

Insight from Nordic III

**Fifth European Bifurcation Club Meeting
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European Bifurcation Club



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Nordic-Baltic Bifurcation Study III

Participating Centers

Denmark

Aarhus University Hospital	(81 pts)
Odense University Hospital	(17 pts)
Aalborg University Hospital	(7 pts)
Rigshospitalet Copenhagen	(2 pts)

Latvia

Paul Stradins Hospital, Riga	(71 pts)
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Sweden

Örebro Hospital	(10 pts)
Uppsala University Hospital	(1 pt)
Falun Hospital	(1 pt)

Finland

Oulu University Hospital	(149 pts)
Tampere University Hospital	(24 pts)
Turku University Hospital	(13 pts)
Kajaani Central Hospital	(12 pts)
Rovaniemi Central Hospital	(5 pts)
Kemi Central Hospital	(1 pt)
Kuopio University Hospital	(1 pt)

Norway

Feiring Heart Clinic	(33 pts)
Tromsø University Hospital	(32 pts)
Rikshospitalet	(13 pts)

EuroIntervention

Percutaneous coronary intervention of bifurcation lesions: state-of-the-art. Insights from the second meeting of the European Bifurcation Club

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WHAT IS STILL DEBATED:

- A validated software for QCA of bifurcations is still being waited for.
- An accurate evaluation of the functional significance of ostial SB stenosis is necessary.
- Should we do systematic kissing balloon inflation?
- Are DES really more thrombogenic? If yes, how to reduce the risk?
- What is the future of dedicated bifurcation devices?
- The optimal strategy for the treatment of distal left main bifurcation is under development, clinical trials and registries will help to define it.



Background

- In coronary bifurcation lesions, stenting of the main vessel and optional stenting of the side branch is the preferred bifurcation stenting strategy
- In the simple one-stent technique, the indication for mandatory kissing balloon post dilatation is unsettled



Purpose

In a randomized clinical trial, to compare outcome of two different side-branch strategies in coronary bifurcation lesions treated with main vessel stenting using sirolimus eluting stents

