Scientific Tracks & Sessions
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Pharmaceutical Science 2022





2nd European Congress on

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Sessions

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Mass Spectroscopy & Chromatography | Pharmacovigilance & Drug Safety

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Josué Bautista Arteaga, Global Pharmacovigilance Society & JBA Farmacovigilance, Mexico

Title: Effects of Cassia occidentalis extract treatment on reproduction and fertility in male rats

Pratap Chand Mali, University of Rajasthan, India

Title: Design and Synthesis of potent transition state analogs of HIV-1wild type C-SA protease inhibitors

S.N. Sriharsha, Rajiv Gandhi University of Health Sciences, India

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Pharmacovigilance Systems in Latin America for COVID-19 Vaccines Brazil, Chile, Costa Rica and Mexico

Josue Bautista Arteaga
Global Pharmacovigilance Society & JBA Farmacovigilance, Mexico

One of the greatest challenges to pharmacovigilance in Latin America has been the sensitivity and willingness of the population, healthcare professionals and patients, to report adverse events. As vaccination has been one of the key instruments in combatting the COVID-19 pandemic, are these pharmacovigilance systems positively influencing this sensitivity and willingness to be an active part of the surveillance of these vaccines in this public health emergency.

The pharmacovigilance field in Latin-American works through four steps to examine whether the information obtained through these "real-life" (or real-world) reports is in accord with previous knowledge of these vaccines or if they present new relevant safety information that demands action: Analyze risk, understand risk, communicate risk, and mitigate risk. This article overviews the state of COVID-19 vaccinations and the systems established to analyze, understand, communicate, and mitigate their risk in Brazil Chile, Costa Rica and Mexico. e.g. Brazil.

As of the end of November 2021, an estimated 300 million doses of four available vaccines had been administered in Brazil. The National Drug Monitoring Center, which was established as part of the Brazilian regulatory agency ANVISA in 2001, conducts safety surveillance of these vaccines based on five operational pillars:

- Daily evaluation
- Signal detection
- Risk management plan
- Monthly executive summary of AEs
- Periodic quarterly benefit-risk assessment reports

Through these and other paths of action, Brazil, Chile, Costa Rica and Mexico have adapted current structures and created new ones to communicate relevant safety information to their respective populations with transparency and robustness to ensure that the benefits of COVID-19 vaccines continue to outweigh their risks. Therefore, thanks to these innovations and updates of pharmacovigilance systems, significant improvements have been achieved that transcend in building confidence in these tools that drug science has provided us to be able to deal with a pandemic such as COVID-19.

Speaker Biography

Josue Bautista Arteaga is a Pharmacist, his experience is mainly related with the Pharmacovigilance field: ICSRs, PSURs-PRBERs, Signal Management, Risk Management and Risk Minimization, Audits, Inspections, Legislations, Vendor and CRO management, Interaction with Independent PV Organizations, Regulatory Agencies as well as Pharmaceutical Chambers. As part of his PV career, he worked at GlaxoSmithKline, Merck Sharp & Dohme, and Pfizer. Founder of the Global Pharmacovigilance Society (GPS) as well Chairman for the AMERICAS region, in addition he is also member of the International Society of Pharmacovigilance (ISoP). Founder of "JBA Farmacovigilancia", entity aims to build innovative scenarios to learn, share, apply and build knowledge in Pharmacovigilance across the LATAM region. Former president of the Mexican Drug Safety Society.

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Effects of Cassia occidentalis extract treatment on reproduction and fertility in male rats

Pratap Chand Mali
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Objective: Many plants have been explored to control fertility and birth across the world. The present study was designed to investigate the effects of Cassia occidentalis on fertility potential of male albino rats aiming to develop a safe and reversible herbal male contraceptive.

Methods: Hydroalcoholic extract of Cassia occidentalis fruits was administered orally in the male rats at different doses for 60 days. Animals were maintained on controlled conditioned by following CPCSEA and IAEC guidelines for the experiments. The effects of the treatment on body weight, reproductive organs weight, biochemical profiles, sperm counts and motility, hormones and fertility potential was measured. Data were analyzed statistically.

Results: Data reveals that weights of testes and sex accessory reproductive organs were significantly reduced in the rats followed drug treatment. Level of testosterone hormone, sperm motility and density, protein, fructose, ascorbic acid, and sialic acid contents were significantly declined in the extract-treated rats as compared to vehicle-treated controls. Histopathology study of testes of the extract treated rats shoed degenerative changes in the structure of testes and spermatogenic process resulted reduction of fertility.

Conclusions: It can be concluded that Cassia occidentalis extract treatment reduced fertility of rats might be due to antiandrogenic nature of the treatment.

Key Words: Cassia occidentalis, Contraceptive, Fertility, Rats, Hormones.

