Family Doctor

A Journal of the New York State Academy of Family Physicians

Fall 2020

Volume nine, Number two

FEATURE ARTICLES:

- What the Family Physician Needs to Know About Adults with Congenital Heart Disease
- Our On-again Off-again Relationship with Aspirin: Where are we now with Cardiovascular Prevention?
- White Coat Hypertension: Diagnosis and Management
- Taking a Collaborative, Community Health Approach to Address Cardiovascular Health

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Cardiovascular Health

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Family Doctor, A Journal of the New York State Academy of Family Physicians, is published quarterly. It is free to members of the New York State Academy and is distributed by mail and email. Non-member subscriptions are available for $40 per year; single issues for $20 each.

New York State Academy of Family Physicians
16 Sage Estate, Suite 202
Albany, New York 12204
www.nysafp.org
Phone: 518-489-8945
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From the Executive Vice President

By Vito Grasso, MPA, CAE

Our advocacy for a universal system of health insurance founded on a single payment system has met significant resistance over the years from various sources including within the Academy. The experience of COVID-19 has exposed the serious deficiencies in our insurance-employer based model of coverage which we have cautioned against for years. Public impressions of the need for systemic reform will certainly be impacted by the COVID-19 experience. Hopefully there will be greater public support for comprehensive reform that will reduce administrative waste and interference with professional medical discretion.

Additionally, failure of our public health system to respond quickly and effectively to the pandemic can and should be attributed to public policies and actions which interfered with application of medical and scientific knowledge and expertise in responding to the crisis. Indeed, actions by government over the years have eroded the independence of medical professionals and interfered with the patient-physician relationship.

Discussion of how social determinants affect health and disparities in health status has been expanded by the explosion in social consciousness emanating from the aftermath of the murder of George Floyd. Effectively addressing social determinants will require societal commitment well beyond the scope of health care professions. We will certainly need to understand how racist impulses have permeated our social fabric. Much behavior which fosters the disparities in opportunity which become social determinants reflect race-based assumptions and stereotypes. We are unlikely to have much success addressing the impact of social determinants on health without significant progress achieving social justice generally.

The effort to correct injustices caused by personal and institutional prejudices will be contentious and will require a long time. Changing attitudes and beliefs is always more challenging than adjusting policies or creating programs to address specific barriers to equal access.

It is difficult to contemplate how we have each contributed to the problem.

Apathy fostered the failure to recognize or address pernicious racism causing economic policies and practices which have effectively limited opportunities for people of color. I would add people with disabling conditions and the elderly to the list of groups that have been harmed by persistent institutional bias and general indifference to the problems of others. Many people dismiss the idea that anything they might consider doing to change attitudes is simply incapable of having an impact. Such an attitude fosters inaction which, in the context of resistance to injustice, constitutes complicity.

NYSAFP is committed to moving forward in pursuing social justice and health system reform. We have created a committee to begin the process of assessing our own ability to be an effective change agent. Our president, Dr. Jason Matuszak, has appointed a task force on diversity, equity and inclusion chaired by Dr. Keasha Guerrier. That group has met and is identifying resources which may be useful in equipping us to better understand the forces which contribute to systemic and personal prejudices and to identify programs and policies which may help us correct or overcome such forces within our own organization and operations. We will benefit from this process and, if we remain committed to it, will devote ongoing attention to how our actions mitigate the historic imbalance in power and wealth which have existed for too long and which continue to impede our progress in realizing the laudable aspiration that the "self-evident" truths that everyone is created equal and is endowed with "unalienable rights" will no longer be withheld from disadvantaged populations within our own society.

Indeed, actions by government over the years have eroded the independence of medical professionals and interfered with the patient-physician relationship.

President's Post

By Jason Matuszak, MD, FAAFP, FMSSM

We have all found ourselves in places both familiar and, simultaneously, alien. For me, it is sitting amongst cardboard Andrew Cuomo and Getty Lee cutouts, listening to "Take Me Out to the Ball Game" and the crack of the bat as a team physician summoned to the majors from AAA ball as the Toronto Blue Jays have found a temporary home in Buffalo. Sports have returned. The NFL is playing. The NHL and NBA are completing their playoffs and, by the time this goes to print, MLB will have started theirs. But, fans sit at home, replaced by avatars.

The spunky oranges and blazing red leaves of autumn have entered their peak across New York and masked children resolutely return to school, reminding us that despite the lunacy of the world right now, there are still glimmers of courage and normalcy and opportunities to breathe deeply and marvel in the splendor of nature and appreciate the tastes of normal life.

Similarly, while COVID-19 has been central in the focus of the nation, in family medicine, we know that we must not be singularly focused. This issue seeks to remind us to take a step back and remember that cardiac causes are still the number one killer in this country. This is particularly timely because as autumn turns into winter, the mortality rate related to cardiovascular causes peaks. And whether it be the healthy 5k runner, the kids with congenital heart disease, the NCAA Division 1 college football player, or the mature adult with poorly controlled hypertension, cardiac disease and death seize the young and old.

Racial disparities persist in hypertension, stroke, and cardiac outcomes, and may be exacerbated by lack of sufficient representation of persons of color in research studies on cardiovascular conditions and a lack of diversity in those performing the research. With advances in data harnessing, such as that seen with tracking exercise and using smartphone apps to improve lifestyle, it is paramount to ensure questions of health equity are addressed. More importantly, though, we also need to determine how lifestyle opportunities and choices affect and are affected by the other social determinants of health.

It is necessary to focus on lifestyle opportunities and choices because the cardiovascular system in general, and the heart specifically, are eminently pliable and adaptable. When a 74-year-old grandmother proudly proclaimed that she finished first in her age group at the Marine Corps Marathon, it was not nearly as surprising as when she told me that she began running at the age of 68. It is never too late to start.

One of the strengths of the family physician is to assimilate new information onto the existing knowledge base. Nowhere is that more important than when dealing with the current public health crisis. Increasingly robust data has demonstrated COVID-19 is a respiratory virus with profound cardiovascular affects, with implications ranging from strokes and blood clots to direct damage to the heart. As an addition to this issue, we have a special invited column examining some of the most current information about the cardiovascular considerations of COVID-19 for the family physician.

This focus on cardiovascular conditions also reminds us about heart- not just the organ, but also the accompanying imagery and the connotations. You, as family physicians, are the heart of medicine. You are the compassion. You are the strength. You are the ferocity that fearlessly fights for the health and wellbeing of your patients, your community, the system and the country. You continue to do this because of your resilience, your spirit and your determination. Like the 86-year-old Ironman athlete I observed doing Hemingwayan battle with the pace car scooping those who lost to the time cut-off with the clock ticking toward midnight, you have been battered and bloodied by the struggle, but it is your heart that will carry you through. And, we will be ever steadfast in support of you in your battle, cheering you and appreciating you.

One of the strengths of the family physician is to assimilate new information onto the existing knowledge base. Nowhere is that more important than when dealing with the current public health crisis.

White Coat Hypertension:
Diagnosis and Management

By Alisa Liu, MD and Arthi Chawla, MD

White coat hypertension (WCH) is defined as elevated in-office blood pressures with normal out-of-office blood pressures in individuals who are not on anti-hypertensive therapy.[1] It is quite common with a prevalence of 23% worldwide.[2] It is prudent to diagnose WCH to avoid the unnecessary cost and adverse effects associated with anti-hypertensives. However, it is important not to dismiss WCH as benign, as it may be associated with increased risk of progression to sustained hypertension and cardiovascular morbidity and mortality.

Although WCH has been extensively researched since it was first reported in 1988, there is variability between studies.[1] The diagnosis, monitoring, treatment, and associated cardiovascular risk of WCH are all controversial. For example, the cutoff values for when to suspect WCH vary among experts. The American College of Cardiology and American Heart Association define WCH as office blood pressures between 130/80 and 160/100 and out-of-office blood pressures of <130/80.[1] In most studies, the cutoff values are ≥140/90 for in-office blood pressures and <135/85 for out-of-office blood pressures.[1]

After WCH is suspected, it is diagnosed with ambulatory blood pressure monitoring (ABPM). There are differing opinions on when to use ABPM after the first instance of elevated in-office blood pressure. Canadian guidelines recommend using ABPM immediately after the first visit for early detection.[1,3] The Task Force of the Eighth International Consensus Conference on Blood Pressure Monitoring does not recommend ABPM until office blood pressures are ≥140/90 on 3 separate occasions and ≥2 out-of-office blood pressures are <140/90.[4] This accounts for blood pressure variability, as the blood pressure of patients with mild elevation at their first visit decreases by an average of 15/7 by their third visit.[4]

Traditionally WCH was thought to be benign, however patients with WCH have a higher risk of sustained hypertension than normotensive individuals.[1] ABPM can also be used to monitor progression of WCH to sustained hypertension. Risk factors include older age, high-normal daytime blood pressure, and nighttime blood pressure elevation which is often seen with obstructive sleep apnea, diabetes mellitus, and chronic kidney disease.[4] The European Society of Hypertension Working Group

on Blood Pressure Monitoring recommend using ABPM 3-6 months to reconfirm after initial diagnosis, and then annually to monitor for progression to sustained hypertension.[4] In contrast, the National Institute for Health and Care Excellence do not endorse follow-up or monitoring at all.[1]

There is increasing evidence that WCH is associated with target organ damage. A meta-analysis of 25 studies including 7382 individuals with normotension, WCH, and untreated hypertension showed that WCH is associated with increased left ventricular mass index, decreased mitral E/A ratio (the ratio of early (E) to late (A) peak of mitral inflow velocity, a measure of left ventricular diastolic function), and larger left atrial diameter intermediate between normotensive and hypertensive patients.[5] The pathogenesis is likely increased sympathetic activity, which has been documented in WCH.[1,6] WCH is also associated with microalbuminuria and elevated cystatin C, which are markers for renal damage.[7] Even transient stress-induced elevations in blood pressure may induce pathologic remodeling.[5]

Although it is becoming increasingly apparent that WCH is associated with target organ damage, it is less clear whether this leads to an increased rate of cardiovascular events, and whether this is attributable to WCH alone or independent risk factors. In a meta-analysis of 27 studies including 25,786 people with WCH or WCE (white coat effect) and 38,487 people with normotension or controlled hypertension, WCH was associated with an increased risk of coronary artery disease, myocardial infarction, peripheral arterial disease, and hospitalization for congestive heart failure.[8] Interestingly, WCH has not been associated with stroke. On the other hand, a retrospective cohort study of 653 subjects with WCH and 653 subjects with normal blood pressure found that the incidence of cardiovascular events was only higher among WCH patients who were older and had risk factors such as male sex, current smoking, dyslipidemia, and obesity.[9] Therefore, it is possible that WCH is associated with increased cardiovascular risk only in the presence of specific cardiometabolic risk factors.[1]

Perhaps the only clear takeaway from these studies is to recommend lifestyle modifications as opposed to antihypertensives for most patients with WCH. In the Syst-Eur trial, antihypertensives reduced both office and ambulatory blood pressures in patients with essential hypertension but only reduced office blood pressures in patients with WCH.[10] Antihypertensive treatment reduced the incidence of cardiovascular events in patients with sustained, but not white coat, hypertension.[10] Treatment for WCH could be considered in individuals who have elevated out-of-office blood pressure, signs of target organ damage, and high cardiovascular risk based on independent risk factors.[1]

In conclusion, although recommendations vary, we advise counseling patients with white coat hypertension that the diagnosis is not benign, and that lifestyle modifications may reduce their risk of cardiovascular events especially if they have concomitant risk factors.

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***Alisa Liu, MD** is a second-year family medicine resident at The University of Rochester Family Medicine Program in Rochester, NY.*

***Arthi Chawla, MD** is currently faculty at Highland Family Medicine associated with the University of Rochester Family Medicine Program in Rochester, NY.*

A Review of GLP-1RAs & SGLT-2is in Type 2 Diabetes

By Natasha Vadera, MD and Celeste Song, MD, MS

Introduction

Type 2 Diabetes Mellitus (T2DM) is a global pandemic and places an enormous burden on a patient's quality of life and on our healthcare system. In 2017, diabetes was the seventh leading cause of death in the United States and responsible for direct estimated cost of $237 billion dollars and indirect estimated cost of $90 billion dollars.[1] Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of morbidity and mortality in patients with T2DM[2] and the largest contributor to costs in this patient population.[3]

Recent cardiovascular outcome trials cast a spotlight on glucagon-like peptide 1 receptor agonists (GLP-1RAs) and sodium–glucose cotransporter 2 inhibitors (SGLT-2is) for their role in reducing major adverse cardiovascular events (MACE) among patients with T2DM. With these therapies, guidelines are shifting away from solely targeting A1C percent reduction, a disease-oriented outcome, to comprehensively reducing the risk of death and disability from cardiovascular disease, a patient-oriented outcome. In this paper, we outline guidelines and data supporting the use of these agents, and highlight important properties of both classes.

GLP-1RA & SGLT-2is in Current Guidelines

Multidisciplinary guidelines and consensus statements recommend these agents as treatment options next in line after metformin.[2,4-10] The American Diabetes Association (ADA) updates its *Standards of Medical Care in Diabetes* annually and releases an abridged version with evidence-based recommendations most pertinent to primary care.[2] The ADA provides an "A" level recommendation for an "SGLT-2i or GLP-1RA with demonstrated CVD benefit as part of the glucose-lowering regimen among patients with T2DM who have established ASCVD or indicators of high ASCVD risk, established kidney disease, or heart failure."[2,11] GLP-1RAs reduce MACE, all-cause and cardiovascular mortality, and stroke, while giving some reduction in composite renal outcomes. SGLT-2is, while also lowering MACE, all-cause and cardiovascular mortality, additionally reduce the risk of hospitalization from heart failure, and slow the progress of diabetic kidney disease (DKD).[2,12] The AHA[7] and ADA[2] recommend an SGLT-2i for patients with T2DM and an eGFR ≥ 30 mL/min/1.73 m2.[2] The Study of Diabetes (EASD),[13] and the expert consensus decision pathway from the American College of Cardiology[9] echo these guidelines, and both advise clinicians to consider GLP-1RAs and SGLT-2is in patients with either established cardiovascular disease or indicators of high cardiovascular risk in the setting of T2DM. The European Society of Cardiology's guidelines on *Diabetes, Pre-Diabetes and Cardiovascular Disease*[10] mirror an emphasis these agents as not only anti-glycemic drugs, but as agents that can "address organ damage in a more direct manner."[14]

Review of GLP-1RAs

A. Mechanism of Action

GLP-1RAs mimic endogenous incretin GLP-1. They stimulate glucose-dependent insulin release, reduce secretion of postprandial glucagon, and slow gastric emptying.[15]

B. FDA Labels & Evidence

The FDA labels three GLP-1RAs (liraglutide,[16] injectable semaglutide,[17] and dulaglutide[18]) for MACE reduction in patients with T2DM and ASCVD.[2] Liraglutide (Victoza®) is a once-daily injectable, while semaglutide (Ozempic®) and dulaglutide (Trulicity®) are both once-weekly injectable therapies.[19] The first oral GLP-1RA, oral semaglutide, was approved by the FDA after a trial demonstrating cardiovascular safety,[20] and is currently being tested for cardiovascular superiority. Although albiglutide also demonstrated cardiovascular benefit,[21] the manufacturer removed it from the global market for commercial reasons.

Several meta-analyses support the guidelines advocating for the use of GLP-1RAs. An August 2019 systematic review and meta-analysis by Kristensen et al.[22] combined seven trials inclusive of 56,004 patients with T2DM and ASCVD or at risk of ASCVD: ELIXA (lixisenatide),[23] LEADER (liraglutide),[16] SUSTAIN-6 (semaglutide),[17] EXSCEL (exenatide),[24] HARMONY (albiglutide),[21] REWIND (dulaglutide),[18] and PIONEER 6 (oral semaglutide).[20] The authors report number needed to treat estimates for each outcome: all-cause mortality (113), MACE (75), cardiovascular death (175), and stroke (209).[22] This meta-analysis found no increase in risk of severe hypoglycemia, pancreatitis, or pancreatic cancer.[22] A 2019 meta-analysis by Zelniker

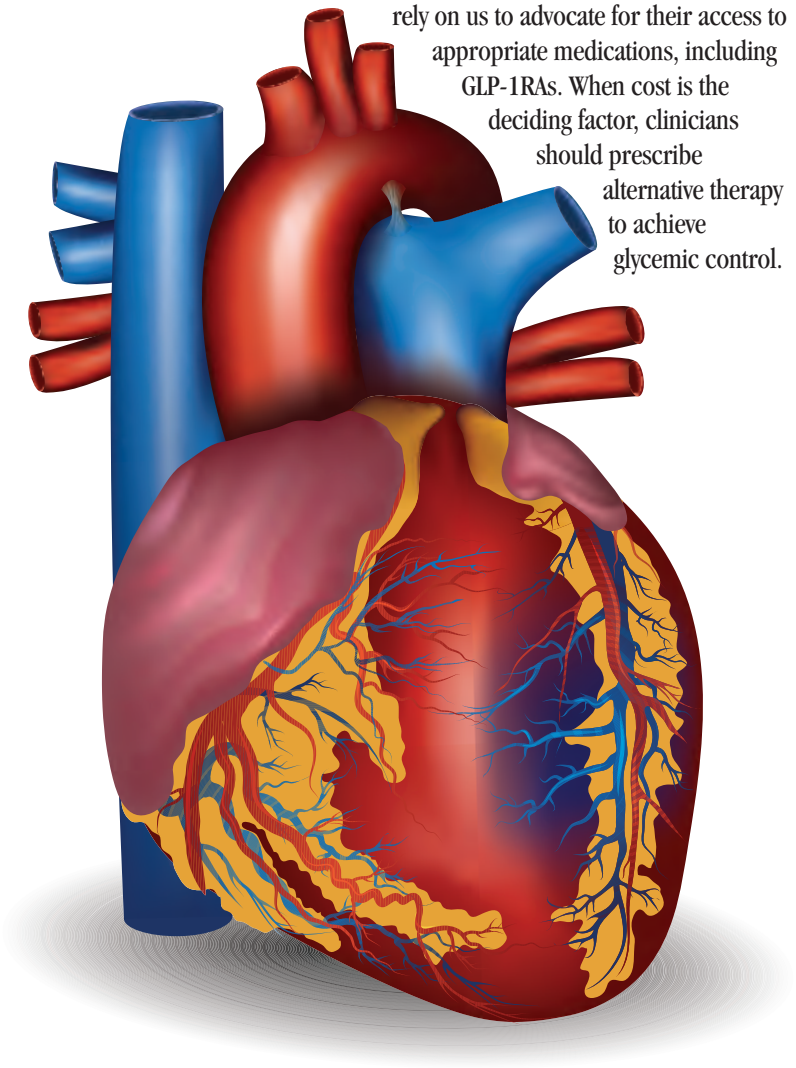
established ASCVD. GLP-1RA reduced composite renal outcomes, but by less than did SGLT-2i. In 2018, a network meta-analysis[26] by Zheng et al.,[27] inclusive of 236 randomized controlled trials and over 170,000 patients for all comparisons, showed all-cause mortality benefit for GLP-1RAs, with absolute risk differences of 0.6% for all-cause mortality and 0.5% for cardiovascular mortality, corresponding to numbers needed to treat comparable to those found by Kristensen, et al. These three large meta-analyses strongly support the use of GLP-1RAs as second line agents after metformin in the treatment of patients with T2DM and ASCVD or risk of ASCVD.

