# Why DCBs should be first line therapy for most femoropopliteal lesions

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- **Honoraria received from:** Abbott Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, TriReme, Veryan, Shockwave, Biotronik, B. Braun
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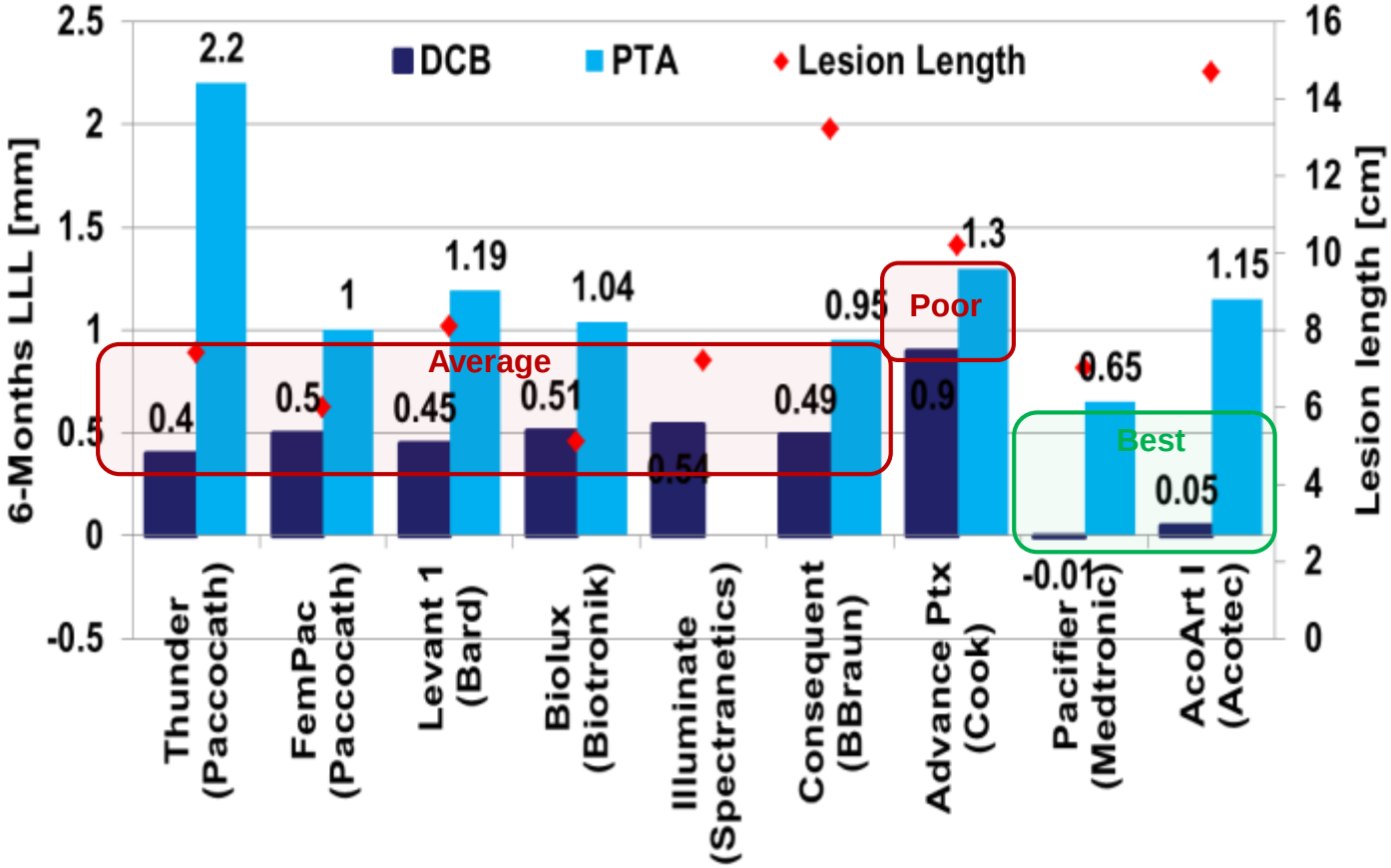
- **Common stock:** QT Medical

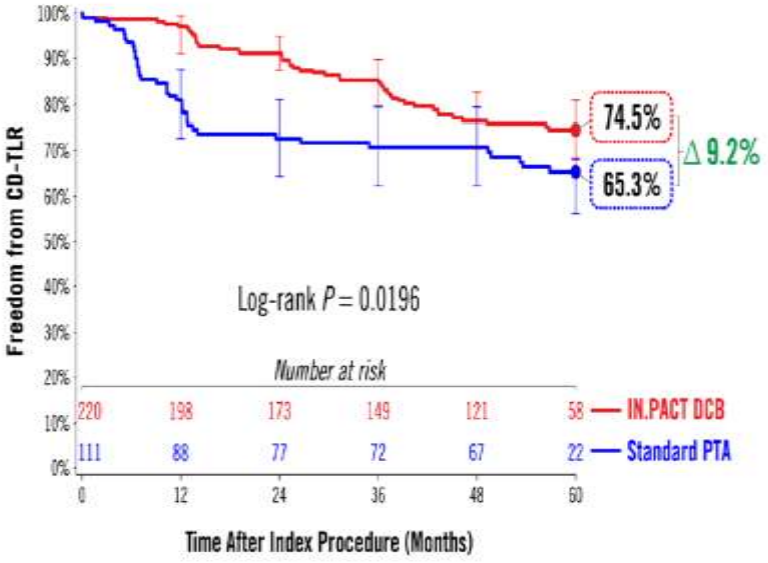
# DCB FIH/Proof of Concept Evidence




Tepe G, et al. *N Engl J Med*. 2008;14;358(7):689-699. Werk M, et al. *Circulation*. 2008;118(13):1358-1365. Scheinert D, et al. *JACC Cardiovasc Interv*. 2014;7(1):10-19. Scheinert D, et al. *J Endovasc Ther*. 2015;22(1):14-21. Werk M, et al. *Circ Cardiovasc Interv*. 2012;5(6):831-840. D.Scheinert. Presented at: Leipzig Interventional Course 2013; January 23-26, 2013; Leipzig, Germany. Schroeder H, et al. *Catheter Cardiovasc Interv*. 2015;86(2):278-286. Albrecht T. Presented at: Leipzig Interventional Course 2016; January 26-29, 2016; Leipzig, Germany. Guo W. Presented at: Leipzig Interventional Course 2016; January 26-29, 2016; Leipzig, Germany.

