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European Bifurcation Club

EBC

BBK 1 -Study

Bifurcations Bad Krozingen

Routine versus provisional T-stenting in the treatment of de novo coronary bifurcation lesions using sirolimus-eluting stents

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DISCLOSURE

M. Ferenc: Speaker honoraria

from Boston, Cordis, Abbott

Study support (partly) by Cordis

Background

In previous studies, stenting of both, side branch and main branch, was not superior to the single stent approach (Colombo et al.; Pan et al.; NORDIC).

Interpretation of these studies is hampered by the use of diverse stenting techniques, high cross-over rates or low proportions of true bifurcations included.

It has been suggested that T-stenting may be safer and more efficacious than crush or culotte stenting, frequently used in previous trials.

Objective

We hypothesized that in the treatment of coronary bifurcation lesions with sirolimus-eluting stents (CYPHER) routine T-stenting of both main and the side branch reduces the restenosis in the side branch compared with provisional T-stenting.

Patient selection

Inclusion criteria

- Stable angina pectoris and/or positive stress test
- De novo bifurcated lesion of a native coronary artery
- Reference vessel diameter of 2.5 to 4.0 mm in the main branch and of ≥ 2.25 mm in the side branch
- > 50% diameter stenosis of main branch and/or side branch

Exclusion criteria

- Acute myocardial infarction within 72 hours
- Contraindication to aspirin, heparin, clopidogrel, stainless steel, sirolimus
- History of bleeding diathesis or coagulopathy
- Intraluminal thrombus, heavy calcification and/or severe tortuosity

Prospective randomized study

April 2005 – August 2006

202 patients with de novo bifurcation lesions

Provisional T-stenting	Routine T-stenting
n = 101	n = 101

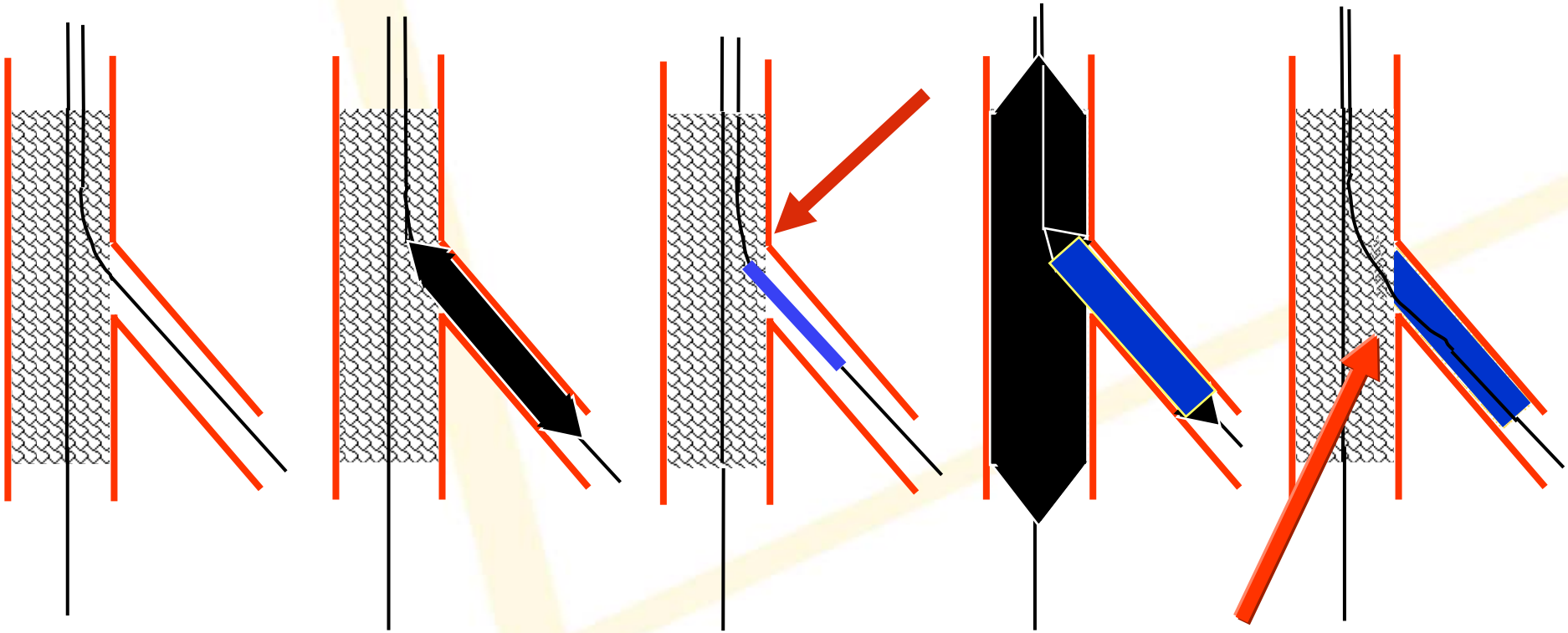
Angiographic follow-up with QCA at 9 months
("Medis" bifurcation program)

Clinical follow-up at 30 days; 1 and 2 years

Primary endpoint

In-segment percent diameter stenosis of the side branch at angiographic follow-up

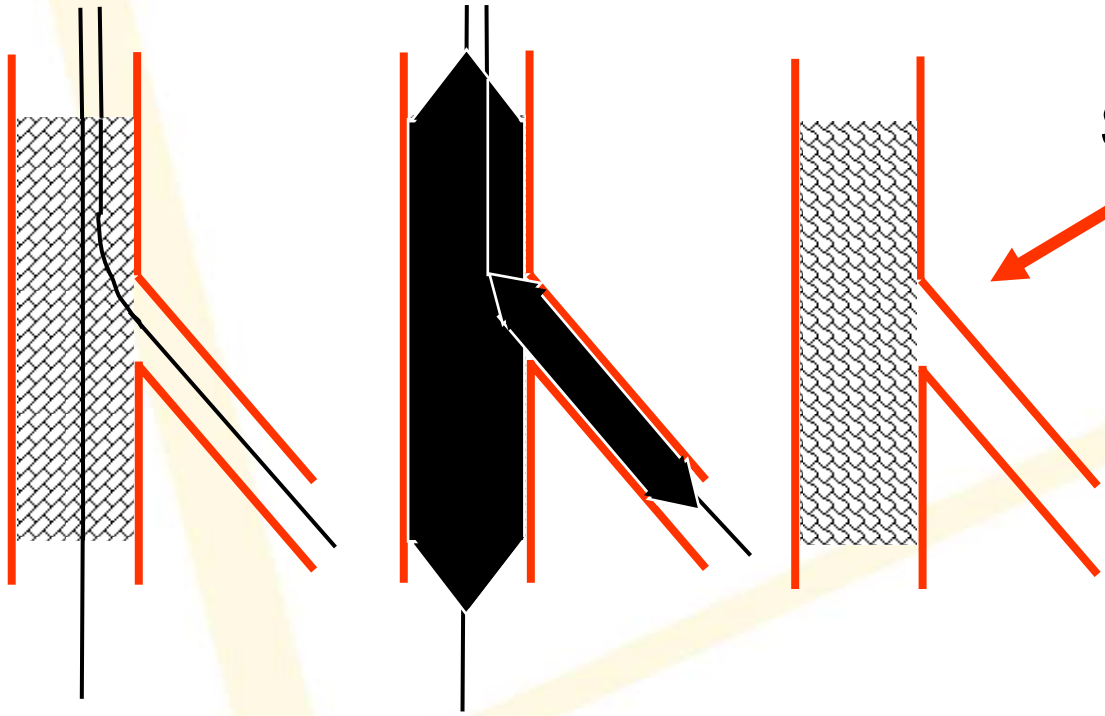
Modified T-stenting



with „mini crush in the carina area“ and „struts protrusion“

Stenting of main branch only

with „final kissing balloon“-dilatation of the side branch



Cross-over for: flow limiting dissections
residual stenosis > 75 %

Power calculation

Hypothesis:	33 % reduction of percent diameter stenosis of the side branch using routine modified T-stenting compared with provisional T-stenting
Goal:	80% power, level of significance 5%
Sample Size:	n = 160 patients (80 patients per study arm)
Complete size:	n = 200 patients (≥ 80% angiographic follow-up)

