National Vascular Registry: Short Report

Use of implantable medical devices in aortic aneurysm repair

December 2022

Royal College of Surgeons of England
ADVANCING SURGICAL CARE

VASCULAR SOCIETY
OF GREAT BRITAIN AND IRELAND

British Society of Interventional Radiology
Registered Charity No: 1084852

HQIP
Healthcare Quality Improvement Partnership

Please cite this report as:

Birmpili P, Waton S, Johal A, Li Q, Atkins E, Boyle JR, Cromwell DA, Pherwani AD, Williams R. *Use of implantable medical devices in aortic aneurysm repair.* London: The Royal College of Surgeons of England, 2022.

FOREWORD

In response to the Baroness Cumberlege review [Cumberlege 2020] and with support of HQIP, the National Vascular Registry has enabled information on implantable devices used in aortic aneurysm repairs to be entered in its datasets from July 2020. This was accompanied by the launch of the revision aortic datasets, which capture revision procedures both after open repair and endovascular stent grafting for abdominal aortic aneurysm (AAA).

Our ability to capture device information enabled us to respond when Medtronic issued a field safety notice in February 2021 and inform vascular units of procedures where the Valiant Navion thoracic stent graft had been used for enhanced surveillance protocols.

We are very encouraged by the steady increase in the proportion of devices captured, now greater than 70% of procedures. The revision aortic datasets are beginning to tell a story of re-interventions for sac size increase after EVAR, and this information will drive quality improvement. The NVR work on aortic devices and revision aortic procedures is being viewed with keen interest worldwide and it is increasingly the view from international vascular societies that registries need to take on the responsibility for collecting and reporting upon implantable devices in the interests of patient safety, accountability and governance [Goodney et al 2022].

This work was made possible by the collaboration of the NVR team with Healthcare Quality Improvement Partnership (HQIP), the Medicines and Healthcare products Regulatory Agency (MHRA), NHS England & Improvement (NHSEI), Digital Health and Care Wales (DHCW), the Association of British HealthTech Industries (ABHI) and our IT partners NEC Software Solutions. We thank our members from the Vascular Society for Great Britain and Ireland (VASGBI) and the British Society for Interventional Radiology (BSIR) along with clinicians, postgraduate doctors in training and data support teams for their immense contribution in making this a success.

In the future, we aim to work closely with the Outcome Registries & Patient Safety Programme within NHS England and Digital Health and Care Wales to capture device information for other conditions such as lower limb interventions and carotid procedures.

Mr Arun Pherwani

Clinical Lead for the NVR

Chair of the Audit & Quality Improvement Committee, Vascular Society for Great Britain & Ireland

INTRODUCTION

The National Vascular Registry (NVR) was established to measure the quality and outcomes of care for adult patients who undergo major vascular procedures in NHS hospitals, and to support vascular services to improve the quality of care for these patients. All NHS hospitals in England, Wales, Scotland and Northern Ireland are encouraged to participate, so that the Registry can support the work of the Vascular Society of Great Britain and Ireland (VSGBI) to improve the care provided by vascular services within the UK.

One of the vascular procedures collected in the NVR is aortic aneurysm repair. An abdominal aortic aneurysm (AAA) is the local expansion of the abdominal aorta, which is usually asymptomatic, but has a risk of rupture. An aneurysm can be repaired by either an open or endovascular method, and an implantable medical device is left inside the patient in both procedures:

- An open repair involves surgically opening the abdomen, clamping the aorta above and below the aneurysm, repairing the aneurysmal section of the aorta and replacing it with a sown-in prosthetic graft.
- In an endovascular repair (EVAR), a stent graft is fed up into the patient's aorta from smaller incisions into the arteries in the groin. This stent-graft then lines the inside of the aorta, and blood flows through it, thus allowing the aneurysm to shrink around it.

The success of the operation relies on the implanted device continuing to prevent aneurysm rupture for the remainder of the patient's life. Patients who undergo open surgical repair are not usually followed up, while patients who undergo endovascular repair are offered regular surveillance assessment with imaging, and 20-25% of patients require a revision procedure [Boyle 2019, Patel 2016, and Singh 2020]. A subsequent procedure can be either a revision EVAR, defined as an endovascular procedure on a patient who has had a previous repair (either open or endovascular), or a revision open, which is an open procedure on a patient with any type of previous AAA repair.

In 2020, the Independent Medicines and Medical Devices Safety Review published its report entitled "First do no harm" [Cumberlege 2020], which focused on the reporting of harmful side effects from medicines and medical devices. It recommended the collection of information on implantable medical devices to monitor safety. This was complemented by a report from the Healthcare Quality Improvement Partnership (HQIP) that highlighted the desirability of a registry for implantable medical devices, which could alert relevant bodies and patients about defective devices [HQIP 2020].

