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Research Article

Balloon-Uncrossable Lesions: Significant Higher Recanalization-Success with Metallic-Tip Catheters 5-year Follow-Up Data from XableCath-Study

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Abstract

Background:

The metallic tip interventional recanalization catheter XableCath showed encouraging results (95.8% success rate) in crossing occluding atheroma in balloon uncrossable lesions after successful passage of a guide wire. Because successful crossing of balloon-uncrossable, mostly calcified atheromatous lesions may be associated with a higher complication rate, we investigated the long-term follow-up of all twenty-two patients (24 separate lesions), who have been included into the XableCath study.

Patients and Methods:

We investigated the long-term outcome (5-year follow-up) of 20 lesions in 18 patients, who had successfully been treated with the XableCath metallic tip interventional recanalization catheter (XableCath Inc., Salt Lake City, Utah) for balloon-uncrossable lesions (18 femoro-popliteal (90.0 %), 1 below-the-knee (5.0 %), 1 common iliac (5.0 %), 12 total occlusions (66.7 %). The primary study endpoint was the rate of target lesion patency resp. target lesion complications (e.a. perforation, aneurysms, dissections, or vessel closure) achieved by duplex-sonography. Secondary endpoints were the abscence of lesion associated major adverse events (MAE) as defined as limb amputations and/or cardiovascular death during the follow-up period of 5 years.

Results:

Follow-up informations after 5 years (incl. duplex-sonography) could have been achieved in 18 successfully treated patients (20 lesions). 3 patients (14.3%) died due to not-target lesion associated cardiovascular reasons. The primary endpoint (patency rate) was 85.0 %, target lesion associated complications (e.a. aneurysms, perforations or dissections) were not documented in any patient (0%), secondary endpoint (target lesion associated major adverse cardiovascular events) did not occur in any patient (0%).

Conclusion:

The metallic-tip interventional crossing catheter XableCath is a feasible, easy to use, time and money-saving option for successful angioplasty of balloon-uncrossable PAD-lesions without a higher rate of target lesion failure or target lesion-associated adverse events during a follow-up period of 5 years after successful recanalization of a balloon uncrossable lesion.

Keywords: uncrossable stenosis; recanalization; metallic tip catheter; xablecath; balloon-uncrossable failures

Introduction

Due to demographic changes and increasing life-expectancy, there is growing interest in percutaneous peripheral interventions for complex peripheral lesion and chronic total occlusions (CTOs), i.e., in patients with critical limb ischemia.

Despite various advances in device technology (including newer generation recanalization guidewires), interventional techniques and maneuvers (e.a. buddy-wire, anchoring-, subintimal-, grenadoplasty), the balloon uncrossable lesion remain an unsolved challenge, i.e., after the lesion has been successfully crossed with a recanalization guide wire. Analogous to coronaries, inpossibility of successful angioplasty due to failure of balloon placement may occur in up to 7%.

In contrast to the various atherectomy-devices (directional- or rotational atherectomy (SilverHawk™ Plaque Excision System (Medtronic, Minneapolis, MN, USA), Rotablator™, Boston Scientific Inc. Maple Grove, MN), which can only be applicated with special and mostly less effective recanalization wires, the XableCath metallic-tip recanalization device showed very encouraging results (95.8% success rate) including no periprocedural adverse rates (Dahm). XableCath was very easy-to-use, less treatment-time demanding and as the main advantage could be applicated with any guide-wire of your choice [1]. Like time- and money consuming excimer laser techniques, the unique mechanism of XableCath (XableCath Inc., Salt Lake City, Utah) were its higher crossing abilities based on its unique metallic-tip creating a pilot channel making balloon placement possible (Figure 1a, Figure 1b).

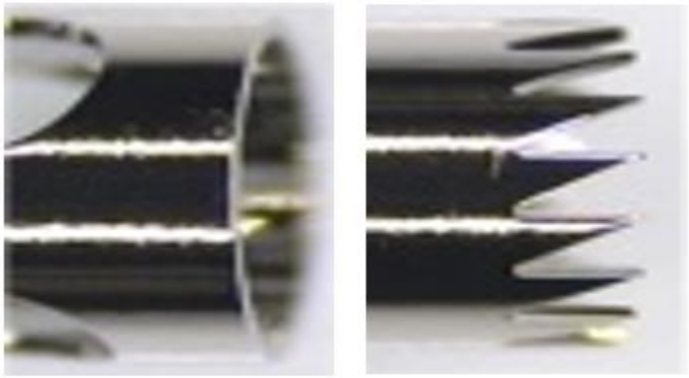

Figure 1a: XableCath (blunt-type)

Figure 1b: XableCath (abrasive-type)

In order to investigate probably long-term effects of the the plaque modification of a metallic-tip catheter in this frequently heavily calcified-atheromatous lesions, we analyzed the the 5-year follow-up data of 18 patients successfully treated in the XableCath study.

