

CARDIOVASCULAR

Resolving the blind spot of transoesophageal echocardiography: a new diagnostic device for visualizing the ascending aorta in cardiac surgery

B. van Zaane^{1 3 4*}†, A. P. Nierich¹†, W. F. Buhre³†, G. J. Brandon Bravo Bruinsma² and K. G. M. Moons^{3 4}†

¹Department of (Thoracic) Anaesthesia and Intensive Care and ²Department of Cardiothoracic Surgery, Isala Clinics, PO Box 10500, 8000 GM Zwolle, The Netherlands. ³Division of Perioperative Care and Emergency Medicine, ⁴Julius Centre for Health Sciences and Primary Care, University Medical Centre Utrecht, PO Box 85500, 3808 GA Utrecht, The Netherlands

*Corresponding author: Department of (Thoracic) Anaesthesia and Intensive Care, Isala Clinics, Groot wezenland 20, 8011 JW Zwolle, PO Box 10500 8000 GM Zwolle, The Netherlands. E-mail: b.van.zaane@isala.nl

Background. Atherosclerosis of the ascending aorta (AA) and stroke after cardiac surgery are related. Knowledge of the location of AA-atherosclerosis pre-sternotomy allows changes in surgical strategy to avoid manipulation of the AA. The gold-standard for assessment of AA-atherosclerosis is intraoperative epiaortic ultrasound scanning (EUS). Transoesophageal echocardiography (TOE) is unable to detect atherosclerosis in the distal AA due to the 'blind spot'. A new method [A-View[®] (Aortic-view) method] using a fluid-filled catheter may enhance the assessment of distal AA-atherosclerosis. The aim of this study was to evaluate whether the A-View[®] method indeed visualizes the distal AA and to assess the safety of this technology.

Methods. In a cross-sectional diagnostic study, 41 patients undergoing cardiac surgery including sternotomy underwent the same work-up including TOE, the A-View[®] method, EUS, and routine operative monitoring.

Results. With the A-View[®] method, the distal AA was visible in all (100%) patients. There were no clinically important side-effects associated with the use of the A-View[®] catheter; however, in one patient the endotracheal tube was accidentally dislocated leading to a decrease in SaO₂. Severity of atherosclerosis visualized with the A-View[®] method compared with EUS results showed good agreement between the two methods [Kappa of 0.69 (0.50–0.88)]. The Bland–Altman analysis showed poor agreement in plaque-size measurements (bias 0.05 cm², limits of agreement –0.63 to 0.74 cm²).

Conclusions. The A-View[®] method offers a minimally invasive and safe approach to preoperatively resolving the blind spot of TOE. Compared with EUS, the A-View[®] method yielded satisfactory results in the detection of AA-atherosclerosis. The A-View[®] method seems a promising tool for patients undergoing cardiac surgery to direct surgical management.

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Stroke after cardiac surgery is often caused by emboli from atherosclerotic plaques in the ascending aorta (AA). These are produced by cannulation, clamping and declamping

during conventional on-pump cardiac surgery.¹⁻⁵ In the presence of severe atherosclerosis, the use of alternative surgical strategies that avoid or reduce manipulation of the AA is desirable.^{2 6-8} The best use of such strategies requires a diagnostic test that can visualize the AA, particularly the distal part, preferably before surgery.

The gold-standard for intraoperative detection of atherosclerosis of the AA is epiaortic ultrasound scanning (EUS).⁴ However, since its introduction in the 1980s this technique has not gained widespread acceptance. It lengthens the surgical procedure, endangers the sterile field, is time-consuming, and is not available in many hospitals. Most importantly, EUS is performed after sternotomy, just before cannulation.^{4 9 10} At that point, changes in surgical strategy are less feasible.

Transoesophageal echocardiography (TOE) is a minimal invasive method to visualize the extent of atherosclerosis before and during cardiac surgery. TOE overcomes some of the problems of EUS, is widely available and used during cardiac surgery.¹¹ The major disadvantage of TOE

is that the distal part of the AA, that is, the place where the cannula is introduced, cannot be visualized due to the so-called blind spot.¹² The blind spot is caused by the interposition of air, located in the trachea and main bronchi, between the echo-transducer and the AA (Fig. 1).

