MARCH 2001 volume VI, issue 3

CARDIOLOGY Rounds™

As presented in the rounds of the Division of Cardiology, St. Michael's Hospital, University of Toronto

Catheter-based reperfusion for acute myocardial infarction

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Despite tremendous progress in the development of newer thrombolytic agents, morbidity and mortality in the acute phase of myocardial infarction (MI) remains high. In ST-elevation MI, coronary thrombosis results in complete occlusion of the infarct artery. Rapid, complete, and sustained restoration of anterograde coronary flow is needed to preserve left ventricular function and improve clinical outcomes.[1,2] Percutaneous coronary intervention (PCI) may overcome many of the limitations of pharmacologic reperfusion. In this issue of *Cardiology Rounds*, we will review the available literature on primary angioplasty and discuss the role of PCI as the initial reperfusion strategy.

There are several advantages of PCI over thrombolysis. Unlike thrombolysis, there are very few contraindications for PCI. Primary angioplasty is particularly useful in patients with cardiogenic shock, in which thrombolysis is not effective. Coronary angiography provides detailed anatomical information that may be important in identifying patients who require surgical intervention. Angioplasty treats not only the occlusive thrombus, but also the underlying stenosis. Consequently, angioplasty may reduce the risk of recurrent ischemia and reinfarction, compared with thrombolysis. Thrombolytic agents restore coronary patency in 60%-85% of patients and normal (TIMI grade 3) flow in only 50%-60% of patients.[3-5] In contrast, PCI achieves patency rates of over 90% and TIMI grade 3 flow rates of over 70%.[6] Thrombolytic therapy is associated with a risk of major bleeding. Intracranial hemorrhage occurs in about 1% of patients and is fatal in 60% of cases.[7] Hemorrhagic complications of PCI are less frequent and are most often limited to the access site.

The primary disadvantages of PCI are that it is not as widely available as thrombolysis and there is often a delay in achieving catheter-based reperfusion. Most hospitals are not equipped with the facilities to perform angioplasty. Moreover, hospitals that do perform angioplasty are generally not staffed 24 hours a day and may therefore be unable to provide urgent angioplasty in a timely manner during off hours. The initial benefit of primary angioplasty may be attenuated by the occurrence of reocclusion and restenosis. However, the use of stents and glycoprotein (GP) IIb/IIIa inhibitors during primary angioplasty may help preserve long-term vessel patency and sustain the clinical benefits.

Primary angioplasty vs thrombolysis: Randomized trials

A number of randomized trials comparing thrombolysis with primary angioplasty were performed prior to the era of stenting and GP IIb/IIIa inhibitors (Table 1).[6,8-16] Although none of these studies was individually powered to demonstrate a difference in mortality, a meta-analysis[17,18] showed a significantly lower mortality (4.4% vs 6.5%, p=0.02) and the composite of death and MI (7.2% vs 11.9%, p<0.001) with angioplasty. Angioplasty was also associated with a much lower incidence of intracranial hemorrhage (0.1% vs 1.1%, p=0.0005).

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Table 1: Primary angioplasty vs thrombolysis trials

Study	Number of patients	Thrombolytic agent	Door to balloon time (min)	Major endpoint	Results
Zwolle/Zijlstra[8]	185	SK	62	i) Recurrent Ischemia ii) IRA Patency iii) LVEF	Less recurrent ischemia, higher LVEF, higher patency rate with PCI
Zwolle/Zijlstra (low risk)[10]	95	SK	68	Death, reinfarction and stroke at 6 months	Lower rate of reinfarction with PCI
Ribeiro[9]	100	SK	238	IRA patency at 48 hours	No significant difference
Grinfeld[13]	112	SK	63	i) ST resolution ii) TIMI-3 flow rate	Improved ST resolution and higher TIMI-3 flow rate with PCI
DeWood[14]	90	Duteplase	126	NA	No difference in death/reinfarction
PAMI/Grines[6]	395	t-PA (3 hours)	60	Death / Reinfarction	Less death/reinfarction with PCI
Gibbons[11]	103	Duteplase	45	Infarct Size (Sestamibi)	No difference
Ribichini[15]	83	t-PA (1.5 hours)	40	Death / Reinfarction/ Recurrent ischemia	Lower rate of ischemic events with PCI
Garcia[16]	189	t-PA (1.5 hours)	84	Death, reinfarction and stroke	Lower rate of ischemic events with PCI
GUSTO IIb[12]	1138	t-PA (1.5 hours)	114	Death, reinfarction and stroke	Less events with PCI at 30 days, no difference at six months

SK = streptokinase
t-PA = tissue plasminogen activator

Primary angioplasty vs thrombolysis: Registries

The mortality benefit of primary angioplasty seen in the randomized trials was not confirmed in large registries, raising the question of whether the trial results were generalizable to "real world" clinical practice. The MITI (Myocardial Infarction Triage and Intervention) Project Registry[19] compared outcomes in 1050 patients treated with angioplasty with 2095 patients treated with thrombolysis within 6 hours from the onset of symptoms. No differences in in-hospital mortality (5.6% versus 5.5% p=0.93) or 3-year mortality were found between these two groups. Other large registries[20] have also failed to document a benefit of primary angioplasty over thrombolysis.

