

# TCTAP 2022

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## Comparison of Clinical Outcomes After DCB and DES In Very Small Coronary Artery Disease

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# Disclosure

- No conflicts of interest

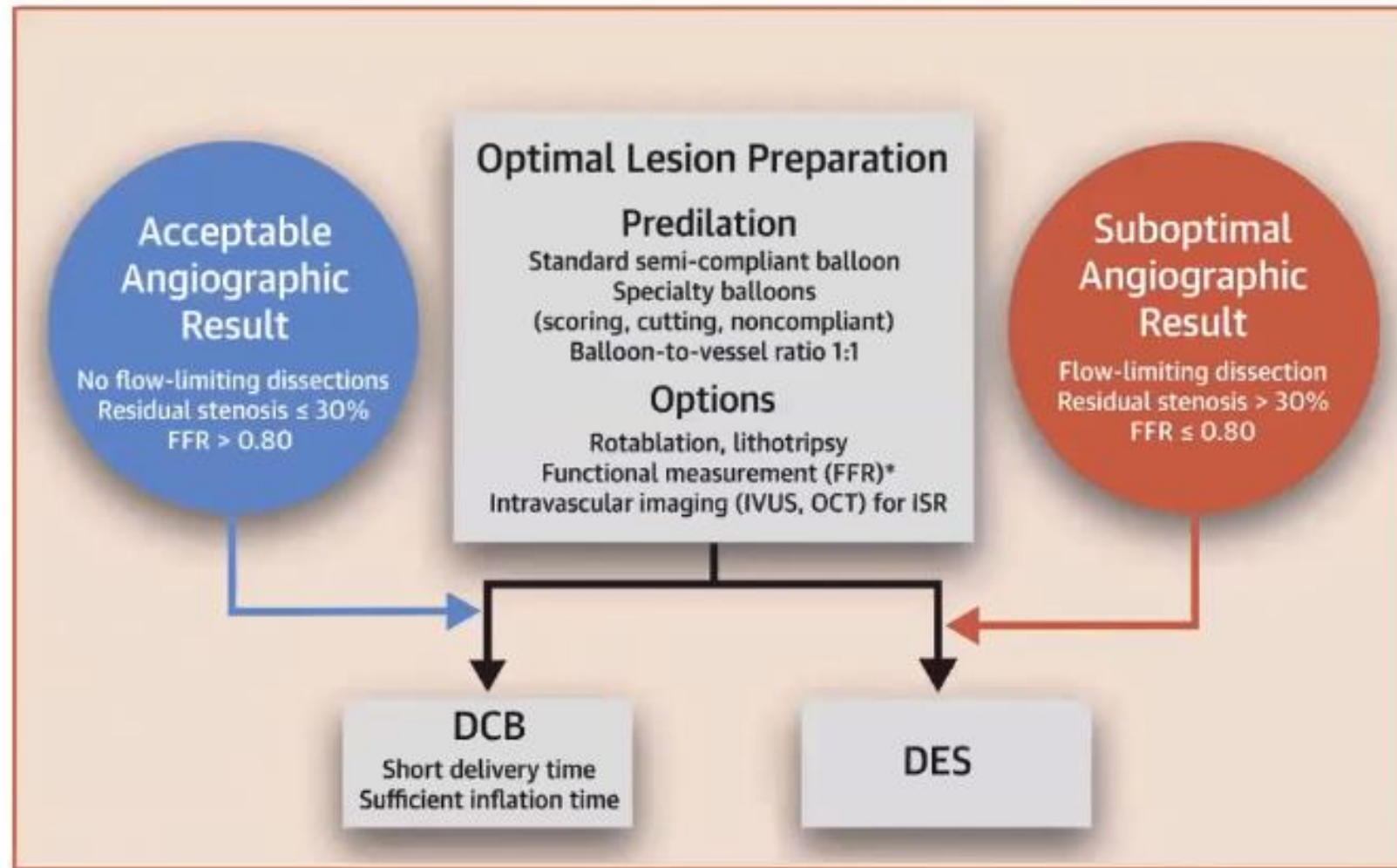
# Background

- **Small vessel disease intervention**  
**In 30-50% PCI; DM & Female**  
**Risk and benefit ?**  
**Dissection, perforation and restenosis**
- **DCB** use in de novo very small vessel (VSV) PCI,  
RVD  $\leq 2.25$ mm: Efficacy and safety: **unknown**

J Am Coll Cardiol. 1998 May;31(6):1291-8.