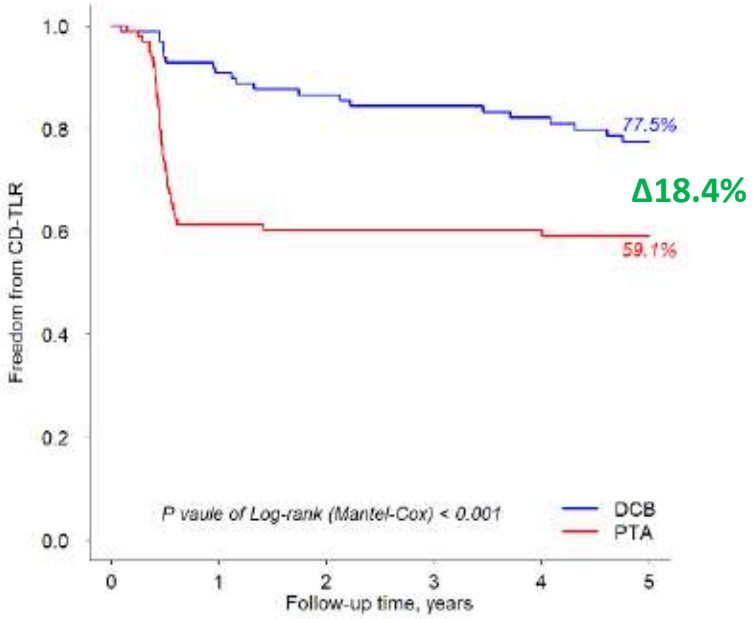
# DCB 5-year Freedom from TLR

## IN.PACT SFA Trial:
### Freedom from CD-TLR through 5 Years




Laird J. VIVA 2018.

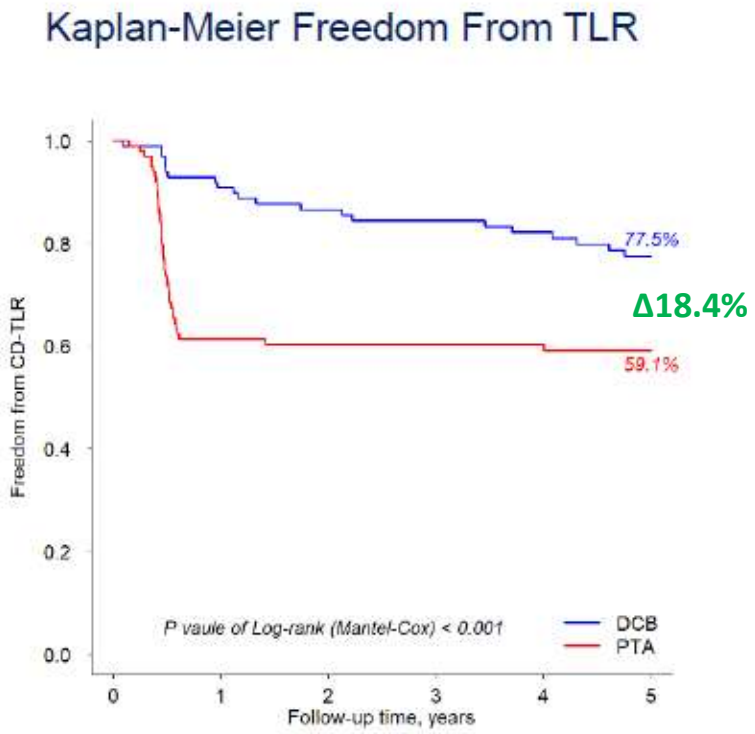
## ACOART I Trial
### Kaplan-Meier Freedom From TLR




