EBC

The Nordic-Baltic PCI Study Group

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

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Nordic-Baltic Bifurcation Study IV

One-stent vs. two-stent techniques

- for true bifurcation lesions with major SBs

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Design

- 450 patients
- 1:1 randomization
- Primary endpoint: 6m MACE
- Angiographic substudy with 8m FU
- Study stents:
  - Cypher Select+ (first 225 patients)
  - Xience V (last 225 patients)

- Main vessel (MV) ≥**3.0mm**
- Side branch (SB) ≥**2.75mm**

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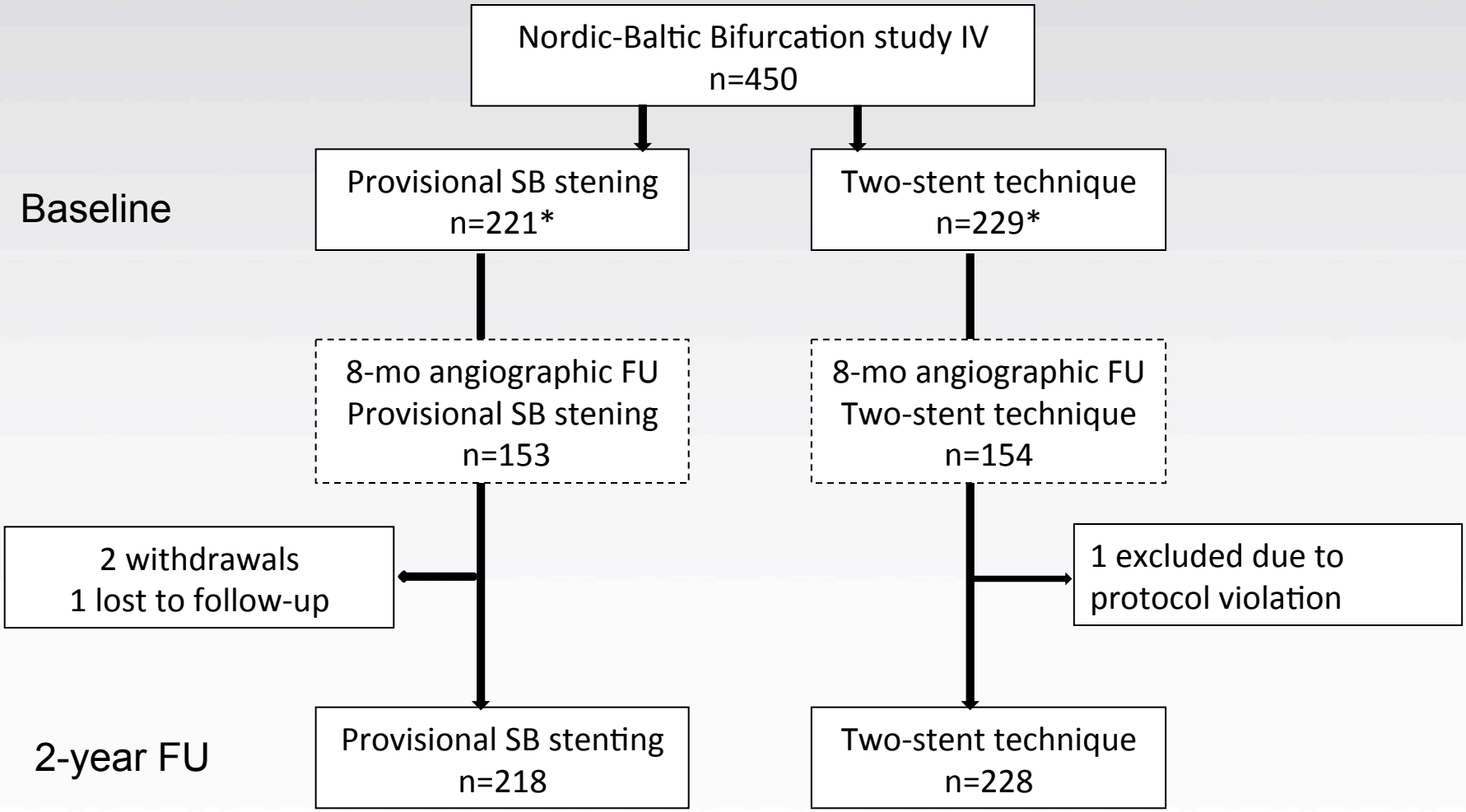
Patient flowchart