Speaker Biography

Pratap Chand Mali did M.sc in Zoology and Ph D in Reproductive Biology. Prof. Mali main research interest is to develop a male contraceptive from traditional medicinal plants to control fertility; he published 100 research papers in the journals of international repute. He is an active Member of (i) Indian Science Congress Association (ii) Indian Society for the Study of Reproduction and Fertility (ISSRF) (iii) Society for Reproductive Biology and Comparative Endocrinology (SRBCE) and associated with the 12 Journals includes Frontiers in Reproductive Bioscience, Journal of Life Medicine (JLM),International Journal of Zoology Research, Agricultural and Biological Sciences Journal, International Journal of Plant Research, International Journal of Life Science and Engineering, International Journal of Life-Sciences Scientific Research, International Journal of Pharmacology and Biological Science and Journal of Medical Science and Clinical Research. He has been participated in more than 75 Seminars/ Symposium / Conferences / Workshops in India and abroad. He organized International Conference on Multidisciplinary Approaches to Diabetes Research & Health (ICMADRH - 2010), University of Rajasthan, Jaipur, India, November 14-16, 2010 and National Workshop on Biomedical Instruments & Technologies (NWBIT- 2015) organized at Department o Zoology, University of Rajasthan, Jaipur on March 13-14 th 2015.He is recipient of 2 Awards 1.Asia-Pacific Council on Contraception (APCOC) Talents Encouragement Award by organizer of the Second Congress of the Asia-Pacific Council on Contraception on “Contraception for all: how, why, what and when?” held at Macau, China on December 4-6, 2008 and 2. Conferred: Best Citizen of India Award, 2010. Dr. Mali supervised seven research scholars have been awarded Ph. D degree and 2 are persuing.

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Design and Synthesis of potent transition state analogs of HIV-1 wild type C-SA protease inhibitors

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Increasing number of HIV/AIDS infected patients and related deaths, along with severe treatment-associated complications, make the HIV/AIDS pandemic more complex than ever.1,2 The introduction of HIV protease inhibitors (PIs) in the mid-1990s dramatically changed the situation for HIV/AIDS patients.3-6 Combination therapy initially including one protease inhibitor and two nucleoside reverse transcriptase inhibitors, the so-called highly active antiretroviral therapy (HAART) furnished a sharp decline in HIV/AIDS related mortality for patients receiving this therapy.[7,8]

Based on this concept we have designed and synthesized eleven novel PCU-lactam peptide analogs with the modification of substituent amino acids. It was shown that the lactam bond of compound 5 is virtually non-hydrolyzable.

The rationale behind using the cage lactam is that when it is incorporated into a short peptide, this cyclic amide bond could perhaps serve as non-cleavable peptide bond under protease conditions. The lactam hydroxy group could also serve as a transition state mimic since it is a norstatin type isoster

(Fig 1). If that were to be the case, then this family of cage peptides could potentially exhibit HIV protease inhibitor characteristics.

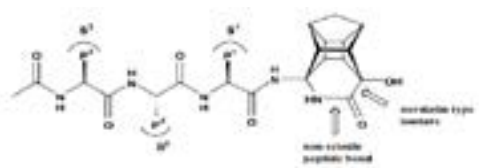

Figure 1: General structure of proposed non cleavable pentacylcloundecane-lactam Norstatin type HIV-1 protease inhibitor.

In conclusion, all eleven synthesized novel compounds displayed good inhibitory activity against wild type C-SA HIV-1 protease in which compound 6a and 6k being the most potent compared to reference standards atazanavir and lopinavir. These novel compounds are expected to have an improved membrane permeability imposed by the PCU skeleton. Their activity is expected to remain analogous under in vivo testing since the PCU should have the added advantage of increased permeability across the cell membrane. Further optimization as well as in-depth structural and biological studies of the selected protease inhibitors are the subject of our ongoing investigation

Speaker Biography

S.N. Sriharsha completed his doctorate in Medicinal Chemistry. He is a Principal, Professor, and Research Director, Hill Side College of Pharmacy and Research Centre and Academic Council Member RGUHS. Industry worked at Senior Positions: Dr. Reddys Bangalore, Biocon and Mili Health care (Russian Based Company), New Delhi. Awards and Achievements:Key note Speaker in International drug Discovery conference on Pharmaceutical Science and drug manufacturing in Thailand 2021. Presented Research paper against corona virus. Key note Speaker in International drug Discovery conference on Pharmaceutical R&D and Biopharmaceutics in Kaulalumpur, Malaysia 2019. Presented HIV drug discovery paper. International Advisory board in Bioleagues. Award for the Excellency in Scientific Research in 2018 in recognition to significant contribution in the field of Research and Development in Oriental University, Indore, MP. Director Pharma Companies:Bhuvika Health Care Bangalore and Mili health care, New Delhi. Services: Pharma Technical consultancy services R&D(Synthetic and formulation), Plant set up, Exports, contract manufacturing, regulatory, BA/BE studies, Clinical, analytical support, DMF and Dossier support etc.

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