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CHUAN-YU GAO
Department of Cardiology, Henan Provincial People's Hospital, China

ROBERT WHITBOURN

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Evaluation of Abciximab on Dissolution of Newly Formed Thrombus Developed During Coronary Angioplasty and Stenting

CHUAN-YU GAO, ROBERT WHITBOURN*, ANDREW MACISAAC*, PATRICIA FOX*, MICHAEL JELINEK*

From the Department of Cardiology, Henan Provincial People's Hospital, China; and *the Department of Cardiology, St. Vincent's Hospital Melbourne, Fitzroy 3065, Australia

GAO ET AL.: ***Evaluation of Abciximab on Dissolution of Newly Formed Thrombus Developed During Coronary Angioplasty and Stenting.*** *The study observed the effect on thrombus of the glycoprotein IIb/IIIa antagonist abciximab. We studied retrospectively 72 patients, who had definite or possible thrombus that was newly developed during cardiac intervention. They were given abciximab, 0.25 mg/kg body weight intravenous bolus, followed by 12 hours intravenous infusion at 0.125 μg/min/kg body weight, maximum 10 μg/min (standard ReoPro protocol) or just given abciximab bolus. The result showed that the combination of abciximab and balloon dilation decreased thrombus score (2.29 ± 1.46 vs 1.29 ± 1.37 in PTCA group, p<0.0005; 1.82 ± 1.32 vs 0.33 ± 0.81 in Stenting group, p<0.0005); TIMI flow got a good restoration (1.04 ± 0.79 vs 2.50 ± 0.76 in PTCA group, p<0.0005; 1.38 ± 0.70 vs 2.96 ± 0.20 in Stenting group, p<0.0005). Q-MI, Non-Q-MI, death, revascularization and CABGs in hospital were not different between PTCA and Stenting groups and between "standard ReoPro" and "ReoPro bolus only" (p>0.05), but patients who were treated using standard ReoPro protocol had more bleeding complications (p<0.05) and prolonged hospital stay (5.59 ± 3.91days vs 2.56 ± 0.73 days, p<0.05) than the patients did who had only abciximab bolus. So "ReoPro bolus only" may have same clinical efficacy like "standard ReoPro protocol" does and has less bleeding complication. (J HK Coll Cardiol 2000;8:138-144)*

Abcixmab (ReoPro), complication, coronary angioplasty, coronary stenting, coronary thrombosis, prognosis

摘要

本文回顧性觀察了血小板表面糖蛋白ⅡⅡa/ⅢⅢb受體拮抗劑 ReoPro 對心臟介入過程中新形成的冠狀動脈內血栓的臨床療效。有72名患者在干預的過程中新出現了明確的血栓，或有可能出現了血栓，對這些患者首先以0.25 mg/kg體重彈丸式靜脈推注 Abciximab，隨后連續12小時以10 μg/min靜脈注射（標準的 ReoPro 用法），或僅做彈丸式注射。結果顯示，聯合應用 Abciximab 和球囊擴張降低了血栓評分（PTCA組2.29 ± 1.46 vs 1.29 ± 1.37，p<0.0005，支架組1.82 ± 1.32 vs 0.33 ± 0.81，P<0.0005）；TIMI血流恢復良好（PTCA組1.04 ± 0.79 vs 2.50 ± 0.76，p<0.0005，支架組1.38 ± 0.70 vs 2.96 ± 0.20，P<0.0005）。Q波心肌梗死，非Q波心肌梗死，死亡，CABGs和需要再次血管成形的患者在兩組（ReoPro 標準方案以及 ReoPro 靜脈注射組方案）中無顯著差異（p>0.05），但 ReoPro 標準方案（靜脈注射+靜脈滴注12小時），比 ReoPro 靜脈注射組方案有較多的出血併發症和較長的住院時間（p<0.05）。因此單使用"ReoPro 靜脈注射組方案"與"使用 ReoPro 標準方案"所獲得的臨床療效相似，同時可減低出血併發症狀。

