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Регистрация и анализ осложнений в нейрохирургической клинике: проспективное наблюдательное исследование

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АННОТАЦИЯ

Обоснование. На сегодняшний день в медицине, в том числе в нейрохирургии, системное управление рисками для улучшения качества лечения является одной из наиболее актуальных задач. К ключевым индикаторам качества лечения в нейрохирургии относят характеристики его исходов, структуру и число осложнений.

Цель. Сформулировать наиболее краткое и в то же время полноценное определение понятия «осложнение» и разработать классификационную схему, позволяющую в максимальной степени учитывать осложнения у нейрохирургических пациентов.

Материалы и методы. Определение нейрохирургического осложнения было сформулировано как любое нежелательное непреднамеренное отклонение от идеального течения процесса лечения пациента с нейрохирургической патологией. В исследование были включены пациенты, оперированные по поводу нейрохирургической патологии в Центре нейрохирургии (Москва) с января 2019 по декабрь 2020 года. Для регистрации неблагоприятных событий была создана электронная база данных, куда вносили информацию обо всех нейрохирургических осложнениях.

Результаты. На основании анализа ежегодных отчётов лечебных и диагностических подразделений усреднённая частота развития осложнений составила 25–29 на 1000 операций (2,5–2,9%). Изучение нейрохирургических осложнений позволило структурировать общие параметры, имеющие ключевое значение для регистрации и анализа нейрохирургических осложнений, и сформулировать оригинальную классификационную схему, использование которой даёт возможность учесть большинство позиций, связанных с развитием осложнений и, соответственно, их анализом.

Заключение. На основании анализа данных литературы, серии дискуссий внутри сообщества нейрохирургов и собственного опыта мы предложили определение термина «нейрохирургическое осложнение» и подход к регистрации осложнений. С помощью разработанной классификационной схемы возможно получить объективные данные и проводить доказательный анализ, позволяющий оценить осложнения как результат применения системы контроля качества лечения путём получения максимально полного объёма данных об осложнениях в нейрохирургической клинике.

Ключевые слова: нейрохирургические осложнения; классификация осложнений; классификационная схема осложнений; неблагоприятные события.

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Registration and analysis of complications in the neurosurgical clinic

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ABSTRACT

BACKGROUND: Currently, in medicine, including neurosurgery, systemic risk management to improve treatment quality is one of the most urgent tasks. The key indicators of treatment quality in neurosurgery are the characteristics of its outcomes, structure, and number of complications.

OBJECTIVE: To formulate the most concise and complete definition of "complication" and develop a classification scheme that allows the maximum consideration of complications in patients with neurosurgical problems.

MATERIALS AND METHODS: A neurosurgical complication was defined as any unwanted, unintended deviation from the ideal course of the treatment process for a patient with neurosurgical pathology. The study included patients operated on for neurosurgical pathology at the Center for Neurosurgery (Moscow) from January 2019 to December 2020. To record all complications, an electronic database was created, where information about all neurosurgical complications was entered.

RESULTS. Based on the analysis of annual reports of medical and diagnostic departments, the average incidence of complications was 25–29 per 1000 operations (2.5–2.9%). The study of neurosurgical complications made it possible to determine the general parameters that are of key importance for the registration and analysis of neurosurgical complications and formulate an original classification scheme, and its use makes it possible to consider most of the factors associated with complications and, accordingly, their analysis.

CONCLUSION: In the literature analysis, a series of discussions within the neurosurgical community, and our experience, we proposed a definition of «neurosurgical complication» and an approach to registering complications. With the help of the proposed classification scheme, we could obtain objective data and conduct evidence-based analysis, which makes it possible to evaluate complications using a treatment quality control system by obtaining the most complete amount of data on complications in a neurosurgical clinic.

Keywords: neurosurgical complications; classification of complications; classification scheme of complications; adverse events

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BACKGROUND

Systemic risk management to improve the quality of treatment is one of the most urgent tasks in medicine, especially in neurosurgery. The key indicators of the quality of treatment in neurosurgery include the characteristics of its outcomes and the structure and number of complications. The advantages of using a single structured approach for analyzing these indicators are obvious. These advantages are due to the ability to impartially assess the probability of complications when using different surgical technologies, the ability to compare various surgical technologies in terms of the incidence of complications, the ability to create a reasonable prognosis for the development of complications, the ability to have a rational discussion with the patient about the risks and outcomes of treatment, the ability to conduct a comparative analysis of the treatment results in various clinics, entities, and regions, and the ability to generate one of the key sections of the specialized (neurosurgical) register.

