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POSTER PRESENTATION

Abstract No. AP-01

Abstract Title: A review on need of *Vatsanabha* (*Aconitum ferox*) *Shodhana* and its Pharmacovigilance concern

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Background: Practice of Indian system of medicine is considered to be the safest form of therapy, however incidence of ADR owing to the consumption of traditional drug necessitates the introduction of Pharmacovigilance of ASU drugs. *Vatsanabha* is one such drug mentioned in various Ayurvedic formulation, on which many reports have been publishing regarding its ADR.

Methods: A thorough literary review was carried out through various classical text books like *Bhaishajyaratnavali, Bhavapraksha, Rasatarangini* etc and various databases like Pubmed, science direct, Google scholar, Dhara using the key word *Vatsanabha*, ADR, *Aconitum ferox*, A total of 6 papers was found to be relevant and selected for the literary review.

Results: Reports are published regarding the ADR, like Hypotension, Bradycardia due to consumption of aconite based Ayurvedic medicine. Studies proved that the impact of *Shodhana* process in the classic method using cow's urine is found to be more safe than any other purification methods. TLC studies shown that pseudoaconitine and aconitine were converted into less toxic substance like veratroyl pseudoaconine benzoylaconine respectively only through traditional *Ayurvedic Shodhana*.

Conclusion: *Vatsanabha* is a toxic plant with *Gunas* like *vikasi, vyavayi, sookshma* in prominence. Purification method should be proper and in suitable medium so as to modify these *Gunas* and mitigate its noxious effect.

Keywords: ADR, *Shodhana*, *Vatsanabha*, *Aconitum ferox*

Abstract No. AP-02

Abstract Title: Standardisation & investigation of preliminary phytoconstituents at three stages of fruiting of figs of *Udumbar* (*Fius racemosa Linn.)*

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Background: *Udumbar* (*Ficus racemosa* Linn.) is a plant seen mostly all over India. It's every part i.e. root, stem, leaves, fruits, *ksheer* are used in treatment of various diseases Diabetes, Diarrhoea, Cancer by its pharmaceutical & nutritional properties. Though having medicinal property abundant amount of its fruits are wasted. It green fruit is eaten as vegetable in villages & ripened fruits are eaten. *Udumbar* trees are seen in so often *Udumbar* fruiting is in clusters & 2-4 times in year. Feasibility of fruits are good. They can be eaten directly or with honey/sugar/jaggery/ghee. Therefore it will be cheapest, easily available nutrition to children, in pregnant woman, malnourished patients of cancer, diabetes, HIV, Koch's etc as compared to available costly nutritious, pharmaceutical drugs.

Methods: Samples were collected in 5 seasons of its fruiting throughout year from Kharghar –Navi Mumbai & are authenticated. Collection of equal amount of samples each at three stages of figs of *Udumbar (Ficus racemosa Linn*.) i.e Unriped figs (Bright green), Middle stage between Unriped & ripened (Reddish orange), Ripened Figs (Red) from different clusters of same plants randomly. Standardization were done according to Ayurvedic Pharmacopia of India. Study were done in 3 stages i.e Pharmacognostic study, preliminary phytoconstituents study and analysis of collected data by ANOVA method done.

Results: *Ficus racemosa* is with ripened fig showed - LOD-0.11%, ASH-8.05%, AIA-0.746%, ASE-8.896%, WSE,-28.304%, pH-5.2. Proteins-9.34, Carbohydrates-22.88, Fixed oils: 2.736**,** Unripened fig- LOD-0.11%, ASH-9.842%, AIA-1.26%, ASE-9.764%, WSE-16.264%, pH-5.2. Proteins-9.07%, Carbohydrates-21.64%, Fixed oils: 5.12% Primary metabolites present as Carbohydrates, Proteins & fats. Presence of secondary metabolites like Tannin, Glycosides, Steroids, Caumarins, Flavonoids in all stages of ripened & unripened figs. Alkaloids & saponins are not traceful. Calcium, Phosphorus, Iron, Silica, Potassium etc.are present in all stages.

Conclusion: ANOVA test done for statistical evaluation.There are no significant difference in view of Physicochemical & phytoconstituents evaluation at three stages of figs of *Udumbar*.

Keywords: ANOVA, Phytoconstituents, Primary & secondary metabolites, *Udumbar*.

Abstract No. AP-03

Abstract Title: Good cultivation, collection practice and pharmacovigilance

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Background: Over several decades of Indian medicinal history, Ayurvedic drugs are marked as safe to administer than they are effective. Even in the absence of sophisticated testing methodologies then, these drugs seldom caused any adverse effects. This is due to nothing but the ingenious rules and ethical principles this science followed right from the selection of sowing ground to the manufacturing of dosage forms. According to WHO, the number of reports of adverse effect owing to herbal drug usage has been increasing exponentially, Analysis revealed amongst its several reasons "Quality compromise of the herbal medicine" is the second leading one. Mandatory execution of the GACP guidelines will be the early remedy for the situation. This paper illustrates some of the issues of improper cultivation and collection practice and to provide some suggestion for its correction.

Methods: Collecting information from different journals, databases and by interrogating herbal cultivators of Kerala and enlisting all the issues concerning the subject to find out suitable solution.

Results: It is revealed that amongst several issues concerning cultivation and collection practice, improper execution of GACP guideline has the prior importance. Adequate remedial measures are equipped after discussion with subject scholars.

Conclusion: Field of herbal cultivation is facing the most dangerous situation in the last few decades. 70% of the issues are avoidable by proper correction and implementation of stringent rules. Hence it is imperative to follow the GACP guidelines through every steps of herbal drug development

Keywords: Good cultivation, collection Practices, Pharmacovigilance, adverse drug reaction

Abstract No. AP-04

Abstract Title: A cross sectional survey on the knowledge and attitude of ayurvedic practitioners of Kerala towards pharmacovigilance

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Background: The popular perception of Ayurvedic medicines of being devoid of any adverse drug reaction is at stake. Owing to the increased industrialization in this field, there is an alarming increase in the rate of adverse drug reactions. To tackle these issues, National Pharmacovigilance Programme for AYUSH drugs was introduced. An indepth research was conducted to assess the knowledge and attitude of Ayurvedic Practitioners of Kerala towards Pharmacovigilance and the extent to which they report adverse drug reactions (ADRs) to the higher centres.

Methods: A validated web based questionnaire was designed and a cross sectional survey was conducted among 100 Ayurvedic clinical practitioners in different districts of Kerala (n=100). Inclusion criteria were Clinical practitioners and excluded Teaching faculties and PG Scholars. Statistical method employed was Descriptive statistics.

Results: Statistical analysis revealed that only 58% physicians are aware of the existence of National Pharmacovigilance Programme. 56% does not have the idea of the higher reporting centres. 80% are unaware of the existence of Peripheral Pharmacovigilance centre in Kerala. 60% are ignorant that ADRs should be reported and 77% are not familiar with the standard form for ADR reporting of Ayurvedic medicines.

