5-YEAR EVAR OUTCOMES ARE EQUIVALENT BETWEEN GENDERS

RESULTS FROM THE ENGAGE REGISTRY

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Indications, Safety, and Warnings

5-year EVAR Outcomes Are Equivalent Between Genders

Results from the ENGAGE Registry

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Disclosure

Speaker Name: Marc Schermerhorn

X I have the following potential conflicts of interest to report:

X Consultant for Abbott, Cook Medical , Endologix and Phillips

- ❑ Receipt of honoraria and travel support
- ❑ Participation in a company sponsored speakers‘ bureau
- ❑ Employment in industry
- ❑ Shareholder in a healthcare company
- ❑ Owner of a healthcare company

❑ I do not have any potential conflict of interest

Then….

Prior studies of gender differences in EVAR demonstrate females are more challenging in terms of presentation, suitability, and clinical outcomes

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Does Gender Influence Outcome of AAA Endoluminal Repair?

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ELSEVIER

Influence of Gender on Abdominal Aortic Aneurysm Repair in the Community

Daiva l\n-iJanskyt£',ı $.Jw-,£-n£' $:JiaJhu.b,• /i,tiHn $.in!Jh.• EJJai Fa.rakJte
and Miu* H. Afeis:Jne" J S lanle a.nd Ev rm., Wmhi.ng,tcn

BackgroLS1d: Women nave been shown to @xp@f1i!OCe ff@OOf outoomes tolo'Mng mac1 and IIC)tutc!!d abdortrw"liAJ aoruc (AJ\A.) trMfflc!!l'd 1n m r@p&lr (EVAR) and q:,e,i, surglC&i lepa. (OSA) groups_ The goal of ow study was l:> compare geoder-speafc p , - atlt'.ln management, and early OIRXJme9 a112r AAA lepa:.r using a s1ate wide E991rY·

Methods: We ua.112.ed me Wasnngton Sta1es Vasouhr IntervenllOnal Care and Oul comes sesamern ProgramreglSllydal a I'I 19 hosp--ats from .A/ty2010 Septembet" 2013. O@mographlcs. pre:38nta1JOn. procedwa1 diiLil. and OUJCOme:i m1 we and em-erg@J\1 AAA r@PiWgro.4)1: e anatyzed.

Aesub:! We 1d & Ned 1231 pam• (19.8'Jr.. wom@n) who lridMWeN nae, (86A1'. or rt.l)t:uted AAA (13,C) repa.-a. Nne 1!a01.JS1anlj sevanf)l-tv.o (79_0,C.) t!l had EVAR and 259 (2t°"-) hadOSR. Men and women wete of eq LMVa.lem age and hada..m..ar comotb ddles. @XeepI lha1 women had i.ess <nrona,y artery disease (P < 001) and were more likely to sul1er from aTOI"IIC obst:ructllie p,*nonary dtsea:se (P = 0-05). Women had smaher ane rysm dameters (S.8:s-1.1 vs 6.2 :t: 18""1. P < OJJ1) aime, time of p ('" e at>ooandmen had &Jightty hllgner SlCldence of rupture aJ larger aneuysm sa.e. Men were mere e>t 10 la"Idergo EVAR. wnn &!glllficanl cifferellClli& Sl ..cnw (82..1% VII-74.1,... p -; 0-01), but not n.l)Ued repaw. Women had agndm m mJy higher mortaity raJea jolO"M.ng @&a.Ne EVAR (31% va. 0..619i., P - 01). bu1 no1 Aftf!rl' n.1)1:U"l!d or f!tiil!!CNt! open r@pllilr. FolOWV'lg t N EVAR. women v.,ere le99 Edy'O be cl90ha,ged 'O hom,e .a.her longel' hospa.alaiays (3 \IS. 2 days.. P<0 01)..

Conclusions: Desprae pres@NalJOn at a Slffl£iuage. wan a sn,a.J,,,EW anei..sysm c1Lame1er. and SJrlllarmedlcal comorbid"l...es. women expen,enoesl.A':eantlaly YllOl"Se h0sptaloutc:ome9 pq:na:r iiy dnven by e1ea:r..e pmcedUres. l..lti.l:zauon of endovas.cular 1n YilCfllen st'l emans towef" ccmpared WI.VI m en. Imp-ovemem of electNe outcomes. ,I¥0ffl«.wll 'y di!p8nd on 18Chnica8d'V.inC8m@nli .. f@I)&lrt and dinar em•:ra;egtn tha1 fTlilY b&?w881l g@lld@ni.

Abdominal aortic aneurysms in women

Ruby C. Lo, MD, and Marc L. Schermerhorn, MD, *Boston, Mass*

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From *the* Society for Clinical Vascular surgery

Sex differences in mortality and morbidity following repair of intact abdominal aortic aneurysms

Sarah E_ Decry. MD•.b Peter A_ Soden. MD• Sara L Zettervall. MD. MPH• Kate E_ Shean. Mo•
Thomas C. F_ Bodc,-,s_ MD Alexander B_ Pothot MD Ruby C_ Lo. MD and
Marc L Schermerhorn. MD. FACS. Boston M a

ABSTRACT

Obj t i M@die:.a M h !.hownint:. a riop@f.atiw rt.ality n w n oomp.ar@d with MM follo\Mng 4:!ndOW.!ieular and OoP@n abdominal aortic aneuryvn (AAA) r@J)dr. How -r. a receit rt:!gional u:u of high-volu centers adjusting for anatomy but imited i1 sanple size did not show sex to be predictive of wo,se outcomes.. This study aimed to evaluate sex dfferences after ntact AAA repair n a national clinical registry.

Meth:xl.s: The targeted vascubr module of the National Suigal Quality Impravemeit Program Yt1as queried to idt:!ntify piitiern undergoing endovascular aneurysm repair (EVARJ or open repair for intact nfrarenal AAA from 2011 to 2014.. Univariatit analysis \Nii.S pa-formed uwtg tlw Rshilr ct tvst and Mal'"ln'wtitnit)' test. Multivariable bgiruc rvgrm.sion Vl.es used to account For dfferences in comorbidites. aneurysm detaits. and opefative characteristics.

Re!iUIU: We identifiOO 6661 patients 'M)(11B1) who un d e rw: intact AAA repair (EVAR: B women vs 881i& mert P 001).. Women were older (med an age 76 vs 73 years; P <OOll. had smaleraneurysms (median. 54 vs 5.5 crn P < OO l.and had morechronic obstructive pulmonary disease (22% vs f7'MI; P < OOll.Among patients undergoing EVAR. v.ornen had longer oper-ath.e times (mediar\. 13,8 [interqu artile range, I03 T70J vs 131 (106 181] minutes P < _QI) ard mo,e oA:4:!n underw-eit renal (6..3% 4J9 P <OJ) and lower extremity (6.6*, vs 3.8%; P <O l) re-.,asculatlz.ation_Aft:r open iepair women hzl short"' op<>ratw time (215 077 3041 vs 226 [163641 minutes: P = _Q2l but 111.<>men1.,..fr<>qUently underwent ov.er extremty revasrularization (l196 vs 8.2C1:& P = _03 Thirty<lay mortality was h'Qher in women after EVAR (3..2% vs 1..26; P < 001) and open repair (8.. l6 vs 4 (n6; P- 04 Afti!f adjusting for repair type. age f aneul')l'Sm diameter, and oomorbiitie$i. female sex was independently associated with m ortalty (odds ratio (ORL \7; 95% confidence interval lC-11U Z.6; P 02) and major complications (OR. l.4; CI 11'-7; P 01) after intact 1J,,A1t,, repair HOWE"Ver. after adjust ng for aortic size index: rath9r than for aortic diarT)Qoter. thea!. at:ion b e n female sec and mortality (OR.1 CD .98.-24; P =06) and major O>Mplieatien, PR 1I'Cl.O H 4, P = .24) wa @due@d.

