BREAKTHROUGHS IN BLOOD

ADVANCEMENTS INTO ACTION

We address the “So what?” and “Now what?” of medical research, with a focus on transfusion clinical trials and guidelines.

Albumin Infusion and Acute Kidney Injury in High-Risk Cardiac Surgery Patients

Yahya Shehabi
Prof Intensive Care Medicine
Monash University – University New South Wales

The eyes are all on Australia vs Canada

Funding & Disclosures

Unrestricted seed grant from CSL Melbourne

- CSL was not involved in the design, conduct, data collection, analysis or preparation of this presentation
- ALBICS-AKI participated in CSL pharmacovigilance program

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Nil other related COI

Critical Care Physicians

Albumin is a fluid, not a blood product

Can J Anesth/J Can Anesth (2022) 69:818–831
https://doi.org/10.1007/s12630-022-02237-w

REPORTS OF ORIGINAL INVESTIGATIONS

Albumin use for fluid resuscitation in cardiac surgical patients: a survey of Canadian perioperative care providers

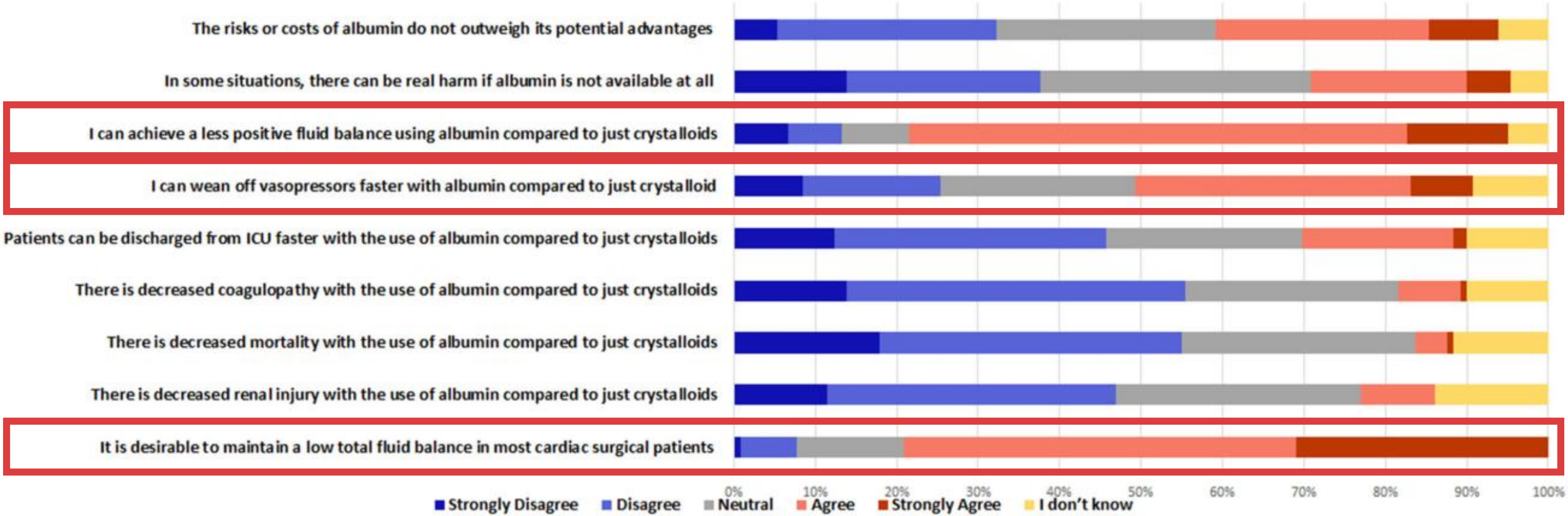


Figure Perceptions of the impact of albumin use in cardiac surgical patients

Defending albumin – an Australian sport

The SAFE trial

- 6997 patients
- 64% ventilated
- APACHE II 18.8(±8)
- 4% albumin vs normal saline
- Resuscitation in ICU
- 28-day mortality
- Organ failure
- ICU/hospital stay

The NEW ENGLAND JOURNAL of MEDICINE

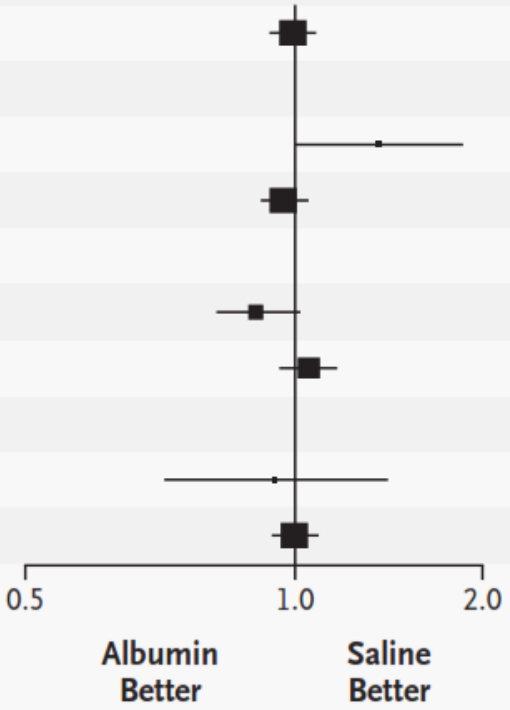
ORIGINAL ARTICLE

2004

A Comparison of Albumin and Saline for Fluid Resuscitation in the Intensive Care Unit

The SAFE Study Investigators*

Patients	Albumin Group	Saline Group	Relative Risk (95% CI)
	no. of deaths/total no.		
Overall	726/3473	729/3460	0.99 (0.91–1.09)
Trauma			
Yes	81/596	59/590	1.36 (0.99–1.86)
No	641/2831	666/2830	0.96 (0.88–1.06)
Severe sepsis			
Yes	185/603	217/615	0.87 (0.74–1.02)
No	518/2734	492/2720	1.05 (0.94–1.17)
ARDS			
Yes	24/61	28/66	0.93 (0.61–1.41)
No	697/3365	697/3354	1.00 (0.91–1.09)



Albumin is the dominant colloid used in resuscitation

RESEARCH ARTICLE

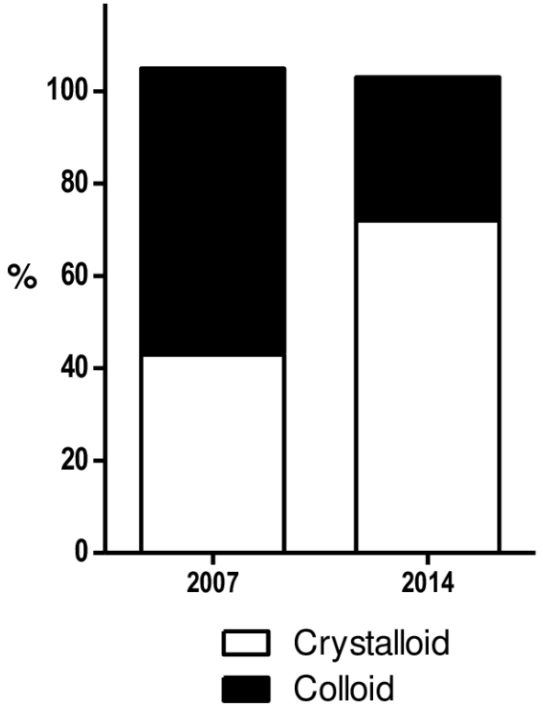
Patterns of intravenous fluid resuscitation use in adult intensive care patients between 2007 and 2014: An international cross-sectional study

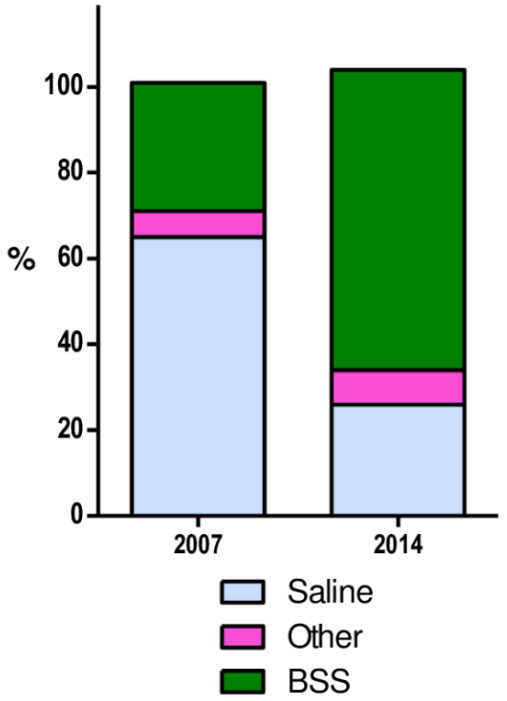
Naomi E. Hammond[1,2,3,4]*, Colman Taylor[1,3], Simon Finfer[1,2,3], Flavia R. Machado[5], YouZhong An[6], Laurent Billot[3,7], Frank Bloos[8], Fernando Bozza[9], Alexandre Biasi Cavalcanti[10], Maryam Correa[1], Bin Du[11], Peter B. Hjortrup[12], Yang Li[1], Lauralyn McIntryre[13], Manoj Saxena[1,4,14], Frédérique Schortgen[15], Nicola R. Watts[1], John Myburgh[1,4,14], for the Fluid-TRIPS and Fluidos Investigators[¶], The George Institute for Global Health, The ANZICS Clinical Trials Group, BRICNet, and the REVA research Network

