Theme 3

Pharmacovigilance protocols in Traditional Ayurvedic medicines of Herbal origin

Utilizing herbal drugs in chemotherapy: An alternative strategy

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Abstract

Anticancer drugs have serious adverse effects reported. Even if these drugs are used overlooking their adverse effects, there is no promise for the cure of disease (Cancer). Many a time, death may occur due to the severe toxic effects of the chemotherapeutic agents. Anti-cancer drugs cause severe damage to all most all the systems of the human body. Many of the chemotherapeutic drugs for the cancer treatment are molecules identified and isolated from plants and/or their derivatives. Most importantly plant drugs have less or no side effects or adverse reactions. In India, hundreds of plants have been explored for their therapeutic applications in cancer. Though there are many highly potent anti-cancer molecules gifted by plants, yet there is no therapeutic application of plant/plant extract for the same use. But there is enormous evidence that hundreds of plants have the potential to reduce the drug induced toxicities in human beings. Hence we have made an attempt the screen herbs for their potential to reduce the drug induced toxicities in cancer treatment. The present topic discusses the different approaches in screening herbs for their potential to reduce the toxicities of anticancer agents and their agonistic activity.

Keywords: Anticancer, Adverse effect, Herbal Drug.

Unique medicinal plants of North Eastern Region and development of phytopharmaceuticals

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Abstract

North Eastern Region of India is part of both Eastern Himalaya as well as Indo-Burma biodiversity Hotspots. Due to unique biogeographic location, this region forms major biomes with unique medicinal & aromatic plants, microbes and animals. The traditional communities of this region are using these local bioresources for curing many diseases using herbal medicines. Medicinal and aromatic plants are valuable resources for the traditional healthcare system practiced by many traditional healers of this region. Indigenous knowledge and traditional uses of medicinal plants of the region are not properly documented, evaluated and scientifically validated. In this context, IBSD has established Phytopharmaceutical Mission to promote the documentation, scientific validation and evaluation of these bioresources and traditional healthcare practices. This includes ethnobotany, ethnopharmacological perspectives of medicinal plants including chemical profiling, quality evaluation and evidence-based validation.

Keywords: Microbes, Eastern Himalaya, Traditional healers.

Biomarkers as a Tool for Herbal Drug Discovery

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Abstract:

Biomarkers act as an indicator of normal biological processes, pathogenic processes or responses to an exposure or intervention. They can be of several types like Diagnostic Biomarkers, *Monitoring biomarker,* Pharmacodynamic/response biomarkers, Predictive biomarkers, Prognostic biomarkers, Safety, Susceptibility/risk, Complex biomarkers, Digital biomarkers. DNA act as Biomarker or as Molecular Marker. DNA markers are reliable for informative polymorphisms as the genetic composition is unique for each species and is not affected by age, physiological conditions as well as environmental factors. DNA based molecular techniques are PCR- based methods, Hybridization based methods, Sequence based methods. Molecular markers are significantly used in screening of herbal drug discovery. Genetic variation/genotyping, Authentication of medicinal plants, Marker assisted selection of desirable chemotypes, Medicinal plant breeding, applications in foods and nutraceuticals, DNA markers as new Pharmacognostic tool, these all are application of the molecular markers. DNA-

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based molecular markers are in progress in many research institutes all over the world. This technique remains important in plant genome research with its applications in Pharmacognostic identification and analysis. ISSR–PCR has been found to be an efficient and reliable technique for the identification of zygotic plantlets in citrus interploidy crosses. AFLP analysis has been found to be useful in predicting phytochemical markers in cultivated Echinacea purpurea. Sequence characterized amplified region (SCAR), AP–PCR, RAPD and RFLP have been successfully applied for differentiation of these plants and to detect substitution by other closely related species. This presentation briefly discusses biomarkers, DNA as Biomarker or Molecular Marker and its application in herbal drug discovery.

Keywords: Biomarker, Pharmacodynamic, AFLP.

