

Routine Kissing Is Not Necessary

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

Company

- Abbott Vascular, Boston Scientific
- Abbot Vascular, Biosensors, Biotronik, Boston Scientific, Cordis J&J, Medtronic

Consensus from European Bifurcation Club, 2014

Kissing balloon inflations in simple stenting

No clinical advantage of a routine kissing strategy in single-stent treatment has been shown³¹⁻³⁴. Theoretical advantages of kissing balloon inflation after single-stent treatment include restoration of anatomy^{35,36}, expansion of the proximal MV, apposition of jailing struts and balloon treatment of ostial SB lesions. Disadvantages include increased procedural complexity³¹, risk of SB dissection, risk of creating a metal carina³⁷, stent distortion and accidental stent crush by proximal abluminal rewiring.

Routine kissing inflations using the provisional technique have caused significant debate during the EBC meetings. It was agreed that, in the absence of an angiographically tight lesion at the ostium of the SB after MV stenting, kissing balloon inflations are not routinely required. When a tight lesion (>75% DS or TIMI flow <3) is present in the SB after MV stenting, it is known that kissing balloon inflation will reduce the physiologically significant proportion of SBs from 30% to 5%38. Therefore, kissing balloon dilatation may be performed in angiographically significant (>75% DS or TIMI flow <3) ostial SB lesions as there appears to be no overall penalty for doing so31. It is unknown if FFR-guided SB intervention in non-LMCA bifurcations provides improved clinical outcome compared to angiographically guided SB intervention (see section on FFR).

EBC consensus:

Simple stenting:

Kissing balloon inflations may be used when an angiographically significant (>75% DS or TIMI flow <3) ostial SB lesion remains after MV stenting.

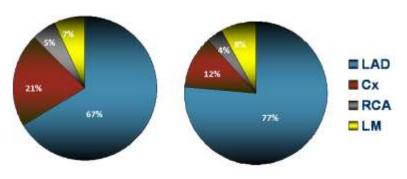
Two-stent technique:

Final kissing balloon dilatation is mandatory in any two-stent technique.

Nordic Baltic Bifurcation Study III Procedura data

Nordic-Baltic Bifurcation Study III: A prospective randomized trial of side branch dilatation strategies in patients with coronary bifurcation lesions undergoing treatment with a single stent

No kissing (n=239) Kissing (n=238)

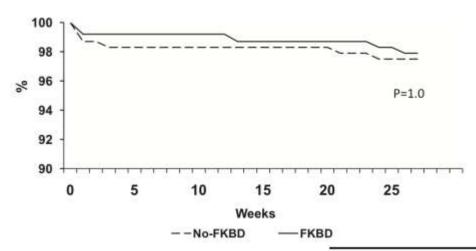


True bifurcations (Medina classification 1,1,1 - 1,0,1 - 0,1,1): 50.8% FKBD vs. 49.0% No FKBD, p=0.71

| | No FKBD n=239 | FKBD n=238 | P |
|---|------------------|---------------|--------|
| LVEF, % | 59±10 | 58±11 | 0.44 |
| Mean lesion length, mm* | | | |
| MV | 17.7±10.2 | 17.3±8.6 | 0.58 |
| SB | 3.6±4.2 | 3.4 ± 3.9 | 0.62 |
| MV mean stent length, mm* | 22.9±10.5 | 23.6±11.1 | 0.50 |
| Proximal reference diameter, mm* | | | |
| MV | 3.4±0.4 | 3.4±0.6 | 0.58 |
| SB | 2.7 ± 0.4 | 2.6 ± 0.3 | 0.05 |
| MV stented, n (%) | 238 (99.6) | 238 (100) | 1.00 |
| SB stented, n (%) | 0 (0) | 3 (1.3) | 0.12 |
| SB dilatation through MV stent, n (%) | 3 (1.3) | 79 (33.3) | 0.0001 |
| FKBD, n (%) | 2 (0.8) | 231 (97.1) | 0.0001 |
| SB dilatation through MV stent or FKBD, n (%) | 4 (1.7) | 231 (97.1) | 0.0001 |
| Treatment successful, n (%)† | 236 (98.7) | 236 (99.2) | 1.00 |
| Procedure time, min | 47±22 | 61±28 | 0.0001 |
| Fluoroscopy time, min | 11±10 | 16±12 | 0.0001 |
| Contrast volume, mL | 200±92 | 235±97 | 0.0001 |

