The Use of Primary Stenting or Balloon Percutaneous Transluminal Coronary Angioplasty for The Treatment of Acutely Occluded Saphenous Vein Grafts. Results From the Brazilian National Registry - CENIC

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Objective - *We conducted a comparative analysis of the in-hospital outcomes of patients who underwent primary percutaneous transluminal angioplasty (PTCA) or stent implantation because of an acute myocardial infarction (AMI) related to an acute vein graft occlusion.*

Methods - *Since 1991 the Brazilian Society of Hemodynamic and Interventional Cardiology has maintained a large database (CENIC). From these, we selected all consecutive patients, who underwent primary PTCA or stenting in the first 24 hours of AMI, with the target vessel being an occluded vein graft. Immediate results and major coronary events occurring up until hospital discharge were analyzed.*

Results - *During this period, 5,932 patients underwent primary PTCA or stenting; 158 (3%) of the procedures were performed because of an acute vein graft occlusion. Stenting was performed in 74 (47%) patients. Patients treated with stents had a higher success rate and lower mean residual stenosis compared with those who underwent primary balloon PTCA. The incidence of reinfarction and death were similar for stenting and balloon PTCA.*

Conclusion - *Primary percutaneous treatment of AMI related to acute vein graft occlusion is still an uncommon practice. Primary stenting improved luminal diameter and offered higher rates of success; however, this strategy did not reduce the in-hospital reinfarction and death rate, compared with that occurring with PTCA treatment.*

Keywords: coronary angioplasty, bypass, myocardial infarction, stents

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The acute and long-term outcomes of catheter-based reperfusion therapy using the well-known methods of percutaneous transluminal coronary angioplasty (PTCA) and coronary stenting for the treatment of acute myocardial infarction (AMI) have already been validated [1-2].

Since 1985, intracoronary stenting has been progressively used in the daily routine of invasive cardiology centers, both in Brazil and worldwide, because it provides better acute and late results [3]. Many randomized studies had already demonstrated the safety and efficacy of intracoronary stenting for the treatment of patients during the first 12 hours of AMI [4,5].

These randomized studies tested primary coronary stenting in native coronary arteries. Patients with prior bypass surgery who presented with AMI related to the occlusion of saphenous vein grafts (SVG) were systematically excluded. Historical data analyzing patients with occlusion of SVG that received intravenous thrombolysis demonstrate a lower rate of successful reperfusion, probably related to the great amount of thrombus mixed with atherosclerotic debris located inside this grafts that reduces the blood flow velocity and prevents better results [6-8].

The contemporary goal of catheter-based reperfusion techniques is to widen the range of patients who may benefit from these methods. One of these subgroups is the patient who has undergone previous bypass surgery because of occlusion of the SVG [9,10].

The cumulative data regarding this angiographic subgroup of patients is scarce and available primarily for those who received balloon angioplasty. The acute results were significantly inferior when compared with results from patients who underwent primary PTCA of native coronary arteries, including the success and mortality rates [10-12]. Until now, no data exist about the application of stenting for the treatment of SVG after the first hours of AMI onset. However, the number of patients who undergo bypass

surgery but return for additional medical treatment because of an AMI is progressively growing, which is the better catheter-based reperfusion method to use in these patients remains an important issue [13-15].

In 1991, the Brazilian Society of Interventional Cardiology created a nationwide database registry of the percutaneous coronary interventions performed in our country (CENIC - Central Nacional de Intervenções Cardiovasculares) [3,16].

The objective of this current analysis, is to assess the in-hospital results included in this nationwide registry (CENIC) that were obtained in for patients treated in the first 24 hours of AMI onset, with the culprit AMI vessel related to the occlusion of an SVG and comparing the 2 catheter-based reperfusion methods, primary balloon and stenting.

Methods

From January 1996 through December 1999, the CENIC database registry received spontaneous contributions from 215 invasive cardiologists, who reported 50,113 consecutive procedures of percutaneous coronary intervention performed in 185 different Brazilian hospitals in all geographic regions of our country. A specific data base sheet reporting the clinical, angiographic, and procedural results was completed by each physician and sent to the CENIC database coordinating center.

