Annual Journal 2022 - Volume 31

BAPA

Bangladeshi-American Pharmacists' Association

- PHARMACISTS AID IN THE FIGHT AGAINST CORONAVIRUS
- DIABETES: A GLOBAL EPIDEMIC
- SIDE EFFECTS OF ANTILIPID MEDICATIONS
- RECREATIONAL DRUGS: CANNABIS, MARIJUANA, AND HEMP
- THE DASH DIET

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Departed Souls

We deeply regret and mourn the departure of our fellow friends.
We miss them a lot and remember them in our prayers.
In this day of the Convention we will miss their presence.

Nazir Ahmed
Mohammad Azim
Mohammed Hakim Bhuiyan
Manju Biswas
Utpal Kanti Biswas
Amanullah Chowdhury
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Disclaimer: If we missed anybody's name it is an unintentional mistake.

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BANGLADESHI – AMERICAN PHARMACISTS' ASSOCIATION

31st Annual Convention Programs

AUGUST 26TH - 28TH, 2022

OMNI NEW HAVEN HOTEL AT YALE

155 Temple St, New Haven, CT 06510

BAPA CONVENTION SCHEDULE AT-A-GLANCE (Offering 8 continuing education credits this year)

Day 1	Friday, August 26, 2022
3:00 PM - 7:00 PM	Registration & Room Check in Lobby
8:00 PM - 11:00 PM	Dinner Buffet 19th Floor Rooftop Restaurant
3:00 PM - 9:30 PM	Prayer Room Church
4:00 PM - 10:00 PM	Vendors Showcase Grand Ballroom D

Day 2	Saturday, August 27, 2022
8:00 AM - 11:00 AM	Breakfast Buffet Grand Ballroom ABC
7:00 AM - 11:59 PM	Vendor Grand Ballroom D
10:00 AM - 1:00 PM	**Continuing Education "Diabetes"** Temple
10:00 AM - 7:00 PM	Prayer Room Church
11:30 AM - 12:30 PM	Cookies & Coffee Outside Temple
1:00 PM - 2:00 PM	Lunch Buffet Grand Ballroom ABC

2:00 PM - 5:00 PM	**Continuing Education "Update on Pharmacy Laws, Regulations, and Issues of Important Current Pharmacy Events"** Temple
4:30 PM - 5:30 PM	Cookies & Coffee Outside Temple
5:00 PM - 7:30 PM	Free Time
7:30 PM - 9:30 PM	Formal Dinner Program featuring Keynote Speaker Syed Zaki Hossain and Dhaka University Faculty Nurun Nahar Grand Ballroom ABC
9:30 PM - 1:00 AM	Cultural Show Grand Ballroom ABC
11:00 PM	Cookies & Coffee Ballroom area

Day 3	**Sunday, August 28, 2022**
8:00 AM - 11:00 AM	Breakfast Buffet Ballroom AB
9:30 AM - 10:00 AM	Past Presidents Breakfast Breakout Session Grand Ballroom C
7:00 AM - 12:00PM	Vendor Grand Ballroom D
10:00 AM - 12:00 PM	**Continuing Education "Evolving Dyslipidemia Landscape"** Temple
8:00 AM - 2:00 PM	Luggage Storage & Prayer Room Church
1:00 PM	CHECKOUT

Message from the PRESIDENT

Dr. Sabrina A. Rahman

Dear BAPA Members,

It is my honor to welcome you to our 2022 Annual BAPA Convention as president of the Bangladeshi American Pharmacists Association! It is with heartfelt gratitude I extend a token of appreciation for our members, sponsors, and guests for joining us this year and committing to make this event a success. I would like to extend a special thanks all our sponsors who you will see throughout this journal that have contributed to our organization and are an essential foundational point to our organization.

As the youngest president of this organization to date, I am honored to have been given an opportunity to lead such a prestigious organization with a long-lasting legacy. It is with a sincere mindset I wish to maintain the same level of excellence as those who have proceeded me while reestablishing a deep-rooted purpose for this organization. It is my vision and mission to pull in the newest pharmacists and bring new ideas and innovations to our organization. I would like to extend a thank you to my executive committee and board, without whose support and understanding I would not be in this position as the president.

As a first generation Bangladeshi American in New York, the importance of preserving the Bangladeshi culture is a very high priority in my life. Without this organization my life could have turned out to be completely different, but because of my father Mohammed Rafiqur Rahman who is a member of the first batch of BAPA my life turned out the way it did and for that I feel indebted to this organization for my continued success. The uncles and aunties of this organization, although of no blood relation, have been just that, real uncles and aunties who have been an essential part of my up brining. When they say it takes a village, they really mean it. The support, love, and generosity I have seen between the members of this organization carries on in the children of BAPA.

On a personal note, I had made a change in my pharmacy career this past year from a well- known environment in a community setting and immersing myself in the pharmaceutical industry, where everything I am learning is a fresh new perspective. At first it was intimidating (and remains to be here and there) but despite the learning curve, I am extraordinarily proud of myself for taking on a new challenge and grateful for the amount I am learning in this new position. Many strategies and objectives I have learned in my new position in the industry are beneficial to carry into BAPA while planning for future events and thinking how to grow BAPA. The reason I was fortunate to come into this new position was due to networking and my connections within the Bangladeshi American Pharmacist community. To see a success story, rather, to live a success story like this has changed my life and my dreams are for our members to have the same opportunities and successes for themselves.

As pharmacists, we are an essential part of the healthcare communities and must continue to strive to serve our patients. Through networking, collaboration, education, and advocacy, my goals are while in presidency include to promote and empower the members of this organization and the profession of pharmacy. I would like to thank everyone for participating in our convention and wishing everyone a safe, healthy, and successful year!

Kind regards,

Dr. Sabrina A. Rahman

President, BAPA

Message from the VICE PRESIDENT

Dr. Lamisa Ahsan

Welcome to our 2022 annual BAPA convention. It has been an honor to serve you as Vice President of the 2022-2023 Executive Committee. Thank you for the trust you put in us and for being part of bringing our ideas and events to fruition.

COVID-19 has taught the world the importance of Pharmacists in the healthcare field, whether it's administering vaccines or counseling patients. Our profession plays an important role in improving the health and quality of life of our patients. BAPA Conventions and events gives us an unique opportunity to take a break from our routine and to reflect upon our profession, the many factors impacting our profession, and also our shared Bangladeshi heritage. Let's also take this opportunity to encourage students and younger pharmacists to explore the many aspects of our profession and guide them through their journey. I encourage the younger generation to actively engage in our programs and to continue raising our banner well into the future.

In my time with this organization, I have seen it grow tremulously. We are now an official nonprofit and large professional network. I hope that BAPA continues to expand with your support and serves as a platform to discuss ideas, advancements, and network.

I would like to thank the executive committee for their hard work in hosting this convention and bringing together this publication. I hope you enjoy your time at our annual convention, make connections, and memories.

Thank you,

Dr. Lamisa Ahsan

Vice President

A MESSAGE FROM OUR KEYNOTE SPEAKER

"The Greatest Satisfaction in Life is achieved through Giving."

Syed Zaki Hossain

A veteran of the engineering and manufacturing industries, Zaki Hossain worked diligently over 10 years for three different engineering firms, before founding Modern Packaging Inc. in 1989.

Hossain, originally born in Bangladesh received his BS in Mechanical Engineering from the prestigious Bangladesh University of Engineering & Technology in 1976. Then, he received a MS in Engineering from Polytechnic Institute in Brooklyn, New York.
Currently as VP & GM and founder of Modern Packaging, Hossain leads a successful company specializing in the custom designing and manufacturing of packaging equipment.
Hossain is also the co-founder and Vice President of PDF Seal Inc, a producer of pre die cut foil lids, used primarily by the dairy, yogurt, juice, & condiment food packaging industries
He was involved in design and developing of machines to produce K-Cup for Keurig in late 90's. Committed to the innovation of the latest technological advances in the industry.

To further his philanthropic mission, Hossain opened a coffee manufacturing plant in Farmingdale, NY. Pintail Coffee Inc. 100% profits come from Pintail Coffee Inc. are donated to feed the hungry people.
Hossain is also a major financial sponsor for several not-for-profit organizations including: **SAKHI**, committed to ending violence against women of South Asian descent in the U.S.
Chairman of the Board of VAB, **Volunteers Association of Bangladesh**, dedicated to the mobilization of funds and resources in support of promoting secondary education of needy children,

Shaheed Rowshan Ali College, a public college dedicated to the education of women from low income backgrounds. Long Island Muslim Society, promoting interfaith education and community outreach to uphold and encourage tolerance across religions, and the Computer Literacy & Smart Board Education Programs in both Mukul Nikaton School and Ghorasal High Schools in Bangladesh, by donating the funds to purchase new computers. He also helps to train Infection Control Program and how to handle traumatic emergency cases training programs in 60 hospitals throughout Bangladesh. Together with his wife, Hossain funds an annual scholarship awarded to the Valedictorians of East Meadow and Hicksville high schools located on Long Island.

In April of 2008 his generous contribution led to the opening of the Zaki Hossain Center for Hypertension, Diabetes and Vascular Disease at Nassau University Medical Center, striving to advance the care of Nassau County residents, particularly the medically undeserved.

In 2014, Hossain was elected Chairman of the Foundation Board and continues to serve as a dedicated member committed to helping all Long Islanders obtain essential coverage and quality health care.
In 2012, Hossain was elected to the Board of Trustees of the Long Island Energeia Partnership, a leadership consortium LI dedicated to identifying and creatively addressing serious, complex and multi- dimensional issues challenging the Long Island region.

In 2015, Hossain was elected to the Board of Trustees of Molloy University where he serves as Chairperson on the Advancement Committee as community service. Recently, Hossain has made large donation for scholarships as well as Workforce Development Initiative.

In 2016, Hossain was elected to the Island Harvest Board of Trustees where he serves as a board member on the Island Harvest Board of Directors as well as Chairperson of the Capital Funding Initiative. Island Harvest is Long Island's largest hunger relief organization where Hossain made a donation capital funding for a new building purchased for this organization. He is also providing fund to start building a Kidney Hospital in Sylhet which is under construction process from 2021. Where under privileged patient will be treated.

Most recently, Hossain and his wife made an immensely generous donation of Cardio Thoracic ICU to Northwell Health. This donation promises to build a state-of-the-art facility that is not just one of the largest but the most advanced in the world. Throughout his life Hossain has always tried to help those around him and give back to the community in which he lives. He continues to do so in hopes of making a positive difference in his community and in the lives of others.

articles

Pharmacists Aid in the Fight Against Coronavirus

By Rafi Reyasat, PharmD

Since the pandemic began, the role of various healthcare workers evolved, as a unified approach was and continues to be required in the fight against the COVID-19 virus. Many professions had to step up during the peak of the pandemic when emergency rooms were full, such as Nurses and PA's working double and triple shifts. Pharmacists became the chief immunizers for the pandemic, immunizing over 100 million Americans. Since most of the country is now immunized, we've seen sharp declines in the mortality rates. In December 2021, the FDA issued Emergency Use Authorizations (EUA) for an oral agent to aid in the fight against COVID-19, Paxlovid (nirmatrelvir and ritonavir).

" PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death." The initial EUA stated " PAXLOVID may be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs". However, on July 06,2022, the FDA revised the Emergency Use Authorization (EUA) to authorize state-licensed pharmacists to prescribe Paxlovid to eligible patients given that the following conditions are met:

- Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and

- Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non prescribed) that the patient is taking to assess for potential drug interaction.

Paxlovid (nirmatrelvir and ritonavir) is an oral antiviral drug most effective if administered within 5 days of onset of COVID-19 symptoms. Ritonavir, when coadministered with nirmatrelvir, increases the blood concentration of nirmatrelvir increasing its effectiveness against SARS-CoV-2. However,

ritonavir may also increase blood concentrations of other concomitant medications. Therefore, it's imperative to have access to a list of all currently prescribed and over the counter medications in order to check for potential drug interactions with Paxlovid. Patients must also bring up to date (within the last 12 months) laboratory blood work in order for the pharmacist to review kidney and liver functions.

Paxlovid dosing includes

1. Standard Dosing: 300 mg nirmatrelvir (150mg tabletsx2) with 100 mg ritonavir (100mg tabletx1) taken simultaneously for 5 days

OR

2. Paxlovid Renal Dosing: for patients with moderate renal impairment (eGFR >30 mL/min to <60 mL/min) 150 mg nirmatrelvir (150 mg tabletx1) with 100 mg ritonavir (100mg tabletx1) taken simultaneously for 5 days.

Under the current limitations, licensed pharmacists should refer patients to their physicians for clinical evaluation should there be insufficient information available for review of hepatic/renal function or DDI's or if there is modification of a different drug needed due to a DDI.
The revision of authorization for Paxlovid use has opened up the role of pharmacists to aid in the fight against this deadly virus plaguing the world. With careful consideration and working in close proximity to other healthcare professionals, pharmacists can now take the measures needed to lessen the burden of COVID-19 on our healthcare system. The administration of Paxlovid by Pharmacists, under the correct circumstances could help lower hospitalizations, morbidity and mortality resulting from COVID-19. a The American Society of Health-Systems Pharmacists (ASHP) recognized the important role pharmacists continue to play in the pandemic in a recent statement:

"ASHP is pleased to see the FDA remove this barrier to patients' access to this critical treatment," said Tom Kraus, ASHP vice president of government relations. "Pharmacists have played a vital role in our pandemic response efforts and are well-positioned to help patients, particularly those in rural and underserved communities, benefit from this medication."

In continued efforts, we pharmacists can now lend further helping hands to the ongoing fight against this pandemic that has touched each of our lives.

References:

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Diabetes: A Global Epidemic

By Kazi M. Anam MS, RPh, ND

Diabetes mellitus is taken from the Greek word *diabetes* meaning siphon - to pass through and the Latin word *mellitus* meaning sweet. A review of history shows that the term “diabetes” was first used by Apollonius of Memphis around 250 to 300 BC. Ancient Greek, Indian, and Egyptian civilizations discovered the sweet nature of urine in this condition, that is how the term diabetes mellitus originated. Mering and Minkowski, in 1889, discovered the role of the pancreas in the pathophysiology of diabetes. In 1922, Banting, Best, and Collip purified the hormone insulin from the pancreas of cows at the University of Toronto, leading to the availability of an effective treatment for diabetes. Over the years, exceptional work has taken place, and multiple discoveries, as well as management strategies, have been created to tackle this growing problem. Unfortunately, diabetes is one of the most common chronic diseases in the US and worldwide.

Diabetes is becoming a global epidemic. Diabetes also causes other conditions like heart disease, stroke, kidney disease, eye disease, neuropathy, high blood pressure, dislipidemia, cancer etc. It is very important that all health professionals focus on this issue. Since pharmacists are very accessible to patients and routinely interact with them and their families, they can play a major role in educating patients and helping them manage their individual therapeutic goals as well as diet and lifestyle.

According to the CDC in the USA about **37.3 million** people have diabetes and another **96 million** have prediabetes. Every year about 25% of healthcare costs are directly attributed to the treatment of diabetes. This figure will continue to rise as the number of diabetics are rising significantly. Fortunately many newer medications and injectables are available now to treat diabetes – however overall awareness of the importance of diet, lifestyle and screening is very very important to reduce morbidity and mortality and overall management of diabetes.

