EMO GVM
CENTRO
CUORE COLUMBUS s.r.l.

ANGIOPLASY SUMMIT 2009
TCT ASIA PACIFIC

Seoul, Korea: 22-24 April 2009

Complex Interventions I

Lessons from the CACTUS Trial

Speaker - 12'

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CACTUS trial

Coronary Bifurcation **A**pplication of the **C**rush **T**echnique **U**sing **S**irolimus-Eluting stents

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CACTUS trial

Coronary Bifurcation Application of the Crush Technique Using Sirolimus-Eluting stents

Endpoint Committee	G. Biondi-Zoccai, MD C. Briguori, MD, PhD J. Cosgrave, MD
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Data Management and Corelab & Statistics	MCR, Mediolanum Cardio Reasearch
Statistics	E. Bonizzoni, PhD
Sponsor	Cordis Corporation, a Johnson & Johnson company

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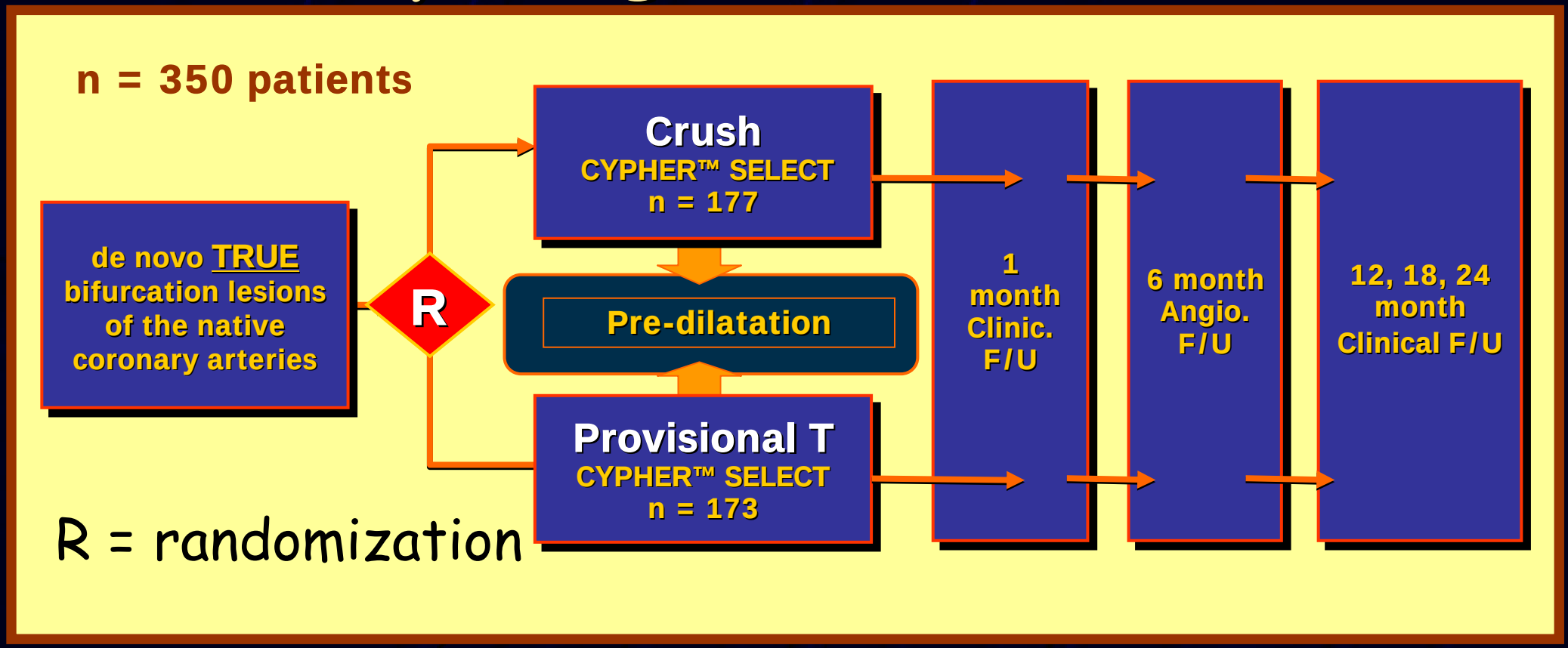
Study Design and Time Frame