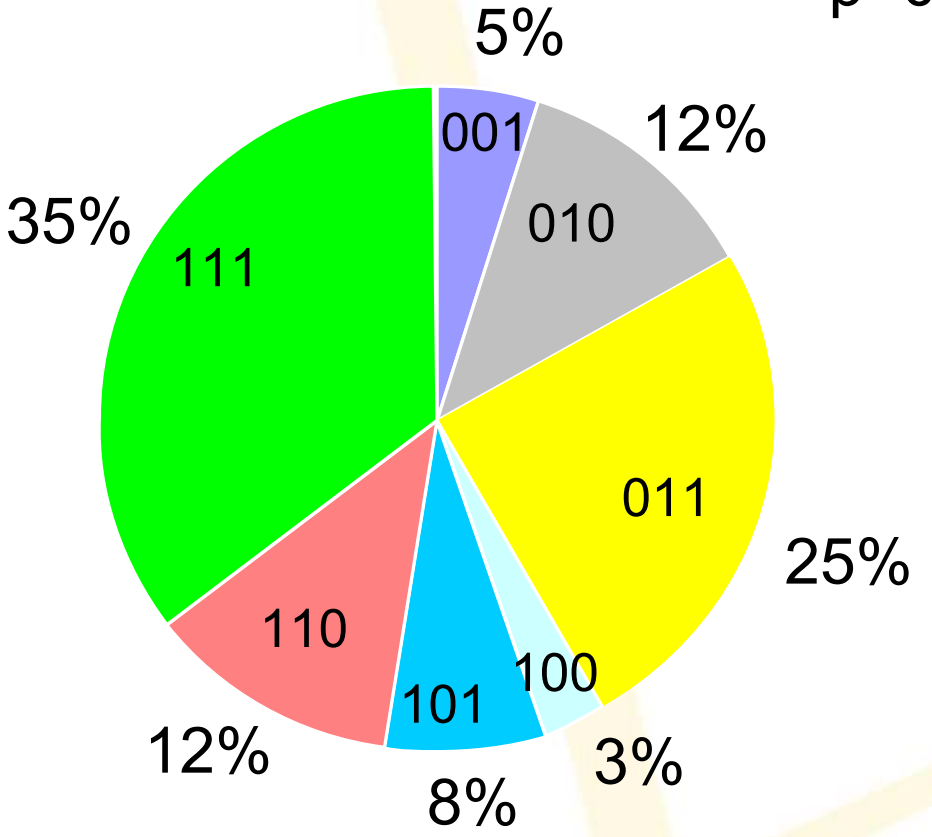
→ Intention to treat analysis

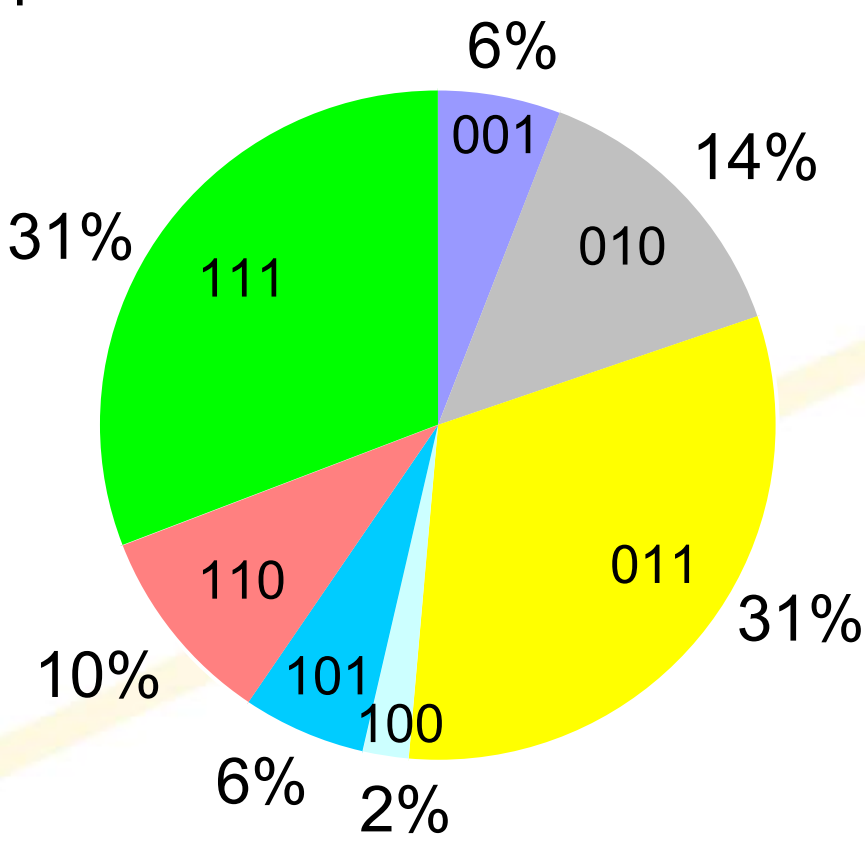
Baseline demographics

	Provisional T-Stenting n = 101	Routine T-Stenting n = 101	p-Value
Age (yrs)	66.7 ± 9.2	66.9 ± 10.5	0.92
Male sex (%)	79.2	78.2	0.50
Previous MI (%)	18.8	20.8	0.43
History of PCI (%)	44.6	51.5	0.20
2 or 3-vessel disease (%)	65.3	74.2	0.45
History of CABG (%)	4.0	3.0	0.50
Ejection fraction (%)	59.1 ±12	60.8 ±12	0.30
Diabetes (%)	25.7	18.8	0.16

