Journal of
Pharmacovigilance and Drug Safety

VOLUME 10 ISSUE 2 JULY-DECEMBER 2013

ISSN 0972 8899
Official Publication of
Society of Pharmacovigilance, India

Editor-in-Chief
Dr. Anurag Tomar

India: Towards achieving Global Standards of Pharmacovigilance

XIII Annual Conference & International Symposium
Society of Pharmacovigilance, India

November 22 - 24, 2013

Venue: Auditorium, Institute of Rural Management Anand (IRMA)
Anand - 388 001, Gujarat, INDIA

Organised by:
Department of Pharmacology,
Pramukhswami Medical College,
Karamsad, Anand, Gujarat, INDIA

H M Patel Centre for Medical Care & Education

Supported by :

National Coordination Center for
Pharmacovigilance Programme of India (PVPI)
Indian Pharmacopoeia Commission, Ghaziabad

Medical Council of India

Council of Scientific & Industrial Research

Indian Council of Medical Research

H M Patel Centre for Medical Care & Education

India: Towards achieving Global Standards of Pharmacovigilance

XIII Annual Conference
Society of Pharmacovigilance India
and
International Symposium

SOPICON 2013

November 22 - 24, 2013

Organized by:

Department of Pharmacology, Pramukhswami Medical College,
Karamsad - 388325, Gujarat, (India) • Website : www.charutarhealth.org

Executive Committee

Society of Pharmacovigilance, India

Patron

Prof. K. C. Singhal

President

Prof. C. P. Thakur

Vice-President

Prof. G. P. Singh
Prof. Shafiqa Aslam

Secretary

Dr. Sandeep Agarwal

Secretary International Affairs

Dr. Syed Zia Ur Rehman

Treasurer

Prof. Govind Mohan

Editor In Chief

Dr. Anurag Tomar

Members

Dr. Rajyashree Sharma (Aligarh)
Prof. Santanu Tripathi (Kolkata)
Dr. Rabinarayan Acharya (Jamnagar)
Prof. B. G. Shivananda (Bangalore)
Prof. Harihar Dixit (Patna)
Prof. Sagun V. Desai (Waghodia)

Organizing Secretary (SOPICON 2013)

Dr. Barna Ganguly

Organizing Committee

Patron
Dr. Amrita Patel

Patron SOPI
Dr. K. C. Singhal

Chairperson
Dr. Utpala Kharod

Organising Secretary
Dr. Barna Ganguly

Scientific Committee
Dr. Bharat M. Gajjar
Dr. Anuradha Joshi
Dr. Alpa Gor
Dr. Komal Gaur

Registration Committee
Dr. Alpa Gor
Dr. Anuradha Joshi
Dr. Nazima Mirza
Dr. Akanksha Prajapati

Finance Committee
Dr. Nazima Mirza
Dr. Bharat M. Gajjar
Dr. Nitin Kothari

Souvenir Committee
Dr. Anuradha Joshi
Dr. Alpa Gor
Dr. Nazima Mirza
Dr. Komal Gaur
Dr. Krunal Dalal

Accommodation & Transport
Dr. Barna Ganguly
Dr. Nitin Kothari
Dr. Krunal Dalal

Food Committee
Dr. Alpa Gor
Dr. Barna Ganguly
Dr. Akanksha Prajapati
Dr. Urvi Kumbhani

Support Staff

Mr. Mahendra Chauhan
Mr. Lalabhai Chauhan
Mr. Narendra Macwan
Mr. Kantibhai Solanki

There are no really safe biologically active drugs.
There are only safe physicians.

