Bioresorbable vascular scaffolds in acute STEMI (PRAGUE-19 study)

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Potential conflicts of interest

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

Consultant: ABBOTT VASCULAR, ASTRAZENECA, BAYER HEALTHCARE PHARMACEUTICALS, BOEHRINGER INGELHEIM, BOSTON SCIENTIFIC, DAIICHI SANKYO, ELI LILLY, MEDTRONIC, SANOFI

Background

- Bioresorbable vascular scaffolds (BVS) are safe and effective in chronic stable CAD.
- Their use was not yet reported in acute STEMI.
- STEMI with low Killip class may be ideal setting for BVS (younger pts., less calcium, benefit from stent resorbtion may be lasting)

- Aim: to analyze the feasibility and safety of BVS implanted during primary PCI in this highly thrombogenic condition.

Methods

- ***Academic*** (no industry support) prospective single center registry
- 87 consecutive STEMI pts underwent emergent CAG during 5 months period (Dec 16, 2012 – May 15, 2013)
- Study is planned for 3 years follow-up (incl. CTA at 1 year and CAG+OCT at 3 years)
- ***Early outcomes*** presented here

22/87 (25%) pts fullfilled the prespecified inclusion / exclusion criteria for BVS implantation

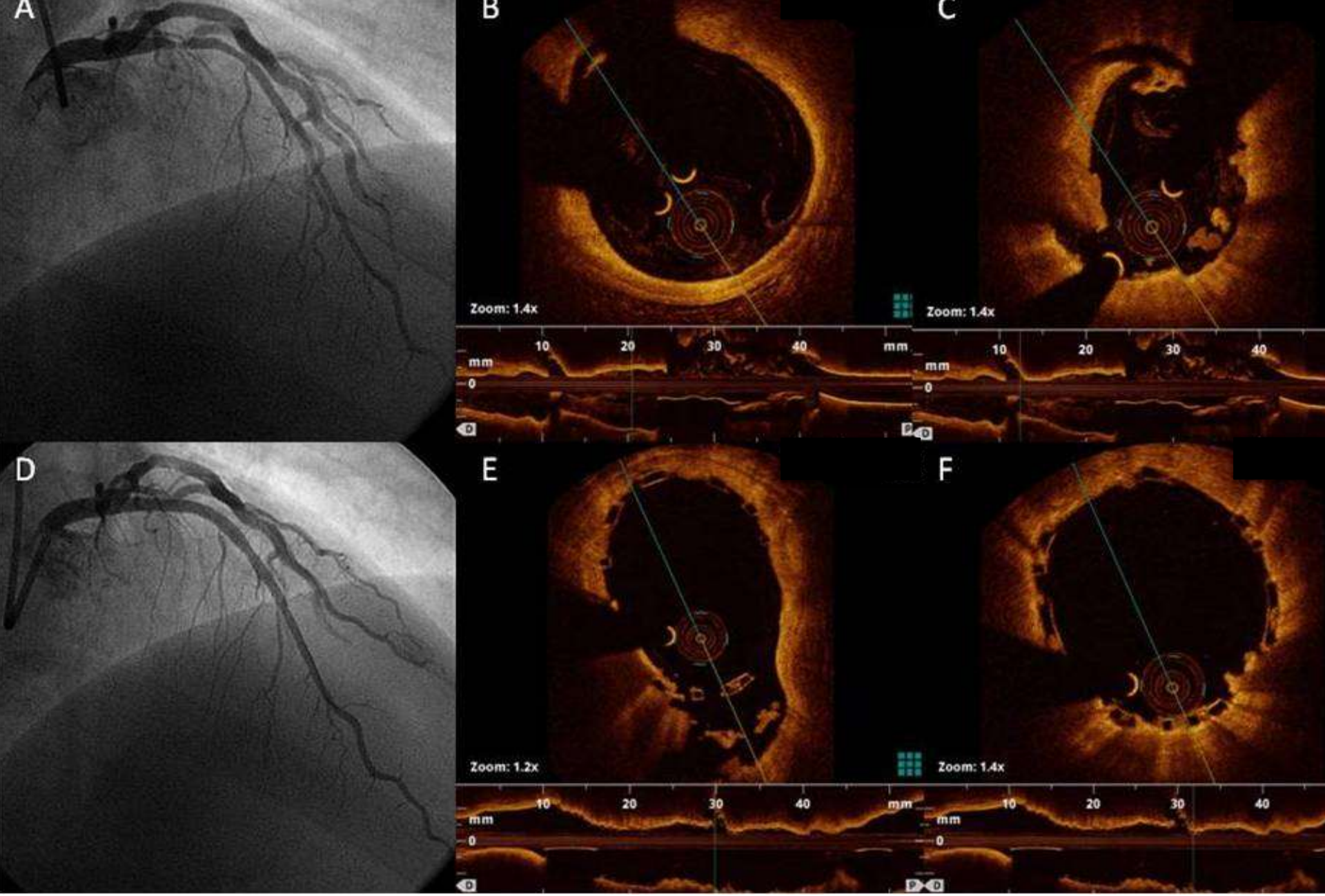
Inclusion criteria	Exclusion criteria - clinical	Exclusion criteria - angiographic
STEMI <24 hours from symptom onset	Killip III-IV class (i.e. high likelihood of death within BVS absorbtion time)	Infarct artery reference diameter <2,3 mm or >3,7 mm (i.e. not suitable for currently available BVS sizes)
Signed written informed consent	Any other disease with probable prognosis <3 years	Lesion lenth >24 mm (i.e. precluding single BVS implantation)
	Indication for oral anticoagulation (e.g. atrial fibrillation)	Extensive infarct artery calcifications or severe tortuosity
	Contraindication to prolonged DAPT or high likelihood of non-compliance to DAPT	STEMI caused by in-stent restenosis or stent thrombosis
	No stent: not needed (POBA, thrombus aspiration etc.) or not possible (failed PCI or failed stent delivery)	