Distribution of Medina classification

p=0.91





True bifurcation = 68 %

Provisional T-Stenting

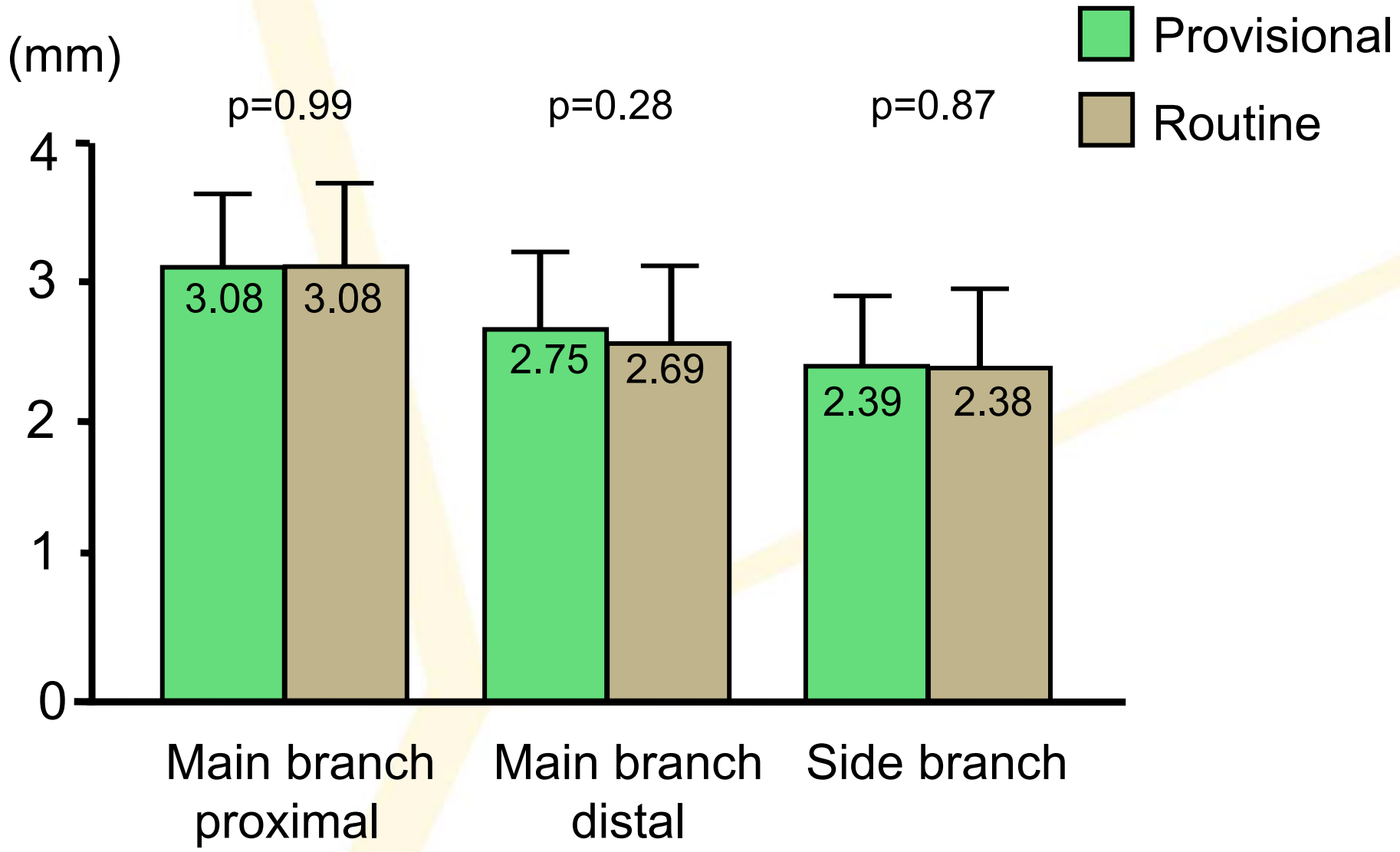
True bifurcation = 68 %

Routine T-Stenting

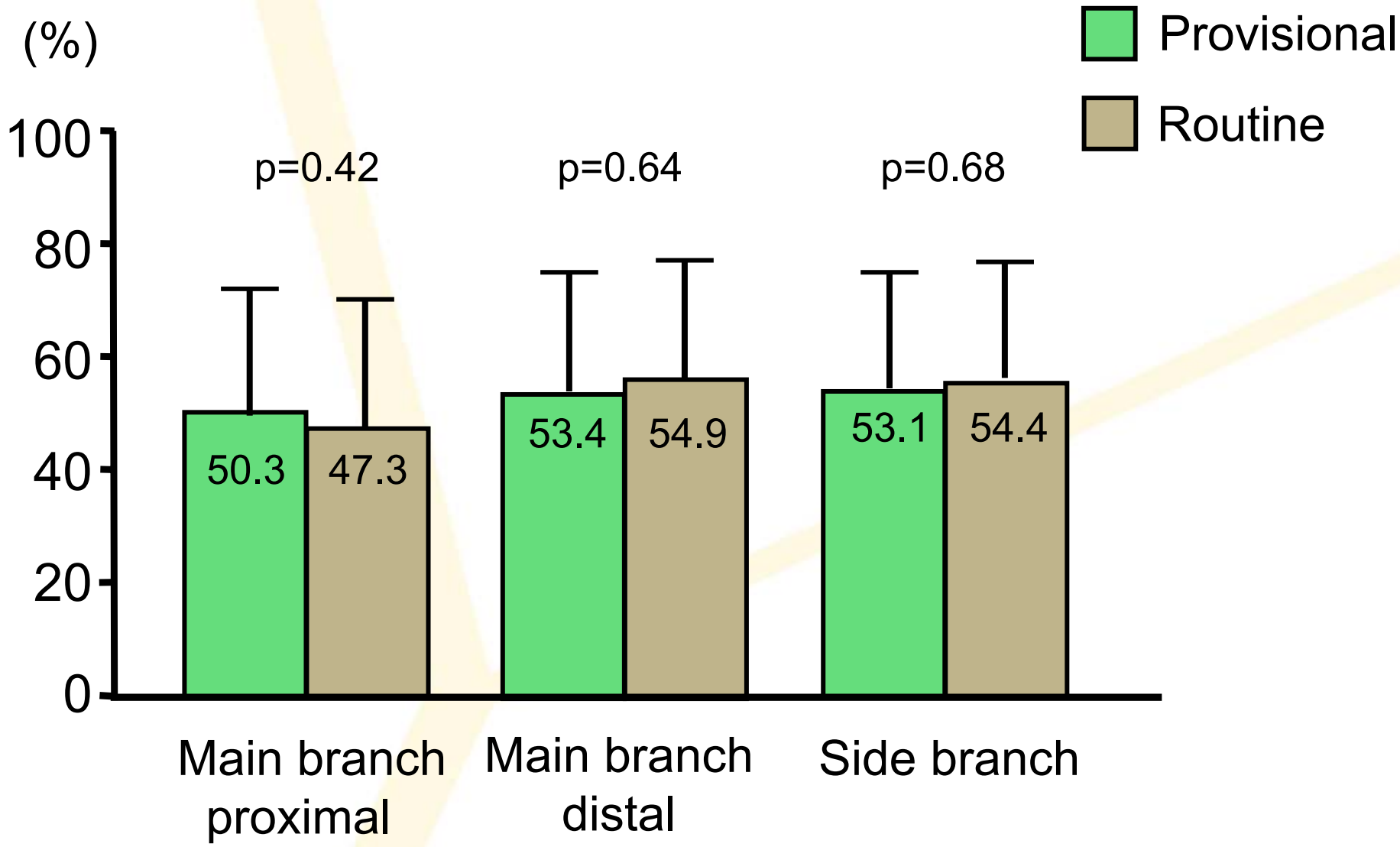
Procedural data

	Provisional T-Stenting n = 101	Routine T-Stenting n = 101	p-Value
Cross-over (%)	18.8	3.0	<0.001
Final kissing balloon (%)	100	100	1.0
Multi vessel PCI (%)	35.6	34.7	0.50
Max. inflation pressure (atm)	13.49	13.71	0.53
Procedure time (min)	51 ± 23	56 ± 25	0.16
Fluoroscopy time (min)	13 ± 7	15 ± 9	0.20
Contrast volume (ml)	204 ± 86	203 ± 109	0.94