Scheinert D, LINC NY June 2019

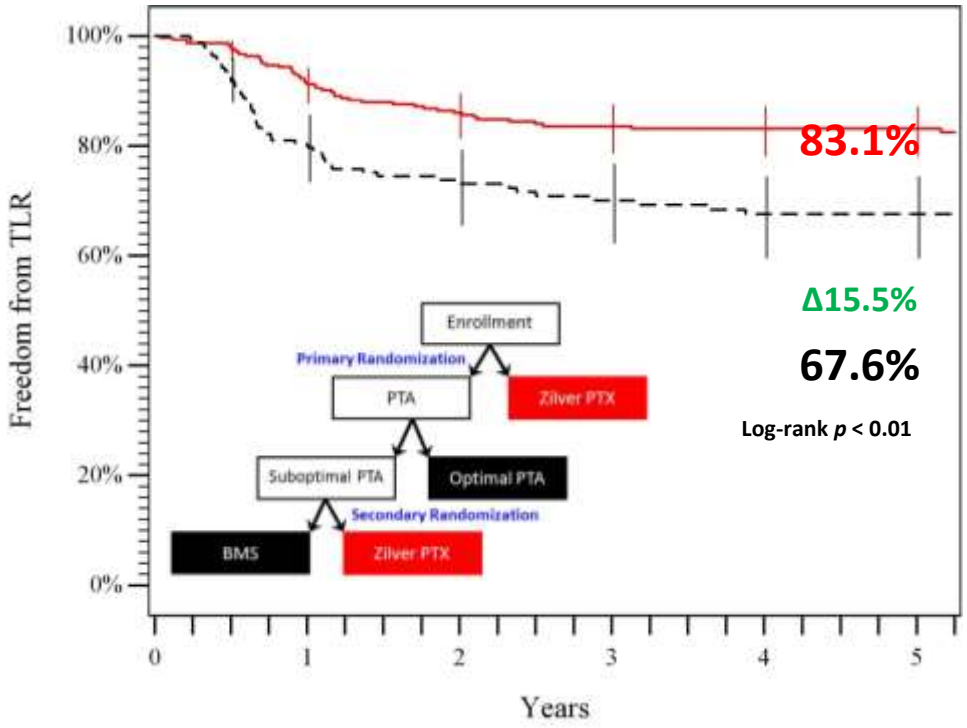
# DCB vs DES 5-Year Freedom from TLR

## ACOART I Trial




Scheinert D, LINC NY June 2019

## Zilver PTX vs Standard Care




Dake M. VIVA 2015

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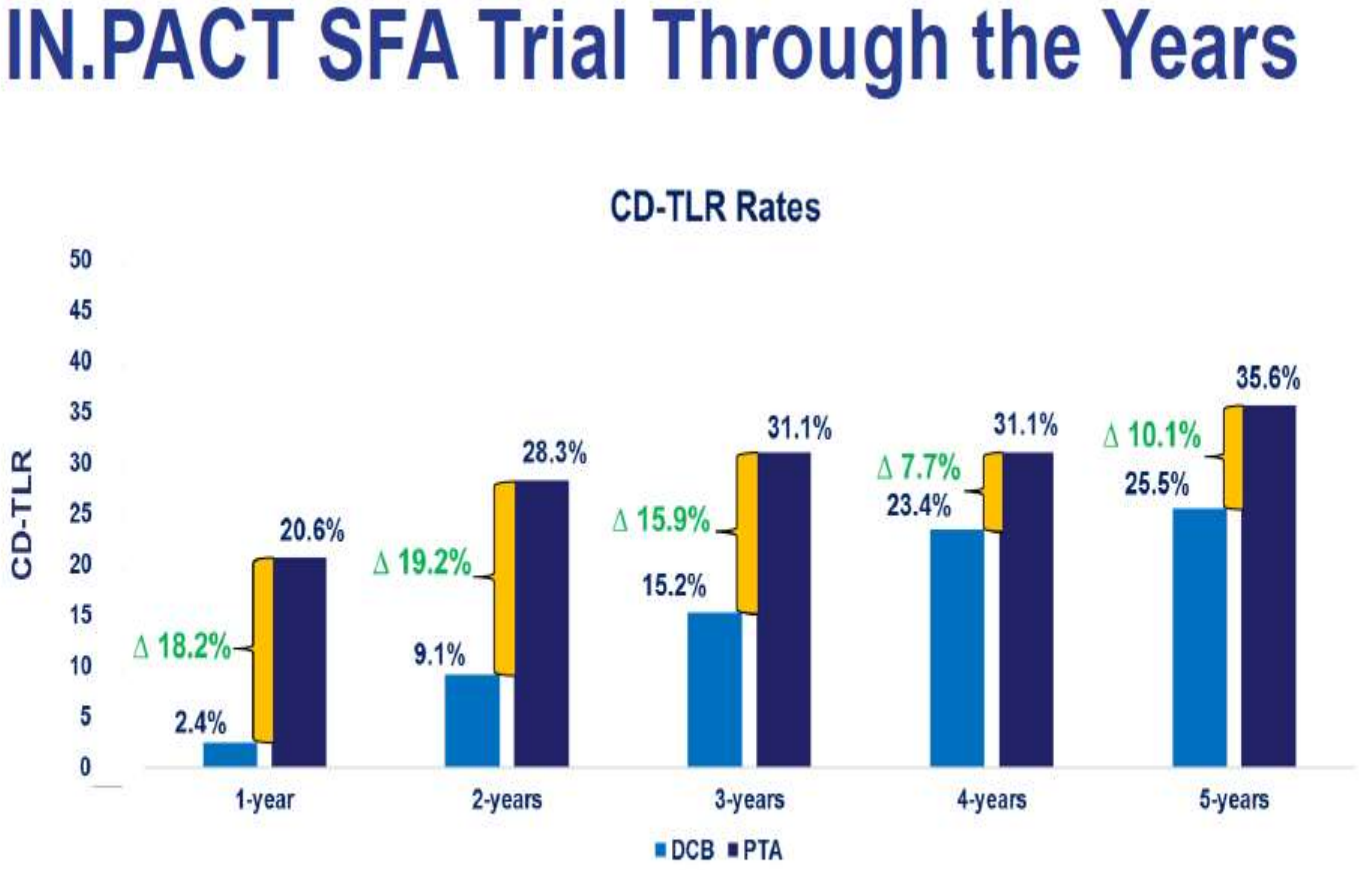
# INPACT SFA RCT 5-Year Follow-up





