The British Society of Interventional Radiologists

Third BSIR Iliac Angioplasty & Stenting Report

2008

Prepared by

Jon G Moss FRCS FRCR
Raman Uberoi MRCP FRCR
on behalf of the British Society of Interventional Radiologists

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Peter Walton MA MB BChir MBA
Dendrite Clinical Systems

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Preface

The members are to be congratulated on the publication of the Third BSIR Angioplasty and Stenting report. With 4,295 patients entered this is now a very powerful data-set. But for what use?

From the beginning the data were to be used to set standards in Vascular Intervention. BIAS is now the cornerstone of the Royal College of Radiologists document *Achieving Standards in Vascular Radiology*.

We had also intended that the registry should act as the vascular *index procedure* for BSIR members. An index procedure should be commonly performed and have identifiable outcomes. These outcomes can then be used by BSIR members to confirm that they are working safely within the boundaries of well documented UK practise. Such outcomes will soon be freely available to all members from the BSIR website. It will be apparent from this publication that there is probably some discrepancy between the way that complications are recorded between units. For this reason the BSIR is currently undertaking a major piece of work aimed at standardising the way that complications are reported.

And what of the future?

BIAS should be very important to all the BSIR members undertaking Vascular Intervention. In the future re-certification will require that outcomes relevant to a radiologists practise are documented and compared. What better way than contributing to this world-class registry?

Peter Gaines

President, BSIR

Foreword

In 1999 I became BSIR President with a mandate to facilitate the use of BSIR income, generated from the annual meeting, for research pump priming, educational grants and UK wide data collection. I would love to tell you, with regard to the latter that I struggled through adversity and emerged triumphant. This was not the case. Once given the nod, Gaines P and Moss J went for it and the result was the first BIAS registry, followed by all the other impressive pieces of BSIR collaborative data collections (ROST *etc*). I'm quietly proud of all of them. Proud to have helped facilitate but, far more importantly, proud to be a member of such an active an vibrant society that looks outwards with such unlimited horizons.

What is the point of BIAS 3? It's not a great piece of science and it will not change the vascular world. Its importance is that it says to patients that the interventional radiologists in hospital X are confident enough in their own abilities and results to submit data to a national registry for scrutiny. It tells them that the same radiologists are working within a safe framework. Ultimately it gives them confidence. I can hear you snorting into your well earned John Smiths. Sober up. Dame Janet Smith *via* the GMC has set us on a course of revalidation which is going to demand your sobriety. Revalidation, composed as it is of recertification and relicensing, will add a whole new dimension to your working lives and proving that you are safe and effective will be core to this. The RCR continues to strive to make revalidation relevant and as simple as possible but it is at the mercy of the GMC ultimately. The BSIR will continue to provide you with vehicles like BIAS to help you sail through the process.

It's a brave new world we are stepping into. Get used to it.

Tony Nicholson

Dean of the Royal College of Radiologists

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Prelude

Introduction

This is the third National iliac angioplasty and stent report (BIAS III) conducted by the BSIR. Since its launch in 2000 BIAS has logged over 4,000 patients and is the largest iliac artery registry worldwide. BIAS is now recognised as the BSIR first index procedure used for performance-monitoring.

Iliac interventions are carried out in two distinct patient-populations: claudicants and those with critical ischaemia these groups have very different outcomes, particularly complications.

Participation remains an issue with all voluntary registries, and 35 centres contributed data to BIAS III. It is however disappointing to report that 10 major previously participating vascular units no longer contribute to BIAS III. On a more positive note 18 new centres have contributed.

Technology continues to evolve and the usage of stents has increased from 34% of patients in BIAS I to 57% in the current report.

It is gratifying to report that the technical success rate for endovascular iliac artery intervention for athero-occlusive disease is very high (96%). Similarly the reported mortality rate is low (2.0%).

Incomplete participation, no formal external validation, incomplete and incorrect data entry remain challenges for the future.

One of the continuing criticisms of BIAS has been a lack of regular feedback to participants. This has now been addressed by the implementation of individualised web-based funnel plots. This will facilitate the appraisal process and in the future revalidation.

Executive summary

The highlights of the report are outlined below.

- 2,233 procedures were entered by 37 centres over 43 months
- A wide range of workload exists between centres ranging from 292 to 1 case
- The commonest indication for treatment is claudication (62.4%)
- Stenting is now the commonest endovascular intervention used in 57% of procedures
- Daycase care has increased from 13% to 25% over the last 8 years
- Of 66 operators 13 performed over 50% of the recorded cases and 25 performed over 75% of the recorded cases
- 80% of the cases were performed by consultants
- Technical success rate in crossing the lesion was >98%
- The systemic complication rate was 5.8% increasing to 11.6% in the critical limb group
- Leg complications were reported in 3.2% of legs; in the critical ischaemia group 4.6% of legs had one or more complications.
- 0.7% of patients had either a worsening level of ischaemia or an unexpected amputation
- Overall mortality was 2.0% including 0.2% related to claudication; there was no mortality for daycase procedures
- No centres breached the 99.9% alarm line on a funnel plot used to examine a composite outcome determined from data on systemic & leg complications

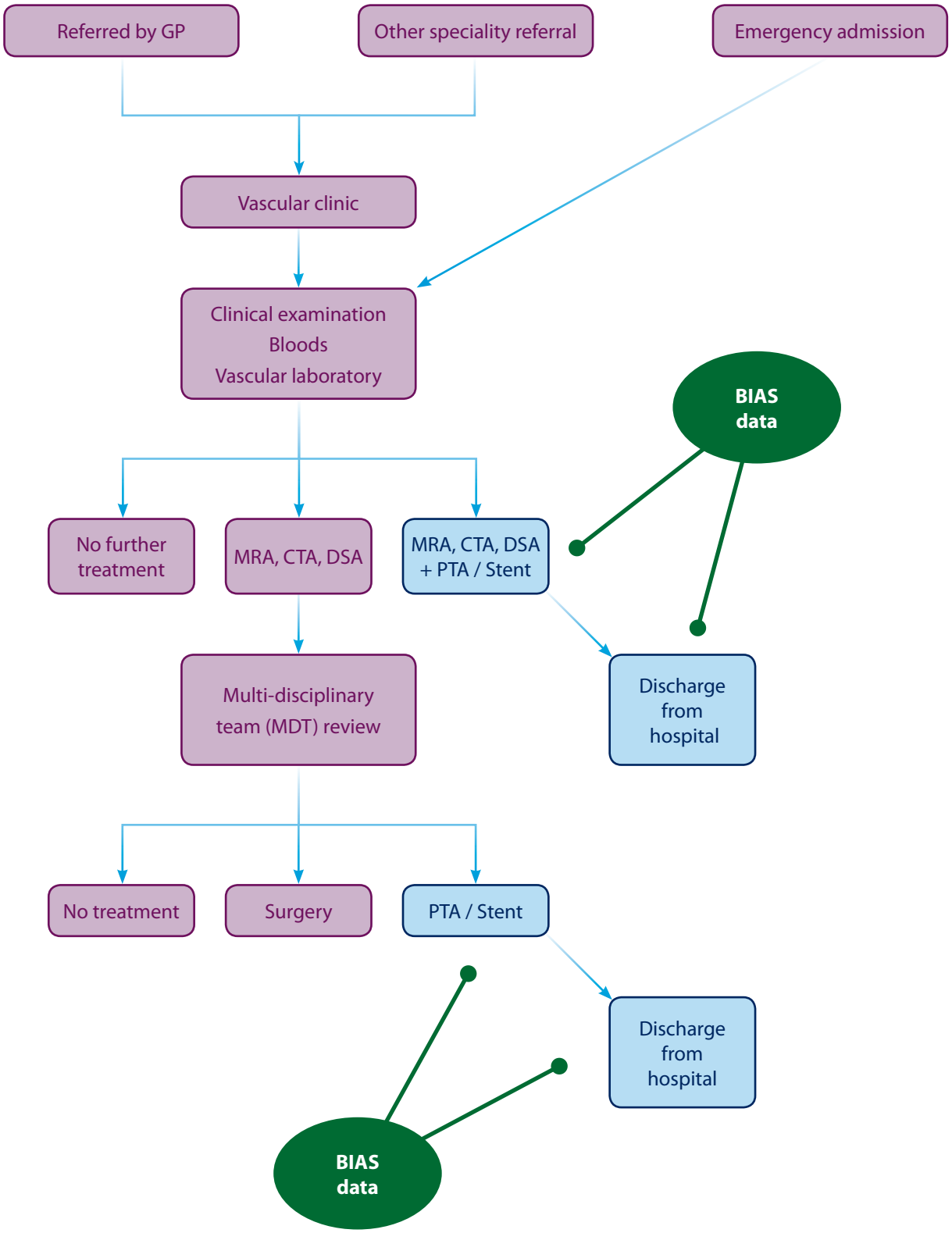
Raman Uberoi

Chairman BSIR Audit & Registries Sub-committee

Jon Moss

Co-opted member BSIR Audit & Registries Sub-committee

The patient journey



The basic principles of iliac angioplasty

Who are Interventional Radiologists?

They are doctors who have trained firstly in radiology to understand the imaging of the body, and then in Interventional Radiology. This is a form of minimally invasive treatment that uses images (*e.g.*, X-rays) to guide how the doctor treats the patient.

What is angioplasty and stenting ?

Angioplasty is a technique where a small collapsed balloon on a catheter is inserted into an artery and, using X-rays to guide it, placed across a diseased and narrowed part of a blood vessel (usually an artery). When the balloon is inflated it stretches the narrowing, restoring the lumen of the artery (Fig 1 & Fig 2).

A stent is a metal tube that is delivered in the same way on a catheter across the diseased segment of the artery (Fig 3). When the stent is released it expands and restores the lumen of the vessel (Fig 4 & Fig 5; Fig 6 & Fig 7).

The stent is left in the body, whereas with angioplasty the balloon is removed. These procedure are usually carried out by specialist doctors called interventional radiologists.

When is a stent needed as opposed to only an angioplasty?

In general angioplasty is used when the iliac artery is narrowed, whereas a stent is used when either the angioplasty does not work or the artery is completely blocked (Fig 6). Stents are approximately 6-10 times the cost of angioplasty and also make the procedure a little more complex.

Why is one of these procedures needed?

Atheroma causes narrowing of the arteries all over the body. As the disease progresses, the narrowings can become complete blockages otherwise known as an occlusion. When this occurs in the iliac artery it restricts the blood entering the leg, and causes a cramping pain during walking. If the disease progresses the pain can be present even at rest, and finally the tissue of the foot and leg can die and become gangrenous, sometimes requiring amputation of the affected leg.

Fig 1 A collapsed balloon

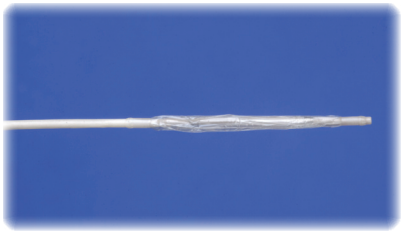


Fig 2 An inflated balloon

Fig 3 Stents

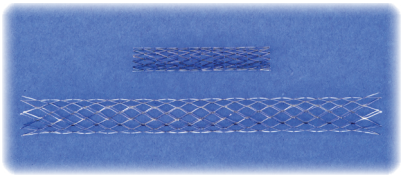


Fig 4 Schematic drawing of the iliac arteries showing an occluded left common iliac artery crossed by a catheter

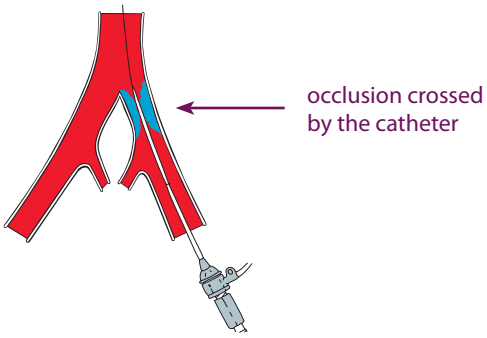


Fig 5 The same left common iliac artery after a stent is deployed, restoring blood flow to the leg

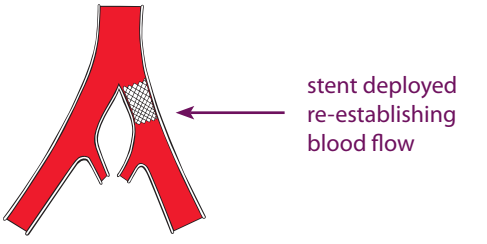


Fig 6 A right common iliac occlusion (highlighted by an arrow) in a patient with critical limb ischaemia

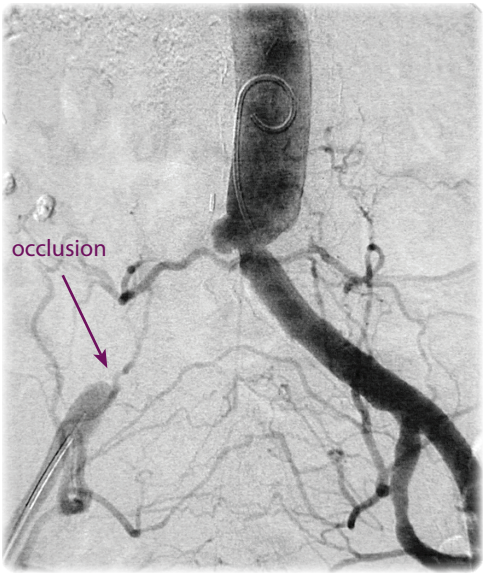
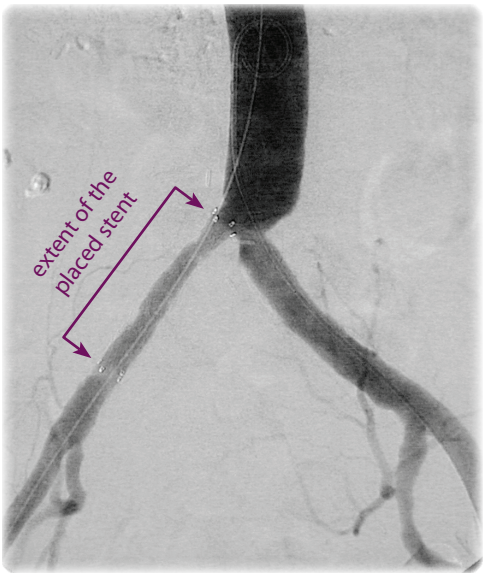


Fig 6 A stent has been placed (between the two arrows), restoring blood flow to the leg



Is this instead of a bypass operation ?

Basically, the answer to this question is: yes.

Although a blocked iliac artery can be treated by a bypass operation, bypass is a much more complex, invasive and risky procedure (see the Fourth National Vascular Database Report 2004). Angioplasty and stenting are much less invasive for the patient, usually requiring only local anaesthetic and can therefore be performed on a daycase basis.

Are there any problems with angioplasty and stenting ?

Although this procedure is a type of keyhole surgery, it still carries some risk of complications. Complications following iliac angioplasty or stenting are usually minor events, such as bruising at the groin, but can also be more serious, such as a rupture in the treated artery, and can even be fatal on occasion.

The risk of developing a complication depends on many factors, which include the patient's general health, the type of blockage in the diseased vessel and the medical team's experience in carrying out these procedures. In addition, the artery can narrow down again after the treatment; this is more common after angioplasty and stenting than after a bypass operation.

What is the purpose of this report & registry ?

We are trying to collect the results of this procedure for all hospitals in the UK. Complete data collection would provide information on how frequently the procedure is being performed, why it is being used and where.

Perhaps more importantly, we want to measure and compare the complication rates in different hospitals and ultimately expand this kind of analysis to look at the individual doctor's performance, to ensure everyone is reaching a satisfactory standard of safety. This should reassure doctors, patients and the government that we are monitoring what is happening & taking measures to correct sub-optimum performance if it were detected. This so-called quality assurance is an essential part of contemporary medical practice.

Contributors

Hospital	Contributor
Derbyshire Royal Infirmary	Dr Peter M Bungay Dr Mario de Nunzio Dr J Graham Pollock
Diana Princess of Wales Hospital, Grimsby	Dr Richard W J Harries
Eastbourne District General Hospital	Dr Hugh J Anderson
Falkirk & District Royal Infirmary	Dr Emma Beveridge
Frenchay Hospital, Bristol	Dr Lyn Jones
Gartnavel General Hospital	Dr S Chandramohan Dr Richard Edwards Dr Ram Kasthuri Dr Navin Mathias Prof Jonathan Moss Dr Ian Robertson
George Eliot Hospital	Dr Kevin Vallance
Guy's & St Thomas's	Dr Stephen D Thomas
Hairmyres Hospital	Dr Adrian Mizzi
John Radcliffe, Oxford	Dr Suzie Anthony Dr Jane Phillips-Hughes Dr Raman Uberoi
Kings Mill Hospital	Dr Christopher A Squirrell Dr Philip Panto
Leeds Teaching Hospital	Dr Simon J McPherson
Leighton Hospital	Dr Salman Zaman
Lister Hospital	Dr Fida Alaedin Dr Christopher King
Manchester Royal Infirmary	Dr Nicholas Chalmers Dr Gerry Murphy
Norfolk & Norwich University Hospital	Dr Simon Girling
North Bristol NHS Trust	Dr Lyn Jones
Northampton General Hospital	Dr Davis Thomas
Northern General Hospital, Sheffield	Dr John Bottomley Dr Trevor Cleveland Dr Christine Davies Prof Peter Gaines Dr Steven Thomas Dr Douglas Turner

Hospital	Contributor
Pennine Acute Hospital Trust	blank
Queen Elizabeth Hospital, Gateshead	Dr Colin Nice
Royal Bolton Hospital	Dr James Lay
Royal Group of Hospitals Trust, Belfast	Dr Anthony Collins Dr Peter K Ellis Dr Peter Kennedy Dr Mark Loveday
Royal Lancaster Infirmary	Dr Janet Lavelle
Royal Sussex Hospital	Dr Timothy N Doyle Dr Phil Thompson
Royal West Sussex NHS Trust	Dr Briony J Burns
South Manchester University Hospital	Dr Raymond Ashleigh Dr John Butterfield Dr Jonathan Tuck
Southern General Hospital, Glasgow	Dr Keith Osbourne Dr Grant Urquhart
Southmead Hospital, Bristol	Dr Lyn Jones Dr Eric Loveday Dr Mark J Thornton
St Georges' Hospital	Prof Anna-Marie Belli
St Helier, Carsholton	Dr Tiz North
Stirling Royal Infirmary	Dr Emma Beveridge Dr Dugald Glen
Torbay Hospital	Dr John Isaacs Dr Richard Seymour
University Hospital of N Staffordshire	Dr Mark Cowling
University Hospital of Wales, Cardiff	Dr Andrew Gordon Dr Andrew Wood
University Hospital Aintree	Dr Aldo M Camenzuli Dr Elizabeth A O'Grady
Victoria Infirmary Glasgow	Dr Andrew C Downie
Wythenshawe Hospital	Dr Raymond C Ashleigh Dr John Butterfield

Conventions used in the report

There are a number of conventions used in the report in an attempt to ensure that the data are presented in a simple and consistent way. These conventions relate largely to the tables and graphs, and some of these conventions are outlined below.

Conventions used in tables

On the whole, unless otherwise stated, the tables in this report record numbers of patient-entries (see the example below reproduced from page 23).

		Gender			
		Female	Male	Unspecified	**All**
Age / years	<45	13	21	1	**35**
	45-49	41	78	0	**119**
	50-54	51	142	0	**193**
	55-59	77	209	0	**286**
	60-64	103	257	0	**360**
	65-69	119	250	0	**369**
	70-74	124	216	0	**340**
	75-79	114	172	0	**286**
	80-84	73	75	0	**148**
	85-89	35	30	1	**66**
	>89	15	8	0	**23**
	Unspecified	2	6	0	**8**
	All	**767**	**1,464**	**2**	**2,233**

The numbers in each table are colour-coded so that patient-entries with complete data for all of the components under consideration (in this example **both** the age **and** the gender) are shown in regular black text. If one or more of the database questions under analysis is blank, the data are reported as unspecified in purple text. The totals for both rows and columns are highlighted as bold text.

