Vascular Quality Registry Papers of Note

SEVSG Meeting

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Emily Spangler

UAB MEDICINE

Knowledge that will change your world

Comparison of Direct and Less Invasive Techniques for the Treatment of Severe Aorto-Iliac Occlusive Disease

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Aim: Compare Outcomes of Aorto-femoral Bypasses with Femoral Bypass and Hybrid Stenting Procedures

- Review of procedures from 2006-2013 in the VQI
  - 1872 procedures for aortoiliac occlusive disease
  - Propensity score matching left a cohort with 1085 patients
    - 1094 Aortobifemoral bypass (ABF) or Aortounifemoral bypass (AUF)
    - 711 Cross femoral bypass (CFB) and hybrid procedures of femoral endarterectomy with patch angioplasty and iliac stenting (EPS)

- Primary outcome: 1 year survival
- Secondary outcomes:
  - 1 year primary patency
  - major amputation

- Unit of analysis of the patient – only earliest procedure included in sample

- Concomitant procedures excluded:
  - ABF, AUF, and CFB cases were excluded if concomitant endovascular intervention or infrainguinal bypass
  - EPS surgeries excluded if vessels other than iliac and femorals treated

Propensity Score Matching

- Goal: compare like patients to like patients
- Stepwise logistic regression of baseline patient characteristic variables that were statistically significant across comparison groups
- One to many matching
- Tests of if cohorts appropriately matched, including reviewing if balanced by indication of claudication vs CLI.

Table 1 – Baseline Characteristics

Table I. Baseline characteristics (stratified by procedure) and comparison of matched and unmatched cohorts

Variable	Unmatched cohort: ABF/AUF (N = 1,133); N (%)	Unmatched cohort: CFB/EPS (N = 739); N (%)	P value[a]	Bias reduction in matched cohort
Median age, years	60 (53–66)[b]	67 (60–75)[b]	**<0.001**	93.9%
Female	466 (41.13)	291 (39.38)	0.47	
Nonwhite race	95 (8.38)	89 (12.04)	**0.013**	54.9%
Diabetes	263 (23.21)	216 (29.23)	**0.005**	84.7%
Overweight/obese	576 (50.84)	395 (53.45)	0.34	
Coronary artery disease	241 (21.27)	250 (33.83)	**<0.001**	94.9%
Prior CABG or PCI	226 (19.95)	223 (31.53)	**<0.001**	78.8%
Congestive heart failure	65 (5.74)	97 (13.13)	**<0.001**	74.0%
COPD	344 (30.36)	266 (35.99)	**0.014**	96.7%
Smoking	1,102 (97.26)	689 (93.23)	**<0.001**	93.6%
Hypertension	871 (76.88)	641 (86.74)	**<0.001**	61.2%
Dialysis	6 (0.53)	22 (2.98)	**<0.001**	100%
Positive stress test	136 (12.00)	75 (10.15)	0.13	
Statin	791 (69.81)	517 (69.96)	0.37	
Aspirin	791 (69.81)	516 (69.82)	0.51	
Ambulatory	1,105 (97.53)	706 (95.53)	**0.003**	
Indication				84.6%
Claudication	632 (55.78)	312 (44.22)	**<0.001**	
Critical limb ischemia	477 (42.10)	409 (55.35)	**<0.001**	
Prior bypass	138 (12.18)	146 (19.76)	**<0.001**	98.8%
Prior percutaneous peripheral intervention	255 (2.51)	228 (30.85)	**<0.001**	90.1%
VSGNE CRI			**<0.001**	75%
0–4	749 (66.11)	299 (40.46)		
5 to 7	312 (27.54)	306 (41.41)		
≥8	54 (4.77)	109 (14.75)		
Overall sample mean percent bias				
Unmatched cohort				23.1%
Matched cohort				3.1%