Possible explanations for the discrepant results include a bias of primary angioplasty being used more often for the sickest patients, or the inability of many clinical centres to perform angioplasty as quickly and as successfully as during randomized trials. In the NRMI-2 registry,[20] the median "door to balloon time" was almost 2 hours. In this and other studies,[21] the time until balloon inflation has been correlated with left ventricular function and survival. The second issue is that in the trials, PCI was performed in selected, dedicated, "high volume" centres by skilled operators. The relationship between volume of procedures and outcome in primary PCI has been well documented.[22,23] In the MITI registry, the procedure was performed in "low volume hospitals" in more than 20% of cases.

Stenting for acute MI

Coronary stenting has been shown to reduce the incidence of restenosis and repeat target vessel revascularization (TVR). Several trials[24-30] have compared balloon angioplasty with stenting in the setting of acute MI (Table 2). These

Table 2: Trials of PTCA and stenting versus PTCA alone in acute myocardial infarction							
Name/Author	Number of patients	6 months Death/MI (%)			6 months TVR (%)		
		Stent	Balloon angioplasty	p-value	Stent	Balloon angioplasty	p-value
Suryapranata[24]	227	3.0	9.0	0.06	4.0	17.0	0.002
FRESCO[25]	150	2.7	2.7	1.0	6.7	25	0.006
GRAMI*[26]	104	3.8	15.2	0.046	1.9	9.6	0.08
PASTA[27]	136	13.0	5.0	0.08	16	33.3	0.016
STENT-PAMI[28]	900	6.6	4.9	0.27	7.7	17.0	<0.001
STENTIM[29]	211	6.0	6.5	0.9	16.8	26.4	0.1
CADILLAC[30]	2032	N/A	N/A	NS	6	13	<0.001

* In-hospital results
N/A = Not available NS = Not significant

studies were not statistically powered to detect differences in mortality or reinfarction rates. However, there was a consistent and statistically significant reduction in TVR at up to one-year follow-up.

- The STENT-PAMI study found a disturbing trend towards lower post-procedural TIMI-3 flow rates (89% vs 93%, p=0.1) and higher mortality at 6 months (4.2% vs 2.7%, p=0.3) with stenting.
- Similar trends were observed in the smaller STENTIM-2 study.
- The much larger CADILLAC trial did not find any difference in post-procedural TIMI flow rates or mortality, and allayed the concern that stent implantation in acute MI may be detrimental.
- A recent study[31] randomized 123 patients with acute MI to undergo primary angioplasty with stenting or thrombolysis. Stenting was associated with lower rates of repeat TVR and recurrent unstable ischemia at 6 months, with a trend towards lower rates of death, reinfarction, or stroke (12.9% vs 21.3%, p=0.2).

GP IIb/IIIa inhibitors

The pivotal role of platelets in acute coronary syndromes and ischemic complications of PCI has been recently recognized. GPIIb/IIIa inhibitors have been shown to reduce ischemic complications during elective and urgent PCI.[32-35] Several studies[30,36-39] have evaluated the role of abciximab in primary PCI (Table 3).

In the RAPPORT trial,[37] 483 patients undergoing primary angioplasty were randomly assigned to treatment with abciximab or placebo. The incidence of death, reinfarction, urgent repeat TVR, and repeat TVR was assessed within 7 days, 30 days, and 6 months. At 7 days, abciximab was associated with a lower rate of reinfarction (0.9% vs 3.7% p=0.06) and TVR (1.4% vs 6.3% p=0.008). However, by 30 days, only the difference in urgent TVR remained statistically significant (1.8% vs 7.9% p=0.004).

