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## Effect of Optimal Medical Therapy: BEST-CLI Trial

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**DISCLOSURES**

NO FINANCIAL DISCLOSURES

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ORIGINAL ARTICLE

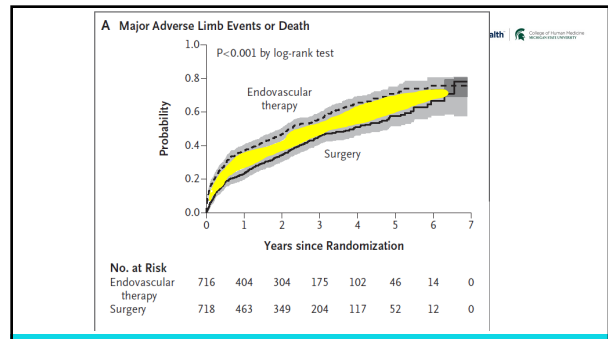
### Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia

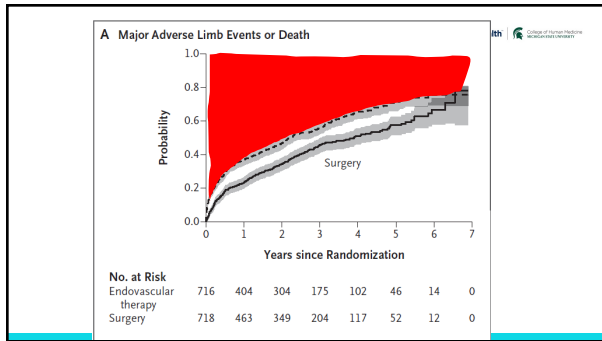
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**Background and Objectives**

- The use of guideline-directed optimal medical therapy (OMT) is considered a cornerstone of treatment in patients with chronic limb threatening ischemia (CLTI).
- The Best Endovascular vs Best Surgical Therapy in Patients with CLTI (BEST-CLI) compared revascularization strategies in patients with CLTI.
- In this pre-specified analysis, we studied the effect of OMT intensity on the outcomes of patients with CLTI.





### Methods

- A multispecialty committee defined OMT criteria during the trial design.
- OMT included metrics that each received 1 point: hypertension management, lipid-lowering and anti-platelet medication use, and tobacco cessation.
- Patients were stratified by OMT scores from 0 to 4.
- OMT scores were assessed for the duration of the trial.
- The association of Major Adverse Limb Events (MALE), Major Adverse Cardiovascular Events (MACE), and death were examined.

### OMT scoring

OMT Criteria	Points
Controlled blood pressure	1
- <150/90 mmHg in patients aged >=60	
- <140/90 in those aged <60 years	
Not currently smoking	1
On at least 1 lipid lowering medication	1
On at least 1 antiplatelet agent	1
Controlled diabetes mellitus as evidenced by HbA1c < 7	*

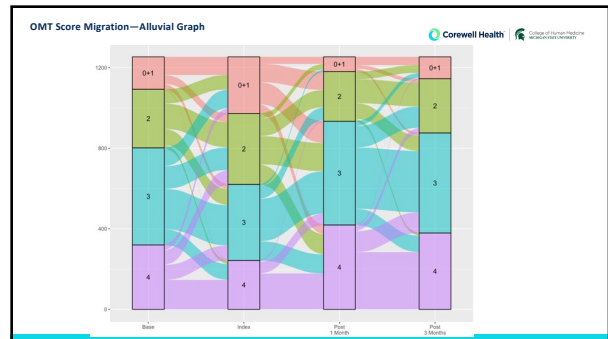
\*not used in further analyses due to missing values

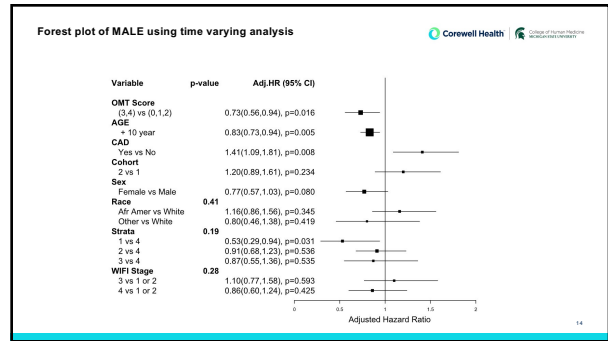
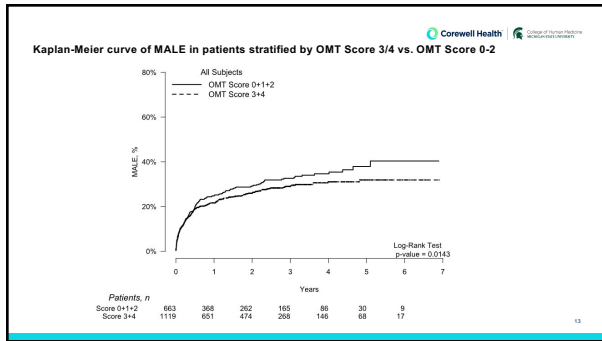
### Results—Baseline Characteristics Stratified by OMT Score

