

# Safety and Validity of the Proposed European Society for Vascular Surgery Infraarenal Endovascular Aneurysm Repair Surveillance Protocol: A Single Centre Evaluation

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## WHAT THIS PAPER ADDS

Adopting the European Society for Vascular Surgery's 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms, whereby patients are risk stratified post-endovascular aneurysm repair (EVAR), depending on sac size reduction and presence of endoleak at their 30 day computed tomography angiogram, is both safe and effective at detecting patients who require intervention. Patients could therefore have a reduced follow up regimen, with the added benefit of associated cost savings, which would reduce the lifetime cost of EVAR.

**Objective:** Long term surveillance after endovascular aneurysm repair (EVAR) is essential to detect late complications, but there is variation in practice. The European Society for Vascular Surgery (ESVS) made a recommendation for a new surveillance protocol; one element involves risk stratifying patients depending on sac size reduction and presence of endoleak at their 30 day computed tomography angiogram into low risk groups (delayed imaging to five years) or higher risk groups (continue with the current protocol). The aim was to test this suggested protocol retrospectively within an EVAR patient cohort.

**Methods:** Data on EVARs performed from October 2009 to October 2019 were collected. Information gathered from an existing surveillance programme was used to assess the proposed ESVS protocol. All patients who underwent re-intervention were reviewed to see whether adopting the proposed ESVS protocol would have detected these events.

**Results:** In total, 309 procedures were included. Altogether, 219 of these patients had no endoleak (70.9%) and 86 had a type II (27.8%) endoleak. Only four developed a type I or III endoleak. No patient in the low risk cohort (no initial endoleak or sac shrinkage > 1 cm) required secondary intervention. Five year follow up data were available for 103 patients. In the type II endoleak group, there were 28 secondary interventions in 22 patients. No patient experienced a ruptured aneurysm within five years post-operatively. Had the proposed ESVS protocol been followed, all patients requiring a secondary intervention or with increasing sac size would have been detected/captured. Further, adherence to the ESVS guidelines would have resulted in 103 patients with a five year follow up history qualifying for reduced surveillance. A further 120 patients who had reached the three and four year follow up timepoints could have qualified for a reduced surveillance, reducing imaging cost further.

**Conclusion:** Adopting the proposed ESVS EVAR surveillance protocol safely identified "low risk" patients who did not go on to require a secondary intervention. These patients could benefit from reduced surveillance scanning.

**Keywords:** Abdominal aortic aneurysm, Endoleak, Endovascular procedure

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## INTRODUCTION

The incidence of abdominal aortic aneurysms (AAAs) in the UK is around 1.3%, with over 3 000 patients undergoing AAA repair every year.<sup>1,2</sup> Given its minimally invasive nature and reduced hospital and 30 day mortality vs. conventional open

repair,<sup>3</sup> endovascular aneurysm repair (EVAR) has become the preferred treatment modality for AAA, accounting for 63% of repairs in 2019 in the UK.<sup>1</sup> However, patients who undergo EVAR are more likely to experience post-procedure aortic/stent graft related complications requiring re-interventions than those undergoing open surgery, including endoleak,