Dual antiplatelet therapy was recommended in all pts for at least 6 months

Study endpoints

Primary angiographic endpoint: bifurcation in-segment restenosis (lumen diameter stenosis > 50%) at six-months

Primary clinical endpoint: major adverse cardiac events (MACE) at 6 and 12 month

Secondary angiographic endpoint: minimal lumen diameter (MLD) and percent of stenosis (%) on both branches at 6 months

Study hypothesis: 25% restenosis in the Prov.-T and 10% in the Crush. Analysis performed by intention to treat.

Clinical characteristics (I)

	Crush (n=177)	Prov.-T (n=173)
Age (years)	64±10	66±10
Gender (M/F)	142/35	132/41
Diabetes (%)	23.7	22.0
Hypercholesterolemia (%)	63.8	70.5
Hypertension (%)	70.6	79.8
Current smokers (%)	20.3	16.8
LVEF (%)	55±9	57±8

Clinical characteristics (II)

	Crush (n=177)	Prov.-T (n=173)
Previous MI (%)	44.6	35.3
Previous PTCA (%)	31.1	26.6
Previous CABG (%)	4.5	5.8
Family history of CAD (%)	46.9	35.8
Unstable angina (%)	44.0	47.4
Stable angina (%)	31.1	36.4
Silent ischemia (%)	17.5	13.3

