Journal of Pharmacovigilance & Drugs Safety
An Official Publication of Society of Pharmacovigilance, India

Ayush Suraksha 2019 *Issue 2 (Special Issue) July-December 2019* *Abstracts*

Invited speakers

Abstract Title: Medical Vigilance Programmes

Author Name: Dr Anupama Sukhlecha

Author's affiliation: M P Shah Govt. Medical College, Jamnagar

Pharmacovigilance Programme of India (PvPI) is running successfully all over India since 2010. Vigilance programmes have also been started in allied medical fields, some of which are:

Pharmacovigilance of herbal medicines:

The use of herbs as traditional medicines is expanding rapidly across the world. It could be difficult to identify the causes of herbal medicine-associated adverse events since the amount of data on each event is generally less. Ayurveda, Siddha, Unani and various traditional systems come under this category. Ayush suraksha has taken a lead in reporting adverse reactions due to herbal medicines.

Hemovigilance Program of India (HvPI):

This was implemented to monitor adverse events and incidences associated with blood donations and transfusions. It was launched under PvPI on Dec 10, 2012 in collaboration with National Institute of Biologicals, NOIDA. There are transfusion reaction reporting forms and software Hemovigil through which information reactions is uploaded. The data is collated to identify trends, recommend best practices and interventions required to improve patient care and safety.

Vaccine vigilance:

Vaccines are a miraculous invention of the mankind. But they may also cause adverse reactions. Regulatory authorities have defined guidance and formats for reporting vaccine-related events. Vaccine reporting formats in Pvdge for report submissions are:

- Vaccine Adverse Event Safety Reporting forms (VAERS)
- CIOMS form for vaccine reporting-Vaccine XML for submissions to VigiFlow-Global database (as per CDSCO office order of May 2015)

Materio-vigilance Programme of India (MvPI):

This modern concept of monitoring and safety of medical devices is known materiovigilance. Medical devices could range from simple devices such as tongue depressors and thermometers to advanced devices such as medical robots and cardiac pacemakers. The manufacturers, importers, and device user facilities need to report certain device-related adverse events and product problems. It is also meant to generate independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders. The biotechnology wing of the Sree Chitra Thirunal Institute of Medical Sciences and Technology in Thiruvananthapuram has been designated as the national collaborating center for the program which would be under CDSCO.

Cosmetovigilance:

It is the ongoing and systematic monitoring of the safety of cosmetics in terms of human health. The aim is to detect adverse effects of cosmetic products, and to prevent adverse effects by taking appropriate measures. It is the responsibility of manufacturers to determine that products and ingredients are safe before they are marketed and then to collect reports of adverse reactions. The practical consequence of cosmetics legislation is a requirement for continuous observation of cosmetic products after marketing.

Ecopharmacovigilance (EPV):

Introduced in 2006 by Dr S Z Rahman (as Pharmacoenvironmentology)

Activities of EPV include:

- Increasing the availability of environmental data on medicinal products
- Tracking emerging data on environmental exposure, effects and risks after product launch
- Using environmental risk management plans to manage risk throughout a drug's life cycle
- Following risk identification, promoting further research and environmental monitoring

Promoting a global perspective on EPV issues

Abstract Title: Indonesian Traditional Herbal Medicine (*Jamu*) for High Cholesterol Problems

Author Name: Swandari Paramita*[1,2]

Author's affiliation: [1]Department of Community Medicine, Faculty of Medicine, Mulawarman University, Samarinda, East Kalimantan, 75119, Indonesia

[2]Research Center for Medicine and Cosmetic from Tropical Rainforest Resources, Mulawarman University, Samarinda, East Kalimantan, 75119, Indonesia

Background: High cholesterol levels (hypercholesterolemia) has been recognized to cause various disease, most notably the cardiovascular disease. Unfortunately, most anti-hypercholesterolemic drugs deliver several side effects for patients, by which medicinal plants have begun to attract attention for treating hypercholesterolemia. Traditional medicine using medicinal plants in Indonesia is called *jamu*. Scientific *jamu* for hypercholesterolemia is the result of traditional medicinal plants research conducted by the Ministry of Health Republic of Indonesia, based on empirical composition that has been carried out by literature studies so that they are suitable for use in the community.

Methods: The ingredients consist of main and additional components.

Results: The main composition consists of medicinal plants which have a direct effect in reducing blood cholesterol levels. Additional compositions are medicinal plants intended to improve the quality of life and fitness of patients. Medicinal plants in the main components of the scientific *jamu* for hypercholesterolemia are Chinese teak leaves (*Senna alexandrina* Mill.); Dutch teak leaves (*Guazuma ulmifolia* Lam.);
tempuyung herbs (*Sonchus arvensis* L.); and green tea herbs (*Camellia sinensis* (L.) Kuntze). Medicinal plants in the additional components of scientific *jamu* for hypercholesterolemia are *temulawak* (*Curcuma xanthorrhiza* Roxb.); turmeric (*Curcuma longa* L.); and *meniran* herbs (*Phyllanthus niruri* L.).

Conclusions:

Keywords: Indonesian traditional medicine, high cholesterol, *jamu*

Abstract Title: Traditional Medicines and Off-label Usage in Elderly: Can We Really be Pharmacovigilant Enough?

Author Name: Ashok Kumar Dubey

Author's affiliation:

Elderly population all over the world has increased to a total of about 900 million, contributing to more than sixty percent of the total population. Indian elderly population has tripled in the last fifty years and it is projected to increase to more than one thirty million by the 2021 census. This age-group is the most heterogenous with prevalence of multi-morbidity and practice of poly-pharmacy. There is altered pharmacokinetic and pharmacodynamic profile due to ageing. Evidence-based practice is also compromised in the elderly due to their under-representation in the clinical trials. Usage of traditional medicines and off-label drugs is particularly common in this age group. More than 60 percent of elderly patients today use traditional medicines. Most of these patients practice self-prescribing of traditional medicines and are ignorant about possible drug-drug interactions with drugs from other systems of practice. Similarly, off label prescribing, which refers to the use of a drug in conditions other than those for which it is officially approved, is quite a common medical practice, especially in elderly patients, because many drugs used in this population are approved after clinical trials on adult participants. Off label drug usage is associated with significantly higher risk of adverse drug reactions (relative risk 1.67, with a 25 % increase in risk for every additional off label drug used). There has to be a multipronged approach for better healthcare of the elderly patients including judicious prescribing, evaluating and generating supportive evidence along with regulatory support to create a robust pharmacovigilance system. The complexities of physiology, diseases, practiced therapies and the response to the drugs in the elderly need us to be even more pharmacovigilant for this age group.

ORAL PRESNTATION

Abstract No. AO-01

Abstract Title: *Moringa oleifera* lam. enriched biscuits induced adverse drug reaction- a case report

Author's Name: Meena Shamrao Deogade[1], Vishakha Kumbhare[2], Anita Wanjari[3], Shilpa Gaidhane[4]

Author's affiliation: [1]Professor & Head of Dravyaguna vigyan, [3]Professor & Head of Rasashastra-Bhaishjya Kalpana, [4]Professor Medicine, Mahatma Gandhi Ayurved College Hospital and Research Centre, Wardha (M.S.)
[2]Scientist- E, Forest Research centre for skill development Chhindawada (M.P.)
[4]Jawaharlal Neharu Medical College, sawangi (M), Wardha (M.S.)

Background: *Moringa oleifera Lam.* (*Shigru/Moringa*) is used as day to day edible product and as well as medicinal purpose for its enriched nutrients and medicinal values. Thus the biscuits of *Shigru* leaves were prepared to carry out a clinical trial to correct Iron deficiency anaemia in females. Out of 51 recruited participants during the clinical trial, one case of adverse drug reaction was reported.

Methods: An 18 year female participant with 39 kg weight included in research trial as her Hb% was 10.2 and serum ferritin was 3.85. *Moringa oleifera* enriched biscuits were given in a dose two biscuits twice daily since 7 September 2019. She has reported after 5 days i.e. on 12 September 2019 with the complaint of red rash over back and arm. She was advised to withdraw the biscuits immediately got relief within 24 hours. After restarting the biscuits, she reported again rash with itching, then a case of ADR recorded and Ayurveda treatment has been initiated

Results: After Ayurveda medication within 12 hours she got relief from itching and red rash disappeared gradually.

Conclusion: *Moringa* is even though commonly used as in many edible forms; the *Moringa* enriched biscuit reported 1 ADR out of 51 recruited participants. This is important and helpful for pharmacovigilance to record and control adversity that affects the issues of consumers and regularization of Ayurveda health care system.

Keywords: *Moringa oliefera, Shigru*, Adverse drug reaction, Pharmacovigilance, *Shatadhauta Ghruta, Laghusutashekhara Rasa, Avipattikara churna*

Abstract No. AO-02

Abstract Title: Analytical study of *Brahmi* (*Bacopa monnieri* Linn.) accession with special reference to its quality control pertaining to pharmacovigilance

Author's Name: Dr. Priyanka Wate*[1], Dr. Pramod Khobragade[2]

Author's affiliation: *[1]Assistant Professor, Dept. of Dravyaguna vigyana, M S Ayurvedic Medical College, Gondia, [2] Professor & Head of department, Dept. of Dravyaguna vigyana, DMAMCH & RC, Nagpur

Background: *Brahmi* (*Bacopa monnieri* Linn.) is a renowned medicinal plant globally used for enhancing memory and intellect. Due to unorganized harvesting & trading, lack of Good Agricultural & Collection Practices, its substitute drug *Mandukaparni* is routinely used though it has different action. Due to sub-standard raw material, finished products exhibit ADR issues. Hence, study on *Brahmi* accessions in three seasons of year, planted at different locations was carried out with emphasis on quality control & pharmacovigilance. The aim of this analytical study was to evaluate *Brahmi* accession with special reference to quality control.

