

Increased Short-Term and Mid-Term Major Complications Were Observed in Elderly Patients with Renal Dysfunction after Surgical Ventricular Restoration

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ABSTRACT

Background: This study was conducted to explore the impact of renal dysfunction on short-term and mid-term outcomes in elderly patients.

Methods: Patients over 65 years of age receiving surgical ventricular restoration (SVR) were included in the study. They were stratified through estimated glomerular filtration rate (eGFR), with a cutoff point of 60 mL/min/1.73m². Risk-adjusted analysis, including propensity score matching, was carried out to compare short-term and mid-term outcomes between the two groups of patients.

Results: From January 1999 to December 2015, a total of 280 elderly patients underwent SVR. Of the patients, 79 had eGFR lower than 60 mL/min/1.73m² and were considered to have renal dysfunction. Mortality was higher in the renal dysfunction group than the normal renal function group, with marginal significance (adjusted *P* value = .06). The need for mechanical supports (adjusted *P* value = .04) was higher in the renal dysfunction group. Hemofiltration (adjusted *P* value < .01) and requirements for transfusion (adjusted *P* value = .03) were significantly higher in the renal dysfunction group than in the group with normal renal function. The presence of renal dysfunction was associated with higher risk of major adverse cerebro-cardiovascular events (MACCE) than normal renal function (HR = 2.34, 95% CI = 1.34 - 4.08, *P* = .003).

Conclusion: Compared to patients with normal renal function, elderly SVR patients with renal failure have a higher incidence of short-term mechanical support, mid-term mortality, and MACCE events.

INTRODUCTION

Chronic ischemic cardiomyopathy lays a heavy burden on health systems worldwide [Moran 2014; Jessup 2003]. When compared with their younger counterparts, elderly patients with coronary heart disease are more susceptible to heart failure, and according to the literature, elderly patients account for more than one-third of those with ischemic cardiomyopathy [Wong 2014; Shafazand 2009]. In fact, chronic

ischemic cardiomyopathy is not only risky, but also resource consuming, representing a serious medical issue [Moran 2014]. There are a number of approaches for treatment, with surgical ventricular restoration (SVR) still among options available for standard of care because it excludes the wall with motion abnormalities and restores left ventricular geometry [Castelvecchio 2016; Zheng 2009; Menicanti 2007]. However, SVR is high-risk, especially due to the higher incidence of postoperative complications and mortality in elderly patients [Wakasa 2014; Hernandez 2006].

Renal dysfunction is a common comorbidity in elderly patients with ischemic cardiomyopathy [Jong 2002; Dries 2000]. Previous studies have shown that renal dysfunction significantly increased the risk of cardiac surgery [Lin 2009; Soltero 2005; Liu 2000]. However, there is limited number of studies focusing on elderly patients with renal dysfunction that received SVR, and a lack of mid-term and long-term follow-up data. In addition, most previous studies used serum creatinine level rather than estimated glomerular filtration rate (eGFR) as the measuring criteria for renal dysfunction, affecting objective assessment of this issue [Hernandez 2006].

This study involved patients with SVR over a 16-year period at a single center. Patients were stratified using eGFR to explore the impact of renal dysfunction on short-term and mid-term outcomes.

METHODS

Patients

The data collection procedures are described elsewhere [Hu 2010]. As an overview, from January 1999 to December 2015, 1128 consecutive patients underwent surgical ventricular reconstruction at Fuwai Hospital, Beijing, China, and were considered for the study. Of these patients, 280 with ages more than 65 years were considered “elderly,” and were eligible for the study [Li 2008]. Patients were divided into two groups according to eGFR level as calculated by the modification of diet in renal disease (MDRD) equation: those with eGFR < 60 mL/min/1.73m² were considered to have renal dysfunction, and those with eGFR ≥ 60 mL/min/1.73m² were considered to have normal renal function [Levey 2003; National Kidney Foundation 2002; Levey 1999]. GFR < 60 is equivalent to chronic kidney disease (CKD) stage 3 and higher.

