WHEN TO DO ELECTIVE INTERVENTION IN MULTI-VESSEL DIABETIC PATIENTS?

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CAD AMONG DIABETICS IS:

- More prevalent
  - Diabetics are 2-4 times more likely to develop CVD than those without diabetes
  - 80% of pts with T2DM will develop CVD
  - The CVD risk in DM is greater among women (3.5) than in men (2.6)
  - DM comprise 25-30 percent of those who undergo revascularization
- Anatomically more extensive disease (multi-vessel disease anatomy, distal disease)
- More silent ischemia
- Worst long term outcomes, even in revascularized patients.
- Similar indications for revascularization as non-diabetics.

CURRENT EVIDENCE: PCI VS CABG

Year of publication	Study	N	Baseline characteristics					Primary endpoint			Max clinical follow-up				
			Age (y)	Wo-men (%)	Dia-betes (%)	MVD (%)	EF (%)	Definition	y	Results	y	Death	MI	Revasc.	Stroke
Balloon angioplasty															
1993	RITA-I [146]	1011	-	19	6	55	-	Death or MI	2.5	9.8% vs. 8.6%	6.5	7.6% vs. 9.0%	10.8% vs. 7.4%	44.3% vs. 10.8%[a]	1.8% vs. 2.0% (at 2.5 y)
1994	GABI I [47]	359	-	20	12	100	-	Angina	1	29% vs. 26%	13	25.0% vs. 21.9%	4.3% vs. 5.6%	82.9% vs. 58.8%[a]	-
1994	EAST [148]	392	62	26	23	100	61	Death, MI, or a large defect at thallium scan	3	28.8% vs. 27.3%	8	20.7% vs. 17.3%	3.0% vs. 10.3%[a] (at 3 y)	65.3% vs. 26.5%[a]	0.5% vs. 1.5% (at 3 y)
1955	CABRI [149]	1054	60	22	12	99	63	Death	1	3.9% vs. 2.7%	4	10.9% vs. 7.4%	4.9% vs. 3.5% (at 1 y)	33.6% vs. 6.5%[a] (at 1 y)	-
1996	BARI [150]	1829	62	27	25	100	57	Death	5	13.7% vs. 10.7%	10	29.0% vs. 26.5%	-	76.8% vs. 20.3%[a]	0.2% vs. 0.8% (in

BMS = bare-metal stents; CABG = coronary artery bypass grafting; EF = ejection fraction; MI = myocardial infarction; MV = multivessel; MVD = multivessel disease; PES = paclitaxel-eluting stents; Revasc = revascularization; SES = sirolimus-eluting stents; TVR = target-vessel revascularization; y = years.
[a]$P<0.05$.
[b]Non-inferiority met.
[c]Non-inferiority failed only trials with at least 100 patients per treatment arm were included.
Age and ejection fraction are reported as means.

Year of publication	Study	N	Baseline characteristics					Primary endpoint			Max clinical follow-up				
			Age (y)	Women (%)	Diabetes (%)	MVD (%)	EF (%)	Definition	y	Results	y	Death	MI	Revasc.	Stroke
BMS															
2001	AWESOME [151]	454	67	-	31	82	45	Death	3	20% vs. 21%	3	20% vs. 21%	-	-	-
2001	ERACI II [152]	450	62	21	17	100	-	Death, MI, stroke, or repeat revascularization	0.1	3.6% vs. 12.3%[a]	5	7.1% vs. 11.5%	2.8% vs. 6.2%	28.4% vs. 7.2%[a]	0% vs. 0.9% (at 30 d)
2001	ARTS [153]	1205	61	23	17	99	61	Death, MI, stroke, or repeat revascularization	1	26.2% vs. 12.2%[a]	5	8.0% vs. 7.6%	6.7% vs. 5.6%	30.3% vs. 8.8%[a]	3.8% vs. 3.5%
2002	SoS [154]	988	61	21	14	100	57	Repeat revascularization	2	21% vs. 6%[a]	6	10.9% vs. 6.8%[a]	5% vs. 8% (at 2 y)	21% vs. 6%[a] (at 2 y)	-
2003	OCTOSTENT [155]	280	60	29	11	29	-	Death, MI, stroke, or repeat revascularization	1	14.5% vs. 8.5%	1	0% vs. 2.8%	4.4% vs. 4.9%	15.2% vs. 4.2%[a]	0% vs. 0%
2005	Thiele [156]	220	62	25	30	0	63	Cardiac death, MI, or TVR	0.5	31% vs. 15%[a]	5.6	10% vs. 12%	5% vs. 7%	32% vs. 10%[a] (TVR)	-

BMS = bare-metal stents; CABG = coronary artery bypass grafting; EF = ejection fraction; MI = myocardial infarction; MV = multivessel; MVD = multivessel disease; PES = paclitaxel-eluting stents; Revasc = revascularization; SES = sirolimus-eluting stents; TVR = target-vessel revascularization; y = years.
[a] $P<0.05$.
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Age and ejection fraction are reported as means.

