Comprehensive CME-JA Course Description

Aspirin Therapy in 2022: New Horizons

Program Director:

C. Michael Gibson, M.S., M.D.
Interventional Cardiologist, Beth Israel Lahey; CEO Baim Institute for Clinical Research (FKA Harvard Clinical Research Institute) and Boston Clinical Research Institute, PERFUSE

Planning Committee

Dominick Angiolillo, M.D., Ph.D., FACC
University of Florida College of Medicine
Interventional Cardiologist, UF Health Cardiovascular Center - Jacksonville

John Fanikos, R.Ph., B.S., M.B.A.
Adjunct Professor, Massachusetts College of Pharmacy and Health Sciences
Chief of Pharmacy, Brigham and Women's Hospital

Eva Kline-Rogers MS, RN, NP
University of Michigan
Cardiovascular Nurse Practitioner, Ann Arbor Michigan
and Co-director for MCORRP
(Michigan Cardiovascular Outcomes Research and Reporting Program)

Faculty

Asif Ali, MD
Clinical Assistant Professor, University of Texas Health Science Center
Cardiovascular & Preventive Medicine, Houston Cardiology Consultants

Jennifer Goldman, RPh, PharmD, CDES, BC ADM, FCCP
Massachusetts College of Pharmacy & Health Science
Professor of Pharmacy Practice
Provider, Well Life Medical, Peabody, Mass

Emilly Anjudar, APRN
Advanced Clinical Nurse Practitioner
Vascardio Heart & Vascular Institute Hialeah, Florida

John Mulder, IV PA-C, AACN
Interventional Cardiology APP Leader
Spectrum Health Medical Group, Grand Rapids, MI

Keri McGovern, RN
Cardiac Catheterization Lab, Beth Israel Deaconess Medical Center, Boston, MA

*Faculty Disclosures are located on the program slides and at the end of the Course description.

Target audience:

This activity is intended for a healthcare provider (HCP) audience of cardiologists, internal medicine, and primary care physicians, cardiologists, pharmacists, nurse practitioners (NPs), physician assistants (PAs), and nurses.

The goal of this activity is to increase clinician knowledge on the Class 1A guidelines for aspirin therapy, the data of aspirin therapy in secondary prevention for cardiovascular disease, and the differences in aspirin formulations in 2022.

Upon completion of this activity, participants will:

- Have increased knowledge regarding the
    - Latest clinical guideline statements for the use of aspirin therapy in the setting of post procedural CAD, NSTEMI, STEMI.
    - Relevant data in secondary prevention of cardiovascular disease and differentiate primary and secondary prevention.
    - Tailoring of the aspirin formulation and dose for patients starting aspirin therapy or experiencing issues on therapy.
- Have greater competence related to
    - Evaluating the differences in available aspirin formulations
    - Recommending aspirin therapy and tailoring it the individual patient profile
    - Educating patients starting aspirin therapy on benefits, common side effects, and how to take it

Educational learning objectives

Upon completion of this activity, participants should be able to:

1. Articulate the ACC/AHA guidelines on aspirin therapy recommendations
2. Differentiate primary and secondary prevention populations to relay the benefit of aspirin therapy in high- risk primary prevention and secondary prevention
3. Explain benefit and risks of Aspirin therapy
4. Articulate the major differences in aspirin formulations (Immediate release plain and PL-ASA and delayed release enteric coated)
5. Cite major education points to relay to patients when starting aspirin therapy.

Program Rational and Overview

Approximately one person in the United States has a myocardial infarction every 40 seconds, and more than 1 million coronary events occur each year, of which one third are recurrent events[1]. Antiplatelet therapy and hypercholesterolemia agents have been important therapies to reduce atherothrombotic events after acute coronary syndromes (ACS). First applied for antiplatelet therapy was aspirin and approximately 30 million Americans are eligible for daily aspirin therapy for prevention of secondary thrombotic events. Aspirin has quite a history and is one of the most studied agents in modern medicine. This course is designed to address the gaps in aspirin therapy knowledge and practice by reviewing the evidence on aspirin that all health care providers should be aware of in recommending aspirin therapy.

Aspirin dates back 4000 years to the herbal remedies used by the Sumerians, who noted the pain remedies of the willow tree on early clay tablets and the willow bark was used to treat rheumatic disease, pain, fever. The synthetic formulation of aspirin made pharmaceutically available in 1899 by Bayer, registering the trade name of Aspirin and 50 years ago enteric coated aspirin was developed to address the GI issues of plain tablets-immediate release aspirin[2,3]. Widespread adoption of 325 mg enteric-coated aspirin took place in the 1980s on with ISIS-2 demonstrating reduction in ischemic events in patients experiencing acute myocardial infarction symptoms with results of aspirin alone being similar to streptokinase alone, and aspirin and SK combined offering further reduction in mortality[4]. Thus, the latter half of the 20th Century recognized aspirin therapy in emergent use in acute coronary syndrome and through the work of the Antithrombotic Trialists' Collaboration, as essential in cardiovascular disease prevention and in acute cardiovascular events[5].

