Comparison of Registered and Published Primary Outcomes in Cardiovascular Randomized Controlled Trials

41

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Type of submitter

Fellow in Training

Abstract

Background: Selective reporting can confound the interpretation and validity of randomized controlled trials (RCT). Therefore in 2005, the International Committee of Medical Journal Editors mandated protocol registration for RCT's.

Objective: To investigate the consistency between trials registered with an international clinical trials registry and published primary outcomes among cardiovascular RCT's.

Methods: We searched the MEDLINE database for Phase II and III RCTs published beyond July 2005 through May 2018. For every registered RCT, we determined the time of registration, the measured outcome, the number of outcomes in the published article and corresponding registry. The findings obtained from registry and published article were evaluated for consistency.

Results: Of the 154 RCTs identified, 134 (87.1%) were registered appropriately per ICMJE guidelines with 126 registered with clinicaltrials.gov. Of these, 73 (54.4%) registered a sample size which remained unchanged from the time of registration to publication. 100 (74.6%) RCTs were registered before enrolment, 27 (20.1%) during the study and 7 (5.2%) after completion. These single and multi-center trials were conducted in North America (42.5%), Far East (18%), Europe (18%), and internationally (18%), most of which studied drugs (88%). Primary outcomes involved hard endpoints in 34 (26.1%) RCTs while 99 (73.8%) reported surrogate outcomes. Most trials were funded by the industry (80.5%) and research foundations/academic institutions (17.9%).

Conclusion: Despite mandatory registration, compliance with trial registration continues to lag. In conclusion, the data suggest that only half the phase 2 and 3 trials had a sample size and primary outcome appropriately registered prior to enrollment with outcomes and a sample size unchanged on completion of the study.

Categories

2nd year Fellow: Research

Program/Institution Name

Cleveland Clinic Foundation

Acute Kidney Injury following Index versus Staged Percutaneous Coronary Intervention in Acute Coronary Syndrome with Multivessel Involvement: A Meta-Analysis

59

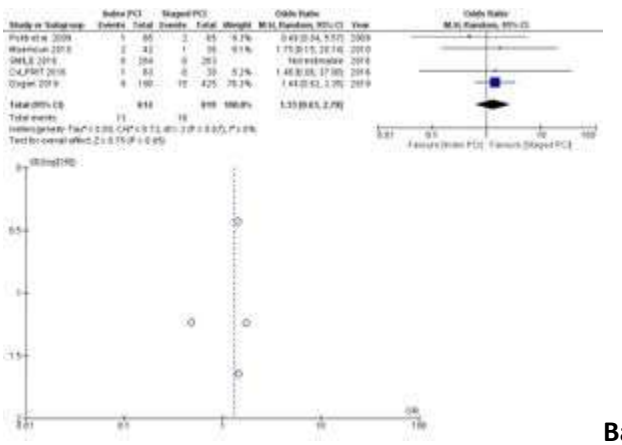
Sindhu Avula, Jay Shah, Ma'en Al-Dabbas, Syed Sohail Ali

Mercy Saint Vincent Medical Center

Type of submitter

Fellow in Training

Abstract



Background:

While dealing with a case of acute coronary syndrome (ACS) with multivessel involvement, it remains debatable whether to perform immediate complete revascularization of both the infarct and non-infarct related arteries, index percutaneous coronary intervention (PCI), or immediate revascularization of only infarct-related artery and leaving other narrowed arteries to be treated during another elective procedure (staged PCI). With increasing dose of contrast material used during PCI, the rate of AKI increases. Whether staged delivery of contrast material during PCI plays a role in preventing AKI is controversial. Also, AKI is a major complication of PCI associated with extended hospital stay and poor outcome.

Hypothesis:

Treatment of multivessel PCI during index hospitalization is associated with higher AKI.

Methods:

A systematic search of PubMed/Medline and EMBASE data was performed for all the studies comparing the outcome AKI after index vs staged PCI for multivessel ACS. We calculated comprehensive odds ratio (ORs) and 95% confidence intervals (CIs) using a random-effects model.

