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Non-invasive Assessment of Arterial Stenoses in Angioplasty Surveillance: A Comparison with Angiography

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Objectives: *Comparison of non-invasive arterial measurements with angiography and their use for angioplasty surveillance.*
Design: *Prospective assessments of arterial stenoses in patients undergoing angioplasty in a 9 month surveillance period.*
Materials: *Fifty consecutive patients undergoing angioplasty.*
Methods: *(i) One hundred and thirty-one sets of clinical assessments, ankle brachial Doppler pressure indices and colour Duplex velocities and diameters were compared to time-matched angiographic diameter stenosis. (ii) Fifty patients undergoing femoropopliteal angioplasty (32 stenoses and 18 occlusions) were studied with ankle branchial Doppler pressure indices and colour Duplex and angiography during a 9 month surveillance period.*
Results: *(i) Symptoms, pulses, resting ABPI, and exercise ABPI showed no useful correlation with angiography. Duplex velocity ratio and Duplex diameters showed correlation and agreement with angiography respectively. (ii) On surveillance, restenosis was universal but not always clinically significant. Angioplasty caused a rapid improvement in ABPI and imaging studies which worsened at later times. ABPI did not predict clinical failure however, Duplex and angiography predicted all clinical failures.*
Conclusions: *Restenosis should be assessed with imaging of the angioplasty site during angioplasty surveillance.*

Key Words: Angioplasty; Restenosis assessment; Angiography; Duplex; Surveillance.

Introduction

Restenosis, the progressive loss of the luminal diameter achieved by angioplasty, is the major factor which complicates peripheral angioplasty. Paucity of reported studies with effective imaging surveillance has prevented objective documentation of changes at angioplasty sites. Arterial stenosis has traditionally been defined with angiography. However, in most studies stenosis based on pulses and ankle brachial Doppler indices (ABPI) have been used to classify lesions and restenosis rates based on arbitrary cut-off limits are reported.[1–10] Pulses and ABPI assessments of stenoses are of limited value because they are not specifically related to the stenosed artery site. Angiography is an invasive procedure and the "gold standard" but recent reports using Duplex ultrasound to measure arterial stenoses have validated this assessment.

We report a prospective study of 50 patients undergoing femoropopliteal angioplasty in whom ankle brachial Doppler indices, Duplex ultrasound and angiography have been used to assess restenosis during a 9 month surveillance study. In a preliminary analysis of the data clinical assessment, resting and exercise ankle brachial Doppler indices and Duplex ultrasound measurement of arterial stenoses were compared to simultaneous angiographic measurements.

Materials and Methods

Prospective surveillance studies were undertaken in 50 patients with lifestyle limiting lower limb claudication who were underwent arterial investigation. The median duration of symptoms was 18 months (range 3–84 months). All patients who underwent outpatient angiography and, at later date, femoropopliteal angioplasty were entered into the study. Angioplasty was performed via an antegrade puncture of the common femoral artery via a 6F sheath inserted under local anaesthesia. The lesion was crossed with a guide wire,

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laser fibre or laser ablation prior to standard balloon angioplasty following administration of 2000–3000 units of heparin. All patients commenced or continued on 75 mg of aspirin postoperatively for an indefinite period.

Arterial patency was assessed after the outpatient arteriogram and 1 day after angioplasty using non invasive tests as follows: symptoms, pulses, resting and exercise ankle-brachial Doppler pressure indices (ABPI), and Duplex ultrasound. At the initial clinical assessment the history of the presenting complaint was taken and the claudication distance was measured by walking on a treadmill. Claudication distances were graded as follows: grade 1 = 15–100 yards, grade 2 = 100–400 yards, grade 3 > 400 yards. Pulses were graded for their presence and strength, by comparing them to the opposite limb pulse where present, or using estimations based on the trained clinical experience of the main researcher (IN) as follows: no pulse 1, weak pulse 2, normal pulse 3.

ABPI measurement of arterial pressure was performed by taking the first audible indication of pulsatile flow on releasing an occluding tourniquet. Duplex ultrasound scanning was performed with an Acuson 128 (Acuson Computer Sonography, U.S.A.) and extended from the common femoral artery to the tibioperoneal trunk in all cases. In the presence of multiple stenoses the target lesion was identified initially by reference to the preangioplasty angiograms and later by permanent ink skin marks which were placed and then photographed under fluoroscopic guidance, at the time of angioplasty.

Duplex diameters were measured as the colour-filled lumen on longitudinal images of the artery at the point of the highest systolic velocity and also at a nearby normal artery. Although the imaging studies are the best available methods of arterial assessment the presence of multifocal lesion can make some measurements unreliable especially if the normal adjacent artery also has some disease present.

Percent diameter stenosis (PDS) was measured on Duplex as the ratio of the diameter reduction at the stenosis to the diameter of the "normal" lumen (i.e. no lumen = 100% diameter stenosis). Peak systolic velocity (PSV) was measured on Duplex ultrasound after the cursor had been positioned in the centre of the arterial lumen and at an angle of insonation at 60°. Three recordings of the PSV at the angioplasty site was compared to that at the proximal area of "normal" artery, and a velocity ratio (VR = mean lesion PSV/mean "normal" PSV) was calculated. Non-invasive tests were repeated at 1, 3, and 6 months and 9 months, or earlier if symptoms returned. These tests were compared to arteriography by assessing complete sets of studies which were obtained during the surveillance study. Angiographic assessment included imaging of the limb vasculature down to and including the crural vessels. Diameters were measured by the consultant vascular radiologist (MR) who did not know the results of the NIAA, and PDS was calculated as above.

