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EC PULMONOLOGY AND RESPIRATORY MEDICINE

Research Article

Visual Analog Scale-An easy Method of Cough Assessment in Children

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Received: September 23, 2019; **Published:** October 24, 2019

Abstract

Background: Cough is the most common symptom for which medical help is sought. In pediatric practice, cough is the most frequent symptom of respiratory infections, which represent the most common diseases in preschool children. The visual analog scale (VAS) has been used to assess cough severity in children suffering from chronic cough.

Methods: The study was conducted in the Children's Hospital for Lung Diseases and Tuberculosis, Medical Centre "Dr. Dragisa Misovic". All patients were presented with prolonged cough (due to upper and/or lower respiratory tract infectious with or without atopic constitutions) up to two weeks. They have been taking alongside their therapy a Herbiko® kid's syrup with honey.

Results: 109 patients were included in the study. According to results on VAS after the treatment all participants experienced no cough or cough several times but without disturbing daily activity. None of the participant had cough that interfere daily activities. ANOVA test with repeated measurements has showed that there is a statistically significant improvement of cough severity on VAS before and after the treatment with natural product.

Conclusion: Herbal products was found safe and effective in reducing symptoms of prolonged dry, productive and mixed cough. Cough monitoring is a very important both for clinical studies and practice. VAS is a simple and a very useful tool for monitoring cough severity.

Keywords: *VAS; Cough; Assessment; Children*

Introduction

Cough is the most common symptom for which medical help is sought. In pediatric practice, cough is the most frequent symptom of respiratory infections, which represent the most common diseases in preschool children. Cough associated with respiratory infections is mostly acute and directly provoked by the inflammation of the nasal or pharyngeal mucosa. Chronic cough is associated with chronic pulmonary diseases (chronic bronchitis, allergic asthma, eosinophilic bronchitis, bronchiectasis, recurrent pneumonia), as well as serial or repeated viral respiratory diseases in preschool or school age children. Certainly, in pediatric population, the most frequent causes of chronic, prolonged and/or repeated cough are disorders such as asthma, allergic rhinitis and /or rhinosinusitis with postnasal drip [1,2]. Despite extensive and detailed analysis on diagnosis and treatment of chronic cough, it is still difficult to objectively assess and make a

clear perception of serious cough. The usual approach through clinical measurements and validated questionnaires are being widely used. The gold standard for measurement of cough frequency has been digital recording which still needs to be thoroughly developed in future. Morbidity due to serious coughing is quite high, while assessment of cough patients, especially children, is incomplete without taking into account clinical impact of the disease and the patients' personal view. In this regard, the visual analog scale (VAS) has been used to assess cough severity in children suffering from chronic cough. VAS includes a scale from 0 to 100 mm, where patients can indicate the cough severity during the last two weeks [3]. It has been shown as useful for children to arrange VAS scaling system as a colored scheme or traffic lights scheme. Most importantly, VAS (visual analogue scale) is an easy method of cough assessment that allows continual use at every visit, if necessary.

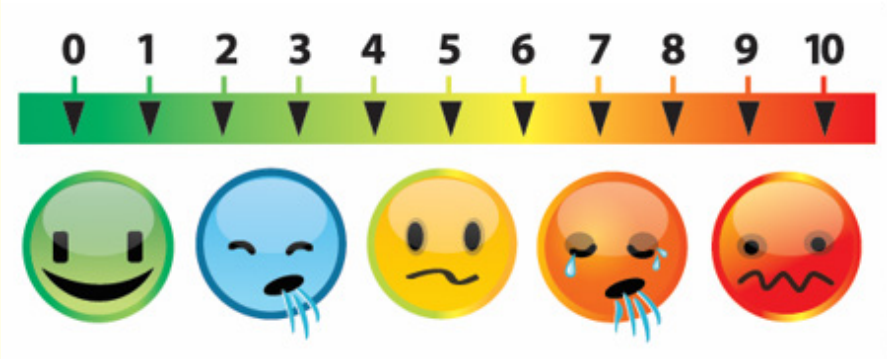

Figure 1: *Visual Analog Scale 1- No cough; 1-3 I cough sometimes, but it causes no difficulties , 4 - 6 I have a cough, but I still go to school and do sports; 7- 8 I have persistent cough that prevents me going to school an ddoing sport activities, 9 - 10 I have cough that presents agreat deal of discomfort.*

The cough visual analogue scale (VAS) represents a simple instrument, using a 100 mm linear scale where patient can indicate the severity of their cough between the two extremes: zero is no cough while 100 mm is the worst cough imaginable. Patients should be specifically told what time period is being monitored, as the final score is presumed to be the integrated sum over that time period (e.g. past 24 h, or past 48 h). One particular group tested the repeatability and responsiveness of this measuring scale method and found it very satisfactory in both respects.

