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Minithoracotomy vs Conventional Sternotomy for Mitral Valve Repair
A Randomized Clinical Trial

Enoch F. Akowuah, MD; Rebecca H. Maier, MSc; Helen C. Hancock, PhD; Ehsan Kharatikoopaei, PhD; Luke Vale, PhD; Cristina Fernandez-Garcia, PhD; Emmanuel Ogundimu, PhD; Janelle Wagnild, PhD; Ayesha Mathias, BSc; Zoe Walmsley, MSc; Nicola Howe, PhD; Adetayo Kasim, PhD; Richard Graham, MBChB; Gavin J. Murphy, MD; Joseph Zacharias, MD; for the UK Mini Mitral Trial Investigators

IMPORTANCE The safety and effectiveness of mitral valve repair via thoracoscopically-guided minithoracotomy (minithoracotomy) compared with median sternotomy (sternotomy) in patients with degenerative mitral valve regurgitation is uncertain.

OBJECTIVE To compare the safety and effectiveness of minithoracotomy vs sternotomy mitral valve repair in a randomized trial.

DESIGN, SETTING, AND PARTICIPANTS A pragmatic, multicenter, superiority, randomized clinical trial in 10 tertiary care institutions in the UK. Participants were adults with degenerative mitral regurgitation undergoing mitral valve repair surgery.

INTERVENTIONS Participants were randomized 1:1 with concealed allocation to receive either minithoracotomy or sternotomy mitral valve repair performed by an expert surgeon.

MAIN OUTCOMES AND MEASURES The primary outcome was physical functioning and associated return to usual activities measured by change from baseline in the 36-Item Short Form Health Survey (SF-36) version 2 physical functioning scale 12 weeks after the index surgery, assessed by an independent researcher masked to the intervention. Secondary outcomes included recurrent mitral regurgitation grade, physical activity, and quality of life. The prespecified safety outcomes included death, repeat mitral valve surgery, or heart failure hospitalization up to 1 year.

RESULTS Between November 2016 and January 2021, 330 participants were randomized (mean age, 67 years, 100 female [30%]); 166 were allocated to minithoracotomy and 164 allocated to sternotomy, of whom 309 underwent surgery and 294 reported the primary outcome. At 12 weeks, the mean between-group difference in the change in the SF-36 physical function T score was 0.68 (95% CI, −1.89 to 3.26). Valve repair rates (≈ 96%) were similar in both groups. Echocardiography demonstrated mitral regurgitation severity as none or mild for 92% of participants at 1 year with no difference between groups. The composite safety outcome occurred in 5.4% (9 of 166) of patients undergoing minithoracotomy and 6.1% (10 of 163) undergoing sternotomy at 1 year.

CONCLUSIONS AND RELEVANCE Minithoracotomy is not superior to sternotomy in recovery of physical function at 12 weeks. Minithoracotomy achieves high rates and quality of valve repair and has similar safety outcomes at 1 year to sternotomy. The results provide evidence to inform shared decision-making and treatment guidelines.

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Visual Abstract

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Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Enoch F. Akowuah, MD, Department of Cardiac Surgery, South Tees Hospitals NHS Foundation Trust, Marton Rd, Middlesbrough, TS4 3BS UK (enoch.akowuah@nhs.net).

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Mitral valve repair surgery is the preferred treatment for patients with degenerative mitral regurgitation.[1,2] When compared with mitral valve replacement, it results in lower mortality and better preservation of left ventricular function.[3]

Conventional mitral valve repair surgery (sternotomy) is routinely performed via full sternotomy, enabling easy access to the heart, flexibility in myocardial protection strategies, and multiple ways of accessing the mitral valve and easing de-airing to prevent air emboli, which cause cerebrovascular accidents. The sternotomy is immobilized using wires, bands, or plates to allow sternal union around 12 weeks after surgery.[4] The invasiveness of sternotomy is associated with delayed return to presurgery physical function levels and an increase in postoperative complications.[5]

A video-assisted thoracoscopically guided minimally invasive approach to mitral repair, performed via a 4- to 7-cm lateral thoracotomy, completely avoiding sternotomy, is increasingly demanded by patients who believe it accelerates physical recovery and improves cosmesis.[6] Surgeons who favor this approach argue it reduces the time taken to recover physical function after surgery, postoperative complications, and costs by reducing hospital stay.[7,8]

Uptake of minithoracotomy is variable, with low rates in the US and the UK but high rates in Germany.[9-11] Variation is attributable to the absence of high-quality evidence from randomized clinical trials (RCTs) demonstrating equivalent or superior benefits compared with sternotomy.[12,13] There are also concerns that the increased technical complexity of minithoracotomy may impair the ability to repair complex valve lesions[14] or increase perioperative complications, particularly vascular injuries and stroke.[15,16] Consensus documents and recent guidelines have recommended that a high-quality trial is required to address this uncertainty.[17,18]

The UK Mini Mitral Trial compared the effectiveness and safety of minithoracotomy vs sternotomy mitral valve repair undertaken by expert surgeons in a multicenter RCT. It was prespecified that for minithoracotomy to be superior it would require significantly better recovery of physical function at 12 weeks after surgery, widely perceived as the most important benefit from this approach.

Key Points

Question Is minimally invasive mitral valve repair better at improving physical function at 12 weeks than conventional sternotomy mitral valve repair for degenerative mitral regurgitation?