Conc:lusons Women were at higher risk for 30 day death and mi:4or complications after ntact AAA repair. Some of this disparity m.ayb@expla t'll:!d bydft@r«"lees n aortic size in x. which should be further =Va a tod:!t e r m i t:1-19 id4:!al th-""hold fo, .,pai,_D Va"" Sur9 2017,65cl006 13-l

VIVA 17

Now…

Do gender differences really exist with new generation devices?

Early data from ENGAGE shows no early differences

Outcomes after endovascular abdominal aortic aneurysm repair are equivalent between genders despite anatomic differences in women

Luc Dubois, MD, MSc, Teresa V. Novick, RN, Jeremy R. Harris, MD, Guy DeRose, MD, and Thomas L. Forbes, MD, *London, Ontario, Canada*

Objective: Prior work confirms gender-specific anatomic differences in patients undergoing endovascular aneurysm repair, but the clinical implications remain ill defined. The purpose of this study was to compare gender-specific early outcomes after endovascular aneurysm repair using a large international registry.

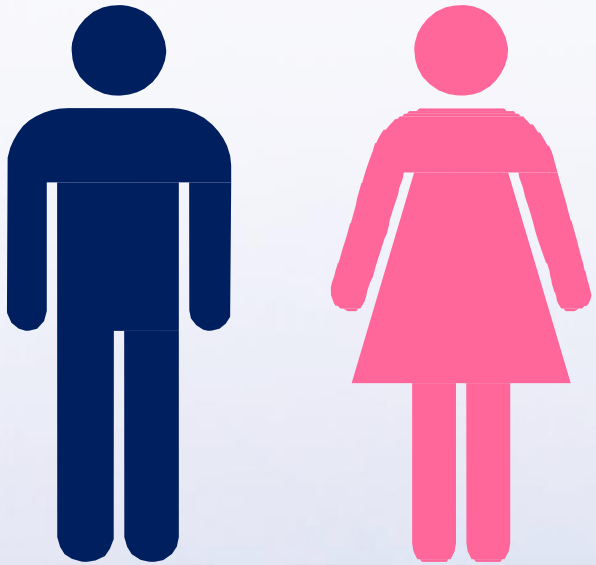
Methods: Over the 2-year period ending in 2011, 1,262 patients (131 women, 10.4%; 1,131 men, 89.6%) with infrarenal aneurysms treated with the Endurant stent graft were prospectively enrolled in the ENGAGE registry and followed clinically and radiographically.

Results: Women were older (75.5 ± 7.0 vs 72.8 ± 8.1; $P = .0003$) and had smaller aneurysms (57.8 ± 9.5 vs 60.6 ± 11.9 mm; $P = .01$). Women's infrarenal aortic necks were of narrower diameter (21.8 ± 3.4 vs 24.0 ± 3.5 mm; $P < .0001$), shorter length (24.3 ± 11.8 vs 27.3 ± 12.4 mm; $P = .009$), and greater angulation (37.7 ± 26.2° vs 29.4 ± 23.3°; $P = .0002$). More women had an infrarenal neck angle >60° (19.2% vs 9.1%; $P = .001$). Technical success was achieved in equal numbers of women and men (97.7% vs 99.2%; $P = .10$). On completion angiography, the incidence of any endoleak (21.5% vs 15.4%; $P = .08$) and type I endoleak (1.5% vs 1.1%; $P = .60$) did not differ between genders. At the 1-month follow-up, there were no differences between women and men with respect to endograft occlusion (2.5% vs 1.9%; $P = .70$), and differences observed in any endoleak (17.2% vs 11.4%; $P = .08$) and type I endoleaks (3.3% vs 1.2%; $P = .08$) did not reach statistical significance. Freedom from major adverse events was similar for women and men at 30 days (98.5% vs 95.8%; $P = .23$) and 1 year (85% vs 89.8%; $P = .40$). Survival at 30 days (100% vs 98.6%) and 1 year (92.5% vs 91.6%; $P = .99$) was similar for women and men.

Conclusions: This large multinational registry confirms the previously observed prevalence of suboptimal neck anatomy in women. Even though women have shorter and more angulated infrarenal necks, their technical outcomes at 30 days and clinical outcomes at 1 year were similar to those of men. Much longer follow-up is necessary to determine whether these outcomes proved durable. (J Vasc Surg 2013;57:382-9.)

Scientific Question

Are long-term (5 years) gender differences observed with the Endurant Stent Graft?



The ENGAGE Registry

Largest Contemporary EVAR Registry with single manufacturer's stent graft: ENDURANT

1263 Patients

30 Countries

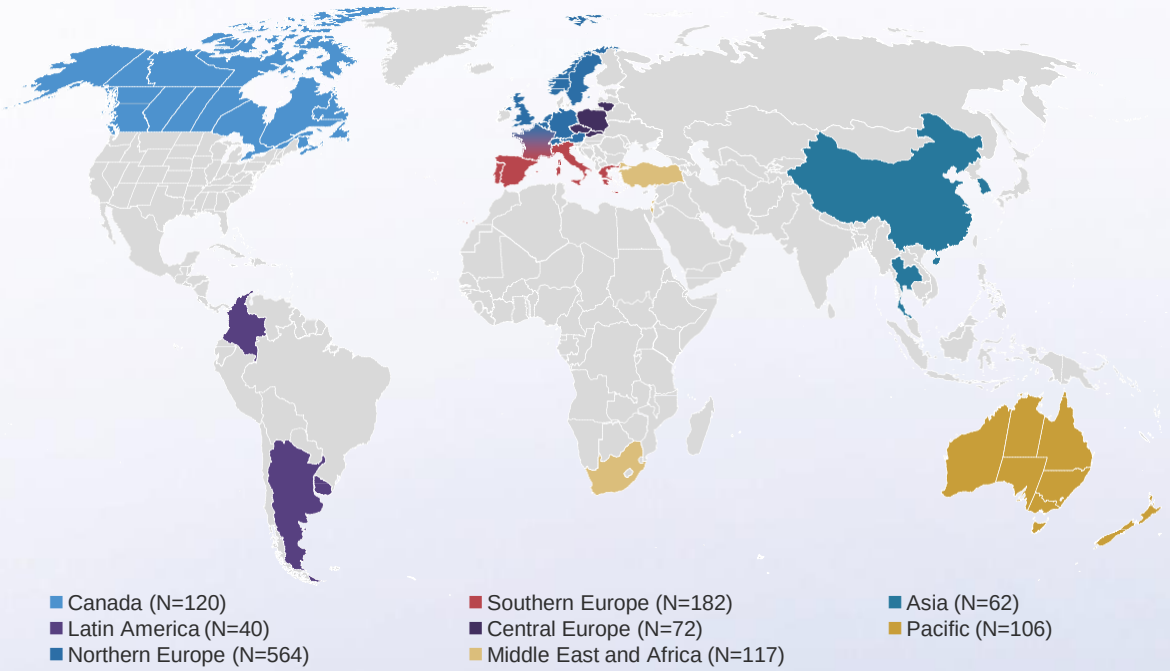
6 Continents

Real world patients:

Limited inclusion/exclusion criteria

Real world practice:

Limited procedural specifications
- Standard follow-up



14 publications and > 100 presentations at major International/National conferences characterizing ENDURANT clinical outcomes

The ENGAGE Registry

Patients **Consecutively Enrolled**

Follow-up:

30-day, Annual Visits Through 10 Years

Extensive Monitoring On-going

100% Data Management Review

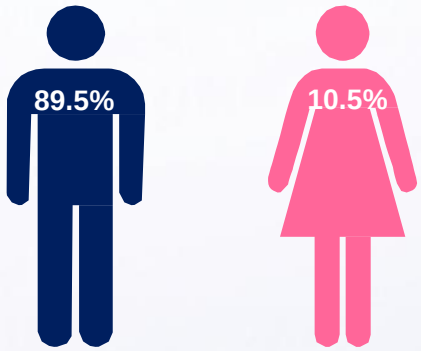
Independent Data Monitoring
(100% Endpoints)

Independent Clinical Event Committee

High Quality Data

ENGAGE – Baseline Characteristics

Male (N)	Female (N)
1130	**133**



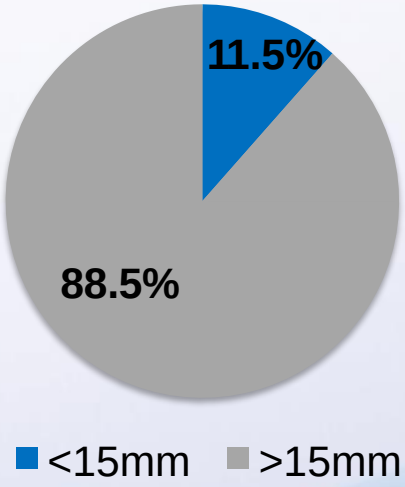
Baseline Characteristic (mean±SD)	Male (N = 1130)	Female (N = 133)	p-Value
Age (yrs)	72.8±8.1	75.7±7.1	**<0.001**
Max. Aneurysm Dia. (mm)	60.6±11.8	57.9±9.6	**0.012**
Prox. Neck Dia (mm)	23.9 ±3.5	21.8±3.3	**<0.001**
Distal Neck Dia. (mm)	25.1±4.0	22.9±4.1	**<0.001**
Rt. Iliac Artery (Dist. Dia.; non-aneurysmal) (mm)	14.3±3.5	12.9±3.5	**<0.001**
Lt. Iliac Artery (Dist. Dia.; non-aneurysmal) (mm)	13.9±3.5	12.5±2.9	**<0.001**

Women: Older, with smaller diameter proximal necks and narrower access vessels

ENGAGE – Baseline Characteristics

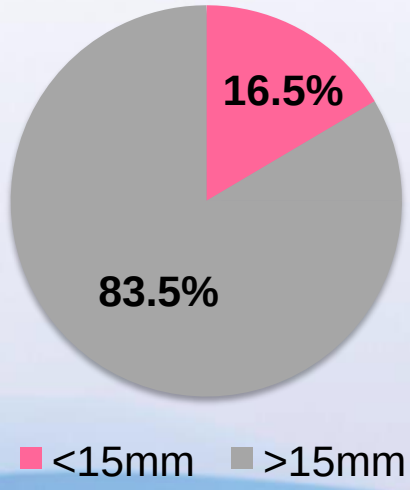
Baseline Characteristic (mean±SD)	Male (N = 1130)	Female (N = 133)	p-Value
Proximal Neck Length (mm)	**27.3±12.4**	**24.5±11.9**	**0.014**

Prox. Neck Length – Male



P-Value = 0.088

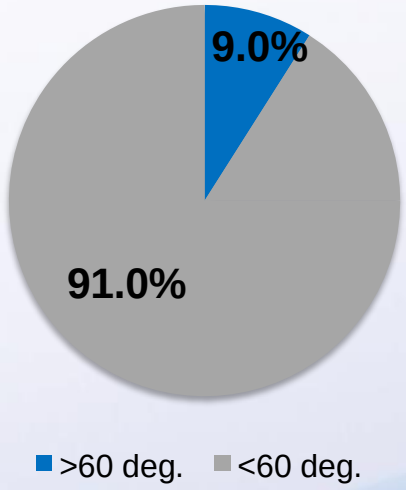
Prox. Neck Length – Female



ENGAGE – Baseline Characteristics

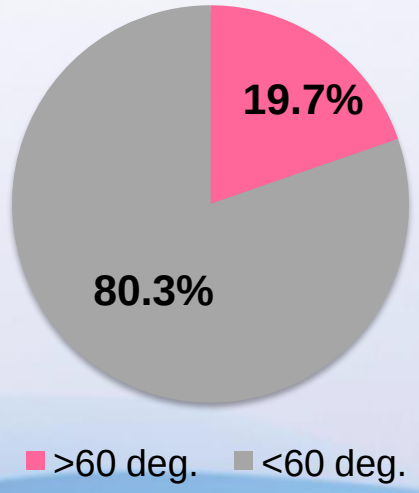
Baseline Characteristic (mean±SD)	Male (N = 1130)	Female (N = 133)	p-Value
Infrarenal Neck Angle (deg)	29.4±23.3	38.1±26.2	<0.001

