ReoPro Observational Registry (RAPOR): insights from the multicentre use of abciximab in Asia

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ABSTRACT

Introduction: The pattern of use of abciximab in real-life clinical patients undergoing percutaneous coronary intervention (PCI) in 11 high-volume centres in Singapore, Malaysia, Thailand, Philippines, India, Pakistan and Korea was prospectively examined.

Methods: These centres enrolled 224 consecutive patients over eight months to receive abciximab during PCI for the study. The cohort consisted of 82.1 percent males, with mean age of 55 (±11) years and mean weight of 67 (±17) kg.

Results: The use of abciximab during PCI ranged between 6.2 percent and 21.6 percent. The indications for the use of abciximab were: acute coronary syndromes (34.3 percent), complex coronary lesions (17.9 percent) and multivessel PCI (17.7 percent). Based on a risk scoring system devised for this registry, majority (60.0 percent) of the patients was considered high risk when abciximab was used. Among the patients enrolled, 36.6 percent received abciximab as a "bail-out". The overall in-hospital ischaemic event rates were low at 4.0 percent. The complication rates included major bleeding 0.7 percent, thrombocytopenia 2.7 percent and need for blood transfusion 2.8 percent. There was a trend towards a higher incidence of in-hospital non-Q myocardial infarction in the "bail-out" group (2.1 percent versus 7.3 percent, p-value equals 0.07).

Conclusion: Abxicimab was uncommonly used among patients (9.4 percent) undergoing PCI in this Asian region, with the operators reserving it mainly for high-risk patients.

Keywords: abciximab, adjuvant drug therapy, angioplasty, coronary disease, percutaneous coronary intervention

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INTRODUCTION

Percutaneous coronary intervention (PCI) has been shown to be effective in reducing coronary ischaemia in patients with coronary artery disease[1,2]. However, despite the use of coronary stenting, there exist acute and medium-term complications which include abrupt closure and restenosis[3,4]. The platelet glycoprotein (GP) IIb/IIIa receptor antagonists, in inhibiting "the final common pathway" of platelet aggregation, are effective in preventing thrombus formation and known to reduce ischaemic complications following percutaneous revascularisation[5-8]. More recently, studies including a large meta-analysis showed that in patients undergoing PCI, GP IIb/IIIa receptor antagonists confer a significant and sustained decrease in the risk of death[9,10].

Abciximab, a monoclonal antibody to platelet GP IIb/IIIa receptor (c7E3 Fab, ReoPro, Centocor BV, Leiden, The Netherlands) has been the most evaluated agent of this class of drugs[11-14]. The Evaluation of c7E3 Fab in the Prevention of Ischaemic Complications (EPIC) trial showed a marked 35% reduction in acute ischaemic events at 30 days with the use of abciximab. There was however doubling of the incidence of major bleeding complications[12]. In the follow-up Evaluation of PTCA to Improve Long-Term Outcomes by c7E3 Glycoprotein IIb/IIIa Receptor Blockage (EPILOG) study, the use of abciximab and low-dose weight-adjusted heparin was able to achieve a significant 56% reduction in the composite clinical endpoints without any associated increase in haemorrhagic complications[13].

An initial single Asian centre experience with abciximab has been previously reported[15]. To further define the safety and efficacy of the use of this drug in the Asian population, a multicentre prospective registry known as RAPOR (ReoPro Observational Registry) was set up. The registry was formed with the following four objectives, namely: (1) To examine the pattern of abciximab use among Asian patients undergoing PCI and the

clinical indications; (2) To evaluate the short- and medium-term efficacy and safety of abciximab in Asian patients; (3) To evaluate the effectiveness of abciximab when used in an elective manner versus "provisional" use of the agent; and (4) To explore the efficacy and safety of the use of a new low-dose weight-adjusted heparin regimen for Asian patients receiving abciximab.

METHODS

Between August 1999 and March 2000, a total of 11 high-volume centres in seven Asian countries enrolled 224 consecutive patients who received abciximab during PCI for this registry study. The participating centres included: Escorts Heart Institute and Research Centre, Batra Heart Centre, Apollo Hospital, Jaslok Hospital (from India); Asan Medical Centre and Chonnam National University Hospital (from Korea); National University Hospital of Singapore; National Heart Institute of Malaysia; Armed Forces Institute of Cardiology, Pakistan; St Luke's Medical Centre, Philippines and Ramathibodi Hospital, Mahidol University, Thailand.

