

Comparison of **DK crush versus **culotte** stenting for
unprotected distal left main bifurcation lesions:
A multicenter, randomized, prospective **DKCRUSH-III study**
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Shao-Liang Chen, MD, FACC
Jun-Jie Zhang, MD, FSCAI

Nanjing First Hospital
Nanjing Medical University
Nanjing, China

On behalf of the DKCRUSH-III Investigators

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Background

- ULMCA distal bifurcation lesions are technically demanding, often requiring double-stenting and resulting in less favorable long-term outcomes.
- Previous studies showed that **double kissing (DK) crush** and **culotte** stenting were effective for bifurcation lesions.
- Their durability and safety have never been randomly compared.

Objectives

- To investigate the difference in major cardiac adverse event (MACE) at 1-year after **double kissing (DK) crush** vs. **Culotte** stenting for ULMCA distal bifurcation lesions

Sample size estimation

- We hypothesized that the rate of a 1-year MACE rate would be 5% in the DK crush and 15% in the Culotte group, respectively.

A total sample size of 358 was needed to detect the difference with 80% power (Type II error=0.20, $\alpha=0.05$, 2-sided tailed).

The enrollment was extended to 420 patients (15% increment) because of the considerable uncertainty.

Inclusion criteria

- Age ≥ 18 years
- Patient has silent ischemia/stable/unstable angina or NSTEMI
- Patient has STEMI > 24 -hour from the onset of chest pain to admission
- LMb (Medina 0,1,1 or 1,1,1) with/without ostial/shaft lesions
- Diameter of LAD or LCX ≥ 2.5 mm by visual estimation
- Downstream lesions in LAD or LCX could be covered by two stents
- LMb with CTO lesion in LAD, or LCX or RCA after recanalization

Exclusion criteria

- Pregnant
- Life expectancy <12 months
- Allergy to the drugs used
- LVEF<30%
- eGFR<40ml/min
- LM RVD>5.0mm by visual estimation
- Difference in RVD between LAD and LCX >1.0mm by visual estimation
- Severe calcification needing rotational atherectomy
- LMb restenosis lesion

