IN-PACT CORO trial: INtimalhyPerplasia evAluated by oCT in de novo COROnary lesions treated by drug-eluting balloon and bare-metal stent. Final results.

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Conflict of interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Consulting Fees/ Speaker Fees	Medtronic

Study design

Single-centre, prospective, randomized, three-arm clinical trial to assess the impact of drug-eluting balloon (**DEB**) use, either before (pre-dilation, **Pre-DEB**) or after stenting (post-dilation **Post-DEB**), on intimal hyperplasia, evaluated by OCT, in stable patients undergoing bare metal stent (**BMS**) implantation for *de novo* coronary lesions (NCT01057563)

Main clinical inclusion criteria	non-diabetic patients with a stable coronary artery disease, undergoing elective PCI with bare metal stent
Main angiographic inclusion criteria	▪ *de novo* non-complex lesions located in straight coronary segments ▪ lesion length ≥10 mm and ≤25 mm ▪ vessel size requiring a single stent with diameter between 3.0 and 3.5mm.

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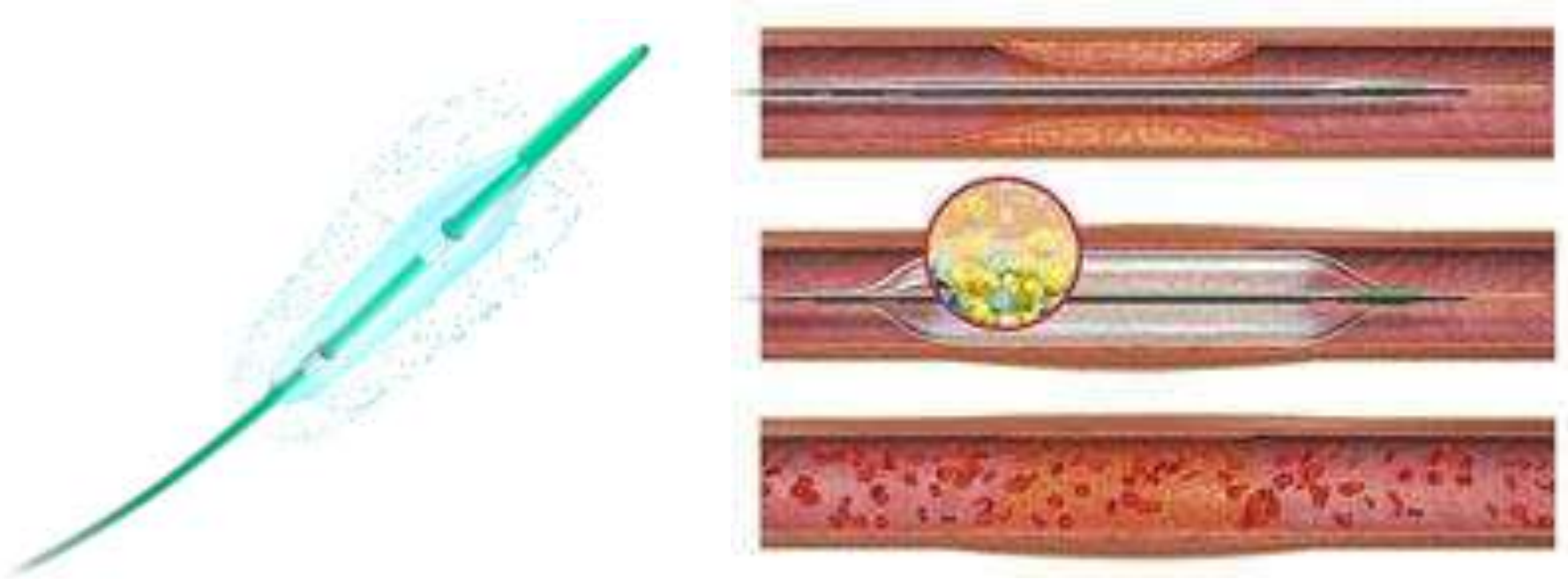
Tested drug-eluting balloon

Paclitaxel-eluting In-Pact Falcon balloon



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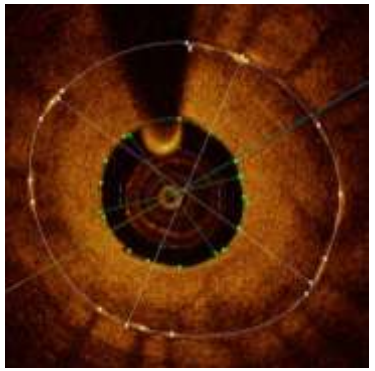
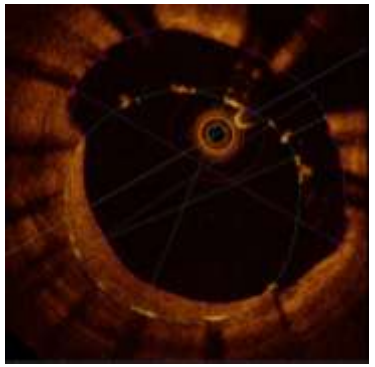
Study hypothesis

Drug-eluting balloon (**DEB**) may reduce intimal (OCT-detected) hyperplasia in PCI with BMS implantation.