Findings In this randomized clinical trial involving 330 patients, minimally invasive repair was not superior to sternotomy as determined by recovery of physical function at 12 weeks. Both techniques achieved high-quality and durable valve repair at 1 year with similar postoperative complications.

Meaning Minimally invasive mitral valve repair does not improve physical function at 12 weeks compared with sternotomy, but outcomes at 1 year show minimally invasive repair is as safe and effective as sternotomy for degenerative mitral regurgitation. These findings can inform shared decision-making and treatment guidelines.

Methods

Study Design

UK Mini Mitral Trial was a multicenter, superiority, RCT of minithoracotomy (intervention) vs sternotomy (control) involving patients with degenerative mitral valve disease undergoing mitral valve repair. The trial design and protocol (Supplement 1) were previously published.[19] The statistical analysis plan is available in Supplement 2.

Conducted across 10 UK National Health Service (NHS) centers, day-to-day management was by a trial management group. Independent oversight committees were appointed by the funder. Ethical approval was given by NHS Wales Ethics Committee 6 (16/WA/0156).

Participants

Participants were adults (≥18 years) with degenerative mitral regurgitation requiring mitral valve repair (**Figure 1**). All participant cases were discussed by a mitral valve heart team who made the diagnosis of degenerative mitral regurgitation and confirmed suitability for valve repair. Concomitant surgery for atrial fibrillation or tricuspid valve repair was allowed. Exclusions were concomitant coronary or aortic valve surgery that would have required another surgery. A complete list is included in trial protocol (Supplement 1). All participants provided written informed consent. Data on ethnicity was self-reported by participants and collected by the research team (**Table 1**).

Expertise-Based Randomization and Blinding

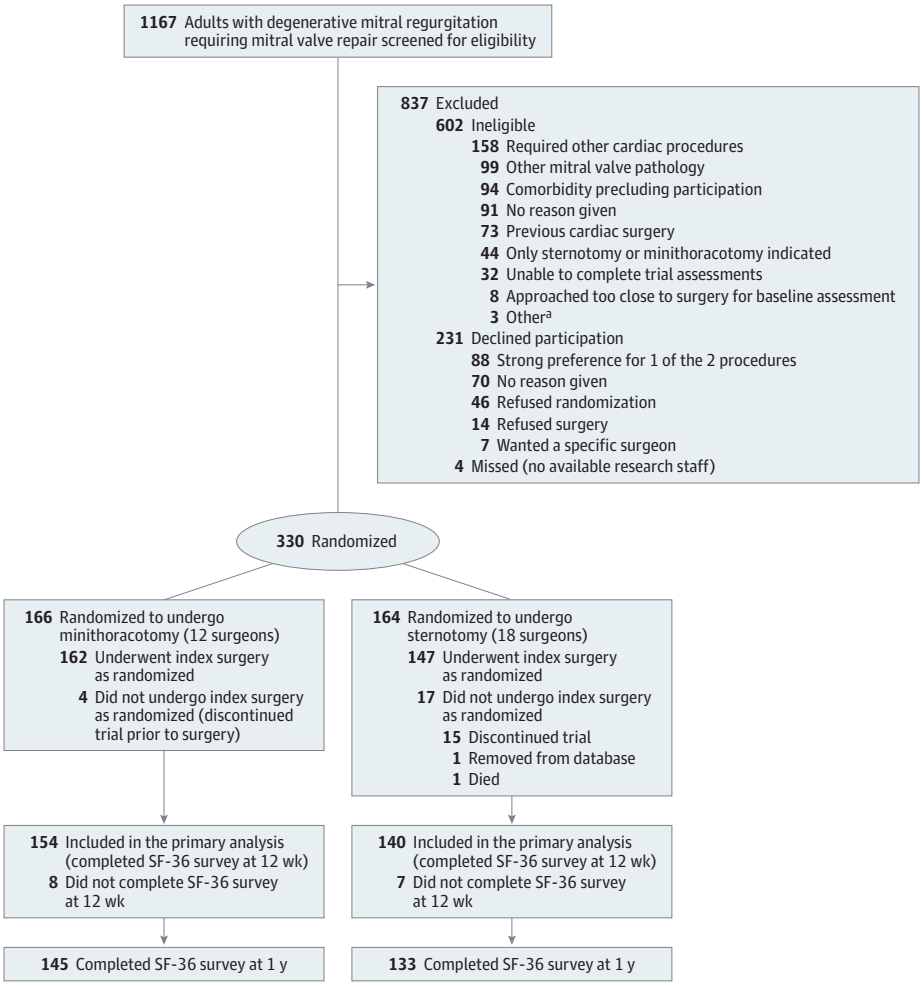
The key design challenge was to account for the surgical learning curve, the major limitations and criticisms of previous studies comparing the 2 procedures and a challenge for all trials comparing surgical techniques.

Both minithoracotomy and sternotomy mitral valve repair are technically complex procedures with steep learning curves. Expertise-based allocation was therefore adopted, following extensive consultation, to minimize bias, with participants allocated to an expert surgeon for each technique. Competency was determined by the trial steering committee after a review of individual practice for participating surgeons who were required to have performed at least 50 procedures of their allocated technique. Surgeons only performed 1 type of surgery in the trial, with each site having at least 1 surgeon expert in either minithoracotomy or sternotomy mitral valve repair.