Study endpoints

- **Primary endpoint**

MACE (cardiac death, MI and TVR) at 1-year

- **Secondary endpoint**

In-stent restenosis (ISR) at 8-month

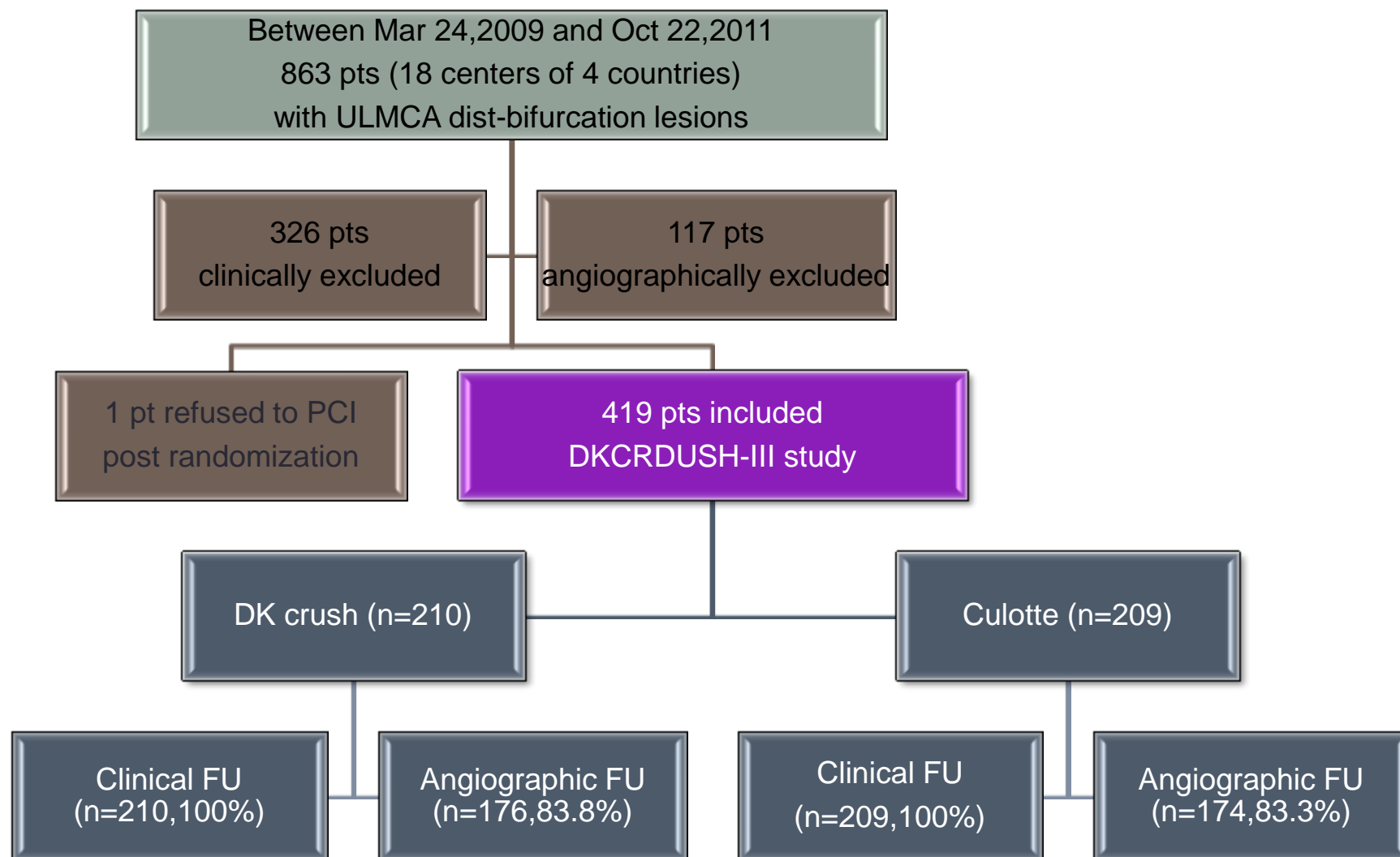
- **Safety endpoint**

Stent thrombosis (ST) at 1-year

Statistical analysis

- The t test or Wilcoxon rank sum scores was used to analyze continuous variables.
- The χ^2 test or the Fisher's exact test was used to analyze categorical variables.
- Survival rate-free from events were generated by Kaplan-Meier analysis.
- Pre-specified subgroup analyses were performed by Forest Plot.
- Statistical significance was taken as a P value <0.05 .
- All analyses were performed with the statistical program SPSS 16.0.

DKCRUSH-III study Flow Chart



Baseline clinical characteristics (1)

	DK crush (n=210)	Culotte (n=209)	p
Male, n (%)	162(77.1)	167(79.9)	0.552
Age, yr	64.3±10.3	63.3±9.2	0.296
Hypertension, n (%)	148(70.5)	128(61.2)	0.055
Hyperlipidemia, n (%)	87(41.4)	88(42.1)	0.921
Diabetes, n (%)	67(31.9)	63(30.1)	0.298
Current smoking, n (%)	58(27.6)	54(25.8)	0.914
Body mass index	24.63±3.46	24.83±3.20	0.314

Baseline clinical characteristics (2)

	DK crush (n=210)	Culotte (n=209)	p
>2-week acute MI, n (%)	18(8.6)	12(5.7)	0.344
Previous MI, n (%)	32(15.2)	29(13.9)	0.258
Unstable angina, n (%)	165(78.6)	174(83.3)	0.263
Stable angina, n (%)	21(10.0)	20(9.6)	1.000
Silent ischemia, n (%)	6(2.9)	3(1.4)	0.503
Previous PCI, n (%)	47(22.4)	31(14.8)	0.059
LVEF, %	58.7±11.3	58.8±10.6	0.296
<40%, n (%)	18(8.6)	9(4.3)	0.110
eGFR, ml/min	84.97 ± 21.89	83.39 ± 22.09	0.463
<60ml/min, n (%)	28(13.3)	27(12.9)	0.560

