

Outcomes Registry for Cardiac Conditions in Athletes

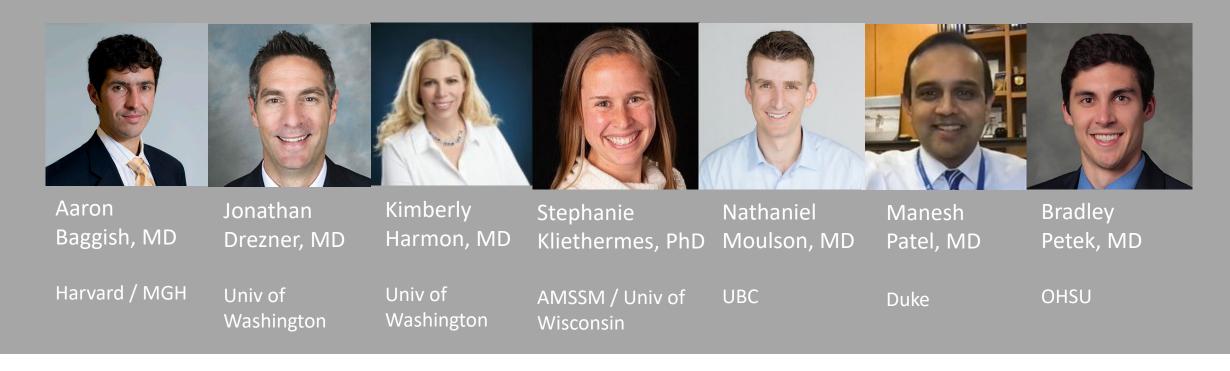
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Outcomes Registry for Cardiac Conditions in Athletes (ORCCA Registry)







HARVARD MEDICAL SCHOOL TEACHING HOSPITAL CENTER FOR SPORTS CARDIOLOGY





Corrigan Minehan Heart Center



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OUTCOMES REGISTRY FOR CARDIAC CONDITIONS IN ATHLETES

Circulation

ORIGINAL RESEARCH ARTICLE

SARS-CoV-2 Cardiac Involvement in Young Competitive Athletes

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BACKEROUND: Cardiac involvement among hospitalized patients with severe coronavirus disease 2019 (COVID-19) is common and associated with adverse outcomes. This study aimed to determine the prevalence and clinical implications of COVID-19 cardiac involvement in young competitive athletes.

METHODS: In this prospective, multicenter, observational cohort study with data from 42 colleges and universities, we assessed the prevalence, clinical characteristics, and outcomes of COVID-19 cardiac involvement among collegiate athletes in the United States. Data were collected from September 1, 2020, to December 31, 2020. The primary outcome was the prevalence of definite, probable, or possible COVID-19 cardiac involvement based on imaging definitions adapted from the Updated Lake Louise Imaging Criteria. Secondary outcomes included the diagnostic yield of cardiac testing, predictors for cardiac involvement, and adverse cardiovascular events or hospitalizations.

RESULTS: Among 19 378 athletes tested for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, 3018 (mean age, 20 years [SD, 1 year]; 32% female) tested positive and underwent cardiac evaluation. A total of 2820 athletes underwent at least 1 element of cardiac trial utesting (12-least ECG, troponin, transthoracic echocardiography) followed by cardiac magnetic resonance imaging (CMR) if clinically indicated. In contrast, primary screening CMR was performed in 198 athletes. Abnormal findings suggestive of SARS-CoV-2 cardiac involvement were detected by ECG (21 of 2999 [0.7%)), cardiac troponin (24 of 2719 [0.9%)), and transthoracic echocardiography (24 of 2556 [0.9%]). Definite, probable, or possible SARS-CoV-2 cardiac involvement was identified in 21 of 3018 (0.7%) athletes, including 15 of 2820 (0.5%) who underwent clinically indicated CMR (m=119) and 6 of 198 (3.0%) who underwent primary screening CMR. Accordingly, the diagnostic yield of CMR for SARS-CoV-2 cardiac involvement was 4.2 times higher for a clinically indicated CMR (15 of 119 [12.9%)) versus a primary screening CMR (6 of 198 [3.0%)). After adjustment for race and sex, predictors of SARS-CoV-2 cardiac involvement included cardiopulmonary symptoms (odds ratio, 3.1 [95% CL, 1.2, 77]) or at least 1 abnormal triad test result (odds ratio, 37.4 [95% CL, 1.3, 105.3)]. Five (0.2%) athletes required hospitalization for noncardiac complications of COVID-19. During clinical surveillance (median follow-up, 113 days [Interquartile range==00 146]), there was 1 (L0.3%) adverse cardiac event, likely unrelated to SARS-CoV-2 infection.

