
# Incidence and Predictors of Recurrent Restenosis after Drug-Eluting Balloon Angioplasty in Patients with Restenosis of a Drug-Eluting Stent

## A Preliminary Analysis from the ICARUS Cooperation

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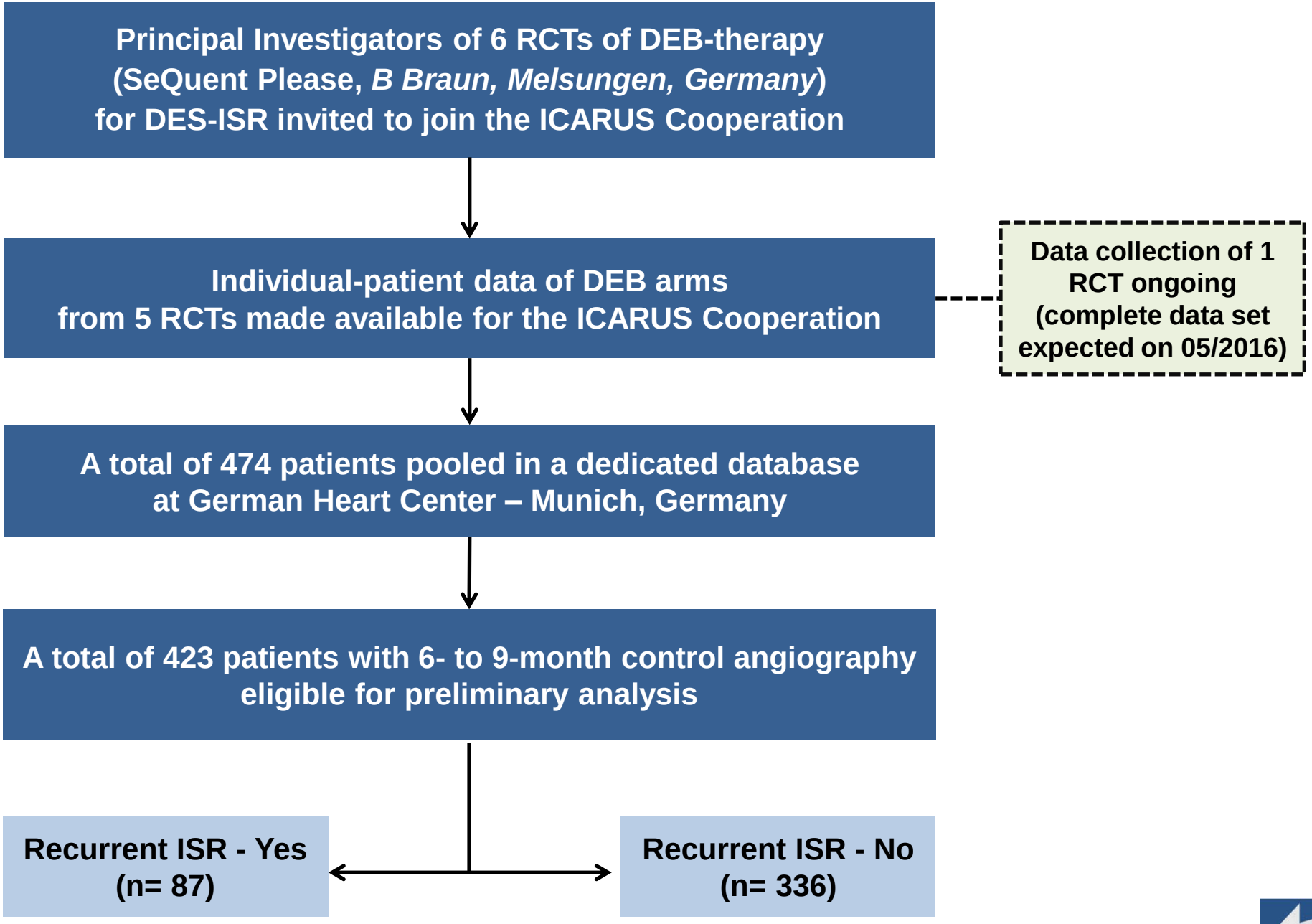
On behalf of the ICARUS Investigators