Cardiovasc Revasc Med. 2010 Jul-Sep;11(3):189-98.

## CENTRAL ILLUSTRATION: DCB-Only Strategy for PCI in Coronary Artery Disease



Jeger, R.V. et al. J Am Coll Cardiol Interv. 2020;13(12):1391-402.

# Drug-Coated Balloon Versus Drug-Eluting Stent for Small-Vessel Disease



## The RESTORE SVD China Randomized Trial

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- Inclusion:**
- Age  $\geq 18$  years
  - Stable angina or stabilized ACS
  - Reference vessel diameter  $\geq 2.25$ mm and  $\leq 2.75$ mm for small vessel cohort,  $\geq 2.00$ mm and  $< 2.25$ mm for very small vessel cohort, lesion length  $\leq 26$ mm
- Exclusion:**
- AMI within 1 week
  - Severe congestive heart disease or NYHA IV, left main disease, CTO, 3-vessel treatment, bifurcation (diameter of the side branch  $> 2.0$  mm), target lesion severe calcification or thrombus, and ISR



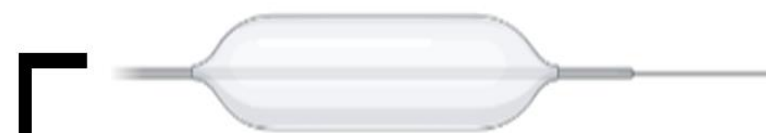
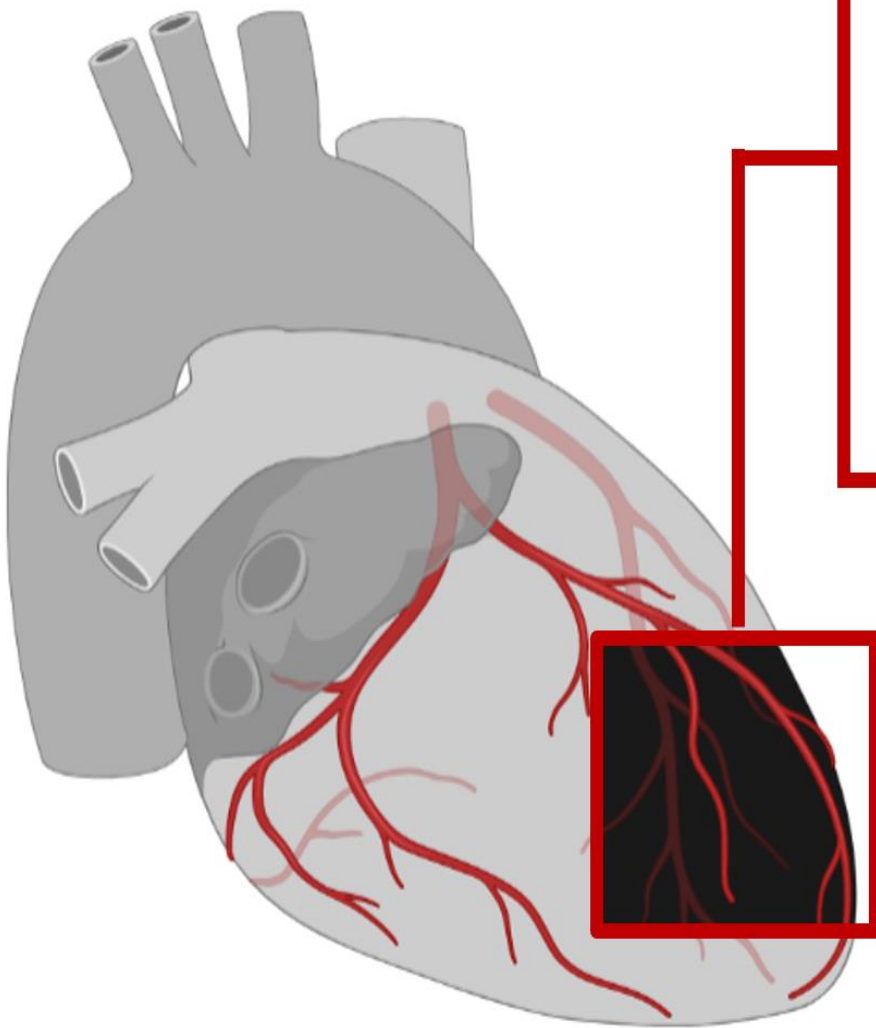
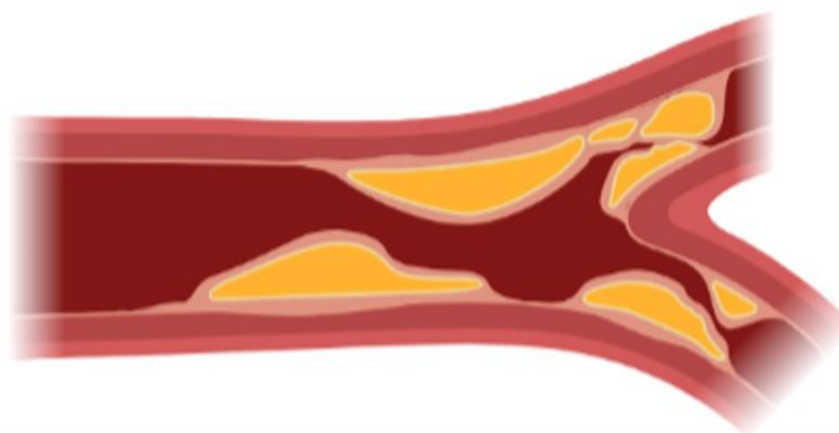
**Primary Endpoint**  
In-segment diameter stenosis (%) at 9 months

