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The Value of Duplex Ultrasound versus Contrast Enhanced CT Scan in the Follow-up of Endoluminally Repaired Abdominal Aortic Aneurysm: a Blinded Comparison

Kamal D M, FRCS(C)* Steinmetz O K, FRCS(C)** Obrand DI, FRCS(C)***

Objective: 1) To compare the accuracy of Duplex ultrasound to contrast-enhanced CT scan with respect to aneurysm sac diameter measurement and endoleak detection in patients with endovascular abdominal aortic aneurysm repair (EVAR). 2) To evaluate whether contrast-enhanced ultrasound (Levovist) improves the accuracy of color duplex ultrasound for the detection of endoleaks.

Setting: Two McGill University Teaching Hospitals (Royal Victoria & Jewish General) in the period between February 1998 and December 2000.

Design: Prospective, Comparative, Data collection and analysis.

Method: Fifty-one patients who had endoluminal repair of infrarenal abdominal aortic aneurysm were evaluated concurrently with both contrast enhanced CT scan and duplex ultrasonography. By the end of the study period, 89 concurrent results were available for diameter measurements and 86 for endoleak detection.

In addition, at one hospital 38 contrast enhanced (Levovist) duplex examinations were performed after the initial non-enhanced duplex evaluation was completed. The findings of the contrast enhanced examination were compared to the non-enhanced examination.

Anteroposterior (AP) and transverse (T) aneurysm diameters were compared between CT and duplex ultrasound. The presence or absence of endoleak was also defined by both modalities.

Result: Diameter measurements were consistently larger by CT [mean (SD) CT - duplex AP diameter difference (cm) = 0.25 (0.34) cm, p=0.001]. Changes in aneurysm diameters between serial scans were comparable between CT and duplex.

For endoleak detection, the sensitivity, specificity, negative and positive predictive values for duplex ultrasound were 50%, 86.7%, 61.9%, and 82% respectively when compared to contrast enhanced CT. (Kappa coefficient (95% confidence interval) = 0.4 (0.2-.06), (P <0.05).

There were 21 discrepancies in endoleak detection between the 2 imaging modalities. Three discrepancies were found in aneurysms that had increased in size from baseline and were detected by CT scan alone. The detection of endoleaks by duplex was not influenced by the addition of ultrasound contrast.

Conclusion: Duplex ultrasonography had comparable accuracy with CT for evaluation of aneurysm diameter post EVAR. There was only moderate agreement between duplex and CT for detection of endoleaks. CT was more reliable for detecting endoleaks associated with aneurysm growth. Contrast enhanced duplex did not change the accuracy of duplex ultrasonography for detection of endoleaks.

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* Consultant Vascular Surgeon
Bahrain Defense Force Royal Medical Services
Kingdom of Bahrain
** Chief-Vascular Surgery
Department of surgery
McGill University Health Centre
Royal Victoria Hospital & Montreal General Hospital
*** Chief-Vascular Surgery
Department of Surgery
Jewish General Hospital
Canada

Endoluminal repair of abdominal aortic aneurysm (AAA) was first described by Parodi in 1991 and has now become established as an alternative to open surgical repair in patients at high risk for open repair of AAA because of the reduced peri-operative morbidity and mortality[1,2,3]. Although this procedure is less invasive, requires few or no blood transfusions, and is associated with a decreased length of hospitalization, control of the aneurysm sac is uncertain, and the possibility of early or delayed complications always exists. These complications include graft failure, migration, kinking, thrombosis, and the development of endoleak. The latter is the "Achilles heal" of this procedure and is defined as "persistent blood flow into the aneurysmal sac from within or around the graft (graft related) or from patent collateral arteries (non-graft related)"[4]. Although not all endoleaks result in aneurysm growth, it is clear that some types of endoleak can lead to increase pressure within the native aneurysm sac leading to its expansion and eventual rupture[5-7]. The incidence of EL reported in the literature varies widely (4-49%) and is dependent on factors related to patient selection, technical factors and duration of graft placement[4,8-15]. Aneurysms that continue to enlarge after endovascular repair are thought to be at risk of rupture and further investigations are needed to detect and treat the endoleak. Thus, unlike conventional open aortic aneurysm repair, postoperative follow-up for EVAR patients is imperative, and likely needed for the remainder of their life. It has been reported that approximately 25% of patients will undergo some type of secondary intervention[16].

