



Bulgarian Bifurcation and Complex Coronary Interventions Course

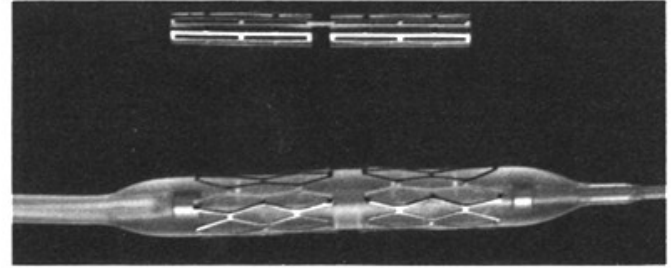
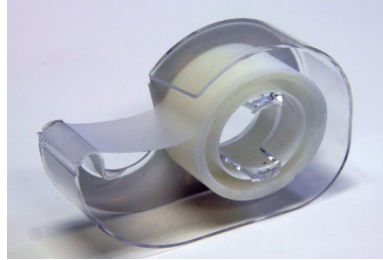
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Tokuda Hospital, Sofia



When 2 stents are preferred ?

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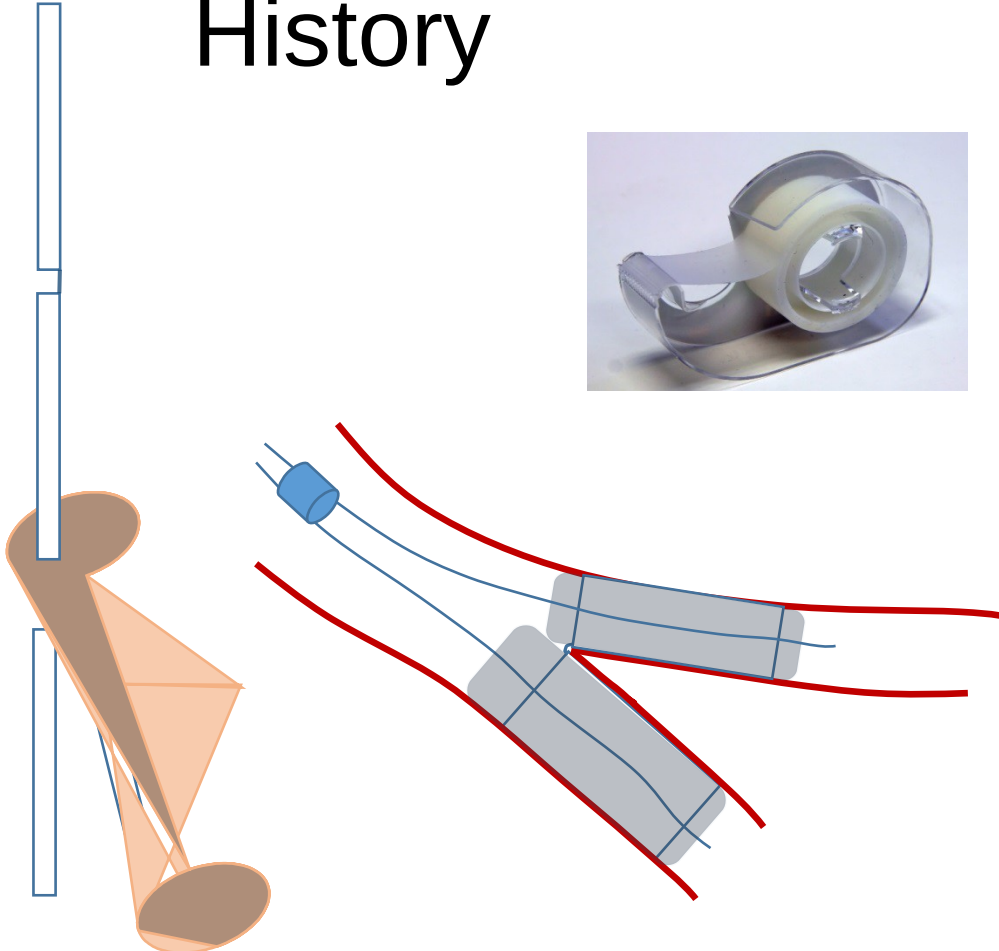
History



Cathet Cardiovasc Diagn. 1996 Nov;39(3):320-6.
The V-stent: a novel technique for coronary bifurcation stenting. Schampaert E1, Fort S, Adelman AG, Schwartz L.

Abstract

...A novel technique of coronary bifurcation stenting is reported. A 15 mm Palmaz-Schatz stent is **bent 180 degrees** at its bridge articulation into a V- configuration and **mounted on two balloon-catheters** linked together by **adhesive tape**. This unified stent delivery system was used successfully in five cases of porcine coronary bifurcation stenting.



