ROLE OF DISTAL PROTECTION DEVICE IN PREVENTION OF DISTAL EMBOLIZATION DURING PCI OF SAPHENOUS VEIN GRAFTS AT AFIC/NIHD; AN EXPERIENCE OF 26 CASES

FARHAN TUYYAB , AYAZ AHMED, AZHAR MAHMUD KAYANI, WAQAR AHMED, AFSAR RAZA, SOHAIL AZIZ

ABSTRACT

Background: Failure of Saphenous vein grafts (SVG), an almost universally used conduit in coronary artery bypass grafting (CABG) patients, is a common problem. Distal embolization during percutaneous coronary intervention (PCI) of SVG can have serious consequences. Use of embolization protection devices (EPD) has resulted in lesser incidence of such complications. Spider Rx is a distal protection filter device , experience and results of use of this device are presented.

Material and Methods: This study was conducted at the interventional cardiology department of Armed Forces Institute of Cardiology National Institute of Heart Diseases during a period from Feb 2007 to May 2009. All patients having indications for PCI, angina CCS class I to IV, to vein grafts more than three years after CABG were included. Patients with acute myocardial infarction and totally occluded SVGs were excluded. No flow or slow flow phenomenon and pre and post procedure CKMB, at six and twenty four hours, levels were measured.

Conclusion: Spider RX distal embolization protection is easy to use and its use resulted in embolization protection comparable to that of other devices reported in literature.

INTRODUCTION

Coronary artery bypass grafting (CABG) is an established form of revascularization that relieves angina and prolongs survival. Saphenous vein bypass grafts (SVG) are currently used in almost all coronary artery bypass graft operations. Despite recent technical improvements, recurrent angina occurs in approximately 10% patients per year, primarily due to SVG failure. It is estimated that more than 40% of the SVGs are occluded 5 years after surgery, and 75-90% have significant disease after 10 years[1,2,3]. In patients presenting with unstable angina more than 5 years after CABG, 85% have culprit lesions in vein grafts[4,5,6]. Vein graft failure is a common problem and generally has worse outcomes. Repeat CABG carries a 2 to 4 fold increase in peri-procedural mortality and myocardial infarction, and is associated with less symptomatic improvement[7,8]. Percutaneous transluminal coronary angioplasty of SVGs is another method for revascularization. Andreas Gruentzig reported 50 pts treated with PTCA in 1979, 5 were SVG dilatations 3 (60%) developed restenosis, he concluded that a different type of disease may explain high rate of restenosis[9]. Atherosclerosis in vein grafts differs from that in native vessels as it is diffuse and concentric, fibrous caps are thin or absent, lesions are friable and finally vein grafts are much larger vessels[10]. PTCA to SVGs is associated with an increased incidence of restenosis, especially of proximal part, periprocedural distal embolization and no reflow[11,12,13]. This type of embolization may block microvascular perfusion in the grafted coronary artery, leading to myocardial infarction, reflected by elevation of myocardial enzymes. Incidence of biomarker elevation after SVG intervention without EPDs exceeds 15-20%. Elevation of myocardial

Department of interventional cardiology
Armed Forces Institute of Cardiology,
The Mall Rawalpindi.

enzymes after SVG interventions is in turn strongly related to mortality with a reported rate of 31% of acute myocardial infarction and a tenfold increase in inhospital mortality[14,15]. Mechanical plaque disruption by balloons and stents is the principal cause. Higher thrombus burden, lesion length, ulceration, angulations, SVG diameter, baseline % stenosis and plaque volume have all been related with distal embolization[16]. Despite all these factors embolization remains unpredictable. To prevent distal embolization and thereby reduce mortality after catheter based interventions various strategies have been developed including distal balloon occlusions with aspiration of material proximal to the occlusion site and placement of filters to capture embolic material during dilatation. Benefits of embolization devices have been proven in many trials and their use is a class one indication as per ACC/AHA guidelines. It has been shown by SPARK ,FIRE, BLAZE and BLAZE II trials and registry that use of filter devices reduces periprocedural complications and distal embolization equivalent to other devices[17,18]. This study is an evaluation of 26 cases in which spider RX distal filter protection device was used during intervention of SVGs. The purpose of the study was to evaluate the role of filter wire in prevention of distal embolization and periprocedural myocardial damage in local settings.

