18th Annual Pharma Middle East Congress

November 05-07, 2018 Abu Dhabi, UAE

Workshop (Day 1)

Dr Royida Al Marastani, J Pharma Care Health Sys 2018, Volume 5
DOI: 10.4172/2376-0419-C4-035

Dr Royida Al Marastani

SEHA-Ambulatory Healthcare Services, UAE

It is not a visit; it is a journey. The Customer Journey Mapping (CJM)

Aim: To encourage the employees across all departments to think outside of the box and improve services quality through Customer Journey Mapping (CJM)

Objectives: What you want to provide to the customer What the customer would like to receive Essentials components of effectives CJM

Methodology: A literature search was performed by key factors Customer Journey Mapping (CJM)

Introduction: CJM It is a storytelling tool used to engage users and it is also a powerful way to teach organizations more about their customers. CJM identifies the positives and negatives of your process. Giving you a chance to improve the overall experiences.

Discussion: Return customers are the lifeblood of any business, and the ways to grow your repeat customer base based on:

1. Stay in touch
2. Assume they won't remember you
3. Keep the experience fresh and relevant
4. Surprise them
5. Collaborate
6. Have the right people on the front-line
7. Make it easy for customers to reach you
8. Listen
9. Show your appreciation

Customer service is part of the overall customer experience, and is reactive (unlike customer experience which is proactive)

After CJM implantation, you can learn directly from the customer and you can understand the customer Finally, How to make an excellent impression on people you encounter and enhance your professional image by implantation of Customer Journey Mapping (CJM)

Conclusion: To be able to walk in a customer's shoes, your business will have a better understanding of your customers likes and dislikes, what they are having trouble with, and what doesn't work for them. This is all necessary information to improve services quality through implantation of Customer Journey Mapping (CJM) and always exceed your customer expectation

Biography

Senior Pharmacist with more than thirty years of experience in the UAE in Abu Dhabi in Primary Health Centers (PHC), Urgent Care Center (UCC) and Ambulatory Health Services (AHS) and MSc in Clinical Pharmacy UK. She is a lecturer from 2003 in Ministry of Health (MOH), in CPE/CME pharmacist's program from 2011 in SEHA/ Ambulatory Healthcare Services (AHS). Her roles include conducting research, conference abstracts, invited presentations in the national & international conferences, focusing on pharmaceutical care based on safety and efficacy of the medications.

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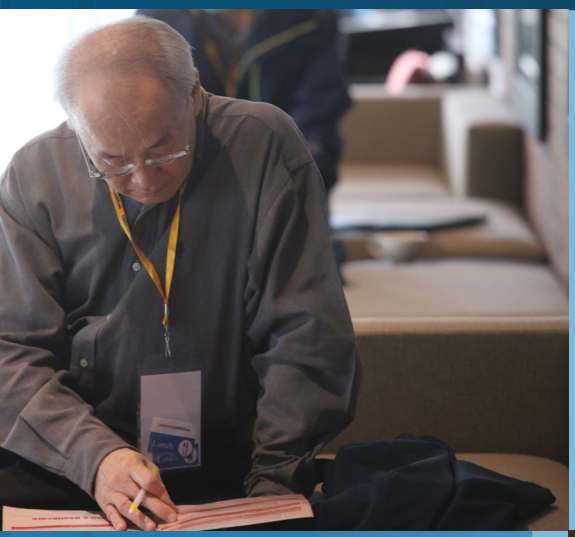

Scientific Tracks & Abstracts (Day 1)

Alap Choudhari, J Pharma Care Health Sys 2018, Volume 5
DOI: 10.4172/2376-0419-C4-035

Recent developments in abuse-deterrent and tamper-resistant opioid formulations and its changing regulatory requirements