# Disclosure Statement of Financial Interest

- I (Bo Xu) have no relevant conflicts of interest to disclose

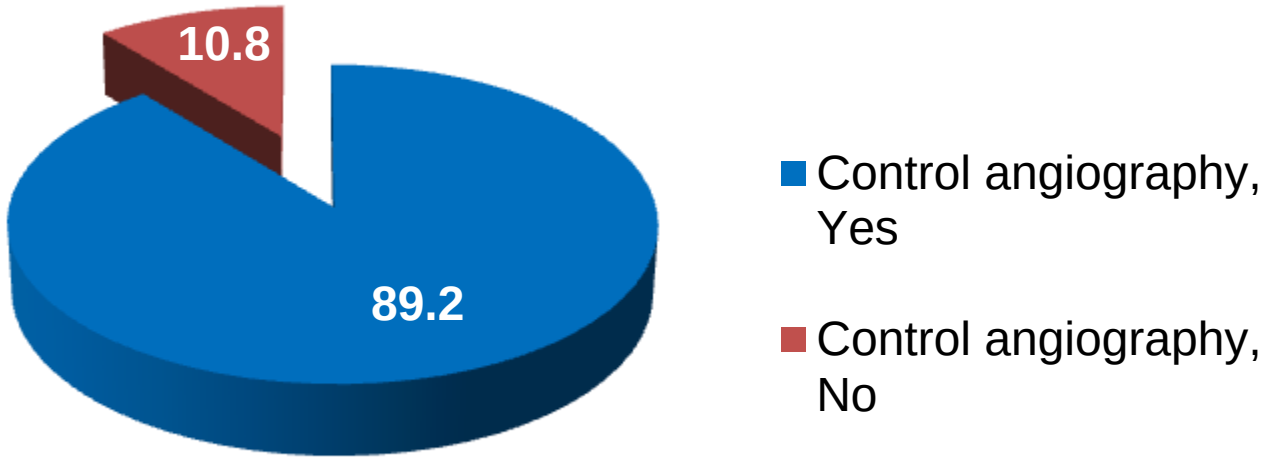

Principal Investigators of 6 RCTs of DEB-therapy
(SeQuent Please, *B Braun, Melsungen, Germany*)
for DES-ISR invited to join the ICARUS Cooperation
Individual-patient data of DEB arms
from 5 RCTs made available for the ICARUS Cooperation
Data collection of 1 RCT ongoing (complete data set expected on 05/2016)
A total of 474 patients pooled in a dedicated database
at German Heart Center – Munich, Germany
A total of 423 patients with 6- to 9-month control angiography
eligible for preliminary analysis
Recurrent ISR - Yes
(n= 87)
Recurrent ISR - No
(n= 336)

# Main Trial-Level Characteristics of Patients Included in DEB Arms

| Trial name | Patients, n | Age, y | Male gender, % | Diabetes, % | Stable CAD, % | Lesions, n |
|---|---|---|---|---|---|---|
| **Habara et al. 2011** | 25 | 69.9 | 76 | 56 | 100 | 25 |
| **Habara et al. 2013** | 53 | 69.4 | 83 | 58 | 94 | 56 |
| **ISAR DESIRE 3** | 137 | 67.7 | 77 | 41 | 81 | 172 |
| **PEPCAD China ISR** | 109 | 61.8 | 88 | 44 | 37 | 113 |
| **RIBS IV** | 154 | 66.0 | 82 | 49 | 48 | 154 |

