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DKCRUSH V

Double Kissing Crush versus Provisional Stenting for Left Main Distal Bifurcation Lesions: The DKCRUSH-V Randomized Trial

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on Behalf of

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ChiCTR-TRC-11001213

Disclosures

Imad sheiban

NONE

Background

- Approximately 80% of patients undergoing left main (LM) stenting have disease involving the distal bifurcation.
- The DKCRUSH III trial demonstrated that the routine 2-stent DK crush technique is superior to culotte stenting for LM CAD.
- However, most pts with LM distal bifurcation lesions are treated with provisional stenting.
- DK crush has never been compared with provisional stenting for treatment of LM distal bifurcation disease.

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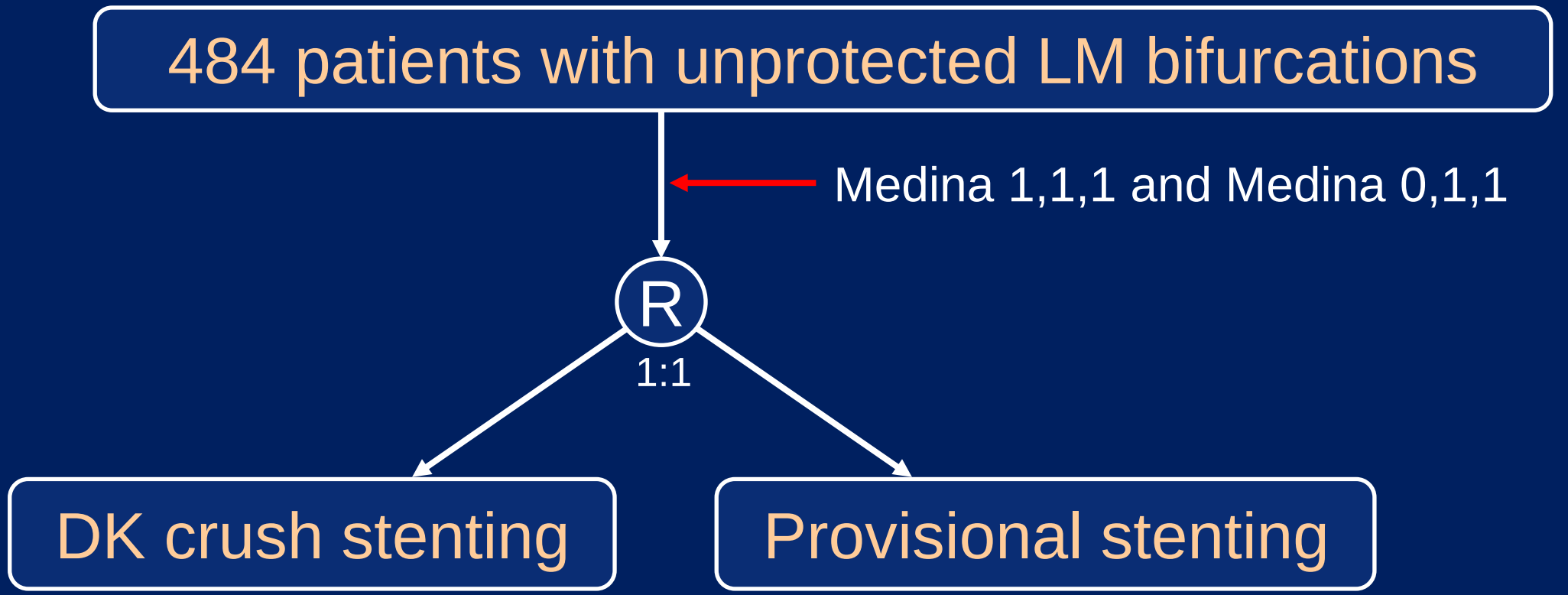
Study Design



Clinical follow-up: 1, 6, 12 months

Angiographic follow-up: 13 months

Primary endpoint: TLF at 12 months

Major Inclusion Criteria

- Silent ischemia, stable/unstable angina
- AMI >1 month
- *De novo* LM distal bifurcation
  - Medina 1,1,1, or 0,1,1
- Non-LM lesions treatable by 2 DES

