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BETTER CLINICAL OUTCOME WITH FINAL KISSING

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INTRODUCTION

- SORRY FOR THE TITLE OF PRESENTATION BUT…

- we know (dedicated trial, NORDIC III) that Kissing balloon does not reduce major adverse events in patients at low risk undergoing provisional approach…

- but… is MACE at 6-months the best end-point to evaluate the clinical effect of kissing balloon in a low risk population?

A NEW PROSPECTIVE STUDY ON BIFURCATED LESIONS

SEA-SIDE

Sirolimus vs Everolimus –eluting stent randomized Assessment in bifurcated lesions and clinical SIgnificance of residual siDE-branch stenosis

registered in ClinicalTrials.org website, NCT00697372

AIM OF THE SB STUDY

TO ASSESS IF RESIDUAL SIDE-BRANCH STENOSIS EVALUATED BY 3DQCA MAY BE ASSOCIATED TO POST-PCI INDUCIBLE ISCHEMIA

BACKGROUND

- Standard 2D angiography is not adequate to assess side-branch ostial lesions (especially after main vessel stenting) but 3DQCA may be more accurate

- The clinical significance (correlation with inducible ischemia) of residual side branch stenosis is not well established

- Stresst est is frequently adopted to follow patients treated by PCI but no data are available about its results in patients treated on bifurcated lesions

STUDY DESIGN & METHODS

150 patients with bifurcated lesion scheduled for DES implantation (no contraindication to prolonged double antiplatelet therapy, no AMI)

Randomization 1:1 Cypher or Xience

PCI with Provisional TAP-stenting

Incomplete revascularization and/or EKG not interpretable

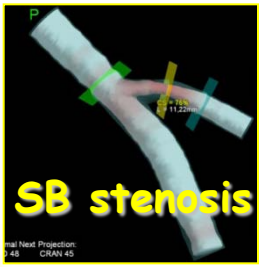
COMPLETE REVASCULARIZATION (no other stenosis ≥50%) & EKG interpretable (n=60)

Ergometric test (within 5 days) to asses residual ischemia (BLIND TO ANGIO DATA)

Off-line 3D QCA (Paieon) to assess residual stenosis on SB (BLIND to CLINICAL DATA)

CHARACTERISTICS OF THE STUDY POPULATION

Patients with SB cross-sectional area stenosis ≥ 50% at 3DQCA

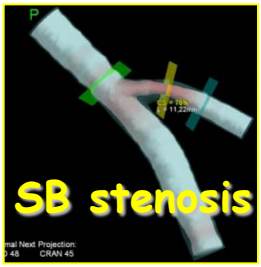


Patients with SB cross-sectional area stenosis <50% at 3DQCA

11	Pts number	49
36%	Acute Coronary Syndrome	37%
9% 64% 27%	Distal Left Main LAD/Diag Other bifurc	14% 61% 25%
37%	Multivessel Disease	41%
36% 36% 28%	Medina 1,1,1 Medina 1,1,0 or 1,0,1 or 0,1,1 Other Medina	29% 37% 34%

3DQCA BEFORE AND AFTER PCI

Patients with SB cross-sectional area stenosis ≥ 50% at 3DQCA



Patients with SB cross-sectional area stenosis <50% at 3DQCA

	3DQCA BEFORE PCI	
71±18%	MV cross-sectional stenosis	77±16%
66±12%	SB cross-sectional stenosis	54±25%
72±22°	Bifurcation angle	67±17°
	3DQCA AFTER PCI	
21±10%	MV cross-sectional stenosis	28±13%
54±31%	SB cross-sectional stenosis	18±15%
69±11°	Bifurcation angle P<0.001	60±13°