The Year of Double Bifurcation Stenting - 1998

- Modified "T" stenting: a technique for kissing stents in bifurcational coronary lesion. Kobayashi Y, Colombo A, Akiyama T, Reimers B, Martini G, di Mario C. Cathet Cardiovasc Diagn. 1998 Mar;43(3):323-6.
- Cathet Cardiovasc Diagn. 1998 Sep;45(1):54-6. Stent by stent crush: procedural outcome and angiographic follow-up. Eeckhout E, Vogt P.
- Placement of coronary stents in bifurcation lesions by the "culotte" technique. Chevalier B, Glatt B, Royer T, Guyon P. Am J Cardiol. 1998 Oct 15;82(8):943-9.
- Coronary stenting of bifurcation lesions using "T" or "reverse Y" configuration with Wiktor stent. Carrié D, Elbaz M, Dambrin G, Saint-Griec F, Dugrand B, Fourcade J, Buel J. Am J Cardiol. 1998 Dec

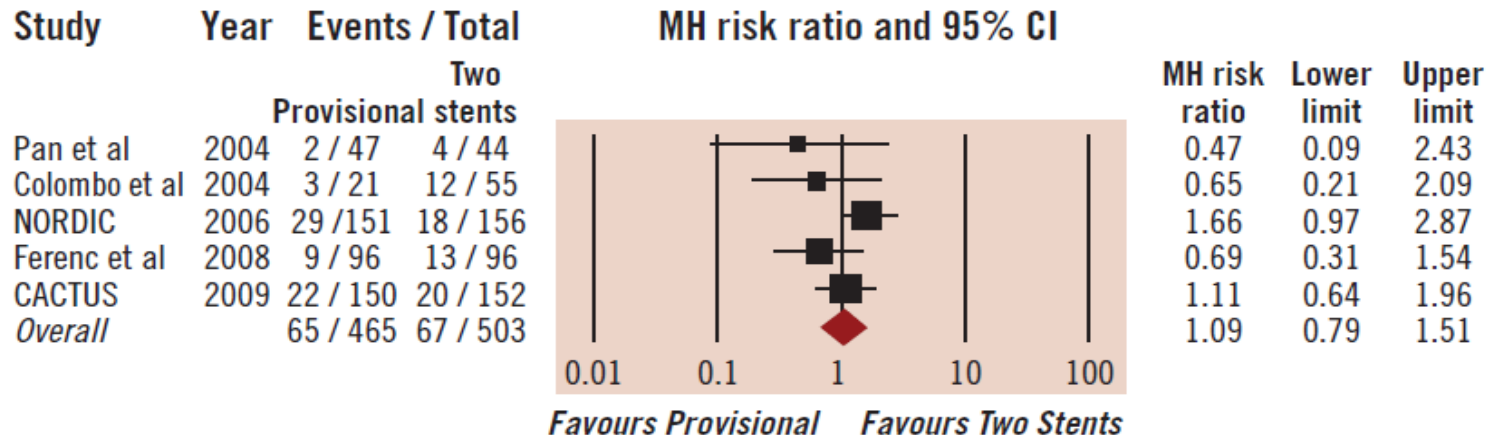
Randomized bifurcation trials

	Patients (N)	Randomization	Primary End Point	Outcome (Provisional vs Systematic Unless Otherwise Specified)
NORDIC	413	Provisional vs systematic (crush, culotte, T)	Death, MI (nonprocedural), TVR, or stent thrombosis at 6 mo	2.9% vs 3.4% (P=NS)
CACTUS	350	Provisional vs systematic (crush)	Death, MI, TVR at 6 mo	15% vs 15.8% (P=NS)
BBC ONE	500	Provisional vs systematic (crush, culotte)	Death, MI, TVF at 9 mo	8.0% vs 15.2% (P<0.05)
Ferenc et al.	202	Provisional vs systematic (T)	Death, MI, TVF at 9 mo Angiographic restenosis (side branch) 9 mo	23.0% vs 27.7% (P=NS)
Colombo et al.	85	Provisional vs systematic (crush, T, culotte)	Angiographic restenosis (either branch) 6 mo	18.7% vs 28.0% (P=NS)
Pan et al.	91	Provisional vs systematic (T)	Angiographic restenosis (either branch) 6 mo	7% vs 25% (P=NS)
NORDIC 2	424	Systematic (crush vs culotte)	Death, MI (nonprocedural), TVR, or stent thrombosis at 6 mo	Crush 4.3% vs culotte 3.7% (P=NS)

Meta-analysis on side branch restenosis in provisional vs. two-stent strategies

Side Branch Restenosis

Angiographic outcome -> No difference



Test for heterogeneity: $Q=5.3$, $df=4$, $P=0.26$ $I^2=25\%$
 Test for overall effect: $Z=-0.53$, $P=0.60$

