FIVE YEARS OF PERIPHERAL PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY: THE ST. LUKE'S HOSPITAL EXPERIENCE.

A. Zammit, D. Gatt, D. Mallia

ABSTRACT

This article reviews the first series of 54 cases of Percutaneous Transluminal Angioplasty on the peripheral vasculature performed at the Radiological/Surgical Department at St. Luke's Hospital, Malta, over a five year period. After describing in detail the technique used, the indications and the objective criteria utilised for assessment are reviewed and analysed. The two year patency rate for femoro-popliteal and iliac stenoses was 93% and 86% respectively, while for corresponding occlusions, the figures were 42% and 0% respectively. Thus, while the results were very encouraging for femoro-popliteal stenoses and occlusions, they were unacceptable for iliac occlusions. As expected the major risk factors were smoking, diabetes mellitus and associated ischaemic heart or cerebrovascular disease. This series had no mortality and there was minimal morbidity, mainly at the site of arterial access. Elective surgery for iliac re-stenosis was only required in one patient.

Keywords: *percutaneous transluminal angioplasty, femoro-popliteal stenosis, iliac stenosis, risk factors, morbidity*

Introduction

Despite some sporadic successful attempts at Percutaneous Transluminal Angioplasty (PTA) on the peripheral arteries in 1986/87 the first determined effort at an organised peripheral angioplasty service commenced at the Radiological Department`s Angiography Suite at St. Luke's Hospital on 16th February 1988. In PTA atheromatous plaques causing stenosis or occlusion of arteries are crushed against the arterial wall by means of a balloon inserted percutaneously. This technique was first introduced in 1964 by Dotter and Judkins. [1] In the Dotter technique coaxial catheters of increasing diameters (catheters that can be threaded progressively onto each other) were introduced into the stenotic or occluded artery. This method invariably necessitated that any degree of arterial dilatation had to be accompanied by an undesirable similar dilatation of the puncture site. The resultant large puncture site inevitably gave rise to haemorrhagic problems which limited the effectiveness and use of the technique in this form. In 1974 Gruntzig and Hopff [2] managed to overcome these problems by the introduction of what is now familiarly known as the Gruntzig Balloon catheter. In this catheter, a double lumen balloon permits the introduction of a guide wire through one lumen, and the injection of contrast under high pressure into a specially constructed balloon which expands with uniform and parallel walls to a predetermined diameter, through the other. Angioplasty is an alternative and complimentary therapeutic method to vascular surgery for peripheral vascular disease and nowadays is often used in patients who would not previously have been treated due to their poor general condition or due to the mildness of their

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symptoms. Percutaneous transluminal angioplasty is indicated for haemodynamically significant stenoses (stenosis greater than 50%) and for treatment of short occlusions (less than 5 cm in length). Occlusions that are longer than 5cm are best tackled surgically since with angioplasty the results are poor. Three year patency rates of approximately 85% after aorto-iliac and 65% after femoro-popliteal angioplasty can be expected[3] and there is no doubt that some angioplasties are performed instead of surgical reconstructions. Gruntzig and Kumpe described their modified Technique of Angioplasty for the first time in the English language Medical literature in 1979.[4] In order to dilate the diseased segment by this method, a common femoral artery approach is used with retrograde catheterisation for the iliac segments and antegrade catheterisation for the femoro-popliteal segment. Lesions involving the common femoral artery cannot be tackled from the ipsilateral side due to reduced space for manipulation and contralateral common femoral approach with a cross-over technique is necessary. Angioplasty on the infra-popliteal arteries have not yet been carried out locally. The following is a summary of the technique. After arterial puncture a guidewire is passed through the stenosis or obstruction and this is followed using Seldinger technique by a Gruntzig catheter. The Angioplasty catheter is then inflated to around 8 to 10 atmosphere pressure to compress the atheroma into the arterial wall and widen the narrowed or obstructed segment. Research has shown that atheroma is not only flattened into the arterial wall but there is a widening of the wall at the angioplasty site. There are various sizes of balloon diameters ranging from 4-10 mm for use anywhere from the iliac to the popliteal segments, the balloon being chosen to match the diameter of the artery. Primary failures of the technique resulting in unsuccessful angioplasty is often the result of failure to pass the guidewire through the obstructed segment. This type of failure is more unlikely with stenotic segments which are usually easily bypassed by the guidewire.

Method

Fifty four consecutive patients referred for PTA were included in this study. The study took the form of a detailed assessment of each patient at various stages after the angioplasty. The series details are shown in Table I.

