

# BRS Failure: Insights from Imaging

Yoshinobu Onuma<sup>1,2</sup> Yohei Sotomi<sup>3</sup> Patrick W. Serruys<sup>4</sup>

 Thorax Centre Erasmus MC, Rotterdam, 2 Cardialysis B.V., Rotterdam
 Academisch Medisch Centrum, Amsterdam
 International Centre for Cardiovascular Health, Imperial College, London

# BRS failure: Imaging findings

- Early Thrombosis
- Acute disruption
- Very late Scaffold thrombosis

Late discontinuities (Intravascular or intraluminal Dismantling)

- Restenosis
- Neoatherosclerosis
- Others (Aneurysm)



## **ABSORB 1-Year Meta-analysis**

ABSORB II, ABSORB III, ABSORB Japan, ABSORB China Device Thrombosis (Def/Prob) (pooled)



#### Stone et al. Lancet 2016

## What is the reported rate of Early Scaffold

## **Thrombosis?**

Ishibashi et al. EuroIntervention Updated

Study	Indication	Ν	Acute ST N (%)	Subacute ST, N (%)	Early ST, N (%)	Imaging	
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Onuma et al., ABSORB A	SAP	30	0	0	0	IVUS/OCT	
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Serruys et al., ABSORB II	SAP / UAP	335	1 (0.3)	1 (0.3)	2 (0.6)	IVUS	SAP/UAP
ASSURE registry	SAP / UAP	183	0	0	0	-	0.3%
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Gori et al	ACS	150	1 (0.7%)	1 (0.7%)	2 (1.4%)	-	ACS
POLAR ACS	ACS	100	0	0	0	-	<b>1.0%</b>
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Diletti et al., BVS STEMI	STEMI	49	0	0	0	OCT	
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Ielasi et al., RAI registry	STEMI	74	0	1(1.4%)	1(1.4%)	OCT/IVUS 4.4%	1.5%
TROFI II	STEMI	95	0	1 (1.1%)	1 (1.1%)	OCT	
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Capodanno et al., GHOST-EU registry	All-comer	1189	5 (0.4%)	11 (0.9%)	16 (1.3%)	IVUS 14%/OCT 14%	
	Average F/U: 7.1 Months	8094	16 (0.2%)	50 (0.6%)	66 (0.8%)		

# **#1 Acute scaffold thrombosis: Proximal landing at plaque**



**Karanasos et al. Circ Intervention2015** 

## #2 Early scaffold thrombosis: Overlap



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#### **#3.** Acute scaffold thrombosis: Malapposition Jaguszewski et al. EHJ 80 yo male presenting with Non-STEMI



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## #4 Subacute scaffold thrombosis: Oversizing

Sabate et al. 2015 EHJ (TROFI II)

1<sup>st</sup> PCI Post **Device size 3.0** LAD Scaffold Proximal Dmax 1.9753 Distal Dmax 2.0492 Diameter **Over sizing** 

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Automatic

6 days Sub-acute Scaffold Thrombosis







**Distal Dmax minus nominal scaffold size** 





(%)

15



The implantation of a "large" Absorb scaffold in a relatively small vessel had a higher risk of MACE at 1year. The selection of nominal scaffold size below the diameter of both proximal and distal Dmax might lead to a denser polymer surface pattern, which could be associated with MI after procedure.

diameter of Absorb)

Complete mismatch (Both Dmax < nominal



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## 3 criteria to judge acute disruption on OCT

### **Stacked Struts**

**Overhang Struts** 

## Isolated & Centered Strut



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**#1. Suspected Acute disruption: Cohort A** Stented segment 35 10 15 **OCT before** A B C D Ε post dil K B D С Ξ \* Post dilatation with a 3.5 mm compliant balloon at 18 atm С D B 42 days , after procedure A' 5 10 0 V Onuma et al. 1

mm

EI 2010

**#2. Acute disruption and Late Thrombosis** -161 days after implantation, 2 days after cessation of DAPT

Pre-procedure

E

Post-procedure

acute disruption at proximal edge

No thrombus at disruption site



#### Scaffold thrombosis on 161 days



<u>underexpansion</u> at mid scaffolded part (overlap)

Late scaffold thrombosis after DAPTdiscontinuation in overlapping BVS with underexpansion.

event

#### Thrombus at underexpansion site

Karanasos A et al. Circ Cardiovasc Interv 2015;8.

