AABPS 2019 MARYLAND

5th Convention

July 5-6, 2019 (Friday & Saturday)
Bethesda North Marriott Hotel and Conference Center

Bethesda, Maryland

Innovations in Patient Care, Drug Research and Development

www.aabps.org

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BETHESDA, MARYLAND

AABPS

PROGRAM THEME

Innovations in Patient Care, Drug Research and Development

2019

The United States Capitol building at Washington, DC

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PRESIDENT
PEOPLE'S REPUBLIC OF BANGLADESH
BANGABHABAN, DHAKA

21 Ashar 1426
05 July 2019

Message

I am indeed delighted to learn that the American Association of Bangladeshi Pharmaceutical Scientists (AABPS) is going to hold the 5th AABPS Convention at the Bethesda North Marriott Hotel and Conference Center, Bethesda, Maryland, USA. On the eve of the convention, I take this opportunity to extend my sincere thanks and appreciations to the members of the American Association of Bangladeshi pharmaceutical Scientists living in North America.

Pharmaceutical Scientists have the ample opportunity to produce quality medicine and provide pertinent knowledge and expertise to the pharmaceutical sector both at home and abroad. I am pleased to know that our Pharmaceutical Scientists are making valuable contributions to the local and global pharmaceutical market showing their best talents and knowledge. Today pharmaceutical industry is one of the leading sectors of the country and our Government is fostering this important sector. It is heartening to note that Bangladesh is now exporting world-class pharmaceuticals in various countries around the globe meeting the demand of local market.

I am happy to know that AABPS, a non-profit organization, has been making significant contributions in the field of pharmaceutical sciences and related areas in North America. I hope AABPS will impart its expertise in pharmaceutical developments, manufacturing and pharmacy education, and thereby eventually help Bangladesh in capturing the global market. I believe that the organization will continue its efforts in advancing the professional networking and improving the collaboration with Bangladesh and throughout the world.

I wish the 5th AABPS Convention a grand success.

Khoda Hafez, May Bangladesh Live Forever.

Md. Abdul Hamid

AABPS President and Executive Committee

MESSAGE

On behalf of American Association of Pharmaceutical Scientists (AABPS), it is my honor to welcome our members, speakers, guests, sponsors, volunteers and family members to the 5th AAPBPS Convention in Bethesda, Maryland. I thank you for making the extra effort and taking precious time out of your July 4th holiday weekend to attend the Convention.

The AABPS was first formed by a group of pharmaceutical scientists of Bangladeshi descent in 1997 in recognition of the need for an organization to nurture, grow and share the diverse experience and knowledge existing within our scientific community, and to provide stimulation and guidance to the future generation of scientists. This year we commemorate the 22nd year of establishment of AABPS.

Over this period, we have successfully proven that our knowledge, experience and capability can significantly contribute to pharmaceutical development here in North America as well as in Bangladesh. Accordingly, we have a unique opportunity to leverage and offer our expertise to catalyze growth and innovation in pharmacy education and the pharmaceutical industry sector in Bangladesh. This year we have been particularly fortunate to have received strong support and sponsorship from the Bangladeshi pharmaceutical sector. We welcome representatives from the Bangladeshi pharmaceutical sector at this year's Convention.

Moving into the 21st century there has been transformative growth in the pharmaceutical and biomedical sciences driven by technology innovations, fundamental understanding of disease pathways and treatment modalities. Fittingly, the theme of this year's Convention is "*Innovation in Patient Care, Drug Research and Development*". At this convention, we are proud to offer you a rich lineup of scientific experts and industry leaders as speakers. We are also offering an inaugural Continuing Education forum. In addition, we have organized roundtable discussions and parallel sessions, notably a session on collaboration opportunities in Bangladesh and a special session for student presentations. Developing the next generation of pharmaceutical scientists is the strategic imperative of the current Executive Committee.

We would like to offer our gratitude to all sponsors, donors, and volunteers serving the convention committees this year. Our special thanks to Dr. Muhammad Jamil Habib, this year's convener. The convener is a prestigious but challenging responsibility which Dr. Habib fulfilled marvelously. We also thank Dr. Zahur Islam for his valuable advice and support. Please let us know if you have any questions or suggestions about AABPS or the Convention. Finally, all work and no play make for a boring day. Lest be said there is good food and entertainment at the end. Be safe, enjoy yourself, and don't leave early!

Imran Ahmed, Ph.D.
President, AABPS

Convention Committee

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- Ashequr Rahman
- Qamrul Majumder
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- Abu Bakar Siddique **Chair**
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- Mamoon Rashid

Convention Committee Chair

MESSAGE

It is with great pleasure, I welcome you to the 5th Convention of AABPS in Bethesda, Maryland. I am honored to serve as your convener to this year's convention. We have been working very diligently over the past year to bring to you a world-class program. Please accept my warm greetings and best wishes.

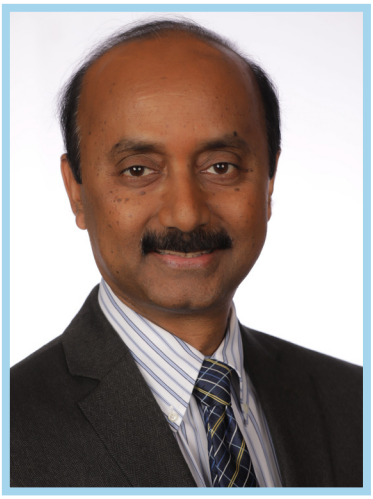
The theme of this convention is "Innovations in Patient Care, Drug Research and Development". I am very happy to see that our members are making excellent contributions in the pharmaceutical community in USA and abroad. The theme reflects these contributions of our scientists and professionals.

We have developed a great program for you. I am sure you do not want to miss any of these activities. On Friday night, we have a wonderful dinner session by Dr. Abu Serajuddin, Professor at St. John's University College of Pharmacy. You will get an in-depth knowledge and understanding of the development of advanced drug delivery system. During the opening general session on Saturday, you will learn about the future of pharmacy education and how to lead in

this fast-changing profession delivered by Dr. Toyin Tofade, Dean of the College of Pharmacy, Howard University. Be sure to join your colleagues at our key-note speaker session by Dr. Badrul Chowdhury, Senior Vice President and Chief Physician-Scientist, AstraZeneca Pharmaceuticals, who will bring the latest technology on the delivery of new antibody engineered drug delivery on asthma. You do not want to miss other invited speeches where you will learn 3D printing and biosimilar drugs for personalized medicine. After the lunch break, we will bring a continuing education (CE) program on recent development in diabetes therapeutics. You will be able to learn and contribute during the forum discussion on the collaboration and job opportunities in Bangladesh Pharma sector. Be sure to attend this forum. You will have the opportunity to hear from Dr. Omar Faruk Khan on his path to leadership position in academia. Finally, there will be a fascinating speech by Dr. Shakil Ahmed during our Saturday night dinner, telling his story on rising to the top of the corporate world. Please join me in listening, learning, experiencing and networking during the whole period of AABPS convention 2019.

This convention could not have been successful without the support of all volunteers who worked in various committees. Special thanks to Mohammad Absar (Abir) and Daniel Kuddus for their dedicated work on the cultural program, to Mamoon Rashid for an outstanding job for the high-quality magazine and the banner, to Mohammad Hossain and Atiqur Rahman who helped me with the venue. I cannot give enough thanks to Shahid Alam, Imran Ahmed and Zahur Islam who worked tirelessly with me on every front. Their vision has made this function possible.

AABPS has come a long way to foster excellence in education and research in our community. It will continue to grow as we stay focused to our objectives and continue to strive for the best.



I hope you will have a very engaging and productive meeting at the convention. Be sure to spend some time to explore the city, its fine dining and various tourists' attractions.

I wish you a pleasant stay in Maryland and great success in our convention.

Sincerely

Muhammad Jamil Habib, Ph.D.
Convener, AABPS Convention 2019
Vice President, Executive Committee, AABPS

AABPS Executive Committee

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AABPS 2019 MARYLAND

The 5th AABPS Convention

Convention **Schedule**

Friday, July 5, 2019

TIME	TITLE	RESPONSIBLE	ROOM
6:00 PM – 7:00 PM	Set-up and Registration	Ashequr Rahman, PhD *Reviewer, FDA, Silver Spring, MD*	Foyer
6:00 PM – 6:30 PM	Meeting of the Convention Committee	Muhammad Jamil Habib, PhD *Convener and Vice President, AABPS*	Brookside A/B
6:30 PM – 9:30 PM	Session 1: Dinner Program	MODERATOR Arshad Jamil, MS *Senior Research Scientist, Heritage Pharmaceuticals, Eatontown, NJ*	Brookside A/B
6:30 PM – 7:15 PM	***Development of advanced drug delivery systems to meet patient needs and provide better therapy***	Abu Serajuddin, PhD *Professor, College of Pharmacy, St. John's University, Queens, NY*	Brookside A/B
7:15 PM – 7:30 PM	Brief Question & Answer		
7:30 PM – 9:30 PM	**Group Dinner Buffet** Commonwealth Indian Restaurant, 11610 Old Georgetown Road, Rockville, MD 20852		

Saturday, July 6, 2019

TIME	TITLE	RESPONSIBLE	ROOM
7:30 AM – 6:00 PM	Registration	Rehana N. Kuddus, M.Pharm, Maniza Habib, Mahnaz Habib, Nahid Kamal, PhD	Foyer
7:30 AM – 8:30 AM	**Breakfast and Networking**		Salon A/B, and Patio
Morning Sessions			
8:30 AM – 8:45 AM	Session 1: Welcome	Speakers	Salon A/B
8:30 AM – 8:38 AM	Welcome Address	Imran Ahmed, PhD *President, AABPS*	Salon A/B
8:38 AM – 8:45 AM	Opening Remarks	Muhammad Jamil Habib, PhD *Convener and Vice President, AABPS*	Salon A/B
8:45 AM – 9:35 AM	Session 2: Opening General Session	MODERATOR Muhammad Jamil Habib, PhD *Associate Dean, College of Pharmacy, Howard University, Washington DC*	Salon A/B
8:45 AM – 9:30 AM	***The future of pharmacy education: A call to lead***	Toyin Tofade, MS, PharmD, BCPS, CPCC, FFIP *Dean, College of Pharmacy, Howard University, Washington DC*	Salon A/B
9:30 AM – 9:35 AM	Brief Question & Answer		
9:40 AM – 10:25 AM	Session 3: Keynote Speech	MODERATOR Atik Rahman, PhD *Division Director, FDA, Silver Spring, MD*	Salon A/B
9:40 AM – 10:20 AM	***Antibody engineered for enhanced NK-cell mediated eosinophil depletion: Development of benralizumab for asthma***	Badrul Chowdhury, MD, PhD *Senior Vice President, AstraZeneca, Maryland*	Salon A/B
10:20 AM – 10:25 AM	Brief Question & Answer		
10:25 AM – 10:35 AM	**Break**		Salon A/B and Patio

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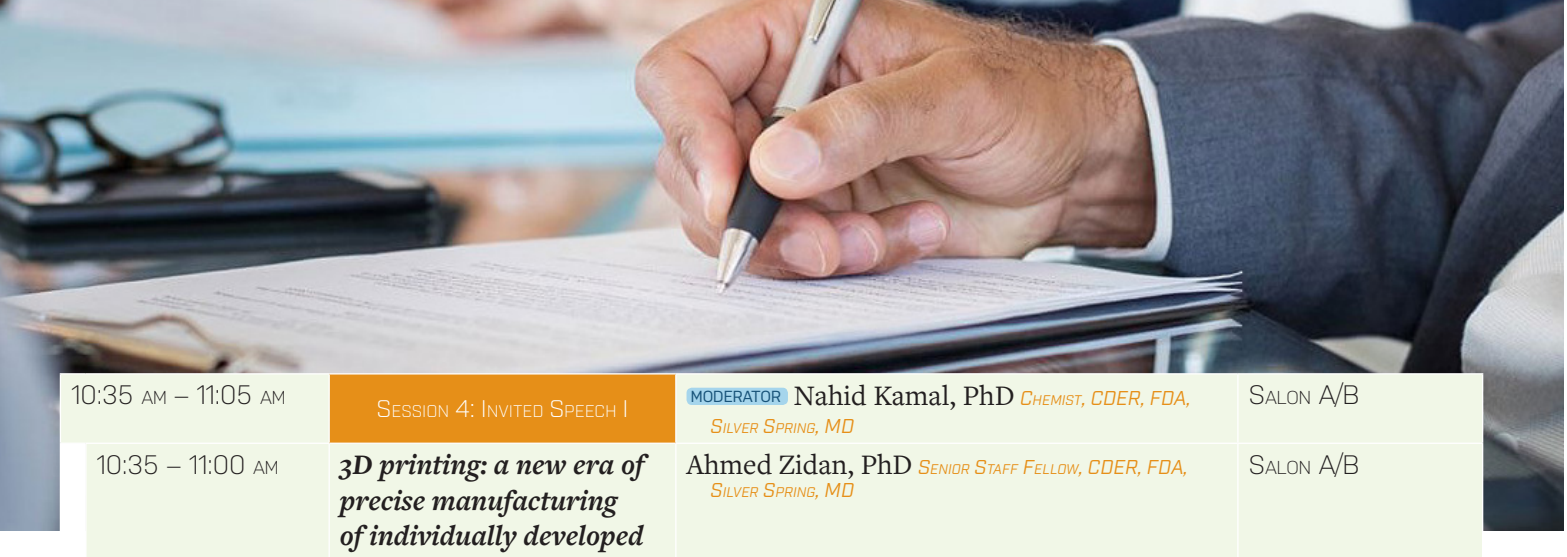


