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Epidemiology of tumors of the spinal cord and spine in Ukraine in 2000-2019

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of Medical Statistics, Romodanov Neurosurgery Institute, 32 Platona Mayborody St., Kyiv, 04050, Ukraine, e-mail: anna.neuro@gmail.com **Objective**. To determine the dynamics and state of neurosurgical care for tumors of the spinal cord and spine (TSCS) in Ukraine.

Materials and methods. The work is based on the analysis of hospitalizations and surgical treatment of patients with TSCS in neurosurgical departments of Ukraine in 2000-2019.

Results. In 2019, 1,325 patients with TSCS were hospitalized in neurosurgical departments of Ukraine, which is 2,3 times more than in 2000 (567), per 1 million population - almost 3 times (34,7 vs. 11, 6). Over 20 years, the number of operated patients increased 2,8 times (from 385 to 1079), per 1 million population - 3,6 times (from 7,9 to 28,3), there was an increase in surgical activity by 20% (from 67,9 to 81,4%), a decrease in the general and postoperative mortality - twice (from 2,6 to 1,2% and from 2,6 to 1,3% respectively).

Patients with TSCS account for 1,5% of all patients hospitalized in neurosurgical departments of Ukraine, 12,8% of all CNS neoplasms and 5,2% of all spinal pathology. Vertebral tumors account for 42,64% of all TSCS and extramedullary tumors have an incidence rate similar to vertebral tumors (42,64%), intramedullary tumors account for 14,72%.

In 2019, 74.4% more patients with extramedullary tumors were hospitalized than in 2000 (565 and 324 respectively), and 84.5% more were operated on (463 and 251 respectively). The rate of increase is even higher per 1 million population. In 2019, there were 14.8 hospitalizations per 1 million population for extramedullary tumors, which is 2.2 times greater than in 2000 (6,6 hospitalizations), and 12,1 operations, which is 2,4 times greater than in 2000 (5,1 operations).

In 2019, patients with intramedullary tumors were hospitalized 2,2 times more than in 2000. (195 and 89 respectively), were operated 2,5 times more (151 and 61 respectively). The rate of increase is even higher per 1 million population. In 2019, there were 5,1 hospitalizations for intramedullary tumors per 1 million population, which is 2,8 times greater than in 2000 (1,8 hospitalizations), and 4,0 operations, which is 3,2 times greater than in 2000. (1,2 operations).

In 2019, patients with vertebral tumors were hospitalized 3.7 times more than in 2000 (565 and 154 respectively), were operated 6,4 times more (465 and 73 respectively). The rate of increase is even higher per 1 million population. In 2019, there were 14,8 hospitalizations per 1 million population for vertebral tumors, which is 4,7 greater than in 2000 (3,1 hospitalizations), and 12,2 surgeries, which is 8,2 greater than in 2000 (1,5 operations).

C**onclusions.** The introduction of modern neuroimaging methods and advanced treatment methods into clinical practice has contributed to an increase in the number of hospitalizations and surgical interventions in TSCS.

Key words: tumors of the spinal cord and spine; extramedullary tumors; intramedullary tumors; vertebral tumors

Introduction

Tumors of the spinal cord and spine are quite rare pathology, they account for 0.5% of all newly diagnosed tumors and 5–12% of all primary neoplasms of the central nervous system (CNS) [1].

Tumors of the spinal cord and spine include a wide range of neoplasms with highly variable clinical symptoms and prognostic signs.

There are primary (develop from their own nerve tissue and spinal cord membranes) and secondary (metastasize from malignant tumors of other organs (lungs, stomach, kidneys, etc.).

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This work is licensed under a Creative Commons Attribution 4.0 International License https://creativecommons.org/licenses/by/4.0/ According to the topographic principle, tumors of the spinal cord and spine are divided into vertebral tumors, extradural and intradural. Among intradural neoplasms there are two subtypes: extramedullary and intramedullary tumors of the spinal cord (*Fig. 1*).

Primary spinal cord tumors account for 4 to 16% of all CNS tumors. The overall incidence is 0,74–2,50 per 100 thousand of population [2–4].

In adults, 88-90% of spinal cord tumors are extramedullary, intramedullary tumors are much less common (about 10-12%) [5].

In India in 2014, the incidence of all spinal tumors was 0,24 per 100 thousand population per year [6].

