

Pharmaceutical Industry Research and Cost Savings in Community-Acquired Pneumonia

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Objective: To provide financial justification for continuing pharmaceutical research in an environment that has met with increasing resistance from insurance carriers to paying for the care of patients enrolled in research studies.

Study Design: Matched case-control study of patients enrolled into inpatient community-acquired pneumonia (CAP) pharmaceutical research protocols.

Patients and Methods: Case patients were enrolled into a CAP pharmaceutical research trial. Control patients were obtained from a prospective cohort study of CAP. Cases were matched to controls on the basis of age, sex, pneumonia severity index (PSI) grade, and comorbid illnesses as measured by the PSI and Acute Physiologic and Chronic Health Evaluation II (APACHE II) scoring systems. Financial data were obtained from hospital billing records.

Results: Twenty-five cases were identified and matched to appropriate controls. There was no statistically significant difference in mean PSI and APACHE II scores between cases and controls. There was a significant reduction in the total charges for hospital care of patients enrolled into a pharmaceutical industry trial (\$6267 vs \$9979; $P = .03$). As expected, the most dramatic reduction was in pharmacy charges (\$642 vs \$1797; $P = .002$), but there were trends toward lower charges in all cost subgroups. Interestingly, there was also a strong trend toward reduced length of hospital stay associated with enrollment in a pharmaceutical trial (4.5 vs 6.0 days; $P = .06$).

Conclusion: Enrollment in a pharmaceutical research protocol results in significant cost savings in patients admitted to the hospital with CAP and may lead to earlier hospital discharge.

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For editorial comment, see page 822.

Pharmaceutical industry research is not only necessary for the development of new drugs, but it also provides a source of funding for many research centers. The pharmaceutical industry sponsor provides the antibiotics required for the study in community-acquired pneumonia (CAP) tri-

als. Intuitively, this should reduce the cost to the hospital and/or the insurance carrier providing the care for patients requiring hospitalization.

Recently, we have faced situations where insurance carriers have refused to pay for any of the care of a patient enrolled into an inpatient CAP research protocol; insurance carriers felt that patients enrolled in research studies were more costly. Hospital administrators also question the costs associated with clinical research. Because very few data in the medical literature compare the cost of care for patients admitted into research protocols with the cost for patients who receive routine care, we undertook a case-control study.

METHODS

Subjects

Case patients were admitted to the Methodist Healthcare University Hospital, a large, private, tertiary care center, and were enrolled into 1 of 2 pharmaceutical industry CAP protocols: one comparing an everninomicin with a third-generation cephalosporin and the other comparing 2 quinolones. All controls were patients who met the inclusion criteria for the same study, but declined to participate in a pharmaceutical trial.

Controls were matched to cases if they met the following criteria: same sex, same age (± 4 years),

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same Pneumonia Severity Index (PSI) grade¹ on admission, same comorbid illnesses as measured by the PSI, and the same chronic organ failures as measured by the Applied Physiology and Chronic Health Evaluation II (APACHE II) scoring system.² Control patients also had to be admitted to the hospital within 6 months of the matched case admission.

Data Collection

Obtaining accurate cost data is difficult. We utilized the itemized hospital billing record for comparison because it most accurately reflects actual patient charges. Clinical data regarding investigations, treatment, length of stay, and outcome were obtained from the patient's medical record. PSI scores were calculated by using the clinical and laboratory data available at the time of admission. APACHE II scores were calculated by using the worst physiologic variables during the first 24 hours after presentation. Charlson Index scores³ for cases and controls also were calculated.

Data Analysis

Quantitative variables are expressed as means ± standard deviations. Differences between groups were evaluated by 2-tailed paired Student *t* tests with significance set at *P* < .05.

matched (63.8 ± 21.8 in cases vs 63.1 ± 22.9 in controls; *P* > .10). However, mean APACHE II scores suggested that case patients (11.2 ± 3.9) had slightly more severe CAP than their matched controls (9.3 ± 4.6) (*P* = .03). There was no significant difference in the mean Charlson Index scores between case (0.72 ± 0.73) and control (0.68 ± 0.69) patients (*P* > .10), and there were no deaths in either group.