For the last 50 years, why has diabetes cases been increasing worldwide? The answer might be the sugar, carbs, processed foods and a sedentary lifestyle. Consumption of sugar has been steadily going up in the USA and worldwide for the last 50 years. Similarly, obesity, type 2 diabetes, prediabetes and insulin resistance have been going up in the USA as well as globally.
According to the American Heart Association, on average, a person in the US consumes about 60 pounds of sugar a year. About 47% of all added sugars are coming from beverages: soft drinks, fruit juices, energy drinks, coffee-tea etc. This is probably true in most countries in the world. Urbanization and rapid growth of fast foods, processed foods and the option of quick delivery in most cities of the

world. Whether it is New York, London, Dhaka, Delhi, or Beijing anyone can order food through an app and have it delivered promptly.

The human genome is not ready for this severe assault of sugar and processed foods. Thousands of years ago, food was neither highly processed nor so easily accessible throughout the day. These days, many of us eat three meals or more, with additional snacks. Let's break this scenario down. A person wakes up in the morning and typically will have some type of breakfast. Most of the time, it will be some type of cereal, juice, egg, etc. This is followed up by a snack before lunch. Lunch may consist of carb-heavy, highly processed food. This too may be followed up by a snack before dinner. Culturally, dinner may be the biggest meal of all. Then, while watching TV, one may consume another round of snacks before finally going to bed. Now, let's examine what happens inside our body. After we eat, the blood sugar starts to rise, insulin is secreted which helps us store this sugar in the liver as fat and glycogen while some sugar is used to produce energy inside the cells. If this happens continuously, we develop fatty liver. Now, the groundwork is done for metabolic syndrome or insulin resistance.

Glucose is very toxic to all the blood vessels. It is now understood that damage to microcapillaries starts many years before a person is officially diagnosed as diabetic. Normal fasting glucose level in our blood is 70 mg to 100mg/dl. The average human has about 5 liter or 50 deciliters of blood. That means normal total glucose in blood is about 3500mg or 3.5gm to about 5000mg or 5 gms. That is just one teaspoonful glucose distributed within the whole body. Now imagine a person is drinking a soft drink or a glass of fruit juice that has about 30 to 30gms of sugar. Immediately, insulin will be secreted and these sugars will be pushed into the liver as fat or glycogen and some would be utilized by the cells for energy. However, if this sugar and carb intake continues, cells soon become resistant to insulin, resulting in diabetes.

Sugar and carbs have infiltrated our food culture and it is now next to impossible to eat a meal without sugar. It is basically hidden in all types of foods and beverages. Most consumers think fruit juice is a healthy beverage. But in reality, eight ounces of juice can contain as much as 20 gms of sugar. Thus, consumers need to be very alert of all the refined sugars and carbs hidden in seemingly healthy foods or beverages. Consuming whole foods and avoiding processed foods and sugars, engaging in intermittent fasting and exercise can turn this epidemic around. Diabetes mellitus is primarily a lifestyle disease. Some patients can keep their blood sugar level within normal limits by modifying their diet and exercise if they are motivated. For most patients management and treatment involves a four-step approach:

- Diet
- Exercise
- Medication
- Blood glucose monitoring

Medications:

- Oral medications
- Non-insulin injectables
- Insulins

Diabetes treatment is fairly complex and an individualized approach needs to be taken to manage each patient. What would be good for one patient may not be good for another patient.

Oral medications:

Biguanides: Only medicine in this class is Metformin. When metformin was introduced in 1995 it was a game changer. Most widely used medication for type 2 diabetes. This is the first line of therapy. Metformin has several advantages as an initial monotherapy:

- It is highly effective - low risk of developing hypoglycemia
- Does not promote weight gain or loss.
- Cost is low and there are no major side effects other than lactic acidosis in Kidney impaired patients
- Metformin reduces production of glucose in the liver
- Reduces intestinal absorption of glucose and
- Also promotes insulin sensitivity

Metformin Side Effects:

- Diarrhea, nausea and stomach cramping.
- A rare life threatening side effect is lactic acidosis that happens to about less than 1 person in every 100,000 patients.

Dosing: Metformin IR dose ranges from 500mg to 2550mg/day (Maximum dose)
Metformin ER dose ranges from 500mg to 2000mg/day (Maximum dose)
Contraindicated in patients with: known hypersensitivity to metformin, chronic heart failure, metabolic acidosis, diabetic ketoacidosis, abnormal creatinine clearance from shock, septicemia or myocardial infarction.

Sulfonylureas:

- Glipizide (Glucotrol, Glucotrol XL)(Introduced in 1971)
- Glyburide (Diabeta, Micronase)(Introduced in 1984)
- Glimepiride (Amaryl)(Introduced in 1995)

These medications primarily lowers blood glucose by promoting release of insulin in the pancreas.

Common side effects: Nausea, vomiting, diarrhea, constipation, dizziness, drowsiness, weight gain, skin rashes. May cause hypoglycemia.

Thiazolidinediones(Glitazones):

- Pioglitazone was introduced in 1999.
- Works by reducing insulin resistance, improving insulin sensitivity and allowing insulin produced by the body to work more effectively.

Side effects: Anemia, edema, weight gain, macular edema,bone loss and fracture in women.
Contraindication: Known hypersensitivity, ketoacidosis.
Pioglitazone doses: 15 mg to 45mg daily.

Meglitinide:

- Repaglinide (Prandin)
- Nateglinide (Starlix)

These medications lowers glucose by releasing more insulin from the pancreas.
Side effects: Anxiety, blurred vision, chills,cold sweats, confusion, cold pale skin, depression, dizziness

Alpha-glucosidase inhibitors

- Acarbose (Available from 1999.)
- Miglitol (Glyset)(Available from 1999)
- They work by slowing down breakdown of starches and some sugars.
- Do not cause weight gain
- Do not cause hypoglycemia

Possible side effects: stomach pain, gas, diarrhea
Acarbose (Precose) doses: 25 mg to 100mg 3 times daily with first bite of each meal

Miglitol (Glyset) doses:25 mg to 100mg 3 times daily with meals

Dipeptidyl-Peptidase - 4 (DPP-4) Inhibitors

- Saxagliptin (Onglyza)
- Sitagliptin (Januvia)
- Linagliptin (Tradjenta)
- Alogliptin (Nesina)

These medications stimulate the release of insulin when blood level of glucose is increasing. They also inhibit the release of glucose from the liver.

They do not cause weight gain and also do not cause hypoglycemia unless combined with insulin or sulfonylurea. Possible side effects: Upper respiratory tract infection, sore throat, headache.

Sodium-glucose co-transporter 2 (SGLT2) inhibitors:

- Canagliflozin (Invokana)
- Dapagliflozin (Farxiga)
- Empagliflozin (Jardiance)

They work by blocking reabsorption of glucose by the kidneys. Promote weight loss. May lower blood pressure. Possible side effects: Urinary tract infection, yeast infection

Glucagon-like Peptide (GLP-1) Agonists [oral]:

- Samaglutide (Rybelsus): This is the only oral Glucagon-like Peptide -1 agonist.

This works by increasing insulin secretion and reducing Glucagon release in the pancreas. Also it slows down emptying of the stomach.
Side effects: The following serious adverse reactions are described in the prescribing information: Risk of Thyroid C-cell Tumors, Pancreatitis, Diabetic Retinopathy Complications, Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin, Acute Kidney Injury, Hypersensitivity, Acute Gallbladder Disease

Non-Insulin injectables:

GLP-1 agonists injectables:

- Dulaglutide (Trulicity) (weekly)(introduced in 2014)
- Exenatide extended release (Bydureon BCise) (weekly)(Introduced in 2017)
- Exenatide (Byetta) (twice daily)(Introduced in 2005)
- Semaglutide (Ozempic) (weekly)(Introduced in 2018)
- Liraglutide (Victoza) (daily)(Introduced in 2010)
- Liraglutide (Saxenda) (2015)
- Lixisenatide (Adlyxin) (daily)(2016)

These drugs mimic the action of a hormone called glucagon-like peptide 1. When blood sugar levels start to rise after meals, these drugs stimulate the body to produce more insulin. The extra insulin helps lower blood sugar levels. These drugs also slow the movement of food from the stomach into the small intestine. As a result, people may feel full faster and longer, so they eat less.

Adverse effects: Some of the common side effects are: nausea, vomiting and diarrhea
Major side effects could be: Risk of Thyroid C-cell Tumors, Pancreatitis, Diabetic Retinopathy
Complications: Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin, Acute Kidney Injury, Hypersensitivity, Acute Gallbladder Disease.

Doses:
Dulaglutide (Trulicity): 0.75mg to 3 mg once a week by SC.
Exenatide extended release (Bydureon BCise) (weekly)(Introduced in 2017): 2mg once a week by SC.
Exenatide (Byetta)(Introduced in 2005): 5 mcg-10 mcg two times daily by SC.
Liraglutide (Victoza) (Introduced in 2010): 0.6mg to 1.8mg daily SC
Lixisenatide (Adlyxin)(2016): 10 mcg to 20 mcg SC daily.

GIP and GLP-1 receptor agonist:

- Tirzepatide (Mounjaro)(2022): This is the first agent in this class. It is both GIP and GLP-1 receptor agonist.

This works in 3 ways: It increases insulin production only when blood sugar is rising – so it does not cause hypoglycemia. It decreases liver sugar production. It slows the speed at which the stomach empties to the intestine.
Tirzepatide(Mounjaro) has a big impact in Weight loss, Cholesterol and A1C.

Herbs and spices that lower blood sugar:

Gymnema (Gymnema sylvestre):

This is a plant native to India and Africa with a history of use in Ayurvedic medicine. Gymnema contains chemicals that reduce how much sugar the stomach absorbs. It might also increase the amount of insulin in the body and increase the growth of cells in the pancreas, which is where the body makes insulin. Available as 300 mg to 100mg capsules/tablets.

Cinnamon:

Cinnamon is a spice and is widely used. This also reduces sugar level in blood. Typically available as 500mg to 1500 mg capsules/tablets

Bitter Melon:

Originated in Africa but it totally domesticated in many of the Asian countries. In Bangladesh it is known as Korolla. This is also very good in reducing blood sugar level. Typically available as 500 to 1500mg capsules/tablets

Fenugreek:

Fenugreek is native to the Mediterranean, Europe, and Asia. Fenugreek seems to slow sugar absorption in the stomach and stimulate insulin. Both of these effects lower blood sugar in people with diabetes. Fenugreek is a herb similar to clover. The seeds have a sweet taste and are used in foods and medicine. Typically available as 500mg to 1000mg capsules.

Chromium:

Chromium has been in use for quite some time in diabetes supplements. Some studies show chromium reduces blood glucose levels and it also improves insulin resistance. Currently dose between 50mcg to 1000mcg is in use. I do not recommend more than 200mcg/ day.

Toxicity: Nausea, Vomiting, diarrhea, vertigo etc.

Nutritional support:

If a person is diabetic, these are the supplements commonly recommended:

- Multivitamins
- B-Complex
- Vitamin B-12 injection or liquid spray
- Vitamin D
- R- Alpha Lipoic Acid.

Side effects of antilipid medications

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INTRODUCTION

Antilipid medications are some of the most common medications prescribed in the world, most notably HMG-CoA reductase inhibitors (statins) leading the way. These medications affect lipid metabolism in various ways, including preventing production of endogenous cholesterol, increased cellular uptake, and decreased gastrointestinal absorption, among other various mechanisms. Other medications included in this chapter are fibrates, PCSK9-inhibitors, ezetimibe, omega-3 fatty acids, and green tea extract. Various disease states warrant use of these medications including hyperlipidemia/dyslipidemia, ischemic stroke, and diabetes. This chapter is a culmination of side effects, adverse reactions, genotype analysis, and pharmacokinetic investigation into numerous antilipid medications available worldwide.

Hmg-CoA reductase inhibitors

Atorvastatin

PATIENTS WITH MUSCLE SYMPTOMS

This parallel-group, outcome-assessment-blinded, randomized controlled clinical trial looked at the effect increasing the dosing administration time of atorvastatin had on patients who experienced muscle symptoms, which was defined as muscle pain, tenderness, or cramps for $\geq$2 weeks. The intervention group received atorvastatin every other day (EOD), while the control group received atorvastatin daily. Outcomes that were analyzed included composite myalgia and myositis, LDL-cholesterol levels, and percentage reduction of LDL-cholesterol levels from baseline, assessed at 24 weeks. A total 1822 patients were screened, which led to 47 patients enrolled in the EOD dosing and 52 enrolled in the daily dosing in the per protocol analysis. Mean dosing for the EOD dosing was nearly double the dose of once daily dosing (17.6 mg vs 8.9 mg), while myalgia and myositis incidence was reported at 79.6% in the EOD group compared to 69.2% in the daily dosing. While the primary outcome was seen more frequently in the EOD group, in addition to myalgia alone (77.6% vs 59.6%) and myalgia and myositis at 12 weeks (85.7% vs 78.8%), none of the parameters the authors assessed were of statistical significance. An inferiority analysis was performed with regards to the mean LDL-cholesterol levels showing EOD dosing inferiority to daily dosing. The authors hypothesized that the results of their trial suggest that EOD dosing was not more favorable than daily dosing, and larger studies are needed to fully assess these dosing strategies (Wijekoon et al., 2020) [C].

Another multicenter, randomized, double-blinded crossover trial assessed the effects of atorvastatin on self-perceived muscle symptoms (SAMS) in patients with coronary heart disease (CHD). A total of 982 patients were initially screened, and of those 77 were randomized to the 7-week trial with atorvastatin 40 mg or placebo. The patients were then switched to the other group for 7 weeks. One week washout periods were done at the beginning of the trial and in between switching groups. Overall, atorvastatin did not affect the intensity of muscle

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spasms, as 12 patients actually reported more pain with placebo. The authors concluded that atorvastatin does not affect SAMS in patients with CHD (Kristiansen et al., 2020) [C].

DRUG TRANSPORT POLYMORPHISMS

This pharmacogenetic study assessed the effects of genotypes on the metabolism of atorvastatin in 60 non-related Mexican men. Data was taken from a controlled, randomized, crossover clinical study after a single 80 mg dose of atorvastatin. Upon review of the pharmacogenetic data, 4 types of metabolizers were identified: slow, intermediate, normal and fast. Of the genes that were analyzed, 5 specific polymorphisms had a significant effect on different pharmacokinetic parameters. C_{max} was influenced most significantly by ABCB1-rs1045642, with dominant carriers seeing a statistically lower C_{max} than non-dominant carriers. Another gene SLCO1B1-rs4149056 was shown to be associated with higher AUC in both homozygous and heterozygous carriers ($P \leq 0.038$). CYP2D6-rs1135840 led to a higher elimination rate, and constant yet significantly lower half-life than homozygous genotypes ($P \leq 0.022$). The combination of SLCOB1 and ABCB1 had statistically significant effects on multiple parameters (C_{max}, AUC, Cl) ($P \leq 0.040$). Lastly, the CYP2B6-rs4149056 influenced variable C_{max} values while NAT2-rs1208 influenced variable AUC. The authors concluded that the variations of these patient's metabolism of atorvastatin from within the same population strongly suggests variable metabolism between different populations as well (León-Cachón et al., 2020) [c].