Angiography was repeated at 6 months, or at the time of clinical deterioration. Correlations coefficients were used to assess the value of symptoms, pulses, resting and exercise ABPI and Duplex velocities as predictors of single view angiographic stenosis. Duplex diameters were compared to angiography by assessing the agreement between the two methods.

Surveillance results are presented for pulses, resting and exercise ABPI, Duplex diameters and velocities and angiographic diameters. The restenosis report includes early technical failures according to the intention-to-treat method. Primary success rates have been analysed by the Kaplan-Meier life table method. Ethical approval was obtained from the Ethical Committee of the Middlesex Hospital and a fully informed written consent was obtained from all patients prior to the study for regular follow-up with Duplex ultrasound and angiography.

Results

The 50 patients studied all had intermittet claudication and the patient details are shown in Table 1. Their median claudication distance of 100 yards (range 15–800 yards) (Table 2).[12] On the initial arteriogram all patients had lesions which were confined to the femoropopliteal arteries and no inflow problems were seen. There were 32 stenoses (median length 10 mm) and 18 occlusions (median length 45 mm). The calf vessel runoff was good (two or three runoff vessels) in 48 patients, one had only one runoff vessel and the other had collaterals only. Only one limb was treated

Table 1. Details and vascular risk factors for the 50 patients who underwent the surveillance study.

Sex	31 men	19 women
Median age	67 years	range 40–80
Smoking	22 smokers	
	20 ex-smokers	
	8 non-smokers	
Hypertension	5	
Diabetes	5	
Hyperlipidaemia	1	
Angina	7	
Previous myocardial infarction	4	
Previous stroke	2	
Aspirin	15	

Table 2. Symptom classification by SVS/ISCVS guidelines.

Category	Patients
1	19
2a	7
2b	3
2c	17
2d	3
3d	1

in each patient. In addition to the target lesion 10 patients had one, three patients had two and one patient had three additional stenoses treated.

One hundred and thirty-one synchronous sets of angiograms and non-invasive tests (obtained pre-angioplasty, postangioplasty and at 6 months) were compared. Symptoms and pulses showed no correlation with angiographic diameter stenosis. Resting ABPI and exercise ABPI showed a generalised decreasing trend with increasing angiographic PDS, Duplex velocity ratio showed a generalised increase with increasing PDS (Fig. 1a). PDS determined by Duplex showed virtually 100% correlation (Fig. 1a).[13] We have assessed by how much Duplex PDS is likely to differ from the arteriographic PDS and Fig. 1b shows this comparison. In the surveillance study 50 angioplasties were attempted of which six were not successful and four developed acute occlusions within 24 h of angioplasty. Thus, 40 patients (80%) underwent surveillance. Eleven of these 40 patients (22%) required re-intervention because of marked deterioration in clinical symptoms during the 9 month period of the study. Seven patients (14%) had left hospital after a primary successful angioplasty (six failed within 3 months and only one failed at 7 months). Two patients who underwent successful angioplasty and who had good luminal patency at their 6 month assessment failed to attend for the 9 month assessment. The primary clinical success rate was 66% at 9 months. The surveillance results were expressed by the Kaplan-Meier life table analysis method (Fig. 2). Greatest failure occurred within 24 h of angioplasty (20%), thereafter another group of patients failed within 3 months (12%). Two patients showed no improvement in popliteal pulse or ABPI despite technically successful angioplasty being confirmed on both DSA and Duplex ultrasound. Both had further disease of the distal superficial femoral artery.

Mean pulse grades rose from 1.72 to 2.75 in response to angioplasty. Although there was no pulse in eight failures (grade 1), three patients who failed at 3 months had a weak pulse (grade 2). In contrast, three patients who did not develop symptoms had no pulse (grade 1) and three others had weak pulses (grade 2) during the surveillance period. Both resting and exercise ABPI showed marked improvement which was maintained at 3 months (Fig. 3). At later times there were reductions in the ABPI values for the total population towards the preangioplasty levels. ABPIs of angioplasty failures always fell below the median values of primary successes. However, there was overlap with the population range which was more marked for resting than for than exercise ABPI. No absolute measurement of ABPI (resting or exercise) was predictive of clinical failure.

Angiography and Duplex ultrasound imaging demonstrated gradual luminal loss (restenosis) from the immediate postangioplasty lumen with time in almost all patients, however, this was not often clinically significant. These imaging modalities detected all failures (Fig. 2). The maximum Duplex velocity ratio for primary success was 2.8 whilst the minimum velocity ratio for patients who failed was 3.8 (except for occlusions who had velocity ratios of zero). Duplex diameters were comparable to the arteriographic findings. Both showed increasing PDS with time. Primary successes differed from the failures. The maximum PDS for primary successes for both Duplex and angiography fell below 60% whilst the minimum values for failures were always greater than 60%. In addition in two patients who developed new stenoses at other sites during the follow-up period these lesions were identified by both Duplex and arteriography. There were no patients in whom Duplex identified a stenosis which was not confirmed on the arteriography.