Alap Choudhari
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In recent year's number of opioids prescribed to patients for treating acute and chronic pain has significantly increased in United States. Steady rise in use of prescription opioids lead to an escalating misuse of these opioids which resulted in serious health consequences for the abusers. The opioids abuse epidemic has reached to a stage where it's affecting entire communities resulting in to a staggering financial burden due to the monetary costs associated with its nonmedical use, including reduced productivity and increased healthcare utilization. The problem of this magnitude requires a comprehensive approach which includes partnership of the regulatory agencies and industry. To confront the staggering human and economic toll created by opioid abuse and addiction, employing novel abuse deterrent technologies is one part of a comprehensive intervention strategy that can deter abuse of prescription opioid analgesics without creating barriers to the safe use of prescription opioids. Abuse deterrent and abuse resistant are the type of formulations where the opioid abuse can be prevented by using a physical barrier that makes manipulation of dosage form more difficult or using a combination of a substance making it less rewarding for abusers. Some significant technological advances are made by researchers and institutions to develop the formulation which can achieve the tamperproof formulation while maintaining the desired pharmacokinetic profile for the opioids. Current discussion includes review of the epidemiology of the crisis as background for the development of abuse deterrent technologies and provides a comprehensive overview of most recent technologies that are currently employed or are under study for incorporation into abuse deterrent technologies. These technologies can be mainly divided in 5 different classes' physical barrier, chemical barrier, antagonists, aversive agents and prodrug approach. The discussion also includes the updated regulatory requirements to generate data sufficient for a description of a product's abuse-deterrent properties.

Biography

Alap Choudhari is working in pharmaceutical industry as a research scientist for more than 15 years. His primary area of research work is focused on the development of solid oral, liquids and transdermal formulations. In his current assignment he is responsible to develop difficult to develop and complex generic formulations. Dr. Choudhari and his team has developed generic formulation for 6-8 abuse deterrent formulations and filled them with regulatory agencies. Due to his constant interactions with the regulatory agencies, he has knowledge of most updated requirements which the agencies are trying to enforce to make these formulations more difficult to abuse and safe for the patients. He is also involved in the development of in-house abuse deterrent formulation platform which is being used for various opioid formulations.

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Notes:

Faiza Meftah, J Pharma Care Health Sys 2018, Volume 5
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The role of independent prescribers' pharmacists in primary and secondary care in the United Kingdom

Faiza Meftah
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Clinical pharmacists, as members of multidisciplinary clinical teams, play a pivotal role within different specialties in UK hospitals and primary care setting. Their role extends from routine review of prescriptions, medicines information, formulary applications and drug history-taking through medicines reconciliation, assisting prescribers in prescribing decisions, optimizing drug therapy and Therapeutic Drug Monitoring (TDM), to facilitating patient discharge from hospitals and counselling patients on their medication prior to discharge. Recently a new role for appropriately qualified pharmacists has emerged where they can prescribe any medicine independently within their competency. This interesting development is expected to bring added benefits to interdisciplinary care teams, which will be illustrated through a real example during the presentation. The main aim of the independent prescribers' pharmacists are to improve patients' access to medication as well as patient's care without compromising safety and also enables a better use of healthcare professional skills and contribute to flexible team working within primary and secondary care services. This extended role could be applied in hospitals in the Middle East with positive impact on patient's care.

Biography

Faiza Meftah is the Lead Pharmacist for Surgery at Papworth Hospital NHS Foundation Trust in Cambridge, United Kingdom. She has completed her Master's degree in Pharmacy from the University of Nottingham, UK and Post-Graduate Diploma in Clinical Pharmacy from the University of East Anglia, UK. She has worked as a Clinical Pharmacist and is also an Independent Prescriber from the University of Anglia Ruskin, Cambridge, UK and runs clinics for patients prior to their cardio-thoracic surgeries at Papworth Hospital. She is also an Educational Supervisor for Pharmacy Technicians undertaking the Accredited Checking Course and an accredited Smoking Cessation Advisor. She is a Member of the General Pharmaceutical Council, The British Heart Foundation and an Active Member of the UK Clinical Pharmacists Association. She is one of the contributors of the National Handbook of the Peri-Operative Medicines first launched in 2016.