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# What is the reported incidence of very late thrombosis? Number (n=12 – denominator unknown)



#### Follow-up duration (months)

## Imaging findings associated with Late/very late scaffold thrombosis

Reported imaging findings associated with Late/very late scaffold thrombosis	Ν
Malapposition	8
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Criteria of late discontinuities are the same with acute disruption. But the findings should be absent at baseline and present at FUP

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#### Assessment of OCT late discontinuities in Cohort B1/B2



## **#1 VLST** with Late discontinuity and Uncovered struts

The cause for thrombus formation was late scaffold strut discontinuity with the particular finding of a long scaffold strut freely floating in the lumen.

#### VLST at 19 months

Uncovered struts were frequently observed (10%) and the majority of struts were covered by thrombus.





## **#2 VLST at 2 years with late discontinuities**

Karanasos A et al. Eur Heart J 2014;35:1781.

#### Post-procedure







#### Scaffold thrombosis



# late discontinuity



thrombus

# BRS complications: Imaging findings

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## **Overview of Restenosis/ID-TLR**

last update: 5<sup>th</sup> Feb 2016

#### NA: not available

			Binary restenosis	
Trial name	Follow-up period (M)	Patient number	(%)	ID-TLR (%)
			(in-segment)	
ABSORB Japan	12	272	1.9	2.6
EVERBIO II	9	75	10.7	10.0
TROFI II	6	95	0.0	1.1
Absorb Cohort B	36	101	5.9	7.0
ABSORB II	12	335	NA	1.2
ABSORB EXTEND	12	512	NA	1.8
GHOST-EU	6	1189	NA	2.5
BVS-RAI	7.3	122	NA	4.1
BVS EXAMINATION	12	290	NA	1.7
BVS STEMI first	1	49	0.0	0.0
AMC registry	6	135	5.0	6.3
ASSURE registry	12	183	2.8	2.8
GABI-R (euroPCR 2015)	1	1536	NA	NA
POLAR ACS	12	100	0.0	1.0
Prague 19	6	40	0.0	2.5
ABSORB III	12	1322	0.0	3.0
ABSORB China	12	238	3.9	2.5
CTO ABSORB	6	35	5.7	0.0
Robaei et al	12	100	3.0	4.0
Costopoulos et al CCI	6	92	NA	3.3
Costpoulos et al CRM	12	108	NA	0.9
Gori et al	12	75	4.0	9.3
Jagszewski et al	4.9	98	NA	2.0
Kajiya et al	1.77	11	NA	NA
Mattesini et al	8.5	35	NA	0.0
Ojeda et al	13	42	4.8	2.4
Weibe et al	4.4	25	0.0	0.0

	<b>Total population</b>	Average FUP	Weighted average
<b>Binary Restenosis</b>	1565	11.8 M	3.21%
ID-TLR	5668	10.3 M	2.73%

# Early (<6M), late (6-12M) and very late (>12M) angiographic scaffold restenosis in the ABSORB cohort B trial

- Myocardial bridge
- Proximal geographic miss
- Malapposition

 Late restenosis and scaffold area



Nakatani et al. Eurointervention, Serruys et al. JACC, Serruys, Onuma et al. Circulation, Ormiston et al. Circ Intervention

### **#1.** Late ISR day 354 due to neointimal hyperplasia

#### Type 1C ISR (QCA MLD: 0.79 mm, %DS: 64.0%, LL: 1.58 mm)



Nakatani et al. El 2014

Circularity of the scaffold was maintained throughout the pullback.

## **#2. Very late ISR on day 833 in Absorb Cohort B**

Nakatani et al. El 2014



Type 1B ISR at the distal margin of the scaffold segment QCA MLD: 0.72 mm, %DS: 63.7% and LL: 1.38 mm)



#### **#** Neoatherosclerosis

Vascular Scaffold

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Andrea Mangiameli, MD, \* Yohei Ohno, MD, \* Guilherme F. Attizzani, MD, \*| Davide Capodanno, MD, PaD, \* Corrado Tamburino, MD, PaD\*|

Neoatherosclerosis as the Cause of

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D: Neointimal rupture (white arrow) with mural thrombus (red asterisk)

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## **Evagination at 12 M FUP**



Out of 90 pts, 55 (54%) of the BVS (50(56%) of the patients) had at least one evagination (6.1+6.2 evaginations per BVS).