We analyzed the data sheets for primary PTCA during the first 24 hours of AMI without previous infusion of thrombolytics, and treating, as the culprit infarct vessel, an SVG. From the original 50,113 patients, 5,932 (12%) received primary PTCA procedures, and 158 (3%) underwent mechanical reperfusion of an SVG, either with balloon or stenting.

The pharmacological and invasive procedures were performed according to the daily routine of each center, and coronary stents were implanted according to the technician's discretion.

The global analysis of the files demonstrated that more than 90% of these patients received aspirin and ticlopidine (PO) when stents were implanted plus intravenous heparin.

All the stents were implanted with final balloon pressures higher than 10 atm. The measurement of left ventricular function and severity of coronary artery stenoses were qualitative. Procedural success was defined as a residual stenosis less than 50% with TIMI 2 or 3 flow. The major complications, occurrence of reinfarction, new bypass surgery, or death, were analyzed after the end of the in-hospital phase. A comparative analysis was performed of balloon versus stenting, regarding the occurrence of procedural success and major complications after the procedure.

The categorical variables are depicted as absolute numbers and their percentages, and the continuous variables are depicted as averages and standard deviation.

We used the Student t test to analyze the continuous variables and the chi-square test to analyze the categorical variables, with Fisher's exact test applied when necessary.

Results

Of the 158 data sheets included in the analysis, 84 (53%) were for patients who underwent balloon and 74 (47%) for patients who underwent stenting. The use of coronary stents during AMI increased steadily from 1996 until 1999. The percentage of their use grew by 20, 34, 49 and 55%, respectively, in the four years analyzed.

The clinical profiles of these patients are demonstrated in table I. The demographics are similar. More than 70% of the patients were male, 25% were diabetic, and nearly 50% had already undergone previous elective angioplasty. The mean time since the bypass operation and the occurrence of AMI was 7.1 years for stenting and 6.5 years for balloon angioplsty. The former AMI was located in the wall anterior in 42% of the stent group and in 39% of the balloon group. Neither variable was statistically significant.

The angiographic characteristics are displayed in table II. In both groups, 71% of the patients presented with triple-vessel coronary heart disease. The number of patients of angioplasty group (74%) with impairment of left ventricular function (ejection fraction <45%) was significantly greater in balloon compared to those undergone to coronary stenting (55%, p=0.016). Patients who underwent balloon angioplasty also had a more significant rate of thrombus-containing lesions. No other differences were noted. The SVGs were anastomosed to the left anterior descending artery in 40% of the patients and lesions with a length greater than 10mm were present in more than 60% of the patients.

Abciximab infusion was used in 15% of the stent patients and in 11% of the balloon angioplasty patients. The mean average of the stent diameter was 3.51mm, with a mean length of 22.6mm. The operators implanted slotted-tube or multicellular stents in the majority of the patients (95%) (table III).

The in-hospital results are demonstrated in table IV. Patients who underwent primary stenting had a significantly higher success rate compared with those patients who received balloon angioplsty (97 vs. 81%, p=0.001, respectively). The mean final diameter stenosis

Table I - Clinical profile between the groups analyzed, primary stenting or balloon angioplasty, performed during acute myocardial infarction, for the treatment of occluded saphenous vein grafts

Variables	Stent	PTCA	p
Number of patients		74	84
Male gender	56 (76%)	60 (71%)	0.547
Mean age (years)	64.5+14	63.2+12	0.531
range (years)	44 - 83	44 - 72	-
Diabetes mellitus	16 (22%)	22 (26%)	0.503
Previous PTCA	35 (47%)	35 (42%)	0.477
Mean time bypass surgery/AMI (years)	7.1+3	6.5+4	0.293
Anterior MI	31 (42%)	33 (39%)	0.739

PTCA- balloon percutaneous transluminal angioplasty; AMI- acute myocardial infarction.