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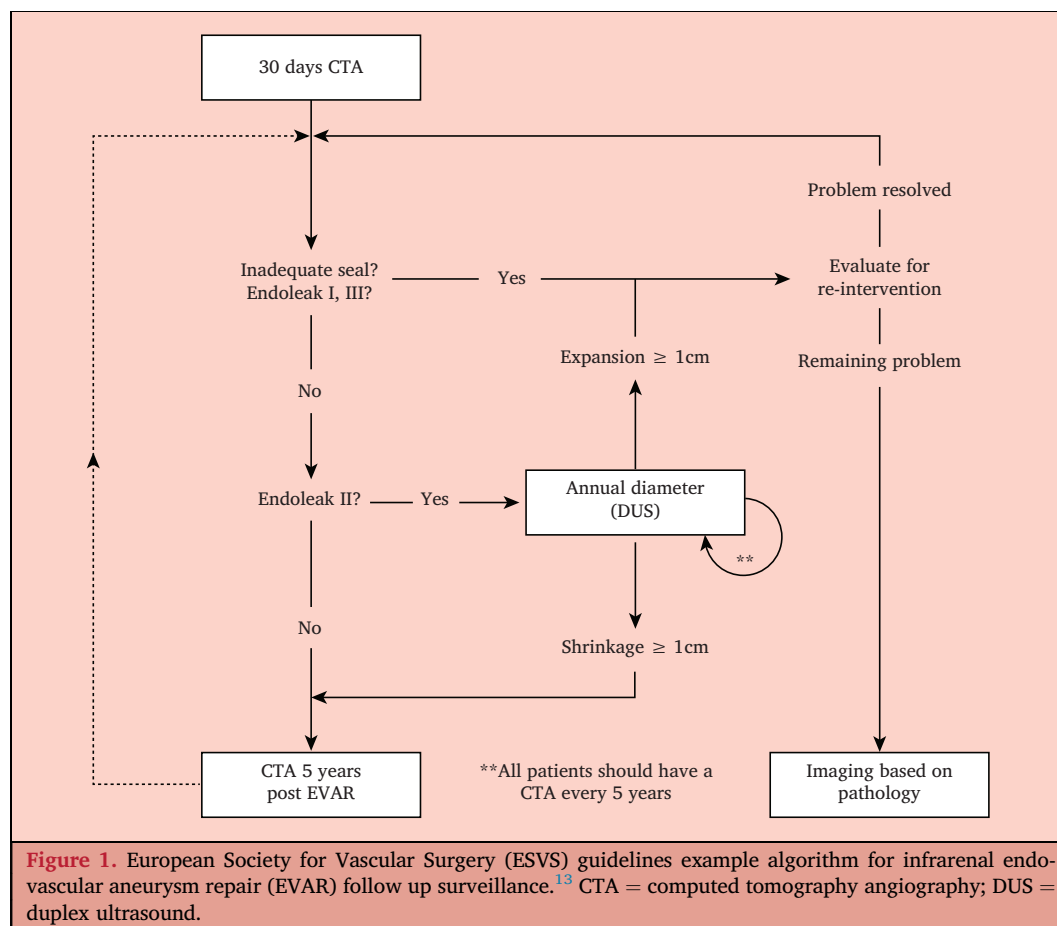
stent migration, aneurysm sac growth, and delayed sac rupture.<sup>4</sup> In order to help diagnose these complications early to prevent sac rupture and death after EVAR, regular imaging follow up has been regarded as mandatory.<sup>5,6</sup>

The presence of an endoleak can affect sac size over time due to the increasing pressure in the aneurysm sac.<sup>7,8</sup> Type II endoleaks arising from retrograde filling via aortic branch vessels are the most common, but they usually resolve within six months post-operatively.<sup>4,9,10</sup> However, some endoleaks persist. Historically, regular follow up imaging has been advocated to identify potential endoleaks and stent related complications early.<sup>5,11,12</sup> Current recommendations, which vary from centre to centre, mostly include regular follow up with computed tomography angiography (CTA) at 30 days, 12 months, and then annually (CTA or aortic duplex ultrasound (DUS)).<sup>4,11,12</sup> However, the true value of prophylactic regular follow up imaging after EVAR is uncertain, as in many cases it may not identify significant findings that require re-intervention.<sup>4,11,13</sup> Regular follow up imaging incurs a significant cost, which has implications for the lifetime cost of EVAR;<sup>14</sup> therefore, risk stratification to reduce unnecessary follow up imaging is desirable.

The European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms proposed a recommendation for a new EVAR surveillance protocol (Fig. 1).<sup>13</sup> Those without

endoleak on early imaging with adequate intra-operative seals and anatomy within the instructions for use (IFU) could be considered for limited follow up, with delayed imaging until five years after repair (i.e., the “low risk group”). Sac shrinkage during follow up indicates successful exclusion of the aneurysm from arterial pressure, and has been shown to be a predictor of low EVAR failure risk in the first five post-operative years.<sup>15,16</sup> The presence of a type II endoleak at early follow up can occasionally lead to re-intervention owing to the risk of sac expansion;<sup>16</sup> therefore, these patients need regular follow up to assess for sac expansion or sac shrinkage (i.e., the “intermediate risk group”). However, those with a type II endoleak who show sac shrinkage  $> 1$  cm can be regarded as low risk owing to the perceived successful exclusion of the aneurysm from arterial pressure and can therefore undergo limited follow up according to the low risk group.<sup>15–17</sup> If a type I or type III endoleak were to be identified at the initial scan, assessment and consideration for treatment for such patients would be appropriate (i.e., the “high risk group”). After five years, it is recommended that all patients receive repeat aortic imaging in line with current guidance owing to a risk of late rupture after EVAR.<sup>13</sup>

The aim of this study was to test retrospectively the proposed protocol within an EVAR patient cohort, to assess how the newly proposed surveillance programme would perform and whether or not it is feasible to adopt this approach.



