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The **BYPASS-CTCA** Study: A Randomised Controlled Trial assessing the value of **Computed Tomography Cardiac Angiography (CTCA)** in Improving Patient-related Outcomes in Patients with prior CABG undergoing Invasive Coronary Angiography

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Disclosure Statement of Financial Interest

I, **Daniel Jones** DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

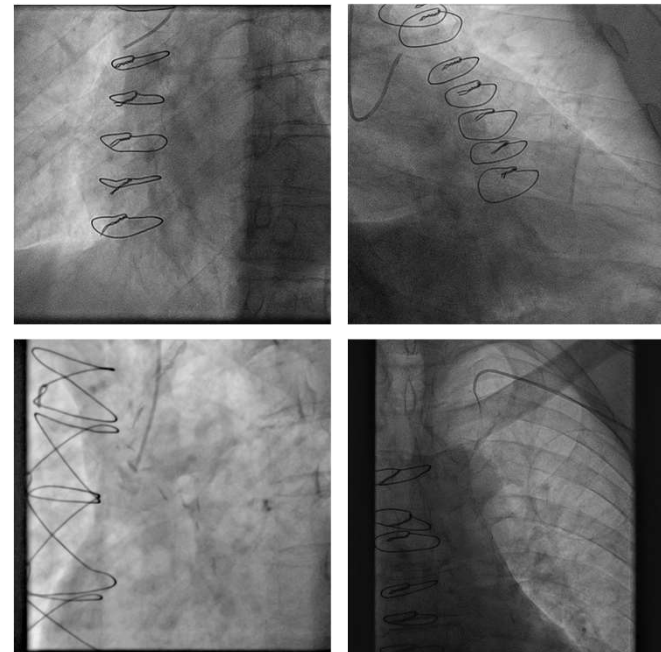
Faculty disclosure information can be found on the app

- CABG is the commonest adult cardiac procedure in the developed world
 - Worldwid
 - 250,000
- The long-term failure of bypass grafting is due to atherosclerosis
- Particularly true
 - 85% of surgeries each year

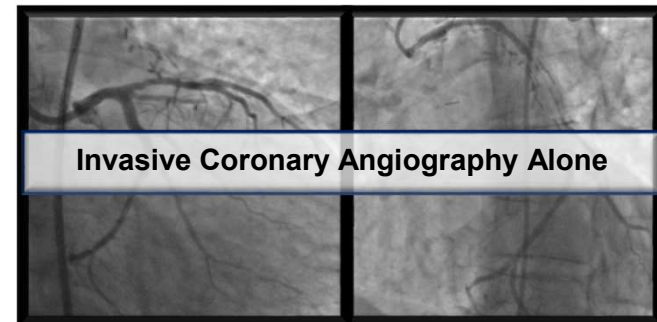
1 in 5 patients will require invasive coronary angiography within 3 years



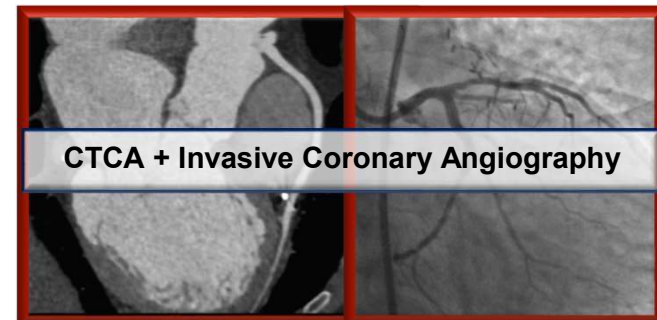
- Invasive Coronary Angiography in patients with previous CABG is more complex and challenging
- No operation is the same
- Longer Procedures
- Greater Contrast
- Subsequent Contrast-Induced Nephropathy
- Femoral Access
- Poor Patient satisfaction
- Higher Radiation
- Increased Complication Rates



- Observational studies¹ suggest that Computerised Tomography Coronary Angiography (CTCA) may provide useful pre-procedural planning information prior to Invasive Coronary Angiography
- The BYPASS-CTCA study was designed to test whether adjunctive CTCA can **reduce procedure time**, **improve patient satisfaction** and **prevent procedural complications** in patients with previous CABG undergoing planned ICA



VS





St Bartholomew's Hospital



- 688 patients
- Single Centre Study, St Bartholomew's Hospital, London, UK.
- 3rd Generation Dual Source CT scanner



- Sponsor: Queen Mary University of London
- Adopted by Barts Cardiovascular CTU
- Funded by National Institute of Health Research RfPB Scheme



Inclusion Criteria

- Patients undergoing invasive coronary angiography
- Stable Angina and NSTEMI-ACS
- Previous Coronary Artery Bypass Grafting (CABG)
- Aged ≥ 18
- Patients able and willing to give written informed consent.

