*Technical Results and Clinical Outcomes of the new DIRECT – STENT Coronary Stent.

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Background: Since the introduction of coronary stenting, a number of new coronary stents with various design features have been used to improve the overall efficacy of device. The DIRECT – STENT Coronary stent is new stent (patent pending) with a unique design that is unlike any other commercially available stent. The DIRECT – STENT design has a very low profile, even and smooth crimped surface, is flexible, and designed to be used in most cases of direct stenting cases.

Objective: The clinical study was conducted over one year with the main objective being the assessment of safety and immediate clinical efficacy of the DIRECT – STENT deployment in the coronary circulation, in some cases with total oclusion.

Method: A total number of 56 stents of various lengths (10,13,16,19,23,26) was deployed in 56 patients from December 2000 to June 2001. 66% of the patients were male and 34% female, mean age of 62±6.83 years. Hypertension (35.7%), previous AMI (17.8%) and diabetes mellitus (32.1%) were the most common comorbidities. Lesions were type A in 6% of the cases, type B in 74.5% and type C in 19.5%. Implatation of the stent was elective in 64.3% and for bail – out situations in 35.7% of the lesions. Stent were implanted after predilation of the lesion in 78.6% of the cases, and directly in 21.4%.

Inclusion criteria were patients with symptomatic coronary artery disease and / or documented myocardial ischemia by exercise stress test or angiographic evidence of greater than 70% diameter stenosis by QCA analysis. Patients were excluded if they had contraindication to antiplatelet therapy or significant unprotected left main coronary artery disease.

Results: The immediate angiographic success rate was 98.22% and the immediate clinical success rate (angiographic success with no major complications during in - hospital stay was 96.43%.

The minimum lumen diameter was 2.64±0.28 mm or 85.1% stenosis prior to intervention and 3.04±0.13 mm or 2.18% residual stenosis after the stent deployment DIRECT – STENT coronary stents were implanted in LAD in 39% of the cases, RCA in 51% and LCX in 10%.

During the mean in - hospital stay of 2.3±0.7 days, one patient suffered an AMI and one patient needed bypass surgery because of technical insuccess: the stent didn't cross the culprit lesion. In late clinical follow up, all of the patients with initially successful procedure were asked to return to a stress test. It was positive in 9 of 54 patients, thus reaching a clinical restenosis rate of 18%.

Conclusion: This study established the safety and efficacy of the DIRECT- STENT coronary stent in the treatment of the native coronary artery disease. The study also

demonstrated that DIRECT – STENT coronary stent can also be safely used in select cases for direct stenting procedures. Futher clinical studies are needed to demonstrated safety and efficacy of direct stenting with DIRECT- STENT. The prosthesis is being developed to permit deployment without predilation in the majority of cases.

* This clinical research was developed at Hospital Universitário Evangélico de Curitiba and Hospital de Clínicas da UFPR.

Case report: coronaric graft-stent deployment in the treatment of carotid blowout.

Introduction

The “carotid blowout syndrome” (CBS), which refers to the heamorrage caused by the rupture of the carotid artery and 1-4 (ajnr) its branches, may be a severe complication of rhinopharyngeal carcinoma. It is strongly associated with local invasion, radiation-induced necrosis and recurrent tumors 2(ajnr) for head-and-neck cancers.
The reported neurologic morbidity and mortality rates associated with this syndrome are, respectively, 40% and 60%. 3 Surgical management of CBS has proven to be technically difficult because exploration and repair of the previously irradiated field are challenging. Endovascular procedures, as embolization or stent deployment, are reported as a good alternative to surgery.1-5
Stent graft placement for CBS treatment seems the best choice in order to achieve haemostasis and to prevent neurologic morbidity (articolo di Chang). We report a case of an internal carotid blowout, determined by a rhinopharyngeal cancer, successfully treated with a covered balloon expandable graft-stent.

Case Report

A 38-year-old smoker woman with recent diagnosis of spinocellular rhinopharyngeal carcinoma, on chemiotherapy, was admitted to our hospital for massive pharyngeal haemorrhage, loss of consciousness with loss of sphincter control.

The recent anamnesis included several imaging studies, which highlight a 4 X 3 cm lesion with necrotic core, infiltrating and narrowing the left internal carotid artery and jugular vein, extending from the left tonsillary lodge to the parapharyngeal region, with invasion evidence of the parotid gland, medial left pterygoid muscle, pterygopalatin fossa, middle ear, and mastoid cells, with bone erosion. Further imaging examinations and biopsies of the rhinopharynx determined the stadium of the lesion as T4N2M0 EBV/EBER negative. Conservative therapy including routine medication, blood transfusion and local compression showed almost no effect.

The patient was then referred to the angiographic suite of the Interventional Radiology Department in order to undergo an emergency angiography. A tetravasal cerebral angiography, obtained through a 5 Fr retrograde right transfemoral access, showed severe narrowing of the left ICA, probably due to vasospasm, and patterns suggesting bleeding in the left ECA. Moreover the angiography showed a reduced representation of left intracranial vessels without visualization of left ACA. It was, thus, decided to perform an embolization of the bleeding small distal ECA branches. A 4 Fr 120 cm long Vertebral (Terumo -) was, then, advanced over an 180 cm long angled standard guidewire (terumo, japan) into the left ECA and , afterwards, a superselective catheterization of the small bleeding branches was performed with a Progreat catheter (terumo – specifiche da inserire) and superselective embolization of different vessels showing active bleeding, with 150, 250 and 350 mn PVC particles (Contour – Boston scientific), was carried out. After a few

minutes another angiography of the common carotid artery was performed, showing resolution of the ICA vasospasm, presence of bleeding due to a laceration of the distal third of the extracranial portion of the ICA, and an irregular shaped reduction of the proximal third of the carotid lumen, imputable to intraluminal thrombosis. In order to control the haemorrage and to restore a physiologic vessel patency with regular blood flow through the ICA, it was decided to deploy a covered stent-graft.

The following procedural steps required an introducer exchange with a 45 cm long 9 Fr introducer sheat (Radifocus – Terumo – Tokyo, Japan). After the removal of the former guidewire, a 300 cm long 0,014 in guidewire (Choice - Boston Scientific -) was advanced into the ICA till the intrapetrous segment of the ICA over the 4 Fr Vertebral catheter. Subsequently the Vertebral catheter was withdrawn and a 6 x 20 mm Fluency graft-stent was advanced over the guidewire; however the guidewire resulted unfit in order to provide a sufficient support for advancing the Fluency stent into the distal third of the extracranial internal carotid artery. A 260 cm long 0,035 in angled stiff guidewire (Terumo – asdas), instead, provided enough support but the traumatism of the stent with the vessel wall, due to its profile and low flexibility, was considered dangerous and, in order to avoid an extension of the vessel laceration, it was decided to opt for a different stent. A 6 x 15 mm Direct-stent (InSitu tecnologies), characterized by higher flexibility, a lower profile and reduced vessel traumatism, was chosen and a 8 Fr 80 cm long 40 DEG was positioned as guide catheter.

After the fluoroscopic guided placement of the Direct-stent over the lacerated portion of the ICA, the device was deployed inflating the balloon with a manometric syringe (Encore – Boston Scientific, xx) at 6 atm pressure. A check angiography demonstrated the recovery of the physiologic vessel patency and blood flow and exclusion of the lacerated segment of the ICA. A subsequent cerebral angiography showed an improvement in the perfusion of the MCA and its distal branches, with an unmodified angiographic pattern regarding the ACA and its distal branches.

As a clinical result interruption of the rynopharingeal bleeding and normalization of heart frequency and blood pressure was obtained, with resuscitation and stabilization of the patient's condition.

A 2 week duplex ultrasound follow-up showed the persistent patency of the ICA.

Discussion

Carotid blowout syndrome (CBS) is one type of arterial injury which can occur following head and neck tumors, radiation treatment, chemotherapy and surgery. Radiation therapy, in particular, is characterized by a higher risk of CBS. Patients with CBS have a 60% risk of neurological morbidity and 40% of mortality. These risks are considerably higher in patients, like the one presented in this case report, presenting massive bleeding and carotid thrombosis. (4 e 5 di KIM, 4 di chen).

Treatment of CBS comprehends open surgery with resection and reconstruction or carotid artery ligation, and endovascular procedures; the latter ones include embolization with steel and/or platinum coils, gelatin sponge particles, polyvinil alcohol based foams, detachable balloons and, more recently, stent-graft placement (13 di Chen). Surgical procedures are characterized by an unsatisfying average 60% rate of major complications such as death and stroke (3 di chang, bao Luo – articolo-), and have been more and more replaced by endovascular embolization techniques. These ones have shown many advantages over surgical techniques, such as more distal access to the bleeding points, reduced operative time, no need for general anesthesia and a more precise demonstration and localization of bleeding points.

Embolization of a ICA founds its rationale in the progressive and slow narrowing of the arterial lumen induced by the pharyngeal tumor and the radio/chemotherapy, which stimulates the hemodynamic compensation by the hypertrophy of the controlateral carotid and vertebrobasilar system, thus limiting the eventual brain damage caused by complete ICA occlusion.However, even if characterized by a lower morbidity and mortality rate rather than surgical procedures, embolization of the ICA still presents an unsatisying 15-20% rate of developing immediate or delayed cerebral ischemia.

Several recent studies report endovascular treatment with a stent-graft for CBS as a quick and effective method, determining lower morbidity compared to surgical procedures or permanent arterial occlusion by endovascular techniques. Moreover, it is a less time-consuming procedure, which should be preferred in life-threatening situations such as profuse and active bleeding, responsible for unstable vital signs.6-14 (pyun)

Though several case reports describe a relatively high rate of recurrent active bleeding (1,14,15 pyun), the immediate clinical results in patients who underwent placement of a covered stent for CBS have been considered favorable in many reports (6-14 pyun).

Covered stents already in clinical use for the endovascular treatment of CBS are covered carotid stents as Wallgraft (Boston Scientific) and unconventionally usedd oesophageal covered stents as NITI-S (Taewoong Medical Co.). In the first instance we chose to deploy the Fluency plus vascular stent-graft (Bard – xxx) because of its high radial expansion force and its 2 mm flared bare ends, in order to minimize the risk of dislocation and subsequent endoleak. We subsequently decided not to deploy the Fluency plus stent because of its reduced vessel compliance and its important vessel attritus, determined by the high profile of the stent, which made the stent placement difficult and the thromboembolic risk too high.

In need of a lower profile stent-graft, also because of the non existence of stent-grafts designed for the endovascular treatment of CBS, we opted for an unconventional use of the coronaric “Direct Stent” stent graft (In-situ technologies, xxx). Direct-Stent is one of the thinnest stent-grafts currently in commerce, designed for the treatment of ruptures, dissections and aneurysms of the coronaric arteries, characterized by a good flexibility and accessibility to tortuous anatomies. These characteristics allowed us to successfully cross the lesion, with a reduced vessel thraumatism and avoiding further secondary thromboembolic occlusions, and correctly deploy the stent. As a result, a satisfying hemostasis was obtained, and the vessel patency was nearly completely restored.

