Elective percutaneous coronary intervention does not improve outcomes in patients with stable coronary artery disease (a prospective cohort study)

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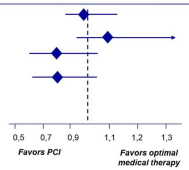
Efficacy of PCI* vs optimal medical therapy in patients with stable CAD

Meta-analysis of randomized control trials: TOAT (2002), Hambrecht et al (2004), DECOPI (2004), OAT (2006), MASS II (2007), COURAGE (2007), JSAP (2008), BARI 2D (2009)

n=7229, mean follow-up 4,3 years

Outcomes	Relative risk [95% CI]
CV death	0.98 [0.84-1.16], p=0.83
Non-fatal MI	1.12 [0.93-1.94], p=0.22
Revascularization	0.78 [0.57-1.06], p=0.11
Freedom from angina	0.80 [0.60-1.05], p=0.10



Previous studies have not shown benefits of percutaneous coronary intervention in patients with stable coronary artery disease

* - most of patients received bare-metal stents

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Purpose of the study

➢ **to compare the long term efficacy of percutaneous coronary intervention with drug-eluting stents and optimal medical therapy in patients with stable coronary artery disease**

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Study design

Inclusion criteria:
- age≥ 35 yrs
- documented CAD (at least one criteria: coronary stenosis ≥70%, history of MI, positive stress-test)
- no thrombotic events within last two months

Non-randomized, open, cohort, prospective trial, treatment strategy was determined by attending physician

PCI group: DES (Cypher – 95% pts) & optimal medical therapy — Mean follow-up 4,1±1,6 yrs

Optimal medical therapy (OMT) group — Mean follow-up 5,6±1,3 yrs

optimal medical therapy according to current evidence-based guidelines (β-blockers, statins, antiplatelets, ACE inhibitors)
Duration of double antiplatelet therapy after PCI - at least 12 month

Study outcomes:
- Vascular events (VE): CV death + acute coronary syndrome ischemic stroke + transient ischemic attack + peripheral arterial thrombosis
- Vascular events & revascularizations in any affected arterial area

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Study population
(risk factors profile)

Variable	Overall n=481	OMT group (1) n=179	PCI group (2) n=302	P 1-2
Gender (male/female), n	481 (370/111)	179 (128/51)	302 (242/60)	0,03
Age, yrs (M±m)	59,3±0,4	61± 0,6	58±0,5	0,0001
Arterial hypertension, n (%)	409 (85%)	153 (85,5%)	256 (84,8%)	NS
Hyperlipidemia*, n (%)	449 (93,3%)	158 (88,3%)	291 (96,4%)	0,001
Smoking • in history, n (%) • continued, n (%)	176 (36,6%) 115 (24,0%)	66(36,9%) 43 (24%)	110(36,4%) 72 (23,8%)	NS NS
Obesity (BMI> 30 kg/m^2), n (%)	154 (32,0%)	60 (33,5%)	94 (31,1%)	NS
Diabetes mellitus, n (%)	90 (18,7%)	41 (23%)	49 (16,2%)	NS
Atrial fibrillation, n (%)	35 (7,3%)	13 (7,3%)	22 (7,3%)	NS
Serum creatinine, mg/dl (M±m) Creatinine clearance, ml/min (M±m)	1,05±0,01 91,1±1,3	1,07±0,02 84,2±1,9	1,01±0,01 95,1±1,6	0,02 0,005

** Serum cholesterol > 5,2 mmol/l and/or current intake of lipid lowering drugs*

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Study population
(affected vascular beds)

Variable	Overall n=481	OMT group (1) n=179	PCI group (2) n=302	P 1-2
Coronary artery disease (inclusion criteria)	481 (100%)	179 (100%)	302 (100%)	
•Stable angina	460 (95,6%)	170 (95%)	290 (96%)	NS
- rare effort attacks*, n(%)	99 (20,6%)	60 (33,5%)	39 (12,9%)	0,03
- functional class II, n (%)	179 (37,2%)	54 (30,1%)	125 (41,4%)	0,004
- functional class III / rare rest attacks , n (%)	182 (37,8%)	56 (31,3%)	126 (41,7%)	0,003
•ACS > 2 month ago, n(%)	388 (80,7%)	140 (78,2%)	248 (82,1%)	NS
•PCI > 2 months ago, n(%)	75 (15,6%)	30(16,7%)	45 (15%)	NS
•CABG > 2 months ago, n(%)	63 (13,1%)	23(12,8%)	40 (13,2%)	NS
Cerebrovascular disease (Ischemic stroke /TIA > 2 months ago/carotid artery stenosis > 50%/carotid surgery/angioplasty > 2 months ago), n (%)	89 (18,5%)	47 (26,3%)	42 (13,9%)	0,001
Peripheral arterial disease (ABI <0,9/ Intermittent claudication, Fontaine stage II-III/peripheral surgery/angioplasty > 2 months ago), n (%)	112 (23,3%)	47 (26,3%)	65 (21,5%)	NS
Angiographic characteristic:				
• **Angiography was performed, n (%)**	362 (75,3%)	60 (33,5%)	302 (100%)	<0,0001
• 1-vessel disease, n (%)	141 (29,3%)	16 (26,7%)	125 (41,4%)	0,04
• 2-vessel disease, n (%)	128 (26,6%)	14 (23,3%)	114 (37,7%)	0,04
• 3-vessel disease or proximal LAD, n (%)	86 (17,9%)	30 (50%)	56 (18,5%)	<0,0001
• Ejection fraction, M±m	55,7±0,4	54,7±0,8	56,1±0,4	NS

