



KLE College of Pharmacy, Bengaluru

KC General Hospital, Malleshwaram



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Pharma Insight



Newsletter

A Quarterly Newsletter from Department of Pharmacy Practice, KLE College of Pharmacy, Bengaluru

About college

KLE College of Pharmacy is the constituent unit of KLE Academy of Higher Education (Deemed to be University), Belagavi, which is Re-Accredited by NAAC "A" grade by UGC, up to January 2021. We are running B.Pharm, M.Pharm, Pharm.D, PhD in a spacious well-equipped building of its own with hostel, library and sports facilities. The pharmacy curriculum is approved by Pharmacy Council of India (PCI) and All India Council for Technical Education (AICTE) and the UG programme is accredited by the NBA (National Board of Accreditation) and AICTE, New Delhi.

Department of Pharmacy Practice

KLE Academy of Higher Education and Research (KAHER), Belagavi has started Doctor of Pharmacy course in its constituent college, KLE College of Pharmacy, Bengaluru in the year 2014. To impart education, the pharmacy practice department is having adequate infrastructure and facilities as per the requirement of statutory bodies for the students from Doctor of Pharmacy course. All the faculty members have rich experience to make the student excel in her/his studies and suit professional opportunities in the hospital, clinical research and pharmaceutical industries.

Our department is associated with K.C. General Hospital, Malleshwaram, which is located just 2.5 kilometres away from the college premises. Moreover, bus facility is available from Hostel to the college and hospital. Pharm D. Interns are also carried to nearby hospitals.

Further, the department is keen to have collaboration with other hospitals. clinical research organizations and pharmaceutical industries towards the research projects and pharmacy practice

KAHER DONATES THREE CRORE FOR COVID-19 CRISIS



In order to treat Corona infected patients in the region of Belagavi, Karnataka, Flu clinic was opened in KLE Society's Dr Prabhakar Kore Hospital and Medical Research Centre, Belagavi. Flu clinic is located in the Trauma Centre of the hospital. The clinic is working 24hours with specialised pulmonologists, physicians and nursing staff. Forty two beds are reserved for the patients affected with Corona virus infection; six beds were equipped with ventilator facility. In addition, Honourable Chancellor of KLE Academy of Higher Education and Research (KAHER), Belagavi and Member of Rajya Sabha, Dr Prabhakar B. Kore has donated one crore to Prime Minister Care Fund and two crores to Chief Minister, Karnataka to help the

government to fight against the Covid-19 induced crisis.

TOPICAL FORMULATION OF PILOCARPINE FOR DIAGNOSIS OF CYSTIC FIBROSIS

Cystic fibrosis (CF) is a progressive, genetic disease inherited in an autosomal recessive manner. An elevated level of chloride (60 mMol/L) in sweat is indicative of CF. The sweat in patients is normally induced by stimulation of cholinergic muscarinic receptors. Measurement of chloride levels following pilocarpine iontophoresis remains the standard test for diagnosing cystic fibrosis in infants. However, the iontophoresis is cumbersome and usually is associated with several side effects such as skin burn, skin rashes and erythema. In this context, the present study aimed to develop a topical formulation that delivers adequate amount of

The drug delivery of the formulation was compared with iontophoresis of aqueous solution of pilocarpine nitrate in vitro across porcine skin. The pilocarpine levels in the skin exposed to topical pilocarpine solution under mild hyperthermia was found to be significantly higher compared to that seen after iontophoresis. The topical formulation was further subjected to clinical evaluation to assess the efficacy of the product to induce sweat production. Based on these results, it was found that the topical formulation can be developed for rapid delivery of pilocarpine as an alternative to complicated biophysical approaches of dermal drug delivery.

Fatima T, Shivakumar HN, Murthy SN et al. J. Pharma. Sci. 2020; 109: 1747-51

Dr. H.N. Shivakumar, Vice-Principal & Head, Department of Pharmaceutics

Section Editor : Dr. Rahul R Section Editor: Dr. Mahesh N M Print at: Ashok Printers, 080-23155235 Pharma Insight 16 Pharma Insight

DEPARTMENT SERVICES

Publications

Type	Published	Accepted	Communicated		
Research articles	2	1	1		
Period is January to April 2020					

Adverse Drug Reactions Reported by Interns

Generic name	Dosage form	Adverse Drug Reaction		
Fluconazole	Tablet	Rashes		
Ferric Carboxymaltose	Injection	Rashes		
Ferric Carboxymaltose	Injection	Swelling all over the body		
Cyclosporin	Capsule	Increased heart rate		
Ferric Carboxymaltose	Injection	Itching		
Amoxicillin	Tablet	Toxic Epidermal Necrolysis		
Telmisartan	Tablet	Hyponatremia		
*Period is January to April, 2020				

Case Presentations and Journal Club Presentations

Type of presentations	Class room	Hospital	Online		
Case presentation 101 54 25					
Journal Club			25		
Case presentations of students from II to VI Pharm D courses					
Journal Club presentations from Pharm D. interns.					
*Period is January-April 2020					

Section Editor : Dr. Rini S V

PHARMACY PRACTICE IN INDIA

PCI CIRCULARS/NOTIFICATIONS

The honourable supreme court of India in its judgement dated March 5, 2020 has passed common judgement upholding that the Pharmacy Act 1948 shall only prevail with regard to recognition and or approval of pharmacy courses/pharmacy institutions/intake capacity and degrees and diplomas in pharmacy. Accordingly, the norms and regulations set by the Pharmacy Council of India (PCI) and other specified authorities under the Pharmacy Act shall be followed by the concerned institutions imparting education for degrees and diplomas in pharmacy [Ref. No: 14-56/2019-PCI(A)/9851-55 dated Mar 11, 2020].

