

CLINICAL EFFICACY OF TIOTROPIUM BROMIDE IN PATIENTS WITH THE COMBINED PATHOLOGY OF ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE.

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Summary

The aim of this study was to evaluate the effect of adding of tiotropium bromide on symptoms, quality of life and disease control in patients with combined pathology of asthma and chronic obstructive pulmonary disease (COPD; ACOS) who were on treatment with inhaled corticosteroids (ICS) or ICS/long-acting β 2-agonists but have severe symptoms and lung function disturbance.

Inclusion criteria were: ACOS patients over 30 years, on basis therapy, but existing severe symptoms and lung function decline. The study included 43 ACOS patients (26 men and 17 women, average age $57,7 \pm 1,57$ years, mean FEV1 $60,39 \pm 2,71$ %), they all completed the study. Patients were on stable therapy 2 months before the study (ICS or ICS/LABA + SABA as needed). Tiotropium bromide 18 mcg Handihaler or 5 mcg Respimat was added to therapy for 2 months. Patients underwent examinations before the study – the 1st visit (screening, inclusion and exclusion criteria); lung function measurement, conducting questionnaires before treatment – the 2nd visit; lung function measurement, questionnaires after 2 months treatment – 3d visit.

Methods. All patients underwent lung function measurement, St. George's Respiratory Questionnaire (SGRQ), Asthma Control Questionnaire (ACQ7), The Asthma Control Test (ACT), The Asthma Quality of Life Questionnaire (AQLQ S), EQ-5D health questionnaire, The MRC breathlessness scale, COPD Assessment Test (CAT) before and after the treatment and Baseline Dyspnea Index (BDI) before and Transition Dyspnea Index (TDI) after the treatment.

Results. We received the data about the dynamics of symptoms, quality of life, control of the disease in patients with ACOS during therapy with the addition of tiotropium bromide. ACQ7 score significantly decreased from $2,59 \pm 0,13$ to $2,13 \pm 0,15$ ($p = 0,003$). Clinically-significant difference for ACQ 7 reached 44 % ACOS patients ($n = 19$). Average ACT score significantly increased from $14,09 \pm 0,6$ to $16,74 \pm 0,66$ ($p = 0,0003$). 60 % of patients reached clinically-significant difference ($n = 26$).

According to the AQLQ S, symptoms domain changed from $3,98 \pm 0,14$ to $4,68 \pm 0,19$ ($p = 0,0005$), activity domain changed from $4,51 \pm 0,15$ to $4,96 \pm 0,17$ ($p = 0,008$), the emotions domain increased from $4,3 \pm 0,18$ before treatment to $4,94 \pm 0,22$ at the end of treatment ($p = 0,002$). MRC index significantly decreased from $1,79 \pm 0,06$ to $1,12 \pm 0,11$, before and after treatment, respectively ($p = 0,01$). 67 % of patients reached clinically significant difference ($n = 29$). BDI mean score before the treatment was $6,21 \pm 0,21$, that marked a significant dyspnea. TDI score after treatment was $1,88 \pm 1,19$, indicating a significant positive trend in the level of dyspnea in patients after treatment.

There was a significant improvement in all four domains of SGRQ after the treatment. Symptom score decreased from $64,48 \pm 2,76$ to $55,15 \pm 3,31$ ($p = 0,003$), activity score – from $49,52 \pm 3,15$ to $39,1 \pm 3,2$ ($p = 0,002$), impact score – from $35,82 \pm 3,04$ to $26,64 \pm 2,88$ ($p = 0,01$), total quality of life score decreased from $44,73 \pm 2,67$ to $35,15 \pm 2,77$ ($p = 0,001$). EQ5D rate significantly decreased from $3,0 \pm 0,27$ to $2,56 \pm 0,32$ after treatment ($p = 0,02$). Visual analogue scale score significantly increased from $59,05 \pm 2,13$ to $65,23 \pm 2,34$ ($p = 0,008$).

Conclusions. We received considerable positive dynamics in symptoms, quality of life and self-assessment of health in patients with ACOS. The positive effect was achieved in patients with mild and severe course of disease, in patients with primary disease asthma and COPD, and with different disease duration. Tiotropium bromide can

Наблюдалось достоверное и клинически значимое улучшение по всем четырем доменам респираторного опросника госпиталя Святого Георгия. По шкале симптомов средний балл уменьшился с $64,48 \pm 2,76$ до $55,15 \pm 3,31$ ($p = 0,003$), по шкале ограничения активности — с $49,52 \pm 3,15$ до $39,1 \pm 3,2$ ($p = 0,002$), по шкале влияния — с $35,82 \pm 3,04$ до $26,64 \pm 2,88$ ($p = 0,01$), общий балл качества жизни уменьшился с $44,73 \pm 2,67$ до $35,15 \pm 2,77$ ($p = 0,001$).

Общий тестовый показатель EQ5D достоверно снизился с $3,0 \pm 0,27$ до $2,56 \pm 0,32$ после лечения ($p = 0,02$). Определялось достоверное увеличение общей оценки качества жизни по визуальной аналоговой шкале с $59,05 \pm 2,13$ до $65,23 \pm 2,34$ ($p = 0,008$).

Выводы. По данным наблюдения была получена значительная положительная динамика симптомов, качества жизни и самооценки уровня собственного здоровья. Положительный эффект достигнут у больных как с легким, так и тяжелым течением заболевания, у больных с начальным заболеванием как БА, так и ХОЗЛ в анамнезе и при разной продолжительности заболевания.

Тиотропия бромид может быть рекомендован в базисной терапии больных с АХПС различной степени тяжести, учитывая его высокую клиническую эффективность в отношении основных симптомов, влияния на качество жизни, физическую выносливость, эмоциональное состояние, высокую оценку положительного влияния, полученную как врачами, так и пациентами.

Ключевые слова: бронхиальная астма, хроническое обструктивное заболевание легких, комплексное лечение, тиотропия бромид, одышка, качество жизни, контроль заболевания.

be recommended as a basic treatment of patients with different degrees of severity of ACOS, considering its high clinical effectiveness against major symptoms, effects on quality of life, physical activity, emotional state.

Key words: asthma, chronic obstructive pulmonary disease, complex treatment, tiotropium bromide, dyspnea, quality of life, control of the disease.

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