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CLINICAL BIBLIOGRAPHY

Microporous Surface with Biodegradable Polymer Sirolimus-Eluting Stent System

YUKON FAMILY

Highlights from RCT's

Objective	Journal	Number of Patients	Duration (in years)	Conclusion
Examine the relationship between stent surface topography and outcome in patients undergoing implantation of stents with rough and smooth surfaces.	Catheterization & Cardiovascular Interventions	200		A rough stent surface does not increase late lumen loss after stent implantation as compared with a conventional smooth stent surface. https://translumina.com/wp-content/uploads/2021/09/Lit_2_Dibra-Microporous-stent-study-CCI.pdf
To investigate the Safety & Efficacy of these novel stent platforms in an established pre-clinical model	Biomaterials			The pre-clinical assessment of RESs with resin-based or dual drug coating indicated an adequate efficacy profile as well as a beneficial effect for vascular healing processes https://translumina.com/wp-content/uploads/2020/12/2008-Biomaterials.pdf
Aim of this study was to test the Safety & Efficacy of Biodegradable Polymer DES with that of Permanent Polymer DES at **12 months**	European Heart Journal	605	1	A Biodegradable polymer Rapamycin-eluting stent is non-inferior to permanent polymer-based DES in terms of clinical efficacy over **1 year.** https://academic.oup.com/eurheartj/article/29/16/1975/408201
Comparing the **3 year** efficacy and safety of biodegradable polymer with permanent polymer stents and of Everolimus-eluting stents (Xience) with Sirolimus-eluting stents (Cypher)	Journal of the American College of Cardiology	2603	3	At **3 years**, Yukon proved equivalence to Xience in terms of late loss, TLR and Primary composite MACE https://www.jacc.org/doi/pdf/10.1016/j.jacc.2011.06.027
Long-term outcomes of biodegradable versus durable polymer drug-eluting stents in patients with acute **ST-segmentelevation myocardial infarction**	Eurointervention	497	4	A **4 years**, MACE was significantly reduced following treatment with Yukon demonstrating superior clinical outcomes to DP-SES https://boris.unibe.ch/48191/7/deWaha%20EuroIntervention%202015.pdf

Highlights from RCT's

Objective	Journal	Number of Patients	Duration (in years)	Conclusion
Long-term outcomes of biodegradable polymer versus durable polymer drug-eluting stents in patients with **diabetes mellitus**: A pooled analysis of individual patient data from **3 randomized trials**	International Journal of Cardiology	1094	4	At **4 years**, the incidence of Definite or probable stent thrombosis was significantly reduced among patients treated with BP-DES,a difference driven by significantly lower stentthrombosis rates with BP-DES between 1 and**4 years**. In diabetes, BP-DES demonstrated comparable clinical outcomes to DP-SES at **4 years**. Rates of stent thrombosis weresignificantly lower with BP-DES. https://translumina.com/wp-content/uploads/2020/12/2013-International-Journal-of-Cardiology.pdf
Comparing long-term outcomes in patientstreated with biodegradable polymer DES vs. durable polymer sirolimus-eluting stents (SES) : **Meta analysis**	EuropeanHeart Journal	4062	4	At **4 years**, Yukon showed reduction of risk by **50%** in definite stent thrombosis and by **78%** in very late stent thrombosisas compared to first generation DES withsimilar efficacy https://www.researchgate.net/publication/221976499_Biodegradable_polymer_drug-eluting_stents_reduce_the_risk_of_stent_thrombosis_at_4_years_in_patients_undergoing_percutaneous_coronary_intervention_A_pooled_analysis_of_individual_patient_data_from_the
To compare the efficacy and safety of biodegradable polymer Sirolimus-eluting stents versus permanent polymer Everolimus-eluting stents versus permanent polymer Sirolimus-eluting stents at **5 year follow-up**	Eurointervention	2063	5	Yukon and permanent polymer XIENCE stents showed comparable clinical outcomes at **5 years** https://www.researchgate.net/publication/268795606_Five-year_outcomes_from_a_trial_of_three_limus-eluting_stents_with_different_polymer_coatings_in_patients_with_coronary_artery_disease_final_results_from_the_ISAR-TEST_4_randomised_trial
To assess the **10-year clinical outcome** of new-generation biodegradablepolymer-based Sirolimus-Eluting stents (Yukon Choice PC) versus permanent polymer-based Everolimus stents (XIENCE) in patients with and without **diabetes mellitus**	Journal of The American Heart Association	1951	10	At **10 Years**, Yukon Choice PC is proven tobe non-inferior to Xience in the category of New generation DES in the subgroup of patients with Diabetes Mellitus. https://www.ahajournals.org/doi/10.1161/JAHA.120.020165

