

Original Research Article

A study of effect of medications on patients with non complicated acute bronchitis

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ABSTRACT

Background: Authors define acute bronchitis as a self-limiting infection of large airways, which is characterized by cough without pneumonia. NSAIDs (Non-steroidal anti-inflammatory drugs) are prescribed in patients with Lower Respiratory Tract Infections (LRTI). In cough, fever and chest pain it is common practice to prescribe NSAIDs or antibiotics. Authors have conducted assessment of effect of medications in the resolution of cough of patients with uncomplicated acute bronchitis.

Methods: It was a single blinded randomized clinical trial conducted in patients admitted to pulmonary medicine department of government medical college Shivpuri. Patients were from age group 18 to 70 years presenting with respiratory tract infection of less than one week's duration, with cough as the predominant symptom and diagnosed with non-complicated acute bronchitis. Patients were randomized into two groups, group A and B according to medications.

Results: Among 120 participants were randomized (60 to ibuprofen and 60 to antibiotic). The median number of days with frequent cough was slightly lower among patients of group A (12 days) compared with those receiving amoxicillin-clavulanic acid (14 days). No significant difference was found. Adverse effect was seen in 24 patients, which was most common in group B (15.25%) than group A (9.15%). $p < 0.05$.

Conclusions: No significant differences were observed in the number of days with cough between patients with uncomplicated acute bronchitis treated with ibuprofen or amoxicillin-clavulanic acid.

Keywords: Acute bronchitis, Cough, Sputum, Lower respiratory tract infection, Medications

INTRODUCTION

Authors define acute bronchitis as a self-limiting infection of large airways, which is characterized by cough without pneumonia.¹ It is one of the most prevalent disease, which is responsible for most of the visits in primary care centre.^{2,3}

Persistent cough for 2 or 3 weeks is bothersome for some patients, which can last for up to 4 weeks or more.⁴ Acute bronchitis is mainly a viral infection.^{5,6} Acute bronchitis

reflects an inflammatory response of the epithelium of the bronchi to infections. Thickening of the bronchial and tracheal mucosa corresponding to the inflamed areas can be observed microscopically.

These findings are evident with proximal lower airway inflammation observed with PET.⁷ Most patients with acute bronchitis receive antibiotics.⁸ This over-prescription constitutes a global problem and is an important factor in increasing the levels of antibiotic resistance.⁹ Several approaches for controlling acute

cough have included narcotic cough suppressants, expectorants, antihistamines, decongestants, herbal remedies, and β_2 agonists.^{10,11}

Even though all these drugs are widely prescribed in patients with acute bronchitis, evidence is that their use may be helpful for adults with cough.

The prevalence of bronchitis in adults >35 years or older in India has been reported to be 3.49% (4.29% in males and 2.7% in females).⁸

NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) are prescribed in patients with lower respiratory tract infections (LRTI). In cough, fever and chest pain it is common practice to prescribe NSAIDs or antibiotics.¹³ The effectiveness of these drugs for reduction in duration and intensity of cough has not been evaluated in previous studies. Also, no studies have been published for comparing the role of NSAIDs with antibiotics. So, this study was conducted to assess the effect of medications in the resolution of cough of patients with uncomplicated acute bronchitis.

METHODS

It was a single blinded randomized clinical trial conducted by pulmonary medicine department of government medical college Shivpuri.

Study population was patients admitted to pulmonary medicine department of government medical college Shivpuri. Study Period was August 2019 to December 2019

Inclusion criteria

- Patients of age group 18 to 70 years presenting with respiratory tract infection of less than one week's duration, with cough as the predominant symptom and diagnosed with non-complicated acute bronchitis were included in this study. Other symptoms were dyspnoea, wheezing, chest discomfort which were for less than one-month duration were also included.

Exclusion criteria

- Those with age less than 18 years and more than 70 years were excluded. Those with respiratory tract infection of more than one-week duration or any other systemic disease as cardiac or renal infection, morbid causes etc were excluded.

Patients were randomized into two groups, group A receiving ibuprofen 600 mg three times daily and group B receiving amoxicillin-clavulanic acid 500 mg/125 mg three times daily for 10 days. Thereafter duration of symptoms was measured and recorded. Number of days with frequent cough was recorded after the medication.

