

ROULEAUX CLUB ANNUAL ESSAY COMPETITION

## Rouleaux Club Winning Essays 2023

The Rouleaux Club run an annual essay competition to help promote interest in vascular surgery. Entrants are asked to write 1,500 words on one of three topics selected by the RC Executive. The essays are marked by the committee and the prizes are awarded to the best essay at the annual Vascular Society meeting. There are two prize categories, one for medical students and another for junior doctors. Following the November VS ASM, we are delighted to publish the winning essays.

### STUDENT CATEGORY

#### Is surgical bypass underutilised for patients requiring lower limb revascularisation?

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#### Introduction

For decades, surgical bypass provided the mainstay of treatment for the most advanced presentation of peripheral arterial disease (PAD), now referred to as chronic limb-threatening ischaemia (CLTI).<sup>1-3</sup> However, the introduction and technical advancements of less-invasive endovascular approaches has led to an undeniable global decline over the past 10-20 years, as demonstrated in Figure 1.<sup>4-7</sup>

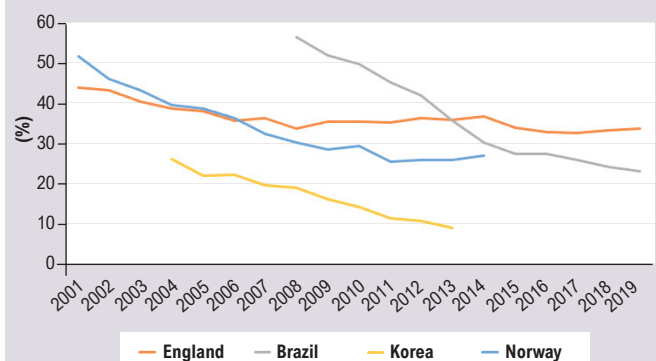
Due to a widely acknowledged paucity of high-quality evidence, guidelines remain inconsistent and unclear with their recommendations. Given that CLTI affects 11% of the estimated 230 million living with PAD,<sup>8-10</sup> and the constant strive to minimise procedural and disease-related complications, it is important to question whether the above decline is justified. Following critical evaluation of the evidence and current guidelines, it will be argued that the decline in rates of surgical bypass is justified by the growing body of evidence to suggest endovascular revascularisation as an adequate, less-invasive and lower-cost alternative.

#### Reviewing the evidence

Only three large-scale randomised-control trials (RCTs) comparing patient outcomes following endovascular and surgical revascularisation for CLTI have been published, and provide a seemingly conflicting range of results. It is important that results are not taken solely at face-value, and are instead interpreted in context through critical appraisal.

The demand for an RCT comparing the two techniques was first met by the BASIL-1 trial in 2005.<sup>11</sup> 452 patients with severe limb ischaemia (synonymous with CLTI) due to infra-inguinal disease were randomised to receive a surgery-first or angioplasty-first approach. At 2 years, there was no significant difference in amputation-free survival (the primary outcome). However, it is important to question the relevance of these results to modern clinical practice, given that endovascular techniques have

**Figure 1** The global decline in proportion of surgical bypass revascularisation procedures. Depicted is a graphical representation of the decline in the proportion of revascularisation procedures represented by surgical bypass for peripheral arterial disease in four different countries using data from four large-scale epidemiological studies.<sup>4-7</sup>



advanced rapidly since the completion of this trial. There is growing evidence to support a plethora of novel techniques, including stenting, drug-eluting technology and atherectomy.<sup>12,13</sup> The endovascular-first strategy was limited mostly to angioplasty alone, with stent-usage largely excluded. Thus, it no longer represents the ideal endovascular strategy for patients with CLTI. Given the rapid technical advancements of endovascular procedures, it is not unsurprising that technical failure rates have substantially decreased since this trial.<sup>14-16</sup> Furthermore, the trial was not specific regarding anatomical complexity, making it difficult to apply the results to a clinical environment in which decisions are frequently made with this in mind. Finally, in the surgical group, both autologous and prosthetic grafts were employed, with the latter now considered inferior.<sup>17</sup> Therefore, an ideal surgical strategy is also not represented.

