A Prospective Randomized Study of Inpatient IV Antibiotics for Community-Acquired Pneumonia*

The Optimal Duration of Therapy

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Study objective: To compare therapeutic outcome and perform a cost-benefit analysis of inpatients with community-acquired pneumonia (CAP) treated with a shortened course of IV antibiotic therapy.

Design: A prospective, randomized, parallel group study with a follow-up period of 28 days.

Setting: Bronx Veterans Affairs Medical Center (VAMC) and the Castle Point VAMC; university-affiliated VAMC general medical wards from September 1993 to March 1995.

Patients: Seventy-two male veterans and 1 female veteran with 75 episodes of CAP defined by a new infiltrate on chest radiograph and either history or physical findings consistent with pneumonia. Study population was 42%(31) black, 33%(24) white, and 25%(18) Hispanic.

Interventions: Patients were randomized (1:1:1) to 1 of 3 treatment groups: group 1 received 2 days of IV and 8 days of oral therapy; group 2 received 5 days of IV and 5 days of oral therapy; and group 3 received 10 days of IV therapy. Antibiotics consisted of cefuroxime, 750 mg every 8 h for the IV course, and cefuroxime axetil, 500 mg every 12 h for the oral therapy.

Measurements and results: No differences were found in the clinical course, cure rates, or resolution of chest radiograph abnormalities among the three groups. A significant difference was found in the length of stay (LOS) among the three groups. The mean±SD LOS was 6±3 days in group 1, 8±2 days in group 2, and 11±1 days in group 3. The shortened LOS could potentially save $95.5 million for the Department of Veterans Affairs and $2.9 billion for the US private sector.

Conclusions: Adult patients hospitalized for CAP who are not severely ill can be successfully treated with an abbreviated (2-day) course of IV antibiotics and then switched to oral therapy. A longer course of IV therapy prolongs hospital stay and cost, without improving the therapeutic cure rate.

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Key words: antibiotic; community-acquired pneumonia; cost; length of stay

Abbreviations: CAP=community-acquired pneumonia; CDR=Cost Distribution Report; DVA=Department of Veterans Affairs; HSCRC=Health Services Cost Review Commission; ICD-9=International Classification of Diseases, 9th Revision; LOS=length of stay; PTF=patient treatment file; VAMC=Veterans Affairs Medical Center

Community-acquired pneumonia (CAP) is the cause of more than 1 million hospital admissions per year with a treatment cost of more than $15 billion,1 9.8% of the total hospital cost of care for 1985.2 Standard therapy of inpatient CAP consists of a mean of 7.5 days of IV therapy followed by a change to oral antimicrobial therapy and hospital discharge.1 Alternately, a mean of 11 days of antibiotic treatment is given if the patient is treated only with IV therapy.1

There are few protocols that describe the optimal duration of IV and oral antibiotic therapy in patients with CAP.3-5 An extended course of IV therapy prior to switching to oral medication may prolong hospital length of stay (LOS) and increase the cost of care.6,7 The purpose of this study was to determine if a shortened course of IV antibiotic therapy prior to switching to oral antibiotic would result in an equivalent therapeutic outcome in hospitalized patients with CAP.

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when compared to the common 5- to 8-day IV course. Additionally, we determined if this shortened IV course would result in a shorter LOS and decreased cost of care.

Materials and Methods

Methods:

This study was performed at the Bronx Veterans Affairs Medical Center (VAMC) and the Castle Point VAMC. The investigational review boards at both hospitals approved the study and all patients provided signed informed consent prior to enrollment.

Study Protocol.

Study participants were recruited from patients admitted to an inpatient acute medical ward, after the treating emergency department or clinic physician determined that the CAP should not be treated in an outpatient setting. Patients with the hospital admission diagnosis of pneumonia were examined by study staff to determine if they met study entry criteria.

Entry Criteria

Patients who met the following criteria were randomized and entered into the study: new pulmonary infiltrate on chest radiograph and one of the following: (1) clinical history consistent with pneumonia (eg, fever, chills, cough, sputum, chest pain); and (2) physical findings suggestive of pneumonia (localized crackles or bronchial breath sounds).