* in most pts with rare attacks physical activity was limited because of concomitant intermittent claudication or/and cerebrovascular disease

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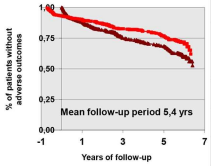
Clinical variables and risk of VE and revascularizations in patients with stable CAD

Cumulative incidence of adverse outcomes (n=481)



Vascular events

VE & revascularizations

*Cox proportional hazards model**

Risk factor	RR*	95% CI	p
Angina severity: class II-III vs class I	1,6	1,1-2,4	0,01
Previous myocardial infarction	1,3	0,9-1,8	0,1
Left main / 3-vessel coronary disease	1,45	1,0-2,1	0,05
Previous ischemic stroke / TIA	1,6	1,0-2,5	0,05
Peripheral arterial disease	1,3	0,9-1,7	0,1
BMI ≥ 31,6 кг/м^2	1,6	1,1-2,3	0,02
Renal impairment (creatinine clearance < 60 ml/min)	1,5	0,95-2,2	0,06

** Adjusted for age and sex; both in PCI- and OMT- groups*

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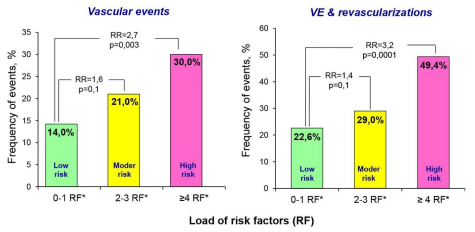
Frequency of adverse outcomes according to load of risk factors* in patients with stable CAD



Multifactor analysis revealed a highly significant associations between total load of risk factors* and frequency of events in pts with stable CAD

* - see picture 6

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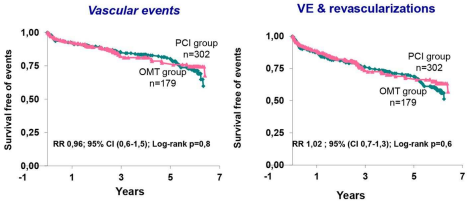
The occurrence of adverse outcomes was similar in PCI and OMT groups



Our next step was to analyze the outcomes in PCI and OMT groups taking in account the total load of risk factors*

* - see picture 6

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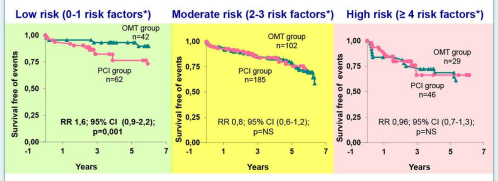
Frequency of vascular events in treatment groups stratified by load of risk factors*



The elective PCI doesn't improve long term prognosis; moreover in low risk patients it may be associated with increased risk of vascular events

* - see picture 6

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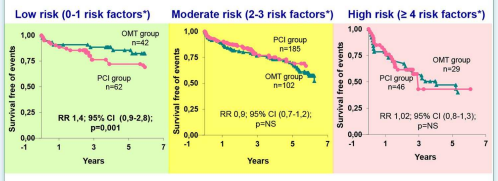
Frequency of VE and revascularizations in treatment groups stratified by load of risk factors*



The elective PCI doesn't improve long term prognosis; moreover in low risk patients it may be associated with increased risk of VE & revascularizations

* - see picture 6

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Conclusion

- PCI even with drug-eluting stent implantation doesn't improve long term prognosis in patients with stable CAD
- in low risk patients the elective PCI may be associated with increased risk of vascular events and need for revascularizations

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Declaration of interest: The authors have declared that no competing interests exist.