International Journal of Cardiology 306 (2020) 147–151

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Current trends in mitral valve surgery: A multicenter national comparison between full-sternotomy and minimally-invasive approach

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ARTICLE INFO

Article history:
Received 7 November 2019
Accepted 25 November 2019
Available online 26 November 2019

Keywords:
Cardiac surgery
Mitral valve surgery
Minimally-invasive approach
Mortality

ABSTRACT

Background: Mitral valve surgery (MVS) is evolving. Compared to standard sternotomy (S-MVS), minimally invasive method (Mini-MVS) has been increasingly adopted in the last years with encouraging results for both repairs and replacements. We evaluated trends of surgical approaches and operative outcomes in a multicenter study involving 10 cardiac surgical centers in Italy.
Methods: Patients who received isolated mitral valve surgery, including only a concomitant tricuspid valve repair, from January 2011 up to December 2017. Minimally invasive approach (right anterior mini-thoracotomy) and standard sternotomy was performed in 2602 and 1947 patients, respectively. Stratifying by surgery, 1493 patients per group were paired using a propensity matching procedure.
Results: The minimally invasive approach has been progressively more frequent over the years (from 27.5% in 2011 to 71.7% in 2017). Compared to S-MVS, Mini-MVS patients were younger with less preoperative comorbidities and less frequently operated for valve replacement or in association with tricuspid repair. The 30-day mortality was lower in the Mini-MVS (overall 1.2% vs 2.7%; $p < 0.001$) as well as the incidence of most postoperative complications. Subjects paired by propensity score had similar 30-day mortality (1.9% vs 1.8%, $p = 0.786$) but lower blood transfusion and permanent pace-maker insertion. Cardiopulmonary bypass and cross-clamp time, initially longer in the Mini-MVS patients, became shorter in recent years for the minimally invasive approach.
Conclusions: In a large multi-institutional recent cohort, minimally invasive mitral valve surgery has drastically increased being the preferred technique and appears to be safe with procedural duration shorter than the beginning.

1. Introduction

Treatment of heart diseases is rapidly evolving with a tendency to offer minimally invasive or transcatheter interventions rather than standard full sternotomy operations that have been successfully utilized in the past decades. Management of mitral valve disease is no different: the use of new transcatheter mitral repair or prosthesis techniques is in sight for the future [1,2] and minimally invasive techniques to perform standardized surgical operations are increasingly utilized. Surgery through right mini-thoracotomy approach has established itself as an optimal option to treat pathologies affecting atrio-ventricular valves [3,4]. Experienced and specifically trained surgeons can achieve excellent results as those obtained with standard sternotomy, with many studies reporting better pain control, faster recovery and a shorter hospital stay as compared to conventional surgery [5]. Despite encouraging

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https://doi.org/10.1016/j.ijcard.2019.11.137
0167-5273/

results and excellent reports from leading institutions and surgeons, minimally invasive is not yet considered a standard of care nor mentioned as the technique of choice in guidelines. It is still many surgeons' belief that minimally invasive cardiac surgery is not safe, prolongs intervention time and can be performed only by a selected minority of very skilled surgeons. The aim of the present study is to evaluate trends of surgical approaches, operative outcomes and variations in operation times in a multicenter large cohort of patients undergone mitral valve surgery either with standard full sternotomy (S-MVS) or minimally invasive approach (Mini-MVS).

2. Methods

Data from 10 Italian cardiac centers sharing the same clinical and administrative database were analyzed from January 2011 up to December 2017. In all centers cardiology and cardiac surgery divisions are unified in a single department sharing the same clinical and administrative organization. All patients who received mitral valve surgery through a standard sternotomy or minimally invasive approach (right anterior mini-thoracotomy) were considered for the analysis. Excluded from the analysis were patients with any kind of previous cardiac operations and requiring any concomitant procedures except tricuspid valve repair. Patients receiving emergent operations were also excluded. No other exclusion criteria were applied.

Clinical and administrative databases are prospectively utilized in all centers. All patients sign an informed consent form to allow clinical and administrative data storage and utilization for scientific purposes. Because of the retrospective nature of this study, the local Ethics Committees waived the need for patient consent.

