Professor David L Hare
Potential Conflicts of Interest

INDUSTRY

Payment for research projects, consultancies, travel, advisory boards, and/or lecture fees from: Abbott, Amgen, AstraZeneca, Bayer, Boehringer-Ingelheim, CSL-Biotherapies, Lundbeck, Menarini, Merck, Pfizer, Regeneron, Sanofi, Servier, Vifor

RAPCO RESEARCH FUNDING

Heart Foundation (Australia): G09M4392 - Buxton BF, Hare DL.

RAPCO

#AHA2022
Late-Breaking Science Session

RAPCO 15-Year Clinical Outcomes

Radial **A**rtery **P**atency and **C**linical **O**utcomes Study – **RAPCO**
The 15-Year RCT clinical outcomes comparing radial artery with right internal thoracic artery or with saphenous vein

Professor David L Hare
Professorial Fellow, University of Melbourne;
Senior Cardiologist, Austin Health
Australia

For Hamilton G, Raman J, Moten SC, Matalanis G, Rosalion A, Dimagli A, Seevanayagam S, Gaudino MF, Hare DL, on behalf of the RAPCO Investigators
From the Brian F Buxton Cardiac Surgical Unit, Austin Health, Melbourne Australia

THE UNIVERSITY OF MELBOURNE

BRIAN F BUXTON CARDIAC SURGICAL UNIT

Austin Health

RAPCO 15-Year Clinical Outcomes

For over 30 years, the accepted primary graft for CABG has been LITA-LAD*

Left Internal Thoracic Artery (LITA) → **Left Anterior Descending (LAD)**

The conduit for the second most important target vessel has remained unclear

*Loop FD. N Engl J Med 1986; 314:1-6

RAPCO Trial Structure

Single center study stratified for randomization into 2 separate, but integrated, trials

I. RAPCO-RITA – RA vs. FRITA

Age <70 years or < 60 years if diabetes

II. RAPCO-SV – RA vs. SVG

Age ≥70 years or ≥ 60 years if diabetes

Joint Hypotheses

- Graft Patency - 10Y
- MACE - 10 & 15Y

Original Power Calculations

- Based on 10Y Graft Patency

Randomization

Primary graft LITA-LAD

- Randomization wrt 2nd graft
- Generated random numbers
- Sealed envelopes held by 3rd party

*ClinicalTrials.gov ID: NCT00475488

RAPCO

RAPCO Trial Structure

Single center study stratified for randomization into 2 separate, but integrated, trials

I. RAPCO-RITA – RA vs. FRITA

Age <70 years or < 60 years if diabetes

II. RAPCO-SV – RA vs. SVG

Age ≥70 years or ≥ 60 years if diabetes

EXCLUSIONS

General, Medical, Target Vessel, RA, RITA, SV

Medical

- LVEF<35%
- Class 4 CKD with serum creatinine >300umol/L (3.39mg/dL)
- FEV_1 <1L
- Marked obesity BMI >35kg.m^{-2}

RA

- Allen >10s or DBI <0.8
- Atherosclerosis or >mild calcification
- Luminal narrowing >20%
- Diameter <1.5mm or wall >1.0mm