Vascular Region	**patients**
Iliac	9
Femoro-popliteal	36
Total	45
PATIENTS EXCLUDED FROM SERIES:	
Non-compliant	5
passed away (> 1 month after) *	2
not traced by computer	2
Total	9
Total Overall	**54**

* If before one month this would be a complication of Angioplasty.

Table I - PTA sample

The Fontaine Classification was utilised to assess the degree of disease severity as is shown in Table II.

GRADE I	ASYMPTOMATIC
GRADE IIA	MILD CLAUDICATION > 250 METRES
GRADE IIB	DISABLING CLAUDICATION < 250 METRES
GRADE III	REST PAIN/ISCHAEMIC NIGHT PAIN
GRADE IV	TISSUE LOSS/ULCERATION/GANGRENE

Table II - Fontaine Classification of severity of peripheral disease

We have found this classification useful both in the history related assessment and in treadmill exercise testing. The success of the angioplasty was gauged by using a series of objective criteria that could be assessed by evaluating symptomatic improvement, treadmill exercise tolerance, measurement of ankle/brachial pressure indices, colour/duplex ultrasound examination and angiography or IV DSA where indicated. (See Table III).

Clinical success:	1) A non-palpable pulse being restored. 2) Improvement of one grade in Fontaine classification.
Treadmill Exercise Testing:	1) Intermittent claudication distance doubled. 2) Improvement of one grade in Fontaine classification
Ankle-Brachial Indices:	1) An increase of 0.1 to 0.2
Colour / Duplex Ultrasound:	1) Monophasic waveform becomes Bi- or Triphasic distal to the stenosis. 2) Velocity Ratio < 2 at the Angioplasty site.
Angiography / IV DSA:	1) Residual stenosis < 30 %.
Pressure Measurement:	1) A pressure gradient should be < 5mm Hg.

Table III - Criteria for Angioplasty Success Assessment.

Angiography and IV DSA were avoided as far as possible as they were considered invasive procedures. From the clinical point of view direct patient questioning was essential in order to determine changes in the claudication distance and all claims of such improvements were cross tested by means of treadmill exercises. All peripheral pulses were examined digitally and restoration of common femoral, popliteal, dorsalis pedis or posterior tibial pulses noted and recorded. As already mentioned all patients underwent treadmill exercise testing and their ankle/brachial indices were measured utilising continuous wave doppler ultrasound from the dorsalis pedis artery and the brachial or radial arteries by placing pneumatic pressure cuffs on the calf and on the arm. These systolic pressures are then given as a ratio of ankle systolic pressure over the brachial systolic pressure and the index thus produced is a highly sensitive indicator of the degree of peripheral vascular insufficiency. An increase of 0.1 - 0.2 in this index is equivalent to angioplasty success. In our vascular assessment we followed up pressure measurements with doppler ultrasound (Duplex US) scanning . Duplex US[5-7] and lately colour doppler ultrasound[8,9] are non-invasive methods of assessment of PVD or follow-up after procedures such as angioplasty or surgery. Duplex ultrasound has been found to be useful in the haemodynamic assessment of PVD and Sacks et al[6] have found Duplex US reliable in the detection of residual stenosis after PTA. In view of the fact that the same authors have warned that duplex US performed immediately after PTA is frequently misleading, we have carefully avoided the early post-PTA period for our follow up assessment. In our study all Duplex US scans were performed from 4 weeks to a year after the procedure. All Duplex examinations were performed using ATL Ultramark 4 with a 5MHz Rotating Transducer with a directable pulsed doppler angle with simultaneous real-time imaging and doppler wave form acquisition. We have constantly utilised an angle of 60 degrees throughout the study. Duplex US sampling from normal peripheral arteries results in a triphasic waveform with forward systolic flow, followed by a reverse flow in early diastole, followed by a forward mid-diastolic flow.

Such flow patterns occur in high resistance circulation such as is the case in the peripheral arteries (Fig I) as opposed to a low resistance circulation where continuous flow is essential to supply such organs as brain or kidneys.

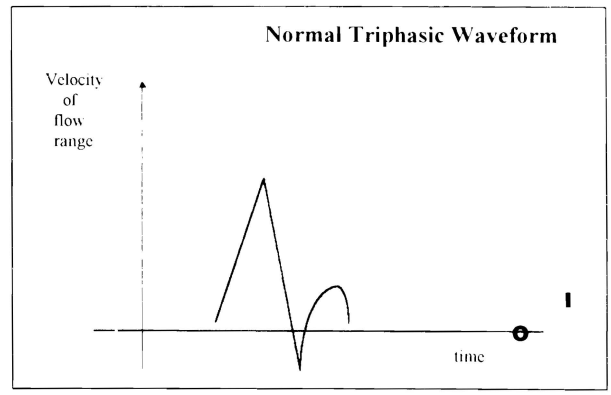

Figure I- Normal Triphasic Waveform.