We have modified conventional TOE to overcome this limitation.¹³ This new diagnostic method, referred to as the A-View[®] (Aortic-View) method, uses a saline-filled balloon catheter (Fig. 1) to replace the air in the trachea during the investigation. This fluid creates an ultrasound conducting window and the possibility of imaging the distal part of the AA that is normally invisible. New diagnostic methods should undergo evaluation before introduction into clinical practice.¹⁴⁻¹⁷ The present diagnostic study describes the first phase of the evaluation process, that is, the technical and safety evaluation. The technical evaluation addresses to what extent the A-View[®] method is capable of imaging the distal AA, and the safety evaluation whether the method leads to unexpected complications due to the use of the device.

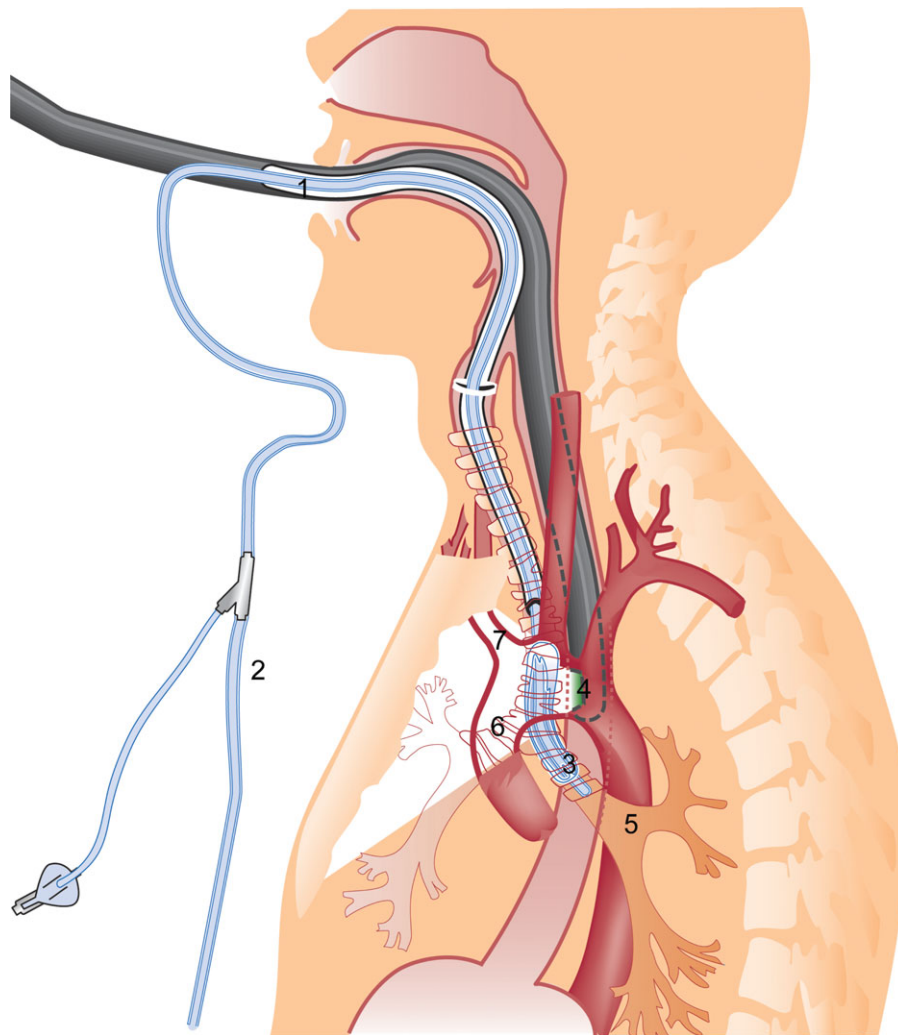


Fig 1 Longitudinal cross-section illustrating the anatomic interrelation of structures, the A-View[®] balloon catheter and the TOE probe (1, ET; 2, A-View[®] catheter; 3, balloon of A-View[®] catheter; 4, TOE probe; 5, left main bronchus; 6, AA; and 7, innominate artery).

