



# Overview of the Nordic-Baltic Bifurcation 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.

# Nordic-Baltic Bifurcation Studies

Prospective, multicenter, large-scale randomized trials

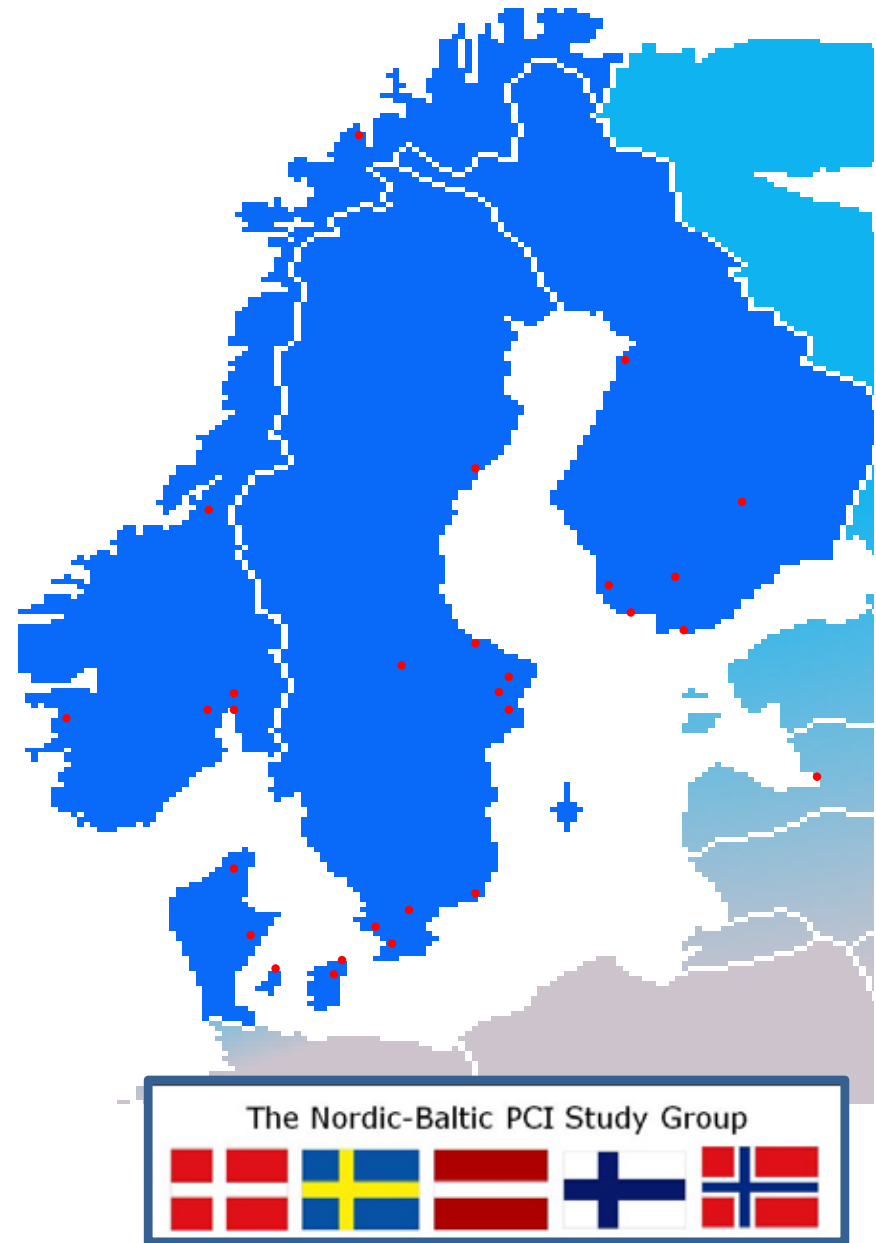
**Nordic Bifurcation Study (NORDIC I):** the randomized study on simple versus complex stenting of coronary artery bifurcation lesions */completed/*

**Nordic Stent Technique Study (NORDIC II):** the first randomized clinical and angiographic comparison of the crush and the culotte bifurcation stent techniques */active, not recruiting/*

**Nordic-Baltic Bifurcation Study III (NORDIC III):** A prospective randomized trial of side branch dilatation strategies in patients with coronary bifurcation lesions undergoing treatment with a single stent */active, not recruiting/*