PROCEDURAL CHARACTERISTICS

Patients with SB cross-sectional area stenosis ≥ 50% at 3DQCA

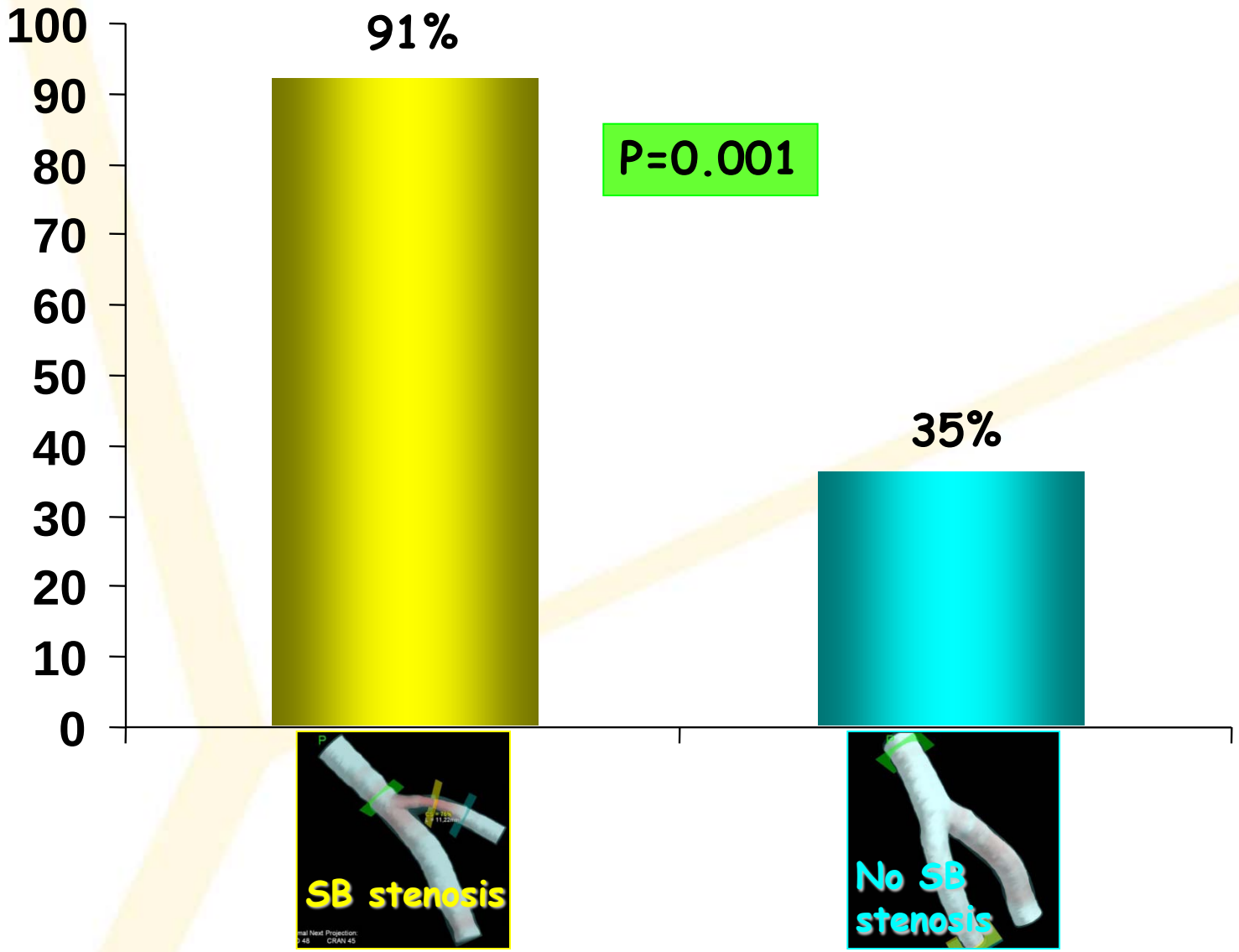
Patients with SB cross-sectional area stenosis <50% at 3DQCA