The primary outcome of the study was the incidence of 30-day mortality. For discharged patients, the follow-up was performed at internal outpatient clinics or at referral centers. Secondary outcomes were cardiopulmonary bypass and cross-clamp time as well as the occurrence of major post-operative complications: stroke, kidney function worsening, permanent pacemaker insertion, reopening for bleeding, postoperative atrial fibrillation, low cardiac output. All major outcomes have been reported according to VARC-2 definitions [6].

2.1. Surgical techniques

The choice of performing a minimally invasive approach was based on surgeons' preference. In all centers both standard sternotomy and minimally invasive approach are routinely adopted. For Mini-MVR a double-lumen endobronchial tube was predominantly used to allow single lung ventilation. In most cases a 19 Fr venous cannula was placed in the superior caval vein through the right jugular vein under TOE guidance for CPB venous return. Femoral vessels were exposed over the groin with a 3 cm incision. Femoral artery (19 Fr– 21Fr cannula) and femoral vein (23/25 Fr two-staged cannula) were cannulated using the Seldinger technique and under TOE guidance. A 5–6 cm incision was then made at the inframammary fold in female patients and over the nipple in male patients; more recently a periareolar incision was also performed in male patients and women with small breast. The thoracotomy was performed at the level of the 3rd or 4th intercostal space. Rib spreader was used in most cases to allow a better visualization. Two ports were placed in the 4th and 6th intercostal space for intracardiac suction line, carbon dioxide delivery and thoracoscopy insertion. The pericardium was opened 2–3 cm above the phrenic nerve and in most of the cases two retraction stitches were passed. The field was flooded by carbon dioxide delivered at 3–4 l/min. CPB was started and the patient cooled down 30–32 °C. Vacuum assisted venous drainage was utilized (maximum negative pressure −40 mmHg). Cold blood cardioplegia was used in most cases and the dose repeated every 20–30 min.

In standard MVR, median sternotomy and pericardial opening was performed in usual manner. CPB was established with double venous and aortic cannulation, cold blood intermittent cardioplegia delivered anterograde and mitral valve exposed through the inter-atrial groove in most cases. Vacuum assisted venous drainage was not utilized.

Several techniques were used for mitral valve repair, usually a combination of annuloplasty, leaflet resection and sliding, placement of neochordae and repair of the commissures. In valve replacement cases, standard stented mitral valve prostheses have been implanted (mechanical prostheses: CarboMedics and Bicarbon aortic valves families, CarboMedics/LivaNova, London, United Kingdom; biological prostheses: porcine Hancock II and Mosaic™, Medtronic, Minneapolis, MN; pericardial: Carpentier-Edwards, Edwards Lifesciences, Irvine, CA).

2.2. Statistical analysis

Data are reported as mean ± standard deviation, median (interquartile range) or percentage for categorical variables. We used the Student's *t*-test to compare continuous variables. Associations between categorical variables were evaluated by using Chi-squared test. Since many pre-operative variables were different between groups, we evaluated a propensity score-matched cohort by using an automated procedure to pair patients 1:1 from the two surgical approaches. The propensity score was based on multivariable logistic regression model for minimally invasive surgery including gender, age, arterial hypertension, diabetes mellitus, hypercholesterolemia, renal dysfunction, lung disease, previous disabling stroke, history of cancer, atrial fibrillation, peripheral vascular disease, coronary artery disease, ejection fraction category. Matching was performed in a 1:1 ratio selecting patients, stratified by surgery (mitral valve replacement or repair and presence of tricuspid valve repair), with the lowest absolute difference in propensity scores within a maximum caliper width of 0.25 of the standard deviation of the linear predictor of the propensity score [7]. The success of matching was evaluated by computing absolute standardized differences in the distribution of patient characteristics in the matched cohort before and after matching. Post-matching standardized differences <10% indicate successful balance. A conditional logistic regression model, appropriate for matched data, was used to compare data of paired patients. A logistic regression model was used to evaluate multivariate predictors of mortality in the overall population. Odds Ratios (ORs) with 95% Confidence Interval (95%CI) were estimated. Model calibration was verified by Hosmer-Lemeshow test. Discrimination evaluation was based on area under the receiver operating curve (AUC). Mixed regression models with centers as random effect were used to explore the relationship between CPB and cross-clamp time in isolated mitral valve surgery with the year of procedure to test whether a reduction in duration was present. All analyses were conducted using STATA software, version 14 (Stata-Corp LP, College Station, Tex). The p value was 2-sided, and the level of statistical significance was 0.05.