GREEN TEA EXTRACT AND METABOLISM

This randomized, double-blind, three-phase crossover study evaluated 12 healthy male volunteers and the effects of green tea extract on drug transport and metabolism of atorvastatin. Patients were initially randomized to receive atorvastatin 40 mg, atorvastatin 40 mg plus one 300 mg capsule of green tea extract, or atorvastatin 40 mg plus one 600 mg capsule of green tea extract. There was a 1-week washout period between the intervention groups. Effects on metabolism were measured by blood samples drawn at various times including before atorvastatin was taken and then at specific hour intervals. Pharmacokinetic evaluation of the groups demonstrated a large difference including lower AUC and C_{max}, and a higher clearance between both groups of green tea intervention and the control group. The authors conclude that the results from this study are in agreement with several other studies looking at green tea extract drug interactions, and that the concomitant administration of green tea extract with atorvastatin led to significant decreases in serum atorvastatin concentrations (Abdelkawy et al., 2020) [c].

REDUCTION IN CEREBRAL VASOSPASMS AND INFARCTION POST SUBARACHNOID HEMORRHAGE

This randomized trial assessed the use of atorvastatin in patients post subarachnoid hemorrhage (SAH) and the effects atorvastatin has on the incidence of cerebral vasospasm and infarction. A total of 592 patients were initially assessed for inclusion in the protocol, with a total of 159 patients selected for the atorvastatin group to receive 20 mg/day and 158 patients selected for placebo. All patients in the protocol received nimodipine. Patients selected were 60–90 years old and of Chinese ethnicity. The primary endpoint was Glasgow outcome scale at 6 months, with secondary outcomes being cerebral vasospasm, 30-day all-cause mortality, cerebral infarction, and delayed ischemic neurologic deficit. There was no statistical difference in baseline characteristics, Glasgow outcome scale, or multiple subgroup analyses between both groups. Postoperative cerebral vasospasms ($P \leq 0.04$) and vasospasm-related new infarctions ($P \leq 0.027$) were lower in the atorvastatin group vs placebo. The author concludes that atorvastatin in addition to nimodipine reduces cerebral vasospasms and new infarction in patients with history of SAH. Additionally, they saw a reduction in delayed ischemic neurological deficits and 30-day mortality, but these parameters were not clinically significant (Chen, Zhao, & Ye, 2020 [C]; Chen, Li, et al., 2020 [C]).

EFFECTS ON INFLAMMATORY FACTORS

This double-blind, randomized clinical study looked at low dose atorvastatin in patients with traumatic brain injury (TBI). A total of 60 patients were included from the Golestan Hospital in Iran that were ages 18–50 with a moderate or severe decrease in the Glasgow Coma Scale (GCS). Exclusion criteria included GCS of 3–4, the need for surgical intervention, and history of brain tumors, stroke, or previous craniotomy. Inflammatory markers assessed included C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) and white blood cells (WBC). The atorvastatin group had significantly lower levels of CRP ($P < 0.0001$), ESR ($P < 0.0001$), and WBC ($P < 0.0001$) at days 1, 10 and 14 while also showing a significantly reduced length of stay in the ICU ($P = 0.03$). The authors concluded that the administration of atorvastatin in patients with TBI could reduce inflammatory markers and when extrapolated on a larger patient population could have further positive effects on ICU length of stay and GCS after discharge (Soltani et al., 2020) [c].

Another randomized trial was conducted looking at effects of atorvastatin on inflammatory markers in patients post cardiac surgery. These 116 patients underwent elective cardiopulmonary bypass (CPB) to perfuse ischemic injured tissue. Ischemia reperfusion injury causes production and formation of reactive oxygen species (ROS) which leads to further deleterious compounds

and tissue damage. Furthermore, an imbalance of nitric oxide and ROS places patients at an increased risk of developing post-surgical atrial fibrillation (AF). This study aimed to assess the effects of atorvastatin (dosed at 80 mg) on lowering the production of ROS and reducing post-surgical AF. They first assessed the impact of CPB and cardiac surgery on various inflammatory markers including ROS and the balance of nitroso-redox balance, by drawing levels both before and after surgery. In the treatment arm, patients received perioperative atorvastatin 80 mg. Perioperative treatment of atorvastatin prevented the effects of CPB and reperfusion on all parameters but did not have a significant effect on postoperative right atrial effective refractory period, troponin release, and NT-proBNP. The authors concluded that while peri-operative atorvastatin preserved atrial NO-redox balance, it does not have any effect on postoperative AF (Jayaram et al., 2020) [C].

This randomized, double-blind study aimed to assess the combination of febuxostat and atorvastatin (20 mg or 40 mg) on the reduction of tumor necrosis factor-*a* (TNF-a), interleukin-18 (IL-18), and CRP levels. Seventy patients were enrolled and divided between febuxostat 40 mg plus atorvastatin 40 mg and febuxostat 40 mg plus atorvastatin 20 mg. Statistically significant differences were observed in reduction of carotid patch size, patch thickness, total number of plaques, as well as reduction of TNF-a, IL-18, and CRP ($P < 0.05$) after 90 days of treatment. No statistical differences were observed in side effect profiles of either regimen. The authors concluded that the 40 mg atorvastatin group experienced statistically significant reductions in inflammatory markers and thus improved their inflammatory state leading to good clinical benefits (Zhang, Xu, et al., 2020) [c].

STRENGTHENING EFFECTS OF BONE MARROW MONONUCLEAR CELLS

This clinical trial, set up as a 2×2 factorial design, enrolled 100 patients with ST-elevated myocardial infarction (STEMI) and separated them into four groups that received bone marrow mononuclear cells (MNCs) or placebo in addition to regular dose or intensive dose atorvastatin (IA). Their primary endpoint was change of left ventricular ejection fraction (LVEF) at 1-year follow-up from baseline which was assessed using magnetic resonance imaging (MRI). Secondary endpoints included other parameters of cardiac function, remodeling and regeneration as determined by MRI, echocardiography, positron emission tomography (PET), and biomarkers. No baseline characteristics were statistically significant. Subgroup analyses performed on the patients in total receiving placebo vs MNCs showed statistical significance in LVEF (adjusted difference; 5.0 vs 10.0; $P = 0.01$) and scar size reduction (mm^3; adjusted difference; 2.60 vs −2.65; $P = 0.01$). Actual group analyses showed the IA groups that received placebo vs MNCs had improved LVEF (adjusted difference; 5.0 vs 12.6; $P = 0.001$) and scar size reduction (mm^3; adjusted difference; 3.06 vs −3.13; $P = 0.026$). Upon review of the data obtained, the authors concluded that pretreatment with IA positively augments the efficacy of MNC transplantation and thus proving its place in stem cell therapy (Yang et al., 2020) [C].

Pitavastatin

CONTRAST-INDUCED NEPHROPATHY PREVENTION

The PRINCIPLE-II trial was a prospective, randomized, double-blinded, placebo-controlled multicenter clinical trial assessing the renal protective effects of pitavastatin in patients with chronic kidney disease receiving contrast after a coronary procedure. A total of 70 patients with documented chronic kidney disease (eGFR <60 mL/min/1.73 m^2) were included and randomized into 2 groups. The treatment group received pitavastatin 4 mg 7 days before and 3 days after the procedure, and the control group received placebo. None of the baseline or biochemical characteristics were statistically significant. While contrast-induced nephropathy (CIN) occurred more frequently in the placebo group (9.1% vs 5.4%) the incidence was not significant. The authors touched on similar studies of other equipotent statins having similar effects seen in this study, and thus concluded that pitavastatin may provide benefit in prevention of nephropathy in patients with CKD (Kang et al., 2020) [c].

PLAQUE REDUCTION IN ATHEROSCLEROSIS

This study compared the effects of pitavastatin and atorvastatin on the reduction of femoral total plaque areas (FTPA) and lipid and glucose metabolism in patients with lower extremity atherosclerotic disease (LEAD). A total of 63 patients were included in the study and randomly assigned to receive pitavastatin 2 mg or atorvastatin 10 mg daily for 48 weeks. There were no significant differences in the groups in regard to FTPA, lipid metabolism, glucose metabolism, as well as reduction in low-density lipoprotein (LDL) and triglycerides (TGs). Significant differences were observed on HDL levels, shown to be higher in the pitavastatin group ($12.9 \pm 10.3\%$ vs $7.2 \pm 11.7\%$; $P < 0.05$). The authors concluded that both statins were shown to reduce FTPA and lower LDL and TG, while pitavastatin was also shown to raise HDLs (Zhou et al., 2020) [c].

EFFICACY OF COMBINATION FENOFIBRATE IN MIXED DYSLIPIDEMIA

A multicenter, randomized, double-blinded, parallel, therapeutic confirmatory trial looked at the efficacy and tolerability of pitavastatin alone and in combination with fenofibrate in the treatment of mixed dyslipidemia in

Korean patients. Included patients were required to meet ≥1 of the following criteria: high risk of CHD (≥20%), active CHD, other atherosclerotic disease, and diabetes. The primary efficacy endpoint was the mean percentage change in non-HDL-C from baseline at 8 weeks. Patients were randomized into 2 main groups: the monotherapy groups consisting of pitavastatin 2 mg and the combination groups, receiving fenofibrate 160 mg in addition to pitavastatin 2 mg. The primary endpoint was significant, with a percentage change of −7.38% of non-HDL-C in the combination group vs 5.07% in the monotherapy group. Changes in LDL-C overall (7.73% vs. 6.93%) and HDL-C at 4 weeks (49.79% vs 2.25%) was also significant. No adverse drug events were considered significant. There was no significant difference in adverse drug reactions between groups, while the combination group did have elevated liver function tests (alanine transaminase (ALT) and aspartate aminotransferase (AST)) (2.33% vs 0.58%). The authors concluded that the combination of pitavastatin with fenofibrate was shown to be extremely effective in improving lipid panel values in high risk patients with CHD while having a safety profile similar to monotherapy (Ihm et al., 2020) [C].

VERSUS ATORVASTATIN IN PATIENTS WITH HYPERCHOLESTEROLEMIA

This randomized, controlled, parallel, and multicentered clinical trial was performed to determine if pitavastatin 2 mg daily would reduce cardiovascular events more than atorvastatin 10 mg daily. Patients included in the study had hypercholesterolemia defined as total cholesterol (TC) ≥220 mg/dL and/or LDL-C ≥140 mg/dL, one or more atherosclerotic disease state (Type 2 diabetes (T2DM), coronary artery disease (CAD), prior percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG), among other inclusions. The primary outcome was cardiovascular death, sudden death of unknown origin, nonfatal myocardial infarction (MI), nonfatal stroke, transient ischemic attack (TIA) or heart failure (HF) requiring hospitalization. Pitavastatin was shown to prevent the primary outcome more efficiently than atorvastatin (2.9% vs 8.1%, HR 0.366, $P=0.01$). The mean difference of LDL-C at 1 year, which was not significantly different between groups (average LDL-C after 1 year: pitavastatin 95 mg/dL vs atorvastatin 94 mg/dL) was also noted. Adverse drug effects (ADEs) were not significantly different between groups, including incidence of rhabdomyolysis and onset of type 2 diabetes mellitus. The authors concluded that pitavastatin significantly reduced CV effects while having a similar effect on LDL-C reduction when compared to atorvastatin (Moroi et al., 2020) [C].

Lovastatin

MILD ACTIVE RHEUMATOID ARTHRITIS

This randomized, double-blind, placebo-controlled 12-week trial assessed the effects of lovastatin and its anti-inflammatory properties in patients with mildly active rheumatoid arthritis. The primary endpoint was the reduction of mean log CRP, while secondary endpoints included disease activity, rheumatoid factor (RF) and anti-CCP levels. After exclusion criteria was applied, a total of 64 patients were randomized into the trial, with 30 patients receiving placebo and 34 receiving lovastatin. The analysis showed statistically significant results in the ≥20% reduction of CRP at day 84 group of lovastatin vs placebo (9/12 vs 3/15; $P=0.007$) and the ≥15% reduction of CRP at day 84 group of lovastatin vs placebo (10/12 vs 5/15; $P=0.019$). ADEs were reported in 59 patients for a total of 219 singular events (109 in the lovastatin vs 110 in placebo). Most of the ADEs reported were not significant, with 4 patients in the lovastatin group experiencing musculoskeletal events vs 2 patients in the placebo group. One patient was hospitalized for an upper respiratory tract infection that was deemed to not be due to the study drug. However, the authors concluded that while lovastatin has a significant effect on CRP levels, the overall benefit in RA patients was minimal (Aranow et al., 2020) [c].

Simvastatin

SAFETY AND EFFICACY WITH CARBOPLATIN AND VINORELBINE

The purpose of this study was to evaluate a chemosensitizing effect of a statin (simvastatin) in a cohort of patients with metastatic breast cancer (MBC). This study was a prospective, single-centered, randomized, double blinded, placebo-controlled trial that included MBC patients with an Eastern Cooperative Oncology Group (ECOG) Performance Status Scale ≤2 and scheduled to be treated with a chemotherapy regimen consisting of carboplatin and vinorelbine every 3 weeks at a hospital in Damascus, Syria. Patients were enrolled and randomly divided to receive a 15-day course of either simvastatin (40 mg) or placebo 7 days prior to the first day of each chemotherapy cycle and then continued for 8 days. Primary endpoints were objective response rate (ORR) and toxicity, and the secondary endpoint was overall survival (OS). Eighty-two patients met the inclusion criteria. Results show ORR 35% in simvastatin vs 32.5% in the placebo group ($P=0.57$). OS was 15 months in the simvastatin group and 17 in the placebo group ($P=0.57$). Grade ≥3 neutropenia occurred in 30% in simvastatin vs 40% in control groups which was not significant. Also, anemia incidence was similar (20%) in both groups. Simvastatin did not result in clinically significant increase in chemotherapy-related toxicities: CK elevated ≥5 times the upper limit of the normal range or ALT ≥3 times the upper limit of the normal range. Some other adverse events reported in this study include thrombocytopenia, injection site reaction, creatinine elevation, and alteration in left ventricle function. None of these adverse events were statistically significant. Also, this study

shows elevated baseline values of C-reactive protein (CRP >10 mg/L) and lactate dehydrogenase (LDH >480 U/L) were significantly associated with shorter OS. The authors conclude that simvastatin at 40 mg combined with carboplatin and vinorelbine in MBC patients is safe but without a beneficial increase of tumor response to chemotherapy (Alarfi et al., 2020) [c].

SIMVASTATIN AND RIFAXIMIN IN DECOMPENSATED CIRRHOSIS

This is a double-blind, randomized, placebo-controlled, phase 2 trial in patients with decompensated cirrhosis and moderate-to-severe liver failure in nine university hospitals in six European countries (Italy, France, Holland, Germany, the UK, and Spain). This study included adult patients with Child-Pugh score B or C disease. Patients were randomly assigned in (1:1:1) ratio to receive either simvastatin 40 mg/day plus rifaximin 1200 mg/day, simvastatin 20 mg/day plus rifaximin 1200 mg/day, or placebo of both medications for 12 weeks. The primary endpoint was development of liver or muscle toxicity, which was defined by changes in liver aminotransferases (aspartate aminotransferase [AST] and alanine aminotransferase [ALT]), alkaline phosphatase (AP), and creatine kinase (CK). The full analysis included 44 patients (16 in the simvastatin 40 mg/day plus rifaximin 1200 mg/day group, 14 in the simvastatin 20 mg/day plus rifaximin 1200 mg/day group, and 14 in the placebo group). When the first 10 patients completed treatment, it was stopped prematurely in the simvastatin 40 mg/day plus rifaximin group as recommended by the data safety monitoring board. There was a significant increase in AST and ALT compared with the placebo group (mean differences for AST ($P = 0.0009$) and ALT ($P = 0.0025$)). However, there was no significant difference at 12 weeks in AST between the simvastatin 20 mg/day plus rifaximin and placebo group ($P = 0.728$) and for ALT ($P = 0.698$). Also, there was no significant difference in AP between the simvastatin 40 mg/day plus rifaximin or the simvastatin 20 mg/day plus rifaximin groups compared with placebo. Patients in the simvastatin 40 mg/day plus rifaximin group showed an increase in CK at the end of treatment compared with patients in the placebo group ($P = 0.014$). However, there was no significant change in CK in the simvastatin 20 mg/day plus rifaximin group ($P = 0.992$). Three (19%) patients in the simvastatin 40 mg/day group developed liver and muscle toxicity consistent with rhabdomyolysis. The number of patients who stopped treatment because of adverse events was significantly higher in the simvastatin 40 mg/day plus rifaximin group (56%) compared with the other two groups (14%, $P = 0.017$). There were no other serious adverse reactions reported during the study. In conclusion, the authors determined that treatment with simvastatin 40 mg plus rifaximin in patients with decompensated cirrhosis is associated with a significant increase in adverse events requiring treatment withdrawal, especially rhabdomyolysis, liver and muscle toxicity compared with simvastatin 20 mg plus rifaximin. Therefore, simvastatin 20 mg should be the recommended dose in patients with decompensated cirrhosis (Pose et al., 2020) [c].