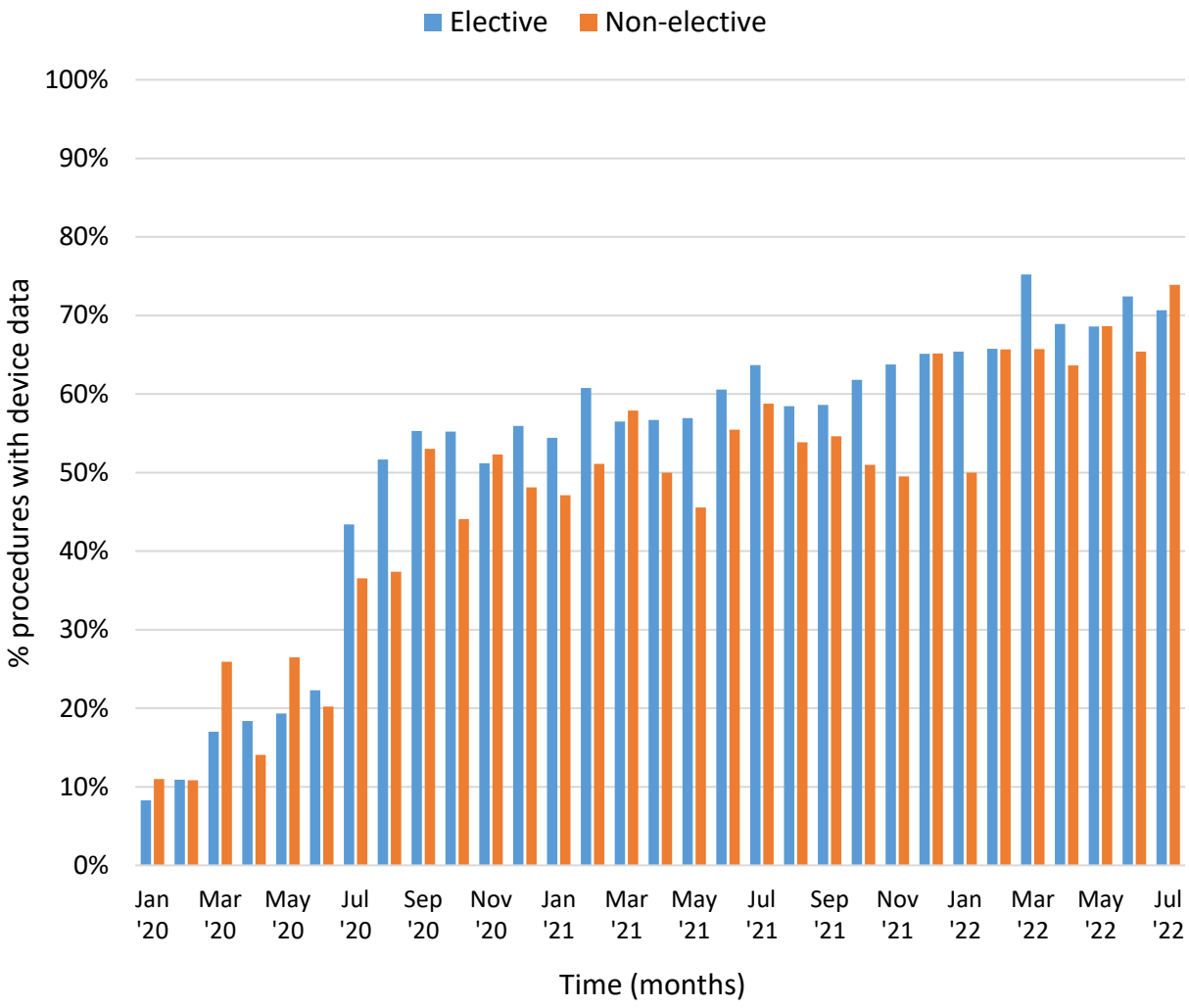
The publication of these reports in July 2020 coincided with the launch of a dataset capturing information on implantable devices used in AAA repairs in the National Vascular Registry. The first report on device information captured in the NVR was published in June 2021 [Waton et al. 2021]. The report described the development of the dataset by the NVR team, NEC Software Solutions and the Association of British HealthTech Industries (ABHI) and reported information on 1,056 procedures that contained device information. The aim of this report is to provide information on

medical devices implanted during primary and revision AAA repair procedures during the past three years. This report presents basic descriptive information, and we expect to provide information on re-interventions and outcomes once data have been collected for a longer period of time.

