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Original Article

Comparative Evaluation of Different Treatment Protocols in Treating Paediatric Patients with Community Acquired Pneumonia: An Institutional Based Study

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ABSTRACT

Background: Respiratory infection is one of the leading causes of death in children in our country. According to the Infectious Diseases Society of America a comprehensive guidelines for the diagnosis and treatment of paediatric community acquired pneumonia advocated the treatment course of 10 days where mild dose was seen as effective as heavier dose in mild to moderate cases. As a primary drug of choice majority of physicians use β-lactams to treat mild paediatric pneumonia with 10 or more days of therapy. **Material and method:** The study and analysis so conducted for a time period of 6 months, for a total of 66 patients in the paediatric department of our medical college and hospital. As study sample children from age 6 months to 10 years presenting with community acquired pneumonia were selected. . All these findings were first analysed and documented manually and later on presented electronically. Also the probable side effects were also recorded. An effort was made to understand if patient took any secondary antibiotic apart from amoxicillin, which came out to be negative in all cases. **Results**: The symptoms of fever and wheezing were still seen in group B till the second week of completion of antibiotic course. Also the side effects of amoxicillin (nausea, upset stomach, mild itching and flatulence) were more evident in group A than in group B. GROUP A patients showed considerable relief from symptoms as soon as the antibiotic course finished. **Conclusion**: The inclusion of fever as a major criterion did diminish the probability of selecting participants with pertussis, which is much less likely to be associated with the symptom of fever, or any other non-infectious conditions. The requirement for participants to present with a respiratory symptom or sign decreased the probability of involving those with infections of other organ systems who are originally diagnosed with pneumonia.

Key words: nausea, pneumonia, Respiratory

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INTRODUCTION

Respiratory infection is one of the leading causes of death in children in our country. [1] [2]According to the Infectious Diseases Society of America a comprehensive guidelines for the diagnosis and treatment of paediatric community acquired pneumonia advocated the treatment course of 10 days where mild dose was seen as effective as heavier dose in mild to moderate cases. As a primary drug of choice majority of physicians use β-lactams to treat mild paediatric pneumonia with 10 or more days of therapy. [3]While the 5-day and 10-day regimes have similar success rates, macrolides have lost their monopoly due to the increased prevalence of macrolide-resistant pneumococci.[4] [5] [6]Also, the half-life of azithromycin is 68 hours. So, a 5-day course of azithromycin is in effect much longer than a 5-day course of any regular β-lactams with a half-life ~ 2 hours, so it can be concluded that the potential success rate of short-course β-lactam therapy cannot be concluded. On the other hand a 3-days protocol had failed terribly.In this age and time of increasing antibiotic resistance, the lack of awareness of optimal use of antibiotics for the treatment for paediatric community acquired pneumonia is a cause for concern.To overcome this concern of antibiotic resistance optimizing antimicrobial prescription has been seen as the main strategy to deal with escalating antimicrobial resistance.Beyond the threat of antibiotic resistance, recent studies are suggestive of a close association

between the use of antibiotics and the development of obesity and/or allergy.[7-16]Our principal concern in this study was that in previously healthy children diagnosed with community-acquired pneumonia treated with 5 days regime of oral high-dose amoxicillin lead to non-inferior rates of clinical cure at 14–21 days post-enrolment compared with the standard protocol of 10 days of oral high-dose amoxicillin.