Eligible participants were randomized at sites in a 1:1 ratio to mitral valve repair via minithoracotomy or sternotomy using a 24-hour, central, secure, web-based randomization system with concealed allocation. A minimization scheme accounted for the baseline 36-Item Short Form Health Survey (SF-36) version 2 physical functioning T score, presence of atrial fibrillation, and presence and severity of tricuspid regurgitation.

Masking of patients and clinical teams was not possible. Instead, a central independent researcher, blind to allocation, collected all SF-36 data beyond baseline for all participants. A central independent core laboratory masked to allocation interpreted all echocardiograms.

Figure 1. Patient Selection, Allocation, and Flow in the UK Mini Mitral Trial



[a] Two were private patients and 1 was a prisoner.

SF-36 indicates 36-Item Short Form Health Survey version 2 physical functioning.

Trial Surgical Interventions

Trial interventions are described in detail in Supplement 1. For the minithoracotomy, a 4- to 7-cm right lateral minithoracotomy and thoracoscopic guidance were used. For the sternotomy, the sternum was divided completely according to standard surgical technique.

Both procedures required cardiopulmonary bypass. For the sternotomy, cardiopulmonary bypass was established by siting cannulas centrally in the right atrium, venae cavae, and ascending aorta. For the minithoracotomy, peripheral cannulas and femoral vessels were used.

Mitral valve repair techniques were determined at the discretion of the operating surgeon. In both groups, valve and cardiac function were assessed with intraoperative echocardiography. Repeat cross-clamping to improve the quality of valve repair after echocardiogram examination was encouraged (**Table 2**).

Outcomes

The primary outcome was physical functioning and associated return to usual activities measured by SF-36 physical functioning scale as change from baseline 12 weeks after the index surgery.[21] The SF-36 T score ranges from 5.22 to 56.11 corresponding to 0 (no physical activity) and 100% (maximum physical activity) on the percentage scale.

Secondary outcomes included SF-36 physical functioning scores at 6, 12, 18, 24, and 36 weeks and 1 year; physical activity and sleep captured by wrist-worn accelerometers at baseline and 6 and 12 weeks; residual mitral regurgitation assessed via transthoracic echocardiography at 12 weeks and 1 year; and overall quality of life assessed using the European quality of life 5-dimension 5-level (EQ-5D-5L) scale up to 1 year.[22,23] The EQ-5D-5L values range from −0.594 (worse than death) to 1 (perfect health).

Safety outcomes included postoperative complications up to 12 weeks after surgery and a composite safety outcome of death, reintervention on the mitral valve, and hospitalizations for heart failure assessed up to 1 year after surgery. All other adverse events up to 1-year were tabulated.

Statistical Analysis

A full description of the sample size calculation is in the published protocol.[19] The sample size was calculated using the SF-36 physical functioning at 12 weeks and a minimal

Table 1. Demographics and Baseline Clinical Data

Characteristic	No./total (%) of participants	
	Minithoracotomy (n = 166)	Sternotomy (n = 163)
Demographics		
Age at randomization, mean (SD), y	67.3 (10.1)	67.0 (11.5)
Sex, No. (%)		
Male	118 (71.1)	111 (68.1)
Female	48 (28.9)	52 (31.9)
Ethnicity, No. (%)		
Asian	3 (1.8)	3 (1.8)
Black	0	1 (0.6)
Middle Eastern	0	1 (0.6)
White	163 (98.2)	155 (95.1)
Unknown	0	3 (1.8)
BMI, mean (SD)	26.5 (4.2)	26.2 (4.2)
No.	165	160
Clinical history[a]		
Atrial fibrillation	69/165 (41.8)	69/160 (43.1)
Heart failure	42/165 (25.5)	45/160 (28.1)
Pulmonary hypertension	30/162 (18.5)	24/150 (16.0)
None	132/162 (81.5)	126/150 (84.0)
Moderate (PA systolic 31-55 mm Hg)	17/162 (10.5)	16/150 (10.7)
Severe (PA systolic >55 mm Hg)	13/162 (8.0)	8/150 (5.3)
Asthma	17/165 (10.3)	13/160 (8.1)
Chronic obstructive pulmonary disease	14/165 (8.5)	11/160 (6.9)
Diabetes	7/165 (4.2)	15/160 (9.4)
Stroke	7/165 (4.2)	13/160 (8.1)
Previous myocardial infarction	6/165 (3.6)	5/160 (3.1)
Kidney failure	6/165 (3.6)	5/160 (3.1)
Peripheral vascular disease	4/165 (2.4)	1/160 (0.6)
NYHA functional class		
I, No symptoms on moderate exertion	18/166 (10.8)	20/163 (12.3)
II, Symptoms on moderate exertion	46/166 (27.7)	32/163 (19.6)
III, Symptoms on light exertion	53/166 (31.9)	52/163 (31.9)
IV, Symptoms at rest	11/166 (6.6)	14/163 (8.6)
No assessment	38/166 (22.9)	45/166 (27.6)
Urgency[b]		
Elective	148/162 (91.4)	132/50 (88.0)
In-house urgent	14/162 (8.6)	18/150 (12.0)
Euroscore II, mean (SD), No.[c]	1.7 (1.6); 16	1.7 (1.4); 15
Baseline physical function (SF-36 score)[d]		
Low (0 to ≤33)	36 (21.7)	36 (22.1)
Medium (>33-≤66)	60 (36.1)	58 (35.6)
High (>66)	70 (42.2)	69 (42.3)

Abbreviations: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; NYHA, New York Heart Association; PA, pulmonary artery; SF-36 PF; 36-Item Short Form Health Survey version 2 physical function score.