Results:

We found 3 RCTs, one post hoc analysis (CvLPRIT) and one registry (Dogan) comprising a total of 1433 PCI procedures (614 index and 819 staged PCI). The primary outcome was development of AKI. Our study demonstrated that there was no significant difference in the occurrence of AKI between the two groups (OR= 1.33; 95% CI: 0.63-2.78, I^2 = 0%, P=0.45). There was no heterogeneity among the included trials . Funnel plot looks asymmetrical which suggests higher than minimal publication bias.

Conclusion:

This study provides further information about the differences in the outcomes between the index and staged PCI in multivessel ACS. We couldn't find a significant association between the type of PCI and the risk of developing AKI. Hence, renal complications shouldn't be considered as an important factor while deciding the type of PCI in such patients.

Categories

2nd year Fellow: Research

Program/Institution Name

Mercy St Vincent Medical Center

High Sensitivity Troponin and the Risk of Atrial Fibrillation in Chronic Kidney Disease: Results from the Chronic Renal Insufficiency Cohort (CRIC) Study

25

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Case Western

Type of submitter

Fellow in Training

Abstract

Background: Patients with chronic kidney disease (CKD) are at increased risk for atrial fibrillation (AF). There is a need for novel biomarkers to reliably and accurately predict new onset AF in high risk patients. High sensitivity troponin (HsTP) is a relatively new assay that allows detection of very low troponin concentrations with high precision. The utility of HsTP for evaluating the risk of AF in CKD has not been established. We sought to explore the association between HsTP and the risk of incident AF in chronic kidney disease.

Methods: The Chronic Renal Insufficiency Cohort (CRIC) is a prospective cohort of 3939 individuals (21-74 years) with mild to moderate CKD using age related criteria for GFR using the simplified MDRD formula. High sensitivity troponin T was measured at study enrollment. Patients with prior history of AF were excluded. Patients were followed for new onset adjudicated AF, and the association between HsTP and incident AF was examined using Cox regression model.

Results: A total of 3,217 participants free of AF at enrollment were included in this analysis. Over a median follow up of 7.1 year [IQR 5.0-8.4] years, 252 patients developed new-onset AF (12 events per 1000 person-year of follow-up). The incidence of new onset AF was 2.46% (75 events) at three years, 7.06% (192 events) at six years, and 11.5% (250 events) at nine years. (Q4 vs Q1; HR 2.19, 95% CI: 1.31-3.66). Compared with lowest quartile of HsTP (Q1), patients in third quartile of HsTP (HR 2.40, 95% CI: 1.58-3.65, P<0.001), and fourth quartile of HsTP (HR 4.43, 95% CI: 2.98-6.59, P<0.001) had higher incidence of AF. HsTP had modest discrimination of AF risk, with 3-year AUC of 0.66, 6-year AUC of 0.70, and 9-year AUC of 0.67.

Conclusion: High sensitivity troponin levels are associated with increased risk of atrial fibrillation in patients with mild to moderate chronic kidney disease. This association remains significant despite adjustment for traditional AF risk factors and chronic renal disease.

Categories

2nd year Fellow: Research

Program/Institution Name

CWRU University Hospitals Cleveland Medical Center

PentaRay® Multi-Electrode Mapping Catheter for Atrial Tachyarrhythmia in Adults with Congenital Heart Disease

33

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Type of submitter

Fellow in Training

Abstract

Background:

Ablation of atrial tachyarrhythmia in adults with congenital heart disease (ACHD) is challenging due to complex anatomy and high burden of scar. The use of three-dimensional electroanatomic mapping systems (3D-EAM) is recommended and acute success rates using EAM are estimated to be greater than 80%. High density mapping with the PentaRay® (Biosense Webster) multi-electrode mapping catheter has been used safely for ablation of ventricular tachycardia in ischemic and non-ischemic cardiomyopathy patients. However, high density mapping has not been studied for ablation of atrial tachyarrhythmia in ACHD patients. We proposed the addition of high density mapping with PentaRay® mapping catheter to 3D EAM (EAM+P) allows for rapid acquisition of high resolution maps resulting in shorter procedure time.

Methods:

This is a single center retrospective cohort study of ACHD patients who underwent ablation procedures for atrial tachyarrhythmia from 2013 – 2017. Patients were divided into two cohorts: those who underwent ablation with EAM and those who underwent ablation with EAM with addition of PentaRay® high density mapping catheter (EAM+P).