Major Exclusion Criteria

- Cardiogenic shock
- Severe calcification requiring rotational atherectomy
- In-stent restenosis
- Need for oral anticoagulation
- CTO lesions with failed recanalization

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Protocol Procedures

- Complete revascularization of all ischemic territories with DES (EES, SES, ZES)
- IVUS guidance strongly recommended
- DAPT pre-loading and treatment for ≥1 year
- FKBI and POT strongly recommended
- Guideline-directed medical therapy

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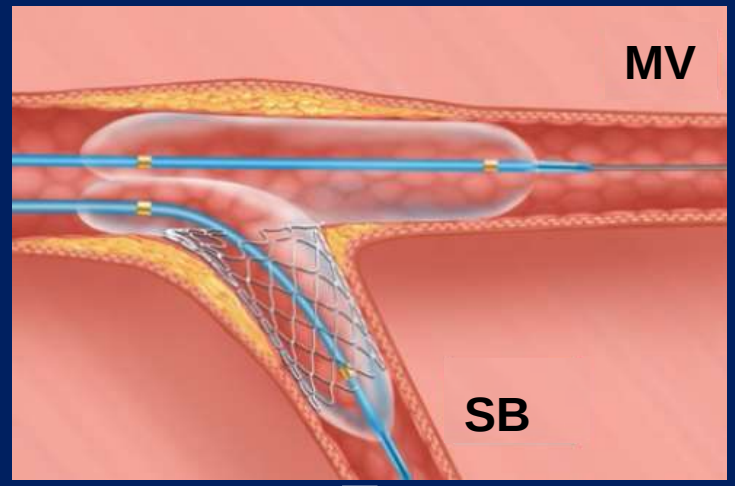
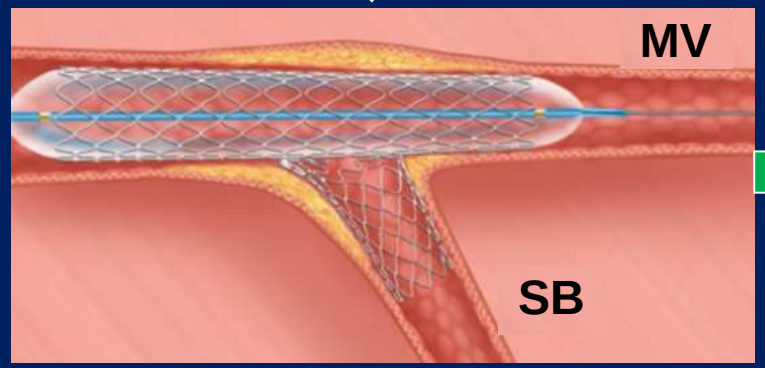
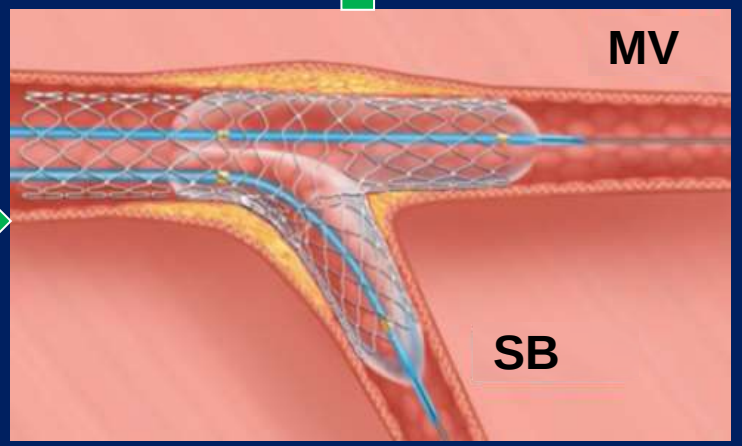
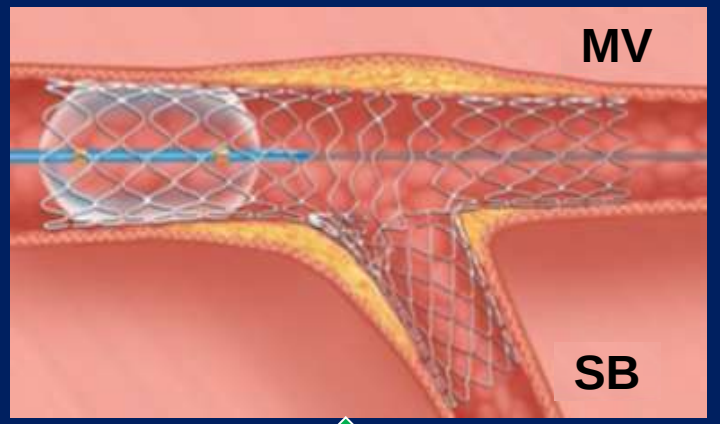
Stenting Techniques

