Aspects on Imaging and Endovascular Treatment of Aortic Dissection and Aneurysm

MATS-OLA ERIKSSON
Aortic aneurysm and dissections are potentially life-threatening conditions. The advent of endovascular aortic repair (EVAR) and thoracic endovascular aortic repair (TEVAR) has reduced perioperative mortality and morbidity and are now established therapy methods for treatment of aortic disease. Adequate pre- and intraoperative imaging is important for optimal results in endovascular procedures. However, the standard use of CT and angiography may not always be sufficient to provide necessary information required for treatment, and complementary techniques are warranted in selected cases.

TEVAR in acute complicated type B aortic dissections is proven effective in several reports, but long-term clinical outcome and aortic remodelling are still not fully evaluated.

Intravascular phased array imaging (IPAI) was used in patients undergoing EVAR and TEVAR for aortic aneurysm and dissection. The combined information from IPAI and fluoroscopy allowed exact positioning of the stent graft. The colour Doppler function facilitated detection of blood-flow in relevant arteries during and after the procedures, and it also facilitated control of ceased flow in excluded false lumens or aneurysms.

Clinical early and long-term results after TEVAR for acute complicated type B aortic dissections were investigated in all patients treated between 1999 and 2009 at Uppsala University Hospital. Results were favourable regarding survival and permanent neurological complications. Long-term follow-up of aortic morphological changes in the same patient group showed overall significant reduction of aortic and false lumen diameters, and an increase of true lumen diameter. Total thrombosis of the false lumen occurred more often in patients with DeBakey IIIa aortic dissection, than in IIIb.

In conclusion, IPAI may be a complementary tool to traditional imaging modalities in EVAR and TEVAR in selected cases. Long-term clinical outcome is excellent with favourable aortic remodeling after TEVAR in patients with acute complicated type B aortic dissection.

Keywords: Aneurysms, aorta, stents, ultrasound, colour Doppler, vascular, interventional, aortic dissection, complicated, TEVAR, EVAR, re-intervention, survival, thrombosis, false lumen, aortic remodelling

Mats-Ola Eriksson, Uppsala University, Department of Radiology, Oncology and Radiation Science, Radiology, Akademiska sjukhuset, SE-751 85 Uppsala, Sweden.

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List of papers

This thesis is based on the following papers, which are referred to in the text by their Roman numerals.

I. Eriksson MO, Wanhainen A, Nyman R.

II. Eriksson MO, Nyman R.

III. Steuer J, Eriksson MO, Nyman R, Björck M, Wanhainen A.

IV. Eriksson MO, Steuer J, Wanhainen A, Thelin S, Eriksson LG, Nyman R.
    Morphological outcome after endovascular treatment of complicated type B aortic dissection. Submitted

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### Abbreviations

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<th>Abbreviation</th>
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<tr>
<td>AAA</td>
<td>Abdominal aortic aneurysm</td>
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<tr>
<td>ADSORB</td>
<td>Acute Dissection Stent grafting OR Best medical treatment</td>
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<tr>
<td>BMT</td>
<td>Best medical treatment</td>
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<td>CO₂</td>
<td>Carbon dioxide</td>
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<td>CT</td>
<td>Computed tomography</td>
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<td>DSA</td>
<td>Digital subtracted angiography</td>
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<td>DT</td>
<td>Datortomografi</td>
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<td>EVAR</td>
<td>Endovascular aortic repair</td>
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<td>Fr</td>
<td>French</td>
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<td>INSTEAD</td>
<td>INvestigation of STEnt grafts in patients with type B Aortic Dissection</td>
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<td>IPAI</td>
<td>Intravascular phased array imaging</td>
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<td>IRAD</td>
<td>International Registry of Aortic Dissection</td>
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<tr>
<td>IVC</td>
<td>Inferior vena cava</td>
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<td>IVUS</td>
<td>Intravascular ultrasound</td>
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<tr>
<td>TEVAR</td>
<td>Thoracic endovascular aortic repair</td>
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Introduction

Over the last decade, the technique of endovascular treatment of aortic pathology has developed dramatically. The applicability of stent graft technology in the thoracic and abdominal aorta is expanding, and provides possibilities to treat patients with challenging anatomical and clinical constraints. Likewise, linked to the progresses in modern technology, the development of imaging modalities has resulted in sophisticated methods of obtaining detailed anatomical and physiological information. However, these new technologies require accumulation of data regarding long-term outcome and usefulness.

This thesis aims to discuss clinical and morphological results, as well as the implementation of new diagnostic tools, in endovascular management of aortic disease.
Background

Abdominal aortic aneurysm (AAA) and endovascular aortic repair (EVAR)

Aortic aneurysm is a dilatation of the aorta. The disease was first described by Andreas Vesalius (1514-1564)\(^1\). Risk factors for development of abdominal aortic aneurysm (AAA) are male gender, age, smoking and heritage\(^2\). A diameter of 5 to 5.5 cm, or rapid progress is considered threshold for repair in patients, in order to avoid rupture\(^3\).

Freeman and Leeds did the first successful surgical reconstruction of an AAA in 1951\(^4\). In 1953, Bahnson performed the first successful repair of a ruptured AAA\(^5\). Synthetic material (Dacron) for vascular graft implantation was developed and introduced by DeBakey in 1958\(^6\). The inlay technique, leaving the native aneurysmatic aorta in place and inserting a vascular graft, was first described by Orr and Davies in 1974 and is the gold standard for open surgical technique of AAA reconstruction today\(^7,8\).

Endovascular aortic repair (EVAR) treatment of abdominal aortic aneurysms with the use of stentgrafts was first described by Volodos in 1986\(^9\). Following the first English report by Parodi in 1991, the technique and materials have evolved considerably\(^10\). The stentgraft is usually positioned and deployed distally to the origin of the renal arteries and subsequently landed in the right – and left common iliac artery. The stentgraft is adapted to the arterial walls causing a sealing and thereby excluding the aneurysmal sac. According to the Swedish National Registry for Vascular Surgery (SWEDVASC), 50% of all elective abdominal aortic aneurysms in Sweden 2011 were treated with endovascular technique\(^11\). EVAR causes less trauma, blood loss, and need for postoperative care and is associated with lower perioperative mortality compared with open surgery\(^12\). However, the EVAR technique has limitations regarding anatomical constraints, and requires higher needs for secondary interventions as well as long-term surveillance\(^13\).

