The role of magnetic resonance angiography for endoprosthetic design

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Objectives: Many patients with aortic aneurysms have renal insufficiency and may be at increased risk when conventional imaging modalities (contrast-enhanced computed tomography and arteriography) are used for aortic endograft design. Our objective was to determine if magnetic resonance angiography (MRA) could be used as the sole imaging modality for endoprosthetic design.

Methods: A total of 96 consecutive patients who underwent endovascular repair of thoracic (5) and abdominal (91) aortic aneurysms (April 1998–December 1999) were included in this study. Data were collected prospectively. Gadoliniumenhanced MRA was used preoperatively in place of conventional imaging if renal insufficiency or a history of severe contrast reaction was present. The control group underwent conventional imaging. Endografts used included Ancure, AneuRx, and Talent.

Results: Fourteen patients (14.6%) had their endografts designed solely with MRA. Intraoperative access failure; proximal and distal extensions (unplanned); conversion to open, aborted procedures; and endoleaks occurred with equal frequency in both the MRA-designed and control groups (16.7% vs 18.3%, respectively; P = .33). Despite baseline renal insufficiency, there was no significant rise in the creatinine level after endograft implantation in patients with an MRA design (preoperative level, 1.8; postoperative level, 1.9; P = .5).

Conclusion: MRA may be successfully used as the sole modality for aortic endograft design. The use of MRA for this purpose is noninvasive and minimizes nephrotoxic risk. (J Vasc Surg 2001;33:488-94.)

Endograft repair of an abdominal aortic aneurysm (AAA) was first reported by Parodi et al in 1991.¹ Since that time, aortic endografting has become widespread and may even be considered the current standard of care for the repair of AAAs in patients with significant medical comorbidities, which would make open repair risky. The development and proliferation of aortic endograft devices have certainly been enhanced by the involvement of industry. Currently, there are a large variety of endograft devices that are in varying stages of clinical trials. To date, only the Ancure (Guidant-Endovascular Technologies [EVT], Menlo Park, Calif) and AneuRx (Medtronics, Santa Rosa, Calif) possess conditional Food and Drug Administration approval.

In the current study we used the previously named devices and a significant number of Talent (World Medical-Medtronics, Sunrise, Calif) devices, which, like the AneuRx devices, are modular and fully supported with nitinol stents. Additionally, a row of proximal bare springs allows suprarenal fixation while preserving flow to the kidneys.

The success or failure of an aortic endograft procedure

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0741-5214/2001/\$35.00 + 0 **24/6/112211** doi:10.1067/mva.2001.112211 depends as much on precise preoperative measurement and endograft design as on intraoperative technique. Therefore, accurate preoperative imaging is essential. The most commonly used modalities are the combination of unenhanced and intravenous contrast-enhanced computed tomography (CT) of the abdomen and pelvis with 3-mm cuts and biplanar aortography performed with a radiopaque marker catheter. These studies allow the assessment of iliac tortuosity and calcification and allow accurate measurement of the diameter and lengths of endografts required for successful exclusion of the aneurysm.

Unfortunately, a significant number of patients are unable to safely undergo these procedures because of either renal insufficiency or an allergy to the contrast dye. The incidence of contrast-related nephropathy in patients with baseline renal insufficiency can range from 9% to 93%, depending on the contrast agent used, underlying comorbidities, volume, and preprocedure preparation.²

Magnetic resonance angiography (MRA) is performed to obtain images without the use of ionizing radiation or contrast dye. Gadolinium-enhanced delayed images allow visualization of both the flow lumen and the aneurysmal (adventitial) wall and allow visualization of all major branches in multiple projections, allowing endograft design with a workstation.

The purpose of this study was to compare the early outcome of aortic endografts designed solely with the use of MRA with regard to intraoperative access failure, unplanned use of proximal and distal extensions, conversion to an open procedure, aborted procedures, and the incidence of endoleaks. Additionally, radiation time, radiation dose, and procedure time were compared. These parameters were

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Competition of interest: nil.

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Fig 1. Gadolinium-enhanced MRA of an AAA with descending thoracic dissection. Note dissection continuing into left common iliac artery. A single right renal artery and two left renal arteries are demonstrated. Main left renal artery is fed partially by false lumen of dissection.

compared with those in a control group whose endografts were designed with conventional modalities.

