Fast-Track Endovascular Aortic Repair

Final Results from the Prospective LIFE Registry

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Least Invasive Fast-Track EVAR (LIFE) Registry

Primary Objective of the *LIFE Registry is* to demonstrate the **clinical and cost benefits** associated with the ultra-low profile (14F) *Ovation Abdominal Stent Graft* platform under ***the least invasive conditions*** defined in the **Fast-Track EVAR protocol**:

- ***Percutaneous Access***
- ***No General Anesthesia***
- ***No ICU Admission***
- ***Next-day Discharge***

LIFE Registry: Study Design

- **Prospective, non-randomized, post-market study**
- **250 patients, up to 40 U.S. centers**
- **Independent Clinical Events Committee (CEC)**
- **Primary endpoint**
  - **Major Adverse Event within 30d (10.4% target performance goal)**
- **Secondary endpoints**
  - **Treatment Success (completion of Fast-Track protocol)**
  - **Procedure, fluoroscopy, and anesthesia time; access complications; ambulatory status; hospital stay; quality of life**
  - **Freedom from type I/III endoleak; conversion to open repair; rupture; AAA-related reintervention; mortality**

Investigative Sites and PIs

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Miriam Hospital
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Douglas Spriggs

Temple University Hospital
Grayson Wheatley

Patient Selection

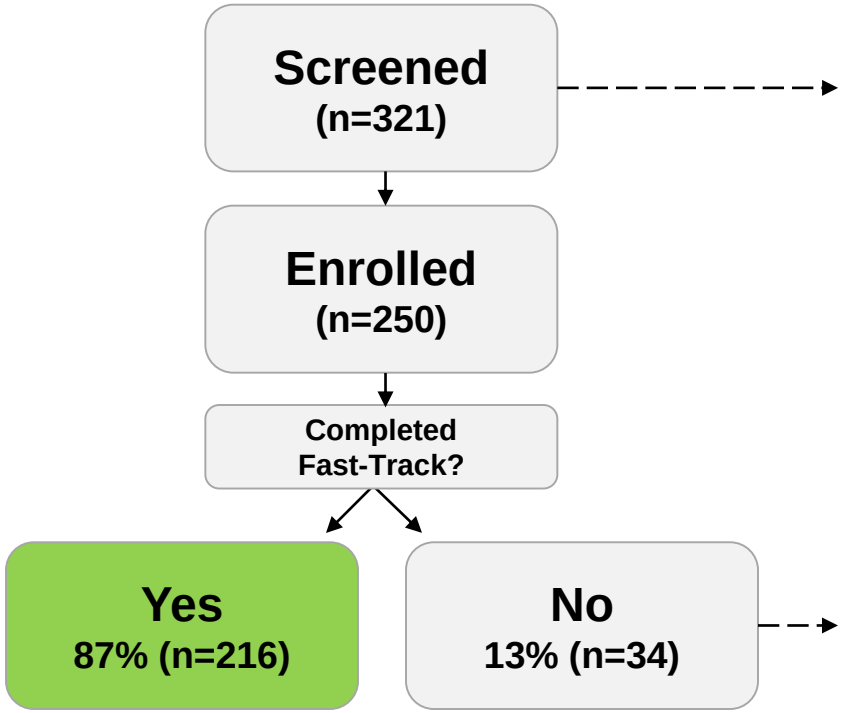
Inclusion Criteria*

- Infrarenal AAA >5cm, >0.5cm growth in past 6 months, or max diameter >1.5x the transverse adjacent aortic segment
- Meets indications ***for use with Ovation Abdominal Stent Graft platform***
- Suitable femoral arteries that allow use of the Perclose ProGlide Suture-Mediated Closure (SMC) System

*Abbreviated for Fast-Track related inclusion criteria; full list at clinicaltrials.gov Identifier: NCT02224794

Fast-Track Completion

Fast-Track attempted in 100% and completed in 87% of patients; Bilateral PEVAR successful in 97% of patients



Reasons for Screen Failure	
Anatomic	8 (Unsuitable AAA anatomy for Ovation; small or inadequate access, <5mm)
Other	63 (EVAR contraindicated; planned adjunctive procedures)

