TINTIN trial

Physician initiated, prospective, non-randomized multi-center trial, Investigating the safety and efficacy of the Treatment with the Luminor DCB and The IvolutioN stent of iVascular in TASC C and D femoropopliteal atherosclerotic disease

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TINTIN trial

DESIGN:
Prospective, multi-center, physician initiated clinical study

OBJETIVE:
Evaluate the 12 month outcome of the combination therapy with the Luminor DCB and the iVolution stent of iVascular for the treatment of long femoropopliteal lesions (TASC C & D).

ENROLLMENT: 100 subjects

PRINCIPAL INVESTIGATOR: Dr. Koen Deloose, A.Z. Sint-Blasius, Dendermonde.

PRIMARY ENDPOINT: Freedom from TLR at 12 months

SECONDARY ENDPOINTS: PP at 6 and 12 months, freedom from TLR at 6 months, Rutherford improvement, adverse Events.

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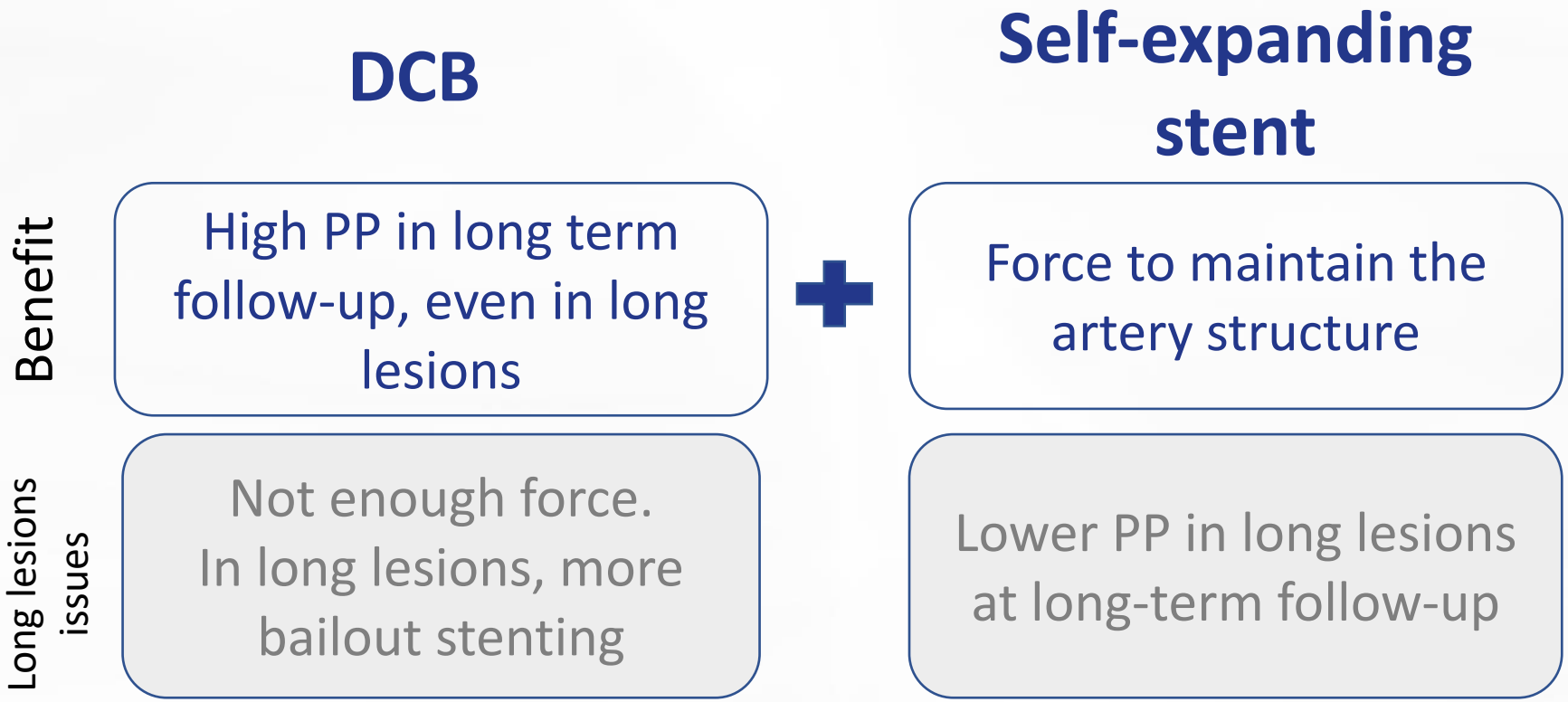
TINTIN trial_ Why a combination therapy?