CONCLUSIONS: SARS-CoV-2 infection among young competitive athletes is associated with a low prevalence of cardiac involvement and a low risk of clinical events in short-term follow-up.

Key Words: athletes = COVID-19 = myocarditis = return to sport = SARS-CoV-2

ORCCA Phase 1 Goals and Milestones

Objective: Study of Acquired Cardiac Pathology following SARS-CoV-2 Infection

Incidence & Implications of SARS-CoV-2 cardiac complications Moulson Circ 2021, Petek Circ 2022 (1-year f/u)

Prevalence of "Long COVID" in NCAA Athletes Petek BJSM (2021)

Diagnostic approaches to cardiac SARS-CoV-2

Moulson JAHA 2022, Petek J. Electrocardiol. 2022,

Yield and Pitfalls of Large-Scale Screening

Petek JACC Imaging 2022, Petek JASE 2022, Klein Heart 2023



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Journal of the American Heart Association

PROTOCOL

Rationale and Design of the ORCCA (Outcomes Registry for Cardiac Conditions in Athletes) Study

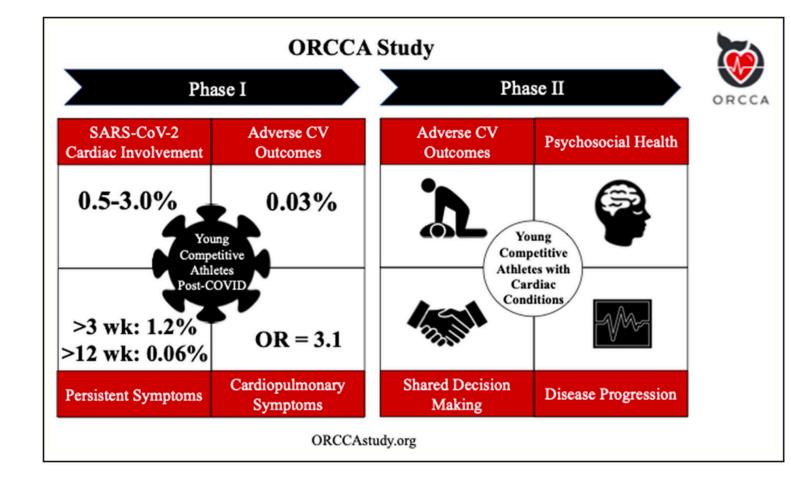
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BACKGROUND: Clinical practice recommendations for participation in sports and exercise among young competitive athletes with cardiovascular conditions at risk for sudden death are based largely on expert consensus with a paucity of prospective outcomes data. Recent guidelines have taken a more permissive approach, using a shared decision-making model. However, the impact and outcomes of this strategy remain unknown.

METHODS: The ORCCA (Outcomes Registry for Cardiac Conditions in Athletes) study is a prospective, multicenter, longitudinal, observational cohort study designed to monitor clinical outcomes in athletes with potentially life-threatening cardiovascular conditions. The study will assess sports eligibility decision-making, exercise habits, psychosocial well-being, and long-term cardiovascular outcomes among young competitive athletes with cardiovascular conditions. Competitive athletes aged 18 to <35 years diagnosed with a confirmed cardiovascular condition or borderline finding with potential increased risk of major adverse cardiovascular events are eligible. Outcomes will be monitored for an initial 5-year follow-up period or until age 35, and metrics of psychosocial well-being and composite adverse cardiovascular events including arrhythmias, sudden cardiac arrest/sudden cardiac death, and evidence of disease progression will be compared among athletes who continue versus discontinue competitive sports participation.