Data were collected on standardised case-report forms by study coordinators at the clinical sites. These were sent to National University Hospital, Singapore for data collation and statistical analysis. Patients' demographical and angiographical characteristics were documented. The usage of abciximab either on an elective or provisional (bail-out or rescue) basis was established; and if the drug was discontinued, the reasons were recorded. The indications for use of abciximab were categorised into clinical, angiographical or technical factors. A risk scoring system was devised for this registry and the pattern of use of abciximab based on this risk score was documented. Angiographical and clinical results, procedural complications, bleeding and in-hospital events were also entered into the registry.

Abciximab was administered in the standard regimen of bolus (0.25 mg/kg), followed by maintenance infusion of 0.125 mg/kg/min (maximum dose of 10 ug/min). Operators followed a proposed new low-dose weight-adjusted heparin for patients receiving preplanned abciximab. A dose of 50 U/kg of heparin was administered when baseline activated clotting time (ACT) <150 seconds, 25 U/kg for ACT of 150-199 seconds and no bolus heparin if the ACT is >200 seconds. The target ACT was between 200 to 250 seconds. The maximum heparin bolus allowed was 5000 U. Heparin dose and activated clotting times before and after abciximab administrations were recorded.

Table I. Patient and angiographical characteristics.

Patient characteristics	
Males	184/224 (82.1%)
Mean age	55±11 years
Mean weight	67±17 kg
Hypertension	46.4%
Smoking (active)	27.2%
Diabetes mellitus	29.9%
Non-insulin dependent diabetics mellitus	28.1%
Insulin dependent diabetics mellitus	1.8%
Positive family history of ischaemic heart disease	15.6%
History of previous myocardial infarction	30.8%
History of congestive cardiac failure	5.0%
Previous cerebrovascular disease/ transient ischaemic attack	3.6%
Previous percutaneous coronary intervention	8.9%
Previous coronary artery bypass grafting	7.1%
Angiographical characteristics	
Number of vessels treated in one percutaneous coronary intervention	
Single vessel	71.9%
Multivessel	28.1%
Artery location	
Left anterior descending	45.3
(Proximal left anterior descending)	24.7
Right coronary	32.1
Left circumflex	18.8
Left main	0.9
Saphenous vein	2.9
Types of intervention	
Stenting	76.5%
Rotablation	4.1%
American College of Cardiology/ American Heart Association Classification	
A	8.9
B1	38.5
B2	32.2
C	20.4
Lesion complexities	
Calcification	15.6
Thombus	39.6
Saphenous venous graft (mean age 141±51 months)	2.9
Vessel Size	
<2.5 mm	9.2
2.6-3.0 mm	28.6
>3.0 mm	62.2

Table II. Indications for use of abciximab.

Clinical indications			
Acute ischaemic symptoms	34.3%		
Diabetes mellitus	23.7%		
LV ejection fraction <40%	13.4%		
Technical indications		**Angiographical indications**	
Multiple stent implantation	9.4%	Intracoronary thrombus	50.0%
"Bail-out" stenting	3.6%	Type C coronary lesions	17.9%
Rotational atherectomy	3.1%	Multivessel PTCA	17.4%
Small vessel (<2.5 mm) stenting	1.8%	Reduced TIMI flow after PTCA	10.3%
Stent thrombosis	1.8%	Extensive coronary disease	8.9%
Suboptimal stent results	1.3%	PTCA of saphenous vein graft	4.5%
Coronary dissection (no stent)	1.3%	PTCA of last remaining vessel	0.4%

PTCA = percutaneous transluminal coronary angioplasty; LV = left ventricular

Table III. RAPOR risk score.

Clinical factors	**Risk score**	**Clinical factors**	**Risk score**
Acute ischaemia		Accompanying conditions	
Unstable refractory angina	3	Diabetes mellitus	2
Acute or evolving MI	3	LV ejection fraction <40%	2
Anatomical factors	**Risk score**	**Technical factors**	**Risk Score**
Evidence of intracoronary thrombosis	3	Coronary dissections not treated with stent implantation	3
Markedly reduced coronary flow after dilatation (TIMI 0-2)	3	Multiple stent implantation: (total length ≥40 mm)	2
Type C coronary lesions	2	Suboptimal stent deployment	3
Multivessel PTCA	1	"Bail-out" stenting	3
Extensive coronary lesions	1	Stenting of vessels <2.5mm	1
PTCA on the last remaining vessel	3	Rotational atherectomy	1
PTCA of the saphenous vein graft stenosis	3	Directional atherectomy	1