**Table 1** Summary of the three RCTs comparing surgical and endovascular revascularisation for CLTI or its equivalents.

Trial	Year	Randomised	Main findings	Limitations
BASIL-1 <sup>11</sup>	2005	452	<ul style="list-style-type: none"> <li>No significant difference in amputation-free survival between surgical and endovascular groups</li> </ul>	<ul style="list-style-type: none"> <li>High rate of technical failure in the endovascular group</li> <li>Outdated endovascular techniques</li> </ul>
BEST-CLI <sup>18</sup>	2019	C1 - 1434 C2 - 396	<ul style="list-style-type: none"> <li>C1 - For those with an adequate autologous vein, surgical bypass associated with significantly reduced incidence of MALE or death</li> <li>C2 - For those without an adequate autologous vein, rates of MALE or death were comparable between groups</li> </ul>	<ul style="list-style-type: none"> <li>High rate of technical failure in the endovascular group relative to contemporary data</li> </ul>
BASIL-2 <sup>21</sup>	2023	345	<ul style="list-style-type: none"> <li>Significantly improved amputation-free survival with endovascular-first strategy compared to bypass-first strategy for those requiring infra-popliteal revascularisation</li> </ul>	<ul style="list-style-type: none"> <li>Availability of adequate autologous vein not accounted for</li> <li>Heterogeneity in bypass graft-type</li> </ul>

The long-awaited BEST-CLI trial<sup>18</sup> sought to address these limitations by investigating a greater number of patients, with emphasis on availability of autologous vein graft. Two parallel cohorts were investigated. Cohort 1 (n=1,434) included patients with CLTI and an identified adequate great saphenous vein, while cohort 2 (n=396) included those without. Patients in each were randomised to undergo either surgical or endovascular revascularisation. The primary outcome was a composite of major adverse limb events (MALE) or death, which occurred significantly less in the surgical group in cohort 1. In contrast, the incidence of the primary outcome in cohort 2 was comparable between the two groups. While these findings seem to suggest a bypass-first approach be optimal for those with an adequate great-saphenous vein, it has not been without criticism.<sup>19,20</sup> Despite taking place roughly 15 years after the BASIL trial, the technical failure of endovascular therapy in cohort 1 was 15%, a figure similar to that of the BASIL trial, and higher than reported in contemporary data.<sup>15-17</sup> The primary composite outcome was mainly driven by reintervention rates, with no significant difference between the two groups in cohort 1 with regards to death or above-ankle amputation. Given the high percentage of technical failure in the endovascular group, it is unsurprising that 42.5% of first reinterventions in this group occurred within the first 30 days. Furthermore, there was a large degree of heterogeneity in endovascular procedure techniques. It appears the single best surgical-first intervention has not been compared to the single best endovascular-first treatment available at the time; results should be interpreted with this in mind. Furthermore, data regarding the anatomical complexity of disease is yet to be published, again making application to real-world clinical scenarios challenging.

The results of the BEST-CLI trial are seemingly contradicted by the findings of the BASIL-2 trial<sup>21</sup> published in 2023. This was the first to find improved outcomes with endovascular intervention compared to bypass in the context of CLTI. BASIL-2 specifically investigated those requiring infra-popliteal revascularisation, which made up 55% of revascularisation procedures included in the BEST-CLI trial. All 345 patients were randomised to receive either endovascular-first or vein-bypass-first treatment, with the primary outcome (amputation-free survival) significantly higher in the