FKBD: finalized by a kissing balloon dilatation Niemela M et al. *Circulation*. 2011;123:79-86

Nordic III Clinical Outcomes at 6-Months Follow-Up



Kaplan-Meier curves for MACE-free survival (cardiac death, non procedure-related index lesion MI, TLR, definite stent thrombosis)

| | No FKBD (n=239), n (%) | FKBD (n=238), n (%) | Р |
|---------------------|---------------------------|------------------------|------|
| Noncardiac death | 0 (0) | 1 (0.4) | 0.49 |
| Cardiac death | 0 (0) | 2 (0.8) | 0.24 |
| Index lesion MI* | 3 (1.3) | 1 (0.4) | 0.62 |
| TLR | 4 (1.7) | 3 (1.3) | 1.00 |
| CCS class ≥2 angina | 29 (12.0) | 28 (11.7) | 1.00 |
| Stent thrombosis | 1 (0.4) | 1 (0.4) | 1.00 |

The χ^2 test was used.

^{*}Not procedure related.

Nordic III

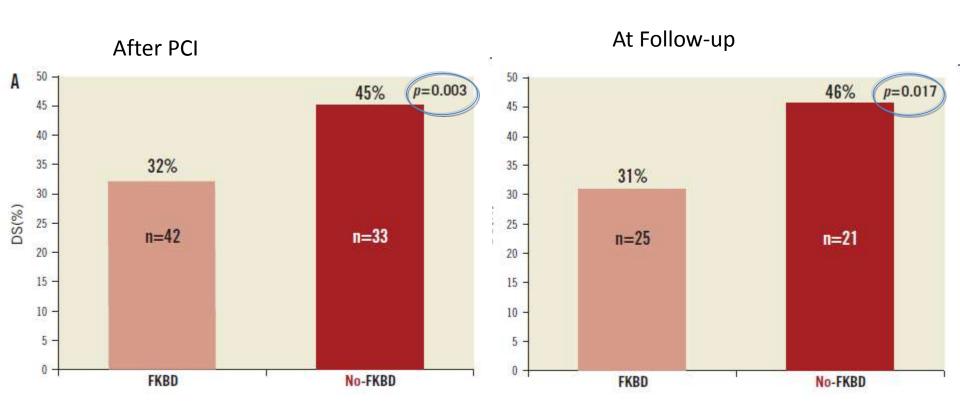
True Versus Nontrue Bifurcation Subgroup Comparison: 8-Month Angiographic Follow-Up

| | True | e Bifurcation Subgroup | Nontrue Bifurcation Subgroup | | | |
|-----------------------|---------------------------------------|------------------------|------------------------------|-----------------|----------------|------|
| Variable | FKBD (n=92) | (n=92) No FKBD (n=80) | | FKBD (n=72) | No FKBD (n=82) | Р |
| In-segment MV | · · · · · · · · · · · · · · · · · · · | | | | | |
| DS, % | 22 ± 15 | 22±15 | 0.85 | 22 ± 14 | 21±12 | 0.90 |
| ≥50% DS, n (%) | 3 (3.8) | 2 (2.2) | 0.67 | 3 (4.2) | 1 (1.2) | 0.34 |
| Ostial 5 mm of the SB | | | | | | |
| MLD, mm | 1.71 ± 0.42 | 1.50 ± 0.53 | 0.005 | 1.79 ± 0.54 | 1.77±0.61 | 0.79 |
| DS, % | 25 ± 14 | 32±21 | 0.009 | 23 ± 15 | 27±19 | 0.21 |
| ≥50% DS, n (%) | 7 (7.6) | 16 (20) | 0.024 | 6 (8.3) | 9 (11) | 0.79 |