Also found good correlation with cough-specific quality of life, but no correlation with cough reflex sensitivity [4-7].

When discussing cough therapy, certain specific treatments directed at the cause of cough are frequently unsuccessful in children for various reasons. Overlapping of symptoms are quite usual and serial cough episodes in preschool age children are frequent. The pharmacological treatment deemed successful at one time, does not secure effectiveness for the next episode. Even in asthmatic children, cough does not necessarily need to be related to asthma, so therapy might prove to be inefficient and cough to be resistant to antiasthmatic drugs. Additional phytotherapeutic treatment could be the best option for those cases [4]. New research will probably bring the science closer to an ideal cough monitor. Recent experience has led to the idea of what an ideal cough monitor should look like: compact and robust, used in 24h recording sessions in ambulances, with automatic cough detection to a high degree of specificity, validated against manual counting procedures and carrying a high degree of sensitivity in detecting cough and rejecting non-cough events, with reproducibility and responsiveness of the system itself [8].

Nature is a treasury of herbs with healing properties. These herbs used to be a part of traditional medicine from ancient times. During modern times, healing properties of herbs have been proven by clinical studies and their effect on various conditions and diseases established. Today, more than 10,000 herbs are in use in medicine and there are on-going researches of their healing properties all over the world. Herbs contain many active ingredients and may have several actions to support the body's health, while many of them maintain a gentle adverse effect profile. Therapeutic value of herbal remedies is based on the connection between the chemical structure of active substances in herbs and their pharmacological effects on the body. Complexity of chemical composition and ingredients ranging from 2 - 3 and sometimes even 30 - 40 identified elements in some herbal species, can explain therapeutic effect of the same plant for different conditions. Herbal remedies can be used in treatment or prevention of disease, as addition to main therapy as well as a main drug, or to stimulate or strengthen the body's normal functions. Nowadays, phytotherapy is complementing the concept of modern therapy, working synergistically to restore health. There is no area of health issues so far where phytotherapy does not fit well with other health systems. In south-east European region, use of herbal preparations in therapy or as a prophylactic agent has a long and rich tradition. The growing use of medicinal plants by the population is due to its low cost, easy access and history of traditional use. Conditions like cough, flu, or common cold with respiratory symptoms can successfully be treated with herbal remedies, especially in children. In pediatric population, the largest number of respiratory episodes accompanied by coughing are of viral origin. Usually, cough in this age group does not require antibiotics, so use of herbal remedies for symptomatic therapy can be of great help. Remedies with herbal extracts in them have a positive effect on the upper respiratory tract due to active ingredients such as phlegm, saponosides and essential oils. Herbs that are most commonly used as cough remedies are: marchmallow (root), chamomile (blossom), basil (leaf) and rosehip (fruit). Marshmallow root is well known for its' high mucilaginous contents and is traditionally used for soothing dry and irritant cough. Mucus provides protection of upper respiratory tract mucous membranes by coating prevents irritation and eases coughing [9]. Rosehip fruit is the best source of vitamin C, that together with other active substances like flavonoids and anthocyanins contribute to its' anti-inflammatory and antioxidant effect [10,11].

Chamomile blossom exhibits anti-inflammatory and antibacterial effect when introduced to cough syrup formulations. This helps soothe muscles in respiratory tract, relieving the "tickle" in the throat and it promotes restful sleep [12]. Basil is also often used in cough syrups due to an ingredient eugenol, which is the main component of basil essential oil. It shows anti-inflammatory effect which contributes to soothing the cough [13]. Although, honey is not of herbal origin, it is often used in phytotherapy as an adjuvant in various formulations. Honey acts as a demulcent, with a high viscosity and stickiness that does an incredible job of coating and soothing irritated mucous membranes. Due to these effects, honey represents a common component in cough syrups [14]. Regardless of their specific effects when applied singularly, traditional use have shown that a combination of certain components can be the optimal solution. In optimal combinations, these herbal formulations show synergistic effect. Different herbal ingredient will target a specific kind of cough, so various conditions could be covered using a mixture. As a result of optimal formulations, cough can be eased faster and easier, which can positively influence overall state of the patient, as well as the main cause of the cough [15].

