

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

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ChiCTR-TRC-11001213



Disclosures

Shao-Liang Chen

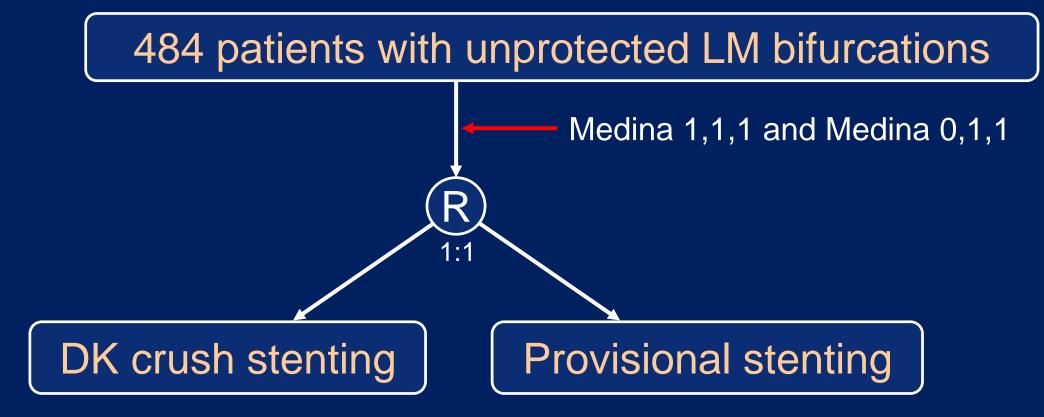


Background

- 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.



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

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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

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- Severe calcification requiring rotational atherectomy
- In-stent restenosis
- Need for oral anticoagulation

CTO lesions with failed recanalization

Protocol Procedures

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- 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

