

Initial Clinical Experience of Intracoronary Coil (Gianturco-Roubin) Stents for Management of Acute Dissection After Balloon Angioplasty

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Dissections after percutaneous transluminal coronary angioplasty (PTCA) are risk factors for acute or subacute vessel closures. Intracoronary stenting was developed to avoid these complications by pressing the intimal and medial flaps against the vessel wall, thus reducing the risk of acute closure from thrombus formation. Thirty three coil (Gianturco-Roubin) stents were implanted into the coronary arteries of 32 patients with dissections after PTCA during the period of March 1993 to December 1993. The indications for stent implantation were acute closure in 6 (18.8%), threatened closure in 6 (18.8%) and suboptimal result in 20 (62.4%) patients. Stent insertion were successful in 30 (94%) patients. The diameter stenosis in an immediate angiographic finding after stenting was decreased from 87% to 18% by caliper estimation. Emergency coronary artery bypass graft surgery was required in 1 (3%) patient. A non-Q wave myocardial infarction occurred in 1 (3%) patient. Complications included hematoma of the arterial access site requiring blood transfusion in 4 (12.5%) patients and hemopericardium in 1 (3%) patient. Our initial clinical experience of flexible coil coronary stent imply that stenting is efficacious treatment for acute dissections that are causing acute or threatened closure following angioplasty. The long term follow-up result in all groups of patient who received coronary stents is needed for better evaluation of new devices and prognosis.

Key Words: Dissections, flexible coil stent

Percutaneous transluminal coronary angioplasty (PTCA) is recommended as a first step of standard treatment on selected groups of patient with atherosclerotic coronary artery disease. Although there are continuous improvement of equipment and technical aspects of the procedure, there are several serious

limitations on PTCA. In particular, the incidence of acute complications after PTCA, such as dissection and abrupt closure have been reduced but they remain unpredictable factors (Gruentzig *et al.* 1987; Simpendorfer *et al.* 1987; Mabin *et al.* 1985). The pathological mechanisms that underlie complications are as yet only partially understood. However, together with endothelial damage and thrombosis, it is generally agreed that localized dissection of the arterial wall, intimal flap formation, and elastic recoil of the distended arterial segment play an important role (Meier 1988; Zollikofer *et al.* 1984; Essed *et al.* 1984). Current practice for treating dissections or acute closure usually consists initially of a repeated angioplasty (Hollman *et al.* 1983) or the

Received May 26, 1994

Accepted August 24, 1994

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use of thrombolytic therapy to deal with the thrombotic component of the obstruction (Shofer *et al.* 1982). Prolonged balloon inflation with perfusion catheters often temporarily maintain coronary blood flow while the patient awaits surgery, but they do not constitute definite management (Hinohara *et al.* 1986). Moreover, emergency coronary artery bypass surgery after failed PTCA is associated with an increased mortality and morbidity when compared with elective procedure (Pages *et al.* 1986). Intracoronary stents with various designs have been developed to treat dissections or acute closure after PTCA (Sigwart *et al.* 1987; Serruys *et al.* 1991; Schatz *et al.* 1991). Among them, flexible coil (Gianturco-Roubin) stent is composed of a continuous single strand of surgical grade stainless steel wire with a form of interdigitating loops of cylinder (Roubin *et al.* 1987). We report the initial clinical experience of flexible coil (Gianturco-Roubin) stent in coronary arteries with dissections after PTCA.

MATERIALS AND METHODS

Study patients

Thirty three stents insertion were attempted in 32 patients during the period of March 1993 to December 1993. The indications for stenting were acute closure in 6, threatened closure in 6 and suboptimal result with dissection after PTCA in 20 patients (Fig. 1). Written consent were received from all patients after full explaining the purpose and procedure of stenting.

Definition

Acute closure: occlusion of a vessel with Thrombolysis in Myocardial Infarction trial (TIMI) grade 1 or 0 flow, was based on the angiographic appearance of the vessel immediately before stent insertion (Fig. 2).