MI = myocardial infarction; LV = left ventricular; PTCA = percutaneous transluminal coronary angioplasty

RESULTS

The patient population consisted of 82.1% males, with mean age of 55 (±11) years and mean weight of 67 (±17) kg. 30 percent of Asian patients in this registry had diabetes mellitus. Most patients had single vessel PCI (71.9%) with stenting performed in 76.5% and involving large-calibre vessels (>3.0mm) in 62.2%. The left anterior descending artery was the target vessel in 45.3%. More than half of the angiographical lesions were classified as ACC/AHA Types B2 and C. About 40% of all lesions contained thrombus. The detailed patient and angiographical characteristics are shown in Table I.

The overall percentages of abciximab use during PCI in this study was 9.4% (224/2393) (ranging from 6.2% to 21.6%). The percentages of abciximab use in each centre were: Escorts Heart Institute and Research Centre, 25/390 (6.9%); Batra Heart Centre, 19/180 (10.6%); Apollo Hospital, 18/168 (10.7%); Jaslok Hospital, 25/116 (21.6%); Asan Medical Centre, 23/389 (8.0%); Chonnam National University Hospital, 22/255 (8.6%); National University Hospital of Singapore, 40/251 (15.9%); National Heart Institute of Malaysia, 20/258 (7.7%); Armed Forces Institute of Cardiology, Pakistan 12/170 (7.1%); St Luke's Medical Centre, 10/154 (6.5%) and Ramathibodi Hospital, 10/162 (6.2%). Abciximab was used in an elective manner in 142 out of 224 cases (63.4%), with the remaining 36.6% using abciximab in a rescue manner. The full bolus and maintenance dose were completed in 207 patients (92.4%). In the remainder, reasons for discontinued therapy included bleeding in five patients (2.2%), death in two patients (0.9%) and thrombocytopenia in one patient (0.4%).

The indications for the use of abciximab were: acute coronary syndromes (34.3%), complex coronary lesions (17.9%), and multivessel PCI (17.4%). Diabetes mellitus was an indication for the use of abciximab in 23.7% of the patients. The different

Table IV. Procedural complications, in-hospital events and complications with abciximab use.

PTCA procedural complications		**In-hospital events**	
Non-flow limiting dissection	6.3%	Myocardial infarction	1.8%
No reflow	4.5%	(Q wave MI)	0.0%
Acute thrombosis	1.8%	(Non-Q wave MI)	1.8%
Distal embolisation	0.9%	Death	1.8%
Vasospasm	0.9%	Emergency PTCA	0.4%
Suboptimal stent expansion	0.4%	Emergency CABG	0.0%
Ventricular tachycardia / fibrillation	0.4%	Total	4.0%
Side-branch occlusion	0.4%		
Complications of abciximab use		**Sites of bleeding**	
Major bleeding	0.4%	Vascular haematoma (<5cm)	10.7%
Minor bleeding	4.0%	Vascular haematoma (>5cm)	2.2%
Blood transfusion	1.8%	Gingival	3.1%
Platelet transfusion	0.4%	Genitourinary	0.4%
Thrombocytopenia	2.7%	Gastrointestinal / Intracranial	0.0%

PTCA = percutaneous transluminal coronary angioplasty; CABG = coronary artery bypass grafting; MI = myocardial infarction

Table V. Comparison of elective and rescue/provisional usage of abciximab.

	Total	Elective use	Provisional use	Fisher's test (p-value)
In-hospital events				
Non-Q wave MI	4/224 (1.8%)	1/142 (0.7%)	3/82 (3.7%)	0.14
Q wave MI	0/224 (0.0%)	0/142 (0.0%)	0/82 (0.0%)	–
Death	4/224 (1.8%)	2/142 (1.4%)	2/82 (2.4%)	0.62
Emergency PTCA	1/224 (0.4%)	0/142 (0.0%)	0/82 (0.0%)	–
Emergency CABG	0/224 (0.0%)	0/142 (0.0%)	0/82 (0.0%)	–
Total	*9/224 (4.0%)*	*3/142 (2.1%)*	*6/82 (7.3%)*	*0.07*
Complications				
Major bleed	1/224 (0.7%)	0/142 (0.0%)	1/82 (1.2%)	0.36
Minor bleed	9/224 (4.1%)	5/142 (3.5%)	4/82 (4.9%)	0.72
Blood transfusion	4/224 (2.1%)	2/142 (1.4%)	2/82 (2.4%)	0.62
Platelet transfusion	1/224 (0.7%)	1/142 (0.7%)	0/82 (0.0%)	1.00
Thrombocytopenia	6/224 (2.7%)	5/142 (3.5%)	1/82 (1.2%)	0.41
Total	*21/224 (9.4%)*	*13/142 (9.2%)*	*8/82 (9.8%)*	*1.00*