Infrarenal Neck Angle > 60˚ - Male



P-Value = <0.001

Infrarenal Neck Angle > 60˚ - Female



ENGAGE – Baseline Risk Factors

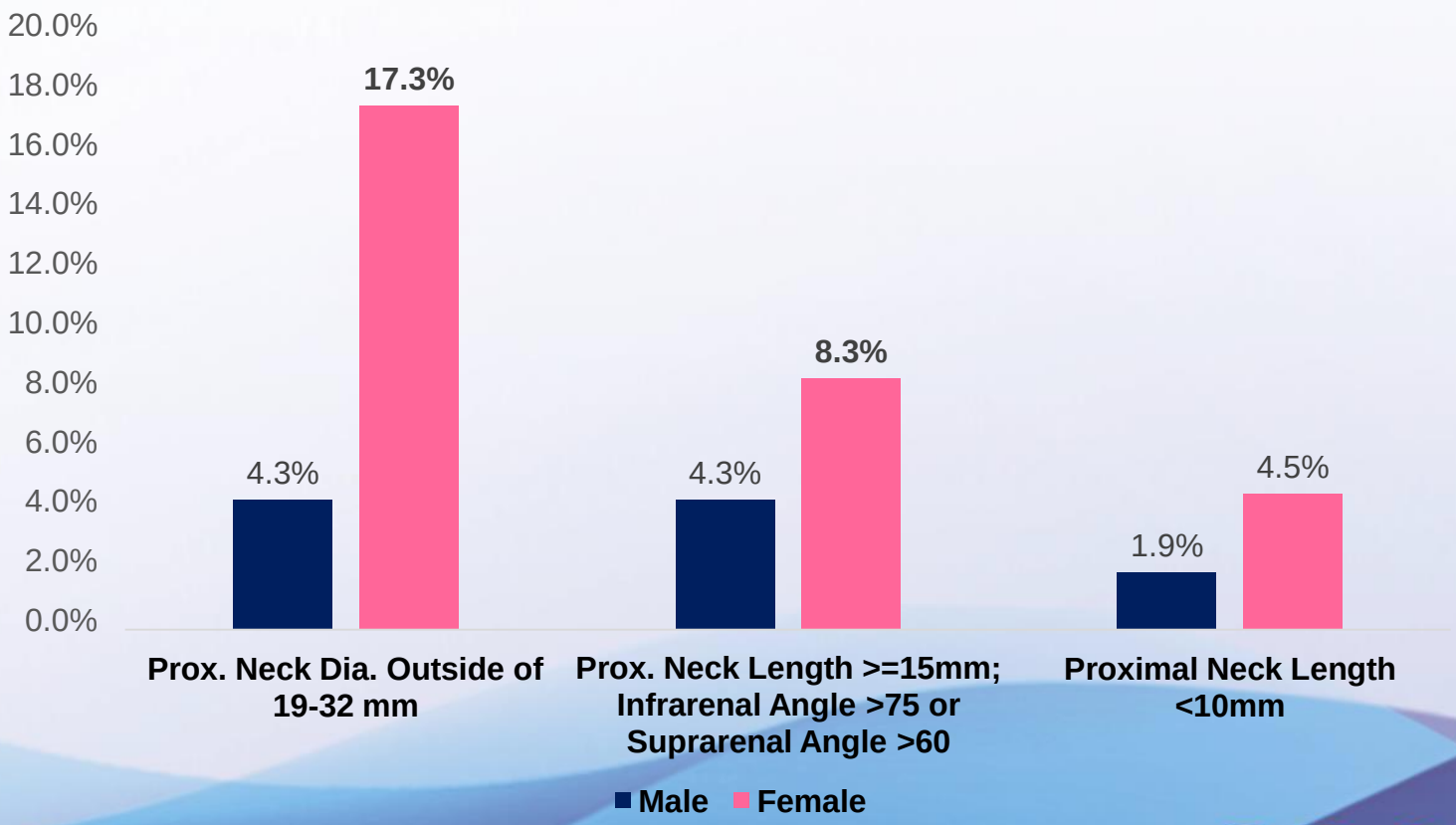
Risk Factor	Male (N = 1130)	Female (N = 133)	p-Value
Tobacco Use	50.1%	42,4%	0.094
Hypertension	75.1%	78,2%	0.435
Hyperlipidemia	60.1%	64.8%	0.297
Diabetes	18.8%	21,1%	0.531
Cardiac Disease	54.7%	45.1%	0.035
Coronary Artery Disease	36.4%	21.4%	<0.001
Cardiac Revas. (Incl. CABG or PTCA)	28.9%	12.9%	<0.001
Pulmonary Disease	25.4%	26.0%	0.887
Renal Insufficiency	15.5%	16.5%	0.745
Vascular Disease	31.2%	29.3%	0.662
Family History of Aneurysms	6.2%	12.0%	0.012

ENGAGE – Procedure Information

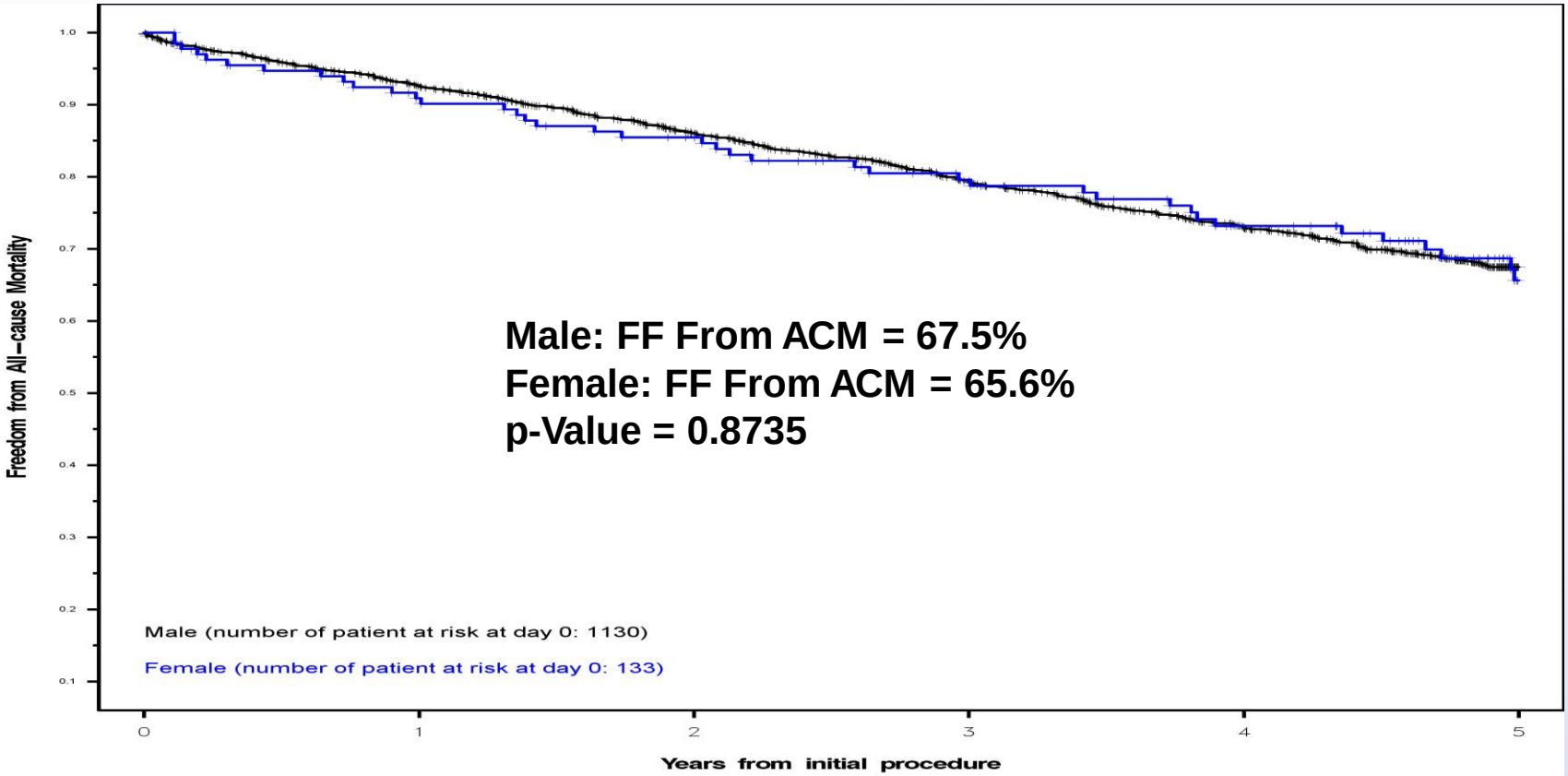
Measurement (Mean±SD)	Male (N = 1130)	Female (N = 133)	p-Value
Duration of Implant Procedure (min)	99.7±44.5	97.4±48.9	0.580
Hospital Stay (Days)	6.4±6.1	7.9±9.8	0.017
Duration of ICU (Hours)	10.4±44.6	7.7±18.2	0.312
Successful Delivery and Deployment of Endurant	99.5%	99.2%	0.746