CDSCO CIRCULARS/NOTIFICATIONS

The Ministry of Health and Family Welfare along with its various stakeholders, partner Ministries and agencies is working round the clock to ensure the safety of every Indian in the wake of spread of Covid-19. In this regard, the department has already ensured that adequate supply of hydroxychloroquine tablets for all the patients, health workers and household contacts of confirmed cases for prophylactic treatment of Covid-19 cases as alone drug treatment. However, this drug should be utilised as per the prescription of physicians and it is not advised for patients with cardiac irregularities or diseases. In addition, the department has directed public not to consume any medicines without prescriptions as they may produce adverse effects [April 16, 2020].

PHARMACY PRACTICE SERVICES IN INDIA: ROBOTICS

Pharmacist comprises the third largest healthcare professionals in the world and pharmacy practice has been evolving steadily over the last decade. In India today, pharmacists have expanded their role from dispensing to pharmaceutical care by maximizing the benefits of medications and their safety.

Advancements in healthcare technology continue to drive innovation in the pharmacy. New health information technology (HIT) and the increasing awareness and use of robotic dispensing systems have made pharmacy operations faster and more efficient, while at the same time improving patient safety. Technology innovations have also led to more streamlined and coordinated workflows, which are helping pharmacies, optimize operations throughout their entire drug delivery cycle. Taking medicine distribution to the next level, a robot is helping to curb queues at the pharmacy counter of a hospital, Aster MedCity, Kochi, Kerala. Pharmacists scan and store medicines into the robots vault. The system can handle 35,000 packs of medicines and over 3000 prescriptions per day. The machine dispenses medicines from the pharmacists' terminal within seconds of billing and customers receive medicines in five minutes, thereby reducing the waiting time for patients at the pharmacy from 25 minutes to 10 minutes on average

Advantages

- Accuracy: Robotic systems are more accurate and consistent than humans
- Tirelessness: A robot can perform a 96 man-hour project in 10 hours.
- Reliability: Robots can work 24 hours for seven days a week without stopping or tiring.
- Return on investment: There is quick turn-around with return on investment. Plus, with the increase in quality and application speed, there are increased production possibilities.
- Production: With robots, throughput speed increases, which directly impacts production. Because robots have the ability to work at a constant speed without pausing for breaks, sleep, vacations and potential to produce more than a human worker.
- Quality: Robots have the capacity to dramatically improve product quality. Applications are performed with precision and high repeatability every time.
- Speed: Robots work efficiently, without wasting movement or time.
- Flexibility: Robots are easily reprogrammed. Changes in their End of Arm Tooling (EOAT)

- developments and vision technology have expanded the application-specific abilities of packaging robots.
- Safety: Robots increase workplace safety. Workers are moved to supervisory roles, so they no longer have to perform dangerous applications in hazardous settings.
- Savings: Greater worker safety leads to financial savings. There are fewer healthcare and insurance concerns for employers. Robots also offer untiring performance which saves valuable time. Their movements are always exact, so less material is wasted.
- Reduced chances of contamination: Removing people from the screening process reduces the potential for contamination and the potential for dropped samples when handling them in laboratories.
- Work continuously in any environment: Another advantage in the laboratory is that robots are pervious to many environments that would not be safe for humans.

Disadvantages

- Expense: The initial investment of robots is significant, especially when business owners are limiting their purchases to new robotic equipment. The cost of automation should be calculated in light of a business' greater financial budget.
- Dangers and fears: Although current robots are not believed to have developed to the stage where they pose any threat or danger to society, fears and concerns about robots have been repeatedly expressed in a wide range of books and films that the principal theme is the robots' intelligence and ability to act could exceed that of humans, that they could develop a conscience and a motivation to take over human race
- Expertise: Employees will require training in programming and interacting with the new robotic equipment. This normally takes time and financial output.
- Return on investment: Incorporating industrial robots does not guarantee results. Without planning, companies can have difficulty achieving goals

https://timesofindia.indiahttps://www.pharmatutor.org

https://timesofindia.indiatimes.com/city/kochi/ Hospital- has-robot-to-dispense

Ms. Aluru Sai Srilekha, IV Pharm D

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NEW DRUGS/DRUG FORMULATIONS APPROVED IN INDIA

Generic Name	Dosage form	Route & Strength	Indications	Approval Date	
Cidofovir dihydrate	Tab	IV; 75mg/ml (5ml vial)	CMV retinitis in HIV patients	Jan 3, 2020	
Dacomitinib	Tab	PO; 15mg, 30mg, 45mg	Metastatic non-small cell lung cancer	Jan 3, 2020	
Alpelisib	FC Tab	PO; 50mg, 150mg, 200mg	Metastatic breast cancer	Jan 3, 2020	
Isavunconazole sulfate	Cap	PO; 100 mg	Invasive aspergillosis, Invasive mucormycosis	Feb 14, 2020	
Azelnidipine	Tab	PO; 8 mg	Stage 1 Hypertension	Mar 4, 2020	
Riboflavin	Eye drops	Local; 0.1%w/v	Keratoconus & corneal ecstasis following refractive surgery	Mar 11, 2020	
Pixantrone	Powder for Inj.	IV; 29mg powder for concentrate for solution of infusion	Refractory aggressive Non- Hodgkin's B cell Lymphoma	Mar 11, 2020	
Bilastine (20mg) + Montelukast (10mg)	Tab	PO; 20mg + 10mg	Allergic Rhinitis	Mar 11, 2020	
Obeticholic acid (5mg) + Obticholic acid(10mg)	Tab	PO; 5mg + 10mg	Primary biliary Cholangitis	Mar 11, 2020	
PO- Per Oral IV- Intravenous Tab- Tablet FC- Film Coated Cap-Capsule Inj-Injection					