## METHODS

This was a retrospective study of consecutive patients who underwent EVAR at a single vascular centre between October 2009 and October 2019. Patients with a minimum follow up of at least one year after EVAR were included. Patients lacking data or with incomplete post-operative imaging; those who had died before their 30 day CTA; and those that underwent solely iliac repair were excluded. Post-operative surveillance imaging both on CTA or DUS were reviewed for the presence of endoleak, sac size, and any further secondary interventions. The operators at this centre adhere to the IFUs of the stent grafts used; however, such data were not collected prospectively. The study was carried out in line with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.

Data from an existing surveillance programme were used to assess the proposed ESVS protocol. Current follow up protocols at the authors' institution involved a CTA at one month and at one year, and DUS at one year and then an annual DUS thereafter in those without complications. Patients in whom an endoleak or significant sac expansion were identified were discussed at the weekly multidisciplinary team meeting, where a decision was made as to the frequency and modality of further follow up on a case by case basis. The average per scan cost of a CTA is £338 and a DUS £88.<sup>18</sup>

For the purpose of this study, a combination of dual phase (arterial and portal venous) CTA and/or DUS performed at one month and 12 months as a part of routine follow up were reviewed for the presence of endoleak and assessment of sac size. Further imaging after 12 months was reviewed for any evidence of persistence of type II or other endoleak, persistent sac growth, and secondary intervention. Based on the initial 30 day CTA, patients were categorised into (1) low risk (no endoleak); (2) low risk (type II endoleak with > 1 cm sac shrinkage); (3) intermediate risk (type II endoleak with < 1 cm sac shrinkage or sac expansion); and (4) high risk (type I or III endoleak). All patients who underwent secondary intervention were identified and their surveillance data were reviewed to see whether or not adopting the proposed ESVS protocol would have detected the events. Any patients who developed features resulting in a change to their "risk" (e.g., a low risk patient who developed an endoleak or sac expansion therefore increasing their risk, or an intermediate risk patient who showed evidence of sac shrinkage > 1 cm therefore reducing their risk) were identified and analysed. Analysis was performed using GraphPad Prism version 8 (GraphPad Inc., La Jolla, CA, USA).

## RESULTS

A total of 336 patients underwent infrarenal EVAR within the study period. Of these, 27 were excluded owing to iliac only intervention ( $n = 14$ ); no imaging at 30 days ( $n = 8$ ); and death before 30 days ( $n = 5$ ; two related to EVAR and three not related to EVAR). In total, 309 patients were included for analysis with an overall median follow up of 36 months (range 12 – 120 months) (Table 1). A total of 137

patients had follow up to five years; demographics are shown in Table 2. Altogether, 219 of these patients had no endoleak (70.9%); 86 had a type II (27.8%) endoleak. Only four patients developed a type I or III endoleak.

### Low risk (no endoleak)

In total, 219 of 309 (70.9%) had no evidence of any type of endoleak at their 30 day CTA. The median length of follow up for these 219 patients was 36 months (range 12 – 120 months). There was a median sac size reduction of 1 mm (range 23 mm reduction – 9 mm increase) at 30 days. In total, 151 patients had three year follow up data available, with a median sac size reduction of 10 mm. Of these 151 patients, 103 had five year follow up data available, at which point there was a median sac size reduction of 12 mm. Twenty-two were found to have evidence of secondary type II endoleak formation at some point within five years post-operatively, which was always associated with sac size reduction, and only five of these cases showed ongoing type II endoleak at five years post-operatively. No patient required secondary intervention for any reason within five years.

### Low risk (type II endoleak with > 1 cm sac shrinkage)

Four of 86 patients with evidence of a type II endoleak at 30 days showed sac shrinkage > 1 cm at 30 days (median sac size reduction 16 mm [range 10 – 27 mm]) with a median follow up of 15 months (range 12 – 36 months). None of these four patients had any further sac expansion or required re-intervention. In two of these four patients, the endoleak resolved on subsequent imaging by one year.