Aim of the Study

The aim of this study were to show that VAS-visual analog scale is a useful method for obtain the clinical efficacy of registered herbal product Herbiko® kid's syrup with honey, (producer AbelaPharm, Beograd, Serbia) in terms of improvement of cough in children with upper or/and lower respiratory tract infectious with or without atopic constitution (asthma and/or allergic rhinitis).

Methodology

Our study was a real life observational study. The study was conducted in the Children's Hospital for Lung Diseases and Tuberculosis, Medical Centre "Dr Dragiša Mišović", Belgrade, Serbia. The protocol was approved by the Ethical Committee of the hospital. Informed consent was obtained from all parents or caregivers of the participants. All patients included in this research were presented with prolonged cough (due to upper and/or lower respiratory tract infectious with or without atopic constitutions) up to two weeks. They

have been taking alongside their therapy a Herbiko® kid's syrup with honey (notification number 5711, from 26th of August. 2014., by the manufacturer AbelaPharm d.o.o according to the summery of product characteristics (5 ml of syrup tree times per day in school aged children). Herbiko® kid's syrup with honey is herbal mixture of chamomillae flos tincturae, althae radix, osmium basilicum, primulae radix extractum fluidum, Vitamin C and honey.

Baseline procedures included medical history (cough episodes in the first and second year of life, the number of respiratory infections and antibiotics usage during the first two years of life, hospitalization due to respiratory problems) physical examination and recording of vitals.

Primary end points

Primary end points analyzed were changes in day/night time cough scales evaluated over a period of 14 days from baseline on 6 point evaluation scale. Six point scale for evaluation. Parents were also asked to determine cough into three categories: productive cough, dry cough or mixed cough. For a subjective determination of cough severity we decided to use VAS - visual analog scale (Figure 1). The cough visual analogue scale (VAS) represents a simple instrument, using a 100 mm linear scale where patient can indicate the severity of their cough between the two extremes: zero is no cough while 100 mm is the worst cough imaginable (Figure 1). Parents were also asked to judge the efficacy of herbal product on a certain numeric scale. (-7 deterioration of cough/red zone, 0 steady state - yellow zone +7 amelioration of cough -green zone). Beside clinical evaluation we have investigated the quality of life of participants in terms of kinder garden attendance for preschool children and physical activity for both pre and school age children.

Statistical analysis

The sample size was calculated with the software package G power. Descriptive and analytical statistical methods were used. The following descriptive variables were described: measures of central tendency (mean, median), measure of dispersion (standard deviation, interval of variation). Analytical statistical methods were used to test differences, parametric and nonparametric variables. Student's t test and analysis of variance of repeated measurements were used. Chi square test, McNemar test, Mann-Whitney test, Wilcoxon test, Friedman test were also included. All data were analyzed in SPSS 15.0 software package. (SPSS Inc., Chicago, Illinois, USA).

Results

109 patients were included in the study with statistically no differences between genders. 65 boys and 44 girls were participated. The youngest patient was two and a half year old whereas the oldest one included in the study was 18 years old. Average age of the children who took the product was 8.15 years old (Figure 2). According to the medical records more than 70% of children have experienced at least one episode of cough in the first and second year of life. Half of the children included in the study have been treated with antibiotics in the first year of life. Whereas almost 3\4 of participates have been prescribed antibiotics during the second year of life mostly due to respiratory infections. More than three quarter of children in the study had more than 3 episodes of respiratory infectious (rhinitis, sinusitis, pneumonia were included). Fortunately, only 43% of them were hospitalized due to those respiratory problems. And almost a half of children had some kind of chronic disease (such as asthma, allergic rhinitis, atopic dermatitis).