INFORMATION ON DEVICES CAPTURED IN THE NVR

In total, there were 10,678 AAA procedures in the NVR performed from 1st January 2020 to 31st July 2022 and 5,383 (50%) contained information on implanted devices. The ability to enter device information was activated in July 2020, but some hospitals have entered data into the NVR IT system on procedures performed before this date. The proportion of AAA procedures on the NVR with device data increased during 2020, reached 60% in 2021 and 70% in 2022. The patterns for elective and non-elective procedures were fairly similar (Figure 1). The percentage of procedures with a device recorded varied greatly between hospitals. 17 had a rate of above 80%, whereas 10 had a rate of less than 15% (with four hospitals entering no device data at all).

Figure 1: Percentage of AAA procedures with device information between January 2020 and July 2022, by month of operation and mode of admission

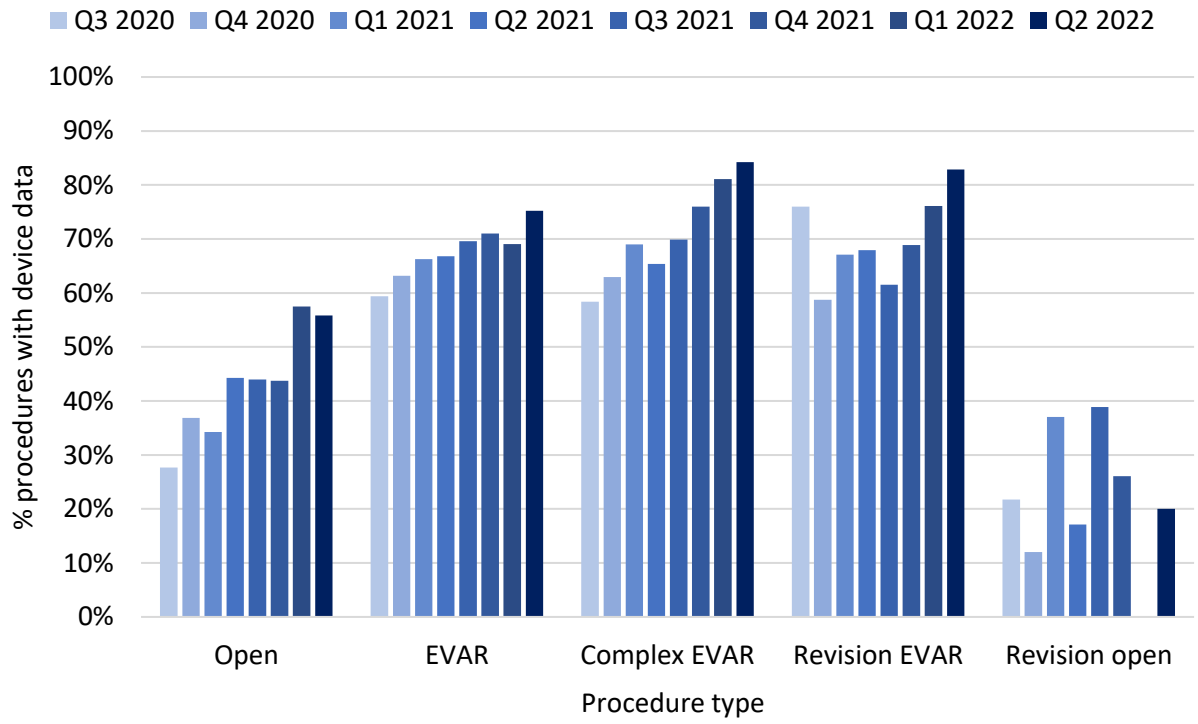


The highest proportion of procedures with device information was observed for revision EVAR (63%), followed by EVAR (58%) and complex EVAR (59%) procedures (Table 1). Proportionally fewer open repairs had a device recorded; 37% of primary open and 22% of revision open procedures. This may be due to the fact that not all open repair grafts were available in the device dataset for selection on the NVR in July 2020, and so the numbers were lower at the start. The completeness of the dataset for open repairs increased over the data collection period, once the additional grafts were added, but it has not reached the levels of endovascular procedures yet (Figure 2).

Table 1: Device information available by type of AAA repair between January 2020 and July 2022

Repair type	Elective	Non-elective	Total	% with device information
Open	1,042	387	1,429	37%
Infra-renal EVAR	1,924	500	2,424	58%
Complex EVAR	849	268	1,117	59%
Revision open	18	22	40	22%
Revision EVAR	259	114	373	63%
Total	4,092	1,291	5,383	50%

Figure 2. Percentage of AAA procedures with device information by quarter of the year and type of procedure



