VA | U.S. Department of Veterans Affairs
Office of Research and Development
Cooperative Studies Program

REGROUP

A Prospective, Randomized Trial Comparing Endoscopic vs. Open Vein Grafts in CABG Surgery

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for the REGROUP Trial Investigators

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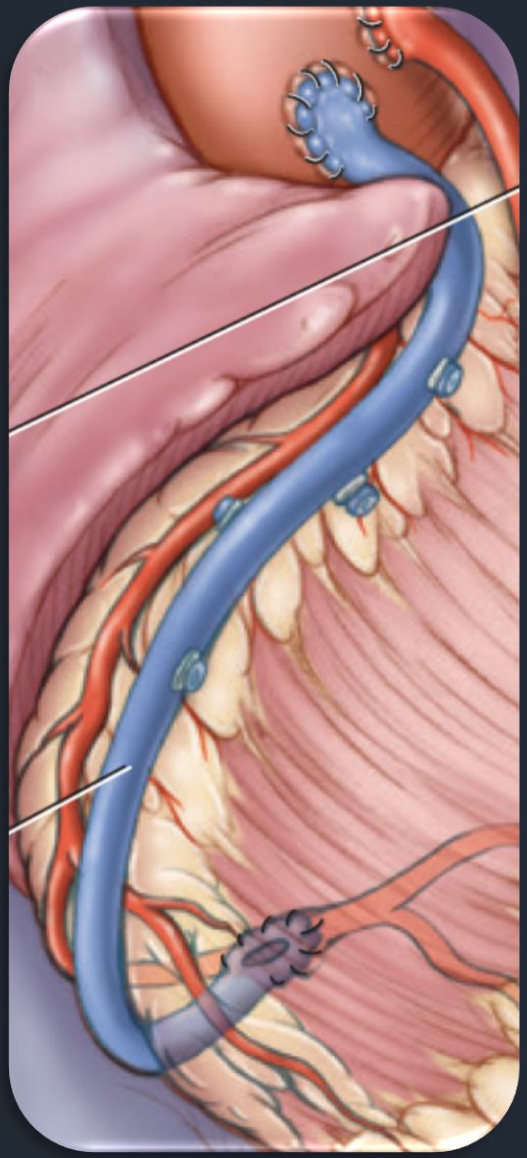
Saphenous Vein-Graft