Stenting Techniques

DK crush

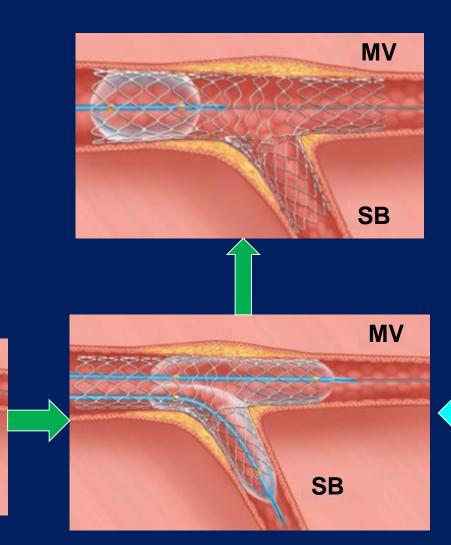
SB

SB

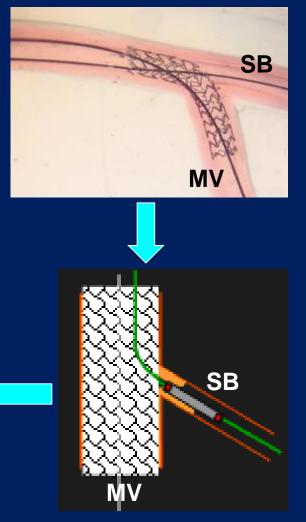
MV

MV

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Provisional



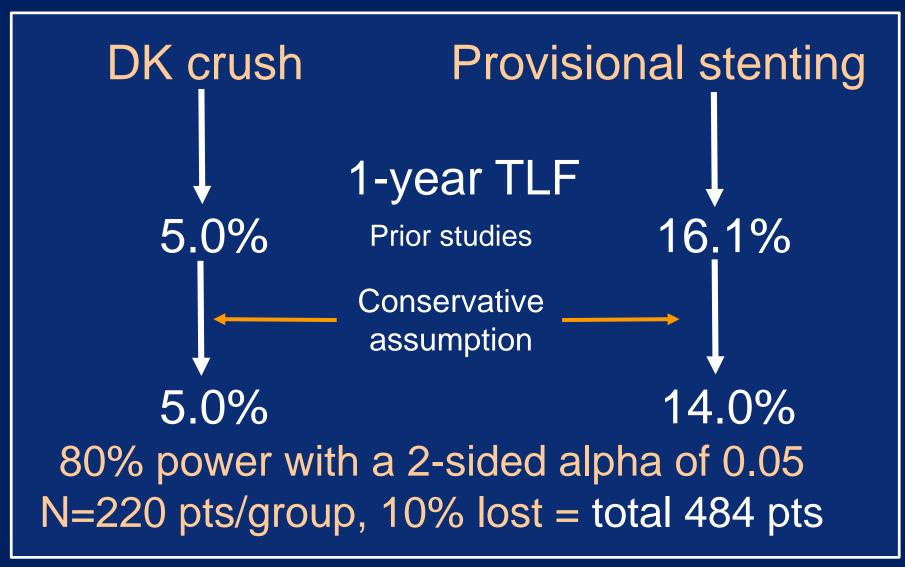
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Endpoints