METHODS

A total of 96 consecutive patients who underwent endovascular repair of thoracic (5) and abdominal (91) aortic aneurysms were included in this study. This study met with approval by our institutional review board and human ethics committee. The repairs were performed between April 1998 and December 1999 and included all aortic endograft procedures performed during this period. All data were collected prospectively and reviewed retrospectively. Gadolinium-enhanced MRA was used preoperatively in place of conventional imaging if renal insufficiency or a history of severe contrast reaction was present. For the purposes of this study, renal insufficiency was defined as the patient having a creatinine level of more than 1.5 mg/dL before imaging. There were no patients undergoing dialysis. No patients in the MRA group received any preoperative contrast-enhanced study at either our institution or an outside institution. The only screening studies used were unenhanced CT or ultrasound scan. The control group underwent conventional imaging, which included unenhanced and intravenous contrastenhanced CT of the abdomen and pelvis with 3-mm cuts, as well as biplanar aortography with a radiopaque marker catheter. There was no crossover between groups. A single vascular surgeon (R.F.) designed all endografts.

MRA was performed on a 1.5 Tesla system (Signa, General Electric Medical Systems, Milwaukee, Wis).

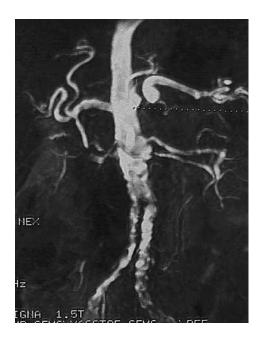


Fig 2. A 2-D time of flight MRA of patient in Fig 1. Aneurysm is successfully excluded with preservation of all renal arteries.

Coronal single shot fast spin echo localizers followed by axial single shot fast spin echo sequences, followed by sagittal type 3 Dearing strain dynamic gadolinium enhancement with 30 cc of contrast and postcontrast axial sequences.

CT imaging of the abdomen and pelvis was performed. After acquisition of initial unenhanced localizing images with 10-mm cuts, a test dose injection with 16 cc of nonionic contrast material at a rate of 4 cc/s was used to demonstrate a circulation time. Subsequently, a CT angiography (CTA) study was performed with 100 cc of nonionic contrast material injected at 4 cc/s with a scan delay depending on the calculated circulation time. A 3mm slice collimation was used from the celiac artery to the proximal femoral vessels.

A transfemoral aortogram was performed with a marker catheter in the aorta and pelvis. Anteroposterior and lateral views of the aorta were obtained with the catheter positioned at the level of the renal arteries, as well as anteroposterior and right and left anterior oblique views of the pelvic vessels with an aortic bifurcation injection.

Early outcome parameters of all procedures were analyzed by determination of the following end points: intraoperative access failure, unplanned use of proximal or distal extensions, conversion to an open procedure, aborted procedures, and the incidence of any endoleak. Additionally, total radiation time, radiation dose, and procedure length were noted. Preoperative and postoperative creatinine levels of all patients were routinely obtained. Statistical analysis included the Fisher exact test and χ^2 testing.



Fig 3. Gadolinium-enhanced MRA of saccular thoracic aortic aneurysm.



Fig 4. Status of patient in Fig 3 after stent graft repair. Note limitation of MRA to demonstrate lumen within a stented graft.

RESULTS

Fourteen patients (14.6%) had their endografts designed solely with MRA (Figs 1-5). The reasons for choosing MRA were renal insufficiency in 12 patients and a history of severe contrast dye reaction refractory to periprocedural steroid and antihistamine preparation in two patients. None of the procedures with MRA-designed endografts resulted in failure to obtain access or needed to be aborted. Three of the 82 control procedures with conventional imaging design had to be aborted because of failure to obtain access. This was not statistically significant. There were no conversions to an open procedure in either group.

Nine (11%) of 82 control procedures had an intraoperative proximal leak after placement of the main graft body, whereas there were none in the MRA group. These were all immediately and successfully addressed with proximal covered extensions. This was not statistically significant. Two additional patients in the control group required the use of an unplanned proximal extension, although they did not demonstrate a proximal endoleak. No proximal extensions were needed in the MRA group. This was not statistically significant.

With regard to distal endoleaks and extensions, there were three (21%) of 14 distal endoleaks noted during the procedure in the MRA group and 12 (14%) of 82 distal endoleaks in the control group (not statistically significant). All distal endoleaks were immediately and successfully resolved with distal covered extensions.

There were five (36%) cases requiring the use of unplanned distal extensions in the MRA group as compared with 41 (50%) cases in the control group (not sta-

tistically significant). There were no instances of junctional or graft material endoleak in the MRA group, and only three (3.7%) instances of a junctional or graft leak in the control group (not statistically significant).