MATERIAL AND METHOD

The study and analysis so conducted for a time period of 6 months, for a total of 66 patients in the paediatric department of our medical college and hospital. As study sample children from age 6 months to 10 years presenting with community acquired pneumonia were selected. Following criteria was devised out: (a) body temperature more than 37.7^{o} C. (b) Tachypnoea on examination with more than 60 breaths per minute at age less than 1 year, more than 50 breaths per minute at age 1–2 years, more than 40 breaths per minute at age 2–4 years, and more than 30 breaths per minute at age more than 4 years. (c) Cough on examination or history of cough. (d) Increased work of breathing on examination which is characterized by the presence of scalene muscle use, or considerable suprasternal recessions/in-drawing or intercostal retractions, or subcostal recessions/in-drawing. (e) On auscultation findings like focal crackles, bronchial breathing, etc. (f) Chest radiograph suggestive of bacterial community acquired pneumonia. A set exclusion criteria was maintained, (a) patients on steroid therapy due to asthma, (b) cystic fibrosis, (c) anatomic lung disease, (d) bronchiectasis, (e) congenital heart disease, (f) history of repeated aspiration, (g) malignancy, (h) conditions requiring treatment with immune suppressants, (i) primary immunodeficiency (j) advanced HIV infection, (k) renal dysfunction. Also any child suffering or detected with penicillin allergy were also excluded.All study participants received an oral high-dose amoxicillin divided into three times daily for 5 days. The dose range of 75–100 mg/kg/day within weight strata was established to simplify medication administration and to reduce potential dosage errors. After the first 5 days of amoxicillin, half of the participants received a second 5 days of high dose amoxicillin dose which was identically to the first 5 days and the other half of the participants received a lower dose of 50-65 mg/kg/day for the same five days. Patients were then followed up after 21 days on the following grounds; (a) any improvement in dyspnoea and increased work of breathing, with no recorded tachypnoea. (b) Any record of fever episode as a result of bacterial respiratory illness from day 4 to day 21. All these findings were first analysed and documented manually and later on presented electronically. Also the probable side effects were also recorded. An effort was made to understand if patient took any secondary antibiotic apart from amoxicillin, which came out to be negative in all cases. All the data was arranged in a tabulated form and analysed. The information was expressed as percentage.

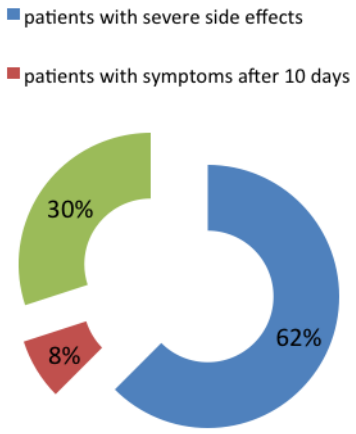
RESULTS

It was established that all the 66 patients had taken the high dose amoxicillin for initial 5 days period. The group A patients were given the same high dose for next 5 days making it a standard protocol for treatment of community acquired pneumonia.(TABLE 1). The group B patients were given a low dose amoxicillin for next five days. Patients were evaluated and examined after 3 weeks. Interestingly, symptoms had subsided in both groups but the extent and time duration taken by the group B patients was quiet extended when compared with group A. (GRAPH 1). The symptoms of fever and wheezing were still seen in group B till the second week of completion of antibiotic course. Also the side effects of amoxicillin (nausea, upset stomach, mild itching and flatulence) were more evident in group A than in group B.(GRAPH2). GROUP A patients showed considerable relief from symptoms as soon as the antibiotic course finished. This was again established by the sputum samples, oral swab test and blood samples collected from every sample patient. Patients were then recalled after 4 months and were examined, showing reoccurrence of symptomsin some patients of group A. Group B patients presented with no symptoms what so ever. Same was established with the blood samples collected from each patient.