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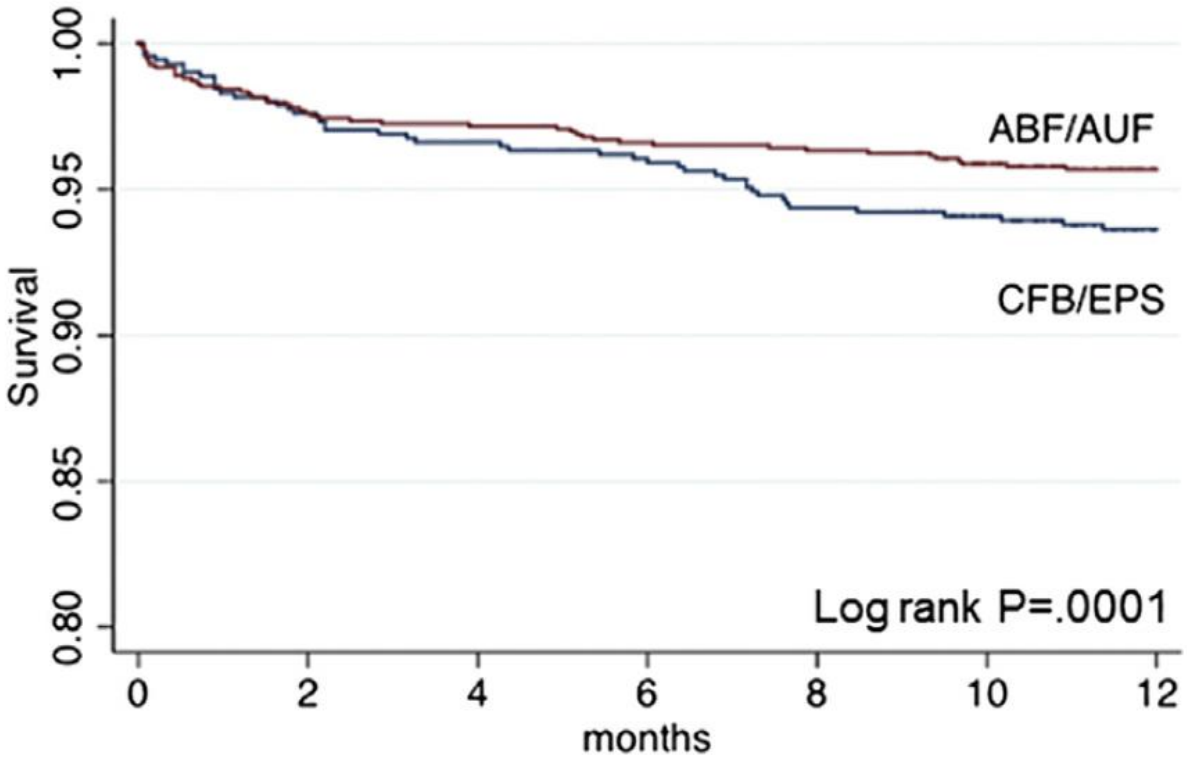
Figure 1– Survival by Procedure