Methods

Study population

After approval by the institutional medical ethical committee and written informed consent, 41 consecutive patients scheduled for elective cardiac surgery through a sternotomy were included. The study took place in a general teaching hospital (Isala Clinics, Zwolle, The Netherlands). The study was conducted in compliance with the protocol and in accordance with the moral, ethical, and scientific principles governing clinical research as set out in the Declaration of Helsinki (1989) and Good Clinical Practice. Patients were included between September 2005 and January 2006, and are a random sample of the target population in which the device is to be used, that is, cardiac surgery patients. Only patients older than 18 yr of age were included. Patients scheduled for off-pump surgery or cardiac re-operation were not included. Furthermore, patients with contra-indications to TOE (oesophageal dysfunction) or contra-indications for the A-View[®] method (severe COPD, tracheal dysfunction) were also excluded.

Design and measurements

The study followed a cross-sectional diagnostic design. All consecutive patients underwent the same systematic work-up, including a standardized conventional TOE, the A-View[®] method, EUS (reference standard), and haemodynamic monitoring. All ultrasound data were recorded for subsequent off-line analysis.

Heart rate, mean arterial pressure, oxygen saturation, and end-tidal CO₂ were continuously recorded. Before and after the A-View[®] method, bronchoscopy was performed to detect possible side-effects caused by the A-View[®] catheter.

The study was a systematically designed and conducted diagnostic study and no intervention was performed. Treatment decisions were based upon current guidelines and routine clinical care practice.

Conventional TOE

After induction of anaesthesia and intubation, a standard TOE (Vivid I, General Electronics, Solingen, Germany or Philips HP Sonos 2500, Best, The Netherlands) was performed according to the guidelines of the American Society of Echocardiography and the Society of Cardiovascular Anaesthesiologists.¹⁸ The main test result for the present study was whether the AA distal to the right pulmonary artery could be visualized. Visualization was attempted twice, before and after the initiation of cardiopulmonary bypass (CPB). Before CPB, visibility was defined as visualization of the aorta from the right pulmonary artery to the innominate artery. During CPB, visibility was defined as the ability to visualize the flow

from the aortic cannulae of the CPB-circuit. TOE images were digitally stored to enable off-line analysis by one experienced anaesthesiologist (A.P.N).

The A-View[®] method

The A-View[®] method was performed using the conventional TOE probe together with the A-View[®] catheter (Cordatec Inc., Zoersel, Belgium). The TOE probe was positioned in the mid-oesophageal position enabling visualization of the proximal AA and right pulmonary artery. The A-View[®] catheter was then introduced into the trachea via the endotracheal (ET) tube. To facilitate ventilation of the patient, a Y-connector was used. As the AA is in close anatomic relation to the left main bronchus, the A-View[®] catheter was placed in the left main bronchus to optimize imaging. This was performed via the semi-rigid shaft of the A-View[®] catheter, which allowed us to create a curve of about 30° in the distal end of the catheter to facilitate easy positioning. The 24 cm marker on the A-View[®] catheter balloon was lined up with the 24 cm mark at the ET tube to prevent too deep insertion. As the total distance from the marker until the tip of the A-View[®] catheter is 34 cm, the catheter then protruded 10 cm from the ET tube. Retraction of the ET tube together with the A-View[®] catheter was used to enhance visualization if the balloon of the ET tube overlapped the distal AA. After checking the correct position of the catheter by auscultation, and interrupting ventilation, the balloon was filled with sterile saline. The A-View[®] method was performed by retracting the TOE-probe from the mid oesophageal view until the AA was seen (20–30 cm from the incisors). When necessary, lateral flexion of the tip of the echo-probe was used to obtain adequate imaging. After completion of the investigation, the ET tube was repositioned if necessary using the catheter as a guide wire. Subsequently, saline was aspirated from the A-View[®] catheter, the catheter was removed, and ventilation was resumed.

