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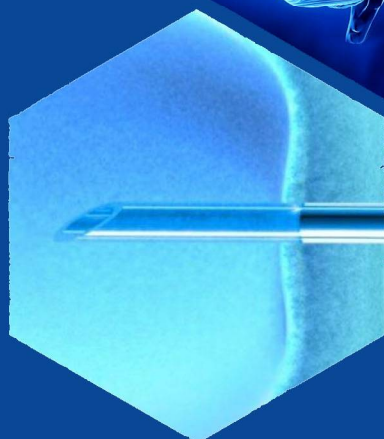
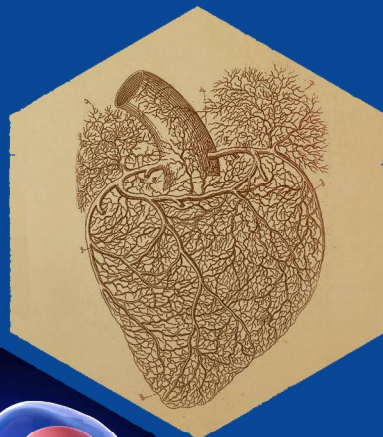
ISSN: 2181-0664

DOI: 10.26739/2181-0664

tadqiqot.uz/uzbek-medikal-journal

UZBEK MEDICAL JOURNAL

Special Issue 2



2021

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ЎЗБЕК ТИББИЁТ ЖУРНАЛИ УЗБЕКСКИЙ МЕДИЦИНСКИЙ ЖУРНАЛ UZBEK MEDICAL JOURNAL

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COMPARATIVE EVALUATION OF NEW OSTEOPLASTIC MATERIALS BASED ON THE RESULTS OF ACUTE TOXICITY STUDIES

 <http://dx.doi.org/10.26739/2181-0664-2021-SI-2-5>

ABSTRACT

Three series of experiments were carried out and lethal doses of the new osteoplastic material 47.5 V were determined by the intraperitoneal and intragastric injection of the material to laboratory animals. A comparative evaluation with Bioactive glass BG-1D was also carried out. It was found that the LD₅₀ of 47,5B was 4274.51:4770.58 mg/kg for intragastric injection and 2358.31:2895.65 mg/kg for intraperitoneal injection to rats. In animals getting Bioactive glass BG-1D, these indicators changed slightly, amounting to 3439.04:3810.53 mg/kg and 1732.77:2730.93 mg/kg, respectively. Thus, according to the classification of substances according to the degree of toxicity, these materials can be attributed to practically non-toxic substances (according to the results of intraperitoneal injection of the material suspension to rats and mice) and low-toxic substances (according to the results of intragastric injection of the material suspension to rats).

Keywords: osteoplastic material, median lethal dose, acute toxicity.

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СРАВНИТЕЛЬНАЯ ОЦЕНКА НОВЫХ ОСТЕОПЛАСТИЧЕСКИХ МАТЕРИАЛОВ ПО РЕЗУЛЬТАТАМ ИЗУЧЕНИЯ ОСТРОЙ ТОКСИЧНОСТИ

АННОТАЦИЯ

Проведены три серии экспериментов и определены летальные дозы нового остеопластического материала 47,5В при внутрибрюшинном и внутрижелудочном пути введения препарата лабораторным животным. Также проведена сравнительная оценка с Биоактивным стеклом BG-1D. Обнаружено, что LD₅₀ 47,5В составила 4274,51:4770,58 мг/кг при внутрижелудочном введении и 2358,31:2895,65 мг/кг при внутрибрюшинном введении крысам. У животных, получавших Биоактивное стекло BG-1D, этот показатель незначительно изменялся, составив 3439,04:3810,53 мг/кг и 1732,77:2730,93 мг/кг соответственно. Таким образом, согласно классификации веществ по степени токсичности данные материалы можно

отнести к практически нетоксическим веществам (по результатам внутрибрюшинного ведения суспензии веществ крысам и мышам) и к малотоксичным веществам (по результатам внутрижелудочного введения суспензии веществ крысам).

Ключевые слова: остеопластический материал, полуплетельная доза, острая токсичность.

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ЯНГИ ОСТЕОПЛАСТИК ХОМАШЁЛАРНИ ЎТКИР ЗАХАРЛИГИНИ ЎРГАНИШ НАТИЖАЛАРИ АСОСИДА ҚИЁСИЙ БАҲОЛАШ

АННОТАЦИЯ

Янги 47.5В номли остеопластик материалнинг ҳалокатли дозалари аниқлаш учун лаборатория ҳайвонларига препаратни интраперитонеал ва интрагстрал йўналишида юборилган холда уч қатор тажриба ўтказилди. Биофаол шиша BG-1D билан ҳам қиёсий баҳолаш амалга оширилди. Бунда 47,5Внинг ЛД₅₀ каламушларга интрагстрал йўналишида юборилган холда 4274.51:4770.58 мг/кгга тенг келди, ва каламушларга интраперитонеал йўналишида юборилган холда 2358.31:2895.65 мг/кгга тенг келди. Биофаол шиша BG-1Dни қабул қилган ҳайвонларда ушбу курсаткичлар бир оз узгарган равишда, 3439.04:3810.53 мг/кг ва 1732.77:2730.93 мг/кг мос келди. Шундай қилиб, захарлилик даражасига кўра моддалар таснифи буйича ушбу материаллар деярли захарли бўлмаган моддалар (интрагстрал йўналишида юборилиши натижаларига кўра) ва паст захарли моддалар (интраперитонеал йўналишида юборилиши натижаларига кўра) қаторига киритилиши мумкин.