Exclusion Criteria

- ST segment myocardial infarction
- Haemodynamic or Clinical Instability
- Subjects with $eGFR < 20$ ml/min or on renal replacement therapy
- Current life-threatening condition other than vascular disease
- Pregnancy or unknown pregnancy status.
- Inability to tolerate beta-blockers
- Known contrast allergy.

Co-Primary Endpoints

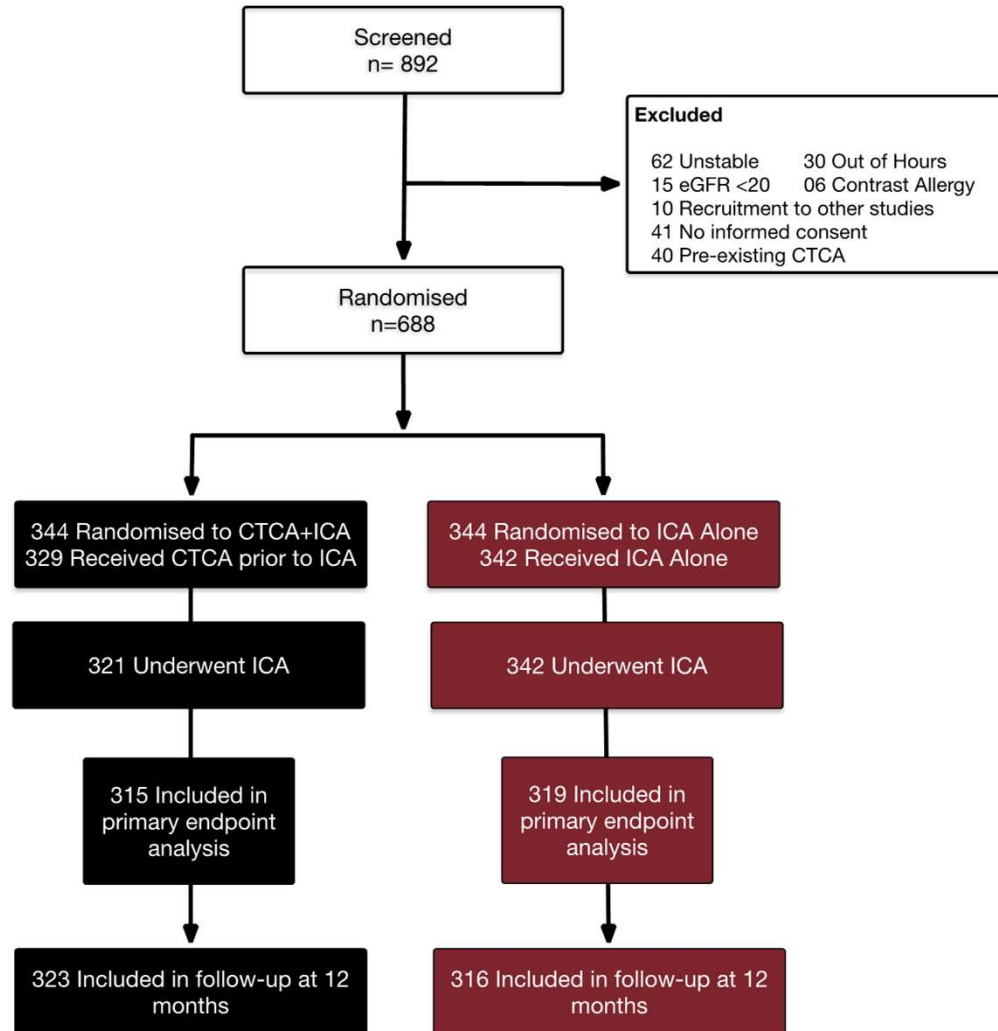
- Procedural duration
- Patient satisfaction scores post ICA¹
- Incidence of Contrast-Induced Nephropathy (KDIGO criteria)²

Sample Size

- Powered to detect all 3 primary study endpoints.
- 688 patients provides:
 - 80% power for CIN reduction of 60% assuming 12% CIN rate and allowing for a Bonferroni correction ($\alpha=0.017$) and 10% drop-out
 - 90% power to detect 15% reduction in procedure time and improvement in patient satisfaction

