

Medtronic

Join our

Medtronic Aortic Lunch Symposium Tuesday June 21st @ ESCVS | IMAD Meeting







Join our physician-led Medtronic Aortic lunch symposium focusing on Sac Regression, ESAR and ChEVAR. During this session you will be able to interact with the experts.



Medtronic Lunch Symposium Tuesday June 21st, Room Pieds Legers 12:30-13:30

- Defining EVAR Therapy Success: Is Sac Regression the New Paradigm?
- Tailoring complex endovascular repair with off-the-shelf solutions

Moderated by prof. Lee Bouwman



Program details

12:30 - 12:33 Welcome and introduction *Prof. Lee Bouwman*

12:33 – 12:50 Significance of sac regression and drivers of EVAR outcomes ENGAGE 8 year data *Prof. Lee Bouwman*

12:50 – 13:10 Addressing the unmet needs of challenging neck anatomy patients 3 year data ESAR Wide necks *Mr. Colin Bicknell*

13:10 – 13:30 On-label ChEVAR: Why optimal device combination and standardized procedure yields durable results *Prof. Konstantinos Donas*



Significance of sac regression and drivers of EVAR outcomes ENGAGE 8-year data

Prof. Lee Bouwman Zuyderland Medical Centre Heerlen The Netherland



Disclosures

Consultant:

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Key determinants of EVAR therapy success



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No/low incidence of endoleaks No endoleaks is a marker of success

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Positive AAA sac dynamics If AAA sac isn't growing \rightarrow good clinical scenario



Goncalves et al: Sac Dynamic and Post-operative Course



VQI evidence links sac regression to better long-term survival



O'Donnell TFX, Deery SE, Boitano LT, et al. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. J Vasc Surg. 2019;69(2):414-422.



Deery et al: Sac Expansion Associated with Worse Survival



Aneurysm sac expansion is independently associated with late mortality in patients treated with endovascular aneurysm repair

Sarah E. Deery, MD, MPH,^a Emel A. Ergul, MS,^a Marc L. Schermerhorn, MD,^b Jeffrey J. Siracuse, MD,^c Andres Schanzer, MD,^d Philip P. Goodney, MD, MS,^e Richard P. Cambria, MD,^a and Virendra I. Patel, MD, MPH,^a for the Vascular Study Group of New England, *Boston and Worcester, Mass; and Lebanon, NH*

Deery et al. J Vasc Surg. 2018;67:157-64.

- Patients with sac expansion vs. sac stable/regression
- Sac expansion independently predicted late mortality
- Sac regression predicted decrease in late mortality

Variable	Death hazard ratio	95% CI	<i>P</i> value
Sac expansion	1.5	1.1-2.0	.01
Sac regression	0.6	0.5-0.8	<.001
Age, by decade	1.6	1.4-1.8	<.001
Congestive heart failure	1.4	1.1-2.0	.02
Chronic obstructive pulmonary disease	1.5	1.2-1.8	<.001
Concurrent iliofemoral bypass	3.1	1.5-6.7	<.01

CrossMark

5yr ENGAGE Analysis: Sac Dynamics Associated with Survival

ENGAGE Registry – 1263 real world subjects enrolled 2009-2011

Presented at ESVS 2020 (Bockler et al.)

Under submission with EJVES (Li et al.)

Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair – a new paradigm for success

SVS definitions for sac change





5yr ENGAGE Analysis: Freedom from All Cause Mortality



p-values are for comparisons to the sac decrease group

Under submission with EJVES (Li et al.)



5yr ENGAGE Analysis: Multiple Cox Regression for ACM through 5 Years



Hazard ratio (HR) > 1 denotes increased risk for all cause mortality. Backwards selection with a stay criterion of 0.1 was used, with anatomic characteristics forced into the model.

Under submission with EJVES (Li et al.)

5yr ENGAGE Analysis: Freedom from Major Adverse Events



p-values are for comparisons to the sac decrease group Under submission with EJVES (Li et al.)



5yr ENGAGE Analysis: Freedom from Secondary Endovascular Procedures



p-values are for comparisons to the sac decrease group



5yr ENGAGE Analysis: Freedom from Type IA Endoleaks



p-values are for comparisons to the sac decrease group



5 Year Sac Dynamics based on First Year Sac Status



Under submission with EJVES (Li et al.)