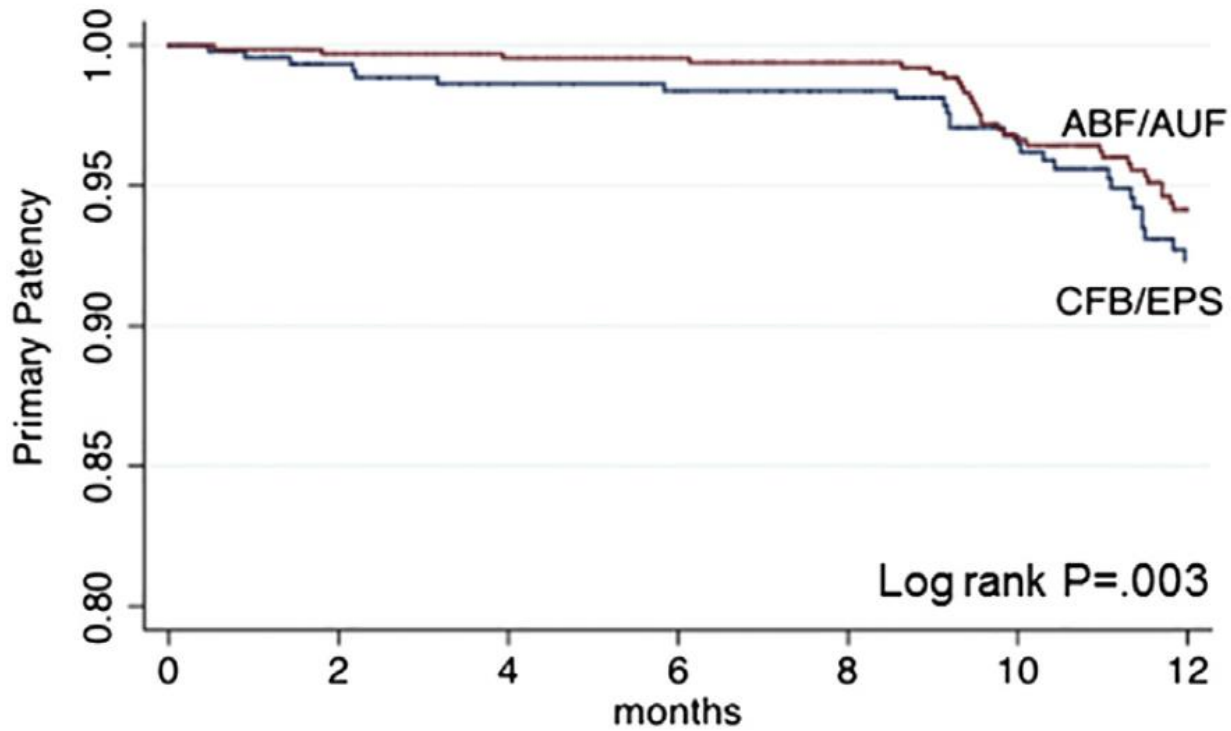


Number at risk

CFB/EPS	710	693	686	682	670	647	590
ABF/AUF	1092	1066	1061	1055	1052	1025	960

Fig. 1. Kaplan-Meier analysis for survival, stratified by procedure.