The main objectives of surveillance post EVAR include determining the aneurysm size, screening for endoleaks, and assessing changes in the configuration of the endograft. Currently, the two most common options are Duplex ultrasound and contrast enhanced CT scan. Contrast enhanced CT scan has emerged as the postoperative follow-up study of choice after EVAR and is reported to be highly sensitive in detecting endoleaks and provide accurate and reproducible aneurysm diameter measurements[17,18]. Its limitations, however, include:

1. Relatively invasive and expensive.
2. Repeated exposure to radiation.
3. Risk of contrast nephropathy - in an already vulnerable population - as well as contrast hypersensitivity.

Duplex ultrasound on the other hand, is a procedure that is simple, inexpensive, and complication-free. It is a well established dependable tool for screening the population at risk for abdominal aortic aneurysm development and for surveillance of aneurysm diameters [19-22]. However, it is operator dependent and its utility will depend on how accurately it correlates with CT scan for postoperative aneurysm sac diameter measurements, endoleak, and graft related complications. Contrast-enhanced ultrasound using (Levovist) is claimed to enhance sensitivity of routine Duplex in detecting endoleaks and had been reported to be comparable or even superior to Contrast CT for endoleak detection[23,24].

The aim of this study is to determine:

1. The accuracy of duplex ultrasound as compared to contrast CT scan with respect to aneurysm sac diameter measurements and endoleak detection in the follow-up of patients with endovascular repair of abdominal aortic aneurysm.
2. The value of contrast enhanced ultrasound (Levovist) compared to routine duplex ultrasound for endoleak detection.

METHOD

This prospective blinded study was performed between February 1998 and December 2000. During the study period, 63 patients (12 patients were excluded) underwent successful endoluminal repair of AAA at the McGill University Health Center were prospectively evaluated by contrast enhanced computed tomography scan and duplex ultrasound examinations in their postoperative follow-up and were included in this study. For both imaging modalities, the maximum antero-posterior (AP) and transverse (T) diameters of the aneurysm sac were determined. The presence or absence of endoleak was also determined. If an endoleak was demonstrated, an attempt was made to classify it. At one hospital, after completion of duplex study, contrast-enhanced ultrasound was performed after injecting levovist intravenously, and the aneurysm sac was thoroughly evaluated for the presence or absence of endoleak. Quality of Duplex examinations was rated as good, limited, or poor. The radiologist performing the CT was blinded to the ultrasound result and vice versa. Personal characteristic data were obtained by the primary investigator from patients' hospital charts during the period of the study.

The following patients/scans were excluded from the study:

1. Patients who were followed-up elsewhere.
2. Patients who were followed-up by CT scan only (no Duplex performed).
3. If the concurrent (paired) study was done more than one month apart.
4. If the CT scan was done without contrast, it was excluded from endoleak detection comparison.

Imaging Protocols:

CT: There was a slight difference in the CT scan and ultrasound protocols in the two hospitals. At one hospital, the contrast enhanced CT scan was performed using a Picker CT Twin Flash Spiral Helical Unit, a pitch of two, slice thickness of 3.2 mm, with an increment of 1.6 mm. A total intravenous contrast of 150 cc was injected at a rate of 4 cc/second. Image acquisition started 15-25 seconds after contrast injection. Aortic aneurysm sac was measured in both the axial and the aortic plane. At the other hospital, the CT scan was performed using a Seimens Plus4 machine, a pitch of one 10 x 10 mm, or a pitch of one and a half 0.8 x 1.2 mm, reconstruction every 0.7 mm. A total of 100-150 cc of intravenous contrast was injected with a power injector at a rate of 1.5 cc/second. Image acquisition started 60-70 seconds after contrast injection. Aortic aneurysm sac was measured in both the axial and the aortic plane. An endoleak was defined as persistent blood flow between the stent graft and the wall of the aneurysm. This was further divided into a type-I endoleak when it appeared to be from leakage around the proximal or distal ends of the graft, type-II when the blood flow in the native aneurysmal sac seemed to be caused by collateral vessels from lumbar arteries and/or inferior mesenteric artery, and type-III at the junctions between modular stents[4].

