

SURFACTANT THERAPY IN PATIENTS WITH SEVERE UNCONTROLLED BRONCHIAL ASTHMA

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ABSTRACT

Actuality: Severe uncontrolled asthma has a large burden on the health care system and society. One of the most important problems is an application of the new "target" drugs for severe BA.

Objective: Establishing the efficacy and safety of the adjunctive use of natural lung surfactant in patients with severe uncontrolled BA.

Methods of research: The diagnosis and treatment of severe BA were conducted in accordance with GINA-2017. The primary endpoint was the BA control level assessed by ACQ-6 questionnaire. The second endpoint was FEV1 level on spirometry at the end of the study. For document processing Fisher's F-criteria, the Mann-Whitney tests were used.

Results: The examined group included 13 patients with severe BA who received inhalation of surfactant during 12 weeks at a dosage of 25 mg 3 times a week in addition to basic BA therapy. The control group included 15 patients with severe BA. The maintains therapy, etc. ICS-doses, severity of the disease and co-morbidity prevalence were comparable in both groups. ACQ-6 score levels were comparable in both groups on the treatment start: 3,3 [2,66; 4,0] against 3,0 [2,5; 3,3] ($p > 0.1$). After 12-week treatment period ACQ-6 score decreased significantly: 1,8 [1,3; 2,2] against 2,6 [2,1; 3,0] ($p < 0.05$). Median FEV1 levels were comparable in both groups on the treatment start: 48% [40; 55] against 45% [38; 55] ($p > 0.1$). After 12-week treatment period there was a significant increase in the FEV1 in interventional group: 69% [54; 77] against 52% [46; 59] ($p < 0.05$). Severe adverse reactions haven't been established.

Conclusion: An adjunctive therapy of the lung surfactant to the treatment of severe BA may potentially improve asthma control and the FEV1 levels.

Footnotes

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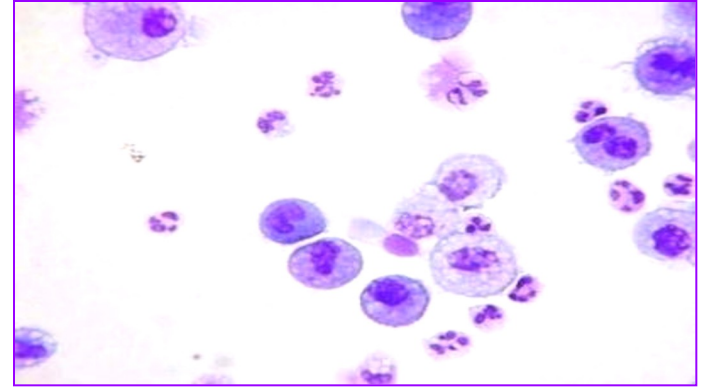
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Relevance

- ✓ Bronchial asthma was carried to the group of socially important diseases by WHO experts;
- ✓ Annually 250 000 people die because of asthma worldwide;
- ✓ In Transbaikalia Region asthma mortality:
1,9 on 100 000 (2018);
- ✓ Severe uncontrolled asthma has a large burden on the health care system and society;
- ✓ One of the most important problems is an application of the new "target" drugs for severe BA.

Theoretical prerequisites

At some forms of bronchial asthma, including infectious\neutrophil, there may be a violation in the surfactant system that drive to chronic persistent airflow inflammation, remodeling, lung hyperinflation.



Introduction

AIM OF THE STUDY

- ✓ To find out the efficacy and safety of an adjunctive use of natural lung surfactant in patients with severe uncontrolled BA.

Methods

- ✓ Severe asthma diagnosis according to GINA-2017;
- ✓ ACQ-6 questionnaire (≥ 1.5);
- ✓ Spirometry (FEV₁);
- ✓ Fisher's F-criteria, the Mann-Whitney test;



Randomisation

- ✓ After signing the Informed Consent patients were randomized into 2 groups:
- ✓ The examined group included 13 patients with severe BA who received **inhalation of surfactant during 12 weeks at a dosage of 25 mg 3 times a week** in addition to basic asthma therapy;
- ✓ The control (placebo) group included 15 patients with severe BA;
- ✓ The maintains therapy, etc. ICS-doses, severity of the disease and co-morbidity prevalence were comparable in both groups.



Initial indicators

	Surfactant group (n=13)	Control group (n=15)	p-level
ACQ-6	3.3 [2.66; 4.0]	3.0 [2.5; 3.3]	p>0.1
FEV1 (%predicted)	48% [40; 55]	45% [38; 55]	p>0.1

Results (after 12-week treatment period)

	Surfactant group (n=13)	Control group (n=15)	p-level
ACQ-6	1.8 [1.3; 2.2]	2.6 [2.1; 3.0]	p<0.03
FEV1 (%predicted)	69% [54; 77]	52% [46; 59]	P<0.05

SAE's

- ✓ Severe adverse reactions were not revealed in the study

Conclusion

- ✓ An adjunctive therapy of the lung surfactant in severe bronchial asthma may potentially improve asthma control and increase FEV1 levels.