

## **The DEFINITION II Trial**

**Multicentre, Randomised Comparison  
of Two-Stent and Provisional Stenting  
Techniques in Patients with Complex  
Coronary Bifurcation Lesions**

**NCT02284750**

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**On Behalf of DEFINITION II trial Investigators**





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## Potential conflicts of interest

**Speaker's name : Shao-Liang Chen**

☒ I do not have any potential conflict of interest to declare





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## Why this study?--Background

- Stenting of coronary bifurcation lesions (CBL) is associated with suboptimal clinical results, compared to non-CBLs
  - ESC 2018 guidelines: 2-stent may be preferable for complex CBL
  - No universal definition of CBL's complexity
  - DEFINITION criteria, defying the complex CBL, has not been tested in RCT
- Compared the treatment effect between Provision and 2-stent



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## What did we study?-Endpoints and assumption

- **Primary endpoint:** Target lesion failure(TLF)
- **We hypothesized:** the 1-year TLF rate---  
14% (provisional) vs. 7% (2-stent)
- **A total of 660 patients**  
80% power  
2-sided alpha of 0.05  
including 10% loss to follow-up

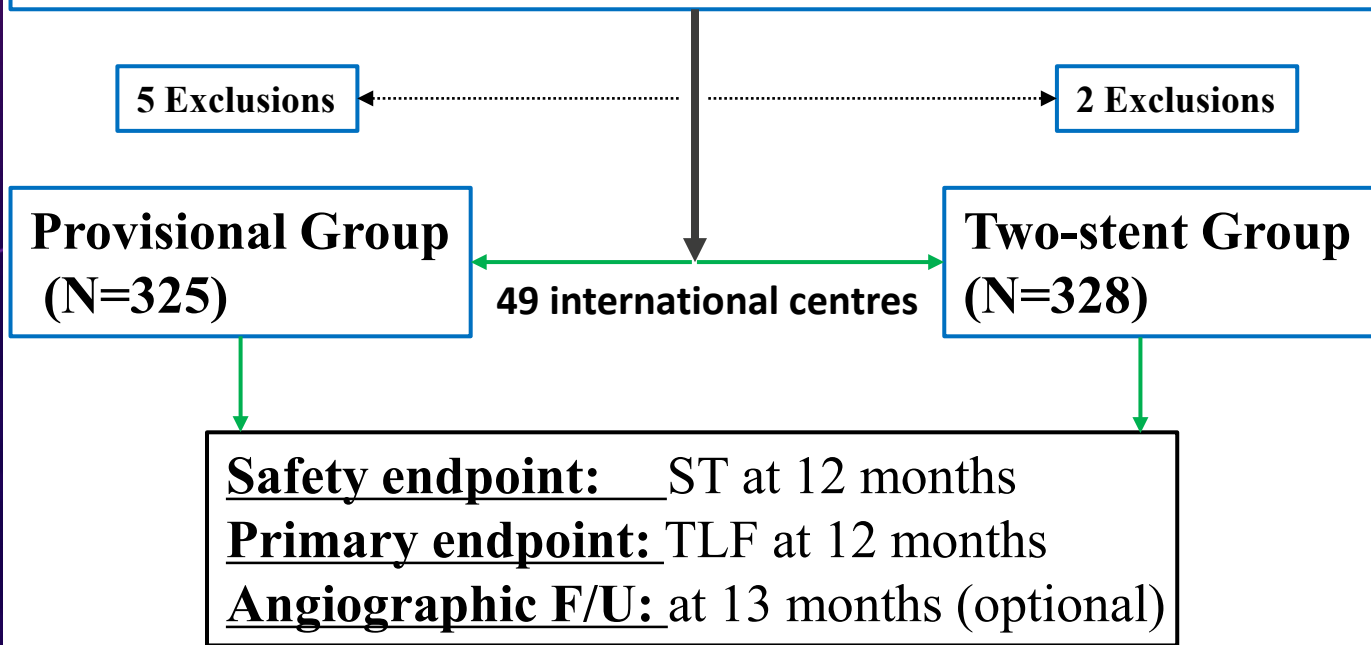




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## How was the study executed?—Study flowchart

**DEFINITION** criteria defined 660 pats with complex CBL



ST, stent thrombosis; TLF, target lesion failure=CD+TV-MI+TLR







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## What are the essential results?

	Two-stent (n=328)	Provisional (n=325)	<i>P</i> value
<b>Age, yr</b>	63 ± 11	64 ± 10	0.289
<b>ACS, n (%)</b>	232 (70.8)	237 (73.0)	0.803
<b>LM bif., n (%)</b>	94 (28.7)	94 (28.9)	1.000
<b>Lesion length in SB, mm</b>	20.71 ± 10.1	19.88 ± 9.3	0.287
<b>Trans-radial, n (%)</b>	258 (78.7)	262 (80.6)	0.535
<b>Two-stent, n (%)</b>	302 (92.1)	73 (22.5)	<0.001
--mostly used	DK crush (77.8%)	TAP (64.4%)	
--FKBI post-2-stent, n (%)	287 (95.0)	70 (95.9)	0.392
--POT after FKBI, n (%)	255 (88.9)	64 (91.4)	0.417



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## Why is this important?

	2-stent (n=328)	Provisional (n=325)	p
<b>All-cause death, n (%)</b>	9 (2.7)	11 (3.4)	0.629
<b>Cardiac death, n (%)</b>	7 (2.1)	8 (2.5)	0.772
<b>Definite ST, n (%)</b>	3 (0.9)	3 (0.9)	0.982





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## The essentials to remember

- DEFINITION criteria is reliably to differentiate simple from complex CBL
- Systematic two-stent is associated with less rate of 1-year TLF for patients with complex CBL, compared to provisional approach, mainly driven by fewer TVMIs and clinically-driven TLRs
- Incidence of the ST was comparable between two groups
- DK crush is most commonly used in the two-stent group (77.8%), but TAP is the mostly used 2-stent in the provisional group
- The underlying mechanisms for increased TVMI after provisional are unclear and further study is warranted







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The essentials to remember

**Thanks for your attention!**

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