Some tables record percentage values; in such cases this is made clear by the use of an appropriate title within the table and a % symbol after the numeric value. Yet other tables might report average numbers (the patient's age at a given time, for example) and, again, this is made clear by the use of an appropriate title within the table.

Rows and columns within tables have been ordered so that they are either in ascending order (calendar years; Low, Medium, High) or with negative response options first (No; None) followed by positive response options (Yes; One or more).

Row and column titles are as detailed as possible within the confines of the space available on the page. Where a title in either a row or a column is not as detailed as the authors would have liked, then footnotes have been added to provide clarification.

There are some charts in the report that are not accompanied by data in a tabular format. In such cases the tables are omitted for one of a number of reasons:

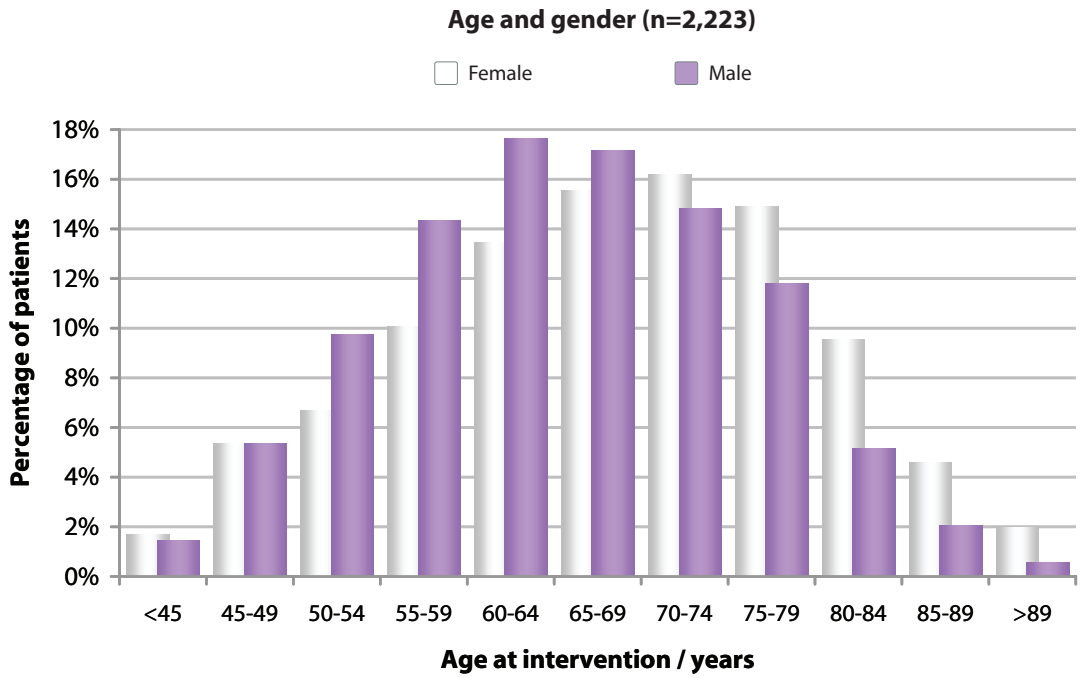
- insufficient space on the page to accommodate both the table and graph.
- there would be more rows / columns of data than could reasonably be accommodated on the page (for example post-operative length-of-stay).
- the tabular data had already been presented elsewhere in the report.

Conventions used in graphs

The basic principles applied when preparing graphs for the report were based, as far as possible, upon William S. Cleveland's book *The elements of graphing data* [i]. This book details both best practice and the theoretical bases that underlie these practices, demonstrating that there are sound, scientific reasons for plotting charts in particular ways.

Counts: The counts (shown as n= in each graph's title) associated with graphs are affected by a number of independent factors and will therefore vary from chapter to chapter and from page to page. Most obviously, many of the charts in the report are graphic representations of results for a particular group (or sub-set) extracted from the database, such as male patients, patients receiving a stent during their procedure, and so on. This clearly restricts the total number of database-entries available for any such analysis. In addition to this, some entries within the group under consideration have data missing in one or more of the database questions being examined (reported as unspecified in tables); entries with missing data are excluded from the analysis used to generate the graph because they do not add any useful information.

For example, in the graph on page 23 (reproduced below), only the patient-entries with both the patient's age data **and** gender recorded are included in the analysis; this comes to 2,223 patient-entries (13 + 41 + 51 + 77 + 103 + 119 + 124 + 114 + 73 + 35 + 15 + 21 + 78 + 142 + 209 + 257 + 250 + 216 + 172 + 75 + 30 + 8 from examining the table; the 10 patient-entries with one or more unspecified data-items are excluded from the chart).



Confidence interval: In the charts prepared for this report, most of the bars plotted around rates (percentage values) represent 95% confidence intervals. The width of the confidence interval gives us some idea of how certain we can be about the calculated rate of an event or occurrence. If the confidence intervals around two rates do not overlap, then we can say, with a specified level of confidence, that the rates in these two populations are different; if the bars do overlap, we cannot make such an assertion.

i. Cleveland WS. The elements of graphing data. 1985, 1994. Hobart Press, Summit, New Jersey, USA.

Simple distributions

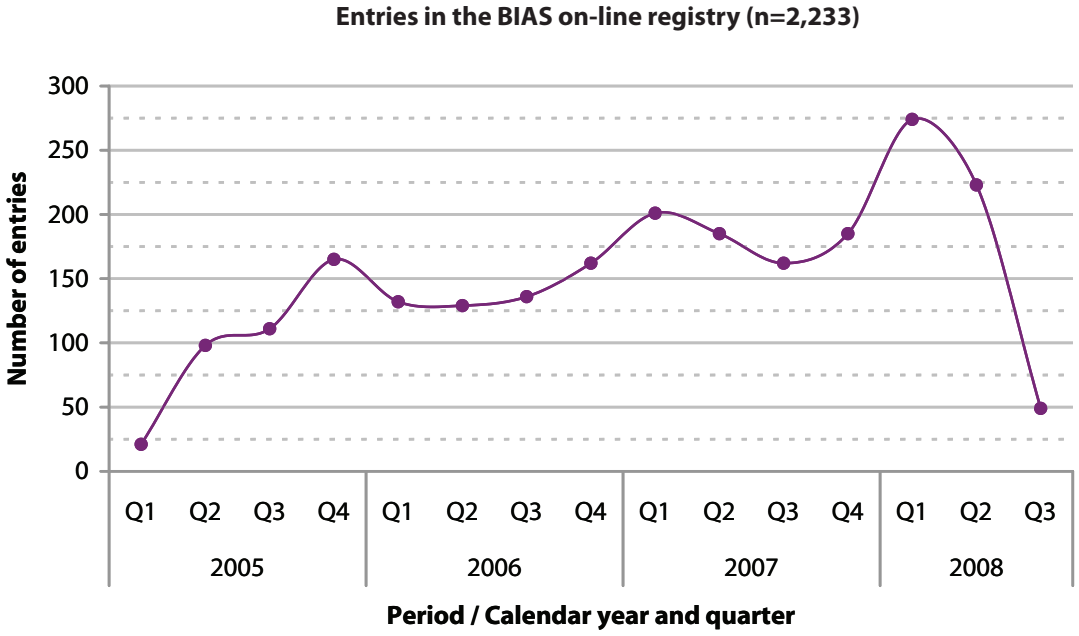
Simple distribution analyses

Overview

Data in the registry

- BIAS I recruited 1,054 over a period of 11 months.
- BIAS II recruited 1,098 over a period of 23 months
- BIAS III recruited 2,233 over a period of 43 months.

		Database			
		BIAS I	BIAS II	BIAS III	**All**
Calendar year	2000	224	–	–	**224**
	2001	830	–	–	**830**
	2002	–	12	–	**12**
	2003	–	93	–	**93**
	2004	–	731	–	**731**
	2005	–	262	395	**657**
	2006	–	–	559	**559**
	2007	–	–	733	**733**
	2008	–	–	456	**456**
	All	**1,054**	**1,098**	**2,233**	**4,295**



Contributing hospitals

BIAS I had data from 60 hospitals, BIAS II 36 hospitals and BIAS III 38 hospitals.

However, not all centres have contributed consistently across the life-span of BIAS. Twenty-six centres contributed to both BIAS I and BIAS II, and twenty-five have contributed to all three iterations of the registry. There have been 18 new hospitals contributing to web based BIAS III registry; disappointingly however, 10 centres (see following table) who contributed to BIAS I and II did not contribute to BIAS III despite the easy access and utility of BIAS III.

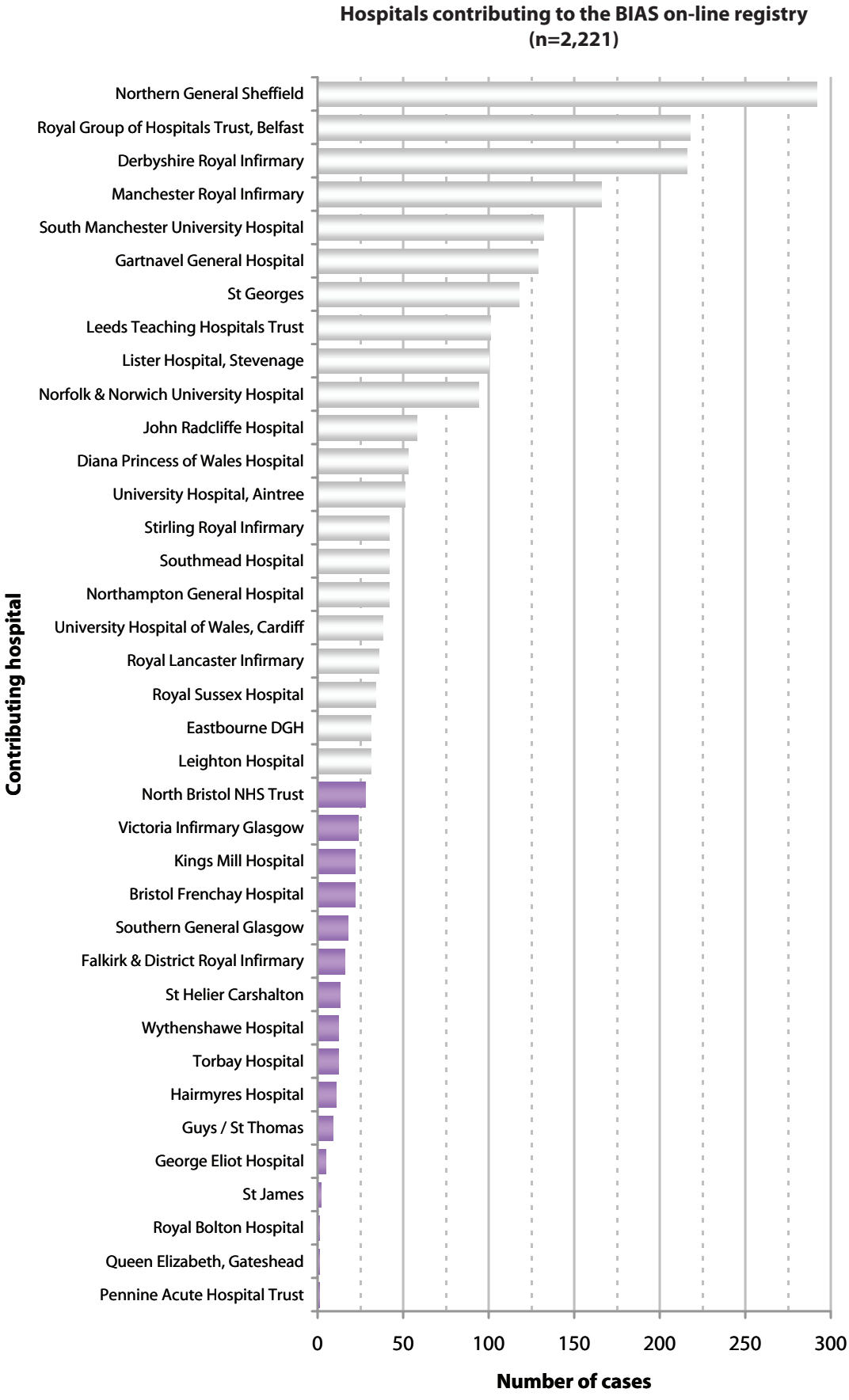
It is not clear why previously contributing centres failed to participate in BIAS III, but part of the explanation may be the result of hospital amalgamation or transferring of vascular services elsewhere. We're sad to see that the following previous BIAS contributing centres have not contributed to BIAS III and we would encourage these centres, along with all centres carrying out iliac intervention, to contribute their data particularly as this is now designated an index procedure by the society. The BSIR would welcome feed back from members regarding any obstacles to data collection.

Simple distribution

	BIAS I	BIAS II	BIAS III	Entries recorded
Ayr Hospital	●	●		14
Bolton Hospital		●		20
City General Hospital, Stoke-on-Trent		●		10
Conquest Hospital	●			10
Derbyshire Royal Infirmary	●	●	●	337
Derriford Hospital	●			2
Diana Princess of Wales Hospital, Grimsby		●	●	87
Doncaster Royal Infirmary	●			17
Eastbourne District General	●	●	●	50
Edinburgh Royal Infirmary	●	●		63
Falkirk Royal Hospital		●	●	22
Freeman Hospital	●	●		43
Frenchay Hospital, Bristol		●	●	37
Frimley Park Hospital, Camberley		●		6
Gartnavel General Hospital	●	●	●	191
George Elliot Hospital	●	●	●	16
Glan Clwyd District General Hospital	●			4
Gloucestershire Royal Hospital	●			23
Guy's & St Thomas's Hospital			●	9
Halton General Hospital	●			26
Hammersmith Hospital	●			3
Harrogate District Hospital	●			3
Hairmyres Hospital			●	11
Hull Royal Infirmary	●			53
John Radcliffe Hospital	●	●	●	87
Kings Mill Centre	●		●	27
Kingston Hospital NHS Trust	●			6
Law Hospital	●			7
Leeds General Infirmary	●	●	●	156
Leighton Hospital	●	●	●	69
Lewisham Hospital	●			20
Lister Hospital	●	●	●	140
Manchester Royal Infirmary	●	●	●	349
Musgrove Park Hospital	●			8
Ninewells Hospital	●			24
Norfolk & Norwich Hospital		●	●	148
North Bristol NHS Trust			●	28
Northampton General Hospital			●	42
Northern General Hospital	●	●	●	439
Northwick Park Hospital		●		24
Pennine Acute Hospital Trust			●	1

	BIAS I	BIAS II	BIAS III	Entries recorded
Pinderfields Hospital NHS Trust	●			120
Princess Royal Hospital	●			1
Queen Elizabeth Hospital, Gateshead			●	1
Raigmore Hospital	●			7
Rotherham General Hospital	●			5
Royal Albert Edward Infirmary	●			6
Royal Berkshire Hospital	●			9
Royal Bolton Hospitals NHS Trust	●		●	1
Royal Free Hospital	●	●		37
Royal Glamorgan Hospital	●	●		21
Royal Group of Hospitals, Belfast			●	218
Royal Gwent Hospital	●			7
Royal Hampshire County Hospital	●			9
Royal Lancaster Infirmary			●	36
Royal Liverpool Univ. Hospital		●		12
Royal London Hospital	●			30
Royal Shrewsbury Hospital	●	●		102
Royal Sussex Hospital			●	34
Royal United Hospital	●			12
Royal Victoria Hospital		●		96
Sandwell General Hospital	●			5
South Cleveland Hospital	●	●		42
South Manchester Univ. Hospital	●	●	●	187
Southampton General Hospital	●	●		70
Southern General Hospital	●	●	●	15
Southmead Hospital	●	●	●	87
St Helier's Trust Hospital	●	●	●	34
St James's Univ. Hospital	●		●	2
St Mary's Hospital	●			26
St Mary's NHS Trust	●			0
St George's Hospital	●	●	●	170
St Richard's Hospital	●			7
Stafford District General Hospital	●	●		26
Stirling Royal Infirmary	●		●	60
Torbay Hospital		●	●	43
Univ. Hospital of Wales	●		●	44
Univ. Hospital Aintree			●	51
Victoria Infirmary	●	●	●	63
Wellington Hospital	●			7
Wythenshawe Hospital			●	12
York District Hospital	●			25
Totals	**60**	**36**	**37**	**4,372**

Simple distribution



Age and gender

This plot of the age and gender distributions shows very little difference to those seen in the two previous versions of the database. On the whole, the women are, on average, slightly older than the men.

		Gender			
		Female	Male	Unspecified	**All**
Age / years	<45	13	21	1	**35**
	45-49	41	78	0	**119**
	50-54	51	142	0	**193**
	55-59	77	209	0	**286**
	60-64	103	257	0	**360**
	65-69	119	250	0	**369**
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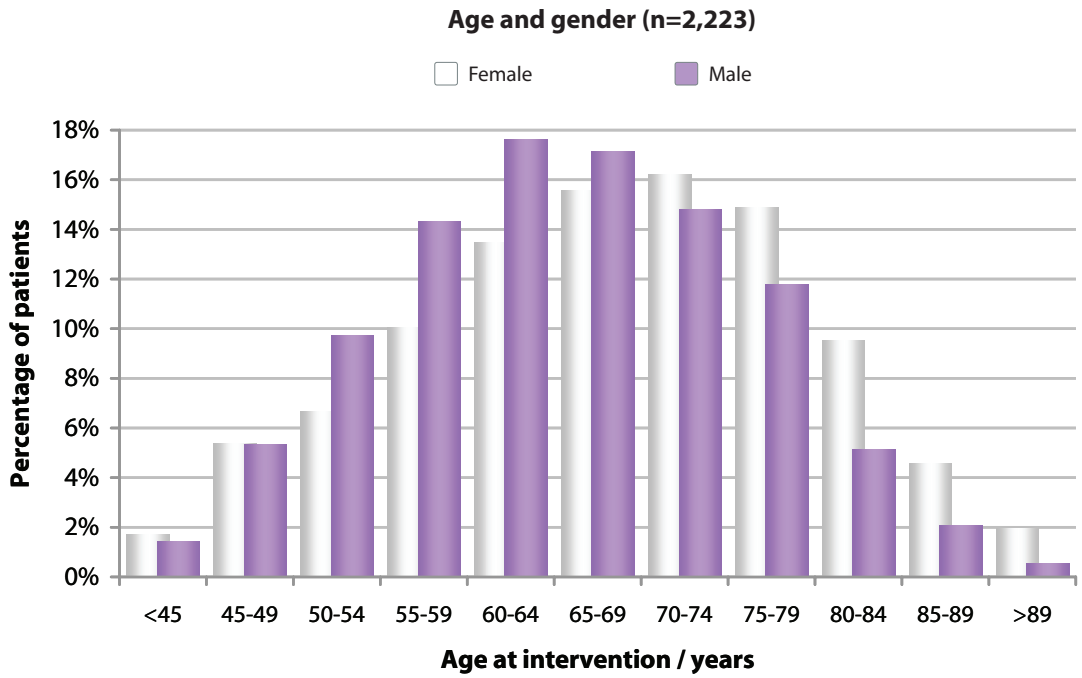
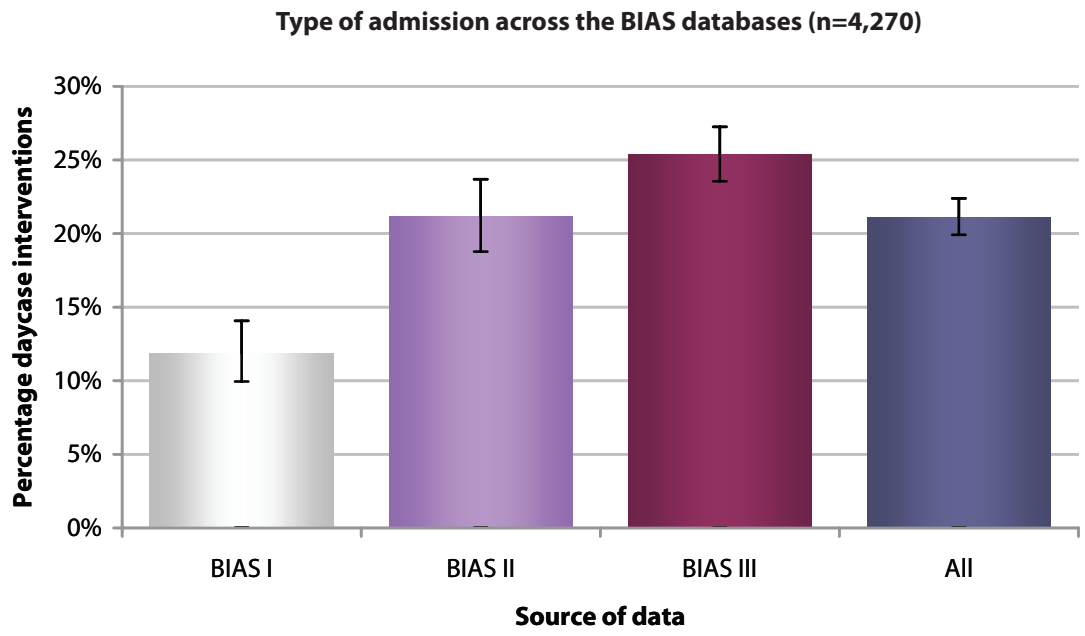