Conclusion: The present study brought into light the lack of knowledge of National Pharmacovigilance Programme and ADR reporting of Ayurvedic medicines. This study has unveiled the urgent need for a regular training and reinforcement for the ADR reporting among the Ayurvedic Practitioners.

Keywords: Cross sectional survey, Pharmacovigilance for Ayurvedic medicines, ADR

Abstract No. AP-05

Abstract Title: Environmental Pharmacovigilance (EPV): An emerging branch of Science- A review.

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Background: Environmental Pharmacovigilance (EPV) is a developing branch of science relating to the detection, assessment, understanding and prevention of Adverse Environmental Impacts (AEI) of Pharmaceutical products. It identifies risk levels of pharmaceutical residues mainly in water & soil for Environmental Risk Assessment (ERA) and its effective management. These spotting activities are necessary not only after launch of a new pharmaceutical product but also through its whole Life cycle. The branch is aimed to find out significant environmental issues related to Pharmaceuticals in Environment (PIE).

Results: The main components of Environmental Pharmacovigilance (EPV) are- Environment, Pharmaceutical Product, Product user (Human/ animal)/ dealer and Victims of the risks developed. The victims may be non-targeted human population, wild life species or aquatic inhabitants etc. The documentation of this vigilance search is completely limited as it is quite difficult to differentiate the relative impact of pharmaceuticals and other Environmental stimuli. Moreover, management plans require deep knowledge of Physico-chemistry, pharmacokinetics, toxicology and other sciences, which make it very specific. Though Environmental Risk Assessment is already included in regulatory approval process for new drugs, its implementation is poor in Developing countries.

Conclusion: There is great need to focus on this branch of vigilance in order to save the world from fatal hazards.

Keywords: Environmental Risk Assessment, Pharmaceuticals, Adverse Environmental Impact, Regulatory approval process

Abstract No. AP-06

Abstract Title: Review on Adulteration of Ayurvedic raw drugs

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Background: The genuiness, purity and quality of the drugs have direct impact on the medicinal preparation. Now a days most of the drugs obtained from raw materials are adulterated. Destructive harvesting, deforestation, lack of adequate cultivation, high price and demand, in contrast to the smaller population size of the plant, have motivated adulteration. Deliberate adulteration rather than by mistake is a serious offense and is the most important reason for adverse drug effects these days. This paper intends to disclose three of such adulteration on market samples(*trivrith*, *sariba, tila taila*) by reviewing dissertation works done at Govt ayurveda college Thiruvanthapuram, Dravyaguna dept viz.

Methods: Review of Physico chemical evaluation of the samples and comparing it with API standards of the drug.

Results: From the review it is revealed that other species of periplocaceae used instead of *Hemidesmus indicus*, *trivrith* shoot is used instead of root, mineral oil present in *thila taila*.

Conclusion: From the above results, it is evident that these drugs were not in compliance with their phytochemical standards. Either deliberately or accidently drugs were adulterated. This can cause mild to severe consequences even in its judicial administration with respect to dose etc. Illiberal rules and their mandatory executions are needed to get rid of these disagreeable acts. Without those, all the efforts to globalize this science of living will be pointless.

Abstract No. AP-08

Abstract Title: Analytical study of *Hinguleshwar Rasa*

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Background: In *Rasashastra* each and every step mentioned in basic principles of formulation is very important. There is need to validate & standardize the process by using different analytical technique for seeing what changes happen during the whole process.

Methods: In this study we have carried out *Hingula Shodhana, Vatsanabha Shodhana* & then prepared *Hinguleshwara rasa* as per classical reference.

Results: In ICP AES test of purified *Hingula* we found elements like CR, NA, W. but these element were not present in sample of unpurified *Hingula*. In the sample of purified and unpurified *Vatsanabha* we did not find any different significant element in this test. In *Hinguleshwara rasa* we did not find elements which were present in purified *Hingula* & purified *Vatsanabha* like CR, GA, NI, and W. In FEG-SEM we got images of given samples. In XRD, we did not find any structural changes in unpurified and purified Hingul & purified *Hingula* used in *Hinguleshwara rasa*. HPTLC finger print analysis help to check quality of formulation as well as it was used for batch to batch consistency. Because of its reliability and simplicity it was used as a tool for quality control of formulation.

Conclusion: The Analytical tests done on *Hinguleshwara Rasa* like ICP AES, FEG SEM, XRD, HPTLC reveal presence of 19 elements ,reduce particle size, basic structure of *Hingula* (Cinnabar) is maintained and Phyto-constituence of *Pippali* were prominently seen in final product.

Keywords: *Hinguleshwar Rasa, Hingul, Vatsanabh*, ICP AES, FEG SEM, XRD, HPTLC

Abstract No. AP-09

Abstract Title: Glimpse of Pharmacovigilance in Sutrasthana of *Charaka Samhita*

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Background: *Charaka Samhita*(C.S.), one of the celebrated lexicon of Ayurvedic literature consists of 8 sections *(Sthana*) and contains total 120 (Adhyaya)chapters, 9035 *Sutras* (formula). Highly useful for therapeutic purpose. It covers the preventive and curative data of

various disease conditions. In this article, an attempt has been made to collect the Pharmacovigilant(PhV) aspects described in different Sutras of C.S.

Methods: first *sthana- Sutrasthana* of C.S. has been reviewed and the relevant data is presented consicely.

Results: In Sutrassthana, Pharmacovigilant aspect of different food articles is described in 120 *sutras*. Ten *sutras* depicts the contraindications regarding the drugs and food use in different conditions, Materovigilance is mentioned in five sutras, ineligibility for treatment is portrayed in six *sutras*, complications caused by different drugs are shown in nine *sutras* and Basic principles governing the vigilant aspect of any drug, food, and regimen are described in thirty two sutras. Thus total 182 *shlokas* from *Sutrasthana* of *Charaka samhita* are related to PhV concept

Conclusion: Compiled data regarding safety issues and PhV can open new window for further researches in future for Ayurveda scholars

Keywords: Pharmacovigilance, safety issues, basic principles

Abstract No. AP-10

Abstract Title: Medicinal plants to be critically analyzed before consumption, while planning a pregnancy: evidence based research data

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Background: Since time immemorial, Ayurveda enlists both safe and unsafe medicinal plants to be taken during pregnancy. Herbs may contain substances that can cause uterine contractions causing miscarriage, premature birth, or injury to the fetus. In classical texts of Ayurveda, few plants are enlisted for their probable adverse effect but recent research reports certain plants for their teratogenic, embryotoxic and abortive effects in experimental animals. To provide the best available information on benefits and untoward effects of herbal medicine use during pregnancy.

Methods: Medicinal plants, which are commonly use in Ayurvedic Pharmacopoeia, either as a drug or used as diet, and reported for their anti-implantation, antifertility, teratogenic, embryotoxic and abortive effects were searched from web based engines and modern books.

Results: Present study reports that about 22 plants having reported for their adverse effects related to female reproductive system. Among these, 8 drugs (*Apamarga*, *karavellka* etc) are having abortifacient activity, 19 drugs (*Atibala*, *Bilwa* etc) having anti-implantation and anti-fertility activity.