Duplex Ultrasound: There were no special dietary instructions to the patients to follow for the day before the examination in either hospital. “ATL 5000”, and occasionally “Toshiba 6000” machines were used. Ultrasounds were done with a 3 MHz curved probe or a 10 MHz linear probe depending on the body habitus of the patient. Gray scale was used for aneurysm diameter measurements (in the plane of the aorta). A color Doppler (duplex) was used for detection of endoleaks, characterized by detection of a colour and spectral signal outside the limits of the prosthesis.

Levovist:

Levovist (used in one of the 2 hospitals) was injected after the completion of the standard ultrasound examination and the above steps for endoleak detection were repeated.

Statistical methods:

Using Pearson's correlation, alpha = 0.05 (level of significance), beta = 0.2, the sample size was estimated to be n = 75 (number of concurrent studies). The Paired Student T-test was used to compare differences in aneurysm diameter measurements, Pearson product-moment correlation coefficients for correlation between Duplex and CT scan over time, and Kappa statistics was utilized to compare the level of agreement between imaging modalities in the study[25,26].

RESULT

Sixty-three consecutive patients successfully underwent EVAR (Figure 1), 12 patients were excluded. The remaining 51 patients had a total of 100 paired studies, 11 of which were excluded from analysis because more than one month had elapsed between the concurrent examinations. Of the 89 paired studies, 3 were excluded from endoleak detection comparison because no contrast was used in CT scan. Table 1 describes the characteristics of the study sample.

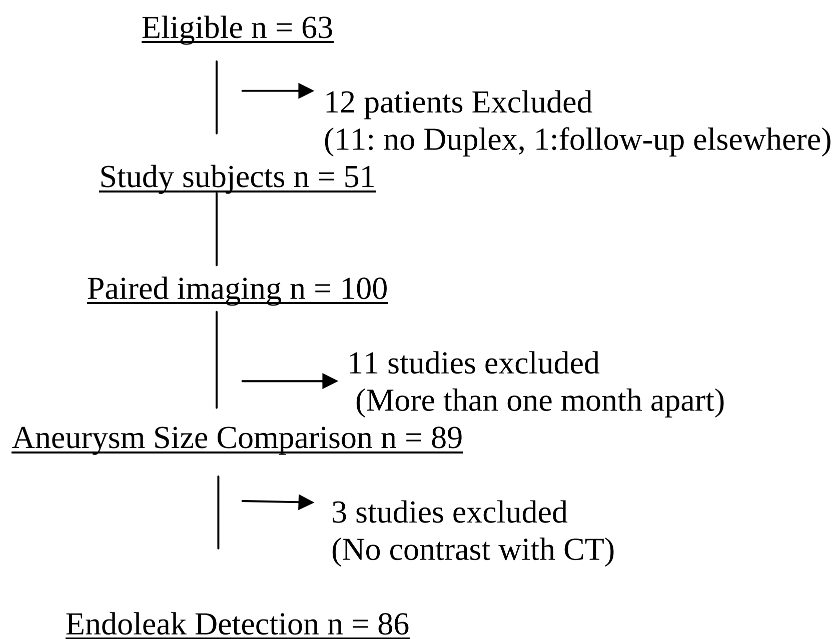

Figure 1: Study Population and Study Sample

Table 1: Personal Characteristics

Variable	N	%
Hospital:		
Royal Victoria	28	54.9
Jewish General	23	45.1
Gender:		
Male	45	88.2
Female	06	11.8
Age (year):		
Mean +/- SD	51	76.6 +/- 7.6
Range		59-92
Obesity	09	17.6
Coronary Artery Disease	33	64.7
Congestive heart failure	04	07.8
Hypertension	30	58.8
Diabetes Mellitus	04	07.8
Chronic Obstructive Pulmonary Disease	14	27.5
Dyslipidemia	13	25.5
Remote Cerebro-vascular Accident	08	15.7
Cigarette smoking	17	33.3
Chronic Renal Failure	4	07.8
Graft type:		
Vanguard	19	37.3
Talent	31	60.8
Zenith	01	02.0
Graft Morphology:		
Bifurcated	46	90.2
Aorto Uni-Iliac	05	09.8

When comparing aneurysm diameters, we found that the mean aneurysm diameter measured by CT scan is greater than those measured by ultrasound by 2.5 mm (+/- 3.4 standard deviation) (Table 2a). There was no significant difference in aneurysm diameter measurements when the analysis was stratified by obesity, hospital, and quality of ultrasound. There was high correlation between the two modalities when comparing the change in aneurysm diameters measurement between the first and second (r for AP = 0.7, r for T = 0.3), and the second and third follow-up examinations (r for AP = 0.9, r for T = 0.8) (Table 2b). Due to the fact that aneurysm tortuosity makes it difficult to rely on the T diameter, we consider the AP diameter to be more accurate than the T diameter and therefore, more reliable and clinically relevant.