**Table 1**

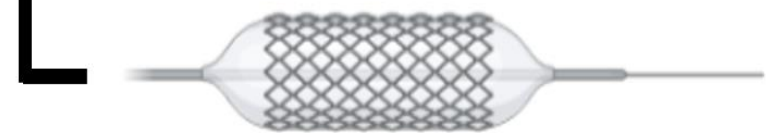
**Characteristics of included studies.**

| Study                    | Randomized controlled trials |                  |                          |            |                           |             | Nonrandomized trials   |            |                             |            |                           |     |
|--------------------------|------------------------------|------------------|--------------------------|------------|---------------------------|-------------|------------------------|------------|-----------------------------|------------|---------------------------|-----|
|                          | Jeger et al<br>(N = 758)     |                  | Latib et al<br>(N = 182) |            | Cortese et al<br>(N = 57) |             | Sim et al<br>(N = 287) |            | Giannini et al<br>(N = 181) |            | Sinaga et al<br>(N = 335) |     |
| Year                     | 2018                         |                  | 2012                     |            | 2010                      |             | 2018                   |            | 2017                        |            | 2016                      |     |
| Device type              | 1 versus 5 or 6              |                  | 2 versus 4               |            | 3 versus 4                |             | 1 or 2 versus 7        |            | 2 versus 5 or 6             |            | 1 versus 8                |     |
| Vessel diameter          | <3 mm                        |                  | <2.8 mm                  |            | <2.75mm                   |             | <2.25 mm               |            | <2.8 mm                     |            | <2.5mm                    |     |
| Follow up duration       | 12 mo                        |                  | 6 mo                     |            | 9 mo                      |             | 12 mo                  |            | 12 mo                       |            | 12 mo                     |     |
| Variables                | DCB                          | DES              | DCB                      | DES        | DCB                       | DES         | DCB                    | DES        | DCB                         | DES        | DCB                       | DES |
| Participants (n)         | 382                          | 376              | 90                       | 92         | 28                        | 29          | 87                     | 200        | 90                          | 91         | 172                       | 163 |
| Mean age                 | 67                           | 68               | 65                       | 66         | 68                        | 67          | 58                     | 61         | 65                          | 66         | 61                        | 62  |
| Men                      | 295                          | 262              | 72                       | 71         | 22                        | 22          | 70                     | 154        | 72                          | 71         | 132                       | 117 |
| Current smokers          | 82                           | 72               | 15                       | 10         | /                         | /           | 42                     | 59         | /                           | /          | 52                        | 73  |
| Dyslipidemia             | 262*                         | 259*             | 71                       | 73         | 17                        | 13          | 70                     | 153        | 71                          | 71         | 120                       | 118 |
| Hypertension             | 324                          | 332 <sup>†</sup> | 72                       | 75         | 21                        | 20          | 69                     | 136        | 72                          | 74         | 125                       | 113 |
| Diabetes                 | 123 <sup>‡</sup>             | 133 <sup>‡</sup> | 39                       | 35         | 13                        | 11          | 55                     | 108        | 39                          | 37         | 88                        | 80  |
| Previous MI              | 160                          | 133              | 46                       | 33         | 5                         | 6           | /                      | /          | 46                          | 53         | /                         | /   |
| Previous PCI             | 235                          | 241              | 52                       | 39         | 3                         | 4           | 32                     | 48         | 52                          | 52         | /                         | /   |
| Previous CABG            | 37                           | 34               | 9                        | 12         | 3                         | 4           | 8                      | 15         | 9                           | 15         | /                         | /   |
| Multivessel disease      | 313                          | 285              | 56                       | 56         | /                         | /           | 63                     | 156        | 55                          | 65         | /                         | /   |
| Bifurcation lesion       | 22                           | 29               | /                        | /          | 6                         | 7           | /                      | /          | /                           | /          | /                         | /   |
| Target vessel            |                              |                  |                          |            |                           |             |                        |            |                             |            |                           |     |
| Left anterior descending | 128                          | 116              | 10                       | 12         | 15                        | 15          | /                      | /          | 10                          | 16         | 71                        | 67  |
| Left circumflex          | 179                          | 183              | 10                       | 16         | 5                         | 3           | /                      | /          | 10                          | 12         | 55                        | 56  |
| Right coronary artery    | 75                           | 77               | 8                        | 9          | 8                         | 11          | /                      | /          | 8                           | 10         | 45                        | 38  |
| Target lesion            |                              |                  |                          |            |                           |             |                        |            |                             |            |                           |     |
| Lesion length (mm)       | /                            | /                | 15.4 ± 6.2               | 14.4 ± 5.6 | 12.4 ± 5.9                | 11.4 ± 7.1  | 18.6 ± 8.3             | 20.3 ± 7.8 | /                           | /          | /                         | /   |
| Diameter stenosis        | /                            | /                | 81.9 ± 9.6               | 83.3 ± 8.7 | 86.0 ± 12.1               | 89.1 ± 10.6 | 87.6 ± 14.2            | 90.1 ± 9.1 | 81.9 ± 9.6                  | 82.4 ± 8.5 | /                         | /   |
| Procedural success       | 96%                          | 98%              | /                        | /          | 96%                       | 100%        | 97%                    | 96%        | /                           | /          | /                         | /   |
| Device success           | /                            | /                | 98%                      | 97%        | /                         | /           | 92%                    | 99%        | 98%                         | 97%        | /                         | /   |