PTCA = percutaneous transluminal coronary angioplasty; CABG = coronary artery bypass grafting; MI = myocardial infarction

indications were categorised in Table II. A risk score (1 to 3 points for each risk factor) to guide the operators on the use of abciximab was also provided (Table III). The use of abciximab was highly recommended if the total risk score was 6 and above, generally recommended if the total score was 4 or 5, and moderately recommended if the risk score was 3 or below. With this scoring system, 60.0% of abciximab use was associated with RAPOR risk score of ≥6, while 22.0% of the cases had risk score of ≤3.

A total of 340 lesions were treated with an angiographical success (defined as <50% diameter stenosis) rate of 98.2% (334/340). The mean percentage diameter stenosis was reduced from 88 (±12)% to 5 (±12)%. Clinical success, defined as procedural success with no in-hospital myocardial infarction, death or emergency intervention (PTCA/CABG) was achieved in 215 of 224 patients (96.0%). Detailed procedural complications and in-hospital events were listed in Table IV. Complications associated with abciximab use and sites of bleeding were also included.

In-hospital events and complications registered in RAPOR arising from elective versus rescue/provisional use of abciximab were compared (Table V). There was a trend towards a higher incidence of in-hospital ischaemic rates in the "bail-out" abciximab group

Table VI. Comparison of clinical outcomes of RAPOR with EPIC and EPISTENT.

	RAPOR (n=224)	EPIC[12] (n=708)#	EPISTENT[14] (n=794)*
In-hospital events			
Non- Q wave MI	4/224 (1.8%)	(4.4%)	(3.5%)
Q wave MI	0/224 (0.0%)	(0.8%)	(0.9%)
Death	4/224 (1.8%)	(1.7%)	(0.3%)
Emergency PTCA	1/224 (0.4%)	(0.8%)	(0.6%)
Emergency CABG	0/224 (0.0%)	(2.4%)	(0.8%)
Total	*9/224 (4.0%)*	*(10.1%)*	*(6.2%)*
Complications			
Major bleed	1/224 (0.7%)	(14.0%)	(1.5%)
Minor bleed	9/224 (4.1%)	(16.9%)	(2.9%)
Blood transfusion	4/224 (2.1%)	(15.0%)	(2.8%)
Platelet transfusion	1/224 (0.7%)	(6.0%)	
Thrombocytopenia	6/224 (2.7%)	(5.2%)	–
Total	*21/224 (9.6%)*	*(51.1%)*	–

PTCA = percutaneous transluminal coronary angioplasty; CABG = coronary artery bypass grafting; MI = myocardial infarction; # refers to "abciximab bolus and infusion" arm of the EPIC trial; * refers to "stent plus abxicimab" arm of the EPISTENT trial.

(2.1% vs 7.3%, p=0.07) driven mainly by an increased incidence of non-Q myocardial infarction as defined by elevation of creatine kinase or MB isozyme level more than twice the upper limit of normal. There was however no difference in the bleeding and vascular complications in the two groups (9.2% vs 9.8%, p=ns).

In this registry study, a new low-dose weight-adjusted heparin regimen was recommended for Asian patients receiving abciximab. The heparin bolus dose was significantly lower in patients receiving abciximab electively compared to those who received abciximab provisionally (5535 [±2531] units vs 6944 [±3678] units, p=0.0009). The ACT before and after abciximab administration was also significantly lower in the elective group (265 [±60] vs 295 [±75] seconds, p=0.001 and 280 [±53] vs 301 [±76] seconds, p=0.04, respectively).

DISCUSSION

This is the first time that real-world platelet glycoprotein IIb/IIIa inhibitors usage during PCI have been evaluated in these Asian countries in the form of a prospective registry. Previous double-blinded randomised control trials on the use of abciximab were conducted in Western countries[12-14]. Compared to patients enrolled in EPISTENT[14], this Asian cohort is younger, with a mean age of 55 (±11) years. In addition, about 20% of patients in the EPISTENT trial have diabetes mellitus[14]. This is higher (30%) in RAPOR, reflecting on the prevalence of diabetes mellitus in the Asian region. RAPOR has shown excellent efficacy of abciximab despite inclusion of a higher number of patients with diabetes mellitus. This is consistent with recent literature that the use of glycoprotein IIb/IIIa antagonists are effective and beneficial in diabetic patients[16,17].