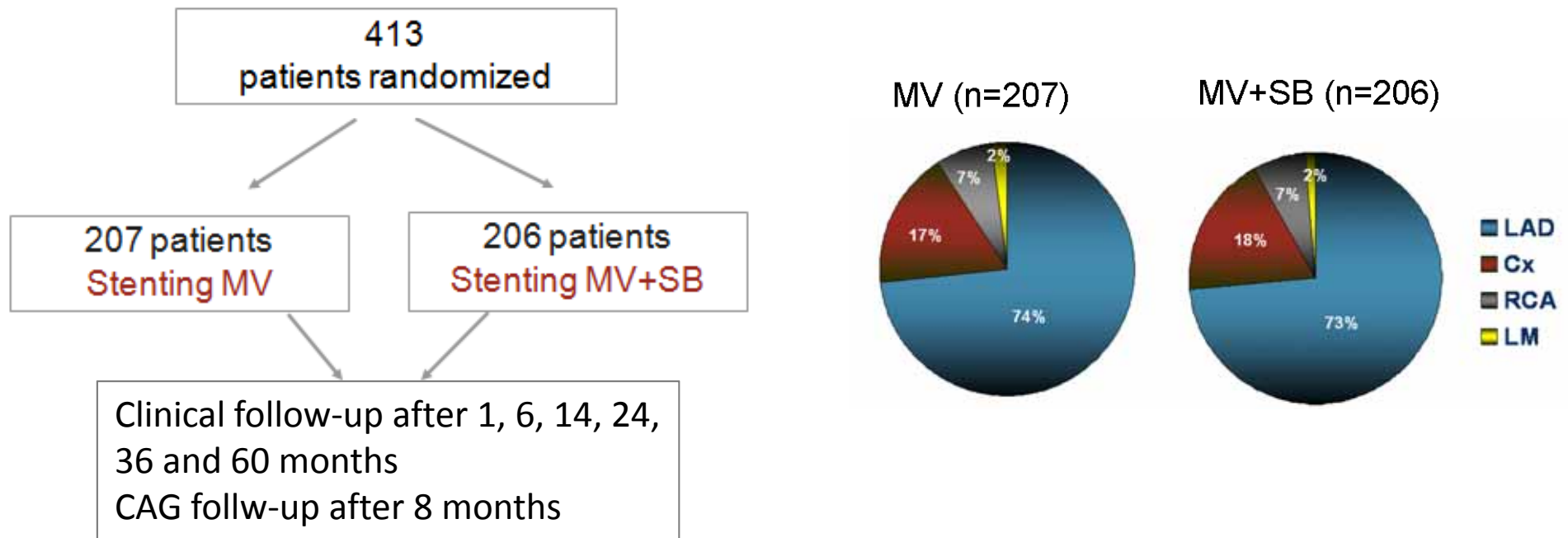
**Nordic-Baltic Bifurcation Study IV (NORDIC IV):** A strategy of stenting both main vessel and side branch compared to a strategy of stenting the main vessel and only stenting the side branch if necessary */active, not recruiting/*

*Nordic-Baltic PCI network*



# NORDIC I

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



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

# Nordic I

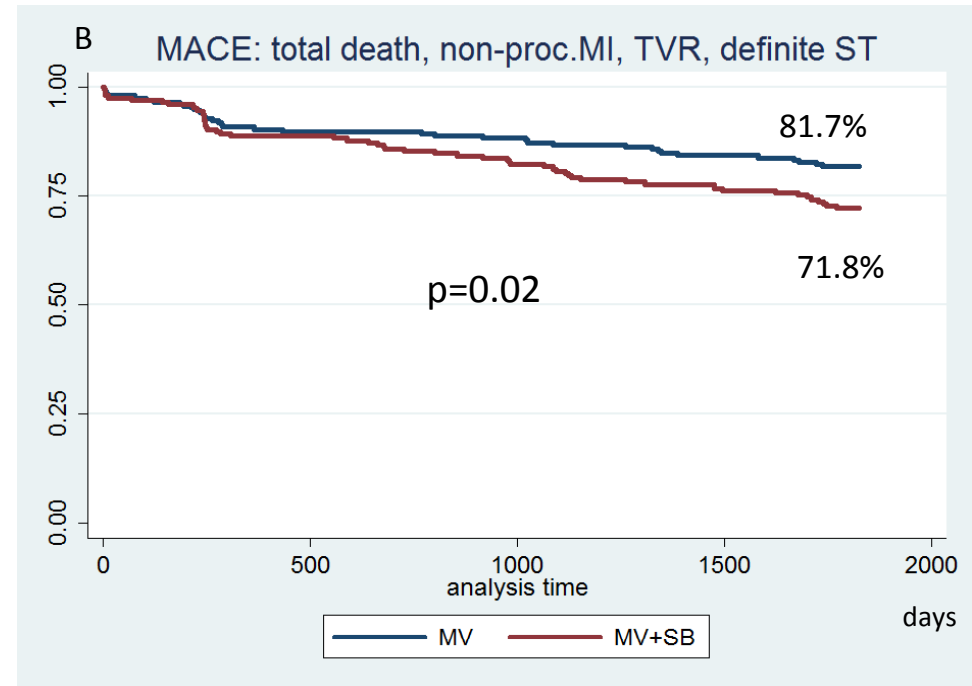
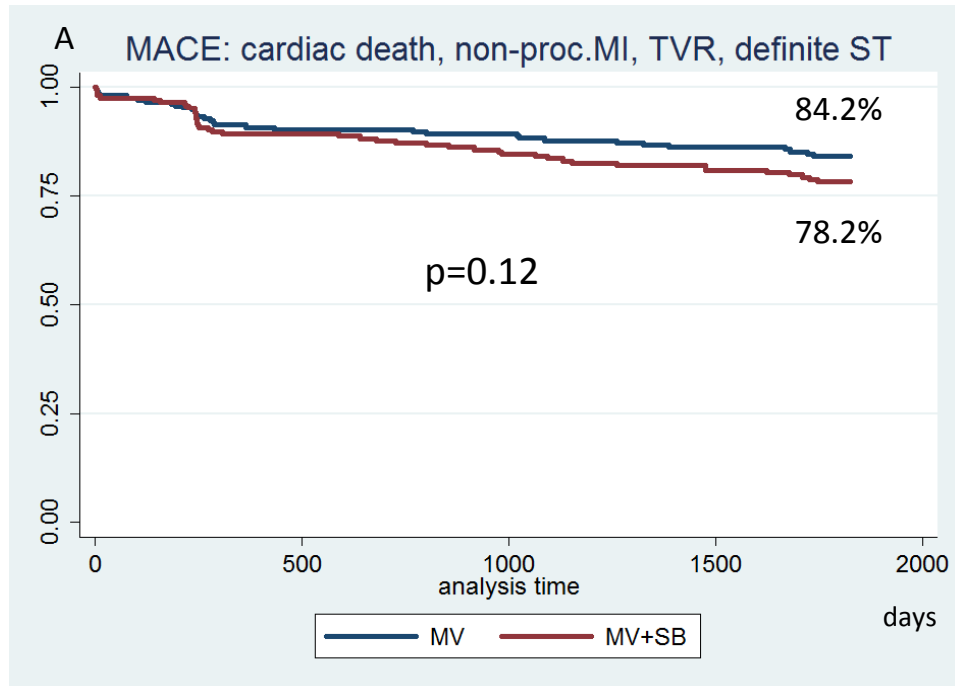
## Procedural Success, Procedure Time and Procedure Related Biomarker Elevation