In the registration and analysis of neurosurgical complications, the lack of unified terminological concepts approved by the professional community is the most significant problem. Currently, the concept of "complication" in neurosurgery has no clear definition, which gives rise to discussions about what is considered a complication of surgical treatment and what is its consequence. These inconsistencies do not allow an unequivocal comparison of adverse outcomes, complications, and consequences of surgical treatment [1].

Nowadays, it is practically impossible to comparatively analyze complications at different time intervals in one or more medical institutions due to the lack of a unified standardized system for registering complications. Furthermore, it is important to consider almost exclusively postoperative complications or complications directly related to surgical intervention when assessing the outcomes and quality of treatment, while complications can also potentially be associated with diagnostic procedures, pharmacotherapy, and the unfavorable course of concomitant diseases. Additionally, although the proportion of these complications is significantly less, they contribute to the efficiency of the diagnostic and treatment process, whether it is the preoperative period, the time of the immediate surgical procedure, or the postoperative course in the early and long-term periods.

These factors often lead to a situation where professionals underestimate the significance of a complication or deny its presence, using nonspecific terms such as "mild" or "primary" when describing an adverse event.

Thus, this study aimed to formulate the most concise and complete definition of the concept of "complication" and to develop a classification scheme that can be used to consider complications in neurosurgical patients to the fullest extent.

An analysis of the literature enabled us to identify a significant number of studies that contributed to the study of the problem of surgical complications and, at the same time, a wide variety of terminological concepts that define complications. Sokol and Wilson considered a complication as "any unwanted, unintended, and direct result of a surgery, affecting the patient, which would not have occurred if the surgery course had been as proper as could be reasonably expected." However, the authors admitted that the presentation of each adverse event as a complication is quite subjective [2].

Houkin et al. presented a different approach, discussed the term "adverse events," and characterized adverse events as any events that resulted in longer hospital stays than expected, all events requiring additional treatment, and all events leading to deficiency or deterioration (temporary or permanent) in patients, which occurred after the procedure, even if they were unavoidable due to the underlying disease. Thus, according to the authors, the designation of adverse events most probably corresponds to what we see through the patient's eyes [3]. In this regard, it is advisable to consider any adverse event as a complication without highlighting the possible "consequences" after neurosurgical care.

Martin et al. reported 10 criteria that should be considered in the report on complications, used to describe fully adverse events that occurred (Table 1) [4].

In the last decade, several complication classification schemes have been proposed for use in neurosurgery. However, they tended to focus on scoring specific complications [5]. In 1992, Clavien et al. published a classification of general surgery complications based on four gradations of their severity [6]. Terminologically, the authors divided all adverse events into complications, failure to achieve the treatment goal, and consequences. The authors defined "complication" as any unforeseen deviation from the normal course of the postoperative period, including asymptomatic complications such as arrhythmia or atelectasis. The authors considered "consequence" as a condition that inevitably arises after the surgery as a natural reaction (e.g., the inability to walk after amputation of the leg). Finally, "failure to achieve the goal of treatment" was defined as a condition where complications or adverse events did not occur, but the initial goal of the surgery (treatment) was not achieved (e.g., residual tumor after surgery). This work demonstrated an attempt to formally define the concept of "complication," highlighting it among other pathological conditions.

Later, Dindo et al. modified this classification by introducing a 5-level system with several sublevels, focusing primarily on the treatment type required when a complication occurs [7]. Furthermore, Lichterman defined "complication" in craniocerebral injury as "a pathological process secondary to the trauma of the brain and its covering. It is not always present but can occur under the influence of additional exogenous and endogenous factors" [8]. This definition can be considered applicable to other neurosurgical pathologies. However, since the pathophysiology of many complications has not been fully

Table 1. Criteria for describing the occurrence of an adverse event

№	Criteria	Requirements
1	Data collection	Pro- or retrospective nature of data collection
2	Duration of the follow-up period	The report describes the moment of the occurrence of complications (in the first 30 days after discharge or during the initial hospitalization)
3	Outpatient stage	Complications identified after discharge should be included in the analysis
4	Definition of complications	The report must contain at least one definition of a complication with its specific criteria
5	Lethal outcomes with causes indicated	The number of patients deceased in the postoperative period is recorded along with the cause of death
6	Incidence and total number of complications determined	The number of patients with complications and the total number of complications are recorded
7	Procedure (surgery)-specific complications included	
8	Complication severity assessment used	One of the classifications designed to assess the severity of complications (including major and minor) should be used
9	Data on the duration of hospitalization	The report contains information on the duration of stay in the clinic of patients with complications
10	Risk factors included in the analysis	Risk assessment (indicated tools for risk assessment)

studied, the problem of underestimating their consequences, even with the formal definition of complications, is significant for the patient and the clinic [1].