Pharmacovigilance Protocols In Traditional Ayurvedic Medicines Of Herbal Origin

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Abstract

Diabetes is a very complex, chronic metabolic disorder characterized by elevate level of glucose in blood. This elevated blood glucose leads over time to serious damage to the heart, blood vessels, eyes, kidneys and nerves. Diabetes is may be due to the rapid change in dietary patterns, physical inactivity, and increased body weight, especially the accumulation of abdominal fat is some of the primary reasons for increased diabetes. According to WHO about 422 million people worldwide, and India ranked 2 in the cases of diabetes according to "the Hindu". About 1.5 million deaths are directly attributed to diabetes each year. Herbal medicines treat a chronic condition with little side effects and health promotion for enhancement of the span and quality of life. Many herbal drugs are used in the treatment of diabetes like; Aloe vera, Bitter gourd, Garlic, Onion, Neem, Mango etc. In this work we performed pharmacovigilance study to detect, understand and prevent the adverse effects or any other possible herbal drug, traditional and complementary medicines related problems used in treatment of diabetes.

Keywords: Diabetes, Herbal drug, Adverse drug reaction, Pharmacovigilance.

Pharmacovigilance of Herbal Drugs

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Abstract

The importance of herbal remedies in pharmacovigilance systems is becoming one of the primary tasks, due to the constantly ascending potential of herbal products and herbal medicines worldwide. Nowadays, the drug development is focused on finding new active compounds or combinations. There is an increasing awareness at several levels of the need to develop pharmacovigilance practices for herbal medicines. The current model of pharmacovigilance and its associated tools have been developed in relation to synthetic drugs, and applying these methods to monitoring the safety of herbal medicines presents unique challenges in addition to those described for conventional medicines. Several problems relate to the ways in which herbal medicines are named, perceived, sourced, and utilized. This may be because of differences in the use of nonorthodox drugs (e.g., herbal remedies) which may pose special toxicological problems, when used alone or in combination with other drugs. The purpose of pharmacovigilance is to detect, assess, and understand, and to prevent the adverse effects or any other possible drug-related problems, related to herbal, traditional, and complementary medicines.

Keywords: Adverse drug reaction, Medicines, Pharmacovigilance.

Pharmacovigilance and ADR Reporting

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Abstract

WHO International drug monitoring program was set up following Thalidomide disaster since 1978. It is conducted by Uppsala Monitoring center (UMC) Sweden. In India, WHO sponsored and World back funded national Pharmacovigilance program of India. Pharmacovigilance started about 170 years ago, although it was not yet named as such at that time. It is structured activity in the professional health field, with important social and commercial implication aimed at monitoring the risk/benefit ratio of drug, improving patient's safety and the quality of life. In the commentary we report the milestones

of the pharmacovigilance up to the present day. Pharmacovigilance is the pharmacological science related to the collection, detection, assessment, monitoring and prevention of adverse effect with pharmaceutical products. As such Pharmacovigilance heavily focused on adverse drug reaction. Pharmacovigilance of India (PvPI) is situated in CDCSO (Ghaziabad) NCC. All health workers have to report the ADR. We have to report about all suspected reaction, including minor ones of new drug & established drugs. MCI made mandatory to have Pharmacovigilance committee see its functioning. Frequent training, workshop is required to sensitize health care workers.

Keywords: Pharmacovigilance, Adverse drug reaction, MCI, UMC.

Pharmacovigilance protocols in Traditional Ayurvedic medicines of Herbal origin

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Abstract

Traditional medicines of herbal origin being widely accepted therapeutic agents as antidiabetics, antiarthritics, hepatoprotectives, cough remedies, memory enhancers, and adaptogens. However, the commonest myth regarding usage of herbal medicines is that these medicines are completely safe, and can therefore be safely consumed by the patient on his/her

own, without a physician's prescription. This belief has led to large-scale self-medication by people and often leading to disappointing end-results or unwanted after-effects by consumption of medications. Given the current scenario of the usage of the traditional and alternative medicine at a global scale, it becomes imperative to ensure the safety of the patients consuming these medications. This makes the science of pharmacovigilance, a significant domain in the field of medicine and public health as well. The purpose of pharmacovigilance is to detect, assess, and understand, and to prevent the adverse effects or any other possible drug-related problems, related to herbal, traditional, and complementary medicines. The safety and quality of herbal medicine should be ensured through greater research, pharmacovigilance, greater regulatory control, and better communication between patients and health professionals. Pharmacovigilance in herbal medicine in India is perhaps an unthought of concept as yet; but we need to wake and monitor the safety of herbal medicines. In addition, systematic pharmacovigilance is essential to build up reliable information on the safety of herbal medicines for the development of appropriate guidelines for safe effective use.

