The Canadian Cardiac
Chronicle

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If Winter comes, can Spring be far behind? *Percy B. Shelley*

It has been a long, hard winter of lockdowns, physical distancing, and social isolation. But as the days get longer and the first signs of spring appear, the hope for some return to normalcy grows. As of this writing, over 11 million Canadians have received at least one dose of the vaccine. The numbers of people getting vaccinated in the United States are even more impressive. Despite these promising signs, COVID-19 continues to wreak havoc on our health system and we once again salute the efforts, and admire the resilience, of the healthcare workers who are at the forefront of the battle against this epidemic.

We are likely going to be studying the impact of COVID-19 well into the future. As described in this edition of the Chronicle, the CVC is actively involved in the Multi-Organ Imaging with Serial Testing in COVID-19 infected patients (MOIST) Study (PI: Dr. Ian Paterson), which will shed light on the extent and time-course of multi-organ involvement in the disease. Work is also underway as part of the Canadian Institutes of Health Research (CIHR) funded Improving Canadian Outcomes Research On the Novel SAR-CoV-2 using Analytics: the CORONA Consortium (PIs: Drs. Douglas Lee and Finlay McAlister). One of the study's objectives is to use artificial intelligence machine learning (AIML) methods to identify people who are likely to test positive for COVID-19, and to identify patients at a higher risk of mortality among those who tested positive in Ontario and Alberta. The study is linking public health COVID-19 screening data with healthcare administrative data in the two provinces.

Healthcare administrative data include, among others, data on hospitalizations, outpatient visits, pharmaceutical dispenses, and laboratory tests in each province. At present, the CVC's population-health data repository contains longitudinal data on all patients diagnosed with cardiovascular disease in Alberta over the last two decades. As highlighted in the Featured Publications section, Dr. Kevin Bainey has recently used these data to examine the impact of invasive versus conservative management on long-term outcomes in patients with stable ischemic heart disease who have high-risk coronary anatomy, a question that has not yet been addressed in the context of clinical trials. Our faculty and trainees continue to use these population-level data to examine practice and policy relevant questions. Other recent examples include our examination of differences in the way men and women with myocardial infarction are managed and how it impacts their risk of developing heart failure; the impact of drug-drug interactions in patients with atrial fibrillation; and our estimation of the proportion of patients with acute coronary syndromes who would be potentially eligible for PCSK9i therapy in Alberta.

Despite the pandemic, CVC is growing, adding new projects and people. Enrollment into the EMPAgliflozin on hospitalisation for heart failure and mortality in patients with aCuTe Myocardial Infarction (EMPACT-MI) trial has begun at eight Canadian sites. I would also like to take this opportunity to introduce five additions to the CVC family: Christina Williams (CRA), Kaitlynn Braulio (Regulatory Specialist), Carlene Morrison (CRA), Kevin Challacombe (Research and Data Coordinator) and Hena Qureshi (Senior Health Economist).

And speaking of families, May 9th is Mother's Day in Canada and I would like to end by sending warm wishes to all the moms in CVC's immediate and extended family! Glimpses of your children (both the 2-legged and 4-legged variety) as they photobombed zoom meetings, has definitely been one of the positive consequences of the transition to working from home during the pandemic. We appreciate all your hard work as you juggle work and childcare responsibilities in these challenging times.

Warm wishes,

Padma Kaul

Dr. Padma Kaul
CVC Co-Director

STREAM-2

There is continuing interest in the outcomes of this trial designed to determine efficacy and safety of early fibrinolytic treatment, with half-dose tenecteplase and additional antiplatelet and antithrombin therapy, in subjects with acute ST-elevation myocardial infarction. Our steady enrollment continues to bring us closer to reaching our target enrollment goal and obtaining insights on care for STEMI patients.

Data entry is an integral part of clinical research and STREAM-2 is not an exception. We encourage our local team to continue to pay special attention to details to ensure that all appropriate data is collected. Thank you for keeping your data up to date!

If you are interested in further information regarding this trial, please contact Clinical Trial Project Lead Courtney Gubbels at 1-800-707-9098 ext 2 or via email at **courtney.gubbels@ualberta.ca**.