We used the same definitions for the test results of the A-View[®] method as for conventional TOE. Furthermore, the presence and severity of aortic atherosclerosis of the visualized part (i.e. distal AA) was described with a five-grade ranking system;¹⁹ grade I: normal aorta, grade II: extensive intimal thickening, grade III: protruding atheroma <5 mm, grade IV: protruding atheroma >5 mm, and grade V: mobile plaques. A-View[®] images were digitally stored and interpreted off-line by the same anaesthesiologist (A.P.N). Before the study, we performed a pilot-study of 15 patients, to exclude the effect of a learning curve of the anaesthesiologist in the interpretation of the A-View[®] images.¹³

Epi-aortic ultrasound scanning

The epi-aortic ultrasound scan was performed after sternotomy and opening of the pericardium before cannulation of the AA by the cardiac surgeon. A transthoracic ultrasound

probe (M4S, General Electronics, Solingen, Germany) or an epiaortic probe (Philips, Best, The Netherlands) was placed on to the AA. For optimal imaging of the AA, the pericardium was filled with saline at body temperature. Short and long axis views of the proximal and distal AA were obtained. The epiaortic ultrasound scan was used as the reference test for comparison with the A-View[®] method of examining the presence, severity, and location of AA-atherosclerosis. EUS was performed by the attending cardiac surgeon and interpreted off-line by the same anaesthesiologist (A.P.N).

Outcomes

The primary outcome of this study was the visibility of the AA based on the A-View[®] method compared with conventional TOE, both before initiation of CPB, that is, visualization of the AA from the right pulmonary artery to the innominate artery and after initiation of CPB, that is, visualization of the aortic cannula flow. A number of secondary outcomes were examined. Complications due to the use of the device, including cardiopulmonary side-effects such as hypoxemia and hypercarbia and damage due to the placement of the A-View[®] catheter into the trachea and main left bronchus were actively sought and recorded. The presence and severity of atherosclerosis in the distal AA, visualized with the A-View[®] method, was compared with EUS as reference standard. Absence of atherosclerosis was defined as grade I–II and the presence as grade III, IV, or V of the grading described earlier.¹⁹ On the basis of a previous report,²⁰ the size of the plaque (cm²) was also determined by both techniques. Finally, the duration of the three methods examination was compared.

Statistics

As for therapeutic phase 1 studies, there are no formal rules for power calculations of phase 1 diagnostic studies. However, we estimated that 40 patients should be included, assuming that the A-View[®] method enables visualization of the distal AA (the primary endpoint) in 95% of patients with a standard error of 6% (power = 0.80; alpha = 0.05, two-sided). This number of 40 patients was more than enough to compare the visibility rates of the A-View[®] method with conventional TOE. For example, assuming that with conventional TOE the AA is visible in 10% of patients, only six patients are needed. The number of 40 patients would also suffice for the evaluation of the percentage of unexpected events due to the use of the device, based on an expectation of unexpected events in 10% of patients with a standard error of 7.5% (power = 0.80; alpha = 0.05, two-sided).

Frequencies of patients in whom the innominate artery (before CPB) and the aortic cannula flow (after initiation of CPB) could be visualized with conventional TOE and with the A-View[®] method were compared. The frequency of adverse effects related to the A-View[®] catheter was quantified. The degree of agreement between the A-View[®]

method and EUS for grades of atherosclerosis was estimated using the Kappa-statistic. A 2 by 2 table of the presence of AA-atherosclerosis (grade III–V) vs absence (grade I–II) was constructed. A standard correction of adding 0.5 to all cells of the table was applied, as the table contained one zero cell. Positive and negative predictive value, sensitivity, specificity, and the likelihood ratios with their 95% confidence intervals (CI) were calculated. In patients with atherosclerosis, the Bland–Altman method was used to study the agreement in plaque size with the A-View[®] method vs EUS. Average measurement duration (in minutes) of the A-View[®] method and EUS was compared using a paired *t*-test.

Results

Conventional TOE, the A-View[®] method, and epiaortic ultrasound were performed in all patients. The mean age of the patients was 67 (range 42–94) yr. The study population consisted of 28 (68.3%) males and 13 females (31.7%). Sixteen patients underwent isolated coronary bypass surgery, 15 had only valve surgery, and 10 patients had combined bypass and valve surgery.

