Objective: Minimally invasive aortic valve replacement (MIAVR) has been demonstrated as a safe and effective option but remains underused. We aimed to evaluate outcomes of isolated MIAVR compared with conventional aortic valve replacement (CAVR).

Methods: Data from The National Institute for Cardiovascular Outcomes Research (NICOR) were analyzed at seven volunteer centers (2006–2012). Primary outcomes were in-hospital mortality and midterm survival. Secondary outcomes were postoperative length of stay as well as cumulative bypass and cross-clamp times. Propensity modeling with matched cohort analysis was used.

Results: Of 307 consecutive MIAVR patients, 151 (49%) were performed during the last 2 years of study with a continued increase in numbers. The 307 MIAVR patients were matched on a 1:1 ratio. In the matched CAVR group, there was no statistically significant difference in in-hospital mortality [MIAVR, 4/307, (1.3%); 95% confidence interval (CI), 0.4–3.4% vs CAVR, 6/307 (2.0%); 95% CI, 0.8%–4.3%; P = 0.752]. One-year survival rates in the MIAVR and CAVR groups were 94.4% and 94.6%, respectively. There was no statistically significant difference in midterm survival (P = 0.677; hazard ratio, 0.90; 95% CI, 0.56–1.46). Median postoperative length of stay was lower in the MIAVR patients by 1 day (P = 0.009). The mean cumulative bypass time (94.8 vs 91.3 minutes; P = 0.333) and cross-clamp time (74.6 vs 68.4 minutes; P = 0.006) were longer in the MIAVR group; however, this was significant only in the cross-clamp time comparison.

Conclusions: Minimally invasive aortic valve replacement is a safe alternative to CAVR with respect to operative and 1-year mortality and is associated with a shorter postoperative stay. Further studies are required in high-risk (logistic EuroSCORE > 10) patients to define the role of MIAVR.

Key Words: Aortic valve disease, Aortic valve replacement, Minimally invasive surgery.

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potential advantages, there has been limited uptake of these techniques with only 5% to 10% of isolated AVRs being performed in the USA and across Europe.12,16,17 The potential drawbacks of minimally invasive cardiac surgery are perceived increases in operative and cross-clamp times that may place patients at increased risk of adverse outcomes.

There are no clear data guiding clinical practice with regard to which patient groups would benefit from minimally invasive approaches. The objective of this research was to investigate the current real-world experience with MIAVR and report contemporaneous multicenter results for MIAVR versus a propensity-matched cohort of conventional AVRs (CAVRs) within the same institutions.

METHODS

Data Source, Validation, and Study Population

Prospectively collected data were extracted from The National Institute for Cardiovascular Outcomes Research, National Adult Cardiac Surgery Audit (NACSA) database in November 2013 for all adult cardiac surgery procedures performed in the UK. As described elsewhere, reproducible cleaning algorithms were applied to the database to clean the data.18 Briefly, duplicates were removed; transcriptional discrepancies were harmonized; conflicting data and extreme values were corrected or removed. The data are returned annually to each unit for local validation as part of the NACSA program.

For this study, procedures were included if they corresponded to an isolated AVR (conventional or minimally invasive) performed in a participating hospital with a procedure date between December 1, 2006, and November 30, 2012. Transcatheter aortic valve implantations (TAVIs) were identified and excluded. Patients were identified as having undergone MIAVR using pseudonymized National Health Service (NHS) or hospital numbers supplied by each participating center; all other patients were assumed to have undergone CAVR. Exclusion criteria for this study were indication (or missing data) of nonelective surgery, previous cardiac surgery, critical preoperative state, use of preoperative intravenous nitrates, and renal dysfunction (defined as patient on dialysis or preoperative serum creatinine > 200 μmol/L).