Exclusion Criteria

Patients were excluded if they were pregnant or lactating; had empyema, septic shock, or respiratory failure; had an allergy or hypersensitivity to cephalosporins; had received systemic antibiotics in the past 72 h; or they had been admitted to the study in the past 90 days.

Antibiotic Treatment Protocol

A parallel-group, open-label, randomized study was performed. At the time of diagnosis of pneumonia, patients were randomized (1:1:1) into one of three treatment groups. Group 1 received 2 days of IV therapy and 8 days of oral therapy; group 2 received 5 days of IV therapy and 5 days of oral therapy; and group 3 received 10 days of IV therapy only. Cefuroxime, a second-generation cephalosporin antibiotic (Zinacef; Glaxo Wellcome Inc; Research Triangle Park, NC), was administered for the IV portion of the study at a dosage of 750 mg every 8 h. The dosage of cefuroxime was adjusted for changes in renal function. Cefuroxime axetil (Ceftin; Glaxo Wellcome Inc) was given at a dosage of 500 mg every 12 h for the oral treatment segment of the study.

Monitoring and Evaluation

Baseline evaluation and laboratory tests were performed following randomization and included complete medical history, physical examination, temperature (IVAC Inc; San Diego), WBC count, and an initial screening chest radiograph. An expectorated sputum sample was requested prior to therapy and, when obtained, was sent for Gram's stain and culture. Two venous blood cultures were obtained from each patient.

Oral temperatures were taken three times daily, while the patient was in the hospital and on follow-up clinic visits. Patient WBC count was repeated every 2 days while hospitalized. Chest radiographs were taken at the time of hospital admission, at days 5 and 10, and every 2 weeks thereafter until the infiltrate completely resolved. Chest radiographs were reviewed by a radiologist for diagnostic confirmation. If this review revealed that a disease process other than pneumonia was responsible for the initial chest radiographic findings, the patient was withdrawn from the study (early withdrawal).

Patients were discharged from the hospital solely at the discretion of the medical house staff and ward attending staff. Patients were examined at follow-up visits by 1 of the investigators on study days 10 to 14 and 26 to 28.

Assessment of Patient Outcome

Patients were classified as a therapeutic success if their CAP was successfully treated within the constraints of the study protocol, including resolution of fever and leukocytosis by day 28. A therapeutic failure was declared if the CAP was not successfully treated within the constraints of the study protocol. This included persistent fever or leukocytosis, institution of additional antibiotic therapy within the study period, or readmission to the hospital for the same infection.

Patient Withdrawal Criteria

Patients were withdrawn from the study, and were not included in the analysis of therapeutic success or failure, if any of the following occurred: (1) the radiologist review of the chest radiograph did not support the initial impression of acute pneumonia (early withdrawal); (2) a patient was unable to tolerate the prescribed oral or IV medication regimen; (3). 15% or more of the antibiotic doses were not administered; (4) organisms resistant to cefuroxime were isolated; (5) prolonged antibiotic therapy for a disease process other than pneumonia was required; and (6) mortality occurred as a result of a disease process other than pneumonia.

Microbiological Evaluation

Baseline sputum culture was interpreted as diagnostic of infection if there was moderate growth of Streptococcus pneumoniae, Haemophilus influenzae, or an enteric Gram-negative organism, or heavy growth of Staphylococcus aureus. All bacterial isolates were tested for cefuroxime susceptibility by the Kirby-Bauer technique (disk diffusion method). Blood and pleural fluid cultures were cultured and processed (BACTEC; Becton Dickinson Diagnostic Instrument Systems; Sparks, Md). Mycoplasma pneumoniae acute and convalescent titers were processed on weeks 1 and 4 in patients who were therapeutic failures and in patients in whom a causative organism was not identified.

Data Analysis

Groups 1, 2, and 3 were compared at baseline for age, smoking history, temperature, WBC count, chest radiograph (number of lobes involved and presence of pleural effusion), and positive blood cultures. Patients completing the study were compared for differences in temperature, WBC count, chest radiograph resolution, and hospital LOS. LOS analyses were performed 2 ways: (1) excluding patients hospitalized beyond 12 days, and (2) including all patients who were therapeutic successes with the last day of the study (day 28) considered as the last day of hospital stay.