Very small vessel: 2.0 - 2.25 mm

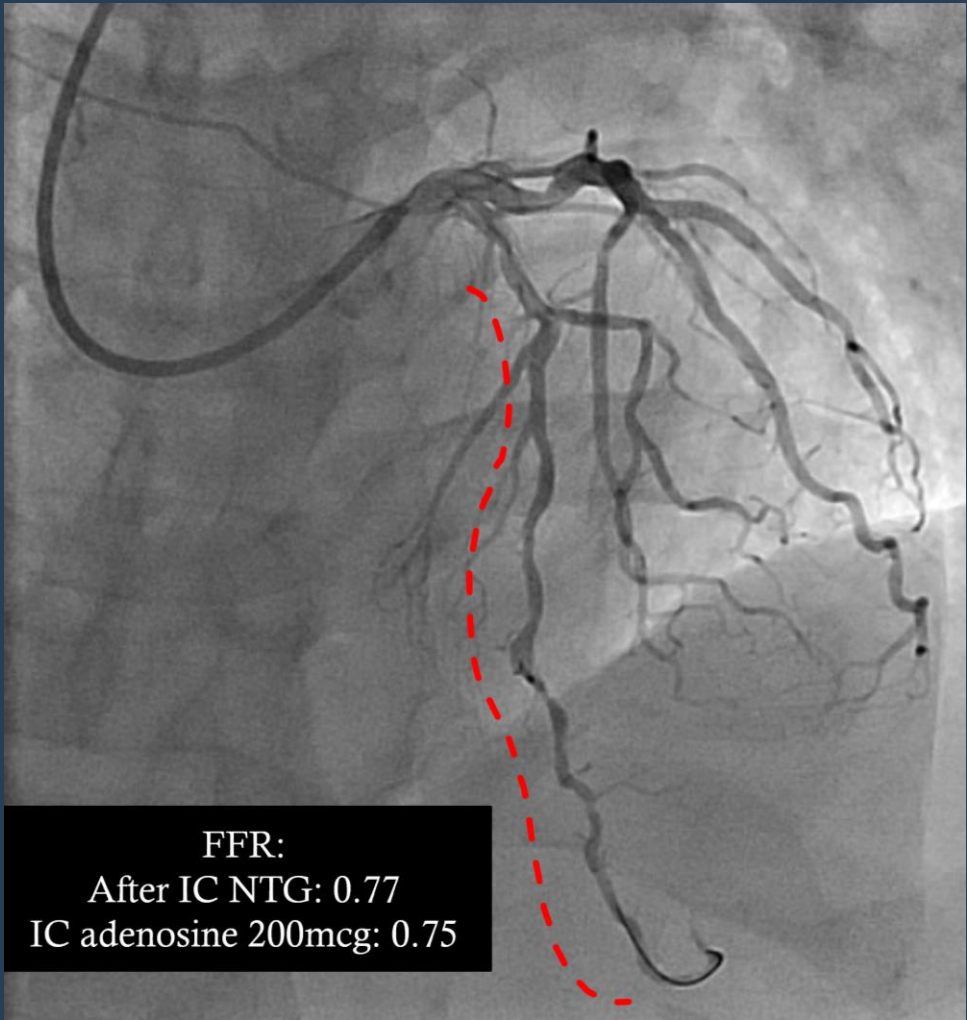


Drug-eluting balloon (DEB)



Drug-eluting stent (DES)

## dLAD diffuse stenosis



## DCB



## Final outcome





2018 Jan to 2020 March  
193 Patients

216 de novo  
VSV intervention

DCB

55 Patients  
58 Lesions

DES

151 Patients  
158 Lesions

Follow-up 12 months

# Patient characteristics

|                                    | DCB (n=55) | DES (n=151) | P value |
|------------------------------------|------------|-------------|---------|
| <b>Clinical data</b>               |            |             |         |
| Age, years                         | 65.1±11.1  | 66.0±10.4   | 0.611   |
| Male gender, n (%)                 | 44 (80.0%) | 123 (81.5%) | 0.813   |
| Body mass index, Kg/m <sup>2</sup> | 26.5±3.8   | 25.6±3.8    | 0.130   |
| Smoking, n (%)                     | 23 (41.8%) | 54 (35.8%)  | 0.427   |
| Heart failure, n (%)               | 14 (25.5%) | 32 (21.2%)  | 0.516   |
| DM, n (%)                          | 27 (49.1%) | 78 (51.7%)  | 0.745   |
| HTN, n (%)                         | 50 (90.9%) | 126 (83.4%) | 0.179   |
| Dyslipidemia, n (%)                | 47 (85.5%) | 111 (73.5%) | 0.073   |
| Atrial fibrillation, n (%)         | 7 (12.7%)  | 8 (5.3%)    | 0.069   |
| ESRD, n (%)                        | 5 (9.1%)   | 13 (8.6%)   | 0.914   |
| History of MI, n (%)               | 7 (12.7)   | 11 (7.3)    | 0.221   |
| History of CVA, n (%)              | 3 (5.5)    | 12 (8.0)    | 0.542   |