Subjects Implanted Outside of IFU

Subjects Implanted Outside of IFU	Male (N = 1130)	Female (N = 133)	p-Value
	16.1%	32.3%	<0.001

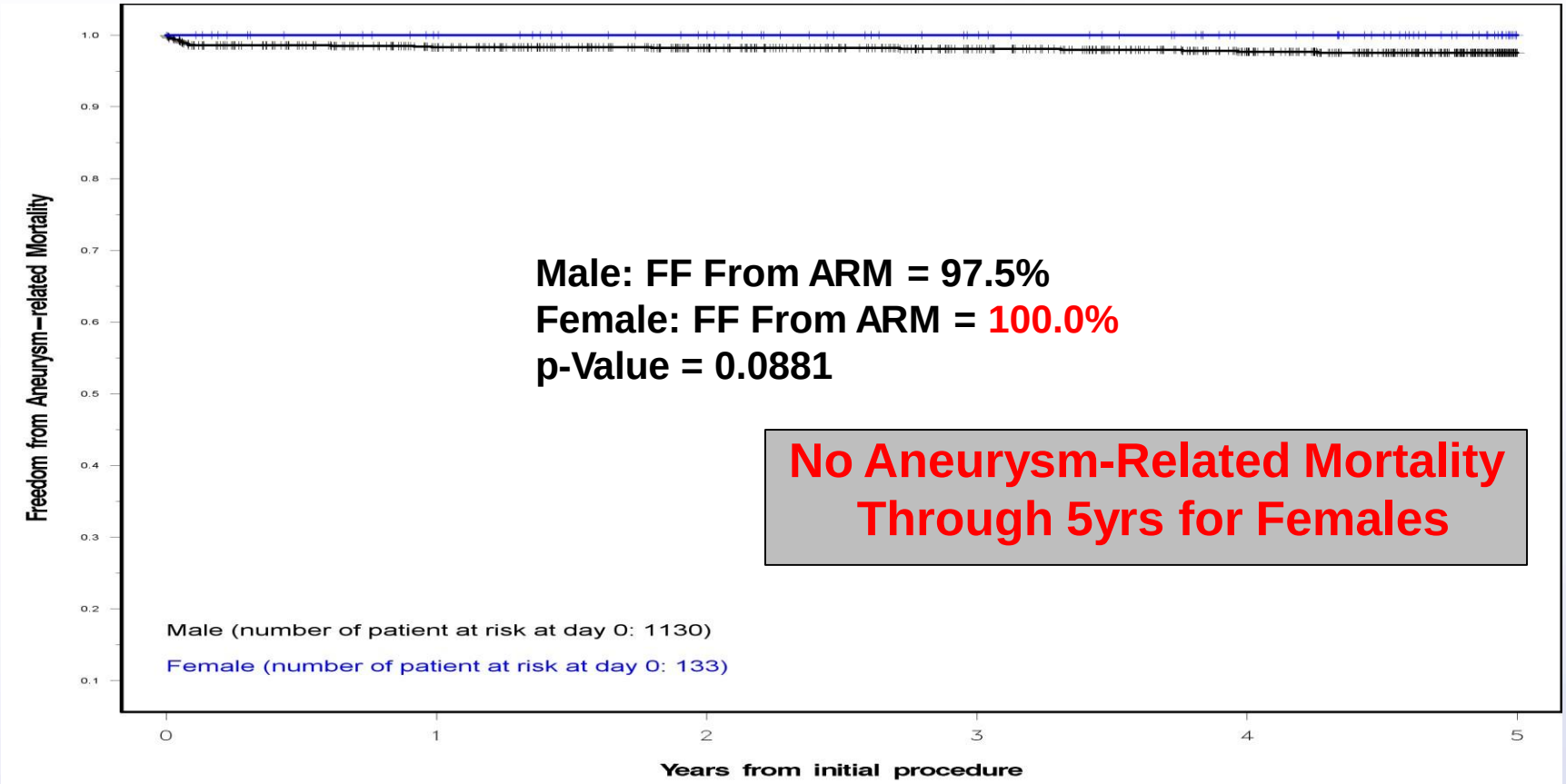


5 Year Freedom From All-Cause Mortality



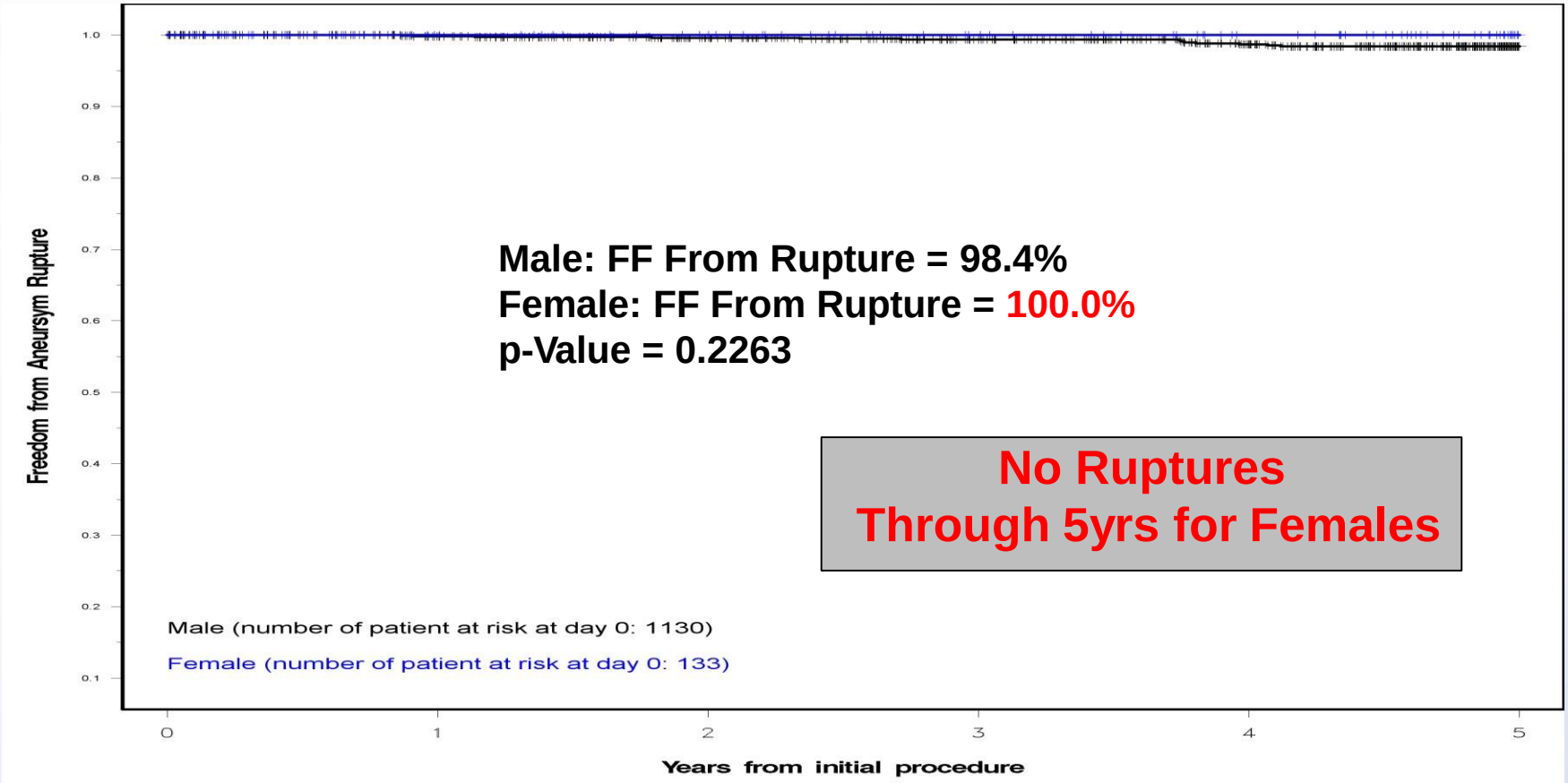
	Male						Female					
	0-30D	**31D – 1Y**	**1Y – 2Y**	**2Y – 3Y**	**3Y – 4Y**	4Y – 5Y	**0-30D**	**31D – 1Y**	**1Y – 2Y**	**2Y – 3Y**	**3Y – 4Y**	**4Y – 5Y**
No. at Risk[1]	1130	1110	1032	893	803	703	133	133	118	105	90	76

