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The efficacy and safety of inhaled use decamethoxin antiseptic solution in patients with infectious exacerbation of chronic bronchitis

Key words: *chronic bronchitis, infectious exacerbation, decamethoxine, nebulizer.*

According to current definition chronic bronchitis (CB) – a chronic inflammatory disease of the airways, accompanied by increased mucus production, changes in its physical and chemical properties and manifested chronic cough for 8 weeks a year for the last 2 years [1–4]. A characteristic feature of chronic bronchitis course and one of the most common causes of the patient's medical care is the emergence of this disease exacerbations [5–8, 10]. Found that patients with chronic bronchitis suffer from one to four or more exacerbations during the year in average, and their incidence can progressively increase with age [11–15]. The frequency of exacerbations of chronic bronchitis is one of the most important factors that determine the quality of life of patients [17–20]. With all the variety of provoking factors upper respiratory infections is considered as the main cause of the exacerbation of chronic bronchitis, which according to most authors causes 60–80 % of all exacerbations [20–22]. The most important pathogens in causing infectious exacerbation (IE) of CB is bacterial pathogens – 40–50 %. Among them, the top spot belongs to *H. influenzae* (30–50 % of cases), *S. pneumoniae* (14–30 %), *M. catarrhalis* (15–17 %) [12, 14, 20, 22]. Recently, more attention is attracted to the role of viral infections in exacerbations of chronic bronchitis. It is believed that 15–40 % of cases with chronic bronchitis are caused by viral or viral-bacterial pathogens [23–27].

Under current international consensus guidelines, basic principle of treating patients with acute exacerbation of chronic bronchitis is mucolytic and antibacterial therapy [32–37] and, if necessary, bronchodilator and anti-inflammatory therapy [38–40].

In clinical practice antibiotic therapy in patients with chronic bronchitis and chronic obstructive pulmonary disease (COPD) is empirical usually, as developed guidelines that allow justifying its use. The most practical in this regard are the features that characterize the clinical situation and allow some to differentiate different versions of exacerbations

of chronic bronchitis. According to them, the main indications for antibiotic therapy in exacerbations of chronic bronchitis / COPD is the presence of purulent sputum, increased its amount and suffocation (type I and II exacerbation of chronic bronchitis by N. Anthonisen), and hard to aggravation of signs of acute respiratory failure [32, 34, 35, 41].

Despite the proven role of infection, including viral etiology, the development and progression of chronic bronchitis [9–14] issues of diagnosis, treatment and prevention of virus-induced exacerbation of chronic bronchitis is not completely resolved. This is largely due to the large number of known respiratory viruses (over 200 species), the difficulty of etiological diagnosis, especially the pathogenesis of viral infection (intracellular replication of viruses and the need for adequate treatment primarily at onset), limited arsenal of antiviral drugs and vaccines with proven clinical efficacy against respiratory pathogens, etc. [28–31].

Recently in the literature, there is an evidence of the use of some antiseptics, including surface-active agent decamethoxine in infectious diseases of the lower respiratory tract [42–44]. Its unique feature is the lack of interaction with human cells, so it is not absorbed from the surface of the mucous membranes and therefore there is no risk of systemic side effects. It also does not cause irritation of the mucous membranes, and thus the local side effects. The results of experimental studies have shown that it has a strong antiseptic bactericidal activity against gram-positive, gram-negative and anaerobic organisms. Also noted its fungicidal, virulicidal and sporocidal action [44, 45]. Decamethoxine has anti-inflammatory mechanism is explained by the inhibition of serotonin production cells and a decrease in exudation. The drug has also desensitizing and antispasmodic effect [42, 43]. Decamethoxine positive feature is its ability to increase the sensitivity of microorganisms to antibiotics [44]. Decamethoxine effectively used in the treatment of patients with local abscess,

carbuncle, cellulitis, in the treatment of patients with purulent destructive processes in lungs, by inhalation in patients with COPD and pneumonia [46-49].

It should be noted that the use of nebulized drugs has one of the leading places in the treatment of patients not only with obstructive respiratory diseases, but also for any inflammatory diseases of the upper and lower respiratory tract. With this method of administration in the form of aerosol particles of suitable size directly enters the target organ, resulting in maximum therapeutic effect is achieved in the shortest time [50-53].

The aim – to determine the effectiveness of inhaled antiseptic 0.02 % decamethoxine (Decasan, Yuria-Pharm, Ukraine) in the treatment of patients with infectious exacerbation of chronic bronchitis.

