

Study identifies treatments associated with lower bleeding rates following cardiac procedures

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In a study that included data from more than 1.5 million patients, use of vascular closure devices and the anticoagulant bivalirudin were associated with significantly lower bleeding rates for patients following a percutaneous coronary intervention (PCI; procedures such as balloon angioplasty or stent placement used to open narrowed coronary arteries), according to a study in the June 2 issue of *JAMA*. The researchers also found that patients who may benefit most from these treatments, those at greatest risk of bleeding, were least likely to receive them.

Percutaneous coronary intervention is performed approximately 1 million times a year in the United States. "Periprocedural bleeding is the most common noncardiac complication of PCI and is associated with risk of early mortality as well as higher costs of care," the authors write. They add that bleeding around the time of the procedure is modifiable through the use of bleeding avoidance strategies such as vascular closure devices and bivalirudin. "The association between the use of bleeding avoidance strategies and post-PCI bleeding as a function of a patient's preprocedural risk of bleeding is unknown."

Steven P. Marso, M.D., of Saint Luke's Mid America Heart Institute, Kansas City, Mo., and colleagues analyzed bleeding rates after PCI procedures associated with the use of manual compression, vascular closure devices, bivalirudin, or both strategies (vascular closure devices plus bivalirudin) in patients across a spectrum of preprocedural bleeding

risk. The analysis included data from 1,522,935 patients undergoing PCI procedures performed at 955 U.S. hospitals, participating in the National Cardiovascular Data Registry (NCDR) CathPCI Registry, from January 2004 through September 2008.

Overall, bleeding occurred in 30,429 patients (2 percent). "Manual compression was used in 35 percent of patients, vascular closure devices in 24 percent, bivalirudin in 23 percent, and vascular closure devices plus bivalirudin in 18 percent. Bleeding events were reported in 2.8 percent of patients who received manual compression, compared with 2.1 percent receiving vascular closure devices, 1.6 percent receiving bivalirudin, and 0.9 percent receiving both strategies," the researchers write. According to the NCDR CathPCI bleeding risk model, bleeding risk was classified as low (less than 1 percent) in 31 percent of patients, intermediate (1 percent - 3 percent) in 49 percent, and high (greater than 3 percent) in 20 percent of patients. Observed rates of bleeding in these categories were 0.72 percent, 1.73 percent, and 4.69 percent, respectively.

"In high-risk patients, use of both strategies was associated with lower bleeding rates (manual compression, 6.1 percent; vascular closure devices, 4.6 percent; bivalirudin, 3.8 percent; vascular closure devices plus bivalirudin, 2.3 percent)," the authors write. "Use of both strategies was used least often in high-risk patients (14.4 percent vs. 21.0 percent in low-risk patients)."

"The results of this study suggest the need for additional research to better understand why higher-risk patients are least likely to receive bleeding avoidance strategies but also suggest the need to test interventions to overcome the risk-treatment paradox, such as enabling physicians to purposefully direct bleeding avoidance strategies to patients by providing preprocedural estimates of post-PCI bleeding."

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