Audit of Diagnostic and Interventional Craniocervical Catheter Angiographic Procedures at the Singapore General Hospital⁺

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Abstract

Introduction: Catheter angiography is an established imaging modality of evaluating cerebral and head and neck vascular diseases. It is, however, an invasive procedure with a small risk of complications. The aim of our study was to evaluate the prevalence of peri-procedural complications in a local hospital setting. Materials and Methods: A total of 88 patients underwent diagnostic and interventional craniocervical procedures over 6 months in our department. The casenotes of 83 patients were retrospectively reviewed for complications arising from a total of 99 procedures carried out. Results: A new focal neurological deficit developed in 3 different patients after a procedure, giving a prevalence of 3.0%. All these occurred in diagnostic procedures and were permanent deficits with correlative computed tomography (CT) or magnetic resonance (MR) imaging findings of acute cerebral infarction. All these occurred in high-risk patients who had severe underlying cerebrocarotid vascular compromise. There was 1 case of contrast medium-induced nephropathy (1.0%), occurring in a patient with pre-existing renal impairment. Local complications included 1 case of iatrogenic external iliac artery dissection (1.0%) and 5 cases (5.1%) of small and uncomplicated puncture site groin haematomas. Conclusion: The most significant complication associated with a craniocervical angiographic procedure was the development of post-procedural stroke in patients with significant preexisting cerebrocarotid vascular compromise. In the absence of this risk factor, craniocervical catheter angiography is a relatively safe procedure.

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Key words: Cerebral angiography, Cerebral infarction, Complications

Introduction

Catheter angiography has long been considered the diagnostic standard by which the accuracy of other vascular imaging modalities are compared, given its superior contrast and spatial resolution, as well its high selectivity and ability to show the full extent of vascular disease, presence of contralateral disease, patterns of collateral vessels, and its accuracy in depicting the dynamics of flow. It has established applications in neurological and head and neck imaging.

Craniocervical catheter angiography is, however, an invasive procedure with small but definite risks of complications. The most significant of these is a cerebral thrombo-embolic event, leading to a transient ischaemic attack or stroke. This is believed to be due to the dislodgement of de novo thrombus or thrombus of a diseased artery by the catheter or guide wire tip, due to their manipulation and contrast injection. Selective cannulation of stenosed arteries, catheter-induced arterial dissection, and contrast medium neurotoxicity are also thought to be causative or contributory factors.

In the conventional cerebral angiography of the 1980s, the overall incidence of neurological complications was approximately 1% to 3%.^{1,2} Most of these were transient, with the incidence of permanent neurological deficits at approximately 0.1% to 0.4%. More recent studies at the turn of the last decade employing intra-arterial digital subtraction angiography (IA-DSA) report an overall neurological complication rate of 0.9% to 1%, of which permanent deficits comprised 0.3% to 0.5%.^{3,4} A very recent, prospective and large study showed an overall rate of 1.3% with a permanent deficit rate of 0.5%.⁵ In patients referred for ischaemic stroke or occlusive cerebrovascular

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disease, the incidence was higher, at approximately 3% to 4% and 1% to 1.3% for overall and permanent deficits respectively.⁶⁷

Many authors have cautioned against generalising these data, given the heterogeneity of the mix of patients, study aims, definitions and methodology used in these studies.^{6,8,9,10} In particular, in most previous studies, a large majority of patients referred for ischaemic stroke or occlusive cerebrovascular disease had mild disease and hence the rates of the neurological complications may not reflect the risk in patients with severe disease, for whom carotid endarterectomy would be beneficial.

To our knowledge, the complication rates of craniocervical catheter angiographic procedures performed locally have not been published. We thus present our findings from a recent audit of our complication rates at the Singapore General Hospital (SGH). Our objective was to evaluate the outcome of diagnostic and interventional craniocervical catheter angiographic procedures with regards to their peri-procedural complications in a local hospital setting.

Materials and Methods

A total of 88 patients underwent diagnostic and interventional craniocervical catheter angiographic procedures over a 6-month period from 1 January to 30 June 2002. The casenotes of 83 patients were available and retrospectively reviewed. Their demographics, clinical history, including co-morbid diseases, and indications for catheter angiography were recorded. Pertinent details of the procedures and their attendant peri- and post-procedure complications were obtained from casenotes as well as angiogram reports. Supplementary demographic and laboratory data were obtained from the hospital's electronic records.

