

A bovine pericardium rigid prosthesis for left ventricle restoration: 12 years of follow-up

Prótese rígida de pericárdio bovino para remodelamento ventricular esquerdo: 12 anos de seguimento

Lindemberg Mota SILVEIRA FILHO¹, Orlando PETRUCCI², Karlos Alexandre de Souza VILARINHO³, R. Scott BAKER⁴, Fernando GARCIA⁵, Pedro Paulo Martins de OLIVEIRA⁶, Reinaldo Wilson VIEIRA⁷, Domingo Marcolino BRAILE⁸

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Resumo

Introdução: O infarto do miocárdio pode levar à dilatação do ventrículo esquerdo e numerosas técnicas têm sido descritas para remodelar o ventrículo ao seu formato original. O objetivo deste estudo foi comparar nossa experiência com a cirurgia de Dor modificada, usando prótese rígida, com a técnica de exclusão septal ventricular anterior (SAVE). Foi avaliado também o EuroScore como índice preditivo da mortalidade tardia.

Métodos: Avaliamos 80 pacientes que foram submetidos a remodelamento ventricular entre 1997 e 2007. Oito pacientes foram excluídos por dados incompletos. A cirurgia de Dor modificada (grupo MD) foi constituída por 53 pacientes e 19 no grupo com exclusão septal anterior (grupo SAVE). Os pacientes foram classificados de acordo com o formato do ventrículo como tipo I, II ou III. Curvas de sobrevivência de Kaplan-Meier e regressão de Cox foram utilizadas para analisar a sobrevida nas duas técnicas e a mortalidade esperada foi avaliada utilizando o EuroScore para a mortalidade operatória e após 12 anos de seguimento.

Resultados: A mortalidade operatória foi comparável nos dois grupos quando avaliados pelo EuroScore. Os grupos

foram comparáveis quanto a dados clínicos, com exceção, que o grupo MD apresentava maior número de pacientes com balão intra-aórtico no pré-operatório (5,7% vs. 0; $P < 0,01$). A curva actuarial considerando o formato dos ventrículos foi comparável avaliando-se todos os pacientes, sendo que o formato tipo I apresentou discreta melhor sobrevida após 12 anos de seguimento. As técnicas MD e SAVE demonstraram sobrevidas semelhantes após 12 anos de seguimento ($71,5 \pm 12,3$ vs. $46,6 \pm 20,5\%$; $P = 0,08$). Avaliando o EuroScore para todos os pacientes, observamos que nas categorias utilizadas, ou seja, 0-10%; 11-49% e maior que 50% de mortalidade esperada, a sobrevida após 12 anos de seguimento foi diferente ($70,9 \pm 16,2$ vs. $67,5 \pm 12,7$ vs. $53,0 \pm 15,5$; $P = 0,003$).

Conclusão: A técnica MD demonstrou melhora consistente da fração de ejeção no seguimento tardio. As duas técnicas apresentaram sobrevida comparáveis. O EuroScore pode ser um índice útil para avaliação da sobrevida tardia.

Descritores: Disfunção Ventricular Esquerda. Aneurisma Cardíaco. Infarto do Miocárdio. Ventrículos do Coração/cirurgia.

1. Mestre em Cirurgia, Médico Assistente Disciplina de Cirurgia Cardíaca da Universidade Estadual de Campinas (UNICAMP), Campinas, SP, Brasil.
2. Pós-doutorado; Professor Assistente Doutor da Faculdade de Ciências Médicas (FCM) da UNICAMP, Campinas, SP, Brasil.
3. Mestre em Cirurgia; Médico Assistente Disciplina de Cirurgia Cardíaca da UNICAMP, Campinas, SP, Brasil.
4. Bachelor of Science - Laboratory Manager from Division of Cardiothoracic Surgery, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, USA.
5. Médico.
6. Doutor, Professor Assistente Doutor da FCM/UNICAMP, Campinas, SP, Brasil.
7. Livre Docente, Professor Adjunto da Disciplina de Cirurgia Cardíaca da FCM/UNICAMP, Campinas, SP, Brasil.

8. Livre Docente, Editor-Chefe da RBCCV. Professor Emérito e Pró-Reitor de Pós-graduação da Faculdade de Medicina de São José do Rio Preto (FAMERP). Professor Livre-Docente da Unicamp, Campinas, SP, Brasil.

Work done at Universidade Estadual de Campinas, Campinas, SP, Brazil.

