Joint Coronary Revascularisation Meeting,
8-9 December 2017, Busan, South Korea.

Drug-eluting balloons – research and practice in the ASEAN Region

Prof Dr Alan Fong
MBChB(Bristol), MRCP(UK), FRCP (Edin), FACC, FESC, FAPSIC, FNHAM, FAsCC, FSCAI
Consultant Cardiologist, Sarawak General Hospital Heart Centre;
& Head, Clinical Research Centre, Sarawak General Hospital;
Adjunct Professor, Swinburne University of Technology, Sarawak Campus

Disclosures

- None

ASEAN

10 countries, approx. 700 million population

Common issues in CV disease

- Multi-ethic population
- Large land mass
- Developing countries

- Cardiovascular care providers
- 'Spending power' of patients
- Guideline – practice mismatch

- Increasing prevalence of CV risk factors
- Complex CAD for PCI

Existing and emerging roles for DEB in PCI

- ISR
- Small vessel disease
- Long diffuse disease
- Bifurcations

- Acute coronary syndrome
- Chronic total occlusions
- Stabilisation of the vulnerable plaque

Drug eluting balloon and DAPT Strategy

- It is a balloon!
- ACS population – typically still a 12 month DAPT
- Stable CAD population:
  - ESC DAPT Update 2017: 6 month DAPT [Class IIa,B] or in HBR, 1 month DAPT [Class IIb,C] or 3 month DAPT [Class IIa,B]
  - German Consensus DEB in PCI 2011: 1 month DAPT only in a DEB-only strategy

What have we done in the ASEAN Region?

Sharing our opinion

Coronary – *Innovation*
Coronary stents: new platforms, new coatings, new drugs
euro PCR

Six-month clinical and safety outcomes, and preliminary 9-month angiographic follow-up, from a prospective, single centre registry of a novel combination therapeutics strategy: paclitaxel-eluting balloon and bioengineered progenitor cell-attracting stainless steel stent in percutaneous treatment of coronary artery stenosis (POTENT)

A.Y.Y. Fong, T.K. Ong, C.K. Ang, B.C. Chang, K.L. Yew, M.A. Nor Hanim, S.K. Chua, S.K. Tan, R. Annuar, K.B. Lau, K.H. Sim
Sarawak General Hospital, Kuching, Malaysia

Aims: The safety and efficacy of a novel percutaneous coronary intervention (PCI) combination 'POTENT' strategy performed by paclitaxel-eluting balloon (PEB) angioplasty followed by stenting with bioengineered progenitor cell-attracting stainless steel stents (BPS) to treat occlusive coronary artery disease (CAD) have not been established. Our primary objectives were to ascertain the safety and efficacy of the POTENT strategy, utilising clinical, biomarker and angiographic parameters.

Methods and results: Consecutive patients at a single centre requiring PCI were screened between 4/12/2008 and 4/6/2009, with 50 patients enrolled. Following PCI, patients received mandatory 3 months DAPT, and scheduled for 9-month angiographic follow-up. 49 patients were preloaded with Aspirin and Clopidogrel 'dual antiplatelet therapy' (DAPT) >6 hours prior to PCI; all patients were preloaded with a Statin-class drug. 'Sequent Please®' PEB (B.Braun, Germany) and 'Genous®' BPS (Orbus Neich, Hong Kong SAR) were devices used in this strategy. All patients completed 6 months clinical follow-up. 86% were male, with a mean age of 56±10years; 30% were current smokers; 60% had hypertension, 68% dyslipidaemia and 32% diabetes; 16% had elevated Troponin T pre-PCI. At baseline, patients had a mean left ventricular ejection fraction 54.0±15.0%. 80% of patients had PCI via the radial artery; 6 Fr guiding catheters used in all cases. In total, 53 index lesions were treated. In total, 51 PEB (mean dimensions: 2.67±0.38mm by 20.39±5.37mm) and 53 BPS (mean dimensions: 3.08±0.33mm by 17.45±5.37mm) were used. 40% of index lesions required a separate pre-dilatation procedure, and 32% required a separate post-dilatation procedure. Post-PCI, 21.4% of patients had a detectable Troponin rise, while 61.3% of patients had a detectable NT-proBNP rise, with 12.5% having a >2X increase over baseline. No in-hospital and 30-day MACE was recorded. At 6 months clinical follow-up, there were 3 recorded MACE (1 unstable angina event with complete instent restenosis requiring PCI, 1 non-ST elevation MI event with late stent thrombosis requiring PCI and 1 cardiac death at home). To date, 30 of 37 qualifying patients completed 9-month angiographic follow-up, demonstrating a mean instent restenosis of 16.0±16.0%. Using the POTENT strategy, the cost saving per patient per year on antiplatelet therapy compared to a drug-eluting stent strategy was RM 1,412.64 (USD 415.48).

Conclusions: At 6 month follow-up, the POTENT strategy for PCI is safe and effective treatment of CAD, with projected cost savings on DAPT. The subgroup of 30 patients with 9-month angiographic follow-up showed no significant restenosis.

CRC
Research that matters to patients

Case Report

Recurrent In-Stent Restenosis With Total Occlusion Remedied With Drug-Eluting Balloon Angioplasty

A Case Report

Shah Mohd Shah AZARISMAN,[1] MD, Mahmood Zulkifli SABRUDDIN,[2] MD, *and* Mohd. Ali ROSLI,[2] MD

SUMMARY

We report a 69 year old female who presented with chest pain to the Emergency Department of the National Heart Institute Malaysia. Her history revealed that she had had 2 separate episodes of chest pain beginning in 2002, resulting in total occlusion of her mid left anterior descending artery (LAD) requiring percutaneous coronary intervention and stenting on both occasions. Cine angiogram on her current admission revealed recurrent target lesion in-stent restenosis with total occlusion of the distal LAD. Intravascular ultrasound revealed multilayered suboptimally deployed stents in the LAD. Successive drug-eluting balloon deployments resulted in sustained patency of the LAD after 1 year. (Int Heart J 2011; 52: 61-63)

