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6 Keywords: Aortic aneurysms, Endovascular Aortic repair, intraoperative imaging control

ARTICLE HIGHLIGHTS

Type of Research: Single-center retrospective cohort study

Key Findings: Completion contrast-enhanced cone beam computed tomography (ceCBCT) reduced the rate of late stent-graft related complications in 100 EVAR patients (HR=0.39, 95% CI 0.16-0.95, p=.038) compared to standard 2D angiogram with a postoperative computed tomography angiography (CTA). At 5 years, the freedom from late stent-graft related complications was higher in the ceCBCT strategy group at 81.7% [95 % CI (70.1-95.2)] vs 61.6% [95 % CI (47.0-80.6)] (p=.033).

Take home Message: A workflow including routine intraoperative contrast-enhanced cone beam computed tomography (ceCBCT) to assess the technical success after EVAR reduces the late stent-graft related complications rate.

Table of Contents Summary:

In this retrospective single-center study including 100 consecutive patients undergoing EVAR in a hybrid room, completion contrast enhanced cone beam computed tomography (ceCBCT) reduces the rate of late stentgraft-related complications compared to a 2D-angiogram and postoperative computed tomography angiography. Intraoperative CBCT may help to improve long term outcomes after EVAR.

ABSTRACT

Objective:

To evaluate whether a combination of intraoperative ceCBCT and postoperative contrast enhanced ultrasound (CEUS) assessment after infra-renal endovascular aortic repair (EVAR) could reduce late stent-graft related complications and consequently re-interventions.

Methods:

All consecutive patients receiving infra-renal bifurcated stent-grafts in our hybrid room (IGS 730, GE Healthcare) during two discrete periods were included in this study: i) from November 2012 to September 2013, a 2D completion angiogram was performed after each EVAR, followed by computed tomography angiography (CTA) before discharge (group 1), ii) from October 2013 to January 2015, an intraoperative ceCBCT was performed, followed by CEUS within the first postoperative days (group 2). Comparative analyses of outcomes were undertaken.
The primary endpoint was late stent-graft related complications, a composite factor incorporating aneurysm-related death, type 1 or 3 endoleaks, kink or occlusion of iliac limb and aortic sac enlargement beyond the first 30 postoperative days. The secondary endpoint was all stent-graft related re-interventions. All-cause and aneurysm related deaths were also reported.

Results:

Overall, 100 consecutive patients (50 in group 1 and 50 in group 2) were enrolled with a median follow up of 60 months [IQR 41-69]. At 60 months from the index procedure, freedom from late

stent-graft related complications in each group was 61.6% (95 % CI [47.0-80.6]) for group 1 and 81.7% (95 % CI [70.1-95.2]) for group 2 (p=.033).

Intraoperative CBCT was independently associated with a reduced rate of late stent-graft related complications after multivariate analysis (HR = 0.39, 95% CI 0.16-0.95, p=.038), but did not appear to significantly protect against stent-graft related re-interventions (HR=0.53; 95% CI 0.20-1.39, p=.198) or all cause death (p=.47).

Conclusion:

This study is the first to report the influence of routine ceCBCT on late outcomes after EVAR and shows a potential reduction in late stent-graft related complications associated with its use.

INTRODUCTION

Endovascular aortic repair (EVAR) has become the primary treatment option for aortic aneurysms with suitable anatomy. Early experience of EVAR was marred by relatively high rates of complications and re-interventions for various reasons, including the construction of the device implanted, adherence to anatomical criteria set out by manufactures and relatively primitive planning facilities. It has been reported that 15 % of patients underwent ≥1 reintervention during follow-up [1], with up to 1/3 of them occurring within the 30 postoperative days [2]. Type 1 and 3 endoleaks, stent-graft migration, thrombosis and accidental renal artery coverage were the most common reasons for re-intervention during the early proliferation of EVAR[3-6].

It is possible that some stent-graft related complications might be caused by technical issues not identified on the final 2D-angiogram. Completion uniplanar angiography (usually anteroposterior) is recommended for evaluating technical success after EVAR although it has been shown to be insufficient to detect all procedural issues, with both sensitivity and specificity to detect endoleaks estimated respectively at 63% [IC95=60-70%] and 77% [IC95=58-100%]; while for CTA (Computed Tomography Angiogram) it is 92% [IC95=80-100%] and 90% [IC95=85-92%] respectively [7,8,9].

Potential technical failures may therefore only be detected on the postoperative CTA, necessitating early re-intervention and incurring additional cost and potential morbidity that could impact on quality of life. In addition, the cost-effectiveness of EVAR is diminished by secondary interventions, which is a subject of ongoing debate regarding the validity of the technique as a whole. There is a need for post-operative imaging strategies that are able to

accurately detect of high flow endoleaks and other more subtle correctable issues with stent-graft integrity. [10,11,12].

Completion contrast-enhanced Cone Beam Computed Tomography (ceCBCT) is an intraoperative 3D-imaging modality offering high-spatial resolution and volumetric data which can be reconstructed and processed at a workstation during a procedure. Several studies have established the short-term benefits of ceCBCT [13-16] in EVAR. Postoperative contrast-enhanced ultrasound (CEUS) is highly sensitive method of depicting and classifying endoleaks and is routinely performed before patient' discharge at our institution.[17]

In a previous work ceCBCT has shown to reduce both radiation exposure and contrast media volume after infrarenal and complex EVAR compared to a strategy incorporating 2D angiography and postoperative CTA [18]. Moreover, higher rates of high-flow endoleaks and limb kinks were detected with ceCBCT intraoperatively enabling immediate correction during the initial procedure.