Discussion

Non-imaging non-invasive measurements of arterial stenosis showed poor correlation with angiographic stenosis although ABPI and Duplex velocities showed a consistent trend. Duplex diameter measurements showed good agreement with angiographic diameters. In both methods the measurement is localised to the diseased segment and site specificity is ensured. Duplex velocity measurement which also localises to the site of angioplasty did not, at first sight, show useful correlation with angiographic diameters. The main reason for this discrepancy was the abrupt reversal of velocity ratio from a high value to zero when a tightly stenosed vessel occluded. When total occlusions were excluded velocities showed better correlation with angiography. This agreed with previous studies which have shown Duplex velocities to be a good predictor of angiographic stenosis.[14,15] The high correlation shown between Duplex and arteriographic PDS indicated that the two methods were

linearly related, however, it did not necessarily mean the two methods agreed. In this study, Duplex measurements tended to give readings within 0.16 of the arteriographic mean. The limits of agreement (–0.18 and 0.14) were consistent with interobserver variability on angiography measurement[16] and allow us to use Duplex percentage diameter stenosis as a measure of arteriographic percentage diameter sten-

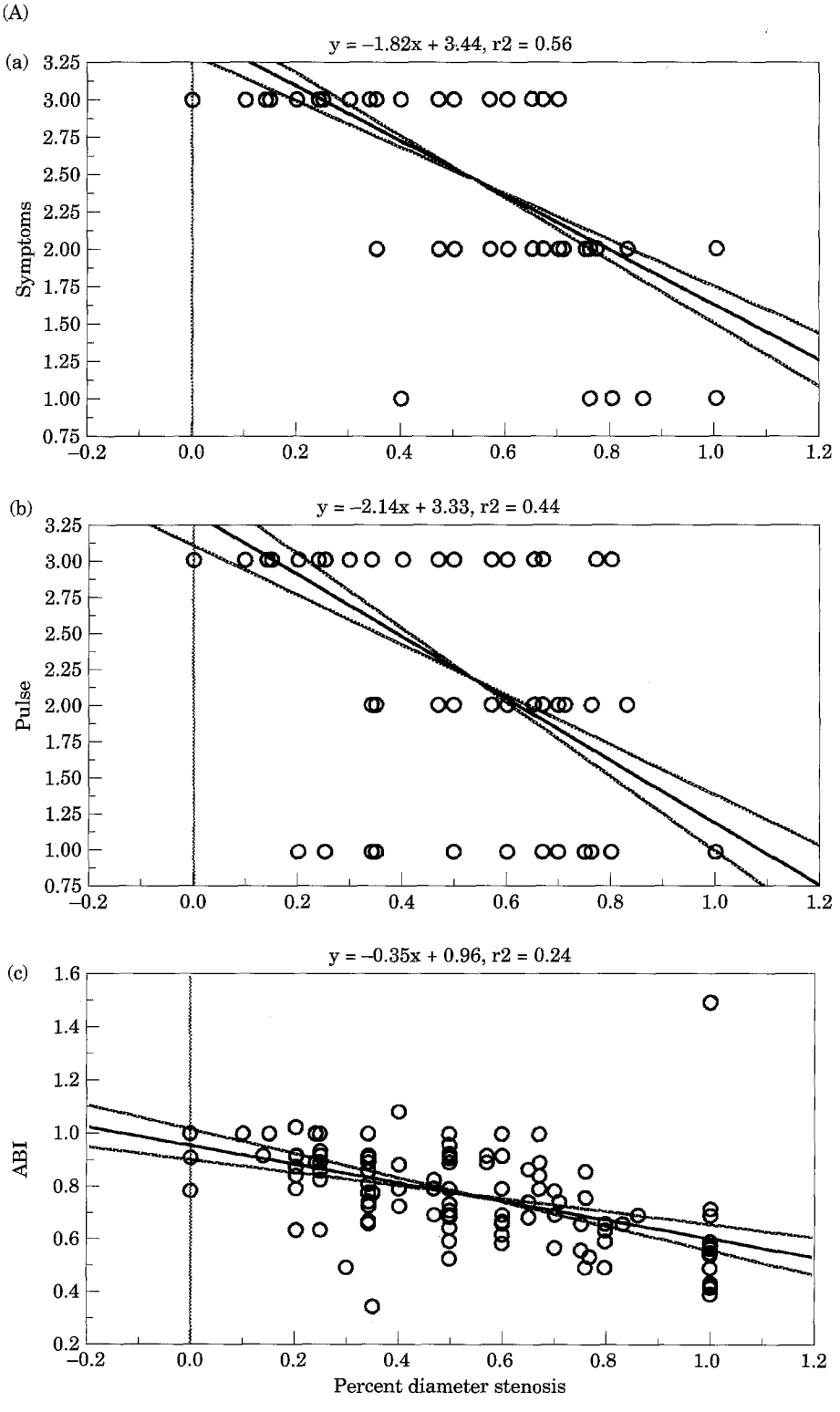

Fig. 1A (a–c).

osis. During surveillance pulses and symptoms proved unreliable for predicting angioplasty success or failure. ABPI was lower for clinical failures than for the primary successes, however, the two populations were not mutually exclusive. We found that velocity ratios of up to 2.8 could be associated with an asymptomatic state whilst the minimum velocity which was consistently associated with symptoms