– Harold A Kaminetzsky (1963)

NIMS UNIVERSITY
Jaipur, Rajasthan

Prof. (Dr.) K.C. Singhal
M.D., Ph.D. (Med.), D.Sc.
Fiams, Fian, Fips
Vice-Chancellor

I am happy that SOPI has come of age and is holding its 13th Annual meet at a place of successful cooperative movement in India i.e. Anand in Gujarat. Post marketing pharmacovigilance involves the review and management of safety information from many sources. The data obtained suffers from inconsistent standards, unpredictability, non harmonized global regulations, public and media scrutiny. Regardless of these factors the regulators, pharmaceutical houses, patients, healthcare professionals and other stakeholders are only looking at the outcomes but are distantly apart in combining their skills and resources for the welfare of humanity. We hope that conference will involve discussions of these vital issues. Involvement of patient has started demonstrating positive contribution for patient safety, vis-a-vis drug regulatory decisions. Patient medication experiences reporting as initiated by some countries, may be introduced in India as despite repeated concerted efforts the contribution of physicians is not upto the mark. Another factor which needs to be looked into is medical error recording and reporting by health care professionals. Errors are essential components of any Health Care System. These are encountered in nearly all hospitals but not reported. Should we recognize, identify and report in concerted manner, it will bring enormous benefits to patients and society at large. I hope and believe that with the efforts of Prof. Barna Ganguli and her team the deliberations at the conference will be useful to physicians and pharmacists for furthering the mission of SOPI for the welfare of humanity.

Prof. (Dr.) K.C. Singhal
(Patron of SOPI)

Shobha Nagar, Delhi-Jaipur Highway, Jaipur-303121 (Rajasthan) • Website: www.nimsuniversity.org
Mobile: +919784737000 • Fax: +91-141-2605050 • E-mail: vc@nimsuniversity.org, kcsinghal@yahoo.co.in

CHARUTAR AROGYA MANDAL
Post Box No. 7, VALLABH VIDYANAGAR - 388 120, GUJARAT, INDIA • PHONE: 260145 • Fax: 02692 - 260156
CHAIRMAN

Amrita Patel
Chairman
Charutar Arogya Mandal

MESSAGE

I am indeed happy that the Department of Pharmacology of Pramukhswami Medical College is organising the XIII Annual Conference of Society of Pharmacovigilance, Indian and International Symposium on November 22nd to 24th, 2013.

With the expanding formulary, both in terms of number of items as well as their complexicity, it has become more important than ever to pay attention to not just whether the medicines being prescribed are the correct ones but also that they are rationally prescribed. Therefore, while on the one hand, it is important to discuss and debate how to ensure that safety in terms of prescription is ensured and where there are cases of adverse reactions, how these are appropriately reported and addressed, it is equally important to also see pharmacovigilance in terms of how it can be used to ensure the affordability in treatment.

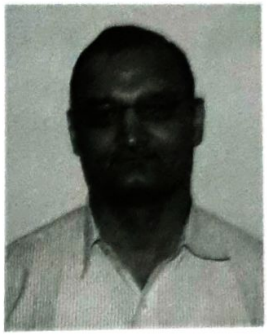
I hope that the Conference will address issues like rationality in prescription of drugs and affordability as much as drug safety.

I wish the event every success.

(Amrita Patel)

CHARUTAR AROGYA MANDAL

Pramukhswami Medical College • HM Patel Institute of Post Graduate Studies • GH Patel School of Nursing
Khushalbhai M Patel Institute of Physiotherapy • Smt. LP Patel Institute of Medical Laboratory Technology
Shree Krishna Hospital & Medical Research Centre • MS Patel Cancer Centre • Bhanubhai & Madhuben Patel Cardiac Centre



Sandeep Desai
Chief Executive Officer
Charutar Arogya Mandal

MESSAGE

I am indeed very happy that the Department of Pharmacology of Pramukhswami Medical College is organizing the XIII Annual Conference of Society of Pharmacovigilance, Indian and International Symposium on November 22nd to 24th, 2013.

There is growing concern, amid awareness of the various errors that take place in treatment, that errors related to drug administration form a significant proportion of adverse events in treatment. As the number of medicines keeps increasing together with their complexicity, it is important that these errors are not only recognized, but also documented as well as ways found to ensure that these are not repeated.

I am sure these issues will be discussed in greater detail at the Conference.

I wish the Conference all success.

(Sandeep Desai)

Shree Krishna Hospital, Gokalnagar, Karamsad - 388 325
Post Box No. 7, Vallabh Vidyanagar - 388 120, Gujarat (India)
Phone: 02692 - 222130 • Mobile: 99789 35011 to 99789 35026 • Fax: 223466

H M Patel Centre for Medical Care & Education

Dr Utpala Kharod
Dean
Pramukhswami Medical College
Karamsad – 388325

MESSAGE

It gives me immense joy to write this message for the 13th Annual Conference of Society of Pharmacovigilance, India, and International symposium organized by our Department of Pharmacology.

