

Interventional Cardiology



NEWS



RESEARCH HIGHLIGHTS



Low clopidogrel response could predict mortality in PCI patients, study suggests

A recent study indicates that low platelet response to clopidogrel may predict cardiovascular events in high-risk populations undergoing percutaneous coronary intervention (PCI).

A total of 461 unselected patients undergoing urgent or elective PCI were prospectively enrolled in the study. The patients' platelet activation was measured using a vasodilator-stimulated phosphoprotein flow cytometry test (VASP-FCT). The new platelet VASP-FCT assay was specific to the P2Y₁₂ adenosine diphosphate receptor pathway.

The patients were then classified as either low response to clopidogrel or 'response' to clopidogrel, depending on their platelet activation, which was expressed as the platelet reactivity index in this study. The results of the study were based on a PRI cut-off of 61%.

In total, 60.1% patients were considered responders, owing to their platelet activation falling below the 61% cut-off. The other 39.9% of patients had platelet reactivity above the cut-off and as such were classified as low clopidogrel responders.

The patients were followed-up at 9 ± 2 months and the researchers looked at the difference in mortality and major adverse cardiac events between the two groups. The researchers observed that higher rates of cardiac death and a trend towards more major adverse cardiac events were observed in the low clopidogrel responder group.

However, when an alternative platelet reactivity index cut-off of 50% was used instead of 61%, no difference in cardiovascular mortality was observed between the two clopidogrel response groups.

The risk that was related to low clopidogrel response was found to be dependent upon the type of stent fitted, since in patients that were fitted with drug-eluting stents, the risk of cardiac events was significantly higher.

The study was led by Olivier Morel (University of Strasbourg, France) and was recently published in the *Journal of the American College of Cardiology Interventions*. In the paper, the authors state that, "Overall, our study validates for the first time the usefulness of the VASP assay after PCI to predict hard clinical end points."

The authors concluded that, "Altogether, these data strongly suggest that the evaluation of platelet responsiveness to clopidogrel could be useful for the management of patients treated with [drug-eluting stent]."

The results of this study highlight the importance of a 61% threshold for identifying patients who are at an increased risk of cardiac events following PCI. However, in the accompanying editorial, Sotirios Tsimikas, (University of California, CA, USA) and Gregor Leibundgut, (UCSD and the University Hospital Basel, Switzerland) caution that "Further studies are needed to assess their predictive value in higher-risk subsets such as [STEMI], [acute coronary syndrome], and complex coronary anatomy and interventions."

Source: El Ghannudi S, Ohlmann P, Meyer N et al.: Impact of P2Y₁₂ inhibition by clopidogrel on cardiovascular mortality in unselected patients treated by percutaneous coronary angioplasty. A prospective registry. *J. Am. Coll. Cardiol. Interv.* 3, 648-656 (2010).



Transcatheter valve-in-valve implantation used in elderly patients with degenerated bioprostheses

A minimally invasive procedure has been successfully used in elderly patients with degenerated bioprostheses, as an alternative treatment for patients who are at high surgical risk.

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“Reoperation and valve replacement is the standard treatment for xenograft degeneration, but it is not always advisable for patients at high surgical risk...”

The study, which was recently published in *Catheterization and Cardiovascular Interventions*, examined five patients who had experienced tissue valve degeneration 15.4 ± 5.2 years after aortic ($n = 4$) and mitral ($n = 1$) valve replacement. Reoperation and valve replacement is the standard treatment for xenograft degeneration, but it is not always advisable for patients at high surgical risk; for example, the elderly.

The five patients studied by Mortiz Seiffert (University Heart Center, Hamburg, Germany) and colleagues had a mean age of 82.0 ± 6.5 years, and were considered to be high-risk patients owing to their predicted operative mortality calculated at $55.8 \pm 18.9\%$. Each of the patients received a 23-mm Edwards Sapien valve deployed into the degenerated valve prosthesis via transapical access.

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“Transcatheter valve-in-valve implantation offers an alternative treatment option for elderly patients...”

Results showed that the mean transvalvular gradient was reduced from 31.2 to 19.0 mmHg in patients with valves implanted in the aortic location and 9–3 mmHg in those who had valves in the mitral position. No significant regurgitation was reported. However, two of the

five patients died within 30 days of valve-in-valve implantation owing to low cardiac output and acute hemorrhage, respectively.

“Transcatheter valve-in-valve implantation offers an alternative treatment option for elderly patients who have disproportional operative risks,” summarized Seiffert.

