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# **HYDratation and bicarbonate to prevent acute Renal injury after EVAR**

# **HYDRA trial**

**Athanasios Saratzis** MBBS MRCS FHEA PhD  
NIHR Academic Clinical Lecturer  
NIHR Leicester Biomedical Research Centre

Virginia Chiocchia; Ahamed Jiffry; Neelam Hassanali; Surjeet Singh; Chris Imray; Matthew Bown; Asif Mahmood



# Disclosures

**Salary: National Institute for Health Research (NIHR)**

## **CONSULTANCIES**

**General Electric:** consultancy, trial steering committee

**Novartis:** consultancy, trial planning

**Amgen:** investigator in clinical trial (paid)

## **TRAVEL, BURSARIES, AWARDS, PRIVATE GRANTS**

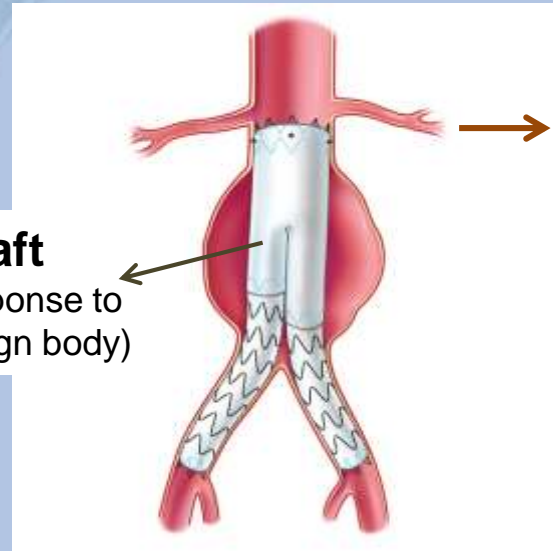
**Maquet**

**British Society for Endovascular Therapy**

**Vascutek Terumo** (educational grant)

AKI → abrupt loss of kidney function

## Potential mechanisms in EVAR



### Stent-Graft

Inflammatory response to implantation (foreign body)

### Renal arteries

Coverage of accessory arteries in 10%  
Occlusion of orifice  
Dissection or stenosis

### AAA

Significant inflammatory infiltrate  
(not excised as in open repair)

### Lower limbs

Ischaemic during the procedure (45-120 minutes)  
Ischaemia reperfusion injury

### Contrast



# Implications of AKI in EVAR

Series of 950 EVARs with long-term FU

**Incidence: 20 - 25%**

*Saratzis et al. Ann Vasc Surg. 2016*  
*Saratzis et al. EJVES 2016*  
*Saratzis et al. CJASN 2015*

## Implications

Short term mortality	HR: <b>4.8</b> (95% CI: 2.3-5.6)
Long term mortality	HR: <b>2.4</b> (95% CI: 1.4-3.1)

## **AKI after EVAR associated with:**

Short-term **survival**

Long-term **survival**

Long-term **cardiovascular events**

**£4.2 million** extra treatment costs

**5,180 bed days**

*Saratzis et al. Kidney International 2017*

# Research question

## **How can we prevent AKI in EVAR ?**

- Mechanisms and patient co-morbidities in EVAR-related AKI very different to other interventions
- No RCT investigating AKI prevention in EVAR

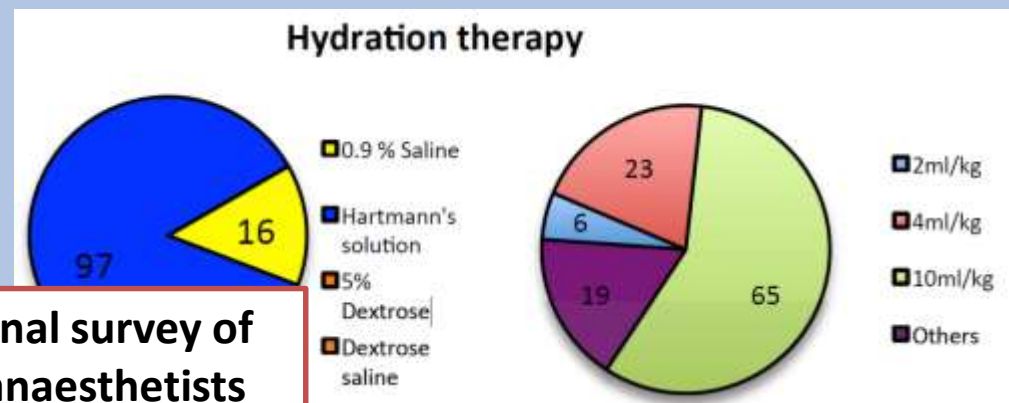
## Methods:

### 1) Create an EVAR specific AKI intervention:

Evidence review, patient input (interviews), national survey of anaesthetists, **focus groups** → **Delphi**

- 10ml/kg/hr before & 2ml/kg/hr after (Hartmann's)
- 8.4% NaHCO<sub>3</sub> 1ml/kg over 1 hour @ induction

### 2) RCT to test it



**National survey of  
131 anaesthetists**



- **Blinded placebo controlled prospective multicentre randomised controlled trial**
- Supported by Oxford CTU
- **Primary outcome:** AKI incidence (AKIN criteria)
- Reporting 1 year pilot-trial data today

# Randomisation: 2 centres in the pilot 1<sup>st</sup> year

**GROUP 1:** hydration

**GROUP 2:** hydration & bicarbonate 1mmol/kg bolus

**EVAR**

**2 hours:** urine sample

**6 hours:** urine sample

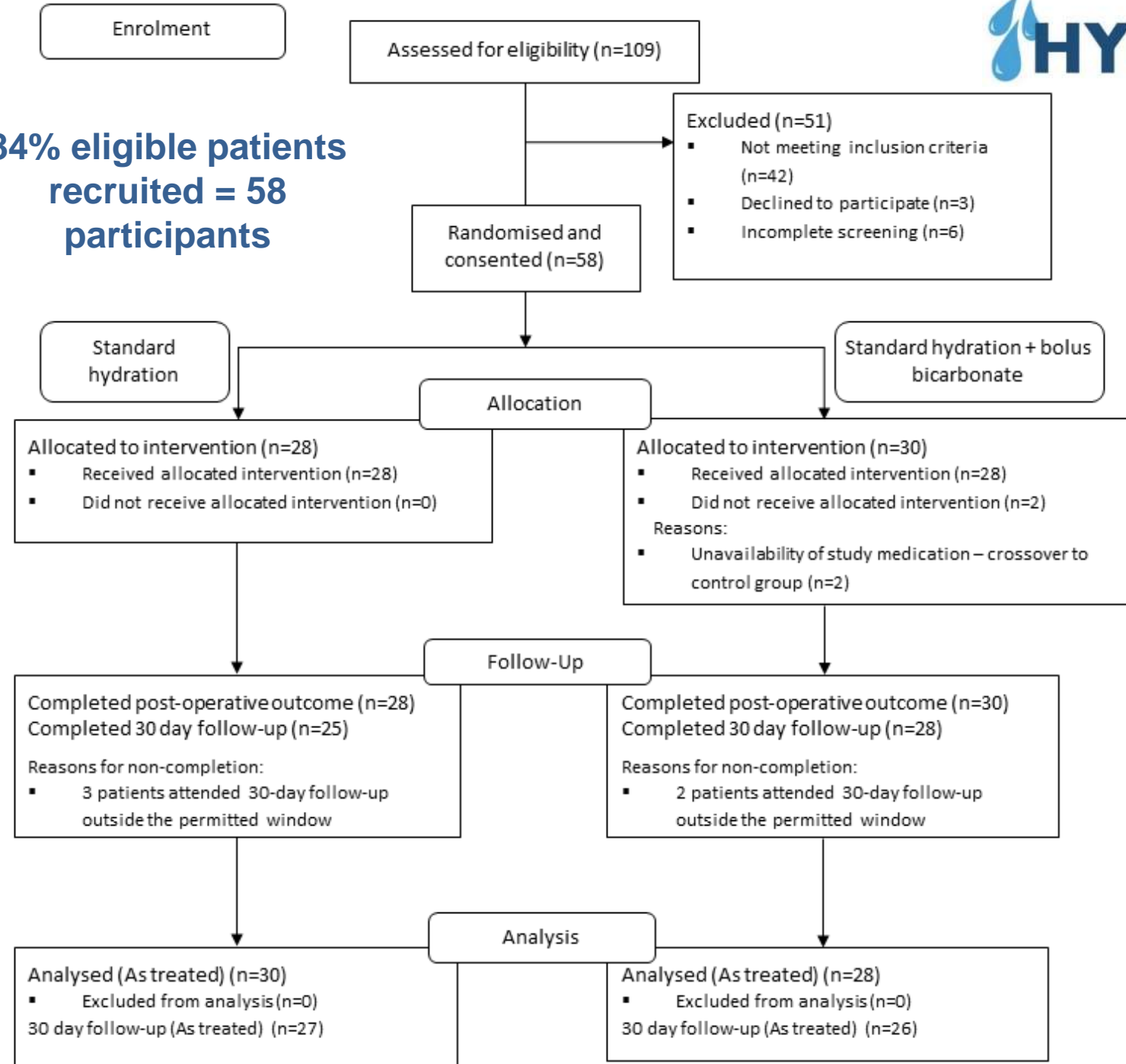
**24 hours:** urine and blood sample

**48 hours:** blood sample

**FOLLOW-UP**



**84% eligible patients recruited = 58 participants**



Analysed (As treated) (n=30)  