1. Tepe G. et al. Circ 2015;131:495-502
2. Laird J.R. et al. JACC 2015;66:2329-2338
3. Schneider P. et al. Circ-CI 2018;11:1-8
4. Schneider P. VIVA 2017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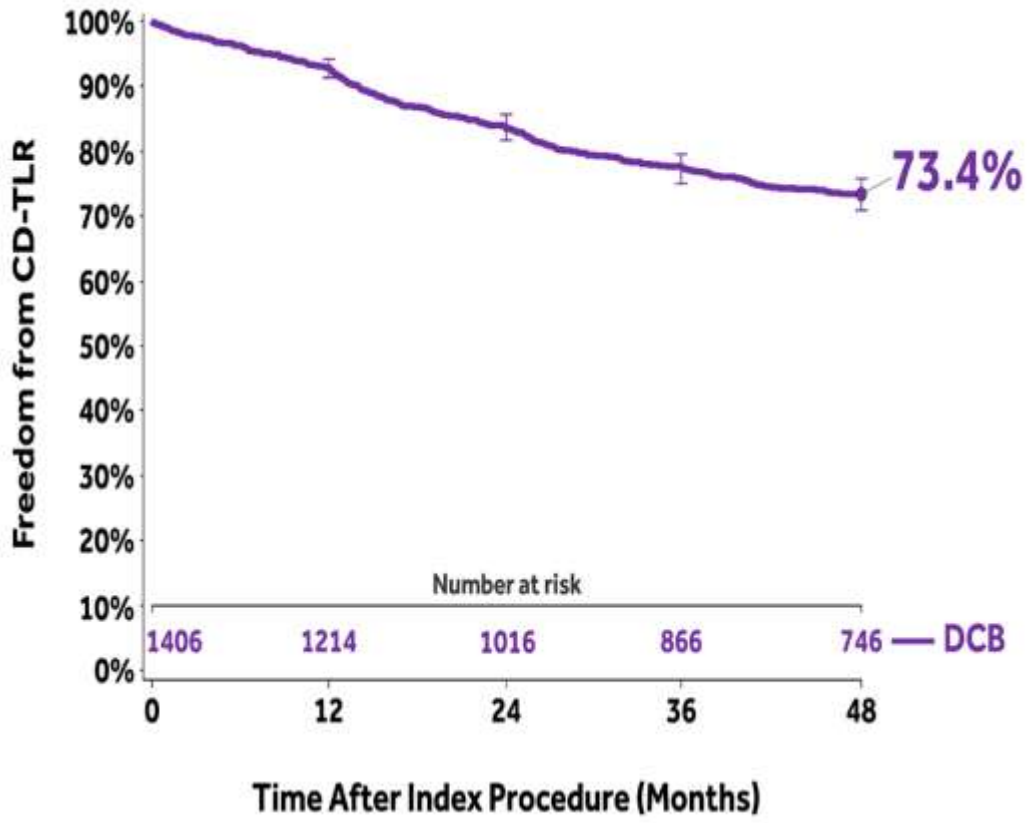
Laird J. VIVA 2018

# IN.PACT Global Study: Full Clinical Cohort

## 4-Year Effectiveness Outcomes

### Freedom from CD-TLR through 4 Years




**3-Yr. FF CD-TLR = 76.9%[1]** **Δ**

**4-Yr. FF CD-TLR = 73.4%[2]** **3.5%**

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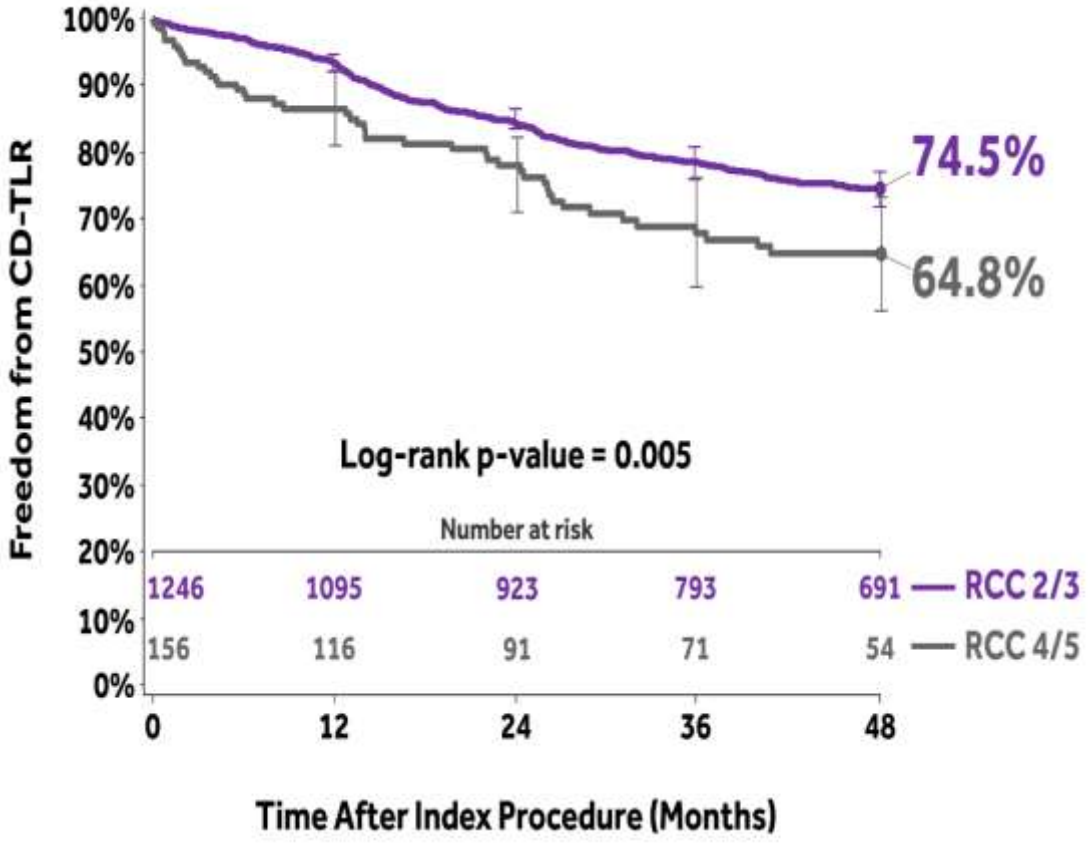
1. G. Tepe IN.PACT Global 3-year Results CIRSE 2019
2. Zeller T IN.PACT Global 4-year Results VIVA 2019

