The Royal College of Radiologists

Radiology

Standards in vascular radiology

Board of the Faculty of Clinical Radiology
The Royal College of Radiologists

Foreword

These standards for vascular radiology replace *Achieving Standards in Vascular Radiology* BFCR(07)13 which has now been withdrawn. The standards needed updating because of the accurate information we now have in the United Kingdom on success and complication rates for vascular procedures and because of the new position interventional radiology (IR) has as a distinct subspecialty. The former is due in large part to the dedication and hard work of UK vascular radiologists who have contributed so much data to the various IR databases which the British Society of Interventional Radiology has devised and run. The latter brings with it increased professional responsibilities for all vascular radiologists in the clinical care of their patients. I would like to thank Dr Jai Patel in particular for his thoughtful and insightful review and update. I would also like to thank Dr David Kessel for his advice.

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1. Introduction

There is increasing professional and public awareness of the importance of governance issues, in particular the need to demonstrate acceptable individual and institutional performance and outcomes based on data from prospective and contemporary audit.

In keeping with the report of the findings of the Bristol Royal Infirmary Enquiry, 'National standards of clinical care should reflect the commitment to patient-centred care and thus in future be formulated from the perspective of the patient. The standards should address the quality of care that a patient with a given illness or condition is entitled to expect to receive from the National Health Service (NHS).'[1]

This document sets out standards of practice based on the best available evidence. These standards should apply to a vascular radiology service in order to:

- Comply with General Medical Council (GMC) recommendations
- Ensure patient safety
- Maintain acceptable outcomes from angiographic and interventional procedures.

The procedures and mechanisms necessary to ensure compliance with the standards are described as are the actions that are required when there are queries regarding performance. It is recognised that a 'one size fits all approach' to standard setting is never perfect, hence emphasis is placed on systems to detect and review complications and to identify and rectify causes of abnormal outcomes. References are given which outline the evidence base for the standards and support the process of auditing performance.

2. GMC: Good medical practice

Interventional radiologists must comply with the principles and values set out in GMC's *Good Medical Practice.*[2] This document emphasises those elements that are particularly relevant to the practice of interventional radiology.

Doctors must:

- Maintain and improve their own performance and ensure that it conforms to nationally described standards[2]
- Ensure that suitable arrangements exist to provide for their patients' care when they are off duty[2]
- Record any concerns that might compromise patients' safety and draw these to the attention of their employing body[2]
- Ensure that patients are properly consented before undertaking treatment.[2,3]

3. Patient safety in interventional radiology

Patient safety is paramount in interventional radiology. The following areas are critical in ensuring this.

3.1 There is a duty to ensure adequate monitoring and care for patients undergoing interventional procedures.[4–6]

3.2 There is a duty to ensure that there are formal arrangements to secure provision of elective and emergency services.[7,8]

3.3 There is a duty to ensure that there is provision for sedation and analgesia to be administered in a timely and safe fashion.[4]

3.4 There is a duty to ensure that interventional radiologists* have adequate training to perform interventional procedures.[6,9]

3.5 Interventional vascular radiological procedures should be performed in a dedicated interventional room.[6]

3.6 Radiation doses must be kept as low as reasonably practicable during interventional procedures.[10]

4. Standards of practice relating to interventional radiology

4.1 Standard setting is a complex process; standards should, as far as possible, be evidence-based and supported by professional consensus relating to national practice. The most reliable standards are contemporary and derived from prospective collection of a large volume of outcome data for defined procedures. For interventional radiology, this is optimally achieved by systematically collecting and submitting performance data to National Registries. For vascular radiology in the United Kingdom, iliac artery angioplasty and stenting has been established as an index procedure.

4.2 The British Society of Interventional Radiology (BSIR) performed the British Iliac Angioplasty and Stenting (BIAS)[11] national audit of outcomes in iliac artery intervention. This has helped define procedural outcomes and complications for a range of clinical indications. This allows a robust analysis of individual outcomes in comparison with nationally established performance indicators.

4.3 Further standards relating to the practice of vascular radiology have been described in the United States and published by the Society of Interventional Radiology (SIR).[12] These standards are based on historic data derived from published medical literature, hence may not apply directly to contemporary practice.

4.4 Other interventional vascular procedures are currently being studied and when sufficiently robust data is available, standards for other interventional procedures will be issued.

