14th World Congress on

Toxicology and Pharmacology

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Scientific Tracks & Abstracts

(Day 1)

Brian Waters et al., Toxicol Open Access 2018, Volume 4
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A comprehensive method for the screening of drugs in severely decomposed human tissues by fast gas chromatography/tandem mass spectroscopy (Fast GC-MS/MS)

Brian Waters, Kenji Hara, Natsuki Ikematsu, Mio Takayama, Aya Matsusue, Masayuki Kashiwagi and Shin-Ichi Kubo
Fukuoka University, Japan

Statement of the Problem: Drug screening is an important reference in forensic autopsy investigations. In postmortem toxicology, often the samples provided for analysis are in a severe state of putrefaction or decomposition. The presence of breakdown products such as lipids and amino acids make extraction of the compounds of interest difficult. Also, developing an analytical method capable of detecting trace levels of analytes from the interfering substances present in these complex matrices adds to the challenges.

Methodology & Theoretical Orientation: For this study, putrefied and decomposing tissue samples from actual cases autopsied at our department were analyzed. Human tissue specimens consisted of liver, kidney, spleen, lung, muscle and brain, if available. The drugs detected from these specimens included phenobarbital, chlorpromazine, promethazine, aripiprazole, amlodipine, telmisartan, rosvastatine, chlorpheniramine, etizolam and zolpidem. Specimens of 0.3 g were treated with urease, acidified or alkalized and extracted with acetonitrile. Lipid-removal and solid-phase extraction cartridges were employed while carefully monitoring the pH of samples to ensure the adequate removal of interfering substances. The extracts were evaporated and reconstituted in n-propyl acetate:methanol (1:1) for fast GC-MS/MS analysis.

Findings: The developed method was successful in clearly identifying drugs from putrefied specimens. The use of tandem mass spectrometry helped to reduce the influence of background noise and interfering substances.

Conclusion & Significance: Putrefied specimens are often the only remaining samples left from severely decomposed cadavers. The combination of a robust preparation method and analysis with fast GC-MS/MS could aid the forensic medicine and toxicology communities in elucidating important information from these often-overlooked biological matrices.

Recent Publications

1. Hara K, Waters B, Ikematsu N, et al. (2016) Development of a preparation method to produce a single sample that can be applied to both LC-MS/MS and GC-MS for the screening of postmortem specimens. *Legal Medicine*; 21: 85-92.
2. Waters B, Ikematsu N, Hara K, et al. (2016) GC-PCI-MS/MS and LC-ESI-MS/MS databases for the detection of 104 psychotropic compounds. *Legal Medicine*; 20: 1-7.

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1. Butzbach D (2010) The influence of putrefaction and sample storage on post-mortem toxicology results. *Forensic Science, Medicine and Pathology*; 6: 35-45.
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3. Wiebe T, Watterson J (2014) Analysis of tramadol and O-desmethyltramadol in decomposed skeletal tissues following acute and repeated tramadol exposure by gas chromatography mass spectrometry. *Forensic Science International*; 242: 261-265.

Biography

Brian Waters has received his Master of Science degree in Criminalistics from California State University Los Angeles, USA. After working as a Criminalist for the County of Los Angeles, Department of Coroner/Medical Examiner for almost 8 years, he has joined as an Assistant Professor in the Department of Forensic Medicine at Fukuoka University in Japan. His specialty is postmortem forensic toxicology and he has published academic papers on fast gas chromatography-mass spectrometry, the analysis of novel psychoactive compounds, preparation methods for postmortem samples and the analysis of volatile hydrocarbons in blood.

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Fabio de Oliveira, Toxicol Open Access 2018, Volume 4
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Snake venom peptides: Potential therapeutic agents in thrombotic diseases

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The snake venoms are constituted of a true biochemical arsenal, consisting of several proteins and peptides with activities that have aroused the curiosity of researchers for centuries, in an attempt to understand its systemic action in order to get pharmacological applications. A number of snake venom proteins that interfere on platelet aggregation have been isolated from these venoms. However, there are no reports in the literature of small peptides interfering in aggregation. In the present work, we identify and characterize, for the first time, a heptapeptide (BaltPAi: platelet aggregation inhibitor from *B. alternatus* snake venom) and a decapeptide (BmooPAF: platelet-activating factor from *B. moojeni* snake venom), which potentially inhibits and induces the platelet aggregation, respectively. BmooPAi shows a rather specific inhibitory effect on collagen-induced platelet aggregation in human platelet-rich plasma, whereas it has little or no effect on platelet aggregation induced by adenosine diphosphate. The results presented here suggest that the BaltPAi consists of an amino acid sequence present in the C-terminal region of snake venom phospholipase A_2 enzymes. This sequence would be responsible for the inhibition of platelet aggregation as well as for the cytotoxicity effects of tumor cells caused by these enzymes. Assays with monoclonal antibodies (anti-integrin α2b and anti-GP1BA) show a significant inhibitory effect on BmooPAF-induced platelet aggregation. On the other hand, anti-GPVI antibody shows no effect on platelet function. These findings, associated with molecular docking, indicate that BmooPAF induces platelet aggregation via binding to the GPIbα platelet receptor leading to αIIbβ3 integrin activation. These toxins could be of medical interest as tools for the development of novel therapeutic agents for the prevention and treatment of thrombotic disorders.

Recent Publications

1. De Queiroz, F de Oliveira, et al. (2017) The role of platelets in hemostasis and the effects of snake venom toxins on platelet function. *Toxicon*; 133: 33-47.
2. F de Oliveira, et al. (2016) Biochemical and functional characterization of BmooSP: A new serine protease from *Bothrops moojeni* snake venom. *Toxicon*; 111(130): 138.

Biography

Fabio de Oliveira has completed his PhD in 2001 from National University of Brasília in Brazil. He was the Director of Innovation and Transfer of Technology of the Federal University of Uberlandia. Currently he is the Professor of the postgraduate program in Genetic and Biochemistry and in Cellular and Structural Biology of the same university. He has experience in the area of biochemistry, biophysics and biotechnology with emphasis in isolation and characterization of pharmacologically active principles present in venom of Brazilian snakes.

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Notes:

Mahmoud Ibrahim Shoulkamy et al., Toxicol Open Access 2018, Volume 4
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Ionizing radiation induces developmental abnormalities but not lethality of sea urchin embryos

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[3]National Research Centre, Egypt

The Fukushima nuclear power plant accident occurred in Japan on March 2011, initiated by tsunami following a great earthquake cause the discharged of radioactive materials into the environment. This accident received considerable attention for their effect on marine ecosystems. Sea urchins are model organisms in developmental biology research and their embryos are sensitive to toxins and used to study the developmental and cytological effects of anthropogenic pollutants and environmental stressors. In the present study sea urchin embryos were used as a model system to assess the effect of ionizing radiation on the viability and early development of marine invertebrate animals. Sea urchin embryos were culture in filtered sea water at 16 °C at the different developmental stages were irradiated with X-rays (70 kV, 0.2 mm Al filter, dose rate=1.46 Gy/min) and further incubated in filtered sea water at 16 °C. Irradiation of embryos at the different stages of development (32-cell, mid-gastrula and early *Pluteus* larva) at doses up to 30 Gy did not reduce the viability of embryos. However, irradiated embryos exhibited dose-dependent developmental abnormalities. Typical abnormalities observed for gastrula embryos were delayed development and a reduced number of primary and secondary mesenchyme cells and those for mid *Pluteus* larva were delayed development, skeletal abnormalities, separated body rod tips and fused arms. Interestingly, the frequency of X-rays induced abnormalities increases when embryos were irradiated before mid-blastula transition (MBT) and starts to decrease thereafter. The analysis of apoptosis of X-ray irradiated embryos resulted in the absence of apoptotic response when embryos were irradiated before MBT. However, there is immediate apoptotic response was observed when embryos were irradiated after MBT.

