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Intravascular Ultrasound Predictors of Outcome After Peripheral Balloon Angioplasty*

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Objective: *This study investigates the potential role of intravascular ultrasound (IVUS) in the outcome in patients undergoing percutaneous transluminal angioplasty (PTA) of the superficial femoral artery.*
Materials: *Angiographic and the qualitative and quantitative IVUS data obtained at the narrowest site derived from 39 patients before and after PTA were analysed.*
Results: *Angiographically the diameter of the remaining stenosis seen after PTA was classified as < 50% in 31 patients (success); in eight patients a failure was encountered. Evaluating at 6 months the functional and anatomic results of the PTA in 31 patients, the intervention was a success in 14 patients (Group I) and a failure in 17 patients (Group II). The remaining eight patients defined as angiographic failure following PTA comprised Group III. Neither qualitative nor quantitative IVUS data obtained before PTA could predict outcome. Conversely, after PTA, the extent of dissection was significantly more severe in Groups II and III than in Group I. Similarly, significant differences were found between Groups I and II for mean free lumen area (13.2 vs. 9.7 mm^2, respectively) and mean free lumen diameter (4.1 vs. 3.5 mm, respectively). Quantitative data obtained in Group II were similar to those in Group III.*
Conclusion: *This preliminary study demonstrates that following PTA the extent of dissection, free lumen area and diameter seen with IVUS are predictive factors of patency. Future studies with more patients are mandatory to further highlight the sensitivity of these observations.*

Key Words: Intravascular ultrasound; Balloon angioplasty; Angiography; Superficial femoral artery; Restenosis.

Introduction

Since the introduction of intravascular ultrasound (IVUS) numerous investigators have acknowledged the opportunity of this technique to obtain unique additional information about the vessel wall in comparison to angiography.[1–16] One of the benefits of IVUS is the ability to provide more insight in the ultimate effect of balloon angioplasty (PTA) and to measure accurately cross-sectional free lumen area and percentage (%) area stenosis in both coronary and iliofemoral arteries. Studies in which IVUS parameters are related to the occurrence of restenosis are limited to coronary arteries.[11,12] It appeared that qualitative and quantitative variables, other than dissection, derived from IVUS were not of predictive value for restenosis.[11,12]

The purpose of this study was to determine whether IVUS data on morphologic and quantitative parameters, obtained at the site of the smallest free lumen area seen before and after PTA of the superficial femoral artery are predictors of the outcome. This may answer the question whether one single cross-section with the most significant free lumen area obstruction, obtained with IVUS, can be used exclusively for future decision-making. Analysis of the IVUS data combined with angiographic data, clinical and hemodynamic follow-up data up to 6 months, form the basis of this study.

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Patients and Methods

Study group

In this multicentre study, EPISODE (Evaluation of Peripheral Intravascular Sonography On Dotter Effect), in which four university hospitals cooperate, angiographic and IVUS data were collected from 39 patients who underwent a PTA for treatment of *de novo* symptomatic superficial femoral artery occlusive disease. Patients were referred for disabling claudication (n = 29), rest pain (n = 4), and/or ischaemic ulceration (n = 6). The decision to perform a PTA was made in consultation between the vascular surgeon and intervention radiologist. There were 23 men and 16 women: age range 36–85 (mean 64) years. The investigation was approved by the local Committee on Human Research. Patients were included in the study after written informed consent and if they were assumed to be able to return for the follow-up at 1 and 6 months. All PTA procedures were preceded and followed by standard angiography and IVUS study. Experienced vascular radiologists performed or directly supervised the PTA procedure and scored the angiographic results. Each hospital was responsible for collection and analysis of the data including angiographic, IVUS, clinical and hemodynamic follow-up data. Data were stored using a database program written specifically for this study.

Angiography

Before PTA the length of the diseased segment subjected to dilation and the type of lesion (stenosis or occlusion) involved were scored angiographically. After PTA the outcome (success or failure) was defined. Success was classified semiquantitatively as remaining diameter stenosis < 50% using the alleged normal vascular segment as reference.

