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Cost Effectiveness Of Everolimus-Eluting Stents Compared To First Generation Drug-Eluting Stents In Contemporary Clinical Practice

Robert Applegate[1], Matthew Sacrinty[1], Sanjay Gandhi[1], Michael Kutcher[1], Renato Santos[1], Timothy Smith[1], William Little[1]
[1]Wake Forest School of Medicine, Winston-Salem, NC

Background: Everolimus-eluting stents (EES) reduce adverse clinical outcomes compared to first generation drug-eluting stents (DES) and cost less. Whether EES demonstrate cost-effectiveness compared to DES within high risk patient subgroups is uncertain.
Methods: Percutaneous coronary intervention with EES (n=1,003) and 1st generation DES (n=992) were performed at a single center (Wake Forest Baptist Medical Center) between January 2007 and December 2010. One-year target lesion revascularization (TLR) incidence and costs in 2010 dollars were prospectively evaluated and compared within patient subgroups. Follow-up was >94% for both groups.
Results: Overall baseline characteristics were similar, except for higher use of EES for ST-elevation myocardial infarction. Clopidogrel use at 1 year was 88% EES vs. 91% DES (p=0.02). Overall, EES was associated with 1.1 less TLR events per 100 patients compared to DES. Aggregate 1-year costs were $765 less ($1,293 less to $197 less) with EES (p=0.005). EES demonstrated economic dominance (lower costs and TLR incidence) compared to DES in all patient subgroups (see Table).

Cost effectiveness results for patient subgroups

Subgroup	Aggregate Cost with EES, $	Aggregate Cost with DES, $	Δ EES-DES, $	Num TLRs Avoided per 100 pts	C/E Ratio $/TLR Avoided with EES	<$10,000 per TLR Avoided, %*	C/E Ratio $/QALY Gained	<$50,000 per QALY Gained, %*
All patients (N=1995)	5172	5937	−765	1.1	Dominant	98.6%	Dominant	95.5%
Males (n=1399)	4997	5942	−945	2.4	Dominant	99.2%	Dominant	97.7%
Females (n=596)	5625	5927	−303	0.6	Dominant	60.2%	Dominant	47.4%
Age ≥75 y (n=356)	4598	6020	−1421	4.1	Dominant	99.0%	Dominant	98.2%
Age <75 y (n=1639)	5288	5918	−630	1.3	Dominant	91.0%	Dominant	81.7%
Diabetics (n=655)	5462	6673	−1211	3.6	Dominant	97.7%	Dominant	94.3%
Non-diabetics (n=1340)	5032	5574	−542	0.9	Dominant	89.8%	Dominant	80.1%
ST-elevation MI (n=419)	4776	5303	−527	0.1	Dominant	45.0%	Dominant	57.6%
Non-ST-elevation ACS (n=1197)	5221	6065	−844	2.5	Dominant	98.5%	Dominant	93.6%
Off-label indications (n=1607)	5388	6218	−830	2.2	Dominant	98.4%	Dominant	95.9%
On-label indications (n=388)	4343	4681	−338	0.3	Dominant	55.1%	Dominant	49.7%

*Percentages based on 1,000 bootstrap resamplings. ACS indicates acute coronary syndrome; MI, myocardial infarction; QALY, quality adjusted life year; TLR, target lesion revascularization.

Conclusions: In this prospective observational registry EES was economically dominant compared to 1st generation DES in a variety of patient subgroups, including PCI for acute coronary syndrome and off-label indications.

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Final Three Year Results Following Resolute Zotarolimus-Eluting Stent Implantation in the RESOLUTE International Trial

Franz-Josef Neumann[1], Petr Widimsky[2], Jorge Belardi[3]
[1]Universitäts-Herzzentrum Freiburg - Bad Krozingen, Bad Krozingen, Germany, [2]Charles University, Prague, Czech Republic, [3]Instituto Cardiovascular de Buenos Aires, Buenos Aires, Argentina

Background: The RESOLUTE International (R-INT) trial has demonstrated the safety and effectiveness of the Resolute zotarolimus-eluting stent (R-ZES) through 2 years in a real-world population of patients with coronary artery disease requiring percutaneous coronary intervention (PCI). Concerns regarding long-term safety of drug-eluting stents, particularly in complex patients and lesions, require ongoing follow-up of clinical trials to confirm safety and effectiveness.
Methods: The R-INT observational trial prospectively enrolled 2349 patients at centers across Europe, Argentina, India, and South Africa to undergo PCI using the R-ZES. Minimal exclusion criteria assured a broad representation of real-world clinical practice. The primary endpoint was a composite of cardiac death and target-vessel myocardial infarction (CD/TV-MI). A key secondary endpoint was ARC definite and probable stent thrombosis. Dual antiplatelet therapy with aspirin and clopidogrel was recommended for 6 months and was prescribed thereafter at operator's discretion. Death, TV-MI, stent thrombosis, and target vessel revascularization (TVR) events were adjudicated using the same definitions and criteria as employed in the Global RESOLUTE Clinical Program.
Results: Two year follow-up was available for 2296 (97.7%) of patients enrolled. Baseline characteristics include 78% males, mean age of 63.5 years, with 20% presenting with acute MI and 26.1% with unstable angina; 30.5% of patients had diabetes mellitus. Two-thirds of the patients were considered complex based on clinical and lesion characteristics. At 2 years 43.9% of patients were receiving dual antiplatelet therapy. Two year clinical outcomes include 5.9% CD/TV-MI, 4.5% death, 4.9% target lesion revascularization, and 6.3% TVR. Very late definite and probable stent thrombosis was 0.1% for the period between 1to 2 years.
Conclusions: At 2 years after R-ZES implantation there is a very low rate of stent thrombosis and clinical event rates are consistent with 2 year results in 1121 patients treated with a R-ZES in the RESOLUTE All Comers trial. The final 3 year clinical follow-up of this large, observational study will be reported.