Patients & Methods:

Study population: 18 patients, who had successfully been treated for balloon-uncrossable lesion using the metallic tip XableCath recanalization catheter were enrolled into the study. All patients gave written informed consent, and the study was conducted according to the principles of the Declaration of Helsinki.

Data collection: Information concerning patients' demographics, clinical presentation, angiographic findings, procedural success, XableCath plaque-modifying procedure-data (acute results, procedural complications, and complication rates) were recorded in a central cohort database. In this study primary and secondary endpoints were registered after >60 months, including primary (target vessel-associated complications: vessel closure, perforation, aneurysms, persistent minor or major dissections, limb amputation), and secondary endpoints (target lesion associated cardiovascular death).

Study endpoints and definitions: The primary study endpoint was the rate of target lesion associated vessel complications as defined as vessel closure, perforation, aneurysms, persistent minor or major dissections, limb amputation. Secondary endpoints were defined as target vessel associated cardiovascular death.

Vessel perforation was defined as persistent extravascular collection of contrast medium beyond the vessel wall with or without associated clinical complications. Vessel dissections were defined according to the classification of Huber et al.

Vessel closure was defined as reduced antegrade flow caused by total occlusion of the target lesion.

Statistical Analysis: Statistical analysis was performed at the Department of Biometrics, EMA University Greifswald, Germany. Categorical factors are described using percentages and frequency of characteristics or event. Continuous measures are described using means with standard deviations. The baseline factors considered were age, gender, diabetes, hypertension, left ventricular function (LVEF). A p-value of <0.05 was considered significant. Statistical analysis was performed using a standard statistical package.

Results:

XableCath facilitated plaque modification was successfully carried out in 23 separate lesions (21 patients, mean age of 75 ± 17 years (range 54-93 years, 50.0 % females). Follow-up informations at >60 months regarding primary and secondary endpoints was obtained in 18 patients (mean age of 72 ± 16 years (range 54-93 years, 50,0 % females), 3 patients (14.3 %) died after 2 (n=1), 3 (n=1) and 5 years (n=1) due to non-target lesion associated cardiovascular deaths (Table 2).

Variables	n = 18	(20 lesions)
Female	9	(50%)
Age (years)	72,0 ± 16.0	(54–93)
Diabetes Mellitus	15	(83.3%)
Hyperlipidemia	14	(77.8%)
Hypertension	16	(88.9%)
Glomerular filtration rate (GFR) ml	49.9 ± 26.9	(30–79)
Left ventricular ejection fraction (LVEF)	51.1 ± 15.5	(37–64)
PAD (Rutherford 3/4)	12	(66.7%)
(Rutherford 5/6)	8	(38.9%)
Lesion characteristics		
Femoro-popliteal	18	(90.0%)
Common iliac	1	(5.0%)
Below the knee	1	(5.0%)
Lesion length (mm)	54 ± 36	(12-248)
calcification	17	(94.4%)
total occlusions	12	(66.7%)

Table 1: Baseline characteristics (5-year follow-up patients)

Results (XableCath 5-Year Follow-up)	
Number of lesions	20
Primary Endpoint	
TL-patency	17 (85.0 %)
TL-complications	0 (0 %)
Secondary Endpoint	
TL-associated CV-death	0 (0 %)
Non-CV-death	3 (14.3 %)

Table 2: Results (XableCath 5-Year Follow-up)

(TL - target lesion; CV - cardiovascular)

Primary endpoints: Table 2 depicts target lesions associated vessel complications (vessel closure, perforation, aneurysms, persistant minor or major dissections, limb amputation).