CONCLUSIONS: The ORCCA study aims to assess the process and results of return to sport decision-making and to monitor major adverse cardiovascular events, exercise habits, and the psychosocial well-being among young competitive athletes diagnosed with confirmed cardiovascular conditions or borderline findings with potential increased risk of major adverse cardiovascular events. The results of this work will generate an evidence base to inform future guidelines.

Key Words: athletes a cardiovascular disease a shared decision making a sudden cardiac arrest





Background

- 1. Prevalence of most "high-risk" CV conditions far exceeds contemporary incidence of SCA among young athletes
- 2. Most key conditions associated with SCA exist along a phenotypic spectrum
- 3. Disqualification of young competitive athletes has important implications for long-term health and wellness

No definitive long-term outcomes data to support contemporary practice



Primary Aim:

 Assess the Cardiovascular (CV) outcomes in young competitive athletes with CV conditions with potential increased risk of major adverse CV events who elect to continue or discontinue participation in organized sport

Study Design:

• Prospective, multicenter, longitudinal, and observational study



Key Secondary Aims:

- 1. Process and outcome of competitive sport eligibility decisions
- 2. Physical activity and exercise habits (volume and intensity)
- 3. Psychological impacts including depression, anxiety, and quality of life of living with a cardiovascular condition
- 4. Rates and magnitude of disease progression
- Changes to or implementation of a specific emergency action plan including personnel training and automated external defibrillator (AED) availability



Enrollment Criteria

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Enrollment Criteria

Age 18 to <35 at the time of enrollment

Eligible cardiac diagnosis or eligible borderline finding (diagnosed at any time)

Participating in competitive sport (collegiate, semi-professional, professional, elite, national) at time of enrollment or within the last 2 years, including athletes that returned to sport, stopped voluntarily, or were excluded from sport



Pathologic Cardiovascular Conditions

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Competitive athletes* ages 18 to <35 years old diagnosed with one of the following:

Pathologic Cardiovascular Condition

- Cardiomyopathy
- Primary electrical disease including the cardiac channelopathies or unexplained sudden cardiac arrest

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- Myocarditis
- Coronary artery disease/anomaly
- Congenital heart disease**
- Valvular heart disease+
- Aortopathy



OUTCOMES REGISTRY FOR CARDIAC CONDITIONS IN ATHLETES

Pathologic Cardiovascular Conditions

Condition	Definition
Primary electrical disease	Inherited genetic abnormalities of the cell ionic and electrical functions or electrical system structural abnormalities leading to an increased risk for cardiac arrhythmias and sudden cardiac death
Congenital heart disease	Moderate or greater complexity of adult congenital heart disease per the 2018 American College of Cardiology/American Heart Association Adult Congenital Heart Disease Guidelines (<u>excludes isolated small ASD/VSD,</u> <u>patent foramen ovale, repaired ASD/VSD without residual</u> <u>shunt, repaired patent ductus arteriosus</u>).
Valvular heart disease	Primary structural abnormality (bicuspid, prolapse, myxomatous, congenital, or rheumatic) with moderate or greater regurgitation/stenosis or other associated abnormality (ie, bicuspid aortic valve with aortopathy or mitral valve prolapse with mitral annular disjunction)
Aortopathy	Known inherited diagnosis at risk for aortic dissection (eg, Marfan Loeys-Dietz) or <u>absolute aortic dimension</u> ≥45mm in men or ≥40mm in women



Pathologic Cardiovascular Conditions

Athletes with cardiovascular conditions outlined in the inclusion criteria, but who have <u>undergone procedural</u> <u>treatment</u>, including "curative" procedures such as <u>cardiac</u> <u>ablation</u> (eg, accessory pathway modification) and <u>valvular replacement</u>, or the <u>placement of internal cardiac</u> <u>devices such as a permanent pacemaker or implantable</u> <u>cardioverter-defibrillator</u>, are also eligible for enrollment.