3. Results

During the study period, 4549 patients underwent mitral valve surgery in 10 hospitals. In 1947 cases a full sternotomy was performed while in 2602 a minimally invasive approach was chosen. Utilization of Mini-MVS has increased over the years becoming the most practiced approach (Fig. 1). The overall number of procedures performed per year increased from 454 in 2011 up to 776 in 2017. During the study period all but one center performed >40 mitral procedures per year. One center performed a mean number of 20 mitral procedure/year, 5 centers between 40 and 60 procedures/year, 2 centers between 60 and 100 and 2 centers >100 procedures/year. Patients in S-MVS group were older, had a higher rate of comorbidities and greater pre-operative risk profile evaluated by EuroSCORE II (Table 1). By using a matching technique, 1493 patients per group were paired to select two similar sub-samples of procedures. The model used to generate the propensity score had good discrimination and calibration in predict the surgical approach (AUC = 0.68 and Hosmer-Lemeshow test p = 0.434). No difference in demographic and pre-operative data was observed between the two matched groups (Table 1). Absolute standardized differences between groups of pre-operative data before and after matching were reduced in the matched sub-sample than the overall population (Supplementary Fig. 1).

Table 2 reports intra- and post-operative data by surgical approach in the overall population and in the subgroups paired by propensity score. Most of the patients had a valve repair rather than replacement. Mitral valve repair was performed in 68.8% of the patients: 58.3% of the S-MVS patients and 76.7% of the Mini-MVS. Tricuspid valve repair was more frequently associated in S-MVS patients (22.9% vs. 8.6%, $p < 0.001$). Cardiopulmonary bypass and cross-clamp time were significantly longer in the Mini- than S-MVS in the overall population and in subjects paired by propensity score (Table 2). In isolated mitral valve surgery (Fig. 2, excluding tricuspid valve repair), cardiopulmonary bypass and cross-clamp time remained stable over the study period for S-MVS while became shorter in recent years especially in Mini-MVS operations: reductions of 3.5 ± 1.6 min ($p = 0.028$) for interventions performed during 2014–15 and 4.0 ± 1.7 min ($p = 0.018$) for interventions performed during 2016–17.

Overall mortality within 30 days occurred in 85 patients (1.9%): 53 (2.7%) in S-MVS group and 32 (1.2%) in the Mini-MVS ($p < 0.001$). There was no variation in mortality across the years with stable lower mortality in Mini- than S-MVS. The incidence of postoperative complications was also more frequent in the MVS patients (Table 2). In the subjects paired by propensity score, post-operative data showed in mini-MVS patients a lower need of blood transfusion and permanent pace-maker insertion (Table 2). No difference was detected in 30-days mortality, renal function worsening, wound infection, reopening for bleeding, re-intubation, confusion/delirium, stroke and post-operatative length of stay.

Supplementary Fig. 2 shows mortality in isolated surgeries for the overall population and the matched subgroups. Mitral valve repair had lower mortality in Mini- than S-MVS (not significant in the propensity paired procedures). Higher rates were observed for both approaches in isolated mitral valve replacement (Supplementary Fig. 2).

4. Discussion

Minimally invasive mitral valve approach is now an established procedure, we demonstrate in a large, multi-center population that with adequate training and team commitment the majority of mitral valve procedures can be performed safely with a minimally invasive approach. However its adoption remains hectic among cardiac centers and some concerns still exist in terms of safety. Also, it requires a steep learning curve, thus conventional sternotomy continues to be the standard practice in many circumstances [8]. In recent 2018 STS database report [9], only 23% of mitral valve operations were performed with the utilization of less invasive approaches, this trend has not changed significantly since the previous report published in 2010 [10].