Methods: Methanolic extract of wild and cultivated accession of *Brahmi* collected in summer, rainy & winter season of year 2016 was subjected to HPLC. Quantification of Bacoside A was done using standard marker compound.

Results: Minimum percentage of Bacoside A was seen in winter, moderate in summer & maximum in rainy season. Quantity of Bacoside A was higher in cultivated sample as compared to wild sample. Moderate humidity, high temperature & average rain fall in rainy season are suitable for production of quality raw material of *Brahmi*. It is advisable for herbal industries to track raw material as per these quality standards to obtain maximum efficacy as well as safety of finished products.

Conclusion: Sub-standard herbal products due to spurious raw material can affect clinical outcome along with ADR issues. Above analytical research work on Brahmi would help to enlighten about Good Agricultural & Collection Practices with minimum ADR issues.

Keywords: *Brahmi*, Pharmacovigilance, Quality control

Abstract No. AO-03

Abstract Title: Safety study of *Shodhita* (Processed) *Bhanga* (*Cannabis sativa* L.) leaves in established animal experimental models

Author's Name: Swagata Tavhare[1], Mukesh Nariya[2], Rabinarayan Acharya[3]

Author's affiliation: 1 Assistant professor, Department of Dravyaguna, GJP-IASR, New VV Nagar, Anand, Gujarat, 2. Professor & Head, Pharmacology lab, 3. Department of Dravyaguna, IPGT & RA, Gujarat Ayurved University, Jamnagar

Background: 'Safety' is one of the prime fundamental principle and critical component of quality control. *Bhanga* (*Cannabis*) is known for its wide ranging pharmacological actions. Ayurveda, to reduce intoxicant (*Madakari*) effect, recommends its use after certain processing known as *Shodhana*. To evaluate the safety of *Jalaprakshalana Shodhita Bhanga* (Water-wash processed *Cannabis*) through acute toxicity and gross behaviour study.

Methods: Acute toxicity and gross behaviour study was conducted following OECD guideline 425 (modified, adopted 23rd March 2006) in female wistar strain albino rats weighing 160 ± 20 g. Test drug (Fine powder water-wash processed *Cannabis sativa* L. leaves) in the dose 2000 mg/kg (Limit test), 400, 175, 100, 55 and 22.5 mg/kg was orally administered in selected animal along with cow milk (50 ml) mixed with sugar (4 g), as an adjuvant. Observations were made at ½, 1, 2, 3, 4, 5, 6, 24 hours after dose administration and thereafter daily once for mortality during entire period of the study (14 days). Gross behavioural changes like circling, grooming, licking, rearing, sniffing, hyperactivity, straub's tail were assessed by assigning scores on 0-3 point scale.

Results: At various studied dose levels significant gross behavioral changes were found with mortality of 33.33% at limit dose i.e. 2000 mg/kg.

Conclusion: *Jalaprakshalana Shodhita Bhanga* leaves powder administered orally is found safe from 22.5mg/kg to 400mg/kg animal dose in studied animal experimental model.

Keywords: *Bhanga*, *Cannabis*, *Shodhana*, Acute toxicity, Gross behaviour, Safety

Abstract No. AO-05

Abstract Title: Pharmacovigilance for safer use of drugs in Ayurveda through experimental study

Author's Name: Dr. Nilima Narayan Rao Wadnerwa

Author's affiliation: Asso. Prof., MGACH & RC, Salod, Wardha, Maharashtra

Background: Heavy metals are used in Ayurvedic medicine since ancient period. Case reports published in national and international journals and newspapers regarding heavy metals poisoning after the use of drugs in Ayurveda has created a negative impact on public towards the use of Ayurvedic medicine. On the ground where formulations of Ayurved are targeted to contain high levels of heavy metals, there is urgent need to have pharmacovigilance for these drugs regarding their safety in the treatment. Hence, an experimental study was conducted to assess the toxicity and to identify the factor responsible for the toxicity of the arsenical compounds *Rasamanikya* which is a very popular medicine used for various ailments.

Methods: Physical and physico-chemical properties of three different market preparations of *Rasamanikya* were studied by using advance methods (ICP-AES and XRD) and the sample containing highest level of Arsenic was subjected to chronic toxicity study in rats. Hematological and biochemical parameters were assessed at 30, 60 and 90 days and histopathological study was conducted at the end of the study.

Results: All the three samples showed variation in concentration of arsenic and its crystal size. Traces of nineteen other metal compounds were found in all samples other than Arsenic and Sulphur. There were no significant differences observed in most of hematological and biochemical parameters up to 60 days in Wistar

rats. No significant differences in body weight and relative organ weight were observed. Minimal to mild changes were observed in liver and kidney which were pathologically insignificant.

Conclusion: LD 50 of *Rasamanikya* may be more than 2000 mg/kg and *Rasamanikya* is safe for 15 days duration in the therapeutic dose in human beings. Chronic Arsenic toxicity due to *Rasamanikya* is not possible if it is consumed in therapeutic dose for 10- 15 days. But there is an urgent need of standardization of method of preparation and standardization of contents to prepare *Rasamanikya* and its use for therapeutic purposes.

Keywords: Pharmacovigilance, Heavy metal toxicity, *Rasamanikya*, Chronic Arsenic toxicity

Abstract No. AO-06

Abstract Title: Pharmacovigilance in Ayurveda – Where are we and way to go ahead

Author's Name: Dr. Shubhashree M.N.[1], Dr. Raghavendra Naik[2], Dr. Sunona George[3], Dr.B.K. Bharali[4]

Author's affiliation: 1. Research Officer (S-2), 2. Research Officer (Ayu), 3. Programme Assistant, National Pharmacovigilance Programme, Asst. Director Incharge, Regional Ayurveda Research Institute for Metabolic disorders (RARIMD), Bangalore.

Background: Due to the widespread publicity, there is a raising demand for Ayurvedic medicine not just in India, in other countries also. However, safety is still a major concern from western viewpoint. Thalidomide disaster was a wakeup call to initiate steps regarding Pharmacovigilance in conventional medicine. Ayushsuraksha web portal is a major initiative taken up for recording the Adverse drug event (ADE)/Adverse drug reaction (ADR) for AYUSH Drugs.

Methods: This paper intends to take stock of all the activities initiated so far, to spread the concept of Pharmacovigilance and intends to throw light on the possible measures which can be taken up in future at different levels . For instance –Conducting periodic CME's, making the drug information easily accessible in a portal or website with possible side effects/ADR, methods to avoid or combat the ADR will be useful to educate physicians. Hospitals and teaching institutions should conduct periodic audits for assessment and reporting of ADE, in different departments. It is equally essential to educate all stakeholders of health like pharmacist, nurses/matrons, medicos, doctors about the reporting of ADE/ADR to Peripheral Pharmacovigilance centres (PPvC) / Ayushsuraksha

Results: Real world evidence goes a long way in capturing data pertaining to medicine consumption e.g AHMIS (AYUSH Hospital Information Management Systems). Just as the world is waking up to the overusage of antibiotics, survey has to be conducted all over the country to assess whether Guggulu is overprescribed and has any long term effects as patients continue to consume for months together, assuming all herbal drugs are safe. The paper discusses at length the measures which can be taken up in future in this regard.

Conclusion:

Keywords: Pharmacovigilance, AYUSH, Ayushsuraksha

Abstract No. AO- 07

Abstract Title: Preclinical safety studies of *Rasamanikya*, an Ayurvedic Arsenical Formulation in Rats

Author's Name: Vikas Kumar[1], Shivanand Biradar[2], Galib R[3], B. J. Patgiri[4]

Author's affiliation: 1. Ph.D Scholar, Dept. of RSBK, IPGT & RA, GAU, Jamnagar; 2. Lecturer, Dept. of RSBK, Sai Ayurvedic college, Sholapur; 3. Associate Professor, Dept. of RSBK, AIIA, New Delhi; 4. Professor, Dept. of RSBK, IPGT & RA, GAU, Jamnagar

Background: In Ayurveda, use of metals and minerals is being major concern on heavy metal contents by scientific fraternity of conventional system though they are used in Ayurvedic therapeutics without any noticeable side effects since ages. So it is need of hour to evaluate the safety profile of such medicines. To evaluate the safety of *Rasamanikya* through acute and chronic toxicity studies.

Methods: *Rasamanikya* was administered at a maximal dose of 2000 mg/kg to overnight fasted rats and observed closely for behavioral changes, signs of toxicity and mortality if any, continuously for the first six hours and thereafter periodically up to 14 days. In the chronic toxicity, the drug was administered daily at the doses of 22.5, 112.5 and 225 mg/kg along with honey and ghee as an adjuvant to rats for 90 days followed by a 30 days recovery period.