The diagnostic procedures were performed by consultant staff neuroradiologists, or advanced radiology trainees and fellows under staff supervision. The therapeutic or interventional procedures were selectively performed by 1 of only 2 interventional neuroradiologists.

All procedures were performed using single-plane IA-DSA. Transfemoral catheterisation was performed in all except 1 patient who had bilateral iliac arterial occlusion, thence necessitating a transbrachial route. In the majority, a 5F Headhunter (H1) catheter was employed exclusively for selective cannulation, with a mix of other catheters used as needed in the rest. In all diagnostic studies indicated for carotid artery stenosis, preliminary arch angiography was routinely carried out using a 5F pigtail catheter. A 5F or 6F vascular sheath was routinely employed to facilitate catheter and guide wire exchanges except in the sole carotid artery stent placement procedure where a slightly larger 7F vascular sheath was used. Meticulous technique was observed to avoid distal air or thrombus embolism, and frequent flushing of the catheter and vascular sheath with heparinised saline was performed. At the end of all procedures, sustained manual compression of the puncture site to secure local haemostasis was routinely observed in the angiography suite.

The sole contrast medium used was an iodinated nonionic water-soluble media, Iopamiro 300 (iopamidol), diluted 2:1 with normal saline and injected either by a mechanical injector or at standard rates by hand.

A complication was defined as an untoward systemic, local or neurological event occurring during or within 24 hours of the procedure.¹¹

A neurological complication was defined as

- i) a transient ischaemic attack if it resolves within 24 hours;
- ii) a stroke if it lasts more than 24 hours, and
 - persistent if it resolves within 7 days,
 - permanent if it lasts more than 7 days.

Contrast medium nephrotoxicity was defined as an impairment of renal function (showed by an increase of serum creatinine by at least 25% or 44 umol/L) within 3 days of intravascular contrast medium administration in the absence of an alternative aetiology.¹²⁻¹⁵

Mann-Whitney U and Fisher's exact probability tests were used for statistical analysis where appropriate prerequisites were met. A P value of <0.05 was deemed significant. A confidence interval of 95% was also chosen.

Results

Of the 83 patients studied, 49 (59.0%) were male and 34 (41.0%) female. The age range was 1 to 82 years with both the mean and median ages at 51 years (Fig. 1).

A total of 99 procedures were carried out. Eighty-two (82.8%) and 17 (17.2%) were for diagnostic and therapeutic or interventional indications, respectively.

The diagnostic indication (n = 82) were:

i) acute intracranial haemorrhage (ICH) (39.0%; n = 32).

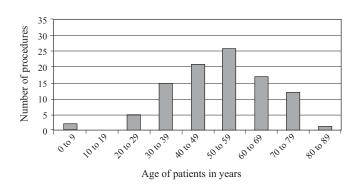


Fig. 1. Bar chart showing age distribution of all procedures.

- ii) diagnostic confirmation/follow-up of craniocervical aneurysms and vascular malformations outside of the setting of acute ICH (35.3%; n = 29, of which 6 were for specific investigation of third cranial nerve palsy).
- iii) evaluation of cerebrocarotid occlusive vascular disease. [15.9%; n = 13, of which 12 were for pre-treatment evaluation of extracranial internal carotid artery stenosis and 1 was performed for evaluation of possible occlusion of the middle cerebral artery (MCA). All the patients with extracranial internal carotid artery stenosis had symptomatic and severe disease (at least 70% stenosis).]
- iv) acute oronasal haemorrhage (4.9%; n = 4), Wada test (3.7%; n = 3) and assessment of skull base tumour (1.2%; n = 1) were the indications in the remainder of the cases.

The therapeutic or interventional indications (n = 17) were:

- i) embolisation/endovascular treatment of craniocervical aneurysms, vascular malformations and tumours.
 [94.1%; n = 16, of which 2 (11.8%) had clinically apparent active oronasal haemorrhage.]
- ii) endovascular stenting for internal carotid artery (ICA) stenosis was carried out in the remaining case (5.9%; n = 1).