4 / 7	TYPE OF DES (SES-EES)	21 / 28
9%	MV Direct Stenting	44%
3.4±0.5 mm 27±8 mm	MV STENT Diameter MV STENT Lenght	3.3±0.3 mm 29±13 mm
27%	>1 Overlapping stent in MV	26%
0%	SB stenting (TAP)	10.2%
36%	Final kissing balloon *	69%

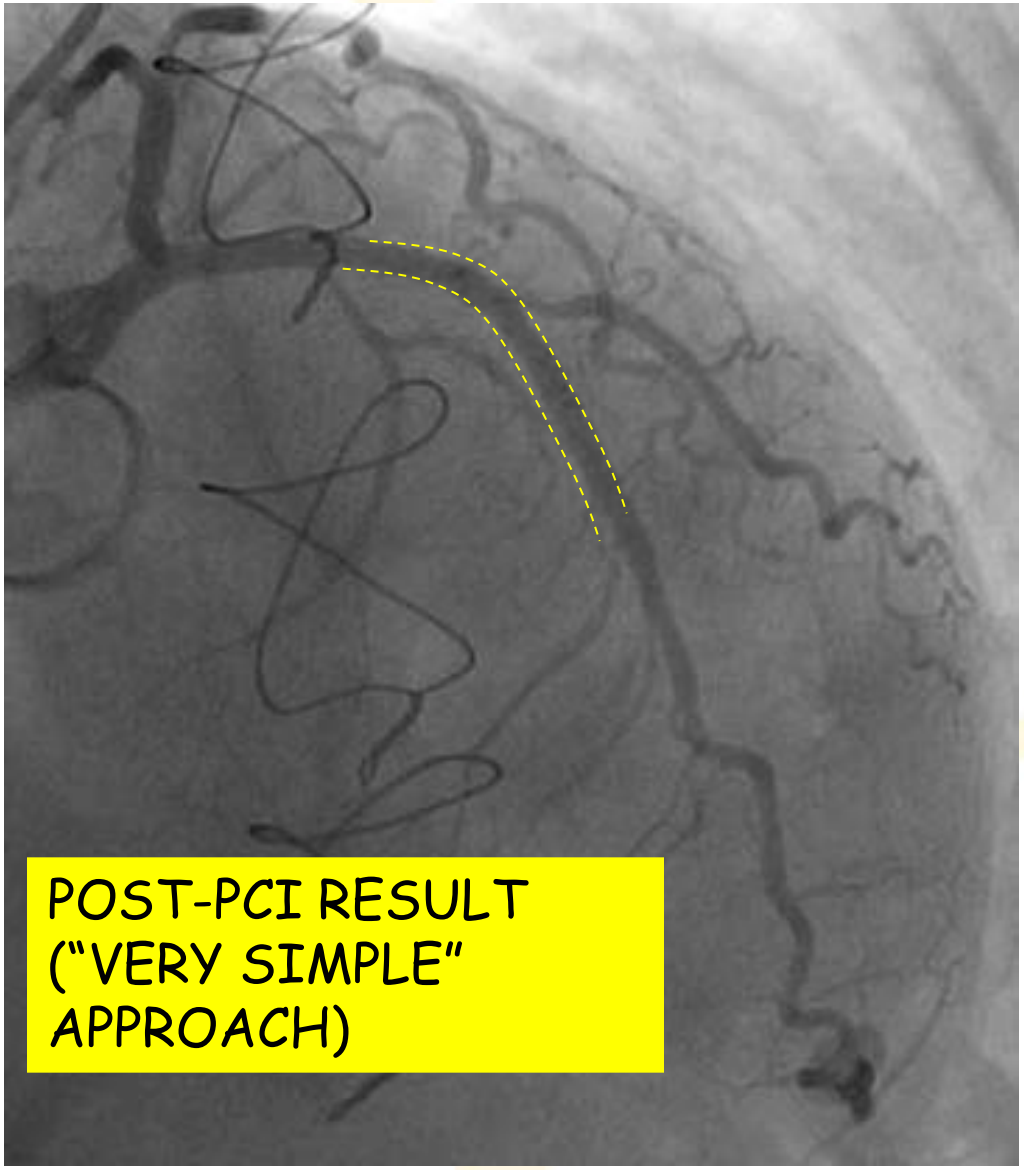
P<0.05

PRIMARY END-POINT: POST-PCI INDUCIBLE ISCHEMIA

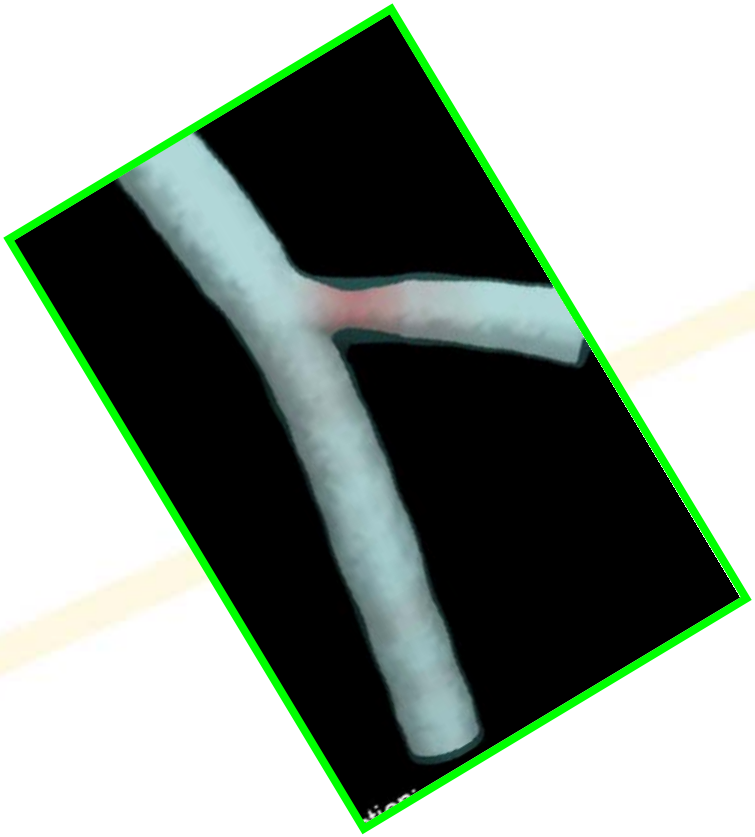
≥1 mm ST-depression @ ergometric test within 5 days