To compare the efficacy and safety of biodegradable polymer-based Sirolimus-eluting stents (Yukon Choice PC)versus permanent polymer-based Everolimus-eluting stents (Xience) versus early generation permanent polymer-based Sirolimus-eluting stents(Cypher) at **10-year follow-up**	Circulation	2603	10	At **10 years**, Yukon Choice PC showed equivalence in term of MACE rate, Mortality and TLR rate compared to Xience and superiority over Cypher over the same outcomes. Yukon Choice PC showed the lowest rate of definite /probable stent thrombosis with a significant risk reduction than the Cypher stent (**50% reduction**) and a numerically lower than Xience(**29% reduction**) https://www.ahajournals.org/doi/epub/10.1161/CIRCULATIONAHA.118.038065

Clinical Studies at Glance

Influence of Stent Surface Topography on the Outcomes of Patients Undergoing Coronary Stenting : A Randomized Double-Blind Controlled Trial

Objective

The objective of this study was to examine the relationship between stent surface topography and outcomes in patients undergoing implantation of stent with rough and smooth surface considered an important determinant of the bare stent performance. Specifically designed rough surface may increase the drug storing capacity of stent but its direct impact on the risk of thrombosis and restenosis is not known.

No. of Patients

A total 2000 patients with significant stenosis in native coronary vessels were randomly assigned in a double-blind way to receive either a rough or a smooth-surface stent.

Primary End Point

The primary endpoint of the study was late lumen loss.

Secondary End Point

Secondary endpoint included angiographic restenosis and clinical outcomes.

Results

These results show that a rough stent surface does not increase late lumen loss after stent implantation as compared to a conventional smooth stent surface,

Author

Alban Dibra, 1 MD, Adnan Kastrati, 1* MD, Julinda Mehilli, 1 MD, Jürgen Pache, 1 MD, Randolf von Oepen,2 PhD, Josef Dirschinger,3 MD, and Albert Schömig,1,3 MD

Journal Published

Catheterization and cardiovascular Interventions 65:374-380 (2005)

Impact Factor - 2.044

The pre-clinical assessment of Rapamycin-Eluting, Durable Polymer-free stent coating concepts

Objective

To investigate the safety and efficacy of these novel stent platforms in established pre-clinical model

Results

Pre-clinical assessment of Yukon Choice PC indicated an adequate efficacy profile as well as a beneficial effect for vascular healing processes.

The natural resin shellac is identified as potential resin-based coating for prolinged drug release and inhibits inflammatory processes that can be associated with adverse outcomes.

Author

Kristin Steigerwald a,1, Sabine Merl a,1, Adnan Kastrati a, Anna Wieczorek a, Marc Vorpahl a, Raimund Mannhold b, Michael Vogeser c, Jörg Hausleiter a, Michael Joner a, Albert Schömiga, Rainer Wessely a,*

Journal Published

Biomaterials (2008)

Impact Factor - 10.317

Randomized, non-inferiority trial of three limus agent-eluting stents with different polymer coatings: The Intracoronary Stenting and Angiographic Results: Test Efficacy of 3 Limus-Eluting Stents (ISAR-TEST-3) Trial.

Objective

Aim of this study was to test the safety and efficacy of Biodegradable Polymer DES with that of Permanent Polymer DES at 12 months.

