

Analysis of the immediate outcomes of a comparative randomized study between aorto-saphenous mechanical anastomosis versus conventional anastomosis

Análise dos resultados imediatos de estudo comparativo entre anastomose mecânica aorto-safena versus convencional

Rodrigo MILANI¹, Paulo Roberto Slud BROFMAN², José Augusto Moutinho de SOUZA³, Laura BARBOZA⁴, Maximiliano Ricardo GUIMARÃES⁵, Alexandre BARBOSA⁴, Alexandre Manoel VARELA⁶, Marcel Rogers RAVAGNELLI⁷, Francisco Maia da SILVA⁸

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Abstract

Objective: To evaluate the immediate results of mechanical aorto-saphenous anastomosis compared with conventional anastomosis.

Method: We evaluated 12 patients. The mean age ranged from 62.33 ± 7.30 years. Of 12 patients submitted to surgery without extracorporeal circulation, 10 (83.3%) patients were male. Thirty-three proximal anastomoses were evaluated, 21 of them being performed through the conventional manner and 12 with the St. Jude Symmetry aortic connector. The time spent on anastomosis, and free flow and patency on the 4th day postoperative were analysed.

Results: The mechanical anastomosis was successfully performed in all patients. Electrocardiographic alteration compatible with myocardial infarctation (MI) on the 2nd day postoperative was observed only in one patient. The patient

was referred to angiographic restudy, becoming evident a conventional proximal anastomosis occlusion for the marginal branch. Three patients had atrial fibrillation. The average time spent to perform the mechanical anastomosis was 44.08 ± 9.26 seconds against 3.86 ± 0.61 minutes of the conventional anastomosis ($p = 0.0022$). The average blood free flow observed in the mechanical anastomosis was 302.75 ± 82.76 mL/min versus 190.75 ± 51.53 mL/min ($p = 0.0022$). In the angiographic restudy performed on the 4th postoperative day, it was detected the occlusion of three mechanical anastomosis. There was no new conventional anastomosis ($p = 0.2500$).

Conclusion: The present study showed a statistically significant superiority for mechanical anastomosis of the saphenous vein with the aorta when evaluated the blood free flow and the time to perform the anastomosis. In relation

1. MD, MSc, PhD; Cardiovascular Surgeon- PUC/PR.
2. MD, MSc, PhD in Surgical Clinics; Cardiovascular Surgeon PUC/PR.
3. MSc; Cardiovascular Surgeon of Santa Casa in Curitiba.
4. MD; Resident em cirurgia cardiovascular.
5. Specialist in Cardiovascular Surgery; Surgeon of Santa Casa in Curitiba.
6. Master in Cardiology; Hemodynamicist of Santa Casa in Curitiba.
7. MSc; Hemodynamicist of Santa Casa in Curitiba.
8. Master in Health Sciences; Cardiologist - PUC/PR.

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Correspondence address: Rodrigo Milani. R. Cezar Correia de Souza Pinto Jr., 54 - Santa Felicidade - Curitiba, PR, Brasil. CEP: 82015-220
E-mail: rodrigo.milani@sbccv.org.br

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to the artery condition in the postoperative angiography, one cannot say there was statistically significant difference between the procedures studied.

Descriptors: Myocardial revascularization, methods. Surgical equipment. Anastomosis, surgical, instrumentation. Coronary artery bypass, instrumentation

Resumo

Objetivo: Avaliar os resultados imediatos das anastomoses mecânicas aorto-safena, comparando-as às anastomoses convencionais.

Método: Foram analisados 12 pacientes, com idade média de $62,33 \pm 7,30$ anos, sendo 10 (83,3%) do sexo masculino. Os pacientes foram submetidos à operação sem circulação extracorpórea, com 33 anastomoses proximais avaliadas, sendo 21 anastomoses convencionais e 12 feitas com o conector aórtico Symmetry da St. Medical. Foram analisados tempo gasto para confecção da anastomose, fluxo livre com pressão arterial sistólica de 100 mmHg e patência no 4º dia de pós-operatório.

