PALAIS DES CONGRES BIARRITZ 8/9/10 JUIN 2016
www.appac.fr

APPAC
ACTUALISATIONS ET PERSPECTIVES EN PATHOLOGIE CARDIOVASCULAIRE

Actualités du ballon actif

F. De Poli CH Haguenau

PLAN

- Les produits
- Les indications
- Les études
- Les perspectives

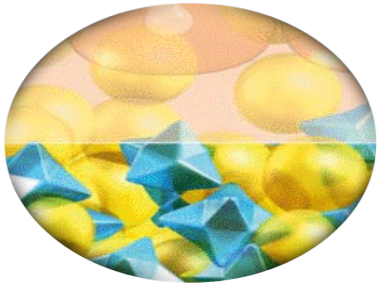
Des ballons, des coatings et le paclitaxel

DEB Brand	In.Pact ™ Falcon ™ DEB	SeQuent Please ™ DEB	Cotavance ™ DEB	Pantera Lux ™ DEB	DIOR II ™ DEB	Protege ™ DEB
						
Drug Carrier (Type)	Urea (Biocompatible Spacer)	Iopromide (Contrast Media)	Iopromide (Contrast Media)	BTHC (Contrast Media Analog)	Shellac (Resin)	None

SEQUENT PLEASE NEO

Qu'est ce qui a changé ?

→ Franchissement des lésions optimisé
→ Portfolio élargi intégrant désormais les longueurs 35 et 40 mm et le diamètre 2.25 mm



Qu'est ce qui ne change pas ?

→ La technologie Paccocath (Paclitaxel/Iopromide) validée par de nombreuses études cliniques
→ la nécessité de bien préparer les lésions

Recommandations ESC 2014

Repeat revascularization

Recommendations	Class[a]	LoE[b]	Ref[c]
Early post-operative ischaemia and graft failure			
Coronary angiography is recommended for patients with: • symptoms of ischaemia and/or abnormal biomarkers suggestive of perioperative myocardial infarction • ischaemic ECG changes indicating large area of risk • new significant wall motion abnormalities • haemodynamic instability.	I	C	
It is recommended to make the decision on redo CABG or PCI by *ad hoc* consultation in the Heart Team and based on feasibility of revascularization, area at risk, comorbidities and clinical status.	I	C	
PCI should be considered over re-operation in patients with early			
If PCI is performed, revascularization of the native vessels or IMA diseased SVGs should be considered.			
Disease progression and late graft failure			
Repeat revascularization is indicated in patients with severe sympto therapy if technically feasible.			
PCI should be considered as a first choice if technically feasible, rat			
PCI of the bypassed native artery should be the preferred approac			
IMA, if available, is the conduit of choice for re-do CABG.			
Re-do CABG should be considered for patients without a patent I			
Re-do CABG may be considered in patients with lesions and anato PCI.			
PCI may be considered in patients with patent IMA graft if technica			
DES are recommended for PCI of SVGs.			
Distal protection devices are recommended for PCI of SVG lesions if technically feasible.	I	B	484,485
Restenosis			
Repeat PCI is recommended, if technically feasible.	I	C	
DES are recommended for the treatment of in-stent re-stenosis (within BMS or DES).	I	A	501,502,508 511,524
Drug-coated balloons are recommended for the treatment of in-stent restenosis (within BMS or DES).	I	A	507– 511,524
IVUS and/or OCT should be considered to detect stent-related mechanical problems.	IIa	C	
Stent thrombosis			
Emergency PCI is recommended to restore stent and vessel patency and myocardial reperfusion.	I	C	
DAPT with use of potent $P2Y_{12}$ inhibitors (prasugrel or ticagrelor) is recommended over clopidogrel	I	C	
Adjunctive thrombus aspiration and high-pressure balloon dilation should be considered.	IIa	C	
IVUS and/or OCT should be considered to detect stent-related mechanical problems.	IIa	C	
Hybrid procedures			
Hybrid procedure, defined as consecutive or combined surgical and percutaneous revascularization may be considered in specific patient subsets at experienced centres.	IIb	C	

Restenosis

Repeat PCI is recommended, if technically feasible.	I	C	
DES are recommended for the treatment of in-stent re-stenosis (within BMS or DES).	I	A	501,502,508 511,524
Drug-coated balloons are recommended for the treatment of in-stent restenosis (within BMS or DES).	I	A	507– 511,524
IVUS and/or OCT should be considered to detect stent-related mechanical problems.	IIa	C	

Les utilisations les plus fréquentes

- Resténose intrastent nu et actif,
- Branche fille dans les dilatations de bifurcations,
- Les petits vaisseaux,
- Le vasculaire périphérique.

Les publications (2015 et 2016)

- Beaucoup de registres, quelques essais randomisés,
- Effectifs faibles, données disparates,
- Mais beaucoup de convictions,
- Florilège des plus récentes.

Resténose intrastent DES

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
© 2015 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER INC.

VOL. 66, NO. 1, 2015
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2015.04.063

A Prospective Randomized Trial of Drug-Eluting Balloons Versus Everolimus-Eluting Stents in Patients With In-Stent Restenosis of Drug-Eluting Stents

The RIBS IV Randomized Clinical Trial

Fernando Alfonso, MD,* María Jose Pérez-Vizcayno, MD,† Alberto Cárdenas, MD,† Bruno García del Blanco, MD,‡ Arturo García-Touchard, MD,§ José Ramón López-Mínguez, MD,‖ Amparo Benedicto, MD,* Mónica Masotti, MD,¶ Javier Zueco, MD,# Andrés Iñiguez, MD,** Maite Velázquez, MD,†† Raúl Moreno, MD,‡‡ Vicente Mainar, MD,§§ Antonio Domínguez, MD,‖‖ Francisco Pomar, MD,¶¶ Rafael Melgares, MD,## Fernando Rivero, MD,* Pilar Jiménez-Quevedo, MD,† Nieves Gonzalo, MD,† Cristina Fernández, MD,‡ Carlos Macaya, MD,‡ for the RIBS IV Study Investigators (under the auspices of the Interventional Cardiology Working Group of the Spanish Society of Cardiology)

ABSTRACT

BACKGROUND Treatment of patients with drug-eluting stent (DES) in-stent restenosis (ISR) remains a major challenge.

