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Limb Salvage for Diabetic Patients with Peripheral Arterial Disease

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Abstract

- According to the Center for Disease Control (CDC) (2017), the total number of patients diagnosed with diabetes is exceeding 30.2 million and rapidly increasing.
- According to the CDC (2016), approximately 8.5 million people in the United States have peripheral artery disease (PAD), which includes 12-20% of individuals who are older than age 60.
- According to a study performed by Swaminathan et al. (2014), 186,000 patients underwent lower extremity amputation (LEA). Data also shows that patients undergoing LEA have a mortality rate of 20% noted within one year, and a 40% to 50% mortality rate indicated within 18 months.
- The review of literature analyzed studies that compared vascularization procedures to determine whether early diagnosis and intervention provide benefit to reduce lower extremity amputation in diabetic patients with PAD and critical limb ischemia (CLI), and to determine cost effectiveness.
- Research suggests that limb salvage is cost efficient with early detection, proper patient compliance and use of a multidisciplinary approach. However, unpredictable factors such as poor patient compliance may skew cost analyses and validate claims to dispute reduction of costs.

Introduction

•The purpose of this scholarly project is to research diabetic patients with PAD and determine if early detection and intervention can increase limb salvage, decrease mortality, provide a higher quality of life and reduce healthcare costs.

•Research suggests that a multi-faceted treatment approach, involving aggressive risk-factor modification, antiplatelet therapy, and revascularization procedures can potentially reduce LEAs and healthcare costs.

Statement of the Problem

•The number of lower limb amputations in the diabetic population with PAD is increasing at an alarming rate. Limb amputation has been known to cause depression, decreased quality of life, increase patient mortality and increased healthcare costs.

•According to Sanguily (2015), studies have shown that patients who undergo limb amputation due to diabetes above or below the knee have a 40 to 50 percent death rate within 18 to 24 months. Options for limb prevention need further research so that patients can have access to a higher quality of healthcare, affordable healthcare, and ultimately a better quality of life.

Research Questions

•Will Early Detection, and Revascularization Interventional Therapy Prevent Limb Amputations in Diabetic Patients With PAD?

•What is The Key to Success to Increase Limb Salvage in Diabetic Patients with PAD?

•Is Early Detection, Revascularization Interventional Therapy and Limb Salvage for Diabetic Patients with PAD Cost Effective?

Literature Review

Limb Amputations in Diabetic Patients with PAD

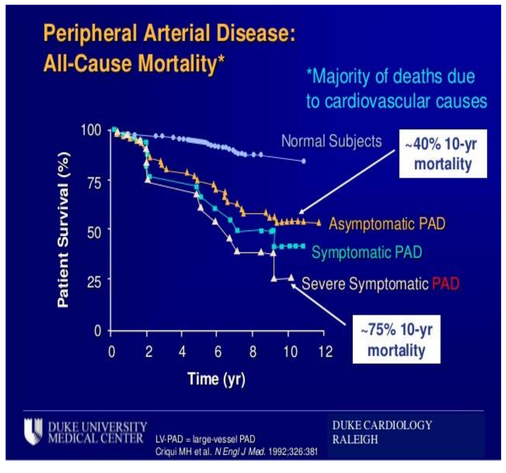
- Approximately 18 million Americans suffer from PAD.
- An estimated two million of these patients suffer from CLI.
- Patients with CLI have an amputation rate of roughly 40%.
- Approximately 25% of those patients have a mortality rate within the first year of amputation and a 40% mortality rate within 18 months.
- Patients who received early evaluation via angiography due to risk factors and comorbidities increased the diagnosis of PAD/CLI by 83%. The rate of lower limb amputations decreased by 30% with a 90% success rate of limb salvage (Sanguily, 2016).

Potential Candidates

- Elderly patients between ages 49 – 70 with any of the following: Regardless of symptoms.
- History of smoking
- Diabetes
- HTN
- CAD
- Atherosclerosis
- Dyslipidemia

Cost of Limb Salvage Vs. Amputation

- Year 2014, Costs of limb amputations accounted for approximately $11 billion.
- Research suggests that limb salvage is not only more cost efficient than limb amputation, but also increases quality of life.
- Research supports that limb salvage can be achieved by;
- Early evaluation and detection
- Early intervention
- Multidisciplinary treatment approach
- Proper patient compliance