Aortic dissection and thoracic endovascular aortic repair (TEVAR)

Aortic dissection is defined as a separation of the layers in the aortic wall caused by a rift in the intima, the innermost layer, and is believed to be a result of degeneration of the middle layer, the media\(^14\). A tear in the intima allows blood to escape from the vessel lumen and enter the diseased media. This blood filled space creates the false lumen. The pro-
gress of the dissection is usually antegrade. As a result of the damage, the aortic wall becomes weaker and more susceptible to rupture. In 1761, the celebrated Italian anatomist Giovanni Battista Morgagni was the first to describe the pathologic characteristics of aortic dissection \(^{15}\).

There are currently two separate classifications of aortic dissections that are frequently used in clinical practise (Fig. 1). The Stanford classification has 2 subgroups, A and B. Type A dissection is defined as the involvement of the ascending aorta, regardless of the location of the primary intimal tear, whereas type B involves solely the descending aorta \(^{16}\). The DeBakey classification further divides the dissections into:

I: Primary intimal tear in the ascending aorta with the dissection propagating at least to the aortic arch and often beyond it distally.

II: Primary intimal tear in and limited to the ascending aorta.

IIIa: Primary intimal tear distal to the left subclavian artery and involvement of the descending thoracic aorta.

IIIb: Extension down to the abdominal aorta \(^{17}\).

In rare cases type III dissections propagates retrogradely into the aortic arch and ascending aorta.

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DeBakey – Stanford classification of aortic dissection
Modern surgical treatment of thoracic aortic disease was first undertaken in the 1950s by DeBakey who reported segmental resection of the aorta, replacing it with a graft 18. In aortic dissection, the goal with open surgery is to prevent rupture and re-establish perfusion to vital organs. However, the technique entails a great risk of surgically related complications with significant morbidity and mortality, ranging from 30% to 50% 19-24.

Typical clinical presentation of aortic dissection is acute onset of pain. The pain is at maximum at onset and may migrate with the extent. Acute aortic dissection is most common in the sixth- and seventh decades of life. Males are affected two to five times more often than females. Other predisposing factors are hypertension, connective tissue disorders (Marfan’s syndrome, Ehler-Danlos syndrome), aortitis, congenital cardiovascular malformations, pregnancy and use of cocaine 25,26.

Acute type B dissections can be classified as either complicated or uncomplicated. Complications include direct- or indirect malperfusion of visceral or limb arteries, rupture/impending rupture, or intractable pain. Approximately 30-42% of all acute type B dissections are complicated. Among these, ischemic manifestations are seen in 30-50%, with a mortality rate between 50 and 85% if left untreated 27-29.

The advent of the TEVAR technique, first introduced by Dake et al in 1994, has led to a new era in the management of several life-threatening conditions affecting the thoracic aorta 30. In acute complicated type B dissection, several studies have shown the TEVAR technique feasible 31-33. By using stent grafts, the aim is to cover the primary intimal tear in the aortic wall in order to induce thrombosis of the false lumen and re-establish blood-flow into the true lumen. If enhanced blood-flow in the true lumen after TEVAR does not provide sufficient flow into aortic branch vessels, additional interventional procedures such as selective stenting of affected arteries have to be undertaken.

In uncomplicated type B aortic dissection, medical therapy with primarily lowering of blood pressure and pain management is traditionally the preferred treatment and the International registry of Aortic Dissection (IRAD) reports good early survival 26. This treatment strives to prevent aortic expansion, rupture and further dissection by reducing the stress on the aortic wall 34. Control of heart rate has also been shown to further improve outcome 35. Long-term mortality however is relatively high with an estimated 50% mortality at 5 years and late expansion of the false lumen in approximately 25% of the patients at 4 years 36. Late complications are estimated to occur in 20% to 50% of patients. These seque-
Laes include new dissection with associated new complications such as rupture of a weak false lumen and, most commonly, saccular or fusiform aneurysmal degeneration of the thinned walls of the false lumen, which can lead to rupture and exsanguination. Furthermore, patency of the whole false lumen is a predictor of dissection related death and events. The location of the most dilated aortic segment is important as a factor in determining prognosis of type B dissection in the chronic period (defined as more than 14 days after onset of the acute dissection).

**Imaging modalities**

**Digital subtraction angiography (DSA) and fluoroscopy**

After Röntgen had discovered the X-ray in 1895, Berberich and Hirsch reported the first arteriograms obtained in human subjects in 1923, using 20% strontium bromide. In 1924, Brooks introduced diagnostic clinical angiography with injection of sodium iodide. In 1953, Sven-Ivar Seldinger described a method of angiography using retrograde puncture of the common femoral artery. This facilitated the use of angiography, which earlier had to be performed using direct puncture of a peripheral artery or the aorta. Since then, the Seldinger technique is the standard method for angiography in endovascular procedures.

The term digital subtraction angiography refers to techniques which subtract two images that are obtained before and after contrast media is administered to the patient for the purpose of studying blood vessels. Images of bone and soft tissue are subtracted to permit viewing of the blood vessels, in order to enhance the diagnostics. During the stent graft procedure, DSA is used to visualise the aorta and aortic branch vessels for proper placement of the stent graft and for completion control. Both contrast enhanced computed tomography (CT) and DSA use iodine contrast media which is nephrotoxic and may induce renal failure, especially in patients with reduced renal function. Impaired renal function can be caused by a reduction in renal blood-flow, and is common in patients with ruptured aortic aneurysms, aortic type B dissection with occlusion of one or more renal arteries, and in aortic dissections treated with lowering of the blood pressure to avoid progression of the dissection or rupture.

Digital fluoroscopy is the most utilized radiographic technique in endovascular procedures. It uses an x-ray source and an x-ray image intensifier to obtain movie-like real-time information consisting of combined consecutive x-ray images in order to supervise the manoeuvring of catheters, guidewires and devices inside the patient.
Computed tomography (CT)
The basic principle for image generation in CT is a rotating x-ray source around the examined object with detectors on the opposite side. The total amount of gathered information is then processed and reconstructed into an image. In acute situations, CT is usually the most useful technique. With use of spiral acquisition, particularly multidetector arrays, very accurate imaging of the aorta is possible. Studies can be conducted quickly and usually at any time of day or night. To depict blood-vessels, iodine contrast media is used and contrast-enhanced CT is currently the standard imaging modality for preoperative diagnostics, planning and follow-up in EVAR and TEVAR procedures.

