



British Society of Interventional Radiology Iliac Angioplasty and Stent Registry: fourth report on an additional 8,294 procedures

C. Miller^a, R. Frod^a, T.C. See^b, C.J. Hammond^{a,*}

^aDepartment of Vascular Radiology, Leeds Teaching Hospitals NHS Trust, UK

^bDepartment of Interventional Radiology, Cambridge University Hospitals NHS Foundation Trust, UK

ARTICLE INFORMATION

Article history:

Received 16 November 2018

Accepted 31 January 2019

AIM: To provide an update of current practice in iliac artery intervention in the UK.

MATERIALS AND METHODS: Ninety-nine interventional units across the UK completed online submission forms for iliac angioplasty and stent procedures between 2011 and 2014 (inclusive) for the British Iliac Angioplasty and Stenting (BIAS) IV registry.

RESULTS: Data for 8,294 procedures were submitted during the study period. A total of 12,253 iliac segments were treated in 10,311 legs. The commonest indication was claudication ($n=5219$, 64.4%). Of the cases performed, 6,582 (80.8%) were performed electively with 3,548 (44.8%) of the procedures performed as a day-case and 6,586 (54%) of the lesions were treated with stents. Successful endovascular intervention (residual stenosis $\leq 49\%$) was achieved in 11,847 (97%) of treated segments, with residual stenosis in 1.5%. One point five percent of lesions could not be crossed with a wire. Limb complications were recorded in 366 (3.5%), resulting in 141 patients undergoing an unplanned intervention and 173 (2.2%) patients had a systemic complication. There were 84 deaths prior to discharge, of which 13 (15%) were procedure related. Both systemic and limb complication rates were higher in patients undergoing treatment for critical ischaemia.

CONCLUSION: Iliac stenting and angioplasty are associated with high technical success with a low complication rate. These data provide up-to-date statistics for patient information and future audit and benchmarking purposes.

© 2019 The Royal College of Radiologists. Published by Elsevier Ltd. All rights reserved.

Introduction

The British Society of Interventional Radiology [BSIR] Iliac Artery Angioplasty and Stenting [BIAS] Registry was launched in 2000 with the intention of ascertaining benchmarks for standards of practice for endovascular iliac intervention.¹ Since its inception, three incremental reports

on the BIAS dataset have been published.^{1–3} This study provides an updated (and final) review of the BIAS dataset of current practice, complications, and outcomes from iliac intervention in vascular interventional units throughout the UK from January 2011 to December 2014.

Materials and methods

Between 2011 and 2014 (inclusive), UK interventional radiologists (IRs) were invited to submit details for iliac angioplasty and stent procedures they undertook. Patient

* Guarantor and correspondent: C. J. Hammond, Department of Vascular Radiology, Leeds Teaching Hospitals NHS Trust, Leeds LS1 3EX. UK. Tel.: +441133923504; fax: +441133925217.

E-mail address: christopherhammond@nhs.net (C.J. Hammond).

demographics, indications, type of procedure, length of stay in hospital, complications, and outcomes prior to discharge were recorded via a bespoke online portal maintained by Dendrite Clinical Systems Ltd ([Electronic Supplementary Material Appendix S1](#)). Long-term outcome measures were not assessed. The registry was closed in 2015, and final analysis of the dataset was undertaken by Dendrite Clinical Systems in late 2016. Analyses undertaken were informed by those undertaken on prior iterations of the BIAS dataset (to allow for comparison). Results are presented as proportions (for categorical variables). Proportions of datasets were calculated to include missing data points in the denominator. Comparison between proportions was undertaken using Fisher's exact or χ^2 test.

Ethics approval and consent to participate

Data in the registry were collected prospectively and were pseudo-anonymised with the use of a local identifier only. The only demographic data obtained were date of birth and sex. Local identifiers were automatically stripped from the data for analysis. No retrospective case note or imaging review was undertaken. At the time of registry inception (2000), UK ethical approval for pseudo-anonymised national registry data acquisition was not considered necessary and was not sought.

Data were entered via a secure online portal and were maintained in encrypted format on Dendrite servers, the security of which was certified under the UK National Health Service (NHS) Information Governance Toolkit Certification Scheme. Dendrite is registered as a data processor with the Information Commissioner in the UK. The registration provides further guarantees about data security, integrity, and processing. At the time of registry inception, it was not considered necessary for consent to be obtained for

holding pseudo-anonymised data under these information governance standards. No formal consent process was therefore undertaken.