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A Novel Bioactive and Coating-Free Stent Surface Exhibits a Reduction in Neointimal Hyperplasia by Decreasing Platelet Aggregation and Promoting Endothelialization

Lynn Bailey[1], Adam Groothuis[1], Arik Zucker[2], Stefano Buzzi[2], Armin Mäder[2], Algirdas Ziogas[3], Vincent Milleret[3], Martin Ehrbar[3], Elazer Edelman[4]
[1]CBSET, Inc., Lexington, MA, [2]Qvanteq AG, Zurich, Switzerland, [3]University Hospital Zurich, Zurich, Switzerland, [4]Harvard-MIT Biomedical Engineering Center, Cambridge, Massachusetts

Background: Qvanteq has applied its novel coating-free bioactive surface technology onto bare metal stents (BMS).
Methods: In-Vivo: Integrity BMS, Qvanteq-treated Integrity stents (QBM), and Resolute DES were randomly implanted in a swine coronary artery model up to 90d with angiographic and histopathological assessments. In-Vitro: treated (QBM) and untreated CoCr disks were incubated with heparinized human blood for 2 hrs and the adherent blood components were investigated by immunofluorescence microscopy or SEM. Proliferation assays were performed using human aortic endothelial cells for up to 96 hrs.
Results: In-Vivo: Quantitative angiography demonstrated a reduction ($p<0.05$) of late lumen loss and percent stenosis in QBM compared to BMS at 30d and DES at 30 and 90d. Neointimal area was decreased ($p<0.05$) in QBM compared to BMS and DES. Light microscopy showed vascular injury, inflammation, and adventitial fibrosis of the QBM was reduced ($p<0.05$) compared to DES at 30d. Endothelialization was complete in the QBM and BMS groups and near complete in the DES group. Analogous results were obtained with treated Multi-Link and Omega stents compared to their untreated BMS and DES counterparts. In-Vitro: A 10-fold decrease in platelet adhesion and a 5-fold increase in neutrophil recruitment were observed on the QBM surface compared to the untreated surface. Proliferative endothelial cell assays at 2d were slightly higher for QBM (85.8%±3.2 coverage) compared to untreated surfaces (78.6%±11.2). At 4d cell growth was comparable with confluent cell coverage on both surfaces (≥95% coverage).
Conclusions: The QBM surface significantly reduced neointimal hyperplasia in swine coronaries compared to both BMS and DES, independently from stent design and/or alloy, without adverse vascular healing effects. In-Vitro data indicate that those results may be related to a significant reduction of adherent platelets combined with enhanced neutrophil adhesion, which promote reendothelialization and decrease neointimal hyperplasia by locally regulating acute inflammatory response and endothelial recovery. Therefore, this novel approach may be an effective alternative to DES in reducing clinical in-stent restenosis.

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Late Catch-up Restenosis of Drug Eluting Stents: Evidence from Comparison with Bare Metal Stents in Japanese CAD Patients

Yuki Horita[1], Masatoshi Ikeda[1], Isao Inoki[2], Masanobu Namura[1], Kenji Sakata[1], Hedenobu Terai[3]
[1]Kanazawa Cardiovascular Hospital, Kanazawa City, Ishikawa Prefecture, [2]Kanazawa Cardiovascyular Hospital, Kanazawa City, Ishikawa Prefecture, [3]Kanazawa Cardiovascular Hospital, Kanazawa city, Ishikawa Prefecture

Background: Although incidence of initial restenosis in coronary stenting lesions was dramatically decreased by use of drug-eluting stent (DES), few data exist regarding late catch-up restenosis of DES during long term follow-up in Japanese patients. Therefore, we clarified the efficacy of DES for restenosis in the initial and late catch-up in comparison with those of bare metal stent (BMS).
Methods: We analyzed 1478 lesions of BMS and 2959 of DES. DESs consisted of the 2091 sirolimus (SES; Cypher & Cypher-Select), 357 paclitaxel (PES; Taxus & Taxus-

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