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THE RESULTS OF EXPERIMENTAL COMPUTER MODELING IN STABILIZATION OF TRANSPEDICULAR SYSTEMS USED IN THE SURGICAL TREATMENT OF VARIOUS PATHOLOGIES OF THE SPINE

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The proposed method was experimentally modeled using the Solid Works computer program and put into practice in 32 patients aged 13–65 years in the period 2014–2018, with various pathologies of the spine. Of these, 22 (68.75 %) are female, 10 (31.25 %) are male. The patients were operated with transpedicular systems of various configurations. To prevent spontaneous displacement of the screws in the long-term postoperative period, a technique was proposed for creating an additional support point by conducting a transverse connector through a transverse hole made in the spinous process of the vertebra. 2 situations were considered. In the first case, a fixed vertebra with a classically drawn transverse connector and the applied driving forces of pulling the screws out of the vertebral body in eight different directions. The second case was similar to the first one with a difference in conducting the connector through the spinous process of the vertebra. In both groups, the displacement distance increases with an increase in the angle of the vector of the applied force. The force for the screws to exit the channel was 26.561 N/mm^2 (MPa). In the second case, it was 31.095 N/mm^2 (MPa). The difference was 5 N/mm^2. The method of creating an additional support point for transpedicular systems by passing a transverse connector through the spinous process of the vertebra, a statically proven method, increases the stability of transpedicular systems.

Keywords: loosening of the implant, fixation of the transpedicular screw, loosening of the transpedicular screw, spinal surgery.

Т.Я. Джалілов

РЕЗУЛЬТАТИ ЕКСПЕРИМЕНТАЛЬНОГО КОМПЬЮТЕРНОГО МОДЕЛЮВАННЯ ДЛЯ СТАБІЛІЗАЦІЇ ТРАНСПЕДИКУЛЯРНИХ СИСТЕМ, ЯКІ ЗАСТОСОВУЮТЬСЯ ПРИ ХІРУРГІЧНОМУ ЛІКУВАННІ РІЗНИХ ПАТОЛОГІЙ ХРЕБТА

Запропонований метод експериментально змодельовано за допомогою комп'ютерної програми Solid Works і впроваджено в практику у 32 хворих у віці 13–65 років в період 2014–2018 років, з різними патологіями хребта. З них 22 (68,75%) жіночої, 10 (31,25%) чоловічої статі. Хворі були оперовані транспедикулярного системами різної компоновки. Для профілактики самовільного зміщення гвинтів у віддаленому післяопераційному періоді була запропонована методика створення додаткової точки опори шляхом проведення поперечного коннектора через поперечний отвір, проброблений в остистому відростку хребця. Були розглянуті 2 ситуації. У першому випадку фіксований хребець з класично проведеним поперечним коннектором і застосовані рушійні сили витягування гвинтів з тіла хребця в восьми різних напрямках. Другий випадок був аналогічний першому з різницею в проведенні коннектора через остистий відросток хребця. В обох групах відстань зсуву збільшується зі збільшенням кута вектора застосовуваної сили. Сила для виходу гвинтів з каналу була 26.561 N/mm^2 (MPa). У другому випадку, вона склала 31.095N/mm^2 (MPa). Різниця була 5 N/mm^2. Метод створення додаткової точки опори транспедикулярним системам шляхом проведення поперечного коннектора через остистий відросток хребця, статично доведений метод, збільшує стабільність транспедикулярних систем.

Ключові слова: розхитування імпланта, фіксація транспедикулярного гвинта, розхитування транспедикулярного гвинта, операція на хребті.

This work is a fragment of a doctoral dissertation: "Optimization of the use of polysegmental correcting transpedicular systems in the surgical treatment of deformities and degenerative dystrophic processes of the spine".

In 1959, G. G. Boucher was the first to conduct a transpedicular fixator into the vertebral body through the leg, describing the possibility of fixing the vertebra [2].