C. Additional Benefits

Weight loss and the low risk of hypoglycemia are other important patient-centered outcomes to highlight when introducing patients to this drug class.[15-18,22] Because the GLP-1RA mechanism of action is glucose-dependent, there is very low risk for hypoglycemia unless a patient is on a concurrent sulfonylurea and/or insulin.[19]

D. Barriers and Proposed Solutions

Cost: Insurance coverage and out of pocket cost limit the use of this therapeutic class. Staff assistance with prior authorizations can help reduce administrative paperwork for clinicians and identify other agents in the same class on formulary. If insurance costs remain prohibitive despite requests for prior authorization, patients may benefit from commercially available prescription discount programs such as GoodRx (www.goodrx.com) or SingleCare (www.singlecare.com). In our current health care system, inaccessibility of medicine due to cost is a common problem, even for mainstays of treatment such as insulin. Our patients rely on us to advocate for their access to appropriate medications, including GLP-1RAs. When cost is the deciding factor, clinicians should prescribe alternative therapy to achieve glycemic control.



Side Effects & Tolerability: Gastrointestinal side effects, including nausea, and/or vomiting, diarrhea, bloating, are common though generally transient side effects that can lead to early discontinuation of treatment.[28,29] A slow dose escalation strategy can reduce these side effects and improve long term success with therapy. Knowledge that side effects are generally transient also facilitates an adequate length for medication trials. We recommend standardized patient instruction templates in the EMR to help clinicians efficiently counsel.

Route of Administration: To address fear around self-administrating an injectable medication, consider viewing the brief video tutorial available on each brand's website. These carry more impact than written or verbal instructions and can ease patient concerns. Highlighting that the 32-gauge pen needles used for GLP-1RA administration present minimal to no pain,[19] as compared to finger-stick glucose measurements also helps to alleviate fear. The advantage of once weekly dosing of dulaglutide and semaglutide can offset concern about daily injections.

E. Contraindications

Contraindications include a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2, pregnancy, and breastfeeding.[19] Concerns for medullary thyroid cancer and multiple endocrine neoplasia syndrome type 2 are "based exclusively on observations in rodent models with uncertain human clinical relevance, as reflected in US product labeling."[19] Relative contra-indications include a history of gastroparesis, pancreatitis, or gastric surgical procedure.[19] GLP-1RAs may be used in advanced chronic kidney disease (CKD) at any eGFR level without dose adjustment.[19]

Review of SGLT-2is

A. Mechanism of Action

SGLT-2is inhibit sodium-glucose co-transporters in the renal proximal tubule, preventing glucose reabsorption and leading to increased urinary excretion of glucose. This lowers glycemic index in an insulin-independent manner.[12]

B. FDA Labels & Evidence

The FDA labels three SGLT-2is for MACE reduction in patients with T2DM and ASCVD: canagliflozin (Invokana®),[30,31] empagliflozin (Jardiance®),[32] and dapagliflozin (Farxiga®).[33] In addition to ASCVD risk reduction, SGLT-2is offer benefit to patients with heart failure and diabetic kidney disease.

Empagliflozin gained FDA approval in December 2016 "to reduce the risk of cardiovascular death in adult patients with T2DM and cardiovascular disease."[32,34] Canagliflozin followed in 2018, with approval for similar ASCVD reduction purposes.[30] After CREDENCE, the FDA added DKD and heart failure as indications for canagliflozin.[35] Dapagliflozin has a similar indication for ASCVD benefit, in addition to "Fast Track" designations for renal protection and heart failure benefit, based on compelling data from DAPA-HF.[36]

Two 2020 meta-analyses (Lo et al.;[37]Arnott et al.[38]) evaluated cardiovascular and renal outcomes of SGLT-2i from four large randomized clinical trials: EMPA-REG,[32] CANVAS,[30] DECLARE-TIMI,[39] and CREDENCE[31]. For patients with and at high risk for ASCVD, both meta-analyses showed reductions in all-cause mortality, death due to cardiovascular disease, MACE, hospitalization from heart failure, and

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progression of renal disease.[37,38] Lo et al.[37] report numbers needed to treat for all-cause mortality (143), a composite cardiovascular outcome (167), death from cardiovascular causes in all patients (250), death from cardiovascular causes in patients with eGFR <60 mL/min/1.73 m^2 (65), and hospitalization from heart failure (91). In the network meta-analysis by Zheng et al.,[27] SGLT-2is reduced absolute risk of all-cause mortality by 1%, cardiovascular mortality by 0.8%, and hospitalization from heart failure by 1.1%, comparable to the numbers needed to treat in Lo et al.[37] The Zelniker et al. meta-analysis[25] reported similar outcomes for secondary prevention of ASCVD. Both SGLT2is and GLP-1RAs improved composite renal outcomes, with the most benefit noted for SGLT-2i. The same authors published a meta-analysis in the *Lancet* focused only on SGLT-2is.[40] This paper adds that SGLT-2is have a role in primary prevention of hospitalization from heart failure. Usman et al.[41] released a 2018 meta-analysis including 35 trials of SGLT-2is, strengthening the case that the benefits noted above are a class effect. Overall, these five meta-analyses give strong and consistent evidence for the ASCVD benefit of SGLT-2is.

C. Additional Benefits

SGLT2-is are oral rather than injectable. They lead to weight loss,[34] reduce systolic blood pressure,[42] and improve dyslipidemia.[43] The insulin-independent mechanism of action confers very low risk of hypoglycemia.[19]

D. Barriers

Cost: Cost of medications poses the same problem as it does for GLP-1RA, for which we provide the same guidance as above.

Side Effects & Tolerability: Genital mycotic infections are the most common adverse events associated with use of SGLT-2is,[44-46] which is thought to be related to glucosuria. The FDA issued a warning in 2015 for the risk severe UTIs though this was not statistically significant in more recent literature.[44] Patients who are elderly, frail, or more vulnerable to volume shifts require close monitoring for orthostatic hypotension or acute kidney injury, due to diuretic-like properties of this drug class.[14,30,47] Euglycemic DKA is a rare but serious complication.[14] Overall, the risk SGLT-2i-related DKA is more significant in T1DM and low in patients with T2DM[48] when appropriately prescribed.[49] A "Sick Day Strategy" in the *Canadian Journal of Diabetes*[50] recommends holding SGLT-2is when patients become ill or unable to maintain oral intake. The FDA recommends discontinuing SGLT-2is three days prior to surgery.

E. Contraindications

SGLT-2is are contraindicated in patients with an eGFR <30 due to unclear efficacy and safety,[19,51] Pregnant or breastfeeding patients should not use SGLT-2is. The FDA published a black box warning after CANVAS[30] (canagliflozin) showed an almost two-fold higher rate of lower limb amputation.[47] There was no increased risk of amputation in CREDENCE[31] (canagliflozin), DECLARE-TIMI[39] (dapagliflozin), or EMPA-REG[32] (empagliflozin). It would be "prudent not to use an SGLT-2i in patients with ischemic extremities, and to avoid the use of canagliflozin in patients with significant peripheral vascular disease."[47] The FDA issued a Drug Safety Communication after twelve cases of Fournier's gangrene associated with use of SGLT-2is.[47,52]

Therapeutic Inertia

Therapeutic inertia, recently defined by Khunti et al.[53] as "the failure to advance therapy or to de-intensify therapy when appropriate to do so," contributes to poor clinical outcomes in patients with T2DM. The slow uptake of GLP-1RAs and SGLT-2is, despite the available data and guideline recommendations, illustrates this clinical inertia. Honigberg et al.[19] point out that "less than 8% of individuals with T2DM and ASCVD were given

Table	GLP-1 Receptor Agonist (GLP-1RA)	SGLT-2 Inhibitor (SGLT-2i)
Efficacy	High (0.8 – 2%)	Intermediate (0.5 – 1.0%)
Risk of Hypoglycemia	Minimal to none	Minimal to none
Weight Change	Loss	Loss
Cost	High	High
Oral / SQ	Predominantly injectable, with one new oral formulation	Oral
FDA Approval for ASCVD & Related Benefits	Liraglutide Dulaglutide Semaglutide (injectable not oral)	Canagliflozin Empagliflozin Dapagliflozin
ASCVD & Related Benefits	- All-cause and CV mortality - MACE (composite) - Stroke - Composite Renal Outcomes (smaller effect)	- All-cause and CV mortality - MACE (composite) - Heart Failure Hospitalizations - Composite Renal Outcomes
Renal Dosing	- Exenatide not indicated w eGFR < 30 - Lixsenatide: caution w eGFR <30	- Canagliflozin: Not recommended with eGFR <45 - Dapagliflozin: Not recommended with eGFR <60, contraindicated with eGFR <30 - Empagliflozin: Contraindicated with eGFR < 30
Side Effects	- **FDA Black Box:** Risk of Thyroid C-Cell Tumors* - Common: Gastrointestinal (nausea, abdominal discomfort, diarrhea) - Injection site reactions - Acute pancreatitis risk***	- **FDA Black Box Risk:** Risk of Amputation (Canagliflozin), ** Fournier's gangrene - Common: Genital mycotic infections, risk of volume depletion and acute kidney injury - Euglycemic DKA (rare)**

*Extrapolated from rodent studies, **CANVAS[30] findings only, ***Not reproduced in meta-analyses

GLP-1RA prescriptions."[19,54,55] Similarly, surveys on use of SGLT2-is show these are not widely used in appropriate patient populations.[56]

Waiting for perfect data is a form of therapeutic inertia and may withhold benefit from patients who have significant disease burden. Any practicing clinician, no matter how astute, would be challenged to synthesize and apply all the individual SGLT2-i and GLP-1RA studies currently published. Each individual study has various strengths and sources of bias, with similar yet varying composite end points and secondary analyses. In this paper, we take a summative perspective, focusing on recent high-quality meta-analyses which give strong evidence for benefit with low risk of harm.

Since metformin, we have not had an agent that lowers morbidity and mortality in patients with T2DM; in fact, the most commonly prescribed treatments in T2DM are insulin and sulfonylureas[57] which are both associated with increased mortality and weight gain.[58,59] With GLP-1RAs and SGLT2-is, the numbers needed to treat to prevent MACE[16,17,32] are comparable to those observed for therapies like statins, aspirin, and antihypertensives, all standard of care in ASCVD treatment and prevention.[34]

Other contributors to therapeutic inertia include cost, prior authorizations, patient concern, and time required for education and counseling. A team-based approach to address these barriers is integral to successful adoption of these therapeutic modalities. We recognize that medication selection ultimately depends on patient-specific factors and shared decision-making.

We recommend GLP-1RAs and SGLT-2is as second line medications after metformin in patients with T2DM given their overall demonstrated safety and efficacy, favorable metabolic effects on weight, and anti-hyperglycemic potency. GLP1-RAs and SGLT-2is reduce the risk of MACE and all-cause and cardiovascular mortality in patients with established ASCVD,[25] with a targeted effect of GLP1-RAs on fatal and nonfatal stroke, and a greater reduction with SGLT-2is on the risk for hospitalization for HF and progression of DKD.[14] As primary care physicians, we are the front lines caring for patients with T2DM and play a powerful role in reducing associated death and disability. We encourage clinicians to adapt these guideline-recommended treatment options to optimize cardiovascular outcomes for patients with T2DM.

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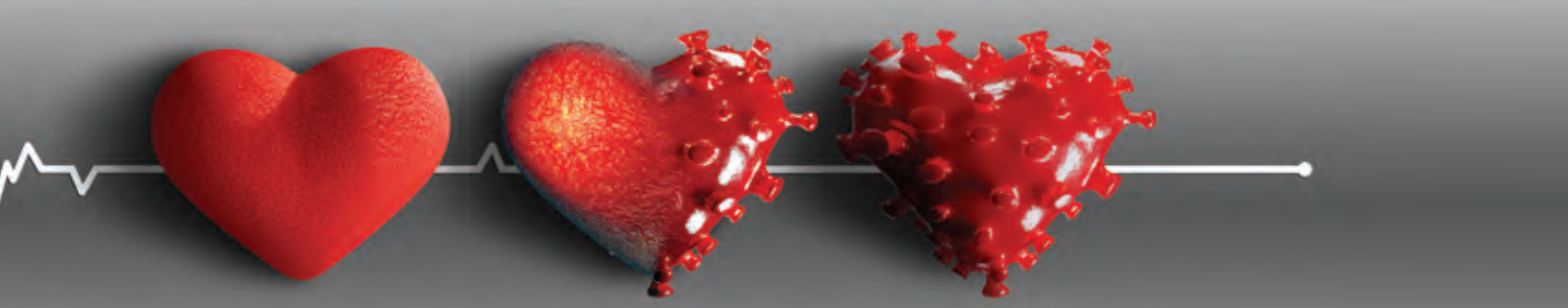
Natasha Vadera, MD *is currently an attending physician at Highland Family Medicine, and the Assistant Director for the Primary Care Clerkship at University of Rochester School of Medicine & Dentistry. Dr. Vadera graduated from Brandeis University with a double major in biology and health policy. She spent two years working as a Clinical Research Associate in Andover, MA and then obtained her MD from New York Medical College and completed her residency in family medicine from the University of Rochester with concentrations in research and medical education. During her residency, she found an interest in quality improvement and has presented on the topic.*

Celeste Song, MD, MS *attended medical school at the University of Rochester School of Medicine and Dentistry and did her residency at the Tufts/Cambridge Health Alliance Family Medicine Residency, where she developed her interests in evidence-based medicine and medical education. Following residency, she had a faculty development fellowship through the University of Rochester Department of Family Medicine, and earned an MS in Health Professions Education through the University's Warner School of Education. Dr. Song now practices primary care at Highland Family Medicine, serves as an Associate Residency Director for the University's Family Medicine Residency, and leads the evidence-based medicine curriculum for the residency.*



Cardiovascular Considerations/ Complications of COVID-19 for the Family Physician

By Nathaniel Moulson, MD and Aaron Baggish, MD, FACC, FACSM

Introduction

The novel SARS-CoV-2 virus (COVID-19) causes systemic multisystem disease from which the cardiovascular system is not spared. The interaction between COVID-19 and the cardiovascular system affects populations ranging from the otherwise young and healthy to those with multiple co-morbidities including pre-existing cardiovascular disease, hypertension, and diabetes.[1] From a strictly cardiac standpoint, the most concerning effect is that of direct viral myocardial invasion and the resultant inflammation known as myocarditis.[2] This *"COVID-19 myocarditis"* has garnered significant medical and media attention as this complication may occur in otherwise young and healthy patients with the potential to lead to cardiovascular morbidity and mortality. At present, our understanding of COVID-19 myocarditis and the other cardiovascular effects of COVID-19 remains limited. Primary care clinicians face the challenge of assessing patients who present with a multitude of symptoms, including those which potentially represent cardiac involvement. These symptoms may be classical chest pain presentations of pericarditis and myocarditis but will more likely include symptoms of uncertain etiology or of unclear significance such as persistence of shortness of breath, fatigue, or reduced exercise tolerance. Patients may also present following symptom recovery, or after an asymptomatic COVID-19 diagnosis, with questions pertaining to the safety of resuming exercise. In competitive athletes and highly active persons (CAHAP), early resumption of high-intensity physical activity may potentially worsen underlying myocarditis and increase the risk of exercise related arrhythmias, and cardiac arrest.[3] Deciphering which of these patients require cardiovascular work-up to detect cardiac involvement and the significance of abnormal test results, in particular those from cardiac magnetic resonance imaging (CMR), is an area of clinical uncertainty lacking guiding evidence. Clinicians must therefore rely on expert opinion, a high index of suspicion, and sound clinical judgment to navigate this challenging clinical arena.

