Hospitalized patients with COPD: analysis of prior treatment

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Abstract

Objective: Although COPD is a prevalent disease, it is undertreated, and there are no available data regarding previous treatment of COPD in Brazil. This study aimed to determine the appropriateness of maintenance treatment in COPD patients prior to their hospitalization and to identify variables associated with inappropriate treatment.

Methods: This was an observational, cross-sectional, analytical study involving 50 inpatients with COPD at two hospitals in the city of Florianópolis, Brazil. The patients completed a questionnaire on parameters related to the maintenance treatment of COPD. Non-pharmacological management and pharmacological treatment were assessed based on the recommendations made by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) in 2011 and by the Brazilian National Ministry of Health in the chronic respiratory diseases section of its Caderno de Atenção Básica (CAB, Primary Care Guidebook).

Results: In most of the patients, the COPD was classified as being severe or very severe. Regarding non-pharmacological management, 33% of the patients were smokers, only 32% had been advised to receive the flu vaccine, 28% had received pneumococcal vaccine, and only 6.5% of the patients in the B, C, and D categories received pulmonary rehabilitation. Regarding GOLD and CAB recommendations, pharmacological treatment was inappropriate in 50% and 74% of the patients, respectively. Based on GOLD recommendations, 38% were undertreated. A low level of education, low income, not receiving oxygen therapy, and not receiving the flu vaccine were associated with inappropriate treatment.

Conclusions: The application of various non-pharmacological management recommendations was unsatisfactory. Regarding the GOLD recommendations, the high rate of inappropriate maintenance treatment was mainly due to undertreatment. In Brazil, even in severe COPD cases, optimizing treatment to achieve greater benefits continues to be a challenge.

Keywords: Pulmonary disease, chronic obstructive/therapy; Pulmonary disease, chronic obstructive/prevention and control; Clinical protocols.

Resumo

Objetivo: Embora a DPOC seja uma enfermidade prevalente, ela é subtratada, e dados sobre o tratamento prévio são desconhecidos em nosso meio. Buscou-se verificar a adequação às recentes diretrizes no que se refere ao tratamento de manutenção em pacientes com DPOC antes de sua hospitalização e identificar possíveis variáveis associadas à inadequação do tratamento.

Métodos: Estudo transversal, observacional e analítico, que incluiu 50 portadores de DPOC, internados em dois hospitais na cidade de Florianópolis (SC). Aplicou-se um questionário sobre parâmetros relacionados ao tratamento de manutenção da DPOC. Avaliou-se o manejo não farmacológico e a adequação do tratamento farmacológico à terapia preconizada pelo Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2011 e pelo Caderno de Atenção Básica (CAB) do Ministério da Saúde do Brasil sobre doenças respiratórias crônicas.

Resultados: Na maioria dos pacientes, a DPOC foi classificada como grave ou muito grave. Em relação ao manejo não farmacológico, 33% eram tabagistas, apenas 32% foram orientados a receber vacinação anti-influenza, 28% receberam vacina anti-pneumocóccica, e somente 6,5% dos pacientes nas categorias GOLD B, C e D realizaram reabilitação respiratória. O tratamento farmacológico foi inadequado em 50% e 74% da amostra, respectivamente, em relação às recomendações do GOLD e do CAB. Baseado nas recomendações do GOLD, 38% foram subtratados. Baixa escolaridade, baixa renda, não utilização de oxigenoterapia e ausência de vacinação anti-influenza associaram-se à inadequação do tratamento.

Conclusões: Não foram seguidas satisfatoriamente várias recomendações do manejo não farmacológico. Segundo o GOLD, a elevada inadequação do tratamento de manutenção foi principalmente devida ao subtratamento. No Brasil, mesmo nos casos mais graves, a otimização do tratamento da DPOC para se obter benefícios mais evidentes continua a ser um desafio.

Descritores: Doença pulmonar obstrutiva crônica/terapia; Doença pulmonar obstrutiva crônica/prevenção & controle; Protocolos clínicos.
Introduction

A respiratory disease characterized by chronic airflow obstruction that is not fully reversible, with systemic manifestations, COPD is preventable and treatable, being associated with an abnormal inflammatory response (primarily to the inhalation of cigarette smoke, noxious particles, and toxic gases).[1]

The prevalence of COPD is high, as demonstrated by studies conducted in Brazil. Menezes et al. evaluated individuals over 40 years of age living in the metropolitan area of São Paulo, Brazil, and found that 15.8% had COPD.[2] It has been estimated that there are over seven million adults with COPD in Brazil. (2) The disease accounts for a large number of deaths, being the fifth leading cause of death in Brazil, and estimates indicate that COPD will have become the fourth leading cause of death in the country by the next decade.[3]