POST-PCI INDUCIBLE ISCHEMIA: AN EXAMPLE

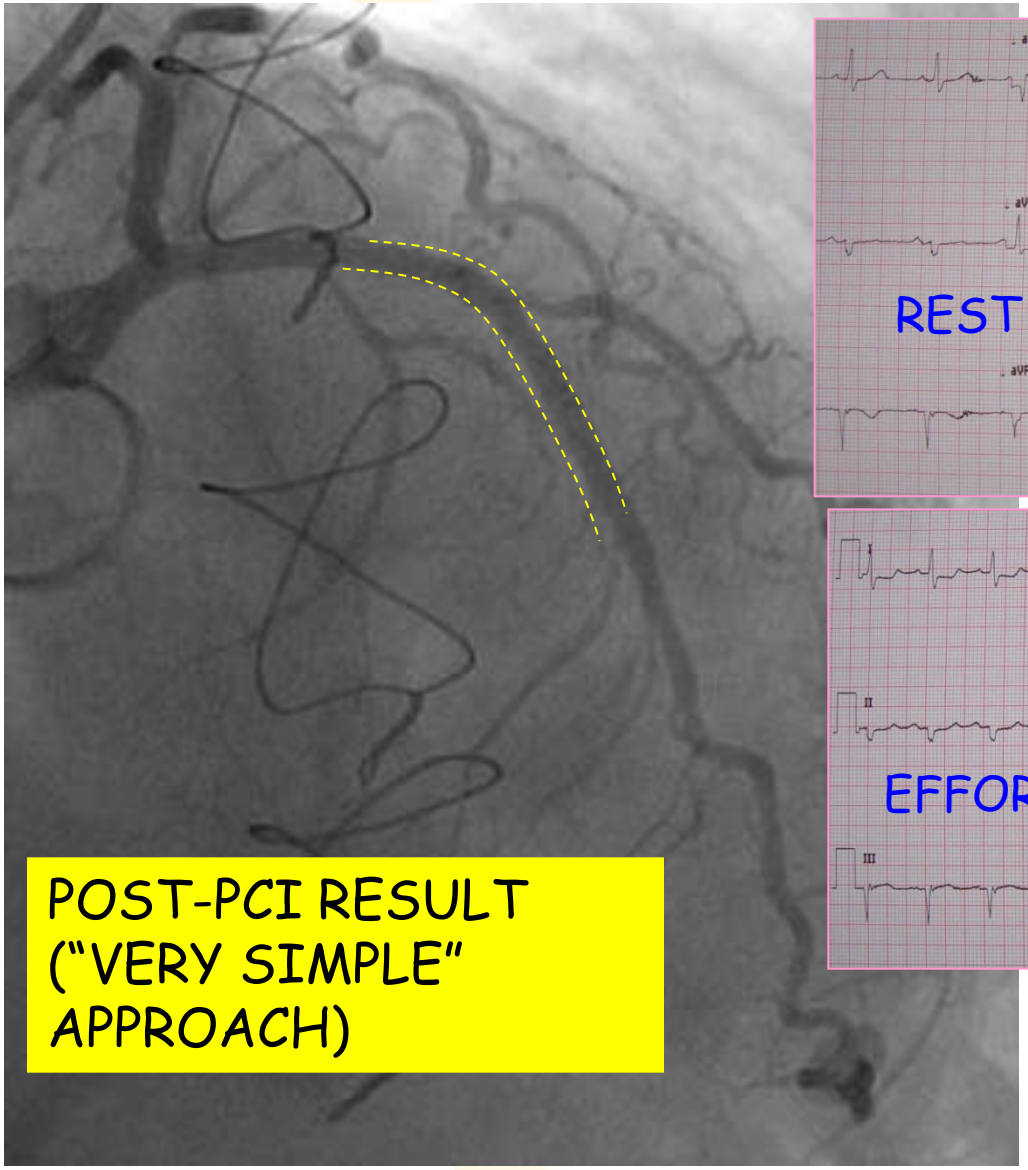


POST-PCI RESULT ("VERY SIMPLE" APPROACH)

