Standards of angiography & percutaneous transluminal angioplasty and their application to current practice

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Citation

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Abstract

OBJECTIVES To review standards of angiography and angioplasty in the light of a study of post-intervention complications. METHODSData for early (24-hours) and 30-day complications after diagnostic angiography (DA) and percutaneous transluminal angioplasty (PTA) were prospectively examined over a 28-month period. Complication rates were compared with the published standards. RESULTS758 patients were included. Major complications occurred in 1.18%. The commonest complication was haematoma (n=16, 2.11%), of which two were major. Systemic problems (nausea, vomiting, vasovagal syncope, transient hypotension and transient arrhythmias) accounted for 1.45%. Arterial occlusion, minor vessel rupture, distal emboli and renal failure constituted the remainder with an incidence of 0.66%. No pseudoaneurysms or arteriovenous fistulae occurred. The 30-day mortality rate was 1.82%.CONCLUSIONThis study demonstrated lower mortality and morbidity than published standards in 2001. Standards of DA developed by the Society of Cardiovascular and Interventional Radiology (2001- SCVIR) could be extended to include PTA. Pseudoaneurysm appears to be avoidable.

INTRODUCTION

Since the first angiogram performed by Forsmann in 1929 [1] , there has been an enormous improvement in the morbidity profile of this procedure [2] . Advances in contrast media safety, catheter and wire technology and radiographic technological improvements have contributed to this. Standards for diagnostic angiography were set by the UK Royal College of Radiologists and Society of Cardiovascular and Interventional Radiology in 2001 but the acceptable morbidity and mortality standards for percutaneous transluminal angioplasty were not clearly defined [3] .

The aim of this study was to measure the incidence of early complications of diagnostic angiography (DA) and percutaneous transluminal angioplasty/stent (PTA) by three operators in a single centre, using standard equipment and well-described angiographic techniques. Differences in technique between the operators were examined to determine if there was any difference in outcome consequent upon their use. We also sought to examine the efficacy of an established technique for avoiding the serious complications of pseudoaneurysm or arteriovenous fistula after these procedures.

METHODS

A prospective study of 758 patients, who underwent elective and emergency radiological intervention, was performed between August 2004 and December 2006. A multidisciplinary team of interventional radiologists and vascular surgeons selected the patients.

Data was recorded electronically immediately after each procedure on a computerised database, which incorporated patient and procedure details, diagnostic and interventional study findings and complications. The 30-day complication data was derived from the case notes recording the subsequent in-patient stay (where appropriate) and the routine out-patient review. The results were compared with the standards of diagnostic angiography devised by the UK Royal College of Radiologists (RCR) and the Standards of Practice Committee of the Society of Cardiovascular and Interventional Radiology (SCVIR) [4,5] .

TECHNIQUE

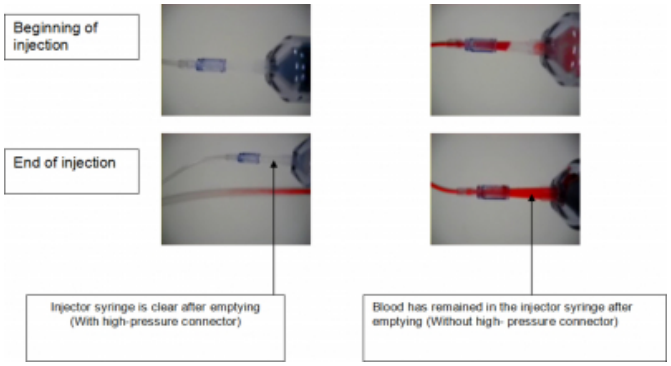
All procedures were performed or directly supervised by one of three consultant interventional radiologists in a dedicated angiography suite equipped with a Siemens Multistar Digital Subtraction Unit. Diagnostic femoral angiography was

performed using a 19 G single puncture needle Kimal Ltd. UK; 150 cm, 0.035", 3mm J wire (Boston Scientific Ltd., UK) and a 4 French pigtail catheter (Boston Scientific Ltd., UK). The catheter was introduced over a guide wire using the Seldinger technique [4] . Two of the three operators routinely connected the catheter directly to the pump, whereas a third used a transparent high-pressure connecting tube in-between pump and catheter. Observation shows that utilising the first technique is associated with a small amount of blood entering and remaining at the tip of the injector syringe. This theoretically could be a source of embolisation (Figure 1).