OBJECTIVES This study evaluated the comparative efficacy of drug-eluting balloons (DEB) and everolimus-eluting stents (EES) in patients presenting with DES-ISR.

METHODS The study design of this multicenter randomized clinical trial assumed superiority of EES for the primary endpoint, in-segment minimal lumen diameter at the 6- to 9-month angiographic follow-up.

RESULTS A total of 309 patients with DES-ISR from 23 Spanish university hospitals were randomly allocated to DEB (n = 154) or EES (n = 155). At late angiography (median 247 days; 90% of eligible patients), patients in the EES arm had a significantly larger minimal lumen diameter (2.03 ± 0.7 mm vs. 1.80 ± 0.6 mm; p < 0.01) (absolute mean difference: 0.23 mm; 95% CI: 00.7 to 0.38), net lumen gain (1.28 ± 0.7 mm vs. 1.01 ± 0.7 mm; p < 0.01), and lower percent diameter stenosis (23 ± 22% vs. 30 ± 22%; p < 0.01) and binary restenosis rate (11% vs. 19%; p = 0.06), compared with patients in the DEB arm. Consistent results were observed in the in-lesion analysis. At the 1-year clinical follow-up (100% of patients), the main clinical outcome measure (composite of cardiac death, myocardial infarction, and target vessel revascularization) was significantly reduced in the EES arm (10% vs. 18%; p = 0.04; hazard ratio: 0.58; 95% CI: 0.35 to 0.98), mainly driven by a lower need for target vessel revascularization (8% vs. 16%; p = 0.035).

CONCLUSIONS In patients with DES-ISR, EES provided superior long-term clinical and angiographic results compared with DEB. (Restenosis Intra-Stent of Drug-Eluting Stents: Drug-Eluting Balloon vs Everolimus-Eluting Stent [RIBS IV]; NCT01239940) (J Am Coll Cardiol 2015;66:23-33) © 2015 by the American College of Cardiology Foundation.

- JACC 2015
- Etude multicentrique randomisée ttt de ISR par DEB (Sequent) 154 patients / EES (Xience)155 patients
- Endpoint primaire : diamètre min à 9 mois EES >DEB p<0,01
- Resténose 11 vs 19% p=0,06
- MACE 10%vs 18% p=0,04

Resténose intrastent DES

International Journal of Cardiology 203 (2016) 690–696

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Treatment of drug-eluting stents in-stent restenosis with paclitaxel-coated balloon angioplasty: Insights from the French "real-world" prospective GARO Registry

V. Auffret [a,b,c,1], J. Berland [d,1], P. Barragan [e,1], M. Waliszewski [f,1], L. Bonello [g,1], N. Delarche [h,1], A. Furber [i,1], F. Albert [j,1], D. Carrié [k,1], H. Eltchaninoff [l,1], M. Pansieri [m,1], M. Schneeberger [n,1], C. Piot [o,1], P. Marcollet [p,1], M. Bedossa [a,b,c,e,1]

[a] CHU Rennes, Service de Cardiologie et Maladies Vasculaires, Rennes, F-35000, France
[b] INSERM, U1099, Rennes, F-35000, France
[c] Université de Rennes 1, LTSI, Rennes, F-35000, France
[d] Clinique Saint Hilaire Rouen, Service de Cardiologie, F-76000, France
[e] Polyclinique Les Fleurs Ollioules, Service de Cardiologie, F-83190, France
[f] Medical Scientific Affairs, B. Braun Melsungen AG, Germany
[g] Département de Cardiologie Centre Hospitalo, Universitaire Nord, Marseille, F-13915, France
[h] Centre Hospitalier de Pau, Service de Cardiologie, F-64000, France
[i] Centre Hospitalier Universitaire Angers, Service de Cardiologie, F-49100, France
[j] Centre Hospitalier de Chartres, Service de Cardiologie, F-28018, France
[k] CHU de Toulouse, Service de Cardiologie, F-31059, France
[l] CHU de Rouen, Service de Cardiologie, F-76000, France
[m] Centre Hospitalier Avignon, Service de Cardiologie, F-84000, France
[n] Hôpital Albert Schweitzer, Colmar, Service de Cardiologie, F-68024, France
[o] CHU de Montpellier, Service de Cardiologie, F-34090, France
[p] Centre Hospitalier de Bourgon, Service de Cardiologie, F-18000, France

ARTICLE INFO

Article history:
Received 11 December 2014
Received in revised form 3 August 2015
Accepted 4 November 2015
Available online 06 November 2015

Keywords:
Drug-eluting stent in-stent restenosis
Paclitaxel-coated balloon
Target lesion revascularization

ABSTRACT

Background: Data about paclitaxel-eluting balloon (PCB) angioplasty to treat drug-eluting stents (DES) in-stent restenosis (ISR) were mainly collected in selected patient populations in the setting of randomized trials. The main goal of this prospective registry was to confirm the positive findings of these studies in an unselected population in clinical practice.