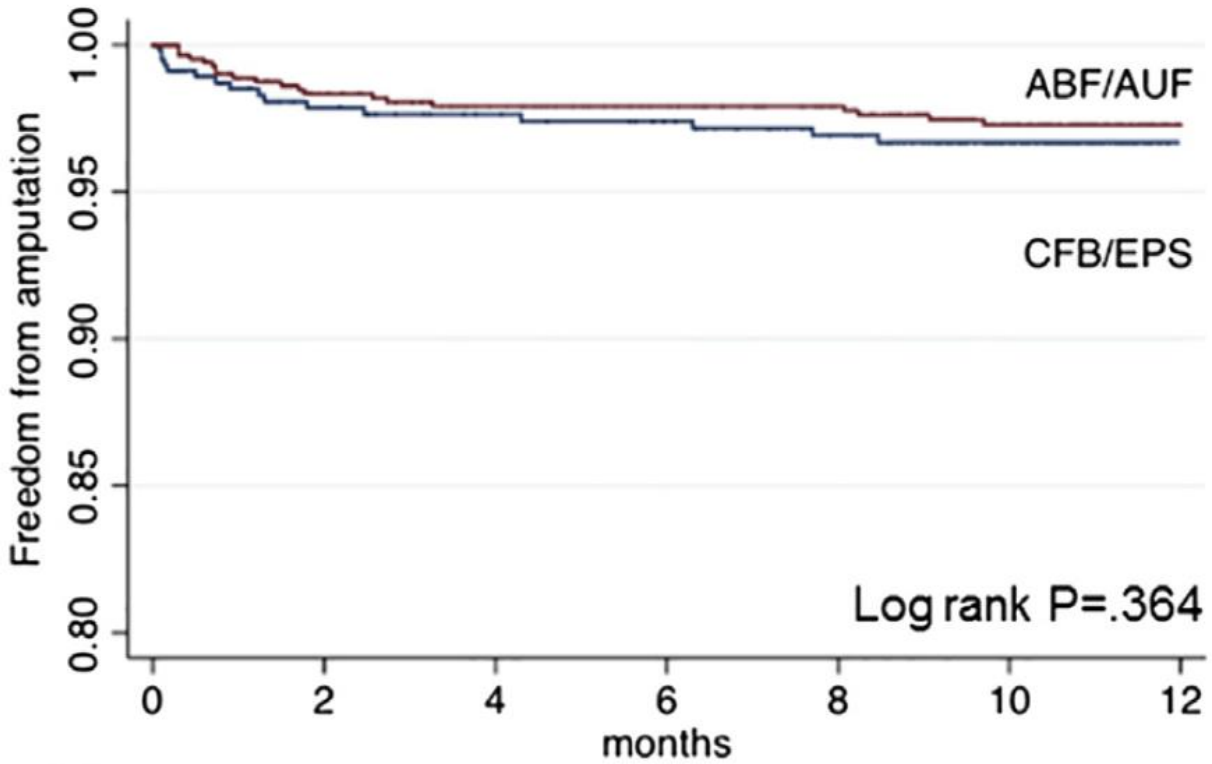
Figure 2 – Primary Patency by Procedure



Number at risk							
CFB/EPS	467	424	410	402	386	334	228
ABF/AUF	715	651	633	615	586	503	374

Fig. 2. Kaplan-Meier analysis for primary patency, stratified by procedure.

Figure 3– Freedom from Amputation by Procedure



Number at risk

CFB/EPS	639	441	428	420	400	350	244
ABF/AUF	1090	711	688	671	645	551	407

Fig. 3. Kaplan-Meier analysis for major amputation, stratified by procedure.

CLI Sub-analyses

- Procedure type not an independent predictor of mortality
  - Age>65, increased VSGNE CRI score correlated with mortality, preop ambulatory status protective
- ABF/AUF a significant predictor of primary patency after adjusting for prior history of PVI and race
- Procedure type not an independent predictor of amputation in CLI
  - Prior amputation, CHF, prior lower extremity bypass predictive

Limitations

- Long-term followup limitations
- Missing data
- Propensity matching can only adjust for observable differences

Conclusions

- Direct open approach to aortoiliac occlusive disease demonstrated better 1 year primary patency than less invasive strategies in propensity matched comparisons
- However, treatment approach was not a predictor of 1-year survival or limb salvage, suggesting that patient factors and procedure indication have a greater impact on outcome.

The Role of Femoral Endarterectomy

From the Society for Vascular Surgery

A national Vascular Quality Initiative database comparison of hybrid and open repair for aortoiliac-femoral occlusive disease

Marco Zavatta, MD,[a] *and* Matthew W. Mell, MD, MS,[b] *Padova, Italy; and Stanford, Calif*

Aim: Compare Open Aortoiliac Revasc with CFE to Endovascular Revasc with CFE

- Review of procedures from 2009-2015 in the VQI
  - 2351 procedures for aortoiliac occlusive disease (open or endo) with common femoral endarterectomy (CFE)
    - 879 open aortoiliac revascs with CFE
    - 1472 endo aortoiliac revascs with CFE
- Patients with aneurysms, undergoing extra-anatomic revascularization, concomitant infrainguinal procedures or procedures distal to the CFA, acute ischemia, and at centers with <50% LTF reporting excluded

Outcomes

- Early outcomes:
  - 30-day mortality
  - Length of Stay (LOS)
- Late (1-year) outcomes:
  - 1-year mortality
  - Improvement in ABI
  - Improvement in ambulatory status
  - Primary patency
  - Need for re-intervention
  - Major ipsilateral amputations

Demographics

- Endo-CFE patients generally a little more ill

Variable	OR-CFE (n = 879)	ER-CFE (n = 1472)	*P* value
Demographics			
Age, years	63 ± 9	68 ± 9	<.001
Male gender	60.2	60.1	.98
Ambulatory status			
Ambulatory	83.7	77.5	.004
Ambulatory with assistance	13.0	18.0	
Wheelchair	3.0	4.1	
Bedridden	0.3	0.4	
Risk factors			
Smoking hystory			
None	3	4	<.001
Previous smoker	33	49	
Current smoker	64	46	
Diabetes	29	37	<.001
CAD	25	33	<.001
Prior CABG	18	23	.02
Prior PCI	18	21	.26
CHF	9	13	.003
COPD	32	35	.10
CKD	2.1	3.8	.02
Dialysis	0.7	3.5	<.001
ASA class	3.1 ± 0.5	3.1 ± 0.5	.35