The main co-morbid diseases (Tables I and II) elicited from the case notes were systemic hypertension, hyperlipidaemia and diabetes mellitus (DM). Hypertension was present in 35 patients, accounting for 43 procedures (43.4%), hyperlipidaemia was present in 16 patients accounting for 21 procedures (21.2%), while DM was present in 14 patients, accounting for 15 procedures (15.1%). A history of established atherosclerotic vascular disease, such as ischaemic heart disease, cerebrovascular accident

Table 1. Co-morbid Diseases

Disease	No. of patients	No. of procedures (%)
Systemic hypertension	35	43 (43.4)
Hyperlipidaemia	16	21 (21.2)
Diabetes mellitus	14	15 (15.1)
Established atherosclerotic disease	17	19 (19.1)
Renal impairment	3	3 (3.0)

Table 2. Co-morbid Diseases in Patients with Carotid Artery Stenosis

Disease	No. of patients	No. of procedures (%)*
Systemic hypertension	6	6 (46.2)
Hyperlipidaemia	3	4 (30.8)
Diabetes mellitus	7	8 (61.5)
Renal impairment	2	2 (15.4)

* based on a total of 13 procedures

or peripheral vascular disease was elicited in 17 patients accounting for 19 procedures (19.1%). Three procedures (3.0%) were performed in 3 patients with renal impairment, which were deemed to be of mild severity with the preprocedure serum creatinine ranging from 144 umol/L to 173 umol/L.

In the subgroup of procedures performed in patients who had carotid artery stenosis, the prevalence of hypertension, hyperlipidaemia and DM was generally higher than in the study population, at 46.2%, 30.8% and 61.5% respectively.

No procedures were performed on patients with preexisting coagulopathy, although 12 of the 17 therapeutic procedures necessitated the administration of systemic heparin during the procedure.

The mean undiluted volume used per examination was 130 mL, with a range of 45 m/L to 300 mL.

The most significant complication was the development of a new focal neurological deficit, related to 3 separate procedures in 3 different patients, giving an overall prevalence of 3.0% (95% CI, 1.0-8.5). All these occurred in diagnostic procedures, during or within 18 hours of procedure. They were all permanent deficits, persisting for more than 10 days, and all had correlative CT/MR imaging findings of acute cerebral infarction. The ages of these patients were 50 years and above with a mean of 66 years, significantly higher than the mean age of the study population (P < 0.002).

One patient was a 67-year-old woman who had acute subarachnoid haemorrhage (SAH) in the left Slyvian fissure 5 days prior to procedure. Angiographically, there was severe left MCA vasospasm. The patient was on oral nimodipine administered by the ward. No additional vasodilator drug was administered during the procedure. A relatively large amount of contrast medium of 180 mL was used during the procedure. The patient developed mild right-sided hemiparesis during the procedure and soon became hemiplegic. CT brain 2 days later showed an acute left MCA territory lobar infarct. Her neurological deficits persisted for more than 10 days before improving.

The other 2 patients had pre-existing severe stenosis/ occlusion of the ICA secondary to atherosclerotic disease. Multiple risk factors such as hypertension, hyperlipidaemia, diabetes mellitus and aortic aneurysm were amongst some common co-morbidities. One patient was a 50-year-old man who had a carotid artery ultrasound 1 day prior to the angiogram. This documented an unstable mobile plaque in the severely stenosed left ICA. At catheter angiography, the left ICA was found to be occluded. Eighteen hours postangiography, the patient developed right-sided hemplegia with global aphasia. MR imaging confirmed cerebral infarction. The deficit persisted at follow-up nearly 6 months later. The other was an 82-year-old man who had severe stenosis of left ICA at angiography. Two hours postprocedure, he developed acute right-sided brachiofacial neurological deficits and an immediate MR imaging showed a correlating acute left MCA territory infarct. He had persistent right upper limb deficit approximately 2 weeks post-procedure.

A total of 13 (12 diagnostic and 1 therapeutic) procedures were performed for the indication of internal carotid artery stenosis. No procedures performed for other indications detected significant carotid artery stenosis. Hence, the prevalence of neurological complications in this subgroup was 15.4% (95% CI, 4.3-42.3), approximately 5 times the overall figure. This explains the significantly higher prevalence of post-angiographic stroke in these patients compared with the rest of the patients (Fisher's exact probability test, P < 0.05).

