
Use of an objective measure of time to recovery after cardiac surgery

The STET randomised controlled trial

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Aim

- To compare morbidity and healthcare resource use when beating heart coronary artery bypass surgery is carried out via
 - a conventional median sternotomy (OPCAB)
 - or**
 - a left anterolateral thoracotomy (ThoraCAB)

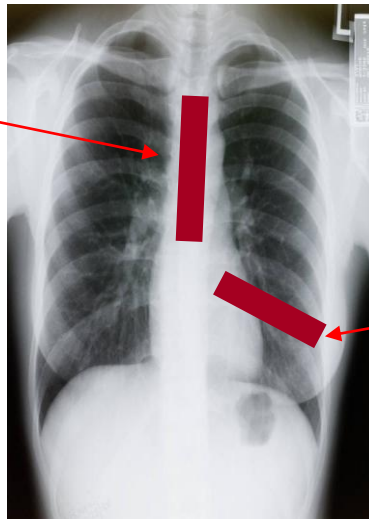
Overview

- Design
 - Two centre, open, parallel-group RCT (Bristol and Massa Carrara, Italy)
- Population
 - Adult patients undergoing primary isolated coronary artery bypass surgery
- Intervention
 - Incision via a median sternotomy versus incision via a left anterior thoracotomy
- Follow-up to 12 months post-surgery

STET trial hypothesis

- Recovery will be faster if the surgery is carried out via a left anterior thoracotomy (ThoraCAB) incision opposed to the standard median sternotomy (OPCAB) incision

**OPCAB
incision**



**ThoraCAB
incision**

Choice of primary outcome

- Interest often lies in post-operative morbidity
 - An obvious endpoint is time to hospital discharge post-surgery
 - The decision of when to discharge a patient usually lies with the clinical team
 - In an open RCT this could be subject to biases
- To minimise these potential biases an objective measurement of recovery was sought

Primary outcome

- Time from surgery until the patient was classified as **fit for discharge** from hospital

Fitness for discharge

- Clear x-ray
 - no evidence of pleural effusion requiring drainage, lung collapse/consolidation or pneumothorax
- No suspected infection
 - systemic LRTI, wound infection (in-hospital ASEPSIS score >20) or sepsis (culture positive infection or IV antibiotic treatment for suspected infection *and* SIRS)
- Normal routine blood test results and temperature
- Physically fit
 - ability to walk 70m, oxygen saturation on air $\geq 95\%$, and having had bowel movements

Results

- Recruitment took place from February 2007 to September 2009
- 191 patients were enrolled (138 UK, 53 Italy)
- 184 patients were included in the analyses

