was a composite of cardiovascular (CV) mortality and hospitalization for worsening HF.

Median follow-up was 22.9 months. There was an 18% relative risk reduction [RRR] (absolute risk reduction of 4.2%) for the primary endpoint in patients who received ivabradine (HR, 0.82; 95% CI, 0.75 to 0.90; p<0.0001; Figure 1). The beneficial effect of ivabradine was driven mainly by a 26% RRR in hospitalizations for HF (HR, 0.74; 95% CI, 0.66 to 0.83; p<0.0001). Results were consistent among subjects, except that subjects with baseline HR ≥77 bpm had a greater reduction in the primary endpoint with ivabradine (p=0.029; Figure 2).

Figure 1. Primary Endpoint: Cardiovascular Mortality/ Hospitalization for Worsening HF.

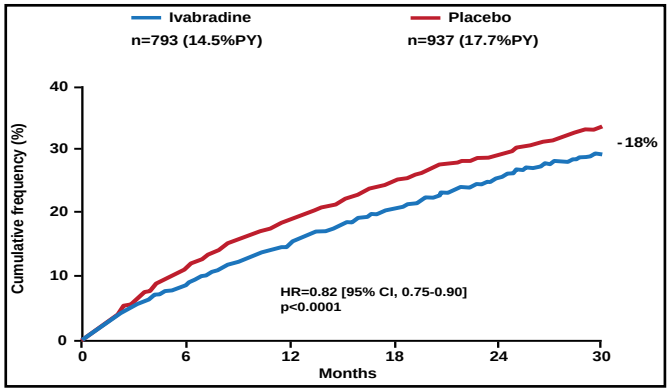

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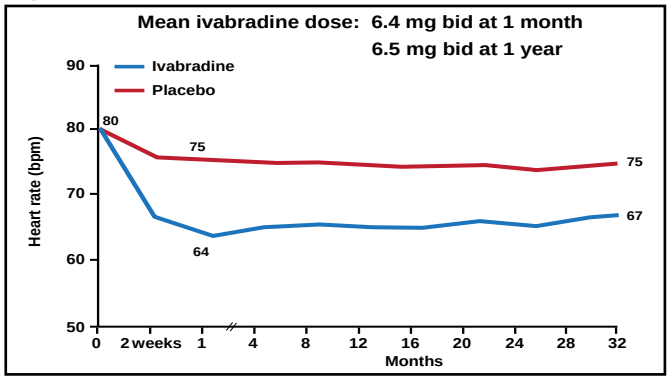
Figure 2. Mean Heart Rate Reduction.



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Deaths due to HF were significantly lower in subjects who received ivabradine versus placebo (HR, 0.74; 95% CI, 0.58 to 0.94; p=0.014). Although there were fewer CV (HR, 0.91; 95% CI, 0.80 to 1.03) and all-cause deaths (HR, 0.90; 95% CI, 0.80 to 1.02) in the ivabradine group, the differences were not significant (p=0.128 and p=0.092, respectively). There was a modest but significant (p=0.0003) improvement in NYHA class in the ivabradine group. Ivabradine was safe and well tolerated.

Bilateral Versus Single Internal Mammary CABG: One-Year Results from the ART Trial

The use of bilateral internal mammary artery (BIMA) grafting is safe according to one-year data from the Arterial Revascularization Trial (ART). David P Taggart, MD, PhD, Professor of Cardiovascular Medicine, University of Oxford and John Radcliffe Hospital, Oxford, UK, presented findings from the one-year analysis of ART, a large international, multicenter, randomized clinical trial of 3102 patients comparing the use of bilateral versus single internal mammary artery grafting in coronary artery bypass grafting (CABG) patients. The study is the largest randomized trial of two surgical procedures ever undertaken in cardiac surgery and is funded for 10 years to determine whether or not BIMA reduces long-term mortality and the need for repeat revascularization. One-year analyses focused on the safety and feasibility of this interventional approach.

For the overall study, the primary endpoint is survival at 10 years and the secondary endpoints include 30 day and cause specific mortality, the need for revascularization, clinical events, quality of life measures, and cost-effectiveness measures. Follow-up analysis at one year included 3069 patients who were randomized to either single internal mammary artery (SIMA) grafting (n=1540) or BIMA (n=1529). Patients were well-matched at baseline. The use of BIMA increased the mean surgery length by 23 minutes and the mean ventilation time by 105 minutes. Outcomes for the preliminary analysis included all-cause mortality, cerebrovascular accident (CVA), myocardial infarction (MI), revascularization, and wound reconstruction at 30 days and at one-year, excluding wound reconstruction for the one-year analysis.

Thirty day and one-year mortality did not increase with the use of BIMA. The rate of all-cause mortality at 30 days was 1.2% for both groups. The rate of CVA, MI, and revascularization at 30 days was also similar between the two groups (1.2% vs 1.0% for BIMA, 1.5% vs 1.4% for BIMA, and 0.4% vs 0.7% for BIMA, respectively). BIMA was associated with a slight increase in the risk of sternal wound reconstruction compared with SIMA (0.6% vs 1.9% for BIMA amounting to a difference of 1.3%). The rate of CVA, MI, and revascularization at one-year were similar for SIMA versus BIMA (1.8% vs 1.5%, 2.0% for both, and 1.3% vs 1.8%, respectively). The rate of all-cause mortality for BIMA was 2.5% compared with 2.3% for SIMA.