Cardiovascular Effects of COVID-19

The cardiovascular effects of COVID-19 were some of the earliest described extra-pulmonary complications. *Cardiac injury*, as defined by an elevation in troponin, was shown to occur in a high frequency of hospitalized and critically ill patients in initial reports from Wuhan, China.[4] This cardiac injury is more likely to occur in patients with pre-existing cardiovascular disease including hypertension and is associated with increased COVID-19 disease severity and mortality in hospitalized patients.[2] The exact mechanism for this cardiac injury remains under investigation. However, in the hospitalized and critically ill patient population this almost certainly represents multiple, potentially overlapping, etiologies. This includes mechanisms common to all critical respiratory illness such as oxygen supply-demand mismatch and resultant type II myocardial infarction or "demand ischemia", and type I myocardial infarction or "plaque rupture" potentially precipitated by the stress of critical illness, in addition to COVID-19 specific mechanisms. The proposed COVID-19 specific mechanisms remain incompletely defined but are a major focus of clinical interest and ongoing research. These mechanisms include cytokine storm, micro-thrombosis, myocarditis and pericarditis from either direct viral invasion and/or secondary inflammation.[2] In severe cases myocarditis may be fulminant and result in cardiogenic shock requiring mechanical circulatory support.[5]

In the population of patients who suffer non-severe disease, i.e. who do not require hospitalization, the incidence, etiology, and prognostic significance of COVID-19 cardiac injury or involvement remains uncertain. Patients who suffer non-severe disease do not experience the hemodynamic and metabolic stressors of critical illness and by definition do not have severe or fulminant cardiac involvement. Therefore, if cardiac injury or involvement is suspected or detected in this non-severely affected population, the etiology is presumably more likely to represent COVID-19 specific etiologies such as non-severe pericarditis or myocarditis. This however has not been studied. Any cardiac presentation or result also needs to be considered within the appropriate clinical context of the patient. The presence of a COVID-19 infection should not preclude a standard clinical assessment and work-up for other common etiologies of troponin elevation and cardiac symptoms, particularly in those with traditional cardiovascular risk factors.

As COVID-19 related myocarditis has become an increasingly recognized entity, concern has mounted regarding the prevalence of minimally symptomatic or asymptomatic occult disease. The main concern being that this occult myocarditis may increase the risk of adverse cardiac events such as arrhythmias or sudden cardiac arrest. The need to detect this potential subclinical involvement, including in which populations, and how this is best accomplished are yet other areas of clinical uncertainty. The sensitivity of specificity of cardiovascular investigations including electrocardiograms, troponin levels, echocardiography, and CMR employed in this screening context need to be carefully considered and interpreted in order to ensure the appropriate identification of disease and avoid overdiagnosis by attributing abnormalities of uncertain significance to COVID-19 cardiac involvement.

Cardiac Magnetic Resonance Imaging and COVID-19

A high reported prevalence of CMR abnormalities potentially suggesting occult COVID-19 myocarditis in several recent small cohort studies has attracted significant medical and media attention. A initial study by Puntmann et al.[6] reported CMR abnormalities in up to 78% of a 100-patient cohort of hospitalized and non-hospitalized COVID-19 patients. The presence of CMR abnormalities were independent of illness severity and significantly increased compared to both healthy and risk-factor matched controls. The CMRs were not clinically indicated (i.e. performed on a research screening basis) and were performed a median of 71 days after COVID-19 diagnosis. Ventricular size and function were not found to be outside of the normal range, suggesting a lack of myocardial dysfunction. A second study looking at collegiate athletes reported four athletes out of 26 with CMR findings consistent with myocarditis by the Lake Louise imaging criteria, of which two athletes were clinically symptomatic.[7] Eight additional athletes had evidence of late gadolinium enhancement (LGE) of unclear significance. This study did not include a control group for comparison or report the result of other clinically relevant cardiac investigations.

While these findings are certainly hypothesis generating, at present their clinical and prognostic significance remain unclear. Importantly, isolated CMR findings of abnormal tissue characterization, even if consistent with imaging criteria for myocarditis, does not in and of itself constitute a diagnosis of clinical myocarditis. A clinical diagnosis requires either the presence of symptoms or the presence of other investigation evidence of active cardiac involvement including elevated troponin levels, new ECG changes, or new cardiac imaging functional abnormalities such as a decrease in ejection fraction or new wall motion abnormality.[8,9] This is because abnormal CMR tissue characterization is not specific to myocarditis and may reflect a variety of potential etiologies. The lack of CMR control data, particularly for young athletic populations make the presence of isolated LGE in particular difficult to interpret. Isolated LGE is a non-specific finding and may in fact be related to high levels of endurance athletics, depending on the location.[10] In the absence of control populations, pre-COVID-19 comparative imaging, and longitudinal follow-up to assess for radiographic persistence and clinical outcomes, these isolated CMR abnormalities require careful interpretation and should not be used in isolation for a diagnosis of myocarditis.

Patients who are found to have CMR abnormalities following COVID-19 infection should be reviewed by a cardiovascular specialist with adequate expertise in multimodal cardiac imaging to ensure the results are appropriately interpreted. The use of non-clinically indicated CMRs for the screening of *asymptomatic* persons, either athletes or non-athletes, following a COVID-19 infection and prior to either the resumption of physical activity, or for further risk stratification, is not currently recommended by any cardiovascular or sporting society and should only be performed as part of a dedicated research study.

Myocarditis and Exercise

Despite the clinical uncertainty pertaining to the significance of cardiac investigations and diagnosis of myocarditis in *asymptomatic* patients described above, patients who are *symptomatic* and/or fulfill criteria for a clinical diagnosis of myocarditis based on contemporary guidelines should follow well established clinical guidelines for management pertaining to sport and exercise. Myocarditis is a well-described etiology of sudden cardiac death in young athletes under the age of 35.[3] The mechanism of this sudden death is arrhythmic, presumably precipitated from the hemodynamic and metabolic stressors of exercise placed upon the vulnerable myocarditis substrate. Additionally, exercise has been shown to worsen the myocardial inflammation and damage from myocarditis in animal models.[11] It is for these reasons the American Heart Association (AHA) and American Cardiology of Cardiology (ACC) 2015 Eligibility and Disqualification Recommendations for Competitive Athletes recommend avoidance of sport for 3-6 months following a confirmed diagnosis of myocarditis.[3] This recommendation can be extrapolated to all patients wishing to participate in moderate to high intensity activity following myocarditis attributable to COVID-19.

Prior to the resumption of exercise, patients should undergo a resting echocardiogram, at least 24-hours of ambulatory ECG monitoring, an exercise stress test, and testing of serum biomarkers of myocardial injury, inflammation and heart failure. The presence of abnormalities on any of this testing should prompt a referral to cardiology for further evaluation.

Patients with isolated COVID-19 pericarditis should not participate in moderate to intense physical activity until complete resolution of the acute phase of the illness. If there is any evidence of myocardial involvement (i.e. troponin elevations or ventricular dysfunction), this becomes a diagnosis of perimyocarditis and patients should be treated as myocarditis with respect to exercise considerations.

"Return-to-Play" post COVID-19

Patients wishing to return to exercise following a COVID-19 infection will range from those participating at moderate intensities mainly for health benefits, to competitive athletes and highly active persons performing high-intensity activities at volumes many times higher than the average person. Several expert opinion "return-to-play" algorithms have been proposed to help guide and standardize clinical practice.[12,13] These algorithms were developed with a focus on the competitive athlete due to the organizational medical clearance requirements prior to resumption of sport. However, the extrapolation of their use to non-competitive athletes is reasonable and provides a preliminary framework to guide clinicians during these assessments. The extent of testing and monitoring

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may need not be as in depth for non-competitive athletes. This however should be an individualized decision based on the presence or absence of persistent symptoms, the patients underlying comorbidities, and the intensity of regular exercise performed.

Cardiovascular testing in non-competitive athletes or exercisers who do not require cardiovascular clearance to return to exercise is not required if exercise has already been resumed following an appropriate convalescent period (~2 weeks) and the patient is clinically asymptomatic following their gradual return to exercise. In other words, the performance of cardiovascular testing weeks to months following disease resolution, in the absence of symptoms, and following resumption of normal activity and exercise, is not recommended. In patients who either experience persistent symptoms or who develop new symptoms, clinically appropriate investigations are recommended. Potential concerning symptoms may include dyspnea on exertion, chest pain or tightness, exertional fatigue, palpitations, presyncope, syncope or decreased exercise tolerance. A low index of suspicion for cardiac disease including myocarditis is recommended in these patients following documentation of suspected of confirmed COVID-19 infection.

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Nathaniel Moulson, MD *is completing a fellowship in cardiovascular performance at Massachusetts General Hospital under the supervision of Dr. Aaron Baggish. He completed his medical school and cardiology training at the University of British Columbia. His clinical and research interests are in the cardiovascular care of athletes and highly active persons.*

Aaron Baggish, MD, FACC, FACSM *is Associate Professor of Medicine, Harvard Medical School, and Director of the Cardiovascular Performance Program at Massachusetts General Hospital. He serves as team cardiologist and physician for numerous athletic organizations including US Soccer, US Rowing, Harvard University Athletics, the New England Patriots, Boston Bruins, New England Revolution, and is medical director for the BAA Boston Marathon. Dr. Baggish received his medical degree from the University of Connecticut School of Medicine and then completed internal medicine training and cardiovascular fellowship at the Massachusetts General Hospital. His on-going research focuses on heart function and heart disease in athletic individuals.*

Upcoming Events

2020

November 8
Fall Cluster, Board only
Albany, NY

2021

January 21-24
Winter Weekend
Virtual Conference

February 28
Winter Cluster
Renaissance Albany

March 1
Lobby Day
Renaissance Albany
and Capitol

For updates or registration information for these events go to www.nysafp.org

TWO VIEWS:
Treating Hypertension

VIEW ONE

ADDRESSING HYPERTENSION THROUGH INTEGRATIVE MEDICINE APPROACHES IN THE CLINICAL SETTING

By Sandy Wang, MD and Sachiko Kaizuka, MD

Hypertension is the most common cardiovascular disease that family medicine physicians will actively manage in clinic.[1] It is also a complex multifactorial illness that is affected by lifestyle choices (diet, physical activity), mental emotional health, medications, supplements, genetics, and comorbid illnesses.[2] Despite well studied therapies being available for many decades, high blood pressure is still poorly controlled in the United States.[3] Antihypertensive use has already increased by 14% in one decade,[4] with only half of hypertensive patients' blood pressures adequately controlled,[5] and 70% of those individuals eventually requiring combination therapy.[6] Moreover, 45% of patients with hypertension and 84% of those with uncontrolled hypertension do not adhere to their antihypertensive regimen.[7]

With the mainstay of hypertensive treatment being pharmacotherapy, non-pharmaceutical therapies are often overlooked as they may not provide as impressive of blood pressure lowering effect.[8] However, even a mild weight or blood pressure reduction has been associated with improved mortality caused by stroke, heart disease, and all-cause mortality.[9,10] The PREMIER clinical trial demonstrated that the combination of lifestyle changes reduced blood pressure more than individual lifestyle factors.[11] Approaching hypertension with an integrative medicine mindset may provide more realistic and long-term sustainability for many patients.[2,10] The need for integrative medicine education for physicians is urgent, and in this paper, we will review and provide updated evidence-based integrative medicinal approaches to treating hypertension including physical activity, dietary modifications, mind – body therapies, and herbal supplements.

Starting Physical Activity

Some of the easiest and most cost effective interventions involve lifestyle modifications. Thirty minutes of aerobic exercise three times a week can reduce systolic BP by 3-4 mm Hg, and physicians should help patients find activities that are both enjoyable and appropriate for their needs.[2]

For those individuals who have time concerns, finding ways to incorporate busy work with activity can help motivate them as well as alleviate the mental stress of a long to-do list. For example, doing sit ups while watching TV, reading while on a stationary bike, or listening to podcasts while on walks, are all potential ways to get activity in.

If a patient faces inertia in starting physical activity, it may be worthwhile to consider starting a graded exercise therapy, in which

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VIEW TWO

CONSIDERATION OF COMBINATION THERAPY FOR TREATMENT OF HYPERTENSION IN THE CLINICAL SETTING

By Jasdeep Singh Bajwa, DO; Arthi Chawla, MD and Sandy Wang, MD

Hypertension is a growing major public health concern in the United States, affecting nearly 77 million Americans; the prevalence of hypertension is expected to increase, approximately, by an additional 30 million by the year 2030.[4] Uncontrolled hypertension is a known risk factor for cardiovascular disease, and additionally can lead to stroke, end-stage renal disease and death. Adequate control of hypertension can reduce the incidence of these comorbidities and reduce mortality. Although pharmaceutical options to better control hypertension have improved over the last three decades, hypertension remains inadequately managed, resulting in significant economic burden on both patient and the healthcare system.[8] Primary care physicians face challenges in balancing efficacious therapy in order to lower BP and in reducing cardiovascular end points, while emphasizing practical applications in consistently achieving and maintaining goal BP in clinical practice.[14]

First-line treatment with most hypertensive patients begin with lifestyle modifications, which includes incorporating the DASH (Dietary Approaches to Stop Hypertension) diet and implementing regular exercise. In patients with inadequate response to these lifestyle modifications, initiating pharmacological therapy would be the next step with respect to special populations (ACE-I/ARB in non-Black and CCB/thiazides in Black individuals.[10]) Most treated patients only receive monotherapy, which has low potency even at high doses.[15] Low-dose combination therapy holds considerable promise in this regard since at low doses most side-effects are avoided, and most benefits are maintained.[15] Additionally, combination therapy may have up to 11% cardiovascular risk reduction compared to those starting on monotherapy.[2]

New studies suggest that combination therapies have a number of advantages over monotherapy for a number of reasons; the different mechanisms of action work synergistically;[5] they result in more rapid blood pressure control;[3] they are more affordable[1] and they decrease the adverse effects of high-dose monotherapy.[5] They can also neutralize counter regulatory mechanisms and improve tolerability for patients.[6,7] For example, calcium channel blockers (CCBs) stimulate arterial vasodilation to a greater extent than venodilation, thereby causing fluid accumulation in interstitial spaces and limiting its upward titration. Adding ACE-I/ARBs can increase both arterial and venous dilation and thus function to counteract some of the CCB-induced arterial dilation, which is thought to result in a

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physical activity is introduced gradually, increasing in intensity as patients gain strength. Examples could be as little as 5-10 minutes a day, but must follow a strict balanced exercise plan which includes mandatory periods of rest such as 30-second periods between sets of 20 repetitions.[12] By making these small, graded changes, patients make cognitive changes by decreasing their negative beliefs associated with activity and fatigue, and improving their feelings of self-efficacy.[13]

Dietary Modifications

While physicians hold positive views of the importance of nutrition, almost 2/3 report lack of training or deficits of knowledge about nutrition as major barriers for implementing these practices in clinic.[14] Clinicians can address dietary changes through salt intake, the DASH (Dietary Approaches to Stop Hypertension) and Mediterranean diets, portion control and mindful eating. Counseling patients on salt intake of their diet requires not only addressing how much salt a patient is adding to their dishes, but educating them on reading food labels in processed foods. It is also important to address diets deficient in potassium that can cause sodium retention and result in systolic blood pressure increases up to 7 mm Hg.[15] Plant foods have high mineral content and provide natural sources without the need for supplementation.[16]

The DASH diet consists of a diet rich in fruit and vegetables, high in low fat dairy products, potassium, magnesium, calcium, and low in total saturated fats. The Mediterranean diet is also popular and shares many similarities with the DASH diet, but emphasizes olive oil as its main fatty acid[17] as it confers antioxidant protective effects on vascular health.[18] Many clinicians may have heard of DASH before, but may not be familiar with the specific recommendations. Below (Figure 1), we provide specific examples of servings to help guide clinicians, keeping in mind that patients with diabetes would benefit with less of the grains category and focus more on the other low glycemic index options. It is important to implement gradual changes with patients, so as to not overwhelm long term habits and help instill long term educational understanding. Taking a full dietary history and identifying culprits such as the "C" foods (cookies, chips, cold cuts, crackers),[2] and then creating a tangible plan on substitutions/portion control can help patients keep track of their progress.

Figure 1. Dietary Approaches to Stop Hypertension[2]

Category	Number of Servings	Serving Examples
Grains	6-8	1 slice bread ½ cup of dry cereal ½ cup of pasta or cooked rice
Vegetables/ Fruits	4-5 each	1 medium fruit or vegetable ½ cup of fresh, frozen, or canned fruit ½ cup of dried fruit ¾ cup of fruit/vegetable juice
Oils	2-3	1 tsp of mayonnaise 1 Tbsp of low fat mayonnaise 1 Tbsp of regular salad dressing 1 Tbsp of light salad dressing 1 tsp of oil (preferably olive, canola, avocado)
Low fat dairy	2-3	1 cup milk or yogurt 1 ½ oz of cheese
Beans, nuts, seeds	1	½ cup of cooked beans 1/3 cup nuts 2 Tbsp of sunflower seeds
Seafood, poultry, meat	0-2	3 oz of broiled or roasted options
Sweets	5 per week	1 cup of low fat fruit yogurt 1 Tbsp of syrup, sugar, jam

Portion Control

Sometimes, patients can become overwhelmed with numbers; it can be difficult to correlate serving size with real life application. Clinicians can work with patients on portion control by using a patient's hand to help guide their decisions when they are in the store, at a meal, or preparing their own food. See Figure 2.

It is also important to discuss with patients their relationship with food; this exploration can help with stress, weight gain, and improve blood pressure. Some core practices to help patients include:[2]

1. Avoiding mindless or automatic eating, but being aware of the experience of eating
2. Learning to check oneself between physical and psychological hunger
3. Savoring the taste of food, stopping when taste buds are tired
4. Learning to stop before becoming overly full
5. Choosing foods that bring both personal satisfaction and nutrition
6. Learning to be receptive to creating a healthy relationship to eating and food

Figure 2. Portion Control Real Life Application in the Clinic[19]

Source: www.guardyourhealth.com

Mind-Body Medicine

Research has shown that patients who combine relaxation response training with lifestyle modifications were twice as likely to successfully eliminate one antihypertensive medication than those who only eliminated lifestyle risk factors.[20] Meditation, deep breathing, and prayer are also known to induce "relaxation response," which is thought to

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corresponding reduction in lower-extremity edema.[4] Moreover, the comorbidities that exist or that arise from the sequelae of poorly controlled hypertension would benefit from these synergistic mechanisms, such as starting lisinopril for renal-protective benefits in diabetes.[12] Furthermore, treatment for patients with chronic kidney disease and proteinuria should include an ACEI or ARB plus a thiazide diuretic or a calcium channel blocker.[8]

Despite these promising findings, 45% of patients with hypertension and 84% of those with uncontrolled hypertension do not adhere to their antihypertensive regimen, with persistence and compliance listed as possible barriers.[13] Fortunately, single pill combination therapies are now available, with research demonstrating simplification of a drug regimen improves persistence in prescribed therapy.[11] Combination therapy is available either as fixed-dose combination (FDC), which includes at least 2 active agents combined in a single pill (also known as a single-pill combination), or as a free-equivalent combination (FEC, also known as a free combination), which involves separate use of the corresponding drug components.[17] A number of studies have indicated that the FDC can have a better impact on blood pressure control as well as reducing the use of medical resources by increasing patients' adherence (compliance) and persistence to treatment.[17] Use of FDC in hypertension is associated with superior persistence and reduced mortality compared with use of two pills, suggesting a higher priority for the use of fixed-dose combinations.[16]

In summary, while the problems associated with inadequate blood pressure control are multifactorial, many are interrelated. Research and literature suggest that low-dose combination therapy may help with better hypertension control by reducing side effects associated with high dose monotherapy regimens and utilizing the synergism of multiple mechanisms of action. The global socio-economic burdens of uncontrolled hypertension contribute significantly to the total amount of disability adjusted life years and an increasing amount of medical resource consumption. Single pill combination therapy can help combat these effects by reducing pill burden, leading to improved compliance, fewer physician visits and fewer hospitalizations for uncontrolled hypertension and cardiovascular events.[12] We recommend that family medicine physicians consider these medications in hypertensive patients requiring further medication titrations.