Lesion characteristics (1)

	DK crush (n=210)	Culotte (n=209)	p
Three vessel disease, n (%)	149(71.3)	145(69.5)	0.130
Left main trunk, n (%)			
Chronic total occlusion	1(0.4)	0	0.653
Ostial	31(15.2)	42(20.4)	0.197
Mid shaft	71(34.8)	60(28.7)	0.102
Whole trunk	45(21.8)	39(18.9)	0.159
Distal bifurcation			0.896
Medina 1,1,1	207(98.7)	198(94.8)	
Medina 0,1,1	3(1.3)	11(5.2)	

Lesion characteristics (2)

	DK crush (n=210)	Culotte (n=209)	p
Distal main vessel*, n (%)			
Severe tortuous	25(11.9)	28(13.4)	0.662
Mild-moderate calcification	30(14.3)	30(14.4)	1.000
Thrombus-containing	0	0	NS
Chronic total occlusion	10(4.8)	12(5.7)	0.209
TIMI Grade 0~2	23(10.9)	20(9.6)	0.320
Side branch, n (%)			
Severe tortuous	38(18.1)	45(21.5)	0.393
Mild-moderate calcification	19(9.1)	20(9.6)	0.786
Thrombus-containing	0	0	NS
Chronic total occlusion	9(4.3)	12(5.7)	0.512
TIMI Grade 0~2	19(9.1)	22(10.5)	0.280

Lesion characteristics (3)

	DK crush (n=210)	Culotte (n=209)	p
Syntax score (points) 0~22, n (%)	30.67±12.89 69(32.9)	31.51±15.60 54(25.8)	0.254 0.462
NERS score (points) <20, n (%)	26.03±10.70 55(26.2)	26.12±10.55 47(22.5)	0.677 0.241

Procedural characteristics (1)

	DK crush (n=210)	Culotte (n=209)	p
Trans-radial approach, n (%)	122(58.1)	123(58.9)	0.976
IIb/IIIa used, n (%)	35(16.7)	39(18.7)	0.834
Supported device, n (%)			
IABP	6(2.9)	7(3.3)	0.860
Impella	3(1.4)	3(1.5)	0.989
IVUS assessment, n (%)	145(69.0)	154(73.7)	0.331
Stent types, n (%)			0.703
Firebird-2	78(37.1)	75(35.9)	
Xience V	132(62.9)	134(64.1)	

Procedural characteristics (2)

	DK crush (n=210)	Culotte (n=209)	<i>p</i>
Main vessel stent			
Number, n	1.38 ± 0.45	1.39 ± 0.49	0.556
Diameter, mm	3.40 ± 0.34	3.34 ± 0.40	0.106
Length, mm	33.48 ± 14.01	35.74 ± 15.99	0.124
Side branch Stent			
Number, n	1.20 ± 0.39	1.14 ± 0.35	0.159
Diameter, mm	3.04 ± 0.41	3.03 ± 0.41	0.587
Length, mm	25.90 ± 13.83	26.72 ± 11.86	0.519
Post-dilation, n (%)			
Main vessel	205(97.6)	200(95.7)	0.693
Side branch	202(96.2)	200(95.7)	0.810
FKBI, n (%)	209(99.5)	208(99.5)	1.000

Procedural characteristics (3)

	DK crush (n=210)	Culotte (n=209)	p
Angiographic success, n (%)	204(97.1)	208(99.5)	0.122
Procedural success, n (%)	203(96.7)	201(96.2)	0.800
Complete revascularization, n (%)	180(85.7)	171(82.0)	0.351
Procedural time, min.	56.88±33.11	54.87±32.09	0.529
Fluoroscopy time, min.	26.57±14.39	27.66±17.53	0.487
Contrast volume, ml	184.40±22.01	170.10±7.22	0.048
Non-left main lesions			
Stent number, n	1.41±0.73	1.26±0.53	0.410
Stent diameter, mm	2.89±0.42	2.99±0.46	0.468
Stent length, mm	36.86±27.33	32.33±15.34	0.468
Staged procedures, n (%)	82(39.0)	72(34.4)	0.711