Intravascular ultrasound

The IVUS study was performed using mechanical 30 MHz imaging systems. In two hospitals a CVIS system was used (Sunnyvale, Ca, U.S.A.), in two other hospitals a Du-MED system (Rotterdam, The Netherlands) was used. Care was taken that systems were calibrated properly. Catheters used contained a guide wire lumen (CVIS 0.014"; Du-MED 0.018" or 0.035"). A radiopaque ruler was used to match the IVUS data obtained before and after PTA with the angiographic data. Before, and immediately after, intervention the IVUS catheter was advanced distally beyond the lesion and cross-sections were recorded during pull-back of the catheter. If lesions consisted of a total occlusion, attempts were made to advance the guide wire and subsequently the IVUS catheter into and across the lesion. These attempts were terminated if major resistance was encountered. Images were recorded with 1 cm interval. Under fluoroscopic control the location of the IVUS catheter was systematically compared with the radiopaque ruler; its location was indicated manually on the video monitor.[5,6] The resulting images were displayed on the monitor via a video-scanned memory and stored on an S-VHS system.

The videotapes were reviewed for analysis and all cross-sections within the dilated segment obtained before and after PTA underwent qualitative and quantitative analyses (interval 1 cm). For the present study, qualitative and quantitative data viewed at the cross-section with the smallest free lumen area seen in each patient before and after PTA were selected.

Qualitative analysis. Cross-sections were assessed for lesion topography and morphology before PTA and for vascular damage after PTA (Table 1). Criteria for evaluating the morphologic features with IVUS have been described previously.[3–6] A lesion was judged to be present when the lesion thickness was 0.5 mm or more. The topography of the lesion may be either eccentric or concentric (Figs. 1–3). An eccentric lesion was defined as a lesion involving one part of the circumference of the vessel wall in a cross-section which leaves the remaining part disease-free. Plaque composition may include fibromuscular/fibrous (echo-soft), calcification (echo-hard with shadowing) and lipid deposit (echo-poor). After PTA the presence of dissection, plaque rupture and internal elastic lamina rupture was documented. In the absence of these features 'no effect' was scored. First, the incidence of these features seen before and after PTA was scored. Second, the extent of the normal vessel wall,

Table 1. Qualitative and quantitative intravascular ultrasound data evaluated in the cross-sections showing the smallest free lumen area before and after balloon angioplasty of the superficial femoral artery

Qualitative	Quantitative
Eccentric, concentric	Free lumen area
Soft, hard, lipid	Free lumen diameter
Dissection	Media-bounded area
Plaque rupture	Plaque area
Internal elastic lamina rupture	% area stenosis

the composition of the lesion and the severity of vascular damage involved were graded semiquantitatively as a sector of the circumference (in steps of 30°; range 0–360°). For instance, an eccentric lesion may involve 180° of the circumference leaving the remaining 180° disease-free (normal). If part of the circumference could not be analysed due to a strut or guide wire interposition, then that segment was classified as not analysable.

Quantitative analysis. Quantitative measurements were performed using a digital video analyser system.[17,18] Images that contain strong backscatter echoes from flowing blood may present difficulties in the determination of the lumen boundary on a still-frame. For quantitative analysis echo images have to be replayed on a separate video monitor to facilitate distinction between the luminal boundary from the echoes of blood backscatter. Analysis included measurement of free lumen area, free lumen diameter and media-bounded area (Table 1, Figs. 1–3). The plaque area was calculated by subtracting free lumen area from media-bounded area. The % area stenosis (obstruction) was calculated as plaque area divided by media-bounded area. In the absence of a visible tunica media on IVUS the adventitia was used as reference. When extensive dropout due to calcification was encountered, media-bounded area was not calculated.