Key words: In-stent restenosis, Angioplasty, Drug-eluting balloon

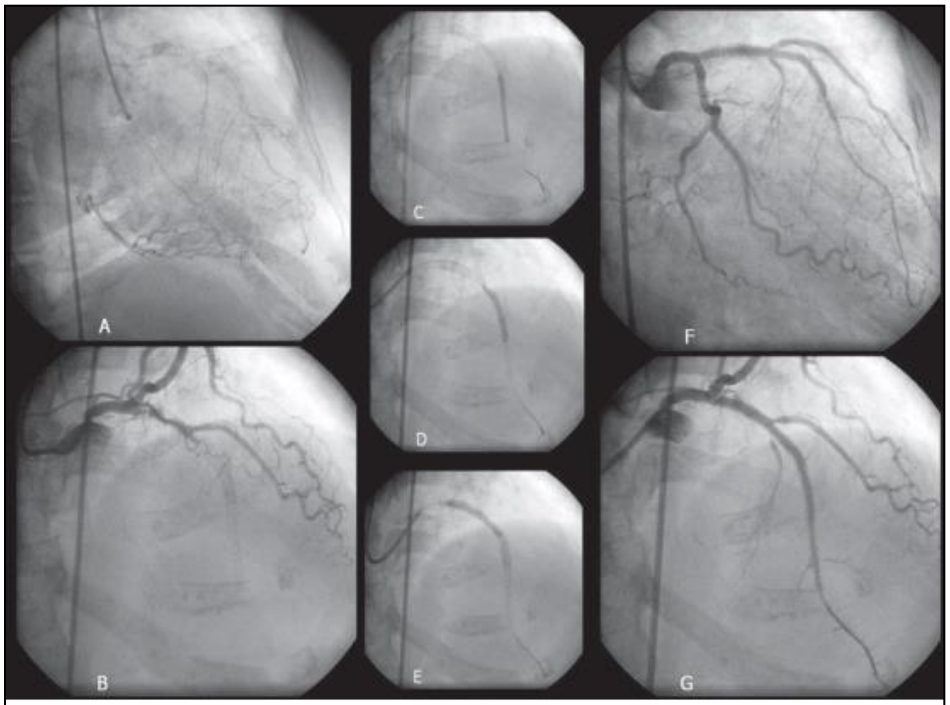


Figure 2. **A:** Repeat right-sided cine (AP cranial view) showing the RCA with retrograde collateralization of the distal-mid LAD. **B:** Repeat left-sided cine (AP cranial view) showing significant in-stent restenosis of the mid LAD stent and total occlusion of the D_1 stent and distal LAD stent just beyond D_2. **C-E:** Successive distal to proximal deployment of the Sequent Please® drug-eluting balloons (DEB). (C: 2.5 mm × 30 mm at 8 atm/45 seconds, D: 3.0 mm × 26 mm at 16 atm/40 seconds and E: 3.5 mm × 26 mm at 16 atm/40 seconds) **F:** Post-DEB cine (RAO caudal view) showing patent stents with moderate ISR of the proximal stent but TIMI III flow to the distal LAD. **G:** Post DEB cine (AP cranial view) showing occluded D_1 stent but patent LAD stents.

Int Heart J
January 2011

Paclitaxel-eluting balloon angioplasty and cobalt-chromium stents versus conventional angioplasty and paclitaxel-eluting stents in the treatment of native coronary artery stenoses in patients with diabetes mellitus

Rosli Mohd Ali[1], MD; Ralf Degenhardt[2]*, PhD; Robaayah Zambahari[1], MD; Damras Tresukosol[3], MD; Wan Azman Wan Ahmad[4], MD, Haizal bin Haron Kamar[4], MD, Sim Kui-Hian[5], MD, Tiong Kiam Ong[5], MD, Omar bin Ismail[6], MD; Safari bin Elis[6], MD; Wasan Udychalerm[7], MD; Hanns Ackermann[8], PhD; Michael Boxberger[9], PhD; Martin Unverdorben[2,10], MD, PhD

1. National Heart Institute, Kuala Lumpur, Malaysia; 2. Clinical Research Institute, Center for Cardiovascular Diseases, Rotenburg an der Fulda, Germany; 3. Siriraj Hospital Mahidol University, Bangkok, Thailand; 4. University Malaya Medical Center, Kuala Lumpur, Malaysia; 5. Sarawak Hospital, Kuching, Malaysia; 6. Penang Hospital, Pulau Penang, Malaysia; 7. King Chulalongkorn Hospital, Bangkok,Thailand; 8. Institute for Biomedical Statistics, Goethe-University, Frankfurt/Main, Germany; 9. Clinical Science, Vascular System, BBraun, Berlin, Germany; 10. Scientific Affairs, BBraun Medical Inc, Bethlehem, PA, USA

KEYWORDS

- drug eluting balloon
- diabetes mellitus
- coronary
- restenosis
- clinical outcome

Abstract

Aims: Coronary lesions in diabetics (DM) are associated with a high recurrence following percutaneous coronary intervention (PCI), even after drug-eluting stent (DES) deployment. Encouraging clinical data of the drug-eluting balloon catheter (DEB) SeQuent Please warrant its investigation in these patients.

Methods and results: Eighty-four diabetic patients (60.8±9.1years, 76.2% male) were randomised to either the DEB SeQuent™ Please or the DES Taxus™ Liberté™ to compare the 9-month clinical and angiographic outcome of PCI in native coronary arteries. Comparing the DEB vs. the DES the 9-month results (follow-up

EuroIntervention 2011;7:K83-K92

Table 2. Procedural data, angiographic findings at intervention and 9-month angiographic and clinical follow-up (intention-to-treat analysis).¶

	Drug-eluting balloon	Drug-eluting stent	Difference (95% CI)	p^1
Procedural data				
	n=45	n=39	N/A	
Predilation	14(31.1%)	38 (97.4%)	–0.66 (-0.831 to –0.49)	<0.0001
9-month clinical follow-up (one event per patient)				
Target lesion revascularisation	3 (8.9%)	4 (10.3%)	–0.01 (–0.18 to 0.11)	0.84
Myocardial infarction	1(2.2%)[3]	1 (2.6%)[4]	–0.00 (–0.09 to 0.09)	0.54
Death	3 (6.0%)	0 (0%)	0.06 (–0.03 to 0.16)	0.29
Cardiac	2 (4.4%)[5]	0 (0%)	0.04 (–0.04 to 0.13)	0.54
Non-cardiac	1(2.2%)[6]	0 (0%)	0.02 (–0.04 to 0.09)	0.94
Stent thrombosis	0 (0%)	1 (2.6%)	–0.03 (–0.10 to 0.05)	0.94
Target lesion revascularisation, myocardial infarction, stent thrombosis, or cardiac death	6 (13.3%)	6 (15.4%)	–0.02 (–0.20 to 0.15)	0.96
Target lesion revascularisation, myocardial infarction, stent thrombosis, or all-cause death	7 (15.6%)	6 (15.4%)	0.00 (–0.18 to 0.18)	0.78
Angiographic follow-up	39 (86.7%)	36 (92.3%)	–0.05 (–0.21 to 0.10)	0.63
Late lumen loss				
In-stent	0.51±0.61 mm	0.53±0.67 mm	–0.02 (–0.32 to 0.27)	0.87
In-segment	0.37±0.59 mm	0.35±0.63 mm	0.02 (–0.23 to 0.30)	0.91
Late lumen loss index				
In-stent	0.30±0.37 mm	0.30±0.40 mm	–0.00 (–0.17 to –0.18)	0.97
In-segment	0.23±0.44 mm	0.20±0.42 mm	0.03 (–0.17 to –0.23)	0.77
Binary restenosis rate				
In-stent	5 (12.8%)	4 (11.1%)	0.02 (–0.16 to 0.19)	0.89
In-segment	5 (12.8%)	5 (13.9%)	–0.01 (–0.19 to 0.17)	0.84
Patterns of in-stent restenosis[2]			N/A	0.27
I	3/5 (60.0%)	2/5 (40.0%)		
II	2/5 (40.0%)	0/5 (0%)		
III	0/5 (0%)	1/5 (20.0%)		
IV	0/5 (0%)	1/5 (20.0%)		
Proximal in-segment	0/5 (0%)	1/5 (20.0%)		

¶All values are mean±standard deviation or N (%). CI, confidence interval; [1] Bold *p*-values indicate statistical significance at the α=0.05 level; [2] Patterns of in-stent restenosis in patients with repeated restenosis (Mehran classification); [3] Myocardial infarction due to occlusion of a non-target vessel; [4] Myocardial infarction due to occlusion of target vessel; [5] One death due to pulmonary oedema after acute coronary syndrome. Second death was sudden cardiac death preceded by acute shortness of breath; [6] Death after acute renal failure, no ECG change and no ischaemia

EuroIntervention 2011;7:K83-K92

Letter to the Editor

Treatment of Coronary In-stent Restenosis with Drug-eluting Balloon Catheter: Real-world Outcome and Literature Review

Dear Editor,

Currently, coronary stent implantation is employed in approximately 90% of percutaneous coronary intervention (PCI) cases. Despite the use of drug-eluting stents (DES), coronary in-stent restenosis (ISR) remains an Achilles' heel of PCI and can occur in about 10% of patients in the real-world population.[1,2] We explored the efficacy of a novel approach using drug-eluting balloon (DEB) in the treatment of our patients with ISR.