Correspondence address: Orlando Petrucci.
Rua João Baptista Geraldí, 135 – Campinas, SP, Brasil – Zip code:13084-115
E-mail: petrucci@cardiol.br

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Abstract

Background: Myocardial infarction might result in dilated left ventricle and numerous techniques have been described to restore the original left ventricle shape and identify tools for late survival assessment. The aim of this study is to compare our experience with a modified Dor procedure using a rigid prosthesis to the septal anterior ventricular exclusion procedure (SAVE) for left ventricle restoration. The EuroScore index for prediction of late follow up survival was evaluated.

Methods: We evaluated 80 patients who underwent left ventricle restoration between 1999 to 2007 and eight patients were excluded with incomplete data. A modified Dor procedure with rigid prosthesis (MD group) was performed on 53 patients and 19 underwent the septal anterior ventricular exclusion procedure (SAVE group). The patients were classified according their left ventricle shape as type I, II or III. Kaplan-Meier and Cox proportional hazard ratio regressions analysis were performed to assess survival after both techniques and expected surgical mortality using EuroScore index ranking after 12 years of follow up.

Results: The operative mortality was comparable in both groups ranked by EuroScore index. The groups were

comparable for all clinical data, except the MD group had more patients using intra-aortic balloon pumps before surgery, (5.7% vs. 0; $P < 0.01$). Kaplan Meier analysis by left ventricle shape showed comparable survival for all patients, with slightly higher survival for type I. Kaplan Meier analysis of all death showed equivalent survival curves for both techniques after 12 years of follow up (71.5 ± 12.3 vs. 46.6 ± 20.5 years; $P = 0.08$). Kaplan Meier analysis of EuroScore index for all patients showed a difference between the three ranked categories, i.e., 0 to 10%, 11 to 49% and higher than 50% expected surgical mortality after 12 years of follow up (70.9 ± 16.2 vs. 67.5 ± 12.7 vs. 53.0 ± 15.5 ; $P = 0.003$).

Conclusion: The MD procedure showed consistent ejection fraction improvements after long term follow up. Survival was comparable for all ventricular types and for the MD and SAVE procedures. The EuroScore index is a useful index for late survival assessment of ventricular restoration techniques.

Descriptors: Ventricular Dysfunction, Left. Heart Aneurysm. Myocardial Infarction. Angina, Unstable. Heart Ventricles/surgery.

INTRODUCTION

Numerous surgical techniques have been attempted in patients with ventricular aneurysm to restore the left ventricle to its original shape. The first technique for ventricular aneurysm was described by Cooley et al. [1]. Jatene [2], in 1985, emphasized the theoretical significance of geometry of the left ventricle chamber after surgical repair. Later, Dor et al. [3] showed results with an endoventricular circular patch plasty in patients with scar areas in the left ventricle after myocardial infarction. Dor et al. [4] also reported that the same technique could be used as an alternative treatment to heart transplantation for patients with ischemic dilated cardiomyopathy.

In 1991, Braile et al. [5] described a modification of the Dor procedure (MD) which uses a novel prosthesis assembled with a bovine pericardium and a radiopaque elliptical ring. This prosthesis is placed in an oblique direction between the apex and the septum, excluding the scarred region as well as the septum scar, and further rebuilds the left ventricle into an elliptical form [5]. This novel prosthesis allows for reproducible results and a new apex reconstruction that contributes to heart twisting and left ventricle restoration. Using patch placement in an oblique direction between the apex and the septum, but just below the aortic valve, the septal anterior ventricular exclusion (SAVE) procedure was developed to better reconstruct elliptical form in the presence of a left ventricle septal involvement [6].

Recently, the STICH study showed no clinical benefits by adding the ventricular restoration to coronary artery bypass grafting (CABG) when compared to CABG alone [7]. Of note, this study did not examine left ventricle shape before the surgical procedure and thus could not assess results due to patient selection or distinct left ventricle shape abnormalities with restoration procedures. Di Donato et al. [8] stratified patients with dilated ischemic cardiomyopathy who underwent the left ventricle restoration procedure and stratified them according to three basic left ventricle shapes. However, they were unable to show any late survival differences among the three different categories, perhaps due to study size limitations. The EuroScore index has been described for quality of cardiac surgical care and more recently it was proven useful for intensive care unit stay, follow up survival, and quality of life assessment [9-11].

We described our experience with the MD procedure and compare it to or use of the SAVE procedure. At the same time, we analyze the effect of left ventricle shape and the EuroScore index on late survival follow up. We hypothesized that MD is an efficient procedure for ventricular restoration based on the left ventricle shape and that the EuroScore might be of value for late survival assessment.