Underdiagnosis of COPD is common. In the study by Menezes et al., 88% of the patients with COPD had never undergone spirometry and therefore had an unconfirmed diagnosis of COPD.[2] In a study evaluating patients treated at primary care clinics in the city of Aparecida de Goiânia, Brazil, 71% had never undergone spirometry and therefore had an unconfirmed diagnosis of COPD.[4]

Undertreatment of COPD is also common. Of the COPD patients in the metropolitan area of São Paulo in the last decade, only 2% reported having received a physician diagnosis of COPD, and only 18% reported that they were receiving treatment for the disease.[2] The consequences of delayed, inappropriate treatment are disastrous and include increased exacerbations, loss of lung function, increased morbidity, and increased mortality.[2,5] However, data on the maintenance treatment of COPD are scarce in Brazil.[6]

In the present study, we analyzed non-pharmacological management and the appropriateness of pharmacological maintenance treatment in COPD patients prior to their hospitalization at either of two referral hospitals for the treatment of respiratory diseases in the southern Brazilian state of Santa Catarina. We chose to evaluate inpatients because we assumed that they were more likely to present with COPD that is more severe and less likely to be underdiagnosed and undertreated (as a result of their having previously sought health care).[6,7]
variables were expressed as absolute numbers and proportions. We compared the distribution of categorical variables between the patients receiving appropriate treatment and those receiving inappropriate treatment on the basis of the 2011 GOLD guidelines using the chi-square test and, when necessary, Fisher's exact test. In addition, we used univariate analysis in order to identify factors potentially associated with inappropriate treatment in comparison with the treatment recommended in the 2011 GOLD guidelines, determining the crude OR and its confidence interval for that outcome. The level of significance was set at $p < 0.05$.

The present study was approved by the Human Research Ethics Committee of the Polydoro Ernani de São Thiago University Hospital (Protocol no. 2425). All participants gave written informed consent.

### Results

We evaluated 50 inpatients with COPD (21 patients admitted to one of the aforementioned hospitals and 29 admitted to the other). Most of the patients were male, were over 65 years of age, were normal weight or overweight, had up to 8 years of schooling, were retired, had a per capita family income of up to one time the national minimum wage, were former smokers, and had a smoking history of $\geq 20$ pack-years. One third of the patients were active smokers. As can be seen in Table 1, most of the patients were classified as having disease that is more severe, 76% being classified into category C or D on the basis of the 2011 GOLD criteria and 64% being classified as having severe or very severe disease on the basis of the CAB criteria.

Regarding knowledge of disease, 64% reported having emphysema, 64% reported having chronic bronchitis, and 40% reported having COPD. Regarding non-pharmacological maintenance treatment before admission, 14 patients were still smokers. Most (78%) reported that they had been advised by their physicians to quit smoking. Among those who had quit smoking, 95% had done so with no medications or cognitive behavioral therapy (Table 2).

We analyzed the appropriateness of treatment, as well as undertreatment and overtreatment, by comparing the treatment given with the treatment recommended in the 2011 GOLD guidelines. Undertreatment was defined as the complete absence of pharmacological treatment or the use of drug combinations other than those recommended for each category (A, B, C, or D). Overtreatment was defined as the unwarranted use of long-acting bronchodilators and ICs. On the basis of the 2011 GOLD parameters, the sum of the proportions of undertreatment and overtreatment resulted in the proportion of inappropriate treatment. A second analysis of the overall appropriateness of pharmacological treatment was performed on the basis of the CAB parameters. We opted to use the CAB guidelines and the 2011 GOLD guidelines because they represent the latest clinical protocols for COPD nationwide and worldwide, respectively.

Statistical analysis was performed with the Statistical Package for the Social Sciences, version 15 (SPSS Inc., Chicago, IL, USA). Categorical
disease on the basis of the CAB guidelines, 69% and 50%, respectively, received inappropriate treatment (Table 3).

Table 4 shows the use of different classes of maintenance medication among the different 2011 GOLD categories of patients. Of the sample as a whole, 14% received no pharmacological treatment at all. In addition, only 3 (6%) used theophylline, all of whom were category D patients. Of the sample as a whole, 38% were undertreated, 8% (patients in categories A and B) receiving no pharmacological treatment at all. For the remainder (30%), undertreatment was identified by the lack of use of short- or long-acting bronchodilators, as well as by a slight predominance of lack of IC use in patients in categories C and D. Overtreatment was found in 12% of the patients (in categories A and B), all of whom used ICs and 1 of whom used an LABA + IC combination (LABA + IC).