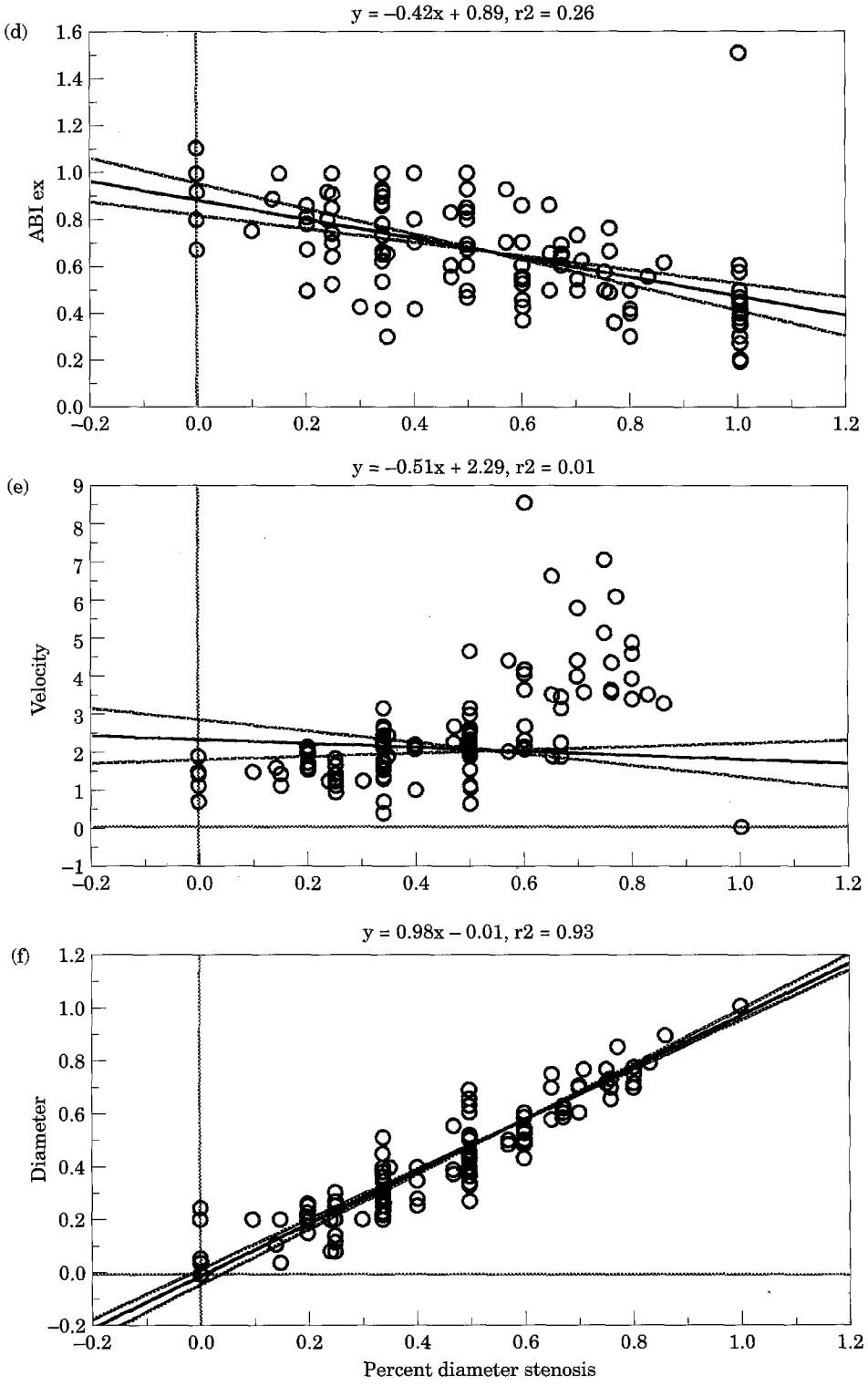

Fig. 1A (d–f).

was 3.8. These velocity results contrast with those of Legemate *et al.* who reported that Duplex velocity ratios of 2.5 correlated better with symptoms.[15] The relationship between velocity and symptoms appears complex and requires further study. Duplex and angiographic diameters clearly differentiated clinical failures and primary success on surveillance. Reporting PDS for individual patients may be more useful than percentages of patients who have been classified according to artificial diameter losses. Choosing 50% or 75% PDS to define restenosis in a population will give markedly different rates. Our angioplasty failure rate of 34% (based on individual measurements) can be compared to the failure of 54% rate reported by Vroegindeweij *et al.* based on arbitrary classification for failure of greater than 50% stenosis (Duplex and angiography).[19] They found that severe calcification of vessels prevented Duplex visualisation of stenoses, however, we had no patients in whom the extent and severity of calcification prevented effective Duplex assessment of the diseased arterial segment. Other limitations in the Duplex ultrasound diagnosis of lower limb arterial stenoses, as a result of the presence of adjacent segment disease, have recently been highlighted.[17]