Results: In acute toxicity, *Rasamanikya* at the dose of 2000 mg/kg did not produce any observable toxic effects or mortality. Safety of *Rasamanikya* at therapeutic and five-fold therapeutic dose level has been revealed in the chronic toxicity study. Mild to moderate pathological changes on different haematological, serum biochemical and cytoarchitecture of different organs were observed at ten-fold therapeutic dose level.

Conclusion: Based on these observations, it can be concluded that *Rasamanikya* is safe at therapeutic dose levels when used judiciously along with specified adjuvants.

Keywords: Arsenic, *Haratala*, *Rasamanikya*, safety, *Shodhana*, toxicity

Abstract No. AO- 08

Abstract Title: The role of adjuvant as bio-enhancer in Ayurveda drug safety and its Pharmacovigilance overview.

Author's Name: Aniket Kamble[1*], [2]Shraddha Dhundi, [3]Swapnil Chowdhary, [4]B. J. Patgiri

Author's affiliation: 1.* MD scholar, 2 Ayurvedic Physician 3. Assistant professor, 4. Pofessor, Department of Rasa Shastra and bhaishajya kalpana, IPGT & RA, Jamnagar.

Background: Pharmacovigilance (PV) plays vital role in healthcare system. It is a science related to detection, assessment, analyzing and prevention of adverse drug effect. There is raising demand of Ayurveda medicine over worldwide and hence it is a matter of concern related safety of drug. Drugs carry a number of risks and understanding the science behind adverse drug reactions can help increase the safety of new medicines through pre-clinical studies. *Anupana/sahapana* are the adjuvants that increases the drug absorption thus enhancing the bioavailability of drug. The bio-enhancement leads to reduction in therapeutic dose of principal drug, thus reducing the possibilities of toxicity and side effects of drug.

Methods: In-vivo acute and chronic toxicity study was carried out on test drug *Makardhwaja* and attempt was made to study its effect on ponderal and different bio-chemical parameter with and without adjuvant.

Results: Insignificant changes were observed in body weight, Haematological and biochemical parameters in all treated group even at 10 times TED (therapeutically equivalent dose) level in a drug with adjuvant group. Analysis of the data related to biochemical parameters indicated consistent increase in serum urea level all the three dose levels and elevation in serum creatinine at TED level in without adjuvant group.

Conclusion: This study provide sufficient data for establishing the safety when used along with *Sahapana/Anupana*. Hence, it can be taken in practices for improving the understanding drug safety issues during the drug development and it's post-approval.

Abstract No. AO-09

Abstract Title: Acute and Chronic Toxicity of *Rasa Parpati* in Charles Foster Albino Rats

Author's Name: Jigisha patel[1], Ankesh Agrawal[2], Galib[3], B. J. Patgiri[4]

Author's affiliation: 1. PhD Scholar, 4. HOD, RSBK Dept, IPGT & RA, Jamnagar, 2. Medical Officer, 3. Associate Professor, RSBK Dept, AIIA, Delhi

Background: *Rasa parpati* is an unique Ayurvedic mercurial formulation extensively prescribed by Ayurvedic physicians to treat different ailments. Considering toxicity concerns of traditional formulations for containing heavy metals like Mercury, Arsenic, Lead etc.; it becomes, imperative to evaluate safety aspects of such formulations. In Ayurveda, metals and minerals are advocated to be processed through the specified guidelines before their therapeutic application. An attempt has been made to evaluate the impact of *Shodhana* on safety aspects of *Rasa parpati* through acute and chronic toxicity of *Rasa parpati* that was prepared by two different samples of raw materials. One by using *Hingulottha parada* and *Shuddha gandhaka* (HRP) while, another with *Ashuddha parada* and *Ashuddha gandhaka* (ARP).

Methods: Oral acute toxicity of test drugs was carried out at limit dose of 2000 mg/kg orally along with adjuvant in Charles foster female rats. In chronic toxicity, both ARP and HRP were orally

administered at therapeutically equivalent dose (22.5 mg / kg), TEDx5 (112.5 mg/kg), TEDx10 (225 mg/kg) levels along with adjuvant for 90 days. Two recovery groups were also studied in the experiment.

Results: Acute toxicity revealed that, both the test drugs did not produce any signs and symptoms of toxicity and mortality up to oral dose of 2000 mg/kg in rats. Chronic administration of HRP for 90 days revealed that, the drug at TED X10 dosese has potential to produce liver and kidney toxicity however, can be relatively safe at therapeutic dose level. ARP has potential for liver, kidney and GI tract toxicity with deposition in other organs. The recovery study suggests that, after discontinuation of HRP the observed changes are reversible in nature while, in ARP some of the observed changes are irreversible in nature.

Conclusion: It is concluded that HRP was found to be safer than ARP at different dose levels suggesting safely use at therapeutic dose level.

Keywords: Ayurveda**,** Mercury**,** *Parada*, *Rasa Parpati*, Safety, Toxicity

Abstract No. AO-10

Abstract Title: Acute and subchronic toxicity study of *Gomutra* (Cow urine) *Shodhita* (processed) *Bakuchi* (*Psoralea corylifolia* Linn.) seeds powder

Author's Name: Jigyasa Pathak1*, Mukesh B.Nariya2*, Rabinarayan Acharya3*

Author's affiliation: *Ph.D Scholar, Dept. of Dravyaguna, **Head, Dept of Pharmacology, ***Professor & Head, Dept. of Dravyaguna, I.P.G.T. & R.A., Gujarat Ayurved University, Jamnagar, Gujarat, India.

Background: *Bakuchi* is frequently administered, for a long duration, in the treatment of *Switra*. Present study has been designed to ascertain the role of *Shodhana* on safety profile of *Gomutra* (cow urine) *Shodhita* (processed) *Bakuchi* seed powder, through acute oral toxicity and sub-chronic toxicity in rats.

Methods: *Bakuchi*, a known corrosive drug, was processed with *Gomutra* (cow urine) and administered to rats at dose of 2000 mg/kg, in powder form, in acute toxicity study. For subchronic toxicity study, it was administered for 60 consecutive days at the dose of 270 mg/kg (TED), 1350mg/kg (TED 5) and 2700mg/kg (TED 10). The effect of drug was assessed on ponderal changes, haematological, serum biochemical, and histopathology of various organs.

Results: In acute toxicity study, no signs of toxicity and mortality were observed during 14 days of observation. Sub chronic toxicity study, at therapeutic equivalent dose level (TED) and five times the therapeutic equivalent dose (TED 5) levels no significant sign and symptoms of toxicity were observed. Significant decrease in Hb was observed in TED and TED 10 group. Significant decrease in MCH and MCHC was observed in TED 5 and TED 10 groups. Degenerative changes were observed in the kidney, liver and stomach at therapeutic equivalent dose (TED) X 10 dose levels.

Conclusion: The observed effect of the *Bakuchi* in acute toxicity study at the dose of 2000 mg/kg suggest that drug is devoid of any serious toxic effect or adverse effect in rats. In sub-chronic toxicity, specific degenerative organ changes were observed at highest dose which suggest that the drug may produce toxic changes depending upon the dose administered.

Keywords: Acute toxicity, *Bakuchi, Psoralea corylifolia* L., *Shodhana,* Subchronic toxicity

Abstract No. AO- 11

Abstract Title: Pharmacovigilance concerns of *Tamra Bhasma* (Incinerated Copper) and its formulations –Facts

Author's Name: Swapnil Chaudhari* BJ Patgiri**

Author's affiliation: * Assistant Professor, ** Professor & Head, Dept of RS&BK, IPGT&RA, Jamnagar

Background: *Tamra Bhasma* (TB) is one among herbo-metallic mercurial preparations extensively used in routine ayurvedic practice. It is reported as poison as or more than that if not processed or purified properly as per classical methods. In current scenario, *Bhasma* preparations used in ayurveda are always under stern observations for containing heavy metals like mercury (Hg) which may raise the question of their safety. Recent articles pertaining to the alarming level of heavy metals, especially Hg in ayurvedic formulations have created a lot of controversy regarding the safety and efficacy of these formulations. Aim of the present study is to screen and compile such available published reports on safety of *Tamra Bhasma* and its formulations from different databases and provide brief information on their safety and toxicity aspects.

Methods: Available published reports on safety of *Tamra Bhasma* and its formulations from different databases are screened and compiled to provide brief information on their safety and toxicity aspects.

Results: Published reports on *Tamra Bhasma, Hridayrnava Rasa, Arogyavardhini Rasa* and *Garbha Chintamani Rasa* revealed that these formulations are found to be safe at therapeutic doses with suitable adjuvant when accessed through acute, sub chronic, chronic and genotoxicity studies in experimental animals.

Conclusion: *Tamra Bhasma* and its formulations are found to be safe at therapeutic doses when administered with suitable adjuvant in experimental models. Mere presence of metallic fractions doesn't have any relation with the toxicity of metallic preparations. Different manufacturing techniques to which the metals subjected ensures safety of these formulations. Pharmacovigilance concern for these formulations may not arise if compliance of code of conduct during pharmaceutical procedures.

Keywords: Heavy Metal, Pharmacovigilance, Safety, Tamra Bhasma and Toxicity

Abstract No. AO-12

Abstract Title: Assessment of safety of *Tankanodaka Shodhita* (borax water processed) *Vatsanabha* (*Aconitum ferox* Wall.) through acute toxicity study.