# IN.PACT Global Study: Clinical Cohort

## Claudicant vs CLI: Reintervention

### Freedom from CD-TLR through 4 Years

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Zeller T IN.PACT Global 4-year Results VIVA 2019

# DCB "Real-World" Registries

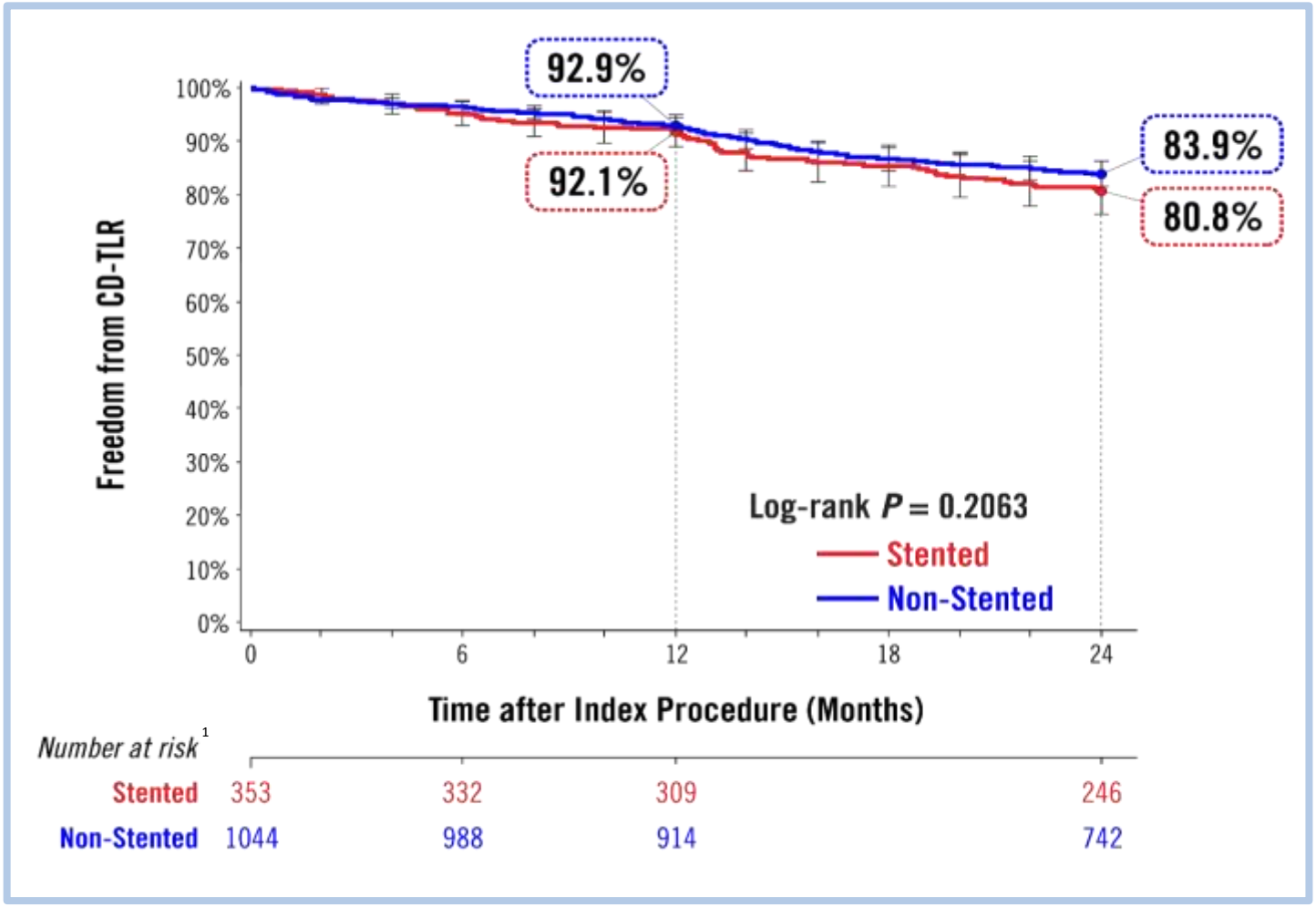
| | Global[1] | Long Lesion[2] | Long Lesion[3] | CTO[4] | ISR[5] | Clinical[6] | ILLUMENATE Global[7] Stellarex |
|---|---|---|---|---|---|---|---|
| **Follow-up** | 691 subjects Complete follow-up CEC & site-reported outcomes | 107 & 102 subjects for safety & effectiveness, respectively; Core lab-adjudicated | 157 subjects Complete follow-up; Core lab-adjudicated | 126 subjects Complete follow-up; Core lab-adjudicated | 131 subjects Complete follow-up; Core lab-adjudicated | 1406 subjects Complete follow-up; CEC & site-reported outcomes | 371 subjects Complete follow-up; Core lab-adjudicated |
| **12-mo Outcomes** | | | | | | | |
| 1° Patency (%) | NR | 68.9% | 91.1% | 85.3% | 88.7% | NR | 81.4% |
| FF TLR/CD-TLR(%) | 94.3% | 87.8% | 94.0% | 89.1% | 92.9% | 92.6% | 94.8% |
| **Bail-out Stent (%)** | **25.2%** | **39.8%** | **40.4%** | **46.8%** | **14.5%** | **25.3%** | **17.3%** |
| Amputations (%) | 0.5% (3/632) | NR | 0.0% | 0.0% | 0.0% | 0.2% (3/1311) | 0.3% (1/371) |
| **Key Lesion Characteristics** | | | | | | | |
| Length (cm) | 10.1cm | 21.3cm | 26.4cm | 22.9cm | 17.2cm | 12.1cm | 7.5cm |
| CTO (%) | 31.2% | 52.1% | 60.4% | 100.0% | 34.0% | 35.5% | 31.3% |
| $Ca^{2+}$ (%) | 50.2% | 78.9%[2] | 71.8% | 71.0% | 59.1% | 68.7% | 56.2%[7] |