 ▪ Excluded from analysis (n=0)  
 30 day follow-up (As treated) (n=27)

Analysed (As treated) (n=28)  
 ▪ Excluded from analysis (n=0)  
 30 day follow-up (As treated) (n=26)

# Demographics & anatomy

## PILOT ROUND: 1<sup>st</sup> YEAR

Demographics	Control	Intervention	Total (N = 58)
<b>Age</b>	75.5 (70, 80)	74.5 (73, 80)	75 (71, 80)
<b>Female</b>	3 (10%)	3 (10.7%)	6 (10.3%)
<b>AAA diameter</b>	6.2 (5.9, 6.6)	6.7 (5.8, 8.1)	6.3 (5.8, 6.9)
<b>Neck length</b>	2.1 (1.5, 2.6)	2.0 (1.6, 2.6)	2.0 (1.6, 2.6)
<b>Neck calcification</b>	4 (14.3%)	3 (10.0%)	7 (12.1%)

# Baseline characteristics

- Patients **comparable** in terms of:

## **Cardiovascular risk factors**

Major **established AKI risk-factors** including eGFR

**Contrast** volume

**Duration** of procedure

97% of patients had a suprarenal fixation device

**PILOT ROUND: 1<sup>st</sup> YEAR**

# Results

- 84% recruitment rate
- No NaHCO<sub>3</sub> AEs → **high-dose NaHCO<sub>3</sub> safe**

