DES vs DCB + BMS
Are they the same?
Insights from the REACT study

Koen Deloose, MD

Head Dept Vascular Surgery

AZ Sint Blasius, Dendermonde, Belgium

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Disclosure slide

Speaker name: Koen Deloose, MD

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

☒ Consulting: Abbott, Asahi, Biotronik, Boston Scientific, CTI vascular, CyndRX, GE Healthcare, Gore, iVascular, Terumo

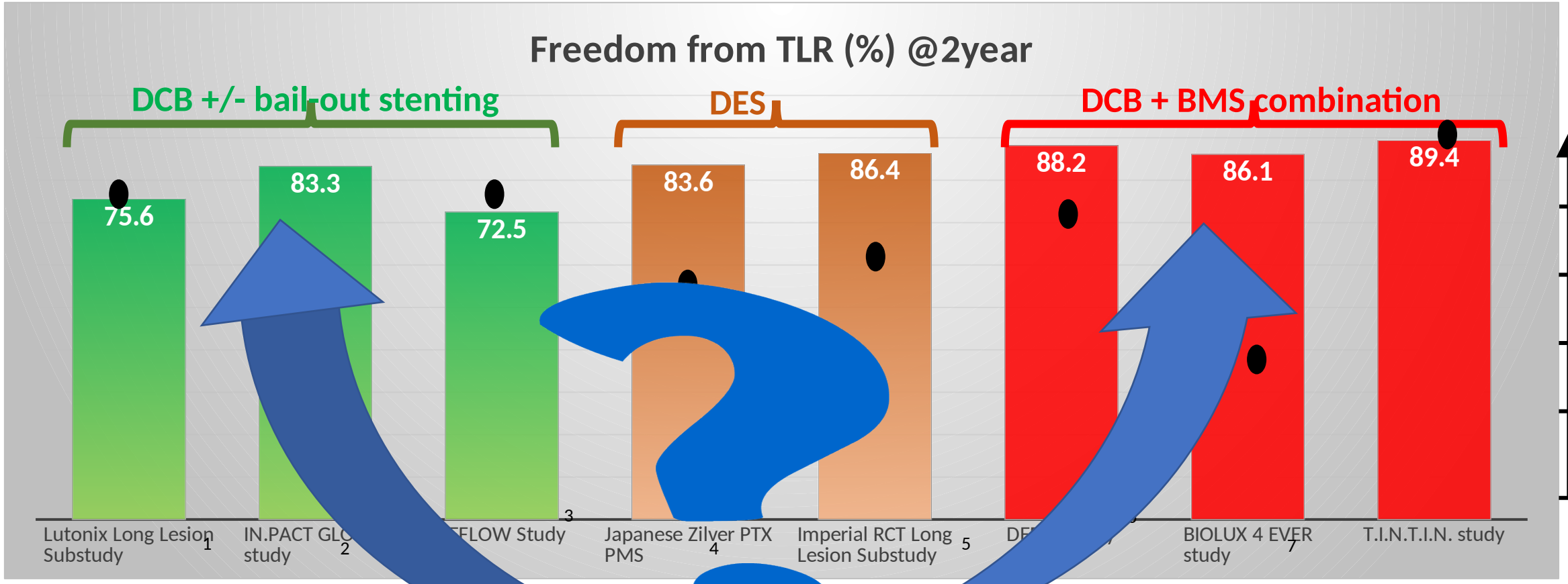
❑ Stockholder of a healthcare company
❑ Employment in industry
❑ Owner of a healthcare company
❑ Other(s)

❑ I do not have any potential conflict of interest

Answer…

NO….THEY ARE NOT THE SAME…

Available 2yr data, complex lesions …



# pts	118	1773		905	50	65	120	100
Bailout stenting	39,8	21,2	35		nvt	100	100	100

1. Montero-Baker M et al. JVS doi.org/10.1016/j.jvs.2018.08.024
2. Micari A et al. JACC Cardiovasc Interv 2018 May,11(10) ; 945-953
3. Deloose K. presented @LINC 2020
4. Kimihiko Kichikawa et al. Cardiovasc Interv radiol 2019 Mar;42(3):358-364
5. Vermassen F. VIVA LBCT Webinar june 2020
6. Bibombe P et al. Vascular 2018 Vol 26(1) :3-11
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Results from different trials are not directly comparable.
Information provided for educational purposes.