Characteristics (Overall N = 1782)	Score 0 & 1 (N = 227)	Score 2 (N = 436)	Score 3 (N = 673)	Score 4 (N = 446)	P-Value
<b>Demographic</b>					
Age (Yrs)					
Mean ± SD	64.1 (8.8) (227)	66.0 (10.0) (436)	67.4 (9.5) (673)	69.6 (9.1) (446)	<.001
Median (IQR)	63.4 (56.5-70.7)	65.5 (58.6-72.8)	67.1 (60.8-74.0)	69.8 (63.9-75.2)	
I (Min, Max)	(27.9-88.9)	(28.7-91.1)	(42.6-91.8)	(35.2-94.1)	
Gender					0.280
Male	68.3% (155/227)	69.5% (193/436)	72.1% (485/673)	74.4% (232/446)	
Female	31.7% (72/227)	30.5% (133/436)	27.9% (188/673)	25.6% (114/446)	
<b>Medical History</b>					
BMI (kg/m²)					<.001
Mean ± SD	28.4 (5.7) (222)	27.8 (6.0) (425)	28.0 (6.0) (658)	28.8 (5.9) (435)	
Median (IQR)	25.6 (22.1-29.4)	26.9 (23.4-31.1)	27.3 (23.8-31.7)	28.0 (24.4-30.0)	
I (Min, Max)	(16.4-48.9)	(14.4-65.0)	(15.9-81.0)	(14.3-92.9)	
Hypertension	75.3% (171/227)	81.2% (367/436)	89.7% (604/673)	92.8% (414/446)	<.001
Lipid disorders	38.8% (88/227)	61.7% (269/436)	81.0% (545/673)	87.7% (391/446)	<.001
Diabetes	61.5% (139/227)	68.6% (299/436)	71.6% (482/673)	76.2% (340/446)	<.001
Current smoking	74.4% (169/227)	54.8% (239/436)	33.7% (227/673)	0.0% (0/446)	<.001
Secondary artery disease	21.1% (48/227)	46.6% (204/436)	67.3% (453/673)	66.1% (295/446)	<.001
Coronary heart failure	3.2% (7/227)	3.2% (14/436)	6.2% (42/673)	9.2% (41/446)	<.001
Stroke	10.6% (24/227)	10.3% (45/436)	15.3% (103/673)	15.5% (69/446)	0.060
Chronic obstructive pulmonary disease	14.5% (33/227)	15.6% (68/436)	17.5% (118/673)	11.2% (50/446)	0.037
End-stage kidney disease	6.6% (15/227)	10.6% (47/436)	11.3% (76/673)	12.4% (55/446)	0.144

### Multivariable Cox regression Models

Covariate (Effect at baseline)	MALE HR (95% CI), p-value	Major Reinterventions	MACE	Survival
Age (additional 10 years)	<b>0.89 (0.79, 0.99) p&lt;0.002</b>	0.91 (0.80, 1.05) p=0.192	<b>1.23 (1.12, 1.35) p&lt;0.001</b>	1.07 (0.99, 1.16) p=0.098
CHF	1.43 (0.97, 2.12) p=0.072	1.36 (0.83, 2.21) p=0.219	<b>1.71 (1.27, 2.31) p&lt;0.001</b>	<b>1.60 (1.22, 2.11) p&lt;0.001</b>
ESRD	<b>1.44 (1.05, 1.98) p&lt;0.023</b>	0.91 (0.58, 1.43) p=0.686	<b>3.21 (2.55, 4.04) p&lt;0.001</b>	<b>1.98 (1.57, 2.44) p&lt;0.001</b>
Female Sex	0.83 (0.65, 1.06) p=0.133	0.87 (0.65, 1.16) p=0.337	0.96 (0.79, 1.17) p=0.708	0.86 (0.73, 1.03) p=0.100
Infrapopliteal Disease	1.11 (0.88, 1.40) p=0.365	0.86 (0.68, 1.16) p=0.369	1.12 (0.93, 1.36) p=0.230	1.14 (0.96, 1.35) p=0.127
Prior Infrapopliteal Revascularization	1.07 (0.70, 1.63) p=0.765	1.13 (0.68, 1.87) p=0.648	1.19 (0.85, 1.66) p=0.321	1.19 (0.89, 1.59) p=0.241
Randomized to Open Surgery	<b>0.52 (0.42, 0.65) p&lt;0.001</b>	<b>0.41 (0.31, 0.54) p&lt;0.001</b>	0.91 (0.77, 1.08) p=0.298	<b>0.70 (0.60, 0.82) p&lt;0.001</b>
OMT Score (34 vs 0/1)	<b>0.74 (0.57, 0.96) p&lt;0.023</b>	<b>0.73 (0.54, 1.00) p=0.051</b>	0.82 (0.73, 1.16) p=0.471	0.82 (0.67, 1.01) p=0.063





**Conclusions**

- In a clinical trial setting of patients with chronic limb threatening ischemia, medical therapy use improved modestly early in a trial environment but was highly variable through the trial follow up.
- Higher OMT scores were associated with reduced risk of MALE and major reintervention in patients undergoing revascularization for CLTI.
- More intensive medical therapy was not associated with lower risk of MACE, including death.