Materials and Methods

A total of 53 patients who presented to the National University Heart Centre, Singapore, with coronary ISR

Procedural success was defined as residual stenosis of <30% of the luminal diameter with TIMI grade III antegrade flow. Clinical follow-up was achieved by means of telephonic interviews, outpatient follow-ups or hospital records. The study endpoints were major adverse cardiac events (MACE) of death, myocardial infarction (MI), repeat target vessel revascularisation (TVR) and stent thrombosis at 1- and 6-month follow-ups.

Results

A total of 53 patients were enrolled in this study. The mean age of the patients was (59.7 ± 10.7) years, and males constituted 83.0% of the cohort. Diabetes mellitus

Table 1. Results of Clinical Follow-up (n = 53)

Variable	No. (%)
Target vascular revascularisation	
At 1 month	1 (1.9%)
At 6 months (2 CABG)	4 (7.5%)
Myocardial infarction	
At 1 month	0 (0.0%)
At 6 months	4 (7.5%)
Death	
At 1 month	0 (0.0%)
At 6 months	0 (0.0%)
Stent thrombosis	
At 1 month	0 (0.0%)
At 6 months	0 (0.0%)
MACE no. (%)	
At 1 month	1 (1.9%)
At 6 months	5 (9.4%)

CABG: coronary artery bypass graft; MACE: major adverse cardiac events

Clinical Efficacy and Safety of SeQuent Please Paclitaxel-Eluting Balloon in a Real-World Single-Center Registry of South-East Asian Patients☆,☆☆,★

Hee Hwa Ho *, Yau Wei Ooi, Kwok Kong Loh, Julian Tan, Than Htike Aung, Fahim Haider Jafary, Paul Jau Lueng Ong

Department of Cardiology, Tan Tock Seng Hospital, Singapore

ARTICLE INFO

Article history:
Received 3 November 2013
Accepted 18 November 2013
Available online 27 November 2013

Keywords:
Drug-eluting balloon
Percutaneous coronary intervention
South-East Asia
Registry
Outcomes

ABSTRACT

Background: Drug eluting balloon (DEB) is a new therapeutic option for treatment of obstructive coronary lesions in percutaneous coronary intervention (PCI). There is limited data on the safety and efficacy of DEB in Asian patients in contemporary clinical registries. We evaluated the clinical efficacy and safety of SeQuent Please paclitaxel-eluting balloon in our cohort of South-East Asian patients in real world clinical practice.

Methods: Between January 2010 to November 2012, 320 patients (76% male, mean age 61.3 ± 11.2 years) with a total of 337 coronary lesions were treated with SeQuent Please drug-eluting balloon (DEB). The primary endpoint was major adverse cardiac events (MACE) ie a composite of cardiovascular death, target vessel related myocardial infarction (MI) and target lesion revascularization (TLR) at 9 months follow-up.

Results: The majority of patients presented with acute coronary syndrome (76%).The most common indication for the use of DEB was small vessel disease (54%) followed by instent restenosis (21%), bifurcation lesions (6%) and others (19%). An average of 1.23 ± 0.5 DEB were used per patient, with mean DEB diameter of 2.6 ± 0.6 mm and average total length of 24.0 ± 11.1 mm.

At 9 months follow-up, 5.3% of patients developed MACE. MACE was mainly driven by TLR(4%) followed by target vessel related myocardial infarction (2.6%) and cardiovascular death (1%).

Conclusion: SeQuent Please DEB was a safe and effective treatment modality in our cohort of South-East Asian patients with a low incidence of MACE observed at 9 months follow-up.

IJC Heart & Vessels 1 (2013) 37–41

Table 1
Baseline Clinical Characteristics of Patients.

	N = 320
Mean age (years)	61.3 ± 11.2
Male:Female,n, %	242: 78 (76 : 24)
Ever smokers,n,%	173 (54.1)
Diabetes,n, %	155 (48.4)
Hyperlipidemia,n,%	261 (81.6)
Hypertension,n,%	257 (80.3)
Previous myocardial infarction,n,%	102 (32.0)
Previous PCI,n,%	137 (42.8)
Previous CABG,n,%	24 (7.5)
LVEF(%)	45 ± 13
Presentation:	
STEMI,n,%	48 (15)
NSTEMI/UAP,n,%	194 (61)
Stable angina,n,%	78 (24)

*PCI denotes percutaneous coronary intervention, CABG coronary artery bypass graft, LVEF left ventricular ejection fraction, STEMI ST elevation myocardial infaction, NSTEMI/UAP denotes non STEMI/unstable angina pectoris.

Table 2
Baseline Angiographic Features and Procedural Data of Patients.

	N = 320
No.of obstructive coronary artery:	
1,n,%	70 (22)
2,n,%	112 (35)
3,n,%	138 (43)
Target vessel:	
LAD,n,%	124 (37)
RCA,n,%	62 (18)
LCx,n,%	58 (17)
Others,n,%	93 (28)
Lesion type:	
Small vessel,n,%	182 (54)
ISR,n,%	72 (21)
Bifurcation,n,%	20 (6)
De novo,n,%	17 (5)
Others,n,%	46 (14)
PCI Approach:	
DEB alone therapy ,n,%	276 (82)
DEB and bare metal stenting,n,%	61 (18)
Mean number of DEB per patient	1.2 ± 0.5
Mean diameter of DEB, mm	2.6 ± 0.6
Total length of DEB (average),mm	24.0 ± 11.1
Glycoprotein IIb/IIIa inhibitors,n,%	232 (72)

* LAD denotes left anterior descending, RCA right coronary artery, LCx left circumflex, ISR instent restenosis, DEB drug-eluting balloon.

MACE denotes major adverse cardiac events, TLR target lesion revascularization, MI myocardial infarction

IJC Heart & Vessels 1 (2013) 37–41

Letter to the Editor

Differences in clinical and angiographic profiles between Asian and Western patients with coronary artery disease: Insights from the prospective "real world" paclitaxel-coated balloon registry

Paul Jau Lueng Ong [a], U. Zeymer [b], M. Waliszewski [c], Julian Tan [a], Hee Hwa Ho [a,*]

[a] *Department of Cardiology, Tan Tock Seng Hospital, Singapore, Singapore*
[b] *Klinikum Ludwigshafen, Germany*
[c] *Medical Scientific Affairs, B. Braun Melsungen AG, Melsungen, Germany*

ARTICLE INFO

Article history:
Received 25 February 2014
Accepted 22 April 2014
Available online xxxx

Keywords:
Angiographic
Asian
Clinical
Percutaneous coronary intervention
Profile
Western

versus Western patients in a prospective, "real world" paclitaxel-coated balloon (PCB) registry and report on the findings.

The SeQuent Please Small Vessel 'PCB only' Registry [5] was an international, prospective, multi-center study which enrolled 447 patients (mean age of 66.1 + 10.9 years, 36.7% diabetics) with 471 de novo lesions of small reference diameters (2.0–2.75 mm in diameter). The registry assessed the safety and efficacy of PCB angioplasty for small vessel coronary CAD in Europe and Asia with the intention-to-treat lesions without additional stenting.

The Asian countries included in the study were Singapore, Malaysia and Iran while the remaining countries were all Western countries (Germany, France and Italy). For our analysis, the clinical characteristics, angiographic profiles and clinical outcomes were compared between the 2 pre-specified groups (Asian versus Western patients).

http://dx.doi.org/10.1016/j.ijcard.2014.04.239
0167-5273/

Table 1

Table 2
Angiographic features, procedural data and clinical outcomes.