The Primary target lesion patency rate after >60 months was 85,0%. Vessel closure (15,0%) occurred without clinical sequelae (e.a. limb amputation; vascular surgery)

Secondary endpoints: Target lesion associated cardiovascular death after XableCath lesion modification did not occur in any patient (0%).

Discussion:

Due to demographic changes and increasing life-expectancy, instant necessary percutaneous peripheral interventions of challenging lesions as the last remaining option for limb salvage is often limited due to impossibility to insert a balloon for angioplasty. To overcome the main reason for the inability to let a balloon pass into the atheromateous lesion, the metallic tip of the XableCath offer more tangential power to overcome the atheroma forces or he can successfully abrade the prolapsing atheroma edges in contrast to the commonly available support catheters or balloons with a plastic tip. More over the XableCath support catheter is easy to use, time and money saving and highly effective in making balloon angioplasty possible in patients with balloon-failures and frequently without remaining therapeutic options as limb amputation.

XableCath apparently do not induce short- or long-term target lesion reactions (e.a. restenosis, obstructions, dissections, aneurysms) and in contrast to the blunter forces of plastic support catheter and balloon tips, it probably includes even less vessel remodelling due to its more precise „cutting "abilities. XableCath modifies the lesion without cutting deep into the vessel structures including potential disadvantages (i.e., perforations), which is frequently the case after using the competing atherectomy devices i.e., in subintimal recanalization. Using the metallic tip XableCath support catheter vessel perforations or major dissections did not occur in any patient, while procedure primary success was 95.8% and secondary success rate was 100% [1]. Even the potential risk of the XableCath (embolization of atheroma-debris due to its abrasive abilities), no reduction of vessel flow, detectable thromboembolizations or no-reflow phenomena was documented ad hoc or at 60 months follow-up.

In summary, XableCath-facilitated angioplasty represents a safe-, effective, easily applicable and cost-effective new therapeutic option to make treatment of balloon-uncrossable lesion treatable. Interventionists and manufacturers should finally consider, time has come to change the well accepted paradigm, that catheter-tips should be made of plastic.

Conclusion:

The metallic-tip interventional crossing catheter XableCath is a feasible, easy to use, time and money-saving option for successful angioplasty of balloon-uncrossable PAD-lesions without a higher rate of target lesion failure or target lesion-associated adverse events during a follow-up period of 5 years after successful recanalization of a balloon uncrossable lesion.

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References:

1. Mahmood A, Banerjee S, Brilakis ES. (2011). Applications of the distal anchoring technique in coronary and peripheral interventions. *J Invasive Cardiol*, 23: 291-294.
2. Hirokami M, Saito S, Muto H. (2006). Anchoring technique to improve guiding catheter support in coronary angioplasty of chronic total occlusions. *Catheter Cardiovasc Interv*, 67: 366-371.
3. Michael TT, Banerjee S, Brilakis ES. (2013). Subintimal distal anchor technique for "balloon-uncrossable" chronic total occlusions. *J Invasive Cardiol*. 25: 552-554.
4. Pagnotta P, Briguori C, Mango R, Visconti G, Focaccio A, et al. (2010). Rotational atherectomy in resistant chronic total occlusions. Catheter Cardiovasc Interv. 76: 366-371.
5. Fang HY, Fang CY, Hussein H, et al. (2010). Can a penetration catheter (Tornus) substitute traditional rotational atherectomy for recanalizing chronic total occlusions? *Int Heart J*, 51: 147-152.
6. Fernandez JP, Hobson AR, McKenzie D, Shah N, Sinha MK, et al. (2013). Beyond the balloon: excimer coronary laser atherectomy used alone or in combination with rotational atherectomy in the treatment of chronic total occlusions,non-crossable and non-expansible coronary lesions. *EuroIntervention*, 9: 243-250.
7. Fernandez JP, Hobson AR, McKenzie DB, Talwar S, O'Kane PD. (2011). How should I treat severe calcific coronary artery disease? *EuroIntervention*, 7: 400-407.
8. Antman EM, Cohen M, Bernink PJLM, McCabe CH, Horacek T. (2000). The TIMI Risk Score for Unstable Angina/Non–ST Elevation MI", *JAMA*. 284(7):835-842.
9. Huber MS, Mooney JF, Madison J, Mooney MR. (1991). Use of a morphologic classification to predict clinical outcome after dissection from coronary angioplasty. *Am J Cardiol*, 68:467-471.

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