DK crush

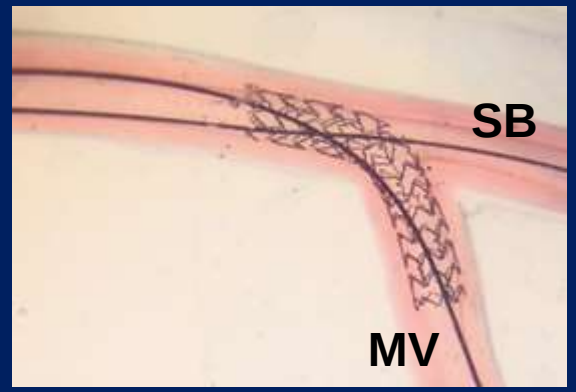


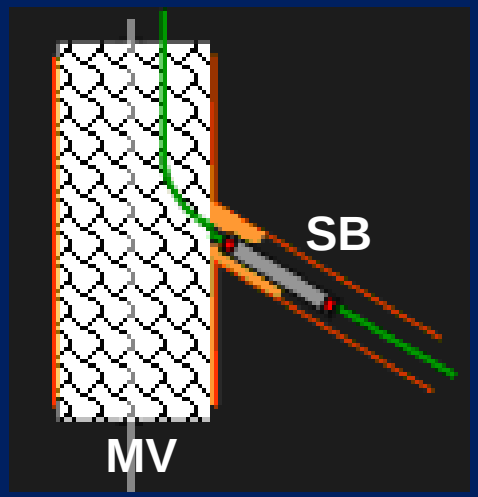






Provisional

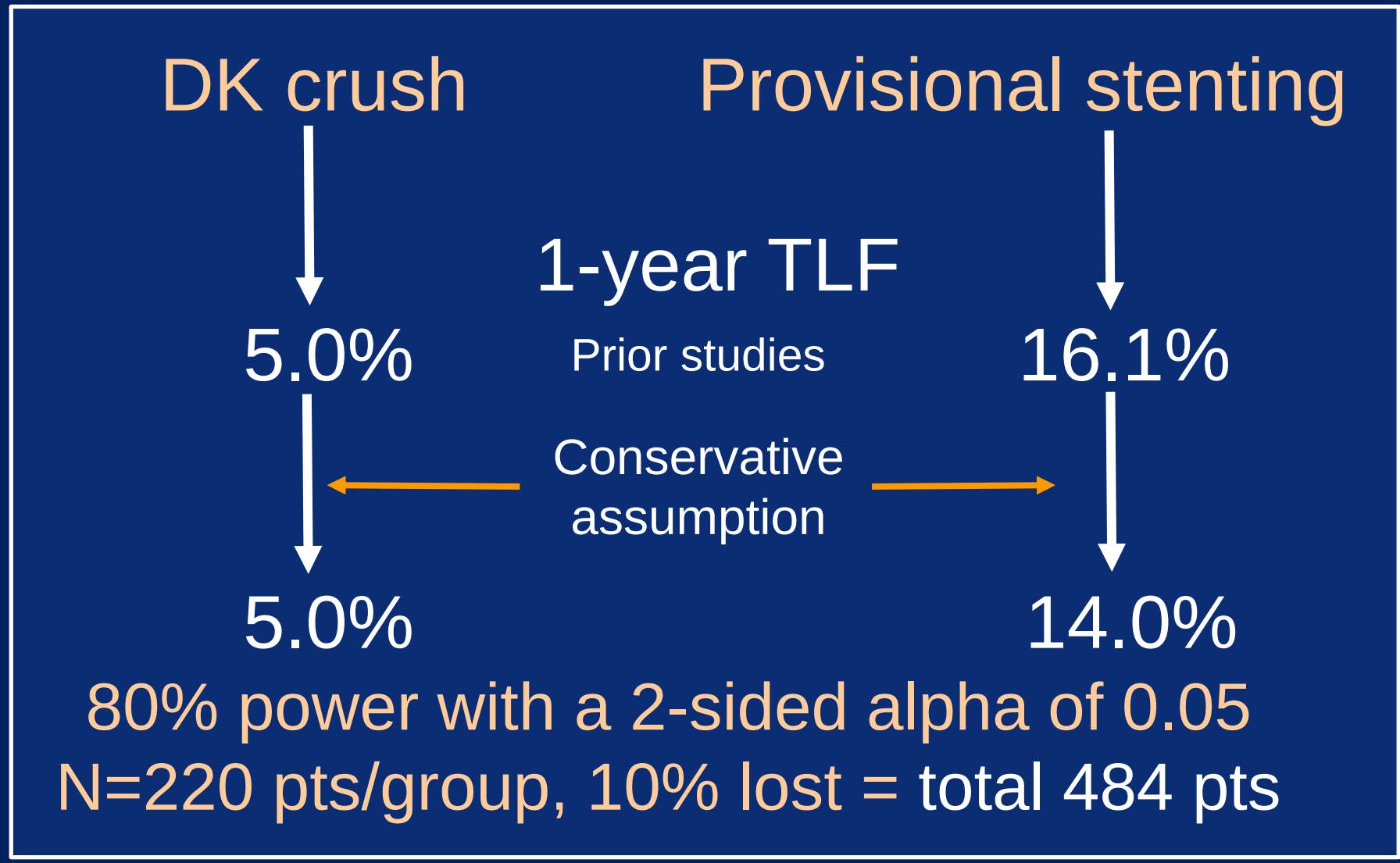




Endpoints

Endpoints	Timing of follow-up	Powered for
Primary composite endpoint		
TLF: CD, TVMI, or TLR	12 months	Superiority
Secondary endpoints		
CD, TVMI, TLR separately	12 months	-
Angina	12 months	-
Stent thrombosis	12 months	-
In-stent restenosis	13 months	-

Assumptions and Statistical analysis



80% power with a 2-sided alpha of 0.05

N=220 pts/group, 10% lost = total 484 pts

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Study Organization

- Principal Investigator: Shao-Liang Chen
- Executive Committee: PIs plus Jun-Jie Zhang, Ling Lin, Imad Sheiban, Teguh Santoso, Yaling Han
- Statistics Committee: Feng Chen (chair), Jing Kan, Xiao Jiang
- Site management and data monitoring: CCRF (Beijing), Lin Lin, Linda Liason (Indonesia)
- Data management: CCRF and Rod Byrne Information Technology Co. (China)
- Clinical Endpoints Committee: Bao-Xiang Duan (Director), Mingfan Cha, Linda Cheng
- QCA Core Lab: CCRF

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Enrollment

484 patients with LM distal bifurcation lesions (Medina 1,1,1 or Medina 0,1,1) at 26 centers in China, Indonesia, Thailand, Italy and the United States

Randomize, 1:1

Provisional stenting (N=282)		**DK crush (N=282)**
100%	12-mo clinical F/U	100%
65.3%	13-mo angio F/U	66.3%

Baseline Data (i)

	DK crush (N=240)	Provisional (N=242)
Age (years)	65 ± 9	64 ± 10
Male	82.9%	77.7%
Diabetes	28.8%	25.6%
- Insulin-treated	27.5%	29.0%
Hypertension	72.9%	64.5%
Hyperlipidemia	47.5%	47.5%
Current smoker	34.2%	32.2%
Prior PCI	13.8%	17.8%
Prior CABG	0.8%	0.8%
Congestive heart failure	15.4%	13.6%
- LVEF <30%	4.6%	2.9%
Prior stroke	1.3%	1.7%

Baseline Data (ii)

