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Impact of Sex on 3-Year Outcome After Percutaneous Coronary Intervention Using Bare-Metal and Drug-Eluting Stents in Previously Untreated Coronary Artery Disease

Insights From the RESEARCH (Rapamycin-Eluting Stent Evaluated at Rotterdam Cardiology Hospital) and T-SEARCH (Taxus-Stent Evaluated at Rotterdam Cardiology Hospital) Registries

Yoshinobu Onuma, MD, Neville Kukreja, MA, Joost Daemen, MD, Hector M. Garcia-Garcia, MD, MSc, Nieves Gonzalo, MD, Jin Ming Cheng, MSc, Piet Hein van Twisk, MSc, Ron van Domburg, MD, PhD Patrick W. Serruys, MD, PhD, on behalf of the Interventional Cardiologists of Thoraxcenter

Rotterdam, the Netherlands

Objectives We investigated the impact of sex on outcomes after percutaneous coronary intervention (PCI) with drug-eluting stent (DES).

Background Women have a higher risk of adverse outcomes after PCI than do men. However, long-term outcomes of women after contemporary PCI with DES have not been fully investigated.

Methods We performed a retrospective cohort study of 4,936 consecutive patients (28.2% women) who underwent PCIs between 2000 and 2004, before and after introduction of DES (bare-metal stent [BMS] group: n = 2,131, DES group: n = 2,805), to assess the impact of sex on long-term PCI outcomes and to compare outcome after PCI of women between the DES and BMS eras.

Results Compared with men, women undergoing PCIs were 5 years older and more frequently have comorbidities such as diabetes mellitus and hypertension. In patients treated throughout the BMS and DES eras, there were no differences by sex for risk of all-cause death, myocardial infarction, or target vessel revascularization 3 years after procedure. The procedural complexity was higher in the DES era, nevertheless, risk for target vessel revascularization and major adverse cardiac event at 3 years were significantly lower in women treated with DES than in women treated with BMS (adjusted hazard ratio [HR] for target vessel revascularization: 0.52 [95% confidence interval (CI): 0.36 to 0.75], adjusted HR for major adverse cardiac event: 0.63 [95% CI: 0.48 to 0.83]).

Conclusions Although women had worse baseline characteristics, no differences in 3-year outcomes were observed between men and women. Compared with BMS use, DES use has decreased revascularization rate equally in women and men. (J Am Coll Cardiol Intv 2009;2:603–10) © 2009 by the American College of Cardiology Foundation

From Thoraxcenter, Erasmus Medical Center, Rotterdam, the Netherlands.
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Coronary heart disease remains the leading cause of death among men and women in developed countries (1), and in Europe, around 25% of coronary revascularization is performed on women (2). In the early balloon angioplasty era, several studies found that female sex was an independent predictor of in-hospital mortality and that compared with men, women had lower rates of angiographic success, higher incidence of procedural complications and in-hospital death, and worse long-term outcomes after percutaneous

See page 611

coronary intervention (PCI) (3–5). In the bare-metal stent (BMS) era, sex-based differences in outcomes have decreased in patients undergoing PCI (6,7). In a large prospective registry study of 4,374 patients treated with BMS, women had lower rates of restenosis at 6-month angiographic follow-up compared with men, and women less frequently required target vessel revascularization (TVR) at 1 year: female sex was an independent predictor of freedom from restenosis (8). Furthermore, a recent study (9) performed in patients treated with BMS demonstrated that female sex conferred a long-term survival advantage after PCI despite the presence of higher risk characteristics.

Abbreviations and Acronyms

BMS = bare-metal stent(s)
DES = drug-eluting stent(s)
MACE = major adverse cardiac event
MI = myocardial infarction
PCI = percutaneous coronary intervention
PES = paclitaxel-eluting stent(s)
SES = sirolimus-eluting stent(s)
TIMI = Thrombolysis In Myocardial Infarction
TVR = target vessel revascularization

Clinical practice of PCI has changed since the introduction of the drug-eluting stent (DES) with a significantly lower rate of restenosis compared with BMS use (10). There is currently a paucity of published data available on the comparison of sex after PCI using DES. Pivotal trials of sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES) have included only a small number of women and were limited to patients with elective PCI and selective angiographic characteristics. In these low-risk populations, sex was not independently associated with adverse outcomes (11,12). Recently, using the National Heart, Lung, and Blood Institute (NHLBI) dynamic registry including high-risk patients, Abbott et al. (13) reported that adjusted 1-year outcomes in BMS and DES were independent of sex. However, the impact of sex on long-term outcome in unselected patients after PCI has not yet been fully investigated. Therefore, we performed an analysis using the RESEARCH (Rapamycin-Eluting Stent Evaluated at Rotterdam Cardiology Hospital) and T-SEARCH (Taxus-Stent Evaluated at Rotterdam Cardiology Hospital) registries' data to assess the impact of sex on long-term PCI outcomes and to compare outcome after PCI of women between the DES and BMS eras.

Methods

Study design and patient population. Between January 1, 2000, and December 31, 2004, 5,358 patients underwent PCI in our institution using BMS, SES, or PES. Initially, all patients were treated with BMS, but on April 16, 2002, our institution adopted the use of SES (Cypher, Cordis, Warren, New Jersey) as the default strategy for all coronary interventions, as part of the RESEARCH registry (14). On February 16, 2003, SES was replaced by PES (TAXUS, Boston Scientific, Natick, Massachusetts) as the default stent, as part of the T-SEARCH registry (15). The exclusion criteria were PCI for a lesion involving a previously implanted stent (n = 287) or patients receiving only BMS (n = 135) in the DES era, because of the unavailability of the adequate size of DES (Fig. 1). In total, 4,936 patients were included in the current study. We defined the BMS group as patients treated in a period before introduction of SES (January 2000 to April 2002, n = 2,131) and the DES group as those treated after introduction of SES (April 2002 to December 2004, n = 2,805).

Procedures and medications. All procedures were performed according to standard clinical guidelines at the time (14,15). During this period of study, primary PCI was the default strategy for all patients with ST-segment elevation myocardial infarction presenting within 6 h of symptom onset. The patients are transferred either directly by the ambulance service or by local emergency departments directly to our catheter laboratory. Angiographic success was

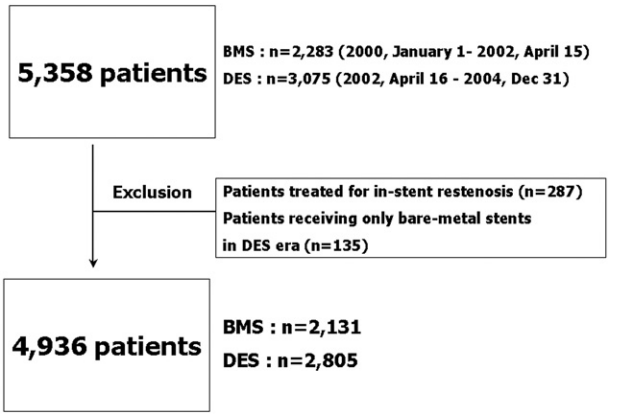

Figure 1. A Flowchart of Patient Selection

Out of 5,358 patients who underwent percutaneous intervention in a single center from 2000 to 2004, 4,936 patients were included in this analysis after exclusion of 422 patients. BMS = bare-metal stent(s); DES = drug-eluting stent(s).