Year of publication	Study	N	Baseline characteristics					Primary endpoint			Max clinical follow-up				
			Age (y)	Women (%)	Diabetes (%)	MVD (%)	EF (%)	Definition	y	Results	y	Death	MI	Revasc.	Stroke
PES															
2009	SYNTAX [157]	1800	65	22	25	100	-	Death, MI, stroke, or repeat revascularization	1	17.8% vs. 12.4%[a,c]	5	13.9% vs. 11.4%	9.7% vs. 3.8%[a]	25.9% vs. 13.7%[a]	2.4% vs. 3.7%
SES															
2011	Boudriot [158]	201	68	25	36	72	65	Death, MI, or repeat revascularization	1	13.9% vs. 19%[c]	1	2% vs. 5%	3% vs. 3%	14% vs. 5.9%	-
2011	PRECOMBAT [159]	600	62	24	32	90	61	Death, MI, stroke, or TVR	1	8.7% vs. 6.7%[b]	2	2.4% vs. 3.4%	1.7% vs. 1.0%	9.0% vs. 4.2%[a]	0.4% vs. 0.7%

BMS = bare-metal stents; CABG = coronary artery bypass grafting; EF = ejection fraction; MI = myocardial infarction; MV = multivessel; MVD = multivessel disease; PES = paclitaxel-eluting stents; Revasc = revascularization; SES = sirolimus-eluting stents; TVR = target-vessel revascularization; y = years.
[a] $P<0.05$.
[b] Non-inferiority met.
[c] Non-inferiority failed only trials with at least 100 patients per treatment arm were included.
Age and ejection fraction are reported as means.

CURRENT EVIDENCE: PCI VS CABG IN DIABETICS

Year of publication	Study	N	Baseline characteristics				Primary endpoint			Max clinical follow-up					
			Age (y)	Women (%)	MVD (%)	EF (%)	Definition	y	Results	y	Death	CV Death	MI	Revasc	Stroke
PCI vs. CABG															
2013	SYNTAX[a,24b]	452	65	29	100	-	Death, MI, stroke, or repeat revascularization	1	26.0% vs. 14.2%[c] Sx-Score 0–22: 20.3% vs. 18.3%; Sx-Score 23–32: 26.0% vs. 12.9%; Sx-Score ≥33: 32.4% vs. 12.2%[c]	5	19.5% vs. 12.9%	12.7% vs. 6.5%[c]	9.0% vs. 5.4%	35.3% vs. 14.6%[c]	3.0% vs. 4.7%
2010	CARDia[247] (DES/BMS vs. CABG)	510	64	26	93	-	Death, MI, or stroke	1	13.0% vs. 10.5%	1	3.2% vs. 3.2%	-	9.8% vs. 5.7%	11.8% vs. 2.0%[c]	0.4% vs. 2.8%
2012	FREEDOM[171] (DES vs. CABG)	1900	63	29	100	66	Death, MI, or stroke	3.8	26.6% vs. 18.7%[c] Sx-Score 0–22: 23% vs. 17%; Sx-Score 23–32: 27% vs. 18%[c]; Sx-Score ≥33: 31% vs. 23%	3.8	16.3% vs. 10.9%[c]	10.9% vs. 6.8%	13.9% vs. 6.0%[c]	12.6% vs. 4.8%[c] (at 1 y)	2.4% vs. 5.2%[c]
2013	VA-CARDS[248] (DES vs. CABG)	207	62	1%	-	-	Death or MI	2	18.4% vs. 25.3%	2	21% vs. 5.0%[c]	10.8% vs. 5.0%	6.2% vs. 15.0%	18.9% vs. 19.5%	1.0% vs. 1.2%

BMS = bare-metal stent; CABG = coronary artery bypass grafting; CV = cardiovascular; DES = drug-eluting stent; EF = ejection fraction; MI = myocardial infarction; MT = medical therapy; MVD = multivessel disease; PCI = percutaneous coronary intervention; PES = paclitaxel-eluting stent; Revasc = revascularization; SES = sirolimus-eluting stent; Sx-Score = SYNTAX score; y = years.

[a] $P<0.05$.

[b] Randomization stratified by revascularization modality.

[c] Three-vessel disease.

[d] Subgroup analysis.

Age and ejection fraction are reported as means.