Recent Publications

1. Shoulkamy M I, Nakano T, Ohshima M, Hirayama R, Uzawa A, Furusawa Y, Ide H (2012) Detection of DNA-protein crosslinks (DPCs) by novel direct fluorescence labeling methods: distinct stabilities of aldehyde and radiation-induced DPCs. *Nucleic Acids Research*; 40(18): e143.
2. Ide H, Shoulkamy M I, Nakano T, Miyamoto-Matsubara M, Salem A M (2011) Repair and biochemical effects of DNA-protein crosslinks. *Journal of Mutation Research*; 711(1-2): 113-122.

Biography

Mahmoud Ibrahim Shoulkamy has his expertise in DNA damage response to environmental and anticancer agents and risk sciences of radiation and chemicals. He has received his Doctoral degree from Graduate School of Science, Hiroshima University, Japan in 2013 in the field of DNA damage and its repair mechanisms. In 2013, he was appointed as an Assistant Professor (special appointment) in Graduate School of Science, Hiroshima University, Japan until 2016 and currently he is working as an Assistant Professor in Zoology Department, Faculty of Science, Minia University, Egypt.

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Ahmad M Khalil et al., Toxicol Open Access 2018, Volume 4
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In vivo characterization of the biochemical and histological changes induced by the stonefish (*Synanceia verrucosa*) venom in rats

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Statement of the Problem: The stonefish (*Synanceia verrucosa*) is one of the most dangerous venomous fishes ever known. Stonefish venom may be life-threatening to humans, envenomation can be quite hazardous, provoking extreme pain and imposing significant socioeconomic costs, as the victims may require days to weeks to recover from their injuries. Very little research has been undertaken on marine creatures, particularly venomous fish. The purpose of this study is to evaluate the toxicity of the stonefish (*S. verrucosa*) venom as well as biochemical and histological changes in a rat model.

Methodology: Fish samples were collected by SCUBA diving from the northern sites of the Red Sea (Gulf of Aqaba/Jordan). The crude venom was extracted from the spines and biochemical and histopathological changes induced by intramuscular injection of the sub lethal dose of the venom of were examined in Sprague-Dawley rats.

Findings: The 24h LD_{50} of the venom was estimated to be 38 µg venom/kg body weight. The levels of the serum biochemical markers; alanine transaminase, lactate dehydrogenase and creatine kinase increased 6 hours after administration and remained significantly high till 24 hours. Envenomed animals exhibited symptoms like convulsions, muscular dis-coordination and paralysis, urination and respiratory failure. Envenomation caused massive damage to liver tissues. Similarly, extended treatment of rats was manifested as interstitial hemorrhage and widening of kidney tubules. Furthermore, the venom caused neuropathological alterations such as spongiosis of brain tissue and had myotoxic effect on cardiac tissues.

Conclusion & Significance: The *S. verrucosa* venom contains edema-causing factors and is hepatotoxic, nephrotoxic, myotoxic and neurotoxic to the test rat model. The findings may encourage the health care industry to develop an indigenous anti-venom related valuable pharmaceutical product.

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2. Subramaniyan A, Saravanamurugan R, Sangeetha P (2016) Haematological and biochemical changes in lionfish (*Pterois russelii*) venom treated Swiss albino mice. *International Journal of Pharma and Bio Sciences*; 7(1): (B) 83-88.
3. Saravanamurugan R, Subramaniyan A (2015) Neuromuscular modulatory activity of lion fish *Pterois russelii* venom in mice. *Life Science Archives (LSA)*; 1(4): 233-239.
4. Maghamiour N, Naser Safaie N (2014) High creatine kinase (CK)-MB and lactate dehydrogenase in the absence of myocardial injury or infarction: A case report. *Journal of Cardiovascular and Thoracic Research*; 6(1): 69-70.
5. Gomes H L, Andrich F, Fortes-Dias C L, Perales J, Teixeira-Ferreira A, Vassallo D V, Cruz J S, Figueiredo S G (2013) Molecular and biochemical characterization of a cytolysin from the *Scorpaena plumieri* (scorpionfish) venom: evidence of pore formation on erythrocyte cell membrane. *Toxicon*; 74: 92-100.

Biography

Ahmad M Khalil has received his PhD in Cytogenetics from The Ohio State University, USA in 1987. He chaired the Department of Biological Sciences at Yarmouk University, Jordan (2001-2003). He has founded Biotechnology MSc Program in 2003. In Arabic, he authored a book in radiation biology, a unit in molecular biology, a chapter in genetics. He has written 35 single-authored scientific articles of general interest. He has published 45 research papers in peer-reviewed international journals. He has received several awards and fellowships and is active Reviewer and Member in Editorial Board of several local, regional and international journals.

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Tissue distribution of Suvorexant in three postmortem cases

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Statement of the Problem: Suvorexant (Belsomra®) is a relatively new insomnia medication that has been available in the US and Japan since 2014. It is a dual orexin receptor antagonist that promotes sleep by inhibiting the binding of orexin neurons to the OX1R and OX2R receptors. In this report, we describe the detection and quantitation of Suvorexant from the postmortem specimens of three recent autopsy cases handled by our department.

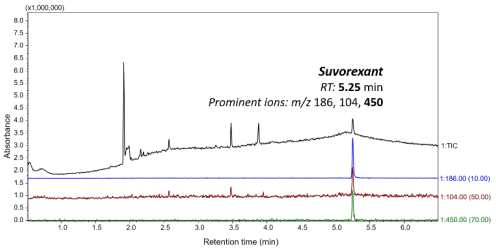

Figure-1: *A GC-MS chromatogram of Suvorexant extracted from an autopsy blood sample.*

Methodology & Theoretical Orientation: Suvorexant was identified by fast GC-MS during routine screening and quantitated by a fully validated LC-MS/MS method. Quantitation was achieved by positive electrospray ionization in the selected reaction monitoring mode. Monitored transitions were m/z 451>186 for quantitation and m/z 451>104 for qualification. Diazepam-d5 was used as an internal standard.

Findings: Suvorexant was detected and quantitated in the body fluids and tissues of three autopsy cases. The specimens included cardiac blood, peripheral blood, urine, liver, kidney, spleen, pancreas, lung, muscle, fat and cerebrospinal fluid. Tissue distribution across the three cases will be presented and discussed.

Conclusion & Significance: The use of Suvorexant as an insomnia medication has recently increased around the world. To our knowledge this is the first instance of Suvorexant being quantitated from actual autopsy cases. It is possible the presence of this medication in clinical and forensic samples has been missed due to its high boiling point and thus late elution in gas chromatography. We were able to detect Suvorexant in three cases by using fast GC-MS which significantly reduced its retention time. It is likely that this compound will be encountered more often by the forensic and clinical toxicology communities going forward.

Recent Publications

1. Hara K, Waters B, Ikematsu N, et al. (2016) Development of a preparation method to produce a single sample that can be applied to both LC—MS/MS and GC—MS for the screening of postmortem specimens. *Legal Medicine*; 21: 85-92.
2. Waters B, Ikematsu N, Hara K, et al. (2016) GC-PCI-MS/MS and LC-ESI-MS/MS databases for the detection of 104 psychotropic compounds. *Legal Medicine*; 20: 1-7.