Conclusion

In summary, the unconventional use of the balloon expandable “Direct Stent” may represente a safe and useful tool for the endovascular treatment of the CBS. Although long term follow up is needed in order to value the eventuality of bleeding recurrence, the immediate clinical results have been very satisfying. This case report highlights the usefulness and versatility of endovascular stent-graft placement of this covered stent for rescue treatment of life threatening carotid blowout syndrome.

PARMA 3/09/2010

HOSPITAL: OSPEDALE MAGGIORE DI PARMA

DEPT.:VASCULAR SURGERY

PROCEDURE : INTVL. RADIOLOGY

OPERATORS: DR.LARINI, DRA MARCATO (RADIOLOGIST)

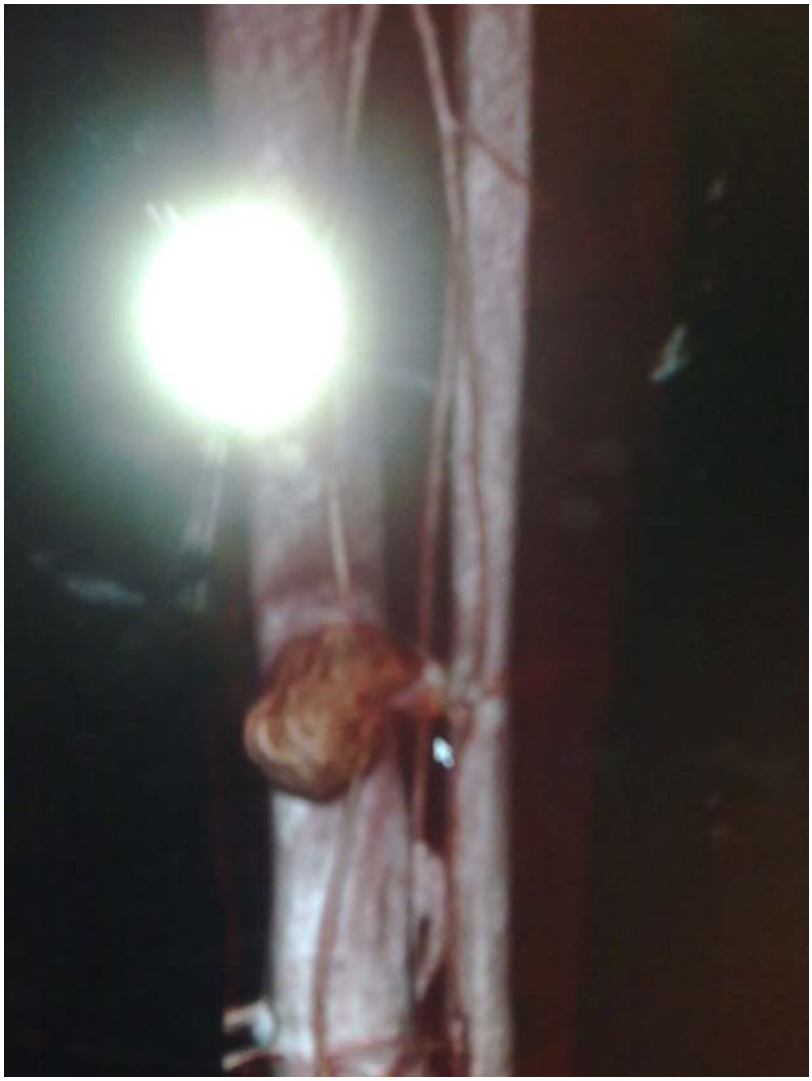
30 YEARS PATIENT WITH LARGE PSEUDO ANEURISM OF POSTEROR TIBIAL THIRD MEDIUM (BASE OF IMPLANTATION 5 MM) CAUSED BY AN EXTRANEAL TOOL IN A JOB ACCIDENT.

PROCEDURE IN FLOW FAVOUR POSITIONING THE STENT-GRAFT INSITU 3,0 PER 19 MM LOT 20100874

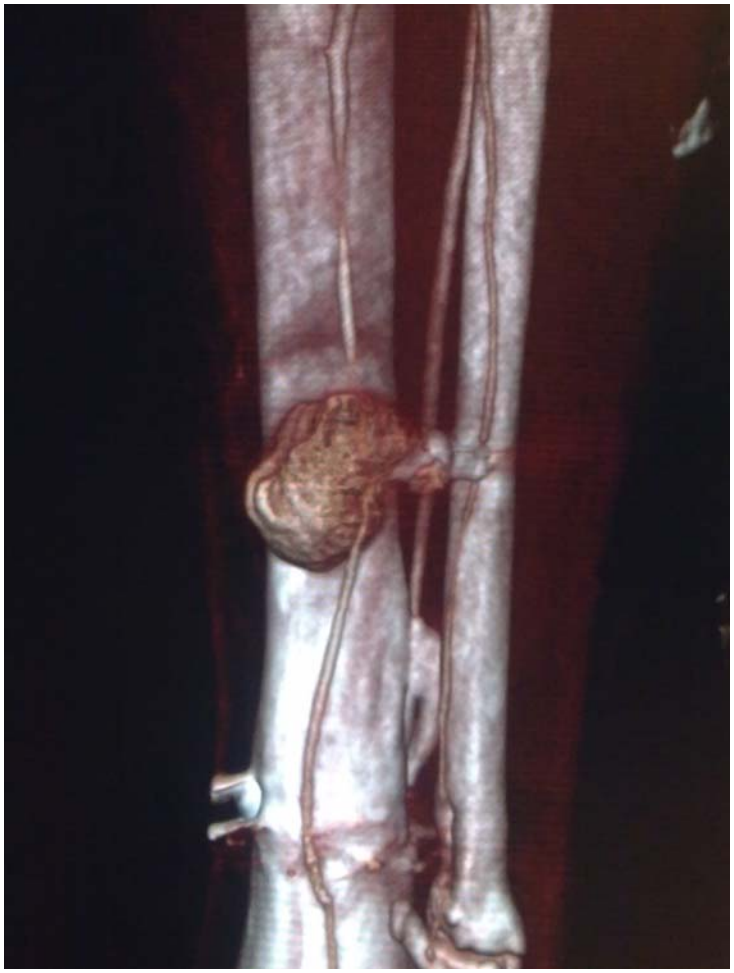
FINAL ANGIOGRAPHY : TOTAL EXCLUSION OF THE SAC

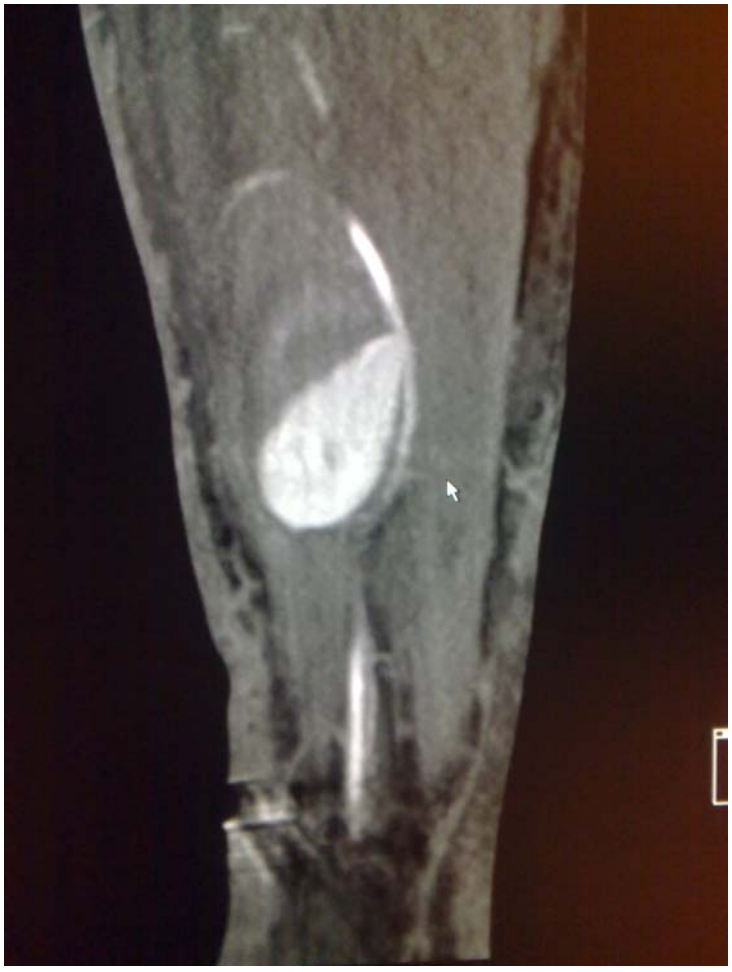
DAY AFTER : ECODOPPLER WITH GREAT FLOWS AND PATENCY .

FOLLOW-UP IN ONE MONTH.



Case Report - Insitu Stent-Graft





ENDOVASCULAR TREATMENT OF CORONARY FISTULAS

Hemodinamics Department, Hospital Cardiomedica, Lima, Peru.

Definition

A coronary fistula is an abnormality -congenital or acquired- in which blood is shunted into a vessel or other structure deviating its flow from the myocardial artery network.

Case

We report the successful percutaneous treatment of two Left Anterior Descending (LAD) coronary artery Fistulas by means of STENT GRAFT implantation.

In July 24 2009, a 62 year old female with a history of hypertension, non-smoker was admitted for the treatment of two fistulas in the Left Anterior Descending (LAD) coronary artery. The fistulas caused the blood to travel from the LAD to the Pulmonary artery and the Inferior Vena Cava. The patient was treated with a 3.5x19 coronary Stent Graft (*Direct-Stent Stent Graft, InSitu Technologies Inc , IGH, Minnesota, USA*) successfully covering the fistulas. 6 months follow up reports no-mace.

Implant performed at Cardiomedica Hospital, Lima, Peru in July 2009. Implant made by Dr. Victor Galvez

Figure 1: Selected coronary angiography shows fistulas on the Left Anterior Descending (LAD) before STENT GRAFT implant. **Figure 2**: After the procedure, clearly showing the exclusion of the fistulas.

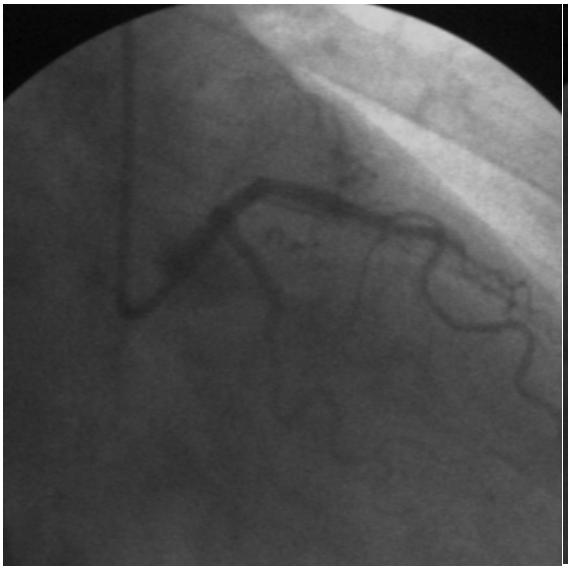


Figure 1

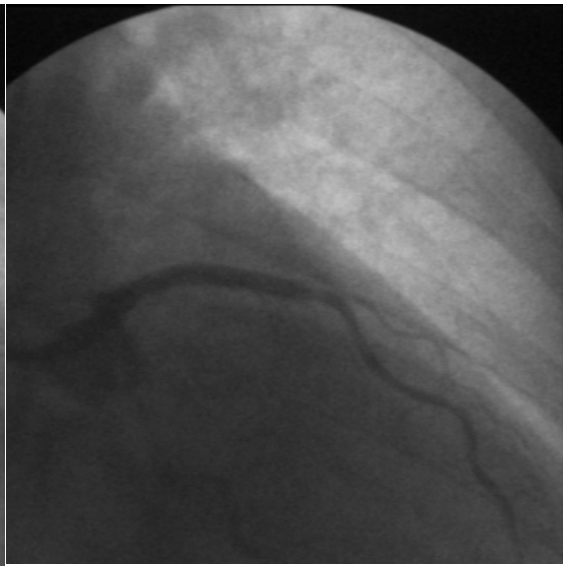


Figure 2

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CLINICAL RESEARCH

Incidence, Predictors, Management, Immediate and Long-Term Outcomes Following Grade III Coronary Perforation

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Objectives The aim of this study was to evaluate the incidence, predictors, management, and clinical outcomes in patients with grade III coronary perforation during percutaneous coronary intervention.

