The British Society of Interventional Radiology

Fourth

Iliac Angioplasty Study Report

2018

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Foreword

My thanks to the many people who have contributed to the British Iliac Angioplasty and Stenting (BIAS) registry. The BSIR is very proud to have instigated and supported this project, which is now in its fourth (and final) report stage. BIAS has been one of the vanguard registries in the United Kingdom. This report joins its three predecessors, and is not only useful for its content, but is also a tribute to all those BSIR members who have taken the time to complete data entry. The society realises that much of this has been given freely, and often in individuals' *spare* time. As President, on behalf of The Society, I thank you all for that.

BIAS is (to the best of The Society's knowledge) the largest iliac artery endovascular intervention registry worldwide, with over 13,000 patients entered over its 16 years of operation. It demonstrates the commitment of the British Interventional Radiology community to ensuring that this index procedure for vascular interventional radiology is delivered safely and is benchmarked for future delivery. We can see that patients experience good outcomes at follow up, which is key. BIAS also provides us with excellent longitudinal information about the way services are delivered, for example the ever-increasing use of day-case facilities.

The BSIR's rich history in supporting and developing registries is an enviable one. Going forward, The Society encourages members to continue to contribute to the National Vascular Registry (which has taken over the role of documenting iliac intervention from BIAS, as well allowing the recording of more distal peripheral interventions). At the same time, we ask members to consider other areas where data submission by Interventional Radiologists into new registries might establish benchmarks for safe and effective practice. Anyone with enthusiasm and ideas for future registries is encouraged to contact the Registries and Audit Committee *via* the BSIR website (www.BSIR.org).

Many congratulations and thanks to you all.

Trevor Cleveland

President, British Society of Interventional Radiology

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Executive summary

The British Society of Interventional Radiology (BSIR) British Iliac Angioplasty and Stenting (BIAS) registry was closed to data collection in 2016 after the expansion of the National Vascular registry (NVR) to include peripheral intervention cases. In total 117 centres have contributed to BIAS since its inception in 2000.

This is the final report from BIAS summarising data on 8,294 procedures reported to the registry between 2011 and 2014 inclusive. At peak data entry (2013) nearly 50 patients *per* week were reported. Ascertainment rate is crudely estimated at 60%.

The demographics of patients undergoing iliac intervention have not altered substantially since BIAS III. Most interventions (64%) are done for claudication though the proportion of patients undergoing intervention for critical ischaemia increases with increasing age. 1 in 5 procedures are done urgently. There has been a progressive increase in the use of daycase facilities with 44.8% of patients treated *via* this route (compared with 25% in BIAS III).

Nearly 90% of cases were performed by a consultant radiologist. The number of cases where a trainee was the principal operator has decreased since BIAS III.

54% of lesions were stented and overall 97% of interventions were technically successful (with a residual stenosis of <50%). A closure device was used in 42% of cases, with greater use in daycase patients than inpatients.

Only 3% of patients in the registry had no systemic follow up recorded. Vital status and limb status at discharge was recorded for 94.9% of patients and 98.3% of legs respectively. This indicates excellent engagement of the IR community in gathering follow up data.

Overall rates of systemic complication (2.8%), limb complication (4.3%), unplanned additional intervention (1.7%) and death attributable to the procedure (0.1%) were low. Rates of vessel rupture were very low (0.1%), which has implications for service organisation.

Patients experiencing a systemic complication are at a substantially greater risk of death than other patients though the reasons for this are likely to be multi-factorial.

Of the centres contributing to the registry, only 3 had rates of complication that lay outside the 99.9% alarm lines on funnel plots. Since BIAS III individual centres (and clinicians) have been able to obtain their specific data, which allows reflection, analysis and amendments to services and practice as necessary.

Introduction

The British Society of Interventional Radiology Iliac Artery Angioplasty-Stent Registry (BIAS) was first launched in 2000. After 16 years of data collection, the registry was closed for submission on March 2016. The decision to close BIAS was taken after gradually declining data entry and the advent of the National Vascular Registry. The BSIR Registries and Audit Committee considered that the presence of two competing registries would hamper data collection in both. This is the fourth and final report (BIAS IV) from the BIAS database.

BIAS remains the largest iliac artery registry worldwide with 13,877 cases submitted from 117 centres in the United Kingdom.

A note on the conventions used throughout this report

Conventions used in tables

Unless otherwise stated, the tables and charts in this report record the number of interventions.

Entries with complete data for all of the components under consideration are shown in regular black text. If one or more of the database questions under analysis is blank, the data are reported in red text.

Conventions used in graphs

Entries with missing data are excluded from the analysis used to generate graphs.

Confidence intervals: the bars plotted around rates represent 95% confidence intervals.

In some analyses there may be insufficient data to calculate the standard error around the average for each sub-group under analysis; in which case the arithmetic average is plotted without error bars.

Findings

Demographics and indications

Number of entries

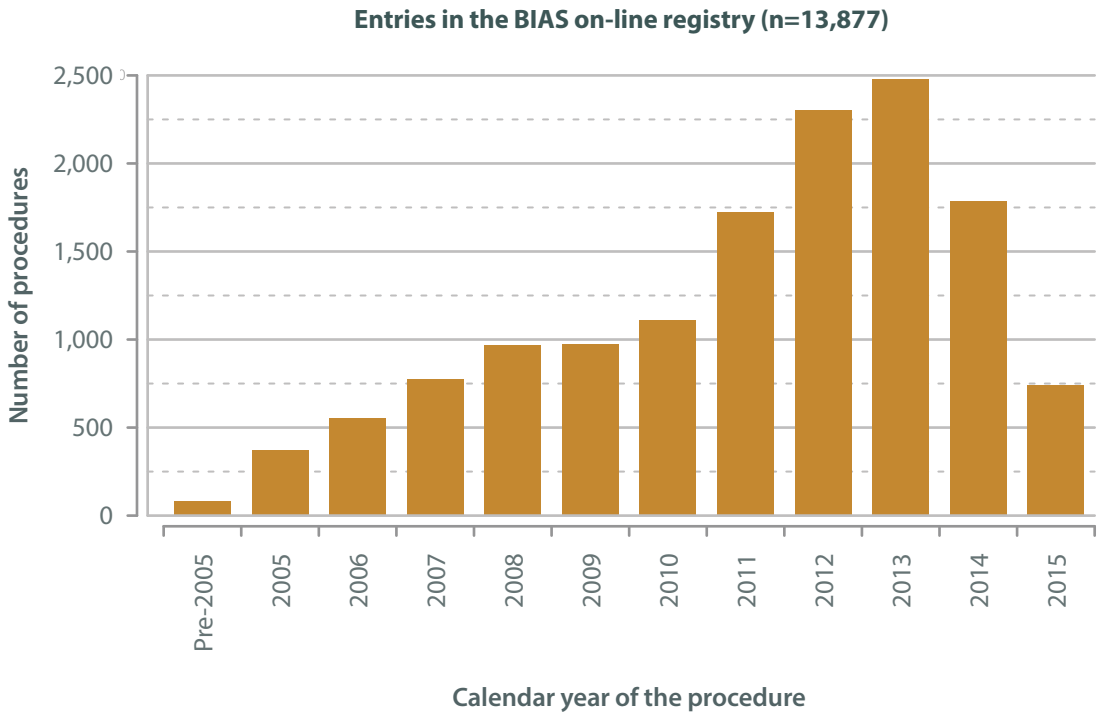
For the period covered by this report (2011-2014 inclusive) 8,294 patients were entered into the registry. At closure of the registry there were 13,877 entries in total (entered between 2000 and 2016).

The National Vascular Registry (NVR) peripheral endovascular intervention subset was launched in late 2013 and collects data on all lower limb endovascular interventions (not just iliacs). Interrogating NVR for cases where an iliac intervention was undertaken, the number of patients entered annually remains substantially lower than the number entered into BIAS at peak recruitment (2011-2014). The reasons for this are likely to be multi-factorial, though lack of clarity about which registry to enter cases into may have contributed. The data suggest that there are opportunities to improve data entry to NVR, as interventional radiologists have demonstrated good engagement in the past with BIAS.

Ascertainment rates were not evaluated in BIAS, though they are estimated from Hospital Episode Statistics (HES) in NVR. As a crude first estimation, if it is assumed that the ascertainment rate in NVR is the same for iliac and more peripheral intervention then an average of 3,600 iliac interventions are performed annually in the United Kingdom giving an estimated ascertainment rate for BIAS for the years covered by this report of about 60%.

The distribution of entries to BIAS by year is indicated below.

