

Prospective, Multicenter, Randomized trial Comparing DK vs Classical crush for the treatment of true coronary bifurcation lesions: two-year follow-up results

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On Behalf of DKCRUSH-1 Investigators**

Background

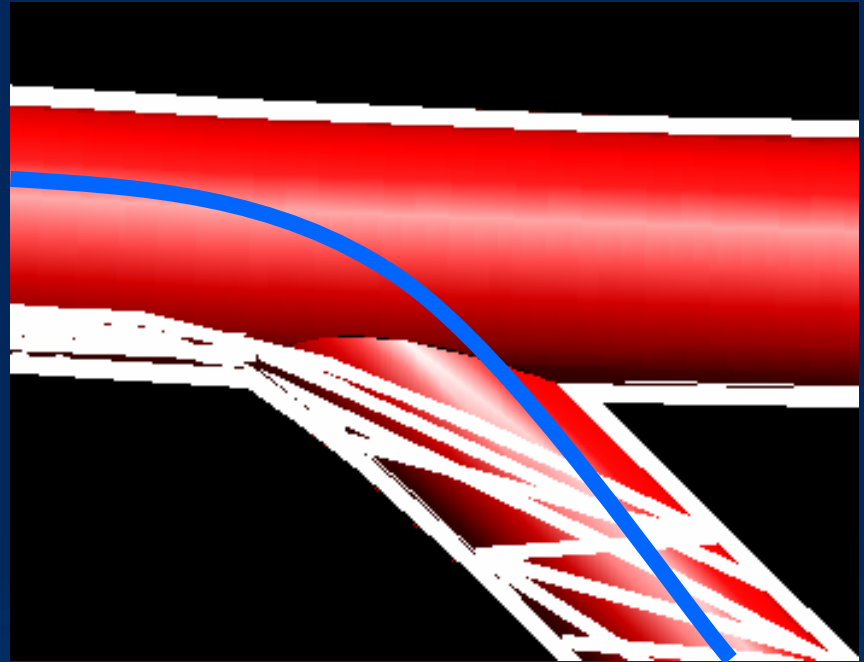
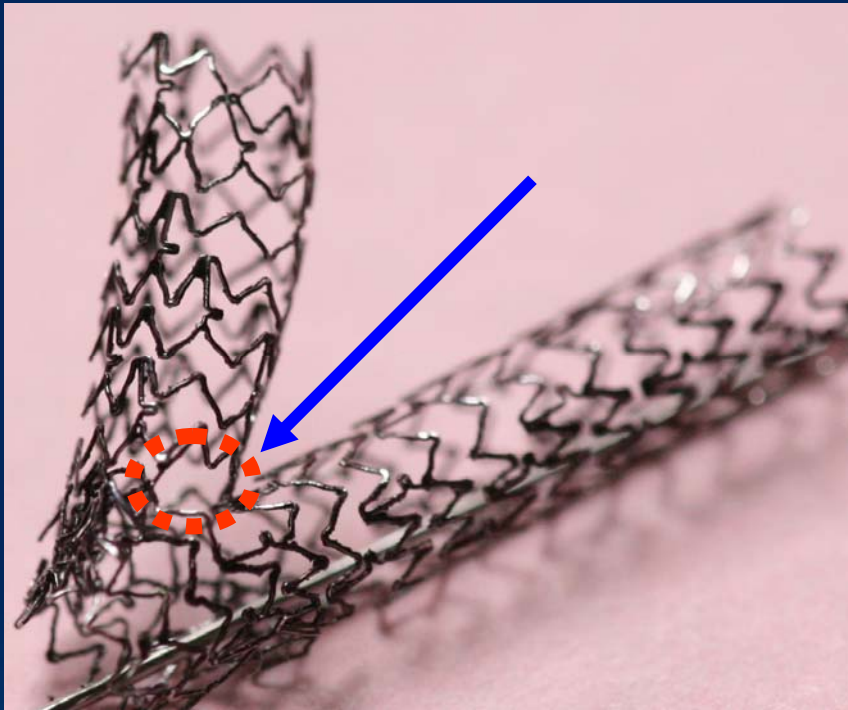
× Classical crush