Background Grade III coronary perforation is a rare but recognized complication associated with high morbidity and mortality.

Methods From 24,465 patients undergoing percutaneous coronary intervention from May 1993 to December 2009, 56 patients had grade III coronary perforation.

Results Most lesions were complex: 44.6% type B2, 51.8% type C, and 28.6% chronic total occlusions, and within a small vessel (≤2.5 mm) in 32.1%. Glycoprotein IIb/IIIa inhibitors were administered in 17.9% of patients. The device causing perforation was intracoronary balloon in 50%: 53.6% compliant, 46.4% noncompliant; intracoronary guidewire in 17.9%; rotablation in 3.6%; and directional atherectomy in 3.6%. Following perforation, immediate treatment and success rates, respectively, were prolonged balloon inflation 58.9%, 54.5%; covered stent implantation 46.4%, 84.6%; coronary artery bypass graft surgery (CABG) and surgical repair 16.0%, 44.4%; and coil embolization 1.8%, 100%. Multiple methods were required in 39.3%. During the procedure (n = 56), 19.6% required cardiopulmonary resuscitation and 3.6% died. In-hospital (n = 54), 3.7% required CABG, 14.8% died. The combined procedural and in-hospital myocardial infarction rate was 42.9%, and major adverse cardiac event rate was 55.4%. At clinical follow-up (n = 46) (median: 38.1 months, range 7.6 to 122.8), 4.3% had a myocardial infarction, 4.3% required CABG, and 15.2% died. The target lesion revascularization rate was 13%, with target vessel revascularization in 19.6%, and major adverse cardiac events in 41.3%.

Conclusions Grade III coronary perforation is associated with complex lesions and high acute and long-term major adverse cardiac event rates. (J Am Coll Cardiol Intv 2011;4:87–95) © 2011 by the American College of Cardiology Foundation

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Grade III coronary perforation or coronary rupture is an extremely rare but well recognized complication of percutaneous coronary intervention (PCI) (1,2). It is defined by the Ellis criteria as a perforation resulting in extravasation of blood through a frank perforation (≥1 mm) or spilling into an anatomic cavity (3). Previous studies reporting the incidence, predictors, and management of coronary perforation have encompassed all 3 grades of coronary perforation, but there have been no studies specifically focusing on these aspects in the grade III subgroup alone. The incidence of grades I to III coronary perforation ranges from 0.1% to 3.0% (1,3–6).

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Studies have reported predictors of coronary perforation as: female sex (2,3), calcified and noncompliant arteries (7,8), type C coronary lesions, previous coronary artery bypass grafting (CABG), the use of atheroablative devices (2), older patient groups, hypertension and non–ST-segment elevation myocardial infarction (9).

Abbreviations and Acronyms

CABG = coronary artery bypass graft
GPI = glycoprotein IIb/IIIa inhibitors
IVUS = intravascular ultrasound
MACE = major adverse cardiac event
MI = myocardial infarction
PCI = percutaneous coronary intervention
PTFE = polytetrafluoroethylene
ST = stent thrombosis
TLR = target lesion revascularization
TVR = target vessel revascularization

Grade III coronary perforation is the most serious form of perforation and is associated with the highest mortality rates ranging from 7% to 44% of cases (9–12). It is also associated with very high rates of cardiac tamponade of up to 40% (10) and the need for emergency CABG in 20% to 40% (9,10). Treatment modalities include prolonged balloon inflation, covered stent implantation, pericardiocentesis for cardiac tamponade, CABG, and microcoil embolization (13). Often a combination of these techniques is required to achieve adequate hemostasis. Newer techniques such as covered stent deployment have meant that emergency CABG requirements have decreased (14). However, the incidence of coronary perforation with a higher proportion of grade III perforation appears to be increasing because of higher rates of PCI in complex patient and lesion subgroups and the widespread use of glycoprotein IIb/IIIa inhibitors (GPI) (5).

The aim of this study was to report the incidence, predictors, treatment, and long-term outcomes of all patients with grade III coronary perforation as a complication of PCI in the real-world setting of 2 institutions with high volumes of coronary intervention.

Methods

Patients. We analyzed data that had been prospectively collected following PCI in 2 institutions, San Raffaele Scientific Institute and EMO-GVM Centro Cuore Columbus Hospital, Milan, over a 16-year period from May 1993 to December 2009. All cases of grade III coronary perforation had been prospectively entered into the PCI database as defined by the Ellis et al. (3) criteria; a retrospective analysis of these cases was performed by 2 physicians (R.A. and A.I.) with information collection from the database. All original angiograms were reviewed by a technician (M.F.) to confirm the occurrence of grade III perforation. A detailed review with clarification of all information from clinical documentation and coronary angiography was then performed for all cases by the same physicians (R.A. and A.I.) at both institutions. Both physicians involved in this task had not taken part in the procedures analyzed.

Study definitions. Grade III coronary perforation or coronary rupture was defined by the Ellis et al. (3) criteria as extravasation of blood through a frank perforation (≥1 mm) or into an anatomic cavity chamber on coronary angiography (3). Cardiac tamponade was defined as the presence of 1 or more of the following: 1) systemic hypotension (systolic blood pressure <90 mm Hg) with evidence of pulsus paradoxus on clinical or invasive assessment; 2) evidence of pericardial fluid collection by angiography or by echocardiography with echocardiographic features of tamponade: significant respiratory variation in transmitral Doppler velocity, dilated inferior vena cava with failure to collapse on inspiration, or diastolic collapse of the right ventricular free wall. Periprocedural myocardial infarction (MI) was defined as a 3-fold increase in creatine kinase-myocardial band. Successful treatment of grade III perforation was defined by the absence of any angiographic evidence of contrast extravasation or clinical or echocardiographic signs of cardiac tamponade. Angiographic restenosis was defined as >50% diameter stenosis by quantitative coronary angiography within a previously stented segment. *Target lesion revascularization* (TLR) was defined as the need for any repeat revascularization for a stenosis within the stent or within the 5-mm borders adjacent to the stent. *Target vessel revascularization* (TVR) was defined as the need for any repeat revascularization on a treated vessel. *Major adverse cardiac event* (MACE) was defined as a combination of all cause mortality, MI, TLR, TVR, and need for CABG. *Stent thrombosis* (ST) was defined using the Academic Research Consortium (15) definitions and cumulative ST as a combination of all episodes of ST during follow-up.

Procedure. All patients were treated with aspirin and a loading dose of a thienopyridine before the procedure. During the procedure, all patients were then treated with intravenous heparin with an initial 100-U/kg bolus followed by further heparin as necessary to achieve a target activated

clotting time >250 s. Ten patients (17.9%) were also treated with concomitant GPI therapy at the discretion of the operator. Coronary intervention was then performed as usual with pre-dilation, and stent implantation using standard techniques via the femoral artery as have previously been described (16). At the time of perforation, an emergency echocardiogram was performed when tamponade was suspected; however, there were instances in which pericardial drainage was performed without prior imaging if the clinical scenario demanded it. Post-operatively, all patients received aspirin unless there was a specific contraindication, and those patients receiving an intracoronary stent received dual antiplatelet therapy with aspirin and a thienopyridine therapy as determined by contemporary guidelines. Following cessation of thienopyridine therapy, all patients continued to take aspirin indefinitely.

Data collection. All patients were followed-up at regular intervals with clinic visits or telephone interviews. Additional data were obtained from primary care physicians, referring cardiologists, or relatives when necessary. All repeat interventions and complications were prospectively entered into a dedicated database. Clinical follow-up was obtained in all patients, and angiographic follow-up was obtained in 56.5% of patients following successful treatment of grade III coronary perforation.

End points. Adverse procedural and in-hospital events were defined as the need for cardiopulmonary resuscitation, MI, acute ST, necessity for urgent CABG, and death. The long-term primary end points were defined as death from any cause, MI, TVR, TLR, need for CABG, and MACE at any time during the in-hospital stay or at follow-up. We defined the secondary end points as the incidence of restenosis, and ST, defined as probable, possible, or definite.

Statistical analysis. All statistical analysis was performed using SPSS statistical software (version 16.0, SPSS Inc., Chicago, Illinois). Continuous variables are expressed as mean ± SD or median ± interquartile range (25th percentile to 75th percentile) as appropriate. Categorical variables are expressed as counts and percentage.

Multivariable logistic regression analysis was used to determine independent predictors of grade III coronary perforation, using purposeful selection of covariates. Variables associated at univariate analysis with grade III coronary perforation (all with $p < 0.2$) and those judged to be of clinical importance from previously published literature were eligible for inclusion into the multivariable model-building process. Candidate variables included sex, circumflex artery lesion, mid-vessel lesion location, coronary occlusions, stent implanted, directional atherectomy, rotablation, calcified lesion, bifurcation lesion, intravascular ultrasound (IVUS) performed, diabetes mellitus, tortuous vessel, cutting balloon pre-dilation, and previous CABG. Model discrimination was measured by the C-statistic and calibration by the Hosmer-Lemeshow goodness-of-fit test (17).

Results

Baseline patient and lesion demographics. From 24,465 interventional procedural records, we found 56 patients who had coronary intervention complicated by grade III coronary perforation, leading to an incidence of 0.23%. The baseline clinical demographics of these patients are presented in Table 1. Most patients were men, and most patients had presented with stable angina.

Most perforations were situated in the left anterior descending artery, and 32.1% of these lesions were within a small vessel (≤2.5 mm). Ninety-six percent of lesions were complex with type B2 lesions in 44.6% and type C lesions in 51.8% of patients. In addition, 28.6% of lesions were chronic total occlusions. The baseline lesion characteristics are outlined in Table 2.

Procedural characteristics. All patients were treated with intravenous heparin and a further 17.9% received GPI during the procedure as either a bolus dose or infusion. Multivessel PCI was performed in 42.9%. Most patients received an intracoronary stent; directional atherectomy was performed in 5.4%; and cutting balloon pre-dilation was carried out in 10.7%. In addition, IVUS was used to guide PCI in 50.0% of cases. The baseline procedural characteristics are shown in Table 3.