	All Patients (N = 447)	Asian (N = 73)	Western (N = 374)	p-Value
Number of lesions	471	82	389	
Target vessel				
LAD, n,%	193 (41.0)	34 (41.4)	159 (40.9)	0.17
LCx, n,%	126 (26.8)	25 (30.5)	101 (26.0)	
RCA, n,%	94 (20.0)	19 (23.2)	75 (19.3)	
Others, n,%	58 (12.3)	4 (4.9)	54 (13.9)	
Calcification, n,%	112 (23.8)	8 (9.8)	104 (26.7)	0.001*
Bifurcation, n,%	45 (9.6)	6 (7.3)	39 (10.0)	0.43
Severe tortuosity, n,%	45 (9.6)	1 (1.2)	44 (11.3)	<0.001*
AHA/ACC type B2/C lesion	182 (38.6)	29 (35.4)	153 (39.3)	0.53
Reference vessel diameter, mm	2.14 ± 0.35	2.03 ± 0.17	2.17 ± 0.38	0.02*
Lesion length, mm	15.5 ± 7.0	17.9 ± 10.7	15.0 ± 6.0	0.003*
No. of PCB, n	478	82	396	
PCB diameter, mm	2.33 ± 0.31	2.29 ± 0.26	2.34 ± 0.32	0.06
PCB length, mm	19.2 ± 4.5	20.4 ± 4.6	18.9 ± 4.4	0.002*
Overall technical success, n,%	473 (99.0)	81 (98.8)	392 (99.0)	–
Clinical outcomes				
30-day MACE, n,%	1 (0.3)	0 (0)	1 (0.3)	0.62
9-month MACE, n,%	18 (4.7)	2 (2.7)	16 (5.1)	0.38
9-month TLR, n,%	14 (3.6)	1 (1.4)	13 (4.2)	0.25
9-month MI, n,%	7 (1.8)	1 (1.4)	6 (1.9)	0.75
9-month cardiac death, n,%	0 (0)	0 (0)	0 (0)	–

LAD = left anterior descending artery; LCx = left circumflex; RCA = right coronary artery; ACC/AHA = American College of Cardiology/American Heart Association; PCB = paclitaxel-coated balloon; MACE = major adverse cardiac event; TLR = target lesion revascularization; MI = myocardial infarction.
* Denotes p value < 0.05.

http://dx.doi.org/10.1016/j.ijcard.2014.04.239
0167-5273/

ORIGINAL ARTICLE

Prospective 'real world' registry for the use of the 'PCB only' strategy in small vessel de novo lesions

U Zeymer,[1] M Waliszewski,[2] M Spiecker,[3] O Gastmann,[4] B Faurie,[5] M Ferrari,[6] M Alidoosti,[7] C Palmieri,[8] T N Heang,[9] P JL Ong,[10] U Dietz[11]

For numbered affiliations see end of article.

Correspondence to
Prof. Uwe Zeymer, Klinikum der Stadt Ludwigshafen am Rhein, Bremserstrasse 79 D-67063 Ludwigshafen, Germany; zeymeru@klilu.de

Received 27 August 2013
Revised 23 September 2013
Accepted 17 October 2013
Published Online First
26 November 2013

ABSTRACT

Background This prospective registry assessed the safety and efficacy of paclitaxel coated balloon (PCB) angioplasty for small vessel coronary artery disease in Europe and Asia with the intention to treat lesions without additional stenting. The use of PCBs in small vessels seems to be associated with favourable outcomes; however, prospective data for the use of PCBs without stenting are limited.

Methods The SeQuent Please Small Vessel 'PCB only' Registry was an international, prospective, multicentre registry enrolling patients with de novo lesions of small reference diameters (≥2.0 mm, ≤2.75 mm). The primary end point was clinically driven target lesion revascularisation (TLR) at 9 months. Secondary end points were acute technical success, in-hospital outcomes, 9-month major adverse cardiac events (MACE) (death, myocardial infarction, or TLR), and the occurrence of definite lesion and vessel thrombosis.

Results A total of 479 patients (66.1±10.9 years, 36.7% diabetics) were enrolled, 105 (23.5%) with an acute coronary syndrome, 41 (9.2%) with ST elevation myocardial infarction (STEMI), and 60 (14.8%) with non-STEMI. The initial procedural success rate was 99.0%;

sustained angiographic and clinical benefits with the Paccocath coating technology to treat BMS-ISR[1–4] as well as DES-ISR.[5–7] However, for PCBs there are only four studies on de novo lesions. One study was conducted on patients with diabetes,[8] one on small vessel disease,[9] and one on bifurcation lesions.[10] In addition, PCBs were studied with and without the additional implantation of stents coated with endothelial progenitor cells.[11] PCBs demonstrated favourable LLL in all of these studies. Nevertheless, the data from angiographic end point trials in small vessel de novo lesions are limited to the single armed PEPCAD I trial,[9] the PICCOLETTO trial,[12] and the recently published results of the BELLO study.[13] With the exception of the prematurely terminated PICCOLETTO trial, PCB catheters with a paclitaxel-spacer matrix (Paccocath or Freepac) were associated with consistently low LLL (<0.20 mm) if PCBs were used without additional stents (drug coated balloon only concept). Therefore, we conducted a prospective registry to determine the technical success rate and the target lesion revascularisation (TLR) rate after 9 months following PCB treatment in coronary arteries with small

Zeymer U, *et al*. *Heart* 2014;**100**:311–316. doi:10.1136/heartjnl-2013-304881