In the control group, 21 were treated empirically with either levofloxacin or trovafloxacin, 3 received a third-generation cephalosporin and a macrolide, and 1 received a third-generation cephalosporin and doxycycline. All 25 control patients received at least 48 hours of intravenous therapy before switching to oral therapy.

Case patients tended to have shorter hospital stays (4.5 ± 2.2 days) than control patients (6.0 ± 3.9 days) but the difference did not quite reach statistical significance (*P* = .06). There was no significant difference in the time taken to become afebrile between case (2.3 ± 2.2 days) and control (2.9 ± 2.2 days) patients (*P* > .10).

An analysis of the hospital charges for case and control patients is shown in the Table. Although there was a trend toward lower charges in all categories for patients enrolled in a pharmaceutical research protocol, only the reductions in pharmacy, supply, and total charges reached statistical significance.

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RESULTS

Twenty-five cases were matched to appropriate controls. Twenty-three case patients were enrolled in the quinolone comparison protocol, and 2 were enrolled in the other protocol. One additional case patient was excluded because an appropriate control could not be identified using our matching criteria. One potential control patient also was rejected, despite meeting all matching criteria, because of the development of septic shock on the fourth day after admission, substantially inflating the cost of that admission.

There was no significant difference in age between case (56.3 ± 17.0 years) and control (55.1 ± 18.4 years) patients (*P* > .10). Comparison of the total PSI points showed the 2 groups to be well

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DISCUSSION

We have shown a significant reduction in the charges for hospitalized patients enrolled in phar-

Table. Summary of Costs

Charge Item	Cost (\$)		<i>P</i>
	Cases	Controls	
Laboratory	1531 ± 754	1906 ± 1533	>.10
Room	1102 ± 546	1636 ± 1300	.06
Supplies	745 ± 568	1280 ± 1069	.03
Pharmacy	642 ± 440	1797 ± 1539	.002
Radiology	470 ± 615	741 ± 1061	>.10
Intravenous solutions	330 ± 387	566 ± 777	>.10
Total	6267 ± 3367	9979 ± 8084	.03

maceutical industry research trials. As expected, the major saving was in pharmaceuticals, but there also was a strong trend toward reduction of charges in other categories. Although cases and controls were well matched by our selection criteria, the reduction in charges was still seen, even though patients enrolled in a pharmaceutical trial had slightly more severe illness as measured by the APACHE II score.

We analyzed hospital charges as a surrogate marker for actual costs because information on those charges is easier to obtain. The actual cost would be expected to be lower than the charges; hence, our estimates of the savings from enrollment in a pharmaceutical industry trial are slightly optimistic.

It is possible that the advantage observed in patients enrolled in the pharmaceutical trial could be due to increased efficacy of antibiotic therapy. However, as neither trial reported any therapeutic benefit for the study drug over the comparator,⁴ we believe that this is unlikely to explain our findings. Another potential bias is that patients who refused consent for a pharmaceutical trial may have been less ill than those who consented. We could find no evidence of this, however. In fact, our results suggest that, if anything, the case patients were more ill than the matched controls.

Although our findings cannot be generalized to research protocols involving diseases other than CAP, they should be reassuring to researchers, hospital administrators, and insurance carriers. The trend toward reduced length of hospital stay is particularly interesting and may reflect the increased surveillance of research patients and attention to discharge protocols. This increased surveillance does not generate any additional cost because the clinical data are collected by nursing staff as part of routine patient care.

There are few studies of treatment costs for patients enrolled in research protocols in the med-

ical literature. Enrollment in a clinical cancer trial was not associated with a substantial increase in the cost of medical care⁵ and could result in cost savings due to reduced drug costs.^{6,7} In the current financial climate, it is likely that researchers will be faced with increasing pressure from administrators and insurance carriers to justify the continuation of research protocols, creating both practical and ethical issues.

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CONCLUSION

In conclusion, our results suggest that enrollment in a pharmaceutical industry research protocol reduces the cost of hospital care. This provides financial justification for continuing pharmaceutical research, at least in CAP, for researchers, hospitals, and insurance carriers.

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