SAFETY AND EFFICACY IN CHC WITH SOFOSBUVIR/DACLATASVIR

This study included 100 patients with chronic hepatitis C (CHC) from Armed Forces Hospital in Egypt. Patients were randomly assigned to the drug group ($n = 50$) receiving simvastatin 10 mg in addition to sofosbuvir 400 mg/daclatasvir 60 mg (SOF/DAC) daily for 12 weeks and the placebo group ($n = 50$) receiving placebo plus SOF/DAC regimen. Sustained virological response at 12 weeks after treatment (SVR12), lipid profile, CRP and fibrosis stage were all assessed to determine the efficacy and safety profile. All 100 patients completed 12 weeks of the protocol with no clinically significant side effects or withdrawal from the study. There was an increase in SVR failure rate in placebo (10%) compared to drug group (only 2%) but it was not statistically significant, SVR12 ($P > 0.05$). Lipid profile measurement for patients in the drug group was performed, and the average total cholesterol, LDL and triglycerides (TGs) levels were initially increased at 1 month then decreased with a highly significant difference ($P < 0.001$). The HDL level was increased which was statistically significant ($P < 0.001$). However, in the placebo group, the average total cholesterol, LDL, TGs and HDL levels of patients were increased with a highly significant difference ($P < 0.001$). Also, both groups of patients showed significant reduction in HbA1c at the end of treatment compared to baseline ($P < 0.0001$). Statin was also associated with significantly reduced fibrosis scores. Also, regression analysis showed that high baseline CRP, low baseline hemoglobin level and non-statin use were associated with an increase in the the probability of SVR failure in both groups; $P = 0.03$, $P = 0.0028$, $P = 0.02$, respectively. Safety data of both regimens in HCV patients showed that all patients in both groups continued the study with no withdrawal due to side effects, confirming the safety of statin in CHC patients. Therefore, it was concluded that statins could have an important role in successful treatment of CHC patients receiving sofosbuvir/daclatasvir without adverse events (Mohamed et al., 2020) [C].

DRUG-DRUG INTERACTION WITH FENEBRUTINIB

This study was a phase I, open-label, non-randomized, multicenter, drug-drug interaction (DDI) trial in healthy male and female (non-childbearing) patients to evaluate the effect of fenebrutinib on the pharmacokinetics (PK) of midazolam and its metabolite, 1′-hydroxymidazolam, rosuvastatin, simvastatin, and its metabolite simvastatin acid. The aim of this study was to evaluate the interaction

potential of fenebrutinib with midazolam (CYP3A), simvastatin (CYP3A and OATP1B), and rosuvastatin (BCRP and OATP1B). Each part of the study was a three-period design in which period 1 consisted of a single dose of the "victim" drug (2 mg MDZ, 20 mg rosuvastatin, or 40 mg simvastatin), period 2 consisted of multiple doses of the fenebrutinib to steady-state (~5 half-lives) (6 days of twice daily oral doses of 200 mg), and period 3 consisted of a single dose of the victim drug in combination with multiple doses of fenebrutinib. Blood samples for PK analysis of victim drugs and fenebrutinib were collected prior to the dose and at specified times after victim drug administrations. Blood concentrations of fenebrutinib were collected to verify that steady-state had been achieved prior to coadministration. The study showed that fenebrutinib is a clinical inhibitor of CYP3A and BCRP, but not OATP1B, based on data from clinical DDI with probe substrates and endogenous biomarkers. This study also shows that biomarkers can be used to evaluate complex DDIs and can lead to better DDI management (Jones et al., 2019) [E].

Rosuvastatin

PREVENTION OF KIDNEY TOXICITY IN CHILDREN WITH CYSTIC FIBROSIS

This is an open label, parallel group, randomized controlled clinical trial that included children and young patients between the age of 6 and 18 years with Cystic Fibrosis (CF) at 13 pediatric CF treatment centers in the United Kingdom. Patients were randomized to receive oral rosuvastatin (10 mg daily) or no intervention (control) with intravenous tobramycin, if clinically indicated. The primary outcome was the difference between the groups in mean change in urinary Kidney Injury Molecule-1 (KIM-1) which was 1.08 ($P = 0.48$). In total there were 12 adverse reactions, all mild, reported by five participants randomized to rosuvastatin, and one serious adverse event in each group. One patient (4%) had a recurrence of pulmonary exacerbation during follow-up, requiring hospitalization in the control group. Abnormal blood results requiring increase in hospital length of stay was reported as a serious adverse event for one (5%) participant in the intervention group, but it was not related to the intervention/drug. Some adverse events reported in this study include hypoglycemia, back pain, headache, paresthesia, and increase in alanine aminotransferase, aspartate aminotransferase, and creatine phosphokinase. There was no protective effect of rosuvastatin but there was a lower-than-expected level of nephrotoxicity in the cohort. Thus, the authors conclude it is difficult to confirm or deny the hypothesis that rosuvastatin protects against aminoglycoside nephrotoxicity and larger trials may be needed to confirm the result (McWilliam et al., 2020) [c].

ROLE IN ACUTE RESPIRATORY DISTRESS SYNDROME

Patients with Acute Respiratory Distress Syndrome (ARDS) were enrolled in the Statins for Acutely Injured Lungs from Sepsis (SAILS) trial (rosuvastatin vs placebo). A secondary analysis was done on SAILS study to see if a specific population would benefit from rosuvastatin. The cohort included 585 patients with ARDS. Patients were divided into four different phenotypes, phenotype 3 was defined as high platelets and low serum creatinine, and phenotype 4 was defined as high APACHE III score and high serum glucose levels. Phenotypes 1 and 2 were not explicitly defined. Those with phenotype 3 were classified as the population or group who could benefit from rosuvastatin. Rosuvastatin resulted in a significant reduction in 90-day mortality from ARDS ($P = 0.027$) when compared to the placebo group. Also, it improved the days free of cardiovascular failure ($P = 0.01$) and coagulation abnormalities ($P = 0.02$) in the phenotype 3 cohort. Phenotype 3 had a relatively higher platelet count and lower creatinine than the patients in the other phenotypes. However, rosuvastatin seemed to increase 90-day mortality for patients classified as phenotype 4 ($P = 0.076$), with an adverse event of reducing the days free of renal failure ($P = 0.01$). Therefore, this study concluded that rosuvastatin seems to be harmful in patients with high APACHE score and high serum glucose but beneficial in patients with high platelets and low creatinine. This study was a small study. Therefore, the authors concluded that a larger study may be needed to confirm results and understand the role and mechanism of rosuvastatin in ARDS (Zhang, Lu, et al., 2020) [R].

EFFICACY AND SAFETY WITH LANABECESTAT

Lanabecestat is a human amyloid precursor protein-cleaving enzyme 1 inhibitor that is currently in development. It slows disease progression in patients with early Alzheimer's. The study evaluated the breast cancer resistance protein (BCRP) inhibition potential of lanabecestat on the PK of rosuvastatin, which is a substrate for BCRP activity in healthy adult individuals. This study was an open label, fixed sequence, 2-period crossover study. The safety of lanabecestat and rosuvastatin, the effects of rosuvastatin on the PK of lanabecestat, and the effects of multiple genetic polymorphisms on rosuvastatin exposure/concentration were studied and evaluated. Coadministration of rosuvastatin with lanabecestat did not significantly affect rosuvastatin or lanabecestat concentrations compared to monotherapy. There was a statistically significant change in lanabecestat concentration, but it was not clinically significant. Also, lanabecestat had a little effect on BCRP activity in healthy individuals. Lanabecestat and rosuvastatin were associated with few adverse events (headache, dizziness, nausea, vomiting, diarrhea, and pruritus). Dizziness was the most common

side effect, and all side effects were mild and resolved quickly. There were no deaths or other serious adverse events reported in this study. Also, there was no discontinuation in the study due to adverse events related to treatment. This study concluded that lanabecestat does not significantly impact BCRP activity so the restriction of co-administration with BCRP substrates, such as rosuvastatin, may not be required or necessary (Willis et al., 2020) [c].

DRUG-DRUG INTERACTION WITH AZD5718

AZD5718 is a first-in-class anti-inflammatory drug with the potential to reduce risk of cardiovascular events after myocardial infarction in patients receiving statin therapy. This study was a randomized, open-label, crossover, single-dose, phase 1 pharmacokinetic study to investigate a potential drug-drug interaction with rosuvastatin and the effects of formulation and food intake on AZD5718. It included 12 male individuals. Rosuvastatin (10 mg) was absorbed more rapidly when co-administered with AZD5718 (200 mg). AZD5718 pharmacokinetic was unaffected by coadministration of rosuvastatin. Also, AZD5718 was absorbed less rapidly when formulated as tablets than oral suspension, with reduced relative bioavailability. AZD5718 absorption was slower when 200-mg tablets were taken after a high-fat breakfast than after fasting, but bioavailability was unaffected. AZD5718 was well tolerated, with no severe or serious adverse events. Headache was reported in more than 1 participant. All adverse events were of mild intensity except for poor-quality of sleep in 1 participant and influenza-like symptoms in 1 participant which were moderate intensity. The adverse events that were considered possibly related to AZD5718 include headache, nausea, nasal congestion, oropharyngeal pain, and hot flush which were mild in intensity. There was no clinically significant change in vital signs, electrocardiography parameters, or laboratory parameters. This study showed that coadministration of AZD5718 with rosuvastatin had no clinical effect on the safety or pharmacokinetic profiles of either drug (Ericsson et al., 2020) [c].

Atorvastatin

GLUCOSE HOMEOSTASIS AND COGNITIVE FUNCTION

Patients with type 2 diabetes who were taking simvastatin $\leq$20 mg/day were randomized to 2 groups: one group continued taking the same dose of simvastatin ($n=63$) for 12 weeks and another group switched to atorvastatin 40 mg/day for 6 weeks, and if tolerated, the dose increased to 80 mg/day for 6 weeks ($n=62$). This study aimed to evaluate glucose homeostasis as well as cognitive function in these 2 groups. Fasting blood glucose (FBG), glycated hemoglobin (HbA1c), plasma insulin, homeostatic model assessment of insulin resistance (HOMA-IR), β-cell function (HOMA-B), Montreal Cognitive Assessment (MoCA), and Trail Making Test (TMT) were evaluated at baseline, 6 weeks, and 12 weeks. No differences in baseline characteristics between groups were seen. Change in HbA1c from baseline in the simvastatin and atorvastatin groups was −0.1% and +0.1% ($P=0.03$) at 6 weeks, and −0.1% and +0.1% ($P=0.07$) at 12 weeks. There were no significant differences in FBG, fasting plasma insulin, HOMA-B, HOMA-IR, MoCA, and TMT scores between groups at 6 or 12 weeks. Also, there was no significant correlation between percentage of LDL-C reduction and change in MoCA ($P=0.09$), or percentage of LDL-C reduction and change in TMT test from baseline ($P=0.82$). In addition, there was no self-report of memory loss or any type of cognitive impairment in patients with very low LDL-C levels (LDL-C <40 mg/dL). Therefore, switching from low-dose simvastatin to high-dose atorvastatin in patients with type 2 diabetes resulted in a slight increase in HbA1c (0.1%) at 6 weeks only without causing cognitive decline (Thongtang et al., 2020) [c].

Pravastatin

EFFECT ON STROKE RATES

This is a post hoc analysis of the Japan Statin Treatment against Recurrent Strokes (J-STARS) study that evaluated the benefit of pravastatin at different infarction locations including the anterior circulation stroke (ACS) and posterior circulation stroke (PCS). 1578 patients with a history of non-cardioembolic ischemic stroke were randomly assigned to the pravastatin or control group and they were divided into subgroups: ACS and PCS. The results of this study show that the PCS group ($n=499$) had a significantly higher prevalence of diabetes than the ACS group ($n=1022$, $P<0.001$). During the follow-up, the incidence of all strokes, especially atherothrombotic, was significantly lower in the pravastatin group than in the control group among patients with PCS ($P=0.009$), but the stroke recurrence rates were not significantly different between both groups among patients with ACS ($P=0.123$). Also, pravastatin effect was significant between the ACS and PCS groups ($P=0.003$). This study concluded that pravastatin significantly reduced the recurrence rate of all strokes among patients with PCS but not ACS (Nezu et al., 2020) [M].

PCSK9 INHIBITORS

Evolocumab

Evolocumab vs ezetimibe in statin-intolerant hyperlipidemic patients

This Phase III study was a randomized, double-blind, multicenter trial in Japanese patients conducted for 12 weeks followed by an open label extension period to

determine the safety and efficacy of evolocumab after 52 weeks. Patients who failed at least two statins due to myalgia, myositis, or rhabdomyolysis and met the LDL-C management category threshold in the 2012 Japan Atherosclerosis Society Guidelines for the Diagnosis and Prevention of ASCVD in Japan were randomized 2:2:1:1 into four groups. Each randomized group received either 420 mg evolocumab every 4 weeks (Q4W) + oral placebo daily, 140 mg evolocumab every 2 weeks (Q2W) + oral placebo daily, subcutaneous (SC) placebo Q4W + 10 mg ezetimibe daily, or SC placebo Q2W + 10 mg ezetimibe daily, respectively. Sixty-one patients were randomized to evolocumab ($n = 40$) or ezetimibe ($n = 21$). The co-primary endpoint of percent change from the baseline in mean LDL-C to the mean of weeks 10 and 12 and to week 12, demonstrated differences in the evolocumab-ezetimibe treatment of −39.4% (95% CI, −47.2% to −31.5%) and −40.1% (95% CI, −48.7% to −31.6%), respectively (adjusted $P < 0.0001$). Efficacy results for the co-primary endpoints were similar between patients receiving Q2W and Q4W dosing frequencies. The percent change in LDL-C from baseline to week 24 was −62.0% (SD, 14.0) and was consistent through week 52 (−60.3% [SD, 12.2]). During the double-blind period, the most common adverse events were diarrhea (9.5%) and nasopharyngitis (12.5%) in the ezetimibe and evolocumab groups. The authors concluded that the most common adverse event during the open-label extension was nasopharyngitis (29%) (Koba et al., 2020) [c].