[a] Collected from patient or clinician reports.

[b] Patients admitted to the hospital in heart failure and required urgent surgery during admission.

[c] Euroscore II is operationalized as a value between 1 and 100, with higher values indicating a higher likelihood of dying before discharge from the base hospital.

[d] Baseline physical function scores are reported as percentage scores on a 0 to 100 scale with higher scores indicating better health status.

clinically important change of 10 points on the percentage scale with an SD of 30.[21,24,25] Given these assumptions, 382 participants (191 in each group) would be required to achieve 90% power at a 2-sided significance level of 5% in the absence of correlation between baseline and 12 weeks. Due to challenges with recruitment and to assess our assumptions, a masked sample-size reestimation using baseline SF-36 physical functioning data from 177 trial participants was performed. Using the reestimated SD of 26.3 with 90% power, 288 participants were required to detect a 10-point difference on the percentage scale in SF-36 physical functioning at 12 weeks. The final sample size was therefore reduced to 330, which included attrition.

The statistical analysis plan is provided in Supplement 2. The analysis of the primary outcome was performed according to the modified intention-to-treat principle and included all trial participants who had undergone randomization, received surgery, and contributed data on the primary outcome at 12 weeks.

The primary outcome of SF-36 physical function T score was analyzed using a linear mixed-effects model that adjusted for the minimization factors except for the baseline SF-36

Table 2. Cardiac Operative Data

Characteristics	No./total (%) of participants	
	Minithoracotomy (n = 166)	Sternotomy (n = 163)
Echocardiographic assessments		
Baseline mitral regurgitation[a]		
Moderate	25/158 (15.8)	33/155 (21.3)
Severe	133/158 (84.2)	122/155 (78.7)
Left ventricular end		
Systolic volume, mean (SD), mL	47.0 (18.0)	49.7 (21.4)
No.	157	155
Diastolic volume, mean (SD), mL	147.3 (45.6)	148.7 (46.6)
No.	157	155
Systolic dimension, mean (SD), cm	3.4 (0.6)	3.5 (0.7)
No.	156	157
Diastolic dimension, mean (SD), cm	5.5 (0.7)	5.5 (0.7)
No.	156	157
Left atrial volume, mean (SD), mL	118.0 (49.0)	118.5 (55.5)
No.	158	155
Mitral regurgitation		
Vena contracta, mean (SD), mm	0.8 (0.1)	0.7 (0.2)
No.	127	131
Effective regurgitant orifice area, mean (SD), cm^2	0.6 (0.3)	0.6 (0.2)
No.	139	137
Volume mean (SD), mL[d]	79.2 (30.6)	80.7 (30.9)
No.	138	137
Left ventricular function, %		
Good (>50)	120/162 (74.1)	134/150 (89.3)
Moderate (31-50)	40/162 (24.7)	15/150 (10.0)
Poor (21-30)	1/162 (0.6)	1/150 (0.7)
Very poor (<20)	1/162 (0.6)	0/150 (0.0)
Valve pathology[b]		
Posterior leaflet prolapse	114/159(71.7)	99/147 (67.3)
Anterior leaflet prolapse	14/159 (8.8)	11/147 (7.5)
Bileaflet prolapse	27/159 (17.0)	29/147 (19.7)
Normal leaflets	4/159 (2.5)	8/147 (5.4)
Operative data		
Mitral valve repair	153/160 (95.6)	142/146 (97.3)
Atrial fibrillation surgery[c]	21/160 (13.1)	20/147 (13.6)
Tricuspid valve surgery[c]	2/120 (1.7)	10/111 (9)
Repair technique		
Resection	10/157 (6.4)	28/146 (19.2)
Chords	22/157 (14.0)	39/146 (26.7)
Premeasured loops	89/157 (56.6)	48/146 (32.9)
Edge to edge	8/157 (5.1)	4/146 (2.7)
Mitral valve ring size, mean (SD), mm	31.5 (2.9)	32.7 (2.6)
No.	153	142
Cardiopulmonary bypass time, mean (SD), min	134.8 (41.0)	102.0 (74.6)
No.	159	146
Aortic cross clamp time, mean (SD), min.	85.6 (30.8)	74.5 (24.5)
No.	158	146
Duration of procedure, mean (SD), min.	228.7 (56.4)	184.3 (42.6)
No.	159	145
Repeat bypass run for valve repair or replacement	5/160 (3.1)	7/146 (4.8)

[a] Graded according to the recommendations of the European Association of Cardiovascular Imaging.[20]

[b] Isolated posterior leaflet pathology included patients with only posterior leaflet prolapse (P1, P2, P3, or percutaneous mitral commissure [PMC] and none of anterior leaflets A1, A2, A3, and antero medial commisure [AMC]). Isolated anterior leaflet pathology included patients with only anterior leaflet prolapse (A1, A2, A3, or AMC and none of the posterior leaflets P1, P2, P3, and PMC). Bileaflet pathology included patients with any 1 of P1, P2, P3 or PMC or any 1 of A1, A2, A3, or antero lateral commisure [ALC]). Normal leaflets included patients with no P1, P2, P3, PMC and no A1, A2, A3, and ALC.

