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EBC TWO

The **E**uropean **B**ifurcation **C**oronary study: a randomised comparison of provisional T-stenting versus a systematic **TWO** stent strategy in large calibre true bifurcations

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The EBC two trial is an investigator-initiated trial made possible by unrestricted grants by Terumo Europe and Pie Medical

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Background and Objectives

- Randomised trials of “all-comer” bifurcation lesions show that there is no advantage to systematic dual stent strategies.
- However, these trials included a proportion of patients with no disease in the side branch, or relatively small side branch vessels.
- Expert consensus suggests that “large” bifurcations with significant length ostial side branch disease may merit a systematic two-stent treatment strategy.

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The EBC TWO Trial Hypothesis

"Large true coronary bifurcation lesions (side branch ≥2.5mm) with significant ostial side branch disease (≥5mm length), are best treated with culotte stenting rather than a provisional T technique, with respect to target vessel revascularisation, myocardial infarction and death at 12 months."

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The EBC TWO Trial Organization

Initiator of the trial	European Bifurcation Club
Principal Investigator	David Hildick-Smith, Brighton, UK
Steering Committee	Yves Louvard, Massy, France Thierry Lefevre, Massy, France Jens Lassen, Aarhus, Denmark Olivier Darremont, Bordeaux Manuel Pan, Cordoba, Spain Goran Stankovic, Belgrade, Serbia Miroslav Ferenc, Bad Krozingen, Germany Remo Albiero, Brescia, Italy
Clinical Events Committee	Martine Gilard, Brest, France Philippe Garot, Quincy, France Stéphane Cook, Fribourg, Switzerland
Grants	Terumo Europe Pie Medical Imaging (for Corelab Analysis)
Study Coordination, Management Independent Corelab Analysis Organization of CEC	

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The EBC TWO Trial Methods

- Patient Population:
  - Elective or ACS patients
  - Coronary bifurcation disease requiring revascularisation
  - True bifurcation lesion (1,1,1; 1,0,1; 0,1,1)
  - Side branch >=2.5mm diameter
  - Side branch ostial disease >=5mm length

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TECHNIQUES

- SIMPLE
  - According to 5th EBC Consensus
- COMPLEX
  - According to 5th EBC Consensus

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The EBC TWO Trial - Study Endpoints

Primary Endpoint

- **Composite of Death, Myocardial infarction and Target Vessel Revascularisation at 12 months**

Secondary Endpoints:

- Individual components of the Primary Endpoint (death, MI, revascularisation)
- Angina status (CCS classification and Angina Index)
- Procedural Endpoints:
  - Procedural Success (TIMI 3 flow and <30% stenosis in the main vessel; TIMI 3 side branch)
  - Ability to perform kissing balloons as per protocol
  - Procedure duration, fluoroscopy time , X-ray dose
  - Procedural cost