Written informed consent was obtained from all participants.

The sample size of 120 was estimated. Those visiting OPD of Pulmonary medicine with similar complaints were recruited for the study by taking their consent for participation. 120 participants were randomized (60 to ibuprofen and 60 to antibiotic).

The outcome that was estimated was the number of days with frequent cough in the intention to treat population—that is, the number of days from the randomization visit until the last day the patient had cough items in the symptom. Other outcomes were the efficacy of the treatment at the end of the second follow-up visit and the time of resolution of the total symptom. Authors recorded adverse effects at all visits, and these were ranked by intensity (mild, moderate, severe).

Statistical analyses

Results are presented as percentages, means (standard deviation). Authors compared baseline variables between the groups by the ANOVA test for continuous variables and the χ^2 test for categorical variables.

All analyses were performed with the IBM SPSS Statistics v.19 program (Chicago, USA).

RESULTS

A total of 500 patients were screened for inclusion in the study. 120 participants were included in the study. They were satisfying the inclusion criteria i.e. age group 18 to 70 years presenting with respiratory tract infection of less than one week's duration, with cough as the predominant symptom and diagnosed with non-complicated acute bronchitis.

These 120 patients were randomized (60 to the ibuprofen group, 60 to the amoxicillin-clavulanic acid group.) (Table 1) The mean age was 39.4 years (SD 12.4) years and 81 were men (67.5%) and 39 were females. Rest 81 were males. (Table 2, Figure 1 and Table 3) This implies that male patients were more commonly seen in this study and females were less affected. The median number of days with frequent cough was slightly lower among patients of group A (12 days) compared with those receiving amoxicillin-clavulanic acid (14 days). No significant difference was found. Cough improvement and relief was almost same in both the groups of trial. (Table 4) The median number of days reporting any symptom from the initial visit was 15 days. The duration of days with symptoms was slightly lower among patients assigned to the ibuprofen group A (12 days) and was greater among those receiving antibiotics (Group B 13 days), although the differences were not statistically significant (Table 4) Adverse effect was seen in 24 patients, which was most common in group B (15,25%) than group A (9,15%). $p < 0.05$. (Table 5, Figure 2) Of

these, 24 patients those who reported adverse gastrointestinal events were 16, 4 suspected allergic reactions, and 4 other reasons. Most of the adverse events were mild except no case had severe adverse events observed.

Table 1: Distribution of study population.

Group	Number
Group A (ibuprofen group)	60
Group B (antibiotic group)	60
Total	120

Table 2: Distribution according to age.

	Mean	Sd
Age (in years)	39.4	12.4

Table 3: Distribution according to gender.

Gender	Number
Male	81
Female	39

Table 4: Distribution according to days with cough and other symptoms.

Days with frequent cough	Median
Group A	12
Group B	14
Days reporting any symptom from initial visit	Median
Group A	12
Group B	13

Table 5: Distribution according to adverse effect.

Adverse effect	Present	Absent
Group A	9	51
Group B	15	45
Total	24	96

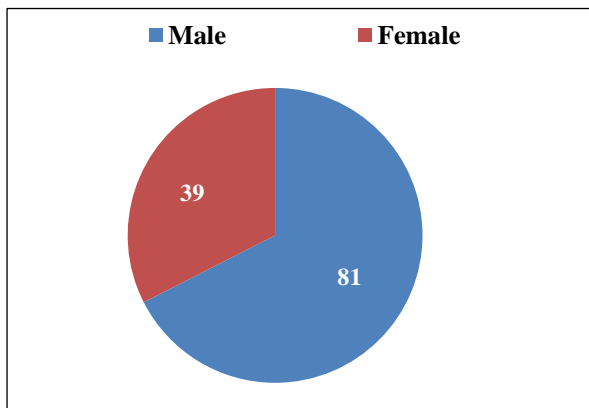


Figure 1: Distribution according to gender.