Author's Name: : Mital Buha*, Mukesh Nariya**, Rabinarayan Acharya***

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

Background: *Vatsanabha* (*Aconitum ferox* Wall.), a schedule E1 drug of Drugs and cosmetic Act 1946, root is extremely lethal and contains highly toxic alkaloids like aconitine, pseudaconitine, indaconitine, etc. Ayurveda pharmacopoeia recommends its internal administration for treating many a disease conditions after proper *Shodhana* (processing) with media like *Gomutra*, *Triphala kwatha*, *Godugdha* and *Tankanodaka* etc. Present study reports the effect of *Tankanodaka Shodhita vatsanabha* through acute toxicity city in experimental animals.

Methods: Acute toxicity (14 days) of *Shuddha Vatsanabha* was assessed by administering 140, 70 and 14 mg/kg of drug suspension in sequential manner. Single dose of drug suspension *Tankanodaka Shodhita Vatsanabha* root powder was administered once orally to overnight fasted rats.

Results: The test drug showed mortality at dose of 140 mg/kg and 70 mg/kg and abdominal writhing syndrome, convulsion like symptoms at all time in comparison to initial reading were also observed while at dose level of 14mg/kg showed no mortality but hyperactivity along with other adverse changes such as CNS depression (hypoactivity, passivity, etc), ANS stimulation in acute oral toxicity.

Conclusion: The drug produced adverse changes even at very low oral dose of 14 mg/kg on single administration which suggest that drug is highly potent hence; suggest for classification as GHS category I when processed with *Tankanodaka*.

Keywords: *Aconitum ferox* Wall., Acute toxicity, *Shodhana*

Abstract No. AO-13

Abstract Title: Concerns of Pharmacovigilance and Drug safety in Ayurveda- A Review

Author's Name: Raghavendra Naik[1], Shubhashree M N[2], Sunona George[3], B K Bharali[4]

Author's affiliation: [1]Research Officer (Ayu), [2] Research Officer (S-2), [3]Programme Assistant, [4]Asst. Director Incharge, Regional Ayurveda Research Institute for Metabolic Disorders, CCRAS, Ministry of AYUSH, Bengaluru-560109

Background: Ayurveda is a science which has been serving mankind since time immemorial, currently practiced in India and many countries. This science not only provides medical cures for disease, but its holistic approaches use distinctive principles of diet, lifestyle etc to uphold the healthy life. Since the decision making regarding choice of drugs and their doses with reference to an individual's needs relies upon the skills (*Yukti*) of the physician, ancient texts clearly mentioned that, if a drug is used without the knowledge of its action, it would certainly act as the poison. To avoid such consequences, classical texts of Ayurveda describes all the possible adverse reactions to medicines when they are prepared or used inappropriately in clinical practice.
Methods: In the current review, concepts related to Pharmacovigilance in Ayurveda were reviewed from different available classical texts and presented in a systematic manner.
Results: Though the word pharmacovigilance is not mentioned in Ayurvedic literature, the concepts and safety issues are presented throughout texts of Ayurveda. Classical texts of Ayurveda have given utmost importance to improvement of patient care and safety in every step of treatment. The concept of pharmacovigilance in Ayurveda includes selection of raw drugs, proper collection guidelines, different processing techniques, and their proper administration in appropriately diagnosed patient. Different classical texts have mentioned various causes for adverse drug reactions like overdose (*Atimatra*), drug-diet interaction, drug intolerance, use of unwholesome drugs (*Asatmya*), idiosyncrasy (*Vaidyakrita*) etc.
Conclusion: The physician who prescribes the medicine should be vigilant enough to assess all the possible adverse effects and their management in clinical practice.
Keywords: Adverse drug reactions, Ayurveda, Pharmacovigilance, *Yukti*

Abstract No. AO-14

Abstract Title: Assessment of dermal toxicity of mustard oil based formulation of *Nerium indicum*

Author's Name: Vivek Kumar Patel[1], R. N. Acharya[2]
Author's affiliation: [1]Ph.D. scholar, [2]Professor & Head, Department of Dravyaguna, IPGT&RA, Jamnagar, Gujarat, India

Background: *Nerium indicum* (family *Apocynaceae)* botanical source of *Rakta Karavira* from the *Upavisha* (semi-poisonous) category, has been mentioned for various therapeutic indications in the form of internal and external administration.
Methods: *Rakta Karavira Taila* prepared from the root bark of *Rakta Karavira* and mustard oil was used for local application. Acute dermal toxicity study was assessed in wistar albino rats at a single dermal dose of 2000 mg/kg body weight while sub-acute dermal toxicity was assessed at repeated dermal dose of 1000 mg/kg body weight, for 28 days.
Results: No mortality and toxicity were observed at single dermal dose level of 2000 mg/kg. At repeated dermal dose of 1000 mg/kg of body weight, statistically significant decrease in weight of testes, significant increase in W.B.C and platelet count while rest of hematological and biochemical parameters showed non-significant changes. Histopathological study showed sinusoidal inflammation in liver, fatty degenerative changes in liver and kidney. Severe degenerative changes in seminiferous tubules and decrease in spermatogenesis were observed in comparison to normal control group.
Conclusion: *Rakta Karavira Taila* containing toxic drug *Karavira* which have potential to produce adverse changes particularly male reproductive system therefore, should not be used for longer duration at higher dose.
Keywords: Acute dermal toxicity, *Karavira, Nerium indicum, Rakta Karavira Taila,* Sub-acute dermal toxicity.

Abstract No. AO-15

Abstract Title: Acute and Chronic Toxicity studies of *Rasasindura*, an Ayurvedic Formulation

Author's Name: Satish Solanki[1], Rohit Gokarn[2], Swapnil Chaudhari[3], Prashant Bedarkar[4], BJ Patgiri[5]
Author's affiliation: [1]PG Scholar, [3]Asst Professor, [4] Associate Professor, [5] Professor &Head, Dept of RS&BK, IPGT&RA, Jamnagar, [2] Associate Professor, Swaminarayana College, Kalol, Gujarat

Background: *Rasasindura* is a unique, Ayurvedic mercurial preparation widely used by practitioners. This work is an attempt to perform acute and chronic oral toxicity evaluation of *Rasasindura* along with an adjuvant *Guduchi Ghana* (solidified aqueous extract of *Tinospora cordifolia* Will.) in rats.
Methods: Oral acute toxicity study of test drug was carried at the limit dose of 2000 mg/kg orally in rats. For chronic toxicity, *Rasasindura* with adjuvant was administered at therapeutic equivalent dose (45 mg/kg, orally), therapeutic equivalent dose×5 (225 mg/kg, orally), therapeutic equivalent dose×10 (450 mg/kg, orally) for 90 days and an additional recovery group of therapeutic equivalent dose×10 for 30-day observation after the treatment period.
Results: Acute toxicity result showed that drug did not produce any signs and symptoms of toxicity or mortality up to an oral dose of 2000 mg/kg in rats. Chronic toxicity results showed that *Rasasindura*, even at a level as high as therapeutic equivalent dose×10 level, had no significant effect whatsoever on the ponderal and hematological parameters. Although the drug produced mild to moderate adverse changes (in kidney, liver, intestine, and stomach) at therapeutic equivalent dose×10 dose level, equivalent of which are unlikely to be ever employed in a clinical trial. The observed changes were not seen at the lower dose levels as well as in the recovery study.
Conclusion: Hence, it is suggested that the *Rasasindura*, along with the adjuvant prepared as per the customary method, is safe for consumption at the therapeutic dose level.
Keywords: Ayurveda, *Guduchi Ghana*, *Rasasindura*, Safety, Toxicity

Abstract No. AO-16

Abstract Title: Pharmacovigilance for non-metallic, non-poisonous herbal drug

Author's Name: Dr Sunitha M P
Author's affiliation: Associate Professor,
Dept Of Dravyaguna Vignana, SAMC & H, Bangalore

Background: An increased importance for the pharmacovigilance of herbal medicines is seen in current times because of the growing demand for the herbal products and herbal medicines globally. The study was aimed to analyse, factors related to herbal raw materials which may become the cause for Adverse Drug Reactions (ADRs) of the herbal drugs, which is presumed to be safe drug. To review the traditional classical references to avoid factors which may be the cause for adverse drug reactions.
Methods: This study was carried out after searching various databases like Pubmed, Google scholar, websites etc and classical texts like Charaka Samhita, Sushrutha Samhita etc. Texts books related to Dravya Guna Vignana.
Results: Knowledge of Aushadha dravya with respect to its *Nama* (Nomenclature, Identification), *Rupa* (Morphology), *Guna* (Properties – Physicochemical and Phytochemical), this covers the most of the guidelines to avoid adverse drug reaction which is similar to the HATC classification. If raw materials are not collected as per the *Dravya Sangraha* explained in *Dravyaguna Shastra* it will become the root cause for anthropogenic contamination, thus leading to ADRs. The *Dravya – Pareeksha vidhi* explained by Acharya Charaka in *Vimanasthana* 8th chapter If all these ten factors are stringently considered while administering the drug ADRs due to Drug related factors, Disease related factors and Patient related factors can be avoided. Application of *Paradi Gunas* in treatment helps in avoiding the ADRs.
Conclusion: : Basic philosophy behind the data management of herbal products and traditional medicines is to achieve a system that is capable of handling all levels of information related to herbal drugs including its ADRs. These ADRs are explained in detail under *Dravya Pareeksha Vidhi*, *Dravya Sangrahana*, and Application of *Paradi Guna* in *Chikitsa*. Hence, by the integration of classical methods of safety assessment tools and modern technical methodologies together if it is adopted, the myth of common people

i.e., herbal drugs are safe can be made Truth. Thus, even a poisonous drug can be used in therapeutics just like ambrosia for that condition without any adverse effect as told in Ayurveda.