Conclusion: Women who are planning for a pregnancy or having history of threatened abortion should avoid these plants either as a drug or diet and should take, if necessary, in consultation with a physician only.

Keywords: pregnancy, antifertility, Medicinal plants.

Abstract No. AP-11

Abstract Title: Role of Eco-pharmacovigilance in the field of Ayurvedic Medicine manufacturing sector

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Background: Eco-pharmacovigilance is an emerging science in pharmacovigilance, deals with the adverse effect of pharmaceutical products on environmental entities. The world has witnessed a sudden decline in the vulture population across the Indian subcontinent due to ADR caused by diclofenac. So we must focus attention on the adverse effects of various pharmaceutical drugs on the environment and non-targeted species. Due to Industrialization, the Ayurvedic medicine manufacturing sector is now controlled by large scale industries.

Methods: The data regarding the details of waste management in Ayurvedic sector was collected from published works in electronic databases and through discussion with the personals in the R&D section of various pharmacies.

Results: Due to increased demand for herbal medicines, the percentage of Ayurveda pharmacies were found to be increasing 0.5% per year in India. When there is an increase in the number of pharmacies, the amount of waste generated will also be increased proportionally. Herbo-mineral medicines were also produced in large scale, so there is always a concern of the presence of heavy metals in these wastes. Waste management became a herculean task for pharmacies and the effect of these various types of waste generated from Ayurvedic medicines on the environment is not properly studied and published yet.

Keywords: Eco-pharmacovigilance, Herbominerals, waste management

Abstract No. AP-13

Abstract Title: Pharmacovigilance: issue Related to Pediatric and Adult Population

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The developmental changes in physiology and consequently in pharmacology influence the efficacy, toxicity and dosing regimens of medicince used in children. It is therefore to review the relevant changes that take place from birth through to adolescence. It should be noted that specific diseases occur in the growing and maturing organism, which are not seen in adult, new born, infants have higher extra cellular fluid volume than any other paediatric population or adults on other hand fat content is lower in premature baby than in full term neonates and infants.

Substantial changes in body proportions and composition accompany growth and development this dynamic process of maturation is one of the differences between the pediatric and adult population. Consequence of the lack of studies of medicines development in childrens and authorization of pediatrics medicine is of great concern like no information is available on effective and safe dosing regimens record in an ethical dilemma exists as to the choice between using off label medications when little or no information is available about their safety and efficacy. It may be necessary to deal with parents and guardians who after reading the prescribing information are apprehensive that a medicine not tested in children or not cleared for use in children is being used to treat their child, warning of possible ADRs and adverse events are insufficient or lacking.

Keywords: Pharmacovigilance, new born

Abstract No. AP-14

Abstract Title: SUSAR Consolidation - New Procurement Approach in Pharmacovigilance

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Background: Pharmaceutical companies outsource SUSARs under their PV services to various suppliers based upon their geography, product and service capabilities. The pharmaceutical companies maintain inhouse resources to ensure the quality of services for SUSAR reporting and maintenance. Suspected Unexpected Serious Adverse Reactions (SUSARs) have become a critical element in analysing the risk and benefit associated with the life cycle of a medicinal product, either in the market or undergoing clinical trial.

Results: Awareness about suspected unexpected serious adverse reactions reporting is still poor amongst contract research professionals in India. Incidence of suspected unexpected serious adverse reactions has to monitor carefully and has to report immediately. The bioethical considerations to be taken into account in determining and implementing health policy and specialties to harmonizing and strengthening drug safety surveillance measures. Average cost incurred for conducting clinical trial was higher.

Conclusion: It has been a dynamic and swiftly changing area of the pharmaceutical industry and has become one of the concerns as well.

Keywords: Suspected Unexpected Serious Adverse Reactions (SUSARS), Prospective Spontaneous reporting, Causality, Severity, Cost

Abstract No. AP-18

Abstract Title: Pharmacovigilance concerns related to Opthalmic health; A critical review of Samhitha and Nigantu

