BVS Expand: First results of wide clinical applications of Bioresorbable Vascular Scaffold

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On behalf of the Thoraxcenter Interventionalists and Yoshi Onuma, Roberto Diletti and Sjoerd Nauta

Thursday 23rd May, 2013 15:25-15:35

Potential conflicts of interest

Speaker's name: Robert-jan van Geuns

☑ **I have the following potential conflicts of interest to report:**

Consultant: Stentys, Abbott Vascular

Employment in industry: …

Honorarium: Speakersbureau, Stentys, Abbott Vascular

Institutional grant/research support: Abbott Vascular

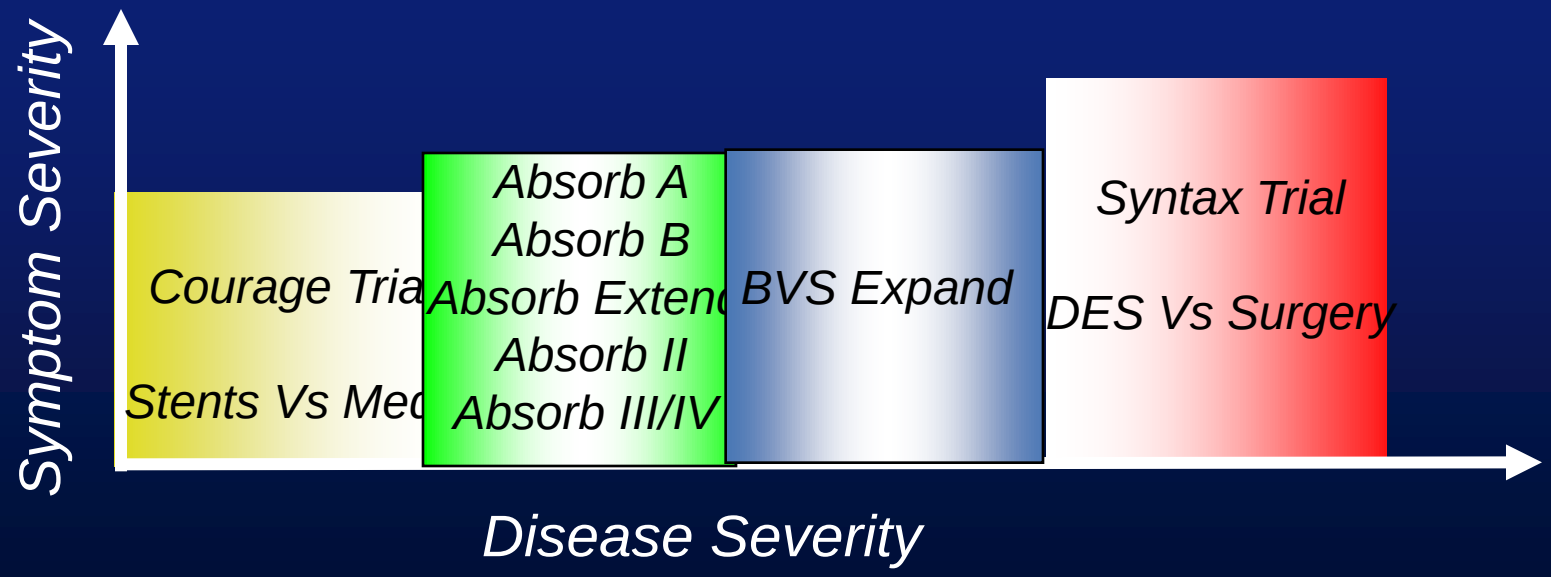
Owner of a healthcare company: …

Stockholder of a healthcare company: …

BVS Expand: Single Center Registry

- *Larger diameter up to 4.0 mm*
- *Longer length: > 32 mm*
- *Bifurcations*
- *Calcified lesions*
- *ACS patients (non-STEMI)*
- *No previous CABG or metallic stent in target vessel*

