

## Original Article

## TO DETERMINE THE FREQUENCY OF CONCORDANCE BETWEEN DUPLEX ULTRASOUND SCAN AND CT SCAN IN DETECTION OF ENDO-LEAK IN PATIENTS FOLLOWING EVAR

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**Objective:** To determine the frequency of concordance between Duplex ultrasound scan and CT scan in detection of endo-leak in patients following EVAR.

**Methods:** This retrospective, descriptive study was conducted at Department of Vascular Surgery, Mater Misericordiae University Hospital Dublin, Ireland. The study was conducted from 14th July, 2014 to 13th July, 2016. Age range 50-70 years were included in the study. All patients who had Endovascular Aneurysm repair (EVAR) were followed up in six months' time using Duplex ultrasound scan and Computerized Tomography (CT). The detection of endo-leak on Duplex ultrasound scan and confirmed by Computerized Tomography (CT). The concordance between the two investigations was estimated by calculating the overall percentage of agreement (concordance) and the  $\kappa$  coefficient. The follow up imaging results were collected by using PACS (Picture archiving and communication system). All the data entered and analyzed using computer software SPSS version 17. Mean and standard deviation was calculated for quantitative variables like Age and BMI. Frequency and percentages were calculated for qualitative variables like gender, co morbidities like hypertension, DM, smoking status and concordance. Effect modifiers gender, BMI and co morbidities DM and HTN were controlled by stratification of data.

**Results:** Total 113 patients were enrolled in this study. In the study, mean age was 68 years with the standard deviation of 3.09. 70.8% of patients were males and 29.2% were females. 46.9% of patients had BMI of 26-30 BMI and 34.5% had BMI >30. Among the total patients, 64.6% patients were diabetic, 77% hypertensive and 88.5% patients were smokers. 70.8% of endo-leaks were diagnosed by Duplex ultra-sound scan, while 77.8% of endo-leaks were diagnosed by CT scan. Cohens kappa value is 0.91 which shows strong association. Concordance between Duplex ultra-sound scan and CT scan calculated as 95.6%.

**Conclusions:** This study concluded that Duplex ultra-sound scan can safely replace CT scan as a surveillance modality. Duplex ultra-sound scan can be used as a primary long-term surveillance imaging modality for patients with post EVAR and it will be more economical for patients without any loss of scan accuracy.

**Keywords:** endovascular aneurysm repair, endo-leak, concordance, comorbidities.

### Introduction

Endovascular aneurysm repair (EVAR) is a type of endovascular surgery used to treat aneurysm of the aorta, most commonly an abdominal aortic aneurysm (AAA). The procedure involves the placement of an expandable stent within the aorta to correct aortic aneurysm without operating directly on the aorta. In 2003, EVAR bettered open aortic surgery as the most common technique for repair of AAA.<sup>1,2</sup> Studies that assign aneurysm patients to treatment with EVAR or traditional open surgery have demonstrated fewer early complications with the minimally-invasive approach. Some studies have also observed a lower mortality rate with EVAR.<sup>3,4</sup>

An endo-leak is the most prevalent and disastrous complication of EVAR and is found in 30-40% of

patients intraoperatively (seen on the on-table angiogram after stent deployment), and in 20-40% during follow-up.<sup>5</sup> Endo-leaks are characterized by persistent blood flow within the aneurysm sac following endovascular aneurysm repair (EVAR). Normally the aortic stent-graft used for EVAR excludes the aneurysm from the circulation by providing a conduit for blood to bypass the sac.<sup>6</sup> Endoleak may become evident intra-operatively, years down the track, or anywhere in between. Thus, endovascular stent placement requires routine surveillance to enable detection of potential complications.