In complex and long lesions the combination of DCB and stent benefits make disappear all the possible issues, making them the perfect treatment for those types of lesions.



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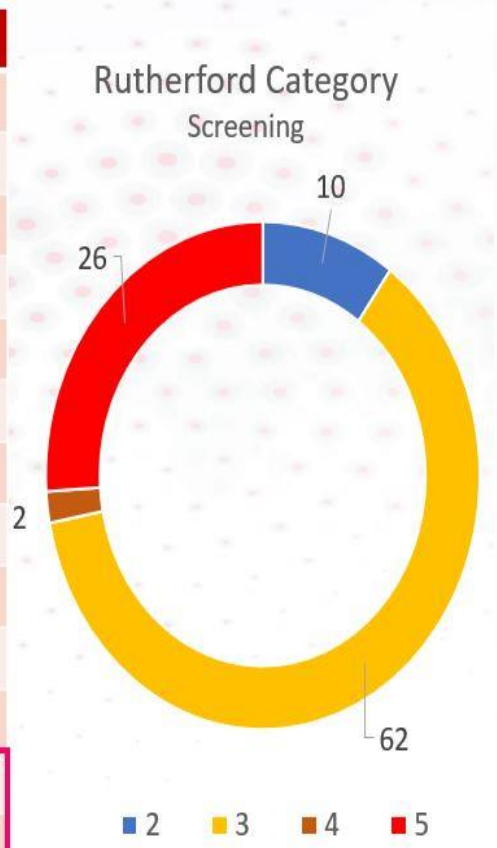
TINTIN trial_Baseline

Patient demographics

	N = 100 out of 100
Male (%)	67 (67%)
Age (min-max ± SD)	73,47 (53 - 92 ± 9,37)
Nicotine (%)	48 (48%)
Hypertension (%)	73 (73%)
Diabetes (%)	37 (37%)
Renal insufficiency (%)	13 (13%)
Hypercholesterolemia (%)	63 (63%)
Obesity (%)	32 (32%)
Previous PAD (%)	40 (40%)
Claudicant (%)	72 (72%)
CLI patient (%)	28 (28%)



Lesion characteristics

	N = 100 out of 100
Lesion length (min-max ± SD)	242,65mm (150mm – 450mm ± 73.72mm)
Reference vessel diameter (min-max ± SD)	5,50mm (5mm – 6mm ± 0.48mm)
Degree of stenosis (min-max ± SD)	93.93% (70% – 100% ± 8.83%)
Occlusion (%)	60% (60%)
Calcified lesion (moderate – severe) (%)	73% (73%)
TASC II C lesion (%)	62% (62%)
TASC II D lesion (%)	38% (38%)

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TINTIN trial_ Procedural characteristics

	N = 100 out of 100
Procedure time (min-max ± SD)	69.3min (25min – 170min ± 27.4min)
Scopy time (min-max ± SD)	17.5min (5min – 51min ± 11.1min)
Contrast (min-max ± SD)	92,6ml (20ml – 200ml ± 36.2%)
Femoral access (%)	100% (100%)
Cross-over performed (%)	77% (77%)
Inflow lesion (%)	14% (14%)
Outflow lesion (%)	21% (21%)
Predilatation performed (%)	88 (88%)
Diameter predilatation balloon (min-max ± SD)	4.62mm (3mm – 6mm ± 0.68mm)
Length predilatation balloon (min-max ± SD)	156.53mm (40mm – 220mm ± 42.95mm)

	N = 100 out of 100
Mean # Luminors used per procedure	1.82 (1 – 4 ± 0.73)
Luminor 18 - 35	<table><tr><th></th><th>Total</th></tr><tr><td>Luminor-18</td><td>106 (58%)</td></tr><tr><td>Luminor-35</td><td>76 (42%)</td></tr></table>
Diameter Luminor (min-max ± SD)	5.29mm (4mm – 6mm ± 0.46mm)
VD 5.50mm	
Mean # iVolutions used per procedure	1.84 (1 – 4 ± 0.69)
Diameter iVolution (min-max ± SD)	5.74mm (5mm – 7mm ± 0.45mm)
Post-dilatation done	85

