial examination of individuals with suspected SSCI, a neurological examination is also recommended [38]. Despite the obviousness of these recommendations, it should be noted that in a number of clinical guidelines they are used as criteria for medical care quality [17, 26]. American Spinal Injury Association (ASIA) scales should be used to perform neurological examination to objectify follow-up measurements. In some clinical guidelines, this is used as a criterion for medical care quality [26]. In complicated SSCI, pain assessment on a visual analog scale is also recommended [17].

The following standard laboratory tests are recommended for patients with SSCI: complete blood count and biochemical blood assay, urinalysis, and so on. If there are indications, additional laboratory tests are recommended [39]. At the same time, it is noted that for patients under consideration, laboratory diagnostics is not of special importance; however, it is essential for their physical status assessment. That said, the fact of its implementation is used in clinical guidelines as a criterion for medical care quality [33]. Also, according to the specialized medical care standard for injuries of the spine, spinal cord and spinal cord nerves, all patients, among other things, should undergo histological examination of central nervous system tissues and brain, and their histological specimen should be examined (the average indicator of provision frequency for each is 1) [34]. This requirement is not completely clear for cases of SSCI in which only conservative treatment was performed. Nevertheless, the standard does not include explanations in this connection. It should be mentioned that when studying this document, there were numerous typos, including in the column of the average frequency of provision. Thus, it cannot be concluded that these types of studies are really intended to be standard for all patients with SSCI [40].

The question of the sequence and scope of instrumental examinations (first of all, radiologic) is probably of the greatest interest and complexity for a spine surgeon in terms of SSCI diagnosis. Meanwhile, it is especially significant that in the relevant standard of specialized medical care, none of the main types of radiologic examinations (X-ray, CT, MRI) has an average frequency of delivery (both primary and follow-up) equal to one [34]. This means that none of these examinations should obligatorily be applied to all patients with SSCI. At the same time, in the clinical guidelines for complicated SSCI of TS and LS, instrumental diagnostics is a criterion for medical care quality. It is the strongest recommendation with the highest certainty of evidence [17].

Generally, there is a lack of common views on the strategy of radiologic examination of patients with SSCI. Therefore, there is a widespread recommendation to perform a plain spine radiography in two standard views for all patients with SSCI [38, 39]. According to the indications, radiography of spine in special views and by special techniques, spine tomography and functional spine radiography are also recommended [38, 41]. A part of the publications emphasizes the priority of CT in SSCI diagnosis. Moreover, it is pointed out that performing radiologic examinations of several modalities in combination is still recommended if necessary [38, 39]. This is the strongest recommendation in clinical guidelines with high certainty of evidence [26]. Spine radiography in standard and special views is separately recommended for the diagnosis of fractures associated with osteoporosis, and if CT is not possible [42]. This is the strongest recommendation in clinical guidelines with the highest certainty of evidence [26]. CT of the entire spine is recommended for patients with multiple injuries [42, 43]. Additionally, if the patient's condition permits, MRI is recommended at the levels where injuries are detected [39, 43]. In some studies, CT and/or MRI (including vascular MRI) of the spine is recommended for all patients with SSCI [39, 41, 44]. This is the strongest recommendation in clinical guidelines with the highest certainty of evidence [16].

In case of any SSCI of the UCS, as well as in complicated SSCI of other localizations, in addition to spine radiography, CT and/or MRI are recommended. For them the highest strength of recommendation and certainty of evidence are indicated [45]. Nevertheless, with an isolated uncomplicated SSCI of the CS in case of absence of consciousness disorders and any pathological changes in the local status, it is recommended to refuse to perform spine radiography. This is the strongest recommendation in clinical guidelines with high certainty of evidence [26]. With complicated SSCI of the LCS, some authors recommend MRI. For similar uncomplicated injuries, spine radiography or CT (depending on the conditions of medical care) are recommended [46]. CT without preliminary spine radiography is recommended for patients with injuries of the upper part of TS [39].