	DK crush (N=240)	Provisional (N=242)
Peripheral artery disease	7.5%	6.6%
Clinical presentation		
- Prior MI	21.7%	21.1%
- Silent ischemia	2.9%	4.1%
- Stable angina	14.2%	10.4%
- Unstable angina	70.0%	74.4%
- Recent MI (>24h)	12.9%	10.7%
eGFR<60 ml/min/1.73 m^2	17.1%	14.5%
Prior TIA	0.4%	0.8%
Body mass index (kg/m^2)	24.7 ± 3.1	24.7 ± 2.9
Anemia (WHO criteria)	25.4%	24.9%

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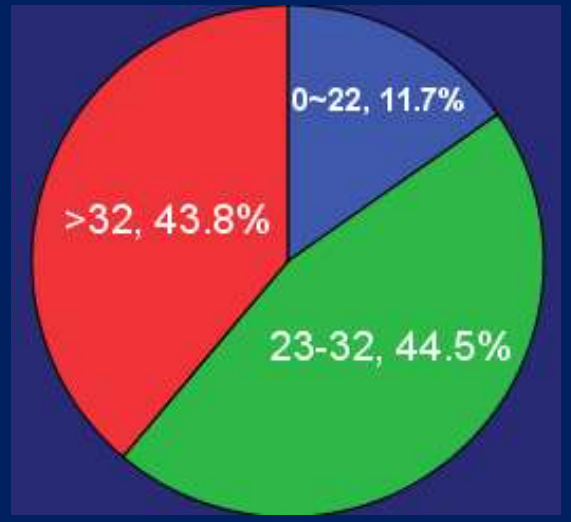
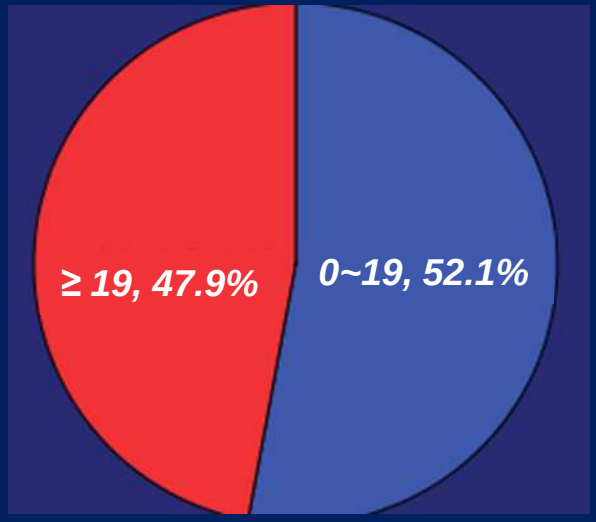
SYNTAX SCORE