[c] These cardiac procedures can be done through the mini-incision and thus were not exclusions.

[d] Calculated by the proximal isoelectric surface area (PISA) method.[20]

physical functioning score, which was included as part of the outcome to calculate change from baseline. Conversion from the percentage scale to T scores is recommended and described in the SF-36 user manual[21] and is fully described in the statistical analysis plan (Supplement 2). Initially, the model accounted for both intrasite and intraparticipant correlation by using a nested covariance matrix to obtain robust SEs. However, on further analysis, it was observed that variation between the multiple sites was negligible, and thus, only intrapatient correlation was embedded in the final model. Treatment effect estimates were expressed as mean differences with 95% CIs and *P* values.

Secondary outcomes were analyzed using all available data in the modified intention-to-treat cohort with linear mixed-effects models for continuous variables. Subgroup analyses were performed in the modified intention-to-treat cohort using the same model as the primary analysis with results visualized as a forest plot with sex, age, valve pathology, and baseline SF-36 score as prespecified characteristics. There was no correction of the type I error rate for multiple testing across secondary end points, so these are considered exploratory. Thus, reported 95% CIs have not been adjusted for multiplicity.

Sensitivity analyses were performed according to participants who had adhered to the eligibility criteria, received surgery based on randomized allocation, and completed at least 12 weeks of follow-up (per-protocol analysis), and actual surgical procedure participants received (as-treated analysis).

There were no item-level missing data in the SF-36 physical functioning scale at 12 weeks, and 294 participants have primary outcome data, more than the 288 participants required. Nevertheless, we also imputed the patient-level missing primary outcome data using an imputation model that was stratified according to randomization assignment and included minimization variables for sensitivity analysis.

Results

Participant flow in the trial is shown in Figure 1. From November 2016 through January 2021, 1167 patients were screened, of which 330 were enrolled and randomized to minithoracotomy (n = 166) or sternotomy (n = 164). Eleven participants withdrew prior to surgery, 1 sternotomy participant was removed from the database at their request, 1 died before undergoing surgery, 3 remained asymptomatic, and 5 did not receive surgery for reasons unknown. Of these, 309 participants (94%) underwent surgery in the trial; 147 of 163 participants (90%) randomized to sternotomy and 162 of 166 (98%) randomized to minithoracotomy.

The 2 groups were well matched for demographic, clinical, and echocardiographic characteristics at baseline. Mean age was 67 years and 100 (30%) were female (Table 1).

Minithoracotomy and sternotomy surgeons had performed a median of 86 and 162 procedures, respectively, prior to enrolling participants. Expertise of the operating surgeons is described in eTable 1 in Supplement 3.

Mitral valve repair was performed in 296 of 309 participants; repair rates were similar in both groups (95.6% in minithoracotomy and 97.3% in sternotomy groups; Table 2).

The mean cardiopulmonary bypass times was 32.9 minutes (95% CI, 19.46-46) longer and aortic cross clamp times was11.42 minutes (95% CI, 5.21-17.63) longer in the minithoracotomy group than in the sternotomy group.

Primary Outcome

The change from baseline in SF-36 physical function T scores at 12 weeks was a mean of 7.62 (95% CI, 5.49 to 9.78) in the minithoracotomy group and 7.20 (95% CI, 5.04 to 9.35) in the sternotomy group. The primary analysis did not demonstrate superiority of minithoracotomy vs sternotomy with a mean difference of 0.68 (95% CI, −1.89 to 3.26) between groups (**Figure 2**).

Results were consistent across the per-protocol and as-treated analyses (eFigure 1 in Supplement 3). Results of the sensitivity analyses for the imputation of missing data were similar to the primary analysis.

The mean change from baseline in the SF-36 physical function percentage scale at 12 weeks was 14.97 points (95% CI, 10.79 to 19.23) in the minithoracotomy group and 14.14 points (95% CI, 9.90 to 18.37) in the sternotomy group. The primary outcome was reanalyzed on the percentage scale and the results were consistent with the standardized T score (see eTable 2 in Supplement 3).

No statistically significant interactions were observed in any subgroup analyses (eFigure 2 in Supplement 3).