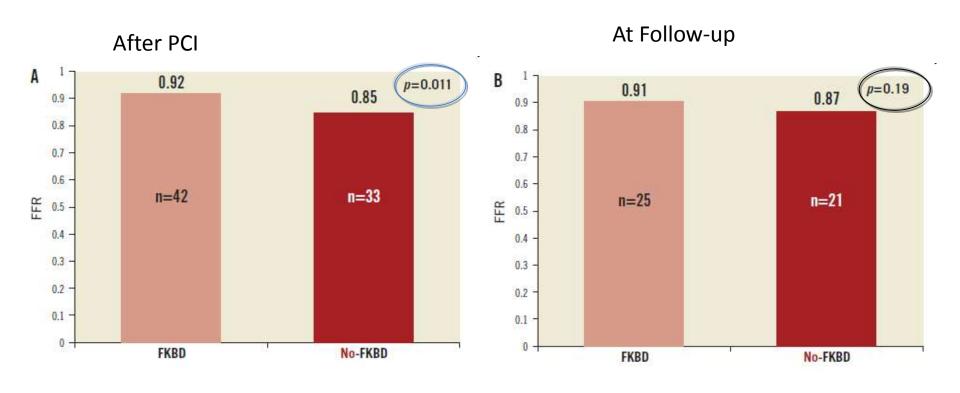
DS indicates diameter stenosis; MLD, minimal luminal diameter. The Fisher exact test, χ^2 test, or independent-samples t test was used.

FKBD reduced angiographic side branch (re)stenosis, especially in patients with true bifurcation lesions

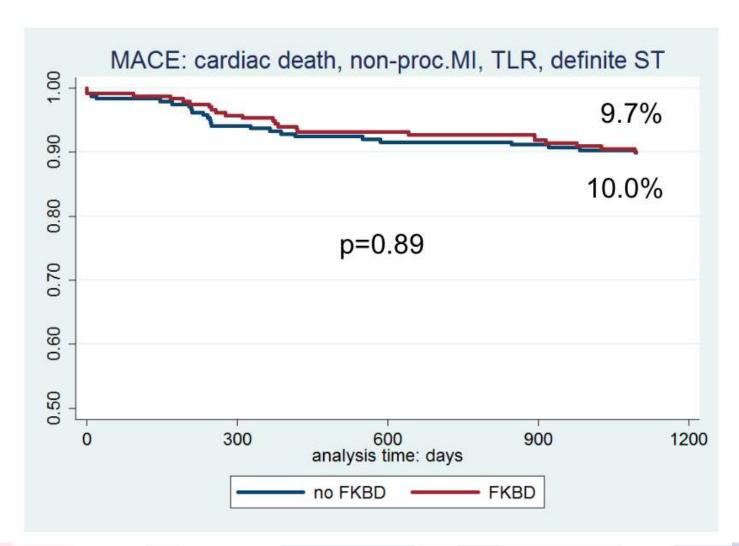
Nordic III FFR substudy: Mean SB stenosis by QCA