Methods: Consecutive patients with DES-ISR treated by PCB angioplasty were recruited in this prospective real-world registry. The primary endpoint was clinically driven target-lesion revascularization (TLR) at 9 months. Secondary endpoints included acute technical success, in-hospital outcomes, 9-month major adverse cardiac events (MACE) a composite of death, myocardial infarction (MI) and TLR and the occurrence of target vessel revascularization.

Results: A total of 206 patients (67.7 ± 10.2 years, 80.6% male, 41.3% diabetics) with 210 lesions were recruited. Unstable coronary artery disease was present in 55.3% of patients. The time from DES implantation to DES-ISR was 3.0 ± 2.4 years. Quantitative analyses revealed that patterns of treated DES-ISR were focal in 55.7% and diffuse in 44.3%. The reference diameter was 2.75 ± 0.64 mm. The 9-month follow-up rate was 90.8% (187/206). At 9 months, the TLR rate was 7.0% (13/187) whereas the rates for MACE, MI and cardiac death were 10.7% (20/187), 4.8% (9/187) and 2.1% (4/187) respectively. Results were consistent in patients with paclitaxel and non-paclitaxel-eluting stents (PES) ISR.

Conclusion: This large prospective registry demonstrated acceptable rates of TLR and MACE at 9 months after treatment of DES-ISR by PCB angioplasty. PCB angioplasty was equally effective in patients with PES-ISR and non PES-ISR.

- IJC 2015
- Registre prospectif français : ttt ISR DES par DEB (Sequent), 206 patients, 210 lésions (diamètre moyen des vx 2,77mm)
- Endpoint primaire TLR 9 mois ➔7%
- Endpoint secondaire à 9 mois MACE➔10,4% , IDM➔4,8% et décès cardiovasculaires ➔2,1%
- Succès primaire ACT 98,6%, stent complémentaire 2,9%
- Donc de bons résultats à court et moyen terme .

Resténose intrastent DES

Catheterization and Cardiovascular Interventions 00:00–00 (2016)

Original Studies

Two-Year Results and Subgroup Analyses of the PEPCAD China In-Stent Restenosis Trial: A Prospective, Multicenter, Randomized Trial for the Treatment of Drug-Eluting Stent In-Stent Restenosis

Bo Xu,[1] MBBS, Jie Qian,[1] MD, Junbo Ge,[2*] MD, Jian'an Wang,[3] MD, Fang Chen
Jiyan Chen,[5] MD, Meng Wei,[6] MD, Yundai Chen,[7] MD, Yuejin Yang,[1] MD, an
Runlin Gao,[1*] MD, on behalf of PEPCAD China ISR investigators

Background: The PEPCAD China ISR trial investigated the safety and efficacy of paclitaxel-coated balloon (PCB) angioplasty in an Asian patient population with coronary drug-eluting stent in-stent restenosis (DES-ISR). **Methods:** A total of 220 patients with coronary DES-ISR were treated with PCB angioplasty or with paclitaxel-eluting stents (PES). This randomized (1:1), single-blind prospective multicenter trial in a Chinese population used 9-month in-segment late lumen loss (LLL) as the primary endpoint. Secondary endpoints included the 24-month clinical event rates. **Results:** Both treatment groups were similar in terms of patient, lesion, or procedural characteristics. After the 12-month follow-up evaluation, additional clinical events only occurred in the PES study group. The combined rate of all-cause mortality and myocardial infarction (MI) in the PCB group was significantly lower than that in the PES group (3.7% vs. 11.8%, $P = 0.03$). Additional subgroup analyses of 9-month in-segment LLL and 2-year target lesion failure in patients with diabetes, small vessels, diffuse ISR, and stent margin restenosis did not show more favorable results for one specific treatment group. **Conclusions:** The 2-year follow-up demonstrated sustained long-term clinical efficacy for both devices. PCB angioplasty was associated with significantly lower overall and cardiovascular mortality/MI rates in patients with DES-ISR lesions while avoiding the use of additional metal layers for drug release (ClinicalTrials.gov identifier: NCT 01622075). ©2016 Wiley Periodicals, Inc.

Key words: paclitaxel-coated balloon; paclitaxel-eluting stents; drug-eluting stent; in-stent restenosis

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 7, NO. 2, 2014
© 2014 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION ISSN 1936-8798/$34.00
PUBLISHED BY ELSEVIER INC. http://dx.doi.org/10.1016/j.jcin.2013.08.011

A Prospective, Multicenter, Randomized Trial of Paclitaxel-Coated Balloon Versus Paclitaxel-Eluting Stent for the Treatment of Drug-Eluting Stent In-Stent Restenosis

Results From the PEPCAD China ISR Trial

Bo Xu, MBBS,* Runlin Gao, MD,* Jian'an Wang, MD,† Yuejin Yang, MD,*
Shaoliang Chen, MD,‡ Bin Liu, MD,§ Fang Chen, MD,|| Zhanquan Li, MD,¶
Yaling Han, MD,# Guosheng Fu, MD,** Yelin Zhao, MMSc,* Junbo Ge, MD†† for the PEPCAD China ISR Trial Investigators

Beijing, Hangzhou, Nanjing, Changchun, Shenyang, and Shanghai, China

Objectives The intention of the PEPCAD China ISR (A Prospective, Multicenter, Randomized Trial of Paclitaxel-Coated versus Paclitaxel-Eluting Stent for the Treatment of Drug-Eluting Stent In-Stent Restenosis) was to demonstrate the efficacy of paclitaxel-coated balloon (PCB) angioplasty in a non-European patient population with coronary drug-eluting stent in-stent restenosis (DES-ISR).

