Prescription Monitoring of drugs used for asthma and COPD: A retrospective, before-after study

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ABSTRACT

Background: Nowadays there is increase in the incidence of chronic diseases such as bronchial asthma and chronic obstructive pulmonary disease. As these diseases require long-term treatment, irrational use of drugs may be possible that might lead to certain consequences. Drug utilisation evaluation is an essential part of pharmaco-epidemiological studies by which understanding of drug use according to the guidelines can be assessed.

Aim: The aim of this study was to find out the difference between the drug utilisation patterns in subsequent visits of patients to the outpatient department.

Methods and materials: In this before-after retrospective study, 104 asthma and chronic obstructive pulmonary disease patients attending the out-patient department of Pulmonary Medicine of a medical college hospital in Hyderabad, India were recruited for the study. At two different visits patient’s prescriptions were assessed and data was collected. Comparisons were made between the two visits for the drugs prescribed.

Results: The results revealed that montelukast was the most prescribed drug in both first (56.7%) and second (54.8%) visits, either alone or in combination and the most preferred inhaler device was pressurised metered dose inhaler with spacer (56.73%) and the drug used through inhalational route was formoterol in both visits (15.3% and 14.4%) as monotherapy followed by fluticasone+formoterol as combination therapy (24% and 21.1%).

Conclusion: Montelukast and formoterol was most prescribed drugs in this study. Apart from physicians, pharmacists can also play a role in correct prescribing practice and standard treatment guidelines by providing feedback of patient understanding, medication adherence and drug response to the treating physician.

Introduction

Drug utilization research/evaluation/review is defined by WHO as “marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences”. Drug utilisation evaluation (DUE) or Drug utilisation review (DUR) is an essential part of pharmaco-epidemiological studies, they together provide a proper understanding of usage pattern of drugs, quality and efficiency of drug use, determinants (social status of patient, therapeutic decisions of prescriber) and the outcomes of the drug use. Socio-cultural factors are the main contributing factor for drug use process. The main aim of performing DUE/ DUR studies is to maintain the rational use of drugs[1,2]. There are three points where DUE can be done: prospective (before the usage) concurrent (ongoing) and retrospective (after the usage)[3]. The essence of drug utilisation audits can be quantitative, qualitative or both. If the audits deal with drug use within a healthcare system/area/group it refers to quantitative audits and if the drug use is collate with the guidelines then it is said to be qualitative[4]. The practice of DUE is usually applied by the pharmacist to check the appropriateness of drugs prescribed, as a prescription is considered to be an abstract of physician’s understanding of disease and management through drugs[5]. Apart from the rational use of drug DUE can play an important role in assisting the physician’s prescribing attitude in accordance with the predetermined standards by allocating them with the feed-back. This information may also helpful in improvising the prescribing and dispensing practices by designing, conducting and imparting educational programmes for healthcare providers[6]. Nowadays there is increase in the incidence of chronic diseases such as bronchial asthma (BA) and chronic obstructive pulmonary disease (COPD), these ailments require long-term or even lifelong therapy which demands the appropriate use of medications to improve the outcome and better quality of life[7]. In India asthma is known to be one of the major cause of morbidity and mortality, comprising about 3-11% of adults and 3-5% of paediatric population[8].

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Similarly the prevalence rates of COPD ranges from 2 to 22 % in men and 1.2 to 19 % in women[9]. Although the understanding and approach towards the management of BA and COPD have gained new treatment paths, the incidence, severity and deaths shoot up over many decades in all age groups[10]. This may be due to financial constraints and compliance of patient[8] or loop hole in the management approach. According to GINA(Global Initiative for Asthma) guidelines, various drugs are suggested for the management of asthma that includes long and short acting β2 agonists (salbutamol, salmeterol, formoterol), corticosteroids (fluticasone, prednisolone, budesonide), xanthene derivatives (theophylline) and leukotriene receptor antagonists (montelukast). These drugs can be used alone or in conjunction with other antiasthmatic drugs[11]. The aim of this study was to find out the difference between the drug utilisation patterns in subsequent visits of patients to the outpatient department.

Patients and methods

Participants
A hospital based, before-after observational study was designed and carried out by clinical pharmacists, and approval was taken from Institutional Ethics Committee. A total of 104 subjects were assessed after taking verbal informed consent. The subjects were recruited from the out-patient Department of Pulmonary Medicine of a medical college hospital and the data was collected at two different visits (with a span ranging from 2 weeks to 6 weeks). The study was carried out for 6 months.