In the univariate analysis, inappropriate pharmacological treatment (on the basis of the CAB guidelines) was significantly associated with up to 8 years of schooling, a per capita family income of up to one time the national minimum wage, and category A or B (i.e., less frequent exacerbations and FEV₁ ≥ 50% of predicted), as can be seen in Table 5. Appropriate pharmacological treatment was significantly associated with the use of home oxygen therapy (OR = 9.33; 95% CI: 1.05–82.78) and influenza vaccination (OR = 5.41; 95% CI: 1.02–28.79), as well as with self-reported physician-diagnosed emphysema.

reported having been advised by their physicians to receive pneumococcal vaccination. Home oxygen therapy was used by 16% of the patients, and only half of those used it daily for ≥ 15 h. Only 6.5% of the patients in categories B, C, and D received pulmonary rehabilitation.

Of the sample as a whole, 50% received inappropriate pharmacological treatment in comparison with that recommended in the 2011 GOLD guidelines. The proportions of inappropriate treatment in categories C and D were 60% and 33%, respectively. Of the sample as a whole, 74% received inappropriate treatment in comparison with that recommended in the CAB. Of the patients who were classified as having severe or very severe disease on the basis of the CAB guidelines, 69% and 50%, respectively, received inappropriate treatment (Table 3).

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Discussion

The objective of the present study was to examine the appropriateness of maintenance treatment prior to hospitalization in patients with COPD that is more severe, a distinct strategy being used in order to select inpatients. Several aspects of the recommended non-pharmacological treatment were not followed. One third of the patients were smokers, a small proportion (28%) had received pneumococcal vaccination, and very few (6.5%) of the patients in category B, C, or D were undergoing pulmonary rehabilitation. Of the sample as a whole, 50% received inappropriate treatment in comparison with that recommended in the 2011 GOLD guidelines, undertreated patients having predominated. The proportion of patients receiving inappropriate treatment was even higher (i.e., 74%) when the CAB was used as a reference for treatment. Inappropriate treatment was found to be associated with a low level of education and low income. Appropriate treatment was found to be associated with physician-diagnosed emphysema, use of home oxygen therapy, and influenza vaccination.

The present study is the first of its kind in Brazil. In the international literature, there are few studies addressing the appropriateness of COPD treatment. In the present study, data

Table 3 – Inappropriate pharmacological treatment for each COPD severity category in the 50 patients included in the study.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
<th>Patients receiving inappropriate treatment</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011 GOLD</td>
<td>A</td>
<td>2/2 (100)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>9/10 (90)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>3/5 (60)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>11/33 (33)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>25/50 (50)</td>
<td></td>
</tr>
<tr>
<td>CAB</td>
<td>Mild</td>
<td>1/1 (100)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>15/17 (88)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>18/26 (69)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Very</td>
<td>3/6 (50)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>severe</td>
<td>3/6 (50)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>37/50 (74)</td>
<td></td>
</tr>
</tbody>
</table>

GOLD: Global Initiative for Chronic Obstructive Lung Disease; and CAB: Caderno de Atenção Básica - doenças respiratórias crônicas (Primary Care Guidebook, respiratory diseases section).

Table 4 – Pharmacological treatment regimens used for the different categories of COPD patients, classified on the basis of the 2011 Global Initiative for Chronic Obstructive Lung Disease guidelines.

<table>
<thead>
<tr>
<th>Categories</th>
<th>Patients (n)</th>
<th>SABA</th>
<th>SAA</th>
<th>SABA + SAA</th>
<th>LABA</th>
<th>LAA</th>
<th>LAB + LAA</th>
<th>IC</th>
<th>LABA + IC</th>
<th>LAA + IC</th>
<th>LABA + LAA + IC</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>2</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (50)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>B</td>
<td>10</td>
<td>2 (20)</td>
<td>0 (0)</td>
<td>3 (30)</td>
<td>1 (10)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (10)</td>
<td>0 (0)</td>
<td>3 (30)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>5</td>
<td>1 (20)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (20)</td>
<td>0 (0)</td>
<td>1 (20)</td>
<td>0 (0)</td>
<td>1 (20)</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>33</td>
<td>16 (48)</td>
<td>6 (2)</td>
<td>7 (21)</td>
<td>1 (3)</td>
<td>2 (6)</td>
<td>1 (3)</td>
<td>2 (6)</td>
<td>4 (12)</td>
<td>2 (6)</td>
<td>13 (39)</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>19 (38)</td>
<td>4 (2)</td>
<td>10 (20)</td>
<td>2 (4)</td>
<td>2 (4)</td>
<td>2 (4)</td>
<td>7 (14)</td>
<td>2 (4)</td>
<td>17 (34)</td>
<td></td>
</tr>
</tbody>
</table>

SABA: short-acting β2 agonist; SAA: short-acting anticholinergic; LABA: long-acting β2 agonist; LAA: long-acting anticholinergic; and IC: inhaled corticosteroid. Values expressed as n (%).