METHODS

Data Collection

After institutional review board acceptance, a

retrospective review of data was carried out on a cohort of patients who underwent left ventricular restoration surgery secondary to ischemic cardiomyopathy at our institution from 1999 to 2007. All patients were analyzed for demographic, echocardiograph, and catheterization data. The patients were divided in two groups based on the surgical technique employed: MD procedure or SAVE. All available preoperative and follow-up data was reviewed.

Preoperative clinical data parameters analyzed were age, gender, New York Heart Association functional class (NYHA), recent myocardium infarction (less than 30 days), intra-aortic balloon pump (IABP) preoperative to the surgery, smoking, site of myocardium infarction, diabetes, unstable angina (needs for intravenous nitrate), peripheral vascular disease, renal failure (defined as serum creatinine > 1.5 mg/dL), arterial hypertension, stroke prior to surgery, presence of single coronary artery disease, and presence of multiple coronary disease.

Preoperative echocardiograph data analyzed were end diastolic ventricular diameter, end systolic ventricular diameter, and ejection fraction. Mitral valve regurgitation was graded as absent, mild, moderate, or severe, on the basis of pulse wave tracing and color Doppler mapping.

The perioperative data, surgical findings, and operative mortality variables analyzed were: cardiopulmonary bypass (CPB) time, CABG, number of anastomosis, endarterectomy, mitral valve repair, ICU length of stay, hospital length of stay, 30 day mortality as ranked by EuroScore, and left ventricular shape classification as proposed by Di Donato et al. [8]. We defined the early postoperative period as 30 days after surgery, and the late postoperative period was defined as periods longer than 31 days after surgery.

Surgical techniques

The technique selection was based on ventricular shape and presence of well-defined area with ventricular scar. Patients with left ventricle enlargement and anterior dyskinetic areas were selected for the MD procedure, and patients with left ventricle enlargement without an evident scar area were selected for the SAVE procedure.

All ventricular restorations were performed by 4 senior surgeons (OP, LMSF, PPMO, and DMB) using the MD or SAVE technique as described below.

Modified Dor Procedure (MD)

After standard cardiopulmonary bypass was initiated, an aortic cross clamp was applied, and blood cardioplegic arrest was performed. Complete coronary revascularization was performed. The left ventricle was opened from the apex along the left anterior interventricular artery into the scar tissue. The procedure was then performed as described by Dor et al. [4] and as modified by Braile et al. [5] using a novel prosthesis. Interrupted mattress stitches were applied

1 cm below the transition region between healthy muscle and scar tissue. This prosthesis was assembled with bovine pericardium and an ellipsoid rigid ring (Figure 1). The prosthesis size was assessed with a device specially made for the purpose. The position of the prosthesis relative to the ventricle septum was chosen in an attempt to reconstruct a new ventricle apex with a smaller left ventricle cavity. The prosthesis was tied and an extra running suture was applied on the prosthesis flap. The final step was a running suture closing the left ventricle wall. Where necessary, a mitral valve repair was performed via left atrium. The aortic clamp was released and the patient was weaned from cardiopulmonary bypass.

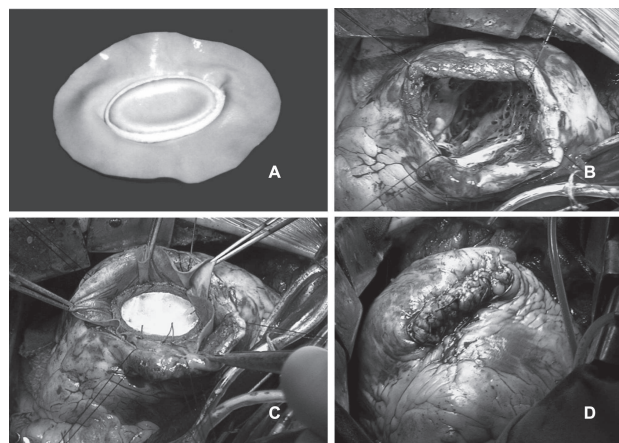


Fig. 1 - (A) The prosthesis assembled with bovine pericardium and a radiopaque ellipsoid ring. (B) Anterior ventriculotomy with an extensive scar at ventricle septum wall. (C) Prosthesis implanted in oblique orientation to the septum. (D) Final aspect of the procedure. (E) Pre-operative oblique anterior angiogram with left ventricle during diastole showing an enlarged cavity

Septal Anterior Ventricular Exclusion (SAVE)

The initial steps were the same as MD group. The left ventricle was opened from the apex to the base along the left anterior interventricular artery. Multiple mattress stitches were placed along the exclusion line of the septum, the direction from the apex to septal site 1 cm below the aortic valve. Similarly, multiple mattress stitches were placed on left ventricle free wall. A bovine pericardial patch was trimmed and placed along the site of the exclusion as previously described [6]. The mitral valve repair was performed via left atrium whenever necessary. The aortic clamp was released and the patient was weaned from cardiopulmonary bypass.