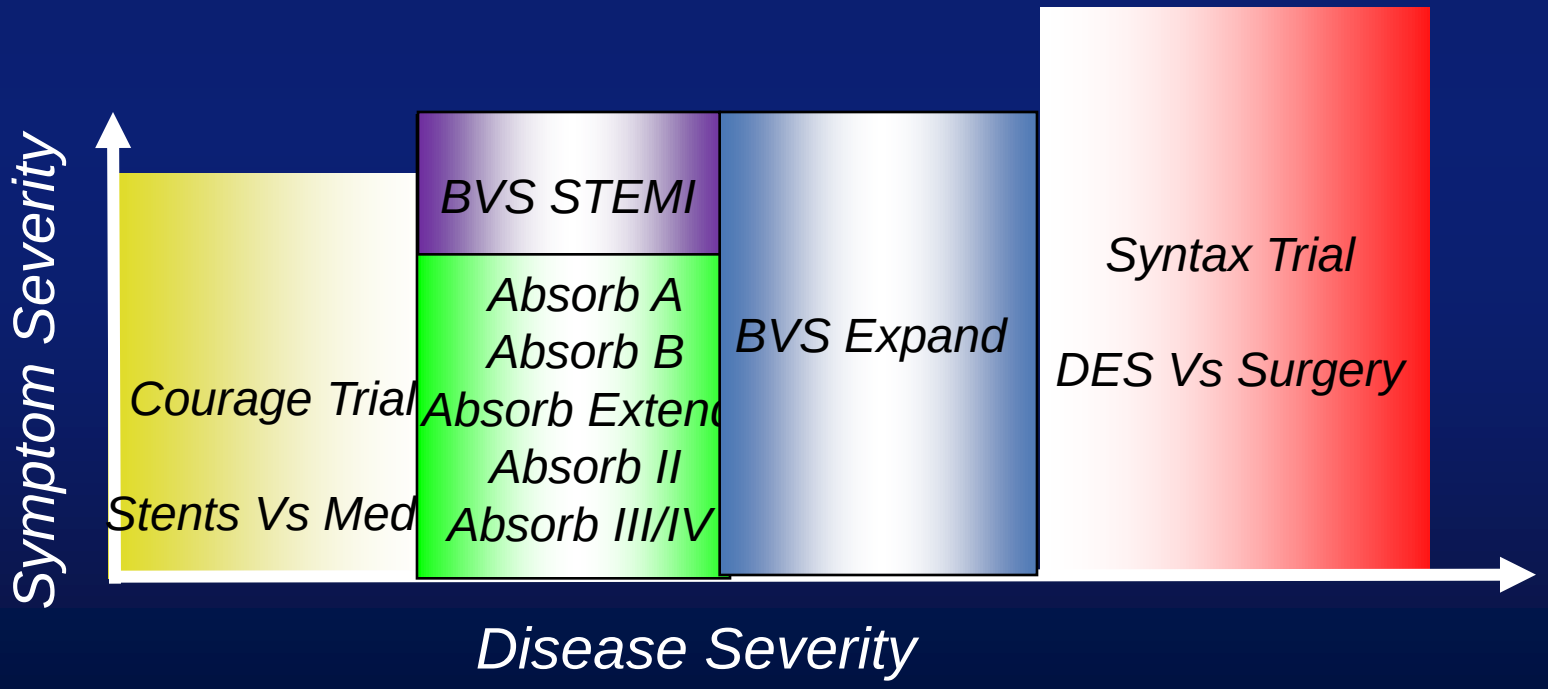
Target: 300 patients
Start Sept 1st 2013



BVS Expand: Single Center Registry BVS-STEMI-First

- Single center registry BVS in STEMI
- OCT at baseline for apposition

Dec 15th



BVS Expand: Single Center Registry

OBJECTIVE

- This monocenter, prospective, observational post market registration will evaluate the long term safety and performance of the BVS coronary stent, in routine clinical practice. Its objective is to measure the incidence of Major Adverse Cardiac Events (MACE) patients with NSTEMI, stable or unstable angina, or silent ischemia