10:35 AM – 11:05 AM	Session 4: Invited Speech I	MODERATOR Nahid Kamal, PhD *Chemist, CDER, FDA, Silver Spring, MD*	Salon A/B
10:35 – 11:00 AM	***3D printing: a new era of precise manufacturing of individually developed pharmaceuticals***	Ahmed Zidan, PhD *Senior Staff Fellow, CDER, FDA, Silver Spring, MD*	Salon A/B
11:00 AM – 11:05 AM	Brief Question & Answer		
11:10 AM – 11:30 AM	Session 5: Invited Speech II	MODERATOR Mohammad Absar, PhD *Clinical Pharmacologist, FDA, Silver Spring, MD*	Salon A/B
11:10 AM – 11:25 PM	***Therapeutic biologics: Manufacturing to precision health***	Zahidul Mondle, PhD, MBA *Lead Tech Product Specialist, GE Healthcare, MD*	Salon A/B
11:25 AM – 11:30 AM	Brief Question & Answer		
11:30 AM – 12:25 PM	**Group Lunch Buffet**		Salon A/B and Patio
Afternoon Sessions			
12:25 PM – 1:25 PM	Session 6: CE Program	MODERATOR Imran Ahmed, PhD *Senior Director, Alcamy Corp, Wilmington, NC*	Salon A/B
12:25 PM – 1:20 PM	***Recent development in diabetes therapeutics***	Oluwaranti Akiyode, PharmD *Professor and Assistant Dean, College of Pharmacy, Howard University, Washington DC*	
1:20 PM – 1:25 PM	Brief Question & Answer		
1:30 PM – 2:15 PM	Session 7: Forum Discussion	MODERATOR Shamim Ahmed, PhD, MBA *COO and CSO, Square Pharmaceutical Co, Dhaka, Bangladesh*	Salon A/B
1:30 PM – 2:15 PM	***Collaboration and opportunities in Bangladesh pharma sector***	Chowdhury Mahmood Hasan, PhD *Director, Ibn Sina Pharmaceutical Co., Professor, Dhaka University, Bangladesh* Salah U Ahmed, PhD *President and CEO, Abon Pharmaceuticals LLC, Northvale, NJ*	Salon A/B
2:15 PM – 2:30 PM	**Afternoon Refreshment Break**		Salon A/B and Patio
2:30 PM – 3:00 PM	Session 8: Invited Speech III	MODERATOR Qamrul Majumder, PhD *Quality Reviewer, FDA Silver Spring MD*	Salon A/B
2:30 PM – 2:55 PM	***The Future of Pharmacy Practice in Bangladesh – "Moving Our Pharmacy Services into the 21st Century"***	Mollick Mahmood MPharm. *Managing, Director, Superior Healthcare Limited*	Salon A/B
2:55 PM – 3:00 PM	Brief Question & Answer		
3:05 PM – 4:30 PM	Parallel Session 9-1: Students Session	MODERATOR Rafia S. Rasu, MPharm, MBA, PhD *Professor, System College of Pharmacy, School of Public Health, University of North Texas Health Science Center, Fort Worth, TX*	Salon A/B
3:05 PM – 3:30 PM	***My journey from Curzon Hall to Charleston – the educational and leadership essential***	Md Omar Faruk Khan, MBA, PhD *Interim Dean, University of Charleston School of Pharmacy, Charleston, WV*	Salon A/B
3:30 PM – 3:35 PM	Brief Question & Answer		Salon A/B
3:35 PM – 4:30 PM	**Research Presentation by Students**		Salon A/B

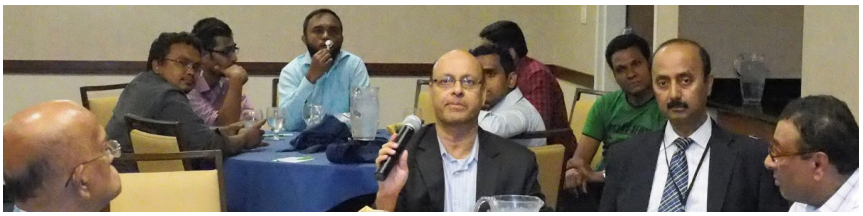
Continued to the next page

MODERATOR Abu Bakar Siddique, PhD *Postdoctoral Fellow at University of Louisiana at Monroe*

Time	Presenter	Institute	Title
3:35 PM – 3:43 PM	**Yousuf Ali**	Texas Tech University Health Sciences Center, Amarillo, TX	*Cytokine-stimulated iNOS Expression Requires Long Chain Fatty Acyl CoA Synthetase (ACSL)*
3:45 PM – 3:53 PM	**Kaniz Fatema**	Idaho State University, Pocatello, ID	*Deletion of the ARID1A in Osteosarcoma Enhances Aggressive Cell Phenotypes*
3:55 PM – 4:03 PM	**Farjana Afrin**	Idaho State University, Pocatello, ID	*An approach to design, synthesis & evaluation of Phthalimide based Sphingosine Kinase Inhibitors.*
4:05 PM – 4:13 PM	**Afsana Tajmim**	University of Louisiana at Monroe, Monroe, LA	*Masking the Pungent Taste of Oleocanthal: An Approach of the Development and Evaluation of Effervescent Formulation against HER2 Positive Breast Cancer Recurrence.*
4:15 PM – 4:23 PM	**Raquib Hasan**	North Dakota State University, Fargo, ND	*Antibiotic Releasing Bone-void Filler (ABVF) Putty for Osteomyelitis Treatment.*

3:05 PM – 4:00 PM	Parallel Session 9-2: Financial Planning Session	MODERATOR Abu Bakar Siddique, PhD *Postdoctoral Fellow at University of Louisiana at Monroe*	Forest Glen
3:05 PM – 3:55 PM	***Financial and retirement planning***	Mizanur Rahman, MBA, MS *Financial Advisor, Blue Ocean Wealth Solutions, East Hills, NY*	Forest Glen
3:55 PM – 4:00 PM	Brief Question & Answer		Forest Glen
4:30 PM – 5:10 PM	Parallel Session 10-1: AABPS General Session	MODERATOR Mohammad Hossain, PhD *Clinical Investigation Leader, GlaxoSmithKline, Philadelphia, PA*	Salon A/B
4:30 PM – 5:00 PM	Future Plans for AABPS	Imran Ahmed, PhD *President, AABPS* Zahur Islam, PhD *Executive Director and Head of Biometrics, US CDMA, Novartis Pharmaceuticals, East Hanover, NJ*	Salon A/B
5:00 PM – 5:10 PM	Financial Report	Jahidur Rashid, PhD *Senior Scientist, Halozyme Therapeutics, Sorrento Valley, San Diego, CA*	Salon A/B
4:00 PM – 4:50 PM	Parallel Session 10-2: Women's Roundtable Session	MODERATOR Rebecca Islam, MBA	Forest Glen
4:00 PM – 4:50 PM	***What can we do for others***	ORGANIZERS Rebecca Islam, MBA *Denville, NJ*, and Maliha Ahmed *Wilmington, NC*	Forest Glen
5:10 PM – 5:30 PM	Session 11: AABPS General Session		Salon A/B
5:10 PM – 5:25 PM	Awards and Recognition	Shahid Alam, MS, MBA *General Secretary, AABPS*	
	Closing Remarks	Imran Ahmed, PhD *President, AABPS*	
5:30 PM – 6:30 PM	**Break**		
Evening Sessions			
6:30 PM – 7:30 PM	**Group Dinner Buffet**		Salon A/B
7:00 PM – 7:30 PM	Session 12: Dinner Speech	MODERATOR Zahur Islam, PhD	Salon A/B
7:00 PM – 7:30 PM	***Rising to the top of the corporate world***	Shakil Ahmed, PhD *Founder and CEO, Princeton Alpha, Princeton, NJ*	Salon A/B
7:30 PM	Entertainment/Cultural Program	PROGRAM DIRECTOR Mohammad Absar, PhD EMCEE Mohammad Absar, PhD and Nahid Kamal, PhD	Salon A/B
10:30 PM	Closing		Salon A/B

AABPS Album



Development of advanced drug delivery systems to meet patient needs and provide better therapy

Abu Serajuddin, PhD

Professor, College of Pharmacy, St. John's University, Queens, NY

In any drug discovery program in a pharmaceutical company or a research institute, what are first produced are only new chemical entities (NCE) or pharmacological agents. They become drugs or medicines only after they are formulated as pharmaceutical products and tested in animals and humans for safety and therapeutic efficacy. For example, majority of NCEs do not dissolve adequately in water present in stomach and intestine after they are taken orally, which results in different and variable amounts of drugs being absorbed and reaching blood stream in different patients. Different drugs may also stay in the body for different periods of time that may not meet patient needs. In addition, the needs of patients may vary depending on types and conditions of diseases. Certain patients need drugs delivered to the body for immediate action, while others may require not only immediate action, but also continued effect. In some other diseases, target exposure or steady state drug level in the body over an extended period of time must be maintained for intended therapeutic outcome. Formulation of NCE into optimal pharmaceutical products for generating the desired therapeutic effect could be extremely challenging. Some of the advanced drug delivery systems developed and new technologies needed to address varied patient needs and for better therapy will be discussed in this presentation.

Speaker's Biography

Friday, July 5
6.30 PM — 7.15 PM
Brookside A/B

Abu Serajuddin, Ph.D., is a Professor of Industrial Pharmacy in the College of Pharmacy and Health Sciences at St. John's University, Queens, New York, USA. He joined academia in 2008 after working for three decades in the pharmaceutical industry. In his latest positions in the industry, Dr. Serajuddin served as the Director/Executive Director of Drug Product Development (1999-2003) and Executive Director of Science, Technology and Outsourcing (2003-2008) for Novartis Pharmaceuticals Corp. He authored over 120 research papers and book chapters and made 140 invited presentations in scientific conferences. He is also a co-inventor in 13 patents. He is a Fellow of American Association of Pharmaceutical Scientists (AAPS) and American Pharmacists Association (APhA). AAPS also honored him with 3 of its highest awards: Research Achievement Award in Formulation Design and Development in 2010, Research Achievement Award in Manufacturing Sciences and Engineering in 2014, and AAPS Lipid-Based Drug Delivery Outstanding Research Award in 2015. At St. John's University, Dr. Serajuddin helped establish the Industrial Pharmacy Innovation Laboratory, where the primary focuses of his research are (1) the development of novel drug delivery systems, especially for poorly water-soluble drugs, and (2) the innovation in processing technologies for solid dosage forms. St. John's University honored him with the University Medal for Outstanding Faculty Achievement in 2019 and the College of Pharmacy and Health Sciences Outstanding Alumni Award in 2018.

The Future of Pharmacy Education: A call to Lead

Toyin Tofade, MS, PharmD, BCPS, CPCC, FFIP

Dean, College of Pharmacy, Howard University, Washington DC

Pharmacy is a growing profession that is facing some current challenges in the job front and it will be critical for all current professionals to participate in the education process of students so that the profession can remain sustainable. We must be willing to provide approach the current challenges strategically by collaborating, engaging communicating and holding all new and budding practitioners to a standard of excellence. At the end of this presentation, participants will be able to:

1. Explain pharmacy education today as expected by ACPE
2. Discuss the Influencers of pharmacy education tomorrow
3. Identify challenges and opportunities
4. Explain a leadership approach to keep the profession going

Speaker's Biography

Saturday, July 6
8.45 am — 9.35 am
Salon A/B

In 2017, she completed the management development program at the Harvard Graduate School of Education.

In 2013-2016, she served as assistant dean of the Experiential Learning Program at the University of Maryland School of Pharmacy in Baltimore.

From 2002 to 2011, she worked at the Wake Area Health Education Center (AHEC), North Carolina. She also served as a clinical associate professor at the University of North Carolina (UNC) Eshelman School of Pharmacy. She worked at UNC hospitals for several years as a pharmacist. She received a master's and PharmD degree both from UNC Chapel Hill and completed a general practice residency at UNC hospitals and another residency focused on clinical pharmacokinetics.

Professor Tofade is active in ASHP, AMHSP, AACP and an FIP Fellow. She has published several papers and given presentations on a variety of topics nationally and internationally. Her current areas of focus include Continuing Professional Development, academic capacity, individual, organizational leadership and relationship systems.

Antibody engineered for enhanced NK-cell mediated eosinophil depletion: Development of benralizumab for asthma

Badrul Chowdhury, MD, PhD

Senior Vice President, AstraZeneca, Maryland

Asthma effects approximately 300 million people worldwide. Globally asthma incidence is increasing with increased industrialization and urbanization. For a long time, treatment of asthma has been non-specific, centered around small molecule beta-agonist drugs and corticosteroids. More recently, monoclonal antibody products have been developed as targeted treatment of specific asthma phenotype. Eosinophils are one such target. Multiple monoclonal antibodies have been developed for treatment of asthma of eisonophilic phenotype. One such monoclonal antibody is benralizumab. Benralizumab is engineered to remove fucose sugar reside in the CH2 region of the oligosaccharide core of the IgG1 antibody resulting in enhanced affinity for the FC-gamma-RIIIA (CD16) receptor on NK cells. The effect is antibody-dependent cell-mediated cytotoxicity (ADCC) of eosinophils by NK cells resulting in rapid and complete depletion of eosinophils. Benralizumab has been shown to be effective in the treatment of asthma of eosinophilic phenotype.

Speaker's Biography

Saturday, July 6
9.40 am — 10.20 am
Salon A/B

Dr. Badrul Chowdhury is a medical doctor trained in Internal Medicine from Wayne State University in Detroit Michigan, and in Allergy and Immunology from NIAID, NIH. He also has a PhD in Immunology from Memorial University in St Johns, Canada. Dr. Chowdhury is an internationally recognized leader in scientific and regulatory aspects of small molecule drug and large molecule biologic product development in the fields of respiratory medicine, allergy and immunology, and rheumatology. Dr. Chowdhury joined AstraZeneca in April 2018 to lead a cross-functional team responsible for the strategy and development of medicines for respiratory, inflammation and autoimmune diseases. He was previously the Director of the Division of Pulmonary, Allergy, and Rheumatology Products, at the US FDA. Prior to his FDA tenure that spanned about 20 years, he was a faculty at the University of Tennessee College of Medicine. Dr. Chowdhury has published extensively, and severed in many committees at the FDA, NIH, and United Nations Environment Program.

