

EBC TWO: EBC MAIN

European Bifurcation Club Trials

David Hildick-Smith
Sussex Cardiac Centre, UK





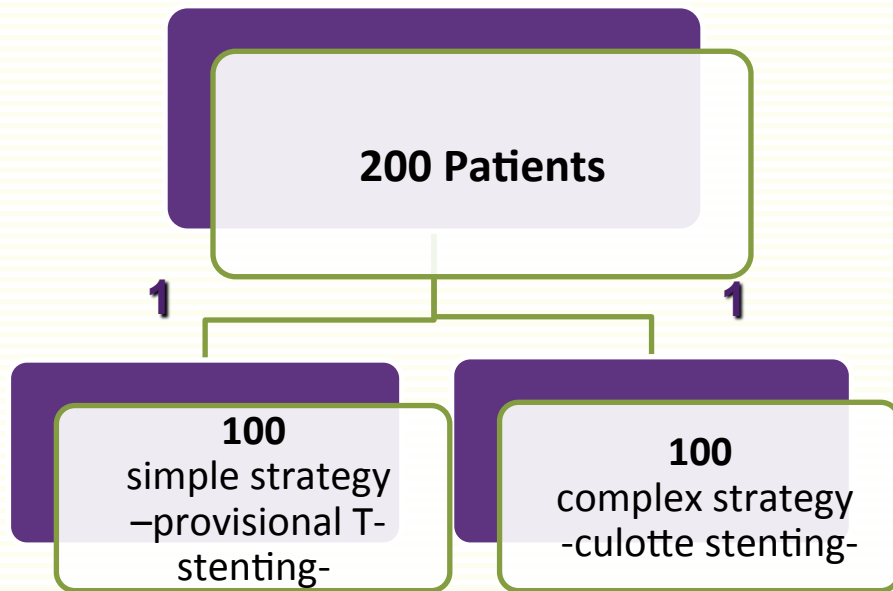
THE **E**UROPEAN **B**IFURCATION **C**ORONARY
STUDY; A RANDOMISED COMPARISON OF
PROVISIONAL T-STENTING VERSUS A
SYSTEMATIC **TWO** STENT STRATEGY IN LARGE
CALIBRE TRUE BIFURCATIONS



General Information

> Study Design

- > 200 Patients with Bifurcation lesion
- > Randomization 1:1



Device



Nobori®

All sizes and lengths

> 19 Centers in 4 countries

- > UK (6)
- > Italy (2)
- > France (7)
- > Spain (4)