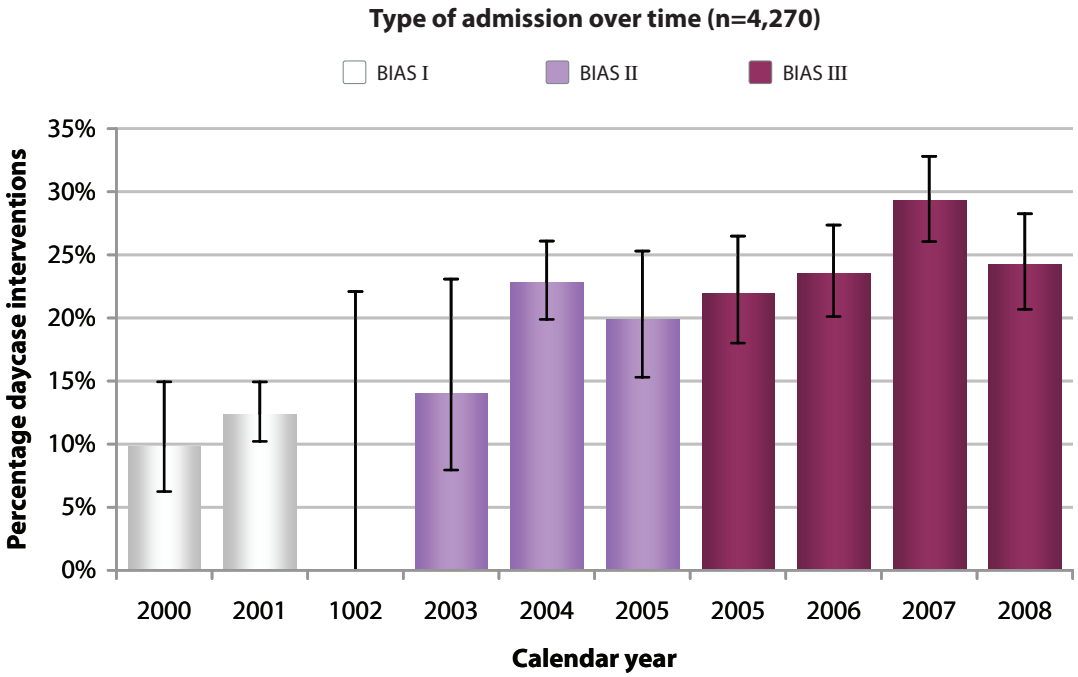
Type of admission

Type of admission over time

The general trend for daycase procedures has continued with an increase from 12% in 2001 to currently 25% of patients being treated as daycases.

		Database								
		BIAS I			BIAS II			BIAS III		
		Daycase	Inpatient	Unspecified	Daycase	Inpatient	Unspecified	Daycase	Inpatient	Unspecified
Calendar year	2000	20	184	20	–	–	–	–	–	–
	2001	98	693	39	–	–	–	–	–	–
	2002	–	–	–	0	12	0	–	–	–
	2003	–	–	–	13	80	0	–	–	–
	2004	–	–	–	167	564	0	–	–	–
	2005	–	–	–	52	210	0	85	302	8
	2006	–	–	–	–	–	–	130	422	7
	2007	–	–	–	–	–	–	212	511	10
	2008	–	–	–	–	–	–	125	390	31
	All	**118**	**877**	**59**	**232**	**866**	**0**	**552**	**1,625**	**56**


Type of admission across the BIAS databases (n=4,270)
Percentage daycase interventions
30%
25%
20%
15%
10%
5%
0%
BIAS I
BIAS II
BIAS III
All
Source of data

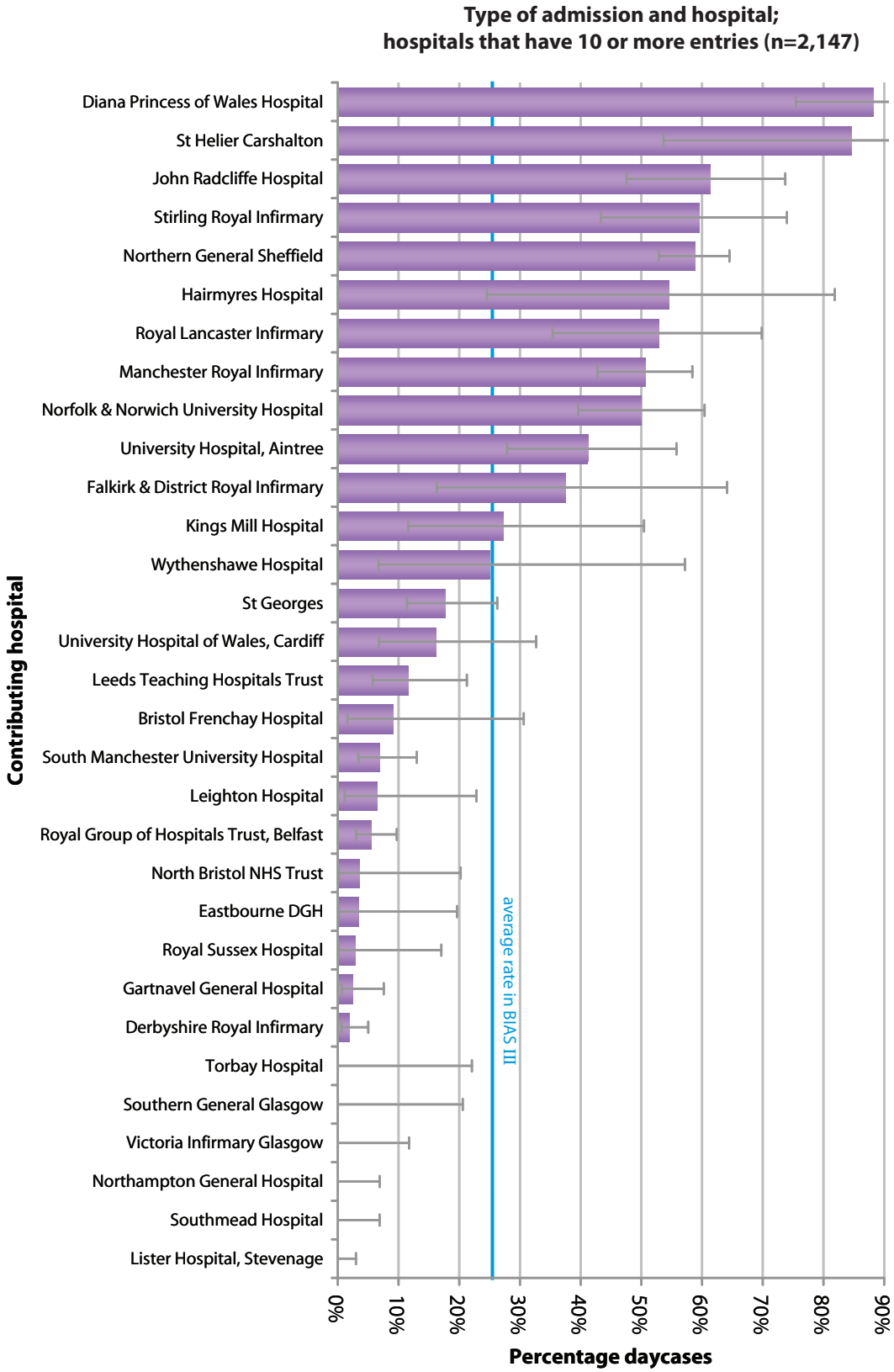

Type of admission over time (n=4,270)
BIAS I
BIAS II
BIAS III
Percentage daycase interventions
35%
30%
25%
20%
15%
10%
5%
0%
2000
2001
1002
2003
2004
2005
2005
2006
2007
2008
Calendar year

Simple distribution

Type of admission at the contributing hospitals

The percentage of procedures carried out varies widely between centres, from 0% to almost 90%.

Although the degree of ischaemia will affect the patient's suitability for daycase care there is undoubtedly a need to expand daycase facilities in many centres. Patient selection does vary in individual hospitals based on their core activities making them less suitable. Centres may wish to use their individual day case rate to support the argument for an expansion in daycase facilities to enable them to more closely match the national average.

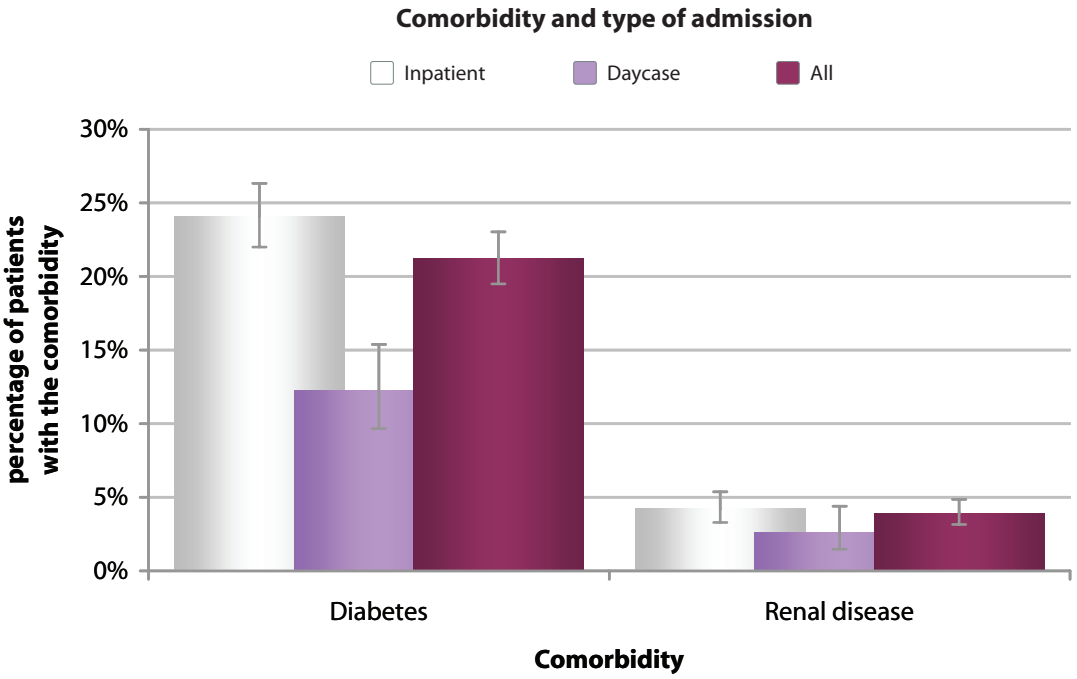


		Type of admission			
		Daycase	Inpatient	Unspecified	Daycase rate
Hospital	Diana Princess of Wales Hospital	45	6	2	88.2%
	St Helier Carshalton	11	2	0	84.6%
	John Radcliffe Hospital	35	22	1	61.4%
	Stirling Royal Infirmary	25	17	0	59.5%
	Northern General Sheffield	170	119	3	58.8%
	Hairmyres Hospital	6	5	0	54.5%
	Royal Lancaster Infirmary	18	16	2	52.9%
	Manchester Royal Infirmary	84	82	0	50.6%
	Norfolk & Norwich Univ. Hospital	47	47	0	50.0%
	Guy's & St Thomas's Hospital	4	5	0	44.4%
	Univ. Hospital Aintree	21	30	0	41.2%
	Falkirk & District Royal Infirmary	6	10	0	37.5%
	Kings Mill Hospital	6	16	0	27.3%
	Wythenshawe Hospital	3	9	0	25.0%
	St George's Hospital	20	93	5	17.7%
	Univ. Hospital of Wales, Cardiff	6	31	1	16.2%
	Leeds Teaching Hospitals Trust	9	69	23	11.5%
	Bristol Frenchay Hospital	2	20	0	9.1%
	South Manchester Univ. Hospital	9	122	1	6.9%
	Leighton Hospital	2	29	0	6.5%
	Royal Group of Hospitals, Belfast	12	205	1	5.5%
	North Bristol NHS Trust	1	27	0	3.6%
	Eastbourne DGH	1	28	2	3.4%
	Royal Sussex Hospital	1	33	0	2.9%
	Gartnavel General Hospital	3	119	7	2.5%
	Derbyshire Royal Infirmary	4	211	1	1.9%
	Lister Hospital, Stevenage	0	99	1	0.0%
	Northampton General Hospital	0	42	0	0.0%
	Southmead Hospital	0	42	0	0.0%
	Victoria Infirmary, Glasgow	0	24	0	0.0%
	Southern General, Glasgow	0	13	5	0.0%
	Torbay Hospital	0	12	0	0.0%
	George Eliot Hospital	0	5	0	0.0%
	St James's Hospital	0	2	0	0.0%
	Pennine Acute Hospital Trust	0	1	0	0.0%
	Queen Elizabeth, Gateshead	0	1	0	0.0%
	Royal Bolton Hospital	0	1	0	0.0%
	Unspecified	1	10	1	9.1%
	All	**552**	**1,625**	**56**	**25.4%**

Comorbidities

The overall instance of renal disease is 21.2% and diabetes 3.9%. These co-morbidities rates are noticeably lower in the daycase group. Comparison with BIAS II shows no significant change in these rates over time and indicates that there is probably a consistency in patient selection for daycase procedures

		Type of admission		
		Inpatient	Daycase	**All**
Comorbidity	Diabetes	24.1% (1,544; 22.0-26.3%)	12.2% (539; 9.7-15.4%)	21.2% (2,112; 19.5-23.0%)
	Renal disease	4.2% (1543; 3.3-5.4%)	2.6% (543; 1.5-4.4%)	3.9% (2,116; 3.2-4.9%)

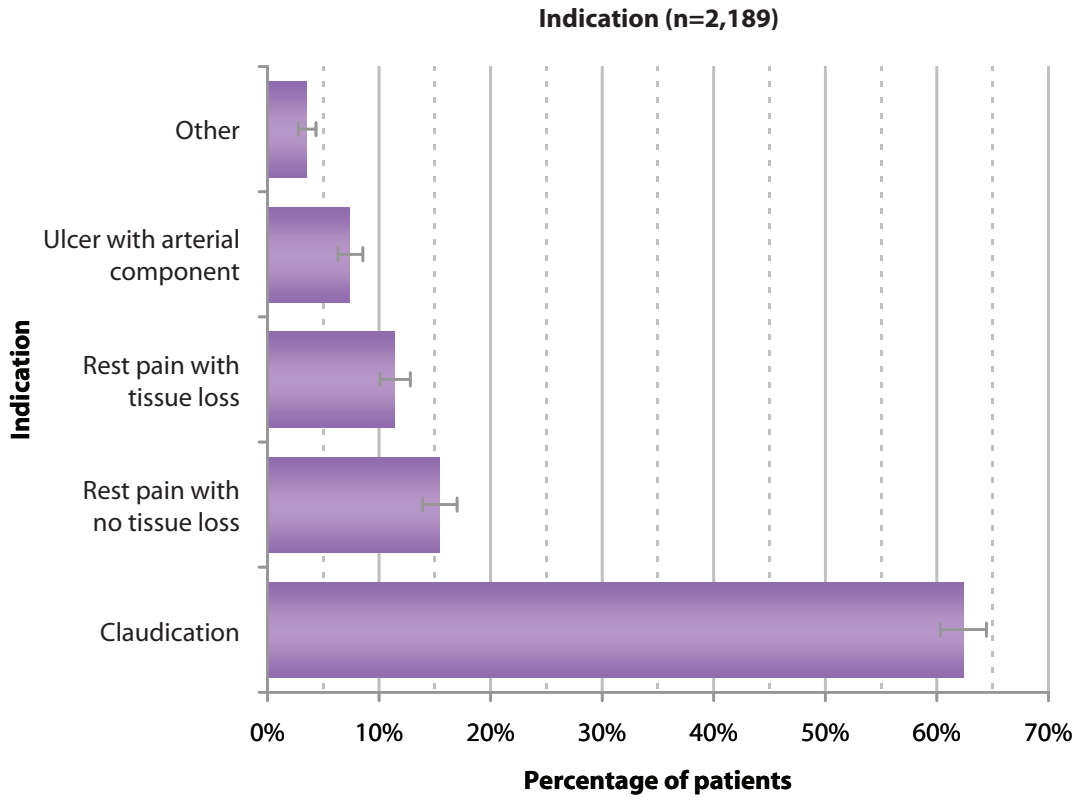


Indication

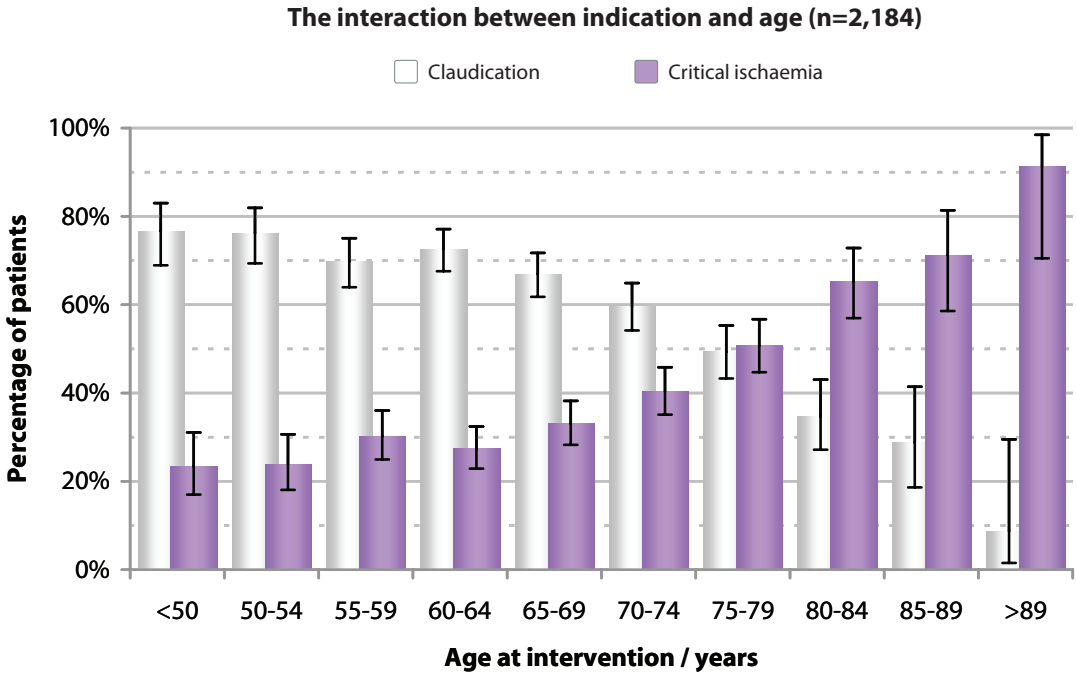
Indications recorded in the registry

Overall patients with claudication make up almost two-thirds and critical ischaemia about one-third of the treatment group. This shows no change from the results reported from BIAS II. Not surprisingly, the number of patients with claudication reduces with increasing age such that from the age of seventy-five onwards critical ischaemia overtakes claudication as the main indication for treatment.

