Long-term follow-up of BRS implantation for complex coronary lesions: a multicentre experience

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Potential conflicts of interest

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- ❑ I do not have any potential conflict of interest to report:

Why this study?

- Bioresorbable vascular scaffolds have emerged as an alternative to second generation drug-eluting stents, with the appealing long-term advantage of reducing late thrombotic events

- The recent publication of long-term data from randomized clinical trials showing a non-negligible incidence of late BVS thrombosis, have raised concerns about this potential benefit

- The aim of this study was to to evaluate the long-term outcomes of BVS implanted with a consistent dedicated implantation strategy in a “real world” setting of patients with a high prevalence of complex lesions.

What did we study?

- Restrospective study from 3 high-volume centers (San Raffaele, Milan, Italy; Centro Cuore Columbus, Milan, Italy; Fortis Healthcare, New Delhi, India) that implanted BVS with a dedicated technique since the beginning:
  - Pre dilatation: the lesion was adequately prepared aggressively in order to avoid balloon indentations and to allow a complete BVS expansion
  - Sizing: liberal use of intravascular imaging in large or small vessels and in long lesions
  - Post dilatation: mandatory high pressure post-dilation with non-compliant balloon

- These principles formed the basis for what is now called PSP

How was the study executed?

- A total of 480 patients (762 lesions) were enrolled between May 2012 and December 2014 at three high-volume PCI centers.

- Primary endpoints:
  - Target lesion failure (TLF): composite of cardiac death, target vessel myocardial infarction (MI), or target-lesion revascularization (TLR)
  - Definite + probable scaffold thrombosis (ST)

- Other secondary endpoints were death from any cause, all myocardial infarctions, target-lesion and target-vessel revascularization

How was the study executed?

	N=480 patients
Age (years)	59.8±11
Male, n (%)	430 (89.6%)
Hypertension, n (%)	285 (59.4%)
Dyslipidemia, n (%)	182 (38%)
Diabetes mellitus, n (%)	171 (35.6%)
eGFR<60, n (%)	74 (15.4%)
Left ventricular ejection fraction (%)	54.5±8.4
Clinical presentation, n (%)	
Stable angina	345 (71.9%)
Unstable angina	111 (23.1%)
STEMI/NSTEMI	24 (5%)

How was the study executed?

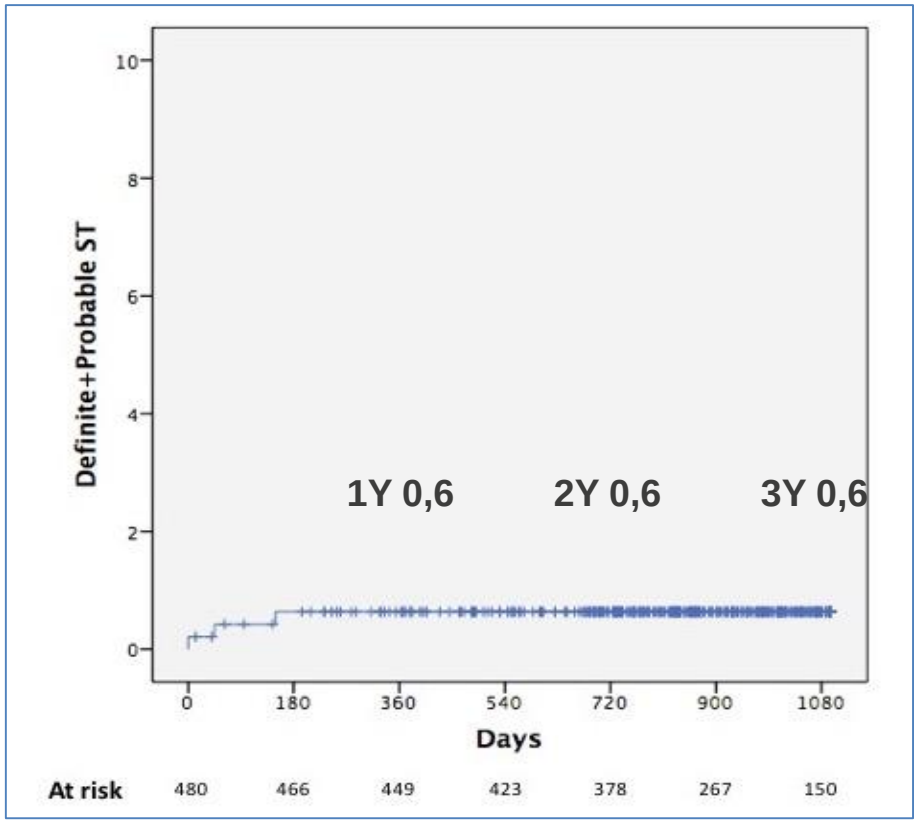
	N=762 lesions, 480 patients
Lesion characteristics	
Target vessel	
Left anterior descending artery	404 (53%)
Left circumflex artery	164 (21.5%)
Right coronary artery	186 (24.4%)
Left main trunk	8 (1%)
Number of lesions per patient	1.6±0.8
ACC/AHA class B2 or C	563 (73.9%)
Bifurcation, n (%)	216 (28.3%)
In-stent restenosis, n (%)	22 (2.9%)
Chronic total occlusion, n (%)	39 (5.1%)
Ostial lesion, n (%)	21 (2.8%)
Severe calcification, n (%)	89 (11.7%)

What are the essential results?