BIO REACT PILOT STUDY

BIO REACT Pilot Study

Design	Global Multicenter Prospective Pilot Diagnostic Study
Objective	• Evaluation of adjunctive procedural assessments to diagnose post drug-coated balloon flow-limiting dissection/residual stenosis additional to angiography *intra-operative EVUS (core lab controlled) *intra-operative IVUS (core lab controlled) • Estimation Biotroniks' REACT algorithm clinical performance • Assessment health care resources

BIO REACT PILOT STUDY

BIO REACT Pilot Study

OPERATOR

PREDILATATION PASSEO 18

DILATATION PASSEO 18 LUX

2 PLANES ANGIOGRAPHY

INTRA OPERATIVE DUS (or IVUS*)

Independent Review Committee

- Dissection grade (A-F)?
- FLD or not FLD ?
- stent needed?
- full, spot stenting?

PULSAR 18 STENT SPOT? LENGTH?…

Final treatment with/without stent based on angiography & adjunctive evaluation findings

NO PULSAR 18 STENT

* IVUS will be conducted exclusively at pre-specified trained centers

Baseline Characteristics

Patient Characteristics	N = 151	%
Male	103	68.2
Age (mean ± SD)	68.70 ± 9.92	
Smoking history	121	80.1
Hypertension	121	80.1
Hyperlipidemia	111	73.5
Diabetics	45	29.8
Insulin dependent	21	13.9
Non-insulin dependent	24	15.9
History of PAOD	90	59.6
Renal disease	27	17.9
Coronary artery disease	46	30.5
Cerebrovascular disease	22	14.6
Cancer	21	13.9

Rutherford classification	N = 149	%
Category 2	26	17.4
Category 3	104	69.8
Category 4	19	12.8
ABI (target limb)	**N=125**	
Mean ± SD 95% CI	0.67 ± 0.169 [0.64, 0.70]	

Lesion Characteristics

Lesion Characteristics	N= 169	%
Proximal popliteal artery	6	3.6
SFA	143	84.6
SFA and proximal popliteal artery	20	11.8
De-novo lesion	142	84.0
Re-stenosis	8	4.7
Occlusion	19	11.2
Lesion length (mm; mean ± SD)	103.75 ± 75.3	
RVD (mm; mean ± SD)	5.23 ± 0.71	
Diam. stenosis (%; mean ± SD)	89.16 ± 11.02	

Calcification PACSS	N	%
Grade 0	41	24.4
Grade 1	37	22.0
Grade 2	44	26.2
Grade 3	22	13.1
Grade 4	24	14.3
TASC Classification		
Type A	48	28.4
Type B	67	39.6
Type C	40	23.7
Type D	14	8.3

Procedural Characteristics

Procedure detail	
Procedure duration (min; mean ± SD)	92.95 ± 42.39
Predilatation	163 (98.2%)
At least one stent required per lesion	60 (35.5%)
Number of stents used / lesion	n (%)
1	47 (27.8%)
2	9 (5.3%)
3	4 (2.4%)
Post dilatation	72(42.6%)
Stent technical success per lesion (1)	98.3%
Procedure success (2)	100%

- (1) Stent technical success: delivery and successful use of Pulsar-18 or Pulsar-18 T3 to the target lesion to achieve a residual stenosis no greater than 30%
- (2) Procedural success: Technical success and no MAEs before discharge

Diagnostic performance procedural DUS added to angiography compared to angiography alone

		Independent Review Committee		
		FLD (+)	**FLD (-)**	Total
Investigator assessment upon Angio and DUS	**FLD (+)**	9 (9.5%)	5 (5.3%)	14
	FLD (-)	23 (24.2%)	58 (61.1%)	81
	Total	32	63	95
		28.1% [13.7 - 46.7]	**92.1% [82.4 - 97.4]**	
		Sensitivity: TP/(TP+FN)	**Specificity: TN/(FP+TN)**	