### Intermediate risk (type II endoleak with < 1 cm sac shrinkage or sac expansion)

Eighty-two of 86 patients with a type II endoleak showed a sac shrinkage of < 1 cm or sac expansion (median sac size reduction 0 mm [range 6 mm reduction – 31 mm increase]). Median follow up was 30 months (range 12 – 120 months). Only 28 of 82 (34%) patients demonstrated sac expansion: 21 by one year and seven more by three years post-operatively. Of the 28 patients, 10 showed sac expansion at a rate of over 10 mm per year during the five year follow up, all of whom received a secondary

**Table 1.** Type of endoleak in 309 patients treated by endovascular aneurysm repair from October 2009 to October 2019

Type of endoleak	Patients ( $n = 309$ )
No endoleak, low risk	219 (70.9)
Type II endoleak	86 (27.8)
Low risk (> 1 cm sac shrinkage)	4
Intermediate risk (< 1 cm sac shrinkage)	82
Type I or III endoleak (high risk)	4 (1.3)
Re-intervention	28 (9.1)

Data are presented as  $n$  (%).

**Table 2. Demographics of 309 patients treated by endovascular aneurysm repair between October 2009 and October 2019**

Demographic	Patients (n = 309)
Mean age (range) – y	75 (50–92)
Male sex	278 (90.0)
Diabetes mellitus	44 (14.2)
Hypertension	202 (65.4)
Chronic obstructive pulmonary disease	58 (18.8)
Ischaemic heart disease	112 (36.2)
Congestive cardiac failure	11 (3.6)
Chronic kidney disease	34 (11.0)
Cerebrovascular accident	28 (9.1)

Data are presented as n (%) unless otherwise stated.

intervention. Conversely, five of the 28 patients with initial sac expansion showed sac shrinkage by five years.

In total, 18 of the initial 82 patients with a type II endoleak (22%) showed sac shrinkage at a rate of over 10 mm a year between 30 days and five years post-operatively; in all of these patients, sac shrinkage was also associated with resolution of the initial endoleak. These patients could therefore have fallen into the low risk category with reduced surveillance.

#### High risk (type I or type III endoleak)

Four patients (1.3%) demonstrated possible type Ia or Ib endoleaks at 30 days post-operatively (median follow up 36 months [range 36 – 60 months]). Two of these underwent extensions, while two had subsequent imaging that suggested these were, in fact, type II endoleaks, and therefore underwent surveillance as per protocol.

#### Re-interventions

There were 28 secondary interventions in 22 patients (four patients had two interventions and one had three). Time to the re-interventions carried out ranged from as early as 30 days to five years and included inferior mesenteric artery/iliolumbar embolisation (n = 20); proximal extensions (n = 4); and iliac extensions combined with embolisations (n = 4). Three of the proximal extensions and two of the iliac extensions were conducted owing to the possibility of a type I endoleak on a diagnostic angiogram done at the time of the procedure. The remaining three extensions (one proximal and two iliac) were performed in those with at least one previous intervention. Only two of the secondary interventions occurred in the absence of sac expansion. A total of five secondary interventions therefore occurred after the development of a new type Ia or Ib endoleak, identified on surveillance imaging; the rest were performed for type II endoleaks.

