薬剤溶出ステントに関する性特異的な情報

TAXUS WOMANスタディの結果、これらの女性患者はリスクが高かったにもかかわらず、薬剤溶出ステント植え込み後の臨床転帰は男性におけるそれと同等であったと報告された

TAXUS WOMAN study reports post-implantation clinical outcomes comparable with those for men despite the higher risk profiles of women patients

TAXUS II、IV、VおよびVIトライアル（TAXUS WOMANスタディ）の結果、パクリタキセル溶出ステントを植え込まれた女性はリスクプロファイルが不良であったにもかかわらず、臨床転帰は男性と同等であった、とESCで発表された。4つのトライアルに組み込まれた患者3,445人のうち955人（27.7%）が女性であった。これらの女性のうち480人が薬剤溶出ステントを植え込まれ475人がベアメタルステントを植え込まれていた。男性と比較し、女性はより高齢であり（平均年齢65.4歳対61.0歳）、対表面積が小さく、糖尿病および高血圧有病率が高く（それぞれ30.4%対21.0%、78.0%対65.1%）、血管径が小さかった（施術前対象血管径2.63mm対2.78mm）。しかし、1および3年後の血管形成術再施行率および主要な有害事象発現率は男女間で差はなかった。

Full Text

Gender-specific analysis of data from the TAXUS II, IV, V, and VI Trials (the TAXUS WOMAN study) suggests that women implanted with paclitaxel-eluting coronary stents have outcomes comparable with those of men despite having poorer risk profiles, according to a presentation at the annual meeting of the European Society of Cardiology.

"This study of data from the TAXUS trials offers encouraging news for women with coronary artery disease," said Ghada Mikhail, MD, Consultant Cardiologist, St Mary's Hospital Trust, London, UK. "Previous trials and registries have demonstrated a less favorable clinical outcome in women compared to men when undergoing coronary revascularization with bare-metal stents. That difference has been previously explained by the smaller vessels and higher risk profile seen in women. These data show, however, that the TAXUS paclitaxel-eluting coronary stent works equally well in women, maintaining its anti-restenotic efficacy advantages and positive safety profile relative to bare-metal stents."

The TAXUS II, IV, V and VI trials evaluated performance of the paclitaxel-eluting stent compared with a bare-metal stent control in patients with coronary artery disease. The TAXUS WOMAN study analyzed pooled results of the women enrolled in these TAXUS trials and compared them with the corresponding endpoints in men.

Of the 3,445 patients enrolled in the TAXUS trials between June 2001 and March 2004, 955 (27.7 percent) were women. Of these women, 480 received drug-eluting stents and 475 received base metal stents. Of the 2,490 men enrolled, 1,238 received drug-eluting stents and 1,252 received base metal stents.

Compared with men, women were older (mean age 65.4 +/- 10.9 years versus 61.0 +/- 10.4 years), had smaller body surface area (1.80 +/- 0.19m^2 versus 2.05 +/- 0.20m^2), had more diabetes (30.4 percent versus 21.0 percent), had more hypertension (78.0 percent versus 65.1 percent), had smaller vessels (pre-procedure reference vessel diameter 2.63 +/- 0.46mm versus 2.78 +/- 0.52mm), and had more history of coronary artery disease (62.2 percent versus 54.7 percent). There were no other significant differences in baseline demographics, lesion or procedural characteristics between the drug-eluting and bare metal stent groups in both genders.

Results show that the drug-eluting stent maintained its advantage in preventing repeat procedures compared to the bare-metal stent control, while showing no significant differences in outcomes based on gender. At one year, the unadjusted rate of target lesion revascularization drug-eluting stent group was 8.1 percent in women versus 6.7 percent in men, while in the bare metal stent group, the unadjusted revascularization rate at one year was 17.5 percent in women versus 16.4 percent in men. At three years, there were continued low revascularization rates in both women and men treated with drug-eluting stents (10.7 percent in women versus 8.8 percent in men, with no difference between men and women).

Comparable results in safety outcomes were seen for women, showing no differences in major adverse cardiac event rates at one year. Adverse event rates in the drug-eluting stent group were 15.6 percent for women versus 13.2 percent for men, while the rate in the bare metal stent group were 24.0 percent for women versus 21.7 percent for men.

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