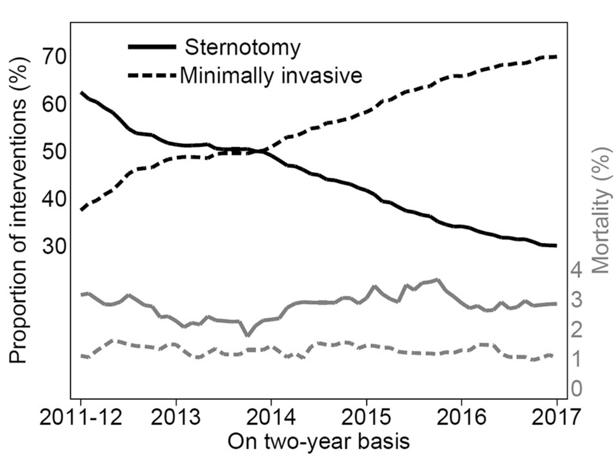

Fig. 1. On two-year basis, proportion of procedures and mortality by surgical approach.

Up till now different studies have highlighted that the minimally invasive solution is as safe as sternotomy and it is as feasible even in case of complex mitral valve repairs [11]. Aim of this study was to evaluate trends of surgical approaches, operative outcomes and variations in operation times in a multicenter large cohort of patients undergone mitral valve surgery. In order to do so, a propensity score matching toward conventional sternotomy was carried out and it generated 1493 couples of patients, the largest multi-center propensity score matched study presented so far. We were able to demonstrate that, in terms of mortality and morbidity, Mini-MVS is as safe as standard sternotomy, moreover it is associated with statistically significant lower number of patients transfused and requiring pace-maker insertion. These results are in line with other smaller propensity matched studies. Grant and colleagues, analyzing data from 3 UK hospitals from 2008 to 2016, performed a propensity matched analysis on 639 pairs of patients demonstrating lower need of transfusion and reduced postoperative length of stay in minimally invasive patients [12]. In the Japan Adult Cardiovascular Surgery Database only 756 patients had a minimally invasive approach out of 6137 operated on the mitral valve between 2008 and 2012. They performed a propensity score matched comparison on 750 pairs demonstrating shorter length of stay in the minimally invasive patients [13].

Tang and colleagues [14] reported lower incidence of post-operative atrial fibrillation, respiratory complications, acute renal failure, lower chest drain output, and fewer use of blood transfusions in the minimally invasive group. Finally Suri and colleagues demonstrated that early outcomes with minimally invasive surgery were similar to those for mitral valve repair performed through sternotomy, with a shorter time to extubation [15].

As all the propensity score matched studies above reported, we did not observe an augmented incidence of neurological events in the minimally invasive group, in fact rate of stroke was very low despite the use femoral artery cannulation.

Interestingly our data demonstrates that with increased team experience, in recent years cardiopulmonary bypass and cross-clamp time have become significantly shorter than the initial phase of our study being nowadays similar to those required in standard sternotomy approach.

Our results cannot be considered representative of the entire national mitral valve surgery experience. The hospitals involved in this study share the same administrative and clinical management devoted to evaluation of clinical outcomes and adoption of innovative techniques. The low early mortality that we observed in our study is in line with rates recently reported for cardiac surgery from New York State that showed a small variation in post-operative outcome among providers [16]. A recent analysis from the STS database reveals that between 2014 and 2018 among 1082 hospitals of the United States only 336 (31.1%) performed a mean of 40 or more mitral valve operations. In these high volume centers the mitral repair rate was higher and cases were more likely to be elective and performed in a minimally invasive approach than in centers that performed fewer than 40 procedures/year [17]. In our study, all but one hospital performed >40 procedures/year and some of them are very high volume centers for mitral valve surgery. The specific dedication and commitment to mitral valve surgery may explain the increased adoption of minimally invasive approach associated with increased referral for surgery.

4.1. Limitations

This study has several limitations. Baseline valve lesions and related repair techniques are not described, and only operative and early postoperative clinical outcomes are available. Although for different surgeons minimally invasive approach is an 'all comers

Table 1
Characteristics of patients by procedure in the overall population and in the subgroups paired by propensity score.