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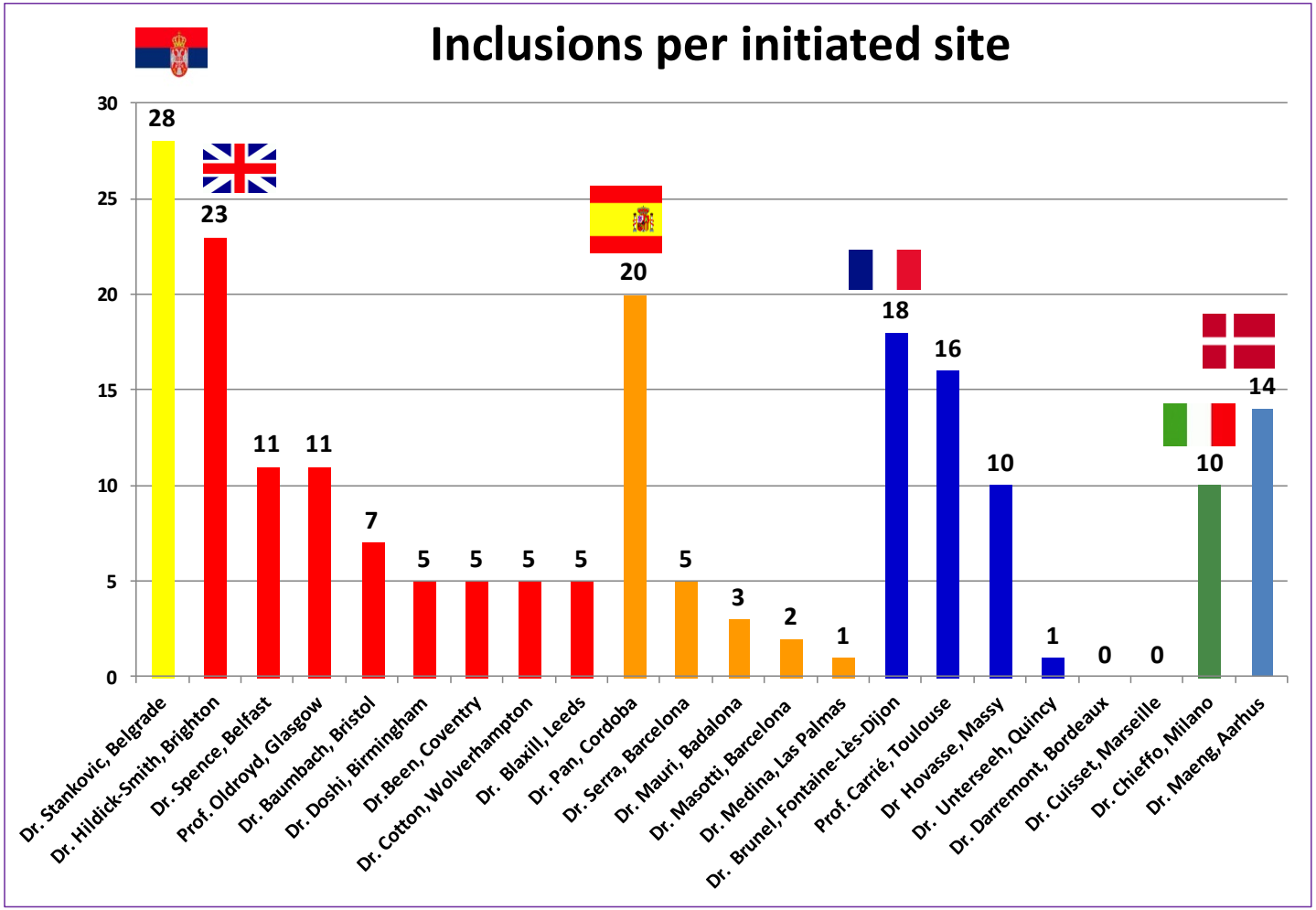
Enrollment

From April 2011 to January 2014 200 patients were randomised in 20 European centers across 6 countries



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Baseline Characteristics

	Provisional T (n=103)	Culotte (n=97)
Age	62.9±10.8	63.5±12.1
Male gender	87 (85%)	76 (78%)
Presentation:		
Stable Angina	71 (69%)	66 (68%)
ACS	32 (31%)	31 (32%)
Risk factors		
Hypertension	65 (63%)	66 (68%)
Diabetes	26 (25%)	30 (31%)
Family history	49 (48%)	48 (49%)
Past medical history		
Previous M.I	40 (39%)	40 (41%)
Previous P.C.I	41 (40%)	40 (41%)
Previous C.A.B.G.	6 (6%)	2 (2%)
Previous Stroke or TIA	6 (6%)	3 (3%)
Peripheral vascular disease	6 (6%)	8 (8%)

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Lesion Characteristics

	Provisional T (N=103)	Culotte (N=97)	p
Site of target bifurcation			ns
LAD-Diag	80 (77.7%)	75 (77.3%)	
Cx-OM	16 (15.5%)	18 (18.6%)	
RCA-PDA/PLV	6 (5.8%)	4 (4.1%)	
Medina classification			0.05
1, 1, 1	83 (80.58%)	66 (68.04%)	
0, 1, 1	12 (11.65%)	23 (23.71%)	
1, 0, 1	6 (5.83%)	7 (7.22%)	

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RESULTS

	Provisional T (N=103)	Culotte (N=97)	p
Main vessel:			
Stent N (%)	103 (100%)	96 (99%)	
Stent length (mm)	23.4 ± 4.8	22.9 ± 5.1	ns
Stent diameter (mm)	3.06±0.32	3.03±0.33	ns
Side branch:			
Stent N(%)	16 (16%)	94 (97%)	
Stent length (mm)	19.87±6.75	20.67±5.49	ns
Stent diameter (mm)	2.61±0.29	2.72±0.25	0.08
Total stent length (mm)	33.57±17.0	51.82±20.25	<0.0001
Total number of stents	1.6±0.8	2.5±0.7	<0.0001
Final kissing balloon inflation successful	97 (94%)	93 (96%)	ns
Procedural success	100 (97.09%)	95 (98%)	ns
Procedure time (min)	67.81±25.61)	82.51±38.86)	0.0018
Fluoroscopy time (min)	20.05±10.05)	26.57±17.13)	0.0011
Diamentor	18262±32363	21291±34547.9	ns
Cost (€)	2257	3263	<0.0001