Materials and methods

For the purpose of determining the effectiveness of treatment of virus-induced IE of CB through the use of inhaled decamethoxine – were examined and treated 121 patients with mild IE of CB. Men were ($42,1 \pm 4,5$ %), the rest were women, the average age of patients was ($43,0 \pm 1,3$) years. All patients were treated on an outpatient or inpatient in NIFP NAMS. The reasons for hospitalization were serious condition of patient, the ineffectiveness of previous treatment or social indications (impossibility of adequate treatment in the outpatient setting).

Disease duration was ($8,6 \pm 0,8$) years in average. Among the risk factors for chronic bronchitis are the most important tobacco smoking (in 76.0 % of patients). The average frequency of exacerbations of chronic bronchitis during the last year was ($2,9 \pm 0,1$) times a year with an average length of ($10,4 \pm 0,2$) days each. In 16.5 % of patients given exacerbation of chronic bronchitis arose during the third year, 9.9 % – for the fourth time. Among the drugs most commonly used in the treatment of the preceding exacerbation of chronic bronchitis were antibiotics – in 96.7 % of patients, including per os in 76.9 % of patients, parenteral – in 23.1 % of patients, antihistamines – 16.5 % of patients mucoregulators in 96.7 %, anti-inflammatory drugs – at 16.7 %. Antiseptics and antiviral drugs almost never used, and flu vaccination had only 4.1 % of patients.

At the initial examination the general condition rated as medium severity in 44.6 % of patients in the other – as satisfactory. Strong cough noted 15.7 % of patients, 53.7 % – moderate, small – 30.6 %. In 31.4 % of patients were dry cough in 52.1 % were mucous sputum and in 14.0 % – muco-purulent, the amount of which in 24.0 % of patients was 30-50 ml/day, the rest – 30 ml/day.

At clinical examination in the majority of patients with small manifestations of rhinitis (in 96.7 % of patients), flushing of the soft palate and the back wall of the throat (in 83.5 %), conjunctival hyperemia (in 52.1 %) headache (in 72.7 %), excessive sweating (in 61.2 %), pain in muscles and joints (in 43.8 %), weakness (51.2 %), photophobia (38.0 %). In 22.3 % of patients had a body temperature above 38 °C, 61.2 % – subfebrile (37-38 °C), the rest – normal.

Auscultation moist wheezing (diffuse or isolated) listened in almost all patients.

The study included patients only if their voluntary consent for the purpose and amount of planned inspections, the need for anti-infective therapy and possible risk of its side effects. Criteria for inclusion of patients in the study: patients older than 18 years; availability of informed consent signed by the patient's wish to participate in this study; availability of symptoms of chronic bronchitis (increase of mucus, improving its purulence, increased cough, fever, spreading of respiratory desists in history); infectious cause of exacerbation of CB confirmed by the results of clinical and / or laboratory studies.

Exclusion criteria: the non-infectious cause of exacerbation of chronic bronchitis; antiviral and antibiotic therapy over the last 2 months about a disease; actual or alleged intolerance of study drug; the presence of pneumonia, severe concomitant diseases (tuberculosis, cancer, HIV/AIDS, alcohol and drug addiction; decompensated cardiac, hepatic and renal failure etc.), patient refuse to participate in the study.

The basis of drug therapy in patients with chronic bronchitis and COPD constituted anti-infective chemotherapy (antibiotic and / or antiseptic inhalation) in conjunction with mucolytics. anti-inflammatory drugs (fenspirid), antihistamines and extra – amino acid L-arginine aspartate. In the presence of comorbidities appropriate drug therapy prescribed.

Volume of therapeutic interventions, route of administration of drugs (inhaled, oral, parenteral) and place of treatment (outpatient, inpatient) determined by the severity of the exacerbation and the response to the initial phase of therapy. Exacerbation severity was assessed by the analysis of anamnesis, severity of clinical manifestation of signs and symptoms and the severity of functional impairment of breathing and circulation.

The basis of rational antibiotic constituted by beta-lactams (amoxicillin/clavulanate (Augmentin, Glaxo Smith Kline, United Kingdom) – oral dose of 625 mg 3 times daily or 1000 mg 2 times a day); respiratory fluoroquinolones (levofloxacin in oral dose of 500 mg 1 time per day) or macrolides – clarithromycin (Fromilid, Krka, Slovenia) in a dose of 500 mg 2 times a day). The total duration of antibiotic therapy was 7-10 days.

As inhalation antiviral therapy nebulized antiseptic decamethoxine (Decasan, Yuria-Pharm, Ukraine) is used in a dose of 2 ml of 0.02 % solution 2-3 times a day for 5-7 days.