Computed tomographic (CT) angiography is the most accepted investigative tool for monitoring patients with endografts as it yields comprehensive images that allows us to determine the diameter of the

aneurysm sac, endograft migration, and endoleak presence.<sup>7</sup> Nevertheless, there are two main concerns regarding CT angiography radiation and contrast agent nephrotoxicity both of which are crucial in patients who will require lifelong surveillance.<sup>8, 9, 10</sup> Although magnetic resonance angiography can yield follow-up information but it must be used with caution in patients with a glomerular filtration of less than 30 mL/min because of the risk of nephrogenic systemic fibrosis, which is a complication that is also related to cumulative contrast agent exposure.<sup>11</sup> Color Doppler (CD) ultrasonography (US) is the noninvasive alternative for follow-up, but the reported sensitivity in endoleak detection ranges from 42% to 97%. First-generation US contrast agents did not improve the CD US results, and reported data did not support their use in EVAR follow-up.<sup>12</sup> Second-generation US contrast agents have an expanded diagnostic capability. These agents consist of gas microbubbles (perfluorocarbon or sulfur hexafluoride) encapsulated by a phospholipid shell that have nonlinear behavior when interrogated with a low-mechanical-index ultrasound beam, resulting in the emission of harmonics that can be detected with specific contrast software. The use of a low mechanical index causes minimal microbubble disruption, enabling real-time blood flow investigation over several minutes.<sup>13</sup> These US contrast agents can be used safely in patients with impaired renal function. The data reported at EVAR show good specificity and sensitivity, and they show that the technique can provide angiodynamic information.<sup>14</sup>

## Methods

A retrospective, descriptive study carried out at Vascular Surgery Department Mater Misericordiae University Hospital, Dublin, Ireland from 14th July, 2014 to 12th January, 2015. Assuming concordance as 75% between duplex ultra-sound scan and CT Power 75%, confidence level 95%, margin of error 8%, total Sample Size (n) was calculated to be 113. Convenience sampling was done (all data available was extracted from computerized records). All patients having aneurysm (non-rupture) and undergoing elective endovascular aneurysm repair between ages of 50-70 years were included in the study. However, patients who failed to get concurrent scans were excluded.

Data of all Patients fulfilling the inclusion criteria

was included in this study. Hospital patient center data base is used to find out the patients. All patients who had Endovascular Aneurysm repair (EVAR) and followed up in six months' time using Duplex ultrasound scan and Computerized Tomography (CT). The detection of endo-leak on Duplex ultrasound scan and confirmed by Computerized Tomography (CT) as per operational definition was taken as concordance. The follow up imaging results was collected by using PACS (Picture archiving and communication system) and Patient center with the help of medical record number.

All the data entered and analyzed using computer software SPSS version 17. Mean and standard deviation were calculated for quantitative variables like Age and BMI. Frequency and percentage were calculated for qualitative variables like gender, comorbidities like hypertension, DM, smoking status and concordance. Effect modifiers gender, BMI and co morbidities DM and HTN were controlled by stratification of data. Post stratification chi square test were applied. A p value < 0.05 was considered statistically significant.

## Results

There were total 113 cases that were enrolled in this study. Mean age found in the study was 68 years with the standard deviation of 3.09. There were 70.8% male patients (80) and remaining 29.2% were female (30). When BMI was checked most of the patients were overweight that is 46.9% cases fall in 26-30 BMI category and 34.5% were found obese that is BMI is >30. Among the total cases 64.6% patients were diabetic, 77% were hypertension, 88.5% patients were smokers. 70.8% endo-leaks were diagnosed by Duplex Ultra-Sound Scan while 29.2% were not. While 77.8% endo-leaks were diagnosed by CT scan. Cohen's kappa value was 0.91 that showed strong association. Sensitivity of Duplex ultrasound Scan was 100%,

**Table-1:** Distribution for endo-leak on duplex ultra sound.

Endo-leak	Frequency (%)
Yes	80 (70.8%)
No	33 (29.2%)
<b>Total</b>	<b>113 (100)</b>

**Table-2:** Distribution for endo-leak on CT.

Endo-leak	Frequency (%)
Yes	85 (75.2%)
No	28 (24.8%)
<b>Total</b>	<b>113 (100)</b>

while specificity 61.7%, PPV was found as 35%. Concordance between Duplex ultrasound scan and CT scan calculated as 70.8% for the presence of endo-leak and 24.8% for the absence of endo-leak between both radiological procedures.