Results

Over the 4-year period 2011–2014 inclusive, 99 institutions contributed data on 8,294 patients undergoing iliac endovascular intervention. The total number of patients entered into the registry gradually increased over the years of its operation, peaking at 2,477 cases in 2013 ([Fig 1](#)). The majority of patients (5,294, 63.8%) were aged 60–79 years at the time of the intervention with 5,539 (66.8%) male patients. Of procedures performed, 3548 (44.8%) were as a day case.

Of the patients, 1,665 (20.5%) had diabetes and 435 (5.4%) of patients had renal disease. Significantly fewer patients with renal disease or diabetes were treated as day cases (31.9% compared to 48.7%, and 34.1% compared to 48.7% respectively, $p < 0.01$).

Indication

The main indication for intervention was claudication in 5,219 (64.4%) cases. This was followed by rest pain without tissue loss (1,093, 13.5%), tissue loss (1,553 cases 18.7%), and bypass graft-related intervention (240 cases, 3%). In 189 cases (2.2%), the indication was not specified. The incidence of critical limb ischaemia increased with increasing age: 60.8% of patients within their eighth decade of life underwent intervention for critical limb ischaemia ([Fig 2](#)).

Of the procedures, 6,582 (80.8%) were performed electively, 1,284 (15.8%) were performed urgently, 231 (2.8%) were performed as an in-hours emergency and 46 (0.6%) were performed as an out-of-hours emergency. One

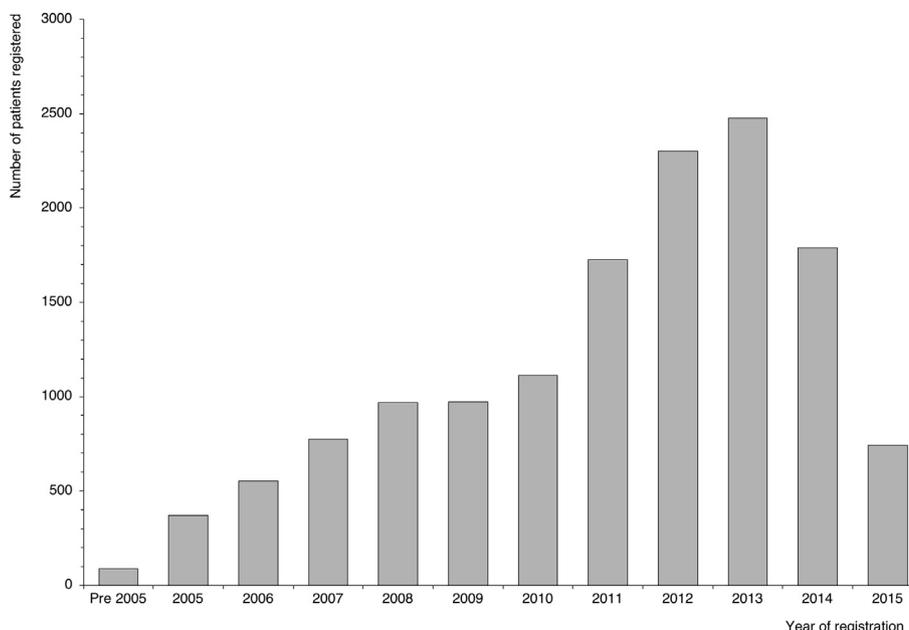


Figure 1 Annual entries into the BIAS registry.