- 91 were randomised to ThoraCAB, 93 to OPCAB

Patient characteristics

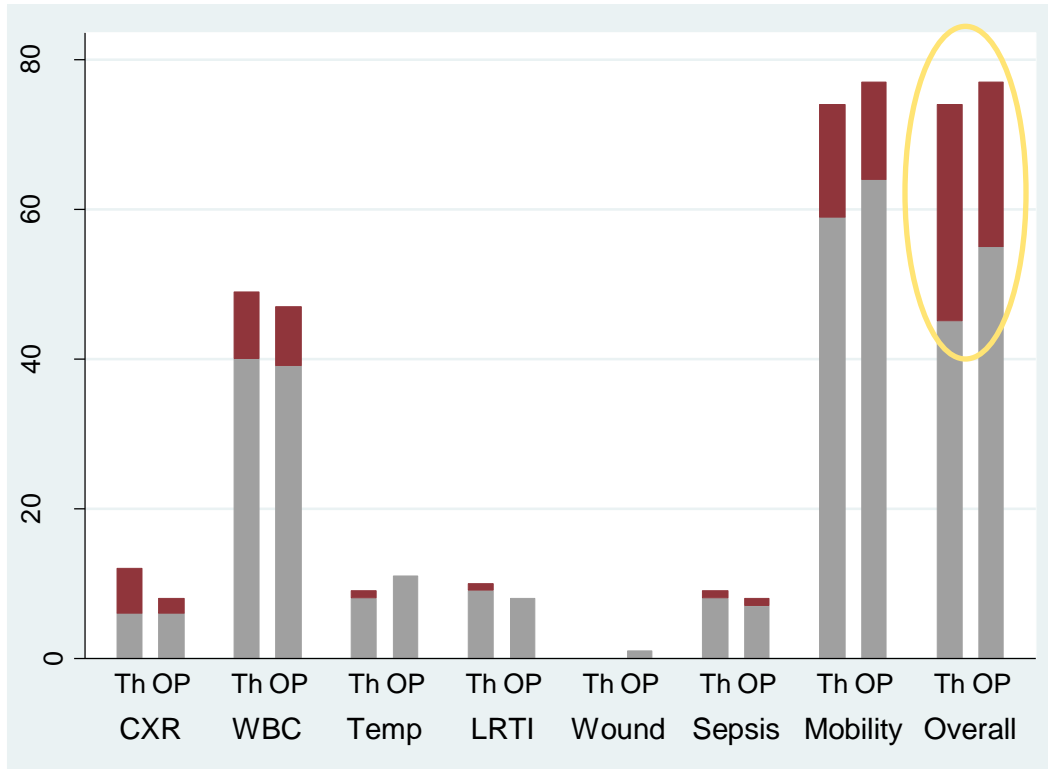
	ThoraCAB (n=91)		OPCAB (n=93)	
	N	%	N	%
Age (yrs, mean, SD)	63.1	8.7	66.7	8.0
Male gender	84	92	80	86
Diabetes	20	22	24	26
Hypertension	66	73	75	82
Good LV function	72	80	69	76
Triple vessel disease	60	66	59	63
EuroScore (median, IQR)	3	1 – 4	3	2 – 4
Urgent operation	20	22	28	31

Operative characteristics

		ThoraCAB (n=91)		OPCAB (n=93)	
		N	%	N	%
Operative time (hrs, median, IQR)		4.1	3.5-4.7	3.3	3.0-4.0
Grafts	1	3	3	4	4
	2	41	47	41	45
	3	42	48	31	34
	>3	2	2	16	17

- Operations took, on average, 50 minutes longer with ThoraCAB
- >3 grafts less common in the ThoraCAB group

Primary outcome composites



Key:

- Met criteria for fitness
- Did not meet criteria for fitness

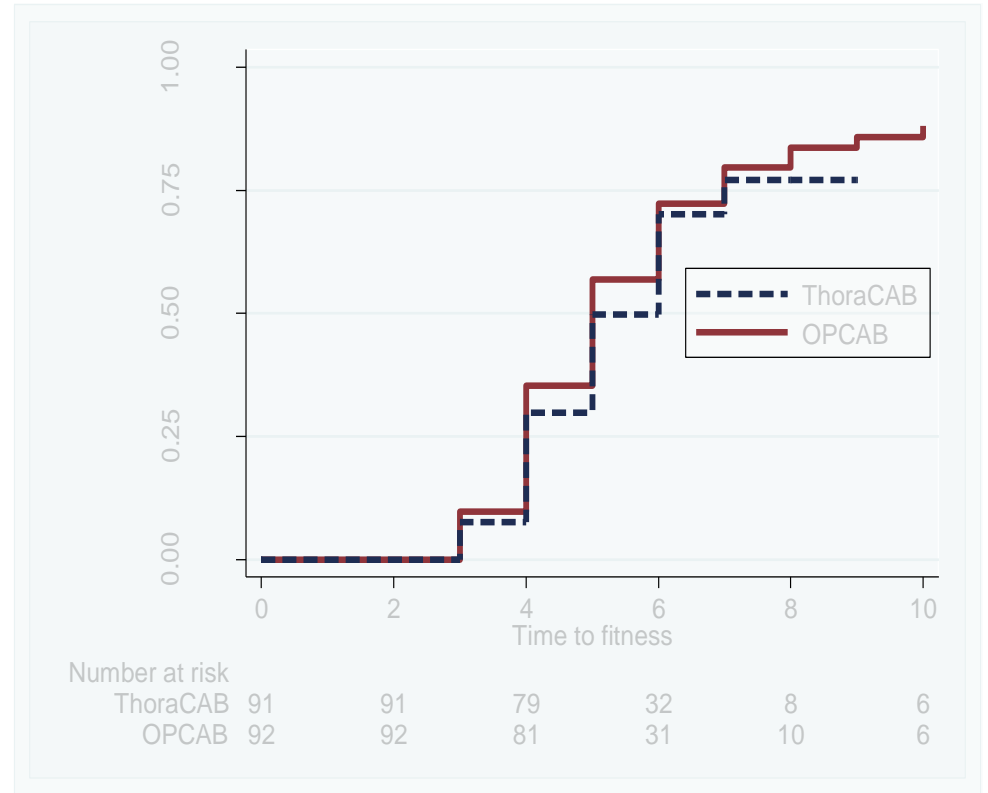
Final component(s) leading to fitness for discharge

