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Surgical Repair of Post Infarction Ventricular Septal Rupture: An 18-Years Retrospective Multicenter Study Where There Was No ECMO

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ABSTRACT

Background: Ventricular Septal Rupture (VSR) is a rare but challenging complication after Myocardial Infarction (MI).

Objectives: The present study aimed to evaluate the surgical outcomes of VSR over 18 years.

Methods: This multicenter study was conducted on 88 patients with post-MI VSR during 2000 - 2018.

Results: A consecutive series of 88 patients with surgical repair of VSR was evaluated. The patients (n = 11) presenting hemodynamic deterioration at the time of hospital admission died before any attempt for surgery. The mean intervals between MI and VSR diagnosis and between admission and operation were 7.5 ± 7.2 and 5 ± 5 days, respectively. VSR location did not influence the outcomes (P = 0.1). Concomitant coronary bypass was done for all patients. Only 25 patients survived and left the hospital (13 patients died in the operating room due to pump weaning failure and 50 patients died in the ICU due to low cardiac output). The predictors of poor prognosis included low ejection fraction (P = 0.01), prolonged pump time (P = 0.01), and operation in the second half of the study period (P = 002). However, the results of multivariate analysis showed that none of them was an independent predictor of perioperative mortality.

Conclusions: The perioperative mortality rate of VSR has remained high in case of inaccessibility to assist devices. Hence, VSR repair is recommended to be limited to certain centers with adequate experiences.

1. Background

Ventricular Septal Rupture (VSR), as a serious and known mechanical complication, occurs in 1 - 3% of cases with transmural Myocardial Infarction (MI) (1-5). It is a life-threatening complication and one of the most challenging emergencies for cardiac surgeons. However, its incidence has decreased significantly during the recent two decades due to the development and routine use of early reperfusion treatments (thrombolytic therapy and percutaneous coronary intervention) (5-8). In the natural course of MI without reperfusion therapy, coagulation necrosis may occur with neutrophils accumulation in the ischemic zone. The neutrophils apoptosis and the released lytic enzymes may contribute to split up of the myocytes into the necrotic part, eventually leading to VSR formation (6, 8, 9). In patients complicated by VSR, the combination of myocardial dysfunction and low cardiac output, acute right ventricular volume, and pressure overload leads to acute heart failure.

Traditionally, surgical defect closure is the only definitive treatment for post-MI VSR, which is disappointing. From the first surgical repair reported by Cooley in 1957, the perioperative mortality has remained high despite numerous advances in cardiac surgery techniques and perioperative care. Indeed, it has the highest mortality rate among all types of cardiac operation. It is also a major source of

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concern, as without defect closure, the mortality rate would be as high as 90%, which has been considered as class I indication for surgical repair (2, 3, 5, 6, 8-13).

The appropriate time for surgery is still under debate. Surgical timing and the associated co-morbidities play an important role in determining the patients' outcomes (4, 12, 14). The current guidelines suggest the immediate surgery, regardless of the patient's clinical status, in order to prevent further hemodynamic deteriorations and organ failures. However, some studies have recommended delaying the surgery by two-four weeks in case the patient is stable with regard to cardiac status (4, 9, 13).

Up to now, limited studies have addressed the experiences regarding the challenging operations of VSR patients in the Iranian population.

2. Objective

The present study aims to evaluate the early surgical outcomes and risk factors of VSR in three tertiary educational hospitals over an 18-year period.

3. Methods

3.1. Study Design

This retrospective database review was performed on consecutive patients who had undergone the surgical repair of post-MI VSR in three tertiary educational hospitals (Imam Khomeini Hospital, Shahid Modarres Hospital, and Rajaie Hospital) in Tehran, Iran during 2000 - 2018. The mentioned timeline was chosen with regard to the availability of acceptable medical records. The patients' informed consent was waived due to the retrospective design of the study.

This retrospective analysis included the patients presented with ST-segment elevation MI whose echocardiographic or angiographic findings showed the presence of interventricular shunts. The exclusion criterion was the presence of congenital Ventricular Septal Defect (VSD).

The demographic and clinical data of the patients including traditional cardiovascular risk factors, angiographic findings, perioperative data, interval between MI and hospital admission, interval between admission and operation, Intra-Aortic Balloon Pump (IABP) usage, Coronary Artery Bypass Graft (CABG) data, and operative and in-hospital mortality rates were obtained from their medical records.

After the diagnosis, medical care was started to reduce systemic vascular resistance and left-to-right shunt as well as to maintain the cardiac output to ensure adequate end-organ perfusion.

