Journal für
Kardiologie
Austrian Journal of Cardiology
Österreichische Zeitschrift für Herz-Kreislauferkrankungen

Distal Protection During Percutaneous Coronary Intervention in Native Right Coronary Arteries

El Mokhtari NE, Steinke F
Krüger D, Tiroke A
Simon-Herrmann G, Simon R, Lins M

Journal für Kardiologie - Austrian Journal of Cardiology 2007; 14 (11-12), 333-334

Krause & Pachernegg GmbH • Verlag für Medizin und Wirtschaft • A-3003 Gablitz
P.b.b. 02Z031105M, Verlagsort: 3003 Gablitz, Linzerstraße 177A/21 Preis: EUR 10,–

Grazer Gefäß- & Gerinnungstage 2025
Donnerstag, 26. Juni 2025
14:30 – 15:00

Vertiefendes Fachwissen

www.amrn.link/aerzte

AMARIN
SYMPOSIUM

Ein neuer Angriffspunkt im leitliniengerechten Risikofaktorenmanagement von pAVK- Patient:innen

Dr. Reinhard B. Raggam, Graz

AMARIN

AT-VAZ-00220, 05/2025

Distal Protection During Percutaneous Coronary Intervention in Native Right Coronary Arteries

N. E. El Mokhtari, F. Steinke, D. Krüger, A. Tiroke, G. Simon-Herrmann, R. Simon, M. Lins

Abstract: Liberation of plaque debris during PCI in native coronary arteries is supposed to be a possible mechanism of the no-reflow phenomenon, which can cause impairment of the distal and microvascular circulations.

Therefore, ten consecutive patients undergoing PCI for complex lesions in their native right coronary arteries were enrolled in a pilot trial, using the triActiv system (Kensey Nash Company) for distal protection.

For all patients, device success (device was successfully delivered to the target location, device operated as intended and was successfully retrieved) could be documented. For the primary (MACE rate at 30 days) and secondary endpoints no events were reported, neither in hospital nor during the follow-up period of 30 days.

Debris was found in all patients in whom the extracted fluid could be investigated (7/10), the average particle size being 28 × 68 µm. This observation suggests that embolization can occur during PCI of native coronary vessels and may be more often present than so far expected. Larger studies, however, are needed to confirm the relevance of this finding.

Kurzfassung: Distale Protektion während perkutaner Koronarintervention in nativen rechten Koronararterien. Durch Freisetzung von Plaquematerial während koronarer Interventionen in nativen rechten Koronararterien kann es zum sogenannten „No-reflow"-Phänomen kommen, welches mit einer Herabsetzung der distalen Gefäßbettdurchblutung verbunden sein kann.

Deswegen wurden 10 Patienten, bei denen komplexe Läsionen der rechten Koronararterie behandelt werden sollten, in eine Pilotstudie mit Einsatz des triActiv-Systems zur distalen Protektion eingeschlossen.

Für alle Patienten konnte ein erfolgreicher Systemeinsatz (erfolgreiches Vorbringen des Protektionssystems nach distal der Stenose, erfolgreicher Einsatz des Systems wie erwartet und erfolgreiche Rücknahme des Systems) dokumentiert werden. Für den primären (MACE-Rate nach 30 Tagen) und die sekundären Endpunkte wurden keine Ereignisse berichtet, weder in-Hospital noch nach 30 Tagen.

Debrismaterial wurde bei allen Patienten (7/10) gefunden, bei denen die Spülflüssigkeit untersucht werden konnte, wobei die mittlere Partikelgröße 28 × 68 µm betrug. Diese Beobachtungen unterstreichen, daß distale Embolisationen häufiger bei koronaren Interventionen in nativen Koronargefäßen auftreten als bisher erwartet. **J Kardiol 2007; 14: 333–4.**

■ Introduction

Effectiveness of percutaneous coronary intervention (PCI) in the larger epicardial parts of the vessel has been proven. In some cases, however, the slow-flow/no-reflow phenomenon may occur and can cause impairment of the distal and microvascular circulations. Liberation of plaque debris during PCI is supposed to be a possible mechanism of this phenomenon [1, 2]. Distal protection devices can reduce microembolism and lead to a better immediate angiographic result and, more importantly, by means of better outcome lead to lower rates of major adverse cardiac events (MACE).

While guidelines for PCI recommend the use of distal protection devices during PCI in saphenous vein grafts (SVG), there is no experience or recommendation for PCI in native vessels [3].

Knowledge about capturing embolic debris during PCI in native coronary vessels is missing. To permit blood flow filter devices require a pore size of about 100 µm but it has been shown that the majority of liberated particles during PCI are smaller [4]. Other devices with a total balloon blockage distal of the lesion may limit the continuous visualization of the target lesion and may cause angina pectoris and after PCI, aspiration of debris material is needed.

■ Patients and Methods

In a pilot trial, the triActiv system (Kensey Nash Co.) was evaluated in ten consecutive patients undergoing PCI for complex lesions in their native right coronary arteries. All patients gave written informed consent and the study was approved by the local ethics committee.