The theme of the conference " India : Towards achieving global standards of Pharmacovigilance" is a much awaited topic of discussion by the medical fraternity due to rapid rate of advancement as well as transformation in field of therapeutics and research.

I am sure that the convergence of the participants from related disciplines from within our country and abroad will not only add to diversity of scientific opinions but will also provide newer and better outcomes.

Animal studies, Clinical trials, Clinical Pharmacology as well as complimentary and alternative medicines need in-depth discussions by many stake holders, and the Conference and the symposium will provide the right climate and platform by fostering communication between healthcare professionals at national and international levels.

I wish the Conference, the Symposium, and the organizers full satisfaction and success in the endeavour.

(Dr Utpala Kharod)

H M Patel Centre for Medical Care & Education

Dr. Barna Ganguly
Prof & HOD Pharmacology
Pramukhswami Medical College
Karamsad – 388325

MESSAGE

"Medicine is a science of uncertainty and art of probability"

- William Osler

We are aware that Adverse Drug Reaction monitoring is important at all levels starting from drug development through early phases of clinical trials to post marketing surveillance and thereof day to day practices. Reporting of adverse events (AEs) is a vital part, be it clinical trial or practice in order to ensure patient safety and help clinicians determine the risk-benefit ratio of new drug or any treatment.

3 days' XIII Annual Conference of Society of Pharmacovigilance, India and International Symposium from 22nd -24th November 2013, aims at the discussion on : "India: Towards achieving global standards of Pharmacovigilance". To achieve this, it is necessary to put forth the integrated effort of all health professionals: clinicians, pharmacologists, drug manufacturers, pharmacists, practitioners from complimentary and alternative medicines. This conference will provide a common platform to look into the present status of pharmacovigilance in India compared to global standards.

I take this opportunity to convey my heart felt thanks to one and all taking part and contributing in this conference in some way or other and making this event successful.

Barna Ganguly

(Dr. Barna Ganguly)

Society of Pharmacovigilance, India

Preamble

In India, surveillance of adverse drug reaction developed countries and some of the not so much developed had established monitoring programme. Many of these had formed National Centres and joined hands with WHO collaborating Centre for International Drug Monitoring at Uppsala Sweden . In 1989, Indian Council of Medical Research (ICMR) for the first time came forward to finance a multicentric ADR Monitoring programme involving six medical colleges at Aligarh, Delhi (2 Centres), Jhansi, Meerut & Vellore. In a span of three years a data for 58,194 patients was collected and report submitted to ICMR. This programme was later converted into task force, the centres were located at 12 medical colleges, Aligarh, Delhi, Jammu, Bhopal, Baroda, Hyderabad, Vellore, Bangalore, Chennai, Culcutta, Mumbai and Guwahati. Both these programmes were coordinated by Prof. K. C. Singhal. It is unfortunate that ADR monitoring forms sent by these 12 centres are lying unattended in a store room of ICMR for past many years. The data has not been analyzed as yet . Ministry of Health and Family Welfare, Govt. Of India established five centres to monitor adverse reactions of some specified new drugs. These centres located at Delhi, Chandigarh, Lucknow, Mumbai and Chennai had practically functioned, little. However, no data from these centres have so far been made public.

International workshop on ADR Monitoring

Society of Pharmacovigilance India (SOPI) was established with a modest beginning at International workshop on ADR Monitoring organized by Prof. K.C. Singhal at Aligarh which was shifted to New Delhi (because of unfavourable circumstances at AMU) from November 12-13, 1998. This workshop was attended by participants of many medical institutions of the country.

Looking at the efforts made by some individuals and government agencies for monitoring of adverse drug reactions it was proposed that there should be a common platform which could provide facilities for training physicians, pharmacists and nurses in the art and science of Pharmacovigilance.