QCA of LM

	DK cursh (n=176)	Culotte (n=174)	<i>p</i>
Days from indexed procedure (d)	223.0 ± 15.3	211.9 ± 14.1	0.109
Left main trunk			
Lesion length, mm	6.36 ± 3.69	6.97 ± 3.86	0.100
Minimal lumen diameter, mm			
Prior-stenting	1.47 ± 0.43	1.49 ± 0.42	0.719
Acute gain, mm	2.34 ± 0.47	2.34 ± 0.49	0.980
Late loss, mm	0.18 ± 0.29	0.23 ± 0.34	0.378
Diameter stenosis, %			
Prior-stenting	59.84 ± 9.35	59.18 ± 8.47	0.772
Follow-up	11.08 ± 7.24	11.81 ± 6.83	0.401
Restenosis, n (%)	0	0	NS

QCA of distal main vessel (LAD)

	DK crush (n=176)	Culotte (n=174)	<i>p</i>
Days from indexed procedure (d)	223.0. ± 15.3	211.9 ± 14.1	0.109
Distal main vessel*			
Lesion length, mm	16.67 ± 9.23	18.65 ± 12.26	0.067
Minimal lumen diameter, mm			
Prior-stenting	1.09 ± 0.42	1.07 ± 0.44	0.984
Acute gain, mm	1.79 ± 0.41	1.79 ± 0.42	0.988
Late loss, mm	0.19 ± 0.32	0.20 ± 0.33	0.938
Diameter stenosis, %			
Prior-stenting	64.62 ± 5.66	65.69 ± 6.46	0.414
Follow-up	16.15 ± 8.33	15.41 ± 7.10	0.622
Restenosis, n (%)	2(1.14)	1(0.57)	1.000

QCA of side branch (LCX)

	DK crush (n=176)	Culotte (n=174)	p
Side branch*			
Lesion length, mm	16.48 ± 11.09	16.97 ± 13.01	0.804
Minimal lumen diameter, mm			
Prior-stenting	1.01 ± 0.43	1.07 ± 0.49	0.597
Acute gain, mm	1.58 ± 0.43	1.58 ± 0.49	0.990
Late loss, mm			
In-stent	0.20 ± 0.30	0.39 ± 0.36	0.001
In-segment	0.09 ± 0.21	0.21 ± 0.30	0.048
Diameter stenosis, %			
Prior-stenting	65.29 ± 7.34	63.36 ± 7.75	0.640
Follow-up	16.39 ± 7.45	25.50 ± 7.36	0.001
Restenosis, n (%)	12(6.82)	22(12.64)	0.037
In-segment	4(2.27)	6(3.45)	0.540
In-stent	9(5.11)	19(10.92)	0.034
Ostial	9(5.11)	16(9.19)	0.045

Clinical follow-up (in-hospital)

	DK crush (n=210)	Culotte (n=209)	p
In-hospital days, d	6.58±4.31	7.19±3.94	0.134
Composite MACE, n(%)	7(3.3)	8(3.8)	0.800
Cardiac death	1(0.5)	1(0.5)	1.000
MI	7(3.3)	8(3.8)	0.800
TLR	0	0	NS
TVR	0	0	NS
CABG	0	0	NS
Stent thrombosis, n(%)	0	0	NS

Clinical follow-up (at 1-month)

	DK crush (n=210)	Culotte (n=209)	p
Composite MACE, n(%)	7(3.3)	9(4.3)	0.622
Cardiac death	1(0.5)	1(0.5)	1.000
MI	7(3.3)	9(4.3)	0.622
TLR	0	1(0.5)	0.499
TVR	0	1(0.5)	0.499
CABG	0	0	NS
Stent thrombosis, n(%)	0	1(0.5)	0.499
Definite	0	1(0.5)	0.499
Probable	0	0	NS

Clinical follow-up (at 12-month)