The study protocol was approved by the Institutional Review Board at Fuwai Hospital. Variables and their definitions were similar to those reported in the STS database (<http://www.sts.org/>). Baseline information related to

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Table 1. Baseline Characteristics

Baseline characteristics	Group 1 (n=79)	Group 2 (n=201)	P
Age (year)	70.5 ± 3.95	68.7±3.08	.012
Gender (male)	68.4%	79.1%	.063
Hypertension	74.7%	58.2%	.013
Hyperlipidemia	57.0%	47.8%	.185
Diabetes mellitus	24.1%	27.9%	.552
BMI (kg/m ²)	23.83 ± 2.96	24.56 ± 2.94	.066
Smoking history	45.6%	49.8%	.596
Stroke	13.9%	13.4%	.914
Previous AF	12.7%	3.5%	.009
PCI history	15.2%	15.9%	.880
CABG history	0%	1.5%	.275
Previous AMI	92.4%	94%	.618
Creatinine μmol/L	133.84 ± 38.3	84.44 ± 14.63	< .0001
eGFR (mL/min/1.73m ²)	47.35 ± 10.19	81.02 ± 15.79	< .0001
NYHA			.038
I (%)	2.3	5.2	
II (%)	47.7	61.5	
III (%)	40.9	30.2	
IV (%)	9.1	3.1	
Involved vessels			.650
0 (%)	1.3	0	
1 (%)	10.3	9.5	
2 (%)	21.8	21.5	
3 (%)	66.7	69	
SinoSCORE	19.2 ± 1.57	18.8 ± 1.56	.061
Pre-operative ultrasound			
Pre-operative EF (%)	42.9 ± 9.0	46.3 ± 10.0	.014
Pre-operative LVEDD (mm)	57.8 ± 7.1	56.9 ± 7.6	.376
Forward flow velocity	0.76 ± 0.24	0.78 ± 0.3	.458

Group 1 includes patients with renal dysfunction; Group 2 includes patients without renal dysfunction.

BMI indicates body mass index; AF, atrial fibrillation; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; AMI, acute myocardial infarction; eGFR, glomerular filtration rate; NYHA, New York heart association; EF, ejection fraction; LVEDD, left ventricular end diastolic diameter.

personal and clinical characteristics, as well as in-hospital events following surgeries, were complete for all 280 patients involved in the study.

We calculated each patient's SinoSCORE, a risk stratification system developed from the Chinese population, of which the variables include age, chronic obstructive pulmonary disease (COPD), previous heart surgery, ejection fraction, the

Table 2. Intraoperative Characteristics

Intra-operative characteristics	Group 1 (n=79)	Group 2 (n=201)	P
Duration of CPB (min)	125.1 ± 63.1	115.0 ± 41.1	.150
Duration for clamping aorta (min)	81.4 ± 32.7	76.4 ± 27.1	.219
No. of ITA graft (mean ± S.D.)	0.93 ± 0.26	0.92 ± 0.27	.821
No. of venous distal anastomoses (mean ± S.D.)	1.46 ± 0.69	1.30 ± 0.74	.104
Mitral valve plasty (%)	7.6	6.0	.618
Mitral valve replacement (%)	3.8	0	.005
Type of SVR			.393
Linear plasty (%)	50.6	48.8	
Modified SVR (%)	3.8	8.5	
Patch plasty (%)	45.6	42.8	

Group 1 includes patients with renal dysfunction; Group 2 includes patients without renal dysfunction.

CPB indicates cardiopulmonary bypass; ITA, internal thoracic artery; S.D., standard deviation; SVR, surgical ventricular restoration.

last preoperative creatinine level, emergent/urgent surgery, unstable hemodynamics, congestive heart failure (within two weeks), and myocardial infarction (within three weeks) [Zheng 2013].