CABG VS PCI IN DIABETICS: A META-ANALYSIS OF CRTS

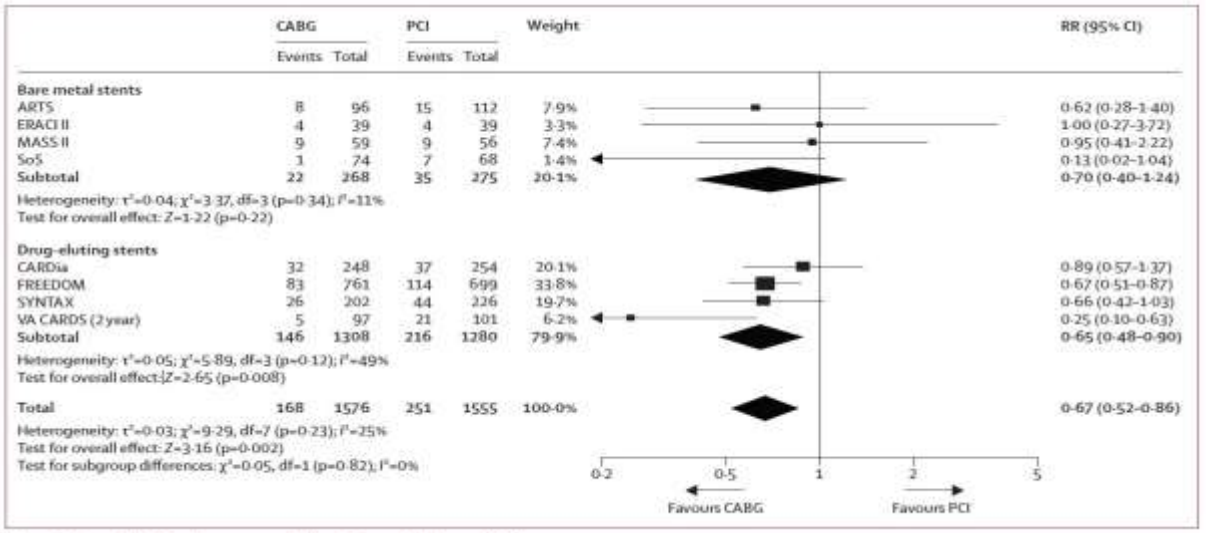
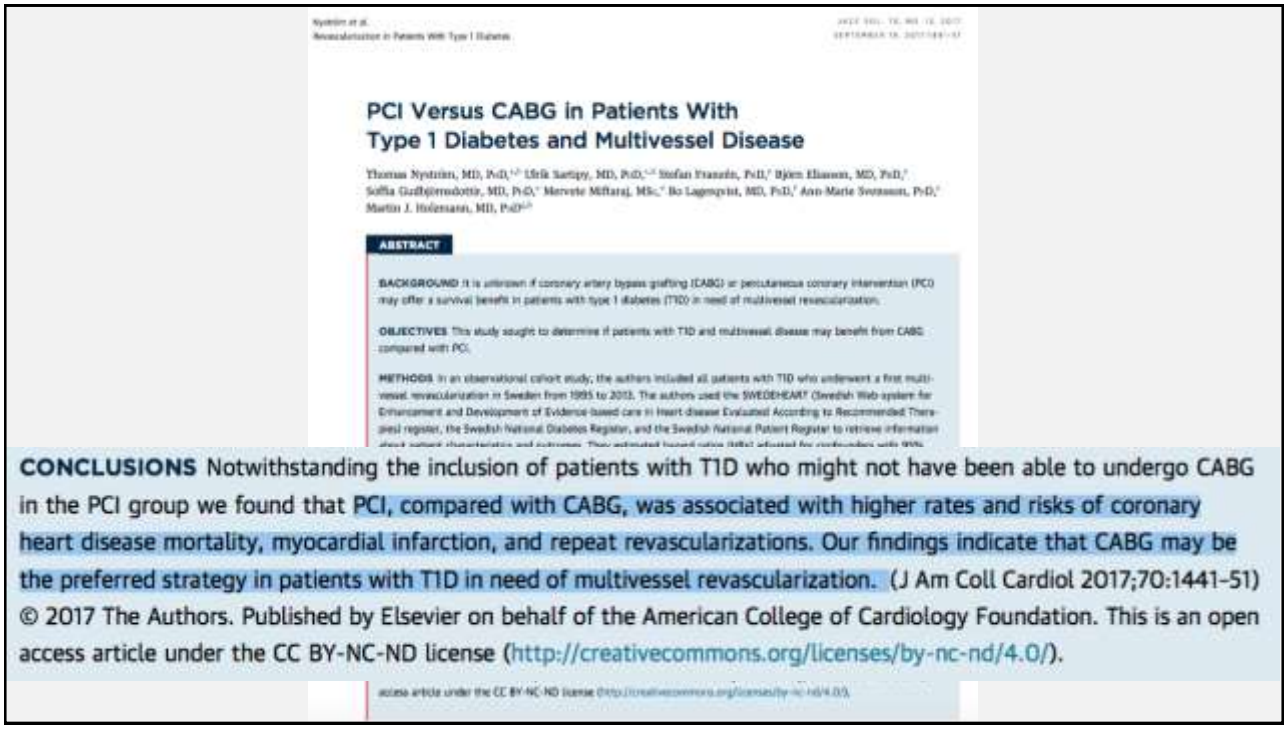


Figure 2: Forest plot for all-cause mortality at 5-year (or longest) follow-up

Verma et al. Lancet Diabetes Endocrinol. 2013; 1: 217-28

TYPE I DIABETES



PCI Versus CABG in Patients With Type 1 Diabetes and Multivessel Disease

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ABSTRACT

BACKGROUND It is unknown if coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) may offer a survival benefit in patients with type 1 diabetes (T1D) in need of multivessel revascularization.

OBJECTIVES This study sought to determine if patients with T1D and multivessel disease may benefit from CABG compared with PCI.