Threatened closure: deterioration in angiographic, electrocardiographic, hemodynamic, or clinical indicators after PTCA and required at least three of the following criteria: 1) postangioplasty residual stenosis more than 50

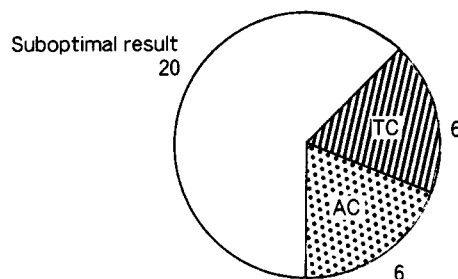


Fig. 1. Indication for flexible coil stent deployment.

AC: Acute closure

TC: Threatened closure

%, 2) significant dissection, 3) TIMI grade 2 distal flow, or 4) clinical evidence of ischemia (typical chest pain or electrocardiographic changes)

Suboptimal result: defined by the following criteria 1) postangioplasty residual stenosis of more than 50%, 2) significant dissection and 3) TIMI grade 3 distal flow

Stenting procedure

The stent is made of monofilamentous stainless steel (0.006 inch diameter) formed into a digitating coil structure and wrapped tightly around a standard, polyethylene compliant balloon dilatation catheter (Fig. 3). This design provides high hoop strength and ensures that stents will not shorten with radial expansion. The expanded diameter of the stent is determined by the diameter of the balloon catheter used and the inflation pressure employed at the time of stent expansion. Stents are supplied in nominal expanded diameters of 2, 2.5, 3, 3.5, 4 mm. The deflated balloon/stent catheter is relatively flexible and can be positioned at the target site by a slightly modified over the wire technique. In general, all large lumen 8F guiding catheters will be suitable for placement of 2.0mm, 2.5mm and 3.0mm stents. Large lumen 9F guiding catheters will be necessary for placement of 3.5mm and 4.0mm stents. If use of 3.5mm or 4.0mm stent is anticipated, the procedure should be started with a 9F guiding catheter (Table 1). Successful use of stent usually requires support of an 0.018 or 0.016

