Dual-therapy stent technology for patients with coronary artery disease
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Chapter 3

Evaluation of clinical outcomes after COMBO stent treatment in patients presenting with acute coronary syndrome


ABSTRACT

**Background** Patients presenting with acute coronary syndrome (ACS) are at increased risk of complications after percutaneous coronary intervention with stent placement compared to patients with stable angina (SA) treated in an elective setting. The novel pro-healing COMBO stent is a bio-engineered drug eluting stent designed to promote vessel healing. Therefore, the stent may reduce this difference in clinical outcomes between elective and ACS-patients and prevent late stent thrombosis.

**Methods and results** The European, prospective, multicenter, 1000 all-comers patient REMDEE registry evaluates clinical outcomes after COMBO stent placement in ACS- and elective patients. The primary endpoint at 12 months is target lesion failure (TLF), a composite of cardiac death, target-vessel myocardial infarction and target lesion revascularization. A total of 49.9% (n=498) of patients presented with acute coronary syndrome. TLF was 7.1% in ACS patients, definite and probable stent thrombosis was observed in 0.5% of ACS patients and in all within 9 days post stenting. We found no significant difference in TLF between ACS and non-ACS patients and a low overall rate of TLF.

**Conclusions** The COMBO stent is a safe and efficient device for patients presenting with ACS. Low ST rate and only early stent thrombosis were observed.
INTRODUCTION

Patients presenting with acute coronary syndrome (ACS) have worse prognosis after percutaneous coronary intervention (PCI) with stent placement compared to patients with stable angina (SA), who are treated with a coronary stent in an elective setting (1,2,3,4,5,6). Drug eluting stents (DES) improved clinical outcomes in ACS, reducing rates of restenosis and target vessel revascularization (TVR) compared to bare metal stents, but at the cost of increased (late) stent thrombosis (7). Higher rates of cardiac death and stent thrombosis often occur early in patients presenting with ST-elevation myocardial infarction (STEMI) and late complications are more often seen in non-ST-elevation myocardial infarction (NSTEMI) (8). To improve clinical outcomes in patients presenting with ACS, novel stent technologies have been developed to target these complications after PCI, such as absorbable polymer stents (Mistent, Micell Technologies)9, polymer-free stents (biolimus stent, BioFreedom, Biosensor)10 and the dual-therapy stent (COMBO, OrbusNeich)11.

The bio-engineered COMBO stent has a dual-therapy strategy, which combines a sirolimus eluting coating with an anti-CD34 antibody layer to promote vessel healing. The aim of the dual-therapy technology is to lower risk for in-stent stenosis and stent thrombosis by early endothelialization of the stent. The COMBO stent has been evaluated in the real-world, all-comers, prospective REMEDEE Registry. The primary endpoint of the registry was target lesion failure, which consists of cardiac death, target vessel myocardial infarction (tv-MI) and target lesion revascularization (TLR). The REMEDEE Registry showed favourable one year clinical outcomes (12).

To date, no data is available on the clinical performance of this dual-therapy device in patients presenting with ACS. Therefore we evaluate clinical outcomes in ACS-patients and patients with SA, whom are treated with the COMBO stent as pre-specified subgroup analyses of the REMEDEE Registry. We hypothesize that ACS-patients do not suffer higher rates of target lesion failure when compared to SA patients when treated with the COMBO stent.

METHODS

Study oversight and definitions

The REMEDEE Registry is an investigator-initiated, prospective, all-comers registry, conducted in nine European sites. A total of 1000 patients with (attempted) COMBO stent placement were included between June 2013 and March 2014. Follow-up was obtained either by outpatient visit or telephone contact at 30 days, 180 days and 365
days post COMBO stent placement. Baseline, procedural and follow-up data were uploaded into the electronic database of the registry. Adverse events were adjudicated by an independent clinical event committee. Study design and primary results of the full cohort have been published previously (12).

**ACS subgroup**

This subgroup analyses was pre-specified in the protocol of the REMEDEE Registry. ACS was defined according to 2011 NSTEMI guidelines of the European Society of Cardiology (13). Patients undergoing emergency PCI or urgent PCI for stabilized STEMI, NSTEMI and unstable angina (UA) were also considered ACS-patients. SA patients were defined as patients with stable angina and/or documented ischemia or angiography driven PCI.