METHODS In an observational cohort study, the authors included all patients with T1D who underwent a first multivessel revascularization in Sweden from 1995 to 2013. The authors used the SWEDEHEART (Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies) register, the Swedish National Diabetes Register, and the Swedish National Patient Register to retrieve information

CONCLUSIONS Notwithstanding the inclusion of patients with T1D who might not have been able to undergo CABG in the PCI group we found that PCI, compared with CABG, was associated with higher rates and risks of coronary heart disease mortality, myocardial infarction, and repeat revascularizations. Our findings indicate that CABG may be the preferred strategy in patients with T1D in need of multivessel revascularization. (J Am Coll Cardiol 2017;70:1441–51)

GUIDELINES

2014 ACC/AHA/AATS/PCNA/SCAI/STS Focused Update of the Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines, and the American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons

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Table 4. Recommendations for CAD Revascularization to Improve Survival

2012 Recommendation	2014 Focused Update Recommendations	Comments
	Class I	
	1. A Heart Team approach to revascularization is recommended in patients with diabetes mellitus and complex multivessel CAD (66). *(Level of Evidence: C)*	New recommendation
Class IIa		
1. CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a LIMA graft can be anastomosed to the LAD artery (58-65). *(Level of Evidence: B)*	2. CABG is generally recommended in preference to PCI to improve survival in patients with diabetes mellitus and multivessel CAD for which revascularization is likely to improve survival (3-vessel CAD or complex 2-vessel CAD involving the proximal LAD), particularly if a LIMA graft can be anastomosed to the LAD artery, provided the patient is a good candidate for surgery (58,61-65,67-69). *(Level of Evidence: B)*	Modified recommendation (changed Class of Recommendation from IIa to I, wording modified, additional RCT added).

European Heart Journal (2014) 35, 2541–2619
doi:10.1093/eurheartj/ehu278

ESC/EACTS GUIDELINES

2014 ESC/EACTS 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)

Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

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Recommendation for the type of revascularization (CABG or PCI) in patients with SCAD with suitable coronary anatomy for both procedures and low predicted surgical mortality

Recommendations according to extent of CAD	CABG		PCI		
	Class[a]	Level[b]	Class[a]	Level[b]	Ref[c]
One or two-vessel disease without proximal LAD stenosis.	IIb	C	I	C	
One-vessel disease with proximal LAD stenosis.	I	A	I	A	107,108,160,161,178,179
Two-vessel disease with proximal LAD stenosis.	I	B	I	C	108,135,137
Left main disease with a SYNTAX score ≤ 22.	I	B	I	B	17,134,170
Left main disease with a SYNTAX score 23–32.	I	B	IIa	B	17
Left main disease with a SYNTAX score >32.	I	B	III	B	17
Three-vessel disease with a SYNTAX score ≤ 22.	I	A	I	B	17,157,175,176
Three-vessel disease with a SYNTAX score 23–32.	I	A	III	B	17,157,175,176
Three-vessel disease with a SYNTAX score >32.	I	A	III	B	17,157,175,176

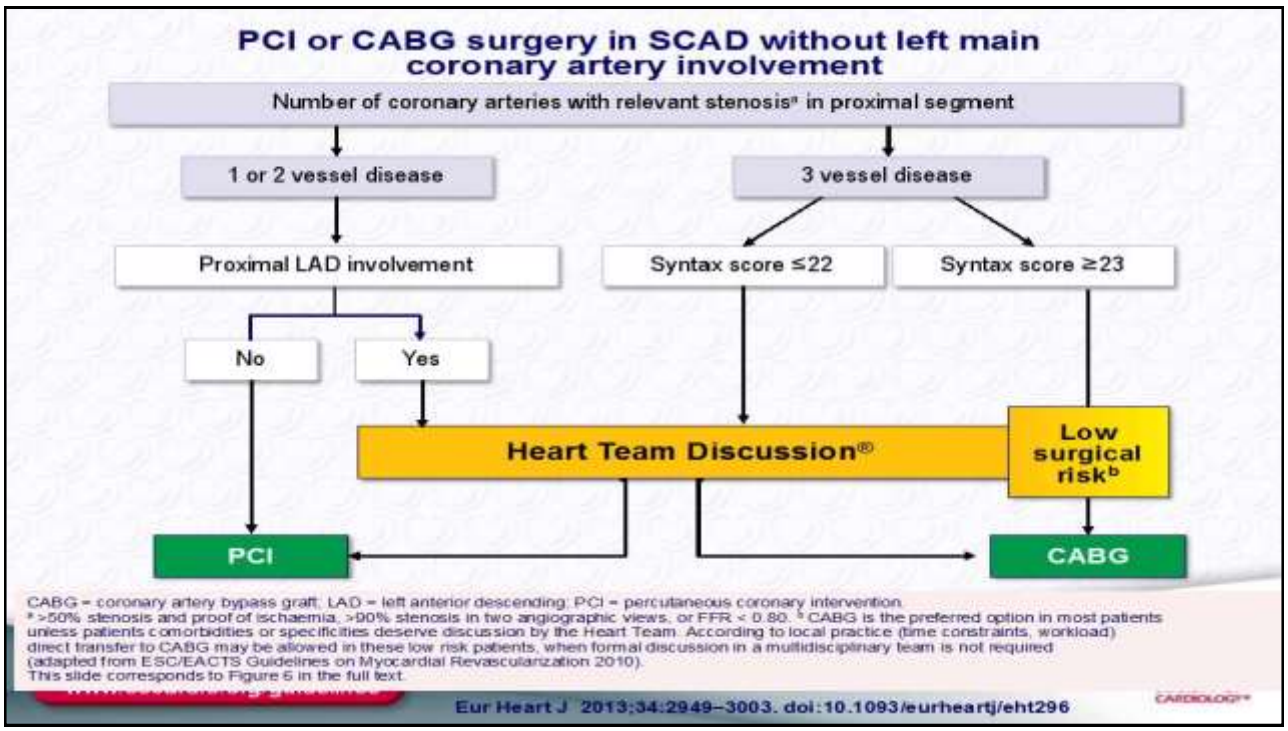
CABG = coronary artery bypass grafting; LAD = left anterior descending coronary artery; PCI = percutaneous coronary intervention; SCAD = stable coronary artery disease.
[a]Class of recommendation.
[b]Level of evidence.
[c]References.

