

What We have Learned from Long-Term NORDIC-BALTIC Studies



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Disclosure Statement of Financial Interest

I, *Indulis Kumsars*, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

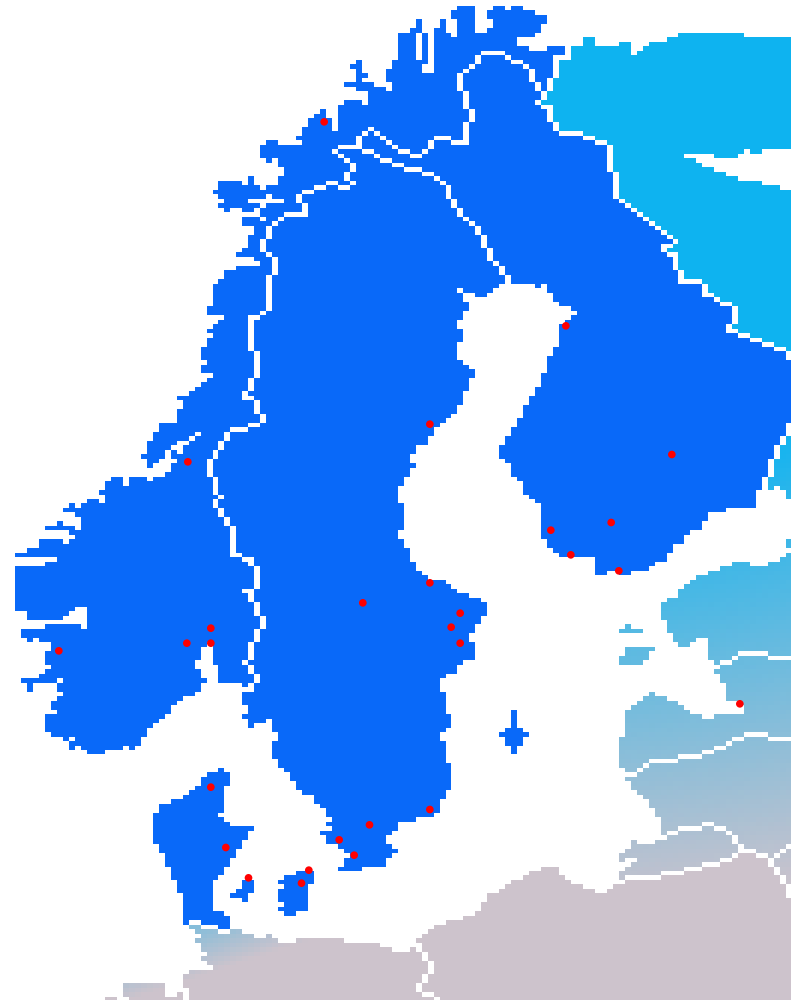
The Nordic-Baltic Bifurcation Studies were an academic studies primarily funded by participating hospitals.

The participating institutions received unrestricted study grants form Cordis and Abbot.

Nordic-Baltic Bifurcation Studies

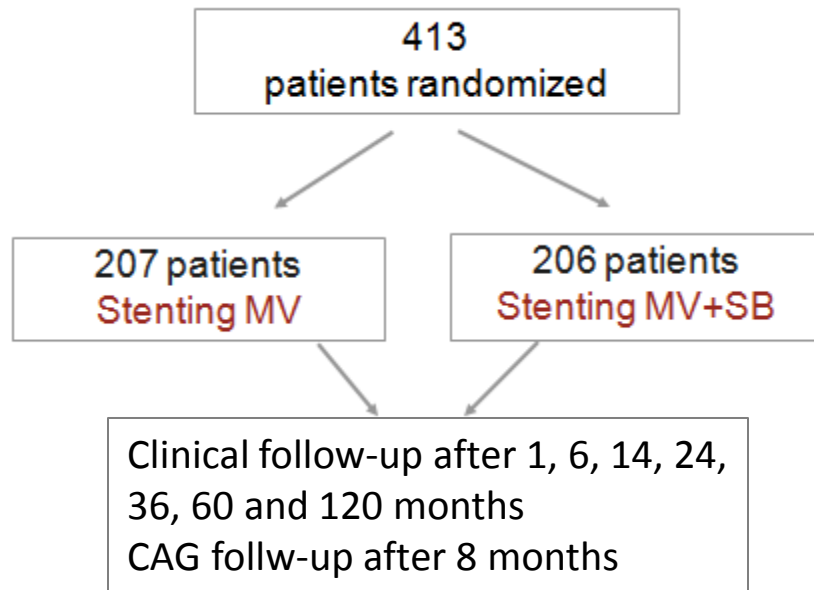
Prospective, multicenter, large-scale randomized trials

- **Nordic-Baltic I**
1 vs 2 stents
- **Nordic-Baltic II**
Crush vs Culotte stenting
- **Nordic-Baltic III**
+/- kissing balloon post dilatation
after MV stenting
- **Nordic-Baltic IV**
1 vs 2 stents in true bifurcations
with large SB

