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Liposome form of lung surfactant. The results of multi-central clinical trials of Surfactant-BL for the treatment of lung tuberculosis with multi-drug resistance

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The number of patients with multiple drug resistance (MDR), i.e. resistance to at least two chemical formulations, isoniazide and rifampicine, is 7.1% in Russia. MDR among treated patients is 90%, while the efficiency of chemotherapy decreases significantly: 21% of patients experienced the closure of the cavities, and 65.5% had discontinuance of bacteria discharge. It was shown that all TB patients with destructive changes have surfactant deficiency. Surfactant formulation, Surfactant-BL (Biosurf, Saint-Petersburg, Russia), has distinct protective properties towards lung structures. It enhances the activity of alveolar macrophages, keeps small bronchi open, adsorbs some bacteria and viruses, stimulates the synthesis of own surfactant. The formulation is efficient for respiratory distress syndrome of newborns and acute respiratory distress syndrome at adults and children.

Materials and methods. According to inclusion criteria two groups of patients were enrolled: the treatment group included 122 patients who had Surfactant-BL in complex treatment of TB, the control group consisted of 118 patients and didn't have Surfactant-BL. **Inclusion criteria.** TB patients of 16-60 years old with bacteria discharge, who had experienced 3-10 months of ineffective TB treatment and were characterized by TB process in 1-2 lobes of the lung and cavities up to 2-3 cm in diameter, were enrolled into the study. Drug resistance was proved by laboratory tests (cytological analysis or bacterial inoculation). **Exclusion criteria:** The patients with clear concomitant diseases or those who had not observed regimen were not included into the study. **Treatment regimen:** The treatment group received standard chemotherapy of 4-5 preparations and inhalations of Surfactant-BL at a dose of 25 mg, 5 times a week during the first two weeks and then 3 times a week at the same dose during the following 6 weeks. The control group had only standard chemotherapy of 5-7 preparations.

Results and discussion: After 2-5 inhalations of Surfactant-BL the patients had improvement and increase in sputum expectoration. No patients experienced cough attack, and they mentioned easy and painless sputum expectoration. After the end of Surfactant-BL therapy in 24.6% of the patients had abacillarity, and 2 months later there were 86.9% of such patients compared to 5.9% and 63.6% in the control group. X-ray examination demonstrated that the resolution of infiltrates differed in the treatment and control groups. Significant infiltrate resolution was registered in 31.5% of the patients of the treatment group 8 weeks after the beginning of the treatment and in 95.1% after 4 month, i.e. at discharge from the hospital, compared to 5.9% and 66.9% correspondingly in the control group. 83.6% of the treatment group compared to 47.4% of the control group had the closure of destruction cavities.