3.2. Surgical Treatment

VSR surgical management was consistent in the studied centers. Accordingly, all patients had midline sternotomy and moderate hypothermic cardiopulmonary bypass using bicaval cannulation and antegrade bloody cardioplegic solution. The longitudinal ventriculotomy approach was done through the infarcted area with direct access to the septal defect. The defect was repaired by one of the two routine techniques, namely Daggett technique of patch closure and David infarct exclusion technique, according to the local routines. Then, large prosthetic patches and interrupted pledget 3 - 0 polypropylene sutures were used by keeping the pledgets on the right ventricular side, being careful to prevent sutures from being cut. The infarct exclusion technique was used for friable margins and too inflamed tissues. In case of a large ventricular aneurysm, it was resected and ventriculotomy was closed by 2 - 0 polypropylene sutures with felt strips placed on each side of the ventriculotomy for reinforcement. If the patients had other stenotic coronary arteries, saphenous vein grafts were used on the cardioplegic heart before ventriculotomy, and proximal anastomoses were performed after the aortic clamp removal. Routine rewarming, de-airing, cardiopulmonary bypass weaning, and primary sternal closure were done. It should be noted that the left internal thoracic artery was not used. Moreover, no records showed cardiac output measurement intraoperatively and post-operatively.

3.3. Statistical Analysis

The data were assessed by descriptive statistics; i.e., frequency, percentage, mean, and standard deviation. The associations between the categorical variables were analyzed by chi-square test or Fisher's exact test. The variables included in univariate analysis with $P < 0.05$ were assessed using multiple logistic regression analysis and the multicollinearity was checked in the model. Accordingly, the variance inflation factor was below 2 for all variables. The Hosmer-Lemeshow test was used to evaluate the goodness of fit for the multiple logistic regression model. Furthermore, Kolmogorov-Smirnov test was applied to evaluate the normal distribution of the quantitative variables, and Mann–Whitney test was utilized for non-normally distributed variables. All statistical analyses were performed using the SPSS software (version 11.5; SPSS Inc, Chicago, IL, USA), and $P < 0.05$ was considered statistically significant.

4. Results

A consecutive series of 99 patients diagnosed with post-MI VSR were recruited from the three aforementioned hospitals between March 2000 and March 2018. Among these patients, 11 had hemodynamic deterioration at the time of hospital admission and died before any attempt for surgery. Consequently, 88 patients (40 males and 48 females) were included in the study and underwent surgeries in the three tertiary centers. The distribution of the risk factors and the patients' preoperative characteristics have been presented in Table 1. The results revealed no significant difference between the survived and dead groups with regard to cardiovascular risk factors, VSR location and size, number of stenotic coronary arteries, and need for IABP support (Table 1). However, the survivors had a significantly higher left ventricular ejection fraction and lower pump time compared to the non-survivors (38.8 ± 8.6% vs. 33.6 ± 9.3%, $P = 0.01$; 113.9 ± 42.4 vs. 147 ± 44.6 min, $P = 0.01$). The mortality rate was similar for the posterior and the anterior VSRs ($P = 0.07$).

The IABP was not used in 36 patients (36.3%), 11 of whom were not operated (100% of the non-operated patients) and 25 were operated (28.4% of the operated patients). The IABP

Table 1. The Demographic and Perioperative Characteristics of the Operated VSR Patients according to the Survival Status