3D printing: a new era of precise manufacturing of individually developed pharmaceuticals

Ahmed Zidan, PhD

Senior Staff Fellow (Pharmacologist) — Division of Product Quality Research, Office of Testing and Research, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research, Food and Drug Administration, MD

The growing demand for customized medicines increases the impact of 3D printing as one of the emerging technologies for precise manufacturing of individually developed dosage forms. In all 3D printing technologies, large number of materials, geometrical and process factors affect the quality of these computationally designed dosage forms and safety of their use. In addition, for printing an identical dosage form, the quality may vary when built using different 3D printers, even when the same model of the printer, printing parameters, process steps, and raw materials are used. Therefore, knowledge of how the variability of each input parameter and processing step affects the final finished product is critical to ensuring its quality. There is no specific guidance concerning the design, manufacturing process and quality testing considerations for 3D printed solid dosage forms. This presentation will then highlight some of specific methodologies and control strategies considerations over the material, geometrical and process parameters for 3D printing of solid dosage forms. A case study of employing 3D pneumatic assisted microextrusion based 3D printing to manufacture modified release tablets and polypills will be presented. considerations for process validation will be also discussed so that quality for all printlets is maintained when built in a single cycle, between cycles, and by different printers. The issue of identifying and linking the critical factors to the critical quality attributes of the printlets will be also highlighted with an emphasis on the regulatory considerations involved.

DISCLAIMER: This presentation reflects the views of the presenter and should not be construed to represent FDA's views or policies.

Speaker's Biography

Saturday, July 6
10.35 AM — 11.00 AM
Salon A/B

Dr. Ahmed Zidan is currently a senior pharmacologist staff at the Office of Testing and Research of CDER at FDA. Dr Zidan is also Adjunct Professor of Pharmaceutics and industrial Pharmacy at Zagazig University. Prior joining FDA, Dr Zidan served as Associate Professor of Pharmaceutics at King Abdulaziz University, Saudi Arabia. Dr Zidan received his B.S. and M.S. degree in Pharmaceutics from Zagazig University, Egypt, and his Ph.D. in Pharmaceutical Sciences from the Howard University. Dr. Zidan has made significant contributions in implementing quality by design (QbD) in the formulation and process design of oral and transdermal drug products, for which he was recognized for various FDA awards. He has made significant contribution in identifying the CQAs of drug products manufactured by emergent technologies such as 3D printing and continuous manufacturing. Dr. Zidan is a member of various working groups at FDA such as Nanotechnology, Transdermal and Additive Manufacturing. He has published over 70 peer-reviewed articles and book chapters in these fields.

Therapeutic biologics: Manufacturing to precision health

Zahidul Mondle, PhD, MB (ASCP), MBA

Product Specialist, BioPharma, GE Healthcare

Biologics are a diverse category of therapeutic products and are generally large, complex molecules that are produced through biotechnology in a living system and are often more difficult to characterize than small molecule drugs. By 2018, biologics had surged, bringing in $234 billion market value, which comprises more than 50% of the total drug sales in 2018. This marketing surge attracted Pharma companies to develop biosimilar products, which are highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. The modern biologics are manufactured inside bioreactors-that house genetically engineered microbes and mammalian cells cultures. Sterile manufacturing environment and subsequent purification of biologics are critical steps, but regulators need quality control assurance in every step of manufacturing process. Therefore, new business is emerging around the process of demonstrating analytical similarity including, but not limited to, purifications, potency tests, and purity tests of biological products. The reason of high demand of therapeutic biologics despite the high cost is because of their inherent functional specificity, which opened the hope of precision or personalized medicine. I will discuss the biologic/biosimilar market trend, their manufacturing process, their quality control process, and their precision mode of functions.

Speaker's Biography

Saturday, July 6
11.10 AM — 11.25 AM
Salon A/B

Completed Master of Science in Biochemistry from University of Dhaka 1992 (88-89 batch). Completed PhD degree in Biochemistry/ Immunology from Ehime University 1998. Earned Clinical Molecular Biologist Board Certification from ASCP 2011. Earned MBA from University of Maryland University College 2014. Worked at Michigan State University as a Postdoc, Neogen Corporation as a scientist, and Pfizer as a Lead Scientist. Currently working at GE Healthcare as a Lead Product Specialist. Provide scientific expertise to Pharma, Biotech, Industrial, and Academia in USA, Canada, and Latin America.

Recent Development in Diabetes Therapeutics

OluwaRanti Akiyode, Pharm.D., BCPS, CDE

Professor of Pharmacy Practice, Director of Professionalism & Professional development, and Assistant Dean of Student Affairs at Howard University College of Pharmacy, Washington DC

This Continuing Education (CE) program is designed for pharmacists and Pharmaceutical Scientists. The presentation will include optimal medication management of clients/ patients with Diabetes and understanding of newer agents and their role requiring pharmacists and other healthcare providers to receive updates in healthcare delivery. It will equip the practicing pharmacist and pharmaceutical scientists with current knowledge and understanding of topics integral to the care and safety of persons with Diabetes. After completing the program, participants should be able to:

- Examine general concepts relevant to Diabetes
- Discuss newer diabetes agents and their role in patient management
- Describe the recent updates to the standards of care for the management of diabetes
- Select appropriate type 2 diabetes agents based on current diabetes guidelines

Speaker's Biography

Saturday, July 6
12.25 PM — 1.20 PM
Salon A/B

Dr. Akiyode is a clinical pharmacist with broad-based experience in clinical diabetes and medication therapy management. She is board certified in pharmacotherapy and certified diabetes educator at Howard University Hospital Diabetes Treatment Center, where she collaborates with endocrinologists in the delivery of medication therapy management services to diabetes patients. At this practice site she provides services to the underserved population in the community; emphasizes prevention care, integrates behavioral and spiritual health with physical health. Dr. Akiyode is a full professor of pharmacy and serves as the Director of Professionalism and Professional Development. She received her doctorate degree in clinical pharmacy from University of Mississippi School of Pharmacy in 2000. She completed a community pharmacy residency program at Leesburg Pharmacy.

Dr. Akiyode's leadership services include the provision of preventative education, education for other health care professionals, and collaborative work on professional associations' position statement/practice synopsis with the goal to enhance patient health outcomes. She was recognized as the Mary Lou Maras Diabetes Educator of the Year in 2011 by the Washington, DC Coordinating Body of American Association of Diabetes Educators. She has extensive knowledge and training in diabetes management and provides education trainings to interprofessional groups of healthcare providers from diverse practice settings at both local and national meetings.

The Future of Pharmacy Practice in Bangladesh – "Moving Our Pharmacy Services into the 21st Century"

Mollick Mahmood Hossain, M.Pharm.

Managing Director, Superior Healthcare Limited

Pharmacy education and the professional pharmacist's journey to competency began in Bangladesh in 1964 and in 1967 respectively with initiation of Pharmacy Education at Dhaka University. That said, the ensuring decades have only built a launching pad into the future. Bangladesh, as a country, has achieved tremendous growth and improvement in economic and social parameters in the last decade. The Healthcare infrastructure has also been growing very fast, with substantial critical consideration of the expected and actually provided standard of care and quality in patient care and related services. There is a convergence occurring. These converging dynamics have brought the role of community pharmacy and clinical pharmacy to the forefront of scrutiny and consideration. There is now definitive recognition that delivering quality health care includes delivering the Right Medicine, at the Right Time, in the Right Way, for the Right Reason, by the Right Persons, to the Right Persons, with the Right Information and Education, at the Right Price, with the Right Follow-up. Proper development of community and hospital Pharmacy infrastructures is an essential component of the process for ensuring quality healthcare services to patient. This presentation will summarize the present pharmacy infrastructure and provide a paradigm for the future evolution of both community and hospital pharmacy services in Bangladesh. This paradigm will emphasize the importance of the pharmacist's role in dispensing medicines, counselling patients and their support system members, and in actually providing patient care. These are three integrated accountabilities and responsibilities not yet conceptualized, designed and implemented in the country. However, they are essential to meeting the needs and expectations of the increasingly more sophisticated and demanding healthcare consumers of Bangladesh. To be clear, Bangladesh has the youngest population of any country in South Asia and it has the fastest growing base of Information Technology-oriented Millennials in South Asia. They are learning what quality healthcare is and what they expected their healthcare industry professionals to provide. This presentation will discuss who can make that happen and how the Key Players and Stakeholders can make that happen.

Speaker's Biography

Saturday, July 6
2.30 PM — 2.55 PM
Salon A/B

Business Management Program – Ryerson University, Toronto, Canada in 2016

Master of Pharm - University of Dhaka in 1988

Bachelor of Pharm - University of Dhaka in 1987

- Over 27 years of national and international marketing, sales & business development experience in Pharma Industry of Bangladesh specially in Beximco & Incepta.
- Co-founder and Ex-Managing Director of Novelta Bestway Pharmaceuticals Ltd. (2009-2016)
- Co-founder and Managing Director of Superior Healthcare Ltd. A venture of community chain pharmacy in Bangladesh. Actively working to develop community pharmacy infrastructure since 2017. It is right time to introduce pharmacy practice in both community and hospital pharmacy settings. Govt. of Bangladesh has taken a policy decision to appoint 2000 pharmacists in hospitals.
- Govt. Position: Ex-Member of the Board of 'Bangladesh Council of Scientific & Industrial Research
- Govt. Position: Ex-Member, IPFF project Evaluation Committee, Bangladesh Bank (Central Bank)
- Member of Bangladesh Pharmaceutical Society (BPS) and Pharmacy Graduates Association (PGA)
- A Life-Long Member of Pharmaceutical Executive Club Ltd.
- Actively involved in different cooperation programs to equip young graduates with proper employment in many areas of Bangladesh specially home district Faridpur for last 15 years.

My Journey from Curzon Hall to Charleston – The Educational and Leadership Essentials

Md Omar Faruk Khan, MBA, PhD

Interim Dean, University of Charleston School of Pharmacy, Charleston, WV

The leadership skills develop as we mature through education and relevant training and experiences. Experience of working at different roles are invaluable in in this regard. I will summarize my journey starting with my pharmacy education at the University of Dhaka, then postdoctoral research as well as MBA education. It will provide an account of my personal education, training and experience as faculty and administrative member along with leadership trainings and reading habits that can transform an ordinary person to do exciting thigs, develop educational and leadership principles and become ready to lead an institute as an interim Dean of the University of Charleston School of Pharmacy.

Speaker's Biography

Saturday, July 6
3.05 PM — 3.30 PM
Salon A/B

Dr. M. O. Faruk Khan is an Interim Dean of University of Charleston School of Pharmacy. Before serving in his role as Interim Dean, Dr. Faruk Khan started his service to the school in August 2018 as the Associate Dean for Academic Affairs. He has published more than 50 scholarly research articles and served as the primary investigator on several grants. He hopes to advance pharmacy education through the publication of the first volume of a new four-volume book series – Medicinal Chemistry for Pharmacy Students. His research specializes in medicinal chemistry and rational drug design; pharmaceutical analyses; organic and peptide synthesis; and enzymology. More recently, his interest has expanded to the area of assessment and educational scholarships.

Khan received his Bachelor's and Master's degrees in Pharmacy from University of Dhaka, in Bangladesh. He completed his Ph.D. in Medicinal Chemistry at the University of Manchester in the United Kingdom and went on to obtain a Master's in Business Administration from Southwestern Oklahoma State University. Khan completed post-doctoral research at Hiroshima University in Japan, then University of Mississippi, and finally at Florida A&M University. Before securing his role at the University of Charleston, Khan served as a Professor and Chair of Department of Pharmaceutical Science and Research at Marshall University School of Pharmacy. Khan also served as Assistant and Associate Professor and Chair of Department of Pharmaceutical Sciences at Southwestern Oklahoma State University (SWOSU) College of Pharmacy before coming to Marshall University. At SWOSU he assumed the inaugural Homer F. Timmons Endowed Professorship and founding Coordinator of SWOSU Center of Research in Pharmaceutical Sciences. Khan is an Academic Research fellow of American Association of College of Pharmacy (AACP). He served in several leadership roles in AACP as well as American Association of Pharmaceutical Scientists. He created several M.S. and Ph.D. level exchange programs with international universities and also partnered with Pharmaceutical Industries in providing analytical services for their drug products. He has also successfully completed the Foreign Pharmacy Graduates Equivalent Examination conducted by the National Association of Board of Pharmacy (NABP), in Chicago, Illinois.

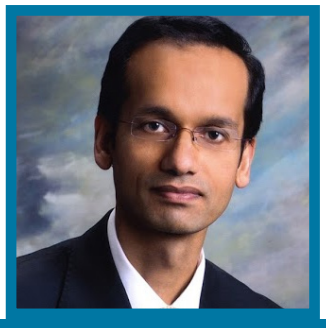
Rising to the top of the corporate world

Shakil Ahmed, PhD

Founder and CEO, Princeton Alpha, Princeton, NJ

There are a large number of successful Bangladeshi professionals in North America, across a broad number of occupations. If you look at the top tiers of firms, however, Bangladeshis tend to be underrepresented. There are a number of reasons for this, but many of them are tied to foundations laid during our upbringing. Reaching the top of the corporate world is not a function of academic credentials or delivering results. To reach the upper echelons and board rooms of corporations, we have to step outside our comfort zones and go against many of the things that have been hammered into our brains since childhood. In this talk, we will explore the main drivers of what it will take to see more Bangladeshis in the boardrooms of the most successful North American companies.

Speaker's Biography



Saturday, July 6
7.00 PM — 7.30 PM
Salon A/B

Dr. Shakil Ahmed is one of the leading pioneers in the field of quantitative finance. He is a private investor who sits on multiple boards and is the chairman of the financial services firm, Active Allocator. He was the founder of Princeton Alpha, a quantitative hedge fund based in Princeton. He had multiple simultaneous senior management roles at Citibank, including Global Head of Market Making, Global Head of Electronic Trading, Global Head of Quantitative Strategies, served on the Executive Committee of the Equities Division, and on the management committee of Citi Alternative Investments.

Shakil started his career at Morgan Stanley, where he spent fourteen years in Process Driven Trading, the main proprietary trading business of the firm. At Morgan Stanley, Shakil quickly rose through the ranks, ultimately becoming Managing Director and reporting directly to the president within six years of starting. Shakil retired from day to day responsibilities in December 2006 and was retained as a Senior Adviser, until joining Citibank in early 2008.