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	-



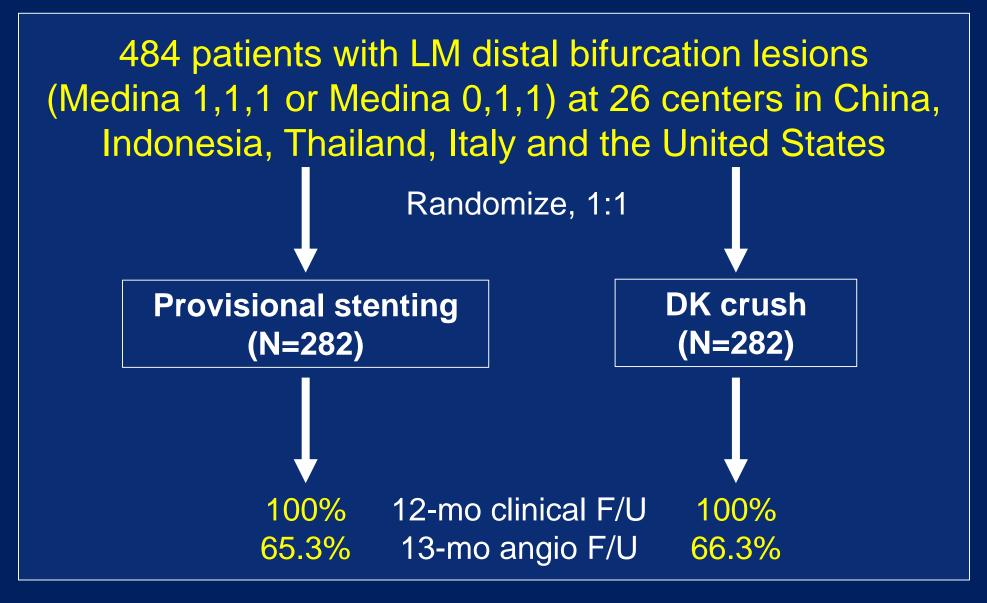
Assumptions and Statistical analysis



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

Enrollment



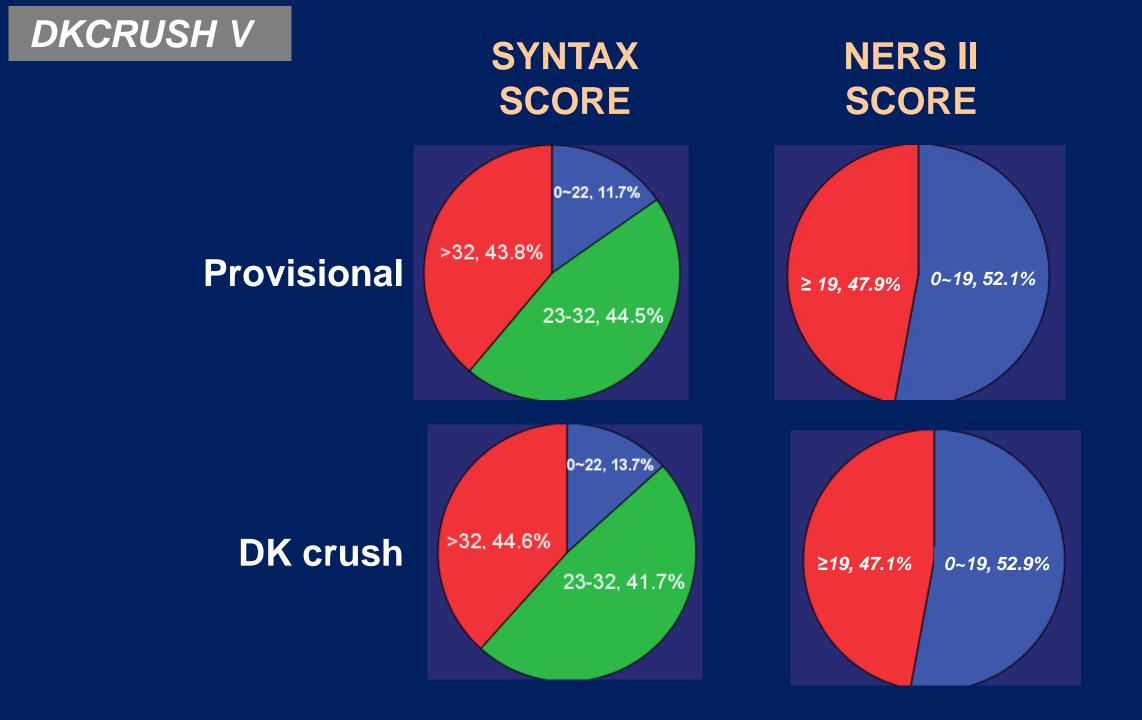
Baseline Data (i)

	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)

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	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%



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^o or ≥70^o, MV reference vessel diameter ≤2.5 mm, MV lesion length ≥25 mm, multiple bifurcations, thrombus-containing lesion, and severe calcification)

PCI Procedures

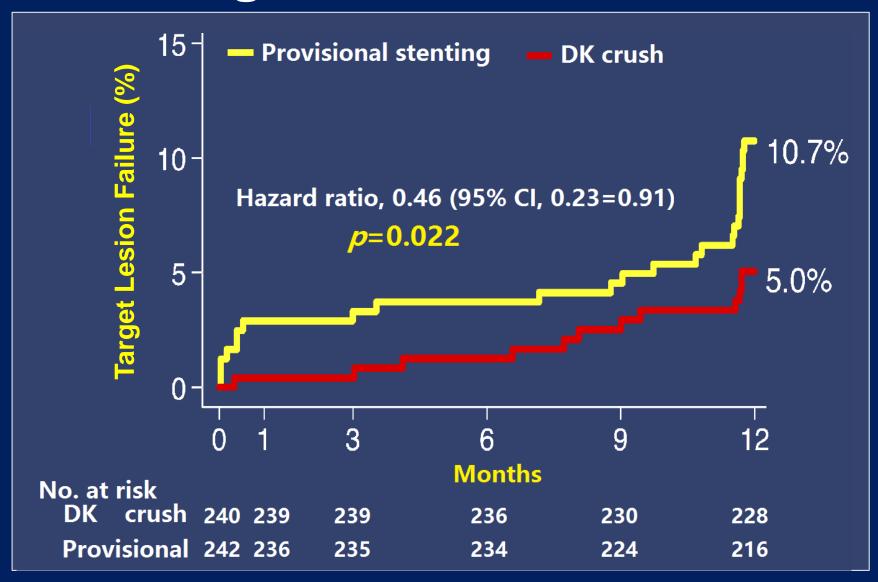
482 patients, 637 procedures, 1234 stents in MV and SB