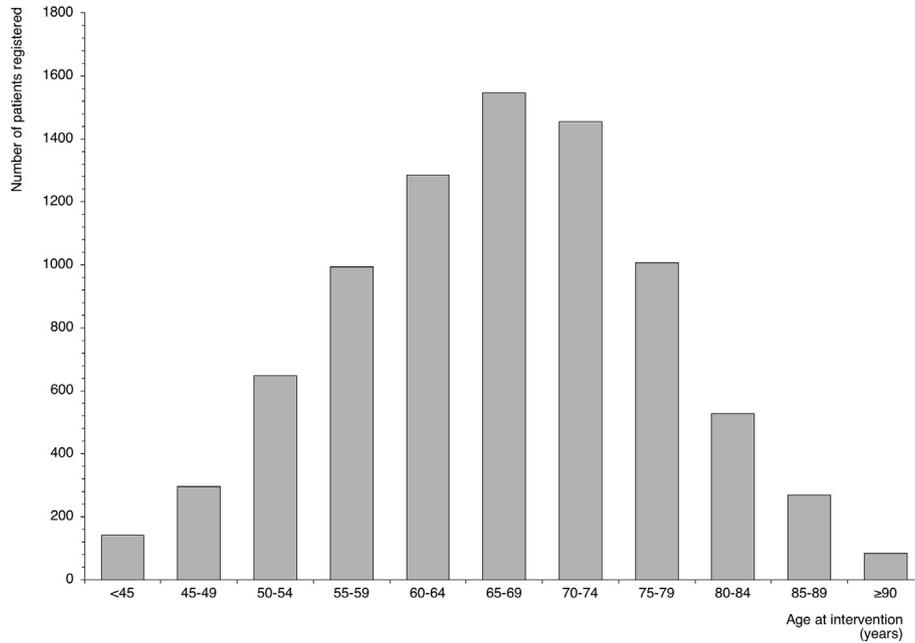


Figure 2 Age of patients entered into the BIAS registry system between 2011–2014.

hundred and fifty-one procedures did not have their urgency specified.

Procedure

Regarding bilaterality, 2,224 (27.3%) patients had bilateral interventions, 5,915 patients had unilateral intervention, and in 155 patients the number of sides treated was unspecified. Taking into account the missing data, there were therefore between 10,518 and 10,673 limbs treated in total.

Data about the procedure undertaken were completed for 10,311 limbs with 12,253 iliac segments treated. The mean number of segments treated per patient was 1.48 (Fig 3). The most common lesion treated was a 50–99% stenosis (7,789 segments, 76%). Sixteen percent of segments treated were occluded. There were 376 cases of CIA and EIA occlusion (representing 752 segments, 6.2%), which represents the most complex (Trans Atlantic Societies Consensus (TASC) D)⁴ iliac lesions.

Regarding treatment, 6,586 (54%) lesions were treated with a stent. A closure device was used in 4,637 (41.8%) of patients. The highest rate of use was in patients undergoing day case procedures, 1,750 (50.2%).

Outcome

Technical success (defined as a residual stenosis of ≤49%) was achieved in 11,847 (97%) of segments treated. A residual stenosis of ≥50% persisted in 1.5% of segments and in 1.5% of segments the lesions could not be crossed (resulting in a failed intervention). There was no significant difference in the rates of residual stenosis between segments treated with angioplasty alone or with stenting ($\chi^2=0.43, p=0.51$).

Limb complications occurred in 366 (3.5%) treated limbs in 359 (4.3%) patients. The most common complication was groin haematoma (150 limbs, 1.5%). The breakdown of complications correlated by indication is detailed in Table 1.

Rates of limb complication were significantly higher in inpatients (inpatients 4.4%, day case 2.6%; $\chi^2=23.11, p<0.001$) and for patients treated with a stent (stent used 4.5%, angioplasty only 2.6%; $\chi^2=25.99, p<0.001$). Of the 359 patients with at least one limb complication, 141 (39%) required an additional unplanned endovascular or surgical procedure (Table 2), for an overall rate of 1.8% (of all 8294 patients). Data was not recorded for limb complications in 114 (1.1%) limbs.

Regarding systemic complications, 173 (2.2%) patients experienced a systemic complication. The most common

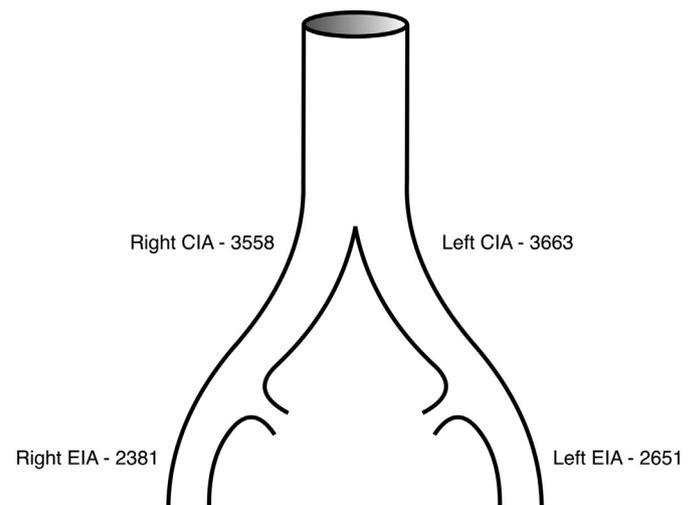


Figure 3 Total number of interventions performed in each iliac segment.

