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Pharmacoepidemiological rationale for the use of antibacterial drugs in community-acquired pneumonia in children of different ages

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Annotation: *Global recommendations for the treatment strategy of community-acquired pneumonia are antibacterial therapy (ABT) - beta-lactams, fluoroquinolones, macrolides - until the results of laboratory tests are available to identify the etiological agent responsible for CAP. etiotropic therapy. According to Russian national clinical guidelines, macrolides, fluoroquinolones, cephalosporins and aminopenicillins are prescribed empirically. Meta-analyses have found better outcomes in patients treated with a combination of macrolides and beta-lactams compared to beta-lactams alone. However, the clinical benefit of adding macrolides to beta-lactams for the empiric treatment of moderate SAP remains controversial, as the difference in treatment results may depend on the age and comorbid conditions of the patients.*
Keywords: *Community-acquired pneumonia, antibacterial therapy, pharmacoeconomic analysis, cost of disease analysis, clinical practice*

Introduction: Lower respiratory tract infections are the third leading cause of death worldwide and the leading cause of death in low-income countries [1] . Community-acquired pneumonia (CAP) is a common disease that causes a significant disease burden for the community, especially in children under 5 years of age, the elderly, and the immunocompromised [2] [3] .

Antibiotics are routinely used to treat CAP [1] . Inadequate management of CAP in hospitalized patients prolongs hospital stay as well as increases the cost of therapy and mortality from CAP. In addition, the emergence of multidrug-resistant (MD) microorganisms creates serious problems in the selection of empiric and specific therapy [4] . In recent years, there has been a steady increase in the number of hospitalizations, including. in intensive care units for CAP, especially in the elderly [5] . Mortality rates range from 2% to 20%, reaching 50% in intensive care unit patients, and vary by health care facility, geographic region, patient category, and age [4] [5] .

Global recommendations for the treatment strategy of CAP consist of empirical prescription of antibacterial drugs - beta-lactams, fluoroquinolones, macrolides [6] [7] - until the results of laboratory studies are obtained to identify the etiological agent responsible for CAP. etiotropic therapy. According to Russian national clinical guidelines [8] [9], macrolides, fluoroquinolones, cephalosporins and aminopenicillins are prescribed empirically. It was noted that there were no significant differences in terms of efficacy and safety between the groups of these antibacterial drugs in the outpatient setting.

First-line empiric antibiotic therapy (ABT) strategies differ in other countries. Thus, in Switzerland and the Netherlands, beta-lactam monotherapy is recommended as a standard for hospitalized patients with CAP in intensive care units [10] [11] In the Gulf countries, inhaled fluoroquinolones are the drug

of choice for initial ABT [6] . The choice of the drug largely depends on the national epidemiological data on antibiotic resistance of the main pathogens of CAP.

Meta-analyses [12] [13] found better outcomes in patients receiving a combination of macrolides with a beta-lactam compared to a beta-lactam alone. However, the clinical benefit of adding macrolides to beta-lactams for empiric treatment of moderate CAP remains controversial [11] [14] , as differences in treatment outcomes may be related to patient age and comorbid conditions [10].

There were also no significant differences in the cost-effectiveness of preferred antibiotic strategies for CAP in non-intensive care settings between beta-lactam monotherapy, beta-lactam/macrolide combination therapy, or fluoroquinolone monotherapy [7] .

Thus, all treatment strategies have approximately the same effectiveness, depend on the regional map of antibiotic resistance and must be determined individually by the doctor for each patient based on risk factors and comorbid conditions [15] .

The aim is to analyze the costs of treatment of CAP with different ABT strategies to optimize the cost structure of the medical organization and budget planning for local health systems.

Material and Methods: A retrospective epidemiological analysis of extracts from the medical records of middle-aged patients treated in multidisciplinary medical organizations according to the World Health Organization classification was performed. 157 medical records were included in the study. Inclusion criteria: diagnosis of community-acquired pneumonia, prescription of therapy with beta-lactam antibiotics. Exclusion criteria were other diagnoses or prescription of other therapy. Research depth - 2 years. The effectiveness of the empirical initial ABT strategy was assumed to be non-replaceable. The information in the medical cards of the patients is recorded in specially created registration cards.

Primary direct medical costs were calculated in accordance with Annexes 12 and 13 of the General Tariff Agreement for 2023 [16] . They include the following costs:

Later, they added the costs of drugs (ABT) and hospitalization (inpatient).

The cost of ABT was calculated based on the cost of a daily dose of an antibacterial drug. To do this, we calculated the arithmetic mean value of the price of 1 mg of the drug for three concluded public contracts posted on the official website of public procurement [17] . Then, the daily dose is determined according to the dosage regimen specified in the instructions for medical use. The cost of ABT per day was calculated as the multiplication of the average daily dose of 1 mg of active substance.

The cost of ineffective therapy includes the cost of treatment with other antibacterial drugs. The cost of ABT was not taken into account when adverse events occurred due to lack of reliable data.

Indirect medical costs (IC) were not considered in this study.

Methods of research: Cost minimization analysis

When analyzing cost-effectiveness analysis (CEA), in a given case - cost minimization analysis (English cost minimization analysis, CMA), the difference in costs per 1 patient for treatment options x and y was calculated using the formula [18] [19].] :

$$CMA = DC\ x - DC\ y\ ,$$

where DC x - direct costs for ABT x; DC y - Direct costs for ABT y .

Economic efficiency analysis

A cost-effectiveness analysis was performed to evaluate initial empiric antibiotics as a cost-of-illness-to-achievement ratio. The cost-effectiveness ratio (CER) was assumed to be inversely

proportional to the number of hospital days before discharge. The calculation was made according to the following formula [18] [19] :

$$CER = (DC + IC) / Ef,$$

where DC is direct medical costs; IC - indirect medical costs (in this study - 0); Ef - treatment efficiency (hospitalization days).

Moral aspects

The study was conducted in accordance with the provisions of the Declaration of Helsinki of the World Medical Association (Fortaleza, Brazil, 2013). Informed consent was not obtained due to the retrospective nature of the study.

Statistical analysis

The obtained data were subjected to statistical processing in MS Excel (Microsoft, USA) and Statistica (StatSoft Inc., USA). The results are presented in absolute and relative values. Treatments prescribed to fewer than 3 patients in our sample were combined into the “Other” category and not used in further statistical analysis.

Conclusions:

The findings of this study indicate that the effectiveness of antibiotic therapy strategies for community-acquired pneumonia (CAP) in children is largely influenced by regional patterns of antibiotic resistance, patient age, and comorbid conditions. A combination of macrolides and beta-lactams appears to offer better clinical outcomes in some cases, although the benefits of adding macrolides to beta-lactams for empiric treatment remain debated. The study highlights that no significant differences exist between the cost-effectiveness of different antibiotic strategies in non-intensive care settings. These results suggest that treatment should be personalized, considering local epidemiological data and patient-specific factors. The implications for clinical practice include the need for tailored antibiotic prescribing protocols, which could optimize both treatment efficacy and cost. Future research should focus on long-term outcomes of different therapy combinations, especially concerning antibiotic resistance development and cost minimization in broader populations.

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