Reasons for Fast-Track Failure	
>1 Midnight Stay	20 (Observation of AEs, social issues, etc.)
General Anesthesia	6
ICU Admission	11
Cut Down	8 (6 ProGlide failures)

Note: Subject may have more than one reason for screen failure, or for moving from Fast-Track protocol

Baseline Demographics

Patient Demographics	
Enrolled	250
Age	73 ± 8
Gender	
Male	83.2% (208)
Female	16.8% (42)
ASA Grade	
I	6.0% (15)
II	22.8% (57)
III	71.2% (178)
IV	--

Vascular Characteristics	
Aortic diameter 13 mm from lowest renal artery (mm)	22.8 ± 3.6
Juxtarenal angle (º)	24.1 ± 17.2
Proximal neck length (mm)	24.1 ± 14.9
Sac diameter (mm)	50.6 ± 7.9
Left iliac min access diameter (mm)	7.9 ± 1.9
Right iliac min access diameter (mm)	7.8 ± 1.8

In-Hospital Outcomes

Fast-Track Group had Faster Procedures and Shorter Recovery

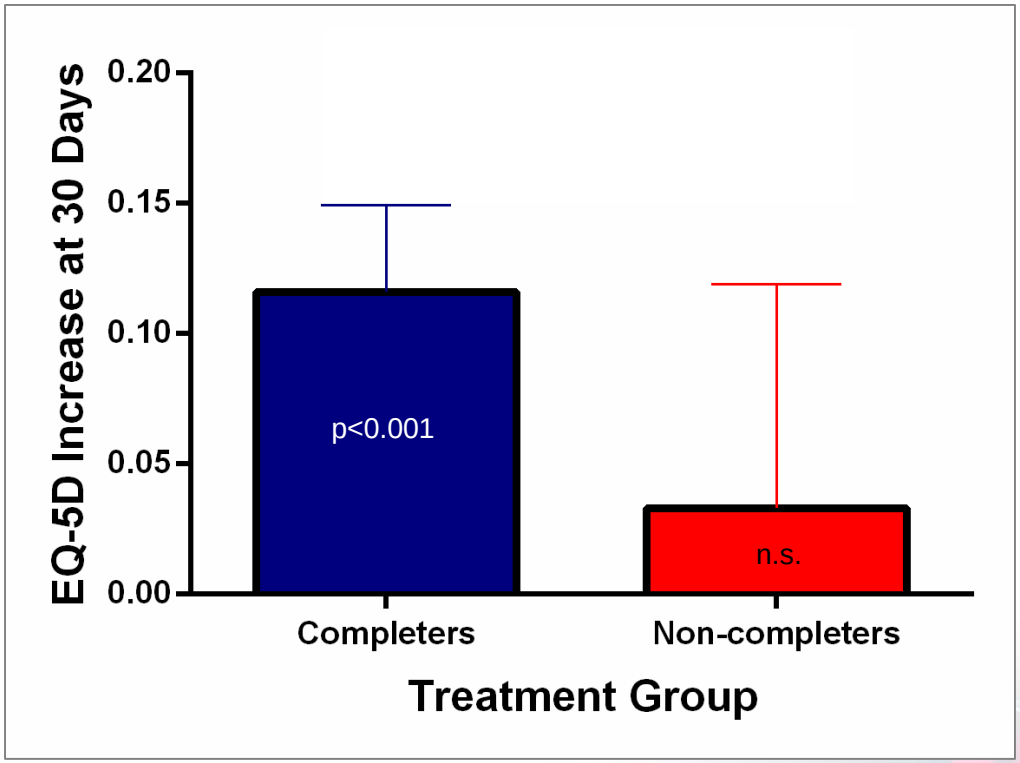
Procedural	LIFE Fast-Track	LIFE Non Fast-Track	
		PEVAR	Cut-Down
Access Technical Success (Successful Bilateral PEVAR)	100% (216/216)	100% (26/26)	0% (0/8)
Blood loss (ml)†	59.0 ± 58.4	51.5 ± 41.3	318.8 ± 304.7
Local/Regional/Conscious Anesthesia	100% (216/216)	85% (22/26)	75% (6/8)
Procedure Time (min)†	84.2 ± 27.8	99.5 ± 33.9	145.9 ± 35.0
Fluoroscopy time (min)†	18.6 ± 8.5	20.8 ± 7.3	25.1 ± 26.5
Recovery			
Hours to ambulation‡	7.9 (0.3, 27.8)	15.8 (1.8, 402.2)	15.4 (4.7, 47.7)
Hours to normal diet‡	5.9 (3.5, 12.1)	18.3 (1.6, 390.2)	6.8 (1.8, 19.6)
No ICU Admission	100% (216/216)	65% (17/26)	75% (6/8)
Hospital Stays / Days†	1.2 ± 0.4	2.9 ± 3.2	1.4 ± 0.5