With the introduction of transpedicular fixation into orthopedic practice, the stability of the fixation of the vertebral segment significantly increased, which made it possible to increase the correction of deformities that appeared in various pathologies. The increase in stability led to an increase in the metal-bone conflict due to the different densities of these substances. Patients may experience weakening and displacement of the implant during implantation of pedicular screw systems, which leads to the appearance of pain syndrome and loss of the received correction. So, in 2014, Abul Kasim and Olin studied 1,666 dislocations of the pedicular screw in 81 patients suffering from idiopathic scoliosis and patients were examined several times during 2 years by low-dose computed tomography, and published the results. 26 (32 %) patients showed signs of loosening of one or more screws, a maximum of 3 screws. Men showed signs of weakening in 57 %, and women in 27 %. One patient with a weakened L4 vertebra screw had a neurological deficit. Out of 26 patients with signs of weakening, 5 patients reported a shift in the lumbar region [1]

For successful and long-term fixation of metal implants inside the bones, a sufficiently dense bone structure is required, non-removable tightening metal elements that hold the rods in rigid and durable structures. Thus, with the classical use of screws, there are three factors for supporting the implant in the bone:

1. The spongy material of the vertebral body, which is the only area of contact between the vertebrae and the metal implant;
2. Tension elements of metal screws and metal rods for fixing screws;
3. Cross connections between the rods to reduce the movements of the rod when the patient moves and again ensure the metal-to-metal contact.

Thus, the point of contact of metal with bone in transpedicular systems is only the threaded part of very hard titanium screws and a fairly soft spongy bone tissue of the vertebral body. The second bone fulcrum of this system has not yet existed.

As a rule, metal and bone are always in conflict during the implantation of metals due to their different densities, which leads to atrophy in the bone due to metal pressure, and can lead to weakening and dislocation of the pedicular screws 3-6 months after surgery. Clinically, this condition is manifested by pain, inflammation, loss of correction in the case of deformation and, finally, in the appearance of a structure under the skin.

In the literature, we have found very few examples of the application of the Solid Works industrial program in the study of bone implants. For example, Zhuang Cui et al. in 2012 used this program to study the operation of subthar arthroereisis [3]. In 2015, Yuichiro Abe et al. We used the 3D-FEM program to study the corrective forces during the correction of the scoliotic arch. It was determined that the screws on the concave side of the curvature experience a greater effect of corrective forces than on the convex side (305.1 N on the concave side, 86.4 N on the convex side of the arc). It was recommended to carry out relaxation of soft and hard tissues to prevent the exit of screws from the vertebrae and does not seek to increase the rigidity of the structure [14]. In 2010, Eric Wagnac et al. We published works on the use of the 3D-FEM program to measure the exit force of screws from the vertebrae and showed it in the range of 500–660N.[4] It should be noted that the FEM program is designed to perform express calculations of solid-state objects in the COMPASS-3D system. In 2020, Laura Marie-Hardy et al. after studying the problem of the exit of screws, we showed that 9.6 % of them occur in the thoracic region and the risk factors are the use of rods with cobalt-chromium composition, osteoporosis, enlarged lumbar lordosis, etc.[7]

The purpose of the study was to describe a new technique for preventing the weakening of transpedicular screws and to demonstrate the results of computer modeling.

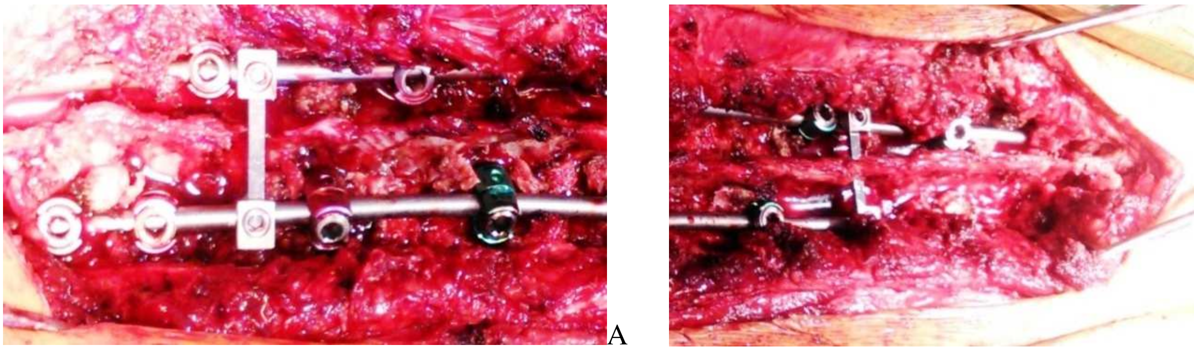
Materials and methods. The study was conducted in the Department of Adult Orthopedics of the Azerbaijan Research Institute of Traumatology and Orthopedics in 2014–2018.