Keywords: Traditional medicines, pharmacovigilance, safety of herbal medicines.

Conservation of biodiversity of plants used for medicine production

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Abstract

The emerging trend in the field of herbal industry clasps an immense prospective to development of quality medicines in India. Herbs are excellent source of medicine, food, flavour, dyes, fragrance, etc in Ayurvedic systems of medicine is in increasing trend. It is estimated that, 95% of the medicinal plants used collected wildly possessing rich active pharmaceutical principles. Although there are around 8,000 medicinal plant species used by different communities in India across different ecosystems, only around 10% of them are in active trade. There is necessitating for encouragement in cultivation and protection of these valuable plants. The scientific techniques of conservation of genetic diversity of these plants like legislation, i*n-situ* conservations and *ex-situ* conservations.

Contemporary developments and future approaches for the modernization of natural products use as medicines, for health and well-being, and strategies to poise the therapeutic use of biodiversity with its proactive conservation through nature-based solutions.

Keywords: Biodiversity, medicinal plants, cultivation, herbal medicine

Preliminary Phytochemical and Acute Toxicity Study of Dried Leaves of *Cinnamomum Camphora*

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Abstract

AIM- The aim of the present investigation is to study the preliminary study of dried leaves of Cinnamomum Camphora. MATERIAL & METHODS- Dried leaves of Cinnamomum Camphora were procured from the medicinal garden and campus of Pharmacy College in the

month of September, Bhopal, Madhya Pradesh, India. Around 500 gm dried leaves of Cinnamomum Camphora were coarsely powdered weighed and filled in Soxhlet apparatus for extraction. First the powdered drug was defatted with petroleum ether (60°C-80°C); Defatted drug was then dried and again filled in soxhlet apparatus for successively extraction with dichloromethane, ethyl acetate, methanol and water as solvent. The extraction was carried out for a period of 72 hrs. The extract obtained was dried in vacuum to remove excess solvent and were weighed for the determination of % yields. Qualitative chemical tests of all extracts were subjected to various chemical tests to detect various Phytoconstituents. The acute oral toxicity studies were carried out according to the guidelines set by the Organization for Economic Co-operation and Development (OECD), revised draft guideline 423. RESULTS- Dried leaves of Cinnamomum Camphora were extracted using pet ether, dichloromethane, ethyl acetate, methanol and water and the percentage yield was found to be 5.2, 7.8, 8.5, 9.7, 9.4 %. The preliminary phytochemical analysis revealed that different active constituent present in different extracts such as carbohydrates, proteins, amino acids, fat, oils, steroids, terpenoids, glycosides, alkaloids, tannins and other phenolics compounds. CONCLUSION- No toxic effects were observed at a higher dose of 2000 mg/kg body weight of Wistar rats. Hence, 1/ 10th dose was selected as effective dose or therapeutic dose. The cut off value of 200 and 1/5 dose double of 400 mg/kg were selected for further activity.

Keywords: Preliminary Phytochemical, Acute Toxicity Study, Dried Leaves, Cinnamomum Camphora, OECD Guidelines.

Adverse event of Medical Devices: Materiovigilance

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Abstract

More than 5% hospitalization are associated with adverse event of medical devices. This number may increase in near future as use of medical devices continuously rising. In-order to identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of patient's health by preventing its recurrences, Materiovigilance Programme of India (MvPI) has been implemented to ensure the safety of medical devices. The initial and ultimate objective of the concept happens to be unfailingly to ensure patient safety as well as impart required guidance for both manufacturers and adept authorities enabling them to superintend cases coherently and appropriately. However, for a long period, there was no proper vigilance system that monitors the adverse events related to medical devices. Medical Device Adverse Event Monitoring Centres (MDMCs) have been established to create awareness about the programme and enhance the quality of reporting. Under MvPI a total of 174 MDMCs have been identified in the country to report the adverse events associated with the use of medical devices, purely on voluntary basis. A standard reporting format called 'Medical Device Adverse Event Reporting Form' has been developed by IPC for collecting and monitoring adverse events associated with medical devices and IVD. Our objective is to increase the awareness and to give insight about Materiovigilance programmed of India.

