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Estimates of Health Care Costs For Lamivudine-Refractory Chronic Hepatitis B (CHB) Patients

Tafesse E[1], Claxton A[2], Granger A[2], Sanders J[3], Apelian D[1], Atillasoy E[4], Iloeje U[1]
[1]Bristol-Myers Squibb Company, Wallingford, CT; [2]RTI-Health Solutions Research Triangle Park, NC; [3]Harvard University, Cambridge, MA; [4]Bristol-Myers Squibb Company, Princeton, NJ

Abstract

Introduction: For patients with chronic hepatitis B, emergence of lamivudine resistance is associated with poor clinical outcomes, more rapid disease progression and poor quality of life. The clinical implications of lamivudune resistance are well described but the health care costs are not. The objective of this study was to evaluate the health care utilization and direct medical cost within the first year of developing a lamivudine refractory infection in chronic hepatitis B (CHB) patients.

Methods: Physician estimates of health care utilization for the care of lamivudine refractory CHB patients were collected in a survey of physicians treating CHB patients in the USA. A questionnaire was mailed to 165 physicians of which 51 responded. Data on health care utilization was computed for each health care cost category (physician visits, hospitalizations, diagnostic tests and radiological examinations). Unit costs were derived based on the Medicare Physician Fee Schedule for procedures, the 2002 Health Care Cost and Utilization Project database for inpatient hospitalization costs, and average wholesale prices for medication costs.

Results: The total non-drug, direct medical cost within the first year of developing a lamivudine refractory infection in a CHB patient was estimated at $2,925. Among the different cost categories, diagnostic tests and specialist visits were the major cost drivers, accounting for an estimated 46% and 41% of the overall cost, respectively. Seventy four percent (74%) of the patients were estimated to require a specialist visit. Only 2% of patients were estimated to require a hospitalization accounting for a negligible proportion of the costs.

Conclusion: The estimated non-drug costs for patients refractory to lamivudine represent a substantial economic burden. In addition, the additional costs of rescue therapy further increase the cost impact and make it considerably higher than the annual direct medical cost for CHB patients who do not develop viral resistance.

Background

Hepatitis B virus (HBV) infection is a major global health care problem. In the US, an estimated 240,000 new cases of chronic hepatitis B (CHB) are diagnosed each year. Successful treatment of CHB requires long-term drug treatment. Lamivudine is one of the most widely used first-line medications that is safe and well-tolerated. However, development of resistance is a major limitation with lamivudine. Resistance typically begins to emerge after 6 to 9 months of lamivudine treatment. In a 5-years study, the rate of resistance for years 1, 2, 3, 4, and 5 were 23%, 46%, 55%, 71% and 65% respectively[1]. Emergence of lamivudine resistance is associated with poor clinical outcomes, more rapid disease progression and poor quality of life. On the other hand, the economic implication of lamivudune resistance is not well described.

Definition

Lamivudine refractory patients were defined as patients with documentation of resistance to lamivudine by the presence of YMDD mutation OR patients on lamivudine for >36 weeks who are viremic (HBV DNA > 700,000 copies/ml) on therapy.

Objective

The objective of this study was to evaluate the health care utilization and direct medical cost within the first year of developing a lamivudine refractory infection in chronic hepatitis B (CHB) patients.

Methods

- A survey instrument was developed and validated in consultation with clinicians. The survey questionnaire asked for the health care utilization one year following the emergence of lamivudine resistance.
- The questionnaire was mailed to 165 physicians in the USA treating CHB patients of which 51 responded.
- For each health care category (physician visits, hospitalizations, diagnostic tests and radiological examinations) means, percentages, standard deviations, and confidence intervals were computed. Unit costs were derived based on the Medicare Physician Fee Schedule for procedures, the 2002 Health Care Cost and Utilization Project database for inpatient hospitalization costs, and average wholesale prices for medication costs.

Results

- Responding physicians were well distributed across different geographical regions (shown in Table 1).

Table 1 • Geographic Distributions of Respondent Physicians

Region	N (%)
Midwest	6 (12%)
Northeast	23 (45%)
South	5 (10%)
West	17 (33%)
Total	**51 (100%)**

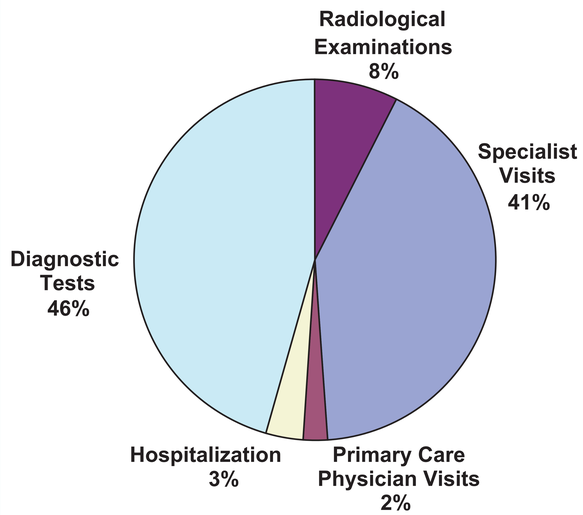
- The total non-drug, direct medical cost within the first year of developing a lamivudine refractory infection in a CHB patient was estimated at $2,925. This estimate does not include cost of salvage medication (Adefovir) which is either added to lamivudine or substituted in place of lamivudine.

Table 2 • Direct Medical Cost During the First Year of Lamivudine Resistance Development

Cost Categories	Cost
Specialist visit	$1,210.87
Primary care physician visit	$66.91
Hospitalization	$98.63
Diagnostic tests including radiological examinations	$1,548.93
Total cost	**$2,925.34**

- During the first year after the development of lamivudine resistance, a CHB patient will have an average of 12.6 specialist visits. In addition, they will have 1.3 primary care physician visits.
- The percentage of CHB patients who will be seen by a specialist and primary care physician are 74.27% and 36.31% respectively. At the same time 2.2% of CHB patients will have a hospital admission.
- Among the different health care utilization categories, diagnostic tests and specialist visits were the major cost drivers, accounting for an estimated 46% and 41% of the overall cost, respectively.

Figure 1 • Percentage of Direct Medical Cost Among Major Health Care Utilization Categories



Conclusions

Development of resistance to lamivudine is associated with a substantial health care utilization. This economic impact is much higher if the cost of rescue therapy is also taken into consideration. In the long term, patients who are infected with lamivudine resistant HBV will have faster disease progression than CHB patients infected with the non-resistant virus[2]. Since advanced CHB is costly, the cost findings in this study are more likely to underestimate the true total long-term cost.

References

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