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Jasdeep Singh Bajwa, DO *is a 2nd year family medicine resident with interests in medical education and clinical reasoning. His passion for medical education not only involves medical students, but teaches his patients to better understand their conditions and management.*

Arthi Chawla, MD *is currently faculty at Highland Family Medicine associated with the University of Rochester Family Medicine Program in Rochester, NY.*

Sandy Wang, MD *is a 2nd year family medicine resident with interests in integrative medicine and preventive health. Her special interests are in dietary approach to chronic conditions and working with patients on lifestyle modifications to better educate and empower their health choices.*

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explain the mechanism of lowering the high blood pressure.[21] Some practices are more familiar, such as yoga and tai chi, but may not be always readily available to patients. One way to start implementing mind-body therapy is creating a trusting space for patients to have their experience heard, become in tune with their chronic illness, and develop their own perspective about their situation.[2] The experience of going through a mind-body interview itself can stimulate a patient's insight and help them recognize healing possibilities that were not previously perceived or realized. The following questions can serve as examples to help patients reflect on their own illness narrative and bring both clinician and patient to a better understanding of the nuances of underlying factors that prevent better blood pressure control.

1. What are the sources of your stress?
2. What brings you joy?
3. In what ways has your condition (hypertension) impacted your life?
4. What do you fear most about this disease?
5. How do you define health and in what respects do you think you could be in better health?
6. When was the last time you felt well? What did it feel like and what did your life look like at that time?
7. Do you think your emotional health impacts your physical health?

Some other simple techniques can be implemented in the clinical setting without requiring much clinician training. For example, progressive muscle relaxation (PMR) is a technique where patients are taught to isolate one muscle group at a time, create tension for 8-10 seconds, and then let the muscle relax and the tension go.[22]

Supplements

Some botanicals and supplements have been shown to reduce blood pressure; some can be incorporated into diet, taken as supplements, or even steeped as teas for those who wish to seek a more natural approach. Vitamin D testing and treatment is controversial, and clinicians should use clinical judgement before considering checking for deficiencies in potassium, magnesium, and vitamin D in patients with hypertension and supplementing if the levels are low or if a patient is on magnesium or potassium depleting medications.[23] Magnesium supplementation at 300 mg daily for a month can reduce blood pressure, raise serum magnesium, and increase effectiveness of antihypertensive medications.[24,25] Starting with low doses of omega 3 or a couple of servings of fatty fish can also improve blood pressure by reducing ACE activity and angiotensin formation, enhance endothelial nitric oxide, and activate the parasympathetic nervous system.[26]

Notable botanicals that can assist with lowering blood pressure include steeping 2 teaspoons of dried hibiscus tea[27] or dandelion leaf.[28] Other supplements include grapeseed extract supplements of 150-300 mg daily (use with caution in patients on warfarin).[29] Fresh 250-500 mL amounts of beetroot juice[30] and adding fresh garlic to foods can also assist in lowering blood pressures.[31]

Conclusion

Non-pharmaceutical interventions are often overlooked in the treatment of hypertension, despite being listed as the first line therapy before starting medications. Research has shown that a combination of lifestyle changes is more efficacious than individual lifestyle factors, and integrative medicine can provide more approachable and sustainable therapy to many patients. However, many clinicians report lack of training or time to fully delve into these topics with patients, leading to a continued reliance on pharmacotherapy. We hope that our paper has provided some tools for our colleagues to consider implementing in the clinical setting to facilitate a more wellness approach to this complex cardiovascular illness.

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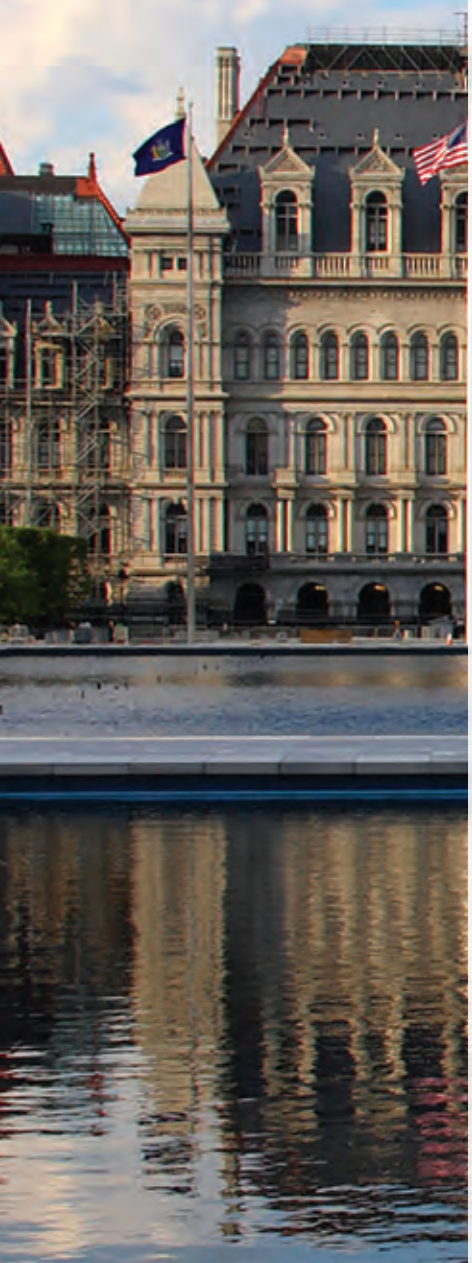
Endnotes continued on page 49.

Sandy Wang, MD *is a 2nd year family medicine resident with interests in integrative medicine and preventive health. Her special interests are in dietary approach to chronic conditions and working with patients on lifestyle modifications to better educate and empower their health choices.*

Sachiko Kaizuka, MD *is Assistant Professor of Family Medicine at University of Rochester Medical Center in Rochester, NY. Dr. Kaizuka is a board-certified family physician and also board-certified in integrative medicine (ABOIM) and medical acupuncture (ABMA). She practices and teaches an integrative approach to clinical medicine and clinician wellbeing.*

Albany Report

By Reid, McNally & Savage



2020 Session Legislative and Albany Update

In late July, the State Legislature held a remote legislative session to address local bills, confirmation of appointees to NYS bodies, and some member priority issues. The State Capitol remained closed to the public and only a few people were permitted in the chambers. This was only the fourth time that lawmakers convened session since the mid-March shutdown. Once to enact the final budget in early April, and subsequent May and June sessions to act on a series of COVID-19 related and police/criminal justice bill packages, respectively. Just over 400 bills were passed by both houses this session, far less than other years given the circumstances.

As state lawmakers continue to press for additional federal funding to fill the $14.5 billion deficit the state faces from revenue declines due to the pandemic, Governor Cuomo has warned that without additional federal aid, state and local governments will have to make cuts to essential services. Currently, the state is withholding 20% of state payments for certain sectors and industries, forcing local governments and organizations to cut staff and services. Other measures include a hiring freeze across departments as well as delayed pay raises for some 80,000 employees and a freeze on new state contracts.

The state received billions in aid from the federal government this year to cover COVID-related expenses and the state's budget plan expects federal aid will be exhausted by the end of the year. The state took out a $4.5 billion short-term bond earlier this year to cover cash flow issues from delayed federal income tax payments, but budget officials are reluctant to borrow to cover this year's deficit. The state estimates an expected $62 billion deficit through 2024.

Some progressive legislators, labor unions and other advocates have urged the state to consider raising taxes on the wealthiest New Yorkers to assist with the deficit and help fund necessary programs. Various legislative proposals include increasing taxes for New Yorkers who make $1 million or more annually, implementation of a "pied-a-terre" tax on second homes in New York City, a new capital gains tax on the state's resident billionaires and the elimination of all or some of the rebate of the stock transfer tax.

During various COVID-19 briefings and news conferences held recently, Governor Cuomo suggested tax increases should first be considered on the federal level before New York raises state taxes. "Why force our state to increase taxes and then put us at a competitive disadvantage," the Governor said. "The best option is federal government do your job and give us the resources we need otherwise the national economy is going to suffer."

In mid-September, Speaker Nancy Pelosi announced that the House would remain in session until the parties have an agreement on another round of emergency coronavirus relief, which would extend the legislative calendar beyond the initial October 2nd recess date. Senate Majority Leader Mitch McConnell offered a so-called "skinny" proposal: a $650 billion relief package that has been rejected by the House as it excluded key demands of Speaker Pelosi and the Democrats.

Return of the Legislature?

While no date is set for a return to Albany, legislators are in a holding pattern until either a clearer picture comes out of Washington post election day and/or if budget officials introduce a deficit reduction plan to which the Legislature would have ten days to counter with their own proposal or accept the Division of Budget recommendations.

The RMS team is closely monitoring the situation as it relates to our advocacy efforts for NYSAFP and we will keep members updated on new developments and actions that need to be taken to prevent members and patients from being negatively affected.

Update on Executive Orders and Legislation

Since the start of the pandemic, the Cuomo administration has been governing largely through Executive Order to both implement reopening of the economy and to combat the spread of COVID. We have developed an *Executive Order Compendium* and a *Reopening Tracker* along with a summary and status of health and mental hygiene legislation that has passed so far this year. Please contact penny@nysafp.org for a complete copy (with links) of the above and summaries of all bills that passed both houses during the 2020 session in the health/mental hygiene areas.

Our On-again Off-again Relationship with Aspirin:

Where are we now with Cardiovascular Prevention?

By Jonathan Brach, DO, and Elizabeth Loomis, MD

Abstract

Salicylic acid has been in medicinal use since the time of ancient Egypt as an anti-pyretic and pain reliever. In 1897, Bayer Pharmaceuticals developed acetylsalicylic acid, which they named aspirin, as a less irritating form of salicylic acid. Aspirin's anti-platelet properties were first noted in the 1950s and by the end of the 1980s, it was widely used in the US for the prevention of heart attacks. In more recent years, aspirin's use in vascular disease has changed. Current recommendations from the USPSTF made in 2016 recommend the use of aspirin in primary prevention of myocardial infarction based on age and medical comorbidities. Recent evidence in the last year now suggests a more selective approach in using aspirin for primary prevention to better balance the harms and benefits of its use. Aspirin continues to be recommended as part of a regimen of secondary prevention for both cardio- and cerebrovascular disease.

Our relationship with aspirin started long ago with the use of salicyline derived from willow tree bark. Ancient Egyptians and Sumerians used salicyline for medicinal purposes related to its anti-inflammatory properties.[1] Since then, many other cultures across the globe utilized salicyline as an analgesic and antipyretic with its scientific debut as treatment for fever and malarial symptoms in 1763.[2,3] From salicyline, salicylic acid was developed as a cheaper, purer alternative. Salicylic acid, however, caused significant gastric irritation and tinnitus as side effects. In 1863, Bayer Laboratories developed acetylsalicylic acid and the name aspirin. With Bayer driving the commercialization of aspirin, its medical use spread widely and triggered further exploration of aspirin's exact mechanism of action and other potential uses.

Based on widespread observation that use of aspirin prolonged bleeding time, in the 1960s, researchers deduced that aspirin inhibited platelet aggregation.[4] During this time, warfarin was being used as an anti-thrombotic to prevent myocardial infarction (MI), so it did not take long until trials of aspirin began for the same indication. The results of one of the most well-known trials were published in 1953 and followed 8000 male patients at higher risk of coronary artery disease on aspirin. This larger trial showed no MIs for these high-risk patients during a several year period.[5] More rigorous studies ensued. In 1985, the Food and Drug Administration approved aspirin for use in treatment of acute myocardial infarctions as well as secondary prevention of MIs.

With its impressive historical pedigree, aspirin does also carry several risks that should be balanced with promoting its widespread use. Routine use of even very low-dose aspirin (<100 mg every day or other day), increases the risk of major gastrointestinal (GI) bleeding by 58% and hemorrhagic stroke by 27%.[6] In addition, aspirin can trigger Aspirin-Exacerbated Respiratory Disease (AERD). AERD is an inflammatory syndrome characterized by asthma, recurrent eosinophilic nasal polyps, and respiratory reactions induced by aspirin and all cyclooxygenase 1 (COX-1) inhibitors. This inflammatory reaction affects both the upper and lower airways and can include abdominal and skin reactions as well. Among all adults with asthma, it is estimated that at baseline 7.2% have AERD with higher rates in those with severe asthma (14.9%).[7]

Our current guidelines on aspirin use in primary prevention of cardiovascular disease from the United States Preventive Services Task Force (USPSTF) were published in 2015.[8] These guidelines support low- dose aspirin as primary prevention of cardiovascular disease in adults aged 50-59 with a greater than or equal to ten-percent, 10-year risk of cardiovascular disease. It also recommends consideration of the use of aspirin in adults aged 60-69 with a greater than or equal to ten-percent, 10- year risk. The USPSTF found insufficient evidence for recommending aspirin in adults younger than 50 years old or older than 70. Cardiovascular risk assessments for these recommendations were done using the risk calculator based on the American College of Cardiology/American Heart Association (ACC/AHA) guidelines.[9] These same USPSTF guidelines did note that

persons who did not have an increased risk of GI bleeds, had a life expectancy of 10 or more years, and were willing to take aspirin daily for at least ten years, were the most likely to benefit from aspirin therapy.

During the past two years, several major studies provided more nuanced evidence on aspirin's use in primary prevention of cardiovascular disease. A large meta-analysis that included several of these newer studies showed aspirin use was associated with significant reductions in overall cardiovascular outcomes compared with no aspirin with a number needed to treat of 265. It also showed an increased risk of major bleeding events in those taking daily aspirin compared with no aspirin with a number needed to harm of 210. There was no significant reduction in total strokes associated with aspirin use compared to no aspirin use.[10] A second recent meta-analysis further concluded that in persons without established cardiovascular disease, aspirin was associated with a lower incidence of myocardial infarction, but not all-cause mortality. Furthermore, it showed that aspirin use was associated with an increased incidence of major bleeding and intracranial hemorrhage.[11]

These more recent studies have led the American College of Cardiology (ACC) and American Heart Association (AHA) to publish guidelines in 2019 recommending that low-dose aspirin only be considered in adults age 40-70 with significant ASCVD risk (>10% 10-year risk). They further recommended against the use of aspirin in adults greater than 70 and adults at any age with a higher bleeding risk regardless of cardiovascular risk.[12]

The use of aspirin continues to be recommended in secondary prevention of cardiovascular disease. While no recent major studies have been published on this topic, many large, well-designed trials previously showed that patients with known cardiovascular disease or a history of occlusive stroke benefit from a daily dose of aspirin. A dose between 75-81 mg likely balances the risks and benefits of routine aspirin use in this high-risk population.[13]

Should primary care physicians be recommending aspirin to their patients for cardiovascular prevention? At least for now, the answer depends on which guidelines the provider follows. It is also likely that these guidelines will continue to change over time to incorporate new research. The good news is that the decision does not fall solely on the primary care provider, but also specialists, pharmacists, and most importantly the patient. We recommend shared decision making as providers explore the risks and benefits of taking aspirin with their patients.

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Jonathan Brach, DO *is a second year family medicine resident at United Memorial Medical Center's Family Medicine residency program in Batavia, NY. He attended Middlebury College in Vermont for his pre-medical studies and Lake Erie College of Osteopathic Medicine in Erie, PA for medical school. Dr. Brach's academic interests include primary care and preventive medicine.*

Elizabeth Loomis, MD *currently serves as Program Director for the United Memorial Medical Center's Family Medicine residency program in Batavia NY. She received her undergraduate and MD degrees from the University of Rochester and completed residency and fellowship training at Lancaster General Health in Pennsylvania. Dr Loomis's academic interests include addiction medicine and maternal child health.*

IN THE SPOTLIGHT

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Additionally, the conference will cover COVID-19. Dr. Linda Prine's presentation, "Lessons Learned from Reproductive Health Care in the Time of Covid-19" will examine how changes made to reproductive health care practices will outlast the pandemic. Dr. William Valenti will present, "COVID Vaccine: Who, How, When?"

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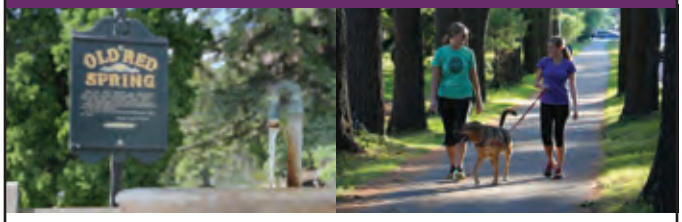

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Doctor: What Do You Mean I Can't Eat Rice?

