

Comparison of Procedural and Long-Term Clinical Outcomes in Critical Limb Ischemia Patients Following Endovascular Treatment in the LIBERTY 360^o Study

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Disclosure

Speaker name: George L. Adams

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

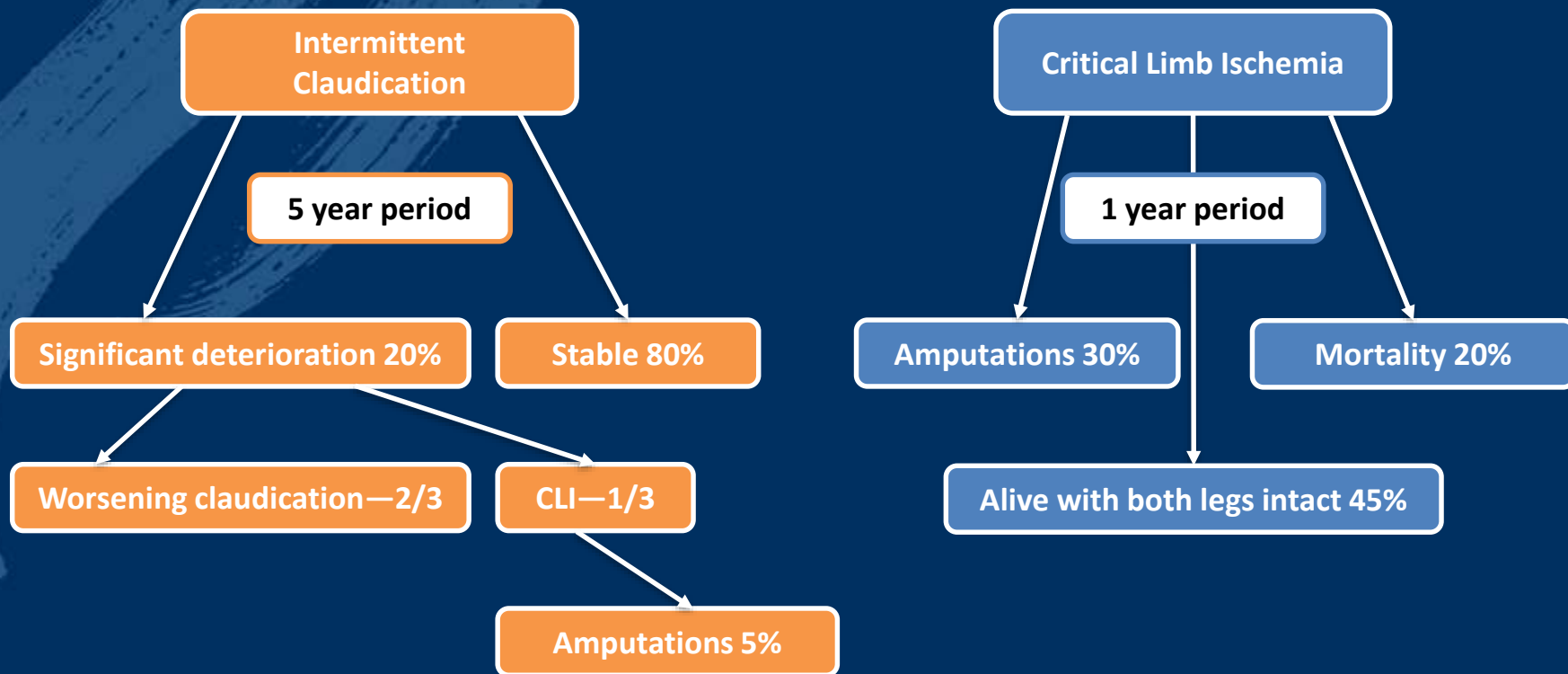
- I do not have any potential conflict of interest

LIBERTY 360 Sites and Principal Investigators

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- Coastal Vascular and Interventional (Huey McDaniel)
- Mid-Michigan Heart and Vascular Center, P.C. (John McClure)
- Rex Hospital (George Adams)
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- Gotham Cardiovascular Research, PC (Cezar Staniloae)
- Mission Research Institute (Jason Yoho, Jamison Wyatt)
- Arkansas Heart Hospital Clinic (Ian Cawich)
- El Paso Cardiology Associates (Mohammad Raja)
- Mercy Gilbert Medical Center (Georges Nseir)
- First Coast Cardiovascular Institute (Issam Moussa, Vaqar Ali)
- St. John Hospital and Medical Center (Thomas Davis)
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- Houston Methodist Sugar Land Hospital (Imran Mohiuddin)
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- Premier Surgical Associates (George Pliagas)
- San Antonio Endovascular & Heart Institute (Stefan Kiesz)
- Midwest Cardiovascular Research Foundation (Nicolas Shammas)
- Riverside Methodist Hospital/Ohio Health (John Phillips)
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- The Heart Institute at Largo (Jesse Klein)
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- Saint Luke's Hospital (Steven Laster)
- Sanford Research (Patrick Kelly)
- Mount Sinai Medical Center Heart Institute – Miami (Robert Beasley)
- Radiology and Imaging Specialists of Lakeland, P.A. (Lawrence Whitney)
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- Florida Hospital Tampa, Pepin Heart Institute (Asad Sawar)
- Florida Hospital (Mark Ranson)
- St. Johns Hospital Springfield (Jeffrey Goldstein)
- Metropolitan Heart Institute (Daniel Dulas)
- Houston Methodist Hospital Research Institute (Alpesh Shah)
- HealthONE Clinic Services - Cardiovascular, LLC (Sameer Mehta)
- St. John Health System (Thomachan Kalapura)
- Chicago Vascular Clinic (Parag Doshi)
- Phoenix Heart Cardiovascular Lab (Rajul Patel)
- Cedars-Sinai Heart Institute (Guy Mayeda)