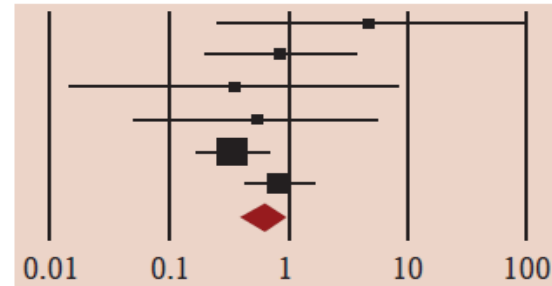
Fixed Effects Model

Meta-analysis on side branch restenosis in provisional vs. two-stent strategies

Myocardial Infarction

Provisional -> Significantly lower

Study	Year	Events / Total		MH risk ratio and 95% CI	MH risk ratio	Lower limit	Upper limit
		Provisional	Two stents				
Pan et al	2004	2 / 47	0 / 44		4.69	0.23	95.00
Colombo et al	2004	2 / 22	7 / 63		0.82	0.18	3.65
NORDIC	2006	0 / 207	1 / 206		0.33	0.01	8.10
Ferenc et al	2008	1 / 101	2 / 101		0.50	0.05	5.43
BBC ONE	2008	9 / 250	28 / 250		0.32	0.15	0.67
CACTUS	2009	15 / 173	19 / 177		0.81	0.42	1.54
<i>Overall</i>		29 / 800	57 / 841		0.57	0.37	0.87



Favours Provisional Favours Two Stents

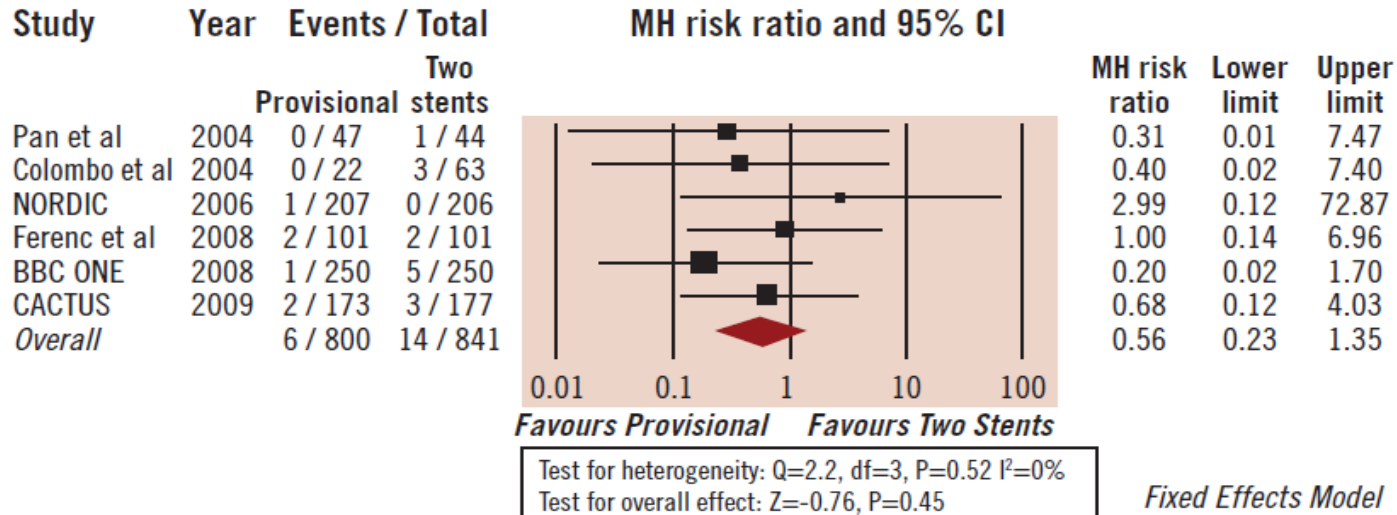
Test for heterogeneity: $Q=5.72$, $df=5$, $P=0.33$ $I^2=13\%$
 Test for overall effect: $Z=-2.58$, $P=0.01$