Primary End-points: neointimal area (stent area minus lumen area) and its percentage (tissue coverage area/stent area × 100) evaluated by OCT at 6 months

Secondary End-points: percentage of uncovered struts, percentage of struts with incomplete strut apposition

Sample sizing: DEB use (either before or after BMS implantation) yields a 50% reduction of mean neointimal area compared with BMS alone (30 pts randomized to have a study with Type I error 5%, Type II error 85%)

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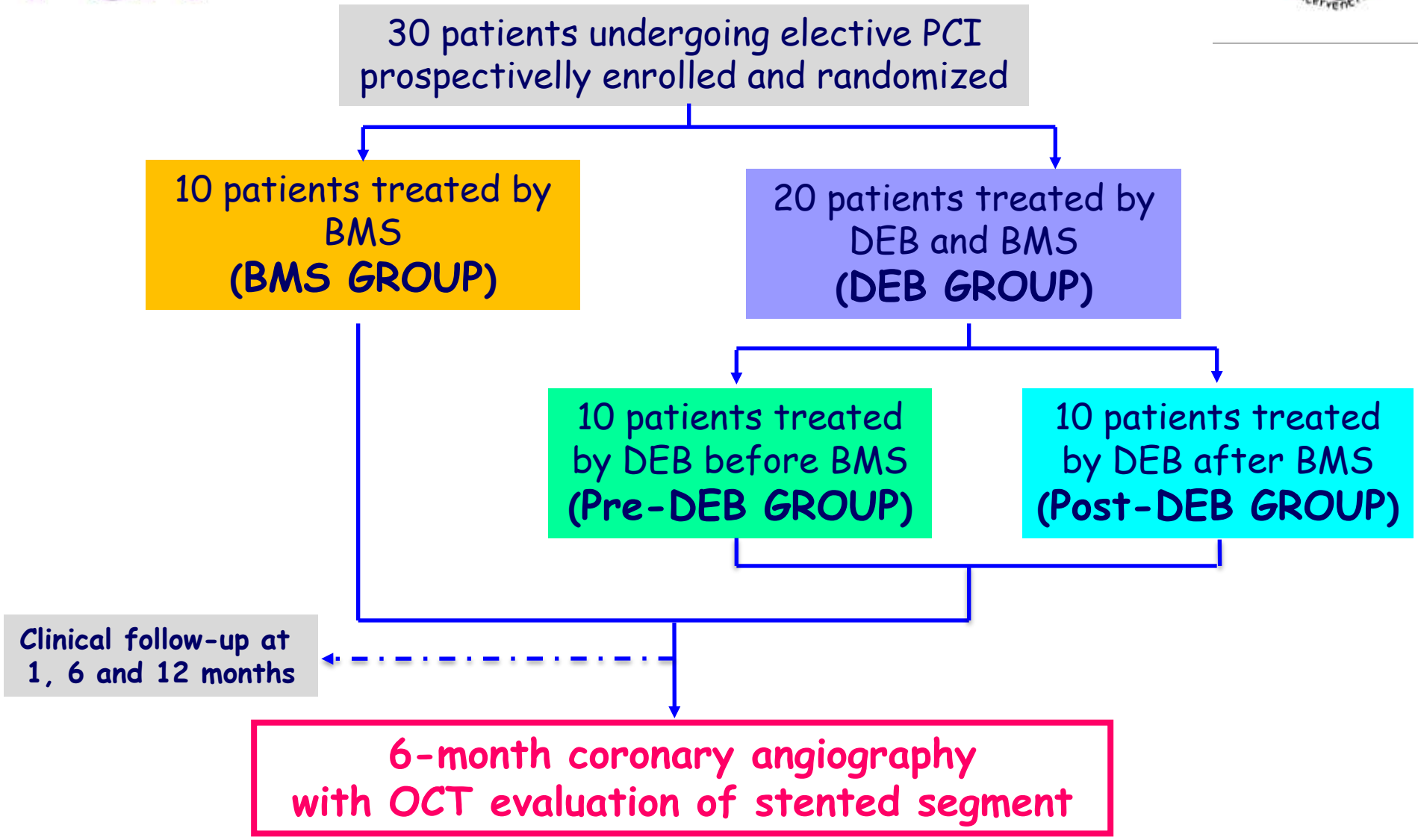
Study flow-chart