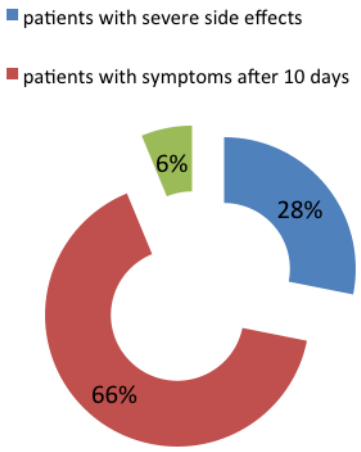
TABLE 1: Characteristics of the study

Group A	**n**	**Group B**	**n2**
number of patients	33	number of patients	33
patients with severe side effects	25	patients with severe side effects	9
patients with symptoms after 10 days	3	patients with symptoms after 10 days	21
patients with reoccurrence of symptoms after 3 months	12	patients with reoccurrence of symptoms after 3 months	2

Graph 1: Group A results



Graph 2: Results of Group B



DISCUSSION

The inclusion of fever as a major criterion did diminish the probability of selecting participants with pertussis, which is much less likely to be associated with the symptom of fever, or any other non-infectious conditions.[17]The requirement for participants to present with a respiratory symptom or sign decreased the probability of involving those with infections of other organ systems who are originally diagnosed with pneumonia. It was mandatory for participants to have a chest radiograph showing a pneumonic infiltrate was likely to increase the chances that they had any infection caused by a bacterial pathogen. The selection of the non-inferiority margin had a considerable impact on trial outcome. It was established that the clinical considerations should establish a determination of the margin.In case the margin is established as an unacceptable by a wide choice of clinicians, a "positive" non-inferiority trial will have little to no impact on the standard practice.A heavy dose of the amoxicillin did presented with desired results within a short period of time, but had severe side effects. Also, patients so treated with heavy dose had chances of reoccurrence of symptoms after some time. In our study, the symptoms of fever and wheezing were still seen in group B till the second week of completion of antibiotic course. Also, the side effects of amoxicillin (nausea, upset stomach, mild itching and flatulence) were more evident in group A than in group B. Group A patients showed considerable relief from symptoms as soon as the antibiotic course finished. This was again established by the sputum samples, oral swab test and blood samples collected from every sample patient. Patients were then recalled after 4 months and were examined, showing reoccurrence of symptomsin some patients of group A. Group B patients presented with no symptoms what so ever. Same was established with the blood samples collected from each patient.On the other hand, patients receiving milder dose took long time to get rid of the symptoms yet, with mild side effects. Also no chances of reoccurrence were seen in this group. This could possibly be due to the antibiotic resistance developed in patients with heavy dose which led to the reoccurrence of the symptoms. The compliance with the medication is, in general, difficult to ensure. Guardians of participants in this trial were reminded far more frequently the need to administer medication. So, they would otherwise be in accord to the measures which are similar to those in other major recent events when comparing short-course and standard-course antimicrobial therapy in children.[18] It is possible that compliance can be suboptimal, which could also predispose to a false conclusion of non-inferiority, especially if compliance to medication drops off after 5 days. From a practical point of view, this is still important finding for clinicians managing patients, and would not greatly affect the generalizability and authentication of the results of the study. A very specific type of adverse effects that have more chances of being caused by short durations of antimicrobial therapy for community acquired pneumonia include recrudescence of community acquired pneumonia. The symptoms associated with this were; fever, cough, difficulty breathing, tachypnoea, abdominal pain, and malaise. It must be understood that, it is also not uncommon for children to experience these symptoms when contracting a new respiratory viral infection. We took keen interest in finding evidence of potentially recrudescent infection when contacting guardians at day 3–5 and day 7–10 respectively. We also made it a point to guardians to contact us if any severe symptoms develop. Any participant with new or worsening respiratory symptoms was reviewed by us and a specialist was consulted whenever it was necessary.

CONCLUSION

After the elaborated study it becomes safe to conclude that the conventional high dose regime had many predictable results as well as side-effects too. The low dose regime took a considerable more time period to avert the symptoms of the community acquired pneumonia but the side effects were mild-non existing. On analysing the out comes after 4 months of the trial period the high dose regime patients were again susceptible to community acquired pneumonia, as comparing with the low dose regime group where symptoms were hardly present. So, the low dose regime is more promising on a longer run but the high dose regime gives instant results. We advise the physicians to understand the effects of both regimes and prescribe wisely.

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