Follow-up data up until the point of discharge were collected through the NACSA, with postdischarge survival data collected through linkage to the Office for National Statistics registry. For a small number of patients discharged alive with no available record linkage, the patients were followed up to the point of discharge only. Database variable definitions used for the study are available at http://www.ucl.ac.uk/nicor/audits/Adultcardiacsurgery/datasets, and variables generated within this study predominately follow the definitions as given by the EuroSCORE model.19

Outcome Measures

The primary outcomes for this study were (1) in-hospital mortality defined as death due to any cause during admission to the base hospital for cardiac surgery and (2) midterm survival. Secondary outcomes were postoperative length of stay (PLOS), cumulative bypass time, and cumulative cross-clamp times. Patients who died in the hospital on the day of surgery were recorded as having a PLOS of 0.5 days.

Missing Data

All missing patient characteristic and preoperative data were imputed using a chain equation method that generates “plausible” synthetic values for each missing risk factor. Because the amount of missing data was low, a single imputation approach was preferred to multiple imputations. Variables used in the imputation models included those listed in Table 1, a hospital-level indicator and in-hospital mortality.20 Imputation was performed using the MICE package (version 2.18) in R.21 All analyses from here onward are based on the imputed data. Missing outcome data (bypass time, cross-clamp time, PLOS) were evaluated on a case-complete basis.

Propensity Score Matching

A propensity-matched analysis was used to account for inherent confounding.22 The propensity score model was developed by fitting a nonparsimonious multiple logistic regression models with AVR type (minimally invasive vs conventional) as the outcome variable with independent variables as listed in Table 1. This model was used to calculate a propensity score for each record. Patients who received MIAVR were then matched (1-to-1 matching) to patients who underwent CAVR using nearest neighbor matching with a greedy matching algorithm.

After matching, the balance between the two groups was evaluated by comparing the patient and preoperative characteristics using standardized differences and graphical comparison of propensity score distributions. An absolute standardized difference of less than 10% supports the assumption of balance between the two groups.23 Propensity matching and diagnostic checking were performed using the MatchIt package in R (version 2.4-21).22

Statistical Analysis

In the matched groups, in-hospital mortality was compared between the MIAVR and CAVR groups using Fisher exact test. In addition, an odds ratio was estimated with a corresponding 95% confidence interval (CI). Midterm survival was compared between the matched groups using Kaplan-Meier survival curve methodology stratified on operation type, and the log-rank test was used to test for differences between them. The hazard ratio for MIAVR was also estimated by fitting a Cox proportional hazards regression model with operation as the sole independent variable. Postoperative length of stay was compared between the two groups using a two-sided nonparametric Mann-Whitney U test. Cumulative cross-clamp times and cardiopulmonary bypass (CPB) times were compared using an independent samples t test.

For the analysis of outcomes in propensity score–matched groups, there is no general statistical consensus on whether an independent or matched-pairs analysis should be applied.24,25 We primarily focus on the independent groups analysis; however, as sensitivity analysis, the data have also been analyzed using methodology suitable for a matched-pairs design. Namely, for in-hospital mortality, McNemar test is used; for midterm survival-stratified log rank tests, stratifying on the matched-pairs is used; for PLOS, the Wilcoxon signed rank test is used; and for cross-clamp and CPB time comparisons, a paired t test is applied. All analyses were
performed in R version 3.0.2 (R Development Core Team, Vienna, Austria). In all cases, a $p < 0.05$ was considered significant.

### Operative Technique

The patients were operated on according to standard AVR techniques. We report the St Thomas' technique that is typical of the minimally invasive strategy. The contributing units have minor variations to this technique and differences dictated by patient-specific anatomical and physiological factors.

The patients were anesthetized in the supine position and intubated with a single-lumen endotracheal tube. Defibrillator pads were placed over the chest wall and back. A transvenous...
pacing system was inserted at some centers via the internal jugular vein. Transesophageal echocardiography was used routinely in most cases to allow assessment of aortic valve anatomy, annular sizing, deairing, and assessment of post-operative valve and cardiac function. After skin preparation and draping, a 4- to 6-cm skin incision usually an upper J hemisterntomy through the third or fourth intercostal space was performed. To enable smaller venous cannulae, vacuum-assisted drainage was used in some patients. A triple-stage venous cannula was used in most cases, placed in the superior vena cava. Some patients necessitated peripheral cannulation, depending on body habitus and cardiac anatomy. The aorta was cannulated for arterial return. The majority of cases used mild hypothermic 32°C to normothermic CPB with aortic cross-clamping. Antegrade blood cardioplegia was used in most cases. Aortic valve replacement was performed using interrupted or semicontinuous technique as per surgeon preference. Before closure of the aorta, the operative field was flooded with CO₂ to minimize the chance of air embolism. The lungs were also inflated to expel air from the left ventricle and aorta. Deairing was monitored using transesophageal echocardiography. On completion, the patient was decannulated, and ventricular pacing wire was placed. The sternum was closed with wires behind a standard chest or Blake drain. The wound was closed in layers.