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

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Lesion characteristics

	Provisional (n=218)	Two-stent (n=228)	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
Angulation > 60-70° (%)*	50.9	51.1	ns

*visual assessment

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Lesion characteristics by QCA

	Provisional	Two-stent	p
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

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Procedural data

	Provisional (n=218)	Two-stent (n=228)	p
SB predilatation (%)	63.9	-	-
SB predilation or final kissing (%)	78.4	-	-
FKBD (%)	36.1	91.2	-
SB stented (%)	3.7	96.0	-
Culotte	-	65.6	-
T-stent	-	7.1	-
Other	-	26.4	-
Tx succesful* (%)	97.7	99.1	ns

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

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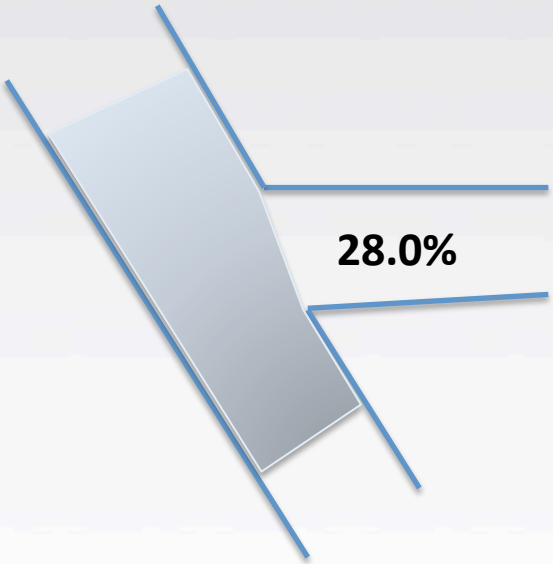
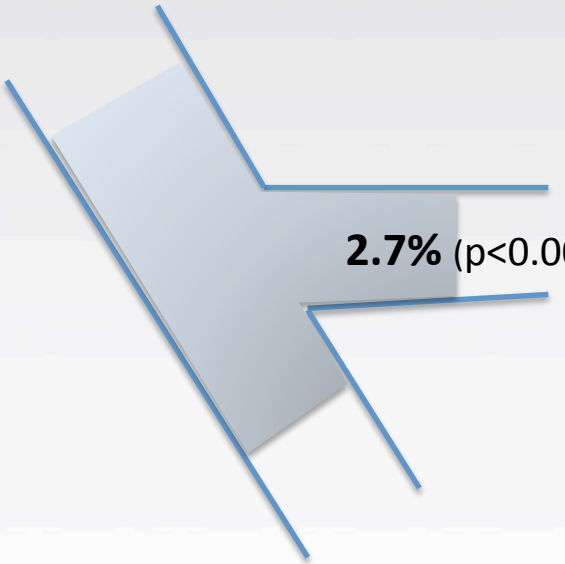
Residual side branch stenosis* (QCA)