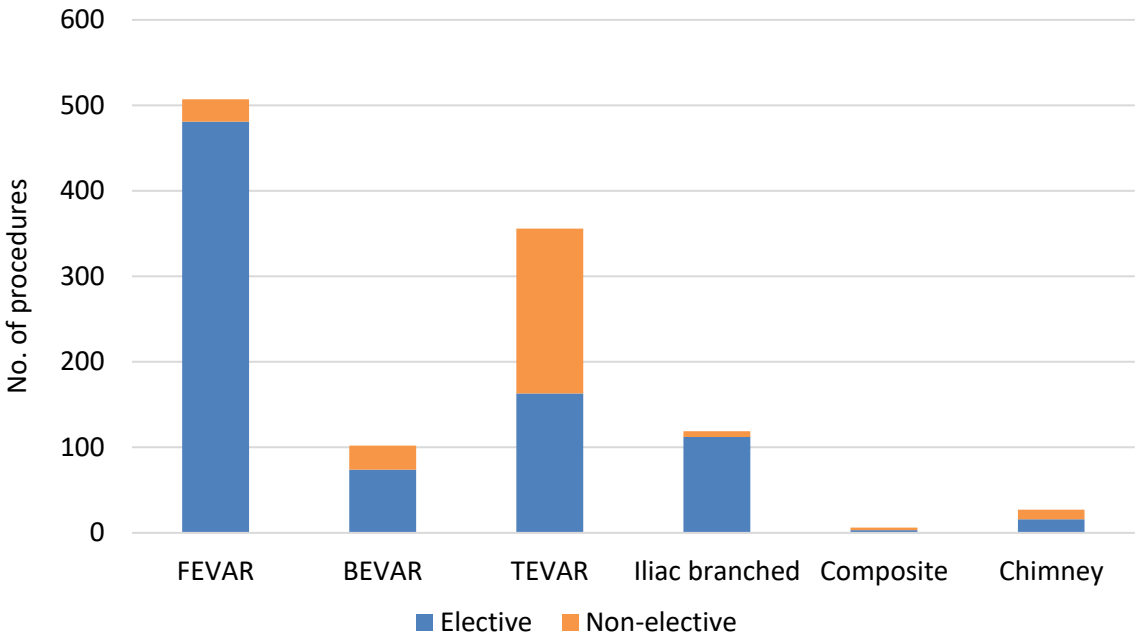
Open procedures

The majority of open repairs with device information recorded in the NVR were elective admissions (73%) and involved an infra-renal clamp (n=1,173, 82%). Most grafts were tube grafts (n=889, 63%), compared to bifurcated (n=529, 37%).

Endovascular procedures

There were 3,541 primary endovascular aneurysm repairs where a device was recorded on the NVR. As expected, the vast majority of procedures were standard infra-renal EVARs (Table 1). The most common complex endovascular procedures involved a fenestrated or thoracic device (Figure 3).

Figure 3: Complex endovascular procedures with device information between January 2020 and July 2022, by admission mode



For endovascular aneurysm repairs, information about the angulation, length and diameter of the aneurysm was collected because the type of stents that might be suitable for a procedure is based on this anatomical information and the manufacturer's instructions for use (IFU). Among the records for infrarenal AAA repairs that had device information:

- 90% of patients had an aneurysm with a neck angulation of 60 degrees or less
- 56% of patients had an endovascular device with a neck length of more than 20mm, 34% had a neck length of 15-20mm, 8% had a neck length of 10-14mm and 2% of less than 10mm
- 74% of patients had a neck diameter between 18 and 25mm, 21% had a neck diameter of more than 25mm, 3% had a neck diameter of more than 30mm and 2% had a neck diameter of less than 18mm.

Revision procedures

Device information has been submitted with 373 revision EVAR and 40 revision open procedures performed between January 2020 and July 2022. The reasons for re-intervention entered in these revision EVAR and open procedure records are described in Figure 4; the type of intervention is shown in Figure 5. For over half of these patients, the revision procedure was due to their aneurysm sac expanding. The most common interventions during revision EVAR procedures were distal extension and relining of the stent grafts.

Figure 4: Number of revision EVAR and revision open procedures between January 2020 and July 2022 by indication