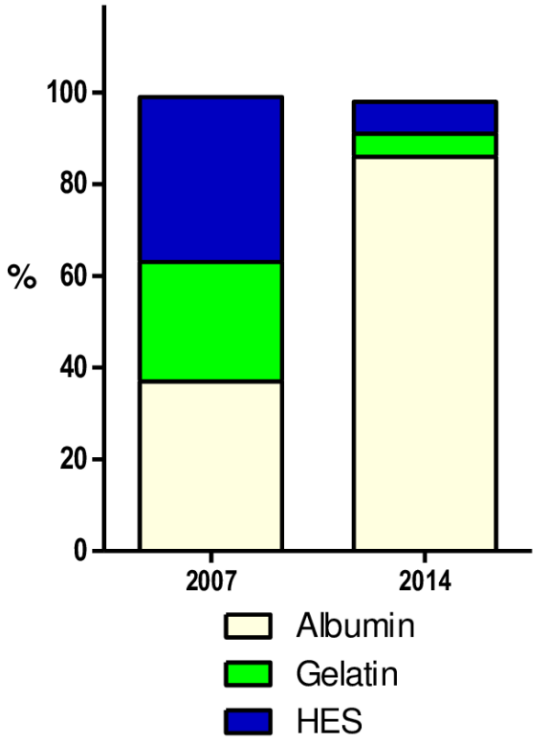
Country / region

Days in ICU

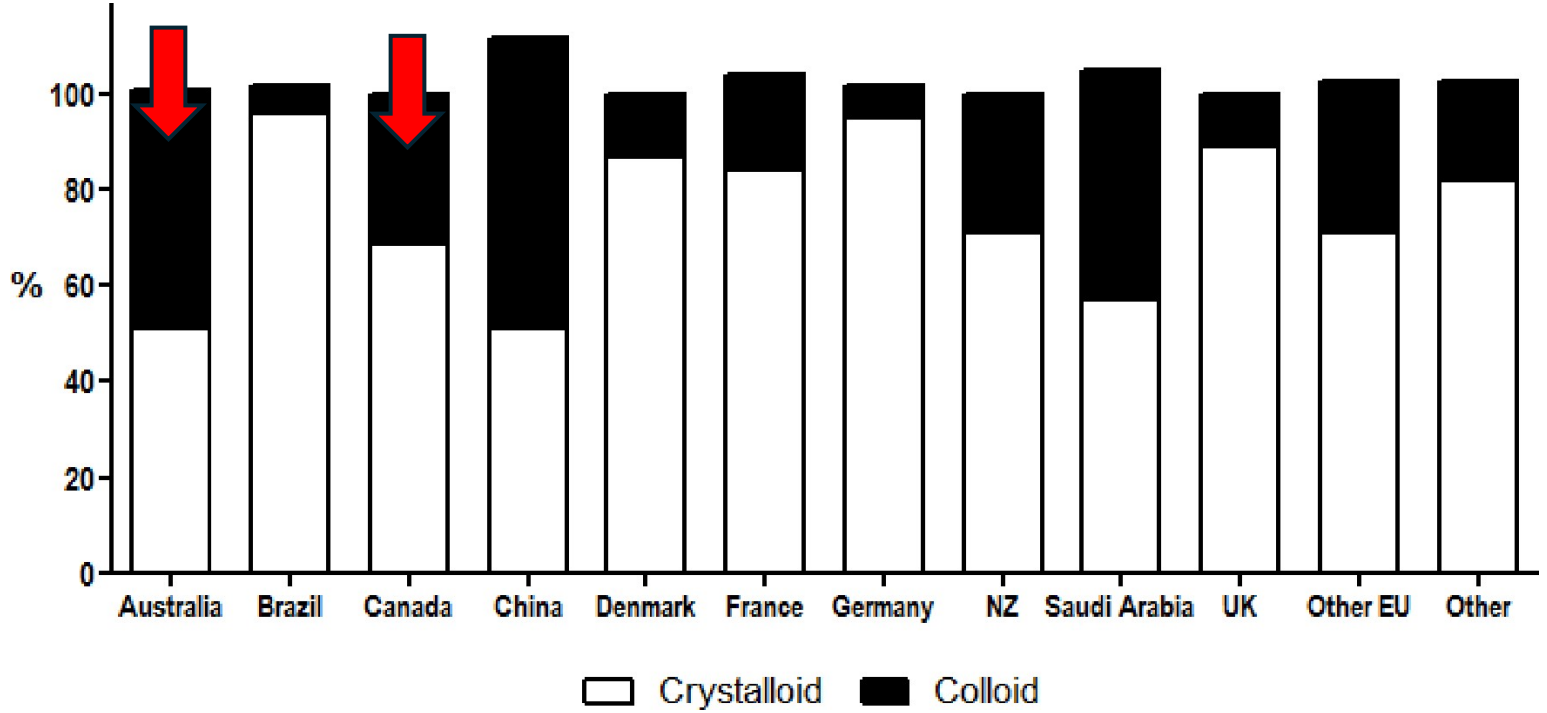
Traumatic Brain Injury





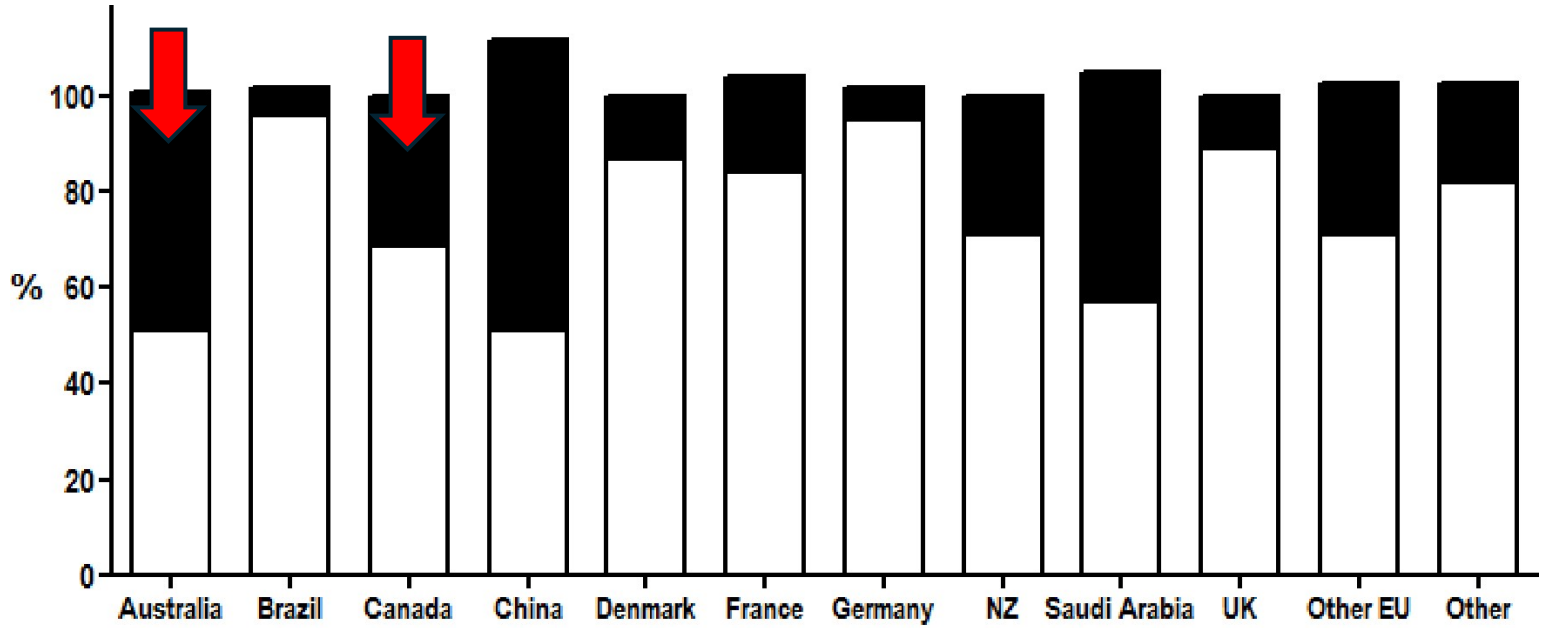


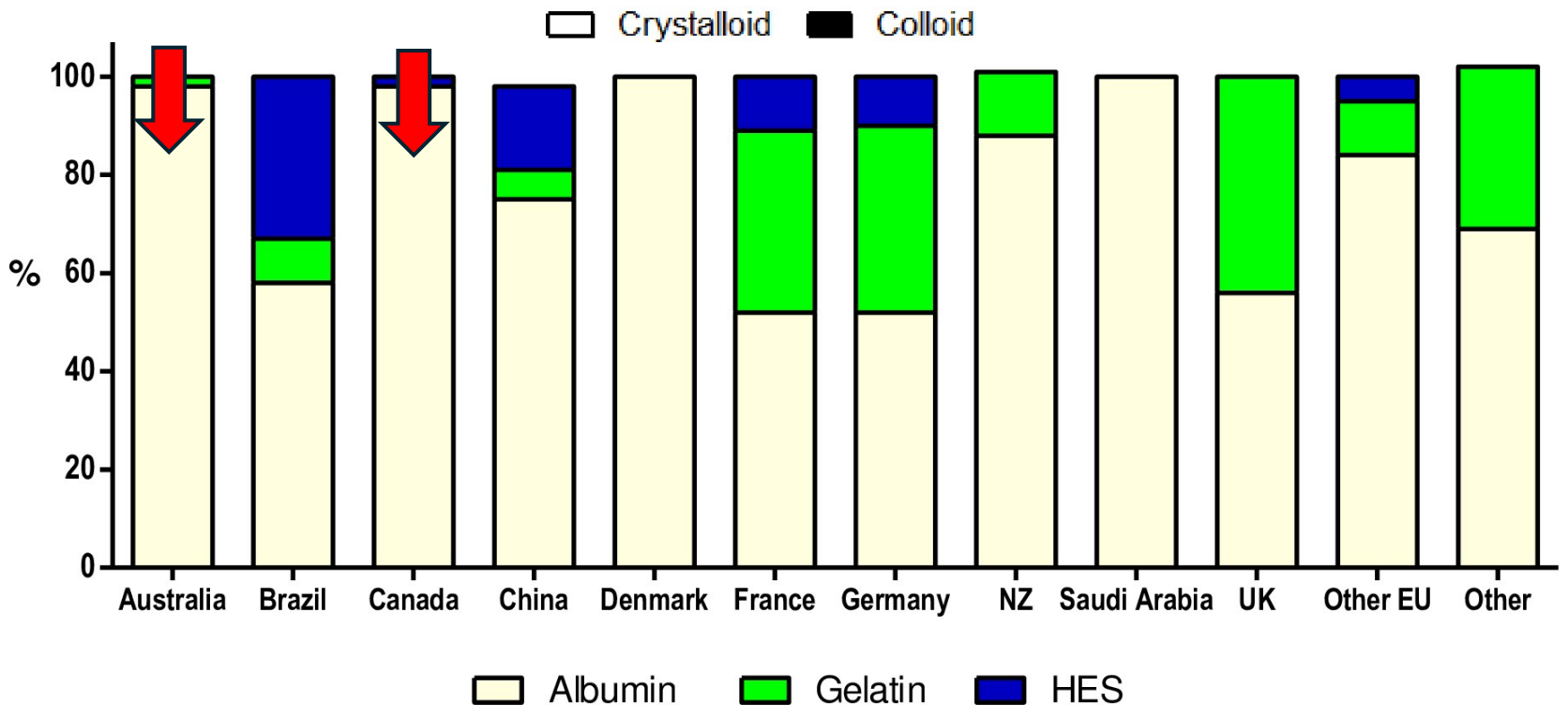
Crystalloids vs colloids



Crystalloids vs colloids

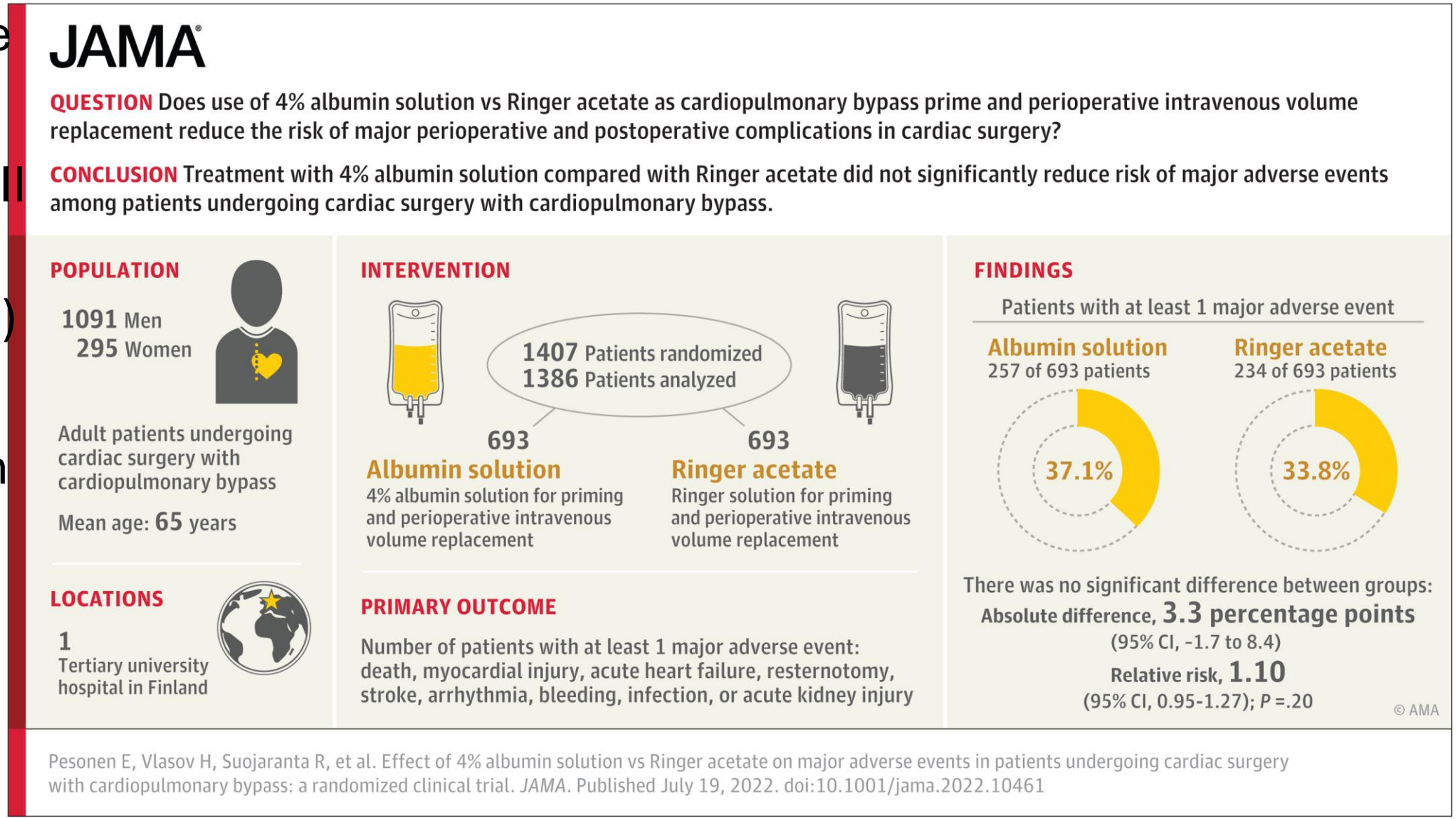
What Colloid?





ALBumin In Cardiac Surgery RCT 2022

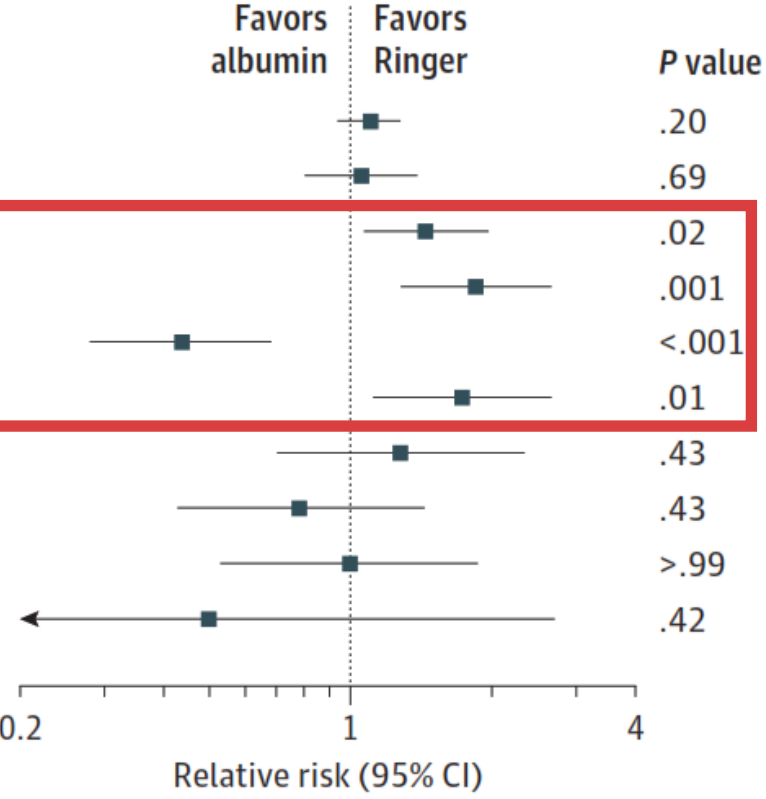
- Single centre
- Low risk pts
- EuroSCORE II 1.7(1-2.8)
- eGFR 80(17)
- CABG 45%
- CPB 110 min
- Post op AKI 2.9%
- Death 0.5%



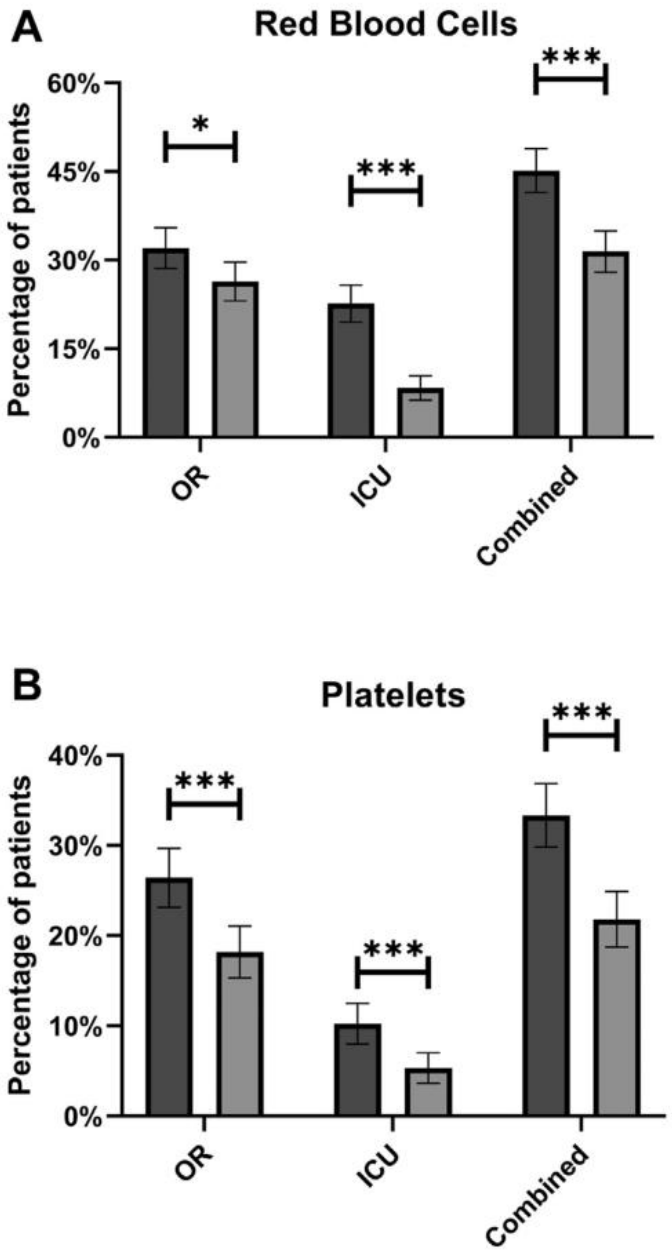
Pesonen E, Vlasov H, Suojaranta R, et al. Effect of 4% albumin solution vs Ringer acetate on major adverse events in patients undergoing cardiac surgery with cardiopulmonary bypass: a randomized clinical trial. *JAMA*. Published July 19, 2022. doi:10.1001/jama.2022.10461

ALBumin In Cardiac Surgery RCT 2022

	No. (%) of patients			
	Albumin (n = 693)	Ringer (n = 693)	Difference (95% CI), %	Relative risk (95% CI)
Major adverse events	257 (37.1)	234 (33.8)	3.3 (-1.7 to 8.4)	1.10 (0.95 to 1.27)
Arrhythmia	91 (13.1)	86 (12.4)	0.7 (-2.8 to 4.2)	1.06 (0.80 to 1.39)
Infection	90 (13.0)	62 (8.9)	4.0 (0.8 to 7.3)	1.45 (1.07 to 1.97)
Resternotomy	74 (10.7)	40 (5.8)	4.9 (2.0 to 7.8)	1.85 (1.28 to 2.68)
Myocardial injury	27 (3.9)	62 (8.9)	-5.1 (-7.6 to -2.5)	0.44 (0.28 to 0.68)
Bleeding	52 (7.5)	30 (4.3)	3.2 (0.7 to 5.7)	1.73 (1.12 to 2.68)
Acute kidney injury	23 (3.3)	18 (2.6)	0.7 (-1.1 to 2.5)	1.28 (0.70 to 2.35)
Heart failure	18 (2.6)	23 (3.3)	-0.7 (-2.5 to 1.1)	0.78 (0.43 to 1.44)
Stroke	19 (2.7)	19 (2.7)	0.0 (-1.7 to 1.7)	1.00 (0.53 to 1.87)
Death	2 (0.3)	4 (0.6)	-0.3 (-1.0 to 0.4)	0.50 (0.09 to 2.72)



Excess transfusion with albumin - ALBICS trial



Albumin Infusion and Blood Loss After Cardiac Surgery

Akseli Talvasto,[1] Minna Ilmakunnas, MD, PhD,[1] Peter Raivio, MD, PhD,[2] Hanna Vlasov, MD,[1] Seppo Hiippala, MD, PhD,[1] Raili Suojaranta, MD, PhD,[1] Erika Wilkman, MD, PhD,[1] Liisa Petäjä, MD, PhD,[1] Otto Helve, MD, PhD,[3,4] Tatu Juvonen, MD, PhD,[2] and Eero Pesonen, MD, PhD[1]

TABLE 2 Multivariable Ordinal Regression Analysis of the Merged Universal Definition of Perioperative Bleeding Classification in the Whole Cohort

Variable	Odds Ratio (95% CI)	*P* Value
Age (y)	1.02 (1.00-1.03)	.02
Male sex	1.36 (1.01-1.87)	.06
Body mass index (kg/m^2)	0.93 (0.90-0.95)	<.001
Preoperative use of acetylsalicylic acid	1.43 (1.08-1.90)	.01
Preoperative use of low-molecular-weight heparin	1.05 (0.70-1.58)	.82
Preoperative platelet count (×10^9/L)	1.00 (1.00-1.00)	.56
Albumin study group allocation	2.23 (1.74-2.87)	<.001
Complex surgery[a]	1.97 (1.49-2.61)	<.001
Urgent surgery[b]	1.54 (1.07-2.22)	.02

ORIGINAL

Twenty percent human albumin solution fluid bolus administration therapy in patients after cardiac surgery-II: a multicentre randomised controlled trial

Geoffrey J. Wigmore[1,2*], Adam M. Deane[1,3], Jeffrey J. Presneill[1,3,4], Glenn Eastwood[5], Ary Serpa Neto[1,4,5,6], Matthew J. Maiden[1,3,7], Shailesh Bihari[8,9], Robert A. Baker[10], Jayme S. Bennetts[10], Rashmi Ghanpur[11], James R. Anstey[3], Jaishankar Raman[5,12,13] and Rinaldo Bellomo[1,3,4,5,14] on behalf of the HAS FLAIR-II investigators

- Multi centre open label
- Low risk pts
- EuroSCORE II 1.5(0.9-2.8)
- Creat 79(68-96)
- CABG 63%
- Cross Clamp 85(68-110) min