Statistical Methods

One-way analysis of variance was used to test for differences among the groups for the variables of age, comorbidity, creatinine, temperature, days until fever resolution, WBC count, WBC resolution, number of lobes involved on chest radiograph, pleural effusion, and LOS. Post hoc pairwise comparisons were performed using the Fisher protected least squares squares test. A $\chi^2$ analysis was used to determine differences in smoking prevalence, in the frequency distribution of chest radiograph resolution among the groups, and in clinical outcome. Confidence intervals were calculated for the between-group differences on the cure rate for each
group. A power calculation was performed on the LOS difference between the two groups. The results are reported as mean±SD. Statistical significance was considered to be at p≤0.05.

Cost Analysis

LOS and cost analyses for 1994 were performed for the patients studied and for all patients with CAP at the Bronx VAMC and in all Department of Veterans Affairs (DVA) facilities using the DVA maintained database of all inpatients, the patient treatment file (PTF). Patients with a diagnosis of CAP, admitted locally to the Bronx VAMC and nationally to all the DVA Hospitals, were selected from the PTF. Parameters used for CAP identification were those listed in the International Classification of Disease Codes (ICD), which approximated the pneumonia diagnosis of the study patient population. Data obtained included the number of hospital admissions, LOS, and days of care. The ICD-9 codes of Pseudomonas species (ICD-9 482.1) and M pneumoniae (ICD-9 483.0) were excluded from the analysis since these infections are not treated by the study antibiotic, cefuroxime, and are therefore not similar to the study population.

The cost per day of an acute medical ward (non-ICU) patient was determined for the Bronx VAMC and nationally in the DVA. Cost data were derived from the Cost Distribution Report (CDR) database. The cost per day includes all direct and indirect costs of patient care. Indirect costs include overhead hospital and labor costs.

The cost per year of patients with CAP was the product of the LOS of the identified patients (PTF) and the cost per day (CDR). Cost savings for the Bronx VAMC and the DVA, nationally for all facilities, for patients identified with CAP was the product of the following: (1) the number of patients admitted to the hospital with CAP; (2) the reduction in LOS that could be realized (actual LOS data from PTF minus LOS results of study group 1); and (3) the cost of care per day (CDR).

RESULTS

Seventy-three patients with 75 episodes of CAP were randomized (1:1:1) into 3 treatment groups from September 1993 to March 1995. The ethnic and racial make-up included 31 (42%) black, 24 (33%) white, and 18 (25%) Hispanic patients. Seventy-two were male and 1 was female. Two patients were enrolled twice, for two distinctly different episodes of CAP. Seventy-one were enrolled at the Bronx VAMC and 4 at the Castle Point VAMC.

The study was completed in 57 (76%) of the 75 episodes of CAP that were included in the data analysis (Fig 1). Of the 18 patients who did not complete the study, 7 were withdrawn on day 2 because they were ineligible for study entry (early withdrawal). Among these seven patients, five did not have a chest radiograph consistent with CAP and two patients had pulmonary edema. The other 11 patients were withdrawn due to resistant organisms or protocol violations (late withdrawal). Two patients each were withdrawn for cefuroxime-resistant enterococcal bacteremia, because of infections due to Mycobacterium tuberculosis or because of pneumococcal endocarditis, and two patients died of disease unrelated to CAP.

No significant differences were noted among the three study groups at baseline when compared for age, sex, smoking history, maximum temperature at the time of hospital admission, the number with fever,
creatine, WBC count, the number with WBC count elevation, the number of lobes involved, or the presence of a pleural effusion (Table 1). The prevalence of concomitant medical illnesses was similar in each study group, a mean of 2.0±0.9 per patient. Illnesses included active drug and alcohol abuse (28%), chronic obstructive lung disease (25%), diabetes (18%), cardiac disease (14%), HIV infection (12%), of which 5 of 7 had AIDS, cancer (9%), asthma (5%), and creatinine concentration greater than 5 (4%).

