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

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.

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Nordic-Baltic Bifurcation Study IV

Participating Centers

Denmark

Aarhus University Hospital	(112pts)
Aalborg University Hospital	(13 pts)
Odense University Hospital	(10 pts)
Rigshospitalet Copenhagen	(3 pts)

Latvia

P.Stradins University Hospital, Riga	(159 pts)

Sweden

Örebro Hospital	(11 pts)
Linköping	(3 pts)
Karolinska University Hospital	(1 pts)

Finland

Oulu University Hospital	(75 pts)
Tampere University Hospital	(8 pts)
Turku University Hospital	(6 pts)
Kuopio University Hospital	(2 pt)

Norway

Tromsø University Hospital	(18pts)
Arendal Hospital	(3 pts)
Feiring Heart Clinic	(2 pts)

Lithuania

Vilnius University Hospital	(21 pts)

Background

- Provisional (simple) stenting is the preferred strategy in treatment of most bifurcation lesions

- It is unknown if this also applies to true bifurcation lesions involving a large side branch

Aim

- To compare provisional stenting and two-stent techniques for the treatment of true coronary bifurcation lesions involving a large side branch

Hypothesis

- Two stent techniques are superior to provisional stenting in treatment of true coronary bifurcation lesions involving a large side branch

Methods

- Open label, randomized, multicenter trial
- 1:1 randomization
- Clinical FU at 0, 1 and 6 months
- Angiographic substudy with 8 months FU
- Study stents:
  - Sirolimus eluting Cordis Cypher Select+ (first 225 patients)
  - Everolimus eluting Abbott Xience V (last 225 patients)

Primary endpoint

Combined endpoint after 6 months:

- cardiac death
- non-index procedure related myocardial infarction
- TLR
- definite stent thrombosis

Secondary endpoints

- Individual endpoints of:
  - Total death
  - Cardiac death
  - Non-index procedure related MI
  - Target lesion revascularization (TLR)
  - Target vessel revascularization (TVR)
  - Definite stent thrombosis
- Procedure related myocardial infarction
- 8-month angiographic follow-up results

Methods

Inclusion criteria

- Age≥18
- Stable Angina, UAP, NSTEMI
- MV≥3.0mm
- SB ≥2.75mm
- Bifurcation stenosis involving both MV and SB
  (≥50%DS by eyeballing)

Exclusion criteria

- STEMI
- Cardiogenic shock
- Other critical illness
- Relevant allergies
- Cr ≥ 200 µmol/L
- SB lesion length >15mm