	Number of entries in the database			Iliac procedures in the NVR
		Count	**Percentage**	**Count**
Calendar year of the procedure	<2005	89	0.6%	
	2005	372	2.7%	
	2006	551	4.0%	
	2007	774	5.6%	
	2008	967	7.0%	
	2009	974	7.0%	
	2010	1,113	8.0%	
	2011	1,725	12.4%	
	2012	2,303	16.6%	
	2013	2,477	17.8%	
	2014	1,789	12.9%	512
	2015	743	5.4%	737
	2016	0	0.0%	924
	2017	0	0.0%	608
	All	**13,877**		


Entries in the BIAS on-line registry (n=13,877)
Number of procedures
2,500
2,000
1,500
1,000
500
0
Pre-2005
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
Calendar year of the procedure

Contributions to the registry for each hospital

	Entries	Rank in the distribution	Continuous contribution
Aberdeen Royal Infirmary	6	99	No
Addenbrooke's Hospital	58	53	Yes
Arrowe Park Hospital	3	105	Yes
Ayr General Hospital	20	82	Yes
Barts & the London	9	97	Yes
Bedford Hospital	15	84	No
Broomfield Chelmsford	33	69	Yes
Calderdale Royal Hospital	1	113	Yes
City Hospital	230	17	Yes
City Hospital Birmingham	2	108	Yes
Colchester General Hospital	53	55	No
Countess of Chester Hospital	53	55	Yes
Croydon Univ. Hospital	12	91	Yes
Cumberland Infirmary	21	79	Yes
Derbyshire Royal Infirmary	678	4	Yes
Derriford Hospital	53	55	Yes
Diana, Princess of Wales Hospital	10	93	Yes
Eastbourne District General Hospital	32	71	Yes
Falkirk & District Hospital	15	84	No
Fife Acute Hospitals	4	102	Yes
Forth Valley Royal Hospital	206	22	No
Freeman Hospital	127	38	Yes
Frenchay Hospital	59	52	Yes
Frimley Park Hospital	219	20	Yes
Gartnavel General Hospital Glasgow	289	12	Yes
George Eliot Hospital, Nuneaton	135	36	Yes
Glan Clywd Hospital Rhyl	47	60	Yes
Hairmyers Hospital East Kilbride	11	92	Yes
Hull Royal Infirmary	360	9	Yes
Jersey General Hospital	21	79	Yes
John Radcliffe Hospital	452	6	Yes
Kettering General Hospital	10	93	Yes
King's College Hospital	4	102	Yes
Kings Mill Hospital Nottingham	127	38	No
Kingston Hospital	2	108	Yes
Lanarkshire Hospital	25	76	Yes
Lancashire Teaching Hospitals	31	73	Yes
Leeds General Infirmary	15	84	Yes
Leeds Teaching Hospitals NHS Trust	661	5	Yes

Contributions to the registry for each hospital

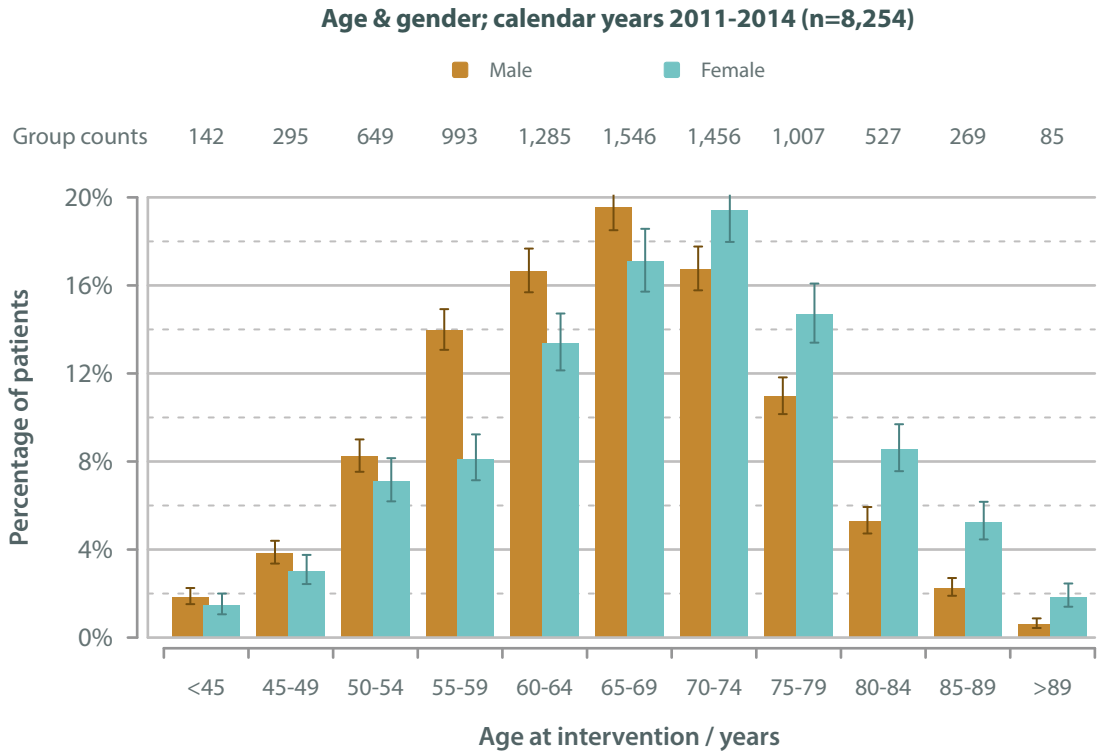
	Entries	Rank in the distribution	Continuous contribution
Leighton Hospital	95	45	Yes
Lister Hospital	10	93	Yes
Lister Hospital Stevenage	286	13	Yes
Manchester Royal Infirmary	283	14	Yes
Medway Hospital	77	48	Yes
Mid Staffordshire Hospitals	1	113	Yes
Morriston Hospital	15	84	Yes
Nevill Hall Hospital Abergavenny	1	113	Yes
New Cross Hospital	83	47	Yes
Ninewells Hospital	104	43	Yes
Norfolk & Norwich Hospital	383	8	Yes
North Hampshire Hospital	6	99	Yes
North Staffordshire Hospital	179	27	Yes
Northampton General Hospital	391	7	Yes
Northern General Hospital	822	2	Yes
Nottingham Univ. Hospitals NHS Trust	198	23	Yes
Pennine Acute Hospitals Trust	1	113	Yes
Peterborough District Hospital	3	105	Yes
Pinderfields General Hospital	710	3	Yes
Princess of Wales Hospital	5	101	Yes
Princess of Wales Hospital Grimsby	57	54	No
Princess Royal Univ. Hospital Orpington	4	102	Yes
Queen Alexandra Hospital	17	83	No
Queen Elizabeth Hospital King's Lynn	61	50	No
Queen Elizabeth Hospital, Gateshead	183	25	No
Queens Medical Centre Nottingham	105	42	Yes
Raigmore Hospital	31	73	Yes
Royal Albert Edward Infirmary	156	30	Yes
Royal Berkshire Hospital	207	21	Yes
Royal Bolton Hospital	154	31	No
Royal Bournemouth General Hospital	10	93	Yes
Royal Cornwall Hospital	173	28	Yes
Royal Derby Hospital	106	41	Yes
Royal Devon & Exeter Hospital	14	89	Yes
Royal Free Hospital	15	84	No
Royal Glamorgan	113	40	Yes
Royal Gwent Hospital	36	66	Yes
Royal Hampshire County Hospital	135	36	Yes
Royal Infirmary of Edinburgh	154	31	Yes

Contributions to the registry for each hospital

	Entries	Rank in the distribution	Continuous contribution
Royal Lancaster Infirmary	42	62	No
Royal Liverpool Univ. Hospital	148	33	Yes
Royal Oldham Hospital	66	49	Yes
Royal Preston Hospital	35	68	Yes
Royal Shrewsbury Hospital	229	18	Yes
Royal Sussex County Hospital	39	64	Yes
Royal United Hospital Bath	165	29	Yes
Royal Victoria Hospital Belfast	849	1	Yes
Russells Hall Hospital	33	69	Yes
Salisbury District Hospital	7	98	Yes
Southampton General Hospital	53	55	Yes
Southend Hospital	148	33	Yes
Southern General Hospital Glasgow	24	77	No
Southmead Hospital Bristol	60	51	Yes
St George's Hospital	354	10	Yes
St Helier Hospital	23	78	Yes
St James' Univ. Hospital Leeds	2	108	Yes
St Peter's Hospital	184	24	Yes
St Richards Hospital Chichester	47	60	Yes
St Thomas Hospital	2	108	Yes
Sterling Royal Infirmary	223	19	Yes
Stoke Mandeville Hospital	49	59	No
Tameside General Hospital	13	90	Yes
Torbay Hospital	104	43	No
Univ. Hospital Aintree	183	25	Yes
Univ. Hospital North Staffs	28	75	Yes
Univ. Hospital of Leicester NHS Trust	140	35	No
Univ. Hospital of Wales	38	65	Yes
Univ. Hospitals of Coventry & Warwickshire	268	16	Yes
Univ. Hospitals South Manchester	21	79	Yes
Victoria Infirmary Glasgow	91	46	No
Warrington & Halton Hospitals NHS Trust	36	66	Yes
West Suffolk Hospital	2	108	Yes
Western Infirmary	40	63	Yes
Whiston Hospital	1	113	Yes
William Harvey Hospital	32	71	Yes
Wirral Univ. Teaching Hospitals Trust	3	105	Yes
Wythenshawe Hospital	322	11	Yes
York Hospital	280	15	Yes

Age and gender

5,294 (63.8%) of patients were aged 60 to 79 years old at the time of intervention. Male patients (5,539; 66.8%) outnumbered females (2,752; 33.2%) by two to one. The age and gender distributions are not changed over those reported in BIAS III.



