

ORIGINAL ARTICLE

Duplex Ultrasound Versus Computed Tomography For Follow Up Of Complications after Evar With Nellix Endograft: First Clinical Experience.

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Summary

Introduction. Contrast-enhanced computed tomography (CT) has become the 'gold-standard' imaging modality for surveillance following EVAR (2, 20). However repeated CT is related to increased cost, risk of contrast nephropathy and radiation exposure. Duplex ultrasound (DUS) is a less invasive but considered less accurate method than CT.

Aim of the study. The aim of this study was to determine the diagnostic accuracy of both imaging modalities for detection of complications in post-EVAR patients where the new generation sac-sealing endograft was used and to compare cost-effectiveness and sensitivity of both imaging modalities.

Methods. Analysis of 23 post-EVAR patients with implantation of new generation sac-sealing endograft device (Nellix®, Endologix, USA) was performed, making a comparison of CT and DUS. Contrast-enhanced computed tomography was taken as the 'gold-standard' investigation. DUS was compared to CT for analysis of sensitivity, post-imaging complications and cost-effectiveness. Statistical analysis of data was performed using v19.0 SPSS software (IBM).

Results. Analysis of CT and DUS studies compared in 23 patients. Both imaging modalities can detect AAA sac dimensions, endoleaks, and graft patency. The cost difference between two imaging techniques is substantial. Our results demonstrate that DUS surveillance during follow-up after EVAR where new generation sac-sealing endograft is used can accurately detect aneurysm size, endoleaks, graft deformations and stenotic or kinked graft limbs while lowering the overall costs of surveillance and eliminating CT related radiation and nephrotoxicity.

Conclusion. CT and DUS imaging can both detect AAA sac dimensions, endoleaks, and graft patency. The cost difference between the two imaging techniques is substantial. Our results demonstrate that in post-EVAR patients where new-generation sac-sealing endograft was deployed DUS surveillance performed by experienced radiologist can accurately detect aneurysm size, endoleaks, graft deformations and stenotic or kinked graft limbs while lowering the overall costs of surveillance and avoiding CT-related complications.

Key words: abdominal aortic aneurysm; endovascular aneurysm repair; aneurysm sac sealing device; duplex ultrasound; computed tomography.

INTRODUCTION

Endovascular aneurysm repair (EVAR) was first described in 1991 and is associated with a lower short- and mid-term morbidity and mortality (13, 14). However, such complications as endoleaks, endograft migration and deformations require life-long post-EVAR surveillance. The importance of these long-term risks is highlighted by recently presented data from the DREAM trial that shows greater 5-year post-discharge mortality in patients treated by EVAR compared with those undergoing open aneurysm repair (14). Endoleak in particular carries great significance, as it is predictive of post-EVAR rupture (27), and therefore, post-EVAR endoleak surveillance has become mandatory. At present contrast-enhanced spiral computed tomography (CT) angiography with specialized 3D reconstruction is considered as the gold standard for endoleak surveillance (1, 20). CT angiography is efficient in defining the anatomy of aneurysm sac, detection of endoleak and

its classification but is associated with adverse factors including high dose of radiation, contrast nephrotoxicity and associated with contrast allergies, and high cost (5, 6, 23, 26). However upon development of new device technologies, and in particular introduction of new generation sac-sealing endograft device (12), DUS may be a good alternative to CT for the follow-up of EVAR patients. This modality is less expensive and does not carry the risks associated with ionizing radiation or contrast induced nephrotoxicity, however the sensitivity and specificity of DUS in comparison to CT in post-EVAR follow-up have been argued.,

AIM OF THE STUDY

The aim of this research paper is to update the sensitivity and specificity values of DUS in comparison to CT for patient follow-up after EVAR with new generation sac-sealing endograft.

MATERIALS AND METHODS

Nellix endograft is a new endoluminal sac-sealing device, which is designed to treat aortic aneurysms by obliterating the aneurysm sac, thus eliminating the potential endoleak space, while maintaining normal blood flow to the lower extremities. The endograft blood-flow lumens are supported with the balloon-expandable endoframes surrounded by the polymer-filled endobags, without the need for proximal and distal fixation. Full details of the device and clinical procedure are described in our previous reports (12, 17, 18).