Preliminary results from ART are promising with regards to the safety and feasibility of BIMA compared with SIMA. Based on these preliminary data, BIMA appears to be safe

for use in CABG patients. Sub-group analyses investigating the effect of diabetes, age, on- versus off-pump, radial artery versus vein grafts, and ventricular function on outcomes will also be evaluated upon completion of the study. ART is expected to be completed in 2015 at which point long-term survival, quality of life, cost-effectiveness, and other analyses will be presented.

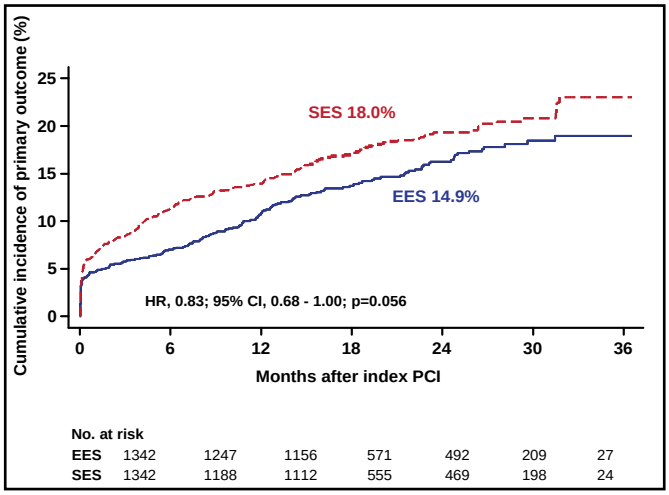
The Impact of EES Versus SES on Long-Term Clinical Outcome: Results from the LESSON-I Study

Long-term follow-up (up to 3 years) that compared everolimus-eluting (EES) and sirolimus-eluting stents (SES) for coronary revascularization revealed that the unrestricted use of EES was associated with lower risk of myocardial infarction (MI), target vessel revascularization (TVR), and stent thrombosis. The Long-term comparison of Everolimus-eluting and Sirolimus-eluting Stents for cOronary revascularizatioN (LESSON-I) data were presented by Stephan Windecker, MD, Bern University Hospital, Bern, Switzerland.

LESSON-I was a nonrandomized, observational study that included 3133 patients with stable angina and acute coronary syndromes who were undergoing percutaneous coronary intervention (PCI) at Bern University Hospital. After propensity score-matching, 2684 patients were included in the analysis (1342 matched pairs), with a median clinical follow-up of 1.3 years. Patients who were undergoing SES implantation prior to April 2003 and those who were previously included in the SIRTAX trial were excluded from this study. The primary endpoint was the patient-oriented composite of death, MI, and TVR through 3 years. The secondary endpoints included death, MI, TVR, TLR, cardiac death or MI, and stent thrombosis, according to the Academic Research Consortium (ARC). Patients who were treated with EES were more complex as compared with patients who were treated with SES. Multivessel treatment was performed in 24% of patients in the EES group (average number of stents was 2.0±1.1) and 16% of patients in the SES group (average number of stents was 1.8±0.9).

At 3 years, the rate of death, MI, or TVR was lower in the EES group than in the SES group (HR, 0.83; 95% CI, 0.68 to 1.00; p=0.056), while the rate of all-cause mortality was similar for both groups (Figure 1). The rates of MI and TVR at 3 years were significantly reduced in EES subjects as compared with SES recipients (3.3% vs 5.0% for MI; p=0.017 and 7.0% vs 9.6% for TVR; p=0.039 respectively). The incidence of definite stent thrombosis up to 3 years was lower in the EES group as well (0.5% vs 1.6% for SES; HR, 0.30; 95% CI, 0.12 to 0.75; p=0.01), and of note, not a single very late stent thrombosis occurred in the EES group. Prof. Windecker concluded that the differences in MI rates were driven by a 70% lower risk of QWMI and were present early but continued to increase during longer-term follow-up. The lower risk of MI in favor of EES was explained at least in part by the lower risk of definite stent thrombosis.

Figure 1. Primary Endpoint.



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The concept that EES was associated with lower rates of MI, partially owing to lower stent thrombosis risk, is interesting and may have clinical implications with regard to the duration of dual antiplatelet therapy. EES appears to be a safe and effective method for coronary revascularization in an all-comers population and may provide more favorable outcomes, particularly related to very late stent thrombosis, compared with SES. However, further investigation in the setting of a large-scale randomized clinical trial is needed in order to confirm these findings.

ATOLL Study Shows Intravenous Enoxaparin is Associated with Better Ischemic Outcomes in Primary PCI for STEMI than UHF

Although the study failed to meet its primary endpoint, results from the ATOLL study, presented by Gilles Montalescot, MD, Pitié-Salpétrière Hospital, Paris, France, indicate that the low-molecular-weight heparin enoxaparin may provide better clinical outcomes than unfractionated heparin (UFH) in ST-elevation myocardial infarction (STEMI) patients who are undergoing primary percutaneous coronary intervention (PCI).