By Xelenia Depeña, MD

When Hippocrates said "let food by thy medicine and medicine be thy food," his patients were probably not faced with the options of fast food, home delivery services that allow you to order from your couch, food injected with hormones, and a diversity of cultural diets.[10] Besides nutrition, people use food as a time for gathering in both joy and sorrow. Of concern is the growing obesity epidemic, particularly in the Hispanic population who make up a large sector of the patient population.[9] This, in turn, has caused an increase of cardiovascular risks for many Hispanics.[1]

As one of many family medicine physicians in New York City, many of the patients we see consume rice in excess. For Hispanics, rice is a staple in the diet, not only because it makes you feel full, but also because it can be prepared for big groups to share.[8] Knowing this about my patient population allows me to use each visit as an opportunity to explore how much rice each patient is consuming, as well as how often. The usual answer is, too much and too often. Unfortunately, other dietary factors such as the added salt in rice, and a lack of exercise contribute to Hispanics having higher rates of diabetes, obesity, and cardiovascular disease compared to non-Hispanic populations.[4] A simple set of questions I use to assess patients' consumption of rice can be seen in Table 1. When I have identified that a patient is consuming an excessive amount of rice, I advise them to reduce their intake by half each week until they have reached the recommended dietary intake. Patients often find this is an achievable goal, and it gives them time to acclimate to their new dietary changes.

Table 1 – Quantifying Rice Intake

1. Do you eat rice? If not, other sources of carbohydrates?
2. How many servings of rice daily?
3. How much rice per serving? Example: una cucharón or dos cucharónes de arroz?

*Cucharón is big spoon in Spanish, primarily used to cook/serve food

As a primary care physician, there is always an opportunity to counsel on nutrition, however, it is no easy feat. Many times I am met with resistance from patients because quite frankly, they do not know what else to eat. Patients frequently ask me, if they cannot eat rice, then what else can they substitute in their meals? It might seem ludicrous to many, however as a physician who is Hispanic as well, nutrition is either taught at home or it is not. Many times in the Hispanic culture we are learning to eat the same way as the generations before us, even though we now have new evidence on optimal nutrition sources. Not to say all Hispanics don't eat healthy or know how to prepare healthy food, however, many of the recipes tend to be high in salt, fat, and sugar. This is where primary care doctors can show their patients the healthy plate picture,[7] and point out there is no need to completely eliminate rice but instead, to reduce the amount.[2] This technique has worked every time for me in practice because the patient can now visualize what their plate should look like and feels empowered. Which takes us into the next important factor of glycemic control.

When patients are diabetic they are at higher risk for a cardiovascular event.[3] Hispanics tend to have a higher risk due to diet amongst other factors. If the primary care physician can tie in the reduced intake of just rice alone, glycemic control will improve. This is when I show my patients that what they did helped them improve their diabetes. Which in turn leads to better compliance with medication because they understand how their diet affects their blood glucose. Just telling the patient to stop eating rice is not enough, and many times patients do not have access to see a nutritionist. Other times it can be a lack of health literacy that can be a challenge for patients to make the dietary changes needed to reduce their cardiovascular risks.[6]

If a patient cannot see a nutritionist, which can occur due to language barriers, lack of cultural awareness, financial concerns or locality, then primary care physicians should take the lead and include a brief nutrition counseling session at each visit, and plan for their patient to follow up on subsequent visits. This is especially important in high risk patients such as those with diabetes, cardiovascular disease, and/or obesity.[5] If we can connect with patients and empower them to make small changes, we can see big outcomes and a reduction of complications or death from heart disease and other chronic diseases.

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Xelenia Depeña, MD *is a board certified family medicine physician who works outpatient in New York City. She also serves as Collaborating Physician Consultant for Optum. She is a graduate from Universidad Iberoamericana Medical School in Dominican Republic and completed her residency training in Chicago, Illinois at AMITA Health (Formerly Presence Health) Saints Mary and Elizabeth Medical Center. Her interests include women's health, working to improve care in underserved and marginalized communities, and preventive medicine.*

Smartphone Applications for CVD Risk Reduction

By Nashita Molla, MD; Jacqueline Gallardo, MD; Anubhav Agarwal, MD; and Joyce Robert, MD

Overview

This article will review the American College of Cardiology (ACC) and the American Heart Association (AHA) guidelines on primary prevention of cardiovascular disease, and how we can use the atherosclerotic cardiovascular disease (ASCVD) risk calculator in our everyday practice. This article will also discuss the novel use of smartphone-based health and wellness applications. With the rise of rates of obesity, targeting adolescent and adult populations using technology as a platform for healthy lifestyle changes is advantageous. There is modest evidence that smartphone health enhances physical activity, weight control and BMI. Specifically, we will take a closer look at Noom Coach and Couch-to-5k smart applications as a possible intervention for cardiovascular disease prevention, as well as applications for blood pressure monitoring.

Primary Prevention of Cardiovascular Disease

Cardiovascular disease (CVD) is among the most common morbidities in America[2] and is only increasing in prevalence.[31] The American Heart Association reports that nearly 50% of Americans over 20 years old have cardiovascular disease.[2] CVD encompasses a broad set of diseases including coronary heart disease, cerebrovascular disease, peripheral artery disease, and aortic atherosclerosis/aneurysm. Risk factors for these atherosclerotic cardiovascular diseases include age, smoking, dyslipidemia, hypertension, diabetes, chronic kidney disease, obesity, psychosocial factors, fruit and vegetable intake, regular alcohol consumption, limited physical activity and family history of CVD.[21] Fortunately, many of these risk factors can be mitigated through positive lifestyle modifications.[21]

All patients between 20-79 years old without known CVD require CVD risk discussions, with those between 40-79 requiring formal CVD risk calculation.[2,13] The most well- known and widely used methods of calculation are the American College of Cardiology/American Heart Association (ACC/AHA) and the 2008 Framingham Atherosclerotic Cardiovascular Disease (ASCVD) risk calculators.[20] Risk calculators can be used to calculate 10-year absolute risk of having cardiovascular events or strokes in men and women over 40 years old with low density lipoprotein cholesterol (LDL-C) 70-189 mg/dL.[14] The risk calculator accounts for age, gender, blood pressure, total cholesterol and high density lipoprotein (HDL), presence of hypertension (HTN), diabetes, and smoking status.[8] Patients with a score of <5% are considered low risk, 5 to 7.4% are considered borderline risk, 7.5 to 19.9% are considered intermediate risk, and >20% are considered high risk. These scores can be used to determine if a patient will require lifestyle changes or primary prevention therapies such as statins or aspirin.[14] Patients with LDL >190 mg/dL are considered very high risk and will require statin therapy for secondary prevention.[14]

Use of Mobile Exercise and Diet Apps to Prevent CVD

CVD is best prevented through the promotion of healthy, active lifestyles.[2] Per AHA, physical activity guidelines recommend 150 minutes of exercise per week (moderate-intensity aerobic activity) or 65 minutes of vigorous aerobic activity per week, or a combination of both. A new hurdle, the COVID pandemic, has further affected the world's population as of late 2019. Among other issues, physical activity is more elusive than ever now that most gyms and exercise facilities are closed and people are leaving their homes less often.[7] A promising development during these unprecedented times is the growing popularity of smartphone exercise applications.[5,30] As physicians, we can use health maintenance visits to provide patients with a list of recommended and available smartphone applications for both Apple and Android users. We may then use the tracking and historical data functions of these apps to review patients' progress.

One program, the Couch to 5K, was developed by Josh Clark in 1996. He found that by creating milestones, people were more likely to be motivated to continue. The program was later turned into mobile apps by multiple developers. These apps use the same basic principle as the original program, where individuals gradually increase the amount of walking and jogging from very little, to being able to run a 5K. Couch to 5K apps provide an array of services including a virtual trainer, running progress, daily challenges, and sleep aids and trackers, most of which are free. Of these free apps, The American Journal of Medicine recommends the Couch to 5K by Active Network LLC.[15]

Couch to 5K Sample Schedule[22]

Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9
8 cycles of running 1 min, followed by walking 1.5 mins.	5 cycles of walking 2 mins, followed by running 1.5 mins.	2 cycles of running 90 sec followed by walking 90 sec. Run 3 min, followed by walk 3 min.	Run 3 min, followed by walk 90 sec. Run 5 min. Walk 2.5 min. Run 5 min.	2 cycles of run 5 min followed by walk 3 min, run 5 min. Walk 3 min. Run 5 min.	Run 5 min, walk 3 min, run 8 min. Walk 3 min. Run 5 min.	Run 25 min.	Run 28 min.	Run 30 min.
Repeat every other day	Repeat every other day	Repeat every other day	Repeat every other day	Repeat every other day	Repeat every other day	Repeat every other day	Repeat every other day	Repeat every other day

The national Diabetes Prevention Program (DPP), a CDC recognized lifestyle program is another option that was originally developed to decrease the risk of diabetes, but can be used to decrease risk of CVD as well.[11,26] This program focuses on decreasing calorie and fat intake and increasing physical activity to 150 minutes per week or more, and multiple studies have found the DPP efficacious.[1,11] The Diabetes Prevention Program was developed into an iPhone app, the DPPSTAR™, which is available to employees through their employers. It is, unfortunately, not currently available to the public. Noom Coach, another mobile app which has met CDC's Diabetes Prevention Recognition Program standards (DPRP), is available to the public at a cost. It is a widely popular mobile app that uses guided self-help treatments based on cognitive-behavior therapy,[6,16] and places a special focus on the psychology of healthy living and mindful eating. Noom allows users to choose whether they want to focus on nutrition or exercise and choose how fast they want to lose weight. In a 2016 study, 77.9% of 35,921 Noom users sustained weight loss over 9 months.[6] The British Medical Journal found that 64% of Noom users lost more than 5% of their body weight.[25] Multiple other studies have found that overweight or obese Noom users have successfully maintained weight loss.[30]

There are thousands of fitness, diet, and wellness applications in the Apple and Android markets. The goal is to find what works best for the patient and which he/she enjoys using. Below is a comparative list of the current top applications.

Role of Blood Pressure Monitoring Apps in Reducing CVD

Lifestyle modification and medical management effectively reduce cardiovascular risk in patients with hypertension. The Centers for Disease Control and Prevention (CDC) notes that the prevalence of hypertension among adults during the years 2015-2016 was 29.0% and was similar among men (30.2%) and women (27.7%).[12] CDC guidelines recommend regular home BP monitoring for HTN management. Smart device health tools are increasingly used to provide patients and healthcare

Comparison of Diet and Exercise Mobile Apps

App	Function	Cost
Noom Coach[6,16,25,30]	Exercise: Psychological approach to weight loss and behavioral change.	$59.00/month
Couch to 5K by Active Network LLC[15]	Exercise: Prepares inexperienced users to run a 5 km race in 3 months.	$1.99 one-time payment
Run Keeper[15]	Exercise: Tracks aerobic exercises and weight loss.	Free- lite, $9.99- pro (one- time payment)
Nike+ Running by Nike Inc.[15]	Exercise: Tracks and provides run metrics including time, miles, calories burned, elevation, average pace, and number of runs.	Free
Weight Watchers International, Inc.- MyWW[9,29]	Diet and Exercise: Food and Fitness Tracker.	$24.99/month
MyFitnessPal by Under Armour[23]	Diet and Exercise: Assists users in tracking daily meals and physical activity.	Free
LoseIt! by Fitnow Inc.[3,32]	Diet: Sets weight goals and tracks food intake.	Free
Fooducate[15]	Diet: Ranks nutrition value of food items from grade A to D and provides alternatives for unhealthy choices.	Free lite, $1.99 pro (one- time payment)
My Meal Mate by the University of Leeds[4,5]	Diet: Food and nutrition tracker for weight management	Free

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professionals with tools and resources to manage chronic disease, including reduction in cardiovascular disease outcomes.[28,33] Smartphone based reminder apps improved adherence and BP among patients with HTN.[27]

A recent study done at Radboud University Medical Center in 2018 provided an overview of the best apps currently available to download in app stores. The study also identified important key features for self-management that can be used by healthcare providers and patients with hypertension to find a suitable app targeting blood pressure monitoring.[17] The app quality was determined by Mobile App Rating Scale scores (MARS score), with 0 being the lowest rating and 5 the highest. MARS score subscale includes engagement, functionality, aesthetics, information and subjective quality. The top 5 Android and iOS apps are listed in Table 1 and Table 2.

Smart Device Technology can Reduce Health Disparities

Health disparities or health inequities can be defined as differences in health outcomes for example mortality, morbidity and burden of disease between populations or sub groups. It also includes the disadvantage referring to unfavorable social, economic and political conditions that many groups of people systematically experience based on their relative position in social hierarchies.[19] Social determinants of health need to be taken into account when counseling patients on ways to decrease CVD risk.[24] For instance, health literacy should be assessed for all patients particularly for those who come from poor educational backgrounds. When prescribing exercise regimens, considerations need to be made in regards to access to facilities for physical activity.[2] Further considerations are listed in Table 3 created by the ACC/AHA.

Mobile apps such as the ones discussed above can be used to reduce health care disparities particularly for decreasing CVD risk.[32] One study utilized a smart tablet and Bluetooth technology to monitor patients' blood pressure, blood glucose, and weight in a rural community primary care clinic that served impoverished adults. The population construct for the study was to include those experiencing health disparities due to social determinants of health, such as low income and lack of insurance. The conclusion of this study revealed that the use of the smart technology and intervention helped reduce systolic and diastolic blood pressure, weight and BMI after a 3- month intervention. This study further proves that the use of smart devices can further reduce cardiovascular disease and health disparities.[18]

Limitations in Using Smartphone Apps

Although many smartphone apps are beneficial, it should be noted that not all applications are productive or even minimally effective.[23] Smartphone apps are more useful for patients who are ready to self-monitor their physical activity, diet or blood pressure.[23] Furthermore, despite their popularity, smart devices can be expensive to purchase or difficult to operate for many patients, making these apps inaccessible to a significant portion of the general population.[15] A multitude of applications have been developed over the past decade to promote better health outcomes through increased physical activity, diet, and BP monitoring, but very few of them have been studied closely by medical professionals. Further collaboration between health behavior experts and app

Table 1: Android Apps for BP monitoring[17]

	Bloeddruk	Beurer HealthManager	S Health	Cardio Journal Blood Pressure	Med M Blood Pressure
MARS overall score (0-5)	4.1	3.7	3.4	3.3	3.3
Price	Free	Free	Free	Free	Free
Personal Data					
Age	x	x		x	x
Gender		x		x	x
Height		x	x	x	
Weight	x	x	x	x	
BP Measurement					
Side (L or R arm)	x				x
Position (sitting or lying)	x				x
Date and time	x	x	x	x	x
Other Features					
Reminder	x			x	
Analysis Tool	x	x	x	x	x
Data export	x	x	x	x	x
Data upload from BP-meter		x			x
Password Protection		x	x		x

Table 2: iOS Apps for BP monitoring[17]

	AMICO MED BP	Braun Healthy Heart	Blood Pressure	Beurer HealthManager	Health Mate
MARS overall score (0-5)	3.6	3.5	3.3	3.3	3.2
Price	Free	Free	Free	Free	Free
Personal Data					
Age	x	x	x	x	x
Gender	x	x	x	x	x
Height			x	x	x
Weight		x	x	x	x
BP Measurement					
Side (L or R arm)			x		
Position (sitting or lying)	x	x	x	x	x
Date and time			x		
Other Features					
Reminder	x	x	x		x
Analysis Tool	x	x	x	x	x
Data export	x	x	x	x	x
Data upload from BP-meter	x		x	x	x
Password Protection	x			x	x

developers needs to take place and should be encouraged.[10] The overall convenience and utility of smart device applications is difficult to deny. Physicians should continue to study and embrace these handheld programs as important tools in the fight against CVD.

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Table 3: Evaluation of ASCVD Risk in Association with Social Determinants of Health[2]

Topic	Example Considerations
Cardiovascular risk	• Assess psychosocial stressors and provide appropriate counseling. • Assess health literacy every 4 to 6 years to maximize recommendation effectiveness.
Diet	• Social and cultural influences should be assessed. • Barriers to healthy diet need to be assessed including food access and economic factors.
Physical activity	• Assess neighborhood environment and access to facilities for physical activity.
Obesity	• Assess for psychosocial stressors, sleep hygiene, and other individualized barriers. • Promote weight maintenance in patients who are unable to achieve recommended weight loss.
Diabetes mellitus	• Assess for environmental and psychosocial factors, including depression, stress, self-efficacy, and social support.
Hypertension	• Assess access to healthy, low-sodium diet and viable exercise options, as well as sleep quality and duration which can increase BP.
Tobacco abuse	• Assess for availability of assistance and arrangement for individualized and group social support counseling.

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Nashita Molla, MD *is a third year family practice resident currently training at Mount Sinai South Nassau Hospital in Oceanside, NY. She completed her undergraduate and medical studies at Wayne State University in Detroit. She is a National Health Service Scholar and intends to work with underserved populations after residency. She enjoys discovering new flavors of bubble tea in her free time.*

Jacqueline Gallardo, MD *is a third year family practice resident currently training at Mount Sinai South Nassau Hospital in Oceanside, NY. She grew up in Los Angeles, California and is interested in working in an outpatient setting with a focus on prevention, pediatrics, geriatrics, integrative medicine and addiction. Outside of medicine, she enjoys exploring the outdoors with her dog, finding new restaurants, and traveling.*

Anubhav Agarwal, MD, CAQSM *is currently an Associate Program Director at the Mount Sinai South Nassau Family Medicine Residency Program. Doctor Agarwal believes that exercise and function are intricately related, and regardless of age, every person deserves an active lifestyle that promotes physical fitness.*

Joyce Robert, MD, FAAFP *is a family physician who practices academic medicine as core faculty at Mount Sinai South Nassau (MSSN) Family Medicine Residency Program. She is also the Director of the Transitional Year Program at MSSN. Dr. Robert appreciates working in underserved areas and addressing health care disparities. She is also a licensed Zumba instructor and likes music and dance as a way to unwind.*

Taking a Collaborative, Community Health Approach to Address Cardiovascular Health: Using Health Promotion Programs as a Bridge to Primary Care for Populations with a History of Substance Use Disorders

By Valentina Sedlacek and Holly Russell, MD, MS

Introduction

Since 2008, preventing chronic disease, such as cardiovascular disease, and "promoting mental health and preventing substance abuse" have been public health priorities across New York as a part of the Prevention Agenda set by the New York State Department of Health.[1,2] It is well documented that long-term substance abuse can lead to significant cardiovascular health problems.[3-8] These public health priority areas are paramount to primary care physicians. The same principles that make family physicians well positioned to care for those with chronic conditions like cardiovascular disease, also make family physicians poised to lead on the long-term management of care for patients with substance use disorders (SUDs).[4] Family doctors often know their patients and their environments well and have established long-term relationships. This established trust is advantageous for effective screening and when a patient begins to show signs of a substance use disorder. Family medicine physician's ability to provide longitudinal, community-based care for diseases that require frequent and long-term attention is ideal for chronic disease and substance use disorder management. But what about those patients who have not connected with the health care system, perhaps because of their substance use disorder? Reaching these patients has been historically challenging for primary care physicians and requires creativity.