THE UNIVERSITY OF MELBOURNE

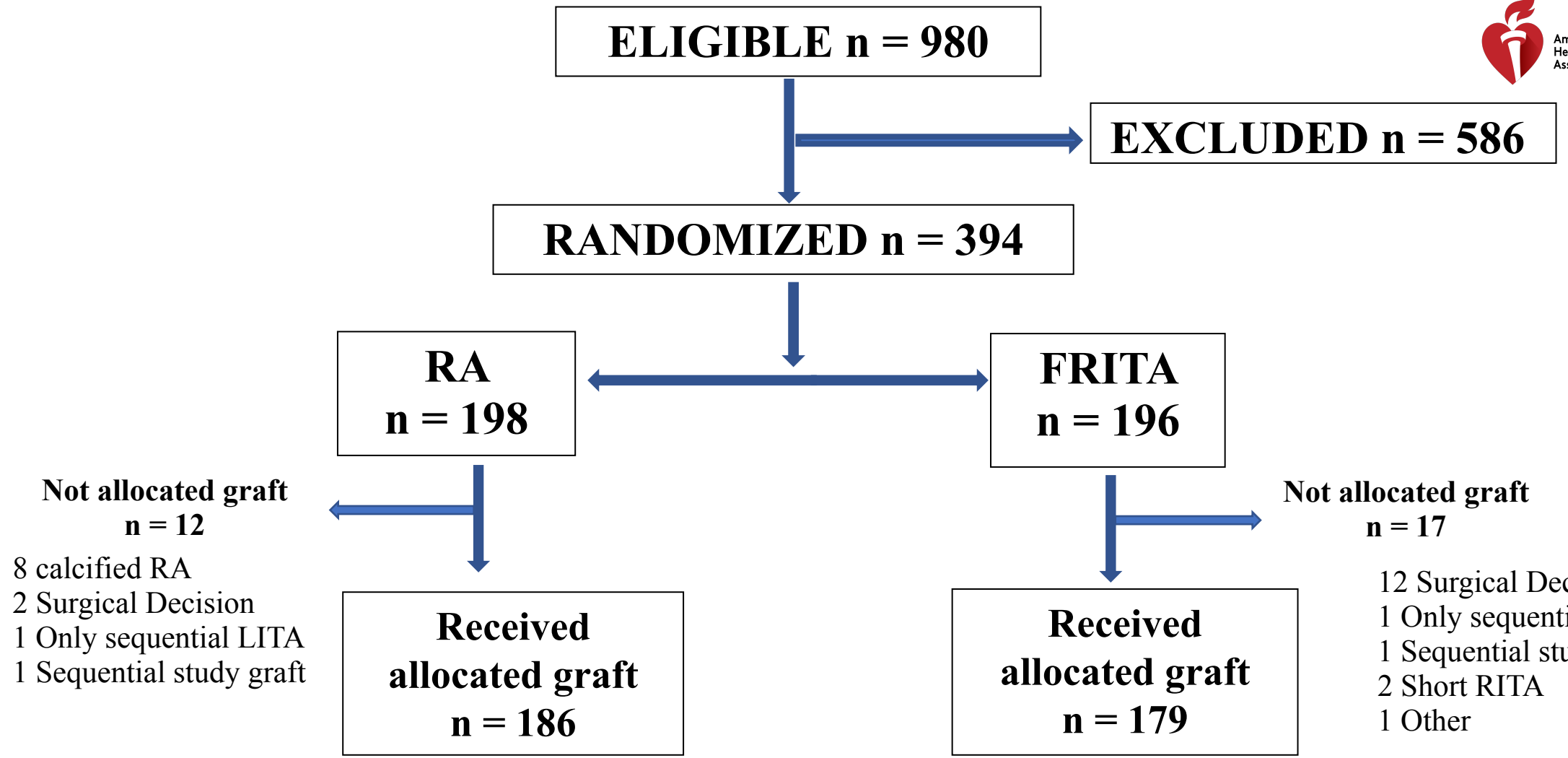
*ClinicalTrials.gov ID: NCT00475488

Austin Health

RAPCO

RAPCO-RITA

#AHA2022
Late-Breaking Science Session



Analyses all on ITT

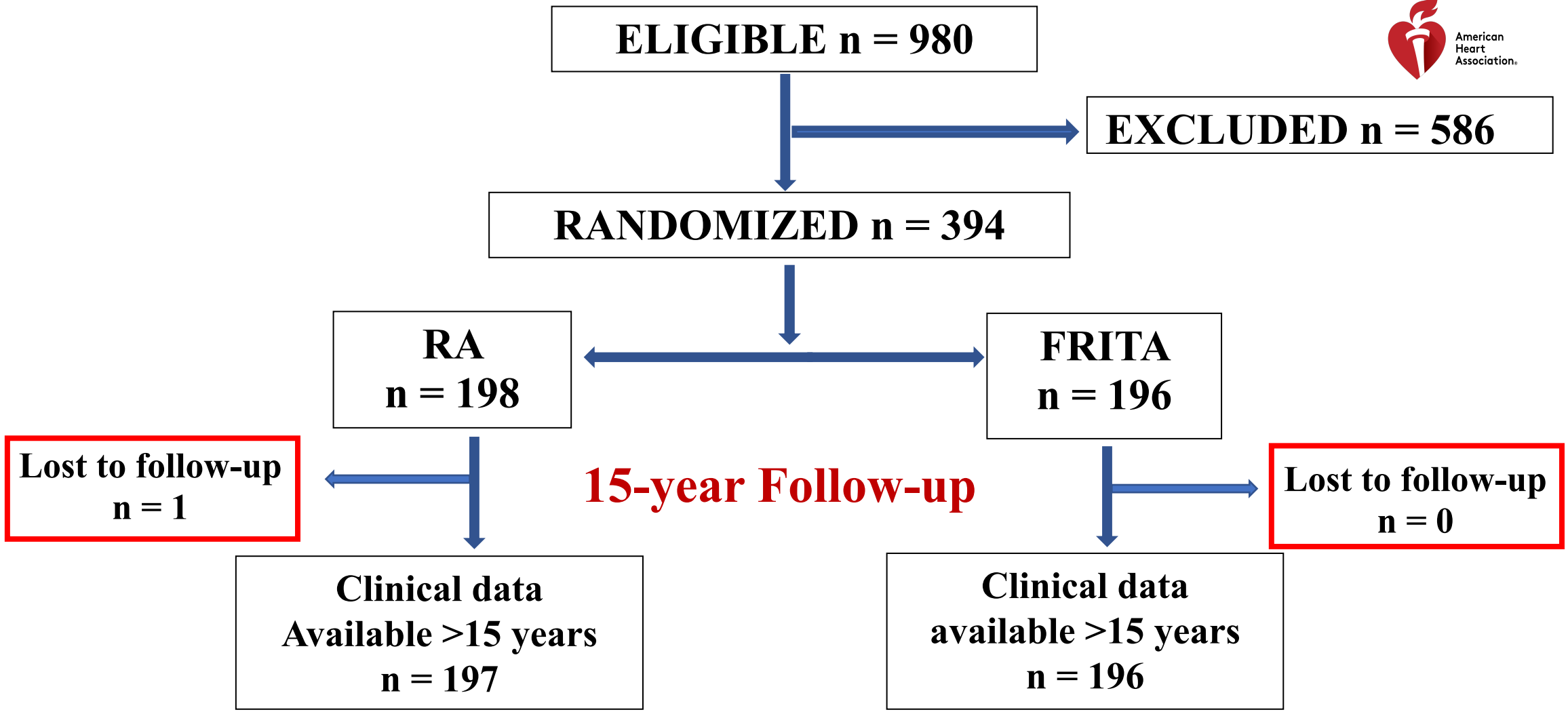
THE UNIVERSITY OF MELBOURNE

Austin Health

RAPCO

RAPCO-RITA

#AHA2022
Late-Breaking Science Session



THE UNIVERSITY OF MELBOURNE

Austin Health

RAPCO

RAPCO-RITA
BASELINE CHARACTERISTICS

#AHA2022

	RITA group	RA group	P-value
Number	196	198	
Age, mean (range)	59.5 (36.2 – 70.9)	59.2 (36.9 – 71.0)	0.72
Male	178 (91%)	175 (88%)	0.51
Diabetes	21 (11%)	22 (11%)	1.0
Hypertension	99 (51%)	113 (57%)	0.23
Elective presentation	161 (82%)	160 (81%)	0.80
