337

Innovation Opportunities within Lymphedema*

Zachary Plona, MD, Lina Ngao[1,*] Benjamin Monteagudo[1,*], Hunter Hutchinson[1,*], Jennifer Schultz[1,*], Youseph Yazdi, PhD, MBA, Soumyadipta Acharya, MD, MSE, PhD
[1]Johns Hopkins University
*These authors should be given equal credit.

OBJECTIVES/GOALS: Lymphedema is a chronic, debilitating disease characterized by progressive swelling due to lymphatic dysfunction. Lymphedema affects 5+ million people in the US, commonly as a consequence of cancer treatment. We identified the most relevant needs within lymphedema based on clinical impact, commercial viability, and technological feasibility. METHODS/STUDY POPULATION: A narrative review of lymphedema management was performed through a combination of literature review via English language PubMed, landscape determination for current solutions and primary ethnography. Lymphedema-focused physicians, patients, physical therapists and researchers were interviewed on Needs were identified and clustered based on common themes. These clusters were further refined through an iterative process of systematic scoring and expert evaluation. Clusters were evaluated on their potential for clinical and commercial impact as well as technical feasibility. RESULTS/ANTICIPATED RESULTS: General clusters identified included improved diagnostic modalities, curative treatment, disease knowledge among non-specialized clinicians and increased insurance coverage. 3 primary needs were determined to represent the best opportunities for technological innovation. There is a need for a quantitative method of evaluating lymphedema. This would allow for both improved tracking of progression for patients undergoing conservative management, and for better evaluation of surgical outcomes. Oncologists and surgeons need a method of prophylaxis in order to decrease the rate of lymphedema development following cancer treatment. Physicians need a method for early diagnosis of subclinical lymphedema to enable early intervention through proactive screening rather than reactive management. DISCUSSION/SIGNIFICANCE: Increasingly medical device design has moved towards a "bedside to benchtop" model where technology development is targeted based on critical needs within the clinical environment. Identification of these critical needs will serve as to guide future technological innovation in creating clinically impactful advancements.

338

Diffusion Basis Spectrum Imaging (DBSI) Prognosticates Outcomes for Cervical Spondylotic Myelopathy after Surgery

Justin Zhang[1], Saad Javeed[1], Jacob K. Greenberg[1], Dinal Jayasekera[1], Christopher F. Dibble[1], Jacob Blum[1], Rachel Jakes[1], Peng Sun[1], Sheng-Kwei Song[1] and Wilson Z. Ray[1]
[1]Washington University School of Medicine

OBJECTIVES/GOALS: Diffusion basis spectrum imaging (DBSI) allows for detailed evaluation of white matter microstructural changes present in cervical spondylotic myelopathy (CSM). Our goal is to utilize multidimensional clinical and quantitative imaging data to characterize disease severity and predict long-term outcomes in CSM patients undergoing surgery. METHODS/STUDY POPULATION: A single-center prospective cohort study enrolled fifty CSM patients who underwent surgical decompression and twenty healthy controls from 2018-2021. All patients underwent diffusion tensor imaging (DTI), DBSI, and complete clinical evaluations at baseline and 2-years follow-up. Primary outcome measures were the modified Japanese Orthopedic Association score (mild [mJOA 15-17], moderate [mJOA 12-14], severe [mJOA 0-11]) and SF-36 Physical and Mental Component Summaries (PCS and MCS). At 2-years follow-up, improvement was assessed via established MCID thresholds. A supervised machine learning classification model was used to predict treatment outcomes. The highest-performing algorithm was a linear support vector machine. Leave-one-out cross-validation was utilized to test model performance. RESULTS/ANTICIPATED RESULTS: A total of 70 patients – 20 controls, 25 mild, and 25 moderate/severe CSM patients – were enrolled. Baseline clinical and DTI/DBSI measures were significantly different between groups. DBSI Axial and Radial Diffusivity were significantly correlated with baseline mJOA and mJOA recovery, respectively ($r=-0.33$, $p<0.01$; $r=-0.36$, $p=0.02$). When predicting baseline disease severity (mJOA classification), DTI metrics alone performed with 38.7% accuracy (AUC: 72.2), compared to 95.2% accuracy (AUC: 98.9) with DBSI metrics alone. When predicting improvement after surgery (change in mJOA), clinical variables alone performed with 33.3% accuracy (AUC: 0.40). When combining DTI or DBSI parameters with key clinical covariates, model accuracy improved to 66.7% (AUC: 0.65) and 88.1% (AUC: 0.95) accuracy, respectively. DISCUSSION/SIGNIFICANCE: DBSI metrics correlate with baseline disease severity and outcome measures at 2-years follow-up. Our results suggest that DBSI may serve as a valid non-invasive imaging biomarker for CSM disease severity and potential for postoperative improvement.

339

A serum exocrine enzyme as a biomarker of response to immunotherapy in type 1 diabetes.

Brittany S Bruggeman[1], Kieran McGrail[1], Nicole Gonzalez[1], Clive Wasserfall[1], Martha Campbell-Thompson[1], Mark Atkinson[1], Michael Haller[1] and Desmond Schatz[1]
[1]University of Florida

OBJECTIVES/GOALS: We assessed the relationship between C-peptide preservation and a serum exocrine pancreatic enzyme (trypsin) in a recently concluded clinical trial. We hypothesized that immunomodulatory treatment resulting in improved beta-cell function would be associated with improved trypsin levels in subjects with recent-onset type 1 diabetes (T1D). METHODS/STUDY POPULATION: In a three-arm, randomized, double-masked, placebo-controlled trial 'Antithymocyte Globulin (ATG) and pegylated granulocyte colony stimulating factor (GCSF) in New Onset Type 1 Diabetes' 89 subjects with recent-onset T1D (duration <100 days) were enrolled and randomized to 3 groups: low-dose ATG (2.5 mg/kg IV) followed by pegylated GCSF (6 mg subcutaneously every 2 weeks for 6 doses), low-dose ATG alone, and placebo. We compared longitudinal serum levels of an exocrine enzyme (trypsin) in a subset of responders to therapy (defined as subjects with at least 60% of baseline area under the curve (AUC) C-peptide levels at 96 weeks, n=4) versus placebo 'responders' (n=2) and non-responders (n=25), and treated (n=19) versus placebo (n=12) subjects at baseline, 2 weeks, and 6 months after treatment. RESULTS/

https://doi.org/10.1017/cts.2022.191 Published online by Cambridge University Press