Background The treatment of DES-ISR is still challenging with no established best strategy. Moreover, there is no study on the effect of PCB in the treatment of ISR in the Chinese population.

Methods PEPCAD China ISR was a 220-patient randomized (1:1), single-blind prospective multicenter trial conducted in China. Patients with coronary DES-ISR received either PCB (SeQuent Please, B. Braun Melsungen AG, Melsungen, Germany) or paclitaxel-eluting stent (Taxus Liberté, Boston Scientific, Natick, Massachusetts) treatment. The primary endpoint was in-segment late lumen loss at 9 months.

Results There were no significant baseline differences between both treatment groups in terms of patient, lesion, or procedural characteristics. At 9 months, in-segment late lumen loss in the PCB group was noninferior to that of the paclitaxel-eluting stent group (0.46 ± 0.51 mm vs. 0.55 ± 0.61 mm; difference: −0.06 mm with 95% confidence interval: −0.23 to 0.10; p for noninferiority = 0.0005). The 9-month rate of binary restenosis and 12-month composite clinical event rates were not significantly different between groups.

Conclusions In a randomized trial of 220 patients, angioplasty with a PCB was noninferior to paclitaxel-eluting stent implantation when used to treat DES-ISR. On the basis of these, as well as previous randomized trial data, PCB angioplasty offers an effective treatment for DES-ISR without the necessity of implanting additional metal layers for drug release. (A Safety and Efficacy Study of Paclitaxel-Eluting Balloon to Paclitaxel-Eluting Stent [PEPCAD]; NCT01622075) (J Am Coll Cardiol Intv 2014;7:204–11) © 2014 by the American College of Cardiology Foundation

- Randomisé multicentrique DEB vs **PES** 220 patients
- Endpoint primaire LL à 9 mois : pas de différence (non inf. comme dans ISARE Desire 3)
- End point secondaires, évènements cliniques, IDM et décès (3,7 vs 11,8% p=0,03)(pas de décès dans le groupe DEB vs 4 dans le groupe stent)
- TLR id

Resténose intrastent nu

Journal of the American College of Cardiology
© 2014 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 63, No. 14, 2014
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.12.006

A Randomized Comparison of Drug-Eluting Balloon Versus Everolimus-Eluting Stent in Patients With Bare-Metal Stent–In-Stent Restenosis

The RIBS V Clinical Trial (Restenosis Intra-stent of Bare Metal Stents: Paclitaxel-eluting Balloon vs. Everolimus-eluting Stent)

Fernando Alfonso, MD,*† María José Pérez-Vizcayno, MD,† Alberto Cárdenas, MD,† Bruno García del Blanco, MD,† Bernhard Seidelberger, MD,* Andrés Iñiguez, MD,§ Manuel Gómez-Recio, MD,‖ Mónica Masotti, MD,¶ M. Teresa Velázquez, MD,# Juan Sanchís, MD,** Arturo García-Touchard, MD,†† Javier Zueco, MD,‡‡ Armando Bethencourt, MD,§§ Rafael Melgares, MD,‖‖ Angel Cequier, MD,¶¶ Antonio Domínguez, MD,## Vicente Mainar, MD,*** José R. López-Mínguez, MD,††† José Moreu, MD,‡‡‡ Vicens Martí, MD,§§§ Raúl Moreno, MD,‖‖‖ Pilar Jiménez-Quevedo, MD,† Nieves Gonzalo, MD,† Cristina Fernández, MD,† Carlos Macaya, MD,† for the RIBS V Study Investigators, under the auspices of the Working Group on Interventional Cardiology of the Spanish Society of Cardiology

Madrid, Barcelona, Vigo, Almería, Valencia, Santander, Palma de Mallorca, Granada, Málaga, Alicante, Badajoz, and Toledo, Spain

Objectives This study sought to compare the efficacy of drug-eluting balloons (DEB) with that of everolimus-eluting stents (EES) in patients with bare-metal stents (BMS) in-stent restenosis (ISR).

Background Treatment of patients with ISR remains a challenge.

Methods This was a prospective, multicenter, randomized trial comparing DEB with EES in patients with bare-metal stents (BMS) in-stent restenosis (ISR). The primary endpoint was the minimal lumen diameter at 9 months' follow-up.

Results A total of 189 patients with BMS-ISR from 25 Spanish sites were included (95 were allocated to DEB and 94 to EES). Procedural success was achieved in all patients. At late angiography (median 249 days; 92% of eligible patients), patients in the EES arm had a significantly larger minimal lumen diameter (2.36 ± 0.6 mm vs. 2.01 ± 0.6 mm, $p < 0.001$; absolute mean difference: 0.35 mm; 95% confidence interval [CI]: 0.16 to 0.53) and a lower percent of diameter stenosis (13 ± 17% vs. 25 ± 20%, $p < 0.001$). However, late loss (0.04 ± 0.5 mm vs. 0.14 ± 0.5 mm, $p = 0.14$) and binary restenosis rate (4.7% vs. 9.5%, $p = 0.22$) were very low and similar in both groups. Clinical follow-up (median 365 days) was obtained in all (100%) patients. Occurrences of the combined clinical outcome measure (cardiac death, myocardial infarction, and target vessel revascularization; 6% vs. 8%; hazard ratio [HR]: 0.76; 95% CI: 0.26 to 2.18, $p = 0.6$) and the need for target vessel revascularization (2% vs. 6%; HR: 0.32; 95% CI: 0.07 to 1.59, $p = 0.17$) were similar in the 2 groups.

Conclusions In patients with BMS-ISR, both DEB and EES provided excellent clinical results with a very low rate of clinical and angiographic recurrences. However, compared with DEB, EES provide superior late angiographic findings.