Visualization of the ascending aorta

Using conventional TOE, the innominate artery was visible in 2 out of 41 (4.9%) patients and after initiation of CPB, the aortic cannula flow was visible in 4 out of 41 (9.8%) patients. With the A-View[®] method, the innominate artery (Fig. 2) and the aortic cannula flow (Fig. 3) were visible in all (100%) patients.

Safety

We did not observe any clinical significant effects on the haemodynamic and ventilatory status of the patients due to

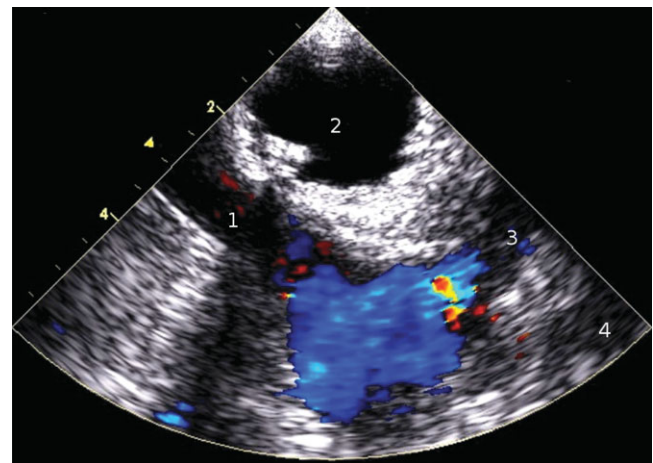


Fig. 2 Image of the AA and the innominate artery as imaged with the A-View[®] method (1, innominate artery; 2, trachea; 3, left carotid artery; and 4, left subclavian artery).

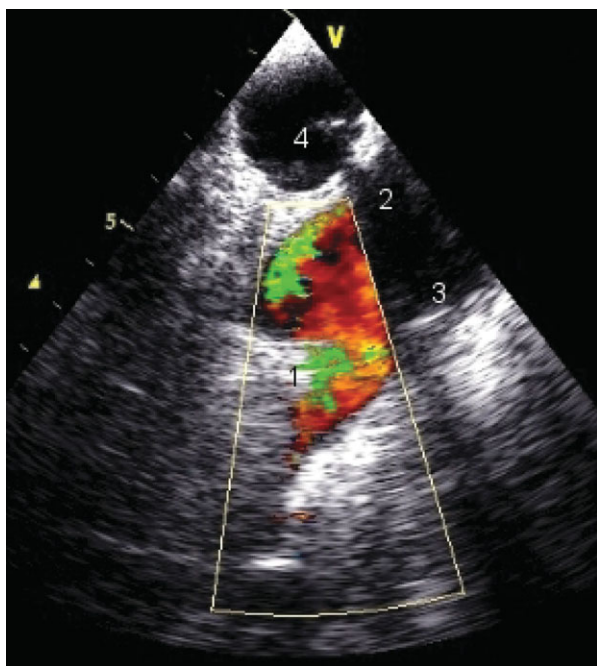


Fig. 3 Image of the AA with the aortic cannulae flow as imaged by the A-View[®] method (1, aortic cannula; 2, dorsal wall of ascending aorta; 3, ventral wall of ascending aorta; and 4, trachea).

the use of the A-View[®] method (Table 1). We observed one unexpected severe complication. In one patient the ET tube was accidentally dislocated while retracting it to optimize imaging, leading to a decrease in Sa_{O_2} from 99% to 53% without clinical consequences. Bronchoscopy revealed insignificant mucosal bleeding after the A-View[®] procedure in seven (18%) patients without any additional interventions needed.

Atherosclerosis

In four patients, the A-View[®] method showed clinical relevant atherosclerosis that was not detected with EUS. In three patients, the A-View[®] method showed atherosclerosis of a higher degree than epiaortic scanning. The Kappa statistic was 0.69 (95% CI 0.50–0.88). After dichotomization the positive predictive value of the A-View[®] method was 80%, and the negative predictive value was 98%.