Number of grafts (mean +/- SD)	3.2 +/- 1.0	3.2 +/- 1.0	0.49
Smoking history	143 (73%)	148 (75%)	0.73
Preoperative MI	68 (35%)	75 (38%)	0.53
Preoperative PCI	27 (14%)	20 (10%)	0.28
Target vessel			
• Circumflex artery	131 (67%)	122 (62%)	0.28
• Right coronary artery	52 (26%)	69 (35%)	0.07
• Ramus or Diagonal artery	13 (7%)	7 (3%)	0.16

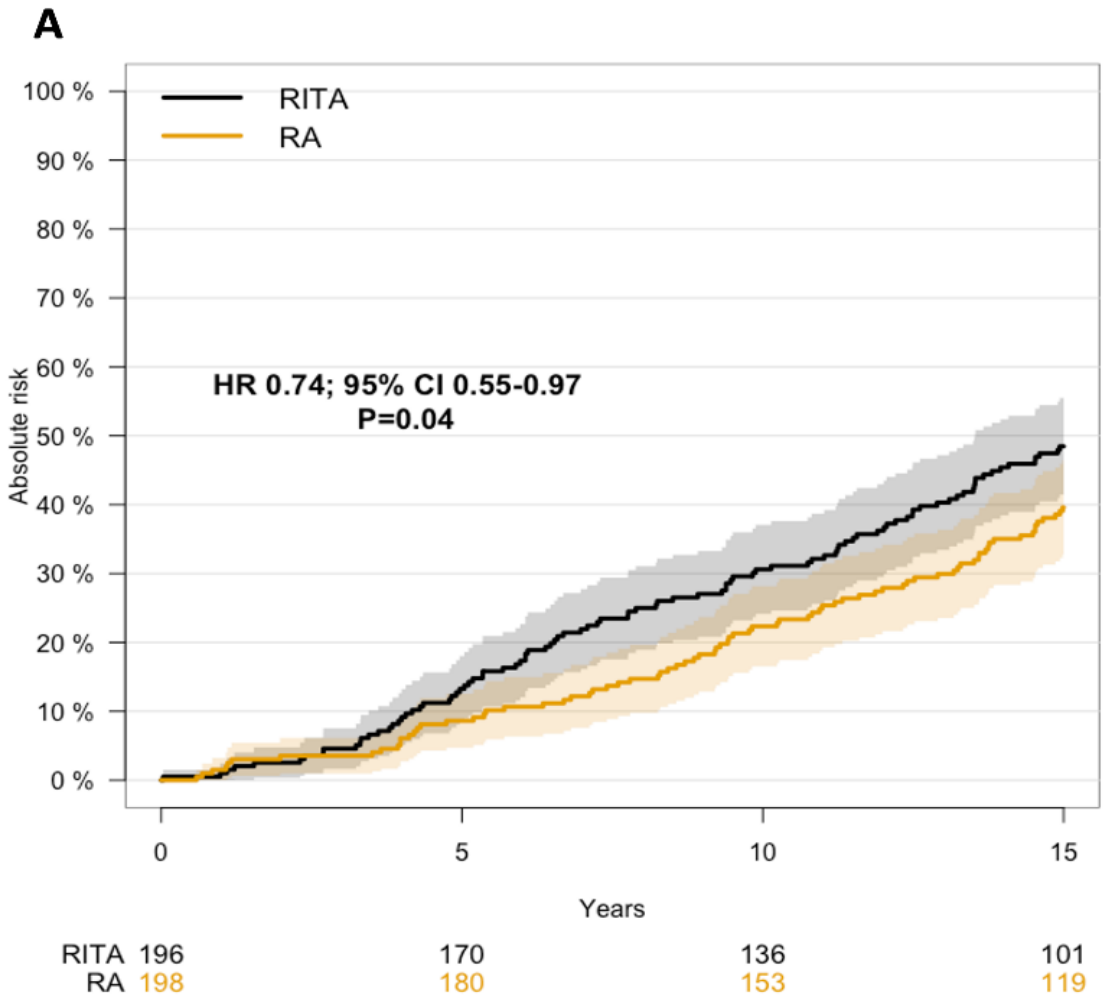
RAPCO

RAPCO-RITA
15-Year RESULTS

#AHA2022
Late-Breaking Science Session

American Heart Association.

MACE: AC-Mortality, AMI, +/or Revascularisation



MACE
RA versus RITA
HR 0.74
p=0.04

RAPCO

RAPCO-RITA
15-Year RESULTS
Components of MACE

#AHA2022
Late-Breaking Science Session

American Heart Association.