Shakil has a Ph.D., an M.S. and an M.Phil. in Computer Science from Yale University. His undergraduate degree was in Computer Science with high honors and high distinction from the University of California, Berkeley.

Host Targeted Antiviral (HTA): Functional Inhibitor Compounds of Scaffold Protein RACK1 Inhibit Herpes Simplex Virus Proliferation

Hemayet Ullah[1*], Wangheng Hou [2], Sivanesan Dakshanamurthy[3*] and Qiyi Tang [2*]

[1]Department of Biology, Howard University, 415 College St., NW, Washington, DC 20059;
[2]Department of Microbiology, Howard University College of Medicine, Seeley Mudd Building, Room 315, 520 W Street, NW, Washington, DC 20059;
[3]Department of Oncology, and Clinical & Experimental Therapeutics Program, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center, Washington DC 20057.

Abstract

Due to the small number of molecular targets in viruses and the rapid evolution of viral genes, it is very challenging to develop specific antiviral drugs. Viruses require host factors to translate their transcripts, and targeting the host factor(s) offers a unique opportunity to develop broad antiviral drugs. It is well documented that some viruses utilize a host protein, Receptor for Activated C Kinase 1 (RACK1), to translate their mRNAs using a viral mRNA secondary structure known as the Internal Ribosomal Entry Site (IRES). RACK1 is essential for the translation of many viruses including hepatitis C (HCV), polio, Drosophila C (DCV), Dengue, Cricket Paralysis (CrpV), and vaccinia viruses. In addition, HIV-1 and Herpes Simplex virus (HSV-1) are known to use IRES as well. Therefore, host RACK1 protein is an attractive target for developing broad antiviral drugs. Depletion of the host's RACK1 will potentially inhibit virus replication. This background study has led us to the development of novel antiviral therapeutics, such as RACK1 inhibitors. By utilizing the crystal structure of the RACK1A protein from the model plant *Arabidopsis* and using a structure-based drug design method, dozens of small compounds were identified that could potentially bind to the experimentally determined functional site of the RACK1A protein. The SPR assays showed that the small compounds bound strongly to recombinant RACK1A protein. Here we provide evidence that the drugs show high efficacy in inhibition of HSV-1 proliferation in a HEp-2 cell line. The drug showed similar efficacy as the available anti-herpes drug acyclovir and showed supralinear effect when applied in a combinatorial manner. As an increasing number of viruses are reported to use host RACK1 proteins, and more than 100 diverse animals and plant disease-causing viruses are known to use IRES-based translation, these drugs can be established as host-targeted broad antiviral drugs.

Introduction

With the small number of molecular targets in viruses and the rapid evolution of viral genes, it is very challenging to develop specific antiviral drugs. Unlike other infectious agents, viruses offer few intrinsic targets for inhibition by antiviral molecules [1]. With their simple structural form and their ability to hijack molecular machinery from host cells to complete their replication cycle, viruses evade most efforts to contain them [2]. However, as viruses require host factors to translate their transcripts, targeting the host factor(s) offers a unique opportunity to develop novel antiviral drugs. In this regard, identification of the ribosome localized host protein Receptor for Activated C Kinase 1 (RACK1) for viral Internal Ribosomal Entry Site (IRES)-mediated translation of non-capped mRNAs has been established as a target for developing antiviral drugs (3, 4). The IRES website documents more than 68 viruses with references for IRES evidence, including in the Human immunodeficiency virus type 1 (HIV-1), Human immunodeficiency virus type 2 (HIV-2); Herpes Simplex Virus-1 (HSV-1), Epstein-

Barr virus (EBV), Encephalomyocarditis virus (EMCV), Foot-and-mouth disease virus (FMDV), IBV Infectious bronchitis virus (IBV), Bovine viral diarrhea virus (BVDV), Classical swine fever virus (CSFV), as well as some plant viruses [16]. As RACK1 is a required protein that aids IRES-based cap-independent mRNA translation from several viruses, functional inhibition of RACK1, without any detrimental effect to the host cells [3], holds promise for the development of an HTA against a broad range of viruses. Here we report the discovery of functional inhibitor compounds for RACK1 and the effectiveness of these compounds against Herpes Simplex Virus-1 (HSV-1) proliferation. This strategy of targeting a host factor, instead of the virus directly, potentially circumvents the damaging effect of resistance developed by viruses after the prolonged use of promising antiviral drugs. As RACK1 is implicated in the many human pathogenic virus proliferation (7-15) and in the metastasis of diverse cancer cells (50-52), Availability of RACK1 inhibitor compounds can potentially be use as a targeted therapeutic compound for many pathogenic conditions.

Results and discussion

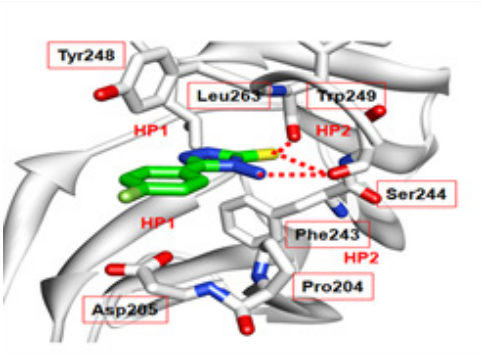


Figure 1: Docked compound at Y248 site of RACK1

Post-translational modifications such as tyrosine phosphorylation and protein sumoylation have been implicated in the regulation of RACK1 function in various organisms [26, 27]. Mutagenesis work has identified Tyr246 as a potential phosphorylation site and has suggested a correlation between enhanced tyrosine phosphorylation of RACK1 and binding of RACK1 to Src tyrosine kinase [26]. Our deduced RACK1A crystal structure showed that the side chain of Tyr248 (Y248) in the RACK1A protein is located at the end of the loop connecting β-strands A and B of blade 6, and is fully exposed to the solvent making it easily accessible for modification [26]. Recently, it was shown by us that mutagenesis of Y248F abolished the homo-dimerization potential of RACK1A proteins [29]. Moreover, while wild-type RACK1A scaffold protein, when used as bait, could interact with almost 100 different proteins, RACK1A-Y248F bait failed to interact with any protein [29], implicating the residue in the functional regulation of RACK1 protein. The requirement for the Y248 residue phosphorylation for both homo-dimerization and interaction with diverse proteins has led us to target the site for isolating small compounds that could bind the Y248 pocket and thus prevent its phosphorylation. SD-29 is identified as a potent binder to the RACK1A Y248 phosphorylation pocket. By the implementation of a structure-based drug design approach, we identified the best-fitting candidate RACK1A Y248 pocket binding small compound- SD-29 the 4-amino-5-phenyl-1,2,4-triazole-3-thiol class of compounds and its analogs are used to provide precise regulation of reported RACK1 mediated specific viral proliferation. Figure 1 shows the docked model of RACK1A with the most potent small compound (SD-29) at the Y248 phosphorylation pocket. Using RACK1A-Y248 phosphorylated targeted antibody, it was shown that the compounds can inhibit stress induced RACK1 Y248 phosphorylation (Fig. 2B original paper)

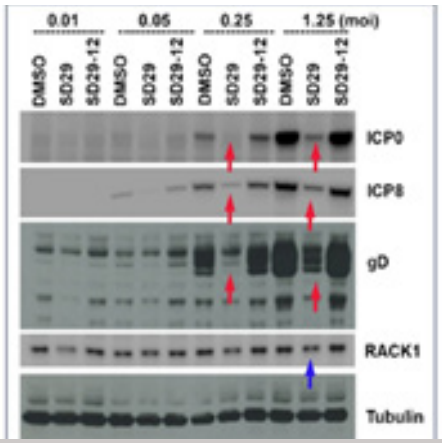


Figure 2: HSV-1 proteins are inhibited by the compound (red arrows)

SD-29 HAS REPRESSIVE EFFECTS ON HSV-1 PROTEIN PRODUCTION

HSV-1 protein levels from SD-29-treated HEp-2 cells were found to be lower than that of DMSO- or SD-29-12- treated HEp-2 cells (Fig.2). We examined three HSV-1 proteins: ICP0 is an immediate early (IE) protein, ICP8 is an early (E) protein, and gD is a late (L) protein. Therefore, our results demonstrated that SD-29 repressed HSV-1 protein production, which can effectively inhibit virus proliferation in the cell line.

AN ANALOG-SD-29-14 SHOWS BETTER EFFICACY

Through similar docking experiments, an analog with chloro at the meta positions of the phenyl ring (SD29-14) instead of the mono-substituted (fluoro) at the para-position of the phenyl ring (SD-29) was isolated. SD29-14 analog showed strong inhibition of HSV-1 proliferation in a dose dependent manner (Figure 3). While SD-29 showed much less efficacy at the 1μM concentration, SD29-14 significantly inhibited the HSV-1 proliferation as evident by the lower luciferase signals (Fig. 3). Availability of the compounds with better efficacy will allow application of the compounds at lower concentration which will circumvent any toxicity that higher concentration of compounds may pose. In addition, the better efficacy will allow the compounds to be tested against other IRES utilizing human pathogenic viruses as well.

COMPARISON OF SD29-14 EFFICACY WITH KNOWN ANTI-HERPES DRUG ACYCLOVIR

Acyclovir is the major anti-herpes drug on the market and evaluated the SD29-14 efficacy with that of acyclovir. As can be seen from Figure 8, application of SD29-14 could effectively inhibit the HSV1-Luc proliferation starting from 1 μM concentration (Fig. 8A). As very low concentration of acyclovir could not show the significant inhibition of HSV1-Luc (data not shown), we used the concentration of 10 μM at which point the drug showed inhibition of the HSV1-Luc proliferation. Our developed drug appears to show efficacy at slightly higher level than that of acyclovir induced effect. Acyclovir is known to be an inhibitor of viral DNA replication while SD29-14 is not known to regulate the viral DNA replication; therefore, we expected that there will be no interaction between the inhibitory pathways of these two drugs. In the absence of interaction, it is expected that the combinatorial treatment may potentially show synergistic effect in inhibition. Therefore, we treated the virus infected cells with different combination of the drugs. As can be seen from the Fig.4, a supralinear effect is apparent at all different concentrations of SD29-14 combined with 10 μM of acyclovir. When the luciferase signal is quantified, it shows a dose-dependent inhibition of HSV1-Luc proliferation in all concentrations of the drugs used either in combination or SD29-14 alone (Fig 8B- original paper). We believe this combinatorial application will allow a better approach to combat the HSV1 which is increasingly becoming resistant to the drugs available on the market.

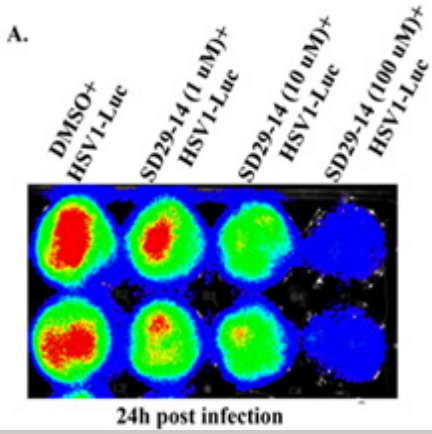


Figure 3: Drug analog shows better efficacy

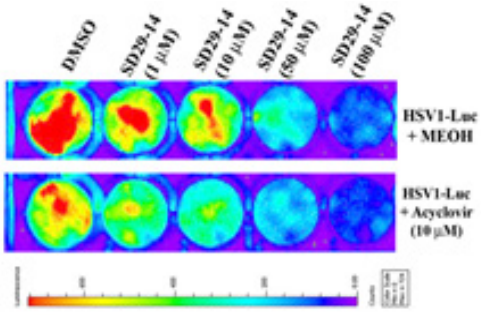


Figure 4: SD29-14 inhibits HSV-1 better compared to existing anti-herpes drug

Conclusions

Viral diseases have historically threatened humanity as well as all other living organisms. The ease with which people travel across continents, urbanization, demographic trends etc. all have accelerated both the emergence and dissemination of viruses around the world. In the area of anti-viral drugs, only few drugs targeting a handful of pathogenic viruses are known to date and more targeted development of antivirals, in the face of emerging viral diseases, are urgently needed. Because viruses have small genome and they mostly use host factors to replicate, it is difficult to find a target to design safe and effective antiviral drugs. Moreover, rapid multiplication of viruses poses a significant barrier to develop durable anti-viral as viruses change over time under selection pressure to become resistance to drugs. Targeting host factors essential for virus replication is an attractive target, however, it is very difficult to find a host factor whose inactivation would not harm the host organism's cells. In this regard, host factor RACK1 protein which is reported to aid translation of IRES based viral mRNAs, has been established as an attractive target to develop antiviral drugs.

Previously it was shown that cultured cells and whole organism like fruit-fly survived without much adverse effects from RACK1 depletion- indicating that RACK1 is not needed for general translation [3]. Here we have developed host factor RACK1 inhibitor compounds targeting an experimentally validated functional site of the protein and the compounds show promising anti-viral effect in cultured cells. As the host factors are not subject to rapid sequence changes, it is expected that these compounds will be established as durable anti-viral drugs and the drugs are expected not to have detrimental side effects. However, testing in animal models and preclinical trials will be essential to establish the efficacy and to find any potential side effects of these compounds. As the target for drug development is established in this research, it will serve as a guide in the future to develop additional analogs to offer an extended range of drugs for diverse RACK1 mediated disease and developmental pathways. In addition, RACK1 protein is reported to mediate diverse signaling pathways both in plants and in human like drought, salt stress in crops [26, 27] and cancer metastasis in human [57]. The availability of the inhibitor compounds will provide an alternative opportunity to target those pathways as well.

