TCT-404
Risk of Stroke of Percutaneous Coronary Intervention in Patients with Stable Coronary Artery Disease: a Systematic Review and Meta-analysis of Contemporary Randomized Clinical Trials

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BACKGROUND Stroke is a rare but serious adverse event associated to PCI. However, the relative risk of stroke between stable patients undergoing a direct PCI strategy and those undergoing OMT has not been established yet.

METHODS We performed a meta-analysis of 6 contemporary randomized control trials in which 5673 patients with SCAD were randomized to initial PCI or OMT. Only trials with stent utilization more than 50% were included. Study endpoint was the rate of stroke during follow up.

RESULTS Mean age of patients ranged from 60 to 65 years and stent utilization ranged from 72% to 100%. Rate of stroke was 2.0% at a weighted mean follow up of 55.3 months. On pooled analysis, the risk of stroke was similar between patients undergoing a PCI plus OMT and those receiving only OMT (2.2% vs. 1.8%, OR on fixed effect = 1.24 95% CI: 0.85-1.79). There was no heterogeneity among the studies (I2 = 0.0%, P = 0.19). On sensitivity analysis after removing each individual study the pooled effect estimate remains unchanged.

Table 1. Characteristics of Included Trials

<table>
<thead>
<tr>
<th>Trial name or description</th>
<th>Year of enrollment</th>
<th>Year of publication</th>
<th>Design of the trial</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Primary endpoint</th>
<th>Number of patients</th>
<th>Definition of OMT</th>
<th>Stent rate (%)</th>
<th>Follow up (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BARI 2D</td>
<td>1991</td>
<td>2001</td>
<td>Single-center RCT</td>
<td>Angiographically documented CAD (≥70% stenosis) and documented ischemia by stress testing in unstable angina or stable angina (≥50% stenosis)</td>
<td>Acute MI, MI, unstable angina, LVEF &gt; 40%, previous PCI or CABG, single vessel disease, ULM fraction ≤ 50%</td>
<td>Composite death + cardiac arrest</td>
<td>1517</td>
<td>OMT</td>
<td>86</td>
<td>30/75</td>
</tr>
<tr>
<td>COURAGE</td>
<td>1997</td>
<td>2001</td>
<td>Single-center RCT</td>
<td>At least one major native coronary artery, epicardial coronary artery and supplying viable myocardium and eligible for PCI and FFR value &gt; 0.90</td>
<td>Aspirin, Beta-blockers, CCB, ACE-I, Angiotensin receptor blockers, CA, ARB</td>
<td>Composite death + cardiac arrest</td>
<td>2287</td>
<td>OMT</td>
<td>60</td>
<td>36/120</td>
</tr>
<tr>
<td>DEFER</td>
<td>2001</td>
<td>2004</td>
<td>Single-center RCT</td>
<td>Stable low-risk CAD (≥70% according to AHA classification or &lt; 60% on quantitative CA)</td>
<td>Acute MI, MI, unstable angina, LVEF &gt; 40%, previous PCI or CABG, single vessel disease, ULM fraction ≤ 50%</td>
<td>Composite death + cardiac arrest</td>
<td>1913</td>
<td>OMT</td>
<td>60</td>
<td>36/120</td>
</tr>
<tr>
<td>FAME 2</td>
<td>2010</td>
<td>2012</td>
<td>Multicenter RCT</td>
<td>Stable or unstable CAD and &lt; 2 vessel disease</td>
<td>Acute MI, MI, unstable angina, LVEF &gt; 40%, previous PCI or CABG, single vessel disease, ULM fraction ≤ 50%</td>
<td>Composite death + cardiac arrest</td>
<td>408 Nitrates 60</td>
<td>OMT</td>
<td>60</td>
<td>36/120</td>
</tr>
<tr>
<td>SAFE</td>
<td>2001</td>
<td>2004</td>
<td>Single-center RCT</td>
<td>Stable or unstable CAD, single vessel disease, ULM fraction ≤ 50%</td>
<td>Acute MI, MI, unstable angina, LVEF &gt; 40%, previous PCI or CABG, single vessel disease, ULM fraction ≤ 50%</td>
<td>Composite death + cardiac arrest</td>
<td>253</td>
<td>OMT</td>
<td>60</td>
<td>36/120</td>
</tr>
<tr>
<td>SWEET</td>
<td>2001</td>
<td>2004</td>
<td>Single-center RCT</td>
<td>Stable or unstable CAD and &lt; 2 vessel disease</td>
<td>Acute MI, MI, unstable angina, LVEF &gt; 40%, previous PCI or CABG, single vessel disease, ULM fraction ≤ 50%</td>
<td>Composite death + cardiac arrest</td>
<td>223</td>
<td>OMT</td>
<td>60</td>
<td>36/120</td>
</tr>
</tbody>
</table>