Methodology

Patients with de novo coronary lesions in native vessels were randomly assigned to receive a BP stent, a PF stent or a PP stent. A total of 605 patients were enrolled: 202 patients received BP stents,202 were treated with PP stents, and 201 received PF stents. Repeat angiography was available for 492 patients (81.3%).

Primary End Point

The primary endpoint was in-stent late lumen loss at follow-up angiogram

Secondary End Point

Definite/Probable Stent Thrombosis

Results

A biodegradable polymer rapamycin-eluting stent is non-inferior to permanent polymer-based DES in terms of clinical efficacy over 1 year.

Author:
Robert A. Byrne*, Adnan Kastrati1, Sebastian Kufner1, Steffen Massberg1, K. Anette Birkmeier1, Karl-Ludwig Laugwitz2, Stefanie Schulz1, Jürgen Pache1, Massimiliano Fusaro1, Melchior Seyfarth1, Albert Schömig1,2, and Julinda Mehilli1 for the Intracoronary Stenting and Angiographic Results: Test Efficacy of 3 Limus-Eluting Stents (ISAR-TEST-4) Investigators

European Hearth Journal (2009)
Impact Factor – 22.673

Biodegradable Poymer Versus Permanent Polymer Drug-Eluting Stents and Everolimus-Versus Sirolimus-Eluting Stents in Patients with Coronary Artery Disease: 3-Year Outcomes From a Randomized Clinical Trial

Objective

Comparing the 3-year efficacy and safety of biodegradable polymer with permanent poymer stents and of Everolimus-eluting stents (Xience) with Sirolimus-eluting stents (Cypher)

A total of 2,603 patients were randomized to receive biodegradable polymer (n=1,299) or permanent polymer (n=1,304) DES. Patients allocated to treatment with permanent polymer DES were randomized to either EES (Xience, n = 652) or SES (Cypher, n = 652)

Primary End Point

MACE comprised cardiac death, MI, or target lesion revascularization (TLR)

Secondary End Point

TLR cardiac death or MI, and definite or probable stent thrombosis.

Results

At 3 years, no significant difference between biodegradable polymer and permanent polymer DES with regard to the primary endpoint. Rates of definite/probable stent thrombosis were also similar in both groups

Author:
Robert A. Byrne, MB BCH, Adnan Kastrati1, MD, Steffen Massberg, MD, Anna Wieczorek, Karl-Ludwig Laugwitz, MD, Martin Hadamitzky, MD, Stefanie Schulz, MD, Jurgen Pache, MD, Massimiliano Fusaro, MD, Jörg Hausleiter, MD, Albert Schömig, MD, julinda Mehilli, MD, fir the ISAR-TEST 4 Investigatorst

Journal Published - JACC, 2011
Impact Factor – 20.8

Long-term outcomes of biodegradable versus durable polymer drug-eluting stents in patients with acute ST-segment elevation myocardial infarction: A Pooled analysis of individual patient data from 3 randomized trials

Objective

Long-term outcomes of biodegradable versus durable polymer drug-eluting stents in patients with acute ST-segment elevation myocardial infarction : A pooled analysis individual patient data from three randomised trials

Methodology

Pooled individual patient-level data from three randomized clinical trials (ISAR-TSET-3, ISAR-TEST-4 and LEADERS) comparing outcomes from BP-DES with DP-SES at four years; 497 patients with STEMI,291 received BP-DES and 206 DP-SES

Primary End Point

MACE comprised cardiac death, MI or target lesion revascularization (TLR)

Secondary End Point

TLR, cardiac death or MI, and definite or probable stent thrombosis

Results

At four years, MACE was significantly reduced following treatment with BP-DES, Trends towards reduction were seen for cardiac death or MI and definite or probable stent thrombosis in STEMI, BP-DES demonstrated superior clinical outcomes to DP-SES at four years.