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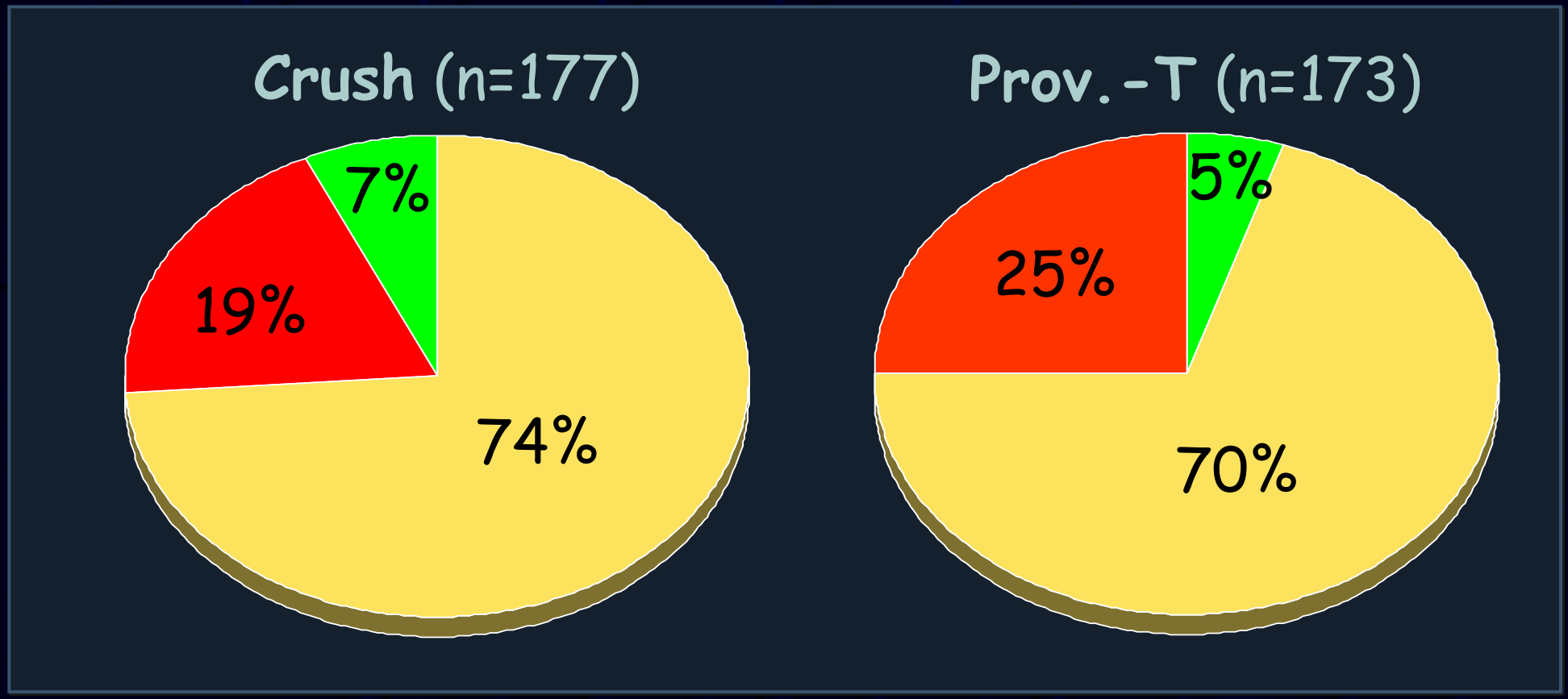
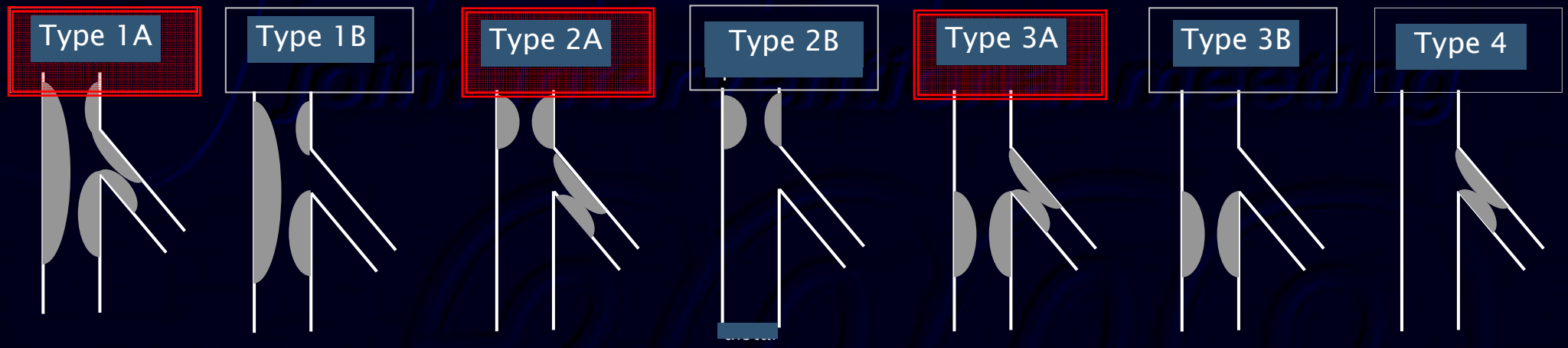
Lesion location



Lesion location

Plaque Distribution



True bifurcation lesion (92%)

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Procedural characteristics

	Crush (n=177)		Prov.-T (n=173)	
	MB	**SB**	**MB**	**SB**
Predilatation (%)	89.8	89.8	90.8	90.8
IVUS (%)	3.4	2.8	4.1	2.3
Total stent le				18.1 ± 6.2 (54 lesions)
Max pressur				12.0 ± 2.4*
Final kissing				.2
IIb-IIIa GP inh				.3

Criteria for provisional stenting Of the side branch:
- TIMI flow grade<3
- residual stenosis >50%
- dissection > type B