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
<b>Definite stent thrombosis</b>	<b>3.0 %</b>	<b>1.5 %</b>	<b>0.32</b>

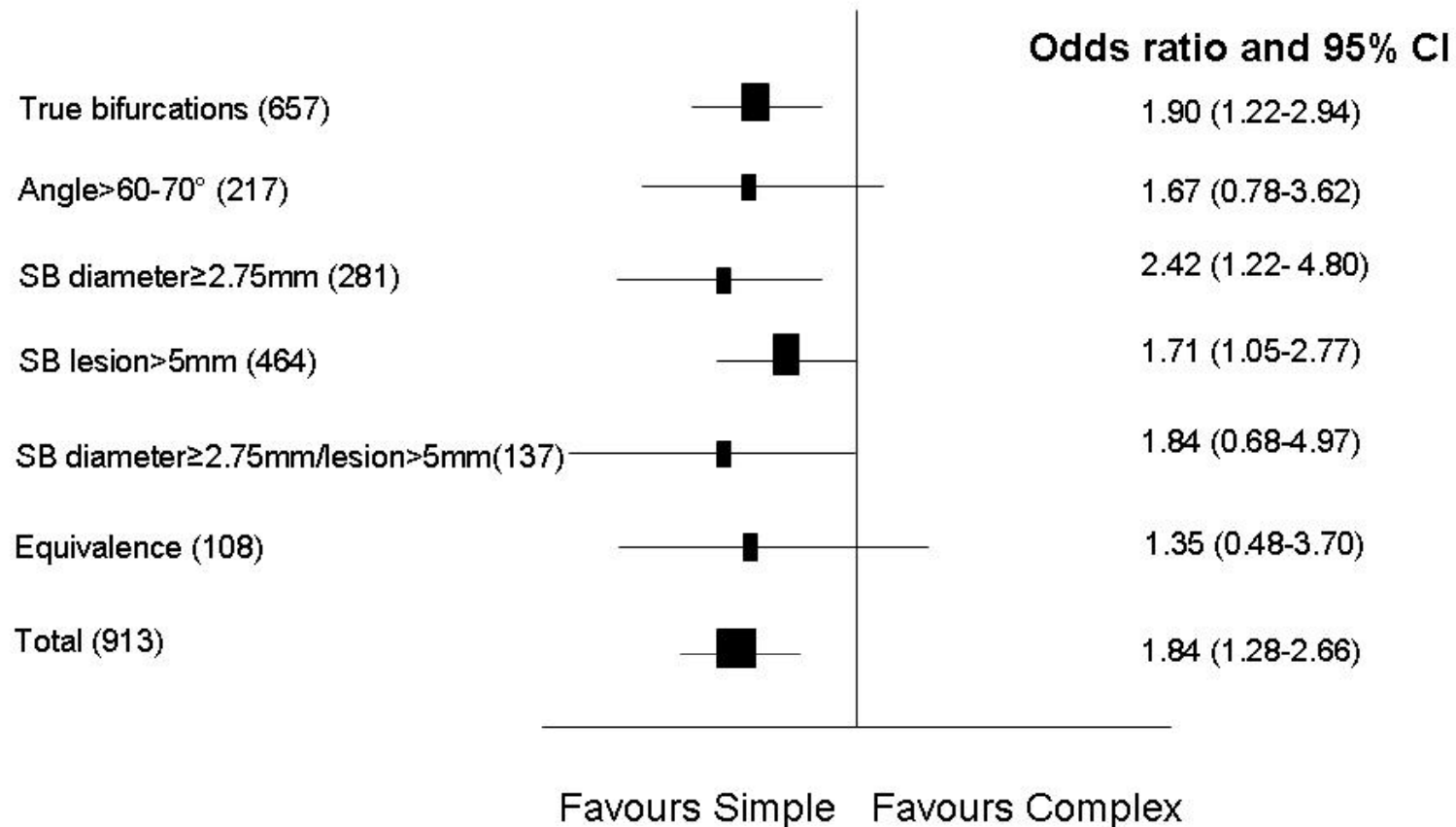
# MACE free survival at 5years follow-up