The Most Common Conduit for CABG

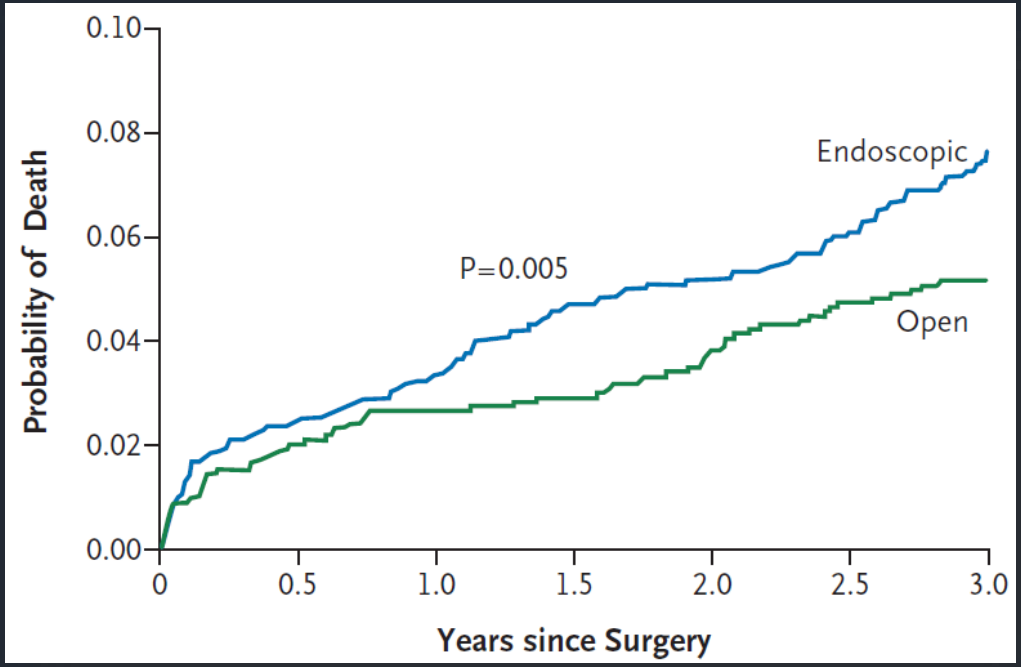
Endoscopic Vein Harvest

Safety of Endoscopic Harvest in CABG

N ENGL J MED 361;3 NEJM.ORG JULY 16, 2009

CONCLUSIONS

Endoscopic vein-graft harvesting is independently associated with vein-graft failure and adverse clinical outcomes. Randomized clinical trials are needed