Sponsored by Leuven Research & Development (LRD) at University of Leuven, Belgium, STREAM-2 is a Phase 4 trial on STrategic Reperfusion in elderly patients Early After Myocardial Infarction

ClinicalTrials.gov Identifier: NCT02777580

EMPACT-MI

Startup is well under way! As of mid-April, globally over 65 sites have been activated and 37 patients have been randomized into this study that aims to evaluate the effect of empagliflozin on hospitalization for heart failure and mortality in patients with acute myocardial infarction. This study is being led in Canada by **Dr. Jay Udell** (Women's College Hospital), **Dr. Shaun Goodman** (CVC Co-Director) and **Dr. Shelley Zieroth** (St. Boniface Hospital).

In Canada, we have activated our first eight sites for enrollment. Congratulations to **Dr. Burstein and Anita Andoh** in Scarborough, ON who were the first site activated in Canada and quickly became our top recruiting site. This team is already setting the bar high for this study in Canada! Hats off to **Dr. Bourgeois and Karen Boyd** in Moncton, NB for quickly randomizing the first patient in Canada only three days after being activated!

We look forward to seeing our other activated sites enroll their first patients soon. Meanwhile, we continue to work through start up with the remaining CVC sites, with the goal to have all sites activated and ready to screen/enroll patients by the end of June.

Training reminders:

- It is the PI's responsibility to ensure each person listed on the delegation log is trained before they participate in the trial.
- GCP, HC Div 5 and Protocol Training records are to be maintained for all staff; other considerations for Sub-Is include training on the IB and Event Review Charter.
- All training documentation is to be maintained by the site in the event of an audit.

For questions about EMPACT-MI, please contact Jodi Parrotta, Clinical Trials Project Lead/QA-Regulatory Compliance Lead at 1-800-707-9098, ext. 3 or via email at **Jodi.Parrotta@ualberta.ca**.

Sponsored by Boehringer Ingelheim, EMPACT-MI is a phase III, stream-lined, multicentre, randomised, parallel group, double-blind, placebo-controlled, superiority trial to evaluate the effect of Empagliflozin on hospitalization for heart failure and mortality in patients with acute myocardial infarction.

ClinicalTrials.gov Identifier: NCT04509674

The Canadian Cardiac Chronicle

SODIUM-HF

Recruitment is now closed and we wish to extend a sincere thank you to all sites for their stellar efforts!

For sites participating in the long-term follow up substudy, approximately a third of eligible patients have been approached to date. Given these challenging times, it is more important than ever to contact your patients ASAP so keep up the great work!

Reminder:

- We cannot have any LTFU patients in this trial! Every patient counts, so the expectation is for sites to search for all potentially LTFU patients until database lock. Thank you for your continued diligence in this regard.

For general study updates and news, follow us on Twitter @sodiumhf.

If you have questions about the SODIUM-HF trial, please contact the Clinical Trials Project Lead, Karin Kushniruk at at 1-800-707-9098, ext. 7 or **karin.kushniruk@ualberta.ca.**

SODIUM-HF

Funded by the Canadian Institute of Health Research (CIHR) and University Hospital Foundation, SODIUM-HF is a multicenter, randomized, open-label **S**tudy **O**f **DI**etary Intervention **U**nder 100 **M**MOL in **H**eart **F**ailure.

ClinicalTrials.gov Identifier: NCT02012179

AEGIS-II

Thank you to everyone involved with AEGIS-II for your ongoing engagement and dedication as we continue to be faced with challenges related to COVID-19. Along with the safety of all AEGIS-II patients, our focus continues to be on enrolling the right patients, retention of those patients, and ensuring that the quality of the data is top notch.

Data quality and data clean metrics are a high priority at this time. With an upcoming analysis of the data, we ask that all sites review the eCRF daily for new queries or missing/overdue items and ensure that these exceptions are resolved within 2 days.

Almost all of our sites have now been re-activated for enrollment following the COVID-19 hold, and of those reactivated sites ¾ of them have enrolled at least one new patient. With thanks to your hard work, the first few months of 2021 produced monthly enrollment numbers that were close to those pre-pandemic!