Table 1

Rates of leg complications by indications for intervention (note that each limb treated may have had more than one complication).

Complications	Claudication		Critical limb ischaemia		Stenosis above/below graft	
	Yes	No	Yes	No	Yes	No
Any complication	233 (3.3%)	6,584	134 (4.3%)	2,961	9 (3.7%)	237
Distal embolism	27 (0.4%)	6,780	35 (1.1%)	3,060	3 (1.2%)	243
Flow limiting dissection	28 (0.4%)	6,779	7 (0.2%)	3,088	0	246
Groin haematoma	104 (1.5%)	6,703	45 (1.5%)	3,050	1 (0.4%)	245
Treated vessel thrombosis	9 (0.1%)	6,798	14 (0.5%)	3,081	1 (0.4%)	245
Device malfunction	12 (0.2%)	6,795	7 (0.2%)	3,088	3 (1.2%)	243
Perforation	26 (0.4%)	6,781	17 (0.5%)	3,078	0	246
Access site thrombosis	13 (0.2%)	6,794	7 (0.2%)	3,088	1 (0.4%)	245
Access site pseudoaneurysm	16 (0.2%)	6,791	11 (0.4%)	3,084	0	246
Nerve damage	2 (<0.1%)	6,805	0	3,095	0	246

systemic complications were deterioration in renal function ($n=30$), myocardial infarction ($n=22$), acute urinary retention ($n=7$), acute heart failure ($n=7$), cerebrovascular accident ($n=6$), and ischaemic bowel ($n=2$). Data on systemic complications was not recorded for 389 (4.6%) patients.

Patients with critical limb ischaemia were significantly more likely to develop a composite endpoint of either a limb or systemic complication compared to patients with claudication (composite endpoint: critical ischaemia 9.2%; claudication 4.9%; $\chi^2=52.31$, $p<0.001$). Inpatient procedures were associated with a higher rate of the composite endpoint than day-case procedures (composite endpoint: inpatients 8.2%; day case patients 3.9%; $\chi^2=60.48$, $p<0.001$). Elective procedures were associated with a significantly lower incidence of the composite endpoint than non-elective procedures (composite endpoint: elective procedures 5.3%, non-elective procedures 9.2%; $\chi^2=36.38$, $p<0.001$).

Mortality

Vital status at discharge was recorded for 7,868 patients (94.8%). There were 84 (1%) deaths recorded prior to discharge and 71 of these deaths were deemed by the reporting clinician to be unrelated to the procedure. One intraprocedural death was recorded. Mortality was significantly higher in procedures for critical limb ischaemia than claudication (3.1%, 0.1%, $p<0.001$) and also in inpatient procedures compared with day cases (1.9%, 0%, $p<0.001$).

Discussion

To the authors' knowledge, the BSIR BIAS registry is the largest iliac artery intervention database worldwide with over 13,000 patients in total being registered in its 16 years of operation. The BIAS registry is now closed having been

Table 2

Clinical outcomes from leg complications.

Action taken	<i>n</i>
None	149 (42.1%)
Observation/hospital stay	88 (24.9%)
Unplanned endovascular therapy	78 (21.2%)
Unplanned surgery	63 (17.8%)
Unspecified	5 (1%)

superseded in late 2013 by the UK National Vascular Registry (NVR), which provides a platform to submit information on all lower-limb endovascular procedures (not just iliac interventions).⁵

There was an upward trend in participation with the BIAS registry (Fig 1), until the advent of the NVR. It is likely that the drop-off in ascertainment in BIAS after 2013 was in part related to competition between the two registries. This led the BSIR to close BIAS in 2015. The total rates of ascertainment for iliac intervention in BIAS at peak recruitment remain substantially higher than those for iliac intervention in the NVR to date,⁶ suggesting that there are opportunities to improve NVR data entry as IRs have demonstrated good engagement in the past with BIAS.

