Thrombus aspiration in a series of patients with stable or unstable angina pectoris and lesion-site thrombus formation

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Background. In acute myocardial infarction, thrombus aspiration prior to percutaneous coronary interventions (PCI) is often beneficial, but this approach has never been studied in patients without acute myocardial infarction. The aim of this retrospective study is to shed light on that topic based on our initial experience with manual thrombus aspiration in patients with stable or unstable angina pectoris and angiographic evidence of lesion-site thrombus.

Methods. We assessed the feasibility (thrombus aspiration without predilatation) of this approach; in addition, we determined angiographic coronary flow and myocardial blush grade.

Results. During 33 months in which a total of 4725 PCI were performed in our centre, manual thrombus aspiration was attempted in 14 patients with stable or unstable angina pectoris with angiographic evidence of thrombus. In nine of these 14 patients, the aspiration catheter could be advanced into the lesion without predilatation; in eight patients visible thrombus was obtained. The corrected TIMI frame count improved during the entire interventional procedure (21.1 ± 11.2 vs. 12.8 ± 5.9 frames; $p=0.015$). Myocardial blush grade, which overall improved during PCI ($p<0.001$), tended to show greater improvement in patients in whom

thrombus aspiration could be achieved (1.6 ± 0.9 vs. 0.7 ± 0.5 ; $p=0.06$).

Conclusions. Preliminary evidence suggests that manual thrombus aspiration may occasionally be considered in selected patients without acute myocardial infarction but with angiographic evidence of lesion-site thrombus. Nevertheless, prospective studies are required to clearly define the role of this approach in clinical practice. (Neth Heart J 2010;18:423-9.)

Keywords: Thrombus Aspiration; Distal Embolization; Aspiration Catheter; Coronary Intervention

Coronary embolisation of atherothrombotic material during percutaneous coronary interventions (PCI) may cause necrosis of otherwise viable myocardium, which can result in reduction of contractile function.¹ In primary PCI for ST-elevation myocardial infarction, thrombus aspiration prior to stent implantation can reduce both incidence and extent of angioplasty-induced atherothrombotic embolisation and myocardial necrosis.²⁻⁴ As recently demonstrated, this approach can improve long-term clinical outcome at one-year follow-up.⁵

Devices for manual aspiration of coronary thrombus are registered for application during primary PCI. However, such treatment may also be beneficial in patients with non-ST-elevation myocardial infarction.⁶ In addition, thrombus aspiration may be useful outside the setting of treatment of acute myocardial infarction, if angiography suggests the presence of thrombus formation (with or without impaired baseline coronary flow). In this study, we report our first experience with thrombus aspiration during PCI in a small series of patients with stable or unstable angina pectoris and angiographic suspicion of thrombus formation.

Methods

Study population

The analysis comprised PCI patients with stable or

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unstable angina pectoris (i.e., without myocardial infarction) in whom the Export Aspiration catheter was applied for thrombus aspiration during PCI in the Thoraxcentrum Twente in Enschede between 1 October 2005 and 30 June 2008. All patients who fulfilled the inclusion criteria as described below were identified from our PCI database.

Stable angina pectoris was defined as the occurrence of typical chest pain only during physical exertion. Unstable angina pectoris was defined as the occurrence of typical chest pain at rest with or without electrocardiographic signs of ischaemia but no ST elevation and no increase of cardiac troponin I $>0.5 \mu\text{g/l}$ (local laboratory threshold of myocardial infarction). In case of angina pectoris after previous myocardial infarction, time between occurrence of infarction to PCI had to be at least ten days with creatinine kinase returned to normal. Patients who presented with acute ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, or thrombus formation as complication of a PCI (e.g., vessel closure after stenting) were not included.

Procedure

Aspiration was attempted by experienced operators based on suspicion of lesion-site thrombus formation with or without impaired baseline coronary flow. Thrombus formation was defined as the presence of a roundish filling defect of the lumen during dye injection (in multiple projections) with or without persistence of luminal contrast following dye injection. Manual thrombus aspiration was performed during catheterisation via the femoral route through a 6F-compatible Export Aspiration Catheter (Medtronic, California, USA) with an internal diameter of 0.041 inch and a crossing profile of 0.068 inch, which was handled over a 0.014 inch guide wire in a monorail fashion. After placement of the guide wire, the Export catheter was carefully advanced through the target lesion during continuous aspiration. Aspiration of in general 2 x 20 ml of blood was performed during multiple passages of the lesion (according to operator's discretion). Aspiration was followed by stent implantation; predilatation was performed before stent implantation if required for stent delivery.

