シロリムス溶出ステントとステント内狭窄に対する近接照射療法

SISRトライアルの結果、シロリムス溶出ステントはベアメタルステント内血栓の患者に対し近接照射療法よりも優れていることが示唆された

SISR trial suggests sirolimus-eluting stents are superior to brachytherapy as treatment for patients with thrombosis in a bare metal stent

長期トライアルのデータから、シロリムス溶出ステントはベアメタルステント内血栓の患者に対し近接照射療法よりも優れていることが示唆された、とAmerican College of Cardiology学会で発表された。SISRトライアルにおいて384人の患者がベアメタルステント内血栓に対する血行再建術に対しステントまたは近接照射療法を施行される群に無作為に割り付けられた。3年後に、薬剤溶出ステントを留置された患者は近接照射療法を受けた患者と比較し、さらなる血行再建術を必要とする確率が有意に低かった（追加の施術を必要としなかった率はステント群で81%、近接照射療法群で71.6%であった）。死亡や心筋梗塞などの安全性のエンドポイントは両群間で有意差がなかった。Academic Research Consortiumの定義で「確実」または「かなり確か」とされた血栓再発率は両群間で差がなかった（ステント3.7%、近接照射2.6%）。

Full Text

A new analysis of long-term trial data suggests sirolimus-eluting stents are superior to brachytherapy as treatment for patients with thrombosis in a bare metal stent, according to a presentation at the annual meeting of the American College of Cardiology. The SISR trial had randomized 384 patients to stenting or brachytherapy for revascularization.

At three years, 81 percent of patients who received the stent had not required target lesion revascularization compared with 71.6 percent of patients receiving brachytherapy. Among patients who did require target vessel revascularization, the survival free rates were 78.2 percent for sirolimus-eluting stent and 68.8 percent for brachytherapy.

Stent thrombosis rates, defined as definite and probable per the Academic Research Consortium definitions, were not significantly different (3.7 percent for the stent versus 2.6 percent for brachytherapy).

Differences in three-year rates of target vessel failure (stent, 75.1 percent; brachytherapy, 67.9 percent) and major adverse cardiac events did not reach statistical significance, likely reflecting progression of coronary artery disease at sites other than the original location of bare metal stent restenosis. Rates f major adverse events were 75.5 percent for the stent and 70.5 percent for brachytherapy.

Patients who received the drug-eluting stent were significantly less likely to need target lesion revascularization at three years compared to patients who received brachytherapy. In addition, there were no significant differences in safety endpoints, such as the rates of death, myocardial infarction, or stent thrombosis between the two treatment arms of this study.

The original trial was designed for nine months of follow-up. This longer-term, follow-up analysis focused on pre-specified safety endpoints, namely death, myocardial infarction and stent thrombosis, as well as target lesion revascularization, an efficacy endpoint, to determine whether any new safety issues emerged and whether the major benefit of the drug-eluting stent, reduction in repeat revascularization procedures, was maintained.

"These data continue to favor the CYPHERR Stent compared to radiation therapy in these patients with complex coronary artery disease," said David R. Holmes Jr., MD, Principal Investigator and Professor of Medicine, The Mayo Clinic College of Medicine, Rochester, MN. "Neither treatment modality in this study was associated with any new safety issues or concerns."

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