Demographics

- Anatomic and disease severity a mixture between the groups

Variable	OR-CFE (n = 879)	ER-CFE (n = 1472)	*P* value
Prior inflow bypass	8.1	3.0	<.001
Prior inflow endovascular	19	18	.60
Prior outflow bypass	9.5	7.5	.10
Prior outflow endovascular	7.2	9.0	.13
Prior major amputation	0.9	1.1	.68
Indication			
Claudication	50	47	<.001
Rest pain	33	25	
Tissue loss	16	24	
Mean preoperative ABI	0.6 ± 0.3	0.6 ± 0.4	.24

Demographics

Table II. Operative characteristics

Variable	OR-CFE, % (n = 879)	ER-CFE, % (n = 1472)	*P* value
Bilateral procedure	83	30	<.001
No. of arteries treated or bypassed[a]			
1	3	1	<.001
2	12	44	
3	3	31	
4	2	14	
5	0	5	
6 or more	80	4	
Type of endovascular procedure			
Angioplasty only	—	4	—
Self-expandable stent	—	37	
Balloon-expandable stent	—	42	
Stent graft	—	17	
Type of open procedure, No. (%)			
Aortobifemoral	708 (81)	—	
Aortoiliac-femoral	9 (1)	—	
Aorto-unilateral femoral	11 (1)	—	—
Unilateral iliofemoral	136 (15)	—	
Bilateral iliofemoral	15 (2)	—	

Outcomes

Table III. Outcomes

Variable	OR-CFE	ER-CFE	*P* value
Early outcomes			
30-day mortality	30 (3.4)	26 (1.8)	.01
LOS, days, median (IQR)	7 (5-11)	3 (2-6)	<.001
Discharge to home	682 (78)	1185 (81)	.09
1-Year outcomes			
1-Year mortality	55 (6.3)	126 (8.6)	.04
1-Year primary patency	236 (81)	334 (80)	.76
Secondary interventions	47 (9.7)	64 (7.5)	.16
Major amputations	15 (2.9)	23 (2.8)	.84
Ambulatory without assistance	377 (77)	596 (70)	.002
Improvement in ABI, mm Hg	0.39 ± 0.37	0.26 ± 0.23	<.001
Improved ambulatory status	348 (82)	465 (65)	<.001

ABI, Ankle-brachial index; *ER-CFE*, endovascular inflow revascularization with common femoral endarterectomy; *IQR*, interquartile range; *LOS*, length of stay; *OR-CFE*, open inflow revascularization with common femoral endarterectomy.
Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation unless otherwise indicated.

Improvement in Ambulation

Table IV, A. Analysis of improvements in ambulatory status at follow-up visit compared with preoperative status

Preoperative ambulatory status	Follow-up ambulatory status	OR-CFE, No. (%)	ER-CFE, No. (%)	P value
Ambulatory	Ambulatory, ABI improved ≥0.15	304 (84)	383 (68)	<.001
Ambulatory with assistance	Ambulatory	35 (71)	68 (63)	.62
Wheelchair	Ambulatory	7 (100)	8 (100)	1.0
Wheelchair	Ambulatory with assistance	2 (100)	4 (100)	1.0
Bedridden	Ambulatory	—	2 (100)	—
Bedridden	Ambulatory with assistance	—	—	—
Bedridden	Wheelchair	—	2 (100)	—

ABI, Ankle-brachial index; *ER-CFE*, endovascular inflow revascularization with common femoral endarterectomy; *OR-CFE*, open inflow revascularization with common femoral endarterectomy.