Society of Pharmacovigilance, India

SOPI aims at organizing training programmes and providing expertise in following and related fields:

1. To promote study of the use and effects of drugs in population in rational way.
2. Determine risk/ benefit ratio of drugs in individual and in population
3. To promote applications of principles of clinical pharmacology to rationale prescribing, the conduct of clinical trials and assessment of outcomes during real life clinical practice
4. To organize training programmes, workshops, seminars, conferences for promotion of pharmacovigilance.
5. To promote research in pharmacoepidermology
6. To institute awards for the development of research in pharmacoepidemiology
7. To provide research assistance in the field of pharmacoepidemiology
8. To award fellowship to eminent scientists from amongst members of the association.

The first international conference was held at Agra in the year 2001. This meeting was scheduled for November 2001, but the terrorist attack at Twin building in US on September 11 and later attack on Indian Parliament on December 13 forced the organizers to reschedule it.

The society was registered under societies registration act of 1860 at Ahmedabad by Prof. R. K. Goyal, Professor of Pharmacology at L.M College Of Pharmacy. The International Society of Pharmacovigilance (ISOP) granted status of associated society to Society of Pharmacovigilance India.

The list of conferences of Society of Pharmacovigilance India, held are listed below.

Year	Institutions	President	Organizing Secretary
2001	S. N. Medical College, Agra	Prof. K. C. Singhal	Prof. Shobha Kulshreshtha
2002	Patel Chest Institute, Delhi	Prof. K. C. Singhal	Prof. Arunabha Ray
2003	S. N. Medical College, Agra	Prof. K. C. Singhal	Dr. Sandeep Agarwal
2004	M.J.P Ruhelkhand University, Bareilly	Prof. K. C. Singhal	Dr. Kamal Kumar Maheshwari
2005	L. M. College Of Pharmacy, Ahmedabad	Prof. K. C. Singhal	Prof. R. K.Goyal
2006	Kripanidhi College of Pharmacy, Bangalore	Prof. D.D. Santani	Dr. R.S. Thakur
2007	NIMS University, Jaipur	Prof. Arunabha Ray	Dr. Anurag Tomar
2008	Calcutta Institute of Pharmaceutical Technology, Uluberia, Howrah	Prof. K. K. Sharma	Prof. Santanu Tripathi
2009	Rajendra Institute of Pharmacy, Sirsa	Prof. K. K. Sharma	Prof. Surinder Goyal
2010	Lady Hardinge Medical College, Delhi	Prof. R. K.Goyal	Prof. H. S. Rehan
2011	Nalanda Medical College, Patna	Prof. R. K.Goyal	Prof. Harihar Dixit
2012	NIMS University, Jaipur	Prof. C. P. Thakur	Prof. Govind Mohan
2013	Pramukhswami Medical College, Karamsad, Anand, Gujarat	Prof. C. P. Thakur	Dr. Barna Ganguly

In the above conferences, experts from various parts of the world participated and contributed. WHO centre for International Drug Monitoring Uppsala, Sweden has always been cooperating with SOPI by supporting and contributing to its meeting and conferences.

SOPI has about 400 life members and 15 honorary members. The official publication of SOPI is peer reviewed "Journal of Pharmacovigilance and drug safety". Journal is provided free of charge to its members.

Society of Pharmacovigilance, India

Oration Awards

Prof. John Autian

Prof. K. C. Singhal

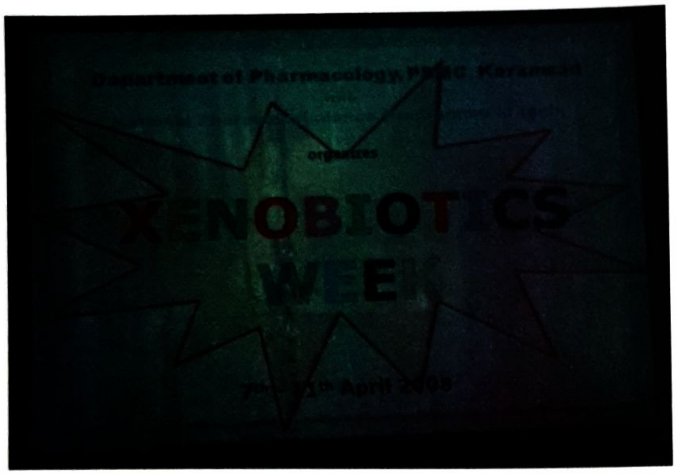
To Acknowledge the contribution of its founders, society of pharmacovigilance india instituted oration awards in the name of Prof, Jhon Autian w.e.f 2002 and Prof. K. C. Singhal wef 2005. SOPI invites prominent persons associated with the discipline of Pharmacovigilance to deliver oration at its annual conferences.