For the experimental testing of the proposed method, the industrial program SolidWorks (France) was used, and a static analysis of two situations was carried out. In the first case, the transverse connector was carried out in the classical way, in the second case through a transverse hole made in the spinous process of the computer model. In each of the variants, the computer pulling of the screws from the vertebrae was carried out at angles 0°,5°,10°,20°,30°,40°,45°,60° since the location of the vertebrae in different parts of the spine is oriented relative to the planes in different ways.

The proposed method was put into practice by the author; the technique of application was created and described. Before using the method in humans, she passed through the ethics committee at the Medical University of Azerbaijan. (Protocol No. 15, 16.10.2020). The technique was used in 32 patients with various spinal pathologies (scoliosis, vertebral fractures and lumbar stenosis). Of these, 22 (68.75 %) are female, 10 (31.25 %) are male aged from 13 to 65 years.

Among patients with idiopathic scoliosis of the spine, 10 (45.4 %) patients were with grade III according to Chaklin, 12 (54.4 %) of grade IV severity. Vertebral osteotomies were not used for surgical correction of severe rigid deformities, which increased the stress falling on the implants and the risks of implant failure. Patients with vertebral fractures consisted of fractures of both columns (according to Denis), with mechanical instability.

Among the patients with spinal stenosis, 3 (75 %) were with anterior spondylolisthesis of the lumbar vertebrae of the 2nd and 3rd degrees with radicular symptoms. All of them were able to perform a complete reduction of the displaced vertebra, which increased the load falling on the implants and could cause their failure in the long-term postoperative period (Fig. 1).

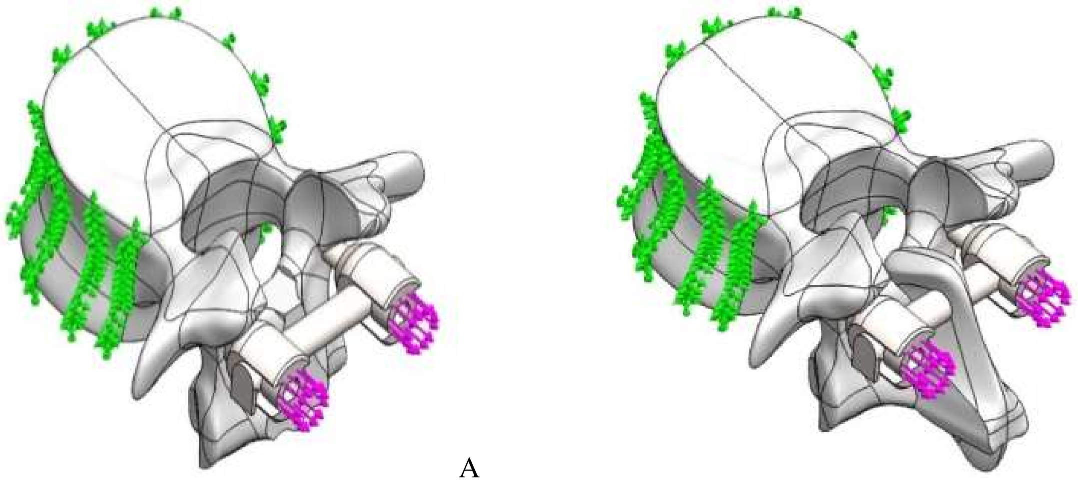


A B

Fig. 1. Comparison of transverse connectors applying: A – the classical conduct of the transverse connector by resection of the spinous process; B – the proposed method of conducting the connector through the hole made in the spinous process

Only 1 patient with scoliosis was re-operated to eliminate the residual pelvic tilt and 1 patient with scoliosis to eliminate the sagittal imbalance. A year after the main operations, the transverse connectors inside the spinous processes were studied. The connectors and the opening of the spinous process were not broken or loosened.

Results of the study and their discussion. The first situation with the control group – in it, a transverse connector was carried out at the site of the resected spinous vertebra. A three-plane model was created with the specified bone density (1800 kg/m^3), modulus of elasticity (1.8 e+010 N/m^2) and screw sizes (14.15). The program applied two opposite increasing forces (350N) to the vertebral body and to the screws directed 180° to each other in the horizontal plane. The force at which the failure of the screws occurred and their exit from the channel in the vertebral body was recorded. This was a force of 26.561 N/mm^2 (MPa) (fig. 2).