If a patient has missed a visit, is contemplating IP discontinuation or consent withdrawal, please contact CVC immediately to ensure that the appropriate processes are followed. PI involvement in each of these situations is very important and should be documented in your source.

Lost to Follow Up patients should be extremely rare, and the expectation is that if a patient cannot be reached at any protocol-specified visit timepoint, you must continue to attempt to locate the patient through to the end of the study and database lock.

We continue to conduct monitoring visits remotely at this time. We appreciate your patience and flexibility with this process.

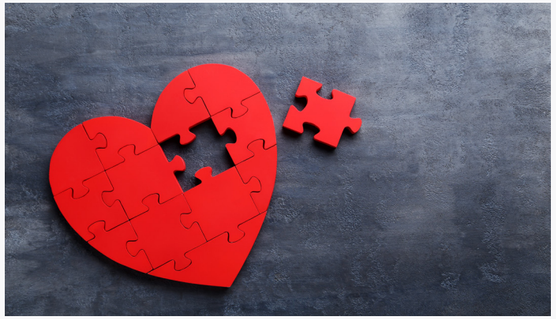
AEGIS-II is a large, international, multicentre Phase 3 trial of infusing an intravenous formulation of apolipoprotein A-I (CSL112) to reduce cardiovascular events in acute coronary syndrome patients. CSL112, an intravenous formulation of apoA-I, enhances cholesterol efflux capacity, and therefore has the potential to reduce plaque burden, stabilize plaque lesions at risk of rupture and decrease the high rate of early recurrent events.

If you are interested in further information regarding this trial, please contact Clinical Trial Project Lead, Lyndsey Garritty at 1-800-707-9098, ext 4 or via email at **lyndsey.garritty@ualberta.ca.**

Sponsored by CSL Behring LLC, this is a Phase 3, Multicentre, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Investigate the Efficacy and Safety of CSL112 in Subjects with Acute Coronary Syndrome.

ClinicalTrials.gov Identifier: NCT03473223

HEART-FID



Thank you to all of our sites for your enrollment contributions! Each one of you is helping bring us closer to our global enrollment goal of 3014 randomized patients. We are now in the final months of recruitment with our target to complete enrollment in September 2021. We wish to encourage you to redouble your efforts to ensure we reach our objective by the fall!

Protocol Amendment

A new Protocol Amendment was recently released and REB submissions are currently underway. As enrollment is nearing completion, we encourage you to complete your REB submission as soon as possible. We would like to activate your site on the new Amendment as soon as next month. Please ensure you send your edited Informed Consent Form(s) to CVC for review prior to REB Submission. Training WebEx's are scheduled and invites have been sent. Please join the training WebEx that is convenient for you and your team.

Sub-Study

With new operational changes providing the option of on-site visits, we expect to see a positive response to sub-study enrollment in Canada. For those sites participating in the sub-study, please continue to offer all eligible participants a choice to participate. We hope to see all participating sites with an enrolled participant this quarter.

Covance Lab Transfer to ALMAC

A reminder of the lab upload process:

- It can take up to 7 days for labs to be processed at Covance and then uploaded to ALMAC
- Unblinded staff need to review the unblinded labs in ALMAC before the participant attends the clinic
- Escalate any issues to CVC as soon as possible. Correcting importing issues is a lengthy process and it make take up to 2 days to resolve.

Following the steps above can ensure that your participant's dosing visit runs smoothly.

If you are interested in further information regarding this trial, please contact Clinical Trial Project Lead Courtney Gubbels at 1-800-707-9098 ext 2 or via email at **courtney.gubbels@ualberta.ca**.

Sponsored by American Regent, HEART-FID is a Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Injectafer® (Ferric Carboxymaltose) as Treatment for Heart Failure With Iron Deficiency

ClinicalTrials.gov Identifier: NCT03037931

FEAST-HF

Thank you to our 3 Alberta sites for continued enrollment during these challenging times – we are over a third of the way towards our recruitment goal. Keep up the great work!

Got Fiber?