- Prospectif multicentrique DEB (sequent)vs DES(xience) dans ISR de BMS
- Diamètre minimal à 9 mois: EES>DEB (2, 36 vs 2,01 p<0,001) (pas de diff. pour le late loss)
- À 1 an critère combiné : décès, IDM, TLR 6 % vs 8% NS
- Evénement dans groupe EES surtout IDM en phase hospitalière pertes de branches

Conclusions In patients with BMS-ISR, both DEB and EES provided excellent clinical results with a very low rate of clinical and angiographic recurrences. However, compared with DEB, EES provide superior late angiographic findings.
(Restenosis Intra-stent of Bare Metal Stents: Paclitaxel-eluting Balloon vs. Everolimus-eluting Stent [RIBS V]; NCT01239953) (J Am Coll Cardiol 2014;63:1378–86)

Méta-analyse traitement resténose 1

JACC: CARDIOVASCULAR INTERVENTIONS
© 2015 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER INC.

VOL. 8, NO. 3, 2015
ISSN 1936-8798/$36.00
http://dx.doi.org/10.1016/j.jcin.2014.09.023

CLINICAL RESEARCH

CORONARY

Comparison Among Drug-Eluting Balloon, Drug-Eluting Stent, and Plain Balloon Angioplasty for the Treatment of In-Stent Restenosis

A Network Meta-Analysis of 11 Randomized, Controlled Trials

Joo Myung Lee, MD, MPH,* Jonghanne Park, MD,* Jeehoon Kang, MD,* Ki-Hyun Jeon, MD,* Ji-hyun Jung, MD,* Sang Eun Lee, MD, PhD,* Jung-Kyu Han, MD, PhD,* Hack-Lyoung Kim, MD, PhD,† Han-Mo Yang, MD, PhD,* Kyung Woo Park, MD, PhD,* Hyun-Jae Kang, MD, PhD,* Bon-Kwon Koo, MD, PhD,* Hyo-Soo Kim, MD, PhD*‡

ABSTRACT

OBJECTIVES A Bayesian network meta-analysis was performed comparing the efficacy and safety of drug-eluting balloons (DEB), drug-eluting stents (DES), or plain old balloon angioplasty (POBA) for treatment of in-stent restenosis (ISR).

BACKGROUND Optimal treatment options for ISR have not been well established.

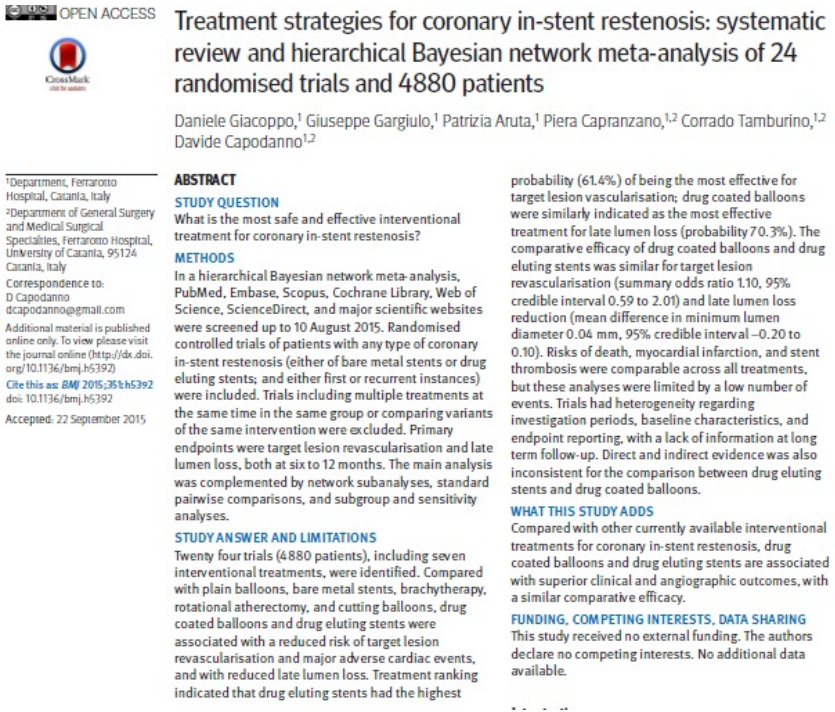
METHODS Randomized, controlled trials comparing DEB, DES, and POBA for the treatment of ISR after percutaneous coronary intervention with bare metal stent or DES were included. The primary outcome was target lesion revascularization (TLR). The pairwise posterior median odds ratio (OR) with 95% credible interval (CrI) was the effect measure.

RESULTS This analysis included 2,059 patients from 11 RCTs. The risk of TLR was markedly lower in patients treated with DEB (OR: 0.22, 95% CrI: 0.10 to 0.42) or DES (OR: 0.24, 95% CrI: 0.11 to 0.47) than in those treated with POBA in a random-effects model. In a comparison of DEB and DES, the risk of TLR (OR: 0.92, 95% CrI: 0.43 to 1.90) was similar. The risk of MI or all-cause mortality was lowest in the DEB group compared with the DES and POBA groups, which did not meet statistical significance. The risk of major adverse cardiac events, which was mainly driven by TLR, was also significantly lower in the DEB or and DES group (OR: 0.28, 95% CrI: 0.14 to 0.53) than in the POBA group, but it was similar between the DEB and DES groups (OR: 0.84, 95% CrI: 0.45 to 1.50). The probability of being ranked as the best treatment was 59.9% (DEB), 40.1% (DES), and 0.1% (POBA) in terms of TLR, whereas it was 63.0% (DEB), 35.3% (POBA), and 1.7% (DES) in terms of MI.

