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A pilot randomized controlled trial of precision care for smoking cessation in the Southern Community Cohort Study

Nicole Senft[1], Maureen Sanderson[2], Rebecca Selove[3], William J. Blot[1], Rachel F. Tyndale[4], Quiyin Cai[1], Karen Gilliam[1], Suman Kundu[1], and Hilary A. Tindle[1]

[1]Vanderbilt University Medical Center; [2]Meharry Medical College; [3]Tennessee State University; [4]University of Toronto

OBJECTIVES/GOALS: Precision care may engage smokers and providers in treatment but is understudied in the community. We piloted guideline-based care (GBC) alone or with Respiragene, a lung cancer polygenic risk score (PRS, 1-10), or metabolism-informed choice of medication using the nicotine metabolite ratio (NMR). METHODS/STUDY POPULATION: Daily smokers (n = 58) with stored biospecimens in the Southern Community Cohort Study were randomized 1:1:1 to GBC, PRS, or NMR, counseled to quit smoking, and co-selected FDA-approved cessation medication (nicotine replacement, varenicline) with a tobacco counselor. In PRS, precision motivational counseling was guided by PRS (i.e., lung cancer risk 10-40-fold that of never-smokers). In NMR, precision medication recommendations consisted of varenicline for faster metabolizers (NMR≥0.31) and nicotine replacement for slow metabolizers (NMR<0.31). Feasibility was defined as achieving at least 50% provider engagement (med prescription) and at least 50% patient engagement (self-reported med use). RESULTS/ANTICIPATED RESULTS: Participants were median age 59, 72% female, 81% Black, 60% with incomes <$15,000; median cigarettes/day was 15 (IQR 8-20) and 52% reported time-to-first cigarette <5 minutes, illustrating moderate nicotine dependence. Providers confirmed medication prescriptions for 40% of patients (32% GBC, 50% PRS, 37% NMR) and 83% of patients reported using medication (prescribed or unprescribed) during the study (90% GBC, 80% PRS, 79% NMR). At 6-month follow-up, 27% (n = 15) reported cessation (39% GBC, 16% PRS, 26% NMR). Among persistent smokers, 46% reported smoking at least 50% fewer cigarettes/day compared to baseline (45% GBC, 38% PRS, 57% NMR). Small sample size precluded statistical comparisons. DISCUSSION/SIGNIFICANCE OF IMPACT: Precision interventions to quit smoking are feasible for community smokers, who engaged at high rates. However, only 40% of providers supported patients' quit attempts with medication prescriptions. Future research should test strategies to raise provider engagement in precision smoking treatment. CONFLICT OF INTEREST DESCRIPTION: R.F.T. has consulted for Quinn Emmanual and Apotex on unrelated topics. H.A.T. reported providing input on design for a phase 3 trial of cytisine proposed by Achieve Life Sciences and being a principal investigator of National Institutes of Health–sponsored studies for smoking cessation that include medications donated by the manufacturers. Other authors declare no potential conflicts of interest.

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Artificial Intelligence-Based Quantification of the General Movement Assessment Using Center of Pressure Patterns in Healthy Infants

Tara Lynn Johnson[1], Namarta Kapil[1], Alexa Escapita[1], Bittu Majmudar[1], Safeer Siddicky[1], Junsig Wang[1], and Erin Mannen[1]

[1]University of Arkansas for Medical Sciences

OBJECTIVES/GOALS: One in six children in the U.S. has a Neurodevelopmental Disability (NDD). Prechtl's General Movement Assessment (GMA) is a qualitative predictor of early motor dysfunction. However, no quantitative biomechanical assessment exists to more accurately identify all patients with NDD. METHODS/STUDY POPULATION: With UAMS IRB approval, as part of a larger study, healthy infants were filmed while lying supine on a force plate for 2 minutes. We studied 12 healthy full-term infants (gestational age: 38.9±1.5 weeks, age: 2.1-7.0 months; 7M, 5F; length: 64.0±5.2 cm; weight: 7.2±1.3 kg). Within our data set there were 3 infants transitioning to fidgety period (≤3 months), 4 in the fidgety period, (3-5 months), and 5 that matured beyond fidgety period (>5 months). Center of pressure (COP) path-lengths were gathered from the force plate at 1000 Hz. We grouped our data with K-means clustering and performed statistical analysis with ANOVA. RESULTS/ANTICIPATED RESULTS: We divided our data into 3 distinct clusters. The first group contained infants with moderate variability of movements which included 2 infants between 3 and 5 months and 2 infants slightly outside of this range. The second group, with mild variability in movements, included 4 infants between 2 and 3 months as well as 2 infants just older than 5 months. The third group, with little variability in movements, included 2 infants older than 5 months. A GMA reader (TJ) qualitatively confirmed these findings with video footage. Using a threshold of $p<0.05$, data sets within the clusters were similar and significantly different from other clusters. DISCUSSION/SIGNIFICANCE OF IMPACT: Fidgety infants have greater variability in COP patterns than their mature counterparts. We anticipate additional COP measurements will correspond with qualitative GMA analyses. Artificial Intelligence-based quantification of the GMA may be useful in earlier detection or prediction of NDD outcomes.