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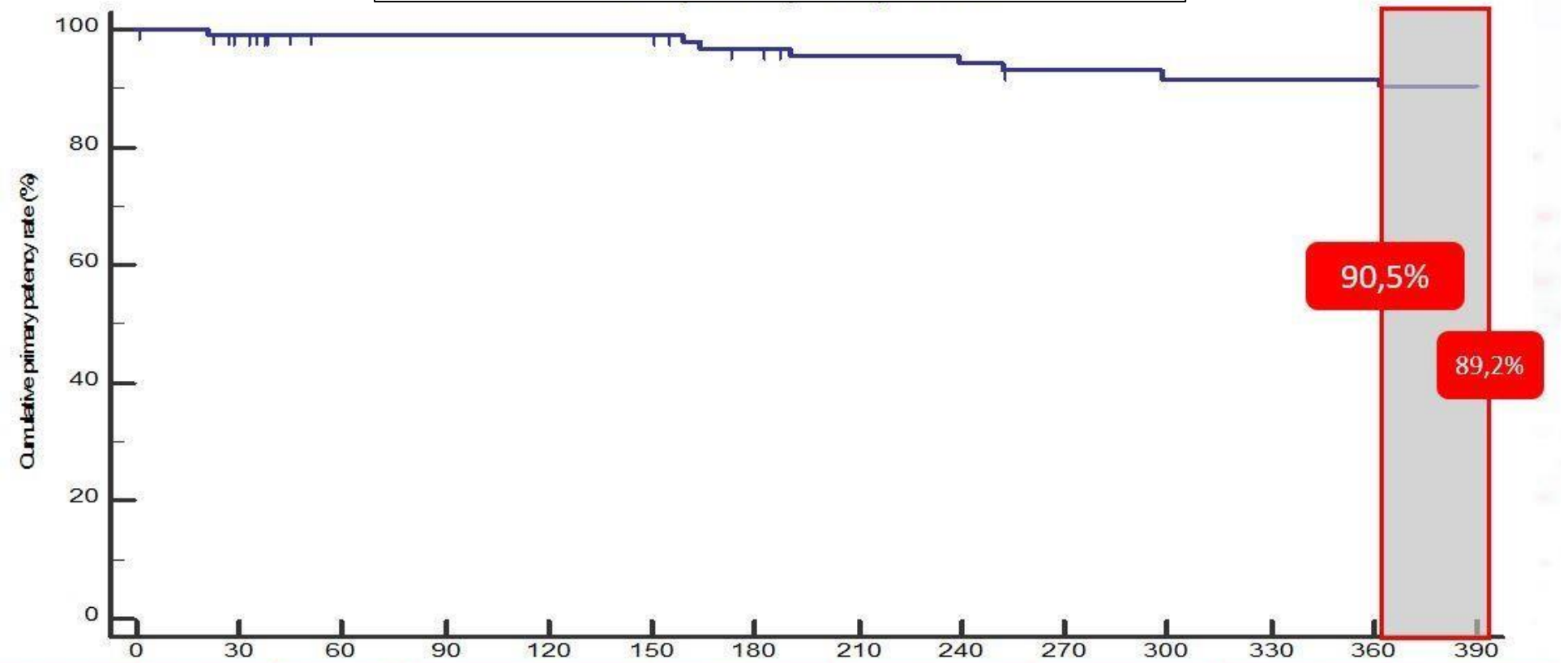
TINTIN_PP 1-year

PRIMARY PATENCY @12M – 100 PT



time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)
at risk	100	93		81	78		73	4
%	100	99		96,5%	95,0%		90,5%	89,2%