Table IV, B. Analysis of improvement in ambulatory status at follow-up visit stratified by indication for revascularization

	Improved, No. (%)		Unchanged, No. (%)		Worsened, No. (%)		
Indication	OR	ER	OR	ER	OR	ER	*P* value
Claudication	153 (84)	231 (68)	12 (6.6)	57 (17)	17 (9.3)	51 (15)	<.001
Rest pain	96 (80)	121 (74)	7 (5.8)	19 (12)	17 (14)	23 (14)	.24
Tissue loss	40 (75)	89 (65)	5 (9.4)	23 (17)	8 (15)	24 (18)	.34

ER, Endovascular revascularization; *OR*, open revascularization.

Factors Associated with Ambulation

Multivariable analysis of factors associated with improved ambulatory status at 1-year follow-up			
	Improved ambulatory status		
Variable	Odds ratio	95% CI	*P* value
Repair type			
ER-CFE		Referent	
OR-CFE	1.83	1.31-2.55	<.001
Age	0.99	0.98-1.00	.30
Male gender	1.11	0.83-1.50	.48
Diabetes	0.99	0.73-1.36	.99
Coronary artery disease	0.97	0.70-1.37	.88
Tobacco use	0.90	0.41-1.99	.80
COPD	0.89	0.65-1.22	.48
Renal failure	0.80	0.25-2.55	.71
Preoperative ambulatory status			
Ambulatory		Referent	
Ambulatory with assistance	0.73	0.48-1.10	.13
Wheelchair/bedridden	0.66	0.29-1.48	.31
Indication			
Claudication		Referent	
Rest pain	1.23	0.87-1.76	.24
Tissue loss	0.94	0.64-1.41	.78

CI, Confidence interval; *COPD*, chronic obstructive pulmonary disease.

Center Volume

- High volume centers had better LOS, discharge to home, and 1- year patency
- Similar early mortality, improved ambulatory status and improved ABI between center volumes

Table VI. Analysis of early and 1-year outcomes stratified by center volume

	OR-CFE				ER-CFE			
Early outcomes	Low (n = 184)	Mid (n = 534)	High (n = 161)	*P* value	Low (n = 305)	Mid (n = 901)	High (n = 266)	*P* value
Thirty-day mortality	1.6	4.3	2.5	.18	2.6	1.6	1.5	.44
LOS, days, median (IQR)	6 (5-11)	7 (5-10)	8 (5-12)	.01	3 (1-5)	4 (2-7)	3 (2-5)	.001
Discharge home	85	77	70	.05	86	79	81	.02
Late outcomes	(n = 102)	(n = 311)	(n = 74)		(n = 180)	(n = 532)	(n = 144)	
One-year mortality	5.9	5.2	1.4	.32	15.0	8.8	11.1	.06
One-year patency	77	77	96	.005	78	77	91	.03
Improved ABI	0.32 ± 0.57	0.39 ± 0.33	0.46 ± 0.41	.17	0.24 ± 0.38	0.27 ± 0.39	0.26 ± 0.28	.99
Improvement in ambulatory status	76	77	79	.89	69	70	69	.97
Reinterventions	9.8	8.7	13.5	.45	6.7	7.7	7.7	.90
Amputations	2.0	2.3	6.8	.09	2.8	2.6	2.7	.99

ABI, Ankle-brachial index; *IQR*, interquartile range; *LOS*, length of stay.
Categorical variables are presented as %. Continuous variables are presented as mean ± standard deviation unless otherwise indicated.

Limitations

- TASC classification not reported for those receiving open repair, limiting disease severity comparison
- Unmeasured treatment bias
- Less able to granularly quantify ambulatory status (no claudication distance capture) or quality of life data

Conclusions

- Endo-CFE improved short term outcomes, equivalent freedom from major amputation
- Open-CFE with better long-term improvement in ABI and ambulatory status
- “Open repair should therefore be considered for patients with aortoiliac-femoral occlusive disease and reasonable surgical risk”

Discussion

- Practice patterns or perceptions similar or different in regards to open aorotoiliac interventions vs hybrid approach in the Southeast?

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Knowledge that will change your world

- VSGNE CRI score was used to stratify patients as high and low risk for postop cardiac events.
  - High risk=VSGNE CRI ≥8 ↔14.3% risk of ACE