Table 1 Haemodynamic and ventilatory variables before and after the A-View[®] method expressed as mean (SD)

	Before the use of the A-View [®] method	After the use of the A-View [®] method
Saturation (%)	100 (1)	98 (3)
End-tidal CO ₂ (kPa)	3.9 (0.5)	4.5 (0.6)
Heart rate (beats min ⁻¹)	65 (11)	66 (11)
Mean arterial pressure (mm Hg)	78 (14)	73 (13)

Table 2 Presence (Grade III, IV, or V) vs absence (Grade I or II) of AA atherosclerosis visualized with the A-View[®] method compared with the EUS result. Sensitivity (95% CI)=97%(90–100%), specificity 81% (66–97%), positive predictive value 80% (64–97%), negative predictive value 98% (91–100%), likelihood ratio of a positive test 5.2 (2.3–12.0), likelihood ratio of a negative test 0.03(0.002–0.50)

		Epiaortic ultrasound scan		
		Presence	Absence	Total
A-View [®] method	Presence	18	4	22
	Absence	0	19	19
	Total	18	23	41

The sensitivity was 97% and the specificity was 81% (Table 2).

In one of the 18 patients with clinically relevant atherosclerosis, the plaque size could not be determined with EUS as the atherosclerotic plaque was too large to image it at once. Therefore, this patient was excluded from the Bland–Altman analyses. Figure 4 shows that there was a poor agreement between the A-View[®] method and EUS with wide limits of agreement and an increasing difference between the two methods with increasing plaque size; mean plaque size 0.42 cm², bias 0.05 cm², limits of agreement –0.63 to 0.74 cm².

Duration

The A-View[®] method took a mean (SD) 4.5 (1.8) min, whereas EUS took 3.1 (1.8) min to obtain images of the entire AA. The mean (95% CI) difference in additional time between the two methods was 1.3 (0.4–2.6) min.

Discussion

In the present study, it is shown that in patients undergoing cardiac surgery imaging of the distal AA is possible before sternotomy using modified TOE technology. With the A-View[®] method, the innominate artery and the aortic cannula flow were visible in all patients. Our findings confirm the results of a recently published study by Li and colleagues.²¹ We have demonstrated that the A-View[®] method allows for the acquisition of a series of images of the distal part of the AA without severe unexpected adverse effects. Furthermore, initial results indicate good diagnostic accuracy of the A-View[®] method when compared with EUS for the detection of presence and severity of atherosclerosis. Mean (SD) duration of both the A-View[®] method and EUS was short, 4.5 (1.8) and 3.1 (1.8) min, respectively, and had no impact on the total surgical time.

Clinical relevance of the A-View[®] method

Diagnostic tests in itself commonly have no direct impact on health improvement but they do (in most instances) via the therapies indicated or chosen based on the results.²²