The distribution of the patients according to nature of cough is showed on figure 3. According to the results 7.5% of the participants don't have problems with daily cough and one quarter has only one episode of daily cough. 41.5% of the children experienced often daily cough several times per day without any impact of that on the quality of life. Around 16% of the children have suffered from cough that interferes with daily activities. One of the commonest reasons for visiting pediatricians is for sure night cough. The main cause of night cough is post nasal drip. A similar situation was in our study where almost ¾ of the children have experienced at least one episode of night cough. Among them 25% have reported sleep disturbance due to the issues with cough (Figure 4). While analyzing daily and night cough we have mentioned that more children have complained for daily cough than for cough problems during the night. Furthermore daily cough has been classified as more severe. The difference is statistically significant. Statistical analysis of cough nature has showed

that mixed type of cough is statistically more common than isolated dry or productive cough (Hi2 = 13.56, df = 2, sig = 0.001). In order to obtain more reliable results and to take into account not only parents perception of cough but as well as children's we decided to use a very friendly and easily understand VAS. We have asked both parents and children to circle a certain number or picture on VAS before and two weeks after the treatment with herbal products. The answers are showed on figure 5 and 6 before starting the treatment with herbal products more than a half of participants complained about cough (from 5 - 10 points on the scale). After the treatment all participants experienced no cough or cough several times but without disturbing daily activity. None of the participant had cough that interfere daily activities. ANOVA test with repeated measurements has showed that there is a statistically significant improvement of cough before and after the treatment with natural product. (M1 = 4.53M2 = 0.8, F = 365.550, sig. = 0.000). Parents were also asked to judge the efficacy of herbal product on a certain numeric scale that has been previously described in methodology. More than 97% of parents have noticed some kind of improvement after two weeks of treatment with natural product. According to the medical data from personal medical history 42% of the children suffered from upper respiratory tract infections, 11% experienced lower respiratory tract infections, while 47% of the participants suffered from asthma and/or other respiratory tract infections. At the end it is also a very interesting to mention that only 2.1% of children have never attended kindergarten. A majority of them started to attend kindergarten between the ages of 2 - 3. Most probably due to issues with respiratory problems more than 50% of patients don't practice any kind of physical activity.