Fixed Effects Model

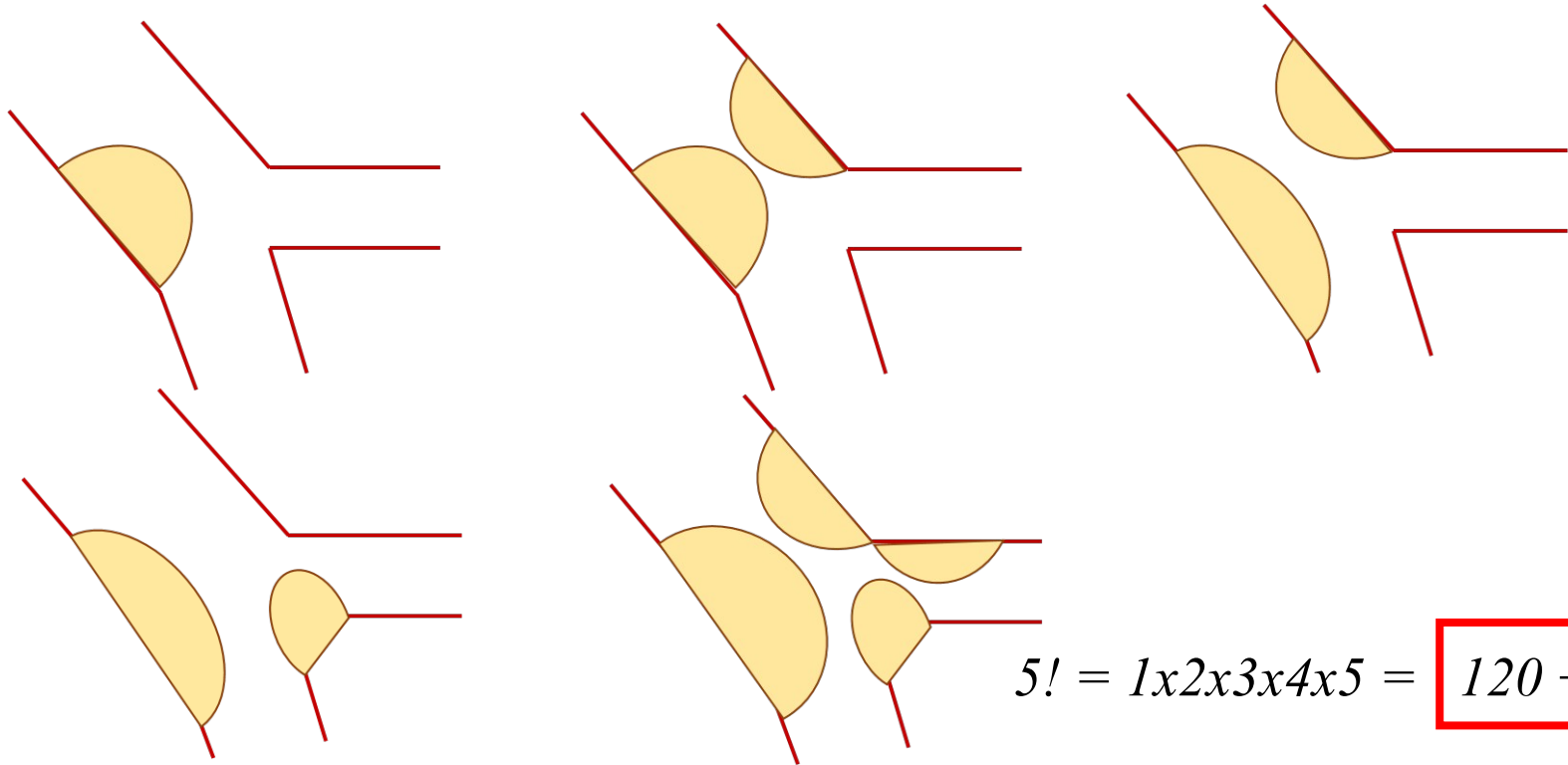
Meta-analysis on side branch restenosis in provisional vs. two-stent strategies