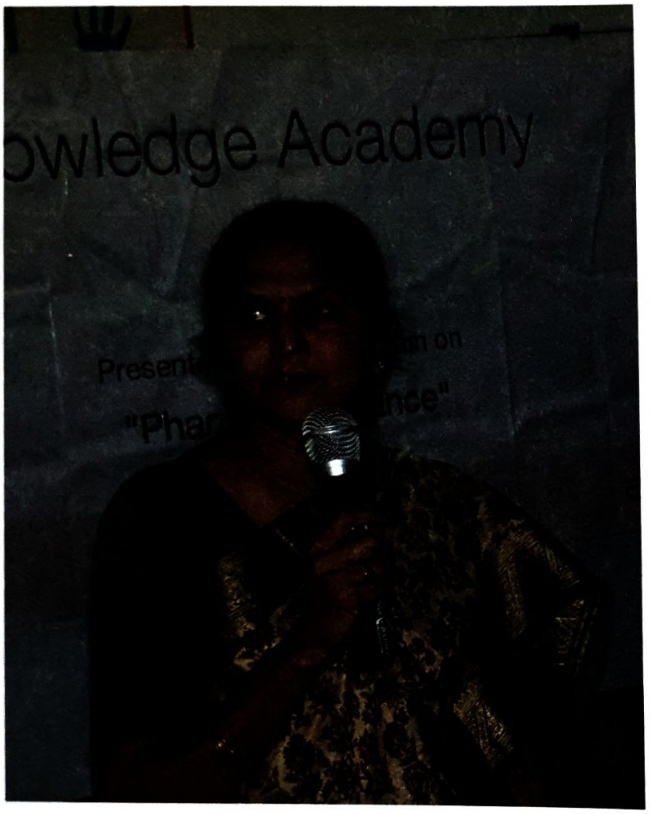
The names of persons who have delivered oration in the previous years are given below.

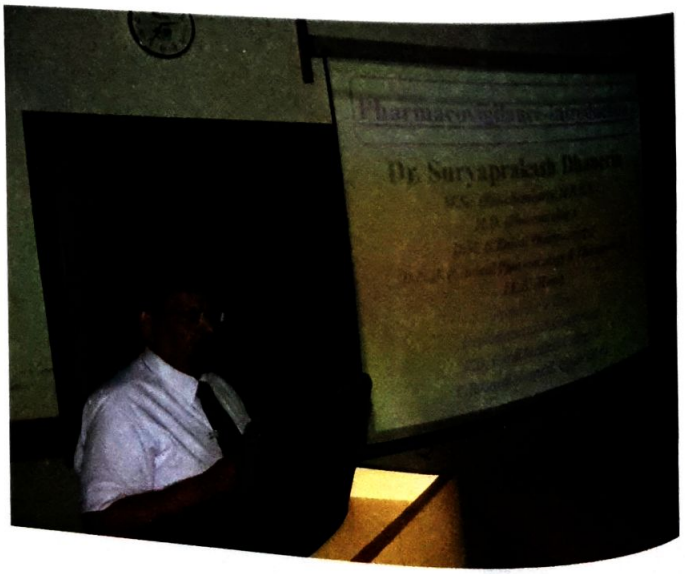
Year	John Autian oration	K. C. Singhal oration
2002	**Prof. K. C. Singhal** J.N.Medical College, A.M.U, Aligarh, India	-
2003	**Prof. I. Ralph Edwards** WHO Centre for International Drug Monitoring, Uppsala, Sweden.	-
2004	**Prof. Peter I. Folb,** University of Capetown, South Africa.	-
2005	**Dr. Marie R. Cooper** WHO, Geneva.	**Prof. Chris J. Van Boxtel** Amsterdam
2006	**Prof. Kees Van Grootheest** The Netherland Pharmacovigilance Centre LAREB.	**Prof. Giampaolo Velo** University of Verona, Italy.
2007	**Dr. Priyadarshini Galappatthy** Sri Lanka.	**Dr. John F. Knight** Johnson & Johnson, Australia.
2008	-	-
2009	**Dr. Marie Lindquist** WHO Centre for International Drug Monitoring, Uppsala, Sweden.	**Dr. Bruce Hugman** (UK)
2010	**Dr. B. M. Katoch** Indian Council of Medical Research, Delhi.	**Dr. Sten Olsson** WHO Centre for International Drug Monitoring, Uppsala, Sweden.
2011	**Prof. C. P. Thakur** Former Union Minister of Health & Family Welfare Government of India, Patna.	**Dr. R. H. B. Mayboom** The Netherland Pharmacovigilance Centre LAREB.
2012	-	Prof. Nicholas R Dunn (U.K)
2013	**Dr. Anick Berard** Professor, Faculty of Pharmacy, University of Montreal, Director, Research Unit on Medications and Pregnancy, CHU Ste-Justine, Montreal	**Dr. Ruth Savage** Department of Preventive and social medicine University of Otago Senior Medical assessor, Centre for adverse reaction monitoring, New Zealand.