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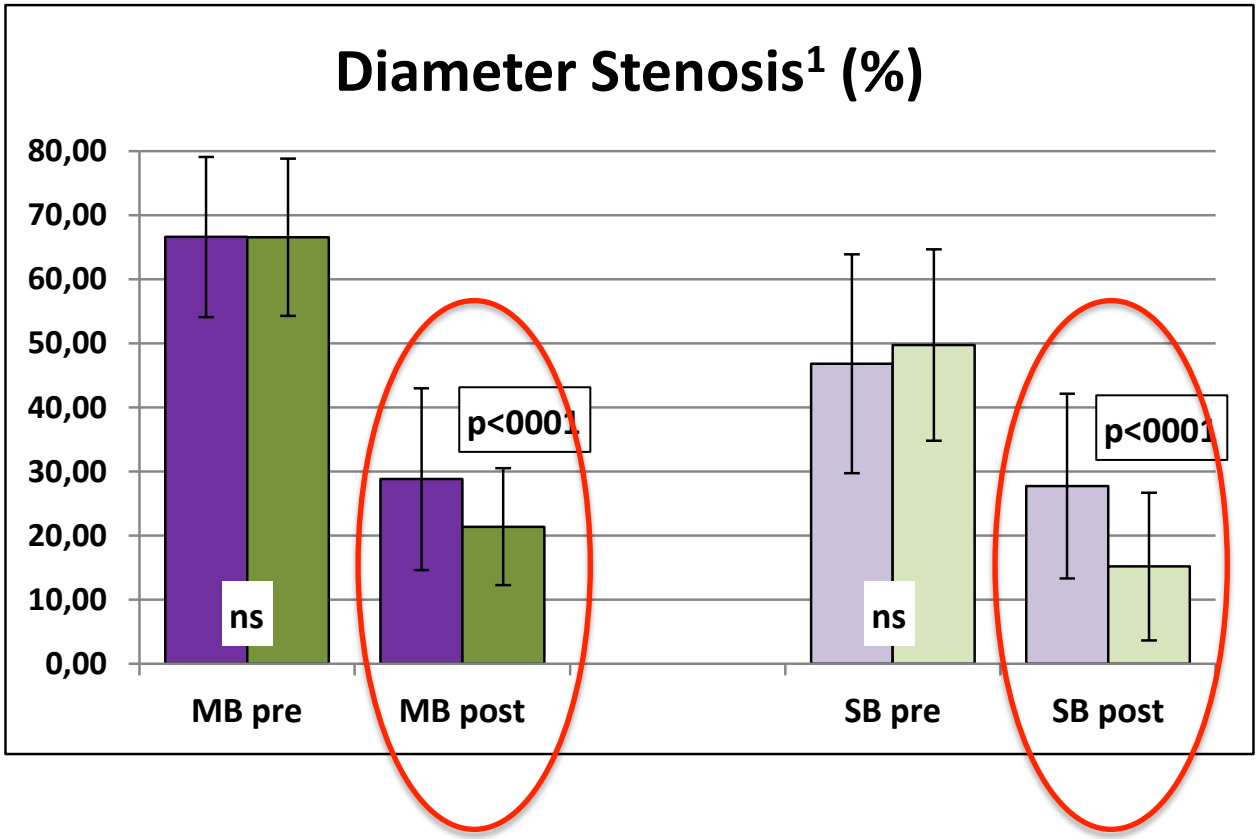
Acute Corelab QCA Results



Provisional T (N=103):

Culotte (N=96):

MB: main branch
SB: side branch

Pre: pre-procedure
Post: post procedure
[1]values refer to *in lesion*

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PRIMARY ENDPOINT

	Provisional T (n=103)	Culotte (n=97)
Death, MI, TVR at 12 months	**8 (8%)**	**10 (10%)**
Death	**2 (2%)**	**1 (1%)**
Myocardial infarction	**5 (5%)**	**10 (10%)**
NSTEMI	5	9
STEMI	0	1
<48H	4	10
TVR	**3 (3%)**	**1 (1%)**
Stent thrombosis	**1 (1%)**	**3 (3%)**
Definite / Probable	1	2
Possible	0	1