	All Operated VSR Patients (n=88)	Survived Group (n=25)	Non-Survived Group (n=63)	P-value
Demographic				
Age (years)	63.6 ± 9.9	60.4 ± 11.3	64.8 ± 9.1	0.06
Sex (male)	41 (46.5%)	12 (48%)	29 (46 %)	1
Risk factors				
DM (%)	49 (55.6%)	9 (36%)	40 (63%)	0.3
HTN (%)	55 (62.5%)	11 (44%)	44 (69.8 %)	0.5
HLP (%)	44 (50%)	17 (68%)	27 (42.8%)	0.7
Lab data				
Pre OP Cr (mg/dl)	1.4 ± 0.6	1.2 ± 0.6	1.5 ± 0.7	0.2
Pre OP AST (IU/L)	91.4 ± 123.8	91 ± 148.4	91.5 ± 121.1	0.9
Pre OP ALT (IU/L)	77.6 ± 101.4	95.5 ± 138.2	74.3 ± 95.2	0.7
Echocardiographic data				
PAP (mmHg)	50 ± 15.9	49.6 ± 18.3	50.1 ± 15.2	0.9
QP/QS (by echo)	1.9± 0.4	1.7 ± 0.5	2 ± 0.2	0.2
VSR location				
Ant (%)	65 (73.8%)	18 (72%)	47 (74.6 %)	0.07
Post (%)	11 (13.6%)	3 (12%)	8 (12.6 %)	
Other (%)	12 (13.6%)	4 (16%)	8 (12.6 %)	
*Large VSR (%)	37 (42%)	10 (40%)	27 (42.8 %)	0.7
Revascularization				
Thrombolytic therapy (%)	15 (17%)	3 (12%)	12 (19 %)	0.2
PCI (%)	5 (5.6%)	2 (8 %)	3 (4.7%)	1
QP/QS (by echo)	1.9± 0.4	1.7 ± 0.5	2 ± 0.2	0.2
Surgery data				
IABP	63 (71.5%)	20 (80%)	43 (68.2 %)	0.3
Pre OP IABP (%)	47 (53.4 %)	17 (68 %)	30 (47.6%)	
MI to VSR diagnosis time (days)	7.5 ± 7.2	10.6 ± 8.6	6.2 ± 6.2	0.06
Admission to surgery time (days)	5 ± 5.1	5 ± 6.4	5 ± 4.5	0.9
CABG				
Single graft	33 (37.5 %)	11 (44 %)	22 (34.9 %)	0.6
2 grafts	39 (44.3 %)	10 (40%)	29 (46%)	
3 grafts	14 (15.9 %)	4 (16%)	10 (15.8%)	
4 grafts	2 (2.2%)	0	2 (3.1%)	
Operation dates (yrs.)				
2000-2009	42 (47.7%)	17 (68%)	25 (39.6%)	0.01
2010-2018	46 (52.3%)	8 (32%)	38 (60.3%)	

Abbreviations: ALT, alanine aminotransferase; Ant, anterior; AST, aspartate aminotransferase; CABG, coronary artery bypass graft; Cre, creatinine; DM, diabetes mellitus; EF, ejection fraction; HLP, hyperlipidemia; HTN, hypertension; IABP, intra-aortic balloon pump; *Large VSR: defined as ≥15 mm by echocardiographic evaluation; MI, myocardial infarction; PAP, pulmonary artery pressure; PCI, percutaneous coronary intervention; Post, posterior; QP/QS, the ratio of pulmonary blood flow to systemic blood flow; VSR, ventricular septal rupture.
Values have been presented as mean ± SD.

was not used either because it was judged unnecessary due to hemodynamic stability or due to the failure of the balloon insertion into the femoral artery. Among the operated patients with IABP support, the mortality rate was 20 in survived and 43 in non-survived patients, and the difference was statistically insignificant (P = 0.3).

The MI diagnosis was based on the fourth Universal Definition of Myocardial Infarction. Additionally, the MI to VSR diagnosis time was defined as the time from the diagnosis of MI to the time of VSR diagnosis by transthoracic echocardiography. The results revealed a longer MI to VSR diagnosis time in survivors compared to non-survivors (10.5 ± 8.5 versus 6 ± 6 days, P = 0.06).

Among the operated patients, 13 (14.77%) showed failure in weaning off the cardiopulmonary bypass due to cardiac failure in the operating room and 50 (56.81%) expired due to low cardiac output and multi-organ failure during the postoperative period in the ICU. The ventricular assist devices were not accessible for these patients. The remaining patients (n = 25, 28.4%) survived and were discharged from the hospitals. The results indicated no significant difference between the two operative techniques (patch closure vs. exclusion technique) with respect to early mortality.

The results of the comparison of the operated patients' data according to time division have been presented in Table 2. Accordingly, all the 11 patients (11.1% of all patients) with cardiogenic shock who died before operation belonged to the first half of the study period. The frequency of VSR was similar in the first and second halves of the study period (18 years), but most survivors were operated in the first half (P = 0.02). The routine use of IABP also increased in the second half, but the difference was not statistically significant (P = 0.1). During the second half, the VSR patients were referred to the referral hospitals faster (P = 0.03), underwent thrombolytic therapy in primary centers prior to transfer (P = 0.01), and had significantly longer

Table 2. The Demographic and Perioperative Characteristics of the Ventricular Septal Rupture Patients according to the Operation Date

