"Real world"スタディの結果、薬剤溶出ステントは安全で有効であることが示された

レジストリのデータから高齢者における薬剤溶出ステントの死亡率に対する有益性が示された

Registry data suggests mortality benefit for drug-eluting stents in elderly

「現実の世界（Real world）」の患者に対するステント留置術を評価した過去最大のスタディの結果、薬剤溶出ステントはベアメタルステントと比較し、重篤な心血管疾患予防の点で優れ、安全性は同等であることが確認されたとのレイトブレイキングクリニカルトライアルの結果が2009年第58回American College of Cardiology学会i2サミットにて発表され、同時にJournal of the American College of Cardiologyオンライン版に掲載された。研究者らは、米国心血管疾患データレジストリ（National Cardiovascular Data Registry）およびMedicare proceduralレジストリの2004～2006年に血行再建術を施行された患者のデータを解析した。そのうち217,675人が薬剤溶出ステントで治療され、45,025人がベアメタルステントで治療を受けた。年齢中央値は薬剤溶出ステント群で74.5歳でありベアメタルステント群で75.3歳であった。30ヵ月間の経過観察期間中の死亡率、非致死性心筋梗塞発症率および血行再建術再施行率は薬剤溶出ステントを使用された患者においてベアメタルステントを使用された患者よりも有意に低かった（ハザード比[HR]はそれぞれ0.75、0.76、0.91）。脳卒中および重大な出血は基本的に差がなかった（HRはそれぞれ0.96および0.91）。さらに、STEMIおよびnon-STEMIに関する長期のハザード比は薬剤溶出ステントの方に良好な値が認められた。

Full Text

The largest-ever study to evaluate stenting in "real-world" patients has confirmed that drug-eluting stents are better than bare-metal stents at protecting patients against serious cardiovascular illness, and are equally safe, according to research presented during the i2 Summit at the American College of Cardiology's 58th annual scientific session.

The study found that during three years of follow-up, drug-eluting stents significantly reduced the risk of myocardial infarction, death and additional heart procedures when compared to bare-metal stents, while provoking no increased risk of stroke or major bleeding.

"Some previous studies have suggested that drug-eluting stents are associated with an excess long-term death rate, whereas others have not," said Pamela S. Douglas, M.D., Geller professor of medicine at Duke University. "The biggest take home message of our study is: Drug-eluting stents are safe."

Several randomized controlled trials have shown that drug-eluting stents are better than bare- metal stents at keeping the coronary artery from constricting with scar tissue, but their findings on long-term safety have been inconsistent. Equally important, randomized controlled trials are very selective about the types of patients they enroll.

"Few patients who currently require stenting would be considered eligible for a randomized controlled trial - only about 20 percent in our population," Douglas said. "Real-world data are required to assess stent safety and performance in the other 80 percent."

For the study, Dr. Douglas and her colleagues analyzed data from the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) on patients over the age of 65 who had a stenting procedure performed from 2004 to 2006. Of these, 217,675 were treated with drug-eluting stents and 45,025 were treated with bare-metal stents. Median age was 74.5 versus 75.3 years in the drug-eluting and bare metal stent groups, respectively. Follow-up information for each patient was obtained from Medicare claims data. The combination of these two data sets created a novel and powerful resource for assessment of post-marketing stent performance in a community setting.

Researchers adjusted the data for 102 patient characteristics such as sex, age and co-existing medical conditions. They found that patients who received drug-eluting stents had significantly lower rates of death (hazard ratio [HR], 0.75), nonfatal heart attack (HR, 0.76) and repeat heart procedures (HR, 0.91) when compared to patients who received bare-metal stents. In addition, there were essentially no differences in rates of stroke (HR, 0.96) or major bleeding (HR 0.91).

The investigators were not able to directly assess rates of stent thrombosis. However, data that Douglas characterized as "suggestive" showed that after one year, the type of heart attack that is associated with stent thrombosis (STEMI) was no more common with drug- eluting stents than bare-metal stents. In addition, the long-term hazard ratio favored drug-eluting stents for both STEMI and non-STEMI heart attacks.

This study was simultaneously published online in the Journal of the American College of Cardiology.

The study was funded by the Cardiovascular Consortium of the Agency for Healthcare Research and Quality (AHRQ), a federal agency in the Department of Health and Human Services, with additional support from ACC-NCDR.

"Today's findings provide important new evidence for decision-making by heart disease patients and their physicians," said AHRQ Director Carolyn M. Clancy, M.D. "These findings should help resolve many lingering questions regarding the safety of drug-eluting stents in recent years."

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