The device causing perforation was an intracoronary balloon in 50.0% (n = 28) of patients with a compliant balloon used in 53.6% (n = 15) and a noncompliant balloon used in 46.4% (n = 13). Perforation occurred during pre-dilation before stent implan-

Table 1. Baseline Clinical Characteristics (n = 56)

Age, yrs	66.5 ± 12.1
Male sex	44 (78.6)
Ejection fraction	55.8 ± 9.1
Prior myocardial infarction	25 (44.6)
Prior PCI	22 (39.3)
Prior CABG	6 (10.7)
Unstable angina (CCS IV)	4 (7.1)
Stable angina (CCS I–III)	46 (82.2)
Silent ischemia (CCS 0)	6 (10.9)
Multivessel disease	42 (76.4)
Renal impairment (plasma creatinine ≥1.4 mg/dl)	4 (7.1)
Cardiovascular risk factors	
Family history of coronary artery disease	22 (39.3)
Hypertension	35 (62.5)
Hypercholesterolemia	38 (67.9)
Current smoker	5 (8.9)
Diabetes mellitus	8 (14.3)

Data presented as percentages and absolute numbers or mean ± SD.

CABG= coronary artery bypass graft; CCS = Canadian Cardiovascular Society; PCI = percutaneous coronary intervention.

Table 2. Lesion Characteristics (n = 56)

Vessel	
Left anterior descending	25 (44.6)
Circumflex	7 (12.5)
Right coronary artery	13 (23.2)
Intermediate	1 (1.8)
First diagonal	3 (5.4)
Second diagonal	1 (1.8)
Obtuse marginal	3 (5.4)
Septal	1 (1.8)
Saphenous vein graft	2 (3.6)
Lesion location	
Ostial	4 (7.1)
Proximal	22 (39.2)
Mid	26 (46.4)
Distal	4 (7.1)
Lesion and vessel morphology	
Type A	0
Type B1	2 (3.6)
Type B2	24 (44.6)
Type C	29 (51.8)
Chronic total occlusion	16 (28.6)
Significant calcification	13 (23.2)
Small vessel ≤2.5 mm	18 (32.1)

Data presented as percentages and absolute numbers or mean ± SD.

tation in 39.3% (n = 11) and during post-dilation following stent deployment in 60.7% (n = 17) of patients. The mean balloon artery ratio was 1.3 ± 0.2 mm in the compliant balloon group and 1.3 ± 0.3 mm in the noncompliant balloon group. The balloon delivering an intracoronary stent caused vessel perforation in 17.8% (n = 10) of patients, whereas this complication was caused by an intracoronary guidewire in 17.9% (n = 10) with most of these wires being non-hydrophilic (n = 8, 80%).

Management and procedural outcomes. Following grade III coronary perforation, pericardiocentesis for cardiac tamponade was performed in 28.6% (n = 16) and an intra-aortic balloon pump was implanted as an emergency in 19.6% (n = 11) of patients. The overall success rate following treatment of perforation was 87.7% (n = 50). The perforation was treated with prolonged balloon inflation in 58.9% (n = 33); however, this technique was only successful in 54.5% (n = 18) of those treated. Covered stent implantation was performed to treat the grade III coronary perforation in 46.4% (n = 26) and had a higher success rate with hemostasis achieved in 84.6% (n = 22) of patients (Fig. 1). Of the cases treated with covered stent implantation, 96.1% (n = 25) had polytetrafluoroethylene (PTFE) stents implanted, and in 1 case, a custom-made saphenous vein graft–covered stent was implanted in the era before the availability of covered stents. From 25 PTFE stents implanted, 22 were Jostent coronary graft stent (Abbott Vascular Laboratories, Redwood City, California) and 3 were Direct-Stent stent grafts (InSitu Technologies Inc., Minneapolis, Minnesota) with 3-, 3.5-, and 4-mm diameters and 12-, 16-, and 19-mm lengths. Implantation of a standard stent was performed in 17.9% (n = 10) of cases but was only successful in treating the perforation in a minority of patients (n = 3, 30.0%). Coil embolization was performed in 1 patient and was successful in sealing the perforation. An emergency CABG was performed in 16.0% (n = 9) but was only successful in sealing the rupture in 44.4% (n = 4). Multiple methods of treatment were required in an attempt to achieve hemostasis in 39.3% (n = 22). During the procedure, cardiopulmonary resuscitation was required in 19.6% (n = 11), and the overall intraprocedural mortality rate was 3.6% (n = 2). The characteristics of grade III coronary perforation and treatment are outlined in Table 4.

Predictors of grade III coronary perforation. Multivariable logistic regression was used to assess predictors of grade III coronary perforation. The c-statistic for the propensity score model was 0.78, indicating excellent discrimination. The Hosmer-Lemeshow goodness-of-fit test p value was 0.99, confirming good calibration and fit of the multivariable model that estimated the propensity score. The significant predictors of perforation are presented in Table 5.

In-hospital outcomes. During the in-hospital period, 1 patient had an acute ST following covered stent implantation and 2 patients required urgent CABG and surgical repair of perforation following presentation pericardial effusion 2 to 3 days following the procedure. The combined procedural and in-hospital MI rate was 42.9% (n = 24). In addition, 14.8% (n = 8) died during the index hospitalization period leading to a total mortality rate of 17.9% (n = 10) and a combined procedural and in-hospital MACE rate of 55.4% (n = 31).

Table 3. Baseline Procedural Characteristics (n = 56)

Glycoprotein IIb/IIIa inhibitors	10 (17.9)
Unfractionated heparin	56 (100)
Multivessel stenting	24 (42.9)
Devices used during procedure	
Compliant balloon	26 (46.4)
Noncompliant balloon	21 (37.5)
Intracoronary stent	44 (78.6)
Cutting balloon	6 (10.7)
Directional atherectomy	3 (5.4)
Rotablation	9 (16.1)
Intravascular ultrasound	28 (50.0)
Type of guidewire used	
Standard (nonhydrophilic)	38 (67.9)
Light support (nonhydrophilic)	7 (12.5)
Intermediate support (nonhydrophilic)	16 (28.5)
High support (nonhydrophilic)	17 (30.3)
Hydrophilic	12 (21.4)

Data presented as percentages and absolute numbers or mean ± SD.

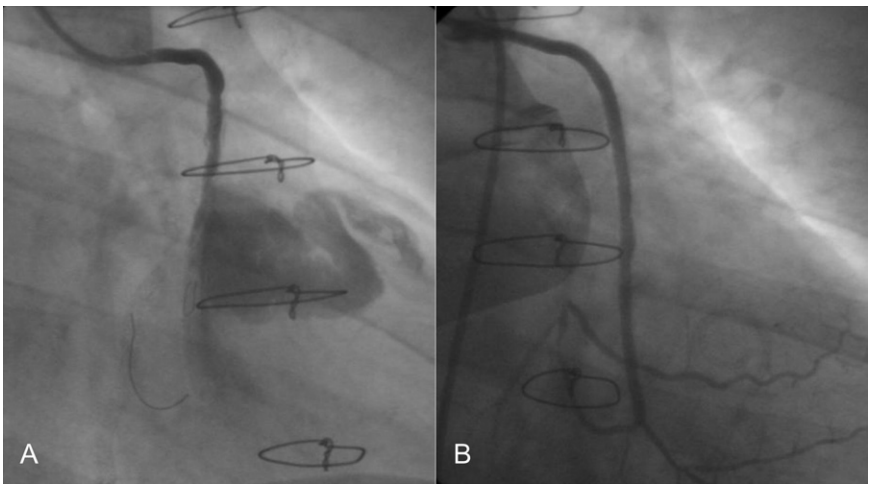

Figure 1. Example of Grade III Coronary Perforation Before and After Treatment

(A) Grade III coronary perforation following percutaneous coronary intervention to saphenous vein graft. **(B)** Successful treatment of coronary perforation achieved following covered stent implantation.

A subgroup analysis of the 10 patients who had GPI and heparin therapy is summarized in Table 6. In this group the proportion of patients who needed multiple treatment methods was higher than the overall group at 50.0% (n = 5), and overall rate of successful treatment of perforation was 80.0% (n = 8). In addition, the procedural and in-hospital MACE rate was 90.0% (n = 9) with 1 death during the procedure and 1 death during the in-hospital period.

Follow-up clinical outcomes. Clinical follow-up was achieved in all patients with median follow-up of 38.1 months (7.6 to 122.8). Most patients (n = 44, 95.7%) were asymptomatic at follow-up with symptoms of stable angina in the remainder (n = 2, 4.3%). The in-stent restenosis rate was 38.5% (n = 10) with 60.0% (n = 6) of these being occlusive. The MACE rate at follow-up was 41.3% (n = 19), which was composed of MI in 4.3% (n = 2), all-cause mortality in 15.2% (n = 7), need for CABG in 4.3% (n = 2), TLR in 13.0% (n = 6), and TVR in 19.6% (n = 9). Definite ST occurred in 4 patients (8.6%), all of whom had covered stent implantation to treat grade III perforation. One of these patients experienced recurrent episodes of subacute ST following PTFE stent implantation at 9 11, and 30 days after the index procedure despite maximal antiplatelet and anticoagulant therapy; on each of these occasions, he had repeat angiography and repeat PCI and went on to have CABG but subsequently died of cardiogenic shock. One patient experienced subacute ST on dual antiplatelet therapy 7 days following the index PCI procedure with implantation of a PTFE stent; he subsequently had repeat PCI with drug-eluting stent implantation. One patient presented with late ST 3 months following PTFE implantation at the index procedure while taking dual antiplatelet therapy; he was treated with conventional balloon angioplasty and made a good recovery. One patient presented with late ST 2 months after PTFE stent implantation while taking dual antiplatelet therapy and was managed conservatively. Long-term clinical and an-

Table 4. Characteristics of Grade III Coronary Perforation (n = 56)

Device causing rupture	
Compliant balloon	15 (26.8)
Mean balloon artery ratio	1.3 ± 0.2
Noncompliant balloon	13 (23.2)
Mean balloon artery ratio	1.3 ± 0.3
Stent delivery system	10 (17.8)
Cutting balloon	4 (7.1)
Directional atherectomy	2 (3.6)
Rotablation	2 (3.6)
Hydrophilic wire	2 (3.6)
Nonhydrophilic wire	8 (14.3)
Action following rupture	
Pericardiocentesis	16 (28.6)
Emergency intra-aortic balloon pump	11 (19.6)
Heparin reversal	24 (42.9)

Data presented as percentages and absolute numbers or mean ± SD.

Table 5. Logistic Regression Analysis for Predictors of Grade III Coronary Perforation

	OR	95% CI for OR	p Value
Type B2/C lesions	3.75	1.47–9.60	0.006
Coronary occlusion	1.91	1.02–3.60	0.045
Rotablation performed	3.47	1.59–7.58	0.002
Intravascular ultrasound–guided procedure	5.36	3.10–9.25	<0.001

CI = confidence interval; OR = odds ratio.