Outcome	RITA N (%)	RA N (%)	Hazard ratio [95% confidence interval]	P
MACE*	95 (48.5)	78 (39.4)	0.74 [0.55 – 0.97]	0.04
Mortality†	59 (30.1)	44 (22.2)	0.69 [0.47 – 1.02]	0.06
Myocardial infarction†	30 (15.3)	26 (13.1)	0.76 [0.45 – 1.29]	0.31
Repeat coronary revascularization†	42 (21.4)	37 (18.6)	0.79 [0.51 – 1.23]	0.30

Absolute↓ 9%; Relative↓ 26%

*Death, myocardial infarction, repeat coronary revascularization
†Analysed using competing risk framework (Gray and Fine)
RA, radial artery; RITA, right internal thoracic artery

RAPCO

#AHA2022
Late-Breaking Science Session

RAPCO-RITA
15-Year RESULTS
Components of MACE

Outcome	RITA N (%)	RA N (%)	Hazard ratio [95% confidence interval]	P
MACE*	95 (48.5)	78 (39.4)	0.74 [0.55 – 0.97]	0.04
Mortality†	59 (30.1)	44 (22.2)	0.69 [0.47 – 1.02]	0.06
Myocardial infarction†	30 (15.3)	26 (13.1)	0.76 [0.45 – 1.29]	0.31
Repeat coronary revascularization†	42 (21.4)	37 (18.6)	0.79 [0.51 – 1.23]	0.30

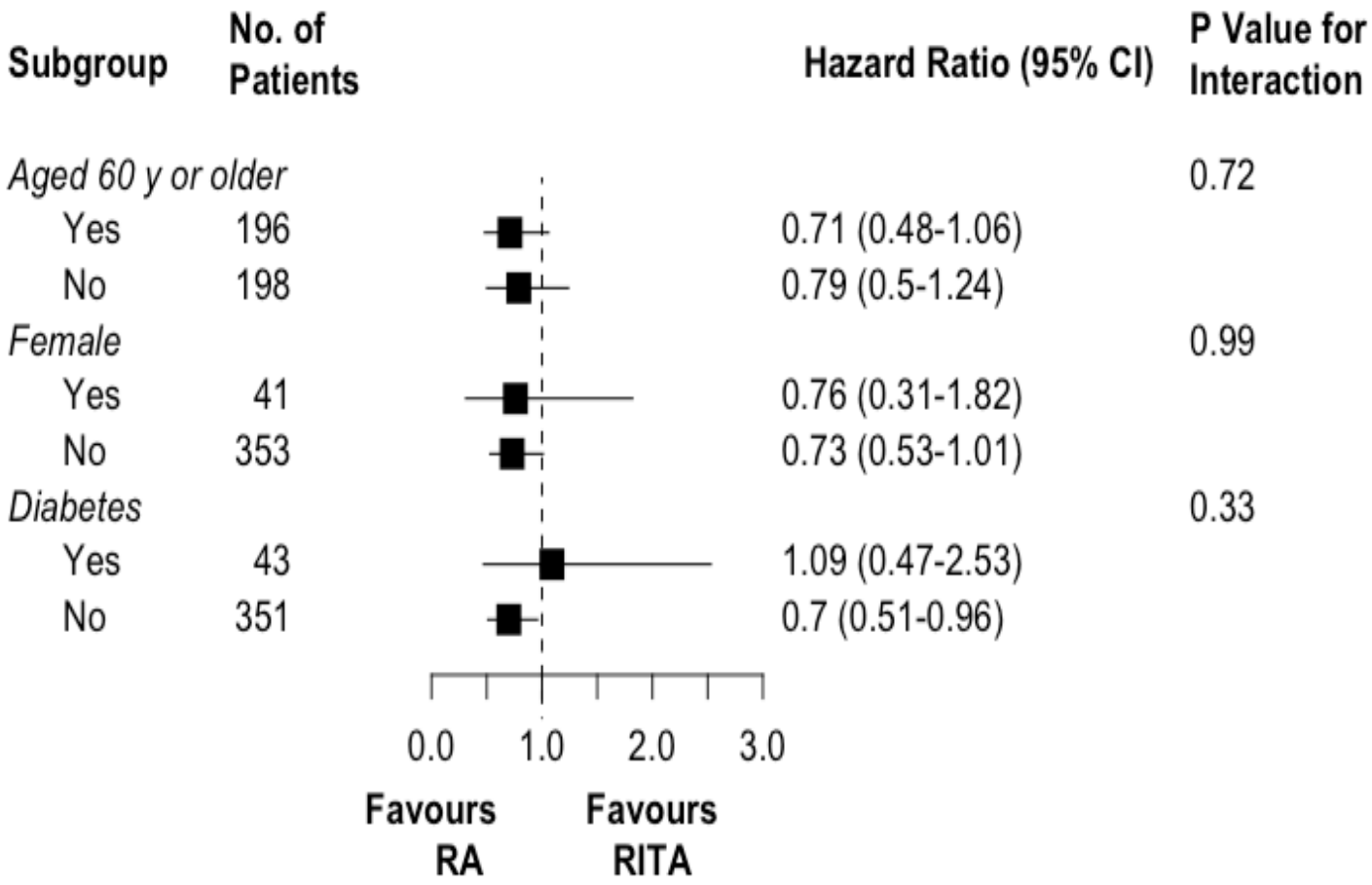
Absolute↓ 8%; Relative↓ 31%

*Death, myocardial infarction, repeat coronary revascularization
†Analysed using competing risk framework (Gray and Fine)
RA, radial artery; RITA, right internal thoracic artery