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2. Iqbal M, Ezzeldin E, Khalil N, Al-Rashood S, Al-Rashood K (2017) Simple and Highly Sensitive UPLC-ESI-MS/MS Assay for Rapid Determination of Suvorexant in Plasma. *Journal of Analytical Toxicology*; 41: 114-120.

Biography

Brian Waters has received his Master of Science degree in Criminalistics from California State University Los Angeles, USA. After working as a Criminalist for the County of Los Angeles, Department of Coroner/Medical Examiner for almost eight years, he accepted a position as an Assistant Professor in the Department of Forensic Medicine at Fukuoka University in Japan. His specialty is postmortem forensic toxicology and he has published academic papers on fast gas chromatography-mass spectrometry, the analysis of novel psychoactive compounds, preparation methods for postmortem samples and the analysis of volatile hydrocarbons in blood.

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Sankaran P K, Toxicol Open Access 2018, Volume 4
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Protective effects of vitamins on Diclofenac induced hepatotoxicity in adult male Wistar albino rats

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Introduction: Drug induced liver injury (DILI) possesses a major clinical problem and has become leading cause of acute liver failure and transplantation. Overstressed liver compromises its detoxification role which may expose it to a variety of diseases and disorders. Diclofenac sodium is a phenyl acetic acid derivative, a widely used NSAID for treatment of inflammatory conditions like osteoarthritis, rheumatoid arthritis, polymyositis, dermatomyositis, dental pain, spondyloarthritis, acute migraine, gout attacks and pain management in gall and renal stones. Though the exact mechanism by with Diclofenac injuries liver is not understood, some studies explain the toxicity by affecting cytochrome P 450 leading to production of active metabolites. This study was done to show the changes in the liver following Diclofenac treatment and to study the heapto-protective effects of vitamin A and C in Diclofenac treated rats.

Methodology: Rats were divided into four groups each 6 rats. Group-1: (n=6) control rats, Group-2: (n=6) rats treated with Diclofenac at dose of 75 mg/kg IP for seven days, Group-3: (n=6) rats treated with vitamin A at dose of 10 mcg/kg orally followed by Diclofenac at 75 mg/kg IP 2 hours later for seven days for seven days, Group 4: (n=6) rats treated with vitamin C at dose of 200 mg/kg orally followed by Diclofenac at 75 mg/kg IP 2 hours later for seven days.

Findings: Following Diclofenac treatment there the liver function test was elevated in Diclofenac treated group which was significantly reduced by the vitamin C compared to vitamin A. The liver acinus showed centriacinar necrosis of hepatocytes after seven days of Diclofenac treatment, which was prevented by administration of vitamin A and C. The hepatocyte necrosis was well prevented by administering vitamin C. So the hepato-protective effects of vitamin C were better compared to vitamin A following treatment with NSAID. So it may be necessary to administer vitamin C in patients treated with Diclofenac.

Recent Publications

1. Karthikeyan G, Sankaran P K, Kumaresan M, Zareena begum, Yuvaraj M (2017) localization of gap junction and neuropeptide as a determinant of neuropathic pain. *Indian Journal of Clinical Anatomy and Physiology*; 4(2): 70-71.
2. Sankaran P K, Jeevapriya t, Vinay Jadhav (2016) Expression of calcitonin gene related peptide (CGRP) in small neurons of trigeminal ganglion and its implications in migraine. *J Pharm Bio Sci*; 7(2): (b)52-55.

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2. Maria Francis Yuvaraj, Ponuswamy Kasirajan Sankaran, Gunapriya Raghunath, Zareena Begum, Kumaresan (2017) Thanatophoric Dysplasia; a Rare Case Report on a Congenital Anomaly. *Int J Pediatr*; 5: N.1(37).

Biography

Sankaran P K is currently working as an Associate Professor in Department of Anatomy, Saveetha Medical College in India. He has been working in developing pain models related to trigeminal neuralgia and its treatment module in animals.

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Karthikeyan G, Toxicol Open Access 2018, Volume 4
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A study on exploring the toxicity of alcohol in the oral mucosa of alcoholics

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Background: Oral cancer is the most common malignancy in nearly half of Indian population. The main causes of oral carcinoma are tobacco, alcohol, poor diet and infective agents. These agents damage the chromosomes to form several secondary nuclei known as micronuclei. This study identifies the occurrence of micronuclei and also evaluates the frequency of micronuclei in stained smears of oral exfoliative cells from healthy subjects and alcoholic subjects.

Materials & Methods: A total number of 60 alcoholic subjects were referred to the Department of Anatomy, Saveetha Medical College for micronucleus assay from the Department of Dentistry. Equal numbers of controls were included with normal looking oral cavities.

Results: Out of 60 alcoholic subjects 43 showed presence of micronuclei and out of 60 control subjects, only 6 showed micronuclei. With these observations it is found that alcohol is one of the factors predisposing to oral carcinoma.

Conclusion: It is evident from our present study, it is clear that in alcohol consumption, the buccal mucosa, which are at high risk for development of oral cancer, show an increase in micro-nuclear frequencies.

Recent Publications

1. P K Sankaran, G Karthikeyan, M Kumaresan (2016) Morphometric study of renal artery and its variations in level of origin. *National Journal of Clinical Anatomy*; 511-142.
2. P K Sankaran, M Kumaresan, G Karthikeyan, Yuvaraj M (2015) Expression of Glial Fibrillary Acidic Protein (GFAP) in the Trigeminal Ganglion of Male Wistar Rats. *Indian Journal of Clinical Anatomy and Physiology*; 2(3): 145-147.

Biography

Karthikeyan G is an Assistant Professor of Department of Anatomy at Saveetha Medical College & Hospital, India. He has upcoming research projects which are granted by Indian Council of Medical Research.

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Notes:

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Scientific Tracks & Abstracts

(Day 2)

Sergey V Brodsky, Toxicol Open Access 2018, Volume 4
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Brain free hemoglobin increase is different among anticoagulant classes

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Background & Aim: Anticoagulant therapy is broadly used to prevent thromboembolic events. Intracranial hemorrhages are serious complications of anticoagulation, especially with vitamin K inhibitors, including warfarin. Novel direct oral anticoagulants (DOAC) reduce, but not completely eliminate the risk of intracranial hemorrhages. The aim of this study was to investigate the severity of brain hemorrhages as measured by free hemoglobin in the brain parenchyma, among different anticoagulant classes in rats.

Methods: Rats were treated with excessive doses (LD50) of different anticoagulant classes (vitamin K antagonists, including brodifacoum and warfarin, heparin, direct thrombin inhibitor and factor Xa inhibitor). Free hemoglobin concentration was measured in the brain.

Results: Vitamin K antagonists resulted in significant increase in free hemoglobin in the brain. Among DOAC, direct thrombin inhibitor dabigatran also increased free hemoglobin in the brain, whereas treatment with factor Xa inhibitor rivaroxaban did not have effect on free hemoglobin concentration.

Conclusion: Our data indicate that different anticoagulant class result in different accumulation of free hemoglobin in the brain and it is more pronounced with vitamin K inhibitors.

Biography

Sergey V Brodsky is an Associate Professor of Department of Pathology, The Ohio State University Wexner Medical Center (OSUWMC), Columbus, OH. He has published more than 25 papers in reputed journals and has been serving as an Editorial Board Member of *American Journal of Physiology, American Journal of Transplantation, ISRN Transplantation and Pharmacological Research*.