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Notes:

Hashem O Alsaab, J Pharma Care Health Sys 2018, Volume 5
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Multifunctional nanoparticles for cancer immunotherapy: An emerging approach for personalized cancer therapy

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Several cancer immunotherapeutic approaches have been recently introduced into the clinics and they have shown remarkable therapeutic potentials. The groundbreaking cancer immunotherapeutic agents function as a stimulant or modulator of the body immune system to fight against or treat cancers. Although targeted immunotherapies such as immune check point inhibitors (CTLA-4 or PD-1/PD-L1), DNA vaccination and CAR-T therapy are revolutionizing cancer treatment, the delivery efficacy can be further improved while their off-target toxicity can be mitigated through nanotechnology approaches. Nanomedicines can be multifunctional drug delivery agents for cancer therapies. However, they have faced several challenges in clinical trials owing to poor targeting ability, insufficient tumor penetration, difficulty in synthesis and scale up and limited understanding of interactions between a tumor and nanoparticles. In this regard, tumor multicomponent targeting drug delivery systems are a rational approach for developing tumor-site-specific therapeutics. The nanoparticles can be co-loaded with drugs, genes and imaging agents, surface decorated with varying targeting ligands that can home to varying tumors and/or tumor multicomponent. Recent research has demonstrated that nanotechnology has multifaceted role for (1) re-educating Tumor Associated Macrophages (TAM) to function as tumor suppressor agent, (2) serving as an efficient alternative for Chimeric Antigen Receptor (CAR)-T cell generation and transduction and (3) selective knockdown of KRAS oncogene addiction by nano-Crisper-Cas9 delivery system. The function of host immune stimulatory signals and tumor immunotherapies can further be improved by repurposing of nanomedicine platform. This presentation will summarize the role of multifunctional polymeric, lipid, metallic and cell-based nanoparticles for improving current immunotherapy.

Biography

Hashem Alsaab has completed his PhD from Dr. Iyer's group in U-BiND Systems Laboratory, Department of Pharmaceutical Sciences, EACPHS Wayne State University, USA and Pharmacy (PharmD) and Master of Science in Pharmaceutical Sciences-Industrial Pharmacy option from University of Toledo, OH, USA. He is currently working as an Assistant Professor of Pharmaceutics and Pharmaceutical Technology, Taif University, Saudi Arabia. He is a Research Scientist with a demonstrated history of working in the higher education and clinical practice. He is skilled in pharmaceutical sciences, cancer research, drug delivery, nanotechnology and biotechnology.

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Zahid Hussain, J Pharma Care Health Sys 2018, Volume 5
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Hyaluronic acid decorated tacrolimus-loaded nanoparticles: Efficient approach to maximize dermal targeting and anti-dermatitis efficacy

Zahid Hussain
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Atopic Dermatitis (AD) is a chronically relapsing eczematous skin disease characterized by frequent episodes of rashes, severe flares and inflammation. Till date, there is no absolute therapy for the treatment of AD. However, Topical Corticosteroids (TCs) are the majorly prescribed class of drugs for the management of AD. However due to numerous local and systemic adverse effects associated with the use of TCs, Topical Calcineurin Inhibitors (TCIs) have alternatively been well prescribed agents. Though, topical route is most preferable however, a limited penetration of therapeutics across the Stratum Corneum (SC) is one of the major challenges to topical formulations. Owing to excellent biomedical achievements of nanomedicines in the last few decades, nano-delivery systems have gained remarkable recognition for targeted delivery of therapeutic payload, reduced off-target effects and improved biopharmaceutical profiles of drugs. Therefore, we aimed to fabricate polymeric Nanoparticles (NPs) to deliver Tacrolimus (TCs) to deeper layers of the skin in order to alleviate its systemic toxicity and improved therapeutic efficacy for treatment of AD. To further optimize the targeting efficiency, TCS-loaded NPs were coated with Hyaluronic Acid (HA). HA plays multifaceted role in regulating the various biological processes and maintaining homeostasis into the body. Plenteous researches have evidenced the biomedical implications of HA in the skin repair, wound healing, tissue regeneration, anti-inflammatory, and immunomodulation. Following the various physicochemical optimizations, the prepared HA-TCS-CS-NPs were tested for *in vitro* drug release kinetics, drug permeation across the stratum corneum, percentage of drug retained in the epidermis, dermis and anti-AD efficacy. Results revealed that HA-TCS-CS-NPs exhibit sustained release profile, promising drug permeation ability, improved skin retention and pronounced anti-AD efficacy. Conclusively, we anticipated that HA-based modification of TCS-CS-NPs could be a promising therapeutic approach for rationalized management of AD, particularly in children as well as in adults having steroid phobia.