Major Secondary Endpoints

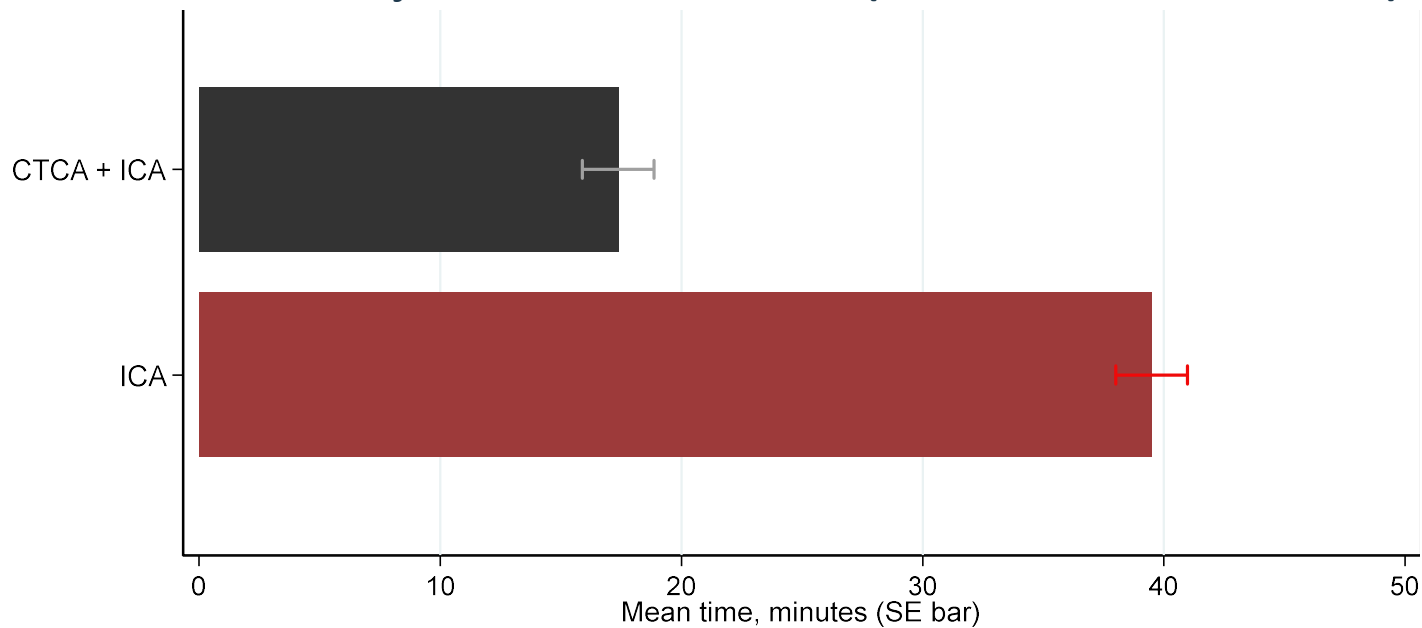
- Procedure Metrics
 - Radial Access
 - Fluoroscopy Time
 - Number of Catheters
 - Contrast Dose (mL)
 - Effective Radiation Dose during ICA
- Procedural Complications
- MACE (All cause mortality, MI, Unscheduled Revascularisation) over 12 months



	CTCA + Angiogram N=344	Angiogram only N=344
Age (years), mean (SD)	68.99 (10.85)	70.55 (9.82)
Sex, n (%)		
Female	51 (14.83)	57 (16.57)
Male	293 (85.17)	287 (83.43)
Ethnicity, n (%)		
Asian	116 (33.72)	144 (41.86)
Black	9 (2.62)	15 (4.36)
White	218 (63.37)	184 (53.49)
Smoking status, n (%)		
Non-smoker	138 (40.12)	161 (46.80)
Ex or Current smoker	206 (59.88)	183 (53.20)
Presentation, n (%)		
ACS	155 (45.06)	155 (45.06)
Unstable angina	25 (7.27)	27 (7.85)
NSTEMI	128 (37.21)	127 (36.92)
Stable angina	191 (55.52)	188 (54.65)

	CTCA + Angiogram N=344	Angiogram only N=344
BMI (kg/m ²), mean (SD)	28.61 (4.98)	28.63 (4.52)
Systolic BP (mmHg), mean (SD)	128.04 (16.78)	130.00 (17.13)
LVEF (%), mean (SD)	50.53 (11.62)	49.40 (11.79)
Diabetes Mellitus, n (%)	169 (49.13)	201 (58.43)
Hypertension, n (%)	293 (85.17)	294 (85.47)
Hypercholesterolemia, n (%)	262 (76.16)	279 (81.10)
Family history, n (%)	39 (11.34)	53 (15.41)
Prior PCI, n (%)	163 (47.38)	169 (49.13)
Prior MI, n (%)	231 (67.15)	236 (68.60)
History of stroke, n (%)	22 (6.40)	27 (7.85)
Creatinine (umol/L), mean (SD)	101.94 (34.62)	99.90 (30.18)
eGFR (mL/min/1.73m ²), mean (SD)	65.79 (18.54)	66.30 (17.73)
Number of Bypass Grafts, mean (SD)	2.86 (1.23)	2.86 (1.28)