MATERIAL AND METHODS

Patients having lesions and PCI to native vessels were excluded. Patients needing PCI via arterial conduits were excluded. Patients having prior PCI procedures to vein grafts were excluded. Similarly patients in whom there was no landing space for the device were excluded. Individuals with risk factors like diabetes, hypertension, smoking, hyperlipidemia and renal failure were included. Coronary angiograms and graft study was done which depicted one or more lesions in SVGs to RCA, OM and LAD. The intervention PCI and stenting was carried out in the lesions having 70% or greater stenosis. All the patients received unfractionated heparin in addition to dispirin and clopidogrel, other standard therapies were continued. After engaging with the guide catheter 0.014 inch guide wire was passed across the lesion and distal protection filter Spider RX deployed distal to the lesion. PCI and stenting was carried out with both BMS and DES stents. After successful dilatation and stent implantation, the device was withdrawn using the retrieval sheath. Before and after the intervention, thrombolysis in myocardial infarction (TIMI) flow scores were assessed. MACE (major adverce cardiac event) were defined as death, MI (Q-wave or non-Q-wave) and clinically driven target vessel revascularization at 30 days. MI was defined as post-procedural elevation of the CKMB > 3times normal

RESULTS

Total number of patients included in the study was twenty six. Table no 1 shows the baseline characteristics. Out of Patients included in the study 21(80%) were males and 5(19.2%) were females. Age ranged between 66+/_ 9.2 years, 18(70%) were diabetics, 22(84.2%) were hypertensive, raised serum cholesterol was present in 4(15.3%) patients and current smokers were 3(11.3%). Seven(26.9%) had family history of premature coronary artery disease. Table no 1 and 2 shows clinical characteristics of patients. Table no 3 shows angiographic and procedural data, 12(46.3%) patients had lesion in SVG to RCA, 11(42.3%) to OM and 3(11.3%) had lesion in SVG to LAD, 22(84%) patients had single lesion and 3(11.5%) had two lesions. Proximal segment of SVG involved in 14(48.2%) lesions, 11(38.4%) patients had mid segment disease and 4(13.7%) had distal stenosis. Graft age was between 7 +/_ 3.2 years. SVGs had a diameter of 2.5 to 4mm on visual assessment, 6(20%) leisons had visible

Table-1 : AGE AND RISK FACTORS

AGE (years)	62+/- 9.2
MALE (n,%)	21 (80%)
FEMAE (n,%)	5 (19.2%)
DIABETIC (n,%)	18 (70%)
HYPERTENSIVE	22 (84.6%)
HYYPERLIPIDEMIA (n,%)	4 (15.3%)
CURRENT SMOKER (n, %)	3 (11.5%)
FAMILY HISTORY OF CAD (n,%)	7 (26.9%)

Table-2 : CLINICAL CHARETERISTICS OF PATIENTS

EF >35% (n, %)	18 (70%)
EF< 35% (n, %)	8 (30.7%)
STABLE ANGINA (n, %)	17 (65.3%)
UNSTABLE ANGINA (n , %)	9 (34.6%)
MEAN GRAFT AGE (years)	7+/_ 3.2

thrombus. (table 3,4,5a and 5b). The guides used for intervention were 6 to 8 French Judkins 3.5 right, Multipurpose and Amplantz right , the wires used were Runthrough, BMW, ATW and Pilot 50. The balloons from 1.5 to 2.5 mm in diameter and 10 to 20 mm in length were used for predilatation. The stents used were BMS in 6(21%) and DES in 23(79%) lesions. The stent diameter was 2.5 to 4mm and length 12 to 30mm. TIMI flow rate comparison (table3,4, 5a, 5b) shows five(17%) lesions showed 0 to 1 TIMI flow 7(24.7%) leisons TIMI 2 flow and 17