關鍵詞：受體阻斷劑（ReoPro）　併發症　冠狀動脈成形　冠狀動脈支架置入　冠狀動脈血栓　預后

Address for reprints: Dr. Chuan-Yu Gao
the Department of Cardiology, Henan Provincial People's Hospital,
7 Weiwu Road, Zhengzhou 450003, China.
Tel: (86) 371 5972157, Fax: (86) 371 5964376

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Introduction

Acute thrombus and abrupt closure during and after coronary intervention procedures are major ischaemic complication. It has been reported that the rate of abrupt occlusion is about 0.5-2%.[1,2] This is responsible for the initiation of the coagulation cascade and, at the same time, of platelet adhesion and activation, finally resulting in the formation of a platelet rich thrombus following percutaneous transluminal coronary angioplasty (PTCA) and Stenting procedure. This process is quite quick, probably new thrombus may be formed in a couple of minutes. A couple of studies have showed that prophylactically GP IIb/IIIa antagonists-abciximab (ReoPro) with standard-dose, weight-adjusted heparin (100 u/kg) or low-dose, weight-adjusted heparin (70 u/kg) before cardiac intervention can substantially reduce the rate of ischaemic complications in particular patients with high risk factors, before, during and after PTCA.[3-6] However, the usefulness of abciximab in acute thrombus developing in the catheter lab has never been evaluated completely.[2,7] In this study, we evaluated and compared the efficacy of abciximab on acute platelet-rich thrombus and in-hospital outcome of the patients in whom intra-coronary thrombus was developed during the cardiac intervention (only PTCA or Stenting procedure) after standard ReoPro protocol or only ReoPro bolus was administered.

Methods

Study Population

We retrospectively studied all angioplasty patients with acute intra-coronary thrombosis developing in catheter lab from April 1996 to April 1998. The patients undergoing elective or urgent percutaneous coronary revascularization with a device approved by the Food and Drug Administration were eligible for inclusion if they had a target lesion with stenosis of at least 70% of the diameter of the vessel. Exclusion criteria were that patients had previously new formed thrombus angiographically in coronary target lesion before cardiac intervention started, for example, acute myocardial infarction with thrombus (two patients) and acute coronary occlusion after cardiac intervention (two patients). All patients gave informed consent.

Study Protocol

All patients were given 150-300 mg of Aspirin orally at least one day prior to the procedure for elective and 300 mg of Aspirin orally at least 1 hour for urgent cases and daily was administered thereafter. Ticlopidine 250 mg was given twice daily for 1-3 days before revascularization and 3 weeks after revascularization. A standard-dose bolus of heparin was given (10,000 u) before the interventional hardware went into the coronary artery with additional weight-adjusted boluses calculated according to an algorithm intended to achieve and maintain an activated clotting time (ACT) of at least 300 seconds. If a new thrombus was seen angiographically during the procedure, a bolus of abciximab of 0.25 mg/kg body weight was administered 10-20 minutes before further inflation of the balloon or activation of the device, followed by an infusion of 0.125 μg/kg/m (maximum, 10 μg/m) for 12 hours (ReoPro standard protocol) or just abciximab bolus was given. The protocol recommended that heparin be discontinued immediately after interventional procedure and that vascular sheath be removed when the ACT was 170 seconds or less, and then intravenous heparin be started 2 hours post sheath removal for over-night at the rate of 10 units/kg/h in two groups. Implantation of stents was discouraged and was reserved as means of maintaining patency after manifest of threatened abrupt closure in 1996, but was encouraged from 1997-1998. Specific guidelines for sites of vascular access stressed the early removal of sheaths, compression of the femoral access site for 30 minutes to achieve haemostasis after removal of the vascular sheath, and strict bed rest and immobilisation of limbs for 6-8 hours after removal of sheaths. Algorithms were provided for the management of uncontrolled bleeding, urgent coronary artery bypass surgery, and thrombocytopenia, and it was recommended that red-cell transfusion be administered according to the clinical guidelines.