to further evaluate the safety and effectiveness of this harvesting technique.



DCRI 2009

Randomized Endovein Graft Prospective (REGROUP) Trial

VA Cooperative Studies Program (CSP) #588 [2013]

REGROUP Design Imperatives:

✓EVH Harvester Expertise

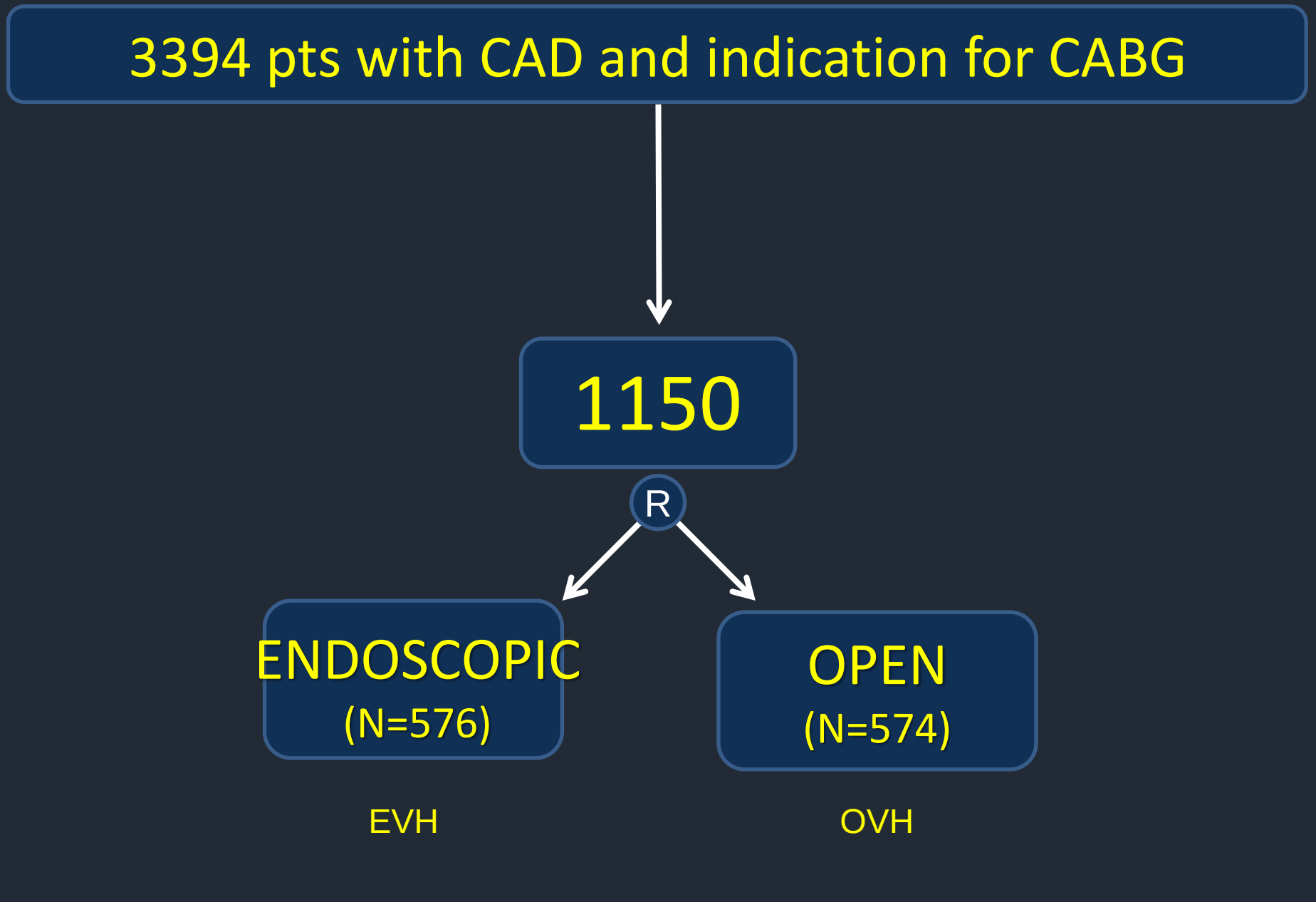
✓Large enough for a meaningful primary outcome:

- *MACE: composite of Death, MI or Repeat Revascularization*

REGROUP - Major Inclusion Criteria

- Indication for CABG using at least 1 vein graft
- On-pump; No associated procedure
- Elective or urgent surgery
- Availability of an expert EVH harvester
  - >100 EVH; <5% Conversion; EVH Program >2 years

REGROUP


3394 pts with CAD and indication for CABG
1150
R
ENDOSCOPIC
(N=576)
OPEN
(N=574)
EVH
OVH

Characteristics of the Patients (N=1150)

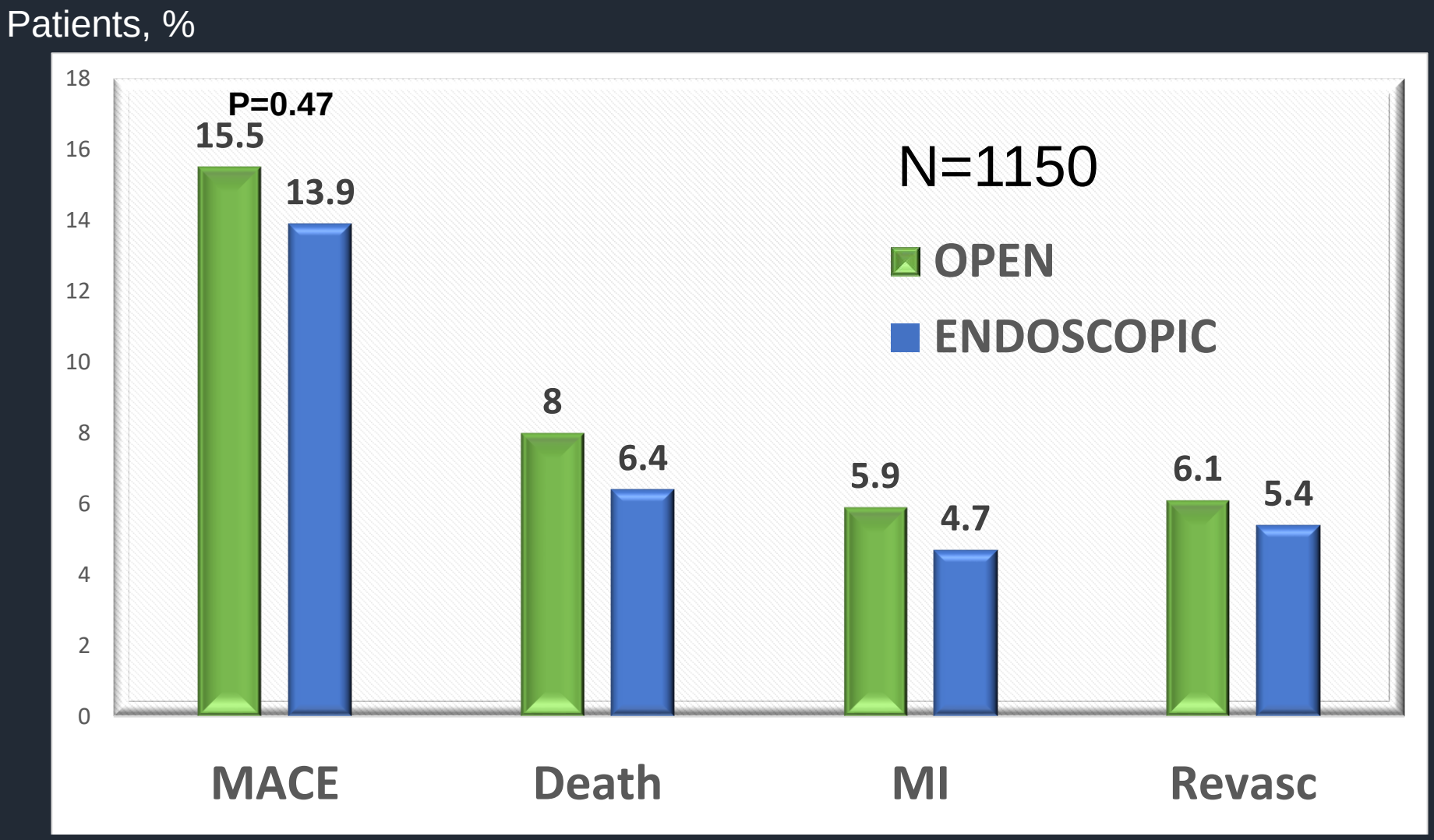
	EVH (N=574)	OVH (N=576)
Age (years)	66.2 ± 6.7	66.6 ± 7.1
Male	99.5%	99.5%
BMI (kg/m^2)	30.3 ± 5.2	30.6 ± 5.2
Hyperlipidemia	85.4%	87.5%
Peripheral vascular disease	13.9%	13.9%
Prior myocardial infarction	38.1%	36.1%
Diabetes	48.8%	51.7%
- Insulin-treated	21.7%	23.9%
Hypertension, medically treated	90.6%	89.7%
NYHA Class III-IV	10.1%	12%
Current smoker	28.5%	26.3%
Prior PCI	27.8%	27.5%
Prior stroke	8.3%	8.4%