	N=762 lesions, 480 patients
Lesion preparation	
Pre-dilation, n (%)	755 (99.1%)
Scoring or Cutting balloon	81 (10.6%)
Rotablator, n (%)	36 (4.7%)
Scaffold implantation	
Total scaffold number per lesion	1.2±0.5
Total scaffold length per lesion, mm	28.1±14.3
Total scaffold number per patient	1.9±1
Total scaffold length per patient, mm	44.4±27.9
Post-dilation	
Post-dilation, n (%)	761 (99.9%)
Post-dilation pressure, atm	22±3.6
Intravascular imaging use, n (%)	373 (49%)

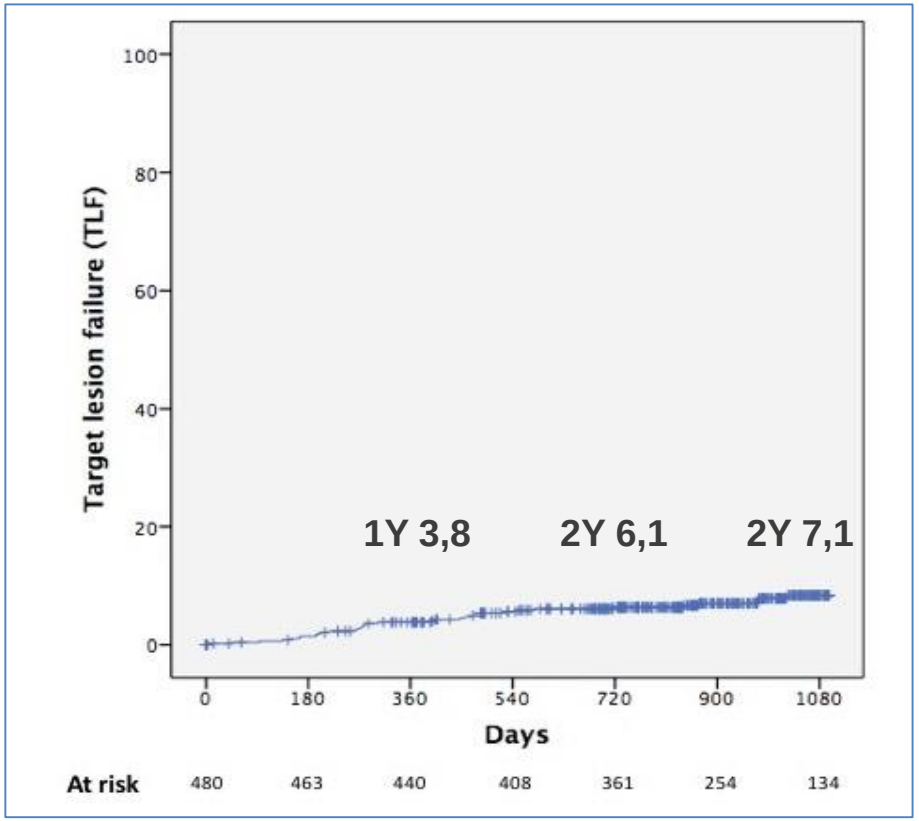
32% of patients received at least one 2.5 mm BVS

What are the essential results?



Clinical FU was available for 98,8% of patients

Median FU was 954 days (IQR 760-1131)



What are the essential results?

	1-year FU	2-year FU	3-year FU
Target lesion failure (TLF)	18 (3.8%)	29 (6.1%)	34 (7.1%)
Cardiac death	3 (0.6%)	4 (0.8%)	5 (1%)
Target vessel MI	2 (0.4%)	3 (0.6%)	3 (0.6%)
TLR	15 (3.1%)	26 (5.4%)	30 (6.2%)
All cause death	6 (1.2%)	7 (1.5%)	11 (2.3%)
Any myocardial infarction	7 (1.5%)	10 (2.1%)	11 (2.3%)
Any revascularization (including staged)	30 (6.3%)	54 (11.3%)	63 (13.1%)
TVR	15 (3.1%)	34 (7.1%)	40 (8.3%)
Definite/probable ST	3 (0.6%)	3 (0.6%)	3 (0.6%)

100% of patients was on DAPT after 12 months

51% of patients did not discontinue DAPT at last contact

The essentials to remember

- This large multicenter registry enrolled patients with high prevalence of complex disease and showed good procedural and long-term outcomes
- The use of a dedicated implantation technique seems to be a mandatory aspect in order to achieve good long term results when implanting BVS
- Scaffold thrombosis rate was low (< 1%) and no late or very-late ST occurred