When choosing anti-infective drug for each patient we took into account medical history (duration of exacerbations, the presence of allergic reactions to certain groups of drugs, comorbidities and the side effects of the drug, previous antibiotic therapy, etc.), available data about the possible agents of infection and level of resistance to antibiotics [41].

As mucolytic therapy were used ambroxol (at a dose of 30 mg 3 times a day orally) and / or acetylcysteine (at a dose of 600 mg 1 time per day orally) for 7-10 days.

To address the objectives of the study all patients included in the study were divided into 3 groups based on comparison of the volume of anti-infection therapies. Groups of patients were completely comparable by gender, age, and severity of major clinical and functional signs of chronic bronchitis. The group 1 included 44 patients whom antibiotic therapy in conjunction with mucolytics were prescribed. The group

2 included 45 patients who have antibiotic and mucolytic and decamethoxine inhalations additionally administered.

The group 3 included 32 patients whom mucolytic drug in combination with the use of inhaled decamethoxine were prescribed.

In all cases, anti-infectious therapy was empirical (were prescribed until the results of bacteriological and virological studies). Volume of additional therapeutic interventions and drug administration routes determined by the severity of exacerbation, related conditions and in response to the initial phase of therapy.

Assessment of the general state of patients and clinical and instrumental signs of IE of CB in study groups performed in early follow-up (visit 1), 3-5 days (visit 2) and 10-14th day (visit 3) after the start. This work was funded by the state budget.

Results and discussion

The positive dynamics of clinical signs seen in all groups of patients during the treatment. However, in significantly more patients in the group 2 and 3 seen disappearance or decreasing of signs of respiratory tract infection on days 3-5 – intoxication (significant reduction in the number of patients with fever, profuse sweating, muscle pain and headache), clinical features of inflammation of the upper respiratory tract (redness of the mucous membranes and conjunctiva, difficulty with nasal breathing), cough and intensity of auscultative signs of inflammation of the lower airways.

Planned treatment carried out in all patients in full. In 5 (11,4 ± 4,7) % patients of group 1 by clinical and laboratory data developed bacterial complications (appearance of purulent sputum and increasing of its amount), which required the another antibacterial drug prescription and extension of treatment time. In patients of a group 2 and 3 premature discontinuation of treatment due to poor compliance, development of infectious complications or adverse toxic and allergic reactions were not.

Data analysis of clinical indicators at the end of observation shows that the therapy contributed to positive outcomes for all patients in the comparison, achieved significant improvement in general condition, reduce clinical signs of airway inflammation, reduce manifestations of intoxication and intensity of coughing as the main clinical manifestations of the exacerbation of CB, etc. The complete elimination of exacerbation (recovery) established in (84,1 ± 5,5) % of patients in a group 1, improvement – in (15,9 ± 5,5) %, in group 2 – (91,1 ± 4,2) % and (8,9 ± 4,2) % of patients, in group 3 – (81,3 ± 6,9) % and (18,7 ± 6,9) % of patients, respectively. The total duration of exacerbation in patients of group 1 was (8,7 ± 1,1) days in patients of groups 2 and 3 – (7,1 ± 0,5) and (7,3 ± 0,3) days, respectively ($p > 0,05$).

Despite the fact that significant differences in treatment outcomes between groups we didn't found, it should be noted that patients in which treatment was used inhalation of antiseptic decamethoxine had some benefits. First of all, it concerns primary causal treatment effectiveness and duration of its use. In patients of the 2nd and 3rd groups therapeutic effect is achieved more quickly, almost no clinical signs of lack of effectiveness of initial therapy and the

development of bacterial complications (increased amount or sputum purulence onset of clinical signs of lower respiratory infection) that would require correction of antibacterial therapy and extend the treatment. As a result, the total duration of antibiotic therapy in patients of group 1 averaged (7,8 ± 0,8) days, and patients in group 2 – (5,7 ± 0,6) days ($p < 0,05$).

In addition, the use of anti-infectious drug via inhalation made possible not only to achieve high clinical efficacy but also reduce the medical burden on the patient and prevent the risk of possible toxic and allergic reactions.

High clinical efficacy of treatment in patients of 3rd group is not inferior to the efficiency of traditional systemic antibacterial therapy in patients of groups 1 and 2 can show a frequent unjustified traditional use of antibacterial drugs in mild exacerbation of CB with viral etiology and the possibility of use of decamethoxine as monotherapy in case of the lack of data of severe exacerbation.

Conclusions

Thus, additional inhalations of decamethoxine in treatment of patients with mild infectious exacerbation of chronic bronchitis has reduced the severity and duration (by 1-2 days in average) of manifestations of intoxication and catarrhal phenomena, reduce the length of infectious exacerbation of chronic bronchitis by 1.6 days, and to avoid unnecessary antibiotics prescription or shorten the length of their use by 2.1 days.