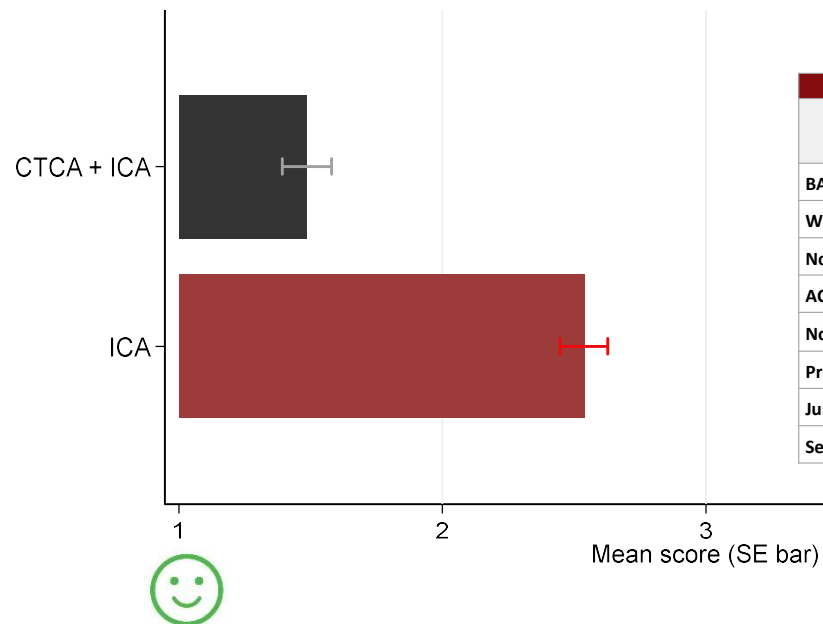
Adjusted difference -20.93 (98.3% CI: -23.50 to -18.35), $p < 0.001$



	Treatment group		Difference (98.33% CI)	P-value	Interaction p-value
	ICA + CTCA N=343	ICA N=342			
BAME (N=284)	18.16 (10.38)	39.11 (16.27)	-20.96 (-24.98 to -16.95)	<0.001	0.379
White (N=401)	16.93 (10.18)	39.83 (17.44)	-22.89 (-26.26 to -19.52)	<0.001	
No ACS (N=375)	18.61 (10.34)	39.07 (17.11)	-20.45 (-23.91 to -16.99)	<0.001	0.087
ACS (N=310)	15.88 (9.99)	40.01 (16.66)	-24.13 (-27.93 to -20.32)	<0.001	
No previous angiogram since CABG (N=368)	17.75 (10.11)	41.26 (16.19)	-23.52 (-27.03 to -20.02)	<0.001	0.211
Previous angiogram since CABG (N=317)	16.98 (10.42)	37.81 (17.40)	-20.83 (-24.61 to -17.06)	<0.001	
Junior operator (N=495)	18.57 (9.23)	37.12 (15.04)	-18.55 (-21.51 to -15.60)	<0.001	0.007
Senior operator (N=168)	18.58 (10.89)	44.13 (19.24)	-25.56 (-31.02 to -20.09)	<0.001	

	Treatment group		OR (95% CI)	P value
	CTCA + ICA N=343	ICA N=342		
ICA procedure (mean (SD), minutes)	17.38 (10.26)	39.50 (16.89)	-22.12 (-24.68 to -19.56)	<0.001
Combined CTCA + ICA (mean (SD), minutes)	22.12 (10.54)	39.50 (16.89)	-17.38 (-19.49 to -15.27)	<0.001
PCI (mean (SD), minutes)	70.40 (34.67)	81.21 (36.35)	-10.81 (-19.16 to -2.45)	0.011

	Treatment group		OR (95% CI)	P value
	CTCA + ICA N=343	ICA N=342		
ICA fluoroscopy time (mean (SD), minutes)	8.10 (5.10)	14.89 (7.53)	-6.78 (-7.77 to -5.80)	<0.001
	CTCA + ICA N=139	ICA N=141	OR (95% CI)	P value
PCI fluoroscopy time (mean (SD), minutes)	22.78 (13.02)	25.23 (13.82)	-2.44 (-5.60 to 0.72)	0.129