Furthermore, alternative approaches to the classification of complications have been reported. In 2001, Bonsanto et al. standardized common adverse postoperative events in neurosurgery and divided them into complicated postoperative period, neurosurgery-associated complications, and nonsurgical complications [9]. The authors adapted their complication classification system specifically for neurological diseases but could not account for the severity of each adverse outcome.

In 2009, Houkin et al. published the results of a study where adverse events were classified based on predictability and the possibility of their prevention [3]. In 2011, Landriel Ibañez et al., for the first time in neurosurgery, attempted to create a systemic specialized classification of complications. The authors defined any deviation from the normal course of the postoperative period within 30 days as a complication. They considered nonsurgical complications as adverse events not directly related to the surgery or surgical technique (e.g., pneumonia, gastrointestinal bleeding, and genitourinary system infections) [10]. However, this classification has not become widespread, and its potential universality has been subjected to evidence-based criticism in the professional community [1].

Furthermore, Gozal et al. proposed the classification of neurosurgical complications based on understanding the main causes of adverse events [5]. This complication scheme was developed based on the authors' previous work on morbidity in endovascular surgery. Adverse events were prospectively pooled for all neurosurgical procedures performed at their academic tertiary medical center over one year into five subgroups: reading errors, procedural errors, technical errors, estimation errors, and critical events. A total of 115 neurosurgical complications were detected and analyzed during the study period. Almost 50% of the complications were critical, and technical errors accounted for approximately one-third of all complications. Among the neurosurgical specialties, the number of complications recorded in vascular neurosurgery was the highest (36.5%), followed by those in the spine and peripheral nerves (21.7%), neurooncology (14.8%), craniocerebral injuries (13.9%), general neurosurgery (12.2%), and functional neurosurgery (0.9%).

MATERIALS AND METHODS

Study design

This was a prospective observational study.

Eligibility criteria and conditions

All patients hospitalized at the Center for Neurosurgery (Moscow) from January 2019 to December 2020 who had adverse events during hospitalization and in the postoperative period were included in this study.

Methods for assessing target indicators

Up to 10 thousand surgeries in all fields of neurosurgery are performed annually at the N. N. Burdenko National Medical Research Center for Neurosurgery, which makes the center a unique place for registration, structuring, and analysis of neurosurgical complications.

A neurosurgical complication was defined as any adverse unintended deviation from the ideal course of the treatment process for a patient with neurosurgical pathology. A