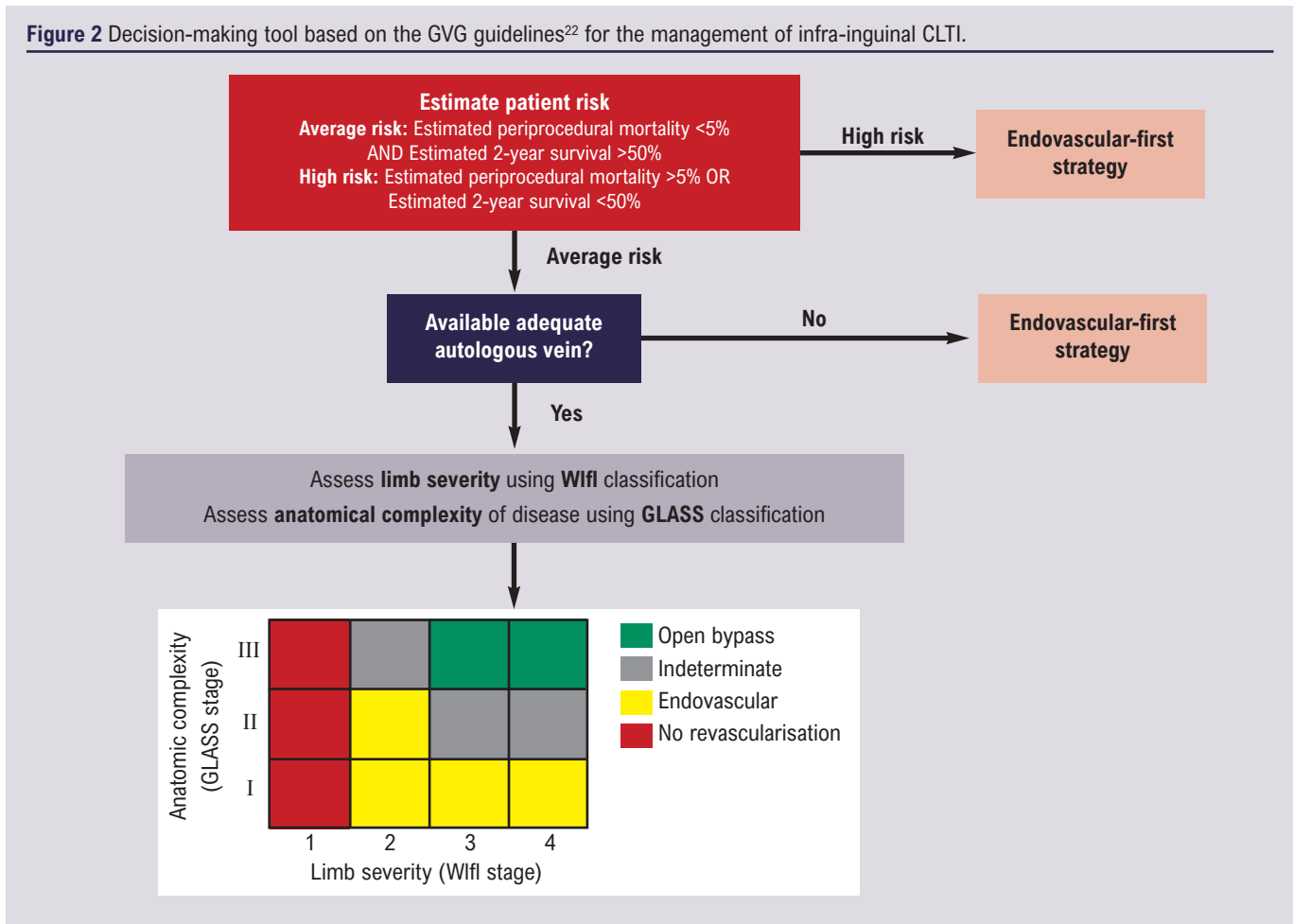
endovascular group. Despite the surgical group being described as “vein-bypass-first”, availability of an adequate great saphenous vein was not part of the eligibility criteria. Vein usage was up to the discretion of the surgeon, with the use of prosthetic grafts permitted, a contradiction to the description of the group and the trial name. Nevertheless, the BASIL-2 trial further demonstrates that endovascular revascularisation can be a suitable, less-invasive alternative to surgical bypass.

Table 1 summarises the findings and limitations of the RCTs published comparing endovascular revascularisation and surgical bypass for those with CLTI. These trials appear to seek a black and white answer to a question which deserves a multi-faceted approach. By doing so, there is a constant lack of appreciation for the important details. Anatomical complexity is often disregarded or an afterthought, and there is consistent neglect for either the “ideal” endovascular strategy or “ideal” bypass graft in all trials. This makes application to real-world scenarios challenging. However, when limitations are accounted for there appears to be a case for endovascular revascularisation as an adequate alternative to surgical bypass, particularly with rapidly improving endovascular techniques and falling associated technical failure. Given that endovascular revascularisation can offer comparable outcomes to bypass in patients with a range of disease-complexity, it is important to critically review current guidelines to ascertain whether they provide a robust foundation for clinical decision making. This evaluation will determine whether circumstance-specific decisions represent a justified growing preference for endovascular revascularisation.

### What are the current guidelines?

Current guidelines are relatively vague, owing to the established limited body of evidence. The most detailed and circumstance-specific guidelines for CLTI decision-making were created in 2019, known as the Global Vascular Guidelines (GVG).<sup>22</sup> It is firstly recommended that any inflow disease, defined as proximal to the origin of the profunda femoris be treated prior to outflow disease. The guidelines then provide a systematic approach, termed Evidence-Based Revascularisation, to decide between an endovascular-first or bypass-first strategy for remaining patients.

