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Title: Clinical and functional effectiveness of roflumilast in severe COPD patients

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**Body:** Objectives: This study aimed to investigate the influence of PDE-4 inhibitor roflumilast on clinical and functional indices in severe COPD patients with concomitant CB over 3 month's therapy. Methods: This was a comparison of 30 patients (average age 49,7 ± 1,3 years) with stable COPD (GOLD III), ≥2 exacerbations in last 12 months and diagnosis of CB in time dimension: we analized their symptom score, PFT indices (Rtot, RV, IC, FVC, FEV₁) during 3 months, when they received standart COPD therapy (LABA+ICS in moderate daily doses) and next 3 months, when roflumilast 500 mcg OD was added to their routine therapy. Study was carried out of budjet cost. Results: During first 3 months of observation mean CAT test was (30,3)  $\pm$  1,4), main problems were with physical load (all patients noted 4 – 5 on question 4), home affairs (question 5: 3-4 points), with sleep and energy (3 – 5 points). Post BD plethysmography revealed increased Rtot (287,5 ± 12,8) %, RV (187,8 ± 9,7)%; Post BD spirometry data also were impaired: FEV, Post BD (38,1  $\pm$  3,7) %, IC (52,8  $\pm$ 4,5) %. Addition of roflumilast lead to the decrease of CAT test score to (24,2  $\pm$  1,6) (p<0,05), tendency to decrease of Rtot (200,4  $\pm$  7,8)%, decrease of RV – to (134,4  $\pm$  8,7)% and to increase of IC (to (72,3 ±3,7) % at the end of next 3 months. Also moved left score in abovementioned points, more answers were checked between 2 and 3. Changes in FEV<sub>1</sub> and FVC were in variability limits. Conclusion: introduction of PDE-4 inhibitor leads to the improvement of COPD control and tendency to increase of functional reserves in severe COPD patients with concomitant CB.