1. Thieme M, et al. (2017). *JACC Cardiovasc Interv*.
2. Bard Lutonix Instructions for Use BAW1387400r3, Section 10.5. Moderate to severe calcification reported; amputations not reported (NR).
3. Presented by Scheinert D, PCR Paris, France 2015.
4. Presented by Tepe G, CX London, UK 2016.
5. Presented by Brodmann M, VIVA Las Vegas, USA 2015.
6. Presented by Jaff M, VIVA Las Vegas, USA 2016;
7. Presented by Zeller T, LINC Leipzig, Germany 2017. Moderate to severe calcification reported.

# IN.PACT Global Study

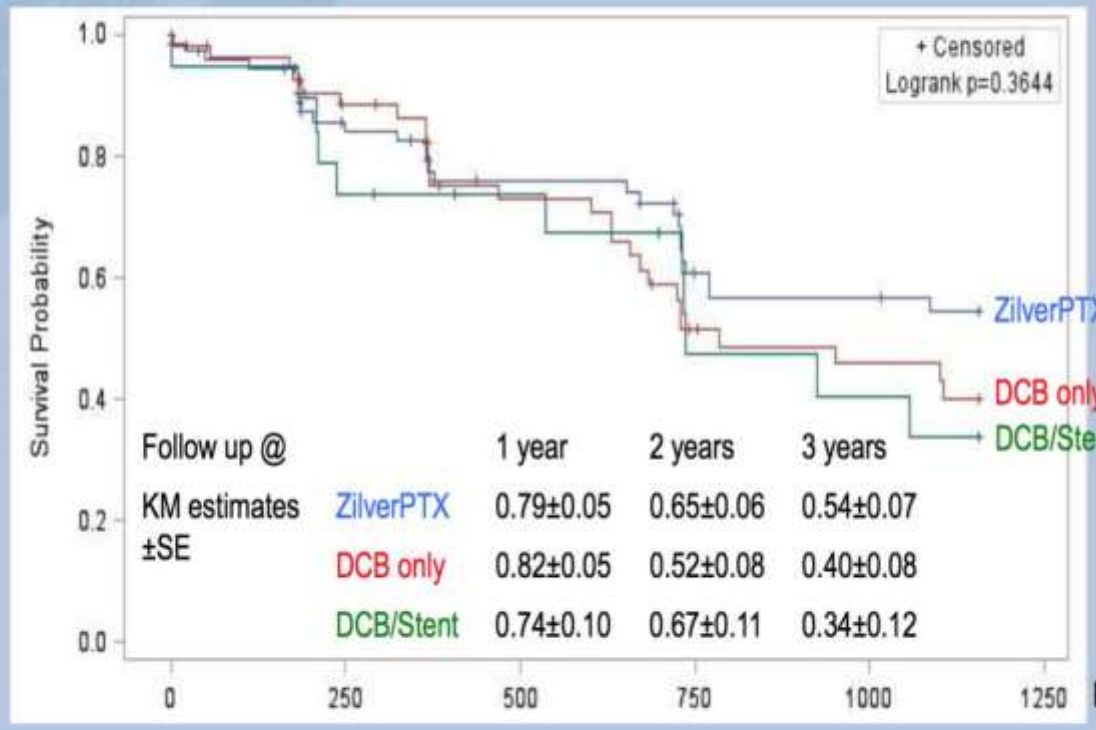
## Stented vs Non-Stented Analysis

**Freedom from CD-TLR Through 2 Years**




1. Number at risk represents the number of evaluable subjects at the beginning of each 60-day window

# Primary Patency @ 36 months
# ZilverPTX vs DCB only vs DCB plus Stent




| Follow up @ | | 1 year | 2 years | 3 years |
|---|---|---|---|---|
| KM estimates ±SE | ZilverPTX | 0.79±0.05 | 0.65±0.06 | 0.54±0.07 |
| | DCB only | 0.82±0.05 | 0.52±0.08 | 0.40±0.08 |
| | DCB/Stent | 0.74±0.10 | 0.67±0.11 | 0.34±0.12 |

| Days | | 150 | 320 | 670 | 1035 |
|---|---|---|---|---|---|
| No@Risk | ZilverPTX | 69 | 53 | 42 | 27 |
| | DCB only | 51 | 42 | 27 | 16 |
| | DCB/Stent | 18 | 13 | 11 | 6 |