Restenosis rates of between 10 and 60% are reported for peripheral angioplasty.[18] Retrospective clinical series have inherent methodological problems. They use subjective criteria such as symptoms and indirect measurements such as clinical signs and ABPI. These may underlie the wide variations in restenosis rate. In addition to the methods of assessment used, inconsistencies in reporting such as variations in case selection, exclusion of initial failures, inclusion of redilatations and the use of different definitions of restenosis also cause confusion.[1–11] Restenosis may not be directly represented by a recurrence of symptoms or the loss of peripheral pulses either because collaterals may develop to improve the blood supply to the limb or the patients activity may be markedly altered after angioplasty. Symptoms, pulses, and ABPI provide useful information on the blood supply to the whole limb, however, they may give little information about the changes at the local sites of treatment. Development of new lesions at other arterial sites, or increase in collaterals around a stricture, influence indirect assessments independently of changes at the angioplasty site. In only one recent report has a prospective study of peripheral restenosis with adequate angiographic or Duplex follow-up been used.[19] Our correlation studies illustrated how restenosis rates could be markedly altered by small changes in the particular PDS value used in its definition. Thus even when imaging methods are used restenosis and restenosis rates from different studies may not necessarily be comparable. Although restenosis rates based on the intention-to-treat basis are desirable, in many series of endovascular procedures only the outcome of

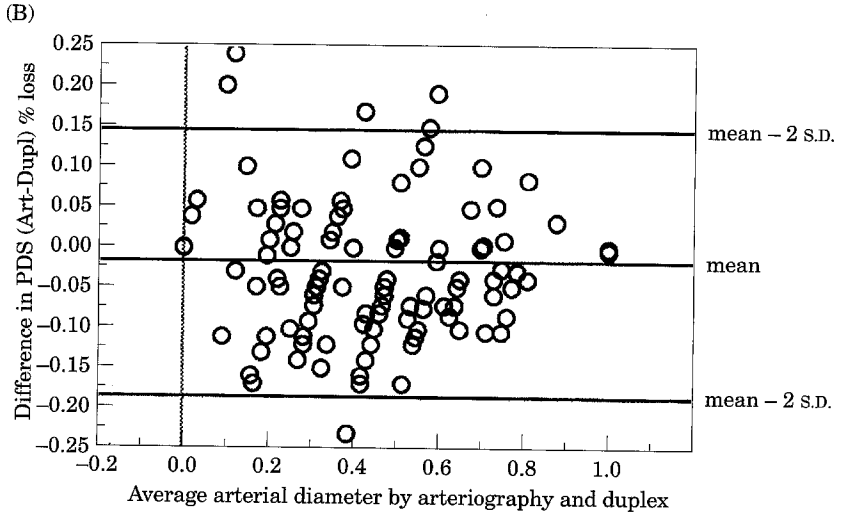

Fig. 1. (A) Graph showing the relationship between percent diameter stenosis measured on arteriography on the x-axis and the following on the y-axis: (a) claudication severity (1 is poor and 3 is good claudication distance); (b) pulse palpation (1 is no pulse and 3 is good pulse); (c) resting ABPI; (d) post-exercise ABPI; (e) Duplex velocity ratio; (f) Duplex diameter stenosis. 'r^2' is the square of the correlation coefficient. The linear regression line and 95% confidence limits for the slope of regression line are shown. Only Duplex diameter showed good correlation with angiographic diameters. ABPI: ankle branchial Doppler pressure indices, V1/V2: Duplex velocity ratio, PDS: percent diameter stenosis. (B) Difference between the mean for PDS data. Graph showing the agreement between percentage diameter stenosis (PDS) measured on arteriography (Art) and Duplex (Dupl). The mean differences is 0.02% with 95% confidence interval −0.16 to 0.11. This shows that most of the differences lie within 2 standard deviations (S.D.) = 0.08) of the mean of 0.02.

the technically successful cases has been analysed. Series which begin with primary successes will have lower restenosis rates.[1,21]

Restenosis rates based on standardised classifications such as that recommended in the guidelines of the Society for Vascular Surgery/Interventional Society for Cardiovascular Surgery (SVS/ISCVS) appear sensible in allowing comparison of reported