Қалит сўзлар: остеопластик хомашё, яримлетал доза, ўткир захарлик.

Introduction. Replacement of bone tissue in large and medium-sized defects resulting from injuries, degenerative pathologies and removal of tumors is still considered one of the main clinical tasks of our time. Therefore, in recent years, there has been a significant increase in the demand for bone grafts.

So far, among all the available synthetic materials used in the production of bone grafts (for example, polymers, ceramics and composites), bioactive glasses (BS) undoubtedly have more advantages in terms of biocompatibility and mechanical properties. They were also optimal as a basis for the manufacture of three – dimensional (3D) scaffolds - products of bone tissue engineering. The development of new bioactive materials for use as the basis of scaffolds that meet all the requirements is an actual tissue engineering problem.

The purpose of the research. The purpose of preclinical toxicological studies of the new silicate glass 47.5 B is to establish the nature and severity of its damaging effect on experimental animals' organisms and compare it with bioactive glass BG-1D of domestic production and evaluate its safety for further use as an osteoplastic material.

Materials and methods of the research. The object of the study was silicate glass (47.5 SiO₂-10 Na₂O-10 K₂O-10 MgO-20 CaO-2.5 P₂O₅ mol.%), originally developed by Verne and co-authors at the Polytechnic Institute of Torino (Italy).

To study acute toxicity, 72 sexually mature male rats with an initial weight of 160-188 g and 30 sexually mature male mice with an initial weight of 20-23 g were used. The animals were quarantined and acclimatized in a vivarium for 14 days. All the animals were kept in the same conditions and on a regular diet.

To assess the acute toxicity, 3 series of experiments were conducted. Animals of the experimental groups were injected with osteoplastic material 47.5 B (white fine-crystalline powder, odorless, moderately soluble in water), in the form of an aqueous suspension:

1) by single intragastric injection to rats in doses of 4000, 4100, 4250, 4500, 4750 and 5000 mg/kg. A suspension prepared *ex tempore* based on a 1% solution of potato starch (1 g of potato starch powder was dissolved in 100 ml of distilled water) was introduced *per os* using a special metal tube.

2) by single intraperitoneal injection of a solution of the substance to rats in doses of 1500, 2000, 2250, 2500, 2750 and 3000 mg/kg.

3) by a single intraperitoneal injection of a solution of the substance in doses of 0,1, 0,2, 0,3, 0,4, 0,5/20 d. In order to prepare a suspension, 1 g of osteoplastic material was dissolved in 9 ml of phys. the solution was placed for 1 day in a thermostat at a temperature of 37 ° C. After 24 hours, this suspension was passed through a filter. The isolated solution was injected to sexually mature male mice intraperitoneally.

In each series of experiments, the animals were randomly divided into six groups, using body weight as a criterion. Each experimental group, in turn, consisted of 6 animals.

The general condition of the laboratory animals was monitored hourly during the first day, and once a day during the subsequent time of the experiment (13 days). The median lethal dose of the material (LD50) was calculated by probit analysis using the StatPlus program (2009).

The studies were carried out in full compliance with the "Guidelines for conducting preclinical studies of medicines. Part One" (2012). Experiments on animals were carried out in accordance with the rules adopted by the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes (ETS 123). Strasbourg, 1986).

The results of the study were statistically processed using the Biostat 2009 software package.

Results and discussion. The study of the acute toxicity of bioactive glass 47.5 B by intragastric injection of the solution was carried out on 36 mature male rats. The experimental animals were observed for 14 days.

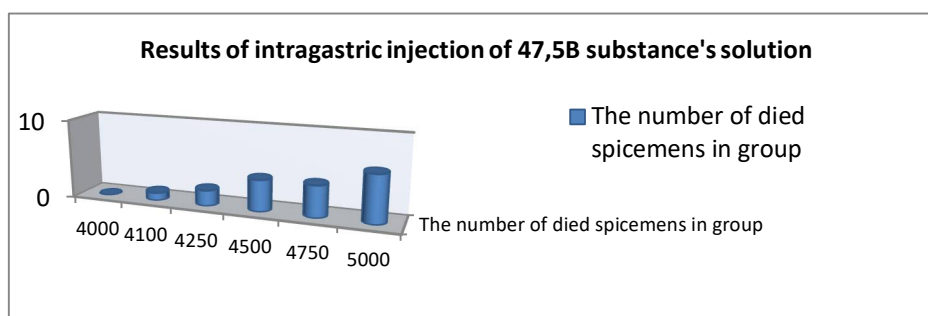
In the course of studying the acute toxicity of osteoplastic materials 47.5 B, we identified some changes in a number of physiological parameters of individuals of the experimental groups. Depending on the dose of the injected substance, there was a decrease in the motor activity of rats and mice, a decrease in food and water consumption, increased breathing and increased sweating. In animals receiving the substance in maximum doses, there were signs of central nervous system depression, a slight decrease in response to tactile, painful, sound and light stimuli, and a decrease in body weight. The timing of rat death was directly related to the dose of the injected osteoplastic material. The animals that received the maximum amount of the substance were the first to die. The death of the first animals that received the drug 47.5 B at the maximum dose was observed on day 6, and the last animals that received the substance fell on the 10th day of the experiment. The remaining animals were in satisfactory condition.