Background: PAD Prognosis

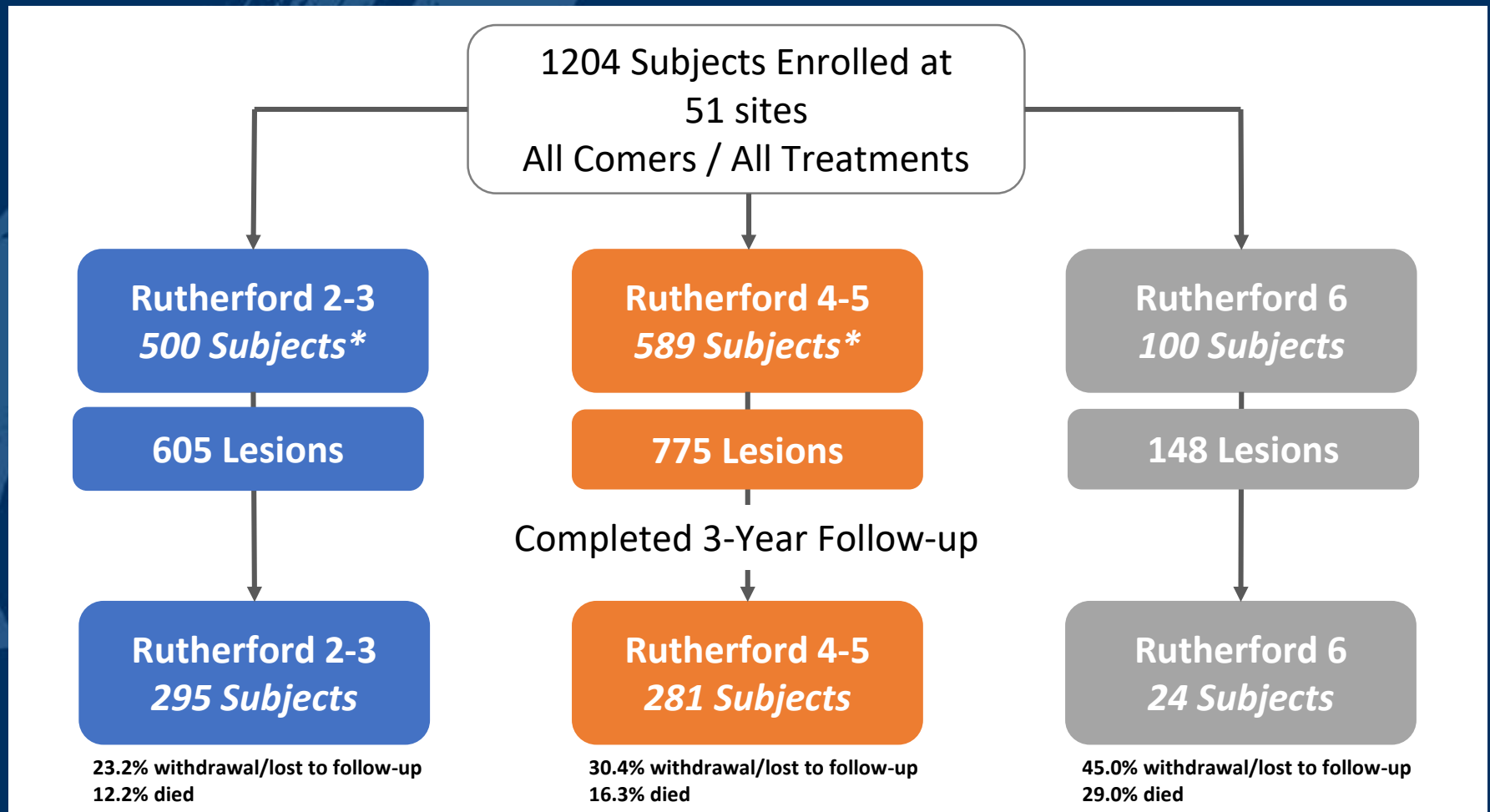
For IC patients, over a 5-year period, significant deterioration appears in 20% of cases, of whom 2/3 with worsening claudication and 1/3 with CLI. For CLI patients, after 1-year, mortality is 20%, amputations are needed in 30%, while 45% are alive with both legs intact.



LIBERTY 360 Study

- **LIBERTY** is a prospective, observational, multi-center study to evaluate procedural and long-term clinical and economic outcomes of **endovascular device interventions** in patients with **symptomatic lower extremity PAD**
- The LIBERTY study **includes any FDA-approved or cleared technology** to treat claudication and CLI
- **4 core laboratories** were utilized for independent analysis
- **1204 subjects** were enrolled at **51 sites** and were followed for **up to 5 years**
- **Endpoints** include: Procedural and lesion success, Major Adverse Events (MAEs), Duplex ultrasound, Quality of life (QoL), Six-minute walk test (6MWT), Economic analysis

Enrollment and 3-Year Follow-up



Core Lab reported lesions.

Rutherford 2, N=97; Rutherford 3, N=403; Rutherford 4, N=285; Rutherford 5, N=304.

*Due to site closure and lack of PI signature, baseline & procedure data from 15 subjects were excluded.

28-May-2019 Data

Key LIBERTY Demographics

In this real-world, all-comers study there was high prevalence of current/former smoking as well as previous PVI for PAD across all groups. Many of these demographics are predictors of 3-year outcomes, in particular previous PVI for PAD.

Subject Demographics	Rutherford Category			P-value
	RC2-3 (N=500)	RC4-5 (N=589)	RC6 (N=100) N=99	
Age (years)	69.7 ± 10.0	70.3 ± 10.9	68.0 ± 13.0	0.139
History of diabetes	241 (48.2%)	407 (69.1%)	79 (79.0%)	<0.001
History of renal disease	137 (27.4%)	232 (39.4%)	43 (43.0%)	<0.001
History of coronary artery disease	298 (59.6%)	375 (63.7%)	54 (54.0%)	0.119
History of MI	115 (23.0%)	155 (26.3%)	15 (15.0%)	0.037
History of Stroke/TIA	77 (15.4%)	92 (15.6%)	9 (9.0%)	0.213
Current/former smoker	370 (74.0%)	378 (64.2%)	61 (61.0%)	<0.001
History of lower extremity PVI for PAD	264 (52.8%)	304 (51.6%)	42 (42.0%)	0.137
Number of lower limb procedures in the last 3 years (target limb)	0.8 ± 1.4	1.3 ± 2.5	1.4 ± 2.0	0.007
History of previous major (above ankle) amputation on non-target limb	5 (1.0%)	29 (4.9%)	15 (15.0%)	<0.001
Number of wounds on target limb at baseline	0.0 ± 0.2	0.8 ± 0.9	1.7 ± 1.1	<0.001

Key LIBERTY Lesion Characteristics

High number of CTOs and BTK lesions treated across all groups. CTOs and lesion length were predictors of 3-year MAE; bailout stent use is a predictor of 3-year death & major amputation (events related to amputation free survival).

Subject Lesion Characteristics	Rutherford Category			P-value
	RC2-3 (N=500)	RC4-5 (N=589)	RC6 (N=100)	
Number of lesions treated	1.2 ± 0.5 N=497	1.3 ± 0.6 N=588	1.5 ± 0.7 N=99	<0.001
Chronic total occlusions	181 (37.3%) N=485	307 (53.1%) N=578	50 (51.5%) N=97	<0.001
Total treated target lesion length (cm)	N=464	N=563	N=95	<0.001
Mean ± SD	10.7 ± 9.9	17.0 ± 13.7	15.3 ± 12.2	
Median [IQR]	7.4 [3.6, 13.2]	13.0 [5.9, 25.8]	12.6 [5.9, 21.0]	
(Range)	(0.7, 57.0)	(0.5, 71.6)	(1.1, 60.2)	
Location of all lesions treated	N=497	N=587	N=98	
ATK only	238 (47.9%)	130 (22.1%)	24 (24.5%)	<0.001
ATK and BTK	120 (24.1%)	164 (27.9%)	28 (28.6%)	0.310
BTK only	139 (28.0%)	293 (49.9%)	46 (46.9%)	<0.001
Bailout stent used	27 (5.4%) N=497	32 (5.4%) N=588	0 (0.0%) N=99	0.025