Provisional SB stent technique



Two-stent technique



*Binary residual stenosis: ≥ 50% diameter stenosis post PCI

QCA by dedicated bifurcation analysis. Medis QAngioXA 7.3

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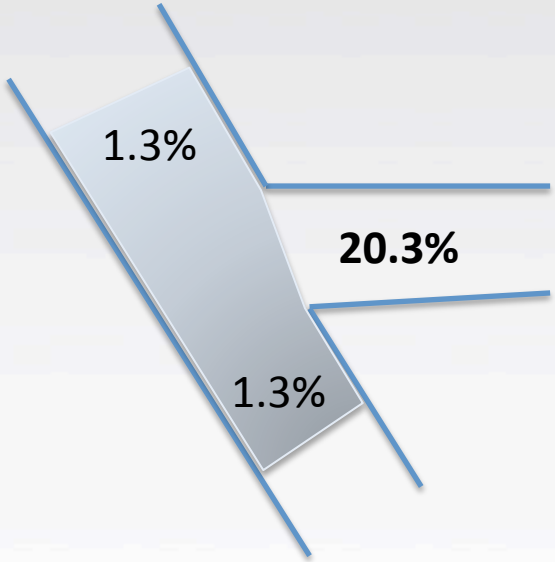
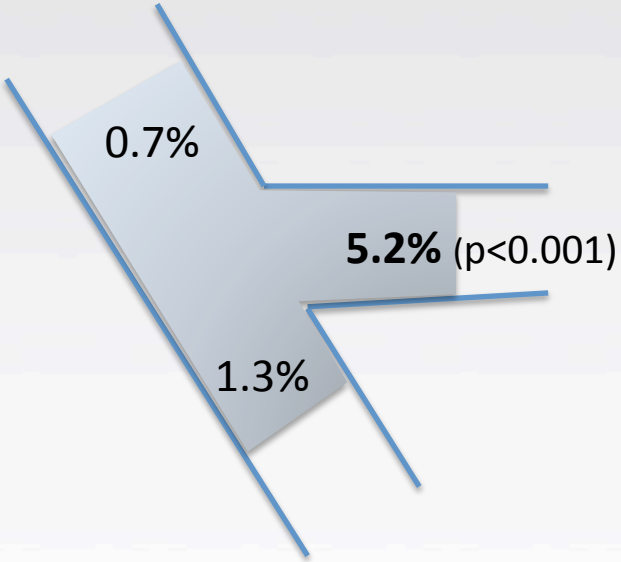
Angiographic restenosis* at 8 months

Provisional SB stent technique



n = 153

Two-stent technique



n = 154

Binary restenosis ≥ 50% diameter stenosis

QCA by dedicated bifurcation analysis. Medis QAngioXA 7.3

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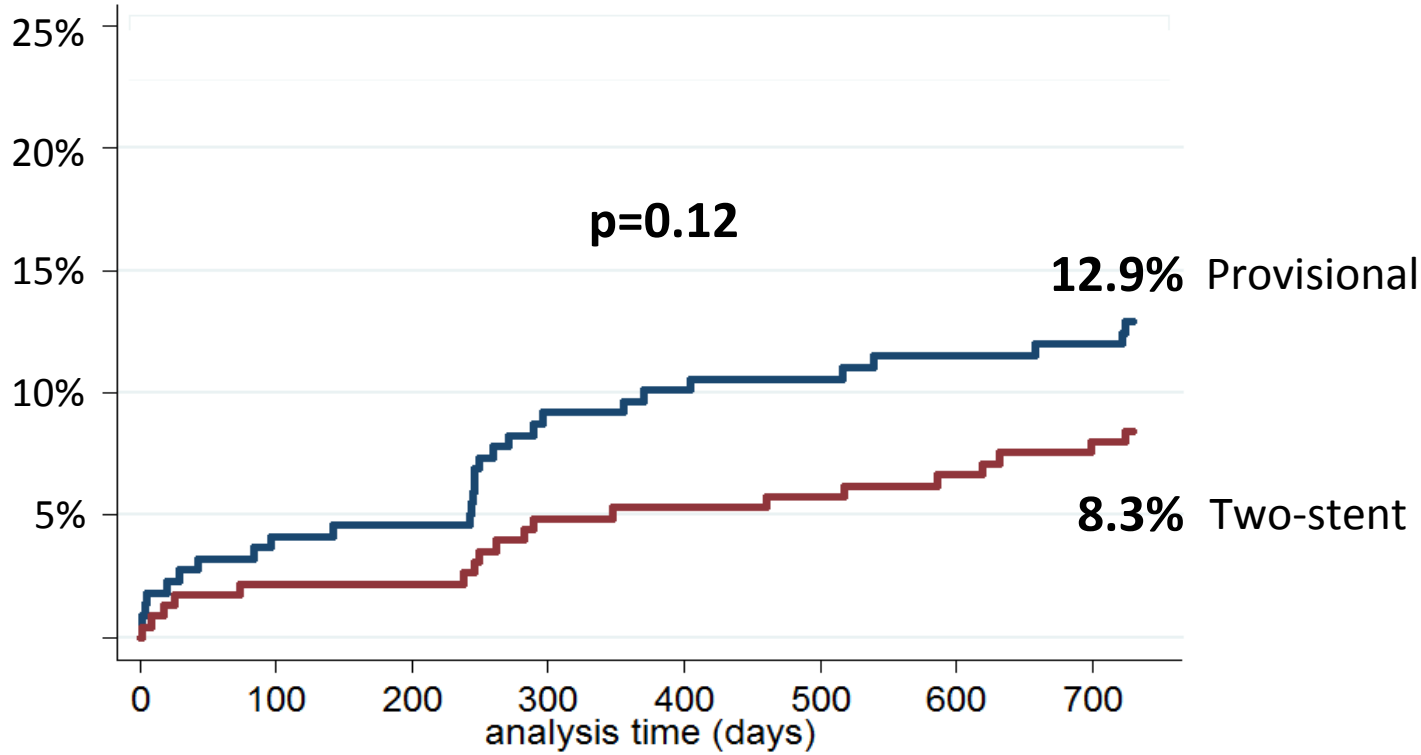
Two-year MACE