# NORDIC I + BBC I

## Endpoints in Simplex versus Complex

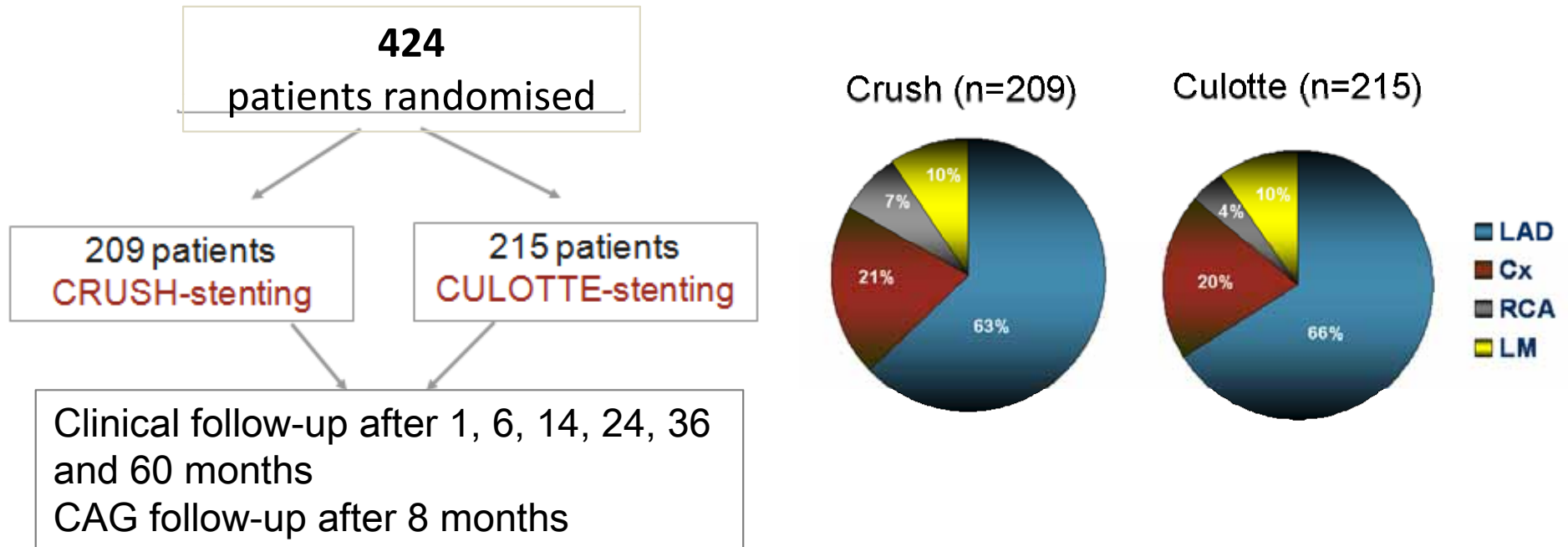
Odds ratio plot of the primary outcome for individual subgroups.





# NORDIC II

***Nordic Stent Technique Study (NORDIC II): the first randomized clinical and angiographic comparison of the crush and the culotte bifurcation stent techniques /active, not recruiting/***



**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

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

# Nordic Stent Technique Study 36 months results

	Crush (n=209)	Culotte (n=215)	p-value
MACE, n (%)	43 (20.6)	36 (16.7)	0.32
All cause death, n (%)	10 (4.8)	14 (6.5)	0.53
Cardiac death, n (%)	7 (3.3)	7 (3.3)	1.00
Non - cardiac death, n (%)	3 (1.4)	7 (3.3)	0.34
MI, n (%)	14 (6.7)	13 (6.0)	0.84
TLR, n (%)	13 (6.2)	13 (6.1)	0.94
TVR	25 (12.0)	21 (9.8)	0.47
Index lesion restenosis, n (%)	24 (11.5)	14 (6.5)	0.09
<b>Definite ST, n (%)</b>	<b>3 (1.4)</b>	<b>10 (4.7)</b>	<b>0.09</b>
Probable ST, n (%)	3 (1.4)	1 (0.5)	0.37
Possible ST, n (%)	5 (2.4)	6 (2.8)	1.00
Definite and probable ST, n (%)	6 (2.9)	11 (5.1)	0.32
Definite, probable, possible ST, n (%)	11 (5.3)	17 (7.9)	0.33