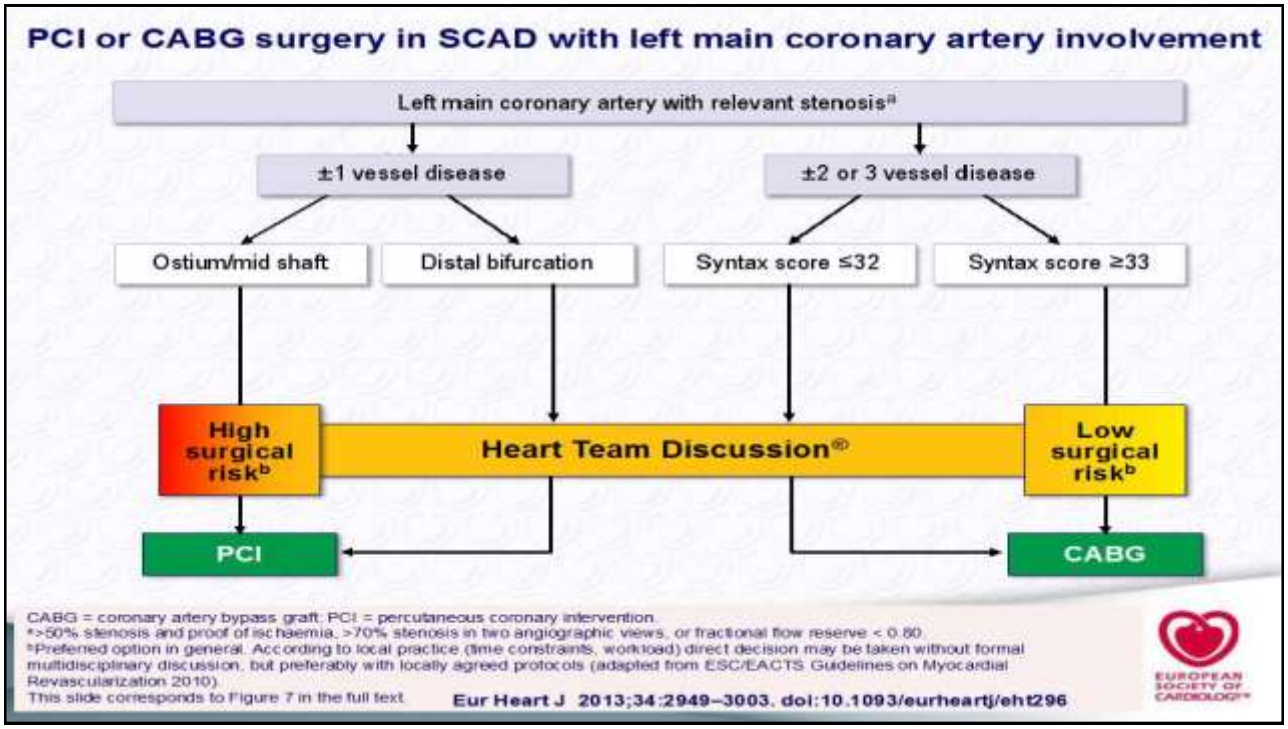
Windecker etl al. ESC guidelines on myocardial revascularization. European Heart Journal (2014) 35, 2541–2619

Specific recommendations for revascularization in patients with diabetes

Recommendations	Class[a]	Level[b]	Ref[c]
In patients presenting with STEMI, primary PCI is recommended over fibrinolysis if it can be performed within recommended time limits.	I	A	363
In patients with NSTE-ACS, an early invasive strategy is recommended over non-invasive management.	I	A	180,338, 364–366
In stable patients with multivessel CAD and/or evidence of ischaemia, revascularization is indicated in order to reduce cardiac adverse events.	I	B	93,367
In patients with stable multivessel CAD and an acceptable surgical risk, CABG is recommended over PCI.	I	A	106,175,349
In patients with stable multivessel CAD and SYNTAX score ≤22, PCI should be considered as alternative to CABG.	IIa	B	346,350
New-generation DES are recommended over BMS.	I	A	351,352