Beyond a significant stenosis, flow is dampened and a monophasic waveform results which is lower in peak systolic velocity than normal. At the actual stenosis the events are different. The flow increases in a haemodynamically significant stenosis. Thus the velocity at the stenosis as compared to the velocity just proximal will be double or more if the stenosis is 50% or more. The reverse is true when a significant stenosis is corrected after angioplasty and the velocity ratio at the angioplasty site should be less than two. The velocity ratio is the velocity at stenosis divided by the velocity just proximal to the stenosis. The criterion for significant stenosis on Duplex US studies was an increase in peak systolic velocity of at least 100% compared to the velocity in the arterial segment proximal to the lesion. This is equal to a velocity ratio ≥ 2.0. With Duplex US, the normal triphasic or biphasic (this occurs when the positive diastolic flow is absent) waveform will change to a monophasic flow in disease and the reverse is true after success in angioplasty so long as the early post-angioplasty period is avoided. In an effort to be least invasive in investigation we have utilised IV DSA in favour of the more invasive angiography. Intravenous DSA is very suitable for follow up of angioplasties particularly in the femoro-popliteal segments. In the iliac segments, the presence of bowel movements may result in poor image resolution. In these examinations the severity of a stenotic lesion was graded as a percentage reduction of luminal diameter. In the post PTA group a residual stenosis $< 30\%$ is equivalent to success[10]. Another method of assessment of stenosis is pressure measurements. Taking pressures from proximal and distal to a significant stenosis results in a pressure gradient of 5mm Hg or more. This is at present the most accurate method of assessment of the significance of a stenosis however it is also an invasive method of assessment and is utilised

less frequently. In the pre-treatment of PTA it is important to start patients at least from the day before on Aspirin 300mgs daily and Persantin 25mgs tds. However no Heparin is given routinely in peripheral angioplasty except in high risk cases such as in the presence of a very irregular angioplasty site which could serve as a nidus for thrombosis. Another indication for anticoagulation is if elastic recoil (collapse of the arterial lumen) occurs at the time of the angioplasty.

Results

Primary successful angioplasties were classified into segments as can be seen in Table IV.

ILIAC	COMMON	3	
	EXTERNAL	6	
TOTAL ILIAC SEGMENTS		**9 Segments**	**20%**
FEMORAL (2.2°o)	COMMON	1	
	PROXIMAL SUPERFICIAL	7	15.5°o
	MIDDLE SUPERFICIAL	14	31°o
	DISTAL SUPERFICIAL	9	20°o
POPLITEAL		5	11°o
TOTAL FEMORO-POPLITEAL		**36 Segments**	**80%**
TOTAL PERIPHERAL ANGIOPLASTIES		**45 Segments**	

Table IV - Sites of primary successful angioplasties (segments).

The segments include the iliac subdivided into common and external, the femoral subdivided into common, proximal, middle and distal superficial and the popliteal. From table IV it is evident that the commonest site for angioplasty was the middle segment of the superficial femoral artery (31% of all peripheral angioplasties) followed by the distal segment of the superficial femoral artery with 20%. This confirms that the vessels in and around Hunter's canal are the ones most commonly affected by atherosclerotic stenoses and occlusions and are consequently the sites most likely to require referral for angioplasty. Only 20% of the total number of peripheral angioplasties were for iliac vessel disease, the rest being situated in the femoro-popliteal region. In this series there was only one patient in the under forty age group and this was a case of popliteal artery stenosis following vascular trauma (Fig. II).

The age for the rest of the series varied between the fifth and the eight decade with a peak in the seventh. The male:female ratio for angioplasty averaged 2:1 for all segments and this reflects the incidence of peripheral vascular disease in the two sexes. The major risk factors encountered were smoking (46%), diabetes (46%), the presence of cardiac or cerebral ischaemia (46%), hypertension (33 %) and obesity (28%). The local high incidence of diabetes which was a contributing factor for the need for angioplasty in 46% of this series is significantly different from the average incidence of 10 to 20% encountered in other series. Although there was no difference in the incidence of angioplasty failures in the iliac region for diabetics and non-diabetics, in the femoro-popliteal segments the incidence of failures was of the order of 4:0 for diabetics as compared to non-diabetics. Thus diabetes can be regarded as an adverse risk factor for angioplasty in the latter region.