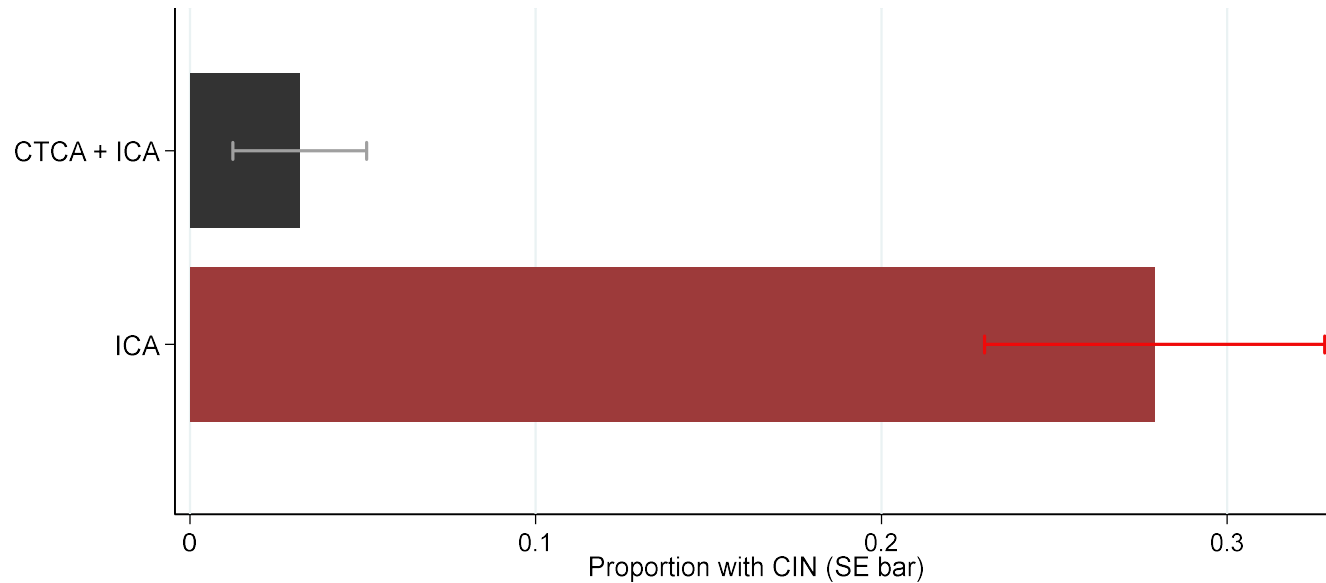


	Treatment group		Covariate adjusted*		
	ICA + CTCA N=321	ICA N=341	Difference (98.33% CI)	P-value	Interaction p-value
BAME (N=277)	1.53 (0.57)	2.52 (0.99)	-0.99 (-1.24 to -0.74)	<0.001	0.455
White (N=385)	1.46 (0.58)	2.55 (1.09)	-1.09 (-1.30 to -0.88)	<0.001	
No ACS (N=365)	1.46 (0.59)	2.52 (1.04)	-1.06 (-1.27 to -0.84)	<0.001	0.904
ACS (N=297)	1.51 (0.56)	2.55 (1.05)	-1.04 (-1.28 to -0.80)	<0.001	
No previous angiogram since CABG (N=352)	1.49 (0.57)	2.54 (1.07)	-1.05 (-1.27 to -0.83)	<0.001	0.988
Previous angiogram since CABG (N=310)	1.48 (0.58)	2.53 (1.02)	-1.05 (-1.28 to -0.82)	<0.001	
Junior operator (N=494)	1.48 (0.58)	2.41 (1.02)	-0.93 (-1.11 to -0.75)	<0.001	0.031
Senior operator (N=168)	1.50 (0.54)	2.75 (1.04)	-1.28 (-1.61 to -0.94)	<0.001	