Author:
Antoinette de Waha1*, MD; Lamin A, King 1, MD; Giulio G. Stefanini2, Robert A. Byrne1, MD, BCh, PhD; Patrick W. Serruys3, MD, PhD, FESC; Bernhard Meier2, MD; Peter Jüni4, MD; Adnan Kastrati1, MD; Stephan Winddecker2,3, MD

Journal Published - Eurointervention 2014

Long-term outcomes of biodegradable polymer versus durable polymer drug-eluting stents in patients with diabetes : A pooled analysis of individual patient data from 3 randomized trials

Objective

Long-term outcomes of biodegradable versus durable polymer drug-eluting stents in patients with diabetes

Pooled individual patient-level data from three randomised clinical trials (ISAR-TSE-3, ISAR-TEST-4 and LEADERS) comparing outcomes from BP-DES with DP-SES at four years; 1094 patients with STEMI, 657 received BP-DES and 437 DP-SES

Primary End Point

Composite of cardiac death, myocardial infarction, and target lesion revascularization

Secondary End Point

Target Lesion Revascularization and Definite or Probable Stent Thrombosis

Results

At 4 years, the incidence of Definite or probable stent thrombosis was significantly reduced among patients treated with BP-DES, a difference driven by significantly lower stent thrombosis rates wit BP-DES demonstrated comparable clinical outcomes to DP-SES at four years. Rates of stent thrombosis were significantly lower with BP-DES.

Author:

Antoinette de Waha a,*1, Giulio G. Stefanini b,1, Lamin A.King a,1, Robert A. Byrne a,1, PatrickW. Serruys c,1,Sebastian Kufner a,1, Bernhard Meier b,1, Peter Jüni d,1, Adnan Kastrari a,1, Stephan Windecker b,c,1

Journal Published

International Journal of Cardiology (2013)

Biodegradable polymer drug-eluting stents reduce the risk of Stent Thrombosis at 4 years in patient undergoing Percutaneous Coronary Intervention : A pooled analysis individual patient data from the ISAR-TEST 3, ISAR-TEST 4, and LEADERS randomized trials

Objective

Comparing long-term outcomes in patients treated with biodegradable polymer DES vs. durable Polymer Sirolimus-eluting stents (SES)

Methodology

Out of 4062 patients included in the present analysis, 2358 were randomly assigned to treatment with biodegradable polymer DES (Sirolimus-eluting (Yukon)-1501 ; biolimus-eluting (Cypher)-857) and 1704 patients to durable polymer SES (Xience).

Primary End Point

MACE comprised cardiac death, MI or target lesion revascularization (TLR)

Secondary End Point

TLR, cardiac death or MI and definite or probable stent thrombosis

Results

At 4 years, the risk of TLR was significantly lower among patients treated with BP DES vs. DP SES. The risk of stent thrombosis was significantly reduced with BP DES vs. DP SES driven by a lower risk of very late stent thrombosis.

Author:
Giulio G. Stefanini1†, Robert A. Byrne2†, Patrick W. Serruys3, Antoinette de Waha2, Bernhard Meier1, Steffen Massberg2, Peter Jüni4, Albert Schömig2, Stephan Windecker1,3, and Adnan Kastrati2*

Journal Published
European Heart Journal 2012

Impact Factor - 22.6

Five-year outcomes from a trial of three Limus-eluting stents with different polymer coating in patients with Coronary Artery Disease: Final results from the ISAR -TEST 4 randomised Trials

Objective

To compare the efficacy and safety biodegradable polymer Sirolimus-eluting stents were permanent polymer Everolimus-eluting stents versus permanent polymer Sirolimus-eluting stents at five year follow-up.

Methodology

603 patients were randomized to treatment with the Yukon Choice PC (n=1,299), Xience (n=652) or Cypher (n=652) stents

Primary End Point

Composite of cardiac death, target vessel-related, MI or TLR

Secondary End Point

Definite/Probable Stent Thrombosis

Results

Biodegradable polymer Yukon Choice PC and permanent polymer XIENCE stents showed comparable clinical outcomes at five years. Permanent polymer CYPHER stents showed numerically higher rates of device-realted adverse events.