5 Year Freedom From Aneurysm-Related Mortality



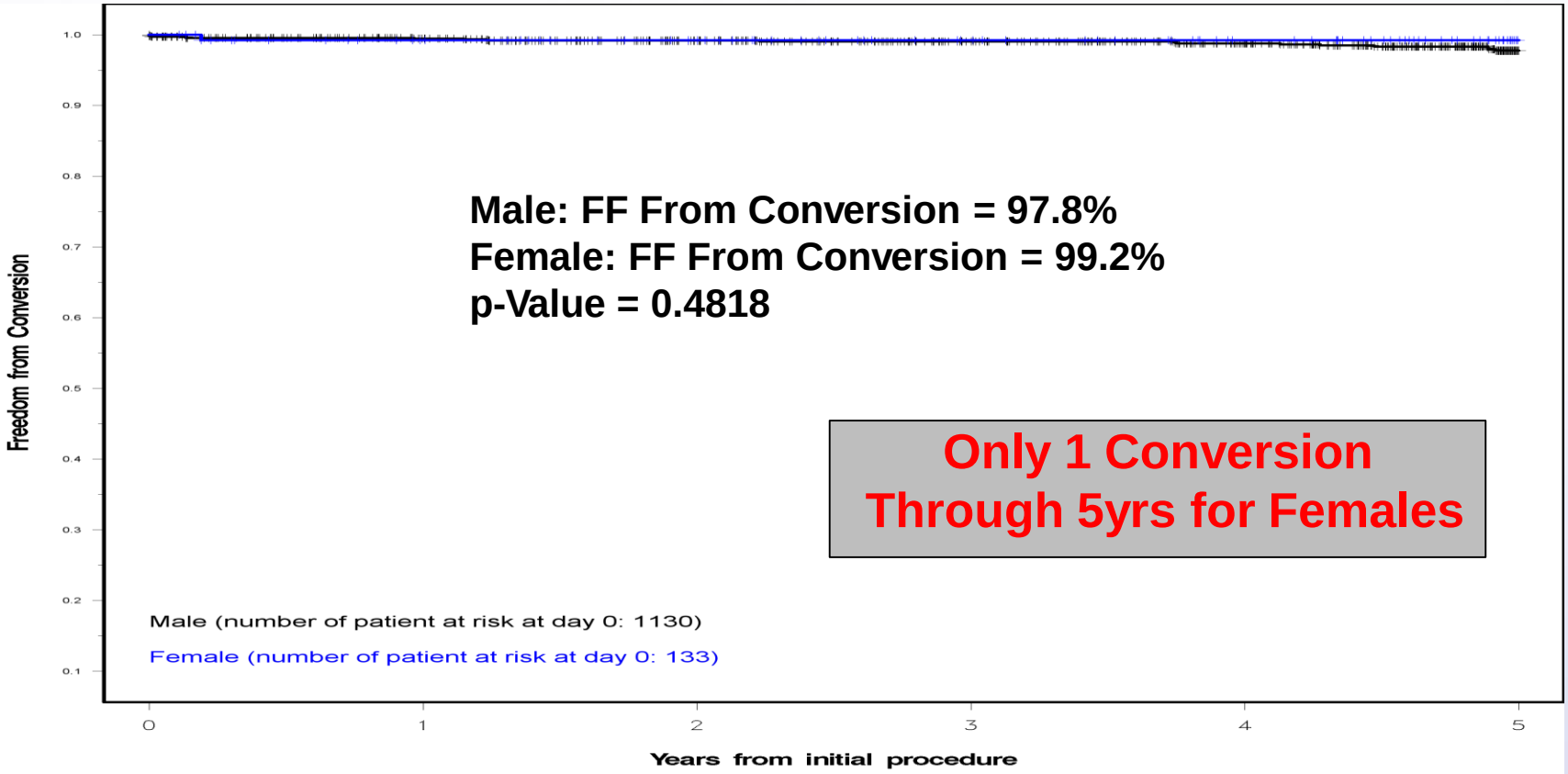
	Male						Female					
	0-30D	31D -1Y	1Y – 2Y	2Y – 3Y	3Y – 4Y	4Y – 5Y	0-30D	31D- 1Y	1Y – 2Y	2Y – 3Y	3Y – 4Y	4Y – 5Y
No. at Risk[1]	1130	1110	1032	893	803	703	133	133	118	105	90	76

5 Year Freedom From Rupture



	Male						Female					
	0-30D	31D – 1Y	1Y – 2Y	2Y – 3Y	3Y – 4Y	4Y – 5Y	0-30D	31D – 1Y	1Y – 2Y	2Y – 3Y	3Y – 4Y	4T – 5Y
No. at Risk[1]	1130	1110	1031	892	801	699	133	133	118	105	90	76