BVS Expand: Single Center Registry

PRIMARY ENDPOINT

- Major Adverse Cardiac Events (MACE): defined as cardiac death, re-MI, emergent bypass surgery (CABG), or clinically driven target lesion revascularization (TLR) by percutaneous or surgical methods at 12 months post-procedure

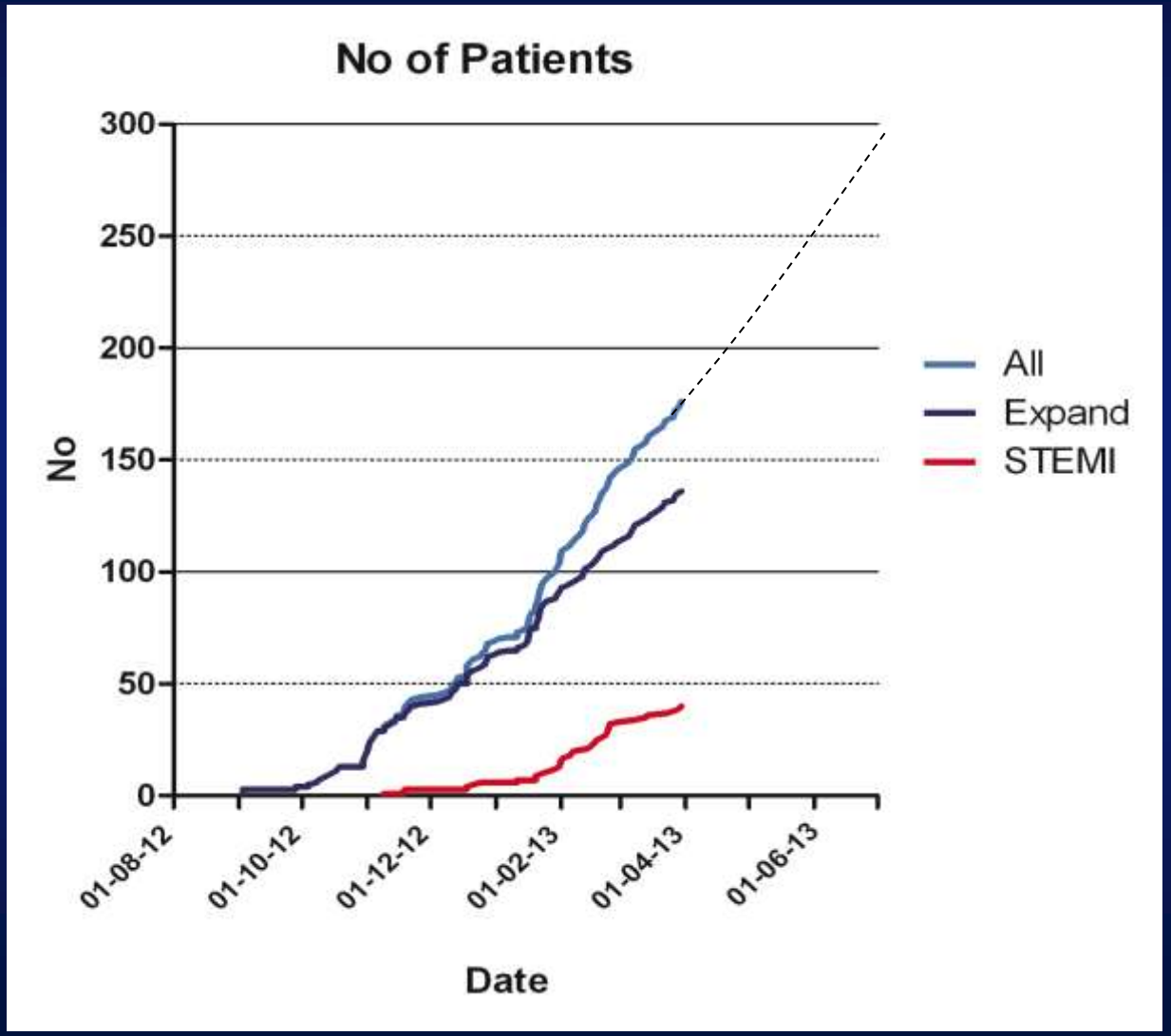
SECONDARY ENDPOINTS

- Success Rates:
  - Device Success: Attainment of <30% final residual stenosis of the segment of the culprit lesion covered by the BVS, by visual estimation
  - Procedure Success: Device success and no peri-procedural complications
  - Clinical success: Procedural success and no in-hospital MACE