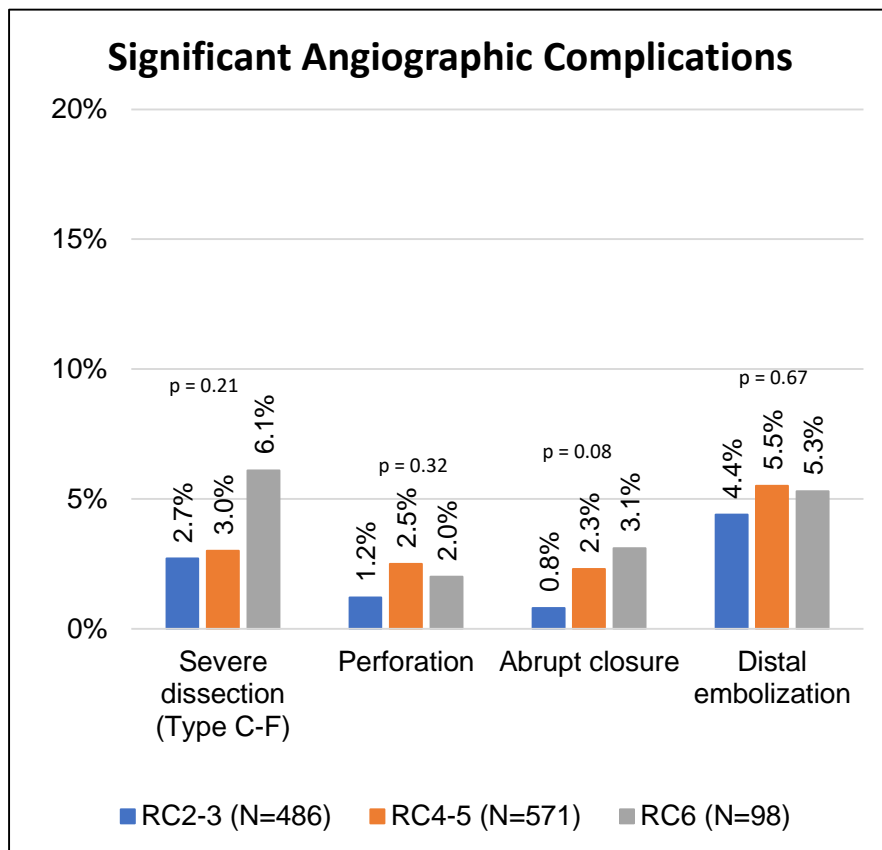
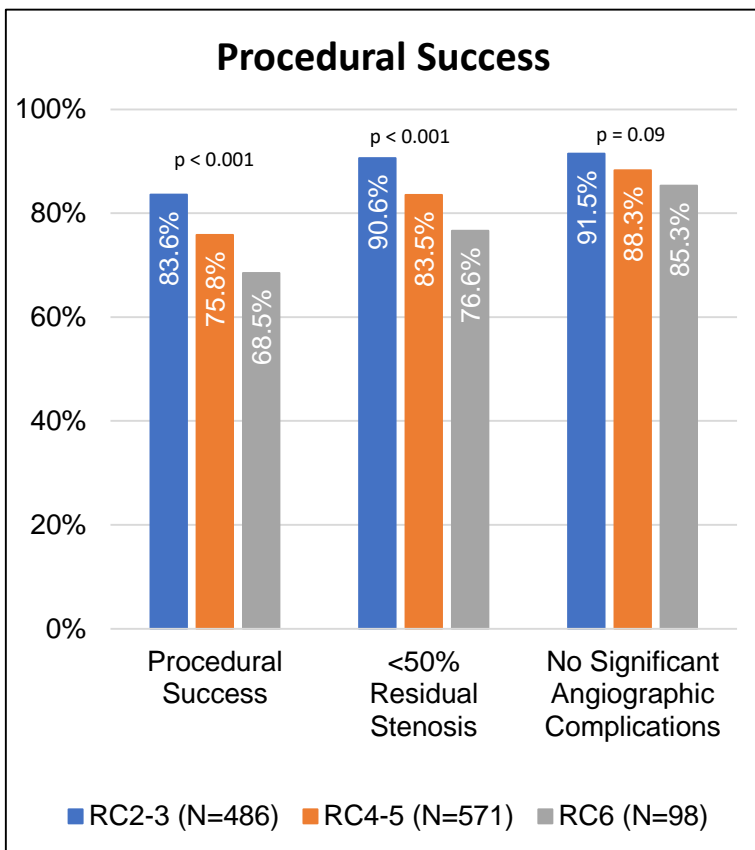
Core Lab reported lesions (Lesions with reported values may be less than total number of lesions treated in each arm).

N (%) or Mean ± SD as appropriate.

28-May-2019 Data

Procedural Success

In RC6 group, <50% residual stenosis in 76.6% of the subjects, and no angiographic complications in 85.3% of subjects.



Severe angiographic complications include: Perforation, Dissection C-F, Distal Embolization, and Abrupt closure. Imputation of significant angiographic complications for procedural success of core lab identified lesions were performed by using site data when the core lab was unable to perform angiographic assessment. P-values were calculating using Monte Carlo Approximation of the Fisher's Exact Test (categorical).

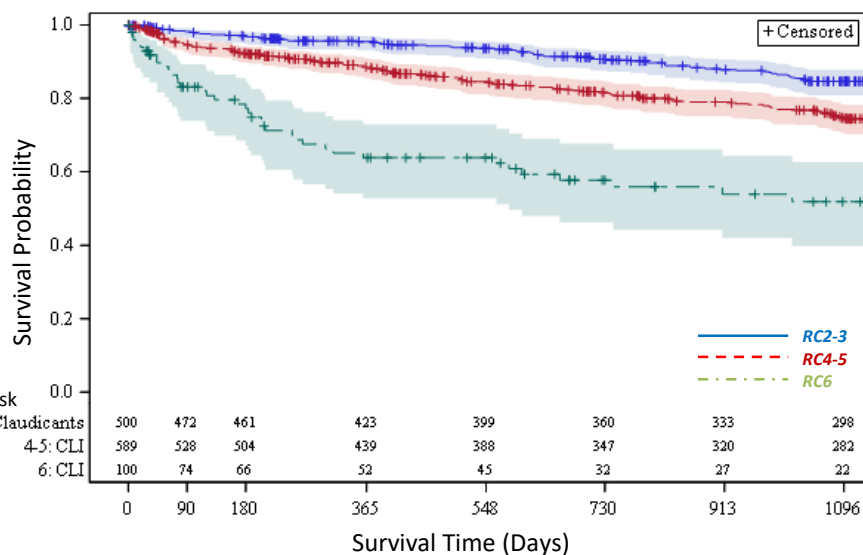
Core Lab reported lesions (Subjects with reported values may be less than total number of subjects enrolled in each arm).

