

# Can Randomized Controlled Trials for AAAs be Misleading?

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# DISCLOSURE

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FACS**

- No relevant financial relationship reported

# Pyramid of Evidence Based Medicine



Ann Thorac Surg 2017;103:351-60

# U.K NICE Draft AAA Guidelines

1.5.6: Do not offer complex EVAR to people with an unruptured AAA if open repair is a suitable option, except as part of a **randomised controlled trial** comparing complex EVAR with open surgical repair

Complex EVAR: outside IFU, PMEG, F/B endografts, parallel stents

# Randomized Controlled Trials

- Results relevant to those who meet inclusion criteria
- Inclusion depends on clinical equipoise
- Results valid to specific centers & practitioners
- Lower event rates in experimental & control group
- Issues of Study Interpretation

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What patients are included?

## RCT's for Open vs Endovascular Repair for RAAAs



Nottingham



AJAX



ECAR



IMPROVE

## RCT's for Open vs Endovascular Repair for RAAAs Early Mortality

	OSR	EVAR	P-value
<b>Nottingham</b>	<b>53%</b>	<b>53%</b>	<b>N.S.</b>
<b>AJAX</b>	<b>25%</b>	<b>21%</b>	<b>0.56</b>
<b>ECAR</b>	<b>24%</b>	<b>18%</b>	<b>0.24</b>
<b>IMPROVE</b>	<b>37.4%</b>	<b>35.4%</b>	<b>0.62</b>

# Care of Patients with an Abdominal Aortic Aneurysm

2018 Practice Guidelines from the  
Society for Vascular Surgery

[vsweb.org/Guidelines](http://vsweb.org/Guidelines)

# The patient with a ruptured aneurysm

Recommendation	Level of recommendation	Quality of evidence
We suggest a door-to-intervention time of <90 minutes, based on a framework of 30-30-30 minutes, for the management of the patient with a ruptured aneurysm.	Ungraded Good Practice Statement	
An established protocol for the management of ruptured AAA is essential for optimal outcomes.	Ungraded Good Practice Statement	
We recommend implementing hypotensive hemostasis with restriction of fluid resuscitation in the conscious patient.	1	B
We suggest that patients with ruptured AAA who require transfer for repair be referred to a facility with an established rupture protocol and suitable endovascular resources.	Ungraded Good Practice Statement	
If it is anatomically feasible, we recommend EVAR over open repair for treatment of a ruptured AAA.	1	C

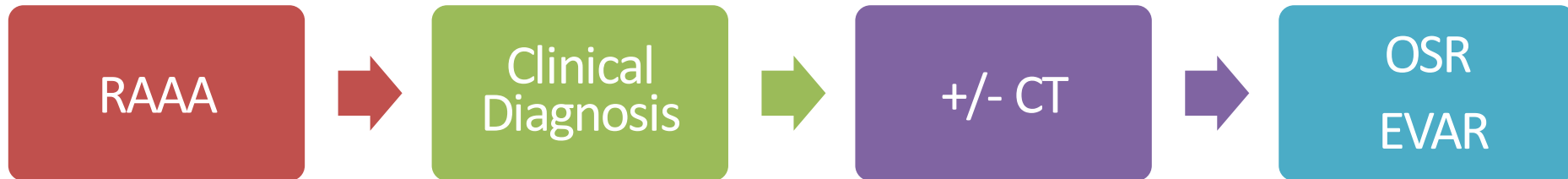
# RCT's for Open vs Endovascular Repair for RAAAs

## Early Mortality

	OSR	EVAR	P-value
<b>Nottingham</b>	<p>But ...</p> <p>Differences in Study Design &amp; Randomization</p> <p>What patients were included?</p>		
<b>AJAX</b>			
<b>ECAR</b>			
<b>IMPROVE</b>			