CABG Procedure

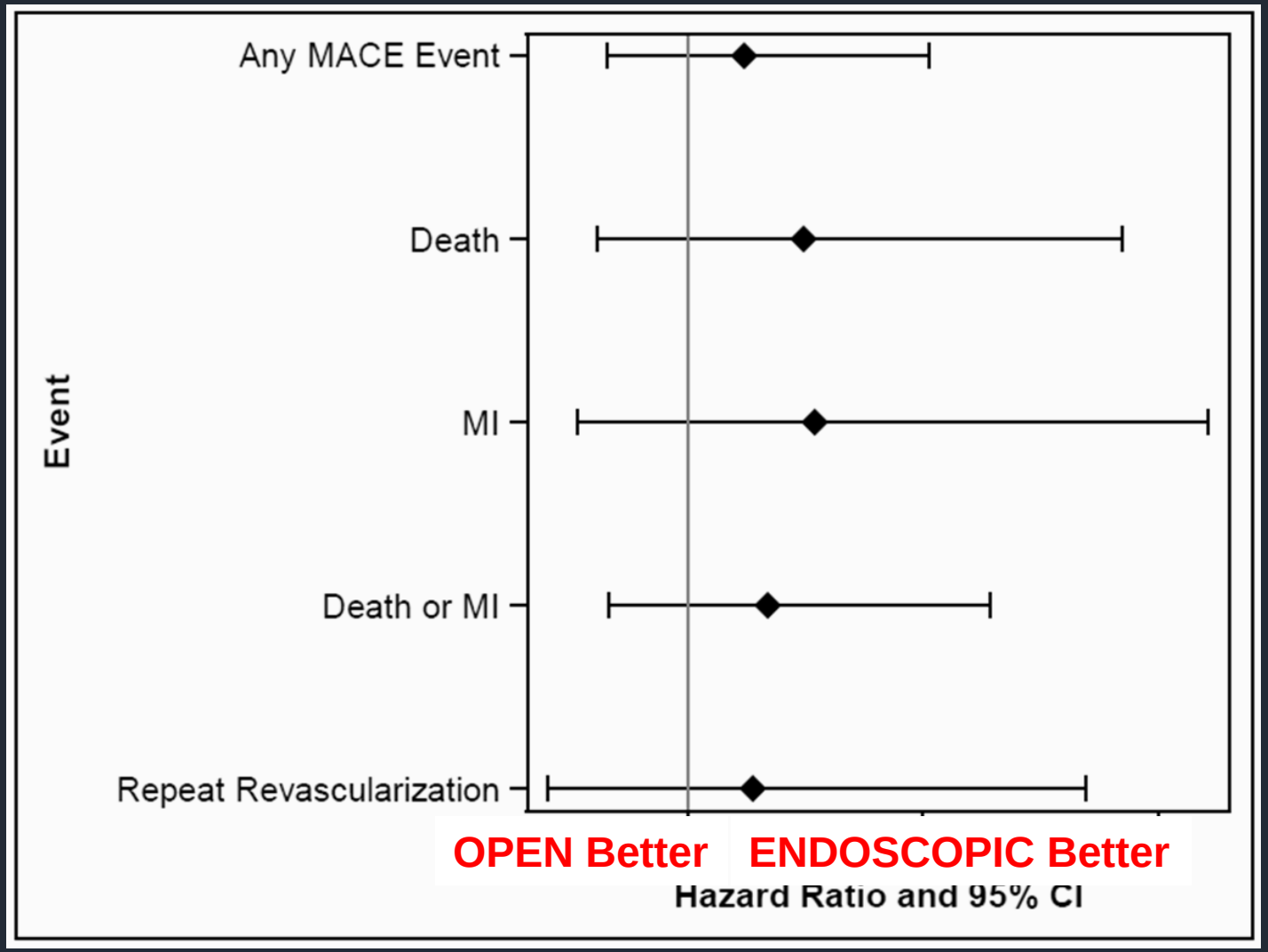
Off-pump CABG	0.5%
Cardiopulmonary bypass time (min)	108.4 ± 35.8
Cross clamp time (min)	76.1 ± 30.8
STS PROM (%)	0.94 ± 0.86
Vein harvest time (min)	59.4 ± 26.7
EVH harvest time (min)*	57.5 ± 24.4
OVH harvest time (min)	61.4 ± 28.7

# Grafts per pt	3.1 ± 0.8
Bilateral ITA	10.3%
Radial artery	1.1%
SYNTAX score	28.5 ± 11.5
Days from randomization to CABG	0.1 ± 1.7
LVEF (%)	54 ± 9.9
Conversion from EVH to OVH (%)	5.6%
Urgent CABG	27%