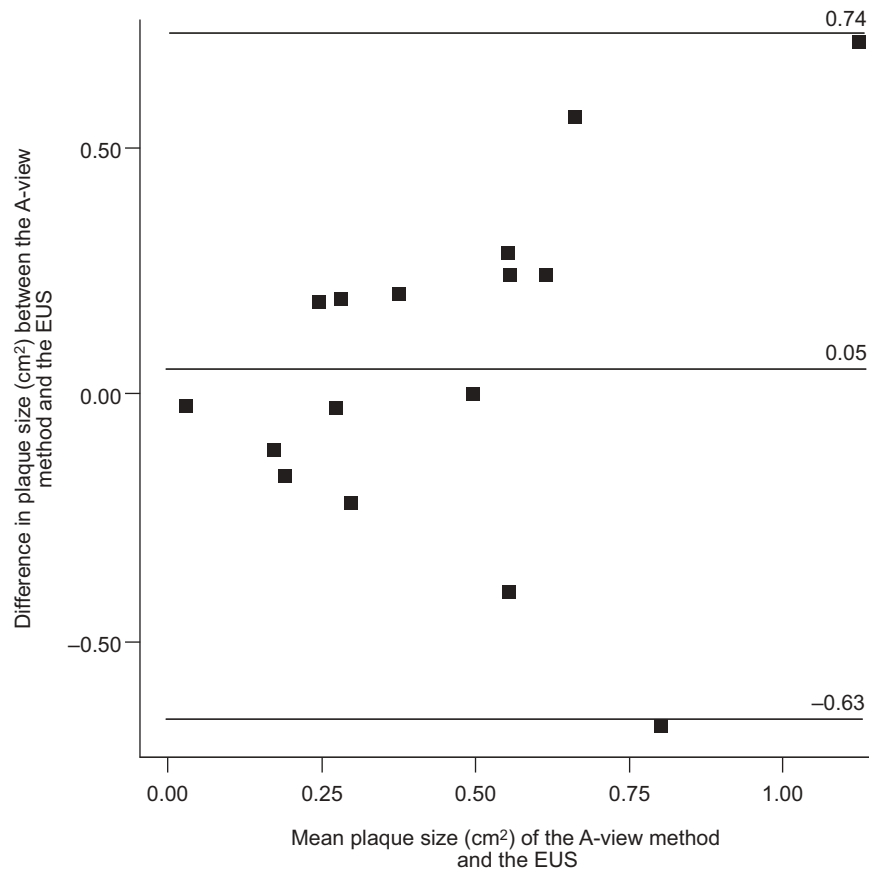


Fig. 4 Bland–Altman plot of the A-View[®] method and epiaortic ultrasound results of patients with clinically relevant atherosclerosis (middle line, bias 0.05; upper line, upper limit of agreement 0.74; and lower line, lower limit of agreement -0.63).

Studies in cardiac surgical patients have shown that the use of EUS of the AA combined with appropriate changes in surgical techniques can reduce the incidence of stroke in case of severe AA atherosclerosis.^{23–25} We have shown that the A-View[®] method is capable of adequately imaging the distal AA. Initial results also show that the A-View[®] method enables the detection of the presence and severity of AA atherosclerosis at a time preoperatively that extensive manipulations of the AA, the major cause of emboli generation, can be avoided. Hence, it can be expected that the benefits of the A-View[®] method are comparable with EUS where the latter is more burdensome to use and often applied too late to allow changes in surgical technique.

Interestingly, assessing the presence and severity of atherosclerosis by the A-View[®] method as compared with EUS showed comparable results, whereas conventional TOE image quality is not sufficient when compared with EUS. As expected, we noticed a difference in image quality between the epiaortic scan and the A-View[®] method but this did not hamper the interpretation of the images or the measurements.

The A-View[®] method revealed in seven patients a more severe degree of atherosclerosis than EUS. There are two potential reasons for this finding. First, since the aorta distal to the innominate artery is not directly exposed to

the surgical field the epiaortic ultrasound probe cannot be placed on this part of the aorta. As a consequence, EUS is only capable of obtaining longitudinal images of the aorta distal to the innominate artery and no transversal images can be obtained. On longitudinal images a different, most likely smaller, cross-section of atherosclerotic plaques is acquired and severity of atherosclerosis is underestimated. Second, the ultrasound beam of EUS is less wide than the TOE ultrasound beam used in the A-View[®] method. Therefore, a larger part of the AA is imaged at once with the A-View[®] method and atherosclerotic plaques may then be better visualized.

Overall, there was a poor agreement between the A-View[®] method and EUS in determining plaque size shown. Poor agreement is most likely because of the different imaging planes of the two methods. The A-View[®] method and EUS obtain different cross-sections of the same plaque and therefore of different plaque sizes. The latter may also be an explanation for the increasing difference between the two methods with increasing plaque size, as a larger plaque has more different cross-sections. However, in clinical practice, this will not have relevant implications as in most cases the location rather than the size of the atherosclerotic plaque will guide surgical management.

Methodological issues

The evaluation of a new diagnostic device needs a phased scientific approach where subsequent studies are indicated only in case of good results in previous phases.^{14–17} The present study addresses the results of the first phase of the evaluation of the A-View[®] method. As the purpose was to study the ability to visualize the AA with the A-View[®] method and its safety, we explicitly performed a single observer study. This observer was the person who developed the A-View[®] method (A.P.N.).¹³ This could lead to an overestimation of the ability of the A-View[®] method to image the distal AA. Given, however, the promising results of the present study and following the guidelines,^{14–17} we conclude it is ethical and safe to conduct additional studies in a larger series of patients to estimate more precisely the intra- and inter-observer variation and the diagnostic accuracy of the A-View[®] method. Finally, studies are needed to address the impact of the use of the A-View[®] method on patient outcome and cost-effectiveness.