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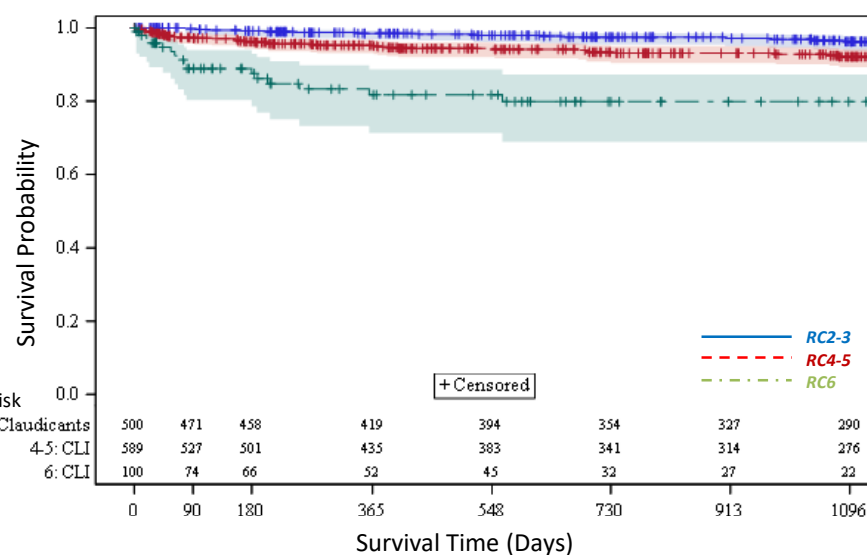
LIBERTY Outcomes through 3 Years

Contemporary endpoint of MALE-POD indicates durable results from 1-year through 3-years (RC2-3: 98.5% to 96.2%, RC4-5: 95.3% to 92.1%, RC6: 81.7% to 79.9%). RC6 subjects that survive past the first year after treatment see similar benefits in amputation free survival as RC2-3 and RC4-5 subjects.

Amputation Free Survival



FF Major Adverse Limb Events/Peri-Operative Death (MALE-POD)



	30-Day	1-Year	2-Year	3-Year
RC2-3	99.6%	95.4%	90.7%	84.6%
RC4-5	98.5%	88.5%	81.4%	74.7%
RC6	92.9%	63.8%	57.8%	51.8%

	30-Day	1-Year	2-Year	3-Year
RC2-3	100.0%	98.5%	97.5%	96.2%
RC4-5	98.6%	95.3%	93.1%	92.1%
RC6	95.8%	81.7%	79.9%	79.9%

Amputation Free Survival: Freedom from major amputation on target limb or death.

MALE-POD: Major Adverse Limb Events include major reintervention of target vessel (surgical bypass), major amputation of the target limb, or peri-operative death.

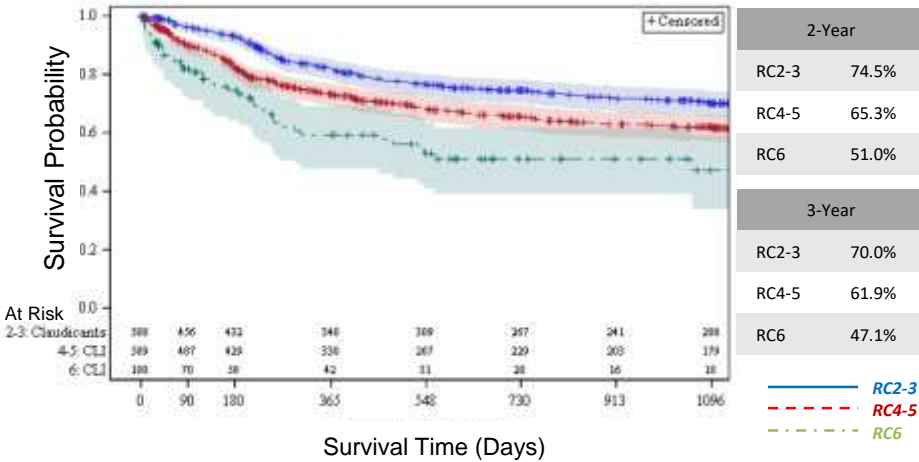
Kaplan-Meier method used to obtain estimate rates. Greenwood's method used to obtain the 95% confidence interval for the estimate.

28-May-2019 Data

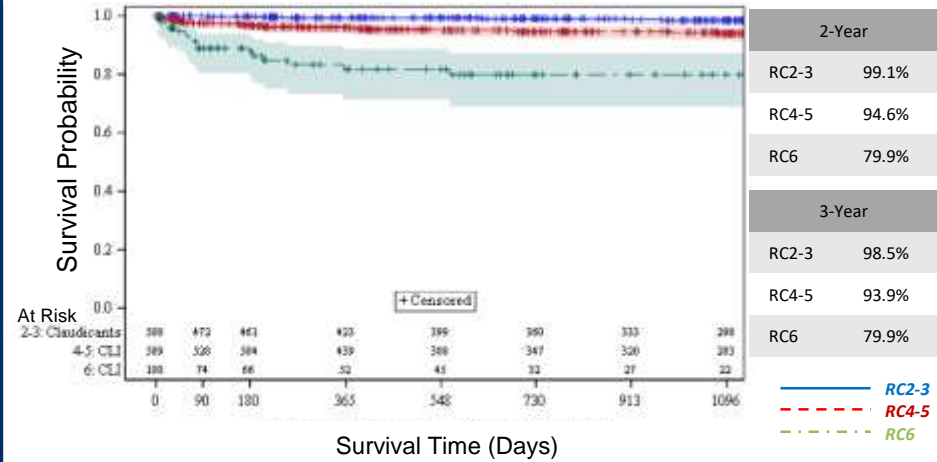
LIBERTY Outcomes through 3 Years

Despite complex demographics (e.g. history of LE PVI, history of MI, CTOs, lesion length) in this real-world study, there was high freedom from major amputation at 3 years in RC2-3 (98.5%), RC4-5 (93.9%), and RC6 (79.9%) and similar freedom from 3-Year TVR/TLR rates in RC4-5 (64.0%) and RC6 (61.6%).

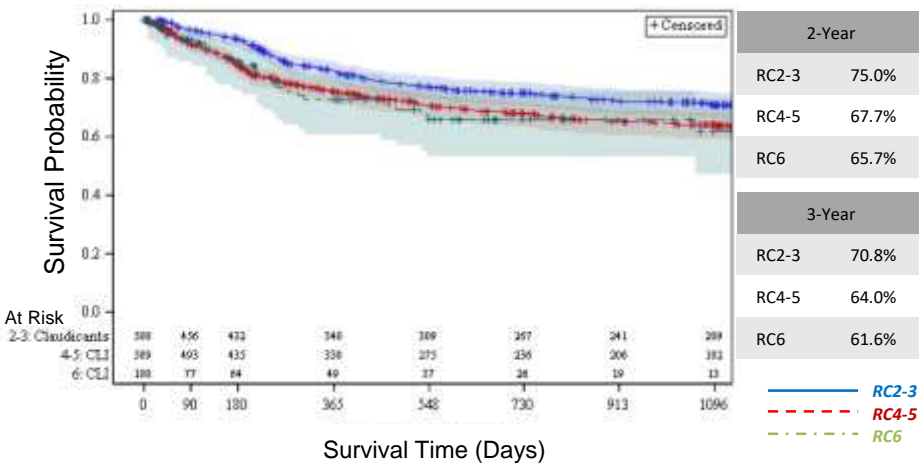
Freedom from Major Adverse Events (MAE)