Table II - Angiographic profile between the groups analyzed, primary stenting or balloon angioplasty, performed during acute myocardial infarction, for the treatment of occluded saphenous vein grafts

Variables	Stent	PTCA	p
Number of patients	74	84	
Saphenous vein graft to:			0.432
- left anterior descending	31 (42%)	33 (39%)	
- right coronary artery	21 (28%)	33 (39%)	
- left circumflex	22 (30%)	18 (22%)	
Presence of thrombus	49 (66%)	68 (81%)	0.035
Lesion length >10mm	44 (59%)	56 (67%)	0.349
Number of vessels diseased (DS >50%)			0.873
- 01 vessel	10 (14%)	9 (11%)	
- 02 vessel	11 (15%)	15 (18%)	
- 03 vessel	52 (71%)	60 (71%)	
Ejection fraction < 45%	41 (55%)	62 (74%)	0.016
TIMI flow grade pre procedure			
- 0 e 1	66 (90%)	77 (92%)	0.596

TIMI- Thrombolysis in Myocardial Infarction; PTCA- primary balloon percutaneous transluminal angioplasty; DS- diameter stenosis.

Table III - Adjunctive medications and procedural results between the groups analyzed, primary stenting or balloon angioplasty, performed during acute myocardial infarction, for the treatment of occluded saphenous vein grafts

Variables	Stent	PTCA	p
Number of patients	74	84	
Abciximab	11 (15%)	9 (11%)	0.434
Mean stent diameter	3.51±1.2mm	Na	
Range	2.5 - 4.5mm	Na	
Mean stent length	22.6±12.6mm	Na	
Stent type		Na	
- slotted-tube or multicellular	70 (95%)		
- coil	4 (5%)		

PTCA- primary balloon percutaneous transluminal coronary angioplasty; na- not applicable.

Table IV - Procedural results and in-hospital major complications between the groups analyzed, primary stenting or balloon angioplasty, performed during acute myocardial infarction, for the treatment of occluded saphenous vein grafts

Variables	Stent	PTCA	p
Number of patients	74	84	
Success	72 (97%)	68 (81%)	0.001
DS (%) post procedure	15±12	40±10	0.0001
Emergency surgery	0	0	-
Reinfarction	6 (8%)	6 (7%)	0.526
Mortality	5 (7%)	7 (8%)	0.474
Mean hospital stay	4.1±3.5 dias	4.9±2.7 dias	0.108

PTCA - primary balloon percutaneous transluminal angioplasty; DS- diameter stenosis.

was also significantly reduced with coronary stenting (15 vs. 40%, p=0.0001). The occurrence of major complications was quite similar between the two groups, either the reinfarction (stent, 8 vs. balloon angioplasty, 7%, p=0.526) or death rates (stent, 7 vs. balloon angioplasty, 8%, p=0.474). No reoperations were necessary in either group.

Discussion

We performed a comparative analysis of the in-hospital results obtained in patients with previous bypass surgery who presented for treatment within 24 hours of AMI onset plus had occlusion of an SVG who underwent primary stenting or balloon angioplasty. The cohort analyzed was part of a large consecutive nonselected nationwide database registry of percutaneous coronary intervention (CENIC).

The analysis of these results was relevant because of the growing potential of this population of patients who already have significant coronary heart disease, and have had a previous bypass operation. Also, it is important to take into account that on average 4% of these vein grafts become occluded per year, associated with an annual MI rate of 3% [13-15].

This subgroup of patients comprises a high-risk subgroup of AMI patients. These patients may benefit most from catheter-based reperfusion techniques during the first 24 hours of AMI [10-12]. The previous data for these patients remains unclear, and very limited data have been presented. The dilemma regarding the better therapeutic approach to this AMI population remains a challenge. Much of the difficulties are related to the cause and pathogenesis of the occluded SVG [6,15]. Intravenous thrombolysis is not an efficacious method for obtaining SVG reperfusion, with a lower rate of TIMI 3 flow reestablishment. Vein grafts usually become occluded with a great amount of thrombus and atherosclerotic debris, which causes extra difficulty in reopening them. The flow is usually slow and the downstream dislodgment of this friable material promotes sluggish or even a no-flow phenomenon. In the angiographic substudy of the randomized trial GUSTO I (Global Utilization of Streptokinase and TPA for Occluded Arteries) [8], 48 (2.5%) of these patients exhibited SVG occlusion. The TIMI flow grade 2 or 3 was reestablished in 48% of these patients, but only 34% of these had TIMI grade 3 flow after intravenous thrombolysis. This is nearly half of that observed in patients that had a native coronary artery as the culprit AMI vessel (p<0.01). The SVG constitutes an independent predictor of thrombolysis failure.