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Background: Pharmacovigilance describes the possible side effects that can occur with different therapeutically useful drugs. It aims to prevent drug induced illness and improve patient safety by assessing drug risk benefits. Ayurveda explains its importance by stating that pure therapeutic procedure is one which pacifies a disease without provoking another. Ayurveda texts delineate pharmacovigilance aspects of various medicines, foods and treatment procedures. The pharmacovigilance concerns related to eye and vision explained in classics need special consideration as eye is the most vital sense organ among all sense organs. To identify and catagorise pharmaco-vigilant aspects of various *Aushadha* (medicine), *Ahara* (diet) and treatment procedures from the available literature giving emphasis on *Nethra* (eye and vision)
Methods: The present review has been undertaken to identify the above mentioned categories of substances which are *Achakshushya* (unwholesome for eyes) from Ayurveda Samhithas and various Nigantus.
Results: About 58 drugs were quoted to produce ocular disturbances when consumed wrongly or against regular protocol. About 34 food items were described to be unwholesome for eye. The regular and over use of *Amla* and *Lavana* rasa and the *Atiyoga* of treatment procedures like *Langhana*, *Vamana*, *Virechana* etc were also mentioned as bad for ophthalmic health.
Conclusion: The present review reports the possible adverse effects on eye and vision due to improper administration of certain drugs, food items and treatment procedures.
Keywords: Pharmacovigilance, Opthalmic health, *Achakshushya*
Abstract No. AP-19
Abstract Title: Possibility of Adverse event while preparing *Sanjivani vati* – A case Report
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Background: Using processed poisons in healthcare is an integral part of Ayurveda. *Bhallataka* (*Semecarpus anacardium* Linn.) is one important and commonly used ingredient in various Ayurvedic formulations. But, its injudicious contact may manifest contact dermatitis. *Sanjivani Vati*, which consists of *Bhallataka,* is one such most commonly used preparation being prescribed in the treatment of Indigestion, gastroenteritis with piercing pain and fever. This study aims at reporting a case of adverse event associated with preparation of *Sanjivani vati.*
Methods: Documentation of observed reactions and its management while preparing *Sanjivani vati* in Laboratory of *Rasashastra* and *Bhaishajya kalpana* at All India Institute of Ayurveda, New Delhi was done.
Results: It was found that the scholar developed itching, burning sensation, redness of skin and blisters after coming in contact with *Bhallataka* directly or indirectly during its *Shodhana* (processing) and preparation of *Sanjivani vati*. The symptoms resolved within 2 weeks on management, but left black scar marks over the area of blisters. The blisters kept on appearing & resolving on exposure to heat, indicating its delayed hypersensitivity reaction.
Conclusion: Tarry oil present in the pericarp of *Bhallataka* fruit causes blisters on contact. Though the drug is herbal; one has to handle it cautiously to avoid adverse event. It is advisable to follow exclusive regulations in terms of diet and deeds before collection and during processing of *Bhallataka*. In this era of Pharmacovigilance, it is important to create awareness regarding precautions among workers involved in such pharmaceutical processes.
Keywords: Adverse events, *Bhallataka,* Pharmaceutical, *Sanjivani vati*
Abstract No. AP-20
Abstract Title: Safety and efficacy of *Ayurvedic* formulations containing *Bhallataka*; Schedule E (1) drug.
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Author's affiliation: 1. MD Scholar, 2. MD Scholar, 3. Associate Professor, 4. HOD of Dept. of Rasashastra and Bhaishajya Kalpana IPGT&RA, Jamnagar.
Background: *Bhallataka* (*Semecarpus anacardium* Linn) is the plant in the family Anacardiaceae. *Bhallataka* is mentioned in *UpavishaVarga* in Ayurvedic texts. The fruits are official part of *Bhallataka* and reported for containing Bilwanol, Anacardiolas the major chemical constituents. It is a common drug indicated therapeutically for the management of various disease like *Arsha*(Piles), *Kushtha*(Skin disease), *Udara*(Ascitis), *Jwara*(fever), *Krimi*(Worm infestation) etc. Number of Ayurvedic formulations includes this drug after its proper *Shodhana Samskara*(Purification process) as injudicious use of *Ashuddha*(impure) *Bhallataka* may results in toxic effects like burning sensation of skin, blister formation, ulcer and so on. Aim of the present review is to compile such available published report on safety and toxicity aspects of *Bhallataka* in Ayurveda.
Methods: In present review, published articles on clinical trials of *Bhallataka* and its formulations containing were reviewed and relevant data of safety and efficacy, toxicity of *Bhallataka* in clinical were critically analyzed. Articles were searched through various search engines like google scholar, pubmed, and websites by searching the word- study on *Bhallataka*.
Results: Total 9 clinical studies showing safety and efficacy of *Bhallataka* and its formulations were found published. Side effects were noted in some cases after external and internal applications. Among them in 6 studies, ADR of *Bhallataka* were observed, in 2 studies, ADR were not mentioned and in one study no ADR were observed.
Conclusion: *Bhallataka* and *Bhallataka* contiaing formulations did not show any serious adverse effect and effective in the clinical management in various diseased. There was no significant derangement in haematological and biochemical parameters in these studies.
Abstract No. AP-21
Abstract Title: Drug genuinity and its role in Ayurvedic pharamcovigilance w.s.r.t *Pippali* (*Piper longum*)
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Background: Herbal preparations constitute the primary therapeutic interventions in Ayurveda. In Kerala more than 200 medicinal plants are taken on large scale for the preparation of medicinal products. *Pippali* is one among the drug which is used in almost all formulations. The genuinity, purity and quality of the drugs have direct impact on the quality of medicinal formulations. In the present study an attempt has made to ascertain the genuineness of fruit of *Pippali* in Kerala market, in concern with pharmacovigilance.
Methods: Samples were collected randomly from different markets of Kerala. Genuiness of samples were analysed formacroscopic, microscopic and physicochemical parameters like total ash, water soluble extractives, TLC and HPTLC.
Results: Marked variations are noted in both macroscopic and microscopic characters. Instead of *Piper longum, Piper retrofractum* is using in many parts of Kerala. HPTLC was performed between the samples which showed marked differences in quantity of Piperine, which is a major chemical constituent of *Pippali*. Some of the samples does not matches with the parameter mentioned in API.
Conclusion: Standardisation of finished products can achieved only by the usage of genuine drugs. . The need of the hour is to take caution right from the collection of raw drug so as to avoid adulteration and substitution, which in turn prove that the AYUSH drugs are safe and scientific in global market.
Keywords: Genuineness, fruit of *Pippali*, physicochemical analysis, HPTLC
Abstract No. AP-22
Abstract Title: Leech Application as a Source of Adverse Reaction – A Case Report

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Background: Leeches have been used for medical purposes especially for skin disorders since centuries in Ayurveda as well as in modern medical care. Among various *Shodhana* therapy, *Raktamokshana (*blood letting*)* is indicated in the management as *Rakta Dushti* is considered one of the prime causes of skin diseases**.** *Jalaukaavacharna Karma* (Leech therapy) is considered as the ideal method to expel out the vitiated blood safely and effectively. In this study, we report a case of an irritant contact dermatitis in a patient who experienced severe redness, itching and painful oozing lesions after applying leeches for the relief of eczema.
Methods: A 21 years old female patient reported at OPD of All India Institute of Ayurveda, New Delhi for the treatment of swelling, painful and itchy lesions with vesicles oozing pus and blood intermittently on her feet and legs. She had taken medication and leech therapy on right foot for eczema 15 days ago. Within one day of leech therapy, she developed the symptoms mentioned above.
Results: Swelling, painful and itchy lesions aggravated in next three days and gradually affected whole body including face, eyes and both hands etc. Biochemical parameters were found normal and patient was treated at AIIA and got mild relief. But, gradually condition got worsened. Finally, she took conventional treatment.
Conclusion: Although, leech therapy has a lot of medical benefits but it can also lead to serious complications. So, Leech must be available in the centers for the therapy itself and should be provided by qualified person who can identify non-poisonous leeches. In house breeding of non-poisonous leeches can also be initiated. Some sensitivity test may be carried out.
Keywords: Adverse reactions, Leech therapy, Pharmacovigilance

Abstract No. AP-23

Abstract Title: Concept of Pharmacovigilance in Ayurveda and measures to prevent ADR

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Background: Ayurveda is a major component of healthcare in India which is thoroughly time tested and presented in scientific manner thousands of years ago. The holistic approach of this ancient science mainly focused on preservation of normal health and curing the diseased one. Ayurvedic chikitsa primarily depends on *Bhisak* (Physician), *Dravya* (Drug), *Rogi* (Patient) and *Upasthata* (Attendant). Though Ayurveda is since centuries, there is a lacuna of systematic documentation related to the occurrence of adverse drug reactions and drug safety. Since the success of any pharmacovigilance system is in the ability to prevent possible adverse drug reactions successfully by understanding available concepts along with contemporary tools, the present review has been planned.
Methods: In the present study, concept of pharmacovigilance is compiled from Ayurvedic classics and presented in a systematic manner along with measures for its prevention.
Results: Though the word pharmacovigilance is not available in Ayurvedic classics, major goals of pharmacovigilance like of drug safety and rational use of medicines are highlighted by Acharyas. Different causes for adverse drug reactions like overdose (*Atimatra*), drug-diet interaction, drug intolerance, use of unwholesome drugs (*Asatmya*), Prakriti *virudda dravyaprayoga*), *Viruddaahara*, idiosyncrasy (*Vaidyakrita*) etc, are being emphasized repeatedly in all major texts. This risk of Adverse drug Reaction can be considerably reduced by following contemporary tools like blood investigations (LFT, RFT), Skin Tests (Scratch test, Patch test), Urine investigations etc.
Conclusion: Understanding the principles of drug safety mentioned in Ayurveda with the help of contemporary tools will help in developing various strategies for improving pharmacovigilance in Ayurveda.
Keywords: ADR, Ayurveda, Herbo-mineral drugs, Pharmacovigilance