CONCLUSIONS Local drug delivery by DEB or DES for ISR lesions was markedly better than POBA in preventing TLR, but not for MI or mortality. Among the 2 different strategies of drug delivery for ISR lesions, treatment with DEB showed a trend of less development of MI than did treatment with DES. (J Am Coll Cardiol Intv 2015;8:382–94) © 2015 by the American College of Cardiology Foundation.

- JACC 2015
- DES/DEB/B conventionnel dans ISR 1er endpoint TLR
- 2059 patients dans 11 études randomisées
- DEB,DES> B conventionnel
- IDM et décès toute cause DES < DEB mais ns
- Rang ttt pour TLR DEB>DES>B conv.
- Rang ttt pour IDM DEB>B conv.>DES (pertes de branches, durée DAPT)

Meta-analyse traitement resténose 2



OPEN ACCESS

Treatment strategies for coronary in-stent restenosis: systematic review and hierarchical Bayesian network meta-analysis of 24 randomised trials and 4880 patients

Daniele Giacoppo,[1] Giuseppe Gargiulo,[1] Patrizia Aruta,[1] Piera Capranzano,[1,2] Corrado Tamburino,[1,2] Davide Capodanno[1,2]

[1]Department, Ferrarotto Hospital, Catania, Italy
[2]Department of General Surgery and Medical Surgical Specialties, Ferrarotto Hospital, University of Catania, 95124 Catania, Italy
Correspondence to: D Capodanno dcapodanno@gmail.com

Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/bmj.h5392)
Cite this as: *BMJ* 2015;351:h5392 doi: 10.1136/bmj.h5392
Accepted: 22 September 2015

ABSTRACT

STUDY QUESTION
What is the most safe and effective interventional treatment for coronary in-stent restenosis?

METHODS
In a hierarchical Bayesian network meta-analysis, PubMed, Embase, Scopus, Cochrane Library, Web of Science, ScienceDirect, and major scientific websites were screened up to 10 August 2015. Randomised controlled trials of patients with any type of coronary in-stent restenosis (either of bare metal stents or drug eluting stents; and either first or recurrent instances) were included. Trials including multiple treatments at the same time in the same group or comparing variants of the same intervention were excluded. Primary endpoints were target lesion revascularisation and late lumen loss, both at six to 12 months. The main analysis was complemented by network subanalyses, standard pairwise comparisons, and subgroup and sensitivity analyses.

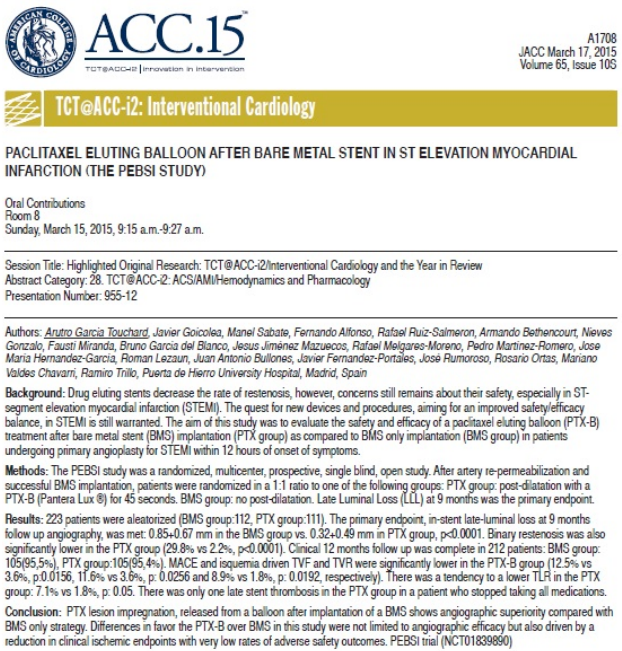
STUDY ANSWER AND LIMITATIONS
Twenty four trials (4880 patients), including seven interventional treatments, were identified. Compared with plain balloons, bare metal stents, brachytherapy, rotational atherectomy, and cutting balloons, drug coated balloons and drug eluting stents were associated with a reduced risk of target lesion revascularisation and major adverse cardiac events, and with reduced late lumen loss. Treatment ranking indicated that drug eluting stents had the highest probability (61.4%) of being the most effective for target lesion vascularisation; drug coated balloons were similarly indicated as the most effective treatment for late lumen loss (probability 70.3%). The comparative efficacy of drug coated balloons and drug eluting stents was similar for target lesion revascularisation (summary odds ratio 1.10, 95% credible interval 0.59 to 2.01) and late lumen loss reduction (mean difference in minimum lumen diameter 0.04 mm, 95% credible interval −0.20 to 0.10). Risks of death, myocardial infarction, and stent thrombosis were comparable across all treatments, but these analyses were limited by a low number of events. Trials had heterogeneity regarding investigation periods, baseline characteristics, and endpoint reporting, with a lack of information at long term follow-up. Direct and indirect evidence was also inconsistent for the comparison between drug eluting stents and drug coated balloons.

WHAT THIS STUDY ADDS
Compared with other currently available interventional treatments for coronary in-stent restenosis, drug coated balloons and drug eluting stents are associated with superior clinical and angiographic outcomes, with a similar comparative efficacy.

FUNDING, COMPETING INTERESTS, DATA SHARING
This study received no external funding. The authors declare no competing interests. No additional data available.

- BMJ 2015
- 4880 patients 24 études
- 1er endpoint TLR et LLL DEB et DES> B conv. BMS, brachythérapie
- En terme de rang DES en 1er pour TLR
- Pour le reste risque décès et IDM identique.