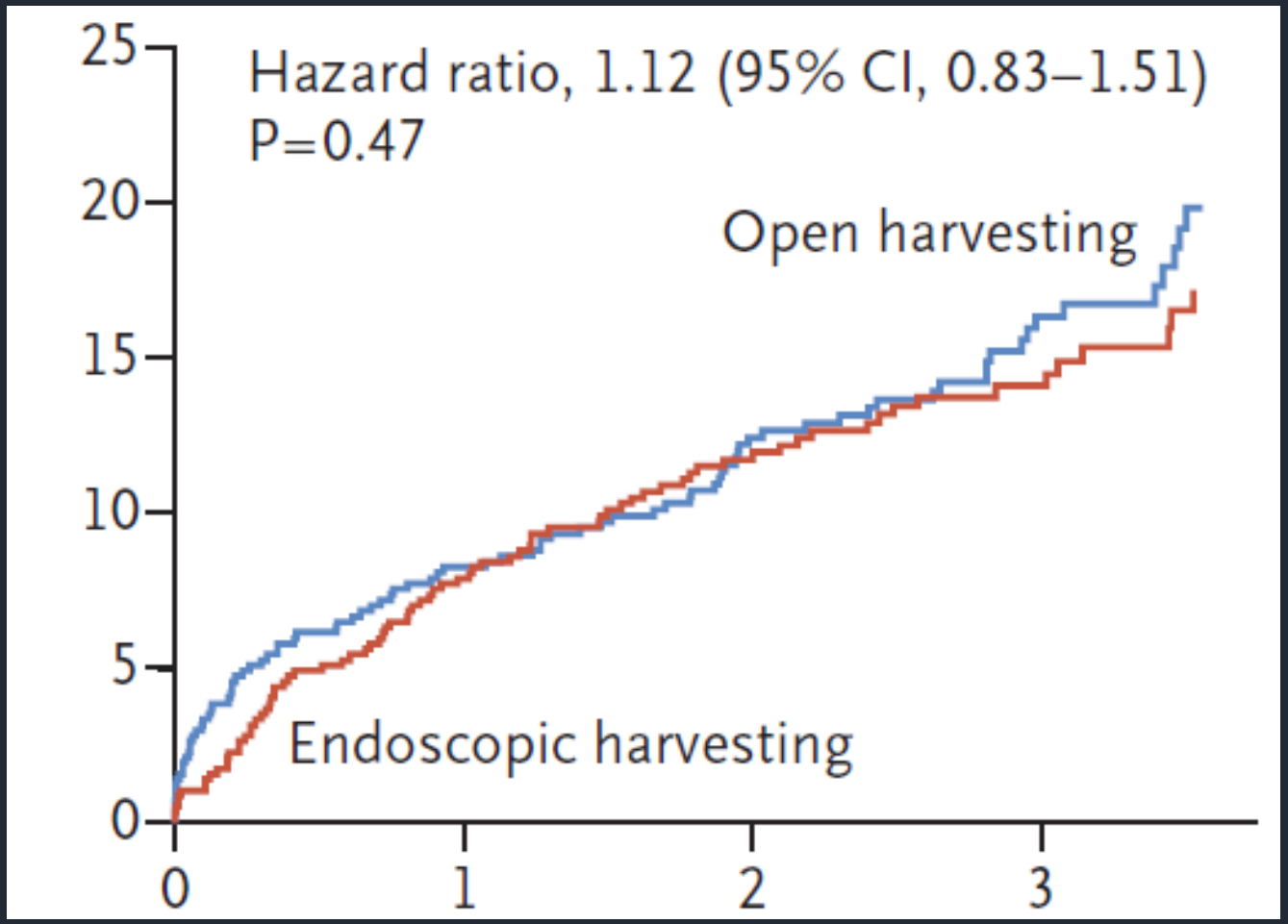
Major Adverse Cardiac Events during Active Follow-up (median 2.78 yrs)