Recent attention has been focused on the role of the gut microbiome in human disease, including its significant role in the pathogenesis of heart failure. Several small studies have shown an interplay between the microbiome and heart failure, and that the gut microbiome can be modulated by dietary interventions, such as the addition of dietary fiber. This trial will explore if modification of the microbiome can mitigate the symptoms of patients with heart failure and whether new avenues for treatment and future research for patients with heart failure will be revealed.

If you are interested in further information about the FEAST-HF trial, please contact the Clinical Trial Project Lead, Karin Kushniruk, at 1-800-707- 9098, ext. 7 or **karin.kushniruk@ualberta.ca**.

Sponsored by University Hospital Foundation and Weston Family Microbiome Initiative, FEAST-HF trial will explore the potential beneficial effects of dietary fiber supplementation, compared with placebo, in patients with Heart Failure

ClinicalTrials.gov Identifier: NCT03409926

MAP-AHF

The **M**RI **A**ssessment of **P**ulmonary Edema in **A**cute ***H***eart **F**ailure study is a single-centre project taking place at the University of Alberta Hospital / Mazankowski Alberta Heart Institute in collaboration with the Peter S. Allen MR Research Centre.

Study recruitment is currently on hold due to the COVID-19 pandemic, but we look forward to seeing it resume in the near future.

Cardiogenic pulmonary edema is a cardinal sign of acute heart failure and is a cause of the primary heart failure symptom, shortness breath, which is most commonly treated with diuretic therapy. While increased lung water is typically reported descriptively (i.e., auscultation and/or chest x-ray), these measures are not sufficiently sensitive to exclude pulmonary congestion.

Further research is needed to a) determine changes is Lung Water Density (i.e., quantification of pulmonary edema on MRI) over the course of hospitalization and standard treatment of Acute Heart Failure, and b) explore whether Lung Water Density is predictive of long term outcomes in the Acute HF population.

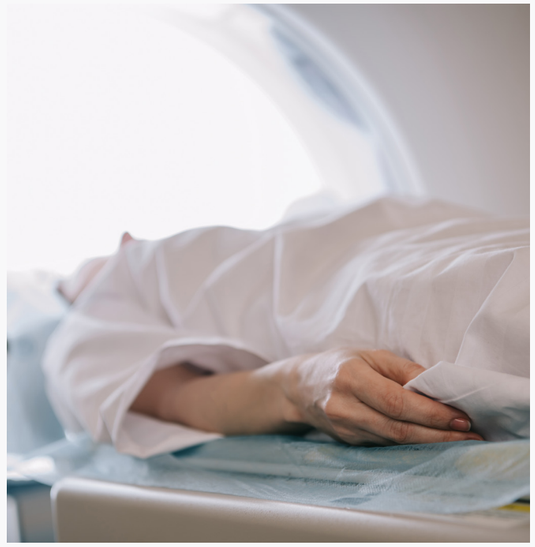
If you are interested in further information about the MAP-AHF study, please contact the Clinical Trial Project Lead, Karin Kushniruk, at 1-800-707- 9098, ext. 7 or **karin.kushniruk@ualberta.ca**.

MAP - AHF

Sponsored by: Canadian Institutes of Health Research MAP-AHF will examine the changes in lung water density over the course of treatment in patients hospitalized for acute heart failure, and will explore whether changes in lung water levels can predict long term outcomes.

ClinicalTrials.gov Identifier: NCT03999138

MOIST Study



Congratulations to **Dr. Ian Paterson and his team** on their very swift recruitment into the **M**ulti-**O**rgan **I**maging with **S**erial **T**esting in COVID-19 infected patients (MOIST) study! We are in the process of expanding the study to the Calgary area and look forward to study completion later this year.

Patients with COVID-19 infection are at significant risk of deterioration from pulmonary and extra-pulmonary causes and the long-term consequences of these abnormalities are unknown. Systemic inflammation is considered a central feature of disease pathogenesis, however, the respective extent and time-course of multi-organ involvement (heart, lungs, brain and liver) has not yet been evaluated. Furthermore, their respective and combined impact on patient morbidity and mortality has not been assessed.

Using novel MRI pulse sequences, the MOIST Study aims to assess the presence, extent and time course of inflammation in the heart, lungs, brain and liver of participants with new or recent COVID-19 infection.