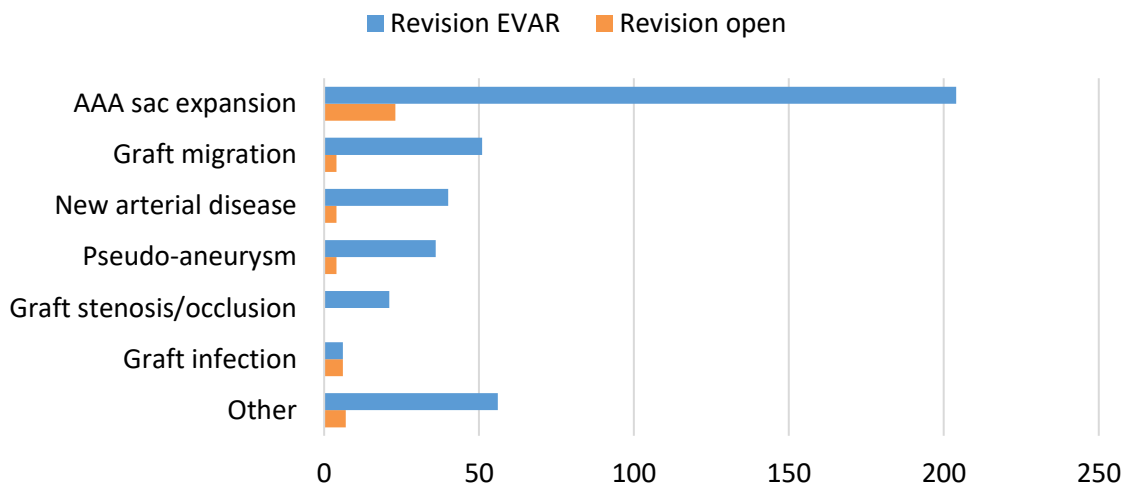
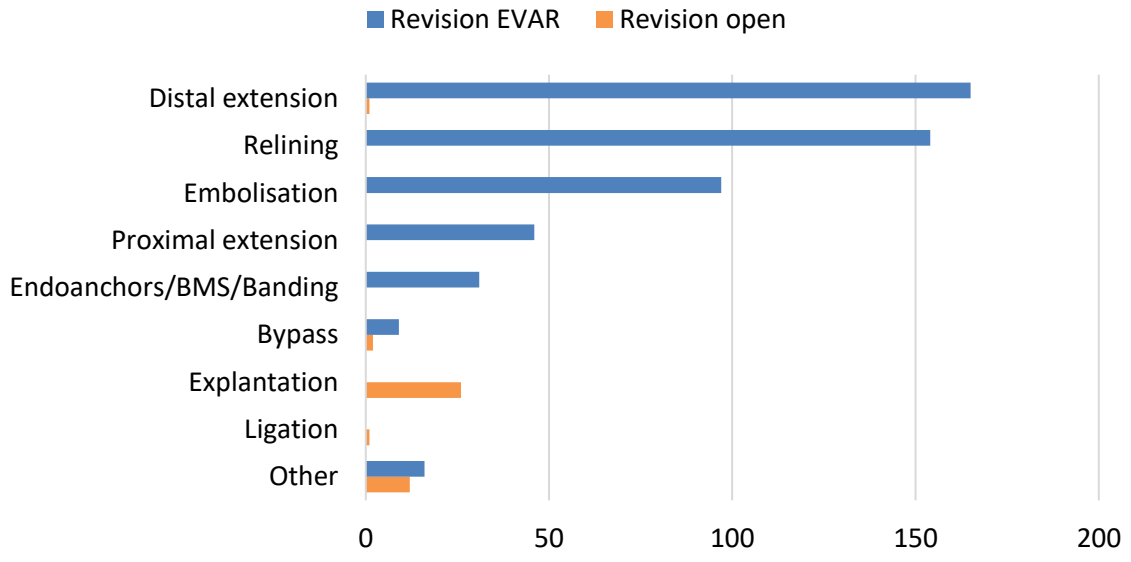


Figure 5: Number of revision EVAR and revision open procedures between January 2020 and July 2022 by type of intervention