Table 6. Treatment and Procedural Outcomes Following Grade III Coronary Perforation

Lesions	Overall Group	Patients Not Treated With GPI	Patients Treated With GPI
Treatment of rupture	n = 56	n = 46	n = 10
Prolonged balloon inflation	33 (58.9)	27 (58.7)	6 (60.0)
Successful	18 (54.5)	16 (59.3)	2 (33.3)
Covered stent implantation	26 (46.4)	20 (43.4)	6 (60.0)
Successful	22 (84.6)	17 (85.0)	5 (83.3)
Standard stent implantation	10 (17.9)	10 (21.7)	0
Successful	3 (30.0)	3 (30.0)	0
Coil embolization	1 (1.8)	1 (2.2)	0
Successful	1 (100)	1 (100)	0
CABG and surgical repair of perforation	9 (16.0)	6 (13.0)	3 (30.0)
Successful	4 (44.4)	3 (50.0)	1 (33.3)
Multiple treatment methods used	22 (39.3)	17 (37.0)	5 (50.0)
Overall successful treatment of rupture	50 (87.7)	42 (91.3)	8 (80.0)
Procedural complications	n = 56	n = 46	n = 10
Cardiopulmonary resuscitation	11 (19.6)	4 (8.7)	3 (30.0)
Death	2 (3.6)	1 (2.2)	1 (10.0)
In-hospital complications	n = 54	n = 45	n = 9
Acute stent thrombosis	1 (1.9)	1 (2.2)	0
Necessity for CABG	2 (3.7)	1 (2.2)	1 (11.1)
Death	8 (14.8)	7 (15.5)	1 (11.1)
Combined procedural and in-hospital events	n = 56	n = 46	n = 10
Myocardial infarction	24 (42.9)	17 (37.0)	7 (70.0)
Major adverse cardiac event	31 (55.4)	22 (47.8)	9 (90.0)

Data presented as percentages and absolute numbers or mean ± SD.
GPI = glycoprotein IIb/IIIa inhibitors; other abbreviations as in Table 1.

giographic outcomes during the follow-up period are presented in Table 7.

Discussion

The main findings of this paper are: 1) the incidence of grade III coronary perforation was extremely rare; 2) predictors of grade III coronary perforation were complex coronary lesions, coronary occlusions, and the use of rotablation and IVUS; 3) multiple methods of treatment are available, but prolonged balloon inflation and covered stent implantation were successful in a reasonable proportion of cases; 4) despite improvements in the treatment of grade III coronary perforation, rates of MI and mortality remained high; 5) the occurrence of grade III coronary perforation following administration of GPI was associated with increased procedural and in-hospital MACE rates; and 6) from 1993 to 2009, the incidence of grade III coronary perforation remained relatively unchanged, but there was an improvement in procedural and in-hospital MACE rates (Fig. 2).

Grade III coronary perforation is a feared and dramatic complication of PCI with poor immediate outcomes and very high mortality rates. It remains a rare event with an incidence of 0.23% in our centers in the context of high volumes of PCI. Over time, the number of cases of grade III coronary perforation has remained constant, as a likely reflection of the increased complexity of procedures. However, even though the combined procedural and in-hospital MACE rate is high at 55%, there has been some improvement over time since the introduction of techniques such as covered stent implantation. Despite the available treatments, these methods are often unsuccessful in achieving hemostasis and multiple modalities are frequently required. Notably, these outcomes were achieved in centers with experienced operators, and success rates may be even less favorable in the hands of less experienced operators. From our study, the commonest cause of grade III coronary perforation was inflation of an intracoronary balloon, with no change in the incidence based on the balloon compliance. Grade III coronary perforation was caused by rotablation, directional atherectomy, and cutting balloon inflation in only a small number of cases; however, this figure may be influenced by the low rates of use of these adjunctive techniques in our interventional practice. Interestingly, in cases of perforation due to an intracoronary guidewire, the wire was nonhydrophilic in the majority, in contrast to previous reports (18). However, as the total numbers of cases were relatively small this finding may be a reflection of the fact that our first-line choice of guidewire is uncoated. An assessment of the predictors of grade III coronary perforation showed that this adverse event was associated

Table 7. Long-Term Outcome During the Follow-Up Period

Follow-up	46
Months	38.1 (7.6–122.8)
Months of dual antiplatelet therapy	1.0 (0–6.0)
Angiographic follow-up obtained	26 (56.5)
Angina CCS class	
Unstable angina (CCS IV)	0
Stable angina (CCS I–III)	2 (4.3)
Asymptomatic (CCS 0)	44 (95.7)
Restenosis	10 (38.4)
Death following discharge	7 (15.2)
Cardiac death	3 (6.5)
Myocardial infarction	2 (4.3)
Need for CABG	2 (4.3)
Target lesion revascularization	6 (13.0)
Target vessel revascularization	9 (19.6)
Stent thrombosis	4 (8.6)
Major adverse cardiac event	19 (41.3)

Data presented as percentages and absolute numbers, mean ± SD, or median (interquartile range).
Abbreviations as in Table 1.

with complex coronary lesions (type B2 or C lesions), coronary occlusions, and the use of rotablation or IVUS during the procedure. In addition, the incidence of definite ST was relatively high at 8.6%; all of these cases were associated with covered PTFE stent implantation and illustrates the thrombogenic nature of these stents, in combination with the increased risk of ST conferred by coronary perforation. This finding highlights the need for less thrombogenic stents for the treatment of coronary perforation.

Previous studies have focused on an analysis of a combined group of all 3 grades of coronary perforation and have suggested that this complication is more common during PCI to type C lesions (2,9); this was confirmed by our study, with a predominance of complex type B2 or C lesions. It has also been suggested that coronary perforation is more prevalent during coronary intervention in females (2); however, sex was not a predictor of grade III coronary perforation in our study. Shimony et al. (9) reported that the incidence of coronary perforation may be associated with intervention to the right coronary artery and attributed this to the tortuous course of this vessel; however, in our study, anatomic lesion location was not a predictor of perforation. This may be a result of differences between the characteristics of vessels with grade III coronary perforation compared with those with less severe forms of perforation. Both the use of rotablation and IVUS were predictors or grade III coronary perforation in our study, reflecting the association between this adverse event and a more complex lesion subset. Notably, the use of IVUS was shown to be associated with coronary perforation in a previous study by our group and is likely to be a reflection of the fact that IVUS is more likely to be used in complex lesions or those in which PCI is complicated, for example, by balloon underexpansion during pre-dilation (19). Regarding treatment of grade III coronary perforation, it appears that we still do not have an ideal modality to treat this dramatic complication despite reported promising outcomes following covered stent implantation and microcoil embolization (20,21). Even with newer treatment methods, multiple treatment modalities were still required in 39% and although successful hemostasis was achieved in 88%, our combined procedural and

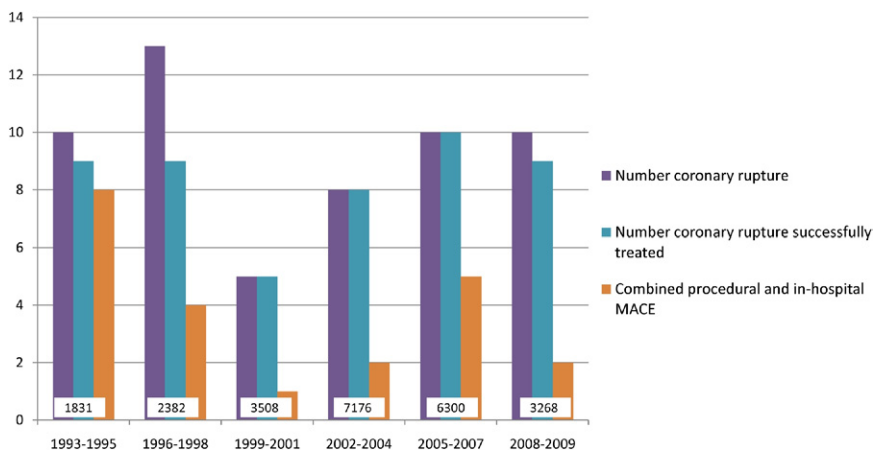

Figure 2. Incidence, Treatment, and Outcomes of Grade III Perforation From 1993 to 2009

Graph showing number of cases of grade III coronary perforation, number of cases of successfully treated, and combined in-hospital and procedural major adverse event rates over each 2- to 3-year period from 1993 to 2009. **Figures in white boxes** represent total number of percutaneous coronary intervention procedures performed within each period. MACE = major adverse cardiac event.

in-hospital mortality rate remained high at 18%, in line with previous reported mortality rates of 7% to 44% in grade III perforation (9–12). Furthermore, the rates of in-hospital MI remained very high at 43%. Based on our experience of the treatment of grade III coronary perforation, we present a proposed treatment flowchart that can be considered in the instance of this adverse event (Fig. 3).

This study also showed that grade III coronary perforation in conjunction with GPI administration was associated with an even greater risk of adverse events. The combined procedural and in-hospital MACE rate in this group was higher than that of the overall group at 90%. In addition, multiple treatment modalities were required in 50% in an attempt to achieve hemostasis with successful treatment of the rupture in 80%. Previous studies have also suggested that the use of GPI may be associated with worse short-term outcomes in patients with coronary perforation and that these agents should be used with caution in high-risk procedures (5).

Study limitations. There are some limitations of this study: 1) it was a retrospective study; 2) the population size was relatively small; 3) angiographic follow-up was not performed in all patients; and 4) it was a descriptive study with no control group, but an attempt to match according to patient or lesion characteristics to such a specific population may be inaccurate and misleading. Previous reports of coronary perforation during PCI have also assessed relatively small numbers of patients, as it is a rare event.

Conclusions

Fortunately, grade III coronary perforation remains a rare complication of coronary intervention, with an incidence that may be rising due to increased complexity of cases in current practice and widespread use of GPI. Predictors of grade II coronary perforation are complex coronary lesions, coronary occlusions, and the use of rotablation and IVUS. An interventional cardiologist must be prepared for this iatrogenic event; all teams should be equipped with the necessary skills and technology required for treatment and should be prepared to react quickly and efficiently in the event of perforation. Despite treatment measures, this