	DK crush (n=210)	Culotte (n=209)	p
Composite MACE, n(%)	13(6.2)	34(16.3)	0.001
Cardiac death	2(1.0)	2(1.0)	1.000
MI	7(3.3)	11(5.3)	0.377
TLR	5(2.4)	14(6.7)	0.037
TVR	9(4.3)	23(11.0)	0.016
For non-left main	0	4(1.9)	0.061
For left main	9(4.3)	20(9.6)	0.036
CABG	2(1.0)	0	0.499
Stent thrombosis, n(%)	1(0.5)	2(1.0)	0.623
Definite	0	2(1.0)	0.248
Probable	0	0	NS
Possible	1(0.5)	0	1.000

TLR/TVR-free Survival Rate at 12-month

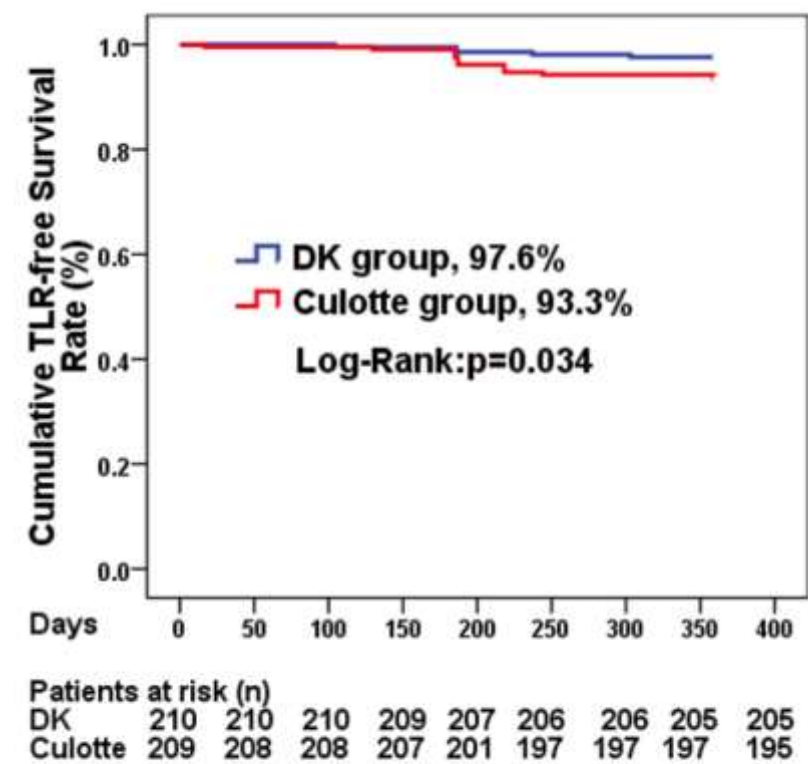


Figure 3. TLR-free survival rate at 12-month

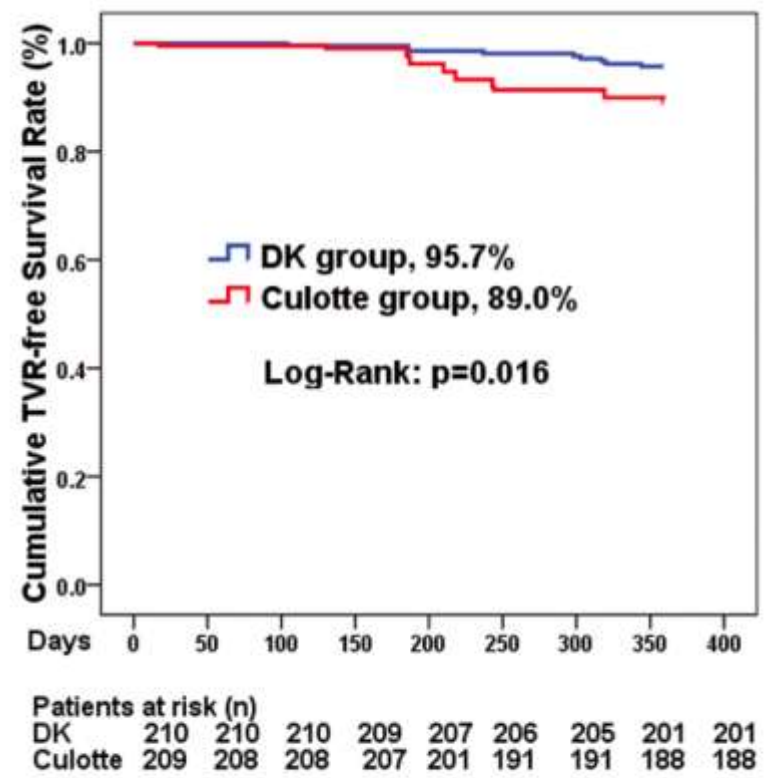
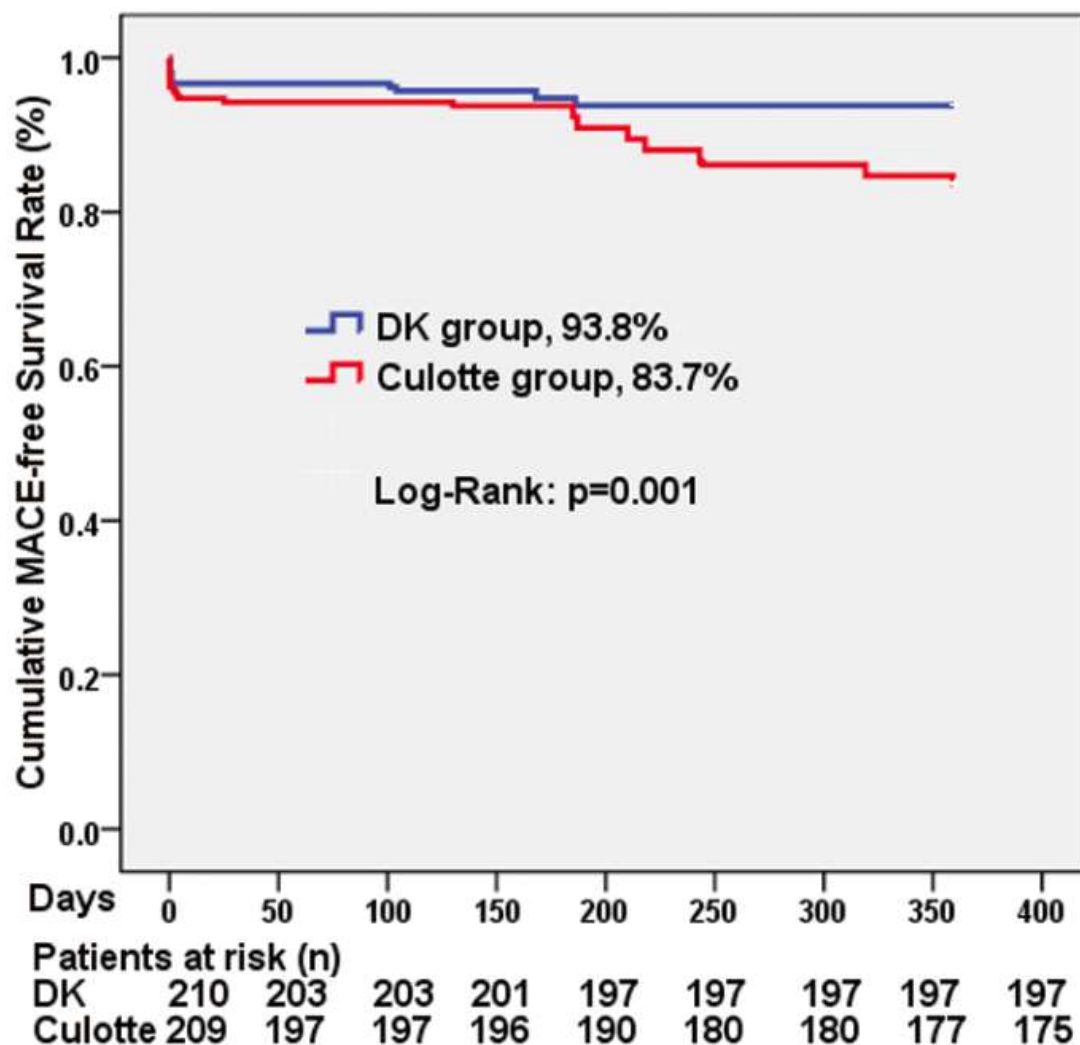