The present study evaluates whether intraoperative completion of ceCBCT combined with early postoperative CEUS could reduce late stent-graft related complications and reinterventions after EVAR.

MATERIAL AND METHODS

Patients' selection

100 consecutive patients treated with infrarenal bifurcated stent-grafts in our hybrid room (IGS 730, GE Healthcare, France) during two different periods were retrospectively included in this study from a prospective database: i) from November 2012 to September 2013, a **2D completion angiogram** (25cc of iodine, at 15cc/sec, (Omnipaque 350, GE Healthcare)) was performed at the end of the procedure for each patient to assess the technical success; and a **computed tomography angiography** (CTA) was then performed before discharge (**group 1, n=50**); ii) from October 2013 to January 2015, an intraoperative **ceCBCT** (40°/sec – 35cc of iodine (Omnipaque 350, GE Healthcare) at 10cc/sec) was performed to assess technical success, followed by contrast enhanced ultrasound (**CEUS)** within the 30-day post-operative period (**group 2, n=50**).

Patients with renal insufficiency (DFG< 60 mL/min) or requiring emergency treatment were excluded from the study.

Procedures

All procedures were performed under fusion imaging guidance, according to the ALARA principles [19,20]. All patients received CookMedical bifurcated infrarenal stentgrafts including standard profile (Zenith Flex platform) and low-profile (Zenith Alpha platform) bifurcated main body, and Spiral-z iliac legs (CookMedical, IN, USA).

The primary technical success of the procedure was defined according to the reporting standards [21].

Technical details

ceCBCT

ceCBCT acquisition (40°/sec) was performed at the end of the procedure. A spin test was run before the acquisition to ensure the absence of collision between the patient, the table and the gantry, and to check whether the acquisition volume is properly centered on the stent-graft.

An automatic power injector (Medrad) was used for contrast media injection with the following parameters: injection of 35 mL of iodine (Omnipaque 350, GE Healthcare), at a flow rate of 10 mL/second with 2 seconds of delay.

The 31x31cm flat panel robotic gantry was rotated over 200 degrees; 150 angiographic projections were acquired during 5 seconds with 1.33 degrees increment. The images acquired during the run were automatically transferred to a dedicated workstation and automatically reconstructed (Advantage Window; GE Healthcare, Milwaukee, USA). The resulting volume was an 18.3 cm diameter cylinder. Reconstructed data were displayed using cross-sectional axial reconstruction, multiplanar (MPR), maximum intensity projection (MIP) and 3D volume rendering (3DVR) views.

2D completion Angiography

Completion angiography was performed using an automatic power injector with the following parameters: injection of 25cc of pure contrast medium (Omnipaque 350, GE Healthcare), with a flow rate at 10 mL/second.

Two experienced endovascular therapists reviewed final control imaging, aiming at depicting any high-flow endoleak (type I or III), limb kinks and evaluating the general integrity of the stentgraft.

Where significant issues were detected, immediate intraoperative correction was provided and are referred later in the manuscript as additional unplanned procedures at the index EVAR.

CTA

In group 1, the postoperative three-phase CTA was performed within 7 days after EVAR on a 64-slice multi-detector CT system (Brillance 64, Philips Healthcare, Best, The Netherlands). The injection protocol included the administration of 120 mL of a contrast agent with 350 mg of iodine per milliliter (Ioversol, Optiject; Guerbet, Roissy, France) at a flow rate of 4 mL/second. The acquisition was initiated by bolus tracking within the aorta at the level of the thoraco-abdominal junction. The triphasic acquisitions (unenhanced, arterial, and delayed phases) were systematically obtained with a maximum tube current of 150-250 mAs, dependent on automatic selection, and a longitudinal dose modulation (ACS & Z-DOM; Philips Healthcare).

Contrast-Enhanced Ultra-Sound (CEUS)

CEUS is an imaging modality used routinely in our centre to follow EVAR results. Three experienced vascular therapists in the department with a combined experience of more than 1,000 examinations lead this service [17,22].

US examinations include a standard morphological examination in B-mode followed by a blood flow analysis in pulse wave modality. CEUS was performed after the administration of an

intravenous bolus of 2.5 mL of SonoVue (Bracco, Milan, Italy), flushed with a 5 mL bolus of isotonic saline solution. Endoleak detection was performed at a low mechanical index (0.2e0.3) and with the focus positioned behind the aorta to delay bubble destruction. For all the patients in group 2, CEUS was performed within the first 30 postoperative days after EVAR.

Data collection

All patients provided informed consent, and the study was registered at the CNIL under the number DEC20-224 (commission nationale de l'informatique et des libertés).

Data were collected in a prospective database with retrospective analyses. Patients' demographic characteristics, medical history, pre and postoperative anatomical measurements and procedural data were collected.

Intra-operative findings (such as limb kink or thrombosis, type 1/3 endoleak, renal artery coverage) were collected; endoleaks present at the completion imaging were classified as primary endoleaks. Resulting intra-operative revisions required were recorded.