Results:

Fifteen ablations were performed in 13 patients using standard EAM, and 11 ablations were performed in 10 patients using EAM+P. There was no difference in mean age (40 vs 34 years) or complexity of CHD (69% vs 60% complex CHD). EAM+P group included an average of 2 + 1 activation maps with an average

of 3956 + 2666 mapping points over an average of 54+ 28 min with MRI overlay (Figure 1). A higher number of sheaths were used for EAM cases compared to EAM+P (p=0.008). The procedure duration was 1.5 times longer in the EAM group compared to EAM+P (p = 0.015). The dose area product was 12 times higher in the EAM group compared to EAM+P (p = 0.001). Acute success rates of ablation were similar in the two groups with 92% success in EAM and 100% success in EAM+P. There recurrence at one year in the EAM cohort 38% vs. 10% in the EAM+P. There were no procedural related complications in either group.

Conclusions:

This is the first study to demonstrate the safety and efficacy of PentaRay® high density mapping catheter in addition to 3D mapping system for ablation of atrial tachyarrhythmia in ACHD patients. The use of PentaRay® high density mapping catheter results in shorter procedure time, decreased fluoroscopy dose and decreased number of access sites. There was no difference in acute success rate with the addition of PentaRay® mapping catheter in the ablation of atrial tachyarrhythmia.