Surgical Procedures

Details of surgical SVR procedures are described elsewhere [Zheng 2009]. As a brief overview, hearts were arrested with antegrade cold blood cardioplegia before the procedures. If concomitant coronary revascularization was to be carried out, all distal anastomoses were performed during the same aortic cross-clamp period and proximal anastomoses were done during the rewarming period. The mitral valve was repaired, when needed, through the ventricular opening with a double-armed stitch at the posterior annulus, from trigone to trigone, and the mitral orifice was undersized with a 28-3024- to 26-mm Hegar sizer. Alternatively, the mitral valve surgeries were done through a trans-atrial septal route when the ventricular opening was not big enough or mitral valve replacement was required.

In our institute, various SVRs were adopted, including standard linear closure, patch repair, and modified ventricular reconstruction, which was developed by our institute [Zheng 2009]. For modified ventricular reconstruction, an incision parallel to the left anterior descending artery was made in the infarcted anterior wall segment. Any thrombus was carefully removed. An endoventricular purse-string suture was placed with a 1-0 prolene line suture. The suture was placed in the scarred tissue above the junctional zone between normal myocardium. The suture was tied, and created an opening of about 2 cm. The ventricular chamber was reduced and kept in satisfactory geometry. The next closure was similar with

Table 3. In-Hospital Outcomes

Post-operative complications	Group 1 (n=79)	Group 2 (n=201)	P	
			Unadjusted	Adjusted
All-cause mortality (%)	2.5	0.5	.18	.06
Peri-operative MI (%)	0	1.9	.55	.97
Peri-operative stroke (%)	0	1.0	.99	.91
Hemofiltration (%)	5.1	0	< .01	< .01
Mechanical support (%)	13.9	6.0	.03	.04
IABP (%)	13.9	5	.02	.01
ECMO (%)	1.5	0.7	.99	.97
LVAD (%)	0	0.5	.99	.99
Transfusion (%)	86.1	74.6	.04	.03
Re-operation for bleed (%)	1.3	3.0	.67	.26
Post-operative ultrasound				
Post-operative EF (%)	44.5±8.4	47.0±9.3	.02	N/A
Post-operative LVEDD (mm)	52.9±6.6	51.7±7.0	.189	N/A
Forward flow velocity	0.82±0.24	0.78±0.3	.133	N/A

Group 1 includes patients with renal dysfunction; Group 2 includes patients without renal dysfunction.

MI indicates myocardial infarction; IABP, intra-aortic balloon pump; ECMO, extracorporeal membrane oxygenator; LVAD, left ventricular assistant device; EF, ejection fraction; LVEDD, left ventricular end diastolic diameter; N/A, not applicable.

standard techniques, however, the level of the suture was adjusted continually to keep the ventricle from being distorted during closure.

Mid-Term Follow-Up

The follow-up protocols are described elsewhere [Hu 2010]. In brief, all surgical patients discharged alive from hospital were required to return for an outpatient follow-up visit at six months after surgery, and then once or twice each year. In addition, all surviving study participants were contacted by telephone again by the research staff using standard procedures and forms. The overall completion of follow-up information in the current study was 100%. For those who had reported any adverse events after discharge, the medical records in the outpatient clinic were further reviewed for confirmation. If major clinical events occurred and were treated in other hospitals, a copy of relevant medical records were required to be sent back by mail.

Statistical Analysis

The primary endpoints were all-cause mortality and a composite of midterm effects of the treatment (major adverse cardio-cerebral events [MACCE]), including all-cause death, revascularization, myocardial infarction (MI), or stroke. The secondary endpoints were in-hospital all-cause deaths, MI, stroke, requirement for hemofiltration, and requirement for mechanical

Table 4. Risk Adjusted Mid-Term Outcomes

Major complications during follow up	Adjusted analysis*				
	Group 1 (n=77)	Group 2 (n=200)	HR	95% CI	P
MACCE (%)	28.6%	17.0%	2.34	1.34 - 4.08	.003
All-cause mortality (%)	16.9%	6.0%	4.12	1.85 - 9.16	.001
Newly occurred MI (%)	2.6%	1.0%	7.31	0.66 - 81.39	.11
Newly occurred stroke (%)	11.7%	11.5%	1.23	0.48 - 2.67	.78
Repeated revascularization (%)	1.3%	1.5%	1.79	0.16 - 20.19	.64

Group 1 includes patients with renal dysfunction; Group 2 includes patients without renal dysfunction.