Follow-up

Follow-up visits were routinely scheduled at 6 and 12 months after the procedure and yearly thereafter. All patients underwent a physical examination at each follow-up visit and had standard blood tests. A three-phase CTA was performed at 12 months after EVAR and every two years thereafter. When iodine injection was contraindicated, a CT scan without contrast media injection was performed. Patient's vascular therapist performed colour duplex ultrasonography

yearly. Additional CTA and/or CEUS were subsequently completed when a significant aortic sac enlargement or high-flow endoleak was reported with the colour duplex US, CTA and/or CEUS were completed.

All available CTA and CT images were analysed on a dedicated 3D-workstation (Aquarius, Terarecon). Aortic sac diameter was measured and collected after centreline reconstruction and endoleaks, stengraft/limb integrity and/or patency were reported.

Overall complications, stent-graft related complications and/or reinterventions occurring within the first 30 postoperative days or during the initial hospitalisation were deemed as early reinterventions and were reported; beyond that initial period, all complications and/or reinterventions were deemed as late complications and/or reinterventions.

Outcomes were assessed in accordance with the SVS reporting standards for EVAR [21,23].

An endoleak observed 30 days after the index EVAR was considered as a secondary endoleak [24].

The reappearance of an endoleak after spontaneous resolution or reintervention was classified as a recurrent endoleak. Mid-term results referred to outcomes measures within the first 5 years of follow-up [23].

Objectives

The primary endpoint was late stent graft related complications, a composite criterion defined as aneurysm-related deaths, secondary high-flow endoleaks including type 1 and 3 endoleaks, secondary kink or occlusion of iliac limb, and aortic sac enlargement (≥5mm) occurring at any time during follow-up after the first 30 postoperative days.

The secondary endpoint was stent graft related reinterventions defined as all stent-graft related procedures occurring after the index EVAR.

The overall mortality of the population was also reported.

Statistical Analysis

All statistical analyses were performed using R 2018 (Vienna, Austria). Descriptive study of the cohort was performed. Continuous variables were expressed as median with inter-quartile range (IQR=[Q1-Q3]) or mean with standard deviation. Categorical variables are presented as a percentage and 95% of confidence interval.

Comparisons between categorical variables were performed with the chi-square test (or Fisher exact test) and between continuous variables with the Student-t test, or with the Mann-Whitney test.

Survival analyses were performed according to the Kaplan-Meier model. Curves were compared with a log-rank test, and then results were adjusted with a hazard ratio cox model according to non-comparable preoperative variables.

When the relationship between the composite criterion and a quantitative covariate was not linear, the covariate was recoded into a binary variable. Recoding threshold was determined by

minimizing the Bayesian information criterion of the model. Multivariate models were constructed by including all variables with p-value <.05 in univariate analyses or considered clinically relevant. A p value <.05 was considered significant.

RESULTS

Overall, 100 consecutive patients were included during the two different study periods. Baseline characteristics are presented in Table 1 and are similar in both groups, with a mean maximum diameter of the aneurysm sac on the preoperative CTA of 54.5 ± 8.4 mm. 80 % of the stent-grafts implanted were low-profile devices (Cook Zenith alpha platform).

Intraoperative findings and immediate revisions

Intra-operative problems were detected in 10% (n=5) and 28% (n=14) of patients in group 1 and 2 (p=.041). The most common findings in group 1 included type 1B endoleak in 3 procedures, type 1A endoleak in 1 procedure and partial renal artery coverage in 1 procedure. ceCBCT identified 5 type 1 A endoleak and 5 type 1b endoleak that required prompt immediate revision. Other findings in group 2 included limb kink in 3 cases and partial renal artery coverage in 1 patient. Additionally, Type 2 endoleaks detection rate during procedures were similar in both groups; 15 patients (30.0%) in group 1 vs. 13 patients (26%) in group 2 (p=.824). Immediate revision at the index EVAR was performed in 4 patients (8%) in group 1 versus 14 (28%) in group 2 (p=.024). Details of intra-operative findings and immediate revisions are reported in **Table II (a&b).**

Late stent-graft related complications

The median time of follow-up was equivalent in both groups (60 months [IQR 40-75] in group 1 versus 60 months [IQR 41,3-62,8] in group 2; p=.419). 26 late complications occurred in 17 patients of group 1 (34%), 9 complications occurred in 7 patients of group 2 (14%), with a

median time from the index procedure at 24 months [IQR 12-60] and 38 months [IQR 24.5-42.5] respectively in group 1 & 2. Late stent-graft related complications are reported in **Table III**.

At 60 months from the index procedure, according to the Kaplan Meier method, the freedom from late stent-graft related complications estimates were 61.6% (95 % CI [47.0-80.6]) in group 1 and 81.7% (95 % CI [70.1-95.2]) in group 2 (log-rank, p=.033) (**Figure 1a**).

Late high-flow endoleaks rates were respectively 18% in group 1 (n=9) and 4% in the group 2 (n=2) (p=.055). Six late type 1A endoleaks were detected in group 1 (12%), whereas only 1 late type 1A endoleak was detected in group 2 (2%). Two late Type 1B endoleaks were detected in group 1 whereas none occurred in group 2. One late Type III endoleak was recorded in both groups. At 60 months from the index procedure the freedom from secondary high flow endoleaks estimates were 77.7% (95 % CI [64.7-93.5]) in group 1 and 93.8% (95 % CI [85.8-100]) in group 2 (log-rank, p=.021) (**Figure 1b**) according to the Kaplan Meier method.

At the end of the follow up, 12 (24%) patients experienced an aortic sac enlargement in group 1 and 4 patients (8%) in group 2 (p=.056).