	ThoraCAB (n=74)		OPCAB (n=77)	
	N	%	N	%
Normal CXR	7	9	4	5
4,000 ≤ WBC count ≤ 12,000	17	23	15	19
36°C ≤ Temp ≤ 38°C	6	8	3	4
No evidence of a LRTI	3	4	3	4
No evidence of Sepsis	3	4	3	4
Physical fitness	61	82	67	87
<i>bowel movement</i>	16	22	15	19
<i>walking</i>	32	43	33	43
<i>O₂ saturation</i>	44	59	48	62

Fitness for discharge

- Time to fitness for discharge was similar in the two groups

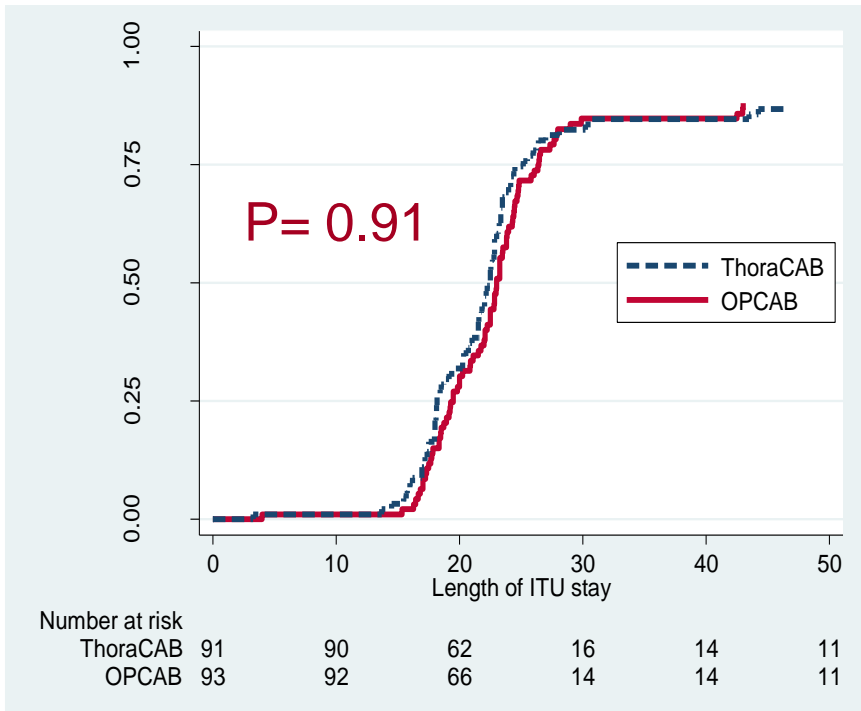
	Median (days)	IQR
ThoraCAB	6	4 – 7
OPCAB	5	4 – 7



