First Generation versus Newer Generations Drug-eluting Stents in Unprotected Left Main Coronary Artery Intervention

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Background

1. Of all subjects undergoing CAG, 4% are found to have left main (LM) coronary artery disease (CAD), 80% of whom have significant stenoses in other epicardial coronary arteries.

Ragosta M, et al. Catheter Cardiovasc Interv. 2006;68:357– 62.

2. For the treatment of unprotected LM coronary artery (ULMCA) disease, although coronary artery bypass grafting (CABG) is recommended by the current practice guidelines, percutanous coronary intervention (PCI) with drug-eluting stents (DES) has recently emerged as an alternative to CABG.

Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Subset of CAD by anatomy	Favours CABG	Favours PCI	Ref.
1VD or 2VD - non-proximal LAD	IIb C	I C	—
1VD or 2VD - proximal LAD	I A	IIa B	30, 31, 50, 51
3VD simple lesions, full functional revascularization achievable with PCI, SYNTAX score ≤22	I A	IIa B	4, 30–37, 53
3VD complex lesions, incomplete revascularization achievable with PCI, SYNTAX score >22	I A	III A	4, 30–37, 53
Left main (isolated or 1VD, ostium/shaft)	I A	IIa B	4, 54
Left main (isolated or 1VD, distal bifurcation)	I A	IIb B	4, 54
Left main + 2VD or 3VD, SYNTAX score ≤32	I A	IIb B	4, 54
Left main + 2VD or 3VD, SYNTAX score ≥33	I A	III B	4, 54

PRACTICE GUIDELINE

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association
Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

2.2. Revascularization to Improve Survival: Recommendations

Left Main CAD Revascularization

CLASS I

1. CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main coronary artery stenosis (24–30). *(Level of Evidence: B)*

CLASS IIa

1. PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%) (13,17,19,23,31–48). *(Level of Evidence: B)*
2. PCI to improve survival is reasonable in patients with UA/NSTEMI when an unprotected left main coronary artery is the culprit lesion and the patient is not a candidate for CABG (13,36–39,44,45,47–49). *(Level of Evidence: B)*
3. PCI to improve survival is reasonable in patients with acute STEMI when an unprotected left main coronary artery is the culprit lesion, distal coronary flow is less than TIMI (Thrombolysis In Myocardial Infarction) grade 3, and PCI can be performed more rapidly and safely than CABG (33,50,51). *(Level of Evidence: C)*

CLASS IIb

1. PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of <33, bifurcation left main CAD); and 2) clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe chronic obstructive pulmonary disease, disability from previous stroke, or previous cardiac surgery; STS-predicted risk of operative mortality >2%) (13,17,19,23,31–48,52). *(Level of Evidence: B)*

The NEW ENGLAND JOURNAL of MEDICINE

Percutaneous Coronary Intervention versus Coronary-Artery Bypass Grafting for Severe Coronary Artery Disease

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Randomized Trial of Stents versus Bypass Surgery for Left Main Coronary Artery Disease