In a multivariate analysis, ceCBCT appeared to independently protect from late stent-graft related complications HR =0.39 (CI95, 0.16-0.95, p=.038).

Stent-graft related reinterventions

At the end of follow-up, a total of 13 reinterventions were performed in 11 patients in group 1 (22 %), and 7 reinterventions were performed in 7 patients in group 2 (14%) with a median time

from the index procedure at 14 months [IQR 12.0-31.5] in group 1 and 45 months [IQR 22.5-50.5] in group 2 (p=.435).

Only one early reintervention was performed in each group. Sixty months after the initial procedure, the freedom-from-reintervention rates were 77.6% (95% CI, 66.2-91.0) in group 1 and 80.8% (95 % CI, 68.7-95.1) in group 2 (p=.27) (**Figure 2**).

The main indication for reintervention in group 1 was high-flow endoleaks (n=7/13, 53.8%); while it was equally high-flow endoleaks (n=2/7, 28.6%), and limb graft thrombosis (n=2/7, 28.7%) in group 2 (**supplemental table 1**). Among the 14 revised patients during initial procedure in group 2, three patients presented a late stentgraft-related complication and necessitated a reintervention.

Survival

A total of 24 deaths were reported during the study period. At 60 months, the estimated survival rates were 83.2% (95% CI, 73.3-94.6) in group 1 and 71.0 % (95% CI, 58.7-85.8) in group 2. There was no significant difference between groups in terms of death from any cause (p=.47). Aneurysm-related mortality occurred in 1 patient in group 1 (late rupture 64 months after the index EVAR). No aneurysm-related death was reported in group 2. Overall estimated survival is reported in **Supplemental Figure I**.

DISCUSSION

This study is the first to report the influence of routine ceCBCT on mid-term outcomes after standard infrarenal EVAR. The analysis suggests a reduction in late stent-graft related complications and also a trend toward reduced stent-graft related reinterventions during follow-up. The incidence of late stent-graft related complications was twice as high in the 2D angiogram group compared to the ceCBCT group after 60 months. The use of ceCBCT appeared to be an independent protective factor in protecting against late stent-graft related complications (OR=0.39, 0.16-0.95, p=.033) during follow-up in the Cox models.

Amongst these late complications, secondary high-flow endoleaks, especially type 1A (12%, n=6) and type 1B endoleak (4%, n=2), were the most prevalent complications when a completion angiogram was performed whereas no type 1B and only one type 1A endoleak was observed in the ceCBCT group (log-rank p=.021).

Primary high-flow endoleaks were the most common finding during the initial procedure when completion ceCBCT was performed, and were also the main indication for immediate revision (n=10/50, 20%). At the end of follow-up, neither of these patients had a recurrent endoleak nor exhibited aortic sac enlargement. Similarly, the proportion of aneurysms exhibiting post-operative expansion appeared to be higher in group 1 (24% vs 8%, p=.056).

These data suggested that prompt correction of primary high flow endoleaks detected with ceCBCT in the initial stage resulted in less sac enlargement and therefore better outcomes at mid-term, but this did not translate into an appreciable survival benefit at 6 years. In line with this finding ceCBCT did not significantly protect against stent-graft related reinterventions in our

study. It is of note that in our survival analysis model patients rated similar whatever the number of late stentgraft-related complication(s) presented and those latter can have been corrected within the same reintervention. This element could explain the discrepancies reported between the number of reinterventions and number of complications.

Reinterventions after EVAR are still relatively common, and the risk is persistent even after six years of the initial procedure [25]. Longer term follow-up of the EVAR 1 trial reported a secondary reinterventions rate approaching 20% at 5 years [26]. A recent meta-analysis of 14 trials estimated the combined re-intervention-free survival after EVAR was 94%, 89.9%, 86.9%, 84.9% at 1, 2, 3 and 4 years respectively [27]. In the cohort presented here, 18% of the patients needed at least one reintervention at the end of the follow up, which is in line with the reported literature.

In our study, the freedom from stent-graft related reintervention estimates did not significantly differ between groups at 5 years; progression of the disease itself remains a potential independent factor of late failure by affecting the sealing zones of the stentgraft.

However, two main differences in the groups can be underlined.

Firstly, the most common indication for reintervention in group 1 was secondary high-flow endoleaks (7/13, 53.8%) when only two high-flow endoleaks required reintervention in group 2 (2/7, 28.6%).

Secondly, the median time from index procedure to reintervention was tripled when ceCBCT was performed (45 months in group 2 compared to 14 months in group 1), which could suggest that late reinterventions in group 1 would be related to small technical failures potentially missed by standard 2D completion angiogram during the index procedure, responsible for earlier adverse outcomes. Average mean time to reintervention when angiogram was performed is similar to those described in literature for EVAR cases [3,28].

Despite these potential advantages, the volume acquired with a ceCBCT is limited and smaller than the fluoroscopic field of view. The size of the flat panel in vascular hybrid rooms usually is up to 41x41cm (CBCT volume=25x25cm) and although the whole stentgraft is generally enclosed in the final volume in EVAR cases, it is generally too small in complex aortic reconstructions. Consequently, two or more acquisitions have to be made to properly evaluate the integrity of the stent-graft and evaluate the technical success, and the spatial resolution is lower than CTA so the images can be altered by artefact [29,30].