- **Post op AKI 22%**
- Death 0.2%

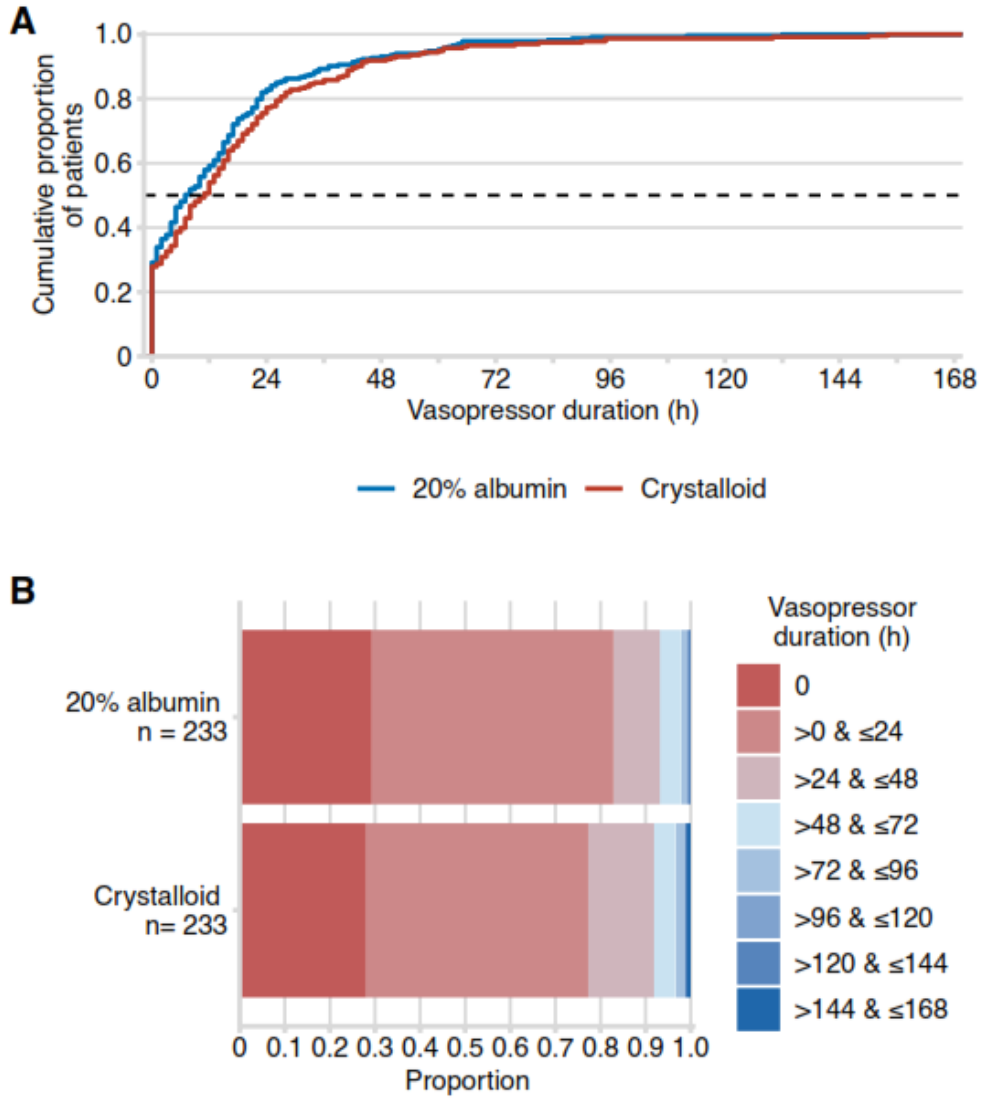


Fig. 2 Vasopressor duration. **A** Distributions of vasopressor hours by study group as the cumulative proportion (y-axis) for each study group by hours (x-axis). Curves that rise faster are more favourable. **B** Vasopressor hours as horizontally stacked proportions by study group. Red represents better values and blue represents worse values

ALBICS-AKI

ALBICS-AKI

Postoperative 20% Albumin Infusion for Acute Kidney Injury in High-Risk Cardiac Surgery

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Monash Health

MONASH University

Austin HEALTH

ST VINCENT'S HOSPITAL MELBOURNE

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Cabrini

THE PRINCE OF WALES HOSPITAL

SCIENTIA MANU ET MENTE

Government of South Australia SA Health

FLINDERS MEDICAL CENTRE

Determinants of Cardiac Sx Associated AKI

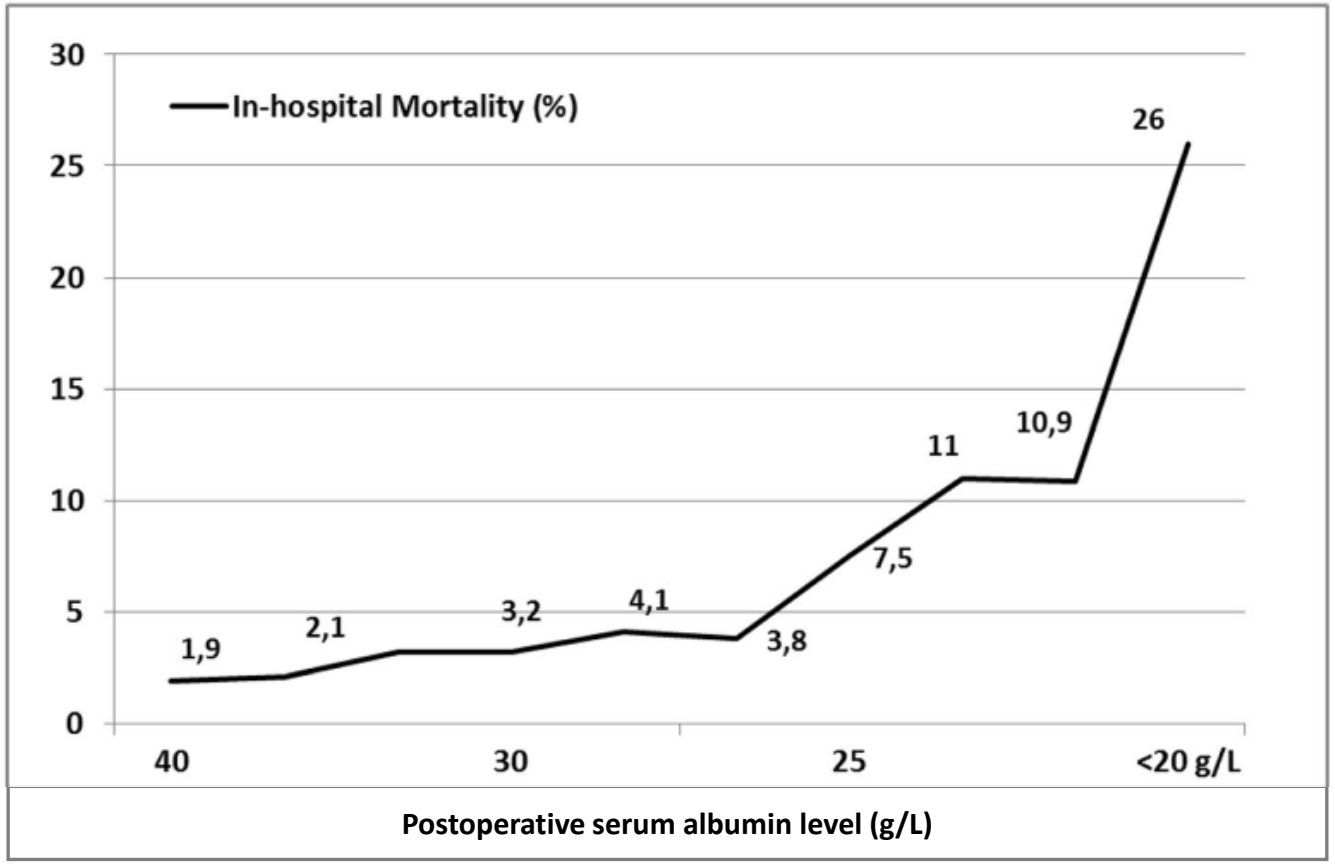
Patient factors

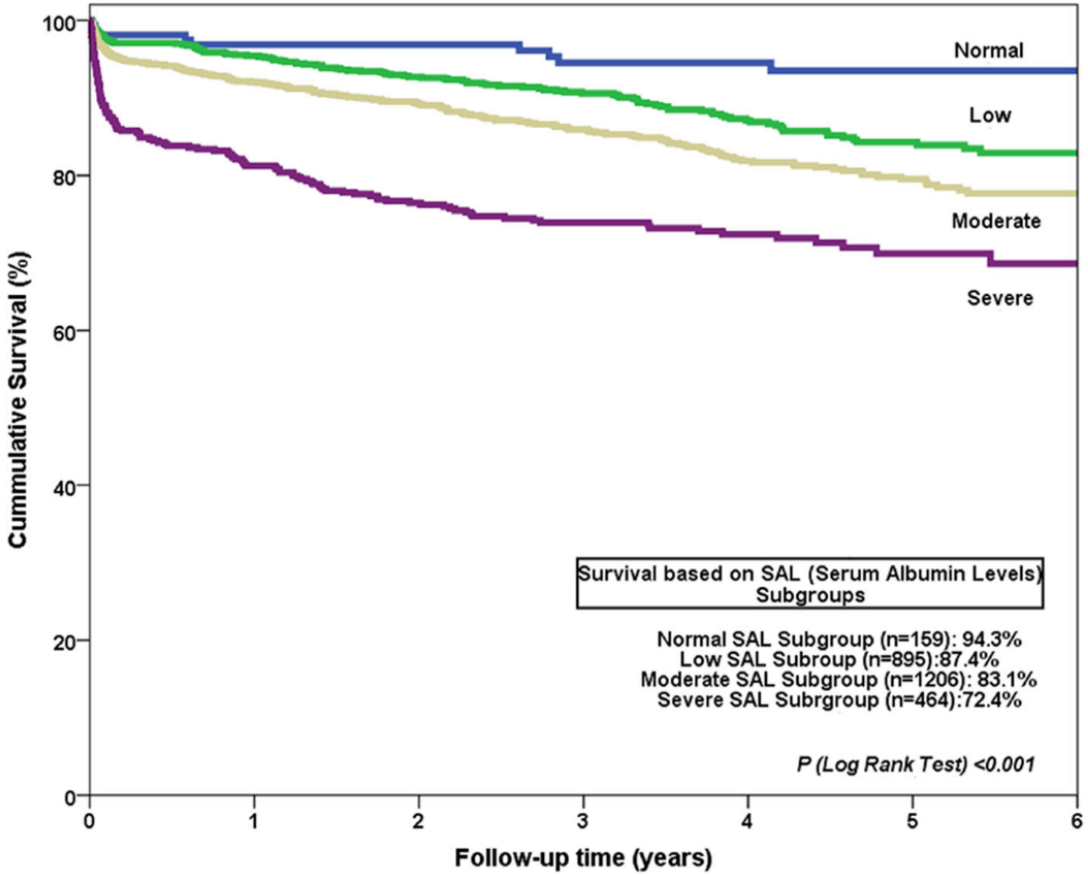
- Age
- CKD
- Diabetes
- Surgical complexity

And factors related to cardiopulmonary bypass

- Hypoperfusion
- Inflammation
- Oxidative stress
- Endothelial damage

Hypoalbuminaemia, dose dependent badness





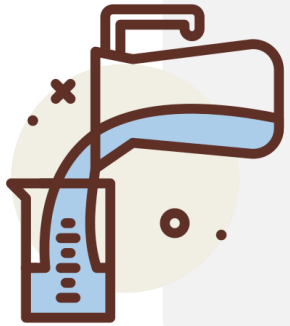
	Normal ≥35 g/l	Low deficit 30-34.9 g/l	Mild deficit 25-29.9 g/l	Severe deficit <25 g/l	p
AKI (%)	3.1% (5/162)	4.4% (41/924)	9.7% (121/1249)	21.7% (105/483)	<0.001

Berbel-Franco et al. J Cardiothorac Surg (2020)

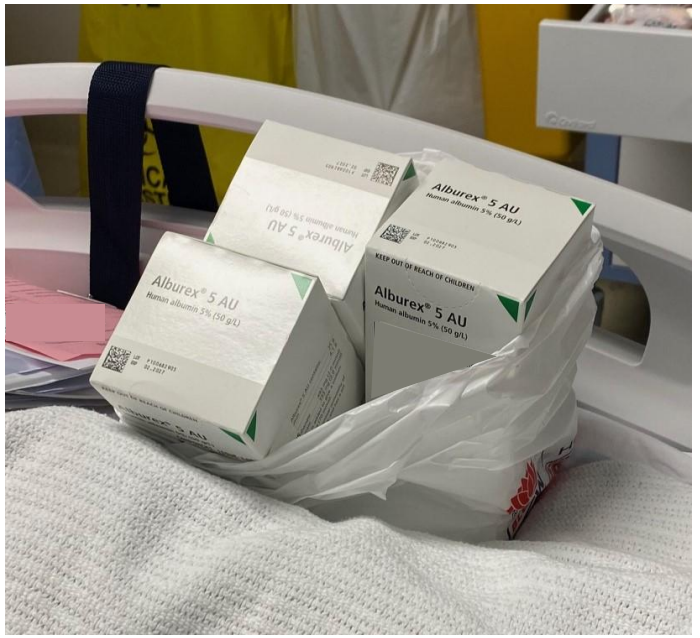
Rationale for albumin

Frequently used volume expander

- ❖An attempt to offset vasopressors
- ❖Minimises postoperative fluid balance*



- ❖ A clinical imperative to consider for albumin replacement in CS
- ❖ More albumin seems desirable



Wigmore et al. Intensive Care Med (2024); Pesonen et al. JAMA (2022);

Recent guidelines on the use of IV albumin in critical care, highlighted the **lack of trials in high-risk cardiac surgery patients**

Callum et al. CHEST (2024)

H_1

A continuous infusion of 20% albumin after high-risk cardiac surgery reduces the risk of postoperative AKI

ALBICS-AKI

Trial design

Multicentre, open-label, parallel-group randomised controlled trial

Inclusion criteria

Any of:

1. Combined cardiac surgery
2. Surgery on the thoracic aorta
3. Any cardiac surgery with eGFR <60ml/min/1.73m^2

Exclusion criteria

- Admitted to ICU > 6h post surgery
- eGFR <15ml/min/1.73m^2
- Albumin < 20g/l
- Dialysis dependent / transplant
- Off-pump surgery
- ECMO / VAD

Randomisation and Intervention

Prior consent from participant or SDM
Web randomisation, stratified by site and
eGFR <60 or ≥60ml/min/1.73m^2

20% albumin
20 ml/h infusion over 15 hours

vs

Usual care

Primary outcome

The occurrence of AKI during the first 7 days after surgery

- Overall and in those with eGFR>60 or <60ml/min/1.73m^2
- Using creatinine-based KDIGO criteria

KDIGO creatinine criteria	
Stage I	1.5-1.9 times baseline; OR ≥0.3mg/dL (≥26.5umol/L) increase in 48h
Stage II	2.0-2.9 times baseline; OR
Stage III	3 times baseline; OR Increase to ≥4.0g/dL (≥353.6umol/L); OR Initiation of RRT

Secondary outcomes

- Major Adverse Kidney Events (MAKE) at day 28
  - composite of AKI stage ≥ 2, RRT, mortality
- AKI stage II or III
- RRT
- Hospital mortality
- Hospital and ICU LOS
- Duration of mechanical ventilation
- Vasopressor/inotrope free days at day 14

Tertiary and safety outcomes

- Serum albumin level at 24h
- Fluid balance at D2
- Blood transfusion requirements at D2
- Fluid overload
- Reintubation
- Re-admission to ICU
- Arrhythmias resulting in significant CV compromise

Statistical principles

Sample size

- Assumed AKI in controls 30%
- 620 participants to detect 10% difference
  - α=0.05, 80% power, 5% inflation for dropouts

mITT = All consented patients – ineligible participants

Primary outcome

- Adjusted for site and eGFR → relative risk (95% CI)
  - Generalized linear mixed models with a binomial distribution and log link

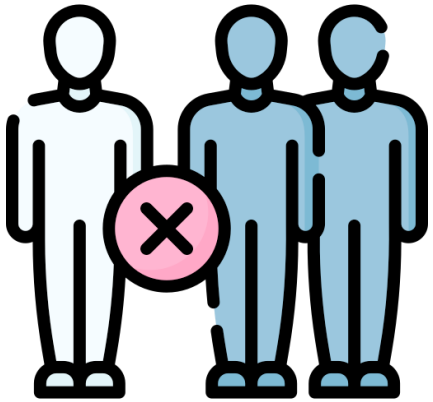
Prespecified sub-groups

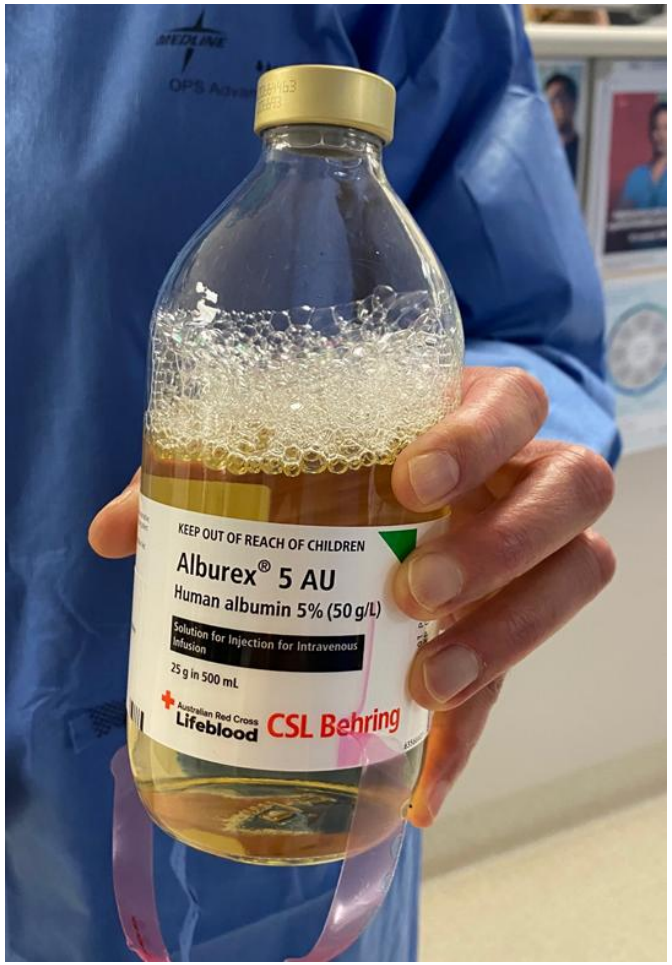
- Baseline eGFR >60 vs <60 ml/min/1.73m^2
- Patient age, above vs below median
- Diabetes status, yes vs no
- Preoperative use of ARB/ARA or ACEi, yes vs no
- Sex, male vs female
- Cardiopulmonary bypass time >120 minutes vs <120 minutes
- Left ventricular function, moderate to severe dysfunction vs normal
- Site and region, Australian sites vs Italian site

