HREVS:
A Randomized Trial of PCI vs CABG vs Hybrid Revascularization in Patients With Coronary Artery Disease

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Hybrid REvascularization Versus Standards, HREVS, NCT01699048

Disclosure Statement of Financial Interest

I, Vladimir Ganyukov, and Co-authors, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Background

- Today, revascularization in multivessel coronary artery disease (MV-CAD) is achieved mainly through CABG or DES-PCI
- Another less-evidenced approach is hybrid coronary revascularization (HCR: LIMA-LAD graft plus DES-PCI for the remaining vessel/s)

Aim

- **To compare, in a randomized trial setting, the current guideline-accepted coronary revascularization (CR) strategies in MV-CAD, including the hybrid approach**

thus

- **HREVS (Hybrid coronary REvascularization Versus Standards) is the first randomized study to assess safety and efficacy of contemporary coronary revascularization strategies in MV-CAD**

HREVS study set-up

- **DESIGN:** Prospective, single-center, randomized, open label, parallel group, safety and efficacy study
- **PRIMARY END-POINT:** Residual myocardial ischemia (RI) by SPECT at 12 months
- **STUDY CENTER:** Research Institute for Complex Issues of Cardiovascular Diseases, Kemerovo, Russian Federation
- **PIs:** Vladimir Ganyukov, MD, PhD
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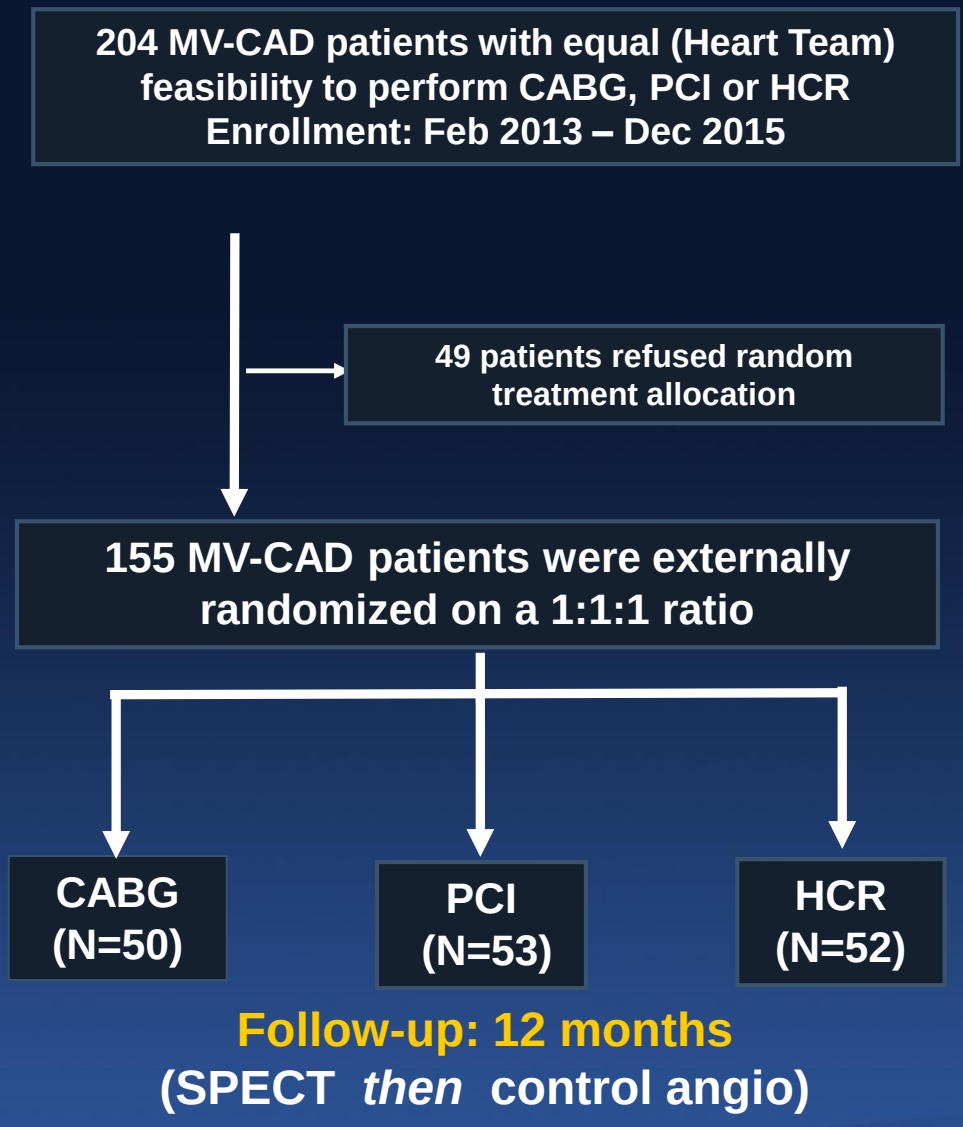

Design characteristics

- Investigator-initiated academic trial conducted jointly by high-volume interventional cardiologists and high-volume cardiac surgeons
- CABG, PCI and HCR arms utilize the best, routinely available techniques and devices
- Powered for the primary end-point of **residual myocardial ischemia (RI) by SPECT at 12 months**