OUTCOMES REGISTRY FOR CARDIAC CONDITIONS IN ATHLETES

Borderline Findings with Potential Risk for Major Adverse Cardiovascular Events

Competitive athletes* ages 18 to <35 years old diagnosed with one of the following:

Borderline findings with potential risk for major adverse cardiovascular events

- Markedly abnormal ECG++ per the International Criteria with normal cardiac imaging^A
- Isolated left ventricular hypertrophy (14-16 mm M, 13-14 mm F)
- Isolated aortic dilatation (40-44 mm M, 34-39 mm F)
- Subclinical ventricular scar or late-gadolinium enhancement on CMR[^]
- Non-compacted LV myocardium with concerns for underlying cardiomyopathy
- Genotype positive/phenotype negative for known pathologic variant of genetic cardiomyopathy or channelopathy
- Unexplained reduction in resting LVEF (45-50%)***
- Clinically significant premature ventricular contractions (PVCs)+++



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Borderline Findings with Potential Risk for Major Adverse Cardiovascular Events

Finding	Definition
Subclinical ventricular scar or late gadolinium enhancement on cardiac magnetic resonance	Excluding isolated right ventricular insertion point late gadolinium enhancement and isolated papillary muscle fibrosis.
Unexplained reduction in resting left ventricular ejection fraction (45%–50%)	Left ventricular ejection fraction as defined on transthoracic echocardiogram and in athletes <u>not</u> participating in an endurance or high dynamic team sport.
Clinically significant PVCS	Frequent PVCs requiring clinical follow-up consisting of either (1) >2000 in 24 hours of non-outflow tract or non-fascicular morphology/origin, or (2) >10000 in 24 hours of outflow tract or fascicular morphology/origin.

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Outcomes Registry for Cardiac Conditions in Athletes (ORCCA) – Phase 2

Aim: To monitor clinical outcomes in competitive athletes diagnosed with cardiovascular conditions

Inclusion criteria:

- Competitive athlete age 18-30
- Cardiovascular diagnosis
- Returned to sport or stopped/excluded

Case identification and enrollment:

- Sports medicine
- Cardiology
- Athletic trainer
- Team physicians
- Partnering institutions / Specialty centers

Data collection for Eligible Athletes:

- Survey/interview → REDCap database
- Direct data capture → REDCap database
- Medical records → REDCap database

Instruments and Outcome Measures

Pathologic Cardiac Disorder

AND Cardiomyopathy/Myocarditis Primary electrical disease Coronary artery disease/anomaly Valvular heart disease/aortopathy

Submit Athlete Information Care Team Member Athlete

ORCCAstudy.org

Initial enrollment

Socioeconomic determinants Diagnostic testing/SDM CV symptoms/Adverse events Exercise habits/participation Psychosocial health

Borderline Findings

OR Abnormal ECG with normal imaging LVH (14-16mm M, 13-14mm F) Aortic dilatation (40-44mm M, 34-39mm F) Subclinical ventricular scar or LGE on CMR LVNC with concerns for cardiomyopathy Genotype +/Phenotype - cardiac condition

Eligibility Assessment/Consent

Telephone / email contact e-Consent / UW REDCap Medical record review

Every 6 months

New diagnostic testing CV symptoms Adverse events Exercise habits/participation Psychosocial health

Long-term SCA/SCD Arrhythmias Mental health Quality of Life

Demographics, sports participation, SDM survey, MACE, EAP survey Global Physical Activity Questionnaire (GPAQ) PROMIS, GAD-7, PHQ-9



ORCCA: Canada





Centre for Cardiovascular Innovation

Centre d'Innovation Cardiovasculaire

- Enrollment of Canadian Athletes through SCBC/UBC
- Goal:
 - 1. Enrollment Jan. 2024 for BC patients
 - 2. Expansion to include across Canada enrollment mid 2024

Contact: Rebecca Mate (<u>rebecca.mate@vch.ca</u>) Website: <u>https://orccastudy.org</u>

Questions?