A significantly larger volume of contrast was used in patients who developed post-angiographic stroke compared with patients who did not (mean of 180 versus 130 mL, P < 0.05).

There was 1 case of contrast medium nephropathy (1.0%; 95% CI, 0.2-5.5), which occurred in the 82-year-old man who also suffered a permanent stroke following the procedure. He had pre-existing renal impairment (serum creatinine 177 umol/L). Prophylactic nephroprotective measures such as IV hydration as well as oral N-acetylcysteine were administered. The volume of contrast medium was 200 mL, well above the average volume of 130 mL used per procedure. His serum creatinine rose to 253 umol/L after 1 day and he became mildly oliguric. Following this, there was only slight recovery of renal function and the serum creatinine remained elevated at 207 umol/L, 11 days post-angiogram. However, dialysis was not required at that time.

There was 1 case of iatrogenic external iliac artery dissection (1.0%), which occurred during the carotid artery stent placement procedure. This was promptly treated with on-table endovascular stenting. There were 5 cases (5.1%; 95% CI, 2.6% to 10.9%) of puncture site groin haematomas. These were small and uncomplicated and were managed expectantly. We noted that 4 out of 5 occurred in patients with systemic hypertension during diagnostic procedures while the remaining case occurred following endovascular carotid stenting which had necessitated the administration of systemic heparin during and immediately after the procedure.

There were no mortalities directly related to the procedures.

Discussion

The most important complication was the development

of a post-angiographic stroke, with a prevalence of 3.0%. This was observed in 3 examinations performed in very high-risk patients with severe underlying occlusive cerebrocarotid vascular disease or cerebral vasospasm.

One patient with acute SAH had vasospasm at the time of examination and was already at very high risk of stroke. A relatively large volume of contrast medium was also used for the procedure. We believe that the areas of cerebral ischaemia might have been predisposed to the neurotoxic effects of the contrast medium injected via the intra-arterial route, although the use of non-ionic contrast is said to decrease the risk.^{16,17} There is also a theoretical risk of vasospasm aggravated by the large volume of intra-arterial contrast injection (product packet insert).

The other 2 patients had a severely stenosed or occluded ICA; in one of these, an unstable plaque was detected sonographically 1 day prior to the carotid angiogram. An increased risk of post-angiographic stroke associated with carotid artery stenosis, with figures ranging from 2% to 11%, has been observed in previous studies.^{4,6,7,10,18} Amongst other factors, the heterogeneity in the severity of carotid artery stenosis of the study population appears to contribute to the variation in figures. A study of 200 symptomatic patients with at least moderate (>30%) ICA stenosis reported a neurological complication rate of 10% and there was a significantly higher rate in patients with severe disease (70% to 99% stenosis).¹⁰

The relatively high prevalence of stroke in our subgroup of patients with carotid artery stenosis was very likely, largely, due to the fact that all our patients with carotid artery stenosis had symptomatic and severe (at least 70% stenosis) disease, being preliminarily screened with ultrasound and deemed probable candidates for endarterectomy. Hankey et al⁶ and Davies and Humphrey¹⁰ had predicted that with the anticipated widespread use of ultrasound to screen patients with severe disease, the number of diagnostic angiograms and their attendant absolute complication rates would fall while the relative risk of angiography would increase as it became more likely to be reserved for patients with severe disease. Gabrielsen⁸ also believed that as patients undergoing cerebral angiography become an increasingly select group, the procedure would pose an apparent higher risk.

For pre-endarterectomy work-up, surgeons in many centres, including ours, require catheter angiography.^{3,4} In the management of these patients, the risk of angiography has to be considered as part of the perioperative risk. For endarterectomy to be beneficial, this total perioperative risk must not be higher than that of conservative (medical) treatment. In large studies of management of patients with carotid artery stenosis, the total perioperative risk of

neurological complications ranged from approximately 3% in asymptomatic patients (Asymptomatic Carotid Atherosclerosis Study, 1995), to 6% in symptomatic patients (North American Symptomatic Carotid Endarterectomy Trial, 1991).^{19,20} The risk contributed by angiography in those studies was between 0.7% and 1.2%, lower than in our study.