Ultrasonography
In brief, the generation of image in ultrasonography is created by an ultrasonic (2-10 MHz) beam, generated by converting electrical energy to mechanical vibrations. Piezoelectric ceramics are generally used and can be arranged in different arrays in a transducer for specific purposes and image formats. Phased array transducers generate a scan with a sector format. The ultrasonic beam is sent into the body and reflected by the different tissues. The beam returns to the transducer as an echo that is registered and processed into an image.

Blood flow is possible to study with ultrasonography using Doppler based techniques. The Doppler Effect is basically a detectable change in frequency caused by the relative movement between a sound wave source and an observer. The movement of blood cells towards the transducer compresses the sound waves and creates shorter wavelengths and higher frequencies than those emitted by the transducer. Movement away from the transducer expands the sound waves and creates longer wavelengths and lower frequencies. When the echoes are processed, orientation of blood-flow and speed can be calculated and displayed either as a sound output or colour. The latter is named colour Doppler.

Intravascular ultrasound (IVUS), was first tested in the 1960s and 1970s, but it was not until the introduction of the ultrasound-tipped catheters in the 1980s that high resolution images of the vessel wall could be obtained. However, these high-frequency catheters (20 to 40 MHz) had limited penetration in depth and were therefore not optimized for imaging of large vessels and structures outside the blood-stream. Transducers with lower frequencies (12 MHz) and with better capabilities for deeper tissue penetration were later introduced and became more feasible and used mainly for intracardiac imaging.
Today, two main technologies are used for clinical purposes: rotating ultrasound element catheters and intravascular phased array imaging (IPAI). IPAI is a frequency agile 5.5-10 MHz, 64-element sector phased array transducer with full Doppler and colour Doppler capabilities (AcuNav, Siemens, Mountain View, CA). The rotating element catheter delivers a 360° axial image, perpendicular to the axis of the catheter and is manoeuvred over a guidewire. This allows for very accurate measurements of diameters and safe handling, but poor steerability. The IPAI device can be tilted in the tip, allowing for good manoeuvrability and optimal imaging depending on anatomical conditions (Fig. 2). IPAI also has deeper tissue penetration than the rotation-based devices, and can be connected to a standard ultrasound platform (Sequoia, Siemens, Mountain View, CA). The Doppler and colour Doppler functions enable detection of blood flow and its direction, which in vascular procedures can be of crucial value (Fig. 3).

Fig. 2.
The IPAI device. Inserted is a close-up view of the catheter tip with the phased-array elements.
An additional form of ultrasound, Transesophageal echocardiography (TEE), can be used for visualization of aortic intimal tears and for identification of the true and false lumen in treatment of patients with aortic type B dissections. TEE has colour Doppler capabilities, which facilitates the detection of the entries, but cannot be used solely as intraoperative diagnostic method for stentgraft planning and for guiding placement. Also, it has to be operated non-sterile due to its intraesophageal placement. Furthermore, as a result of its limited room for manoeuvre, TEE cannot visualize the entire aorta, which limits the inspection of the abdominal aorta and the aortic arch. TEE also has a small risk of oesophageal and gastric perforation.
Rationale of the thesis

The standard use of contrast enhanced DSA and CT may not always be sufficient to reveal the necessary pathological and pathophysiological findings required for optimal treatment of all EVAR and TEVAR patients. IPAI can be performed without iodine contrast media and has Doppler and colour Doppler capabilities enabling visualisation of blood-flow and accurate anatomical guidance, and may thereby be a useful tool in selected cases\textsuperscript{54,55}. The literature regarding use of intravascular phased array imaging in endovascular treatment of aortic dissections is very limited, and in the use for EVAR non-existing.

TEVAR in acute complicated type B dissection is now an established method for therapy. In Uppsala University Hospital, TEVAR was first performed in 1999 and has since been our first-line therapy for this patient category. However, there is still no global consensus on how to optimally treat this complex condition. Although early and mid-term results are favourable, long-term studies on clinical outcome are still warranted, and the long-term changes in aortic morphology following TEVAR of acute complicated type B dissections are yet to be further studied.
Aims of the investigation

General aim

• The general aim of this investigation was to evaluate intravascular phased array imaging as a intraoperative diagnostic tool for planning and guiding endovascular stent graft procedures in the abdominal and thoracic aorta and to evaluate long-term clinical and morphological outcome after endovascular treatment for acute complicated type B dissection.

Specific aims

• To evaluate the feasibility of IPAI in terms of aortic measurements, vessel wall evaluation, and positioning of stent grafts in elective EVAR. (Study I)
• To study the possibility of detecting postoperative endoleaks in EVAR, by means of IPAI. (Study I)
• To report our primary experiences using IPAI as an additive tool for diagnostics and endovascular treatment in TEVAR. (Study II)
• To investigate the early and long-term results of our initial 10-year TEVAR experience of treating patients with complicated acute type B dissections in Uppsala University Hospital between 1999 to 2009, with focus on survival, re-intervention rate and complications. (Study III)
• To analyse whether clinical outcome differed between DeBakey class IIIa and IIIb patients. (Study III)
• To investigate morphological long term changes of the aorta after TEVAR for acute complicated type B aortic dissections in patients treated with TEVAR in Uppsala University Hospital between 1999 to 2009. (Study IV)
• To investigate if changes in aortic morphology after TEVAR differed between DeBakey class IIIa and IIIb. (Study IV)
Patients and Methods

Study I
Thirteen consecutive patients, 11 men and two women were included and examined intraoperatively with IPAI. Nine patients had an infrarenal AAA and were treated with EVAR, three patients with prior EVAR were examined and one patient was treated with endovascular technique for an aortic ulcer in the infrarenal abdominal aorta. All patients underwent a preoperative contrast enhanced helical CT prior to treatment or examination for verification of the diagnosis and for anatomical measurements. The purpose for use of IPAI were to identify and obtain relevant anatomical structures and measurements required for EVAR. After placement of the stent graft, DSA was performed on-table for completion control. Eleven of the patients had a postoperative CT examination and ten of the patients with duplex. The result of the IPAI examination was compared to that of the pre- and postoperative CT examination, the intraoperative angiography and the postoperative duplex.

