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The association of gastrointestinal symptoms and hypertension in persons living with HIV on HAART

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OBJECTIVES/SPECIFIC AIMS: The advent of Highly Active Antiretroviral Treatments (HAART) has allowed HIV-positive individuals to live longer in recent years. This has resulted in a higher incidence of mortalities occurring in these individuals due to cardiovascular pathologies, as opposed to deaths due to HIV. Even with long-term HAART, persons living with HIV (PLWHIV) still exhibit inflammation, which is associated with deleterious cardiovascular outcomes. PLWHIV on HAART have a higher prevalence of hypertension, which is associated with an increased risk of cardiovascular events. Moreover, chronic inflammation has been shown to be related to the translocation of microbes and endotoxins across the gastrointestinal tract. Such microbial translocation (MT) is increased in individuals with digestive disorders and their associated symptoms (e.g., diarrhea, abdominal pain, and nausea). This study aims to explore the pathologies common to both MT-induced inflammation and cardiovascular symptoms by examining the associations between gastrointestinal symptoms and hypertension in PLWHIV on HAART. METHODS/STUDY POPULATION: The sample included 351 PLWHIV on HAART. Pre-existing de-identified data were analyzed. Sample demographics included 56.98 % African Americans, 41.31% Caucasians, ages 20–66 years (mean age = 43.65years), 21% female, 89% male, HIV viral load, CD4 counts. Self-reported data from the Symptom Co-Morbidity Questionnaire and Socio-demographic questionnaire were analyzed with SPSS v.24. RESULTS/ANTICIPATED RESULTS: In total, 86 PLWHIV (24.50%) stated that they have hypertension; 39 subjects (45.3%) reported having diarrhea, 30 subjects (34.8%) reported nausea, and 12 (13.9%) reported constipation and vomiting. Among ethnicities with hypertension and gastrointestinal symptoms, African Americans compared with Caucasians had a higher percentage of diarrhea (28% vs. 17%), nausea (21% vs. 11%), constipation (11% vs. 2%), and vomiting (8% vs. 5%). Women compared with men reported a higher percentage of nausea (28% vs. 24%) and constipation (8% vs. 6%). Men compared with women reported a higher percentage of diarrhea (38% vs. 7%) and vomiting (8% vs. 5%). DISCUSSION/SIGNIFICANCE OF IMPACT: These data support the need for targeted screening to include both blood pressure and associated gastrointestinal symptoms. Further studies supporting these results may assist practitioners to target treatments that may prevent cardiovascular comorbidities.

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The association of preoperative functional capacity and outcomes for head and neck cancer patients undergoing definitive surgical treatment

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OBJECTIVES/SPECIFIC AIMS: To study the role functional capacity plays in surgical outcomes for head and neck cancers. METHODS/STUDY POPULATION: In this single-institution cohort study, we combined preoperative anesthesia assessment information with oncology registry data for newly-diagnosed patients with squamous cell carcinoma of the oral cavity, pharynx, and larynx (HNSCC) treated with definitive surgery at Siteman Cancer Center from 2012 to 2016. Patient-reported exercise capacity was assessed as metabolic equivalents. Metabolic equivalents < 4 was defined as poor functional capacity. The primary outcome measure was overall survival (OS). Kaplan-Meir survival analysis was used to compare the survival of patients with poor functional capacity (PFC) and patients with normal functional capacity (NFC). Cox proportional hazard regression was used to explore the independent prognostic role of functional capacity on overall survival after controlling for other factors. RESULTS/ANTICIPATED RESULTS: A total of 671 patients underwent surgical treatment for HNSCC. The average age was 62 years (range: 19–94 years). Majority of the patients were male (n = 481; 72%), White race (n = 589; 88%), and smokers (n = 528; 79%). Of 671 patients, 22% (n = 146) had PFC. Two-year OS rate in PFC patients was 70% compared with 85% in NFC patients (15% difference; 95% CI: 7%–23%). Unadjusted Cox proportional hazard analysis showed that PFC patients had 2.2 times higher risk of death (95% CI: 1.5–3.2) than NFC patients. After adjustment for age at surgery, BMI, preoperative weight loss, comorbidity score, tumor site, and TNM stage the magnitude of the association between functional capacity and OS decreased (aHR = 1.3; 95% CI: 0.88–1.98). DISCUSSION/SIGNIFICANCE OF IMPACT: Poor functional capacity is associated with decreased overall survival, but the magnitude of the association, while clinically meaningful, decreases after controlling for other important patient and tumor factors. Nevertheless, we believe preoperative functional capacity status is an important patient factor to consider when discussing prognosis and attempting risk stratification. We also believe that functional capacity may be associated with 30-day unplanned readmissions and 90-day complications and are currently performing chart review to ascertain this information.