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Vandana Sanjeev Panda, Toxicol Open Access 2018, Volume 4
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Spinacia oleracea in diet can help control obesity by its regulatory action on appetite

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Nutrients and gastrointestinal peptide hormones such as cholecystokinin (CCK), GLP-1 and peptide YY are involved in the short term regulation of food intake, which interact with long term regulators such as insulin, leptin and ghrelin to maintain energy homeostasis. Plant foods have been proven to be effective in modifying release of these short term satiety signals which regulate the balance between food intake and energy expenditure to maintain body weight. *Spinacia oleracea* (spinach) is a green leafy vegetable rich in antioxidant phyto-constituents such as flavonoids, polyphenols, carotenoids and vitamins. The present study evaluates the appetite suppressing effect of a flavonoid rich extract of the spinach leaf (SOE) in rats. Rats were administered SOE (200 mg/kg and 400 mg/kg, p.o) and fluoxetine (6 mg/kg i.p) as a pre-meal for 14 days. Food intake and weight gain was observed daily during the treatment period. Serum levels of the short term satiety signals CCK and glucose were measured on the 7th and 14th days at different time points after start of meal to study the satiety inducing effect of SOE. SOE and fluoxetine treated rats showed a significant reduction in food intake and weight gain when compared with the normal control rats. On the 7th day of treatment, peak CCK levels were reached in 30 min after start of meal in fluoxetine treated rats and in 60 min in the remaining rats. On the 14th day, CCK peaking was observed in 30 min after starting meal in the fluoxetine as well as SOE 400 mg/kg treated rats. Peak glucose levels in all treatment groups were obtained in 60 min after start of feeding on both days of the study. It may be concluded that SOE exhibited a promising appetite suppressing effect by inducing a quicker than normal release of CCK, thus eliciting an early onset of satiety in rats.

Recent Publications

1. Naik S R, Panda V S (2009) Evaluation of cardio-protective activity of *Ginkgo biloba* and *Ocimum sanctum* in rodents. *Alternative Medicine Review*; 14(2): 161-171.
2. Naik S R, Panda V S (2007) Antioxidant and hepato-protective effects of *Ginkgo biloba* phytosomes in carbon tetrachloride-induced liver injury in rodents. *Liver International*; 27(3): 393-399.

Biography

Vandana Sanjeev Panda has completed her PhD in Pharmacology from Mumbai University, India. Her research for the last few years has changed focus from pure pharmacology to plant drugs and now functional foods where her lab is active in pharmacological evaluation of plant phyto-constituents, bio-molecules and endogenous substances for a variety of biological activities, their mechanistic studies and development of models for these activities. Her major work has been in the area of gastric and hepato-protection, anti-diabetic and cardio-protective activity, and studies on the metabolic syndrome. She has 40+ research papers with 850 citations in high impact factor journals, a number of research awards and scholarships, and industrial projects to her credit. She sits on the Editorial Board of a few journals and is a Reviewer for many reputed journals.

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Food functionalization and preservative activity of bioactive colorant prodigiosin

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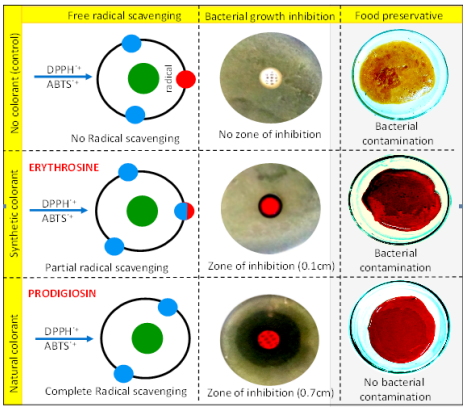
Prodigiosin (PG) is a natural red colored compound, widely used in pharmacological and biological applications. This investigation focused on nutraceutical and food functionalization potential of natural colorant PG was compared synthetic food colorant erythrosine (ER). The antioxidant potential of PG and ER was examined by DPPH and ABTS radical scavenging method. The bactericidal efficiency of PG and ER were analyzed against six foodborne pathogens. The food shelf life extant ability of PG and ER was analyzed using meat extract powder (MEP) as a model food material. The PG (70.19 g/kg) was biosynthesized from *Serratia marcescens* by solid state fermentation. The scavenging activity of PG was calculated to be 99% and 99.9% were DPPH and ABTS, respectively. ER shows DPPH, 81%; ABTS, 85.9% of radical scavenging was achieved. The scavenging ability of PG was confirmed through UV-visible, EPR, fluorescence spectrum and cyclic voltammetry analyses. The bactericidal efficiency of PG against the selected foodborne pathogens exhibited significant inhibition on growth than the synthetic colorant and the shelf life of the food was extended in the presence of PG containing food model. Hence, the PG may be used as food colorant and thus significantly reduce the addition of synthetic colorant in food processing industry. This study will bring an innovative approach on food additive for safe and sustainable food process.



Recent Publications

1. Arivizhivendhan K V, Mahesh M, Boopathy R, Patchaimurugan K, Regina Mary R, Sekaran G (2016) Synthesis of surface modified iron oxides for the solvent free recovery of bacterial bioactive compound, prodigiosin and its algicidal activity. *The Journal of Physical Chemistry B*; 120(36): 9685-9696.
2. Arivizhivendhan K V, Mahesh M, Boopathy R, Regina Mary R, Sekaran G (2016) A novel method for the extraction of prodigiosin from bacterial fermenter integrated with sequential batch extraction reactor using magnetic iron oxide. *Process Biochemistry*; 51(10): 1731-1737.

Biography

Regina Mary R has her passion in educating and empowering the rural young women. She has her expertise in the field of development of bioactive compounds from microorganism for the biomedical application. Her contribution towards preparation of surface modification and bioactive compound conjugated nanoparticle for the treatment of pathogens from water and food system with a molecular mechanistic explanation. She has built this model after years of experience in research, evaluation, teaching and administration both in education institutions. She also has her unique contribution in the field of infection in gastrointestinal track and respiratory track due to the foodborne pathogens and its treatment by probiotics for health benefits of young women.

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(Day 2)

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Lebsir Dalila et al., Toxicol Open Access 2018, Volume 4
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Toxicology of repeated iodine thyroid blocking on adult's thyroid function and on the progeny's brain development

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Statement of the Problem: Thyroid cancer (TC) is the major health consequence of nuclear accident. To prevent TC incidence, a single dose of potassium iodide (KI) is recommended to block thyroid radioiodine uptake. In situation of prolonged exposure like Fukushima disaster, many doses of KI may be necessary. Whereas single dose of KI transiently blocks thyroid function the Wolff-Chaikoff effect, studies about the effects of repeated KI administration are scarce. Thyroid hormones (THs) play an obligatory role in many fundamental processes underlying brain development and maturation, the repeated KI administration could modify (THs) level which may impact body functioning.

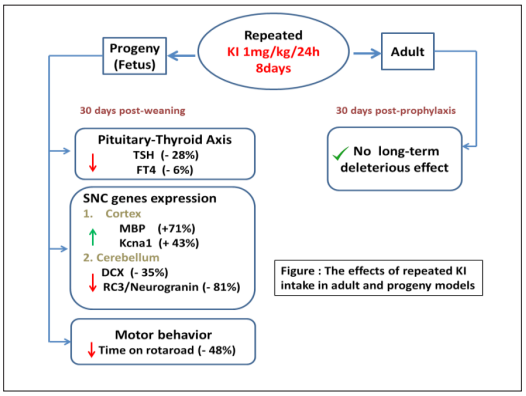

Figure : The effects of repeated KI intake in adult and progeny models

Purpose: To evaluate the impact of repeated administration of KI 1 mg/kg in adult rat especially thyroid function and then in more sensitive model the fetus with a particular focus on their central nervous system (CNS) development.

