Home Treatment For CLI: Sequential Compression Pneumatic Device Recruiting “Capillary Bed”

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Disclosure
- Founder of Tulip Endovascular Innovation, Ireland
- Founder of Embricon Endovascular, Ireland
- Founder of Green Medical, Michigan, USA

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- SFI, NJIC, El, NSAI, HRB
- European Commision, Erasmus+

Primary Amputation

CRITICH Had 53.4% EVR, 34% Surgery
95% Conservative, 2.5% Primary Amputation
CRITICH Revealed Endo Vascular First
Approach Policy is The First Line & Gold Standard
50% of Patients Who Had
Were Unsuitable For Revascularization
20% Were Not Offered

Aggressive Policy of Revascularization

Our Graying Population

CLI Prognosis is Dire & Carries a High Risk of Primary Amputation
With Subsequent Morbidity & Mortality in Unmanaged Patients due To Prohibitive Cardiovascular Risk Factors
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Beyond Salvaged

- After any “successful” revascularisation, it can wind-up with stenosis, occlusion or total failure, without a recognisable persuading component.
- Despite these perceived “failures”, the limb can be salvaged even in the absence of direct in-line flow to the outflow vessels.
- This fosters the wariness that there are further processes at play with neovascularisation & ischaemic skeletal muscle paracrine effect.

Vascular Surgery

- There are upwards of 10 billion capillaries in one adult.
- No one cell in body is greater than two cells away from any given capillary.
- Calf capillary bed density always correlates with functional performance measures.
- Sarcopenia develop capillary bed failure & contraindicate any form of intervention.

Capillary Bed Network

- We witnessed CLI patients with haemodynamic clinical improvement from Fontaine grade V/VI to grade III, after 90 days program on SCBD.
- Programme was designed to control acute CLI symptoms & improve general condition of patients prior to any revascularisation.
- However, at the end of 90 days, CLI patients did not require any intervention, ischaemic ulcer healed & no need for pain medications.

Capillary Bed Modulation

- SCPD salvaged patients.
Works on a Principle of Forced Emptying of Capacitance Vessels. Thereby Increasing Arterio-venous Pressure Gradient & Lead To Increase in Perfusion Pressure

ArtAssist®... Arterial Assist Device™

Increasing Arterial-Venous Pressure Gradient Promotes Healing & Improves Limb Salvage in when Revascularization Options are Unavailable or Exhausted & When Established Treatment Alternatives are Lacking

In A Four-hour Session, The Patient’s Arteries Will Be Expanded Almost 800 Times
Artassist® Simulates Brisk Walking, Without Pain With High Shear Stress That Promotes Endothelial Cells To Release Nitric Oxide & Endogenous tPA

Results

➢ Out Of 262 Limbs Studied 20 Limbs Underwent Major Amputation” 7.6 %”
➢ Thirty-day Mortality Was 0.6 %
➢ 69% All-cause Survival At 4 Years
➢ 94% Limb Salvage At 5 Years
➢ 63 % Freedom From MACE at 5 Years

Adjuvant Maneuvers

Sustained Hemodynamic Improvement

<table>
<thead>
<tr>
<th></th>
<th>Mean Pre SCBD</th>
<th>Mean Post SCBD</th>
<th>Change 95% CI</th>
<th>SD</th>
<th>P value</th>
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<tr>
<td>Toe pressure</td>
<td>39.9</td>
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<td>+15.49 8.06 to 22.92</td>
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<td>Popliteal flow</td>
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<td>+20.47 14.02 to 26.97</td>
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➢ There Were No Device-related Complications
➢ All Patients Managed at Home
All Cause Survival was Equivalent Between Revascularization & SCBD & Both are Superior to Primary Amputation

SCBD Imparts Essential Benefit & a Worthwhile Non-Operative Option To Patients Who Otherwise Would Be at Impending Risk of Limb Loss & are Amputation Bound

SCBD has Superior Limb Salvage, Ameliorated Amputation Free Survival & Provides Rapid Relief of Rest Pain without any Intervention in Patients Living on a Borrowed Time

Conclusion

Acknowledge Limits Of Stand-alone Interventions & Preclude Needless Treatment Failures
Capillary Bed Recruitment Avoid Fiascos Of Surgical or Endovascular Therapy
Reduces Peripheral Resistance & Enhance Endothelial Function
Augments Clinical Outcomes Of Otherwise Failure Bound ‘Good’ Interventions

Conclusion

Transplant - Amputations
SCBD - Amputations