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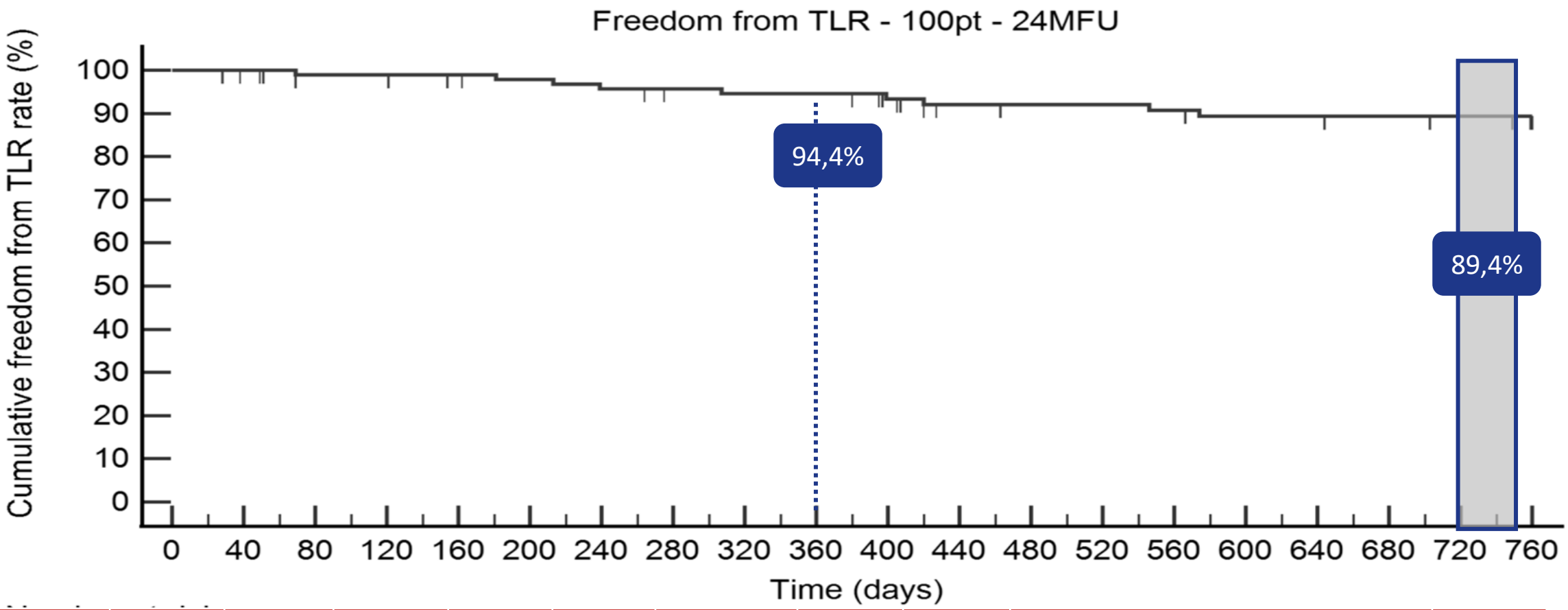
TINTIN_fTLR 2-year



time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)		24MFU (730 days)
at risk	100	99		91	90		84	78		64
%	100	100%		98,9%	97,7%		94,4%	94,4%		89,4

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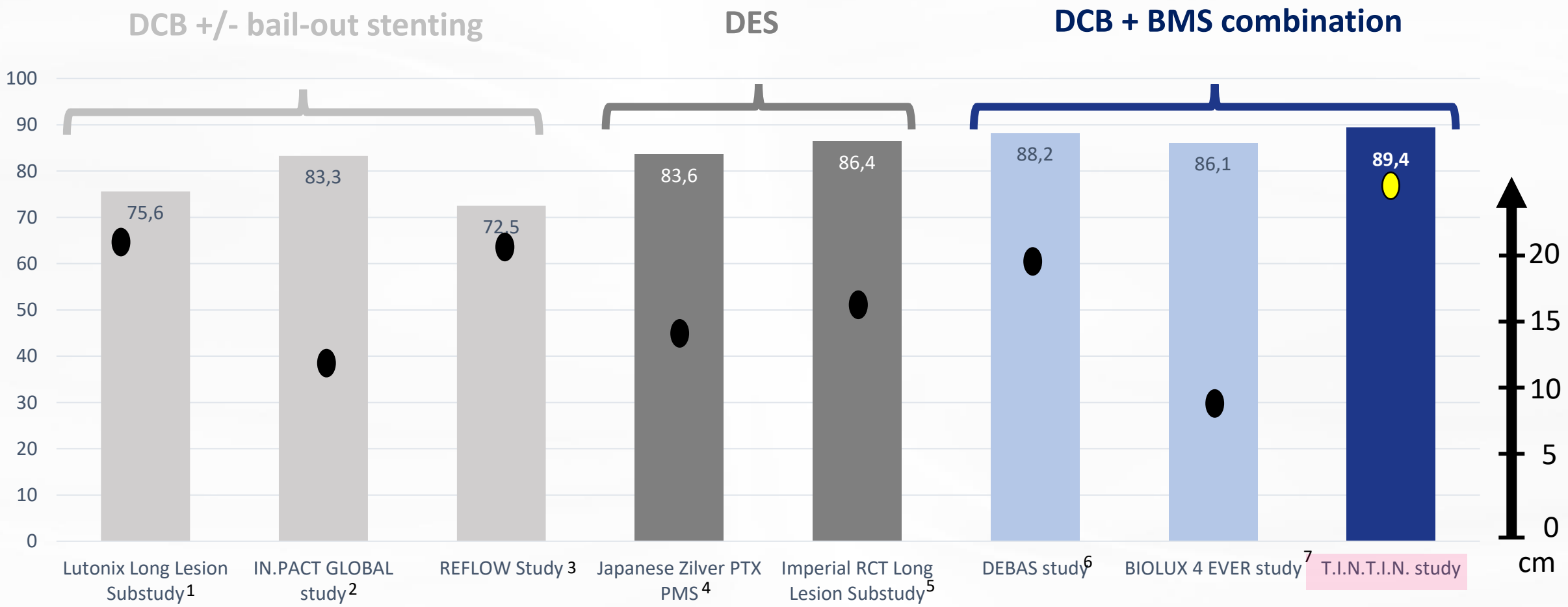
TINTIN_fTLR benchmark with other trials