Resultados: A anastomose mecânica foi empregada com sucesso em todos os pacientes. Um paciente apresentou

alterações eletrocardiográficas compatíveis com IAM, no 2º dia de pós-operatório, sendo encaminhado para reestudo angiográfico, que evidenciou oclusão de anastomose proximal convencional para ramo marginal. Três pacientes apresentaram fibrilação atrial. Não houve óbitos nesta série. O tempo médio gasto para realização da anastomose mecânica foi de $44,08 \pm 9,26$ segundos contra $3,86 \pm 0,61$ minutos da anastomose convencional ($p = 0,0022$). O fluxo livre médio observado nas anastomoses mecânicas foi de $302,75 \pm 82,76$ ml/min contra $190,75 \pm 51,53$ ml/min ($p = 0,0022$). No reestudo angiográfico, feito no 4º pós-operatório, detectou-se oclusão de três anastomoses mecânicas contra nenhuma nova oclusão das anastomoses convencionais ($p = 0,2500$).

Conclusão: O presente estudo apresentou uma superioridade estatisticamente significativa em favor das anastomoses mecânicas da veia safena com aorta, quando avaliado tempo para confecção da anastomose e fluxo livre. Em relação à condição da artéria na angiografia pós-operatória, não se pode afirmar que exista diferença estatisticamente significativa entre os procedimentos estudados.

Descritores: Revascularização miocárdica, métodos. Equipamentos cirúrgicos. Anastomose cirúrgica, instrumentação. Ponte de artéria coronária, instrumentação.

INTRODUCTION

Off-pump coronary artery bypass grafting was first mentioned in the literature in the early 1960s, when Goetz et al. [1] and soon after Kolessov [2] described the anastomosis of the right internal thoracic artery graft to the right coronary artery and the anastomosis of left internal thoracic artery graft to the anterior interventricular branch, respectively. These two graftings were performed without cardiopulmonary bypass.

After these early reports, this kind of surgery without cardiopulmonary bypass was virtually abandoned over almost two decades due to the fast development of cardiopulmonary bypass grafting and the many ways of myocardial protection.

The first consistent reports about the effectiveness of the surgeries for revascularizing the myocardium go backwards to the early 1980s, when Buffolo et al. [3] and Benetti [4] presented results in a significant group of patients showing that with the aid of some surgical maneuvers and the use of drugs to slow the heart rate and oxygen consumption (VO_2), the surgeries without coronary artery bypass grafting were safe, effective, and reproducible, thus, presenting low mortality and morbidity, lower cost, and they were especially highly effective in high-risk patients.

Due to some technical limitations in the use of myocardial revascularization in special with arterial grafts,

the saphenous vein, besides being a good option, is the most used graft in these surgeries with or without coronary artery bypass.revascularization

In order to use the saphenous vein as an implant, in the majority of the cases it is necessary to manipulate the aorta by means of both partial and total clamping, increasing the likelihood of neurologic complications particularly in aortic calcifications. Several studies have shown the association of neurologic complications in myocardial revascularization postoperative associated to the manipulation of aorta.

Aiming at to reduce the manipulation of aorta during myocardial revascularization surgeries, the pharmaceutical industry developed a mechanical suture to perform saphenous vein graft anastomoses without aortic clamping, what in association with the off-pump coronary artery bypass grafting would lead to a reduction in the incidence of neurologic complications. Preliminary outcomes with this type of device are quite satisfactory [5-7]. The purposes of this study are to compare based on the time spent to perform this proximal anastomosis the following: a) the blood flow and the postoperative angiography data; and b) the manual and mechanical anastomoses of the proximal aorta.

METHODS

For a patient to be included in the study the following criteria had to be fulfilled: coronary failure evaluated by

cineangiocoronariography involving three or more vessels requiring myocardial revascularization surgery, the presence of a lesion in the right coronary artery, or in its branches, or in the diagonal artery, and age < 80 yrs.

Patients were excluded if they had been submitted to reoperations; emergency operations; coronary failure either requiring or not to surgery associated to mild aortic valve failure; coronary failure either requiring or not surgery associated to any valve disease; coronary failure requiring surgery associated to aortopathy and surgical treatment; and prior neurologic lesion.