5. Recommendations for recording data

5.1 Individual doctors (interventional radiologists[†]) have a responsibility to demonstrate performance based on evidence drawn from their medical practice.[6]

5.2 Data should be submitted to national registries. Data from iliac artery intervention should be submitted to the British Society of Interventional Radiology BIAS database. Doctors will be able to extract their individual performance data and relate this to contemporary nationally derived outcomes. Statistical data analysis will take into account caseload. This data will be robust evidence of clinical performance that can be used to inform appraisal and recertification.

5.3 The National Institute for Health and Clinical Excellence (NICE) periodically issues recommendations on the performance of specific interventional procedures. Data should be submitted to those registries specified by NICE as part of their recommendation.

5.4 Where there is no national database, it is recommended that radiologists undertaking diagnostic and interventional vascular procedures keep a permanent record of those procedures and any complications that occur. These records may be required for external review. Periodically, results should be compared with the standards below. This is not as effective as comparison with contemporary outcomes derived from many doctors' practice.

6. Recommendations for monitoring practice

6.1 All procedural outcomes and complications should be logged and categorised according to the procedure, the operator and the clinical indication.

6.2 As with any medical team involved in a patient's perioperative care, interventional radiologists[†] should also be involved in any morbidity/mortality review of the case and receive a copy of the discharge summary and, where appropriate, the autopsy report. Clinical outcomes and complications should be reviewed at formal meetings at least four times a year.[13]

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6.3 Documented action should be taken to prevent recurrence of avoidable complications.

6.4 When complication rates for an individual or department exceed an agreed threshold cases should be reviewed with attention to appropriateness of indication and experience of the operator. The results of this review should be recorded and reported to the head of department/medical director as appropriate.

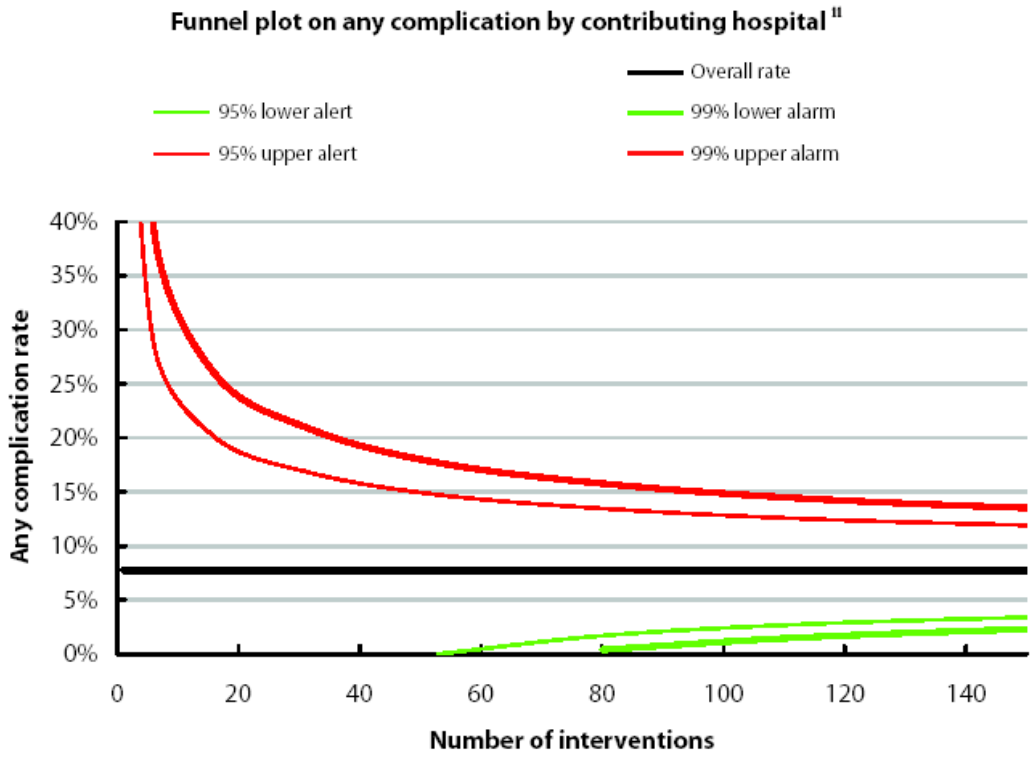
6.5 Suggested thresholds for triggering review are set out below based on data from the British Iliac Angioplasty and Stenting report (BIAS III 2008)[11] and Quality Improvement Guidelines for Diagnostic Arteriography (SIR Standards of Practice committee).[15]

6.6 For iliac intervention, the threshold has been set at the upper 95% confidence interval. This does not indicate unsatisfactory practice, merely that there should be review. Many factors could underlie the result, for example a high proportion of patients with rest pain and tissue loss or with significant co-morbidity.[11]