Sensitivity analysis

For the primary outcome:

- Exclusion of usual care patients who received ≥ 500ml iso-oncotic albumin by D2



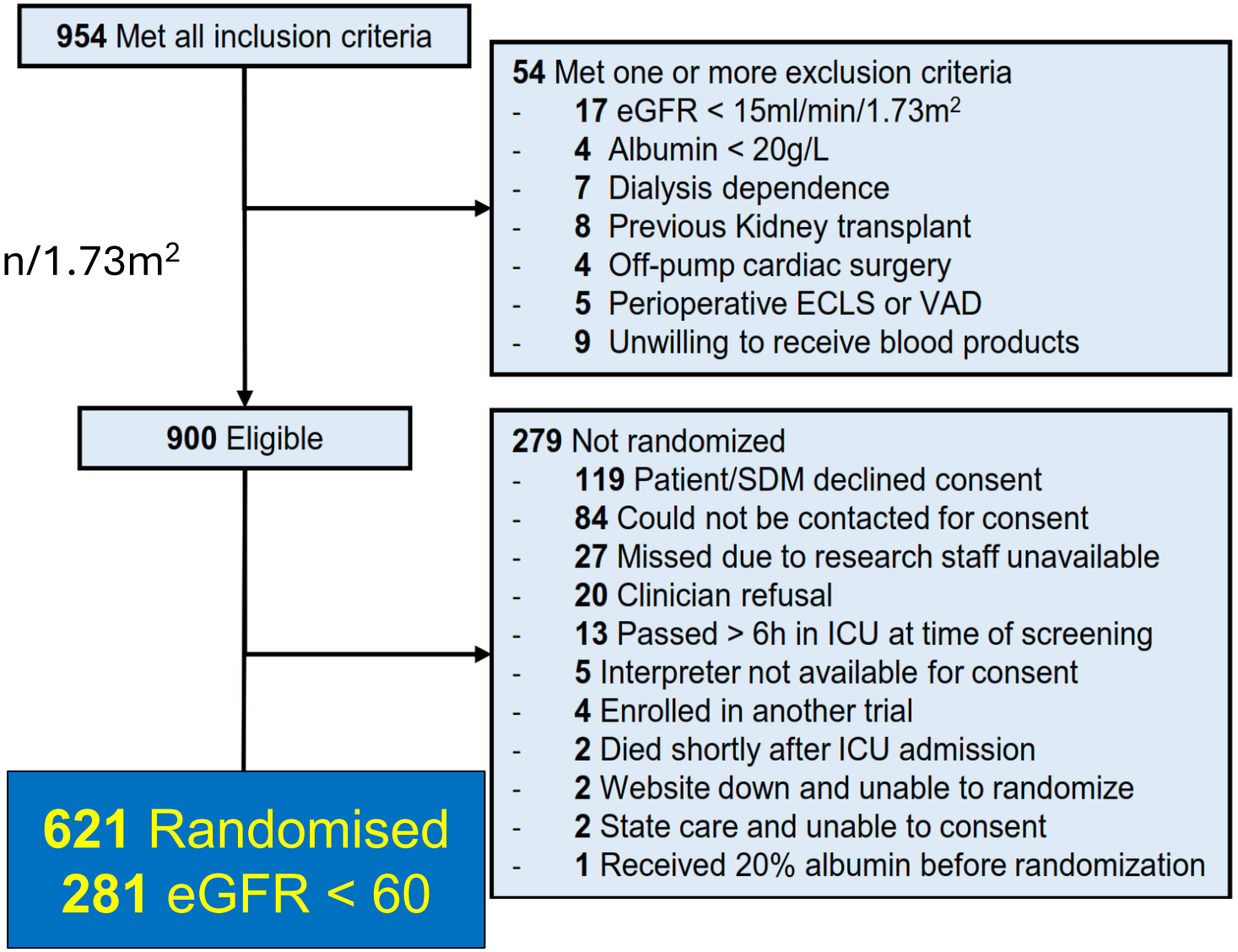


Results

ALBICS-AKI

Participants

- Met all inclusion criteria **954**
- Total excluded **54**
  - Main exclusion eGFR < 15 ml/min/1.73m^2
  - Total eligible **900**
- Not randomised **279**
  - Declined consent **119**
  - Could not be contacted **84**
- Total randomised **621**
  - **281** eGFR < 60 ml/min/1.73m^2



Patient characteristics

Demographics

	20% Albumin	Usual Care
Age	69.1 (11)	68.9 (10.6)
Male	70.7%	74.7%
Weight	81.7 (19)	83 (19.1)

Severity Indexes

	20% Albumin	Usual Care
ASA IV (%)	74.9%	74.3%
APACHE III	50.7 (15.1)	51.8 (14.4)
EuroSCORE II	3.2 [1.9-5.2]	3.3 [1.9-5.3]

Regular Medications prior to ICU admission	20% Albumin	Usual Care
ACE inhibitor	69 (22.5%)	64 (21.1%)
Angiotensin receptor blocker	91 (29.6%)	91 (29.9%)
B Blockers	166 (54.1)	153 (50.3%)
Ca Channel blockers	65 (21.2%)	69 (22.7%)
Statins	169 (55%)	180 (59.2%)
Aspirin	142 (46.3%)	143 (47%)
Insulin	16 (5.2%)	31 (10.2%)
Diuretics	111 (36.2%)	101 (33.2%)

Co-morbidities

	20% Albumin	Usual Care
Hypertension	74.6%	73.4%
Diabetes mellitus	26.7%	32.2%
History AMI	13.7%	16.1%
Angio within 7d	12.7%	12.5%
COPD	6.8%	10.2%
PVD	6.5%	6.3%
Previous CVA	4.6%	4.3%
LVEF = Normal	68.5%	70.4%
LVEF = Mild	15.9%	15.3%
LVEF = Moderate	9.6%	8%
LVEF = Severe	6%	6.3%

Patient characteristics

Renal data

	20% Albumin	Usual Care
Sr Cr	100 (33.3)	103 (36.8)
eGFR >90	14.3%	17.8%
eGFR <60	46.2%	45.7%
eGFR#	61 (16.7)	59.4 (17.7)
Album g/l	37.2 (4.7)	36.4 (5.4)
Hb g/l	132 (18.5)	130 (19.7)

Excluding eGFR>90

Operative Data

	20% Albumin	Usual Care
CABG only	20.8%	22%
CABG + Valve	36.8%	34.5%
Multiple valves	15.3%	11.5%
Aortic surgery	26.4%	33.2%
CBP time min	137 (49.6)	138 (56.4)
X-clamp min	105 (40.5)	106 (45.6)
End CPB Ht%	30.4 (5.0)	30.5 (5.1)

Intraoperative fluids	20% Albumin	Usual Care
Iso-oncotic serum albumin solution -	45 (14.7%)	53 (17.4%)
20% albumin solution	29 (9.4%)	31 (10.2%)
Red blood cells	76 (24.8%)	72 (23.7%)
Other blood products	110 (35.8%)	113 (37.2%)

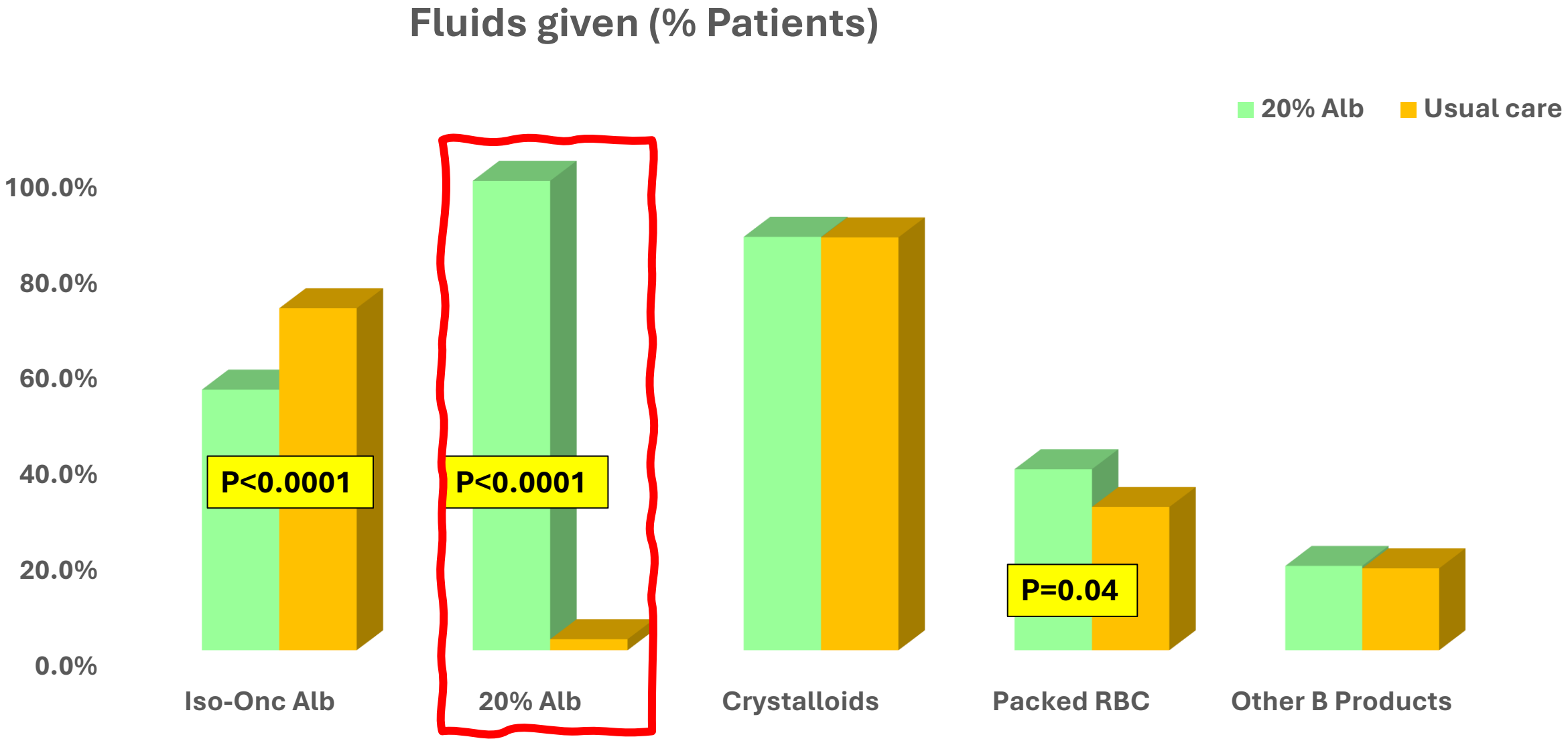
CV Support end CBP

	20% Albumin	Usual Care
Epinephrine	24.1%	23.7%
Dobutamine	19.5%	15.1%
Levosimendan	2.6%	2%
Milrinone	7.8%	7.9%
Norepinephrine	73.6%	72%
Dopamine	1.0%	0%
Vasopressin	2.6%	2.3%
Phenylephrine	0.3%	0.7%
IABP	2%	3%
Intraoperative filtration	2.6%	2.3%

Process Outcomes

ALBICS-AKI

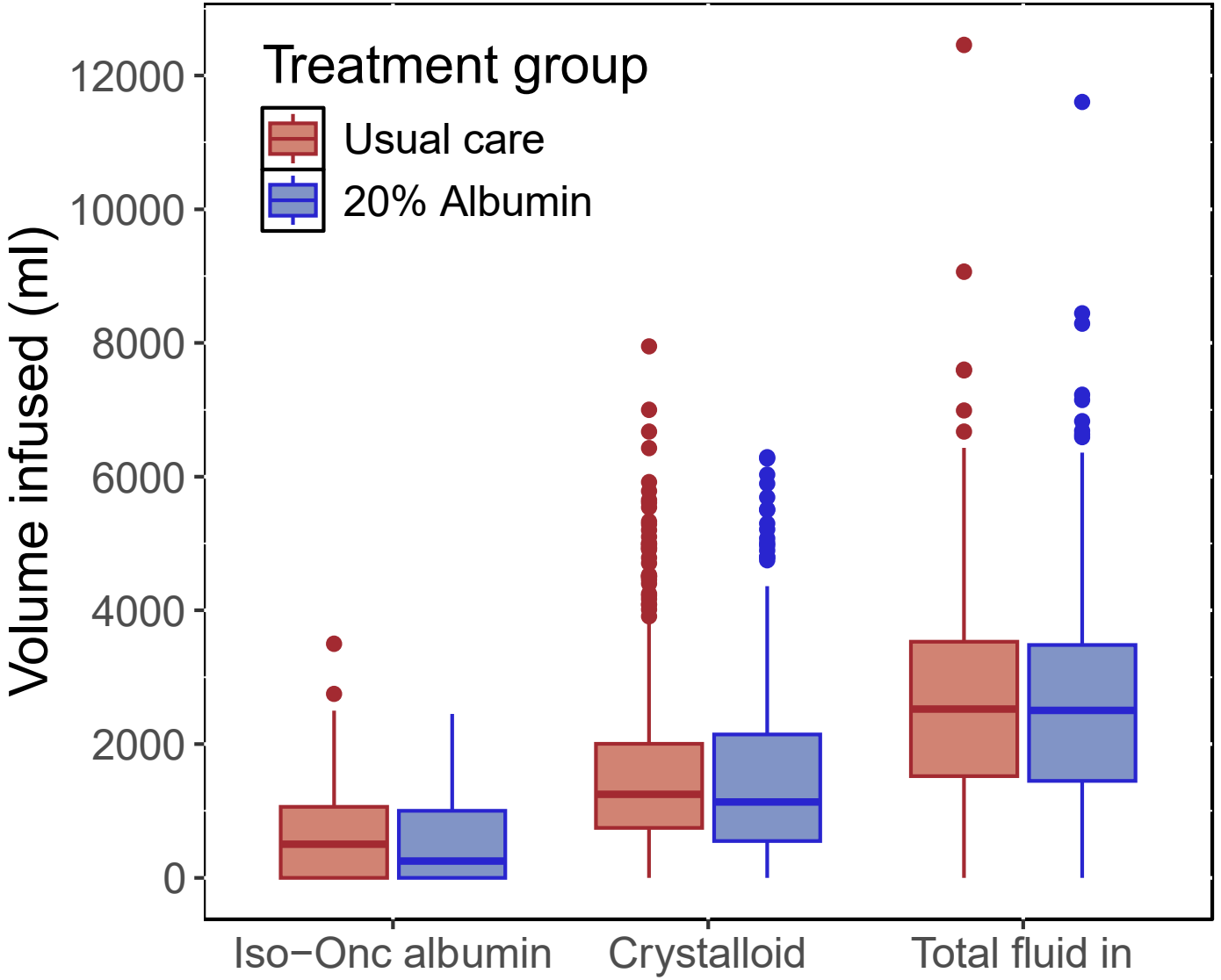
Postoperative fluids to the end of D2



Postoperative fluids by D2

20% albumin (Study Intervention)

- 98 % patients received full dose in intervention arm
- 2.3% usual care received some 20% albumin