40% relative improvement



3.4% vs 27.9%, $p < 0.0001$

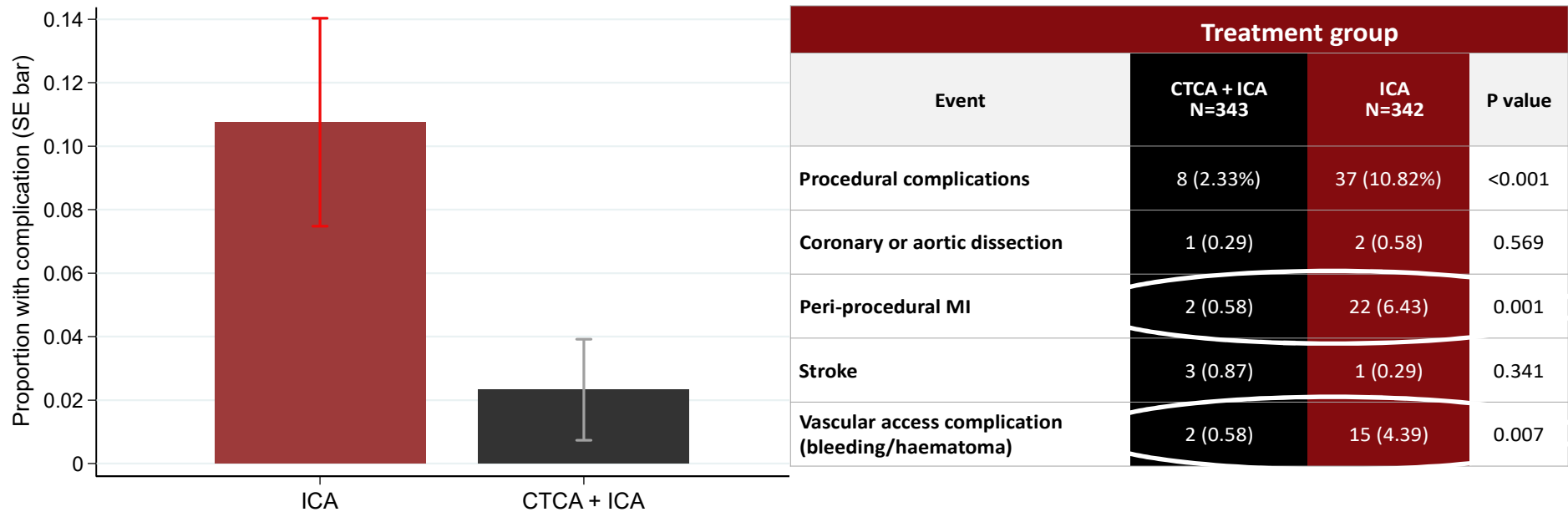


	Treatment group		OR (98.33% CI)	P-value	Interaction p-value
	ICA + CTCA N=315	ICA N=319			
BAME (N=261)	2 (1.79)	36 (24.16)	0.06 (0.01 to 0.34)	<0.001	0.662
White (N=373)	8 (3.94)	53 (31.18)	0.08 (0.03 to 0.22)	<0.001	
No ACS (N=339)	4 (2.38)	41 (23.98)	0.07 (0.02 to 0.26)	<0.001	0.818
ACS (N=295)	6 (4.08)	48 (32.43)	0.09 (0.03 to 0.25)	<0.001	
No previous angiogram since CABG (N=343)	7 (3.70)	47 (30.52)	0.08 (0.03 to 0.23)	<0.001	0.826
Previous angiogram since CABG (N=291)	3 (2.38)	42 (25.45)	0.07 (0.02 to 0.30)	<0.001	
Junior operator (N=454)	10 (4.07)	59 (28.37)	0.10 (0.04 to 0.24)	<0.001	-
Senior operator (N=161)	0	30 (27.03)	-	<0.001	

