Reports of Bleeding-Related Fatalities with Dabigatran and Warfarin: An Analysis Using the Food and Drug Administration Adverse Events Reporting System

Oral Contributions
West, Room 3009
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Background: A pivotal phase III trial has reported similar bleeding rates for dabigatran and warfarin in stroke prevention. However, the incidence of bleeding-related fatalities in clinical practice has not been evaluated. Whether dabigatran is associated with worse bleeding-related outcomes is unknown.

Methods: We evaluated reports of dabigatran and warfarin induced bleeding events from the United States submitted to the FDA Reporting System through 2011-2012. Bleeding events and related fatalities were determined. The bleeding-related mortality rate based on a reported 725,000 dabigatran treated patients was estimated.

Results: Bleeding-related fatalities increased during the reported period for dabigatran compared to a stable number of reports with warfarin (Figure 1). Dabigatran was the primary or secondary agent in 4,270 bleeding events with 638 bleeding-related fatalities. In comparison, warfarin had 827 bleeding events with 44 bleeding-related fatalities. We estimated a lower bound of 88 bleeding-related fatalities per 100,000 dabigatran treated patients. Because of under-reporting bias these estimates represent a lower bound on the population bleeding mortality rates.

Conclusions: The total number of bleeding-related fatalities for dabigatran have greatly exceeded warfarin. Significant reporting bias exists in the FDA reporting system. A more comprehensive data source is needed to determine the true incidence and risks for fatal bleeding episodes.