Biography

Zahid Hussain is currently working as an Assistant Professor in the Department of Pharmaceutics, Faculty of Pharmacy, Universiti Teknologi MARA, Malaysia. He is also the Executive Head of Quality Control Department of Good Manufacturing Practices Unit at Universiti Teknologi MARA, Malaysia. He has authored more than 50 peer-reviewed research/review articles with high impact factor, well-ranked international journals and 3 book chapters. He is recipient of several prestigious honors and awards. He is the Editorial Board Member for 3 international journals and is also the Official Reviewer of more than 30 well-reputed peer-reviewed international journals. His research interests include fabrication, characterization and formulation of nanotechnology-based topical, percutaneous and transdermal drug delivery systems for the efficient management of skin inflammatory disorders including psoriasis, atopic dermatitis and acute-to-chronic wound.

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Rashida Muhammad Umar, J Pharma Care Health Sys 2018, Volume 5
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Comprehensive medication management in oncology patients

Rashida Muhammad Umar
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Cancer is one of the leading causes of death globally with increasing prevalence. Treatment in cancer patients is complicated as it obliges the use of drugs with narrow therapeutic window and high toxicity to treat the cancer, in addition to supportive care medications to treat disease-related and therapy complications and also comorbidities. As such cancer patients are prone to drug-related problems. Comprehensive Medication Management (CMM) is defined by the American College of Clinical Pharmacy as the standard of care that ensures each patient's medication (including non-prescription drugs, traditional and alternative therapies and supplements) are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, safe given to comorbidities and other medications taken and able to be taken by the patient as intended. CMM involves assessment of patient, evaluation of medication therapy, development and initiation of plan to tackle or prevent identified drug-related problems and follow up and medication monitoring. A recent study focused on the evaluation of the effect of this process in hospitalized oncology patients revealed the importance of the process as 481 drug-related problems were recorded in 137 patients. Clinical pharmacist interventions were readily accepted and implemented by physicians showing the acceptability of clinical pharmacist as part of the health-care team and the applicability of the process in improving patient outcome. Oncology-hematology unit has one of the highest rates of medication errors and study results have been consistent with the positive impact of clinical pharmacists on preventing medication errors, optimizing drug usage and maintaining patient safety. The awareness of patient centered pharmacy practice in developing countries is increasing and introduction of clinical pharmacist-led pharmaceutical care programs in the multidisciplinary team will improve therapeutic outcomes and reduce health-related expenditure.

Biography

Rashida Muhammad Umar is currently working as an Assistant Professor at Istanbul Medipol University, Istanbul. She has completed her graduation and post-graduation in Pharmacy from Hacettepe University, Ankara and her PhD in Clinical Pharmacy from Marmara University Istanbul. She is a Lecturer focused on the improvement of pharmacy education and the application of clinical pharmacy in the health care system.

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Notes:

Anteneh Assefa et al., J Pharma Care Health Sys 2018, Volume 5
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Physicochemical characterization of the starch from Ethiopian potato (*Plectranthus edulis*)-A potential pharmaceutical excipient

Anteneh Assefa[1], Anteneh Belete[2] and Tsige Gebre-Mariam[2]
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Starch from the tubers of Ethiopian potato (*Plectranthus edulis*) (Fam. Lamiaceae) has been isolated and examined for its chemical composition, amylose content and physicochemical properties. The yield of starch was about 80.4% on dry weight basis. The proximate composition of the starch on dry weight basis was found to be 0.14% ash, 0.21% lipid, 0.43% protein and 99.22% starch. The amylose content was 30.6%. Its true density and moisture content values were 1.47 g/ml and 11.2%, respectively. Scanning Electron Microscopy (SEM) of the starch granules showed characteristic morphology that was by large oblong (elliptical) with some oval-shaped granules. The starch has normal granule size distribution with a mean particle size of 36.20 µm. The DSC thermograms of *P. edulis* starch obtained from starch-water mixtures (1:1), exhibited higher T0 (69.2 °C), Tp (74.3 °C) and Te (83.3 °C) values than those of potato starch. X-ray diffraction pattern of the starch was typical B-type with a distinctive maximum peak at 17.5° 2θ. The starch possesses higher swelling power and moisture sorption pattern but lower solubility values than those of potato starch at all temperatures studied. Considering the high yield value and some similar physico-chemical properties to those of potato starch, *P. edulis* (Ethiopian potato) can be explored as an alternative source of starch for various applications.