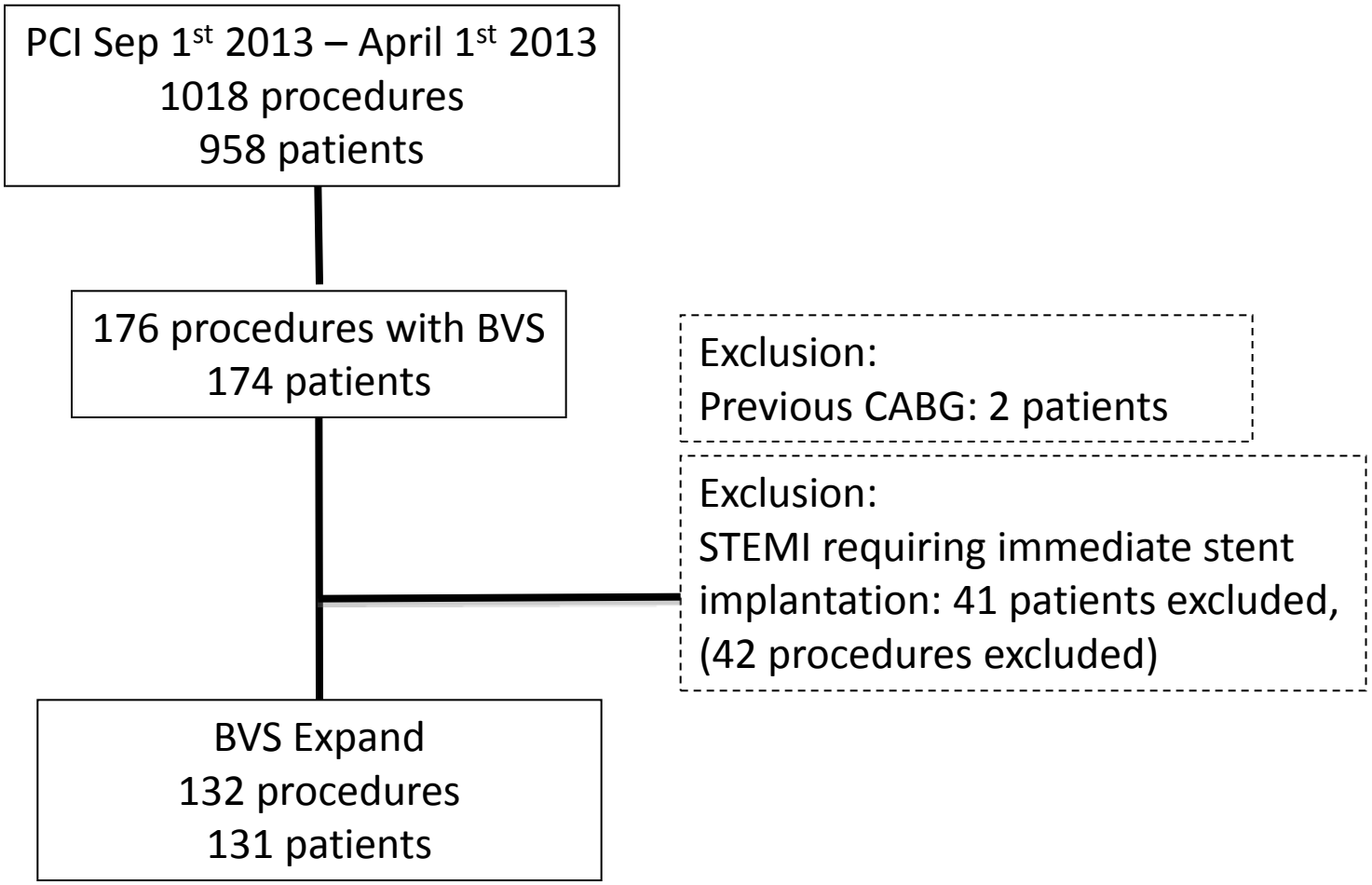
SECONDARY ENDPOINTS

- Major Adverse Cardiac Events (MACE): defined as cardiac death, re-MI, emergent bypass surgery (CABG), or clinically driven target lesion revascularization (TLR) by percutaneous or surgical methods **30 days**, 6, 12, 18 months, 2, 3, 4, and 5 years post-procedure
- Target vessel failure (TVF) defined as cardiac death, target vessel myocardial infarction (MI) [Q or Non Q-Wave], or clinically driven target vessel revascularization (TVR) by percutaneous or surgical methods **at 30 days**, 6, 12, 18 months, 2, 4 and 5 years.
- Health Related Quality-of-Life (HRQL) at 30 days, 6, 12 months, 3 and 5 years