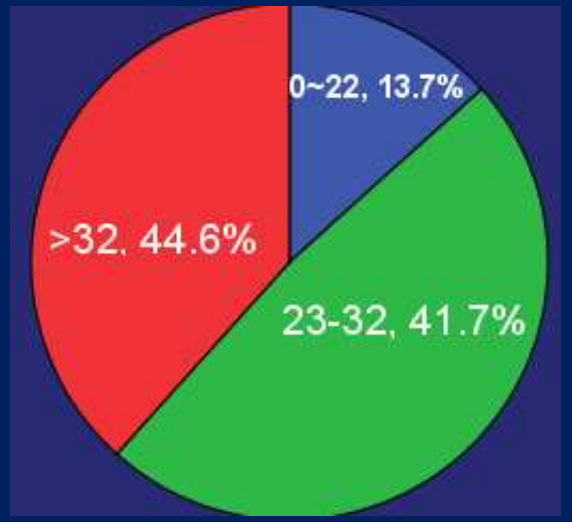
NERS II SCORE

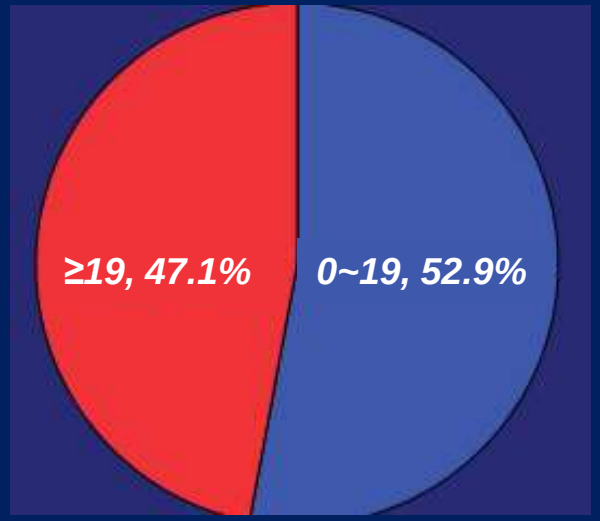
Provisional





DK crush





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Core Lab Data

	DK crush (N=240)	Provisional (N=242)
2- or 3-vessel disease	87.9%	88.8%
LM lesion		
- Ostial	2.9%	2.9%
- Shaft/body	7.9%	8.7%
- Medina 1,1,1	85.0%	78.5%
- Medina 0,1,1	15.0%	21.5%
Calcification	37.1%	39.7%
Chronic total occlusion	12.1%	12.4%
TIMI flow grade <3		
- Main vessel	20.4%	19.8%
- Side branch	12.1%	7.0%
Complex bifurcation lesion*	35.8%	27.3%
IVUS assessment	28.3%	28.9%

Defined as the presence of both major criteria (ostial SB lesion length ≥10 mm and DS ≥70%) plus any two minor criteria (distal bifurcation angle $<45^0$ or $\geq 70^0$, MV reference vessel diameter ≤2.5 mm, MV lesion length ≥25 mm, multiple bifurcations, thrombus-containing lesion, and severe calcification)

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PCI Procedures

482 patients, 637 procedures,1234 stents in MV and SB

	DK crush (N=240)	Provisional (N=242)
Planned staged procedure	13.8%	16.9%
Transradial approach	77.9%	74.8%
6F guiding catheter	54.2%	53.3%
Side branch dilation*	68.3%	39.7%
MV stent length	27.9 ± 9.9 mm	28.8 ± 10.4 mm
SB stent length	21.0 ± 7.3 mm	21.4 ± 7.4 mm
Final kissing inflation*	99.6%	78.9%
POT	99.2%	98.9%
IVUS guidance	42.9%	40.5%
Complete revascularization	72.5%	69.4%
Procedural time, min**	81.9 ± 37.6	66.1 ± 34.5
Contrast volume, ml**	226.7 ± 81.4	190.9 ± 74.8
Angiographic success	98.3%	97.1%