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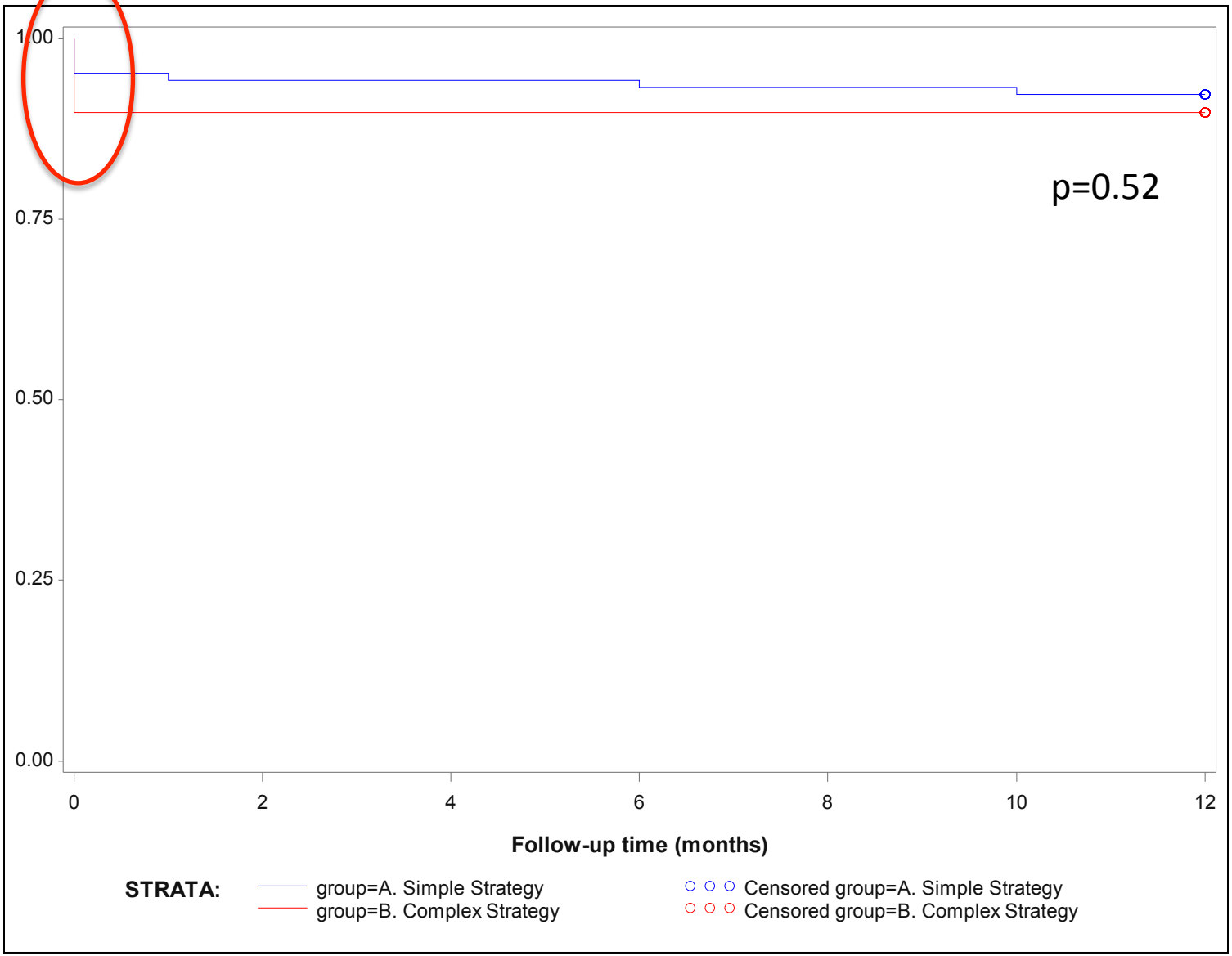
The EBC TWO Trial

12 M Outcome : Death, MI and TVR at 12



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CONCLUSIONS

- Excellent protocol adherence
  - Side branch lesion 10mm by QCA
  - Side branch stent diameter 2.65mm
  - 16% two-stent implantation in provisional group

- Procedural success good in both groups

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CONCLUSIONS

- Acute Results
  - Time, X-ray dose and cost all favoured the provisional strategy
  - Kissing inflation success >95% in both groups
  - Acute gain greater after culotte in both side and main vessels
  - Numerically more periprocedural infarction in the culotte group

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CONCLUSIONS

- 12-month Results
  - No significant difference between provisional and culotte techniques even in this highly complex bifurcation population
- Numerical trends are in keeping with expectations
  - More target vessel revascularisation in the simpler procedure
  - More periprocedural MI and stent thrombosis in the more complex procedure