# Final Kissing Balloon in 2 stent strategy (Nordic I, Nordic II, BBC ONE n=811)

- Total MACE Kiss vs. No-Kiss 8,6% vs. 14.2%,  
p=0,04



# Culotte versus Crush Stenting of Left Main Coronary Artery Bifurcation Lesions: 14-month follow-up

Subgroup Analysis of the Randomised Nordic Bifurcation Stent Technique Study

Matti Niemelä, Kari Kervinen, Andrejs Erglis, Indulis Kumsars, Michael Maeng, Jens F Lassen, Pål Gunnes, Sindre Stavnes, Jan S Jensen, Anders Galløe, Inga Narbute, Dace Sondore, Evald Christiansen, Jan Ravkilde, Terje Steigen, Jan Mannsverk, Per Thayssen, Knud Nørregaard Hansen, Kari Virtanen, Steffen Helqvist, Saila Vikman, Rune Wiseth, Jens Aarøe, Leif Thuesen

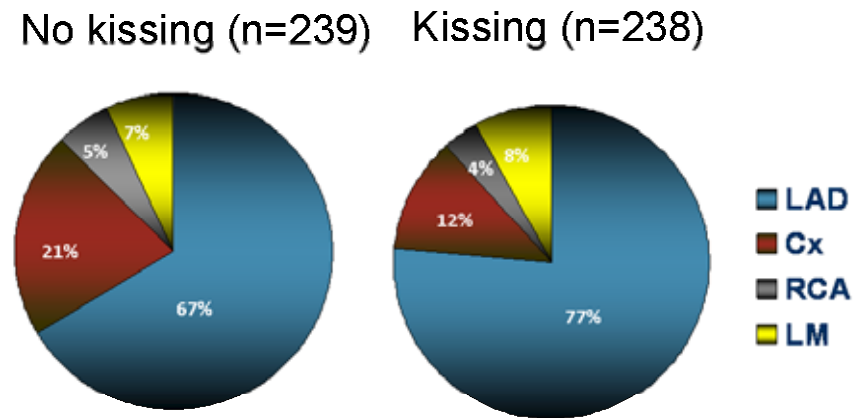
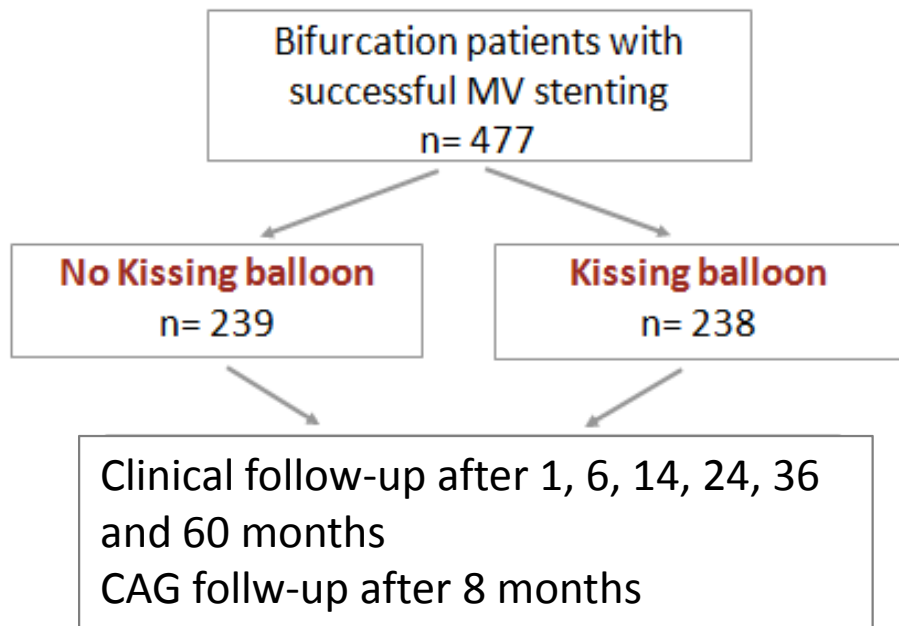
## LM bifurcation lesion stenting 36 months results

	Crush (n=20) n(%)	Culotte (n=21) n(%)	p-value
All cause death	1 (5)	1 (4.8)	0.51
Cardiac death	1 (5)	0 (0)	0.49
MI	2 (10)	0 (0)	0.14
TLR	7 (35)	2 (9.5)	0.049
TVR	7 (35)	2 (9.5)	0.049
ST	1 (5)	0 (0)	0.49
<b>MACE</b>	<b>8 (40)</b>	<b>3 (14)</b>	<b>0.01</b>

\* K. Karvinen et. all in press

# 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



# Background

- The provisional SB stenting strategy has emerged the preferred bifurcation treatment strategy
- Whether routine Final Kissing Balloon Dilatation (FKBD) after MV stenting improves clinical and angiographic outcome is less well known