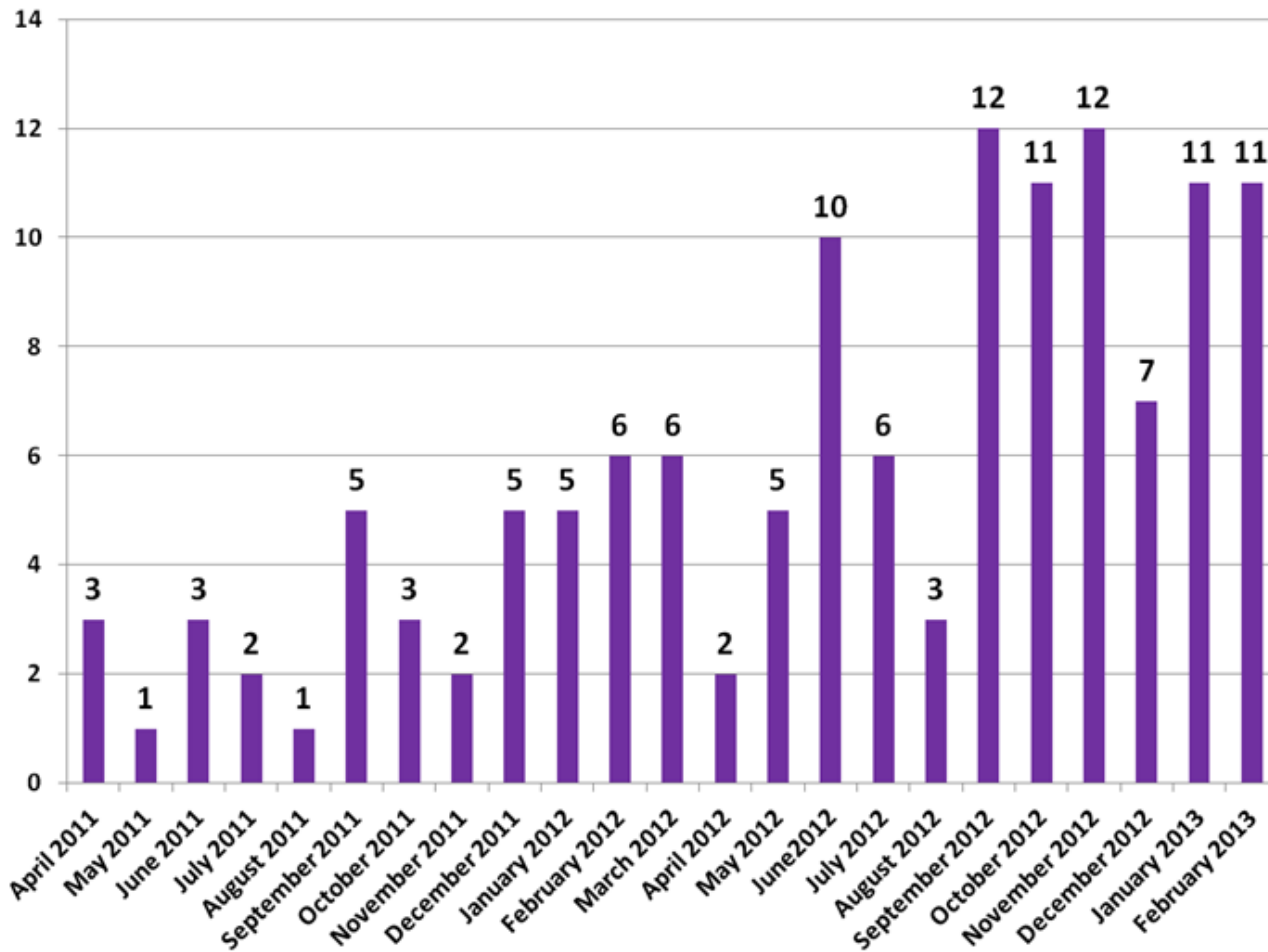
Primary endpoint

- Death, MI, TVR at 12 months

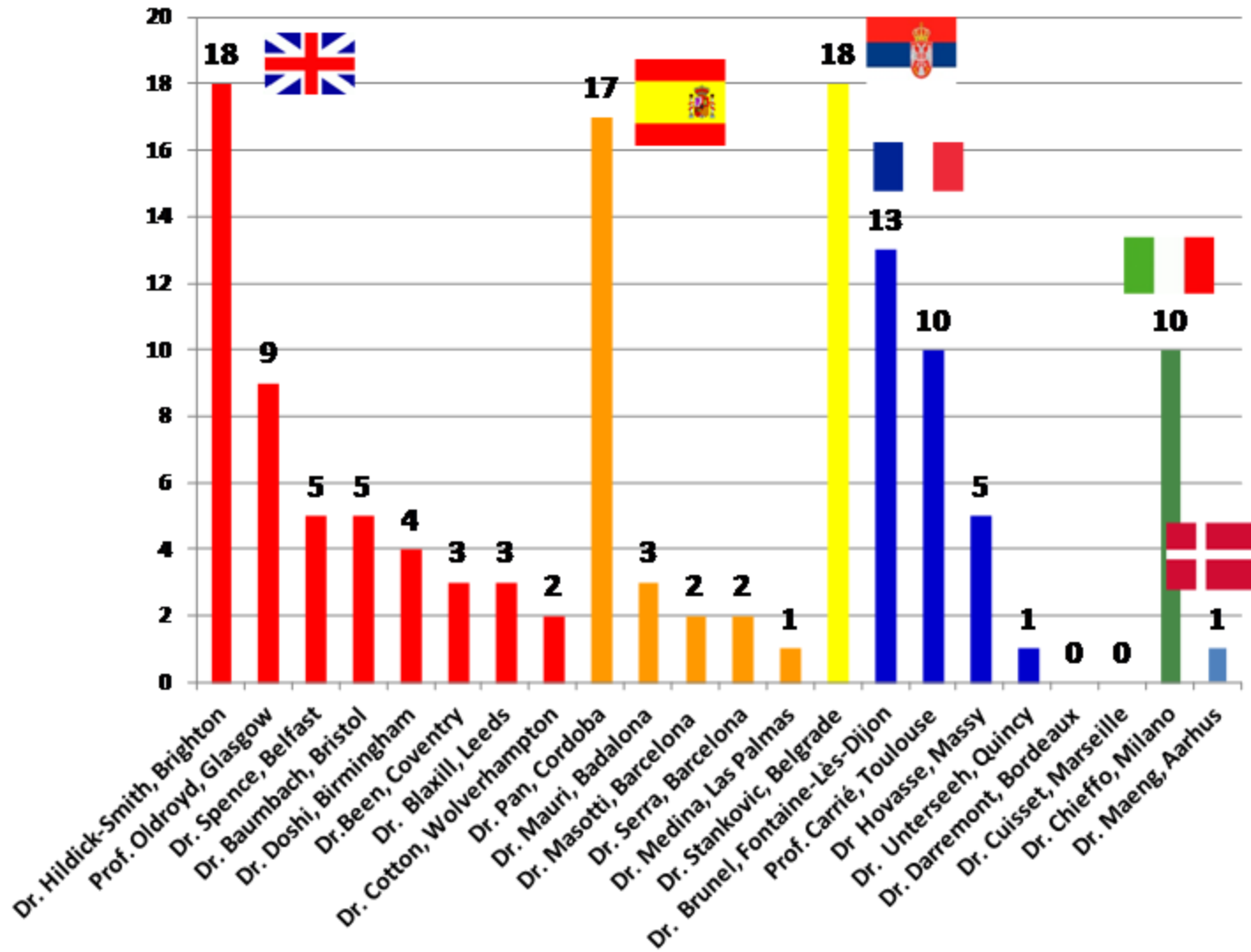
Randomisation

- SIMPLE
 - Provisional T with mandatory kissing balloons
- COMPLEX
 - Culotte with mandatory kissing balloons

Inclusions per months



Inclusions per initiated site



RESULTS

- 200 patients recruited August 2013
- 1-year follow-up complete August 2014
- Submission to PCR LBCT for 2015

Sneak preview

- Primary endpoints met n=19 (9.5%)
 - Death n=3
 - MI n=2
 - TVR n=12
 - Stent thrombosis n=2

EBC MAIN

- The **E**uropean **B**ifurcation **C**lub **L**eft **M**ain
Coronary Study - a randomised comparison of
Single versus Dual Stenting for True Bifurcation
Left Main Coronary Lesions

Hypothesis

- “Left main coronary bifurcation lesions (type 1,1,1 or 0,1,1: both LAD and Cx >2.75mm diameter) are best treated with a planned provisional single stent strategy rather than a planned dual stent strategy, with respect to death, target lesion revascularisation and myocardial infarction at 1 year.”

ANNOUNCEMENT!

- Medtronic have agreed an unrestricted educational grant to support the EBC MAIN study

Inclusion criteria

- Bifurcation distal left main stem stenosis $>50\%$