RAPCO

#AHA2022
Late-Breaking Science Session

RAPCO-RITA
15-Year RESULTS
Pre-specified Sub-group Analyses for MACE



THE UNIVERSITY OF MELBOURNE

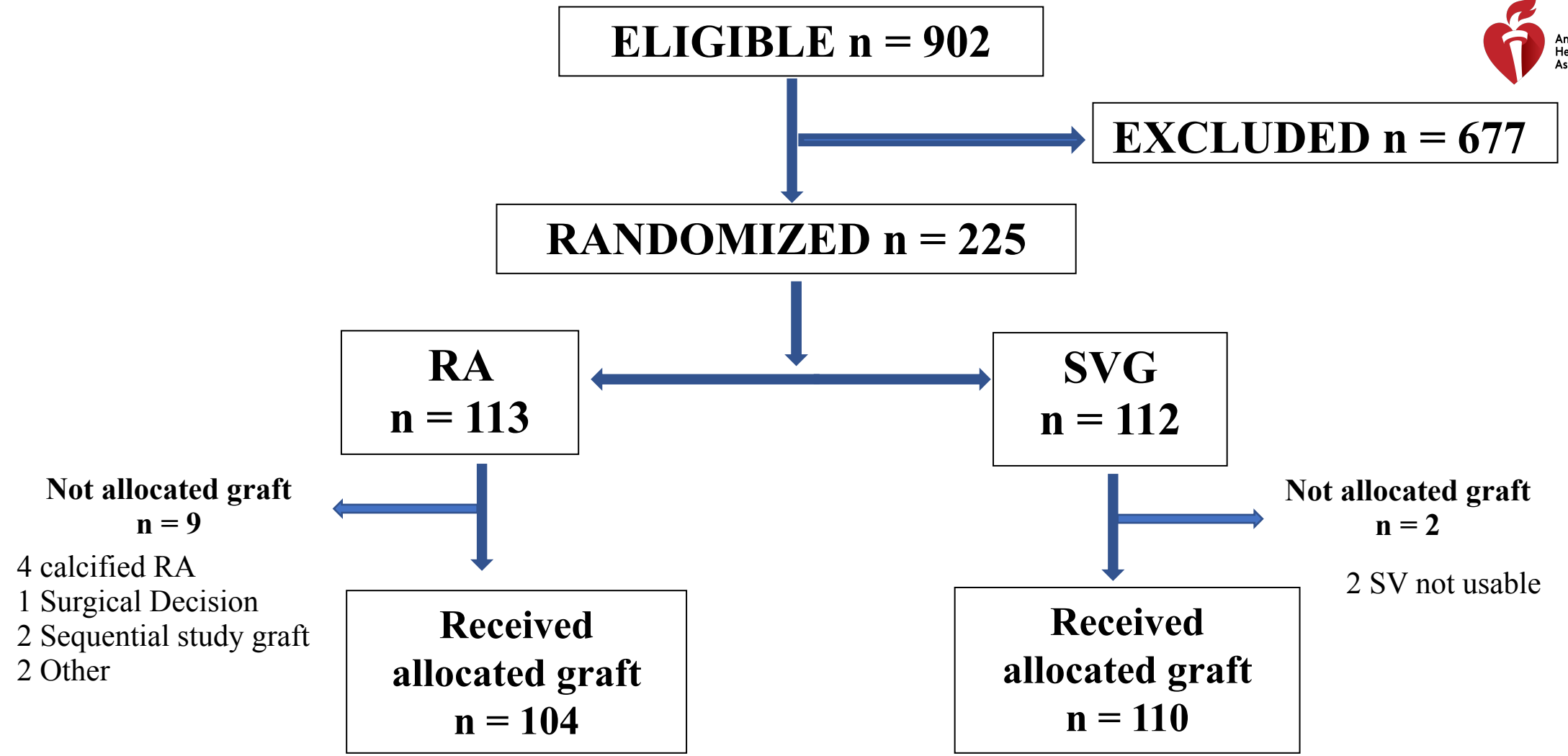
*Age groups dichotomized at the overall mean age of 60 years