**Definition of endpoints**

For this analysis we analyzed target lesion failure (TLF), a composite endpoint of cardiac death, target vessel myocardial infarction and target lesion revascularization. Myocardial infarction (MI) was classified according to the third universal definition of myocardial infarction (14). Since blood samples were not mandatory for enrollment in the registry, no standard post-procedural cardiac markers were assessed. Stent thrombosis was determined as definite or probable according to the Academic Research Consortium (ARC) criteria and grouped as early (within 30 days post-PCI) and late (30 days to 1 year post PCI) (15).

**DAPT duration**

Post-procedural dual antiplatelet therapy (DAPT) was prescribed according to local hospital policy in accordance with the European Society of Cardiology guidelines. Current guidelines advise a duration of 12 months DAPT for patients presenting with ACS. Data on DAPT use were obtained at discharge, 30 days, 6 months and 12 months follow-up. If DAPT was stopped but stop date was unknown at contact moment, stop date was noted one day before the contact moment. Time on DAPT was calculated and evaluated with respect to events.

**Statistical analysis**

For purpose of this analysis the full cohort was divided in two groups according to the indication for revascularization: ACS-patients versus SA patients. Additionally, ACS-patients were grouped into patients with STEMI, NSTEMI and unstable angina. Categorical data are shown with counts and percentages, continuous variables are in mean ±standard deviation, unless otherwise mentioned. Baseline characteristics were compared with student’s T-test, chi-squared test or one-way ANOVA. For time-to-event data, Kaplan-Meier estimates were used for all endpoint analysis. Kaplan-
Meier estimates were compared using the log-rank test. Follow-up was censored at the last known date of follow-up, or at 12 months, whichever came first. All primary and secondary endpoints were evaluated in the unselected patient population, which consisted of all patients who were enrolled after signing an informed consent and in whom placement of a COMBO stent was attempted. P-values <0.05 were considered statistically significant. Statistical analyses were performed using SPSS version 23.0 (Chicago, IL, USA).

RESULTS

Baseline and procedural characteristics

The ACS-patients group consists of 498 (49.8%) patients, elective patients were 500 (50.0%). Indication for PCI was unknown in two patients (0.2%). These patients were excluded from the analyses. Baseline and procedural characteristics are presented in Table 1. Patients treated for SA had more co-morbidities, such as diabetes mellitus, hypertension, hypercholesterolemia and a family history of CAD. The number of current smokers was higher in the ACS-patients (29.3% versus 19.0%, p=0.002). Prior MI (16.1% versus 34.6%, p<0.001) or prior PCI (17.3% versus 43.0%, p<0.001) were more frequent in SA patients. Patients presenting with STEMI had the least comorbidities, compared with NSTEMI an UA patients. A greater proportion of patients with UA had prior MI or PCI compared to patients with NSTEMI or STEMI.

Number of treated lesion was 600 in ACS-patients and 652 in SA patients. Treatment of the left main coronary artery was higher in SA patients (2.8% versus 0.3%, p<0.001). Within the ACS-group, there were more type A lesions in unstable angina subgroup (p<0.001) and more type C lesions in the STEMI subgroup (p<0.001). Device success was lower in ACS-patients (97.1% versus 98.8%, p=0.05), but did not differ significantly within the ACS-group between STEMI, NSTEMI and unstable angina.