Medical treatment

All patients received aspirin, clopidogrel, β -blockers, and lipid-lowering drugs according to current guidelines.⁷ All patients were treated with heparin (5000 IU) according to conventional protocols. The administration of a glycoprotein IIb/IIIa inhibitor was left to the operator's discretion.

Outcome measures and follow-up

All angiograms were reviewed and evaluated off-line by two experienced, interventional cardiologists (blinded for results and success of the technique

as stated in the procedural report) for the presence of intraluminal filling defects and Thrombolysis In Myocardial Infarction (TIMI) flow grade before PCI, after thrombus aspiration and at the end of the PCI. Also, feasibility, accomplishment and occurrence of potential complications (e.g., coronary dissection, perforation) due to the thrombus aspiration were reported.

Feasibility of aspiration procedure was defined as the ability to advance the aspiration catheter into the target lesion without predilatation. Accomplishment of thrombus aspiration was defined as a reduction of the amount of intraluminal filling defect in the angiogram (visually determined) and/or the presence of visible thrombus in the aspirate (recorded in PCI report). Improvement in coronary flow due to thrombus aspiration was defined as improvement in TIMI flow grade by at least one grade (applicable only if baseline TIMI flow grade <3). The occurrence of distal embolisation and no-reflow was assessed and related to the success of thrombus aspiration. Distal embolisation during PCI was defined as migration of a filling defect or the presence of a new distal occlusion of the treated vessel or one of its side branches. No reflow was defined as TIMI flow grade 0-1 not attributable to dissection, occlusive thrombus formation or epicardial spasm. In addition, baseline and final post-PCI angiographic coronary flow was also assessed by means of the corrected TIMI frame count at 12.5 frames/sec. Corrected TIMI frame count was analysed according to Gibson et al.⁸ Baseline and final post-PCI myocardial blush grade was determined as previously described.⁹

After PCI preceded by thrombus aspiration post-procedural peak creatinine kinase (CK) was measured. CK was measured six hours after PCI and was repeated when elevated. All results were confirmed by review of hospital charts and the physician's record.

Statistical analysis

Continuous variables with normal distribution were expressed as mean $\pm$ 1 standard deviation (SD) and were compared by the Student's T test. Continuous variables without normal distribution were presented as median $\pm$ 1 SD and were compared by the Wilcoxon test. Categorical variables were presented as frequencies and were compared by the χ^2 test. Differences were considered significant at a p value <0.05 . Statistical analyses were performed by using SPSS software for Windows, version 15.0.0 (SPSS, Chicago, IL, USA).

Results

Baseline characteristics

Between 1 October 2005 and 30 June 2008, a total of 4725 PCI were performed in our centre.

Table 1. Baseline characteristics of study population.

Patient	Gender	Age	Stable/ unstable angina	Diabetes	Hypercholesterol- aemia	Hyper- tension	Smoking	Previous MI	Previous PCI	Previous CABG
A	F	70	Unstable	-	+	+	-	-	-	-
B	M	45	Unstable	-	+	-	+	-	-	-
C	M	66	Unstable	-	-	-	-	-	-	-
D	F	48	Unstable	-	+	+	+	+	-	-
E	M	54	Unstable	-	-	-	+	-	-	-
F	M	62	Unstable	-	-	+	+	-	-	-
G	M	61	Unstable	-	-	-	-	+	-	-
H	F	69	Unstable	-	+	+	-	-	-	-
I	M	62	Stable	-	+	+	-	-	+	+
J	M	45	Unstable	-	-	-	-	+	-	-
K	M	72	Stable	-	+	-	-	-	+	+
L	M	65	Stable	-	+	+	-	+	+	-
M	M	51	Unstable	+	-	-	+	-	-	-
N	F	61	Stable	-	+	+	+	-	-	-

F=female, M=male, MI=myocardial infarction, PCI=percutaneous coronary intervention, CABG=coronary artery bypass grafting.

Table 2. Technical and procedural characteristics of study population.