Windecker etl al. ESC guidelines on myocardial revascularization. European Heart Journal (2014) 35, 2541–2619





TEAM DEFINITION:

- Treat
- Everything
- Always
- Multi-Stent

POTENTIAL CONFLICTS IMPACTING DECISION MAKING IN TREATMENT OF CAD

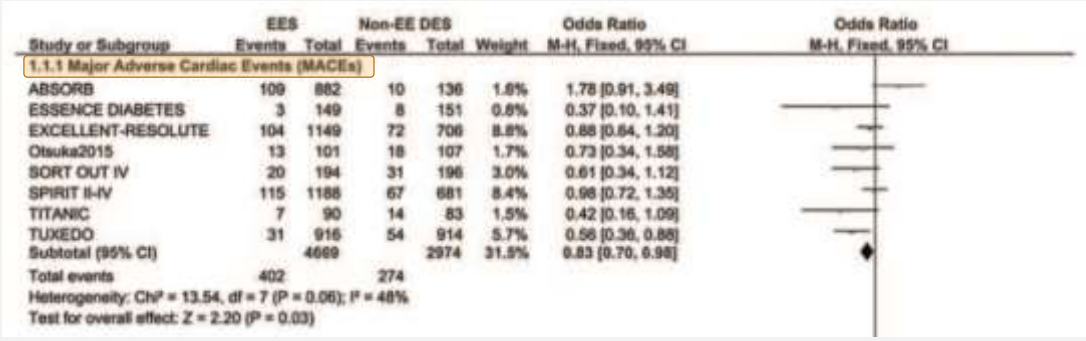
- Self-referral (you tend to do what you can do)
- No appreciation of personal therapeutic limits
- Preservation of patient-referral pathways
- *'Turf protection'* (protection of patient access and salary)
- Personal conflict between interventional cardiologist and/or surgeon
- Conflict of interest with industry
- Patient/Physician Bonding

STENT TYPE

- Neither Paclitaxil nor Sirolimus elluting stents showed superiority in diabetic patients in meta-analyses.

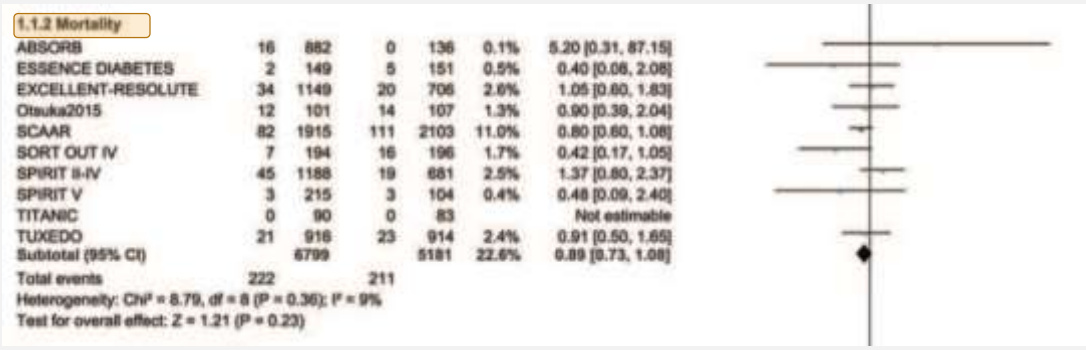
Bundhun et al. Medicine (Baltimore) 2016; 95(27): e4130.

EVROLIMUS-ELUTING STENTS (EES) VS NON EES



Bundhun et al. Medicine (Baltimore) 2016; 95:e3276.

EVROLIMUS-ELUTING STENTS (EES) VS NON EES

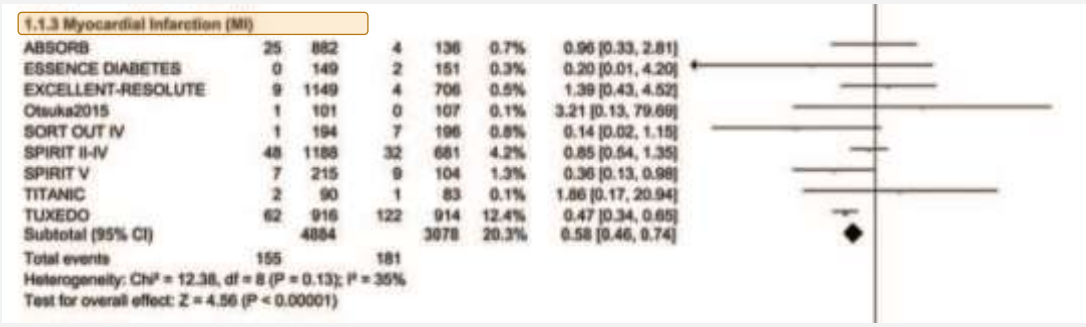


1.1.2 Mortality						
ABSORB	16	882	0	136	0.1%	5.20 [0.31, 87.15]
ESSENCE DIABETES	2	149	5	151	0.5%	0.40 [0.08, 2.08]
EXCELLENT-RESOLUTE	34	1149	20	706	2.6%	1.05 [0.60, 1.83]
Otsuka2015	12	101	14	107	1.3%	0.90 [0.39, 2.04]
SCAAR	82	1915	111	2103	11.0%	0.80 [0.60, 1.08]
SORT OUT IV	7	194	16	196	1.7%	0.42 [0.17, 1.05]
SPIRIT II-IV	45	1188	19	681	2.5%	1.37 [0.80, 2.37]
SPIRIT V	3	215	3	104	0.4%	0.48 [0.09, 2.40]
TITANIC	0	90	0	83		Not estimable
TUXEDO	21	916	23	914	2.4%	0.91 [0.50, 1.65]
Subtotal (95% CI)		6799		5181	22.6%	0.89 [0.73, 1.08]
Total events	222		211			