MACCE indicates major adverse cardio-vascular event; MI, myocardial infarction.

*HR less than 1 in favor of patients with renal dysfunction

supports including intra-aortic balloon pump (IABP), extracorporeal membrane oxygenation (ECMO) and left ventricular assistant device (LVAD). If a similar clinical event occurred more than once in a patient, only the first one was used in analysis.

To minimize potential selection bias, a propensity score analysis was undertaken, for which age and various other baseline variables along with time intervals were used in a logistic regression model to calculate the probability of having renal dysfunction for each patient (Table 1). Risk ratios (RRs) were then estimated using a logistic regression model for in-hospital outcomes and a Cox proportional-hazards model for mid-term follow-up data, with eGFR stratification (eGFR < 60 mL/min/1.73m² or eGFR ≥ 60 mL/min/1.73m²) as the exposure variable; propensity score, year of surgery, and surgeon identities as covariates; and various primary and secondary endpoints as the outcomes. In addition, the Kaplan-Meier method and log-rank test were used to compare the differences in the mid-term outcomes between the two groups.

To help minimize any residual selection bias, an additional propensity score with variables in table 1 along with year of surgery and surgeon identities as covariates was calculated, and a greedy matching algorithm was used to match patients based on the logit of the propensity score with a caliper width of 0.2 of the standard deviation of the logit of the propensity score. For a subset of 154 patients who were discharged alive (77 with renal dysfunction and 77 with normal renal function) and were matched on baseline characteristics, similar analytic procedures were used to examine the differences between the primary end-points. All the statistical analyses were performed using SPSS version 22 (SPSS Inc.).

RESULTS

Patient Characteristics

From January 1999 to December 2015, a total of 280 elderly patients underwent SVR and were included in the

Table 5. Mid-Term Outcomes in Propensity Matched Sample

Major complications during follow up	Adjusted analysis*				
	Group 1 (n=77)	Group 2 (n=77)	HR	95% CI	P
MACCE (%)	28.6%	16.9%	2.21	1.08 - 4.50	.03
All-cause mortality (%)	16.9%	3.0%	5.73	1.62 - 20.28	.007
Newly occurred MI (%)	2.6%	1.3%	2.70	0.24 - 29.84	.42
Newly occurred stroke (%)	11.7%	13.0%	0.92	0.34 - 2.48	.87
Repeated revascularization (%)	1.3%	1.3%	1.20	0.07 - 19.48	.90

Group 1 includes patients with renal dysfunction; Group 2 includes patients without renal dysfunction.

MACCE indicates major adverse cardio-vascular event; MI, myocardial infarction.

study. Of all the patients, 79 had an eGFR lower than 60 mL/min/1.73m² and were considered as having renal dysfunction. Patients with renal dysfunction were slightly older than those with normal renal function (70.5 years of age versus 68.7 years of age), but the groups had similar proportions of females, prior history of diabetes, hyperlipidemia, smoking, acute myocardial infarction (AMI), and stroke, as well as mean levels of BMI and previous history of revascularization (Table 1). However, patients with renal dysfunction were more likely to have hypertension, atrial fibrillation (AF), a marginally significantly higher level of SinoSCORE, and significantly lower ejection fraction when compared with patients without renal dysfunction (42.9% versus 46.3%, Table 1).

The duration of cardio-pulmonary bypass and clamping time were not statistically different between the two groups (Table 2). There was also no significant difference between the two groups in the proportion receiving various types of mitral valve surgeries or SVR (Table 2).

In-Hospital Complications

Table 3 shows the unadjusted and adjusted outcome measures recorded during hospitalization. Overall, the in-hospital mortality was low in both groups, though mortality was higher, with marginal significance, in the renal dysfunction group than in the normal renal function group (adjusted *P* value = .06). The need for mechanical supports (adjusted *P* value = .04) was higher in renal dysfunction group, which was mainly driven by use of IABP (adjusted *P* value = .01). In addition, hemofiltration (adjusted *P* value < .01) and requirements for transfusion (adjusted *P* value = .03) were significantly higher in the renal dysfunction group than in the group with normal renal function.