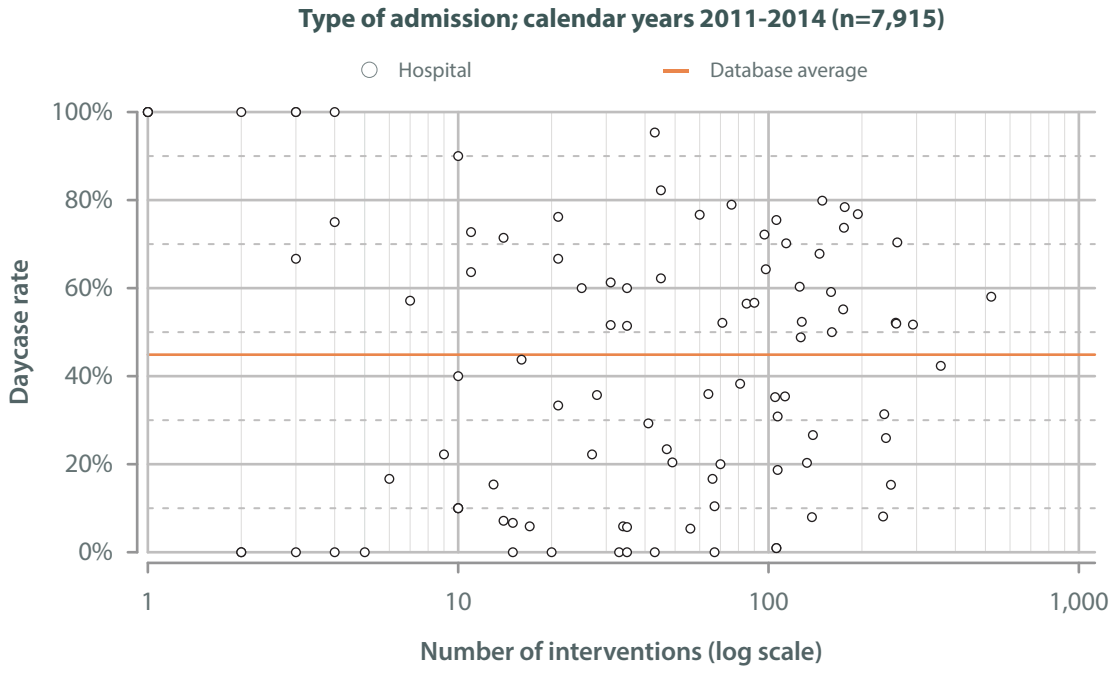
Type of admission

The procedure was performed as a daycase in 44.8% (3,548) compared to 25% in BIAS III, 21% in BIAS II (published 2005) and 11% in BIAS I (published 2001). There has therefore been a steady increase in the use of daycase facilities over time. This decreases procedural cost, reduces stress on hospital inpatient beds, and is often more convenient for patients.

There was no significant correlation between the number of cases entered into the registry and the daycase utilization rate. Smaller centres seem as likely to perform procedures as daycases as larger ones.

Type of admission; calendar years 2011-2014

		Type of admission			
		Inpatient	Daycase	Unspecified	Percentage daycase
Calendar year	2011	779	661	285	45.9%
	2012	1,317	918	68	41.1%
	2013	1,308	1,156	13	46.9%
	2014	963	813	13	45.8%
	All	**4,367**	**3,548**	**379**	**44.8%**



Comorbidity

The two comorbidities recorded in BIAS were renal disease and diabetes.

435 (5.4%) of the patients had renal disease, and 1,655 (20.5%) of the patients were diabetics. These figures are very similar to those recorded in BIAS III (3.9% and 21.2% respectively).

Significantly fewer patients with renal disease are treated as daycases compared to those patients with neither condition (31.9% *versus* 48.7%; p<0.01). Similarly, significantly fewer patients with diabetes are treated as daycases than patients with neither condition (34.1% *versus* 48.7%; p<0.01). This is unsurprising: the management of comorbid conditions (and especially renal disease where admission for hydration may be needed) sometimes requires that patients be managed as inpatients. However, even in patients with both renal disease and diabetes, daycase procedures were possible in a small minority (39; 20.4%) of patients.

Comorbidity and type of admission; calendar years 2011-2014

		Type of admission			
		Inpatient	Daycase	Unspecified	Daycase rate (95% CI)
Comorbidity	Neither renal disease nor diabetes	3,055	2,903	196	48.7% (47.4-50.0%)
	Diabetes alone	933	482	41	34.1% (31.6-36.6%)
	Renal disease alone	156	73	4	31.9% (26.0-38.4%)
	Renal disease and diabetes	152	39	6	20.4% (15.1-27.0%)
	Unspecified	71	51	132	41.8% (33.0-51.1%)
	All	**4,367**	**3,548**	**379**	**44.8% (43.7-45.9%)**

Indication

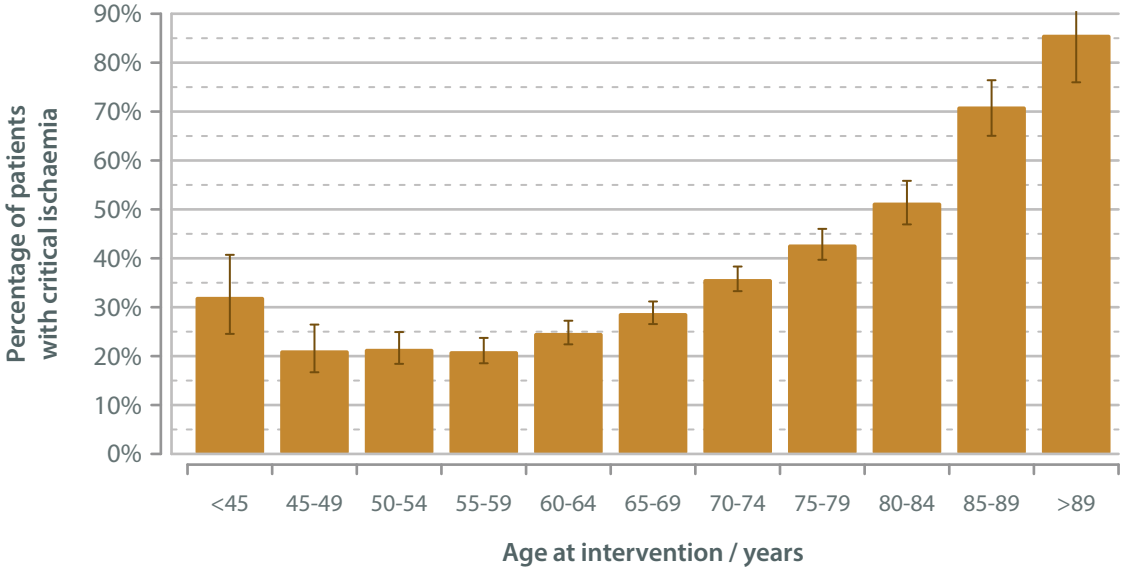
The main indication for intervention was claudication. This is similar to the proportion recorded in BIAS II (62.4%).

Unsurprisingly, the incidence of critical ischaemia in the cohort of patients represented in the registry increases with increasing age. For patients in their 8th decade of life or older, 60.8% underwent intervention for critical ischaemia (defined as rest pain, ulcer or tissue loss).

Indication for intervention; calendar years 2011-2014

Indication	Count	Rate (95% CI)
Claudication	5,219	64.4% (63.3-65.4%)
Rest pain with no tissue loss	1,093	13.5% (12.8-14.3%)
Ulcer (with arterial component)	609	7.5% (7.0-8.1%)
Rest pain with tissue loss	944	11.6% (11.0-12.4%)
Stenosis above / below graft	240	3.0% (2.6-3.4%)
Unspecified	189	
All	**8,294**	

The interaction between age and indication (n=8,077)



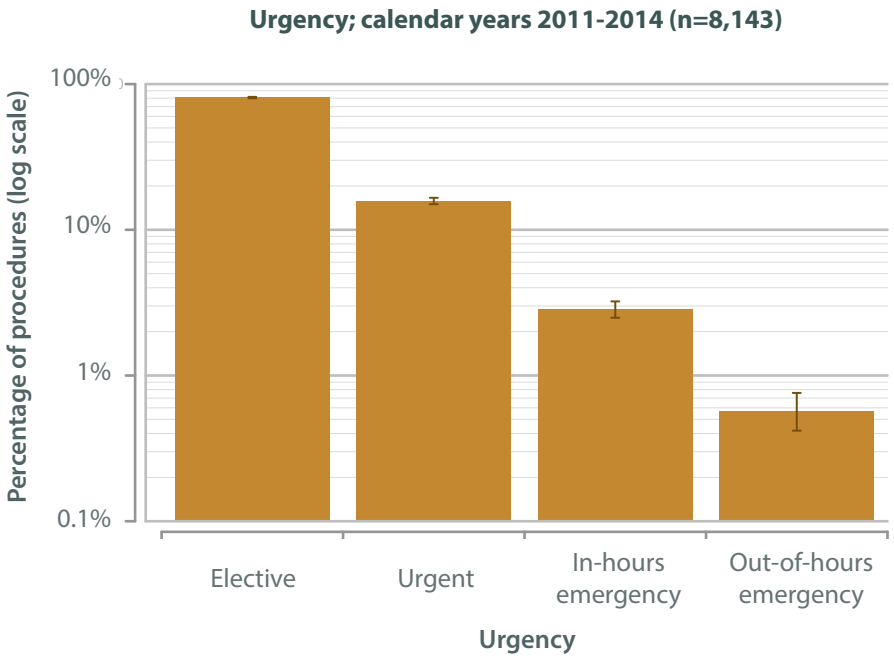
Procedure

Urgency

The majority (80.8%) of the procedures were performed electively, 15.8% were performed urgently, 2.8% were performed as emergencies in-hours and 0.6% as emergencies out of hours. There has been a slight increase in in-hours emergency intervention since BIAS III (1.6 to 2.8%).