- *No kissing balloon postdilatation*
- *Kissing balloon postdilatation*



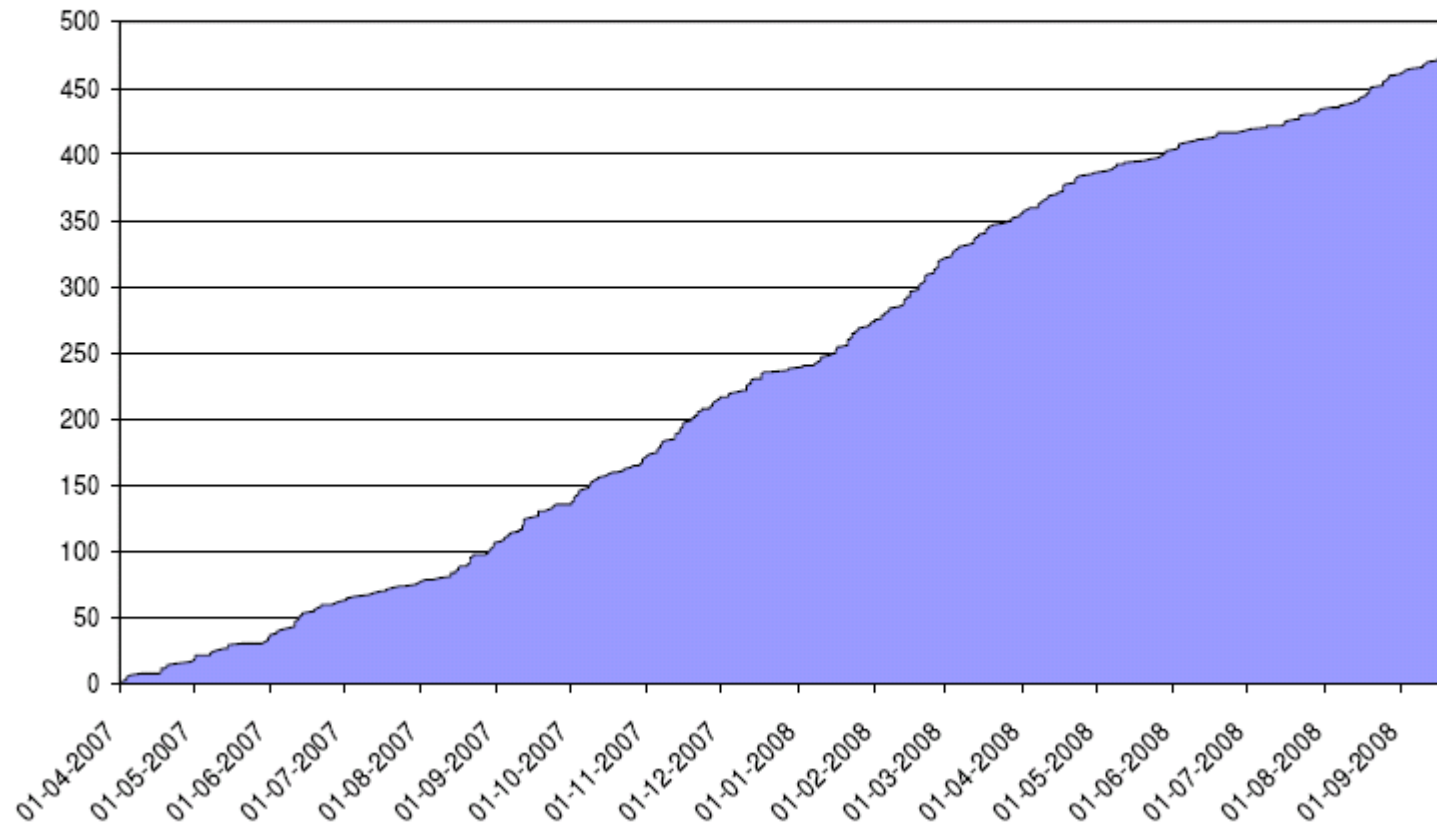
NORD-BIF III “Nordic kiss” main branch stenting only versus main branch stenting and final kissing balloon

- N = 450, MV > 2.5 mm, SB > 2.25 mm
- 1 and 6 month clinical- and 8 month angiographic follow up.
- 14, 24, 36 and 60 month safety follow up
- Inclusion from April 1, 2007.
- Inclusion finalized September 23, 2008



NORD-BIF III “Nordic kiss”

The Nordic Bifurcation Study III





Exclusion criteria

- ST-elevation AMI within 24 hours
- Expected survival < 1 year
- S-creatinine > 200 $\mu\text{mol/L}$
- Allergy to aspirin, clopidogrel, or ticlopidine
- Allergy to sirolimus



Primary Endpoint

At 6 months composite of:

- Cardiac death
- Index lesion myocardial infarction*
- Target lesion revascularisation (TLR)
- Stent thrombosis
 - angiographic confirmation
 - cardiac death