**Figure 2** Decision-making tool based on the GVG guidelines<sup>22</sup> for the management of infra-inguinal CLTI.



This is demonstrated by the decision-making tool shown in Figure 2. This approach is more specific than previous guidelines, and results in a vastly smaller proportion of patients deemed as best suited for a bypass-first approach.<sup>23-25</sup>

While these circumstance-specific guidelines are the most current, they were published prior to publication of the BEST-CLI and BASIL-2 trials. They were fuelled by a variety of prospective and retrospective studies, rather than any of the large RCTs, hence the low level of evidence (level C). Furthermore, the paucity of evidence to guide the Wifl and GLASS based recommendations leave the approach somewhat flawed. Firstly, there exists a large indeterminate range in which no optimal revascularisation approach is recommended, as shown in Figure 2. Additionally, the GLASS staging system is new, and various flaws in its usage have been identified. This includes low inter-observer agreement among clinicians, as well as an inability to predict patency rates following endovascular revascularisation in those with lower stages.<sup>26,27</sup> These flaws merit a holistic approach to decision making, considering a range of different factors, rather than relying entirely on guidelines. This includes patient preferences which will tend to favour the less-invasive endovascular option, costs which again

tend to favour endovascular therapy (although long-term cost-effectiveness is still unclear), and the clinician’s experience.<sup>28-30</sup>

**Conclusion – Is the decline justified?**

There is a growing high-quality body of evidence to justify endovascular revascularisation as an alternative to bypass in a range of patients with varying disease-patterns and severities of CLTI. The low class of evidence underpinning the current guidelines warrants the adoption of a decision-making approach informed by a range of important different factors, particularly in the indeterminate group. Costs and patient preference will play a large role in these decisions, and both will likely favour endovascular therapy over bypass. Therefore, despite the global decline in use of surgical bypass, it is not yet an under-utilised entity in the management of CLTI.

Nevertheless, surgical bypass will remain a crucial management option, particularly following failed endovascular therapy and in those with well-established anatomically complex disease. Thus, in contrast to current attitudes, surgical bypass and endovascular revascularisation should be viewed as complementary techniques with the combined aim of preserving patient function and quality of life, rather than continue to be pitted

against one another. Such an outlook, paired with an improved regard for disease and procedural specificity in future trials, will ensure neither option goes under-utilised in the future.