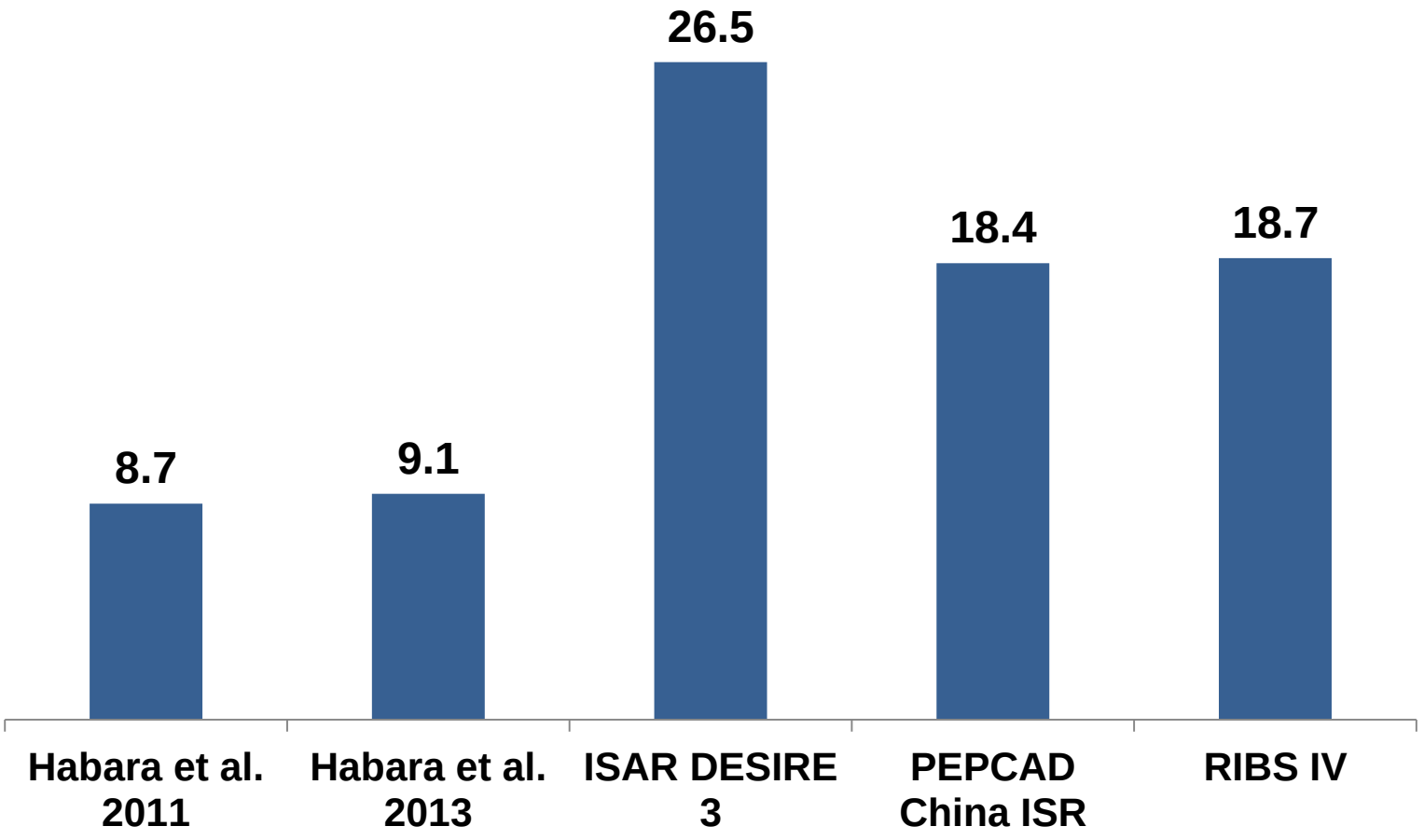
Data are mean or counts

# Lesions Available with Control Angiography (%)

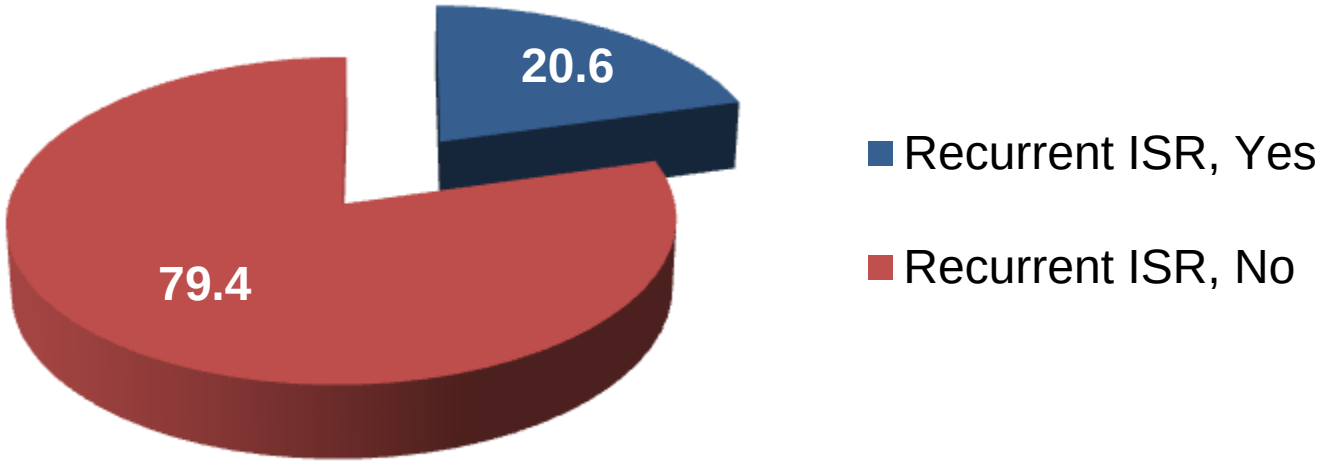



**Control angiography was performed at a median of 214 days (IQR 182; 278) after the index procedure**

# Trial-Level Proportion of Lesions with Recurrent ISR at Control Angiography



# Incidence of Recurrent ISR among Patients Included (%)



# Baseline Clinical Characteristics

| Characteristic | Recurrent ISR | | p |
|---|---|---|---|
| | Yes (n= 87) | No (n= 336) | |
| **Age** | 67.0 (59.5; 74.1) | 67.0 (59.0; 74.0) | **0.62** |
| **Male gender** | 77.9 | 82.7 | **0.31** |
| **Diabetes mellitus** | 50.6 | 42.8 | **0.20** |
| **Smoking habit** | 21.8 | 27.7 | **0.27** |
| **Arterial hypertension** | 71.3 | 75.9 | **0.37** |
| **Dyslipidemia** | 65.5 | 67.6 | **0.72** |
| **History of myocardial infarction** | 43.7 | 45.5 | **0.76** |
| **History of bypass surgery** | 6.9 | 8.3 | **0.66** |
| **Clinical presentation** | | | |
| Stable CAD | 60.9 | 61.9 | **0.87** |
| NSTE-ACS | 23.0 | 20.2 | **0.57** |
| **Left ventricular ejection fraction*** | 60 (52; 65) | 60 (52; 65) | **0.76** |

Data are median (25th; 75th percentiles) or proportion of patients. *Data available for 324 (76.6%) of total number of patients.
CAD: coronary artery disease; NSTE-ACS: non-ST-elevation acute coronary syndrome