Abbreviations: ACE-I = angiotensin converting enzyme inhibitors; ACS = acute coronary syndrome; AHA = American Heart Association; ARB = angiotensin receptor blockers; CA = coronary angiography; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CCB = calcium channel blockers; CCS = Canadian cardiac society; DES = drug eluting stent; FFR = fractional flow reserve; LAD = left anterior descendent artery; LMA = left main artery; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; OMT = optical medical therapy; PCI = percutaneous coronary intervention; STEMI = ST elevation myocardial infarction.
CONCLUSIONS: In patients with SCAD an initial strategy based on a direct PCI is not associated with an increased risk of stroke during long-term follow-up compared to an initial strategy based on OMT alone.

CATEGORIES CORONARY: Angioplasty Overview and Outcomes

KEYWORDS: Optimal medical therapy, Percutaneous coronary intervention, Stable coronary artery disease

TCT-405
Comparative evaluation of outcomes in high-risk acute coronary syndrome and stable patients treated with biodegradable polymer drug eluting stent

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BACKGROUND: The use of DES to treat patients with high-risk acute coronary syndromes – HR-ACS (STEMI/NSTEMI) is increasing. However, controversies still exist related to their safety in this complex patient population. Therefore, the aim of this study was to analyse 1-year clinical outcomes of HR-ACS patients compared with stable patients (SP) presenting with stable angina or silent ischemia when treated with one type of DES.

METHODS: In the frame of large, prospective, single-arm, multicentre, observational e-NOBORI registry, total of 3449 HR-ACS patients and 5149 SP patients were treated with biodegradable polymer Nobori® DES. The primary endpoint of the study was target lesion failure (TLF) defined as composite of cardiac death (CD), target vessel related myocardial infarction (TV-MI) and target lesion revascularization (TLR). An independent clinical event committee adjudicated all endpoint related events.

RESULTS: Baseline characteristics revealed that patients with HR-ACS were younger (62.8±12.5 vs 63.5±12.0 years; p<0.01), were less frequently diagnosed with diabetes (29.0% vs 33.8%; p<0.01), hypertension (61.2% vs 77.5%; p<0.01), hyperlipidemia (54.1% vs 68.4%; p<0.01), peripheral vascular disease (6.4% vs 9.5%; p<0.01), but were more frequently current smokers (20.5% vs 36.4%; p<0.01). Additionally, fewer patients with HR-ACS had history of previous MI (18.0% vs 32.3%; p<0.01), previous PCI (16.0% vs 36.0%; p<0.01) and CABI (4.0% vs 7.9%; p<0.01). LAD was the most frequent target vessel in both groups (44.8% vs 42.9%; p=0.85). Radial access was the more frequent in both groups, but significantly higher in HR-ACS patients (64.9% vs 52.4%; p<0.01). B2 type lesions were more frequent finding in HR-ACS group (35.2% vs 31.6%; p<0.01) while C type was more frequent in SP group (21.0% vs 22.5%; p=0.04). As expected, thrombus burden was higher in HR-ACS group (26.5% vs 21.1%; p<0.01), while lesions were less frequently ostial (9.8% vs 12.0%; p<0.01), at bifurcation (5.0% vs 6.9%; p<0.01) and calcified (28.4% vs 33.4%; p<0.01). One year mortality of any or cardiac causes was significantly higher in HR-ACS group (2.6% vs 1.3% and 1.8% vs 0.9%; p<0.01 for both) who also had higher MI rate (1.8% vs 1.1%; p<0.01). The frequency of target lesion (1.6% vs 1.3%; p=0.24) and target vessel revascularization (2.1% vs 1.9%; p=0.47) showed no significant difference between the two groups. Composite rate of TLF (4.2% vs 3.0%; p<0.01), TVF (4.6% vs 3.4%; p<0.01) and definite and probable stent thrombosis (0.9% vs 0.4%; p<0.01), were all higher in HR-ACS group.