Electrophysiology studies (electromyography, electroneuromyography, evoked potentials) are recommended when indicated. Moreover, individual clinical guidelines for this recommendation indicate the highest strength and certainty of evidence [16, 17]. Regarding invasive examination methods, such as lumbar puncture, myelography or contrast-enhanced computed tomography as well as neck angiography, it is reported that they are recommended as a second stage of instrumental examination and

only for special indications. Particularly, for myelography (CT myelography), these are the difficulty of diagnosis in persons with complicated SSCI based on X-ray and CT findings in combination with the inability to perform MRI [38, 39, 42]. Additional instrumental examinations (ultrasound scan of internal organs, endoscopic procedures, etc.) are recommended if they are required to assess the physical status of the patient. It is true under preoperative preparation or in people with polytrauma [39, 42, 43]. In the case of surgical treatment of patients with SSCI, instrumental studies are recommended both at the pre-, intra-, and postoperative stages [41, 47]. The clinical guidelines give the strongest recommendation with low certainty of evidence. Some clinical guidelines also use it as a quality criterion [15, 16, 26].

It is recommended to consider separately clearing the SSCI diagnosis, especially in the CS, to stop immobilization. In patients with an isolated uncomplicated injury, the clearing of clinical diagnosis is recommended in the absence of any abnormalities of consciousness and pathological changes in local status. It is the strongest recommendation with high certainty of evidence. Nevertheless, in cases where the diagnosis cannot be clinically withdrawn due to complaints or pathological changes in the local status and in the presence of negative spine radiography or CT data, additional negative functional spine radiography or MRI data performed within 48 hours from the injury is enough [26].

Identification of the treatment stategy through the choice between nonoperative and surgical treatment is required in all patients with SSCI. This is the strongest recommendation with the highest certainty of evidence in domestic clinical guidelines. Speaking of this, experts agree that it is recommended to treat patients with uncomplicated stable injuries conservatively. As for patients with complicated or unstable injuries, it is recommended to treat them surgically. In this regard, the vertebral column stability is defined under the morphological characteristics of the injury. However, the classifications used for this purpose range not only depending on its localization, but also on the preferences of certain specialists [38, 43, 48–50]. For individual variants of injuries, contradictory opinions are expressed in terms of optimal treatment policies. This is suitable for fractures of the C2 odontoid process (type II) and for burst fractures of the thoracic and lumbar spine [51, 52].

If it is decided to perform surgical treatment, then decompression of neurovascular structures, open or closed reduction, spine stabilization and spinal fusion performed through anterior or posterior approach are recommended for patients with SSCI [43, 47, 49, 50, 52-58]. In case of complicated SSCI of the TS and LS, the surgery is a criterion for medical care quality in clinical guidelines [17]. If there is an open SSCI, surgical debridement with drainage and sampling for culturing is recommended. In case of dura mater defects, their closure is recommended. In case of combined SSCI, staged identification of operation extent is indicated according to the concepts of "Damage Control" [42, 55, 59–61]. The recommendations also reflect the application of minimally invasive surgery in SSCI. Nevertheless, such instructions often have a rather general character. They do not consider the morphology of an injury, as well as the setting of surgical care in case of SSCI (or they are not designed in the format of recommendation statements) [29, 56, 58, 62]. Generally, despite the large amount of literature devoted to various surgical techniques, there is a shortage of specific recommendations on the choice of the way to perform surgical procedures. The available opinions regarding the optimal approach, technique and extent of the operation are often contradictory.

According to the Russian standard of specialized emergency and urgent medical care for SSCI, spinal immobilization is indicated for all patients [34]. That said, it is not recommended for penetrating neck injuries [26]. The external immobilization of the neck or trunk is recommended for a long time, for the period of treatment. Furthermore, in some clinical guidelines, this is given with an indication of its highest strength with high certainty of evidence. It is used as a quality criterion [26, 33]. It is recommended to choose the external immobilization method depending on the characteristics of clinical manifestations or patient preferences. This is the strongest recommendation with high certainty of evidence [33]. Meanwhile, in patients with SSCI of the CS, in addition to the use of immobilizing bandages and orthotics, some authors recommend the use of halo devices and skeletal traction systems [52].