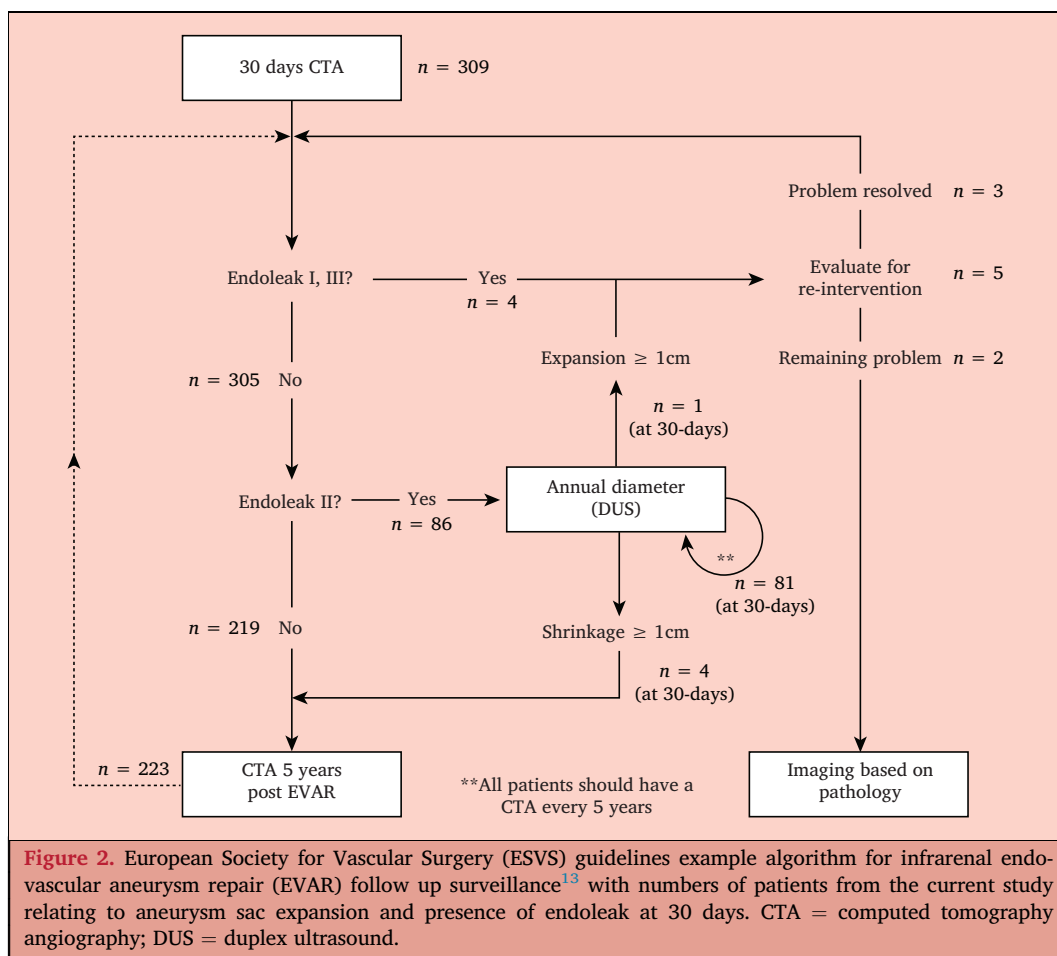
The overall re-intervention rate within five years post-operatively was 9.7%. No patient experienced a ruptured aneurysm within five years; however, two late ruptures were noted at years six and seven post-EVAR, respectively. Had the proposed ESVS protocol been followed, no patient who required secondary intervention or sac size increase

would have been missed (Fig. 2). Adherence to the proposed guidelines would therefore have resulted in 223 of the patients falling into the low risk category. Five year data are available for 103 of these patients, who could have safely qualified for reduced surveillance.

#### DISCUSSION

This study has shown that, in the patient cohort examined, the proposed example ESVS EVAR surveillance algorithm can safely stratify patients into groups at low or higher risk of post-operative complications, and this can be used to decide on the frequency of post-operative imaging. Adherence to the ESVS guidelines could have resulted in a potential 72.2% of patients in the cohort qualifying for reduced surveillance (the “low risk” cohort inclusive of the 219 patients with no endoleak and four with sac shrinkage > 1 cm). Five year data were available for 103 of the patients, who would have qualified for reduced surveillance. The remaining 120 patients had follow up data for 1 – 4 years, with no current evidence of any adverse events. A further 18 patients could have been moved into the low risk cohort on subsequent imaging when they demonstrated sac shrinkage at a rate of > 1 cm/year and could also have received reduced follow up. Had the proposed ESVS protocol been followed, no patient who required secondary intervention or sustained sac size increase would have been missed. Therefore, had these patients just had surveillance imaging at five years, this would have resulted in four fewer duplexes and one fewer CTA per patient. With the average cost of a CTA being £338 and a DUS being £88 per scan,<sup>18</sup> this would have resulted in a cost saving of £690 per patient and potentially an overall reduction in EVAR surveillance costs of £153 870 in the cohort. Regular follow up imaging incurs a significant cost, which has implications for the lifetime cost of EVAR;<sup>14</sup> the cost associated with an annual lifelong protocol represents a third of the total costs of EVAR during a five year period.<sup>19</sup> No patient would have missed a diagnosis of sac expansion or need for secondary intervention with the reduced frequency of post-operative surveillance: saving time and money. Furthermore, all cases of secondary intervention that were required in the intermediate risk group were appropriately detected with annual DUS surveillance imaging.