CONCLUSIONS: The rate of adverse events was low in both groups of patients in this all-comers, unselected patient groups, but as expected, was higher event rates occurred in HR-ACS patients. Based on our data the biodegradable polymer DES seems to be appropriate for both, high risk acute coronary syndromes and stable patients, providing very good safety and efficacy profile.

CATEGORIES CORONARY: Complex and Higher Risk Procedures for Indicated Patients (CHIP)

DRUG-ELUTING BALLOONS AND LOCAL DRUG DELIVERY

TCT-406
The Predictors of Instent Restenosis Again After Drug Eluting Balloon

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BACKGROUND: Percutaneous coronary intervention (PCI) with drug-eluting balloons (DEB) has emerged as an adjunctive treatment for instant restenosis lesion. When compared to drug-eluting stents (DES), DEBs offer advantages such as immediate and homogeneous drug release in the arterial wall, absence of polymers that can induce chronic inflammatory reactions. However, repeat restenosis still exist after DEB use. Our study aimed to find out the predictors of repeat instant restenosis after DEB use during one-year clinical follow-up.

METHODS: From November 2011 to May 2014, 246 patients were diagnosed as coronary artery in-stent restenosis in our hospital. Total 335 coronary in-stent restenosis lesions were treated by DEBs. We compared demographics, risk factors, lesion site, characteristic of coronary artery disease, previous stent and intravascular ultrasound (IVUS) use between one-year patient group and one-year repeat in-stent restenosis group. One-year coronary artery patent group was defined as negative non-invasive examination or no clinical symptoms. Univariate and multivariate logistic regression analyses were performed to identify predictors of repeat in-stent restenosis after DEB use.

RESULTS: The average age of the patients was 64.96±10.68 years, with a range of 29 to 91 years, and 77.2% of the patients were male. One-year repeat in-stent restenosis group had more favorable as non ST segment elevation myocardial infarction, less favorable as stable angina. One-year repeat in-stent restenosis group had higher percentage of co-morbidities such as hypertension, diabetes, old myocardial infarction, heart failure, prior coronary artery bypass grafting and end stage renal disease (ESRD) on maintenance hemodialysis. More ostial lesion (30.5% vs. 46.2%, p<0.02) and more left main bifurcation lesion (19.1% vs. 26.9%, p=0.434) were in one-year repeat in-stent restenosis group. Characteristics of coronary artery disease were similar between two groups and many patients had multiple vessel disease. Previous bare metal stent (BMS) use was dominant in one-year patent group (55%) and previous DES use was dominant in one-year repeat in-stent restenosis group (65.4%). IVUS use was higher in one-year patent group. Only one case had PCI related complication such as balloon-jailed side branch vessel in one-year patent group. Multivariate analysis revealed that only ESRD on maintenance hemodialysis and coronary ostial lesion were independent predictors of repeat in-stent restenosis after DEB use (p<0.034; p=0.016, respectively).