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Thrombotic complications in single ventricle reconstructions for single ventricle physiology congenital heart disease

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OBJECTIVES/SPECIFIC AIMS: Infants with single ventricle congenital heart disease (CHD) who undergo staged surgical reconstruction are among the pediatric patients at highest risk for thrombotic complications. Despite improvements in survival due to medical and surgical advancements, thrombotic complications are common and lead to increased morbidity and mortality, especially during the first two stages of surgical reconstruction. The burden of disease caused by thrombosis is not fully known, and the risk factors associated with thrombosis are not clear. Due to this knowledge gap, prevention of thrombosis with medication, a strategy called thromboprophylaxis, has not been standardized, leading to inadequate prevention of thrombosis. In order to understand the burden of thrombosis and then provide targeted thromboprophylaxis for thrombosis prevention, better characterization of thrombotic complications and the associated factors is needed. Hypothesis: I hypothesize that in infants with single ventricle CHD, the incidence of thrombosis will be more frequent after stage I Versus stage II reconstruction, despite the type of shunt used. Specific demographic, clinical, and surgical variables will be associated with an increased risk for thrombotic complications, and a model to predict which subset of infants is at increased risk will be developed. Specific Aim 1: Characterize the incidence of thrombotic complications at different time points from stage I through stage II of the single ventricle reconstruction (SVR) pathway and determine the demographic, clinical, and surgical factors associated with thrombosis in infants with single ventricle CHD. (1) Determine the incidence of thrombosis in infants with single ventricle CHD. (2) Compare the rate of thrombotic complications between the 2 most commonly used approaches for stage I reconstruction for the group of patients with hypoplastic left heart type of anatomy [modified Blalock-Taussig shunt (MBTS) vs. right ventricle to pulmonary artery shunt (RVPAS)]. (3) Determine the factors (demographic, clinical, and surgical) associated with thrombosis in infants with single ventricle CHD. Specific Aim 2: Determine which subset of infants with single ventricle CHD is at increased risk of developing thrombotic complications across the first 2 stages of surgical reconstruction. (1) Test the identified demographic, clinical, and surgical variables including, but not limited to, gestational age, sex, CHD diagnosis, baseline oxygen saturation, stage of reconstruction, shunt type, and other clinical data available in a univariable and multivariable analysis and study their potential interactions to construct a novel risk predictive model specific for single ventricle CHD. METHODS/STUDY POPULATION: To address the specific aims, I will utilize data from the SVR clinical trial public use data set. This data set includes a prospective cohort of infants, 0–14 months of age, enrolled from any of the 15 participating clinical centers from the years 2005 to 2009. Inclusion criteria for enrollment were diagnosis of hypoplastic left heart syndrome or related single, morphologic right systemic ventricle anomaly, planned Norwood procedure, and informed consent of parent or legal guardian. No additional subjects outside of this data set will be included. Exclusion criteria were a diagnosis of single, morphologic left ventricle anomaly, preoperative identification of anatomy rendering the MBTS or RVPAS technically impossible, and any other major abnormality or acquired extra-cardiac disorder that could independently affect the likelihood of the subject meeting the primary endpoint. The complication of stroke will be excluded from the analyses of factors associated with thrombosis. The complication of thrombosis as defined in this dataset is a composite of events that include arterial or venous thrombosis, thromboembolism, and pulmonary embolism. The data was collected in such a way that it will not be possible to separate these sub-types of thrombosis. Additional thrombotic events of interest are superior vena cava occlusion and inferior vena cava occlusion. Specific Aim 1: Patient data will be extracted from the SVR clinical trial public use dataset to characterize the incidence of thrombotic complications at different time points from stage I through stage II of the SVR pathway and determine the demographic,