After crossing the lesion with a 0.014-inch guidewire, equipped with a temporary occlusion balloon near its tip, the balloon is inflated using a CO_2-filled syringe, thus blocking distal runoff into the coronary microvasculature. A balloon-mounted stent is then railed to the wire and the stent is implanted in the lesion. After retracting the stent balloon, a flush catheter is attached to the wire and advanced to the balloon occlusion site. Saline is then infused in 50 cc/min through the flush catheter and the returning blood and saline from the guiding catheter are evacuated automatically by the closed-loop triActiv pump system (approx. 30 sec) that comes sterile for single use. The aspirated saline, blood, and debris material can be collected and filtered for microscopic analysis.

Primary endpoint of the study was the rate of MACE at 30 days after index procedure (a combined clinical endpoint defined as: death, Q-wave or Non Q-wave MI [CK-MB > 3 × ULN], emergent bypass surgery, repeat target lesion revascularization). Secondary endpoints were: rate of major adverse cardiac and cerebrovascular events (MACCE) at 30 days after index procedure, rate of MACE and MACCE at hospital discharge, rate of acute, procedural and device success and rates of individual adverse events.

■ Results

The average patient age was 67.3 ± 10.6 yrs, range 50–80 yrs, and 80 % were female. Nine pts suffered from angina class CCS III, one pt from CCS class II. Five pts were diabetics and 4/10 pts had a history of myocardial infarction. The left ventricular function was almost normal with an average ejection fraction of 61.3 ± 7.9 % in all pts. In 7/10 pts, a single lesion was treated, and in 3/10 pts, two lesions were treated

Eingelangt am 26. September 2007; angenommen am 1. Oktober 2007
Aus der Klinik für Kardiologie, Universitätsklinik Schleswig-Holstein, Campus Kiel
Korrespondenzadresse: Prof. Dr. med. Markus Lins, Klinik für Kardiologie, Universitätsklinik Schleswig-Holstein, Campus Kiel, D-24105 Kiel, Schittenhelmstraße 12; E-Mail: lins@cardio.uni-kiel.de

during the same procedure. While the total procedural time was 61 ± 2 min, the average occlusion time performing the distal protection was 2.0 ± 0.2 min. Angiographic characteristics are given in table 1 (QCA core lab: Borgess Angiographic Core Lab, Kalamazoo, MI, USA).

The treated lesion was located in the proximal part of the RCA in 5/10 pts and in the mid part of the RCA in the remaining 5. For all pts, a device success (device was successfully delivered to the target location, device operated as intended and was successfully retrieved) could be documented. For the primary and secondary endpoints, no events were reported, neither in hospital nor during the follow-up period of 30 days. In addition, there were no angiographic adverse events such as abrupt closure/total occlusion, distal embolization, threatened abrupt closure, injury to vessel/dissection, vessel spasm or perforation.

After procedure, the contents of the extraction bag were filtered for 7/10 patients in the trial and the debris filters were sent to a pathologist for analysis. Potential embolic debris was extracted in all filters. The size of the filtered particles was measured with 28 × 68 μm approximately.

■ Discussion

Distal embolization of plaque debris during PC of old vein grafts is well recognized as a source of „no reflow“ in the coronary microcirculation and consecutive ischemia, even myocardial infarction or death [2].

Several studies have shown that protection devices such as filter wires or distal blocking balloons with consecutive debris extraction can prevent this complication and they are therefore recommended for PCI procedures in saphenous vein grafts [5–10]. In case of PCI of native coronary arteries, distal embolization from the lesion area seems to be a very rare event. In the situation of complex lesions with recent plaque rupture and/or thrombus burden, however, plaque embolization has been reported with serious clinical sequelae [1, 11].

In the current pilot study, 10 patients were treated for complex lesions of large right coronary arteries and during PCI and stent implantation, a distal protection balloon system with automated flush extraction (triActiv, Kensey Nash Co.) was used to prevent potential embolization. No adverse events were noted, neither in the form of distal flow impairment or “no reflow”, nor due to the additional use of the protection device. TIMI flow could be improved as the TIMI frame count was significantly lower after the procedure indicating successful treatment of the lesion. Thus, the application of the protection system for right coronary lesions seems to be feasible, safe, and effective. The time period necessary to block the distal runoff with the protection balloon was only 2 minutes on average and did not cause any ischemia or discomfort in any patient.

Interestingly, significant debris was found in all patients in whom the extracted fluid could be investigated, the average particle size being 28 × 68 μm. This observation suggests that embolization can occur during PCI of native coronary vessels, and may be more often present than so far expected. Larger studies, however, are needed to confirm the relevance of this finding.