If you are interested in further information about the MOIST Study, please contact the Clinical Trial Project Lead, Karin Kushniruk, at 1-800-707-9098, ext. 7 or **karin.kushniruk@ualberta.ca.**

Sponsored by Canadian Institute of Health Research, the MOIST Study will assess the presence, extent and time course of inflammation in the heart, lungs, brain and liver of participants with new or recent COVID-19 infection.

ClinicalTrials.gov Identifier: NCT04525404

SONOSTEMI-LYSIS

The **SONO**thrombolysis in patients with an **ST**-segment **E**levation **M**yocardial Infarction with fibrino**LYSIS** (SONOSTEMI-LYSIS) Trial is a single-centre project taking place at the University of Alberta Hospital / Mazankowski Alberta Heart Institute. Congratulations to **Dr. Kevin Bainey and his team** for a successful start to recruitment earlier this year!

While prompt reperfusion therapy has been shown to reduce mortality, infarct size and improve left ventricular function in patients with STEMI, reperfusion itself may result in adverse events such as reperfusion injury. In patients with STEMI receiving fibrinolysis therapy, this study will explore whether the addition of sonothrombolysis (i.e., high mechanical index impulses during diagnostic ultrasound) to standard care results in enhanced myocardial perfusion, improved left ventricular function, and better clinical outcomes. If you are interested in further information about the SONOSTEMI-LYSIS study, please contact the Clinical Trial Project Lead, Karin Kushniruk, at 1-800-707- 9098, ext. 7 or karin.kushniruk@ualberta.ca.

SONOSTEMI-LYSIS will explore if the addition of sonothrombolysis to standard care in patients with STEMI receiving fibrinolysis therapy results in improved outcomes.

ClinicalTrials.gov Identifier: NCT04217304

FDA Approval of Vericiguat

VICTORIA was a large randomized placebo-controlled, double-blind, event-driven, multi-center pivotal phase III clinical outcome trial of efficacy and safety of a novel oral sGC simulator vericiguat in patients with heart failure with reduced ejection fraction (HFrEF). A total of 5,050 patients were enrolled in the study at more than 600 centers in 42 countries.

This study focused on patients with HFrEF who were at high risk of death or hospitalization from heart failure. The study was led collaboratively by the Canadian VIGOUR Centre and Duke Clinical Research Institute, and co-sponsored by Merck & Co, Inc. and Bayer AG. Dr. Paul Armstrong served as Chair of the VICTORIA Study.

In January 2021, Merck announced the U.S. Food and Drug Administration approval of vericiguat for use in patients with heart failure. Regulatory approvals by Bayer and Merck are actively underway in other countries and regions, including Canada.

This accomplishment is the result of the collaborative team efforts of so many including the participating sites (many of whom are regular Chronicle readers), the patients who volunteered, the study committees, the study leadership at the CVC, our academic partners at DCRI as well the two sponsors. CVC is gratified that this new therapeutic option will address a key unmet need in patients with heart failure and a recent worsening event. Because of its novel mechanism of action through the nitric oxide-soluble guanylate cyclase- guanosine monophosphate pathway, we anticipate it will likely also open a door to the exploration of new cardiovascular indications.

Visit thecvc.ca/victoria to view the press releases, media, scientific publications, patient information and more.

Dr. Padma Kaul - Heart & Stroke Chair, Cardiovascular Research

The CVC is proud to recognize Dr. Padma Kaul's recent appointment as the Heart & Stroke Chair in Cardiovascular Research.

In this role, Dr. Kaul will be responsible for being a leader in the development of cardiovascular research in Alberta along with developing and maintaining a world-class cardiovascular research program at the University of Alberta including advancing data science and its methods.

In addition, Dr. Kaul will work collaboratively with other cardiovascular research groups and centres in Alberta, Canada and around the world to conduct health services and outcomes research. She will also continue to enhance the training and educational capacities of the broader cardiovascular community by working with the Faculty and the Cardiovascular Research Institute.

Congratulations to Dr. Kaul on this well-deserved accomplishment.