Interobserver. Because data were collected from different hospitals, for the present study the qualitative and quantitative analyses collected from the first 29 patients studied with IVUS were controlled and discussed centrally (University Hospital Rotterdam). Differences between observers were solved by consensus. Ultrasound analyses of the remaining 10 patients were repeated by an independent observer (n = 74 cross-sections before and 64 cross-sections

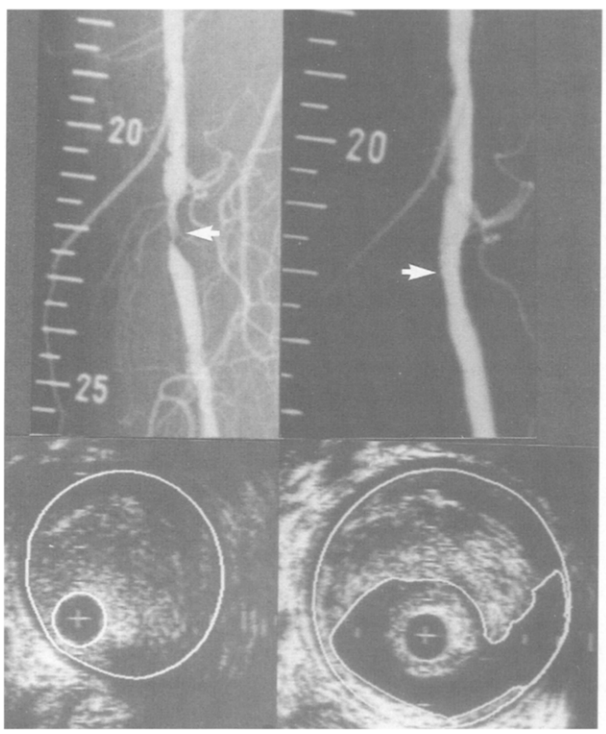

Fig. 1. Corresponding intravascular ultrasound cross-sections and angiograms obtained from a patient before and after balloon angioplasty (PTA) of the superficial femoral artery (Group I: angiographic diameter stenosis < 50%). Before PTA a soft eccentric lesion (330°) was involved at the smallest free lumen area (level 22 cm). After PTA the corresponding cross-section revealed a dissection (60°) and an internal elastic lamina rupture at 4 o'clock. The intravascular ultrasound cross-sections are contour traced off-line facilitating the recognition of free lumen area (FLA; inner contour) and media-bounded area (MBA; outer contour). The FLA increased from 1.9 mm^2 to 18.7 mm^2; the MBA increased from 26.8 mm^2 to 43.0 mm^2; the plaque area decreased from 24.9 mm^2 to 24.4 mm^2; and the free lumen diameter increased from 1.5 mm to 4.9 mm. + = catheter; calibration = 1 mm.

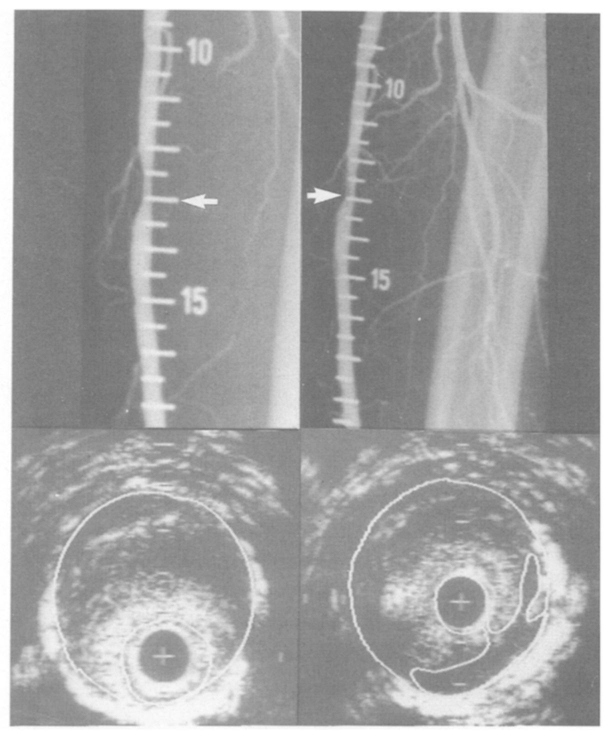

Fig 2. Corresponding intravascular ultrasound cross-sections and angiograms obtained from a patient before and after balloon angioplasty (PTA) (Group II: angiographic diameter stenosis < 50%). Before PTA the smallest free lumen area is seen at level 13 cm. The lesion involved was eccentric and soft in nature. After PTA the lesion became dissected from the arterial wall (dissection = 150°). The free lumen area (FLA; inner contour) and media-bounded area (MBA; outer counter) display the quantitative results. The FLA increased from 3.8 mm^2 to 4.6 mm^2; the MBA increased from 20.3 mm^2 to 21.0 mm^2; the plaque area decreased from 16.5^2 to 16.4 mm^2; and the free lumen diameter increased from 2.2 mm to 2.4 mm. As restenosis developed within 1 month, the patient was referred for repeat balloon angioplasty. + = catheter; calibration = 1 mm.