Biography

Anteneh Assefa is currently working as a Lecturer of Pharmaceutics and Pharmacology at Wachemo University, Ethiopia. He is an expertise of pharmaceutical dosage form design and drug supply chain management.

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Scientific Tracks & Abstracts (Day 2)

Ibrahim Elsayed, J Pharma Care Health Sys 2018, Volume 5
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Design of pharmaceutical experiments using design expert® software

Ibrahim Elsayed
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Design Expert® software is a professional statistical tool used to create the experimental design, study the effects of different factors with the least possible number of trials and optimize the designed process through simultaneous selection of the desired level of each independent variable. Different statistical plans can be utilized as full factorial, response surface and mixture designs. Response surface is the most commonly used design in pharmaceutical research and it includes different sub-designs e.g. central composite and Box-Behnken. Before starting the experimental part, the studied factors and traced responses are loaded into the Design Expert® software to determine the number and compositions/conditions of the experimental trials. After finishing the experimental work, the obtained data are fed into the software to assign different desirability values to the conducted experimental trials. Consequently, we can select the optimum trial having the maximum desirability value to be subjected to further investigations.

Biography

Ibrahim Elsayed is an Associate Professor and Chair of Pharmaceutical Sciences department at Gulf Medical University, Ajman UAE. He has completed his PhD in Pharmaceutics and Industrial Pharmacy from Cairo University. He pursued his Graduation in Health-Professions Education from Gulf Medical University. He has published 16 research articles in reputed international journals like International Journal of Pharmaceutics, International Journal of Nanomedicine and Expert Opinion in Drug Delivery.

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Howaida I Abd-Alla, J Pharma Care Health Sys 2018, Volume 5
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Habitat specialization through chemical characterization, anti-herpes activity and the promising protocol for *in vitro* propagation of *Aloe barbadensis* (Miller) collected from Egypt and Tunisia

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Analyzing the lipid and protein content of leaves and roots of *Aloe barbadensis* collected from Egypt (AEG) and Tunisia (ATUN) was carried out using by GLC and HPLC, respectively. The HSV-1 infected chicken embryo fibroblasts cell lines were used for evaluation of the *in vitro* antiviral effect. A rapid and high frequency shoots multiplication, rooting and acclimatization protocols for elite Aloes using shoot tip explants was developed. Preliminary comparative molecular screening *in vitro* propagated aloes was carried out and randomly amplified polymorphic DNA (RAPD) markers have been used to check for genetic fidelity of aloes plantlet. Shoot tips explants of the two types were cultured on Murashige and Skoog's (MS) basal medium supplemented with different plant growth regulators TDZ, BAP, NAA for shoots proliferation and roots formation. After two weeks, *in vitro* grown plants were transferred to the poly-cups containing 1:1 ratio of soil and sand, respectively for hardening and then transferred to garden showed 75% of survival. The DNA fingerprint genetic integrity of the multiplied shoots and acclimatized plantlets were evaluated by employing RAPD marker assays. There was great variability in chemical constituents of AEG and ATUN. All the tested samples showed effective antiviral activity with IC50 range of 5-6 µg/mL and substantial Therapeutic Indices (TI) range of 80-83. Cytotoxicity assay indicated that CC50 of leaves and roots of AEG and ATUN were greater than 400 and 500 mg/mL, respectively. Shoot proliferation was found to be best (80%) using MS medium containing BAP 2.0 mg/L. Moreover, second subcultures recorded the highest and significant shootles multiplication. 70% of adventitious root formation was observed in half strength MS medium supplemented with IBA. Over 95% of rooted plantlets survived acclimatization was remarked. The current results indicated that the geographical localization had significant impact on the quality of each Aloe.