IDM abstract



ACC.15

TCT@ACC-i2 | innovation in intervention

A1708
JACC March 17, 2015
Volume 65, Issue 10S

TCT@ACC-i2: Interventional Cardiology

PACLITAXEL ELUTING BALLOON AFTER BARE METAL STENT IN ST ELEVATION MYOCARDIAL INFARCTION (THE PEBSI STUDY)

Oral Contributions
Room 8
Sunday, March 15, 2015, 9:15 a.m.-9:27 a.m.

Session Title: Highlighted Original Research: TCT@ACC-i2/Interventional Cardiology and the Year in Review
Abstract Category: 28. TCT@ACC-i2: ACS/AMI/Hemodynamics and Pharmacology
Presentation Number: 955-12

Authors: *Arutro Garcia Touchard, Javier Goicolea, Manel Sabate, Fernando Alfonso, Rafael Ruiz-Salmeron, Armando Bethencourt, Nieves Gonzalo, Fausti Miranda, Bruno Garcia del Blanco, Jesus Jiménez Mazuecos, Rafael Melgares-Moreno, Pedro Martinez-Romero, Jose Maria Hernandez-Garcia, Roman Lezaun, Juan Antonio Bullones, Javier Fernandez-Portales, José Rumoroso, Rosario Ortas, Mariano Valdes Chavarri, Ramiro Trillo, Puerta de Hierro University Hospital, Madrid, Spain*

Background: Drug eluting stents decrease the rate of restenosis, however, concerns still remains about their safety, especially in ST-segment elevation myocardial infarction (STEMI). The quest for new devices and procedures, aiming for an improved safety/efficacy balance, in STEMI is still warranted. The aim of this study was to evaluate the safety and efficacy of a paclitaxel eluting balloon (PTX-B) treatment after bare metal stent (BMS) implantation (PTX group) as compared to BMS only implantation (BMS group) in patients undergoing primary angioplasty for STEMI within 12 hours of onset of symptoms.

Methods: The PEBSI study was a randomized, multicenter, prospective, single blind, open study. After artery re-permeabilization and successful BMS implantation, patients were randomized in a 1:1 ratio to one of the following groups: PTX group: post-dilatation with a PTX-B (Pantera Lux ®) for 45 seconds. BMS group: no post-dilatation. Late Luminal Loss (LLL) at 9 months was the primary endpoint.

Results: 223 patients were aleatorized (BMS group:112, PTX group:111). The primary endpoint, in-stent late-luminal loss at 9 months follow up angiography, was met: 0.85+0.67 mm in the BMS group vs. 0.32+0.49 mm in PTX group, p<0.0001. Binary restenosis was also significantly lower in the PTX group (29.8% vs 2.2%, p<0.0001). Clinical 12 months follow up was complete in 212 patients: BMS group: 105(95,5%), PTX group:105(95,4%). MACE and isquemia driven TVF and TVR were significantly lower in the PTX-B group (12.5% vs 3.6%, p:0.0156, 11.6% vs 3.6%, p: 0.0256 and 8.9% vs 1.8%, p: 0.0192, respectively). There was a tendency to a lower TLR in the PTX group: 7.1% vs 1.8%, p: 0.05. There was only one late stent thrombosis in the PTX group in a patient who stopped taking all medications.

Conclusion: PTX lesion impregnation, released from a balloon after implantation of a BMS shows angiographic superiority compared with BMS only strategy. Differences in favor the PTX-B over BMS in this study were not limited to angiographic efficacy but also driven by a reduction in clinical ischemic endpoints with very low rates of adverse safety outcomes. PEBSI trial (NCT01839890)

- Abstract ACC 2015
- Étude randomisée multicentrique (pebsi) 220 patients , en phase aigue idm , BMS vs BMS+DEB (pantera lux)
- 1er endpoints à 9 mois: LLL 0,87 vs 0,29 p<0,0001, resténose binaire 29,6 vs 2,4% p=0,0003
- 2ème endpoints à 12 mois : mace 12,5% vs 3,6% p=0,0156, TVF p=0,0256, TLR=0,0558, AVC et saignements NS

Traitement de la branche fille

CLINICAL RESEARCH
CORONARY INTERVENTIONS

DANUBIO - a new drug-eluting balloon for the treatment of side branches in bifurcation lesions: six-month angiographic follow-up results of the DEBSIDE trial

Jacques Berland[1]*, MD; Thierry Lefèvre[2], MD, FESC, FSCAI; Philippe Brenot[3], MD; Jean Fajadet[4], MD; Pascal Motreff[5], MD, PhD; Patrice Guerin[6], MD, PhD; Patrick Dupouy[7], MD; Christian Schandrin[8], MD; DEBSIDE trial investigators

1. Clinique Saint-Hilaire, Rouen, France; 2. Institut Hospitalier Jacques Cartier, Massy, France; 3. Centre Cardiologique d'Evecquemont, Evecquemont, France; 4. Clinique Pasteur, Toulouse, France; 5. Hôpital Gabriel Montpied, Clermont-Ferrand, France; 6. Hôpital Guillaume et René Laennec, Nantes, France; 7. Clinique les Fontaines, Melun, France; 8. Pôle Santé République, Clermont-Ferrand, France

KEYWORDS
- bifurcation lesion
- drug-eluting balloon
- side branch

Abstract

Aims: We aimed to evaluate the role of drug-eluting balloon SB inflation, using the novel DANUBIO balloon, after placement of a drug-eluting stent in the main branch in patients with bifurcation lesions.