After the venous and arterial grafts were prepared, the pericardium was opened and fixed with three cotton stitches 3-0 along the cellular subcutaneous tissue to the right and to the left.

The operating table was set in the Trendelenburg position and left lateral. The next step was to stitch the site in accordance to what Lima [8] described in 1999, i.e., in the posterior pericardium between the inferior vena cava and left inferior pulmonary vein.

Before the proximal anastomoses were performed, we choose by lot which portion of the great saphenous vein would be used for mechanical suture, either proximal or distal, as well as which coronary artery would receive the saphenous vein graft-to-coronary artery connector, if the right coronary artery and its branches or the diagonal artery. After that, the full vein had its caliber measured.

Initially, the proximal anastomoses were performed. With the aorta partially clamped, an aortotomy was performed in the conventional way. At this moment, the time spent to construct the manual anastomosis was measured from the beginning until the completion of the surgical knot. When the manual anastomoses were completed, the next step was to withdrawal the proximal clamping of aorta and the accomplishment of the proximal mechanical anastomosis.

From this point on, the appropriate arrangements to use the connector to mechanically suture the aorta began. Due to the technical features of the device, the proximal anastomosis between the aorta and the saphenous vein was necessarily performed first.

The site where the anastomosis in the aorta was to be achieved was selected, recalling that the anastomosis must be performed in a right angle (90°) with the aorta. Each selected connector had a specific aortotome. Once the aortotomy was achieved, the connector system was applied considering the right angle and in a few minutes the anastomosis was completed. The measuring of the time spent to achieve the mechanical anastomosis started at the completion of the aortotomy and ended after the withdrawal of the transference system.

At the completion of all proximal, manual, and mechanical anastomoses the patient's systolic blood pressure was stabilized in 100 mmHg. Then, the distal portion of

saphenous veins anastomosed to the aorta were simultaneously set free in marked receptacles, one in each receptacle for 10 seconds. Thus, the free flow of each anastomosis was evaluated. At the completion of this phase, the construction of the distal anastomoses between the saphenous veins, or left internal thoracic artery and the coronary arteries began.

The approached artery was occluded during the construction of the anastomosis by means of a ligation using a monofilament prolene 4-0 supported by small pieces of silicone to avoid the excess of blood in the surgical field.

The exposure of the target artery was achieved by stabilizing the region of the heart to be approached with the aid of a tissue stabilizer through suction.

The approach of the coronary arteries to be treated began by the vessels of the lateral wall of the right coronary artery and its branches to the diagonal artery, and finally to the anterior interventricular branch. The distal anastomoses were constructed with continuous suture prolene 7-0 in an end-to-side manner. When sequential anastomoses were performed, laterolateral anastomosis followed by an end-to-side anastomosis was performed.

At the 4th postoperative day, the patients underwent a control cineangiocoronariography aiming at to evaluate the proximal mechanical and manual anastomoses. If electroradiographic changes compatible with acute myocardial infarction were found, the patient would be taken immediately to the laboratory of hemodynamics.

The study population included 12 patients aged from 52 to 72 years with a mean age of 62.33 ± 7.30 years, who underwent off-pump coronary artery bypass grafting, and 83.3% (10) were male. The most frequent symptom during the preoperative evaluation was angina pectoris, which was present in all the patients.

As for the New York Heart Association functional class, three patients were classified as class II, four as class III, four as class IV, and one as class I.

Of the 12 patients, nine patients were smokers, 10 had systemic arterial hypertension, four were diabetic, and six had dislipidemia. Three patients had positive family history for coronary disease. Five patients had three or more risk factors for coronary disease. Only one patient did not present any known risk factor.

The electrocardiogram at rest of three patients was normal; three patients had previous ischemia; one had inferolateral ischemia; three patients had previous myocardial infarction, and one patient had previous lateral infarction. Thus, five patients had previous myocardial infarction.

The mean preoperative ejection fraction was $54.17\% \pm 16.73$, ranging from 29% to 74%. Six patients presented an ejection fraction lower than 50%.