[•] www.cdsco.gov.in

Ms. Aswanimol P. V Pharm. D

Infection Prevention and Control in COVID-19 Suspected

Current information about COVID-19 suggests that the two main routes of transmission of the COVID-19 virus are respiratory droplets and contact. Respiratory droplets are generated when an infected person coughs or sneezes. Any person who is in close contact (within one meter) with someone who has respiratory symptoms (coughing, sneezing) is at risk of being exposed to potentially infective respiratory droplets. Droplets may also land on surfaces where the virus could remain viable; thus, the immediate environment of an infected individual can serve as a source of transmission (contact transmission).

Principles of IPC (Infection Prevention and Control) 2. strategies:

1. Ensuring triage, early recognition, and source control

Clinical triage includes a system for assessing all patients at admission, allowing for early recognition of possible COVID-19 and immediate isolation of patients with suspected disease in an area separate from other patients (source control). To facilitate the early identification of cases of suspected COVID-19, health care facilities should:

- encourage healthcare workers (HCWs) to have a high level of clinical suspicion
- establish a well-equipped triage station at the entrance to the facility
- institute the use of screening questionnaires according to the updated case definition
- post signs in public areas reminding symptomatic patients to alert HCWs
- Hand hygiene and respiratory hygiene are essential preventive measures
- 2. Applying standard precautions for all patients

Standard precautions include hand and respiratory hygiene, the use of appropriate personal protective equipment (PPE) according to a risk assessment, injection safety practices, safe waste management, proper linens, environmental cleaning, and sterilization of patient care equipment.

- all patients cover their nose and mouth with a tissue or elbow when coughing or sneezing
- offer a medical mask to patients with suspected COVID-19

perform hand hygiene after contact with respiratory secretions

HCWs should apply WHO's My 5 Moments for Hand Hygiene approach before touching a patient, before any clean or aseptic procedure is performed, after exposure to body fluid, after touching a patient, and after touching a patient's surroundings.

- hand hygiene involve cleansing hands with alcoholbased hand rub or with soap & water
- alcohol-based hand rubs are preferred if hands are not visibly soiled
- wash hands with soap and water when they are visibly soiled.
- 3. Implementing empiric additional precautions
- 3.1 Contact and droplet precautions:
- patients should be placed in adequately ventilated single rooms. For general ward rooms with natural ventilation, adequate ventilation is considered to be 60 L/s per patient
- patients suspected of having COVID-19 should be grouped together
- all patients' beds should be placed at least 1 meter regardless suspected from covid-19
- where possible, a team of HCWs should be designated to care exclusively for suspected or confirmed cases to reduce the risk of transmission
- HCWs should use a medical mask
- HCWs should wear eye protection (goggles) or facial protection (face shield) to avoid contamination of mucous membranes
- HCWs should wear a clean, non-sterile, long-sleeved gown
- HCWs should use gloves; boots, coverall, and apron is not required during routine care
- after patient care, appropriate doffing and disposal of all PPE and hand hygiene should be carried out. A new set of PPE is needed when care is given to a different patient
- equipment should be either single-use and disposable or dedicated equipment (e.g. stethoscopes, blood pressure cuffs and thermometers). If equipment needs to be shared among patients, clean and disinfect it between use for individual patient (Alcohol 70%)
- routinely clean and disinfect surfaces with which the patient is in contact;
- limit the number of HCWs, family members, and visitors who are in contact with suspected or confirmed COVID-19 patients
- 3.2 Airborne precautions for aerosol-generating procedures.

Some aerosol-generating procedures, such as tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before

intubation, and bronchoscopy, have been associated with an increased risk of transmission of coronaviruses.

- perform procedures in an adequately ventilated room
- use a particulate respirator at least as protective as a US National Institute for Occupational Safety and Health (NIOSH)-certified N95, European Union (EU) standard FFP2, or equivalent.
- use eye protection (i.e. goggles or a face shield)
- wear a clean, non-sterile, long-sleeved gown and gloves. If gowns are not fluid-resistant, HCWs should use a waterproof apron for procedures expected to create high volumes of fluid that might penetrate the gown
- limit the number of persons present in the room to the absolute minimum required
- 4. Implementing administrative controls

Administrative controls and policies for the prevention and control of transmission of COVID-19 within the health care setting include, but may not be limited to: establishing sustainable IPC infrastructures and activities; educating patients' caregivers; developing policies on the early recognition of acute respiratory infection potentially caused by COVID-19 virus; ensuring access to prompt laboratory testing for identification of the etiologic agent; preventing overcrowding, especially in emergency departments; providing dedicated waiting areas for symptomatic patients; appropriately isolating hospitalized patients; ensuring adequate supplies of PPE; and ensuring adherence to IPC policies and procedures for all aspects of health care.

5. Using environmental and engineering controls

These controls address the basic infrastructure of the health care facility14 and aim to ensure adequate ventilation in all areas in the health care facility, as well as adequate environmental cleaning. Additionally, separation of at least 1 metre should be maintained between all patients. Both spatial separation and adequate ventilation can help reduce the spread of many pathogens in the health care setting. Ensure that cleaning and disinfection procedures are followed consistently and correctly. Cleaning environmental surfaces with water and detergent and applying commonly used hospital disinfectants (such as sodium hypochlorite) is effective and sufficient. Manage laundry, food service utensils and medical waste in accordance with safe routine procedures.