** p<0.05, ** p<0.001*

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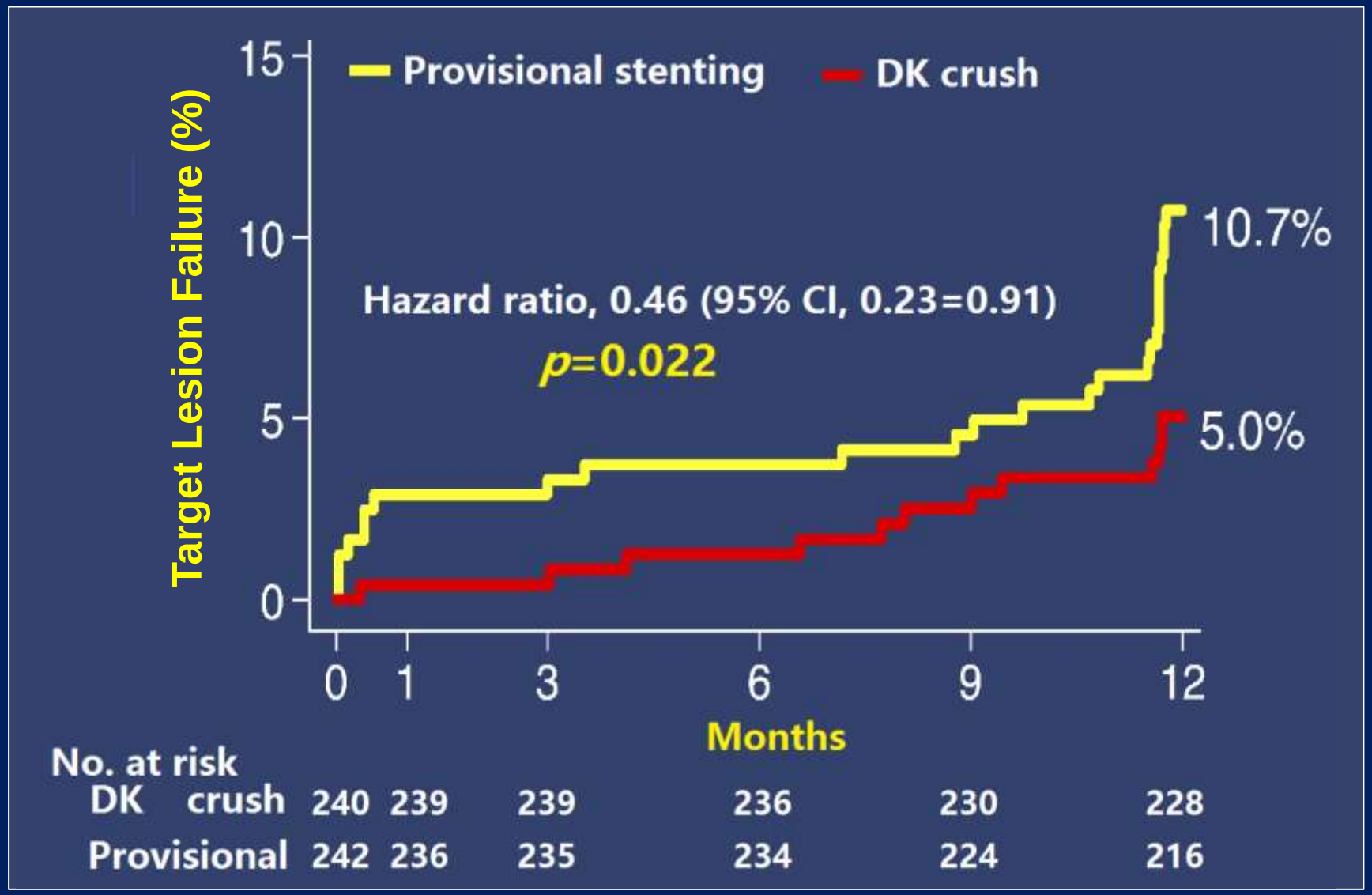
Primary Endpoint
Target Lesion Failure