Urgency of the procedure; calendar years 2011-2014

		Count	Percentage
Urgency	Elective	6,582	80.8%
	Urgent	1,284	15.8%
	In-hours emergency	231	2.8%
	Out-of-hours emergency	46	0.6%
	Unspecified	151	
	All	**8,294**	



The principal operator

The main operators for the procedure were consultants (88.9%) with trainees contributing 10.7%. This represents a substantial decrease in the involvement of trainees in performing iliac intervention. In BIAS III 18.9% of cases were performed by trainees. The reasons for this decrease are not clear. BIAS was designed as a registry of an index procedure and it remains vital that trainees are offered access to these important training cases.

Very few procedures were undertaken by non-radiologists.

The principal operator; calendar years 2011-2014

		Count	Percentage
Specialty and grade of the principal operator	Consultant radiologist	7,233	88.9%
	Trainee radiologist	872	10.7%
	Other	35	0.4%
	Unspecified	154	
	All	**8,294**	

Sides treated

32.5% of patients with claudication and 19.3% with critical limb ischaemia received bilateral interventions. Overall 27.3% of cases underwent bilateral interventions, this has increased slightly compared to 25% in BIAS III.

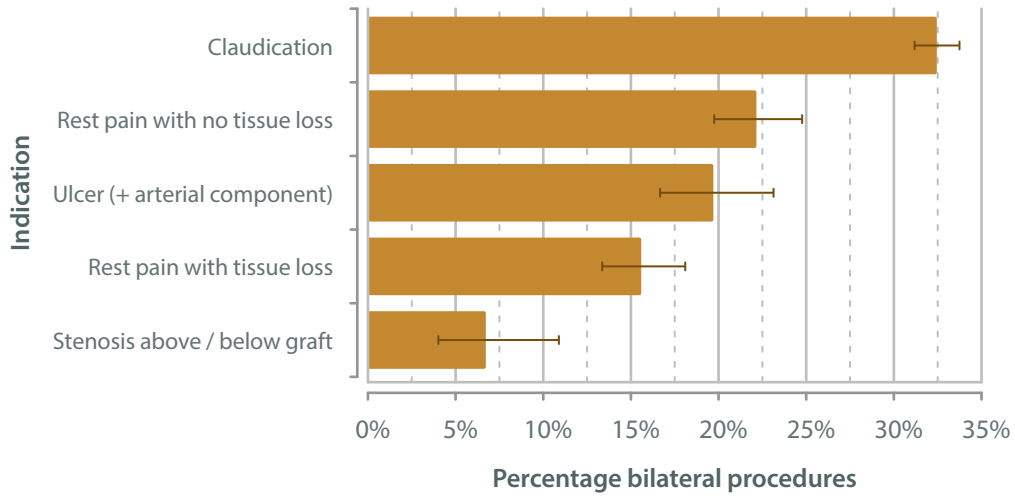
In 8,294 patients there were therefore between 10,518 and 10,673 limbs treated (taking into account cases where the number of sides treated was not recorded). For claudicants between 6,909 and 6,920 limbs were treated in 5,219 patients; for critical ischaemia there were between 3,156 and 3,159 limbs treated in 2,646 patients; for graft stenosis there were between 256 and 258 limbs treated in 240 patients.

It should be noted that a bilateral intervention does not necessarily imply bilateral vascular puncture. Many bilateral iliac interventions can be performed *via* a unilateral groin puncture.

Indication and number of sides treated; calendar years 2011-2014

Indication	Number of sides treated				
	Unilateral	Bilateral	Unspecified	All	Percentage bilateral
Claudication	3,518	1,690	11	**5,219**	32.5%
Rest pain with no tissue loss	850	242	1	**1,093**	22.2%
Ulcer (with arterial component)	489	120	0	**609**	19.7%
Rest pain with tissue loss	796	147	1	**944**	15.6%
Stenosis above/below graft	222	16	2	**240**	6.7%
Unspecified	40	9	140	**189**	18.4%
All	**5,915**	**2,224**	**155**	**8,294**	**27.3%**

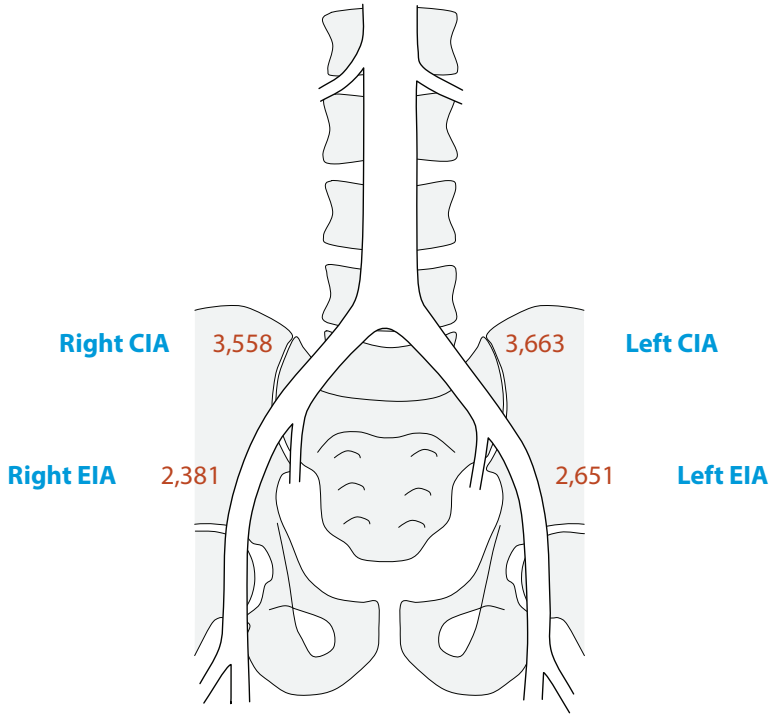
Bilateral intervention rate by indication; calendar years 2011-2014 (n=8,090)



Iliac segments

Data about the procedure undertaken was complete for over 97% of legs treated. Where data were complete for the operation record, 12,253 iliac segments were treated in 10,311 legs.

The mean number of segments treated *per* patient was 1.48. The average number of segments treated *per* leg was 1.19.



Pre-procedure stenosis

The commonest lesion treated was a 50-99% stenosis (9,240 interventions in 12,120 treated segments, 76.2%). 995 segments (8%) treated had sub-significant stenosis. This proportion is unchanged since BIAS III and most likely represents *drive by* angioplasty of segments encountered at interventions for more severe disease elsewhere.

16.4% of lesions treated were occlusions. This is a small decrease when compared with BIAS III (18.8%) and is similar to the rate observed in BIAS II (15.8%). Of note there were 376 cases of CIA and EIA occlusion (representing 752 segments, 6.2% of the total segments treated). This proportion is exactly the same as that observed in BIAS III. These cases are likely to represent the most complex (TASC 4) iliac lesions.

Treated legs: iliac segment and pre-procedure stenosis; calendar years 2011-2014

		Pre-procedure stenosis				
		0-49%	50-99%	100%	Unspecified	All
Iliac segment treated	Common	581	3,841	842	15	**5,279**
	External	194	2,497	391	8	**3,090**
	Common & external	110	1,451	376	5	**1,942**
	All	**885**	**7,789**	**1,609**	**28**	**10,311**

Residual stenosis

Successful endovascular intervention (defined as a residual stenosis of ≤49%) was achieved in 97.1% of treated segments. Residual moderate stenosis was seen in 1.5%, and in 1.5% it proved impossible to cross the lesion. In BIAS III successful endovascular intervention was achieved in 84.7%.

The results highlight the excellent technical outcomes following endovascular intervention for pelvic arterial stenosis, though must be interpreted with some caution as under-reporting of cases with suboptimal outcomes or cases where the lesion was not crossed is a source of potential bias.

Treated legs: iliac segment and residual stenosis; calendar years 2011-2014

		Residual stenosis				
		0-49%	50-100%	Failed to cross	Unspecified	All
Iliac segment treated	Common	5,098	62	93	26	**5,279**
	External	2,997	43	41	9	**3,090**
	Common & external	1,876	36	22	8	**1,942**
	All	**9,971**	**141**	**156**	**43**	**10,311**

Results for angioplasty alone versus stent placement

Where a lesion was successfully crossed, the rates of residual stenosis (≥50%) overall and by segment treated were not meaningfully different for segments treated by angioplasty alone or with a stent (CIAs: 1.5% *versus* 1.0%; EIAs: 1.8% *versus* 0.8%; CIA and EIAs: 1.9% *versus* 1.9% respectively). This result should not be interpreted as suggesting that the results after angioplasty alone are equivalent to those of stenting. Stents are frequently used as a bale-out treatment in the event of unsuccessful angioplasty: a poor result after angioplasty alone is likely to have resulted in stent placement. Data on degree of residual stenosis prior to bale-out angioplasty were not collected in the BIAS dataset.

Failure to cross the lesion occurred in 3.0%, 1.6% and 2.1% of EIA, CIA, and EIA & CIA lesions respectively.