The Canadian Cardiac Chronicle

CVC New Staff

Kaitlynn Braulio recently joined the CVC as a Regulatory Specialist. She graduated last spring with a BSc Honours in Psychology from the University of Alberta where she completed her undergraduate thesis under Dr. Dana A. Hayward with the Visual Attention and Social Processes Lab. She comes to us with recent clinical trial experience in oncology from Translational Research in Oncology. In her spare time, Kaitlynn works as a hockey athletic trainer with the Canadian Athletic Club and can usually be found on the bench cheering on her players. Kaitlynn can be reached at 1-800-707-9098, Option 8 or braulio@ualberta.ca.

Kevin Challacombe recently started working as a Research & Data Coordinator with the CVC. Kevin has over fifteen years of experience working in clinical research environments, providing essential data management and database support across the data lifecycle. Prior to his current role at CVC, Kevin worked in a variety of roles including with the Ontario HIV Treatment Network and as the Manager of the University of Alberta Faculty of Nursing's Health Research Data Repository (HRDR). His primary interests are in Good Clinical Practice, Data Privacy and Security and Clinical Datasets/Databases. Kevin can be reached at challaco@ualberta.ca.

Carlene Morrison recently joined the CVC as a Clinical Research Associate. With over 25 years of experience in clinical research, Carlene brings enriched skills as a productive member of the clinical research community including enhanced interpersonal skills to work with sites, thus ensuring regulatory and protocol compliance in the pharmaceutical, biotech and CRO settings. She comes to us with a wealth of experience in all aspects of clinical research from study startup, feasibility, site management, study closeouts as well as project management responsibilities. Carlene's personal interests include painting and walking with her pet. Carlene will be monitoring sites in eastern Canada.

Hena Qureshi recently joined the CVC as a Health Economist. Prior to working at CVC, she worked as a Health Economics and Outcomes Research Manager for AmerisourceBergen Innomar Strategies. Her role was to develop the economic components needed to show the value of a pharmaceutical product to HTA agencies and payers. Hena also worked at the Government of Alberta, Health Economics and Funding Branch. She led a project to identify and profile high-cost users of the healthcare system. Hena graduated from the University of Calgary with an MSc in Health Economics, and also holds a BSc in Biological Sciences and a BA in Economics. Her research interests and experience are in budget impact analysis, pharmacoeconomic evaluations, systematic literature reviews, and pharmaceutical drug reimbursement. Hena can be reached at hena1@ualberta.ca.

Christina Williams recently started working as a Clinical Research Associate with the CVC. She has over 20 years of clinical research experience with experience ranging from patent management and manufacturing, protocol writing, through Phase I-IV studies, and final study report writing. Christina is based in British Columbia and will be monitoring sites in western Canada.

8th Annual CVC Clinical Trials Colloquium Series - Virtual

While the pandemic prevented us from gathering face to face for the **8th Annual CVC Clinical Trials Colloquium**, it did open up a new opportunity, via a virtual platform, to expand the invitation to our full network of Canadian sites.

As a brief background, the inspiration for the colloquium evolved in 2014 when the CVC Founding Director, Dr. Paul Armstrong and Associate Director - Clinical Trials, Tracy Temple, brought together 13 Canadian Investigative sites to help: (1) identify major impediments to timely and efficient participation in clinical trials; (2) understand how best to add value to the clinical trial experience; and (3) establish a network of high performing sites across Canada. The colloquium has continued to be an excellent opportunity for CVC, our sponsors, and sites across Canada to connect, collaborate and find solutions to key issues affecting clinical research in Canada.

In our first of three planned virtual sessions for 2021, we welcomed Dr. Adrian Hernandez, Vice Dean and Executive Director at the Duke Clinical Research Institute, Duke University School of Medicine on March 3, 2021 as our keynote speaker to talk with us about Clinical Trials During a Pandemic: What We've Learned and Where we are Headed. He reflected on how COVID-19 has, in many ways, forced us to re-engineer the way trials are being conducted and had us question whether the @home virtual trial experience, with more pragmatic elements, may offer a more convenient, flexible, and personalized approach for patients.