In the groups of experimental animals having got BG-1D, the animals receiving the maximum dose of the substance were the first to die by the end of the 2nd day after the injection of BG-1D, and the last animal death was observed on the 8th day of the experiment.

In groups of 6 animals having got a solution at a concentration of 4100 mg/kg - 1 specimens died, 4250 mg/kg - 3 specimens, 4500 mg/kg - 4, 4750 mg/kg – also 4 specimens and in the group of animals treated with a solution at a concentration of 5000 mg/kg, all 6 specimens died (Fig. 1).

In the experimental groups of animals, which were injected smaller doses of the substance solution (4000-4250 mg / kg), the behavior of specimens did not change compared to the original.

Fig. 1



When calculating the median lethal dose LD50 of the 47.5B was 4522.92 (4274.51:4770.58) mg/kg, which allows us to attribute this material to low-toxic substances. The BG-1D also belongs to low-toxic substances according to the results of calculating the median lethal dose LD50 in a similar series of experiments, which was 3625.03 (3439.04:3810.53) mg/kg.

In the second series of experiments, the study of the acute toxicity of bioactive glass 47.5B was carried out by intraperitoneal injection of a solution of 36 sexually mature male rats.

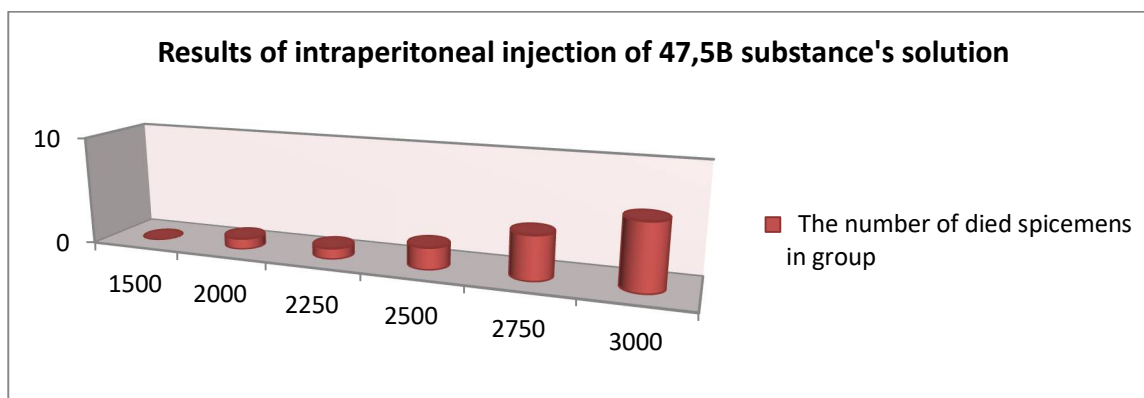
The death of the first animals after intraperitoneal injection of the material 47.5 B at the maximum dose was observed on day 3, and the last animal fell on the 8th day of the experiment.

In groups of 6 animals treated with a solution at a concentration of 2000 and 2250 mg/kg, 1 individual died, 2500 mg/kg – 2 individuals died, 2750 mg/kg – 4 and in the group of animals treated with a solution at a concentration of 3000 mg/kg, all 6 individuals died (Fig. 2).

When examining the site of intraperitoneal administration of the powder suspension, no edema, hyperemia, or structural abnormalities in the adjacent tissues were detected in the animals. These data suggest that 47.5 B does not have a local irritant effect.

In groups of experimental animals having got BG-1D in the same series of experiments, the first animals died by the end of the 5th day after the introduction of BG-1D, and the last animal death was observed on the 10th day of the experiment.

In this series of experiments, when calculating the median lethal dose of material 47.5B, the LD50 was 2626.98 (2358.31:2895.65) mg/kg, and the LD50 of material BG-1D was 2231.85 (1732.77:2730.93) mg/kg.



During the third series of experiments conducted by intraperitoneal administration of the 47,5B and BG-1D materials' suspension to 30 sexually mature male mice, not a single specimens of 6 animals in 5 groups died.

Conclusions. The results of calculating the median lethal doses of the 47.5B osteoplastic material we studied and the BG-1D osteoplastic material compared with it did not reveal significant differences. Thus, according to the classification of substances by the toxicity degree, they can be attributed to low-toxic substances (according to the results of intragastric injection of substances' solution of to rats) and to practically non-toxic substances (according to the results of intraperitoneal injection of substances' solution to rats and mice).

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**UZBEK MEDICAL
JOURNAL**

№SI-2 (2021)

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