5 Year Freedom From Conversion



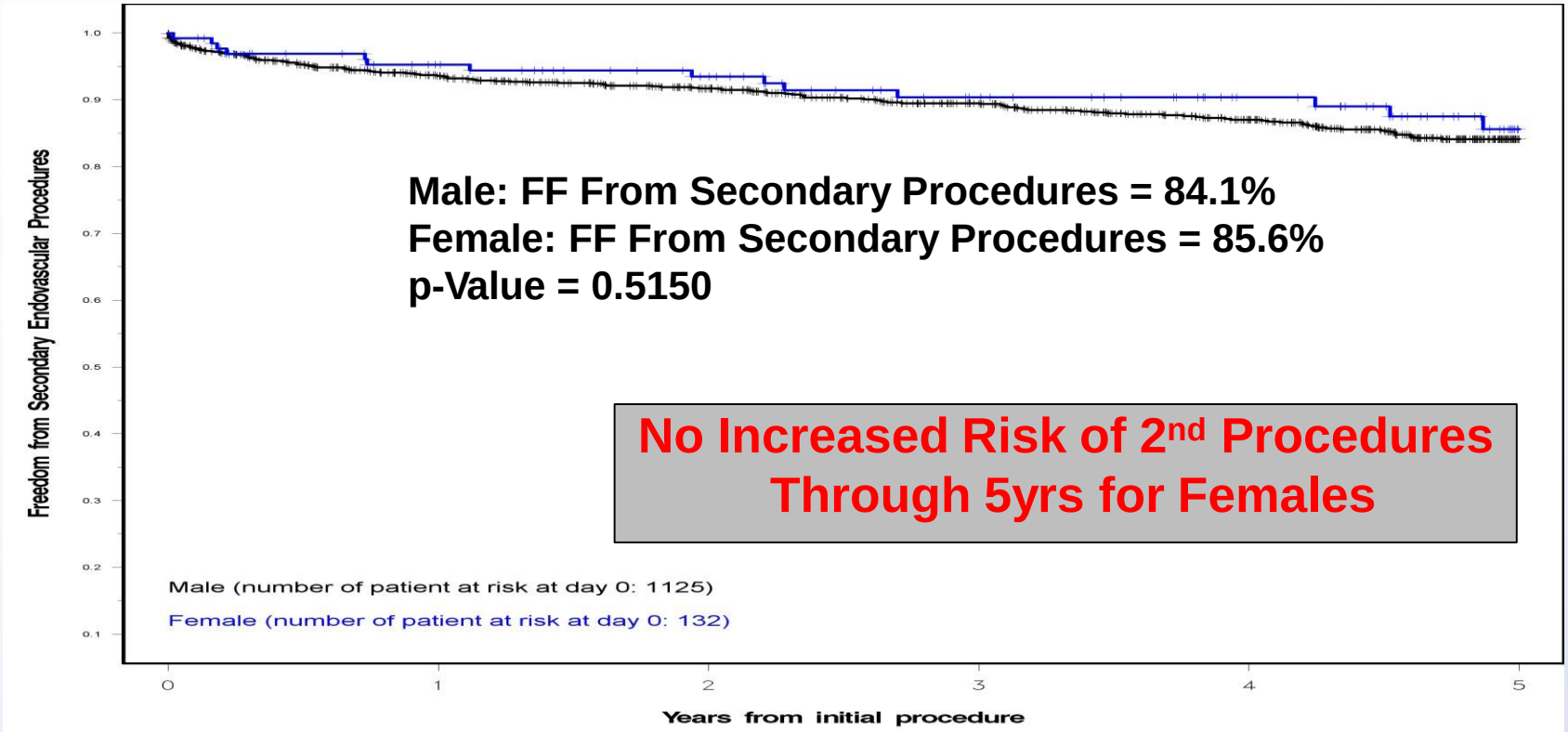
	Male						Female					
	0-30D	31D – 1Y	1Y – 2Y	2Y – 3Y	3Y – 4Y	4Y – 5Y	0-30D	31D – 1Y	1Y -2Y	2Y - 3Y	3Y - 4Y	4Y - 5Y
No. at Risk[1]	1130	1108	1032	893	803	702	133	133	118	105	90	76

Neck Stabilization Markers – Type Ia Endoleak

Type 1a Endoleak	Male	Female	p-Value
At 1 Year	**0.2%** (2/933)	**1.0%** (1/101)	**0.266**
At 2 Year	**0.4%** (3/768)	**1.1%** (1/88)	**0.353**
At 3 Year	**0.6%** (4/632)	**1.4%** (1/73)	**0.422**
At 4 Year	**0.7%** (4/559)	**0.0%** (0/55)	**>0.999**
At 5 Year	**1.3%** (6/449)	**3.8%** (2/52)	**0.197**

Low Type 1a Endoleak Rate for Females

5 Year Freedom From Secondary Procedures

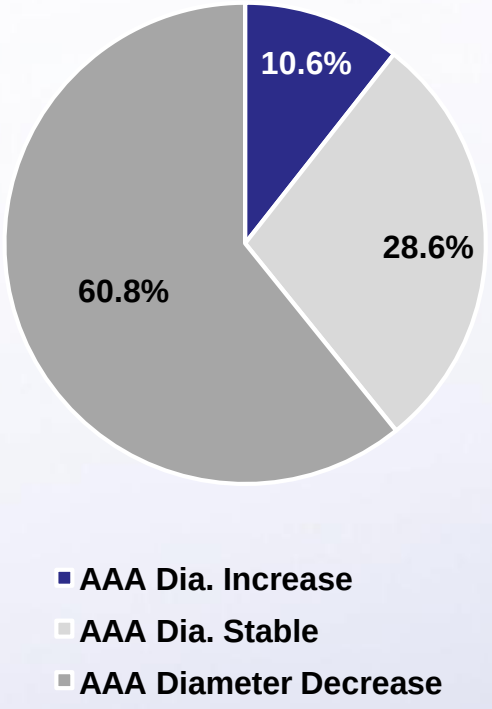


	Male						Female					
	0-30D	31D – 1Y	1Y – 2Y	2Y – 3Y	3Y – 4Y	4Y – 5Y	0-30D	31D – 1Y	1Y – 2Y	2Y – 3Y	3Y – 4Y	4Y – 5Y
No. at Risk[1]	1125	1083	969	824	723	618	132	131	112	97	81	67

AAA Sac Diameter Changes At 5 Years

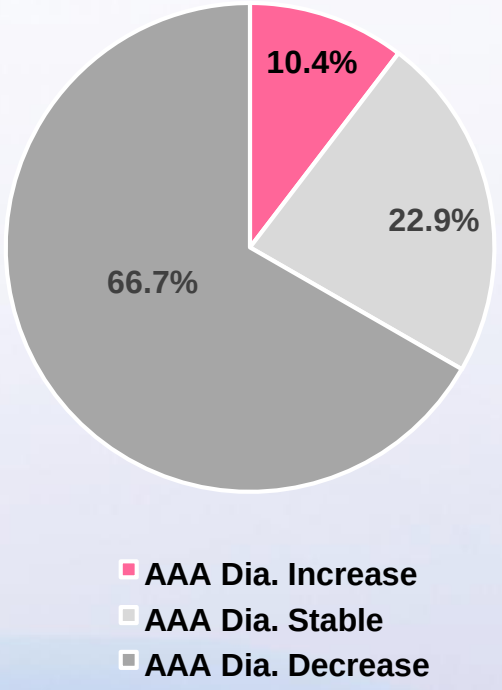
89.4% Stable or Decrease

Male



89.6% Stable or Decrease

Female



AAA Sac Dynamics Equivalent Between Genders

Summary

- Women were older and had less diagnosed cardiac disease
- Women had shorter and more angulated necks, smaller iliacs
- Women were more commonly treated outside of the Endurant Instructions for Use

Conclusion

- With more challenging baseline characteristics and anatomy, women were treated more often outside IFU
- Despite these challenges, 5-year long-term outcomes were **equivalent between the genders** when treated with the Endurant Stent Graft
- Endurant sets a new benchmark for EVAR by **demonstrating equivalent outcomes** between men and women at **30 days, 1 year** and **5 years**

ENDURANT™ STENT GRAFT SYSTEM BRIEF STATEMENT

Brief Statement

Indications

The Endurant™ Stent Graft System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms in patients with the following characteristics:

- Adequate iliac/femoral access that is compatible with vascular access techniques, devices and/or accessories
- Proximal neck length of ≥10 mm
- Infrarenal neck angulation of ≤60°
- Distal fixation length of ≥15 mm
- Aortic neck diameters with a range of 19 to 32 mm
- Iliac diameters with a range of 8 to 25 mm
- Morphology suitable for aneurysm repair

Contraindications

The Endurant Stent Graft System is contraindicated in:

- Patients who have a condition that threatens to infect the graft.
- Patients with sensitivities or allergies to the device materials.