Surveillance protocols following EVAR vary between vascular units across the world and the current protocols used are derived from early trials without much long term data. The Society of Vascular Surgery Guidelines suggest that patients should receive serial CTA imaging at one and 12 months then either yearly CTA or DUS.<sup>4,11,12</sup> However, there is a concern for the potential carcinogenic effects of the cumulative radiation dose and deterioration of renal function with the use of contrast.<sup>5,11</sup> Adherence to annual imaging varies between centres, particularly when small endoleaks are identified, and the frequency of follow up imaging may be altered.<sup>11,20</sup> Furthermore, there may be a burden on patients and their willingness to comply with intense follow up protocol regimes. Moreover, the value of



regular follow up imaging after EVAR is therefore unclear as lack of adherence to follow up does not seem to affect the long term mortality or rupture rate.<sup>21</sup>

Type II endoleaks have a reported incidence of up to 44%;<sup>5,7,11,20</sup> however, most are associated with sac stability, with 50% – 80% resolving spontaneously within six months.<sup>4,10</sup> Fifty-three per cent of the type II endoleaks in the Open vs. Endovascular Repair (OVER) randomised control trial resolved spontaneously.<sup>7</sup> However, a minority persist or are delayed; these can carry a risk of sac expansion and may cause concern. The OVER trial reported that the presence of persistent endoleak resulted in a statistically significant increase in aneurysm diameter over time.<sup>7</sup> However, it was important to note in this trial that, despite the fact that delayed type II endoleaks (detected > 1 year after EVAR) were associated with aneurysm enlargement vs. the early counterparts, these developed in only a very small number of patients (18 of 439), and were not associated with any excess mortality.<sup>7</sup> A study of 2 367 patients undergoing EVAR also found that persistent type II endoleaks correlated with an increase in sac size at follow up and subsequent increased risk of re-interventions.<sup>22</sup> However, only 16% of the 2 367 patients fell into this group; 84% had no endoleak or had resolved by follow up.<sup>22</sup> Furthermore, the secondary intervention rate reported in these studies is low.<sup>7,22</sup> The proposed new ESVS EVAR

protocol thereby acknowledges these concerns. The majority of patients without endoleak at 30 days and one year could safely undergo a reduced surveillance strategy, avoiding a large proportion of scans and excess radiation with potentially significant cost savings. The new protocol still acknowledges the association between sac expansion and persistent endoleak, and these patients would still be followed up regularly.<sup>13</sup> One caveat to the proposed guidelines includes the risk of rupture in the absence of sac expansion. However, this risk is reportedly very small, with only one such rupture reported within five years in the OVER trial and none in the present cohort in five years.<sup>13</sup>

Furthermore, studies used to form the recommendations of the proposed ESVS guidelines found multiple reports of safe reductions in follow up protocols in the low risk patient group without endoleak.<sup>13</sup> Sternbergh *et al.*<sup>19</sup> found that freedom from endoleak at one month and one year was highly predictive of reduced aneurysm related morbidity, as well as beneficial in reducing the carcinogenic effects of radiation and contrast associated kidney injury. Goncalves *et al.*<sup>17</sup> reported that those deemed low risk on the initial post-operative CTA had a significantly reduced risk of aneurysm related events; less intensive follow up appeared to be safe in these patients, which could lead to a reduction in the large number of unnecessary image examinations.<sup>17</sup> A further study by Dias *et al.*<sup>5</sup> found that < 10% of

patients benefitted from the yearly surveillance imaging. Only one re-intervention would have been delayed if routine follow up imaging was stratified on initial risk.<sup>5</sup> Baderkhan *et al.*<sup>23</sup> stratified patients into low and high risk groups based on their initial CTA and found significantly reduced AAA related adverse events and freedom from intervention in the low risk group (absence of endoleak and adequate seal), and concluded that reduced surveillance in this group could be considered. A study by Patel *et al.*<sup>11</sup> concluded that a negative initial post-operative CTA was highly predictive of long term freedom from re-intervention. Data from these studies therefore suggest that a reduced surveillance strategy can be implemented in those deemed to be low risk after their 30 day CTA, which is in line with the ESVS's proposed recommendations. However, many of these studies were observational studies susceptible to bias and there remains a need to perform a prospective study to establish properly the safety of these recommendations before their widespread acceptance. Such a study would also enable a clear cost benefit analysis to be undertaken, to ensure that there is a cost saving associated with reduced surveillance and that there is no impact on late secondary intervention rate as a result.