Forest Plot of Hazard Ratio for Major Adverse Cardiac Events



K-M for MACE over Active Follow-up



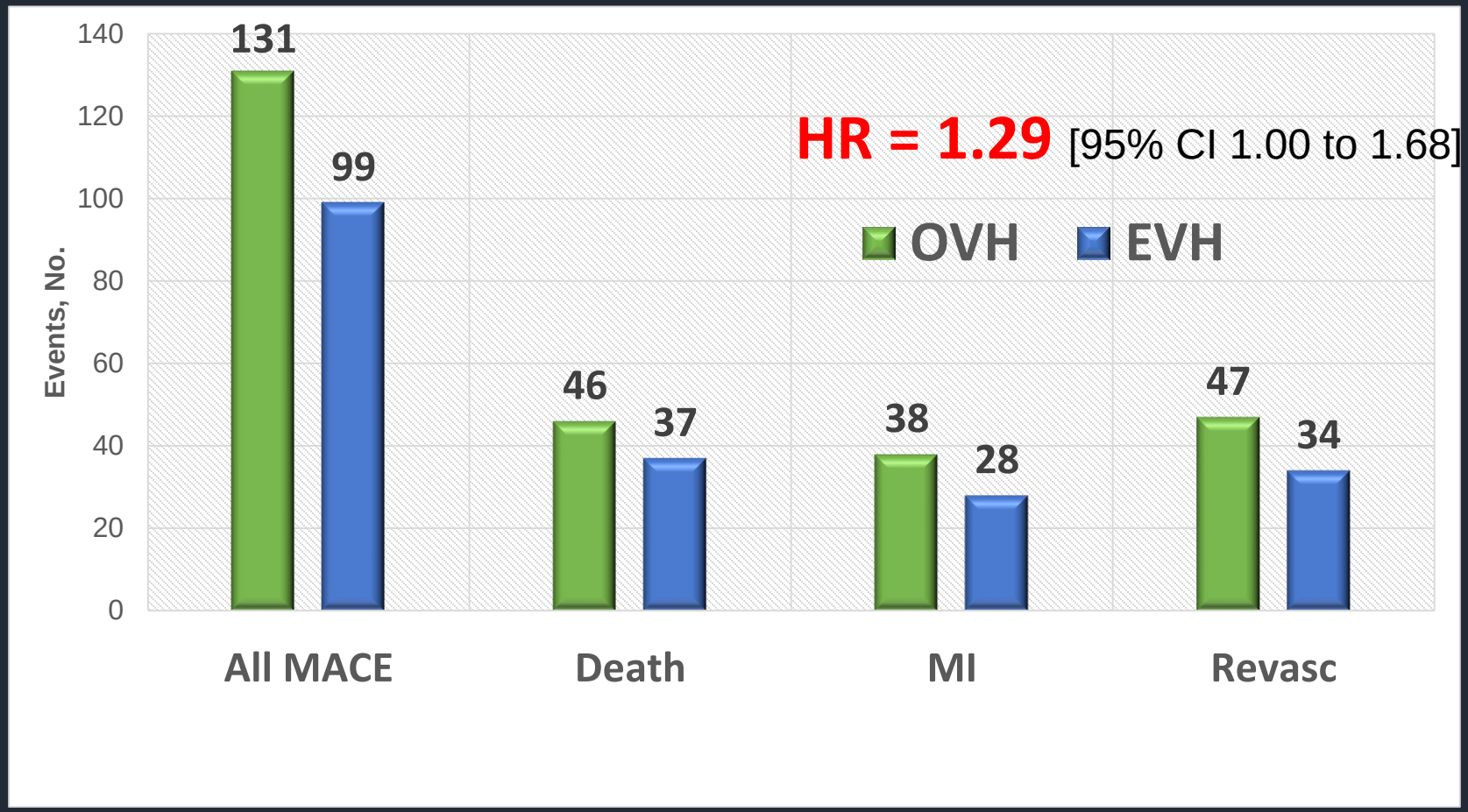
Fewer Vein Harvest Site Complications with Endoscopic

	ENDOSCOPIC	OPEN
Leg wound infections	1.4%*	3.1%
No impact of incisional leg pain on functioning	79.1%*	62.2%
VNA needed to dress wound at home	1.2%*	3.7%
Antibiotics at 6-weeks follow-up	4.6%*	14.4%
I&D under local anesthetic	0.5%	1.2%
Development of pus as an outpatient	1.1%	2.5%
Hospital stay >14 for wound healing disturbance	3.5%	3.7%

CDC and ASEPSIS Criteria

* $P<0.05$

Recurrent Events during Active Follow-up (2.78 years)



Limitations

- No assessment of graft patency by imaging
- Off-pump CABG excluded
- Predominantly male population
- Only expert harvesters participated in REGROUP
- Longer-term follow-up is required to examine whether additional differences emerge

Conclusions

- *No difference in the primary endpoint of death, MI or revascularization between endoscopic and open vein harvest was observed during the active follow-up period* (median 2.78 years)
- Fewer leg wound adverse events were observed for EVH

Endoscopic harvest *performed by an expert* may be considered the preferred vein harvesting modality

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Trial of Endoscopic or Open Vein-Graft Harvesting for Coronary-Artery Bypass

Marco A. Zenati, M.D., Deepak L. Bhatt, M.D., M.P.H., Faisal G. Bakaeen, M.D., Eileen M. Stock, Ph.D., Kousick Biswas, Ph.D., J. Michael Gaziano, M.D., Rosemary F. Kelly, M.D., Elaine Tseng, M.D., Jerene Bitondo, P.A.-C., Jacquelyn A. Quin, M.D., M.P.H., G. Hossein Almassi, M.D., Miguel Haime, M.D., Brack Hattler, M.D., Ellen DeMatt, , Alexandra Scrymgeour, M.S., Pharm.D., and Grant D. Huang, M.P.H., Ph.D., for the REGROUP Trial Investigators*