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Black Bone MRI from the Lab to Clinical Practice: Eliminating Radiation Exposure in Reconstructive Surgery Patients

Marissa Suchyta[1], Christopher Hunt, MD[1], Waleed Gibreel, MBBS[1], Diya Sabbagh, MBBS[1], Kryzysztof Gorny, PhD[1], and Samir Mardini, MD[1]

[1]Mayo Clinic

OBJECTIVES/GOALS: Virtual surgical planning and 3D printing enable streamlined surgeries and increased complexity. These technologies, however, require CT scans and radiation exposure. This project's goal is to optimize and demonstrate the accuracy of Black Bone MRI for surgical planning in reconstructive surgery. METHODS/STUDY POPULATION: Four common craniofacial surgeries were planned and performed on cadaver specimens (maxillary advancement, orbital floor reconstruction with patient-specific implants, cranial vault reconstruction, and fibular free flap reconstruction of the mandible). For each surgical procedure, ten cadaver heads were used. Five of each surgery were planned and 3D printed guides were created utilizing Black Bone MRI versus five with CT scans. Following mock surgeries, all specimens underwent a post-operative CT scan. 3d reconstruction was performed and surgical accuracy compared to the plan was assessed using GeoMagic Wrap, assessing average post-operative deviation from plan. RESULTS/ANTICIPATED RESULTS: In all surgeries, guides created from Black Bone MRI demonstrated high accuracy to surgical plan. Average osteotomy (cut) deviation from plan was not statistically significantly different when Black Bone MRI was used compared to CT scans

for planning and guide creation in the wide variety of craniofacial surgeries performed. The average deviation of post-operative anatomy from pre-operative plan was also not statistically significant when Black Bone MRI versus CT scans were utilized in the surgeries. These results then enabled the translational application of this technology clinically, and we demonstrate a clinical reconstructive craniofacial case planned utilizing Black Bone MRI. DISCUSSION/SIGNIFICANCE OF IMPACT: This study demonstrates that virtual surgical planning and 3d surgical guide creation can be performed using Black Bone MRI with comparable accuracy to CT scans in a wide variety of craniofacial procedures. This could dramatically reduce radiation exposure for patients. The successful segmentation, virtual planning, and 3d printing of accurate guides from Black Bone MRI demonstrate potential to change the pre-operative planning standard of care. This project, overall, also demonstrates the development of new solutions to advance clinical care, thus serving as an example of moving translational science from a concept to the operating room.

Catecholamines and Opioid Therapy Requirements for the Management of Acute Post-Procedural Pain: The clinical Trend to Identify Remarkable Elements in Opioid Drug Dependency

Armando Uribe Rivera[1], Ana Carolina Machado Perez[2], Hans Malmstrom[2], Yang-Fan Ren[2], Linda Rasubala[2], and Adam J Carinci[3]
[1]University of Rochester Medical Center; [2]Eastman Institute for Oral Health; [3]Anesthesiology Department, Strong Memorial Hospital