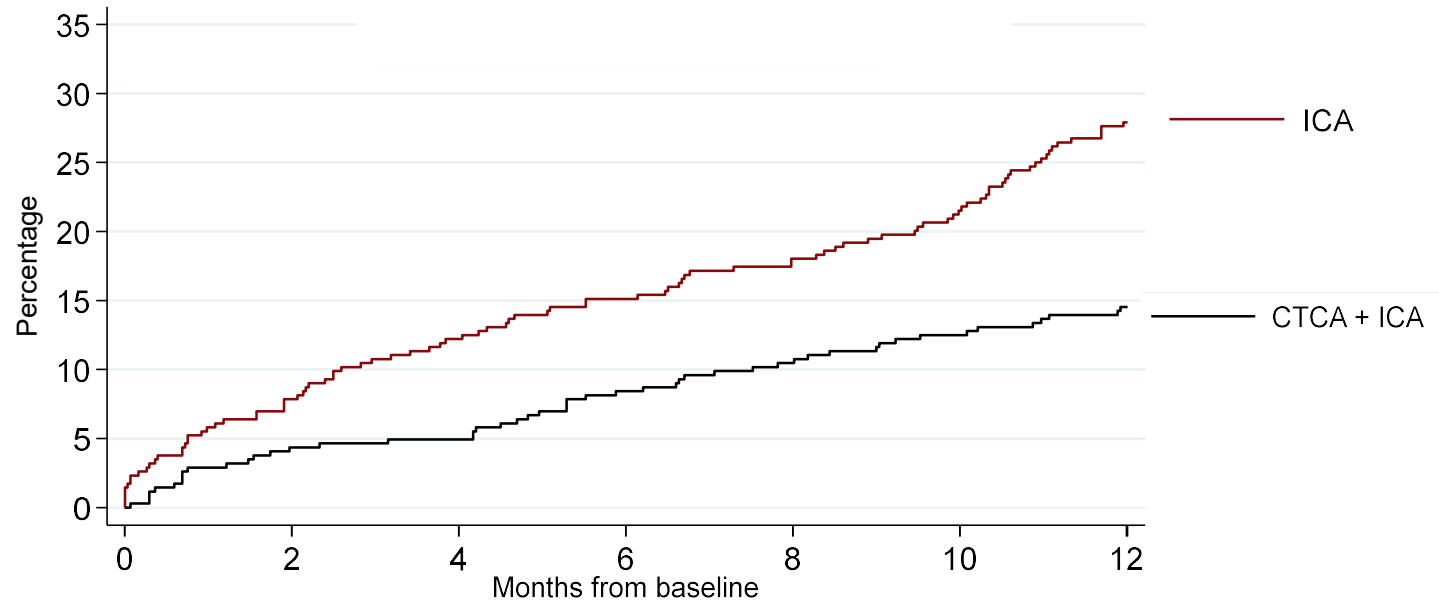
Secondary Endpoints



Treatment group				
Event	CTCA + ICA N=321	ICA N=342	Difference (95% CI)	P value
Number of catheters used during ICA, median (IQR)	3 (2-4)	4 (3-5)	-0.23 (-0.31 to -0.15)	<0.001
Contrast (mls) during ICA, mean (SD)	77.40 (49.05)	173.00 (67.99)	-95.60 (-104.49 to -86.71)	<0.001
Contrast (mls) during ICA +/- CTCA, mean (SD)	148.87 (50.56)	173.00 (67.99)	-24.13 (-33.12 to -15.14)	<0.001
Event	CTCA + ICA N=421	ICA N=342	OR (95% CI)	P value
Radial access, n (%)	247 (76.85)	194 (56.73)	2.55 (1.82 to 3.56)	<0.001
Number of patients with 1 or more grafts not evaluated (could not locate or assumed occluded), n (%)	1 (0.31%)	83 (24.27%)	0.01 (0.00 to 0.07)	<0.001



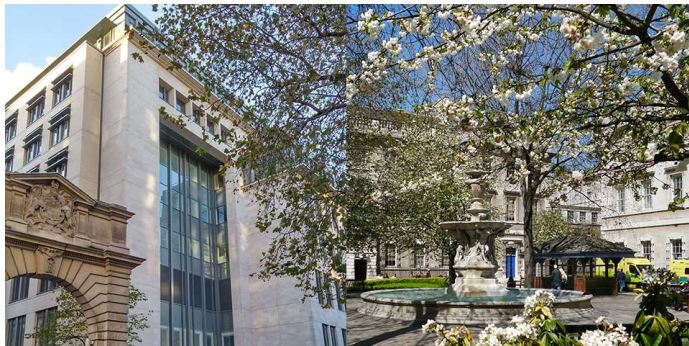
Time to 1st MACE (12 months)



Number at risk		0	2	4	6	8	10	12
CTCA + ICA	344	329	327	315	308	301	294	
ICA	344	317	302	292	282	270	248	

Event	Treatment group		Unadjusted		Covariate adjusted	
	CTCA + ICA n (%) N=344	ICA n (%) N=344	OR (95% CI)	P value	OR (95% CI)	P value
MACE	56 (16.28)	101 (29.36)	0.46 (0.32 to 0.66)	<0.001	0.44 (0.30 to 0.64)	<0.001
All-cause mortality	21 (6.10)	28 (8.14)	0.73 (0.41 to 1.32)	0.301	0.67 (0.36 to 1.22)	0.190
Cardiovascular mortality	6 (1.74)	13 (3.78)	0.45 (0.17 to 1.20)	0.112	0.41 (0.15 to 1.11)	0.079
Non-fatal MI	33 (9.59)	84 (18.60)	0.45 (0.28 to 0.71)	<0.001	0.44 (0.28 to 0.70)	<0.001
Unscheduled revascularisation	20 (5.81)	32 (9.30)	0.60 (0.34 to 1.07)	0.086	0.61 (0.34 to 1.09)	0.092

- In patients with previous CABG undergoing Invasive Coronary Angiography adjunctive prior CTCA
 - Shortens procedure duration
 - Improves patient satisfaction
 - Lowers rates of CIN
- CTCA use resulted in lower procedural complication rates, and reduced rates of MACE at 12 months
- **When logistically possible, CTCA should be considered for any stable post-bypass patient undergoing invasive coronary angiography**