Our ceCBCT protocol has a single-phase acquisition and a 2 second delay with the injection of a moderate volume of contrast agent (35 cc of iodine) in order to properly identify endoleaks. The 31x31cm flat panel robotic gantry is rotated over 200 degrees and 150 frames are acquired during a 5-second spin.

There is a great heterogeneity in literature regarding CBCT protocols, and the optimal setup with a compromise between image quality and the lowest radiation exposure has yet to be defined. In our previous study[18], the median radiation exposure of the final CBCT was 7 Gy.cm^2 (5.25-8)

(i.e. 36% of the total procedure exposure) which is low compared to the range reported in current literature i.e. 43.7 Gy.cm^2 (32,9-54,5) to 71 Gy.cm^2 (35-127) [14,15,16].

The main advantage of the intraoperative CBCT relies on its immediate availability without additional hardware although hybrid rooms come at a hefty price and not every hospital can afford such an investment. Other solutions exist and may offer fusion guidance with a mobile flat panel C-arm in a conventional operating theatre, but these currently lack CBCT completion imaging. Kaladji and al. [31] evaluated the feasibility of one such software package (Endonaut station and the Endozise software (Therenva, Rennes, France)) with a mobile imaging system. The absence of communication between the table and the software remains the main issue, requiring the repetition of the registration process after each table movements, and 3D reconstructions are not possible.

Our study is limited by a retrospective design, although the cohort represents a consecutive series of patients that underwent EVAR. In addition, there was no reasonable way to directly compare and evaluate the diagnostic accuracy of the 3 imaging modalities (angiogram, ceCBCT and CTA) at the same time in a single patient. Indeed, such a comparison would require performing the three exams in a single patient and would increase the radiation and contrast media burden. As expressed in our initial report, a strict comparison between CBCT and CTA would involve not intervening on some abnormalities found with the intraoperative control in order to analyse them with the postoperative CTA which would not be possible.

Last limitation of our study is that latter enclosed exclusively patients having received cook zenith platform (either standard or low profile). Thus, our findings may not be potentially extrapolated to other brands of aortic stentgrafts.

CONCLUSION

This study suggests that contrast enhanced CBCT to assess technical success after EVAR is valuable. This would reduce the late stent-graft related complications compared to a control strategy that only includes a 2D angiogram, while also delaying the term of potential stentgraft-related reinterventions. A systematic use in routine is encouraged when available since no additional radiation/contrast burden has been reported.

REFERENCES

1 Sampram ESK, Karafa MT, Mascha EJ, Clair DG, Greenberg RK, Lyden SP, et al. Nature, frequency, and predictors of secondary procedures after endovascular repair of abdominal aortic aneurysm. *J Vasc Surg* 2003;37:930–7.

2 Greenhalgh RM, Brown LC, Kwong GPS, Powell JT, Thompson SG, EVAR trial participants. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial. *Lancet* 2004;364:843–8.

3 Hobo R, Buth J, EUROSTAR collaborators. Secondary interventions following endovascular abdominal aortic aneurysm repair using current endografts. A EUROSTAR report. *J Vasc Surg* 2006;43:896–902.

4 Stather PW, Sidloff D, Dattani N, Choke E, Bown MJ, Sayers RD. Systematic review and meta-analysis of the early and late outcomes of open and endovascular repair of abdominal aortic aneurysm. *Br J Surg* 2013;100:863–72.

5 Lederle FA, Freischlag JA, Kyriakides TC, Matsumura JS, Padberg FT, Kohler TR, et al. Long-term comparison of endovascular and open repair of abdominal aortic aneurysm. *N Engl J Med* 2012;367:1988–97.

6 Brewster DC, Jones JE, Chung TK, Lamuraglia GM, Kwolek CJ, Watkins MT, et al. Long-term outcomes after endovascular abdominal aortic aneurysm repair: the first decade. *Ann Surg* 2006;244:426–38.

7 Sandford RM, Batchelder AJ, Bown MJ, Sayers RD. Pre-discharge duplex ultrasound scans detect endoleaks not seen on completion angiography after endovascular aneurysm repair. *J Endovasc Ther* 2010;17:349–53.

8 AbuRahma AF. Fate of endoleaks detected by CT angiography and missed by color duplex ultrasound in endovascular grafts for abdominal aortic aneurysms. *J Endovasc Ther* 2006;13:490–5.

9 Armerding MD, Rubin GD, Beaulieu CF, Slonim SM, Olcott EW, Samuels SL, et al. Aortic aneurysmal disease: assessment of stent-graft treatment-CT versus conventional angiography. *Radiology* 2000;215:138–46.

10 van Bochove CA, Burgers LT, Vahl AC, Birnie E, van Schothorst MG, Redekop WK. Cost-effectiveness of open versus endovascular repair of abdominal aortic aneurysm. *J Vasc Surg* 2016;63:827-838.e2.

11 Stone DH, Horvath AJ, Goodney PP, Rzucidlo EM, Nolan BW, Walsh DB, et al. The financial implications of endovascular aneurysm repair in the cost containment era. *J Vasc Surg* 2014;59:283–90, 290.e1.

12 Epstein D, Sculpher MJ, Powell JT, Thompson SG, Brown LC, Greenhalgh RM. Long-term cost-effectiveness analysis of endovascular versus open repair for abdominal aortic aneurysm based on four randomized clinical trials. *Br J Surg* 2014;101:623–31.