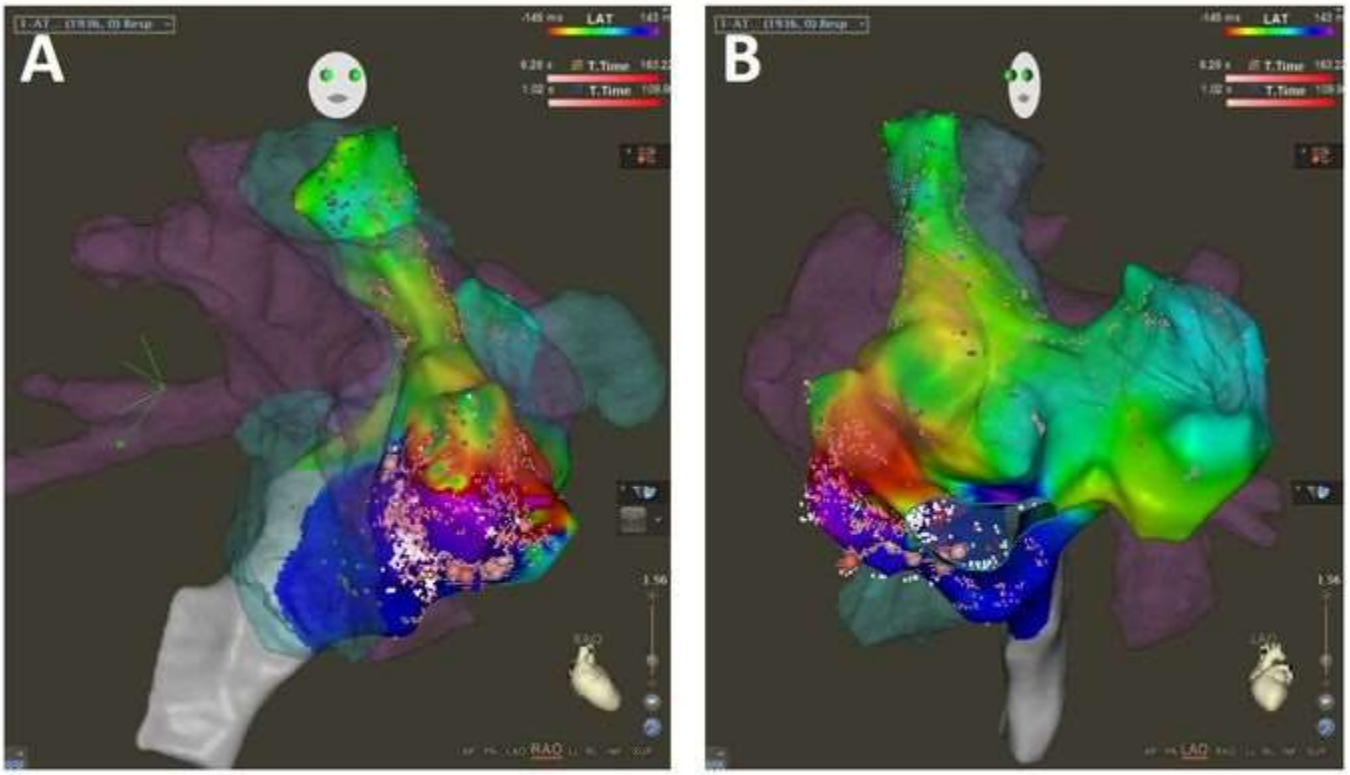

Figure 1. Activation map in a patient with D-Transposition of the Great Arteries s/p Mustard with CMR overlay, demonstrated early meets late activation, consistent with intra atrial reenterant tachycardia, 1942 activation points in 13:52 minutes (A) RAO View (B) LAO View

Categories

Advanced Fellow: Research

Program/Institution Name

Nationwide Children's Hospital/Ohio State University

ASCVD score as a predictor of CAD burden in stable chest pain

39

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Case Western Reserve (Metrohealth)

Type of submitter

Fellow in Training

Abstract

Background: Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of mortality in the United States. Cost-effective screening of patients, particularly those with stable chest pain, toward angiographically significant coronary disease continues to be a challenge. Though the commonly used ASCVD risk calculator is validated to determine the risk of a future ASCVD event (coronary death, nonfatal MI and fatal or nonfatal stroke) in 10 years, it has not been associated with coronary angiography in these patients. We hypothesize that ASCVD risk score can predict angiographically significant CAD in patients with stable chest pain.

Methods: Retrospective chart review from 2017 to 2018 identified 149 consecutive patients with stable chest pain without evidence of acute myocardial injury who had diagnostic coronary angiography performed. Exclusion criteria: previous known history of CAD or coronary angiography, positive EKG changes or cardiac enzymes, and admission to an ICU. Each patient was classified as either ASCVD low risk (<10%) or high risk (>=10%) and each coronary was angiographically graded as normal (0), low (1), moderate (2) or severe (3) stenosis and a cumulative score for CAD burden was calculated.

Results: Seventy-two (48%) patients had low ASCVD risk score and seventy-seven (52%) had high ASCVD risk score. Thirty-three percent of patients with low ASCVD risk score were noted to have angiographically significant CAD (at least 1 vessel with moderate or severe CAD) compared to 53% of patients with a high ASCVD risk score (p-value: 0.015). A high ASCVD risk was also associated with more patients with 2 vessel disease (38% vs 21%, p-value: 0.025), higher mean number of vessels per patient with at least moderate CAD (1.15 vs 0.68, p-value: 0.018) and a higher cumulative CAD burden (5.27 vs 3.4, p-value 0.001) compared to patients with a low ASCVD risk.

Conclusions: A high ASCVD risk score suggests angiographically significant CAD in patients with stable chest pain. However, a low ASCVD risk score does not exclude CAD. One third of the patients in the low ASCVD risk group had angiographically significant CAD. Subgroup analysis suggests very high ACSVD risk score (>30%) is associated with increased left main and multi-vessel coronary disease.

Categories

3rd year Fellow: Research

Program/Institution Name

CWRU MetroHealth

Virtual Visits in Cardiac Electrophysiology: Patient and Physician Preference

55

Peter Hu, Henry Hilow, Divyang Patel, Megan Eppich, Khaldoun Tarakji

Cleveland Clinic

Type of submitter

Fellow in Training

Abstract

Background: Cardiologists have long utilized devices to follow patients with arrhythmias in order to guide management. Virtual visits have been adopted as one modality to follow-up established patients with arrhythmias. Factors contributing to patient and physician preferences with virtual visits are unknown. To our knowledge, there are no prior studies that have collected objective feedback from patients and physicians after virtual visits.

Objectives: To determine patient and physician experience with virtual visits in Cardiac

Electrophysiology.

Methods: We performed a prospective survey of patients and physicians who participated in a virtual visit in the Department of Cardiac Electrophysiology at the Cleveland Clinic from December, 2018 and July, 2019. All established patients in the Department of Cardiac Electrophysiology at the Cleveland Clinic who had a virtual visit were invited to partake in our survey. A constructed, standardized phone script and patient survey questionnaire of 15 questions was implemented for each patient. In addition, for each virtual visit encounter the cardiac electrophysiologist who performed the virtual visit was also invited to participate in a separate physician survey.