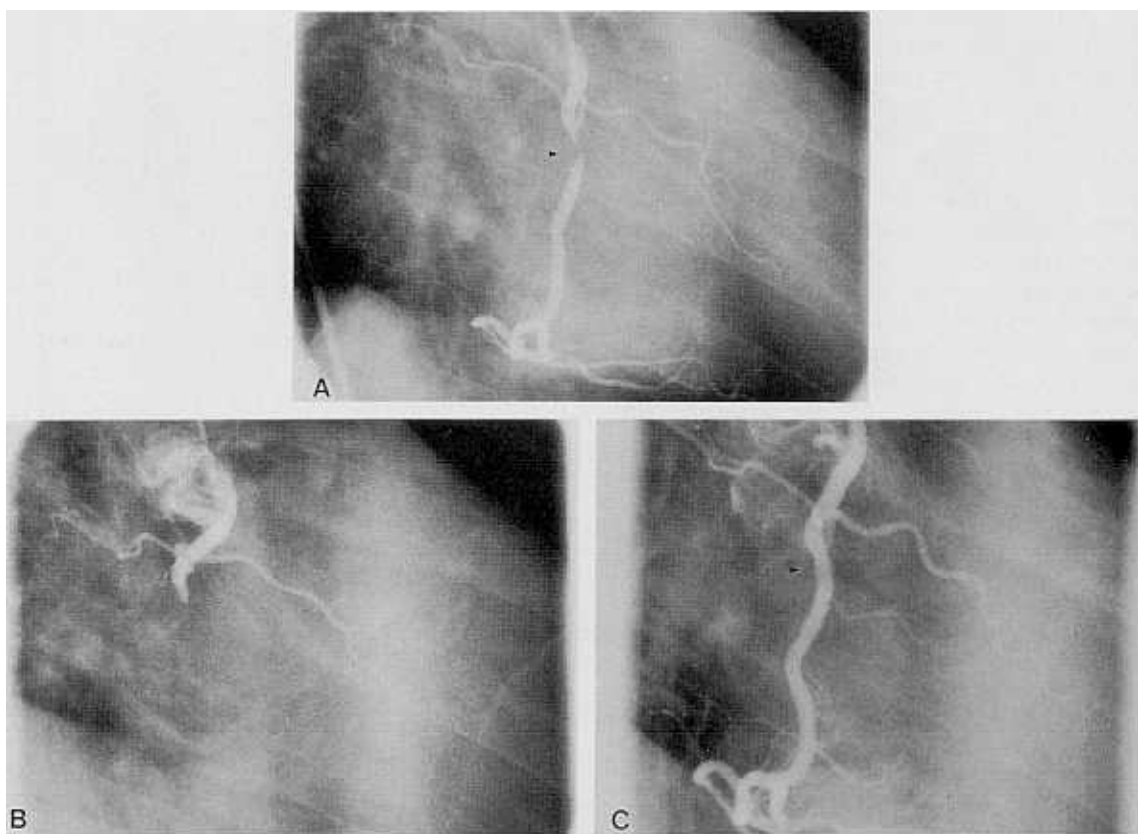


Fig. 2. Example of acute closure after balloon angioplasty.

There was critical narrowing at proximal portion of right coronary artery(A). Abrupt closure after ballooning and TIMI 0 flow were noted(B). TIMI 3 flow was restored and there was no residual stenosis after stenting (C).

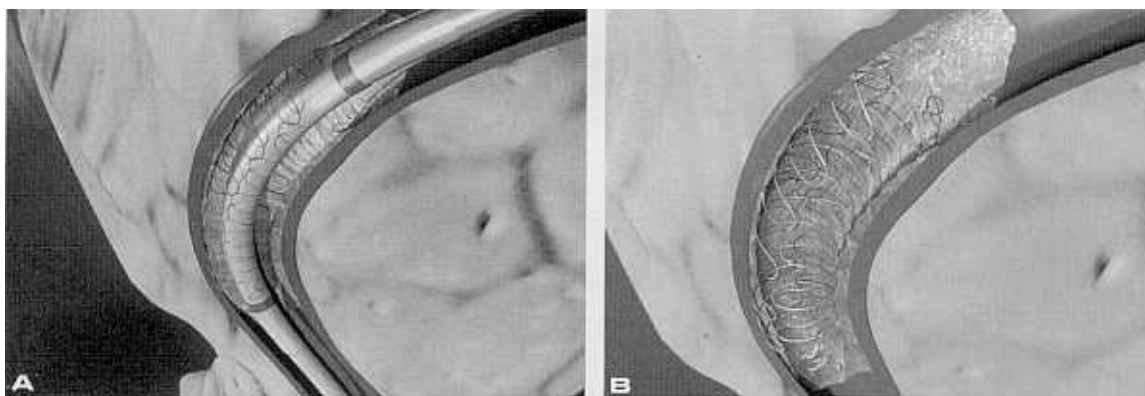


Fig. 3. The stent is made of monofilamentous stainless steel formed into a digitating coil structure(B) and wrapped tightly around a standard, polyethylene balloon catheter(A).

Table 1. Compatibility of Flexible coil stent/balloon sizes and guiding catheters

Guiding catheter required	Stent size (mm)	Balloon size(mm) (at 6 atm)
8F and standard		
Tuohy-Borst	2.0	2.5
Y-adapter	2.5	3.0
	3.0	3.5
9F and large Cook		
Tuohy-Borst	3.5	4.0
Y-adapter	4.0	4.5