31% (54/173) NEEDED PROVISIONAL STENTING IN THE SB

** = p<0.05 for comparisons between crush and prov.-T*

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QCA measurements

	Crush (n=177)		Prov.-T (n=173)	
	MB	SB	MB	SB
Reference diam. (mm)	2.85 ± 0.33	2.30 ± 0.31	2.74 ± 0.35*	2.16 ± 0.33*
Lesion length (mm)	15.8 ± 8.7	5.9 ± 4.7	14.7 ± 8.2	5.7 ± 4.2
Baseline MLD (mm)	0.90 ± 0.38	0.84 ± 0.32	0.83 ± 0.33	0.83 ± 0.30
Baseline stenosis (%)	68 ± 12	63 ± 12	69 ± 12	61 ± 13
Final MLD (mm)	2.71 ± 0.32	1.94 ± 0.39	2.58 ± 0.33*	1.65 ± 0.39*
Final stenosis (%)	12 ± 6	16 ± 11	13 ± 6	27 ± 14*
6-month MLD (mm)	2.24±0.52	1.66 ± 0.51	2.19±0.58	1.52 ± 0.54*
6-month stenosis (%)	25 ± 14	30 ± 19	25 ± 16	31 ± 22

Angiographic follow-up performed in 86% of patients in both groups
** = p<0.05 for comparisons between crush and prov.-T*

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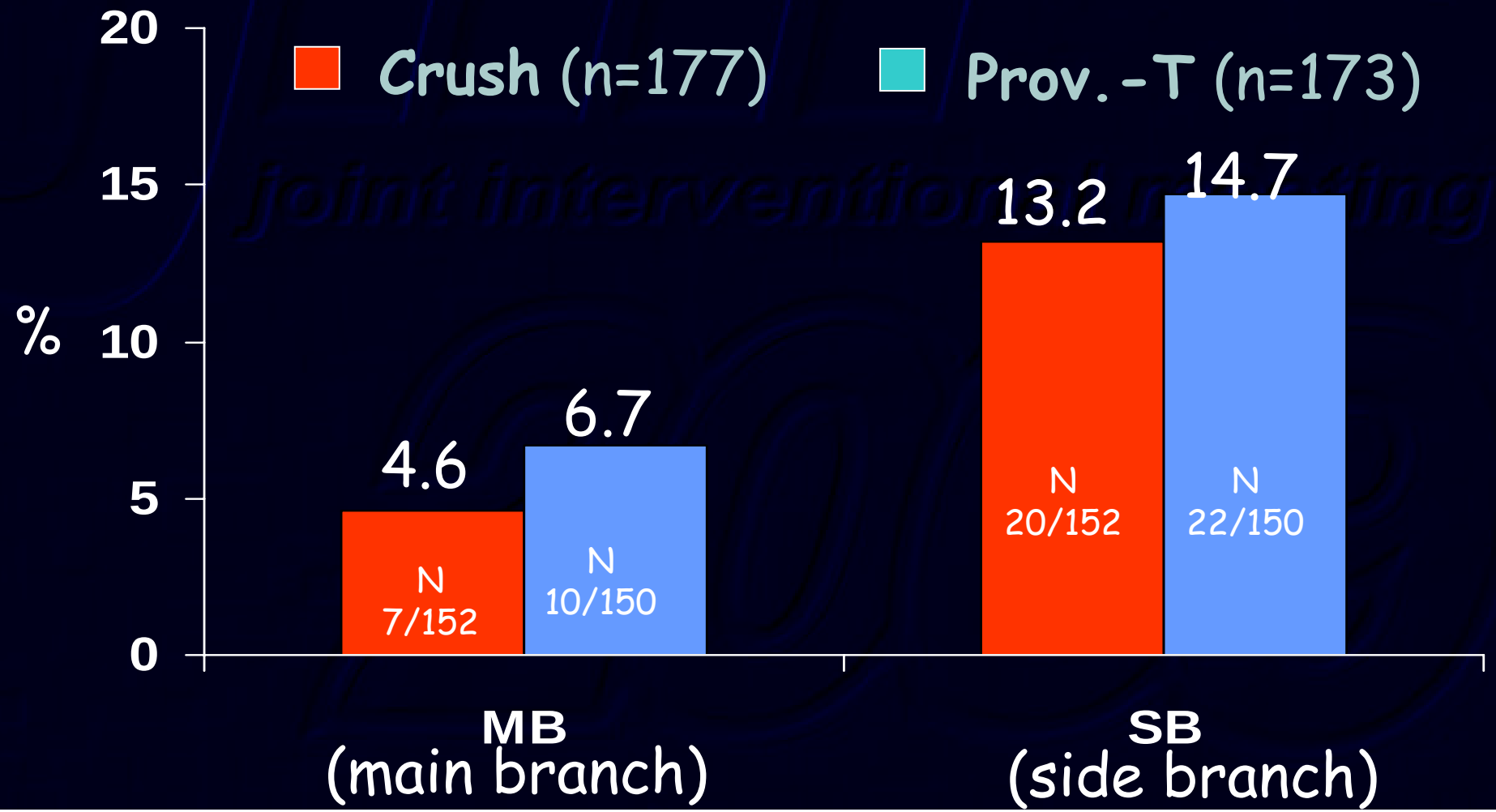
Coronary Bifurcation Application of the Crush Technique Using Sirolimus-Eluting stents