Abstract No. AP-24

Abstract Title: A review on the medicinal plants with adverse effects on *Shukradhatu*

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Background: Among the eight branches of *Ayurveda, vajikarana deals with drugs* for obtaining a healthy progeny. Simultaneously one can trace the references about *Avrishya Dravyas* which interfere in the production of *shukra, in various classical texts.* A single hand information on these plants is lacking. To review adverse effect of certain drugs on *Shukradhatu* described in *Samhita* and *Nighantus*
Methods: Possible adverse effects of medicinal plants on *Shukradhatu* documented in 4 *Samhita* and 7 *Nighantu* were critically analysed. Plants, which are commonly use in Ayurvedic Pharmacopoeia, either as a drug or used as diet, and reported for their antifertility activity in male were searched from various books and web based search engines. The reported information were analysed and possible correlation were made based upon the on concept of Pharmacovigilance of current science.
Results: Study reports, twenty two plants for their adverse effects related to male reproductive system. Among them, 6 drugs (*Dhanyaka, Shigru* etc.) are having *Avrishya* effect, 12 drugs (*Yavani, Shatapushpa* etc.) are *Shukrahrit,* 2 drugs are *shukranashaka* and 2 drugs are *pumstvakaraka.*
Conclusion: The observation of the present review may be helpful in preventing the possible adverse effect of these drugs on *Shukradhatu.*
Keywords: Ayurveda, Dravyaguna, Drug safety, Medicinal plant, Male infertility

Abstract No. Ap-26

Abstract Title: Contribution of Bhaishajya-ratnavali towards recommending four commonly used vegetable as *Apathya:* A review

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Background: Diet plays an important role in the pathophysiology of many diseases. Ayurveda records these dietary items as *Apathya* and categorizes them into *Annavarga* (rice and cereals), *Phalavarga (fruits), Shakavarga (vegetable)*. Different classical texts recorded these plants under various group and highlighted theirs properties and actions. To review and analyze role of classical vegetables mentioned in *Bhaishajya-ratnavali* a compendium of 18th century.
Methods: In the present review, plants described under *shaka-varga* indicated as *Apathya* in different disease condition were compiled from *Bhaishajyaratnavali*.
Results: Bhaishajya-ratnavali records 104 *aharadravya*, among them, 42 are vegetables. It is observed that four vegetables *Kalay*, *Sarsapa*, *Tumbi* and *Upodika* are commonly used. These drugs are mentioned as *Apathya* in 14 different diseases.
Conclusion: The observed results may be helpful in planning further scientific studies to establish a evidence based research on 4 vegetables are indicated as *Apathya* in 14 different diseases.
Keywords: *Apathya*, *Shakavarga*

Abstract No. AP-27

Abstract Title: Contribution of *Bhaisajya Ratnavali* towards three commonly used pulses as *Apathya*: a review

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Author's affiliation: M.D.Scholar* Professor&Head** Department of dravyaguna, IPGT&RA, Jamnagar, GAU

Background: The goal of Ayurveda is to maintain health of healthy individual and prevent diseases of diseased person. *Pathya Ahar* a (wholesome diet) is considered as one of the important factor in maintaining the optimum health whereas *Apathya* (Unwholesome diet) causes of various diseases. Among the different dietary articles, Pulses have been described under the *Shimbidhanya* in Ayurveda. In classical texts of Ayurveda, different vegetables have been mentioned as *Apathya* (Unwholesome diet), which are the cause

(*Nidana*) of various diseased condition. The present review focuses on the role of *Masha, Nishpava, kulatha* commonly used pulses (*Shimbidhanya*) as *Apathya* in causing of various disease. The present review focuses on the role of Three leafy Pulses i.e *Masha, Nispabha, Kulatha,* as *Apathya* in various diseases.

Methods: Pulses described under the group of *shimbidhanya varga*, Contraindicated as *pathya,* in various diseases were compiled from *Bhaisajya ratnavali*.

Results: Analysis of compiled results show that, among 104 *Shaka* (vegetables), 10 are categorised as Pulses, Contraindicated as *Pathya* in various diseases. Among these, *Masha, Nispabha, Kulatha* are frequently used and found contraindicated in more than 19 disease conditions. Majority of the Pulses contraindicated in 8 *srotas* like *Pranavaha-hikka, Arnnavaha-grahani, Udakavaha- trishna, Rasavaha - Jwara, Raktavaha -kustha, Medavaha-medaroga, Mutravaha-mutraghata, Purishavaha-atisara*

Conclusion: The observed results may be helpful in planning further scientific studies to establish an evidence based research on 10 Pulses (*Shimbidhanya*) contraindicated as pathya in 19 diseases related to 8 *Srotas*.

Keywords: *Apthya*, Unwholesome diet, disease, *Shimbidhanya varga*.

Abstract No. Ap-28

Abstract Title: Challenges in implementing Pharmacovigilance Programme for ASU & H drugs

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Background: Pharmacovigilance deals with the Adverse Drug Reaction or any Drug related issues. Identification and reporting of Adverse Drug Reaction/ Adverse events and analysis of its consequences have a positive impact on the public health. Implementation of Pharmacovigilance programme for ASU & H drugs is not an easy task; it has come across with many challenges and barriers. This article highlights the challenges faced during the implementation of Pharmacovigilance Program for ASU & H drugs at Peripheral center.

Methods: It is an explorative study, wherein personal interviews of health care professionals and peer reviewed journals were collected and evaluated. Already published articles and books were also referred for compilation and interpretation of results.

Results: With the span of one year, the centre identifies certain obstacles like signal detection and reporting, collection of the details of the suspected drug, drug regulation etc

Conclusion: Lack of awareness of ADR reporting among the healthcare professionals is considered as the major problem in implementing the programme. Hence certain considerations are made like Improvement in knowledge of Pharmacovigilance, communication with all sectors of health care system, patient education etc which will definitely help in implementing Pharmacovigilance programme.

Keywords: Adverse drug reaction, ASU & H Drugs, challenges, considerations, implementation, Pharmacovigilance programme

Abstract No. AP-29

Abstract Title: Exploring issues of Pharmacovigilance concerns in *Panchakarma*

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Author's affiliation: *PhD Scholar, Dept of Panchakarma, IPGT&RA, Jamnagar, **Director and HOD, Dept of Panchakarma, IPGT&RA, Jamnagar

Background: Ayurveda as treatment system have been in existence since centuries, and *Panchakarma* which is one of its main arsenals is often overlooked upon from the pharmacovigilance point of view. The procedure always goes parallel with drugs which is an area coming under Pharmacovigilance.

Methods: Classical text books having references related to Pharmacovigilance, published articles in peer-reviewed journals, published books and subject-related material available online have been thoroughly screened, compiled, organized and described in a systematic manner.

Results: The quality of drugs is a different aspect but when we consider that the drugs supplied for procedures are often not of good quality or are adulterated, then are chances of ADR being observed by the doctor. The body constitution of any patient can also make him react adversely to any particular drug like *vacha, yastimadhu* etc. Procedural safety is another issue where there are chances of adverse reactions. There are reports of duodenal ulcerations and rectal prolapse developed because of *asthapana basti*. A study in an Ayurvedic teaching hospital showed that Panchakarma produced the highest number of adverse reactions (44.23%) than other factors. Ecopharmacovigilance is also a new aspect which is very much applied here and need to be explored.