**RESULTS**

**Data Set and Demographics**

After applying the study inclusion and exclusion criteria, a final cohort of 4163 procedures was identified (307 MIAVR and 3856 CAVR). Full details are provided in the data flow diagram in Figure 1. The proportion of missing data was less than 2% for all patient and operative characteristics, with the exception of neurological dysfunction (5.0%) and pulmonary hypertension (2.7%). Outcomes were complete as follows: inhospital mortality for all records (100%), postdischarge discharge follow-up survival data in 4088 records (98.2%), PLOS in 4123 records (99.0%), as well as cumulative bypass and cross-clamp times present in 4098 (98.4%) and 4103 (98.6%) records, respectively.

The proportion of AVRs performed as MIAVR cases at the participating hospitals doubled during the 6-year study period from 5.3% to 10.0% (Fig. 2). Of the seven units included, there was one outlying center that performed 25.3% of AVR cases as MIAVR, whereas the others performed between 1.5% and 9.3% of cases as MIAVR (Fig. 3). The distributions of logistic EuroSCORE in the MIAVR and CAVR cohorts have remained comparable throughout the study (Supplementary Digital Content, http://links.lww.com/INNOV/A71).

**Propensity Score Matching**

All 307 MIAVR records were matched to 307 CAVR records. A summary of patient demographics and risk factors before and after propensity matching based on imputed data is given in Table 1. Before matching, there was imbalance in study year, with a 25.4% standardized difference in favor of
A growing number of MIAVR cases were performed in the latter half of the study; proportion of patients in New York Heart Association class IV (6.5), Canadian Cardiac Society IV (10.8), clinically urgent (11.2), being treated for infective endocarditis (9.2), or with neurological symptoms (4.6) was higher in the CA VR group. However, the absolute standardized differences were small (G7%) for all variables after matching, and so the two cohorts were considered adequately balanced (Table 1). The distributions of propensity scores before and after matching are more closely aligned after matching.

In-Hospital Mortality Analysis

For the matched groups, there was no statistically significant difference in in-hospital mortality between the two groups (P = 0.663): CAVR, 6/307 (2.0%; 95% CI: 0.8%–4.3%) versus MIAVR, 4/307 (1.3%; 95% CI, 0.4%–3.4%), yielding an odds ratio of 0.66 (95% CI, 0.19–2.37) for MIAVR. Inferences were unchanged using matched-pairs analysis (P = 0.752).

Survival Analysis

Five records in the CAVR propensity-matched group could not be linked to the Office for National Statistics death registry. These records were therefore censored at point of discharge. Sensitivity analyses with the exclusions did not result in any changes in inferences. The median follow-up time was 2.6 years (interval range, 2 days to 6.7 years). There was no significant difference in midterm survival between the matched MIAVR and CAVR groups as shown in Figure 4 (P = 0.677).

The estimated hazard ratio in the matched groups was 0.90 (95% CI, 0.56–1.46). Survival at 1 year in the MIAVR group was 94.4% (95% CI, 91.9%–97.0%) and in the CAVR group was 94.6% (95% CI, 92.1%–97.2%). Survival at 5 years in the MIAVR group was 87.5% (95% CI, 83.1%–92.2%) and in the CAVR group was 85.5% (95% CI, 80.4%–91.0%). Inferences were unchanged using matched-pairs analysis (P = 0.668).