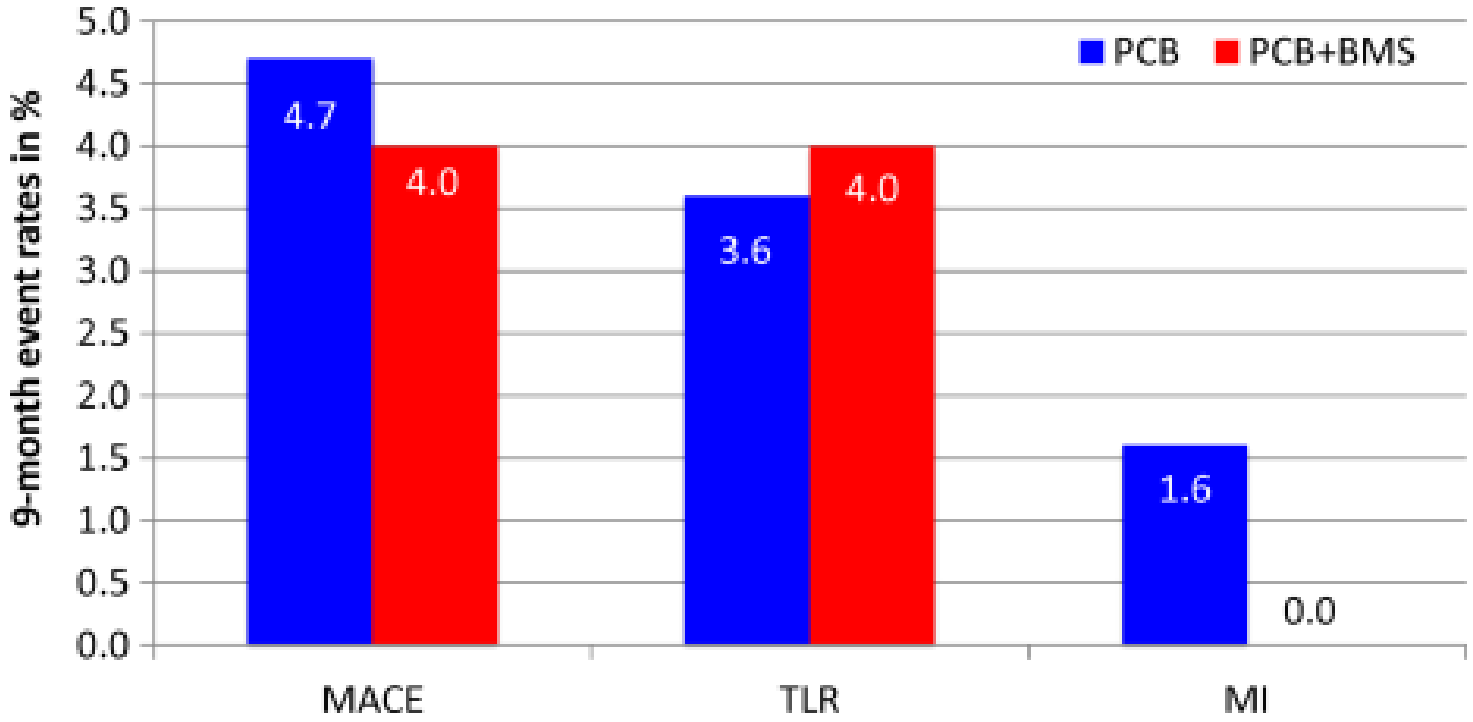


Figure 1 Clinical event rates during 9-month follow-up in patients with paclitaxel-coated balloon (PCB) only or PCB+bare metal stent (BMS). MACE, major adverse cardiac events; MI, myocardial infarction; TLR, target lesion revascularisation.

Zeymer U, *et al*. *Heart* 2014;**100**:311–316. doi:10.1136/heartjnl-2013-304881

Preliminary experience with drug-coated balloon angioplasty in primary percutaneous coronary intervention

Hee Hwa Ho, Julian Tan, Yau Wei Ooi, Kwok Kong Loh, Than Htike Aung, Nwe Tun Yin, Dasdo Antonius Sinaga, Fahim Haider Jafary, Paul Jau Lueng Ong

Hee Hwa Ho, Julian Tan, Yau Wei Ooi, Kwok Kong Loh, Than Htike Aung, Nwe Tun Yin, Dasdo Antonius Sinaga, Fahim Haider Jafary, Paul Jau Lueng Ong, Department of Cardiology, Tan Tock Seng Hospital, 308433 Singapore, Singapore

Author contributions: Ho HH designed this study, data analysis, data intepretation and writing manuscript; Tan J, Ooi YW, Loh KK, Jafary FH and Ong PJL designed this study, data interpretation; Aung TH, Yin NT and Sinaga DA collected data and data analysis.

Conflict-of-interest: The authors report no conflicts of interest.

primary percutaneous coronary intervention (PPCI). Between January 2010 to September 2014, 89 ST-elevation myocardial infarction patients (83% male, mean age 59 ± 14 years) with a total of 89 coronary lesions were treated with DCB during PPCI. Clinical outcomes are reported at 30 d follow-up. Left anterior descending artery was the most common target vessel for PCI (37%). Twenty-eight percent of the patients had underlying diabetes mellitus. Mean left ventricular ejection fraction was 44% ± 11%. DCB-only PCI was the predominant approach (96%) with the remaining 4% of patients receiving bail-out stenting. Thrombolysis in Myocardial Infarction (TIMI) 3 flow was successfully restored in 98% of patients. An average of 1.2 ± 0.5 DCB were used per patient, with mean DCB diameter of 2.6 ± 0.5 mm and average length of 23.2 ± 10.2 mm. At 30-d follow-up, there were 4 deaths (4.5%). No patients experienced abrupt closure of the infarct-related artery and there was no reported target-lesion failure. Our preliminary experience showed that DCB

World J Cardiol 2015 June 26; 7(6): 311-314
ISSN 1949-8462 (online)

in 71 patients (80%). Pre-procedural Thrombolysis in Myocardial Infarction (TIMI) flow was 0 in 70% of patients. At the end of PPCI, TIMI 3 flow was successfully restored in 98% of patients with residual stenosis of 29%.

DCB-only PCI was the predominant approach (96% of patients) with the remaining 4% of patients receiving bail-out stenting for significant recoil/ dissection after treatment with DCB. An average of 1.2 ± 0.5 DCB were used per patient, with mean DCB diameter of 2.6 ± 0.5 mm and average length of 23.2 ± 10.2 mm. The mean inflation pressure for DCB was 10 ± 3 atm and mean inflation time was 54 ± 22 s.

At 30-d follow-up, there were 4 deaths (4.5%). Three patients succumbed due to cardiogenic shock and 1 died of sepsis. No patient experienced abrupt closure of the infarct-related artery (IRA) and there was no reported TVR, target-vessel-MI or target lesion thrombosis.

World J Cardiol 2015 June 26; 7(6): 311-314
ISSN 1949-8462 (online)

Therapeutic Advances in Cardiovascular Disease Original Research

Drug coated balloon angioplasty in elderly patients with small vessel coronary disease

Ther Adv Cardiovasc Dis
2015, Vol. 9(6) 389–396
DOI: 10.1177/1753944715598714

Dasdo A. Sinaga, Hee Hwa Ho, Uwe Zeymer, Matthias Waliszewski, Fahim H. Jafary, Yau Wei Ooi, Jason K. K. Loh, Julian K. B. Tan and Paul J. L. Ong

Abstract

Background: Coronary angioplasty in advanced age is associated with higher rate of comorbidities and complications. Drug coated balloon only angioplasty (DCBA) has emerged as an alternative to treat small vessel coronary disease (SVCD), of reference vessel diameters <2.8 mm, with shorter duration of dual antiplatelet (DAPT). This is the first study to assess the DCBA efficacy in an elderly population with SVCD.

Methods and results: We performed a prospective study of 447 patients (334 patients aged <75 and 113 patients aged ⩾75 years old) acquired from the SeQuent Please Small Vessel 'Paclitaxel-Coated Balloon Only' registry. In the older age group, more patients have hypertension (89% *versus* 77%; $p = 0.006$), renal insufficiency (21% *versus* 6%; $p < 0.001$), atrial fibrillation (17% *versus* 7%; $p = 0.001$), and calcified lesions (33% *versus* 20%; $p = 0.006$). At 30 days, there was one myocardial infarction requiring target lesion revascularization (TLR) in the younger group. No major adverse cardiac event (MACE) was observed in the older group. At 9 months, the MACE rate in the younger group was 4.2% and 6.1% in the older group ($p = 0.453$), with TLR rates at 3.9% and 3.0% ($p = 0.704$) respectively. There was no cardiac death observed.

