

Access to real-time genetic testing data impacts prescriber behavior following minimally invasive stent procedure

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Today, in a late-breaking featured clinical research session at the American College of Cardiology Scientific Sessions 2018, researchers from Penn Medicine present first-of-its-kind data on the impact of real-time CYP2C19 genotype results when prescribing antiplatelet drugs in the clinic.

Following percutaneous coronary intervention (PCI)—a minimally invasive procedure for the treatment of narrowing arteries inside the heart—patients are often prescribed aspirin and antiplatelet medications, which keep stents open by preventing blood platelets from sticking together. However, existing research suggests that some patients—specifically those who carry a mutation of the CYP2C19 gene, which impact the liver's ability to process the antiplatelet drug, clopidogrel—may not benefit from this drug, but instead would require different antiplatelet medications, such as prasugrel or ticagrelor, to prevent heart attack and stroke.

"One of the main things we aimed to do in this study was integrate a clinical trial protocol into the physicians' daily practice, in order to provide the most beneficial medication regimens to patients based on their specific genetic needs, while also identifying what drives physician behavior when prescribing," said senior author Jay Giri, MD, associate director of the Penn Cardiovascular Outcomes, Quality, & Evaluative Research Center and an assistant professor of Cardiovascular Medicine.



"Clinicians were provided with a real-time, rapid response genetic test and an appropriate level of education for using said test, which would identify patients' genetic mutation, CYP2C19 Loss-of-Function (LOF) alleles. We thought this <u>precision medicine</u> approach would impact the medications being prescribed to patients following PCI."

As Giri and his colleagues suspected, access to the genotype data in an everyday clinical setting did, in fact, influence prescriber behavior.

In the study, 504 participants from two Penn Medicine hospitals—the Hospital of the University of Pennsylvania and Penn Presbyterian Medical Center—were randomized into two groups: one group received a rapid point-of-care genotyping of CYP2C19, and the other did not receive any genotyping, which is the current standard of care. 249 participants were genotyped and 255 received the standard care. The participants in the genotyped group received a cheek swab within one day after PCI to determine CYP2C19 genotype, and results were available to clinicians within 90 minutes of the test being done. Physicians were verbally provided genotype results along with decision support, a one page summary of the treatment recommendations by genotype according to the Clinical Pharmacogenetics Implementation Guidelines (CPIC). Ultimately, the treating physician was the sole decision maker in the prescribing.

Researchers found that in the genotyped group, the use of prasugrel or ticagrelor was significantly higher and the use of clopidogrel was lower as compared to the usual care group. In fact, genotype-guided drug recommendations were followed in 71 percent of cases, whereas in 29 percent of cases, physicians did not follow the recommendations.

"This implies that physicians consider factors beyond the genotype when deciding the most appropriate antiplatelet medication for their patients, which is the premise of precision <u>medicine</u>." said lead author Sony



Tuteja, PharmD, MS, a research assistant professor of Translational Medicine and Human Genetics, who presented the results of the study today in a late-breaking featured clinical research session at ACC 2018. "Ultimately we concluded that access to pharmacogenetic test results significantly impacted antiplatelet prescribing behaviors. It remains to be seen whether a reduction in important clinical outcomes like heart attack, stroke, and cardiovascular related death follow what is predicted by the genetics."

Researchers noted that this study raised more questions for the field, specifically, how do physician behave in an era of precision medicine, and will the availability of patient-specific genetic information impact the standard of care?

"Often times we have a situation where the data in large clinical trials will say one thing, but precision medicine data will say another, so we need to figure out what the physician will do in those situations and what drives their decisions," Giri said. "Are clinicians influenced more by a patients' genetic make-up, or by the population-based research they have access to? Ultimately more research is needed to really identify the impact and usefulness of real-time genetic testing for making clinical decisions, which we intend to evaluate for interventional patients. As it turns out, Precision Medicine is a lot more than just precise genetics."

Provided by Perelman School of Medicine at the University of Pennsylvania

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