Bioresorbable Vascular Scaffolds (BVS) in Patients with Acute Coronary Syndrome

The Multicenter Registry in Poland POLAR ACS

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Background / aim of the study

Bioresorbable vascular scaffold (BVS, Absorb) implantation was shown to be safe and effective in patients with stable coronary artery disease. However no scientific data are available on BVS in patients with acute coronary syndromes (ACS).

POLish Absorb Registry for ACS patients (**POLAR ACS**) is a multicenter registry of 100 patients presenting with ACS (unstable angina and myocardial infarction (MI): NSTEMI & STEMI) and treated with Absorb scaffold (PCI BVS).

The aim of the registry is to evaluate safety, clinical device and procedure success and in-hospital MACE (Major Adverse Clinical Events) in ACS. Quantitative Coronary Angiography (QCA) and reperfusion paremeters are analysed for all PCI BVS. All QCA analyses were performed by independent Core Laboratory.

Enrollment has been completed for 88 patients since Nov 2012 till May 2013.

euro PCR 2013

Study flow chart

inclusion & exclusion criteria met

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patient eligible for BVS implantation based on angiography

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PCI
- **Predilatation recommended**
- BVS implantation
- Postdilatation per operator discretion
- OCT / IVUS per local standard

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- clinical device success
- clinical procedure success
- QCA analysis
- myocardial reperfusion assessment

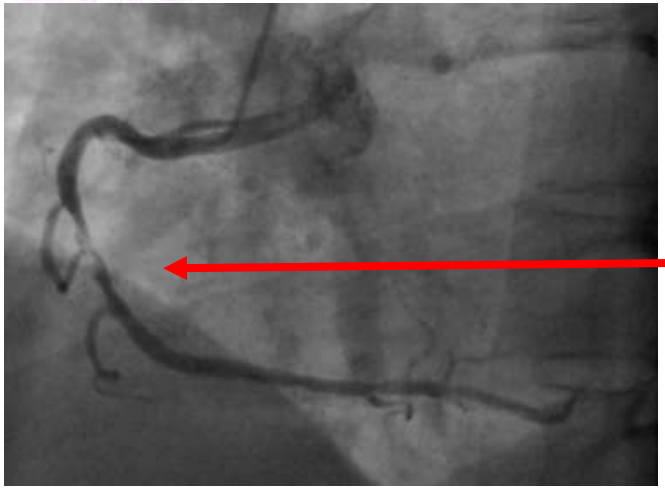
- in-hospital MACE

- OCT/IVUS (per local standard)

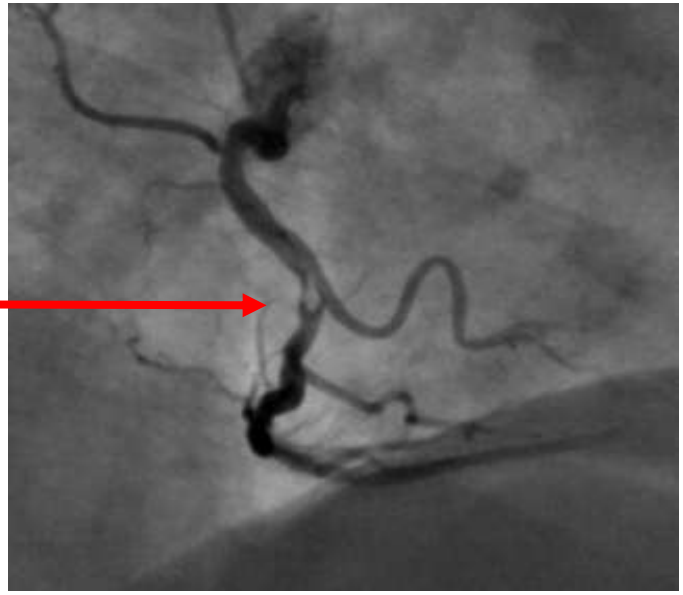
Baseline characteristic	
No of pts enrolled	88
Gender - male	74 %
Age (years)	63 ±11
Initial diagnosis STEMI / NSTEMI / UA	14% / 46% / 40%
Hypertension	76 %
Dyslipidemia	69 %
Smoking	45 %
Family history of CAD	30 %
Diabetes	31 %
Previous PCI	28 %
Previous MI	18 %
Previous CABG	8 %
Stroke	3 %
ASA+clopidogrel **ASA+ticagrelor/prasugrel**	**78%** **22%**