SOPICON 2012,
NIMS University, Jaipur

Pharmacovigilance Activities by Department of Pharmacology, P. S. Medical College, Karamsad







Our Activities Related to Pharmacovigilance
Department of Pharmacology
Pramukhswami Medical College, Karamsad (Gujarat)

Dr. Bharat Gajjar
Associate Professor

Our Department was selected as the peripheral centre for 'National Pharmacovigilance Programme of India' implemented from January 2005 by CDSCO, Government of India.

Adverse Drug Events Reporting :
Total of 210 adverse drug events were collected / reported at our centre during the period of 2005 to 2008.

Major Events Celebrated / Organised:
Celebration of Pharmacovigilance Week 25th March 2007 To 31st March 2007.

1. The objectives of the celebration were to generate awareness regarding reporting of adverse drug events among Health Care Professionals (Doctors, Pharmacists, Nurses, Students including medical, physiotherapy and nursing faculty).
2. To promote rational and safe use of medicines.

The note of this activity was taken in the 'News Letter' published by Uppasala Monitoring Centre, World Health Organization, Sweden (Year 2007).

Undergraduate Students' Activity :
The 7th annual conference of the Society of Pharmacovigilance, India was held at NIMS (National Institute of Medical Sciences, Jaipur) from 24 to 25 November 2007. Four students of II M.B.B.S. (V Semester)- Rohan Batra, Siddharth Patel, Kunjan Modi and Mehul Rathod along with the faculties of Department of Pharmacology (Dr. B. R. Sainath Iyer, Dr. Bharat Gajjar, Dr. Nazima Mirza, Dr. Anuradha Joshi and Dr. Alpa Gor) attended the conference. Students had prepared posters and the same were presented there. These posters were on the theme of Pharmacovigilance and how effectively we can generate awareness among Health care professionals and general population.

Xenobiotics Week :
7th April '08 To 11th April '08

Topics covered: Introduction to Xenobiotics, Use & Misuse of Modern Medicines (Benefits and Hazards of Modern Medicines), Use & Misuse of Complementary & Alternative Medicines (Safety Issues Regarding CAM), Drug Abuse (Dangers of addictions like tobacco and alcohol), Xenobiotics & Sports