All grafts were studied within 30 days for evidence of endoleak. Contrast-enhanced CT was used for postoperative imaging in the control group and MRA in the study group. All postoperative studies used delayed contrast imaging to maximize sensitivity in detecting even slow endoleaks. There was a 16.7% incidence of postoperative (30-day) endoleak in the MRA group and an 18.3% incidence in the control group. Most of these were the type II variety. However, there were two proximal endoleaks present at 30 days postoperatively in the control group and one distal attachment site endoleak in the control group. All 30-day endoleaks were studied with angiography and definitively diagnosed (Figs 6 and 7).

The total procedure time for the MRA-design group and the control group was 2.33 hours and 2.8 hours, respectively, (not statistically significant). The volume of contrast used was 154 mL in the control group as compared with 95 mL in the MRA-design group (P = .058). Total intraoperative fluoroscopy time was 42 minutes in the MRA-design group and 36 minutes in the control group (not statistically significant). The radiation dose was 7249 rad/cm² in the MRA group as compared with 6595 rad/cm² in the control group (not statistically significant).

The mean preoperative creatinine level in the MRAdesign group was 1.8 mg/dL, whereas in the control group it was 1.4 mg/dL. This did not meet with statistical significance. Fortunately, the postoperative creatinine levels in both groups did not vary significantly from pre-

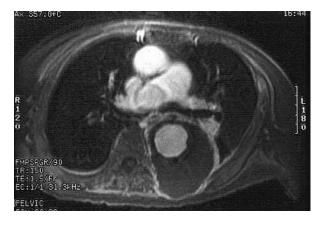


Fig 5. Delayed sequence gadolinium-enhanced MRA demonstrating value of visualizing true dimensions of aneurysm. This is patient's status after stent graft repair. No endoleak is observed.



Fig 6. A 2-D time of flight MRA demonstrating large endoleak of uncertain etiology.

operative levels (1.98 mg/dL for the MRA group and 1.4 mg/dL for the control group).

DISCUSSION

This study demonstrates the feasibility of using MRA as the sole preoperative imaging modality before aortic endografting. When compared with a control group with conventional CT and marker catheter aortography, there was no difference in the incidence of conversion to open procedures, aborted procedures, or ability to obtain access for placement of the device. Additionally, there was no increase in the incidence of unplanned proximal or distal extensions or overall endoleak rate. Admittedly, because most endoleaks were of the type II variety, it would be unlikely for this number to be influenced by the imaging modality chosen to design the endograft. With respect to

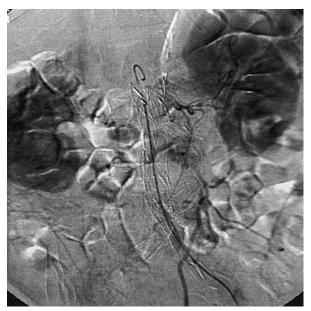


Fig 7. Gadolinium-based contrast arteriogram of patient in Fig 6. This study identifies endoleak resulting from high-riding, patent inferior mesenteric artery that was successfully coil embolized.

type I endoleaks, there was also no significant difference between the groups. A potential for bias exists here because clearly, in an effort to minimize the use of contrast material in patients with renal insufficiency, the technique of completion arteriography may have differed between the groups. Although all proximal completion arteriograms were performed with a pigtail catheter and power injector, there may have been differences in volume, type, and concentration of contrast material between the two groups. It would be expected, however, that any missed type I endoleaks would become manifest on follow-up imaging designed to be sensitive to even slow leaks. Also, there was no significant difference between MRAdesigned procedures and control procedures with regard to fluoroscopy time, radiation dose, and overall operative procedure time.

A primary motivator for this study was to minimize the use of nephrotoxic agents in the performance of aortic endografting of patients with renal insufficiency. In a recent large, prospective, randomized, trial of almost 1200 patients undergoing cardiac catheterization, the incidence of renal dysfunction was 7% in patients receiving an ionic agent and 3% in patients receiving a nonionic contrast agent.³ All patients in this study underwent periprocedural hydration. Renal dysfunction was defined as an increase in the serum creatinine level of 1 mg/dL or more 48 to 72 hours after contrast. Baseline renal insufficiency was an independent risk factor for developing contrast-induced nephropathy. The incidence of clinically severe adverse events was 1.25%.³ In another recent study of patients with baseline renal insufficiency receiving radiocontrast agents, 11% to 40% of patients experienced nephrotoxicity