* Non-procedure related



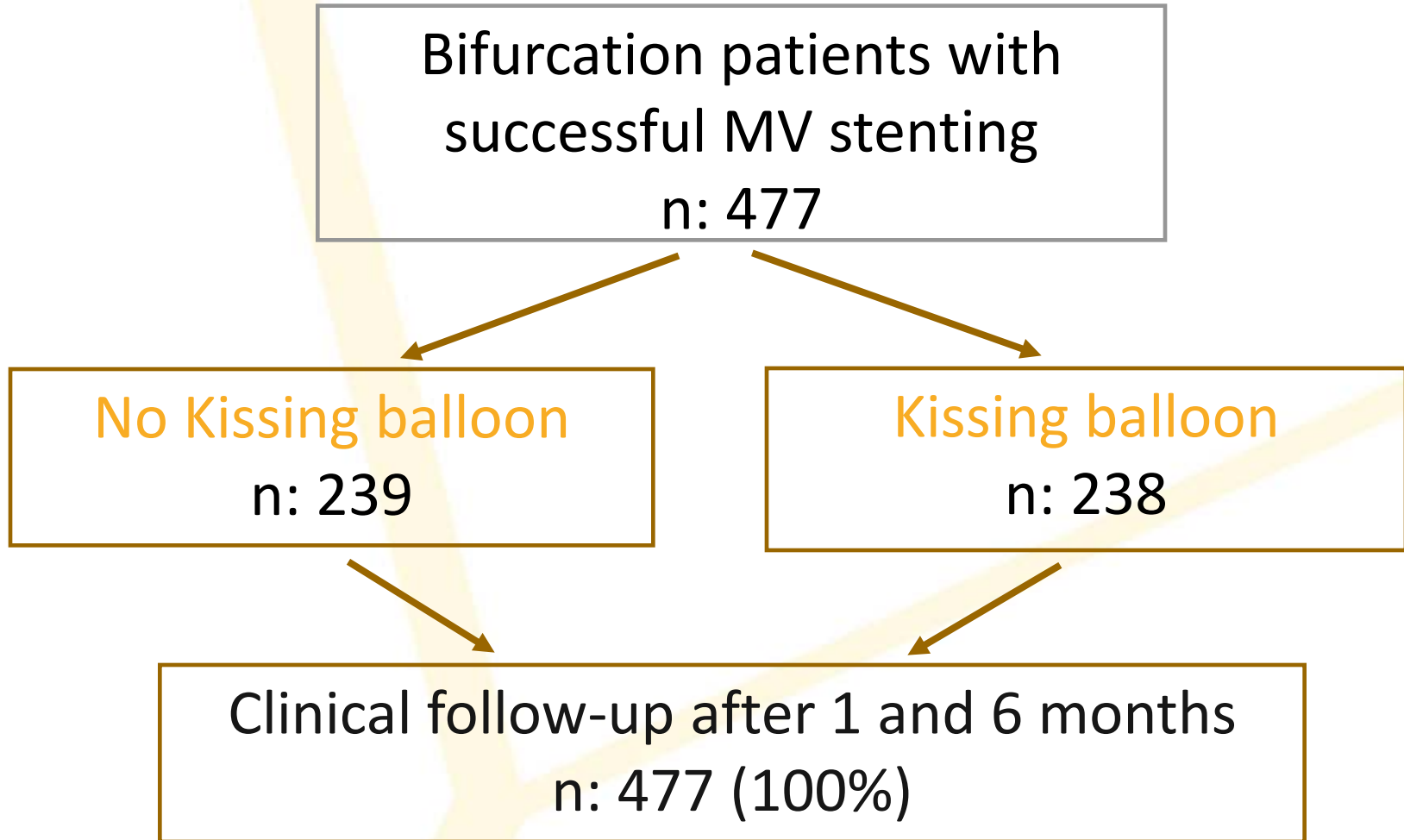
Secondary Endpoints

- Individual endpoints of:
 - Non-cardiac death
 - Cardiac death
 - Myocardial infarction*
 - Stent thrombosis
 - TLR
- Cardiac biomarker release
- CCS-angina score