Table 2a: CT versus Ultrasound: Aneurysm Diameters Measurements

Diameter measured	Difference (CT-US) in aneurysm diameter size (cm)		
	N	**Mean (SD)**	**P-value(*)**
AP	89	0.25 (0.34)	0.001
T	89	0.23 (0.44)	0.001

(*) Results of paired Student t-test
SD: Standard deviation
AP: Anteroposterior
T: Transverse

Table 2b: CT versus Ultrasound: Correlating Aneurysm Diameter Changes Over Time

		CT measurements			
		FU2-FU1 (n=25)		FU3-FU2 (n=12)	
US measurements		AP	T	AP	T
FU2-FU1	AP	0.7			
	T		0.3		
FU3-FU2	AP			0.9	
	T				0.8

Note: Content of this table represents Pearson product-moment correlation coefficients
FU: Follow-up
AP: Anteroposterior
T: Transverse

Duplex ultrasound had sensitivity, specificity, positive and negative predictive values of 50%, 86.7%, 61.9%, and 80% respectively when compared to CT scan for endoleak detection (Table 3). Based on kappa statistics (simple kappa coefficient and confidence interval), the agreement between the two modalities was 0.4 (0.2-0.6) (p-value<0.05). This agreement was not significantly affected when stratified by obesity, hospital or quality of ultrasound.

Table 3: CT versus Duplex: Endoleak Detection

	Endoleak on CT*		
Endoleak on U/S	**Present**	**Absent**	**Total**
Present	13	8	21
Absent	13	52	65
Total	26	60	86

* CT scan is considered the "Gold Standard"
Sensitivity = 50%
Specificity = 86.7%
Positive predictive value = 61.9%

Negative predictive value = 80%
Kappa method of agreement (Confidence Interval) = 0.4 (0.2-0.6)
Note: Underlined is 13 false negative and 8 false positive endoleak for a total of 21 discrepancies between the 2 imaging modalities

There were 21 discrepancies between CT scan and ultrasound (Table 3): 13 false negative (cases where CT scan showed endoleaks undetected by duplex), and 8 false positive (cases where duplex showed an endoleak undetected by CT scan).

When looking at endoleaks discrepancies in terms of aneurysm growth (aneurysm growth was defined as an increase in antero-posterior (AP) diameter on CT scan by more than 2 mm); we found that 3 aneurysms had increased in size. In those 3 scans, endoleak was detected only by CT scan, and not by duplex (Table 4).

Table 4: CT versus Duplex: Discrepancies in Endoleak Detection in Relation to Aneurysm Growth

Aneurysm Growth

	Yes	**No**	**Total**
EL on CT only	3	10	13
EL on U/S only	0	8	8
Total	3	18	21

Note: In three endoleaks (3 different patients) out of 21 discrepancies the aneurysms expanded. All 3 were detected on CT scan only
EL: Endoleak

There was 100% agreement when comparing routine duplex ultrasound to contrast (Levovist) enhanced duplex. Thirty-eight concurrent examinations in 28 patients were available for analysis (Table 5). Results showed kappa coefficient of 1.0 with a confidence interval of 1.0-1.0.