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- **RI = (1) index of revescularization quality**
  (2) long-term outcome determinant

Major Inclusion Criteria

- MV-CAD involving LAD
  - ≥70% DS (QCA) *or*
  - 50 - 69% with FFR ≤0.80 or SPECT evidence of regional ischemia
- Clinical and anatomic feasibility of CABG, PCI and HCR as agreed to by the local Heart Team
- Informed consent to random treatment allocation

Major Exclusion Criteria

- Any prior CABG or PCI
- Left main coronary artery stenosis
- Chronic total occlusion(s)
- Cardiac surgery other than CABG
- Circumstances precluding **equal feasibility** of the three CR strategies

Primary and Secondary Endpoints

Primary endpoint

RI (SPECT) at 12 months

80% power to exclude a 4.2% RI difference (noninferiority margin)

Secondary endpoint

MACCE (Death, MI, stroke or clinically-driven TVR)

Secondary endpoint

TV / graft failure

Baseline Characteristics (1)

	CABG n = 50	HCR n = 52	PCI n = 53	P
Age (years)	61.3±6.8	62.0±7.4	61.7±7.7	0.80
Male	70.0%	75.0%	69.8%	0.90
Current smoker	50%	46.1%	47.2%	0.92
Hypertension	66.0%	65.4%	67.9%	0.96
Diabetes	22.0%	17.3%	20.7%	0.83
COPD	4.0%	7.7%	11.3%	0.43
Cronic kidney disease	0%	1.9%	5.7%	0.32
Peripheral vascular disease	24.0%	30.8%	30.2%	0.70

COPD – chronic obstructive pulmonary disease

Baseline Characteristics (2)

	CABG n = 50	HCR n = 52	PCI n = 53	P
Previos MI	56.0%	51.9%	58.5%	0.79
LVEF (%)	54.0±7.4	56.2±6.3	53.3±9.9	0.159
EuroSCORE II	1.70±0.76	1.71±0.72	1.70±0.79	1.0
SYNTAX Score	19.3±3.0	19.4±3.0	19.5±2.7	0.91
Affected vessels: 2	42%	51.9%	56.6%	0.14
≥ 3	48%	48.1%	43.4%	
№ of index lesions 2	42.0%	36.5%	50.9%	
3	44.0$	42.3%	30.2%	0.15
> 3	14.0%	21.2%	18.9%	

Procedures

	CABG n = 50	HCR n = 52	PCI n = 53	P
Incomplete TVR (per patient)	8%(4)	7.7%(4)	5.7%(3)	0.86
Incomplete TVR (per total number of target lesions in the study group)	3.7% (5/136)	2.7% (4/149)	2.1% (3/146)	0.71
№ of stents 0	-	9.6%(5)	0	NA
1	-	48.1%(25)	0	NA
2	-	32.7%(17)	50.9%(27)	NA
≥ 3	-	9.6%(5)	49.1%(26)	NA
№ of grafts 1	0%	90.4%(47)	-	NA
2	46.0(23)	5.8%(3)	-	NA
≥ 3	54.0%(27)	3.8%(2)	-	NA

30-day outcomes

	CABG n = 50	HCR n = 52	PCI n = 53	P Value
MACCE	8.0% (4)	5.8% (3)	3.8 (2)	0.37
• Death	0% (0)	1.9% (1)	0% (0)	0.66
• Stroke	0% (0)	1.9% (1)	0% (0)	0.66
• MI	8% (4)	5.8% (3)	3.8% (2)	0.37
• Clinically-driven TVR	0% (0)	1.9% (1)	0% (0)	0.66
Conversion to CABG	NA	9.6% (5)	0% (0)	0.027
Bleeding				
•BARC 0-1	80.0% (40)	80.8% (42)	98.1% (52)	
•BARC 2	0% (0)	9.6% (5)	1.9% (1)	0.001
•BARC 3-4	20.0% (10)	9.6% (5)	0% (0)	
Hospital stay (days)	13.8 (12.5, 15.1)	13.5 (12.2, 14.8)	4.5 (3.2, 5.8)	<0.001
Sick-leave (weeks)	23 (21, 25)	16 (15, 18)	8 (6, 10)	<0.001
Inpatient rehabilitation	100% (49)	97.9% (48)	56.8% (29)	<0.001

Primary Endpoint

RI by SPECT (12 mo)

