小径冠動脈病変に対するバルーンとステントの比較 (Abstract 5167)

BASKET-SMALL 2：小径の新規冠動脈病変において、着脱可能なバルーンの成績は永久留置型ステントと同様である

BASKET-SMALL 2: Removable balloon is as good as permanent stent implant in small de novo coronary lesions

小径の新規冠動脈病変において、着脱可能なバルーンの成績は永久留置型ステントと同様である、とのBASKET-SMALL 2トライアルのレイトブレイキングの結果が ESC Congress 2018 で発表され、同時に *Lancet* に掲載された。12か月の時点で、主要心血管イベント（MACE）はステント群（7.5%）とバルーン群（7.6%）とで有意差がなかった（p=0.918）。心臓死、非致死性心筋梗塞、標的病変血行再建術、または大出血の発現率は、2群間で統計的有意差はなかった。

Full Text

A removable balloon is as good as a permanent stent implant for opening small de novo coronary lesions, according to late breaking results from the BASKET-SMALL 2 trial presented in a Hot Line Session at ESC Congress 2018 and simultaneously published in *The Lancet*.

Principal investigator Professor Raban Jeger, of the University Hospital Basel, Switzerland, said: "The results of this trial move us a step closer towards treating small blocked arteries without having to insert a permanent implant."

BASKET-SMALL 2 is the largest randomized trial to examine whether drug coated balloons are as good as drug-eluting stents for opening small de novo coronary lesions. The effectiveness of the two treatments was evaluated by comparing the rate of major adverse cardiac events (MACE) at 12 months.

Between 2012 and 2017 the trial enrolled 758 patients with a first-time lesion in an artery smaller than 3 mm in diameter. The average age of study participants was 68 years, 72% had stable coronary artery disease and 28% had an acute coronary syndrome (myocardial infarction [MI] or unstable angina).

Patients were randomized to receive drug coated balloon angioplasty (382 patients) or second-generation drug-eluting stent implantation (376 patients). The balloon was coated with iopromide and paclitaxel, and the stents were covered with everolimus or paclitaxel.

After the procedure, patients were followed-up for 12 months for the occurrence of MACE, which included death from cardiac causes, non-fatal MI, and the need for target vessel revascularization. Secondary endpoints included the single components of MACE at 12 months, and major bleeding at 12 months.

At 12 months, there was no difference in the rates of MACE between patients who received a stent (7.5%) and patients who underwent the balloon procedure (7.6%) (p=0.918). Professor Jeger said: "The BASKET-SMALL 2 trial met its primary endpoint of non-inferiority for major adverse cardiac events at 12 months. This is a long-awaited milestone in clinical evidence for the drug coated balloon technique, which so far has primarily been used for the treatment of in-stent restenosis."

There were no statistical differences between groups in the rates of the individual components of the primary endpoint at 12 months: rates of cardiac death were 3.1% versus 1.3% (p=0.113), rates of nonfatal heart attack were 1.6% versus 3.5% (p=0.112), and rates of target vessel revascularization were 3.4% versus 4.5% (p=0.438) in the balloon versus stent groups, respectively. The rate of major bleeding at 12 months was similar in the balloon (1.1%) and stent (2.4%) groups (p=0.183).

"The potential benefits of a stent-free option to treat small blocked arteries are numerous," said Professor Jeger. "With no permanent implant left after the procedure, the problem of tissue growth and clot formation within the stent is eliminated. In addition, there may be no need for prolonged treatment with anticlotting medicines, which has been controversial since it increases the risk of bleeding."

He concluded: "Drug coated balloon angioplasty has the possibility to become the standard treatment for small blocked arteries. We will continue to monitor patients in the trial for a further two years for major adverse cardiac events, stent thrombosis, and bleeding."

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Conference News