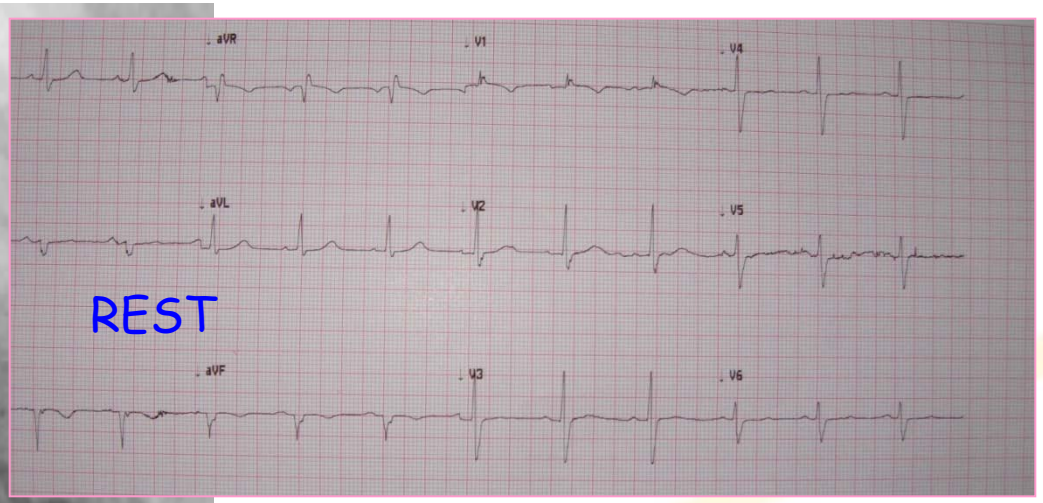


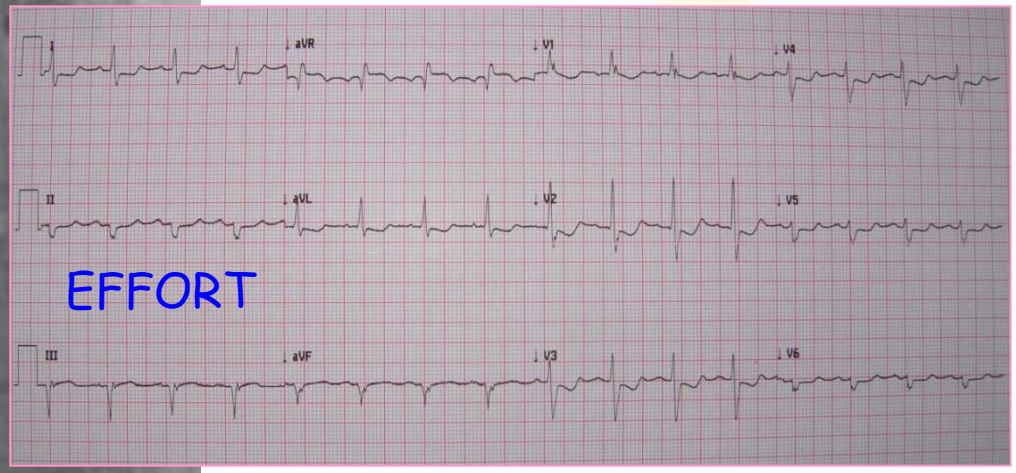
OFF-LINE 3DQCA RECONSTRUCTION

POST-PCI INDUCIBLE ISCHEMIA: AN EXAMPLE



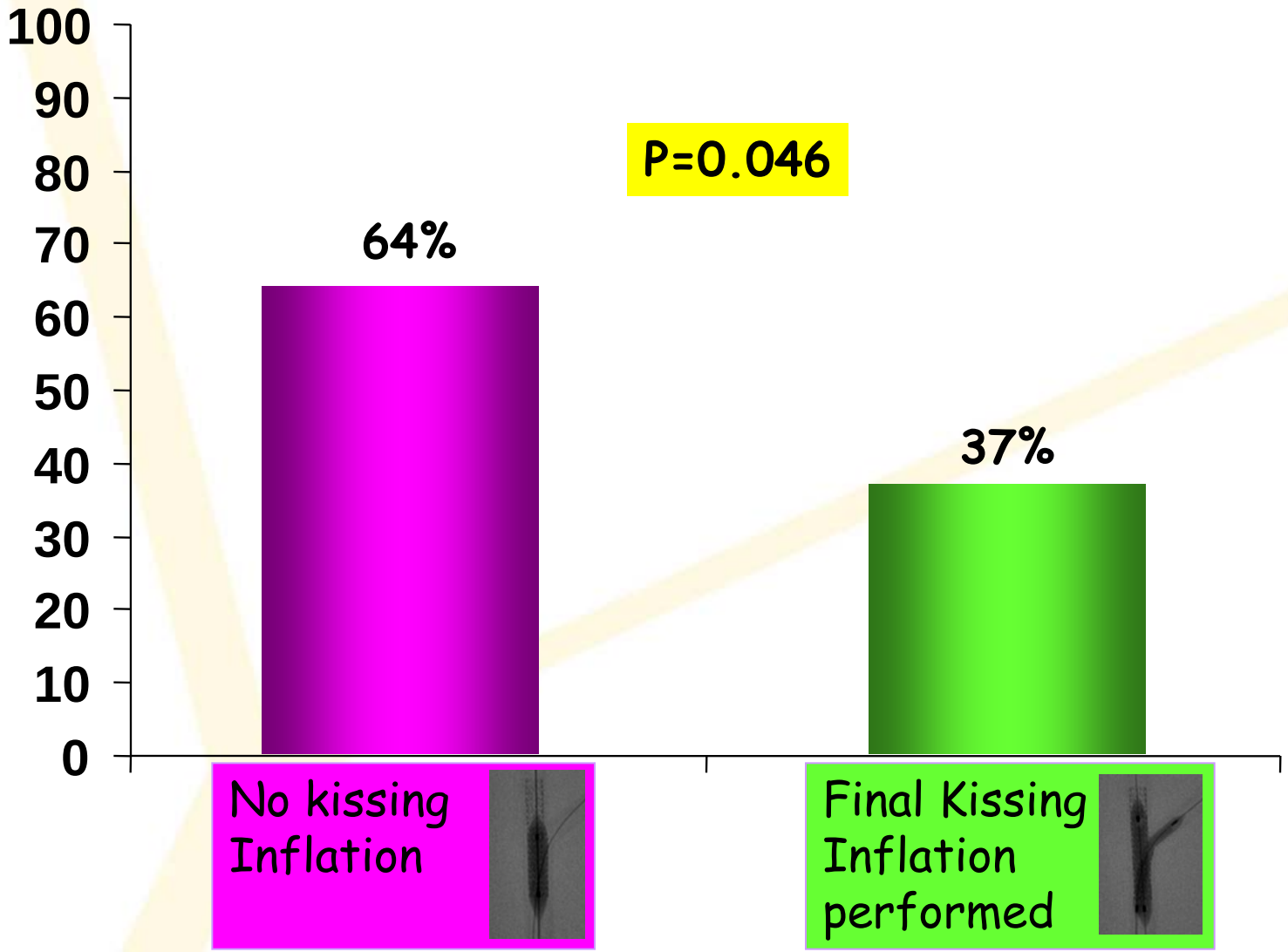
POST-PCI RESULT ("VERY SIMPLE" APPROACH)





PROCEDURAL PREDICTORS OF POST-PCI INDUCIBLE ISCHEMIA

≥1 mm ST-depression @ ergometric test within 5 days



CONCLUSIONS

IN PATIENTS UNDERGOING A PROVISIONAL APPROACH…

1. 3DQCA DETECTS >50% SIDE-BRANCH AREA STENOSIS IN 18% OF THE PATIENTS

2. A ≥50% 3DQCA AREA STENOSIS IS STRONGLY ASSOCIATED WITH POST-PCI RESIDUAL INDUCIBLE ISCHEMIA (pre-defined primary study end-point)

3. FINAL KISSING BALLOON INFLATION IS ASSOCIATED WITH ABSENCE OF POST-PCI RESIDUAL INDUCIBLE ISCHEMIA

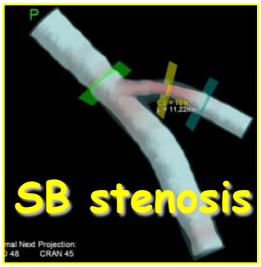
KISSING MAY BE USEFUL !

U.C.S.C. Interventional Cardiology

Thank you for your attention

RESULTS: CLINICAL OUTCOME

Patients with SB cross-sectional area stenosis ≥ 50% at 3DQCA



Patients with SB cross-sectional area stenosis <50% at 3DQCA

20 months	Mean Follow-up	20 months
9%	MACE	4%
0%	MI	4%
9%	TLR	2%
0%	Death	0%
9%	EFFORT ANGINA	12%
82%	INDUCIBLE ISCHEMIA IN THE FOLLOW-UP (>2 MONTHS) *	36%
82%	COMPOSITE # (MACE AND/OR EFFORT ANGINA AND/OR INDUCIBLE ISCHEMIA)	45%

* p=0.006

p=0.03