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Steiner et al. JACC 2018

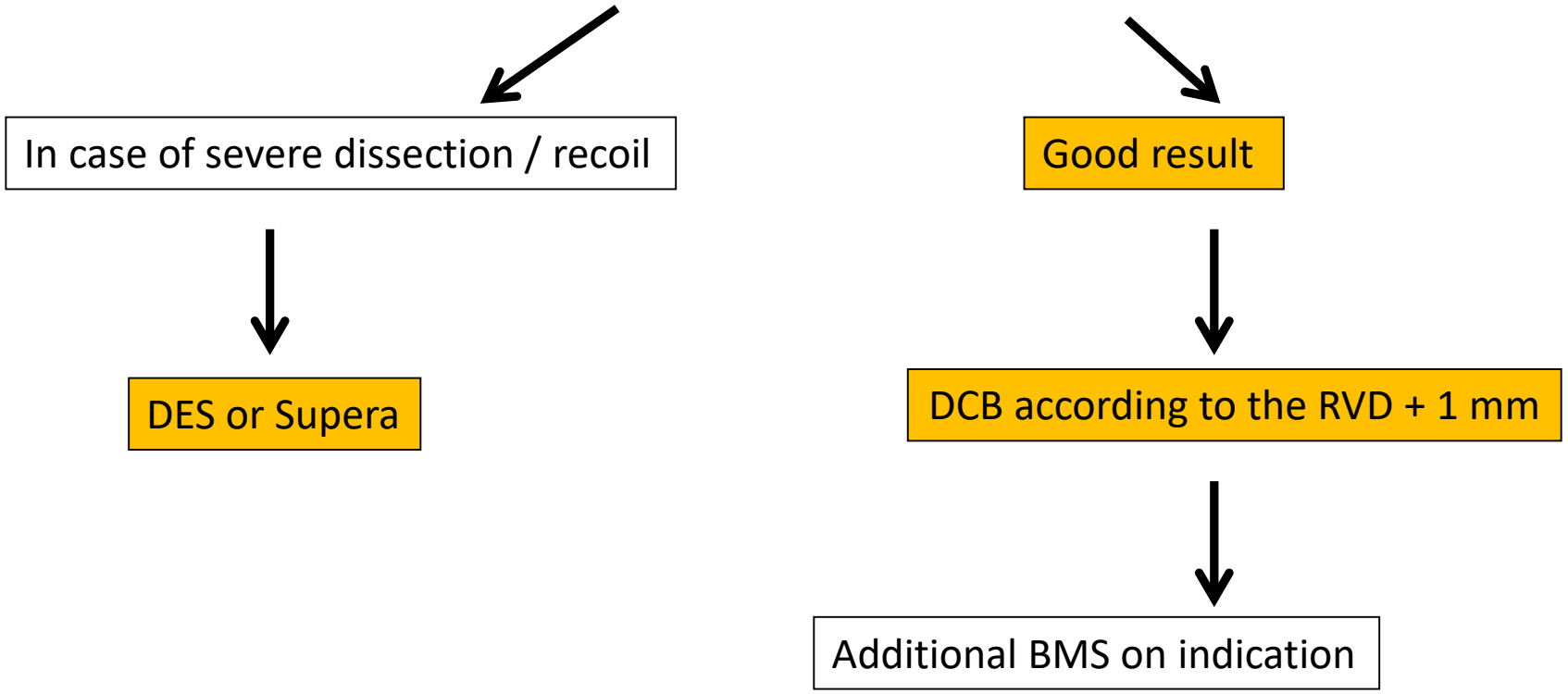
# Conclusions

- In RCT DCB demonstrated sustained benefit over POBA up to 5 years in TASC A & B lesions
- In more challenging TASC C & D lesions DCB
  - have shown promising results in real world registries up to 4 year follow independent of plain DCB angioplasty or provisional stent placement
  - In a RCT not sufficiently powered (REAL PTX) longer lesions showed a trend towards favorable outcomes for a DES full metal jacket
- Nevertheless, minimizing stent length by provisional stent placement following DCB preserves further treatment options
- Alternatively spot atherectomy of lesions areas not responsive to predilatation may further reduce the need for provisional stent placement

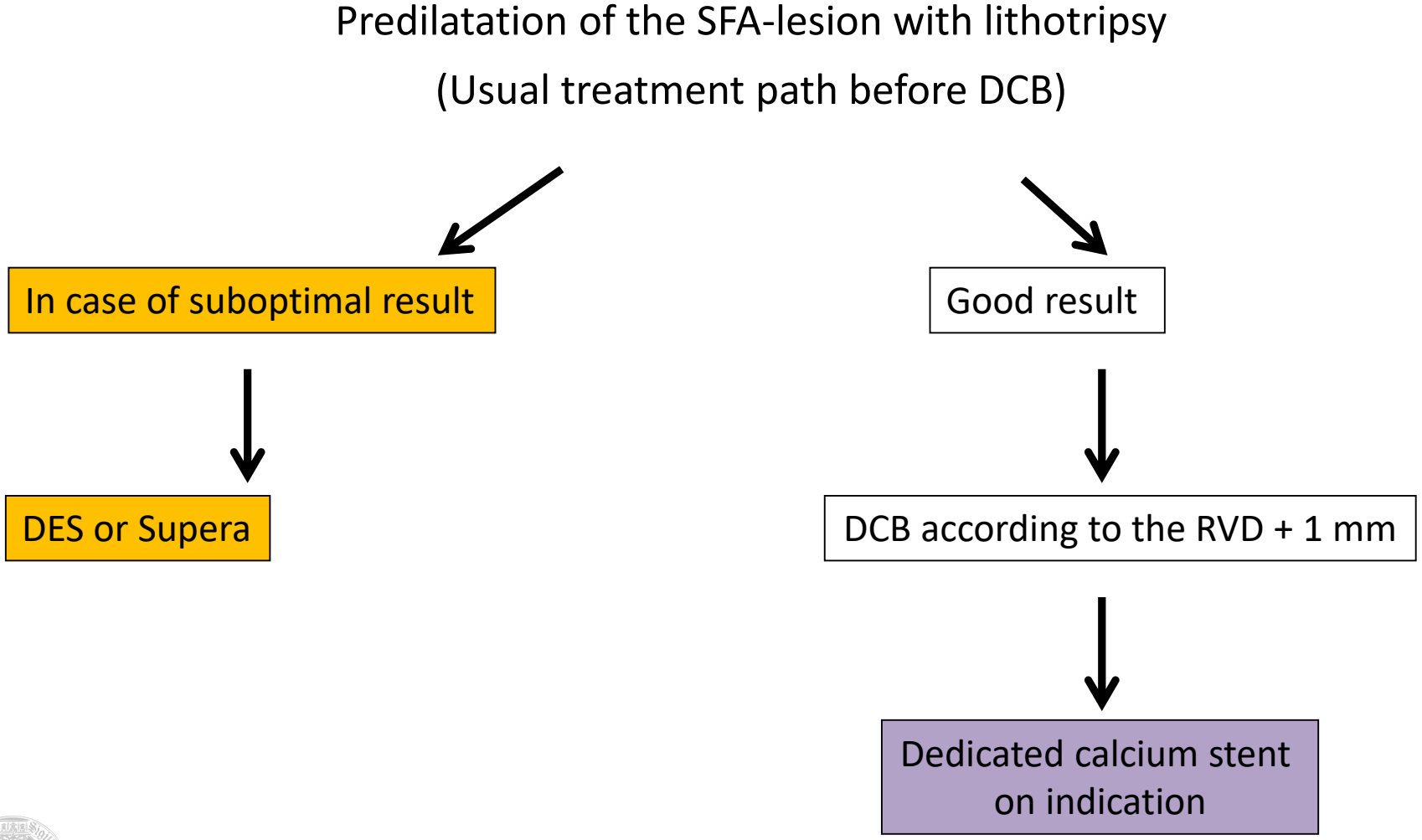
# Treatment Algorithm in TASC A & B Femoropopliteal Lesions (no to moderate calcium)