Compared with BIAS III,³ the demographics of the patients undergoing intervention are unchanged, with the majority of interventions performed for claudication. There has been a large increase in the proportion of patients undergoing day-case procedures (44.8% in the current report compared to 25% in BIAS III and 11% in BIAS I). There has also been an increase in the use of closure devices (42% of all cases in the current report compared with 36% in BIAS III). It is likely that the increase in the use of day-case facilities and the increased use of closure devices are related due to the requirement for early mobilisation for day-case patients. This inference is supported by the greater use of closure devices in day-case procedures compared with inpatient procedures (50% versus 36%).

Importantly, the increased numbers of patients being treated as a day case has not negatively affected safety: the systemic complication rate has decreased compared with BIAS III (2.2% versus 5.8%). These encouraging data may at least be in part due to better patient preparation, although under reporting of systemic complications cannot be ignored.

The increased use of closure devices has not been associated with substantial reduction in the incidence of iatrogenic groin pseudo-aneurysm (0.3% of procedures versus 0.4% BIAS III) and the incidence of significant groin haematoma delaying discharge has marginally increased (1.4% versus 1% BIAS III). Data on the efficacy of closure devices were not collected in BIAS. A Cochrane review comparing closure devices with manual compression in patients following common femoral artery puncture reported lower

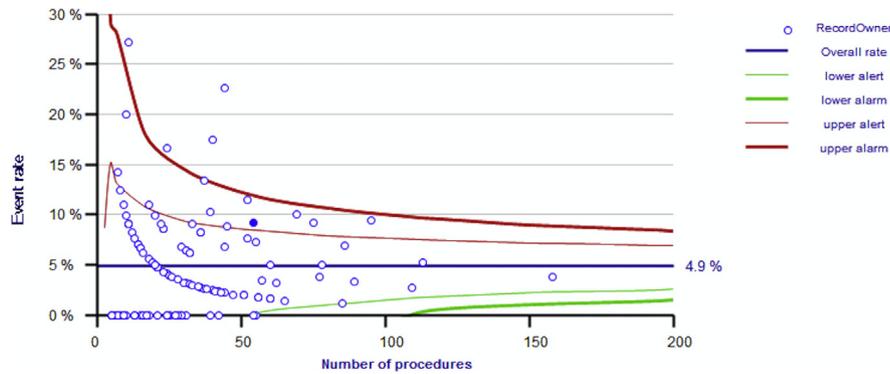


Figure 4 Example funnel plot output from the BIAS system of an individual centre's limb complication rate relative to overall complication rate, showing upper and lower alert and alarm boundaries. The centre's data are represented by the filled data points, other centres' data are represented by the unfilled circle data points. Lying out with an alarm or alert boundary should prompt a review.

haematoma and pseudo-aneurysm rates with certain closure devices but not others⁷ and a recent randomised study has demonstrated differences in the efficacy of different devices.⁸ Closure device effectiveness and outcome may be a useful topic for evaluation in a new registry.⁸ Technical success remains high (97% compared with 98% in BIAS III). The proportion of lesions treated with a stent is unchanged from BIAS III (54%).

The lack of a significant difference in the rates of residual stenosis between segments treated with angioplasty alone or with stenting should be interpreted with caution and does not provide evidence of equivalent short-term efficacy of these procedures: stenting is often used as an adjunct when angioplasty has been unsuccessful or resulted in a poor on-table result. The degree of residual stenosis prior to bail-out stenting were not collected in the BIAS dataset, and it is therefore not possible to differentiate the complication and residual stenosis rates for primary angioplasty versus bail-out procedures from the data. A prospective multi-centre trial would be needed to address this as current evidence is limited.⁹ Similarly (for the same reasons), the increased rate of limb complication associated with stent use should not be interpreted as suggesting the use of stents entails greater risk.