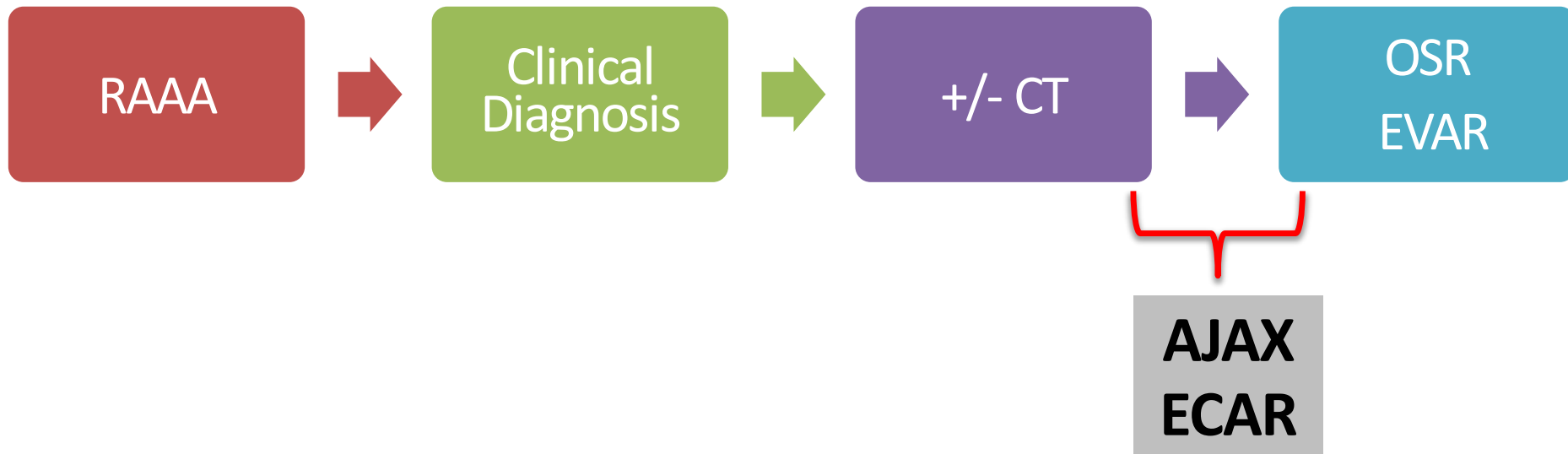
# RCT's for Open vs Endovascular Repair for RAAAs

## Differences in Study Design



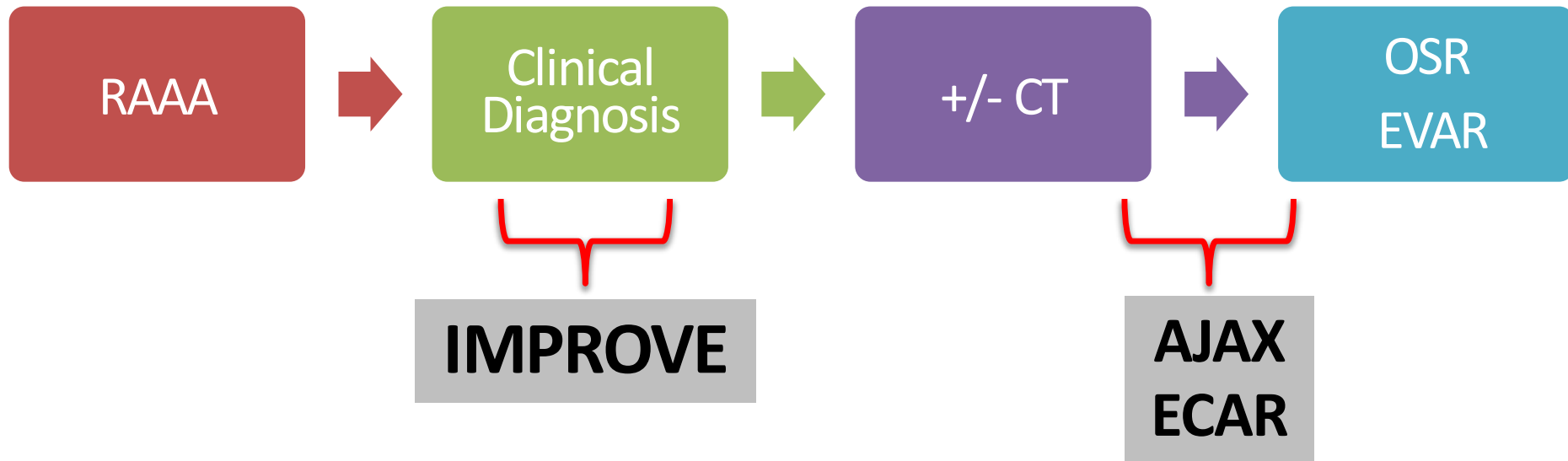
# RCT's for Open vs Endovascular Repair for RAAAs