Following Dr. Hernandez' presentation, we broke out into three regional workshops where we discussed challenges encountered during the pandemic and how sites have overcome challenges associated with institutional hurdles, screening, recruitment, patient follow-up and the approach to monitoring visits. We also discussed the site experience in implementing pragmatic approaches during the pandemic and what has been successful during this time or could be trialed moving forward. As always, this was an interactive and fruitful discussion. We always enjoy this opportunity to openly hear from sites across the country. We came away with some really beneficial information and strategies which our team looks forward to helping implement/share and hope that many of our sites who participated were also able to take tips back to their sites/ institution.

We want to thank everyone for the positive response and taking the time to join us for the first session. We are excited about the upcoming **Colloquium Session #2 on May 19, 2021 from 5:00 – 7:00 pm ET (6:00 AT, 4:00 CT, 3:00 MT, 2:00 PT)** where we will be focusing on **Mentoring and Diversity in Clinical Research**. As you will see from the registration poster above, in this next session we look forward to welcoming keynote speaker Dr. Roxana Mehran from the Icahn School of Medicine at Mount Sinai and Co-founder of Women as One along with our moderators and co-moderators who will lead our workshops and discussion.

We look forward to having you join our next session and encourage you to share this invitation with other colleagues and those interested in getting more involved in clinical research. Once you register via the link, a calendar invitation will be sent out with the details to join us on May 19, 2021.

If you have any questions regarding the CVC Clinical Trials Colloquium, please don't hesitate to reach out to Tracy Temple at **tracy.temple@ualberta.ca** or by phone at 780-952-2140.

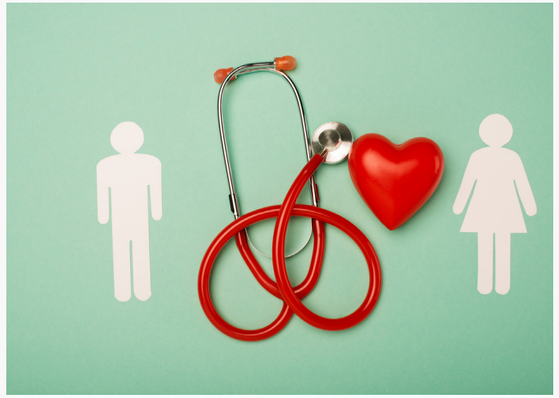
Feature Publications

Drs. Justin Ezekowitz, Ana Savu, Rob Welsh, Finlay McAlister, Shaun Goodman and Padma Kaul recently published their article "Is There a Sex Gap in Surviving an Acute Coronary Syndrome or Subsequent Development of Heart Failure?" in Circulation.

Most studies after myocardial infarction (MI) examining sex differences have focused on mortality or recurrent MI or revascularization; however, heart failure has not been a focus of these reports of outcomes.

In this article, the authors hypothesized that disparities between sexes in the management of MI may have changed over time, and thus altered the prognoses after MI, especially the risk for the development of heart failure. Using a population-based cohort of patients in a single geographic region of 4.3 million people, they examined the outcomes of patients presenting with their first MI, and focused specifically on sex differences in the development of heart failure after MI.

Although some attenuation of differences in clinical outcomes over time has occurred, women remain at higher risk than men of dying or developing heart failure in the subsequent 5 years after ST-elevation myocardial infarction (STEMI) or non-STEMI, even after accounting for differences in



angiographic findings, revascularization, and other confounders. The authors suggest that, given its frequency, further attention should be paid to all patients with acute coronary syndromes for the prevention of future heart failure outcomes.

This research is directly related to Dr. Padma Kaul's role as the CIHR Sex and Gender Science Chair in Diabetes and was featured in the University of Alberta Folio.

Dr. Kevin Bainey

Drs. Kevin Bainey, Wendim Alemayehu, and Rob Welsh, along with their fellow coauthors, recently published their article "Long-Term Clinical Outcomes Following Revascularization in High-Risk Coronary Anatomy Patients With Stable Ischemic Heart Disease" in the Journal of the American Heart Association.

Previous clinical trials have failed to show a reduction in hard clinical endpoints with an early invasive strategy in stable ischemic heart disease (SIHD). However, the influence of left main disease and high-risk coronary anatomy was left unaddressed. Moreover, angiographic disease complexity may be a better predictor of adverse clinical outcome compared with non-invasive metrics of ischemic burden.