Patient	Target vessel	Success thrombus aspiration	TIMI pre-aspiration	TIMI post-aspiration	TIMI after PCI	Corrected TIMI frame count		Myocardial blush grade		Peak CK	Distal embolisation	GPIIb/IIIa inhibitor
						Pre PCI	Post PCI	Pre PCI	Post PCI			
A	LAD	No	2	3	3	18	13	2	2	185	No	Yes
B	LAD	Yes	3	3	3	25	16	2	2	72	No	Yes
C	RCA	No	2	2	3	10	10	1	2	80	No	No
D	RCA	Yes	1	2	2	†	9	0	2	208	No	Yes
E	LAD	No	1	1	2	40	26	1	2	97	No	Yes
F	LAD	No	1	2	3	27	8	2	3	122	No	Yes
G	RCA	Yes	2	1	2	6	6	2	3	191	No	No
H	LAD	Yes	1	2	2	32	11	2	3	147	No	Yes
I	Vein	No	2	2	2	*	*	2	2	155	No	Yes
J	RCA	No	2	2	3	10	10	2	3	46	No	No
K	Vein	Yes	1	2	3	*	*	1	3	194	No	Yes
L	RCX	Yes	1	2	3	†	9	0	2	65	Yes	Yes
M	RCA	Yes	1	2	3	†	7	0	3	32	No	Yes
N	RCA	Yes	1	2	3	26	7	2	3	69	No	Yes

RCA=right coronary artery, RCX=left circumflex artery, LAD=left anterior descending coronary artery, TIMI= thrombolysis in myocardial infarction, CK=creatinine kinase. * Cannot be determined in vein graft, † flow in totally occluded artery.

Of these 4725 patients, a total of 372 patients underwent thrombus aspiration during PCI; mainly patients with acute myocardial infarction. Thrombus aspiration was attempted prior to PCI in 14 patients (aged 59 ± 9 years), who had no myocardial infarction but angiography-based suspicion of thrombus formation; four patients suffered from stable angina and ten from unstable angina. Single-vessel disease was present in seven patients. Baseline and procedural characteristics are presented in table 1.

Procedural characteristics

Technical and procedural characteristics are presented in table 2. In two patients who underwent thrombus aspiration in vein grafts, the corrected TIMI frame count score could not be determined. Two patients with stable angina and one patient with unstable angina had a thrombotic occlusion of the target lesion (with collateral blood supply) prior to PCI; this precluded reliable assessment of the change in coronary flow by the corrected TIMI frame count (the corrected TIMI frame count before PCI is indicated as †).

Angiographic outcome and clinical course

In nine out of 14 patients of the study population the aspiration catheter could be advanced into the target lesion; thrombus aspiration could be performed in all but one of these patients. An example of an attempted thrombus aspiration is demonstrated in figure 1. The corrected TIMI frame count improved during the entire interventional procedure (21.1 ± 11.2 vs. 12.8 ± 5.9 frames; $p=0.015$).

Myocardial blush grade, which overall improved during PCI ($p<0.001$), tended to show greater improvement in patients in whom thrombus aspiration could be achieved (1.6 ± 0.9 vs. 0.7 ± 0.5 ; $p=0.06$). There was only one patient with distal embolisation of a small fragment of thrombus, which occluded a minor side branch following aspiration of the major portion of the thrombus; this event was not associated with an increase in CK. No-reflow did not occur.

Discussion

While in acute myocardial infarction manual thrombus aspiration has shown to reduce atherothrombotic embolisation and microvascular damage, this approach has not yet been studied during PCI for stable or unstable angina pectoris. Although thrombus aspiration has been shown to reduce mortality in patients with ST-elevated myocardial infarction, the use of complex devices has also been associated with higher mortality.^{10,11} Our study population comprised 14 patients only (<4% of all PCI patients with manual thrombus aspiration), in whom we observed that manual thrombus aspiration could be performed with reasonable technical

success which may have contributed to improvement in myocardial flow. Our data underline that this approach was only occasionally performed outside the setting of acute myocardial infarction.

Results of thrombus aspiration

In the present study, there were no major adverse events related to thrombus aspiration or PCI. The aspiration catheter could be advanced into the lesion in almost two thirds of the patients. Compared with previous studies conducted in patients with acute ST-elevation myocardial infarction, the success rate of manual thrombus aspiration was lower in our population (89 vs. 57%, respectively).⁴ In another study, the success rate was approximately 70%.⁶