Abstract No. AO-17

Abstract Title: Pharmacovigilance – Patient Safety in Integrative Cancer Management

Author's Name: Dr. Harish Babu H

Author's affiliation: Assistant Professor**,** Dept of Agada Tantra Evam Vidhi Vaidyaka
Sushrutha Ayurvedic Medical College and Hospital
Prashanti Kuteeram; Jodi Bingipura; Jigani Hobli; Bengaluru

Background: Cancer rates are increasing day by day globally and are main cause for morbidity and mortality too. 12.7 million Cancer cases are recorded by WHO and is said to increase to 21 million by 2030. Ayurveda is recognised for its therapeutic potential in cancer Management as well as cancer Complications. Patients approach to Ayurveda during chemo or Radiation for second opinion and take Ayurveda medicines along with chemo therapy drugs which has increased the concern of Herb-Drug interactions. To identify the potential herb drug interactions in cancer practice. To understand the synergistic or antagonistic actions of Herb-Drug.

Methods: This study was carried out based on databases like Pubmed, Google scholar, websites etc. and classical texts like Charaka Samhita, Sushrutha Samhita etc. Texts books related to pharmacovigilance.

Results: Cancer Medicines in Ayurveda are available by over the counter without any supervision with a belief that "All drugs are safe and can be used by anyone''. This has increased the chances of Drug-herb interactions which is not yet understood completely and requires proper guidelines to monitor the preparation, quality standards and Efficacy.

Conclusion: Integration of different systems is now inevitable in cancer management and has led to multi drug approach. Many Herbal or herbo- mineral formulations in Ayurveda are efficacious in treating cancer or cancer complications or Therapy complications but Their use along with chemotherapy drugs yet unknown, Pharmacovigilance helps in detection, assessment, understanding and prevention of adverse effects or any other drug related problem

Keywords: Integrative oncology; Ayurveda; cancer; Pharmacovigilance.

Abstract No. AO-18

Abstract Title: Critical review on various Basic principles to prevent ADR in children w.s.r. to *Kashyapa Samhita.*

Author's Name: Dr. Sagar M. Bhinde

Author's affiliation: Asst. Prof., Department of Kaumarbhritya, IPGT&RA, Jamnagar, Gujarat

Background: The World Health Organization defines adverse reactions as harmful and unintended responses to a drug and which occur with doses normally used in humans for prophylaxis, diagnosis or treatment of a disease or modifying a physiological function. In 2001, according to a U.S. surveillance study, ADRs were the cause of 244 outpatient visits of children under 15 years of age. Hence the practice of pharmacovigilance for paediatric use medicines requires special attention. But in Ayurveda, the chances of ADR in pediatric patients are even more, if one do not follow the basic principles given in *Kashyapa Samhita*, because there is very little description of pediatric specific management in *Brihatrayi* (three prime *Samhitas* of Ayurveda i.e. *Charaka, Sushruta* and *Ashtanaga Hridaya*) and *Laghhutrayi* (three authentic compiled books of Ayurveda i.e. *Sharangdhara, Madhav Nidana* and *Bhava Prakasha*).

Methods: Scattered references of mode of drug administration, drug dosage and basic principles for pediatric management are critically analyzed and scientific bases are searched from resent researches and from contemporary science.

Results: Pediatric specific drug dosage is given in *Lehadhyaya* and *Bhaishjopkramaniya*. Various basic principles of management are mentioned in *Aushadhbheshajendriyadhyaya*, *Dhupa Kalpadhyaya*, *Bhaishjopkramaniya*, *Yush Nirdeshniya* and many other chapters, which are unique and most important for prevention of ADR.

Conclusion: Ghee is mentioned as a vehicle for infants younger than 8 month, which is not practiced by majority of *Vaidyas* and hence could cause harm to the child. Many such basic principles are covered in *Kashyapa Samhita* to prevent ADR in children. Still if any ADR occurs in children by any means, it is utmost duty of Kaumarbhritya physician to report it to prevent further ADR to any child.

Keywords: ADR in children, Kashyapa Samhita, Kaumarbhritya, Prevention of ADR in Children

Abstract No. AO-19

Abstract Title: The pharmacovigilance concern as mentioned in various chapters of *priya nighantu*

Author's Name: Tarun Sharma[1]*, Rabinarayan Acharya[2]

Author's affiliation: Assistant Professor, PG Dept. of Dravyaguna Vigyana, J. S. Ayurveda Mahavidyalaya, Nadiad, Gujarat, India, 2 Professor, PG Dept. of Dravyaguna Vigyana, IPGT & RA, GAU, Jamnagar, Gujarat, India

Background: Pharmacovigilance plays a crucial role in optimizing drug safety and improving treatment outcomes. There is a necessity to upsurge the pharmaco-vigilant views of prophets who have already mentioned the attainable adverse effects of medicinal plants, minerals, animal products if not administered judiciously. The best illustrations in these lines are evident in *Nighantus* (lexicons) of *Dravyaguna*. *Priya Nighantu,* one among them postulates varied undesirable actions of drugs and even food items once consumed wrong or against regular protocol. The present paper is an attempt to focus on the pharmacovigilant aspects of certain medicinal plants documented in *Priya Nighantu*.

Methods: The present review is about the possible adverse effects caused by inappropriate administration of some medicinal plants that have been documented by author of *Priya Nighantu*. The observations have been given in a tabular form consisting of the name of the plant, part used, botanical name, its effect on *dosha, dhatu, mala* and others.

Results: It is observed that out of total 13 Vargas (classified group), near about 474 drugs of herbal origin were reviewed critically with regards to provocation of *dosha, dhatu, mala* and other possible adverse effects.

Conclusion: After a critical analysis, it is observed that *Priya Nighantu* has a well-developed idea about adverse effects of drug and diets if not consumed according to classical recommendations.

Keywords: *Ayurveda***,** *Dravyaguna***,** Drug safety, pharmacovigilance, *Priya Nighantu*

Abstract No. AO-20

Abstract Title: Perspective of Ayurveda on use of medicinal plants to avoid possible risk in *Garbhini*

Author's Name: Rasika Kolhe[1]*, Vishnu Bavne[2]Author's Affiliation: 1.* Research Officer (Ayurveda) -Regional Ayurveda Institute for Fundamental Research (RAIFR), Kothrud, Pune, 2. Associate professor (Dept. of Stree Roga and Prasuti tantra)- D. Y. Patil School of Ayurveda, Nerul, Navi Mumbai

Background: *Garbhini Avastha* is one of the precious stages of any woman's life and utmost importance has been given to the safety of pregnant woman and healthy progeny. Ayurveda advise code of conduct to be followed right from the *Rajaswala* to *Sutika.* Do's and don'ts are mentioned directly or through fundamental principle. But nowadays many cases of ADR due to Ayurvedic products and medicinal plants have been reported in the journals and news. Prevalence of herbal medicine in pregnant woman is very common. But data on their safety among women and neonates is not available. To compile and critical analysis the information and data regarding use of herbal medicine and their safety in pregnancy.

Methods: Classical references of medicinal plants contraindicated in *Garbhini*, and certain fundamental principle from *Samhita* elucidating the safety aspect of *Garbhini* and *Sutika* have been compiled. Reported data on ADR in pregnancy have been critically analysed and presented systematically.

Results: *Aardrka*(*Zingiber officinale* Roscoe.), *Methika* (*Trigonella foenum greacum L.*), *Markandika (Cassia angustifolia Vahl.), Erand* (*Ricinus communis* L.) have been reported with ADR in pregnant woman. In the classical text *Haritaki, Rasona, Palandu, Suran* etc. are clearly contraindicated, whereas use of hot, spicy,

heavy to digest food, *Kshara* (Alkali preparation), Pulses, *Panchakarma* regime, etc. are also contraindicated.

Conclusion: Understanding of fundamental principle of Ayurveda, do's and don'ts for the use of medicinal plants, Code of conduct and *Garbhopaghatakar Bhav* depicted in classical text will definitely help to create awareness about prevention of possible adverse effects during pregnancy or the postnatal period.

Keywords: Ayurveda, *Garbhini*, Safety, Pharmacovigilance

Abstract No. AO-21

Abstract Title: Cytotoxicity evaluation of seed oil of *Terminalia bellerica Roxb.*using tetrazolium (MTT) assay

Author's Name: Dr. Neha Gaonkar

Author's affiliation: final year, YMT Ayurved Medical College, Kharghar, Navi Mumbai, Maharashtra

Background: Various assays are used to evaluate the cytotoxic effect of drugs on cultured cells. The MTT(dimethylthiazol diphenyltetrazolium bromide) assay is a colorimetric assay based on mitochondrial uptake and succinct dehydrogenase reduction of soluble, yellow, MTT tetrazolium salt to an insoluble blue MTT formazen product. The aim of this study was to evaluate the cytotoxicity of seed oil of *Terminalia bellerica Roxb* using MTT assay.