Secondary outcomes

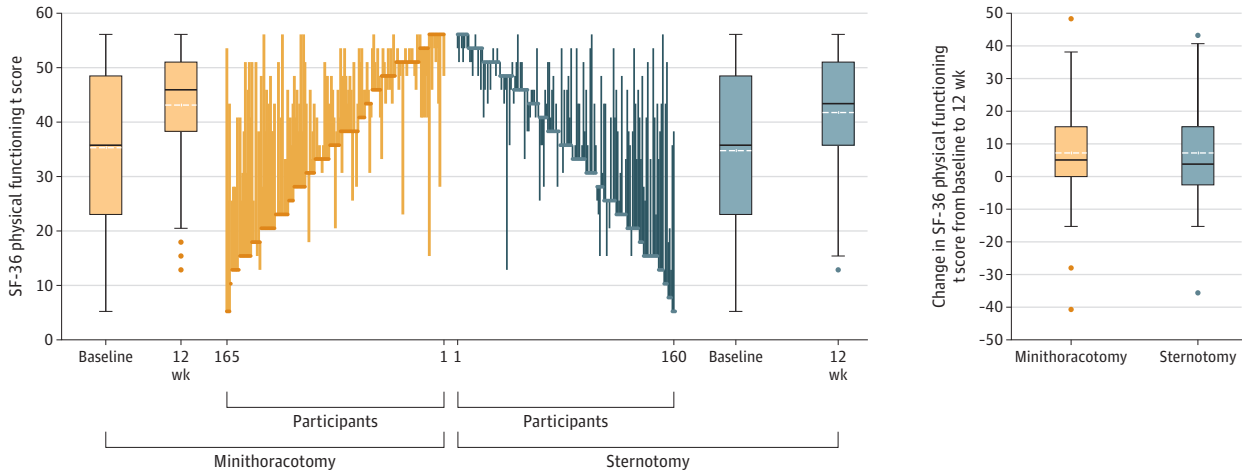
Postoperative echocardiographic assessment demonstrated that the mitral regurgitation grade of none or mild for 147 of 155 participants (95%) in the minithoracotomy group and 134 of 139 (96%) in the sternotomy group at 12 weeks (**Figure 3**). At 1 year, 123 of 133 patients (92%) in the minithoracotomy group and 126 of 137 patients (92%) in the sternotomy had a mitral regurgitation grade of none or mild (eTable 3 in Supplement 3). Full echocardiography data are shown in eTable 3 Supplement 3.

The summary of the SF-36 physical function T scores up to 1 year are shown in eTable 6 and eFigure 3 in Supplement 3. No significant differences between groups were seen at any time point.

Time spent engaging in moderate to vigorous physical activity decreased from baseline to 6 and 12 weeks after surgery in both groups; the difference in mean change in time spent engaging in moderate to vigorous exercise favored minithoracotomy surgery by 9.97 minutes (95% CI, 2.46 to 17.49) 6 weeks after surgery (eFigure 4 in Supplement 3). There was no significant difference in the time spent engaging in moderate to vigorous exercise 12 weeks after surgery. Compared with baseline, sleep efficiency increased by a mean of 5% more (95% CI, 0 to 0.09%) at 12 weeks in the minithoracotomy group vs the sternotomy (eFigure 4 in Supplement 3).

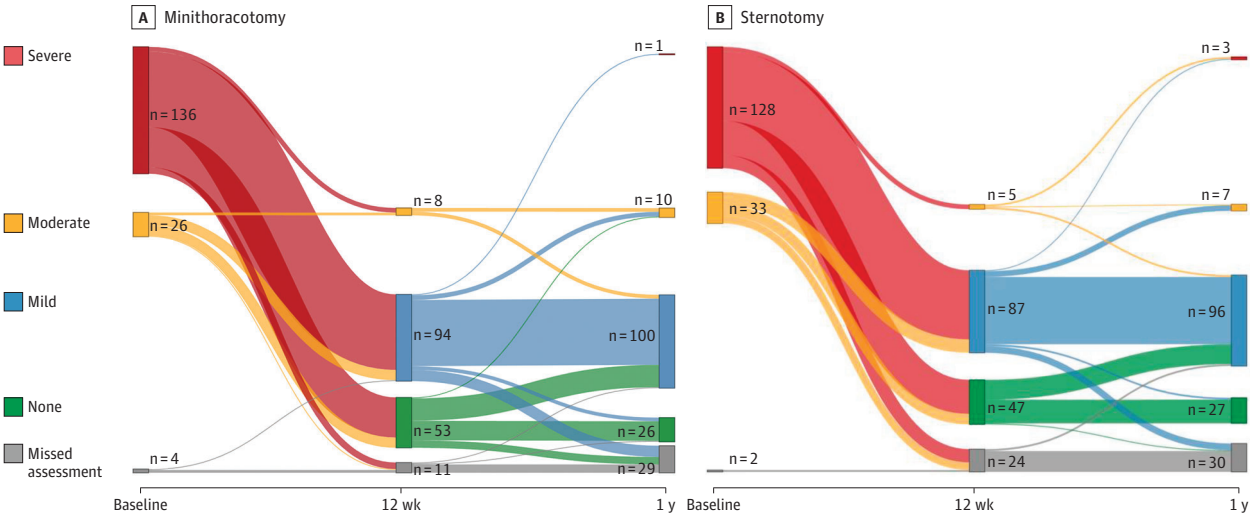
Median postoperative length of hospital stay was reduced after minithoracotomy by 1 day with a median of 5 days (IQR, 4-7) compared with 6 days (IQR, 5-8) after sternotomy

Figure 2. Changes in 36-Item Short Form Health Version 2 Physical Functioning T Score in Patients Undergoing Minithoracotomy vs Conventional Sternotomy



The parallel line plot includes 1 vertical line for each participant. The lines extend from the baseline value to the 12-week value. Ascending lines indicate an improvement. Baseline values are arranged in ascending order for the minithoracotomy group and descending order for the conventional sternotomy group. The ends of the boxes in the boxplots indicate the first and third quartiles; the middle black lines, the median; and the white dashed lines, the mean. Whiskers extend to the upper and lower adjacent values, the location of the furthest point within a distance of 1.5 interquartile ranges from the first and third quartiles. Dots indicate extreme values. For the 36-Item Short Form Health version 2 physical function T score calculation, see the Methods section.