There is an opportunity for family medicine physicians to take a community health approach and form a cross-sectional partnership with a community organization that already has the trust of individuals with a history of substance use disorders in promoting health and recovery. The method is rooted in the same reasoning behind incorporating a community health worker, a trusted member of a community, on clinical care teams.[5-8] Community-based participatory research offers an opportunity to generate health-promoting programs that are well positioned for ready adoption by communities, particularly those which distrust the healthcare system.[6,7]

To date there has been little published on how to design and develop health promotion programs using the principles of community-based participatory research, particularly targeting populations with substance use disorder. The evidence is also limited when it comes to methods of empirically evaluating interventions and health promotion programs within populations with substance use disorder. The gap in the existing knowledge that we aim to address is how to develop such an intervention with a community partner organization that fulfills the principles of community-based participatory research.

An Example from Rochester, New York

An example of this type of health intervention where family medicine goes *to* the community partner is being carried out in Rochester, New York. Highland Family Medicine, an integrated primary care safety-net clinic which is part of the University of Rochester, has partnered with ROCovery Fitness, a community based not-for-profit Recovery Community Organization focused on promoting recovery and sober living through fitness and community for people with and at risk for substance use disorders. Consistent with the principles of community-based participatory research, the idea for this research project came from ROCovery Fitness members who wanted to learn more about healthy living and asked for this type of programming.

The idea of promoting recovery and sober living through fitness and community is well supported in the literature. Research has shown that increased levels of moderate-effort physical activity facilitate alcohol recovery and promote mental and physical health.[8] Exercise and physical activity present an important antidote by providing health benefits in the same areas worsened by substance abuse. Moreover, simultaneous group-based

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intervention efforts further enhance the positive effects of exercise on alcohol use.[9,10] This provides a unique window of opportunity for health education, promotion, and disease prevention.[11]

Family physicians are a natural connection to these types of preventive medicine initiatives.[12] However, it is established that patients with substance use disorders experience significant stigma that can prevent them from accessing evidence-based care or treatment.[13,14] It is estimated by the nonprofit Center on Addiction that only 10% of those with a substance use disorder receive treatment, and fewer still receive screening and early intervention.[15]

The partnership between ROCovery Fitness and Highland Family Medicine has the potential to create a health promotion program that has the approval of ROCovery Fitness, giving the program validity in the eyes of the organization's membership, and creating an opportunity for family medicine students and physicians to share the space with ROCovery Fitness members in a way that would otherwise not be possible. This allows the program to combine knowledge with action and achieve meaningful interactions that have the potential to rebuild trust and reduce stigma related to substance use disorder. Another potential outcome would also be to improve the health and primary care seeking behaviors of ROCovery Fitness members.

Pilot Program and Next Phase of Research Study

The community-based participatory research approach led to the design of a health promotion program at ROCovery Fitness. Focus group data stressed that the importance of keeping an active theme for the program since ROCovery Fitness's community is attracted to their programming due to the active nature. This meant that the program ought to include an opportunity for bi-directional learning and teaching through activities, storytelling, discussion, and sharing.

The topics of the workshops in the program come from the ROCovery Fitness community and include addressing the stigma surrounding medicine and addiction, promoting patient activation and self-advocacy, using health resources, teaching about healthy living guidelines related to goal setting, nutrition, sexual health, dental care, physical activity, preventive health services, and much more. 100% of follow-up survey respondents (n=14) stated that the program outline seemed "consistent with what we talked about during your focus group" and gave an overall rating of 4.7/5 on satisfaction with the draft of the program outline and 4.5/5 on "how excited they are to participate in the ROCovery Wellness program as it is right now."

Most importantly, because the program was created by and comes from the ROCovery Fitness community, it creates an opportunity to rebuild a relationship and trust between ROCovery Fitness members and involved family physicians, residents, and medical students, that opens the door to preventive medicine. One of the most prevailing barriers to accessing primary care services for individuals with substance use disorders is the stigma around addiction in medicine.[16-21] By involving medical students, this collaboration provides an opportunity to train future health providers to better understand, recognize, care for, and treat those with substance use disorders. Contact-based education can decrease stigma by providing an opportunity for interpersonal contact between people with substance use disorders and future medical providers and to positively shape the next generation. The program creates an experiential component to supplement the current medical school curriculum and train future health providers to treat substance use disorders and innovatively think about chronic disease management and preventive medicine. Future plans include evaluating whether participating has a measurable impact on the health seeking behavior of ROCovery Fitness participants and understanding more about the healthcare attitudes of patients with substance use disorders. Additionally, we plan to evaluate whether participation has a measurable impact on the attitudes of involved medical students about patients with substance use disorders.

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Development of the Program

Step 1: Partner Engagement

A partnership between ROCovery Fitness and Highland Family Medicine organically evolved with time and flexibility on the behalf of the family medicine team. The family physician researcher regularly attended task force meetings where multiple community agencies come together to discuss their projects and priorities, and learned about ROCovery Fitness and offered to help with one of their needs in a way that was considered non-traditional. By being willing to be flexible and meet the community agency's needs, the medical team broke down the traditional healthcare/ community agency barrier and was able to share a mutual goal with a community partner. Partnership on subsequent projects, including ROCovery Wellness, was a natural progression. Research team members for this project included outreach engagement specialists from ROCovery Fitness, ROCovery Fitness leadership, the Highland Family Medicine physician and liaison for ROCovery Fitness, and two medical students.

Step 2: Project Design & Implementation

Identified research agenda including topics, questions, and process to achieve project goal through brainstorming sessions as a research team. Focused on sustainability, fostering the unique aspects of the ROCovery Fitness community, capacity building among all partners, and co-learning. Completed University's IRB approval process.

Step 3: Data Collection

Data gathered via:

A. Initial survey to ROCovery Fitness mailing listserv (n=138) that gathered qualitative and quantitative data regarding interest in a health promotion program, health topics of interest, and information about current primary care usage. Survey also recruited focus group participants. For this study, 87% of survey respondents stated that they would attend a monthly health promotion workshop series. 38% of survey respondents said "yes" and 33% said "maybe, need more information" about participating in a focus group, and provided their contact information to be contacted further.

B. Five 1.5-hour focus groups conducted over secured Zoom meetings due to COVID-19. Focus groups were with participants recruited from the initial survey who indicated interest and underwent an approved survey-based consent process (n=16). Focus groups were facilitated by medical students and outreach engagement specialists. Groups used a focus group interview guide, 1-5 participants, were audio and video recorded, and then transcribed.

There was a small incentive for participating in the survey and/or focus groups. Winners would receive a piece of ROCovery Fitness gear that was purchased from the community organization using grant funding.

The following steps were part of an iterative process that included ongoing evaluation of the developing program.

Step 4: Data Analysis

Two members of the research team used grounded theory to identify categories and codes as they emerge from analysis of the focus group transcripts. Each transcript was coded twice, once by one research team member alone, and the second time in collaboration with another research team member. This data was combined with the survey data.

Step 5: Create Program Outline

Research team used the combined analyzed data to determine ten workshop topics and create an outline of each session that included goals, learning and skill-based objectives, and activities.

Step 6: Report Results

Program outline was sent to outreach engagement specialists, ROCovery Fitness leadership, and focus group participants with a follow-up survey asking for feedback.

Step 7: Feedback Collection and Implementation

Feedback was incorporated to develop a final draft of the program outline.

Step 8: Develop Curriculum and Accompanying Participant Workbook

Curriculum was designed using materials closely adapted from the CDC Diabetes Prevention Program, Wilmot Center Institute Promote Health, Prevent Cancer Program, Healthy Living Program curricula designed by the Center for Community Health and Prevention at the University of Rochester, and other widely accessible health promotion, education, and healthy living programs through the Office of Disease Prevention and Health Promotion of the U.S. DHHS. Future evaluative methods will include material adapted from the Center for Self Determination Theory and will be applied for the first time to measure changes in autonomy and competency related to primary health care seeking behavior and general health behavior changes.

Step 9: Financial Support and Program Longevity

Financial support for community-based programs addressing chronic conditions is an important consideration. The development of this program was supported through an annual summer fellowship program through the Center for Community Health and Prevention at the University of Rochester. The current program is housed by ROCovery Fitness using their space for free and run on a completely volunteer basis by medical students and family medicine residents. Due to the COVID-19 pandemic, the program will be entirely virtual. In this format, the program has no direct costs. A small amount of funding was secured through grants and the University of Rochester Medical School Office of Medical Student Inclusion and Enrichment Programs. This funding will go towards supporting the program's longevity and incentivizing participation in the program.

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Conclusion

Cardiovascular disease prevention efforts traditionally focused on individualized counseling with patients on risk management and treatment. More recently efforts have focused on primary prevention, incorporated motivational interviewing, group visits, an emphasis on physical activity and a systemic/ family orientation, with the majority of these initiatives based in the clinic. The cardiovascular disease preventive interventions that happen external to the clinic are largely led by community organizations, such as those designed by the CDC. "Self-management and education" are listed as one of the CDC's "Best Practices for Cardiovascular Disease Prevention Programs."[17,18] An innovative way to address this strategy in family medicine is through the development of health promotion programs that strengthen community organization-clinical partnerships, such as we have outlined.

The CDC's recommended programs generally have little physician involvement when run in the community and are harder to access by populations who are not seeking formal preventive programming. Nevertheless, there are two strong reasons to be creative in medicine today: the high rates of physician burnout, and the COVID-19 pandemic. Increasing a physician's involvement in their community allows them to make a positive difference in spaces other than the clinic where they may experience a loss of autonomy, powerlessness, and frustration leading to their burnout.[19] By incorporating new ways of promoting health and increasing involvement with community organizations, a family physician can experience new ways of improving the health of their community and patients, and improve their overall satisfaction with their job.

Additionally, the COVID-19 pandemic has forced medical professionals to be creative. We must approach things in a new way and try out new means of connecting with our patients and providing health education and skills to individuals. The pandemic has been a tremendous opportunity to change the way we have always done things in family medicine, and in cardiovascular health promotion more generally. It is our hope that by sharing the design and implementation of the ROCovery Wellness program we can encourage other family medicine physicians and practices to use a community health approach when designing health interventions and seek out partnerships in all areas of preventive medicine.

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***Valentina Sedlacek, BA** is a second-year medical student at the University of Rochester School of Medicine and Dentistry in Rochester, NY. In addition to research, she is actively involved in UR Well, the student-run free clinic network for the city of Rochester, and UR Street Outreach. She is a student leader for the Family Medicine and Addiction Medicine Interest Groups, and a founding member of the URMC Medicine in Motion chapter.*

***Holly Russell, MD, MS** is an Assistant Professor of Family Medicine. She is board certified in family medicine and addiction medicine and is the founder and director of the Addiction Medicine Program at Highland Family Medicine. Dr. Russell is the Medical Director of Clinical and Community Programs at the Center for Community Health and Prevention and the Assistant Director for the Primary Care Clerkship at the University of Rochester School of Medicine and Dentistry.*

Case Report:
Sudden Cardiac Arrest Associated with Exertion

By Gary Carl Enders, MD

Case Report

A 50- year-old male was running a 5K race. He was quite active physically and an experienced runner. He had been evaluated for an episode of syncope while doing crunches and weight lifting several years before the race. He was found to have rhabdomyolysis and subsequently was admitted for IV hydration. Medical records for this evaluation were not available, but the patient provided history for this evaluation after his recovery. Subsequent CPK levels tended to be slightly elevated. He had prior history of elevated cholesterol treated intermittently with statins, obstructive sleep apnea, esophageal stricture that was dilated, gout, decompressive laminectomy of the cervical spine and discectomy of the lumbar spine. A cardiac stress ECHO was negative 7 years prior, and no Holter monitor reports were available in his chart. At the time of the race he was taking Naprosyn, omeprazole, ropinirole, and steroid nasal spray. He also had an epi-pen available for severe allergic reactions. His family history was negative for sudden cardiac death.

While running a 5K race, at about 3.5 km, he had seizure like activity and collapsed. His medical provider (me) was also running the race and came upon the scene about 1-2 minutes later. A crowd of people were surrounding him while he was lying on the ground with agonal respirations. Per ACLS algorithm, checking for a pulse was indicated.[18] I was told by one person that he had a pulse. I checked for one myself but didn't find one, so I started chest compressions. With CPR, his breathing improved in depth and rate. When paramedics arrived, the patient was found to be in ventricular fibrillation. He was defibrillated, got a chaotic functional rhythm back, but soon was again in ventricular fibrillation. He was defibrillated again, and got a pulse back, but was having runs of V-Tach so was given amiodarone drip and taken to the nearest ER. It is unclear from his chart if he ever received IV epinephrine. The ER doctor's note says he did get it in the ambulance but this is not documented by the paramedic note. His initial EKG showed a prolonged QT interval, inferoapical ST depressions, ventricular couplets and PVC's (*see Figure 1*). He was subsequently put on a lidocaine drip. The EKG two hours later was normal. His initial labs showed potassium of 3.1 mmol/L, CO2 of 15 mmol/L, mild elevation of transaminases, with normal magnesium of 2.3. Initial creatinine was elevated at 1.6 but improved to normal with hydration and time. Initial troponin was 0.038 ng/ml and peaked at 9.5 ng/ml 10 hours later. Since he never had ST segment elevation this could be considered non-ST elevation myocardial infarction (NSTEMI) caused by either the demand mechanism of running (type 2 or demand ischemia) or more likely, a lack of blood flow to the coronary arteries as a result of cardiac arrest.

He was transferred to a hospital with cardiac catheterization capabilities. His heart catheterization showed a smooth 30-40 percent stenosis of LAD and 30 percent stenosis of proximal RCA. Aspirin was started. Because of elevated liver function tests related to cardiac arrest, statins were not started in the hospital but were recommended to be started later when his liver function tests normalized. Beta blocker therapy was also initiated. The patient received an implantable cardioverter-defibrillator (ICD). A Bruce protocol exercise stress test, 3 weeks after cardiac arrest, was negative for ischemic changes. The patient exercised 8.3 minutes reaching 100 percent of maximum predicted heart rate with the EKG monitor showing some ventricular couplets and PVC's. He went on to make a complete recovery, did cardiac rehab briefly, and gradually returned to doing vigorous exercise. Two months after his cardiac arrest, a Holter monitor showed frequent PVC's and 40 ventricular couplets. An echocardiogram a little over two years later showed preserved biventricular ejection fraction (EF 60 %), and trivial mitral and tricuspid regurgitation. Four years later, he became dizzy after exercising and passed out. His ICD shocked him twice for ventricular tachycardia, and again, he made a full recovery.

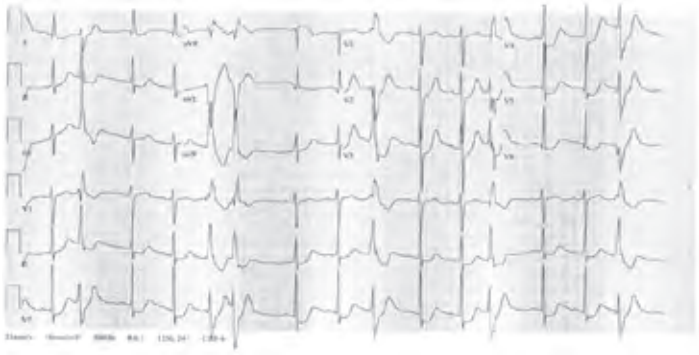

Figure 1: EKG on arrival to hospital showing sinus rhythm with PVC's, ventricular couplets, inferior-apical ST depression and prolonged QT interval

Diagnosis

Cardiac arrest secondary to ventricular fibrillation (possibly proceeded by ventricular tachycardia) with recurrence of ventricular tachycardia post-exertion 4 years later.

Discussion

This patient had an initial cardiac arrest associated with physical exertion, and 4 years later a subsequent episode of ventricular tachycardia causing post-exertional syncope. His initial EKG after the first episode showed a prolonged QT interval and marked ST abnormalities, though the prolonged QT interval could have been by the amiodarone he received after he had recurrent ventricular arrhythmias. Subsequent EKG's have not shown prolonged QT

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interval. He did have mild hypokalemia however, which can be associated with prolonged QT interval.

Sudden cardiac death (SCD) is known to occur during vigorous activity in people who appear healthy.[1-10] A study assessing cardiac arrest during long-distance running races (marathons and half-marathons) in the NEJM found that cardiovascular disease accounted for the majority of cardiac arrests and that hypertrophic cardio-myopathy was also a common cause of cardiac arrest with exertion.[4]

There are other conditions associated with sudden cardiac death which can be congenital or acquired.[1-8,11,12] Chronic heart failure with low ejection fraction is a known risk factor for sudden cardiac death.

Work up for syncope in adults varies depending on the context.[13] True syncope has to be distinguished from other causes of transient loss of consciousness such as seizures, sleep disturbances, accidental falls, and some psychiatric conditions. High risk patients require admission to the hospital. Patients with significant potentially life threatening cardiac arrhythmias should be considered for treatment with an ICD.