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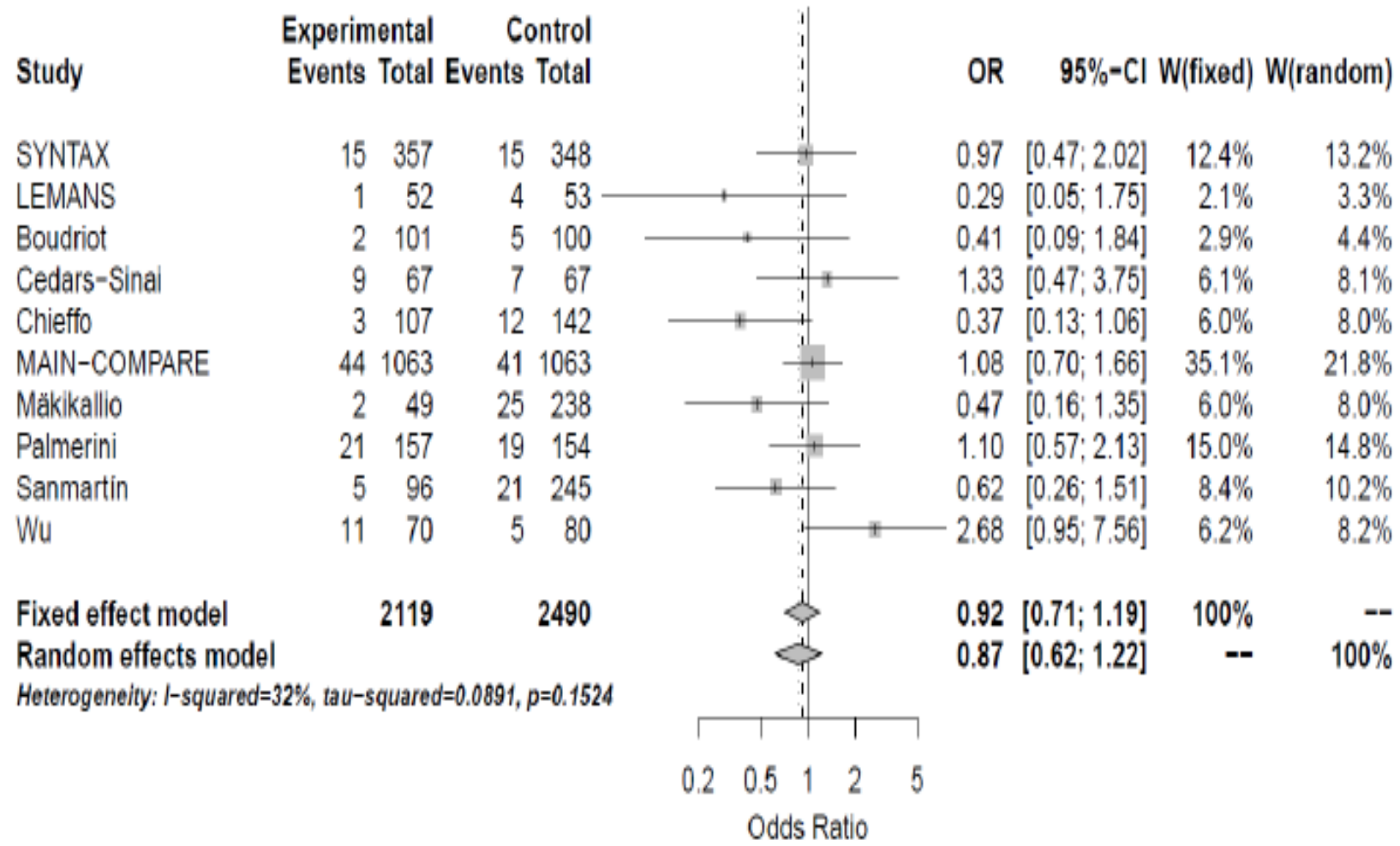
Data Supplement 9. Forest Plot of 1-Year Mortality Rates After PCI or CABG for Unprotected Left Main CAD



Purpose

To investigate whether the newer generations DESs is associated with better outcomes as compared with first generation DESs in treating ULMCA disease in a series of Asian population at real world clinical practice setting.

Methods

1. Study Population

A total 162 patients (pts) who underwent PCI with DESs for ULMCA were enrolled for current study.

2. Study Group

First generation DESs group (n=124 pts)
Second generation DESs group (n= 38 pts)

Methods

1. First generation DESs
   1) Paclitaxel-eluting stents (Taxus™): n=40 pts
   2) Sirolimus-eluting stents (Cypher™):n=84 pts

2. Newer generations DESs
   1) Zotarolimus-eluting stents (Endeavor Resolute™) , n=19 pts
   2) Everolimus-eluting stents (Promus Element™ and Xience™): n=19 pts

Methods

3. Antiplatelet Regimen

1) All pts received Aspirin; 100 mg orally.
2) All pts received Clopidogrel (Plavix®) preloaded 300-600 mg before PCI, followed by daily administration of 75 mg and encouraged to continue at least for 1 year.
3) Usage of adjunctive Cilostazol to dual antiplatelet regimen (asprin + clopidogrel) was depending on physician's discretion. Cilostazol was administered by 200mg post-loading and then 100mg bid for at least one month

Methods

4. Antithrombotic therapy used for PCI

1) Enoxaparin (Clexane®); 60mg bid before PCI and after PCI during the hospital stay (within 7 days).
2) Unfractionated Heparin; a bolus of 50 U/kg prior to PCI for 1st one hour
3) GP IIb/IIIa blocker (Reopro®); depend on physician's discretion.