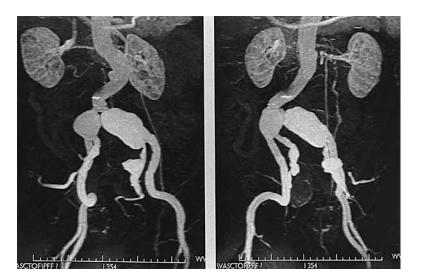


Fig 8. Gadolinium-enhanced MRA demonstrating ability to view vascular structures from all angles to best understand relative anatomy and tortuosity at computer workstation.

as evidenced by an increase in the serum creatinine level of 0.5 mg/dL 48 hours after injection.⁴ Even the use of small amounts of nonionic contrast material to enhance carbon dioxide or gadodiamide contrast studies resulted in a worsening of renal function at 48 hours. Despite minimal contrast use, the mean creatinine level in the MRA group rose from 1.8 mg/dL preoperatively to 1.98 mg/dL postoperatively. Although this was not statistically significant, it does represent a concerning trend, suggesting that reducing contrast load wherever possible would be desirable. The incidence of a relevant systemic reaction to contrast material is approximately 5% with a small percentage of these being severe.⁵ The incidence of a severe reaction is, however, increased in patients with a history of a prior reaction or allergies in general.⁶

Overall, gadolinium has been proved to be quite safe. In a study of 21,000 patients who underwent gadoliniumenhanced MR studies at the University of Michigan, there were only 36 adverse reactions. Of these, two (0.01%) were considered severe, anaphylactoid reactions. The authors note, however, that this is higher than the reported rate of anaphylactoid reactions reported in the literature.⁷

In a retrospective study of more than 15,000 patients who underwent gadolinium-enhanced magnetic resonance imaging (MRI) examinations, Arsenault et al⁸ focused on 151 patients who had a serum creatinine level of more than 2 mg/dL. The overall incidence of adverse events was 3.6% with no severe or life-threatening reactions. The authors note this was not dissimilar to the percentage of adverse reactions in patients with normal renal function. There was no real change in creatinine levels after the procedure, with mean serum creatinine levels of 2.5 mg/dL and 2.3 mg/dL before and after the procedure, respectively.

Prince et al⁹ studied the effects of high-dose gadolinium (0.2 to 0.4 mmol/kg) on renal function. They compared preprocedure and postprocedure serum creatinine levels of patients who underwent both gadoliniumenhanced MR and an iodinated contrast study. The mean change in serum creatinine levels after gadoliniumenhanced MR was 0.7 mg/dL. The mean change in creatinine levels after iodinated contrast was +0.35 mg/dL. The authors note that none of the patients experienced gadolinium-induced renal failure despite the high dose and high prevalence of renal insufficiency. Although these studies demonstrate that the use of gadolinium is less nephrotoxic than iodinated contrast, it should not be inferred that an individual patient is completely free of nephrotoxic risk when undergoing a gadolinium-enhanced study.

MRA imaging techniques used in this study are not those of standard MRA. Standard MRA with two-dimensional (2-D) time of flight only provides imaging that is based on moving particles, and therefore, only demonstrates the flow lumen. In this regard, it has the same limitations of standard angiography in the inability to demonstrate the true aneurysm dimensions. The techniques used in this study required the use of gadolinium-enhanced delayed images, which provided visualization of the flow lumen and the external dimensions of the aneurysm similar to contrast-enhanced CT. This is based on the dynamic acquisition of a heavily T1-weighted gradientecho pulse sequence during the injection of a gadolinium contrast agent. The gadolinium causes a dramatic shortening of the T1 in the vascular tree, thereby creating a high level of contrast with background tissue.

MRA allows the acquisition of true three-dimensional (3-D) data, in contrast to conventional angiography in which only 2-D projection data may be obtained. As such, MRA images may be more revealing in cases of complex, tortuous arterial anatomy. The 3-D capability is also exploited to make accurate measurements for stent graft repair (Fig 8). Additionally, MRA provides higher background suppression than CTA, in which structures such as

bone and calcification may interfere with the creation of maximum intensity pixel images.

MRA examinations typically have relatively short acquisition times. Although an integrated MRI/MRA examination requires approximately 1 hour to perform, the MRA data themselves only require approximately 5 minutes to acquire. Therefore, a "focused" MRA examination may be easily completed in less than half an hour.

MRA provides higher background suppression than CTA. In CTA, structures such as bone and calcification may interfere with the creation of maximum intensity pixel images.

The accurate interpretation necessary to obtain adequate diameter and length measurements requires examination of the images at a computer-driven workstation with the appropriate software and the assistance of an MR radiologist with an interest in MRA. Such equipment and experience may not yet be available at all institutions.