| History of Vascular disease, n (%) | 6 (10.9)   | 15 (9.9)    | 0.838   |
| History of CABG, n (%)             | 3 (5.5%)   | 6 (4.0%)    | 0.645   |
| ACS presentation, n (%)            | 9 (16.4%)  | 36 (23.84%) | 0.251   |

# Lesion characteristics

|  | DCB (n=58) | DES (n=158) | P value |
|--|------------|-------------|---------|
| <b>Very small vessel lesion location</b> |            |             | 0.742   |
| LAD, n (%)                               | 25 (43.1%) | 76 (48.1%)  |         |
| LCX, n (%)                               | 20 (34.5%) | 53 (33.5%)  |         |
| RCA, n (%)                               | 13 (22.4%) | 29 (18.4%)  |         |
| <b>Lesion characteristics</b>            |            |             |         |
| Mean Lesion length, mm                   | 22.7±8.2   | 23.5±8.7    | 0.536   |
| Mean lesion diameter, mm                 | 2.0±0.1    | 2.2±0.1     | <0.001  |
| Diameter stenosis, %                     | 86.6±10.0  | 87.8±10.8   | 0.440   |
| AHA/ACC lesion type                      |            |             | 0.017   |
| Type A lesion, n (%)                     | 11 (19.0%) | 28 (17.7%)  |         |
| Type B1 lesion, n (%)                    | 26 (44.8%) | 38 (24.1%)  |         |
| Type B2 lesion, n (%)                    | 10 (17.2%) | 40 (25.3%)  |         |
| Type C lesion, n (%)                     | 11 (18.9%) | 52 (32.9%)  |         |
| Type B2/C lesion, n (%)                  | 21 (36.2%) | 92 (58.2%)  | 0.004   |
| CTO lesion, n (%)                        | 7 (12.1%)  | 41 (26.0%)  | 0.030   |