* Non-procedure related



Randomization





Baseline demographics

No kissing

n=239

Kissing

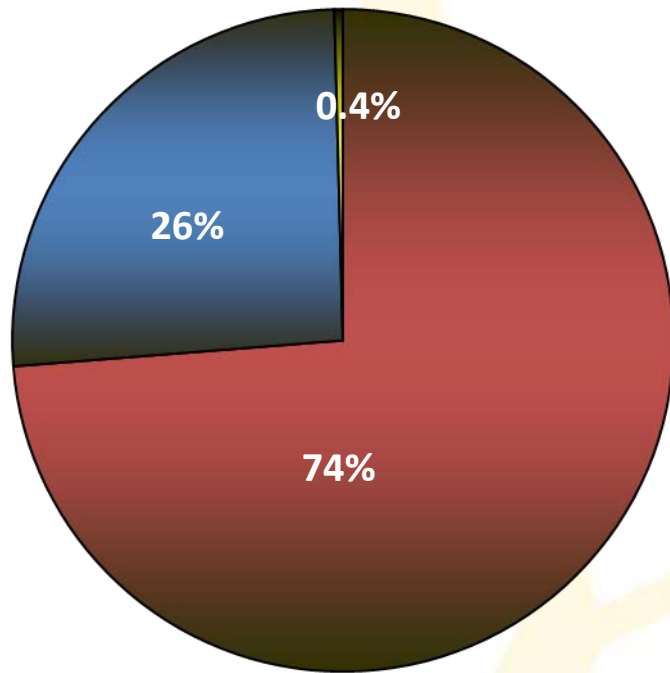
n=238

p value

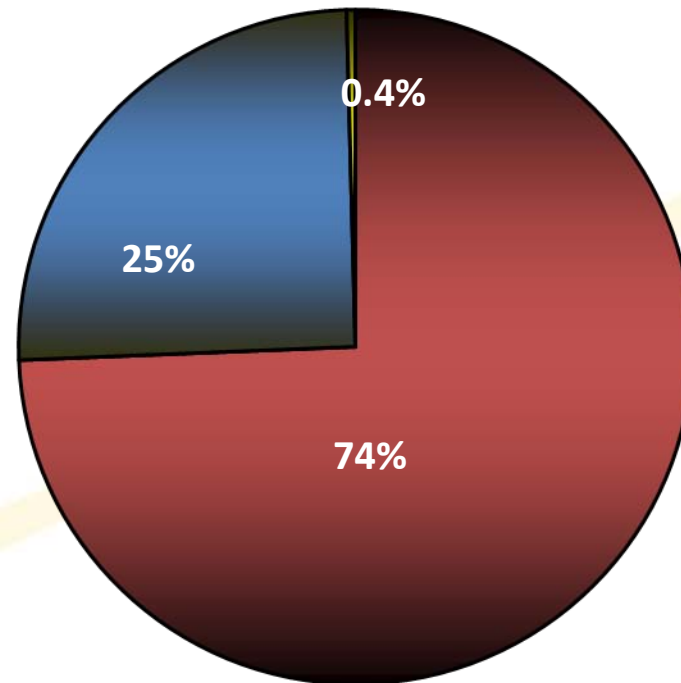
Age, mean+SD	64±10	65±10	ns
Male,%	72.4	73.1	ns
Diabetes, %	16	18	ns
Smoking, %	23	20	ns
Hypertension, %	66	61	ns
Statin Tx, %	84	83	ns
Family history, %	61	56	ns
History of PCI, %	31	24	ns
History of CABG, %	2	3	ns