13 Biasi L, Ali T, Ratnam LA, Morgan R, Loftus I, Thompson M. Intra-operative DynaCT improves technical success of endovascular repair of abdominal aortic aneurysms. *J Vasc Surg*

2009;49:288–95.

14 Schulz CJ, Schmitt M, Böckler D, Geisbüsch P. Intraoperative contrast-enhanced cone beam computed tomography to assess technical success during endovascular aneurysm repair. *J Vasc Surg* 2016;64:577–84.

15 Törnqvist P, Dias N, Sonesson B, Kristmundsson T, Resch T. Intra-operative cone beam computed tomography can help avoid reinterventions and reduce CT follow up after infrarenal EVAR. *Eur J Vasc Endovasc Surg* 2015;49:390–5.

16 Tenorio ER, Oderich GS, Sandri GA, Ozbek P, Kärkkäinen JM, Vrtiska T, et al. Prospective nonrandomized study to evaluate cone beam computed tomography for technical assessment of standard and complex endovascular aortic repair. *J Vasc Surg* 2020;71:1982-1993.

17 Perini P, Sediri I, Midulla M, Delsart P, Mouton S, Gautier C, et al. Single-centre prospective comparison between contrast-enhanced ultrasound and computed tomography angiography after EVAR. *Eur J Vasc Endovasc Surg* 2011;42:797–802.

18 Hertault A, Maurel B, Pontana F, Martin-Gonzalez T, Spear R, Sobocinski J, et al. Benefits of Completion 3D Angiography Associated with Contrast Enhanced Ultrasound to Assess Technical Success after EVAR. *Eur J Vasc Endovasc Surg* 2015;49:541–8.

19 Bevelacqua JJ. Practical and Effective ALARA. *Health Physics* 2010;98 Suppl 2:S39-47.

20 Hertault A, Maurel B, Midulla M, Bordier C, Desponds L, Saeed Kilani M, et al. Editor's Choice - Minimizing Radiation Exposure During Endovascular Procedures: Basic Knowledge,

Literature Review, and Reporting Standards. *Eur J Vasc Endovasc Surg* 2015;50:21–36.

21 Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al. Reporting standards for endovascular aortic aneurysm repair. *Journal of Vascular Surgery* 2002;35:1048–60.

22 Perini P, Sediri I, Midulla M, Delsart P, Gautier C, Haulon S. Contrast-enhanced ultrasound vs. CT angiography in fenestrated EVAR surveillance: a single-center comparison. *J Endovasc Ther* 2012;19:648–55.

23 Oderich GS, Forbes TL, Chaer R, Davies MG, Lindsay TF, Mastracci T, et al. Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries. *J Vasc Surg* 2021;73:4S-52S.

24 White GH, Yu W, May J, Chaufour X, Stephen MS. Endoleak as a complication of endoluminal grafting of abdominal aortic aneurysms: classification, incidence, diagnosis, and management. *J Endovasc Surg* 1997;4:152–68.

25 Zaiem F, Almasri J, Tello M, Prokop LJ, Chaikof EL, Murad MH. A systematic review of surveillance after endovascular aortic repair. *Journal of Vascular Surgery* 2018; 67:320-331.e37.

26 EVAR trial participants. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial. *Lancet* 2005;365:2179–86.

27 Nordon IM, Karthikesalingam A, Hinchliffe RJ, Holt PJ, Loftus IM, Thompson MM.

Secondary Interventions Following Endovascular Aneurysm Repair (EVAR) and the Enduring Value of Graft Surveillance. *European Journal of Vascular and Endovascular Surgery* 2010;39:547–54.

28 Laheij RJF, Buth J, Harris PL, Moll FL, Stelter WJ, Verhoeven ELG. Need for secondary interventions after endovascular repair of abdominal aortic aneurysms. Intermediate-term follow-up results of a European collaborative registry (EUROSTAR). *BJS* 2000;87:1666–73.

29 Nagarajappa AK, Dwivedi N, Tiwari R. Artifacts: The downturn of CBCT image. *J Int Soc Prev Community Dent* 2015;5:440–5.

30 Zhao Z, Gang GJ, Siewerdsen JH. Noise, sampling, and the number of projections in cone-beam CT with a flat-panel detector. *Med Phys* 2014;41:061909.

31 Kaladji A, Villena A, Pascot R, Lalys F, Daoudal A, Clochard E, et al. Fusion Imaging for EVAR with Mobile C-arm. *Ann Vasc Surg* 2019;55:166.

Figure Table Legends

Figure Ia: Kaplan Meier estimates of late stentgraft-related complications probabilities in 100 EVAR patients with a strategy including either an intraoperative 2D-angiogram (2DA) and a postoperative computed tomography angiography (CTA) or a contrast enhanced cone beam computed tomography (ceCBCT) with an early Contrast-Enhanced Ultra-Sound (CEUS).