Methodology & Theoretical Orientation: Adult male rats were subjected to either KI or saline solution over 8 days. Clinical biochemistry, pituitary and thyroid hormones level, anti-thyroid antibodies level and thyroid genes expression were analyzed 30 days after stopping the treatment. The male progeny were subjected to KI indirectly through the treatment of their mothers since (GD9) over 8 days and 30 days after the weaning, we evaluated the same parameters as for the adults, we also assessed behavior and CNS genes expression.

Findings: We didn't report any significant effect of repeated KI intake in adult. On the other hand we obtained a significant decrease of TSH and FT4 in treated progeny, also the treatment significantly altered CNS genes expression and motor behavior of progeny.

Conclusion & Significance: The data of adult may contribute to the ongoing developments of KI guidelines and marketing authorization. Contrariwise toxic effect of repeated KI intake on immature brain requires more research.

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Biography

Lebsir Dalila is currently pursuing her PhD at the Institute of Radioprotection and Nuclear Safety and completed her Master's degree in Experimental Pharmacology at the University of Jijel, Algeria.

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Ajeet Kumar Srivastav et al., Toxicol Open Access 2018, Volume 4
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Superoxide mediated apoptosis in cell organelles by photosensitized 1,2:3,4-dibenzanthracene in HaCaT cells at ambient UV-B and natural sunlight

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Polycyclic aromatic hydrocarbons (PAHs) are recognized as environmental pollutants because of their intrinsic chemical stability, high resistance and toxic property worldwide. 1,2:3,4 dibenzanthracene (DBA) is a PAH, produced by incomplete combustion of fossil fuels, petroleum discharge. It gets adsorbed on atmospheric particles, mixed into soils, used in tattoo ink and remains for the longest time in the ecosystem. DBA showed strong absorption maxima (λmax) in UV-B (290-320 nm) with low absorption under UV-A (320-400 nm). DBA generates the significant amount of ROS such as O_2.-, .OH via type 1 mechanism. *In silico* study of DBA showed the interaction with aryl hydrocarbon receptor. DBA generates ROS photochemically and intracellularly which was confirmed by DCF/DHE fluorescence intensity while genotoxicity was assessed through comet assay, Hoechst staining, micronuclei formation. The generation of CPDs and 6-4 photoproduct formation, confirm the photo-genotoxic potential of DBA. Mitotracker/DAPI, Mitotracker/DHE, Mitotracker/DCF and JC-1 result showed the significant increase in mitochondrial permeability pore complex formation which leads to the release of cytochrome-c in cytosol showed strong evidence for apoptotic cell death by photoirradiation DBA. Cell cycle result showed G2/M phase arrest during cell division. DBA significantly showed over expression of Bax, Parp, Cyt-c, Bak, Caspase 3, Apaf-1, Cathepsin-B, Lamp-1, AhR, tBid, Calpain-7, γH2Ax, Keap-1, Caspase-12, Caspase-9 and lower expression of Bcl-2, Bid, Hmox and procaspase-3 protein expressions and up-regulation of Apaf-1, Cyt-C, Bax, Caspase-3, Calpain-7, Cathepsin-B, Nrf-2, Keap-1, AhR, Cdk-2, Cdk-4, Cycd1, Cycd2, Cycd3, Cdk6, Cyp1a2 and down regulation of Hmox, Bcl-2 genes. The exact mechanism behind DBA phototoxicity was involvement of ROS generation via type-1 mechanism, reduction of an antioxidant level and activation of the apoptotic pathway through mitochondria, nucleus as well as endoplasmic reticulum followed by AhR strongly promotes apoptotic cell death. The study suggests that after the DBA exposure, sunlight/UV-B exposure may avoid preventing from its harmful effects.

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Biography

Ajeet Kumar Srivastav has his research interest in the study of molecular mechanism involved in skin disease, phototoxicity/photogenotoxicity and molecular mechanism involved in skin disease by photosensitive drugs, cosmetics preservatives, hair dyes and PAHs under ambient UV-R/sunlight exposure. Presently, he is working as a Senior Research Fellow at Photobiology Division, Indian Institute of Toxicology Research, Lucknow, India.

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Devi Revathi Ganni, Toxicol Open Access 2018, Volume 4
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Patterns of poisoning and their outcomes in patients admitted to emergency wards of a tertiary care hospital

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Background: Poisoning is a significant health problem in developing countries and is associated with high mortality and morbidity. It is very essential to know the pattern of poisoning since it is inconsistent in diverse geographical locations. Therefore facilitating rapid clinical diagnosis and ensuring appropriate treatment is crucial to reduce the consequences of poisoning.

Aim & Objective: To assess the pattern of poisoning and their outcomes.

Methodology: It is a prospective, observational study conducted in a tertiary care multispecialty hospital for a period of six months. The patient's data was acquired from patient's case sheets, interviewing patients and their caretakers (if possible) and were documented in a suitably designed data collection form.

Statistical Analysis: Chi-square test (X^2 test) ($p<0.001$).

Results: 131 patients (111 poisoning, 20 envenomation) were incorporated in our study, where majority of the patients belong to the age group 21-30 years (X^2 test $p<0.001$). Deliberate self-harm through intentional poisoning was pragmatic in 91 patients followed by 18 accidental and 2 occupational. The frequently utilized poisoning agents were drugs n=49 (47.9%) tailed by other agents n=19 (17.11%) which encompassed nail polish, kerosene, paint thinner, camphor, etc., rodenticides 12 (10.81), insecticides 11 (37.93%), detergents 10 (9.0%), pesticides 6 (5.40%), herbicides 2 (1.80%) and acids 2 (1.80%). The outcomes of the victims were correlated using Glasgow Coma Scale (GCS) and Poison Severity Score (PSS) depicted recuperation in 85 patients took after by discharge against medical advice 17, death 4 and lost to follow up 4.

Conclusion: The trends in deliberate self-harm by poisonous agents is dynamic. Medications were the most well-known methods of poisoning. Educational programs with more accentuation on preventive measures and toxic substance data focuses are important to make mindfulness among the overall population.

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Sathvika Reddy, Toxicol Open Access 2018, Volume 4
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Profile of acute poisoning in patients admitted to emergency wards of a tertiary care hospital

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Background: According to World Health Organization (WHO), more than three million poisoning cases with 251,881 deaths occur annually of which 99% of fatal poisonings occur in developing countries. In India, due to the absence of research and systematic reporting of poisoning incidents, the exact incidence cannot be quantified. In light of that inconspicuous insight with respect to the nature of products, circumstances the outcomes are not clearly identified.

Aim & Objectives: Clinical profile of patients with acute poisoning admitted to emergency wards of a tertiary care hospital.

Methodology: Our study was conducted for a period of 6 months i.e., Nov 2016 to April 2017 in a tertiary care hospital. This prospective observational study included a total of 131 acute poisoning victims. The demographic data such as age, sex, marital status, level of education, occupation, socioeconomic status (Kuppuswamy's socioeconomic scale) and location of intake of poison, time of intake and route of exposure, associated comorbid conditions and outcome of poisoning were recorded and documented.