At Sher-i Kashmir Institute of Medical Sciences (India) a mortality rate of 3.2% was noted for tumors of the spinal cord and spine [6].

In Ukraine, the last study of the incidence of tumors of the spinal cord and spine (TSCS) was carried out in 2007. It covered the period 2001-2005. In 2005, the frequency of detection of TSCS in Ukraine was 4.2% of all neurosurgical spinal pathology. The frequency of intradural extramedullary tumors is 1,009 per 100 thousand population, intramedullary – 0,278 per 100 thousand population, vertebral tumors with neurological manifestations (primary, secondary) – 0,317 per 100 thousand population [7].

Objective: to determine the dynamics and state of neurosurgical care for tumors of the spinal cord and spine in Ukraine.

Materials and methods

The work is based on the analysis of cases of hospitalization and surgical treatment of patients with TSCS in neurosurgical departments of Ukraine in 2000-2019. For the period from 2014 to 2019, there is no data of departments located in the uncontrolled area.

Accounting of the activities of neurosurgical departments (beds) in Ukraine was carried out according to the form approved by the order of the Ministry of Health of Ukraine №295 of 24.11.94. The form regulates the accounting of TSCS by localization (extramedullary, intramedullary, vertebral tumors), but does not take into account the pathohistological structure of tumors.

Population data was obtained from the State Statistics Service of Ukraine [http://www.ukrstat.gov.ua/ operativ/operativ2016/ds/kn/kn_u/arh_kn2016_u.html]. The population of the Autonomous Republic of Crimea, the city of Sevastopol, as well as uncontrolled territories of Donetsk and Luhansk regions were not taken into account when calculating the indicators for 2014-2019.

Statistical analysis was carried out by means of time series analysis using the grouping method. Prognostic models have been made. The calculations were performed using the Microsoft Excel program.

Results and discussion

In 2019, 1,325 patients with TSCS were admitted to the neurosurgical departments of Ukraine, which is 2.3 times more than in 2000 (567), per 1 million population - almost three times more (34,7 and 11,6) . Over 20 years, the number of operated patients increased 2,8 times and in 2019 amounted to 1,079 people, per 1 million population – 3,6 times more(28,3). There was an increase in surgical activity by 20% (from 67,9 to 81,4%), a decrease in overall and postoperative mortality in two times (from 2,6 to 1,2% and from 2,6 to 1,3% respectively) **(Table. 1).**

During 20 years, the proportion of patients with TSCS in the structure of subjects hospitalized in neurosurgical departments of Ukraine increased from 0.7 to 1.5% (*Fig. 2*), in the structure of neurooncological pathology - from 10.0 to 12.8%. (*Fig. 3*) spinal pathology - from 3.2 to 5.2% (*Fig. 4*).

The introduction into clinical practice of modern methods of neuroimaging, in particular the availability of magnetic resonance imaging, contributed to an increase in the detection of pathological tumors of the spinal cord. Thus, the indicators of 2019 show that the proportion of spinal cord tumors accounted for 12,8% of all CNS tumors, which exceeds the corresponding indicators of other countries (4-8% depending on the region) [8].



Fig. 1. Classification of tumors of the spinal cord and spine by topographic type (https:// fcn-tmn.ru/опухоль-спинного-мозга)

28,3 1,3 1325 1,2 34,7 4 16 4 1079 *6102 81, 84,9 1,3 12 1,0 Q 37,2 1207 19 1422 *8102 31, 1169 Ь Ь 1,0 \sim ģ Q 14 1367 *702* 85, 35, 30, ò 1216 26,7 ø 15 1,2 1,1 吕 1031 *9102 31, 84, 23,1 1,9 1113 28,7 896 L0 1,9 17 21 *S102 80, 80,6 27,9 LC. 1,3 ω 6'0 1086 875 4 **2014*** 22, 80,1 0,2 1026 Q 13 1,0 \sim 1281 2013 28, 22, 19,6 24,7 893 1,2 00 6'0 1124 13 2012 79, 23,8 19,3 1088 2 ω 0,7 Q 0,7 883 1102 81 15,2 74,6 20,4 15 1,6 1,9 13 934 697 2010 Year 13,8 72,4 1,7 635 18 2,1 877 Ξ 19,1 600Z territory. 12,6 73,5 1,4 α 1,4 1 790 17,1 581 8002 uncontrolled 725 15,6 11,5 73,7 ω 1,5 1,5 11 534 200Z 72,7 11,7 2,2 2,1 752 547 16 12 16,1 900Z in the I 70,4 13,3 9,3 σ 9 622 438 1,4 1,4 2002 located 15,0 10,7 71,2 3,4 505 709 3,4 17 24 **700** departments 13,3 74,1 9,9 3,0 2,8 19 13 634 470 2003 2,0 659 506 in ∞ 16 2,4 10 13,7 76,8 2002 10, neurosurgical 74,6 2,7 2,5 634 13,1 473 9,8 17 12 **T00Z** 11,6 2,6 385 567 7,9 67.9 15 2,6 10 000Z Ъ population Hereinafter. * Without data Died after surgery, patients Postoperative mortality,% per 1 million million patients Indicato activity,% Ð Total mortality,% per 1 I peopl patients Hospitalized, Hospitalized | population Operated, Operated Surgical Died, I Note.