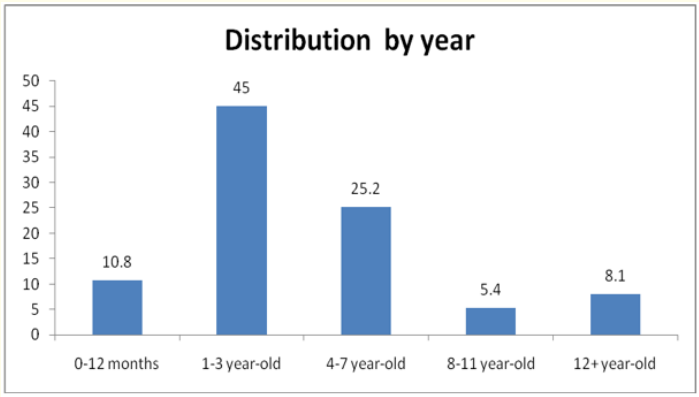

Figure 2: *Distribution by age.*

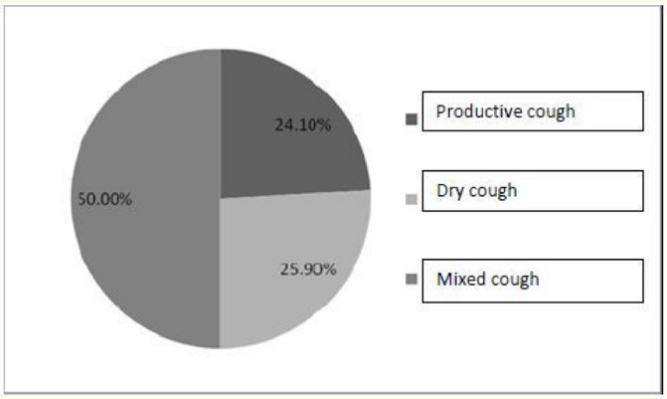

Figure 3: *Distribution by cough nature.*

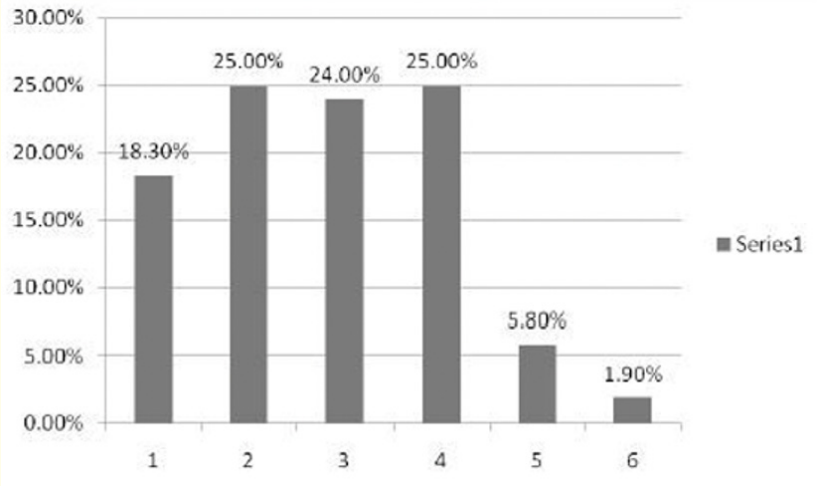

Figure 4: *Six point scale for Night cough.*

1. *No night cough.*
2. *Morning cough.*
3. *Cough that wakes you up in the night or early morning cough.*
4. *Often cough that wakes you in the night.*
5. *Often cough that disturbs sleep.*
6. *Disturbing cough all night long.*