Statistical analysis

All data were expressed as mean \pm SD for continuous variables and expressed as frequency for categorical variables. Comparisons between groups were made using the chi-square test for categorical variables and variance

stabilizing transformations were performed when necessary. Mean values for continuous variables were compared using the t-test or the Wilcoxon rank sums test as appropriate. Kaplan-Meier and Cox proportional hazard ratio regression analysis were performed to assess the survival after ventricular restoration surgery in both techniques. The model was adjusted for mitral regurgitation after surgery, NYHA functional class prior to surgery, NYHA functional class after surgery, ranked EuroScore [12], and technique performed.

A logistic stepwise regression analysis was performed to determine the best fitting model for identification of independent predictors of operative death after ventricular restoration surgery adjusting for stroke prior to surgery, intra-aortic balloon pump prior to surgery, serum creatinine higher than 1.5 mg/dL prior to surgery, NYHA functional class prior to surgery, surgical technique performed, renal failure requiring dialysis, and EuroScore prior to surgery. Independent variables were included in the model if $P < 0.05$ and excluded if $P > 0.01$.

RESULTS

During the period of study, 80 patients underwent left ventricular restoration surgery, however eight patients were excluded from analysis due incomplete medical files and/or catheterization data. All excluded patients were from MD group. There were 53 patients on MD and 19 on SAVE group. The demographics and co-morbidities are summarized in Table 1.

The MD group had more patients with IABP prior to the surgery (5.7% vs. 0; $P < 0.01$). Both groups showed comparable echocardiograph variables prior to surgery and on late follow up. After 2.3 ± 1.6 years of mean follow up in the MD group and 2.6 ± 1.4 years in the SAVE group we observed an improvement in NYHA functional class intragroup analysis, but no difference between intergroup analysis. The ejection fraction was improved in the MD group by intragroup comparison, but was comparable to the SAVE group at late follow up. These data are summarized in Table 2.

Table 1. Patients demographic and preoperative variables.

| Variable | MD Group (n=53) | Save Group (n=19) | P value |
|-----------------------------|---|--|---------|
| Age | 57.8±14.1 | 57.5±8.9 | 0.94 |
| Recent MI | 15 (28.3%) | 2 (10.5%) | 0.21 |
| Gender | M(40) F(13) | M(9) F(10) | 0.11 |
| IABP pre operative | 3 (5.7%) | — | <0.01 |
| Smoking | 28 (52.8%) | 15 (78.9%) | 0.09 |
| Site of MI | Anterior 30 (56.6%) Posterior 23 (43.4%) | Anterior 11 (57.9%) Posterior 8 (42.1%) | 0.86 |
| Diabetes | 12 (22.6%) | 8 (42.1%) | 0.18 |
| Unstable Angina | 33 (62.3%) | 10 (52.6%) | 0.64 |
| Peripheral Vascular disease | 10 (18.9%) | 3 (15.8%) | 0.96 |
| 1-vessel disease | 10 (18.9%) | 6 (31.6%) | 0.55 |
| Stroke | 4 (7.5%) | 2 (10.5%) | 0.93 |
| Serum creatinine >1.5mg/dL | 8 (15.1%) | 3 (15.8%) | 0.76 |
| Arterial hypertension | 46 (86.8%) | 17 (89.5%) | 0.91 |

Table 2. Baseline and late follow up NYHA and echocardiographic data.

| Variable | MD Group | | | SAVE Group | | | Intergroup Pre P value | Intergroup Early Post P value | Intergroup Late Post P value |
|----------|---------------|------------------------|-----------------------|---------------|----------------------|----------------------|---------------------------|-------------------------------------|------------------------------------|
| | Pre (n=53) | Early Post (n=53) | Late Post (n=38) | Pre (n=19) | Early Post (n=19) | Late Post (n=11) | | | |
| EDD (mm) | 59.5±7.7 | 53.0±7.9 (P=0.049) | 56.8±11.7 (P=0.25) | 57.5±4.6 | 54.2±2.8 (P=0.43) | 58.2±7.9 (P=0.52) | 0.24 | 0.97 | 0.68 |
| ESD (mm) | 46.4±9.1 | 40.1±8.2 (P=0.03) | 42.5±9.6 (P=0.08) | 42.9±4.9 | 41.5±3.2 (P=0.76) | 43.9±6.1 (P=0.51) | 0.17 | 0.32 | 0.67 |
| EF (%) | 38.5±3.9 | 52.1±12.5 (P=0.001) | 49.8±9.5 (P=0.002) | 44.3±11.6 | 49.7±8.3 (P=0.35) | 49.2±8.5 (P=0.30) | 0.09 | 0.48 | 0.93 |
| NYHA | 2.4±1.2 | | 1.8±0.9 (P=0.002) | 3.0±1.2 | | 1.7±0.9 (P=0.02) | 0.93 | | 0.82 |
| MR grade | 0.9±0.6 | 0.5±0.6 (P=0.13) | 0.9±0.7 (P=1.00) | 1.0±0.6 | 0.8±0.7 (P=0.85) | 1.1±0.5 (P=0.58) | 0.78 | 0.41 | 0.31 |