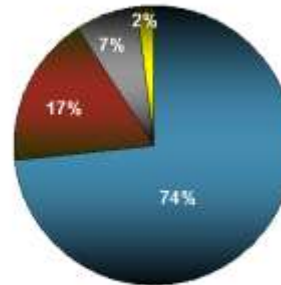


NORDIC I

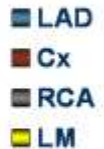
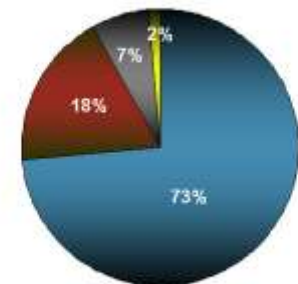
Nordic Bifurcation Study (NORDIC I): the randomized study on simple versus complex stenting of coronary artery bifurcation lesions



MV (n=207)



MV+SB (n=206)



True bifurcations 71%
(DS>50% in MV and SB)

Nordic I

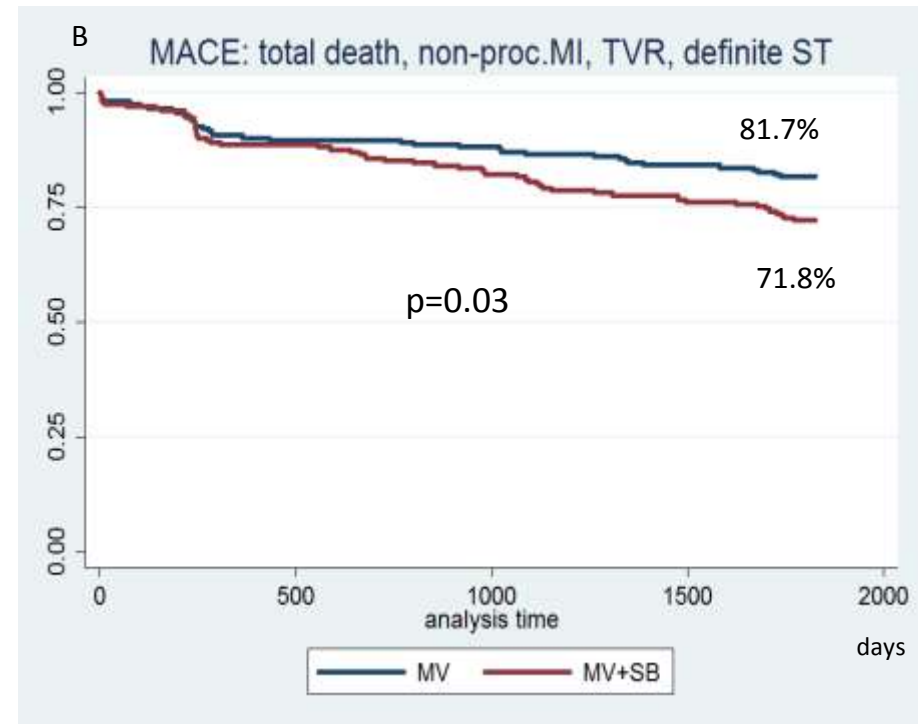
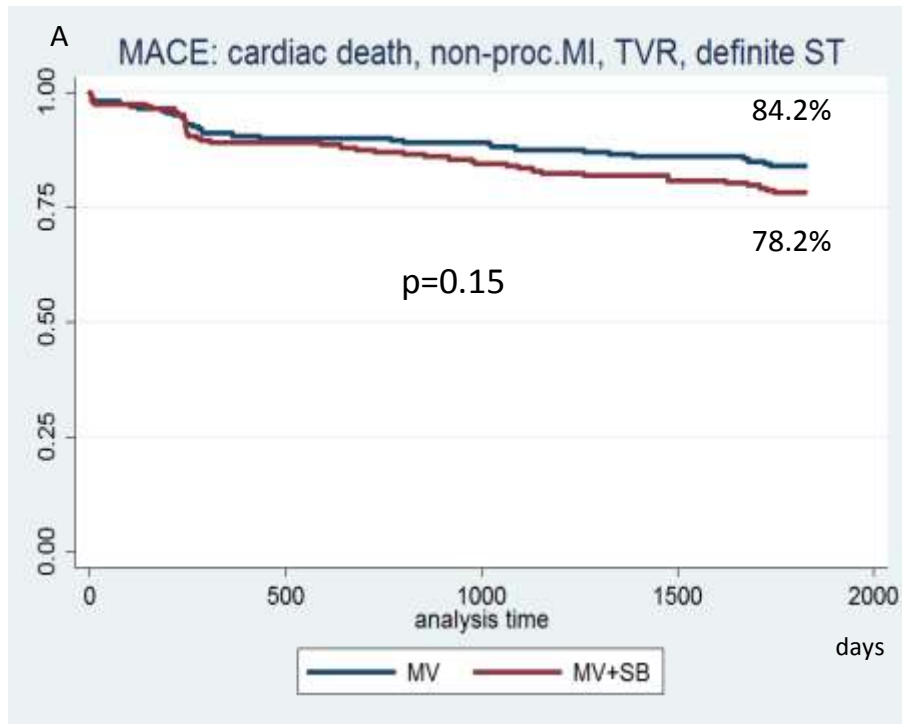
Procedure data

Procedural Characteristics	MV n=207	MV+SB n=206	P value
MV stented	206 (99.5)	203 (98.5)	0.31
SB stented	9 (4.3)	196(95.1)	<0.0001
No. of stents	1.3±0.6	2.2±0.6	<0.0001
Final kissing balloon	65 (32)	152 (74)	<0.0001
Procedural success	200 (97)	194 (94)	0.35
Procedure time, min	62±51	76 ±40	<0.0001
Fluoroscopy time, min	15±9	21±10	<0.0001
Contrast volume, mL	233±93	283±117	<0.0001
Biomarker Elevation	n=153	n=126	P value
>3 elevation (%)	8	18	0.011
>5 elevation (%)	4	13	0.008
>10 elevation (%)	3	5	NS