Indication

No kissing



Kissing

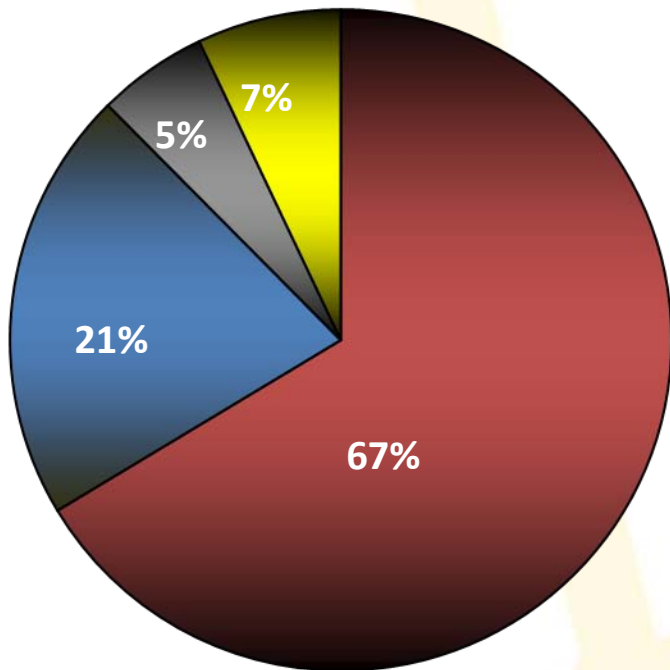


- SAP
- UAP
- SI

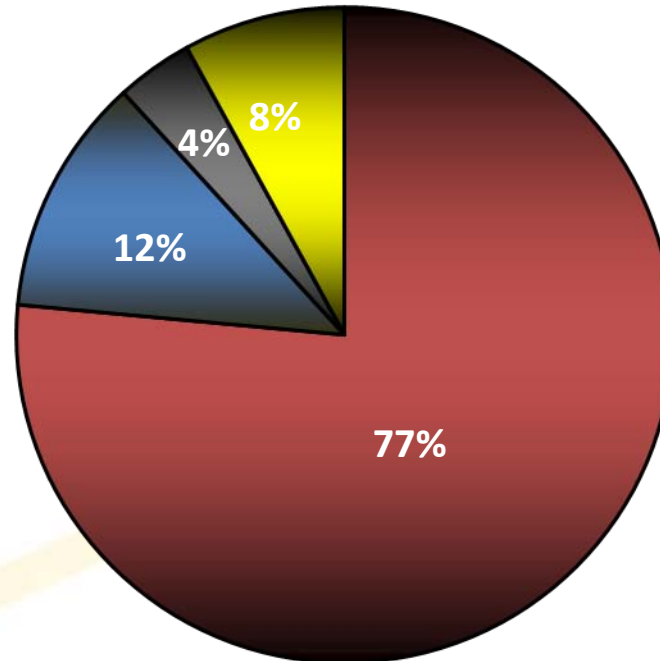
ns

Treated vessels

No kissing



Kissing



ns



Baseline characteristics

	No kissing n= 239	Kissing n= 238	P value
EF (%), mean SD	59 10	58 11	ns
1-VD, %	44.3	52.9	ns
2-VD, %	40.1	36.6	ns
3-VD, %	15.6	9.7	ns



Coronary angiography Visual assessment

	No kissing n=239	Kissing n=238	p value
MV les. length (mm)	17.7 \pm 10.2	17.3 \pm 8.6	ns
MV stent length (mm)	22.9 \pm 10.5	23.6 \pm 11.1	ns
SB les. length (mm)	3.6 \pm 4.2	3.4 \pm 3.9	ns
Prx. MV ref. diam. (mm)	3.4 \pm 0.4	3.4 \pm 0.6	ns
Dis. MV ref. diam. (mm)	3.2 \pm 0.3	3.2 \pm 0.4	ns
SB ref. diam. (mm)	2.7 \pm 0.4	2.6 \pm 0.3	ns



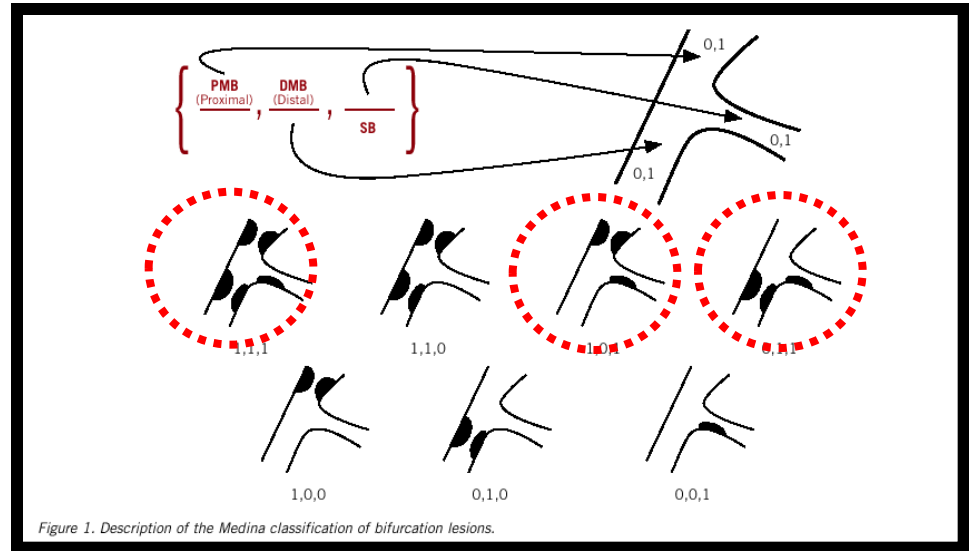
Coronary angiography Visual assessment

	No Kissing n = 239	Kissing n = 238	p
MV prox stenosis before (%)	56.8 \pm 34.1	59.1 \pm 33.1	ns
MV dist stenosis before (%)	66.3 \pm 28.3	69.2 \pm 27.6	ns
SB stenosis before (%)	39.4 \pm 34.4	40.3 \pm 34.4	ns
MV prox stenosis after (%)	1.0 \pm 2.7	1.2 \pm 3.3	ns
MV dist stenosis after (%)	1.6 \pm 3.9	1.9 \pm 4.6	ns
SB stenosis after (%)	41.3 \pm 30.3	26.1 \pm 25.7	<0.000