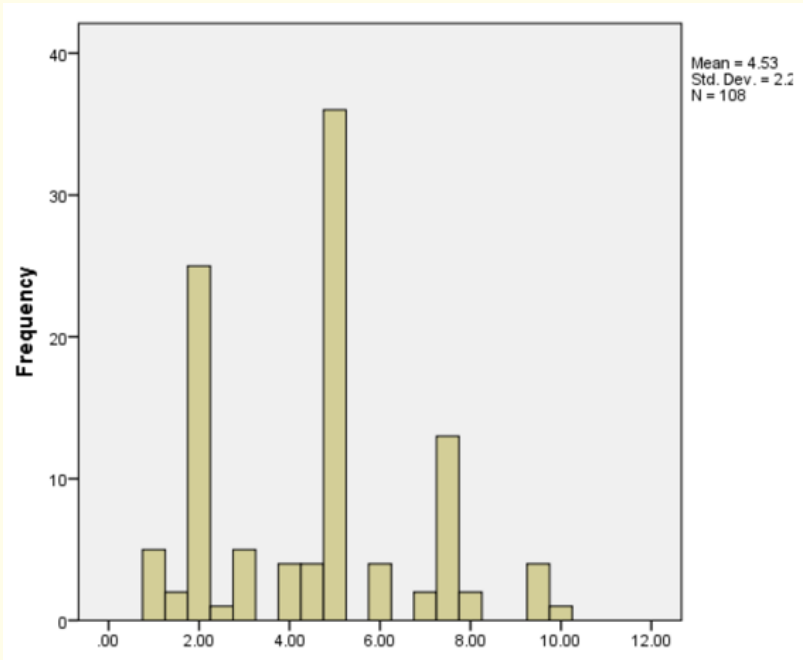

Figure 5: *Cough score before treatment.*

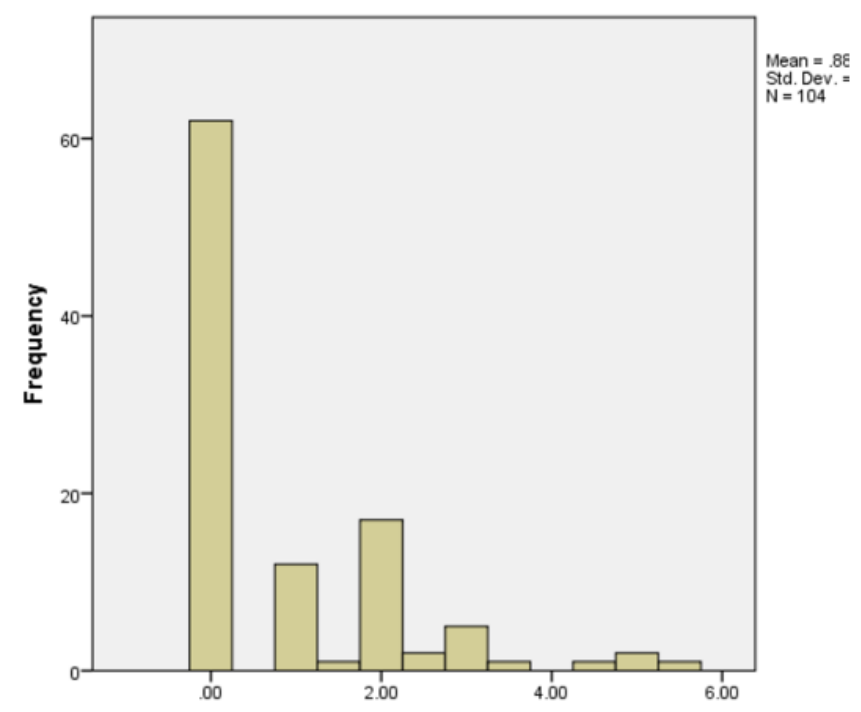

Figure 6: *Cough score after treatment.*

Discussion

Most people have experienced a cough even at least once in their lives. Cough is one of the most common symptoms of much acute or chronic disease. Many different kinds of cough have been described. General practitioners, family doctors and pediatricians see patients complaining about the cough. If cough is associated with high fever and/or other common symptoms such as muscular pains, arthralgia, loss of appetite and with elevated inflammatory parameters, the most probably reason might be upper acute respiratory infections or common cold. In the case of bacterial infections antibiotics are needed to be introduced. On the other side the best option for patients, particularly children with prolonged cough with or without bronchial hyperactivity could be herbal products. Herbal products for prolonged cough are one of the most common prescribed over the count medicine. There are many different types of herbal products on the market. Many studies have showed clinical efficacy of herbal products. Herbal medicines are part of a wide range of treatments such as phytotherapies, hydrotherapies and Traditional Chinese Medicine (TCM), few of which are applied in conventional medicine.

Whilst herbal treatments have a long history of use in varied cultures, randomized controlled trial (RCT) data on their effects is generally lacking [15-18]. Herbal cough treatments with proven clinical efficacy include ivy/primrose/thyme-based preparations which are recommended as expectorants in current European guidelines [10-24].

It is well known that honey itself as well as in combination with other herbal substances is a very efficient in treating deferent kind of cough (dry, productive and mixed). Honey is recommended as a cough medication by the World Health Organization. To date, the efficacy of this treatment has been shown in 2 studies: one tested only buckwheat honey and the other study was not blinded. In a randomized controlled trial, 3 types of honey were compared versus placebo as a treatment of upper respiratory tract infection-associated cough.

These types of honey were superior to placebo in alleviating cough [25]. In accordance with those studies we have also proved that herbal product with honey extracts was a very effective in treatment cough, particularly for nocturnal cough that was noted as more severe than daily symptoms. As we have already mentioned cough in our study was also associated with upper respiratory tract infections in 42% of our patients. This is one of the first studies evaluating clinical efficacy of herbal products for prolonged mixed cough in infants, children and adolescents with visual analog scale VAS. The study has showed that daily cough is more present, more disturbing and more intensive than night cough that is in a correlation with the results from other studies. VAS is a useful method for the evaluation of cough severity as well as the efficacy of certain treatment. Unfortunately, other studies have showed no correlation between VAS and other questionnaires used for cough assessment [26-29]. In our study we found correlation between VAS and other numeric scale that has been used. Besides proving the efficacy of herbal product Herbiko for mixed cough results from our study showed that VAS can be a very useful tool for monitoring cough for both children and parents. VAS was in a correlation with numeric scale according to our data [29].

Conclusion

Herbiko was found safe and effective in reducing symptoms of prolonged dry, productive and mixed cough. No adverse events related to study or study products were reported during the follow up period. Cough monitoring is a very important both for clinical studies and practice. VAS is a simple and a very useful tool for monitoring cough severity. But it can be also used for assessment of clinical efficacy of herbal products that are common prescribed for treating different kinds of cough. Antibiotics are very often misuse for cough treatment so it is of a great importance to have more studies showing positive effects of herbal products that are a very safe and effective for all age groups particularly for children.

Competing Interests

The authors declare no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript, except Davor Korcok and Svetlana Mitorvic who are employed in Abela Pharm who supported the study in terms of logistics and herbal products distribution.

Authors' Contributions

Zorica Zivkovic, Vesna Vekovic, Jasmina Jocic and Olivera Ostojic conceived and designed the study and coordinated the data collection. Davor Korcok and Svetlana Mitrovic revised the study results and drafted the manuscript. Ivana Filipovic and Marco Caminati contributed to data interpretation and manuscript preparation. All authors read and approved the final manuscript.

Funding Source

None.

Ethics Approval and Consent to Participate

The study was approved by the Ethical Committee of the University Hospital "Dr. Dragiša Mišović", Belgrade, Serbia.

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Volume 8 Issue 11 November 2019