	Time ratio	95% CI	P-value
ThoraCAB vs. OPCAB	1.03	0.94 – 1.14	0.53

ICU and hospital stay

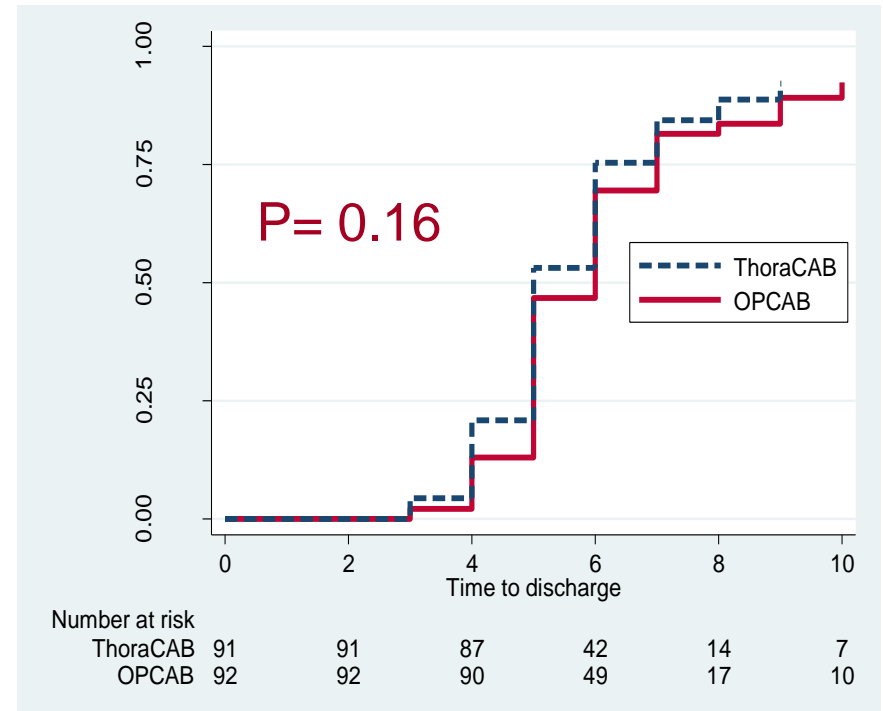
ITU stay (hours)



Median IQR

ThoraCAB	22.4	18.2 – 25.2
OPCAB	23.0	19.5 – 26.4

Hospital stay (days)



Median IQR

ThoraCAB	5	5 – 6
OPCAB	6	5 – 7

Summary

- Using the fitness for discharge outcome
 - Increased the complexity of the trial
 - Led to a significant proportion of censored observations
- Definition of fit for discharge has been revised
 - Some of the more subjective components have been dropped
 - Thresholds for some of the tests have been modified

Revised criteria

Original criteria (STET)

Routine blood test results & temperature

- Temperature: 36 - 38 °C
- WBC count: 4000 - 12000/mm³

Infection

- Systemic LRTI
- Wound infection
- Sepsis

Physical fitness

- Oxygen saturation on air: $\geq 95\%$
- Bowels opened
- Ability to walk 70m

Revised criteria

Routine test results

- Temperature: $\leq 37.5^{\circ}\text{C}$ **or** $< 38^{\circ}\text{C}$ and no indication of potential infection from WBC count or CRP¹
- Pulse: 50 - 100 beats/min
- Respiration: 12 – 22 beats/min

Physical fitness

- Oxygen saturation on air: $\geq 95\%$ (unless known COPD)
- Bowels opened
- Ability to walk 70m (or physio. assessment if unable for unrelated reasons)

¹ Algorithm for combining the temperature, WBC count and CRP data will be developed in collaboration with the clinical team using blinded data

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