		Counts and derived data		
		Count	Percentage	95% confidence interval
Indication	Rest pain with tissue loss	249	11.4%	10.1-12.8%
	Rest pain without tissue loss	337	15.4%	13.9-17.0%
	Ulcer with arterial component	161	7.4%	6.3-8.5%
	Claudication	1,366	62.4%	60.3-64.4%
	Other	76	3.5%	2.8-4.3%
	Unspecified	44		
	All	**2,233**		



Indication and age



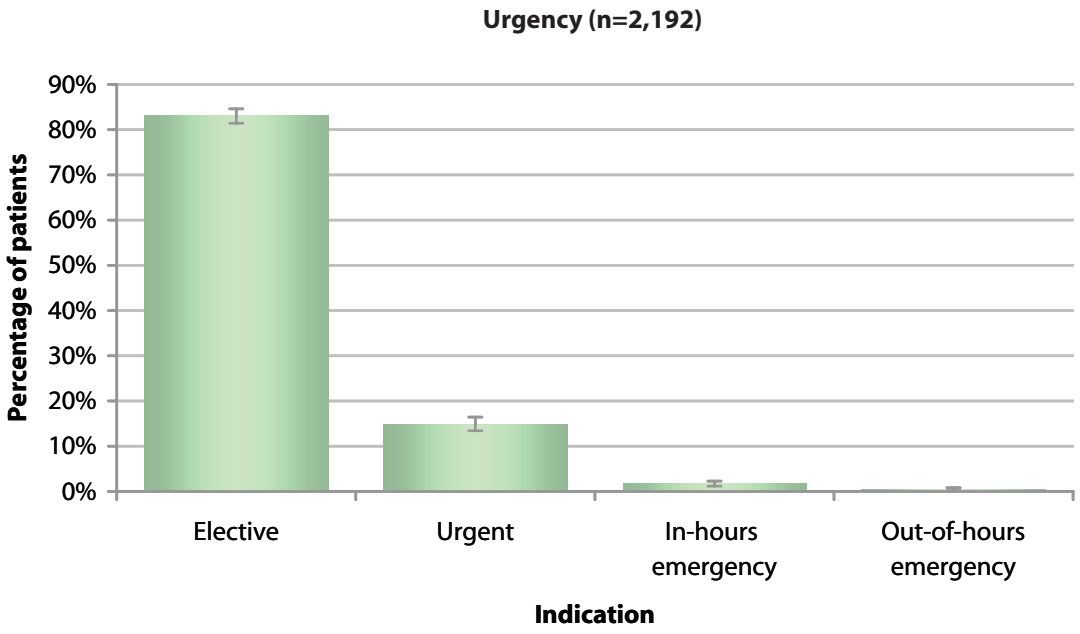
Procedure

Procedure-based data

Urgency

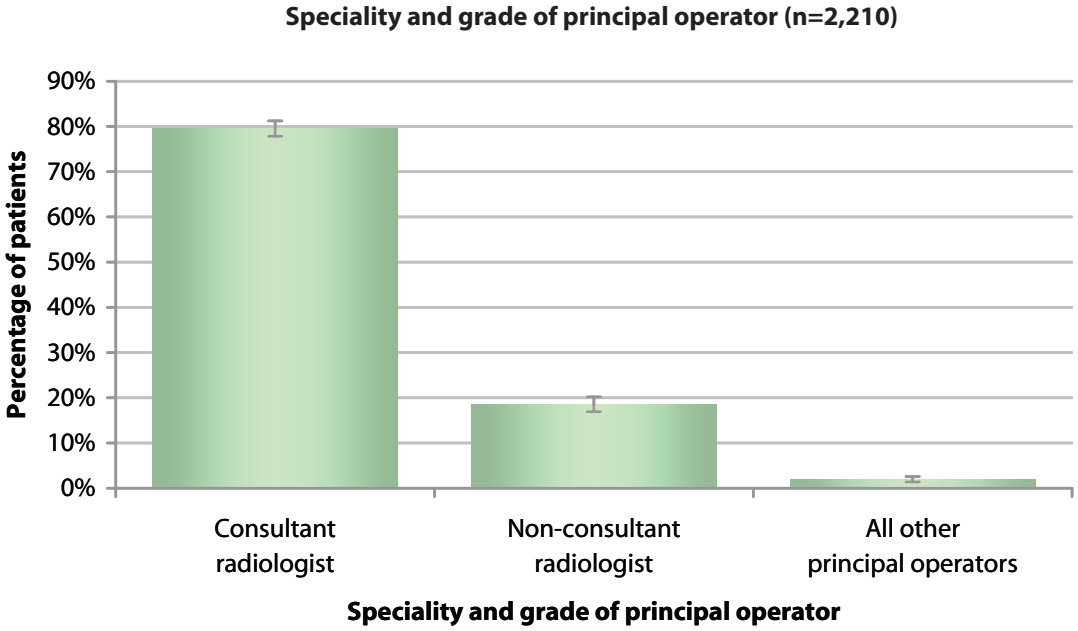
The proportion of elective / urgent cases has not changed since the time of the BIAS II report with only 2.1% of cases needing to be performed on an emergency basis (both in-hours and out-of-hours). Although there is a very low level of out-of-hours activity, this supports the need for the continuation of an out-of-hours service, especially when the proportion of urgent cases (14.9%) is taken into consideration.

		Counts and derived data		
		Count	Percentage	95% confidence interval
Urgency	Elective	1,821	83.1%	81.4-84.6%
	Urgent	326	14.9%	14.9-16.4%
	In-hours emergency	36	1.6%	1.2-2.3%
	Out-of-hours emergency	9	0.4%	0.2-0.8%
	Unspecified	41		
	All	**2,233**		



The principal operator

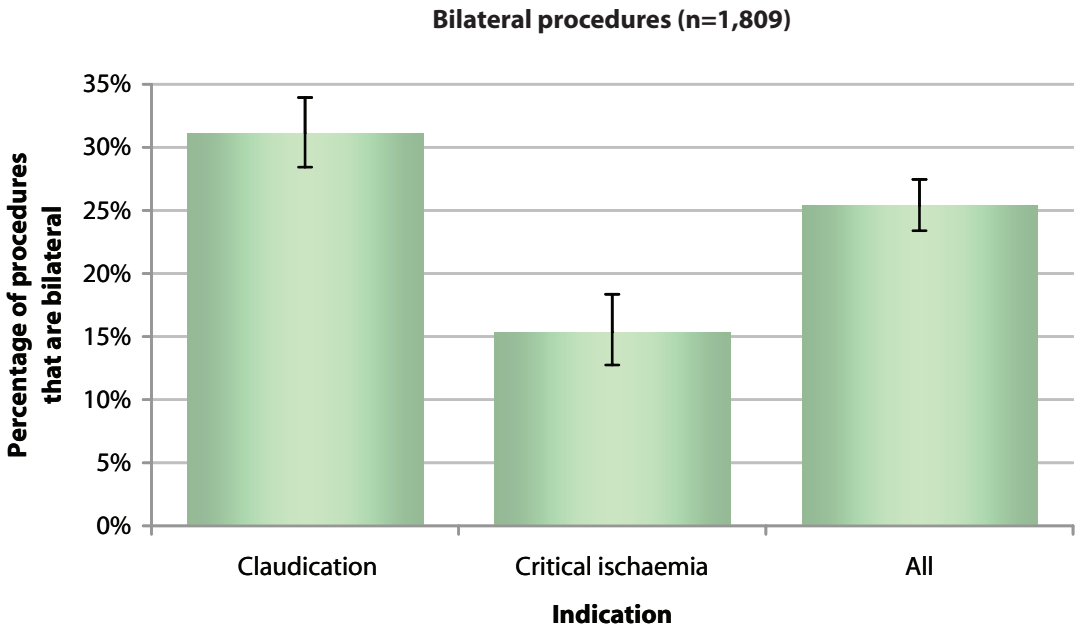
		Grade of the principal operator			
		Consultant	Other	Unspecified	**All**
Speciality	Radiology	1,759	409	3	**2,171**
	Other	16	26	0	**42**
	Unspecified	5	1	14	**20**
	All	**1,780**	**436**	**17**	**2,233**



Number of sides treated

		Number of sides treated			
		Unilateral	Bilateral	Unspecified	All
Indication	Claudication	948	416	2	**1,366**
	Critical ischaemia	689	130	4	**823**
	Unspecified	21	11	12	**44**
	All	**1,658**	**557**	**18**	**2,233**

Procedure

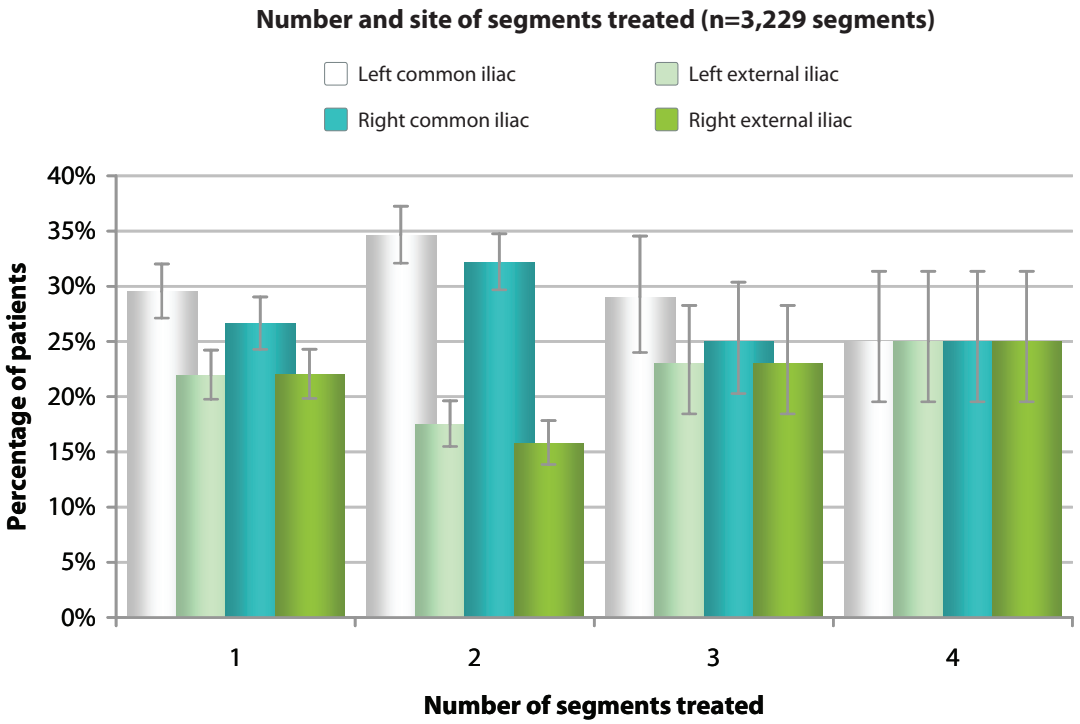


Iliac segments

Number of segments treated

Data from treated legs only; counts of patients

		Right leg iliac segments				
		Common iliac	External iliac	Common & external	Unspecified	**All**
Left leg iliac segments	Common iliac	287	23	31	404	**745**
	External iliac	18	62	13	300	**393**
	Common & external	31	25	55	154	**265**
	Unspecified	364	301	126	21	**810**
	All	**337**	**411**	**225**	**879**	**2,215**

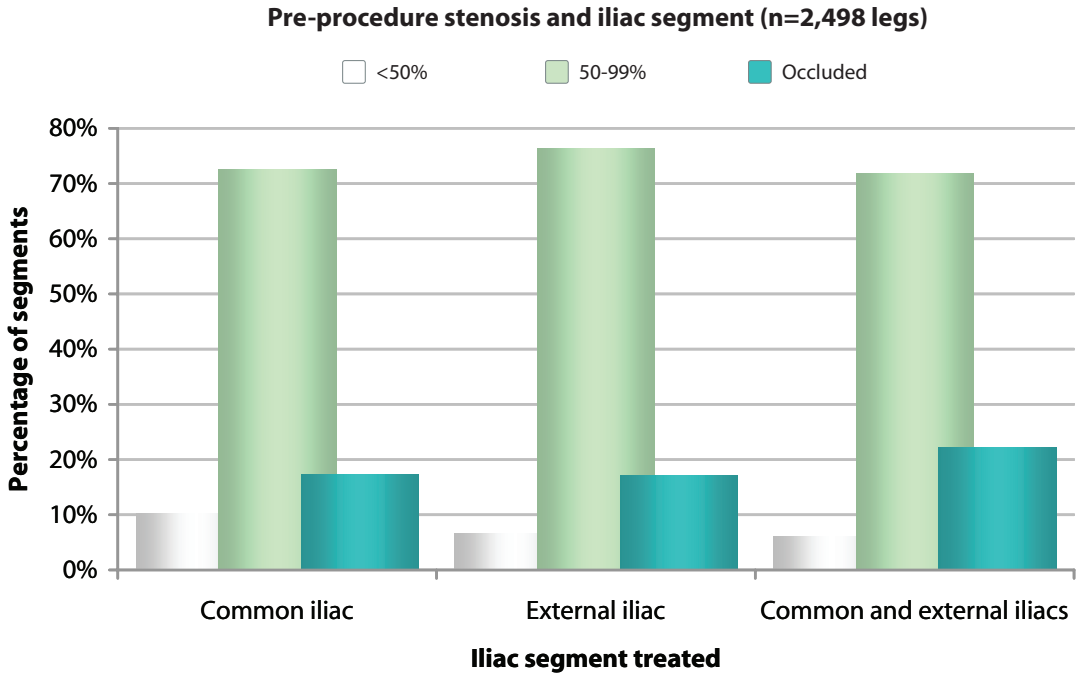


Pre-procedure stenosis

The majority of lesions were stenoses in the range 50%-99%. The proportion of treated vessels that were occluded has increased slightly from BIAS II from around 15.9% to approximately 18.8%. This may suggest increasing operator expertise or confidence. Of interest, there still remain a small percentage of arterial segments (8.0%) with minor stenoses (under 50%), which have been revascularised; this maybe because more severe disease is being treated elsewhere.

Data from treated legs only; counts of legs

		Pre-procedure stenosis				
		<50%	50-99%	Occluded	Unspecified	**All**
Iliac segments	Common iliac	133	940	223	149	**1,445**
	External iliac	48	560	126	70	**804**
	Common & external	28	336	104	22	**490**
	Unspecified	0	9	0	23	**33**
	All	**107**	**1,845**	**453**	**264**	**2,772**



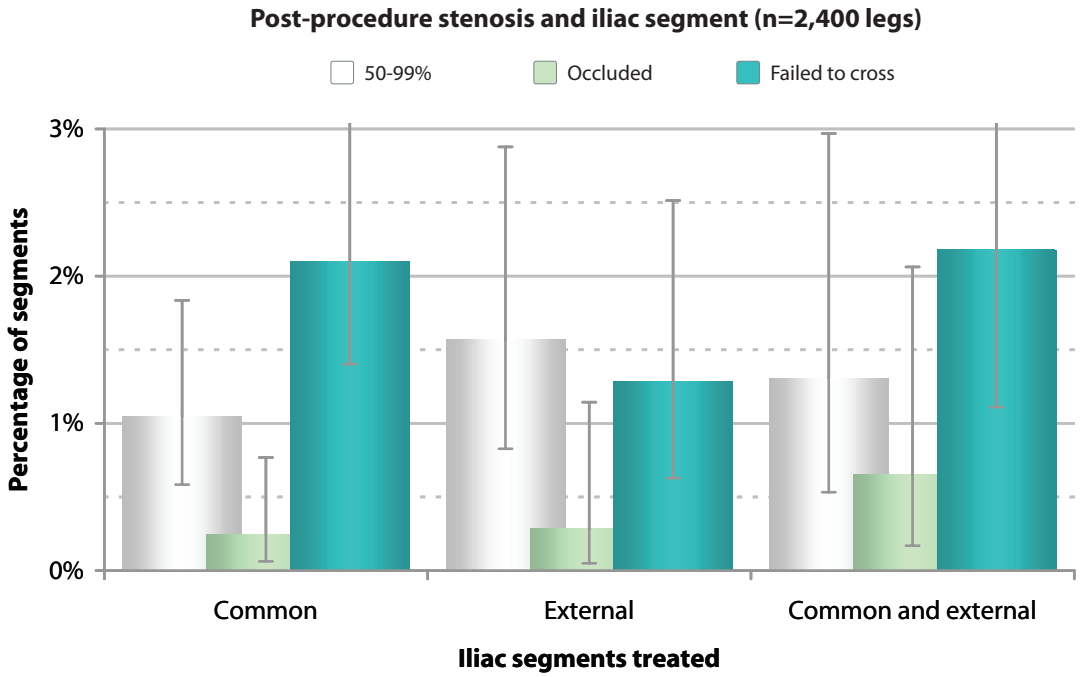
Residual stenosis post-procedure

Residual stenosis and iliac segment

Overall 1.9% of legs and 1.9% of segments could not be crossed with a guidewire. This compares with a rate of 2.3% of legs from BIAS II, however the most likely explanation is that these figures are almost certainly too good to be true and more probably represent reporting bias, in other words if the lesion was not crossed, the patient was not entered into the registry.

Data from treated legs only; counts of legs

		Residual stenosis					
		<50%	50-99%	100%	Failed to cross	Unspecified	All
Iliac segments	Common iliac	1,198	13	3	26	205	**1,445**
	External iliac	679	11	2	9	103	**804**
	Common & external	440	6	3	10	31	**490**
	Unspecified	8	1	0	2	22	**33**
	All	**2,325**	**31**	**8**	**47**	**361**	**2,772**

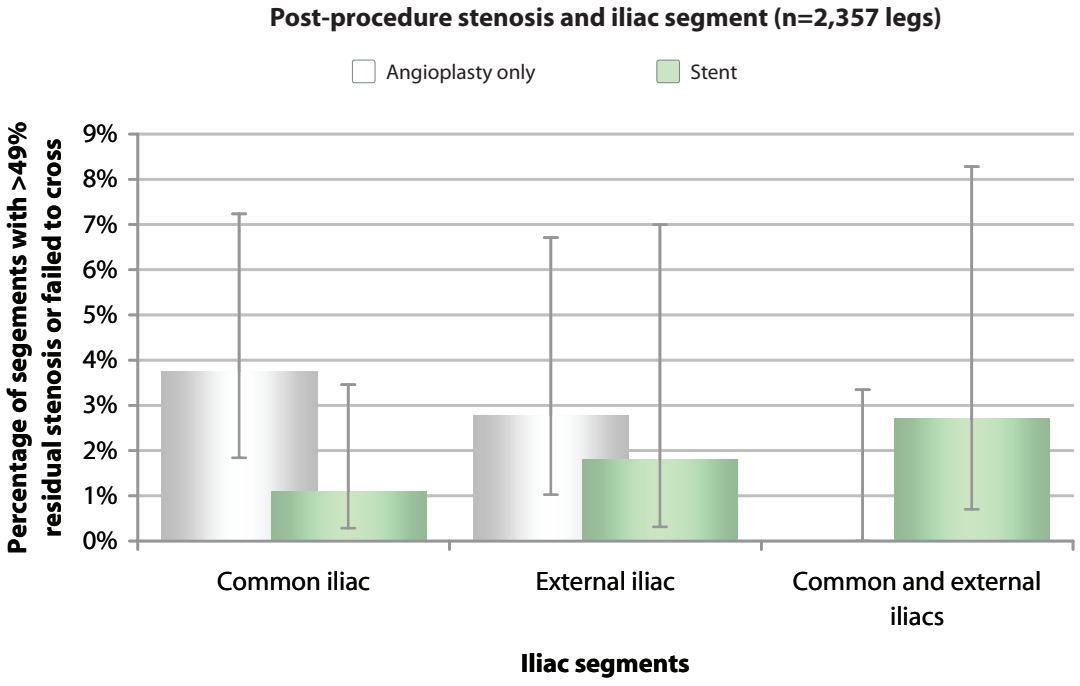


Residual stenosis and type of procedure

Overall 2.6% of legs had a residual stenosis (>50%) in the angioplasty group and 1.5% in the stent group. These results are not significantly different to those previously reported in BIAS II.