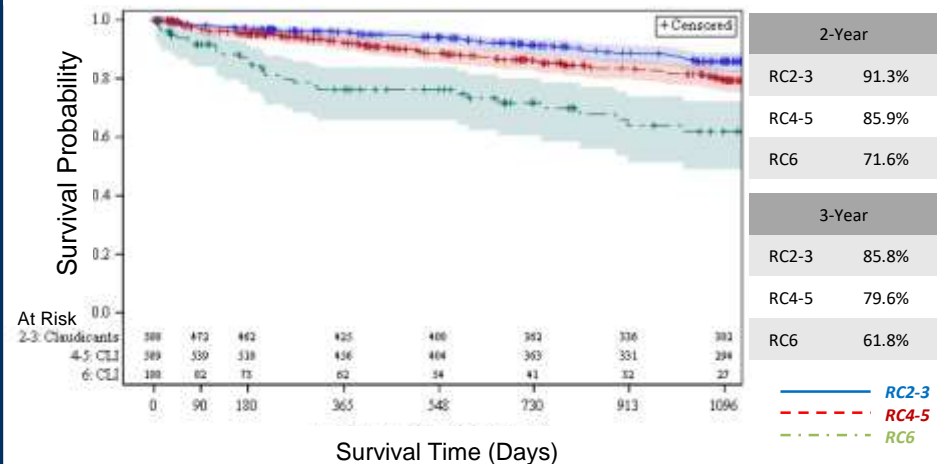
Freedom from Major Amputation on Target Limb



Freedom from TVR/TLR



Freedom from All-Cause Death*



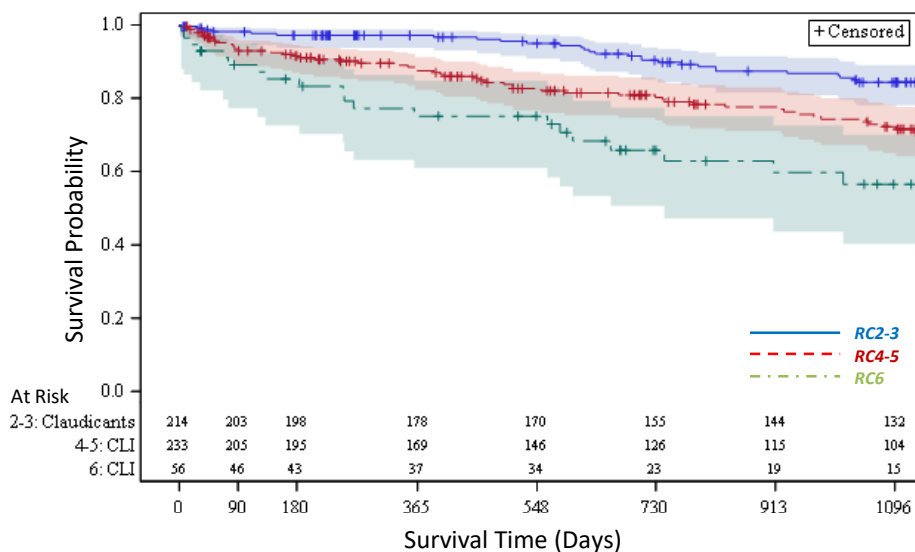
Kaplan-Meier method used to obtain estimate rates. Greenwood's method used to obtain the 95% confidence interval for the estimate.

*All-Cause Death rate shown here is at 3 years, but the Freedom from MAE only includes death within 30-days of the procedure

LIBERTY Orbital Atherectomy (OAS) Subanalysis: Outcomes through 3 Years

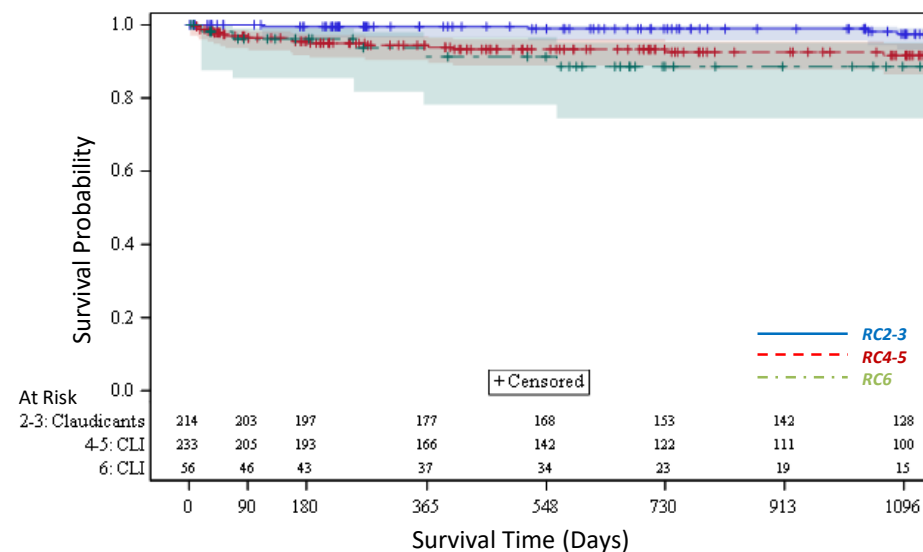
OAS was the most frequently used atherectomy device. Contemporary endpoint of MALE-POD indicates durable results from 1-year through 3-years (RC2-3: 99.5% to 97.4%, RC4-5: 94.4% to 91.6%, RC6: 91.3% to 88.6%).

Amputation Free Survival



	30-Day	1-Year	2-Year	3-Year
RC2-3	99.1%	97.1%	90.3%	84.3%
RC4-5	97.8%	87.5%	80.2%	72.2%
RC6	94.6%	75.1%	65.8%	56.5%

FF Major Adverse Limb Events/Peri-Operative Death (MALE-POD)



	30-Day	1-Year	2-Year	3-Year
RC2-3	100.0%	99.5%	98.9%	97.4%
RC4-5	98.3%	94.4%	92.5%	91.6%
RC6	98.1%	91.3%	88.6%	88.6%

Amputation Free Survival: Freedom from major amputation on target limb or death.

MALE-POD: Major Adverse Limb Events include major reintervention of target vessel (surgical bypass), major amputation of the target limb, or peri-operative death.

