

STENT GRAFT REPAIR OF ABDOMINAL AORTIC ANEURYSM

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INTRODUCTION

The aortic stent graft currently represents a pinnacle in the evolution of endovascular technology - beginning with the DeBakey Dacron, vascular graft (which remains a gold standard), through catheter-based approaches to vascular disease, culminating in the introduction of the endovascular stent by Palmaz in 1985.¹ Subsequently, while searching for a minimally invasive treatment for patients with abdominal aortic aneurysm (AAA) that are too sick for open surgery, Juan Parodi (1991) was the first to combine the Dacron graft with a Palmaz stent.² Parodi sewed Palmaz stents onto the graft, crimped the entire device onto an angioplasty balloon, and became the first to deliver an endoluminal graft into the aorta. By excluding the aneurysm internally, reducing pressure on the aortic wall, and preventing rupture, the repair of aortic aneurysms was changed forever. Since it is unusual for aneurysms to be confined to the aorta alone, bifurcated grafts, which extend into the common iliac arteries, were a natural extension of this technology.³ Parodi's pioneering work led to the development of the first commercially available stent grafts in 1997, the Medtronic Aneurx graft⁴ and the Guidant Ancure graft.^{5,6} Today there are three commercially available grafts in the United States, with another five in development.⁷

Aneurysms of the abdominal aorta are typically repaired when they are greater than 5 cm in diameter. However, there is increasing evidence that the decision to intervene should be based on the size of the aneurysm relative to the patient's native aortic diameter.^{8,9} For example, a small woman with a 5 cm AAA may be at a proportionately higher risk for rupture than a male with an equivalent sized aneurysm. Also, because most AAAs are asymptomatic, with rupture being the most frequent presenting symptom, there is increasing interest in ultrasound-based screening programs to permit early detection and intervention.^{10,11}

TECHNICAL ASPECTS OF ENDOLUMINAL GRAFTS

Endoluminal grafts represent a radical change in the approach to prevention of aneurysm rupture. Instead of opening the aneurysm and sewing a graft into the aorta, endografting requires that blood be routed through the endoluminal graft, a seal be made at the top and

bottom of the aneurysm, and the distending arterial pressure be minimized. The endoluminal graft must essentially have secure fixation and adequate sealing at the attachment zones above and below the aneurysm (in the aorta and iliac arteries). Fixation and sealing have been achieved by a combination of hooks, stent rings with hoop strength (outward force), suprarenal stent attachment and sealing rings.^{3,13,14}

OPEN VERSUS ENDOVASCULAR REPAIR

It has been greatly debated in the surgical community whether endovascular grafting should be reserved only for high-risk patients or should be offered to all patients with suitable anatomy. Currently more than 50% of AAAs can be repaired using endovascular techniques, although some patients are better candidates than others.¹⁵⁻¹⁷ However, in patients who are at extreme risk for an open operative repair, it is permissible to use an endograft, even with unfavorable anatomy.¹⁷

The controversy regarding open versus endovascular repair exists in

part due to the increased costs associated with endovascular stenting and the lack of long-term follow-up data for this procedure.¹⁸ At the present time, placement of an endograft for AAA is more expensive, primarily due to intensive imaging requirements during follow up. Although the device itself is more expensive than a Dacron graft (\$12,000 vs. \$700), initial hospital costs are generally similar due to the need for ICU care, longer length of stays (LOS), and increased respiratory complications associated with

AORTIC ANEURYSM FACTS

- 70% involve the common iliac arteries
- AAA grow on average 0.4 cm/year
- AAA are usually asymptomatic
- Most AAA present for years before incidental detection
- Risk of rupture is directly related to the AAA diameter
- Risk of rupture increases rapidly in aneurysms > 5 cms
- Most ruptured aneurysms are fatal
- Symptomatic aneurysms should be repaired expeditiously

ADVANTAGES OF ENDOLUMINAL GRAFTING

- Delivery through femoral artery possible with X-ray guidance
- General anesthesia can be avoided
- Blood loss is minimized
- ICU stay is not required, hospital stay is reduced
- Return to full function is much more rapid.