	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%

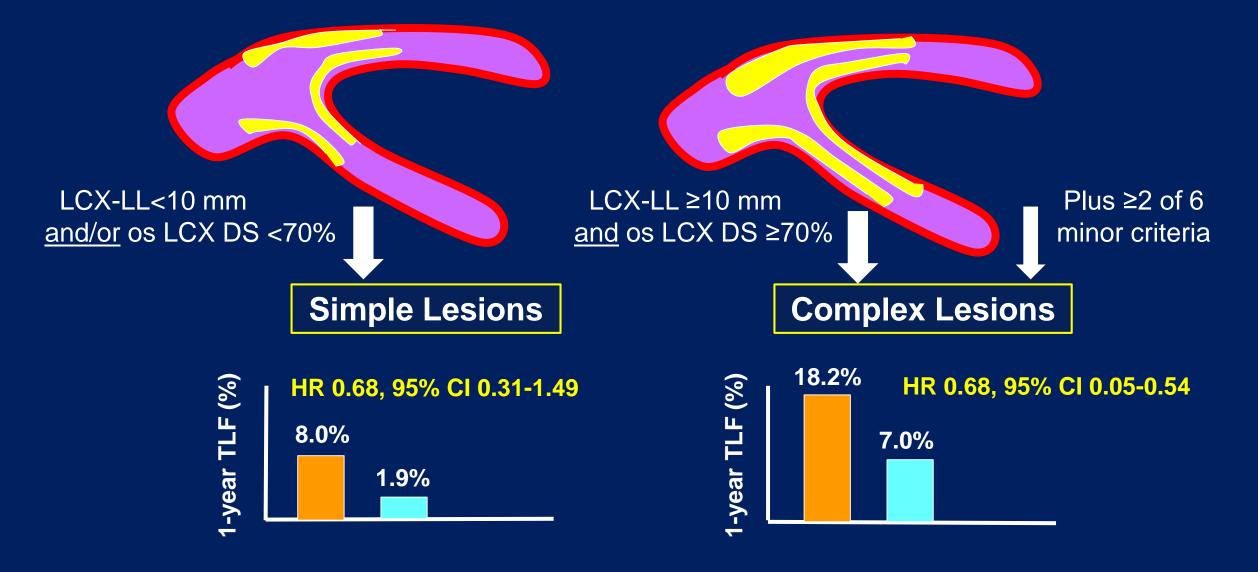
* p<0.05, ** p<0.001

Primary Endpoint Target Lesion Failure

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DKCRUSH V Target Lesion Failure at 1-Year Simple vs. Complex Bifurcation Lesions