Evolocumab use in patients with HIV and dyslipidemia

This randomized, double-blind, multinational trial evaluated the effects of evolocumab in patients with HIV and hypercholesterolemia/mixed dyslipidemia. Patients on stable ART with elevated LDL-C or non-HDL-C and were on maximally tolerated statins were randomized 2:1 to receive 24 weeks of monthly subcutaneous evolocumab 420 mg or placebo, respectively. 467 patients were included; 307 received evolocumab and 157 received placebo. The primary outcome, the percent change in LDL-C from baseline to week 24, illustrated evolocumab reducing baseline LDL-C by 56.9% (95% confidence interval: 52.3%, 61.6%) at week 24, vs placebo. Secondary outcomes, an LDL-C <70 mg/dL and ≥50% LDL-C reduction, were improved for evolocumab vs placebo. Evolocumab significantly improved the primary and all secondary endpoints compared with placebo, with multiplicity adjusted P values <0.0001. Treatment-emergent adverse events (TEAEs) in patients were similar between placebo and evolocumab groups and no new safety concerns were identified. The authors concluded that the most common (2%) TEAEs in the evolocumab group were back pain, influenza, diarrhea, nasopharyngitis, arthralgia, upper respiratory tract infection, pain in extremity, and paresthesia (Boccara et al., 2020) [C].

Comparison of evolocumab and ezetimibe for atherogenic lipid reduction

Summarized data from 1427 patients (477 treated with ezetimibe and 950 with evolocumab) from three Phase 3 evolocumab studies comparing double-blinded evolocumab vs ezetimibe evaluated four distinct populations: those free of CVD receiving each agent as monotherapy, patients with CVD receiving add-on therapy to low- or high-intensity statin, and statin-intolerant patients. Each study randomized patients 1:2 to ezetimibe and evolocumab; overall, 53% patients were female and 90% were Caucasian. Evolocumab reduced LDL-C by a mean 55–61% from baseline to week 12, and ezetimibe lowered LDL-C by 18–20% from baseline, resulting in a significant mean difference of 38–43% favoring evolocumab compared with ezetimibe ($P < 0.0001$) across all four patient populations. Furthermore, evolocumab led to significantly higher proportions of patients achieving LDL-C goals across all patient populations, with the greatest treatment differences seen in the statin-intolerant (67% evolocumab vs ezetimibe) and monotherapy groups (67% evolocumab vs ezetimibe; $P < 0.0001$ for both). Evolocumab also reduced non-HDL-C from baseline by a mean of 48–53% across the four populations, and ezetimibe reduced non-HDL-C from baseline by a mean of 16–17%, resulting in a significant mean difference between groups of 33–37% favoring evolocumab ($P < 0.0001$). The authors concluded that ADEs between evolocumab- and ezetimibe-treated patients were balanced, however, statin-intolerant patients reported AEs more frequently than other populations (0–3.9% in the ezetimibe-treated patients and 1.3–2.9% in the evolocumab-treated patients) (Koren et al., 2020) [C].

Evolocumab in pediatric patients with heterozygous familial hypercholesterolemia (HeFH)

This study was a randomized, double-bind, placebo-controlled trial evaluating the efficacy and safety of evolocumab in pediatric patients with HeFH over 24 weeks. A total of 157 patients between the ages of 10–17 years were randomly assigned 2:1 to receive 420 mg monthly subcutaneous injections of evolocumab ($n = 104$) or placebo ($n = 53$) if they received stable lipid-lowering treatment for at least 4 weeks before screening and had an LDL cholesterol level of 130 mg per deciliter (3.4 mmol/L) or more and a triglyceride level of 400 mg per deciliter (4.5 mmol/L) or less. At week 24, the mean percent change from baseline in LDL cholesterol level (primary endpoint) was −44.5% in the evolocumab group and −6.2% in the placebo group, for a difference of −38.3 percentage points ($P < 0.001$). The absolute change in the LDL cholesterol level (secondary end point) was −77.5 mg per deciliter (−2.0 mmol/L) in the evolocumab group and −9.0 mg per deciliter (−0.2 mmol/L) in the placebo group, for a difference of −68.6 mg per

deciliter (−1.8 mmol/L) ($P < 0.001$). In addition, evolocumab showed a benefit with respect to other secondary lipid-related endpoints, including non-HDL cholesterol and apolipoprotein B. Adverse events during the treatment period were similar between the evolocumab and placebo groups. The authors concluded that the most common adverse events (>2% of the patients in either group) with a higher incidence (by >1 percentage point) in the evolocumab group than in the placebo group were headache, oropharyngeal pain, influenza, influenza-type illness, upper respiratory tract infection, and constipation (Santos et al., 2020) [C].

Alirocumab

Alirocumab in pediatric patients with heterozygous familial hypercholesterolemia (HeFH)

This trial, also known as ODYSSEY KIDS, was a Phase II open-label, dose-finding study evaluating the efficacy, safety, and dose selection of alirocumab in pediatric HeFH patients. A total of 42 HeFH patients who were aged 8–17 years (mean age of 12.4), had body weight (BW) ≥25 kg, and had LDL-C ≥130 mg/dL despite optimal statin/other lipid-modifying therapies were enrolled in 4 cohorts according to BW: cohort #1: 30 mg (<50 kg) or 50 mg (≥50 kg) every 2 weeks (Q2W), #2: 40 mg (<50 kg) or 75 mg (≥50 kg) Q2W, #3: 75 mg (<50 kg) or 150 mg (≥50 kg) every 4 weeks (Q4W), #4: 150 mg (<50 kg) or 300 mg (≥50 kg) Q4W. Baseline LDL-C levels were 160.0–188.9 mg/dL and free PCSK9 was 186.4–201.7 ng/mL across the cohorts. At week 8, the higher dose cohorts (2 and 4) demonstrated the greatest reductions in LDL-C (−46% and −45%, respectively); greater than 72% of patients reached a calculated LDL-C level of <110 mg/dL in both cohorts. Free PCSK9 levels were lowest at week 8 in cohorts 2 and 4 (42.2 and 8.6 ng/mL, respectively). No deaths or serious adverse events occurred. Two patients discontinued treatment due to TEAEs of fatigue and neutropenia, however, neither event was considered related to study treatment. The authors concluded that the most common TEAEs were nasopharyngitis (6/42 patients, 14%), upper respiratory tract infection, viral gastroenteritis, and diarrhea (each reported in 5/42 patients, 12%) (Daniels et al., 2020) [c].

Alirocumab in adults with homozygous familial hypercholesterolemia

This Phase III trial, also known as ODYSSEY homozygous familial hypercholesterolemia (HoFH), was a randomized, double-blind, placebo-controlled, parallel-group study evaluating the efficacy and safety of alirocumab 150 mg every 2 weeks. A total of 69 patients were randomized 2:1 to alirocumab or placebo; at baseline, 67 patients were receiving a statin, 50 were on ezetimibe, 10 were on lomitapide, and 10 patients were undergoing apheresis. Mean baseline LDL-C was 259.6 mg/dL in the placebo group and 295.0 mg/dL in the alirocumab group. The primary efficacy endpoint, the percent reduction from baseline in LDL-C vs placebo after 12 weeks of treatment, demonstrated a least squares mean SE percent change in LDL-C from baseline at week 12 of −26.9% ± 4.6% for alirocumab and +8.6% ± 6.3% for placebo. The difference between groups was −35.6% ± 7.8% ($P < 0.0001$). Alirocumab resulted in significant (all $P < 0.0001$) least squares mean reductions from baseline to week 12 (difference vs placebo) in levels of Apo B (−29.8%), non-HDL-C total cholesterol (−26.5%), and Lipoprotein(a) (−28.4%). TEAEs occurred in 20 patients (44.4%) in the alirocumab group and 12 patients (50.0%) in the placebo group; common TEAEs occurring in ≥5% of patients in any treatment group were upper respiratory tract infection, headache, and diarrhea. The authors concluded that no treatment-emergent serious adverse events, treatment discontinuations due to a TEAE, or deaths were reported in either treatment group during the double-blind period (Blom et al., 2020) [c].

Safety, tolerability, pharmacokinetics, and pharmacodynamics of Alirocumab

This was a phase I, single-center, randomized, double-blind, placebo-controlled, ascending single-dose study of alirocumab following subcutaneous administration in healthy Chinese patients. A total of 31 patients were randomized to one of three sequential ascending dose groups (each completed before initiating the next dose group) with 10 subjects planned per group, 8 to receive alirocumab and 2 to receive matching placebo: group 1, a single dose of alirocumab 75 mg (75 mg/mL × 1 mL) or placebo; group 2, a single dose of alirocumab 150 mg (150 mg/mL × 1 mL) or placebo; and group 3, a single dose of alirocumab 300 mg (2 × 150 mg/mL × 1 mL) or placebo. One patient recipient did not finish the study procedure due to a serious adverse event. Maximum mean LDL-C reductions from baseline were observed on days 8, 15, and 22 with alirocumab 75 (55.3%), 150 (63.7%), and 300 mg (73.7%), respectively. Total cholesterol, non-HDL-C, and apolipoprotein B were also reduced with alirocumab. Alirocumab serum concentrations (6–34 mg/dL) reached maximum at a median of 3–7 days across the dose groups. The authors concluded that the most frequent TEAEs were nasal congestion and dry throat, reported in three of seven or eight subjects in each alirocumab dose group (two of seven in the placebo group). One patient receiving alirocumab 300 mg had a mild local injection-site reaction and none of the alirocumab recipients demonstrated antidrug antibodies (Li et al., 2020) [c].

Alirocumab in high CVD risk patients with hypercholesterolemia

This Phase III study, also known as ODYSSEY EAST, was a randomized, double-blind, parallel-group, multicenter trial conducted in China, India, and Thailand with a total of 61 active sites. 615 patients (456 from China, 112 from India, and 47 from Thailand) were randomized 2:1 to treatment with alirocumab 75 mg Q2W ($n = 407$) or ezetimibe 10 mg daily ($n = 208$) for 24 weeks. A dose increase to 150 mg Q2W in the alirocumab group occurred at week 12 if the week 8 LDL-C was >1.81 mmol/L (>70 mg/dL). Demographics, disease characteristics, and lipid parameters at baseline were similar in the alirocumab and ezetimibe groups. LDL-C levels were significantly reduced from baseline to week 24 by 56.0% and 20.3% in the alirocumab and ezetimibe groups, respectively ($P < 0.0001$ vs ezetimibe). Overall, 18.8% of alirocumab-treated patients received a dose increase to 150 mg Q2W. At week 24, 85.1% of alirocumab-treated and 40.5% of ezetimibe-treated patients reached LDL-C <1.81 mmol/L (<70 mg/dL, $P < 0.0001$ vs ezetimibe). Treatment-emergent adverse events occurred in 68.5% of alirocumab-treated and 63.1% of ezetimibe-treated patients, with upper respiratory tract infection the most common (alirocumab: 13.3%; ezetimibe: 14.1%). The authors concluded that the injection-site reactions occurred more frequently in alirocumab-treated patients (2.7%) than in ezetimibe-treated patients (1.0%) (Han et al., 2020) [C].

Effect of alirocumab on major adverse cardiovascular events in patients with recent ACS

This was study was a prespecified analysis from ODYSSEY OUTCOMES, a randomized, double-blind, placebo-controlled trial comparing alirocumab or placebo in 18 924 patients with acute coronary syndrome and elevated atherogenic lipoproteins despite optimized statin treatment. This analysis investigated whether the effect of alirocumab on major adverse cardiovascular events (MACE) and death varied across the range of baseline renal function, gauged by eGFR calculated using the Chronic Kidney Disease Collaboration equation. Patients with an estimated glomerular filtration rate (eGFR) <30 mL/min/1.73 m^2 were excluded. In 18 918 patients, baseline eGFR was 82.8 ± 17.6 mL/min/1.73 m^2, and low-density lipoprotein cholesterol (LDL-C) was 92 ± 31 mg/dL. Alirocumab decreased LDL-C by 48.5% vs placebo at 36 months but did not affect eGFR ($P = 0.65$). Overall, alirocumab reduced risk of the primary outcome (coronary heart disease death, non-fatal myocardial infarction, ischemic stroke, or unstable angina requiring hospitalization) with fewer deaths. There was no interaction between continuous eGFR and treatment on the primary outcome or death ($P = 0.14$ and 0.59, respectively). Alirocumab reduced primary outcomes in patients with eGFR ≥90 mL/min/1.73 m^2 ($n = 7470$; hazard ratio 0.784, 95% confidence interval 0.670–0.919; $P = 0.003$) and 60 to <90 ($n = 9326$; 0.833, 0.731–0.949; $P = 0.006$), but not in those with eGFR <60 ($n = 2122$; 0.974, 0.805–1.178; $P = 0.784$). The authors concluded that the adverse events were similar in both groups across all categories of eGFR with the only difference being local injection-site reactions with alirocumab (Tuñón et al., 2020) [C].

Bile acid sequestrants

Systemic drug photosensitivity

This is a retrospective review of patients diagnosed with drug-induced photosensitivity over a 16-year period (Jan 2000–Jan 2016). A detailed clinical history was taken from patients including timelines of medications taken as well as symptoms of photosensitivity and were examined for signs of a photo-distributed rash and its morphology. A total of 2243 patients underwent broadband phototesting as well as patch testing to screen NSAIDs, along with laboratory tests. Of these patients, 122 patients were diagnosed with drug-induced photosensitivity. Of the 122 patients, 64 were female, median age was 62. The culprit drugs found included azathioprine and biologics such as TNF-alpha inhibitors and the anti-RANKL agent, denosumab. This review shows that previously reported common photosensitizing drugs remain at the top of the list, in particular quinine and thiazide diuretics which are responsible for 11.5% and 9.8% of cases of drug-induced photosensitivity, respectively. Patients were found to have voriconazole and proton-pump inhibitor induced photosensitivity, at 9% and 9.8%, respectively. Results of this review are comparable to other photo-investigation centres such as the Scottish photobiology service where commonly found culprits of drug-induced photosensitivity included thiazide diuretics, amiodarone, NSAIDs, quinine, doxycycline, and calcium channel antagonists. This review, however, revealed higher frequencies of drug-induced photosensitivity associated with PPI, ACE inhibitors, as well as statins, which were not among previously reported culprits (Alrashidi et al., 2020) [R].

IW-3718 reduces heartburn in refractory GERD

This study is a multicenter, double-blind, placebo-controlled trial evaluating the efficacy and safety of IW-3718, a bile acid sequestrant, as an adjunct to PPI therapy in patients with refractory GERD who are on proton-pump inhibitors and still have symptoms. A total of 280 patients with confirmed GERD were randomly assigned to 4 groups given placebo or IW-3718 at doses of 500 mg, 1000 mg, and 1500 mg twice daily with ongoing label-dose PPI. There was found to be a dose-response trend across all of the treatment arms, the highest response

being the 1500 mg IW-3718 group. 52.9% of patients treated with 1500 mg IW-3718 were heartburn responders, and 37.1% of patients treated with placebo were heartburn responders. Among patients with baseline regurgitation, the greatest mean reduction was seen in the 1500 mg IW-3718 group. ADEs were similar among all treatment groups when compared to placebo (46.2% vs 41.4%). ADEs found more prevalent in the treatment groups included nausea (6.2% vs 2.9%) and constipation (8.1% vs 7.1%). This trial shows that adding 1500 mg IW-3718 to label-dose PPIs significantly reduced heartburn symptoms as well as regurgitation compared to adding placebo (Vaezi et al., 2020) [C].