Table 5 – Variables associated with inappropriate treatment in comparison with the treatment recommended in the 2011 Global Initiative for Chronic Obstructive Lung Disease guidelines.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Treatment*</th>
<th>p</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>inappropriate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per capita income, number of times the national minimum wage</td>
<td>≤ 1</td>
<td>14 (28)</td>
<td>6 (12)</td>
<td>0.021</td>
</tr>
<tr>
<td></td>
<td>&gt; 1</td>
<td>11 (22)</td>
<td>19 (38)</td>
<td></td>
</tr>
<tr>
<td>Schooling, years</td>
<td>≤ 8</td>
<td>25 (50)</td>
<td>20 (40)</td>
<td>0.018</td>
</tr>
<tr>
<td></td>
<td>&gt; 8</td>
<td>0 (0)</td>
<td>5 (10)</td>
<td></td>
</tr>
<tr>
<td>Physician-diagnosed emphysema</td>
<td>Yes</td>
<td>11 (22)</td>
<td>21 (42)</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>14 (28)</td>
<td>4 (8)</td>
<td></td>
</tr>
<tr>
<td>GOLD category</td>
<td>A or B</td>
<td>11 (22)</td>
<td>1 (2)</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>C or D</td>
<td>14 (28)</td>
<td>24 (48)</td>
<td></td>
</tr>
</tbody>
</table>

GOLD: Global Initiative for Chronic Obstructive Lung Disease.
In one study, only 14% of the patients hospitalized for COPD exacerbation had received prior pulmonary rehabilitation. In the present study, it was impossible to evaluate the need for home oxygen therapy, given that we had no access to previous blood gas analyses. In addition, it is impossible to confirm the need for home oxygen therapy during clinical instability. Given the large proportion of patients with FEV₁ < 50% of predicted (i.e., 64%) and the large proportion of category D patients (i.e., 66%), we can assume that the proportion of patients requiring home oxygen therapy was larger than that actually found (i.e., 16%). However, it is of note that half of the patients who were on home oxygen therapy did not receive it for as many hours per day as recommended, i.e. > 15 h.

On the basis of the guidelines analyzed in the present study, pharmacological treatment was found to be inappropriate in 50-74% of the patients. Our data regarding inappropriate COPD treatment are consistent with those found in the literature. One group of authors evaluated patients who had moderate, severe, or very severe COPD and who had health insurance; the authors found that 43% of the patients had received medication prescriptions that were not in accordance with clinical protocols and that 51% had not obtained the medication. One reason for the difference between the two guidelines used in the present study in terms of the proportion of patients receiving inappropriate treatment is that the CAB does not recommend IC use for patients with moderate obstruction. However, in the present study, the patients with moderate obstruction had had a high number of exacerbations in the previous year and were therefore included in GOLD category C or D, for which IC use is recommended in the GOLD guidelines, meaning that a proportion of patients classified as having moderate COPD and into categories C and D used ICs. Using the 2011 GOLD guidelines as a reference for pharmacological treatment, we found that 38% of the patients were undertreated, undertreatment constituting the most common instance of inappropriate pharmacological treatment. In one third of those patients, treatment inappropriateness was due to the complete absence of pharmacological treatment. In the remaining patients, treatment inappropriateness was due to the lack of use of pulmonary rehabilitation.

In a study of the distribution of COPD patients by disease severity in Brazil, a household survey conducted in the city of São Paulo showed that the prevalence rates of mild, moderate, severe, and very severe COPD were 10.1%, 4.6%, 0.9%, and 0.2%, respectively. As expected (because of the strategy adopted), the prevalence rates in the present study were different from those in the general population: severe and very severe COPD (52% and 12%, respectively); and categories C and D (10% and 66%, respectively). Therefore, patients with COPD that is more severe predominated, the benefits of maintenance treatment being greater in such patients.

The sociodemographic characteristics of the COPD patients in the present study were similar to those of those in the study by Menezes et al., who also found a higher prevalence of COPD among males who were over 65 years of age and had a significant smoking history.