Number at risk								
Two-stent tech.	228	221	221	214	212	211	209	206
Provisional tech.	218	209	208	196	194	192	189	187

MACE: cardiac death, non-procedural myocardial infarction, target lesion revascularization and definite stent thrombosis

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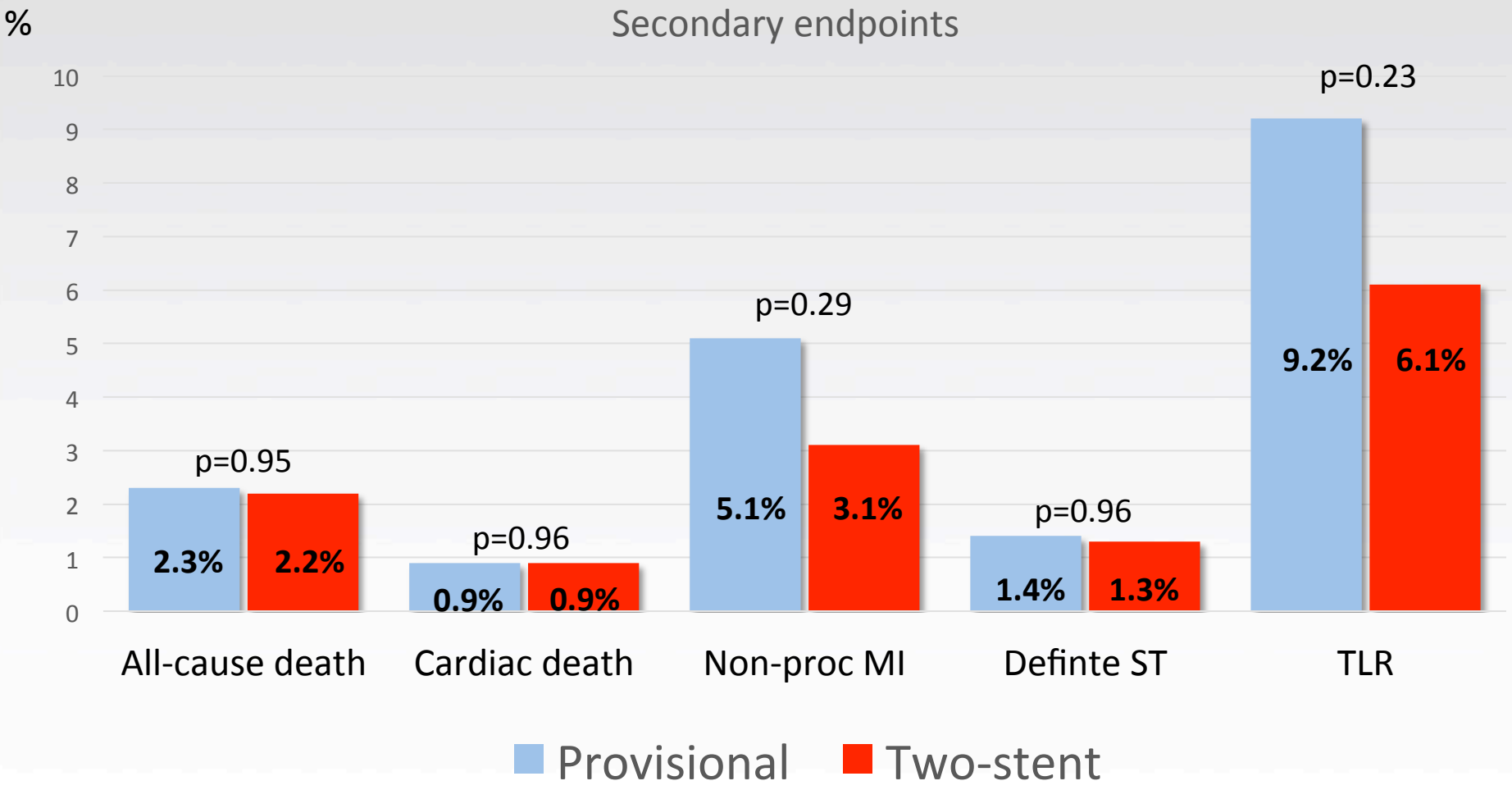
Individual endpoints at 2 years