In this article, the authors examined whether an association exists between revascularization and clinical outcomes in patients with SIHD with high-risk coronary anatomy using a large angiographic disease-based registry.

Their findings demonstrate that, in a large registry of patients with SIHD with coronary angiography, patients with high-risk coronary anatomy appear to survive longer and have a lower risk of myocardial infarction with revascularization. This data challenges the previous clinical trials findings in patients with high-risk coronary anatomy and should be considered when contemplating revascularization in SIHD.

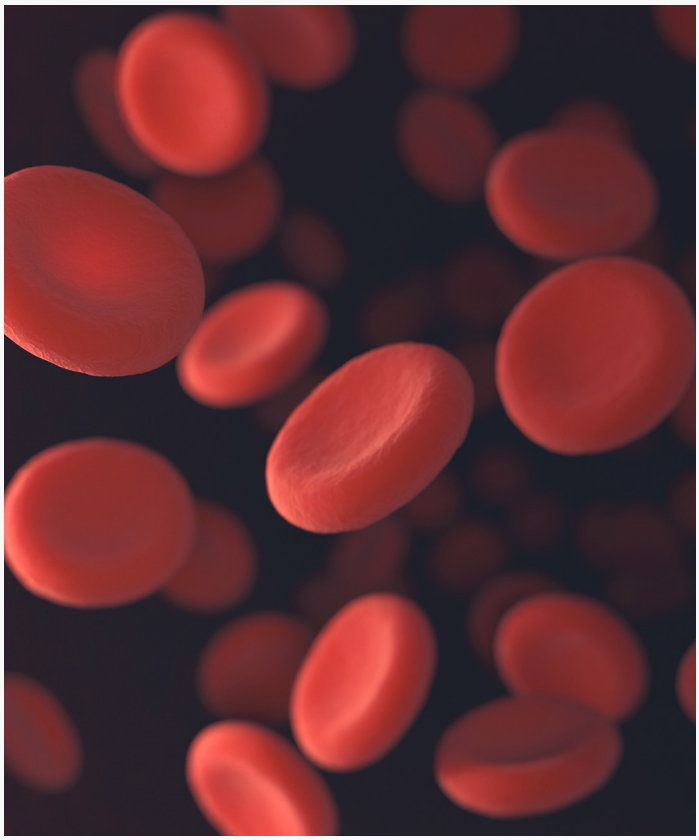
The article was also accompanied by an editorial by Brian A. Bergmark and David A. Morrow, "Beyond the ISCHEMIA Trial: Revascularization for Stable Ischemic Heart Disease in Patients With High-Risk Coronary Anatomical Features".

Feature Publications

Drs. Ana Savu, Kevin Bainey, Robert Welsh and Padma Kaul, along with former CVC trainee, Dr. Debraj Das, recently published their manuscript "Temporal Trends in in-Hospital Bleeding and Transfusion in a Contemporary Canadian ST-Elevation Myocardial Infarction Patient Population" in CJC Open.

Although ST-elevation myocardial infarction (STEMI) management has evolved substantially over the past decade, its effect on bleeding and transfusion rates are largely unknown in a contemporary population. Accordingly, the authors examined temporal trends in bleeding and transfusion in Canadian patients hospitalized with a primary diagnosis of STEMI, and the associations between bleeding, transfusion, and in-hospital mortality.

This study concludes that, despite increases in the number of STEMI episodes over time, the rates of in-hospital bleeding and transfusion have declined in Canada. However, incidence of bleeding and/or transfusion identifies a patient population that is at a significantly higher risk of mortality. Further research is needed to examine the role of cardiac interventions and concomitant medications with bleeding and transfusion in a STEMI population.



Visit the **publication archive** on our website for a comprehensive list of the CVC's publications.

About the Chronicle

This newsletter is published periodically as a service to Canadian investigational sites. The purpose is to provide information of interest to individuals involved in cardiovascular clinical trials managed by the Canadian VIGOUR Centre, University of Alberta in Edmonton, Alberta, Canada.

What did you think of this Chronicle edition?
Send us an email: thecvc@ualberta.ca

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