Table 1. Dynamics of indicators of treatment of patients with tumors of the spinal cord and spine in the neurosurgical network of Ukraine



Fig. 2. The structure of hospitalized patients with neurosurgical pathology in 2019 (according to data of departments of the neurosurgical network of Ukraine)



Fig. 3. The structure of hospitalized patients with neurooncological pathology in 2019 (according to data of departments of the neurosurgical network of Ukraine)



Fig. 4. The structure of hospitalized patients with spinal pathology in 2019 (according to data of departments of the neurosurgical network of Ukraine)



Fig. 5. Dynamics of the structure of hospitalized patients by the type of tumors of the spinal cord and spine in 2019 (according to data of departments of the neurosurgical network of Ukraine)



Fig. 6. The structure of hospitalized patients by the type of tumors of the spinal cord and spine in 2000 (A) and 2019 (B) (according to data of departments of the neurosurgical network of Ukraine)

Over the last 20 years, the structure of TSCS in Ukraine has changed - the proportion of vertebral tumors has increased from 27,2 to 42,6% and the proportion of extramedullary tumors has decreased from 57,1 to 42,6%. The proportion of intramedullary tumors in different years varied insignificantly (15-18%) with a slight tendency to decrease (*Fig. 5* and *Fig. 6*).

Extramedullary tumors

Intradural extramedullary tumors are the most familiar in terms of surgical approach for neurosurgeons. Unlike the neoplasms of other localizations, extramedullary tumors were easily diagnosed before the widespread introduction of magnetic resonance imaging using myelography, and later - computed tomography using myelography. The first case of successful surgical removal was described in 1888 [9]. In addition, extramedullary tumors often determine a characteristic neurological picture, which also greatly simplifies the topical diagnosis.

According to published data, extramedullary tumors are found in different countries in 4-10 cases per 1 million population per year, depending on the region and the general economic level. They account for 40-45% of all tumors of the spine and spinal cord. The average period for diagnosis varies from 10 to 14 months [10–12]. Tumors of the Schwann sheath (schwannomas and neurofibromas) and meningiomas are the most common types in this group (each occurs in almost 30% of cases) [13–15]. Myxopapillar ependymomas of terminal filament make up the majority of other tumors [16]. The rest (10–15%) tumors are rather rare neoplasms (metastases, paragangliomas, hemangioblastomas, lipomas, teratomas, hemangiopericytomas, etc.). In addition, this category includes other space occupying lesions that are not neoplastic in nature, namely arachnoid, dermoid and epidermoid cysts [17].

Analysis of our data revealed that in 2000–2006, the proportion of extramedullary tumors in Ukraine accounted for about 60% of all TSCS. However, since 2007, despite the increase in the absolute number of patients, their proportion has gradually decreased and the last 4 years was about 40% (see **Fig. 6**).

In 2019, 74,4% more patients with extramedullary tumors were hospitalized than in 2000 (565 and 324 respectively), and 84,5% more were operated on (463 and 251 respectively). Per 1 million population, the increase rate is even higher. In 2019, there were 14,8 hospitalizations per 1 million population for extramedullary tumors, which is 2,2 greater than in 2000 (6,6 hospitalizations), and 12,1 surgeries, which is 2,4 greater, than in 2000 (5,1 operations) (*Fig. 7*).