Clinical outcomes

Clinical endpoints are illustrated in Figure 1 and 2, and in Table 2 Kaplan-Meier estimates are presented. The primary endpoint of TLF was 7.1% in ACS-patients (N=35) compared to 4.4% (N=22) in SA patients, p=0.07. Cardiac death occurred in 2.0% of ACS-patients and in 1.4% of SA patients (p=0.44), TV-MI 1.0% in ACS versus 0.4% in SA, p=0.25. Target lesion revascularization was numerically higher in ACS of 5.5% versus 3.2%, p=0.08. Five stent thromboses cases were observed in the ACS group (1.0%), one in elective patients (0.2%), p=0.10. All stent thromboses occurred early (within 9 days).
Table 1. Baseline and procedural characteristics

<table>
<thead>
<tr>
<th></th>
<th>SA (n=500)</th>
<th>ACS (n=498)</th>
<th>p=</th>
<th>STEMI (n=199)</th>
<th>NSTEMI (n=190)</th>
<th>UA (n=109)</th>
<th>p=</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y (SD)</td>
<td>65.9 ±10.1</td>
<td>64.7 ±11.9</td>
<td>0.090</td>
<td>63.1 ±12.1</td>
<td>65.3 ±13.0</td>
<td>66.2 ±11.0</td>
<td>0.056</td>
</tr>
<tr>
<td>Sex, male n (%)</td>
<td>365 (73.3)</td>
<td>372 (74.4)</td>
<td>0.719</td>
<td>135 (75.8)</td>
<td>132 (69.5)</td>
<td>34 (81.0)</td>
<td>0.316</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>23.9 ±4.0</td>
<td>24.5 ±4.0</td>
<td>0.815</td>
<td>23.9 ±3.8</td>
<td>24.1 ±4.5</td>
<td>23.6 ±3.7</td>
<td>0.512</td>
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<td>History of Diabetes Mellitus</td>
<td>106 (21.2)</td>
<td>78 (15.7)</td>
<td>0.001</td>
<td>22 (11.1)</td>
<td>32 (16.8)</td>
<td>24 (22.0)</td>
<td>0.018</td>
</tr>
<tr>
<td>History of hypertension</td>
<td>346 (69.2)</td>
<td>233 (46.8)</td>
<td>&lt;0.001</td>
<td>73 (36.7)</td>
<td>104 (54.7)</td>
<td>56 (51.4)</td>
<td>0.001</td>
</tr>
<tr>
<td>History of hypercholesterolemia</td>
<td>351 (70.2)</td>
<td>210 (42.2)</td>
<td>&lt;0.001</td>
<td>69 (34.7)</td>
<td>86 (45.3)</td>
<td>55 (50.5)</td>
<td>0.007</td>
</tr>
<tr>
<td>Family history of CAD</td>
<td>229 (58.1)</td>
<td>224 (50.3)</td>
<td>0.014</td>
<td>82 (41.2)</td>
<td>92 (48.4)</td>
<td>50 (45.9)</td>
<td>0.084</td>
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<td>Current smoker</td>
<td>95 (19.0)</td>
<td>146 (29.3)</td>
<td>0.002</td>
<td>61 (30.7)</td>
<td>60 (31.6)</td>
<td>25 (22.9)</td>
<td>0.334</td>
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<td>Prior myocardial infarction</td>
<td>173 (34.6)</td>
<td>80 (16.1)</td>
<td>&lt;0.001</td>
<td>19 (9.5)</td>
<td>38 (20.0)</td>
<td>23 (21.1)</td>
<td>0.017</td>
</tr>
<tr>
<td>Prior percutaneous coronary intervention</td>
<td>215 (43.0)</td>
<td>86 (17.3)</td>
<td>&lt;0.001</td>
<td>22 (11.1)</td>
<td>30 (15.8)</td>
<td>34 (31.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>41 (8.2)</td>
<td>27 (5.4)</td>
<td>0.084</td>
<td>3 (1.5)</td>
<td>11 (5.8)</td>
<td>13 (11.9)</td>
<td>0.001</td>
</tr>
<tr>
<td>Number of treated lesions</td>
<td>652</td>
<td>600</td>
<td></td>
<td>223</td>
<td>234</td>
<td>143</td>
<td></td>
</tr>
<tr>
<td>Pre-procedure reference vessel diameter, mm</td>
<td>3.2 ±0.5</td>
<td>3.2 ±0.5</td>
<td>0.041</td>
<td>3.2 ±0.5</td>
<td>3.1 ±0.5</td>
<td>3.1 ±0.4</td>
<td>0.174</td>
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<tr>
<td>Stent length, mm</td>