A B

Fig. 2. 3d models of experimental situations. A) the connector is carried out in the classical way. B) the connector is carried out in the proposed way

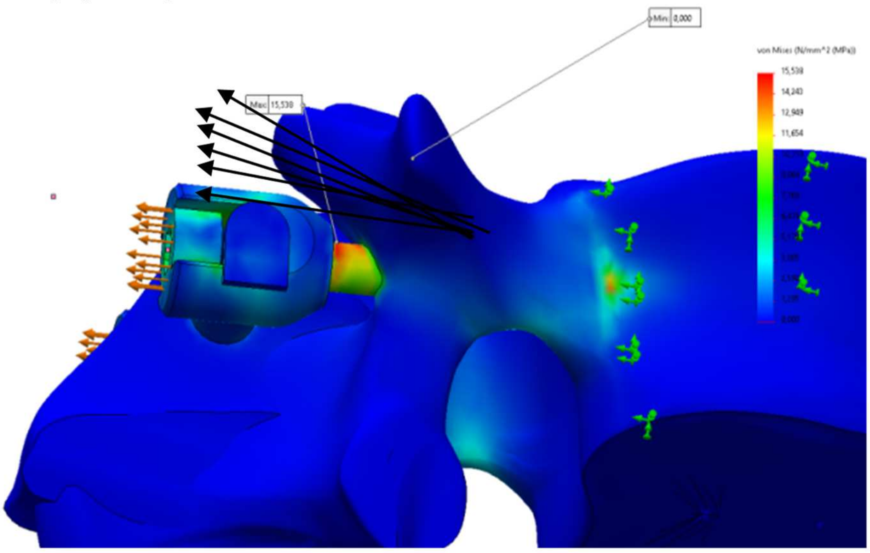


Fig. 3. Directions and values of the vectors of the force acting on the screw head. 8 cases separately from 0°, 5°,10°, 20°, 30°, 40°, 45°, 60 °.

The second control situation was created as our method was conceived; the transverse connector was passed through a hole made in the spinous process. In the second case, when performing similar manipulations with pulling the screws, the screws came out of the channel at a force of 31.095 N/mm^2 (MPa). The difference of 5 N/mm^2 is sufficiently evidence-based for the effectiveness of the method. Also, to assess the force load of the screw heads and different parts of the bone structure of the vertebra, we measured the distance of the fragments from the destruction of the screw-vertebra complex under the action of this force program. We decided to measure these indicators in eight cases and conduct statistical data processing. In the first case, the angle between the pulling and holding forces is 0. In subsequent versions, this angle is equal to 5°,10°,20°,30°,40°,45°, 60° since the location of the vertebrae in different parts of the spine is oriented relative to the planes in different ways. (fig. 3).

As can be seen from fig. 3, the indicators of displacement of fragments in both groups grow at almost the same rate in proportion to the angle of the force vector.

8 cases of displacement of fragments in each group were analyzed (table.1)

Table 1

Displacement indicators (mm) in both groups

	Group	
	1	2
Quantity	8	8
Mean	0.145	0.099
The standard error of the mean	0.037	0.025
Minimum	0.006	0.005
Maximum	0.295	0.201
Median	0.148	0.101

The results of statistical processing according to two dependent criteria: they indicate a statistically significant difference in the digital indicators in the two groups (table 2).