Patient with NSTEMI

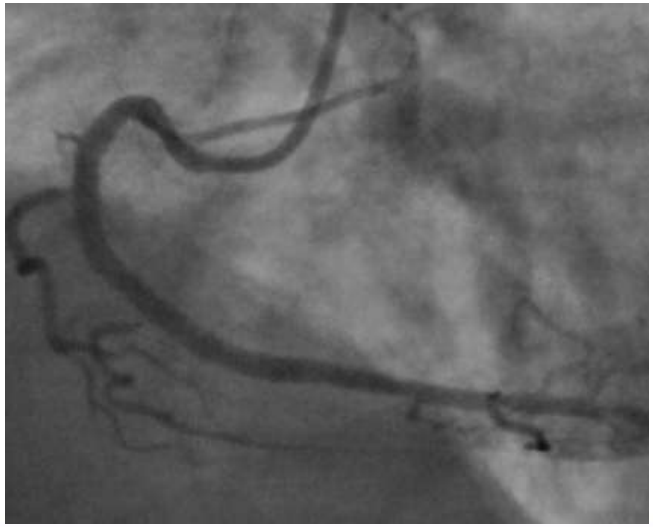
Case example



Baseline angio



Thrombus



Procedure

Thrombectomy

Predil. with non-compliant balloon (3.5x20mm@12 atm)

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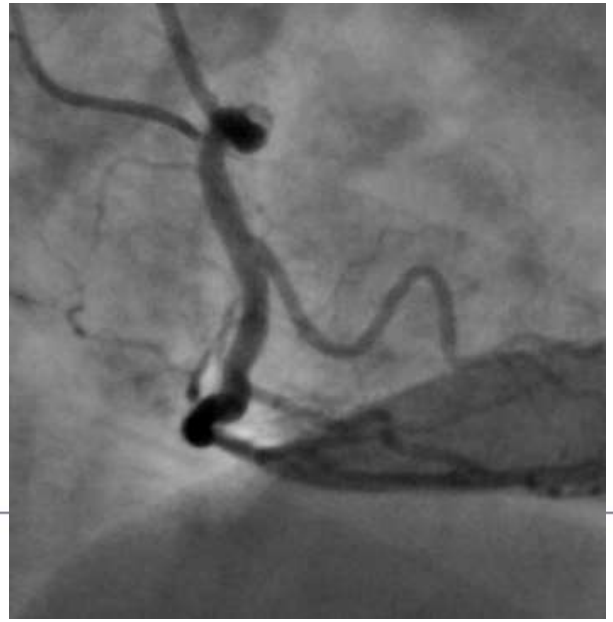
BVS implantation (3.5x28mm @ 12 atm)



Results

POLAR ACS

Aspiration thrombectomy	17% lesions
Predilatation	**89% lesions**
Direct stenting	**11% lesions**
Postdilatation	40% lesions

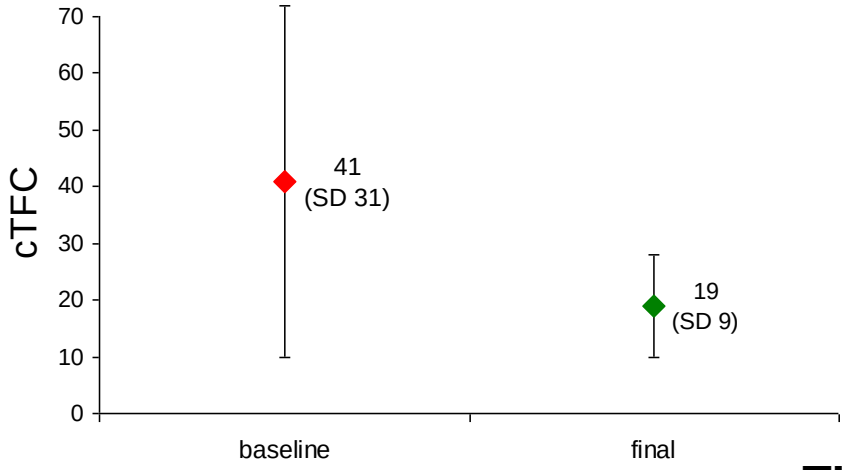
Difference in diameter (balloon for postdil - BVS)	% of patients
0 mm	22.8 %
0.25 mm	13.8 %
0.5 mm	3.4 %
> 0.5 mm	0 %