**Secondary Outcomes**

Postoperative length of stay was significantly longer in the CAVR matched group, with a difference in median values of 1 day (P = 0.004) (Table 2). The mean cross-clamp and CPB times were 6.3 and 3.5 minutes longer for the MIAVR group, respectively (Table 2, Fig. 5); however, this difference was only significant for the cross-clamp times (P = 0.006 and P = 0.333, respectively). Inferences were unchanged using matched-pairs analysis (P = 0.010 and P = 0.355, respectively).

**DISCUSSION**

This study demonstrates that MIAVR has comparable outcomes with those of CAVR with regard to in-hospital mortality and midterm survival when analyzed at 1 and 5 years. Small increases in cross-clamp and CPB times for MIAVR were demonstrated, but these are unlikely to have impact on outcomes. A statistically significant shorter PLOS was present in the MIAVR group. The strength of this study is the propensity-matched comparative analysis of MIAVR outcomes. This study combines contemporary national MIAVR experience to CAVR experience at the same cardiac centers and thus provides accurate real-world outcome data for MIAVR.
We wrote to all centers in the UK to invite them to participate in this study. Nine enthusiastic centers responded, and seven are included where the data collected were robust and complete; other units did not participate, and therefore, this work represents a snapshot of contemporary practice in the UK. The data demonstrates that MIA VRs are increasingly performed, with an increase in numbers as a total percentage of A VRs. The proportion doubles during the study period.

Based on the results of this study, MIA VR is a safe alternative to CA VR, with 98.6% of patients surviving to hospital discharge. The reduction in PLOS in the MIAVR group may be a surrogate marker for reduced postoperative complications. Survival at 1 year exceeds 94% for both MIAVR and CA VR, and there is no difference in midterm survival.

Although the percentage of MIAVRs increased during the study period, MIAVR still represents a small proportion of total caseload even at the enthusiastic centers participating in this study. There are wide variations in the number of centers undertaking MIAVR and the number of surgeons involved at those centers. Practice is known to range between surgeons who have a default minimally invasive approach where all first-time isolated AVRs are performed as minimally invasive operations to those who exclusively perform CA VR.

There are areas of concern for cardiothoracic surgeons regarding technique for CPB during MIAVR. These pertain to the limited cardiac exposure that has numerous theoretical risks (including placement of cannulae, adequate cardioplegia, and cardiac venting). Limited exposure might limit assessment of volume-loaded ventricles, deairing of the heart, placement of pacing wires, or a retrograde cardioplegia cannula. Transesophageal echocardiogram mitigates some of these problems, as well as instillation of CO2 into the operative field, anterior placement of pacing wires, and manipulation of empty ventricles on CPB to avoid right ventricular injury. The data do not allow us to comment on the conversion rate to full sternotomy for technical difficulties. Published data on conversions show it to be in the region of 1% to 3%.13 In the presence of similar CPB and cross-clamp times in our cohort, it is likely that the surgeons undertaking the procedure have achieved the learning curve for the techniques.

### Table 2. The Cardiopulmonary Bypass and Cross-Clamp Times and Postoperative Length of Stay Across the Propensity-Matched MIAVR and CAVR Cohorts

|                | MIAVR | CAVR | Independent Samples Analysis | Matched-Pairs Analysis |
|----------------|-------|------|-----------------------------|------------------------|
| PLOS,* median (Q1-Q3), d | 6 (5–8) | 7 (5–10) | 0.004                       | 0.009                  |
| CPB time,† mean (SD), min     | 94.8 (34.6) | 91.3 (53.4) | 0.333                       | 0.355                  |
| Cross-clamp time,‡ mean (SD), min | 74.6 (28.8) | 68.4 (27.4) | 0.006                       | 0.010                  |

*Two values were missing in the CAVR group.
†Five values were missing in the CAVR group and two values in the MIAVR group.
‡Five values were missing in the CAVR group and two values in the MIAVR group.

CAVR, conventional aortic valve replacement; MIAVR, minimally invasive aortic valve replacement; PLOS, postoperative length of stay; Q1, first quartile; Q3, third quartile.