Methods and results: Fifty-two patients with bifurcation lesions suitable for stenting were enrolled in the DEBSIDE trial at eight French centres between May 2012 and July 2013. Two patients were excluded from the trial because of significant protocol deviations. Systematic Nile PAX stent placement was followed by final drug-eluting balloon inflation, using the DANUBIO balloon, according to the size of the side branch. Clinical follow-up was scheduled at one, six, and twelve months and an angiographic control at six months. The primary endpoint was six-month late lumen loss (LLL) at the ostium of the side branch. Secondary endpoints were main branch (MB) LLL, binary restenosis of the SB and MB, and clinically driven revascularisation rates for both branches. The procedural success rate was 100%. Angiographic control at six months post-procedure was performed in 48 patients (96%). Two patients with no reported clinical events refused the angiographic control. At six-month follow-up the primary endpoint of side branch LLL was -0.04±0.34 mm and the secondary endpoint of MB LLL was 0.54±0.60 mm. There was only one myocardial infarction (2%) and no reported cardiac deaths. Only one patient (2%) had a non-clinically driven target lesion revascularisation (TLR) at the level of the side branch combined with a main branch revascularisation.

Conclusions: Systematic final inflation of a DANUBIO balloon in the side branch after placement of a Nile PAX stent in the main branch for the treatment of a bifurcation lesion is safe and effective and results in very low LLL and a low restenosis rate at the side branch ostium. The DEBSIDE clinical trial was registered at the United States National Institute of Health website (NCT01485081).

Table 3. Side branch late lumen loss at six months in DEBSIDE and previous trials.

Trial	Study device	Technique	Months	SB LLL (mm)
DEBSIDE (2014)	DANUBIO	Predilatation: conventional balloon in MB+SB MB: DES SB: DEB	6	–0.04±0.34
PEPCAD V (2011)[9]	SeQuent Please	MB+SB: DEB MB: BMS	9	0.21±0.47
DEBIUT (2011)[7]	DIOR I	Predilatation: DEB in MB+SB MB: BMS	6	0.19±0.66
Herrador et al (2013)[10]	SeQuent Please	Predilatation: conventional balloon in MB or SB SB: DEB MB: DES	12	0.09±0.40
BABILON (2014)[3]	SeQuent Please	Predilatation: conventional balloon in MB+SB MB+SB: DEB MB: BMS	9	–0.04±0.64

- Eurointervention 2015
- Registre multicentrique français 52 patients de ttt bif avec NILE PAX (DES) avec DEB (Danubio) dans la branche fille (SB)
- 1er endpoint LLL à 6 mois ostia de SB = -0,04 très bas (lésions sb 33)
- 2ème endpoint LLL MB =0,54

Perspectives

- Possible remboursement au titre V de la LPPR paru fin décembre 2015 au titre des DM implantables de moins de 30 jours dits « consommables, onéreux »

Recommandations ESC 2014

Repeat revascularization

Recommendations	Class[a]	LoE[b]	Ref[c]
Early post-operative ischaemia and graft failure			
Coronary angiography is recommended for patients with: • symptoms of ischaemia and/or abnormal biomarkers suggestive of perioperative myocardial infarction • ischaemic ECG changes indicating large area of risk • new significant wall motion abnormalities • haemodynamic instability.	I	C	
It is recommended to make the decision on redo CABG or PCI by *ad hoc* consultation in the Heart Team and based on feasibility of revascularization, area at risk, comorbidities and clinical status.	I	C	
PCI should be considered over re-operation in patients with early			
If PCI is performed, revascularization of the native vessels or IMA diseased SVGs should be considered.			
Disease progression and late graft failure			
Repeat revascularization is indicated in patients with severe sympto therapy if technically feasible.			
PCI should be considered as a first choice if technically feasible, rat			
PCI of the bypassed native artery should be the preferred approac			
IMA, if available, is the conduit of choice for re-do CABG.			
Re-do CABG should be considered for patients without a patent I			
Re-do CABG may be considered in patients with lesions and anato PCI.			
PCI may be considered in patients with patent IMA graft if technica			
DES are recommended for PCI of SVGs.			
Distal protection devices are recommended for PCI of SVG lesions if technically feasible.	I	B	484,485
Restenosis			
Repeat PCI is recommended, if technically feasible.	I	C	
DES are recommended for the treatment of in-stent re-stenosis (within BMS or DES).	I	A	501,502,508 511,524
Drug-coated balloons are recommended for the treatment of in-stent restenosis (within BMS or DES).	I	A	507– 511,524
IVUS and/or OCT should be considered to detect stent-related mechanical problems.	IIa	C	
Stent thrombosis			
Emergency PCI is recommended to restore stent and vessel patency and myocardial reperfusion.	I	C	
DAPT with use of potent $P2Y_{12}$ inhibitors (prasugrel or ticagrelor) is recommended over clopidogrel	I	C	
Adjunctive thrombus aspiration and high-pressure balloon dilation should be considered.	IIa	C	
IVUS and/or OCT should be considered to detect stent-related mechanical problems.	IIa	C	
Hybrid procedures			
Hybrid procedure, defined as consecutive or combined surgical and percutaneous revascularization may be considered in specific patient subsets at experienced centres.	IIb	C	

Restenosis

Repeat PCI is recommended, if technically feasible.	I	C	
DES are recommended for the treatment of in-stent re-stenosis (within BMS or DES).	I	A	501,502,508 511,524
Drug-coated balloons are recommended for the treatment of in-stent restenosis (within BMS or DES).	I	A	507– 511,524
IVUS and/or OCT should be considered to detect stent-related mechanical problems.	IIa	C	