Methods: Mouse fibroblast cells were seeded into a 96 well plate and incubated for 24 hours. After 24 hours investigational samples were added into respective wells in triplicates and incubated for 24 hours.After an exposure, MTT reagent was added to each well and plates were incubated for 4 hours. MTT medium was discarded carefully and the formazen crystals were eluted in SDS reagent. Plate was kept at room temperature for 30 minutes and then was read at 570 nm. Total 4 set of concentrations from 0.1 mg/ml to 1 mg/ml were done, and percent viability was calculated.

Results & Conclusion: Concentrations of 0.1 mg/ml, 0.3 mg/ml,0.5 mg/ml and 1 mg/ml showed percent viability of 97.3%,95.8%,67.1%,45.8% respectively, indicating toxicity above 1 mg/ml.Seed oil of *Terminalia bellerica Roxb* has been described for premature hair graying in the form of *Pratimarsha nasya* which consists of 1-2 drops which justifies the toxicity levels above the concentration of 1 mg/ml.

Keywords: MTT assay, seed oil of *Terminalia bellerica Roxb*.

Abstract No. SO-01

Abstract Title: *Sidd*AR (Siddha Initiative for Documentation of Drug Adverse Reaction): Android Mobile App for AYUSH Pharmacovigilance Programmes: An efficient and easy way of assessing ADR.

Author's Name: Sathiyarajeswaran P[*1], Shree Devi MS[2]

Author's affiliation: [*]1. Director in-charge, Siddha Central Research Institute, CCRS, Chennai., 2. Research Officer(S), Dept of Pharmacy, Siddha Central Research Institute, CCRS, Chennai.

Background: Mobile phones have become integral part of human life. A mobile application helps in delivering food and also helps to conduct delivery. Apart from connectivity, android and iPhone make ease of all activities. One area of those applications is healthcare applications. *"SiddAR"* (**S**iddha **I**nitiative for **D**ocumentation of **D**rug **A**dverse **R**eaction) Android Mobile App is a pioneer app of its kind in AYUSH which helps in documenting, reporting and improve the communication of safety issues related to adverse drug reaction. Siddha Central Research Institute, Chennai is a Peripheral Pharmacovigilance Centre developed *"SiddAR"*, a free smartphone app available on Android stores, for reporting adverse drug reactions and requesting drug safety information instantaneously. In AYUSH, pharmacovigilance contemporary documentation process involves in submission of reports through filled in physical forms or online forms. Rapidity in reporting would be lifesaving and also helps to prevent mortality and morbidity

Methods: A questionnaire comprising of 25 questions in the report form were combined in the App. Algorithms were written and mobile app was designed using Android studio with eclipse plug-in along with SDK tools and manager. The app runs on android based Operating system of version 2.1 or higher.

Results: This Android app helps in real time documentation, lessening the time consumption and promotes the habit of being vigilant with drugs in market and their defects in manufacturing process. This App facilitates the Researcher to document ADR in clinical trials. This app would be a boon to the AYUSH health professionals and support team like nurses, AYUSH pharmacy persons and allied AYUSH persons to report the adverse events caused by or possibly by drugs and to stream line the process of ADR reporting and analysis.

Conclusion: *"SiddAR"* ADR android mobile app can be an effective alternative method to manual ADR analysis and can become an important tool in strengthening the AYUSH Pharmacovigilance programmes.

Keywords: *"SiddAR",* Android mobile APP, ADR, Siddha, AYUSH, pharmacovigilance.

Abstract No. SO-02

Abstract Title: *Serankottai* induced contact dermatitis during *Suthi* process in Siddha - A case report

Author's Name: Juliet. L [*1] Karthikraja.S.R[2] Reena.V.L[3], Aarthi.V [4] Sathiya, Rajeshwaran. P[5]

Author's affiliation: [*1]*Research Officer (Siddha), Siddha Central Research Institute, Chennai, Tamilnadu, India.* [2]*Research Associate, Siddha Central Research Institute, Chennai, Tamilnadu, India,* [3]*Assistant Research Officer (Chemistry), Siddha Central Research Institute, Chennai, Tamilnadu, India, 4 Research Officer (Siddha), Central Council for Research in Siddha, Chennai, Tamilnadu, India, 5 Director i/c, Siddha Central Research Institute, Chennai, Tamilnadu, India.*

Background: In Siddha, the famous quote 'Chukkuku pura nanju ,Kadukaiku aga nanju', reveals that most of the plants are adjoined with the toxic part /chemical which has to be removed by the Suthi process before its medicinal uses. Any untoward medical occurance during treatment is the ADR (Adverse drug reaction). *Serankottai* (*Semecarpus anacardium* nuts- SA nuts) is enormously used in Siddha medicine for various challenging diseases like Rheumatoid arthritis, Cancer, Psoriasis, etc. It comes under poisonous herbs of Siddha, Schedule-E (1) drugs in Drugs and cosmetics rule. This study reports about the toxic signs developed by unprocessed *Serankottai* and its management through Siddha medicines.

Methods: Reporting of a single case, presented with contact dermatitis- 2 days after the exposure of unprocessed *Serankottai* during Siddha purification method in Siddha manufacturing unit and the negative rechallenge of the symptoms by Siddha antidotes were discussed.

Results: It is to report that, unprocessed *Serankottai* induced contact dermatitis has been successfully managed by proper *Siddha* antidotes like *Puli ilai kudineer* (Tamarind leaf decoction)-120 ml thrice a day and *Sengal podi ottradam* (Brick powder Fomentation) twice a day for 1 week as mentioned in *Gunapadam mooligai vagupu and Sattam saarndha maruthuvamum nanju maruthuvamum.*

Conclusion: Proper purification of Toxic plants reduce toxicity to end user. Siddhars have documented step by step SOP in purification of toxic plants. They have also prescribed remediation helping in negative rechallenge. Here a case has been reported with clinical manifestations like blisters and boils after getting consent as per the CARE Guidelines to reveal the negative rechallenge in pharmacovigilance.

Keywords: *ADR, Pharmacovigilance*, *Semecarpus anacardium-nut, Suthimuraigal*

Abstract No. SO-03

Abstract Title: Siddha traditional testing methods to ensure the quality, safety and preventing adverse drug reactions in ASU medicines

Author's Name: Sivakkumar. S[1], Juliet.L[2], Visweswaran .S[1], Muthukumar .N.J[3]

Author's affiliation: [1*] Associate Professor, Department of Gunapadam, National Institute of Siddha, Chennai, [2] Research Officer (Siddha), Siddha Central Research Institute , Chennai, [3] Director, National Institute of Siddha, Chennai.

Background: AYUSH system of medicine is popularized all over the world. In these systems heavy metals and minerals are being used for higher order medicine like *Parpam*, *Chenduram*, *Kattu* , *Pathangam* preparation. The usage of these ingredients may cause Adverse Drug Reaction when it's not properly processed and

prepared as per guidelines. The monitoring and documentation of pharmacovigilance events are more important to ensure the safety of ASU metallic formulation preparations. This study is aimed to collect various traditional testing methods for metallic products to ensure the safety of higher order medicines.

Methods: In this paper various testing methods have been discussed for metallic and mineral preparations like Mercury, Arsenic, Lead, Silver, Gold, Copper, Iron, Magnet, Tin, Zinc based Siddha medicines. These testing methods help to find out the presence of metals and minerals whether it is in metallic unprocessed form in the final products.

Results: If the treated metals are present in its metallic form in the finished product, it may be a reason for ADR events after administration to the patients. This result of the testing methods, checks authenticity and need of repeating adopted pharmaceutical operating processes like grinding, frying, melting, incineration for the removal of toxic substances or discard the medicine because of improper processing.

Conclusion: This review concludes that, following these Siddha traditional testing methods particularly for higher order medicines before administering the patients, definitely helps to prevent the ADR. The author recommended using these methods extensively for entire AYUSH system of medicine for providing better and safe health care service.

Keywords: Siddha Testing Methods; ADR; Pharmacovigilance.

Abstract No. SO-04

Abstract Title: *"DOOR MAN"* (Documentation of Objectionable advertisement and Reporting under Magic and Remedies Act Notification) Android Mobile App for AYUSH Magical Remedial Act Programmes: An efficient and easy way of assessing Magic Remedies Act.

Author's Name: Shree Devi MS [*1], Sathiyarajeswaran P [2]

Author's affiliation: [*]1. Research Officer(S), Dept of Pharmacy, Siddha Central Research Institute, CCRS, Chennai., 2. Director in-charge, Siddha Central Research Institute, CCRS, Chennai.