![Figure 5](image-url) Corner density distributions of cumulative CPB and cross-clamp times by AVR type in the propensity-matched cohort. Note the horizontal axis is on a logarithmic-transformed scale to aid interpretation. AVR, aortic valve replacement; CPB, cardiopulmonary bypass.
There is apparent clinical equipoise between the two techniques. Minimally invasive AVR is safe, and multiple benefits have been reported in retrospective, propensity-matched, and randomized prospective studies. Previous studies of MIAVR have demonstrated reduced length of stay, with no change in mortality or operative times.\textsuperscript{12,27} The meta-analyses of multiple randomized trials have demonstrated decreased length of ITU stay and hospital stay,\textsuperscript{11,12} ventilation times,\textsuperscript{10} blood loss,\textsuperscript{10,11} and incidence of arrhythmias\textsuperscript{10} as well as improvement in pulmonary spirometry, sternal stability, and wound pain.\textsuperscript{15,28} However, a need remains for large adequately powered study to conclusively determine the advantages of MIAVR and in which patient population these benefits apply to.

Intuitively, these advantages might specially apply to higher-risk elderly patients with poorer physiological reserves and who might tolerate minimally invasive procedure better with a quicker recovery.\textsuperscript{29} The reasons for these reported benefits could be the maintenance of the bony continuity of the ribcage with preservation of respiratory dynamics, improved sternal stability, reduced pain, and less risk of chest and sternal infections. There might also be a reduction in bleeding as less bone marrow and periosteum are exposed with reduced cardiac dissection during surgical access.

The role of minimally invasive techniques in surgical AVR within the setting of sutureless valve technology and TAVI needs to be defined. Surgical AVR remains the criterion standard for patients requiring AVR. At present, although TAVI is only recommended for patients who are high-risk for surgical AVR, data from German registries have begun to demonstrate that “risk creep” is already occurring in transcatheter aortic valve procedures with some centers advocating expanding TAVI to younger lower-risk groups.\textsuperscript{30} In addition, a number of TAVI studies on intermediate-risk patients are on the way. The PARTNER II trial seeks to evaluate outcomes in patients with aortic stenosis and The Society of Thoracic Surgeons (STS) score of 4% to 6% and compare patients to CAVR. Patients with concomitant coronary artery disease will be randomized to percutaneous coronary intervention plus TAVI versus coronary artery bypass graft surgery plus AVR. As a noninferiority study, it will directly compare CAVR with transaortic (TAo) TAVI, transapical (TA) TAVI, or transfemoral-TAVI. Additional nested registries will also analyze outcomes in patients who are unsuitable for femoral access that are randomized to TA-TAVI or transapical TAVI versus surgery. This strategy will seek to marry the advantages of the miniAVR access approach with balloon deployed TAVI device. Similarly, the Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial will include patients older than 70 years with an STS score of 3% to 8%.

The stent valve evolution will deliver a greater range of sizes of prosthesis through smaller totally percutaneous delivery systems. Novel valve designs are currently in early human studies to improve the incidence of paravalvular leak, for instance, with the addition of sealing cuffs to variations of nitinol frames.\textsuperscript{31} Numerous cerebral embolic protection devices aim to catch debris from the aorta and reduce the neurological morbidity from the procedure.\textsuperscript{32} Percutaneous closure devices for femoral access vessels are being routinely used with smaller delivery sheaths, and percutaneous left ventricular apex closure is in animal testing stages.\textsuperscript{33}

If surgeons are to remain actively engaged in the heart valve team driving technical improvements in TAo and TA techniques, this is likely to begin with assessing the impact of MIAVR for surgical cases and likely to evolve into completely minimally invasive/port access implantation of transcatheter devices for high/intermediate-risk patients. One of the centers involved in this study has an active TAo-TAVI program, and it is likely that these techniques will develop in parallel.\textsuperscript{34} The presence of the heart team at units undertaking transcatheter valve procedures is increasing referrals of elderly comorbid patients now undergoing open AVR.\textsuperscript{2,35–37} However, a recent decline in CAVR work has been observed with up to 40% of aortic valve operations being performed by TAVI in 2012.\textsuperscript{37,38}