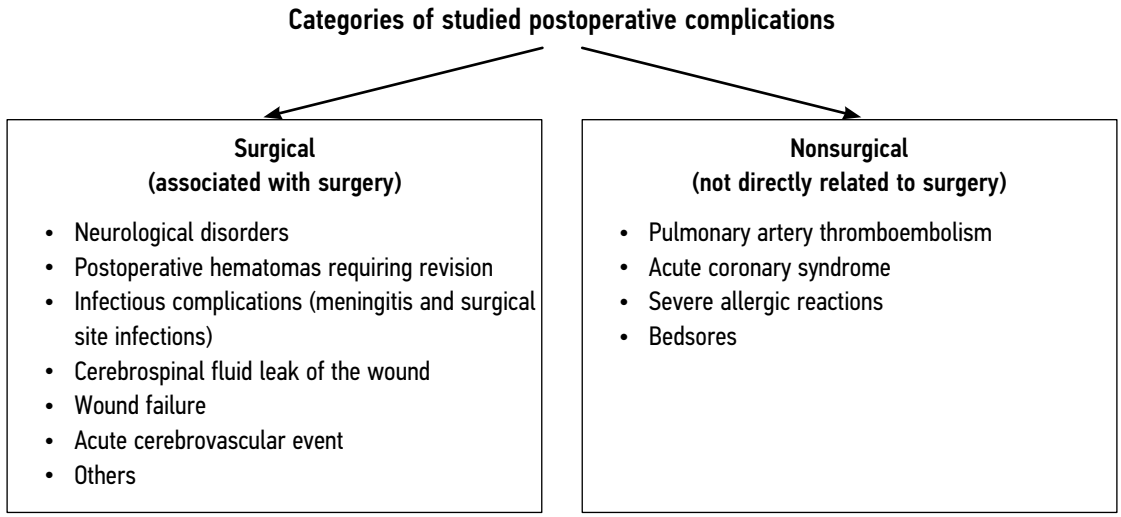

Fig. 1. Primary categories of studied complications

database was created to register complications, where employees entered all adverse events that occurred in the departments. At the initial stage, obvious adverse events arising during treatment were selected for registration, which were classified as surgical and nonsurgical (Fig. 1).

The staged implementation of the system for registering and analyzing complications included creation of a working group for assessment and analysis of complications, studying previous experience in registering complications, identification of the main groups of complications, and creation of a database on the web platform ("redcap"); collection and processing of data and identification of the advantages and disadvantages of the approach; preparation of reports, discussion of results, and forming their presentation; development of a definition and classification scheme for neurosurgical complications; and informatization.

Statistical analysis

Data collection was performed using a specialized clinical data management system REDCap. Quantitative indicators were analyzed using descriptive statistics tools. The distributions of categorical variables were presented as percentages, and those of continuous quantitative variables were presented as average values. Statistical hypothesis testing for differences between groups with and without complications was performed using the nonparametric Mann–Whitney test for continuous quantitative variables and the χ^2 test and Fisher's exact test for categorical variables. However, their results are not presented in this paper due to the small number of cases in the group of complications, the heterogeneity of their structure, and the impossibility of providing an acceptable statistical power of tests. Thus, we presented only point estimates.

RESULTS AND DISCUSSION

Study object

Patients with neurosurgical pathology who had complications during treatment were included in this study.

Primary study outcomes

The analysis of annual reports of medical and diagnostic units from 2019 to 2020 showed that the average complication rate was 25–29 per 1,000 surgeries (2.5%–2.9%). The ratio of the incidence of the main types of registered complications is shown in Fig. 2. The largest proportion of complications was represented by infectious processes (associated or nonassociated with surgical intervention), an increase in neurologic deficit, postoperative bleeding (hematoma), and cerebrospinal fluid leak.

Indirect signs of a complicated course were also considered when analyzing adverse events, which were

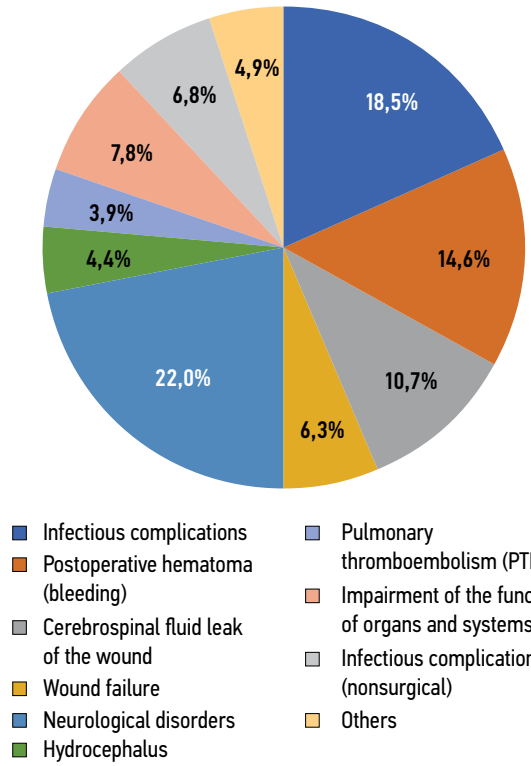

Fig. 2. The frequency ratio of the main types of complications studied.

Note. п/о — postoperative, ТЭЛА — pulmonary embolism.