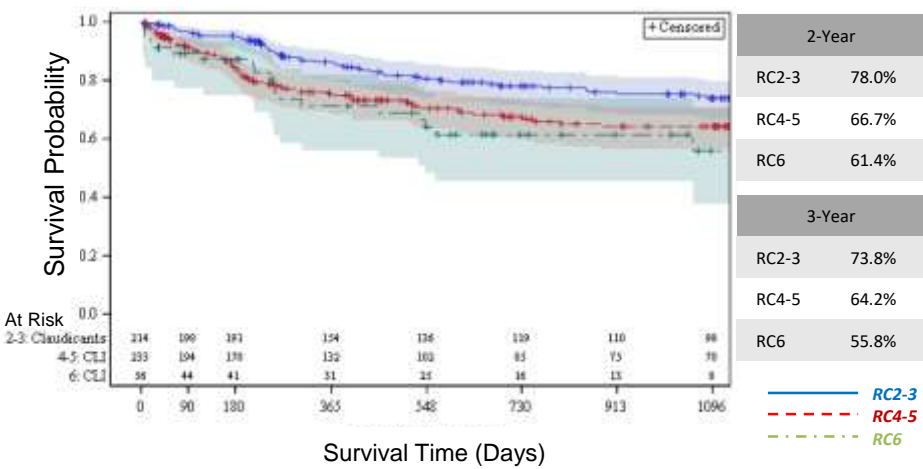
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28-May-2019 Data

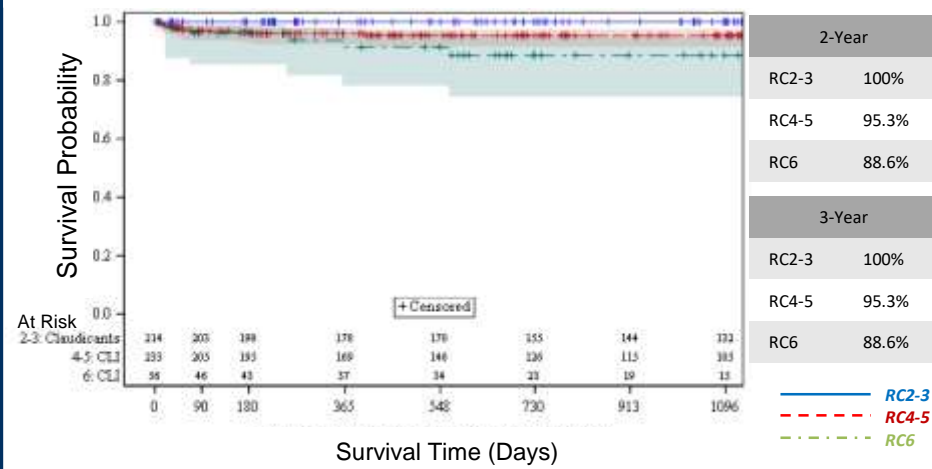
LIBERTY Orbital Atherectomy (OAS) Subanalysis: Outcomes through 3 Years

High freedom from major amputation in all Rutherford Classes (RC2-3, 100%; RC4-5, 95.3%; and RC6, 88.6%) with no additional unplanned major amputations reported after 2 years. Similar rates of freedom from TVR/TLR were seen across all Rutherford Classes.

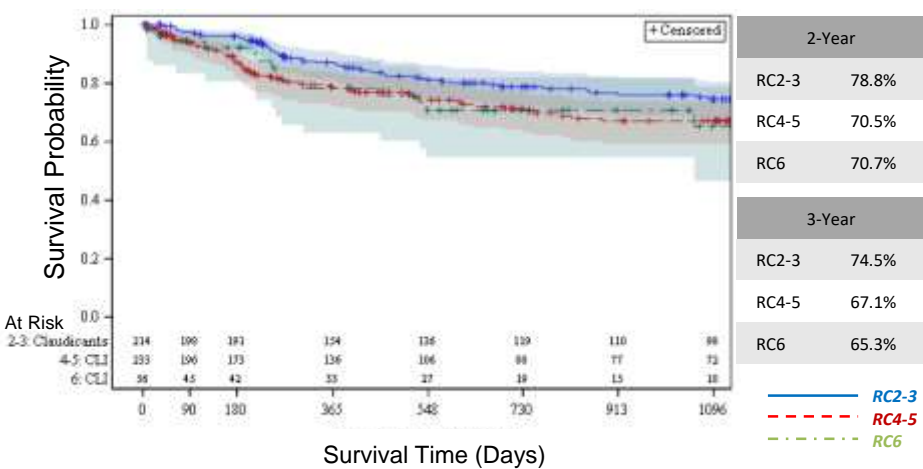
Freedom from Major Adverse Events (MAE)



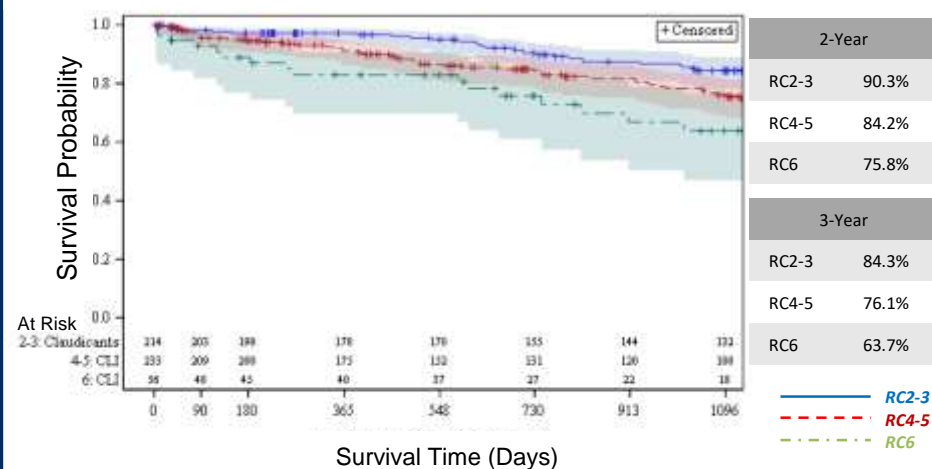
Freedom from Major Amputation on Target Limb