Study II
Eleven patients, nine males and two females were included. Indications for treatment were chronic type A dissection with dilatation of the descending thoracic aorta in 1 patient, pseudoaneurysm after surgery of type A dissection in 1 patient, chronic type B dissection with dilatation of the descending thoracic aorta in 2 patients, acute complicated type B dissections in 3 patients with visceral ischemia, 1 patient with a ruptured aortic aneurysm in the thoracic aorta and one with elective thoracic aortic aneurysm. One patient was treated with complementary stent graft and embolization of type 2 endoleakage after previous TEVAR and 1 patient was treated for an aortic ulcer with intramural haematoma. The patients included in the study were selected due to uncertainties regarding diagnostic findings in the preoperative CT work-up. All patients underwent a preoperative helical CT-scan to verify the diagnoses, detection of entries, false lumen dilatation, rupture, aortic branch vessel ischemia and for stent graft sizing. IPAI was used before stent graft deployment to detect entries and for guiding stent graft placement. After deployment of the stent graft, DSA and IPAI were performed to demonstrate ceased blood flow in the false lumen or aneurysm, and patency of the great vessels of the aortic arch and abdominal aorta. The result of IPAI was correlated with those of DSA and postoperative CT.
**Study III and IV**

During the period 1999-2009, a total of 60 patients underwent primary endovascular stent-graft treatment for acute complicated type B dissection. 22 were diagnosed with DeBakey IIIa dissection, and 38 with IIIb. Ten of these patients were treated for acute complications occurring during hospitalization for the primary aortic dissection event but >14 days after symptom onset. Median time to treatment was 1.5 days, and 22 days for the 10 patients treated after more than 14 days. If TEVAR alone did not relieve malperfusion, additional stenting was undertaken. All re-interventions after the initial TEVAR procedure were documented. Cross-linkage of the Swedish Cause of Death Register and the Population Register provided follow-up data regarding survival in the patient group.

Radiological follow-up with CT was divided into three time periods; early (1 – 8 months), intermediate (9 – 24 months) and late (2 – 9 years). The maximum total diameter of the descending and abdominal aorta was measured at the preoperative CT examination. The abdominal aorta was defined as starting right proximal to the celiac artery. The diameter of the true lumen and false lumen at the level of the maximum aortic diameter were also analysed, as well as degree of thrombosis of the false lumen. False lumen thrombosis was defined as total, partial (presence of thrombus but also blood flow) and none. The same measurements were performed on follow-up CT examinations, where the previous levels of measurement were used as reference for analysis of aortic remodelling. If dilatation occurred in another part of the aorta than the reference site, this was noted and added as a secondary point for measurement.

**Comments**

Two patients were excluded in study IV as the CT findings showed aneurysmatic enlargement in both cases but with no defined false lumen to be measured. They were both successfully treated with stentgraft. Therefore, the total number of included patients in study IV were 58, divided into 21 with DeBakey IIIa aortic dissection and 37 with DeBakey IIIb.

The initial intention for radiological follow-up was to examine the patients post-operatively at 1 month, 3 to 6 months, 12 months and thereafter annually. However, follow-up was undertaken both in Uppsala University Hospital and in several regional hospitals. Differences in routines and patient compliance did not allow for this strict time regimen to be followed as planned. Therefore, an arbitrary division into three time periods was undertaken as presented above.
Statistics and ethics

Results with continuous variables were presented with means or medians and ranges. Categorical results were presented with frequencies. Analysis of categorical data was done with Fisher’s exact test, and the Mann-Whitney test for age comparisons. To calculate life-table estimates for death and re-intervention, the Kaplan-Meier method was utilised. Estimation of changes in diameter during follow-up was done using Wilcoxon Signed rank test. Statistical Package for Social Sciences (SPSS) for Windows 16.0 and 20.0 were used for data processing and statistical analysis.

All studies were approved by the Research Ethics Committee of Uppsala University Hospital.
Results

Study I
The phased array elements had a characteristic shape and could be identified simultaneously in both the fluoroscopic and ultrasonographic image. These findings made it possible to use the catheter as a reference marker and could be used for positioning of the stent graft (Fig 4). The combined information from IPAI and fluoroscopy allowed reliable identification of all vessel origins from the aorta and iliac arteries. The colour-Doppler facilitated the identification of the vessel origins and the demonstration of patency of the renal and internal iliac arteries after stent graft deployment.

In the first 4 patients, IPAI was inserted and maneuvered in the inferior vena cava (IVC) in order to not interfere with the stent graft procedure. However, visualization from this position was found difficult, despite good tissue penetration, mainly due to tortuosity of the aorta. An intra-arterial positioning was undertaken with superior image quality and resolution. All measurements required for stent graft sizing could be obtained by rotating or using pull-back technique. However, detection of endoleaks was found difficult, as the blood flow from the leakage was usually parallel to the probe causing an unfavourable Doppler-angel to accurately detect signals and movements in the aneurysmal sac. No endoleaks were found with IPAI. Post-operative CT detected type-1 endoleak in 2 patients and type-2 endoleak in 1. These endoleaks were not detected on follow-up duplex.

Comments
In the work-up process, the operating physician had to evaluate the relevant CT images before undertaking the procedure. During the operation, combined information from DSA and CT is used for correct positioning of the stent graft. The Acunav device was maneuvered by the same operator as was conducting the stent graft procedure, therefore no blinded comparison between the modalities was possible, and no statistical analysis was undertaken.
Fig. 4.
Side view of the IPAI catheter as it appears on fluoroscopy. Phased-array elements (arrow) facing to the left.
Study II
In the 7 patients with aortic dissections, the IPAI probe detected the primary intimal tear, re-entries and their relation to aortic branches. After stent graft deployment, IPAI demonstrated ceased blood flow in the false lumen and adequate filling of relevant aortic branch vessels. Reduced or stopped blood flow in the false lumen had a characteristic appearance using IPAI, as more sluggish and echogenic, and could be detected even without colour Doppler. In 3 patients with aortic aneurysms and pseudoaneurysm, the IPAI device provided further visualisation of the topographic anatomy of the aneurysm/ pseudoaneurysm and adjacent aortic branches. In order to detect the entries and branch vessels the IPAI probe had to be rotated 360° to scan the entire circumference of the aortic lumen. The good tissue penetration, the colour Doppler function and the perpendicular blood flow against the probe made it possible to clearly visualize the entries and branch vessels.

After stent graft placement, exclusion of the aneurysmal sac was possible to evaluate by detection of ceased blood flow inside the sac. Exact positioning of the stent graft was facilitated by the colour Doppler function and unnecessary covering of, for example, intercostal arteries could easier be avoided. Furthermore, IPAI could in some patient cases provide diagnostic information regarding entries and false lumen blood flow that were not seen on CT or DSA.