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**DOCTOR CATEGORY**

**Discuss the role of Artificial Intelligence (AI) in improving current management of Abdominal Aortic Aneurysms (AAA)**

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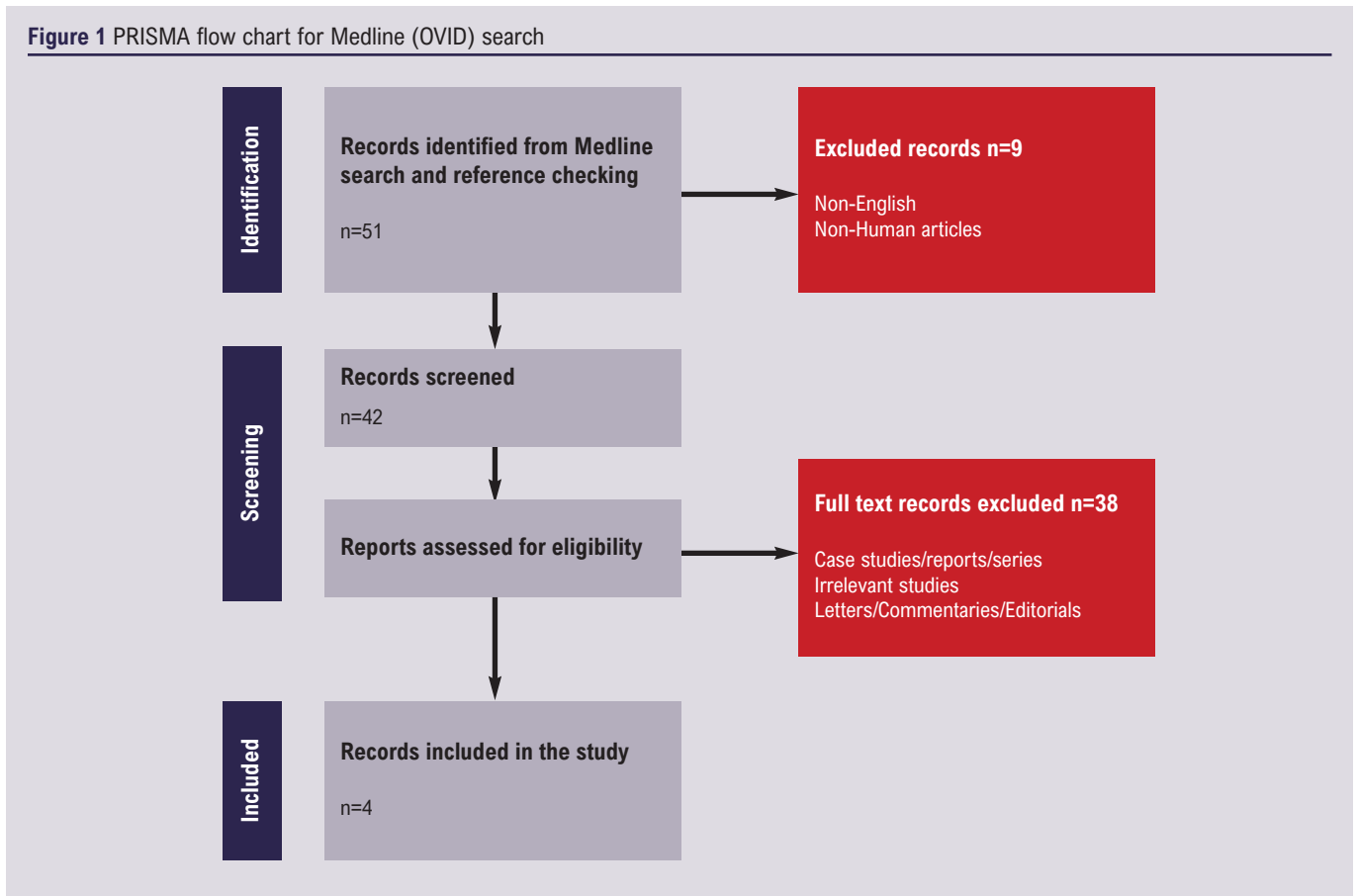
**Introduction**

Abdominal aortic aneurysmal disease encompasses a diverse spectrum of pathologies and clinical presentations ranging from incidental findings on imaging to a patient presenting in extremis following rupture. The management of this diverse patient cohort depends largely on clinical presentation and patient characteristics. Artificial intelligence (AI) has permeated modern medicine at an unprecedented rate. In the healthcare landscape, the primary utility of AI lies in clinically tailored neural networks and machine learning. In the field of Vascular Surgery, several AI technologies have been, or are currently being developed in relation to pre-operative planning, improving intra-operative efficiency and assessing post-operative outcomes for patients with abdominal aortic aneurysms (AAA). Despite the exponential development of these technologies, they are not without their limitations, and the current National Health Service is far from implementing them into routine clinical practice.

**Literature review**

Electronic searches were performed on both Medline (1946 to August 2023) and Embase (1974 to August 2023) using the OVID interface as well as Medline using the PubMed interface. The search terms were as follows: (artificial intelligence OR AI OR machine learning OR neural network\*) AND (abdominal aortic aneurysm\* OR AAA) AND (management OR treatment). These keywords were searched in the subject headings, in title and in abstract. All reference lists of the included papers were also screened to identify any pertinent studies. The results were current as of August 2023.

732 papers were found using the reported search on Embase (61) and Medline (51) using the Ovid interface whilst 620 were found on Medline using the PubMed interface. Case reports, case studies, editorials, duplicates, and literature reviews were excluded. An example of the screening and eligibility assessment process for the search results obtained from the Medline (Ovid) interface is outlined in the PRISMA diagram below (Figure 1).