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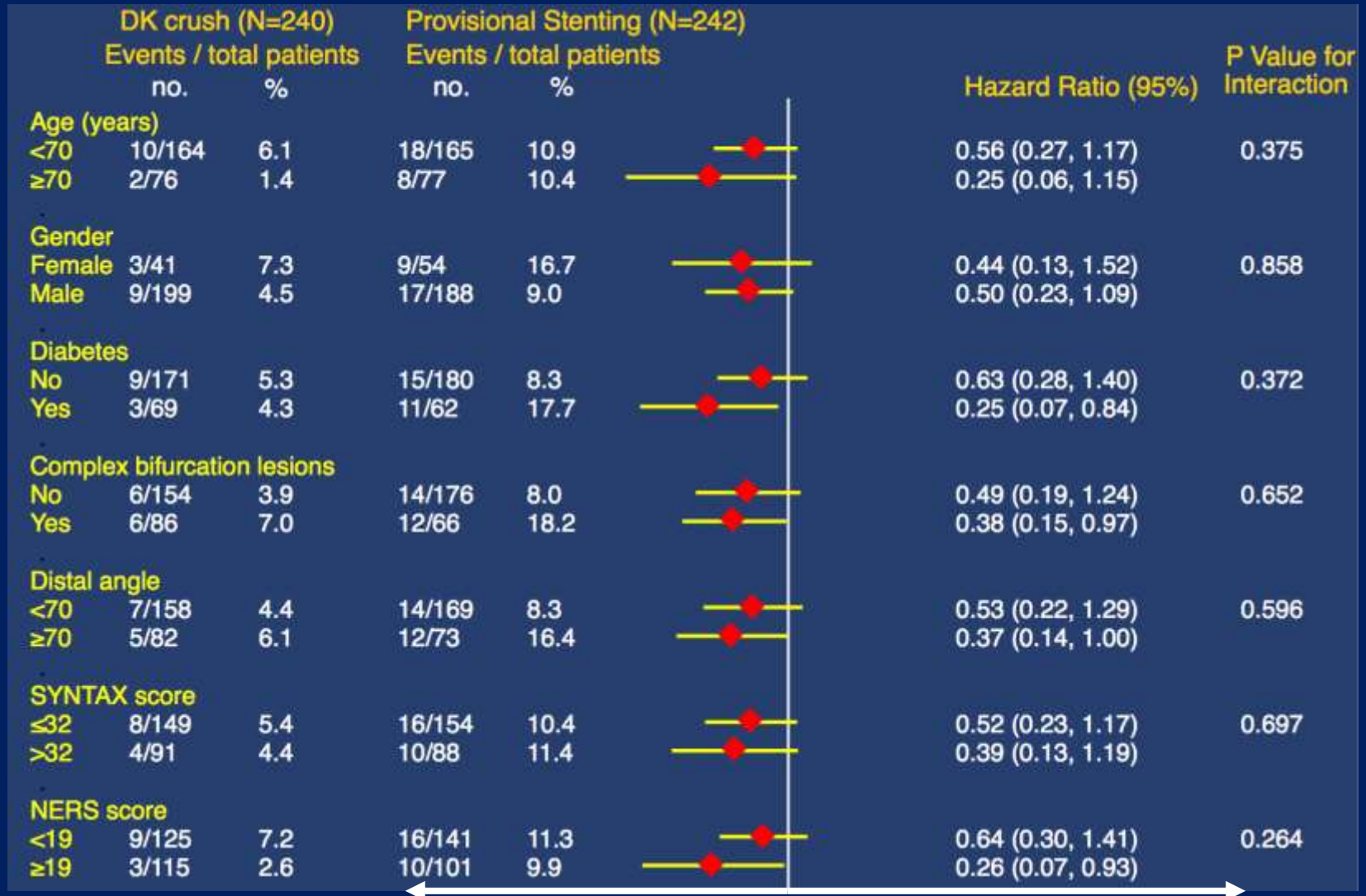
Target Lesion Failure at 1-Year
Subgroup analysis