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Results: patients' details[1]

	BMS group	DEB group	P	Pre-DEB group	Post-DEB group	P
Risk factors						
Hypertension	8 (80%)	15(75%)	0.76	9 (90%)	6 (60%)	0.30
Dyslipidemia	8 (80%)	16(80%)	1.00	8 (80%)	8 (80%)	1.00
Smoking	7 (70%)	17(85%)	0.37	9 (90%)	8 (80%)	1.00
Family history	4 (40%)	3 (15%)	0.18	1 (10%)	2 (20%)	1.00
Treated vessel						
LAD	1 (10%)	5 (25%)	0.63	1 (10%)	4 (40%)	0.30
LCx	4 (40%)	5 (25%)	0.43	3 (30%)	2 (20%)	1.00
RCA	5 (50%)	10 (50%)	1.00	6 (60%)	4 (40%)	0.66
Stent characteristics						
N° of stent >1	0 (0%)	1 (5%)	1.00	0 (0%)	1(10%)	1.00
Stent length	16.3±4.9	19.3±8.4	0.31	25.9±10.4	27.2±12.9	0.83

Results: patients' details[2]

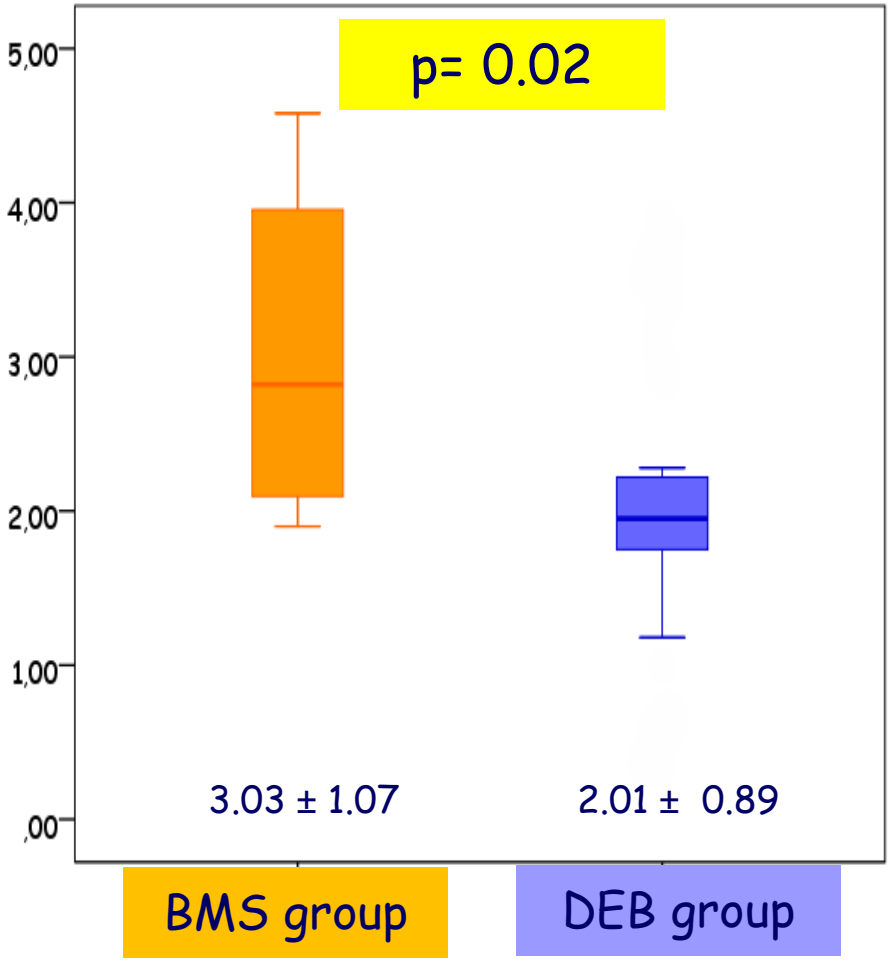
	BMS group	DEB group	p	Pre-DEB group	Post-DEB group	p
Number of DEB						
0	10 (100%)	0 (0%)	0.001	0 (0%)	0 (0%)	1.00
1	0 (0%)	17 (85%)	0.001	9 (90%)	8 (80%)	1.00
2	0 (0%)	3 (15%)	0.53	1 (10%)	2 (20%)	1.00
Number of pre-dilation balloons						
0	3 (30%)	6 (30%)	1.00	4 (40%)	2 (20%)	0.63
1	7 (70%)	10 (50%)	0.44	5 (50%)	5 (50%)	1.00
2	0 (0%)	4 (20%)	0.27	1 (10%)	3 (30%)	0.58
Number of post-dilation balloons						
0	1 (10%)	0 (0%)	0.33	0 (0%)	0 (0%)	1.00
1	8 (80%)	18 (90%)	0.58	9 (90%)	9 (90%)	1.00
2	1 (10%)	2 (10%)	1.00	1 (10%)	1 (10%)	1.00
Procedural duration, min	17.7±8.5	26.5±11.4	0.08	25.9±10.4	27.1±12.9	0.26