Collecting and handling laboratory specimens from patients with suspected COVID-19.

ensure that HCWs who collect specimens use appropriate PPE (i.e. eye protection, a medical mask, a long-sleeved gown, and gloves). If the specimen is collected during an aerosol-generating procedure, personnel should wear a particulate respirator at least as protective as a NIOSH-certified N95, an EU standard FFP2, or the equivalent

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- ensure that all personnel who transport specimens are trained in safe handling practices and spill decontamination procedures
- place specimens for transport in leak-proof specimen bags (secondary containers) that have a separate sealable pocket for the specimen (a plastic biohazard specimen bag), with the patient's label on the specimen container (the primary container), and a clearly written laboratory request form
- ensure that laboratories in health care facilities adhere to appropriate biosafety practices and transport

- requirements, according to the type of organism being handled
- deliver all specimens by hand whenever possible. DO NOT use pneumatic-tube systems to transport specimens
- document clearly each patient's full name, date of birth and "suspected COVID-19" on the laboratory request form. Notify the laboratory as soon as possible that the specimen is being transported.

https://www.who.int/publications

Ms. Aneesha Mathew, V Pharm D

WHO & FDA NEWS

NEW DRUGS APPROVED BY FDA

Brand Name	Generic Name	Route & Therapeutic dose	Indiacations	Approva l Date	
AYVAKIT	Avapritinib	PO, 300mg OD	Metastatic GIT Stromal Tumour	Jan 9, 2020	
TEPEZZA	Tepropumumab	IV, 10mg/kg/day	Thyroid Eye Disease	Jan 21, 2020	
TAZVERIK	Tazemetostat	PO, 800mg bid	Epithelioid sarcoma	Jan 23, 2020	
PIZENSY	Lactitol	PO, 20g Powder OD	Chronic Idiopathic Constipation (Adults)	Feb 12, 2020	
NEXLETOL	Bempedoic acid	PO, 100mg/day	Heterozygous familial hypercholesterolemia	Feb 21, 2020	
VYEPTI	Eptinezumab-jjmr	IV IFU Once/3 months, 300 mg	Migraine (Adults)	Feb 21, 2020	
BARHEMSY S	Amisulpride	IV, 5 - 10mg/day	Postop Nausea and vomiting	Feb 26, 2020	
NURTEC ODT	Rimegepant	PO, 75 mg/day	Migraine	Feb 27, 2020	
SARCLISA	Isatuximab	IV, 10mg/kg/day	Multiple myeloma	Mar 2, 2020	
ISTURISA	Osilodrostat	PO, 2mg tid	Cushing's Disease	Mar 6, 2020	
ZEPOSIA	Ozanibod	PO, 0.92mg OD	Relapsing Multiple sclerosis	Mar 25, 2020	
TUKYSA	Tucatinib	PO, 300 mg bid	Advanced metastatic HER 2 positive Breast cancer	Apr 17, 2020	
PEMAZYRE	Pemigatinib	PO, 13.5mg/day	Cholangiocarcinoma	Apr 17, 2020	
TRODELVY	Sactizumabgovitecan -hziy	IV IFU, 10mg/kg/wee k	Metastatic triple negative breast cancer	Apr 22, 2020	
ONGENTYS	Opicapone	PO, 50mg OD	Parkinson's disease experiencing "off" episodes	Apr 24, 2020	
PO: Orally, IV: Intravenous; IV INF: Intravenous Infusion; OD: Once daily; bid: Two times a					

PO: Orally, IV: Intravenous; IV INF: Intravenous Infusion; OD: Once daily; bid: Two times a day; tid: Three times a day

Mr. Midhun J Madhu, III Pharm D

NEW MEDICAL DEVICES APPROVED BY FDA

Device name	Indication	Approval Date
Liaison® Xl Murex Anti -Hbc Liaison® Xl Murex Control Anti-Hbc - P180038	Blood Assay — Used to detect HBV antibodies in blood.	Jan 02, 2020
Abbott medical Infinity™ DBS Neurostimulation System -P140009/S039	Implantable neuro -stimulation device used in advanced levodopa—responsive Parkinson's disease.	Jan 20, 2020
Flow Re -Direction Endoluminal Device (FRED®) System - P180027	Stent indicated for the treatment of brain aneurysm by reducing or stopping blood flow to the aneurysm.	Jan 22, 2020
Bulkamid Urethral Bulking System - P170023	Treat stress urinary incontinence in women due to weak pelvic floor (urethral spincter) muscles.	Feb 14, 2020
Ventana Medical Systems CINtec PLUS Cytology - P190024	Detect proteins p16 and Ki67 in pap test specimens obtained from women with HPV infection.	Mar 10, 2020
Alto [™] Abdominal Stent Graft System – P120006/S031	Stent indicated for the repair of aneurysm of the infra renal abdominal aorta.	Mar 13, 2020
Venous Wallstent - P980033/S050	Stent intended to reopen narrowed regions of iliofemoral vein.	Mar 17, 2020
Liaison® Xl Murex Anti-Hbs, [Also contains Liaison® Xl Murex Control Anti-Hbs, and Liaison® Xl Murex Anti-Hbs Verifiers - P180039, to ensure that the test is working properly]	Detect human antibodies against the hepatitis B virus (HBV) in blood.	Mar 18, 2020
The cobas HPV for use on the cobas 6800/8800 Systems – P190028	Detect HPV (Human papillomavirus) in cervical samples.	Apr 03, 2020
The therascreen BRAF V600E RGQ PCR KIT—P190026	Detect the V600E mutation in BRAF gene tumour tissue in patients with metastatic colorectal cancer.	Apr 15, 2020