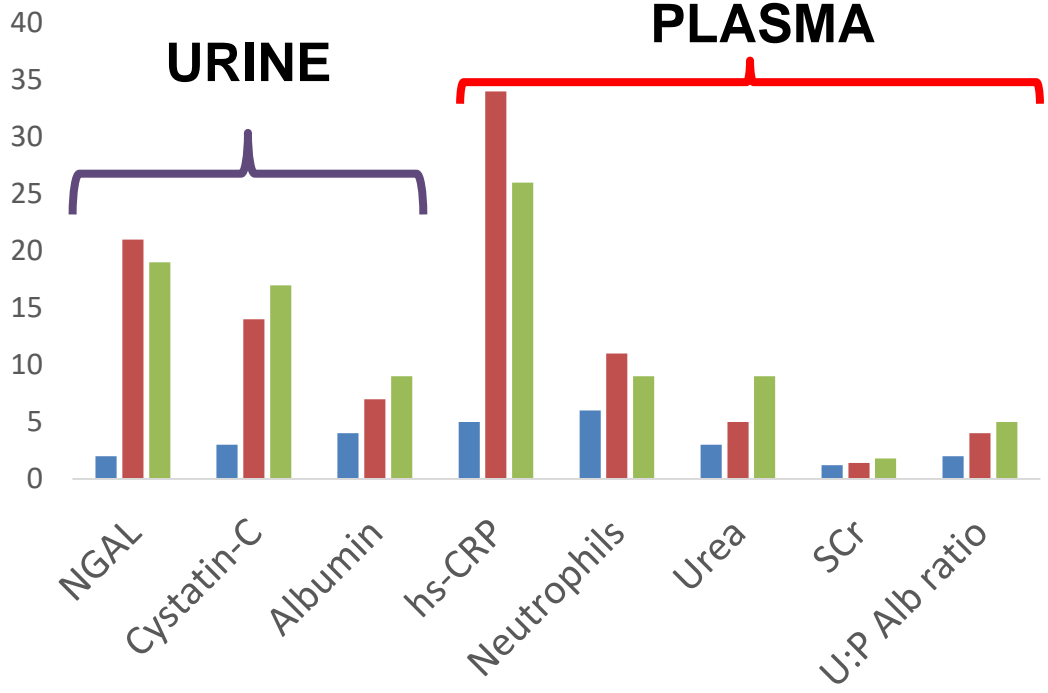
AKI incidence	
Controls	33%
Intervention	7%

Major complications	
Controls	10% (2 life-threatening)
Intervention	0

## URINE

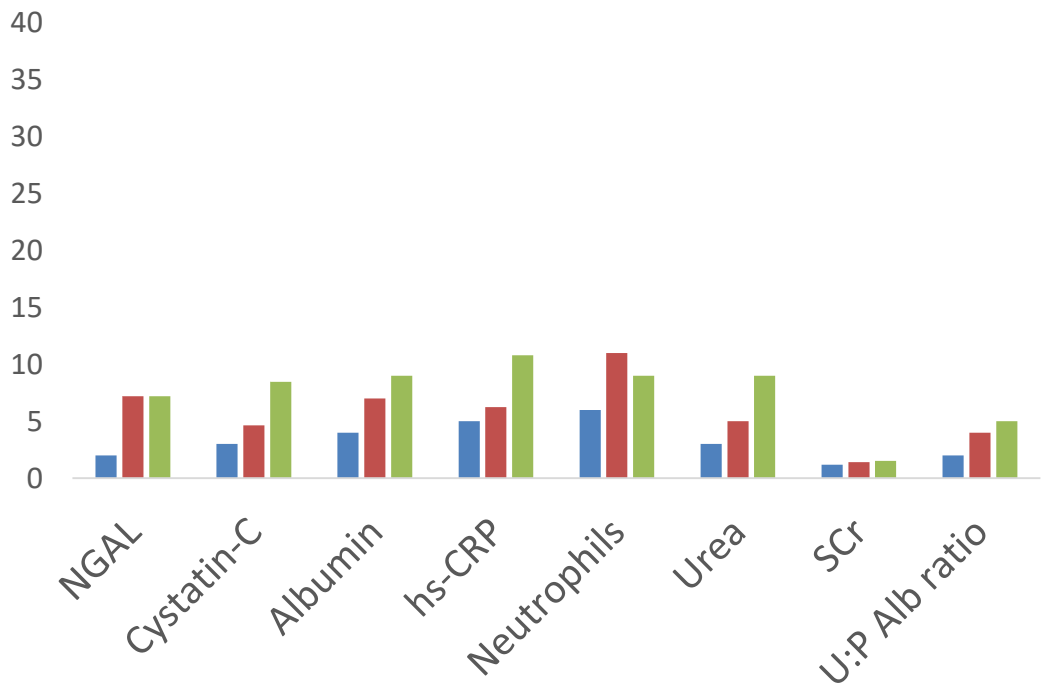
## PLASMA



Control

Markers of **tubular ischaemia & inflammation** over 2 days

Intervention



# Conclusions

## **High-dose NaHCO<sub>3</sub> promising AKI prevention strategy**

- Safe
- Cheap
- Easily reproducible
- Acceptable by patients & clinicians
  
- Definitive RCT: currently in planning; 782 recruits

# Acknowledgements

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