† mean ± std / ‡ median (min, max)

As of August 2, 2016

Quality of Life Improvement

QOL Change was Highly Significant among Fast-Track Completers

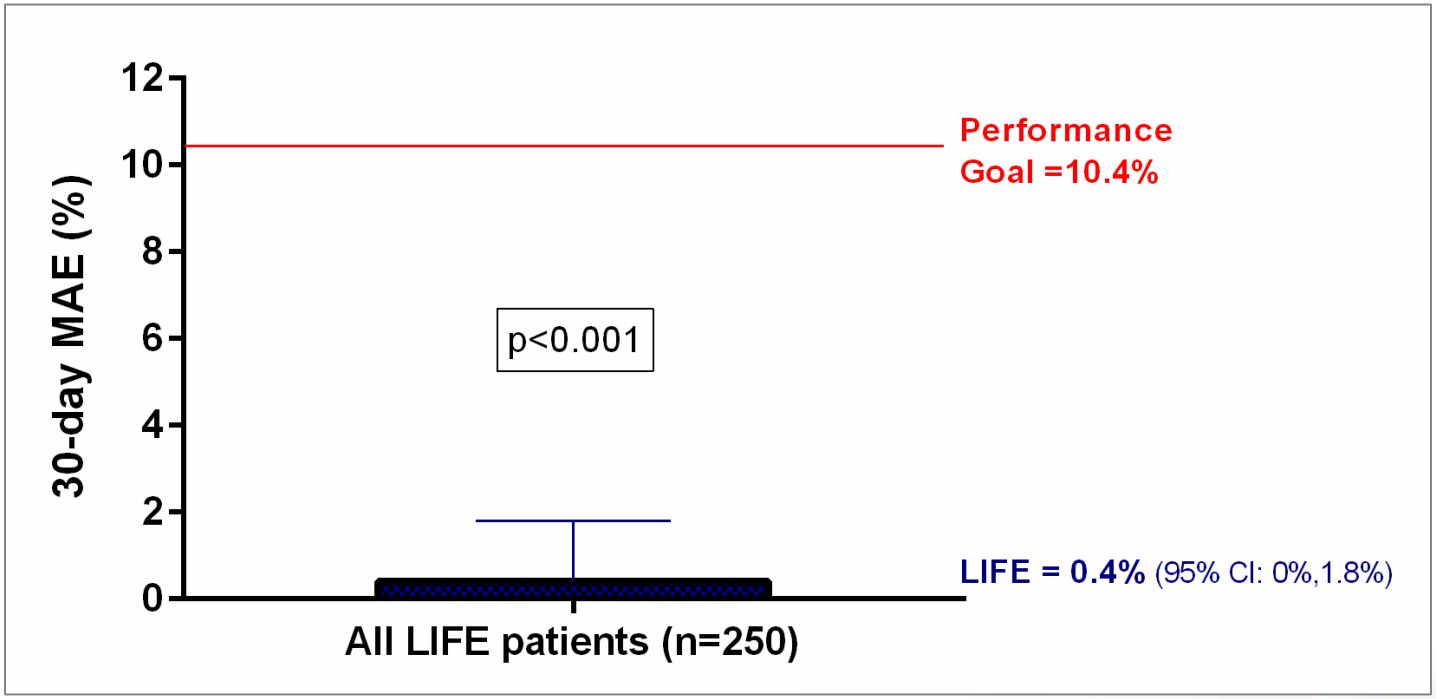


EQ-5D includes a visual analog scale where health is rated from 0 (worst imaginable health) to 100 (best imaginable health)

As of August 2, 2016

Major Adverse Events

No Device-Related or Procedure-Related MAEs



[1] MAE non-device nor procedure-related: death due to acute respiratory failure 28 days post procedure