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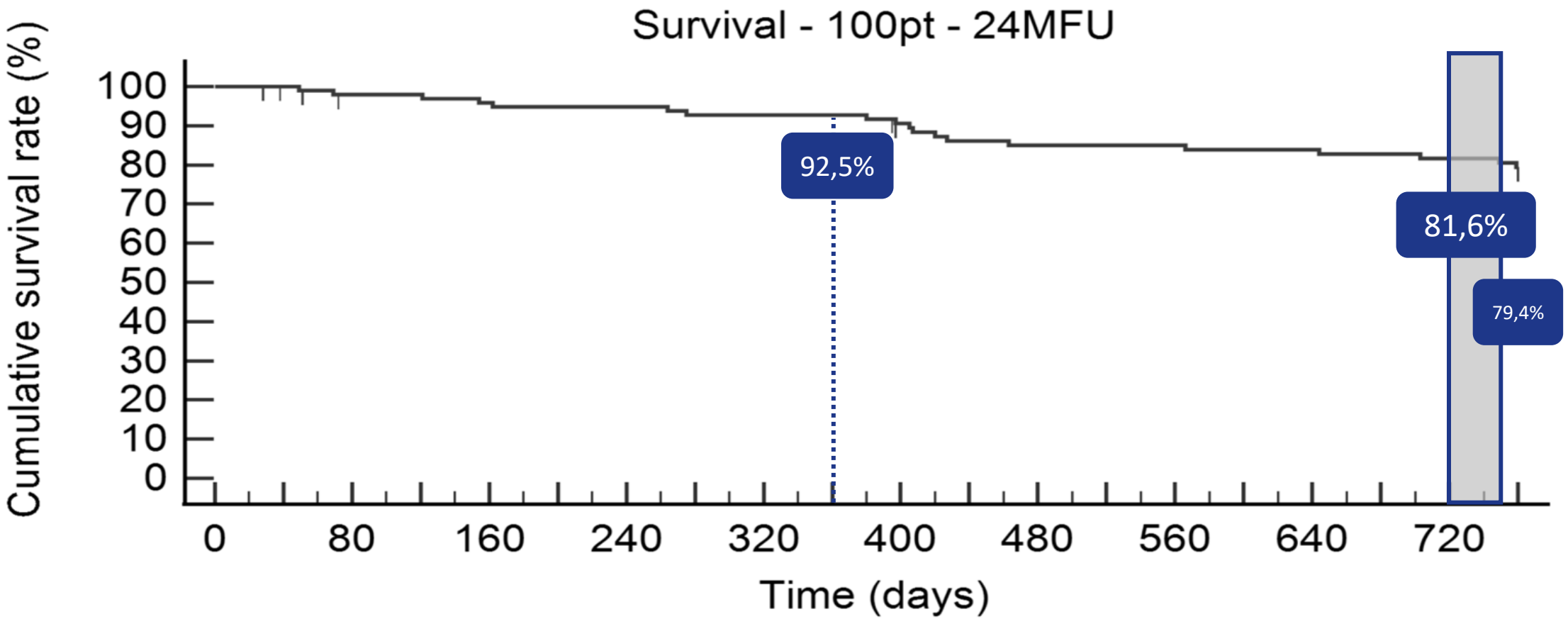
1. Montero-Baker M et al. JVS doi.org/10.1016/j.jvs.2018.08.024
2. Micari A et al. JACC Cardiovasc Interv 2018 May,11(10) ; 945-953
3. Deloose K. presented @LINC 2020
4. Kimihiko Kichikawa et al. Cardiovasc Interv radiol 2019 Mar;42(3):358-364
5. Vermassen F. VIVA LBCT Webinar june 2020
6. Bibombe P et al. Vascular 2018 Vol 26(1) :3-11
7. Deloose K et al. JEVT 2020 Dec;27(6):936-945