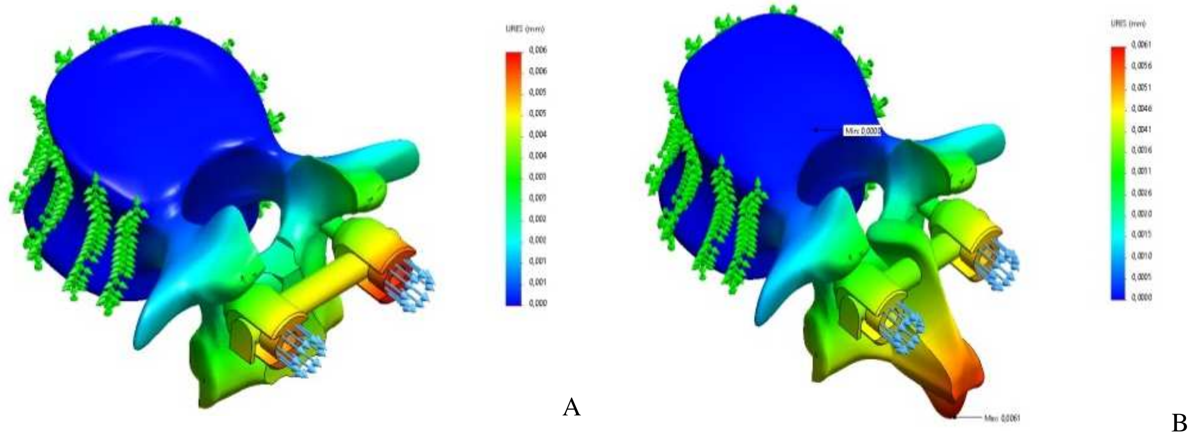
Table 2

Statistical ranks

		N	Average rank	Sum of ranks
	Negative grades	8a	4.50	36.00
	Positive ranks	0b	0.00	0.00
	Matching observations	0c		
	Total	8		
a. Maximum offset (mm) – gr2 < Maximum offset (mm) – gr1				
b. Maximum offset (mm) – gr2 > Maximum offset (mm) – gr1				
c. Maximum offset (mm) – gr2 = Maximum offset (mm) – gr1				
Statistical criteria [a]				
	Maximum offset (mm) – gr2 – Maximum offset (mm) – gr1			
Z	-2.521b			
Asimp. value. (double-sided)	0.012			
a. Wilcoxon's criterion of sign ranks				
b. Based on positive ranks.				

As can be seen from table 2, there are only 8 negative ranks, i.e. cases when the bias in group 2 is less than in the first group, which was required to be proved. There are no unfavorable results, i.e. positive ranks. The displacement distances of fragments in the second group, regardless of the angle of the thrust vector, significantly decrease (mean 0.099) compared to the first group (0.145) p=0.012. In both groups, the mixing distance increases with an increase in the angle of the vector of the applied force.

The program has given numerical and illustrative values in which the maximum indicators are colored red. (fig. 4).



A B

Fig. 4. Analysis of the distance of mixing of fragments in case of violation of the integrity of the bone at an angle of extension of 0°. A – in the classical version of the passage of the transverse element. B – with the proposed option of passing through the spinous process.

As can be seen from fig. 4, the screw heads experience the maximum force and when the bone or screws are destroyed, they will experience the maximum separation of fragments. This zone is colored red by the program. In the second case, when the connector passes through the process, the screw heads are already colored yellow, and begin to experience less force, and the tip of the spinous process is colored red, which proves the supportability of the spinous process and the effectiveness of the method. At the same time, the maximum force from the screw heads to the spinous process is mixed, and the screw heads are better protected and less susceptible to destructive forces.

The method was applied in 32 patients with various pathologies of the spine. No complications associated with the proposed method were observed in the postoperative period. We think that the technology does not require the use of any special tools and skills, so it can be easily used. The proposed method of conducting cross-links of spinal systems creates an additional reference point for the pedicular helical system, but the number of cross-links passing through the spinous processes can be increased individually, depending on the pathology and bone density.

Patients may experience weakening and displacement of the implant during implantation of pedicular screw systems. In 2014, Mavrogenis et al. considered that the weakening occurs due to the rigidity of the rods, proposed using rods made of polyethyletheretorketon (PEEK) and applied it in practice [10]. Since PEEK is more elastic and resistant to body tissues, it has a great potential for use in the future. Kang et al. they also spread information about the use of polymethylmethacrylate cement for more stable support of screws in patients with osteoporosis [6]. In 2016, Lehitl and co-authors compared the use of a solid transpedicular screw supplemented with high-viscosity cement, and a fenestrated screw with cement and special pulling mechanisms for a total of 54 osteoporotic human corpses. As a result, the screws with a solid leg and high-viscosity cement during separation tests provide screw stability comparable to more expensive fenestered screws, and it was recommended to use 1 ml of cement for the thoracic region and 3 ml of cement for the lumbar spine [8]. Leitner and co-authors associate the weakening of the pedicular screw with a chronic infection [9]. Ohe M. et al. provide information on the use of pedicular screws with a thin surface coating of hydroxyapatite in patients with osteoporosis [12]. In 2018, Fu J. and the co-authors report that in order to solve the problem in patients with osteoporosis and partially solve this problem, it is necessary to use new expensive expandable pedicular screws. [5].