OBJECTIVES/GOALS: To compare the opioid drug requirements amongst those individuals with high levels of catecholamines in blood and acute post-procedural pain, by ICD9/10 codes (experimental) to those with normal levels of catecholamines and acute post-procedural pain (AP-PP) only (controls) METHODS/STUDY POPULATION: In collaboration with both the Informatics and the Biostatistics Departments at CTSI and under the auspices of the IRB at the University of Rochester, we completed the collection of ~8,000 electronic health records(EHRs) of adults 18 years and older with surgical appointments at Strong Memorial Hospital (SMH), who met inclusion criteria, from January 2006 to September 2019 and received Fentanyl therapy for AP-PP management. Subjects were categorized in a two-arm-matched case-control fashion. A ratio of 1(Experimental):1(Control) was utilized. Analytic comparisons were completed using normal distribution statistical methods with p >0.1 for significance. RESULTS/ANTICIPATED RESULTS: After removal of duplicates and exclusion of EHRs, a total of 17 subjects met inclusion criteria for the experimental group. We matched controls (n = 17) with experimental subjects for age, gender and surgical procedure for accurately compare opioid requirements in the postoperative recovery. Mean age of subjects was 69(+/- 10.1235) years old. Most of subjects were females (70%). Mean Fentanyl requirement was significantly different in the experimental group 466.17(625.621)mcg compared to 215.58(353.323)mcg in the controls (p value 0.07832) DISCUSSION/SIGNIFICANCE OF IMPACT: It is suggested that healthy individuals with genetic variations in pain pathways including; the COMT and MAOA rendered individuals with higher levels of catecholamines in the body driving abnormal responses to pain sensitivity. We emulated this genetic variation for clinical purposes using ICD10/9 codes of those with conditions related to higher catecholamine levels in the body.

Based on our preliminary results, we suggest that COMT and MAOA genetic variations could impact opioid drug use and the current opioid dependency and epidemics in the U.S. This study will address remarkable questions and identify strategies about this topic.

Clinical Implementation of Monte Carlo Dose Calculation for Patient-Specific Radiotherapy Quality Assurance

Holly Marie Parenica[1], Christopher Kabat[1], Pamela Myers[1], Neil Kirby[1], Pavlos Papaconstadopoulos[2], Nikos Papanikolaou[1], and Sotirios Stathakis[1]
[1]University of Texas Health Science Center San Antonio; [2]Netherlands Cancer Institute

OBJECTIVES/GOALS: The Monte Carlo dose calculation method is often considered the "gold standard" for patient dose calculations and can be as radiation dose measurements. Our study aims to develop a true Monte Carlo model that can be implemented in our clinic as part of our routine patient-specific quality assurance. METHODS/STUDY POPULATION: We have configured and validated a model of one of our linear accelerators used for radiation therapy treatments using the EGSnrc Monte Carlo simulation software. Measured dosimetric data was obtained from the linear accelerator and was used as the standard to compare the doses calculated with our model in EGSnrc. We will compare dose calculations between commercial treatment planning systems, the EGSnrc Monte Carlo model, and patient-specific measurements. We will implement the Monte Carlo model in our clinic for routine second-checks of patient plans, and to recalculate plans delivered to patients using machine log files. RESULTS/ANTICIPATED RESULTS: Our Monte Carlo model is within 1% agreement with our measured dosimetric data, and is an accurate representation of our linear accelerators used for patient treatments. With this high level of accuracy, we have begun simulating more complex patient treatment geometries, and expect the level of accuracy to be within 1% of measured data. We believe the Monte Carlo calculation based on machine log files will correlate with patient-specific QA analysis and results. The Monte Carlo model will be a useful tool in improving our patient-specific quality assurance protocol and can be utilized in further research. DISCUSSION/SIGNIFICANCE OF IMPACT: This work can be implemented directly in clinical practice to ensure patient doses are calculated as accurately as possible. These methods can be used by clinics who do not have access to more advanced dose calculation software, ensuring accuracy for all patients undergoing radiotherapy treatments.

Clinical utility of precision medicine approaches to guide anti-platelet selection for adult patients with acute coronary syndromes (ACS), following percutaneous coronary intervention (PCI)

Scott Mosley, PharmD[1], Samantha Yeung, PharmD, MS[1], David Shavelle, MD[2], Leonardo Clavijo, MD, PhD[2], and Tien Ng, PharmD[1]
[1]University of Southern California School of Pharmacy; [2]Keck School of Medicine at University of Southern California

OBJECTIVES/GOALS: Our goal is to determine if a precision medicine approach to guide anti-platelet therapy for patients with ACS, post PCI, is feasible for a diverse urban population. Also, we will evaluate if guided therapy reduces major adverse cardiovascular