We believe the observed complication rate overestimates the true rate as there is a baseline rate of neurological events, regardless of the angiographic procedures in these patients. Some events are likely to represent part of the natural history or evolution of the underlying ischaemic disease. This view has been expressed before.^{2,4,8} In the patient who had an unstable ICA plaque, it is not unexpected for a stroke to have occurred, the angiographic procedure notwithstanding.

We believe that the accuracy of the rate of complications observed is also limited by a relatively small sample size. These factors may contribute to the wide range of complication rates in various studies, especially the ones with small numbers studied.

A significant increase in the neurological complication rate has been consistently associated with an increase in the patient's age as neurological complications very rarely occur below the age of 40 to 50 years.^{1,2,4,5,21} In our study, all 3 patients with neurological complications were at least 50 years with a mean of 66 years, significantly above the mean age of the study population. Compared with the general study population, the prevalence of various atherosclerosis-related co-morbid diseases such as systemic hypertension, hyperlipidaemia and DM was expectedly higher in the subgroup of patients who had carotid artery stenosis, including those who developed post-angiographic stroke. It is, however, unlikely that increased age or the mere presence of co-morbid diseases are independent risk factors for the development of neurological complications, but rather, the underlying cerebral vascular stenosis which appears to be the most important causative risk factor.

The use of a significantly larger volume of contrast medium was also associated with the development of postangiographic stroke. We postulate that this may be an aggravating factor in patients who are already in cerebral vascular compromise. Although contrast medium has inherent neurotoxic/cerebral vasospastic effects which are usually clinically insignificant, their effects may become significant in very high-risk patients or when large amounts are injected. A prospective study of silent cerebral embolism documented by acute lesions on MR imaging following diagnostic cerebral and neurointerventional angiography reported the use of a significantly higher volume of contrast medium in patients with lesions.²²

The absence of any neurological complications in patients

who underwent interventional procedures was a little surprising, given the increased duration and extent of catheter manipulation of these procedures in general. Several reasons may explain this observation. The first is the small number of such procedures. Second, interventional procedures have the benefit of a prior diagnostic angiogram as a guiding road map against hazardous territories. Third, the administration of systemic heparin in a majority of these procedures decreased the risk of thrombo-embolism. Fourth, all except 1 of these patients who underwent such procedures did not have significant pre-existing cerebrocarotid occlusive vascular disease. The long experience of the 2 interventional neuroradiologists who performed all the therapeutic procedures may have been an important factor as well.

Digital subtraction angiography (DSA) has replaced cutfilm changers in most developed radiology departments. DSA, with a superior contrast resolution, may allow reduced contrast load and time of study, and should theoretically lower the likelihood of complications. Grzyska et al,²³ in a large series of 1095 patients, attributed their lower neurological complication rate (0.4% transient, 0.1% permanent) to the use of DSA and non-ionic iso-osmotic contrast material. This was also the view of Waugh and Sacharias.³ However, later studies in which DSA and nonionic contrast material were used demonstrated similar neurological complication rates to those of series that were performed with cut-film angiography and ionic contrast material.4,5 One reason DSA in those studies and in ours did not consistently show a lower prevalence of neurological complications may be the lack of widespread availability of biplane systems in realising true reductions in procedural times and contrast volumes. We hope that, with a new biplane DSA facility in our department, installed since July 2002, we will be able to demonstrate a reduction in stroke complications. We share Pelz's view that only prospective randomised and truly comparative studies will be able to demonstrate any advantage conclusively.9

The neurological complication rate has been reported to be lower when performed by more experienced radiologists.^{5,10,18,21} However, this observation may be confounded by the higher prevalence of other risk factors such as underlying vascular disease in patients whom had undergone cerebral angiography by less experienced operators and the fact that most of these studies did not randomise the patients to the operators. In our study, the operators have a varying range of experience, from the junior registrars and fellows to diagnostic neuroradiologists, general interventional radiologists and experienced subspecialised interventional neuroradiologists. We did not randomise the procedures to the operators and were not able to verify whether experience makes a significant difference in stroke rates. However, we suggest that allocating all high-risk patients to the most experienced operators may reduce the rate of post-angiographic stroke. This may not be always feasible logistically due to the rotating nature of the department roster schedule and during after hours, when the ready availability of experienced operators is limited.