Nordic III FFR substudy: Mean FFR in Side Branch



Nordic III MACE-Free Survival at 36-Month Follow-Up



Nordic III Clinical Outcomes at 36-Months Follow-Up

True bifurcation lesions

| | No-FKBD (n=118) | FKBD (n=12 | Service I Market II | | | | |
|-------------------------------------|--------------------|---------------|---------------------|------------------------------|--------------------|-----------------|--------|
| MACE (%) | 12.7 | 9.1 | 0.37 | | | | |
| MACE total death (%) | 14.4 | 12.4 | 0.65 | | | | |
| Total death (%) | 2.5 | 5.0 | 0.33 | | | | |
| Cardiac death (%) | 1.7 | 0.9 | 0.58 | | | | |
| Non-procedural MI (%) | 4.2 | 4.1 | 0.97 | | | | |
| Stent thrombosis, definite (%) | 1.7 | 8.0 | 0.55 | Non-true bif | urcation I | esions | |
| Target lesion revascularization (%) | 10.2 | 5.8 | 0.21 | Hom true briancation resions | | | |
| | | | | | No-FKBD (n=121) | FKBD (n=117) | р |
| | | | MACE (%) | | 7.4 | 10.3 | 0.44 |
| | | | MACE total | death (%) | 9.1 | 13.7 | 0.27 |
| | | | Total death | (%) | 1.7 | 6.8 | 0.046* |
| | | | Cardiac dea | th (%) | 0 | 2.6 | 0.10 |
| | | 1 | Non-proced | ural MI (%) | 1.7 | 1.7 | 0.97 |
| | | , | Stent throm | bosis, definite (%) | 0.8 | 0.9 | 0.98 |

Target lesion revascularization (%) 6.6

0.94

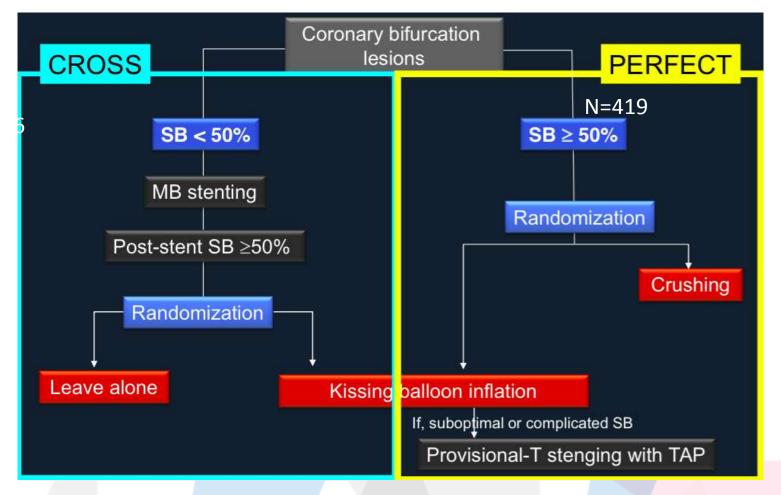
6.8

CROSS and PERFECT trials

306 patients with non-diseased SB (>2.0mm and < 50% stenosis)

419 patients with diseased SB (>2.0mm and 50% stenosis)

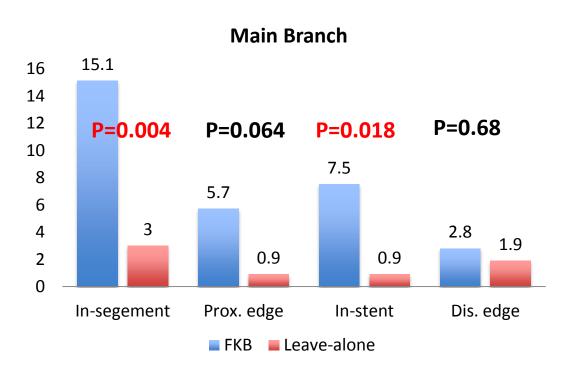
Randomized trial, 15 centers in Korea

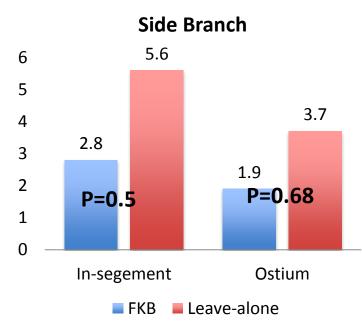


CROSS trial: Angiographic primary endpoint and Restenosis

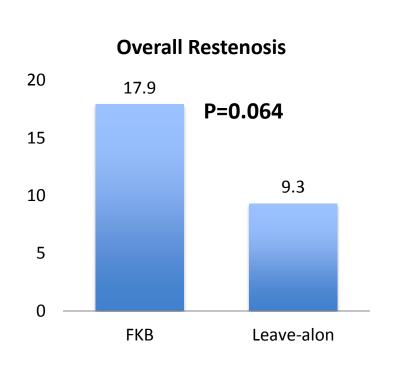
CROSS study angiographic primary endpoint: SB in-segment % DS:

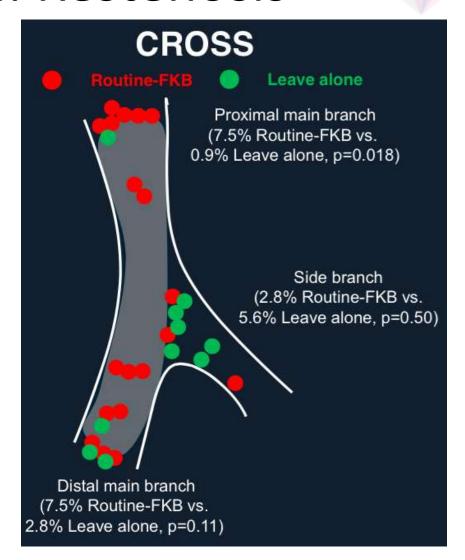
- 31.1 ± 14.5 % in the routine FKB group
- $34.9 \pm 15.8 \%$ in the leave alone group
- Non-inferiority p < 0.001, Superiority p = 0.074





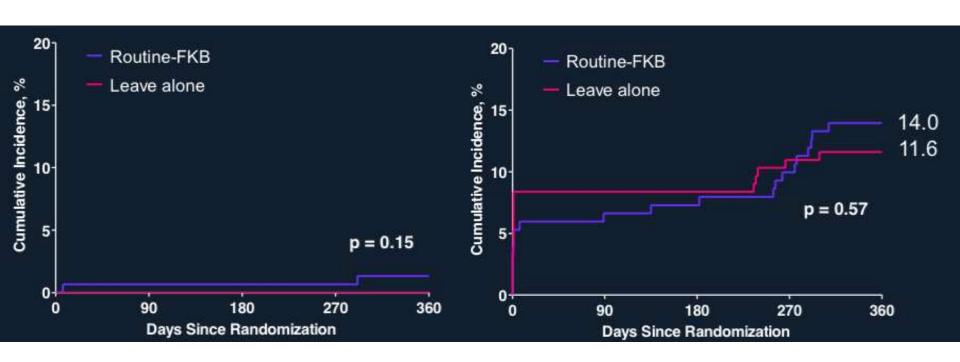
CROSS trial: Restenosis





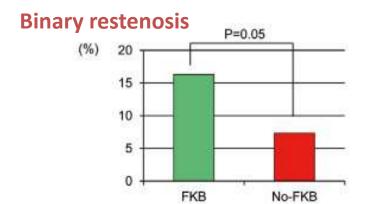
CROSS trial: Clinical outcomes



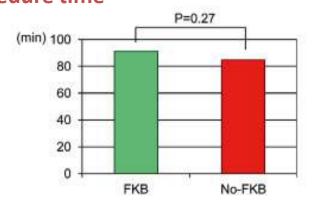


Subanalysis of the TAXUS Japan Postmarket Surveillance Study

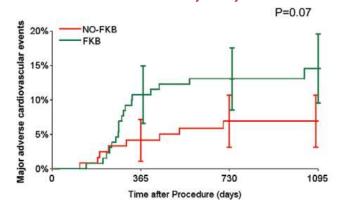
Of 2132 patients enrolled in the TAXUS Japan Postmarket Surveillance Study (2007-2008) patients with bifurcation treated with a single cross-over stenting with FKB (FKB: n=132) were compared to those treated without FKB (no-FKB: n=121).