As of August 2, 2016

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Clinical Outcomes

Clinical Outcomes	LIFE Fast-Track	LIFE Non Fast-Track
Safety (Treatment Through 30 Days)		
Freedom from AAA Rupture	100% (216/216)	100% (34/34)
Freedom from Conversion to Open Repair	100% (216/216)	100% (34/34)
Freedom from AAA-Related Reintervention	100% (216/216)	100% (34/34)
Freedom from Mortality	99% (215/216)	100% (34/34)
Effectiveness (1 to 40 days)*		
Freedom from Type I Endoleak	99% (189/190)	100% (27/27)
Freedom from Type III Endoleak	100% (190/190)	100% (27/27)

As of August 2, 2016
*One month window ranges from 1 to 40 days; results assessed and reported by investigative site

Economic Analysis: Fast-Track vs. Standard EVAR

- **PREMIER Control group: 8,306 patients treated with elective infrarenal EVAR at 3,750 U.S. geographically diverse hospitals, academic and community based**
- **Analysis is based on inpatient discharge between 2012-2015**
  - **EVAR without rupture**
  - **40-day follow-up to assess re-intervention rate**
- **Costs were calculated related to:**
  - **Access**
  - **Anesthesia**
  - **ICU stay**
  - **Hospital stay**

The Advisory Board research and analysis, EVAR ICD-9 procedure code 39.71: 50th percentile tier, 2015 MEDPAR data.
Vascular Quality Initiative (VQI): SVS PSO COPI Report 2014, EVAR across VQI centers from 2011 – 2014.
Endologix PEVAR Trial: Nelson et al. *J Vasc Surg* 2014;59:1181-94

LIFE Fast-Track EVAR is More Cost Effective

	PREMIER EVAR	LIFE FAST-TRACK	SAVINGS
Anesthesia	General, 84% **$500**	Local, 100% **$300**	**$200**
Access	Cutdown* **$300**	Bilateral PEVAR **$1,200**	**($900)**
ICU	1.4 Days, 51% **$15,300**	0 Days, 0% **$0**	**$15,300**
Non-ICU	2.3 Days **$12,900**	1.2 Days **$6,700**	**$6,200**
30 day Reintervention	$29.4k, 1.1% **$300**	0% **$0**	**$300**
TOTAL	**$29,300**	**$8,200**	**$21,100**

STANDARD EVAR: Average costs per patient

Index anesthesia costs based on all charge master line items related to anesthesia

*30% applicability based on anatomic criteria, with 23% bilateral / 7% unilateral PEVAR (Manunga et al, J Vasc Surg, 2013)

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30d Hospital Readmissions

- Most common EVAR readmission drivers are MI, renal, respiratory and wound complications
- Median EVAR readmission cost $17,700 (if for graft occlusion) to $23,600 (if for endoleak)
- Cost drivers are due to additional surgeries, ICU services, and length of stay

LIFE readmission rate is *5x less* than contemporary EVAR reports

	EVAR **ACS NSQIP** **Gupta 2014**	**EVAR** **ACS NSQIP** **Chen 2016**	**LIFE Registry**
EVAR Cases (N)	2369	3886	250
Time Period	2011	2012-2013	2015-2016
Unplanned 30d Readmission	**7.9%**	**8.1%**	**1.6%**
Operation during Readmission	28%	-	**0%**

ACS NSQIP: **American College of Surgeons – National Surgical Quality Improvement Program**

Chen SL et al. Perioperative Risk Factors for Readmission Following EVAR. Presented at SCVS, 2016.

Gupta PK, et al. Unplanned readmissions after vascular surgery. J Vasc Surg 2014;59:473-82.

Conclusions

- **LIFE Registry** is the first-ever prospective study to **demonstrate safe and effective patient outcomes** when utilizing a Fast-Track EVAR protocol:
  - Percutaneous access, no general anesthesia, no ICU admission, and next day discharge
- No device-related or procedure-related MAEs
- 100% freedom from rupture, conversion, or secondary interventions
- Fast-Track EVAR offers significant perioperative cost savings compared to standard EVAR
  - Hospital and ICU stay is main cost driver
  - Low 30d hospital readmission rate
- Results warrant establishment of Fast-Track Protocol in experienced EVAR centers

THANK YOU