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# Angiographic and Procedural Characteristics - I

| Characteristic | Recurrent ISR | | p |
|---|---|---|---|
| | Yes (n= 89) | No (n= 368) | |
| **Target vessel** | | | |
| Left main coronary artery | 1.1 | - | **-** |
| Left anterior descending coronary artery | 36.0 | 45.1 | **0.12** |
| Left circumflex coronary artery | 27.0 | 21.5 | **0.27** |
| Right coronary artery | 36.0 | 31.5 | **0.42** |
| Bypass graft | - | 1.9 | **-** |
| **Complex (type B2/C) lesion** | 62.6 | 44.8 | **0.003** |
| **Chronic occlusion** | 5.6 | 1.6 | **0.04** |
| **Bifurcation** | 28.1 | 21.5 | **0.17** |
| **Ostial** | 28.3 | 19.5 | **0.18** |
| **Restenosis morphology (Mehran pattern)** | | | |
| I A | 1.1 | 2.4 | **0.10** |
| I B | 12.4 | 20.1 | |
| I C | 36.0 | 41.6 | |
| I D | 6.7 | 4.6 | |
| II | 31.5 | 36.1 | |
| III | 6.7 | 3.5 | |
| IV | 5.6 | 1.6 | |

Data are mean (SD) or proportion of lesions

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# Angiographic and Procedural Characteristics - II

| Characteristic | Recurrent ISR | | p |
|---|---|---|---|
| | Yes (n= 89) | No (n= 368) | |
| **Index stent type** | | | |
| BES | - | 1.9 | |
| EES | 29.2 | 19.3 | |
| PES | 6.7 | 7.6 | **0.47** |
| SES | 30.3 | 37.0 | |
| ZES | 12.4 | 10.6 | |
| DES (not specified) | 21.3 | 23.6 | |
| **Lesion length, mm** | 12.8±7.8 | 10.5±5.6 | **0.001** |
| **Vessel size, mm** | 2.58±0.49 | 2.67±0.45 | **0.09** |
| **Initial minimal lumen diameter, mm** | 0.77±0.42 | 0.91±0.42 | **<0.001** |
| **Initial diameter stenosis, (%)** | 69.9±15.6 | 66.0±14.5 | **0.03** |
| **Predilation** | 92.1 | 94.3 | **0.49** |
| **Maximal balloon diameter, mm** | 2.92±0.45 | 3.04±0.42 | **0.03** |
| **Maximal balloon pressure, atm** | 14.7±4.5 | 14.5±4.7 | **0.64** |
| **Balloon-to-vessel ratio** | 1.14±0.17 | 1.16±0.18 | **0.54** |
| **Final minimal lumen diameter, mm** | 2.12±0.40 | 2.19±0.43 | **0.47** |
| **Final diameter stenosis, (%)** | 18.2±10.2 | 17.8±8.9 | **0.77** |

Data are mean (SD) or proportion of lesions

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# Predictors of Recurrent ISR

| Variable | Odds Ratio [95% Confidence interval] | p |
|---|---|---|
| **Complex (type B2/C) lesion** | 1.56 [0.90; 2.73] | **0.11** |
| **Chronic occlusion** | 1.58 [0.35; 7.09] | **0.55** |
| **Lesion length (for 5 mm increase)** | 1.17 [0.93; 1.48] | **0.16** |
| **Vessel size (for 0.5 mm reduction)** | 1.45 [1.02; 2.06] | **0.038** |
| **Initial diameter stenosis (for 10% DS increase)** | 1.13 [0.92; 1.38] | **0.25** |
| **Balloon-to-vessel ratio (for 0.1 unit increase)** | 0.86 [0.72; 1.04] | **0.12** |

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# Summary

The preliminary data from the ICARUS cooperation demonstrates that

- In a population of patients undergoing angiographic surveillance after DEB angioplasty for DES-ISR the overall rate of recurrent restenosis was approximately one in five
- The treatment of lesions located in small vessels remains important predictor of recurrent restenosis after DEB angioplasty for DES-ISR
- The completion of data collection and analysis will help to definitely disclose the incidence and predictors of recurrent restenosis in patients receiving DEB angioplasty for DES-ISR