Clinical end-points at 5-year follow-up (n=404, 98%)

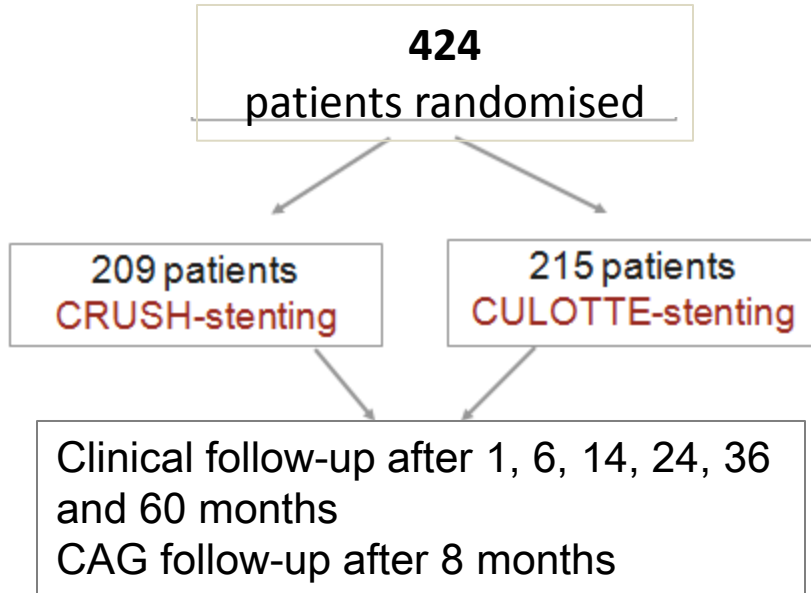
	MV	MV+SB	p
All cause death	5.9 %	10.4 %	0.16
Cardiac death	2.5 %	4.0 %	0.40
Myocardial infarction	4.0 %	7.9 %	0.09
Target lesion revascularization	11.3 %	15.3 %	0.24
Target vessel revascularization	13.4 %	18.3 %	0.14
Target vessel revascularization by CABG	2.0 %	3.5 %	0.38
Definite stent thrombosis	3.0 %	1.5 %	0.32

MACE free survival at 5years follow-up

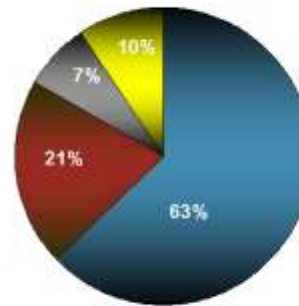


NORDIC II

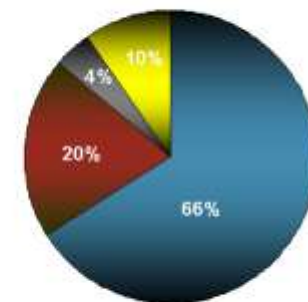
Nordic Stent Technique Study (NORDIC II): the first randomized clinical and angiographic comparison of the crush and the culotte bifurcation stent techniques



Crush (n=209)



Culotte (n=215)



■ LAD
■ Cx
■ RCA
■ LM

**True bifurcations: 73.3% Crush vs. 82.3% Culotte, p=0.03
(Medina classification 1,1,1 - 1,0,1 - 0,1,1)**

Procedure data I

	CRUSH n=209	CULOTTE n=215	p-value
Aspirin Tx (%)	99.0	99.5	ns
Clopidogrel Tx (%)	99.5	100.0	ns
GPIIb/IIIa Tx (%)	46.2	47.2	ns
Bivalirudin Tx (%)	18.1	20.5	ns
Procedure time (min)	74±39	73 ± 28	ns
Fluoro time (min)	22 ± 15	22 ± 14	ns
Contrast (ml)	276 ± 104	283±117	ns