Freedom from TVR/TLR



Freedom from All-Cause Death*

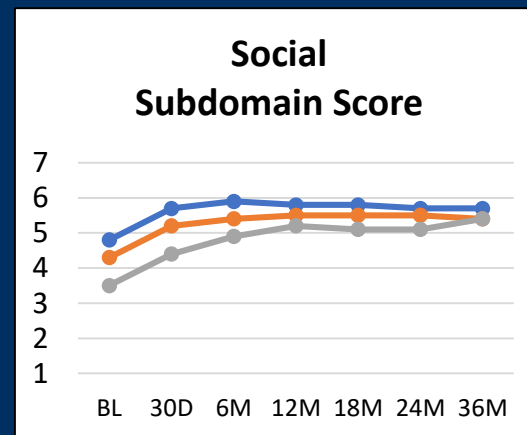
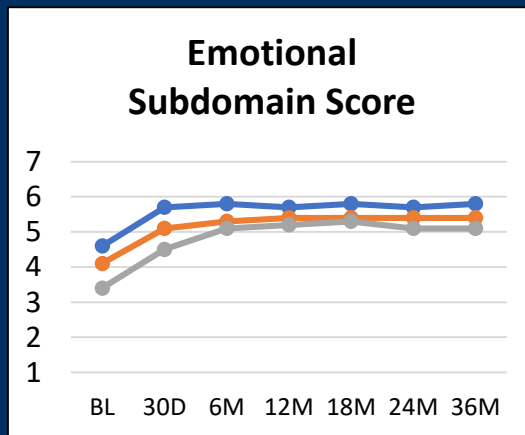
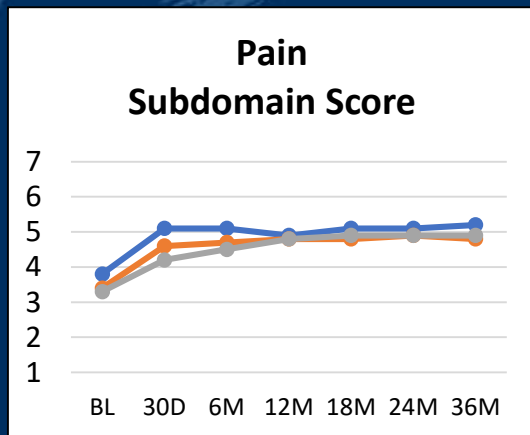
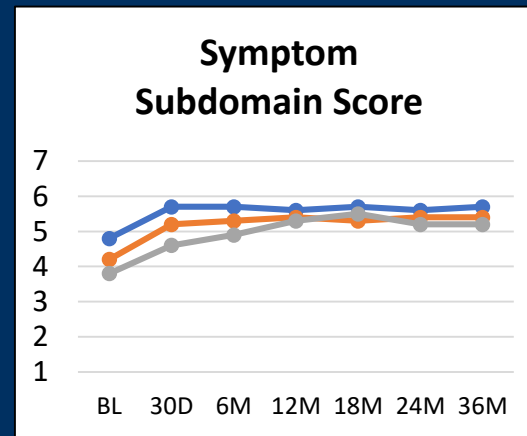
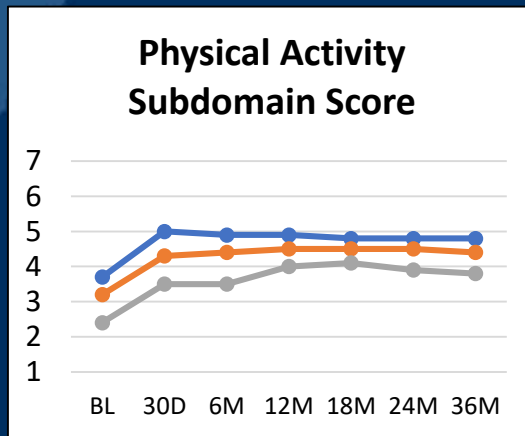
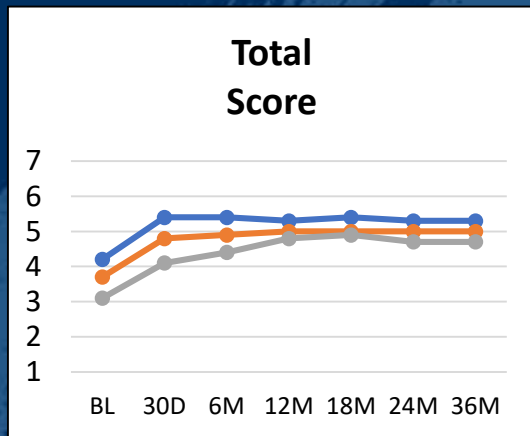


Kaplan-Meier method used to obtain estimate rates. Greenwood's method used to obtain the 95% confidence interval for the estimate.

*All-Cause Death rate shown here is at 3 years, but the Freedom from MAE only includes death within 30-days of the procedure

Quality of Life: VascuQol

Quality of life improved significantly by 30 days post-procedure and was maintained out to 3 years in all Rutherford Classes.



— Rutherford 2-3 — Rutherford 4-5 — Rutherford 6

Total Score	RC2-3	RC4-5	RC6
Change from baseline to 3 years	1.0 ± 1.3 N=274	1.1 ± 1.5 N=262	1.1 ± 1.4 N=20
P-value	<0.001	<0.001	0.003

Vascular Quality of Life Questionnaire; a PAD-specific health-related quality of life instrument
 Higher subdomain scores indicate better rating of health.
 Mean Total Score differences assessed via paired t-test.
 28-May-2019 Data

Predictor Analysis: 36-month Death & Major Amputation

Independent predictors of 36-month death & major amputation (events related to amputation free survival) are highlighted in red. In this elderly population, common comorbidities associated with death are accompanied by PAD-specific predictors such as wounds, Rutherford category, previous major amputation of the non-target limb, and bailout stent use.

Variable	Unadjusted Hazard Ratio [95% CI]	p-value	Adjusted Hazard Ratio [95% CI]	p-value
Number of wounds on target limb at baseline (1 unit increase)	1.61 [1.47, 1.78]	<0.001	1.36 [1.18, 1.56]	<0.001
Rutherford category	NA	<0.001	NA	<0.001
RC2-3 vs. RC4-5	0.55 [0.41, 0.74]	<0.001		
RC2-3 vs. RC6	0.21 [0.14, 0.31]	<0.001		
RC4-5 vs. RC6	0.37 [0.26, 0.54]	<0.001		
History of renal disease	2.11 [1.62, 2.73]	<0.001	2.14 [1.60, 2.85]	<0.001
Previous major amputation on non-target limb (above ankle)	3.29 [2.13, 5.06]	<0.001	2.39 [1.45, 3.94]	0.001
History of myocardial infarction	1.59 [1.20, 2.10]	0.001	1.62 [1.17, 2.22]	0.003
History of diabetes	1.53 [1.16, 2.03]	0.003		
Age (1 year increase)	1.02 [1.00, 1.03]	0.007	1.02 [1.00, 1.03]	0.009
Most severe PARC calcification grade	NA	0.011		
Distal treated region	NA	0.012		
Number of lower limb procedures in the last 3 years (1 procedure increase)	1.06 [1.01, 1.12]	0.020		
Target lesions treated (1 lesion increase)	1.26 [1.03, 1.54]	0.022		
Race (non-White vs. White)	1.42 [1.04, 1.94]	0.026		
Bailout stent used	1.70 [1.05, 2.76]	0.030	1.79 [1.04, 3.06]	0.034
History of coronary artery disease	1.35 [1.02, 1.78]	0.037		
History of stroke/TIA	1.43 [1.02, 1.99]	0.038	1.61 [1.11, 2.32]	0.012
Predominantly calcified plaque morphology	1.35 [1.01, 1.81]	0.041		
Total treated lesion length (cm, 1 unit increase)	1.01 [1.00, 1.02]	0.072		

Additional non-significant variables included in the unadjusted model (not listed in above table): gender, BMI, ethnicity, history of hypertension, history of hyperlipidemia, history of smoking, history of previous lower extremity peripheral vascular interventions for PAD, most severe TASC lesion type, chronic total occlusions (CTO), <50% residual stenosis on all lesions post-procedure, subject had significant angiographic complication

Predictors determined from Cox proportional hazard regression using stepwise selection. Contrast statement used to estimate Hazard Ratio between 2 levels of Rutherford Category. P-values based on Wald test; however a Type 3 test was used for categorical variables. Covariates found significant in a univariable model with an alpha of 0.1 were placed into a multivariable model; final multivariable model was created using stepwise selection with an entry criteria of 0.15 and a stay criteria of 0.05.

Predictor Analysis: 36-month MALE-POD

Independent predictors of 36-month MALE-POD are highlighted in red. Common predictors such as presence of CTO, history of renal disease, and Rutherford category are seen in this analysis.