All values compared to pre operative time. Late post: MD group mean follow up 2.3 ± 1.6 years; median follow up: 3.4 years. SAVE group mean follow up 2.6 ± 1.4 years; median follow up: 3.3 years

Table 3. Operative findings, perioperative variables and ranked mortality.

| Finding | MD Group (n=53) | SAVE Group (n=19) | P value |
|--------------------------------------|-----------------|-------------------|---------|
| CPB time | 106.0±26.6 | 76.1±26.7 | <0.001 |
| CABG | 44 (83%) | 18 (94.7%) | 0.37 |
| Number of anastomosis | 2.1±1.1 | 1.9±0.7 | 0.51 |
| Endarterectomy | 4 (7.5%) | 0 (0.0%) | 0.51 |
| Mitral valve repair | 6 (11.3%) | 2 (10.5%) | 0.75 |
| Inotropes prior to surgery | 32 (60.4) | 9 (47.7%) | 0.49 |
| IABP after surgery | 14 (26.4%) | 1 (5.3%) | 0.11 |
| Renal failure* | 4/53 (7.5%) | 0/19 | 0.51 |
| ICU length time (days) | 7.1±12.7 | 6.7±5.9 | 0.89 |
| Hospital length time (days) | 10.9±11.6 | 10.63±6.3 | 0.88 |
| Ventricle shape classification | | | |
| Type I | 32 (60.4%) | — | <0.001 |
| Type II | 21 (39.6%) | — | 0.003 |
| Type III | — | 19 (100.0%) | <0.001 |
| 30-day mortality ranked by EuroScore | | | |
| 0 -10% | 1/24 (4.2%) | 0/11 | 0.69 |
| 11 - 49% | 3/23 (13.0%) | 1/3 (33.3%) | 0.95 |
| > 49% | 1/6 (16.7%) | 4/5 (80.0%) | 0.14 |

CPB - cardiopulmonary bypass, CABG - coronary artery bypass graft. * renal failure defined as need of dialysis

The MD group experienced a longer CPB time vs. the SAVE group (106.0 ± 26.6 vs. 76.1 ± 26.7 min; $P < 0.001$). The MD group showed no patients with ventricle shape type III classification while the SAVE group showed no patients with ventricle shape type I and II classification. The surgical findings, perioperative variables and ranked mortality are summarized in Table 3. The operative mortality was comparable in both groups ranked by EuroScore.

The logistic stepwise analysis for operative death showed a positive correlation to functional class prior to surgery ($P = 0.03$), functional class after surgery ($P = 0.05$), and renal failure ($P = 0.02$). There were three late cardiac deaths and one late death due gastric neoplasm in the MD group. The SAVE group had one late cardiac death. The Kaplan Meier analysis with all death showed equivalent survival curves with both techniques after 12 years of follow up (71.5 ± 12.3 vs. 46.6 ± 20.5 years; $P = 0.08$), excluding operative mortality the Kaplan Meier analysis also showed comparable curves (79.1 ± 13.1 vs. 66.7 ± 27.2 years; $P = 0.62$). Median survival after surgery for the SAVE group was 6.3 years while the MD group had >70% survival calculation after 12 years of follow-up (Figure 2A and 2B).

The Kaplan Meier analysis ranked by EuroScore for all patients who underwent ventricular restoration procedure showed a difference between the three ranked categories, i.e., 0 to 10 %, 11 to 49% and higher than 50% expected mortality after 12 years of follow up (70.9 ± 16.2 vs. 67.5 ± 12.7 vs. 53.0 ± 15.5; $P = 0.003$, Figure 2C). The Kaplan Meier analysis by Di Donato classification [8] for all patients who

underwent ventricular restoration showed comparable survival among all three classifications types (Figure 2D).