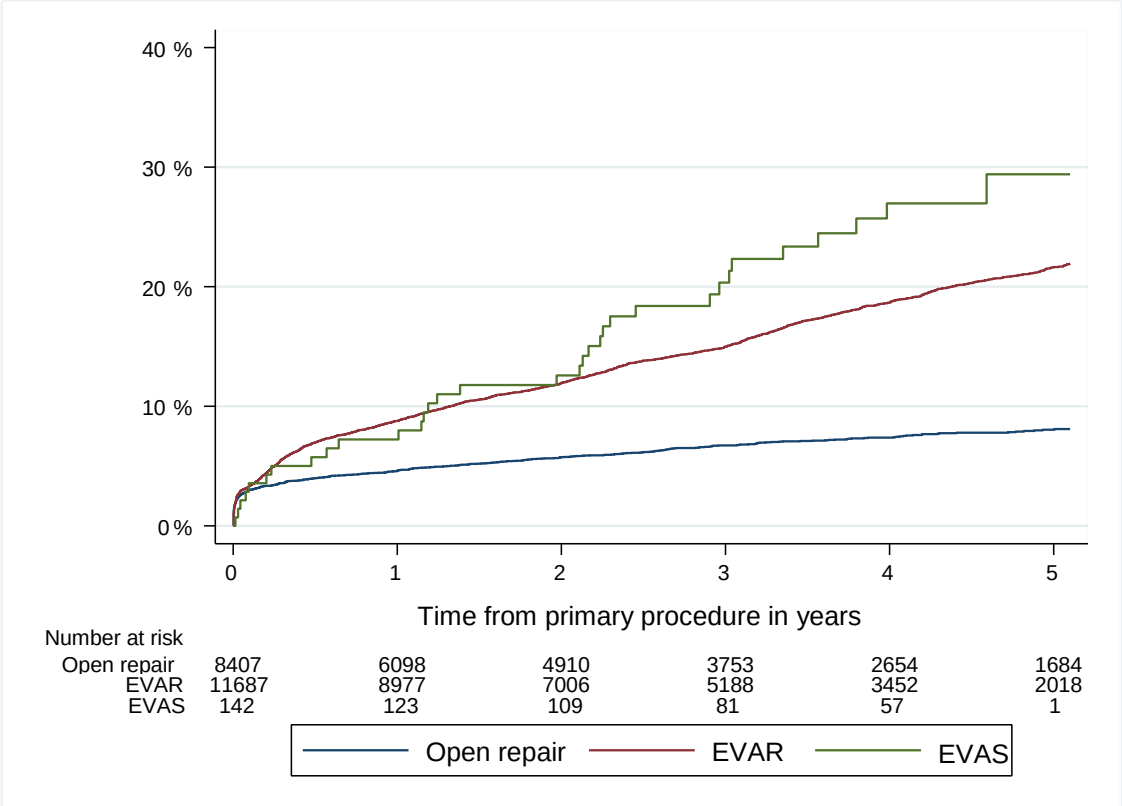


The above analysis was extended by examining primary AAA repairs that were captured in the NVR from January 2014 to December 2020. Subsequent revision procedures and mortality data were obtained from a linked English Hospital Episode Statistics (HES) database and the Office for National Statistics (ONS) Death registry. Follow-up data were available for 23,387 primary AAA repairs (8,407 open repairs, 11,687 infra-renal EVAR, 3,151 complex EVAR and 142 EVAS). Table 2 shows the revision rate at 1-, 3-, and 5-year follow-up by type of primary repair, and Figure 6 depicts the failure rate for open repairs, EVAR and EVAS procedures. Complex EVAR procedures were excluded as it was not possible to differentiate unplanned revision procedures from 2-stage interventions. Figure 6 should be interpreted with caution because it only includes linked aortic procedures and it is possible that some re-interventions were not captured in HES due to coding issues. It is anticipated that it will be possible to estimate revision rates for each device as more data is collected within the NVR and this may help identify failing devices early.

Table 2. Revision rate at 1-, 3- and 5-year follow-up by primary AAA repair type from January 2014 to December 2020

	Total	1-year	3-years	5-years
Open repair	8,407	4.6%	6.7%	8.0%%
EVAR	11,687	8.8%	15.0%	21.6%

Figure 6. Kaplan-Meier curve indicating time to re-intervention by type of initial AAA repair



Device components

The 5,383 procedure records analysed in this report contained 14,820 devices. The 1,470 primary and revision open surgical procedures involved 1,549 grafts, with the majority having only one per open procedure. In contrast, most endovascular aortic procedures required the use of more than one device component. The devices used in the endovascular repairs are summarised in Table 3, grouped according to the device classification developed by the NVR and manufacturers (see glossary for an explanation of the different components).

Limb devices, which include iliac extensions, were the most frequently used component, followed by main body devices. Peripheral stents were commonly used in complex EVARs for splanchnic vessels. Aortic extension devices included cuffs and abdominal tubes. Endo-anchors were used in 37 primary infra-renal EVARs, 11 complex EVARs and 21 revision EVARs, occasionally combined with cuff and limb devices in revision procedures. Other less frequently used devices were coils, converters and occlusion devices (Table 3). There was also a small number of biologic patches and 6-8mm diameter polyester grafts used in endovascular procedures, which likely represent femoro-femoral bypasses and other lower limb procedures, performed in addition to the aneurysm repair.

Table 3. Type of devices entered in NVR between January 2020 and July 2022 by type of endovascular repair

	Type of endovascular repair								
Component	**EVAR**	**FEVAR**	**BEVAR**	**TEVAR**	**Iliac branched**	**Chimney**	**Composite**	**Revision EVAR**	**Total**
Main body	2,349	772	172	586	107	26	8	81	4,101
Limb	4,773	767	149	13	410	47	9	432	6,600
Peripheral stent	52	1,140	424	68	55	12	11	106	1,868
Coil	132	37	12	<10	28	0	<10	110	326
Aortic Extension	89	16	13	12	<10	<10	0	77	218
Endoanchor	53	<8	<8	8	<8	<8	0	25	97
Open graft/ patch	24	<6	<6	<6	0	0	0	6	44
Converter	<6	<5	0	0	0	0	0	<5	<10
Occluder	<6	0	0	0	0	0	0	<5	<10

The NVR IT system also asks users to report whether each device component was used as per the manufacturer's instructions for use (IFU). The responses received for the entered devices are shown in Table 4. Deviation from the manufacturer's instructions for use was most common among complex AAA repairs, particularly in relation to the use of peripheral stents.