**Clinical Outcome**

The rates of therapeutic successes were similar in each study group (Table 2). The confidence limits for the hypothesis that there was no significant difference between the 2-day vs the combined 5- and 10-day antibiotic treatment groups were −16% (lower) and 17% (upper). There were no differences in clinical outcome among the three groups with regard to fever, leukocytosis, or chest radiograph resolution. The fever responded in 3±1 days and the WBC count declined by 4±1 days for all patients classified as a therapeutic success.

There were 6 of 57 (11%) therapeutic failures. One group 1 patient developed septic shock secondary to pneumococcus in the first 24 h. A second patient initially responded to therapy, was discharged from the hospital on day 4, but returned on day 12 with fever and responded to alternate antibiotic therapy. (M. pneumoniae serologic tests were not processed, but the patient was not treated for atypical infection.) One group 2 patient developed septic shock secondary to pneumococcus in the first 24 h and a second patient developed pneumococcal empyema while receiving IV therapy. A third patient remained febrile while receiving IV cefuroxime therapy; bacterial cultures and M. pneumoniae titers were negative. Lastly, the one group 3 failure developed a necrotizing pneumonia with penicillin-resistant pneumococcus.

Resolution of infiltrate on chest radiographs was not different among the three groups. Of the 57 patients who completed the study, 3 were excluded from chest radiograph analysis because of a failure to obtain radiographs at the appropriate times and 6 were therapeutic failures. Of the other 48 patients, chest radiograph resolution was seen in 14 of 48 (29%) patients by 2 weeks and in 40 of 48 (83%) by 4 weeks.

**LOS analysis** was performed for the 46 of 57 (81%) therapeutic successes with an LOS of 12 days or less. The mean ±SD LOS and range in days was significantly shorter in group 1 (6±3; range, 4 to 11) than in group 2 (8±2; range, 5 to 11) or group 3 (11±1; range, 10 to 12). Differences between each group were significant. Thirteen patients were eliminated from this LOS analysis because of a stay longer than 12 days (7 patients) or because of therapeutic failure (6 patients). None of the 7 patients who remained in the hospital beyond 12 days did so because of pneumonia-related causes. To detect a difference in LOS of 4 days between group 1 and the combined groups 2 and 3 with an effect size of 1.2 and 94% power, a sample size of 15 subjects per group was needed. When the LOS analysis was extended to include all therapeutic successes up to the last study day (day 28), the mean ±SD LOS in days was 8±4 (range, 4 to 15) in group 1, 10±6 (range, 8 to 28) in group 2, and 11±2 (range, 11 to 17) in group 3, with only the difference between groups 1 and 3 being significant.

**Microbiology**

Among the 68 patients remaining after early withdrawal (Fig 1), with a confirmed diagnosis of CAP, the causative organism was identified in 32 (47%) patients. Four of these 68 patients were withdrawn due to the isolation of a cefuroxime-resistant organism (2 had blood cultures positive for Enterococcus and 2 had M. tuberculosis). All other bacterial isolates were sensitive to cefuroxime.

A bacteriologic diagnosis was made in 23 of 57 (40.4%) evaluable patients who completed the study.

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**Table 1—Hospital Admission Data of Evaluable Patients (n=57)**

<table>
<thead>
<tr>
<th>Group</th>
<th>1 (n=20)</th>
<th>2 (n=20)</th>
<th>3 (n=17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td>63±12</td>
<td>57±14</td>
<td>56±14</td>
</tr>
<tr>
<td>Lobes 1/2/3</td>
<td>16/4/0</td>
<td>15/5/0</td>
<td>12/4/1</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Active smoking</td>
<td>12</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>WBC, /mm³</td>
<td>13.9±5.9</td>
<td>12.7±6.9</td>
<td>13.7±4.6</td>
</tr>
<tr>
<td>WBC ≥10.8/³mm³</td>
<td>12</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>Tmax, °C</td>
<td>38.6±0.80</td>
<td>38.4±0.88</td>
<td>38±0.89</td>
</tr>
<tr>
<td>T ≥37.5°C</td>
<td>17</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>Creatinine, mg/dL</td>
<td>1.7±1.1</td>
<td>1.6±1.8</td>
<td>1.3±0.5</td>
</tr>
</tbody>
</table>

*LOB=number of involved lobes on hospital admission chest radiograph; Tmax=maximal temperature the first 24 h; T=temperature. Age, T, and creatinine expressed as mean±SD.