The impact of several risk factors on survival was assessed using Cox proportional hazard regression with stepwise analysis adjusting for the previously described variables. The hazard ratio for ranked EuroScore was 8.5 (IC 95%: 1.1 to 64.9; $P = 0.04$). The employed technique was not an independent variable for death and was not included in the model.

A typical type I Di Donato classification [8] is shown in Figure 3, showing successful restoration of an elliptical postoperative shape after surgical repair.

DISCUSSION

The significance of our findings are that left ventricle restoration technique using this prosthesis is reproducible and the EuroScore index is important for predicting long term survival after ventricular restoration. The MD technique indicated a slight superiority on survival during late follow up when compared to the SAVE procedure, but this did not reach statistical significance, likely due to power of the sample size. Furthermore, on late follow up survival, a trend also approached significance with the Di Donato left ventricle classification [8].

Interventions in dilated ventricles after myocardial infarction were first introduced by Cooley et al. [1], in 1964. Later, Jatene [2] described a new technique for left ventricle reshaping and made important observations about the

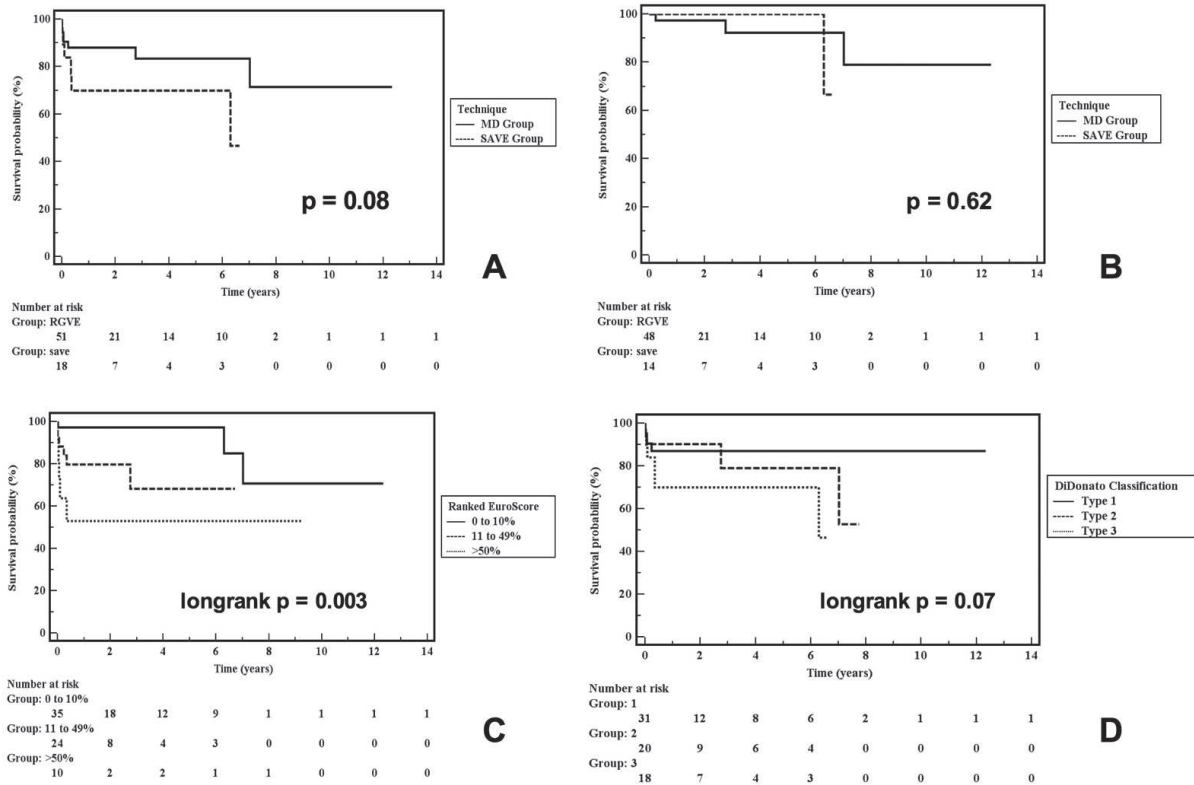


Fig. 2 - (A) Survival curve with all mortality for the two different surgical techniques. (B) Survival curve without operative mortality for the two different surgical techniques. (C) Survival curve with all mortality cases ranked by EuroScore. (D) Survival curve with all mortality cases with Di Donato left ventricle classification