In 2018, Mizuno T. and the co-authors tested the cross-link model and the cross-bar model for stability and proved that the cross-link model is more stable than the cross-bar model [11]. The authors claim that the operation with a pedicular screw does not provide sufficient stability during torsion. This leads to pseudoarthrosis, weakening of the pedicular screws and, ultimately, to damage to the implant. They use a 6-axis material testing machine. As samples, they prepared an intact model, a damaged model, a model with cross rods and a model with cross ties. They measured the range of motion during bending and rotation tests.

Conclusion

The proposed methods of increasing the stability of screws due to additional cementation do not create an additional fulcrum of the system, only increase the stability of the already known ones and are associated with economic costs for cement, etc.The method of creating an additional fulcrum for transpedicular systems by conducting a transverse connector through the spinous process of the vertebra creates an additional fulcrum that is not anatomically connected with the screw channel. Experimental modeling of the situation can be reliably performed using the SolidWorks program. The results of the study were applied clinically, no long-term clinical complications were detected. The method can be considered statically proven (the difference between the groups is 5 N/mm2) it gives an increase in the stability of transpedicular systems. The method is quite simple in execution and does not require any additional economic costs.

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DAILY PROFILE OF BLOOD PRESSURE AND STATE OF COGNITIVE FUNCTION IN PATIENTS WITH ARTERIAL HYPERTENSION

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The article is devoted to the problem of arterial hypertension as the most important risk factor for the development of cognitive impairment. In 39 and 32 patients with arterial hypertension with cognitive dysfunctions, a significant impairment of the arterial pressure daily profile by systolic and diastolic blood pressure was found, against 19 and 16 of patients with similar indices in the group without cognitive impairment. With the decrease of the MoCA-test scores, there were correlations of the daily index of systolic and diastolic blood pressure and, as well as indices of systolic blood pressure variability per day and night. We have found that patients with hypertonic disease of stage II with the presence of cognitive impairment are characterized by a significant prevalence of the pathological types of arterial pressure daily profile."Non-dipper" and "Night-peaker" (46.2 % and 19.2 %, respectively).

Key words: hypertonic disease, blood pressure monitoring, cognitive impairment.

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ДОБОВИЙ ПРОФІЛЬ АРТЕРІАЛЬНОГО ТИСКУ ТА СТАН КОГНІТИВНОЇ ФУНКЦІЇ У ПАЦІЄНТІВ З АРТЕРІАЛЬНОЮ ГІПЕРТЕНЗІЄЮ

Стаття присвячена проблемі артеріальної гіпертензії як найважливішому фактору ризику розвитку когнітивних порушень. У 39 і 32 пацієнтів на артеріальну гіпертензію з когнітивними дисфункціями виявлено достовірне порушення добового профілю артеріального тиску по систолічному і діастолічному артеріальному тиску, проти 19 і 16 пацієнтів по аналогічним показникам в групі без когнітивних порушень. Зі зниженням показників шкали МоСА-тесту корелювали показники добового індексу систолічного і діастолічного артеріального тиску, а також показники варіабельності систолічного артеріального тиску за день і ніч. Нами встановлено, що пацієнти на гіпертонічну хворобу ІІ стадії з наявністю когнітивних порушень характеризуються достовірним переважанням патологічних типів добового профілю артеріального тиску "Non-dipper" і "Night-peaker" (46,2 % і 19,2 %, відповідно).

Ключові слова: гіпертонічна хвороба, моніторинг артеріального тиску, когнітивні порушення.

The work is a fragment of the research project "Changes in the structural and functional state of the heart, blood vessels in patients with arterial hypertension: provoking and restraining factors, development of complications and treatment options", state registration No. 0120U103231.

To date, hypertension (AH) is considered not only as a leading risk factor for brain stroke, coronary heart disease, heart and kidney failure, premature death, but also is an independent risk factor for cognitive dysfunction in all age groups, up to the degree of dementia [2]. Currently, more and more attention is drawn to the intermediate stage of cognitive disorders (CD) development, when they have not yet reached the degree of dementia, but are already beyond the age norm [15].

The role of AH in the formation of cognitive disorders has been shown in a number of large studies, such as Baltimore Longitudinal Study on Aging, EVA Gothenburg, Honolulu-Asia Aging Study, ARIC (Atherosclerosis Risk in Communities) [7].