# Lesion characteristics

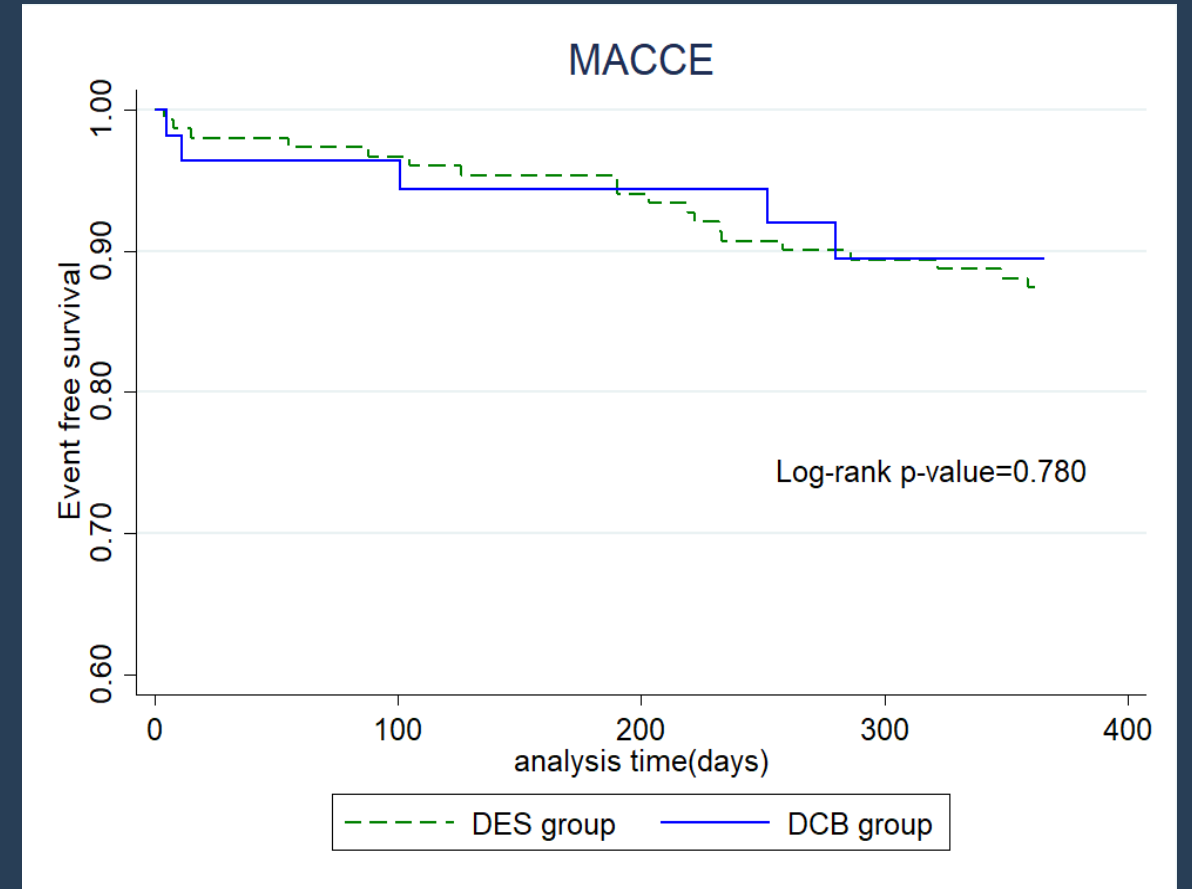
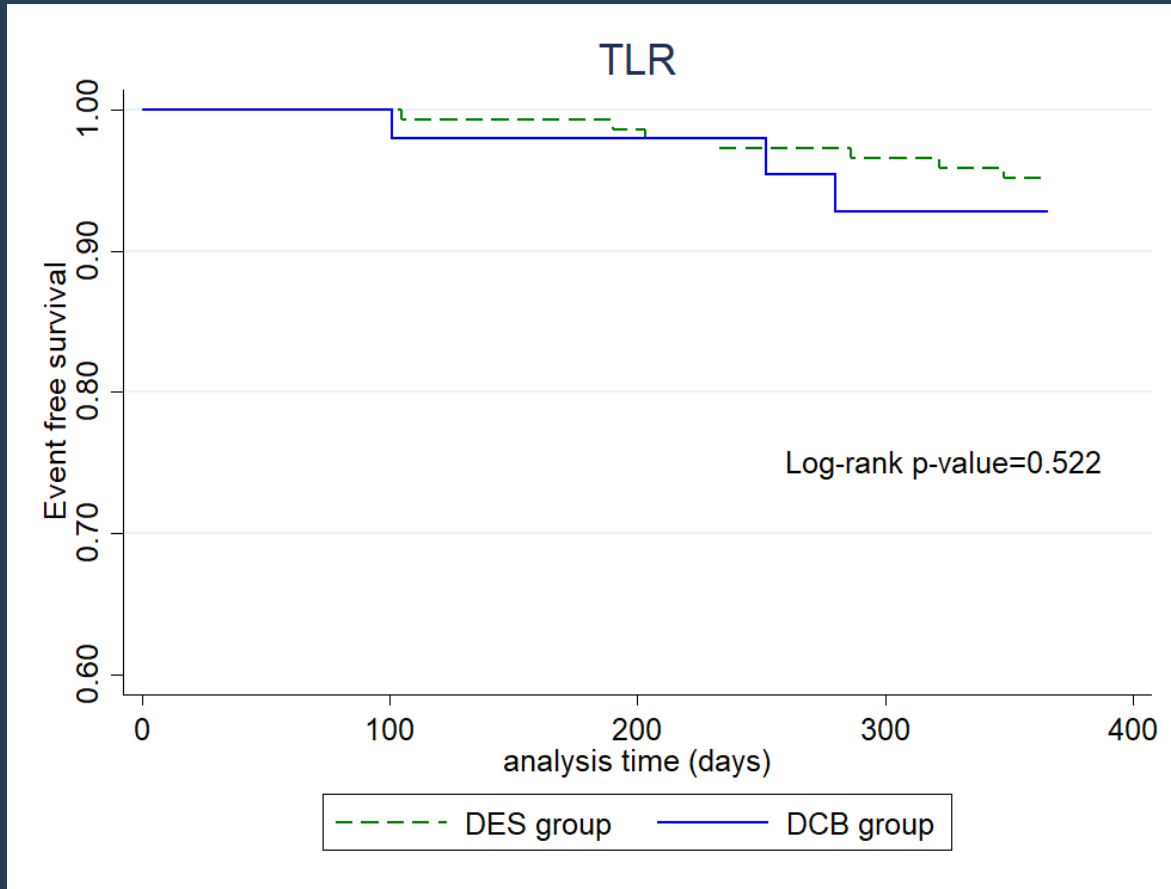
|                                | DCB (n=58) | DES (n=158) | P value |
|--------------------------------|------------|-------------|---------|
| <b>Device profiles</b>         |            |             |         |
| Mean device diameter, mm       | 2.0±0.1    | 2.2±0.1     | <0.001  |
| Device diameter 2.0 mm, n (%)  | 47 (81.0%) | 42 (26.6%)  | <0.001  |
| Device diameter 2.25 mm, n (%) | 11 (19.0%) | 116(73.4%)  | <0.001  |
| Mean device length, mm         | 26.2±7.5   | 26.7±8.6    | 0.667   |
| Device length>30 mm, n (%)     | 6 (10.3%)  | 43 (27.2%)  | 0.009   |
| <b>Procedures profiles</b>     |            |             |         |
| Rotational atherectomy, n (%)  | 1 (1.7%)   | 7 (4.4%)    | 0.351   |
| Scoring/Cutting balloon, n (%) | 13 (22.4%) | 2 (1.3%)    | <0.001  |
| IVUS/OCT, n (%)                | 16 (27.6%) | 53 (33.5%)  | 0.405   |
| Complications, n (%)           | 1 (1.7%)   | 4 (2.5%)    | 1.000   |