**Table-3:** Endo-leak on Duplex Ultra-Sound scan.

Endo-leak on Duplex Ultra-Sound Scan	Endo-leak on CT (Yes)	No	Total
Yes	80	0	80
No	05	28	33
<b>Total</b>	<b>85</b>	<b>28</b>	<b>113</b>

**Table-4:** Stratification with respect to gender, hypertension, smoking status and BMI for Duplex ultrasound scan.

Characteristic	Yes	No	Total	P-value
<b>Gender</b>	59	21	80	
	21	12	33	0.41
	80	33	113	
<b>Hypertension</b>	65	21	87	
	14	12	26	0.54
	80	33	113	
<b>Smoking Status</b>	73	33	100	
	07	27	13	0.60
	80	33	113	
<b>BMI</b>	09	0	9	
	12	0	12	
	31	22	53	0.55
	28	11	39	
	82	33	113	

## Discussion

Color Duplex Ultrasound (CDUS) is an inexpensive, harmless, non-invasive and widely available imaging modality which is the investigation of choice for the screening and surveillance of AAA prior to intervention. Aneurysm sac size and blood flow within the residual aneurysm sac can be determined using CDUS which could therefore be capable of replacing CT as the primary surveillance tool following EVAR. Recent guidelines from the European Society for Vascular Surgery state that CDUS is a safe and sensitive method of endo-leak detection, but caution that it should not be a standalone modality for follow up after EVAR. Although initial reports comparing duplex ultrasound scan with CT suggested that sensitivity and specificity were comparable. There were total 113 cases that were enrolled in this study. Mean age found in the study was 68 years with the standard deviation of 3.09. These results are inconsistent with research conducted by Greenhalgh et al.,<sup>1</sup> illustrated the mean age of 70 years while most of

the studies like Chahwan et al.,<sup>15</sup> showed the mean age in range of 65-75 years. In the study 70.8% cases were found as male and remaining 29.2% were female. Chahwan et al.<sup>15</sup> calculated 76.9% of patients as male while 23.1% patients as females.

In this study most of the patients were overweight, that is 46.9% cases fell in 26-30 BMI category and 34.5% were found obese with BMI >30. Park et al.<sup>16</sup> in their research evaluated that obesity was the one of the most important factor that leads to the procedures like EVAR. In this study, 64.6% patients were found diabetic. Committee (2005)<sup>17</sup> in a study showed 68% DM patients that underwent EVAR. 77% of participants were hypertensive, 88.5% patients were smokers and 11.5% patients were non-smokers. Gidlund et al.<sup>18</sup> showed significant association of hypertension with EVAR patients. In this study, 70.8% endo-leaks were diagnosed by Duplex Ultra-Sound Scan while 29.2% were not. While 77.8% endo-leaks were diagnosed by CT scan. Cohen's kappa coefficient was 0.91 that shows strong association. Sensitivity of Duplex ultra-sound scan was 100%, while specificity was 61.7%. PPV was found as 35%. Gray et al.<sup>19</sup> in a research showed that CDUS was found to have a sensitivity of 100% and a specificity of 85.7% in the detection of endo-leaks. The positive predictive value was 28.7% and negative predictive value 100%. In this study, there were no endo-leaks which were detected on CT but missed on CDUS. Manning and colleagues<sup>20</sup> in a series of 132 patients reported values similar to our own, documenting a 45% positive and 94% negative predictive value for CDUS when compared to CT for postoperative surveillance following EVAR. Specificity of CDUS for endo-leak detection was 67% when compared with CTA and sensitivity for CDUS was 86%. Their conclusions was broadly similar, suggesting CDUS as a first line screening tool which allowed selection of a smaller cohort of patients in whom CT was necessary.

## Conclusion

It is concluded that Duplex ultra-sound scan safely replace CT scan and it can be considered as a primary long-term surveillance imaging modality for patients with post EVAR that may be economical for patients without any loss of scan accuracy. However, abnormalities that may result in Duplex ultra-sound scan can be further proceeded to CT scan in a very small group of patients.