Stent Thrombosis

Provisional -> "Trend" for lower



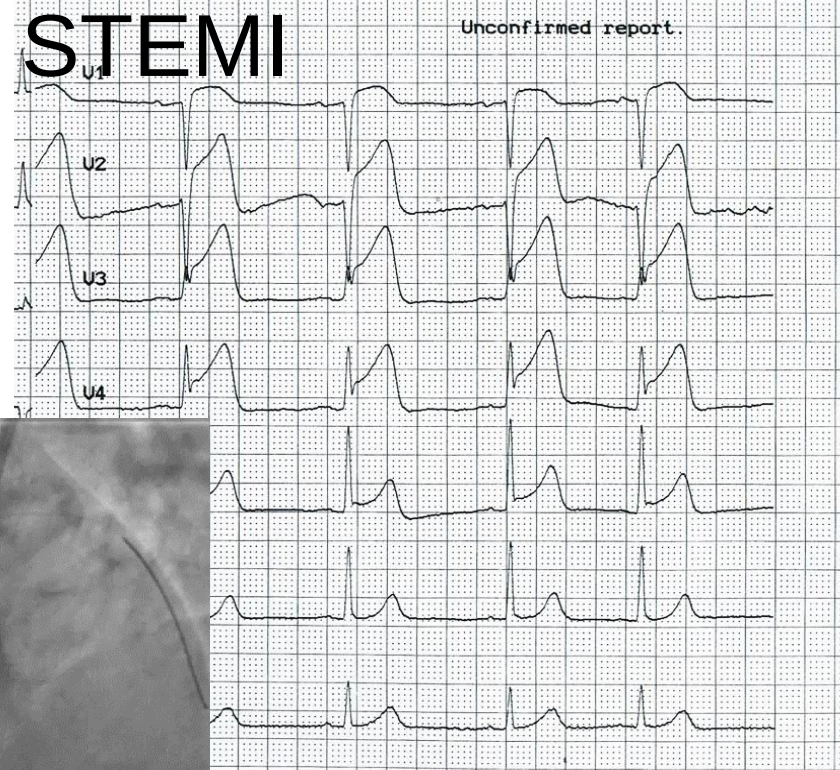
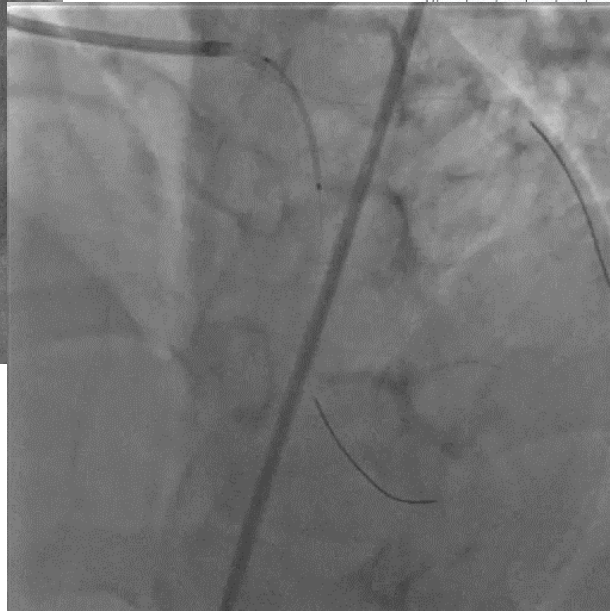
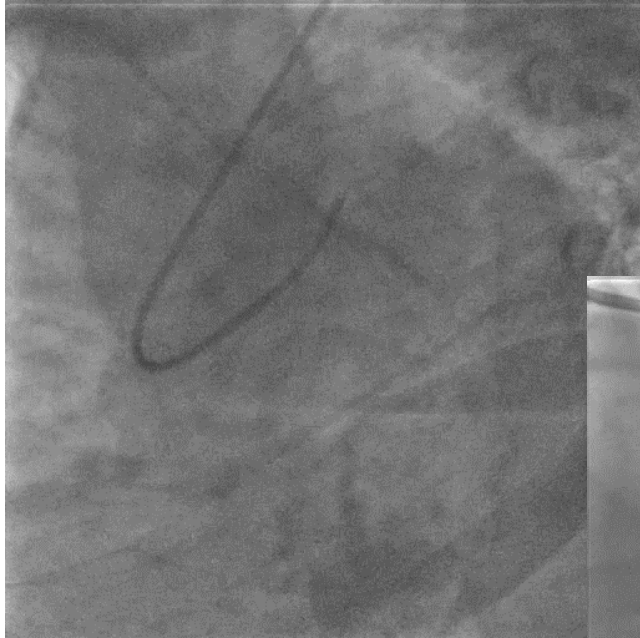
Does it make sense at all of the dispute
on one or two stents in bifurcations?



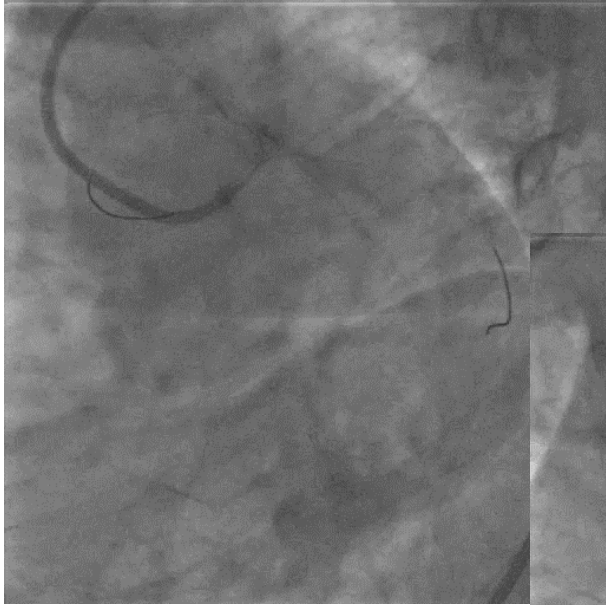
$$5! = 1 \times 2 \times 3 \times 4 \times 5 = 120 + \infty$$

M. K. I. acute anterior wall STEMI

Unconfirmed report.