Results from different trials are not directly comparable. Information provided for educational purposes

TINTIN_Survival 2-year



time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)		24MFU (730 days)	24MFU (760 days)
at risk	100	99		91	91		89	88		73	23
%	100%	100%		94,6%	94,6%		92,5%	91,7%		81,6%	79,4%

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TINTIN_Safety profile

SAFETY PROFILE – 100 PT

Primary safety endpoint (100 patients)	30 days
Device or procedure related death (N)	0
CD-TLR (N)	0
Target limb major amputation (N)	0

MAEs	180 days	210 days	365 days	730 days
Death (N)	5	5	7	17
CD-TLR (N)	1	2	5	9
Target limb major amputation (N)	0	0	0	0
Thrombosis (N)	1	1	1	1

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TINTIN_Safety profile

Analysing the main causes of death the conclusion was that deaths were due to the complexity of the patients treated

Subject	Description	Date of decease
001-005	Post Transplant Lymphoproliferative diseae	Death (22/01/2019)
002-003	Nacrose for elimination fixator ankle - respiratory collapse	Death (15/11/2017)
002-014	Ionic disorder, acute renal insuffienciency	Death (21/07/2018)
002-018	Acute heart decompensation with hyperkalemia. Pneumonia	Death (08/02/2019)
002-020	Subacute ischemia left hemicerebellum posterior paramedian and in medulla oblongata	Death (25/07/2018)
005-003	General unwell	Death (13/07/2018)
006-015	Large incranial bleeding	Death (12/12/2018)
010-002	Subject found death at home (cause not known)	Death (12/08/2018)
001-003	Cause unknown	Death (28/08/2019)
001-007	Cardiac arrest	Death (25/03/2020)
001-013	Epileptic seizure	Death (25/07/2020)
001-014	CVA	Death (04/02/2020)
002-002	Dialysis catheter sepsis	Death (23/10/2018)
002-008	Patient died, cause unknown	Death (29/01/2019)
002-011	Lung cancer	Death (13/03/2019)
002-032	Deteroriation of general condition	Death (14/11/2019)
002-035	Metastasis of lung neoplasia in left side of the cerebellum	Death (29/08/2020)
063-001	Pneumonia	Death (28/09/2019)
064-006	Patient died in her sleep	Death (23/06/2019)

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TINTIN_ Conclusions

- Long lesion length is probably the most important restenosis-risk factor although there are more influencing predictors
- The combination of VESSEL PREP, DRUG ELUTION & SCAFFOLDING the key to success in real life lesion treatment
- Belgian T.I.N.T.I.N. trial, using the combination Luminor DCB and iVolution stent shows impressive 12 & 24 months results in lesions of 24 cm, 60% CTO's & 28% CLI patients : primary patency of 90,5% @1yr and freedom from TLR of 89,4% @2yr ; the mortality seems to be related to the very diseased population.
- Benchmarking of this combination shows slightly better results than DCB and bail-out stenting and at least equivalent results as modern DES.

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TINTIN_Key messages

Study in long lesions:
Main length of 24.3 cm

PP at 1 year:
90.5%

fTLR at 2-year:
89.4%

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Luminor clinical trials

iVasTriam
The iVascular Clinical Trial Program

LUMINOR registry
Real world registry, 1-year follow-up BTK subgroup. N= 215
PP: 85.9%; fTLR:89.6%

EffPac
Randomized controlled trial (Luminor vs PTA). N=171
3.5-year follow-up. fTLR=90.1%, PP=69.6%

TINTIN
Prospective trial in complex SFA lesions. N=100
2-year follow-up. fTLR= 89.4%

Until 5-year FU

MERLION
Prospective BTK trial. N= 50
1-year follow-up. fTLR= 81.6%

BIBLIOS
Prospective BTK trial, N=150

LUMBRA
Real world registry in Brazil. N=200

LUMIFOLLOW
France Registry. N=500

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Luminor messages

luminor

The best DCB ever

1

No risk of death

The safest DCB for the patients at long-term follow-up

2

To treat all type of lesions

Best efficacy evidence in different indications

3

Not all DCBs are the same

TransferTech nanotechnology makes the difference

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Thank you

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