Variable	Unadjusted Hazard Ratio [95% CI]	p-value	Adjusted Hazard Ratio [95% CI]	p-value
Number of wounds on target limb at baseline (1 unit increase)	1.66 [1.41, 1.97]	<0.001		
Rutherford category	NA	<0.001	NA	0.006
RC2-3 vs. RC4-5	0.42 [0.23, 0.77]	0.005		
RC2-3 vs. RC6	0.13 [0.06, 0.26]	<0.001		
RC4-5 vs. RC6	0.31 [0.17, 0.55]	<0.001		
<50% residual stenosis on all target lesions post-procedure	0.43 [0.24, 0.76]	0.004		
Previous major amputation on non-target limb (above ankle)	3.05 [1.40, 6.68]	0.005	2.57 [1.05, 6.27]	0.038
Total treated lesion length (cm, 1 unit increase)	1.02 [1.01, 1.04]	0.007		
Target lesions treated (1 lesion increase)	1.52 [1.12, 2.07]	0.007		
Age (1 year increase)	0.97 [0.95, 0.99]	0.008	0.97 [0.95, 1.00]	0.026
Chronic total occlusions (CTO) (at least 1 vs. 0)	1.91 [1.17, 3.12]	0.010	2.56 [1.43, 4.61]	0.002
History of renal disease	1.78 [1.11, 2.86]	0.017	2.22 [1.28, 3.85]	0.005
Number of lower limb procedures in the last 3 years (1 procedure increase)	1.09 [1.01, 1.18]	0.035		
Most severe TASC lesion type	NA	0.036		
Distal treated region	NA	0.046		

Additional non-significant variables included in the unadjusted model (not listed in above table): gender, BMI, race, ethnicity, history of diabetes, history of coronary artery disease, history of myocardial infarction, history of stroke/TIA, history of hypertension, history of hyperlipidemia, history of smoking, history of previous lower extremity peripheral vascular interventions for PAD, predominant calcified plaque morphology, most severe PARC calcification grade, bailout stent use, subject had significant angiographic complication

MALE-POD: Major Adverse Limb Events include major reintervention of the target vessel (surgical bypass), major amputation of the target limb, or peri-operative death.

Predictors determined from Cox proportional hazard regression using stepwise selection. Contrast statement used to estimate Hazard Ratio between 2 levels of Rutherford Category. P-values based on Wald test; however a Type 3 test was used for categorical variables. Covariates found significant in a univariable model with an alpha of 0.1 were placed into a multivariable model; final multivariable model was created using stepwise selection with an entry criteria of 0.15 and a stay criteria of 0.05.

28-May-2019 Data

Predictor Analysis: 36-month Major Adverse Events

Rutherford Category is a predictor of major amputation and all-cause death. Like the 24-month analysis, number of wounds on target limb at baseline is the only consistent predictor for all 36-month outcomes assessed, illustrating the importance of early detection and treatment, as well as proper wound care.

Variable	Major Adverse Events		Target Vessel Revascularization		Major Amputation		All-Cause Death	
	Adjusted Hazard Ratio (95% CI)	P-value	Adjusted Hazard Ratio (95% CI)	P-value	Adjusted Hazard Ratio (95% CI)	P-value	Adjusted Hazard Ratio (95% CI)	P-value
Rutherford category*					NA	<0.001	NA	0.042
Age (1 year increase)	0.99 [0.98, 1.00]	0.009					1.03 [1.01, 1.05]	<0.001
History of myocardial infarction					2.65 [1.35, 5.23]	0.005		
History of stroke/TIA							1.84 [1.25, 2.71]	0.002
History of renal disease					2.01 [1.06, 3.82]	0.032	2.08 [1.52, 2.85]	<0.001
History of previous lower extremity peripheral vascular interventions for PAD	1.54 [1.21, 1.97]	0.001	1.51 [1.17, 1.94]	0.001				
Number of target limb procedures in the last 3yrs (1 proc. increase)	1.08 [1.03, 1.14]	0.002	1.08 [1.03, 1.14]	0.003	1.12 [1.02, 1.23]	0.023		
Previous major amputation on non-target limb (above ankle)							1.88 [1.04, 3.40]	0.038
Number of wounds on target limb at baseline (1 unit increase)	1.27 [1.14, 1.41]	<0.001	1.21 [1.07, 1.36]	0.002	1.43 [1.10, 1.85]	0.007	1.40 [1.20, 1.63]	<0.001
Chronic total occlusions (At least 1 vs 0)	1.86 [1.43, 2.42]	<0.001	2.29 [1.79, 2.92]	<0.001				
Total treated lesion length (cm, 1 unit increase)	1.01 [1.00, 1.02]	0.040						

* RC4-5 vs. 6, and RC2-3 vs. 6 are significant (p<0.05) when using contrast to estimate Hazard ratio between 2 levels of Rutherford category.

Additional variables included in the model (not listed in above table): gender, BMI, race, ethnicity, history of hypertension, history of hyperlipidemia, history of smoking, history of diabetes, history of coronary artery disease, number of core lab reported lesions, predominant calcified plaque morphology, most severe PARC calcification grade, most severe TASC lesion type, bailout stent use, distal treated region, <50% residual stenosis on all lesions post-procedure, subject had significant angiographic complication.

MAE: Death to 30 days, Major amputation on target limb, TVR

Predictors determined from Cox proportional hazard regression using stepwise selection. P-values based on Wald test; however a Type 3 test was used for categorical variables. Covariates found significant in a univariable model with an alpha of 0.1 were placed into a multivariable model; final multivariable model was created using stepwise selection with an entry criteria of 0.15 and a stay criteria of 0.05.
28-May-2019 Data

Conclusions

- LIBERTY represents the largest, contemporary **real-world experience with various endovascular strategies across the full range of RC patients** including many PAD patients for whom longitudinal data are sparse, particularly RC6 patients.
- **High freedom from major amputation at 3 years** in RC2-3 (98.5%), RC4-5 (93.9%), and RC6 (79.9%) **and in an OAS sub-analysis** in RC2-3 (100%), RC4-5 (95.3%), and RC6 (88.6%) with **no additional amputations reported after the 2 year visit**.
- **Freedom from MALE-POD rates indicate durable results from 1-year through 3-years** (RC2-3: 98.5% to 96.2%, RC4-5: 95.3% to 92.1%, RC6: 81.7% to 79.9%). RC6 subjects that survive past the first year after treatment see similar benefits in amputation free survival as RC2-3 and RC4-5 subjects.
- **Quality of life improved significantly by 30 days post-procedure** and was **maintained out to 3 years** in all Rutherford Classes.
- **The adjusted 3-year predictor model of amputation & death** (events related to amputation free survival) identifies PAD-specific predictors such as **wounds, Rutherford category, previous major amputation of the non-target limb, and bailout stent use**.
- The unadjusted 3-year predictor model of MALE-POD indicates many traditional predictors are significant, yet when accounting for potential covariates, those associated with **disease progression were most strongly correlated with 3-year MALE-POD**.
- The results of this novel all-comers PAD study continue to suggest that **PVI is a reasonable treatment option for RC2-3 and RC4-5**.
- **Primary amputation is not necessary in RC6**—PVI can be successful in this patient population, **as evidenced at 3 years by high freedom from major amputation (79.9%) and improvement in QoL**.

Comparison of Procedural and Long-Term Clinical Outcomes in Critical Limb Ischemia Patients Following Endovascular Treatment in the LIBERTY 360^o Study

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