clinical outcome @ 12-month

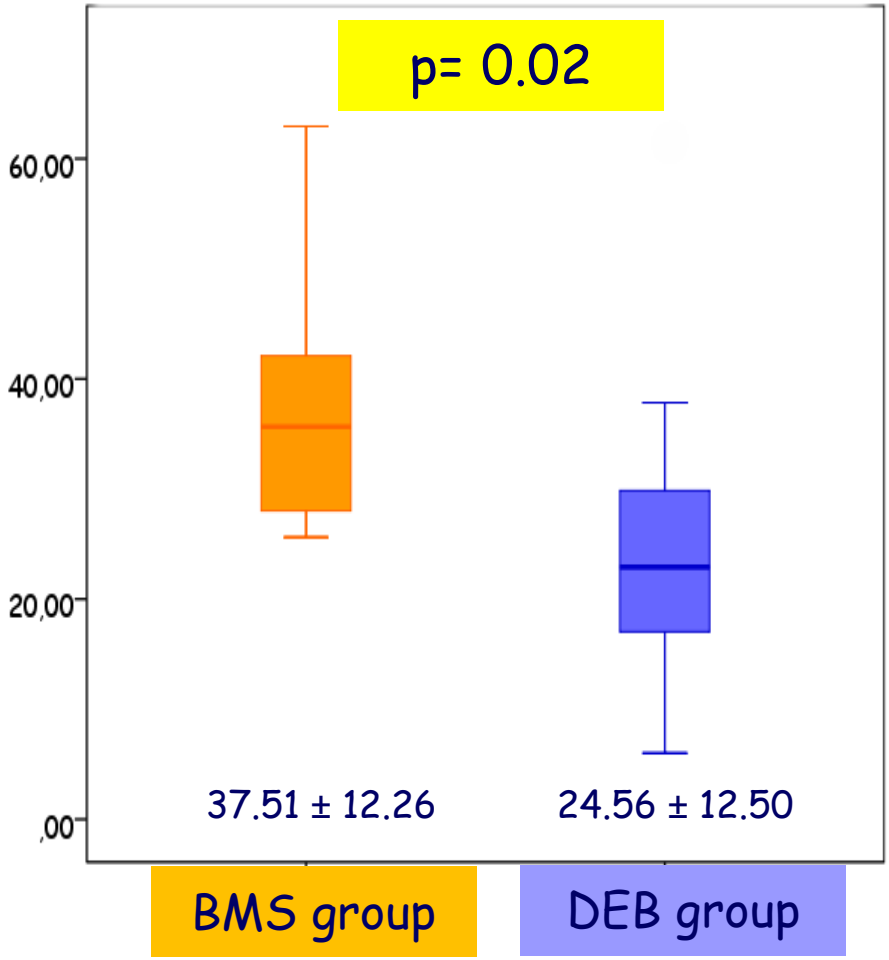
	BMS Group	DEB Group	p
Death	0 (0%)	0 (0%)	1.00
MI	0 (0%)	0 (0%)	1.00
TVR	3(30%)	4(20%)	0.66

PRIMARY END-POINT (Neointima at 6-month OCT)

Neointima area (mm^2)