The common femoral artery (CFA) was located by standard palpation technique [5] . Using a one-piece 18G needle, two operators punctured retrogradely at an angle of 45 °- 60 ° but the third radiologist punctured at 90 ° to the skin surface (to allow easy conversion to antegrade intervention if required). The latter technique involves angling the needle to 45 ° as soon as arterial access has been gained followed by wire insertion in all cases.

Figure 1

Figure 1: The angiography with and without high-pressure connecting tube



A 3mm standard 0.035" J-wire was used to allow insertion of the catheter. Intermittent heparinised saline bolus flushes were used by all operators to prevent clot formation during every procedure. Two of the operators withdrew the pigtail catheter directly out of the CFA by traction at the end of the procedure while a third straightened it by introducing the guidewire into the aorta first prior to withdrawal. The purpose of the latter manoeuvre is to minimise trauma to the ipsilateral common iliac artery on removing the catheter.

Table 1 illustrates the detail of sheaths utilised in this study. The CFA was punctured in all cases. The operator who performed the puncture was responsible for applying compression immediately after the procedure.

A sheath (Boston Scientific Ltd., UK) was used in 392 (52%) of cases. The sizes of sheath are shown in table 1. Latterly, during the period of the study, an arterial closure device (AngioSeal ®, St. Jude Medical UK) was considered particularly in patients on anti-coagulants and/or platelet inhibitors.

Applying an effective pressure can reduce the rate of haematoma after the procedures. We assed the effect of 0.4 bar pressure applied on the superficial femoral artery (SFA) under the guide of ultrasound compared with applying a similar pressure on the CFA (Figure 2).

Figure 2

Table 1: Detail of sheaths utilised in this study

Sheath	% of cases (No)
4-French	1.53% (n=6)
5-French	60.20% (n=236)
6-French	36.1% (n= 145)
7-French	1.02% (n=4)
Arterial closure device(Angioseal®)	11.39% (n=45)

MEDICATION FOR ALL PROCEDURES

Lidocaine 1% was used for local anaesthetic in all procedures. Fentanyl (50 micrograms) or midazolam (1-2mg) were required in 7.12% (n=54) of cases. All patients who underwent PTA or stenting received intra-arterial heparin (3000-5000 IU) during the procedures. One individual who underwent diagnostic angiography also received heparin. 21.64% (n=164) of angioplasty cases received glyceryl trinitrate (100-500 micrograms) during the procedure.

DIAGNOSTIC ANGIOGRAPHY

28.9% (n=108) were carried out as outpatient procedures and 25.13% (n=94) of angiographies were emergencies. Clinical indications for diagnostic angiography were claudication 49.73% (n=186), 34.22% ulceration (n=128), and rest pain 16.05% (n=60). The CFA was used for access in 98.7% of cases and only 1.3% (n=5) had brachial or radial artery cannulation. For 89.04% (n=333) procedures, a 4 French catheter was used. Antegrade angiography was used for 16.53% (n=60) of cases, retrograde angiography was performed on 83.47% (n=303) of patients.

PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY

Balloon angioplasty was performed on 384 patients. 78.65%

(n=302) of these procedures were performed electively and the remainder were emergency procedures. Table 2 summarises the details of these angioplasty procedures. Endoluminal balloon angioplasty was performed on 83.8% (n=322) of patients, 12.8% (n=49) of cases had subintimal angioplasty and 3.4% (n=13) individuals had both endoluminal and subintimal procedures.

Figure 3

Table 2: Angioplasty details

Stent Placement		
Stent inserted	21.01% (n=79)	
Primary & secondary stent placement simultaneously with angioplasty	2	
Secondary stent placement after the first stent placement	7	
Segments		
Single segment angioplasty	55.20% (n=212)	
2 segment angioplasties	28.10% (n=108)	
3 segment angioplasties	7.80% (n=30)	
4 segment angioplasties	4.70% (n=18)	
Not recorded	4.20% (n=16)	
Bilateral procedures	23.96% (n=92)	
Angioplasty Sites		
Femoral artery*	(n=209)	
Inferapoliteal artery**	(n=208)	
Popliteal artery	(n=142)	
Iliac artery***	(n=139)	
Not recorded	(n=16)	
*Femoral artery:(common and superficial) **Inferapoliteal artery: (anterior tibial, posterior tibial, common peroneal) *** Iliac artery: (common and external iliac)		
Direction		
Antegrade	**Retrograde**	
51.9% (n=195)	48.1% (n=181)	
Clinical indications for angioplasty		
Claudication	**Rest pain**	**Ulcer**
38.26% (n=145)	20.32% (n=77)	41.42% (n=157)