As expected, there are some limitations to using MRA as the sole preoperative imaging modality. For instance, MRA does not obviate the need for real-time imaging during the procedure itself. In certain instances, however, we have been able to use gadolinium-enhanced fluoroscopy to limit or eliminate the use of standard contrast material during endograft placement. There are a number of people who cannot undergo an MRI. These include patients with certain metallic implants, pacemakers, and metal in the eye due to trauma. Additionally, a number of people are too claustrophobic to tolerate an MR examination or are unable to maintain a breath hold for the required duration. MRA is susceptible to a variety of artifacts, including artifacts from cardiac/respiratory motion, metallic objects, and aircontaining structures. MRA cannot depict the lumen of an intravascular stent. The MRA images are also limited by intravascular coils. This is particularly pertinent because a number of patients undergo preoperative embolization of the hypogastric artery if exclusion of an iliac artery aneurysm is planned. In the past, MRA has been considered lacking, in that accessory renal arteries may be missed and 3-D performance is inferior.¹⁰ In our experience accessory renal arteries are easily observed on MRA images.

It remains unclear whether patients whose aortic endografts possess a stainless steel framework can safely undergo MRA imaging. It appears that nitinol-supported grafts can be imaged with MRA without difficulty. There is perhaps some theoretical concern for imaging endoluminally placed stent grafts with MRA because heating of the metallic stent may be problematic. Hilfiker et al¹¹ studied nitinol-based stent grafts in vitro to assess heating and imaging characteristics. The authors report no temperature changes associated with the stent during scanning. Additionally, the hooks on the Guidant graft do not appear to be problematic with respect to MRA imaging quality in our experience.

Patients who underwent MRA imaging for endograft design were followed up with MRA. There did not seem to be any difficulty picking up endoleaks with MRA; however, this was not formally studied by having concurrent CT angiograms. All endoleaks, however, were further studied with angiography for definitive diagnosis and for attempted repair. The use of MRA for the follow-up of patients who received an aortic endograft has been reported.¹² In their study, Engellau et al¹² evaluated 15 consecutive patients who received nitinol-based stent grafts for treatment of an AAA. The authors report that MRA provided the relevant information needed for follow-up of endoluminally treated AAAs and was particularly useful in evaluating periaortic inflammation, thrombus reorganization, and vertebral body infarction.

Clearly, not all studies may be needed in all patients. The rigidity used currently in obtaining both a CT angiogram and a marker catheter aortogram is largely to satisfy study protocols and Food and Drug Administration guidelines. Most, if not all, length and diameter measurements can be taken from the cross-sectional imaging. Currently, angiography is useful in that CTA shows stenoses poorly, and if a vessel is particularly tortuous, the length measurements obtained with CTA may be artificially shortened. In the future, it is likely that the studies selected will be more individualized depending on comorbidities, physical examination, and vascular anatomy.

In this study, patients underwent MRA imaging because of a relative contraindication to studies requiring iodinated contrast agents. For this reason, there is no direct comparison between MRA and CTA with regard to actual measurements. It is possible, therefore, that patients who were rejected by MRA may have been candidates if measured with CTA and angiography. Thurnher et al,¹³ at the University of Vienna, compared 61 patients with AAAs who underwent gadolinium-enhanced MRA, CTA, and digital subtraction angiography. The authors report that MRA and CTA were equivalent with respect to evaluating the proximal extent of the aneurysm and all aortic dimensions. MRA was superior in assessing iliac vessel disease in their study because of a larger field of view. They found MRA to be inferior in the depiction of accessory renal arteries and in the accuracy of grading renal artery stenoses. Other authors have reported favorable results with MRA to measure the dimensions required for successful aortic endograft placement as well.14,15

Unfortunately, MRA does not adequately demonstrate the extent of arterial calcification. It is particularly important to know the extent of iliac artery calcification because this bears on one's ability to achieve access to the aortic aneurysm via the femoral route. A highly calcified iliac artery or aortic bifurcation may not safely permit advancement of the device, and this would be important to know preoperatively. Therefore, we recommend obtaining nonenhanced CT imaging of the abdomen and pelvis in addition to MRA because this would not involve the use of contrast material and the additional ionizing radiation is negligible. It is possible that the combination of nonenhanced CT and MRA may become the procedure combination of choice in planning an endograft procedure.

Clearly, this study was not designed to demonstrate superiority of one preoperative imaging technique over another. It is likely that the small numbers, particularly in the MRA group, may not allow for some true differences to achieve statistical significance. However, we believe we have demonstrated that the use of MRA as the sole preoperative imaging modality can allow accurate endograft design.

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Submitted May 10, 2000; accepted Oct 2, 2000.

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