Treatment of chronic total occlusions in native coronary arteries by drug-coated balloons without stenting - A feasibility and safety study

Philine J. Köln a,1, Bruno Scheller b,1, Houn Bang Liew c,1, Tuomas T. Rissanen d,1, Wan Azman Wan Ahmad c,1, Ralf Weser e,1, Telse Hauschild e,1, Amin Ariff Nuruddin b,1, Yvonne P. Clever b,1, Hee Hwa Ho b,1, Franz X. Kleber a,1

a Charité - Universitätsmedizin Berlin, Berlin, Germany
b Universitätsklinikum des Saarlandes, Homburg, Germany
c Sahib Heart Centre, Kota Kinabalu, Malaysia
d North Karelia Central Hospital, Joensuu, Finland
e University of Malaya Medical Centre, Kuala Lumpur, Malaysia
f Evangelisches Krankenhaus Paul Gerhardt Stift, Lübeck Germany
g Klinikum Ernst von Bergmann, Potsdam, Germany
h National Heart Institute, Kuala Lumpur, Malaysia
i Tan Tock Seng Hospital, Tan Tock Seng, Singapore, Singapore
j Cardio Centrum Berlin, Academic Teaching Institution, Charité - Universitätsmedizin Berlin, Berlin, Germany

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ABSTRACT

Background: Chronic total occlusions remain one of the biggest challenges for interventional cardiologists and the high risk of restenosis and stent thrombosis is still a major problem. Drug-coated balloons showed favorable results for the treatment of in-stent restenosis and other lesion types. The aim of this study was to evaluate the feasibility and outcome of a drug-coated balloon only approach for chronic total occlusion.

Methods: We included 34 patients with a native chronic total occlusion treated only by drug-coated balloons. A visual residual stenosis of 30% or less without major dissection was considered a satisfactory percutaneous intervention result according to the German Consensus Group recommendations for drug-coated balloon use. We collected clinical and procedural data. Angiograms were conducted during the procedure and at follow-up. Quantitative coronary analysis was performed and mean and minimal luminal diameter and late luminal changes were assessed.

Results: The recanalization was considered satisfactory in 70.4% (n = 27). Restenosis occurred in 11.8% (n = 4) and reocclusion in 5.9% (n = 2). Out of the 27 patients with a satisfactory initial result, 3.7% (n = 1) had reocclusion and 3.7% (n = 1) had restenosis. In the subgroup without satisfactory result (n = 7), restenosis occurred in 3 patients (42.9%) and reocclusion in 1 patient (14.3%). A luminal increase was found in 67.6% (n = 23) and mean late luminal gain was 0.11 ± 0.49 mm. Angina class improved significantly (p < 0.001). There was no death or myocardial infarction.

Conclusions: Drug-coated balloon angioplasty without stenting is a feasible and well-tolerated treatment method for chronic total occlusions if the predilatation result is good.

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1. Introduction

Chronic total occlusions (CTO) of coronary arteries remain one of interventional cardiologists’ biggest challenges and the reported prevalence in patients with significant coronary artery disease (CAD) ranks between 16 and 52% [1,2]. CTO is defined as a coronary occlusion without antegrade flow (except for collateral flow) that has been present for at least three months [3]. Even though success rates and long-term outcomes have improved over the last years [4,5] due to progress in terms of technology and operator experience, the occurrences of diffuse restenosis, delayed stent coverage, and late stent thrombosis (ST) are still concerns in the percutaneous treatment of CTOs [6,7]. If successfully conducted, the clinical short- and long-term outcomes of patients after recanalization of a CTO are favorable [8,9,10]. Compared to treatment with bare metal stents (BMS), the implementation of drug-eluting stents (DES) as a treatment option for CTO

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