TMG

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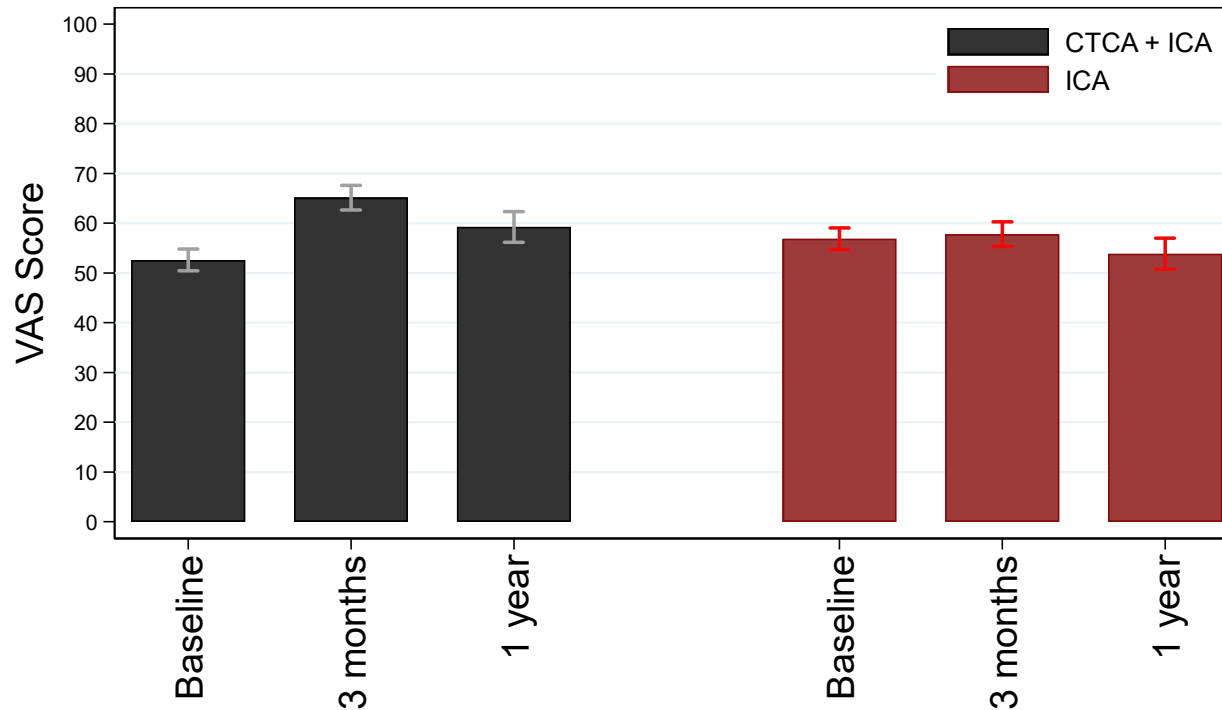
TSC

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Ajay Gupta
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Quality of Life (EQ5D-5L at 12 months)

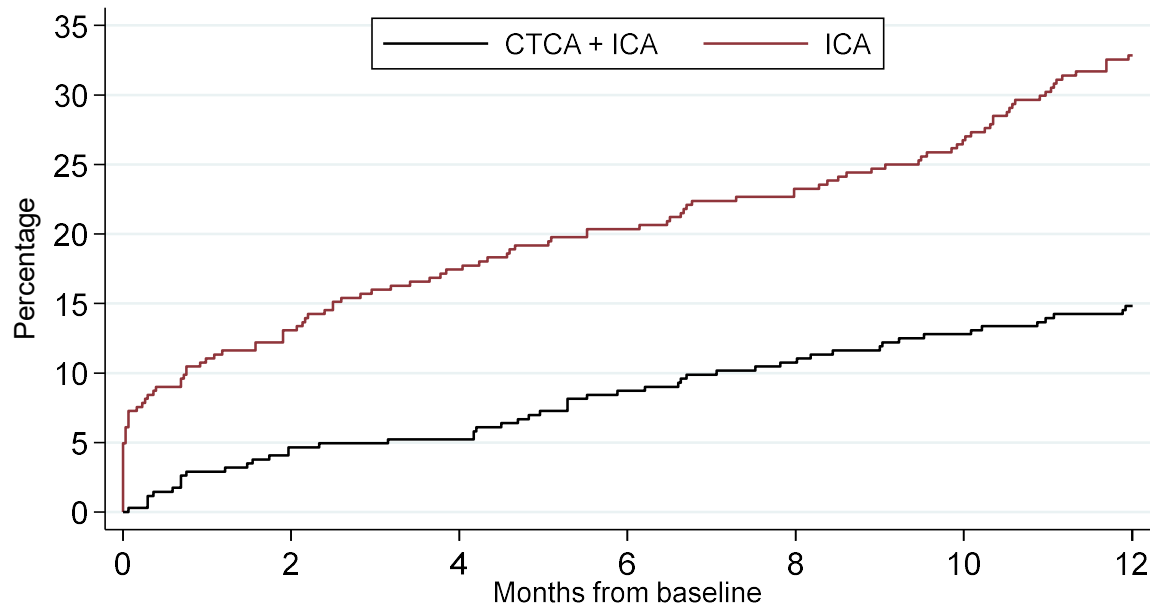


Adjusted difference at 3 months: 10.1
(95% CI: 7.1-13.1), $p < 0.001$

Adjusted difference at 12 months:
7.7 (95% CI: 3.4 to 11.9), $p < 0.001$

Adjusted for baseline creatinine & ACS.

Time to 1st MACE (12 months)



Number at risk		0	2	4	6	8	10	12
CTCA + ICA		344	328	326	314	307	300	293
ICA		344	299	284	274	264	252	231

BYPASS CTCA

