Revascularization Outcomes

Monday, March 31, 2008, 10:00 a.m.-11:30 a.m.
McCormick Place, Room S106a

Long-term Clinical Outcome After Implantation of Drug-eluting Compared to Bare-metal Stents in a Real World Population: Three-Year Results of the BASKET Trial

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Background: As compared to bare-metal stents (BMS), drug-eluting stents (DES) have been shown to reduce restenosis and target vessel revascularization (TVR) in pivotal trials with selected patients and simple lesions up to five years. The initial enthusiasm was recently tamished by the findings of late and very late stent thrombosis after DES in real world registries and meta-analyses. The Basel Stent Kosteneffectivitaets Trial (BASKET) was the first prospective randomized trial demonstrating an increased rate of clinical thrombosis associated events after DES compared to BMS up to 18 months (BASKET-LATE). It is unknown, whether these differences are maintained during long-term follow-up.

Methods: A total of 826 patients treated by PCI/stenting within one year (May 05, 2003 and Jul 31, 2004) were included and randomized to one of two DES (Cypher®, n=264) or a cobalt-chromium-based BMS (Vision®, n=281). Excluded were only patients with in-stent-restenosis, vessel diameter >4mm or no consent. Patients were followed-up during 3 years for major adverse cardiac events, death, TVR, myocardial infarction and stent thrombosis. Patients were advised to stop dipyridamole after 6 months. The protocol did not allow control angiography without a clinical indication.

Results: The total population consisted of 79% men with an average age of 64±11 years presenting with stable angina in 42%, acute MI in 21% and unstable coronary syndromes in 36%. Patients had received 1.8±1.1 stents, with a total stent length of 54±20mm per patient. There were no significant differences between the 3 patient groups in any of these parameters. The clinical follow-up up to 3 years will be completed by end of June 2007 and the complete results including subgroup analyses will be available at the time of the ACC annual meeting 2008.

Conclusions: The 3 year clinical effectiveness findings from BASKET will demonstrate 1) whether there is an ongoing trend for an increased rate of late thrombosis associated events after DES compared to BMS and 2) if yes, whether these events outweigh the benefits of DES regarding the reduction of restenosis.

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Short-and Long-term Health Related Quality of Life and Anginal Status in Patients Treated for Multivessel Coronary Artery Disease: Insights Into the ARTS-II Trial

Ron T. van Domburg, Joost Daemen, Marie-Claude Morice, Bernard de Bruyne, Antonio Colombo, Carlos Macaya, Gert Richardt, Jan Fajadet, Christian Hamm, Keith D. Dawkins, Pascal Franchxl, Monique Schuijer, Kristel Wittebol, Magdaelen Pieters, Hans P. Stoll, Patrick W. Serruyts, Erasmus Medical Center, Rotterdam, The Netherlands

Background: To determine the health related quality of life (HRQL) following sirolimus-eluting stent (SES) (CYPHER®) implantation in patients with multivessel disease and to compare outcomes with the historical results of the two arms of the Arterial Revascularization Therapies Study (ARTS-II) trial using the same inclusion and exclusion criteria. Patients were stratified by clinical site to ensure that the participating rates varied from 100% at baseline to 93% at 12 months. The ARTS-II study is a 45 center, single-arm study. The HRQL outcomes were compared to the outcome of the historical cohorts of the randomized ARTS-I trial using the same inclusion and exclusion criteria. Patients were stratified by clinical site to ensure that at least 1/3 had 3-vessel disease to achieve a number of treated lesions per patient up to 180 per arm. There were no significant differences between the 3 patient groups in any of these parameters. The clinical follow-up up to 3 years will be completed by end of June 2007 and the complete results including subgroup analyses will be available at the time of the ACC annual meeting 2008.

Methods: A total of 826 patients treated by PCI/stenting within one year (May 05, 2003 and Jul 31, 2004) were included and randomized to one of two DES (Cypher®, n=264) or a cobalt-chromium-based BMS (Vision®, n=281). Excluded were only patients with in-stent-restenosis, vessel diameter >4mm or no consent. Patients were followed-up during 3 years for major adverse cardiac events, death, TVR, myocardial infarction and stent thrombosis. Patients were advised to stop dipyridamole after 6 months. The protocol did not allow control angiography without a clinical indication.