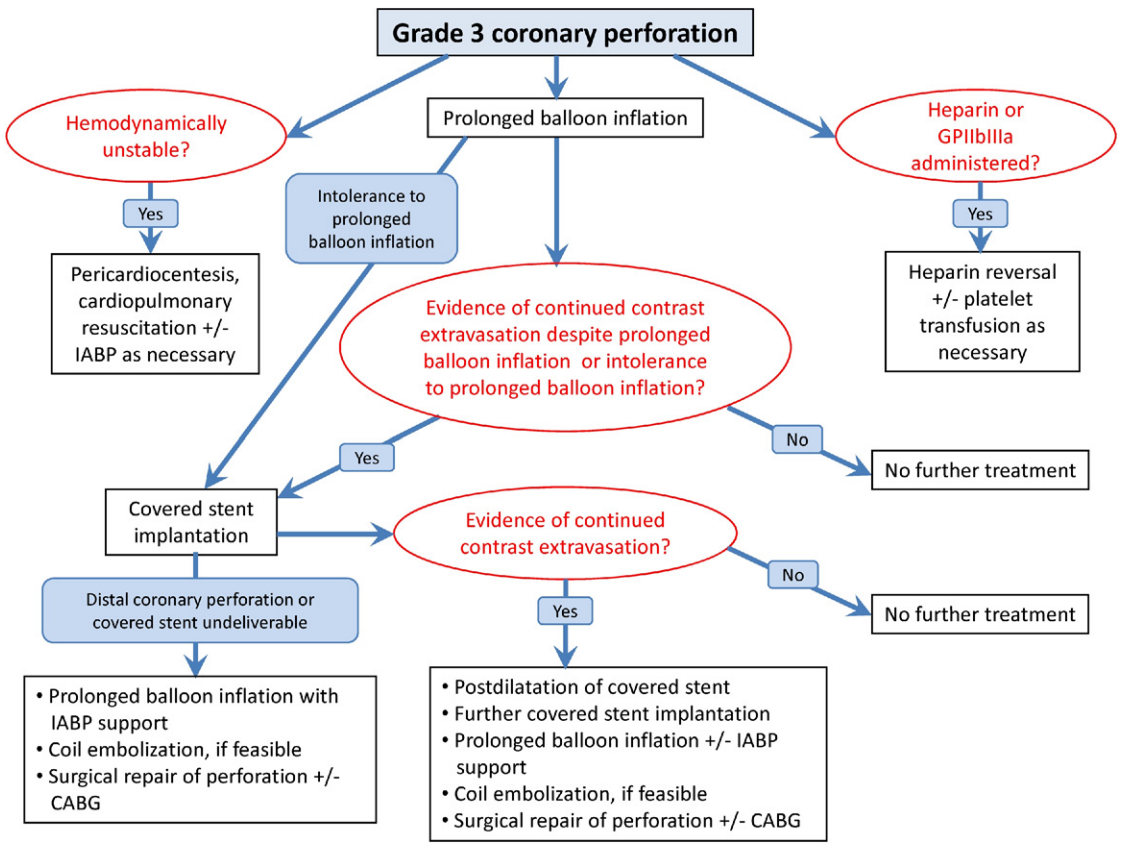

Figure 3. Flowchart for the Treatment of Grade III Coronary Perforation Based on Our Experience

An algorithm for the management of grade III coronary perforation based on our experience of the most successful and appropriate methods of treatment. CABG = coronary artery bypass graft; GPIIbIIIa = glycoprotein IIb/IIIa inhibitors; IABP = intra-aortic balloon pump.

complication is still associated with poor adverse outcomes and there remains a need for improved technology to treat this dreaded complication.

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Key Words: coronary intervention ■ coronary perforation ■ management ■ percutaneous.

Coronary Perforation: An Inconvenient Complication

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EDITORIAL COMMENT

Coronary Perforation

An Inconvenient Complication*

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Coronary perforation is one of the most challenging and feared complications of percutaneous coronary intervention (PCI). The angiographic images of a large perforation are spectacular and are often debated during complication case review sessions at interventional cardiology meetings. Therefore, even if most interventional cardiologists have not been exposed personally, they are perfectly aware of this rare complication. Coronary perforation has been classified by Ellis et al. (1) in 1994, type III being the most severe form of perforation. It was originally defined as an active extravasation through a large breach (at least 1 mm) in the integrity of the adventitia of an epicardial artery in the pericardial space or in a cardiac chamber. This complication is rare (0.1% to 3.0%), often requires pericardiocentesis for tamponade, as well as combination of interventional techniques to seal the perforation, and occasionally surgical repair (2). The morbidity and mortality of large perforations is known to be high.

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In this issue of *JACC: Cardiovascular Interventions,* Al-Lamee et al. (3) reviewed the incidence, predictors, management, and clinical outcome of type III perforations during PCI in a large tertiary referral center. Over a 16-year period, this complication was noted in 56 of 24,465 consecutive patients undergoing PCI, thus giving a reported incidence of 0.23%.

A review of the literature reveals abundant data on perforation during PCI (1,2). The findings of the current observation are in accordance with common knowledge and provide some new, added value. Albeit rare, the incidence of perforation has not decreased over time, probably reflecting the increased complexity of PCI practice. This complexity is illustrated by the independent predictors of perforation seen in the present study: complex coronary anatomy (type B2 and C lesions), chronic total occlusion, rotational atherectomy, and intravascular ultrasound use. These predictors have all been identified previously (2,4). The highest risk was related to intravascular ultrasound use, reflecting PCI in complex lesion subsets, according to the investigators. They also speculate further in this context, on the role of higher balloon pressures or larger balloon sizes to optimize the angiographic result according to pre-defined intravascular ultrasound criteria. This is perfectly in line with the most common cause of perforation in the present study: compliant or noncompliant balloons and the stent-balloon delivery system. Interestingly, the second most frequent cause of perforation in the present study was guidewire exit (10 patients). Guidewire exit perforation usually causes "relatively small leaks" in the distal coronary bed or a side branch and is nowadays mostly successfully treated by coiling or particle embolization technology. It is therefore unclear why guidewire exit leads so frequently to type III perforation in this cohort.

Concomitant glycoprotein IIb/IIIa antagonist use increased dramatically the complication rate and decreased, despite applying different treatment modalities, hemostasis success. Even if the number of patients is too small to draw any firm conclusions, it makes common sense to pay particular attention to perforations in these patients, treating them more aggressively and reversing any antiplatelet activity if possible. It is known that guidewire exit and glycoprotein IIb/IIIa antagonist do not sit well with each other. Although enough information is not available in the present article, if frequently associated, this may possibly explain the high prevalence of guidewire exit as a cause of type III perforation in this study.

The treatment of a type III perforation remains a challenge for every catheterization laboratory team. It integrates continuous assessment of the hemodynamic status and the need for appropriate treatment of tamponade if needed, as well as an immediate attempt to seal the perforation. Both conditions are closely interrelated and failure to treat either will affect the immediate prognosis of the patient. Placement of a pericardial drain in the emergency setting is difficult particularly if tamponade is caused by the acute accumulation of a relatively modest amount of blood. Echocardiographic and fluoroscopic guidance are of critical importance in this situation. Any additional complication due to inadvertent myocardial puncture will further compromise the patient's outcome. The investigators observe currently that hemostasis often requires multiple treatment modalities: prolonged balloon inflation, implantation of a standard or covered stent, coil embolization, and/or surgical repair. Even if precise data are lacking, it seems that most patients could be treated by a combination of prolonged balloon inflation and implantation of a covered stent. This is important new information that is highlighted by a dramatic increase in procedural success and a clear reduction

*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

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in in-hospital morbidity and mortality during this 16-year observation period. Without doubt, covered stents (84.6% in the present series) have the highest potential to seal large perforations. They are probably responsible in large part for the increased success rate in managing large perforation. There are, however, clear downsides. First, covered stents are bulky and proper stent delivery may be difficult or impossible. A helpful technique not described in the current article is the "double guiding catheter" technique. This consists of prolonged or intermittent (in patients with extensive ischemia) balloon inflation through the initial guiding catheter while preparing femoral access for an 8-F guiding approach. Upon balloon deflation through the initial guiding catheter, a guidewire is advanced through the second guiding catheter distal to the site of perforation to deliver the covered stent. The advantage of the technique is that temporary sealing of the perforation can occur while simultaneously preparing better support for stent delivery. The paper by Al-Lamee et al. (3) yields another important message and a second drawback of polytetrafluoroethylene-covered stents, in particular. The incidence of definitive stent thrombosis was 8.6% and only occurred after placement of polytetrafluoroethylene-covered stents. This is higher than with metallic noncovered stents suggesting a higher thrombogenicity of this platform. The role of possible suboptimal stent expansion of this double-layer metallic device is unknown. Furthermore, the type of long-term antiplatelet strategy may also have been important. Prasugrel, because of its lack of intrinsic resistance, might be considered as the thienopyridine of choice, although there are no data available.

The present article provides an algorithm for managing type III perforation. It is straightforward and comprehensive. The only uncertainty concerns the role of heparin reversal with protamine sulfate. Opinions clearly diverge on this subject. On the one hand, it may assist in sealing a perforation, but on the other, bleeding may persist and prolonged balloon inflation and simultaneous heparin reversal may lead to proximal vessel thrombosis. It is our belief that no universal guidance can be given based on the data available. Decisions should be pragmatic and individualized dependent on the hemodynamic status of the patient, concomitant IIb/III antagonist use, activated clotting time, and the duration of prolonged balloon inflation.

One particular form of type III perforation is termed *cavity spilling* (cardiac chamber, coronary sinus). Apparently, this complication was not encountered in this observational study. In general, management should be less aggressive because of the lack of associated acute hemodynamic compromise.

A large type III perforation is an inconvenient complication. In-hospital mortality was high at 14.8% and the rate of myocardial infarction was 42.9%. This proportion increased further during follow-up. Even in the experienced hands of these operators, the reported results are not better than what can be found in literature, indicating a need for better therapeutic devices.

In conclusion, this article has drawn our attention again on a dramatic but rare complication of PCI: type III perforation. The key messages are as follows. 1) Concomitant IIb/IIIa antagonist use increases the complications rate substantially and diminishes the ability to seal a perforation successfully. Its effect should be reverted if possible. 2) Polytetrafluoroethylene-covered stents have the greatest potential to seal type III perforations and probably explain increasing procedural success over the period observed. However, these potentially "life-saving" devices are definitely more thrombogenic. The investigators' conclusion is apposite: "This complication is still associated with poor adverse outcomes and there remains a need for improved technology in order to treat this dreaded complication."

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Key Words: coronary intervention ■ coronary perforation ■ management ■ percutaneous.

PARMA 3/09/2010

HOSPITAL: OSPEDALE MAGGIORE DI PARMA

DEPT.:VASCULAR SURGERY

PROCEDURE : INTVL. RADIOLOGY

OPERATORS: DR.LARINI, DRA MARCATO (RADIOLOGIST)

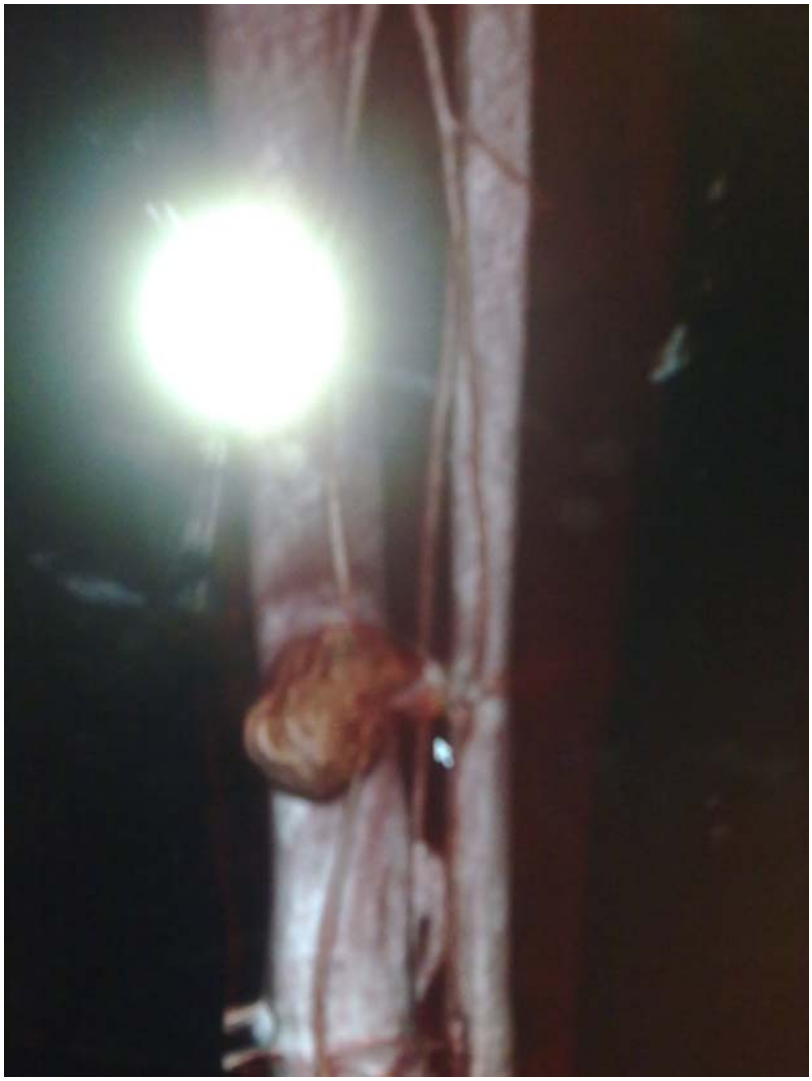
30 YEARS PATIENT WITH LARGE PSEUDO ANEURISM OF POSTEROR TIBIAL THIRD MEDIUM (BASE OF IMPLANTATION 5 MM) CAUSED BY AN EXTRANEAL TOOL IN A JOB ACCIDENT.