after PTA). Interobserver differences of the qualitative data were expressed as Kappa's coefficient and total percentage of agreement. Interobserver differences in the measurements of the free lumen area and media-bounded area were expressed as mean values and standard deviation of the paired differences.

Follow-up

After discharge (usually the day after the procedure) patients returned for follow-up at 1 month and at 6 months, or until an adverse event occurred. Criteria for evaluating the continuous success of PTA have been described previously.[19] Success and failure were defined using a combination of clinical and objective vascular laboratory findings. Unequivocal success of PTA was defined as improvement in the clinical condition by at least one Fontaine level (i.e. from ulceration to ischaemic night pain, or rest pain to disabling claudication, or claudication to asymptomatic); and on haemodynamic improvement.[19] Haemodynamic improvement is defined as an improvement in the ankle/brachial index (ABI) of at least 15%. In the presence of noncompressible vessels the ABI was not used. In addition, the information provided during the intervention of both the radiopaque ruler and patella were used as reference when the balloon dilated segment was studied with duplex. The ratio between the peak systolic velocities evidenced within the treated segment and proximal to the stenosis was used to determine the diameter stenosis.[20] A diameter stenosis $<50\%$ (PSV ratio <2.5) was defined as a successful PTA. Both vascular laboratory findings (ABI and Duplex) were decisive in assessing the outcome.

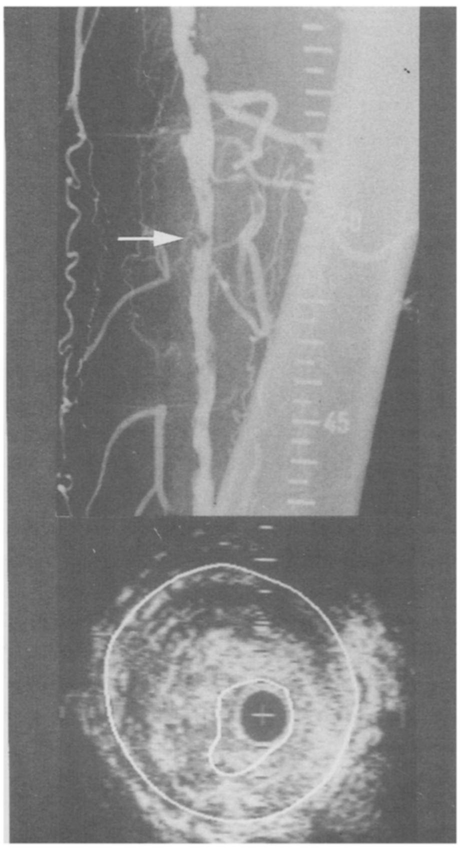

Fig. 3. Intravascular ultrasound cross-section and angiogram obtained from a patient after angiographically defined non-successful balloon angioplasty (Group III). Vascular damage was not encountered (no effect = 360°). The free lumen area (FLA; inner contour) and media-bounded area (MBA; outer counter) display the quantitative results: FLA = 6.6 mm^2, MBA = 56.6 mm^2, plaque area = 50 mm^2 and free lumen diameter 2.9 mm. Two days later the patient was referred for bypass surgery. + = catheter; calibration = 1 mm.

Statistical analysis

The IVUS data are presented as mean ± standard deviation. The IVUS data were divided into two groups according to the data evidenced angiographically ($<50\%$ diameter stenosis and failure) and further subdivided at follow-up. The Student's *t-test* was used to compare the IVUS data before and after PTA between the groups; a p value <0.05 was considered statistically significant.