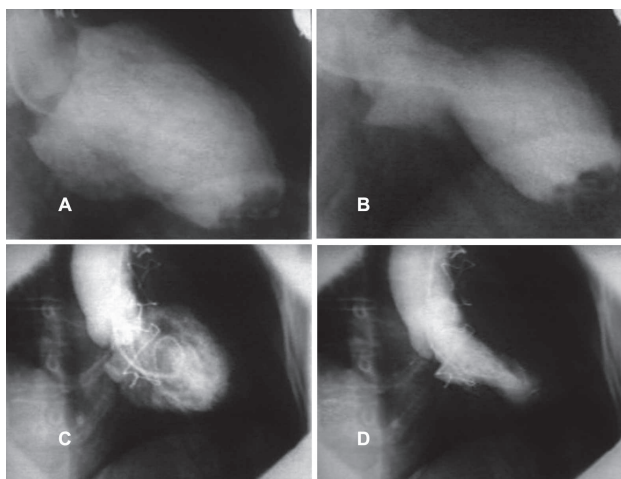


Fig. 3 - (A) Pre-operative oblique anterior angiogram with left ventricle during diastole showing an enlarged cavity. (B) Pre-operative oblique anterior angiogram with left ventricle during systole showing an enlarged cavity and dyskinetic anterior wall. (C) Post-operative oblique anterior angiogram with left ventricle during diastole with a normal left ventricle volume. (D) Post-operative oblique anterior angiogram with left ventricle during systole with normal volume and shape

geometry of left ventricle shape. Subsequently, Dor et al. [3] advanced the idea reporting their geometric approach to the left ventricle restoration after myocardial infarction [13]. Then in 1991, Braile et al. [5] reported their initial experience with a novel prosthesis which was assembled with an ellipsoid rigid ring and bovine pericardium. This prosthesis allowed for an undemanding sizing assessment and reproducible implantation.

The classification proposed by Di Donato et al. [8] was applied retrospectively to all anterior oblique left ventricle angiograms. The MD group showed an improvement on NYHA functional class with steady end diastolic and end systolic diameters after a mean follow up of 2.3 years. The ejection fraction increased in the MD group comparing intragroup preoperative values and postoperative values after 2.3 years of mean follow up. In contrast, the SAVE procedure showed an improvement on NYHA functional class, but an increase of end diastolic diameter with steady systolic diameter after a mean follow up of 2.6 years.

The MD group showed a longer CPB time with no increase in operative mortality, hospital length of stay, and ICU length of stay. The surgical mortality observed were the same predicted by EuroScore index in both technique

groups. It should also be noted that both techniques provided good overall survival in a very sick patient population with 52% of them presenting in class III of IV of NYHA functional class.

The remodeling process that occurs after myocardial infarction enlarges chamber diameters and increases wall tension by Laplace's law. The augmented wall stress results in increased oxygen consumption, decreased subendocardial blood flow, and reduced systolic shortening [14]. Not surprisingly, the importance of left ventricle volume reduction has been shown by several prior reports [15-18] and the remain left ventricle cavity volume was important.

Using the MD technique we demonstrated left ventricle diameters were reduced in the early postoperative time and remained steady after 2.3 years of follow up. In addition, the MD technique reshaped the left ventricle into a more elliptical form (Figure 3). We were unable to show any predictive echocardiograph parameter for late survival in our series. Our findings are similar to Isomura et al. [6] in a similar series of patients when comparing a classic Dor procedure to a SAVE procedure. They emphasized that left ventricle reshaping is more important than left ventricle volume, and in our series we show the MD procedure is capable of restoring the left ventricle into an elliptical shape. Furthermore, the MD procedure also showed a reduction in end diastolic and an end systolic ventricular volume.

In recent report Di Donato et al. [8] demonstrated the influence of left ventricle shape over the left ventricle volume. She proposed a classification shape system for technique and patch site placement choice. All images from her study were assessed with echo 2 chamber apical view that most resembled the right anterior oblique angiographic projection. Assessment of left ventricle shape by Di Donato classification was carried out retrospectively in this series using the right anterior oblique angiographic projection. Similarly, in our series, the choice between the two techniques was primary made on right anterior oblique angiographic projection; and secondly, by echocardiograph images, and visual and tactile inspection during the surgery procedure.

Patients showing left ventricle enlargement and no evident dyskinetic or akinetic areas underwent the SAVE procedure, i.e. type III by Di Donato classification. The patients with evident scar, with a well delimited "neck" and with dyskinetic and/or akinetic areas were submitted to the MD procedure, i.e. type I and II by Di Donato classification.