Study III
The dominant indication for treatment in the DeBakey IIIa group was rupture/haematoma/pleural effusion. In the IIIb group, 58% had involvement of one or more distal vascular regions. In 77% of the patients, 1 stent graft was used and the median covered length of the aorta was 20 cm (range, 10-33 cm).

Stenting of end-organ arteries was done in 13 patients in addition to TEVAR. Seventeen patients developed renal malperfusion. Ten resolved spontaneously after TEVAR, five after renal artery stenting and 2 after temporary renal replacement therapy. One of these patients also developed an abdominal compartment syndrome following an intestinal reperfusion syndrome and needed a decompression laparotomy. Four patients underwent right hemicolecotomy, of whom 2 had stents in the superior mesenteric artery. Five patients were treated with iliac stenting.

In order to prevent neurological complications, cervical debranching was carried out in 4 patients prior to the TEVAR procedure and nine had cerebral fluid drainage catheters inserted. Seven patients (12%) suf-
fered from post-operative neurological complications. Four developed post-procedural spinal ischemic symptoms and they all got spinal drainage catheters. Three patients recovered but 1 remained paraplegic. Three patients had signs of cerebral lesion after TEVAR. One patient recovered fully, one partially and one remained hemiparetic. Two patients had neurologic symptoms before the TEVAR procedure. One had paraplegia and recovered with minor sequelae and one with severe intracranial bleeding and distal malperfusion died 2 days after admission.

Median follow-up time was 3.7 years. Thirty-day mortality was 3%. Survival at 3 years was approximately 90%, and 87% at 5 years.

Nineteen patients underwent one or more re-interventions. Actual freedom from re-intervention was 68% ± 6% at 3 years and 65% ± 7% at 5 years. No differences were seen in freedom from re-intervention between the DeBakey IIIa and IIIb groups.

**Study IV**

Fifty-eight patients were analysed, 21 with DeBakey IIIa and 37 with DeBakey IIIb aortic dissection. Seven patients had to be excluded due to lack of follow-up data. Thus, a total of 51 patients, 17 with DaBakey IIIa and 34 with DeBakey IIIb were included in the study. Mean follow-up time was 2.9 years (1.8-5.1 years) in the IIIa group and 3.8 years (1.6 -8.9 years) in the IIIb group.

In the IIIa group the maximum thoracic aortic diameter decreased from mean 44 mm (range, 35-64 mm) at the preoperative CT-scan to 39 mm (31-57) mm at the last follow-up CT, p=0.011. The width of the thoracic true lumen increased from 29 (18-38 mm) to 34 mm (31-39), p=0.041, and the false lumen decreased from 16 (8-46) to 5 mm (0-25 mm), p=0.008. In the abdominal aorta, the average maximum aortic diameter did not differ between the preoperative CT-scan and the last follow-up CT-scan, p=0.372. In one patient with an abdominal aortic aneurysm, not present at the time for diagnose of the dissection, there was a slight increase of the aneurysmal sac diameter. Complete thrombosis of the false lumen was eventually seen in 14 patients (82%). Three patients ended up with partial thrombosis of the false lumen. None of these patients had any increase in aortic or false lumen diameter.

In the DeBakey IIIb group, there was a decrease in thoracic aortic diameter from mean 39 mm (range, 28-64) at the preoperative CT-scan to 36 mm (29-53) at the last follow-up CT, p=0.039. The thoracic true lumen diameter increased from 18 (6-37) to 33 mm (15-42), p<0.001, and the false lumen diameter decreased from 20 (6-32) to 3 mm (0-26), p<0.001.
In the abdominal aorta the total diameter did not change, p=0.592, but the true lumen diameter increased from 14 (1-30) to 20 mm (4-48), p<0.001, and false lumen diameter decreased from 17 (4-33) to 13 mm (0-40), p=0.002. Complete thrombosis of the whole false lumen both along and distal to the stent graft, was achieved in 13 patients (38%). In eight of these patients, primary complete thrombosis was seen within 7 months (1-26 months), of whom 7 had dissections reaching down to the renal arteries and 1 to the aortic bifurcation. An additional 5 patients had complete thrombosis of the false lumen after re-intervention. Ten of the 13 patients with complete thrombosis had complete regression of the false lumen on the latest follow-up CT (Fig. 5).

In 21 patients, partial thrombosis of the false lumen was seen on the last follow-up CT. All of these patients had complete thrombosis along the stentgrafted section of the thoracic aorta, five after re-intervention. The rate of complete thrombosis was significantly higher among patients with type IIIa dissection (82%) compared with type IIIb dissection (38%), p=0.006.

A total of 17 patients (33%) required a secondary intervention, 12 due to dilatation, endoleakage and sealing of re-entries, and 5 for other indications. An aortic dilatation of the thoracic and abdominal aorta below the stent graft was seen in an additional 4 patients who have not undergone re-intervention. These patients are under current clinical surveillance.

**Comments study III and IV**

In study III, 19 patients were reported to have undergone re-intervention. After careful evaluation of the radiological documentation in study IV, there were discrepancies in two cases. One patient was examined with DSA aortography the day before the stent graft procedure. This was registered as re-intervention in the clinical documentation. Another patient with severe bowel ischemia was scheduled for acute stenting of the superior mesenteric artery and the celiac trunk after TEVAR, but died due to intracerebral haemorrhages before the procedure. Thus, 17 patients underwent re-intervention in total.
Fig. 5.
Morphological outcome regarding false lumen thrombosis in the DeBakey IIIa and IIIb group. Primary total or partial thrombosis refers to outcome after the first TEVAR procedure. Total and partial thrombosis at the bottom of the chart shows final outcome at last CT follow-up.
General discussion

The use of IPAI in EVAR and TEVAR

With the introduction of interventional radiology in the 1960s, imaging has become an integrated part of the therapeutic arsenal\textsuperscript{56,57}. Breakthroughs in the clinical use of minimally invasive procedures have led to the breathtaking progress and refinement of operating techniques and materials that has characterized the evolution in this field\textsuperscript{58}. Imaging techniques are under constant development and during the last decades, diagnostic radiology has undergone the fastest technical advancements of all medical disciplines. The advent of endovascular techniques to treat aortic disease require more sophisticated imaging methods for planning, guiding and follow-up. Especially in the intraoperative situation, the outcome is highly dependent on proper visualisation of vital anatomic landmarks for correct positioning of the devices. Dynamic imaging and assessment of patho-physiological processes can also be crucial for accurate diagnostics and completion control. These demands can normally be met using DSA alone, but in certain cases, alternative methods must be used.