Biography

Howaida I Abd-Alla has completed her PhD from the University of Cairo, Egypt and is specialized in Metabolomics Natural Products Chemistry. She has pursued her Post doctorate at Laboratoire des Interactions Moléculaires et Réactivité Chimique et Photochimique UMR CNRS 5623, Université de Toulouse, France. She worked as a Professor in the Chemistry of Natural Compounds Department, National Research Centre, Egypt. She is currently working as the Head of the department where her research focuses primarily on isolation, purification and identification of natural compounds from medicinal plants, bacteria and marine organisms using advanced techniques for identification (1D and 2D NMR analysis), synthesis of derivatives of natural products and bioactive assays *in vivo* and *in vitro* in natural products for use in treating different diseases.

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Mohamed Bouheroum et al., J Pharma Care Health Sys 2018, Volume 5
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The cytotoxicity effect of two saponins from *Gymnocarpos decander* species on Hela cells

Mohamed Bouheroum[1], Houria Bechlem[1], Teresa Mencherini[2] and Nunziatina De Tommasi[2]
[1]Constantine 1 University, Algeria
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The modern pharmaceutical industry relies mainly on the diversity of plant secondary metabolites to find new molecules with novel biological properties, in this perspective our objectives are the inventory as well as the chemical and pharmacological evaluation of Algerian species, in order to valorize and rationalize their traditional uses and to isolate compounds of potential therapeutic interest. The n-butanol and ethyl acetate extracts of *Gymnocarpos decander* (Caryophyllaceae) were able to isolate five new products including two saponins and three flavanol glycosides, with three known products. The extract obtained undergoes chromatographic and spectroscopic investigations in order to isolate and establish the structures of the molecules that compose them by using various spectroscopic experiments (UV, 1D NMR and 2D and SM). In addition, the cytotoxicity tests of the new compounds (1-5) isolated from the Butanol phase of *Gymnocarpos decander* performed on the three cell lines Jurkat T (leukemia), Hela (cancer of the cervix) and MCF7 (breast cancer), have shown that only the products one and two (both saponins) have a cytotoxic effect vis-a-vis the three cell lines, in particular Hela cells. These results of anti-proliferative activity are encouraging and stimulate further research projects on the species of this family.

Biography

Mohamed Bouheroum has his research studies in Phytochemistry on Algerian Medicinal Plants looking for bioactive molecules. He has completed his Master's degree from Manchester University and PhD from the Constantine 1 University, Algeria. He is currently working as a Professor and Chief of a Team performing phytochemistry researches on Algerian medicinal plants in Varenbimol laboratory at Constantine 1 University, Algeria.

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Anteneh Assefa et al., J Pharma Care Health Sys 2018, Volume 5
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Comparative disintegrant properties of Ethiopian potato (*Plectranthus edulis*) starch against Irish potato starch and its optimization in paracetamol tablet formulations

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Starch is the most commonly used pharmaceutical disintegrant in tablet formulations. The aim of the present study was to assess the disintegrant property of Ethiopian potato (*Plectranthus edulis*) starch in comparison to Irish potato starch and its optimization in paracetamol tablets formulations-prepared by wet granulation method. Tablet properties such as crushing strength, friability, disintegration time and dissolution rate of the tablets were studied for both comparison and optimization studies. The results of comparative study showed that the properties of paracetamol tablets formulated with both starches as disintegrants were affected by their concentration and the Compression Force (CF) and *P. edulis* starch exhibited a favorably comparable disintegrant property with Irish potato starch in paracetamol tablet formulations. The study also showed that the CF and disintegrant concentration had significantly affected the response variables (i.e. the crushing strength, friability and disintegration time); hence, these factors were further optimized using central composite statistical design. The optimal conditions were obtained at a CF of 14.40 KN and disintegrant concentration of 5.96%. Under these conditions, the crushing strength, friability and disintegration time were 101.8 KN, 0.3% and 1.34 min, respectively. These values closely matched with the predicted values of the responses at the aforementioned levels of the factors. Thus, the results of this study indicated that Ethiopian potato (*P. edulis*) can be used as an alternative source of starch for its application as a disintegrant in the tablet formulations.