#### Gori et al. EHJ 2015



## # Case of Aneurysm

Mechanism: Unknown

However, implies localized inflammatory response with involvement of metalloproteinase.





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# Conclusion

- Malapposition, scaffold edge landing on plaque, overlap, devicevessel size mismatch and underexpansion are frequently observed in cases of early scaffold thrombosis.
- Acute disruption is caused by overexpansion and could relate to scaffold thrombosis.
- Late discontinuities are common and benign phenomenon associated with bioresorption (40%). Late discontinuities are however frequently observed in cases of late/very late scaffold thrombosis. It remains unclear whether it is the cause of thrombosis or not. Further research is needed to investigate what impacts the differential outcomes of late discontinuities.
- Reported causes of restenosis in the Absorb are not different from those of drug-eluting metallic stent.
- OCT-defined neo-atherosclerosis warrants further investigation.
- Due to a lack of systematic and serial imaging, it remains unclear how much additional risks will be associated with each imaging abnormality.

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#### Assessment of OCT late discontinuities in Cohort B1/B2

<sub>097969003</sub> BL	6M	2Y	BL	1Y	3Y
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100353005			102921009		
		HERDEN KURT	106255004 LAD		
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10353008			106256005		
10035301			106256006		
145896001			115782001		
115896002			115782002		
Conort B2 BL	1Y	ЗҮ	115782004	MANNER HIS	AND
097969005	なななない	an a	115782006		
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Sabate et al. 2015 EHJ (TROFI II)

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Automatic

6 days Sub-acute Scaffold Thrombosis



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mm

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Pre-procedure

E

Post-procedure

acute disruption at proximal edge



#### Scaffold thrombosis on 161 days

No thrombus at disruption site



<u>underexpansion</u> at mid scaffolded part (overlap)

Late scaffold thrombosis after DAPTdiscontinuation in overlapping BVS with underexpansion.

event

#### Thrombus at underexpansion site

Karanasos A et al. Circ Cardiovasc Interv 2015;8.

#### **#3. Worsening of acute disruption by imaging follow-up** Scaffolding PRE

#### RVD 2.24

At baseline, acute disruption was observed in a few cross sections (small disruption)



Onuma et al. JACC intervention 2014

# #3. Worsening of acute disruption by imaging follow-up 6M FUP (Asymptomatic)

OCT







#### Lifting of a strut at 6M - Presumably iatrogenic

Onuma et al. JACC intervention 2014



#3. Worsening of acute disruption by imaging follow-up
 Iatrogenic lifting of a strut at 6M and subsequent formation of tissue arch at
 24M





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The cause for thrombus formation was late scaffold strut discontinuity with the particular finding of a long scaffold strut freely floating in the lumen.

#### VLST at 19 months

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## **#3 VLST** at 2 years with late discontinuities

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#### Post-procedure







#### Scaffold thrombosis



# late discontinuity



thrombus

#### **#4 VLST at 2 years with late discontinuities**



**Baseline pre-procedure** 

Räber et al. JACC 2015, Courtesy of Dr. Sabate

#### VLScT 21 months

#### VLScT after thrombectomy

#### **#3 VLST** at 2 years with late discontinuities



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# Conclusion

- Malapposition, scaffold edge landing on plaque, overlap, device-vessel size mismatch and underexpansion are frequently observed in cases of early scaffold thrombosis.
- Acute disruption could relate to scaffold thrombosis. It can be worsened by follow-up procedure.
- Late discontinuities are frequently observed in cases of late/very late scaffold thrombosis.
- It appears that the fate of late discontinuities varies from scaffold thrombosis to no events (well covered). Further research is needed to investigate what impacts the differential outcomes of late discontinuities.
- Reported causes of restenosis in the Absorb is not different from those of drug-eluting metallic stent.
- Anecdotal case of OCT-defined neo-atherosclerosis warrants further investigation.
- Due to a lack of systematic and serial imaging, it remains unclear how much additional risks will be associated with each imaging abnormality.