inch guide wire. A standard 0.018 inch guide wire with a soft, flexible tip is recommended to improve tracking and catheter support. Prior to starting the case, if stenting is anticipated, an 0.018 inch guide wire compatible balloon system is preferred. To expand the stent, the balloon is inflated to the stent expansion pressure indicated on product label (usually 5 to 8 atm) for 30 to 60 seconds. After complete balloon deflation was ensured, the balloon catheter was slowly advanced approximately 1 mm to disengage the wings of the balloon from the stent, then withdrawn leaving the expanded stent in place. Angiography was repeated and further inflations were performed inside the stent if necessary to produce an optimal lumen result. At the end of the procedure, catheters were removed and sheaths were left in place. The patient was taken to the coronary care unit and electro-cardiographic monitoring and blood samples for creatine kinase and lactic dehydrogenase isoenzyme estimations were performed. The arterial sheath may be removed at the same day of the stenting procedure or at the next morning. In either case, continuing good antiplatelet therapy is essential. If the arterial sheath is to be removed at the same day, heparin infusion was discontinued after the stenting procedure. Activated clotting time (ACT) was measured 1 hour after discontinuing heparin, then every 30 to 60 minutes thereafter. Arterial sheath was removed when ACT is 150 seconds or less. If the arterial sheath is to be removed at the next day, heparin infusion was started at 1000 units/hour

and adjust infusion rate to maintain PTT between 45 and 80 seconds. Heparin infusion was discontinued the next morning and ACT was measured every 60 minutes. The arterial sheath was removed when ACT is 150 seconds or less. A heparin infusion was restarted one hour after sheath removal at approximately 1000 units/hour with monitoring of PTT. Dextran infusion was continued at least 24 hours after the procedure. To minimize groin bleeding, the protocol of gradual ambulation has been found effective (George *et al.* 1993). 1) day 1: complete bed rest, keeping leg with puncture site immobile 2) day 2: patient may move and sit up in bed 3) day 3: begin to ambulate cautiously. Titration with coumadin was initiated. Calcium channel blocker, dipyridamole and coumadine were continued for 2 months after discharge to maintain a target prothrombin time between 17 and 22 seconds. Aspirin was continued indefinitely.

RESULTS

Study patients

Stent was attempted in 32 patients. There were 27 men and 5 women. The mean age was 54.6 ± 10.4 years (range: 33-71). Single-vessel disease was present in 16 (50%), double-vessel disease in 8 (25%), and triple-vessel disease in 8 (25%) patients. The mean left ventricular ejection fraction was $63.5 \pm 11.9\%$ (range: 40-85) (Table 2). The indications for stent implantation were acute closure in 6, threatened closure in 6 and suboptimal result in 20 patients. A single stent was implanted in 31 patients. In one patient, two stents were implanted in right coronary and left circumflex artery. A stent was placed in the left anterior descending artery in 13, in the right coronary artery in 13, and in the left circumflex artery in 7 patients. Among the stents placed, 2.5 mm in diameter was inserted in 3 %, 3 mm in 69.7% and 3.5 mm in 27.3% of patients. The data about the distribution of the diameters of stents used and the vessels in which they were implanted are summarized in Table 3. Stenting resulted in an angiographic improvement in the diameter stenosis from 87.

Table 2. Demographics of the study patients

Sex(M/F)	27/5
Age(mean, years)	54.6(33-71)
Clinical diagnosis	
Stable angina	12
Unstable angina	9
Old MI with stable angina	7
Acute MI	4
Single-vessel disease	16(50%)
Multi-vessel disease	16(50%)
Ejection fraction(%)	63.5(40-85)

MI: Myocardial infarction

Table 3. Distribution of the diameters of stent used and the vessels

Vessel	Stent diameter and length(mm)				
	2.5/20 (n=1)	3.0/12 (n=3)	3.0/2.0 (n=20)	3.5/12 (n=3)	3.5/20 (n=6)
LAD	1	1	7	1	3
RCA		2	8	2	1
LCX			5		2

LAD: Left anterior descending coronary artery

RCA: Right coronary artery

LCX: Left circumflex coronary artery

0±9.8% before stenting to 18.3±10.9% after stenting by caliper estimation. The deployment of the stents were failed in two patients. The reasons for failure to deploy the stents were related to either the inability to cross the lesion with the stent/balloon catheter due to inadequate guide wire and guiding catheter support or to anatomy-related factors.