Indications for an Implantable cardioverter-defibrillator (ICD) include two different groups:[14,15]

1. Secondary prevention of sudden cardiac death (SCD) in those that have been resuscitated from sustained ventricular tachycardia (VT) or ventricular fibrillation (VF). Those with a completely reversible cause or life expectancy less than 1 year would be excluded. Patients with VT/VF within 48 hours of acute MI would also be excluded.
2. Primary prevention of SCD in patients at increased risk of life-threating VT/VF:
   - This can include patients with low left ventricular ejection fraction related to ischemic heart disease. Patients with prior MI must be at least 40 days post-MI with persistent left ventricular ejection fraction less than 30-35 percent despite guideline directed therapy.
   - Other patients that may be at risk for life threatening arrhythmias such as congenital long QT syndromes, hypertrophic cardio-myopathy, arrhythmogenic right ventricular cardiomyopathy, Brugada syndrome, catecholaminergic polymorphic VT and other high risk conditions may be candidates for ICD.

The wearable external cardioverter-defibrillator may be a temporary alternative to ICD in patients at high-risk of sudden cardiac death. One such instance would be post-MI with ejection fraction less than 35 percent and NYS heart failure classification II or III and less than 40 days post MI. However, the VEST Clinical Trial reported in the NEJM in 2018 did not show a significantly lower rate of arrhythmic death in patients prescribed the device than the control group.[16] Noncompliance with wearing the device was found to be associated with higher risk of death, but this was not the primary outcome for the trial.

Subcutaneous ICD is an alternative to transvenous ICD when pacing therapy for bradycardia, antitachycardia pacing, or resynchronization therapy is not needed. This device is extra-thoracic and avoids complications related to placing leads in veins and into the heart. One study showed that this device was not inferior to transvenous ICD in terms of device related complications and inappropriate shocks.[17]

Conclusions

If a patient appears be in cardiac arrest and someone says they have a pulse, re-check for a pulse yourself. The patient's condition may have changed (v-tach degenerating to v-fib) or maybe there was never really a detectable pulse. Per 2015 American Heart Association BLS guidelines for adults, lay-trained rescuers should check for no breathing or only gasping; if the patient is not breathing or only gasping, those rescuers should begin CPR with compressions. A provider trained in basic life support should do a simultaneous pulse check lasting no longer than 10 seconds and start chest compressions if no pulse is felt.[18]

Apparently healthy and fit individuals can still have cardiac arrest associated with exertion. Fortunately, this is quite uncommon, but risk increases with age.

ICD can reduce subsequent mortality in patients with prior cardiac arrest from sustained VT or VF. Appropriate patients surviving SCD or at risk for SCD because of predisposing conditions, should be referred to a cardiologist that can implant ICD.

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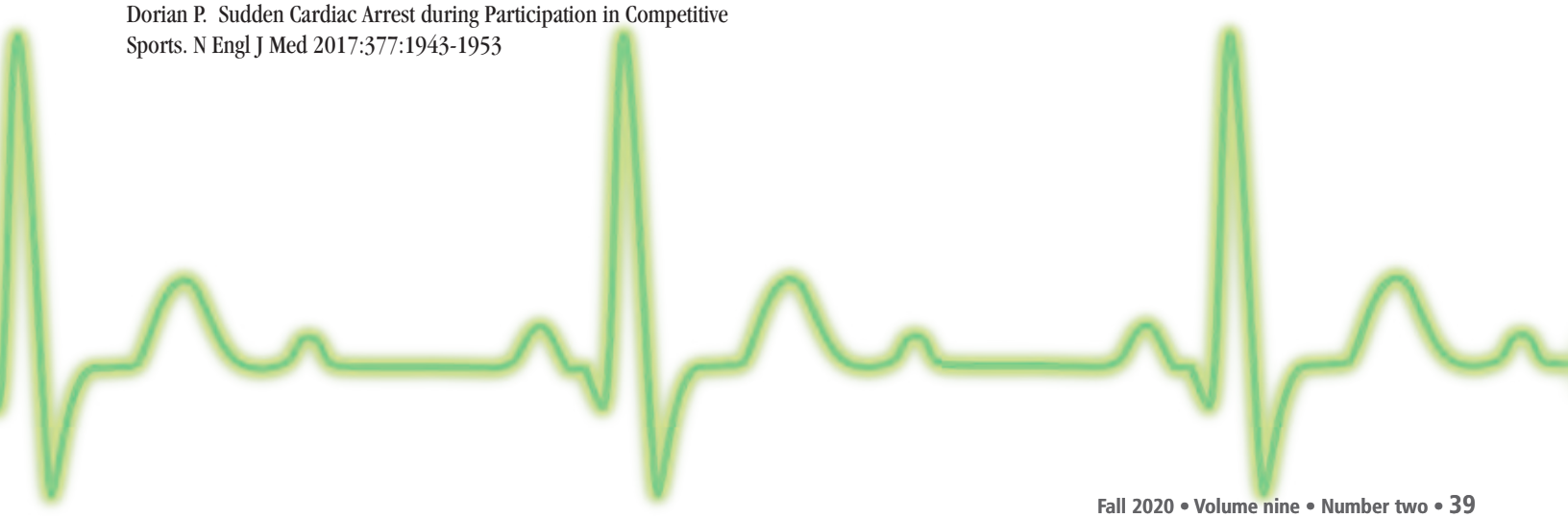
Gary Enders, MD, FAAFP *is board certified in family medicine. He is a graduate of SUNY Upstate Medical University and St. Joseph's FP residency in Syracuse. He has provided medical care in the Corning, NY area for 37 years, including inpatient and outpatient family medicine, low risk OB and emergency medicine. He is currently semi-retired doing per diem walk-in care with Guthrie Medical Group. He helped provide primary care for uninsured poor patients with the Health Ministry of the Southern Tier for 17 years and has done 9 short term medical mission trips in other countries.*



Building Bridges and Filling Gaps

By Kevin Dooley, MD

In April 2019, our medium-sized community hospital began a transitional care program. This was an outreach effort to help patients get timely and adequate time slot appointments after an acute-care stay. Transitional care visits were first reimbursed in 2013, but few in our community were billing for that service. Perhaps providers were deterred by the required actions and documentation, or perhaps it was simply easier to bill a simple office visit commensurate with the level of care. Our hospital care managers often found it challenging to book a follow-up visit in a timely fashion, so it was clear there was a need.

We designed our team to be small: two dedicated practitioners and a support staff consisting of a nurse, medical assistant, nurse case manager and receptionist. With a small staff we believe we get to know our patients well. We introduce our patients to each team member so we have a connection if they should call after hours. We cover our call after hours, and all patients are given our cell phone numbers.

I have worked as a family doctor for 25 years, but have always also worked part- or full-time as a hospitalist. For two years, I served as a family doctor providing home care to those in need. Partnered with The Eddy VNA, a local certified home health agency, I cared for homebound patients as the primary care doctor. We easily met our goals of reducing readmissions and ED visits by almost 50%. We also cared for many who chose to die at home, 50% more than the national average. The key to the success of the program was providing direct care and contact with the visiting nurses for the most fragile and at-risk patients. It was both rewarding and exhausting, but it taught me that just a bit more attention for our high-risk population works.

Our hospital has performed well in meeting metrics of the Medicare-measured readmission rate, but we wanted to do better to avoid any penalties. Although Medicare transitional care visits are partly defined by a follow-up in 7 or 14 days, we all know these visits should happen much sooner, ideally within 2- 3 days of discharge, once new prescriptions are filled and questions begin to arise. As we enter more value-based contracts this fact was to be a tool in our toolbox to meet future goals.

Medicare follows readmission rates for our patients admitted with COPD, CHF, MI, and pneumonia, among others. During my home-care years, I found COPD patients could be well managed at home since they often already had oxygen and nebulizers. The key was prompt

intervention. I didn't do a lot of routine check-up visits; I kept most of my day open for urgent, need-based visits; rapid intervention with oral steroids and appropriate antibiotics was usually successful. Today with our Transitional Care Program, I also find many opportunities to enhance patients' discharge plan of care through post-acute visits with our COPD patients. These patients, like our diabetic patients, need a lot of medications and equipment for their everyday life. In our visits we have the gift of time, enough time to discover what may be missing in their home treatment: a significant number are missing at least one element of their presumed home regimen, whether it be nebulizer medication, tubing, a working neb machine, or costly inhalers. Most often, they just need a simple spacer for their HFA inhalers. We provide spacers free of charge and take the time to demonstrate how to use them.

CHF patients, especially, need close follow-up. Many of these patients have significant adjustments to their diuretic regimen while hospitalized, and without close monitoring they may suffer dehydration, acute kidney injury, hypokalemia, and readmission. Many readmissions could have been avoided if closer follow-up had been arranged. Often these patients are fragile and need extra time and attention that may not be available in a busy primary care office.

Another problem in caring for discharged patients is that some discharge summaries are not available in a timely fashion. There are a variety of reasons for this. Doctors as authors have different writing styles, and that makes it difficult to sift through the clutter and static of "copy and paste" summaries; and quickly-dictated reports may omit data that you may be curious about, such as lab results. Certainly labs were done, but they may not have been highlighted in the final discharge summary if they were not remarkable or omitted to simplify the bigger picture of the admission. Providers outside of the hospital have to spend a fair amount of time getting additional records during a patient follow-up visit. Our team, on the other hand, has access to the hospital electronic medical record, and we know how to navigate it well; should we have questions, we personally know the doctors, care managers, specialists, lab personnel, and others who provided hospital care, and we have their cell phone numbers.

We make it clear to patients when they leave our office that they should call us for any reason until they reconnect with their family physician. We offer them concierge-like service during this fragile time. And yes, we give them our cell phone numbers. We hope to reduce the burden of the call to a primary care office from the symptomatic complex patient who was just hospitalized.

Interestingly, our transitional care service has found new roles to fill, not only building bridges back to primary care, but also filling healthcare gaps our community faces. Like many communities in New York state, we have seasonal visitors who may be here for days or months, so we serve as a medical home for these out-of-town visitors when they are discharged from the ED or the hospital. Fortunately, we have a dedicated patient concierge to act as a central new patient appointment facilitator. She may send us patients to be seen as they wait for their coveted new patient appointment, which may be months away. Seeing these un-doctored patients is very rewarding. From the ED we see many patients with new hypertension and diabetes. Although in everyday life in the office, this care could be quite mundane, the opportunity to start new meds and educate patients with information they've never heard before is very satisfying, especially if they have plenty of questions.

Treating and evaluating these patients can be challenging. Some patients have been leery of medical professionals and bring with them barriers in education, preconceived notions, or limited socioeconomic support. However, we are able to take the time to build new bridges and break down walls in the caregiver-patient relationship. And it is rewarding to diagnose not only new diabetes or hypertension, but often, advanced and rare diseases. We can get them on the right care pathway with our close ties to so many in our medical community.

Our team also makes home visits for those in need. We don't advertise this but reserve it for those who have no other option. I learned in my previous role as a home care doctor that this is always productive. Having access to their medications firsthand lets us witness exactly what they are taking. We meet family members; thus, advance care discussions are more easily begun. Our care for these patients relieves the burden of PCPs trying to care for them blindly when there are so many barriers to their getting to the office in a timely manner, if at all.

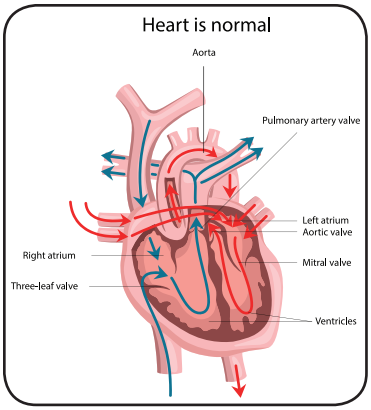
Smaller provider groups can and should schedule to allow roomy urgent, new patient, and soon-after-discharge slots to accommodate those in need. Templating two hours in the morning for the provider routine follow ups, and leaving the rest of the day to accommodate these patients may be one efficient way to model this. Reimbursement is favorable for new patients and the Medicare transitional visit codes. It can be an unpredictable day, but meeting new patients can be interesting and rewarding, and these transitional patients are often so grateful given the nature of their visit. A change of pace in the office may even be welcomed by many providers!

Many health systems have the same challenges we face, and patients are struggling to find a health home. Our community's solution was to create our Transitional Care Program. My partner and I often say, "I wonder what these patients did before we had this program." We are grateful to be part of a program that builds bridges and fills in gaps in our healthcare system.

Kevin Dooley, MD *is a graduate of the University of Maryland School of Medicine and Middlesex Family Residency Program and has worked 25 years as a family physician and hospitalist. After working overseas in Abu Dhabi, UAE in emergency medicine, he returned to serve as a home care physician for two years through the Eddy VNA in the Capital region. Currently he is the medical director of the Transitional Care Program and President of the medical staff at Saratoga Hospital. He lives in Saratoga Springs with his wife, three children nearby, and a fourth on the west coast pursing a medical degree.*

What the Family Physician Needs to Know About Adults with Congenital Heart Disease

By Jeanine Murphy Morelli, MD and Peter Morelli, MD, FACC

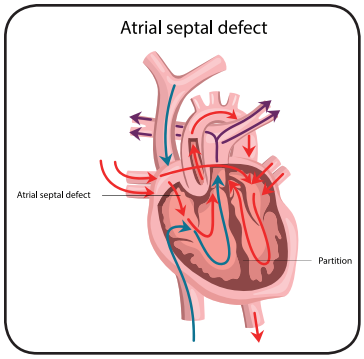


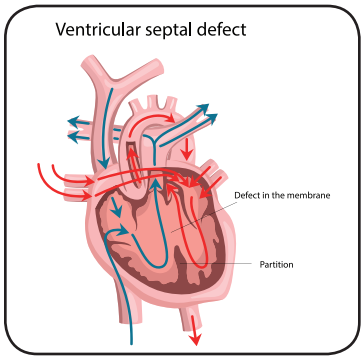
The discipline of medicine continues to produce tremendous advances in health care for virtually all human diseases. No area of medicine has seen more rapid growth in life-saving medical and surgical interventions, than in the area of congenital heart disease (CHD). Such successes have led to a burgeoning population of children surviving into adulthood with repaired, palliated or untreated congenital heart defects. The incidence of CHD remains relatively constant at 8 per 1,000 live births.[1] Due to medical and surgical advances, many are living well into adulthood, thereby creating a reality that there are considerably more adults than children living with some form of CHD. This wonderful truth has led to a very young and growing field in cardiology, the Adult Congenital Heart (ACHD) specialist. The ACHD patient presents unique and complicated cardiac and non-cardiac health and lifestyle issues previously not seen, which require a multispecialty approach to properly care for such a patient. These uber specialists are far and few between at this time, and generally consolidate in large quaternary care ACHD academic centers located in larger towns and cities. Such a reality mandates that the family physician is better equipped with a fundamental understanding of the various congenital heart defects, their surgical repairs, the post-operative sequelae and the long term health and lifestyle considerations that the ACHD patient faces. Some common congenital heart defects that one may see throughout a professional career will be summarized here but cannot provide the detail needed for comprehensive care of the ACHD but can be found in the ACC/AHA 2008 Guidelines for the Management of Adults with Congenital Heart Disease.[2] The different congenital heart defects will be categorized as simple, moderate or complex below in Table 1.

Table 1

Simple Defects	Moderate Defects	Severe Defects
ASD	ToF	Hypoplastic Left Heart
VSD	D-TGA	Valvular Pulm. Atresia
PDA		Tricuspid Atresia
CoAo		

Simple Congenital Heart Lesions

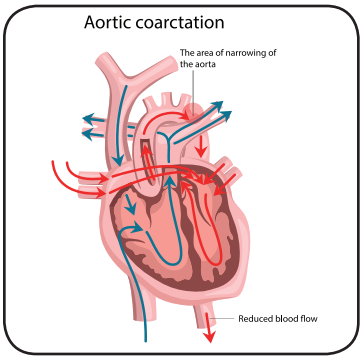




Such "simple" cardiac lesions consist of single defects of the atrial or ventricular septum. Such defects are often termed atrial septal defects (ASD) or ventricular septal defects (VSD). It is important to note that these lesions may be quite complex in their presentation. Sometimes such defects may be multiple, of various sizes, and in various locations along the septal surface. Patent Ductus Arteriosus (PDA) is another single lesion that presents in the newborn period and results when the normal ductus arteriosus fails to constrict and thrombose in the first 1-2 weeks of life. All of these simple lesions produce *a left to right shunt* physiology. Such physiology will produce a cumulative excess pulmonary blood flow compared to the systemic blood flow to the body. The degree of left to right shunting will dictate how symptomatic the child becomes. Those children with large enough septal defects or PDAs display signs of congestive heart failure and cardiac volume overload and require closure, either surgically or percutaneously in the catheterization laboratory. For the sake of this review, all such defects will be closed *only* if the patient has a reactive pulmonary vascular resistance (PVR). If the patient has an unreactive PVR, the defect *cannot* be safely closed and such patients can be very complex and should be followed by the ACHD team in your region for long standing pulmonary HTN concerns.

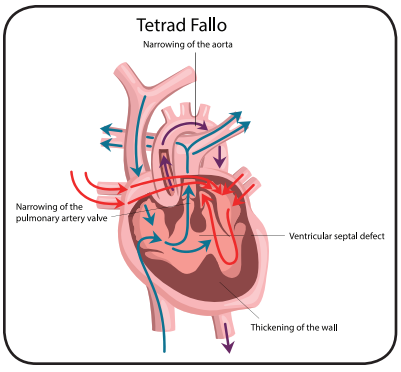
Long term sequelae for closed septal defects and PDAs are very few. ASDs and VSDs may be functionally closed but have a small residual defect or patch leak remain. Such leaks are usually hemodynamically not significant and pose few health issues. The VSD patch leak may pose a small but appreciable endocarditis risk. Both repaired VSDs may demonstrate subtle ECG abnormalities. Repaired VSDs frequently have a residual right bundle branch block (RBBB) pattern on ECG. This has no bearing on the cardiac rhythm or health status of the patient. Small residual VSD patch leaks will reveal a very audible holosystolic murmur which is always a popular finding among trainees but of little significance. Since there is surgical patch material in the heart, the patient has a slight increased chance for atrial or ventricular ectopy and tachyarrhythmias. The practitioner

should always have an increased index of suspicion for patient complaints of palpitations and consider home rhythm monitoring in such situations. The PDA post repair poses little sequelae as well. There may be a small residual shunt that remains producing a residual continuous murmur. There is a theoretical endocarditis risk. Rarely, when the ductus is closed percutaneously with a device, there may be some mild residual left pulmonary artery narrowing due to device protrusion. This is usually well tolerated but may cause a soft murmur of LPA stenosis.