<td>21.8 ±11.7</td>
<td>21.2 ±9.3</td>
<td>0.349</td>
<td>22.1 ±8.4</td>
<td>21.2 ±10.5</td>
<td>19.2 ±8.4</td>
<td>0.030</td>
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<tr>
<td>Location of lesion</td>
<td>0.008</td>
<td>0.075</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>RCA</td>
<td>177 (27.1)</td>
<td>185 (30.8)</td>
<td></td>
<td>81 (36.3)</td>
<td>65 (27.8)</td>
<td>39 (27.3)</td>
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<tr>
<td>LAD</td>
<td>294 (45.1)</td>
<td>256 (42.7)</td>
<td></td>
<td>100 (44.8)</td>
<td>93 (39.7)</td>
<td>63 (44.0)</td>
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<tr>
<td>LCX</td>
<td>152 (23.3)</td>
<td>144 (24.0)</td>
<td></td>
<td>40 (17.9)</td>
<td>68 (29.1)</td>
<td>36 (25.2)</td>
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<tr>
<td>LMCA</td>
<td>19 (2.8)</td>
<td>2 (0.3)</td>
<td></td>
<td>0 (0.0)</td>
<td>1 (0.4)</td>
<td>1 (0.7)</td>
<td></td>
</tr>
<tr>
<td>Graft</td>
<td>13 (2.2)</td>
<td>13 (1.7)</td>
<td></td>
<td>2 (0.9)</td>
<td>7 (3.0)</td>
<td>4 (2.8)</td>
<td></td>
</tr>
<tr>
<td>AHA/ACC lesion classification</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>A</td>
<td>101 (17.7)</td>
<td>97 (15.5)</td>
<td></td>
<td>25 (11.6)</td>
<td>37 (16.9)</td>
<td>39 (28.7)</td>
<td></td>
</tr>
<tr>
<td>B1</td>
<td>132 (23.2)</td>
<td>170 (27.1)</td>
<td></td>
<td>35 (16.3)</td>
<td>62 (28.3)</td>
<td>35 (25.7)</td>
<td></td>
</tr>
<tr>
<td>B2</td>
<td>171 (30.0)</td>
<td>268 (42.9)</td>
<td></td>
<td>59 (27.4)</td>
<td>66 (30.1)</td>
<td>46 (33.8)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>166 (29.1)</td>
<td>91 (14.5)</td>
<td></td>
<td>96 (44.7)</td>
<td>54 (24.7)</td>
<td>16 (11.8)</td>
<td></td>
</tr>
<tr>
<td>Device success</td>
<td>480 (98.8)</td>
<td>462 (97.1)</td>
<td>0.051</td>
<td>179 (95.7)</td>
<td>179 (97.3)</td>
<td>104 (99.0)</td>
<td>0.265</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>p=</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary endpoint: TLF</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac death</td>
<td>7 (1.4)</td>
<td>10 (2.0)</td>
<td>0.444</td>
<td>4 (2.0)</td>
<td>5 (2.7)</td>
<td>1 (0.9)</td>
<td>0.604</td>
</tr>
<tr>
<td>Target vessel MI</td>
<td>2 (0.4)</td>
<td>5 (1.0)</td>
<td>0.249</td>
<td>2 (1.0)</td>
<td>3 (1.7)</td>
<td>0 (0.0)</td>
<td>0.425</td>
</tr>
<tr>
<td>TLR</td>
<td>16 (3.2)</td>
<td>27 (5.5)</td>
<td>0.076</td>
<td>9 (4.5)</td>
<td>16 (8.6)</td>
<td>2 (1.9)</td>
<td>0.044</td>
</tr>
<tr>
<td>PCI</td>
<td>13 (2.6)</td>
<td>21 (4.3)</td>
<td>0.147</td>
<td>7 (3.5)</td>
<td>13 (7.0)</td>
<td>1 (1.0)</td>
<td>0.044</td>
</tr>
<tr>
<td>CABG</td>
<td>4 (0.8)</td>
<td>6 (1.2)</td>
<td>0.505</td>
<td>2 (1.0)</td>
<td>3 (1.7)</td>
<td>1 (1.0)</td>
<td>0.829</td>
</tr>
<tr>
<td>TVF</td>
<td>26 (5.2)</td>
<td>36 (7.3)</td>
<td>0.168</td>
<td>14 (7.0)</td>
<td>19 (10.1)</td>
<td>3 (2.8)</td>
<td>0.073</td>
</tr>
<tr>
<td>TVR</td>
<td>20 (4.0)</td>
<td>28 (5.7)</td>
<td>0.212</td>
<td>10 (5.1)</td>
<td>16 (8.6)</td>
<td>2 (1.9)</td>
<td>0.057</td>
</tr>
<tr>
<td>Stent thrombosis*</td>
<td>1 (0.2)</td>
<td>5 (1.0)</td>
<td>0.100</td>
<td>4 (2.0)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>0.169</td>
</tr>
</tbody>
</table>