Treated legs: type of procedure, iliac segment treated and residual stenosis; calendar years 2011-2014

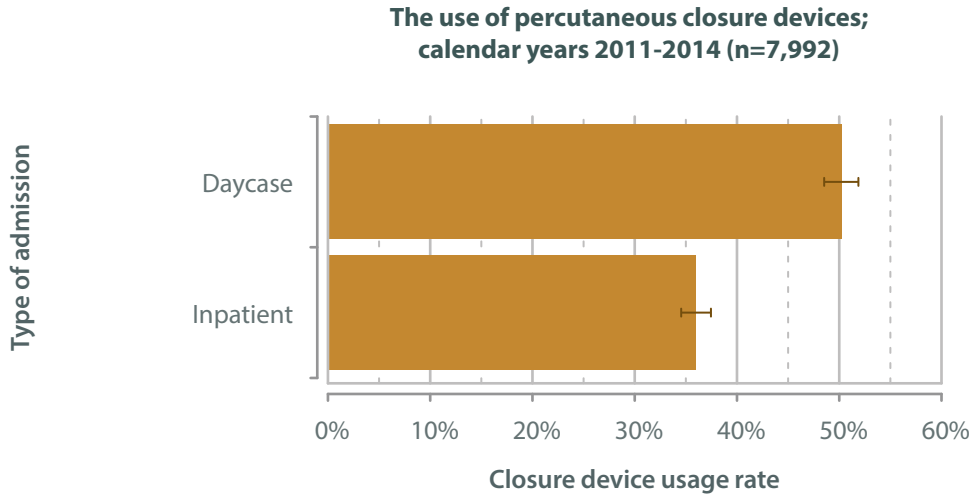
			Residual stenosis				
			0-49%	50-100%	Failed to cross	Unspecified	All
Procedure	**Angioplasty only**	Common	2,014	30	63	8	**2,115**
		External	1,800	33	29	4	**1,866**
		Common & external	784	15	17	4	**820**
	Stent used	Common	3,081	32	10	13	**3,136**
		External	1,197	10	2	5	**1,214**
		Common & external	1,092	21	2	3	**1,118**
	Unspecified	Common	3	0	20	5	**28**
		External	0	0	10	0	**10**
		Common & external	0	0	3	1	**4**

Percutaneous closure device

Closure devices were used in 41.8% of all interventions, with slightly more being used on daycase patients (50.2%) than in inpatients (36.0%). The rate of closure device use in daycases has reduced slightly since BIAS III (daycase: 50.2% *versus* 53.6% in BIAS III) though use in inpatients has increased slightly (36.0% *versus* 32.5% in BIAS III).

The use of percutaneous closure devices; calendar years 2011-2014

		Percutaneous closure device			
		No	Yes	Unspecified	Usage rate
Type of admission	Daycase	1,736	1,750	62	50.2%
	Inpatient	2,718	1,528	121	36.0%
	Unspecified	183	57	139	23.8%
	All	**4,637**	**3,335**	**322**	**41.8%**



Post-procedure

Systemic complications

Overall recording of systemic complications was good. Only 389 patients (4.6%) had no systemic follow up data recorded (compared with 8.8% in BIAS III). Rates of systemic complication were much greater for patients with critical ischaemia than for lower risk patients (claudicants and patients with graft stenosis). Rates of myocardial infarction and deterioration in renal function were 7 times and 10 times greater (respectively) in patients with critical ischaemia (defined as rest pain, ulceration or tissue loss) compared with claudicants. Rates of systemic complication in patients undergoing intervention for graft stenosis are very low, equivalent to those for claudication. Only 1 of 228 patients undergoing intervention for graft stenosis suffered a systemic complication.

The overall rate of systemic complication was 2.2%, compared to 5.8% in BIAS III despite similar casemix (64.4%claudicants, *versus* 62.4% in BIAS III). The rates of complication for patients with claudication and critical ischaemia have fallen since BIAS III (critical ischaemia: 5.1% *versus* 11.6% in BIAS III; claudicants: 0.8% *versus* 2.6% in BIAS III). While this decrease is encouraging the possibility of under-reporting of complications and bias cannot be entirely discounted. However, it is to be hoped that at least some of this large effect is real and relates to improvements in patient preparation and peri-procedural management since 2008.

Other systemic complications recorded were:

- acute confusional state
- blood transfusion
- cardiac rhythm disorders and cardiac arrest
- cellulitis
- chest pain and coronary syndromes
- clostridium difficile colitis
- electrolyte disturbances
- epistaxis
- falls
- GI bleeding
- hypotension or hypertension
- multi-organ failure
- pneumonia
- renal colic
- retroperitoneal haematoma
- seizures
- sepsis
- vasovagal episode

Some of these complications were noted to be related to pre-existing comorbidity.

Systemic complications and indication for intervention; calendar years 2011-2014

Systemic complications[1] and indication		Complication recorded			
		None	Yes	Unspecified	Complication rate
All patients	Any	7,732	173	389	2.2%
	MI	7,883	22	389	0.3%
	Worsening renal function	7,875	30	389	0.4%
	CVA	7,899	6	389	0.1%
	LV failure	7,898	7	389	0.1%
	Bowel ischaemia	7,903	2	389	0.0%
	Urinary retention	7,898	7	389	0.1%
	Other complications	7,791	114	389	1.4%
Critical ischaemia	Any	2,407	129	110	5.1%
	MI	2,517	19	110	0.7%
	Worsening renal function	2,510	26	110	1.0%
	CVA	2,532	4	110	0.2%
	LV failure	2,529	7	110	0.3%
	Bowel ischaemia	2,534	2	110	0.1%
	Urinary retention	2,532	4	110	0.2%
	Other complications	2,456	80	110	3.2%
Claudication	Any	5,059	41	119	0.8%
	MI	5,097	3	119	0.1%
	Worsening renal function	5,097	3	119	0.1%
	CVA	5,098	2	119	0.0%
	LV failure	5,100	0	119	0.0%
	Bowel ischaemia	5,100	0	119	0.0%
	Urinary retention	5,097	3	119	0.1%
	Other complications	5,069	31	119	0.6%
Stenosis above / below graft	Any	227	1	12	0.4%
	MI	228	0	12	0.0%
	Worsening renal function	227	1	12	0.4%
	CVA	228	0	12	0.0%
	LV failure	228	0	12	0.0%
	Bowel ischaemia	228	0	12	0.0%
	Urinary retention	228	0	12	0.0%
	Other complications	227	1	12	0.4%

1. Each **patient** may have one or more systemic complications recorded.

Leg complications

Overall recording of limb outcomes was good with only 114 (1.1%) of limbs treated having no outcome recorded. The overall rate of limb complication was 3.6%, compared to 3% in BIAS III despite similar casemix.

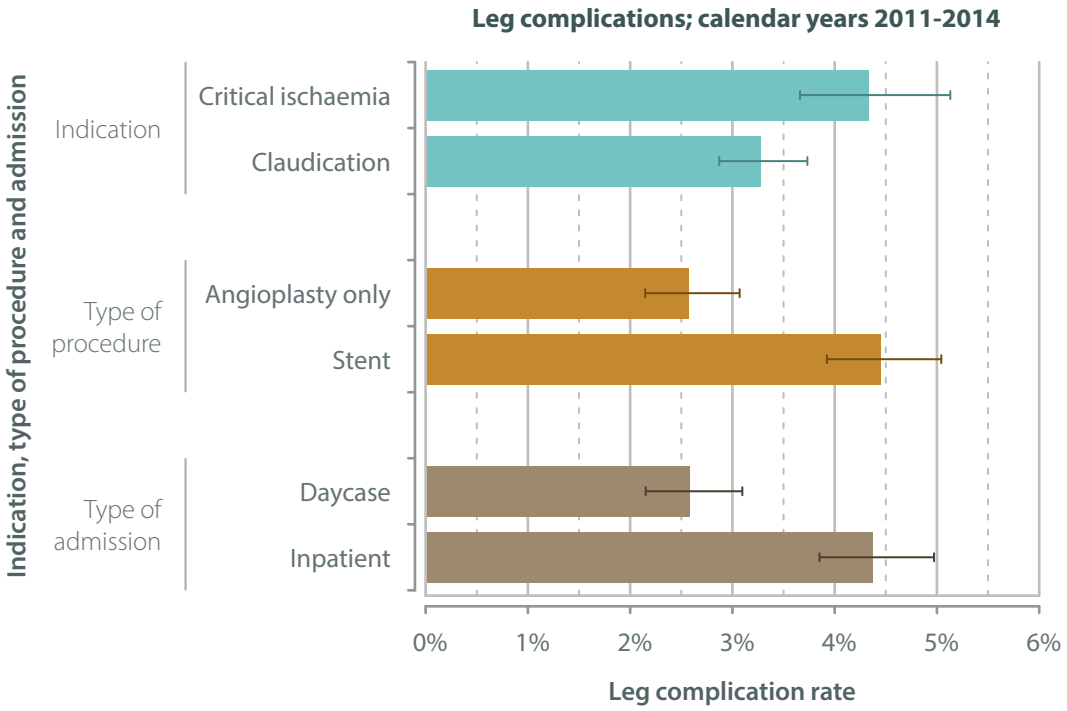
Treated legs: leg complications and indication; calendar years 2011-2014