Various studies have shown that clinical protocols are not widely implemented. A study conducted in Brazil showed that 34% of general practitioners do not use clinical protocols for the management of COPD. Failure to follow the guidelines for the non-pharmacological maintenance treatment of COPD is consistent with the results of the present study; for example, 33% of the patients had not quit smoking, although smoking cessation has an impact on the rates of disease progression and mortality. Similar data are found in the international literature. In the present study, the proportion of patients who had been advised by their physicians to receive influenza and pneumococcal vaccination was low. Similarly, Menezes et al. found that only 30.6% of the COPD patients had received influenza vaccination, the proportions of vaccinated patients with severe and very severe COPD being 39% and 46%, respectively. A study evaluating COPD patients with respiratory failure admitted to the ICU also showed low vaccination rates, only 66.66% having received influenza vaccination and only 45.83% having received pneumococcal vaccination. Only 6.5% of the patients in the present study received pulmonary rehabilitation, which is recommended in the 2011 GOLD guidelines for patients in categories B, C, and D. Other studies have shown low rates of pulmonary rehabilitation.
at least one of the classes of drugs recommended in the GOLD guidelines.

It is known that COPD is underdiagnosed—88% of the COPD patients in the metropolitan area of São Paulo had an unconfirmed diagnosis of COPD—and undertreated. The present study included only patients with a diagnosis of COPD confirmed by spirometry; a confirmed diagnosis might be, in and of itself, a determining factor for better treatment. It is possible that the problem of undertreatment is even worse in patients with milder disease treated at less advanced centers and without a confirmed diagnosis.

Overtreatment (i.e., inappropriate IC use) was found in 12% of the patients (GOLD categories A and B). This finding is relevant because overtreatment affords no clear benefits and increases the risk of hospitalization for pneumonia, as well as increasing the incidence of oral candidiasis, ecchymosis, and cataracts.(13-16) A recent systematic review showed that there is evidence for IC use only in patients with severe COPD and symptoms and in those with moderate or severe COPD, symptoms, and more than two COPD exacerbations per year.(5) Incorrect prescription of LABA + IC is common among patients with moderate disease treated at primary or secondary health care facilities.(17-20) Studies have shown that 45% of patients with moderate COPD receive ICs only, whereas 60% receive LABA + IC.(21,22) In the present study, half of the patients in categories A and B used LABA + IC. One study showed that 50% of COPD patients admitted to the ICU for respiratory failure used systemic corticosteroids, meaning that at least 50% of the patients had received inappropriate non-pharmacological treatment.(10) This reinforces the hypothesis that the use of clinical protocols is low, given that none of the major clinical protocols in Brazil include the use of systemic corticosteroids as a treatment option.(1,8)

Variables such as a low level of education and low income were significantly associated with a higher proportion of patients receiving inappropriate treatment. Given the context, this was expected. Inappropriate treatment was found to be significantly associated with being in category A or B. Given that the proportion of patients in those categories was low in the present study, it is impossible to determine whether treatment is most inappropriate in patients with disease that is less severe (in whom the number of hospitalizations is lower); if this is indeed the case, then health care is primarily focused on advanced disease. In contrast, appropriate treatment was significantly associated with home oxygen therapy and influenza vaccination. The external validity of the present study could have been higher if the number of participants had been larger. In addition, for the evaluation of maintenance treatment, different recruitment strategies can be used in order to increase the representation of all GOLD categories.

In the present study, a physician diagnosis of emphysema was associated with an increased rate of patients receiving appropriate treatment. This might be due to the fact that patients give greater weight to the term emphysema and therefore seek treatment more often.

The present study was conducted before the approval of the 2013 Brazilian National Ministry of Health clinical protocol and therapeutic guidelines for COPD and, therefore, before the proposal for providing COPD patients with specific medication. The present study can therefore serve as a historical control for future epidemiological studies and contribute to the reorganization of COPD care.

On the basis of the evidence presented here, we conclude that the non-pharmacological management of COPD is currently unsatisfactory, as demonstrated by the significant proportion of active smokers, the low use of pneumococcal vaccination, and the lack of use of pulmonary rehabilitation. The same is true for the pharmacological treatment of COPD, the high rate of patients receiving inappropriate treatment being mainly due to undertreatment. Even in severe COPD cases, optimizing treatment to achieve greater benefits continues to be a challenge. Therefore, there is a need for further educating physicians and patients regarding COPD, as well as a need for more smoking cessation programs and pulmonary rehabilitation centers, together with a need for increasing the availability of medications for the treatment of COPD.

References


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