Data from treated legs only; counts of legs

Porcedure and iliac segments			Residual stenosis					
			<50%	50-99%	100%	Failed to cross	Unspecified	All
	Angioplasty only	Common iliac	549	10	1	5	39	**604**
		External iliac	395	7	0	3	25	**340**
		Common & external	195	2	1	1	2	**201**
		Unspecified	4	1	0	0	2	**7**
		All	**1,143**	**20**	**2**	**9**	**68**	**1,242**
	Stent	Common iliac	645	3	2	0	166	**816**
		External iliac	281	4	2	0	76	**363**
		Common & external	244	4	2	1	29	**280**
		Unspecified	4	0	0	0	3	**7**
		All	**1,174**	**11**	**6**	**1**	**274**	**1,466**

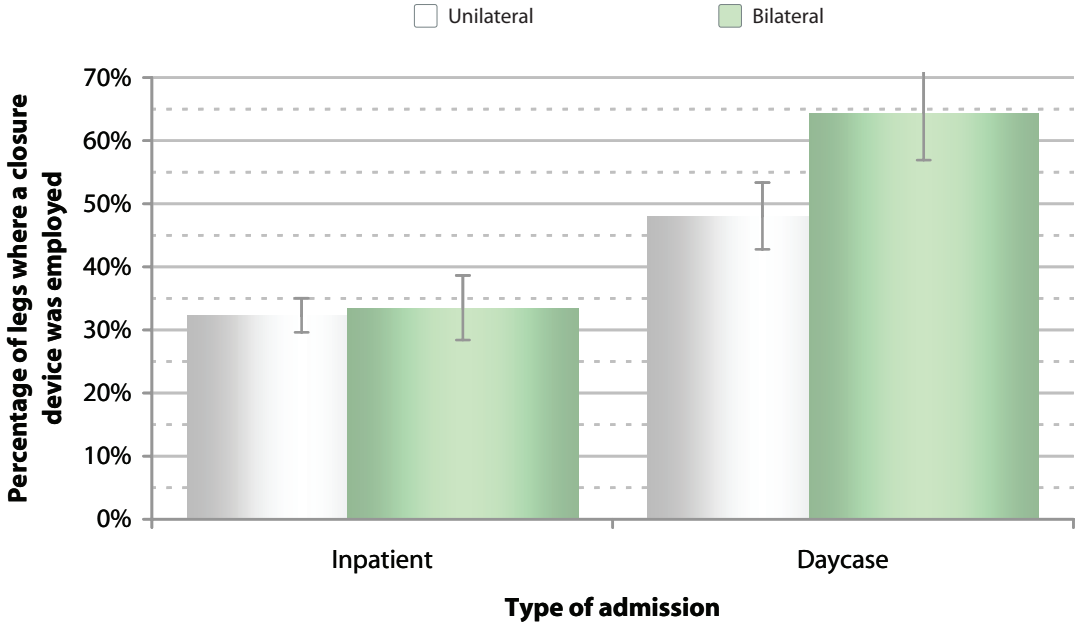


Percutaneous closure device

There has been a significant increase in percutaneous closure device usage in both daycases (to 53.6%) and in inpatients (to 32.5%) compared to the results reported in BIAS II.

Number of sides and type of admission			Closure device			
			No	Yes [i]	Unspecified	All
	Unilateral	Inpatient	802	382	80	**1,264**
		Daycase	186	172	4	**362**
		Unspecified	12	8	12	**32**
		All	**1,000**	**562**	**96**	**1,658**
	Bilateral	Inpatient	228	114	15	**357**
		Daycase	66	119	3	**188**
		Unspecified	5	4	3	**12**
		All	**299**	**237**	**21**	**557**
	Unspecified	Inpatient	0	0	4	**4**
		Daycase	0	0	2	**2**
		Unspecified	0	0	12	**12**
		All	**0**	**0**	**18**	**18**

The use of percutaneous closure devices and type of admission (n=2,069 patients)



i. Includes those entries where a closure device was used on one side of a bilateral procedure, but not on the other. A total of 41 entries recorded a procedure where the patient had a closure device deployed on one side but not the other.

Post-procedure

Post-procedure

Database definitions for complications and outcomes

Complications

Complications are classified into two broad groups: leg complications and systemic complications. Leg complications relate only to the limb or limbs, whereas systemic complications include all other events. A composite complication rate is also used, which is simply derived from the sum of both leg and systemic complications.

Leg complications

- None
- Distal embolism
- Flow limiting dissection
- Groin haematoma
- Treated vessel thrombosis
- Device malfunction
- Perforation
- Access site thrombosis
- Access site false aneurysm

Systemic complications

- None
- Myocardial infarction
- Worsening renal function
- Other

Outcomes

In addition, the treatment of the leg complications was recorded together with the final outcome for both the limb and the patient.

Treatment as a result of complications

- None
- Observation / increased hospital stay
- Unplanned endovascular therapy
- Unplanned surgery
- Amputation

Leg status at discharge

- Limb intact
- Worsening level of ischaemia
- Expected amputation
- Unexpected amputation

Patient status at discharge

- Alive
- Died during procedure
- Died in hospital

There are several weaknesses with the current classification of complications and outcomes in the BIAS registry. These primarily relate to a perceived lack of uniformity and consistency in data collection between centres. An example might be the complication of groin haematoma, which can vary from mild bruising to a massive haematoma requiring active management. Incidents spanning the entire breadth of this spectrum might reasonably be recorded in the registry, but if the clinicians have different thresholds for recording a groin haematoma then their apparent results will vary accordingly.

The dictionary of terms in the appendices at the end of this report is an attempt to clarify the definitions for data on complications in the BIAS dataset, which should help contributors to further improve the quality of their data and introduce increased consistency across the registry.

Further challenges include the enthusiasm and time-frame within which data on complications are sought and recorded. For example, a daycase patient suffering a groin haematoma after hospital discharge may never have their complication recorded in the BIAS registry. Similarly, those physicians who religiously visit patients on the wards post-procedure will understandably have a higher reported complication rate than those who simply use the period immediately post-procedure in the recovery room to garner information on possible complications.

Independent third-party assessment is the gold standard and is almost impossible to achieve with a project such as this.

Systemic complications

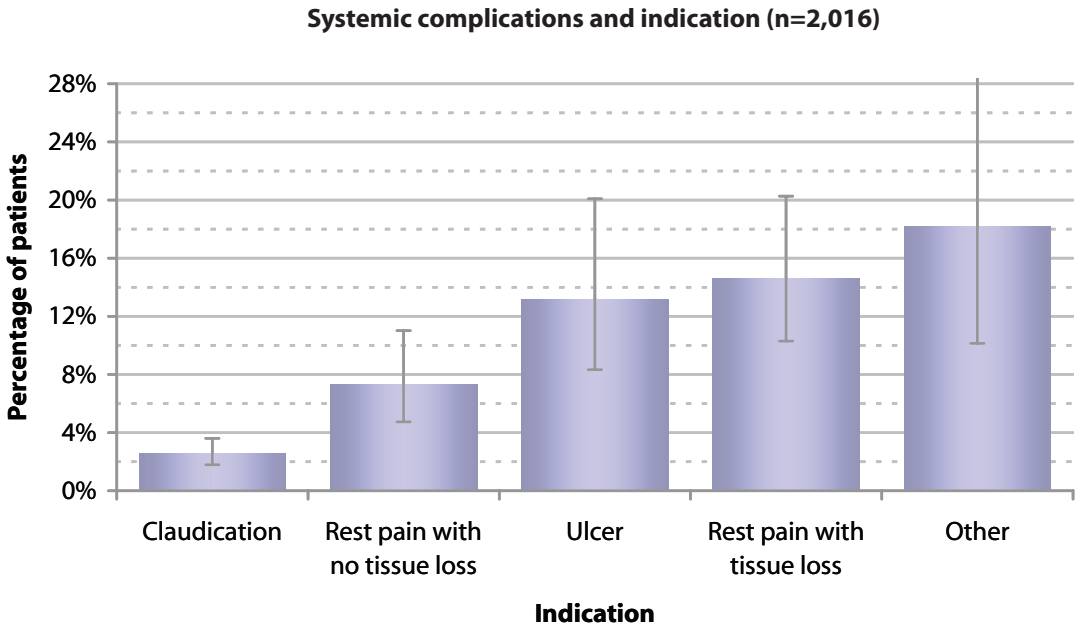
Systemic complications and indication

Complications are probably one of the most important outcome measures within the registry and form the basis of benchmarking between both hospitals/individual doctors and the national average.

Overall the systemic complication rate is 5.8%, with patients presenting as claudicants having just a 2.6% complication rate (2.5% in BIAS II). Patients with critical leg ischaemia by contrast suffer a 11.6% complication rate (10.6% in BIAS II). The increased age, comorbidity and disease extent probably account for the 4-fold difference in complication rates in the critical leg ischaemia patient group compared to the claudicant cohort.

This information may be useful when consenting patients and advising on risk.

		Systemic complications [ii]			
		No	Yes [iii]	Unspecified	Complication rate
Indication	Rest pain with tissue loss	181	31	37	14.6%
	Rest pain with no tissue loss	279	22	36	7.3%
	Ulcer with arterial component	125	19	17	13.2%
	Claudication	1,260	33	73	2.6%
	Other	54	12	10	18.2%
	Unspecified	18	2	24	
	All	**1,917**	**119**	**197**	



ii. Excluding in-hospital death.

iii. Defined as any one or more of the following: *MI*, *Worsening renal function* or *Other*. This definition does not take account of leg-specific complications.

Details of recorded systemic complications

However, accurate and consistent reporting of these data is paramount to the value of the registry. A good example of the problems of data collection is the analysis of systemic complications:-

- The web-based database currently provides 4 options for capturing data on complications: *None*, *MI*, *worsening renal function* and *other*
- The most frequently recorded category was *Other* with 109 entries
- Of these *Others* at least 12 should have been posted as leg complications
- The remainder were a mixture of complications ranging from a few serious procedure-related issues to some very minor complications and a few completely spurious comments
- Therefore, the BSIR Audit Committee has decide to remove the *Other* option from the systemic complication question in the database and to expand the number of specified systemic complication listed to try capture all relevant events (such as stroke, pulmonary embolus and retroperitoneal haematoma) so as to permit meaningful tracking of important complications in the future
- In addition, complications will be graded according to severity
- A dictionary of terms is included in the Appendix

If only the *true* major complications are analysed this brings the overall complication rate down to about 1.0%, which is reassuring.

		Counts and derived data		
		Count	Percentage	95% confidence interval
Systemic complications [iv]	None	1,917	94.2%	93.1-95.1%
	MI	12	0.6%	0.3-1.1%
	Worsening renal function	10	0.5%	0.2-0.9%
	Other	109	5.4%	4.4-6.4%
	Unspecified	197		
	Patient denominator	**2,233**		

iv. In this question either the option *None* or one or more of the defined patient-complications may be selected; this means that the sum of the instances recorded against *None* and the positive systemic complications may be greater than the total number of patients, which is recorded in the row labelled *Patient denominator*.

Expanded detail on *Other* systemic complications

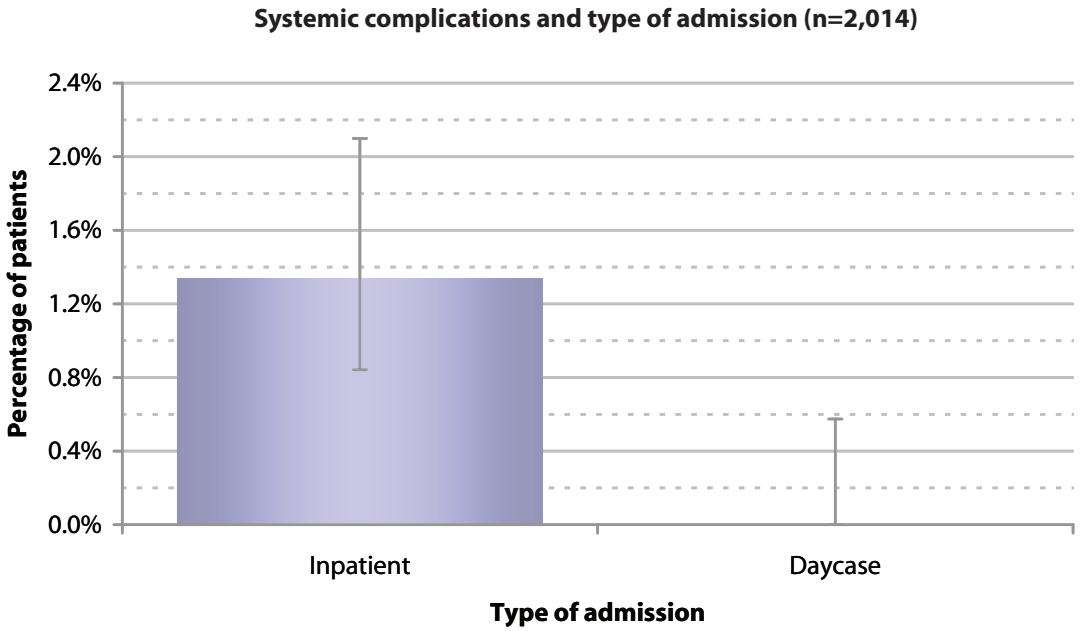
- (left) access vessel thrombosis requiring unplanned surgery post discharge
- 1 day post op increased pain; significant velocity gradient on doppler; stent inserted
- acute aortic stenosis, cardiac failure
- acute renal failure, foot sepsis
- angina - no changes on ECG
- brachycardia / ventriculum ectopics
- CA lung and prostate, cerebral mets; transferred for hospice care, died in hospice
- cellulitis (below knee)
- chemical sympathectomy for pain (R) foot; readmitted for B/K amp; RIP acute ischaemia (L) leg; PVD
- chest infection
- collapse, cause unknown ×2
- colonic adenoma, bronchopneumonia
- comorbidities, general deterioration during admission
- confusion, general disorientation
- confusion, chest infection, wound infection, post fem / fem Xover bypass
- continued ischaemia of foot due to diabetes - further amputation of toes & forefoot.
- creatinine 93 - foot cold and pale - ?TIA - desaturated - deceased
- CVA
- delay in discharge due to femoral endarterectomy and fem-pop bypass
- delayed discharge waiting for R angioplasty performed
- diagnosed lung cancer
- dissection contra-lateral common iliac successfully stented at time of procedure. No sequelae
- dizziness ?vertigo
- femoral endarterectomy
- fem-pop bypass, right forefoot amp
- flow limiting dissection in EIA (not site of PTA) requiring surgery; CM allergy also so done with CO2
- further management required
- further ops, fem distal bypass & endarterectomy, amp 2nd-5th toes R foot
- had planned fempop bypass at same time
- haematuria not related to stent
- hospital acquire pneumonia; left forefoot amputation after fem-fem xover graft
- hospital stay lengthened by fall, ribs & pneumothorax
- hypotension, sepsis
- hypotension 2 hours post procedure, scans showed no bleed, recovered with fluids
- hypotension, sepsis and UTI
- hypotensive, recovered with IV fluids. No sequele.
- infected wound
- ischaemic finger tips
- itiutiry
- lateral cutaneous nerve palsy r leg
- left iliac perforation and retroperitoneal haematoma; managed conservatively
- LRTI
- LVF
- minor right groin haematoma[xover technique R/L legs] Stayed in hospital to allow Rt SFA angioplasty via left groin
- multi-organ failure ×2
- multiple co-morbidities, condition deteriorated during the admission
- multiple pathology, basal pneumonia
- no case notes available - cause of death unknown ×2
- no specific complication from RIGHT EIA angioplasty, but LEFT leg (continued to) deteriorate - note left leg was the symptomatic leg, R iliac angioplasty was done to improve inflow to the right CFA with a view to subsequent fem-fem X-over graft.

- no specific complication relating to the procedure, but later the patient developed HAP and ultimately died in hospital
- none related to the angioplasty; went to surgery though for his left leg and developed pneumonia post operatively
- ongoing foot ischaemia due to diabetes - left toes amputated
- PE
- patient had Lt common iliac stent inserted; Rt stent encroached on Lt side
- patient had other procedures at same time
- pneumonia / LVF
- poor healing post great toe amputation, further toes lost, also had SFA + peroneal artery angioplasty
- poor wound healing post amputation 1st and 2nd toes
- post endartarectomy - multi drug resistant coliform infection in wound site
- post fem-pop bypass, serious respiratory complications requiring intubation and ICU admission
- post stent fem-pop bypass, occluded, amputation, not related to iliac stenting
- postural hypotension
- pressure sores
- prolonged hospital stay due to BKA
- pseudo aneurysm treated by compression
- pt developed pneumonia
- pulm oedema + hospital acquired pneumonia
- pulmonary oedema ×2
- respiratory failure post fem-pop bypass
- retroperitoneal haematoma - did not delay discharge
- rhabdomyolysis, ARF, Rt calf compartment syndrome, ischaemic sigmoid colon (Occ IMA), resp failure, hosp acq pneumonia!
- right femoro popliteal bypass at time of procedure- wound infection
- rupture requiring admission
- ruptured Lt EIA; blood transfusion
- sepsis ?secondary to ulcers
- sepsis, bronchopneumonia, pulmonary oedema.
- septic shock from gangrenous Lt leg; died of sepsis despite AKA 6 days post stenting
- severe bradycardia during angioplasty; Rx atropine; recovered; no MI
- she moans alot
- small bilateral haematomas
- small haematoma requiring pressure bandage
- sudden onset calf pain, hospitalised
- rynovitis right knee and pyrexia
- thrombin injections to femoral aneurysm, AKA, died
- thrombosis of right CFA requring endarterectomy
- transferred to ITU; pneumonia with bilateral effusions
- type1 respiratory failure, hospital acquired pneumonia, NSTEMI, ARF
- upper abdominal pain and nausea during procedure, no intervention required
- urinary retention ×2
- urinary retention requiring in-out catheter
- URTI
- UTI, septicaemia within 24 hours
- vasovagal episode on ballooning EIA
- vaso-vagal episode post-procedure ×6
- vasovagal reaction, hypotensive, stroke
- worsening ischaemia Rt leg, ischaemic perforation of colon, Hartmans procedure, resp failure, prolonged ICU admission
- wound sepsis, anaemia, necrosis R buttock

Systemic complications and type of admission

The following analysis shows systemic complication rates by admission type and excludes all complications defined as *Other* (see notes on previous page).

		Systemic complications [v]			
		No	Yes [vi]	Unspecified	**All**
Type of admission	Inpatient	1,474	20	131	**1,625**
	Daycase	520	0	32	**552**
	Unspecified	21	1	34	**56**
	All	**2,015**	**21**	**197**	**2,233**



v. Excluding in-hospital death.

vi. Defined as any one or more of the following: *MI* or *Worsening renal function*. This definition does not take account of leg-specific complications.