Data Collection

For each patient, routine demographic and clinical data, procedural result and in-hospital complications were prospectively entered into a computerised database. All data were verified by

retrospective review of patient records and coronary angiograms.

Angiographic Analysis

Angiograms were analysed before the procedure, just before the administration of abciximab and after the procedure. Cine angiograms of patients with thrombus developing in the catheter lab were interpreted and verified by two experienced cardiac interventionalists (Dr. Robert Whitbourn and Andrew MacIsaac) for morphologic features similar to those used in the American College of Cardiology/American Heart Association guideline,[8] visual determination of coronary thrombus score was performed using the previously reported TIMI scale of 0 to 4: 0=no thrombus; 1=haziness; 2=definite thrombus <1/2 vessel diameter; 3=definite thrombus 1/2 to 2 vessel diameter; 4=definite thrombus >2 vessel diameters. [9,10] New development of thrombus was defined as an increase in the coronary thrombus grade by at least one level during the course of the angioplasty procedure. Visual determination of coronary flow performed using the TIMI flow scale: 0=no flow past the lesion; 1=flow past the lesion but not filling the entire vessel; 2=flow pass the lesion filling the entire vessel, but slower than that of non-affected vessels; 3=normal flow.[11]

Study End Points and Definition

All clinical data were obtained before patients were discharged or transferred to thoracic cardiac department for coronary artery bypass grafting (CABG). Success was defined as a final diameter stenosis of less than 50% in the absence of any major complication. Major complications were emergency artery bypass surgery, Q-wave myocardial infarction (Q-MI) , death and target lesion revascularization. Significant Q-waves in two or more continuous electrocardiographic leads was defined as Q-wave myocardial infarction. Non-Q MI was defined as at least two fold increase in serum level of cardiac creatine phosphokinase (CPK-MB).

Data Management and Statistical Analysis

All means were expressed with ±1 SD. The student t test was used for numerical variables and the chi square test was used for categorical data.

Result

Patients Demographics

Demographic data from the study patients are shown in Table 1. A high proportion of patients were men and had hypertension or hypercholesterolemia. Most patients had been admitted with the acute ischaemic syndromes of unstable angina in both groups of stenting or PTCA (56% and 51% respectively).

Lesion Characteristics and Thrombosis

As shown in Table 1 and Table 2, most procedures were performed in native coronary vessels (87.5%) with about half of these vessels in the left anterior descending coronary artery (LAD, 47.2%). The majority of target lesions were judged to be of high clinical risk and high lesion risk. Some degree of intra-lesion thrombus was noted before the procedure. Incidence of definite thrombus in both PTCA and Stenting groups was 2.87 % and 1.88% respectively ($p>0.05$), incidence of possible thrombus was 3.72% and 4.69% respectively ($p>0.1$), the incidence of thrombus combining definite with possible was 6.59% and 6.57% respectively ($P>0.9$). Prevalence of thrombus in vessel sequence was Graft >LAD>RCA>LCX in both groups of PTCA and Stenting (but all $p>0.25$). Here did not see significantly statistical difference among different kind of stents ($X^2=4.729$, $p>0.25$).

Procedure Characteristics

44 patients in the stenting group underwent a predilation before deployment of stents and 5 cases had primary stenting without predilation. When a new developing thrombus was identified, we performed a balloon post-dilation 10 minutes after ReoPro was given. In balloon PTCA group, all patients underwent redilation when a new developing thrombus was present after ReoPro was given for at least 10 minutes. As shown in Table 3, a significant improvement occurred in all three values.