DISADVANTAGES OF ENDOLUMINAL GRAFTING

- No long term, follow up (5-yr. data recently available)
- Remodeling may lead to re-pressurization
- Back pressure from lumbar arteries may cause aneurysm growth
- Routine CT follow up is mandatory
- Approximately 10% require catheter-based intervention in first 24 months

open surgery. In addition, preoperative evaluation of an aneurysm for endografting is more time consuming than for open AAA repair. The physician has to carefully evaluate the aortic anatomy & determine whether the patient is a suitable candidate. This is largely determined based on preoperative evaluation of the aneurysm anatomy through CT scanning. A virtual endograft, and new techniques for measuring aneurysms and following them post-implantation have been developed as a result of aortic endografting.¹⁹

Jordan et al.¹ reported their experience with both open and endovascular AAA repair in both low and high risk patients.¹⁶ The authors concluded: "Both high-risk and low-risk patients can undergo endovascular repair with a lower rate of short-term systemic complications and a shorter LOS when compared

to open AAA repair. While we do not have complete understanding regarding the long-term durability of these endovascular grafts, our delayed intervention, thus far, has been minimal. For that reason and due to the lower rate of early complications, high-risk patients should be preferentially considered for EVAR over open AAA repair. Considering that low-risk patients also had fewer complications, patients who are anatomically suitable may be offered EVAR with a varying degree of emphasis, depending on their physiologic risk, and with cautious consideration about the unknown long-term durability."¹¹

Further, the authors noted that patients who underwent endografting had fewer complications and a shorter LOS. When complications do occur, there is less morbidity than with open AAA repair, and patients have fewer additional hospital days due to complications.¹⁵ Future technical developments will permit an increasing number of patients to be treated with endovascular techniques.

COMPLICATIONS OF AORTIC ENDOGRAFTS

Endograft complications can occur during both insertion and follow-up procedures. During initial clinical trials, iliac artery injury occurred in up to 7% of cases due to the size of the devices and poor patient selection. However, as devices become smaller and more flexible, and with improved preoperative imaging, the incidence of injury has decreased. In less than 1% of cases thrombi associated with the aneurysm dislodge resulting in embolization to the lower extremities, kidneys or intestine. Groin complications related to the surgical exposure of the femoral arteries also occur due to infection, lymph leak and groin hematoma; however, these are rarely limb or life

threatening. Delayed complications can also occur and are often due to aneurysm remodeling. When an aneurysm is excluded, it shrinks both in diameter and length. This can result in bending and dislodgement of the endograft with resultant pressurization of the endograft. This is called an "endoleak" as blood is entering the aneurysm. A high pressure or type 1 endoleak occurs when the graft has failed to seal at the aortic or iliac artery seal zones. This type of endoleak, which can lead to late rupture, must be detected and addressed. A type 2 endoleak, which is much more benign, occurs when flow in the lumbar arteries or inferior mesenteric artery reverses after the endograft is inserted and causes pressure to be applied to the AAA. Management of a type 2 endoleak is much more controversial, and in most cases can be observed in the absence of aneurysm growth.

FURTHER APPLICATIONS FOR STENT GRAFTS INCLUDING RUPTURED ANEURYSMS

Endovascular grafting is now being increasingly utilized in treatment of atherosclerotic occlusive disease, vascular trauma, and in dialysis access. Thoracic aortic endografting is being evaluated in prospective trials in the United

ENDOGRAFTS FOR RUPTURED AAA

- Permissive hypotension - do not aggressively restore blood pressure
- Place balloon in descending thoracic aorta via left brachial artery
- Emergent CT scan to size for endograft
- Emergent placement of endograft via femoral arteries

The Methodist Hospital will soon begin a phase 2 clinical trial involving the first truly percutaneous endograft. The Trivascular device, which will be used during the investigation, has a very small profile permitting insertion via a 12 Fr sheath.

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States with the potential to deliver even greater benefits than infrarenal AAA repair when compared to the open surgical procedure. Another very exciting development is the use of stent graft technology to reduce the extremely high mortality of the ruptured abdominal aortic aneurysm.

A ruptured aneurysm in a patient who survives to reach a hospital remains approximately 50%. This has not been impacted by improved anesthesia, surgical or ICU care. Recently, however, the vascular surgery group from Montefiore has reported that emergent endografting, with "permissive hypotension" until the endograft has been placed, resulted in a significant reduction in perioperative mortality.^{20, 21} These data have now been replicated at several major centers. This approach has challenged many of the concepts for treatment of ruptured AAA, long held by vascular surgeons. It is likely to become the standard of care.

FUTURE DEVELOPMENTS

- Branched vessel endografts permit treatment of aneurysms involving the renal arteries
- Biologic modifications encourage cell in growth into the graft
- Smaller more durable devices permit true percutaneous insertion
- External monitoring of endograft pressure
- Ultrasound screening programs for early detection of AAA
- Increasing use of emergent endografting for ruptured AAA

In summary, although we are early in the evolution of endograft development, this technology represents a major step forward in minimally invasive therapy for AAA, with particular advantage for patients at high risk for open AAA repair.

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