Inclusion and exclusion criteria
Patient suffering from asthma and COPD of varied duration who visited the hospital for acute exacerbation of the disease, or came for review were included. Those who were suffering from long-term complications of COPD and asthma like pulmonary hypertension, cor pulmonale, other respiratory conditions interfering with pulmonary ventilation or gas exchange, ischemic heart disease, chronic kidney disease, micro and macro-vascular complications of hypertension and diabetes mellitus were excluded.

Analysis
Microsoft word and Excel have been used to calculate the percentages and to generate graphs, tables.

Results
During this “pre-post” retrospective study a total of 104 [BA, n=93(89.42%); COPD, n=11(10.58%)] subjects [male=47 (45.19%); females=57 (54.81%)] were interviewed and their prescriptions were assessed. Data was collected at two points i.e. at first and second visit. The demographic and clinical data of the study population is depicted in table 1. The highest number of subjects were belonging to the age group 50-60 (n=20), 60-70 (n=20) and the lowest was in between 80-90 (n=2) with mean ± SD 49.7±17.9.

Table 1: Demographic and clinical data of the subjects

<table>
<thead>
<tr>
<th>Disease distribution</th>
<th>Gender distribution</th>
<th>Age category</th>
<th>10-20</th>
<th>20-30</th>
<th>30-40</th>
<th>40-50</th>
<th>50-60</th>
<th>60-70</th>
<th>70-80</th>
<th>80-90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>Male</td>
<td>47</td>
<td>3</td>
<td>16</td>
<td>12</td>
<td>16</td>
<td>20</td>
<td>20</td>
<td>15</td>
<td>2</td>
</tr>
<tr>
<td>COPD</td>
<td>female</td>
<td>57</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Demographic and clinical data of the subjects
The pattern of drug prescription in accordance to category of drugs is presented in table 2. The highest number of drug used was montelukast belonging to class Leukotriene receptor antagonist in both first (56.7%) and second (54.8%) visit either alone or in combination. Whereas the least preferred drug was tiotropium bromide (0.96%). Montelukast when used as monotherapy, was utilised same in both the visits (40.3%) and prednisolone stood second (35.5%) in the first visit whereas in second visit it descended to (12.5%). In contrast only one subject (0.96%) was not prescribed with oral drug in the introductory visit; this percentage arose up to 18.2% in the final visit. Different drugs used as monotherapy in both the visits is depicted in figure 1. The vastly used drug in combination with other antiasthmatic drugs was also montelukast. It was used in conjunction with antihistaminics, β2 agonists and xanthenes derivatives. The utilization of combine oral therapy is illustrated in figure 2.
Table 2: Drug utilization according to class of drug

<table>
<thead>
<tr>
<th>Category</th>
<th>Name of the drugs</th>
<th>Drug Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1st visit n=104 (%)</td>
</tr>
<tr>
<td><strong>Β-agonists</strong></td>
<td>Salbutamol,</td>
<td>5 (4.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>42 (40.3)</td>
</tr>
<tr>
<td><strong>Corticosteroids</strong></td>
<td>Deflazocort, prednisolone</td>
<td>59 (56.7)</td>
</tr>
<tr>
<td><strong>Leukotriene inhibitors</strong></td>
<td>Montelukast</td>
<td>58 (55.7)</td>
</tr>
<tr>
<td><strong>Antihistaminics</strong></td>
<td>Levocitrizine, Fexofenadine, hydroxizine</td>
<td>30 (28.8)</td>
</tr>
<tr>
<td><strong>anticholinergics</strong></td>
<td>tiotropium bromide</td>
<td>3 (2.8)</td>
</tr>
<tr>
<td><strong>methylxanthines</strong></td>
<td>Acebrofylline, Theophylline</td>
<td>15 (14.4)</td>
</tr>
<tr>
<td><strong>Mucolytics</strong></td>
<td>Acetylcystine</td>
<td>5 (4.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 (0.96)</td>
</tr>
</tbody>
</table>