Keyword: Materiovigilance, Adverse event, Medical devices.

HPTLC Method Development and Validation of Bioactive for Treatment of Ulcerative Colitis: Application in a Polyherbal formulation

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Abstract

Ulcerative Colitis is a chronic inflammatory disease of the gastrointestinal tract with conventional therapies involving amino salicylates, immunosuppressants, and corticosteroids. However, the side effects associated are life-threatening. Therefore, herbal products with adequate standardization are looked upon as safe alternatives. The phytochemicals such as Curcumin (C), Quercetin (Q), Luteolin (L), and Gallic acid (G) have demonstrated evidence as effective agents either alone or in combination. To establish effective quality controls, the aim of the current study was to develop, and validate an HPTLC method for simultaneous determination of the four markers and establish its utility in a polyherbal formulation. Individual standards were spotted on aluminum precoated silica gel $60F_{254}$ TLC plate of 8mm band length. The plates were developed on a pre-saturated chamber containing mobile phase of Toluene: Ethylacetate: Formic acid (6:4:0.5 v/v/v). The plates were visualized and scanned at 280 nm for G and 378 nm for C, Q and L. The analysis resulted in well-resolved, peaks with R_f values of 0.14, 0.23, 0.31, 0.42 for G, L,Q and C respectively. The method developed was further validated according to ICH Q2 (R1) guidelines. The responses were linear in the range of 100-1000 ng/ spot for C, 200-1200 ng/spot for G and Q, and 200-1400 ng/spot for

L. Additionally, the method was found robust and sensitive in simultaneously determining the four markers with adequate precision and accuracy. Further, the developed method was applied in a marketed formulation (Zealous Ibzess R_X), and the percentage content obtained for G-2.81±0.36% Q–0.093±0.01, L–0.091±0.00, C-1.33±0.18%.

Keywords: (Ulcerative Colitis, Phytochemicals, Standardization, HPTLC.

Materiovigilance: An Indian Perspective

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Abstract

Materiovigilance is the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of patient's health by preventing its recurrences. Post marketing surveillance of medical devices has been initiated in many countries, but it is still not as developed and robust as that of medicines. Materiovigilance program of India was launched on July 6, 2015, at Indian Pharmacopeia Commission with objectives to track the adverse events associated with the use of medical devices, to generate safety data, create awareness among the different stakeholders, and recommend the best practices and interventions to improve the patient's safety. There is an upsurge in the use of medical devices in recent years. Despite that, there are not adequate measures to protect the patients from the untoward occurrences associated with the use of medical devices.

Keywords: Adverse event, medical device, post marketing, vigilance.

A Prospective Observational Study to Monitor and Report Adverse Drug Reactions Due to Hydroxyurea in a pediatric patient with Sickle Cell Disease

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Abstract

Background: Hydroxyurea that are the mainstay of treatment of sickle cell patients and linked to adverse drug reactions but safety data on pediatric patient is still unknown. **Objective:** The main objective of our study to determining the pattern of ADRs due to Hydroxyurea in a Paediatric patient with sickle cell disease. **Methodology:** A prospective observational study total of 300 subjects received Hydroxyurea treatment. They were screened for possible ADRs. Possible risk factors for the development of ADRs were also assessed. The causality and severity assessment of the observed ADRs was done by WHO-UMC scale, Naranjo's algorithm, and Hartwig-Siegel scale respectively. Preventability and Predictability assessment of ADRs was also done. **Result:** The prevalence of ADRs in patients receiving HU is 24.33%. Females are found to be at higher risk for developing adverse drug reactions compare to male. Polypharmacy and Multiple comorbidities are also considered to be possible risk factors. The maximum number of ADRs fall into the possible criteria of causality assessment by the WHO-UMC scale and Naranjo's algorithm. All the observed ADRs fall into the mild and moderate category of severity by the Hartwig-Seigel scale. **Conclusion:** Intense monitoring by clinical pharmacist and increased awareness in a health care professionals can help improve the rate of ADR(s) occurrence in patients.

Keywords: Adverse Drug Reaction, Paediatric, Pharmacovigilance, Hydroxyurea, Sickle cell disease