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Primary and Secondary Endpoints

	DK crush (N=240)	Provisional (N=242)	*P* value
Primary endpoint components at 1 year			
- Cardiac death	1.2	2.1	0.48
- Target vessel MI	0.4	2.9	0.03
- TLR	3.8	7.9	0.06
Secondary endpoints at 1 year			
- All-cause death	2.9	2.1	0.58
- Any revascularization	5.4	7.9	0.32
- Angina	4.5	9.3	0.06
Primary endpoint components at 30 days			
- Cardiac death	0	1.7	0.046
- Target vessel MI	0.4	1.7	0.10
- TLR	0.4	0.4	1.00
Stent thrombosis (def/prob)			
- 30 days	0.4	2.5	0.06
- 1 year	0.4	3.3	0.02

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Primary and Secondary Endpoints

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Primary endpoint components at 30 days			
- Cardiac death	0	1.7	0.046
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Stent thrombosis (def/prob)			
- 30 days	0.4	2.5	0.06
- 1 year	0.4	3.3	0.02

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Quantitative Coronary Analysis

317 patients underwent 13-month angiographic follow-up

	DK crush (N=159)	Provisional (N=158)	P value
SB lesion length ≥10 mm	50.0%	42.9%	0.14
SB diameter stenosis, %	65.8 ± 7.9	65.3 ± 8.3	0.87
MV lesion length, mm	22.4 ± 12.9	23.5 ± 12.8	0.36
MV diameter stenosis, %	60.8 ± 7.2	61.8 ± 8.1	0.51
Cross-over to 2 stents	-	47.1%	
LM complex restenosis	7.1%	14.6%	0.10
- Main vessel	1.9%	5.7%	0.09
- Side branch*	5.0%	12.0%	0.09
Non-LM restenosis	5.7%	7.6%	0.41

*Restenosis within implanted stents was defined as a QCA DS >50% at follow-up.
For PS patients without a SB stent, restenosis in the SB was defined as a QCA DS >75%.

Limitations

- IVUS-guidance <50%
- Less use of POT and final kissing inflation in provisional stenting group
- Findings from the present study do not apply to LM lesions with <50% DS of the SB, for which provisional stenting should remain the standard approach

Conclusions

In the present multicenter randomized trial, a planned DK crush 2-stent strategy reduced TLF at 1-year compared to a provisional stent strategy in patients with true distal LM bifurcation lesions

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DKCRUSH-V Randomized Trial

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