The use of balloon angioplasty to treat stenosis located in SVGs also has some limitations. The obtainment of TIMI 3 flow is lower because of the great amount of thrombus usually found. The occurrence of elastic recoil when the lesion is located in the aorto-ostial segment is another potential cause of failure or final suboptimal result [18]. Older vein grafts with more degenerated atherosclerotic debris, increase the risk of downstream embolization with plugging of the distal coronary microvasculature, an angiographic complication very difficult to treat [6,8,10,12]. As a consequence of all these difficulties, less than 200 AMI patients with occlusion of SVGs were analyzed in previous studies [19].

The largest experience with primary balloon angioplasty for the treatment of occluded SVGs during AMI comes from a subgroup analysis of the international randomized study PAMI 2 (Primary Angioplasty in Acute Myocardial Infarction) [12]. From the initial 1,100 patients included in the trial, only 32 (2.9%) underwent primary angioplasty of an SVG during AMI. The in-hospital results were quite similar to those observed in the CENIC registry data. In the PAMI 2 trial, angioplasty were performed less often when the culprit vessel was an SVG (72 vs. 90%, p=0.001) compared with native coronary arteries. TIMI 3 flow was observed less in vein grafts than in native arteries (70 vs. 94%, p<0.00001), and as a result, the death rate was higher in the SVG group compared with the native artery group (9.4 vs. 2.5%, p=0.02). Historical consecutive series of primary balloon angioplasty procedures performed for an occlusion of an SVG has already demonstrated a lower success rate, when compared with that in the treatment of native coronary arteries (86 vs. 94%, p<0.0001) [11].

Primary coronary stenting is a more recent approach to treating patients during AMI, offering better acute and one-year follow-up results, compared with that for balloon PTCA [4,5].

Large nationwide database registries, like the CENIC, allow the analysis of real-world results, not always observed in randomized controlled trials. The CENIC registry combines a consecutive nonselected series of AMI patients, treated by 185 different invasive physicians, in centers with a higher and lower volume of PTCA procedures. Because the presence of an occluded SVG is a systematic exclusion in randomized studies, a contemporary analysis of large registries will help us in defining the best catheter-based reperfusion technique for this subgroup of patients.

The analysis revealed that the treatment of SVG during AMI is still an uncommon procedure, being only 3% of all primary angioplasty procedures performed in the last four years. Primary stenting was the strategy selected by the Brazilian invasive cardiologists in nearly half of the patients. The clinical and angiographic profile of the patients revealed a group with moderate to severe complexity. The mean age is higher than expected with extensive coronary heart disease plus a significant reduction in left ventricular function. The mean time from the bypass operation until the occurrence of the former AMI is greater than 6 years resulting in more degenerated SVGs. The culprit stenoses were more diffuse, and more than 90% of them exhibited an initial vein graft with TIMI grade flow 0. The patients selected for stenting had stenosis with less thrombus, according to the judgment of the invasive physicians.

The group of patients selected for primary stenting had a higher success rate with lower residual stenosis when compared with those who underwent primary balloon angioplasty. However, despite this initial favorable geometric impact, the occurrence of major in-hospital complications, such as reinfarction and death, were similar between the two groups. This finding shows a very positive trend in the balloon angioplsty patients. These patients presented with a significantly higher rate of thrombus-containing lesions and more depressed left ventricular function, compared with that in the coronary stenting group, predisposing them to greater chances of major coronary events, which, however, did not occur.

The comparative analysis of stenting or balloon angioplasty in native vessels included in randomized trials was similar to those found here in this registry of SVGs. The STENT PAMI trial found higher one-year mortality rates when a routine stenting strategy was applied [4,5]. The CENIC registry already compared the in-hospital results in patients who underwent stenting or balloon PTCA. The mortality rate was significantly lower for stent patients, but only when this strategy was used in patients admitted in Killip Class >2 [16]. The small number of patients analyzed here with occlusion of the SVG does not permit conclusions to be made regarding the treatment of patients in Killip Class 3 or 4.