Table 4. Percentage of devices that followed instructions for use (IFU) between January 2020 and July 2022 by type of endovascular repair and admission mode

Component	IFU followed (%)							
	EVAR		Complex EVAR		Revision EVAR		Total	
	Elective	Non-elective	Elective	Non-elective	Elective	Non-elective	Elective	Non-elective
Main body	96.5	95.9	97.0	94.7	93.2	96.9	96.6	95.4
Limb	97.9	98.2	96.9	91.3	98.8	95.1	97.7	97.2
Peripheral stent	90.5	100.0	76.4	52.8	94.5	100.0	77.7	58.4
Coil	96.9	100.0	100.0	100.0	100.0	100.0	98.8	100.0
Extension	98.5	100.0	96.7	100.0	96.2	95.7	97.3	98.2
Endoanchor	89.8	n/a	100.0	83.3	100.0	n/a	93.9	85.7
Open graft/patch	100.0	100.0	100.0	100.0	80.0	n/a	96.7	100.0
Converter	n/a	n/a	n/a	-	n/a	n/a	100.0	n/a
Occluder	n/a	n/a	-	-	n/a	n/a	n/a	100.0

Note: IFU information was missing for 558 components.

The percentage is not shown (n/a) if there were fewer than 5 devices in each category.

CONCLUSION

This report summarises the information collected in the NVR for devices implanted during open and endovascular primary and revision AAA repairs between January 2020 and July 2022. A recent systematic review of Randomised Controlled Trials supporting the use of implantable devices for vascular procedures concluded that there is a need for a more robust implantable device regulation and approval systems [Wardle et al. 2022]. It is anticipated that as the available data on implanted devices in NHS patients increases, it will be possible to extend this work on re-interventions and device safety. Our clinical colleagues are encouraged to continue entering aortic device data and revision aortic procedures into the NVR.

We are very grateful to the surgeons and interventional radiologists, postgraduate doctors and data support colleagues for their hard work in submitting device and revision aortic data to the NVR. In time, these data will mature and become an invaluable source of information for patients, clinicians, commissioners, industry partners and device manufacturers with the ultimate aim of driving patient safety and quality improvement.

REFERENCES

Boyle JR. Is In Hospital Mortality Following EVAR Still a Valid Outcome Measure? Eur J Vasc Endovasc Surg. 2019; 57(4):520.

Cumberlege "First do no harm" The report of the Independent Medicines and Medical Devices Safety Review July 2020. https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

Goodney P, Mao J, Columbo J, Suckow B, Schermerhorn M, Malas M, et al. Use of linked registry claims data for long term surveillance of devices after endovascular abdominal aortic aneurysm repair: observational surveillance study. BMJ. 2022; 379: e071452

Healthcare Quality Improvement Partnership (HQIP). Proposal for a medical devices registry: HQIP 2020. https://www.hqip.org.uk/wp-content/uploads/2020/03/Final-HQIP-Proposal-for-a-medical-devices-registry-SHORT-report.pdf

Patel R, Sweeting MJ, Powell JT, Greenhalgh RM; EVAR trial investigators. Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial. Lancet. 2016; 388(10058): 2366-2374.

Singh AA, Boyle JR. Readmission and Re-intervention are Better Measures of EVAR Quality. Eur J Vasc Endovasc Surg. 2020; 60(4): 518.

Wardle BG, Botes A, Ambler GK, Rudd S, Qureshi M, Bosanquet DC, et al. Editor's Choice - Systematic Review and Narrative Synthesis of Randomised Controlled Trials Supporting Implantable Devices for Vascular and Endovascular Procedures. Eur J Vasc Endovasc Surg. 2022; 64(1): 57-64.

Waton S, Birmpili P, Johal A, Li Q, Cromwell D, O'Neill R, Williams R, Pherwani AD, Boyle JR. Developing and implementing implantable medical device capture for aortic aneurysm repair. London: The Royal College of Surgeons of England, 2021.

