Clinical Area: **AeuRx stent graft for abdominal aortic aneurysm**
Keywords: **Abdominal aortic aneurysm, stent graft, aneuRx, clinical trial**
Reference: **Zarins CK, White RA, et al. Aneu Rx stent graft versus open surgical repair of abdominal aortic aneurysm: Multicenter prospective clinical trial. *J Vasc Surg* 1999; 29: 292-308**

Study Type: Non randomized clinical study.
Study Aim: To evaluate the safety and effectiveness of the Medtronic AneuRx stent graft system in the treatment of infrarenal abdominal aortic aneurysms (AAA), and to compare it to the open surgical repair.

Outcomes: AneuRx stent graft success rate. Procedure morbidity and mortality rates. Rate of endoleaks.

Design

- *Number of subjects:* N=250, n=190 in the stent grafting group, and n=60 in the surgical repair group.
- *Description of study population:* Stent graft group: 51 (85%) men, and 9 (15%) women. The age ranged from 49-97 years with a mean of 69 ± 7 years. 83% were smokers and 15% had a family history of AAA. Surgery group: 171 (90%) men and 19 (10%) women, 45-91 years old (mean =73 ± 8 years). 85% were smokers, and 8% had a family history of AAA.
- *Setting (clinical or community):* Clinical at 12 study sites.
- *Inclusion criteria:* (1) Non-ruptured infrarenal aortic and aortoiliac aneurysms >5 cm in diameter, or 4-5cm diameter that increased by 0.5 cm in the past 6 months, twice the diameter of the infrarenal neck, or saccular. (2) Infrarenal neck 18-26 mm in diameter, at least 1 cm below the most inferior renal artery. (3) An Iliac artery with a lumen that allows access with a 21F delivery catheter on one side and a 16F sheath on the contralateral side, and maximum distal iliac artery diameter of 16 mm.
- *Exclusion criteria:* Age < 18 years, suprarenal, thoracic, inflammatory, traumatic, acutely ruptured or leaking aneurysm, acute renal failure, pregnancy or lactation, connective tissue disease, active systemic infection, morbid obesity, hypercoagulability, < 1 year life expectancy, and any problem to prevent follow-up or giving consent.
- *Power:* not mentioned.
- *Method of randomization:* Non-randomized. It was not specified how patients were assigned for each treatment group.
- *Exposure/Intervention:* The endovascular stent graft procedure was performed by a team with a vascular surgeon and interventional radiologist, in an operating or endovascular procedure room, under general, or epidural anesthesia, The self –expanding stent graft (contained in a delivery sheath) was introduced through a retrograde approach through small femoral arteriotomies. The femoral artery was exposed through a groin incision. Intraoperative imaging was performed by fluoroscopy, angiography, or intravascular ultrasound scanning.
  The patient in the surgical control group underwent aneurysm repair under general anesthesia, and with the standard open surgery techniques. The aneurysm was approached either transperitoneally or retroperitoneally. It was then excluded by suturing in a prosthetic tube or bifurcated graft.
- *Source of outcome data (e.g. patient self-report, doctor report, lab results):* Clinical evaluation. Patients with stent graft underwent imaging with contrast CT scan or color duplex ultrasound at 1 month and CT scan at 6, and 12 months.
- *Length of follow-up:* 12 months.
- *Completeness of follow-up:* Not discussed.

Validity

- *Is the study type appropriate for the questions being asked?* The study was non-randomized. RCT would be ideal.
- *Was the study population typical of patients with this disease?* Yes.
- *Were the treatment/control groups comparable at baseline?* The differences were statistically insignificant.
- *Was the intervention compared to placebo and/or best accepted intervention?* Yes.
- *Was there compliance with the intervention?* Yes.
- *Was there equal intensity of observation of study and control subjects?* The two groups were followed-up at the same rate, but the stent group underwent an ultrasound or CT scan, which apparently were not done for the surgical controls.
- *Was the process of observation likely to affect the outcome?* Probably not.
- *Intention to treat analysis?* Yes

Conclusions regarding validity of methods:

The study was controlled, however patients were not randomly selected for the procedures performed. There was no blinding, and the follow-up was not universal among the two groups. Data on completeness of follow-up was deficient.