Midterm Outcomes

There were 77 patients with renal dysfunction and 200 with normal renal function discharged alive. Midterm outcomes are shown in Table 4 and Figure 1. After an average

Supplemental Data: SinoSCORE Risk Factors and Weights

Risk factor	Definition	P	Score
Patient-related factors			
Age 65 – 69	In years	< .001	3
70 – 74		< .001	5
≥ 75		< .001	6
BMI ≥ 24	BMI	.019	–2
BMI < 18		.002	5
Chronic renal failure	Documented past history or any previous serum creatinine > 176 μmol/L	< .001	6
Extracardiac arteriopathy	Any one or more of the following: claudication, carotid occlusion or > 50% stenosis, previous or planned intervention on the abdominal aorta, and limb arteries or carotids	.011	5
Chronic obstructive pulmonary disease	Long-term use of bronchodilators or steroids for lung disease	.024	4
NHYA stage III	NHYA definition	< .001	3
NHYA stage IV		< .001	7
Cardiac factors			
Preoperative atrial fibrillation or flutter	Within 2 weeks	.035	2
Ejection fraction < 50%	Assessed by echocardiography (measured before surgery)	< .001	4
Preoperative critical stage	Any one or more of the following: preoperative cardiogenic shock, ventricular fibrillation or flutter, and preoperative IABP implantation	< .001	4
Operation-related factors			
Non-elective surgery	Non-elective procedure	< .001	5
Combined valve surgery	Surgical procedures with either valve	< .001	4

BMI indicates body-mass index; NYHA, New York Heart Association; IABP, intra-aortic balloon pump.

of 4.1 years of follow-up, a total of 56 patients (20.2%) had developed MACCE. Patients with renal dysfunction had an associated higher risk of MACCE than those without renal dysfunction (HR = 2.34, 95% CI = 1.34 - 4.08, *P* = .003). Moreover, mortality was significantly higher in the renal dysfunction group than in the normal renal function group (HR = 4.12, 95% CI = 1.85 - 9.16, *P* = .001). With the exception of revascularization, the rates of various midterm outcome measures were generally higher in renal dysfunction group (Table 4).

In the propensity score-matched analyses involving 77 patients with renal dysfunction and 77 patients without renal dysfunction, there remained statistically significant 1.21 times ($P = .03$) and 4.73 times ($P = .007$) higher rates of MACCE and all-cause deaths in renal dysfunction group than in normal renal function group (Table 5). Similarly, the results for various secondary outcome measures were largely unchanged (Table 5).

DISCUSSION

SVR is a high-risk procedure. According to data from the Society of Thoracic Surgeons (STS), across the United States, SVR-related mortality reached 9.3%, and postoperative major complication rate reached 33.5% [Hernandez 2006]. Numerous studies put into question the efficacy of this procedure and caused

extensive discussion within the community [Michler 2013; Rouleau 2010; Buckberg 2010; Buckberg 2009]. In this context, it has become critically important to explore risk stratification, weigh benefits against risks, and select the appropriate patients.

Our center employed three kinds of SVR. The operation indications were enlarged dyskinetic left ventricle, accompanied by angina and/or heart failure after MI. It may be a concern that different types of surgeries will confound the results. However, our previous single-center study showed that different SVR approaches had no significant impact on the short-term and long-term outcomes under the premises of appropriate indication selections [Zheng 2009]. In addition, in this study there was no significant difference in the distribution of various surgical approaches between the two groups ($P = .39$). Therefore, we believe that different surgical methods will not affect the results.