Statistical Analysis: Chi-square test (X^2 test) ($p<0.001$).

Results: Among 131 patients dominant part of the patients fall under the age group of 21-30 years where male (n=64) and female (n=67). Deliberate self-harm was significantly found in literates (n=53) (X^2 test $p<0.001$), married population (n=64) (X^2 test $p<0.001$), homemakers (n=36) trailed by job holders (n=34), abiding in urban territories (n=133) belonging to upper middle class sector (n=50). Patients with a history of comorbidities were n=35. The frequent route of intake of poisonous agents is oral. Analgesics and anti-pyretic were commonly abused.

Conclusion: Poisoning with varying socio-demographic and socio-economical pattern is a growing health problem in developing countries. Intentional poisoning is very common among younger age group, thereby indicating a necessity for effective counseling and medical management strategies.

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Mahalakshmi K et al., Toxicol Open Access 2018, Volume 4
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Localization of connexin 36 and calcitonin gene related peptide as a determinant of neuropathic pain in the trigeminal ganglion

Mahalakshmi K, P K Sankaran and G Karthikeyan
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Introduction: The trigeminal ganglion consists of pseudo-unipolar neurons surrounded by satellite glial cells and processes innervating craniofacial region. The gap junctions are trans-membrane proteins formed between the cell membranes of adjacent cells and calcitonin gene related peptide are neuropeptides secreted by sensory neurons.

Materials & Methods: In present study the immune-histochemical localization for connexin 36 gap junctions and CGRP was done in the trigeminal ganglion of male Wistar rats. Localization was done in six rats in each group after standardization of dilution ratio for each antibody.

Result: The result showed connexin 36 was present between the satellite glial cells and between satellite glial cell and neuron. The localization was also found in the Schwann cells surrounding axon. CGRP was localized densely in the cytoplasm of small neurons. The large neurons showed fine less densely stained localization in the cytoplasm.

Conclusion: The excited neuron can influence the surrounding satellite glial cells and neurons through gap junctions and by paracrine actions altering its environment leading to pathological role in inducing painful conditions like migraine. By blocking this gap junction and neuropeptide using antagonist, migraine can be managed.

Biography

Mahalakshmi K is currently pursuing her MBBS from Saveetha Medical College, SIMATS under the mentorship of Dr. Sankaran, Department of Anatomy, SIMATS in India. Her research is on the localization connexin 36 and calcitonin gene related peptide as a determinant of neuropathic pain in the trigeminal ganglion.

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Bryan Joel Devaraj et al., Toxicol Open Access 2018, Volume 4
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Localization of glial fibrillary acidic protein in rat migraine model Wistar rats

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Purpose: The trigeminal ganglion consists of pseudo-unipolar neurons surrounded by satellite glial cells and processes innervating craniofacial region. The gap junctions are trans-membrane proteins formed between the cell membranes of adjacent cells and calcitonin gene related peptide are neuropeptides secreted by sensory neurons. Glial cells which surround the pseudo unipolar neurons directly modulate neuronal function and activity by changing the ionic concentrations in and around the neurons.

Methodology: The rats were divided into two groups: Group-1 (n=6): control rats, Group-2 (n=6): Nitroglycerine treated rats 6 mg/kg. Then immune-histochemical localization of glial fibrillary acidic protein in trigeminal ganglion was done in both groups after standardizing dilution ratio.

Findings & Conclusion: GFAP was present in satellite glial cells surrounding the neuron and in the nerve fibers in control rats. In migraine model rats there was increased intensity of GFAP in the satellite glial cells and nerve fibers indicating its role in allodynia. Up-regulation of GFAP in painful conditions like migraine and neuralgic conditions may be an important factor in activating surrounding neurons by releasing interleukins and TNF from the satellite glial cells. The antagonist to GFAP can block the inflammatory cascade and can be used in the treatment of migraine.

Biography

Bryan Joel Devaraj is currently pursuing his MBBS from Saveetha Medical College, SIMATS. His area of research is drug development under the mentorship of Dr. Sankaran, Department of Anatomy, SIMATS in India.

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Siva V K et al., Toxicol Open Access 2018, Volume 4
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Intravenous iron sucrose and oral iron therapy in iron deficiency anemia during pregnancy: A comparative study in Indian population

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Background: Nutritional anemia is one of major the contributory factor in high maternal mortality and morbidity in most of the countries. Iron deficiency is the principle cause for nutritional anemia.

Objective: To compare the efficacy of oral iron therapy with intravenous iron therapy in the treatment of iron deficiency anemia during pregnancy.

Methodology: This comparative study was undertaken at a tertiary care teaching hospital among 110 pregnant anemic patients whose baseline hemoglobin and serum ferritin levels were recorded prior to treatment. The patients were divided into two groups; group A (n=58) received intravenous iron-sucrose and group B (n=52) received oral iron therapy. The patients were followed up for further investigations and side effects.

Results: Out of 110 patients, 50% had mild anemia (10.9-10 gm%), 34.5% patients had moderate anemia (7-9.9 gm%) and 15.5% (6-6.9 gm%) patients had severe anemia. Group A showed statistically significant rise in hemoglobin regardless the severity.

Conclusion: Intravenous iron-sucrose administration increased hemoglobin level and serum ferritin levels more rapidly, without any serious adverse effect in comparison with oral ferrous sulfate in women with iron deficiency anemia in pregnancy.

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Anish S Bharatwaj et al., Toxicol Open Access 2018, Volume 4
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The foe that extends a helping hand: Oncolytic virotherapy, present and future prospective

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Introduction: The saga of finding strains of virus that can selectively destroy tumor cells started in the 1960s and is still ongoing. The approval of Talimogene Laherparepvec by the FDA for treatment of malignant melanoma is proof of our advancements. It is now proposed that viruses carry out oncolysis by 4 ways, of which intracellular replication and expression of cytotoxic products of replication are most significant. Other mechanisms include induction of anti-tumor response and transgene expression causing cell apoptosis. Of the viruses studied, herpes virus (Strains HSV1716 and G207) and adenovirus (ONYX-015 and ICOVIR) are most noteworthy.

Methodology: The analysis took place in Saveetha Medical College between July and December 2016. Data regarding clinical trials were obtained from clinical trials database, United States of America and US Food and Drug Administration drug approval information. Descriptive statistics was done and SPSS 2017 was used to find the inference.

Result: 11 trials have been carried out with seven viruses so far, herpes virus, adenovirus, reovirus, newcastle virus, parvovirus, polio virus and morbili virus. Of clinical importance are the strains of herpes virus, reovirus and newcastle disease virus. The strain HSV1716 showed radiological evidence of tumor reduction in phase II and G207 showed no adverse effects with 5 disease free stable patients. Both strains are administered intra tumor. The reovirus dearing strain in phase II showed 3 stable patients and Phase III is underway. Newcastle disease virus ulster strain showed increased progression free survival period and overall survival.

Conclusion: Many more trials and meta-analysis are required to provide evidence based results. Moreover some studies indicate that addition of other factors like angiogenesis inhibitors will aid in virotherapy. Some studies support the use of chemotherapy and radiotherapy following virotherapy, while others claim equal or inferior efficacy. In the coming years, however, virotherapy is expected to cause a paradigm shift in oncology.

Biography

Anish S Bharatwaj is currently pursuing MBBS from Saveetha Medical College. He is immensely passionate about the field of neurology and oncology. He is extremely interested in the art of research and has done two researches in social and preventive medicine and pathology.