Safety Outcomes

ALBICS-AKI

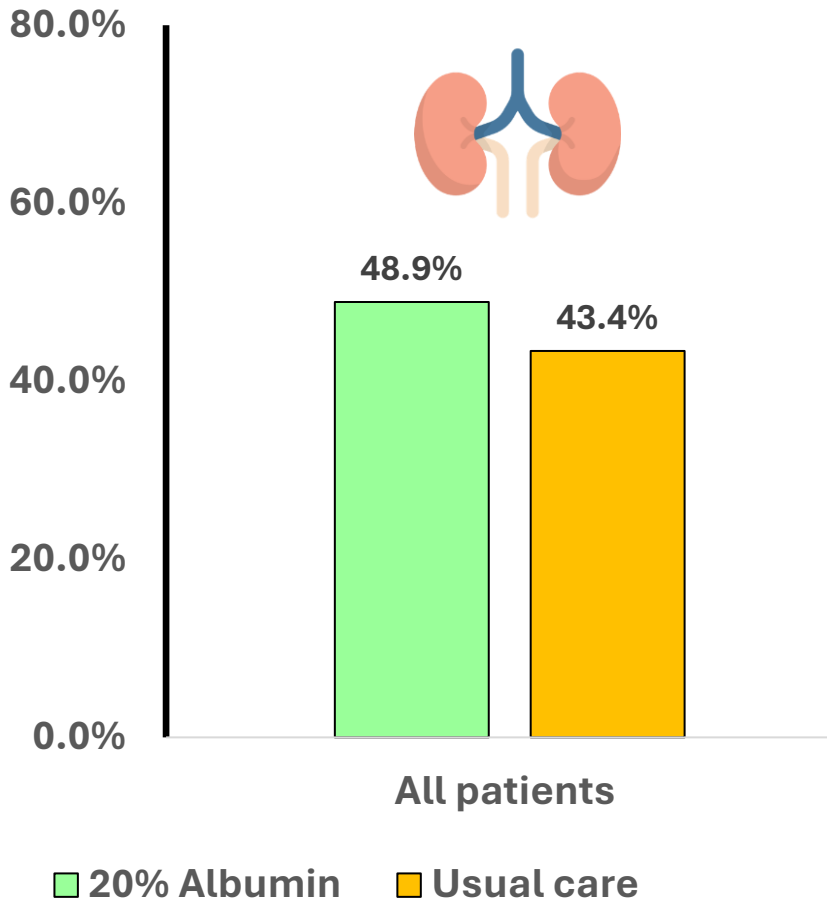
Safety outcomes (% of patients)

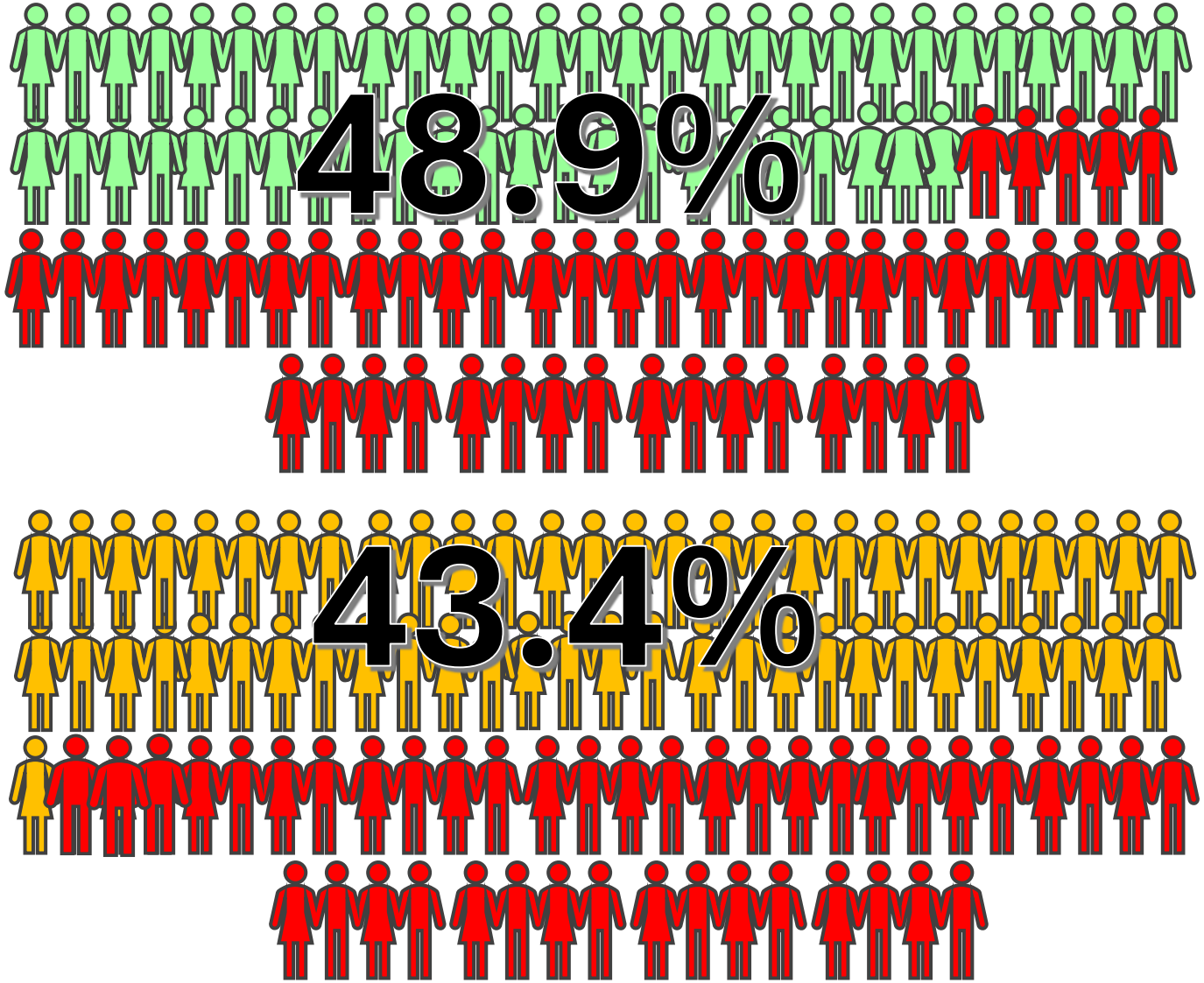
Event	Albumin N= 307	Usual care N = 304	P value
One + event	16.9%	12.8%	0.15
Allegic reactions	0.7%	0%	0.25
VF/VT/Arrest	8.8%	6.6%	0.30
Fluid overload	8.5%	5.9%	0.38
Blood Tx	37.8%	29.9%	0.04
Reintubation	2.6%	3.0%	0.79
ICU Readmission	3.3%	5.3%	0.22
Return to theatre	6.8%	10.2%	0.14

Primary Outcome

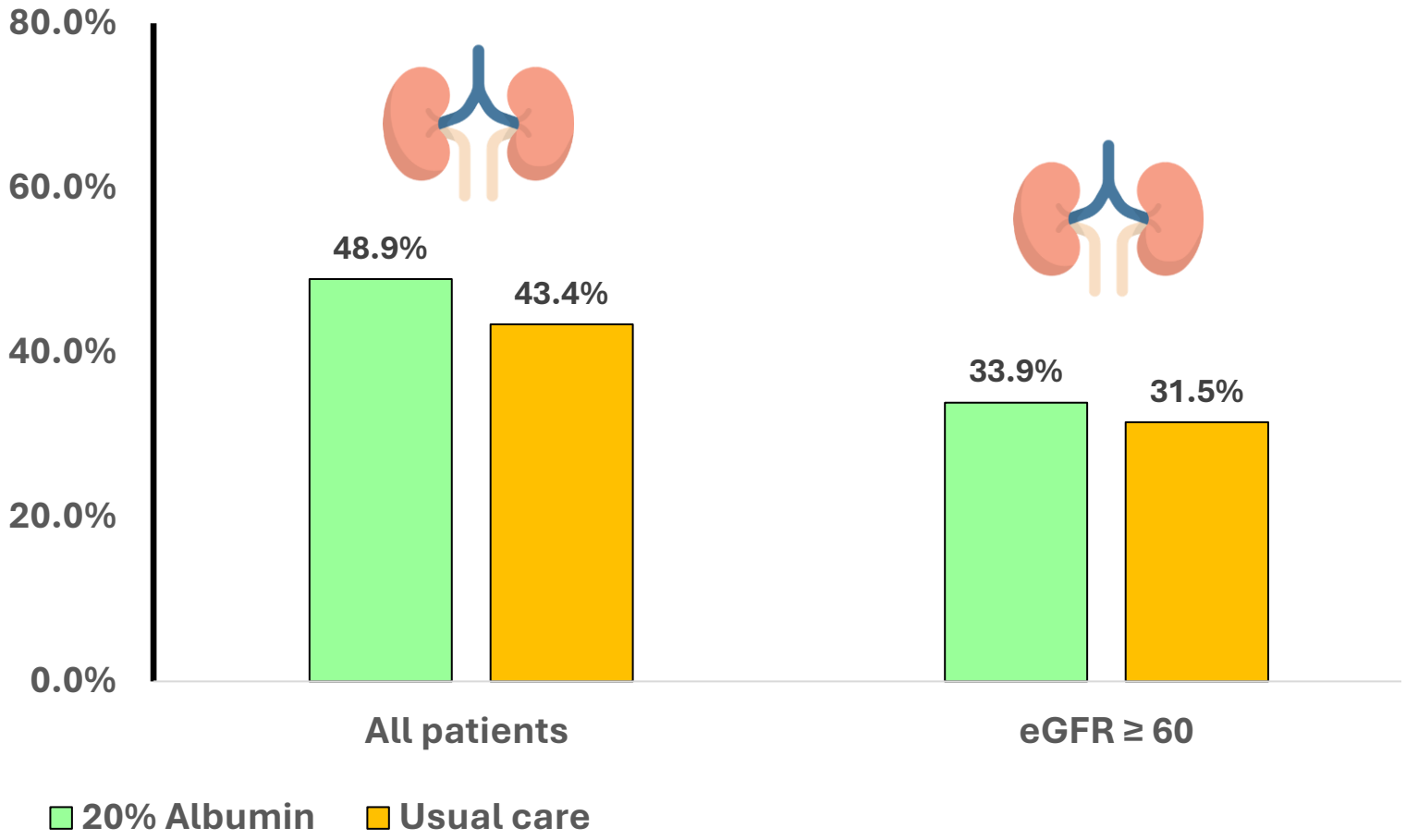
ALBICS-AKI

KDIGO defined AKI I-III

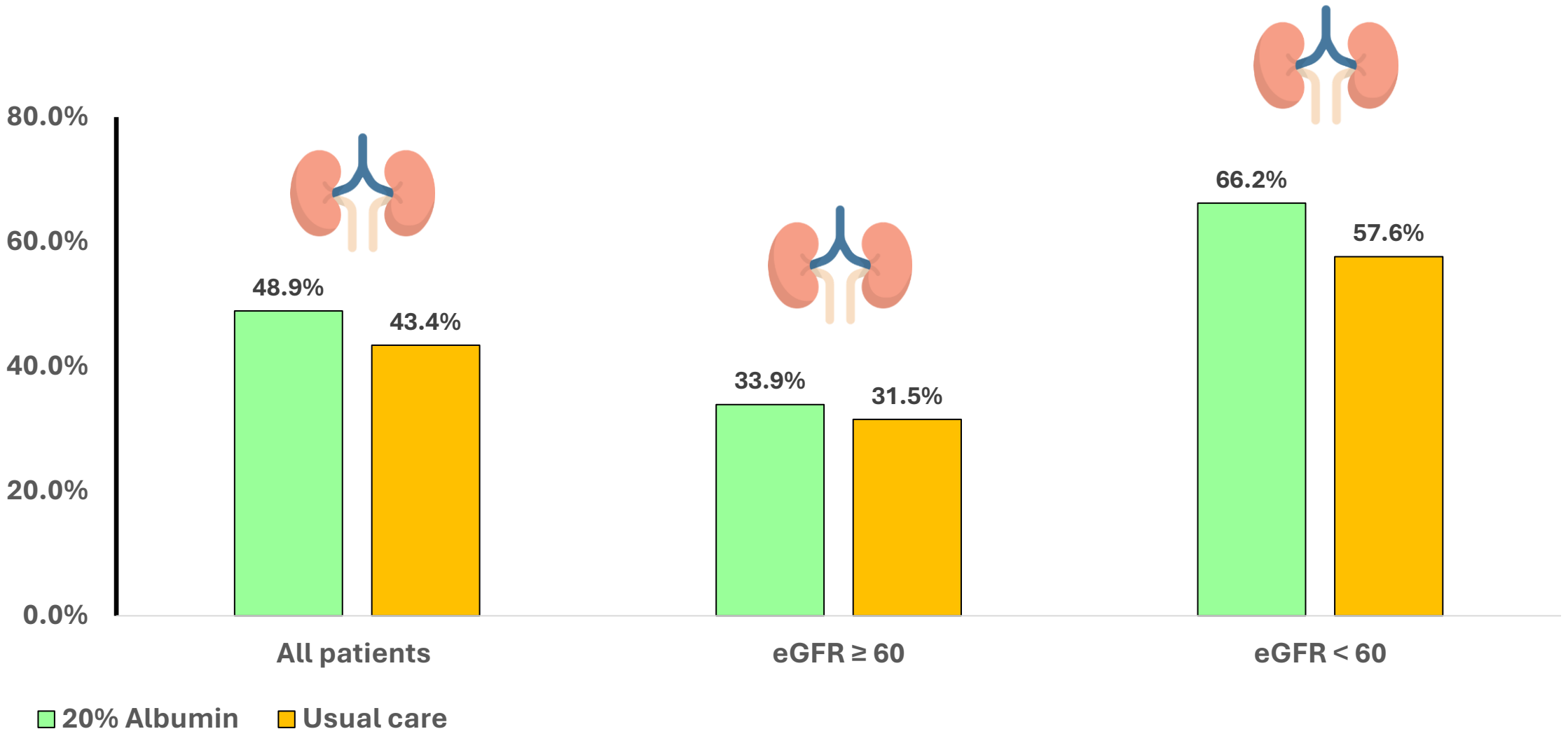




KDIGO defined AKI I-III



KDIGO defined AKI I-III



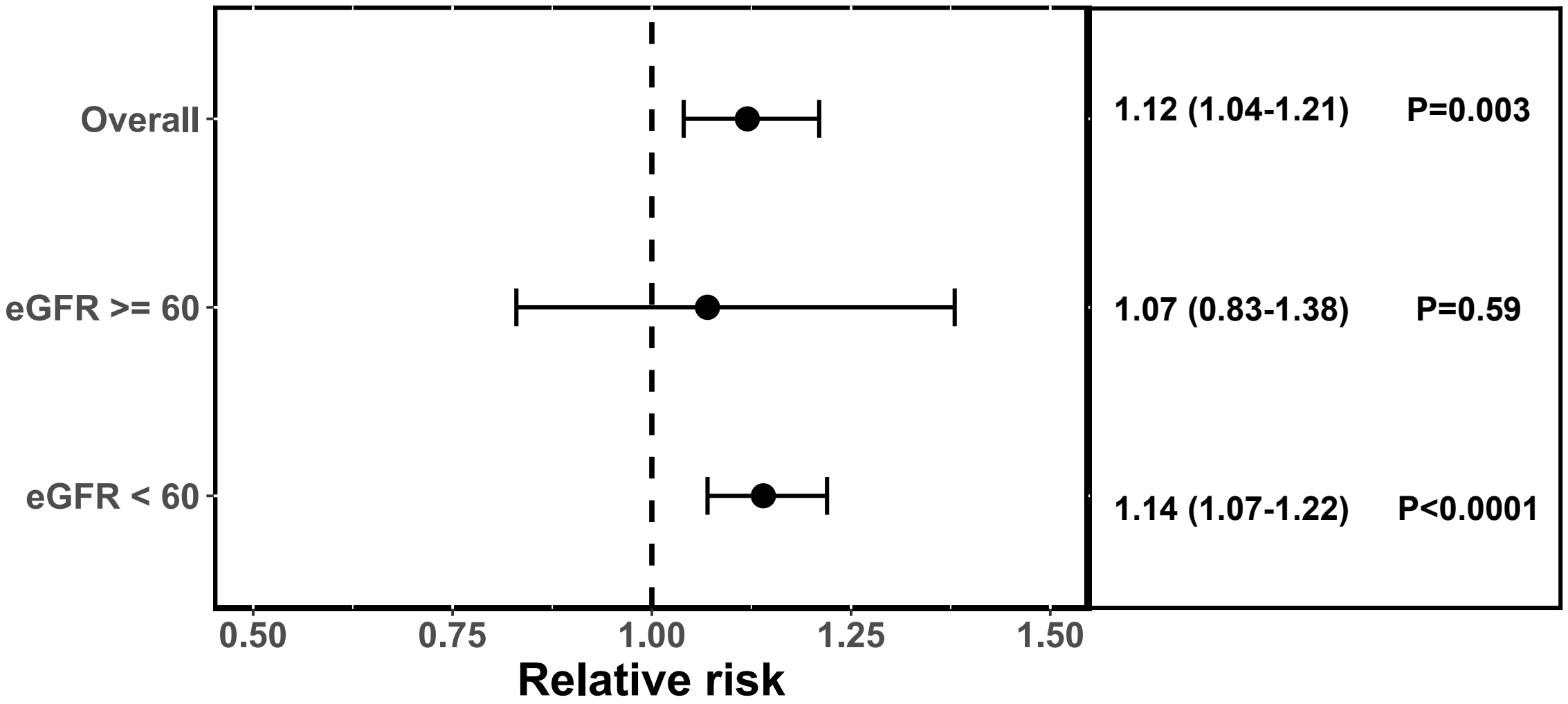
Event	Albumin N (307)	Usual care N (304)	Risk Diff (95% CI)	Unadj RR (95% CI)
AKI I to III	150/307 (48.9%)	132/304 (43.4%)	5.4% (-2.5 to 13.3)	1.13 (0.95 - 1.34)
AKI I to III eGFR ≥ 60	56/165 (33.9%)	52/165 (31.5%)	2.4% (-7.7 to 12.5)	1.08 (0.79 - 0.47)
AKI I to III eGFR < 60	94/142 (66.2%)	80/139 (57.6%)	8.6% (-2.7 to 20)	1.15 (0.96 - 1.38)