Austin Health

RAPCO

RAPCO-SV

#AHA2022
Late-Breaking Science Session



Analyses all on ITT

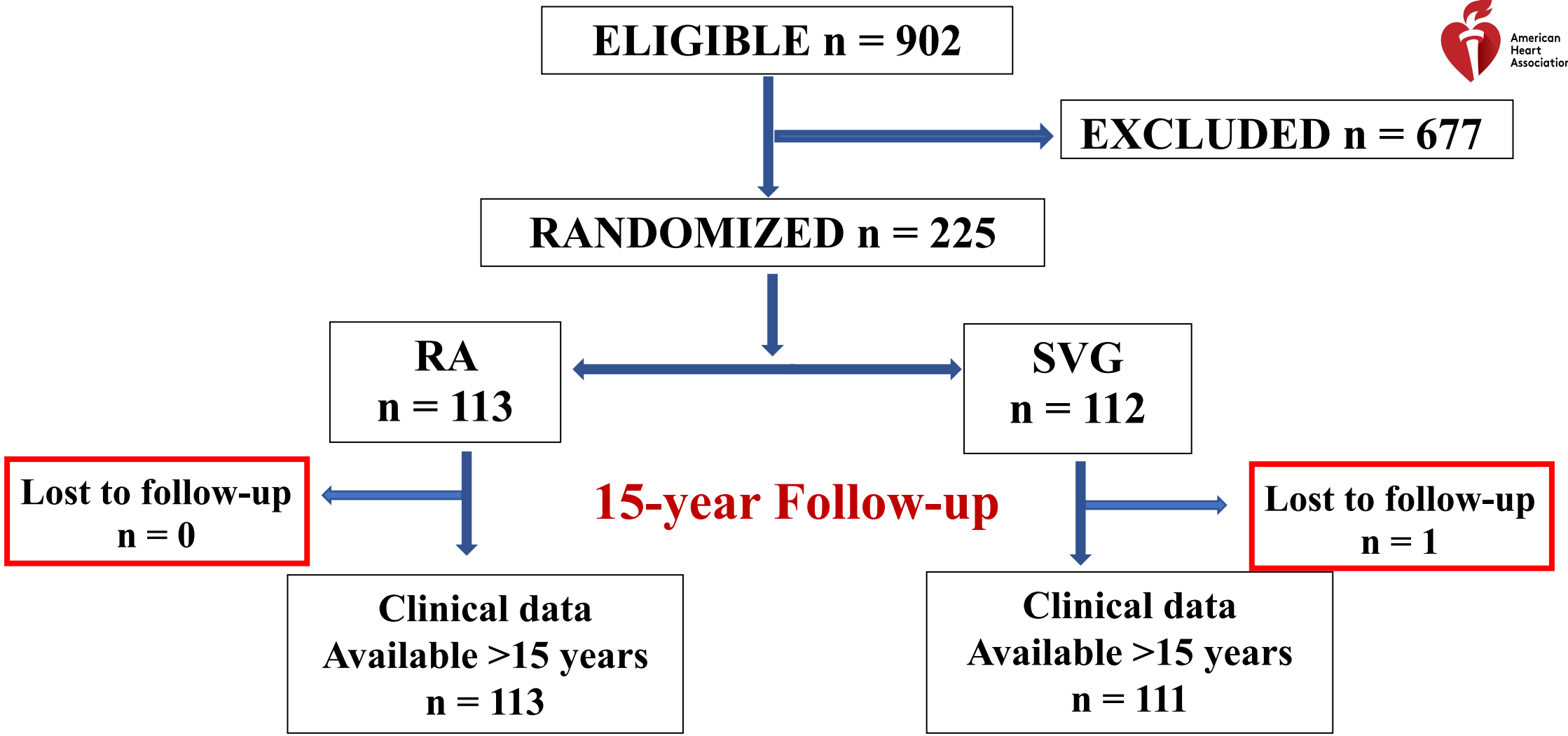
THE UNIVERSITY OF MELBOURNE

Austin Health

RAPCO

RAPCO-SV

#AHA2022
Late-Breaking Science Session



THE UNIVERSITY OF MELBOURNE

Austin Health

RAPCO

RAPCO-SV
BASE-LINE CHARACTERISTICS

#AHA2022

	SV group	RA group	P-value
Number	112	113	
Age, mean (range)	73.1 (60.5 – 80.7)	72.6 (61.0 – 83.5)	0.43
Male	91 (81%)	91 (81%)	1.0
Diabetes	52 (46%)	50 (44%)	0.79
Hypertension	78 (70%)	68 (60%)	0.16
Elective presentation	91 (81%)	87 (77%)	0.51
Number of grafts (mean +/- SD)	3.3 +/- 0.7	3.2 +/- 0.9	0.26
Smoking history	76 (68%)	75 (66%)	0.89
Preoperative MI	36 (32%)	43 (38%)	0.40
Preoperative PCI	12 (11%)	11 (10%)	0.83
Target vessel			
• Circumflex artery	67 (60%)	77 (68%)	0.19
• Right coronary artery	41 (37%)	29 (26%)	0.08
• Ramus or Diagonal artery	4 (4%)	7 (6%)	0.36