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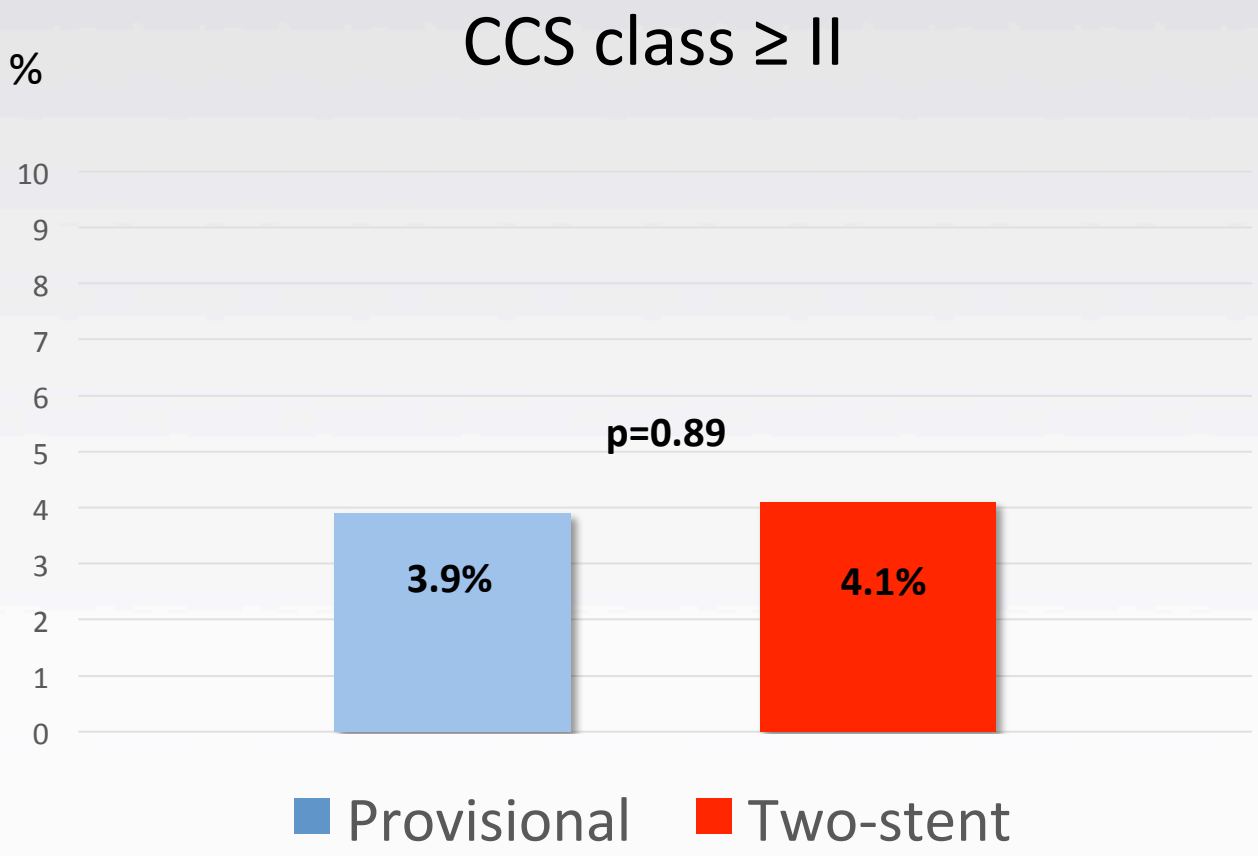
Angina pectoris at 2 years