Table 5: Duplex Ultrasound versus Levovist Duplex Ultrasound: Endoleak Detection

EL on ultrasound	**EL on Levovist ultrasound**		
	Present	**Absent**	**Total**
Present	7	0	7
Absent	0	31	31
Total	7	31	38

Note: A perfect agreement between the two methods (Levovist did not add to the accuracy of routine DUS)
EL: Endoleak

DISCUSSION

Duplex ultrasound was accurate and reliable in measuring aneurysm diameters despite under-estimating diameters by an average of 2.5 mm because this was consistent. However, it only moderately agreed with CT for endoleak detection. There were 21 discrepancies between the two imaging modalities in our study: 8 occasions where duplex showed an endoleak undetected on CT (false positive), and 13 occasions where CT showed endoleaks undetected on duplex (false negative). At the end of the study period, each discrepancy was reviewed with the radiologists in an attempt to know why this occurred. We postulated two possible explanations for endoleaks detected only by duplex:

1. On five occasions, even after thoroughly re-reviewing the studies, we were unable to determine with certainty whether these findings represented very small endoleaks that the CT scan did not detect or merely small calcifications within the wall of the aneurysm.
2. Small but definite endoleaks simply missed on CT (three occasions). Although these were considered false positives in relation to the CT scans, it is likely that they are true endoleaks missed on the CT.

We postulated five different explanations for endoleaks detected only by CT scans (for examples see Figures 2, 3, 4):

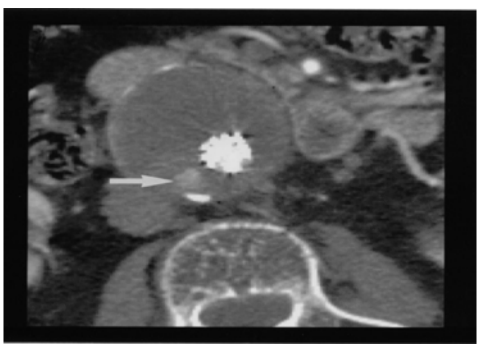

Figure 2: Contrast CT scan 6 months after EVAR. An endoleak is noted in the posterolateral aspect of the aneurysm sac (arrow). This was missed on Duplex. However, it was not associated with aneurysm growth.

Figure 3: Contrast CT scan 6 months post EVAR. Note the presence of curvilinear column of contrast extravasation within the aneurysm sac (arrow). This was not associated with aneurysm growth. Such linear endoleaks, peripheral in location may not be detected on Duplex (as in this case). Here, when the ultrasonic probe was held in

the usual position, the sound waves became perpendicular to the direction of the endoleak flow. This can be avoided future scans by more vigilant examinations, taking care to attempt scanning from all possible angles.

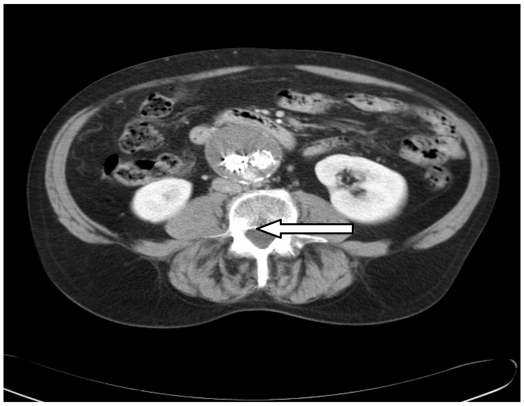

Figure 4: Endoleak not detected on Duplex: this CT scan was done 13 months post EVAR. There is a peri-graft endoleak posterior to the bifurcation (arrow) without increase in aneurysm size. Interestingly, this finding was also present on CT scan 6 months earlier, also not detected by Duplex. Possible explanation is that ultrasound waves hit the metal stent and is reflected back, that's to say cannot penetrate through the metal stent to examine what resides behind it.

1. Missed on duplex because they were located directly behind the metal stent, and therefore, the wave forms did not penetrate through (five occasions). This constituted the majority of endoleaks undetected by duplex (false negatives) and has been noted in a previous report[27].
2. What was felt to be an endoleak on CT was interpreted as small bulging of the stent graft (four occasions).
3. Short, linear endoleaks, peripheral in location not picked-up because the sound waves were perpendicular to the direction of the endoleak (two occasions). This can be avoided in the future by more vigilant examinations, taking care to attempt scanning from all possible angles.
4. In one occasion where the endoleak was very small and possibly an artifact.
5. In one case the iliac limb had migrated proximally causing a type-I endoleak in the pelvis. This was not seen on duplex ultrasound but discovered on CT. The size of the aneurysm was noted to increase on both examinations. That patient underwent successful urgent secondary endovascular procedure to apply an extension stent graft in that limb. A likely explanation that the ultrasound was not complete and did not fully evaluate the pelvis.

Limitations of our study are as follows. Eleven of 63 patients (17.5%) eligible for the study were excluded as they were followed-up only by CT scans.