Conclusion: Panchakarma is a section where there are many chances of adverse reactions and are often disregarded upon due to the negligence or lack of expertise with the medical fraternity. Proper awareness and training for the same will help in its resolution.

Abstract No. AP-30

Abstract Title: A review on toxicity studies carried on *Devasunda* (*Pittosporum floribundum* Wt. & Arn.), A Promising Ethno medicinal Plant from Orissa.

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Author's affiliation: *Ph.D. scholar, ** Professor & Head Department of Dravyaguna, IPGT&RA, Jamnagar, Gujarat, India

Background: *Pittosporum floribundum* Wt. & Arn. (Pittosporaceae) is known as '*Devasunda'* in Orissa. In Ayurveda system high doses of bark acts as narcotic, used as antidote to snake poison and used in curing asthma, arthritis, inflammation. To review Acute and Subacute toxicity studies on plant *Devasunda* (*Pittosporum floribundum)* for Pharmacovigilance aspect.

Methods: Research papers published on acute and sub-acute toxicity and also on other aspects for pharmacovigilance aspects for the plant *Devasunda*, (*P.floribundum*) as on available public domains has been reviewed for this study.

Results: Acute Toxicity: The stem bark aqueous extracts showed high toxic effects showing LD 50 at 1337.5 mg/kg b.wt with at the log dose of 3.126 and the probit values 5.13.The ethanol and methanol extracts showed LD50 at 1843.6 mg/kg b.wt with log dose 3.265 mg/kg b.wt, the probit value 5.13. Toxicity was observed with aqueous extracts until the death of all (100%) animals at 1800 mg/kg b.wt and with the methanol and alcohol extracts at 2500mg/kg b.wt. Sub-Acute Toxicity: The drug *P.floribundum* bark extracts may be recommended at sub-acute doses between 10 mg to 75 mg/kg b.wt. The drug may be recommended as sub lethal dose with respect to the LD50 value of aqueous extracts as 134 mg/kg b.wt and 184 mg/kg b.wt as per the OECD guidelines of 1/10 dose to that of respective LD50 values.

Conclusion: *P. floribundum* bark extracts also used as anti-inflammatory drug by the herbalist may also recommended at lower doses between 10 -75 mg/Kg. b.wt to reduce the inflammation, arthritis without causing damage to the organels. The **anesthetic effect** for about 30-45 minutes at lower doses also recommended as **analgesic and sedative** drug.

Keywords: *Pittosporum Floribundum*, Devasunda, Acute Toxicity, Subacute toxicity, ethnomedicine

Acknowledgements: K. Naga Malleswari , N. Yasodamma and C. Alekhya, Department of Botany, Sri Venkateswara University, Tirupati.

Abstract No. AP-31

Abstract Title: Impact of pharmaceuticals on various environmental entities

Author's Name: Dr. Revati Bhat, Dr. Mayuri Dhok, Dr. Jayashree Changade, Dr. Nilima Ghangale, Dr. Abhijeet Shirkande

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Conceptual study of the adverse effects of pharmaceuticals both on-the environment and on humans through indirect non-therapeutic exposure.

Environmental pharmacovigilance is described as monitoring of the adverse effects of pharmaceuticals both on- the environment and on humans through indirect non-therapeutic exposure. Pharmaceuticals are described as potent group of chemical substances that bear biological effects at low concentrations

According to Ayurveda, every living being is made from the five basic elements: Pruthvi, Agni Aap, Aakash and Vayu. Like the law "*Pindi te Brahmandi*", these elements make up the environment too. As the various pharmaceuticals affect the human body, they affect these elements. Most of the times, the pharmaceuticals directly or through their process of preparation, cause pollution and contamination of these elements and which then affects the food and public health.

Simple things like disposal of Ayurvedic medicines containing Mercury, Lead, Arsenic etc., disposal of industrial waste produced by pharmacies into air and sewage, pollute the air, water, and soil therefore directly affecting plants, marine life and thus human food. Hence, there is a need for preparation of a proper disposal channels for pharmaceuticals and their waste

Conclusion: The pharmacies and pharmaceuticals are therefore affecting the environment and human beings indirectly in addition to their direct therapeutic effects.

Abstract No. UP-01

Abstract Title: Challenges in Monitoring the Safety of Unani Medicines

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Pharmacovigilance (PV) is related to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. WHO established its Programme for International Drug Monitoring in response to the thalidomide disaster detected in 1961. Safety is a fundamental principle in the provision of herbal medicines and herbal products for health care, and a critical component of quality control. Unani medicine is an ancient system of medicine originated from Greece. It is more commonly practiced in Indian Subcontinent and has an age-old concept and principles of drug management. It has drugs from natural identity and source. Adverse drug reaction from Unani system of medicine are least reported. Many drugs are prepared and marketed without any safety requirements. Drugs like Habbe shifa have shown that Unani drugs may be associated with ADRs. The current challenges in Pharmacovigilance of Unani medicines includes drug safety problems, lack of quality control, lack of information about the mechanisms of action. Interactions between herbs and drugs may increase or decrease the pharmacological or toxicological effects of either component. Synergistic therapeutic effects may complicate the dosing of long-term medication. Monitoring the safety of Unani medicines have to go a long way so the common people may be advised to take the medicine with care. This paper will deliberate on the challenges in the safety of Unani medicine.

Keywords: Pharmacovigilance; Unani System of Medicine; Adverse drug reaction; Safety of Unani Medicine

Abstract No. SP-01

Abstract Title: Implementation of pharmacovigilance in siddha medicine and practical challenges

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Siddha system of medicine was practiced from pre Vedic era and time immemorial. According to Siddha principles, the nature that causes diseases and it is again nature that offers their cure. After thalidomide disaster the Western medical world aware about the importance of Pharmacovgilance while practicing modern medicines. Not only for modern medicine but Pharmacovigilance is important for any other system of medicines. World Health Organization recently widened its concerns in Pharmacovigilance to include Herbals and traditional medicines. While implementing Pharmacovigilance program in Siddha medicine, So many things has to include when recording Adverse Drug Reactions, the lacking of proper pharmacological studies, pharmacokinetic and dynamics also. The current models of Pharmacovigilance and its tools have been developing in relation to synthetic drugs, safety monitoring of Siddha medicine is improved by modifying existing methodology for safety profiles of Siddha drugs. In this article deals the briefs of challenges faced in Siddha Medicine while implementing Pharmacovigilance Programme.