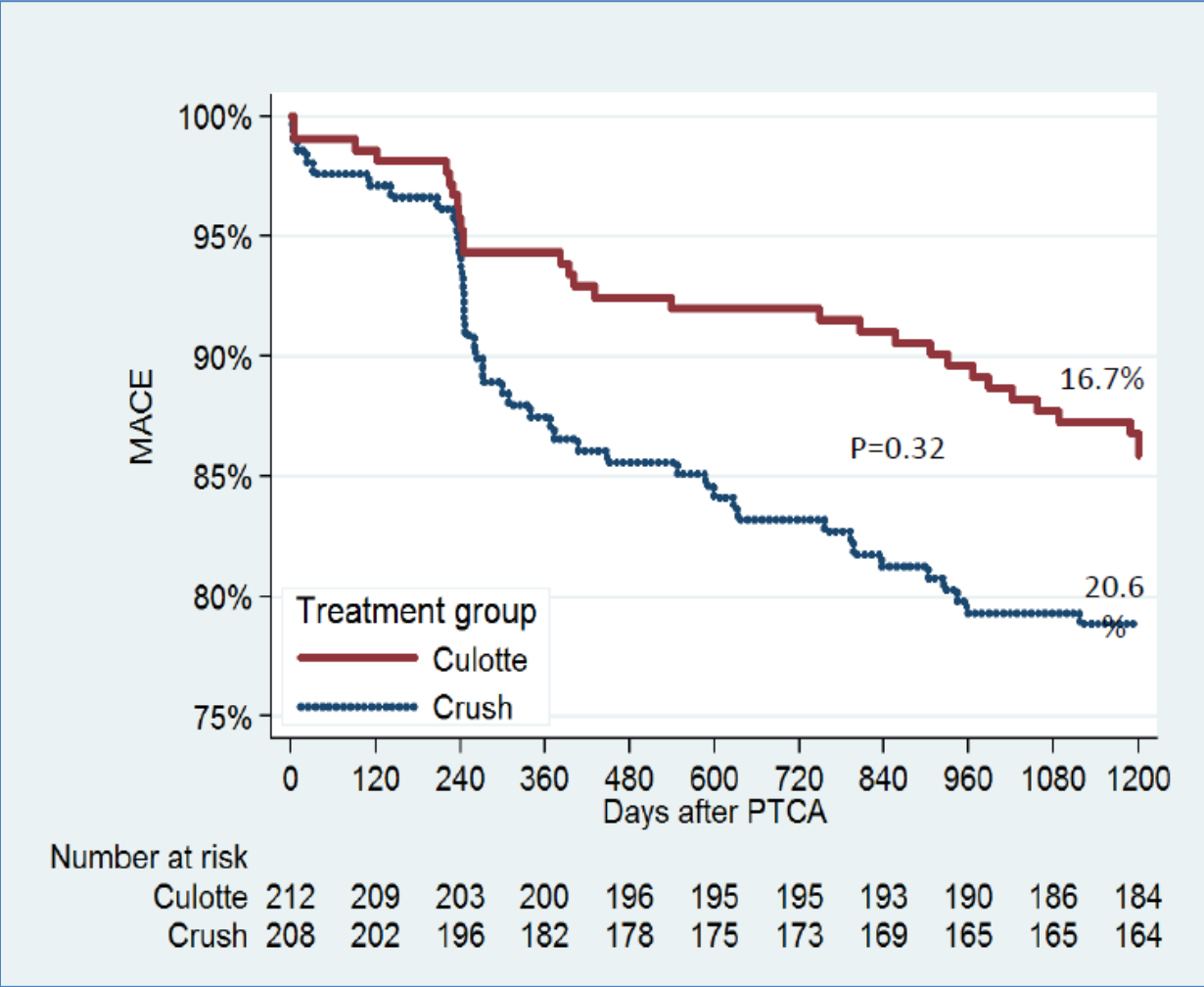
Procedure data

	Crush n = 209	Culotte n = 215	P Value
MV stented, %	99.5	99.1	ns
SB stented, %	98.6	97.7	ns
Final kissing balloon	84.3	91.6	0.02
Tx acc. to ran., %	96.7	96.7	ns
Tx successful, % (residual sten.<30% of MV+TIMI III flow in SB)	97.6	97.7	ns

Endpoints after 3 years

	Crush (n= 209)	Culotte (n= 215)	p-value
Total death (%)	4.8	6.5	0.53
Cardiac death (%)	3.3	3.0	0.54
MI (%)	6.7	6.0	0.84
TLR (%)	6.2	6.1	ns
TVR (%)	12.0	9.8	0.47
Definite ST (%)	1.4	4.7	0.09
Definite, probable and possible ST (%)	5.3	7.9	0.33

MACE free survival at 3years follow-up

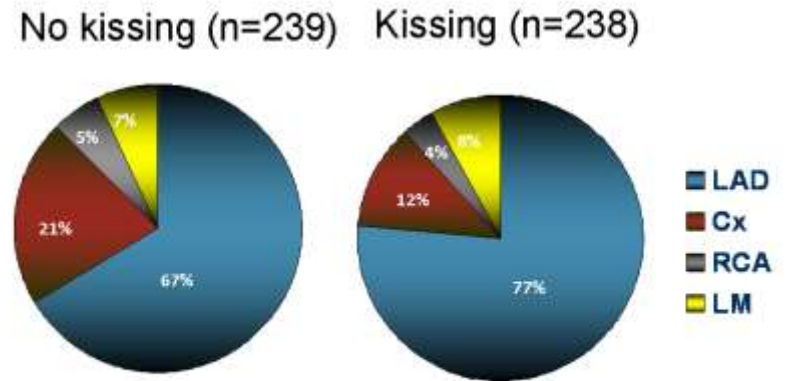
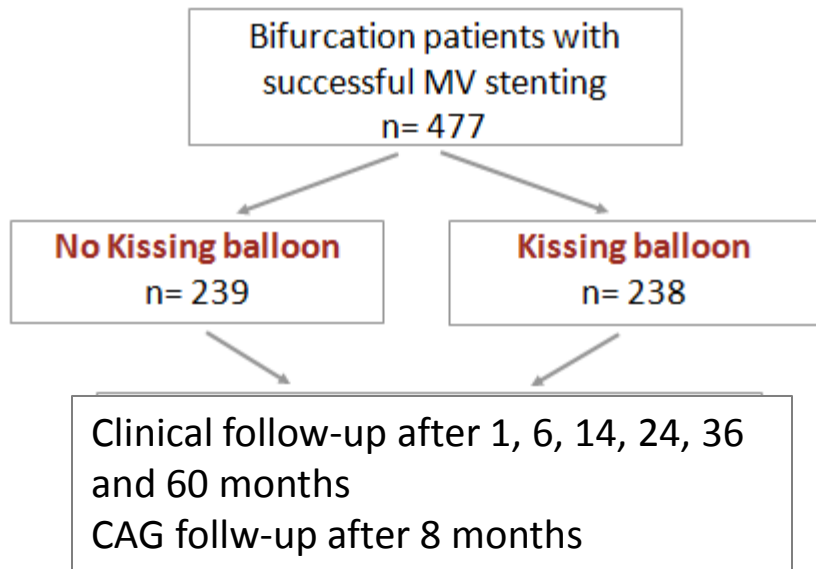