M. K. I. acute anterior wall STEMI



Randomized comparison of provisional side branch stenting versus a two-stent strategy for treatment of true coronary bifurcation lesions involving a large side branch.

Two-year results in the Nordic-Baltic bifurcation study IV

Indulis Kumsars, Niels R. Holm, Matti Niemelä, Andrejs Erglis, Kari Kervinen, Evald H. Christiansen, Michael Maeng, Andis Dombrovskis, Vytautas Abraitis, Aleksandras Kibarskis, Terje K. Steigen, Thor Trovik, Gustavs Latkovskis, Dace Sondore, Inga Narbute, Christian Juhl Terkelsen, Markku Eskola, Hannu Romppanen, Lisette Okkels Jensen, Mika Laine, Tuija Vasankari, Pål Gunnes, Lasse Hebsgaard, Ole Frobert, Fredrik Calais, Jens Aaroe, Juha Hartikainen, Svend Eggert Jensen, Jan Ravkilde, Thomas Engstrøm, Leif Thuesen, Jens F. Lassen

For the Nordic-Baltic PCI Study Group

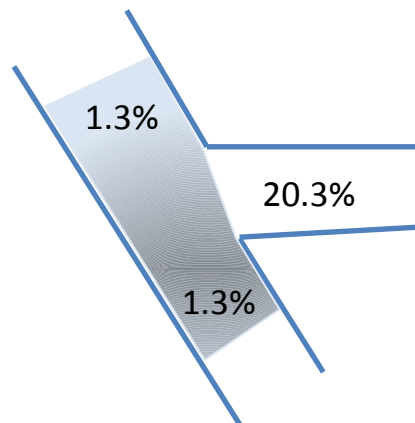
Lesion characteristics by QCA

Main vessel	Ref. diameter (mm)	3.3±0.6	3.2±0.7	0.79
	Diameter stenosis (%)	58.8%±16.3	56.9%±16.1	0.25
Side branch	Ref. diameter (mm)	2.4±0.5	2.5±0.5	0.73
	Diameter stenosis (%)	44.3%±18.5	47.3%±17.6	0.09
	Lesion length (mm)	5.7±3.4	5.8±3.3	0.59