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## References

- 1- Greenhalgh, R. M., and E. V. A. R. The. "Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomized controlled trial." *The Lancet*; 2004; 364.9437: 843-848.
2. Greenhalgh RM, Powell JT. "Endovascular repair of abdominal aortic aneurysm". *N. Engl. J. Med*; 2008;.358 (5): 494501.
3. Park, B., Dargon, P., Binette, C., Babic, B., Thomas, T., Divinagracia, T., Menzoian, J. O. (2011). Obesity is not an independent risk factor for adverse perioperative and long-term clinical outcomes following open AAA repair or EVAR. *Vascular and endovascular surgery*, 45(7), 607-613.
4. Lederle FA, Freischlag JA, Kyriakides TC, Padberg Jr FT, Matsumura JS, Kohler TR, et al. Outcomes following endovascular vs open repair of abdominal aortic aneurysm: a randomized trial. *JAMA*; 2009;302(14):1535e42.
5. Cao, P., De Rango, P., Verzini, F., &Parlani, G. (2010).Endoleak after endovascular aortic repair: classification, diagnosis and management following endovascular thoracic and abdominal aortic repair.*Journal of Cardiovascular Surgery*, 51(1), 53.
6. Bashir, M. R., Ferral, H., Jacobs, C., McCarthy, W., & Goldin, M. (2009).Endoleaks after endovascular abdominal aortic aneurysm repair: management strategies according to CT findings. *American Journal of Roentgenology*, 192(4), W178-W186.
7. Stavropoulos SW, Charagundla SR. Imaging techniques for detection and management of endoleaks after endovascular aortic aneurysm repair. *Radiology* 2007;243 (3):641655.
8. Brenner DJ, Hall EJ. Computed tomography: an increasing source of radiation exposure. *N Engl J Med* 2007;357(22):22772284.
9. De Jong PA, Mayo JR, Golmohammadi K, et al. Estimation of cancer mortality associated with repetitive computed tomography scanning. *Am J Respir Crit Care Med* 2006;173(2):199203.
10. Mills JLSr, Duong ST, Leon LR Jr, et al. Comparison of the effects of open and endovascular aortic aneurysm repair on long-term renal function using chronic kidney disease staging based on glomerular filtration rate. *J VascSurg* 2008;47(6):11411149.
11. Prince MR, Zhang HL, Prowda JC, Grossman ME, Silvers DN. Nephrogenic systemic fibrosis and its impact on abdominal imaging. *Radio Graphics* 2009;29(6):15651574.
12. McWilliams RG, Martin J, White D, et al. Detection of endoleak with enhanced ultrasound imaging: comparison with biphasic computed tomography. *J EndovascTher* 2002;9(2):170179.
14. Claudon M, Cosgrove D, Albrecht T, et al. Guidelines and good clinical practice recommendations for contrast enhancedultrasoundultrasound (CEUS) - update 2008. *Ultraschall Med* 2008;29(1):2844.
15. Chahwan, Santiago, et al. "Elective treatment of abdominal aortic aneurysm with endovascular or open repair: the first decade." *Journal of vascular surgery*; 2007;45.2: 258-262.
16. Park, B., Dargon, P., Binette, C., Babic, B., Thomas, T., Divinagracia, T., . . .Menzoian, J. O. (2011). Obesity is not an independent risk factor for adverse perioperative and long-term clinical outcomes following open AAA repair or EVAR. *Vascular and endovascular surgery*, 45(7), 607-613.
17. Committee, L. R. o. E. P. (2005). Lifeline registry of endovascular aneurysm repair: long-term primary outcome measures. *Journal of Vascular Surgery*, 42(1), 1-10.
18. Gidlund, K. D., Wanhainen, A., &Björck, M. (2011). Intra-abdominal hypertension and abdominal compartment syndrome after endovascular repair of ruptured abdominal aortic aneurysm. *European Journal of Vascular and Endovascular Surgery*, 41(6), 742-747.
19. Gray, C., et al. "Use of colour duplex ultrasound as a first line surveillance tool following EVAR is associated with a reduction in cost without compromising accuracy." *European Journal of Vascular and Endovascular Surgery*; 2-12: 44.2; 145-150.
20. Manning, Brian J., et al. "Duplex ultrasound in aneurysm surveillance following endovascular aneurysm repair: a comparison with computed tomography aortography." *Journal of vascular surgery*;2009: 49.1: 60-65.