The BIAS dataset is limited in that the data entry was voluntary and not uniform between different sites. The possibility of inclusion bias must be considered; this is evident in the rate of failure to cross a lesion (1.5%), which is lower than anticipated, although only marginally lower than that reported in the literature (2.4–2.8%^{10,11}). Further the scope of the data collected was limited as in most large registries in so much as detailed assessment of the lesions treated, procedural technicalities including equipment and devices used, and the specifics of patient aftercare and outcome were not recorded. The assessment of outcomes and complications was made by the reporting clinician with no reference to core-laboratory review of angiographic imaging, independent case note review, or systemic adverse event (AE) or serious adverse event (SAE) reporting. In addition, complications did not have defined objective parameters on the data input form, for example, worsening renal function, leading to further possible inclusion bias.

Missing data points could also have an influence on the results, particularly the incidences of complications considering the small overall number. The possibility of reporting and anchoring biases must also be considered. The size of the patient cohort and the number of centres contributing means these risks are mitigated to some extent. The present results are a reasonable assessment of current UK practice in iliac endovascular intervention.

Outcomes recorded in BIAS were limited to the duration of the inpatient or day-case hospital stay. They do not therefore address important longer-term outcomes, such as symptom relief, ulcer healing, vessel patency, and re-intervention rates.

Benchmarking of endovascular practice is essential to ensure patients are provided with assurances about the quality of care they are to receive, and to allow clinicians to assess their practice and outcomes and implement changes where appropriate. The BIAS dataset provides a large-scale assessment of current endovascular practice and outcomes in the UK and provides suitable benchmarks against which services can be assessed. Since the publication of the BIAS III report,³ UK IRs were able to access their individual data within BIAS and compare their practice with these new benchmarks (Fig 4).

In conclusion, BIAS is the largest registry of endovascular iliac intervention worldwide. Excellent technical outcomes have been demonstrated with low rates of systemic and limb complication in UK practice. These data provide a benchmark for the ongoing assessment, accreditation, and review of services providing iliac intervention. All clinicians undertaking iliac intervention are encouraged to engage with the collection of these data and compare it with the BIAS dataset.

Conflict of interest

The authors declare no conflict of interest.

Acknowledgements

The authors acknowledge the many individual contributors to the BIAS registry, Dendrite Clinical System Ltd for

maintaining the registry and the BSIR for instigating and funding it on behalf of its membership.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.crad.2019.01.026>.

References

1. Gaines P, Moss J, Kinsman R. *BIAS 1 report*. British Society of Interventional Radiology, Dendrite Clinical Systems Ltd; 2001.
2. Gaines P, Moss J, Uberoi R et al. British society of interventional radiology second BIAS report. Dendrite Clinical Systems Ltd; 2005
3. Uberoi R, Milburn S, Moss J, et al. British society of interventional radiology iliac artery angioplasty-stent registry III. *Cardiovasc Intervent Radiol* 2009;**32**(5):887–95.
4. Norgren L, Hiatt W, Dormandy J, et al, on behalf of the TASC II Working Group. Inter-society consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg* 2007;**45**(1):s5–67.
5. Vascular Services Quality Improvement Programme. In: National vascular registry data entry system. Available at: <https://www.vsqip.org.uk/nvr-data-entry-system/>. Accessed 10 Mar 2018.
6. Hammon C, See TC, Walton P, et al. *BIAS IV report*. British Society of Interventional Radiology, Dendrite Clinical Systems Ltd; 2018.
7. Robertson L, Andras A, Colgan F, et al. Vascular closure devices for femoral arterial puncture site haemostasis. *Cochrane Database Syst Rev* 2016 Mar 7;**3**:CD009541.
8. Klein-Wiele O, Baliota M, Kara K. Safety and efficacy of clip-based vs. suture mediated vascular closure for femoral access haemostasis: a prospective randomized single center study comparing the Starclose and the Proglide device. *Catheter Cardiovasc Interv* 2018;**91**(3):402–7.
9. Bekken K, Jongsma H, Ayez N, et al. Angioplasty versus stenting for iliac artery lesions. *Cochrane Database Syst Rev* 2015;**5**:CD007561.
10. Kokkinidis D, Alvandi B, Hossain P, et al. Midterm outcomes after endovascular intervention for occluded vs stenosed external iliac arteries. *J Endovasc Ther* 2018;**25**(2):183–91.
11. Soga Y, Lida O, Kawasaki D, et al. Contemporary outcomes after endovascular treatment for aorto-iliac artery disease. *Circ J* 2012;**76**(11):697–704. 2.