Four recent studies have assessed the use of abciximab as an adjunct to stenting in AMI:

- The STOPAMI[36] trial randomized 140 patients with acute MI to thrombolysis with tPA or primary angioplasty with stenting and abciximab. Using serial sestamibi scans, a greater extent of myocardial salvage was accomplished with stenting and abciximab.
- Neumann et al[38] demonstrated greater improvement in regional wall motion and peak coronary flow velocity after primary angioplasty with abciximab compared to heparin alone. Thus, abciximab may not only improve epicardial coronary patency, but it may also enhance microvascular perfusion. A substudy of this trial revealed that the mechanism of benefit may be a modulation of monocyte Mac-1 integrin expression, leading to reduced platelet-monocyte interaction.
- In the ADMIRAL study, 300 patients were randomized to abciximab or placebo. The rates of reinfarction (4.7% vs 2.0%, p=0.09) and urgent TVR (14% vs 6%, p=0.03) were significantly lower in the abciximab group. There were no statistically significant differences in major bleeding.
- The CADILLAC (Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications) trial[30] randomized more than 2000 patients presenting within 12 hours from the onset of AMI into 1 of 4 treatment groups: balloon angioplasty alone, balloon angioplasty with abciximab, stenting alone, and stenting with abciximab. The rates of major adverse cardiac events (MACE) – death, non-fatal MI, or repeat TVR during 6 months follow-up –

Table 3: Trials of abciximab for primary angioplasty				
Trial/Author	**PCI Procedure**	**Control Group**	**Number of patients**	**Results**
STOPAMI[36]	Stenting + abciximab	TPA	140	Improved myocardial salvage and clinical outcome with PCI
RAPPORT[37]	PTCA + abciximab	PTCA + Placebo	483	Improved 7-day clinical outcomes, 30-day TVR and 6-month urgent TVR rates
Neumann[38]	Stenting + abciximab	Stenting + Placebo	200	Improved coronary flow and regional wall motion
ADMIRAL[39]	Stenting + abciximab	Stenting + Placebo	300	Improved 30-day reinfarction and TVR rates
CADILLAC[30]	PTCA + abciximab or Stenting + abciximab	PTCA + Placebo or Stenting + Placebo	2032	6-month clinical events reduction with stents Reduced mortality and event rate by abciximab in PTCA patients Reduced subacute thrombosis (both stents and PTCA) with abciximab

were 10.8% for the stent group, 10.9% for the stent plus abciximab group, 15.2% for the balloon angioplasty with abciximab group, and 19.3% for the balloon angioplasty alone group. No significant differences in death or reinfarction were found between groups. The subacute (30 days) thrombosis rate was significantly reduced by abciximab (1.75 vs 0.6% p=0.07 in the PTCA group and 1% vs 0% p=0.03 in stent group).

The reasons for the disparity between the results of the ADMIRAL and CADILLAC stent arms remain speculative, but the frequent initiation of abciximab prior to arrival in the catheterization laboratory in ADMIRAL was associated with enhanced reperfusion prior to angioplasty; this may have contributed to the more favorable clinical outcomes. The concept of facilitated PCI has recently been proposed; in this scenario patients presenting with acute MI are started immediately on pharmacologic reperfusion therapy (eg, low-dose thrombolytic therapy and GP IIb/IIIa inhibitor) and are brought to the catheterization laboratory as early as possible. Thus, facilitated PCI combines the benefits of pharmacologic and catheter-based reperfusion strategies. Ongoing studies will determine the safety and clinical utility of this combined approach to reperfusion.

Thus, PCI may be the best treatment modality for AMI and stenting provides better short- and long-term angiographic and clinical (TVR) results. The use of abciximab in this setting is probably beneficial only in the acute period. The main issue, however, is the technical feasibility of this treatment. In most trials, the time needed to open the artery by PCI (randomization to balloon time) was 30 minutes longer than the time needed to start thrombolytic therapy (randomization to needle time). The 1999 American College of Cardiology/American Heart Association (ACC/AHA) guidelines state that PCI can be considered as a treatment alternative to thrombolytic therapy for patients with AMI, providing that it can be performed within 90 minutes.

Conclusions

Percutaneous coronary intervention is an effective means of establishing reperfusion for patients with acute MI when performed rapidly and in specialized centres by experienced operators. Coronary stenting improves the durability of benefit by reducing the need for repeat revascularization. GP IIb/IIIa inhibitors enhance reperfusion prior to angioplasty, reduce the incidence of reocclusion and other ischemic complications after successful reperfusion, and improve microvascular perfusion. In randomized trials, PCI appears to be superior to thrombolysis in preventing subsequent death and reinfarction. However, these improved outcomes may not be realized if angioplasty cannot be successfully performed within 90-120 minutes of hospital presentation. Facilitated PCI offers the potential of combining the benefits of thrombolysis and mechanical reperfusion, and merits further study.

