There is No Future for Stem Cell Technology to Treat CLI
Art-assist is Better & Cheaper
Beats Revascularization

Prof Sherif Sultan\textsuperscript{1,2}
MD FRC\textsuperscript{\textregistered} FACS PhD
Professor of Vascular & Endovascular Surgery
Chairman of Western Vascular Institute
1. Western Vascular Institute, UHG\textsuperscript{\textregistered}, Ireland
2. Galway Clinic, RCSI, Galway, Ireland

Disclosure
- Founder of Tulip Endovascular Innovation, Ireland
- Founder of Embricon Endovascular, Ireland
- Founder of Green Medical, Michigan, USA
- Research Education Grants:
  - Cordis, Medtronic, Endologix, Gore, Vascular Solutions
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Primary Amputation

Aggressive Policy of Revascularization

SVS Objective Performance Goals
- 30-Day Amputation Rate Was Doubled For By Pass & Tripled For Endovascular
- Infra-popliteal Disease Is Stronger Predictor Of MALEs Than Advanced Age & Tissue Loss
- Infra-popliteal Endo-Option Is Risky & Harmful As Outcomes Of Endo Or Bypass Had Failed To Meet SVS OPG Safety Bench Marks For MALEs & Amputation
Vascular Surgery

- After any "successful" revascularisation, it can result in 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 and ischaemic skeletal muscle paracrine effect.

Stem Cell Failure in CLI

- Established proof of principle that therapeutic angiogenesis is regarded as a method of treatment for "no-option" patients suffering from CLI, "did not reach its zenith.
- Preclinical studies: spectacular efficiency of angiogenic therapy was not translated into clinical expected results.

5. CELL THERAPY DELIVERY: THE FUTURE

Stem cell research is in its infancy, and there are many questions to be answered. Before we can hope for this treatment option to provide acceptable clinical outcomes and sustainable results.

After a couple of billion dollars; placebo effect is as good as stem cell therapy.
Works on a Principle of Forced Emptying of Capacitance Vessels Thereby Increasing Arterio-venous Pressure Gradient & Lead To Increase in Perfusion Pressure Who Otherwise Would be at Impending Risk of Limb Loss & are Amputation Bound

ArtAssist®...Arterial Assist Device ™
Increasing Arterio-venous Pressure Gradient

Points on a Principle of Forced Emptying of Capacitance Vessels thereby Increasing Arterio-venous Pressure Gradient & Lead To Increase in Perfusion Pressure Who Otherwise Would be at Impending Risk of Limb Loss & are Amputation Bound

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

Capillary Bed Recruitment
Non-Operative Limb Salvage

Patients & Methods

- 18463 Referred with PVD From 2002-2018
- 1512 (12%) Had CLI, 623(41%) Had Intervention, 269 (18%) Had OMT
- 620 (41.6%) Were Not Fit For Any Intervention & 37(10.3%) Had Primary Amputation
- 583 (89.7%) Used Home SCPD For 90 Days
- 274 (47%) Used SCPD For More Than 150 Days

Capillary Bed Modulation

- 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
The Clinical Efficacy of SCBD Therapy 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

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Conclusion

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