Results

Intravascular ultrasound studies were completed successfully with good quality in all patients. No complications related to angiography or IVUS were encountered. Because the IVUS catheter could not be advanced across the lesion, IVUS data were not available before PTA in five patients (Fig. 3).

The level showing the smallest free lumen area on IVUS before PTA did not necessarily correspond to the level showing the smallest free lumen area after PTA: in 29 patients the levels corresponded within <5 cm; in three patients the distance was between 5 and 10 cm; in two patients the distance was 11 and 14 cm, respectively; in five patients IVUS data were not obtainable at the smallest free lumen area (vide supra).

Angiographically, the PTA procedure was classified as $<50\%$ diameter stenosis (success) in 31 patients and

Table 2. Incidence (%) of lesion topography and morphology seen before and pathologic features seen after ballon angioplasty (PTA) of the superficial femoral artery with intravascular ultrasound at the site showing the smallest lumen area

	Angiographic success (n=31)		Angiographic failure
	Group I (n=14) success	Group II (n=17) failure	Group III (n=8)
Before PTA*			
Concentric	71%	88%	63%
Hard	29%	41%	0%
Lipid	7%	6%	0%
After PTA*			
Dissection	43%	71%	50%
Plaque rupture	36%	12%	0%
IEL rupture	14%	18%	12%

n= number of patients.
IEL= internal elastic lamina.
* Differences were not significantly different.

as a failure in eight patients (Table 2). The 31 patients were followed using a combination of clinical and objective vascular laboratory findings to show the degree of success and the time of failure up to the census date of 6 months. Success was scored in 14 of the 31 patients (Group I); failure was scored in 17 of the 31 patients (Group II). Nine of the 17 failures occurred within 1 month after PTA. Of the patients failed: seven had no further treatment within 6 months; three had repeat PTA; five had vascular surgery; and two underwent amputation. The eight patients, classified angiographically as failure following PTA, comprised Group III; all these patients subsequently underwent vascular reconstructive surgery.

The mean length of the diseased segment subjected to dilation was 13.4 cm (range 4–32 cm). No significant differences in the length of the diseased segment was encountered in Group I (12 ± 7 cm) and Group II (11 ± 5 cm). The length of the diseased segment in Group III (21 ± 11 cm) was significant different from that seen in Groups I and II. Angiographically, a stenosis was present in 23 patients and an occlusion in 16 patients. The ratio stenoses *vs.* occlusions in the three groups was: seven stenoses *vs.* seven occlusions in Group I; 14 stenoses *vs.* three occlusions in Group II; and two stenoses *vs.* six occlusions in Group III.

Qualitative analysis

Data on lesion topography and morphology seen before and pathologic features seen with IVUS after PTA are summarised in Tables 2 and 3. Due to strut or guide wire interposition a mean of 10° of the cross-sectional image per cross-section could not be analysed for all groups. When considering the incidence of topography (eccentric/concentric), morphology (soft/hard/lipid) and pathologic features (dissection, plaque rupture and internal elastic lamina rupture), no significant difference between the three groups of patients was encountered (Table 2). In addition, no significant difference in extent of lesion topography and morphology was encountered between the three groups of patients (Figs. 1–3). Conversely, the extent of dissection seen after PTA in Groups II and III was significantly higher compared with the data from Group I (Table 3).

Quantitative analysis

Quantitative data obtained before and after PTA are summarised in Table 4. Before intervention, no significant differences in the quantitative data were observed between the three groups of patients. As result of PTA, a significant increase in free lumen area and free lumen diameter and a significant decrease in % area stenosis was noted in all groups. In addition, after PTA significant larger values were encountered in free lumen area and free lumen diameter in Group I *vs.* Group II. No significant differences were seen in media-bounded area, plaque area and % area stenosis between Groups I and II. Free lumen area, free lumen diameter and % area stenosis seen in Groups I and III were significantly different (see Table 4).