Biography

Anteneh Assefa is currently working as a Lecturer of Pharmaceutics and Pharmacology at Wachemo University, Ethiopia. He is an expertise of pharmaceutical dosage form design and drug supply chain management.

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Maha AlMolaiki, J Pharma Care Health Sys 2018, Volume 5
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Association between Proton Pump Inhibitors use and New Onset of Ischemic Stroke in A Tertiary Hospital, King Abdul-Aziz Medical City-Central Region Saudi Arabia: Retrospective Study

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Background: Stroke is a rapid loss of brain function due to disruption of blood supply to the brain and a major cause of mortality and morbidity worldwide. In Saudi Arabia the incidence of ischemic stroke is 69%. Risk factors are: hypertension, diabetes mellitus, smoking, dyslipidemia. Proton pump inhibitors (PPIs) one of the world's most frequently prescribed medications contributed to many adverse effects. Retrospective study found a significant increase in risk of new onset ischemic stroke in the PPIs users. Prospective cohort study found no association.

Aim: assess the likelihood of developing new onset ischemic stroke among patients who were using PPIs for 6 months or more versus patients who were not using PPIs.

Method: Case-control study at King Abdulaziz Medical City central region, from January2016 to January2017.Sample size calculations based on probability type I error of 0.05,80%power, estimated to be 400[200 ischemic stroke(cases) and 200 non-ischemic stroke(controls)]. Each group obtained by simple random sampling, medications reviewed if patients were using PPIs. The association between PPIs use, demographic data, clinical factors and development of ischemic stroke evaluated by using Odds Ratio (OR) and 95%confidence interval (CI). Continuous data expressed as mean ±SD. Categorical data analyzed using the Chi-square test.

Result: 128 patients met the inclusion criteria.64 patients with 47 on PPIs had new onset ischemic stroke (meanage69.14±11.57, 53.13%were male), 64 patients with 39 on PPIs without ischemic stroke (mean age 60.88±12.49, 54.69%were female). Primary endpoint: there was insignificant association between patients with previous exposure to PPIs and ischemic stroke (Odds Ratio (OR) 0.396; 95% (CI) 0.111–1.415),In comparison to the retrospective study. For secondary endpoint: the incidence of ischemic stroke was insignificant between patients who used different doses, 20mg orally daily in ischemic and non-ischemic stroke (29.79%Vs.48.72%, respectively), and 40mg orally daily in ischemic stroke and non-ischemic stroke (70.21%Vs.51.28%, respectively), P=0.0723.

Table (1) Baseline Characteristics

Characteristics	Outcome		p-value
	Ischemic (N=64)	Non-Ischemic(N=64)	
Age (years)	69.14 (11.57)	60.88 (12.49)	0.0003
Gender			0.3767
Male	53.13%	45.31%	
Female	46.88%	54.69%	
weight	75.50(14.46)	84.54(19.32)	0.0031
Height	159.88(10.22)	160.44(9.17)	0.8338
Smoking			0.3436
Yes	1.56%	3.13%	
No	56.25%	43.75%	
Not available	42.19%	53.13%	
Previous medical history			
Hypertension	92.19%	54.69%	<0.0001
Diabetes mellitus	67.19%	67.19%	1.0000
Dyslipidemia	68.75%	73.44%	0.5586
Heart Failure	7.81%	14.06%	0.2573
Myocardial Infarction	0.00	4.69	0.0797
Atrial Fibrillation	12.50%	3.13%	0.0481
Coronary Artery Disease	21.88%	20.63%	0.8644
Chronic Kidney Disease	9.38%	7.81%	0.7525
Peripheral Vascular	1.56%	3.13%	0.5591
Disease	9.38%	0.00	0.0121
Carotid Artery Stenosis			
Chronic Kidney Disease	73.44%	60.94%	0.1321
Peripheral Vascular	51.56%	37.50%	0.1095
Disease	21.88%	21.88%	1.0000
Carotid Artery Stenosis			
Doses			0.0723
20mg orally once daily	29.79%	48.72%	
40mg orally once daily	70.21%	51.28%	
Indications			
Refractory gastroesophageal	1.56%	3.13%	0.5591
reflux disease	3.13%	6.25%	0.4030
Non-Steroidal Anti-inflammatory Drugs use	3.13%	17.19%	0.0085
Other			

Table (2) Predictors risk factors of ischemic stroke.