Leg complications

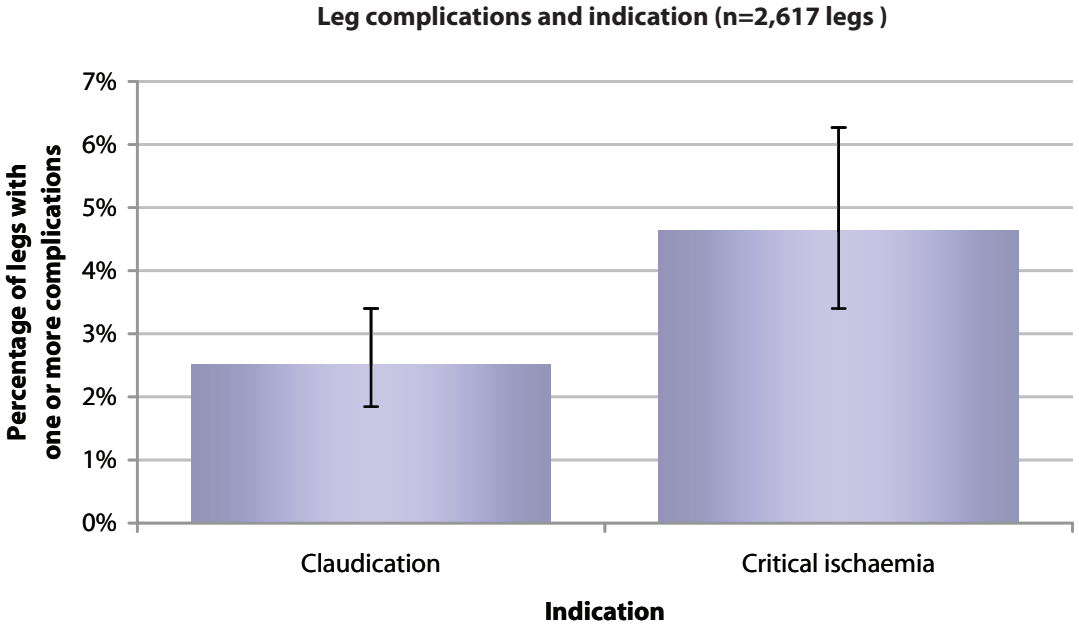
Leg complications and indication

It is gratifying that overall approximately 97% of all patients experience no leg complications. Furthermore the leg complication rate did not differ significantly between the stent and angioplasty groups. However the leg complication rate was higher in the critical ischaemia group (4.6%) compared to the claudicant group (2.5%).

Reporting levels may vary between institutions as in some cases only immediate complications are recorded as data entry is completed in the catheter laboratory and for others somewhat later on the post-operative wards. Some centres follow up patients after discharge via telephone interview and consequently may capture more complication data.

Data from treated legs only; counts of legs

		Leg complications			
		No	Yes [vii]	Unspecified	**All**
Indication	Claudication	1,668	43	69	**1,780**
	Critical ischaemia	864	42	43	**949**
	Unspecified	33	1	9	**43**
	All	**2,565**	**86**	**121**	**2,772**

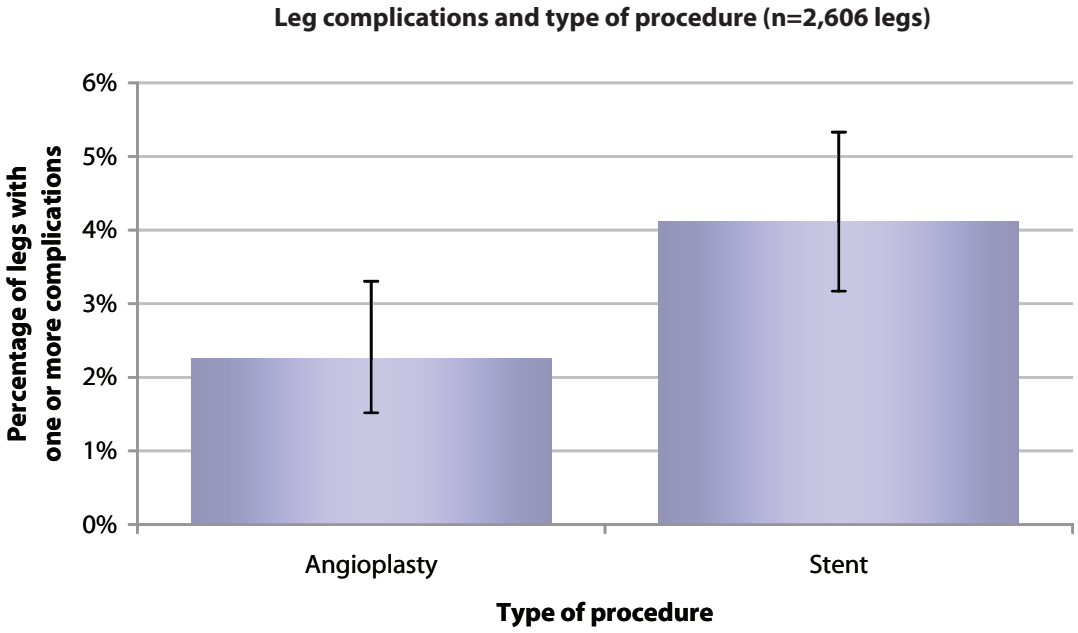


vii. Defined as any one or more of the following: *Access site false aneurysm*; *Access site thrombosis*; *Device malfunction*; *Distal embolism*; *Flow limiting dissection*; *Groin haematoma*; *Perforation*; *Treated vessel thrombosis.*

Details on leg complications

Data from treated legs only; counts of legs

		Type of procedure			
		Angioplasty		Stent	
		Count	Rate	Count	Rate
Leg complications	None	1,172	97.7%	1,349	95.9%
	Distal embolism	6	0.5%	11	0.8%
	Flow limiting dissection	5	0.4%	8	0.6%
	Groin haematoma	12	1.0%	18	1.3%
	Treated vessel thrombosis	2	0.2%	6	0.4%
	Device malfunction	2	0.2%	2	0.1%
	Perforation	1	0.1%	8	0.6%
	Access site false aneurysm	0	0.0%	5	0.4%
	Access site thrombosis	1	0.1%	3	0.2%
	Unspecified	43		59	
	Leg denominator	**1,242**		**1,466**	

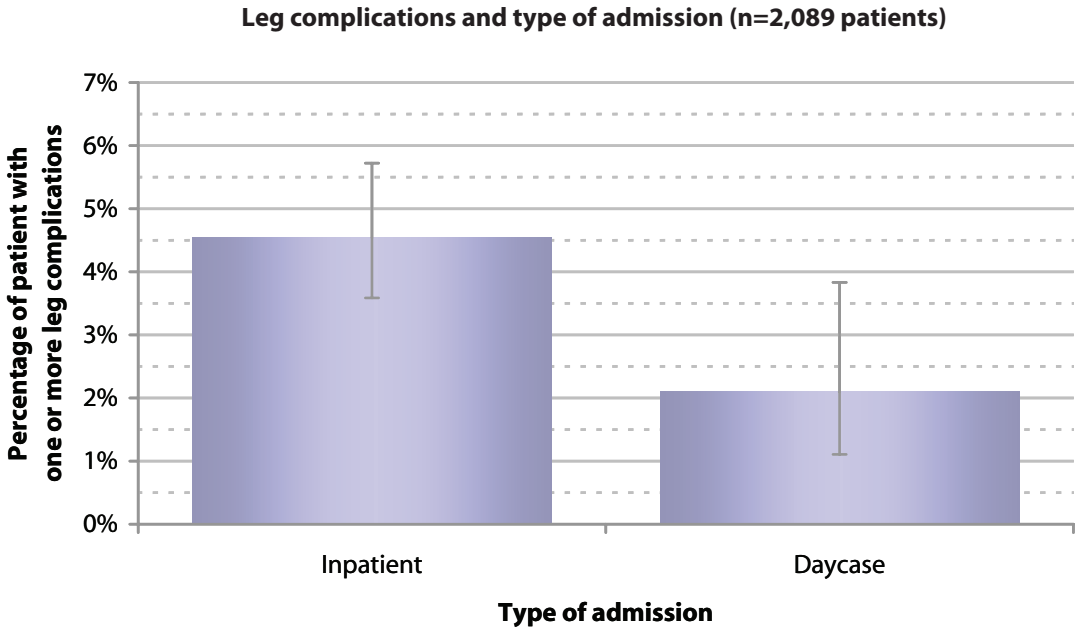


Leg complications and type of admission

The chart below compares leg complication rates and for the two different types of hospital admission. From a chi-squared statistical test, it is clear that there is a significant difference in leg complication rates between the patients treated as daycases and those treated as inpatients (χ^2=5.60; p=0.018).

Data on a patient-by-patient basis

		Leg complications			
		No	Yes [viii]	Unspecified	**All**
Admission	Inpatient	1,493	71	61	**1,625**
	Daycase	514	11	27	**552**
	Unspecified	24	3	29	**56**
	All	**2,031**	**85**	**117**	**2,233**

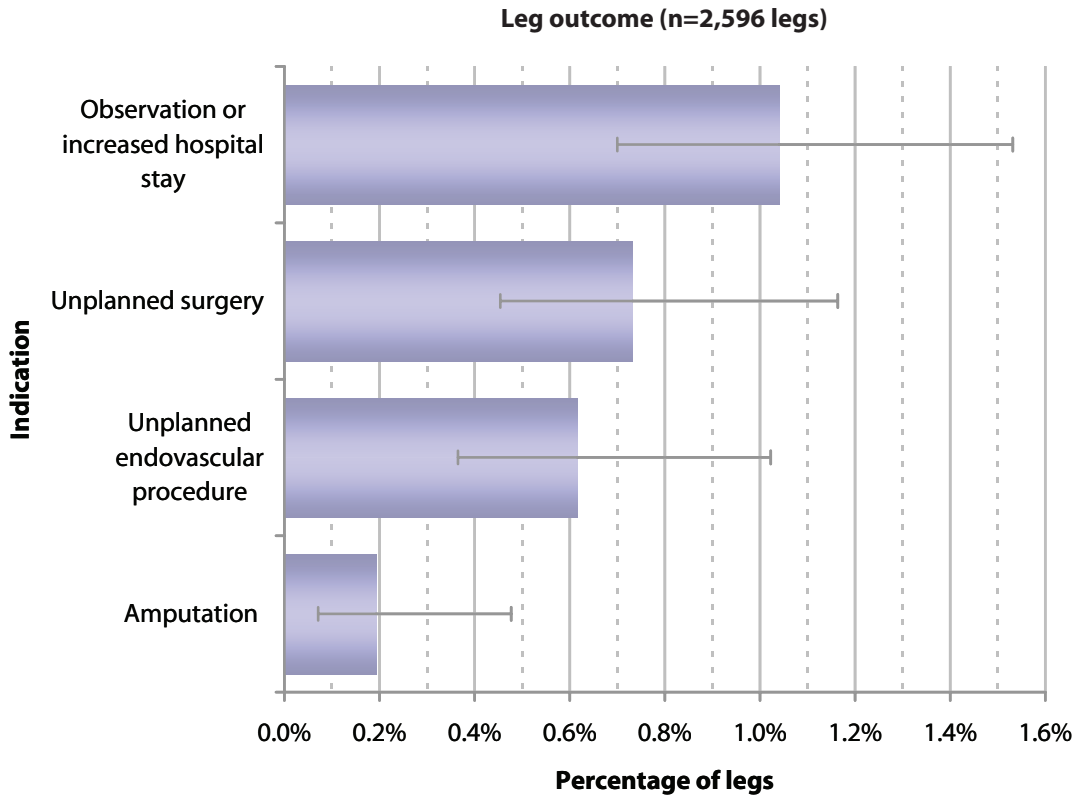


viii. If either treated leg has a recorded complication the patient is deemed to have had a leg complication.

Outcome resulting from leg complications

Outcome per leg

		Data - leg [ix]	
		Counts	Rate
Outcome [x]	None	2,534	97.6%
	Amputation	5	0.2%
	Observation / increased stay	27	1.0%
	Unplanned endovascular procedure	16	0.6%
	Unplanned surgery	19	0.7%
	Unspecified	176	
	Leg denominator	**2,772**	



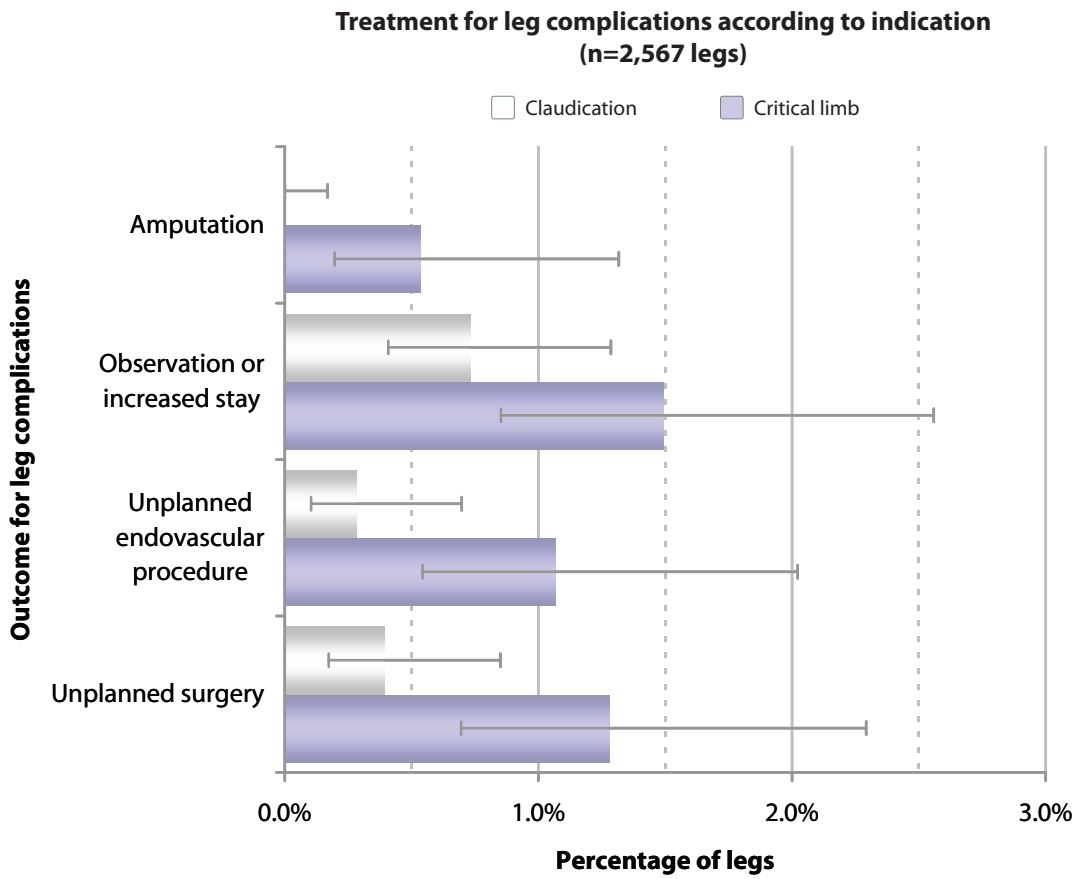
ix. Where recorded as undergoing a procedure.

x. In this question either the option *None* or one or more of the defined treatments may be selected; this means that the sum of the instances recorded against *None* and the treatments may be greater than the total number of patients, which is recorded in the row labelled *Patient denominator*.

Outcome for leg complications and indication

The overall rates for leg complications, on a by-patient basis, are 4.6% for the patients with critical limb disease (n=1,054; 95% CI: 3.5-6.1%) and 3.4% for patients with critical ischaemia (n=1,037; 95% CI: 2.4-4.7%).

		Indication			
		Claudic'n	Critical ischaemia	Unspecified	**All**
Outcome [xi]	None	1,670	836	28	**2,534**
	Amputation	0	5	0	**5**
	Observation / increased stay	13	14	0	**27**
	Unplanned endovascular procedure	5	10	1	**16**
	Unplanned surgery	7	12	0	**19**
	Unspecified	86	76	14	**176**
	Leg denominator	**1,780**	**949**	**43**	**2,772**

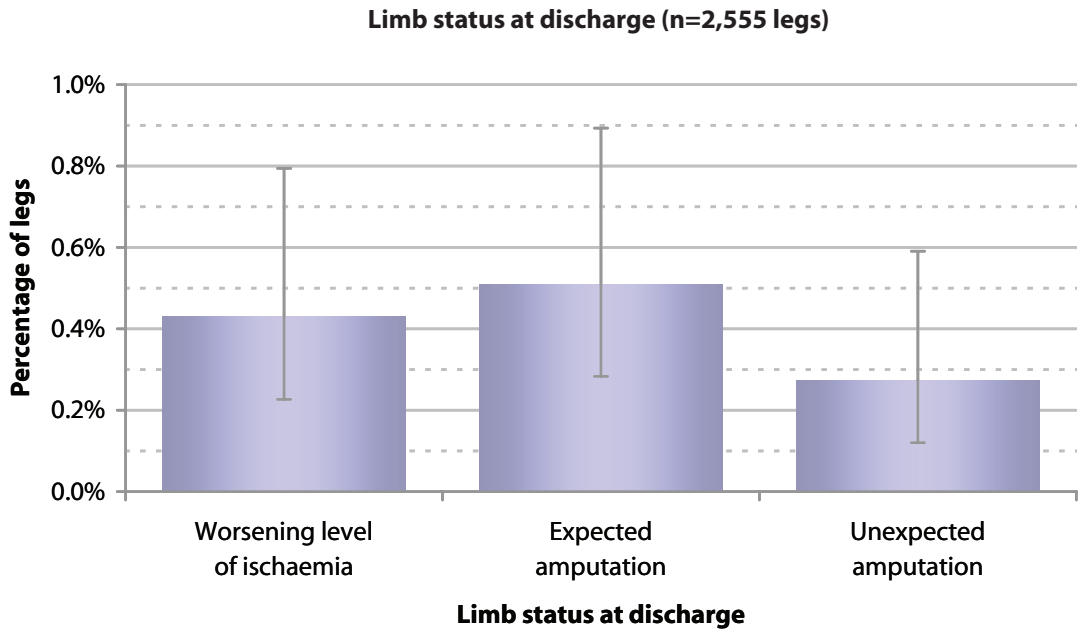


xi. In this question either the option *None* or one or more of the defined treatments may be selected; this means that the sum of the instances recorded against *None* and the treatments may be greater than the total number of patients, which is recorded in the row labelled *Leg denominator*.

Limb status at discharge

Only 1.2% of patients can expect to be discharged from hospital with a deterioration in their limb ischaemia or with an unexpected limb amputation.

		Data - leg [xii]	
		Counts	Rate
Limb status	Limb intact	2,524	98.8%
	Worsening level of ischaemia	11	0.4%
	Expected amputation	13	0.5%
	Unplanned amputation	7	0.3%
	Unspecified	317	
	Number of legs	**2,772**	

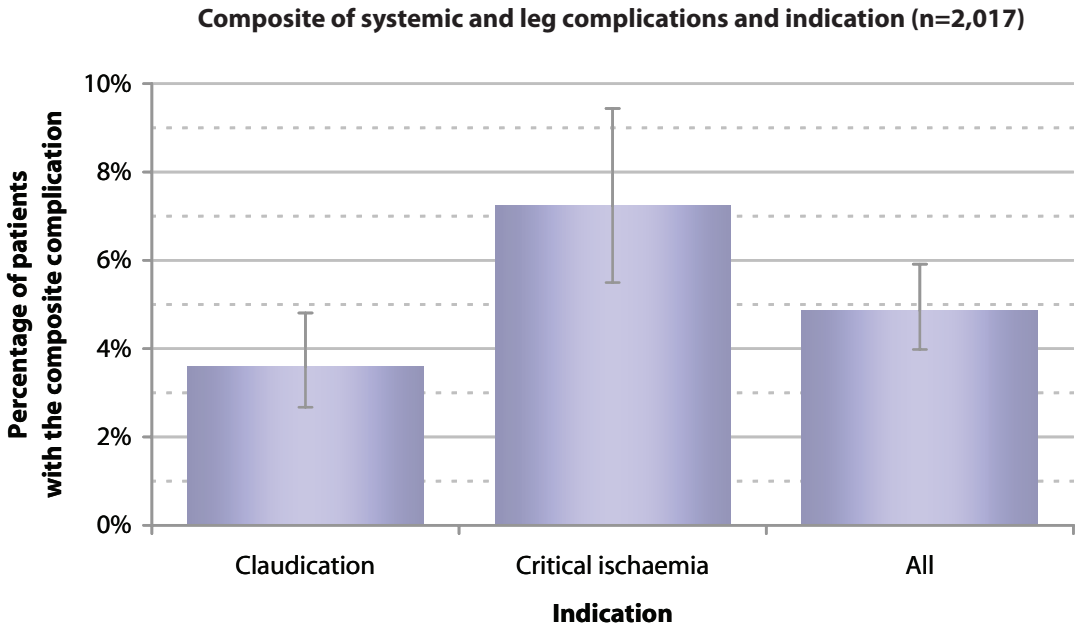


xii. Treated legs only.