Condensed version of the manuscript published in the Journal Oncotarget (Cover page):

Oncotarget. 2019; 10:3209-3226. https://doi.org/10.18632/oncotarget.26907

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For complete references: Please see the original paper

Formulation Development for Inhaled Therapy of Multidrug- Resistant Tuberculosis

Chintan J Bhanushali[1], Ahmed S Zidan[2], Ziyaur Rahman[3], Muhammad J Habib[4*]

[1]Medical Affairs & Safety Management at Diagno Search Lifesciences, Thane, India [2]Faculty of Pharmacy, Zagazig University, Zagazig, Egypt. [3]Irma Lerma Rangel College of Pharmacy, Texas A&M Health Science Center, Kingsville, Texas [4]College of Pharmacy, Howard University, Washington DC

Correspondence

Introduction

Tuberculosis (TB) remains, in the 21st century, the infectious disease causing the most morbidity and death (1). Multiple bacteria, Mycobacterium tuberculosis (M.TB), along with M. bovis, M. africanum and M. microti, are known to cause TB (2). Pulmonary TB, its most common form, is a highly contagious and life-threatening infection (2). Current clinical treatment includes front-line drugs, such as rifampicin (RFP), isoniazid (INH), pyrazinamide (PZA), ethambutol, streptomycin and p-amino salicylic acid (PAS). Resistance to one or more front-line drugs may be a result of incomplete adherence to chemotherapy, prescription errors, case management and use in the HIV pandemic (3). M. TB strains can be resistant to either isoniazid, rifampicin, or both isoniazid and rifampicin. Strains that are resistant to both are known as multi-drug resistant (MDR) strains, and are causative agents of MDR tuberculosis. MDR-TB requires treatment with second-line drugs that have limited efficacy, for a prolonged period, and are more toxic (4). Also, the second-line drugs used for treatment of MDR- TB are 4-10 times more likely than standard therapy for drug-susceptible TB to fail. Patients that fail treatment have a high risk of death. This project aims at the preparation of porous poly (lactic-co-glycolic acid) [PLGA] microparticles encapsulating a combination of second-line medications for MDR-TB, namely ethionamide (ETA) and pyrazinamide (PZA).

Result and Discussion

PREPARATION AND CHARACTERIZATION OF DRUG-LOADED POROUS MICROPARTICLES

M.TB harbor mainly in lung macrophages, so the microparticle formulation should offer the advantage of deep lung delivery and maximum phagocytosis. In the preliminary screening of the PLGA 50:50 polymer of different inherent viscosities, PLGA 50:50 (0.55-0.75 dl/g, carboxylate end group) was selected. The encapsulation efficiency for the ETA was relatively high for PLGA 50:50 with inherent viscosity of 0.55-0.75 dl/g, as compared to other PLGA 50:50 polymer types

FLOW PROPERTIES

The flow properties of the microparticles can have significant impact on the nebulization efficiency of the formulation. Poor flow properties can lead to formation of aggregates, resulting in low nebulization efficiency and increase in the aerodynamic diameter of the formulation. The tapped density of the porous microparticles was 0.29 ± 0.03 g/ml, indicating that particles were lighter and fluffier. Carr's index was 13.7 ± 0.14 % and Hausner's ratio was less than 1.25, which represents good flow property. The angle of repose of the porous microparticles measured by fixed funnel method was 36.88 ± 2.560 indicating good flow property.

SEM RESULTS

The SEM analysis of the microparticles revealed that the microparticles prepared by the above method were spherical and porous in nature (Fig.1). Optimum porosity was observed with 2% NH_4HCO_3. A further increase in the concentration of the effervescent agent NH_4HCO_3 resulted in cracks on the surface of microparticles and loss of shape.

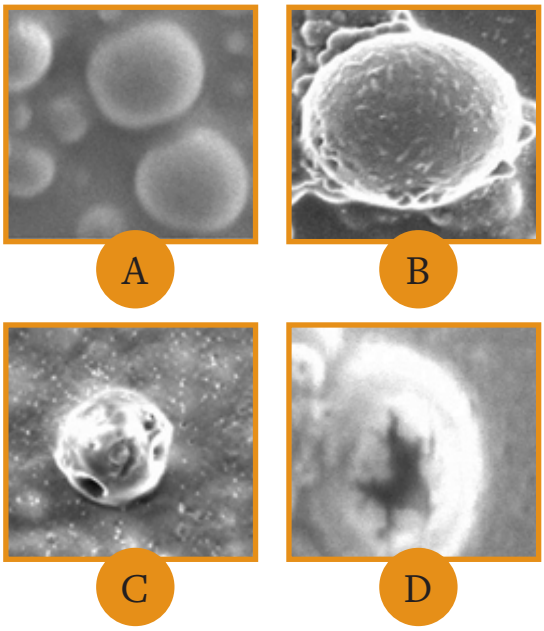

Fig.1. SEM of drug-loaded microparticles prepared with different concentrations of NH_4HCO_3. A) 0.5 % NH_4HCO_3 B) 1 % NH_4HCO_3 C) 2 % NH_4HCO_3 D) 3 % NH_4HCO_3

AERODYNAMIC PROPERTIES OF DRUG-LOADED MICROPARTICLES

The porous particles were prepared in our lab, so as to target lung macrophages harboring M.TB bacilli. The aerodynamic diameter favorable for lung delivery is in the range of 1-5 µm (2). Table I represents the amount of microparticles collected on each stage after nebulization. The FPF of the particles, defined as the percentage of microparticles collected on Stage 3 or below, was 42 ± 3.5 %. The MMAD, defined as the particle size at which the line crosses the 50th percentile (Fig.2), was 2.35 ± 0.33 µm, within the range for deep lung delivery.

Table I. Amount of microparticles collected on each stage of the impactor after nebulization

Stage	Before (g)	After (g)	Difference (g)	Net (mg)	% Size range	Cumulative % less than size range	ECD
F	26.2928	26.2947	0.0019	1.9	6.35	0	0
7	26.2860	26.2887	0.0027	2.7	9.03	6.35	0.4
6	26.2625	26.2688	0.0063	6.3	21.07	15.38	0.7
5	26.2295	26.2342	0.0046	4.6	15.38	36.45	1.1
4	26.2096	26.2127	0.0031	3.1	10.37	51.84	2.1
3	26.1619	26.1633	0.0014	1.4	4.68	62.21	3.3
2	25.0447	25.0494	0.0047	4.7	15.72	66.89	4.7
1	24.2324	24.2339	0.0015	1.5	5.02	82.61	5.8
0	24.3217	24.3254	0.0037	3.7	12.37	87.63	9.0

IN VITRO RELEASE STUDY

The in vitro drug release from a polymeric controlled delivery system is by three main mechanisms: 1) Fickian Diffusion 2) Anomalous transport 3) Case II transport. A generalized expression for the release mechanism from the polymeric controlled drug delivery system can be written as:

$$\frac{Mt}{Mt_{\infty}} = kt^{n}$$

where k is a constant, incorporating characteristics of the macromolecular network or particle system that makes up the formulation, Mt and M∞ are the absolute cumulative amount of drug released at time t and infinite time, n is the diffusional exponent which is indicative of the transport mechanism.

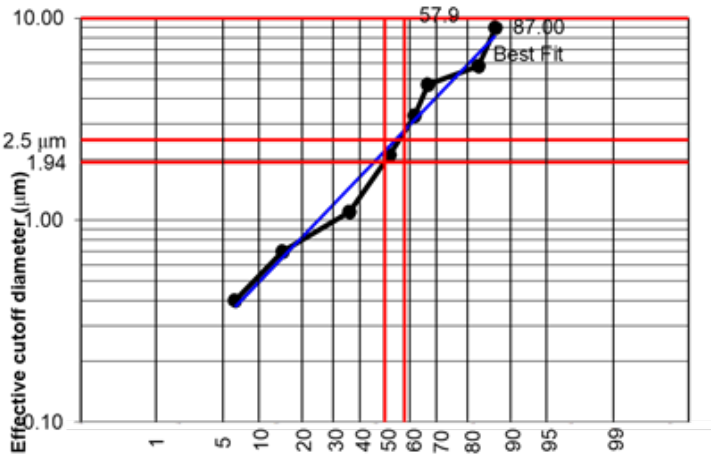

Fig. 2. Plot of Cumulative % less than size range vs Effective cutoff diameter (ECD) on a log-probability paper. The 50th percentile is the Mass Median Aerodynamic Diameter (MMAD).

his power law was first introduced in the pharmaceutical field in 1985 and is also known as the Peppas equation (5). The Peppas equation is valid for the first 60 % of the normalized drug release. In the case of the spherical controlled delivery systems, Fickian drug diffusion and relaxation drug transport are defined by n equal to 0.43 and 0.85, respectively (Table II). Anomalous drug transport is intermediate between Fickian and Case II and is defined by values of n between 0.43 and 0.85.

Table II. Exponent n of the Peppas equation and drug release mechanism from polymeric controlled delivery system for different geometries

Thin film	Cylinder	Sphere	Drug release mechanism
Exponent, n			
0.5	0.45	0.43	Fickian diffusion
0.5<n<1	0.45<n<0.89	0.43<n<0.85	Anomalous transport
1.0	0.89	0.85	Case II transport

The in vitro release profile of ETA and PZA from porous PLGA microparticles is shown in Fig.3. The in vitro release data of ETA was best fitted in the Peppas equation with n = 0.43 with an R2coefficient of 0.9986, indicating Fickian diffusion. The % burst release for ETA was only 2.6 %. Only 10 % of total PZA encapsulated in the porous microparticles was released within 8 hours, after which we observed that a decrease in concentration of PZA may be due to its degradation in PBS pH 7.4 at 37.50C. Janssen et al. observed a degradation of doxorubicin under similar conditions (6).

Discussion

For optimal inhalation therapy, the particles must be delivered deep into the lungs. Mean geometric diameter and mass median aerodynamic diameter (MMAD) are the two main physical characteristics that are considered when designing inhalable formulations. The porous microparticles prepared and characterized in our project had mean geometric diameters in the range of 1.33 µm to 3.47 µm, and the aerodynamic diameters varied from 1.1µm to 2.8 µm. The geometric diameters and aerodynamic diameters were within the window for deep lung delivery. Numerous experimental (7) and theoretical (8) studies have demonstrated that particles with mean aerodynamic diameters of 1–3 µm deposit minimally in the mouth and throat and maximally in the lung's parenchymal (i.e., alveolar or "deep-lung") region.

Besides, the geometric diameter range of 1.33 µm-3.47 µm is also favorable for phagocytosis by lung macrophages. The treatment of MDR-TB involves a high-dose combination of three to four drugs for around 21 months (3). M.TB have a slow generation time of 15-20 hrs, a physiologic characteristic that contributes to its virulence and resistance. We attempted to prepare and characterize a nebulizer-compatible porous microparticle formulation loaded with a combination therapy for treatment of MDR-TB. We selected two basic drugs, ETA and PZA, to be encapsulated in porous PLGA microparticles to minimize their interaction. Porous PLGA microparticles were prepared using ammonium bicarbonate in the double emulsion method as described by Yang et al (9). The maximum loading efficiency for ETA and PZA was 37.63 % and 8.77 %, respectively. Possible leakage of PZA from the primary emulsion due to its hydrophilicity

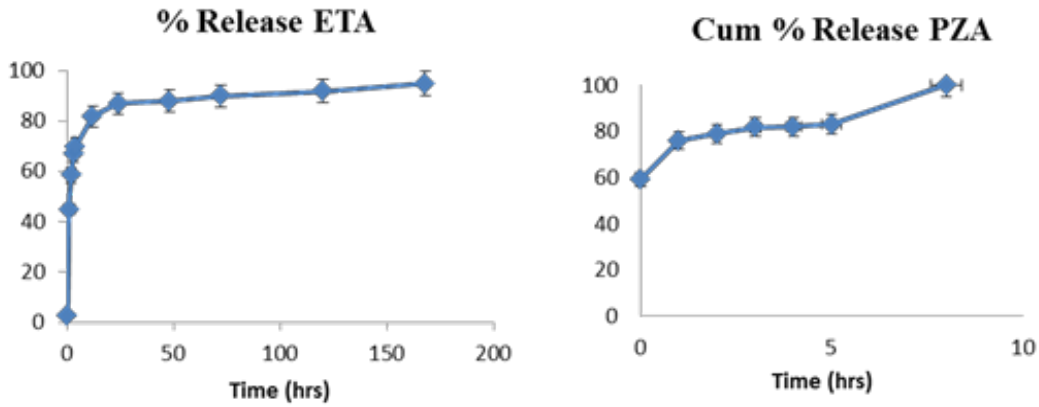

Fig. 3. In vitro release of ETA and PZA from porous microparticles in PBS pH 7.4 at 37±5 °C

could have been the reason for its low loading efficiency. DSC and FTIR studies showed no significant interactions among ETA, PZA and PLGA. The in vitro release of ETA from porous PLGA microparticles lasted for more than seven days and followed Fickian diffusion. PZA release from porous PLGA microparticles in PBS pH 7.4 lasted for only eight hours, after which we observed degradation of PZA. The porous microparticles characterized and developed in our lab are suitable for treatment of tuberculosis and other respiratory infections which require deep lung delivery.