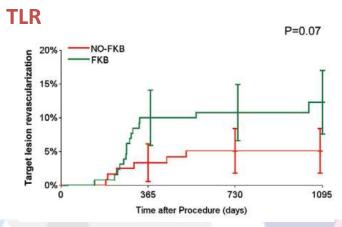


Procedure time



MACE: cardiac death, MI, TVR

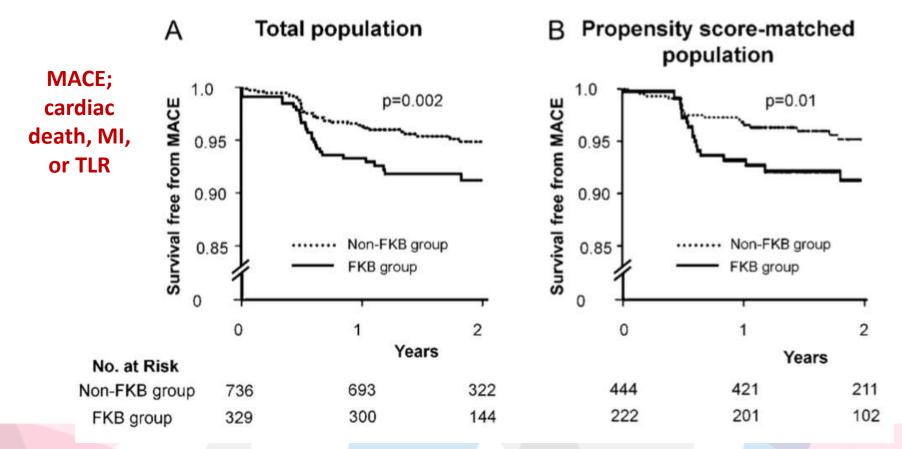




Results from COBIS registry

Consecutive patients (non-FKB group, n=736; FKB group, n=329) after PCI with DES for non-left main bifurcation lesions were enrolled from 16 centres in Korea (2004 -2006).

Propensity score-matching analysis was also performed in 222 patient pairs (444 from the non-FKB group and 222 from the FKB group).

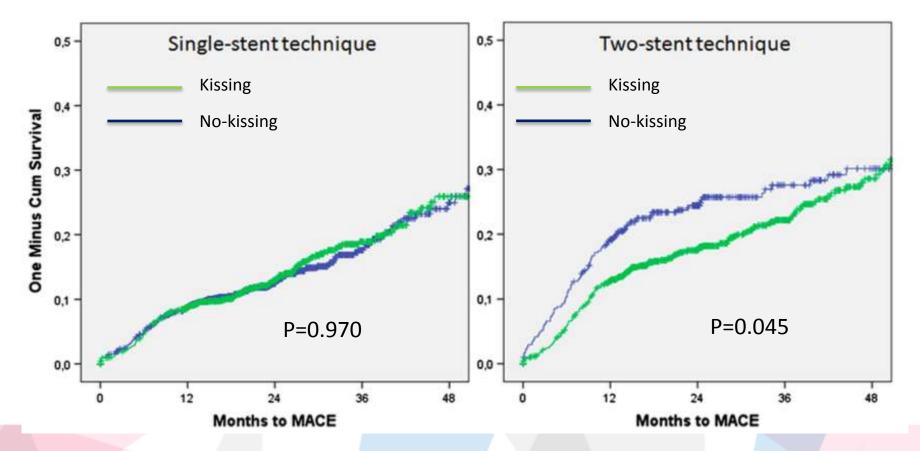


Results from i-BIGIS registry

An Italian multi- center, retrospective, observational clinical study, inde- pendent of commercial funding, enrolling consecutive patients undergoing bifurcation PCI between 2002 and 2006.

MACE (death, MI, or TLR)

P< 0.001 at overall log-rank test, P = 0.970 in the single-stent group, P = 0.045 in the two-stent group



Conclusion

- There is no clinical advantage of a routine kissing postdilatation and it can be avoided in bifurcation lesions uneventfully treated with single-stent PCI.
- Final kissing balloon dilatation is mandatory in any two-stent technique.



However, probably a bad kiss is worse than no kiss at all, but a good kiss is still nice.

/David Hildick-Smith. Heart 2012;98:175e176/