Acute Result

In the stenting group, no-reflow phenomena occurred in one patient after a 3.0 by 13 ACS Duet stent was deployed in the native LAD, and distal emboli occurred in 2 cases when new thrombus were identified (in native LAD and RCA respectively). The TIMI flow

Table 1. Demographics and lesion characteristics of 72 study patients with definite or possible thrombus

	PTCA group (%) n=23	Stenting group (%) n=49	p value
Sex M/F	15/8 (65/35)	38/11 (77/23)	NS
Ages (years)	63.6±12.7	61.2±11.6	NS
Risk Factors			
Hypertention	14 (60.9)	32 (65.3)	NS
Diabetes mellitus	5 (21.7)	12 (24.5)	NS
High Cholesterol	13 (56.5)	32 (65.3)	NS
Family History	14 (60.9)	31 (63.3)	NS
Smoking History	9 (39.1)	22 (44.9)	NS
Indication			
Unstable Angina	13 (56.5)	25 (51.2)	NS
Stable Angina	7 (30.4)	19 (38.8)	NS
Post-AMI	3 (13.0)	5 (10.2)	NS
Intervention Vessel			
LAD	11 (47.8)	23 (46.9)	NS
LCX	1 (4.3)	8 (16.3)	NS
RCA	8 (34.8)	15 (30.6)	NS
Graft	6 (26.1)	3 (6.1)	<0.05
ACC/AHA Type			
A	0 (0.0)	0 (0.0)	NS
B	7 (27.0)	16 (32.7)	NS
C	19 (73.0)	33 (67.4)	NS
Vessel Diameter(mm)	3.13±0.48	3.06±0.40	NS

Note: NS=no statistically significance

Table 2. The treated vessels, the used stents and the thrombus developed during cardiac intervention

	Number of treated vessels	Thrombus present (%)	Thrombus possible (%)	Thrombus present+possible (%)
PTCA vessel	349	10 (2.87)	13 (3.72)	23 (6.59)
LAD	132 (37.8)	6 (4.55)	7 (5.30)	13 (9.85)
RCA	117 (33.5)	1 (0.85)	4 (3.40)	5 (4.27)
LCX	76 (21.78)	0 (0.00)	1 (1.32)	1 (1.32)
Graft	24 (6.88)	3 (12.5)	1 (4.17)	4 (16.67)
Stented vessel	746	14 (1.88)	35 (4.69)	49 (6.57)
LAD	302 (40.48)	6 (1.98)	16 (5.30)	22 (7.28)
RCA	253 (33.91)	3 (1.19)	13 (5.14)	16 (6.32)
LCX	149 (19.97)	3 (2.01)	4 (4.76)	7 (4.69)
Graft	42 (5.63)	2 (4.76)	2 (4.76)	4 (9.52)
Used stents	939	14 (1.49)	35 (3.73)	49 (5.22)
Nir stent	734 (78.17)	9 (1.23)	24 (3.26)	33 (4.50)
ACS ML stent	79 (8.41)	0 (0.00)	6 (7.59)	6 (7.59)
AVE micro II	89 (9.48)	5 (6.33)	4 (4.49)	9 (10.11)
J&J PS	17 (1.81)	0 (0.00)	0 (0.00)	0 (0.00)
Others	20 (2.13)	0 (0.00)	1 (5.00)	1 (5.00)

Note:

1. LAD=left descending artery; RCA=right coronary artery; LCX=left circumflex artery; PTCA=percutaneous transluminal coronary angioplasty
2. Prevalence of thrombosis during interventional procedure was similar between PTCA and Stenting(thrombus present and possible: 6.59% vs 6.57%, $p>0.9$, $X^2=0.0025$; thrombus present: 2.87% vs 1.88%, $p>0.25$, $X^2=0.6745$; thrombus possible: 3.72% vs 4.69%, $p>0.1$, $X^2=0.1379$)
3. Prevalence of coronary artery subject to thrombosis was similar too between PTCA and Stenting. The sequence was Graft >LAD >RCA> LCX ,but all $p>0.25$
4. Prevalence in different stents subject to thrombosis in catheter lab was no significant difference, $p>0.25$, $X^2=4.729$
5. PTCA patients=339; Stented patients=713; The number of used stents=939