Table-3 : ANGIPGRAPHIC AND PROCEDURE DATA

TOTAL NO OF GRAFT (n)	29
SVG TO LAD/diagonal (n ,%)	4 (13.7%)
SVG TO LCX (n ,%)	12 (44.3%)
SVG TO RCA (n ,%)	13 (44.8%)
REFERENCE VESSEL DIAMETER (mm)	2.5-4
INITIAL DIAMETER STENOSIS (%)	70 to99 %
PROXIMAL SEGMENT (n,%)	14(48.2%,)
MID SEGMENT(n,%)	11(38%)
DISTAL SEGMENT(n,%)	4(13.7)

Table-4 : LESION CHARACTERISTICS

LESION CHARACTERISTICS	
LENGTH (mm)	8-28
THROMBUS	6
ECCENTRIC	10
STENT IMPLANTATION	29
FINAL DIAMETER STENOSIS (%)	10+/_10%
SPIDER RX DIETAL PROTECTION DEVICE	29

Table-5a : TIMI FLOW AND PROCEDURAL COMPLICATION

INITIAL TIMI FLOW	
TIMI 0,1	5 (17.2%)
TIMI 2	7 (24.5%)
TIMI 3	17(58.6%)

Table-5b : FINAL TIMI FLOW

TIMI 0,1	2(7%)
TIMI 2	2 (7%)
TIMI 3	25 (86%)

(58.6)showed TIMI 3 flow. After procedure 25(86%) leisons showed TIMI 3 flow and 02 (7%) showed TIMI 2 flow. None of the patients had no flow and 2(7.6%) patients showed slow flow. In both these groups TIMI flow did not change. The patients with slow flow had thrombus burden.The flow improved after intravessel nitroglycerin and calcium channel blokers. Table no 6 shows procedural complications. CKMB level measurement showed 4(15.3%) patients had two times while 1(3.8%) patient had three times raised levels than the preprocedural levels. l. Only one patient showed elevation of CKMB level greater than 3 times. Table no 7 shows MACE which in our study were 3.8 %. Twenty six patients under went PCI to SVGs with the help of spider RX. Graft age was 7+/_ 3.2 years. Most of the patients were male. Twelve (46%) Patients had lesions in SVG to right coronary (RCA), eleven (42.3%) in SVG to obtuse marginal(OM) branches of left circumflex artery and three (11.3%) had lesions in SVG to left anterior descending artey(LAD). Most of the patients had proximal and mid shaft lesions. Most of the patients i.e.; twenty-four (92.7 %) received Drug Eluting Stents. Only one patient had major adverse cardiac event i.e.; non Q wave myocardial infarction.

Table-6 : PROCEDURAL COMPLICATION

CPK ELEVATION UPTOTWO TIMES	4(15.3)
CPK THREE ELEVATION UPTO THREETIMES	1(3.8%)
CPK>THREE TIMES	1(3.8)%
NO REFLOW	0
DISTAL EMBOLIZATION	NIL
DISSECTION	NIL
PERFORATION	NIL

Table-7 : MAJOR ADVERCE CARDIC EVENTS AT 30 DAYS

DEATH	NIL
MYOCARDIAL INFARCTION	
NON Q MI	01(3.4%)
Q WAVE MI	NIL
TARGET VESSEL REVASCULARIZATION	NIL
STROKE	NIL
BLEEDING NEEDING TANSFUSION	NIL
CKMB ELEVATION > 3 TIMES	013.4%)