Fibric acid derivatives

Fenofibrate administration on abdominal aortic aneurysm

This randomized double-blind parallel trial examined the effects of a short course of fenofibrate on abdominal aortic aneurysm (AAA) pathology in people with large AAAs awaiting aortic repair. A total of 43 patients, ages 60 years of age and older who were scheduled to undergo open AAA repair were randomized to receive fenofibrate of 145 mg/day or placebo for at least 2 weeks before AAA repair. There was no difference seen in AAA wall osteopontin concentrations between the treatment arms. The number of infiltrating macrophages was also assessed in AAA biopsies that were collected from both the fenofibrate treatment group as well as the placebo group and no difference was observed. There was no difference in aortic MMP-9, MMP-2 activities, or plasma D-dimer concentrations between the treatment groups. Fenofibrate did not influence concentrations of osteopontin or density of macrophages within the AAA wall and this suggests that fenofibrate is unlikely to be effective in treating AAA before aortic repair. This study shows that a short course of 145 mg of fenofibrate/day did not lower concentrations of osteopontin or decrease aortic macrophage density in patients with large AAAs (Moxon et al., 2020) [c].

Fenofibrate as adjuvant therapy in patients with type 2 diabetes mellitus

This prospective randomized controlled parallel study evaluated the impact of fenofibrate 300 mg orally/day when given as an adjuvant therapy to glimepiride/metformin in patients with type 2 diabetes mellitus through assessing its impact on endothelial dysfunction biomarkers: ADMA, SDC-1, CRI-1, CRI-2. A total of 75 patients were classified into three groups: Group 1 was the control group of 25 healthy subjects, Group 2 was 25 patients with T2DM receiving glimepiride/metformin 2:500 mg/day, and Group 3 was 25 patients with T2DM receiving glimepiride/metformin 2:500 mg/day + fenofibrate 300 mg/day. After 3 months of treatment, there was a significant decrease in BMI, SBP, DBP, glycemic panel, and lipid panel, and a significant increase in HDL-C in treatment Group 3. In treatment Group 2, there was no significant decreases of these parameters, and only a significant increase in SBP and a decrease in HDL-C. There was a significant reduction in both CRI-1 and CRI-2 by 56.61% and 66.7%, respectively, in treatment Group 3, while a significant increase in both CRI-1 and CRI-2 was seen in treatment Group 2 at 17.97% and 21.99%, respectively. Pearson's correlation coefficient analysis was applied to treatment Group 3 and after 3 months of therapy, it revealed that there was a significant positive correlation between endothelial dysfunction biomarkers SDC-1 and ADMA, and CRI-1 and CRI-2. No ADEs were reported by the treatment group. This study revealed that the addition of fenofibrate as adjuvant therapy to glimepiride/metformin significantly improved vascular endothelial dysfunction, lipid panel, blood pressure, as well as BMI in patients with T2DM who were never on previous lipid-lowering medications (Hegazy et al., 2020) [c].

Potential herb-drug interactions

This study used data from the Shanghai Aging Study to investigate the prevalence of potential herb-drug interactions in community-dwelling older adults in Shanghai (ages 60 and above) to identify patterns and factors associated with potential herb-drug interactions. This study revealed that among 1227 patients who used any combination of drug-herb or herb-herb, 43.3% of them were exposed to at least one potential herb-drug interaction. Out of 1227 elderly adults, 531 (43.3%) were exposed to at least one potential herb-drug interaction, 1641 herb-drug interactions were considered category X, while 876 herb-drug interactions were rated category D. Of importance, 863 (99.8%) of category D herb-drug interactions involved medications such as anticoagulant/antiplatelet properties. Herbs with anticoagulant properties can enhance the toxic effects of drugs with antiplatelet properties and bleeding risk may be increased. The most involved herbs were ginko, licorice, calculus bovis, hawthorn, and ginseng. The most involved drugs were antithrombotic agents, calcium channel blockers, diuretics, and drugs that act on the renin-angiotensin system. Red yeast rice is a category C herb and has an herb-drug interaction with fenofibrate. Fenofibrate and derivatives may enhance the ADEs of HMG-CoA reductase inhibitors. The prevalence of potential herb-drug interactions in the community was high in this study and although these interactions are only a potential hazard, this study helped shade light so that we can take actions to prevent them from occurring. 43.3% of the elderly community who used any combination of an herb-drug was exposed

to potential herb-drug interactions, and more than 50% were associated with anticoagulant properties (Chi et al., 2020) [C].

Coenzyme a vs fenofibrate in hyperlipidemia

This multicenter, double-blind, double-mimic, randomized clinical trial investigated the lipid-lowering efficacy and safety of coenzyme A vs fenofibrate in Chinese patients with moderate dyslipidemia. A total of 417 patients ages 18–75 diagnosed with moderate dyslipidemia were randomized into a fenofibrate group which received 200 mg orally once daily, and a coenzyme A group which received 400 mg orally once daily. After treatment for 4 and 8 weeks, triglycerides were reduced by 31.62% and 33.13%, respectively, in the fenofibrate group, and 17.29% and 23.80%, respectively, in the coenzyme A group. An extraordinary decrease in TG levels was found in the fenofibrate group when compared to the coenzyme A group and this difference was found to be significant. The incidence of ALT/AST elevation was 4.3% and creatine kinase elevation was 1.5% in the fenofibrate group. In the coenzyme A group, the incidence of ALT/AST elevation was 0.5% and CK elevation was 0%, both found to be significantly lower than in the fenofibrate group. This study supported the TG lowering effects of both fenofibrate and coenzyme A; however, the extent of lipid lowering was relatively weaker in the coenzyme A group. Coenzyme A was found to be less effective than fenofibrate in HDL-C modifications, but as effective in lowering non-HDL-C as fenofibrate. With the expanded use of fibrates, more side effects have been seen, most being liver dysfunction and gastrointestinal symptoms. The incidence of side effects caused by fenofibrate in this trial was found to be significantly higher than that caused by coenzyme A (Chen, Li, et al., 2020) [C].

Fenofibrate and microalbuminuria

This study was a randomized, no placebo, controlled study that evaluated the efficacy of fenofibrate in decreasing microalbuminuria in patients with T2DM and concomitant hypertriglyceridemia. A total of 56 patients were randomized into two groups: fenofibrate treatment group and control group for 180 days. There was no difference in the reduction of fasting blood glucose levels and HBA1c levels between the two treatment groups. Uric acid levels, triglyceride levels, as well as UACR levels were significantly decreased in the fenofibrate treatment group compared with baseline levels. HDL-C levels were also significantly increased when compared to baseline in the fenofibrate treatment group as well. There was a positive correlation between the decrease in UACR and the decrease in triglycerides and uric acid levels when given the fenofibrate treatment. Fenofibrate can help improve and reduce microalbuminuria in patients with concomitant T2DM and hypertriglyceridemia, without increasing impairments in eGFR (Sun et al., 2020) [c].

PK of ozanimod with gemfibrozil, itraconazole, or rifampin

This phase 1, randomized, open-label study focused on assessing the single-dose pharmacokinetics of ozanimod and its metabolites as well as to assess the effects of gemfibrozil, itraconazole, and rifampin on the single-dose PK of ozanimod. A total of 40 patients were randomized to receive either a single oral dose of ozanimod, oral doses of gemfibrozil + a single dose of ozanimod, oral doses of itraconazole + a single dose of ozanimod, or oral doses of rifampin + a single dose of ozanimod. In the single dose of ozanimod alone group, there were dose-proportional increases in Cmax and AUC for both the parent drug, ozanimod as well as its metabolites CC112273 and CC1084037. Itraconazole, a strong inhibitor of CYP3A and P-glycoprotein increased ozanimod AUC by 13%, while rifampin, a strong inducer of CYP3A and P-gp, reduced the AUC of ozanimod by 24%. This implies that there is a CYP3A4 and P-gp involvement in the metabolism of ozanimod. Gemfibrozil, a strong inhibitor of the CYP450 system, increased the AUC for the metabolites of ozanimod, CC112273 and CC1084037 by 47% and 69%, respectively. The metabolites of ozanimod were found to have similar single-dose PK properties, with CYP2C8 being the main enzyme in the metabolism of these metabolites, and CYP3A4 and P-gp being enzymes for the metabolism of ozanimod (Tran et al., 2020) [c].

Fenofibrate and triglyceride levels in spinal cord injury

This open-label trial was carried out in 15 patients with spinal cord injury to determine the safety profile of 145 mg of fenofibrate once daily for 4 months and whether serum triglyceride levels were reduced as a result of therapy. A total of 4 patients experienced an adverse event (gastrointestinal), 3 of which were severe enough to discontinue the medication. Serum triglyceride levels were taken at baseline as well as at month 2 when the decision was made on whether to continue or withdraw from the medication based on if there was at least a 25% reduction in serum TG levels. This study showed that once-daily fenofibrate given as monotherapy in patients with spinal cord injury who do not have very high triglyceride levels that necessitate treatment, does not increase the severity of ADRs that can occur with fenofibrate therapy (La Fountaine et al., 2020) [c].

Ezetimibe

Safety profile from ODYSSEY EAST in China, India, and Thailand

This study included 615 patients from China, India, and Thailand with hypercholesterolemia at high cardiovascular risk on maximally tolerated statin. Those patients were randomized in 2:1 to alirocumab 75 mg every 2 weeks with dose increase to 150 mg every 2 weeks at week 12 if week 8 LDL-C level was >70 mg/dL or ezetimibe (10 mg daily) for 24 weeks. Safety data was assessed throughout this study. Overall, 68.5% and 63.1% of patients experienced at least 1 adverse event in the alirocumab and ezetimibe groups, respectively. Adverse events of special interest include general allergic events, local injection site reaction, neurological and neurocognitive events, ophthalmologic events, cardiovascular events, ischemic stroke, unstable angina, congestive heart failure, and ischemia driven coronary revascularization procedure. Adverse events occurring in $\geq$2% of patients include infections, blood and lymphatic system disorder, metabolism and nutrition disorder, psychiatric disorder, vascular disorder, respiratory, thoracic and mediastinal disorders, nervous system disorder, eye disorder, gastrointestinal and hepatobiliary disorders, cardiac disorders, vascular disorder, dizziness, cough, palpitations, musculoskeletal and connective tissue disorder, renal and urinary disorder, anthemia, pyrexia. Injection-site reactions were observed more frequently in patients treated with alirocumab (2.7%) than in patients treated with ezetimibe (1.0%) but they were mild in intensity. Percentage of patients who experienced serious adverse events was 10.1% in the alirocumab group and 11.2% in the ezetimibe group but there was no pattern in occurrence between the two groups. The percentage of patients reported with adverse events leading to permanent discontinuation were similar between the groups. Three deaths were reported in each of the treatment groups (0.7% vs 1.5% in the alirocumab and ezetimibe groups, respectively). Primary causes of deaths were cardiovascular in 2 (0.5%) patients in the alirocumab group vs 2 (1%) patients in the ezetimibe group. Positive Anti-Drug Antibody (ADA) baseline status was reported in 5 patients: 4 (1.0%) in the alirocumab group and 1 (0.5%) in the ezetimibe group. A total of 29 patients, 28 in the alirocumab group (7.1%) and 1 in the ezetimibe group (0.5%) developed a positive ADA response. But the majority was transient in the alirocumab and placebo groups and 1.8% of the alirocumab group had persistent response. The proportion of patients with diabetes mellitus or diabetic complication was similar between treatment groups (6.4% in the alirocumab group vs 5.8% in ezetimibe group). The author concluded that there were also few cases of hepatic disorders and abnormal laboratory values (>3 times upper limit of normal for creatine kinase, alanine aminotransferase, and aspartate aminotransferase) (Han et al., 2020) [C].

Safety profile in Japanese patients

This is a double-blind, randomized, multicenter, phase 3 study that randomized patients to receive either evolocumab or ezetimibe at 30 sites in Japan. This study was conducted in a 12-week period and designed to assess the safety and efficacy of the two drugs in lowering LDL-C. Percent change in mean LDL-C from baseline to weeks 10 and 12 and to week 12 in evolocumab and ezetimibe treatment differences were −39.4% (95% CI, −47.2% to −31.5%) and −40.1% (95% CI, −48.7% to −31.6%), respectively ($P < 0.0001$).

The safety profile and data show the incidences of treatment adverse events were 61.9% in ezetimibe groups vs 57.5% in evolocumab group in the double-blind period and 79.3% with evolocumab plus standard of care in the open-label extension. The most common adverse events were diarrhea (9.5%) in the ezetimibe group and nasopharyngitis (12.5%) and pharyngitis (10.0%) in the evolocumab group in the open label period. During the extension period, the most common adverse event was nasopharyngitis (29%). In the double-blind period, 2 patients on ezetimibe (9.5%) experienced serious adverse events: acute myocardial infarction and osteoarthritis vs. none in evolocumab group. In the open-label extension, 4 patients (6.9%) experienced serious adverse events: myocardial ischemia, mass, lung neoplasm malignant, and transient ischemic attack but none of these events were considered related to treatment. In the double-blind period, no patients on ezetimibe and 2 patients (5%) on evolocumab discontinued the investigational product due to treatment emergent adverse events: muscle weakness and cough. In the open-label extension, 1 patient (1.7%) discontinued because of abnormal liver function. There was no elevation in liver function tests during open label extension. One patient experienced elevated creatine kinase (CK) but had elevated CK at baseline. There were no deaths in the study. The authors concluded that evolocumab was superior to ezetimibe in reducing LDL-C in Japanese patients with hypercholesterolemia and statin intolerance (Koba et al., 2020) [c].

Efficacy and safety profile

Data was summarized from 1427 patients from three phase-3 evolocumab studies comparing double-blinded evolocumab vs ezetimibe. These studies evaluated four patient populations which include those free of cardiovascular disease (CVD) receiving each agent as monotherapy with either drug, patients with CVD receiving add-on therapy to low or high-intensity statin, and

statin-intolerant patients. Efficacy and safety were reported at week 12. Evolocumab was better than ezetimibe in lipid goal achievement in the four patient populations analyzed. Serious adverse events occurred in 0–3.9% of patients receiving ezetimibe and in 1.3–2.9% in patients receiving evolocumab. Muscle related adverse events occurred at rates of 3.2% vs 2.6%, 4.5% vs 0.9%, 2.7% vs 1.8%, and 22.5% vs 12.2% (ezetimibe vs evolocumab) in the mono-therapy, low-intensity statin, high-intensity statin, and statin intolerant populations, respectively.

The decision to discontinue subcutaneous treatment by patients or physicians occurred at similar rates to the discontinuation rates for oral treatment in the high-intensity statin and mono-therapy treatment groups. Rates of drug discontinuation due to muscle events were <1% in each group except for statin-intolerant patients. In the statin-intolerant population, 5.9% vs 2.4% of patients in the ezetimibe vs evolocumab treated groups stopped oral drug treatment due to muscle symptoms. The authors concluded that evolocumab provided substantive atherogenic lipid improvements across a broad range of patients, leading to greater reductions in LDL-C and non-HDL levels when compared to ezetimibe (Koren et al., 2020) [C].