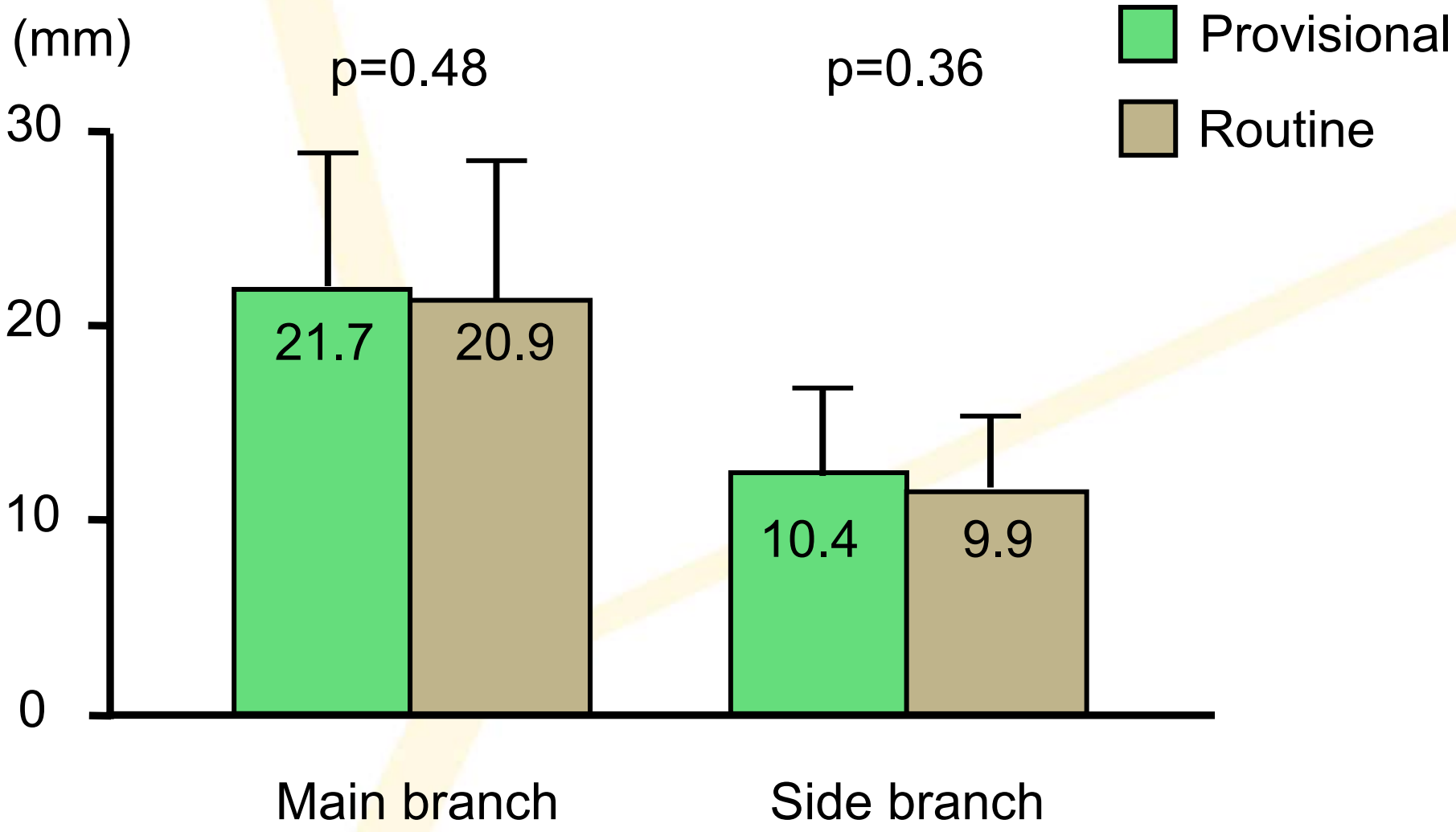
Reference diameter pre PCI



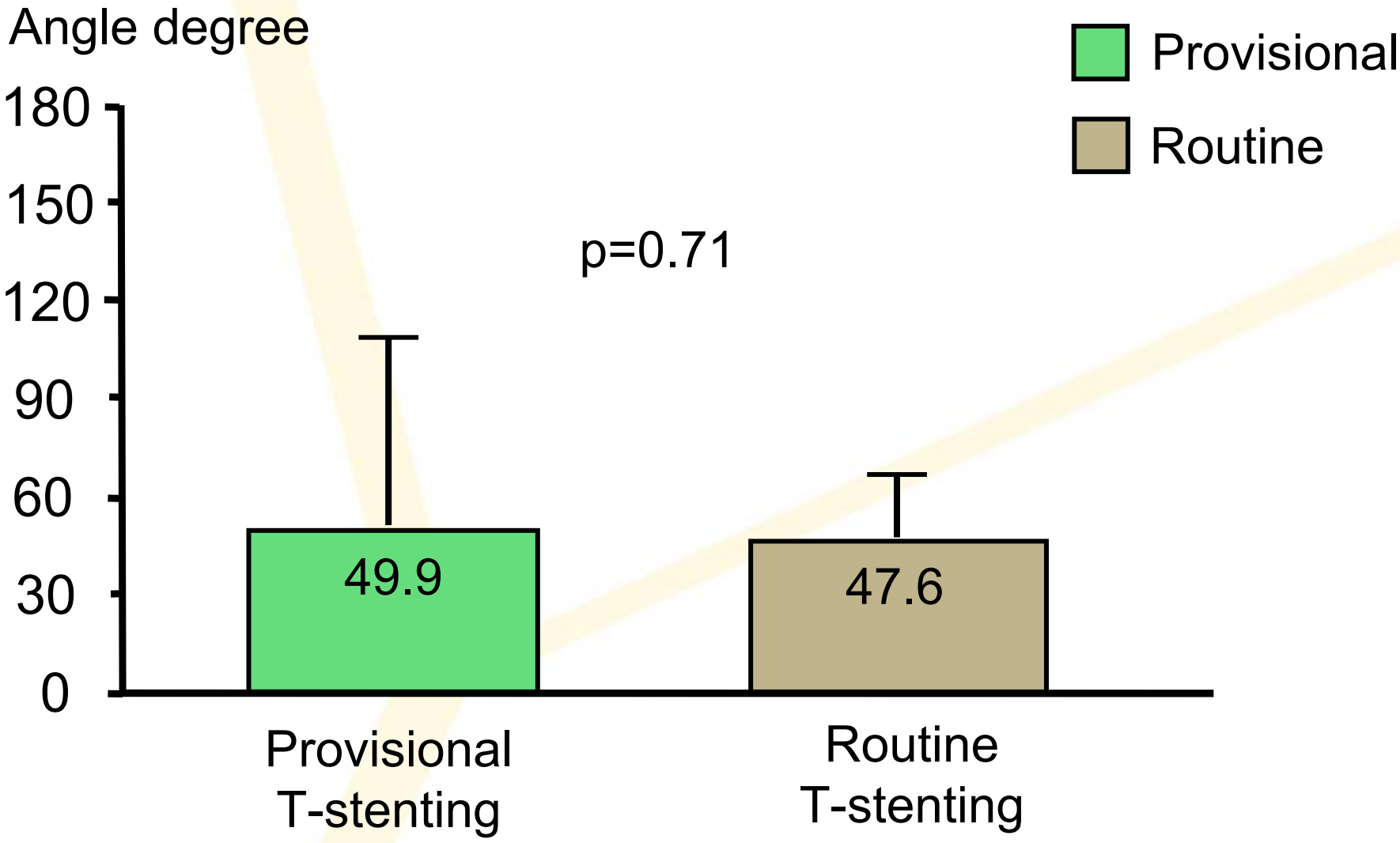
Percent diameter stenosis pre PCI



Length of stenosis pre PCI

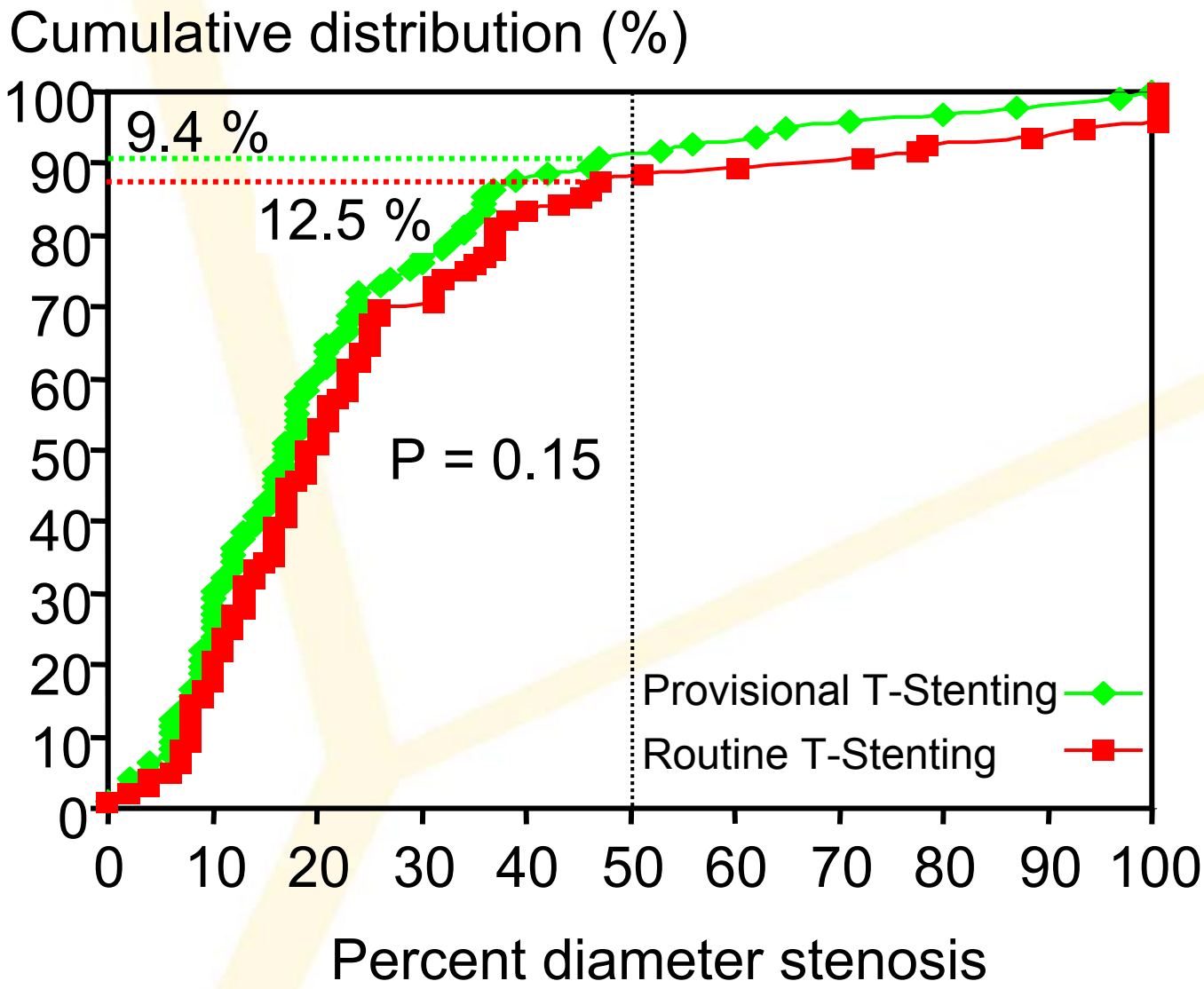