Table 3. Extent of the normal vessel wall and lesion morphology seen before and severity of pathologic features seen after ballon angioplasty (PTA) of the superficial femoral artery with intravascular ultrasound at the site showing the smallest free lumen area

	Angiographic success (*n*=31)		Angiographic failure
	Group I (*n*=14) success	Group II (*n*=17) failure	Group III (*n*=8)
Before PTA			
Normal	24°±48°	6°±21°	24°±33°
Hard	12°±21°	57°±93°	0°
Soft	306°±96°	267°±135°	279°±108°
Lipid	3°±9°	3 ±6°	0°
After PTA			
Dissection	18°±21°	78°±69° *	75°±102°
Plaque rupture	15°±21°	6°±15°	0°
IEL rupture	6°±18°	12°±24°	12°±30°
No effect	330°±30°	249°±81° *	279°±99°

Data represent the mean and S.D. of the degrees (°) involved along the boundary of the cross-section image.
n= number of patients.
IEL= internal elastic lamina.
* Differences between Groups I and II are significant ($p<0.05$).

Table 4. Quantitative intravascular ultrasound data obtained at the site showing the smallest free lumen area before and after balloon angioplasty (PTA) of the superficial femoral artery

	Angiographic success (*n*=31)		Angiographic failure
	Group I (*n*=14) success	Group II (*n*=17) failure	Group III (*n*=8)
Before PTA			
Free lumen area (mm^2)	6.0±3.6	3.6±2.0	3.4±1.6
Free lumen diameter (mm)	2.7±0.8	2.1±0.5	2.0±0.5
Media-bounded area (mm^2)	26.4±8.4	25.3±5.3	25.3±7.1
Plaque area (mm^2)	20.4±6.4	22.2±6.0	22.0±7.7
% area stenosis	77.7±9.2	86.5±7.3	84.4±10.8
After PTA			
Free lumen area (mm^2)‡	13.2±3.6	9.7±3.2*	7.2±2.8†
Free lumen diameter (mm)‡	4.1±0.5	3.5±0.6*	3.0±0.6†
Media-bounded area (mm^2)	29.3±8.5	29.1±11.6	32.4±12.6
Plaque area (mm^2)	16.1±8.2	21.5±8.2	25.2±12.1
% area stenosis‡	51.8±16.9	61.7±20.3	75.4±9.9†

Data represent the mean and S.D.
n= number of patients.
* Differences between Groups I and II are significant ($p<0.05$).
† Differences between Groups I and III are significant ($p<0.05$).
‡ Differences in quantitative data between before and after PTA are significant ($p<0.05$) for all groups.

Interobserver variability

There was moderate agreement for topography (eccentric/concentric) and morphology (soft/hard) and dissection (Kappa values 0.54, 0.59 and 0.46; total agreement of 77%, 91% and 73%). A poor agreement was observed for lipid, plaque rupture and internal elastic lamina rupture (Kappa values 0.0, 0.02 and 0.08; total agreement of 96%, 72% and 70%). The interobserver differences of the area measurements before and after intervention were $+0.6 \pm 2.3$ mm^2 and $+0.6 \pm 2.1$ mm^2, respectively, for free lumen area and -0.3 ± 3.5 mm^2 and -1.7 ± 3.4 mm^2, respectively, for media-bounded area.

Discussion

Given the fact that there is a lack of correlation between angiography and the outcome after PTA, there clearly is a need for a better understanding of the mechanism of restenosis and failure in angioplasty.[1] Since the introduction of IVUS, it has been suggested that this technique is capable to uncover the parameters related to success and failure of PTA. For this purpose we started in September 1992 a multicenter study named EPISODE in which four university hospitals participated. One of the aims of this study was to address the question of whether qualitative and quantitative lesion characteristics — as assessed by IVUS before and after PTA of the superficial femoral artery — are predictors of the long-term outcome. The present study is the first in which IVUS data, obtained at different centres before and after PTA, are analysed in a uniform manner. Besides IVUS studies, the investigation includes a systematic follow-up including clinical assessment, Doppler and Duplex studies.