Effect of FKBD on end points

	FKBD+	No-FKBD	P-value
MACE (%)	18	24	0.3
Non-procedural MI (%)	5	18	0.001
Definite ST (%)	2	8	0.04

NORDIC III

Nordic-Baltic Bifurcation Study III: A prospective randomized trial of side branch dilatation strategies in patients with coronary bifurcation lesions undergoing treatment with a single stent



True bifurcations: **50.8%** Kissing vs. **49.0%** No kissing, p=0.71

Medina classification 1,1,1 - 1,0,1 - 0,1,1

Procedure data

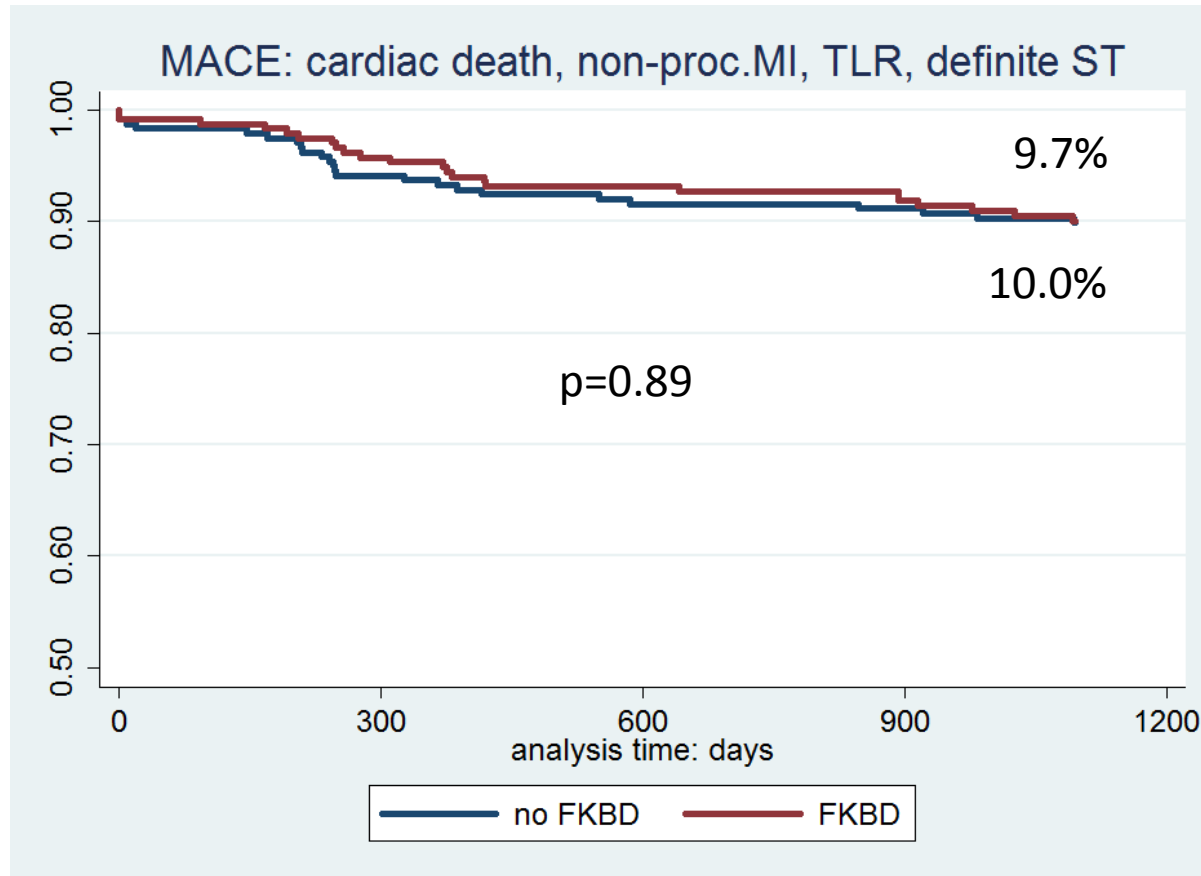
	No FKBD n=239	FKBD n=238	p-value
SB predilatation, (%)	27.6	29.0	0.76
Final Kissing (%)	0.8	97.1	0.0001
SB dilatation thr. MV stent or FKBD	1.7	97.1	0.0001
SB stented, n (%)	0(0)	3 (1.3)	0.12
Tr. successful*, n (%)	236(98,7)	236 (99.2)	ns
Procedure time (min)	47 <u>+ 22</u>	61 <u>+ 28</u>	0.0001
Fluorosc. time (min)	11 <u>+ 10</u>	16 <u>+ 12</u>	0.0001
Contrast (ml)	200 <u>+ 92</u>	235 <u>+ 97</u>	0.0001