Predilatation of the SFA-lesion with a 1:1 sized balloon

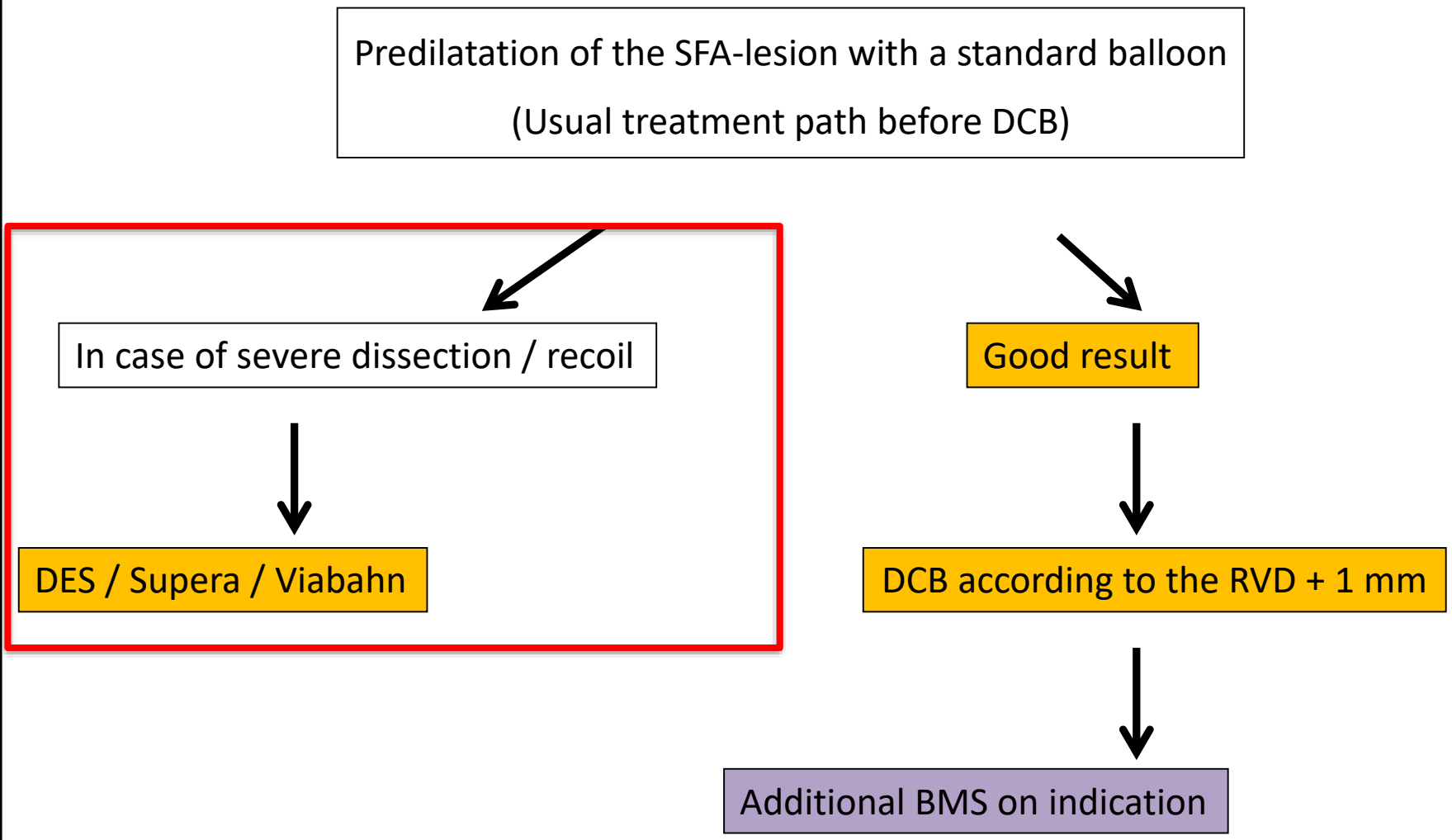
(Usual treatment path before DCB)



# Treatment Algorithm in TASC A & B Femoropopliteal Lesions (severe calcium)



# Treatment Algorithm in TASC C & D Femoropopliteal Lesions



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