Figure 3. Mitral Regurgitation Severity From Transthoracic Echocardiogram Data at Baseline, 12 Weeks, and 1 Year



Mitral regurgitation was graded according to the recommendations of the European Association of Cardiovascular Imaging. The Sankey plots include all participants in each group, displayed with bars proportional to the number in each category of mitral regurgitation severity at each time point.

Echocardiography demonstrated reduction in mitral regurgitation to none or mild for 92% of participants at 1 year with no difference between groups. Transthoracic echocardiogram assessments were missed by 10.6% of participants at 12 weeks and 17.9% at 1 year (Supplement 3).

(1 day, 95% CI, 0.00003-1.00002; P = .004; eTable 7 in Supplement 3). The proportion of patients discharged early (defined as ≤4 days after surgery) was greater following minithoracotomy (33.1% for minithoracotomy vs 15.3% for sternotomy); the odds of being discharged early was 2.81 higher in minithoracotomy group (95% CI, 1.6-4.94, P = <.001; eTable 7 in Supplement 3).

Quality of life measured derived from responses to EQ-5D-5L questionnaire at each time point are shown in eTable 4 in Supplement 3. There was no difference in scores between groups at any time point.

Postoperative Complications and Safety

At 12 weeks, 1 participant (0.6%) in the minithoracotomy and 4 (2.5%) in the sternotomy group died. Stroke with permanent neurological deficit occurred in 1 participant (0.6%) in the minithoracotomy group and 5 (3.5%) in the sternotomy group (**Table 3**). Reoperation for bleeding during the index operative

Table 3. Postoperative Complications Measured up to 12 Weeks After Surgery

	No. (%) of participants	
	Minithoracotomy (n = 166)	Sternotomy (n = 163)
Death[a]	1 (0.6)	4 (2.5)
Transient ischemic attack	7 (4.2)	3 (1.8)
Stroke with permanent deficit	1 (0.6)	5 (3.1)
Myocardial infarction[b]	0	1 (0.6)
Tracheostomy	3 (1.8)	0
Acute kidney injury[c]	3 (1.8)	4 (2.5)
Prolonged ventilation (>48 h)	4 (2.4)	3 (1.8)
Prolonged intensive care stay (>48 h)	21 (12.7)	19 (11.7)
Intraoperative conversion from minithoracotomy to Sternotomy	9 (5.4)	
Mitral valve replacement	8 (4.8)	5 (3.1)
Reoperation for bleeding during index hospital stay	1 (0.6)	4 (2.5)
Received red blood cell or blood product transfusion[d]	44 (26.5)	45 (27.6)
Wound pain scores, mean(SD)[e]		
3 d	2.6 (2.4)	3.0 (2.3)
6 wk	1.5 (1.9)	1.9 (1.9)
12 wk	0.8 (1.3)	1.0 (1.6)
New postoperative atrial fibrillation[f]	20 (12.1)	22 (13.5)
Wound infection[g]		
Thoracotomy		
Deep	0	
Superficial	7 (4.2)	
Sternal		
Deep		3 (1.8)
Superficial		9 (5.2)
Groin		
Deep	1 (0.6)	
Superficial	8 (4.8)	

[a] One additional patient died prior to surgery in the sternotomy group.

[b] One patient with a myocardial infarction died.

[c] Defined as 150% increase in serum creatinine over baseline with or without replacement therapy.

[d] Includes platelets, fresh frozen plasma, and cryoprecipitate.

[e] Measured by a visual analogue scale of 0 to 10, with 0 being no pain and 10 being the most severe pain experienced.

[f] Patients in sinus rhythm sinus rhythm preoperatively and in atrial fibrillation postoperatively.

[g] Wound infections were classified as deep infections when requiring hospital admission and intravenous antibiotics and superficial when requiring only oral antibiotics and treated as an outpatient basis.

stay occurred in 1 participant (0.6%) in the minithoracotomy group and 4 (2.5%) in the sternotomy group (Table 3). Changes in New York Heart Association scores at 6 and 12 weeks were similar and are shown in eFigure 5 in Supplement 3.

At 1 year, 4 minithoracotomy and 4 sternotomy participants had died; 0 vs 1 had undergone repeat mitral valve surgery; and 3 vs 5 had been hospitalized for heart failure. The odds ratio for the prespecified composite safety outcome was 0.88 (95% CI, 0.34-2.25; P = .78; eTable 8 in Supplement 3).

At 1 year, 136 patients (82%) in the minithoracotomy group and 124 (76%) in the sternotomy group experienced an adverse event (eFigure 6 in Supplement 3).

Discussion

This multicenter, RCT of minithoracotomy vs sternotomy mitral valve repair demonstrated no difference between the groups for the primary outcome of mean change in SF-36 physical function T score from baseline to 12 weeks. This finding was consistent across all prespecified secondary and sensitivity analyses.

Analysis of secondary outcomes demonstrated that time spent undertaking moderate to vigorous physical activity was higher among participants receiving minithoracotomy at 6 weeks, although the treatment effect was small at an average of 9 minutes and was not different at 12 weeks. Serial quality of life scores and physical function T scores were not different between groups.

Although repair techniques were at the discretion of the surgeons and differed between the 2 procedures, high rates of valve repair and low rates of recurrent mitral regurgitation were observed in both groups. Cardiopulmonary bypass times were longer with minithoracotomy, but postoperative complications and adverse events were similar. There was no difference between the 2 groups with respect to the prespecified safety outcome.