In contrast to the routine use of abciximab in some centres in the United States, RAPOR documented that abciximab was uncommonly used among patients (9.4%) undergoing PCI in this Asian region. There was a significant proportion (37%) receiving the drug as a "bail-out". This was likely due to the financial constraint associated with the use of the drug. The cost of using abciximab, which is not subsidised, was estimated to be S$3,000 for an average-sized Asian patient weighing 67kg in this registry. It was thus not surprising that RAPOR operators seemed to reserve its use mainly for high-risk patients. The implementation of the RAPOR risk score was to guide operators and to provide a logical framework for administration of abciximab to patients who were likely to benefit most. Indeed, the majority (60%) of the patients who had received the drug had a RAPOR risk score of 6 and above.

Despite the more selective use of abciximab for patients undergoing PCI, the real-world clinical outcomes in RAPOR, in terms of in-hospital ischaemic events and in-hospital complications, were comparable to those of randomised controlled trials, as shown in Table VI. In EPIC and EPISTENT, though patients were followed-up for 30 days, most of the events occurred in hospital. Consistent with our study, there have been analyses suggesting that selective use

of abciximab for patients undergoing coronary intervention are associated with outcomes equivalent to those reported for routine use but with significant cost savings[18].

The risks and benefits with GP IIb/IIIa receptor blockers during coronary intervention have to be balanced adequately. As shown in the EPIC trial, there was doubling of incidence of major bleeding complications associated with the use of abciximab. Other clinical studies have also shown the use of adjuvant abciximab during PCI was associated with increased risk of bleeding[19] and thrombocytopenia[20]. Concurrent administration of high doses of heparin may have potentiated the haemorrhagic tendency. An initial study suggested that the associated bleeding may be reduced by using lower doses of heparin and early removal of vascular sheath[21]. The EPILOG investigators prospectively randomised abciximab with standard dose, weight-adjusted heparin (initial bolus of 100 U/kg of body weight), abciximab with low-dose weight-adjusted heparin (initial bolus of 70 U/kg of body weight), and placebo with standard dose weight-adjusted heparin. Minor bleeding was more frequent among patients receiving abciximab with standard-dose heparin, though there was no significant difference among the groups in risk of major bleeding[13].

Patients from the Asian region, in general, have lower body weight compared to their western counterparts. It was also plausible that concomitant administration of a lower dose heparin, lower than that in EPILOG, may retain the same efficacy but further reduce bleeding tendency. For this registry, the new low-dose weight-adjusted heparin was administered according to activated clotting times. This is logical and the resultant significantly lower activated clotting times are supposed to translate to lower bleeding tendency. Instead, there was no significant difference in bleeding complication rates between the "bail out" group and the "elective" usage group. On the contrary, there was a non-significant trend towards lower in-hospital ischaemic event rates in the RAPOR elective arm compared to the provisional arm, suggesting that lower dose of heparin administration did not result in higher major adverse cardiac events. There are, however, other factors such as angiographical features, which are in favour of better outcomes in the elective arm. For instance, patients with thrombus, eccentric lesions or lesions length more than 20 mm are known to be at higher risk for ischaemic complications after coronary stenting[22].

Recently, more data have shown that the use of prophylactic abciximab in elective coronary stenting in high-risk population is effective in reducing the incidence of in-hospital adverse cardiac events[23]. Similarly, the use of abciximab as a rescue agent during PCI allowed for safe discharge from hospital, though it may be associated with higher heparin use[24] and high peri-procedural non-Q wave myocardial infarction[25]. These are consistent with the results from RAPOR. Though follow-up data is not available from our study, others have shown improvement in longer term survival by this brief intervention with abciximab during percutaneous coronary revascularisation[10,26,27].

In conclusion, the conduct of this prospective registry study has allowed for examination of the "real world" usage of abciximab. The percentage use of abciximab in this Asian region was 9.4%. Abciximab and the use of a new low-dose weight-adjusted heparin regimen have been shown to be effective and safe in this study. There was a trend towards higher incidence of in-hospital ischaemic events when abciximab was used provisionally compared to electively, though there was no difference in bleeding rates. The prudent use of abciximab in this region reflects the rationalisation process by interventionists when using this expensive but effective therapy, reserving its use in high-risk cohort of patients who will benefit most from this treatment.

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