Of the 498 patients with ACS, a total of 199 (40.0%) patients presented with STEMI, 190 (38.2%) patients with NSTEMI and a 109 (21.9%) patients had a PCI for UA. The occurrence of TLF in STEMI, NSTEMI and UA is shown in Figure 2. TLF at twelve months follow-up was 6.5% in STEMI patients (N=13), 10.1% in NSTEMI (N=19) and 2.8% in unstable angina (n=3), p=0.06. The difference in TLF was driven by a higher TLR in the NSTEMI patient group (8.6%) compared with 4.5% in STEMI and 1.9% in unstable angina, p=0.04. Cardiac death was 2.7% in NSTEMI patients, 2.0% in STEMI patients and 0.9% in unstable angina patients, p=0.06.

**DAPT duration**

Mean duration of DAPT for ACS-patients was 333± 90 days, median of 365 days (range 0-365days). Mean duration of DAPT for stable patients was 335± 88 days with median of 365 days (range 0-365days). Stent thrombosis (definite and probable) did not occur after DAPT cessation within 12 months follow-up in either patient groups.

![Figure 1](image.png)

**Figure 1** Comparison of target lesion failure in ACS and elective patients by cumulative event rate by Kaplan-Meier method.
DISCUSSION

Main findings
This is the first study evaluating clinical outcomes in ACS and SA patients treated with the dual-therapy COMBO stent. This pre-specified subgroup analysis of the REMEDEE registry patients yields three main findings. First, there was a numerically, but non-significant higher number of patients with TLF in the ACS arm compared to the SA arm. Second, at 12 months follow-up we observed no late stent thrombosis in both the ACS and the SA group and early stent thrombosis only in 1.0% and 0.2% respectively. Third, patients with NSTEMI had the highest rate of TLF, which was driven by a significant higher rate of TLR in this group.
Clinical outcome after PCI in ACS-patients

Comparison of these results with historical ACS stent studies should be done with caution, since studies report different end points of various indication groups at numerous time points. Nonetheless, recent stent studies continue to show higher adverse events in ACS compared to patients with SA \((^{16,17})\). Similar clinical outcomes as our outcomes have been reported in SORT OUT III ACS substudy, with the primary endpoint of major adverse cardiac events (MACE) in ACS-patients at one year of 9.7\% in zotarolimus-eluting stent treatment, compared to 5.0\% with sirolimus-eluting stent treatment (SES) \((^{18})\). The SORT OUT IV substudy evaluated clinical outcome in ACS-patients at 18 months follow-up, MACE was 7.3\% with the everolimus-eluting stent (EES) and 8.9\% with SES \((^{19})\). In comparison with the clinical outcomes of ACS patients treated with first generation SES, the sirolimus eluting COMBO stent shows improved results. In a study evaluating long term safety and efficacy of first generation SES, BMS and second generation EES in ACS patients, first generation SES showed a high 30-day MACE rate of 8.0\% and definite and probable ST rate of 5.1\%, at 3 year follow-up MACE rate was 34.6\% and definite and probable ST was 7.5\%.\(^{20}\)

However baseline characteristics and risk profile of stable and unstable patients are very different and therefore these results are only hypothesis-generating. In our subgroup analysis of patients with diabetes mellitus (DM) we conducted a multivariable analysis with DM, female sex, advanced age \((\geq 65\text{ years})\), smoking, hypertension, hypercholesterolemia, chronic kidney disease (CKD), peripheral vascular disease, previous stroke and ACS. \(^{21}\) DM, CKD and hypertension were the only predictors of higher TLF (DM: HR = 2.96, 95\% CI: 1.58–5.53 \(p = 0.001\), CKD: HR = 2.91, 95\% CI: 1.29–6.60 \(p = 0.010\) and hypertension: HR = 0.51, 95\% CI: 0.27–0.95 \(p = 0.036\)).