Angle of bifurcation pre PCI

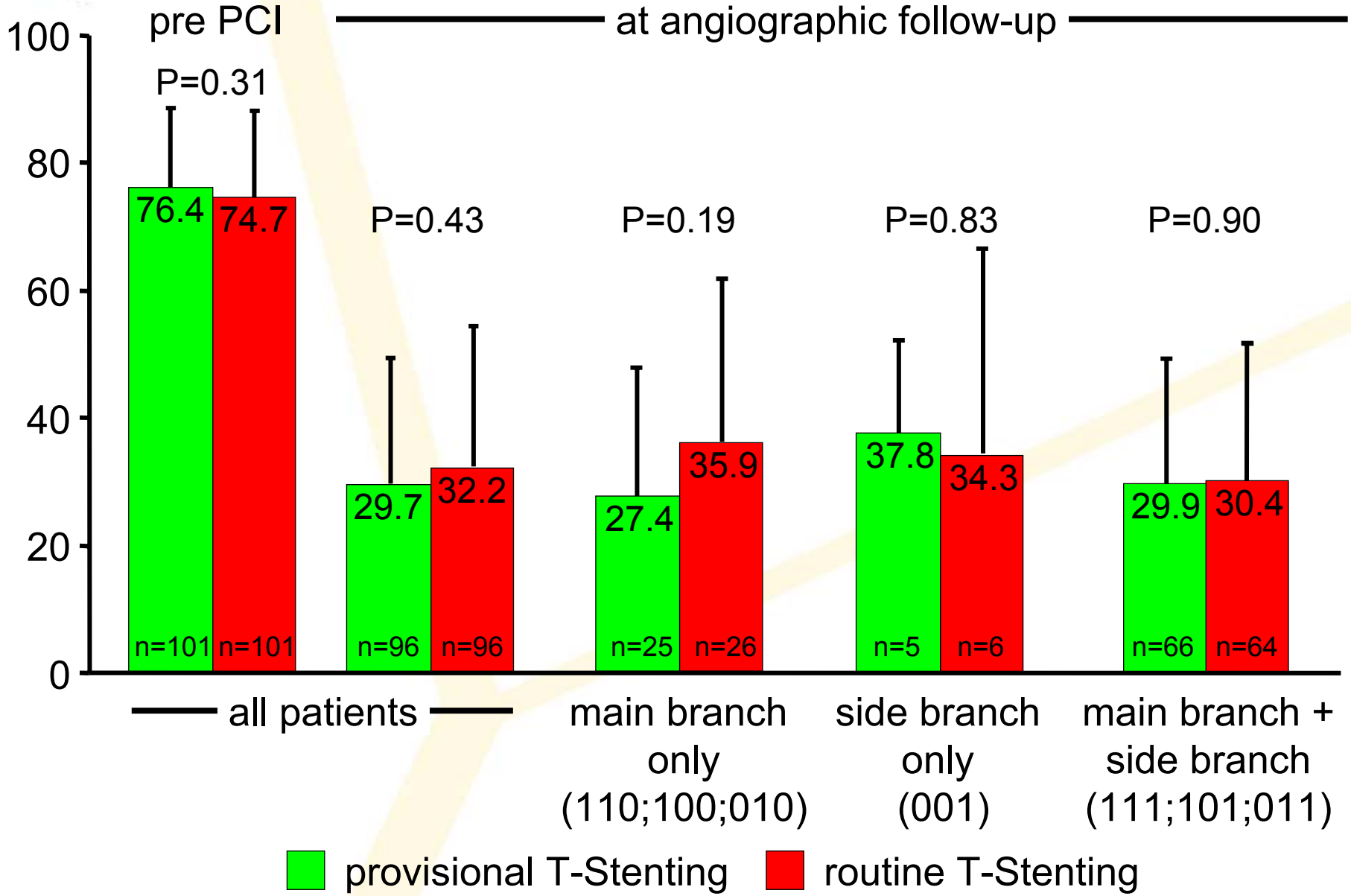


Primary endpoint

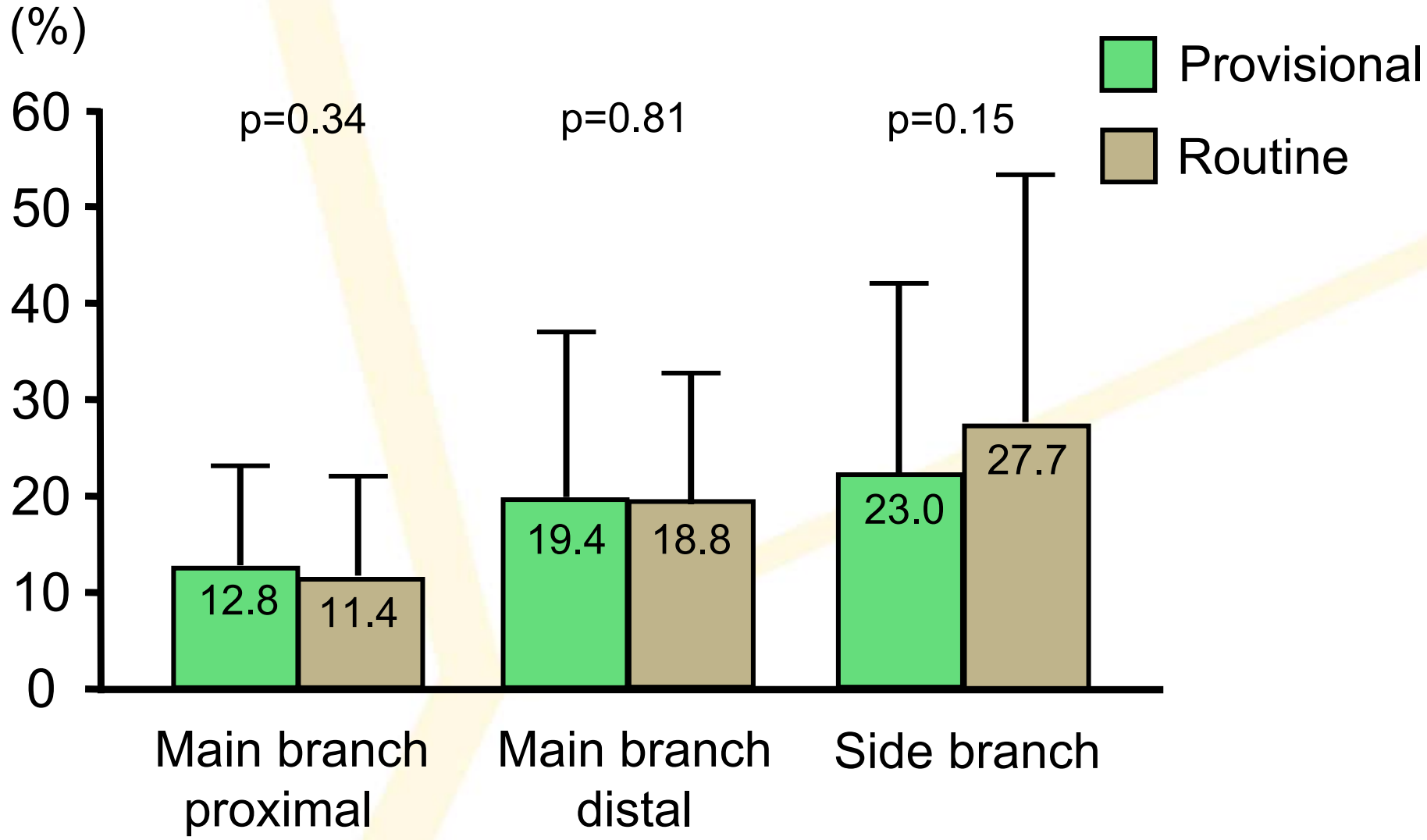
In-segment percent diameter stenosis of the side branch at 9-month follow-up