PROCEDURE IN FLOW FAVOUR POSITIONING THE STENT-GRAFT INSITU 3,0 PER 19 MM LOT 20100874

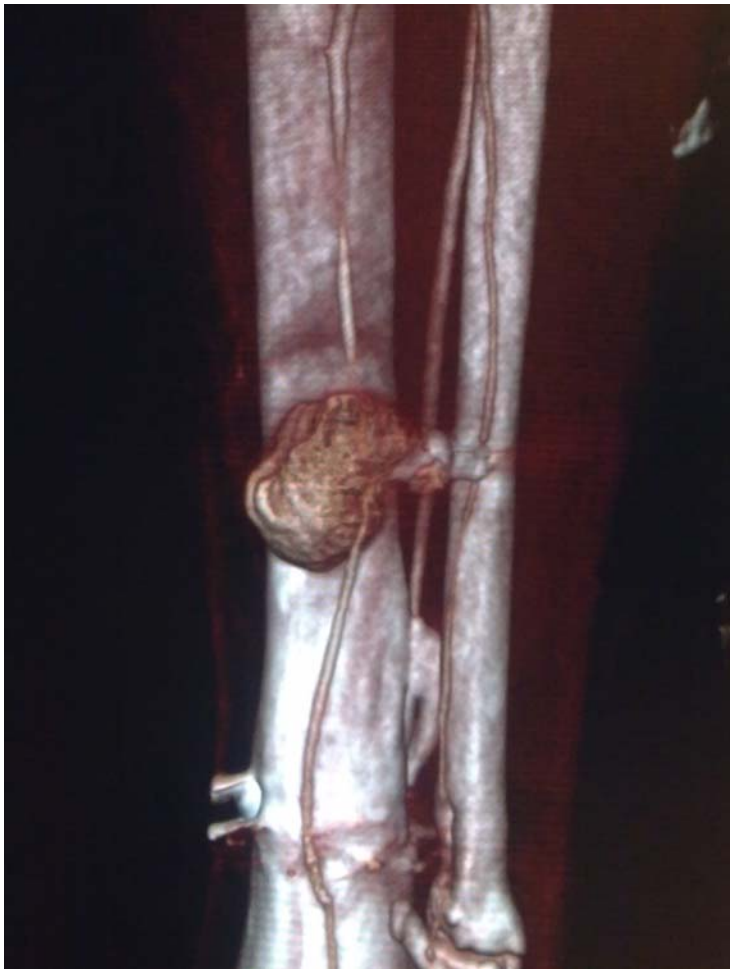
FINAL ANGIOGRAPHY : TOTAL EXCLUSION OF THE SAC

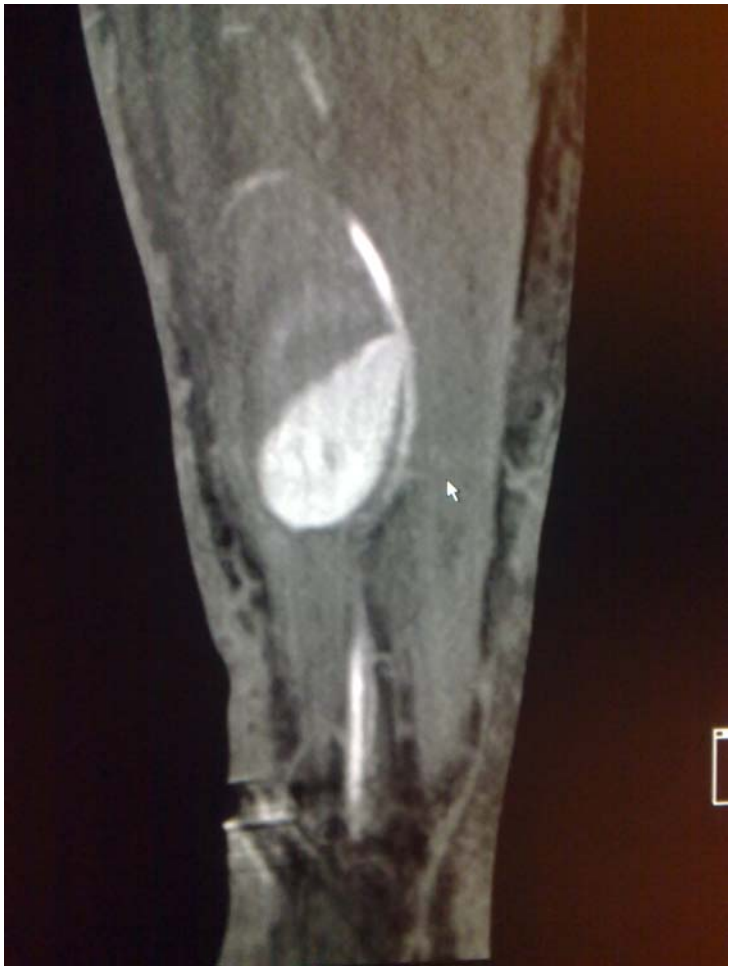
DAY AFTER : ECODOPPLER WITH GREAT FLOWS AND PATENCY .

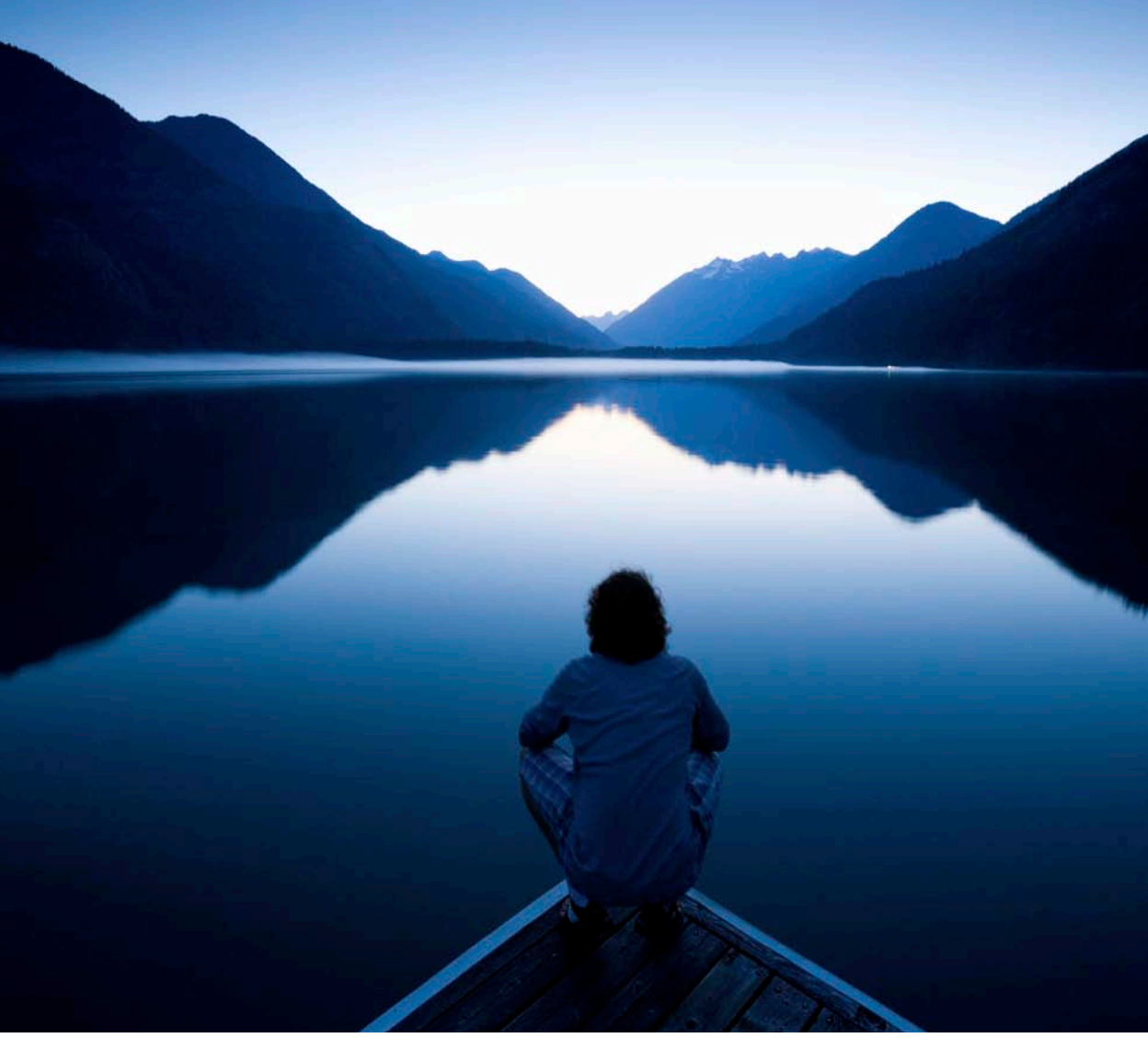
FOLLOW-UP IN ONE MONTH.



Case Report - Insitu Stent-Graft







Get peace of mind...

The Direct-Stent® Stent Graft

InSitu Technologies® Inc.
Extending Life and Improving Health™

With thousands distributed worldwide, get peace of mind knowing you have a flexible, trackable and safe device on hand for those emergency and high risk procedures.

Aneurysm?
Rupture?
Dissection?
Fistula?

You are Covered.

Indications

When emergency situations arise, surgical backup is not always an option. Get peace of mind, equip your cath lab with the Direct-Stent® Stent Graft today.

Indication For Use:

The Direct-Stent® Stent Graft Rx is indicated for use in the treatment of free perforations, defined as free contrast extravasation into the pericardium, in native coronary vessels or saphenous vein bypass grafts greater than or equal to 2.25mm in diameter.

The Direct-Stent® Stent Graft has also been used to treat the following conditions:

Ruptures
Dissections
Fistulae
Aneurysms
Saphenous Vein Grafts

Case 1

ENDOVASCULAR TREATMENT OF CORONARY FISTULAS

Hemodinamics Department, Hospital Cardiomedica, Lima, Peru.