Another single lesion commonly encountered is **coarctation of the aorta (CoAo)**. This is a discrete or long segment narrowing of the proximal descending aorta. Such defects may present early on in infancy with severe obstruction and heart failure, or it may present as an adolescent or young adult with occult, unexplained hypertension (HTN). Typically, the repair of choice is a resection of the stenotic aortic isthmus with end-to-end anastomosis. The long term sequelae of such a repair may be chronic hypertension. Such HTN may result despite no residual gradient across the repair site. One may reveal HTN only during exercise and thus a graded exercise stress test can be very informative. It is always imperative to perform upper and lower extremity blood pressure (BP) assessment each and every visit. Long term recoarctation should be suspected when there is hypertension in the upper extremity and normal to low BP in the lower extremity. Referral back to the ACHD center would be indicated if this is found. Coarctation of the aorta survivors may have subtle LV affects which may result in elevated LV mass and diastolic noncompliance. Symptoms of LV dysfunction including exertional intolerance, exertional syncope or chest pain, require further investigation with your ACHD center.

Moderate Congenital Heart Lesions



Such commonly seen defects are tetralogy of Fallot (TOF) and transposition of the great arteries (D-TGA). Both of these heart defects present with various degrees of cyanosis early in infancy. Both require early surgical repair in infancy. TOF involves various levels of right ventricle (RV) and pulmonary valve (PV) obstruction and a large VSD. The essential components of the repair involve resection of the RV infundibular (sub-pulmonic valve region) obstruction, various degrees of pulmonary valvuloplasty, and VSD patching. The cyanosis is corrected immediately post-op and children routinely do very well throughout childhood. Long term issues for TOF survivors is dependent on the degree of residual RV anatomic obstruction, degree of pulmonary valve stenosis or insufficiency, and RV systolic and diastolic function. The family physician should assess the patient for any symptoms of RV dysfunction, such as peripheral edema and exertional intolerance. Signs of RV dysfunction are edema, JVD and hepatomegaly. Exam findings of pulmonary stenosis or insufficiency murmurs may be heard and progression of the murmur should alert the practitioner of progressive issues requiring imaging studies. The ECG findings typically reveal normal sinus rhythm with postoperative findings of a right bundle branch block. Markedly prolonged QRS greater than 180 msec correlates with RV dysfunction and risk for ventricular arrhythmia. In coordination with an ACDH specialist, echocardiography and ultimately cardiac MRI can be done to assess the RV size, morphology and function. An important measurement is the RV volume indexed for body surface area (BSA). Dilated RV volumes beyond 160 ml/m2 correlates with impending RV dysfunction and may direct the ACHD specialist to intervene surgically or percutaneously.

D-TGA occurs embryologically when the great vessels arise from the opposite ventricle. This ventriculo-arterial discordance results in severe cyanosis as the RV pumps deoxygenated blood to the Aorta and the LV pumps oxygenated blood to the pulmonary artery. Early surgical intervention reestablishes the normal ventriculo-arterial relationship through the Jatene arterial switch operation (ASO). The critical aspect to this repair involves successful reimplantation of the coronary arteries to the new neo-aortic root. Improper anastomosis of the coronaries to their new aorta could result in ischemia to the myocardium. Those survivors into adulthood who have had an excellent ASO require lifelong assessment of their coronary blood flow. Clinical concerns of progressive exercise intolerance or *exertional* chest pain, syncope or arrhythmia should alert the practitioner to possible coronary concerns. These adults also may have a component of PA stenoses that results from the arterial switch. This will cause a systolic murmur but usually is well tolerated. Periodic assessment at the ACHD clinic involves echocardiography, cardiac MRI/MRA and exercise stress testing with the help of the ACHD specialist.

Complex Congenital Heart Lesions

This is a very large group of cardiac lesions that include valvar pulmonary atresia, single ventricle heart lesions including hypoplastic left heart syndrome and tricuspid atresia. This is a very diverse category of lesions that clinically may present very differently. Some may produce severe cyanosis while others primarily may present with heart failure. The common features in this group of congenital heart diseases is that most of these lesions require multiple staged surgeries or surgical revisions. Typically, these patients have great improvements in their cardiac physiology, cardiac output and tissue oxygenation. However, these patients are not considered cured but, instead, well palliated. Also, these patients often will have multi-organ system affects that their family physician should monitor and assess periodically. For the sake of this generalized review, we will concentrate on the single ventricle cardiac lesions. When a newborn has only one adequately sized and

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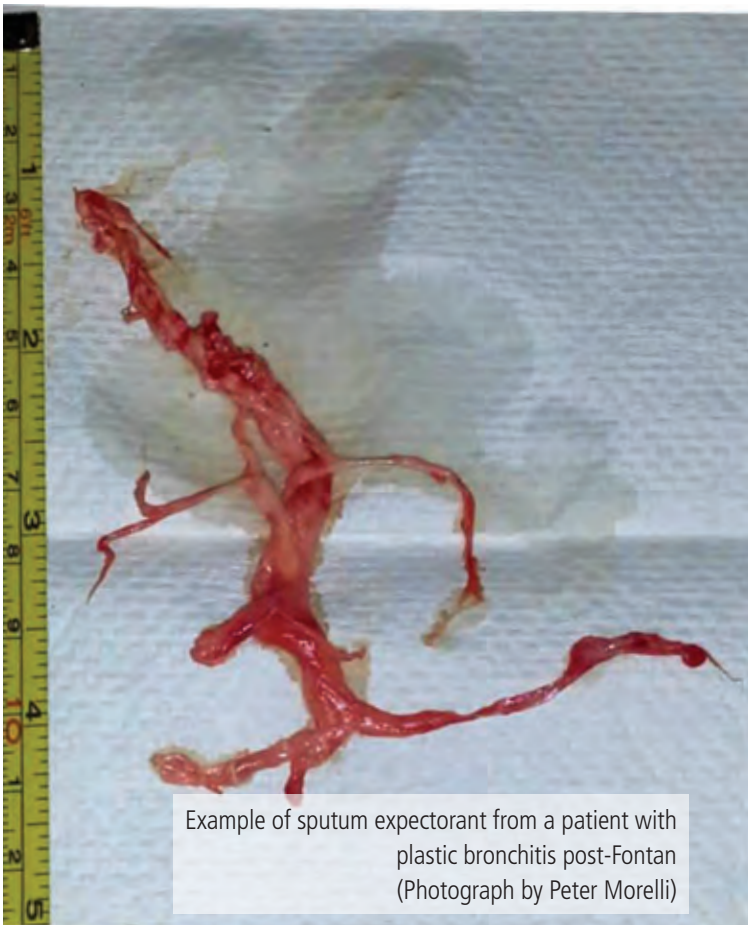
functional ventricle, they will require a staged surgical palliation, usually entailing 2-3 stages of surgery over the first 2-3 years of life. The premise is as follows: There is only one ventricle but two circulations- the systemic and pulmonary circulations. Initially the oxygenated and deoxygenated blood in the body is all mixing in the single ventricle. Ideally, the child requires separation of the circulations, and thus this staged surgery has been developed. If one were to devise a palliated state for this child, and only one ventricle to work with, it would be logical to use that one ventricle for the much higher resistance systemic circulation, so the single ventricle will be dedicated to pumping blood to the aorta leaving no pumping chamber for the pulmonary circuit. Presently, the surgical palliation offered for these children are the bidirectional Glenn shunt (BDG) which connects the superior vena cava (SVC) directly to the pulmonary artery. This surgery is followed by the Fontan anastomosis which entails connecting the inferior vena cava (IVC) to the pulmonary artery. After both surgeries the patient often is referred to as the post-Fontan patient. Both of these palliations result in passive venous pressures driving the cyanotic venous blood directly into the pulmonary circulation. In general, these children grow adequately and maintain oxygen saturations in the low to mid 90% range. Their exercise capacity is adequate but limited due to not having a subpulmonic ventricle pumping blood into the pulmonary artery. As they progress into young adulthood, the practitioner may be in tune to potential long-term sequelae in this population. Atrial arrhythmias, including atrial flutter and fibrillation, are common findings. The patient may complain of tachycardia and palpitations. They may also endorse increasing fatigue due to loss of atrio-ventricular synchrony which is essential for maintaining their reduced cardiac output. Patients may present with leg and belly edema. The family doctor should be suspicious for a hypoproteinemic state. Protein losing enteropathy (PLE), resulting in loss of protein in the stool, occurs in a small percentage of patients. Appropriate lab work would include a blood test for hepatic panel and stool studies for a 24- hour collection of alpha 1 anti-trypsin. PLE is very difficult to treat and prompt referral to your ACHD specialist should be arranged. Patients with PLE have a 5-year transplant-free survival of about 50%. Some palliated single ventricle patients develop pulmonary symptoms unique to this physiology. Thick, tenacious casts of fibrin are expectorated in the form of the bronchial tree. This condition is called plastic bronchitis. The mechanism of both PLE and plastic bronchitis is not fully elucidated, but has some relation to elevated systemic venous and lymphatic pressures and is somewhat due to chronic reduced cardiac output. Another long-term concern in this population of young adults post-Fontan is liver disease. Again, likely due to elevated venous and lymphatic pressures coupled with chronic reduced cardiac outputs, the liver may become fibrotic, cirrhotic and dysfunctional. Rarely, hepatocellular carcinoma has been seen. This condition is termed FALD, or Fontan Associated Liver Disease. The above conditions of PLE, plastic bronchitis (see photo) and FALD are poor prognostic signs for a failing Fontan and such patients are quite complex requiring the intensive services of the ACHD specialist. Failing Fontan patients often require consultation with the transplant teams at the ACHD center.



Example of sputum expectorant from a patient with plastic bronchitis post-Fontan (Photograph by Peter Morelli)

Special Considerations

The following special situations are common concerns the ADCD patient may present with to their primary care provider seeking answers.[1] The following situations assumes a fairly typical postoperative result in the various congenital heart lesions.

1. Exercise Recommendations

The Simple lesions-post repair in a timely fashion, as is the standard practice in the developed world, typically carry with it an excellent prognosis. There are no exercise restrictions and antibiotic prophylaxis for endocarditis is not recommended. However, residual coarctation of the aorta stenoses may require restrictions in type and intensity of exercise.

Table 2

CLASS OF DEFECT	EXERCISE	SBE PPX	CONTRACEPTIVES WITH ESTROGEN	PREGNANCY
SIMPLE-REPAIRED	NO RESTRICTIONS	6 MOS POST OP	YES	LOW RISK
MODERATE-REPAIRED	MAY NEED EXERCISE TESTING	6 MOS POST OP	YES	LOW RISK
COMPLEX-PALLIATED	LIMITED	PROBABLY	NO	MODERATE RISK

The Moderate lesions post repair usually result in excellent cardiac output and individuals can exercise fully and are unrestricted. **TOF** patients with progressive RV dysfunction, pulmonary stenosis or insufficiency will have exertional intolerance and should have formal stress testing and cardiac MRI imaging at the ACHD center.

D-TGA patients have reestablished normal ventriculo-arterial concordance and usually can tolerate exercise very well. If such an individual experiences exertional chest pain or intolerance, formal stress testing and possible detailed imaging to assess adequacy of coronary blood flow may be warranted.

The Complex single ventricle lesions, even post palliation, have limitations to maintaining adequate cardiac output with peak exercise. These patients can perform moderate exercise well, but are counselled to self-limit whenever they feel fatigued. They should maintain their cardiopulmonary fitness as well as possible and are encouraged to perform light regular cardiopulmonary exercise and maintain skeletal muscle mass with light strength training and ADLs. Marked drop off in their activities may be a harbinger of the above sequelae of the Fontan physiology.

2. Contraception

The simple lesions do not mandate special contraceptive considerations.

The moderate lesions do not have specific contraceptive recommendations.

Of course any individual with comorbidities of hyperlipidemia or a strong family history of premature coronary artery disease may need to consider estrogen-free modalities

The complex lesions of single ventricle palliation have considerable risk for thromboses formation and subsequent occlusion of the low flow venous dependent pulmonary circulation. Estrogen containing modalities are contraindicated in this population. Progesterone only contraceptives may put the patient at risk for fluid retention that could result in systemic edema or pulmonary congestion. IUD devices may be beneficial, though carry a small risk for endocarditis. Such patients would greatly benefit from consultation with the ACHD specialists.

3. Pregnancy Considerations

Since pre-conception counseling is extremely important for this population, the family doctor has an important role in bringing up family planning goals for their patients with CHD during their reproductive years. The fetus of a patient with CHD is at increased risk of having a similar or novel heart defect. If the father has CHD, the fetus has a 5% risk of having CHD. The risk of a fetus having CHD is 7% if the mother has CHD. The fetus has a 12% risk if the parents have aortic stenosis. Genetic counselling is always recommended for such couples. ACE inhibitors are contraindicated during pregnancy. Beta blocker therapy is a safer antihypertensive approach during pregnancy. Anticoagulation can complicate pregnancy significantly. Coumadin's teratogenic affects make it contraindicated in the first two trimesters and usually is replaced by heparin products, which in turn may provide slightly reduced anticoagulation protection for the mother.

Simple lesions of the septal defect type -post repair do not carry any specific pregnancy concerns or precautions. However, those pregnant patients with repaired coarctation of the aorta with or without significant HTN do have a mildly increased maternal mortality risk during pregnancy. Those with known residual recoarctation of the aorta should consider re-intervention prior to pregnancy. They also may require further antihypertensive therapy during the hypervolemic state of pregnancy.

Moderate lesions such as well repaired D-TGA typically would carry little or no increased maternal mortality risk during pregnancy. Repaired TOF often has some degree of RV dilation or dysfunction and various amounts of pulmonary valve insufficiency. The hypervolemic state of pregnancy is usually well tolerated in these mothers, however they may show mild increase in exertional fatigue or systemic edema.

Severe lesions of single ventricle type in a young woman can tolerate a routine pregnancy, as it is a high preload and low afterload state thru 2/3 of the pregnancy. Later in the 3rd trimester and during labor, maternal vascular afterload increases and may aggravate compromised single ventricular output. These women may experience higher incidence of peripheral edema, ascites, and atrial arrhythmias. Pre- pregnancy stress testing may alert the provider to the woman's ability to increase her cardiac output to increase as will be needed during the pregnancy as well of the predilection to arrhythmia. In line with this complex group, those women with markedly elevated pulmonary vascular resistance pose a unique risk during pregnancy and have high maternal and fetal morbidity and mortality. This complex population absolutely requires the detailed services of the ACHD center and its obstetric and anesthesia specialists. Pregnancy is contraindicated in women with a cardiac output of less than 30% and those in NYHA Class III and IV.[3]

Extreme maternal pregnancy risks include those with Marfan syndrome and Eisenmenger syndrome. Eisenmenger syndrome is when a cardiac defect has caused irreversible high pulmonary artery pressure. In the pregnancy state when volume is increased, this would increase the left to right shunting resulting in severe cyanosis and polycythemia and maternal mortality approached 50%.[3] In Marfan syndrome, if the aortic root is dilated more than 5.0 cm, the increase in blood volume in the pregnancy state can result in acute rupture and death.

4. Subacute Bacterial Endocarditis (SBE) prophylaxis

Simple lesions post-repair, require SBE prophylaxis only during the 6-months post- operative period. Long term SBE prophylaxis is not indicated in this group of CHD patients.

Moderate lesions typically do not require SBE prophylaxis after the 6-month post-operative period. The TOF patient requiring an RV to PA conduit does not require lifetime SBE prophylaxis as it is a tissue based conduit. The rare post-op TOF patient with a residual right to left VSD patch leak, should receive SBE prophylaxis.

Severe lesions of single ventricle type may require SBE prophylaxis if they have a Fontan baffle leak resulting in right to left shunting or if there is indwelling prosthetic valve material.

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Conclusion

A child born with congenital heart disease today can thankfully expect, with high probability, surviving well into adulthood. Depending on the type of defect and the surgical repair offered, their health care provider should be prepared to follow such a patient for many years. The family doctor may find their ACHD patient displaying unique and complicated multi-system health issues as described above. With the help of their local cardiologist and periodic follow up in regional ACHD centers, the family doctor should feel adequately equipped to address situations of female contraception, pregnancy considerations, activity recommendations and endocarditis prophylaxis. Having a primary care role in the health maintenance of this interesting population can prove to be a rewarding aspect of your practice.

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Jeanine Murphy Morelli, MD *is a Clinical Assistant Professor and Deputy Chief of the Division of Family Medicine at the Renaissance School of Medicine at Stony Brook University. She attended medical school at Upstate Medical Center in Syracuse where she met and married former classmate and co-author Peter Morelli. After completing her residency training in family medicine at Stony Brook, she has worked at LSU-MC Shreveport, in private practice for Greater Cincinnati Associated Physicians and as medical director of the Elsie Owens Health Center before returning back to Stony Brook Family Medicine in 2013.*

Peter Morelli, MD, FAAC *is Clinical Associate Professor of Pediatrics at Renaissance School of Medicine at Stony Brook University, Director of Stony Brook's Children's Duchenne's Muscular Dystrophy Clinic and Founder and Director of Fit Kids for Life. He attended medical school at Upstate Medical Center, completed his residency training at Stony Brook, completed his fellowship training at Cincinnati Children's Hospital in pediatric cardiology. He served in the US Air Force and worked at Columbia Presbyterian Hospital before returning to Stony Brook's Children's Hospital.*

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