Table 1: Angiographic characteristics before and after procedure

	Baseline	Final	p-value
Lesion length (mm)			
mean ± SD	14.93 ± 8.65		
Baseline lesion classification (ACC/AHA classification)			
Type A	2/10		
Type B1	2/10		
Type B2	4/10		
Type C	2/10		
TIMI grade			
0–1	0/10	0/10	
2	3/10	0/10	
3	7/10	10/10	
TIMI frame count			
mean ± SD	71.3 ± 33.8	37.6 ± 20.3	0.07
Reference vessel diameter (mm)			
mean ± SD	3.29 ± 0.61	3.48 ± 0.57	0.42
Minimal lumen diameter (mm)			
mean ± SD	0.97 ± 0.44	2.98 ± 0.38	0.33
Acute gain (mm)			
mean ± SD		2.01 ± 0.53	
% diameter stenosis (%)			
mean ± SD	70.05 ± 13.41	13.19 ± 12.83	0.44

SD: standard deviation

Literature:

1. Topol EJ, Yadv JS. Recognition of the importance of embolization in atherosclerotic vascular disease. Circulation 2000; 101: 570–80.

2. Piana RN, Palik GY, Moscucci M, Cohen DJ, Gibson CM, Kugelmass AD, Carrozza JP Jr, Kuntz RE, Baim DS. Incidence and treatment of “no-reflow” after percutaneous coronary intervention. Circulation 1994; 89: 2514–8.

3. Silber S, Albertsson P, Avilés FF, Camici PG, Colombo A, Hamm C, Jørgensen E, Marco J, Nordrehaug JE, Ruzyllo W, Urban P, Stone GW, Wijns W; Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology. Guidelines for percutaneous coronary interventions. The Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology. Eur Heart J 2005; 26: 804–47.

4. Müller-Hülsbeck S, Jahnke T, Liess C, Glass C, Grimm J, Heller M. Comparison of various cerebral protection devices used for carotid artery stent placement: an in vitro experiment. J Vasc Interv Radiol 2003; 14: 613–20.

5. Webb JG, Carere RG, Virmani R, Baim D, Teirstein PS, Whitlow P, McQueen C, Kolodgie FD, Buller E, Dodek A, Mancini GB, Oesterle S. Retrieval and analysis of particulate debris after saphenous vein graft intervention. J Am Coll Cardiol 1999; 34: 468–75.

6. Grube E, Schofer JJ, Webb J, Schuler G, Colombo A, Sievert H, Gerkens U, Stone GW. Evaluation of a balloon occlusion and aspiration system for protection from distal embolization during stenting in saphenous vein grafts. Am J Cardiol 2002; 89: 941–5.

7. Baim DS, Wahr DW, George B, Leon MB, Greenberg J, Cutlip DE, Kaya U, Popma JJ, Ho KK, Kuntz RE. Randomized trial of a distal embolic protection device during percutaneous intervention of saphenous vein aorto-coronary bypass grafts. Circulation 2002; 105: 1285–90.

8. Stone GW, Rogers C, Hermiller J, Feldman R, Hall P, Haber R, Masud A, Cambier P, Caputo RP, Turco M, Kovach R, Brodie B, Herrmann HC, Kuntz RE, Popma JJ, Ramee S, Cox DA. Randomized comparison of distal protection with a filter-based catheter and a balloon occlusion and aspiration system during percutaneous intervention of diseased saphenous vein aorto-coronary bypass grafts. Circulation 2003; 108: 548–53.

9. Carrozza JP Jr, Mumma M, Breall JA, Fernandez A, Heyman E, Metzger C; PRIDE Study Investigators. Randomized evaluation of the TriActiv balloon protection flush extraction system for the treatment of saphenous vein graft disease. J Am Coll Cardiol 2005; 46: 1677–83.

10. Sievert H, Wahr DW, Schuler G, Schofer JJ, Sutsch G, Pavliska J, Skowasch M. Effectiveness and safety of the Proxis system in demonstrating retrograde coronary blood flow during proximal occlusion and in capturing embolic material. Am J Cardiol 2004; 94: 1134–9.

11. Gorog DA, Foale RA, Malik I. Distal myocardial protection during percutaneous coronary intervention: when and where? J Am Coll Cardiol 2005; 46: 1434–45.

Mitteilungen aus der Redaktion

Besuchen Sie unsere Rubrik

☑ Medizintechnik-Produkte

Neues CRT-D Implantat
Intica 7 HF-T QP von Biotronik

Artis pheno
Siemens Healthcare Diagnostics GmbH

Philips Azurion:
Innovative Bildgebungslösung

Aspirator 3
Labotect GmbH

InControl 1050
Labotect GmbH

e-Journal-Abo

Beziehen Sie die elektronischen Ausgaben dieser Zeitschrift hier.

Die Lieferung umfasst 4–5 Ausgaben pro Jahr zzgl. allfälliger Sonderhefte.

Unsere e-Journale stehen als PDF-Datei zur Verfügung und sind auf den meisten der marktüblichen e-Book-Readern, Tablets sowie auf iPad funktionsfähig.

☑ Bestellung e-Journal-Abo