6.7 Complication rates 3–4 standard deviations (sd) from the mean should raise significant questions concerning operator performance and patient selection. It should be noted that the Society of Cardiothoracic Surgeons use 99.99% (3 sd) as their defined standard for operative mortality from primary coronary artery bypass surgery.[14]

6.8 Confidence intervals are much wider in a low-volume practice (Figure 1). In these circumstances, a single event can cause a complication rate to exceed threshold limits; for example if a patient experienced a stroke during an operator's second carotid stent this would suggest a 50% stroke rate. This does not make the data less reliable but means that the data analysis should be viewed critically and in context. This is a clear indication that the case should be reviewed and if the complication was unavoidable this should be recorded.

Figure 1.



6.9 In low-volume practice, it may be necessary to group complications together and review the overall major complication rate rather than the incidence of specific complications. This can be calculated as follows:

Overall major complication rate =

$$\frac{\text{The number of procedures with major complication}}{\text{Total number of procedures}} \times 100\%$$

6.10 SIR has suggested that if the major complication rate exceeds 1% for diagnostic angiography, this should trigger a review of performance.[15]

7. Implications for practice

7.1 Demonstration of satisfactory performance is likely to form a key element of individual consultant appraisal and revalidation and also departmental certification. It can only reliably be demonstrated by submitting data to national registries.

7.2 Trusts must ensure that there are formal arrangements for cover for out-of-hours emergencies and periods of leave.

7.3 The time required to collect and record data should be reflected in the consultant job plan.

7.4 Departmental certification is likely to depend on satisfactory demonstration of individual, departmental and trust compliance with the above recommendations for practice.

7.5 Whenever necessary, additional education and training should be undertaken to correct deficiencies in performance.

Recommended standards for diagnostic and interventional vascular radiology

These supersede the standards issued in 2007. It should be noted that the current rates of complication for iliac intervention established by BIAS III are considerably lower than the complication rates quoted for diagnostic studies in the previous standards.

DIAGNOSTIC VASCULAR PROCEDURES **ANGIOGRAPHY**[†]	**Upper limit of complications**		
	Threshold	**–**	**–**
Puncture site			
Haematoma (requiring transfusion, surgery or delayed discharge)	0.5%	–	–
Occlusion	0.2%	–	–
Pseudoaneurysm/AV fistula	0.2%	–	–
Non-puncture site			
Distal embolisation	0.5%	–	–
Arterial dissection/subintimal passage of catheter	0.5%	–	–

INTERVENTIONAL VASCULAR PROCEDURES **ILIAC ARTERY ANGIOPLASTY ± STENTING**[‡]	**Rate**	**Confidence intervals**	
		95%[a] **Upper alert**	**99%**[b] **Upper alarm**
Outcome			
>50% residual stenosis	3.7%	3.2–4.3	3.0–4.6
Unplanned intervention			
Delayed discharge	1.3%	1.0–1.8	0.9–2.0
Unplanned endovascular procedure	0.9%	0.6–1.3	0.6–1.5
Unplanned surgery	0.9%	0.6–1.3	0.6–1.5
Amputation	0.2%	0.1–0.5	0.1–0.6
Puncture site			
Haematoma (requiring transfusion, surgery or delayed discharge)	1.5%	1.2–2.0	1.1–2.1
Occlusion[‡]	0.5%	–	–
Pseudoaneurysm	0.2%	0.07–0.36	0.06–0.45
Non-puncture site			
Distal embolisation	0.8%	0.54–1.10	0.48–1.22
Unintended occlusion of selected vessel/flow-limiting dissection	0.5%	0.34–0.81	0.30–0.90
Vessel rupture/perforation requiring intervention or surgery	0.5%	0.28–0.73	0.25–0.83
Emergency/unplanned surgery	0.9%	0.6–1.3	0.6–1.5

Thresholds: [a]95% alert – trigger for informal review of practice; does not necessarily reflect unsatisfactory practice in itself.
[b]99% alarm – trigger for formal review of practice; should raise questions concerning operator performance/ case selection.

Sources

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[‡] The British Society of Interventional Radiology. *Third BIAS Report 2008*. Oxfordshire: Dendrite Clinical Systems, 2008.[11]

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15. Society of Interventional Radiology Standards of Practice Committee. Quality Improvement Guidelines for Diagnostic Arteriography. *J Vasc Interv Radiol* 2003; **14:** S283–S288. (*http://www.sirweb.org/clinical/cpg/S283.pdf*)

Approved by Council of British Society of Interventional Radiology

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