Complications

There was no in-hospital mortality. A non-Q wave myocardial infarction occurred in 1 (3%) patient. One of two patients who was failed stent deployment underwent emergency bypass graft surgery. There was no subacute thrombosis of stent. Other complications included blood loss requiring transfusion and

Table 4. Complications

	Patients(no)
Non-Q wave MI	1
Emergency CABG	1
Arterial puncture site hematoma	4
Hemopericardium	1

CABG: Coronary artery bypass graft, MI: Myocardial infarction

hemopericardium. There were 4 patients with femoral access site hematoma requiring blood transfusion in whom femoral arterial sheaths were removed at the next day of stenting procedure (Table 4). Hemopericardium necessitating the drainage occurred in 1 patient probably bleeding from the dissection at bifurcation site after angioplasty which was aggravated with anticoagulation after stenting.

DISCUSSION

Despite major improvements in equipment and operator skill, restenosis and acute vessel closure remain the main limitations of PTCA (Gruentzig *et al.* 1987; Simpendorfer *et al.* 1987; Mabin *et al.* 1985). Especially, acute vessel closure and resultant myocardial infarction or the need for emergency coronary artery bypass graft surgery remain significant problem in clinical practice. Coronary dissection after PTCA is regarded as a major underlying mechanism in acute vessel closure. Current practice for treating dissection and acute occlusion usually consists initially of a repeated angioplasty holding the dissection flap against the vessel wall (Hollman *et al.* 1983). Prolonged balloon inflation with autoperfusion catheter often temporarily maintain coronary flow while the patient awaits surgery (Hinohara *et al.* 1986), but they can not constitute definite management. When these measures are insufficient to maintain a stable luminal patency, emergency bypass surgery is the only treatment recommended for ongoing ischemia. Emergency coronary bypass surgery

after failed PTCA is associated with an increased mortality and morbidity when compared with elective procedure (deFeyter *et al.* 1991; Reul *et al.* 1984; Cowley *et al.* 1984; Golding *et al.* 1986; Talley *et al.* 1990). Intracoronary stents with various designs have been developed to treat dissections or acute closure after PTCA (Sigwart *et al.* 1987; Serruys *et al.* 1991; Schatz *et al.* 1991). The development of intravascular stents can be traced to Charles Dotter who introduced the concept of percutaneous intravascular stenting with the development of the transluminal coil spring end-arterial tube grafting in 1969, and nitinol coil in 1983. Foley *et al.* (1992), compared the efficacy between perfusion balloon and intracoronary stents after failed PTCA (residual stenosis more than 50%, the length of dissection longer than the lesion length, TIMI 0-2 flow, or residual stenosis more than 70% following PTCA with an appropriate sized balloon) and reported that prolonged inflation with the perfusion balloon had a relatively low success rate in the setting of failed PTCA and stent implantation had a high immediate success in this difficult setting. Several investigators demonstrated the efficacy of balloon-expandable Palmaz-Schatz stent and self-expanding Medivent stent in bail-out situation. Sigwart *et al.* (1988), reported 11 patients who received emergency implantation of self-expanding wall stent in whom the only complication was non-Q wave myocardial infarction in two patients. However, DeFeyter *et al.* (1990), reported a higher rate of death (7%), Q wave myocardial infarction (10%), non-Q wave myocardial infarction (10%), and emergency or elective coronary artery bypass surgery (60%) in 15 patients treated with same device. Haude *et al.* (1991), examined 15 patients who received the balloon-expandable Palmaz-Schatz stent for failed PTCA caused by dissections associated with ischemia and reported a major complication rate of 27%. Hermann and colleagues (1992) reported the results of emergent use of Palmaz-Schatz stent after failed PTCA and suggested that emergency stenting might be a useful and effective treatment for failed angioplasty with high initial success rate. However, the substantial portion of patients had sub-acute thrombosis of stents, careful anti-coagu-