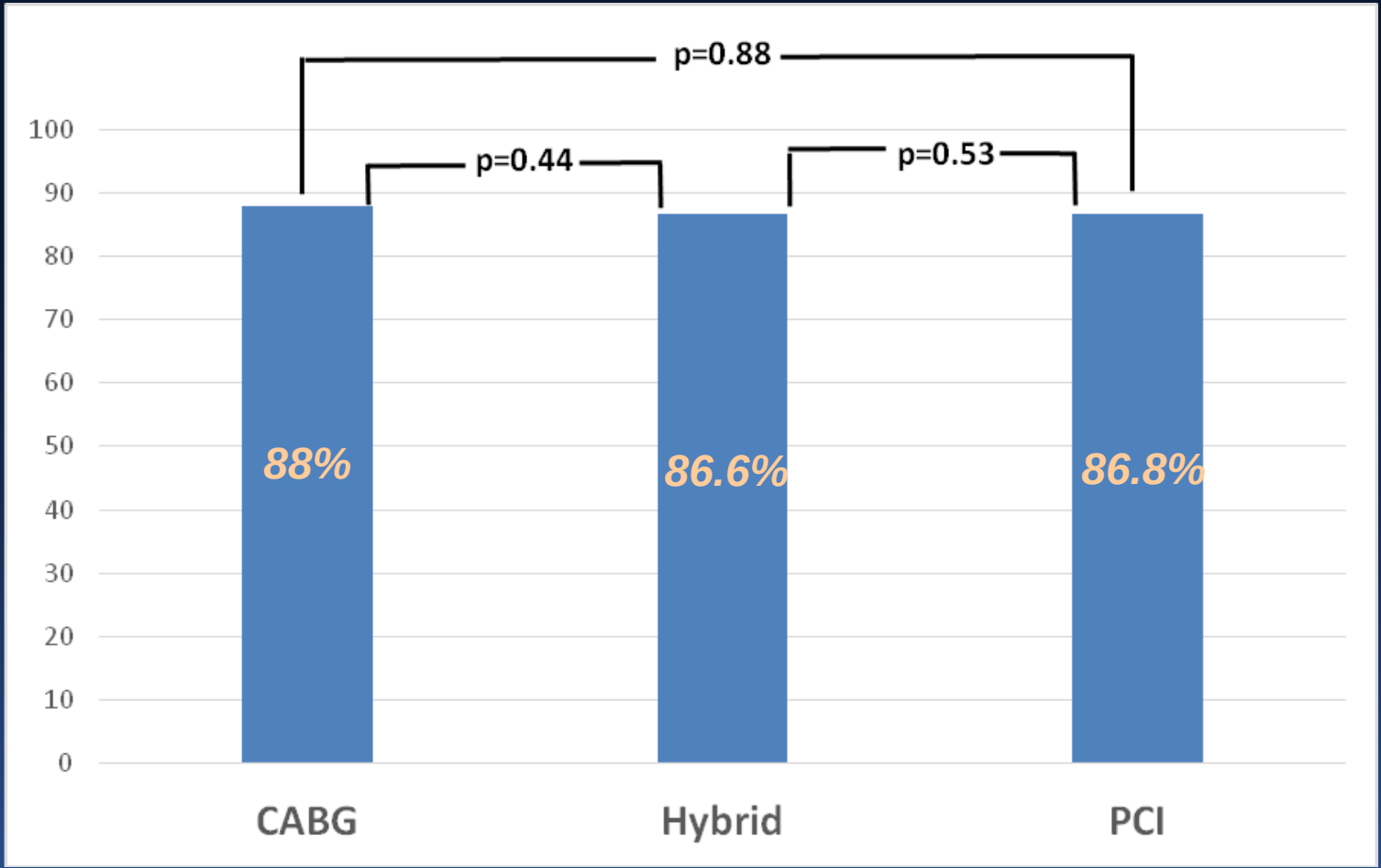
	CABG n = 49	HCR n = 49	PCI n = 51	P
Residual ischemia (%)	6.7	6.4	7.9	0.46
95% CI	(4.6, 8.8)	(4.3, 8.5)	(5.9, 9.8)	

P for non-inferiority = 0.39

12-month clinical outcomes

	CABG n = 50	HCR n = 52	PCI n = 53	P
MACCE	12.0%(6)	13.4%(7)	13.2(7)	0.83
• Death	2.0%(1)	5.8%(3)	3.8%(2)	0.78
• Stroke	0%(0)	3.8%(2)	0%(0)	0.21
• MI	8.0%(4)	5.8%(3)	7.5%(4)	0.66
• Clinically-driven TVR	2.0%(1)	1.9%(1)	5.7%(3)	0.54
Angiographically-driven TVR	2.0%(1)	11.5%(6)	11.3%(6)	0.14
Total TVR	4.0%(2)	13.5%(7)	17%(9)	0.095
TV or graft failure	12.0%(6)	11.5%(6)	11.3%(6)	0.98

MACCE-free survival at 12 months



Conclusions

- At 12 months, residual myocardial ischemia and MACCE were similar across the three study arms (CABG, HCR, PCI)
- PCI (2nd generation DES) showed the shortest hospital stay and sick-leave duration

Extended follow-up will determine longer-term outcomes

Interpretation

- HREVS at 12 mo provides no evidence for HCR benefit(s) in patients in whom PCI, CABG, or HCR are equally feasible

- **Shorter hospitalization** and **quicker recovery** (return to work) with MV (DES) **PCI** may provide healthcare system benefits

(longer follow-up required)

Thank you for your attention!

Back-up

Limitations

- Study not powered for clinical endpoints
- Average Syntax score in the HREVS study (19.4) is in the lower-intermediate range (attibutable to the protocol requirement of equal treatment feasibility with 3 modalities)
- 12-month follow-up may not be sufficient in the context of potential longer-term differences