Computer-automated monitoring system may help identify medical devices with potential safety risks

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Implementation in Massachusetts of a computer-automated safety surveillance system of clinical outcomes registries for cardiovascular devices resulted in the identification of a drug-releasing stent that had significantly higher rates of major adverse cardiac events than similar stents, according to a study in the November 10 issue of *JAMA*. The findings indicate that this type of system appears feasible and useful in identifying new cardiovascular devices with early low-frequency potential safety issues that are not observed in premarket approval studies.

"Monitoring the safety of approved medical products is of vital public health importance, given that in clinical practice such medical products are often used in numbers far greater and in patient populations more diverse than when studied in premarket evaluations and clinical trials," the authors write. "Ensuring the safety of medical devices challenges current surveillance approaches, which rely heavily on voluntary reporting of adverse events. Automated surveillance of clinical registries may provide early warnings in the postmarket evaluation of medical device safety."

Frederic S. Resnic, M.D., M.Sc., of Brigham and Women's Hospital and Harvard Medical School, Boston, and colleagues examined in-hospital safety signals for recently introduced cardiovascular devices using an automated safety surveillance system to assess the feasibility of such an

approach to provide early warnings regarding their safety. The study included an analysis of seven newly introduced cardiovascular devices, using clinical data captured in the Massachusetts implementation of the National Cardiovascular Data Repository CathPCI Registry for all adult patients undergoing percutaneous coronary intervention (PCI; procedures such as balloon angioplasty or stent placement used to open narrowed coronary arteries) from April 2003 through September 2007 in Massachusetts. Patient, physician, and hospital data for 74,427 coronary interventional procedures performed during the study period were evaluated.

Of the 21 safety analyses performed, 3 (14 percent) generated a repeated or sustained safety signal involving 2 implanted devices, prompting detailed sensitivity analysis per study protocol. The safety alerts included an increased risk of postprocedural heart attack as well as an increased risk of major adverse cardiac events (MACE) following implantation of Taxus Express2 drug-releasing stents. By the end of the study period the rate of postprocedure heart attack was 27.6 percent higher for Taxus Express2 drug-releasing stents compared with alternative drug-releasing stents (2.87 percent vs. 2.25 percent; absolute risk increase, 0.62 percent). The rates of MACE were increased by 21.1 percent, driven by the increased postprocedural heart attack difference for the Taxus Express2 drug-releasing stent relative to the MACE rate for the control population (4.24 percent vs. 3.50 percent; absolute increase, 0.74 percent); and a sustained safety alert for MACE was triggered beginning in July 2007. No increased risk of death was observed among the exposure groups.

An increased rate of major vascular complications following implantation of the Angio-Seal STS vascular closure device was observed. By the end of the observation period, the matched subset of Angio-Seal STS case patients experienced a 51.3 percent increased risk of major vascular complications compared with the control population

(1.09 percent vs. 0.72 percent; absolute increased risk, 0.37 percent).

Sensitivity analyses confirmed increased risk following use of the Taxus Express2 stent but not the Angio-Seal STS device.

"In conclusion, automated safety surveillance of medical devices is feasible using automated monitoring tools applied to detailed clinical registries and can efficiently help identify emerging potential postmarket safety risks. Automated medical product surveillance can complement existing public health strategies, providing an additional mechanism to assess the comparative safety of approved medical products and improve the quality of health care delivered," the authors write.

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