The MD group had no patients with type III Di Donato classification, perhaps due to our preference for technique choice based on lack of an evident tissue scar area on the left ventricle. The type III shape had higher mortality, perhaps indicating an end stage of ischemic cardiomyopathy [8]. In our series, all patients with type III underwent to the SAVE procedure with a slightly increase

on late mortality, but without statistical significance. The SAVE procedure also showed a trend to increase the end diastolic diameter after 2.6 years of follow up. This perhaps was due a patient and technique assignment method. However, the groups were comparable based on clinical parameters and risk score stratification; with the only main difference being the left ventricle shape. We showed that patients with type I and II Di Donato classification had increased survival rates compared to type III and these data are consistent to original Di Donato's paper [8].

The RESTORE Group study found an improvement of ventricular function after surgical ventricular restoration, although this registry has no uniformity among the surgical techniques used [14]. Some centers performed surgical techniques using direct ventricle closure in selected patients, while other centers placed an endocardial patch in all patients [14,19]. In our series, all patients were submitted to the same standardized procedure in one single institution with similar results to the RESTORE Group study. Similarly we showed an improvement of NYHA functional class on late post-operative time.

Recently, the STICH study compared patients who underwent CABG only, to patients who underwent CABG in addition to a surgical ventricular reconstruction procedure in patients with dilated cardiomyopathy and ejection fraction less than 35%. They showed a reduction in left ventricle volume, but these ventricular changes were not associated with greater improvements on a six minutes walking test, symptoms or hospitalization for cardiac causes, or with a reduction in death rate [7]. Of note, the STICH study did not take into consideration the ventricle shape and excluded patients with recent myocardial infarction, a need for aortic valve procedure or coexisting noncardiac disease resulting in a life expectancy less than 3 years. Furthermore, this study did not consider the left ventricle shape for post-operative results. Moreover, results of the two groups (CABG alone vs. CABG plus ventricle restoration) are uncannily similar [20], making interpretation of group comparisons difficult [8].

Almost certainly, the ejection fraction is not important, but the technique selection and the choice of ventricle site exclusion are [6,14,18,21-26]. In this series, we assigned the technique used based on left ventricle shape and intraoperative inspection. Versteegh et al. [27] performed magnetic resonance imaging (MRI) at pre and post-operative time in a small series of patients with dilated ischemic cardiomyopathy. With MRI assessment, they showed a restoration of the elliptical left ventricle shape and improvement left ventricle contractile function.

The role MRI for planning and follow up of the operative left ventricle restoration procedure was also assessed by Lloyd et al. [28]. The MRI allowed choosing the site for left ventricle exclusion, evaluation of dyskinetic

or akinetic areas, and detection of the presence or absence of nonviable irreversible scar.

The rationale for a rigid ring at the left ventricle apex is allowing one fixed point for heart twisting and ventricular apex reconstruction. This ventricle reshaping from a spherical chamber to conical one lets the muscle fiber orientation return to a normal oblique orientation [19,29]. We demonstrated a conical shape after MD procedure with a prosthesis placement below the scar leaving a smaller left ventricle chamber. The use of a patch in the SAVE procedure might not provide enough support for new left ventricle apex reconstruction and allows for the possibility that late ventricle shape could actually worsen.

Our findings show a persistent late ejection fraction improvement along with steady diastolic and systolic diameters after 2.3 years in the MD group. This suggests that this technique provides an easier way to reshape the dilated left ventricle in ischemic cardiomyopathy with type I and II left ventricles shapes.

The EuroScore index was initially created to evaluate cardiac surgical care [12]. Recently, this index has been used as predictor for ICU length of stay and quality of life after cardiac surgeries [9,10]. We ranked the patients with EuroScore index, in addition to observing an increase survival rate during late follow up of patients with lower expected mortality index ranked by EuroScore at preoperative time. The EuroScore index takes into account some clinical critical variables for late follow up such as ventricular function, peripheral arterial disease, and chronic lung disease [12]. These variables are important for late follow up survival and our findings suggest that they are important considering the EuroScore index for late outcomes follow up.

Limitations

This work has inherent retrospective study limitations. The drug medications were not reported or standardized. The quality of life was assessed by NYHA functional class. The interval of late follow up echocardiography measurements was not standardized. Future studies will be necessary to test whether or not this novel prosthesis has advantages over SAVE procedure.

CONCLUSIONS

Our data show ventricle shape improvements with MD procedure and stable diameters after 2.3 years mean follow up. Our findings suggest that surgical ventricle restoration improves NYHA functional class when appropriate technique is employed and left ventricular shape is important for late follow up. The EuroScore ranked index used in our study may help to identify patients with lower survival indexes at late follow up.

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