Regardless of the chosen treatment strategy (conservative or surgical), a number of additional therapeutic measures are recommended when providing medical care to patients with SSCI. It is recommended to provide resuscitation care aimed at maintaining vital functions [39, 42, 43, 62]. According to the standard of specialized medical care for SSCI, in all cases, the implementation of an anesthesia care is indicated [34]. A comprehensive treatment of pain with the use of medications of various modalities and additional analgesic techniques is recommended in patients with SSCI [57]. This is a quality criterion in clinical guidelines [33]. The following methods of vertebral augmentation are recommended for such patients when indicated: vertebroplasty, kyphoplasty and stentoplasty – the strongest recommendation in clinical guidelines with high certainty of evidence [33]. Besides to analgesic therapy, additional pharmacological treatment is recommended for SSCI [43]. This is the strongest recommendation with the highest certainty of evidence. It is also a criterion for medical care quality in clinical guidelines [13–16].

According to the specialized medical care standard for SSCI, prescription of glucocorticosteroids, H2 histamine antagonists and antimuscarinics, as well as infusion and transfusion therapy is indicated for all patients [34]. This is reflected in the clinical guidelines. Regarding the use of glucocorticosteroids, it should be noted separately that recommendations for pulse therapy in patients with SSCI in combination or without combination with gangliosides are spread quite widely today. Yet recently, in some domestic clinical guidelines, a

strong recommendation against their use has appeared. It is based on the evidence of the highest certainty [26].

Patients with spinal injury, especially with complicated SSCI of the CS, are recommended to take medication and physical measures to prevent thromboembolic complications. This is the strongest recommendation with the highest certainty of evidence [26]. Moreover, the administration of anticoagulants is used in clinical guidelines as a quality criterion [26, 33]. It is also recommended to implement anti-decubitus measures and physical therapy to prevent hypodynamic complications. According to the specialized medical care standard for SSCI, all patients are administered physical means of thromboprophylaxis [34].

From other drug treatment areas, sepsis prevention measures through rational antibacterial therapy, as well as control over the treatment of concomitant pathology, are recommended for patients with SSCI. It is separately noted that in the presence of osteoporosis, the administration of an appropriate therapeutic pattern is recommended [63]. This recommendation is used as a quality criterion for the provision of medical care in clinical guidelines. Its strength ranges, depending on the pharmacological agent, from medium to strong with average certainty of evidence [33].

A course of physiotherapy using treatment agents of various modalities in accordance with the requirements of the relevant standard is essential for all patients with SSCI [34]. Patients with vertebral fractures associated with osteoporosis are recommended to stay in bed for no more than 3 days; later, mobilization of these patients is necessary. This is the strongest recommendation with high certainty of evidence. It is also used as a quality criterion for the provision of medical care [33]. In case of complicated SSCI, these terms are extended, but no more than up to 6 months. On the other hand, there are recommendations for prolonged bed rest, even with uncomplicated SSCI [29]. Physical treatment is recommended for all mobilized patients [63]. This is the strongest recommendation in clinical guidelines with high certainty of evidence. It also acts as a quality criterion for the provision of medical care [33]. Nevertheless, according to some clinical guidelines, manual therapy is not recommended for patients with osteoporosis. This is the strongest recommendation given the high certainty of evidence [33]. If one or another surgical option is used in the early postoperative period, mobilization, physical loads limitation and rehabilitation treatment are recommended for patients with SSCI [53]. In the late and long-term postoperative periods, rehabilitation courses are recommended. Drawing up a program of the stage of rehabilitation treatment for SSCI is a criterion for medical care quality in clinical guidelines [13–16]. Moreover, in cases of complicated injuries of the TS and LS, it is recommended to include social and psychological counseling in this program [17]. It is separately recommended to control the patient's compliance with rehabilitation prescriptions.

At the outpatient treatment stage, repeated examinations with follow-up instrumental studies are recommended for patients with SSCI. Moreover, in some clinical guidelines, the criterion for medical care quality is the achievement of adequate fracture union [13]. In others, the criterion is the very fact of follow-up [17].

As for the methodology of developing recommendation statements, this issue was not covered in most of the papers reviewed. This information is given in the clinical guidelines. Nevertheless, it is almost identical from document to document. The information is insufficient in terms of clinical guidelines development, judging by its essential stages according to international guidelines [3, 64–67].