*residual stenosis <30% of MV+TIMI III flow in SB

Individual endpoints at 3 years follow-up

	No-FKBD (n=239)	FKBD (n=238)	p-value
Total death (%)	2.1	5.9	0.03
Cardiac death (%)	0.4	2.1	0.10
Non-procedural MI (%)	2.9	2.9	0.99
Stent thrombosis, definite (%)	1.3	0.8	0.65
Target lesion revascularization (%)	8.4	6.3	0.39

MACE free survival at 3 years follow-up



True bifurcation lesions

	No-FKBD (n=118)	FKBD (n=121)	p-value
MACE (%)	12.7	9.1	0.37
MACE total death (%)	14.4	12.4	0.65
Total death (%)	2.5	5.0	0.33
Cardiac death (%)	1.7	0.9	0.58
Non-procedural MI (%)	4.2	4.1	0.97
Stent thrombosis, definite (%)	1.7	0.8	0.55
Target lesion revascularization (%)	10.2	5.8	0.21



Randomized Comparison of Provisional Side Branch Stenting versus a Two-stent Strategy for treatment of True Coronary Bifurcation Lesions Involving a Large Side Branch.

The Nordic-Baltic Bifurcation Study IV

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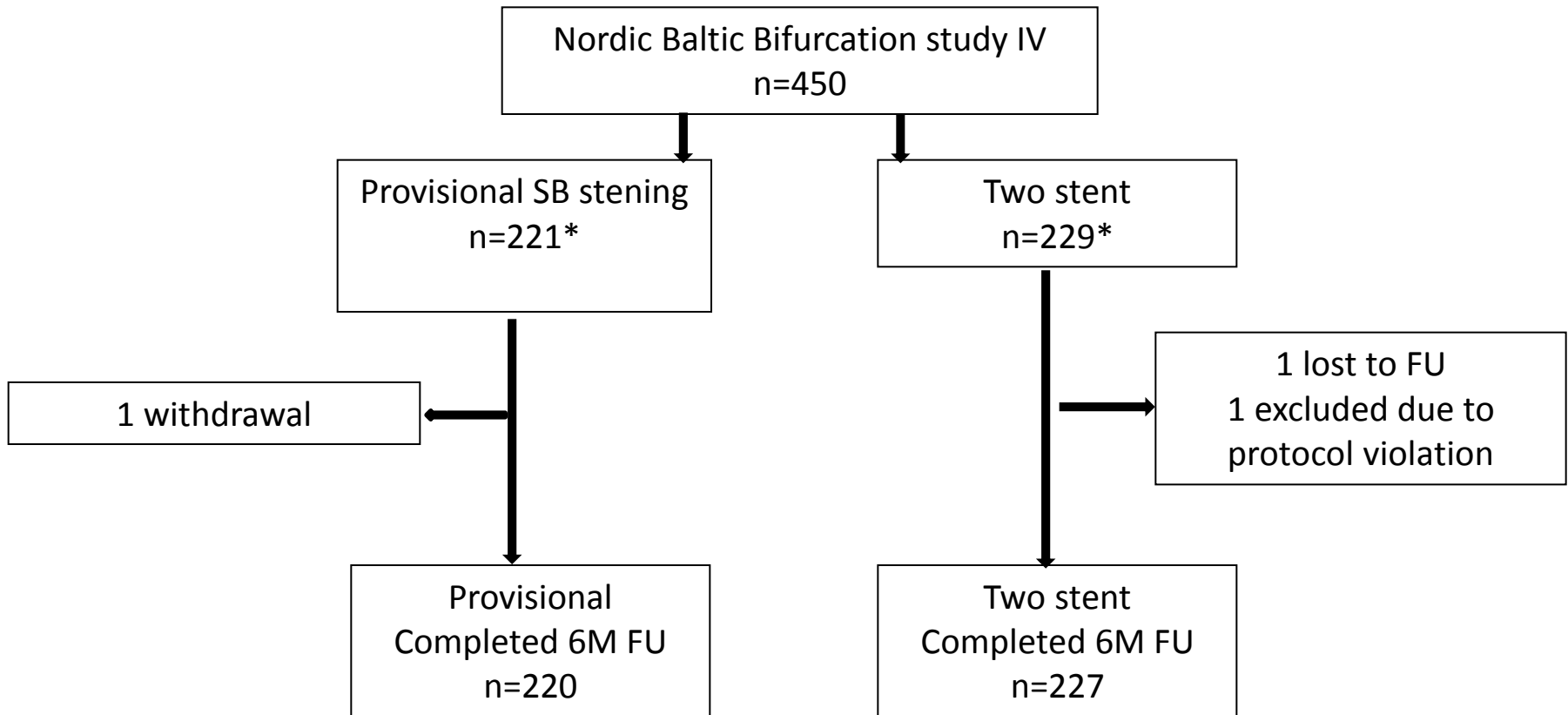
For the Nordic-Baltic PCI Study Group



Aim

- To compare provisional stenting and two-stent techniques for the treatment of **true coronary bifurcation lesions involving a large side branch ($SB \geq 2.75\text{mm}$)**

Patient flowchart



*numbers not balanced due to block randomization and sites with less than 4 inclusions