https://www.fda.gov/medical-devices

Ms. Winny John, III Pharm D

[•] https://www.fda.gov/drugs/new-drugs-fda

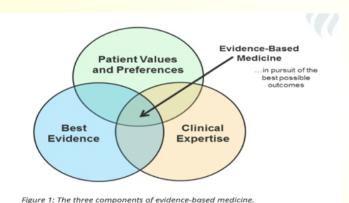
EVIDENCE - BASED MEDICINE

Evidence-based medicine (EBM) is the care of • patients using the best available research evidence to guide clinical decision making. It is the process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients.

Principles of Evidence Based Medicine:

- Evidence alone is never enough to make a clinical decision (or a decision about guidelines or evidence)
- Decisions and Recommendations should be guided by a hierarchy of strength of evidence

It is the integration of best research evidence with clinical expertise and patient values.



Why EBM?

- To improve patient healthcare.
 - To bridge the gap between best available research evidence and clinical practice.
 - To reduce the mortality due to poor healthcare practices.
 - A new treatment might have fewer side effects.
 - A new treatment could be cheaper or less invasive
 - A new treatment may be necessary in case people develop resistance.

- To keep knowledge and skills up to date.
- To save time to find the best available medical information.

Practice of EBM:

It involves five essential steps

- ASK: Formulate an answerable clinical question
- ACCESS: Track down the best evidence
- APPRAISE: Appraise the evidence for its validity and usefulness
- APPLY: Integrate the results with your clinical expertise and your patient values/local conditions
- ASSESS: Evaluate the effectiveness of the process

Evaluating the Evidence:

PICO (Population, Intervention, Comparison and Outcomes) model is generally followed when answering a clinical question.

- Population Patients' characteristics, disorder or problem of interest
- Intervention The intervention, diagnosis, treatment or prognosis is being considered
- Comparison Any alternate therapies available
- Outcomes The final desired outcome

EBM is the best practice to promote rational medication use and decision making. It helps in detection of adverse drug reactions, drug-drug interactions and can be a measure to reduce disease burden. Clinical pharmacists can play a vital role in implementing and practicing EBM in the hospital with their therapeutic knowledge and skill.

- https://www.eupati.eu/pharmacoepidemiology/evidence
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3789163
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3789163

Dr. Rahul R, Assistant Professor, Department of Pharmacy Practice, KLE College of Pharmacy, Bangalore

INVITED ARTICLES

SARS-CoV-2 - Still To Public, Brain Teaser To Researchers

SARS-CoV-2 (Severe Acute Respiratory Syndrome Corona Virus-2) is a disease of public health concern. Globally above 5736415 and in India above 157777 people are infected with SARS-CoV-2. These numbers are increasing every day. This disease drastically affected the economic burden of all the countries.

Beta Corona virus is single stranded RNA infects humans most likely by ACE2 (Angiotensin converting enzyme) receptors. Spread by droplet infection by cough, sneezing, touching the surfaces where viruses are deposited in the parts of the human body such as eyes, nose, mouth. Clinically, presents with headache, cough and fever, difficulty in breathing, fatigue, diarrhea (in few), shock and finally death. In few subjects, it has produced multi-organ failure without affecting the lungs.

Prevention is the first step to be followed with strict social distancing, wearing mask, hand wash. The disease can affect any one. But frequently affects high risk individuals such as who are aged above 60yrs, diabetic, chronic respiratory diseases, close contacts, health workers and immune-compromised. THERE IS NO SPECIFIC TREATMENT OR VACCINES IS AVAILABLE FOR SARS-CoV-2 INFECTION AS ON TODAY.

Various combinations of antiviral and other drugs like Oseltamavir, Ribavarin, Penciclavir, Remdesivir, Ritonavir, Ganciclovir, lopinavir, Favipiravir, Nitazoxamide, Nafamostat, Chloroquine, Interferon, Azithromycin, Corticosteroids and Anticoagulants are available and are being used for its treatment. Other new drugs on trial are: EIDD 2801, Leronlimab and Ivermectin.

Recent update with combination of Remdesivir and Chloroquine has improved the outcome in 36 out of 53 critically ill patients in US study. Chloroquine used in Brazil had two groups, one receiving higher dose had arrhythmias, was forced to stop. Anticoagulants and Plasma therapy have helped in multi-organ failure. Vaccines are under trials but takes months to come into pharmaceutical market.

Chloroquine and Hydroxychloroquine is an age old drugs used in malaria, rheumatoid arthritis,

systemic lupus erythematosus. Hydroxychloroquine is also used prophylactically for health workers, close contact with SARS-CoV-2 infected patients. It is to be used with caution in old age, heart problems, prolonged QT interval, patients on certain drugs like digoxin, amidarone, antihypertensives, quinolones, azithromycin etc. as it can induce arrhythmias and sudden deaths. Chloroquine is a weak base, which increases the pH of the endosomal vesicles where virus is not able to enter cell. It also as immune modulatory effects there by decreasing the severity of the disease.