Other authors have commented on the fact that although TAVI is an attractive and viable treatment for selected high-risk patients (eg, porcelain aorta, truly frail patients, previous cardiac surgery, patient grafts), surgical minimally invasive access AVR should be regarded as a criterion standard for all the rest of the patients. The functional outcomes are excellent, including valve durability, low incidence of stroke, and no paravalvular leak, which are of paramount importance. For octogenarians, the results of MIAVR are better than often assumed.\textsuperscript{29,38} Even when MIAVR is performed in patients with mean logistic EuroSCOREs of 17% (leading into the accepted TAVI range), the midterm survival is good, with inhospital mortality of 7.8% and freedom from all-cause death at 5 years at 72.4%.\textsuperscript{2,39} Outcomes in 175 octogenarians from a cohort of more than 1000 MIAVR patients demonstrated an operative mortality of 2%.\textsuperscript{13}

Minimally invasive AVR might offer additional advantages to the sutureless valve technologies that are perceived to be an alternative treatment for high surgical risk patients with severe aortic stenosis. Sutureless valves aim to minimize CPB and cross-clamp times by using novel rapid valve deployment techniques. One-year outcomes for the Edwards INTUTITY Valve System as part of the TRITON trial report MIAVR in 48.8% of cases with overall cumulative survival of 92.5% at 9.8 months. The CPB and cross-clamp times are reported as 75 minutes and 46.6 minutes with 54% of cases being isolated AVR.\textsuperscript{2,5} There are other INTUTITY studies that are planned; with CADENCE-MIS, the benefits of MIAVR coupled with rapid deployment valves will be studied versus CAVR and standard valves. The use of Percival S and ATS 3f Enable has demonstrated similar reduction in bypass times of less than 30 minutes.\textsuperscript{3,40} Comparison with STS data show 60% decrease in operative time, which might reduce the effects on myocardial ischemia and hypoxia.\textsuperscript{27}

Treatment of aortic valve disease is undergoing exciting and rapidly expanding technological developments that offer clinical and quality-of-life improvements to patients. A heart valve multidisciplinary patient-centered approach is vital to deliver best care to our patients.

**Future Research**

There seems to be genuine clinical equipoise between MIAVR and CAVR. Before widespread adoption of MIAVR
can be recommended, there is a need for a well-constructed, adequately powered prospective randomized controlled study comparing MIAVR with CAVR. To demonstrate differences in mortality, the study would need to be powered to include very large number of patients. Pragmatic approach would involve high-risk patients in whom the clinical benefits would be more pronounced for the minimally invasive techniques. The benefits in terms of reduced ITU and hospital stay need to be balanced against the costs of mini techniques. Although majority of the procedure is performed using standard AVR equipment and valves, trials are already underway to compare the impact of sutureless valves. It is likely that the most benefit from these procedures will be in higher-risk elderly patients with limited physiological reserves. Increased patient preference for minimally invasive techniques and improvement in quality-of-life surveys are also important end points that will need to be considered in the randomized trials.

CONCLUSIONS

This propensity-matched study of minimally invasive aortic valve surgery is based on multicenter, “real-world” experience and shows that MIAVR is a safe and feasible procedure with excellent early and midterm outcomes for patients with aortic valve disease. In line with other authors, we have shown benefits in shorter hospital stay that might lead to more widespread use.

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**CLINICAL PERSPECTIVE**

This study evaluated the outcomes of isolated minimally invasive aortic valve replacement (MIAVR) compared with conventional aortic valve replacement (CAVR) by performing a propensity-matched study from the UK National Database. Data were analyzed from seven volunteer centers from 2006 to 2012. Three hundred seven consecutive MIAVR patients were matched in a 1:1 ratio with CAVR patients. There was no statistically significant difference in the in-hospital mortality or 1-year survival. Although there was a significantly longer cross-clamp time in the MIAVR group, median postoperative length of stay was lower in the MIAVR patients by 1 day. The authors concluded that MIAVR was a safe alternative to CAVR with a shorter postoperative length of stay.

This is an excellent multicenter study evaluating MIAVR. The propensity matching is a strength of this article but does not fully compensate for selection bias. The authors recommended that a prospective, randomized study is needed to better evaluate MIAVR. Although this is true, unfortunately, it will be difficult for surgeons experienced in the minimally invasive technique and for patients to be randomized between MIAVR and CAVR.