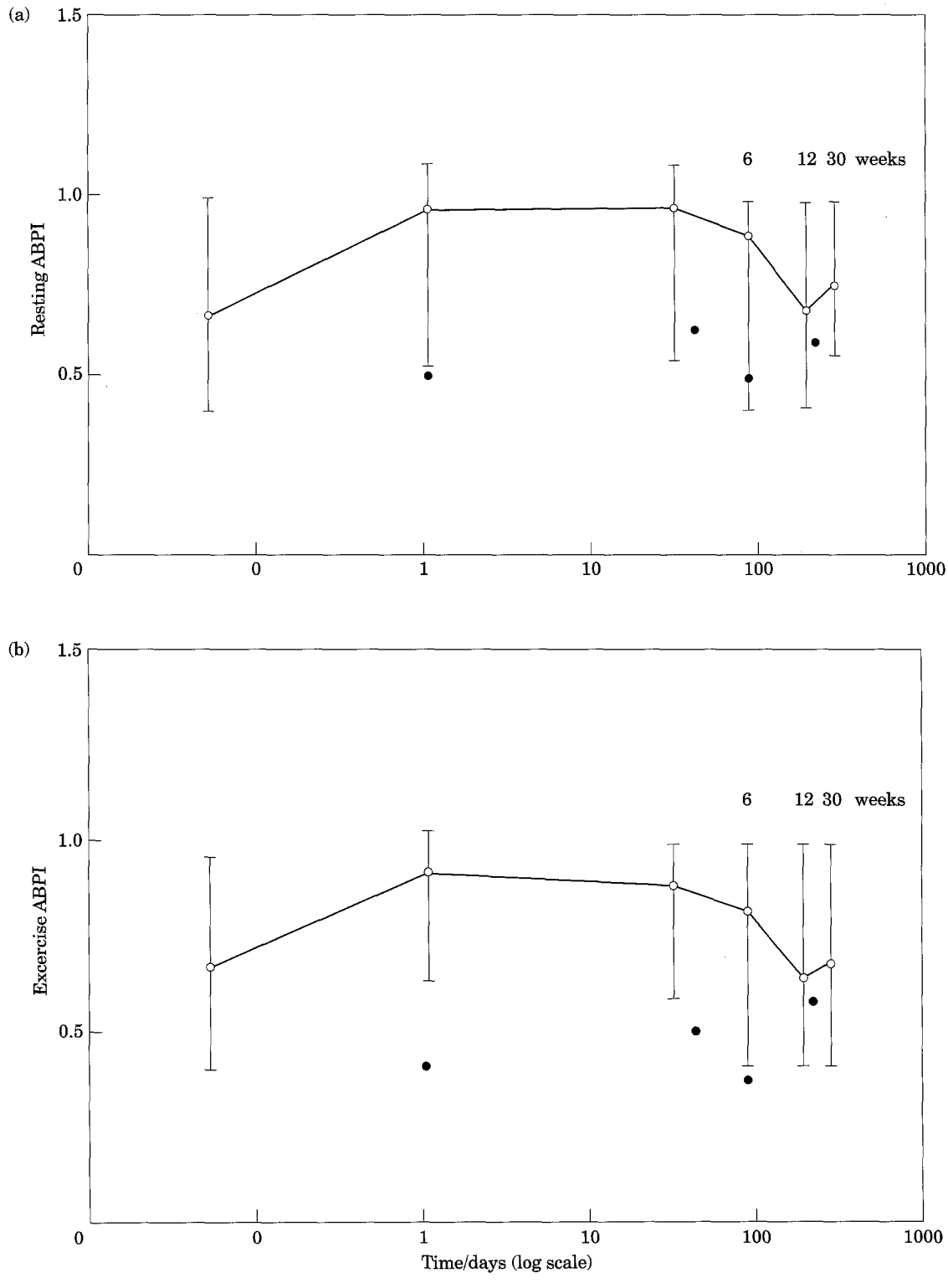

Fig. 2 (a–b).

studies.[12,21] Standardised classifications involve grouping together sets of measurements for convenience of analysis, however, in so doing important individual patient data is sacrificed. The SVS/ISVS recommendations group together clinical symptoms and ABPI to produce a composite measure of patency, but this does not improve the sensitivity or specificity of the individual measurements.

