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Title: The evaluation of the efficacy and safety of phospholipids' inhalation in patients with bronchial asthma (BA): A prospective randomized placebo-controlled study

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Body: Background. The new method of BA treatment based on the reparation of damaged cell membranes by phospholipids was proposed. The aim of the study was to evaluate the efficacy and safety of phospholipids' inhalation (PhLI) in BA patients during the 24-week course of treatment. Materials and methods. The prospective, single-blind, randomized, placebo-controlled, parallel-group study was performed. 58 patients (age 67.5 ± 12.3 ; male 68.3%) with partly controlled and uncontrolled BA were enrolled ($FEV_1 > 50\%$). Group1 contains 30 patients who received a PhLI by compressor nebulizer once a day in addition to traditional therapy; group2 - 28 patients who received a traditional therapy only (control). The lung function test was performed in each clinical visit, as well as PEF measurements were performed twice daily by the patient itself. Usage of short-acting β_2 -agonists and the asthma symptoms score were also determined. Results. It was shown the statistically significant increase of FEV_1 level in group1 compared with control (79.3 ± 8.7 vs $72.9 \pm 9.2\%$; $p=0.01$). The PEF increase was also determined in group 1 (557.0 ± 120.6 vs 486.3 ± 98.3 l/min; $p=0.03$). The strong correlation between these two parameters was observed ($r=0.94$; $p=0.0052$). The number of inhalations of bronchodilator reliever medication was significantly lower in group 1 (1.7 ± 0.8 vs 2.9 ± 1.6 ; $p=0.027$) as well as asthma symptoms score (4.2 ± 1.1 vs 6.3 ± 1.0 ; $p=0.01$). Conclusion. The results obtained demonstrate that a phospholipids' inhalation in addition to traditional therapy of BA has a significant positive effect both in clinical status and lung function test in patients with BA.