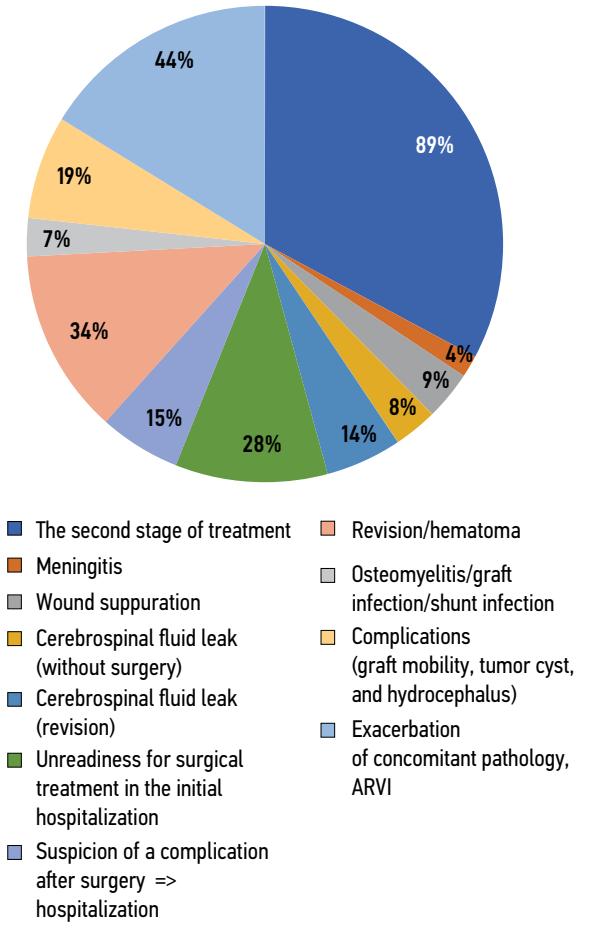

Fig. 3. Ratio of leading causes of readmissions.
Note. ОРВИ is an acute respiratory viral infection.

characterized, in particular, by the duration of the patient's stay in the hospital, repeated hospitalizations within 30 days (Fig. 3), and unscheduled transfers to the resuscitation and intensive care unit (ICU). The proportion of surgical patients with a longer hospital stay than planned was 28.9%–30.9%, and the proportion of patients with repeated hospitalizations was 2.9%–3.3%.

Unscheduled transfer from the clinical department to the ICU was one of the important indicators of the complicated course of the disease. In different years, this figure was 1.53%–1.69%. The most common causes of unscheduled transfers included depression of consciousness, neurologic deficit, intractable fluctuations in blood pressure, convulsive syndrome of varying severity, and inflammatory complications (meningitis, abscesses, and sepsis). The ratio of the frequency of the main reasons for transfers to the ICU is shown in Fig. 4.

The analysis of the above factors enabled us to structure the general parameters that are of key importance for the registration and analysis of neurosurgical complications. Neurosurgical complications can be defined as any adverse unintended deviation from the ideal course of the treatment process for a patient with neurosurgical pathology. This definition is quite brief but enables us to avoid conditional assumptions, such as the definition "an adverse, unintended and direct result of a surgery that affected the patient, which would not have happened if the surgery had been as good as possible," and has a sufficient degree of universality, in contrast to the definition "a pathological process secondary to the trauma of the brain and its covering. It is not always present but can occur under the influence of additional exogenous and endogenous factors" [1, 2, 8].

A preliminary analysis of the registered complications showed that, for a complete assessment of them from the viewpoint of quality and safety of the medical activity, it is not sufficient to consider only postoperative complications