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ЭФФЕКТИВНОСТЬ И БЕЗОПАСНОСТЬ ИНГАЛЯЦИОННОГО ПРИМЕНЕНИЯ ДЕКАМЕТОКСИНА В ЛЕЧЕНИИ ПАЦИЕНТОВ С ИНФЕКЦИОННЫМ ОБОСТРЕНИЕМ ХРОНИЧЕСКОГО БРОНХИТА

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Резюме

Исследование включало оценку эффективности и безопасности применения ингаляционных форм 0,02 % раствора антисептика декаметоксина для лечения пациентов с инфекционным обострением хронического бронхита (ХБ). Добавление декаметоксина способствует уменьшению термина достижения безсимптомного состояния (в среднем на 1–2 дня) и сроков госпитализации — на 1,6 дня.

Цель исследования — изучить влияние ингаляции 0,02 % раствора антисептика декаметоксина на течение заболевания у пациентов с инфекционным обострением ХБ.

Объект исследования — 121 пациент с инфекционным обострением ХБ. Критерии инфекционного обострения ХБ — нарастание респираторных симптомов (кашель, гнойный характер мокроты). Пациенты были рандомизированы в 3 группы (44, 45 и 32 человека соответственно). Группы были сопоставимы по возрасту, полу и типу обострения. Пациенты 1-й группы получали стандартную терапию: антибиотик, муколитик, антипиретик; 2-й группы — в дополнение к стандартной терапии — ингаляции 0,02 % раствора декаметоксина (декасан, Юрия-Фарм, Украина) через небулайзер (2 мл 2 раза в сутки); 3-й группы — ингаляции 0,02 % раствора декаметоксина (декасан, Юрия-Фарм, Украина) через небулайзер (2 мл 2 раза в сутки) в сочетании с муколитиком.

Методы исследования: клинико-функциональные, статистические.

Результаты. При добавлении к стандартному лечению обострения ХБ ингаляций 0,02 % раствора декаметоксина среднее время исчезновения симптомов обострения было на 1–2 дня меньше, а средний термин госпитализации сократился на 1,6 дня по сравнению с 1-й группой.

Выводы. Результаты исследования позволяют рекомендовать добавление ингаляции 0,02 % раствора декаметоксина к стандартной терапии обострения ХБ и избежать неоправданного назначения антибактериальных препаратов.

Ключевые слова: хронический бронхит, инфекционное обострение, декаметоксин, небулайзер.

THE EFFICACY AND SAFETY OF INHALED USE DECAMETHOXIN ANTISEPTIC SOLUTION IN PATIENTS WITH INFECTIOUS EXACERBATION OF CHRONIC BRONCHITIS

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Summary

The study evaluated the efficacy and safety of adding inhaled nebulizer solution of decamethoxine in the treatment regimen of patients with acute exacerbation of chronic bronchitis. Adding decamethoxine allow to reduce the term to the achievement of asymptomatic state by 1–2 days and hospital stay by 1,6 days.

The purpose of the research: is to study the effect of inhalation of decamethoxine 0,02 % solution in patients with infectious exacerbation of chronic bronchitis.

The object of the study: 121 patients with acute exacerbation of chronic bronchitis were included to the study. As a criterion of exacerbation considered the increase of respiratory symptoms (cough, sputum purulence, etc.) when receiving maintenance treatment. Patients were randomized into three groups (44, 45 and 32 people in each). The groups were comparable for age, sex and type of exacerbations according to the Anthonisen classification. Patients of the group 1 received the standard therapy: antibiotics, mucolytics, antipyretic. Patients of the group 2 in addition to standard therapy received inhalations of 0.02 % solution of decamethoxine (decasan, Yuria-Pharm, Ukraine) via nebulizer (2 ml 2 times a day). Patients of the group 3 received mucolytic and inhalations of 0.02 % solution of decamethoxine (decasan, Yuria-Pharm, Ukraine) via nebulizer (2 ml 2 times a day).

Methods of research: clinical and functional, statistics.

Results. In the groups with inhalations of 0.02 % solution of decamethoxine the average time of the disappearance of clinical symptoms of exacerbation was 1–2 days shorter and the average time of hospitalization was 1,6 days less comparing to the group of the standard therapy (group 1).

Conclusions. This finding allows to conclude the feasibility of adding inhalations of 0.02 % solution of decamethoxine to the standard treatment scheme in patients with acute exacerbation of chronic bronchitis.

Key words: chronic bronchitis, infectious exacerbation, decamethoxine, nebulizer.

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