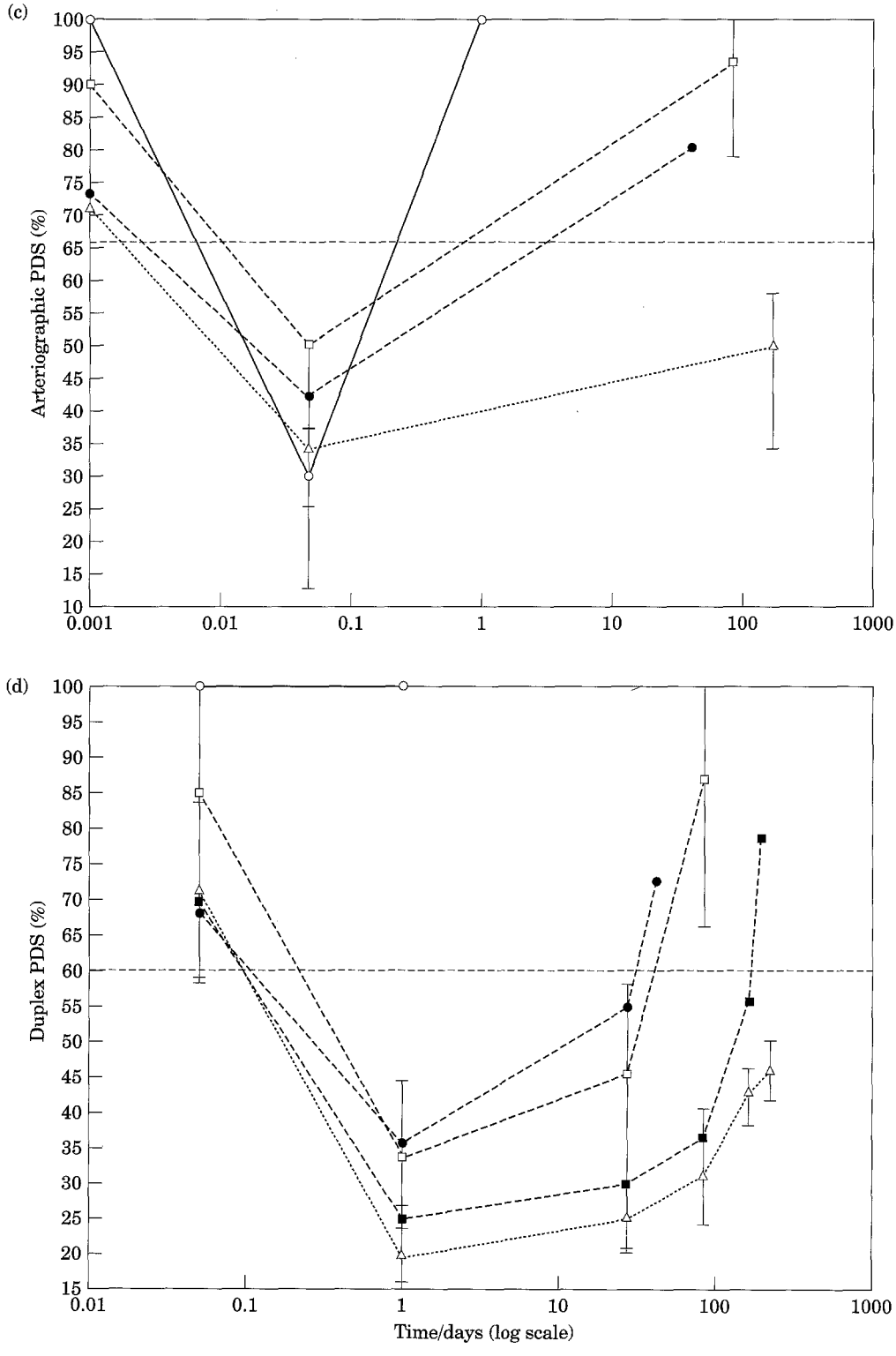

Fig. 2 (c–d).

Measurement of absolute minimal luminal dimensions by biplanar angiography represent an improvement on uniplanar views for measuring restenosis. Biplanar views increase the accuracy of arterial disease detection however this is rarely used in routine practice except where a suspicious lesion requires further clarification.[22] Multiple angiographic views would be required for full definition of eccentric stenoses and the irregular borders produced by angioplasty. Limitations of angiography have been confirmed by intravascular ultrasound measurements of angioplasty luminal dimensions.[23] Our justification for using single view angiography (our current surveillance) rather than biplanar views was because we compared the non-invasive tests to the current practice.

We have shown that some degree of angioplasty "restenosis" is almost universal although it may not be clinically significant. Restenosis appears to be a continuously evolving process in all patients. Using serial angiography in clinical coronary angioplasty. Serruys *et al.* and Nobuyoshi *et al.* showed restenosis to occur within 3–6 months of intervention.[25,26] In the present study all but one patients who developed angioplasty failure did so within 3 months of the procedure. The time-course of restenosis previously shown for coronary angioplasty is now demonstrated in the peripheral circulation.