 - And ischaemic symptoms or FFR <0.8 or IVUS <6
- Left main diameter $<6\text{mm}$
- True bifurcation lesion type 1,1,1 or 0,1,1
- LAD and Cx diameter both $\geq 2.75\text{mm}$
- Unprotected left main
- Patient ≥ 18 years old

Exclusion criteria

- STEMI <72 hours preceding
- Cardiogenic shock
- Chronic total occlusion of either vessel
- >2 additional lesions to be treated
- SYNTAX score >32
- Left ventricular ejection fraction $\leq 20\%$
- Patient life expectancy less than 12 months

Study design

- Multicentre
- Prospective
- Randomised
- 450 patients
- 20 centres
- Resolute ONYX stent
 - 4.5mm stent opens to 5.75mm diameter

Endpoints

- **Primary:**
 - Death, Myocardial infarction and Target Lesion Revascularisation at a median of 12 months
- **Secondary:**
 - Death, MI, TLR, individually
 - Angina status
 - Stent thrombosis
 - Death, MI, TLR at 3 yrs, 5 yrs
- **Procedural:**
 - Procedure success and MACE
 - In-hospital MACE
 - Procedure duration, fluoroscopy, diamentor and cost

Techniques

- SINGLE STENT
- provisional T according to EBC Consensus 2013
- Including POT and kissing balloons

Techniques

- DUAL STENT
- Operator choice (culotte, dkcrush, T, TAP)
- Including POT and kissing balloons

Discussion....