DISCUSSION

After CABG saphenous vein graft attrition is approximately 7% during first year, than 1to 2% per year from 1 to 6 years and 4% per year from 6 to 10 years. After ten years only 40% vein grafts are free of significant stenosis[19-24]. In our evaluation of 26 cases with critical stenosis the graft age was 7 +/_ 3.2 years. The options available to tackle this problem are reoperation or PCI if lesion is suitable. Even in most experienced centers, the risk of redo CABG of in hospital death and non fatal non Q wave MI is triple

than that of initial operation[25-27]. PCI and stenting to native vessel or SVGs lesions can be done with less risk. As a result PCI is currently the preferred treatment for SVGs lesions. Atheroseclerotic plaques in vein graft are morphologically similar to those in native coronary arteries but contain more foam cells, cholesterol crystals and necrotic debris[28,29]. Consequently the plaque in older vein grafts are more softer and friable, and associated with thrombus fragmentation and distal embolization during intervention[29,30]. PCI in SVGs is associated with higher than average rate of complications predominantly due to embolization of thrombus and debris in to distal microcirculation[31-33]. This embolization is depicted by slow flow or no reflow phenomenon and raised CKMB levels. CKMB level greater than 3 times normal is associated with significant myocardial damage. Elevation of myocardial enzymes after SVGs intervention is in turn strongly related to late mortality[34]. Dorros and coworker noted three embolic events in 53 procedure[35]. To protect distal embolization and thereby reduce late mortality after catheter based SVG interventions, various strategies have been developed including balloon occlusion with aspiration of material proximal to the occlusion site or placement of filters to capture embolic material. Balloon devices are easier to cross , aspirate large and small particles, reliably trap debris and are easy to retrieve. Disadvantages of balloon occlusion devices are that there is no ante grade flow, 5-10 % patients are intolerant, there is risk of balloon induced injury and imaging is difficult during the procedure. In a large study SAFER (Saphenous vein graft Angioplasty Free of Embolic Randomized trial) the use of distal protection device PercuSurge Guardwire was compared with no device. Eight hundred patients were enrolled but trial was stopped after 550 patients as significant reduction in MACE at 30 days was noted additionally reduction in the incidence of both small and large CKMB elevation was present[36]. It has been shown by prospective randomized trials that filter wires provides equivalent protection when compared to distal balloon occlusion with aspiration[36,37,38]. In our review of 26 cases Spider RX distal protection filter wire was used to prevent distal embolization. We evaluated pre and post procedure TIMI rates as well as slow and no reflow phenomenon. No flow was not seen in any of the patients. CKMB elevation two times normal was noted in four patients three times normal in 1 and more thanthree times normal in one patient. Thus MACE was noted in 1 patient who had more than 3 times CKMB elevation. He had post procedure chest pain and mild ST segment depression indicating non-Q- MI. Patient improved with nitroglycerine and heparin infusion. Restudy of the lesion after 2 hrs did show TIMI 2 flow and no residual thrombus or stenosis. In a large study TRAP trial TRAP Vascular Filtration System a nitinol basket shaped filter was used in 337 patients during PCI of SVGs showed lower incidence of CKMB elevation > 5 times and non Q wave infarction[39]. In a study evaluating distal protection device PercuSurge Guardwire in 105 patients visible debris was aspirated in 93% patients but only 5% had CPKMB levels rising more than three times normal. In our evaluation of 26 cases DES were used in 24 patients the use of DES in SVGs is associated with lower MACE (major adverse cardiac events i.e. death, MI, Target lesion revascularization TLR). Emmanouil and colleages reviewed 14 published studies and concluded that use of DES as compared to BMS is associated with lower MACE and TLR at 06 months[41]. Use of DES in vein grafts, however, remains controversial as long term follow up has not conclusively favored DES[42].

CONCLUSION

PCI of vein grafts remains challenging but excellent results are possible with use of distal embolization device Spider Rx where indicated. In our experience Spider Rx was easy to use and yielded excellent and comparable results.

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