Implantation techniques

Provisional SB stenting

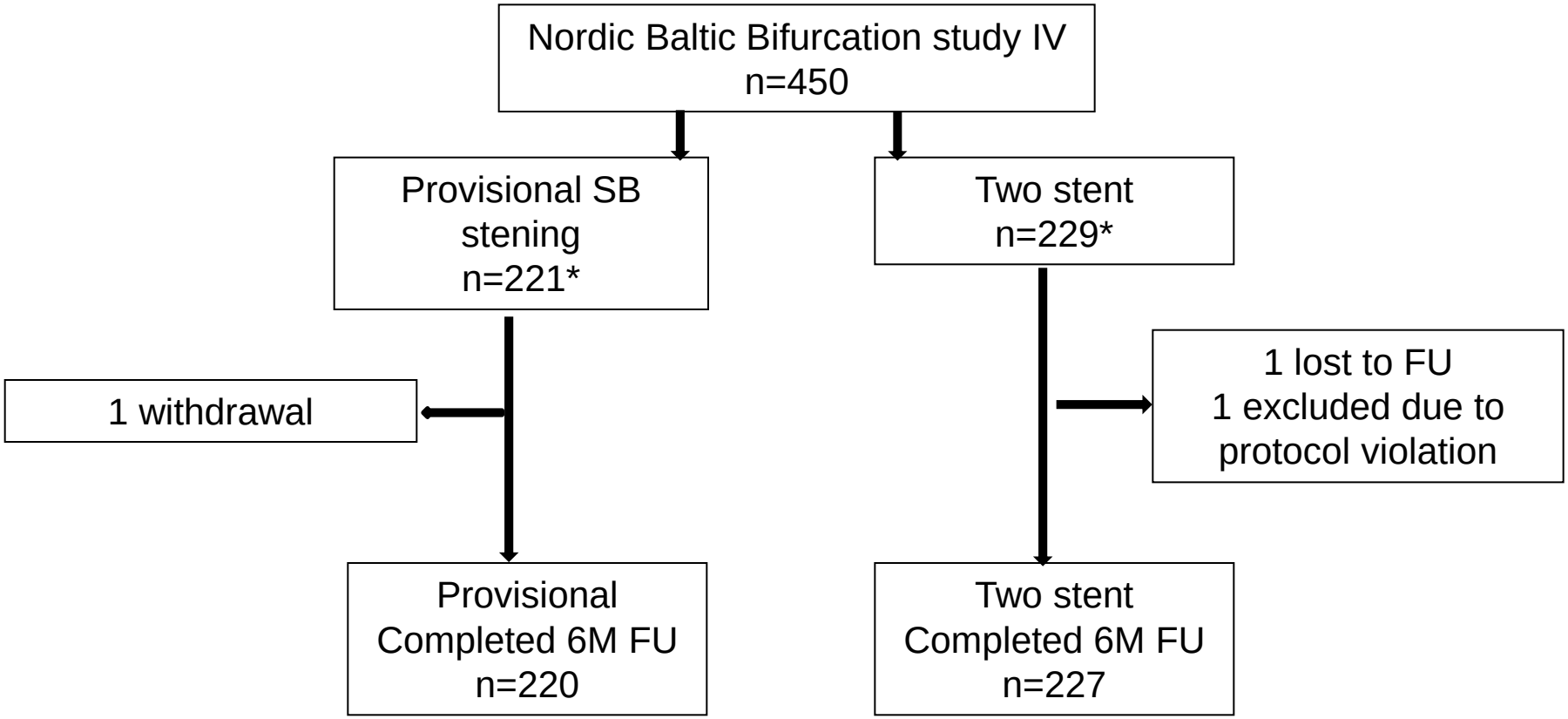
- Two wires
- Predilatation
- MV stenting
- **If TIMI flow<III or >75%DS** in ostial SB: kissing balloon dilatation
- **If SB TIMI flow <III** after kissing balloon dilatation, SB stenting using a T- or Culotte technique

Implantation techniques

Two-stent techniques

- Two wires
- Predilatation of segments to be stented
- Culotte stenting recommended
  - T-stenting and mini-crush allowed
- Final kissing balloon dilatation

Patient flowchart



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

Baseline clinical characteristics

	Provisional (n=221)	Two-stent (n=229)	p
Age (yrs)	64±12	63±11	ns
Diabetes (%)	16.3	15.3	ns
Active smoking (%)	19.1	21.1	ns
Statin treatment (%)	81.8	81.1	ns
Hypertension (%)	70.0	65.6	ns
Family history (%)	50.7	47.4	ns
History of PCI (%)	35.5	33.5	ns
History of CABG (%)	3.6	1.8	ns

Lesion characteristics

	Provisional (n=221)	Two-stent (n=229)	p
LAD/diagonal (%)	74.1	76.7	ns
CX/obtuse marginal (%)	16.8	17.6	ns
RCA PDA/PLA (%)	6.4	4.0	ns
LM/LAD/CX (%)	2.7	1.3	ns
Ref. diameter main vessel (mm)*	3.5	3.4	0.04
Ref. diameter side branch (mm)*	2.9	2.9	ns
Lesion length SB (mm)*	7.4	8.0	<0.0001
Angulation > 60-70° (%)*	50.9	51.1	ns

*visual estimation

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

Procedural data II

	MV (n=203)	MV+SB (n=202)	P-value
MV stented (%)	99.5	98.5	0.37
SB stented (%)	4.4	95.0	<0.0001
Kissing balloon (%)	32	74	<0.0001
Tx successful (%)	97	94	0.25