Procedural data

	Provisional (n=221)	Two-stent (n=229)	p
SB dilatation (%)	64.3	78.0	-
SB dilation or final kissing (%)	78.7	-	-
Final kissing balloon dilatation (%)	36.1	91.2	-
SB stented (%)	3.7	96.0	-
Culotte	-	65.6	-
T-stent	-	7.0	-
Other	-	26.4	-
Tx succesful* (%)	97.7	99.1	ns

* (Residual stenosis <30% of MV + TIMI flow III in SB)



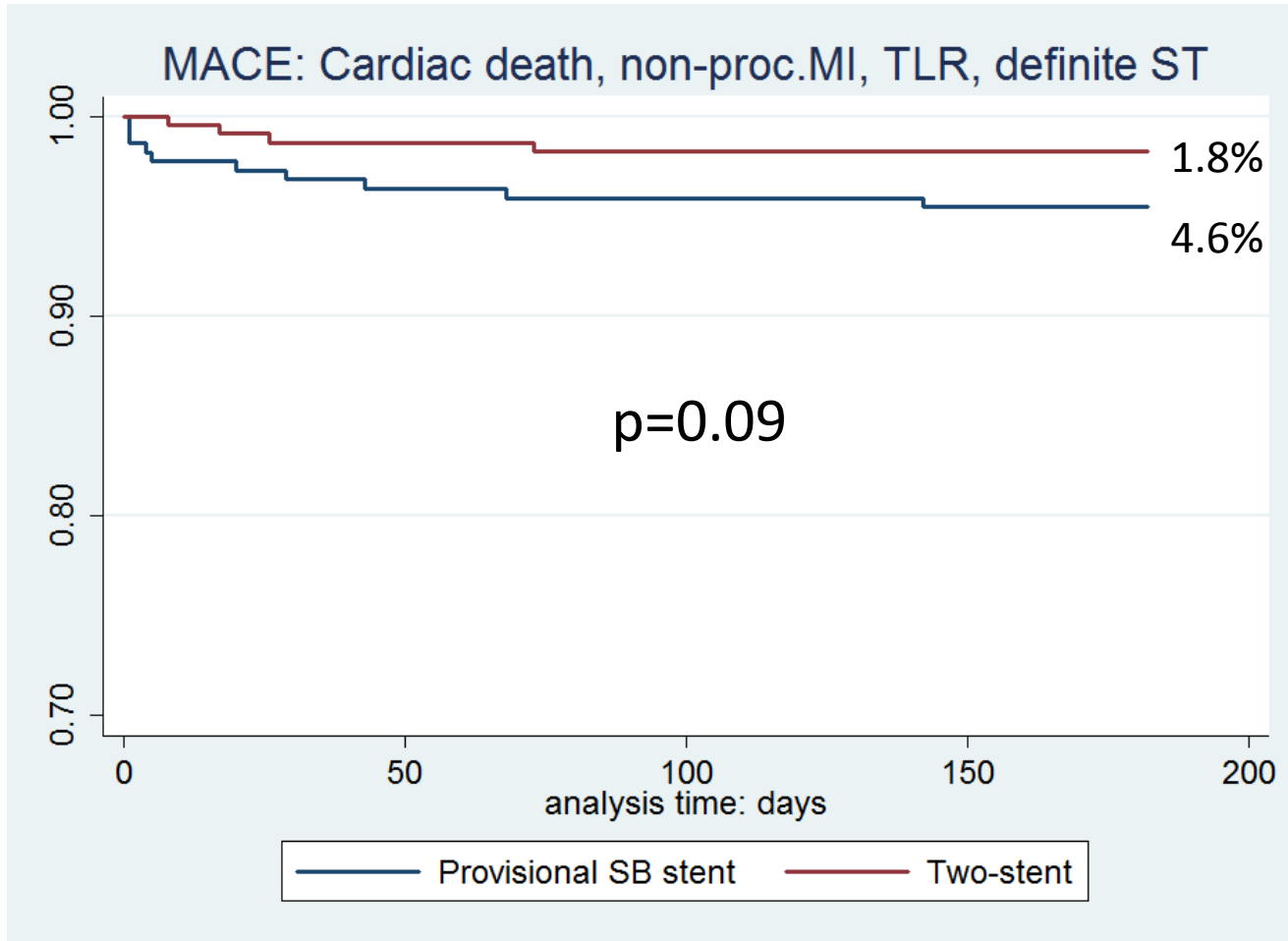
Procedural data

	Provisional (n=221)	Two-stent (n=229)	p
Procedure time (min)	73.9	92.6	<0.0001
Contrast volume (mL)	187	238	<0.0001
Flouroscopy time (min)	14.0	22.8	<0.0001
Tx succesful* (%)	97.7	99.1	ns
Procedural CK-MB>5x UPL** (%)	3.0	3.1	ns
Procedural CK-MB>3x UPL** (%)	6.0	6.1	ns