6-month in-segment binary restenosis

Angiographic F.U. performed in 86% of pts in both groups



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Coronary Bifurcation Application of the Crush Technique Using Sirolimus-Eluting stents

	Crush	T-Prov	
30 days MACE (days 0-30)			
Q wave MI	3 (1.7%)	2 (1.1%)	1.00
Non-Q wave MI	15 (8.5%)	12 (6.9%)	0.69
TLR	3 (1.7%)	1 (0.5%)	0.63
TVR (including TLR)	3 (1.7%)	1 (0.5%)	0.63
Death	0	0	-
6-month MACE (days 31-180)			
MI	1 (0.5%)	1 (0.5%)	1.00
TLR	10 (5.6%)	10 (5.8%)	1.00
TVR (including TLR)	11 (6.2%)	12 (6.8%)	0.83
Death	0	1* (0.5%)	0.49

*= non cardiac death (ischaemic stroke confirmed by autopsy)

Stent thrombosis

	Total	Acute (first day)	Subacute (days 2-30)	Late (days 31-180)
Crush (n=177)	3 (1.7%)	1 (0.5%)	2* (1.1%)	0
Prov.T (n=173)	2 (1.1%)	0	1 (0.5%)	1 (0.5%) (definitive)

p = 0.62 for comparisons between crush and prov.-T

** One patient did not take thienopyridine therapy after discharge*

Stent thrombosis

	1	2	3	4	5
Technique	Crush	Crush	Crush	Prov.-T	Prov.-T
Days from procedure	1	7	6	7	72
Thienopyridine	Yes	Yes	No stop day 1	Yes	Yes
Number of stents	2+1	1+1	2+1	1	1+1
Total stent length (mm)	83	65	72	13	41
Final kissing	Yes	No	Yes	Yes	No
Diabetes	No	No	Yes	Yes	No
Lesion location	LAD-diag.	LAD-diag	LAD-diag	LAD-diag	RCA
Clinical consequences	Q-wave MI and TLR	Non Q-wave MI and TLR	Q-wave MI and TLR	Q-wave MI and TLR	Q-wave MI and TLR

Conclusions

- 31% cross over from provisional to 2 stents
- Significantly larger final side branch MLD with crush
-No difference in cumulative 6-months MACE
-No difference in binary in-segment restenosis both in the main branch and in the side branch.
- No difference in 6-month stent thrombosis:
  (1.7% with crush vs 1.1% with prov.-T; p=0.62)

My Interpretation of the Results

- No advantage in routine double stenting
- No penalization for implantation of 2 stents
- In bifurcations with disease of the SB extending more than 5 mm from the ostium the crossover rate to 2 stents it is likely to be well over 31% therefore a prospective trial will be difficult to be performed