Differences in quality and nature of the studied target lesions may explain differences in success rates between the setting of acute myocardial infarction and thrombus aspiration as performed in the present study. For instance, culprit lesions in acute myocardial infarction are often physically soft which facilitates the passage of the aspiration catheter; in addition, they will generally show a greater thrombus load which facilitates aspiration. Also, acuteness of clinical presentation results in an earlier presentation in the intervention theatre, which means that the thrombus is generally fresher compared with the setting of stable angina pectoris. Finally, thrombus composition may differ: in patients with (un)stable angina (i.e., settings with generally preserved flow) thrombus will essentially be white, while in acute myocardial infarction there will be a mixed thrombus formation with red stagnation thrombus secondary to flow cessation.¹²

In addition, severely calcified lesions may resemble intraluminal filling defects, suggestive of the presence of intracoronary thrombus formation. Significant flow impairment such as generally found in the setting of acute myocardial infarction will often help to distinguish between the two. In stable angina pectoris with preserved antegrade flow the differentiation between thrombus and calcified lesions may be more difficult. Intravascular ultrasound (IVUS) can analyse plaque composition and identify calcium.^{13,14} Nevertheless, as the identification of thrombus by IVUS is limited and introduction of the imaging probe can induce distal embolisation, operators may sometimes – in case of doubt – chose for direct use of an aspiration catheter. Optical coherence tomography (OCT) may be an alternative imaging technique to distinguish between thrombus and calcified lesions.

Myocardial perfusion and coronary flow

In the setting of acute myocardial infarction, aspiration-induced prevention or reduction of (micro) embolisation improves myocardial reperfusion. Burzotta et al. also found significant improvement of myocardial blush grade in patients with success-

Figure 1. Two examples of PCI with coronary thrombus aspiration. From a subtotal lesion in the proximal circumflex artery (A, arrow), a large amount of thrombus was aspirated (panel B) which improved flow. Stent implantation resulted in a very favourable angiographic result with Thrombolysis In Myocardial Infarction (TIMI) 3 flow (C). In another patient, a subtotal occlusion of the right coronary artery (D, arrow) was treated by thrombus aspiration and balloon dilatation which reduced thrombus load and improved the lumen dimensions but not coronary flow (E); the asterisk () in panel D indicates an additional plaque ulceration proximal to the target lesion. After coronary stenting TIMI 3 flow was achieved (F).*

ful thrombus aspiration compared with patients without aspiration.^{16,17} In their non-ST-elevation myocardial infarction population, Vlaar and co-workers found a marked reduction in thrombus score (40% before vs. 7% after aspiration) and an increase in TIMI 3 flow (36% before vs. 66% after aspiration).⁶

In our present study, improvement in myocardial blush grade tended to be greater in patients with accomplished thrombus aspiration ($p=0.06$). In other words: myocardial perfusion may benefit from thrombus aspiration in patients with stable or unstable angina. This might be the result of prevention of very mild distal microembolisation,¹⁹ which may not affect coronary flow on such subtle levels. In fact, the lack of additional improvement in coronary flow in the present study could have been expected, as patients with (un)stable angina generally have an initial coronary flow more favourable than in the setting of acute myocardial infarction. Consequently, in our study population there is less room for (aspiration-/PCI-induced) coronary flow improvement. Moreover, in chronic coronary ob-

structions, PCI-induced improvement of corrected TIMI frame count can only be expected if baseline coronary diameter obstruction is $>75\%$.¹⁸

Limitations of the study

Although the cases analysed in this study were accumulated during almost three years in our centre (>1900 PCI performed annually), the study population remained relatively small. The retrospective character of this study, however, implies some potential selection bias and the relatively small number of cases examined suggests a careful interpretation of the data. Nevertheless, in these patients the decision to perform thrombus aspiration was taken after careful consideration by experienced interventional cardiologists; nevertheless, in the absence of the use of IVUS or OCT, even experienced operators have a limited ability to distinguish intracoronary thrombus formation from calcified lesions.

Clinical implications

Clinically stable angina pectoris is not necessar-

ily associated with histological stable atherosclerotic plaques²⁰ and may occasionally show thrombus formation at lesion site. We previously demonstrated that distal embolisation has significant prognostic implications even in patients undergoing elective PCI.²¹ While thrombus aspiration will not be able to prevent embolisation from the necrotic core of an atheroma,¹⁵ it can remove (or reduce) thrombus load of complicated lesions in selected cases- thrombotic material that may otherwise embolise during PCI.

Conclusion

Based on our preliminary evidence in the present study, manual thrombus aspiration may occasionally be considered in selected patients without acute myocardial infarction but with angiographic evidence of lesion-site thrombus. Nevertheless, prospective studies are required to clearly define the role of this therapeutic approach in clinical practice.

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