23 post-EVAR (Nellix®, Endologix, USA) patients have been prospectively followed-up upon discharge, at six, twelve and twenty-four months at Pauls Stradins Clinical University Hospital (Riga, Latvia). The approval of ethical committee for the study was obtained and all patients have signed informed consent forms.

Two imaging modalities were used for post-procedural follow-up: DUS (Phillips iU22 xMatrix with multifrequency probe 2-4 MHz) with multifrequency probe (2-4, 12 MHz) and 64-layer CT (General Electric LightSpeed). DUS protocol included the assessment of AAA external diameter measurements in B-mode before and after EVAR in AP and transversal planes. Colour Doppler (spectral analysis, flow velocity) was used for stent graft, proximal neck and iliac arteries assessment. Contrast-enhanced computed tomography was taken as the 'gold-standard' investigation. Standard duplex ultrasound was compared to CT. Analysis was performed by two experienced radiologists participating in the trial. Statistical analysis was done using SPSS software, v19.0 (IBM).

RESULTS

All 23 post-EVAR patients have been prospectively followed up using DUS and CT imaging modalities. Four patients have been followed up for the period of six months, seven patients for the period of twelve months and twelve patients for the period of twenty-four months.

Measurements compared between CT and DUS are provided in Table 1. All separately analysed parameters are provided in Figures 1-7. AAA size correlation between DUS and CT in dynamical follow-up has provided good correlation between two imaging modalities ($r_2=0.9379$, $r=0.9684$, $p<0.001$) (Figure 1) with DUS taking considerably shorter time of assessment (22 ± 8 min, CT 94 ± 28 min; $p<0.001$).

In one patient both DUS and CT detected type 2 endoleak on early follow-up. Another patient had a graft stenosis more than 50% detected by both DUS and CT, however DUS allowed more precise values by flow velocity determination.

DUS was found to be a considerably more cost-effective method (DUS 18.50 LVL and CT 146.00 LVL).

DISCUSSION

Although previous authors have compared DUS and CT scans for surveillance after EVAR, CT scan remains the 'gold standard' for assessment of aneurysmal diameter,

detection of endoleak, and graft patency (2, 19, 20, 22). The benefits of CT as an imaging modality compared with DUS imaging include that it is highly reproducible, less influenced by body habitus, and offers faster image acquisition. However, among the limitations of CT are repeated radiation exposure, potential contrast-related complications, including allergy and renal insufficiency, and high costs (22, 23, 26).

AAA size reduction over time has been used as a surrogate marker for successful exclusion, thrombosis of the aneurysm sac, and decreased risk of rupture (23, 31). Many authors have shown that CT and DUS imaging are equivalent for measuring AAA sac size after EVAR (2, 19, 20).

Endoleak detection by DUS imaging in our study was as or more accurate than by CT, which is similar to the results provided by other authors (1, 27). Moreover, we believe that DUS imaging is more accurate than CT in detecting endograft related complications such as migration, deformation, kinking, and stenosis. Colour-flow images give physiologic as well as anatomic information that CT does not. We believe that DUS imaging can almost always accurately determine if structural defects are causing a flow-related problem and graft migration.

It was shown in previous studies that cost savings is substantial when DUS imaging alone is used for midterm and long-term follow-up versus the accepted approach that requires multiple CT scans (5, 6, 7, 22, 24). Kim *et al* estimated that current reimbursement for long-term EVAR surveillance and secondary procedures using traditional protocols average a net loss of \$2235 per patient (16). Although hospital system charges vary by institution, in the setting of Latvian challenging economy the saving of 127.50 LVL (respectively 182.14 Euro). Inflation and decreasing reimbursements over time affect cost and charges, which makes a true cost analysis difficult. We performed our cost analysis using 2008 health care system charges to reflect the potential cost savings for the current economic climate and with today's health care system, which is significantly different than that of 1998, when our study began. Regardless, the cost savings are substantial when CT and DUS are compared for EVAR surveillance.