IPAI operating technique and initial findings

Thrombus in an aortic aneurysmal sac can detach and embolize distally if manipulated. Furthermore, in the acute dissection, both the intima and the outer wall of the false lumen are inflamed and fragile, and manipulation in the aortic arch can increase the risk for cerebral embolization and progress of the dissection. As the IPAI catheter does not run over a guidewire, we choose to use a 12 Fr. introducer sheath with constant saline flush for the device to be manoeuvred in, in order to reduce the risk for vascular trauma. (Fig 5) The introducer sheath could be placed safely in the aorta and the use of continuous saline was thought to facilitate the conduction of the ultrasonic beam through the introducer sheath wall. The image quality was found unimpaired using this setup. Whenever a specific object needed to be further scrutinised, the introducer sheath could be pulled back to allow flexion of the catheter-tip, which can be useful when detecting blood-flow parallel to the probe, hence creating a more favourable Doppler angle. This can be useful for example in the detection of type I and II endoleaks. Best diagnostic results with the IPAI probe was seen with the probe in an intra-arterial position. With the probe placed in the IVC or iliac veins, the tortuosity of the aorta and iliac arteries caused difficulties in accurate identification of the relevant object due to the increased distance.
Fig. 6.
Thoracic aortic stent graft after deployment. A 12 Fr. introducer sheath (arrow) is positioned through the stent graft for manoeuvring of the IPA1. A transesophageal echocardiography probe is seen in the top of the image (hollow arrow).
The phased-array elements in the catheter tip had a characteristic appearance on fluoroscopy that allowed correct orientation of the probe. The distal and proximal edges of the elements corresponded to the cranial and caudal part of the line representing the phased-array elements in the ultrasonographic image. This finding provided an exact determination of position of the depicted object, and a possibility to use the probe as a reference marker in endovascular aortic procedures. Measurements of distance were easily done using pull-back technique, positioning the probe at one location and withdrawing it to another. The distance is then measured outside the patient. Accurate measurements of diameter were found to be more difficult. The probe had to be rotated 180° and the two distances to the aortic walls added. The easy detection of the phased-array elements on fluoroscopy facilitated this procedure, and the obtained distances correlated to the CT findings. However, rotating ultrasound element catheters that generate an axial image of the aorta are probably more precise for this purpose.

When examining the blood flow with IPAI in an excluded aneurysm or false lumen with fully or significantly reduced perfusion after stent graft deployment, it appeared more echogenic and sluggish. This phenomenon was clearly detectable without colour Doppler and considered a favourable sign of good exclusion of the aneurysm or false lumen after coverage of the intimal tear. However, small type II endoleaks were difficult to visualize even with the colour Doppler function, as it was difficult to discriminate this from movement artefacts in the aneurysmal sac.

**Clinical applications of IPAI**

In patients with ruptured aortic aneurysm or acute dissection, a reduction in blood pressure is an important medical treatment action to prevent further progress. Reduced renal function combined with decreased blood pressure and administration of iodine contrast media, both in the pre-operative planning with CT and during the peroperative DSA, can lead to further impairment due to the nephrotoxicity of these substances. Furthermore, in patients with allergy to iodine contrast media, or severe co-morbidity, not making the patient suitable for open surgery, the use of IPAI may be a useful alternative method for guiding stent graft procedures and for completion control. Carbon dioxide (CO₂) angiography is a safe and commonly utilised alternative in patients with contraindications to use of iodine contrast media. In the abdominal aorta, this technique is a viable option, however in the ascending aorta and aortic arch, CO₂ can not be used due to risk for cerebral infarction. In this region, IPAI may be the most potent alternative for guiding stent graft deployment.
Using IPAI in the EVAR patient where no iodine contrast media can be used or has to be reduced, the celiac trunk and superior mesenteric artery must be identified to avoid errors in identification of the renal arteries. The diameters of the aortic neck and iliac arteries can be obtained on a non-contrast work-up CT. IPAI can verify patency of the arteries and detect potential presence of thrombus. Distances from renal arteries to internal iliac arteries can be measured by pull-back technique or on the non-contrast CT. Using the phased array elements as a reference markers at the most caudal location of the renal arteries and location of the internal iliac arteries, the stent graft can be deployed under simultaneous inspection with fluoroscopy and IPAI. Patency of the renal and internal iliac arteries can be verified immediately after deployment. One patient in study I was treated under guidance of IPAI solely. Diameter measurements were obtained from the preoperative CT, and the clinical result was excellent.

In study II, IPAI provided information in 2 of the cases reported, that significantly altered or facilitated the therapeutic strategy. In one patient, primarily diagnosed with a type A aortic dissection, IPAI revealed a the primary intimal tear in the mid aortic arch, which was treated with a right to left carotid by-pass and a stent graft placed just distal to the brachiocephalic artery, covering both the left carotid and subclavian arteries. An open surgical reconstruction of the ascending aorta could be avoided. In another patient with a large pseudoaneurysm at the distal anastomosis of an ascending aortic graft due to a type A aortic dissection, intraoperative DSA could not clearly visualize the entry into the pseudoaneurysm and the flow into the aneurysmal sac. Neither was completion aortography after stent graft deployment conclusive with DSA. The IPAI device was placed in the left brachiocephalic vein, which provided clear demonstration of stasis in the aneurysmal sac after stentgraft deployment. In all 11 cases, IPAI facilitated the procedure by giving further diagnostic information, supplementing those provided by DSA in 10 cases, and altered the therapeutic strategy in 1.

Placement of the stent graft in thoracic dissections and aneurysms require careful planning. To minimize the risk for spinal ischemia, unnecessary occlusion of intercostal arteries should be avoided when deciding landing zone for the stent graft. An accurate identification of the location of the primary tear can prevent coverage of a too long portion of the descending aorta. This is especially important when other collaterals are occluded, as in patients with previous abdominal aortic surgery, coverage of the left subclavian artery or internal iliac arteries due to stent graft treatment and/or embolization. In the thoracic dissection cases, the intimal tears could be detected and visualised in the intimal
flap. To scan the aorta, the IPAI probe had to be rotated 360° in order to fully examine the whole circumference. Fluoroscopic observation of the radiopaque phased array elements could be used to ensure 360° rotation. Blood flow in the primary intimal tear and re-entries was perpendicular to the probe, making the colour Doppler very useful for detection. These findings were also described in another study that reports IPAI to be superior to rotating ultrasound catheters and TEE in detecting communications between the true and false lumen. Several authors also report the use of IVUS feasible in endovascular aortic therapy.