QCA by dedicated bifurcation analysis. Medis QAngioXA 7.3

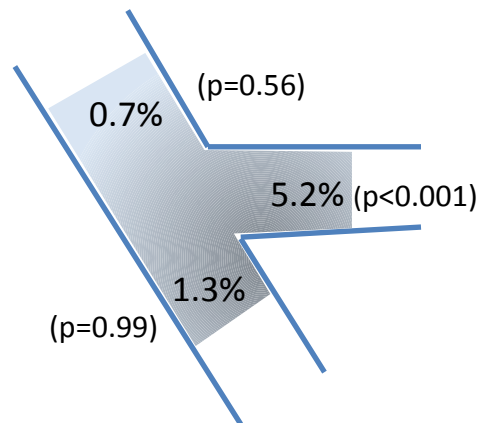
Angiographic restenosis at 8 months

Provisional SB stent technique



n = 153

Two-stent technique

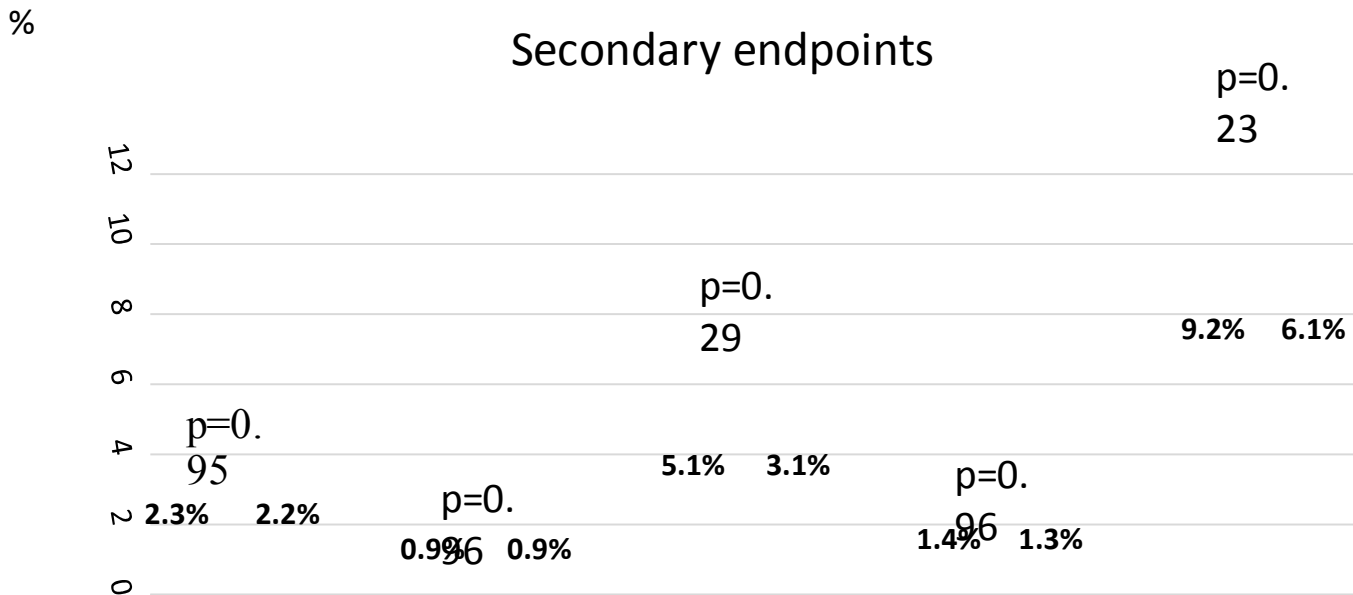


n = 154

Binary restenosis $\geq 50\%$ diameter stenosis

QCA by dedicated bifurcation analysis. Medis QAngioXA 7.3

Individual endpoints at 2 years



The European **B**ifurcation **C**oronary study: a randomised comparison of provisional T-stenting versus a systematic **TWO** stent strategy in large calibre true bifurcations

David Hildick-Smith, Goran Stankovic, Manuel Pan, Philippe Brunel, Didier Carrie, Michael Maeng,
Mark Spence, Keith Oldroyd, Alaide Chieffo, Thomas Hovasse, Andreas Baumbach, Jens Lassen,
Thierry Lefevre and Yves Louvard *on behalf of the EBC TWO trial investigators*

*The EBC two trial is an investigator-initiated trial made possible by unrestricted grants by
Terumo Europe and Pie Medical*

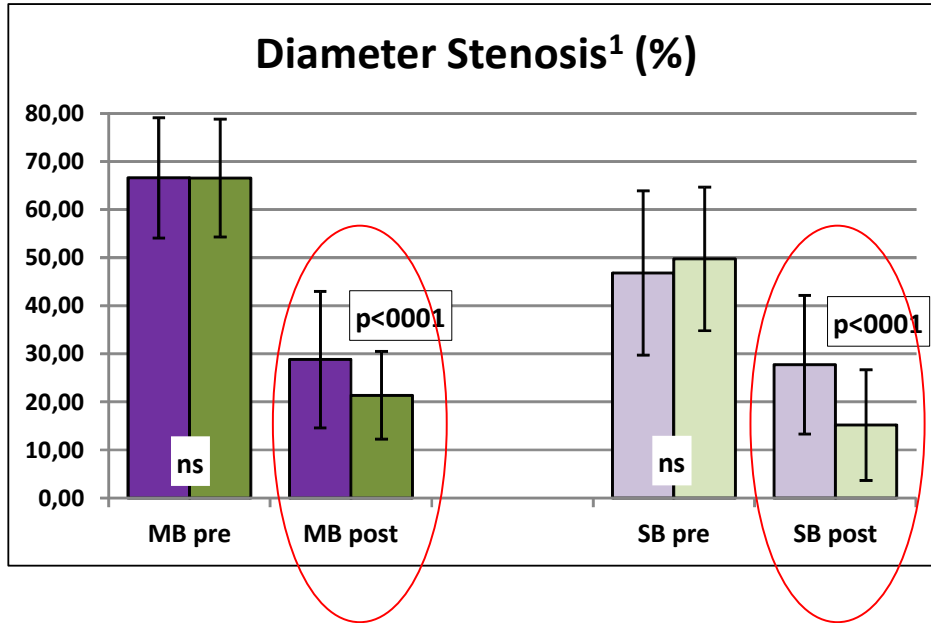
The EBC TWO Trial Hypothesis

“Large true coronary bifurcation lesions (side branch $\geq 2.5\text{mm}$) with significant ostial side branch disease ($\geq 5\text{mm}$ length), are best treated with culotte stenting rather than a provisional T technique, with respect to target vessel revascularisation, myocardial infarction and death at 12 months.”