This study has some potential weaknesses. DUS imaging is more operator-dependent and has more interobserver variability than CT and is significantly affected by the patient's body habitus and fasting status. DUS imaging with contrast may prove to be especially useful for obese patients but is not necessarily any better in most patients, especially considering the extra cost and more difficult technique required to use this method.

The accuracy of DUS imaging to detect post-EVAR complications may vary depending on different graft designs, however, in our experience with new generation sac-sealing endograft we found that DUS is a better or at least as sensitive as CT in post-EVAR follow-up.

CONCLUSIONS

Although DUS is often used to augment CT scanning in post-EVAR follow-up, this evidence suggests that it is suitable for sole use in graft complications detection after EVAR. Our study confirms that DUS is a safe and sensitive modality for endoleak detection, graft migration and deformations detections, potentially obviating the need for patient exposure to high radiation doses and nephrotoxic agents in recurrent CT imaging. Further studies are required to understand whether DUS can completely replace CT imaging in the follow-up of patients after EVAR with new generation sac-sealing device.

Conflict of interest: None

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Table 1: Measurements compared between CTA and DUS

CTA	DUS
Transverse luminal size in the maximum stent graft deformation area	Maximal systolic blood flow (PSV) in the area of maximum stenosis
Luminal stenosis of stent graft in the maximum stent graft deformation area	Spectral blood flow in the external iliac artery
Angular deformation of the stent graft	

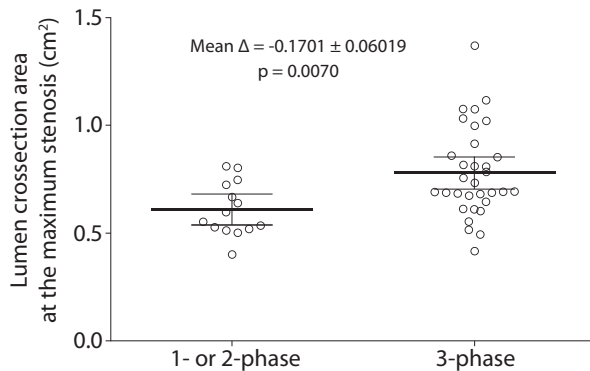


Fig. 1. The analysis showing that patients with 3-phased blood flow had a stent graft lumen approximately 17 mm² larger than those patients with a changed spectrum

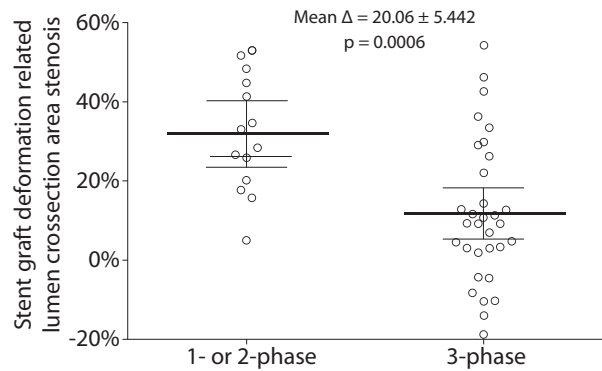


Fig. 2. Patients with unchanged blood flow spectrum had stenosis of stent graft most of the times < 20%. The average difference between registered stent graft stenosis in patients with changed and unchanged blood flow spectrum comprised 20%

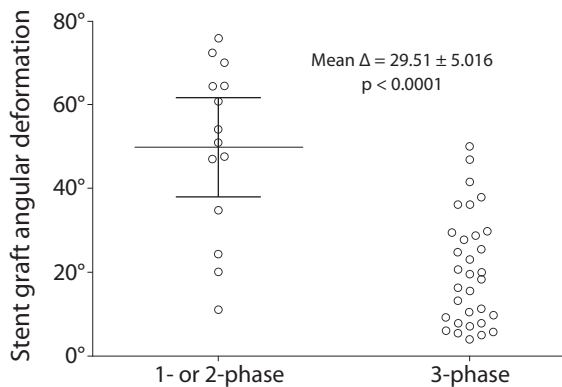


Fig. 3. Patients with changed blood flow spectrum had angular deformation >30° than those patients with 3-phased blood flow spectrum