Background: ***"DOOR MAN"*** (**D**ocumentation **O**f **O**bjectionable advertisement and **R**eporting under **M**agic and Remedies **A**ct **N**otification) Android Mobile App is a pioneer app of its kind in AYUSH which helps in documenting, reporting and improve communication of safety issues related to false claims, magic and misleading advertisements. Siddha Central Research Institute, Chennai is a Peripheral Pharmacovigilance Centre developed *"DOOR MAN"*, a free smartphone app which will be available on Android stores, after beta version deployment. In recent times, the incidence of false claims, magic and misleading advertisements with embellished claims on efficacy has increased by multiple folds. These Indian legislations govern the 'Schedule J of Drugs and Cosmetics Rules' and 'Drugs and Magic Remedies Act' advertisement related to drugs, treatments and procedures. As per the statement from Honourable Minister, Ministry of AYUSH has come across 804 instances of misleading advertisements/claims allegedly of herbal/AYUSH products & services including Ayurvedic medicines during the period of last two years and current year from April, 2015 to January, 2018 as reported from the Advertising Standards Council of India (ASCI) and the Grievances Against Misleading Advertisements (GAMA) portal maintained by the Department of Consumer Affairs. This Android Application helps to enforce Drugs and Magic Remedies Act, in AYUSH, which will attempt to capture the advertisements, videos, Tv shows, Pamphlets related to drugs, treatments and procedures appearing irrespective of their rationality, truthfulness and violation of Indian Legislations specific to Drug and Magic Remedies Act.

Methods: A questionnaire comprising of 15 questions in the report form were combined in the App. Algorithms were written and mobile app was designed using Android Studio with Eclipse plug-in along with SDK tools and manager. The app runs on android based Operating System of version 2.1 or higher.

Results: This Android app helps in capturing real time Misleading advertisements, tele-marketing, multi-level marketing, direct selling which promotes various products by making unrealistic claims. It will lessen the time consumption and promotes the habit of being vigilant against violation of Drugs and Magic Remedies Act. This App shall facilitate the AYUSH Physician, Pharmacist, Health Worker, Nurse, Social Worker, NGO, others (including public) to report. This app would be a boon to the AYUSH community which has responsibility to preserve legacy and ensure its credibility which should not be compromised for cheap publicity or short-term economic gains.

Conclusion: ***"DOOR MAN"*** android mobile app can be an effective method to capture Misleading Advertisements and can become an important tool in strengthening the AYUSH Community.

Keywords: *"DOOR MAN",* Android mobile APP, Drugs and Magic Remedies Act, Siddha, AYUSH, Misleading advertisements.

Abstract No. HO-01

Abstract Title: Contaminants of medicinal herbs & its prevention

Author's Name: Dr. Ramesh Bawaskar

Author's affiliation: Research Officer (H)/S-3, Regional Research Institute for Homoeopathy, Navi Mumbai under CCRH, Ministry of AYUSH, Govt. India, New Delhi

Background: As per the WHO report around 80% of people around the globe rely on herbal medicines for some aspects of their primary health care. In 2016 the global herbal medicine market was around USD 71.19 billion which expected to reach USD 5 trillion by 2050. An increase in popularity has also concerns and fears over the contamination of herbal products.

Methods: The recent available literature on various contaminants of herbal products is searched in a database like MedlinePlus, PubMed, AMED, Scopus, EMBASE, ProQuest, CAM-QUEST, CINHAL and aim to address the issues related to plant contaminants & strategy to prevent & screen such major common contaminants.

Results: It is found that the cultivation of medicinal plants is mostly based on social, religious & cultural values of that particular geographical region due to this the recent advances in the medicinal science & pharmaceutical industry is ignored. Chemical contaminants (Pesticide residues, toxic elements such as heavy metals, etc) and biological contaminants (microbes and other organisms) are major common contaminants of medicinal herbs and herbal products.

Conclusion: Over the past decade, numerous news-catching episodes in developed communities indicated adverse effects of ASU&H drugs may be due to contaminated heavy metals, chemical toxins with excessive or banned pesticides, microbial contaminants, etc. This contamination of medicinal plants may be related to the source of these herbal materials if they are cultivated in a contaminated environment or during the collection of these plant materials or the supply to industry and while manufacturing of the finished product, etc. Poor regulatory framework across the globe is the main concern for the production of herbal medicine. To prevent and screen for contamination with safety and traditional values of medicinal herbs and herbal products appropriate regulatory framework is required. To ensure the safety & efficacy of herbal products standard operating procedure (SOP) from cultivation to finished product is required this includes good agricultural practice, good supply practice, good manufacturing practice (GMP), etc.

Abstract No. HO-02

Abstract Title: Standard operating procedures of monitoring suspected adverse drug reaction of Homoeopathy drugs.

Author's Name: Prof. Premnidhan Pal Chowdhury

Author's affiliation: Program co – ordination, Peripheral Pharmacovigilance Centre at Govt., Homoeopathic Medical College & Hospital, Bhopal, M.P.

Background: It is the universal law that action of any substance has its equal and opposite reaction. The reaction of drug is studied on lower animals, healthy person or on diseased person. A particular system of medical treatment in the universe is differed as their principles of treatment are different. It is evident that homoeopathic drug action is established and recorded after application on healthy individuals and the curative action of the particular drug has been also established by application on diseased individuals. It is the question whether homoeopathic drugs has any suspected adverse drug reaction or not. For that a standard operating procedures is required for monitoring the suspected drug reaction of homoeopathic drugs.

Methods: WHO defined the adverse drug reaction in 2002 as"a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function". History reveals that several patients of different diseased conditions are treated by homoeopathic drugs without showing any adverse reaction. The monitoring method include group of patient and doctors education on the terms adverse reaction, adverse effect and side effects, communication through whats App or SMS on mobile any phenomena occurred after taking medicine and recording of doctor and patients observation on a case record form in a teaching hospital or in a community.

Results: All the information of both the patients and doctors are to be scrutinized properly on the behalf of homoeopathic principles and WHO principles of detection of adverse reaction or effect.

Conclusion: It is to be concluded that this standard operating procedures are either helpful for monitoring the adverse reaction of homoeopathic drugs or a new procedure may be developed.

Abstract No. MO-01

Abstract Title: Anti-retroviral therapy (ART) regimens and associated adverse events: A prospective observational study in a Tertiary Care Hospital of South Odisha

Author's Name: Chinmaya Mahapatra[1], Jai Prakash[2], Y. Roja Ramani[1*], M.V. Ram Chandra Rao[3], Prasana Kumar Kar[3], Supriya Sahoo[3]

Author's affiliation: [1]Department of Pharmacology, M.K.C.G. Medical College & Hospital, Berhampur, Odisha., [2]Senior Principal Scientific officer, Indian Pharmacopoeia Commission, Ghaziabad, U.P., [3]ART Centre, M.K.C.G. Medical College & Hospital, Berhampur, Odisha

Background: HIV prevalence in Odisha has reduced to 0.13% from 0.31 % (2010) since the advent of antiretroviral therapy (ART). It has been proven to be efficacious and also lifesaving in patients living with HIV (PLHIV). However their associated adverse events [AEs] are a matter of serious concern. Therefore the present study was conducted to evaluate the AEs following various ART regimens.

Methods: This was a prospective observational study (September 2018 - August 2019) among PLHIV and receiving ART from the outpatient setting of ART centre of M.K.C.G. Medical College & Hospital, Berhampur, Odisha. Data were collected and analyzed to find out the demographic characteristics, causality and severity of adverse events (AEs) with different ART regimens.

Results: The study showed that, 317 patients were identified to be suffering from one or more adverse events. Female gender, 40-49 years age group were more prone to adverse events. Among them, Eight (8) cases were labeled as 'serious' category and were hospitalized. 97.5% patients were graded as 'possible' [WHO-UMC causality assessment scale]. Patients were administered 10 types of ART regimen of which most AEs (217) were observed with Tenofovir + Lamivudine + Efavirenz (TLE). Most commonly observed adverse events were acid peptic disease (89), myalgia (85), acute respiratory tract infection (18), anemia (15), neuritis (15).

Conclusion: ART regimen has considerably reduced the morbidity and mortality of PLHIV, but increased numbers of AEs, demands intensive monitoring and timely intervention for tackling the associated AEs to improve patient compliance and quality of life.

Abstract No. MO-02

Abstract Title: Pellagroid Dermatitis due to Phenytoin Medication Error in an adult woman with Generalized Epilepsy

Author's Name: Dholakia HJ[1], Singh AP[2]

Author's affiliation: 1-Second year resident, 2 – Professor & Head of Department, Department of Pharmacology, PDU Medical College, Rajkot, Gujarat, India

Background: Phenytoin is an antiepileptic drug used for treatment of Generalized Tonic Clonic seizures and partial seizures. It has very narrow therapeutic Index. Its therapeutic range is 10-20 mcg/dL. Pellagroid Dermatitis is a rare ADR of Phenytoin.

Case report: A 25 years female, having epilepsy since 1 month was prescribed phenytoin 100mg thrice a day. She, due to misunderstanding; took 3 tablets of 100mg, together at bed time and plasma level of phenytoin was elevated to 33.44mcg/dL along with Pellagroid Dermatitis, Diarrhea and Giddiness. Rashes were distributed bilaterally, on the exposed areas of back of hands up to rim of sleeves (Pellagra Gloves). Area involved in legs is up to the edge of trousers or skirt. As Tab. Phenytoin was withdrawn, diarrhea and giddiness improved. She was given Tab. Niacinamide 250mg twice a day. Patient was shifted to tab. Valproate 200mg thrice a day orally.