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Conclusions: The 3 year clinical effectiveness findings from BASKET will demonstrate 1) whether there is an ongoing trend for an increased rate of late thrombosis associated events after DES compared to BMS and 2) if yes, whether these events outweigh the benefits of DES regarding the reduction of restenosis.

Very Long-term Clinical Outcomes of the DESIRE (Drug Eluting Stents in the Real world) Registry

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Background: Drug-eluting stents (DES) have markedly reduced the need of repeat intervention in the treatment lesion of selected patients. However, very long-term efficacy and safety of these new devices for the treatment of “real-world” pts is still unclear.

Methods: The DESIRE registry is a non-randomized single-center registry with consecutive pts treated solely with DES between May 2002 and May 2007. The primary end point was long-term occurrence of MACCE and stent thrombosis (ST). Pts were clinically evaluated at 1, 3 and 6 months and then annually up to 5 years. ARC definition...
of ST was adopted.

**Results:** A total of 2,081 patients (2,864 lesions and 3,120 stents) were included. The mean age was 63 years with 29% of diabetics. Mean reference vessel diameter and lesion length were 2.76±0.47mm and 16.3±8.2mm respectively. Procedural success was achieved in 98.5% of the cases. Follow-up was obtained in 96.5% of the patients. In the long-term follow-up, TLR was performed in 3.3% of the patients. Q-wave MI occurred in only 0.7% of these patients and total ST rate was 1.6% (n=33) with 17 cases (51.5%) classified as definite. The figure shows the survival-free of MACE curve up to 5 years. Cox’s multivariate analysis showed treatment of acute myocardial infarction, lesion calcification, residual stenosis and stent length as independent predictors of ST.

**Conclusion:** The use of DES in an unselected population is associated with long-term safety and effectiveness with acceptable low rates of adverse clinical events.

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**Risk of Death or Emergency Cardiac Surgery in Contemporary Elective Percutaneous Coronary Interventions; Implications for Percutaneous Coronary Interventions Without Onsite Bypass Surgery**

Hitinder S. Gurm, Dean E. Smith, Eva Klite-Rogers, Share David, Michael O'Donnell, Richard McNamara, Mauro Moscucci, University of Michigan Medical Center, Ann Arbor, MI

**Background:** There is ongoing debate on the safety of elective percutaneous coronary intervention (PCI) without onsite surgical backup. There are, however, limited data on the frequency of need for emergency coronary artery bypass surgery (CABG) in contemporary elective PCI.

**Methods:** We evaluated the incidence and predictors of emergency CABG and mortality among patients undergoing elective PCI in a large regional consortium.

**Results:** Our cohort comprised of 53,940 patients who underwent elective PCI at 19 hospitals in Michigan between 1997 and 2006. A total of 143 (0.27%) patients needed emergency CABG while 97 (0.18%) died during the index hospitalization. The independent predictors of mortality were age > 80 years (OR 5.04), age 70-79 years (OR 3.07), female gender (OR 2.01), history of dialysis dependent renal failure (OR 3.68), history of prior CABG (OR 0.32), history of chronic obstructive pulmonary disease (OR 2.22), three vessel disease (OR 2.11), and intervention on three or more lesions (OR 2.86). The independent predictors of emergency CABG were prior history of CABG (OR 0.07), prior history of PCI (OR 0.56), three vessel disease (OR 2.96) and calcified lesion (OR 2.27). In patients with no prior history of coronary revascularization, the presence of coronary artery calcification and 3 vessel disease was associated with a 2.12% incidence of emergency CABG and a 1.16% mortality rate, when compared to an emergency CABG rate of 0.28% and a mortality rate of 0.1% in patients without these adverse angiographic characteristics.

**Conclusion:** The incidence of emergency CABG and in-hospital mortality in elective PCI is low but not insignificant. Adverse angiographic characteristics identify patients at extremely high risk of emergency CABG and in hospital mortality. These findings might have important implications in the selection of patients for elective PCI in centers without on site cardiac surgery.