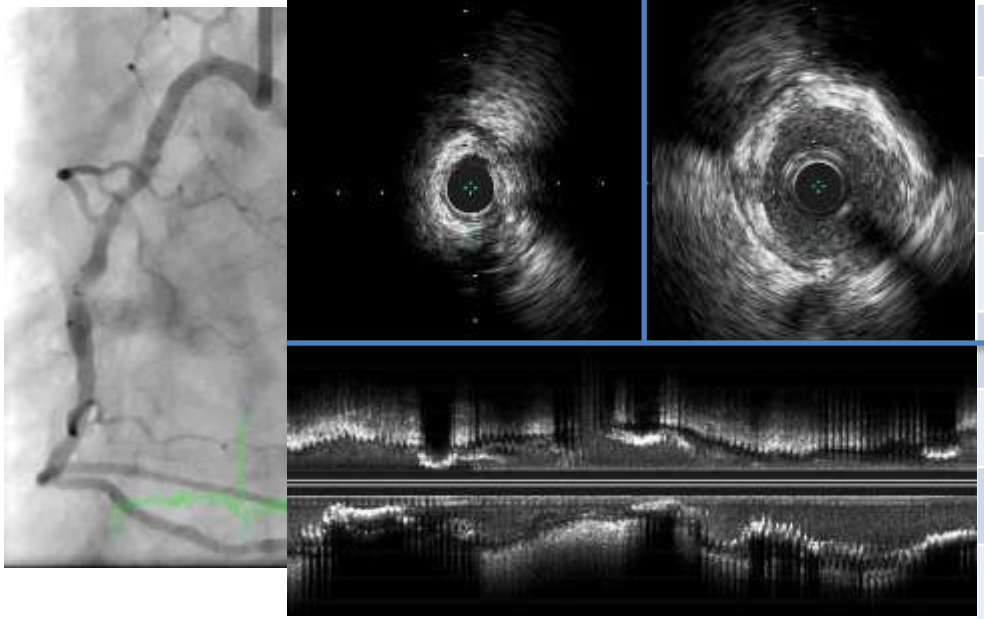
BVS Expand + BVS-STEMI-First

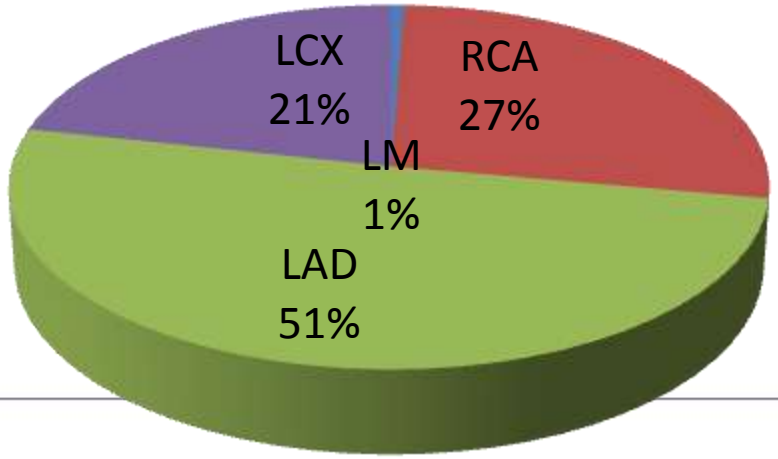


Patient Inclusion



Baseline characteristics





	BVS-Expand
N	131
Male	99 (75%)
Hypertension	68 (52%)
Hypercholestorolemia	61 (46%)
Diabetes	26 (20%)
Smoking	66 (50%)
Family	53 (40%)
Renal failure	9 (7%)
Prior MI	20 (15%)
Prior PCI	16 (12%)
Prior CABG	0 (0%)
Prior CVA	11 (8%)
PAD	15 (11%)
COPD	9 (7%)

Procedural characteristics

Implantation instruction

- Use online QCA
- Avoid under sizing, as postdilation is limited to 0.5 mm
- Proper lesion preparation = sufficient large balloon (min 2.5 mm)
- Use more supportive wires
- Direct stenting possible in ACS

	All (N=132)
MVD	39 (30%)
Bif	33 (25%)
CTO	11 (8%)
STEMI	0 (0%)
Overlap	46 (35%)
Total scaffolds	239
Scaffolds per procedure	1.8

Lesion Length: BVS EXPAND 20.3 mm (N=36)

Lesion Length: Cohort B: 9.9 mm
Extend: 11.7 mm

SECONDARY ENDPOINTS

- Success Rates:
  - Device Success: Attainment of <30% final residual stenosis of the segment of the culprit lesion covered by the BVS, by visual estimation
  - Procedure Success: Device success and no peri-procedural complications
  - Clinical success: Procedural success and no in-hospital MACE

Procedural Outcome

	All (N=132)