**Prediction models, image segmentation and automation**

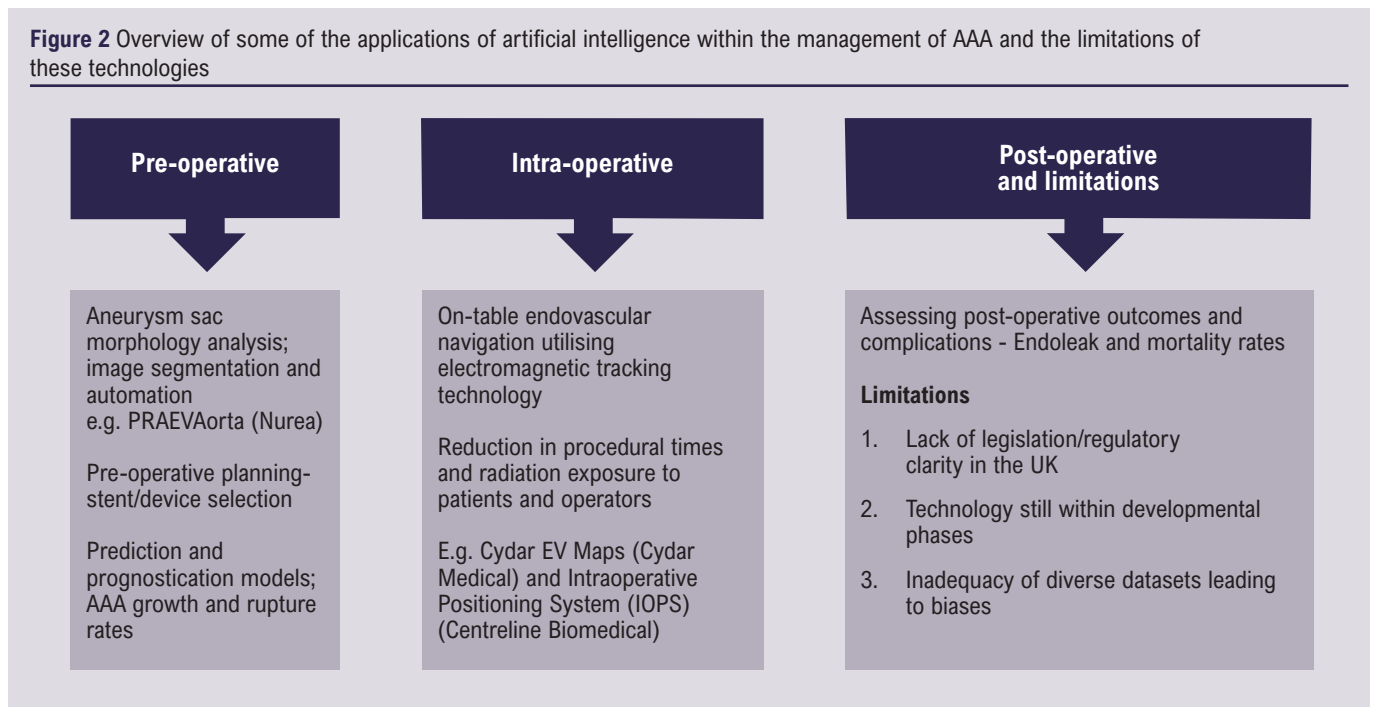
In the United Kingdom, guidelines from the Society for Vascular Surgery and the European Society for Vascular Surgery<sup>1,2</sup> have clear recommendations for the diagnosis and management of patients with AAA. Decisions regarding treatment rely on careful evaluation of the risks associated with operative intervention compared to the risk of aneurysmal growth and rupture. Although initial aneurysmal diameter is a well-established, independent risk factor for rupture, other patient and aneurysm specific factors have been implicated.<sup>3</sup> In practice, estimating sac progression and predicting the risk of rupture can be difficult for clinicians, consequently, AI prediction and prognostication models have been developed to assist vascular surgeons with this undertaking. The maximal aortic diameter is often used in this decision-making process, however, a major downfall of utilising this single measurement, lies in its inability to provide details of the three dimensional (3D) volumetric evaluation of the aneurysm sac. To acquire such characteristics, manual image analysis would need to be undertaken, a laborious and specialist endeavour. Furthermore, in even the most experienced hands, significant discrepancies have been identified, with one study reporting up to 87% of diameter measurements falling outside of the clinically acceptable error range ( $\pm 5$  mm) in abdominal aortic aneurysms (AAAs).<sup>4</sup> Specific deep learning workstations have been designed to perform analysis of images generated from CT-Aortograms, allowing for more accurate three-dimensional (3D) evaluation of the complete aortic anatomy. The advantages of acquiring volumetric data for these aneurysms cannot be understated and one can appreciate how this type of analysis can improve the sensitivity of estimating disease