Figure 1: Comparison of drugs used as monotherapy through oral route

Figure 2: Comparison of drugs used as combination therapy through oral route
Along with the oral therapy all the study subjects were prescribed with inhalation therapy. The different types of inhalation devices used during the study period were as follows. Pressurised metered dose inhaler (pMDI): 10 (9.62%), pMDI with spacer: 59 (56.73%), rotahaler: 3 (2.88%), revolizer: 14 (13.46%), autohaler: 4 (3.85%), evohaler: 12 (11.54%), starhaler: 2 (1.92%). Through these devices the most commonly prescribed medication as a monotherapy in both the visits was formoterol (15.3% and 14.4%) and the least was triamcinolone (0.96%). Whereas in combination therapy of fluticasone+formoterol (24% and 21.1%) was found to be considerably more utilized for first and second visit on the contrary beclomethasone+levosalbutamol was less prescribed (2.8%) in both pre and post visits. The different drugs used as monotherapy and combination therapy is described in figure 3 and 4 respectively.

**Figure 3:** Comparison of drugs used as monotherapy therapy through inhalational route

**Figure 4:** Comparison of drugs used as combination therapy through inhalational route

**Discussion**

Drug utilisation evaluation is the mainstay for the rational use of drugs. Apart from contributing to policy makers for designing guidelines, DUE also help in reducing adverse effects and cost of therapy. In many countries including India safe and effective use of drug is gaining more concern [5] because inappropriate use and prescribing of drugs leads to complication in the health care system for delivering efficacious provisions [8]. Guidelines for rational prescribing practices are put forth to improve the standards of prescribing [12,13].

In our study it has been found that all enrolled patients were prescribed with both oral and inhalational therapy. The most common oral drug prescribed was montelukast in both the visits. This is supported by a study carried out by T.Rajathilagam et al [14] in which they concluded that montelukast was used in half of the subjects when used in combination and in contrast with many other studies [3,4,10,11] which revealed that $\beta_2$ agonists are widely utilized antiasthmatic. Use of montelukast alone and in conjunction with antihistamines warrants improvisation in quality of life asthma patients [15, 16] and also helpful in medication adherence as it is to be taken once daily.

On the contrary, only one patient was not prescribed with an oral antiasthmatic in first visit and in second visit this number increased to 19.
Prednisolone, owing to its effectiveness in lowering inflammation caused by asthma[17] was used extensively in first visit, this might be due to treatment for acute exacerbation which was supported by a study performed by Bateman et al.[18]. The least prescribed oral drug was tiotropium bromide and salbutamol followed by methylxanthines. β2 agonists are more effective than anticholinergics for treating asthma[19]. Although long acting beta agonists (LABA) shown more effectiveness in lowering exacerbations of asthma than montelukast[20] the later was preferred, because LABA was prescribed to the patients through inhalation route either alone or in combination and also might be due to good patient adherence.

On grounds of better drug delivery and less side effects inhalers are widely used modality for treating pulmonary disorders[3,6]. In our findings formoterol and salmeterol (mono and combined) was the most preferred drug administer by inhalers. The least prescribed was triaminolone followed by hydrocortisone as monotherapy and beclomethasone +levosalbutamol in combination therapy. This data was similar for the first and second visits except formoterol + budesonide and salmeterol + fluticasone; these combinations were more prescribed in second visit than the first.

The preferred inhalation device was pMDI over the dry powder inhaler (DPI) due to aggregation of drug particles in DPI because of humidity.[21] this is in contrast with the study performed by Sanoj Varkey et al.[2] Fluticasone was the most prescribed inhaled corticosteroids (ICS) among other ICS’s as it is more cost effective than others[16,22,23].

Our study focuses on the comparison of prescribing practice in first and second visit, this can reveal the treatment approach, practice guidelines, and patient’s health related quality of life and also pharmacist’s dispensing and patient education practices.

**Conclusion**

The findings of this study reveal that treatment modality can be modified in accordance with the patient condition and guidelines. If more than two drugs are to be needed for better treatment and quick suppression of symptoms then the drugs must be prescribed by keeping in view of patient medication adherence and dosage form. Apart from physicians, pharmacists can also play a role in correct prescribing practice and standard treatment guidelines by providing feedback of patient understanding, medication adherence and drug response to the treating physician. The most commonly prescribed tablet as mono and combination therapy was montelukast in both the visits and through inhalation route, fluticasone was most preferred drug.

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**References**