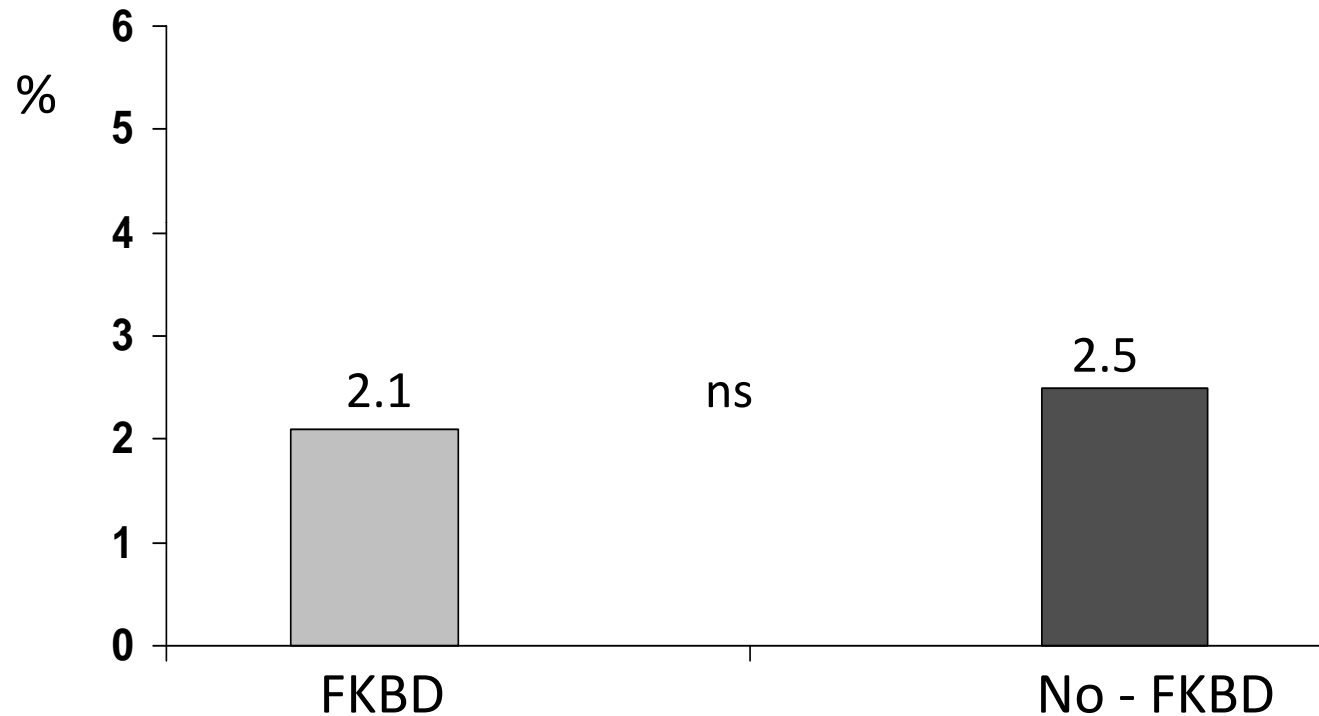
# Procedure data

	<b>No FKBD</b> n=239	<b>FKBD</b> n=238	<b>p-value</b>
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
<b>Procedure time (min)</b>	<b>47 <u>+22</u></b>	<b>61 <u>+28</u></b>	<b>0.0001</b>
<b>Fluorosc. time (min)</b>	<b>11 <u>+10</u></b>	<b>16 <u>+12</u></b>	<b>0.0001</b>
<b>Contrast (ml)</b>	<b>200 <u>+92</u></b>	<b>235 <u>+97</u></b>	<b>0.0001</b>