Drugs are to be taken with precaution and under supervision. Avoid Ibuprofen during cold, cough, fever during this season, starting of ACEI for new case of hypertension and nebulizers. All the above drugs are to be provided with prescriptions only and ELECTRONIC ALERTS FOR ADVERSE EFFECTS. Prioritize the drug delivery to the needy patients. Individuals dispensing the drugs are informed to take utmost care by wearing mask, social distancing. Pharmacists are required to monitor the above, thereby decreasing the complications by Ibuprofen and Chloroquine. Also counsel all the people to wear mask and maintain social distancing. Regarding the unnecessary wastage of PPE (Personal Protective equipment) should be educated. Investigational Pharmacists with clinicians can play a significant role regarding: information about new drug, pharmacokinetics and safety profile, recommend alternative drugs if resistance occurs, counsel patients regarding adverse effects of the drugs and evidence literatures to clinicians, ensure continuous manufacturing and supply of new drugs during pandemic and see that physicians does not use suboptimal dosage when shortage is there. PHARMACIST SHOULD WORK PROACTIVELY TO HELP IN SPEEDY RECOVERY OF PATIENTS.

It is challenging in the world for the scientists as every day few developments are taking place. It effects all caste, religion, rich, poor, educated, uneducated. Stay safe, work safe!

> Dr. Bindumathi PL, Senior Consultant, Internal Medicine, Aster CMI, Bengaluru

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ALUMNI/INTERNS EXPERIENCE

Internship Voyage at Aster CMI Hospital, Bangalore

Pharm D. internship in a reputed hospital having prominent clinical pharmacy division provide us an insight about how clinical pharmacists in India work efficiently. My internship at Aster CMI hospital has truly been a great learning experience as it enhanced my knowledge and professional skills to attain functional independency. Aster CMI is a multispeciality hospital equipped with well experienced team of healthcare professionals. Clinical pharmacists Dr Praveen Kumar, Dr Renoy Philip and Dr Tazmiya have operational independence as well as they carry forth a wide range of significant clinical pharmacy services in the hospital and also look after interns from the allotted institutions. During our internship period, we were posted in various departments such as cardiology, internal medicine, gasteroenterology and endocrinology along with rotational shifts in outpatient and inpatient pharmacy.

The whole team of doctors at each department were highly welcoming and indeed accepted our views and suggestions which alone made us understand the importance of our profession. Ward round participation enabled us to create a good rapport with physicians and queries regarding drugs retained us up to date with current scenarios. We had case presentations on different challenging cases and also published case reports in collaboration with doctors of assigned department. The primary activities involved were adverse drug reactions monitoring, patient counselling and auditing of medications, storage of medications, prescriptions, vaccines and narcotics.

Prescription auditing at assigned floors/wards were done on a daily basis to identify the appropriateness of therapy with respect to drug, dose, dosage form, indications, contraindications, drug-drug interactions, drug-food interactions, intra venous incompatibility, drug intending and dilutions. Any error identified during this process would be rectified in-situ and later entered into the online incident reporting form. The major interventions were immediately

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notified to the corresponding physician thereby providing them vital pharmacokinetic and pharmacodynamic inputs to ascertain optimum therapeutic care. Medication reconciliation undertaken by clinical pharmacist with detailed review of medication history was performed to ensure that the patient is not placed at risk for duplication or dosing errors.

The adverse drug reactions management was well supervised which was then documented and reported to Pharmacovigilance Prgram of India (PvPI). Every phase of narcotics and vaccines management ranging from its purchase to post-administrative documentation audit were also carried out. Unlabelled and near expiry drugs were checked and reported while executing medication storage audit. Antimicrobial Stewardship (AMS Audit) steered by microbiology department and infection control team were undertaken by us to track antibiotics and its compliance with antibiotic policy of the hospital. Additionally, we got an opportunity to be trained in diabetic clinic that offers services such as NeuroScan and ABI tests for patients to rule out diabetic neuropathy. We participated in hospital organised conferences & workshops accredited by Indian pharmaceutical association in sponsorship with Glaxo Smithkline. Also we were privileged and honoured to sit with entire group of specialists and other members for weekly case presentations by chief physician from each department.

Overall it was a remarkable experience we received in Aster CMI Hospital. I am thankful to my preceptor Dr. Praveen Kumar who took his personal time of the day for appreciation and constructive criticism that helped us in the journey of becoming a professional. With the great support of our college management and teachers, we were lucky enough to get trained in such a serene hospital environment. I hope this article may encourage every intern to maximise each exposure you get and work hard to become the best possible version professionally and personally.

Aneena A. Philip, Pharm D. Intern

USE OF REMDESIVIR FOR PATIENTS WITH COVID-19



Remdesivir (GS-5734) was developed by Gilead Sciences and emerged from a collaboration between Gilead, the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). No specific antiviral drug has been proven effective for treatment of patients with severe corona virus disease (COVID-19). Remdesivir, a nucleoside analogue prodrug, has inhibitory effects on pathogenic animal and human corona virus including severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) in vitro, and inhibits Middle East respiratory syndrome corona virus, SARS-CoV-1, and SARS-CoV-2 replication in animal models. It may shorten the time it takes to recover from the infection. Treatment is given by injection into a vein.

Dosage

IV: Limited data available; dosing used in clinical trials: 200 mg as a single dose on day 1, followed by 100 mg once daily for a total duration of 5 to 10 days (Gilead 2020; NIH 2020a; NIH 2020b; NIH 2020c).

Activation

Remdesivir is a Prodrug that is able to diffuse into cells where it is converted to GS-441524 monophosphate via the action of esterases and phosphoramidase this in turn is further phosphorylated to its active metabolite triphosphate by nucleotide phosphate kinases.