## Clinical outcomes

|                                | DCB (n=55) | DES (n=151) | P value |
|--------------------------------|------------|-------------|---------|
| Vessel/stent thrombosis, n (%) | 0 (0.0%)   | 1 (0.7%)    | 1.000   |
| TLR, n (%)                     | 3 (5.5%)   | 7 (4.6%)    | 0.522   |
| All cause death, n (%)         | 1 (1.8%)   | 9 (6.0%)    | 0.290   |
| non-fetal ACS, n (%)           | 1 (1.8%)   | 3 (2.1%)    | 0.952   |
| Stroke, n (%)                  | 0 (0.0%)   | 2 (1.3%)    | 0.470   |
| HF related admission, n (%)    | 0 (0.0%)   | 3 (2.0%)    | 0.336   |
| MACCE <sup>¶</sup> , n (%)     | 5 (9.1%)   | 19 (12.6%)  | 0.780   |

¶ MACCE: Composite endpoint including TLR, non-fetal ACS, Stroke, HF related admission and all-cause death

# Clinical outcomes



## Predictors of MACCE in VSV PCI

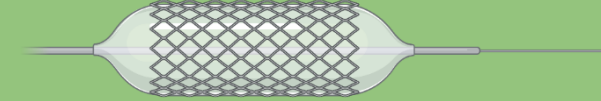
- Female
- ACS
- DAPT

|                       | Univariable Cox regression |         | Multivariable Cox regression |         |
|-----------------------|----------------------------|---------|------------------------------|---------|
|                       | HR (95% CI)                | P value | HR (95% CI)                  | P value |
| DCB PCI               | 0.87 (0.32-2.33)           | 0.780   |                              |         |
| Female gender         | 2.42 (1.04-5.67)           | 0.041   | 3.04 (1.27-7.31)             | 0.013   |
| Age, years            | 1.00 (0.96-1.04)           | 0.991   |                              |         |
| Body mass index       | 1.06 (0.95-1.17)           | 0.302   |                              |         |
| ACS presentation      | 2.64 (1.17-5.94)           | 0.019   | 2.56 (1.13-5.76)             | 0.024   |
| Diabetes Mellitus     | 2.35 (0.98-5.67)           | 0.057   |                              |         |
| Heart failure         | 2.28 (1.00-5.22)           | 0.050   |                              |         |
| Hypertension          | 1.94 (0.46-8.23)           | 0.371   |                              |         |
| ESRD                  | 1.55 (0.46-5.21)           | 0.476   |                              |         |
| Atrial fibrillation   | 2.61 (0.89-7.65)           | 0.080   |                              |         |
| Lesion length, mm     | 0.99 (0.94-1.03)           | 0.523   |                              |         |
| Device diameter 2.0mm | 0.76 (0.33-1.79)           | 0.534   |                              |         |
| Device length>30mm    | 0.425 (0.13-1.42)          | 0.165   |                              |         |
| ACC/AHA B2C lesion    | 1.18 (0.52-2.65)           | 0.693   |                              |         |
| CTO lesion            | 0.66 (0.22-1.92)           | 0.440   |                              |         |
| Statin use            | 0.54 (0.23-1.26)           | 0.153   |                              |         |
| Beta blocker use      | 0.60 (0.26-1.34)           | 0.210   |                              |         |
| DAPT < 3 months       | 5.01 (2.14-11.76)          | <0.001  | 6.02 (2.49-14.54)            | <0.001  |
| CKD*                  | 1.72 (0.77-3.83)           | 0.188   |                              |         |
| LDL<70 mg/dL          | 0.55 (0.19-1.60)           | 0.272   |                              |         |

2018/01 to 2020/03  
193 Patients and 216  
Lesions in NTUH

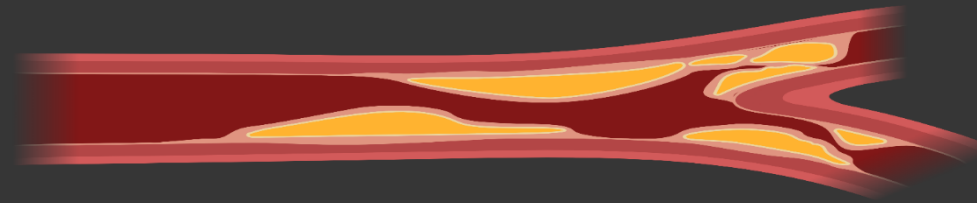


**DCB (N=55)**



**DES (N=151)**

### Very small vessel ( RVD: 2.0 - 2.25 mm) PCI



12 Months follow-up

Ischemia driven TLR

**5.5%**

**4.6%**

P = 0.522

MACCE

**9.1%**

**12.6%**

P = 0.780



## Conclusion

- DCB in treating **de novo very small CAD** is associated with comparable outcomes to DES.
- **DCB is an alternative treatment** option for very small vessel intervention.
- **Female, use DAPT < 3m, ACS presentation** are the independent predictors of MACCE in VSV PCI.