# An open randomized controlled trial of median sternotomy versus anterolateral left thoracotomy on morbidity and health care resource use in patients having off-pump coronary artery bypass surgery: The Sternotomy Versus Thoracotomy (STET) trial

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**Objective:** Our objective was to compare off-pump coronary artery bypass surgery carried out via a left anterolateral thoracotomy (ThoraCAB) or via a conventional median sternotomy (OPCAB).

**Background:** Recent advances in minimally invasive cardiac surgery have extended the technique to allow complete surgical revascularization on the beating heart via thoracotomy.

**Methods:** Patients undergoing nonemergency primary surgery were enrolled between February 2007 and September 2009 at 2 centers. The primary outcome was the time from surgery to fitness for hospital discharge as defined by objective criteria.

**Results:** A total of 93 patients were randomized to off-pump coronary artery bypass surgery via a median sternotomy (OPCAB) and 91 to off-pump coronary artery bypass surgery via a left anterolateral thoracotomy (ThoraCAB). The surgery was longer for patients in the ThoraCAB group (median, 4.1 vs 3.3 hours) and there were fewer with more than 3 grafts (2% vs 17%). The median time from surgery to fitness for discharge was 6 days (interquartile range, 4-7) in the ThoraCAB group versus 5 days (interquartile range, 4-7) in the OPCAB group ($P = .53$). The intubation time was shorter, by on average 65 minutes, in the ThoraCAB group ($P = .017$), although the time in intensive care was similar ($P = .91$). Pain scores were similar ($P = .97$), but more analgesia was required in the ThoraCAB group (median duration, 38.8 vs 35.5 hours, $P < .001$; tramadol use, 66% vs 49%, $P = .024$). ThoraCAB was associated with significantly worse lung function at discharge (average difference, –0.25 L, $P = .01$) but quality of life scores at 3 and 12 months were similar ($P = .52$). The average total cost was 10% higher with ThoraCAB ($P = .007$).

**Conclusions:** ThoraCAB resulted in no overall clinical benefit relative to OPCAB. (J Thorac Cardiovasc Surg 2013;146:306-16)

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Minimally invasive cardiac surgery (MICS) aims to reduce the inflammatory response, organ dysfunction, and morbidity attributable to surgical access, cardiopulmonary bypass (CPB), and manipulation of the aorta, while achieving complete revascularization. Minimally invasive direct coronary artery bypass (MIDCAB) via a left anterior small thoracotomy represented a milestone development, conferring the survival benefit of the left internal thoracic artery to the left anterior descending artery while avoiding sternotomy and CPB.[1-3] The technique was then extended to patients with multivessel disease by combining MIDCAB with percutaneous coronary intervention to non–left anterior descending artery vessels to provide truly minimally invasive hybrid multivessel revascularization.[4,5] However, hybrid procedures were only possible in selected patients with favorable anatomy. Moreover, logistical issues remained, and the reintervention rate was high.[6-8] Rather, MIDCAB led to renewed interest in off-pump coronary artery bypass (OPCAB) where complete revascularization could be achieved without CPB and often without aortic manipulation, albeit via a sternotomy incision.[9,10] In

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**Abbreviations and Acronyms**

CABG = coronary artery bypass graft
CI = confidence interval
CPB = cardiopulmonary bypass
$FEV_1$ = forced expiratory volume after 1 second
FVC = forced vital capacity
IL = interleukin
MICS = minimally invasive cardiac surgery
MIDCAB = minimally invasive direct coronary artery bypass
OPCAB = off-pump coronary artery bypass surgery via a median sternotomy
RCT = randomized controlled trial
SIRS = systemic inflammatory response syndrome
ThoraCAB = off-pump coronary artery bypass surgery via a left anterolateral thoracotomy
TR = time ratio

randomized controlled trials (RCTs), OPCAB reduced the inflammatory response and severity of organ injury and used fewer health care resources,[11] with equivalent long-term graft patency, quality of life, and survival compared with coronary artery bypass grafting (CABG) with CPB.[12,13]

The increasingly high-risk population referred for surgery, the morbidity associated with sternotomy, economic considerations, and the desires of patients for less postoperative pain and a quicker return to normal living have led to pressure to further refine MICS techniques. To extend the advantages of OPCAB, several groups have developed a technique whereby complete revascularization may be performed on the beating heart through a lateral thoracotomy incision (ThoraCAB) with minimal morbidity and rapid hospital discharge.[14-16] Concerns remain, however, as to whether in unselected patients technical precision may be compromised[3] or whether excessive rib retraction may result in increased postoperative pain.[17] We carried out an RCT to evaluate whether ThoraCAB represents a clinical benefit beyond that conferred by OPCAB.