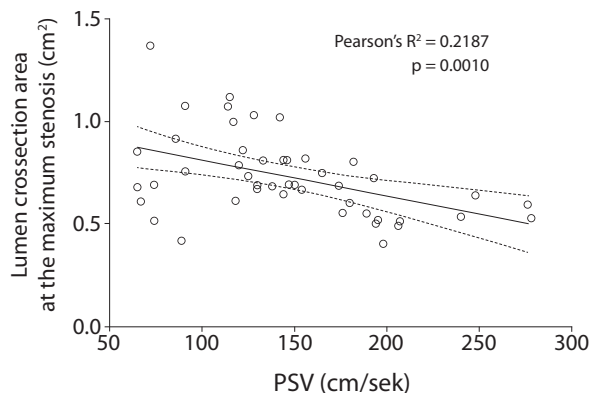


Fig. 4. Correlation between luminal cross-sectional area at the level of maximum stenosis and PSV is weakly expressed. Pearson's correlation coefficient is ~0.22, however this correlation is statistically significant ($p=0.001$)

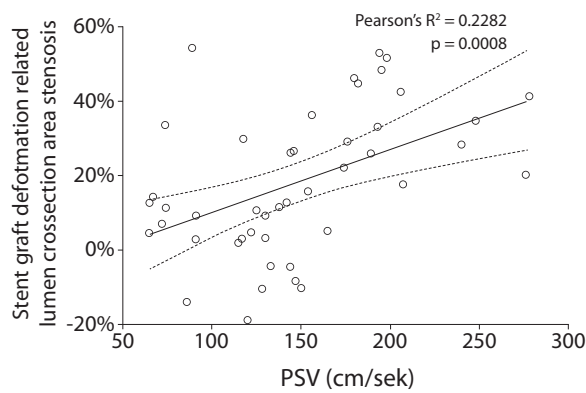


Fig. 5. Similar correlation was found also between cross-sectional stenosis and PSV

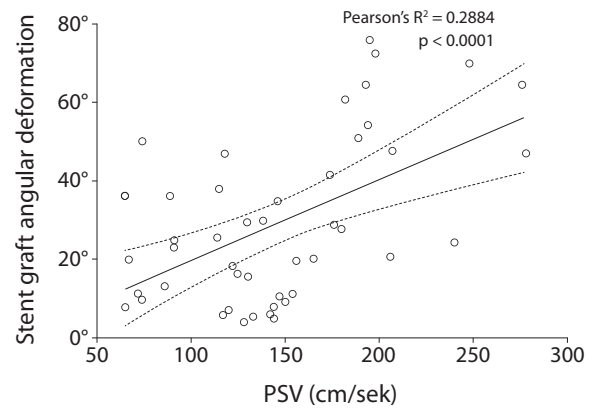


Fig. 6. Correlation of stent graft angular deformation with PSV approximated 0.3 with high statistical significance ($p < 0.0001$)

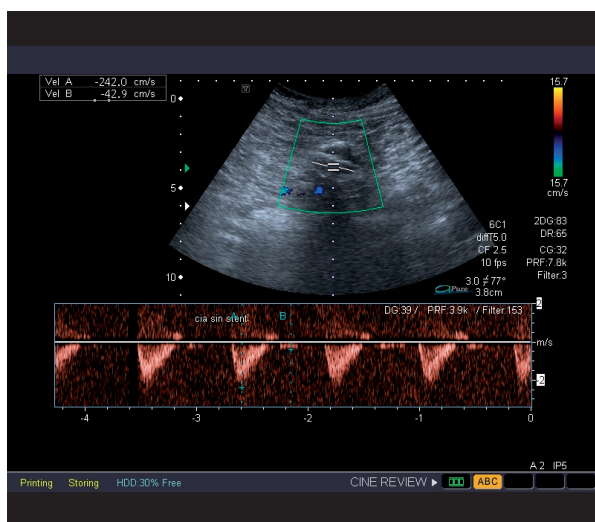


Fig. 7. Patient DUS and CT image in post-EVAR follow up with graft stenosis detected (242 cm/s in DUS equal to approximately 60% stenosis)