

Recommended approach for preventing blood clots after stent placement may not be as beneficial as once thought

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Each year, one million Americans undergo percutaneous coronary intervention after a heart attack, or to alleviate symptoms of chest pressure. Current American Heart Association guidelines recommend that patients who undergo PCI, a minimally invasive procedure to open clogged arteries, be prescribed dual antiplatelet therapy (DAPT) to prevent blood clots, and that they continue using the combination of aspirin and a second antiplatelet medication for at least one year after the procedure with continuation of DAPT beyond one year for patients with acceptable bleeding risk.

The guidelines still in place today are based on previous research, including the DAPT Study—a large clinical trial of patients undergoing PCI with a stent in 2009-2011—that found using DAPT beyond one year after PCI decreased ischemic events but posed a higher risk of bleeding. Questions have since been raised on whether the evidence is representative of real-world populations and practice patterns that have changed over time.

To better understand whether the results of prior trials of DAPT duration are applicable today, researchers at Beth Israel Deaconess Medical Center (BIDMC) developed new analytic methods to update a previously conducted trial to better reflect contemporary practice. The findings, published in *Circulation*, suggest that because of improvements in stent technology and changes in the types of patients receiving stents, the risks of DAPT may now outweigh the benefits for the average patient.



"Clinical research can become outdated as practices and technologies evolve," said corresponding author Robert W. Yeh, MD, MSc, director of the Smith Center for Outcomes Research in Cardiology and an interventional cardiologist at BIDMC. "By extrapolating what an older trial might have shown had it been conducted today, we found that many patients who've received stents and are currently on combination antiplatelet therapy may actually benefit from stopping one of those antiplatelet drugs—adding to growing evidence that aspirin and drugs like it may be less useful than previously thought."

Yeh and colleagues extrapolated the results of 5,743 DAPT Study participants to 568,540 patients undergoing PCI with a stent between July 1, 2016 and June 30, 2017 as registered in the National Cardiovascular Data Registry CathPCI registry. Using new analytic methods developed by Issa Dahabreh, MD, of the Smith Center at BIDMC, the team estimated a contemporary "real-world" treatment effect of 30 months versus 12 months of DAPT after coronary stent procedures. Compared to the previous trial population, contemporary registry patients had more comorbidities and were more likely to present with heart attack and receive second generation drug-eluting stents. After reweighting trial results to represent the registry population, the researchers no longer saw a significant effect of prolonged DAPT on reducing stent thrombosis or heart attack, but increased risk of bleeding persisted.

Additionally, the team used their previously developed risk tool called the DAPT Score to stratify subgroups of patients who may or may not benefit from prolonged DAPT. They found that the projected ischemic benefits of prolonged DAPT in the subgroup of patients with DAPT score less than two disappeared, while the bleeding risk persisted. In contrast, in the subgroup of patients with DAPT score of two or greater, ischemic benefits of prolonged DAPT persisted, though were slightly attenuated, with negligible increase in bleeding.



"While patients at highest risk of ischemic event small group of patients should likely remain on these medications, longer duration DAPT may have more limited benefits and greater harms for most," said lead author Neel M. Butala, MD, MBA, a research fellow in the Smith Center. "These results illustrate the importance of a nuanced interpretation of clinical trials to guide clinical decision-making. The methods may be applicable across various cardiovascular conditions to help ensure that evidence is up-to-date and appropriate for real world populations."

More information: Neel M. Butala et al, Estimation of DAPT Study Treatment Effects in Contemporary Clinical Practice: Findings from the EXTEND-DAPT Study, *Circulation* (2021). DOI: 10.1161/CIRCULATIONAHA.121.056878

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