Author:
Sebastian Kufner1*, MD; Robert A. Byrne1, MD,BCh, Phd; Marco Valeskin1; Stefanie Schulz1, MD;Tareq Ibrahim2, MD; Petra Hoppmann2, MD; Simon Schneider2, MD; Karl-Ludwig Laugwitz2,3 MD;Heribert Schunkert1,3, MD; Adnan Kastrati 1,3, MD; for the Intracoronary Stenting And Angiographic Results: Test Efficacy of 3 Limus-Eluting Stents (ISAR-TEST 4) Investigators

Journal Published
Eurointervention 2014

Recommended by EUROPEAN SOCIETY OF CARDIOLOGY

Yukon Choice PC is the DES to be recommended in ESC Guidelines 2018 for clinical Use

Ten-Year Clinical Outcomes of Biodegradable versus Durable Polymer New- Generation Drug-Eluting Stent in Patients with Coronary Artery Disease with and without Diabetes Mellitus

Objective

The aim of this study is to assess the 10-year clinical outcomes of new-generation biodegradable polymer based Sirolimus-Eluting stents (Yukon Choice PC) versus permanent polymer-bases Everolimus-Eluting stents (Xience) in patients with and without diabetes mellitus

Methodology

1951 patients were randomized (560 patients with DM and 1391 patients without diabetes mellitus) to treatment with the Yukon Choice PC (n=1,299), XIENCE (n=652) or CYPHER (n=652) stents

Primary End Point

The primary end point of this analysis was major adverse cardiac event, the composite of death, myocardial infarction, or target lesion revascularization

Secondary End Point

Definite/Probable Stent Thrombosis

Results

At 10 years there was no difference concerning clinical event rates in patients treated with Yukon Choice PC versus Xience, in neither of the prespecified subgroups of patients with and without diabetes mellitus.

Author:
Jörg Hausleiter, Albert Schömig, Julinda Mehilli, and ISAR-TEST 4 Investigators Laugwitz, Martin Hadamitzky, Stefanie Schulz, Jürgen Pache, Massimiliano Fusaro, Robert A. Byrne, Adnan Kastrati, Steffen Massberg, Anna Wieczorek, Karl-Ludwig

Jouranl Published
Journal of The American Heart Association (2021)

Impact Factor - 5.501

Ten-Year Clinical Outcomes From a Trial of Three Limus-Eluting Stents with Different Polymer Coating in patients with Coronary Artery Disease : Results From the ISAR-TEST Randomized Trial

Objective

To compare the efficacy and safety of biodegradable polymer-based sirolimus-eluting stents (BP-SES; Yukon Choice PC) versus permanent polymer-based Everolimus-eluting stents (PP-EES; Xience) versus early generation permanent polymer-based sirolimus-eluting stents (PP-SES; Cypher) at -year follow-up

Methodology

2,603 patients were randomized to treatment with Yukon Choice PC (n=1,299), XIENCE (n=652) or CYPHER (n=652) Stents

Primary End Point

Major adverse cardiac event, the composite of death, myocardial infarction, or target lesion revascularization

Secondary End Point

Definite/Probable Stent Thrombosis

Results

At 10 years Yukon Choice PC showed equivalence in terms of MACE rate, Mortality aand TLR rate compared to Xience and superiority over Cypher over the same outcomes. Yukon Choice PC showed the lowest rate of definite/probable stent thrombosis with a significant risk reduction than the cypher stent (50% reduction) and a numerically lower rate than Xience (29% reduction)

Author:
Sebastian Kufner, MD Michael Joner, MD Anna Thannheimer Petra Hoppmann, MD Tareq Ibrahim, MD Katharina Mayer, MD Salvatore Cassese, MD, PhD Karl-Ludwig Laugwitz, MD Heribert Schunkert, MD Adnan Kastrati, MD Robert A. Byrne, MB, Bch, PhD On behalf of the ISAR-TEST 4 (Intracoronary Stenting and Angiographic Results: Test Efficacy of 3 Limus-Eluting Stents) Investigators

Journal Published
Circulation 2018

Impact Factor - 24

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