The slight difference in imaging protocols and imaging devices used in the two hospitals may have accounted for discrepancies in endoleak detection between the two modalities. For example, early acquisition time in CT scans may have missed a low flow endoleak that would have appeared later on delayed images. This could have increased our false positive rate on duplex ultrasound.

Several early reports on aortic endograft trials have only included endoleaks diagnosed with CT scans and have ignored evaluation with ultrasound[28,29,30]. Several research groups had studied the role of duplex in the postoperative follow up of endoluminally repaired AAA patients, some compared it to CT scan (CT/angio), and others did not. Heilberger et al reported that Duplex can identify endoleaks from branched vessels that were missed on CT scan[23]. Duplex scanning allows a real-time sampling of the AAA sac and provides a dynamic rather than static picture. These advantages could potentially make it more reliable than CT for the evaluation of the origin and extent of the endoleak. In 1998, Sato et al compared endoleak detection rate for duplex ultrasound with CT scan (sensitivity = 97%, and negative predictive value = 98%). The study had poor specificity (74%), and positive predictive value (66%). With improvements in ultrasound imaging, some of the false positives when compared with CT imaging may truly represent endoleaks. This was suggested after re-examining the videotaped studies of duplex that showed an endoleak present, and CT scans that showed no endoleaks[31]. In their study, only 19% of duplex studies were considered to be technically adequate. This suggests significantly wide variation in duplex performed at different centers due to technical factors limiting its general recommendation as equal or superior alternative to CT in postoperative aortic endograft surveillance. Similar results were obtained by Wolf et al who included a comparison of aneurysm diameter and had all concurrent examinations separately reviewed by a panel of both radiologists and vascular surgeons[32]. They found that the number of endoleaks identified on CT and missed on duplex scans exceeded the number of those identified on duplex scans and missed on CT. In all patients with endoleaks, which were thought to involve the attachment sites and to warrant arteriography and reintervention, duplex ultrasound demonstrated the endoleak whenever it was performed. Wolf et al concluded that a well performed duplex scan delivers results very similar to high quality CT angiography.

D'Audiffret et al found ultrasound to have a sensitivity of 96%, a specificity of 94%, a positive and negative predictive values of 89% and 98% respectively, when compared to CT scans[33]. In that study, however, the presence and origin of endoleak was agreed upon by the entire radio-surgical team. In addition, it is not clear whether blinding was exercised with respect to results and findings of each imaging modality for concurrent examinations. Radiologists and surgeons interpreting one imaging modality may have been aware of the result of the other concurrent examination.

Compared to CT scan, duplex scan correctly identified the trend (increase or decrease) of evolution of native aneurysmal sac in73% of examinations. Inter-observer variability, poor patient preparation, overweight patients, and lack of aneurysmal wall echogenicity may lead to duplex ultrasound inaccuracy in some cases.

The report by Pages et al obtained similar results to our study; for endoleak detection the sensitivity, specificity, positive and negative predictive values were 48%, 94%, 74%, and 81%, respectively[27]. In our study, however, routine duplex ultrasound was followed by Levovist duplex ultrasound on 38 occasions and read by the same radiologist. Two type-2 endoleaks (Figure 4) were present on CT scan and missed on routine duplex on different follow up examinations. In both occasions, Levovist duplex failed to detect the endoleaks. Hence, it did not add any value to routine duplex accuracy. Considering its cost and time, we believe that there is no benefit obtained from adding Levovist to routine duplex ultrasound scanning.

CONCLUSION

Duplex ultrasonography had comparable accuracy with contrast enhanced computed tomography for evaluation of aneurysm diameter measurement following endovascular repair of abdominal aortic aneurysm. There was only moderate agreement between duplex ultrasound and contrast CT for detection of endoleaks. CT was more reliable for detecting endoleaks associated with aneurysm growth. Contrast enhanced (Levovist) duplex scanning did not change the accuracy of routine duplex for detection of endoleaks.

Based on the results of our study, we recommend continuing the use of duplex ultrasound as an adjunct only and not as an alternative to contrast enhanced computerized tomography scan in the follow up of endoluminally repaired AAA. We do not believe, based on our results, that contrast enhanced duplex ultrasound can improve the accuracy of routine duplex ultrasound for endoleak detection.

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