The EBC TWO Trial Methods

- Patient Population:
 - Elective or ACS patients
 - Coronary bifurcation disease requiring revascularisation
 - True bifurcation lesion (1,1,1; 1,0,1; 0,1,1)
 - Side branch ≥ 2.5 mm diameter
 - Side branch ostial disease ≥ 5 mm length

Acute Corelab QCA Results



Provisional T (N=103):
■ ■

Culotte (N=96):
■ ■

MB: main branch
SB: side branch

Pre: pre-procedure
Post: post procedure
¹values refer to *in lesion*

PRIMARY ENDPOINT

	Provisional T (n=103)	Culotte (n=97)
Death, MI, TVR at 12 months	8 (8%)	10 (10%)
Death	2 (2%)	1 (1%)
Myocardial infarction	5 (5%)	10 (10%)
NSTEMI	5	9
STEMI	0	1
<48H	4	10
TVR	3 (3%)	1 (1%)
Stent thrombosis	1 (1%)	3 (3%)
Definite / Probable	1	2

CONCLUSIONS

- 12-month Results
 - No significant difference between provisional and culotte techniques even in this highly complex bifurcation population
- Numerical trends are in keeping with expectations
 - More target vessel revascularisation in the simpler procedure
 - More periprocedural MI and stent thrombosis in the more complex procedure

An Angiographic Tool for Risk Prediction of Side Branch Occlusion in Coronary Bifurcation Intervention



The RESOLVE Score System (Risk prEdiction of Side branch Occlusion in coronary bifurcation interVENTion)

TABLE 5 Frequency Distribution of SB Occlusion Across Different Risk Groups

	Low-Risk Group (Quartile I)	Intermediate-Risk Group (Quartile II + III)	High-Risk Group (Quartile IV)	p Value
Range	0-2	3-9	≥10	
SB occlusion rate in training dataset (n = 1,200)	1/98 (1.0)	29/770 (3.8)	58/332 (17.5)	<0.001
SB occlusion rate in validation dataset (n = 401)	0/47 (0)	9/239 (3.8)	21/85 (19.8)	<0.001

Gao, MD,*

the
sed

A multivariable risk score (RESOLVE [Risk prEdiction of Side branch Occlusion in coronary bifurcation interVENTion]) was constructed with incremental weights attributed to each component variable according to its estimated coefficients.

TABLE 4 Scores Attributed to Each Variable

Risk Factor	Level	Point
Plaque distribution	At the opposite side of SB	0
	At the same side of SB	1
MV TIMI flow grade before stenting	TIMI 3	0
	TIMI 2	6
	TIMI 1	11
	TIMI 0	17
Pre-procedural diameter stenosis of bifurcation core (%)	<50	0
	50- $<$ 70	2
	≥70	3
Bifurcation angle (°)	<70	0
	70- $<$ 90	4
	≥90	6
Diameter ratio between MV/SB	<1.0	0
	1.0- $<$ 1.5	2
	1.5- $<$ 2.0	6
	≥2.0	9
Diameter stenosis of SB before MV stenting (%)	<50	0
	50- $<$ 70	4
	70- $<$ 90	6
	≥90	7

Conclusion

S



Two-stent cases

- If I do 300 cases per year and...
- 15% of cases are bifurcations...
- 10% are for >2.5mm diameter >5mm length

- 4 cases per year

“There is nothing more likely to go wrong than a complicated bifurcation strategy undertaken as something of a novelty”

DHS, EBC 2008-15

for large
e disease?

Is, UK



September 2015

Conclusion S

*
Comment:

...which probably goes into a complication if you do it four times a year.

For a skill-requiring procedure (culotte, DK-crush, dedicated stents, etc.) we could be a little more liberal with the indications.

This approach might be granted in the future with a safe and successful two-stent PCI when it is really necessary.



Use the provisional approach

- It will be faster, simpler, easier
- It will use less contrast
- It will use less radiation

- AND..
- When you do need to, you can still put in that second stent if necessary*

Technique	Advantage	Disadvantage
Culotte	Homogenous drug and metal distribution Suitable for wide angle bifurcations	Double metal layer at proximal MB Not suitable if the diameter of prox. MB>>>SB Need to rewire of MB for FKB
Mini crush	Facilitated SB re-access	Crossing through double stent layers at SB rewiring Not suitable for wide angle
Step crush	6 F compatible Facilitated SB re-access	Need to rewire the SB for FKB Not suitable for wide angle
DK crush	Less stent distortion Improved stent apposition	Time-consuming complex procedural steps
T/TAP	Suitable for wide angle bifurcations Easy FKB	Not suitable for shallow angle bifurcations Protrusion of the stent into the MB
V	No unnecessary coverage of the prox. MB No need of SB reopening Both branch patency during the procedure	≥7 F guiding necessary Risk of proximal MB dissection Not suitable if plaque in the prox. MB
SKS	Suitable for large prox. MB No need of SB reopening Both branch patency during the procedure	≥7 F guiding necessary Unnecessary double barrel in the prox. MB (LM) Difficult reintervention in the future (neocarina)