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

# Primary composite end point of MACE (cardiac death, index lesion MI, TLR, stent thrombosis)

after 6 months



# *Nordic III*

## Routine Final Kissing in 1 Stent Strategy

### Angiographic Restenosis

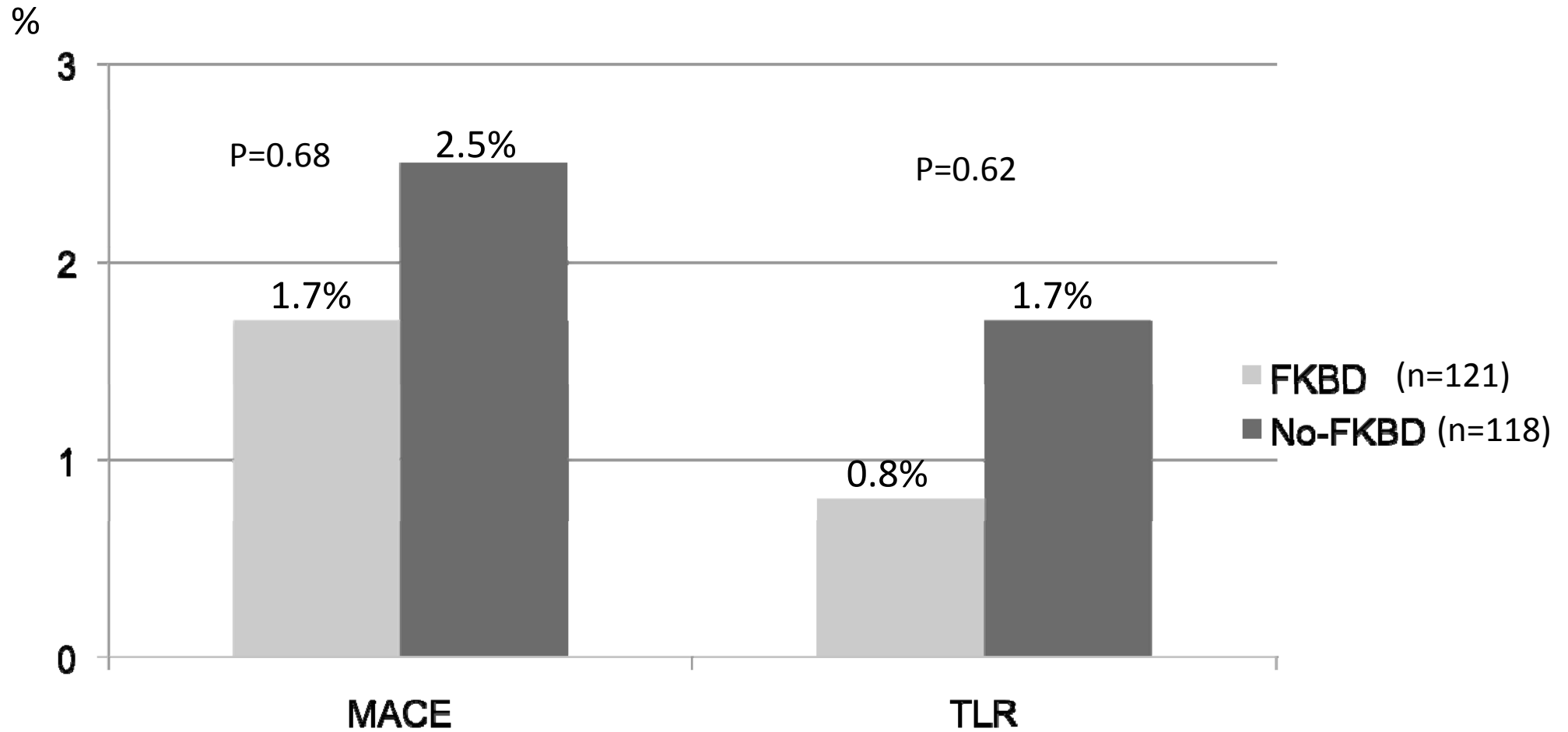
Variable	True Bifurcation Subgroup			Nontrue Bifurcation Subgroup		
	FKBD (n=92)	No FKBD (n=80)	<i>P</i>	FKBD (n=72)	No FKBD (n=82)	<i>P</i>
In-segment MV						
DS, %	22±15	22±15	0.85	22±14	21±12	0.90
≥50% DS, n (%)	3 (3.8)	2 (2.2)	0.67	3 (4.2)	1 (1.2)	0.34
Ostial 5 mm of the SB						
MLD, mm	1.71±0.42	1.50±0.53	0.005	1.79±0.54	1.77±0.61	0.79
DS, %	25±14	32±21	0.009	23±15	27±19	0.21
≥50% DS, n (%)	7 (7.6)	16 (20)	0.024	6 (8.3)	9 (11)	0.79

DS indicates diameter stenosis; MLD, minimal luminal diameter. The Fisher exact test,  $\chi^2$  test, or independent-samples *t* test was used.

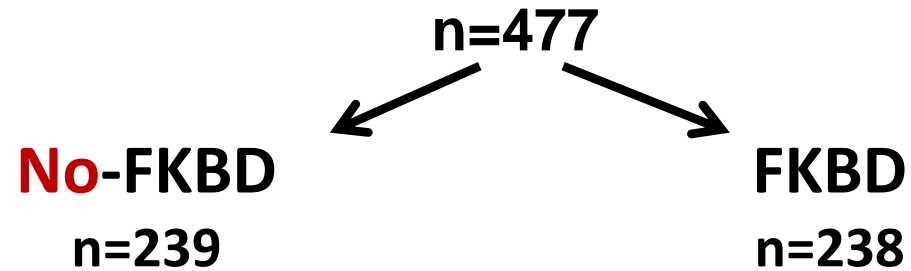
FKBD reduced angiographic side branch (re)stenosis, especially in patients with true bifurcation lesions

# True bifurcation subgroup

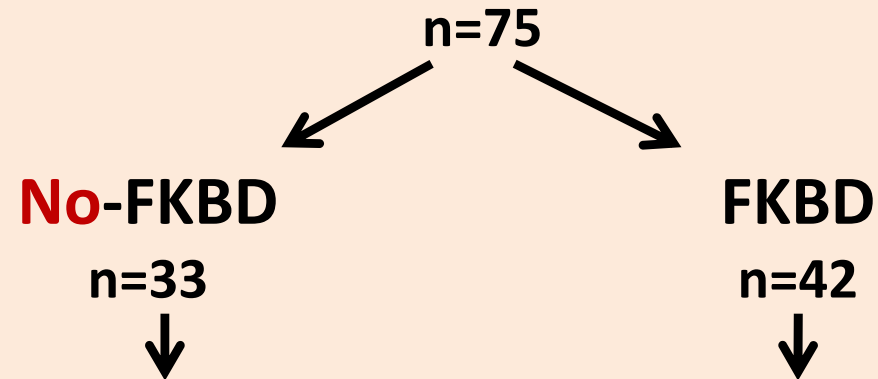
## MACE and TLR at 6 month clinical FU



# Nordic-Baltic III



## SB FFR Substudy



*8-month  
follow-up*

Angiographic (n=33)  
FFR (n=21)

Angiographic (n=42)  
FFR (n=25)

# Objectives

- To compare FFR and QCA data of the SB after MV stenting
- To evaluate the effect of FKBD on SB FFR data
- Consistency of SB FFR data at 8-month follow-up