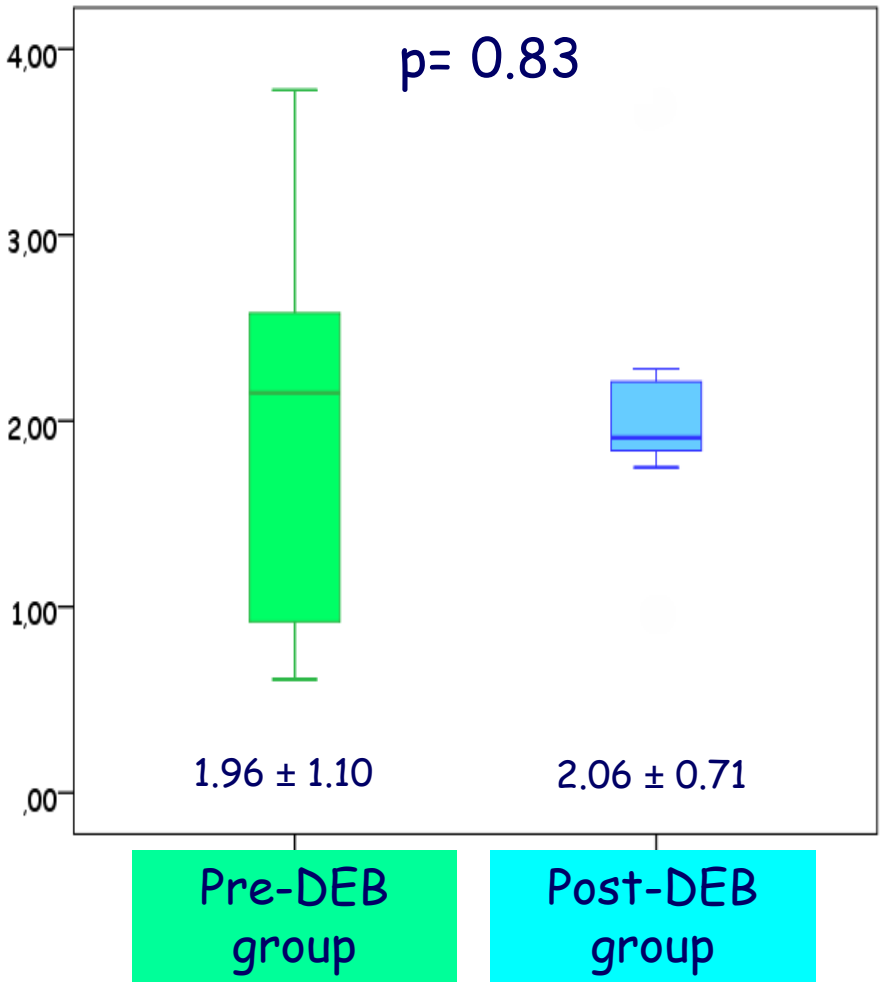


Percentage of neointima area

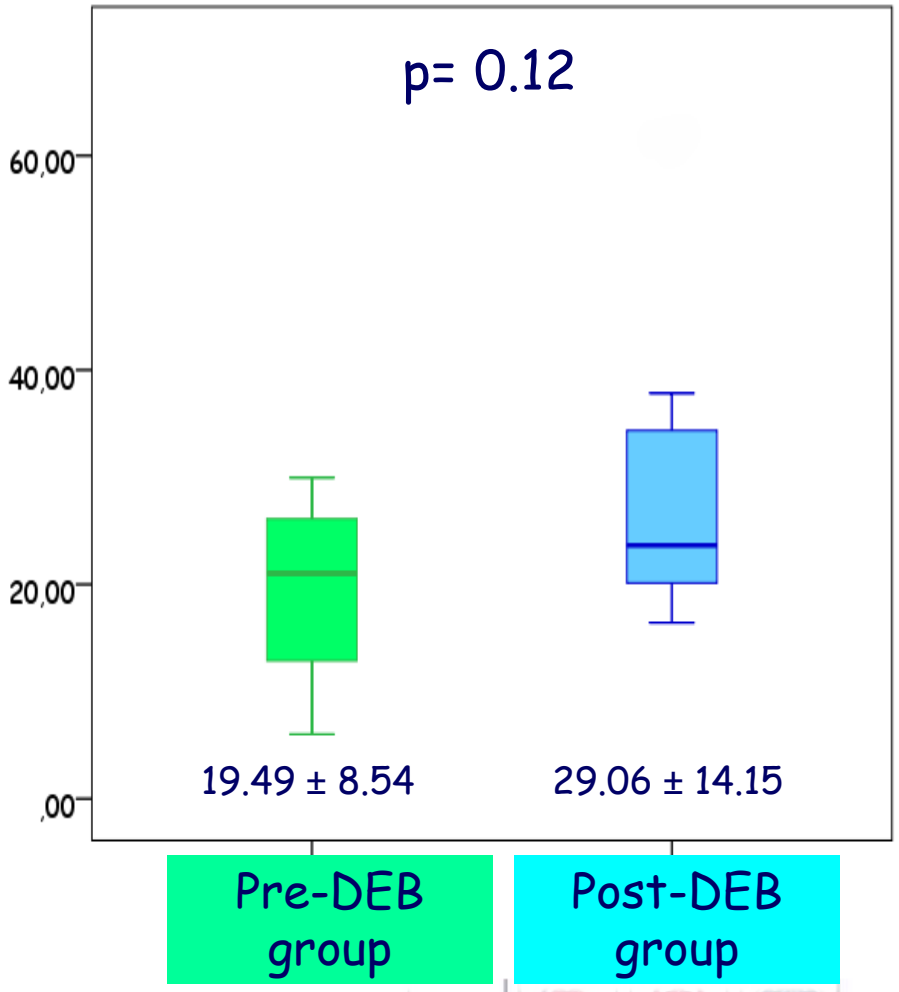


PRIMARY END-POINT by DEB tecnique

Neointima area (mm^2)