Results: 100 patient and physician virtual visit encounters were included. The average age of patients who participated in a virtual visit was 65 years old. 70% were male and 30% were female. The average distance patients participated in their virtual visit was 656 miles. Of the 100 patients who participated in a virtual visit, 64 elected to complete a survey, 10 patients declined, 17 patients were unable to be reached on follow-up, and 9 patients were not included due to technical difficulties. Of those who responded, 51 patients participated in their first virtual visit, 4 participated in their second virtual visit, and 8 participated in their third or more virtual visit. 38/64 (59.4%) of patients preferred a virtual visit for their next visit, 12/64 (18.8%) preferred an in office visit, 13/64 (20.3%) responded that their decision for a virtual or office visit depended on their specific needs, 1/64 (1.6%) did not have a preference. A total of 14 cardiac electrophysiologists participated in 100 virtual visits. 9/100 visits were not included due to technical error and inability to complete the virtual visit. Of the 91 virtual visits by physicians, 62/91(68.1%) preferred a virtual visit for their next visit, 7/91 (7.7%) preferred an in office visit, 10/91 (11.0%) responded that their decision for a virtual or office visit depended on the indication

for follow-up, 6/91 (6.6%) did not have a preference, and 6/91 (6.6%) did not indicate their preference for their next visit.

Conclusions: Both patients and physicians showed favorable responses to virtual visits, with a majority of patients and physicians preferring a virtual visit over an in-office visit for their next encounter. Factors such as convenience, cost, feasibility, and reason for follow-up were important determinants that affected both patient and physician preference.

Categories

3rd year Fellow: Research

Program/Institution Name

Cleveland Clinic Foundation

Incidence of New onset Atrial fibrillation in newly diagnosed colon, lung and prostate cancer

3

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Mercy St Vincent Medical Center

Type of submitter

Fellow in Training

Abstract

Back Ground

Atrial fibrillation is the most prevalent arrhythmia with global burden of 33.5 million patients with estimated prevalence of 2.7 to 6.1 million in United States. Incidence of 2% is reported among age <65 year.

Objective

It has been proposed that necrosis and fibrosis of atrial tissue lead to fluctuation in membrane potential contributing to Atrial fibrillation. Malignancies have higher burden of inflammation and we tested the hypothesis of inflammation and reported the trend of atrial fibrillation among prostate, colon and lung cancer patients.

Methods: Retrospective data analysis for the 515 patients including prostate, colon and lung cancer has been done. Inclusion criteria is adults >18 years age with newly diagnosed cancer. Exclusion criteria is severe MR, severe MS and history of coronary bypass surgery. New onset atrial fibrillation has been defined as new paroxysmal or persistent atrial fibrillation diagnosed 6 months before or after the diagnosis of cancer.

Results:

Among 182 Colon cancer patients who met the criteria, 13 patients (7.1%) are diagnosed with atrial fibrillation. 6 patients have new onset atrial fibrillation and 7 patients have history of atrial fibrillation. New onset atrial fibrillation is found in 26 (19.6%) patients out of 133 lung cancer patients meeting the criteria. We have found 6.2 % incidence of atrial fibrillation among 145 prostate cancer patients. 8 patients have been reported to have history of atrial fibrillation and 1 patient has new onset atrial fibrillation among 145 prostate cancer patients.

Conclusion: We have observed higher prevalence of atrial fibrillation among lung cancer patients compared to prostate and colon cancer patients. Prevalence may be higher but not picked up because of paroxysmal nature. Large scale studies in future can predict correlation and help risk stratify these patients with screening EKGs.

Categories

3rd year Fellow: Research

Program/Institution Name

Mercy St Vincent Medical Center

Implications of Various Diagnostic Criteria on the diagnosis of Cardiac Sarcoidosis: A Single Center Experience

54

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The Ohio State University Wexner Medical Center

Type of submitter

Fellow in Training

Abstract

Background: Sarcoidosis has been called the "great mimicker" due to the many ways it can present and be diagnosed. Cardiac Sarcoidosis (CS) has a prevalence of 2.2/100,000, with multiple diagnostic criteria, taking into account clinical and histologic characteristics.

Objective: To compare published diagnostic criteria for CS in patients referred for suspected CS.