The trial addresses a major area of uncertainty in cardiac surgery and a topic that has been identified as a research priority by participants.[26] The importance of identifying the best surgical approach is especially pressing as new percutaneous treatments for degenerative mitral regurgitation emerge.

The trial has several strengths. First, to our knowledge, it is the largest RCT to date to compare the 2 techniques and accounts for the impact of the learning curve on outcomes.[27] Expertise-based randomization created challenges, with some participants moving between expert surgeons after randomization, but it ensured a comparison of the 2 techniques undertaken by skilled surgeons. Second, the choice of recovery

of physical function as the primary measure of effectiveness was made after extensive stakeholder engagement. We consulted patients about the factors that would influence their decision about which procedure they would prefer if referred for mitral valve repair surgery. They expressed the view that the most important factor would be recovery of physical function after surgery.[24,25,28] The tool has a 4-week recall period, takes only a few minutes to complete, has high precision, and in this trial was captured by an independent assessor blinded to allocation. Third, the minimal clinically important difference was determined following clinical and patient engagement to reach consensus and reference to the literature.[24,25] The minimal clinically important difference and conversion to T scores in our analysis is endorsed in the SF-36 version 2 user manual[21] and enables comparability with a UK population. A secondary analysis in untransformed physical function data had the same result.

Only 1 RCT comparing minithoracotomy vs sternotomy mitral valve repair has been reported previously.[29] The single-center RCT trial recruited 140 participants with Barlow disease and reported broadly similar results, specifically no difference in mortality, morbidity, or recurrent mitral regurgitation between the groups. Alternatively, propensity-matched comparisons of observational data have shown associations between minithoracotomy and reduced risk of short-term complications, although these analyses do not provide the protection against biases that randomization does.[30,31] All previous analyses have been limited by lack of echocardiographic or clinical data beyond the immediate postoperative period, creating a key knowledge gap. This is addressed in the current trial by ascertainment of clinical and echocardiographic outcomes to 1 year. These new data will provide important information to support shared decision-making and treatment guidelines.

Limitations

This trial has important limitations. First, it was not blinded. To minimize bias, the SF-36 and all echocardiographic measures were independently assessed by personnel masked to allocation. Moreover, detection bias attributable to participant unmasking would have likely favored the less invasive therapy, suggesting that this was not a source of bias in this trial. Second, to avoid the impact of a learning curve and to account for surgical expertise, set criteria for the minimum number of operations performed for all surgeons were achieved prior to performing surgery in the trial. As such, the results may not be applicable for nonexpert surgeons or centers.

Conclusions

The UK Mini Mitral trial confirms in a multicenter RCT that minithoracotomy mitral valve repair achieves high-quality and durable valve repair up to 1 year with similar safety outcomes to sternotomy. But at 12 weeks, the change in physical function from baseline was not significantly different.

ARTICLE INFORMATION

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Author Affiliations: Department of Cardiac Surgery, the James Cook University Hospital, South Tees Hospitals NHS Foundation Trust, Middlesbrough, United Kingdom (Akowuah, Graham); Academic Cardiovascular Unit, the James Cook University Hospital, South Tees Hosptials NHS Foundation Trust, Middlesbrough, United Kingdom (Maier); Newcastle Clinical Trials Unit, Newcastle University, Newcastle Upon Tyne, United Kingdom (Hancock, Mathias, Walmsley, Howe); Department of Anthropology, Durham University, Durham, United Kingdom (Kharatikoopaei, Wagnild, Kasim); Population Health Sciences Institute, Newcastle University, Newcastle Upon Tyne, United Kingdom (Vale, Fernandez-Garcia); Department of Mathematical Sciences, Durham University, Durham, United Kingdom (Ogundimu); Now with GSK, United Kingdom (Kasim); Department of Cardiovascular Sciences and NIHR Leicester Biomedical Research Unit in Cardiovascular Medicine, University of Leicester, Leicester, United Kingdom (Murphy); The Lancashire Cardiac Center, Blackpool Teaching Hospitals NHS Foundation Trust, Blackpool, United Kingdom (Zacharias).

Author Contributions: Dr Akowuah had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Akowuah, Maier, Hancock, Kharatikoopaei, Vale, Kasim, Murphy, Zacharias.
Acquisition, analysis, or interpretation of data: Akowuah, Maier, Hancock, Kharatikoopaei, Vale, Fernandez-Garcia, Ogundimu, Wagnild, Mathias, Walmsley, Howe, Kasim, Graham, Murphy.
Drafting of the manuscript: Akowuah, Maier, Hancock, Kharatikoopaei, Vale, Fernandez-Garcia, Ogundimu, Wagnild, Mathias, Walmsley, Howe, Kasim, Graham, Murphy.
Critical revision of the manuscript for important intellectual content: Akowuah, Maier, Hancock, Kharatikoopaei, Vale, Fernandez-Garcia, Mathias, Kasim, Graham, Murphy, Zacharias.
Statistical analysis: Akowuah, Kharatikoopaei, Ogundimu, Wagnild, Kasim.
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Other - health economics analysis: Vale, Fernandez-Garcia.
Other - trial management: Mathias, Walmsley.

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Members of the steering committee and independent data monitoring and ethics committee: Are listed in Supplement 5.

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