Currently, the importance of preservation of the coronary microvasculature is becoming stronger. The quality of TIMI 3 flow is important not only in the epicardial portion of the vessel but also in micro-coronary circulation. The percutaneous treatment of SVGs during AMI constitutes a higher risk subgroup for the occurrence of distal embolization, generating platelet and thrombus plugs that can easily affect distal coronary flow. The use of intravenous glycoprotein receptors was reduced in less than 15%, which is similar to that found in stenting or balloon PTCA [20,23].

New bypass surgery, on either an emergency or elective basis was not necessary in either group. The use of intracoronary stents may have contributed to that. Stents had an extraordinary capacity for correcting sub-optimal balloon PTCA results. In the previous CENIC registry results, the necessity for emergency bypass surgery were lower for both balloon PTCA and stenting (0.4 and 0.5%, respectively) [16].

The objective of this registry analysis is to give a more clear definition of which is the best catheter strategy during AMI related to vein graft occlusion. Primary stenting may help patients avoid new emergency bypass surgery and obtain a greater success rate with a reduced residual stenosis. However, this strategy did not promote a significant reduction in the major AMI complications, such as reinfarction or death rates. A more recent approach to this problematic group of patients is the association of routine antiplatelet therapy or devices that can promote distal coronary flow protection. These trials are ongoing and in the near future may clarify this issue [24].

Until more consistent data are obtained from larger randomized series, the catheter-based strategy for this subgroup of patients will remain a challenge. Stenting should be indicated only in the presence of suboptimal balloon angioplasty results (DS >50% or flow limiting dissections), because the death rate was not altered by the routine stent approach. The use of stents to treat long segments of diffuse degenerated vein grafts should not be compared with the implantation of stents in native coronary stenosis. The association of previous antiplatelet pharmacology infusion,

such as abciximab, may help because recent trials have demonstrated that up to 25% of vessels can be opened with TIMI 3 flow when this drug is infused in the emergency room [25]. The retrospective analysis of PAMI trials showed that patients who underwent primary PTCA with a previous TIMI 3 flow had better angiographic results and a reduced death rate [26]. New percutaneous devices, such as those for distal protection, may help prevent embolization of this friable degenerated material to the downstream coronary circulation [27,28].

The CENIC registry has its own limitations. The device selection was not performed in a random fashion but at the operator's discretion. This individual selection for each patient of the respective device may have promoted some bias in this series. However, this constitutes a common finding in the data of large registries. Primary stenting has already been demonstrated to have greater advantages over balloon PTCA, when the outcome of the procedure was analyzed at least six months after the procedure [4,5], and when used to treat AMI or in elective stenting of vein grafts [29]. Until now, our Brazilian registry does not have long-term follow-up data on these patients.

Summarizing, the catheter-based reperfusion treatment of saphenous vein grafts during AMI is still an uncommon practice, being only 3% of this primary PTCA nationwide registry. Brazilian invasive cardiologists decided on primary stenting in 50% of these patients, obtaining higher success rates with lower residual stenosis, compared with that in primary balloon PTCA. However, the occurrence of reinfarction or death was not modified by this strategy. Emergency bypass surgery in this cohort of patients was not necessary.

The adverse clinical and angiographic scenario observed in this subgroup of patients with AMI suggests the need for addition of new pharmacological and percutaneous devices to obtain better results in the future.

The following invasive cardiologists, members of the Brazilian Society of Interventional Cardiology, had participated in the CENIC registry, from 1996 until 1999:

Adnam Salmam, Adriano Caixeta, Alberto Najjar, Alberto Sottomayor, Alcides Zago, Aldegio Caldeira, Aldo Duarte, Alexandre Abizaid, Alexandre Azmuz, Alexandre Varela, Álvaro Moura, André Labrunie, André Pessanha, Ângelo de Paola, Ângelo Tedeschi, Anselmo Salgado, Antenor Queiroga, Antenor Portela, Antenório Aiolfi, Antônio Carlos Silva, Antônio Forte, Antônio Ferreira, Antônio Esteves Filho, Antônio Godinho, Antônio Souza, Antônio Secches, Antônio Botelho Silva, Antônio Azevedo, Antônio Muniz, Antônio Vianna, Ari Mandil, Arthur Barreto, Augusto Lima, Caio Pessoa, Carlos Zapata, Carlos Gottschall, Carlos Areas, Carlos Cardoso, Carmine Scianni, Charles Vieira, Clacir Staudt, Cláudia Alves, Celso Takimura, Celmo Souza, Clemente Greguolo, Costantino Costantini, Deborah Nercolini, Décio Salvadori, Edgar Victor, Edson Bocchi, Edson Peixoto, Ederval Key, Edmur Araújo, Eduardo Nogueira, Eduardo Costa, Eduardo Nicolelo, Elias Ayres Neto, Enio Gueiros, Esmeralci Ferreira, Euler Mesquita, Eulógio Martinez, Evandro Osterne, Expedito Ribeiro, Fábio Brito, Fausto Feres, Fernando Santana, Fernando DeVito, Flávio Barbosa, Flávio Leboute, Francisco Cardoso, Francisco Cruz, Francisco Falcão, Francisco Stella, Frederico Silva, Galo Maldonado, Gilberto Nunes, Gilvan Dourado, Gustavo Alvarez, Gustavo Ramalho, Haroldo Glavan, Heitor Carvalho, Hélio Castello Jr, Hélio Figueira, Helman Martins, Itamar Oliveira, Ivan Lessa, James Glesser, Jamil Saad, João Batista Loures, João Batista Guimarães, João Batista Oliveira, João Otávio de Freitas, João Roberto Carvalho, Jocelino Soares, Jorge Guimarães, Jorge Camargo Neto, Jorge Haddad, Jorge Buchler, José Alfredo Sejópoles, José Domingos Almeida, José Klauber Carneiro, José Albino Souza, José Antônio Jatene, José Marin Neto, José Mangione, José Augusto de Souza, José Augusto Araújo, José Gomes Filho, José Barreto, José Breno de Souza Filho, José Carlos Mello, José Carlos Brito, José Eduardo Sousa, José Henrique Mota, José Luiz Attab, José Marconi Souza, José Maiello, José Maria Bastos, José Maria Gomes, José Ribeiro de Souza, José Silvério Guimarães, José Tadeu Mourão, José Nogueira Paes, José Walter Nogueira, Júlio Cesar Andrea, Júlio Teixeira, Klermann Lopes, La Hore Rodrigues, Lázaro Garcia, Lélio Silva, Leônidas Alvarenga Henriques, Leslie Aloan, Luciano Abreu, Luciano Façanha, Ludmilla Oliveira, Luis Campos, Luis Maria Yordi, Luiz Lessa, Luiz Alberto Mattos, Luiz Alberto Maneschy, Luiz Antônio Gubolino, Luiz Bastos, Luiz Finzi, Luiz Lavalle, Luiz São Thiago, Luiz Fernando Morrone, Luiz Kajita, Manoel Cano, Marcelo Cantarelli, Marcelo Queiroga, Márcio Truffa, Márcio Silva, Marco Perin, Marcos Flávio Ribeiro, Marcos Marino, Marcos Gama, Mário Salles, Maurício Barbosa, Miguel Ratti, Milton Soares Neto, Milton Ferreira Filho, Moisés Lima, Murilo Furukawa, Nahaniel Rodrigues, Newton Stradler, Nílton Machado, Nílton Oliveira, Nílson Ramos, Norberto Duda, Norival Romão, Noriaki Takeshita, Paulo Jorge, Paulo Almeida, Paulo de Andrade, Paulo Caramori, Paulo Galvão, Paulo Sérgio de Oliveira, Paulo Soares, Pedro Abílio Rezek, Pedro Horta, Pedro Beltrão, Pedro de Andrade, Pedro Pascoli, Pierre Labrunie, Rafael Przytyk, Raimundo de Melo, Raul Mora, Ricardo Barbosa, Ricardo Cavalcanti, Rinaldo Carneiro, Roberto César, Roberto Freire, Roberto Otsubo, Roberto Botelho, Rodolfo Alencar, Rodolfo Staico, Rogério Guimarães, Ronaldo Bueno, Ronaldo Villela, Ronei Matos, Salvador Cristovão, Samuel Silva, Sérgio Berti, Sérgio Leandro, Sérgio Prata, Siguemituzo Arie, Valter Lima, Vasco Miller, Vicente Motta, Virgílio Mares, Walkimar Veloso, Wilson Coelho, Wilson Oliveira, Wilson Pimentel e Wilson Vieira.

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