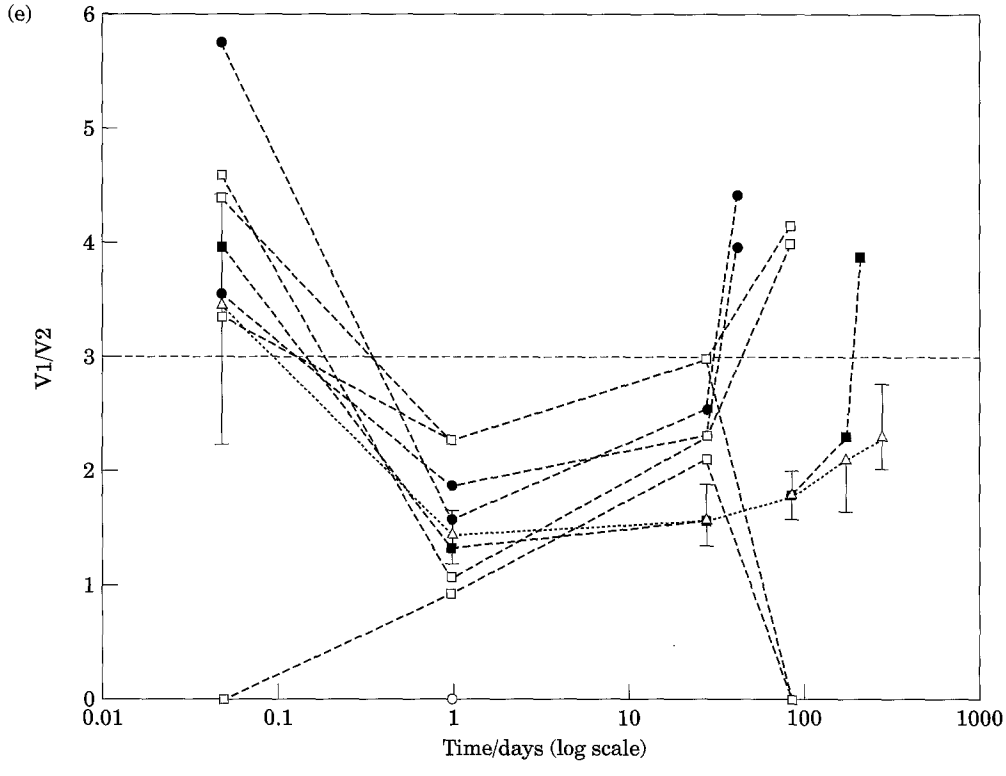

Fig. 2. (A) Temporal changes on angioplasty surveillance. (a) Graphs showing resting ABPI on the y-axis against time, in the log scale, on the x-axis: Overall angioplasty causes a rapid improvement in ABPI. These values fall with time and approach the preangioplasty levels at 9 months. ABPI for clinical failures fall below the median values of non failures but overlap with some of normal population. (○) ABI rest; (●) failures rest. (b) Graph showing exercise ABPI on the y-axis against time, in the log scale, on the x-axis. This shows early improvement and later deterioration similar to resting values. Exercise ABPI showed less overlap with clinical failures than did resting ABPI. (○) ABI ex; (●) failures ex. (c) Graph showing arteriographic PDS on the y-axis against time, in the log scale, on the x-axis. This shows increasing PDS with time for all patients; however, the increase was more pronounced for patients who required re-intervention. (—○—) acute reocclusions; (– – –●– – –) failures at 6 weeks; (– – –□– – –) failures at 12 weeks; (– – –■– – –) failures at 30 weeks; (...△...) PTA success. (d) Graph showing Duplex PDS on the y-axis against time, in the log scale, on the x-axis. This shows increasing PDS with time for all patients. The increase was more pronounced for patients who required re-intervention. (—○—) acute reocclusions; (– – –●– – –) failures at 6 weeks; (– – –□– – –) failures at 12 weeks; (– – –■– – –) failures at 30 weeks; (...△...) PTA success. (e) Graph plotting Duplex velocity ratio (V1/V2) against time (in the log scale) on the x-axis for individual patients who required reintervention for PTA failure. This shows a large increase of velocity ratio with time for patients who failed by restricturing. Reocclusions all have zero velocity in the lumen. (—○—) acute reocclusions; (– – –●– – –) failures at 6 weeks; (– – –□– – –) failures at 12 weeks; (– – –■– – –) failure at 30 weeks; (...△...) PTA success. Values of measurements are shown for individual patients who underwent successful PTA and had subsequent failure. Median values and interquartile ranges are shown for patients who did not require further intervention for failure.

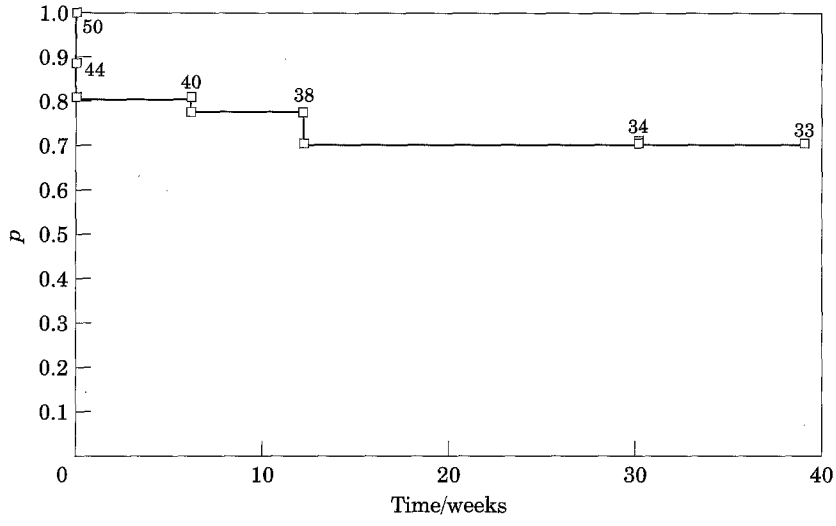

Fig. 3. Graph showing the probability of continued patency of PTA (i.e. avoiding re-intervention) against time. This shows the failure rate after PTA. The two early drops represent uncompleted PTAs and acute occlusions which occurred within 24 h of successful PTA respectively. Two further loss events are seen at 6 and 12 weeks, after which only one patient failed to the end of the observation period at 40 weeks.

Objective clinical studies using Duplex and angiographic surveillance have been reported more recently. Miller *et al.* reported on 69 patients with a technical success rate of 90% but a 9 month patency of only 45%. This poor intermediate success led them to advise caution and restraint in the use of angioplasty. Henderson *et al.* also reported on 52 patients who underwent angioplasty with Duplex follow-up at 6 months, and in whom only 20% had no restenosis.[26] This study is difficult to interpret because there were many exclusions from their initial number of 52 patients. Vroegindeweij *et al.* have reported on 62 patients with a technical success rate of 82%, and with Duplex and angiographic follow-up to 3 years.[27] Their restenosis rates at 1 and 3 years were 58% and 33% for Duplex and 53% and 30% for angiography respectively. In comparison we have reported 88% technical success and 34% significant restenosis rate on both Duplex and angiography. These studies have shown that colour Duplex ultrasound appears to be a good method of angioplasty surveillance, however it has important limitations in the presence of multiple stenoses.[28]

Restenosis rates should be reported using the life table method. For example, in our study, the rate of clinical failure could be 34% or 17.5% depending on whether the figures were analysed on an intention-to-treat basis or whether only those who left hospital with primarily successful angioplasties were considered.

The clinical and non-invasive tests used to monitor peripheral angioplasties to date have not provided the accuracy of information which is required if interventions aimed at preventing restenosis are to be critically assessed. In clinical trials of interventional vascular procedures aimed at preventing restenosis the angioplasty site must be imaged directly. Such imaging avoids the confusion that occurs when the arterial anatomy and the symptoms are de-coupled. Imaging studies are likely to be the most sensitive methods for detecting small changes at the angioplasty sites that may occur during angioplasty surveillance. Duplex compared very favourably to arteriography in the assessment of angioplasty treatments. As it is non invasive this should the preferred method of imaging endovascular treatments in leg arteries.

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