## METHODS

### Study Design

A 2-center, open, parallel-group RCT (ISRCTN 77366282) was used.

### Participants

Participants included adults (>16 years and <80 years) undergoing nonemergency primary CABG on the beating heart without the use of CPB and cardioplegic arrest. Patients who had undergone heart or lung surgery previously or for whom the surgeon was unwilling to carry out the surgery via either method were excluded.

### Study Settings

The study was conducted at the Bristol Heart Institute, Bristol (United Kingdom) and Ospedale Pasquinucci, Massa Carrara (Italy), 2 specialized regional cardiac surgery centers. Three surgeons, 2 in Bristol and 1 in Italy, participated. The study was approved by the Southmead Research Ethics Committee (ref. 07/Q2002/53) and by the Comitato Etico Locale of the Ospedale Pasquinucci (protocol number 150).

### Interventions

Patients were randomized to CABG on the beating heart through either a median sternotomy (OPCAB, control) or a left anterolateral thoracotomy (ThoraCAB, experimental). OPCAB was carried out as described previously[9] with subsequent modifications subsumed into the current standard protocol, for example, use of an intracoronary shunt when performing a distal anastomosis. ThoraCAB, and associated anesthetic technique, was carried out as described by Guida and colleagues.[14] With the left side of the patient elevated to approximately 30°, an anterolateral incision is made on the fourth or fifth intercostal space from the midclavicular to the anterior axillary line, sparing the latissimus dorsi. The left lung is usually deflated; if single lung ventilation is not possible, the left lung is gently compressed using a laparotomy sponge. The left internal thoracic artery is harvested under direct vision. The pericardium is incised from the pulmonary artery toward the ascending aorta and then toward the right atrial appendage. Traction sutures are positioned on the pericardium to rotate the ascending aorta to the right side. Proximal graft anastomoses on the aorta are performed first with a side-biting clamp in the conventional way. The pericardium is then incised parallel to the left phrenic nerve to expose the posterior and lateral wall vessels. Distal anastomoses are performed with an Octopus stabilizer (Medtronic Inc, Minneapolis, Minn) and intracoronary shunt.

Postoperative management was in accordance with institution-specific protocols. A protocol for postoperative pain relief for ThoraCAB patients was written by cardiac anesthetists and intensivists in Bristol. A policy of early extubation was adopted for all patients. For ThoraCAB patients, at the time of wound closure the surgeon sutured in place a paravertebral catheter to provide a paravertebral block (infusion of 0.125% bupivacaine, 5-10 mL/h); a 15- to 20-mL loading bolus of 0.25% bupivacaine through the catheter and injections into the intercostal spaces (0.125% bupivacaine) were also given before chest closure. Pain relief in the event of failure of the paravertebral catheter included the following: (1) local analgesia, intercostal blocks, up to 6 spaces injecting 5 mL 0.125% bupivacaine into each space, repeated 4 to 6 hourly if required; (2) adjuvant analgesia, intravenous ketoralac/diclofenac (up to 30 mg); (3) adjuvant analgesia, nurse administered intravenous morphine (up to 5-mg boluses); and (4) adjuvant analgesia, intravenous ketamine infusion (1.5-3 $\mu g \cdot kg^{-1} \cdot min^{-1}$). All patients had patient-controlled analgesia.

### Outcome Measures

**Primary outcome.** The primary outcome was the number of days from surgery until fit for discharge from the hospital. Patients were classified fit when (1) the chest x-ray film was clear with no evidence of pleural effusion requiring drainage, lung collapse/consolidation, or pneumothorax, (2) there was no suspected infection, (3) routine blood test results and temperature were normal, and (4) the patient was physically fit.

The definition was modified partway through the trial after feedback from the independent Data Monitoring and Safety Committee. Initially, components 3 and 4 were *not* included. These data were collected retrospectively for the Bristol patients recruited before the change but were not available for the Italian patients. The definitions applied to minimize the susceptibility to detection bias are described in Appendix E1.

**Secondary outcomes.** Secondary outcomes were as follows: (1) the patient's judgment about his or her readiness for discharge; (2) biochemical inflammatory markers, that is, complement activation (C3a and C5) and interleukin (IL-6, IL-8, and IL-10)[18] assessed preoperatively, at the end of the operation, and 4, 12, and 24 hours postoperatively; (3) pulmonary function