* Residual stenosis <30% of MV + TIMI flow III in SB

** Assessment possible in 327 patients

MACE free survival at 6 months



Individual endpoints at 6 months

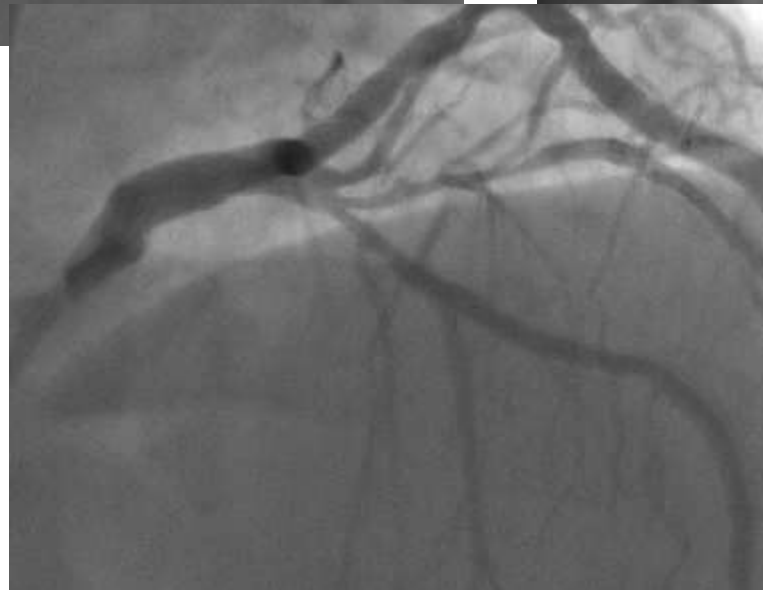
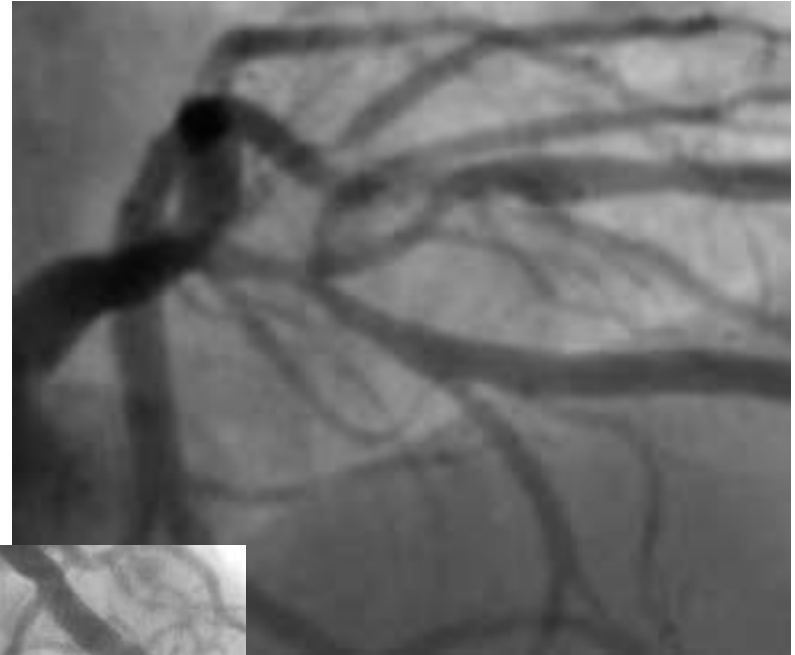
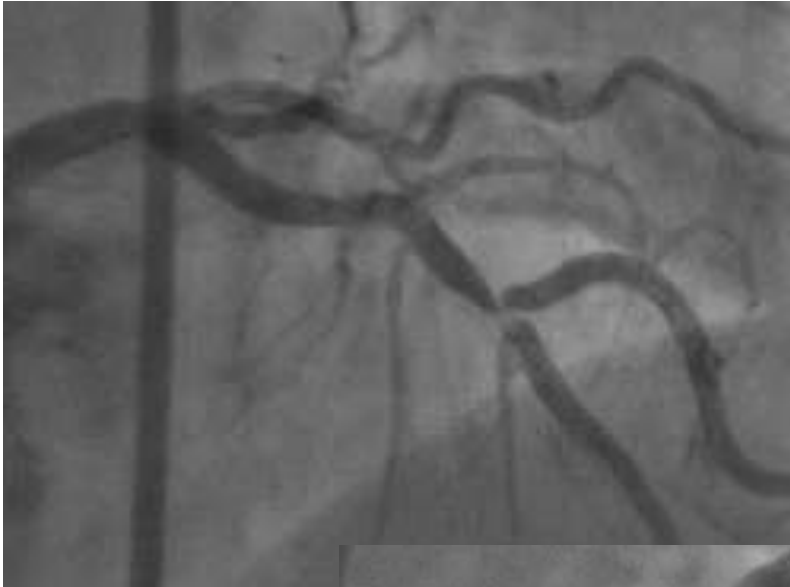
	Provisional (n=220)	Two-stent (n=227)	p
Total death (%)	0	0.4	0.32
Cardiac death (%)	0	0	-
Non-procedural myocardial infarction (%)	1.8	0.9	0.50
Stent thrombosis (%)	0.9	0.4	0.54
Target lesion revascularization (%)	3.2	1.3	0.18
Target vessel revascularization (%)	3.7	1.3	0.11
Angina CCS class \geq II	2.7	1.3	0.39

The Nordic-Baltic experience

1. **Keep it simple!** MV stenting without final kissing balloon dilatation may be used in most cases
2. True bifurcations with a large SB may need two stents
3. If you need 2 stents- do it, but do it properly!



Medina 1,1,1 and Medina 1,1,1





Thank You for attention!