# Conclusions

## FFR substudy

- In the FKBD group, the SB FFR post PCI was significantly increased as compared to the no-FKBD group. No difference was detectable at follow-up
- No significant changes in mean SB FFR during follow-up in both treatment groups
- Angiography overestimated the functional severity of SB lesions after MB stenting



# Nordic-Baltic Bifurcation Study IV

simple vs. complex

n=450

- **Inclusion criteria:**

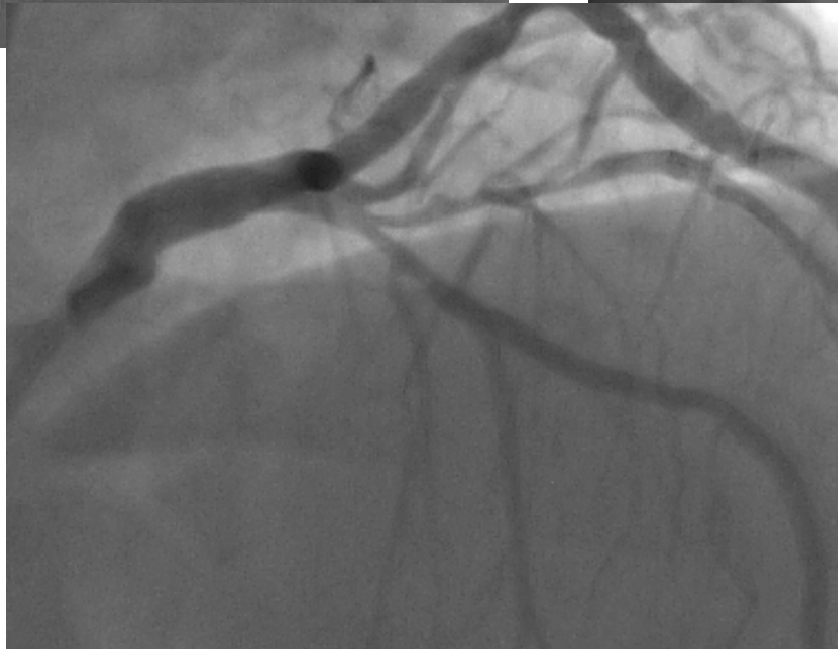
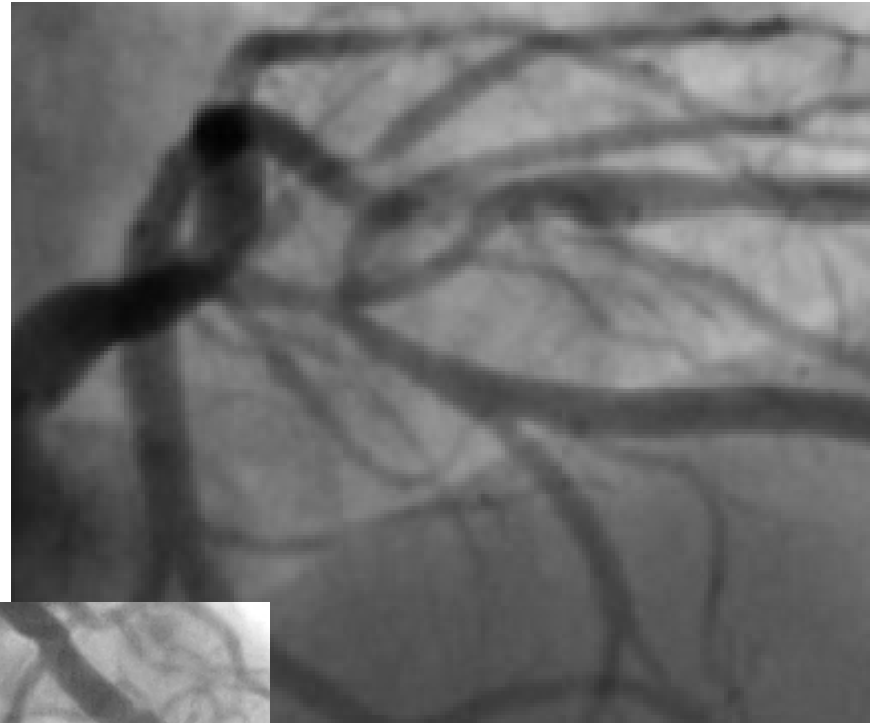
- Genuine bifurcation lesion (Medina type 1,1,1 or 1,0,1 or 0,1,1)
- MV by visual estimate  $\geq 3.0\text{mm}$
- SB by visual estimate  $\geq 2.75\text{mm}$

- **Exclusion criteria:**

- ST elevation infarction within 24 hours
- SB lesion length  $\geq 15\text{mm}$

Enrollment finished at December, 2012

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



# Conclusions:

## Keep It Simple!

- The technique of stenting of MV and optional stenting of SB can be recommended as the routine bifurcation stenting technique
- A strategy of routine kissing balloon dilatation of SB through the MV stent does not improve the 6-month clinical outcome, although FKBD may reduce angiographic SB (re)stenosis, especially in patients with true bifurcation lesions
- Angiography overestimate the functional severity of SB lesion after MV stenting
- If you need 2 stents- do it, but do it properly!



Thank You for attention!