- **Low sensitivity**
  - → Too many so called “false negative” cases (independent RC as reference)
  - → Physician (with US) and reviewers (only angio) often disagree on the presence of FLD: 14.7% (14/95) vs 33.7% (32/95)
- **High specificity**
  - → Low false positive (independent RC as reference)
  - → Physicians (with US) and reviewers (only angio) agree on the absence of FLD: 85.3% (81/95) vs 66.3% (63/96)

Intraprocedural Assessment (DUS)

Intraprocedural assessment	N
Duplex sonography (DUS)	139 (82.2%)
Intravascular ultrasound (IVUS)	31 (17.8%)

Lesion characteristics	N=139
Mean lesion length	106.34 mm
Mean RVD	5.18 mm
At least one stent required per lesion	50 (36.0%)
Mean stented length	99.22 mm
Lesion > 15 cm	
Lesion > 15 cm (n, %)	30 (21.6%)
Mean lesion length	234.6 mm
At least one stent required per lesion	16 (53.3%)
Mean stented length	206.9 mm

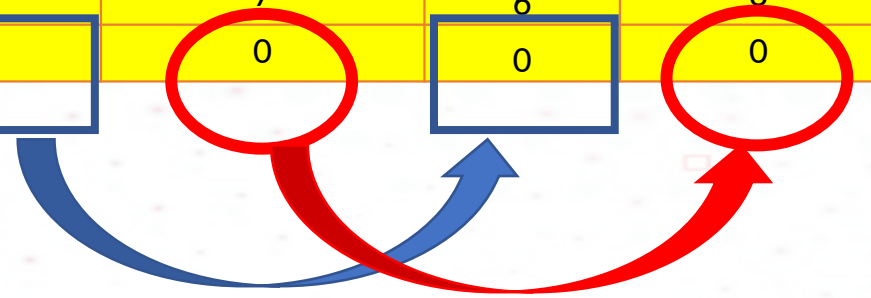
NHLBI dissection type	Lesions (n, %)	FLD (n) Angio alone	Willingness to stent Angio alone	FLD (n) Post DUS	Final stenting approach
A	26 (18.7%)	1	3	1	4
B	20 (14.4%)	4	11	4	8
C	14 (10.1%)	8	12	5	12
D	13 (9.4%)	9	11	7	12
E	1 (0.7%)	1	1	0	1
Total dissection	74	23	38	17	37
No dissection	65 (46.8%)	0	0	3	13

Intraprocedural Assessment (IVUS)

Intraprocedural assessment	N
Duplex sonography (DUS)	139 (82.2%)
Intravascular ultrasound (IVUS)	31 (17.8%)

Lesion characteristics	N=29
Mean lesion length	91.5 mm
Mean RVD	5.46 mm
At least one stent required per lesion	8 (27.6%)
Mean stented length	125 mm

NHLBI dissection type	Lesions (n, %)	FLD (n) Angio alone	Willingness to stent Angio alone	FLD (n) Post IVUS	Final stenting approach
A	3 (10.3%)	0	0	0	0
B	9 (31.0%)	5	6	5	7
C	1 (3.4%)	0	0	0	0
D	1 (3.4%)	1	1	1	1
Total dissection	14	6	7	6	8
No dissection	15 (51.7%)	0	0	0	0



Summary

- DCB in combination with stenting seems today the key of treatment for simple & complex fempop disease like proven in different clinical trials and benchmarked with DES trials
- Defining – Evaluating – Deciding on recoil & flow limiting dissections on angiography alone remains difficult and subjective
- BIO REACT pilot study is the first study evaluating the extra value of intra-operative EVUS & IVUS compared to angiography alone in fempop disease
- Adding EVUS/IVUS seems to show a high specificity (agreement on abscence FLD) but low sensitivity (disagreement on presence FLD) in diagnostic performance compared to angio alone
- Surprisingly, the intraprocedural assessment EVUS/IVUS seems to have a minor impact on the physicians' prior opinion on stenting. If this is due to a lack of confidence, experience, historical preferences or lack of real value of these techniques in this decision-making process, needs further investigation