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Young Researchers Forum

(Day 3)

Soma Sri Harsha et al., Toxicol Open Access 2018, Volume 4
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A rare case of Modafinil dependence: A case report

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Modafinil, a non-amphetamine psycho-stimulant, is indicated for narcolepsy, shift work sleep disorder and severe obstructive sleep apnea syndrome. Modafinil is prescribed at the dose of 100 mg once in a day or as two doses, 12 hours apart in a day. Unlike classical stimulant medications like methylphenidate, Modafinil has been thought to produce its wake-promoting effects independent of dopaminergic actions it has also been found that it reduces cocaine dependence and withdrawal phenomenon. Modafinil is a very beneficial medication and this particular finding in and of itself should not affect the way it is prescribed for the treatment of narcolepsy or even for the treatment in some instances off-label for (attention-deficit/hyperactivity disorder) ADHD or for cognitive impairment in patients with schizophrenia, because under those conditions, the patient is being monitored properly. However, it is directly pertinent to the concept of the misuse of Modafinil, which is increasingly being utilized by healthy individuals with the expectation of improved cognitive performance. Modafinil is claimed to have very low liability for abuse and dependence.

Biography

Soma Sri Harsha is currently pursuing his MBBS from Saveetha Medical College, SIMATS. His area of research is in the field of drug development, under the mentorship of Dr. V Krishnan, Department of Pharmacology, SIMATS in India.

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Krithika M et al., Toxicol Open Access 2018, Volume 4
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Fertility effect of *Cycas circinalis* L. extract on male Wistar rats

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Infertility is a major public health concern. In Siddha System of Medicine many herbs were used for treating male sexual disorders. The use of herbs remarkable increased over the past few years and researcher now focuses on herbs. The present study was taken to analyze the fertility effect of an herb *Cycas circinalis* on male albino rats. A total of 18 healthy adult male albino rats were taken and divided into 3 groups with 6 rats in each group. One group of animal was administered orally *Cycas circinalis* extract (200 mg/kg bodyweight) and compared to the normal control and positive control albino rats given testosterone 10 µg/kg body weight subcutaneously. Various parameters were compared among the groups and the drug's efficacy was analyzed. The administration of the drug showed significant positive results in positive control followed by experimental group. Since the synthetic hormonal preparation have grave side effects it is better to go with herbal aphrodisiacs for better results without any side effects.

Biography

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Administration of vitamin E increases BDNF and NGF in chronic stress induced rats

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Long-term elevation of glucocorticoids hinders immune function, increasing the susceptibility to disease and neuro-degeneration. This study evaluated the hypothesized neuroprotective effect of antioxidant and piracetam, in chronic restraint stress induced rats. Healthy Wistar rats were divided into 4 groups (n=6) each. Group-I was kept control. Stress group received chronic restraint stress for 6 hours per day for 21 days (Group-II). Group-III was administered vitamin E (40 mg/kg) and group-IV was administered piracetam (336 mg/kg). Evaluation parameters were measurement of serum brain derived neurotrophic factor (BDNF) and serum nerve growth factor (NGF). The oxidative stress markers, SOD, CAT, glutathione peroxidase, glutathione reductase and malondialdehyde were measured. Serum nitric oxide levels were also measured. Histological analysis of CA1 region of hippocampus was done to evaluate the structural changes of pyramidal neurons. Spontaneous alteration behavior was analyzed using Y maze. The results revealed that vitamin E caused statistically significant ($p<0.001$) increase in serum BDNF and NGF and caused statistically significant ($p<0.05$) increase in antioxidant enzymes (catalase, super oxide dismutase, glutathione peroxidase, glutathione reductase), with significant ($P<0.001$) decrease in malondialdehyde concentrations. Vitamin E caused increase in neuronal cell size and volume in CA1 pyramidal layer of hippocampus and showed statistically significant ($p<0.001$) increase in spontaneous alteration behavior in Y maze. The findings of study are suggestive of neuroprotection, offered by administration of vitamin E compared to piracetam against chronic restraint stress induced rats. In conclusion naturally available dietary vitamin might serve as an adjuvant therapy in order to avoid progression of brain damage during stress.

Biography

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Rithu Baskaran et al., Toxicol Open Access 2018, Volume 4
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All is not well: Irrational nutraceutical zinc preparations in Indian scenario, a systemic analysis

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Introduction & Scope: In a report of by World Health Organization in 2003, detailed description of morbidity and mortality prevention of diarrheal illness among children by effectiveness of zinc is provided. Role of zinc in diarrheal illness when used approximately is evident by other pharmaco-epidemiologic studies as well. However, zinc should be administered as per dosage recommendation given vide infra in discussion and should be curtailed in adding with other nutraceuticals which is neither effective nor safe as zinc has its own adverse effects. Hence this observational study was conducted to analyze the currently available rational and essential zinc formulation in our country.

Objective: To critically analyze the essentiality and irrational zinc preparations available in Indian markets.

Methods: This was conducted as cross-sectional analysis by department of pharmacology of our tertiary care hospital between June and December 2016. Data regarding various formulations of zinc were retrieved from current index of medical sciences and drug India database. Rationality assessment was done using prescribed guidelines and approved formulations of zinc by central drug standard control organization. Essentiality was checked using national list of essential medicine India, 2013 and latest version of WHO list essential medicine bulletin. Dosage regulation was assessed using Indian pharmacopeia guidelines, National Institute of Nutrition, India recommendation and upper daily intake toxicity intake, United States of America (USA).

Results: Our study results showed wide variation in the number of zinc preparation. Total number of formulation available in the market is 335. Among zinc preparation, the preparation that contains 20 mg of zinc as recommended by various guidelines is 10 in number. About 325 preparations of zinc are added with one or more nutraceuticals. None of these fixed dose combinations of zinc containing preparation is recommended as essential fixed regimen.

Conclusion: Zinc has lot of relevance in treating recurrent diarrheal illness, especially in pediatric cases, however legal, regulatory and educational measures should be followed to curtail all the irrational zinc prescription development, promotion, marketing and prescription.

Biography

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Karthikeyan Swaminathan et al., Toxicol Open Access 2018, Volume 4
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Changing trends of clinical trials in India

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Introduction: India is fast emerging as one of global hubs for conducting clinical trials. Even then, it is estimated that out of 1,18,804 clinical trials in 178 countries, less than 2,000 (<2%) are being done in India compared to 9,352 (8%) in neighboring China (WHO). Number of deaths resulting from clinical trials has increased to an unendurable figure of 2,868 during the period 2005-2012. Till April 2013, only 12 clinical trials have been approved by the authority as compared to almost a three digit figure in last year. This was a rationale to analyze the current trends of trials in India.

Objective: To review number of clinical trials in India from 2011 to 2016 and study designs and to note the number of serious adverse events and deaths due to clinical trials.

Methods: Data was collected and categorized from the clinical trial registry India-forum. In order to review the recent statistics and trend, only active trials that open to recruitment were included. Negative impact of trials on Indian trial participants (death/adverse events), data was obtained from official web of health and family welfare department.

Results: Our observational study shows there is steady decline in number of global clinical trials in India, from 56 to merely 19 in 2016. Majority were active controlled trials (61) and multiple arm trials than placebo based trials (7). SAE related to the trials were confirmed in 2209 cases by Drug Controller General of India including 1335 deaths.

Conclusion: Because of time-consuming government approvals and rising allegations of unethical tests further hindering possibilities of gathering a large sample size of people. Dr. Singh, Drug Controller General of India (DCGI), gave relaxed norms will help India register its presence in the international market as it will give Indian scientists and doctors the much needed liberty. With relaxed norms we will give more research opportunities to scientists in India without compromising ethics.