			Complication recorded			
			No	Yes	Unspecified	Complication rate
All legs		Any complication	**9,831**	**366**	**114**	**3.6%**
Leg complications[1] and indication	Critical ischaemia	Any complication	2,961	134	45	4.3%
		Distal embolism	3,060	35	45	1.1%
		Flow limiting dissection	3,088	7	45	0.2%
		Groin haematoma	3,050	45	45	1.5%
		Treated vessel thrombosis	3,081	14	45	0.5%
		Device malfunction	3,088	7	45	0.2%
		Perforation	3,078	17	45	0.5%
		Access site thrombosis	3,088	7	45	0.2%
		Access site false aneurysm	3,084	11	45	0.4%
		Nerve damage	3,095	0	45	0.0%
	Claudication	Any complication	6,584	223	56	3.3%
		Distal embolism	6,780	27	56	0.4%
		Flow limiting dissection	6,779	28	56	0.4%
		Groin haematoma	6,703	104	56	1.5%
		Treated vessel thrombosis	6,798	9	56	0.1%
		Device malfunction	6,795	12	56	0.2%
		Perforation	6,781	26	56	0.4%
		Access site thrombosis	6,794	13	56	0.2%
		Access site false aneurysm	6,791	16	56	0.2%
		Nerve damage	6,805	2	56	0.0%
	Stenosis above / below graft	Any complication	237	9	8	3.7%
		Distal embolism	243	3	8	1.2%
		Flow limiting dissection	246	0	8	0.0%
		Groin haematoma	245	1	8	0.4%
		Treated vessel thrombosis	245	1	8	0.4%
		Device malfunction	243	3	8	1.2%
		Perforation	246	0	8	0.0%
		Access site thrombosis	245	1	8	0.4%
		Access site false aneurysm	246	0	8	0.0%
		Nerve damage	246	0	8	0.0%

1. Each **leg** may have one or more leg complications recorded.

Treated legs: leg complications broken down by indication, type of procedure and type of admission; calendar years 2011-2014

Indication, procedure and admission			Leg complications: No	Yes	Unspecified	Rate (95% CI)
	Indication	Critical ischaemia	2,961	134	45	4.3% (3.7-5.1%)
		Claudication	6,584	223	56	3.3% (2.9-3.7%)
		Unspecified	49	0	5	
	Type of procedure	Angioplasty only	4,626	122	53	2.6% (2.1-3.1%)
		Stent used	5,174	241	54	4.5% (3.9-5.0%)
		Unspecified	32	3	7	
	Type of admission	Daycase	4,449	118	9	2.6% (2.2-3.1%)
		Inpatient	5,089	233	96	4.4% (3.9-5.0%)
		Unspecified	294	15	9	



Outcome resulting from leg complications

359 (2.5%) patients suffered at least one leg complication though in the majority of these (149 patients, 42.1% of those experiencing a complication) the outcome was unaffected and in a further 88 patients (24.9%) no intervention was required after a period of observation in hospital. Unplanned interventions (either an additional endovascular procedure or surgery) were needed in 141 patients (39.0% of those experiencing a complication and 1.8% of the whole cohort). Rates of unplanned intervention were 1.3% in BIAS III.

Some patients had more than one outcome resulting from a complication (*e.g.,* unplanned endovascular intervention and unplanned surgery).

8,000 (96.5%) patients had a leg outcome recorded. Recording of outcomes was better in patients in whom a leg complication was noted (354 of 359; 98.6%).

Patient outcome resulting from leg complications; calendar years 2011-2014

Outcome[1]			Count	Rate (95% CI)
	All patients	None	7,797	97.5% (97.1-97.8%)
		Observation / increased hospital stay	88	1.1% (0.9-1.4%)
		Unplanned endovascular therapy	78	1.0% (0.8-1.2%)
		Unplanned surgery	63	0.8% (0.6-1.0%)
		Unspecified	294	
		All patients	**8,294**	
	Patients with leg complications	None	149	42.1% (36.9-47.4%)
		Observation / increased hospital stay	88	24.9% (20.5-29.8%)
		Unplanned endovascular therapy	78	21.2% (17.1-25.9%)
		Unplanned surgery	63	17.8% (14.0-22.3%)
		Unspecified	5	
		All patients	**359**	

Although unplanned intervention and prolonged length of stay were observed in a higher proportion of patients with critical limb ischaemia than in other groups the difference was not statistically significant and was not meaningfully different from the rates observed in BIAS III (claudicants: 2.3% *versus* 1.4% in BIAS III; critical ischaemia 3.1% *versus* 3.8% in BIAS III).

Patient outcome from leg complications and indication; calendar years 2011-2014

Indication and outcome[1]		Outcome reported			
		No	Yes	Unspecified	Rate (95% CI)
Critical ischaemia	Any outcome	2,509	81	56	3.1% (2.5-3.9%)
	Observation / increased hospital stay	2,558	32	56	1.2% (0.9-1.8%)
	Endovascular therapy	2,562	28	56	1.1% (0.7-1.6%)
	Unplanned surgery	2,561	29	56	1.1% (0.8-1.6%)
Claudication	Any outcome	5,024	116	79	2.3% (1.9-2.7%)
	Observation / increased hospital stay	5,087	53	79	1.0% (0.8-1.4%)
	Endovascular therapy	5,093	47	79	0.9% (0.7-1.2%)
	Unplanned surgery	5,109	31	79	0.6% (0.4-0.9%)
Stenosis above / below graft	Any outcome	224	6	10	2.6% (1.1-5.9%)
	Observation / increased hospital stay	227	3	10	1.3% (0.3-4.1%)
	Endovascular therapy	227	3	10	1.3% (0.3-4.1%)
	Unplanned surgery	227	3	10	1.3% (0.3-4.1%)

1. Each **patient** may have one or more systemic complications recorded.

Limb status at discharge

Limb status at discharge was recorded in 98.3% of legs.

At discharge 98.9% of limbs were intact. The remaining had worsening ischaemia or amputation. In only 11 of 10,311 legs (0.1%) did iliac intervention result in unexpected amputation. This compares with 0.3% in BIAS III.

Treated legs: limb status at discharge; calendar years 2011-2014

		Count	Percentage
Limb status	Limb intact	10,026	98.9%
	Worsening level of ischaemia	20	0.2%
	Expected amputation	77	0.8%
	Unexpected amputation	11	0.1%
	Unspecified	177	
	All	**10,311**	

Composite outcome using systemic & leg complications data

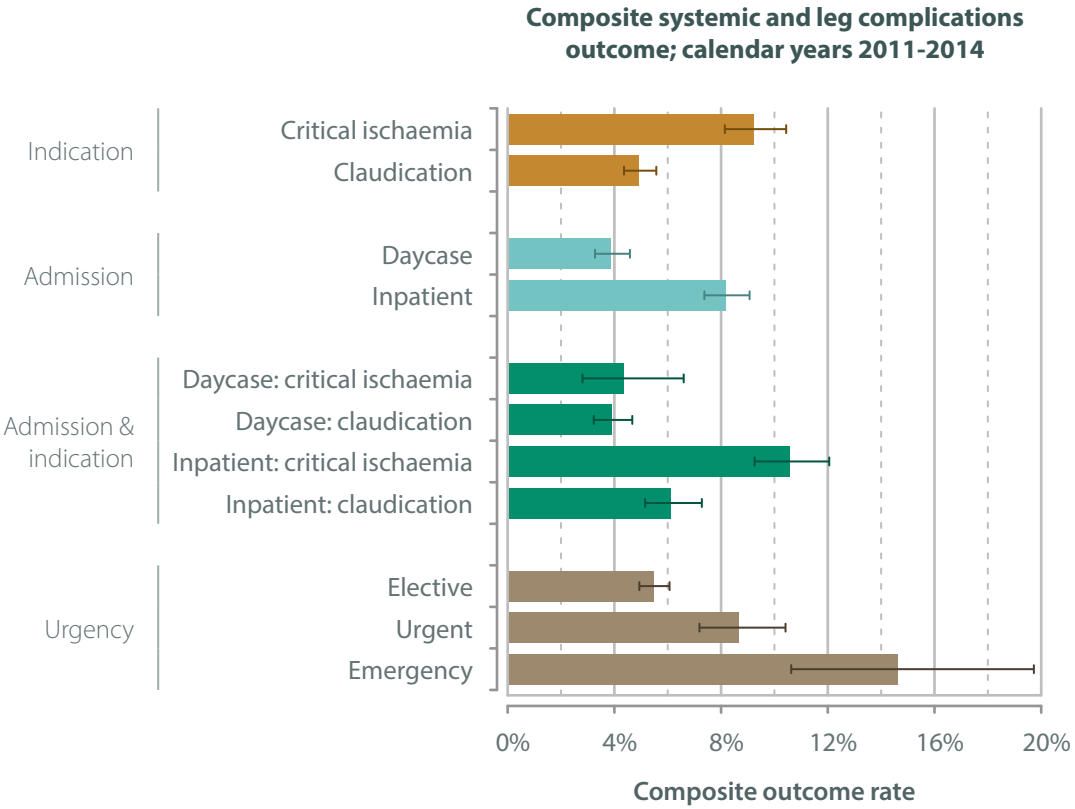
The composite outcome of systemic complication or leg complication was more frequent in patients with critical limb ischaemia than in claudicants (9.2% *versus* 4.9%). This is unsurprising: as previously noted patients with critical ischaemia had higher rates of both systemic and leg complication than claudicants (5.1% *versus* 0.8% of patients, and 4.3% *versus* 3.3% of legs respectively).

