Two-year updates from the RESOLUTE clinical programme

There are wide-ranging challenges associated with the management of patients with coronary artery disease (CAD) and diabetes. Such patients tend to exhibit unfavourable coronary anatomy and experience higher adverse event rates owing to – amongst other complications – endothelial dysfunction, impaired platelet function and increased smooth muscle cell proliferation.[1,2] Indeed, diabetes has continued to be associated with an increased risk of restenosis and poor clinical outcomes, even with the use of drug-eluting stents.[3,4] In addition, patients with diabetes who are undergoing stent implantation have increased on-treatment platelet reactivity, which may contribute to a higher rate of post-procedural bleeding events. Efforts to use platelet function testing to identify patients at increased risk of stent thrombosis show a modest predictive value[5], suggesting that alternative avenues should be pursued to improve treatment for patients with diabetes.

Progress has been made recently in this field, with data presented at the 61st Annual Scientific Sessions of the American College of Cardiology (ACC) from the global RESOLUTE clinical programme[6–8] and the approval by the U.S. Food and Drug Administration of the novel Resolute Integrity zotarolimus-eluting stent (ZES; Medtronic, Inc.) for the treatment of CAD in patients with diabetes. This stent is constructed from a single, continuous strand of sinusoid cobalt alloy wire, helically wrapped and then fused into a distinctive pattern. The structure provides excellent flexibility combined with radial strength, giving easier access to, and smoother tracking within, distal and tortuous vessels[9]; this is likely to be pertinent in the treatment of patients with diabetes, owing to their challenging coronary anatomy.

Within the global RESOLUTE programme – which consists of a large randomized controlled trial and multiple confirmatory single-arm studies – 5,130 patients received a Resolute ZES. Because of similarities between the stent platforms employed in the Resolute and the Resolute Integrity ZES, clinical results generated with the Resolute ZES are also applicable to the Resolute Integrity ZES.

A two-year pooled analysis of safety outcomes assessed cumulative incidences in patients who had received a Resolute ZES (N=5,130) up to 720 days post-implantation. Data showed a relatively low cumulative incidence of target lesion failure, cardiac death and target vessel myocardial infarction, target lesion revascularization and definite/probable stent thrombosis (table 1).[6] The proportion of patients using dual antiplatelet therapy across all study regions was 89.4% at 12 months and 45.6% at 24 months.[6] Ongoing follow-up will evaluate the generalizability of the safety data beyond two years and in specific higher-risk patients. A two-year update was also provided on 1,535 patients with diabetes in the RESOLUTE programme.[8] These patients had higher comorbidities at baseline compared with those without diabetes, and 43% were classed as 'complex diabetics'. Even in this challenging patient population, data were encouraging. Similarly to patients without diabetes, relatively low two-year cumulative incidences of cardiac events were observed (table 1).[8] Interestingly, similar data were reported for the for the high-risk subgroup of patients with insulin-dependent diabetes and with those who were not insulin-dependent (fig. 1).[8] These data pave the way for improved treatment for patients with diabetes and CAD.

table 1

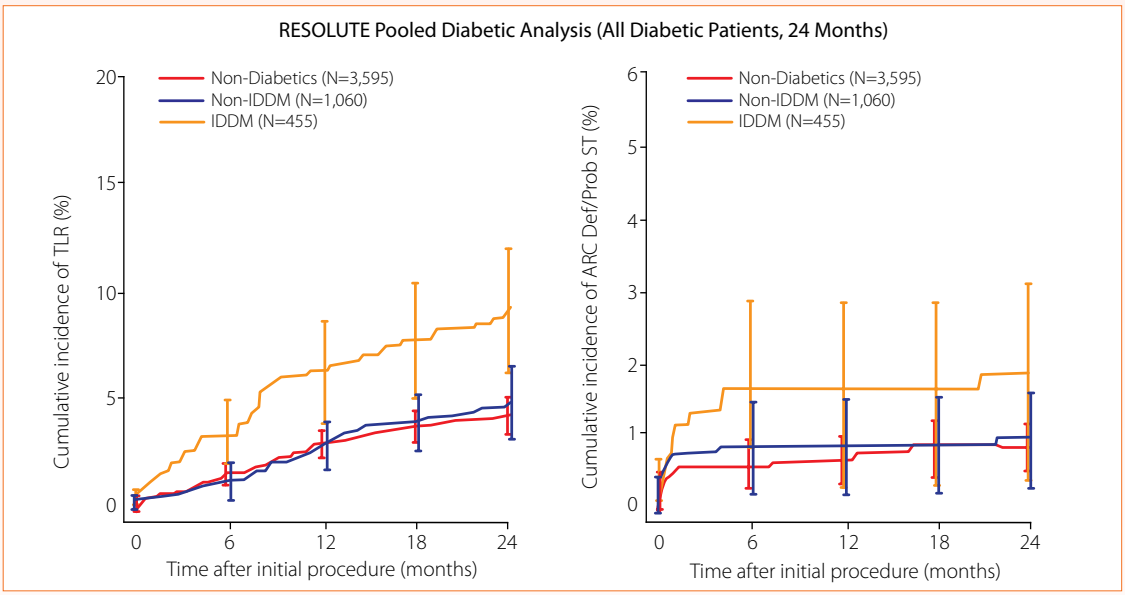
Two-year safety outcomes from pooled analyses in patients from the RESOLUTE programme

Cumulative incidence at two years (%)	Target lesion failure	Cardiac death and target vessel myocardial infarction	Target lesion revascularization	Definite/ probable stent thrombosis	Cardiac death	Target vessel myocardial infarction
Overall pooled analysis (N=5,130)	9.3%	5.4%	4.7%	0.9%	Not reported	Not reported
Analysis of diabetic patients (n=1,535)	11.1%	Not reported	5.8%	1.2%	3.4%	3.8%

fig. 1

Cumulative incidence of target lesion revascularization and definite/probable stent thrombosis in pooled *post-hoc* analysis of patients with diabetes, compared with patients without diabetes

IDDM: insulin-dependent diabetes mellitus



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