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Commentary: How Could Precision Medicine Impact Pharmaceutical Science and Technology

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Since the beginning of the human genome project there has been considerable speculation as to how this resource and knowledge it enabled will transform disease treatment and prevention that takes into account individual variability in genes, environment, and life styles. Pharmacogenomics- a relatively new field of study- combines pharmacology and genomics to develop effective, safe medications and doses that will be tailored to a person's genetic makeup. Pharmacogenomics, in turn, was the catalyst for the concept of personalized medicine that eventually evolved into precision medicine subsequent to kick-off the Precision Medicine Initiative in 2015. If current trends holds it is expected that new parenteral products will be increasingly complex requiring nonstandard manufacturing technologies subjected to higher standards of regulatory scrutiny and market expectations. Notably, with the emphasis on precision medicine- an emerging approach of disease treatment and prevention that takes into account individual variability in genes, environment and lifestyles for each person- there will be a greater number of biologics drugs, multidrug combination products, drug device combinations and targeted drug delivery systems introduced to the market. Parenteral manufacturing of these complex drug products will require special equipment, technologies and control strategies. It will also require highly skilled process engineers, manufacturing operators and quality assurance personnel. Furthermore, a greater number of new molecules will be highly potent requiring special containment facility, environmental controls and operator training that is not commonly available in many of today's manufacturing facilities. These new parenteral product will bring with them the challenges of new packaging technologies far removed from standard stoppers and vials. Even the vial manufacturers themselves are creating glass engineered to be stronger, more inert, and highly scratch resistant. Process Analytical Technology (PAT) will need to evolve to keep up with the control strategies employed with more complex treatments. It is possible, with the appropriate use of PAT, a solid understanding of critical process parameters, and robust control strategy, that drug products could be released parametrically (not only terminally sterilized products) which would greatly reduce the time to patient. (CPG Sec. 490.200 Parametric Release of Parenteral Drug Products Terminally Sterilized by Moist Heat)

With the advent of precision medicine certain types of finished dosage forms are gaining importance – such as self-administered drugs and combination products. The therapeutic landscape is rapidly changing away from a "one size fits all" to a "personalized and precision medicine" paradigm that will integrate basic science, diagnostic testing and clinical management of complex health conditions with the primary focus on prevention. In a global survey of leaders in the pharmaceutical industry conducted by the consulting firm- PwC (PwC Strategy&Precision Medicine Study-2017), 92% of the respondents identified precision medicine as an opportunity and 84% have it on their corporate agenda. Regarding specific therapeutic areas where precision medicine will likely be viable over the next five years, the top two responses were oncology and orphan diseases. The resultant impact on drug products of the future will be an increasing need for patient tailored flexible dosing; fixed dose and free combination multidrug treatments; kits comprising diagnostic testing and drug products; "smart" drug delivery systems comprising drug-device combinations; specialty "convenience" packaging for an increasing geriatric population; high potency compounds; and, of course a shift to large molecule therapeutics including proteins, Mabs, Fabs and scFvs. In addition, there will be a greater need for targeted drug delivery systems such as liposomes, multiparticulates, trigger and activated drug delivery systems and ancillary routes of parenteral administration more amenable to self-administration, controlled and sustained release. Finally, there will be a transformative introduction of digital technology for remote and real-time monitoring of drug treatment. This cutting edge digital technology is still speculative or evolving and hence, the impact on pharmaceutical manufacturing is not yet clear.

Based on current trends the market becoming more niche in nature. There are more specialty manufacturers of parenteral products. Research and development sponsor are increasingly seeking the services of specialty parenteral manufacturer or a company with broader experience. As a consequence of precision medicine there is an increasing emphasis on open innovation involving greater industry-academia collaboration. With the spiraling cost of drug discovery and high attritions in early development, it is expected that a greater proportion of cutting edge, innovative research will be conducted by small biotech and inventors often referred to as "two men and a patent". The goal will be to rapidly advance promising candidates to first-in-human, proof of concept studies to create attractive licensing opportunities that will be picked up by large pharma's for expensive, downstream development and commercialization. On the other hand, large pharma's deploy sophisticated due diligence assessments that require innovators and inventors to demonstrate high probability of technical success and develop ability of their asset. Many of these inventors are likely to be academicians, investors and basic scientists with scant CMC background. Hence, these customers are likely to expect from manufacturers of parenteral products a high degree of CMC expertise manifest by successful regulatory applications (INDs, CTA, CTX) and de risking of critical technical issues that could delay scale-up and downstream development (i.e. time to market). Parenteral manufacturers of the future will need to provide not just manufacturing services but also end-to-end formulation development, CMC and technology transfer services including the creation of viable due diligence information packages for out licensing.

Based on current trends we expect the importance and value-proposition of Parenteral Manufacturing to exponentially increase in the next decade and the foreseeable future. Most importantly, Parenteral Manufacturers need to move away from a myopic "fill-finish" mentality to a fully integrated development mindset that is in line with client expectations, patient needs and regulatory requirements. It will require "out of the box" thinking and strategic, at-risk investments since it will be too late otherwise. This will take innovation, courage and collaboration across R&D and placing smart bets for a win-win.

From the perspectives of poison, person and price — what impacts will the USP <800> make?

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**Correspondence*

In about five months from now, the USP<800> is scheduled to be official enforcing major shifts in the process of compounding hazardous drugs in the pharmacies. December 1, 2019 is the currently scheduled date for its becoming official, although the older, unofficial versions have been (October 1, 2016) introduced to allow the pharmacists and facilities adjust their process and facility with the new one. The key components will be the proper training of the employees, renovating and/or reconstructing the facility to conform the engineering compliance, addressing the limitations pertaining to the staff, space and other resources in most of the busy hospital systems, and last but not the least, the adversely affected healthcare cost. The implementation requires a great expense, inviting compounding-related price hike, but also the noncompliance may trigger revoking of the licensure as well as monumental financial loss.

The discouraged-yet-tacitly-accepted widely pervasive malpractice of *pace-over-perfection* has been significantly exposing pharmacy compounders to the hazardous drugs (HD) including chemotherapeutics. Every year, over 8 million US health care workers are potentially exposed to hazardous medications. The major objective of USP <797> is, "to prevent harm, including death to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins, variability in the intended strength of correct ingredients, unintended physical or chemical contaminants and ingredients of inappropriate quality in Compounded Sterile Preparations (CSPs). These standards are applicable to both hazardous and non-hazardous compounding. Therefore, there is a need for precise standards for handling hazardous medications. The goal of USP <800> is to protect the patients, healthcare workers, and the environment. It includes, but not limited to, the receipt, storage, mixing, preparing, compounding, dispensing, administering, disposing and otherwise altering, counting, crushing, or pouring of drugs and drug products.

Then comes the candid query — does it only affect the compounding pharmacies? The answer to whom it may concern is any entity that has the term "pharmacy" associated, since every pharmacy has the capacity to handle and dispense HD. As a result, USP <800> is applicable to all types of pharmacy operations and no one is exempt from it. As a matter of fact, failure to comply with USP<800> after December 1, 2019 can affect the license of the pharmacy and pharmacist-in-charge. Many state board of pharmacy changed their laws to implement USP<800> prior to this federal effective date. Depending on the types of HD products dispensed or handled, the facilities have to be concerned about HD waste disposal.

One of the most significant changes in the practice of non-sterile compounding is the redefinition of the term 'non-sterile compounding' per se. Previously, the reconstitution to prepare a suspension from the powder, for instance, was not regarded as compounding which will be considered as compounding if not dispensed immediately. Personnel involved in non-sterile compounding of HD must be fully aware of and properly trained on USP <800> rules before compounding the products. Facilities must follow standards set in USP <795> and other USP general chapter references in USP <795>. Handling of final dosage forms in a Containment

Primary Engineering Controls (C-PEC) is not required unless manipulating in such a way that produces particles, aerosols or gasses. Non-sterile compounding facilities now have to have dedicated space and dedicated personnel depending on the HD products (NIOSH list) and compounding methods practiced. Any drug enlisted in Tables 1,2 and 3 of NIOSH list, if used as an API in the form of creams, liquids, or low- aerosol formulations should follow containment strategies and work practices outlined in USP <800>. A systematic assessment of risk of all the HD drugs and dosage forms can help the pharmacies to determine the course of action. For smaller facilities, implementing USP<800> is challenging, which will mandate the hiring of new, trained personnel or at least outsource the help from a third party.

Small compounding facilities that handle HD once in a blue moon will surely consider the return of investing costs associated to engineering alteration. They may quit accepting HD prescriptions, eventually. This process may not only result in the shrinking of HD compounding sites in the community, but also financially affect the independent compounding pharmacy business. However, despite the discomfort in the pharmacy business operation, the commencement of USP <800> is believed to protect compounding personnel, whose being safe determines the safety of the patients at large.

AABPS Graduate Students Travel Awards

The AABPS is delighted to announce five graduate students as the recipient of prestigious travel award.

Bangladeshi Graduate students, including US-born children of Bangladeshis, enrolled to an MS, PhD or PharmD program in the USA with research focus on any of the following areas are eligible to apply:

- Pharmaceutical Sciences
- Medicinal Chemistry
- Biomedical Science

JUNIOR GROUP

Students enrolled to the *MS program*, students in their *first two years of the PhD* program and students enrolled to PharmD program will belong to this group.

SENIOR GROUP

Students enrolled to the PhD programs who are currently in their *third year or above* belong to this group.

THE AWARD

This year, five graduate students applied for the grant. All of them were recommended for a grant worth $500.00, and the award is to be collected in the award giving section of the event. The recipients will present their 8-minute research talk in the convention.

Cytokine-stimulated iNOS Expression Requires Long Chain Fatty Acyl CoA Synthetase (ACSL)

Yousuf Ali[1], Margaret Teresa Weis[1]

[1]Department of Pharmaceutical Sciences, Texas Tech University Health Sciences Center, Amarillo, TX

PURPOSE/RATIONALE

Nitric Oxide (NO) is derived from three isoforms of Nitric Oxide Synthase (NOS) - neuronal nitric oxide synthase (nNOS), inducible nitric oxide synthase (iNOS), and endothelial nitric oxide synthase (eNOS). NO, synthesized by eNOS, regulates vascular tone in a way that it considered as neuroprotective. In contrast, during ischemia iNOS is induced and produce a large amount of NO. Excessive nitric oxide (NO) is cytotoxic to nerve cells and leads to neuronal cell death. Long chain fatty acyl CoA synthetase (ACSL) catalyzes the ligation of fatty acid to coenzyme A, the first and rate-limiting step for fatty acid utilization. Triacsin C is a fungal metabolite which inhibits ACSL1, ACSL3, and ACSL4. Our lab has shown that Triacsin C reduces the infarct volume and inhibits iNOS expression in the mouse middle cerebral artery occlusion (MCAO) model of stroke. In the current study, we wanted to see whether iNOS expression is modulated by ACSL activity.

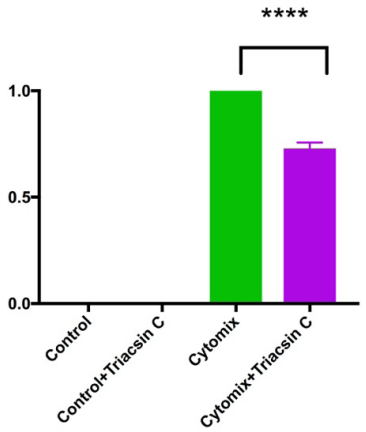

Fig. 1: iNOS Gene Expression in C6 Astrocytoma Cells.

METHODS

qPCR analysis: Cells were stimulated with cytokine mix, (TNFα, 60 ng/mL; Ilβ, 2 ng/mL; IFNγ, 100 units/mL), in the presence or absence of 5μM Triacsin C for 24 hours. RNA was extracted following the RNeasy Plus Mini Kit (Qiagen) instruction. The concentration and purity of RNA were determined by Spectrophotometer. 20 μl first strand cDNA was synthesized from 1 μg total RNA for each sample using Superscript III First-Strand (Invitrogen). One μl cDNA was amplified using SYBR Green PCR Master Mix (Applied Biosystems) in the CFX96 Touch Real-Time PCR Detection System (BioRad). β-actin (cat 330001 PPM02945B), iNOS (cat 330001PPM02928B), and eNOS (cat 330001 PPM03801A) primers for bEnd.3 cells and β-actin (cat 330001 PPR06570C), iNOS (cat 330001 PPR44835A) and nNOS (cat 330001 PPR44930E) primers for C6 astrocytoma cells were purchased from Qiagen. Expression level in fold change was determined by the comparative threshold cycle method (2–ΔΔCt) with β-actin as the control gene.

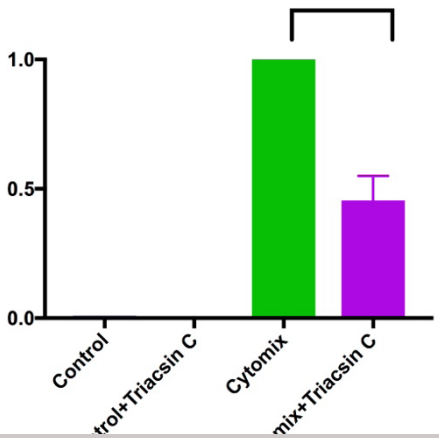

Fig. 2: iNOS Gene Expression in bEnd.3 Cells.

Western blot: bEnd.3 cells were grown to confluence under standard conditions, then challenged with cytokine mixture in the presence or absence of

Triacsin C. After 24 hours, cells were washed with ice-cold PBS buffer and protein extracted using RIPA buffer. Proteins were separated by 4-20% Tris-Glycine gel and transferred to a PVDF membrane then probed with an antibody against iNOS. After blots were visualized, membrane was stripped and re-probed for alpha actin as a loading control.

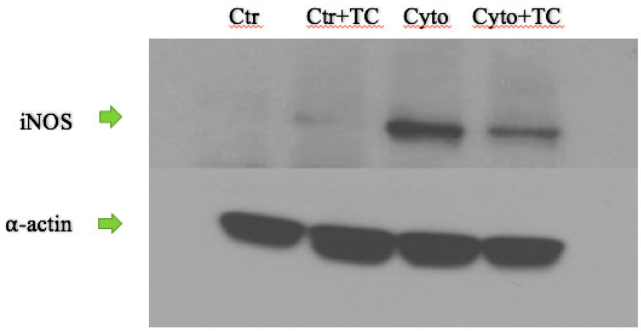

Fig. 3: iNOS protein Expression in bEnd.3 Cells.

RESULTS

Cytomix stimulated iNOS expression in the presence of Triacsin C was 72.9 ± 1.96 % of cytomix group (p = 0.0001, n = 3 independent experiments) in C6 astrocytoma cells and 45.6 ± 6.7 % of cytomix group (p = 0.0001, n = 6 independent experiments) in bEnd.3 cells. We also observed that ACSL inhibition with Triacsin C reduced cytokine-stimulated iNOS protein expression in bEnd.3 cells from our western blot analysis.

We did qPCR for nNOS and eNOS to confirm that nNOS or eNOS expression does not change. No change has been observed in nNOS mRNA expression in any group compared to the control in C6 astrocytoma cells and eNOS mRNA expression in any group compared to the control in bEnd.3 cells (data not shown).