“As the aged population continues to grow, a minimally invasive procedure such as transcatheter valve-in-valve implantation is a promising alternative,” the authors explained.

“However, adequate patient selection and an interdisciplinary approach are crucial to the success of this procedure,” they cautioned.

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 Source: Seiffert M, Franzen O, Conradi L et al.: Series of transcatheter valve-in-valve implantations in high-risk patients with degenerated bioprostheses in aortic and mitral position. *Catheter. Cardiovasc. Interv.* DOI: 10.1002/ccd.22618 (2010) (Epub ahead of print).

Catheter gains US FDA approval for treating peripheral vascular disease

Pathway Medical Technologies has recently announced that its JETSTREAM G3™ catheter has received US FDA approval for the treatment of peripheral vascular disease.

The JETSTREAM G3 catheter is a peripheral revascularization catheter, which has been designed to facilitate the removal of artery-clogging plaque blockages in patients' lower limbs, restoring blood flow in a minimally invasive procedure. The JETSTREAM G3 has a small size and a long catheter length, allowing it to be used to treat peripheral vascular disease blockages below the knee. This is potentially very useful in the growing

diabetic population, who are susceptible to poor circulation, leading to an increased chance of experiencing critical limb ischemia, which can require amputation if not treated.

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“The JETSTREAM G3 ... is potentially very useful in the growing diabetic population...”

Commenting on the device, Malcolm T Foster III, Research Director at East Tennessee Heart Consultants and Physician at Mercy Medical Center West (TN, USA), said, “The JETSTREAM G3 [Small Fixed] gives me a new tool in my

arsenal to treat a wide range of peripheral vascular disease patients, including those with blockages in smaller arteries below the knee ... In particular, patients with diabetes have often faced the threat of amputation owing to poor circulation in the extremities. With JETSTREAM, some of these patients now have a viable option for treating [critical limb ischemia] and saving their limb. My experience with the device has been extremely positive and I look forward to continuing to use this exciting innovation.”

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 Source: Pathway Medical Technologies Inc.: www.pathwaymedical.com



St Jude Medical announce approval of the first flexi-tip ablation catheter

The global medical device company, St Jude Medical, Inc. has recently announced the European approval of the Therapy™ Cool Flex™ Ablation Catheter, which is not currently available in the USA. The announcement was made at the 17th World Congress on Cardiac Electrophysiology and Cardiac Techniques (Nice, France). The catheter is innovative as it is the industry's first to include a fully irrigated, flexible tip.

“The Therapy™ Cool Flex™ Ablation Catheter ... is innovative as it is the industry's first to include a fully irrigated, flexible tip.”

The design of the new catheter is intended to improve the safety and efficiency of ablation procedures. Standard cardiac ablation catheters are thin tubes that are used to help treat cardiac arrhythmia. Catheters can be utilized to improve this condition by delivering radiofrequency energy to the cardiac tissue and creating lesions to interrupt the abnormal electrical signals that contribute to the irregular heartbeat.

There are several features of the Therapy Cool Flex Ablation Catheter that make it superior to conventional irrigated catheter designs. First, the unique flexible tip allows the catheter to bend to conform to the cardiac anatomy and to use various angles of approach.

The laser-cut design improves cooling by allowing fluid to infuse around the entire catheter tip. The catheter electrode tip is irrigated by slits arranged in a zig-zag pattern and also features four ports at the distal end to allow greater irrigation. The effect of the catheter tip bending encourages the slits to open and this directs the cooling saline to the areas that are in the highest need. This improved cooling capability is intended to reduce risk factors that are linked to radiofrequency delivery, such as blood coagulation and tissue charring.

Carlo Pappone (Villa Maria Cecilia Hospital, Cotignola, Italy) described the new catheter, remarking, “I found the Therapy Cool Flex tip to be capable of flexion upon the tissue, which in turn engages a larger surface area. This and other unique features help to improve contact stability and optimize energy transfer to the tissue while reducing catheter induced mechanical stress.”

President of the St Jude Medical Atrial Fibrillation Division, Jane Song, also commented on the approval of the Therapy Cool Flex Ablation Catheter, saying “St Jude Medical has developed a very special and unique treatment solution for physicians with the Therapy Cool Flex Ablation Catheter. We believe that our flexible tip has a strong potential to replace a rigid tip as the new industry standard for irrigated catheter ablation.”

 Source: St Jude Medical: <http://investors.sjm.com/phoenix.zhtml?c=73836&p=irol-newsArticle&ID=1439688>