Event	Albumin N (307)	Usual care N (304)	Risk Diff (95% CI)	Unadj RR (95% CI)	Adj RR (95% CI)	Adj RR P value
AKI I to III	150/307 (48.9%)	132/304 (43.4%)	5.4% (-2.5 to 13.3)	1.13 (0.95 - 1.34)	1.12 # (1.04-1.21)	0.003
AKI I to III eGFR ≥ 60	56/165 (33.9%)	52/165 (31.5%)	2.4% (-7.7 to 12.5)	1.08 (0.79 - 0.47)		
AKI I to III eGFR < 60	94/142 (66.2%)	80/139 (57.6%)	8.6% (-2.7 to 20)	1.15 (0.96 - 1.38)		

Adjusted for site and baseline eGFR

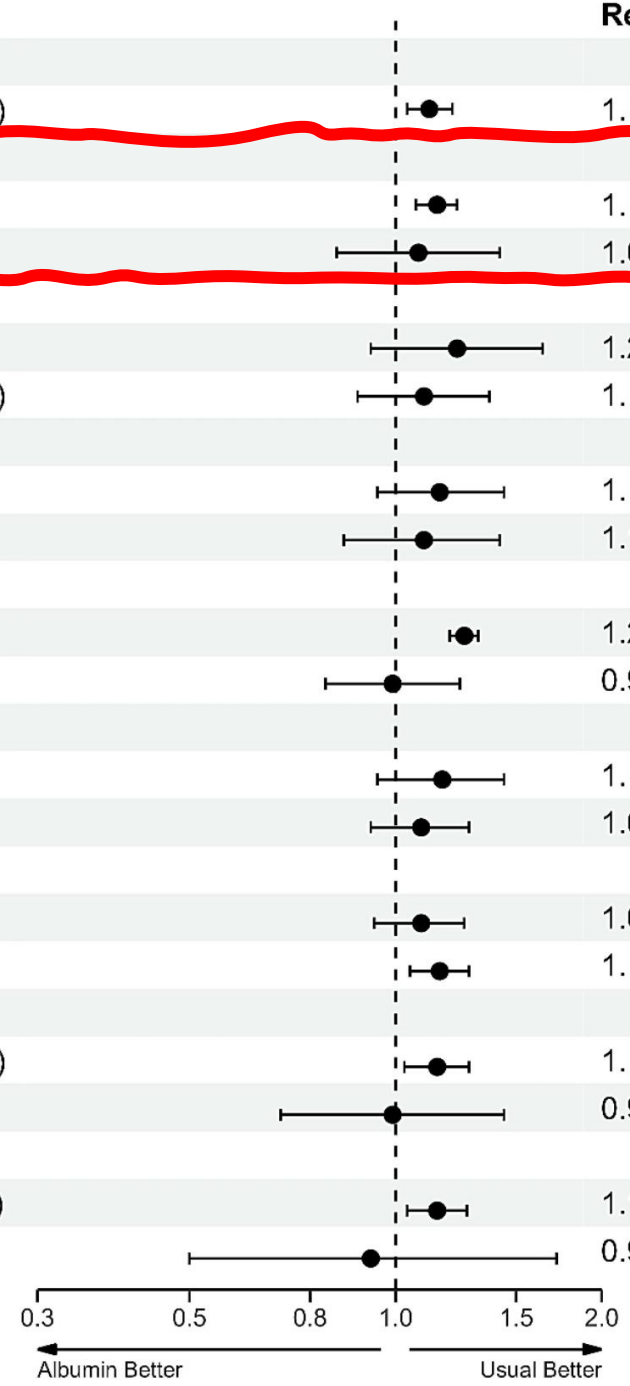
Event	Albumin N (307)	Usual care N (304)	Risk Diff (95% CI)	Unadj RR (95% CI)	Adj RR # (95% CI)	Adj RR P value
AKI I to III	150/307 (48.9%)	132/304 (43.4%)	5.4% (-2.5 to 13.3)	1.13 (0.95 - 1.34)	1.12 # (1.04-1.21)	0.003
AKI I to III eGFR ≥ 60	56/165 (33.9%)	52/165 (31.5%)	2.4% (-7.7 to 12.5)	1.08 (0.79 - 0.47)	1.07 (0.83-1.38)	0.59
AKI I to III eGFR < 60	94/142 (66.2%)	80/139 (57.6%)	8.6% (-2.7 to 20)	1.15 (0.96 - 1.38)	1.14 (1.07-1.22)	<0.0001

Adjusted for site and baseline eGFR


Overall
eGFR >= 60
eGFR < 60
1.12 (1.04-1.21)
P=0.003
1.07 (0.83-1.38)
P=0.59
1.14 (1.07-1.22)
P<0.0001
0.50
0.75
1.00
1.25
1.50
Relative risk

Prespecified subgroups

Subgroup	Albumin	Usual care	Relative Risk (95% CI)
	no. of patients/total no. (%)		
All patients	150/307 (48.9)	132/304 (43.4)	1.12 (1.04-1.21)
Baseline estimated glomerular filtration rate			
< 60	94/142 (66.2)	80/139 (57.6)	1.15 (1.07-1.23)
60 +	56/165 (33.9)	52/165 (31.5)	1.08 (0.82-1.42)
Gender			
Female	43/90 (47.8)	30/77 (39)	1.23 (0.92-1.64)
Male	107/217 (49.3)	102/227 (44.9)	1.10 (0.88-1.37)
Age (years)			
≤ 70	68/148 (45.9)	59/149 (39.6)	1.16 (0.94-1.44)
> 70	82/159 (51.6)	73/155 (47.1)	1.10 (0.84-1.42)
Diabetes			
No	102/225 (45.3)	74/206 (35.9)	1.26 (1.20-1.32)
Yes	48/82 (58.5)	58/98 (59.2)	0.99 (0.79-1.24)
Preoperative ACEi/ARB			
No	71/148 (48)	62/151 (41.1)	1.17 (0.94-1.44)
Yes	79/159 (49.7)	70/153 (45.8)	1.09 (0.92-1.28)
Cardio pulmonary bypass time (hours)			
< 2	62/123 (50.4)	59/127 (46.5)	1.09 (0.93-1.26)
2 +	88/184 (47.8)	73/177 (41.2)	1.16 (1.05-1.28)
Left ventricular ejection fraction			
Mild or no impairment	120/255 (47.1)	106/258 (41.1)	1.15 (1.03-1.28)
Moderate or severe impairment	27/47 (57.4)	25/43 (58.1)	0.99 (0.68-1.44)
Country			
Australia	137/268 (51.1)	119/268 (44.4)	1.15 (1.04-1.27)
Italy	13/39 (33.3)	13/36 (36.1)	0.92 (0.50-1.72)



Planned sensitivity analysis

Effect of any albumin on the primary outcome

- Excluding patients in the usual care arm who received ≥ 500 ml of iso-oncotic albumin by the end of D-2 after surgery

Effect of albumin on the primary outcome

Event	Albumin N (307)	Usual care N (104)	Unadj RR (95% CI)	Adj RR (95% CI)	Adj RR P value
AKI I to III	150/307 (48.9%)	45/104 (44.2%)	1.10 (0.87-1.41)	1.14 # (1.01-1.30)	0.04
AKI I to III eGFR ≥ 60	56/165 (33.9%)	17/57 (29.8%)	1.14 (0.72-1.79)	1.28 (1.02-1.62)	
AKI I to III eGFR < 60	94/142 (66.2%)	29/47 (61.7)	1.07 (0.83-1.38)	1.07 (0.95-1.21)	

Adjusted for site and baseline eGFR

Secondary Outcomes

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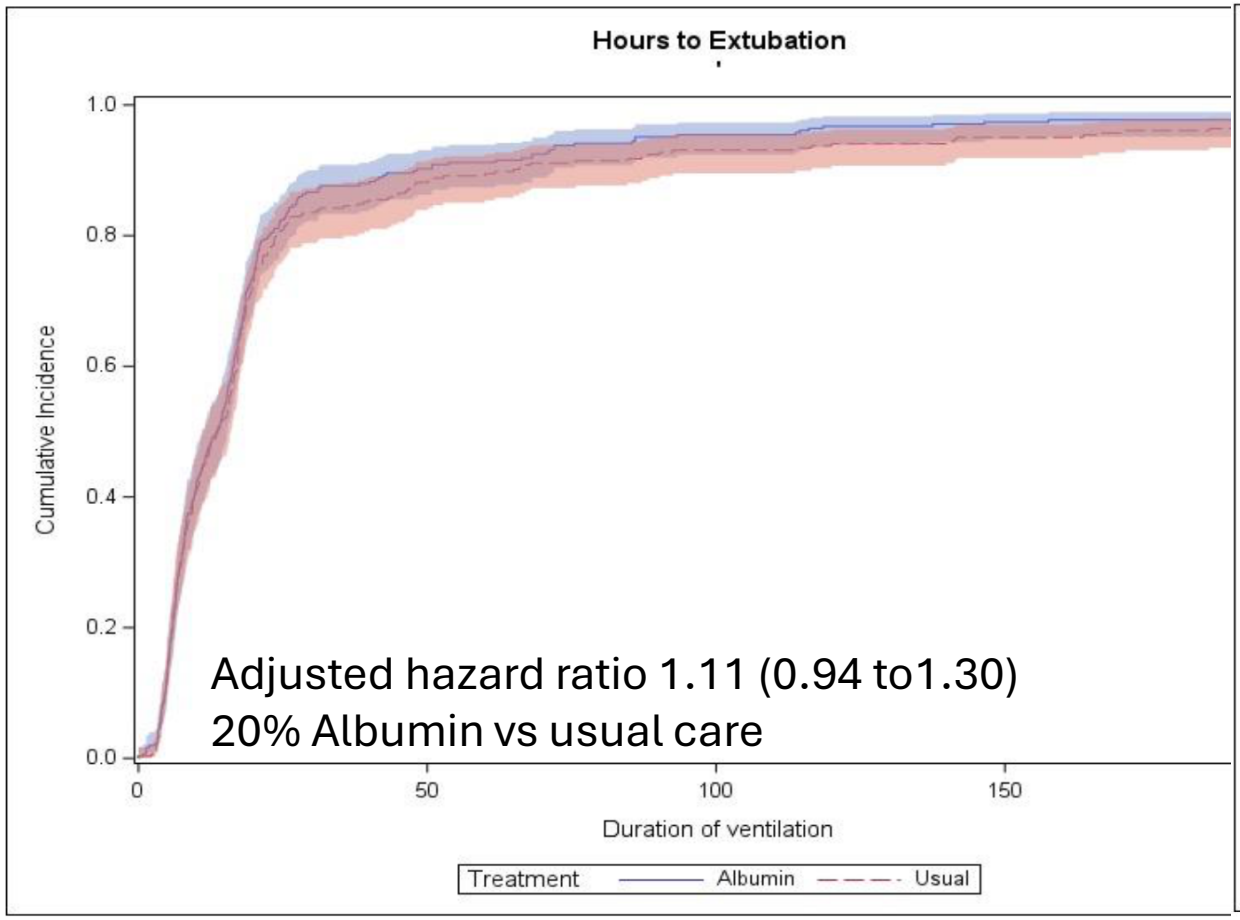
Secondary outcomes

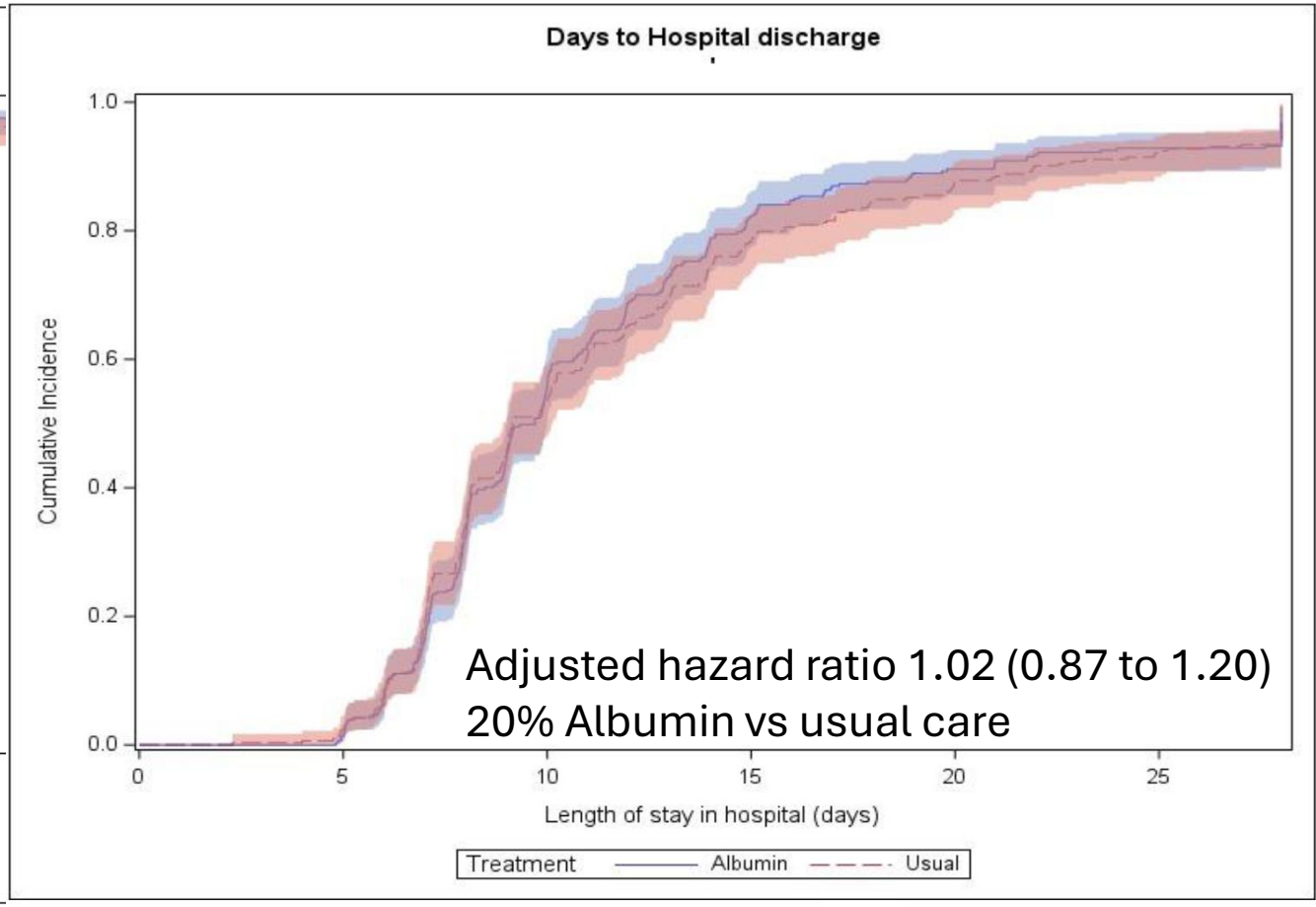
Event	Albumin N (307)	Usual care N (304)	Adj RR # (95% CI)
MAKE @ D-28	10.7%	9.5%	1.13 (0.81-1.56)
MAKE @ D-28 eGFR ≥ 60	17/165 (10.3%)	18/165 (10.9%)	0.94 (0.67-1.33)
MAKE @ D-28 eGFR < 60	16/142 (11.3%)	11/139 (7.9%)	1.43 (0.84-2.43)
Mortality @ D-28	2%	0.7%	2.55 (1.05-6.24)
CRRT to D-28	3.3%	2.3%	1.41 (0.79-2.49)
Sustained AKI II/III	9.1%	9.2%	0.99 (0.69-1.42)