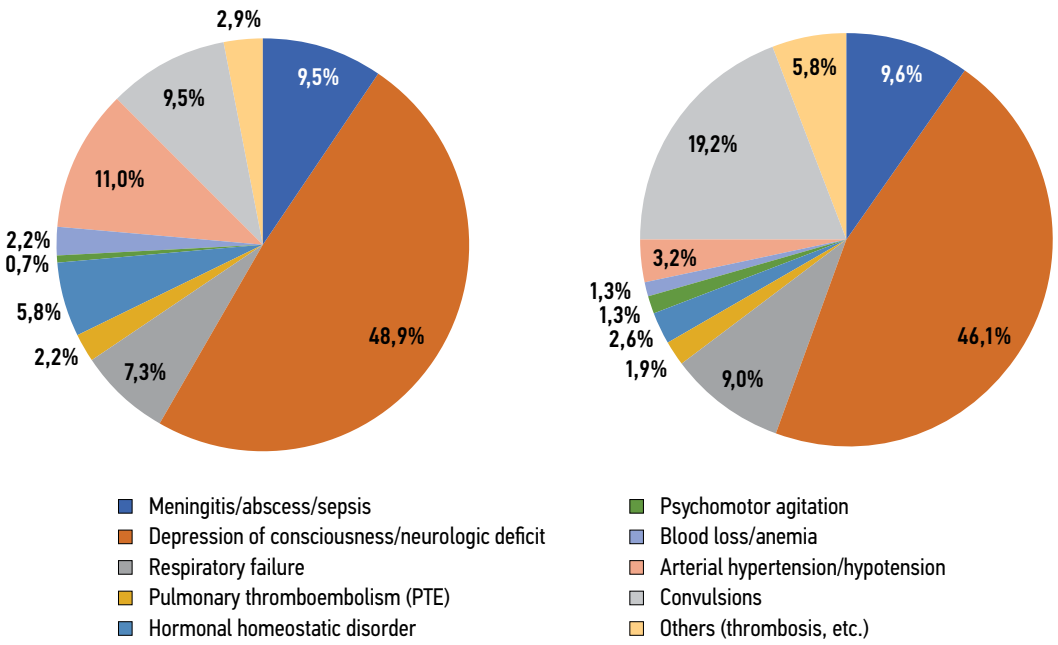

Fig. 4. The frequency ratio of the main causes of transfers to the ICU.
Note. ТЭЛА — pulmonary embolism.

or complications associated with a surgical procedure. The treatment process starts from the establishment of the primary diagnosis, which is currently performed mainly at the prehospital stage. Furthermore, in terms of time parameters, the patient passes through a series of successive stages: the prehospital stage, the preoperative period, the surgical intervention stage, and the postoperative period, including the early and late time periods. Complications can develop at each treatment stage, although the probability of their development and the frequency of registration are different. Additionally, each treatment stage is accompanied by a set of required planned or unscheduled invasive or noninvasive diagnostic procedures and therapeutic measures, which, in addition to the surgery itself, include other therapeutic methods, in particular pharmacotherapy, minor surgical procedures, and in some cases, radiation treatment or other methods. All these therapeutic effects can also be accompanied by the development of complications, which differ depending on the main method, and their complete list can be very extensive [1].

Surgical intervention is not limited exclusively to the main neurosurgical support but includes several anesthetic procedures (intubation, mechanical ventilation of the lungs, and regional or local anesthesia) and additional actions or manipulations (punctures of central or peripheral vessels, catheter insertion, venesection, and others), each of which may be the cause of certain adverse effects or complications.

A developed complication of varying severity has or may have an impact of varying degrees of significance on the course of the underlying process or concomitant disease, which may require a change in the standard treatment regimen and the use of additional techniques, including surgical interventions or their repetition, which may require the use of various forms (emergency or elective) and types (outpatient or inpatient) of medical care depending on the nature and the severity of complications.

When analyzing and structuring complications, the result of its development is one of the most important indicators, which is characterized by varying degrees of harm to the patient's health and life-threatening or fatal outcomes. Finally, it is necessary to provide a list of various diseases or pathological conditions that can lead to an adverse or unintentional deviation from the ideal treatment course to simplify the registration of complications. The list of these diseases includes the main organs and systems of the body and considers both pathogenetically similar and intercurrent conditions. The summation of all the listed factors and conditions enabled us to formulate an original classification scheme, making it possible to consider most of the positions associated with the development of complications and, accordingly, their analysis. A general view of the classification scheme is shown in Fig. 5.

This scheme seems unnecessarily complex and overloaded with unequal factors. However, considering the current level of digitalization and the state of the art of medical information systems, it involves the use of individual items in digital form by adding coding, which enables us to obtain a unique code for each patient in case of an appropriate directory and computer processing, considering the presence of a specific factor for each section of the classification, as