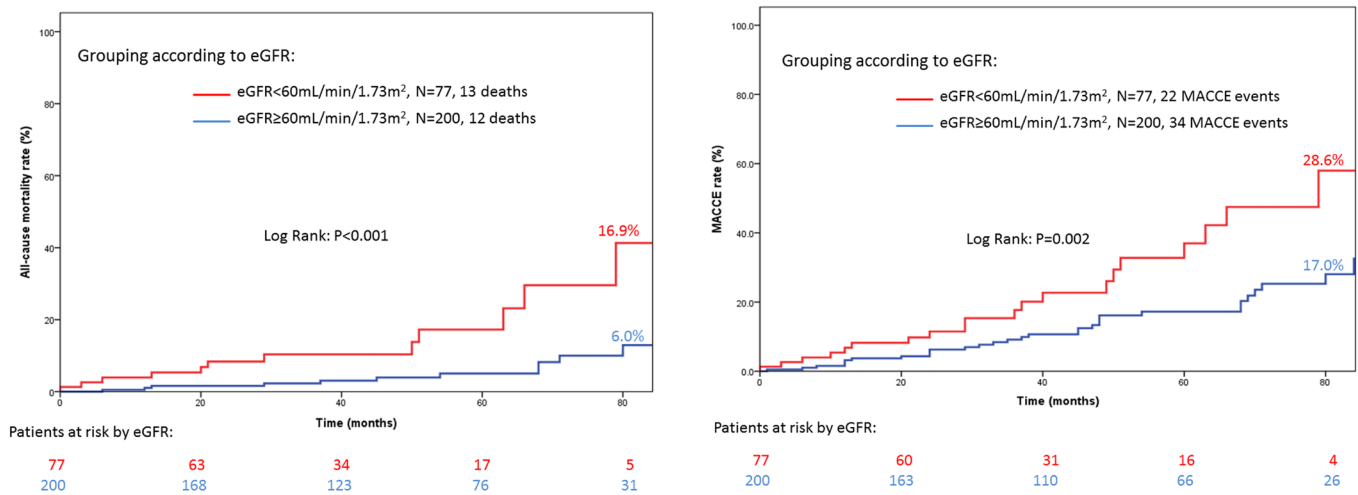


Figure 1. Primary endpoints analysis in 280 patients. (A) All-cause mortality rate in follow up. (B) Major adverse cardio-cerebral event (MACCE) rate in follow up.

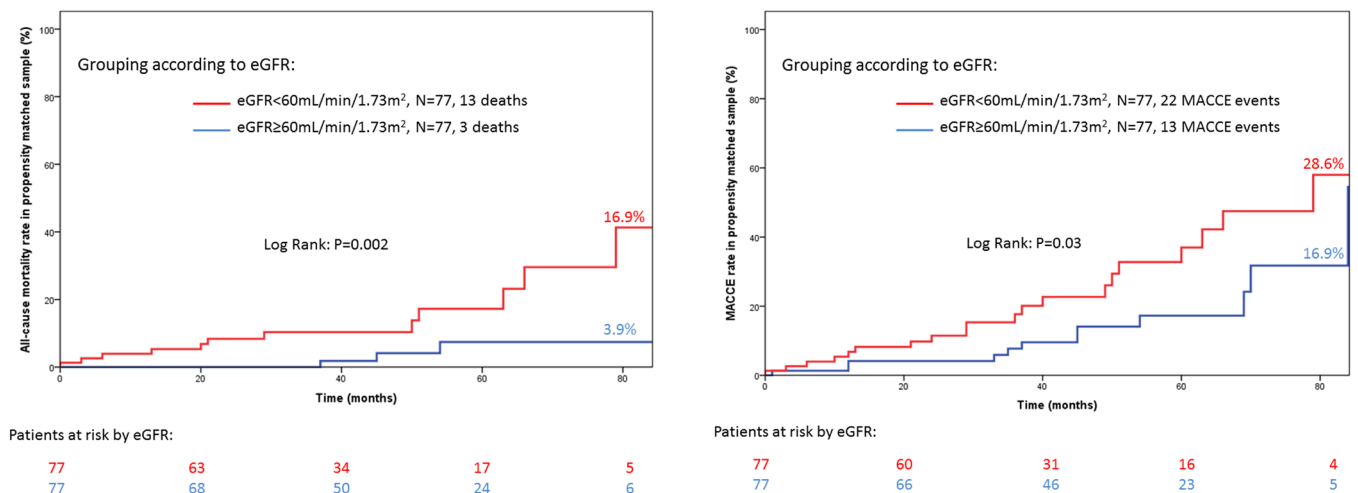


Figure 2. Primary end points in propensity matched patients (n=154). (A) All-cause mortality rate in follow up. (B) MACCE rate in follow up.