Patients with true bifurcation lesions

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



No kissing
n=239

Kissing
n=238

p value

True bifurcation
lesion, n (%)

124 (51.8 %)

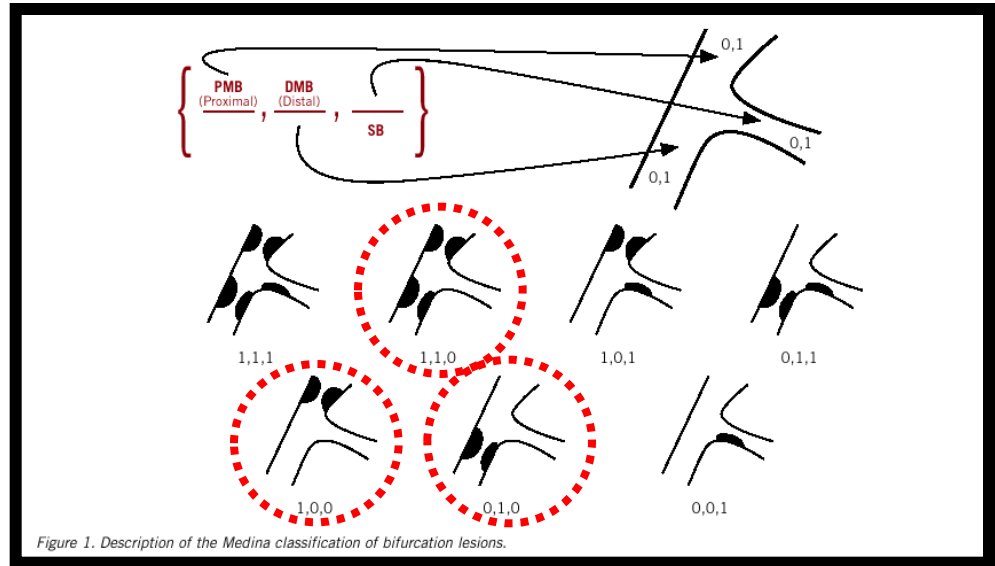
130 (54.6%)

ns



Patients without side branch stenosis

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



No kissing
(n=239)

Kissing
(n=238)

p value

No side branch
stenosis, n (%)

115 (48.2)

105 (45.4)

ns



Procedural data I

	No kissing n=239	Kissing n=238	p-value
Aspirin Tx (%)	99.6	100.0	ns
Clopidogrel Tx (%)	98.7	99.2	ns
GPIIb/IIIa Tx (%)	28.9	29.1	ns
Bivalirudin Tx (%)	20.9	26.2	ns
Procedure time (min)	47 \pm 22	61 \pm 28	0.0001
Fluorosc. time (min)	11 \pm 10	16 \pm 12	0.0001
Contrast (ml)	200 \pm 92	235 \pm 97	0.0001