Heterogeneity: Chi² = 8.79, df = 8 (P = 0.36); I² = 9%
Test for overall effect: Z = 1.21 (P = 0.23)

Bundhun et al. Medicine (Baltimore) 2016; 95:e3276.

EVROLIMUS-ELUTING STENTS (EES) VS NON EES

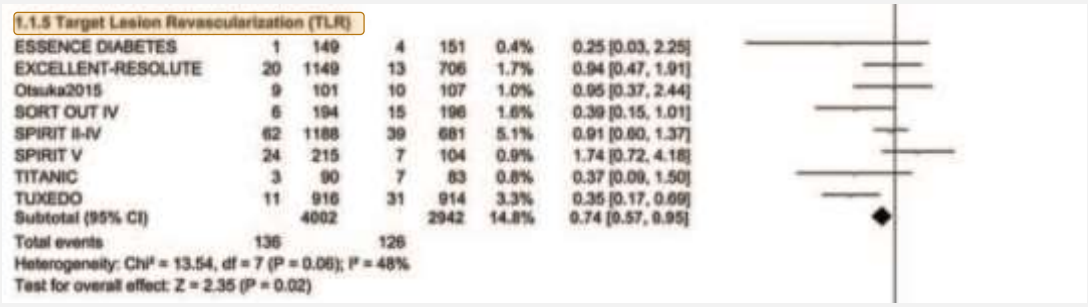


1.1.3 Myocardial Infarction (MI)						
ABSORB	25	882	4	136	0.7%	0.96 [0.33, 2.81]
ESSENCE DIABETES	0	149	2	151	0.3%	0.20 [0.01, 4.20]
EXCELLENT-RESOLUTE	9	1149	4	706	0.5%	1.39 [0.43, 4.52]
Otsuka2015	1	101	0	107	0.1%	3.21 [0.13, 79.69]
SORT OUT IV	1	194	7	196	0.8%	0.14 [0.02, 1.15]
SPIRIT II-IV	48	1188	32	681	4.2%	0.85 [0.54, 1.35]
SPIRIT V	7	215	9	104	1.3%	0.36 [0.13, 0.98]
TITANIC	2	90	1	83	0.1%	1.86 [0.17, 20.94]
TUXEDO	62	916	122	914	12.4%	0.47 [0.34, 0.65]
Subtotal (95% CI)		4884		3078	20.3%	0.58 [0.46, 0.74]
Total events	155		181			

Heterogeneity: Chi² = 12.38, df = 8 (P = 0.13); I² = 35%
Test for overall effect: Z = 4.56 (P < 0.00001)

Bundhun et al. Medicine (Baltimore) 2016; 95:e3276.

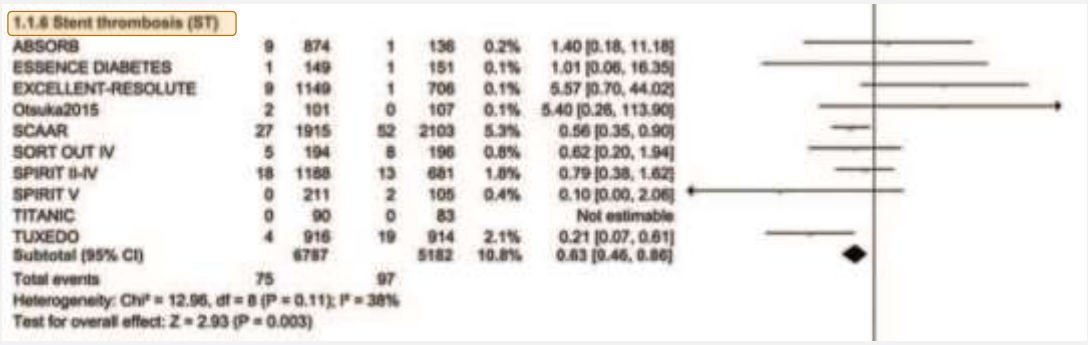
EVROLIMUS-ELUTING STENTS (EES) VS NON EES



1.1.5 Target Lesion Revascularization (TLR)						
ESSENCE DIABETES	1	149	4	151	0.4%	0.25 [0.03, 2.25]
EXCELLENT-RESOLUTE	20	1149	13	706	1.7%	0.94 [0.47, 1.91]
Otsuka2015	9	101	10	107	1.0%	0.95 [0.37, 2.44]
SORT OUT IV	6	194	15	196	1.6%	0.39 [0.15, 1.01]
SPIRIT II-IV	62	1188	39	681	5.1%	0.91 [0.60, 1.37]
SPIRIT V	24	215	7	104	0.9%	1.74 [0.72, 4.18]
TITANIC	3	90	7	83	0.8%	0.37 [0.09, 1.50]
TUXEDO	11	916	31	914	3.3%	0.35 [0.17, 0.69]
Subtotal (95% CI)		4002		2942	14.8%	0.74 [0.57, 0.95]
Total events	136		126			
Heterogeneity: Chi² = 13.54, df = 7 (P = 0.06); I² = 48%						
Test for overall effect: Z = 2.35 (P = 0.02)						

Bundhun et al. Medicine (Baltimore) 2016; 95:e3276.