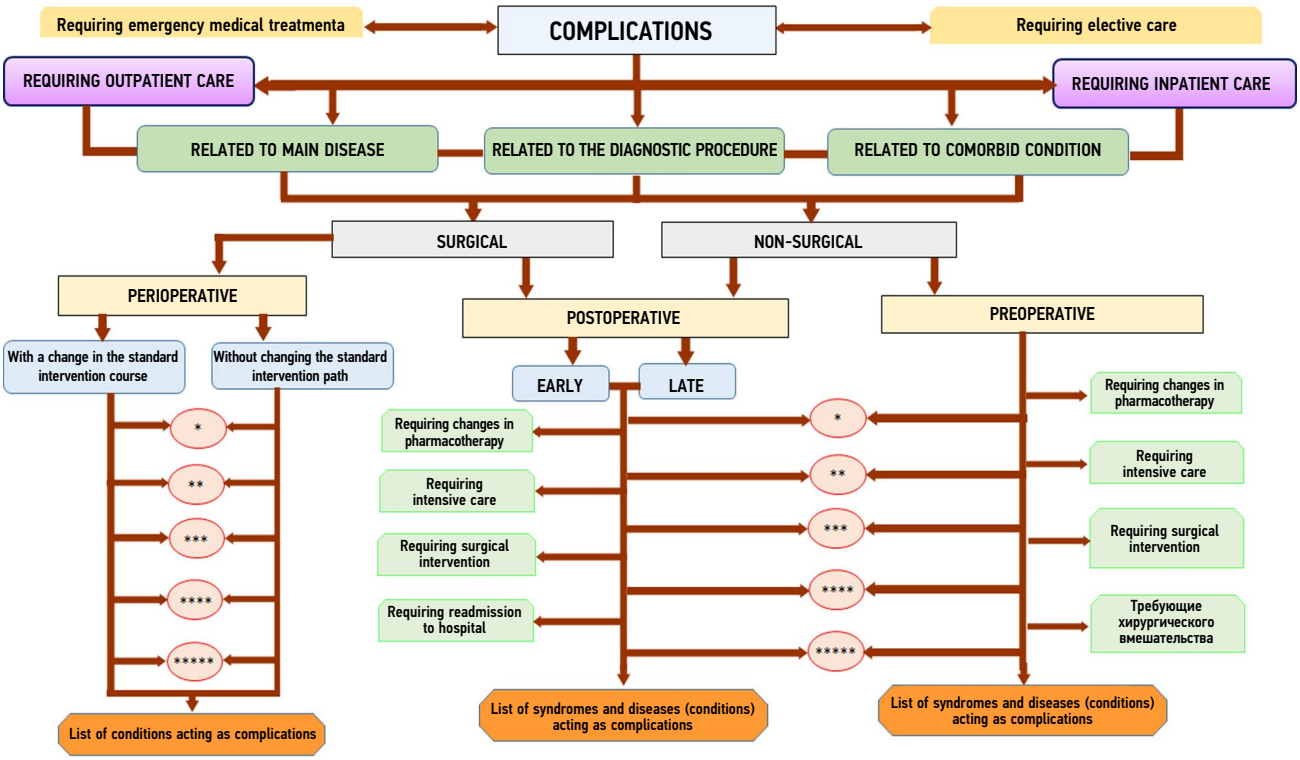

Fig. 5. Classification scheme for neurosurgical complications.

well as encrypting and decrypting this code during computer processing. The proposed coding of temporary, pathogenetic, therapeutic, organizational, and resulting factors in the analysis of complications is shown in Tables 2 and 3.

CONCLUSION

The analysis of the literature revealed a series of discussions in the neurosurgical community. Based on our own

Table 2. The list of factors that need to be taken into account in the development of complications, and their coding

Category designation	Type of complication
According to the surgical intervention	
I	Surgical (indicating the intervention/procedure code*)
II	Nonsurgical
According to the time of occurrence and development	
А	Preoperative
Б	Intraoperative
В	Postoperative early#
Г	Postoperative late##
According to the degree of harm to health	
*	Temporary harm to health requiring supplementary treatment
**	Temporary harm to health requiring hospitalization or its prolongation
***	Permanent harm to health
****	Life-threatening condition requiring resuscitation
*****	Death
According to the association with the pathological process	
α	Associated with underlying diseases
β	Associated with comorbidities
γ	Related to the diagnostic procedure
δ	Iatrogenic
According to the required type of medical care	
AMB	Requiring outpatient treatment
HOS	Requiring inpatient care
According to the required form of medical care	
EM	Requiring emergency medical assistance
PL	Requiring routine medical care
According to the nature of changes in the plan (scheme) of the treatment process	
1	Requiring changes in the standard course of surgical intervention
2	Not requiring changes in the standard course of surgical intervention
3	Requiring a change in the pharmacotherapy regimen
4	Requiring intensive therapy
5	Requiring surgical procedures
6	Requiring surgical intervention
7	Requiring repeated surgical intervention
8	Requiring readmission

Note. * — code of intervention (manipulation) in accordance with the order of the Ministry of Health of Russia N 804n of October 13, 2017 «On approval of the range of medical services», # — early postoperative complications (the first 7 days after surgery), ## — late postoperative complications (later than 7 days after surgery).

