糖尿病患者において薬剤溶出ステントはベアメタルステントに勝る（LBCT, abstract＃5219）

糖尿病患者において薬剤溶出ステントはベアメタルステントと比較し予後を改善することが示された

Drug-eluting stents showed improved outcomes as compared with bare metal stents in diabetics

糖尿病患者において薬剤溶出ステントはベアメタルステントと比較し、血行再建術施行、心筋梗塞および死亡のリスクを低下させるとのLate-Breaking Clinical Trialの結果が、2008年American Heart Association学会で発表された。研究者らは国家の義務的な登録簿データを用いて、2003年4月から2004年9月にかけて米国の非連邦急性期病院で経皮的冠動脈インターベンション（PCI）を施行された患者5,051人を探し出した。これらの病院の糖尿病患者は薬剤溶出ステント（DES）を留置される割合がベアメタルステントを留置される割合よりも2倍多かった（66.1%対33.9%）。3年間の経過観察後、補正前のエンドポイントである死亡の累積はDES患者で14.4%であるのに対しBMS患者で22.2%であった。研究者らはその後、合併症や投与されている薬物などの63の可能性のある交絡因子を調整するため、患者の部分集団をマッチさせた。その結果、3年後のリスクで補正した死亡率はDES患者で17.5%、ベアメタルステントで20.7%であり、有害事象の増加を伴わない、小さいが有意な実質3.2%の死亡率の低下がDES患者において認められた。糖尿病患者における薬剤溶出ステント留置対ベアメタルステント留置（Drug-eluting and Bare Metal Stenting in Patients with Diabetes Mellitus）の結果：Mass-DAC Registryの結果は同時にAmerican Heart Association学会誌であるCirculationに掲載された。

Full Text

Drug-eluting stents reduced the risk of revascularization, myocardial infarction and death in diabetics as compared with bare-metal stents in the largest observational comparison, researchers reported at the American Heart Association's Scientific Sessions 2008. The results from The Drug-eluting and Bare Metal Stenting in Patients with Diabetes Mellitus: Results from the Mass-DAC Registry, were presented as a late-breaking clinical trial. The study is simultaneously published in Circulation: Journal of the American Heart Association.

"We actually saw a significant benefit from using drug-eluting stents in this patient population," said Laura Mauri, M.D., M.Sc., principal investigator of the study and assistant professor of medicine at Brigham and Women's Hospital and Harvard Medical School in Boston, Mass. "First, they significantly reduced the need for repeat procedures which included repeat stenting or bypass surgery. Second, they were associated with lower rates of death and heart attack. So, as a result we can say that these stents appear to be safe in diabetic patients, whose diabetes puts them at higher risk of mortality and heart attack than the general population."

In the largest population-based comparison of stents in diabetics, researchers used data from a mandatory state registry. They identified 5,051 diabetics who underwent PCI at acute-care, non-federal hospitals between April 2003 and September 2004. Diabetic patients at those hospitals were about twice as likely to get drug-eluting (DES) compared to bare-metal (BMS) stents (66.1 percent vs. 33.9 percent), researchers said.

At three years of follow-up, the unadjusted cumulative endpoint of death was 14.4 percent for DES patients compared to 22.2 percent for BMS patients, Mauri said.

The researchers then matched a subset of 1,476 DES and 1,476 BMS patients to control for 63 potential confounders such as concurrent conditions and medications. In that comparison, they found the risk-adjusted mortality at three years was 17.5 percent for DES patients vs. 20.7 percent, a small but significant 3.2 percent absolute reduction in mortality in DES patients, with no excess adverse events.

The choice of BMS or DES was not randomized, but was done at the direction of the treating physician, so it is possible that the patients given DES were different in the number of blood vessel or other characteristics.

Although three-year data were not yet available for rates of myocardial infarction and target vessel revascularization, at two years of follow-up those rates were lower in the DES group compared to the BMS group.

"Diabetic patients represent a large and growing proportion of patients who undergo stenting," Mauri said. "We know that patients with diabetes have a higher incidence of adverse events following the procedure, including higher rates of restenosis, heart attack and death related to heart problems."

"Previous studies indicated that drug-eluting stents reduce the rate of restenosis, but there has been controversy about their safety because of conflicting evidence from smaller studies."

Some of those studies found higher mortality associated with DES while others found no safety differences between the two types of stents. This study showed lower mortality and adverse events.

The Massachusetts Data Analysis Center (Mass-DAC) registry is a special resource to research outcomes after PCI, since the state department of public health requires that every non-federal hospital provide procedural information and outcomes for every adult who undergoes PCI. Such data are intended to monitor and to improve the quality of patient care.

"Through an effort headed by the Division of Health Care Quality at the Massachusetts Department of Public Health, we were able to use clinical data collected from every non-federal hospital in the state that treats patients with stents to monitor safety of the drug-eluting stents," said Sharon-Lise Normand, Ph.D., co-author of the study, director of the Mass-DAC and professor of health care policy (biostatistics) at Harvard Medical School and Harvard School of Public Health. "Surveillance systems such as this are critical to assessing quality and safety in the real-world."

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トピックス一覧

[News01]
ヘッドホンは植込み型心臓デバイスと干渉を起こす
（Abstract＃662/Poster C67[663/Poster C68, 651/Poster C56]）

[News02]
インフルエンザ予防接種は血栓を予防する（Abstract＃524）

[News03]
情動は心房細動に影響する
(Abstract＃1036)

[News04]
CRP、スタチン、および冠動脈リスク
(Late Breaking Clinical Trial [LBCT] , Abstract＃161)

[News05]
2型糖尿病患者に対する低用量アスピリンに関するトライアル(LBCT, abstract＃163)

[News06]
葉酸は安全ではあるが心保護作用はないことが示された(LBCT, abstract＃165)

[News07]
糖尿病患者において薬剤溶出ステントはベアメタルステントに勝る
(LBCT, abstract＃5219)

[News08]
個別に調整した薬物投与によりPCI後の有害事象が軽減する(LBCT, abstract＃1313)

[News09]
Cell-coatedステントは薬剤溶出ステントと同様に有効である(Abstract＃6000)

[News10]
新たな血液検査は救急治療室での心不全を見極める(LBCT, Abstract＃3324)

[News11]
心不全患者において運動は安全であり予後を改善する(LBCT, abstract＃3318)

[News12]
運動療法は心不全患者のQOLを向上する
(LBCT, abstract＃5219)

[News13]
心筋梗塞後の一部の患者においてはタイミングが重要である
(LBCT, abstract＃1313)

[News14]
糖尿病患者におけるアテロームの成長
(LBCT, abstract＃5221)

[News15]
家庭でのINRモニターはクリニックでのケアと同等に有効である
(LBCT, abstract＃5217)