Baseline characteristics

	BVS group Killip I-II only	Other stent group Killip I-II only	Patients with Killip III-IV and/or without stent
N=	22	31	34
Mean age ± SD	58,5 ± 9,96	60,8 ± 13,54	69 ± 13,3
Females %	18%	14%	45%
Mean Killip class ± SD	1,09 ± 0,29	1,14 ± 0,36	2,45 ± 1,26
LAD as infarct artery %	59%	42%	48,6%
LCX as infarct artery %	13,6%	7%	16%
RCA as infarct artery %	27,2%	46%	27%
LMCA as infarct artery %	0%	0%	0%
Diabetes mellitus %	4,5%	10,7%	32%
Prior MI %	4,5%	7%	16,2%
Prior CABG %	0%	7%	2,7%
Prior PCI %	4,5%	3,5%	21,6%

Procedural result and BVS feasibility

- 27/28 BVS successfully implanted to 21/22 patients
- 1 BVS could not be delivered to LCX with sharp take-off (bare metal stent was delivered successfully)
- 19/21 BVS patients had ideal result (TIMI-3 flow, 0% residual stenosis, no dissection)
- 2/21 patients had TIMI-2 flow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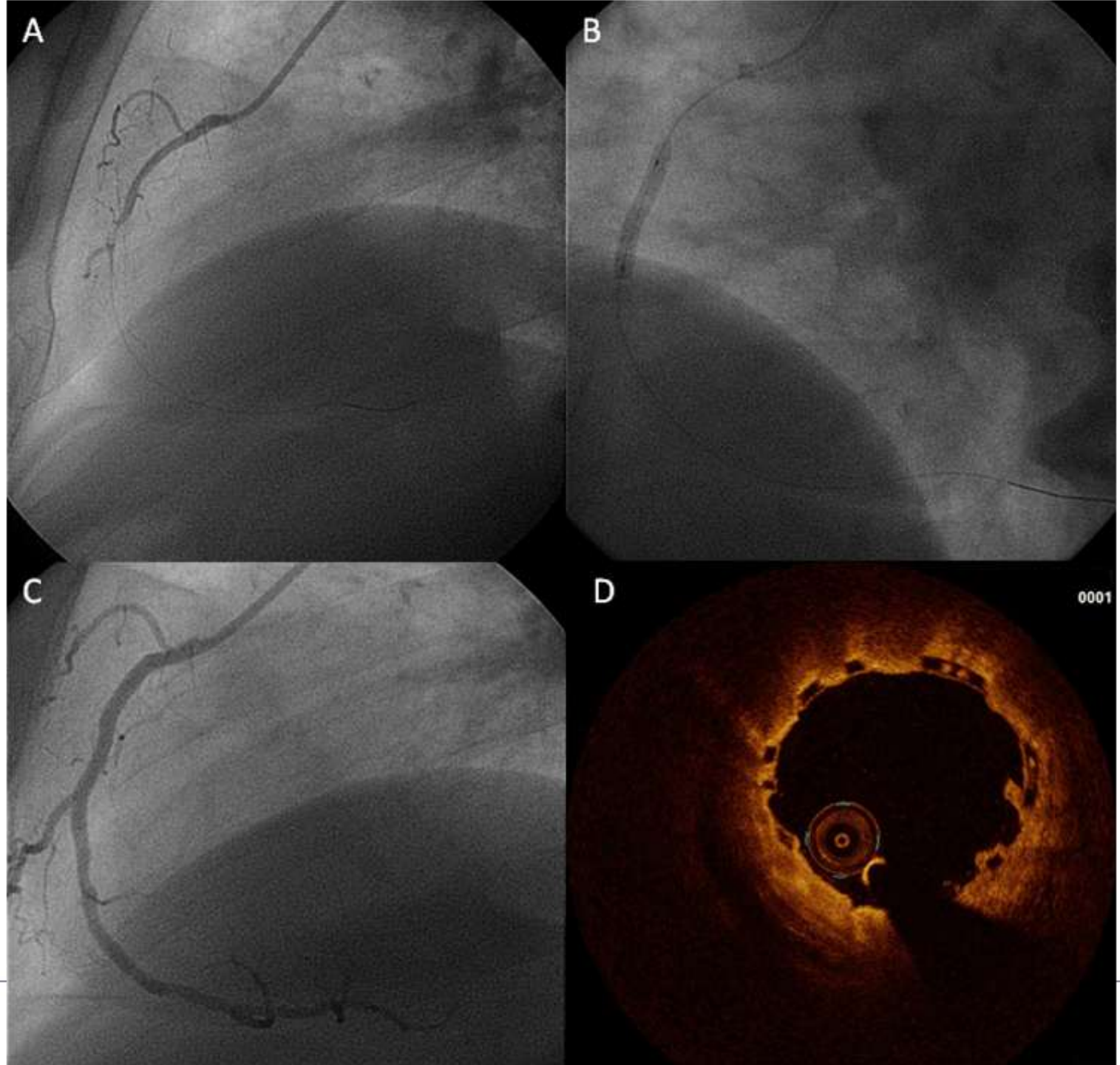
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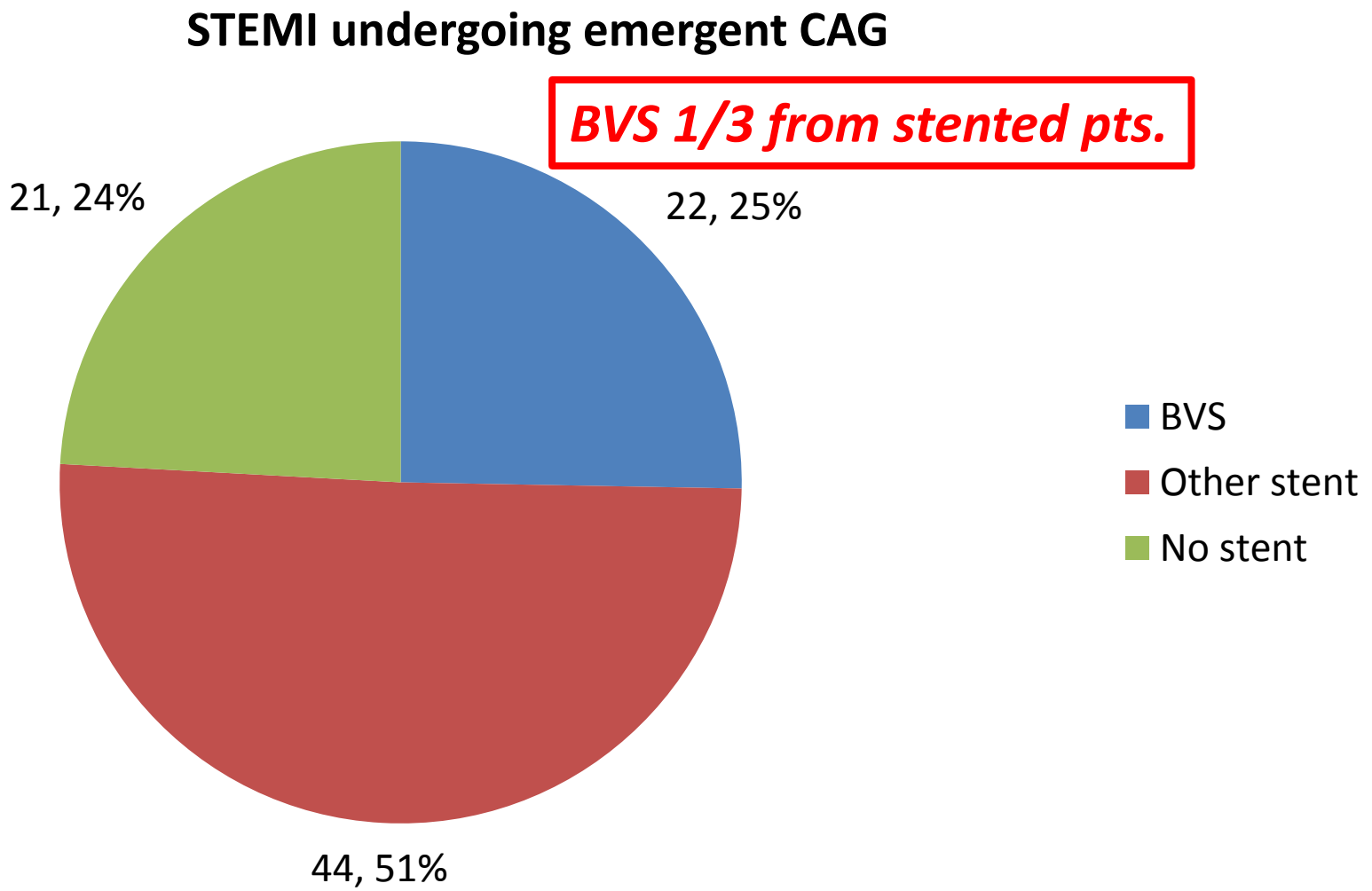
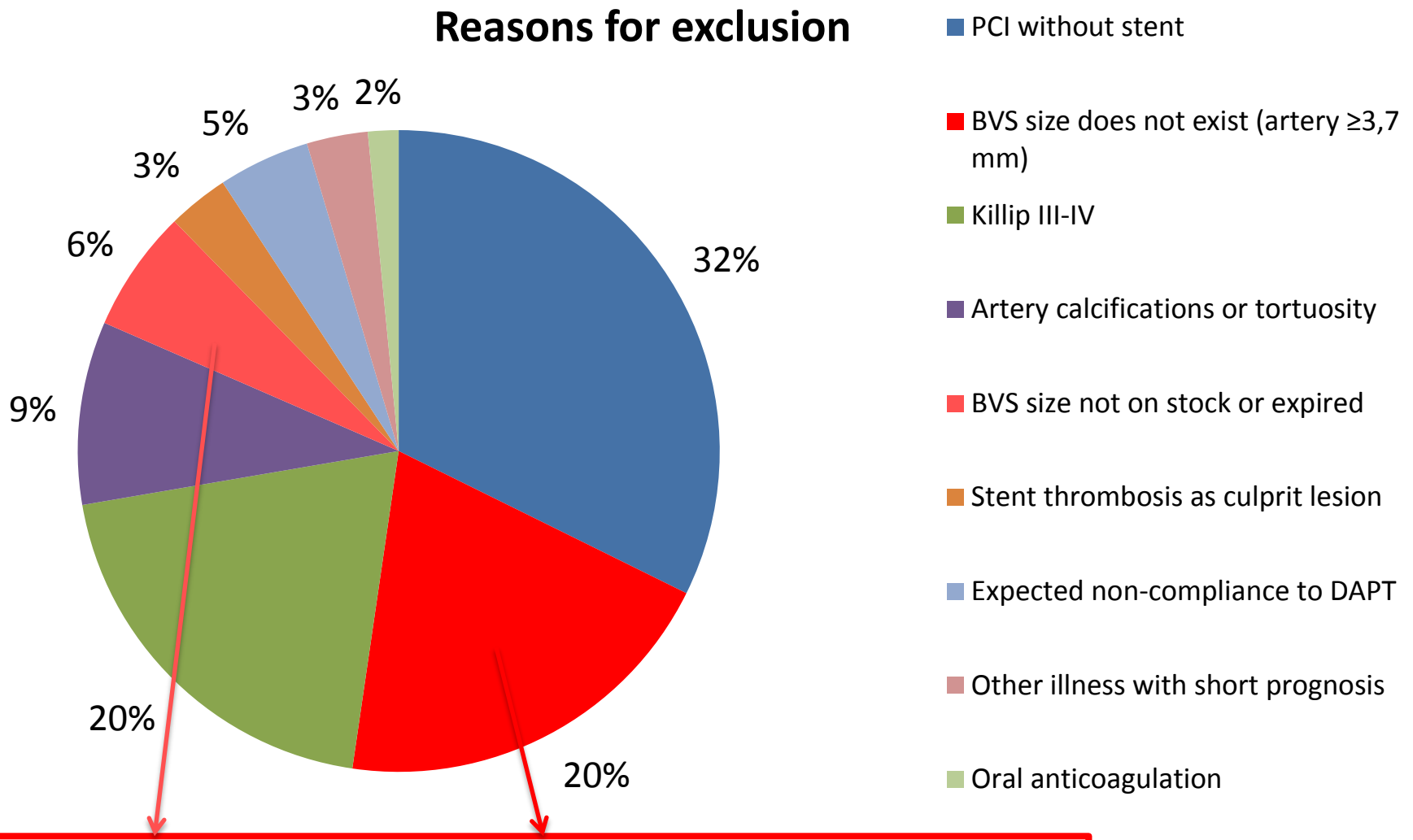
STEMI patients (n=87) with BVS / with other stent / without stent



Why BVS was not implanted to 75% STEMI patients (n = 65)



26% more STEMI pts. might receive BVS if size 4,0 mm would be available and BVS expiration times would be longer

BVS group - safety

- 0% mortality
- 0% reinfarction during hospital stay
- 5% reinfarction (1 BVS thrombosis 3 days after stopping ticagrelor)
- 0% stroke
- 0% clinical restenosis within 5 months

Conclusions

- **BVS implantation in acute STEMI is feasible and safe.**
- **With the currently available size spectrum and expiration times BVS can be used in 25-33% of STEMI patients. Availability of 4,0 mm size would substantially increase this proportion.**
- **OCT can be used safely to control BVS implantation in STEMI.**
- **Long-term follow-up will elucidate the future role of BVS in STEMI.**