Keywords: Pharmacovigilance, Siddha Medicine, challenges

Abstract No. SP-02

Abstract Title: Effect of *Keezhanelli thylam* oil bath in the management of Kudiveri noi (chronic alcoholism)

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Background: Siddha system is an ancient medical system on par with the Ayurvedic system and mainly practiced in south India. As per World health organization (ICD-10), Alcoholism is characterized by Intoxication, harmful use, alcoholic dependence, Withdrawal symptom and psychotic disorders. According to Siddha text, it can be correlated with Kudiveri noi. Despite great progress made in the past two decades, the development of low-toxicity and high efficiency medicines remains a challenging task for alcohol researchers. Ennai muzhuku is the non-invasive and safer mode of therapy used in *Pitham* related diseases. Keezhanelli thylam used for oil bath which is indicated to psychiatric diseases coated in *Theriyar thyla varuka churukam*.

Methods: Patients age between 18-60 yrs of age with classical features of Kudiveri noi from OPD of National Institute of Siddha, Chennai, India were selected for the present work, irrespective of their sex, religion, education, etc. Detailed research profoma was prepared incorporating all the signs and symptoms of disease. Alcohol use disorder identification test (AUDIT) performed before and after treatment.

Results: AUDIT score shows encouraging results of good improvement in 8patients (27%) moderate improvement in 14 patients (46%), mild improvement in 5 patient (17%) and poor improvement in 3 patients (10%) of cases.

Conclusion: From the above results, "Keezhanelli thylam oil bath" is improve the physical and mental and social improvement and also the safer therapy for kudiveri noi patients.

Keywords: Alcoholism, De-addiction, Kudiveri noi, Keezhanilli thylam, Siddha medicine.

Abstract No. SP-03

Abstract Title: Mercury toxicity and its earlier footprints in Siddha system of medicine– Analogous to Pharmacovigilance

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Background: According to Siddhas, Mercury is the chief of all elements and ubiquitous. Due to life-threatening toxicity of mercury, it is considered by WHO as one of the top 10 chemicals of major public health concern. Siddhas believe and proved that Mercury can cure most of the incurable diseases, protect the body from different diseases, maintains good health and facilitates to attain the eight folds of *Siddhi (Attama Siddhigal*). Siddhas take utmost care of

Pharmacovigilance concern successfully in pharmaceutics and therapeutics such as collection and selection of raw drugs, purification, SOP's of formulations, medicinal dosage form, duration of the treatment, choosing of suitable vehicle, and precautions to be taken. Occurrence of ADR is mostly due to errors in above steps. The symptoms and the treatment of ADR caused by mercury and its toxicity is well explained in Siddha literature.

Methods: In mercury, the collection is made by the removal of impurities from the mercurial ore itself, the literature describes impurities and its toxicity (*Thodam & Sattai*).

Results: The purification (ore dressing) of mercury is the process to detoxify the toxin by chelation and increase the efficacy. The science behind the detoxification of mercury needs to be explored for the betterment of health. Insisting upon the ban on mercury, monitoring and reporting of the adverse reaction and adverse event for the mercurial product should be registered and documented for the successive current

Conclusion: Pharmacovigilance practice. Implementation of Pharmacovigilance practice will throw the renaissance to the Siddha system of medicine.

Keywords: Siddha, Pharmacovigilance, Ore dressing, Detoxification, Mercury toxicity, ADR.

Abstract No. SP-04

Abstract Title: Importance, challenges in reporting adverse drug reaction (ADR) in siddha system of medicine & measures to overcome the challenges.

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Background: The objective of the present study is to discuss about the importance, challenges in reporting the Adverse Drug Reaction (ADR) in Siddha System of Medicine & measures to overcome the challenges at different levels.

Methods: Importance of Pharmacovigilance and Adverse Drug Reaction (ADR) related data are mentioned in siddha texts and challenges being faced by a physician, drug manufacturing companies, and drug regulatory authorities and patients while reporting and measures to overcome the challenges have been briefly discussed.

Results: Unlike conventional system of medicine, the most challenging task in Pharmacovigilance of siddha drugs is an Adverse Drug Reaction (ADR) needs to be precisely diagnosed along with multiple drug usage and drug –drug interaction at physician end. Lack of knowledge in reporting Adverse Drug Reaction (ADR) will be a challenge at the level of nurses, attendants, pharmacists and health workers. At the level of drug manufacturers post marketing surveillance of drugs and Periodic Safety Update Reports (PSURs) will be the most challenging. Inappropriate dose, duration, adjuvant and pathiyam and poor follow up are the challenges at the level of patients/consumers. To overcome all these challenges guidelines mentioned in siddha literature with regards to preparation of drugs, dose, duration, adjuvant and pathiyam have to be followed firmly. Physicians, pharmacists, nurses and patients have to be educated by conducting periodical Pharmacovigilance awareness programme.

Conclusion: By reporting & documenting Adverse Drug Reaction (ADR) not only gives scientific validation but also credibility to Siddha drugs. Prevention of adverse drug reaction is the key essence to ensure patients safety.

Keywords: Siddha drugs, adverse drug reaction.

Abstract No. MP-01

Abstract Title: Immunogenicity and approach to correlate immunological adverse events in case of Biosimilars

Author's name: Dr. Saifali Gupta

Author's affiliation

Immune responses to therapeutic protein products may pose problems for both patient safety and product efficacy. Immunologically adverse events, such as anaphylaxis, cytokine release syndrome, and cross-reactive neutralization of endogenous proteins mediating critical functions have caused termination of the product. Because most of the adverse effects resulting from elicitation of an immune response to a therapeutic protein product appear to be mediated by humoral mechanisms, circulating antibody to the therapeutic protein product has been the chief criterion for defining an immune response to this class of products. There are lot of factors may affect immunogenicity of therapeutic protein products. These factors are critical elements in the immunogenicity risk assessment. Ideally, these factors should be taken into consideration in the early stages of therapeutic protein product development. Multi-tiered testing approach should be properly designed to evaluate the immunogenicity of any product.

It is relevant to note that cases of pure red cell aplasia, featuring the development of antibodies that react with, and neutralize the biological activity of, the endogenous cytokine are detected at very low frequency in subjects treated with different recombinant erythropoietin products.

A biosimilar growth hormone candidate manufactured using an early version of the manufacturing process induced antibodies that reacted to the *Escherichia coli*-derived protein impurity in association with a reported increase in antibodies reactive with the human growth hormone product.

In our experience, Adalimumab may have higher antibodies (about 17 -20% antibodies) but are not neutralising antibodies , hence may not be relevant.

Abstract No. MP-02

Abstract Title: Analysis of acute transfusion reactions: A hemovigilance case series study

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Background: A centralized hemovigilance program was launched in the India on December 10, 2012, to assure patient safety and promote public health through a well-structured program for monitoring of adverse reactions associated with blood and blood product transfusions. There is a lack of awareness and proper training about the management of transfusion related adverse reactions which leads to under-reporting of transfusion related adverse reactions. The patients of thalassemia major needs regular blood transfusions in order to survive and continuous monitoring of transfusion related reactions can promote patient care and safety. To observe and analyse the acute transfusion reactions (ATRs) encountered in the Thalassemia ward of the tertiary teaching hospital.