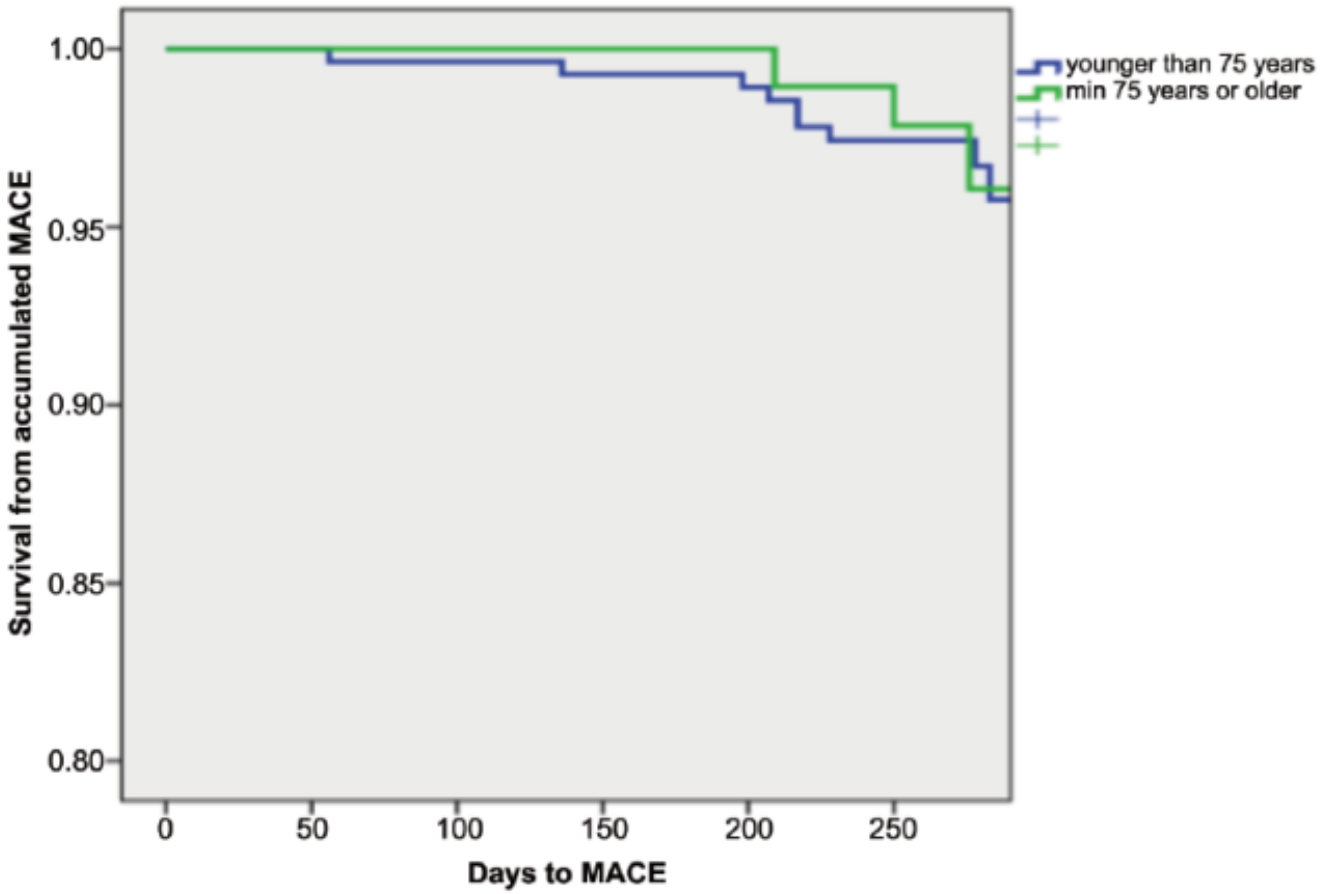


Figure 1. Kaplan–Meier curve of survival from MACE.
The blue and green lines represent group of patients < 75 and ⩾ 75 years of age respectively.
MACE, major adverse cardiac event (log rank $p = 0.527$).

Ther Adv Cardiovasc Dis
2015, Vol. 9(6) 389–396

DOI: 10.1111/joic.12333

PERCUTANEOUS CORONARY INTERVENTION

Drug-Coated Balloons: A Safe and Effective Alternative to Drug-Eluting Stents in Small Vessel Coronary Artery Disease

DASDO ANTONIUS SINAGA, M.D., HEE HWA HO, F.R.C.P., TIMOTHY JAMES WATSON, M.B.B.S., ALYSSA SIM, M.B.B.S., THUZAR TINT NYEIN, M.B.B.S., FAHIM H. JAFARY, M.D., JASON K. K. LOH, M.R.C.P., YAU WEI OOI, M.R.C.P., JULIAN K. B. TAN, M.R.C.P., and PAUL J. L. ONG, F.R.C.P.

From the Tan Tock Seng Hospital, Singapore

Background: *Drug-coated balloons (DCB) have been used to treat de novo small vessel coronary disease (SVD), with promising results and shorter dual antiplatelet therapy (DAPT) duration compared to drug-eluting stents (DES). We compared safety and effectiveness of the two treatments at 1 year.*
Methods: *We reviewed 3,613 angioplasty cases retrospectively from 2011 to 2013 and identified 335 patients with SVD treated with device diameter of ≤2.5 mm. DCB-only angioplasty was performed in 172 patients, whereas 163 patients were treated with second-generation DES.*
Results: *DCB patients had smaller reference vessel diameter (2.22 ± 0.30 vs. 2.44 ± 0.19 mm, $P < 0.001$) and received smaller devices (median diameter 2.25 vs. 2.50 mm, $P < 0.001$) compared to the DES group. DES-treated vessels had larger acute lumen gain (1.71 ± 0.48 mm) than DCB (1.00 ± 0.53 mm, $P < 0.001$). Half the patients had diabetes mellitus. While there were more patients presenting with acute coronary syndrome (ACS) in the DCB group (77.9% vs. 62.2%, $P = 0.013$), they received shorter DAPT (7.4 ± 4.7 vs. 11.8 ± 1.4 months, $P < 0.001$) than the DES group. The 1-year composite major adverse cardiac event rate was 11.6% in the DCB arm and 11.7% in the DES arm ($P = 1.000$), with target lesion revascularization rate of 5.2% and 3.7%, respectively, ($P = 0.601$).*
Conclusions: *In this high-risk cohort of patients, DCB-only angioplasty delivered good clinical outcome at 1 year. The results were comparable with DES-treated patients, but had the added benefit of a shorter DAPT regime.* (J Interven Cardiol 2016;29:454–460)

Variable	= 163)	P-Value
Composite MACE (n,		1.000
Death (n, %)		0.326
Myocardial infarction (		0.398
Target lesion revascula		0.601
Cerebrovascular accide		1.000