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clinical, and surgical factors associated with thrombosis in infants with single ventricle CHD. In addition, I will compare the rates of thrombotic complications between the 2 most commonly used approaches for stage I palliation for the group of patients with hypoplastic left heart type of anatomy (MBTS vs. RVPAS) and will test the hypothesis that the risk of thrombotic complications is associated with the stage of palliative surgery (stage I vs. stage II). Specific Aim 2: We will test identified demographic, clinical, surgical, and newly identified variables in a univariable and multivariable analysis and study their potential interactions to construct a novel risk predictive model specific for single ventricle CHD. RESULTS/ANTICIPATED RESULTS: To determine feasibility for adequate numbers to be able to address the research aims, a preliminary analysis dataset was performed using a dataset from the Pediatric Heart Network. The PHN is a collaborative group of hospitals that participates in clinical research studies in children with CHD. For the SVR clinical trial, the PHN conducted a randomized clinical trial at 15 centers in North America between 2005 and 2009, prospectively enrolling infants with HLHS or single right ventricle anomalies who were to undergo the Stage I Norwood procedure. A total of 920 newborns were screened; 664 were medically eligible and 549 patients were randomized. The primary aim of the trial was to compare survival of infants randomized to receive either the Norwood procedure with the MBTS or the RVPAS. These patients were followed at specific time points, including from baseline (pre-Norwood), at the time of the Norwood procedure, between stage I and II, following stage II reconstruction, and at 14 months of age. At these time points, data were collected that includes demographic, radiologic, clinical, and surgical outcomes. Included in the clinical outcomes are complications, such a thrombosis. There was no screening process to assess for asymptomatic thromboses, suggesting that most, if not all, discovered thromboses were due to clinically relevant effects. A newer iteration of this study (SVRIII) expands the monitoring of this cohort until the Fontan stage at 2–6 years of age, but these data have not yet been released in the public use data set. A descriptive analysis of the frequency of thrombotic complications was assessed at each time point, as well as in aggregate. Data were extracted from the specific time periods of interest, identified as Pre-Norwood, during Norwood Hospitalization, in-between visits, and during Stage II Hospitalization. There were 549 infants who were randomized with available data to analyze. During the Norwood hospitalization, 37 infants had a thrombotic complication. Between Stage I and Stage II outpatient visits, 8 infants had a thrombotic complication. During Stage II hospitalization, 16 infants had a thrombus. Overall, 61 individual patients (11%) had a thrombotic complication. DISCUSSION/SIGNIFICANCE OF IMPACT: This study utilizing data from the Pediatric Heart will be the largest cohort ever utilized for characterizing thrombotic complications and determining the factors associated with thrombosis across the first and second stages of surgical reconstruction. More than 500 (n = 549) subject's data will be analyzed through the first two stages of reconstruction, while the largest analysis before this proposed analysis only included a total of 195 children. Notably, these prior studies did not include a comparison between the 2 shunt types in stage I reconstruction, leaving a gap in knowledge regarding the incidence of thrombosis comparing these groups. The analysis will be the first to address this gap and update the current literature. Preliminary data show that the overall incidence of thrombosis across the first 2 stages of surgical reconstruction was 11%, which is lower than the previously reported overall rates of 40%–50%. Despite the continued lack of evidence-based guidelines for thromboprophylaxis methods, the decreased overall rate is most likely due to more widespread practice of anticoagulation in general. Determining the factors associated with thrombosis across the first and second stages of surgical reconstruction will help identify those at risk. An innovative aspect of this analysis will be the use of disease-specific factors to develop a model to predict thrombosis. Unique factors include cardiac variables like ejection fraction, baseline oxygen saturation, shunt type (MBTS vs. RVPAS), and other echocardiographic parameters. While the use of thromboprophylaxis has been associated with decreased risk of thrombosis, there is no general consensus to guide thromboprophylaxis in this population, which can be burdensome and costly. Determining which subset of infants with single ventricle CHD are at increased risk of developing thrombotic complications will allow for the development of a prediction model to predict those at highest risk of developing a thrombotic complication. Developing a predictive model will be a novel way to identify patients at risk for thrombosis and will set the stage for targeted prevention of thrombosis.