Methods

5. PCI Procedure

; A variety of atheroablative devices were not utilized and mostly simple predilation or was performed to get an adequate luminal diameter which was necessary to accommodate the unexpanded DES and their delivery system.

6. Study Endpoints

; Angiographic outcome at 6 months & major clinical outcomes up to 12 months were compared between the 2 groups.

Statistics

1. All statistical analyses were performed using SPSS 17.0.
2. Continuous variables were expressed as means ± standard deviation and were compared using Student's t-test.
3. Categorical data were expressed as percentages and were compared using chi-square statistics or Fisher's exact test.
4. A *P*-value of 0.05 was considered statistically significant.

Results

Baseline Clinical Characteristics

Variable .n(%)	First generation DES group (n=124)	Newer generation DES group (n=38)	P-value
Gender (male)	80 (65)	32 (84.2)	0.025
Age	64.12±11.32	65.32±8.77	0.497
Prior MI	9 (7.4)	1 (2.6)	0.287
Hypertension	82 (67.8)	29 (76.3)	0.317
Diabetes	47 (38.8)	18 (47.4)	0.351
Hyperlipidemia	21 (17.4)	8 (21.2)	0.607
CVD	6 (5)	2 (5.3)	0.940
LV ejection fraction	50.43±10.96	53.46±10.82	0.145
Peripheral vascular disease	6 (5)	0 (0)	0.173
Smoking (Current)	40 (33.3)	13 (34.2)	0.920

Procedural Characteristics & Outcomes

Variable .n(%)	First generation DES group (n=124)	Newer generation DES group (n=38)	P-value
RVD	3.38±0.51	3.43±0.47	0.624
preMLD	0.95±0.66	0.87±0.52	0.525
postMLD	3.23±0.74	3.24±0.63	0.973
length	22.01±11.65	18.21±7.29	0.082
Stent Diameter	3.32±0.35	3.49±0.47	0.039
Stent Length	22.56±7.37	20.08±5.53	0.031
Inflation pressure	15.28±3.40	11.84±2.85	<0.001
IUVS	59 (47.6)	24 (64.9)	0.065
FKB	55 (44.4)	11 (28.9)	0.091
Bailout stenting	3 (6.7)	1 (5.9)	0.911
Thrombosis	7 (5.6)	3 (7.9)	0.614
Reopro	9 (7.3)	5 (13.2)	0.257

Six months angiographic outcomes

Variable .n(%)	First generation DES group (n=124)	Newer generation DES group (n=38)	P-value
Diameter stenosis (DS), %	16.67±20	14.19±18.1	0.637
ISR (>30%)	21 (24.2)	6 (35.3)	0.352
Binary restenosis (>50%)	14 (16.3)	5 (29.4)	0.202
Follow up MLD	2.84±0.86	2.89±0.87	0.833
Late loss	0.53±0.69	0.61±0.63	0.694
Aneurysm	6 (7.7)	0 (0)	0.237
Thrombus	7 (5.6)	3 (7.9)	0.614

Twelve months clinical outcomes

Variable .n(%)	First generation DES group (n=124)	Newer generation DES group (n=38)	P-value
Total death	13 (11)	2 (5.6)	0.333
Cardiac death	8 (6.8)	2 (5.6)	0.794
Non cardiac death	5 (4.2)	0 (0)	0.209
Q-Myocardial infarction	4 (3.4)	0 (0)	0.263
TLR	11 (9.3)	2 (5.6)	0.477
TVR	16 (13.6)	4 (11.1)	0.702
All MACE	32 (27.1)	6 (16.7)	0.203
TLR MACE	18 (15.3)	4 (11.1)	0.534
TVR MACE	28 (23.7)	6 (16.7)	0.371

Results-Summary (1)

1. Baseline characteristics were similar between the two groups except that newer generations DESs group had a higher male gender .

2. At index procedure, there was trend towards higher use of IVUS in newer generations DESs group whereas more use of final kissing balloon in first generation DESs group.

Results (Summary 2)

3. At six months, there were no differences in major angiographic outcomes and similar results were found in major clinical outcomes up to twelve months.

4. The DES associated aneurysms were found only after the first generation DESs implantation.

Conclusion

In the current study, there were no significant differences between first & newer generations DESs at 6 months angiographic and 12 months clinical outcomes following ULMCA intervention.

Thank You for Your Attention!!