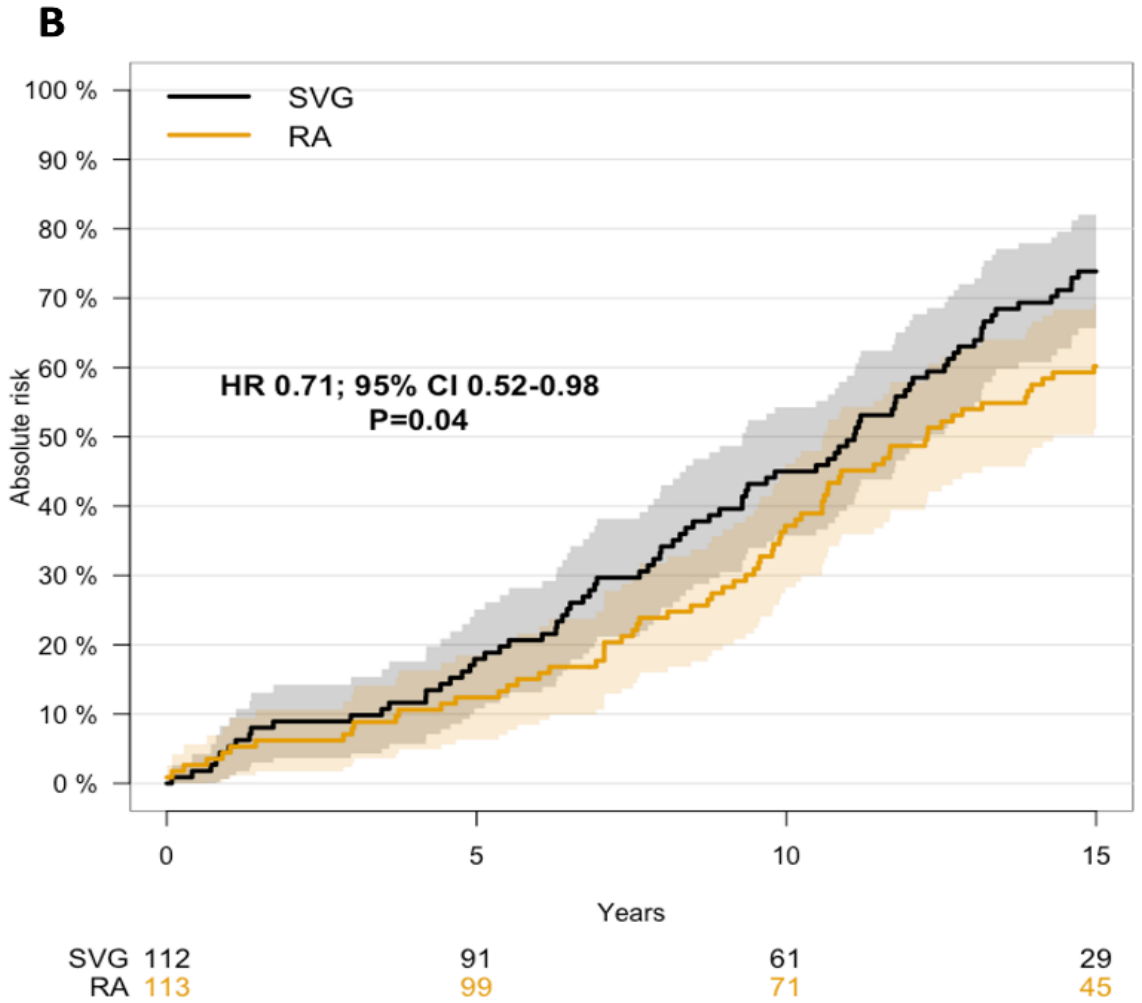
RAPCO

RAPCO-SV
15-Year RESULTS

#AHA2022
Late-Breaking Science Session

American Heart Association.

MACE: AC-Mortality, AMI, +/or Revascularisation



MACE
RA versus SVG
HR 0.71
p=0.04

RAPCO

#AHA2022
Late-Breaking Science Session

American Heart Association.

RAPCO-SV
15-Year RESULTS
Components of MACE

Outcome	SVG N (%)	RA N (%)	Hazard ratio [95% confidence interval]	P
MACE*	82 (73.2)	68 (60.2)	0.71 [0.52 – 0.98]	0.04
Mortality†	71 (63.4)	59 (52.2)	0.74 [0.52 – 1.04]	0.08
Myocardial infarction†	18 (16.1)	13 (11.5)	0.59 [0.29 – 1.21]	0.15
Repeat coronary revascularization†	18 (16.1)	12 (10.6)	0.57 [0.27 – 1.19]	0.13

Absolute↓ 13%; Relative↓ 29%

*Death, myocardial infarction, repeat coronary revascularization
†Analysed using competing risk framework (Gray and Fine)
RA, radial artery; RITA, right internal thoracic artery

RAPCO

RAPCO-SV
15-Year RESULTS
Components of MACE

#AHA2022
Late-Breaking Science Session

American Heart Association.

Outcome	SVG N (%)	RA N (%)	Hazard ratio [95% confidence interval]	P
MACE*	82 (73.2)	68 (60.2)	0.71 [0.52 – 0.98]	0.04
Mortality†	71 (63.4)	59 (52.2)	0.74 [0.52 – 1.04]	0.08
Myocardial infarction†	18 (16.1)	13 (11.5)	0.59 [0.29 – 1.21]	0.15
Repeat coronary revascularization†	18 (16.1)	12 (10.6)	0.57 [0.27 – 1.19]	0.13

Absolute↓ 11%; Relative↓ 26%

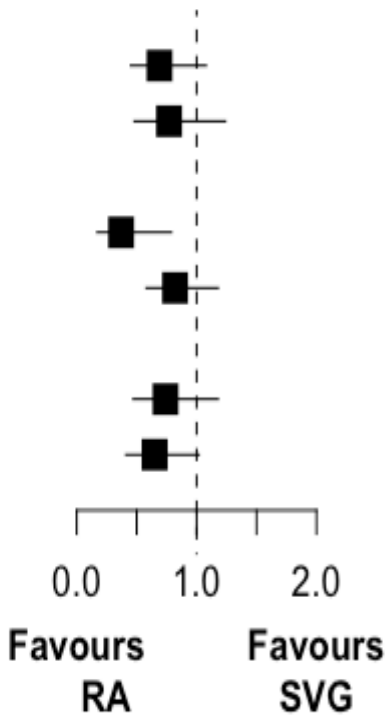
*Death, myocardial infarction, repeat coronary revascularization
†Analysed using competing risk framework (Gray and Fine)
RA, radial artery; RITA, right internal thoracic artery

RAPCO

#AHA2022
Late-Breaking Science Session

RAPCO-SV
15-Year RESULTS
Pre-specified Sub-group Analyses for MACE

Subgroup	No. of Patients	Hazard Ratio (95% CI)	P Value for Interaction
Aged 73 y or older			0.74
Yes	119	0.69 (0.45-1.08)	
No	106	0.77 (0.48-1.24)	
Female			0.07
Yes	43	0.37 (0.17-0.79)	
No	182	0.82 (0.58-1.18)	
Diabetes			0.74
Yes	102	0.74 (0.47-1.18)	
No	123	0.65 (0.41-1.02)	