EVROLIMUS-ELUTING STENTS (EES) VS NON EES



1.1.6 Stent thrombosis (ST)						
ABSORB	9	874	1	136	0.2%	1.40 [0.18, 11.18]
ESSENCE DIABETES	1	149	1	151	0.1%	1.01 [0.06, 16.35]
EXCELLENT-RESOLUTE	9	1149	1	706	0.1%	5.57 [0.70, 44.02]
Otsuka2015	2	101	0	107	0.1%	5.40 [0.26, 113.90]
SCAAR	27	1915	52	2103	5.3%	0.56 [0.35, 0.90]
SORT OUT IV	5	194	8	196	0.8%	0.62 [0.20, 1.94]
SPIRIT II-IV	18	1188	13	681	1.8%	0.79 [0.38, 1.62]
SPIRIT V	0	211	2	105	0.4%	0.10 [0.00, 2.06]
TITANIC	0	90	0	83		Not estimable
TUXEDO	4	916	19	914	2.1%	0.21 [0.07, 0.61]
Subtotal (95% CI)		6787		5182	10.8%	0.63 [0.46, 0.86]
Total events	75		97			
Heterogeneity: Chi² = 12.96, df = 8 (P = 0.11); I² = 38%						
Test for overall effect: Z = 2.93 (P = 0.003)						

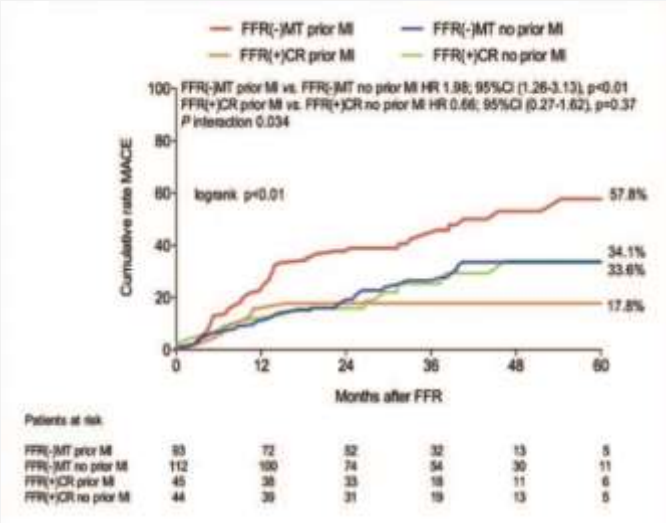
Bundhun et al. Medicine (Baltimore) 2016; 95:e3276.

CONCLUSION

- During this 1-year follow-up period, EES were associated with significantly better clinical outcomes compared to the non-EE DES in patients with T2DM.
- However, further researches comparing EES with non-EE DES in patients with ITDM and NITDM are recommended.

Bundhun et al. Medicine (Baltimore) 2016; 95:e3276.

VALUE OF FFR IN DIABETICS



- **Normal FFR measurements in diabetics, particularly those with prior MI, do not necessarily carry the same benign prognostic value as in other patients.**
- **Complete revascularization in such cases, independent of FFR measurements is recommended.**

Time-to-event estimates for MACE in patients with FFR(−)MT and FFR(+), CR groups according to the presence or absence of previous MI. CR, completely revascularized; FFR, fractional flow reserve; MACE, major adverse cardiac events; MI, myocardial infarction; MT, treated medically.

Kennedy et al. Am J Cardiol 2016; 118:1293–1299.

TAKE HOME MESSAGE

- DM is associated with more extensive CAD with worse short and long-term outcomes.
- CABG is the preferred revascularization strategy in diabetics with multivessel disease.
- CABG still has better outcomes than PCI in type I DM.
- PCI can be done with the same level of recommendation as CABG in left main.
- PCI can be done as a second choice after CABG in left main patients with SYNTAX score 22-32 or 3 vessel disease with SYNTAX score ≤ 22.
- PCI is considered only as a CHIP with left main with SYNTAX <32 or 3 vessel disease with SYNTAX >22.

TAKE HOME MESSAGE

- In a meta-analysis, EES were found to be associated with significantly better clinical outcomes compared to the non-EE DES in patients with T2DM. However, further researches are needed to confirm this finding.
- Normal FFR measurements in diabetics, particularly those with prior MI, do not necessarily carry the same benign prognostic value as in other patients. Complete revascularization in such cases, independent of FFR measurements is recommended.

THANK YOU