	Overall				Match by propensity		
	All	MVS	Mini-MVS		MVS	Mini-MVS	
	n = 4549	n = 1947	n = 2602	p	n = 1493	n = 1493	p
Male gender	2270 (49.9%)	903 (46.4%)	1367 (52.5%)	<0.001	728 (48.8%)	733 (49.1%)	0.821
Age (years)	66 ± 13	68 ± 12	64 ± 13	<0.001	66 ± 12	67 ± 12	0.421
Obesity (BMI > 30 Kg/m^2)	468 (14.6%)	244 (16.9%)	224 (12.7%)	0.001	140 (17.0%)	114 (13.9%)	0.079
Arterial hypertension	2617 (61.1%)	1162 (62.8%)	1455 (59.8%)	0.043	928 (62.2%)	929 (62.2%)	0.961
Diabetes mellitus	356 (8.3%)	176 (9.5%)	180 (7.4%)	0.013	132 (8.8%)	125 (8.4%)	0.625
Hypercholesterolemia	1521 (35.5%)	682 (36.9%)	839 (34.5%)	0.104	532 (35.6%)	525 (35.2%)	0.753
Renal dysfunction	132 (3.1%)	66 (3.6%)	66 (2.7%)	0.108	48 (3.2%)	50 (3.3%)	0.838
Respiratory or lung disease	481 (11.2%)	290 (15.7%)	191 (7.9%)	<0.001	161 (10.8%)	162 (10.9%)	0.938
Previous disabling stroke	52 (1.2%)	33 (1.8%)	19 (0.8%)	0.003	17 (1.1%)	14 (0.9%)	0.591
History of cancer	205 (4.8%)	102 (5.5%)	103 (4.2%)	0.051	72 (4.8%)	69 (4.6%)	0.790
Atrial fibrillation	1235 (28.8%)	670 (36.2%)	565 (23.2%)	<0.001	437 (29.3%)	435 (29.1%)	0.921
Peripheral vascular disease	83 (1.9%)	48 (2.6%)	35 (1.4%)	0.007	31 (2.1%)	29 (1.9%)	0.786
Coronary artery disease	272 (6.4%)	145 (7.8%)	127 (5.2%)	<0.001	101 (6.8%)	93 (6.2%)	0.537
Ejection fraction				<0.001			0.920
>50%	2974 (71.4%)	1177 (65.5%)	1797 (75.8%)		1008 (71.5%)	1014 (72.0%)	
31–50%	1105 (26.5%)	576 (32.1%)	529 (22.3%)		372 (26.4%)	365 (25.9%)	
≤30%	88 (2.1%)	43 (2.4%)	45 (1.9%)		29 (2.1%)	30 (2.1%)	
EuroSCORE II (%)	2.6 ± 3.5	3.0 ± 3.0	2.3 ± 3.7	<0.001	2.6 ± 2.3	2.6 ± 3.5	0.846

Mean ± Standard Deviation or number (percentage). Renal dysfunction: dialysis or creatinine >2 mg/dl. Body Mass Index (BMI) available in 3205 patients (1444 MVS and 1761 Mini-MVS) and 822 paired by matching. Risk factors were available in 4282 patients (1849 MVS and 2433 Mini-MVS) and in all 1493 paired by matching. Ejection fraction was available in 4167 (1796 MVS and 2371 Mini-MVS) and in 1409 paired by matching.

procedure' a bias toward easier valve repair (e.g. isolated P2 prolapse) could not be excluded especially during the first period of the learning curve. No mid-long term follow-up and no financial analysis were carried out.

5. Conclusions

This multi-center propensity score matched study contributes to demonstrate that minimally invasive approach is as safe as conventional sternotomy, exhibiting low mortality and morbidity. Moreover it is associated with some better immediate postoperative outcomes compared to standard sternotomy, such as lower incidence of blood transfusion and pacemaker implant. The adoption of minimally invasive approach has increased dramatically in the course of our observation and the time of the operations have become equal to the standard full sternotomy approach. Minimally invasive techniques should be considered the standard approach for mitral and tricuspid valve surgery.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2019.11.137.

Declaration of competing interest

None declared.

Table 2
Intra- and post-operative data by procedure in the overall population and in the subgroups paired by propensity score.

