Kantonsspital St.Gallen

Drug-coated balloons for small coronary artery disease (BASKET-SMALL 2): an open-label randomised non-inferiority trial

Raban V Jeger,Ahmed Farah,Marc-Alexander Ohlow,Norman Mangner,Sven Möbius-Winkler,Gregor Leibundgut,Daniel Weilenmann,Jochen Wöhrle,Stefan Richter, Matthias Schreiber,Felix Mahfoud,Axel Linke,Frank-Peter Stephan,Christian Mueller, Peter Rickenbacher,Michael Coslovsky,Nicole Gilgen,Stefan Osswald,Christoph Kaiser,Bruno Scheller & BASKET-SMALL 2 Investigators

BACKGROUND

Drug-coated balloons (DCB) are a novel therapeutic strategy for small native coronary artery disease. However, their safety and efficacy is poorly defined in comparison with drug-eluting stents (DES).

METHODS

BASKET-SMALL 2 was a multicentre, open-label, randomised non-inferiority trial. 758 patients with de-novo lesions (<3 mm in diameter) in coronary vessels and an indication for percutaneous coronary intervention were randomly allocated (1:1) to receive angioplasty with DCB versus implantation of a second-generation DES after successful predilatation via an interactive internet-based response system. Dual antiplatelet therapy was given according to current guidelines. The primary objective was to show non-inferiority of DCB versus DES regarding major adverse cardiac events (MACE; ie, cardiac death, non-fatal myocardial infarction, and target-vessel revascularisation) after 12 months. The non-inferiority margin was an absolute difference of 4% in MACE. This trial is registered with ClinicalTrials.gov, number NCT01574534.

FINDINGS

Between April 10, 2012, and February 1, 2017, 382 patients were randomly assigned to the DCB group and 376 to DES group. Non-inferiority of DCB versus DES was shown because the 95% CI of the absolute difference in MACE in the per-protocol population was below the predefined margin (-3·83 to 3·93%, p=0·0217). After 12 months, the proportions of MACE were similar in both groups of the full-analysis population (MACE was 7·5% for the DCB group vs 7·3% for the DES group; hazard ratio [HR] 0·97 [95% CI 0·58-1·64], p=0·9180). There were five (1·3%) cardiac-related deaths in the DES group and 12 (3·1%) in the DCB group (full analysis population). Probable or definite stent thrombosis (three [0·8%] in the DCB group vs four [1·1%] in the DES group; HR 0·73 [0·16-3·26]) and major bleeding (four [1·1%] in the DCB

group vs nine [2·4%] in the DES group; HR 0·45 [0·14-1·46]) were the most common adverse events.

INTERPRETATION
In small native coronary artery disease, DCB was non-inferior to DES regarding MACE up to 12 months, with similar event rates for both treatment groups.

FUNDING
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung, Basel Cardiovascular Research Foundation, and B Braun Medical AG.

type	journal paper/review (English)
date of publishing	28-08-2018
journal title	Lancet (392/10150)
ISSN electronic	1474-547X
pages	849-856