DKCRUSH V Target Lesion Failure at 1-Year Subgroup analysis

Events / total patients no. Events / total patients no. P Value for Hazard Ratio (95%) Age (years) <70 10/164 6.1 18/165 10.9 0.56 (0.27, 1.17) 0.375 270 2/76 1.4 8/77 10.4 0.25 (0.06, 1.15) 0.375 Gender Female 3/41 7.3 9/54 16.7 0.44 (0.13, 1.52) 0.858 Male 9/199 4.5 17/188 9.0 0.50 (0.23, 1.09) 0.372 Diabetes No 9/171 5.3 15/180 8.3 0.63 (0.28, 1.40) 0.372 Ves 6/86 7.0 12/66 18.2 0.49 (0.19, 1.24) 0.652 Ves 6/86 7.0 12/66 18.2 0.33 (0.22, 1.29) 0.596 270 5/82 6.1 12/73 16.4 0.53 (0.22, 1.29) 0.596 270 5/82 6.1 12/73 16.4 0.52 (0.23, 1.17) 0.697 232 8/149 5.4 16/154 10.4 0.52 (0.23, 1.17) 0.697 322 4/91 4.4 10/88 11.4 0.52 (0.2			n (N=240)			ting (N=242)		P Value for
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$\begin{array}{c ccccccccccccccccccccccccccccccccccc$			•					0.075
Gender Female $3/41$ 7.3 $9/54$ 16.7 0.44 0.13 1.52 0.858 Male $9/199$ 4.5 $17/188$ 9.0 0.50 0.23 1.09 0.50 0.23 1.09 0.50 0.28 0.50 0.23 1.09 0.372 Diabetes 0.63 0.28 1.40 0.372 Yes $3/69$ 4.3 $11/62$ 17.7 0.25 0.07 0.858 Complex bifurcation lesions No $6/154$ 3.9 $14/176$ 8.0 0.49 0.19 1.24 0.652 Distal angle <70 $7/158$ 4.4 $14/169$ 8.3 0.53 0.22 1.29 0.596 >70 $5/82$ 6.1 $12/73$ 16.4 0.52 0.23 1.17 0.697 >32 $8/149$ 5.4 $16/154$ 10.4 0.52 0.23 1.17 0.39 0.13 <t< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>0.375</td></t<>								0.375
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Complex bifurcation lesions No $6/154$ 3.9 $14/176$ 8.0 $0.49 (0.19, 1.24)$ $0.38 (0.15, 0.97)$ 0.652 Distal angle <70 $7/158$ 4.4 $14/169$ 8.3 $0.53 (0.22, 1.29)$ $0.37 (0.14, 1.00)$ 0.596 SYNTAX score <32 $8/149$ 5.4 $16/154$ 10.4 $0.52 (0.23, 1.17)$ $0.39 (0.13, 1.19)$ 0.697 NERS score <19 $9/125$ 7.2 $16/141$ 11.3 $0.64 (0.30, 1.41)$ 0.264	Yes	3/69	4.3	11/62	17.7	_	0.25 (0.07, 0.84)	
No $6/154$ 3.9 $14/176$ 8.0 $0.49 (0.19, 1.24)$ 0.652 Yes $6/86$ 7.0 $12/66$ 18.2 $0.38 (0.15, 0.97)$ 0.652 Distal angle<70 $7/158$ 4.4 $14/169$ 8.3 $0.53 (0.22, 1.29)$ 0.596 ≥ 70 $5/82$ 6.1 $12/73$ 16.4 $0.37 (0.14, 1.00)$ 0.596 SYNTAX score 32 $8/149$ 5.4 $16/154$ 10.4 $0.52 (0.23, 1.17)$ 0.697 ~ 32 $8/149$ 5.4 $16/154$ 10.4 $0.39 (0.13, 1.19)$ 0.697 NERS score $<$ $0.64 (0.30, 1.41)$ 0.264								
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<70 $7/158$ 4.4 $14/169$ 8.3 $0.53 (0.22, 1.29)$ 0.596 ≥70 $5/82$ 6.1 $12/73$ 16.4 $0.37 (0.14, 1.00)$ $0.52 (0.23, 1.17)$ 0.697 ≤ 32 $8/149$ 5.4 $16/154$ 10.4 $0.52 (0.23, 1.17)$ 0.697 ~ 32 $4/91$ 4.4 $10/88$ 11.4 $0.39 (0.13, 1.19)$ $0.64 (0.30, 1.41)$ 0.264	Yes	6/86	7.0	12/66	18.2		0.38 (0.15, 0.97)	
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<19 9/125 7.2 16/141 11.3 0.64 (0.30, 1.41) 0.264	>32	4/91	4.4	10/88	11.4	_	0.39 (0.13, 1.19)	
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≥19 3/115 2.6 10/101 9.9 0.26 (0.07, 0.93)								0.264
	≥19	3/115	2.6	10/101	9.9		0.26 (0.07, 0.93)	

Favors DK crush Favors Provisional stenting

DKCRUSH V Primary and Secondary Endpoints

	DK crush (N=240)	Provisional (N=242)	<i>P</i> value	
Primary endpoint components a	t 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 a	t 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	

DKCRUSH V Primary and Secondary Endpoints

	DK crush (N=240)	Provisional (N=242)	<i>P</i> value	
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	
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	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	
Stent thrombosis (def/prob)				
- 30 days	0.4	2.5	0.06	
- 1 year	0.4	3.3	0.02	

DKCRUSH V 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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Double Kissing Crush Versus Provisional Stenting for Left Main Distal Bifurcation Lesions

DKCRUSH-V Randomized Trial

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