With the introduction of P2Y12 inhibitors in combination with aspirin to further reduce events, first with clopidogrel approved by the FDA in 2006, and later prasugrel and ticagrelor -dual antiplatelet therapy (DAPT) was widely accepted and used to also prevent stent thrombosis post PCI. A major concern with use of aspirin and DAPT is bleeding and specifically GI bleeding. Risks of benefit versus bleeding risk for individual patients must be assessed as providers prescribe these therapies. The debate of high dose versus low dose aspirin therapy persisted for several decades and with concerns of bleeding being higher with 325 mg a day, further evidence unveiled low dose aspirin is now considered adequate (75 mg-100mg) in secondary prevention.

Because of the risk versus benefit ratio, aspirin was unseated in primary prevention by pivotal studies in 2018 that changed the primary prevention aspirin guidelines in favor of healthy life habits over Aspirin except in very high- risk individuals[6]. Continuing strong guideline directed statements (Class 1A or 1B) for secondary prevention data for Aspirin exists across a multitude

of disease states including acute myocardial infarction (MI), prior MI, ischemic stroke, peripheral artery disease, and percutaneous or surgical revascularization[7-14]. Providers must be aware of the indications and guidelines for aspirin. The release of the 2021 Revascularization Guidelines from the ACCF, AHA and SCAI have also been a source that needs discernment in DAPT[15]. They were meant to include the research on shortening DAPT and include the evidence for the "aspirin light" and "aspirin free" with previous guidelines as the scaffolding. There is a gap in interpretation for providers.

In the Fall of 2021, the United States Preventative Services Taskforce (USPSTF) released a press statement calling for comments on their recommendations for updating the statements on aspirin in prevention. These statements were regarding "primary prevention patients" and limiting aspirin use for primary prevention unless at high risk for CV disease. The press picking up the release did not clearly specify what primary prevention was for the public. This caused confusion for patients thinking they should stop taking their aspirin. Physicians were being called and asked by patients with post events (MI, ACS, stroke) if they, "should stop taking my aspirin?". Concerned physicians and cardiovascular societies (American Heart Association and American College of Cardiology) rallied and started a campaign to, "Call your doctor before you stop taking your aspirin[16]. You may be on necessary aspirin therapy to prevent another heart attack or stroke or on aspirin for prevention because your physician feels the benefit of aspirin outweighs the risk because of your individual risk for CV disease". Of recent, the USPTSF published in *JAMA* the aspirin use to prevent cardiovascular disease statements[17]. There has been a better press response with the statement added to ask your doctor before stopping, but again patients are confused. An education gap exists not only in the public but with health care providers on the use of aspirin in primary and secondary prevention.

The treatment effect of aspirin is formulation-dependent and is related to how well the formulation is absorbed. With providers change from immediate release/plain aspirin to enteric coated aspirin being before most of current healthcare providers started their education, the differences in the dated formulations of aspirin are not well known and will be reviewed.

Immediate release aspirin is known to be the gold standard in thromboxane inhibition yielding prompt, potent and reliable antiplatelet effect- providers use immediate release aspirin as the first dose of chewable aspirin when a patient is having an event and given pre percutaneous coronary intervention procedure. The change to delayed release aspirin or enteric coated formulation came about because of a perceived GI protection by moving the site of absorption outside of the stomach with a 2 hour delay the coating provides. However, there is evidence that the formulation may not offer GI protection[18,19] and importantly, enteric coated aspirin has erratic absorption (US FDA Label[20]). PL-ASA was placed into clinical development to address the need for a formulation to have bioavailability of immediate release and to help protect the GI tract, it is an FDA approved liquid filled aspirin capsule. PL-ASA is equivalent to immediate release plain aspirin and at the 325 mg dose was found to cause less ulcers and erosions to the gastrointestinal tract at 7 days compared to plain aspirin in a randomized endoscopy study[21]. There are additional aspirin therapies, including an IV form used in Europe and other investigational aspirins.

There is also a gap of evidence that dosage and formulation matter in special populations. These include, early ACS, diabetics, and in heavier weight patients. This evidence will be reviewed.

The last gap the program seeks to address is how to recommend patients take the aspirin daily. Evidence of time of day, taking aspirin with certain medications and food versus an empty stomach will be discussed.

With the changing landscape of prescribed potent antiplatelets and a backdrop of discussion on "aspirin free", "what is aspirin unresponsiveness", and "what to do with heavier and diabetic patient aspirin dosing", it is time to take a look at Aspirin again.

This program seeks to close the gaps of knowledge and education for cardiologists, physicians, pharmacists, advance practice providers, and nurses treating the ACS and post PCI patient with aspirin as an antiplatelet therapy. It will include a review of the dated formulations of aspirin and include the most recent FDA approved aspirin therapy, PL-ASA and other formulations in clinical development. The panel discussion will feature cardiology specialists, PharmDs, Advanced Practice Providers and nurses in disciplinary roundtables discussing the evidence and pragmatic considerations in recommending aspirin therapy and educating patients in the context of the published evidence and realities of treatment in acute care and follow up or the ACS /PCI patient within health systems in the U.S.

Attendees will gain a more thorough understanding of evidence-based decision making regarding the effective use of aspirin therapy in the cardiology patient.

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Faculty Disclosures

C. Michael Gibson, M.S., M.D.

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For Trials that Dr. Gibson actively serves as PI of and receives research grant support on an ongoing basis,

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Equity

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Dominick Angiolillo, M.D., Ph.D., FACC

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

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Preventric: CMO

Jennifer Goldman, RPh, PharmD, CDES, BC ADM, FCCP

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Speaker
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