Results

Primary procedure results

	Surgery (n=60)	***Stent grafting (n=190)***	***P value***
Procedure success rate*	100%	97%	NS
Anesthesia (hours)	4.9 ± 1.8	4.5 ± 1.6	NS
Procedure time (hours)	3.6 ± 1.6	3.1 ± 1.3	NS
Blood loss (ml)	1596 ± 1432	641 ± 636	<0.001
Blood replaced (units)	1.6 ± 3.8	0.3 ± 1.2	<0.05
Pts. requiring transfusion	40%	12%	<0.001
Extubation time (days)	0.9 ± 2.3	0.1 ± 0.3	<0.05
ICU days	2.5 ± 3.1	0.9 ± 1.2	<0.05
Ambulant without help (days)	4.0 ± 4.8	1.5 ± 1.2	<0.001
Regular diet (days)	5.1 ± 2.5	1.4 ± 0.9	<0.001
Hospital days (mean)	9.4 ± 10.8	3.4 ± 2.7	<0.001
Hospital days (range)	3 to 72	1 to 20	

***** Open repair successfully accomplished , stent graft successfully introduced

Morbidity and mortality in 30 days

	Surgery (n=60)		***Stent grafting (n=190)***		***P value***
	Number	***%***	***Number***	***%***	
Mortality	0	0	5	3	NS
Device related	0	0	0	0	NS
Major morbidity	14	23	22	12	<0.05
Surgical complications	7	12	16	9	NS
Medical complications	7	12	6	3	<0.05
Minor morbidity	4	7	10	5	NS

Major Complications

	Surgery (n=60)		***Stent grafting (n=190)***		***P value***
	Number	***%***	***Number***	***%***	
Surgical complications	7	12	16	9	NS
Major abdominal	6	10	2	1	<0.001
Groin/ peripheral	1	2	13	7	NS
Other	-	-	1	1	NS
Medical complications	7	12	6	3	<0.01
MI / arrhythmia	3	5	4	2	NS
Cardiovascular accident	2	3	1	1	NS
Other	2	3	1	1	NS
Hospital LOS (days)	11±7		9±6		NS
Hospital LOS with complications	21±18		8±7		<0.05
Hospital LOS without complications	6±2		3±2		<0.001

Procedure success

	Surgery (n=60)		***Stent grafting (n=190)***		***P value***
	Number	***%***	***Number***	***%***	
*Primary technical success**	59	98	146	77	<0.01
*Primary procedural success***	46	77	148	78	NS
Secondary procedural success†	57	95	169	89	NS
Aneurysm excluded at 30 days	60	100	164	91	<0.05

* No death with complete exclusion of the aneurysm (no endoleaks), and patent graft at discharge

** Patient alive, with a patent graft and aneurysm excluded at 30 days with no major complications, or need for re-operation or intervention.

† Graft patent at 30 days with excluded aneurysm, patient alive and back home. (includes benefits of secondary procedures)

Endoleaks* after stent graft repair

Before discharge	21%
1 month after graft	9%
6 months after graft	9%
12 month after graft	6%

*Endoleaks were diagnosed and localized by contrast infused CT scanning. Early endoleaks may result from inadequate sealing of the graft, flow through the graft, defects in the graft fabric, or iliac branch flow. Late leaks may be due to graft migration, changes in the aneurysm, or iliac artery characteristics.

Authors' conclusions:
The authors concluded that, " Endovascular stent graft repair of infrarenal aortic aneurysms compare favorably with open surgical repair, with a reduced morbidity rate, shortened hospital stays, and satisfactory short term outcomes."

Reviewer's conclusions:
This multicenter clinical trial showed that AneuRx stent graft had a significantly less technical success, and aneurysm exclusion at 30 days, than open surgical repair. On the other hand major morbidities, need for blood transfusion and length of hospital stay were significantly less with stent treatment. However, due to the non-randomization of the study, and possible selection and observation biases, it is difficult to draw conclusions about the efficacy of the procedure. Moreover, the follow-up duration was not long enough to study the outcome of leaks.