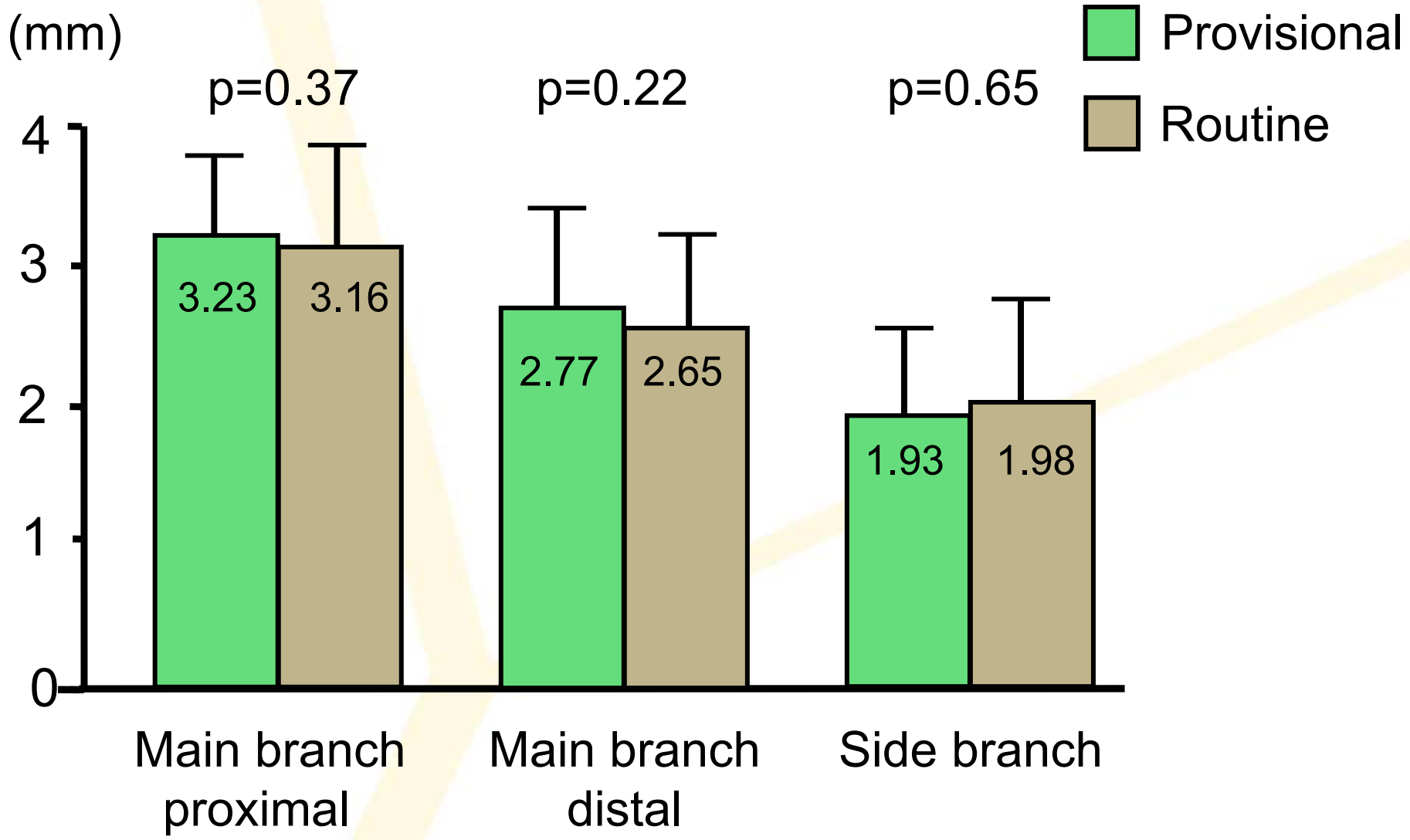
Maximal percent diameter stenosis



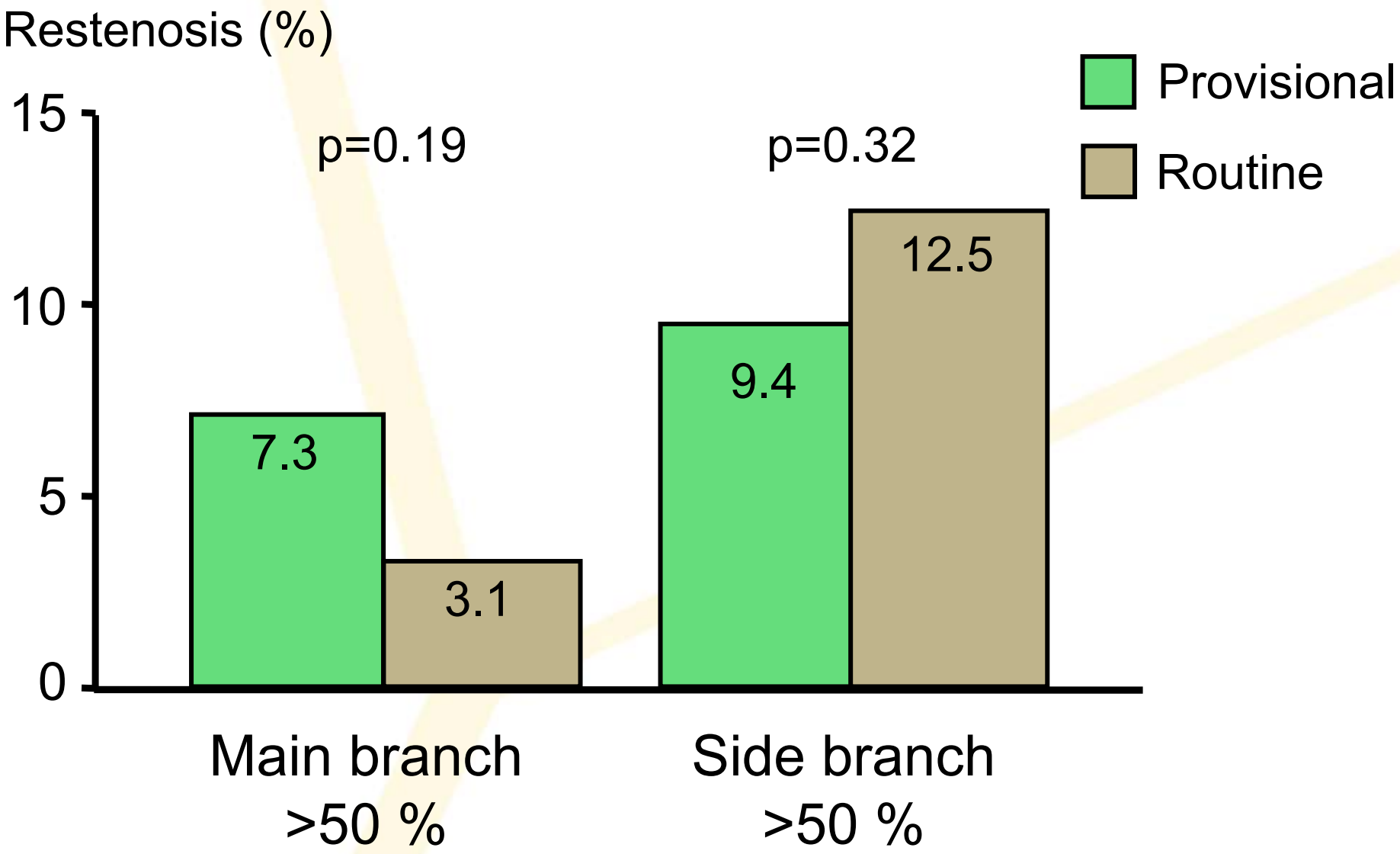
In-segment percent diameter stenosis at 9-month follow-up