CONCLUSIONS

Our data confirms that iNOS expression is modulated by ACSL activity, and supports our hypothesis that the Triacsin C effect on stroke infarct volume is related to the suppression of iNOS expression.

Yousuf Ali

Texas Tech University Health Sciences Center

Mini Presentation

- Saturday (July 6, 2019)
- At 3.35 PM
  - *Salon A/B*

Deletion of the ARID1A in Osteosarcoma Enhances Aggressive Cell Phenotypes

Kaniz Fatema[1], Jared J. Barrott[1]

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PURPOSE

Osteosarcoma is a form of bone cancer that primarily affects children and young adults. In the United States, 400 - 1,000 new cases are diagnosed per year. 30 years ago survival rates went from 20% to 75% with the introduction of aggressive chemotherapy combined with surgery but for the past three decades, the survival rate has remained the same. Patients with metastatic or recurrent diseases have a <20% chance of long-term survival despite aggressive therapies, suggesting genetic complexity and chemotherapeutic resistance. Our research is aimed toward discovering new drugs that can treat patients that do not respond to traditional chemotherapy.

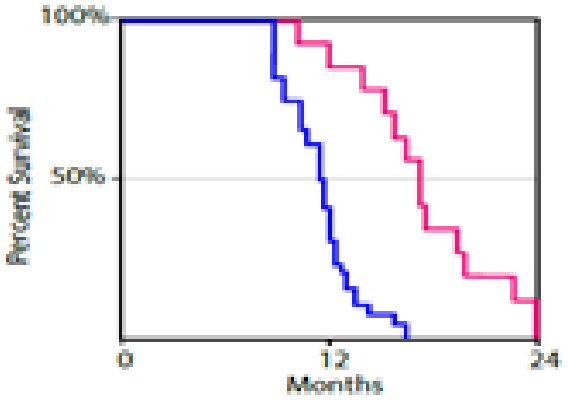

Figure1. Kaplan-Meier plot of mouse osteosarcomagenesis with (Blue) or without (Pink) piggyBac mutagenesis

METHODS

In a forward genetic screen using the transposon piggyBac, we discovered a strong correlation between ARID1A gene repression and increased osteosarcoma rates (Figure 1). ARID1A is a member of the SWI/SNF chromatin remodeling protein complex and plays a role in epigenetics by directing chromosomes to unwind from histones (Figure 2). In an attempt to discover whether ARID1A contributes to sarcomagenesis, osteosarcoma cell lines that putatively express ARID1A were grown in culture dishes. Using CRISPR/Cas9 gene editing, the ARID1A gene was disrupted from the main sequence and various methods were used to test proliferation rates.

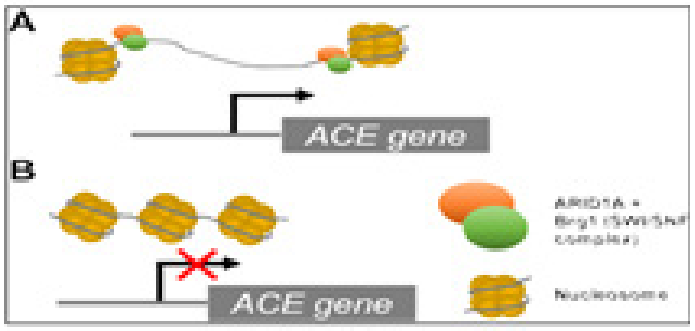

Figure 2. Function of SWI/SNF complex and its role in gene transcription and translation

RESULT AND DISCUSSION

Upon deletion of ARID1A in Osteosarcoma cell lines we found an increase in proliferation and migration (Figure 3). Not only are we testing gene disruption in cell lines, but we are also testing mouse models that have had Arid1a knocked out to determine if osteosarcoma growth rates increased.

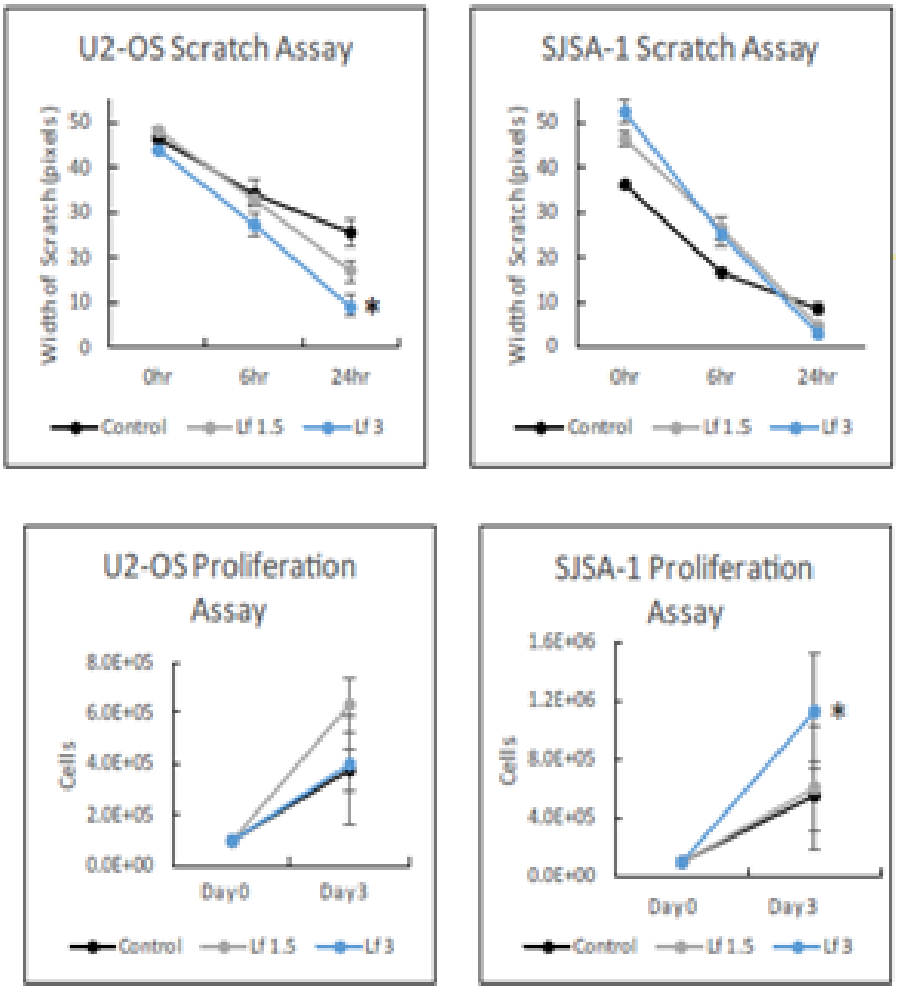

Figure 3. Graphs showing the results from scratch analysis (at 0, 6, and 24 hours) and proliferation assays (over a period of 3 days)

CONCLUSION

We conclude that ARID1A is a potent tumor suppressor in Osteosarcoma and that loss of ARID1A enhances a more aggressive phenotype in the cell lines SJSA-1 and U2-OS. Our long term goal is to provide a therapy that can be tested in humans with osteosarcoma to help those who do not respond to traditional chemotherapy and provide alternative therapy with potentially fewer side effects.

Kaniz Fatema

Idaho State University

Mini Presentation

- Saturday (July 6, 2019)
- At 3.45 PM
  - *Salon A/B*

An approach to design, synthesis & evaluation of Phthalimide based Sphingosine Kinase Inhibitors.

Farjana Afrin[1], Katherine Obuch[2], Srinath Pashikanti[1]

[1]College of Pharmacy, Kasiska Division of Health Sciences, Biomedical and Pharmaceutical Sciences, Idaho State University, Pocatello, ID; [2]Department of Chemistry, Idaho State University, Pocatello, ID.

BACKGROUND

Sphingosine-1-phosphate (S1P) belongs to the Sphingolipid family which regulates growth, survival, and migration of several cell types. S1P is a ligand for five transmembrane G-protein – coupled receptors, S1P1-5 and for several intracellular targets such as histone deacetylases 1 and 2. Sphingosine kinase (SphK) enzyme is the enzyme responsible for transforming Sphingosine to Sphingosine-1-Phosphate. SphKs have been implicated in a variety of diseases such as cancer, sickle cell disease, atherosclerosis, asthma, diabetes, and fibrosis.

PURPOSE

My current efforts included utilizing heteroaromatics which are synthetically stable and have improved solubility (for example, phthalimide). Retaining Structural features of previously synthesized SphKII inhibitor, a rigid phthalimide linker was introduced as the linker of the SphKII analog design. Phthalimide derivatives possess anticancer, antibacterial, antifungal, and analgesic properties. The imide functionality [-CO-N(R)-CO] in phthalimide makes it hydrophobic and neutral to cross different biological membranes in vivo.

METHODS

In the current scheme I have developed 5-substituted-phthalimide based analogs towards targeting sphingosine (SphK) kinase enzyme. A Sonogashira coupling strategy was employed towards synthesis of the new C-C bond. Then regioselective reduction was performed to convert the alkyne chain into alkyl chain. Mitsunobu reaction was performed to introduce the head group. Then standard Boc deprotection allowed me to move forward with the next step. Microwave irradiation was performed to add guanyl moiety to the head group. Finally, the standard Diboc deprotection gave me the final compound.

RESULTS

Several alkyls, aryl substituted Pthalimide analogs were synthesized using the established scheme. The compound characterization was done using proton and carbon NMR & GC-MS. The evaluation of the synthesized compounds are in process.

CONCLUSION

Phthalimide structural motif was utilized in several biologically relevant systems. The scheme involves utilizing alkyl groups with different chain lengths, bulky groups amenable towards synthesis. Structure-Activity Relationship studies will be guided based on the in-vitro based sphingosine kinase assays.

Farjana Afrin
Idaho State University

Mini Presentation

- Saturday (July 6, 2019)
- At 3.55 PM
  - *Salon A/B*

Masking the Pungent Taste of Oleocanthal: An Approach of the Development and Evaluation of Effervescent Formulation against HER2 Positive Breast Cancer Recurrence

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Department of Basic Pharmaceutical and Toxicological Sciences, College of Pharmacy, University of Louisiana at Monroe, 1800 Bienville Drive, Monroe, Louisiana

PURPOSE

(-)-Oleocanthal, a naturally occurring phenolic secoiridoid derived from extra-virgin olive oil (EVOO), is a potential nutraceutical therapeutic in inflammation, neurodegenerative disease and cancer, especially breast cancer. Oleocanthal exerts bitter, astringent and pungent sensation by activating the transient receptor potential cation channel subtype A1 (TRPA1) due to the presence of unsaturated dialdehyde carbonyl moieties. The objective of the present study was to develop an effervescent formulation of oleocanthal by providing effective taste masking of oleocanthal pungency and to assess the efficacy against hormone dependent HER2 positive breast cancer.

METHODS

Physical characteristics of the developed formulations was evaluated using Fourier Transform Infrared (FT-IR) spectroscopy, Differential Scanning Calorimetry (DSC), Scanning Electron Microscopy (SEM) and Confocal Laser Scanning Microscopy (CLSM). The measurement of pH, effervescence time, CO2 content and flow properties were done to ensure the quality of effervescent powder. Taste masking of the formulation was assessed by using Astree electronic tongue generated by Alpha M.O.S., and animal preference test in both male and female Swiss Albino mice. Cell viability of formulated oleocanthal and its placebo was performed to assess the in vitro effect on the growth of human BC cell lines BT-474 and MDA-MB-231 by using MTT assay. In vivo orthotopic BT-474 xenograft model was used to evaluate pharmacodynamic effect of the developed formulation.

RESULT

In this study, we screened different ratios of acid and carbonate sources, and depending on their pH and effervescence time, five effervescent formulations were prepared. pH of all formulations showed the value less than 6 which might be helpful to increase the absorption of effervescent formulations. EF-2 provides higher CO2 content in comparison with other formulations. All formulations exhibited acceptable flowability and effervescence time. In FTIR, the characteristic bands of oleocanthal either disappeared or were reduced in intensity in the spectra of the different effervescent formulations, which may be due to restriction of the drug within the carrier. In DSC, the melting points of EF-1, EF-2, EF-3, EF-4 and EF-5 were 151.50, 152, 157.50, 162.50 and 175 oC respectively, and the melting point of placebos of these five formulations were 161,156, 157, 164 and 173.50 oC respectively. As, oleocanthal is oily liquid at room temperature, it's not possible to assess its melting point. So, it's difficult to predict the entrapment of oleocanthal in the effervescent formulation. But if we considered the endothermic peak of effervescent formulation and placebo, they are different. Based on pH, effervescent time, flow properties and considering all other physical characteristics, EF-2 is superior among five different formulations. In addition, in simulated gastric fluid (pH 1.2) within 10 mins, oleocanthal exhibited 10% dissolution profile while EF-2 exhibited approximately 75% dissolution. On the other hand, in simulated intestinal fluid, oleocanthal exhibited 20% dissolution while EF-2 provided the dissolution profile 75% within 10 minutes. EF-2 formulation had been selected for further all different studies. Morphology of the EF-2 formulation and placebo were examined by using SEM and CLSM. EF-2 formulation containing oleocanthal exhibited different arrangement as compared to placebo with physical mixtures. In Taste masking evaluation of oleocanthal effervescent formulation by using e-Tongue taste map, the discrimination index (DI) for EF-2 formulation and placebo was 84 % and 90 % respectively, while oleocanthal was less than 10 %. The higher DI values demonstrated significance taste difference between only oleocanthal and formulation. The taste analysis of oleocanthal formulations using Alpha MOS e-tongue showed that formulations EF-2 and placebo are the most distinct samples. The animal preference test was also further validating e-tongue results and confirming preference of formulation at orally compared to use of oleocanthal alone. In case of cellular cytoxicity, the IC50 values for EF2 were 21.3 and 16.5 µg/mL in MDA-MB-231 and BT-474 cells, respectively. It's notable that the significance of in vivo activity of oleocanthal is unlike to in vitro activity. To evaluate the in vivo efficacy of EF-2 formulation, BT-474 orthotopic mouse model used in this experiment. At the end of experiment, the mean tumor weight of EF-2 (10 mg/kg) and its placebo were 1.66±0.37 g and 0.74±0.36 g respectively. Furthermore, the mean tumor volume was 1132.38±168.39 mm3 and 352.23±156.88 mm3 for EF-2 formulation and placebo-treated mice groups, respectively. The oleocanthal EF-2 formulation 10.0 mg/kg treatment resulted in approx. 70% tumor growth reduction in comparison with placebo treated control animals.