progression compared to maximum diameter measurements taken in isolation. AI programs have been designed to perform large scale quantitative analysis of AAAs with improved image segmentation by characterising aneurysmal morphology, geometry, and fluid dynamics.<sup>5</sup> This data is then fed into computational AI models with predictive and prognostic capabilities, allowing for recognition of patterns which in turn, can be used to estimate the rates of AAA growth and risk of rupture. PRAEVAorta (Nurea) is a 'decision support AI software' designed by a French company with prediction abilities to describe the evolution of AAA based on geometric and flow characteristics.<sup>6</sup> The same company is currently in the research phase of developing technology which allows for automated analysis of AAA sac measurements pre and post-EVAR.

**Pre-operative planning and intra-operative uses**

Move over SHO, AI is scrubbing in. Artificial intelligence has found its way into the operating theatre with complex machine learning models assisting with preoperative surgical and endovascular planning as well as on-table image guidance.<sup>7</sup> These algorithms have been developed to optimise stent or device selection, endovascular navigation, and stent placement. Cydar Medical, in conjunction with researchers at Kings College London, are utilising a similar type of vascular navigation technology (Cydar EV Maps) in the ARIA trial - ARTificially Intelligent image fusion system in comparison to standard treatment to guide endovascular Aortic aneurysm repair.<sup>8,9</sup> The trial is currently in the recruitment phase. In a similar vein, AI protocols utilising electromagnetic tracking technology have been developed with the aim of improving surgical efficiency by reducing procedural time and decreasing patient and

**Figure 2** Overview of some of the applications of artificial intelligence within the management of AAA and the limitations of these technologies



operator radiation exposure. The Intraoperative Positioning System (IOPS) (Centerline Biomedical) is a 3D image guidance system which employs structural mapping and electromagnetic tracking technology embedded into operating kit (catheters, guidewires) to reduce on-table radiation exposure.<sup>7</sup> Risk assessment and prognostication programs, like those detailed for image segmentation above, were also developed to assess postoperative outcomes, including mortality and potential complications after endovascular repair.<sup>10,11</sup>

### Challenges, limitations, and bias

Most artificial intelligence algorithms require high-quality and diverse databases to ensure accuracy and robustness when translated to real-life settings.<sup>12</sup> One major issue ubiquitous within the fields of AI and machine learning, is the acquisition of such high-quality datasets allowing for training and evaluating ML algorithms. Furthermore, there is often a lack of standardisation when curating the imaging databases used in AI associated vascular surgery algorithms, making it difficult to compare and interpret results across different studies.<sup>13</sup> Another major barrier impeding the uptake of AI in healthcare is the lack of clarity regarding legislation, data security and regulation. In the United States for instance, the Food and Drug Administration (FDA) is responsible for approving and regulating AI and ML tools, however in the UK, explicit regulatory frameworks and legislation do not yet exist. Instead, AI's use within healthcare is currently regulated under fragments of pre-existing general legislation, such as the UK Medical Device Regulations 2002 or the Data Protection Act 2018.<sup>14</sup> This ambiguity can complicate and impede the scientific process and may even lead to frivolous litigation, for example, the class-action lawsuit levied at Google's DeepMind AI, following the patient data scandal at the Royal Free in 2016.<sup>15</sup>

Interestingly, the concept of bias within AI and ML algorithms has become somewhat of an area of controversy. The potential sources for these biases include inherently biased software or program designs and incorrect or unbalanced training data being fed into the algorithms.<sup>16</sup> This is especially important when applying algorithms within vascular surgery, where the patient cohort is increasingly diverse and management and post-operative outcomes are dependent on patient variables such as sex and race.<sup>17</sup> One potential means of mitigating these biases would be the inclusion of large, diverse datasets and proactive algorithmic testing for biases within experimental stages of technological development.

### Conclusions

Artificial intelligence has made substantial advancements in the field of vascular surgery and has the potential to revolutionise the management of patients with abdominal aortic aneurysms by facilitating earlier detection, improving the accuracy of measurements, personalising treatment plans and optimising

operative proceedings. The applications of AI detailed within this piece are by no means exhaustive, and progress within this area is occurring at an unprecedented rate. Despite this, there are many challenges and limitations to the development, commercialisation, and uptake of AI within everyday clinical practice.

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