The following issues of the present study deserve specific comments:

(1) Given the advanced technology and experience with balloon angioplasty in peripheral arteries, results obtained nowadays with PTA should be considerably better than series available a decade ago. However, the overall 6 months success rate, including early failure observed in this study, is markedly low (36%). Failure in this study, noted after angiographically classified < 50% diameter stenosis, was an early phenomenon: 9/17 failures were evidenced within 1 month. Our data are even worse compared to those previously reported by Jeans *et al.*(49%).[21] We realise that variations in results reported from different centers reflect the variation in selection of patients and lesions for intervention. The lesion length is an acknowledged parameter that determines suitability of PTA.[21,22] Becker *et al.* reported a 6 month patency rate of 23% in patients with long (> 7 cm) superficial femoral artery stenosis.[28] In our study, the overall length of the diseased segment subjected to PTA was large (mean 13.4 cm). Nonetheless, no significant difference in length was encountered between the success group (Group I) and the failure group (Group II). Furthermore, it has been suggested that the outcome for stenosis is significantly better than for occlusion.[21–23] Although the number of occlusions in the present study was high 16 (41%) the type of lesion involved (stenosis *vs.* occlusion) did not unequivocally influence the outcome. In Group I the ratio stenosis *vs.* occlusion was seven *vs.* seven, while in Group II this was 14 *vs.* three. These results are in keeping with those of others.[24,25] Altogether, we believe that the high incidence of failure in the present study may be influenced by both the length of the diseased segment as well as the type of lesion involved.

(2) Studies dealing with IVUS both in peripheral and coronary arteries generally consider one arterial cross-section for analysis.[7–16] In the present study, we were able to document different morphologic and quantitative data during pull-back of the IVUS catheter both before and after PTA. Recently, we have executed an *in vitro* study with IVUS to elucidate the effect of PTA on diseased coronary arteries. We learned that the quantitative effects were greater at the site of the smallest free lumen area compared with data obtained from multiple adjacent cross-sections within the dilated segment.[29] Consequently, for the present study we have chosen to select the site showing the smallest free lumen area seen with IVUS for analysis, rather than the available sequence of corresponding cross-sectional levels analysed within the dilated segment.

It proved that the most severely stenotic site seen before PTA may not necessarily correspond with the most stenotic site seen after intervention: in 29/39 cross-sections the levels corresponded closely with a distance < 5 cm. The reason for this may be that the effect of PTA may differ according to the lesion characteristics involved. It is noteworthy, that the observed quantitative changes in the free lumen area and diameter were caused by overstretching of the arterial wall by radial pressure of the balloon, leaving the plaque area virtually unchanged (see also Figs. 1, 2).

(3) Albeit plaque morphology is alleged to be an important determinant in pathologic outcome after PTA, published data do not show consensus.[23–25,30] The presence of calcium may either be prognostic for failure[23] or it does not influence outcome.[25] Similarly, eccentric lesions were more likely to be successfully dilated than were concentric lesions.[24,30] The opposite was claimed by Spies *et al.*[23]: i.e. concentric lesions were easier to treat than eccentric lesions. Similarly, reports on the significance of angiographically evidenced dissection for subsequent restenosis are conflicting. Patients with evidence of dissection may have a decreased long-term patency[31, 32]; others demonstrated that the possibility of restenosis is not more likely in patients with dissection.[30,33–35]

According to the current library the ultimate benefit of IVUS is to provide additional information about the vessel wall in comparison to angiography, and its ability to measure accurately the cross-sectional free lumen area and % area stenosis during treatment of vascular disease.[1–16] The results of the present study show that, irrespective of stenosis or occlusion, both qualitative (soft, hard, lipid, eccentric, concentric) and quantitative IVUS data obtained prior to PTA, were comparable in the three patient groups. This suggests that the qualitative IVUS data obtained before PTA delivered no predictors for the ultimate outcome. These conclusions are consistent with those reported by Tenaglia *et al.*[12]

(4) The incidence of qualitative IVUS data after PTA including dissection, plaque rupture and internal elastic lamina rupture were not associated with the outcome. In contrast, the extent of dissection seen on IVUS related significantly with the outcome. Such a relation was also established by Tenaglia *et al.* in coronary arteries.[12] Others, however, suggested that restenosis was more likely to occur when a concentric plaque was involved without a fracture or dissection.[11] Although in our study the severity of dissection rather than the incidence of dissection was related to the outcome, we believe that care should be taken to designate this feature being of prognostic value given the small number of patients studied.