	First Half of 2000-2009 (n=42)	Second Half of 2010-2018 (n=46)	P
Age (yrs)	63 ± 8	64 ± 8	0.4
Sex (male)	22 (52 %)	19 (41 %)	0.3
DM (%)	21 (50%)	28 (60%)	0.2
HTN (%)	23 (57%)	32 (69%)	0.2
HLP (%)	18 (43%)	26 (56%)	0.3
VSD location			
Ant (%)	31 (74%)	34 (73%)	0.1
Post (%)	4 (10%)	7 (16%)	
Other (%)	7 (16%)	5 (11%)	
Large VSD (%)	15 (35%)	22 (47%)	0.7
EF (%)	37 ± 9	33 ± 9	0.06
PAP (mmHg)	48 ± 17	51 ± 15	0.4
Pre-op Cre (mg/dl)	1.2 ± 0.6	1.6 ± 0.6	0.06
QP/QS	1.6 ± 0.3	2 ± 0.3	0.01
AST (IU/L)	113 ± 120	80 ± 126	0.4
ALT (IU/L)	97 ± 91	68 ± 106	0.3
MI to admission (day)	10 ± 7	6 ± 7	0.03
Admission to surgery (day)	4.5 ± 5	5.5 ± 6	0.4
Pump time (min)	114 ± 38	152 ± 45	0.002
Thrombolytic (%)	5 (11%)	10 (21%)	0.01
PCI (%)	3 (7 %)	2 (4%)	0.5
Pre-op IABP (%)	28 (66%)	19 (41%)	0.1
Operative IABP (%)	7 (16%)	9 (19%)	
Mortality (%)	25 (59 %)	38 (82%)	0.02

Abbreviations: DM, diabetes mellitus; HTN, hypertension; HLP, hyperlipidemia; VSD, ventricular septal defect; Ant, anterior; Post, posterior; EF, ejection fraction; PAP, pulmonary artery pressure; Cre, creatinine; QP/QS, the ratio of pulmonary blood flow to systemic blood flow; AST, aspartate aminotransferase; ALT, alanine aminotransferase; MI, myocardial infarction; PCI, percutaneous coronary intervention; IABP, intra-aortic balloon pump; CABG, coronary artery bypass graft.
Values have been presented as mean ± SD.

operation durations (P = 0.002). However, none of these factors was found to be an independent predictor in the multivariate analysis.

5. Discussion

In the present study, a consecutive series of 88 patients with post-MI VSR was studied for 18 years. To the best of our knowledge, this was the first multicenter study on the surgical repair of VSR in Iran. The significant early mortality after the surgical repair of post-MI VSR was the main finding in this study.

VSR is a well-recognized mechanical complication of acute MI. However, its incidence has been very low in the recent decades owing to revascularization. However, it has remained one of the most serious complications. Development of acute decompensated heart failure is the most important determinant of early outcomes following VSR. Timing of surgery (immediate surgery vs. delay operation) and type of closure (direct patch closure vs. exclusion technique) are two important debates about the surgical treatment of VSR. Evidence has indicated no significant difference between these two operative techniques in terms of early morbidity and residual shunt (1, 7, 9, 11, 15). Nonetheless, a reverse association was observed between VSR mortality and timing of surgery (6, 13, 15).

VSR closure in necrotic tissues is technically difficult. It is believed that in case of stable hemodynamic status, it is better to have an interval to achieve a firm and fibrotic margin of VSR in order to support the tension of sutures. In case of cardiogenic shock, the patient should be operated immediately to achieve a better outcome. Under rare conditions where the patient has neglected the VSR and refers with multi-organ failure, every attempt may be futile. Lower mortality in delayed closure means that patients are in more hemodynamically stable conditions and have a chance for a more effective repair. On the other hand, the need for early surgery means the immediate operation on decompensated heart failure and suturing in inflamed, fragile tissues. The highest operative mortality rate has been reported among the patients who had to undergo surgery to survive (13, 16). The mortality reported in the current study was comparable to the previous studies. The mortality rate for post-MI VSR emergency surgical repair depends on the selected population (0 – 80 %) (1, 4, 9, 11, 12). According to the Society of Thoracic Surgeons (STS) database, the operative mortality rate was more than 40%, with an inverse association between MI and repair time (16). The recent guideline recommends the urgent repair of post MI-VSR as a class I indication, irrespective of the hemodynamic status (9). The STS database introduced the timing of surgery as an important factor influencing the mortality, giving a seven-day cut-off (54% mortality compared to 18%) (15). In another report, surgical repair was associated with 100% mortality during the first 10 days. Nevertheless, all patients survived when the operation was performed three-four weeks later (15). In contrast, in a similar study conducted in a tertiary center in France, the therapeutic management was early surgery as soon

as possible without considering the hemodynamic status along with prophylactic preoperative IABP implantation for all patients (11). In spite of the discrepancies in timing of VSR operation, efforts should be made to prevent further hemodynamic deterioration. It seems that the hemodynamic status is the most important determinant of the outcome, while the timing (early vs. late) does not have such a role.