Composite of systemic and leg complication

The following graph and table below illustrate the total complication rate (4.9%) for the whole group of patients in the registry, and includes all systemic and leg specific events. This shows a 3.6% complication rate for claudicants compared with a 7.2% rate for patients with critical limb ischaemia. The difference is statistically significant (χ^2=12.3; p<0.001) and highlights the need to risk stratify patients when assessing outcomes for individual centres, operators and individual patients.

		Composite complication [xiii]			
		No	Yes	Unspecified	**All**
Indication	Claudication	1,223 96.4%	46 3.6%	87	**1,366**
	Critical ischaemia	667 92.8%	52 7.2%	104	**823**
	Unspecified	19	0	25	**44**
	All	**1,919**	**98**	**216**	**2,233**



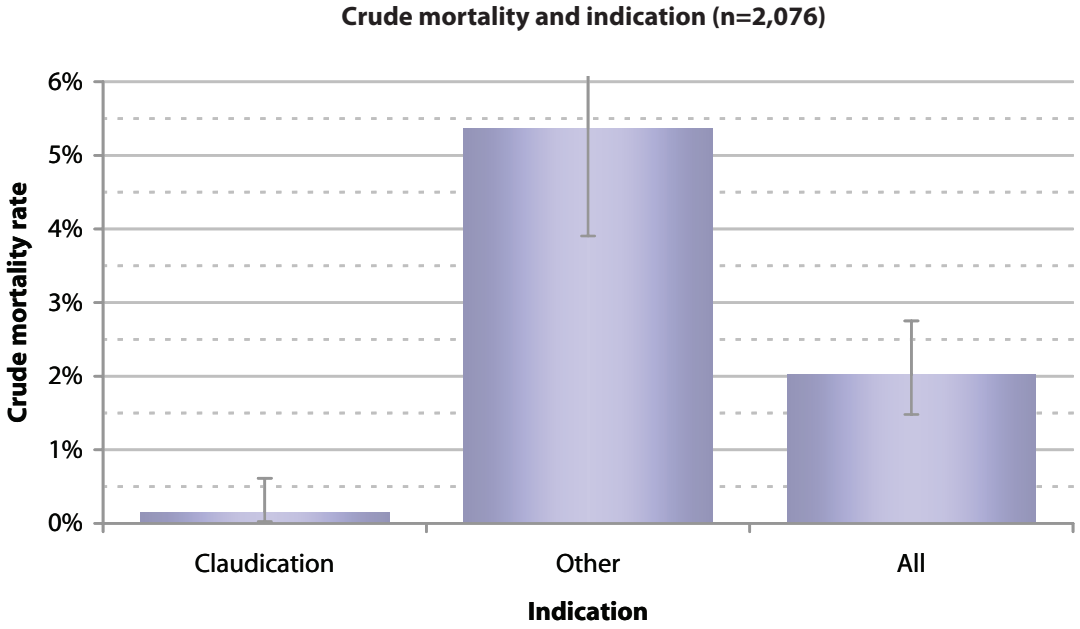
xiii. Defined as any one or more of the following: systemic complications (excluding *Other)*, left leg complications or right leg complications; leg complications are only considered for legs recorded as undergoing a procedure; all appropriate components must be recorded to determine the composite outcome. .

Mortality

Mortality and indication

The overall mortality rate was 2.0%, with almost all of these occurring in the critical limb ischaemic group; however of some concern there were two deaths (0.2%) in the claudicant group (both were female, one aged 73 & the other aged 82; one had a post-procedural MI recorded as a post procedure complication, the other patient's cause of death was unknown). This approximates to an overall mortality rate of 1 patient in every 500 procedures, which may be useful information for consideration in providing patients with informed consent

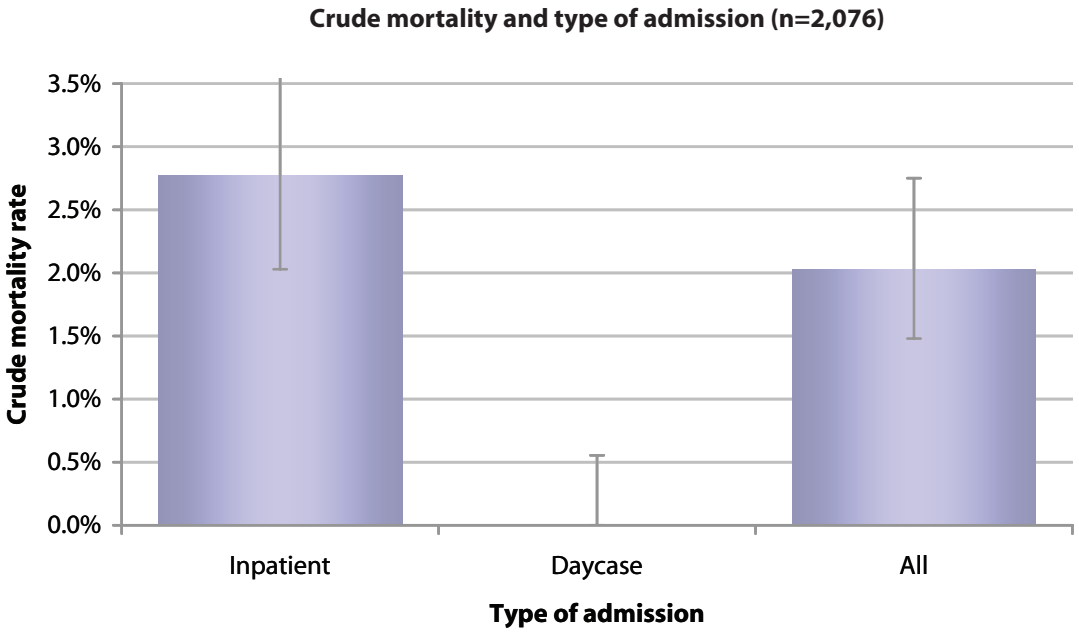
		Patient status at discharge				
		Death	Survival	Unspecified	Mortality rate	95% confidence interval
Indication	Claudication	2	1,309	55	0.2%	0.0-0.6%
	Other	40	706	77	5.4%	3.9-7.3%
	Unspecified	0	19	25	0.0%	0.0-14.6
	All in BIAS III	**42**	**2,034**	**157**	2.0%	1.5-2.8%
	All in BIAS II	**20**	**1,031**	**3**	1.0%	0.5-1.9%
	All in BIAS I	**11**	**1,077**	**10**	1.9%	1.2-3.0%



Mortality and type of admission

There were no deaths in the day case category as found in BIAS I and BIAS II, which suggests ongoing appropriate case selection for day case procedures.

		Patient status at discharge				
		Death	Survival	Unspecified	Mortality rate	95% confidence interval
Type of admission	Inpatient	42	1,473	110	2.8%	2.0-3.8%
	Daycase	0	539	13	0.0%	0.0-0.6%
	Unspecified	0	22	34	0.0%	0.0-12.7%
	All	**42**	**2,034**	**157**	2.0%	1.5-2.8%

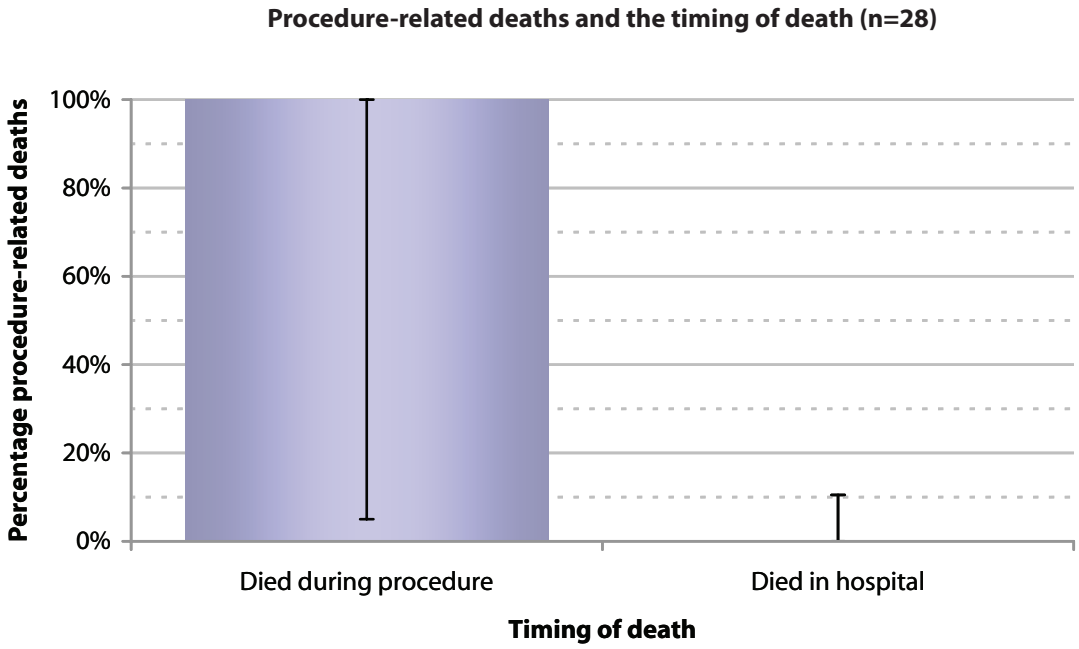


		Patient status at discharge				
		Death	Survival	Unspecified	Mortality rate	95% confidence interval
Type of admission	Inpatient	1,473	42	110	2.8%	2.0-3.8%
	Daycase	539	0	13	0.0%	0.0-0.6%
	Unspecified	22	0	34	0.0%	0.0-12.7%
	All	**2,034**	**42**	**157**	2.0%	1.5-2.8%

Cause of death

Of the 42 deaths recorded in the registry, only one was classified as being procedure related (3.6% of entries where the cause is recorded; 2.3% of all deaths in the registry). These data are somewhat difficult to understand as 3 deaths occurred during the procedure.

		Cause of death			
		Not applicable	Procedure-related	Not procedure-related	Unspecified
Status at discharge	Died during procedure	1	1	0	1
	Died in hospital	4	0	27	8
	Unspecified	0	0	0	0
	All	**5**	**1**	**27**	**9**



Funnel plots

There are, of course, many other different ways to display crude outcome data. When comparing outcomes at different hospitals, one method would be to calculate the outcome rate for each hospital and then rank them in ascending order of outcome rate; it is possible to place 95% confidence intervals around the calculated rate to give some indication of the confidence in that result, but this method tends to draw the eye to the upper and lower reaches of the ranking and does not easily provide information on how each hospital sits with respect to the average outcome rate.

Another method would be to determine the rank-order for the hospitals based on crude or risk-adjusted outcome rates and then plot these ranks with suitable confidence intervals around them. This method will also tend to draw attention to the extremes of the ranking and can generate spurious results.

Shewhart control charts have been suggested as a means of presenting performance in the clinical setting without having to resort to such spurious ranking into league tables [xiv]. These plots show the number of observed events against the volume of cases on a square-root scale; unfortunately this format is not intuitive, obscures the observed event rate and leads to rather approximate control limits. Applying a minor adjustment to this method – plotting the event rate against the number of cases – generates the so-called funnel plot [xv, xvi] which is widely used in meta-analyses to check for publication bias and has been used to compare mortality rates in paediatric cardiac surgery. Exact binomial control limits around the overall rate are superimposed to indicate possible thresholds for alert and alarm respectively.

Funnel plots discourage inappropriate ranking while providing a strong visual indication of divergent performance or special cause variation; they are not a cause for damnation in and of themselves. Advantages over the Shewhart control charts approach include the display of the observed event rates, an informal check on the relationship between the event rate and number of cases, an emphasis on the natural increased variability amongst small-volume centres, intuitive choice of axes (hence easy plotting) and exact binomial control limits that can be calculated using the most popular spreadsheet packages.

This method is, however, not risk-adjusted, and therefore has all the problems associated with not comparing like with like.

xiv. Mohammed MA, Cheng KK, Rouse A and Marshall T. Bristol, Shipman and clinical governance: Shewhart's forgotten lessons. *Lancet* 2001; **357**: 463-467.

xv. Spiegelhalter DJ. Funnel plots for institutional comparison. *Qual Saf Health Care* 2002; **11**: 390-391.

xvi. Spiegelhalter DJ. Funnel plots for comparing institutional performance. *Statistics in Medicine* 2005; **24**: 8: 1185-1202

(see http://www.mrc-bsu.cam.ac.uk/BSUsite/AboutUs/People/davids/davids_Research.shtml)

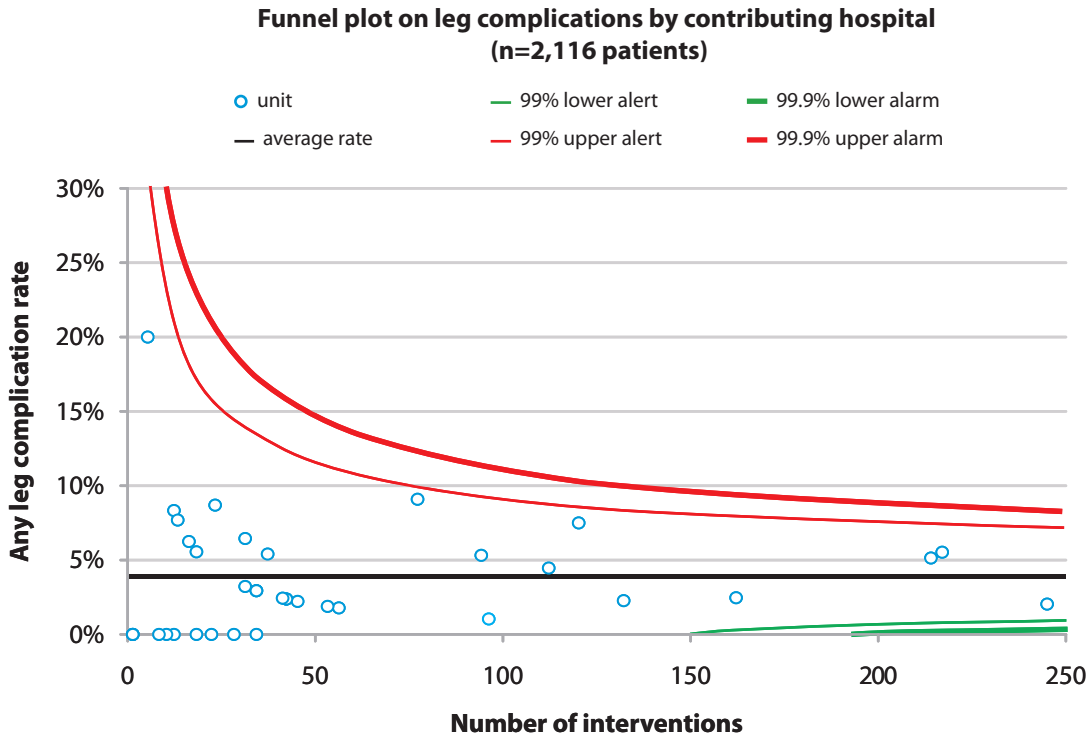
This funnel plot shows the leg complication rate by hospital. Each dot represents one individual hospital and shows the crude complication rate versus the number of procedures performed / submitted to the registry. The black line indicates the average complication rate recorded in the database (3·9%). The upper 99% and 99.9% control limits are shown as thin and thick red lines respectively. Essentially these are about 2.6 and 3.3 standard deviations from the mean respectively. No centre lies outside the upper alert or alarm limits.

It should be obvious that transgressing the upper limits when the case-number is small is very unlikely unless the complication rate is extremely high. Using this approach should reduce the fear of making unjustified judgements based on small numbers of cases.

The Society of Cardiothoracic Surgeons (SCTS) has used this approach to determine whether or not cardiac surgeons are meeting an agreed standard, using mortality following primary coronary artery bypass surgery as their indicator procedure. They consider any surgeon whose crude mortality is within the 99.99% control limit as meeting their defined standard. Their latest report [xvii] actually includes both the names of the surgeons and their hospitals.

It should be appreciated that these funnel plots are **not** risk-adjusted and only use crude outcome data. There are problems applying risk-adjustment to the BIAS data: firstly, there is no satisfactory risk model for iliac angioplasty / stent outcomes and, secondly, generating new risk models requires more extensive and more complete data than are currently available.

It should be possible for future registries to provide individual radiologists with a personalized summary of their activity and position on a funnel plot. An example of how this might look is shown on page 67.



xvii. Keogh B and Kinsman R. Fifth National Adult Cardiac Surgical Database Report 2003. London. Society of Cardiothoracic Surgeons of Great Britain and Ireland. 2004

The outcome under scrutiny

The importance of good-quality data is highlighted by the two funnel plots shown here, plotting outcomes based on two slightly different versions of the composite complication (any systemic complication and / or any leg complication) used earlier in this report.

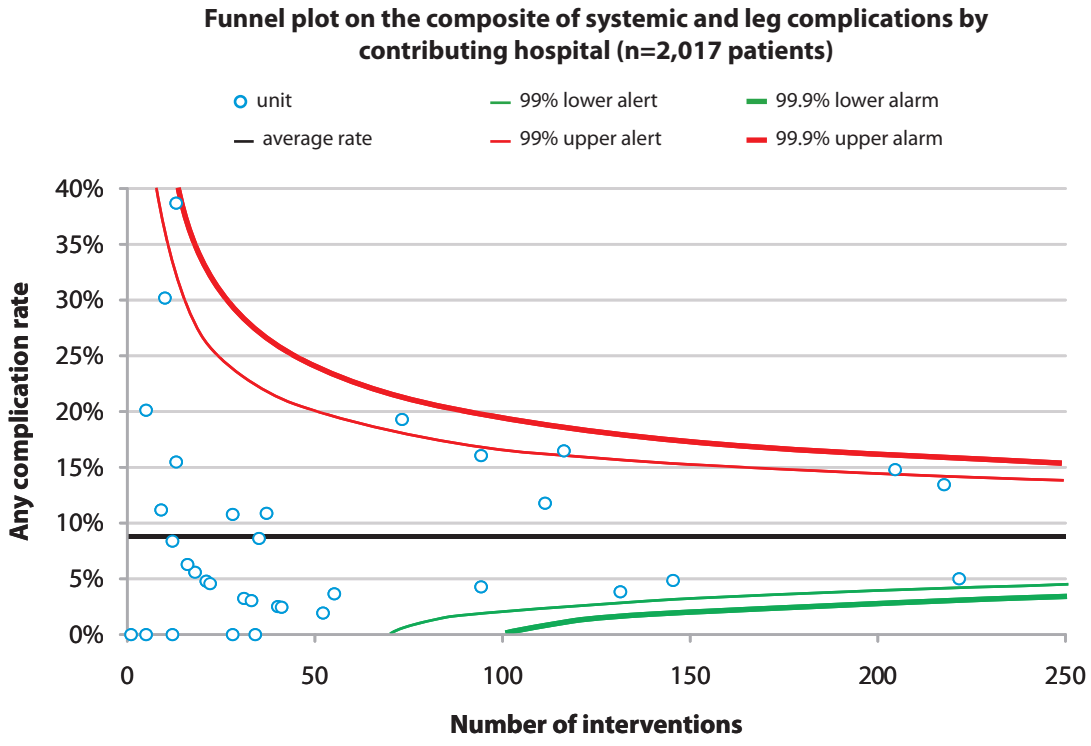
As reported earlier, a quick analysis of the data in the registry showed that many of the systemic complications logged under the *Other* category were really minor events that did not really warrant inclusion as a serious complication. For this reason, the majority of analyses treat the *Other* systemic complications as if they were not a complication. Since the *Others* comprise 97.5% of all the systemic complications reported in the registry (82.4% of entries where it is the sole complication recorded), the decision on whether to include or exclude them from the definition of patients' systemic complications has a large impact on the results.