The extent of aneurysm exclusion is always a big concern for cardiac surgeons. Suma et al found in a study involving 107 patients that the long-term survival could be significantly improved by measuring the border of myocardial scar area through preoperative ultrasound and intraoperative direct visualization in order to determine the strategy for surgical approach and extent of exclusion [Suma 2006]. Surgeons in our center adopted a similar strategy for surgical exclusion of infarcted tissue, ie, clearly defining the border of ventricular aneurysm and removing the scar area as far as possible.

In our study, after stratified comparison by eGFR, it was found that the difference of in-hospital mortalities between groups was marginally significant. However, we also found that the needs for IABP and hemodialysis significantly increased in patients with renal dysfunction after surgeries. A possible explanation for this observation might be the fact that a portion of patients in critical status survived the early postoperative period through inotropic and mechanical supports, thanks to the improvements in intensive care managements in the current era. Moreover, our study found that renal dysfunction had a negative impact on the mid-term prognosis in elderly patients after SVR: during the 16-year follow-up period, renal dysfunction was associated with a 1.21 times and 4.73 times higher risk of MACCE and mortality, respectively. This suggests that more aggressive secondary prevention strategies should be chosen for these cohort.

Old age and renal dysfunction are important risk factors for cardiac surgery [Zheng 2013; Nashef 1999]. However, the impact of these two factors on SVR outcomes is unclear. By analyzing the 16-year follow-up data of 280 elderly patients, we found that the incidence of short-term complications significantly increased in patients with renal dysfunction. Furthermore, the incidence of mid-term mortality and MACCE events was significantly higher than in patients with normal renal function.

Among patients with ischemic cardiomyopathy, the proportion of elderly patients is high, and the prognosis is very poor in patients with renal dysfunction [Shafazand 2009; Jong 2002; Dries 2000]. However, studies are still lacking on the efficacy of SVR in patients with old age and renal dysfunction. Wakasa et al found in a multi-center study involving 596 patients that age was an independent short-term and long-term risk factor for postoperative mortality, but this study did not focus on the relationship between renal function and surgical outcomes [Wakasa 2014]. According to a study involving 731 patients with ventricular aneurysm in 141 centers around the United States, the mortality and complication rates in patients with creatinine > 2mg/dL were 2.5 times higher than in patients with normal creatinine. However, this study could not objectively reflect the renal function, especially in elderly patients, because creatinine was selected rather than eGFR as the index for renal function [Hernandez 2006]. Moreover, the above studies did not explore the impact of renal function on long-term outcomes of SVR.

Limitations

This study had several limitations:

1. In this study, we found that patients in the renal dysfunction group were more likely to require IABP support

than patients with normal renal function. It is possible that more tenuous hemodynamics underlie this phenomenon, but more data is required to give a plausible explanation for this observation.

2. Although discrepancies exist as for whether patients receiving SVR require revascularization or not, in our center, surgeons sought to guarantee complete revascularization. It might be interesting to see the impact of complete revascularization on elderly patients with renal dysfunctions. However, we only had the number of grafts and whether patients have three, two, or single vessel diseases as variables, so it is impossible to make further comparisons in terms of complete revascularization. In our ongoing studies, we may include more data and make more comprehensive comparisons.

CONCLUSION

In SVR, patients with old age and renal failure are a high-risk population. This study observed significantly higher incidence of short-term mechanical support, mid-term mortality, and MACCE events. This study suggests the necessity to establish a comprehensive preoperative, intraoperative and postoperative treatment system in order to improve the short-term and mid-term surgical outcomes in these patients.

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