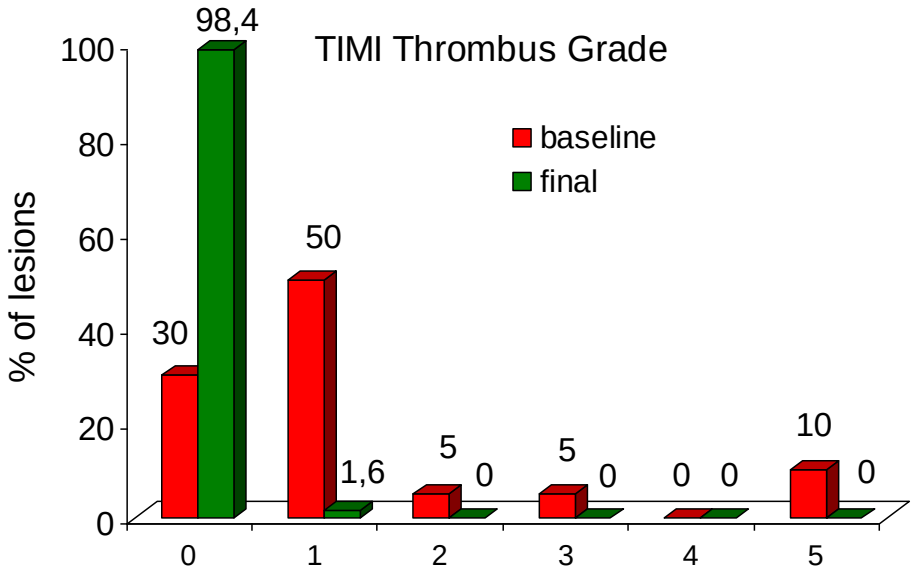
QCA data	Mean ± SD
Ref Vessel Diameter	2.7 ± 0.5 mm
D-max – baseline prox	2.8 ± 0.5 mm
D-max – baseline dist	2.6 ± 0.5 mm
D-max – final prox	3.0 ± 0.5 mm
D-max – final dist	2.7 ± 0.5 mm
MLD baseline	1.2 ± 1.4 mm
MLD post predilatation	1.6 ± 0.4 mm
MLD post BVS	2.1 ± 0.3 mm
MLD post postdilatation	2.3 ± 0.5 mm
%DS baseline	63.0 ± 18.1 %
%DS post BVS	15.6 ± 9.1 %
%DS post BVS & postdilatation	13.5 ± 8.9 %