Omega-3 fatty acids

Efficacy of omega-3 free fatty acids in patients with dyslipidemia

This Phase III study was a randomized, double-blind, placebo-controlled, parallel-group trial conducted between June 2015 and March 2017 to evaluate the short-term efficacy and long-term safety of AZD0585 (a mixture of omega-3 free fatty acids). Subjects were enrolled with low-density lipoprotein cholesterol (LDL-C) levels controlled regardless of statin use and triglycerides (TG) levels between 140 and 499 mg/dL. 383 patients were randomized 2:2:1 to receive 2 g AZD0585, 4 g AZD0585, or placebo once daily for 52 weeks, respectively. The 12-week endpoint, defined as the mean of measurements at week 10 and 12, illustrated a least-squares mean percent change in triglyceride concentrations from baseline of −15.57% (2 g AZD0585), −21.75% (4 g AZD0585), and 11.15% (placebo; $P < 0.0001$ for both AZD0585 doses vs placebo). A significant decrease in serum TG concentrations from baseline compared with placebo was demonstrated in both AZD0585 groups; −26.72% for 2 g AZD0585 vs placebo (95% confidence interval [CI] −36.55, −16.88; $P < 0.0001$) and −32.92% for 4 g AZD0585 vs. placebo (95% CI −42.93, −22.92; $P < 0.0001$). AZD0585 decreased TC, LDL-C, non-HDL-C, and VLDL-C and marginally increased HDL-C in a dose-dependent manner compared with placebo at the 12-week endpoint. Lipid profiles up to week 52 were consistent with those of the 12-week endpoint. No clinically significant safety concerns were raised; the most common ADEs were nasopharyngitis and diarrhea, all of which were of a mild to moderate nature (Yokote et al., 2020) [C].

Reduction of cardiovascular with Icosapent ethyl: Intervention trial USA (REDUCE-IT USA)

REDUCE-IT USA was a multicenter, randomized, double-blind, placebo-controlled involving patients with established cardiovascular disease or with diabetes and other risk factors. A total of 3146 US statin-treated patients with qualifying triglycerides ≥135 and <500 mg/dL and low-density lipoprotein cholesterol >40 and ≤100 mg/dL and a history of atherosclerosis or diabetes mellitus were randomized to icosapent ethyl 4 g/d or placebo. A total of 92.5% of patients were white, 32.3% of were women, and 9.7% were Hispanic; all patients were followed for a median of 4.9 years. The primary composite endpoint of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or unstable angina in a time-to event analysis showed a significant difference between placebo and icosapent ethyl, occurring in 24.7% vs 18.2% of patients, respectively (hazard ratio [HR], 0.69 [95% CI, 0.59–0.80]; $P = 0.000001$). The key secondary composite endpoint of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke in a time-to-event analysis displayed a significant difference of 16.6% in placebo-treated patients vs 12.1% in icosapent ethyl-treated patients (HR, 0.69 [95% CI, 0.57–0.83]; $P = 0.00008$). The US subgroup of REDUCE-IT demonstrated particularly strong reductions across the composite end points as well as all-cause mortality (2.6% absolute risk reduction). The overall tolerability and safety of icosapent ethyl was nearly identical to that of placebo, with two variations of an increase in any bleeding and overall treatment-emergent adverse event rate of atrial fibrillation or flutter. The authors concluded that there were no significant differences in the rates of treatment-emergent adverse events or in serious treatment-emergent adverse events were present (Bhatt et al., 2020) [C].

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Recreational Drugs: Cannabis, Marijuana, and Hemp

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Chemical substances taken for enjoyment, or leisure purposes, rather than for medical reasons can be broadly defined as recreational drugs such as alcohol, tobacco, caffeine, marijuana, heroin, cocaine etc. These are usually started to provide pleasure or improve life in some way, but they can lead to addiction, social problems and even crime. Marijuana contains a psychoactive compound called THC (tetrahydrocannabinol) that produces a "high" when ingested. It is an illegal drug and classified at the federal level as a Schedule I drug under the Controlled Substances Act.

The use of recreational drugs is nothing new in human history. Drug abuse and addiction have been a global issue for nearly a century. Needless to say that many of these illegal drugs were first introduced by doctors as legal over the counter (OTC) and prescription medicines.

There is a common misconception that hemp and marijuana are two different species of plant. In fact, they're just two different names for cannabis plant of *Cannabaceae* family. As long as origin is concerned, science doesn't differentiate between "hemp" and "marijuana," but the law does. Legally, the key difference between the two is tetrahydrocannabinol (THC) content. THC is one of many chemicals found in the cannabis that's primarily responsible for the "high". The term "hemp" is used to mean cannabis that contains 0.3 percent or less THC content by dry weight and "marijuana" refers to the cannabis that has THC content above 0.3 percent. Hemp is the medical marijuana which is federally legal. Usually, when people say "marijuana," they actually mean the cannabis that can get you "high".

Marijuana is perhaps one of the oldest drugs in human history, Before the Civil War marijuana was a major source of revenue for the U.S. It was widely used as a medicinal agent from 1850 to 1937 and was available as over the counter in pharmacies and general stores. After the price of alcohol was raised in 1920 Marijuana became an attractive alternative to alcohol. Studies demonstrated that marijuana use was mostly confined in lower class communities where violence is more common.

The U.S. Food and Drug Administration has evaluated the hemp seed-derived food ingredients such as hulled hemp seed (GRN765), hemp seed protein powder (GRN771), and hemp seed oil (GRN778) as GRAS (Generally Recognized as Safe). Hemp seeds are the seeds of the plant, *Cannabis sativa*. Although hemp is from the same species as marijuana, the seeds themselves do not naturally contain THC, the main psychoactive ingredient in cannabis. Consumption of these hemp seed-derived ingredients is not capable of causing "high". Recent studies demonstrated that marijuana could be beneficial for pain relief, appetite stimulation, and nausea and vomiting control. In more recent years, the medical use of cannabinoids has been linked to the management of neuropathic pain, hypertension, poststroke neuroprotection, multiple sclerosis, epilepsy, and cancer.

The pre-legalization era of medical marijuana was a lucrative market for drug-dealers, smugglers, and growers alike. Ever since, the first legalization of Marijuana in Colorado, the market for marijuana has been shifting heavily towards big legal corporations than criminal gangs, or at least that's what you'd think. The legalized Marijuana is legal to a certain extent: the individual must be over the age of 21, and only allowed to grow 6 plants each. And while dispensaries are lucrative from a business standpoint, from a buyer's standpoint not so much, in part due to the high tax rates. The phrase "the dealers will live on" is a post legalization phrase, denoting the somewhat impractical logistics of the marijuana dispensing pharmacies. In general, the big cities and crowded suburbs, in legalized states, have dispensaries that cater to weed buyers. While the isolated suburbs and rural areas are "weed-starved". This can be attributed to the fact that there simply less buyers in rural areas, and there are often cultural differences, and demographic shifts ranging from racial, religious, to age and ethnicities that inevitably contribute to a corporation's interests in opening a dispensary. Dispensaries, follow the urbanization trend, whereas dealers are legion. They are a sort of everywhere "entrepreneurs".

Some recreational users are often under the age limit. According to the National Institute of Health 1 in 6 teens use marijuana in the United States. That number I'm sure still applies to Colorado and other Legalized Marijuana States. And these teenagers are still getting it from their dealers. Whereas some are simply legally unable to do so, others simply don't identify with marijuana as the solution to their mental health problems due to ethnic or even religious connotations. "Drugs are not the drug user's main problem. While so many factors potentially contribute to the downfall of medical marijuana dispensaries, the corporate economy still successful however as the current medical marijuana industry is rated as a 32-billion-dollar industry with the American government earning a total of 3.7 billion in reported tax from 2019 alone. Overall, the market for marijuana is split, where the gentrified areas of legalized states have, beyond a shadow of doubt, the highest concentrations of medical marijuana dispensaries; while the rural areas and poor suburbs have the lowest concentrations of medical marijuana dispensaries, with the populations of the illegal states still relying on dealers for their marijuana needs. And these are simply observations affected simply by the inner economics of things.

[The writer was an Associate Professor of Pharmaceutical Chemistry, Faculty of Pharmacy, University of Dhaka (2005 – 2016)]

The DASH Diet

By Dr. Lamisa Ahsan, PharmD, Rph

Hypertension also known as high blood pressure is one of the major leading causes of atherosclerosis in the United States and throughout the world. The study of hypertension is important for us as pharmacists because one in every four Americans is affected with this disease. An elevated blood pressure causes the heart to pump faster requiring more energy. The buildup of plaque along the arterial walls causes the heart to need more pressure to pump blood that will circulate though out the body. As many people are trying to reduce the cause of hypertension, one such study involves the use of the Dietary Approaches to Stop Hypertension (DASH) diet. The DASH diet is a comprehensive list of a dietary guideline developed by the National heart, Lung and Blood Institute to lower one's blood pressure. The DASH diet is rich in fruits, vegetables, whole grains, beans, fish, poultry, seeds, nuts and either fat-free or low-fat milk products. The diet is low in saturated fat, sodium, sweets, red meats and cholesterol. A couple of studies on the DASH diet concerning middle aged women nurses, effects of type 2 diabetes, effects of fatal and nonfatal diseases and effects of DASH diet on inflammation and different groups of people such as African Americans have proven that the DASH diet is a successful measure to lower hypertension. It is also important to note that just taking medications every day will not help patients to maintain their blood pressure at a constant level; however as the studies show exercising, eating a well balanced diet and maintaining a healthy diet without the use of alcohol and smoking can more drastically reduce the risk of hypertension (Fung et al, 2008).

Cardiovascular diseases are a group of disorders affecting the heart and blood vessels. According to the World Health Organization (WHO) cardiovascular diseases are the leading cause of death worldwide. In fact 17.3 million people which are about 30% of the global deaths in 2008 were a result of cardiovascular diseases. Of these people 7.3 million died from coronary heart disease and 6.2 million people died from a stroke. Coronary heart disease and stroke are two of the major subclasses of cardiovascular diseases. Heart failure is another major category of cardiovascular diseases and currently 5.8 million people in the United States and over 23 million people worldwide suffer from this disease. Approximately 80% of people suffering from cardiovascular diseases are seen in low income and middle income countries and they present an equal distribution among men and women. In addition, 80% of coronary heart diseases and cerebrovascular diseases are a result of behavioral risk factors. Major behavioral risk factors include unhealthy diet, physical inactivity, tobacco use, and harmful

alcohol consumption. The purpose of the DASH diet is to normalize blood pressure in patients with hypertension depicting the beneficial effects of its usage in a large body of data. The DASH diet is significantly different from normal diets because it contains a controlled lower amount of the usage of total fat, saturated fat and dietary cholesterol while providing larger proportions of potassium, calcium, magnesium, fiber and protein. Thus, other studies have proven that the DASH diet not only improves hypertension but other beneficial effects as well such as the reduction of insulin resistance and controlling fasting blood sugar levels and lipid levels. Overall the DASH diet is a good dietary measure for improving all types of cardiovascular diseases (Salehi-Abergouei et al, 2012).

Dr. Fung and her colleagues at the Harvard School of Public health in Boston, Massachusetts did a study on the Adherence of DASH-Style Diet and Risk of Coronary Heart Disease and Stroke in Women. In this prospective study which lasted 24 years from 1980-2004, the patients' diet was assessed 7 times. A DASH score was evaluated based on eight food and nutrient components. The food components included: fruits, vegetables, whole grains, nuts and legumes, low fat dairy, red and processed meats, sweetened beverages and sodium. The study composed of 88, 517 female nurses from 34 to 59 years of age. The women were also comparatively healthy and did not have a history of cardiovascular diseases or diabetes prior to 1980 to make sure all the subjects were of the same health status and that their prior conditions did not affect our results or change their diet. The purpose of the study was to measure the number of cases of nonfatal myocardial infarction (MI), coronary heart disease (CHD) and stroke. From this study 2, 129 women reported experiencing non-fatal myocardial infarction, 976 cases of coronary heart disease deaths and 3, 105 incidences of stroke. The risk difference was also similar for non-fatal myocardial infarction and fatal coronary heart disease. Furthermore, the results corresponded with a reduced risk of stroke and lower plasma levels (Fung et al 2008).

The DASH diet pattern also portrayed a greater improvement of blood pressure compared to a diet solely based on fruits and vegetables. Furthermore, the DASH-Sodium trial also showed that sodium intake restriction resulted in an even greater reduction of blood pressure. The DASH diet also reduced the levels of low density lipoprotein cholesterol levels. Hypertension and plasma lipid levels are two key factors for the diagnosis of cardiovascular disease. The DASH diet is significant in that it lowers the risk of coronary heart disease and stroke. The data from the observational studies is a measure of adherence to the DASH style diet. A prospective analysis was based on the adherence to a DASH style diet and incidence of coronary heart disease and stroke (Fung et al 2008).
In the course of the study, more than 95% of the patients completed their follow up for the duration

of the experiment of 24 years. In 1980 the participants completed a 61 item food frequency questionnaire (FFQ). The list was expanded to 116 items in 1984. Patients filled out the FFQ's in 1986, 19990, 1994, 1998 and 2002. The FFQs measured the average food intake for the previous year. A standard portion size and nine possible frequencies of consumption responses ranging from "never or less than once per month" to "6 or more times per day" was evaluated for each food item. The scores from each component were summed up to obtain an overall DASH score ranging from 8 to 40. The stroke study was based on computed tomography, magnetic imaging or autopsy. Deaths were analyzed based on state vital statistics records and the National Death Index reported by families of the postal system. To determine biomarker levels blood was collected from 1989-1990 but not all women chose to submit a blood sample. The lifestyle and dietary intakes of women who returned a blood sample were in general similar to those who did not provide a blood sample. The blood samples measured high sensitivity C reactive protein (CRP) levels, interleukin-6, fasting triglycerides, high density lipoprotein cholesterol and low density lipoprotein cholesterol. The body mass index (BMI) was also assessed based on the weight reported in the questionnaire and height reported in 1976. The questionnaire also assessed for smoking status, frequency of aspirin tablets used, multivitamin intake, menopausal status and use of postmenopausal hormones. The questionnaire further asked about average time spent on 10 common activities and was evaluated in hours of moderate to vigorous physical activity. Women with higher DASH scores used multivitamins, exercised more, consumed more fiber and omega 3 fatty acids but less saturated fat, trans fat and total energy. A clear result was seen in the inverse relationship between the DASH score and risk of both coronary heart disease and stroke. Women with more normal weight compared to overweight women and nonsmokers also had a higher DASH score. Furthermore, women assigned in the DASH diet had lower systolic and diastolic blood pressures compared to control which proves the efficacy of the experiment. Thus, the DASH diet exemplifies strong long term benefits as the primary prevention of cardiovascular diseases. The results also signify that intake of red and processed meats lower the DASH score and lead to stroke (Fung et al 2008).

Salehi-Abargouei and his research assistants at the Isfahan University of Medical Sciences at Isfahan, Iran conducted a meta-analysis on the DASH style diet on fatal and nonfatal cardiovascular diseases. They believe that a cohort study is the best method to understand cause and effect relationships between independent and dependent variables because exposure always takes place before the outcome in a long term period and a large population size. A cohort study analyzes risk factors in a group of people who do not have the disease but use correlations to determine the absolute risk

of contracting the disease in the population. A systematic review sets a question to be answered and analyzes different research articles to answer that question in its own paper. The study actually was conducted by analyzing other experiments on Pubmed, ISI web of science and EMBASE. Although over 2, 367 papers were retrieved in the data only six papers were analyzed. The subjects in all experiments did not have prior experience to hypertension which might affect their cardiovascular risk. Six cohort studies were used for systematic review and meta-analysis. Three papers were analyzed from the United States and three papers were analyzed from Europe. Of the papers from Europe, one was from Italy and two were from Sweden. All papers were in accordance with the DASH style diet. Two cohort studies included incidences of cardiovascular diseases, three papers included coronary heart diseases and stroke and lastly two papers were in relation to heart failure. All the studies were in relation to the Cox proportional hazard models therefore no conversions needed to be made for effect sizes (Salehi-Abergouei et al, 2012).