Parameter	p-value	OR	95% Confidence Interval
Proton pump inhibitors	0.1541	0.396	0.111-1.415
use	0.0380	0.961	0.925-0.998
Weight	0.1649	0.303	0.056-1.633
Gender	0.0302	13.367	1.282-139.333
Heart failure	<.0001	43.642	7.544-252.461
Hypertension			

Conclusion: Association between PPIs use with different doses prior the occurrence of new onset ischemic stroke is insignificant, after accounting PPIs indications, several factors contributed to the risk of ischemic stroke.

Inclusion criteria:
Patients 25 years or older with/without a medical history of hypertension, diabetes, dyslipidaemia, ischemic heart disease, heart failure, myocardial infarction, atrial fibrillation, chronic kidney disease on haemodialysis or peritoneal dialysis, who were using anticoagulant and nonsteroidal anti-inflammatory medications.

Exclusion criteria:
Patients with history of ischemic stroke, transient ischemic attack, haemorrhagic stroke, neurological diseases, brain tumor, encephalitis, meningitis, pregnant women.

Primary endpoint: To assess the association between PPIs use and the risk of development new onset ischemic stroke.

Secondary endpoint: To determine the relationship between dose and frequency of PPIs and development of new onset ischemic stroke.

Biography

Maha AlMolaiki has completed her PharmD from King Saud University and has worked assisting as Patient Cares, both in outpatient and inpatient at King Abdulaziz Medical City-Central region. She is currently a Pharma Resident at Pharmacy Residency at King Abdulaziz Medical City-Central Region.

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Development of a reporter assay to determine the bioactivity of anti-IL6/IL6R and anti-EGFR based monoclonal antibodies

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Background & Aim: Biopharmaceuticals will comprise around 27% of the global pharmaceutical market in the near future and monoclonal Antibodies (mAbs) are predicted to take the major share due to their favorable drug properties such as specificity, high efficacy and fewer side-effects. Hence, testing mAbs for their efficacy and stability before batch release is an important aspect of the mAb development and manufacturing program. Here, we aim to design and validate an *in vitro* reporter gene-based assay for the evaluation of anti-IL6/IL6R and anti-EGFR mAbs with immense therapeutic potential and to make the stability testing procedure more robust, precise and rapid in comparison to existing assays.

Method: The HEK293 cell line was first engineered to express the IL6 or EGF receptors and later transfected with the pGL4.21 reporter vector containing the Sis-Inducible Element (SIE) or the Serum Response Element (SRE), respectively. The anti-IL6R mAb, Tocilizumab and the anti-EGFR mAb, Cetuximab were tested for their ability to inhibit IL6 and EGF-dependent reporter gene expression, respectively in these cell lines. The assay was validated according to ICH Q2 (R1) guidelines and was used to test the stability of mAbs manufactured in-house in comparison to available market standards.

Result: Tocilizumab and Cetuximab were found to inhibit IL6 and EGF-dependent reporter gene expression, respectively, in the developed assay. The assay was successfully validated for robustness, specificity, precision, accuracy and in-house and market standards were tested for stability in this assay.

Conclusion: A robust, specific and rapid *in vitro* reporter gene assay for the evaluation of anti-IL6/IL6R and anti-EGFR mAbs was developed. This assay can effectively serve as a surrogate assay in the development and batch release of mAbs/drugs directed to target the IL6 and EGF signaling pathways. In a similar way, cell lines can be engineered to co-express multiple receptors and response elements so that mAbs with two different targets, such as bispecific antibodies or those used in combination therapeutics, can be effectively screened together.

Biography

Kriti Ray is currently pursuing her PhD at Deakin India Research Initiative program initiated between Reliance Institute of Life Sciences, India and Deakin University, Australia. Her study focuses on developing reporter assays for antibody-based therapeutics. She has also worked with siRNA-based therapeutics against cancer and dengue.

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