Methods: A retrospective review of a prospectively maintained database of patients with suspected CS in a multidisciplinary sarcoidosis clinic was performed. Clinical, imaging and laboratory characteristics included in the published diagnostic criteria were collated by chart review. Japanese Ministry of Health & Welfare (JMHW) (2003, 2014, and 2017) and Heart Rhythm Society (HRS) diagnostic criteria for CS were applied to these patients.

Results: A total of 62 patients were referred to the CS, of which 53 (85%) fulfilled one of the published CS criteria. Specifically, 46 (87%) met HRS, 14 (26%) met 2017, 26 (49%) met 2006, and 26 (47%) met 1993 JMHW criteria. When compared, the proportion of patients meeting HRS criteria was significantly higher than the recent JMHW (2017)($p<0.0001$). Nine (15%) patients did not meet any criteria, but had imaging concerning for CS without evidence of extracardiac sarcoidosis (i.e., potentially isolated CS).

Conclusion: There is significant heterogeneity between the published diagnostic criteria for CS. Among the 4 criteria, the HRS criteria appear to be the most liberal, with the newly proposed 2017 JMHW criteria being the most conservative. Further work is needed to delineate the clinical significance of imaging findings of CS in patients who do not fulfill the current diagnostic criteria.

Categories

3rd year Fellow: Research

Program/Institution Name

Ohio State University Hospital

Non-invasive screening for coronary allograft vasculopathy

12

Zarina Sharalaya, Wilson Tang, Paul Cremer, Andrew Noll, Wael Jaber

Cleveland Clinic

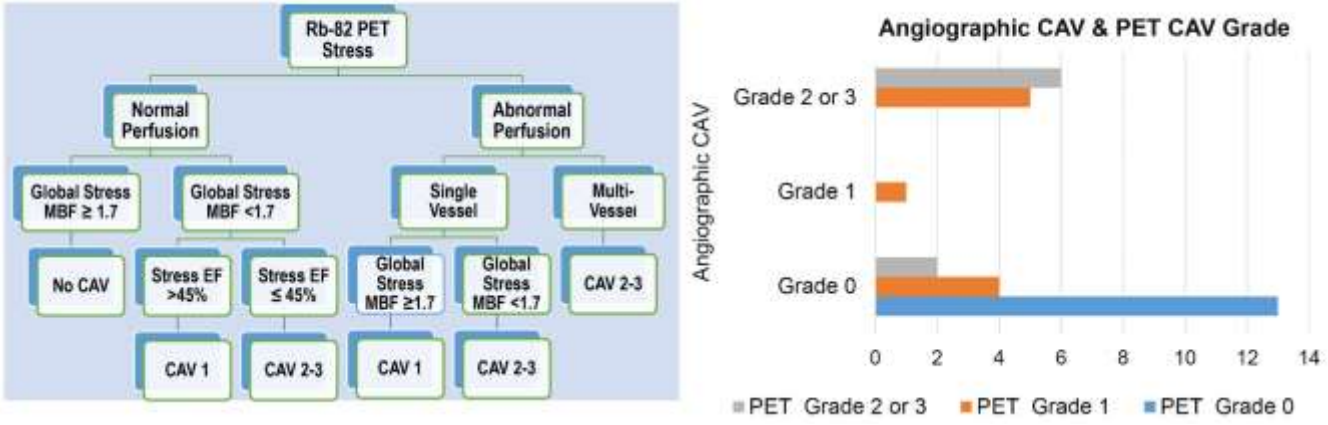
Type of submitter

Fellow in Training

Abstract

Background: Recent studies have shown promising data supporting the use of positron emission tomography (PET) in place of the current invasive gold standard, coronary angiography to screen for coronary allograft vasculopathy (CAV). PET can functionally assess flow using myocardial blood flow (MBF) which correlates with CAV and can portend poor outcomes. Objective: We sought to determine the ability of PET to identify CAV in comparison to coronary angiography. Methods: We retrospectively identified all heart transplant recipients who had regadenoson rubidium-82 PET rest-stress tests and coronary angiography at our institution between November 2012 and March 2019. CAV grade was based on ISHLT criteria according to Figure 1 which is adapted from researchers at Brigham and Women's Hospital. A cutoff of MBF <1.7 was used in their algorithm which we also applied to our sample. Results: We collected data from 31 patients with 44 PET studies. Of this population, 28 patients had coronary angiography performed which resulted in 37 total PET studies for comparison. Of the total collection of PET studies, 36% had CAV 0 (n=16), 36% had CAV 1 (n=16), and 28% had CAV 2-3 (n=12). When analyzing the subset who had both PET and angiography (n=31), of those with grade 0 CAV on PET, all patients also had no angiographic CAV (n=13). Of those with PET grade 2 or 3 CAV, 2 patients had no angiographic CAV and 6 patients had corresponding moderate-severe CAV angiographically. Conclusion: PET appears to be a good screening modality for CAV, as all of those with severe CAV angiographically had at least grade 1 CAV on PET. PET should be strongly considered as the primary method of CAV screening to avoid the risks of invasive angiography in a particularly delicate population of patients.

