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Mini-Sternotomy Versus Conventional Sternotomy for Aortic Valve Replacement

Outcomes following aortic valve replacement (AVR) surgery are generally excellent, with in-hospital observed mortality in the United Kingdom of 1.5% for first-time elective procedures (1). These results are not observed in all populations; in high-risk groups, conventional surgery risks perioperative organ injury and prolonged recovery, with death occurring in up to 31% of patients within 1 year of surgery (2). Minimally invasive surgery combines the durability of surgical repair with reductions in surgical trauma, which together should reduce perioperative morbidity. However, reductions in morbidity and resource use (3) may be confounded by multiple sources of bias and are at odds with the limited evidence from trials that have not shown improved outcomes (4). There is variability in the uptake of minimally invasive surgery internationally, and conventional AVR remains the mainstay for the majority of patients. Minimally invasive surgery requires robust evaluation to better understand its utility.

MAVRIC (Manubrium-limited ministernotomy versus conventional sternotomy for aortic valve replacement) was a single-center, single-blind, randomized superiority trial comparing AVR via manubrium-limited mini-sternotomy using a 5- to 7-cm midline incision (intervention) and conventional median sternotomy using a midline incision from the sternal notch to the xiphisternum (usual care) assessing postoperative red cell transfusion.

The trial was prospectively registered (ISRCTN29567910) and published (5). Patients were stratified by baseline logistic EuroSCORE and hemoglobin and were followed for 12 weeks. The primary outcome was the proportion of patients receiving red cell transfusion within 7 days of surgery.

Using the Fisher exact test with 90% power, 5% alpha, we estimated that 260 patients would be required to detect a 17% reduction in the proportion of patients requiring a red cell transfusion (13% compared with 30%), using a 2-sided test. Allowing for loss to follow-up, the sample size was increased to 270.

A total of 271 patients were randomized using a computer system with concealed allocation; 270 received surgery and contributed to the intention-to-treat analysis. Patients were blinded to the type of sternotomy they received until after they completed their day 2 quality-of-life and pain assessments.

Baseline characteristics were similar between the groups. Mean age 69.3 ± 9.3 years (mini-sternotomy group) and 68.7 ± 8.4 years (conventional group); range 39 to 88 years. Most were male: 57.8% (mini-sternotomy group) versus 64.4% (conventional group). Mean logistic EuroSCORE was 5.2 ± 3.5 (mini-sternotomy group) compared with 5.1 ± 3.5 (conventional group), and mean hemoglobin at randomization was 137.9 ± 14.3 g/dl (mini-sternotomy group) and 137.1 ± 16.1 g/dl (conventional group).

No difference between the mini-sternotomy and conventional groups in red cell transfusion within 7 days was found; 23 of 135 patients in each group received a transfusion, odds ratio: 1.0 (95% confidence interval: 0.5 to 2.0), risk difference 0.0 (95% confidence interval: −0.1 to 0.1) (**Table 1**). Mini-sternotomy reduced chest drain losses, mean 181.6 ± 138.7 ml versus conventional sternotomy, mean 306.9 ± 348.6 ml; this did not reduce red cell transfusions. Mean valve size and post-operative valve function were comparable between mini-sternotomy and conventional groups: 23 mm versus 24 mm, and 6 of 134 moderate or severe aortic regurgitation versus 3 of 130, respectively. Mini-sternotomy resulted in longer bypass time of 82.7 ± 23.5 min versus 59.6 ± 15.1 min and cross-clamp time (64.1 ± 17.1 min vs. 46.3 ± 10.7 min). Three experienced consultant cardiac surgeons (E.A., W.A.O., and A.G.), experts at performing both techniques, performed all operations as part of the trial: surgeon A, 58 of each operation; surgeon B, 43 mini-sternotomy and 35 conventional; surgeon C, 34 mini-sternotomy and 42 conventional. A total of 16 patients required conversion from mini to conventional sternotomy; these occurred due to: difficult vascular access (n = 9), anesthetic emergency (n = 2), and intraoperative complications (n = 5). Conventional sternotomy was more cost-effective, with a 5.8% probability of mini-sternotomy being cost-effective at a willingness to pay of £20,000/quality-adjusted life year.

TABLE 1 Red Cell Transfusions

	Mini-Sternotomy Group	Conventional Sternotomy Group	Odds Ratio (95% CI; p Value)	Risk Difference (95% CI; p Value)
Red cell transfusions				
Post-operatively to 7 days	23/135 (17.0)	23/135 (17.0)	1.0 (0.5 to 2.0; p = 0.9052)	0.0 (−0.1 to 0.1; p = 0.9999)
Post-operatively to discharge	34/135 (25.2)	29/135 (21.5)	1.4 (0.7–2.7)	
Red cell units-post-operatively to 7 days				
Number of patients	23/135	23/135		
Mean ± SD	1.6 ± 0.7	2.3 ± 1.7		
Range (min-max)	1–3	1–9		
Red cell units-post-operatively to discharge				
Number of patients	34/135	29/135		
Mean ± SD	2.5 ± 2.5	2.6 ± 2.0		
Range (min-max)	1–13	1–11		

Values are n/N or n (%) unless otherwise indicated.

The primary analysis was conducted under intention-to-treat principles, with all patients analyzed according to their allocated surgery. Results from additional "per-protocol" and "as treated" analyses were consistent with the intention-to-treat results.

MAVRIC differs from previous trials in size and by including a robust expertise-based trial design (adequately powered, randomization with allocation concealment, clarity in outcome measures and assessment, patients blinded to surgical allocation, and a health economic evaluation). The trial had some important limitations, including the single-center design; however, this will have biased treatment effect estimates away from the null, at odds with our observed effect.

MAVRIC found no additional clinical benefit of minimally invasive AVR, while increased times on cardiopulmonary bypass were observed. Our results are in agreement with the findings of a recent systematic review (4). These results further indicate that patients should be referred by cardiologists on the basis of a surgeon's experience in performing AVR, not necessarily on the basis of access approach.

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