Time (months)	**12**	**24**	**36**	**48**	**60**
Group 1 (2DA + CTA)					
Survival (%) [CI95%]	89.6% [81.4-98.7]	76.6% [65.4-89.8]	76.6% [65.4-89.8]	73.9% [62.1-87.9]	61.6 [47.0-80.6]
Late complications (n)	5	6	0	1	3
Patients at risk (n)	44	38	29	23	18
Group 2 (ceCBCT + CEUS)					
Survival % [CI95%]	100% [100-100]	95.5% [89.7-100]	93.2% [86.1-100]	85.0% [74.5-96.9]	81.7% [70.1-95.2]
Late complications (n)	0	2	1	3	1
Patients at risk (n)	48	42	35	28	22

Figure Ib: Kaplan Meier estimates of secondary high flow endoleaks (type I/III) probabilities in 100 EVAR patients with a strategy including either an intraoperative 2D-angiogram (2DA) and a postoperative computed tomography angiography (CTA) or a contrast enhanced cone beam computed tomography (ceCBCT) with an early Contrast-Enhanced Ultra-Sound (CEUS)

Time (months)	**12**	**24**	**36**	**48**	**60**
Group 1 (2DA + CTA)					
Survival (%) [CI95%]	95.7%% [90.1-100]	91.4% [83.8-99.8]	88.9% [80.1-98.6]	88.9% [80.1-98.6]	77.7 [64.7-93.5]
Secondary high-flow endoleaks (n)	2	2	1	0	3
Patients at risk (n)	47	42	36	28	21
Group 2 (ceCBCT + CEUS)					
Survival % [CI95%]	100% [100-100]	100% [100-100]	100% [100-100]	97.3% [92.2-100]	93.8% [85.8-100]
Secondary high-flow endoleaks (n)	0	0	0	1	1
Patients at risk (n)	48	44	39	33	16

Figure II. Kaplan Meier estimates of stentgraft-related reintervention probabilities in 100 EVAR patients with a strategy including either an intraoperative 2D-angiogram (2DA) and a postoperative computed tomography angiography (CTA) or a contrast enhanced cone beam computed tomography (ceCBCT) with an early Contrast-Enhanced Ultra-Sound (CEUS)

Time (months)	**12**	**24**	**36**	**48**	**60**
Group 1 (2DA+CTA)					
Survival (%) [CI95%]	93.9 % [87.5-100]	85.3% [75.8-96.0]	80.3% [69.5-92.8]	77.6% [66.2-91.0]	77.6% [66.2-91.0]
Reintervention (n)	3	4	2	1	0
Patients at risk (n)	44	39	31	24	19
Group 2 (ceCBCT+CEUS)					
Survival % [CI95%]	98.0% [94.2-100]	95.8% [90.3-100]	93.5% [86.7-100]	87.6% [77.8-98.6]	80.8% [68.7-95.1]
Reintervention (n)	1	1	1	2	2
Patients at risk (n)	47	42	36	30	24

Table I. Baseline characteristics and procedural data of 100 EVAR patients with a strategy including either an intraoperative 2D-angiogram (2DA) and a postoperative computed tomography angiography (CTA) or a contrast enhanced cone beam computed tomography (ceCBCT) with an early Contrast-Enhanced Ultra-Sound (CEUS)

Table IIa. Intraoperative findings in 100 EVAR patients with a strategy including either an intraoperative 2D-angiogram (2DA) and a postoperative computed tomography angiography (CTA) or a contrast enhanced cone beam computed tomography (ceCBCT) with an early Contrast-Enhanced Ultra-Sound (CEUS)

Table IIb. Nature of the immediate revision in 100 EVAR patients with a strategy including either an intraoperative 2D-angiogram (2DA) and a postoperative computed tomography angiography (CTA) or a contrast enhanced cone beam computed tomography (ceCBCT) with an early Contrast-Enhanced Ultra-Sound (CEUS)

Table III. Description of late stentgraft complications and stentgraft related reinterventions in 100 EVAR patients with a strategy including either an intraoperative 2D-angiogram (2DA) and a postoperative computed tomography angiography (CTA) or a contrast enhanced cone beam computed tomography (ceCBCT) with an early Contrast-Enhanced Ultra-Sound (CEUS)

Tables

Table I. Baseline characteristics and procedural data of 100 EVAR patients with a strategy including either an intraoperative 2D-angiogram (2DA) and a postoperative computed tomography angiography (CTA) or a contrast enhanced cone beam computed tomography (ceCBCT) with an early Contrast-Enhanced Ultra-Sound (CEUS)

Characteristics	Overall (n = 100)	Group 1 (n = 50)	Group 2 (n = 50)	*P* value
Male sex	96 (96%)	47 (94%)	49 (98%)	.425
Age, years	71.6 (±8.4)	72.3 (±8.1)	71.0 (±8.6)	.610
Body mass index, kg/m2	27.6 (±4.7)	27.05 (±4.3)	28.2 (±5)	.255
Tobacco use	89 (89%)	46 (92%)	43 (86%)	.338
Hypertension	89 (89%)	46 (92%)	43 (86.0%)	.523
Coronary artery disease	46 (46%)	22 (44%)	24 (48%)	.841
Cerebrovascular disease	15 (15%)	9 (18%)	6 (12%)	.575
eGFR (ml/min)	83.2 (±21.9)	79.2 (±21.1)	87.2 (±22.2)	.075
Diabetes mellitus	24 (24%)	14 (28%)	10 (20%)	.482

COPD	32 (32%)	16 (32%)	16 (32%)	1
Aneurysm Sac maximum diameter (in mm, mean, SD)	54.5 (± 8.4)	54.4 (±5.8)	54.5 (±10.5)	.972
Intervention duration time (min, mean, SD)	97.22 (± 41.58)	99.00 (± 49.54)	95.51 (± 32.62)	.683
Fluoroscopy time (min, mean, SD)	14.78 (± 15.37)	15.15 (± 20.69)	14.42 (± 7.00)	.814

Group 1: 2D angiogram + Computed tomography angiography;

Group 2: Contrast enhanced cone-beam computed tomography + Contrast enhanced Ultra-Sound.