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Trends in anogenital warts incidence: Potential impact of human papillomavirus vaccination, TennCare 2006–2015

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OBJECTIVES/SPECIFIC AIMS: We aimed to assess trends in incidence of genital warts across human papillomavirus (HPV) vaccine-eligible and nonvaccine-eligible age groups to determine the impact of the HPV vaccine among Medicaid enrollees in the state of Tennessee. METHODS/STUDY POPULATION: We analyzed 2006–2014 medical and pharmaceutical claims data from TennCare (Tennessee's Medicaid program) enrollees aged 15–64 years. Incident cases of genital warts were defined as persons 12 months disease free and: (1) a diagnosis of condyloma acuminatum, or (2) a diagnosis of viral warts and genital-specific procedure, or (3) a prescription for genital warts medication and genital-specific procedure. Mann-Kendall trend tests were performed to assess for significant trends in incidence of genital warts by sex and age group; average annual percent changes were calculated to quantify these trends. RESULTS/ANTICIPATED RESULTS: Our analysis is in progress. We hypothesize that we will observe declines in genital warts among younger, vaccine-eligible age groups and no changes in older, nonvaccine-eligible age groups, with largest declines among females aged 15–19 years from 2006 to 2014. We also expect to see declines among younger males due to herd protection, with greater declines after 2011, when the vaccine was approved for males. DISCUSSION/SIGNIFICANCE OF IMPACT: Significant declines among younger compared with older age groups would suggest HPV vaccine effectiveness for preventing genital warts.

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Understanding care delivered to patients with a possible concussion at an urban level 1 trauma center

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OBJECTIVES/SPECIFIC AIMS: Background: Annually, 2.5 million traumatic brain injuries (TBI) occur with nearly 75% classified as mild TBI (mTBI), also known as a concussion. Mild TBI can be subtle and detection requires a high index of suspicion and a regimented evaluation process. This study was done to define the proportion of patients with a possible mTBI evaluated for concussion at a high volume urban trauma center. METHODS/STUDY POPULATION: Methods: A prospective cohort of patients was identified using a 3-question screen at the time of triage: did an injury occur; was the mechanism consistent with mTBI; was there a period of altered mental status. Patients who screened positive were thought to meet a minimum threshold for the evaluation of mTBI. Information about mTBI specific evaluation, management, and education was obtained from the patient's charts. RESULTS/ANTICIPATED RESULTS: Results: 38,484 patients were screened over 16 weeks, of whom 453 (1.18%) screened positive for a possible mTBI and did not meet exclusion criteria. In total, 198 patients had documented loss of consciousness, 101 were diagnosed with mTBI, and 49 received mTBI discharge instructions. Overall, 32.5% of included patients had mTBI listed in the differential or as a diagnosis and 32.3% with loss of consciousness received a mTBI diagnosis. DISCUSSION/SIGNIFICANCE OF IMPACT: Conclusions: Many patients with a possible mTBI were not evaluated, managed, or educated for their potential injury. Changes in physicians' approach to mTBI must occur to increase the proportion of patients receiving appropriate evaluation, management, and education. These results define the current reality of mTBI treatment in the Emergency Department and show the need for further experimental studies targeted at physician decision support interventions to improve mTBI care.

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Utilization of ClinicalTrials.gov registry to demonstrate the extent of dissemination bias in anesthesiology

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OBJECTIVES/SPECIFIC AIMS: The purpose of this study is to evaluate the extent of publication bias in anesthesia and to evaluate the characteristics of studies that are registered and unpublished. METHODS/STUDY POPULATION: We used the advanced search option and the key word "anesthesia" to identify anesthesia related studies in the ClinicalTrials.gov registry. For

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