----Completely cover the ostium of SB

----Final kissing balloon inflation (FKBI) is mandatory to improve clinical outcomes

----FKBI by classical crush: 70~80%

Reasons for failure of FKBI



1.Chen et al. Double kissing(DK) crush for bifurcation lesions. Chinese medical Journal, 2005;10

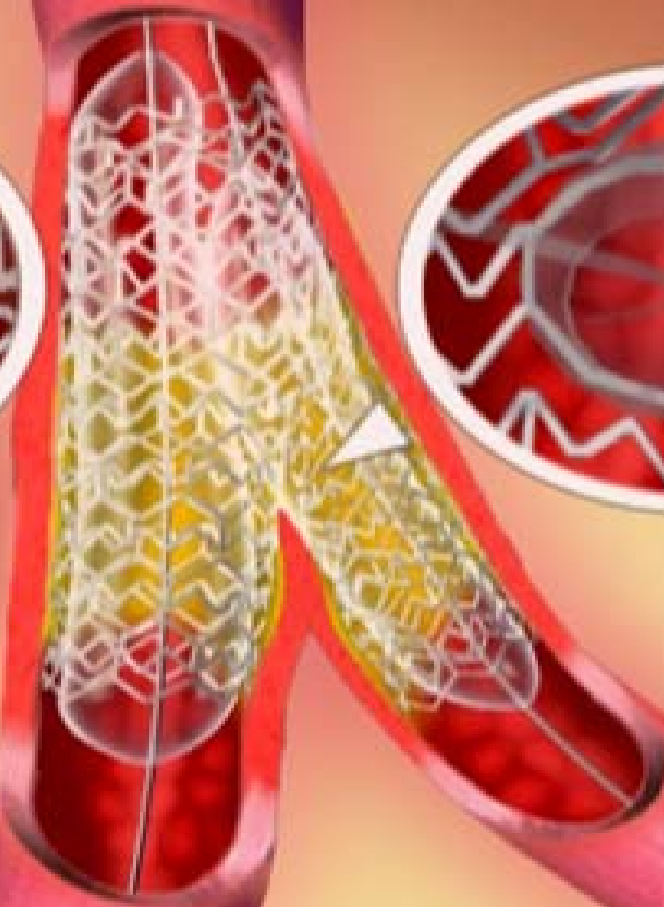
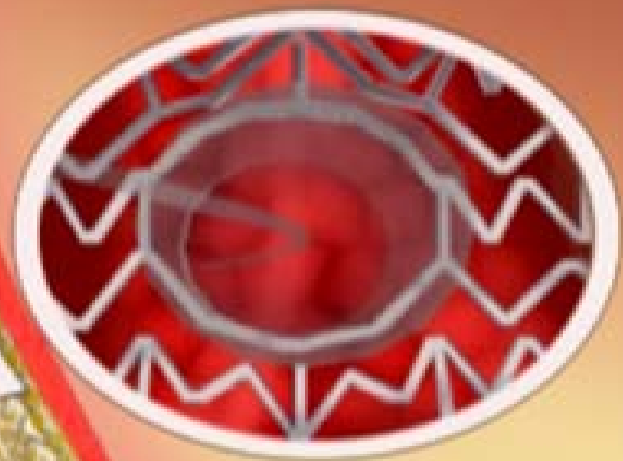
2. DK crush: J Invasive Cardiol,2007

Double kissing(DK)crush

- one layer strut at the orifice of SB
- FKBI:
 - Success rate: 100%
 - Quality of FKBI: improved



**classic
crush**



DK Crush

Stenting SB

Balloon Crush

First kissing

Stenting MV

FKBI

Classical Crush

Stenting SB

MV stenting

FKBI

Important findings from Pilot studies

- FKBI: 100% by DK vs 80% by classical crush
- Unsatisfied kissing (**KUS**)