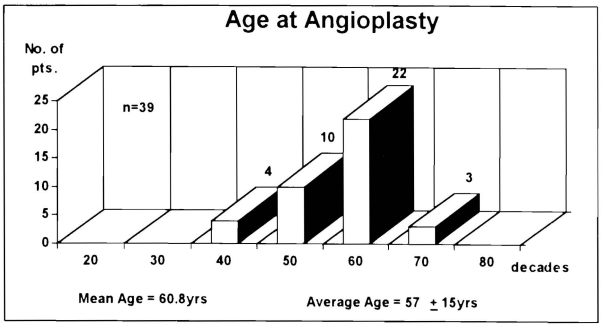

Figure II

In Figures III, IV, V and VI the results of the iliac and femoro-popliteal angioplasties in our series are depicted graphically and compared to a number of series from the USA[11].

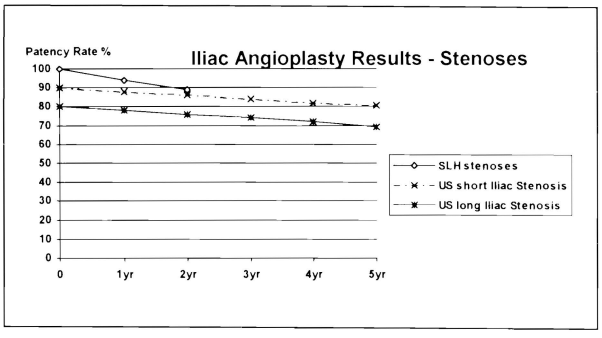

Figure III

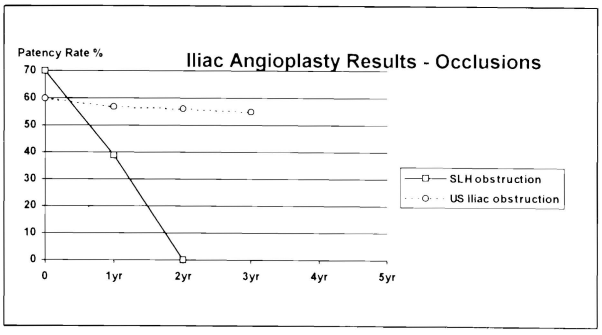

Figure IV

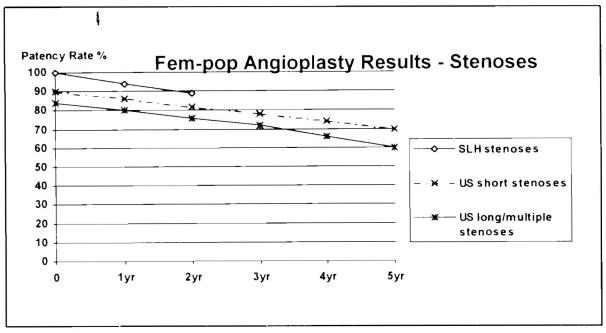

Figure V

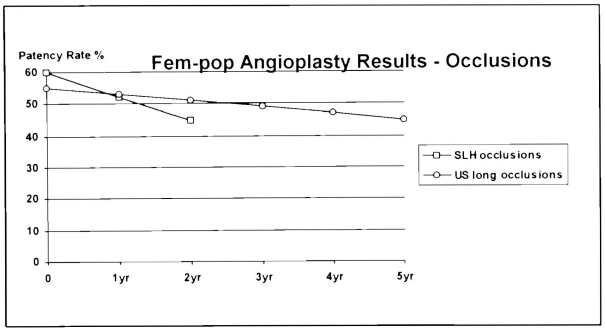

Figure VI

As is evident from this analysis, our results compare very favourably with those obtained in the United States with the sole exception of iliac obstructions where we experienced the same high incidence of early restenosis quoted in other European literature. The recent introduction of intra-arterial stenting mentioned earlier has changed the prognosis significantly for these problematic lesions. In general, success rates were better in the presence of stenoses (85%) than where the angioplasty was carried out for obstruction (56%). The outcome was also different for the two sexes with females faring better than males at a ratio of 67% to 40% in iliac region and 90% to 83% in the femoro-popliteal region. All primary failures were in cases of occlusion (30% for iliac occlusion and 40% for femoro-popliteal occlusion) and they were all in males. No primary failures occurred in angioplasties for stenotic lesions. The overall primary failure rate for iliac and femoro-popliteal regions were 10% and 12% respectively. All iliac occlusions failed primarily or secondarily in either sex.