Surgical activity in extramedullary tumors in 2004 decreased slightly and stabilized at the level of about 80% for the next seven years. In 2011, there was an increase with subsequent stabilization over 10 years at the level of 82-86%. In general, over 20 years, surgical

activity in extramedullary tumors increased by only 5.8% in contrast to overall and postoperative mortality (by 33,3 and 63,9% respectively) **(Fig. 8).**

In 2019, interventions for extramedullary tumors were performed in 66 neurosurgical departments, in 4 - 2-4 operations per month (Spinal Department of Romodanov Neurosurgery Institute; Department of Spinal Neurosurgery of Mechnikov Dnipropetrovsk Regional Clinical Hospital; Center of Neurosurgery of Kyiv Regional Clinical Hospital; International Center of Neurosurgery), in 14 - 2-4 operations per quarter, in 48 - 1-7 interventions per year **(Table 2)**.

During the analyzed period, no fundamental changes in the treatment strategy of extramedullary tumors were noted. Considering that the vast majority of tumors of this localization are classified by the World Health Organization as Grade I, the optimal method of treatment in terms of evidence is the surgical removal [15]. A large number of foreign studies have shown a clear correlation between the level of preoperative neurological disorders and treatment outcomes and do not recommend long-term expectant management [16-20]. Careful preoperative planning,









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Number of operations per year	Number of departments		Operations performed				
	abs.	%	abs.	%			
21-50	4	6,0	137	29,6			
9–18	14	21,2	170	36,7			
1-7	48	72,8	156	33,7			
Total	66	100,0	463	100,0			

Table 2. Distribution of neurosurgical departments of Ukraine by the number of operations performed in 2019 on extramedullary tumors

active introduction of minimally invasive technologies promote early mobilization and rehabilitation of patients, allow to achieve high efficiency of surgical treatment of extramedullary tumors. However, both the above data and our clinical experience indicate that a large number of patients refuse radical removal of the tumor and prefer radiation therapy, which is de facto a backup method and in case of impossibility of surgical intervention is indicated.

Intramedullary tumors

Although intramedullary tumors of the spinal cord are a small part of CNS tumors, but in contrast to the neoplasms of other localizations in the last few decades there has been a significant change in tactical approaches to the treatment of this pathology. Thus, prior to the introduction into clinical practice of radiological studies using contrast in most cases, intramedullary tumors were diagnosed on an autopsy. Until the 1970s, the generally accepted approach was non-intervention and observing inevitable progress of neurological deficits. With the advent of the surgery microscope in the late 1970s, radical and complete removal of intramedullary tumors with good functional results began to appear in literature. Subsequently, the neurosurgical community adopted this approach [21]. The active use of computed tomography using myelography and high-field magnetic resonance imaging made it possible to verify anatomical boundaries and contributed to the introduction of more aggressive principles of microsurgery. Currently, adequate and thorough preoperative intervention planning, intraoperative neuromonitoring and rapid histopathological examination allow to achieve good clinical results and contribute to the expansion of indications for surgical treatment of intramedullary1 tumors [15].

Among intramedullary neoplasms, gliomas account for 80% (astrocytomas - from 60 to 70%, ependymomas - from 30 to 40%. Astrocytomas are more common in children, while ependymomas - in adults. Hemangioblastomas occupy the third place in frequency (from 2 up to 15%) [22].

For 20 years, the proportion of intramedullary tumors varied slightly and accounted for about 15% of all TSCS (see **Fig. 6**).

In 2019, 2,2 times more patients with intramedullary tumors were hospitalized than in 2000 (195 and 89 respectively), were operated – 2,5 times more (151 and 61). Per 1 million population, rate of increase is even higher. In 2019, there were 5.1 hospitalizations per 1 million population for intramedullary tumors, which is 2,8 times greater than in 2000 (1,8 hospitalizations), and 4,0 operations, which is 3,2 times greater than in 2000 (1,2 operations) **(Fig. 9).**

From 2000 to 2014, surgical activity in intramedullary tumors varied significantly (61,7–80,4%). Since 2014, there has been a stabilization of the indicator with a slight upward trend. In general, over 20 years, surgical activity in intramedullary tumors increased by 13%. When analyzing the change of total and postoperative mortality, no tendencies were revealed. During the study period, the values of indicators varied significantly, which is more likely due to the small number of surveillances. **(Fig. 10).**