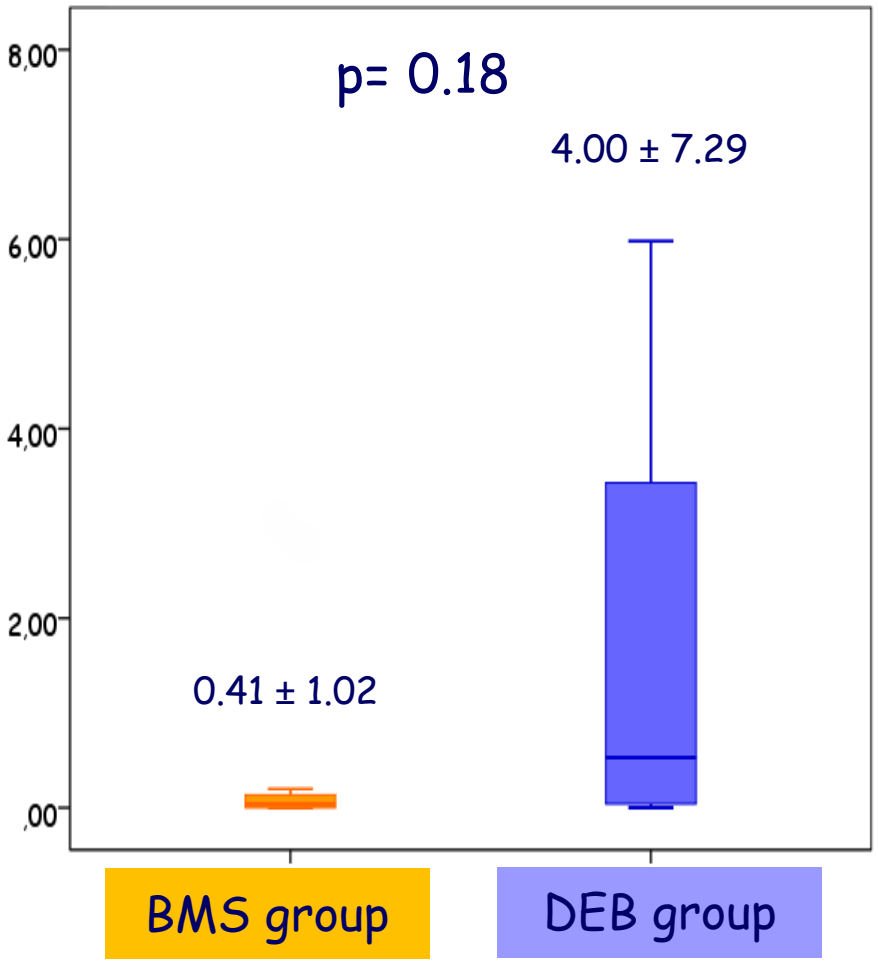


Percentage of neointima area

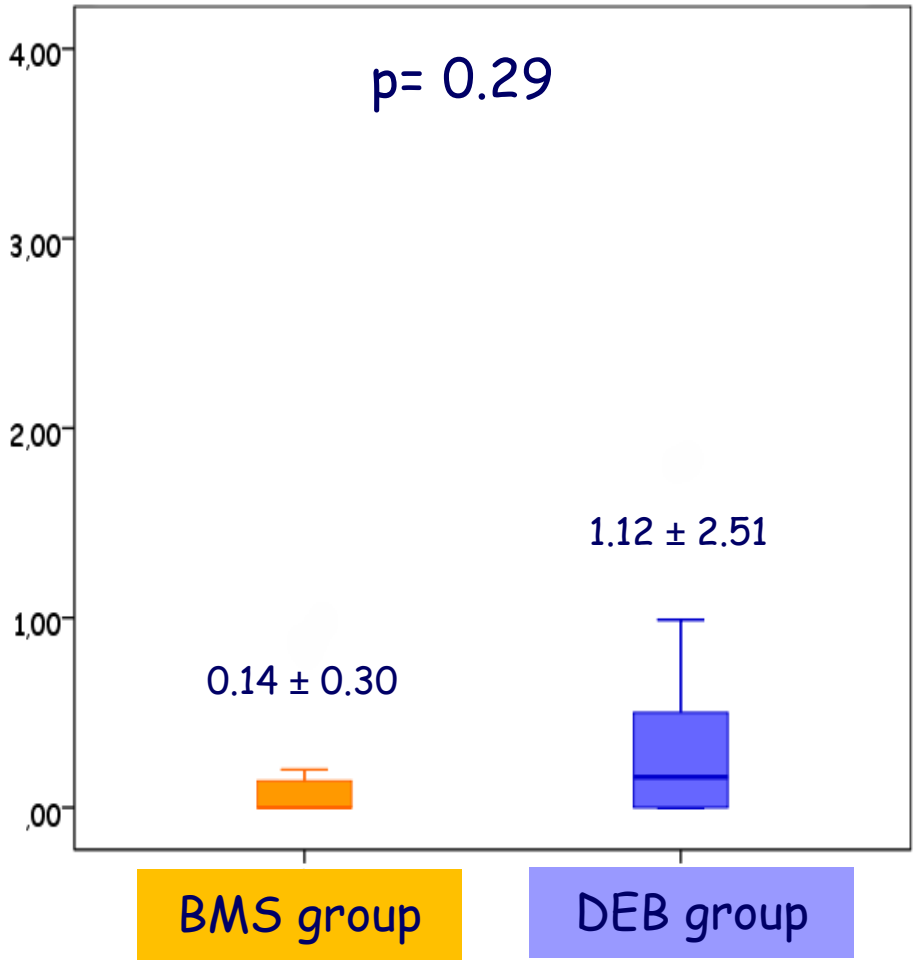


SECONDARY END-POINTS

Uncovered struts percentage

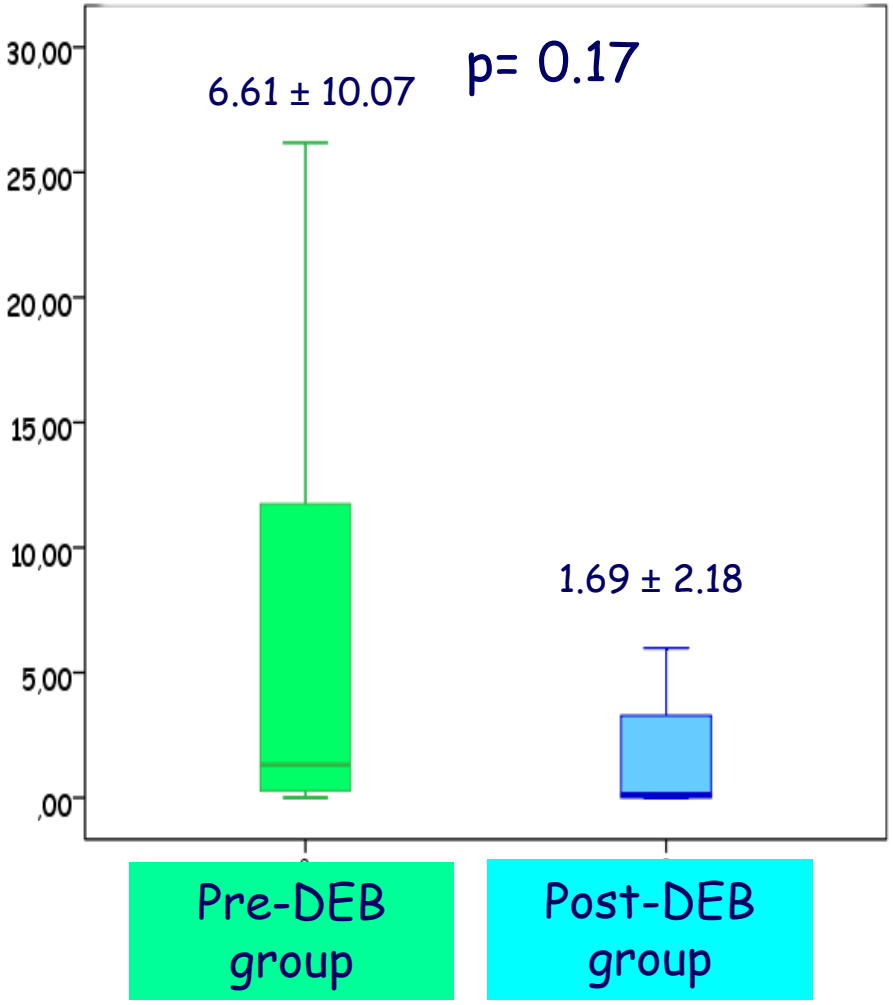


Malapposed struts percentage

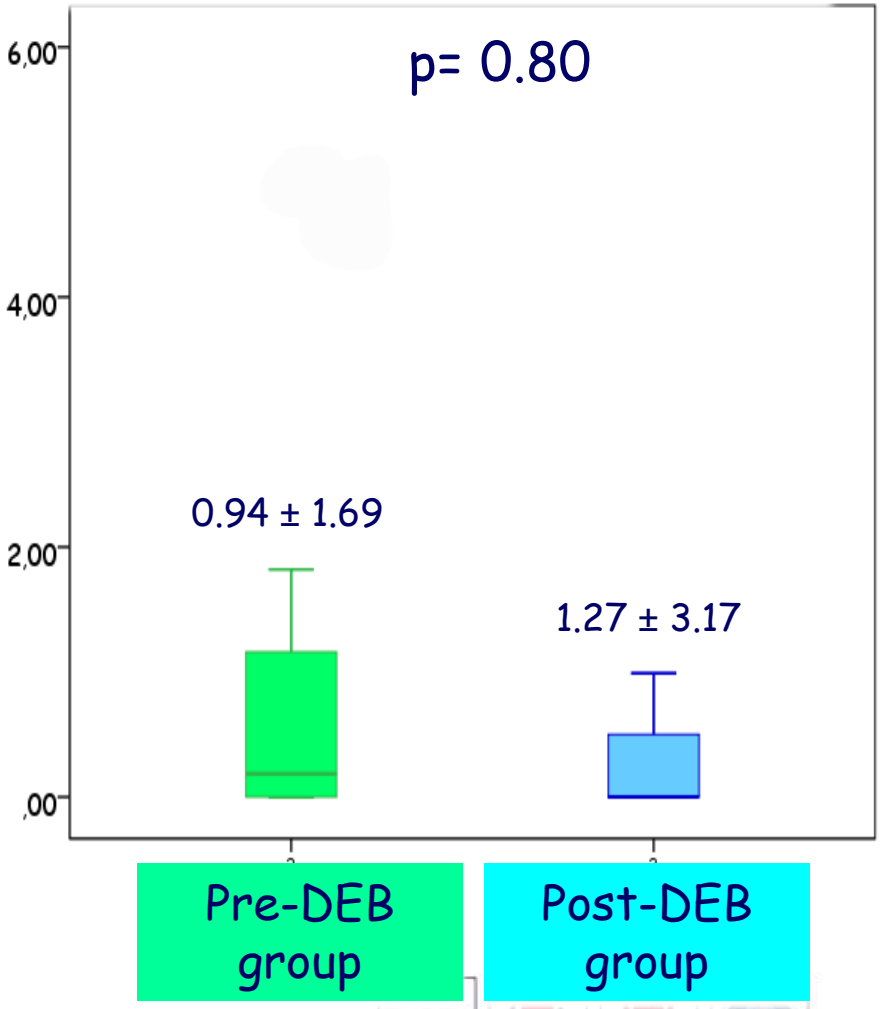


SECONDARY END-POINTS by DEB tecnique

Uncovered struts percentage



Malapposed struts percentage



Conclusions

- In simple, *de novo,* coronary lesions treated by bare metal stent, DEB is associated with a (mild) significant reduction of neointimal hyperplasia at 6-month

- The use of DEB before or after bare metal stent implantation has similar efficacy to reduce neointimal hyperplasia