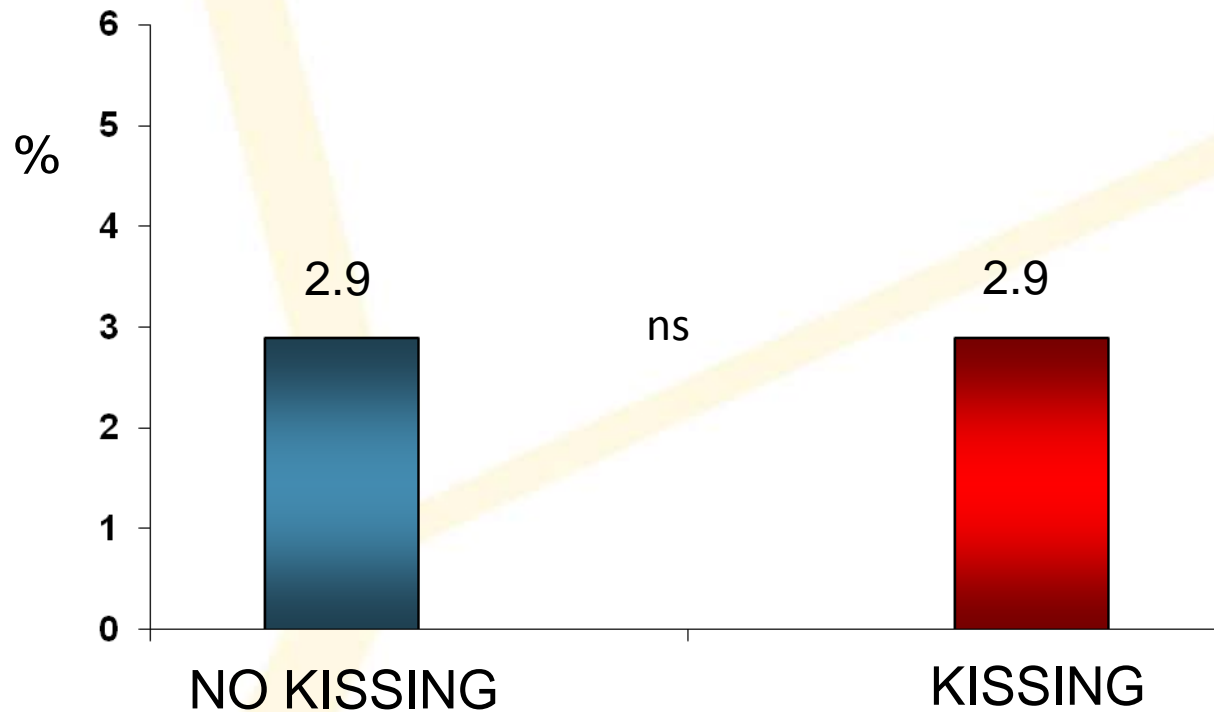
Procedure data II

	No kissing n=239	Kissing n=238	p-value
MV stented, %	99.6	100.0	ns
SB stented, %	0.0	1.3	ns
SB dil. thr. MV stent, %	2.5	33.3	0.0001
Final kissing ball, %	0.8	89.1	0.0001
SB dil. thr. MV stent/kissing, %	2.9	89.9	0.0001
Tx successful*, %	98.7	99.2	ns