(5) Quantitative IVUS data obtained following PTA reveal that the effect of PTA on free lumen area, free lumen diameter and % area stenosis was significant for all three groups of patients. Because of the delay between balloon deflation after PTA and subsequent IVUS examination we assume the quantitative IVUS data obtained following PTA are not subjected to recoil.[7]

The most important observations in the present study are that after PTA significant differences were encountered for free lumen area and free lumen diameter between Group I *vs.* Groups II and III, respectively. The difference in % area stenosis was significant only between Groups I and III (52% *vs.* 75%). Conversely, no significant difference in % area stenosis was noted between Group I (52%) and Group II (62%). Honey *et al.*[11] reported that restenosis was not related to the % area stenosis involved (62% area stenosis: no restenosis *vs.* 59% area stenosis: restenosis). In this respect, it is important to realise that the calculated degree of % area stenosis does not reflect the actual free lumen area size, given the variability in remodeling of the vessel wall.[36,37] In addition, Tenaglia *et al.*[12] reported that neither free lumen area, diameter nor % area stenosis were predictive for the outcome. The reason why quantitative IVUS parameters in our study were of predictive value for failure, while those obtained following coronary balloon angioplasty were not, is merely speculative.

Limitations

This study was aimed to assess the usefulness of the IVUS parameters obtained at the smallest free lumen area site to predict success or failure of PTA in the superficial femoral artery. Other parameters such as patients' demographic data, the type and calibre of balloon used, qualitative angiographic data, run-off and IVUS data of adjacent segments were not taken into account. The IVUS cross-sections used (the smallest free lumen area) were obtained after off-line analysis. However, in order to use IVUS as a decision-making device during intervention one should be able to pinpoint the haemodynamically significant obstructive stenoses. This implies that the investigator needs to have the skill to recognize on-line the significance of the bottle-neck evidenced by IVUS. Images should be immediately reviewed and quantitatively analysed. Although semi-quantitative analysis of % area stenosis can readily be performed,[4] free lumen area and diameter are more difficult to assess — particularly because PTA causes extensive irregularity of the free lumen area contour. Thus, for on-line quantitative analysis, appropriate analytic equipment is required.

Conclusion

This study indicates that IVUS data obtained following PTA may predict whether a patient is likely — or not — to have a long-term, event-free outcome. Failure is more likely to occur in the presence of a large dissection and a small residual free lumen area and diameter evidenced following PTA. Other qualitative and quantitative IVUS parameters seen before and after PTA were considered to be of no prognostic value. The finding on IVUS of significant luminal narrowing at sites with minor diameter stenosis on angiography (< 50%) underscores the difficulty to accurately assess luminal narrowing using angiography alone.

A large number of failures after angiographic successful (< 50% diameter stenosis) PTA have been shown to occur within the first month (53%). This observation suggests that residual stenosis rather than restenosis due to fibrocellular tissue response may be the underlying mechanism responsible for the failures evidenced. A second significant determinant of failure noted in this study may be the length of the diseased segment. Nonetheless, the large number of successfully treated lesions seen in Group I justifies an aggressive approach when attempting angioplasty of lengthy obstructive superficial femoral artery disease.

Our results have important prognostic implications. Knowing the IVUS parameters associated with an adverse outcome this information may be helpful to more rationally decide when reintervention is indicated. The information could, in addition, be used to indicate which of the available therapeutic options (additional PTA, atherectomy, stent implantation or bypass surgery) is warranted for the individual patient.

Confirmation of the hypothesis that free lumen area and diameter seen on IVUS after PTA may serve to influence the course of interventional management might be gained in the near future when more patients in this multicenter study have a complete follow-up.

Note

Recently, 4 additional hospitals were willing to participate in this study, namely: Maria Hospital Tilburg, Catharina Hospital Eindhoven, Groot ZiekenGasthuis Den Bosch, and Slingeland Hospital Doetinchem. Follow-up of these patients is not completed.

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