Warnings and Precautions

- The long-term safety and effectiveness of the Endurant Stent Graft System has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the health and the performance of the implanted endovascular stent graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in the *Instructions for Use*.
- Patients experiencing reduced blood flow through the graft limb, aneurysm expansion, and persistent endoleaks may be required to undergo secondary interventions or surgical procedures.
- The Endurant Stent Graft System is not recommended in patients unable to undergo or who will not be compliant with the necessary preoperative and postoperative imaging and implantation studies as described in the *Instructions for Use.*
- Renal complications may occur: 1) From an excess use of contrast agents. 2) As a result of emboli or a misplaced stent graft. The radiopaque marker along the edge of the stent graft should be aligned immediately below the lower-most renal arterial origin.
- Studies indicate that the danger of micro-embolization increases with increased duration of the procedure.
- The safety and effectiveness of the Endurant Stent Graft System has not been evaluated in some patient populations. Please refer to the product *Instructions for Use* for details.

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ENDURANT™ STENT GRAFT SYSTEM BRIEF STATEMENT

MRI Safety and Compatibility: Non-clinical testing has demonstrated that the Endurant Stent Graft is MR Conditional. It can be scanned safely in both 1.5T & 3.0T MR systems under certain conditions as described in the product *Instructions for Use*. For additional information regarding MRI please refer to the product *Instructions for Use*.

Adverse Events

Potential adverse events include (arranged in alphabetical order): Amputation; Anesthetic complications and subsequent attendant problems (e.g. aspiration), Aneurysm enlargement; Aneurysm rupture and death; Aortic damage, including perforation, dissection, bleeding, rupture and death; Arterial or venous thrombosis and/or pseudoaneurysm; Arteriovenous fistula; Bleeding, hematoma or coagulopathy; Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis); Cardiac complications and subsequent attendant problems (e.g. arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension); Claudication (e.g., buttock, lower limb); Death; Edema; Embolization (micro and macro) with transient or permanent ischemia or infarction; Endoleak; Fever and localized inflammation; Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection); Hepatic failure; Impotence; Infection of the aneurysm, device access site, including abscess formation, transient fever and pain; Lymphatic complications and subsequent attendant problems (e.g., lymph fistula); Neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis); Occlusion of device or native vessel; Pulmonary complications and subsequent attendant problems; Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure); Stent graft: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft twisting and/or kinking; insertion and removal difficulties; graft material wear; dilatation; erosion; puncture and perigraft flow; Surgical conversion to open repair; Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection; Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death); Vessel damage; Wound complications and subsequent attendant problems (eg, dehiscence, infection, hematoma, seroma, cellulitis)

Please reference product I*nstructions for Use* for more information regarding indications, warnings, precautions, contraindications and adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

ENDURANT™ II/ ENDURANT™ IIS STENT GRAFT SYSTEM

Indications

The Endurant™ II/Endurant™ IIs bifurcated stent graft is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms. The Endurant II aorto-uni-iliac (AUI) stent graft is indicated for the endovascular treatment of infrarenal abdominal aortic or aortoiliac aneurysms in patients whose anatomy does not allow the use of a bifurcated stent graft. The Endurant II/Endurant IIs stent graft system is indicated for use in patients with the following characteristics:

- Adequate iliac/femoral access that is compatible with vascular access techniques, devices and/or accessories
- Proximal neck length of ≥10 mm
- Infrarenal neck angulation of ≤60°
- Aortic neck diameters with a range of 19 to 32 mm
- Distal fixation length(s) of ≥15 mm
- Iliac diameters with a range of 8 to 25 mm
- Morphology suitable for aneurysm repair

Contraindications

The Endurant II/Endurant IIs Stent Graft System is contraindicated in:

- Patients who have a condition that threatens to infect the graft.

Patients with known sensitivities or allergies to the device materials.

Warnings and Precautions

- The long-term safety and effectiveness of the Endurant II/Endurant IIs Stent Graft System has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the health and the performance of the implanted endovascular stent graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in the *Instructions for Use*.
- Patients experiencing reduced blood flow through the graft limb, aneurysm expansion, and persistent endoleaks may be required to undergo secondary interventions or surgical procedures.
- The Endurant II/Endurant IIs Stent Graft System is not recommended in patients unable to undergo or who will not be compliant with the necessary preoperative and postoperative imaging and implantation studies as described in the *Instructions for Use.*
- Renal complications may occur: 1) From an excess use of contrast agents. 2) As a result of emboli or a misplaced stent graft. The radiopaque marker along the edge of the stent graft should be aligned immediately below the lower-most renal arterial origin.
- Studies indicate that the danger of micro-embolization increases with increased duration of the procedure.
- The safety and effectiveness of the Endurant II/Endurant IIs Stent Graft System has not been evaluated in some patient populations. Please refer to the product *Instructions for Use* for details.

ENDURANT™ II/ ENDURANT™ IIS STENT GRAFT SYSTEM

MRI Safety and Compatibility: Non-clinical testing has demonstrated that the Endurant II/Endurant IIs Stent Graft is MR Conditional. It can be scanned safely in both 1.5T & 3.0T MR systems under certain conditions as described in the product *Instructions for Use*. For additional information regarding MRI please refer to the product *Instructions for Use*.

Adverse Events

Potential adverse events include (arranged in alphabetical order): amputation; anesthetic complications and subsequent attendant problems (e.g., aspiration), aneurysm enlargement; aneurysm rupture and death; aortic damage, including perforation, dissection, bleeding, rupture and death; arterial or venous thrombosis and/or pseudoaneurysm; arteriovenous fistula; bleeding, hematoma or coagulopathy; bowel complications (e.g., ileus, transient ischemia, infarction, necrosis); cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension); claudication (e.g., buttock, lower limb); death; edema; embolization (micro and macro) with transient or permanent ischemia or infarction; endoleak; fever and localized inflammation; genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, femoral-femoral artery thrombosis, fistula, incontinence, hematuria, infection); hepatic failure; impotence; infection of the aneurysm, device access site, including abscess formation, transient fever and pain; lymphatic complications and subsequent attendant problems (e.g., lymph fistula); neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis); occlusion of device or native vessel; pulmonary complications and subsequent attendant problems; renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure); stent graft: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft twisting and/or kinking; insertion and removal difficulties; graft material wear; dilatation; erosion; puncture and perigraft flow; surgical conversion to open repair; vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection; vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death); vessel damage; wound complications and subsequent attendant problems (e.g., dehiscence, infection, hematoma, seroma, cellulitis)
Please reference product *Instructions for Use* for more information regarding indications, warnings, precautions, contraindications and adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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