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Clinical Investigations
Sputum cultures were obtained in 49 patients and blood cultures were obtained from all patients. Sputum cultures were positive in 29% (14/49) of patients and blood cultures were positive in 13 of 57 (23%). Pneumococcus was the most commonly identified organism, with 9 of 20 (45%) patients culture positive in group 1 (4 sputum/5 blood), 4 of 20 (20%) culture positive in group 2 (1 sputum/3 blood), and 3 of 17 (18%) culture positive in group 3 (1 sputum/2 blood). Two pneumococcal isolates from blood were penicillin resistant but sensitive to cefuroxime. Three sputum cultures were positive for *H influenzae* and one sputum culture each was positive for *S aureus*, *Klebsiella pneumoniae*, or *Escherichia coli*.

The distribution of the 13 positive blood cultures was as follows: group 1, 7 of 20 (35%); group 2, 4 of 20 (20%); and group 3, 2 of 17 (12%); none of these differences were significant. Five of the 6 patients with bacteremia in group 1 were therapeutic successes, including one patient who had *S aureus* isolated. One of these 6 patients was withdrawn from the protocol in the first 24 h while receiving IV therapy due to pneumococcal septic shock and was considered a therapeutic failure.

**Cost Analysis**

The mean LOS for patients with CAP for 1994 in the Bronx VAMC and for all DVA facilities was 13 days\(^1\) (Table 3). The cost per day for acute medical ward admissions in 1994 was $797 at the Bronx VAMC and $718 for all DVA facilities. Locally, 155 patients were admitted with a diagnosis of CAP and nationally, 18,999 CAP patients were hospitalized. Based on these data, the Bronx VAMC spent $1.6 million and all facilities spent $177.3 million on CAP inpatient therapy.\(^1\) If 2 days of IV therapy was used as a treatment guideline for CAP, as in study group 1, and the LOS was reduced to 6 days, there would be a 7-day reduction in LOS at the Bronx VAMC and all DVA facilities. A 7-day reduction in LOS would result in cost savings of $865,000 at the Bronx VAMC, which represents a 54.1% reduction in the cost of care of patients hospitalized with CAP. On a national level for the DVA, there would be a reduction in cost of $95.5 million, which is a 53.9% decrease in the cost of treatment of CAP.

**DISCUSSION**

This study demonstrates that the course of IV antibiotic therapy for the treatment of CAP can be shortened without compromising a satisfactory clinical outcome. In addition, we have shown that, as a result of a shortened IV course of therapy, the hospital LOS can be reduced with substantial cost savings.

Response to antibiotic therapy was rapid and apparent within 2 days of initiating treatment. In therapeutic successes, clinical features such as fever and leukocytosis responded quickly and there was no difference in clinical resolution of pneumonia or chest radiographic infiltrates among the three groups. In therapeutic failures, sustained fever and leukocytosis were evident, which suggested the need for alternate antibiotic treatment or prolonged IV therapy. This study was not performed in a blinded fashion since the use of IV placebo would have interfered with hospital discharge procedures.

The patients in this study were moderately ill, with multiple comorbidities and positive blood cultures in 23% of evaluable patients. Of the patients admitted to the study, 59 of 75 (79%) met criteria for hospital admission for CAP, as outlined by Fine et al.\(^6\) A bacterial pathogen was identified in 47% of study patients with pneumonia, lower than the 55 to 59% reported in studies specifically designed to diagnose the etiology of CAP.\(^7,8\) and may reflect the fact that only expectorated sputum samples were obtained in the present study. No cases of Mycoplasma infection were identified, despite recent studies that reveal it to be a common cause of CAP,\(^7,8\) although most of the patients with these infections are treated as outpatients.\(^3\)
The goal of antibiotic therapy is to produce drug concentrations that exceed the minimal inhibitory concentration for the infecting pathogen at the site of infection.\textsuperscript{10} IV antibiotics rapidly reach bactericidal levels in the serum and cross the alveolar-capillary membrane to reach alveolar lining fluid and interstitium. Passive diffusion along a concentration gradient is the most important mode of transport from the vascular compartment into tissue fluids.\textsuperscript{10-22} With IV antibiotic therapy, accumulation of antibiotic in the lung is rapid; although oral antibiotics achieve lower serum levels of drug, oral therapy can sustain bactericidal pulmonary parenchymal levels.\textsuperscript{3}