Discussion: Phenytoin elimination is dose dependent. At low blood levels 10-15mcg/dl, it follows first order kinetics; as the blood level rises above 20mcg/dl, liver enzymes get saturated and plasma level rises rapidly. Peak plasma level reaches within 3-12 hours of oral administration. Plasma levels in individual's shows emergence of dose-related side effects.

Conclusion: Phenytoin may contribute to niacin deficiency at higher concentration that can manifest as pellagra. As the drug has narrow therapeutic index, therapeutic drug monitoring along with counseling of patient for proper use of medicine must be done.

Keywords: Phenytoin, Pellagroid dermatitis, medication error

Abstract No. MO-03

Abstract Title: Patient knowledge and awareness regarding their prescribed medication

Author's Name: Hetul Patel[1], Minaxi Shah[2], Sumit Patel[3], Akanksha Prajapati[4] and R. K. Dikshit[5]

Author's affiliation: [1]Resident, 2nd year, [2]Professor, [3]Associate Professor, [4]Assistnt Professor, [5]Professor and Head, Department of Pharmacology, GCS Medical College, Hospital and Research Center, Ahmedabad, 380025, Gujarat, India.

Background: Patient's medication knowledge is important for a better outcome, compliance and adherence. Improper information may affect the treatment outcome. Therefore, this work was carried out to evaluate the knowledge in patients regarding their prescribed medications.

Methods: A cross sectional study was carried out in out-patient pharmacy at GCS Hospital, Ahmedabad from January to May 2019. Adult patients (251) were interviewed as per questionnaire and categorised according to their information status regarding disease condition and prescribed medication.

Results: Males and females were 139 (55.4%) and 112 (44.6%) respectively with mean age of 42 years. Patients with no education, primary education, higher education and graduation were 10%, 28%, 45%, 17% respectively. All patients were informed about medication by doctor and pharmacist. Additional source of information were family members and internet. About 45% recalled the appropriate name of drug and 86% graduate patients cross checked their symptoms and/or diagnosis on internet [$p<0.05$]. Only 24% with higher education discontinued the treatment without guidance. [$p>0.05$].Tendency to reuse the old prescription was more in higher education and graduate group [$p<0.05$]. All knew route, frequency and total duration of treatment. None of them were aware about side effects of drugs. Knowledge about indication(s) differed as per education.

Conclusion: Patient's interest, education, clear instructions from doctors as well as pharmacist are major factors associated with improved awareness regarding use of medicines.

Abstract No. MO-04

Abstract Title: Clinical audit of high risk medications use in NICU and PICU

Author's Name: Dr Anjali Goyal, Dr Rhythm Mahajan, Dr Nazima Mirza, Dr Bharat Gajjar, Dr Monica Gupta

Author's affiliation: Pramukh Swami Medical College, Karamsad (Gujarat)

Background: National Quality Forum (USA) has included "identification of all high-alert drugs, and implementing policies and processes to minimize the risks associated with their usage," among the 30 safe practices for better health care. High-risk medications are the drugs responsible for significant patient harm when they are used by error. So, we intended to perform Clinical Audit relating to High Risk Medications (HRM) use in PICU and NICU for possibility of improvement in its safe use.

Methods: Clinical audit of Case Record Sheets from Neonatal and Paediatric Intensive Care Units (NICU and PICU) were done from May to July, 2019. Data entered in files were assessed against

prescribed standards of the Institute, namely (1) HRM highlighted with red colour in prescription, (2) Appropriateness of HRM regimen, (3) Verification of HRM by two nurses or doctors before administration, (4) Monitoring of patients after administering HRM.
Results: Eighteen high risk medications were found prescribed in 8 cases, out of 36 cases evaluated. High risk medications were not highlighted with red colour in any of the prescriptions. The HRM regimen, verification of HRM and monitoring of patients after administering HRM were appropriate in 100% of the cases.
Conclusion: Safety standards of the institute should be followed in total for safer use of HRM. Frequent clinical audit is required to confirm the improvement in compliance.

Abstract No. MO-05
Abstract Title: Pattern of adverse drug reactions among Geriatric population of Anand district
Author's Name: Dr. Zalak Dalwadi
Author's affiliation: 3rd year resident, Pharmacology, Vallabhavidyanagar, Gujarat.
Background: The use of medication among the elderly population has increased tremendously. Elderly are particularly at increased risk of adverse drug reactions attributed mainly to polypharmacy & physiological changes affecting pharmacokinetics & pharmacodynamics of many drugs. The use of certain drugs in elderly patients is associated with increased probability of ADRs in comparison with the administration of the same medications in younger patients. To observe type & pattern of adverse drug reactions among geriatric population.
Methods: It was prospective observational study of two years. Total 500 patients were enrolled. Out of 500 participants, total 55 adverse drug events (ADEs) were observed in 47 participants during past 6 months. These ADRs were confirmed by their treating physicians. Causality was assessed by WHO-UMC probability scale.
Results: On analyzing 500 participants for various diseases, Cardiovascular diseases (43.31%) & Diabetes mellitus (16.03%) were most prevalent, so does the ADEs. Out of 55 observed ADEs, 18 (32.72%) were due to OHAs/Insulin &17 (30.90%) were due to cardiovascular drugs. Most common pattern of observed drug reactions were hypoglycemia and gastrointestinal upset (12.72%) each.
Conclusion: In the elderly population cardiovascular disease & Diabetes mellitus are two major morbidities therefore their treatment optimization & appropriate monitoring is required to prevent ADRs.
Keywords: ADR, Cardiovacular diseases, Diabetes mellitus, Elder populations.

Abstract No. MO-06
Abstract Title: An evaluation of Trigger Tool Method for adverse drug reaction monitoring at a tertiary care teaching hospital
Author's Name: Jaydipsinh Gohil[1], Jigar Panchal[1], Chetna Desai[1], Rajnish Patel[2], Gunvant Rathod[2]
Author's affiliation: 1. Department of Pharmacology, BJ Medical College, Ahmedabad, 2. Department of Surgery, BJ Medical College and Civil Hospital Ahmedabad
Background: Trigger Tool Method (TTM) is an active surveillance method for ADR monitoring. The study aimed to evaluate TTM for ADR monitoring in indoor patients of surgery department.
Methods: This prospective, observational study was conducted at Department of Surgery of a tertiary care hospital in Gujarat. Patients of either gender and more than 18 years of age admitted to two selected surgery units were enrolled with prior informed consent. Preliminary Trigger Tool list (PTTL) comprising 13 drug triggers, 13 patient triggers, 9 laboratory triggers and 12 surgical module triggers was used. Patients were followed up till discharge to monitor occurrence of triggers and adverse events, if any.
Results: A total of 216 patients were included with male: female ratio of 2.17:1 and mean age of 43.08±16.4 years. The mean length of hospital stay was 5.74±3.1 days. Out of 216 patients, triggers were present in 196 patients (90.7%) and no trigger was observed in 20 patients (9.3%). Of the 47 triggers in PTTL, 24 triggers were observed 645 times, of these 14 triggers lead to the detection of 28 ADRs in 26 patients. The rate of ADEs was 12.5/100 patients. Drug trigger was the most common trigger identified (80%). Positive predictive values (PPV) for patient triggers, surgical module triggers, drug triggers, laboratory triggers were 25%, 21.73%, 11.22% and 6.25% respectively. The comprehensive PPV of PTTL was 13.26%.
Conclusion: TTM is an effective method of ADR monitoring in Surgery Department. An awareness of TT helps better detection of ADRs.

Abstract No. MO-07
Abstract Title: Treatment Outcomes of HIV Positive Patients Treated with Protease Inhibitor-Based Antiretroviral Regimens
Author's Name: Pathak JV[1], Gandhi AM[1], Desai CK[1], Desai MK[1], Shah SP[1]
Author's affiliation: 1. Department of Pharmacology, B.J Medical College, Ahmedabad
Background: The increasing resistance of first line drugs in Human Immunodeficiency Virus (HIV) positive patients has led to the use of second line drugs which are protease inhibitor (PI) based antiretroviral regimens. This study aims to evaluate the treatment outcomes – efficacy and safety of protease inhibitor based antiretroviral regimens in HIV positive patients.
Methods: A retro-prospective study was carried out over a period of 24 months in HIV patients taking protease inhibitor-based antiretroviral therapy. CD4 count, plasma viral load (PVL) and adverse drug reactions (ADRs) were analyzed to study the efficacy and safety of the protease inhibitor based antiretroviral regimens respectively.
Results: A total of 227 patients were enrolled and 6 PI based regimens were studied. The mean age of the patients was 42.09 ± 10.09 years. Mean baseline CD4 count and PVL was 206.51 ± 197.55 cells/mm^3 and 280283.9 ± 819934.3 copies/ml respectively. A significant increase ($p<0.05$) in the mean CD4 count was seen in all the regimens with a higher increase in the Raltegravir + Lopinavir + Ritonavir group (76%) at 6 months. Moreover, virological suppression (PVL<400 copies/ml) at 12 months was seen in 73.8% patients (n=84 patients). A total of 96 (42.3%) patients experienced ADRs the most common being hyperbilirubinemia in 25% patients.
Conclusion: PI based regimens showed optimum efficacy and safety with success rate of 73.8% in treatment experienced HIV positive patients.