Results

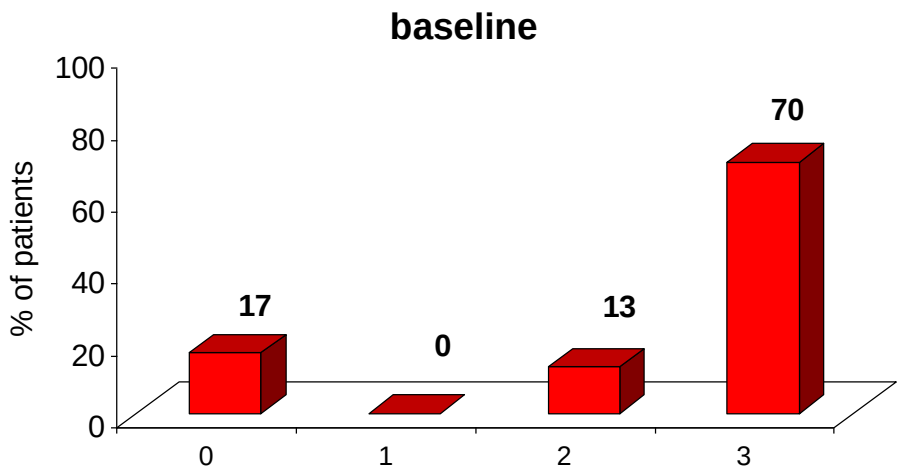
POLAR ACS

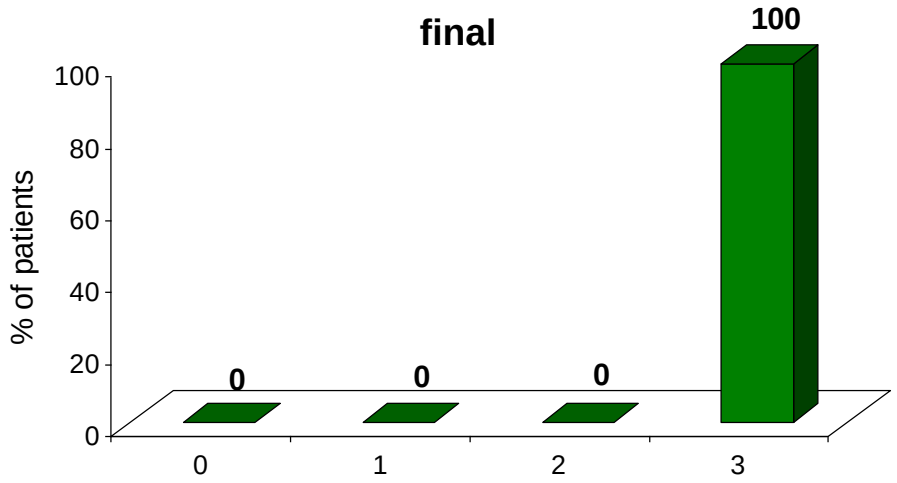
Mean cTFC in study group





TIMI flow

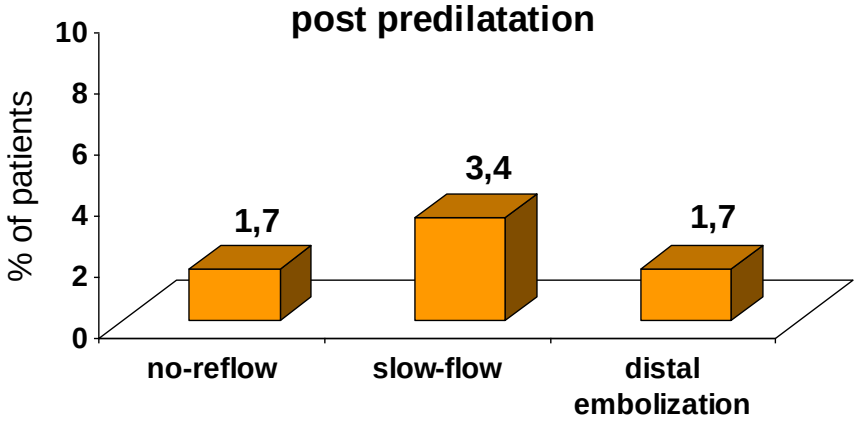


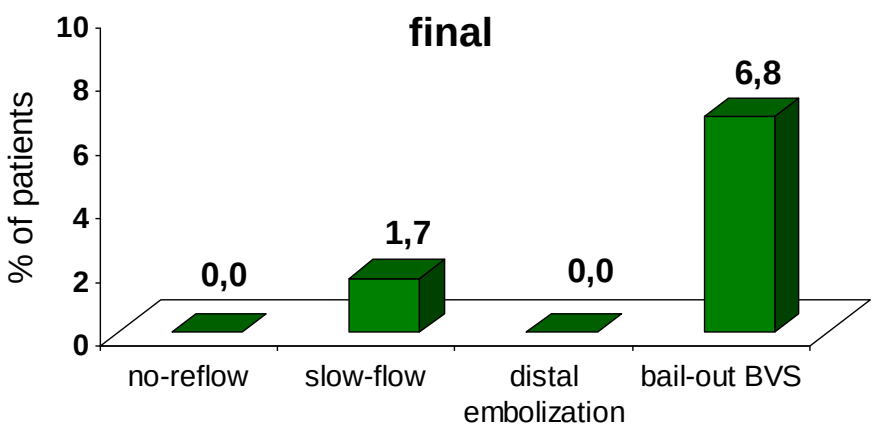


Results

POLAR ACS

Complications





Results of PCI BVS	%
BVS delivery success	100 %
Clinical device success (*)	100 %
Clinical procedure success (*)	100 %
In-hospital MACE	1,6 %

In-hospital MACE (no of pts):

death	0
MI or reMI	0
re-PCI	0
re-PCI (non-TVR)	1
Stent thrombosis	0

* - per definition in the Absorb II study

Conclusions

Bioresorbable Vascular Scaffold (BVS) implantation in patients with ACS was safe.

PCI BVS resulted in decrease of mean cTFC and improvement of final TIMI flow (TIMI 3 in 100% patients).

Clinical device and clinical procedure success was achieved in 100 % cases with only 1,6% in-hospital MACE.

POLAR ACS Registry is ongoing and the first paper will be published as 100 pts will be completed.