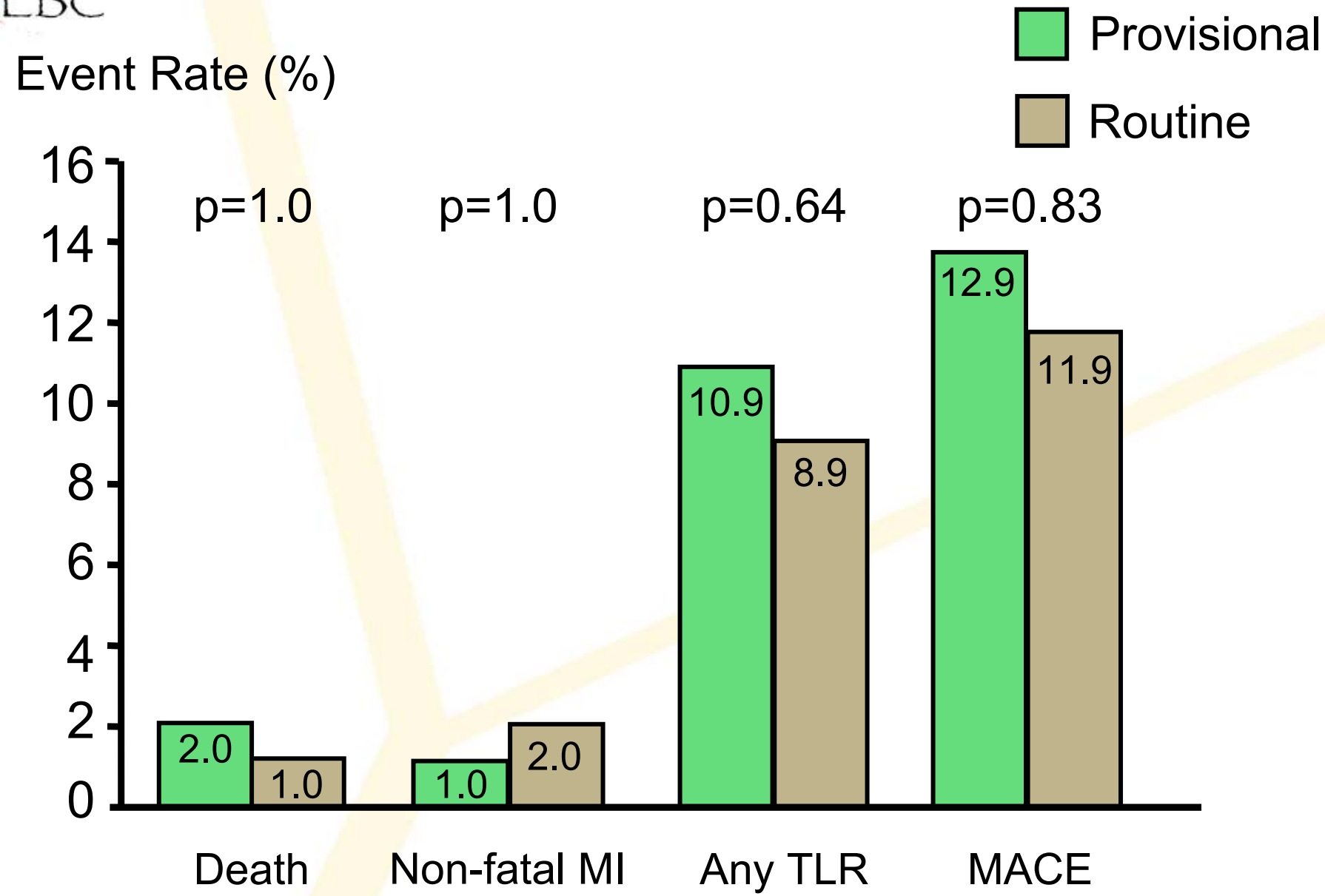
MLD in-stent at 9-month follow-up



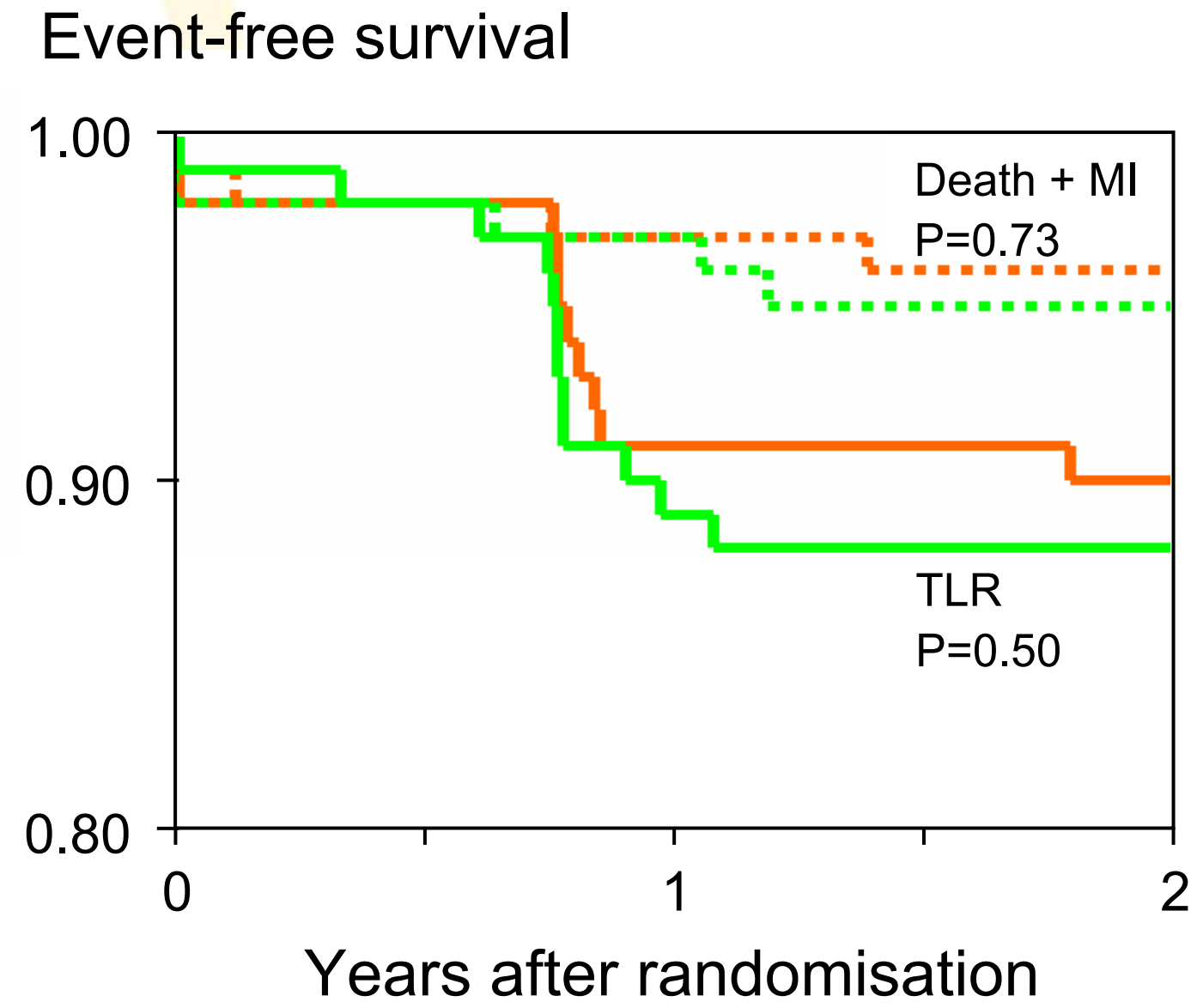
Binary in-segment restenosis



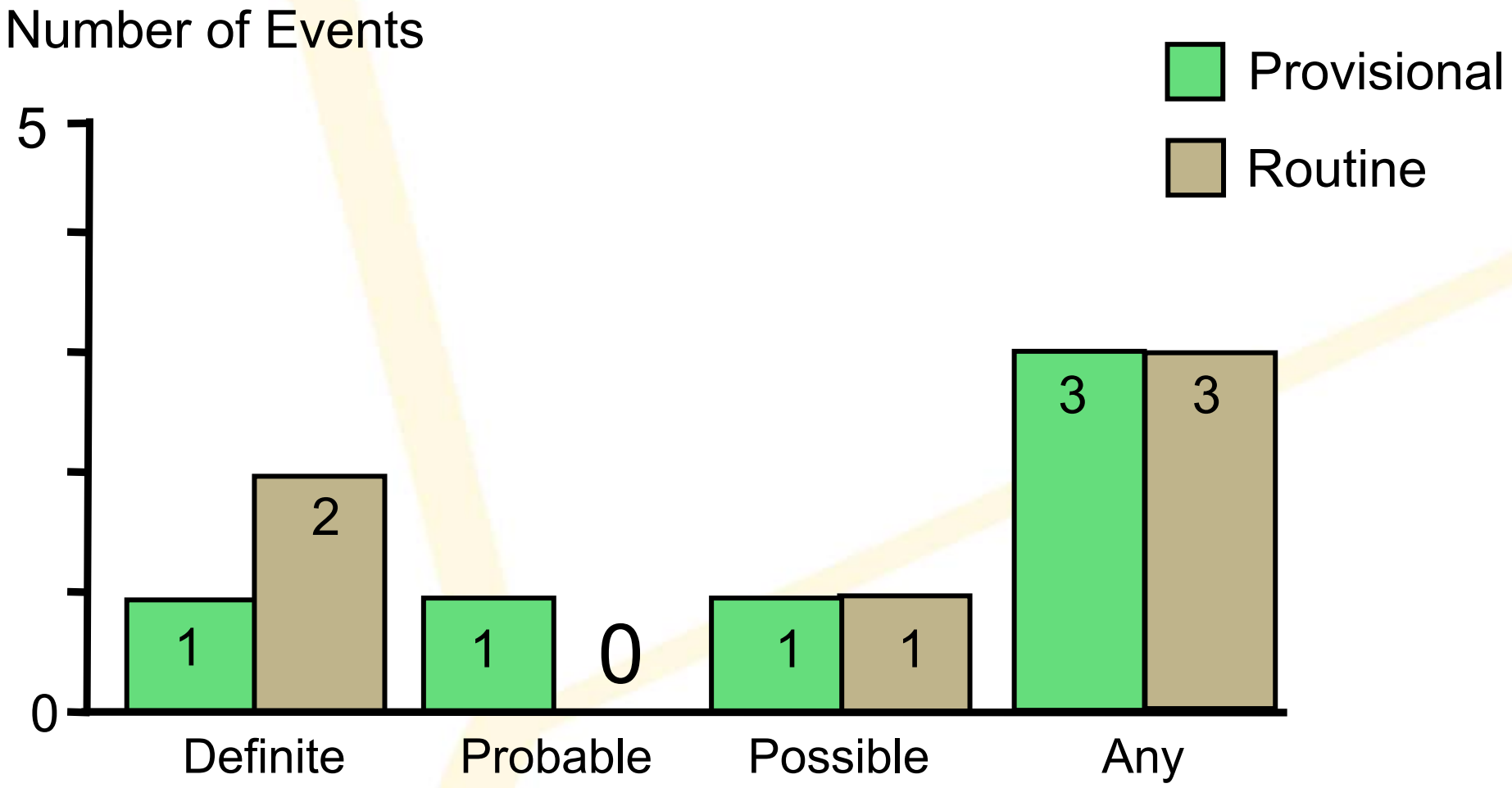
Clinical outcome at 1 year



Clinical outcome at 2 years



Stent thrombosis at 2 year



Conclusions

- Compared with provisional T-stenting, routine T-stenting does not reduce in-segment percent diameter stenosis of the side branch.
- Provisional T-stenting yields a similar angiographic and clinical outcome as the more consumptive routine T-stenting.
- No safety problems were seen between first and second year post PCI

The data will be available in 1-2 weeks in EHJ

(OPEN ACCESS)