Risk stratification is useful in the identification of patients who require hospitalization for treatment of CAP.\textsuperscript{3,16,23-25} Selected patients with pneumonia have been treated with oral antibiotic therapy alone as inpatients\textsuperscript{26,27} or as outpatients.\textsuperscript{3} Once hospitalized, the duration of IV therapy for CAP is presently based on physician assessment of the extent of lung infection, the severity of underlying medical illnesses, and patient compliance with medications. Clinical references either fail to give any guidance on the appropriate duration of IV therapy or suggest IV treatment be continued until the patient’s condition has stabilized and he or she is afebrile.\textsuperscript{3,28-30}

Previous studies of short-course IV therapy for pneumonia have been retrospective,\textsuperscript{31} included patients with infections other than pneumonia,\textsuperscript{32} included patients with a variable duration of IV therapy based on clinical data,\textsuperscript{5,6} or focused on pediatric patients.\textsuperscript{33} To our knowledge, the only CAP protocol to include an initial IV antibiotic course shorter than 3 days was a pediatric study.\textsuperscript{33} Our study differs from previous studies because hospitalized patients with CAP were randomized to fixed intervals of IV therapy and 1 treatment arm included only a very brief course of IV therapy (2 days). In addition, clinical, laboratory, radiographic, and LOS outcome parameters were assessed prospectively.

In our study of hospitalized CAP patients, the use of 2 days of IV therapy resulted in a 2-day decrease in LOS between groups 1 and 2 and a difference of 5 days between groups 1 and 3, when patients with an LOS greater than 12 days were eliminated from the analysis. Patients who remained in the hospital longer than 12 days did so because of concomitant medical illness or for a socioeconomic problem. VA hospitals have a high proportion of patients with multiple medical problems and prolonged nursing requirements resulting in longer LOS for CAP patients admitted to VA hospitals.\textsuperscript{34}

VA cost analysis for 1994 demonstrated a cost savings in the VA system of $95.5 million if CAP was treated with a 2-day IV regimen, prior to switching to oral antibiotic. A similar cost benefit analysis can be applied to the US private sector. In 1992, 897,000 patients were admitted to hospitals with a diagnosis of CAP; they were categorized into the same ICD-9 codes as used in the VA analysis.\textsuperscript{35} Mean LOS for these patients was 10 days\textsuperscript{35} and the average cost of a medical bed in the United States was $816.\textsuperscript{3} If a 2-day IV CAP treatment algorithm was applied nationally, reduction in the LOS from 10 to 6 days (the LOS of study group 1) would result in a cost savings of $2.9 billion. This analysis does not include savings in pharmacy and nursing costs or physicians fees. More recent data from the Maryland Health Services Cost Review Commission (HSCRC) for 20,414 CAP patients in Maryland for 1994 reveals a mean LOS of 8.9 days with an average hospital cost of $7,724 per patient.\textsuperscript{36} The HSCRC database includes all patients with CAP, including patients requiring intensive care; severely ill patients requiring intensive care were excluded from the present study.

The results of the present study suggest that inpatients being treated for CAP can be successfully switched from IV to oral antibiotic therapy after 48 h, provided fever and WBC count are decreasing, even if these values have not yet returned to normal. Larger studies with an increased female: male ratio, a private sector setting, and more intensive risk stratification need to be performed to confirm our findings before these results are applied nationally. Our study further suggests that the use of this clinical treatment protocol in patients with CAP could reduce hospital LOS and cost of care without compromising quality of care.
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