Discussion

Diagnosis of PAD

- Non Invasive Techniques
  - ABI (Ankle/Brachial Index)
  - Exercise Test
  - Segmental Pressures
  - Segmental Volume Plethysmography
  - Duplex Ultrasonography
  - CT Angiogram
  - MRA (Magnetic Resonance Arteriography)
  - Carotid Doppler identifies patients who are at risk for stroke
  - Vascular ultrasound
- Invasive Techniques
  - Peripheral Angiograms
  - CT Angiograms
  - MR Angiograms

PAD Treatment Options

- Medical
  - Peripheral Angiograms
  - CT Angiograms
- Endovascular Therapy
  - Peripheral Transluminal Therapy
  - Peripheral Stenting
  - Angioplasty
  - Laser
  - Cryoplasty
  - Atherectomy
  - Thrombolic Therapy (adjunctive)
- Surgery
  - Bypass Grafts
  - Amputation
  - Endarterectomy

The Multidisciplinary Approach

- Primary Care
- Interventional Cardiology and Interventionists
- Interventional Radiology
- Podiatry
- Wound Care Specialists
- Diabetes Educators
- Others
  - Urologists, Midlevel Providers, Nutritionists, Physical Therapist, Case Management

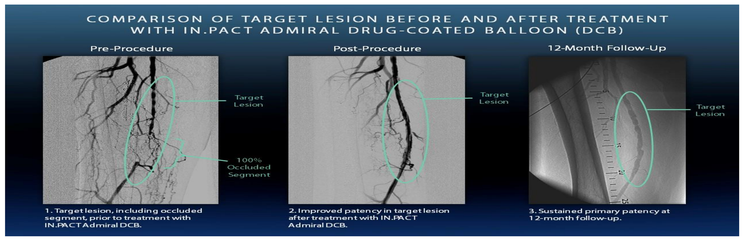
Economic Burden of PAD

- According to (Yost, 2016), in 2014 total amputations cost $28.2 billion.
- The total annual number of minor amputations (toe, foot) performed were 134,000, accounting for $17.6 billion with average costs per patient averaging $112,000 for toe, and $261,000 for foot.
- The total annual number of major amputations (above the knee, below the knee) were 80,000, accounting for $10.6 billion with average costs per patient averaging $128,000 for above the knee amputation, and $188,000 for below the knee amputation
- According to Yost, (2014), post amputation average lifetime cost of caregiving was estimated at $300,000.
- Medicare costs accounted for 58%, Medicaid costs accounted for 13%, and private insurers accounted for 18%.

Applicability to Clinical Practice

SIZE OF TREATMENT EFFECT

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	CLASS I *Benefit >>> Risk* Procedure/ Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/ administer treatment	CLASS IIb *Benefit ≥ Risk Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm*	
				Procedure/test	Treatment
				COR III: Not benefit	Not helpful / No proven benefit
				COR III: Harm	Excess cost w/o Benefit or Harmful / Harmful to Patients
LEVEL A Multiple populations evaluated[a] Data derived from multiple randomized clinical trials or meta-analyses	▪ Recommendation that procedure or treatment is useful/effective ▪ Sufficient evidence from multiple randomized trials or meta-analyses	▪ Recommendation in favor of treatment or procedure being useful/effective ▪ Some conflicting evidence from multiple randomized trials or meta-analyses	▪ Recommendation's usefulness/efficacy less well established ▪ Greater conflicting evidence from multiple randomized trials or meta-analyses	▪ Recommendation that procedure or treatment is not useful/effective and may be harmful ▪ Sufficient evidence from multiple randomized trials or meta-analyses	
LEVEL B Limited populations evaluated[b] Data derived from a single randomized trial or nonrandomized studies	▪ Recommendation that procedure or treatment is useful/effective ▪ Evidence from single randomized trial or nonrandomized studies	▪ Recommendation in favor of treatment or procedure being useful/effective ▪ Some conflicting evidence from single randomized trial or nonrandomized studies	▪ Recommendation's usefulness/efficacy less well established ▪ Greater conflicting evidence from single randomized trial or non randomized studies	▪ Recommendation that procedure or treatment is not useful/effective and may be harmful ▪ Evidence from single randomized trial or nonrandomized studies	
LEVEL C Very limited populations evaluated[c] Only consensus opinion of experts, case studies, or standard of care	▪ Recommendation that procedure or treatment is useful/effective ▪ Only expert opinion, case studies, or standard of care	▪ Recommendation in favor of treatment or procedure being useful/effective ▪ Only diverging expert opinion, case studies, or standard of care	▪ Recommendation's usefulness/efficacy less well established ▪ Only diverging expert opinion, case studies, or standard of care	▪ Recommendation that procedure or treatment is not useful/effective and may be harmful ▪ Only expert opinion, case studies, or standard of care	
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/ beneficial	is reasonable can be useful/effective/ beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit is not recommended is not indicated should not be performed/ administered/other is not useful/beneficial/ effective	COR III: Harm potentially harmful causes harm associated with excess morbidity/mortality should not be performed/ administered/other
Comparative effectiveness phrases[d]	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B			