1. Chen et al. Double kissing(DK) crush for bifurcation lesions. Chinese medical Journal, 2005;10

2. Chen et al. CCT, 2005

3. Chen et al. DK crush: J Invasive Cardiol,2007

4. Chen et al. Catheterization and Cardiovascular Interventions,2008

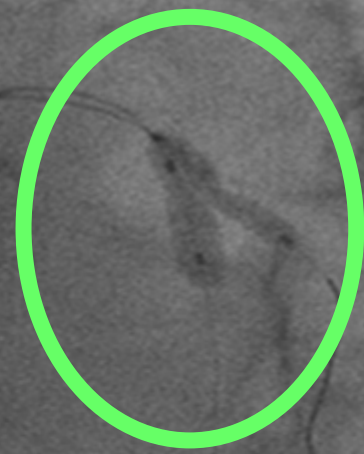
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Study Design

- DK vs Classical crush, 313 patients
- Randomized, multicenter, prospective
- 1^oEP: MACE within 8-month
- 2^oEP: binary restenosis, late loss
- **Within 8-month:**
 - Clinical F/U: 100%
 - Angiographic F/U: 83%
 - IVUS F/U: 72%

1. Chen et al. European Journal of Clinical Investigation, 2008

2. Chen et al. American J Cardiol (suppl. 2007-TCT), 2007

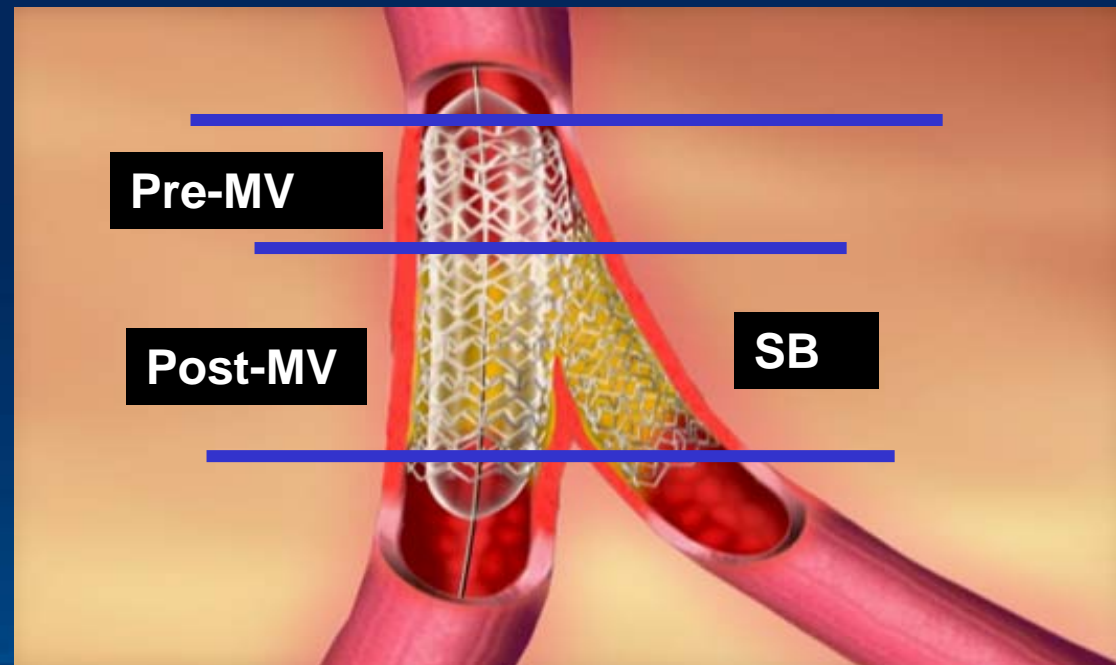
QCA analysis

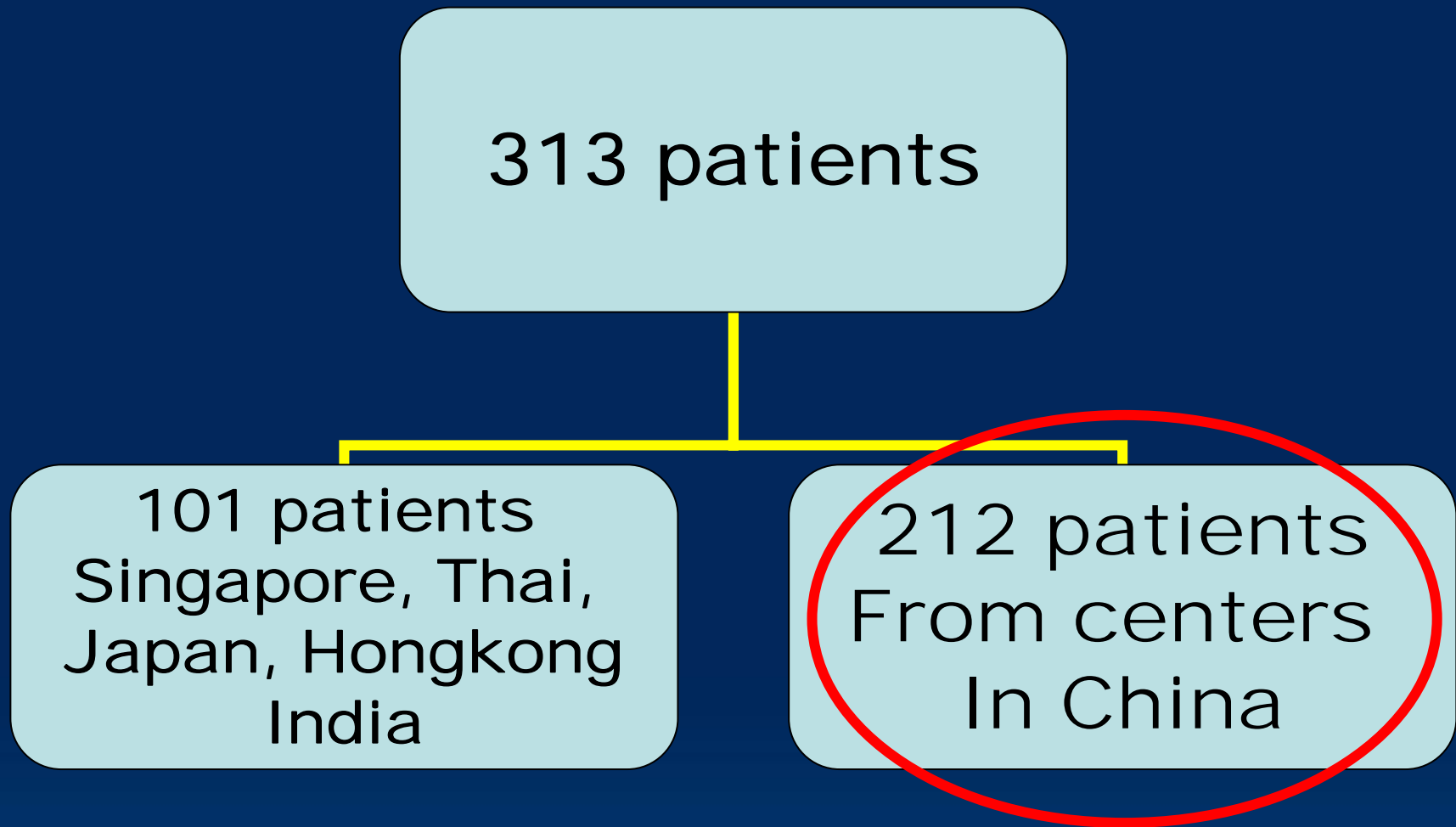
- **Core Lab.:** Wolfson Medical Center
Nanjing Heart center
- **Vessels segments:**

Pre-MV

Post-MV

Side branch





1. **Chen et al.** European Journal of Clinical Investigation, 2008
2. **Chen et al.** American J Cardiol (suppl. 2007-TCT), 2007

212 patients from
centers in China

2 patients died
Within 1 yr.

210 patients
F/U To 2 yr.