lation and follow-up would be mandatory in patients who receive stents on an emergency basis, particularly those with previous acute occlusion. Kiemeneij *et al.* (1993) reported the similar finding. In those patients who had small arterial diameter, angulated lesion, proximal tortuosity and large side branch in the segment to be stented, Palmaz-Schatz stent would not be suitable. Bar *et al.* (1993) compared the efficacy and safety of flexible coil stent and Palmaz-Schatz stent in 678 patients and demonstrated that flexible coil stent was generally selected for more tortuous and smaller vessels than Palmaz-Schatz stent without differences in incidence of stent closure and major cardiac events. The flexible coil (Gianturco-Roubin) stent is made of monofilamentous stainless steel (0.006 inch diameter) formed into a interdigitating coil structure and wrapped tightly around a standard, deflated balloon dilatation catheter. This Flex stent has been under laboratory and clinical investigation since 1985 and approved commercially as a device to treat acute or threatened vessel closure by the Food and Drug Administration at United States. The characteristic shape of this stent, a cylinder of interdigitating loop, provides high hoop strength and ensures that stents will not shorten with radial expansion. George *et al.* (1993) reported the early multi-center experience of coronary stenting with flexible coil stent and demonstrated its usefulness as an adjunct to coronary angioplasty to prevent or minimize complications associated with dissections with 95.4% of procedural success rate. Iyer *et al.* (1992), reported the outcome of flexible coil stent implantation in 30 patients with extensive coronary artery dissections associated with acute (15 patients) or threatened closure (15 patients). Although restenosis (60%) is common in patients with extensive dissections and use of stents less than 2.5mm in diameter, extensive coronary artery dissections can be effectively stabilized using multiple stents. The procedural success rate, incidence of emergency bypass surgery and myocardial infarction observed in this study compares favorably with that reported previously. The stent could not be placed in two patients in whom the procedure was attempted. The rea-

sons of failure to deploy stents were related to various factors, including operator inexperience, complex anatomy and inadequate guiding catheter support (George *et al.* 1993). Four patients in our series required transfusion after the stenting due to the bleeding complications involved the femoral artery puncture site. All of the femoral bleeding complications occurred in these patients whose femoral sheaths were removed at next day of stenting. Agrawal *et al.* (1992) analyzed clinical and procedural variables as predictors of vascular complications in 288 patients treated with flexible coil stents. Blood transfusion was required in 21%, arteriovenous fistula was present in 5% and pseudoaneurysm was present in 9% with especially increased risks in females and the elderly. Hemorrhagic problems may be further reduced in the future through the use of same-day femoral sheath removal, better femoral puncture closure techniques and the use of less thrombogenic stents that will facilitate less aggressive anticoagulation.

Hemopericardium necessitating the drainage occurred in one patient bleeding from the dissection site at bifurcation after angioplasty which was aggravated with anticoagulation after stenting. Thrombosis of the stented artery did not occur in our series of patients. However, several investigators reported the variable incidence of stent thrombosis as a major contributor to adverse outcome. Triana *et al.* (1992) reported a stent thrombosis rate of 8.7% which accounted for 17% of deaths, 23 % of coronary artery bypass surgery and 57% of myocardial infarction in 493 patients stented for acute or threatened closure with flexible coil stents. Agrawal *et al.* (1992) reported 7.6% of stent thrombosis rate in 288 patients stented for various indications (restenosis, acute or threatened closure) and demonstrated that the stent thrombosis remained the major cause of ischemic complications following coronary stenting and was increased in patients with small stents and incomplete coverage of the dissection. Although initial angiographic and clinical results are favorable, restenosis is observed in significant proportion of patients. George *et al.* (1993) reported 39% of restenosis rate which was not influenced by the diameter of the stent used

or by the implantation of multiple stents. Stauffer *et al.* (1992) compared the restenosis between coronary artery stenting and prolonged balloon inflation for acute closure after PTCA in 82 patients and demonstrated that restenosis rate after coronary artery stenting was much lower (4% versus 40%) than that after prolonged balloon inflation. In the current series, we do not have enough follow-up data to evaluate restenosis rate. Further data regarding long-term results would be desirable to consider this device as a definite therapeutic alternative to coronary artery bypass surgery or other measures in bail-out situations.

In conclusion, flexible coil (Gianturco-Roubin) stent is a very useful adjunct to coronary angioplasty to provide a readily applied nonsurgical rescue procedure to correct or prevent the acute or threatened closure of coronary artery and suboptimal outcome after unsuccessful angioplasty.

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