In summary, IPAI can be a helpful complementary technique in selected cases when the use of iodine contrast media cannot be used, or when diagnostics need to be further sharpened. The main drawback is the cost of approximately 2500 Euro per catheter, and the single-use recommendation from the manufacturer. However, the device can be used several times without loss of image quality, and a method for re-sterilisation has been developed in our institution.

Clinical and morphological follow-up after TEVAR in acute complicated type B aortic dissection

Mortality and morbidity
Since the introduction of TEVAR in Uppsala University Hospital, it has been our first-line therapy in patients with acute complicated type B dissection. In the follow-up of all patients treated from 1999 to 2009, 30-day mortality was 3%, survival at 3 years was 90% and at 5 years close to 90%. These results are excellent when compared to other studies (Fig. 7). Neurological complications were seen in 7 (12%) of all patients after TEVAR in study III. Three of the 4 patients with spinal ischemia recovered. Only 1 of 3 patients with cerebral lesions remained hemiparetic, making the incidence of permanent neurologic sequelae in line with previously reported studies. All patients who developed spinal symptoms were given a spinal drainage catheter closely after onset of symptoms and monitored at an intensive care unit. No patient with a pre-operatively inserted drainage catheter developed any neurological symptoms.

Distal malperfusion was seen in more than one-fifth of all patients, most common in the DeBakey IIIb group, due to the extension of the dissection involving the abdominal aorta. The predominant complications in the IIIa group were dilatation and rupture. A reason for this could be the more restricted total volume of the false lumen when limited to the
Kaplan-Meier curves showing survival of patients treated with TEVAR for acute complicated type B aortic dissection. DeBakey IIIa and IIIb are displayed. The number of patients at risk at different time points after treatment is given.

Fig. 7.

Thoracic aorta, and fewer re-entries than in DeBakey IIIb dissections. This might lead to increased pressure in the false lumen, making it more susceptible to rupture.

Ten patients were treated for acute complications after >14 days after symptom onset. The 2-week definition dividing acute dissections from chronic, is an arbitrary time limit mainly based on survival before effective treatment was available. The late occurrence of acute complications in these 10 patients indicate that it may take longer than 14 days for the dissection to stabilize.
Aortic remodelling

Long-term radiological follow-up showed a favourable aortic remodelling, with an overall significant reduction of thoracic aortic diameter, increased true lumen diameter and reduced false lumen diameter. Total thrombosis of the false lumen was seen in 53% of all patients, 41% primary and 12% after re-intervention. The DeBakey IIIa group had a higher degree of total false lumen thrombosis. However, all patients in the IIIb group had total thrombosis of the false lumen along the stent-graft. Several previous reports have described similar morphological outcome after TEVAR for acute complicated type B dissection\textsuperscript{73-76}.

Six patients in the present study developed a dilatation or a type I endoleak without dilatation of the aorta proximal to the stent graft and adjacent to the left subclavian artery. Re-intervention with placement of a proximal stent graft resulted in total or increased thrombosis of the false lumen with reduced or stabilized aortic diameter. These findings indicate that this part of the aorta seem to be susceptible to dilatation and endoleaks. Similar observations have been done by other authors. They recommend, unless contraindicated, routine coverage of the left subclavian artery to minimize the risk for complications in this vulnerable aortic segment\textsuperscript{77}. In the present study, 1/3 of the patients with a proximal dilatation/type I endoleak had their left subclavian artery covered at the first procedure, suggesting this action alone may not be sufficient to avoid later complications. Special consideration should be taken not only to cover the primary entry site, but also to reassure good proximal sealing of the stent graft to prevent the risk for later dilatation and rupture. Forthcoming release of stent graft designs with a branch for the left subclavian artery ought to be useful in this respect.

The extent of the coverage of the descending thoracic aorta to optimize true lumen expansion and promote false lumen thrombosis is often debated. In our institution we routinely place 1 stentgraft to cover the proximal tear and additional stentgrafts are only deployed after signs of major endoleaks or dilatation. The relatively low occurrence of late dilatation in the aortic segments distal to the stent graft in this study, and the risk for spinal ischemia due to extensive coverage could suggest a “less is more” approach, but with careful surveillance. Similar findings have also been reported in another study\textsuperscript{73}. A deviation from this strategy may be appropriate in a patient with a rupture of the false lumen. Retrograde blood-flow into the false lumen can result in persistent extravasation from the rupture site, despite coverage of the primary entry, and could necessitate a longer stent grafted section of the aorta.
Overall in the DeBakey IIIb group, the mean abdominal aortic diameter did not change, which was explained by a simultaneous increase of the true lumen and decrease of the false lumen. However, several studies report an enlargement of the aortic diameter below the stent graft in the thoracic and abdominal aorta in some patients\textsuperscript{75,76,78}, and also a correlation between false lumen perfusion and false lumen dilatation in the abdominal aorta\textsuperscript{77}. In study IV, 5 of 34 patients in the DeBakey IIIb group required re-intervention due to dilatation below the stent graft in the thoracic aorta, or both the thoracic and abdominal aorta. An additional 4 patients had dilatation both in the thoracic and abdominal aorta, not requiring any actions at the moment. These findings further emphasise the importance of accurate radiological follow-up of the whole aorta, especially in patients without complete thrombosis of the false lumen.