Clinical f/u: 100%

Re-angiogram:
N=47

Re-IVUS
N=32

DK :N=104,
lesions=107

Classical :N=106
Lesions=115

With-FKBI:N=78
Lesions=87

no-FKBI:N=28
Lesions=33

Table 1. Baseline Characteristics

	Classical	DK	p
No.patient	107	105	
Age(yr.)	63.8 ± 8.59	64.07 ± 9.11	NS
EHP,%	57.62	53.29	0.833
UAP,%	70.8	69.2	0.881
AMI,%	16.00	15.40	1.000
OMI,%	11.3	8.7	0.647
Smoker,%	23.65	27.11	0.687
previous PCI	11.3%	8.7%	0.647
DM,%	8.5	19.2	0.028

Table 2. Procedural characteristics(1)

	Classical	DK	P
No.Lesions	115	109	
LAD-D,%	61.3	65.38	NS
LCX-OM,%	14.15	12.50	NS
LAD-CX,%	16.04	16.73	NS
RCAd,%	8.51	5.39	NS
FKBI,%	70.75	100	<0.001

Table 2. Procedural characteristics(2)

	Classical	DK	p
Lesion length,mm			
main vessel	20.04 ± 9.69	21.39 ± 11.28	0.859
side branch	10.52 ± 7.50	10.29 ± 6.36	0.554
Stent length,mm			
main vessel	27.02 ± 12.74	28.66 ± 12.26	0.344
side branch	17.99 ± 7.21	17.41 ± 5.65	0.517
Stent number,n			
main vessel	1.12 ± 0.38	1.18 ± 0.41	0.264
side branch	1.05 ± 0.21	1.01 ± 0.09	0.106
Contrast,ml	108.7 ± 71.75	130.36 ± 78.87	0.043
PCI time,min	34.17 ± 18.44	46.64 ± 25.50	<0.001

Table 2. Procedural characteristics(3)

	Classical	DK	p
Bifurcation angle(°)	52.99 ± 23.09	53.65 ± 22.68	0.836
Balloon number,n	2.19 ± 0.83	2.54 ± 0.69	0.004
Maximal pressure,n			
main vessel	12.88 ± 2.74	12.66 ± 2.74	0.627
side branch	12.91 ± 2.77	12.97 ± 2.76	0.902
Balloon diameter,mm			
main vessel	3.59 ± 0.55	3.43 ± 0.56	0.071
side branch	2.79 ± 0.42	2.70 ± 0.55	0.248

Table 2. Procedural characteristics(4)

	Classical	DK	p
Acute gain,mm			
pre-MV	1.95 ± 0.28	2.04 ± 0.28	0.102
post-MV	1.93 ± 0.26	1.98 ± 0.25	0.791
side branch	0.76 ± 0.18	0.85 ± 0.14	0.028
Late loss,mm			
pre-MV	0.48 ± 0.09	0.29 ± 0.08	0.001
post-MV	0.27 ± 0.08	0.23 ± 0.04	0.679
side branch	0.63 ± 0.20	0.44 ± 0.08	<0.001
Restenosis,%			
pre-MV	6.27	6.54	0.543
post-MV	7.39	5.77	0.236
side branch	33.6	12.4	<0.001

Table 3. Clinical follow-up within two-year

	Classical	DK	p
No.Patients,n	107	105	
No.ST,n(%)	4(3.74)	1(0.95)	0.116
definite	2	1	
probable	1	0	
possible	1	0	
Cardiac death,n(%)	2(1.87)	2(1.90)	0.865
MI,n(%)	3(2.80)	2(1.90)	0.541
TVR,n(%)	24(22.43)	13(12.38)	0.017
MACE,n(%)	29(27.10)	17(16.19)	0.013
within first-year	23(21.5)	15(14.3)	0.027

Analysis of overall death

- **7 patients died (3.3%)**
- **Cardiac death: 4 patients(1.89%)**
 - in DK group: 2 death
 - 1 ST, 1 RCA-MI after LAD stent
 - in Classical: 2 death from ST
- **Non-cardiac death:3 patients(1.42%)**
 - all in DK group:
 - 2 from GI bleeding
 - 1 from cancer