Table 3. List of conditions considered as complications in the neurosurgical clinic

Primary coding	Systemic lesions or group of complications	Secondary coding	List of syndromes and diseases (conditions)
a_	Nervous system		
		a1	Edema and swelling of the brain
		a2	Hemorrhagic stroke
		a_3	Ischemic stroke
		a_4	Transient ischemic attack
		a_5	Hemorrhage into the tumor
		a_6	Hematoma in the tumor bed
		a_7	Subdural hematoma
		a_8	Subdural hematoma
		a_9	Hydrocephalus
		a_10	Cerebrospinal fluid leak
		a_11	Meningitis
		a_12	Epileptic syndrome
		a_13	Emergence or increase in neurologic deficit, which was not predicted before surgery
		a_13.1	Transient disorders
		a_13.2	Persistent disorders
		a_14	Positional neuritis of the peripheral nerve
		...	
b_	Cardiovascular system		
		b_1	Acute coronary syndrome (myocardial ischemia)
		b_2	Myocardial infarction
		b_3	Stenosis or thrombosis of the main artery
		b_	Stenosis or thrombosis of the peripheral artery(s)
		b_4	Central vein thrombosis
		b_5	Thrombosis of peripheral veins
		...	
c_	Respiratory system		
		c_1	Nasal hemorrhage
		c_2	Tongue necrosis
		c_3	Tracheoesophageal fistula
		c_4	Lung atelectasis
		c_5	Pneumothorax
		c_6	Hydrothorax
		c_7	Pleurisy
d_	Digestive system		
		d_1	Bleeding from the esophagus veins
		d_2	Gastric hemorrhage
		d_3	Intestinal bleeding
		d_4	Perforation of the stomach (duodenum)
		d_5	Intestinal perforation
		d_6	Intestinal obstruction
		d_7	Acute biliary tract obstruction
		d_8	Acute (toxic) hepatitis

Table 3. Table ending

Primary coding	Systemic lesions or group of complications	Secondary coding	List of syndromes and diseases (conditions)
		d_7	Hepatic insufficiency
		...	
e_	Urinary system		
		e_1	Pyelonephritis
		e_2	Cystitis
		e_3	Acute urinary retention
		e_4	Injury of the urethra
		e_5	Renal failure
		e_6	Anuria
		...	
f_	Endocrine system		
		f_1	Electrolyte metabolism disorder
		f_2	Diabetes insipidus
		f_3	Decompensation of diabetes mellitus
		f_4	Adrenal insufficiency
		...	
g_	Sensory system		
		g_1	Positional trauma of the eye bulb
		g_2	Sympathetic inflammation of the eye bulb
		g_3	Visual impairment
		g_1	Necrosis of the concha of the auricle
		g_2	Hypacusia (anacousia)
		g_3	Hyposmia (anosmia)
		...	
h_	Immune system		
		h_1	Local allergic reactions
		h_2	Quincke's edema
		h_3	Bronchospasm
		h_4	Anaphylactic shock
		h_5	Graft (implant) rejection
i_	Complex of soft tissues and bone structures		
		i_1	Soft tissue necrosis
		i_2	External hemorrhage from soft tissues
		i_2	Hemorrhage from soft tissues with hematoma formation
		i_4	Positional soft tissue compression
		i_5	Soft tissue burn
		i_6	Osteomyelitis
		i_7	Bone graft resorption
		...	
k_	General complications		
		k_1	Sepsis
		k_2	Multiple organ failure
		...	

experience, we proposed a definition of the term "neurosurgical complication" and an approach to registering complications. A classification scheme was proposed to systematize the data on registered complications, which considers most of the factors in the development of complications in the neurosurgical clinic. One of the advantages of the proposed classification is the unification of recorded complications to obtain objective data and conduct evidence-based analysis, which enables us to evaluate complications because of the application of a treatment quality control system by obtaining a complete amount of data on complications in the neurosurgical clinic, regardless of the number of beds, region, amount of care provided, and its specialization. The system is not closed and can be supplemented, if necessary, with additional lines in any section. Furthermore, the expected possibility of its use in a medical information system based on relevant reference information makes the process of registering complications and their subsequent analysis much less labor-consuming.

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