	Overall				Match by propensity		
	All	MVS	Mini-MVS		MVS	Mini-MVS	
	n = 4549	n = 1947	n = 2602	p	n = 1493	n = 1493	p
Intra-operative							
Cardiopulmonary bypass time (min)	96 ± 39	91 ± 34	99 ± 42	<0.001	90 ± 33	100 ± 42	<0.001
Cross-clamping time (min)	71 ± 31	70 ± 27	72 ± 34	0.044	69 ± 27	74 ± 34	0.003
Mitral valve replacement	1418 (31.2%)	812 (41.7%)	606 (23.3%)	<0.001	520 (34.8%)	520 (34.8%)	–
Tricuspid valve repair	671 (14.8%)	446 (22.9%)	225 (8.6%)	<0.001	204 (13.7%)	204 (13.7%)	–
Post-operative							
Blood transfusion	1298 (31.1%)	680 (37.9%)	618 (25.9%)	<0.001	483 (35.8%)	382 (28.3%)	<0.001
Renal function worsening	300 (7.5%)	172 (9.7%)	128 (5.8%)	<0.001	98 (8.1%)	88 (7.2%)	0.441
Atrial fibrillation	744 (23.1%)	339 (26.6%)	405 (20.8%)	<0.001	221 (27.4%)	200 (24.8%)	0.225
Permanent pacemaker insertion	81 (1.8%)	47 (2.4%)	34 (1.4%)	0.009	40 (2.8%)	24 (1.7%)	0.045
Wound infection	59 (1.3%)	30 (1.5%)	29 (1.1%)	0.209	21 (1.4%)	15 (1.0%)	0.320
Reopening for bleeding/complications	137 (3.1%)	73 (3.9%)	64 (2.5%)	0.008	39 (2.8%)	39 (2.8%)	1.000
Re-intubation	96 (2.3%)	56 (3.1%)	40 (1.6%)	0.001	28 (2.0%)	31 (2.2%)	0.691
Confusion/delirium	63 (1.5%)	39 (2.2%)	24 (1.0%)	0.002	25 (1.8%)	20 (1.5%)	0.457
Non-disabling stroke	17 (0.4%)	8 (0.4%)	9 (0.4%)	0.858	5 (0.4%)	4 (0.3%)	0.739
Disabling Stroke	12 (0.3%)	6 (0.3%)	6 (0.3%)	0.722	3 (0.2%)	3 (0.2%)	1.000
Low cardiac output	254 (6.4%)	141 (7.9%)	113 (5.1%)	<0.001	81 (6.6%)	63 (5.1%)	0.116
ICU Length of Stay (days)	1.8 (1.0–2.0)	1.9 (1.0–2.8)	1.8 (0.9–2.0)	<0.001	1.9 (1.0–2.0)	1.8 (1.0–2.0)	0.198
Post-operative days	8 (6–12)	8 (7–14)	8 (6–11)	<0.001	8 (7–13)	8 (6–11)	0.201
30-days mortality	85 (1.9%)	53 (2.7%)	32 (1.2%)	<0.001	27 (1.8%)	29 (1.9%)	0.786

Mean ± Standard Deviation, median (interquartile range) or number (percentage). Low cardiac output: intra aortic balloon pump and/or inotropic use for >2 days. ICU: intensive care unit. Blood transfusion available in (1792 MVS and 2387 Mini-MVS, 1349 paired by matching), renal function worsening in 1779 and 2197 (1214 paired), atrial fibrillation in 1276 and 1946 (807 paired), permanent pacemaker insertion in 1946 and 2511 (1434 paired), reopening 1850 and 2525 (1378 paired), re-intubation in 1794 and 2432 (1379 paired), confusion/delirium in 1794 and 2430 (1377 paired), non-disabling and disabling stroke in 1794 and 2201 (1227 paired), low cardiac output in 1794 and 2203 (1228 paired).

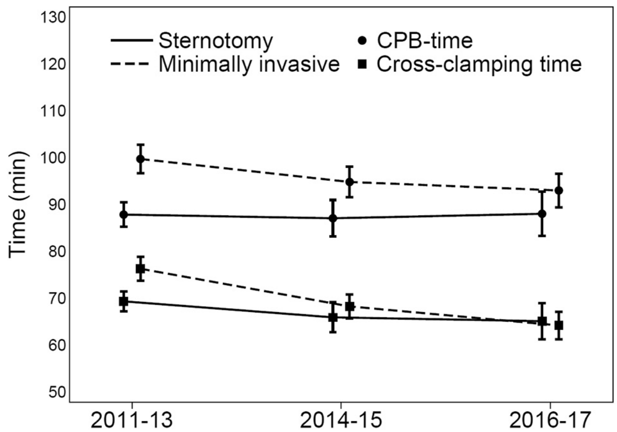

Fig. 2. Mean values with 95% confidence interval of cardiopulmonary bypass (CPB) and cross-clamp time in isolated mitral valve by surgical approach across three consecutive periods.

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