In the present study, simultaneous CABG did not influence the patients' early outcomes. However, other studies have shown that it increased the survival rate and prevented the deterioration of the left ventricular function in patients with three-vessel diseases in the long run (14, 15). Yet, the number of involved coronary vessels did not have any significant effects on the immediate surgical outcomes of patients, as the prevalence rates of two- and three-vessel diseases were similar in the non-survivor group compared to the survivor group (12, 17, 18).

Some reports have attributed the high mortality rates in posterior VSR to the difficulty in operative exposure and the concomitant ventricular dysfunction. Although the location of VSR did not influence the outcomes among the patients under the present investigation, it was helpful in determining the ventriculotomy site (1-3, 11, 16).

The Extracorporeal Eembrane Exygenator (ECMO), as a bridge to recovery from the acute phase, can be applied to stabilize patients' conditions and to avoid further deterioration (19). ECMO was not accessible in the centers under the present investigation. Thus, all the VSR patients were only treated with intravenous inotropic support and IABP, and those with cardiogenic shock refractory to these primary treatments did not survive. Some studies have suggested delayed surgery as an important option for the centers without ECMO support to improve the outcomes (14). IABP decreases the afterload of the left ventricle and improves coronary circulation. Although IABP use did not show a survival benefit, it provided a relative and transient mechanical support.

Recent studies have emphasized the possibility of using mechanical circulatory support (Impella) to decrease the Qp/Qs and the pulmonary artery and capillary wedge pressure as well as to increase the cardiac index (17). This mechanical assistance can be introduced percutaneously. Although it has been used for small series of patients, its benefits seem to exceed those of the IABP. The results of another study conducted on 64 VSR patients in another province of Iran during 2005 - 2015 confirmed that in-hospital mortality could be more than 80% without using assist devices (20).

Trans-catheter closure of post-MI VSR has been demonstrated in case reports and limited single-center series with varying results. Despite using less invasive techniques, mortality has remained high (21). Percutaneous trans-catheter repair has been suggested in the defects less than 15 mm as a temporary option to decrease the shunt and to help stabilize the hemodynamic condition before the surgery (1, 4, 8, 10, 15). This is especially true for the patients who are deemed poor surgical candidates such as those with advanced age and multiple comorbidities. However, it can be a destination therapy in some carefully selected patients (9). There are a few case reports regarding the percutaneous closure of VSR in Iranian hospitals (22).

In the current research, the mortality rate was statistically significant in the second half of the study period. To date, there has been a significant shift to junior surgeons in all centers. Nevertheless, VSR is a rare issue requiring surgical expertise that is not achieved easily. Few surgeons may examine more than a few VSR cases per year. Despite the progress in surgical techniques and perioperative care in coronary bypass surgery during the past years, surgeons are gradually losing their skills in the treatment of such patients (during the present study period, fewer than two patients were found per year in every center). This implies that VSR patients in stable conditions should be transferred to selected centers to improve outcomes.

This retrospective study had some limitations including the small sample size attributed to the rare occurrence of the disease, lack of follow-up of living patients, and incomplete information. Given the multicenter design of the study, it needed a simplified form of data collection with a limited number of variables so as to avoid further missing data. However, the strong point of the study was that the data of the patients undergoing the surgical repair of post-MI VSR were prepared from three high-volume centers during an 18-year period.

5.1. Conclusion

The therapeutic management has not changed during the recent two decades and has been limited to surgery, as trans-catheter VSR closure and ECMO are not accessible easily in Iranian centers. Emergent surgery is required for refractory hemodynamic instability. Thus, VSR repair is suggested to be limited to certain centers with adequate experiences because of the low average annual number.

5.2. Ethical Approval

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5.3. Informed Consent

Informed consent was waived due to the retrospective design of the study.

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Authors' Contribution

Study concept and design: M.F. and Z.M.; analysis and interpretation of data: M.B. and M.F.; drafting of the manuscript: M.F., Z.M., and M.B.; critical revision of the manuscript for important intellectual content: A.T., S.R., and P.S.; statistical analysis: P.S. and Z.M.

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