ENGAGE at 8 years methodology

ENGAGE Cohort 1263 real world subjects Enrollment from 2009-2011

ENGAGE Extended Cohort 390 subjects 8 year follow up compliance: Editor's Choice — Five Year Outcomes of the Endurant Stent Graft for Endovascular Abdominal Aortic Aneurysm Repair in the ENGAGE Registry

Joep A.W. Teijink **, Adam H. Power ^b, Dittmar Böckler ^c, Patrick Peeters ^d, Steven van Sterkenburg ^e, Lee H. Bouwman ^f, Hence J. Verhagen⁸, Marc Bosiers^h, Vincente Riambau¹, Jean-Pierre Becquemin^J, Philippe Cuypers^a, Marc van Sambeek^a

Teijink et al., Eur J Vasc Endovasc Surg. 2019;58(2):175-181



Methodology – ENGAGE 8yr sac dynamics

- > ENGAGE Extended Cohort (n=390)
- > ENGAGE 8y sac analysis
 - SVS definitions for sac change at 1 year
 - 1mo post op imaging used as baseline for determination of 1yr sac status
 - Extended Cohort: 352 had 1mo and 1y imaging



Sac Status Evolution over 8 Years

Stable patients fall into decrease or increase groups over time



Freedom from All Cause Mortality

Sac Decrease significantly better than others



1mo post op imaging used as baseline for determination of 1yr sac status group. Of the 1263 enrolled in ENGAGE, 949 had 1mo and 1yr imaging. Of the 390 patients who reconsented to the extended FU, 352 had 1mo and 1yr imaging

Freedom from Aneurysm Related Mortality

Sac Increase had worst outcomes



imaging. Of the 390 patients who reconsented to the extended FU, 352 had 1mo and 1yr imaging

Freedom from Conversion to Open Repair

Sac Increase had worst outcomes



1mo post op imaging used as baseline for determination of 1yr sac status group. Of the 1263 enrolled in ENGAGE, 949 had 1mo and 1yr imaging. Of the 390 patients who reconsented to the extended FU, 352 had 1mo and 1yr imaging

Freedom from Any Secondary Procedures

Sac Decrease significantly better than others



	No. at risk									
Decrease	441	416	377	340	303	236	155	149	127	
Stable	462	431	365	316	270	200	130	121	102	
Increase	46	37	29	23	19	14	9	8	5	

1mo post op imaging used as baseline for determination of 1yr sac status group. Of the 1263 enrolled in ENGAGE, 949 had 1mo and 1yr imaging. Of the 390 patients who reconsented to the extended FU, 352 had 1mo and 1yr imaging

Freedom from Any Secondary

Procedures

Freedom from Any Endoleak Sac Decrease significantly better than others



1mo post op imaging used as baseline for determination of 1yr sac status group. Of the 1263 enrolled in ENGAGE, 949 had 1mo and 1yr imaging. Of the 390 patients who reconsented to the extended FU, 352 had 1mo and 1yr imaging

8 Year Sac Dynamics based on First Year Sac Status



Risk Factors for All Cause Mortality through 8 Years



*as compared to sac decrease at 1yr as the reference group. HR > 1 indicates increased risk for ACM. Univariate Cox proportional hazards regression was performed on ~40 variables that had missing values imputed. Variables with univariate p-value < 0.1 and 8 pre-selected variables were entered into a multivariable backward selection Cox model with stay criteria 0.1. The pre-selected variables were forced into the final model and are shown above. The following variables (HR) are not plotted but are in the final model with a p-value < 0.05 unless otherwise noted: Alcoholism (1.86), Arrhythmia (1.37), Cancer (1.59), Diabetes (1.37), Pulmonary disease (1.52), Peripheral vascular disease (1.29, p = 0.07).

Limitations

- Post hoc analysis
- Differences in KM survival analyses is potentially influenced by events occurring prior to 1 year
- Reconsent group has some indications of being healthier than non-reconsent group although there were no differences in anatomical criteria
- Imaging modality is not the same for all patients
- Limited number of patients may impact results although measured outcomes look very similar to the larger VQI study

Conclusions

ENGAGE Registry:

Sac regression at one year is associated with higher survival through eight years

Sac regression at one year have significantly fewer events through eight years compared to those with sac increase or sac stable

- > All cause mortality
- > Secondary Procedures
- > Endoleaks

Sac regression at one year is likely to persist through eight years

Sac regression is a new paradigm for success



Significance of sac regression and drivers of EVAR outcomes ENGAGE 8-year data

Prof. Lee Bouwman Zuyderland Medical Centre Heerlen The Netherland

