

Levodropropizine for cough treatment in adults: a randomized controlled trial

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Background. A cough is one of the most frequent cause for seeking treatment. It is often associated with a substantial decrease in quality of life. Levodropropizine is a cough suppressant, that can be prescribed for this condition. In current trial was evaluated levodropropizine effectiveness in improving quality of life in adults with a cough.

Methods. The study had a design of a randomized controlled trial. Adult patients (n=60) were randomized into 2 groups to receive levodropropizine or plantain syrup, a phytotherapy medication. Quality of life was evaluated with an SF-36 scale at baseline and after 7 days of treatment. Additionally, patients' overall health status was assessed with Health, Activity and Mood Scale at pointed above time frames.

Results. After the treatment, it was found a statistically significant improvement in QOL physical component in levodropropizine group compared to control group (

Introduction

Coughing remains one of the most common complaints when applying to a family doctor. According the European Respiratory Society survey 18 277 adults aged 20-48 years from 16 countries were investigated. The night cough was found in 30% of patients, productive cough - 10%, and unproductive - 10% [1]. Cough was noted in 30-40% of adults and caused about 20% of appeals to the doctor and substantially affected the patient quality of life(QOL).

Since the existing methods for evaluating the effectiveness of therapeutic interventions tend to reflect a purely biological approach and do not take into account the diversity of human life, the clinician's interest in quality of patient's life has significantly increased in recent decades [3, 10]. Supporting the quality of life, which is dependent on health, has become one of the important components of health care in the world [6, 7]. The question of quality of life related to health implies a global measure of patient perception and functional status [2, 3, 9].

The quality of life is influenced by a number of factors: the physical, mental and emotional state, the degree of its financial independence, the level of socialization, social status, and the state of the environment [4, 5]. Most people are designed to prolong their lives, improve their quality of life, ability to adapt to exacerbation of their illness and feel comfortable in this situation. Therefore, the main tasks of a physician in caring a patient, is not only the achievement of clinical and laboratory remission and the prevention of progression of the disease, but also the improvement of health and patient well-being[8].

The aim

The purpose of the study is to assess the patient's quality of life and functional statechanges after the treatment with Rapiatus in combination therapy in patients with acute cough on the ARI background.

Materials and methods

The study included 60 patients over the age of 18 with a diagnosis of ARI.

Inclusion criteria: acute cough for at least 12 hours and no more than 7 days, which is the criteria of clinically confirmed ARI (acute pharyngitis, acute laryngitis, laryngotracheitis, tracheitis, tracheobronchitis).

Exclusion criteria: bacterial infection (pneumonia), bronchoobstructive disease, acute respiratory failure, cancer, intolerance to the drug components, exacerbation or decompensation of chronic diseases, pregnancy and breastfeeding, diabetes mellitus.

The patient's condition assessment included the collection and analysis of anamnesis, cough score, and SF-36 (quality of life assessment) [2] at the time of treatment, after 3 and 7 days after the treatment start.

Age, years	43,26±15,04	42,53±18,01	0,864
Sex, men %	11 (36,6%)	12 (40%)	0,786
Smoking, %	7 (23,3%)	6 (20%)	0,74

Table 1. Demographic indicators

The patient's distribution to groups was carried out by random sampling (Table 1): 30 patients received Rapitus syrup 60 mg x 3 times/day, 30 patients control group - Plantain syrup 10 ml 3 times/day. The groups were comparable in terms of development, severity and clinical manifestations of respiratory disease.

The data analysis of clinical disease exacerbations in patients of both groups, showed an acute disease onset with a rise in temperature, intoxication symptoms, catarrhal phenomena in the nasopharynx. All patients were treated with complex treatment according to disease severity (oral rehydration, antipyretics and antibiotics for indications).

During the study, the quality of patients life was assessed using a standardized SF-36 (Medical Outcomes Study 36-Item Short-Form Health Status), which the patient filled out before treatment and each subsequent visit.

SF-36 belongs to non-specific questionnaires for assessing the quality of life. It is widely used in the United States and European countries. In these countries, studies were conducted on individual populations and the results obtained for the healthy population norms and for groups of patients with various chronic diseases (with the allocation of groups by gender and age). The questionnaire consists of 36 items grouped in 8 scales: physical functioning, role-playing, bodily pain, general health, viability, social functioning, emotional state and mental health. Each scale indicators range from 0 to 100, where 100 corresponds to full health.

The following indicators were quantified:

1. Physical Functioning (PF) - measures the degree of self-service, walking, climbing stairs, carrying heavy things, as well as performing significant physical activity. Low scores on this scale indicate that the physical activity of the patient is significantly limited by his state of health;
2. Role-Physical Functioning (RP) - characterizes the restriction degree in everyday activities due to physical health problems. Low scores on this scale indicate that daily activities are significantly limited by the physical condition of the patient.
3. Bodily pain (BP) and its effect on the ability to perform daily activities, including home and

out-of-home work, reflect the intensity of the pain and its impact on the ability to engage in normal activities. Low scores in this scale indicate that the pain greatly limits the activity of the patient;

4. General Health (GH) - assess the patients' health status at the moment and in the continuing treatment. As well as lower score on this scale, lower the assessment of health;
5. Vital activity (Vitality - VT) - assessment of the patient's sense of energy completeness. Low scores indicate patient tiredness and decrease in vital activity;
6. Social Functioning (SF) - is determined by the degree to which the physical or emotional state restricts social activity (communication). Low scores indicate a significant limitation of social contacts, a decrease in the level of communication due to physical and emotional state deterioration;
7. Role-Emotional (RE) - conditioned by an emotional state - involves an assessment of the extent to which an emotional state interferes with the performance of work or other daily activities, including the high cost of time, the reduction of work volume, the decrease in its quality, etc. Low scores on this scale are interpreted as restrictions in the performance of daily work, due to the deterioration of the emotional state;
8. Mental Health (MH) characterizes the mood, the presence of depression, anxiety, a general indicator of positive emotions - characterizes the mood, the presence of depression, anxiety, assesses the overall rate of positive emotions. Low rates indicate the presence of depressive, anxious experiences, absence of mental wellbeing.