- Bare metal stent strut coverage and apposition at 6-month are not affected by drug-eluting balloon use

THANK YOU FOR KIND ATTENTION

Appendinx: exclusion criteria

Clinical exclusion criteria	▪ age <18 years or impossibility to give informed consen ▪ women with child-bearing potential; ▪ diabetes mellitus; ▪ life expectancy less than 6 months or any condition impeding clinical follow-up ▪ significant platelet count alteration ▪ gastrointestinal bleeding requiring surgery or blood transfusions within the previous 4 weeks; ▪ infective, neoplastic or autoimmune diseases; ▪ history of clotting pathology, known hypersensitivity to aspirin, heparin, cobaltchromium, paclitaxel or contrast dye; ▪ renal failure with creatinine value >2.5 mg/dL; ▪left ventricular global ejection fraction ≤30%; ▪ acute myocardial infarction within the past 48 hours; ▪ non ST-elevation acute coronary syndrome within the past 48 hours
Angiographic exclusion criteria	▪ left main coronary artery disease; ▪ lesions in coronary artery bypass grafts; ▪ coronary anatomy not suitable for OCT scan; ▪ bifurcation lesions, chronic total occlusions, severe calcifications or moderate-to-severe tortuosities; ▪ presence of additional non-target lesions requiring treatment, within and outside the target vessel, which are not successfully treated

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