1 in the bivalirudin treatment group (Table 1). In August 2014, upon recommendation from the Data Safety Monitoring Board, the study was permanently terminated due to excess allergic reaction rates associated with REG1 with a clear offsetting benefit to the drug.

No significant differences were observed in the primary efficacy end point with the data available; however, the exploratory end point of stent thrombosis was lower with REG1 at both days 3 and 30 (0.8% vs 0.1% with REG1; $P < .01$). Regarding the primary safety end point, major non-CABG-associated bleeding (BARC type 3 or 5) did not differ between the 2 groups (0.4% vs 0.1%; $P = .10$). Nevertheless, minor and major bleeding rates were higher in REG1, with 6.5% compared with 4.1% at day 3 ($P < .002$).

Dr Mehran concluded with a word of caution in interpreting the efficacy and bleeding data, as early termination limited the number of participants and events. She reiterated that REG1, as currently formulated, resulted an infrequent but unacceptably high rate of severe allergic reactions.

SCOT-HEART: CTCA Potential to Improve Angina Diagnosis, Treatment, and Outcomes

Written by Aimee Spevak

The SCOT-HEART trial [SCOT-HEART Investigators. *Lancet*. 2015] was conducted to determine whether rapid-access chest pain centers would benefit from the addition of computed tomography coronary angiography (CTCA) to diagnose patients presenting with suspected angina due to coronary heart disease (CHD). Use of CTCA improved the provider certainty of diagnosis, influenced changes in treatment, and showed a potential to decrease CHD-related death and nonfatal myocardial infarction (MI).

Clinicians at rapid-access chest pain centers can accurately identify patients with chest pain at high risk for CHD. However, a need remains to reduce the number of patients felt to be at lower risk who are misdiagnosed with noncardiac chest pain, as these patients compose roughly one-third of fatal and nonfatal MI cases within 6 months of presenting with chest pain [Sekhri N et al. *Heart*. 2007].

David Newby, MD, PhD, University of Edinburgh, Edinburgh, Scotland, United Kingdom, presented data from SCOT-HEART, which randomized patients presenting with suspected angina due to CHD to receive diagnosis by standard care alone or standard care plus CTCA. The primary end point of the study was the change in diagnosis of angina due to CHD when using CTCA. The study included patient groups previously excluded from angina trials, as no restrictions were put on presence of arrhythmia, obesity, or calcium score. Patients with renal failure, allergy to contrast media or other inability to undergo computed tomography scanning, pregnancy, or acute coronary syndrome within 3 months were excluded.

Data were collected at 12 centers across Scotland. A total of 4146 patients were recruited and randomized 1:1, half to standard of care and half to standard of care plus CTCA. Baseline characteristics were similar between the 2 groups.

The addition of CTCA to standard testing improved provider diagnosis certainty nearly 4-fold (RR, 3.76; 95% CI, 3.61 to 3.89), while diagnosis (angina due to CHD) frequency decreased (RR, 0.78; 95% CI, 0.70 to 0.86). At 6 weeks of follow-up, clinicians reported further increased certainty in diagnosis; during the follow-up period, CTCA use led to a significant increase in change in diagnosis (23% vs 1% in the standard care group; $P < .001$).

Use of CTCA resulted in a 14% increase in further investigations ($P < .0001$) and an 18% increase in treatment changes ($P < .0001$). Patients were followed up for a median of 1.7 years (range, 0.1 to 4.1); CTCA was associated with a 38% reduction in CHD death and nonfatal MI, which for the prespecified analysis was just under statistical significance (HR, 0.62; 95% CI, 0.38 to 1.01; $P = .0527$).

Prof Newby concluded that the use of CTCA for patients with suspected angina due to CHD was beneficial in a variety of ways: it clarified diagnosis, aided in treatment decision making, increased further testing, and increased diagnosis of CHD. Use of CTCA may improve treatment decisions, reducing fatal and nonfatal MI.

SAPIEN 3 TAVR System Produces Excellent Clinical Outcomes in PARTNER II Trial

Written by Aimee Spevak

The PARTNER II trial [NCT01314313] enrolled high-risk operable, inoperable, and intermediate-risk operable patients with symptomatic severe aortic stenosis (AS) to receive the most recently available transcatheter heart valve (THV). Both patient groups experienced lower-than-expected mortality and stroke outcomes, with low rates of adverse events (AEs) and paravalvular leak.

Since their introduction in 2003, balloon-expandable THVs have continued to evolve. The current SAPIEN 3 (S3) valve, available since 2013, is size 14 French and has several modified features in the valve and its delivery system. To investigate this new iteration of transcatheter aortic valve replacement, the PARTNER II trial was designed to evaluate safety and efficacy outcomes for