CONCLUSION

The current study for the first time showed a well-developed oleocanthal effervescent formulation. The physical and analytical evaluation confirms suitability of the current formulation. The pungency of oleocanthal has been masked significantly and showed better animal taste preference index in the current formulation, while also improved drug release as compared to individual oleocanthal. Current formulation also showed significant tumor growth inhibition against HER2 dependent breast cancer. These results suggest that oleocanthal effervescent formulation can be used in future translational application of breast cancer treatment as a dietary supplement.

Afsana Tajmim

University of Louisiana at Monroe

Mini Presentation

- Saturday (July 6, 2019)
- At 4.05 PM
  - *Salon A/B*

Antibiotic Releasing Bone-void Filler (ABVF) Putty for Osteomyelitis Treatment

Raquib Hasan[1], Jacob Schrefler[1], Codi Schaper[1], Hunter Schleske[1], Amanda Brooks[1]

[1]North Dakota State University, Fargo, ND

PURPOSE

Total joint replacement (TJR) surgery is the number one elective surgery in U.S.A. The number of primary total knee replacement (TKR) and total hip replacement (THR) surgery is expected to be more than 4 million per year by 2030. Simultaneously, the number of revision procedures will also increase to more than 350,000 annually. Infection is the major cause for revision procedures accounting for 25% of all revisions. Infection proneness after revision surgery is remarkably higher (20-30%) than that of primary procedure (1-4%). Current treatments are not adequate to treat these hard-to-treat infections. Currently, treatment procedure includes surgical debridement followed by high dose of systemic antibiotic, non-biodegradable antibiotic-releasing bone cement etc. which do not provide sustained local high drug concentration and the fluctuating drug level may lead to antibiotic resistance. The non-biodegradable bone cement does not provide osseointegration and bone ingrowth while needing an additional surgery for. A biodegradable, antibiotic releasing bone-void filler (ABVF) putty that releases antibiotic at a therapeutic range for 4 - 6 weeks, which is considered the most infection prone period after TJR, and supports osseointegration and bone ingrowth, can be a better treatment option. Moreover, a putty like ABVF can be easily molded and can be press-fitted into bony voids, which surgeons prefer. Here, we report in vivo experimental results of ABVF treatment in a rat osteomyelitic infection model.

METHODS

ABVF putty was fabricated using polymers (PLGA, PEG, PCL), a tri-calcium phosphate and hyaluronic acid substrate (Pro-osteon), and antibiotic (vancomycin). Sprague-dawley rats (>350 grams) were used for the animal study (IACUC protocol 16016). The surgical procedure was as follows: a small incision was made on the skin below the knee of the right hind leg of the rat. A critical defect of 4.2 mm diameter was created in tibial epiphyses using electric drill. High concentration of *Staphylococcus aureus* (ATCC 49230) (1E8 CFU/10 µL) was inoculated into the marrow space using a Hamilton syringe. ABVF putty (treatment group) or, putty without antibiotic (control group) was then put into the defect, and the incision was closed with sutures. The rats were sacrifices after 10 weeks and the bone was harvested for further investigations. X-ray was done on the bones for radiological assessment. µ-CT scan was also done on the bones to see the extent of bone healing or the presence of osteomyelitis. Bacterial colony count was done by snap freezing freshly harvested in liquid nitrogen followed by pulverization using a custom-made bone pulverizer. The pulverized bone was put into sterile phosphate buffered saline followed by sonication to extract bacterial cells. The bacteria were then plated on to blood agar plates for colony counts. PCR was also done to ensure the bacterial species using strain specific primers. Histological evaluation was done by H&E staining. Gram staining was done to see the presence of bacteria. Blood serum was also collected from the rat to measure the creatinine clearance enzymatically to see if the vancomycin caused any nephrotoxicity. For statistical analysis T-test was done to find the significance level.

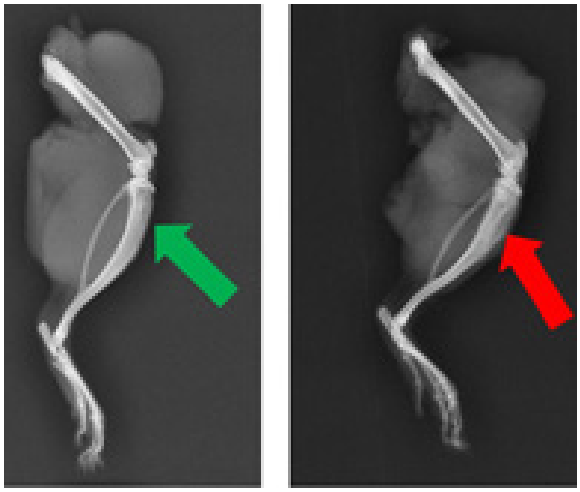

Figure 1: Treatment group (on left) vs control group (on right). Green arrow shows healed bone. Red arrow shows signs of osteomyelitis.

RESULTS

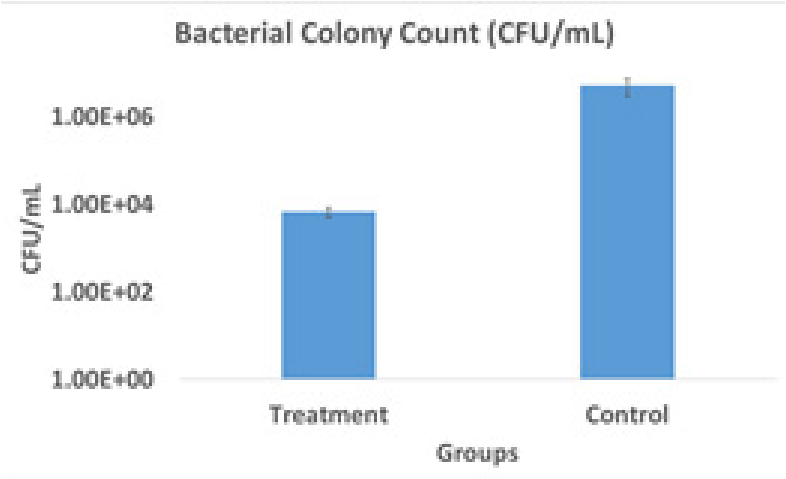

Figure 2: The bars show bacterial colony in treatment and control groups. At p<0.05 bacterial load is significantly lower in treatment group than in control group.

X-ray showed signs of osteomyelitis in the control rats (fig. 1). Whereas, treatment rats showed signs of bone healing (fig. 1). These observations were confirmed by µ-CT images. µ-CT also showed degradation of the putty at the implanted space. Bacteria colony count showed significantly less bacterial load ($p<0.05$) in the treatment rats (6.75E+03 CFU/mL) compared to the control rats (5.30E+06 CFU/mL) (fig. 2), a decrease of more than 3 orders of magnitudes was observed which is considered clinically effective. PCR confirmed the identity of the

bacteria as the inoculated strain. H&E staining showed osseointegration and bone ingrowth and degradation of the putty implant in the treatment rats. Control rats showed severe signs of osteomyelitis in H&E staining. Visual observation showed puss and ectopic bone growth in the control rats confirming osteomyelitis in the tibia. Gram staining showed presence of bacteria in the control rats. Creatinine clearance found to be within the normal range (0.2 – 0.8 mg/dL) for both group of rats confirming that vancomycin did not cause nephrotoxicity in the rats.

CONCLUSION

The ABVF putty showed promising results in the animal experiment to treat osteomyelitits. Clinically effective outcome was achieved. The putty was easy to use and could be press fitted easily. The ABVF putty degraded and showed osseointegration and bone ingrowth. The sustained antibiotic releasing putty that releases drug for up to 6 weeks (in vitro data not shown here), could treat osteomyelitis effectively and can be an efficient treatment options. The sustained antibiotic releasing putty that releases drug for up to 6 weeks (in vitro data not shown here), could treat osteomyelitis effectively and can be an efficient treatment options.

Raquib Hasan

North Dakota State University

Mini Presentation

- Saturday (July 6, 2019)
- At 4.15 PM
  - *Salon A/B*

Cultural Performance

Band name: Jotil

- Suhash (former Souls and Feelings member): vocals and guitars
- Sohel: bass and vocals
- Tony: guitars
- Tomal: drums

List of Registrants

1	Abdullah Mahmud
2	Abu Bakar
3	Abu Serajuddin
4	Afsana Tajmim
5	Ahnaf Rahman
6	Anindita Arpa
7	Anwar Hossain
8	Areeb Siddique
9	Arshad Jamil
10	Ashequr Rahman
11	Ashfiha Rahman
12	Ashraf Ahmed
13	Atik Rahman
14	Ayat Ahmed
15	Ayesha Jaigirdar
16	Azizul Quazi
17	Begum S. Nahar
18	Ch. Mahmood Hasan
19	Daniel Kuddus
20	Dider Bhuiyan
21	Eram Alam
22	Faraz Siddique
23	Farjana Afrin
24	Faruk Khan
25	Hasan Siddique
26	Hasibur Rahman
27	Hasina Akhtar
28	Hemayet Ullah
29	Hosne Arshad
30	Imran Ahmed
31	Ishrak Alam
32	Jahidur Rashid
33	Jaser Kuddus
34	Jennifer Mondle
35	Jerin Mondle
36	Kamrun Nahar
37	Khadija Kubra
38	Laila Mondle
39	M. Jamil Habib
40	Maher Hossain
41	Mahibah Ahmed
42	Maliha Ahmed
43	Masih Jaigirdar
44	Md Ismael Hossain
45	Milad Khan
46	Mizanur Rahman
47	Mohammad Absar
48	Mohammad Ullah
49	Mollick Mahmud
50	Muhammad Amir Ali
51	Nadira Ahmed
52	Nahid Kamal
53	Nasima Nusrat
54	Oliza Khanam
55	Qamrul Ahsan
56	Qamrul Majumder
57	Rafia Rasu
58	Raquib Hasan
59	Rashida Khan
60	Rayan Kuddus
61	Rebecca Islam
62	Rehana Kuddus
63	Rumana Yasmeen
64	Sabiha Alam
65	Salah Uddin Ahmed
66	Sarah Ahmed
67	Sefat A Shums
68	Selim Fakhruddin
69	Selina Ali
70	Shah Rashid Ranju
71	Shahid Alam
72	Shahid Kamal
73	Shamim Ahmed
74	Shanaya Rayya Kamal
75	Suraiya Quazi
76	Tajin Mahnaj
77	Warda Salah
78	Yanah Hossain
79	Yarah Hossain
80	Yousuf Ali
81	Zahidul Mondle
82	Zahur Islam
83	Raqeeb Jamil
84	Mohammad Rahman
85	Arman Sarkar
86	Ruma Sarkar

Food menu

7:30 AM Continental Breakfast

- Orange & Apple Juice
- Fruit Preserves
- Seasonal Whole Fruit
- Variety of Breakfast Breads and Pastries
- Freshly Brewed Starbucks Coffee
  Decaffeinated Coffee & Taylors Teas

12:00 PM Lunch

- Homemade Cole Slaw
- Assortment of Freshly Baked Gourmet Breads and Rolls
- Soup du Jour
- Market Style Pasta Salad
- Deli Meat Platter
- Roast Beef (***Halal***), Chicken Breast (***Halal***) and Tuna Salad
- Assorted Domestic Cheese Display
- Deli Tray Condiments
- Herbed Mayo, Whole Grain Mustard, Dijon Mustard, Horseradish
- Individual Bag of Chips
- Chef's Selection of Assorted Desserts
- Freshly Brewed Starbucks Coffee,
- Decaffeinated Coffee, Taylors Teas & Iced Tea

2:30 PM Coffee Break

- Seasonal Whole Fruit
- Freshly Baked Brownies & Blondies
- Starbucks Coffee, Decaf & Taylor Teas

6:00 PM Dinner buffet

- Garden Salad
- With Two (2) Choices of Dressings
- Assortment of Freshly Baked Gourmet Breads and Rolls
- Grilled Chicken Breast, (***Halal***)
- Baked Herb Tilapia
- Penne Pasta
- Marinara
- Seasonal Vegetable
- Rice Pilaf
- Chef's Selection of Dessert
- Starbucks Coffee & Decaf, Taylors Tazo Tea, Iced Tea

American Association of Bangladeshi Pharmaceutical Scientists (AABPS)

PURPOSE:

The primary purpose of the AABPS, is to serve its membership, and, in specific- the pharmaceutical professionals of Bangladeshi origin residing in North America and working in academia, industry, hospitals, health insurance companies, pharmacies, government or other research institutions- by providing a forum for the interchange of knowledge. AABPS is a non-political, non-religious, not-for-profit, US tax exempt educational organization.

OBJECTIVES:

- To foster communication and collaboration among pharmaceutical scientists and professionals of Bangladeshi origin and residing in North America.
- To support its members in achieving their highest level of professional career through collaboration, consultation, mentoring, education and exchange of knowledge.
- To provide timely scientific programs, ongoing education, publications and networking opportunities for the scientists and professionals involved in discovery, development, manufacture and marketing of pharmaceutical products and services.
- To facilitate communication and contacts between the Association Members and interested personnel in Bangladeshi pharmaceutical industry, government regulatory agency, and academic institutions regarding transfer of knowledge and consulting services on pharmaceutical sciences.
- To promote fraternity and solidarity among the pharmaceutical scientists and professionals.

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- **Profit-Sharing Plans**
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5	Clotrimazole Cream	Clotrimazole 1%	10 gm in plastic laminated tube	72103-524-10
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10	VITAMIN B_1, B_6 & B_{12}	VITAMIN B_1 (as Thiamin Mononitrate), B_6 (as Pyridoxine HCl) & B_{12} (as Cyanocobalamin)	100's (10×10's) in Alu-PVC blister strip	72103-777-00

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