Due to the fact that we first performed the TOE in each patient and subsequently the A-View[®] method, some learning effect cannot be ruled out as the A-View[®] study will be informed by the previous TOE study and this could favour the A-View[®] method. However, the A-View[®] method 'effect' on visualizing the AA was so large compared with TOE, that it is highly unlikely that this could entirely be explained by a learning curve. Moreover, we tried to minimize this error by having the images interpreted in a blinded fashion off-line.

As with phase 1 studies for therapeutic interventions, diagnostic phase 1 studies are not intended to obtain highly precise estimates of the unexpected event rate of the device. The aim is rather to study in a small series of patients the safety of the device. Larger and more formal safety evaluations have to be carried out in post-marketing (phase 4) studies.

We used EUS as reference rather than modern MRI and CT-scanners because epiaortic scanning is at present time the most widely used reference standard for this disorder. MRI and CT have limited application and availability in routine care of cardiac surgery patients. But more importantly, they are not capable of providing real-time images of the AA to direct immediate changes in surgical strategy.

Potential complications of the A-View[®] method

After pre-oxygenation with a $F_{I_{O_2}}$ of 100% an apnoea period of several minutes can be maintained without clinical significant hypoxemia or hypercapnia. Visualizing the AA with the A-View[®] method can be done within this time frame. It is not expected that the temporary apnoea will have harmful effects on the patient.

In one patient, severe hypoxemia was observed when the ET tube was accidentally dislocated after retraction of

the ET tube to optimize imaging of the innominate artery. As the patient was already draped for surgery, we had difficulties in reintubating the patient. This led to a short decrease in Sa_{O_2} from 99% to 53% without clinical consequences. To prevent these adverse events, the A-View[®] method should only be performed before draping, to obtain full and easy airway access to solve these potential ET tube related difficulties. Furthermore, we advise not using the A-View[®] method when intubation problems are expected or when unexpected intubation difficulty has occurred.

Apart from small mucosal point-bleeding caused by the stiff tip of the catheter in seven patients, no patient showed damage of the bronchial or tracheal wall. However, to reduce the incidence of mucosal bleeding an adjustment has been made to the design of the catheter which is now made of a softer material. In none of the patients was any evidence of barotrauma due to the fluid-filled balloon of the A-View[®] catheter observed. Intratracheal balloons filled with water are in use for several other occasions, during intratracheal laser surgery the ET tube cuff is filled with fluid. This technique has never been associated with severe side-effects or an increased incidence of tracheal damage. Pressure on the tracheal wall caused by water has the same physics as air and therefore the same safety guidelines must be used. Although there is some controversy about a 'safe' cuff pressure, most clinicians accept 25 cm H_2O up to 35 cm H_2O as a safe limit.²⁶ Rupture of the trachea is described at pressures above 120 cm H_2O ,²⁷ and usually related to over-distension of the tracheal cuff. The A-View[®] catheter consists of a much more compliant balloon than the standard endotracheal balloon. Hence, if the pressure is kept under the safe limit, the risk for tracheal barotrauma is minimal. To prevent over inflation of the balloon, filling of the balloon should be visualized by TOE. As soon as the image of the trachea and the distal AA appears the appropriate volume is reached for the individual patient.

Balloon rupture is very unlikely because the balloon is made out of polyurethane, an extremely strong material. In case of balloon rupture, a total of 20–30 ml of sterile saline will enter the lungs. It can be expected that this amount of water will be absorbed without clinical implications. In general, we think that the risk of clinical significant harmful effects of the A-View[®] method is small and will not outweigh the gain of the A-View[®] method.

Conclusion

The A-View[®] method offers a fast, easy, safe, and minimally invasive approach of resolving the blind spot of TOE. Compared with EUS, the A-View[®] method yielded adequate results in the detection of AA atherosclerosis and can be used before sternotomy. The surgical strategy can therefore be adjusted to reduce or even avoid manipulation

of the AA in case of severe aortic atherosclerosis. Accordingly, the A-View[®] method seems a promising tool for patients undergoing cardiac surgery to reduce possible postoperative stroke.

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