Adjusted for site and baseline eGFR

Secondary outcomes:
Time to extubation & Hosp LOS

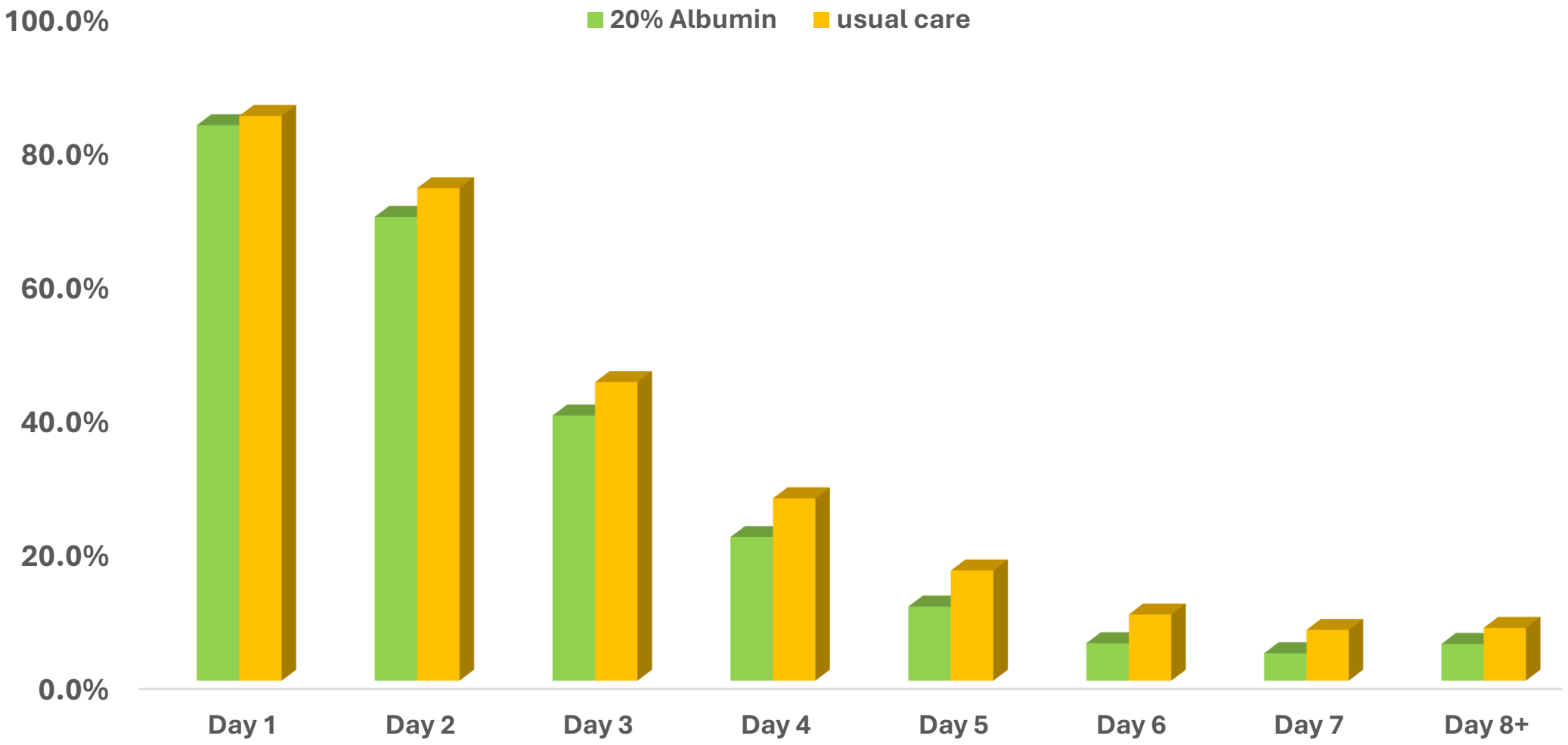


Adjusted hazard ratio 1.11 (0.94 to1.30)
20% Albumin vs usual care



Adjusted hazard ratio 1.02 (0.87 to 1.20)
20% Albumin vs usual care

Daily pressors and inotropes % patients



Pressors and inotropes up to D-14

Vasopressors free days @14-D
Median [IQR] Days

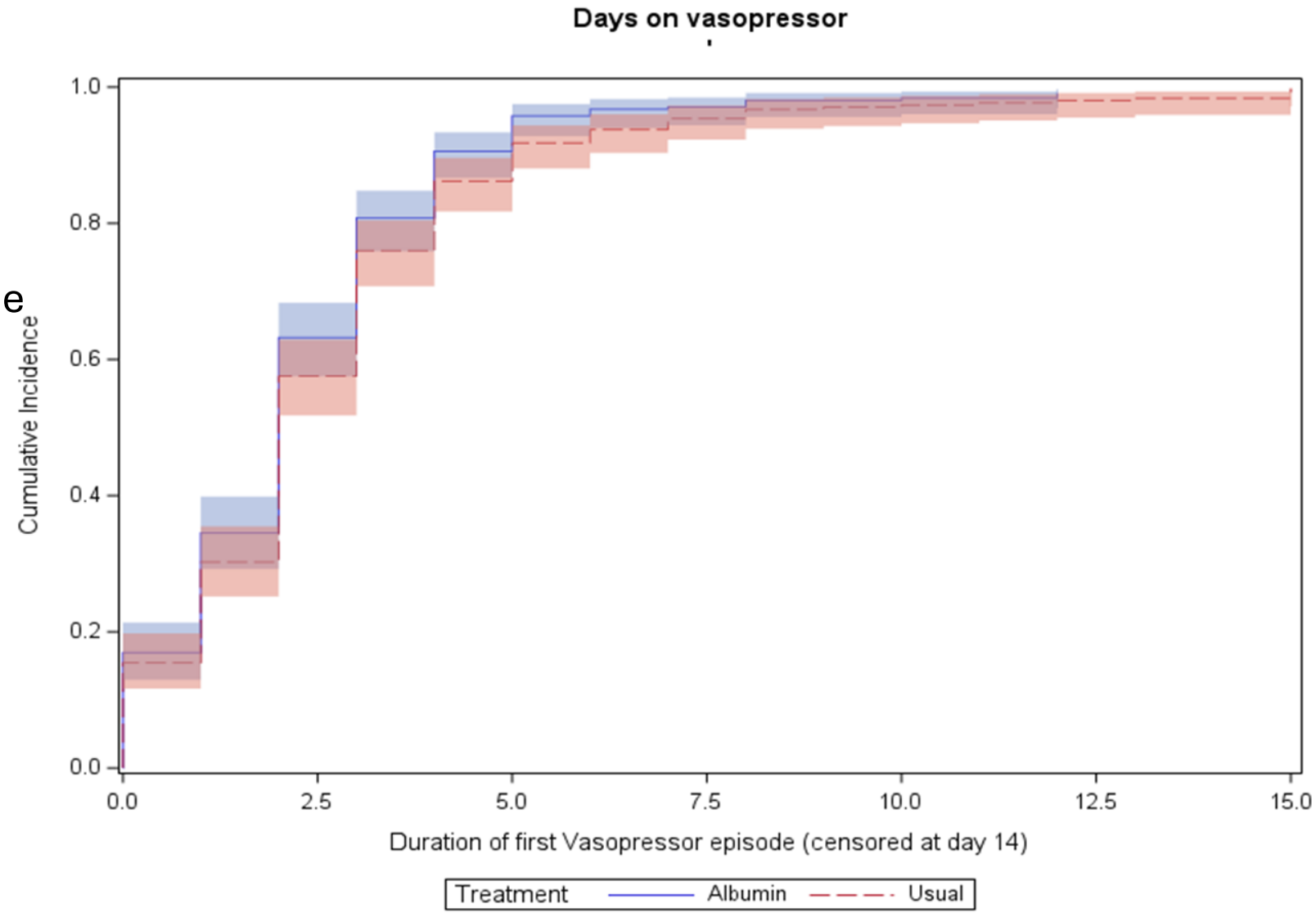
- **20% Alb 12 [11-13] vs 12 [10-13]**
- **Adj HR 1.0 (-0.57 to 0.57)**

Duration of first Vasopressor episode (censored at day 14)

- Median [IQR] 2 [1-3] in both groups

Adjusted HR (95% CI) for risk of vasopressor weaning,
20% Albumin vs usual care

- **Adj HR 1.14 (0.99-1.3)**
- **Adj P = 0.06**



Why and how ?

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Population ?

Timing of the intervention ?

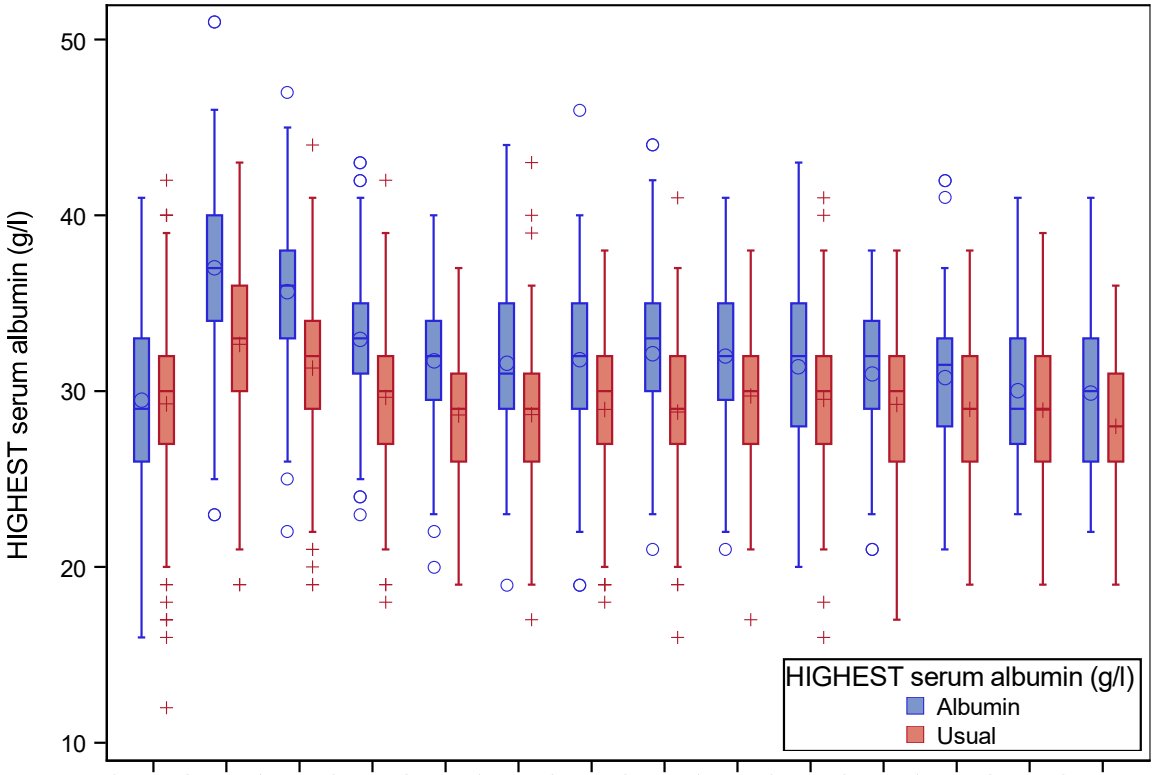
Dose given ?

Is 20% albumin toxic ?

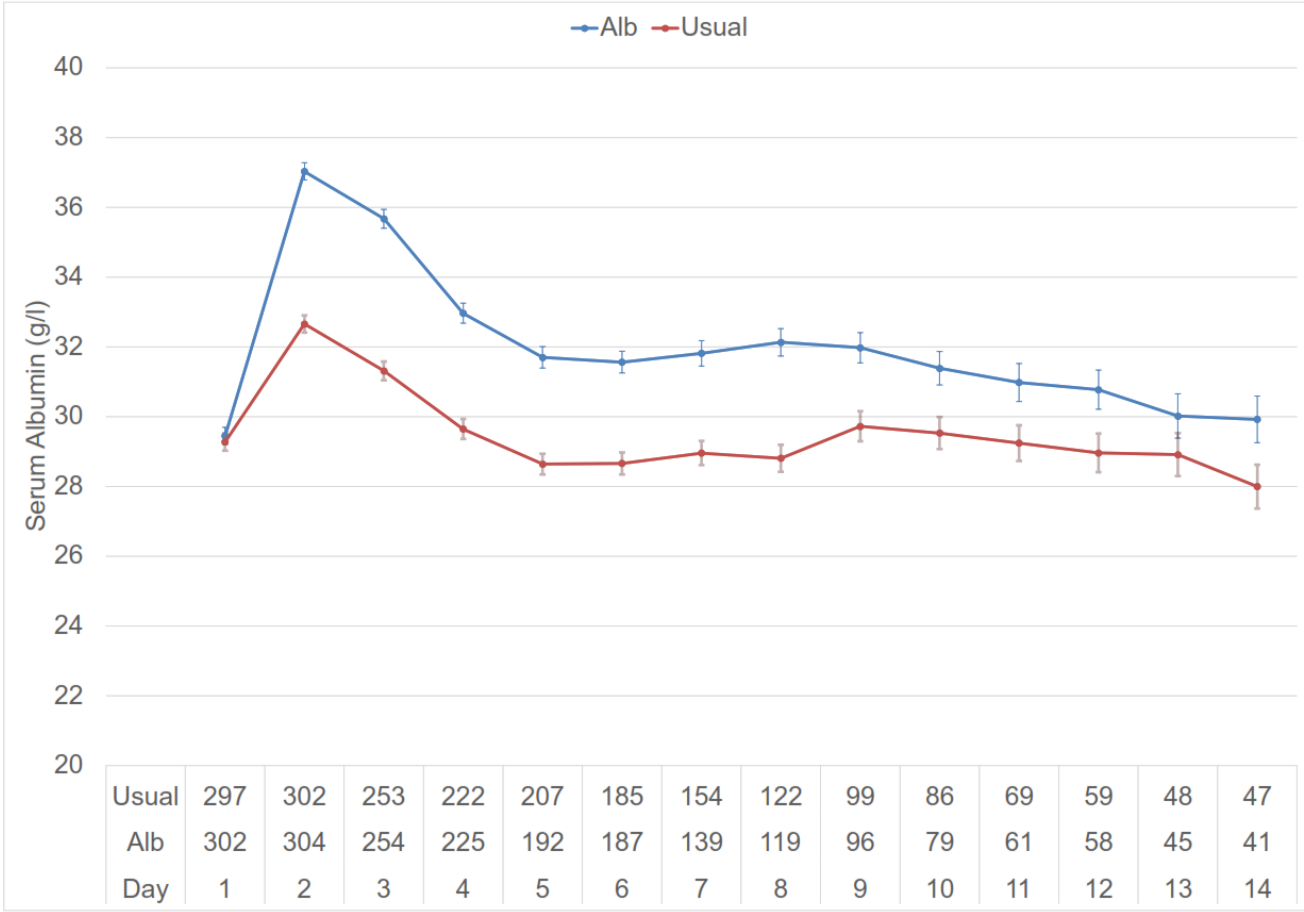
Intrinsic renal mechanisms ?

Site variability in kidney protection ?

Albumin level – the first 14 days



Usual	297	302	253	222	207	185	154	122	99	86	69	59	48	47
Alb	302	304	254	225	192	187	139	119	96	79	61	58	45	41
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14



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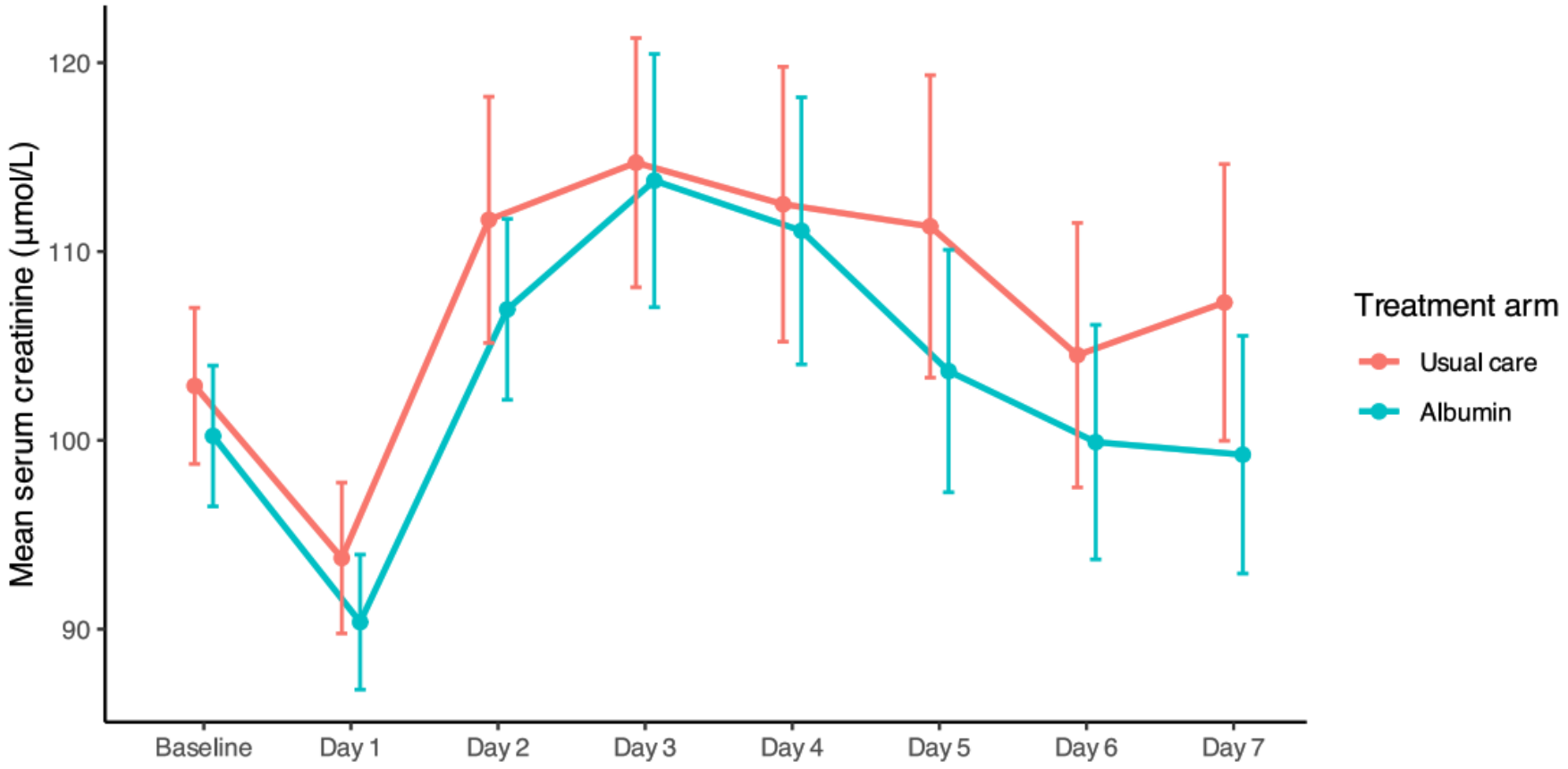
Alb	302	304	254	225	192	187	139	119	96	79	61	58	45	41
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14