To assess the elements of psycho-physiological status, the "Self-esteem.Activity. Mood "scale(" SAN ") was used. This questionnaire is a map (table) containing 30 pairs of words that reflect the studied features of the psycho-emotional state (state of health, mood, activity). In developing the technique, the authors proceeded from the fact that the three main components of the functional psycho-emotional state - well-being, activity and mood can be characterized by polar estimates, between which there is a continuum of intermediate values. Score 4 and lower, obtained by this method, indicates a decrease in well-being, activity and mood. The average mark of the scale 5 and above, indicates a subjects favorable state in the assessment area.

Results and discussion

During the study was found that cough has a significant effect on quality of life in all studied parameters, manifested by a violation of both physical and psycho-emotional capabilities (Table 2). To a greater extent, coughing depended on subjective assessment indicators of the general health state, vital (energy, mood) and social activity (sufficient emotional and physical ability to communicate with other people).

In 3 days treatment course the patient's condition improved, which was reflected in the QL indicators: in the Rapitus group, the physical as well as mental components increased significantly, while only the physical component reacted in the control group. At day 7 treatment in the group receiving Rapitus, there were obtained significantly higher rates compared to the state before treatment: the physical QL component increased (9 ± 1.94 points), and the index of the mental component was (4.29 ± 1.6 points). The general condition of patients receiving Plantain Syrup also improved, but to a lesser extent (by 6.24 ± 0.66 and 4.67 ± 1.51 points, respectively).

Before treatment			
Physical component	42,56±8,92	42,44±8,28	0,96
Psychological component	41,03±8,4	37,93±9,7	0,08
After 3 days treatment			
Physical component	46,73±6,43*	42,96±8,99	0,05
Psychological component	43,92±5,34*	41,88±9,17*	0,29
After 7 days treatment			
Physical component	51,56±6,89**#	48,68±7,62**#	0,08

Psychological component	45,32±6,8#	42,6±8,19#	0,2
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Table 2. Results of life quality assessment using the SF scale 36

The difference in the indicator value in the treatment dynamics is - statistically significant ($P < 0.05$), * - 3 days compared with the state of treatment, ** 7 days compared with 3 days treatment, # 7 days compared with the state before treatment.

The functional patient's status was assessed by means of a differential self-assessment functional state scale (SAN) (Table 3). On the first visit there was not only a decrease in functional indicators, but also their disproportion - prevailing decline in well-being and activity. After 7 days treatment, there was an improvement in all indicators (state of health, activity, mood), and also balanced their proportional relationships. These changes took place in both groups, but positive dynamics was recorded to a greater extent among patients who received Rapitus.

Before treatment			
State of health	2,8±1,3	2,79±1,31	0,97
Activity	2,98±1,04	2,92±1,21	0,85
Mood	3,35±1,45	3,36±1,3	0,98
3 days after the treatment			
State of health	3,55±1,55*	3,31±1,53*	0,57
Activity	3,55±1,2*	3,43±1,44*	0,73
Настрій, бали	4,04±1,64*	3,75±1,53*	0,51
7 days after the treatment			
State of health	4,81±1,35**#	4,35±1,5**#	0,24
Activity	4,63±1,05**#	4,23±1,48**#	0,26
Mood	5,0±1,38**#	4,81±1,44**#	0,6

Table 3. Changes in patient's functional state assessed by differential self-assessment functional state scale (SAN) during the treatment.

The difference in the indicator value in the treatment dynamics is statistically significant ($P < 0.05$), * - 3 days compared with the state of treatment, ** 7 days compared with 3 days treatment, # 7 days compared with the state before treatment.

Conclusion

1. The treatment of patients with unproductive cough during the ARI with Rapitus is associated with a significant ($p < 0,05$) normalization of the main clinical symptoms of the disease: cough, dyspnea, disappearance of sputum and wheezing, intoxication compared with the control group (patients who received Plantain Syrup).
2. The assessment of the quality of life showed that after 3 days Rapitus use, the physical component of quality of life has significantly improved (46.73 ± 6.43 versus 42.96 ± 8.99), while in the control group this indicator is reliably increased only for 7 days (51.56 ± 6.89 against 48.68 ± 7.62).
3. After a 7-day course of therapy, there was an improvement in all indicators (health, activity, mood), and also balanced their proportional relationships. The above changes took place in both groups, but positive dynamics was recorded to a greater extent among patients who received Rapitus.
4. Drug Rapitus is a highly effective and safe for the dry, unproductive cough treatment. The use of the drug significantly reduces the intensity of dry cough, quickly cessation of night coughing, improves the quality of patients life.

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