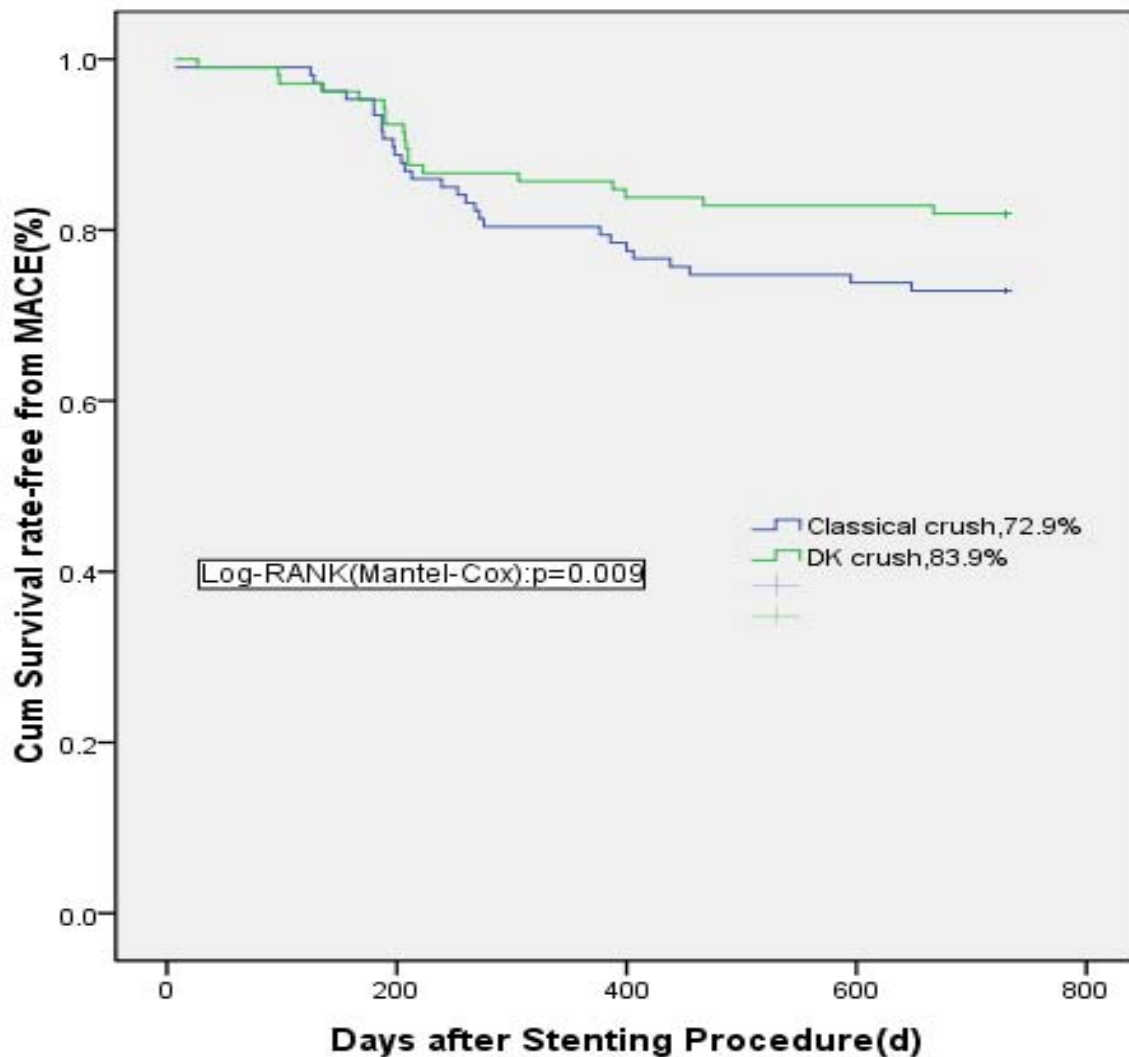


Figure 1. Two years follow-up: classical vs DK

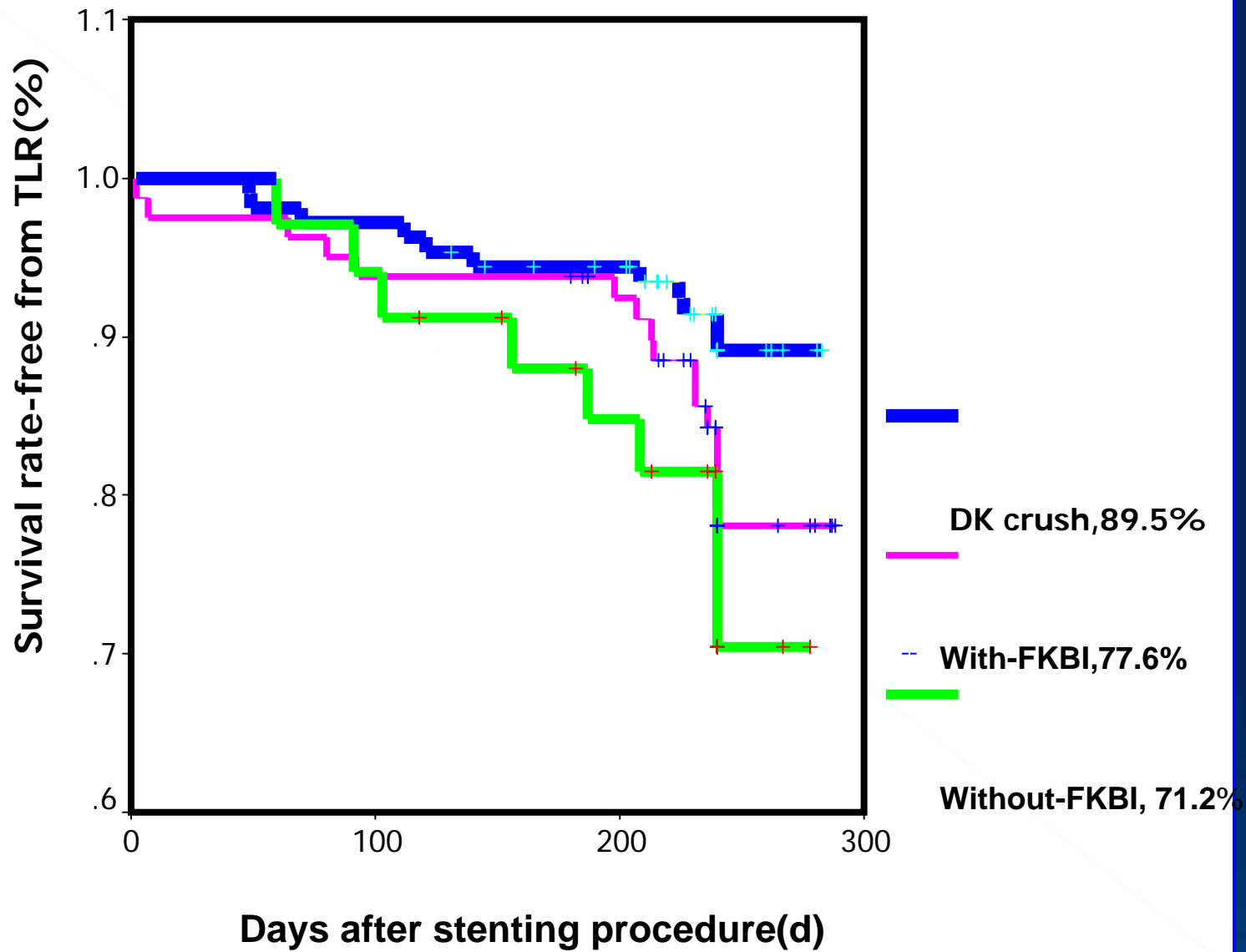


Figure 2. DK vs with- and without-FKBI

Table 4. independent factors of MACE

	HR	95% CI	p
Lack of DK	24.68	4.10~22.09	0.001
Diabetes	15.42	2.79~14.05	0.001
Kissing Unsatisfied	12.22	0.02~0.41	0.002

In Conclusion

- **DK crush is superior to classical crush**
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- **Stratification of diabetes would strengthen the power of DK vs classical crush**
- **Lack of DK crush, diabetes and kissing unsatisfied(KUS) were three independent factors of MACE within 2 years**

Thanks for your attention