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

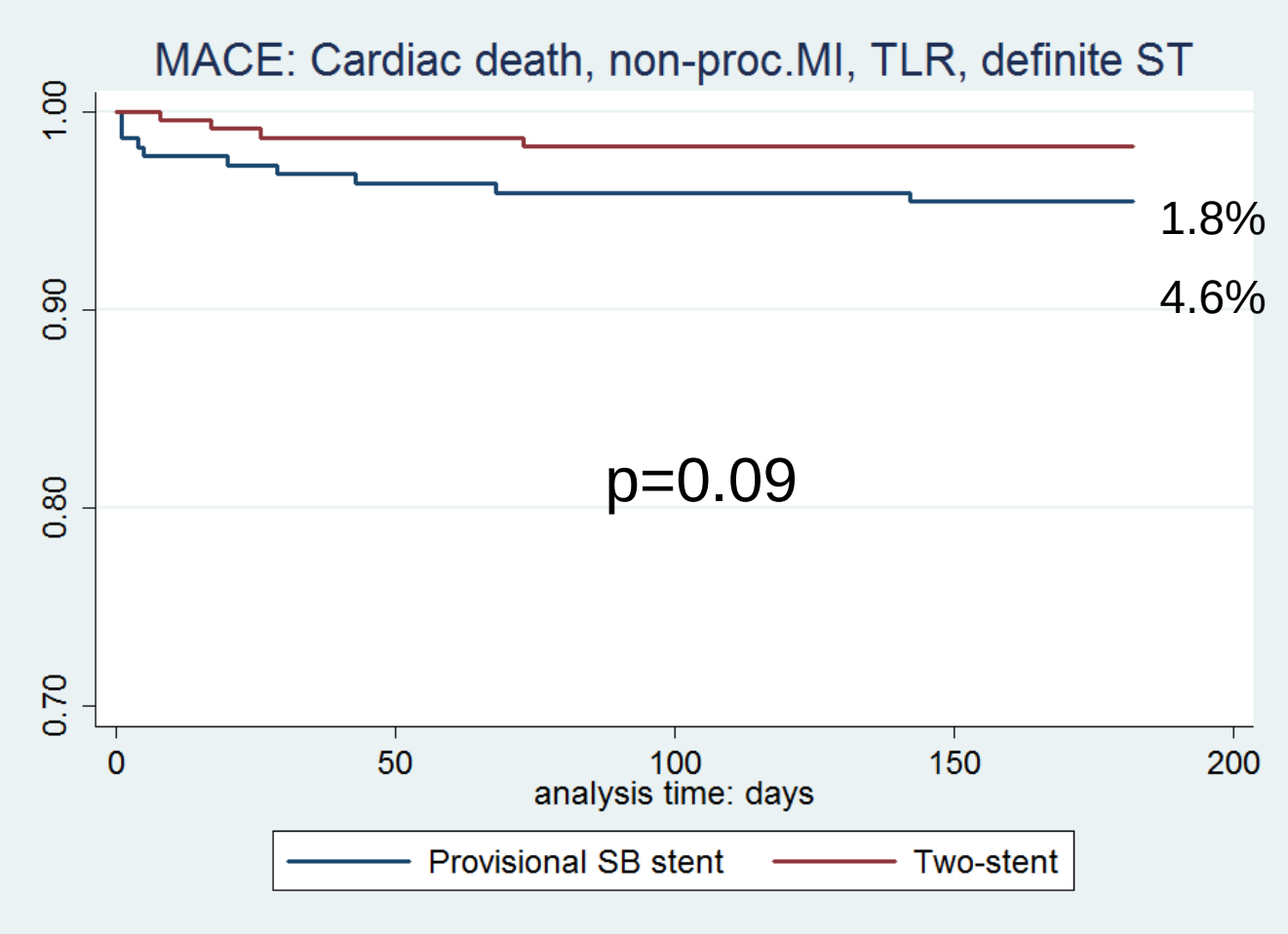
T.Steigen et al. Circulation.2006;114:1955-1961

Procedure related biomarker elevation (279 patients)

	MV (n=153)	MV+SB (n=126)	P-value
>3 elevation (%)	8	18	0.011
>5 elevation (%)	4	13	0.008
>10 elevation (%)	3	5	ns

T.Steigen et al. Circulation.2006;114:1955-1961

Eventfree survival curve at 6 months



Within the first 30 days- 7 events in provisional group vs 3 events in two-stent group

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 ≥ II	2.7	1.3	0.39

Conclusion

- After 6 months, two-stent techniques for treatment of true bifurcation lesions with a large side branch showed no significant difference in MACE rate compared to provisional side branch stenting
- Longer and more complex procedures in the two-stent group did not translate into more procedural myocardial infarctions
- Recommendations on optimal strategy for this lesion subset should await longer term follow-up (clinical follow-up at 24, 36 and 60 months)