COMPLICATION DEFINITIONS

A major complication was defined as one that required hospital admission for treatment (after outpatient procedures), prolonged hospitalization (for in-patients), permanent adverse sequelae or death. Major haematoma was defined as a haematoma requiring transfusion, surgery, greater than 8 cm in transverse diameter or delaying discharge. Minor complications were defined as complications with no sequelae or which required minor treatment or a hospital stay less than 24 hours for observation [2] . Allergic reactions were defined as contrast reactions including urticaria, periorbital, oedema, and wheezing [2] . Contrast material-induced renal failure was defined as a rise of serum creatinine or any clinical evidence of deterioration of renal status including reduced urine output that unexpectedly delayed discharge or resulted in unexpected admission or permanent impairment of renal function [2] .

RESULTS

PARTICIPANTS

374 individuals underwent diagnostic angiography and 384 individuals underwent percutaneous transluminal angioplasty. 48 patients had diagnostic angiography and therapeutic angioplasty at the same visit. Sixty three percent of cases (n=478) were male and 36.94% (n=280) were female. 94.2% (n=714) of the patients were white, 5.8% (n=44) of cases were Asian, black or had a mixed racial origin. The mean age was 72 years (range: 19-96 years).

DIAGNOSTIC ANGIOGRAPHY RESULTS

24-HOUR OUTCOMES

The overall complication rate of diagnostic angiography was 2.13% (n=8). No major haematomas occurred after diagnostic angiography. Vasovagal syncope occurred in 1.07% (n=4) of cases. Vessel occlusion occurred once. All major complications happened within the first 4 hours after the procedures.

30-DAY OUTCOMES

One patient (0.27%) died the day after diagnostic angiography. The death was attributed to acute myocardial infarction, exacerbated by acute on chronic renal failure. No other major complications occurred in this group.

PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY RESULTS

24-HOUR OUTCOMES

The complication rate for PTA and stent placement was 6.51% (n=25). 32 % (n=8) of these occured in emergency cases. Haematoma was the most common complication (n=11). One of these haematomas was retroperitoneal and the rest were located in the groin. Two patients developed major haematomas needing transfusion. Distal embolisation, leading to temporary distal ischaemia, occurred in three cases. These responded to percutaneous aspiration thrombectomy and infusion of alteplase. One patient had rupture of a SFA branch close to the adductor hiatus during balloon angioplasty. This was successfully treated by coil embolisation. Vasovagal syncope occurred in six cases. One

death attributed to myocardial infarction occurred during the procedure. All major complications happened in the first 4 hours after the procedures.

The minor and major complication rates for all procedures are summarised in table 3.

Figure 4

Table 3: Major complications after intervention

Major Complications	No	N&N %	SCVIR 1993 %	SCVIR 2002 %	RCR 2006 %
Puncture site complications	Angiography & PTA		Angiography		Angio - plasty
Major haematoma	2	0.26	3	0.5	4.0
Occlusion	1	0.13	0.5	0.2	0.5
Pseudoaneurysm	0	0	0.5	0.2	n/a
Arteriovenous fistula	0	0	0.1	0.2	n/a
Catheter-induced complications (Other than puncture site)					
Distal emboli	3	0.34	0.5	0.5	0.5
Arterial dissection/subintimal passage	0	0	2.0	0.5	3.0
Subintimal injection of contrast media	0	0	1.0	0.5	n/a
Contrast material reactions					
Contrast reactions	0	0	3.0	n/a	n/a
Major reactions	0	0	0.5	0.5	n/a
Contrast material-related death	0	0	0.01	n/a	n/a
Non-idiosyncratic reactions	0	0	5.0	n/a	n/a
Contrast induced renal failure*	1	0.13	10	0.2	n/a
Unintended occlusion of selected vessel	0	0	n/a	n/a	3.0%
Vessel rupture requiring surgery	1	0.13	n/a	n/a	0.5%
Emergency surgery	0	0	n/a	n/a	3.0%

**Elevation of serum creatinine requiring care that unexpectedly delayed discharge or resultd in unexpected admission, readmission, or permanent impairment of renal function.*

Minor Complications	No	%	SCVIR 1993 %	SCVIR 2002 %
Minor Haematoma	14	1.86	10	10
Systemic complications (Including: nausea, vomiting, vasovagal syncope, transient hypotension, and transient arrhythmias)	11	1.45	5	5

30-DAY OUTCOMES

Eleven (2.86%) patients who underwent PTA did not improve angiographically and went on to have a surgical bypass vascular graft. The 30 day mortality was 1.82% (n=7). All deaths occurred in the emergency group and all had surgical intervention under general anaesthesia between the time of the angioplasty and the time of death. One of these patients had a failed bypass graft and underwent an above knee amputation followed by a below knee amputation. One case was complicated by developing acute renal failure over pre-existing chronic renal failure. The cause of death in all cases was cardiac arrest. No other major complications occurred up to 30 days after percutaneous transluminal angioplasty.