In general, the incidence of contrast-induced nephrotoxicity following examinations with intravascular contrast media is low in patients with normal renal function, ranging from 0% to 10%.²⁴ Pre-existing renal impairment increases the frequency of this complication, ranging from 12% to 27%.²⁴ Diabetics are particularly at risk, with an incidence of up to 50% in one study.14 Our case of contrast medium nephrotoxicity occurred in an elderly patient with pre-existing renal impairment, the single most significant risk factor. The absolute volume of contrast medium used was large, well above the mean and near the upper limit of the maximum dose of 225 mL to 250 mL recommended by the contrast medium manufacturer (Bracco, Milan, Italy). The complication occurred in spite of prophylactic measures. Two recent randomised, prospective studies showed a significantly decreased risk of contrast medium nephropathy following catheter angiography in patients with pre-existing renal impairment when iodixanol, a nonionic dimeric iso-osmolar contrast, was used, compared with iohexol, a non-ionic isomeric contrast medium similar to iopamidol.^{25,26} These findings make strong recommendations for the use of iodixanol, especially in patients with some renal impairment as this would improve the safety of catheter angiography with regard to the risk of contrast medium nephrotoxicity.27

The most common local complication was minor haematoma (5.1%), with no major haematomas requiring transfusion or surgical evacuation. The literature quotes incidences of minor haematoma of as high as 10% whilst major ones requiring transfusion or surgical evacuation are unusual, occurring only in 0.5% of femoral punctures.^{3,28,29} Groin haematomas occurred in our patients in spite of sustained manual compression of the puncture site performed routinely in the angiography suite. Use of large catheters and/or vascular sheaths and the presence of systemic hypertension increase the risk of puncture site haematoma.³⁰ We observed a strong association between the incidence of groin haematomas in patients and systemic hypertension. Four of 43 (9.3%) procedures performed in hypertensive patients resulted in a groin haematoma. Only 1 of 56 (1.8%) procedures performed in non-hypertensive patients developed this complication. This occurred in a patient who underwent carotid artery stenting during which a slightly larger vascular sheath was used and systemic heparin was given during and following the procedure. Understandably, patients undergoing such interventional

procedures are widely recognised to have a relatively higher risk of haematoma.³¹ We suggest closer postprocedural monitoring of the local puncture site in patients with systemic hypertension, and consideration of the use of one of the various arterial closure devices available on the market to secure haemostasis in particularly at-risk patients. However, the clinical benefits will have to be weighed against the possible adverse effects and cost, and further study is needed.

Conclusion

In our study, we found craniocervical catheter angiography a relatively safe procedure in the absence of occlusive cerebrocervical vascular disease. All the neurological complications occurred in patients who already had significant cerebrocarotid vascular compromise and would have been at some risk of stroke due to the severity of their underlying disease regardless of the catheter angiograms. The strong association between post-angiographic stroke in patients and severe carotid artery stenosis is highlighted, the technical advances in catheter angiography over the past 2 decades notwithstanding. Paradoxically, these are patients most in need of angiography. Our findings show that there is an even greater need for a safer, yet accurate imaging alternative to catheter angiography in the evaluation of carotid artery stenosis. Recently developed and refined advanced MR imaging techniques, especially contrastenhanced MR angiography, have been shown to compare favourably to catheter angiography when used in conjunction with Doppler ultrasound findings.³²⁻³⁵ This non-invasive imaging strategy can reduce the need for diagnostic catheter angiography in high-risk patients, reserving it for cases with unclear or discordant findings. In some European centres, where this strategy is already firmly in practice, no negative effect on surgical outcome was found.^{33,36} The total perioperative morbidity/mortality associated with endarterectomy is likely to be significantly reduced with this strategy and may be verified in a prospective study in our local setting.

Other recommendations to further reduce postangiographic stroke include

- that clinicians be judicious in requests for catheter angiography in high-risk patients, requesting for them only when benefits clearly outweigh the risks and when catheter angiographic findings are expected to clearly affect management,
- ii) allocating high-risk patients to more experienced neuroradiologists, and
- iii) the routine use of biplane DSA for all high-risk cases, potentially reducing procedure time and amount of contrast media usage.

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