of the patients was all restored to Grade III 10 minutes after ReoPro was given. Vein graft stenting procedures in two patients, were completed successfully under the support of IABP(intra-aortic balloon pump). Four patients with no-reflow phenomena (one in LAD, one in RCA, two in vein grafts) were noticed in balloon PTCA group when new thrombus was identified. The TIMI flow recovered from I to II 10 minutes after ReoPro was given and at the end of the procedure. One patient who had three vessels disease and used only ReoPro bolus required emergent surgery directly from the catheter lab under the support of IABP after PTCA failed; No patients experienced procedural Q-wave myocardial infarction. In all patients with identified new thrombus, the thrombus only partially blocked target vessels; only one patient, whose saphenous graft underwent balloon PTCA, formed a great longitudinal blood clot that resulted a TIMI grade I flow. His TIMI flow grade was still TIMI I when the procedure finished and he left catheter lab under the support of IABP. No patients developed totally abrupt occlusion due to new formed thrombus, dissection or intimal flaps. So, the procedure successful rate in catheter lab was 100% in stenting and 96% in PTCA group .

In-hospital Complication and Clinical Success (Table 4)

During the remaining hospital course, 40 patients received standard ReoPro treatment (25 cases stenting and 15 cases PTCA), no patients had acute Q-wave

Table 3. Changes of target vessel stenosis, thrombus score and TIMI flow grade of 72 patients

	before procedure		before ReoPro given		at end of procedure	
	PTCA	Stenting	PTCA	Stenting	PTCA	Stenting
Stenosis (%)	93.3±8.2	88.4±9.3	53.0±32.2*	44.8±27.4*	21.7±14.3*	4.4±8.7*
Thrombus score	1.4±1.8	1.0±1.7	2.3±1.5*	1.8±1.3*	1.3±1.4Δ	0.3±0.8*
TIMI flow grade	1.04±0.79	1.38±0.70	1.50±0.91*	1.71±0.62*	2.50±0.76*	2.96±0.20*

Note:

1. Data presented are mean+1SD; "before ReoPro given" means that new thrombus was identified at this stage; TIMI flow means "Thrombolysis in myocardiac infarction" flow.
2. Compared to "before procedure", *: $p<0.05$; Δ: $P>0.05$, but, when comparing to "before ReoPro given", $p<0.05$;

Table 4. In-hospital complication of 72 patients with definite or possible thrombus in different subgroups

	N=49 Stenting	N=23 PTCA	N=40 Standard ReoPro	N=32 ReoPro bolus only
Any access site bleed	26 (53.06)	10 (43.48)	21 (52.50)	15 (46.88)
Access site haematoma	5 (8.16)	1 (4.34)	5 (12.50)	1 (3.12)
Pericardial bleed	1 (2.04)	0	1 (2.50)	0
Thrombocytopenia	1 (2.04)	0	1 (2.50)	0
Blood transfusion	2 (4.08)	0	2 (5.00)	0
Stroke	0	1 (4.34)	1 (2.5)	0
Revascularisation in 24h	0	0	0	0
CABGs	0	1 (4.34)	0	1 (3.12)
Non-Q-MI	2 (4.08)	2 (8.68)	2 (5.0)	2 (6.24)
Q-MI	0	0	0	0
Death	0	0	0	0
Hospital stay (days)	4.43±2.45	3.75±1.91	5.59±3.91	2.56±0.73

Note:

1. Any access site bleeding and main in-hospital complication (Revascularization, CABGs, Q-MI, Death), no different between PTCA and Stenting and between "Standard ReoPro" and "ReoPro bolus only" (all $p>0.05$)
2. Main bleeding complication (access site haematoma, pericardial bleeding, thromocytopenia, blood transfusion), no different between PTCA and Stenting ($X^2=2.56$, $p>0.1$). But "Standard ReoPro" group had litter bit more or life-threatening bleeding complication ($X^2=4.07$, $p<0.05$)