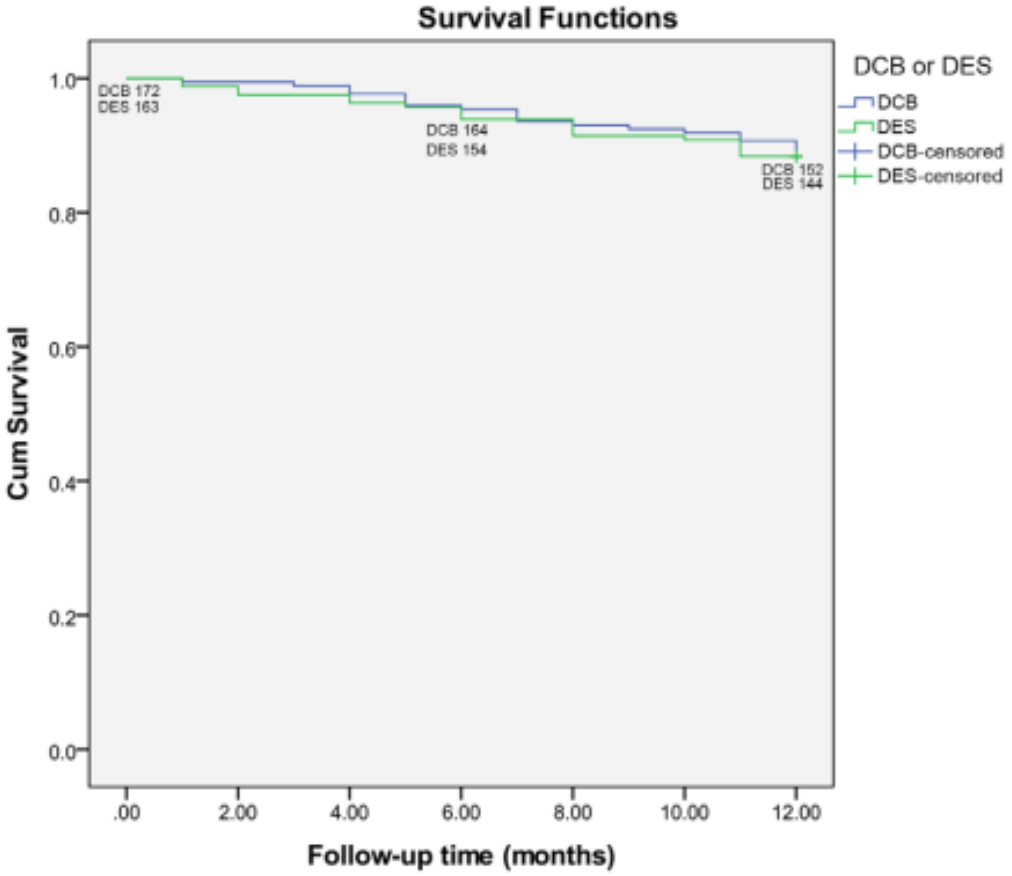


Figure 1. Kaplan–Meier curve in drug-coated balloon- and drug-eluting stent-treated patients over a follow-up period of 1 year. There was no difference in survival from major adverse cardiac events between the two groups during the observation period.

RESEARCH Open Access

The use of paclitaxel coated balloon (PCB) in acute coronary syndrome of small vessel de novo lesions: an analysis of a prospective 'real world' registry

Ahmad Syadi Mahmood Zuhdi[1*], Uwe Zeymer[2], Matthias Waliszewski[3], Martin Spiecker[4], Muhammad Dzafir Ismail[1], Michael Boxberger[3], Marcus Ferrari[5], Imran Zainal Abidin[1] and Wan Azman Wan Ahmad[1]

Abstract

Background: Paclitaxel-coated balloon (PCB) angioplasty in small vessel de novo lesions has favourable outcome and appears to be an alternative to stent implantation. However there is limitted data on its use specifically in small vessel acute coronary syndrome (ACS).

Methods: We analyse patients data from the SeQuent Please Small Vessel 'PCB only' Registry. It was an international, prospective, multicentre registry which enrolled patients with de novo lesions of small vessel diameter (≥2.0, ≤2.75 mm). Patients were divided into the ACS group and the non-ACS group and comparison made between the two groups. The primary end-point was clinically driven target lesion revascularisation (TLR) at 9 months. Secondary end-points were acute technical success, 30-day and 9-month major adverse cardiac events (death, myocardial infarction or TLR) (MACE) and the occurence of definite lesion and vessel thrombosis.

Results: A total of 447 patients were enrolled for this registry of which 105 (23.5 %) patients were ACS (STEMI and NSTEMI). The procedural success rate was 98.1 % in ACS group. The mean vessel diameter for the ACS and non-ACS group were 2.15 ± 0.36 and 2.14 ± 0.35 respectively. Similar mean lesion length of around 15.5 mm was recorded in both groups. Additional stenting was required in 9.3 % ACS and 6.5 % non-ACS, p = 0.308. Reasons for additional

Mahmood Zuhdi *et al. SpringerPlus (2016) 5:373*
DOI 10.1186/s40064-016-2014-y

Table 5 Clinical outcomes in patient populations in ACS and non-ACS patients

Variable	All patients	Non ACS	ACS	p value
Number of patients	447	334	113	–
Patients with clinical follow-up	384 (85.9 %)	301 (90.3 %)	83 (73.5 %)	0.021
Follow-up time (months)	9.4 ± 1.7	9.5 ± 1.7	9.4 ± 1.6	0.875
30-day MACE	1 (0.3 %)	1 (0.3 %)	0 (0.0 %)	0.599
30-day TLR	1 (0.3 %)	1 (0.3 %)	0 (0.0 %)	0.599
30-day MI	1 (0.3 %)	1 (0.3 %)	0 (0.0 %)	0.599
30-day cardiac death	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	–
9-month MACE	18 (4.7 %)	15 (5.0 %)	3 (3.6 %)	0.601
9-month TLR	14 (3.6 %)	13 (4.3 %)	1 (1.2 %)	0.180
9-month MI	7 (1.8 %)	4 (1.3 %)	3 (3.6 %)	0.168
9-month cardiac death	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	–
9-month vessel thrombosis	3 (0.8 %)	3 (1.1 %)	0 (0.0 %)	0.356
Target lesion	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	–
Target vessel	2 (0.5 %)	2 (0.7 %)	0 (0.0 %)	0.457
Non-target vessel	1 (0.3 %)	1 (0.3 %)	0 (0.0 %)	0.599

MACE major adverse cardiac events, *TLR* target lesion revascularisation, *MI* myocardial infarction

Mahmood Zuhdi *et al. SpringerPlus (2016) 5:373*
DOI 10.1186/s40064-016-2014-y

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], Houng Bang Liew [c,1], Tuomas T. Rissanen [d,1], Wan Azman Wan Ahmad [e,1], Ralf Weser [f,1], Telse Hauschild [g,1], Amin Ariff Nuruddin [h,1], Yvonne P. Clever [b,1], Hee Hwa Ho [i,1], Franz X. Kleber [j,*,1]

[a] *Charité - Universitätsmedizin Berlin, Berlin, Germany*
[b] *Universitätsklinikum des Saarlandes, Homburg, Germany*
[c] *Sabah Heart Centre, Kota Kinabalu, Malaysia*
[d] *North Karelia Central Hospital, Joensuu, Finland*
[e] *University of Malaya Medical Center, Kuala Lumpur, Malaysia*
[f] *Evangelisches Krankenhaus Paul Gerhardt Stift, Lutherstadt Wittenberg, 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*

ARTICLE INFO

Article history:
Received 4 August 2016
Accepted 25 September 2016
Available online 27 September 2016

Keywords:
Drug-coated balloon (DCB)
Chronic coronary total occlusion (CTO)
Percutaneous coronary intervention (PCI)
Paclitaxel
Drug-eluting stent (DES)

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 lumen diameter and late luminal changes were assessed.

International Journal of Cardiology 225 (2016) 262–267

A mean number of 1.94 ± 0.78 DCBs was used to cover the formally occluded segment. Mean overall DCB length was 50.42 ± 18.47 mm (1 missing). DCBs were sized according to a balloon-to-vessel ratio of 0.8–1.0 and the mean diameter of DCB was 2.55 ± 0.42 mm. Duration of inflation was at least 30 s in all DCBs and the maximal inflation pressure was 8.81 ± 2.54 bar.

According to the German Consensus Group recommendations [21, 22], the success of recanalization was sufficient for DCB use in 79.4% (n = 27) of cases. In 4 cases (11.8%), a residual stenosis of more than 40% was present according to QCA. Three patients (8.8%) had coronary dissections type C. For one of them the procedure was stopped for that reason and repeated several weeks later. The dissection was no longer visible during the second intervention and the recanalization was conducted successfully. According to the Consensus criteria, the patient would have been stented at the first intervention and therefore was counted as not done according to the Consensus criteria (Fig. 2).

After PCI, most patients (n = 30) received DAPT for at least four weeks with lifelong continuation of aspirin once daily afterwards. Patients who had contraindications for DAPT, such as higher risk of bleeding, received only aspirin lifelong (n = 4).