The meta-analysis based on the six cohort studies consisting of a total population of 260,011 adults exemplified that imitating a DASH style diet can decrease the risks of cardiovascular diseases shown by the following set of data. The relative risks (RR) was 0.80, the confidence interval (CI) was 95% between 0.74 – 0.86, and $P<0.001$. The results also showed that the usage of the DASH diet can reduce the chances of getting a coronary heart disease as shown by the following set of data. The meta-analysis included 144, 337 adults. The relative risk was 0.79, the confidence interval was 95% between 0.71 – 0.88 and $P< 0.001$. The logarithm of the relative risks further proved the negative trend between a DASH diet score and the risk for getting a coronary heart disease. The meta-analysis that measured the risk of getting a stroke and following a DASH style diet included 150, 191 adults. This further proved the affectivity of the DASH style diet. The relative risk was 0.81, the confidence interval was 95% from 0.72 – 0.92 and $P< 0.001$. A linear regression using the logarithm of the relative risks also showed that the usage of using the DASH diet and chances of getting a stroke had a negative relationship. Next, the correlation between the DASH diet and probability of getting a heart failure were analyzed. This meta-analysis included 74, 966 Swedish adults. The results also showed that using the DASH style diet can decrease the chances of getting a heart failure. The relative risk was 0.71, the confidence interval was 95% from 0.58-0.88 and $P< 0.001$. This also showed the negative trend for the risk of getting a heart failure and using the DASH style diet. As the DASH score increased the chances of getting a heart failure decreased portraying an indirect relationship (Salehi-Abergouei et al, 2012).

Salehi-Abergouei's results proved that imitating the DASH like diet significantly reduced the risks for cardiovascular diseases, coronary heart diseases, strokes and heart failure. Cardiovascular diseases were reduced by 20%, coronary heart diseases were reduced by 21%, strokes were reduced by 19%, and lastly heart failures were reduced by 29%. In addition the study proved that following the DASH style diet reduced blood pressure as well. Fruits and vegetables associated with the DASH diet are plant based foods that are associated with lowering blood pressure. The increased proportions of fiber, potassium, magnesium and calcium associated in the DASH diet have made this an effective approach to lower hypertension. Studies have also shown that red meat and refined grain intake increase blood pressure but these types of food are limited in the DASH style diet. In addition to reducing blood pressure, the DASH diet also reduced levels of fasting glucose, total cholesterol, low-density lipo-protein cholesterol (LDL), and inflammation as a result of atherosclerosis. Lastly, the study concluded that developing countries are experiencing a nutritional transition whereas Western countries like the United States that are more developed have less scarcity for having access to fruits and vegetables making it easier for Americans to eat a healthier meal compared to population of Asia and Africa (Salehi-Abergouei et al, 2012).

Dr. Asemi and his fellow doctors at Kashan University of Medical Sciences in Kashan, Iran conducted a study on the effect of the DASH style diet on insulin resistance, inflammation and oxidative stress on pregnant women with gestational diabetes. Gestational diabetes mellitus (GDM) is a condition in which pregnant women without previously diagnosed diabetes exhibit increased high levels of blood glucose during the third trimester. Gestational diabetes mellitus affects 3% to 6% of all pregnant women. The main cause of GDM is increased insulin resistance, increased production of placental hormones like cortisol, progesterone, human chorionic somatomamotropin (HCS) and increased fat deposits resulting in insulin resistance. Furthermore, increased levels of lipid peroxidation and oxidative stress lead to the development of GDM. Development of GDM puts the fetus at risk of macrosomia, prematurity, birth trauma, fetal death, and respiratory distress syndrome. Women are also at risk of developing Type 2 diabetes later on in life. The DASH style diet has previously been studied to lower hypertension however new studies are now being studied on the effects of the DASH diet on cardiovascular risk factors, metabolic syndrome and metabolic profile for diabetic patients. The DASH diet along with exercise and weight loss in hypertensive overweight patients has proven to improve insulin sensitivity and lipid profiles. Because there has been no past study on this subject, the results of this experiment are the first to be published (Asemi et al, 2006).

This randomized study in Kashan, Iran from April 2011 to December 2011 consisted of 32 pregnant

women 16 women for control and 16 women in the variable group with the DASH diet. All women were pregnant between the ages of 18 to 40 years old and about 24 to 28 weeks pregnant at the start of the experiment. All women had no previous history of GDM, nonsmoker, or those who needed insulin therapies were included in the study. The control group was not given the DASH style diet but was provided with acceptable dietary intake for GDM because it would be unethical to reduce their consumption of fruits and vegetables since they were also pregnant. The composition of the control group was 40% to 50% carbohydrates, 10% to 20% proteins and 25% to 30% total fats. The DASH style diet was rich is fruits, vegetables, whole grains, low fat dairy products, low in saturated fats, cholesterol, refined grains and sweets as well as a restriction on sodium intake to less than 2,000 mg/day. Both groups diets were planned on a 7 day menu cycle and thus the participants were choosing from their foods from a prescribed list. After four weeks of the experiment, fasting blood samples, fasting plasma glucose (FPG), serum insulin, insulin resistance, serum hs-CRP, plasma total antioxidant capacity (TAC), and plasma growth stimulating hormone (GSH) were measured or assessed (Asemi et al, 2006).

According to the results the DASH diet compared to the control showed decreased levels of FPG, serum insulin level and HOMA-IR score to detect insulin resistance. It also showed increased concentrations of plasma TAC, and GSH. However, there was not enough data to compare serum hs-CRP levels between the two diets. A significant decrease was also noted in the plasma TAC and GSH levels of the control group compared to the DASH style diet. Increased plasma antioxidant capacity and decreased oxidative stress was also reported in obese individuals with hypertension after consumption of the DASH style diet for four weeks. Many mechanisms can explain the effects of the DASH diet. For example the sugar content was half the amount compared to the control group. The fiber content was 1.5 to 2 times higher than the control. The DASH diet also contains high amounts of arginine rich foods including fish, soy, beans, lentils, whole grains, nuts, parsley and fresh basil. The high arginine content explains the effects of insulin resistance. Improvements in insulin resistance can also be attributed to production of nitric oxide, and improved endothelial function. The effect of the DASH diet on oxidative stress can also be attributed to its high content of anti-oxidant rich fruits and vegetables. The variable group also consumed twice the amount of vitamin C. Vitamin C is a major component of TAC that can decrease the nicotinamide adenine dinucleotide phosphate-oxidase activity, a major superoxide generating enzyme. Arginine composition also explains the beneficial effects of oxidative stress. Arginine has proven to reduce serum levels of angiotensin II and measures of oxidative stress (Asemi et al, 2006).

The Dietary Approaches to Stop Hypertension (DASH) style diet has proven to lower blood pressure and cardiovascular diseases in numerous trials. According to the National Heart Lung and Blood Institute (NHLBI) founder of the DASH diet, the DASH diet was not biased on any group of people and has proven to effectively lower sodium intake in people of all ages, genders, races, obese and non-obese, high or low income families, larger or smaller waist circumferences or higher or lower physical activities (NHLBI, 2001). The DASH style diet has proven to lower hypertension in a group of female nurses over a course study of 24 years (Fung et al, 2008). It has also proven to work effectively in a meta-analysis cohort study comparing 6 different research trials (Salehi-Abergouei et al, 2012). Lastly, the DASH diet was successful in reducing the chances of getting pregnant women from getting gestational diabetes mellitus in Kashan, Iran (Asemi et al, 2006).

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Serving as President of New York City Pharmacists Society

By Dr. Mohammed Taher, PharmD, RPh

It is an absolute honor to serve as the President of New York City Pharmacists Society. Primarily, I want to thank the Board of Directors of New York City Pharmacists Society for selecting me to serve as the president. The intention of the board was clear: they wanted to hand over the baton to the next generation of pharmacists. I believe the dynamics of our current board is at its best at the moment since we have a mixture of many veterans who have served in many capacities at both city and state level, as well as few new generations of pharmacists who bring tons of energy and fresh ideas. Together as a team, we aim to unite the pharmacists of New York City for mutual benefit, encouragement and maintain the standard of pharmacy practice at elevated levels.

I have served as the President of Bangladeshi- American Pharmacists Society from 2016- 2017. Around the same time, I was also invited to join the Board of Directors at the NYCPS. In addition, I currently also serve as the Queens regional rep for PSSNY's board of directors, Vice Chairman of RxPac of New York, and Alumni Board member at my alma mater, Arnold & Marie Schwartz College of Pharmacy and Health Sciences. I believe that to treat pharmacy as a profession we all must be actively involved with various organizations. My passion and desire to make our profession better is the reason I chose to get involved with different organizations and a college of pharmacy to mentor future generations.

One of the pleasures we take in owning independent pharmacies is giving back to the community. Our relationships go beyond just dispensing medications. However, it's not a secret that our businesses have been suffering for the past decade. It has been dominated by PBM abuse. We have been seeing under water reimbursements which has led to many pharmacies going out of business or led them to reduce their pharmacy hours. This has impacted me as well. One of the hardest things I had to do in my young career was notifying my employees and patients that there will be reduced hours because of a lack of financial feasibility. Giving less accessibility to my patients is not something I took lightly. Less wages for my employees, who are working to support their families has been a huge hurdle I have dealt with.

The PBM regulation bill was passed and signed into law in late December of 2021 by Governor Hochul. There is no doubt that it is a victory for independent pharmacies. Allow me to take you down

the memory lane. It was November 14, 2018 when pharmacy owners across the state reached their breaking point. We just could not tolerate any more the oppressive predatory PBM practices. We got tired of being pushed around and as typical New Yorkers we collectively decided to fight back. As such, FixRx was born. We had a clear plan and vision and stuck with our strategy. We consulted with a lobby firm and a public relation firm to figure out the dirty tactics of PBM and to expose them in mainstream media. We began educating every member of the NYS legislature in every part of the state and it began to be clear to them that PBMs were not just stealing money from pharmacies, but also tax dollars of hard-working New Yorkers. We also published our stories in major newspapers and media outlets. Thus, it put more pressure on the law makers to do further investigation. Although we got denied repeatedly, our perseverance finally prevailed. In very late December 2021 Governor Kathy Hochul finally signed PBM regulations into law; some say it is the most stringent PBM law in the country.

Therefore, it's so important for pharmacists to become PSSNY members. New York State lawmakers recognize PSSNY and value our opinion. I have been a PSSNY member since I was a student. It was important for me to stay up to date with all pharmacy related changes and current events. PSSNY works for the advancement of your businesses as well as provides the most up to date information; what most other organizations don't do. Therefore, I urge all pharmacy owners and pharmacists to become members of PSSNY. Your membership not only helps you stay connected but also helps PSSNY thrive.

In conclusion I want to give my heartfelt thanks to all the BAPA members for your support. There is no doubt my journey to become a leader in pharmacy industry started with BAPA back in 2010 when I became secretary. The past leaders or BAPA have been instrumental, and their guidance has made me a better leader today. I reached my position today because you gave me encouragement and kept pushing me forward. For this reason, I will forever be grateful to this organization. I wish everyone a wonderful convention and I looking forward to connecting all PSSNY affiliates together and find a common goal to advance, protect and advance our profession.

Taher with NYCPS outgoing chair to his left and new chair of the board to his right.

Glimpses from Convention 2021

Glimpses from Dinner 2022











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Best Wishes from
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  - Buy/Sell Agreement Funding
  - Executive Bonus Plans
- **Group Employee Benefit Planning**
  - Group Life Insurance
  - Group Disability Insurance
  - Group Vision and Dental
- **Supplemental Voluntary Benefits**

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- **SEP, SIMPLE, 401(k) Plans**
- **Profit-Sharing Plans**
- **Defined Benefit Plans**
- **Pension Payout Alternatives**
- **Lifetime Income Planning**
  - Fixed Annuities
  - Immediate Annuities
  - Variable Annuities

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- **Charitable Giving Strategies**
- **Family Legacy Planning**
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THANK YOU!

On behalf of the BAPA Executive Committee and Executive Board, we would like to thank all of our attendees for joining us in New Haven and making our convention a success. We look forward to see you at all upcoming BAPA Events.

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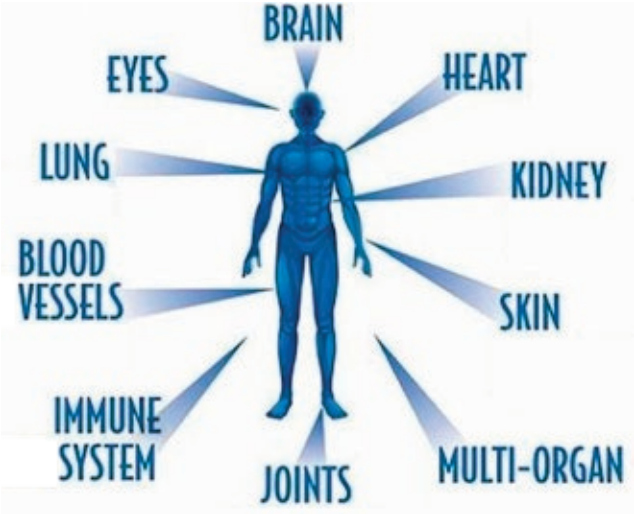

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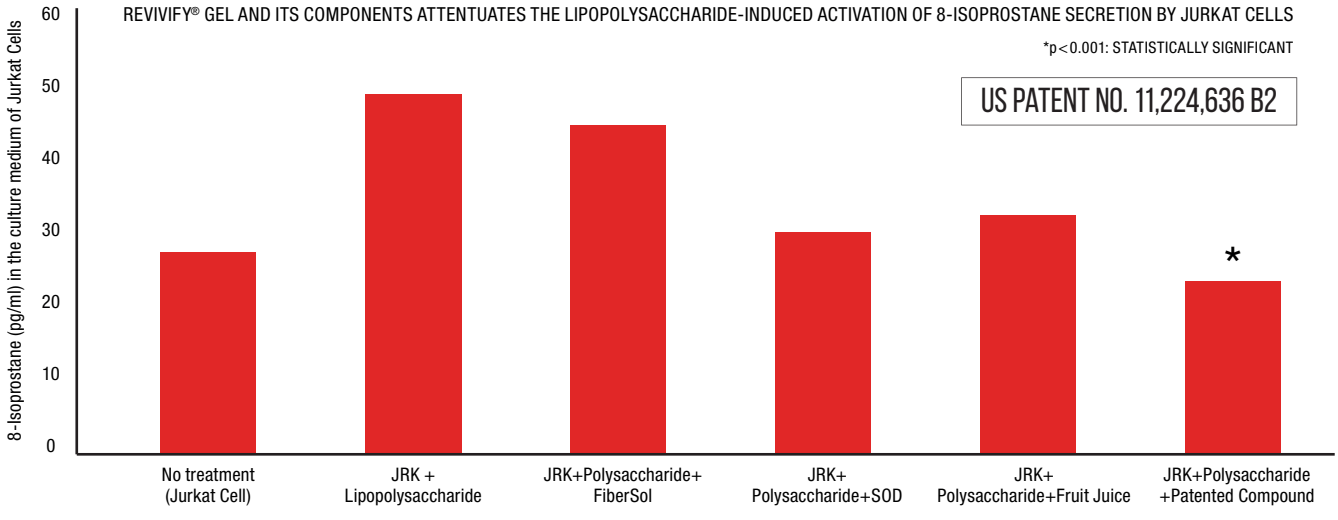

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