Discussion

According to the general consensus of international experts, the problem of clinical guidelines in spine care is far from being resolved [66, 68–70]. Recommendations for medical care offered in international clinical guidelines, as well as in Russian ones, in most cases do not have high strength. They are not based on evidence of high certainty. This explains their weak evidence base worldwide [71–76]. At the same time, cases where the evidence base is available and summarized in literature are not always reflected in Russian clinical guidelines. For example, the complicated SSCI of the CS has strong recommendations in the international clinical guidelines. They are based on the highest certainty of evidence for the use of International Spinal Cord Injury Basic Pain Data Set [77] and Spinal Cord Independence Measure III [78] to evaluate pain and physical function in such patients that are based on the highest certainty of evidence [79]. However, these scales are not referenced in the Russian clinical guidelines. The issues of nutritional therapy in people with complicated SSCI, which are given an important place in international clinical guidelines [80], are poorly covered in domestic guidelines. In international clinical guidelines, a recommendation of medium strength is given against the use of external immobilization in patients with SSCI of the TS and LS, with reference to evidence of medium certainty [81, 82]. Nevertheless, the reasonable doubts regarding the effectiveness of orthotics in SSCI have not been reflected in the Russian clinical guidelines, whereas prolonged bed rest is recommended without convincing evidence. The domestic clinical guidelines have not commented on the current global trend towards abolition of vertebral augmentation techniques (vertebroplasty, kyphoplasty, and stentoplasty) after the publication and meta-analysis of the outcomes of a number of randomized trials. These types of documents have shown no effectiveness of this technique [83]. Regarding the spinal fusion for burst fractures of the TS and LS, international clinical guidelines give a negative recommendation of the highest strength, based on evidence of the highest certainty. However, this evidence was also not reflected in the domestic clinical guidelines [84].

The problem of clinical guidelines for SSCI is aggravated by the fact that, despite the development of guidelines being based on systematic litera-

ture reviews published with a detailed description of the methodology and disclosure of conflicts of interest, even major international clinical guidelines sometimes deviate from international methodological manuals [64, 65], e.g., with no published protocol for literature review, limited strategies for finding evidence, rejection of generally accepted scales for evaluating the certainty of evidence and strength in the formulation of recommendation statements [76, 85, 86]. Methodological implementation of Russian clinical guidelines for SSCI is extremely poor. For the literature reviews underlying the recommendations, due to sparsely presented information, it is difficult to observe their systematic nature. The scales of recommendation strength and certainty of evidence used are contradictory [4]. For the recommendations being formulated and the strength of the recommendation as well as the certainty of evidence claimed for them, it is often difficult to observe the connection with the references. A declaration of a conflict of interest is not common.

Finally, another aspect of the problem of clinical guidelines is the insufficient consideration of the opinions of all stakeholders, such as clinicians, patients, health care managers and the developers of clinical guidelines themselves. This jeopardizes the practical applicability of clinical guidelines [67]. Russian clinical guidelines on SSCI have poor coverage of many issues that are of fundamental importance for a spine surgeon. For example, they do not address choice of the treatment strategy, its urgency, and the way of performing surgical procedures. Some clinically important subpopulations of patients with SSCI have not been considered, for example, with the so-called SCIWORA syndrome (Spinal Cord Injury without Radiographic Abnormality) [87]. Most of the recommendation statements do not consider the specialized medical care setting. Patient representatives are not included in the working groups on the design of clinical guidelines.

Conclusion

Therefore, the study of the documents forming the Russian recommendation base for the treatment of patients with SSCI has shown that they contain a wide range of diagnostic, therapeutic, rehabilitation and preventive recommendations. However, the currently available subject-specific clinical guidelines are not based on high certainty of evidence. The recommendations are largely subjective in nature, since they reflect the preferences of the authors. Thus, these recommendations do not conform to the work settings of not only multidisciplinary emergency hospitals, but in some cases even specialized departments or centers of emergency spine surgery. Thus, today there is an urgent need for guidance documents to be developed for Russian healthcare, of which the items would be based on the results of a comprehensive scientific analysis of the effectiveness of not only modern surgical techniques for the treatment of patients with spinal injuries but also the existing organizational patterns of medical care. This would allow making adequate decisions on the choice of strategy and treatment method for them.

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