In 2019, surgical interventions on intramedullary tumors were performed in 34 neurosurgical departments of Ukraine, in particular in 1 - 3 operations per month (Spinal Department of Romodanov Neurosurgery



Fig. 9. Dynamics of the absolute number and per 1 million population of hospitalized and operated patients with intramedullary tumors in Ukraine (according to data of the departments of the neurosurgical network)



Fig. 10. Dynamics of surgical activity, overall and postoperative mortality in intramedullary tumors (according to data of departments of the neurosurgical network of Ukraine)

Institute), in 4 - 2–4 operations per quarter, in 29 - 1–6 surgical interventions per year **(Table 3).**

The main purpose of surgery in intramedullary tumors is to prevent the progression of neurological deficits. Preservation, rather than restoration of neurological functions, is the most expected result after successful surgical treatment. In fact, significant improvement in severe or prolonged preoperative neurological deficits is rarely seen after technically successful surgical removal of intramedullary tumors. Postoperative complications are more likely in patients with severe preoperative neurological dysfunction. This creates a therapeutic window in which the risk of surgery is actually lower in patients with minimal or no objective neurological disorders. Thus, early clinical diagnosis and early surgical treatment are of crucial importance for the successful management of most patients with intramedullary tumors. It has been noted that posterior column deficiency is a common consequence of dorsal median myelotomy [23]. Certain neurological dysfunction often accompanies even successful surgical removal. However, this is not a limiting factor, since the expected functional disorders with continued growth of intramedullary tumors significantly exceed hypothetical postoperative neurological disorders [24]. All this contributes to an increase in the number of surgical interventions, as evidenced to a certain extent by our data.

Table 3. Distribution of neurosurgical departments
of Ukraine by number of operations performed in
2019 on intramedullary tumors

Number of operations per year	Number of departments		Performed operations	
	abs.	%	abs.	%
39	1	2,9	39	25,8
7–15	4	11,8	43	28,5
1-6	29	85,3	69	45,7
Total	34	100,0	151	100,0

Vertebral tumors

Vertebral tumors are the most pathohistologically heterogeneous group. According to a number of studies, the primary vertebral tumors, account for no more than 5% of the total number of vertebral tumors, which are verified in 2,5-8,5 cases per year, depending on the region. Most tumors (over 70%) are benign [25]. It is noted that for some reasons it is difficult to provide an epidemiologic characterization of primary vertebral tumors. Thus, hemangiomas occur in 10-14% of the adult population of the planet. In most cases, they do not require any therapeutic effect, therefore, in calculations, only patients whose primary vertebral tumors are associated with certain clinical symptoms and / or require specific treatment are most often taken into account.

The vast majority of vertebral tumors are secondary neoplastic processes that occur 40 times more often than primary vertebral tumors. Improvement of complex antitumor methods of treatment and palliative therapy progressively increase patients survival, but at the same time rise the incidence of distant metastases [26]. The spinal column ranks third in the frequency of metastatic spread after the lungs and liver - it accounts for more than 50% of bone metastases [27]. In 40-70% of patients with severe oncopathology metastatic spinal cord injury is registered, in 10-20% of them spinal cord compression. In more than 40% of cases, secondary neoplastic lesion of the spine is the first clinical manifestation of an active oncological process. All this, as well as the progressive and overall incidence of malignant neoplasms cause a significant increase in patients with secondary vertebral tumors that require specialized neurosurgical treatment [28, 29].

According to our data, in Ukraine in 2019 3.7 times more patients with vertebral tumors were hospitalized than in 2000 (565 and 154 respectively), were operated on- 6,4 times more (465 and 73 respectively). Per 1 million population, the rate of increase is even higher. In 2019, there were 14,8 hospitalizations for vertebral tumors per 1 million population, which is 4,7 greater than in 2000 (3,1 hospitalizations), and 12,2 surgeries, which is 8,2 greater, than in 2000 (1,5 operations) **(Fig. 11)**.

Surgical activity in vertebral tumors has been steadily increasing for 20 years. If in 2000 out of 100 specialized patients 47 were operated, in 2019 - 82, which is 74% more. Overall and postoperative mortality in 2000-2009 fluctuated significantly. In 2010, a decrease in the values of both indicators was noted and since then they have not risen above 2%. In general, over 20 years, the total mortality from vertebral tumors in the neurosurgical network of Ukraine decreased by 4.6 times (from 6,5 to 1,4%), postoperative - by 4,8 times (8,2 to 1,7%) (Fig. 12).