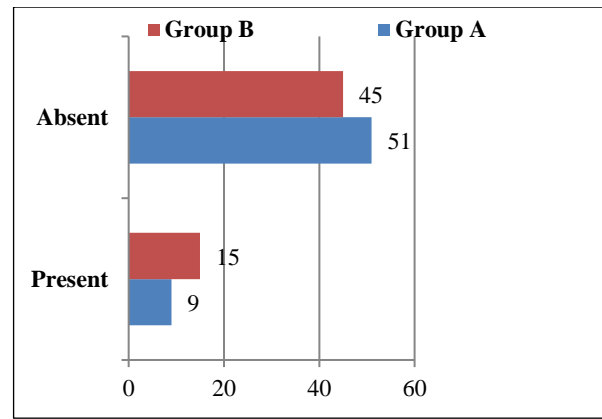


Figure 2: Distribution according to presence or absence of adverse effects.

DISCUSSION

There is an urgent need to assess genuine treatment measures to deal with common infectious disease, particularly as a result of growing patient expectations and increasing antibiotic resistance.

Non-steroidal anti-inflammatory drugs are prescribed in patients with lower respiratory tract infections, usually for alleviating fever and chest pain as well as other common complaints such as cough.¹² Notwithstanding, the effectiveness of these drugs for reducing the duration and intensity of cough has not been analysed in randomized clinical trials. No sufficiently powered studies have been published comparing the role of non-steroidal anti-inflammatory drugs with that of antibiotics. Authors therefore compared the efficacy of ibuprofen and amoxicillin-clavulanic acid in adults with acute bronchitis and discolored sputum.

This study found no differences in the number of days with frequent cough among patients with uncomplicated acute bronchitis and discolored sputum treated with ibuprofen, amoxicillin-clavulanic acid. The trial was sufficiently powered and, to the best of knowledge, the first to allow conclusions on the efficacy of a non-steroidal anti-inflammatory drug in patients with acute bronchitis compared with an antibiotic.

One of the results of this study is that antibiotic treatment was not more effective for cough duration. While systematic analyses of clinical trials suggest that antibiotics may achieve a reduction, to some extent in the duration of the symptoms.^{13,14} A review of the Cochrane Library showed that patients given antibiotics were less likely to have a cough than were those given ibuprofen (risk ratio 0.64, 95% confidence interval 0.49 to 0.85), but these results came from only few clinical trials.⁸ Another randomized clinical trial, based on data from the genomics to combat resistance against antibiotics in community-acquired lower respiratory tract infections in Europe (GRACE) study, not included in the Cochrane

Library review, has recently been published.^{15,16} It constitutes, by far, the largest study carried out, including 16 networks in 12 European countries with 2061 adults aged 18 or older with acute cough of less than one month's duration as the prominent symptom, and once pneumonia was excluded on the basis of clinical grounds. Symptoms rated moderately bad or worse, which was considered as the main outcome, lasted a median of six days in the group allocated to amoxicillin 3 g daily. No significant difference was obtained. Similar to this study design, Stott and colleagues included only patients with acute bronchitis and cough and did not observe any statistically significant differences in the resolution of cough between the group treated with antibiotics and the group assigned to the control.¹⁷

At present, more than 60% of patients receive antibiotics for acute bronchitis, and it is currently one of the five most commonly cited infections for excessive antibiotic use in outpatients.¹⁸⁻²² Many doctors may not give antibiotics on the first visit, but are more likely to prescribe these antibacterial on subsequent visits, mainly if discolored sputum is present. In a prospective study of more than 3000 adults with acute cough due a lower respiratory tract infection in 13 European countries, Butler and colleagues observed that patients who presented discolored sputum were prescribed antibiotics 3.2 times more often than those patients without discolored sputum.²³

The efficacy of antibiotics is well established in purulent exacerbations of severe chronic obstructive pulmonary disease, 41 and recently group demonstrated the efficacy of antibiotic treatment in outpatients with mild to moderate chronic obstructive pulmonary disease with acute exacerbations and increased purulence.^{24,25}

Evidence of the effectiveness of non-steroidal anti-inflammatory drugs in this acute respiratory tract infection is lacking. More studies have been published on the common cold, but these studies failed to show a consistent benefit.²⁶

CONCLUSION

Patients with lower respiratory tract infection report cough as the most common symptom. This study compares the oral anti-inflammatory treatment and an antibiotic to assess the effectiveness for shortening the duration of cough in patients, which is found to be comparable in both the drugs. So, it can be implied in daily practice by physicians and extreme use of antibiotics should be prohibited as it may lead to development of resistance.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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