The analysis of the segmental contraction showed the

following: left ventricular cavity with normal contractibility in four patients; diffuse hypokinesia in three patients; inferior hypokinesia in one patient; anterior hypokinesia in one patient; anterior akinesia in 1 patient; and inferior akinesia in one patient.

On cineangiocoronariography, the left ventricle was normal in six patients; presented a mild contractile deficit in four patients, and important impairment of the ventricular function in two patients. All the 12 patients had impairment of the anterior interventricular branch. Besides, five had impairment of the right coronary artery; six of the posterior interventricular branch; two of the posterior left ventricular branch; three of the circumflex branch; seven of the marginal artery; and eight of the diagonal artery. All the 12 patients presented impairment of three or more coronary arteries.

Statistical Analysis

The Wilcoxon's nonparametric test was used to compare the procedures regarding the time spent with and the flow of the anastomosis, and the binomial test was used regarding to the anastomosis condition in the hemodynamic study carried out in the postoperative period. We considered $p < 0.05$ as statistically significant.

RESULTS

The average of implants per patient was 4.41 ± 0.486 , with all the patients undergoing an implant of the left internal thoracic artery. The left internal thoracic artery was anastomosed to the anterior interventricular branch of 11 patients; to the great saphenous vein in 1 patient; to the diagonal artery in a sequential manner in five patients, and to the saphenous vein in three patients. The left internal thoracic artery was also anastomosed to the diagonalis branch (lateral diagonal branch) in a sequential manner in two patients; the saphenous vein was anastomosed to the lateral diagonal branch in eight patients. The great saphenous vein was anastomosed to the following: left marginal artery of the circumflex branch; right coronary artery; posterior interventricular branch; and posterior left ventricular branch, and the branches were distributed as follows: eight branches to the left marginal artery; five branches to the right coronary artery; six branches to the posterior interventricular branch; and two branches to the left posterior ventricular branch.

The mean time to perform the operation was 162.08 ± 31.5 (IQR 110, 230) minutes. The mean duration for ICU length of stay was 32.67 ± 13.28 (IQR 17, 49) hours. The mean duration for mechanical ventilation time was 2.75 ± 1.91 (IQR 0, 6) hours. The mean duration for hospital length of stay was 6.08 ± 0.67 (IQR 5, 7) days. The mean blood drainage through thoracic and mediastinal drain was 504.17 ± 265.79 (IQR 180, 1050) mL. No patients required reoperation due to bleeding.

Three patients did not require blood transfusion. The mean volume of packed human blood cells was 1.92 ± 1.31 (IQR 0, 3) units.

No patient required inotropic support in the postoperative period. All patients were administered 2.5 mg/h of nitroglycerin endovenously during the period they were at the ICU.

There have been three cases of atrial fibrillation in the postoperative period. All cases were reverted to sinus rhythm in less than 24 hours after the onset by administering a loading dose of 300 mg of amiodarone followed by and continuous infusion of 900 mg within 24 hours. On day 2 postoperatively, one patient presented Electrocardiographic changes compatible with acute myocardial infarction (positive deflection of the ST segment in the lateral wall), and even without presenting a clinical repercussion the patient was referred to the hemodynamic laboratory to perform a new cineangiocoronariography, which showed an occlusion of the saphenous vein bypass graft to the left marginal artery. This anastomosis, which was occluded, was performed in the conventional way. In this series of cases it was not observed the following: postoperative acute renal failure, bronchopneumonia, mediastinitis, and stroke. There was no in-hospital death among the study population.

The total number of anastomoses studied between saphenous vein and aorta was 33. Of these, 12 were successfully performed with the use of an aortic connector and 21 were performed in the conventional way with 6-0 polypropylene continuous suture.

The anastomoses with the aortic connector were directed to the following vessels: anterior interventricular branch (one); diagonal artery (two); lateral diagonal branch (three); posterior interventricular branch (two); and right coronary artery (four). The conventional anastomoses were performed to the following vessels: diagonal artery (one); lateral diagonal branch (five); left marginal artery (eight); posterior left ventricular branch (two); posterior interventricular branch (four); and right coronary artery (one).