Overall inpatients had a higher rate of the composite outcome than daycase patients (8.2% *versus* 3.9%). This was due to a statistically significant increase in the rate of the composite endpoint for patients with critical ischaemia treated as inpatients and a non-significant trend to increased rate of the composite endpoint for claudicants treated as inpatients.

Urgent interventions were associated with a higher rate of the composite endpoint compared to elective procedures (8.7% *versus* 5.5%). There was no significant difference in the composite endpoint rate between patients undergoing emergency interventions in-hours and out-of hours.

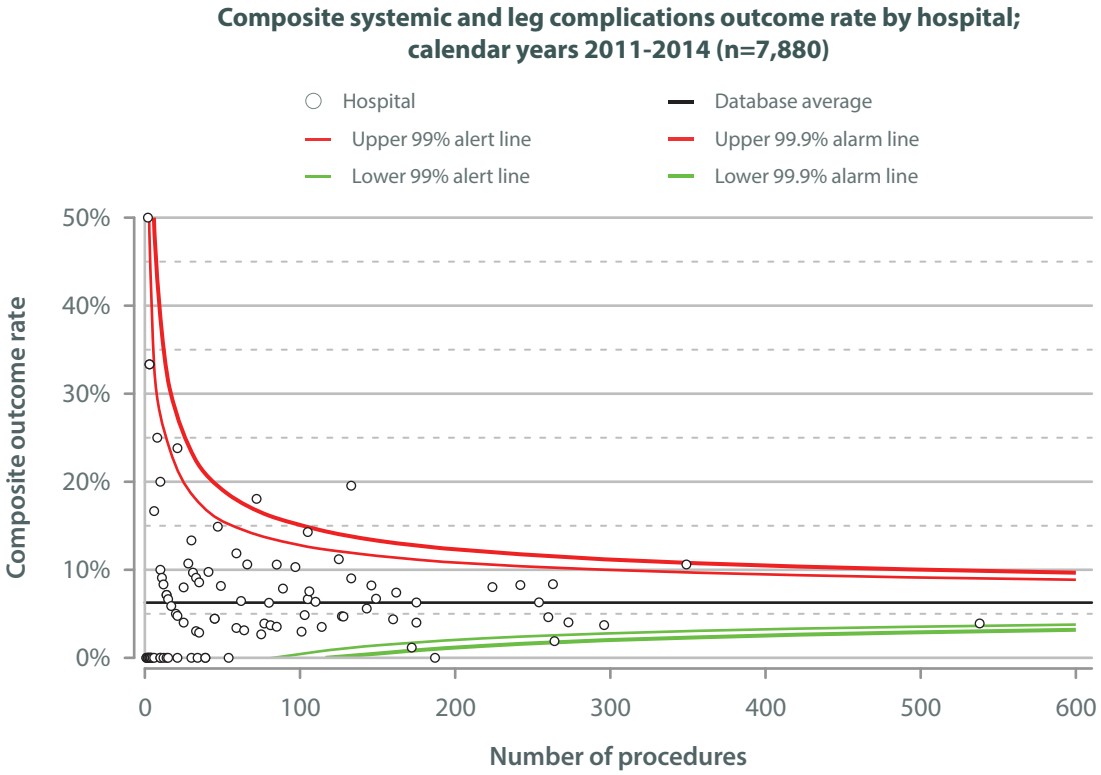
Composite outcome (systemic and / or leg complications where recorded) according to indication, type of admission and urgency; calendar years 2011-2014

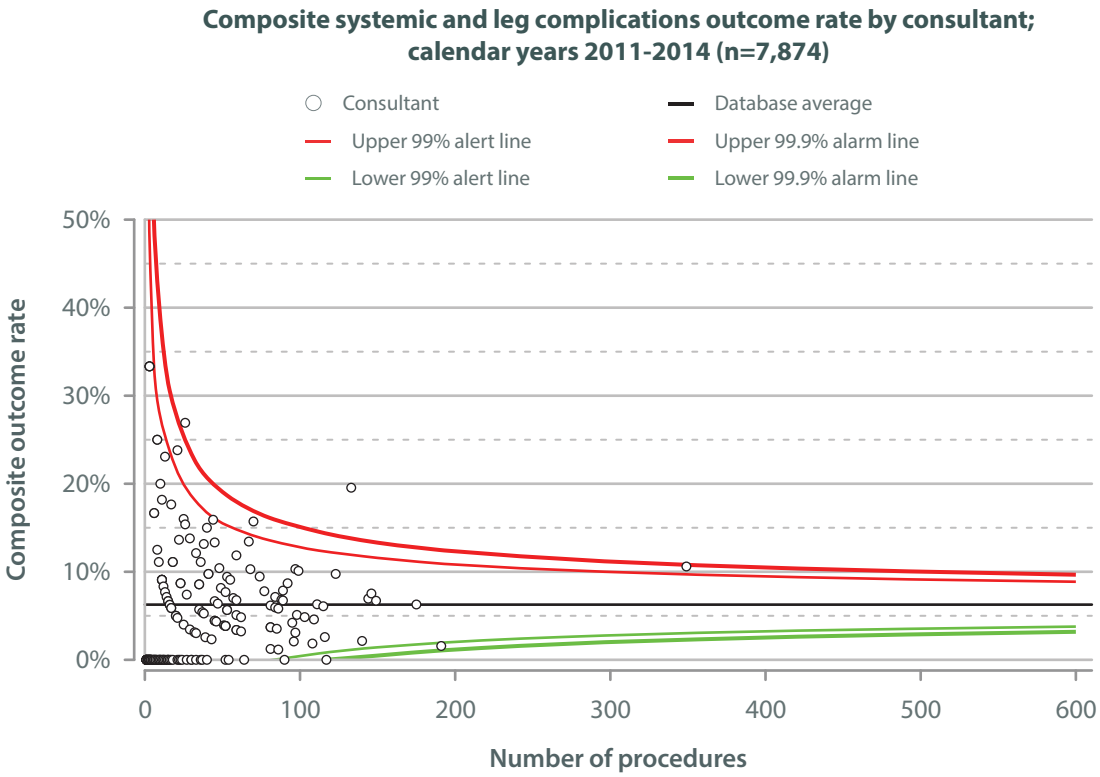
		Composite outcome			
		No	Yes	Unspecified	Outcome rate (95% CI)
Indication	Critical ischaemia	2,292	233	108	9.2% (8.1-10.4%)
	Claudication	4,838	251	98	4.9% (4.4-5.6%)
	Unspecified	37	1	7	
Admission	Daycase	3,372	136	25	3.9% (3.3-4.6%)
	Inpatient	3,804	339	177	8.2% (7.4-9.1%)
	Unspecified	210	19	21	
Admission & indication	Daycase: critical ischaemia	485	22	5	4.3% (2.8-6.6%)
	Daycase: claudication	2,794	113	18	3.9% (3.2-4.7%)
	Inpatient: critical ischaemia	1,725	204	95	10.6% (9.3-12.1%)
	Inpatient: claudication	1,929	126	69	6.1% (5.2-7.3%)
	Unspecified	239	20	26	
Urgency	Elective	6,043	350	154	5.5% (4.9-6.1%)
	Urgent	1,127	107	44	8.7% (7.2-10.4%)
	In-hours emergency	179	30	22	14.4% (10.0-20.0%)
	Out-of-hours emergency	37	7	2	15.9% (7.2-30.7%)
	Unspecified	0	0	1	


Composite systemic and leg complications outcome; calendar years 2011-2014
Indication
Critical ischaemia
Claudication
Admission
Daycase
Inpatient
Admission & indication
Daycase: critical ischaemia
Daycase: claudication
Inpatient: critical ischaemia
Inpatient: claudication
Urgency
Elective
Urgent
Emergency
0%
4%
8%
12%
16%
20%
Composite outcome rate

Funnel plots of composite endpoint (systemic complication or leg complication) by contributing unit and individual consultant are illustrated below. There are 3 units and 2 consultants outside the 99.9% alarm boundaries. There are many potential causes for units or consultants being outliers, including variation in the recording of outcome data (more assiduous data collection or differences in perception of what constitutes a complication within the categories specified in the registry), casemix or error.

The details of why units or individuals are outwith the 99.9% alarm boundaries is not recorded in the registry. At the time of writing there is no formal process for investigating outliers. Individual and unit feedback (in the form of personalised funnel plots) was possible using the BIAS dataset from 2008 and it was a hope of the BSIR that all units and individual consultants breaching the 99% alarm boundaries would review their practice and data to assess why this had occurred and make changes if necessary.




Composite systemic and leg complications outcome rate by consultant; calendar years 2011-2014 (n=7,874)
Consultant
Database average
Upper 99% alert line
Upper 99.9% alarm line
Lower 99% alert line
Lower 99.9% alarm line
Composite outcome rate
50%
40%
30%
20%
10%
0%
0
100
200
300
400
500
600
Number of procedures

Mortality after iliac interventions

Overall there were 84 deaths recorded prior to discharge in the entire patient cohort (1% of 8,294 patients). Patient status at discharge was not recorded in 426 (5.1%) procedures. This compares with an overall mortality in BIAS III of 2%. Most deaths (71; 85%) were considered by the reporting clinician not to be procedure-related (though independent case assessment was not undertaken and the potential for confirmation bias in this figure cannot be discounted). Intra-procedural death (on-table) was vanishingly rare (occurring in a single patient).