Biography

Karthikeyan Swaminathan is currently pursuing MBBS from Saveetha Medical College, SIMATS. His area of research revolves around clinical trials, carried out under the mentorship of Dr. V Krishnan, Department of Pharmacology, SIMATS in India.

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Case study: A unique case of Flunarizine induced extrapyramidal syndrome and depression

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Flunarizine is one of the cerebro-selective calcium channel blockers, commonly prescribed for migraine prophylaxis in neurology clinics. It is considered as non-inferior to Propranolol and Amitriptyline when used to reduce the frequency of migraine attacks. Here we report a case of Flunarizine induced extrapyramidal syndrome and depression. A 37 year old female on tablet Flunarizine 15 mg daily for the past month to treat migraine, shows signs of depression and restlessness, propensity to bend, slow reactions and mask face. Depression was rated using patient health questionnaire and extrapyramidal syndrome was diagnosed by modified Simpson Angus scale and Barnes Akathisia Rating scale. Considering nil organic lesion and improvement of all symptoms with the cessation of Flunarizine, the case was diagnosed as Flunarizine induced depression and extrapyramidal disorder. Our case is unique in the way that our patient developed depression apart from mixed symptoms of extrapyramidal disorder. Exact mechanism of Flunarizine induced depression is not understood. Commonly, the onset of these symptoms varies from 3 months to 20 months after initiating treatment with Flunarizine, whereas in this case, symptoms were seen within the first month of treatment. Depression was evident even when the patient was on other antidepressants prescribed by a psychiatrist, namely Escitalopram and Buspirone. Symptoms improved only after cessation of Flunarizine from the prescription.

Biography

Abirami Raghunath is currently pursuing her MBBS from Saveetha Medical College and Hospital, SIMATS. Her area of research is pharmacovigilance under the mentorship of Dr. V. Krishnan, Department of Pharmacology, SIMATS in India.

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Analysis of chemicals present in the seeds of *Mucuna pruriens* by gas chromatography mass spectrometry

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Mucuna pruriens is a climbing legume used in the treatment of various ailments. It is commonly known as cowitch or velvet bean. Traditionally, it was used in treating male infertility. The main aim of this study was to identify the bioactive materials present in the methanol extract of *Mucuna pruriens* seeds by gas chromatography mass spectrometry (GC-MS) technique. The analysis by GC-MS reveals the presence of 5 major compounds namely, pentadecanoic acid, 14-methyl-, methyl ester, dodecanoic acid, 9,12-octadecadienoic acid (Z,Z)-, methyl ester, 9,12-octadecadienoic acid and 2-myristynoyl-glycinamide. By comparing with the references of earlier studies, it was clear that these major compounds played a major role in its neuro-protective, antioxidant, anti-inflammatory, anticancer, hepato-protective and antimicrobial effects. The presence of antioxidants has been linked with neurogenesis in the brain. The presence of these compounds may authenticate the scientific evidences of many of its proposed therapeutic potentiality of the seeds of *Mucuna pruriens* (MP).

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Hepatoprotective effect of *Phyllanthus niruri* against the Paracetamol induced liver toxicity in albino rat

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To investigate the mode of action of *Phyllanthus niruri* as a prophylactic hepato-protective agent against Paracetamol (PCM) induced liver toxicity in albino rats. Five groups of six animals in each group of Wistar rats with a weight of 180-210 gm were the experimental material. Group-I was served as normal control, administered sodium CMC for all the eight days. Group-II rats were treated only with PCM at a dose of 2.5 gm/kg on 8th day. Group-III animals were administered silymarin at a dose of 50 mg/kg for eight days and PCM at a dose of 2.5 gm/kg on 8th day, while Group-IV is the treated group which was given *P. niruri* aqueous extract at a dose of 200 mg/kg followed by PCM of 2.5 gm/kg on 8th day. Group-V rats were administered with *P. niruri* at a dose of 400 mg/kg for 8 days and PCM at a dose of 2.5 gm/kg on 8th day. Biochemical, histological and immune-histological (IHC) examinations were performed. Histo-pathological picture is in line with the biochemical parameters and IHC study revealed that *P. niruri* acts by preventing the increase in NKT cells subsequently blocking FASL, by anti-apoptotic and by increasing regeneration. *Phyllanthus niruri* aqueous extract at a dose of 400 mg/kg was more effective than at 200 mg and silymarin 100 mg.

Biography

Akshath S U is currently pursuing his MBBS from Saveetha Medical College, SIMATS. His research is on the hepato-protective effect of *Phyllanthus niruri* against the Paracetamol induced liver toxicity in albino rats under the mentorship of Dr. Sankaran, Department of Anatomy, SIMATS in India.

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Drug development: Ethics versus efficacy

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Objective: To analyze the post-marketing status of molecules approved through the expedited review process in the last quintile.

Methods: The observational study was carried out between January 2016 and June 2016. The details of the time taken to approve drugs were collected from the official website on the United States Food and Drug Administration (FDA). The average time taken to review drugs and take a decision following the review was ascertained from the FDA's annual release of novel drugs from 2011 to 2015. Information on adverse drug reaction noted after approval was gathered from FDA Drug Safety Communication and FDA Adverse Event Reporting System (FAERS).

Results: In the last five years, 166 products were approved by expedited review. Of these 45 (27.1%) did not meet the stringent criteria framed for expedited review. Reports of serious adverse event alerts were submitted for 79 (47.5%) of the 166 molecules. 14 (8.4%) drugs were associated with inducing severe autoimmune disorders. It can be observed that a lower average time of review is positively correlated with a greater number of adverse events ($p<0.05$) and 37 (45.7%) of the molecules failed to be of any treatment scenario.

Conclusion: Drug approval by accelerated review should be stringent. Beneficence and non-maleficence are applicable to the global population and should apply equally to subjects involved in trials. Approving drugs on the basis of trivial evidence is non-scientific and absolutely unethical, since it can lead to clinical failure and produce serious adverse events.

Biography

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Synthetic bacteriophages as nanoparticles for intravenous administration of targeted gene therapy for cancer

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We present a first in human case of a 50 year-old patient with end-stage metastatic ovarian cancer infused with a novel, intravenously administered, synthetically engineered bacteriophage-based gene therapy (Metavec) for metastatic solid malignancies. Compared to mammalian virus-based delivery vehicles, bacteriophage-based vectors bring many preferable features for treatment in humans. Their genomes have been extensively sequenced and, with modern technologies, they are relatively malleable allowing them to be extensively modified. Unlike mammalian viruses, bacteriophages are not natural pathogens to humans yet their capsid can have equivocal cargo carrying capacity. To the authors' best knowledge, no other bacteriophage-based applications have succeeded with intravenous administration. This advance in nanotechnology and novel approach could revolutionize medical care. The patient we discuss received a dose-escalating regime up to 1x1011 particles per dose, three times a week for three weeks. The infusions were very well tolerated. Symptoms include nausea, low-grade fever, and also discomfort in areas where larger tumors were present. Post-infusion investigations included serum biochemistry, serum tumor markers, and computed tomography. The paradigm shift, results, and discussion will be presented.

Biography

Keith Potent is currently a PhD candidate in Translational Research at Monash University. After completing undergraduate degrees in Mathematics and Chemistry, Dr Potent has completed his medical degree. He is a practicing doctor in Queensland.

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