myocardial infarction, CABG; but in these patients, one patient who had LAD stenting had life-threatening pericardial bleeding 3 hours post-procedure with pericardial tamponade; one patient who had left internal mammary artery PTCA had small stroke; 6 patients had significant access site bleeding and haematoma (5 patients had stents and 1 had PTCA), but haematomas were all less than 10 centimetres and did not need surgical repair. In another 2 patients, who had vein graft stenting and PTCA respectively, they required blood transfusion and 1 experienced thrombocytopenia; Average hospital stay was 5.59±3.91 days. Another 32 patients (24 cases of stenting and 8 cases of PTCA) just used ReoPro bolus injection and low-dose weight adjusted heparin infusion over-night post-sheath removal 2 hours; In these 32 patients, only one patient who had left circumflex artery PTCA had small access site haematoma. No patients experienced Q-wave MI, acute closure, CABG, revascularisation or death in hospital; Average hospital stay was 2.56± 0.73 days. So, overall clinical success was 100% (49/49) in stenting group, 96% (22/23) in PTCA group, 100% (40/40) in ReoPro standard protocol group, 96.8% (31/32) in ReoPro bolus only group.

Discussion

Abrupt occlusion of the stented vessels occurred in 0.5-2.0%, and the cause of 80% was thrombsis in the coronary artery,[1,2] despite pre-existing use of combined antiplatelet therapy with aspirin and ticliopidine. The current view about new thrombus focuses on platelet activation, and thrombosis.[1-3,12] When interventional devices compress, squash or dilate diseased vessel segments, the coagulation cascade is activated. Activated platelets expose the phospholipid surface and IIb/IIIa platelet glycoprotein receptor on which platelet and fibrinogen combine together and form new thrombus. Fortunately, a new drug, GP IIb/IIIa receptor antagonist, abciximab (ReoPro), has recently showed its ability to prevent the thrombosis[3-6] and dissolve thrombus.[2,7,12]

Despite the documented clinical efficacy of the prophylactic use of abciximab during coronary angioplasty from EPIC study, EPILOG and CAPTURE study, concerns regarding the cost of its use and bleeding complication still exist.[13] Recently, we also noticed that rescue utilisation of abciximab when coronary abrupt closure occurred, produced a satisfactory clinical benefit.[7] We also achieved similar clinically efficacy in both PTCA and stenting groups. Abciximab can effectively restore the TIMI flow grade and decreases thrombus score in these patients who had a newly formed thrombus in the catheter lab. Rapid distal run-off in patients with distal embolisation and no-reflow state will be reestablished within minutes after treatment with the abciximab (Table 3).[14,15]

The previous studies have showed that both ReoPro standard protocol plus standard-dose, weight-adjusted heparin or low-dose, weight-adjusted heparin achieved the same clinical effectiveness during hospital, at 3 months and 6 months follow-up,[4,5] but bleeding complication was more frequent.[4,5,16] As result of cost, bleeding complications and efficacy of abciximab, some doctors modified previous standard abciximab strategy. In the present study, 40 patients received abciximab standard dose regimen (bolus + infusion). In these patients, pericardial tamponade occurred in one case, thrombocytopenia in one case, significant access site haematoma and bleeding in 5 cases. In another 32 patients, who only received ReoPro bolus injection, no significant bleeding complications were noticed (Table 4); only one patient had urgent CABGs directly from catheter lab after PTCA failed, but the reason for CABG was not due to intra-coronary thrombosis, because the patient had multi-vessel coronary disease and bad left ventricular function. Both treatments all achieved the same clinical result.

Conclusion

Dissolution of thrombus and restoration of TIMI flow were readily achieved after administration of abciximab when the development of new thrombus was identified in both PTCA and stenting groups. Both strategies of abciximab bolus only and standard abciximab strategy (bolus + infusion) have the same satisfactory clinical efficacy in hospital, but the patients with standard abciximab protocol have slightly more or life-threatening bleeding complication.

Limitation

This study was a retrospective study, not a double blind clinical study. The strategy of standard abciximab

or only abciximab bolus depended completely on the various treating doctors. Although we achieved a satisfactory clinical result and less bleeding complications in abciximab bolus group, we can not be sure that the strategy has the same long term outcome as "standard abciximab protocol".

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