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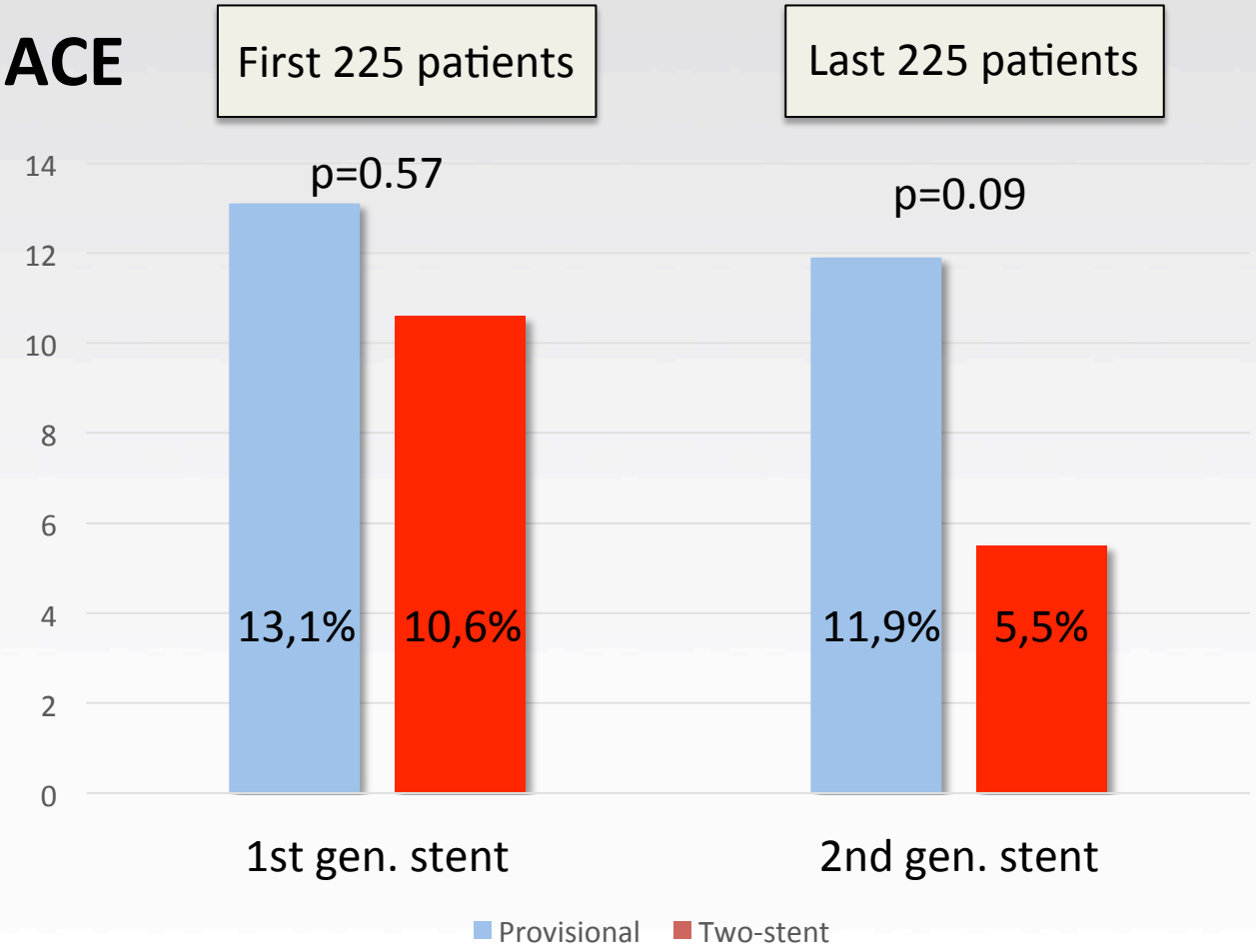
1st and 2nd generation stents

24m MACE



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Conclusion

Nordic-Baltic Bifurcation Study IV

- After 2 years, two-stent techniques for treatment of true bifurcation lesions with a large side branch showed no significant reduction in MACE rate compared to provisional side branch stenting

- Newer generation stents might improve safety after bifurcation treatment and in particular after treatment by two-stent techniques

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Nordic-Baltic Bifurcation Study IV

Denmark

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

Latvia

P.Stradins University Hospital, Riga	(159 pts)

Sweden

Örebro University Hospital	(11 pts)
University Hospital in 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)
Sørlandet Sykehus, Arendal	(3 pts)
Feiring Heart Clinic	(2 pts)

Lithuania

Vilnius University Hospital	(21 pts)

Thank you for your attention

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