The mean time spent to construct the anastomoses with the aortic connector was 44.08 ± 9.26 seconds (IQR 26, 57), while the mean time to construct the conventional anastomoses was 3.86 ± 0.61 minutes (IQR 2.30, 5.23) ($p = 0.0022$).

Regarding the free flow of aorta observed at the completion of the anastomoses, that is, with the distal portion opened to the environment, with systolic blood pressure of 100 mmHg, the anastomoses constructed with the aortic connector presented a volume of 302.75 ± 82.76 mL (mean \pm standard deviation) (IQR 144, 423), while the conventional anastomoses presented a flow of 190.75 ± 51.53 mL (mean \pm standard deviation) (IQR 60, 278) ($p = 0.0022$).

On day 4 postoperatively, all patients, but the one who

had myocardial infarction on the second postoperative, were referred to control cineangiocoronriography, which has shown three occlusions in the group of anastomoses performed with the aortic connector and no new occlusion in the group of conventional anastomoses, except the anastomosis that was occluded in the myocardial infarction patient ($p = 0.2500$).

Among the anastomoses constructed with the connector, those which were already closed, two had been directed to the lateral diagonal branch, and one to the right coronary artery. In 3 cases in which the distal anastomoses were constructed, the coronary arteries were patent.

DISCUSSION

The anastomoses constructed during the off-pump coronary artery bypass grafting, either proximal or distal, in general are constructed with polypropylene continuous suture of varying sizes. In order to perform these anastomoses, a long period of learning, time expenditure, and minimum level of skill is required.

In the last few years, efforts are being made in order to make heart surgeries a low-risk procedure with a fast recovery. This is happening through new technologies that reduce the incidence of neurologic complications, minimize the reactions caused by extracorporeal circulation, and accelerate the recovery.

The last breakthroughs introduced in the market have transformed the coronary surgeries into less invasive surgeries and have made the maneuvers performed on a normal beating heart more accurate, i.e., without extracorporeal circulation, and yet with a more restrict surgical field due to the alternative access pathways to the traditional median sternotomy. These breakthroughs can be exemplified by means of the new stabilizers available in the market, which provide safe access with less hemodynamic repercussion to all vessels of heart; the suction devices that applied to the apex of heart provide its complete manipulation without requiring hand manipulation of the ventricle by the surgeon, thus further decreasing the presence of the hemodynamic instability; and eventually the introduction the robotic surgery, which with the aid of video cameras, allows a very good exposure through a limited access.

Even with these breakthroughs, the anastomoses are still performed in the conventional manner, being required the clamping of aorta and its disadvantages and in the cases of limited access through small incisions or reoperations, the difficulty faced by the surgeons to perform a high-quality anastomosis. Attempts to facilitate this stage of the coronary surgeries, the biomedical industry have started to develop the aortic connectors in order to facilitate the anastomosis between the saphenous vein and the aorta.

The great advantage of this type of device is the significant reduction in the need to manipulate the aorta, once it is not necessary to use the partial clamping to perform the anastomosis. Besides, its usage is extremely fast when compared to the conventional anastomosis, and its application can be performed through a small access. It is further expected from these connectors that the flow through the graft be, at least, the same observed in the conventional anastomoses and that the durability in terms of absence of an occlusion in mid- and short-term be satisfactory as well.

We have to consider three aspects in the evaluation of the devices used to perform the mechanical anastomoses in aorta: the connector-graft interface; the facility in setting the graft and the anastomosis, and the device biomechanical features that is analyzed regarding the long-term graft patency. The ideal connector should allow the minimum manipulation of the graft without metallic material inside the lumen of the vessel, without limiting the angulation in connection to the aorta, be easy to operate and with good long-term outcomes.

The presence of metallic material in contact with the tunica intima of the graft can cause neointimal proliferation leading to appearance of stenosis. The introduction of a metallic rod on the inside of a venous graft can cause an intimal lesion, jeopardizing the mid- and long-term graft outcome. The presence of the device between the saphenous vein and the aorta makes the anastomosis to be more rigid and, therefore, less compliant than the conventional anastomosis constructed with polypropylene, which can cause stenosis.