Mechanism of action

It is a broad spectrum antiviral drug. The active metabolite of remdesivir interferes with the action of viral RNA-dependent RNA polymerase and evades proofreading by viral exoribonulease causing a decrease in viral RNA production. For the RNA-Dependent RNA

Polymerase of MERS-CoV, SARS-CoV-1, and SARS-CoV-2 arrest of RNA synthesis occurs after incorporation of three additional nucleotides.

Adverse effects

The most common adverse effects in studies of remdesivir for COVID-19 include respiratory failure and organ impairment, including low albumin, low potassium, low count of red blood cells, low count of platelets that help with clotting, and yellow discoloration of the skin. Other reported side effects include git-distress, elevated transaminase levels in the blood (liver enzyme) and infusion site reaction.

Clinical studies

With the COVID-19 outbreak increasing in size and a lack of alternative therapeutics, two clinical trials using remdesivir were designed and initiated in China. On February 5, 2020, a phase 3 randomized, quadrupleblind, placebo-controlled clinical trial was registered at Capital Medical University, with the goal to determine safety and efficacy of remdesivir in patients with mild to moderate SARS-CoV-2 infection (NCT04252664. since suspended). A day later, a second trial (NCT04257656, since terminated) was registered at the same location, focused on patients with advanced COVID-19 respiratory disease. Both trials had planned to track the primary outcome as time to clinical improvement, up to 28 days: normalization of fever, oxygen saturation, and respiratory rate, and alleviation of cough which is sustained for 72hr. Both trials delivered remdesivir as a 200 mg loading dose on the first day, with 9 subsequent days of maintenance dosing at 100 mg.

In India the use of remdesivir has not been started though various pharmaceutical industries like Cipla, Glenmark and Dr. Reddy are working on the development.

www.thelancet.com; www.ncbi.nml.nih.gov

Ms. Shristi Nayak, Pharm. D Intern

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LASMIDARTAN- POTENTIAL ROLE IN MIGRAINE

Lasmidartan is a newly introduced medicine for the treatment of acute migraine attack. Lasmidartan was developed by Elli Lilly and relicensed to Colucid Pharmaceuticals in 2006. The drug is protected by the patent till 2031. Migraine treatment generally includes acute treatment and preventive treatment. Current treatment approach towards migraine includes Triptans, NSAIDS, Ergotamine and Topiramate. NSAIDs are prescribed for the acute migraine treatment where as others as prophylactic treatment. Since preventive treatment does not eliminate all migraine attack, patient should also use acute medication. Lasmidartan comes under acute migraine treatment. Vascular and neuronal hypothesis are the suggested pathophysiology for the development of migraine. Since vascular hypothesis is no longer the prevailing theory of migraine pathogenesis, treatments that exclusively act on nonvascular target is focused nowadays. Lamidartan is a potential 5HT1F receptor agonist that lacks vasoconstrictive

Triptans were initially developed and it was the first drug of choice for the treatment of acute migraine attack. However, triptans are shown to increase the cardiovascular risk due to its vasoconstrictor property, hence they are contraindicated in the patients with ischemic heart disease. Lasmidartan is 5HT1F receptor agonist which is not found in the vascular structure it hasn't been shown to have vasoconstrictor effect and safe for the patient with pre-existing cardiovascular disease. Pharmacology profile shows

that effects of triptans are mainly have agonistic action on 5HTT1D and 5HTT1B receptors with less affinity for 5HT1F receptors. In contrast with triptans, Lasmidartan has 450 fold increased affinity for 5HT1F receptor which shows its effectiveness for the treatment of acute migraine attack better than triptans. Limited data is available on the pharmacokinetics of Lasmidartan. Intravenous formulation and oral dose of 50 mg 100mg and 200mg have been studied in phase 2 and phase 3 clinical trials respectively. But 50mg and 100mg tablet are currently in the market. Drug interaction profile shows that the drug must be used in caution with alcohol or other CNS depressants. Safety profile of lasmidartan didn't show any clinically significant drug related morbidities. Adverse drug reaction associated with Lasmidartan is however mild or moderate in intensity. Adverse drug reactions are likely to increase with dose. Common side effects include dizziness, paraesthesia, fatigue, nausea and lethargy.

Clinical trials for lasmidartan to date have been promising as better drug of choice for the treatment of acute attack of migraine as alone or combination with prophylactic treatment but its prophylactic use is yet to be confirmed.

(1) Schulte LH, May A. Brain 2016; 139(7):1987–93, (2) May A, Schulte LH. Nat Rev Neurol. 2016; 12(8):455–464. (3) Humphrey PP et al.Ann N Y Acad Sci. 1990; 600(600):587-600. (4) Maassenvandenbrink A et al. Circulation. 1998; 98(1):25–30.

Mr. Ramshad TP, Pharm D Intern

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KLE NSS Initiatives under the dynamic leadership of Dr. Raman Dang (NSS Chairman & Principal) and Dr. Mamatha.A (NSS Programme Officer & Professor)



University Level NSS Swachhata Camp 2020







University Level Swachhata Camp [Jan. 1-7, 2020]

A special funding through Dr. Mamatha.A, NSS Programme Officer, was obtained from Ministry of Youth Affairs, Government of India for the conduct of University Level Swachhata Camp 2020. The program was inaugurated by Chief guest Dr. S. Sacchidanand, Vice-Chancellor, RGUHS. The function was presided by Dr. Raman Dang, Principal, KLE College of Pharmacy. The agenda for every day was half day of Shramadhaan

activities at various places creating awareness on swacchata with rallies and cleaning activity in and around KLE College campus, KLE Dental College, Hostel, Public parks, streets, BMTC Mahalakshmi Layout bus depot, BBMP health care centre, Subramanyanagar ward and at Kumbarahalli village, Shidalghatta taluk, Chikkaballapura District. Post afternoon sessions were also organized everyday with guest talks by eminent speakers on Swachhatha awareness. 100 NSS volunteers from various universities actively participated in the camp.