In 2019, surgery on vertebral tumors was performed in 44 neurosurgical departments of Ukraine, in particular in 2 departments 1-2 operations were performed per week (Spinal Department and Restorative Neurosurgery Department of Romodanov Neurosurgery Institute) in 11 -1-2 per month, in 31 - 1-10 surgeries per year (Table 4).

It is quite natural that the introduction of more advanced methods of treatment in the practice of health care also affects the surgical approach of primary and secondary vertebral tumors. Thus, the active use of percutaneous puncture cementoplasty methods by

Vertebral tumors

Table 4. Distribution of neurosurgical departments of Ukraine by the number of operations performed on vertebral tumors in 2019

Number of operations per year	Number of departments		Performed operations	
	abs.	%	abs.	abs.
43-90	2	4,5	133	28,6
11-28	11	25,0	195	41,9
1–10	31	70,5	137	29,5
Total	44	100,0	465	100,0

neurosurgeons has significantly increased the number of interventions in hemangiomas of the vertebral bodies that require surgical correction. Moreover, in accordance with international principles of care for patients with lesions of vertebral bodies, an increase in the number of cases of puncture biopsy was recorded, which is necessary both for planning the volume of open surgery and for assessing the advisability of radiation and chemotherapy [30].

18.0



Fig. 11. Dynamics of the absolute number and per 1 million population of hospitalized and operated patients with vertebral tumors in Ukraine (according to data of departments of the neurosurgical network)

Fig. 12. Dynamics of surgical activity, overall and postoperative mortality in vertebral tumors (according to data of departments of the neurosurgical network of Ukraine)

1800

1600

The use of endoscopic and minimally invasive techniques can significantly reduce surgical trauma and the volume of intraoperative blood loss, which is important for patients with advanced neoplastic process [31]. Improving the methods of adjuvant therapy, optimizing En-Bloc resections and the general focus on improving the quality of life of patients has led to a significant expansion of indications for surgical treatment and an increase of number of operations for vertebral tumors in the world and in Ukraine in particular [32, 33].

The last stage of our analysis was the creation of predictive models. Trends were constructed and on their basis the prognosis for 3 years concerning the number of hospitalizations of patients with TSCS was defined **(Fig. 13).** The number of patients with extramedullary tumors has increased by 74.4% for 20 years and according to our prognosis with a probability of 80.5% in 2022 will be about 700. Patients with intramedullary tumors were hospitalized 2,2 times more than in 2000. With 81,5% confidence in 3 years the number of such patients will be about 200. The rate of increase of hospitalizations of patients with vertebral tumors is high. Thus, in 2019 there were 3,7 times more of such patients than in 2000. With 96.6% confidence there will be about 670 in 2022.

Since the coverage of neurosurgical departments that provide information about their activities is almost 100%, it can be assumed that the data presented by us indicate the frequency of detection of TSCS in Ukraine. However, we admit that these data are not accurate, since, firstly, there is no information about which tumors were detected initially, which patients were re-hospitalized. Secondly, some patients with TSCS could be treated in radiosurgical clinics and orthopedic hospitals in Ukraine or abroad.

Conclusions

The introduction of modern methods of neuroimaging and advanced methods of treatment in clinical practice contributed to an increase in the number of hospitalizations and surgeries for tumors of the spinal cord and spine. The highest rate of increase was observed in vertebral tumors, the lowest - in extramedullary tumors.

The largest number of operations for tumors of spinal cord and spine in 2019 was performed in the Department of Spinal Cord and Spine Pathology of the Institute of Neurosurgery named after Acad. A.P. Romodanov, Ukraine (179, that is 15 operations per month).

While maintaining the current trends, the number of patients hospitalized with tumors of spinal cord and spine in neurosurgical departments of Ukraine in 2022 will be about 1570 people.



Fig. 13. Dynamics of hospitalization of patients with tumors of the spinal cord and spine in neurosurgical departments of Ukraine with the construction of trend lines and the prognosis for 3 years

Disclosure

Conflict of interest

The authors declare no conflict of interest. *Ethical norms*

The study did not use personal data of patients, therefore, the approval of the ethics committee was not required.

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