GLOSSARY

Abdominal Aortic Aneurysm (AAA)	This is an abnormal expansion of the aorta. If left untreated, it may enlarge and rupture causing fatal internal bleeding.
Association of British HealthTech Industries (ABHI)	The ABHI is the UK's leading industry association for health technology (HealthTech).
Branched EVAR (BEVAR)	A complex endovascular aortic repair in which separate grafts, attached to the main graft, are deployed on each blood vessel from the aorta.
British Society of Interventional Radiology (BSIR)	The BSIR is a charitable foundation founded to promote and develop the practice of Interventional Radiology.
Complex AAA	A term used to describe aortic aneurysms that are not located below the arteries that branch off to the kidneys. These are categorised into three types: juxta-renal (that occur near the kidney arteries), supra-renal (that occur above the renal arteries) and thoraco-abdominal (more extensive aneurysms involving the thoracic and abdominal aorta).
Chimney EVAR (chEVAR)	A complex endovascular aortic repair where covered stents are used in conjunction with an EVAR device to preserve the blood flow to arteries that branch off the aorta, mainly the renal arteries.
Coil	An endovascular device used to block blood flow into an artery or aneurysm.
Converter	A component placed in the aorta or in an existing main stent graft to direct blood to only one iliac artery, blocking the other.
Endoanchor	A small helical "screw" that fixes an endovascular graft to a patient's aorta in order to reduce the chance of it slipping.
Endovascular Aneurysm Repair (EVAR)	A method of repairing an abdominal aortic aneurysm by placing a graft within the aneurysm from a small cut in the groin.
Endovascular Aneurysm Sealing (EVAS)	A method for repairing an abdominal aortic aneurysm using a device with two stents, each surrounded by a polymer-filled endobag.
Extension	A component used in combination with an EVAR main stent graft to extend it proximally and cover a longer part of the aorta.
Fenestrated EVAR (FEVAR)	A complex endovascular aortic repair that involves the use of a graft that has holes (fenestrations), where smaller peripheral stents are inserted to allow the passage of blood to arteries that branch off the aorta.

Iliac branched device	A device for endovascular repair that preserves the blood flow to the internal iliac arteries.
Instructions For Use (IFU)	Information provided by the manufacturer to inform the user of the device of its safe and proper use, of its intended performances and of any precautions to be taken.
Limb	A component of an endovascular device that is used in the iliac arteries.
Main body	A component of an endovascular device that is used in the aorta.
Infra-renal AAA	An abdominal aneurysm that is located below the point where the arteries branch off the aorta to the kidneys.
Open repair	A method of repairing an abdominal aortic aneurysm by surgically opening the abdomen, clamping the aorta above and below the aneurysm, repairing the aneurysmal section of the aorta and replacing it with a sown-in prosthetic graft.
Peripheral stent	A component used in an endovascular repair in conjunction with an EVAR device to preserve the blood flow to arteries that branch off the aorta, mainly the renal arteries.
Thoracic endovascular aortic aneurysm repair (TEVAR)	A complex endovascular aortic repair that involves the thoracic segment of the aorta higher up in the chest.
Vascular Society of Great Britain and Ireland (VSGBI)	The VSGBI is a registered charity founded to relieve sickness and to preserve, promote and protect the health of the public by advancing excellence and innovation in vascular health, through education, audit and research. The VSGBI represents and provides professional support for over 600 members and focuses on non-cardiac vascular disease.

This report was prepared by

Clinical Effectiveness Unit, The Royal College of Surgeons of England
Ms Panagiota Birmpili, NVR Clinical Research Fellow
Mr Sam Waton, NVR Project Manager
Dr Amundeep Johal, Senior Statistician
Ms Eleanor Atkins, NVR Clinical Research Fellow
Dr Qiuju Li, Research Fellow in Medical Statistics
Prof David Cromwell, CEU Director

Vascular Society of Great Britain and Ireland (VSGBI)
Mr Jon Boyle, Consultant Vascular Surgeon
Mr Arun Pherwani, Consultant Vascular Surgeon

British Society of Interventional Radiology (BSIR)
Dr Robin Williams, Consultant Interventional Radiologist

The Royal College of Surgeons of England is an independent professional body committed to enabling surgeons to achieve and maintain the highest standards of surgical practice and patient care. As part of this, it supports Audit and the evaluation of clinical effectiveness for surgery. Registered charity no: 212808

The Vascular Society of Great Britain and Ireland is the specialist society that represents vascular surgeons. It is one of the key partners leading the audit. Registered charity no: 1102769

The British Society of Interventional Radiology is the specialist society that represents interventional radiologists. It is one of the key partners leading the audit. Registered charity no: 1084852

Commissioned by

The National Vascular Registry is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Its aim is to promote quality improvement in patient outcomes, and in particular, to increase the impact that clinical audit, outcome review programmes and registries have on healthcare quality in England and Wales. HQIP holds the contract to commission, manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP), comprising around 40 projects covering care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual projects, other devolved administrations and crown dependencies. www.hqip.org.uk/national-programmes.
Registered charity no: 1127049