COPD: Chronic obstructive pulmonary disease; eGFR: Estimated glomerular filtration rate (MDRD). Categorical variables are presented as number of patients (%). Continuous variables are presented as mean (±standard deviation).

Table IIa. Intraoperative findings in 100 EVAR patients with a strategy including either an intraoperative 2D-angiogram (2DA) and a postoperative computed tomography angiography (CTA) or a contrast enhanced cone beam computed tomography (ceCBCT) with an early Contrast-Enhanced Ultra-Sound (CEUS)

Variable	Overall (n=100)	Group 1 (n=50)	Group 2 (n=50)	*P* value
Positive Findings	19 (19%)	5 (10%)	14 (28%)	.041
High-flow endoleak	13 (13%)	4 (8%)	10 (20%)	.150
Type 1A endoleak	6 (6%)	1 (2%)	5 (10%)	.207
Type 1B endoleak	8 (8%)	3 (6%)	5 (10%)	.712
Type 3 endoleak	0	0	0	NA
Iliac Limb Kink	4 (4%)	0	5 (10%)	.066
Renal artery coverage	2 (2%)	1 (2%)	1 (2%)	1
Immediate correction	18 (18%)	4 (8%)	14 (28%)	.024
Type 2 Endoleak	*28 (28%)*	*15 (30%)*	*13 (26%)*	*.824*

Group 1: 2D angiogram + Computed tomography angiography;

Group 2: Contrast enhanced cone-beam computed tomography + Contrast enhanced Ultra-Sound. NA: not applicable

Table IIb. Nature of the immediate revision in 100 EVAR patients with a strategy including either an intraoperative 2D-angiogram (2DA) and a postoperative computed tomography angiography (CTA) or a contrast enhanced cone beam computed tomography (ceCBCT) with an early Contrast-Enhanced Ultra-Sound (CEUS)

Group	***Cas number***	***Positive finding***	***Type of immediate revision***
Group 1	1	Type 1B Endoleak	Left iliac limb extension
	2	LRA partial coverage	Stenting of LRA
	3	Type 1B Endoleak	No revision – conservative approach
	4	Type 1B Endoleak	Right limb angioplasty
	5	Type 1A Endoleak	Coda balloon
Group 2	1	Type 1A Endoleak + Limb kink	Coda balloon + kissing balloon
	2	Type 1B Endoleak	Left iliac limb extension
	3	Type 1B Endoleak	Left iliac limb extension
	4	Type 1A Endoleak + Limb kink	Coda balloon + Left iliac limb stenting (nitinol)
	5	Type 1A Endoleak	Coda balloon

	6	Limb kink	Right iliac limb stenting (nitinol)
	7	Limb Kink	Left iliac limb stenting (nitinol)
	8	Type 1B Endoleak	Right iliac limb extension + HA embolization
	9	Type 1A Endoleak	Coda balloon
	10	Type 1B Endoleak	Right Limb extension
	11	Type 1B Endoleak	Right Limb extension
	12	Limb kink	Right iliac limb stenting (nitinol)
	13	RRA partial coverage	Stenting of RRA
	14	Type 1A Endoleak	Coda balloon

Group 1: 2D angiogram + Computed tomography angiography;

Group 2: Contrast enhanced cone-beam computed tomography + Contrast enhanced Ultra-Sound.

LRA: Left renal artery, HA: Hypogastric artery, RRA: Right renal artery.

Table III. Description of late stentgraft complications and stentgraft related reinterventions in 100 EVAR patients with a strategy including either an intraoperative 2D-angiogram (2DA) and a postoperative computed tomography angiography (CTA) or a contrast enhanced cone beam computed tomography (ceCBCT) with an early Contrast-Enhanced Ultra-Sound (CEUS)

Follow Up	**Total (n = 100)**	***Group 1 (n=50)***	***Group 2* (n = 50)**	***P* value**
Mean follow-up, months (SD)	53.7 (±20.8)	55.4 (±22.4)	52.0 (±19.1)	**.419**
Late High-Flow Endoleaks	11 (11%)	9 (18%)	2 (4%)	**.055**
Ia	7 (7%)	6 (12%)	1 (2%)	
Ib	2 (2%)	2 (4%)	0	
III	2 (2%)	1 (2%)	1 (2%)	
Secondary Limb kink	3(3%)	2 (4%)	1 (2%)	**1**
Secondary Limb thrombosis	4(4%)	2 (4%)	2 (4%)	**1**
Aortic sac enlargement >5mm	16 (16%)	12 (24%)	4(8%)	**.056**
Aortic death	1 (1%)	1 (2%)	0	**1**
Mean Maximum sac diameter at the end of FU (mm)	48.0 (±16.5)	49.8 (±17.5)	46.1 (± 15.2)	**.281**

(SD)				
Stentgraft-related reinterventions	18 (18%)	11 (22%)	7 (14%)	**.435**
Secondary type II Endoleak	22 (22%)	16 (32%)	6 (12%)	**.030**

Group 1: 2D angiogram + Computed tomography angiography;

Group 2: Contrast enhanced cone-beam computed tomography + Contrast enhanced Ultra-Sound.

CI: Confidence Interval. SD: Standard Deviation, FU: follow-up.