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

Primary end point

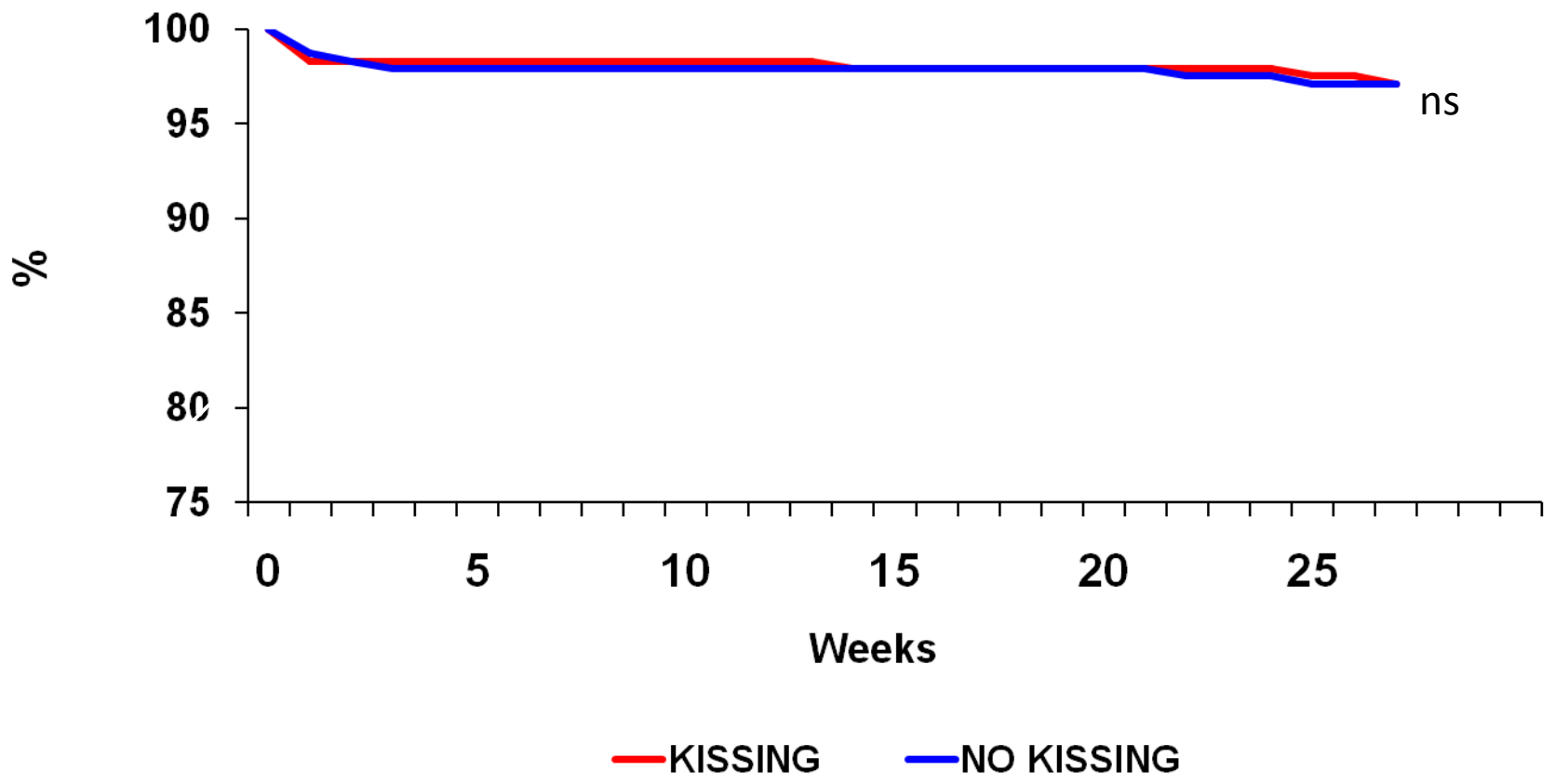
MACE (cardiac death, index lesion MI, TLR, stent thrombosis) after 6 months





Primary end point event free survival

MACE (cardiac death, index lesion MI, TLR, stent thrombosis)





Secondary end points after 6 months

	No kissing n=239	Kissing n=238	p-value
Cardiac death (%)	0.0	0.8	ns
Non-cardiac death (%)	0.0	0.4	ns
Index lesion MI* (%)	2.2	0.0	ns
TLR (%)	2.1	1.3	ns
Stent thrombosis (%)	0.4	0.4	ns

* Non-procedure related



Limitations

Short observation period

Visually assessed implanations angiograms only

Long term follow up and 8-month QCA data
expected to be available at ACC 2010

Conclusion

- In coronary bifurcation lesions, a strategy of routine kissing balloon dilatation of side branch through the MV stent did not improve the 6-month clinical outcome as compared to a strategy of no kissing balloon dilatation
- In the kissing balloon dilatation group, the procedure and fluoroscopy time and the use of contrast were significantly increased

Implications

***“Life can only be understood backwards;
but it must be lived forwards.”***

Soren Kirkegaard





Implications

- Final Kissing is optional (left to the operators descretion)
- Side branch preparation (therapeutic dilatation, if needed) has to be done before implanting the main vessel stent
- Change the stepwise strategy of provisional stenting of the sidebranch



Bifurcation treatment principles

Provisional stenting

- Use MEDINA classification for lesion description.
- Plan the intervention beforehand
- Always use DES
- Therapeutic dilatation in the side branch
- Use jailed wire (double wire technique)
- Optional kissing balloon if the sidebranch is fine.
- Stent main branch and use step-wise provisional sidebranch stenting (T- or culotte-stenting) if needed.
- Ensure full stent coverage and good wall apposition



Thank you for your attention