During the procedures no extraordinary complications were encountered as seen in Table V.

The infrequency of complications we encountered do justice to our enthusiasm for the technique.

Complication	Percentage
Perforations	0%
Distal emboli	0%
Pseudoaneurysm	0%
Thrombosis at Angioplasty site	5%
Spasm in artery at Angioplasty site	7.7%
Puncture site bleeding	2.5%
Large groin haematoma	2.5%
Elective Surgery	2.5 % *
DEATHS	0%

* (Endarterectomy for C. Iliac Restenosis)

Table V

Discussion.

We have noted a high incidence of spasm at the angioplasty site which is correctable by vasodilators and due to this, some clinicians would routinely use vasodilators as premedication. Thrombosis at the angioplasty site occurred in two patients. In this regard an irregular angioplasty site, particularly if coupled with intimal flaps in the lumen is high risk for secondary thrombosis. The presence of irregular angioplasty sites or intimal flaps are strong indications for anticoagulation or intra-arterial stenting. The latter is a recent technique which involves the placement of a metallic stainless steel wire mesh in the arterial lumen that prevents the freshly dilated segment from collapsing again. Bleeding from the puncture site takes the form of external bleeding or development of a groin haematoma. In this regard one must remember that patients are often on antiplatelet aggregation therapy which may occasionally give rise to altered coagulation and consequently produce bleeding tendencies in certain cases. Furthermore, at the end of the angioplasty procedure when the balloon and catheter are being withdrawn from the artery a large puncture hole may be created since, despite advances in balloon technology, this still does not collapse and become as smooth as it is originally at the time of insertion. The one patient who required surgery in the form of an endarterectomy following angioplasty for iliac artery obstruction was in essence a case of restenosis rather than a direct complication of the percutaneous procedure. In this series there were no perforations, no distal emboli and no pseudo-aneurysms at the puncture site. Of obvious significance is the fact that there was no mortality from the procedure.

Peripheral percutaneous transluminal angioplasty is an alternative or complimentary technique to

vascular surgery and continues to be particularly indicated in the presence of stenotic lesions where results are undoubtedly very satisfactory. For obstructive lesions on the other hand, results are less promising though they are better for the femoro-popliteal than for the iliac segment. The new diagnostic techniques of MRI angiography, angioscopy and intra-vascular ultrasound and the recently developed interventional techniques of intra-arterial stenting, arterial drilling and intra-arterial laser atherectomy are still unavailable locally but although with their availability one might expect an improvement in the results for iliac occlusions, it must be pointed out that these procedures are still novel and undergoing full evaluation in major vascular centres in the USA and on the continent. Patients with aorto-iliac disease who for various reasons are unfit for major aorto-iliac surgery can also undergo extra-anatomical bypass surgery in the form of axillo-femoral or femoro-femoral bypass but the long term patency rates for such extra-anatomical prostheses is significantly lower than would be expected for the more anatomical forms of vascular surgical procedures as aorto-iliac endarterectomy or aorto-bifemoral bypass grafting. In such a setting more forms of non-surgical methods of recanalising arteries are essential and inevitable developments.

Our reliance on Duplex US for the assessment of PTA success, stems from the fact that compared to ankle/brachial index (ABI) it also permits localisation of the disease. The accuracy of Duplex scanning is evident from the fact that several studies advocate its use in quantifying stenoses of the carotid arteries[12-14]. The main disadvantage in its comparison with ABI is the fact that the latter can give a quantitative assessment of disease even beyond the popliteal segment. Furthermore the use of Duplex US, ABI and treadmill testing provided the objectivity essential for result analysis which could not be obtained from the patients subjective evaluation of clinical improvement alone.

The long-term results for PTA have been analysed extensively elsewhere[15-31] and will not be reviewed in detail here but our use of life table analysis makes comparative evaluation with these series easy. With smoking, diabetes, ischaemic heart disease, hypertension and obesity as the major risk factors, angioplasty success depends heavily on their adequate treatment and on the cessation of smoking. As there is undoubtedly a definite life span for arterial patency after angioplasty, only meticulous attention to the reduction of these adverse factors can hope to maintain this patency and prolong it. Finally the importance of exercise and the use of long-term anti-platelet aggregation therapeutic agents cannot be overemphasised.

Our results of the past five years are encouraging and as the procedure can be performed under local anaesthesia and is well tolerated by patients, we shall undoubtedly persevere and strive not only to improve our technique but also to introduce newer techniques as soon as these become more widely available.

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