This study had some limitations. It was a single centre retrospective observational study and therefore susceptible to selection and attrition bias, particularly as not all the patients included in this study had reached the five year follow up point. Furthermore, data on landing zone sealing or whether the EVAR was within the IFU were not collected prospectively; however, there has been no mention of inadequate seal zones in the operation notes of any of the procedures. While this information would be useful to assess for the failure/durability of EVAR, the outcomes focused more on sac size and the presence or absence of endoleak. The latter two outcome measures were practical and reliable and were deemed to be more objective assessments with less risk of observer bias. Therefore, outcomes from this study could potentially help design a prospective study with a larger group of patients looking at all the four elements of proposed guidelines giving more accurate validation of the proposed ESVS protocol.

In conclusion, adopting the proposed ESVS infrarenal EVAR surveillance protocol would have safely identified those patients who required re-intervention within the cohort and study setting, while allowing a large proportion of the patients to adhere to a reduced follow up regime. This would reduce the burden of surveillance imaging for patients, while also having an added benefit of associated cost savings, reducing the lifetime cost of EVAR. However, a prospective study evaluating this protocol and assessing the safety and outcomes of this approach would add more validity to allow safe implementation in clinical practice.

#### CONFLICT OF INTEREST AND FUNDING

There is no conflict of interest and no funding was required for the conduct of this study.

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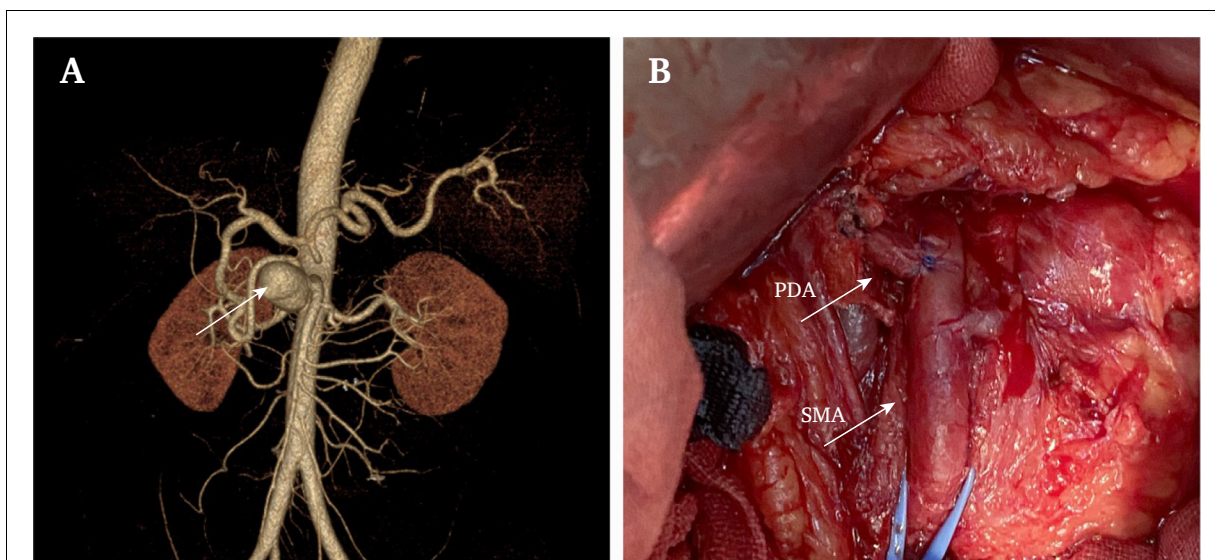
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## COUP D'OEIL

# Open Repair of Isolated Pancreaticoduodenal Aneurysm

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**Figure 1.** A 58 year old man presented with a three year history of intermittent upper abdominal pain with no history of trauma or pancreatitis. (A) Computed tomography angiography (CTA) revealed a 3.5 cm pancreaticoduodenal artery (PDA) aneurysm (arrow). There was no suitable aneurysm neck or landing zone for coil embolisation or exclusion using a covered stent. Open surgical repair was indicated. (B) The aneurysm was resected, and the PDA was re-implanted into the proximal superior mesenteric artery (SMA). The post-operative course was uneventful. Follow up CTA showed that the PDA and SMA were widely patent. The patient's symptoms were completely resolved.

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