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Abstract of Interest

Abciximab Use During Percutaneous Intervention in Patients With Acute Myocardial Infarction Improves Early and Late Clinical Outcomes: Final Results of the CADILLAC Trial

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Background: Abciximab (Abx) improves clinical outcomes in pts undergoing elective percutaneous intervention. We hypothesized that the adjunctive use of Abx during primary PTCA and stenting in AMI would improve the early safety profile of the procedure and reduce late adverse events.

Methods: In the CADILLAC trial, 2082 pts of any age with AMI <12 hrs onset without cardiogenic shock were prospectively randomized in a 2x2 factorial design to primary PTCA or MultiLink stenting, and to Abx or no Abx. The primary endpoint was the 6 month composite occurrence of death, disabling stroke, reinfarction, or ischemia requiring TVR.

Results: A total of 1,054 pts were assigned to Abx (529 to PTCA and 525 to stent), and 1,028 pts were assigned to no Abx (514 to PTCA and 512 to stent). By core lab analysis, TIMI-3 flow was restored in 96.2% of pts assigned to Abx vs. 95.0% assigned to no Abx (p=0.18). Results by intention to treat appear in the table:

	No Abciximab	Abciximab	P Value
30 day death	23 (2.2%)	19 (1.8%)	0.48
30 day disabling stroke	2 (0.2%)	2 (0.2%)	0.99
30 day reinfarction	6 (0.6%)	7 (0.7%)	0.81
30 day ischemic TVR	43 (4.2%)	25 (2.4%)	0.02
30 day MACE	69 (6.7%)	45 (4.3%)	0.01
30 day severe bleed	4 (0.4%)	6 (0.6%)	0.75
6 month MACE	148 (14.4%)	125 (11.9%)	0.09

The reduction in the 30 day MACE rate with abciximab was more pronounced in pts assigned to PTCA (4.3% vs. 8.1%, relative reduction [RR] 47%, p=0.01) than in those assigned to stenting (4.2% vs. 5.3%, RR 21%, p=NS), as was the reduction in 6 month MACE (14.2% vs. 18.4%, RR 23%, p=0.06, and 9.5% vs. 10.4%, RR 9%, p=NS, respectively.)

Conclusion: In patients without cardiogenic shock undergoing mechanical reperfusion therapy for AMI, abciximab use during intervention improves early and late clinical outcomes, especially after primary PTCA, without increasing complications.

Early Stenting Versus Conservative Treatment After Thrombolysis in Acute Myocardial Infarction

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Objectives: Thrombolysis in acute myocardial infarction (AMI) is limited by TIMI III-flow rates of 60% and reocclusion of the infarct related artery. Prior studies showed no benefit of PTCA following thrombolysis compared to thrombolytic therapy alone in AMI. Recent studies, however, have demonstrated superiority of primary stenting versus PTCA alone in AMI. The objective of the SIAM III study (South West German Interventional Study in Acute Myocardial infarction) is to compare the strategy of early coronary stenting (group I) with a conservative treatment (group II) following thrombolysis in AMI.

Methods: SIAM III is a multicenter, randomized, prospective, controlled study. Inclusion criterion is thrombolysis within 12 hours from the onset of symptoms in AMI. Patients of group I are transferred to the interventional center within 6 hours after thrombolysis for coronary angiography including stenting of the infarct related artery. Group II has elective coronary angiography after two weeks with stenting of the infarct-related artery at this time. Primary endpoint is a combined endpoint of death, reinfarction, and target lesion revascularization.

Findings: So far (August 2000), 166 pts have been randomized. During a mean follow-up time of 159±97 days, early stenting was associated with a significant reduction of the combined end point (22.1% vs. 37.7%, p=0.035) of death (5.9% vs 11.6%, ns), reinfarction (2,9% vs 2.9%, ns), and target lesion revascularization (16.2% vs 24.6%, ns). The incidence of ischemic events leading to unplanned rehospitalization or angiography was significantly reduced in group I (2.9% vs. 34.8%, p=0.01). Bleeding complications occurred in 10,3% of pts in group I vs. 7.2% in group II (ns). TIMI III flow rates at the two week angiography were 98.5% in group I vs. 59.0% in group II (p=0.01). Left ventricular ejection fraction two weeks after AMI was 56.7%±11,5% in patients undergoing early stenting compared to 52.5±13.4% in the conservative group (p=0.06).

Conclusions: Early stenting after thrombolysis in AMI is safe. This preliminary data indicate a clinical benefit by this approach compared to conservative treatment after thrombolysis in AMI.

J Am Coll Cardiol 2001;37(Suppl A):343A

Upcoming Scientific Meetings

27 May - 1 June, 2001
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This publication is made possible by an educational grant from

AstraZeneca Canada Inc.