Device success	127 (96%)
Procedural success	126 (95%)
Clinical success	126 (95%)

Failure to Deliver

One patient: DS>30%

Failure to deliver	All (N=5)
LCX	3
LAD	0
RCA	2

Procedural complications	All (N=1)
Side branch Occlusion	1 (1%)
MI	1 (1%)
Q-wave	0 (0
Non-Q-wave	1 (1%)

30 Day outcome

Survival: 100%, FU completed for 80%

30 day outcome	BVS Expand (N=131)
MACE	1 (1%)
Target vessel failure	0 (%)
Cardiac death	0 (0%)
Any MI	1 (1%)
Emergent CABG	0 (0%)
iTLR	0 (0%)
Target vessel MI	0 (0%)
Non-TVR	1 (1%)

>30 days: 2 stent thromboses day 47 and day 120; 1 non-target vessel MI day 162; 1 death day 136.

Survival status is available in 100% with a median follow-up of 137 days (IQR 96-195 days).

Summary

- First real world experience in >130 complex procedures very positive following a strict implantation protocol
- At 30 days only one adverse event for these cases was reported
- Low MACE for current FU
- One death at 136 days, for median FU of 127 days
- Deliveribility:
  - Flexibilty
  - Crossing profile/Strut thickness
- Longer procedural time, more supportive wires, more predilatation.

Bifurcations

	N = 132
Sidebranches >2 mm	33 (25%)
Sidebranches treated	19 (14.4%)
Balloon only	18 (13.6%)
2 scaffolds (Culotte)	1 (0.7%)

Failure to deliver