Regarding the angulation of the anastomosis, the blood flow velocity in the proximity of the graft wall is the main determinant of the stress exerted on the vessel, being associated with intimal hyperplasia. Low velocity means low level of stress, which is considered the primary factor for the proliferation into the tunica intima. A computer flow simulation and hemodynamic studies point out that the best angulation for terminoterminal and terminolateral anastomoses is between 30° and 45° . The majority of the connectors available require the construction of the anastomosis in right angle (90°), what besides the graft fold can lead to hyperplasia of the tunica intima.

In the Symmetry aortic connector tested (St Jude Medical, St Paul, Minnesota, USA), the fixation of the vein to the hooks that will effectively connect the anastomosis should be performed very carefully, because it is in this phase we face two probable failures related to the system operator.

If the hooks are not completely covered a leak can occur at the termination of the anastomosis. On the other hand, if an excess of tissue is left over the hooks, a vein flap can be formed, which is not always detected at the conclusion of the anastomosis, and it can cause stenosis and even be

one of the causes of early occlusion of the anastomoses constructed with the connector. The venous graft must be positioned 0.5 mm over the hooks being equally distributed over the aortic connector. All vein layers should be placed over the hook.

After the system is assembled, the application is relatively simple; it only should be observed an angle of 90° between the system and the aorta. On the withdrawal of the external portion covering the graft, attention is needed in order to avoid an accidentally withdrawal of the anastomosis, as the sheath can tangle with branches of the vein. This can be avoided by placing a clamp along the anastomosis immediately after its emergence.

In the presence of bleeding at the conclusion of the anastomosis, the manufacturer itself does not recommend to try to correct it with the aid of a manual suture, once it can interfere in the functioning of the device. The anastomosis must be withdrawal e it should be constructed again in the conventional manner. In our series, we did not make this kind of problem evident, however in the studies published by Eckstein et al. [9], and Jatene et al. [10], this kind of complication has occurred and the solution was to perform a new anastomosis in the conventional manner.

Another error that can occur after the application of the device, what also would indicate its withdrawal, is the unlevelling of the fixators of the connector with the aorta. This occurs due to an excess of the tunica adventitia, excess of tissue over the hooks, application angle different from that recommend by the manufacturer, or, yet the wall of aorta with less than 1 mm-thickness. In this situation, bleeding is more likely to occur at the conclusion of the anastomosis, and even in the absence of bleeding, all the system must be withdrawal and a new anastomosis must be made in the conventional manner.

The outcomes observed in this series of patients showed superiority of the anastomoses constructed with the connector when we observe the time spent to construct the anastomosis and the free flow. As to the patency of the artery on the coronariographic restudy, it was not detected a statistically significant difference, which can be explained by the relatively small number of the patients screened.

The studies found in the literature make reference to an early experience of the several swervices and its short- and mid-term outcomes, focusing basically the condition of the anastomosis in the angiographic restudy, and in the occasional difficulties experienced by the authors in the application of the device. These outcomes are similar to the outcomes found in our study. Antona et al. [11] have found a 94.7% patency in the catheterism performed in the postoperative period. In a study by Mack et al. [12], comprising 36 patients, it was observed a patency of 86.6%; Wiklund et al. [13] have found a permeability of 90% supported by angiography. Endo et al. [7], in a group of 15

patients, have found on the postoperative angiography all the anastomoses patent and only in two was found 30% of stenoses.

All the studies aforementioned showed a patency rate superior to 75%. The same outcomes were found by another study by Jatene et al. [10], in which in a group of 17 patients screened, 81.8% of the anastomoses constructed with mechanical suture were found patent on an angiographic restudy.

CONCUSION

The mechanical anastomosis between the saphenous vein and the aorta was superior to the conventional anastomosis, when both the time spent in the construction of the anastomosis and the free flow were evaluated. The patency of the grafts on an early angiography does not show any difference between both groups. However, owing the small number of patients enrolled, our results suggest that mid- and long-term studies will be needed to evaluate better the effectiveness and final cost of this type of device.

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