Stent thrombosis

The luminal anti-CD34 antibody layer of the COMBO stent is designed to promote vessel healing. Importantly, in this study we did not see any stent thrombosis after nine days post COMBO placement within 12 months follow up, even in patients who discontinued DAPT. This finding supports the hypothesis of early healing due to the dual-strategy therapy. Acute and early stent thrombosis, as occurred in our study, usually results from mechanical complications such as plaque protrusion, strut-malapposition or dissection unrelated to stent type.
A pooled analysis from the SPIRIT and COMPARE trials demonstrated in a non-randomized comparison of 2381 ACS-patients 0.7% stent thrombosis at two-year follow-up for everolimus-eluting stents and 2.9% for paclitaxel-eluting stents. Important to note is that baseline characteristics between both groups were dissimilar and no adjustment for difference in presenting diagnosis (UA, NSTEMI and STEMI) was done (4).

According to a recent meta-analysis, the bioresorbable vascular scaffold (BVS) (Abbott Vascular) is associated in with a 67% increase in relative risk for stent thrombosis compared to DES (22). Absolute rate of definite and probable stent thrombosis at one year follow-up in ACS-patients treated with the BVS varies between 0.8%-2.6% (22,16,23,24).

**Presenting diagnosis/high risk patient population**

Literature is not conclusive on prognosis after PCI for different indications (9). However, our findings are in line with a previous publication of our group presenting inferior survival rates in the first months after PCI in ACS-patients (25). Our results are confirmed by the prospective NOBORI-2 study that showed a higher long-term cardiac death and MACE in patients following PCI for NSTEMI in comparison with STEMI patients. They report outcomes similar to our results (26). Our results report a higher cardiac death in NSTEMI, but more notable was our observation of a significantly higher TLR in NSTEMI patients, which can partially be explained by the higher number of insulin requiring diabetic mellitus patients. However, these new finding should be explored in randomized trials evaluating novel stent technologies in ACS-patients.

**Future perspectives**

Randomized trials on the performance of the COMBO stent are ongoing. The HARMONEE, Japan-USA Harmonized Assessment by Randomized, Multi-Center Study of OrbusNEich’s Combo StEnt, trial will evaluate clinical outcomes at 12 months of the COMBO stent with the Everolimus Eluting, Xience, stent (Abbott Vascular, Japan). Enrolment of patients in this study has been completed. The randomized (REDUCE) study has completed enrolment (May 2016) and evaluates the safety of 3 months versus 12 months dual-antiplatelet therapy in ACS-patients, treated with the COMBO stent.

In this era, a ‘tailor made’ selected stent strategy according to patient’s individual clinical and anatomic background will be preferred (27). The choice for the COMBO stent in ACS-patients appears safe and effective.
**Limitations**

All limitations following a registry design are applicable to our study. However, this is the first insight into the clinical performance of the COMBO stent in unselected ACS-patients compared to stable angina patients. The REMEDEE Registry is a real-world registry that included high risk patients, allowing a realistic perspective on clinical outcomes after new device technology.

**CONCLUSION**

The novel dual therapy COMBO stent is a pro-healing stent that shows good clinical results in ACS-patients. This device is safe and feasible in patients presenting with acute coronary syndrome, with low stent thrombosis.

**Acknowledgments**

We would like to acknowledge all people contributing to this registry. In particular we would like to thank all patients for their participation, all interventional cardiologists and catheterization laboratory nurses for patient enrollment and data collection.

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**Conflict of interest statement**

The authors have no conflicts of interest to declare.
REFERENCES