Methods: Over the period of 1 month from 1st July to 31st July 2019, a total of 7 ATRs of thalassemia major patients were reported from thalassemia ward of tertiary care teaching hospital. Imputability Assessment of all 7 ATRs have been done by using Imputability Assessment scale given by hemovigilance programme of India (HvPI).

Results: 2 ATRs were of backache with fever with rigors, 2 ATRs were of fever with rigors, 1 ATR was of rigors, 1 was of backache and 1 was of left eye lid swelling out of total 7 ATRs. Febrile non haemolytic transfusion reactions (FNHTRs) constituted 4 ATRs. Remaining 3 were fall into the category of "other reactions." Imputability Assessment indicated that 4 ATRs were "Definite" and 3 were "Probable". All ATRs were of Grade 1 severity.

Keywords: Hemovigilance, Acute transfusion reactions (ATRs).

Abstract No. MP-03

Abstract Title: Acute Demyelinating Encephalomyelitis due to Pentavalent Vaccine in a 6 months old pediatric patient

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Background: The Government of India has decided to introduce pentavalent vaccine in the national immunization programme in selected states. Pentavalent vaccine provides protection to a child from 5 life-threatening diseases – Diphtheria, Pertussis, Tetanus,

Hepatitis B and Hib. DPT (Diptheria+Pertussis+Tetanus) and Hep. B are already part of routine immunization in India; Hib vaccine is a new addition. Together, the combination is called Pentavalent.

Case report: A 6 months old healthy male infant was given pentavalent vaccine as a part of routine immunization in Navagam PHC, Surendranagar and after 1 hour of receiving vaccine patient experienced fever and complex partial seizure. Patient was admitted to Govt. hospital Rajkot on next day and treated with sedatives, antipyretics and antiepileptics. MRI report of patient showed Acute Demyelinating Encephalomyelitis. Patient had on and off episodes of complex partial seizures and was hospitalized for 1 month. He was discharged after stabilizing on oral medications. ADEM is a rare Adverse Event following pentavalent vaccine immunization. The onset of ADEM usually occurs in the wake of a clearly identifiable febrile prodromal illness or immunization and in association with prominent constitutional signs and encephalopathy of varied degrees.

Conclusion: Pentavalent vaccine may cause acute demyelination in white matter of brain and may lead to serious reactions.

Keywords: Acute Demyelinating Encephalomyelitis, AEFI, Pentavalent Vaccine

Abstract No. MP-04

Abstract Title: A case of Digoxin toxicity due to renal insufficiency and drug-drug interaction

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Background: Digoxin is a cardiac glycoside indicated for the control of resting ventricular rate in patients with chronic atrial fibrillation in adults. The drug has a narrow therapeutic range (0.5 – 2 ng/ml) that leads to toxicity. However, we report a case of serious digoxin toxicity.

Case report: A K/C/O AF with CVA, 57 year old male patient presented with c/o vomiting, chest pain, ghabaraman, dizziness and generalized-weakness. The patient was also having renal calculi with on and off hydro-nephrosis. He was prescribed with Digoxin (0.125 mg) 5 day in a weak along with Tab Atorvastatin 40 mg, Tab Aspirin 150 mg and Tab Clopidogrel 75 mg OD since 1 year. The physician observed ECG changes indicating Bradycardia and A-V block as a suspected ADR of Digoxin and was confirmed by Laboratory investigation and causality assessment, immediately Digoxin was stopped. The symptoms improved significantly after withdrawal of the drug and Injection Atropine 0.5 mg intravenously stat. The most frequent causes of toxicity are renal insufficiency and overdosing. Digoxin is primarily excreted by the kidneys; therefore, patients with impaired renal function require smaller than usual maintenance doses of digoxin. Atorvastatin can lead to increase Digoxin plasma concentration by 22% requiring reduction in dosage.

Conclusion: Dosage of Digoxin should be decided only obtaining results of Renal and Liver function test and checking drug-drug interaction with drugs prescribed simultaneously. TDM should be done regularly & periodically in patients with Digoxin Therapy.

Keywords: Digoxin, Renal insufficiency, Drug-drug interaction.

Abstract No. MP-05

Abstract Title: A case report: Iohexol contrast induced diarrhoea in 65 years old female patient

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Background: Various adverse drug reactions with intravenous Iohexol contrast; including diarrhoea, arrhythmias, vision abnormalities, dyspnoea, dyspepsia, dry mouth and urticaria have already been mentioned in the drug information given by FDA. In literature search, there are very limited actual reportings related to this.

Case report: This case report gives the details of 65 years old female patient with diarrhoea after administration of injection Iohexol which was given for some radiological procedure. This case report adds and increases need for awareness of the probability of side effects of Iohexol contrast used intravenously. The report also emphasizes the active vigilance in intravenous Iohexol and other contrast as a potential cause of systemic side effects.

Keywords: Iohexol Contrast, Diarrhoea, Adverse drug reaction

Abstract No. MP-06

Abstract Title: A case report: atropine induced tachycardia in 5 year old boy

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Background: Various adverse drug reactions (ADRs) with topical preparations of atropine; including tachycardia, restlessness, eye pain, blurred vision, photophobia, decreased lacrimation, irritability, delirium, flushed skin of face or neck have already been mentioned in the drug information given by FDA. But very few studies are reported in the literature regarding this.

Case reports: This case report gives the details of 5 year old male child who developed tachycardia following atropine eye ointment prescribed post-operatively in case of ocular injury. This case report adds and increases need for awareness of the probability of systemic side effects of topical atropine formulation. The report also emphasizes the active ADR monitoring in topical pharmaceutical products of atropine and other drugs as a potential cause of systemic side effects.

Keywords: Atropine, tachycardia, topical formulation

Abstract No. MP-07

Abstract Title: Analysis of adverse drug events reported at peripheral ADR monitoring centre in gujarat

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Background: Adverse drug reactions (ADRs) are one of the major health concerns affecting population of all ages causing significant morbidity and mortality. Pharmacovigilance programme of India was introduced in 2010 with the vision to improve patient safety and welfare of Indian population by monitoring safety of medicines and, thereby reducing the risk associated with their use. Pramukhswami Medical College is one of the ADR monitoring centres of India. To evaluate the adverse drug events reported during April 2018 to March 2019 in our centre.

Methods: Adverse drug events reported during the period of April 2018 to April 2019 were analyzed on the basis of demographic profile of patients, drugs causing ADRs with their causality assessment using WHO probability scale. ADRs were also analyzed on the basis of health care professionals who have reported.

Results: Adverse drug events were reported in 36 patients during April 2018 to March 2019. There were 20 male and 16 female patients, among them 15 were below 18 years, 17 were between 18-60 years and 4 were above 60 years. Antimicrobials were the most common culprit group of drugs to cause ADRs. Out of 36 adverse drug events, 1 was classified under certain, 27 were probable and 08 were possible. The maximum adverse drug events i.e. 30 (83.33%) were reported by treating doctors and remaining were reported by other health care professionals.

Conclusion: Even though continuous efforts for adverse drug event reporting awareness, still there is need to sensitize health care professionals to improve reporting.

Keywords: Adverse drug events, Pharmacovigilance, Causality assessment