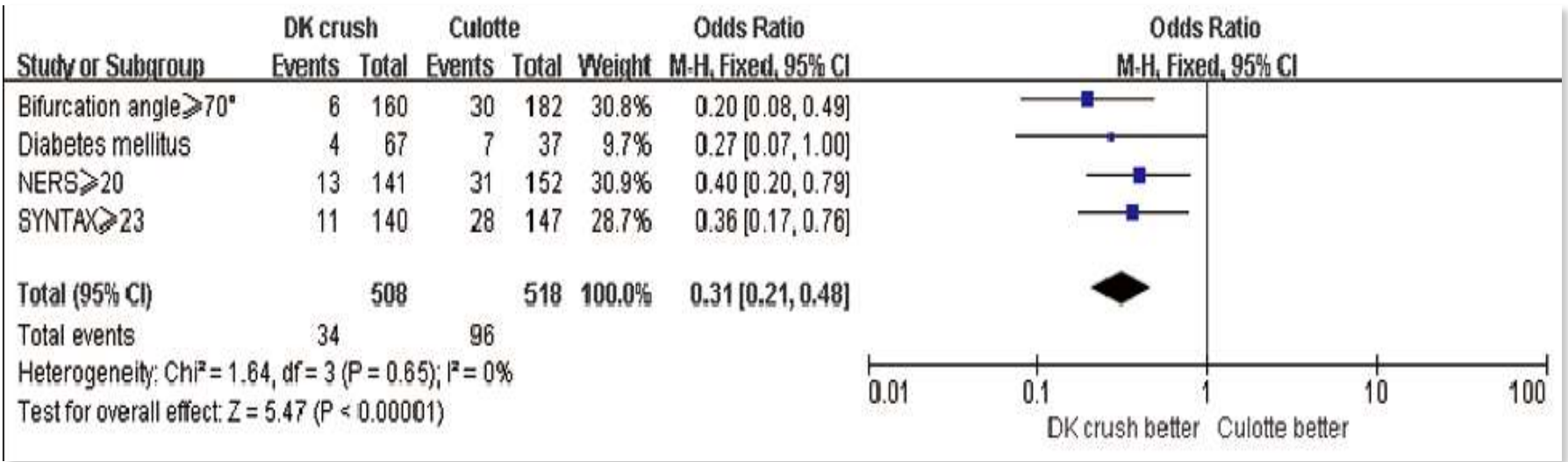


Figure 4. TVR-free survival rate at 12-month

MACE-free Survival Rate at 12-month



Forest plots of 12-month MACE rate in pre-specified subgroups



Major findings

- Culotte stenting was associated with significantly increased 1-year MACE rate , mainly because of the increment of TVR rate.
- Restenotic lesions most localized in the SB, DK crush was associated with less ISR.
- The efficacy of DK crush was demonstrated in patients at intermediate- and high-risk stratified by either SYNTAX or NERS score, also maintained in patients with distal bifurcation angle $\geq 70^{\circ}$.

Limitations

- Some kinds of angle restriction should have been applied in the design of the study.
- We did not include a CABG group to contrast with the stenting techniques.
- The results were achieved in very high volume operators performing these procedures. It remains unclear whether lower volume centers could reproduce these results.

Conclusion

- ◆ Compared to the DK crush, Culotte stenting is associated with significantly increased MACEs in patients with ULMCA bifurcation lesions.
- ◆ DK crush was associated with:
 - less in-stent restenosis of SB
 - less TLR/TVR

Thanks for your attention