References

- Centers for Disease Control and Prevention. (2017). National Diabetes Statistics Report. Atlanta,GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2017.
- Creswell, J., & Abelson, R. (2015). Medicare payments surge for stents to unblock blood vessels in limbs. New York Times; 2015; https://www.nytimes.com/2015/01/30/business/medicare-payments-surge-for-stents-to-unblock-blood-vessels-in-limbs.html
- Florian, D., Diehm, N., Galimanis, A., Husmann, M., Schmidli, J., & Baumgartner, I. (2007). Surgical or endovascular revascularization in patients with critical limb ischemia:Influence of diabetes mellitus on clinical outcome. Journal of Vascular Surgery, 45(4), 751-761. https://doi.org/10.1016/j.jvs.2006.12.022
- Mahoney, E. (2010). High economic burden, rates of revascularization for patients with pad. Cardiology Today, 2010(3),642-651. https://doi.org/10.1161/CIRCOUTCOMES.109.930735
- Mills, J. ((2015). Diagnosis and management of peripheral arterial disease. *Duke Cardiology Raleigh.* https://www.slideshare.net/DukeHeartCenter/diagnosis-and-management-of-peripheral-arterial-disease
- Reed, G., Salehi, N., Giglou, P., Kafa, R., Malik, U., Maier, M., & Shishehbor, M. (2016). Time to wound healing and major adverse limb events in patients with critical limb ischemia treated with endovascular revascularization. Annals of Vascular Surgery, 36, 190-198. https://doi.org/10.1016/j.avsg.2016.02.032
- Saarinen, E., Kauhanen, P., Soderstrom, M., Alback, A., & Venermo, M. (2016). Long-term results of inframalleolar bypass for critical limb ischemia. European Journal of Vascular and Endovascular Surgery, 52(6), 815-822. https://doi.org/10.1016/j.ejvs.2016.08.051
- Sadigursky, D. & Badaro, R. (2017). Retrospective analysis of risk factors associated with limb amputation in diabetic patients. Foot and Ankle Surgery, 23(1), 105. https://doi.org/10.1016/j.fas.2017.07.406
- Sanguily, J., Martinsen, B., Igyarto, Z., & Pham, M. (2016). Reducing amputation rates in critical limb ischemia patients via a limb salvage program: A retrospective analysis. Vascular Disease, 13(5), 112-119. https://www.martinhealth.org/stuff/contentmgr/files/0/7497033ab3d1b7433f6636bbeaff360c/misc/limbsalvageprogramsanguily_wm.pdf
- Swaminathan, A., Vemulapalli, S, Patel, M., & Jones, W. (2014). Lower extremity amputation in peripheral artery disease: Improving patient outcomes. Journal of Vascular Health and Risk Management, 10, 417-424. https://doi.org/10.2147/VHRM.S50588.
- Tsujimura, T., Iida, O., Fujita, M., Masuda, M., Okamoto, S., Ishihara, T., … Mano, T. (2017). Two-year clinical outcomes post implantation of epic self-expanding nitinol stents for the aortoiliac occlusive disease in patients with peripheral arterial disease. Journal of Atherosclerotic Thrombi. https://doi.org/10.5551/jat.41152
- Yost, M. (2016). The socioeconomic cost of amputations. *New Cardiovascular Horizons The Sage Group Research and Consulting.* https://www.ncvh.org/pdf/2015_Orlando/01_Gatlin_A2_A3/1100%20Yost/Yost%20V2.pdf
- Yost, M. (2016). PAD by the numbers. New Cardiovascular Horizons The Sage Group Research and Consulting. https://www.ncvh.org/pdf/2015%20NCVH/5-27-Wed/PDFs/0808_Mary%20Yost_BB.pdf

Acknowledgements

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