By way of a demonstration, the funnel plot labelled **A** show the results when plotting the composite complication outcome defined such that it includes the *Other* systemic complications as an adverse outcome. This gives an average composite complication rate of 8.8%.

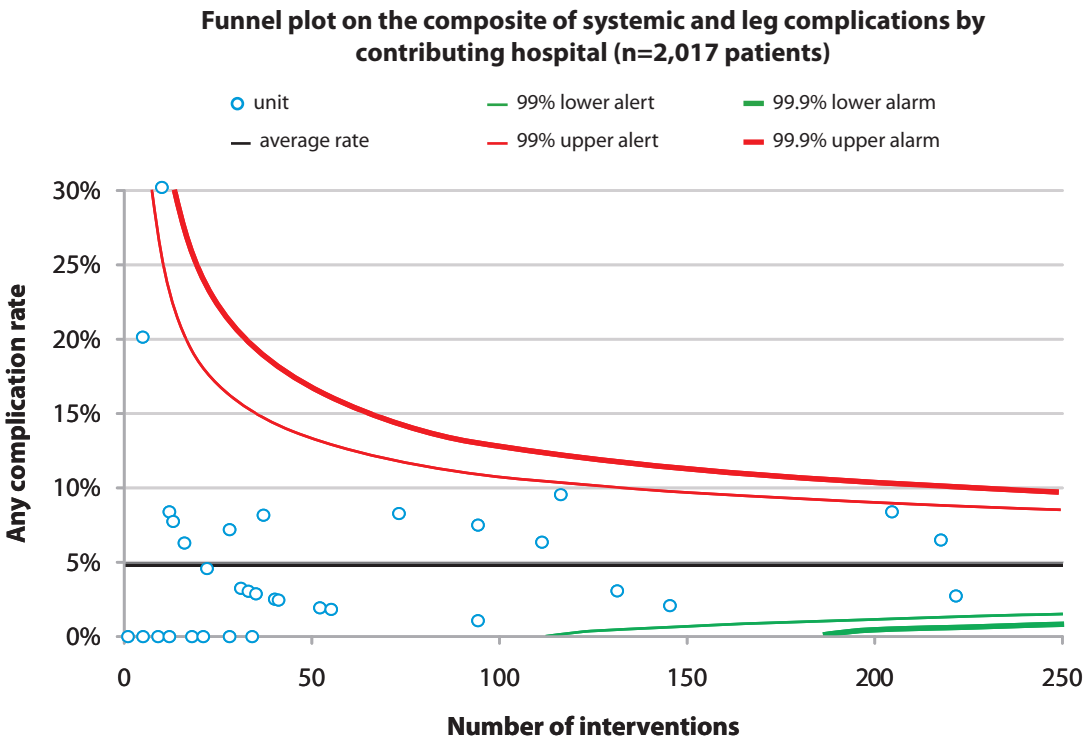
The plot labelled **B** represents an analysis of the same basic data, but the definition of the composite complication has been changed such that the *Other* systemic complications are no longer treated as contributing to the definition of an adverse outcome. This gives a lower overall rate of 4.9% as some of the 98 patient-entries where the *Other* systemic complications response-option was selected will no longer register as having had a complication.

In an attempt to try and avoid this kind of confusion in the future, the next iteration of the BIAS dataset has been modified by removing the *Other* option and adding a small number of new, defined major complication categories to the systemic complications question.

A With *Other* systemic complications included in the definition of the composite complication



B With *Other* systemic complications removed from the definition of the composite complication



Example summary report for one consultant

The page opposite shows an example of the way in which anonymised data from the BIAS database could be used to provide feedback to individual consultants. The analysis presented focuses on leg complications per patient; this particular outcome was selected because it is reasonably well represented in the database and is also well defined. Using this outcome avoids the problems associated with analysing rare events such as mortality and also avoids the problems of dealing with data where the threshold for recording a complication varies between hospitals and possibly even between consultants within a hospital (see the discussion on pages 64-65 of this report, which highlighted the unexpected results in an analysis based on systemic complications).

The example one-page report presented here is for a consultant who has submitted 2,017 cases to the BIAS database. It is made up of two parts:

- a funnel plot that shows how all the consultants' results are distributed around the average composite complication rate and whether or not these results fall within pre-defined control limits. The purple symbol represents the individual consultant's results in comparison to the peer group.
- a more descriptive part that details some of the numbers that the chart is based upon together with some basic derived data: outcome rates with their 95% confidence intervals.

The layout of this report follows a similar format to that presented in the Vascular Society's (VSGBI) most recent report National Vascular Database (NVD) Report [xviii]; the principle difference between the VSGBI's report and the example opposite is that no risk-adjustment is possible for the analyses on the BIAS data because of the lack of a suitable, validated risk model.

The Society of Cardiothoracic Surgery (SCTS) has elected to use this technique to determine whether or not its members are meeting an agreed performance standard, using data on mortality following isolated coronary artery bypass grafting; this is their tracker or index procedure [xix]. The VSGBI have also suggested that they might adopt a similar approach, using data on mortality following non-ruptured AAA to track their members' performance [xviii].

The control limits used by both these specialist societies in their reports were 99.9% to define an alert and 99.99% for an alarm line. The SCTS considers any surgeon whose results fall within the 99.99% control limits as meeting their agreed standard. They argue that when using crude outcome data it is reasonable to use higher limits than when risk adjustment is used. Their arguments against using a risk-adjusted analysis are based around the lack of a contemporary, robust, stable and universally accepted risk model for cardiac surgery. Also, as noted in the VSGBI's NVD Report 2004, using of any single risk-adjusted outcome rate to judge a consultant's results risks lending a spurious degree of credibility to an analysis that takes no account of the many factors that are not patient-related.

A prerequisite for these performance-evaluation techniques is a contemporary and accurate baseline against which to make the comparisons. This requires a comprehensive database, which means it is important that all consultants enter data on all their cases. With a complete database comes the power to make real and valid comparisons, which should then serve as a powerful tool for the whole membership of the BSIR and a shield against unfair criticism.

xviii. Ashley S, Ridler B, Baker S and Kinsman R. Fourth National Vascular Database Report 2004. London. Vascular Society of Great Britain and Ireland. 2005

xix. Keogh B and Kinsman R. Fifth National Adult Cardiac Surgical Database Report 2003. London. Society of Cardiothoracic Surgeons of Great Britain and Ireland. 2004

The British Society of Interventional Radiology

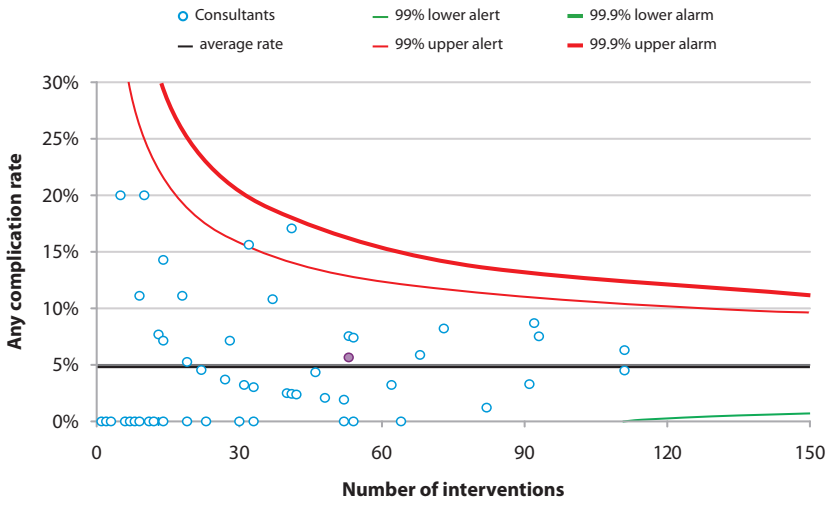
BIAS III summary report by consultant

This report contains data for consultant 4077 for the period January 2005 to August 2008. It shows results based on a composite outcome generated from the systemic complications and leg complications in hospital following treatment for iliac disease.

Patients recorded as having had either an MI or worsening renal function after the procedure OR any one or more of the listed post-procedural complications is deemed to have had a complication; patients reported as having had no system nor any leg complications are designated complication-free.

Only index procedures with known outcomes are included in the analysis.

Funnel plot on the composite of systemic and leg complications by consultant (n=2,017 patients)



Summary statistics

Recorded number of patients having a composite outcome = **3** out of **53**

Complication rate = **5.7%** (95% CI: 1.5-16.6%) *versus* the average rate of **4.9%** (95% CI: 4.0-5.9%)

Prepared by

Dendrite Clinical Systems

BSIR Audit and Registries Committee: registry outliers policy

1. The principal intention of the BSIR index procedure registries is to provide data that allows its members to confirm that they are performing within acceptable boundaries.

2. Inevitably, performance indicators produced by the registries will show a range of performance and simply being in the lower range of performance should not trigger action by BSIR.

3. All doctors have an obligation (GMC duties of a doctor paragraph 43) to protect patients from risk posed by a colleague's performance.

4. Therefore the BSIR has an obligation to take appropriate action if performance data derived from a BSIR registry shows evidence of under-performance of an individual doctor or an institution.

5. At the same time, the BSIR must avoid drawing false conclusions from inadequate data. There are a number of reasons why the data may be inadequate:

    i. the registries are far from complete, with many members contribution partial data or none at all; therefore, there is the possibility of bias in the database.

    ii. furthermore, some registry questions are capable of ambiguous interpretation, so an individual contributor may appear to be an outlier because of an idiosyncratic interpretation of a question.

    iii. some contributors may be more diligent than others in recording particularly the late complications of a procedure and may therefore appear to have a higher complication rate simply as a result of conscientiousness.

6. There must be no sense of a witch hunt. It is important that contributing to the BSIR registries is promoted as a positive effort that enables the great majority of contributors to demonstrate that their performance is of a satisfactory standard.

7. The BSIR will endeavour to support colleagues. Evidence of deviation from acceptable performance must be tackled with sensitivity and tact.

8. Definition of an *outlier*: there may be a range of statistical processes by which an outlier may be identified. For example, the BSIR may define an *outlier* as an event occurring at a frequency which would have a less than 0.2% probability of happening by chance, or is greater than 3 standard deviations from the mean.

9. Once concerns about performance of an individual or a centre have been raised by observation of an outlying result, the Audit and Registries Committee Chair, as the appropriate member of BSIR Council, will contact the individual concerned without delay to discuss the observation.

10. The BSIR Chair will maintain a confidential record of the discussions that take place and any action taken as a result. Review in 2 months if more data needs to be evaluated.

11. It may be that there is an obvious explanation for the data (see para 5) and no further action need be taken. It is likely that the individual is aware of the issue and has already taken steps to address any local problems in which case further review after a period of further audit is appropriate.

12. The BSIR should be able to support a member whose results suggest under-performance by identifying individuals who can offer retraining or mentoring.

13. If after investigation there is evidence of under-performance by an individual or a hospital, it is appropriate that the Medical Director of the relevant Trust be informed. The Medical Director has responsibility for clinical governance within the Trust. This step should be taken only after a dialogue has been established with the relevant individual, and after consultation with the BSIR President. The medical director should be asked to confirm receipt of the letter and this should be documented

14. Some performance measures may indicate improbably high levels of performance. Ideally this situation should also generate a response to the relevant individual. It may indicate a misinterpretation of the registry form, bias or a lack of rigour in form filling.

15. The production of *funnel plots* on a regular basis is to be encouraged. These allow individuals and centres to see at a glance where they lie in relation to the mean and confidence intervals and may thus serve as an *early warning system* in some cases.

16. Valid statistical inferences require adequate numbers of data entries per operator. This requirement must be balanced against the need to report at timely intervals. For a high frequency procedure, it should be possible to produce a registry report on at least a biennial basis.

Appendices

Appendices

Dictionary of definitions for the complications recorded in BIAS II

The definition of complications and outcomes used in data sent to registries is to be standardized. The following lays down the vascular complications related to lower limb endovascular arterial revascularisation:

Clinical outcome following a complication

Minor (no clinical consequence)

a. No therapy, e.g. small haematoma, distal embolus to a small branch vessel without sequelae or further intervention.

b. Minimal therapy *e.g.,* stenting a flow limiting dissection or requiring simple medical therapy *e.g.,* management of a vasovagal attack or contrast reaction, or <24 hours admission for observation.

Major (significant patient consequence requiring therapy)

c. Unplanned hospitalization >24 hours & <48 hours *e.g.,* for transfusion.

d. Unplanned hospitalization >48 hour *e.g.,* surgical bypass graft.

e. Permanent adverse sequelae *e.g.,* unplanned amputation.

f. Death.

Access site complications

- **Haematoma** — Localized collection of blood at the arterial access site. Excludes simple skin discolouration.
- **Retroperitoneal haematoma** — Collection of blood from the arterial access site into the retroperitoneum.
- **Pseudo-aneurysm** — Imaging confirmed false aneurysm at the arterial access site.
- **Thrombosis** — Confirmed occlusion of the access site artery.
- **Infection** — Confirmed procedure related infection.
- **Arterial dissection** — The presence of a flow limiting dissection flap at the arterial access site vessel.
- **Closure device complications**

Target vessel complications

- **Arterial dissection**
- **Occlusion** — Occlusion of the treated section of vessel.
- **Perforation** — Free extravasation of blood (contrast) from the target vessel.

Stent infection

Confirmed procedure related infection.

Device malfunction

Technical problem with endovascular device during deployment.

Distal embolisation

Passage of material into run off vessels resulting in obstruction to blood flow.

Systemic complications

• **Renal impairment**	A deterioration in renal function detected within 10 days of the procedure, indicated by a 25% increase in creatinine level over baseline.
• **Drug reaction**	Contrast Local anaesthetic
• **Cardiac**	**Myocardial infarction:** clinical episode of cardiac chest pain, with appropriate ECG, Troponin ries, and other biochemical markers of MI. **Myocardial ischaemia:** ECG confirmed clinical episode of cardiac chest pain, attributable to exacerbation of chronic stable angina or acute coronary syndrome, but not MI.
• **Cerberovascular**	**TIA:** Temporary less than 24 hours of neurological disability attributable to a vascular territory. **CVA:** Chronic *i.e.*, over 24 hours of neurological disability.

The database form

British Society of Interventional Radiology

The British Society of Interventional Radiology
BSIR Iliac Artery Angioplasty-Stent registry
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Demographics and other identifiers

Unique patient-identifier	
Date of birth	dd / mm / yyyy
Gender	○ Male ○ Female ○ Unknown

Admission details

Consultant code	select from drop-down list
Hospital code	select from drop-down list
Admission type	○ Inpatient ○ Daycase
Date of admission	dd / mm / yyyy

Risk factors

Diabetes	○ No diabetes ○ Type 1 diabetes ○ Type 2 diabetes
Renal system	○ Normal ○ Elevated creatinine >200 µmol l^{-1} / no treatment ○ Acute renal failure - dialysis ○ Chronic renal failure - dialysis ○ Functioning transplant
Indication for intervention	○ Rest pain with tissue loss ○ Claudication ○ Rest pain with no tissue loss ○ Other ○ Ulcer with arterial component

Procedure data

Date of intervention	dd / mm / yyyy
Urgency	○ Elective ○ In-hours emergency ○ Urgent ○ Out-of--hours emergency
Grade of principal operator	○ Consultant ○ Other
Specialty of principal operator	○ Radiologist ○ Cardiologist ○ Surgeon ○ Other
Legs treated	○ Right leg ○ Left leg ○ Right & left legs

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British Society of Interventional Radiology

The British Society of Interventional Radiology
BSIR Iliac Artery Angioplasty-Stent registry
Page 2; Version 1.0

Unique patient identifier

Date of intervention dd / mm / yyyy

Procedure data

	Right leg complete only if treated	Left leg complete only if treated
Lesion site	○ Common iliac ○ External iliac ○ Common & external iliac	○ Common iliac ○ External iliac ○ Common & external iliac
Maximum stenosis	○ 0-49% ○ 50-99% ○ 100%	○ 0-49% ○ 50-99% ○ 100%
Procedure performed	○ Angioplasty only ○ Stent used	○ Angioplasty only ○ Stent used
Closure device used	○ No ○ Yes	○ No ○ Yes
Residual stenosis	○ 0-49% ○ 50-99% ○ 100% ○ Failed to cross	○ 0-49% ○ 50-99% ○ 100% ○ Failed to cross
Leg complications	○ None ☐ Distal embolism ☐ Flow-limiting dissection ☐ Groin haematoma ☐ Treated vessel thrombosis ☐ Device malfunction ☐ Perforation ☐ Access site thrombosis ☐ Access site false aneurysm	○ None ☐ Distal embolism ☐ Flow-limiting dissection ☐ Groin haematoma ☐ Treated vessel thrombosis ☐ Device malfunction ☐ Perforation ☐ Access site thrombosis ☐ Access site false aneurysm

Post-procedure outcomes

	Right leg complete only if treated	Left leg complete only if treated
Treatment as a result of complications	○ None ☐ Observation increased hospital stay ☐ Unplanned endovascular therapy ☐ Unplanned surgery ☐ Amputation	○ None ☐ Observation increased hospital stay ☐ Unplanned endovascular therapy ☐ Unplanned surgery ☐ Amputation
Leg status at discharge	○ Limb intact ○ Worsening level of ischaemia ○ Expected amputation ○ Unexpected amputation	○ Limb intact ○ Worsening level of ischaemia ○ Expected amputation ○ Unexpected amputation

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BSIR Iliac Artery Angioplasty-Stent registry
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Unique patient identifier	
Date of intervention	dd / mm / yyyy

Post-procedural outcomes

Patient complications	○ None ☐ MI ☐ Worsening renal function ☐ Other (specify below)
Other patient complications	
Patient status at discharge	○ Alive ○ Died during procedure ○ Died in hospital
Date of discharge / death	dd / mm / yyyy
Cause of death	○ Not applicable ○ Procedure-related ○ Not procedure-related

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Notes

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Contemporary information on Iliac Angioplasty and Stenting from the BSIR

Interventional radiology is a clinical sub-specialty of radiology. Its practitioners use a range of different imaging techniques such as ultrasound, computerised tomography and x-rays to help them guide devices such as vascular stents into the patient's body in order to treat a variety of diseases entities.

This report is the third in a series that focuses on data from the British Society of Interventional Radiology's British Iliac Angioplasty & Stent (BIAS) registry. This database holds information on procedures that attempt to improve blood-flow in the leg by removing or reducing blockages in the iliac arteries. BIAS is the largest database of its type in the United Kingdom and it is the Society's aim that it will continue to provide contemporary information on:

- the practices in iliac angioplasty & stenting
- indications for treatment
- outcomes
- performance

This report is compiled by radiologists primarily for radiologists, but should also be of interest to those in other associated specialties such as vascular surgery and cardiology.

Data collection and processing are still in an evolutionary stage: although many participate in this project, not all radiologists submit their data, so there is an inevitable disparity between what is recorded in BIAS and what is actually taking place across the country. The Society aspires to using analysis techniques such as risk modelling to delve deeper into these data, but there are still significant constraints that make these advanced investigations inappropriate at the moment, not the least of which is the shortfall in data-capture.

Although the data are now in the public domain, their deficiencies and limitations should not be under estimated; it is probably too early to try and draw any firm conclusions from the analsyes presented in this report. However, BIAS is a platform for continuing the processes of evaluation of clinical practice and comparison of results in an attempt to drive an improvement in standards. The BSIR has approved BIAS as an index procedure and as such practitioners will want compare their results to the national standard, helping to identify and correct poor performance to the benefit of patients and doctors alike.

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