Definition

A coronary fistula is an abnormality -congenital or acquired- in which blood is shunted into a vessel or other structure deviating its flow from the myocardial artery network.

Case

We report the successful percutaneous treatment of two Left Anterior Descending (LAD) coronary artery Fistulas by means of STENT GRAFT implantation.

In July 2009, a 62 year old female with a history of hypertension, non-smoker was admitted for the treatment of two fistulas in the Left Anterior Descending (LAD) coronary artery. The fistulas caused the blood to travel from the LAD to the Pulmonary artery and the Inferior Vena Cava. The patient was treated with a 3.5x19 coronary Stent Graft (Direct-Stent Stent Graft, InSitu Technologies Inc , IGH, Minnesota, USA) successfully covering the fistulas. 6 month follow up reports no-mace.

Implant performed in Lima, Peru in July 2009.

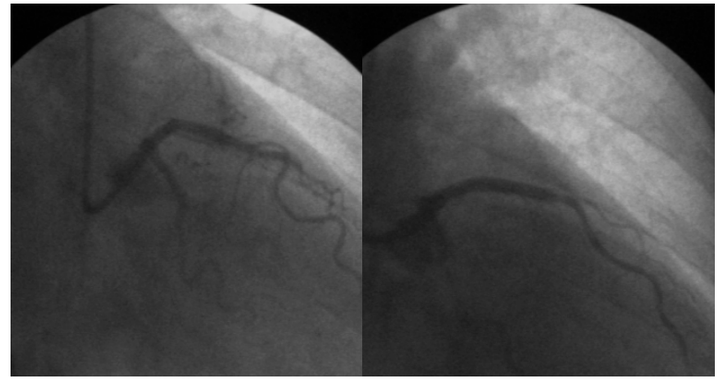


Figure 1. Figure 2.

Figure 1: Selected coronary angiography shows fistulas on the Left Anterior Descending (LAD) coronary artery before Stent Graft implant.
Figure 2: After the procedure, clearly showing the exclusion of the fistulas.

Case 2

STENT GRAFTS IN CORONARY INTERVENTIONS

Dr. Bogart Parra, Caracas, Venezuela, Solaci, July 2008.

Numerous academic reports have demonstrated the feasibility, safety and efficacy of stent grafts for the treatment of coronary perforations, coronary aneurysms, complex lesions (with ulcer or thrombus), lesions on venous grafts and also, in a more debatable case in intra-stent restenosis.

The first generation of grafts were stents covered with vein, followed with the current stents covered with biocompatible polymer membranes. The design used so far in my practice is the InSitu coronary Stent Graft which consists of an ultra thin ePTFE layer, biocompatible on a stainless steel 316L stent. The diameters for this stent start at 2.5mm and go up to 6.0mm, and the available lengths are 10, 13, 16, 19, 23 and 26mm, pre-mounted on a semi-compliant balloon. The evaluation in Venezuela of the feasibility and safety of this stent's implantation as well as its efficacy has been initiated.

An analysis of the predictive occlusion factors for the Stent Graft showed that the lesion's length, the vessel diameter, the minimum luminal diameter post Stent Graft implantation and the amount of pressure administered to the balloon to expand the stent were factors that played an important role as statistically significant in the prediction of occlusion.

A joint registry was made by the Heart Center's Cardiology and Angiology department, Siegburg and the Cardiovascular Research Foundation, New York (1997). It is important to emphasize some angiographic criteria suggested by the authors to implant a Stent Graft: vessels with a diameter >3.0mm and focal coronary aneurysms with more than 50% above the reference diameter. The intra-hospital results report 3 sub-optimal cases (4.5%) due to stent dislodgement, in one of the instances the stent was removed with a "microsnare" and in the other 2 cases the stent was able to be implanted in a site proximal to the lesion. Also the occlusion of secondary branches was reported for 13 patients (18.1%) causing 9 AMI (13%), 2 AMI Q and 7 AMI NO Q.

Long term follow up (159 +/- 49 days) yielded four cases of acute thrombosis (5.7%) between 7 and 70 days after implantation with three AMI Q and one death. Angiographic follow up made in 80% of the cases showed a restenosis rate of 31.6% with 26.8% being subject for TVR. Most of the restenosis occurred at the side of the stent (23.8% vs 8.8% in the center of the stent, $P<0.001$). Intravascular ultrasound follow up found significant restenosis at the end of the graft in comparison with the center ($P<0.001$).

Stephan Baldus and collaborators reported one of the first significant registries on the treatment of de novo lesions of coronary venous grafts with the JO stent, executed in conjunction with three centers in Germany. They reported on the intra-hospital results as well as distant follow up of discharged patients for 190 patients with 127 lesions in venous grafts with a media of 11+/- 5 years (from 1-21 years). They compared this registry in a retrospective study and the authors concluded that there was a lower rate of complications during the procedures and a lower rate of sub-acute thrombosis, mortality and intra-stent restenosis during the follow up.

The authors' preliminary conclusion was that the use of the PTFE JO stent compared with standard stents (JO stent flex) in the treatment of venous coronary grafts was associated with a higher rate of complications and major events during intra-hospital observation and during the follow up with a similar angiographic restenosis.

Embolization and/or dislodgement of the stent from the balloon is common, perhaps due to the inadequate "manual crimping", considering that the polymer layer in the "sandwich" produces a rigid system, rough and thick, provoking a challenging implantation from a technical point of view when compared to standard stents. InSitu Technologies' Direct-Stent Stent Graft which is pre-mounted and commercially available could most likely diminish these challenges and complications. Other frequent complications are the occlusion of the side branches and the possible acute thrombosis of the stent. The first element is an important limitation in the indication of the Stent Graft for lesions in the native coronary arteries. An explanation for the higher incidence of sub-acute thrombosis of the stent could be the late endothelialization of the PTFE, as it has been described in animal studies.

We believe that for coronary perforations the indication of the Stent Graft is irrefutable because when compared with surgery and venous grafts the PTFE Stent Graft represents a less invasive procedure, with more efficient and acceptable results. For aneurysms and/or pseudo-aneurysms the Stent Graft successfully "seals" the lesion and offers a satisfactory alternative to surgery. However, for arteries whose diameters are equal to or less than 3.0mm as well as long lesions (>15mm) the rate of complication and MACE at 6 months is high and a balance risk/benefit should be made.

In conclusion, we consider that the implantation of the Stent Graft is a feasible and safe with high rates of success for the initial procedure. For native coronary arteries it has the limitation related to the occlusion of branches and subsequent AMI. It also has a higher rate of late sub-acute thrombosis that could be present in the first or second month. The most important predictive factors for the thrombus formation are the lesion's length (>20mm), reference diameters equal to or less than 3.0mm, a reduced lumen and a deployment pressure of the stent of <16 ATM.

To avoid sub-acute thrombosis we suggest the implants of Stent Graft to be made in arteries with a higher diameter, guided by intravascular ultrasound, high inflation pressure, prolonged inflations and dual drug therapy (Clopidogrel) and Aspirin for no less than 6 months post-procedure. The usefulness of the Stent Graft to prevent intra stent restenosis has not been studied. Its indication in aneurysms (Figure 3 and 4), pseudo-aneurysms and fistulae is controversial. Its indication is irrefutable and is the best choice for coronary perforations.

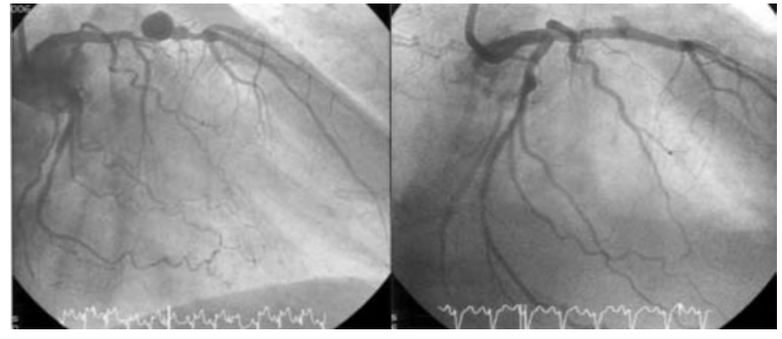


Figure 3.

Figure 4.

Figure 3. Angiography of the Left Coronary Artery showing an aneurysm at the proximal segment of the LAD (10 mm).

Figure 4. Angiography after the implant of an InSitu Direct-Stent® Stent Graft 3.0 x 26 mm sealing the aneurysm.

Features

A covered stent based on our proven platform.

This patented and dependable platform ensures:

- Flexibility and effortless navigation
- High radial strength
- Optimal stent surface area
- Some of the thinnest struts in the world

A multi-layer design and ePTFE polymer to prevent thrombus formation and minimize emboli shedding.

A micro-porous ePTFE polymer to achieve enhanced hemocompatibility and promote endothelialization.

A proprietary crimping technology to ensure maximum deliverability of the Stent Graft.

Increased flexibility and accessibility to tortuous anatomy.

The Direct-Stent®
Stent Graft Rx

Technical Data

One of the lowest crossing profiles of a Graft Stent in the world, beginning at **1.2mm**

Material:	Stainless Steel Alloy, ePTFE Polymer
Shaft Size (Proximal-Distal):	2.0 – 2.7F
Wall Thickness:	0.21mm
Balloon Material:	Semi-Compliant
Premounted Profile:	1.2 – 1.6mm
Optimal Deployment Pressure:	8 – 12 ATM
Rated Burst Pressure:	12 – 16 ATM
Recommended Guidewire:	0.014"
Minimum Guiding Catheter:	6F (2.25-4.5mm), 7F (5.0-6.0mm)
Working Length:	137 – 140cm
Stent Expansion Range:	2.25 – 6.0mm
Stent Lengths:	10 - 38mm

Ordering Info

Coronary (Rx) Sizes

Diameter (mm)	Length (mm)	Catalog Number
2.25	10	6422510
	13	6422513
	16	6422516
	19	6422519
	23	6422523
	26	6422526
	30	6422530
2.5	10	642510
	13	642513
	16	642516
	19	642519
	23	642523
	26	642526
	30	642530
	34	642534
	38	642538
2.75	10	6427510
	13	6427513
	16	6427516
	19	6427519
	23	6427523
	26	6427526
	30	6427530
	34	6427534
	38	6427538
3	10	643010
	13	643013
	16	643016
	19	643019
	23	643023
	26	643026
	30	643030
	34	643034
	38	643038
3.5	10	643510
	13	643513
	16	643516
	19	643519
	23	643523
	26	643526
	30	643530
	34	643534
	38	643538
4	10	644010
	13	644013
	16	644016
	19	644019
	23	644023
	26	644026
	30	644030
	34	644034
	38	644038
4.5	15	644515
	19	644519
	23	644523
	26	644526
	30	644530
	34	644534
	38	644538
5	17	645017
	20	645020
	27	645027
	34	645034
	40	645040
6	17	646017
	20	646020
	27	646027
	34	646034
	37	646037

Find out more...

To speak with an InSitu team member about the Stent Graft or another product from our portfolio of Cardiology or Vascular devices...

contact sales@insitu-tech.com
or visit www.insitu-tech.com

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We have you covered.

Not only do we offer the one of a kind Stent Graft, we have a full portfolio of Cardiology & Vascular devices.