THE OUTCOMES OF DIFFERENT TECHNIQUES

Applying different puncture angles or straightening the pigtail with a wire were not associated with a significant difference in complication rates (p=0.203). Utilising the high-pressure connecting tube between the injector syringe and the catheter did not cause a significant rise in distal clot embolus (p = 0.571). The results applying pressure on different arterial puncture sites showed that while applying a pressure of 0.3 bars on the CFA obstructed the artery effectively, applying 0.4 bars on the SFA did not obstruct it effectively (Figure 2).

DISCUSSION

There has been a marked increase in the number of patients who have undergone endovascular treatment over the last decade [6] . The reported rates of complications after PTA, however, differ between various studies, ranging between 3% and 32.7% [7] . Changes to the SCVIR standards for angiography reflect reduced complication rates between 1993 and 2002. As techniques coupled with technology continue to improve, the fall in complication rates is likely to continue. This is recently reflected in the revised standards published by UK RCR [8] .

The total first 24 hour complication rates in this study were 4.49% (n=34), out of which 26.47% (n=9) were major complications. The total complication rates in this study were within the SCVIR standards. The 30 day mortality rate was 1.82% (n=7). The patients were all urgent or emergency admissions.

Pseudoaneurysm is a recognised, troublesome complication after PTA. Its incidence after percutaneous arterial intervention has been reported as between 0.04% and 18.5% [2] ' [910] . It may be associated with infection, haemorrhage or rupture and treatment may involve bypass surgery or even amputation [11] . Pseudoaneurysm incidence is reportedly higher for CFA puncture compared with brachial and radial punctures. This may be because the CFA is a more frequently used puncture site. Pseudoaneurysm formation in brachial and SFA has been attributed to the weak supportive tissue surrounding these vessels [12] .

Puncture site and appropriate compression are two major factors effective in avoiding pseudoaneurysm and arteriovenous fistula [1314] . Compression is known to be an effective measure in preventing pseudoaneurysms. Katzenschlager and colleagues showed that the incidence of pseudoaneurysm after transfemoral arterial catheterisation with a standardised compression regime reduced from 14.0% to 1.1% by applying continuous pressure for at least 15

minutes after control of local bleeding [16] . In this study, however, the SFA was also used as puncture site and 8-F sheaths were utilised for a few patients. Applying this technique, no pseudoaneurysm or arteriovenous fistula occurred amongst 758 angiographies and angioplasties in our study. This is consistent with published series suggesting that the incidence of pseudoaneurysm formation can be reduced significantly [1516] . Imaging the CFA and SFA under pressure also showed that CFA but not SFA could easily be obstructed.

All major complications in this study occurred in the first 4 hours after the procedure. In keeping with this finding, other studies have suggested that early discharge and outpatient angiography and PTA is a safe strategy in selected patients [17] .

There was no significant difference in complication rates between three operators (p=0.20), indicating that 90 degree puncture is no better or worse at preventing thrombosis, dissection or haematoma formation at the puncture site, although it allows conversion of a retrograde puncture to anterograde approach. It also suggestes that a high-pressure connector does not reduce the incidence of peripheral embololus (p = 0.571). We found that straightening the pigtail with a wire did not confer a benefit in terms of reducing iliac or CFA complications or distal embolisation (p=0.20).

One limitation of our data was the effect of clinical judgment in the reporting of complications. Although the results were recorded contemporaneously, there may be under-reporting of minor complications such as minor haematoma. This study indicates that the latest RCR standards are achievable. There is a need for continuously surveying standards for angiography and percutaneous transluminal angioplasty procedures as it is a rapidly evolving field.

In conclusion, angiography and angioplasty appear to be increasingly safe, possibly as a result of technological improvements, and the majority of the standards of diagnostic angiography developed by the Society of Cardiovascular and Interventional Radiology (SCVIR) could possibly be extended to include percutaneous transluminal angioplasty. Pseudoaneurysm appears to be completely avoidable by application of non-interrupted pressure at the appropriate puncture site after diagnostic angiography and PTA. 90° punctures at the CFA, use of high-pressure connector between catheter and pump and straightening of the pig-tail catheters versus their withdrawal do not confer any measurable benefit or hazard during angiography or angioplasty.

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