## Differences in Study Design



# RCT's for Open vs Endovascular Repair for RAAAs

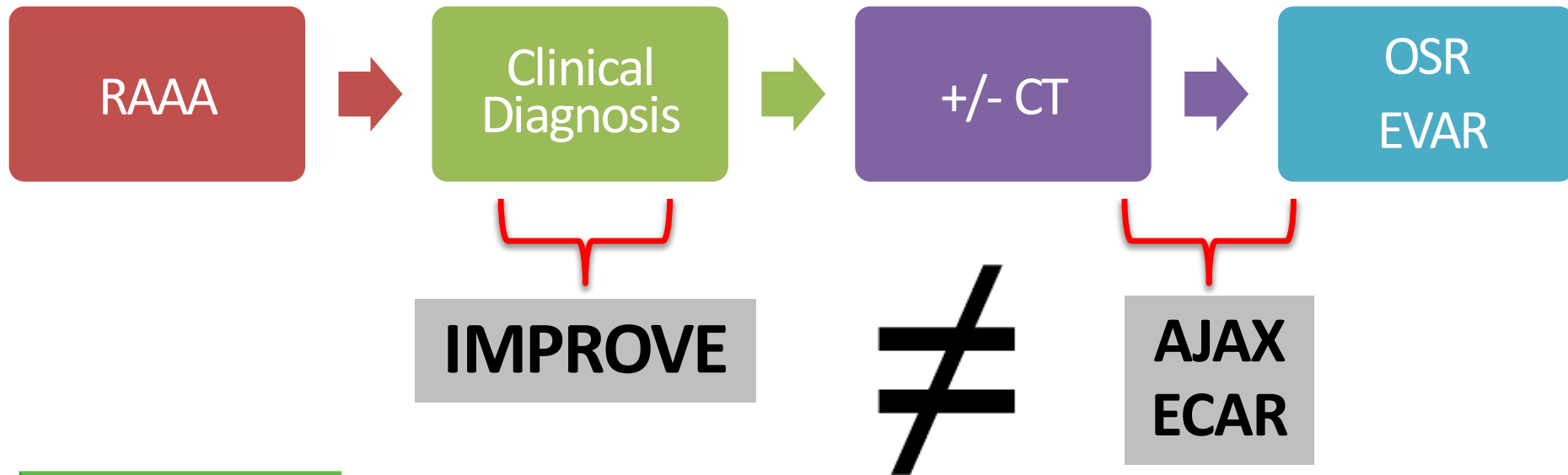
## Differences in Study Design





# RCT's for Open vs Endovascular Repair for RAAAs

## Differences in Study Design



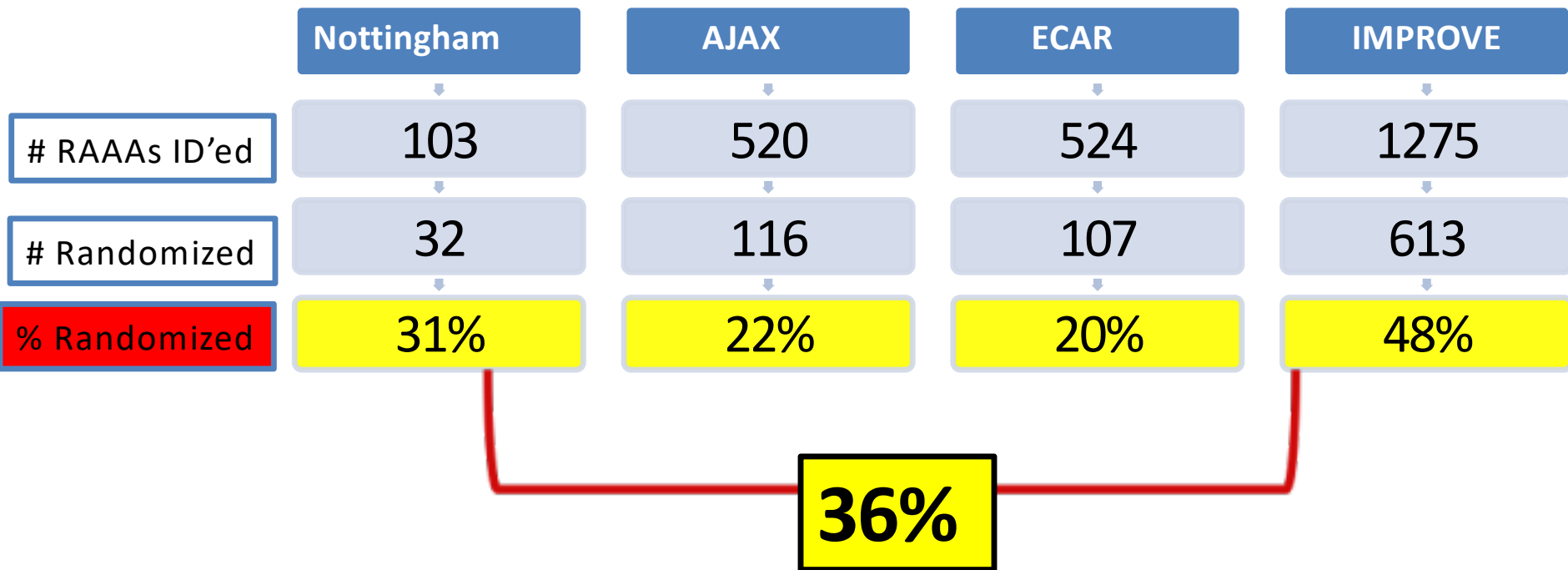
# RCT's for Open vs Endovascular Repair for RAAAs

## What patients were included?

	Nottingham	AJAX	ECAR	IMPROVE
# RAAAs ID'ed	103	520	524	1275
# Randomized	32	116	107	613
% Randomized	31%	22%	20%	48%

# RCT's for Open vs Endovascular Repair for RAAAs

## What patients were included?



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# Interpretation of Negative Trials



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# RCT's for Open vs Endovascular Repair for RAAAs Early Mortality

	OSR	EVAR	P-value	Interpretation
AJAX	25%	21%	0.56	“did not show significant difference ...”
ECAR	24%	18%	0.24	“EVAR was found to be equal ...”
IMPROVE	37.4%	35.4%	0.62	“... not associated with significant reduction ...”

## RCT's for Open vs Endovascular Repair Nonruptured AAAs

	OSR*	EVAR	P-value	Interpretation
EVAR – 1 (4 yr ACM)	29%	26%	N.S.	“EVAR offers no advantage ...”
EVAR – 2 (4 yr ACM)	*No-I 62%	66%	N.S.	“EVAR did not improve survival ...”
DREAM (2 yr ACM)	10.4%	10.3%	N.S.	“... survival advantage ... is not sustained”
OVER (8 yr ACM)	37%	41%	N.S.	“...similar long term survival”
ACE (3 yr ACM/comp)	3.1%	6.8%	N.S.	“open repair of AAA is as safe as EVAR”



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