Walkathon For Future of Bengaluru













Walkathon for Future of Bengaluru [Feb. 15, 2020]

Forty five NSS Volunteers along with NSS Programme Officer attended "Walkathon For Future of Bengaluru" from Vidhanasoudha to Corporation BBMP Office. The programme was organized by BPAC, BCLIP, NSS Karnataka.

COVID 19 Relief Activities [March – April 2020]

Creation of awareness to public was carried out by preparing and sharing online flyers on steps for Hand washing, Steps to wear face mask, Herbal remedies, Ayush Sutra, Myth busters, Creations of Covid 19 Awareness Short Videos through various platforms like youtube (https://youtu.be/Mzv1QkrUrNo), instagram, twitter and whatsapp status.

Actively our NSS volunteers counselled the public with respect to health related issues, hunger help lines, blood donation help lines etc to the needy. Feeding food to poor people and to stray animals were also some of the main activities carried out.

NSS Unit 8 of KLECOP, Bangalore had organized two online training sessions for all the NSS volunteers, students and staff under the direction of NSS Regional Directorate-Bangalore, Ministry of Youth Affairs and Sports, Government of India.

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COLLEGE PROFESSIONAL ACTIVITIES FROM ALL DEPARTMENTS

Department	Activity Type		Total Number		Certification
			Organized	Attended	
Pharmacy Practice	Guest Lecture	Online	1	42	Yes
		College	1	35	
	Certification Course	Online		76	Yes
Pharmacology	Guest Lecture	Online		84	Yes
	Certification Course	Online		5	Yes
Pharmaceutics	Guest Lecture	Online	3	64	Yes
		Online	1	6	Yes
	Certification Course	Online		6	Yes
Pharmaceutical Chemistry	Guest Lecture	Online		90	Yes
v	Certification Course	Online		14	Yes
Pharmacognosy	Guest Lecture	Online	2	18	Yes
Pharmacognosy Note: Period is from Januar		Online	2		18

A Review: Pandemic Novel Coronavirus (COVID-19)

Contagious viral and bacterial diseases such as herpes and legionellosis in the 1970s to HIV, Ebola, the SARS, and now COVID-19 continue to put pressure, stress and bringing dreadful conditions, economic loss across the world. COVID-19 highly transmitted from person to person, thus needing isolation of patients and maintenance of the quarantine.

The epidemic, novel corona virus 2019 was first reported in December 2019 in Wuhan, China. WHO has announced the outbreak of SARS-CoV-2 infection as pandemic on March 11, 2020. The

substantial morbidity and mortality continue to be happening till date. Following vaccines and drugs are under clinical trials towards the prophylaxis and treatment of COVID-19.

 Vaccines: Fusogenix DNA vaccine, Gimsilumab, human monoclonal antibody, AdCOVID, a single dose intranasal vaccine, TJM2, a neutralizing antibody, Virus-Like Particles (VLP) by Medicago, AT-100 (rhSP-D), a novel human recombinant protein.TZLS-501 a monoclonal antibody, Altimmune's intranasal coronavirus vaccine. Drugs:OYA1, strong antiviral, Remdesivir (GS-5734), Actemra, Galidesivir (BCX4430), Regeneron, SNG001, natural Interferon-β, Amnio Boost for ARDS. Remdesivir has been authorized for emergency use in the U.S. against COVID-19.

The spread of COVID-19 can be prevented by

maintaining social distance, well hygienic conditions and sanitization. The research work for its diagnosis, prevention and treatment already initiated across the globe. Repositioning of drug efforts would be helpful in this emergency scenario as pharmacokinetics and pharmacodynamics of the drug are known.

Hariprasad MG, Narayan SS, Biki RA. Global J Med Res. 2020; 20(4):1-6. **Dr Hariprasad MG,** Head, Department of Pharmacology

PHARMACIST AND LANGUAGES: AWARENESS FOR BETTER SERVICES

Each pharmacist completes his/her basic education in either local or English language medium in India. Irrespective of the language medium selected, at least two official languages are learnt as per the state or central education system of our country. English is one and another local language of a state. Both are official languages (Official language is spoken, read and written). Our basic education exposure shows that the pharmacist is capable of serving as healthcare professional in two languages in his/her native state. For example, a pharmacist with basic education from Karnataka state can serve as healthcare professional in Kannada and English languages.

By conventional healthcare working system, we all know that we can serve confidently in two official languages in a particular state. We expect the patients to understand the education/counseling about medications through the official languages. While serving, pharmacist including other healthcare professionals meets the patients who use non-official language (Non-official language is spoken but do not have its own script) in the hospital or community

pharmacy especially on rural/semi-rural side. In support, there are 72 non-official languages used by the people living in Karnataka state beside official language, Kannada. Of these, 50 languages are spoken by tribal people and remaining (22) languages are scheduled (frequently spoken)¹. In such situation, pharmacist services become more challenging while providing the patient education/counseling about medications. Awareness about such language barrier helps pharmacist to provide pharmaceutical care including medication education/counseling that is planned, validated, improved and customized in the language best known to the patient for better care².

- 1. Shivakumar ND. Times of India, August 10, 2013.
- 2. Partida Y. Diabetes Spectrum 2012; 25(1): 19-22.

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