Highest serum albumin for each arm up to day 14. Reported as mean with standard error bars

Mean (SE) of daily creatinine

Days 1-7



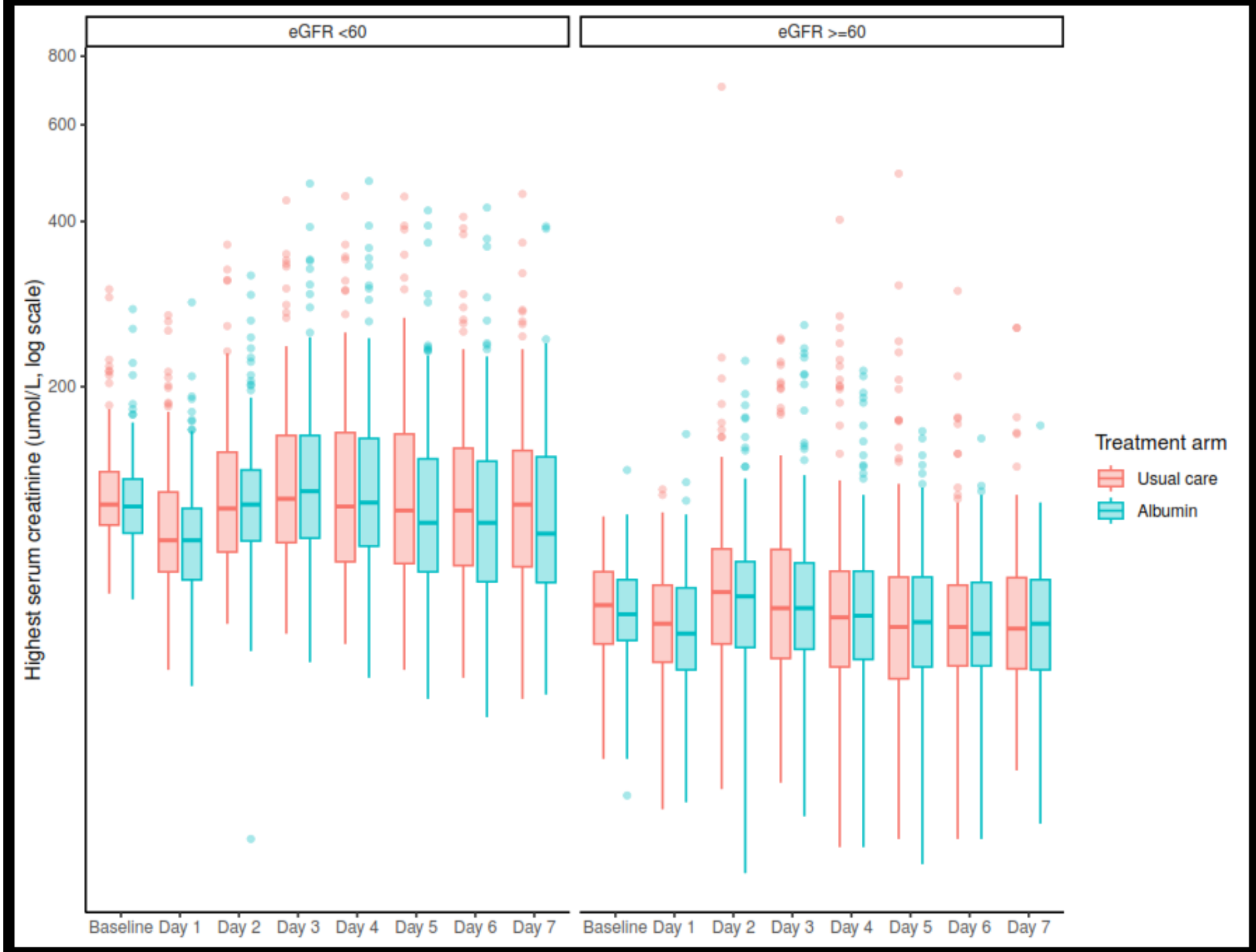
No. at risk

Usual care	304	300	301	299	289	270	256	229
Albumin	307	306	305	300	287	278	271	230

Box Plot of daily creatinine

Days 1-7

Patients that triggered AKI were outliers with very high early creatinine



Post hoc analysis

Association with serum albumin

- No association between serum albumin during days 1-2 and outcome of AKI
- Adjusted analysis also ruled out starting serum albumin as a significant covariate in post op AKI
- The harm observed may not be related to serum concentration of albumin but rather an independent mechanism

Prespecified subgroups

Subgroup	Albumin	Usual care	Relative Risk (95% CI)
	no. of patients/total no. (%)		
All patients	150/307 (48.9)	132/304 (43.4)	1.12 (1.04-1.21)
Baseline estimated glomerular filtration rate			
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Age (years)			
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Country			
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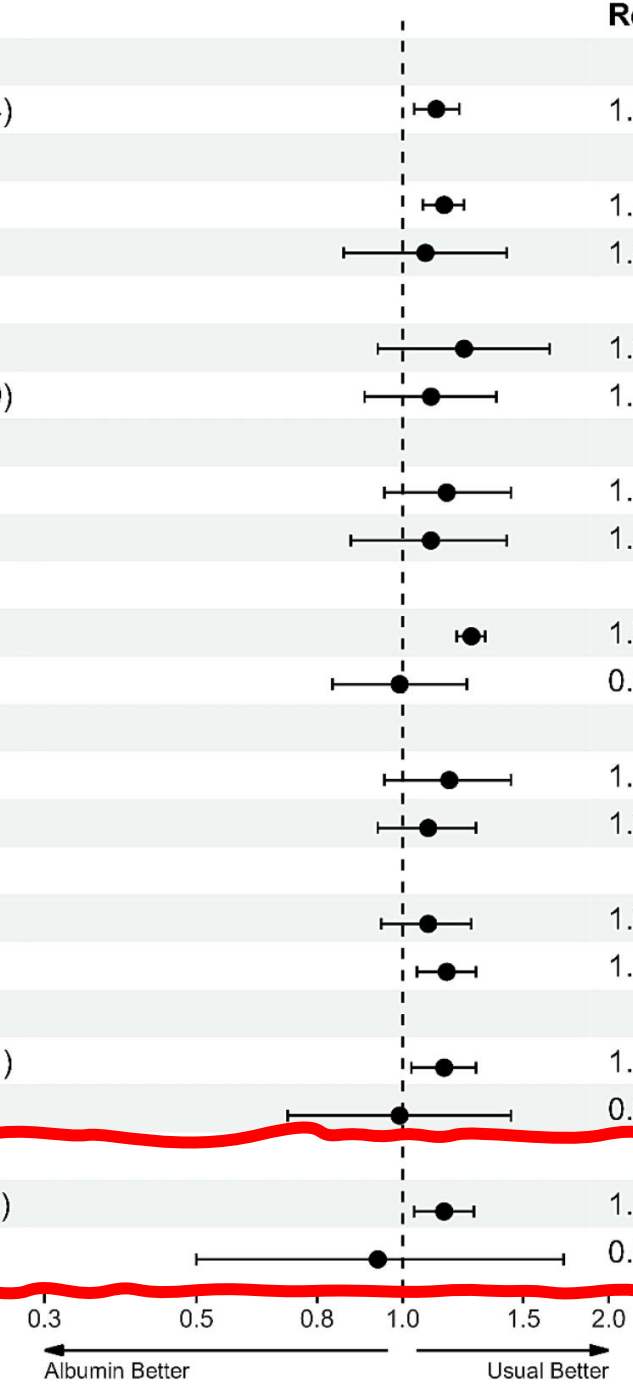
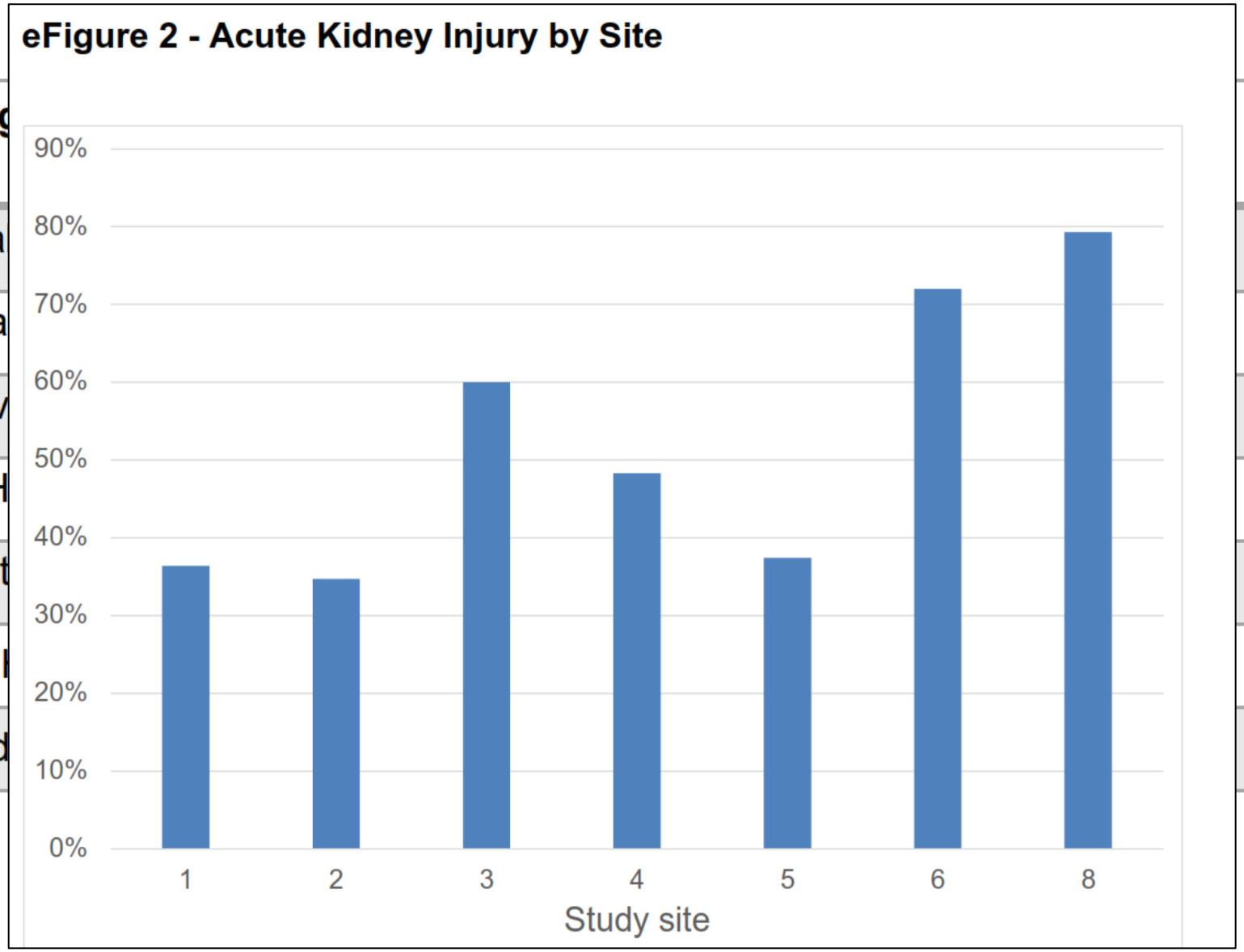
Italy	13/39 (33.3)	13/36 (36.1)	0.92 (0.50-1.72)

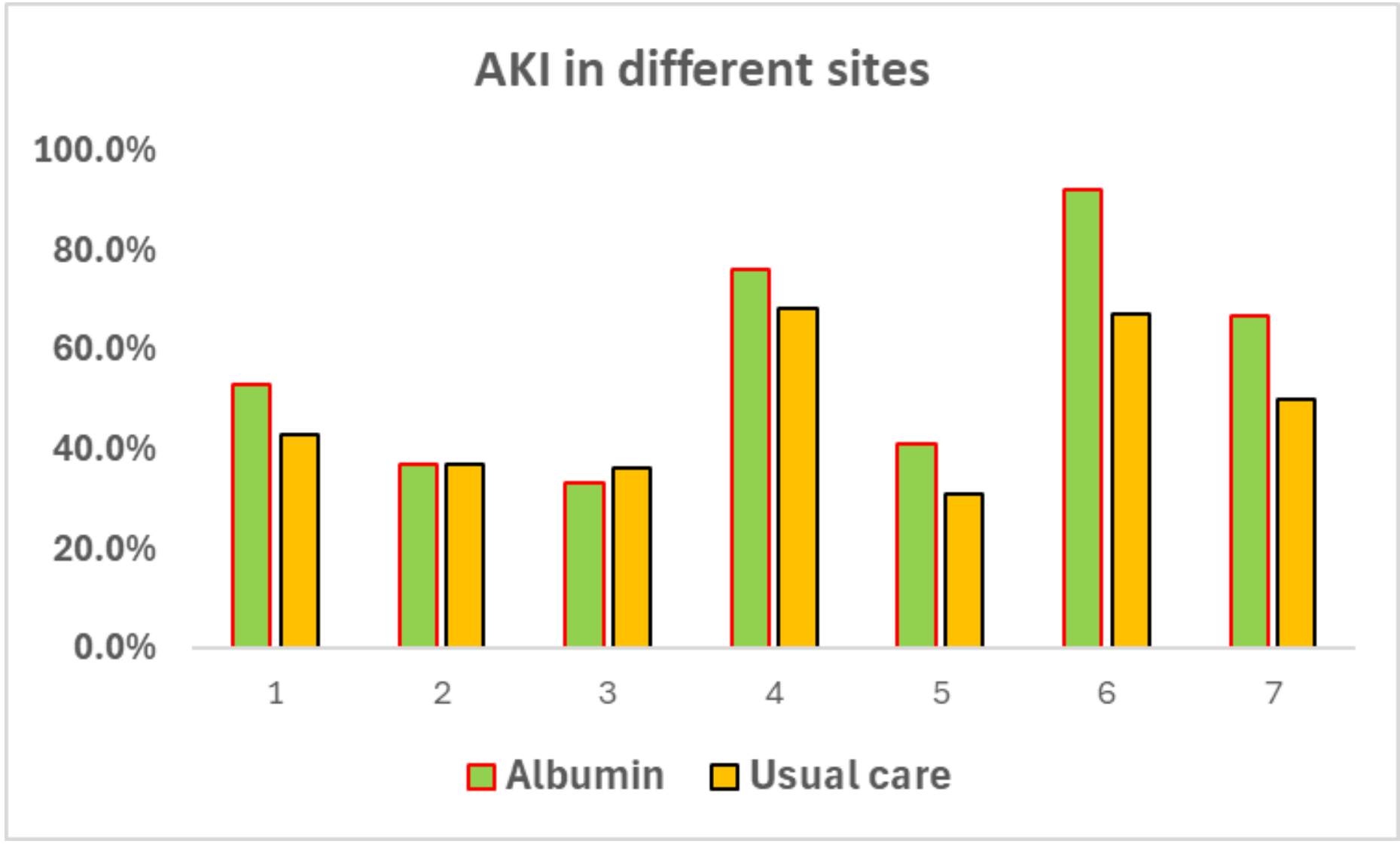


Recruitment numbers by site

Participating	Usual care (N = 304)
Monash Hea	117
Prince of Wa	93
Careggi Univ	36
The Austin H	15
Cabrini Healt	16
St Vincent's	25
Flinders Med	2



Significant site variability











ALBICS-AKI

CCR

JAMA Surgery | Original Investigation

Postoperative 20% Albumin Infusion and Acute Kidney Injury in High-Risk Cardiac Surgery Patients

The ALBICS AKI Randomized Clinical Trial

Yahya Shehabi, MBBS, PhD; Mayurathan Balachandran, MD; Wisam Al-Bassam, MBChB; Michael Bailey, PhD; Rinaldo Bellomo, MD, PhD; Shailesh Bihari, MD, PhD; Alana Brown, GDipAdvClinNurs (CritC); Alastair Brown, MBChB (Hons); David Collins, BSc, MBBS; Phoebe R. Darlison, MD; Mozhu (Alice) Li, MAdvClinNur (CritCare); Raffaele Mandarano, MD, MSc; Vineet Sarode, MD, MPH; Adrian Pakavakis, MBBS, MSc; for the ALBICS AKI Study Investigators