Primary complete thrombosis of the false lumen was observed both in the DeBakey IIIa and IIIb group, suggesting that successful coverage of the primary entry site and a good sealing around the stent graft result in a rapid remodelling and in several cases a normalisation of the aorta. Partial thrombosis of the false lumen was, however, always characterized by blood flow distal to the stent graft. Retrograde flow in the false lumen appears to be the explanation to this phenomenon. The higher degree of primary false lumen thrombosis in the IIIa group, and the fact that most of the patients in the IIIb group with primary thrombosis also had dissections ending at the level of the renal arteries, indicate that a false lumen with fewer re-entries is more prone to favourable remodelling after sufficient treatment. Partial thrombosis of the false lumen that contained blood-flow in the thrombus has been described as a major risk-factor for postdischarge mortality compared to a totally patent false lumen, in a previous study\textsuperscript{79}. Possible mechanisms for this were increased pressure within the false lumen by occlusion of distal re-entries by the thrombus, resulting in a blind sac, as opposed to a total thrombosis that prevents blood-flow and thereby allows for healing. Hypoxia in the arterial wall adjacent to the thrombus may also contribute to increased risk for dilatation and rupture. The results from the present studies suggest that total thrombosis along the stent graft and a patent false lumen below is prognostically more favourable than the partially thrombosed false lumen with blood flow and thrombus along the stent graft.
Uncomplicated type B aortic dissections

In patients with uncomplicated type B aortic dissections, a conservative approach with medical treatment is advocated and IRAD data as well as several other studies report satisfactory early survival in this patient group. However, long-term outcome remains unsatisfactory with an estimated 50% 5-year mortality and frequent late expansion of the false lumen. Ongoing studies aim to investigate whether stent graft treatment in this patient category can result in better survival compared to best medical treatment (BMT). The ADSORB-trial compares BMT and TEVAR+BMT in uncomplicated type B dissections. No published data are available, but preliminary results show no difference in survival between the two groups at 1 year. The INSTEAD trial reports no differences in 2-year survival and adverse event rates despite favourable aortic remodelling in the TEVAR group compared to BMT alone. However, at the 2012 Thoracic Aortic Masterclass in London, 5-year follow-up data were announced, showing a significantly higher freedom from progressive aortic disease and lower mortality in the TEVAR group. The excellent long-term survival combined with the favourable aortic remodelling in patients treated with TEVAR for acute complicated type B dissections in our institution, suggest that TEVAR as first-line therapy may be beneficial even in patients with uncomplicated type B aortic dissections.
Conclusions

General conclusion
• IPAI can be a complementary tool to traditional imaging modalities in EVAR and TEVAR in selected cases. Long-term clinical outcome was excellent with favourable aortic remodelling after TEVAR in patients with acute complicated type B aortic dissection.

Specific conclusions
• IPAI is feasible for diagnostics in planning and guiding EVAR.
• Detection of postoperative endoleak in EVAR was found difficult with IPAI.
• IPAI is a helpful tool in treatment of thoracic aortic pathology.
• Excellent early and long-term results regarding survival, re-intervention and neurological complications were seen after TEVAR in patients with acute complicated type B aortic dissection in Uppsala University Hospital.
• No differences in survival or freedom from re-intervention were seen between the DeBakey IIIa and IIIb groups.
• Favourable aortic remodelling, with an overall significant reduction of thoracic aortic diameter, increased true lumen diameter and reduced false lumen diameter was seen after TEVAR in patients with acute complicated type B aortic dissection in Uppsala University Hospital.
• Total thrombosis of the false lumen occurred more often in patients with DeBakey IIIa aortic dissection than in IIIb.
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Akut komplicerad typ B aortadissektion kännetecknas av en blödning i aortväggen efter aortabågen. Blödningen skapar ett hålrum i väggen som kallas falskt lumen. Dissektionen kan orsaka avstängning av buk- eller extremitetsväggar, dilatation eller ruptur av aorta samt svårbehandlad smärta. Överlevnad har tillståndet hög dödlighet. TEVAR har visat sig ha bättre behandlingsresultat avseende dödlighet och morbiditet jämfört med traditionell öppen kirurgi, och är idag förstahandsmetod vid terapi av denna sjukdom. Någon konsensus om i vilken utsträckning metoden skall användas finns dock ej, och den vetenskapliga rapporteringen av morfologiska långtidsresultat i aorta efter TEVAR är sparsam.

Detta projekt handlar om utvärdering av IPAI vid EVAR och TEVAR i syfte att optimera diagnostik och behandling, samt om klinisk och radiologisk uppföljning av samtliga TEVAR behandlingar av akut komplicerad typ B aortadissektion utförda vid Akademiska Sjukhuset mellan åren 1999 och 2009, med huvudsaklig inriktning på överlevnad, komplikationer och morfologiska förändringar av aorta över tid.
Arbete I
IPAI användes i samband med EVAR med identifiering av relevanta kärlavgångar från aorta, längdmätningar och utvärdering av aortävåggens beskaffenhet. Mätningar för stentgraftets måttbestämning kunde göras och underlättades av färdigdopplerfunktionen. Dessa överensstämde med mått vid DT och angiografi. Informationen från IPAI och genomlysning möjliggjorde exakt positionering av stentgraftet. Placering av ultraljudsproben i aorta gav bättre avbildningskvalitet jämfört med i vena cava inferior. Detektion av endoläckage befanns vara svårt.

Arbete II
IPAI användes intraoperativt i samband med TEVAR av sjukdomar i bröstaorta. IPAI kunde upptäcka och visualisera defekter i aortans innersta vägglager, intiman. Aortagrenar kunde visualiseras och flödesbedömas både under och omedelbart efter stentgraftspalcering. Det var också möjligt att detektera upphört blodflöde i det falska lumener vid dissektion eller i aneurysmsäcken efter stentgraftsinsättning.

Arbete III
Tidiga och långsiktiga kliniska resultat av TEVAR för akut komplicerad typ B dissektion i aorta undersöktes på patienter behandlade för akut komplicerad typ B dissektion vid Akademiska sjukhuset i Uppsala mellan åren 1999 och 2009. Tidig (30-dagars) och långtids (5-år) överlevnad, re-intervention och komplikationer registrerades. Utmärkta resultat i jämförelse med andra publicerade studier konstaterades avseende överlevnad och bestående neurologiska komplikationer.

Arbete IV
Syftet med denna studie var att radiologiskt undersöka långsiktiga morfolologiska förändringar i aorta efter TEVAR för akuta komplicerade typ B dissectioner. Uppföljningen gjordes med DT och visade gynnsamma förändringar med reduktion av genomsnittlig aorta diameter, ökning av äkta lumens vidd samt minskning av falska lumens vidd. Total trombotiserings av det falska lumener sågs oftare i DeBakey IIIa gruppen än i IIIb.
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A doctoral dissertation from the Faculty of Medicine, Uppsala University, is usually a summary of a number of papers. A few copies of the complete dissertation are kept at major Swedish research libraries, while the summary alone is distributed internationally through the series Digital Comprehensive Summaries of Uppsala Dissertations from the Faculty of Medicine.