International Journal of Cardiology 225 (2016) 262–267

2017 ESC focused update on dual antiplatelet therapy in coronary artery disease developed in collaboration with EACTS

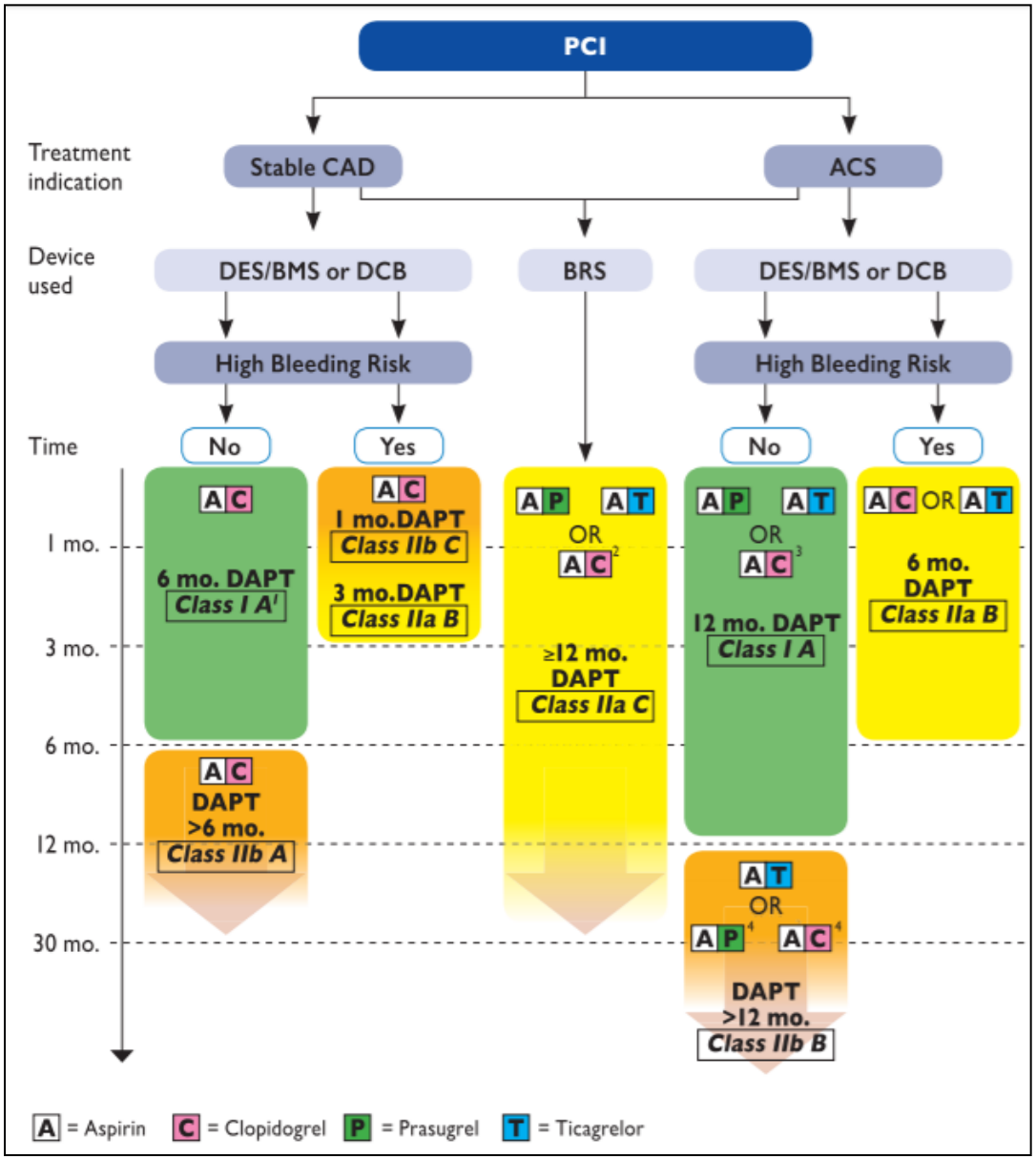
The Task Force for dual antiplatelet therapy in coronary artery disease of the European Society of Cardiology (ESC) and of the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Marco Valgimigli* (Chairperson) (Switzerland), Héctor Bueno (Spain), Robert A. Byrne (Germany), Jean-Philippe Collet (France), Francesco Costa (Italy), Anders Jeppsson[1] (Sweden), Peter Jüni (Canada), Adnan Kastrati (Germany), Philippe Kolh (Belgium), Laura Mauri (USA), Gilles Montalescot (France), Franz-Josef Neumann (Germany), Mate Petricevic[1] (Croatia), Marco Roffi (Switzerland), Philippe Gabriel Steg (France), Stephan Windecker (Switzerland), and Jose Luis Zamorano (Spain)

Additional Contributor: Glenn N. Levine (USA)

Document Reviewers: Lina Badimon (CPG Review Coordinator) (Spain), Pascal Vranckx (CPG Review Coordinator) (Belgium), Stefan Agewall (Norway), Felicita Andreotti (Italy), Elliott Antman (USA), Emanuele Barbato (Italy), Jean-Pierre Bassand (France), Raffaele Bugiardini (Italy), Mustafa Cikirikcioglu[1] (Switzerland), Thomas Cuisset (France), Michele De Bonis (Italy), Victora Delgado (The Netherlands),

European Heart Journal (2017) **0**, 1–48
doi:10.1093/eurheartj/ehx419



European Heart Journal (2017) **0**, 1–48
doi:10.1093/eurheartj/ehx419

So many balloons! Paclitaxel to Sirolimus

Table 1. Established an … **nologies.**

Drug-eluting balloon	IC/	t	Dose density (µg/mm²)
PACCOCATH®	IC/		3
Sequent Please™	IC		3
DIOR II®	IC		3
Freeway™	SFA		3
Elutax™	IC		2
IN.PACT Falcon™	IC		3
IN.PACT Amphirion™	BTK		
IN.PACT Pacific™	SFA		
IN.PACT Admiral™	SFA		
Moxy™	IC/		2
Pantera Lux™	IC		3
Advance 18PTx™	PI		?

BTHC: Butyryl-trihexyl citrate; BT… SFA: Superficial femoral artery. … *ention; PTx: Paclitaxel;*

Summary

- DEB – a useful -> essential part of the cathlab inventory
- Wider applications in the future
- New techniques for use
- More research in conditions (disease burden) more commonly found in developing countries of Asia eg DM-CAD
- Invitations for collaboration

ASEAN to APSC – local to global

Asian Pacific Society of Cardiology

Home | About APSC | Member Societies | Congresses | Fellowship

Home > Scientific Advisory Board

Scientific Advisory Board

APSC SCIENTIFIC ADVISORY BOARD MEMBERS 2015-2018

Chairperson	Dr KK Yeo
member	Dr Wael Almahmeed
member	Dr Piyamitr Sritrara
member	Dr Jiunn-Lee Lin
member	Dr Eugene Reyes
member	Dr Alan Fong Yean Yip
member	Dr Koji Maemura

APSC Fellowship Online Center

GLOBAL HEART

- Submit Papers
- Editorial Board

APSC2017 Highlights

Scientific Advisory Board

APSC-ESC Heart Failure Survey

- Click to Enter Survey

Sarawak General Hospital

Disclaimer

Research/Educational Grants/Lecture Honoraria from Ministry of Health Malaysia, Astra Zeneca, Boehringer Ingelheim, B.Braun, Medtronic, Merck AG, MSD, Novartis AG, Orbus Neich, Pfizer Ltd, Roche Diagnositics, Siemens Diagnositics, Sanofi-Aventis. St Jude Medical.