The Importance of Postapproval Data for Dabigatran

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Dabigatran was approved by the Food and Drug Administration (FDA) in 2010 via the accelerated pathway after a 6-month review. The haste to approve novel drugs places an increasing importance on postapproval data to help better understand risks and benefits. Thus, the postapproval data on the use of dabigatran in the Medicare population are informative in alerting us to risks associated with real-world use. Hernandez et al giving us cause for concern because it appears that the bleeding risk for dabigatran is higher than for warfarin and significantly greater than originally appeared at the time of the FDA approval. These data conflict with the recent Mini-Sentinel analysis from the FDA. The authors note that the FDA failed to adjust for differences in patient characteristics, which would bias the results. This study reminds us of the importance of postmarketing data and of having adequate data on risks and benefits to advise our patients accurately.

Conflict of Interest Disclosures: None reported.


2. Southworth MR, Reichman ME, Unger EF. Dabigatran and postmarketing reports of bleeding. 