Figure 1. PET-Based Classification of CAV and Correlation with CAV Grade on Coronary Angiography.



Categories

3rd year Fellow: Research

Program/Institution Name

Cleveland Clinic Foundation

ORAL PRESENTATION ABSTRACTS

Ventricular Arrhythmia Prevalence and Characteristics for HIV+ Persons and Matched Uninfected Controls

7

Alex Meyer[1], Sanjay Dandamudi[2], Chad Achenbach[3], Frank Pallela[3], Donald Lloyd-Jones[3], Matthew Feinstein[3]

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Type of submitter

Fellow in Training

Abstract

Introduction:

Sudden cardiac death and myocardial fibrosis are common in HIV. No studies to our knowledge have examined the prevalence and morphology of ventricular ectopy or arrhythmia (VEA) for HIV+ versus uninfected persons.

Methods:

We screened 5,041 HIV+ persons and 10,121 uninfected controls (matched 1:2 on demographics and location) at an urban medical center between 2000 and 2016 for VEA using administrative codes. We then reviewed electrocardiographic data to determine (1) whether VEA were present, and (2) VEA morphology (left or right bundle and inferior or superior axis). Prevalence and morphology of VEA were compared by HIV status and markers of HIV severity.

Results:

Of 5041 HIV+ persons, 139 (2.8%) had VEA vs. 165 out of 10121 (1.6%) for controls ($p<0.001$). This association persisted after adjustment for demographics (Odds Ratio [OR] 1.53, 95% Confidence Interval [CI] 1.21-1.94) but was attenuated to non-significance after adjustment for diabetes and hypertension. Compared with HIV+ persons with nadir CD4≥200 cells/mm^3, those with nadir CD4<200 cells/mm^3 had significantly elevated odds of VEA after adjustment for demographics, diabetes, and hypertension (OR 1.65, 95% CI 1.12-2.31). Likewise, each $\log_{10}$ higher peak HIV viral load was associated with a significantly elevated odds of VEA (OR 1.24, 95% CI = 1.07-1.44) after adjustment for demographics, hypertension, and diabetes. Right bundle, superior axis morphology was somewhat more common among HIV+ versus uninfected persons, but this did not reach statistical significance ($p = 0.092$).

Conclusions:

VEA is more common among HIV+ persons but this was attenuated after adjustment for CVD risk factors. Greater HIV viremia and immunosuppression are associated with greater odds of VEA. Compared with uninfected persons, HIV+ persons may more commonly have VEA originating from the left ventricular myocardium, suggesting abnormal myocardial substrate rather than idiopathic outflow tract arrhythmia.

Categories

1st year Fellow: Research

Program/Institution Name

Ohio State University Hospital

Virtual Visits in Cardiac Electrophysiology: Patient and Physician Preference

55

Peter Hu, Henry Hilow, Divyang Patel, Megan Eppich, Khaldoun Tarakji

Cleveland Clinic

Type of submitter

Fellow in Training

Abstract

Background: Cardiologists have long utilized devices to follow patients with arrhythmias in order to guide management. Virtual visits have been adopted as one modality to follow-up established patients with arrhythmias. Factors contributing to patient and physician preferences with virtual visits are unknown. To our knowledge, there are no prior studies that have collected objective feedback from patients and physicians after virtual visits.

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Categories

3rd year Fellow: Research

Program/Institution Name

Cleveland Clinic Foundation