Compared with BIAS III, mortality after iliac intervention for claudication remains rare (0.1% *versus* 0.2% in BIAS III). Intervention for critical ischaemia is associated with death before discharge in 3.1% though this rate has reduced since BIAS III (*non-claudicant* group in BIAS III: 5.4%). Daycase mortality remains very rare in both BIAS III and the current dataset (0.03%).

Timing and cause of death; calendar years 2011-2014

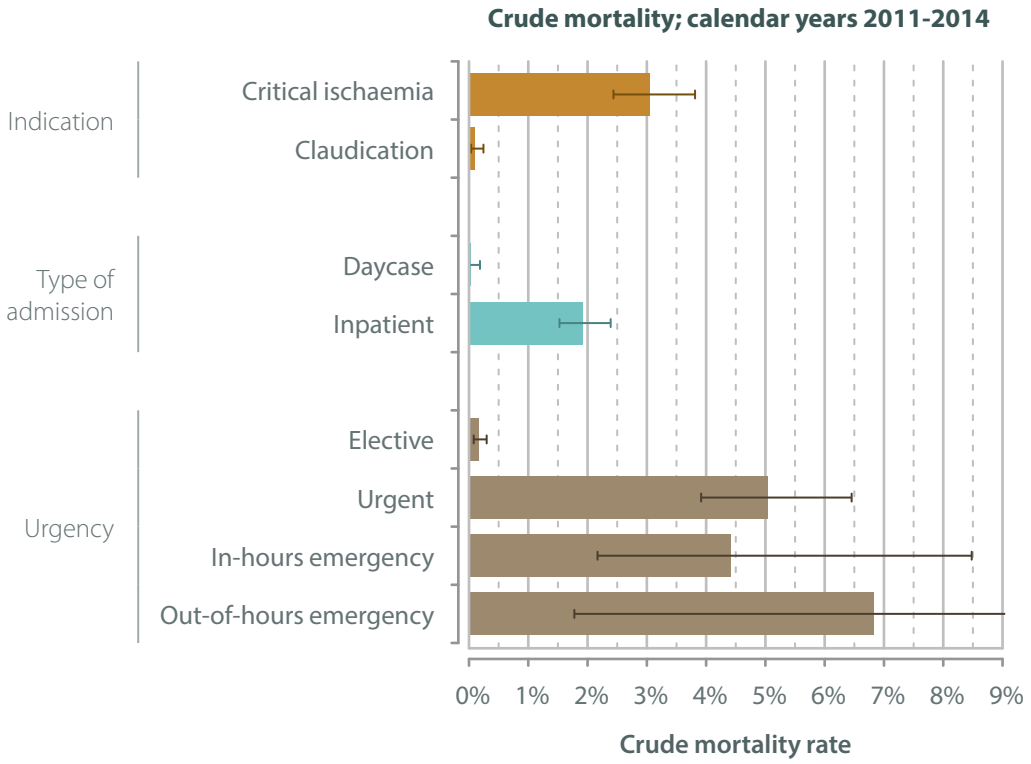
		Cause of death			
		Procedure-related	Not procedure-related	Unspecified	All
Timing of death	Died during procedure	1	0	0	**1**
	Died in hospital	8	71	4	**83**
	Unspecified	0	0	0	**0**
	All	**9**	**71**	**4**	**84**

Patient status at discharge, indication and type of admission; calendar years 2011-2014

		Patient status at discharge			
		Alive	Died	Unspecified	Crude mortality rate (95% CI)
Indication	Critical ischaemia	2,438	78	130	3.1% (2.5-3.9%)
	Claudication	5,079	5	135	0.1% (0.0-0.2%)
	Unspecified	41	0	148	0.0% (0.0-7.0%)
Admission	Daycase	3,504	1	43	0.0% (0.0-0.2%)
	Inpatient	4,053	79	235	1.9% (1.5-2.4%)
	Unspecified	227	4	148	1.7% (0.6-4.7%)
Urgency	Elective	6,380	10	192	0.2% (0.1-0.3%)
	Urgent	1,168	62	54	5.0% (3.9-6.5%)
	In-hours emergency	195	9	27	4.4% (2.2-8.5%)
	Out-of-hours emergency	41	3	2	6.8% (1.8-19.7%)
	Unspecified	0	0	151	
Systemic complications	No	7,633	37	62	0.5% (0.3-0.7%)
	Yes	131	42	0	24.3% (18.2-31.5%)
	Unspecified	20	5	364	

The risk of death before discharge was substantially higher for patients with critical limb ischaemia *versus* claudicants, for patients undergoing urgent procedures *versus* those undergoing elective procedures and for inpatients *versus* patients undergoing daycase procedures.

The occurrence of a systemic complication (MI, worsening renal failure, CVA, LVF, bowel ischaemia, urinary retention and others, detailed on page 23) was associated with a nearly 50-fold increase in risk of death from 0.5% to 24%. The reasons for this are likely to be multi-factorial.



Comparison of various factors from the last two BIAS report

		Database report	
		3rd BIAS report 2009	4th BIAS report 2018
Analysis	Number	2,233	8,294
	Claudication	62%	64%
	Diabetics	21%	21%
	Day case	25%	45%
	Elective	83%	81%
	Lesions stented	54%	54%
	Bilateral	25%	27%
	Residual stenosis <50%	98%	97%
	Closure device	36%	42%
	Limb complications	3.6%	3.0%
	Systemic complications	5.8%	2.8%
	Inpatient survival rate	98%	98%

Appendix

Database form

The British Society of Interventional Radiology
BSIR Iliac Artery Angioplasy-Stent Registry
Baseline section; Page 1; Version 4.0 (26 Oct 2011)

Basic demographic data

All baseline data refer to the condition of the patient when they were originally diagnosed.

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

Registry data

Consultant code	add code — select from the dropdown list
Hospital	add code — select from the dropdown list
Admission type	○ Daycase ○ Elective admission
Date of admission	dd / mm / yyyy

Risk factors

Diabetes	○ No diabetes ○ Type I diabetes ○ Type II diabetes
Renal function	○ Normal ○ Acute renal failure - dialysis ○ Chronic renal failure - dialysis ○ Elevated creatinine >200 µmol l^{-1} / no treatment ○ Functioning renal transplant
Indication for intervention	○ Rest pain with tissue loss ○ Rest pain with no tissue loss ○ Ulcer (with arterial component) ○ Claudication ○ Stenosis above / below graft

Procedure data

Date of intervention	dd / mm / yyyy
Urgency	○ Elective ○ In-hours emergency ○ Urgent ○ Out-of-hours emergency
Grade of principal operator	○ Consultant ○ Trainee
Specialty of principal operator	○ Radiologist ○ Surgeon ○ Cardiologist
Procedure comment	
Legs treated	☐ Left ☐ Right

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The British Society of Interventional Radiology
BSIR Iliac Artery Angioplasy-Stent Registry
Baseline section; Page 2; Version 4.0 (26 Oct 2011)

Unique patient identifier	
Date of intervention	dd / mm / yyyy

Left leg treatment data

Lesion site	○ Common iliac ○ External iliac ○ Common & external iliac
Maximum stenosis	○ 0-49% ○ 50-99% ○ 100%
Procedure performed	○ Angioplasty only ○ Stent
Residual stenosis	○ 0-49% ○ 50-99% ○ Failed to cross
Checkbox thing	○ None ☐ Distal embolism ☐ Flow limiting dissection ☐ Groin haematoma ☐ Treated vessel thrombosis ☐ Device malfunction ☐ Perforation ☐ Access site thrombosis ☐ Access site false aneurysm ☐ Nerve damage
Leg treatment resulting from complications	○ None ☐ Observation / increased hospital stay ☐ Unplanned endovascular therapy ☐ Unplanned surgery
Limb status	○ Limb intact ○ Worsening level of ischaemia ○ Expected amputation ○ Unexpected amputation

Right leg treatment data

Lesion site	○ Common iliac ○ External iliac ○ Common & external iliac
Maximum stenosis	○ 0-49% ○ 50-99% ○ 100%
Procedure performed	○ Angioplasty only ○ Stent
Residual stenosis	○ 0-49% ○ 50-99% ○ 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 ☐ Nerve damage
Leg treatment resulting from complications	○ None ☐ Observation / increased hospital stay ☐ Unplanned endovascular therapy ☐ Unplanned surgery
Limb status	○ Limb intact ○ Worsening level of ischaemia ○ Expected amputation ○ Unexpected amputation

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The British Society of Interventional Radiology
BSIR Iliac Artery Angioplasy-Stent Registry
Baseline section; Page 3; Version 4.0 (26 Oct 2011)

Unique patient identifier

Date of intervention dd / mm / yyyy

Post-procedural outcomes

Systemic complications

- ○ None
- ☐ Urinary retention requiring catheterisation
- ☐ Myocardial infarction
- ☐ Worsening renal function
- ☐ Cerebrovascular accident
- ☐ Pulmonary embolism
- ☐ Left ventricular failure
- ☐ Bowel ischaemia
- ☐ Other

Other systemic complications

Patient status at discharge

- ○ Alive - discharged
- ○ Alive - ongoing admission
- ○ Died during procedure
- ○ Died in hospital

Date of discharge / death dd / mm / yyyy

Cause of death

- ○ Procedure-related
- ○ Not procedure-related