THE UNIVERSITY OF MELBOURNE

*Age groups dichotomized at the overall mean age of 73 years

Austin Health

RAPCO

RAPCO
SUMMARY 15-YEAR RESULTS

#AHA2022
Late-Breaking Science Session

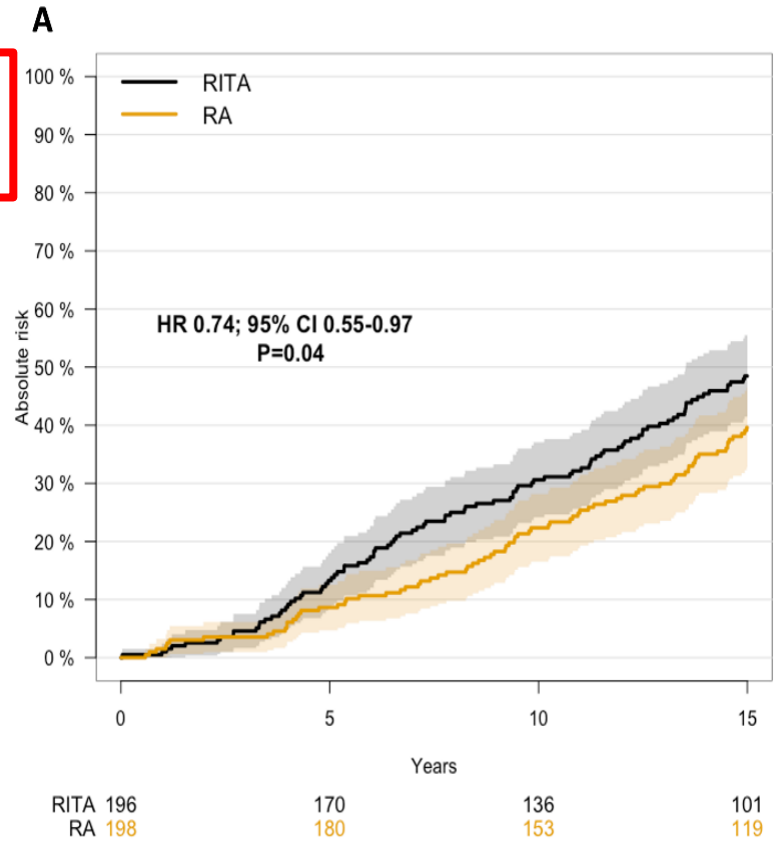
American Heart Association.

RAPCO-RITA

Absolute↓ 9%;
Relative↓ 26%

39% vs 48% MACE

HR 0.74; p=0.04

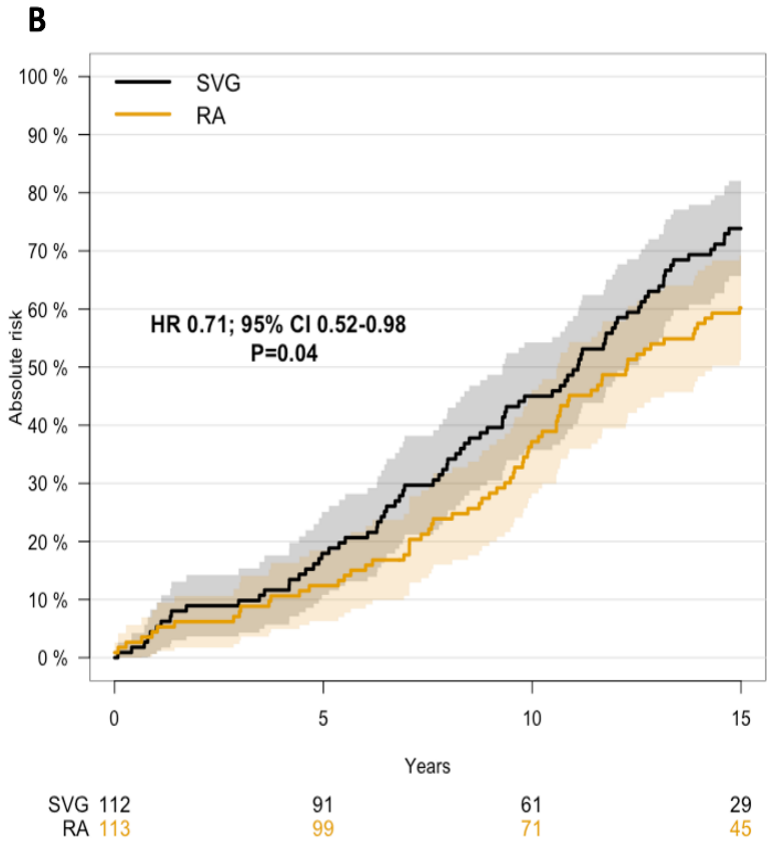


RAPCO-SV

Absolute↓ 13%;
Relative↓ 29%

60% vs 73% MACE

HR 0.71; p=0.04



MACE = AC Mortality, AMI, +/or Revascularisation

THE UNIVERSITY OF MELBOURNE

Austin Health

RAPCO

RAPCO
CONCLUSIONS and IMPLICATIONS

#AHA2022

American Heart Association.

1. **First single RCT program** to demonstrate **better clinical outcomes** using **RA grafting**
   - compared with **both RITA and SV**
2. **Currently in USA:**
   Approx. 200,000 CABG per year
   <10% patients receive a radial artery graft*

2. **All isolated CABG operations should consider using a Radial Artery Graft**
   Unless specific contra-indication

3. **Instrumented radial arteries cannot be assumed to be satisfactory CABG conduits**

Further research is necessary

*ElBardissi AW. STS Database. JCTVS 2012; 143: 273-281