(Chemicals misused in sports e.g. anabolic steroids, diuretics etc), Xenobiotics & Crimes/ Terrorism (Chemicals / Drugs used for crime Purposes e.g. Date-rape drugs, War gases for terrorism etc.), Xenobiotics & Cosmetics (Hazards due to Chemicals Present in routine use cosmetics e.g. Face cream, soaps , shampoos etc.), Xenobiotics & Food -Nutrients(Toxic Hazards due to Packed food items, Preservatives, junk food etc), Chemicals & Reproduction (Chemicals present in environment and work place can be hazardous to reproductive organs of human & animal species), Xenobiotics & Occupation (Chemicals related to occupational exposure), Xenobiotics & Pollution (Hazards due to pollutants present in the environment), Xenobiotics & Agriculture (Chemicals, Preservatives, fertilizers affecting farmers health), Xenobiotics & Pollution (Hazards due to pollutants present in the environment), Xenobiotics & Agriculture (Chemicals, Preservatives, fertilizers affecting farmers health)

CME on Xenobiotics Awareness for Complementary and Alternative Medicine Practitioners (25th May'2008) There were 30 delegates from different faculties like Homeopathy, Ayurvedic & Naturopathy participated in this CME.

The following talks were given by the staff members of the Pharmacology department. The whole session was conducted by interaction with the participants.

Topics

Use & Misuse of Complementary & Alternative Medicines, Use & Misuse of Modern Medicines, Drug Abuse & Crime / Terrorism, Xenobiotics & Sports, Chemicals & Reproduction, Xenobiotics & Cosmetics, Xenobiotics & Food – Nutrients

Poster on Xenobiotics & its association with above mentioned topics were displayed at the entrance of H M Patel academic centre.

CME 2008 :

India Medical Association (IMA) - Anand Branch
& Gujarat State Family Physician's Forum (GSFPF) - Anand Branch On 29.6.2008
The sequence of the academic programme conducted by the staff members of Dept. of Pharmacology, PSMC in the morning session.
Introduction to Xenobiotics, Food & Nutrients, Occupational Hazards, Modern Medicines, Sports & Reproduction, Crime/Terrorism & Drug abuse, Complementary & Alternative Medicines.

Each of the above mentioned talk was conducted in the form of Interactive session and audience had participated actively. Awareness was generated, regarding the Xenobiotics amongst the delegates regarding xenobiotics. Posters on Xenobiotics were displayed in HMPCMCE Academic Center.

Scientific Programme On "Pharmacovigilance" :

A scientific programme on Pharmacovigilance was organised on 14th December 2011 in the afternoon from 2.00 to 5.00 pm by :

Department of Pharmacology
P G Academic Cell
Knowledge Academy, Abbott Health Care Pvt. Ltd.

This programme was mandatory to be attended by all second year Residents and was voluntary for first and third year Residents and other faculty of the institute. This programme was attended by :

Second year Residents (40), First & third year Residents (06), Faculty (PSMC) (19), Faculty (Pharmacy) (04), M. Pharm Students (21)

Total delegates - 90

The resource person for this programme was Dr. Surya Prakash Dhaneria, Professor & Head, R.D.Gardi Medical College, Ujjain.

The salient points which were covered by Dr. Dhaneria on the topic of the programme i.e. Pharmacovigilance were as follows:

1. Definition of terms
2. Scope
3. Objectives
4. Pharmacovigilance Methods
5. Points to be kept in mind while filling an ADR form
6. Problems in ADR monitoring
7. Pharmacovigilance in India – need of the hour.

The speech by Dr. Dhaneria was followed by a healthy discussion on the topic among the delegates.

Advanced Workshop on Pharmacovigilance :

(Adverse Drug Reaction Monitoring)

A scientific programme "Advanced Workshop on Pharmacovigilance" was organized on 8th September 2012 from 8.30 a.m. to 1.45 p.m. by the Department of Pharmacology, Pramukhswami Medical College, Karamsad in collaboration with Indian Pharmacological Society (IPS) and Knowledge Academy ,Abbott Healthcare Pvt Ltd.

The programme was attended by:

Faculty (PSMC) (14), Faculty (Other medical colleges) (01), Residents (PSMC) (17), Residents (Other medical colleges) (26).

Total Delegates = 58

The guest faculty for this programme was Dr Suryaprakash Dhaneria, Professor and Head, Department of Pharmacology, R.D.Gardi Medical College, Ujjain.

Topics- Evaluation of AV and causality assessment, Herbal drugs & importance of regulatory affairs

Other Speakers:

1. Dr Barna Ganguly- Professor and Head, Department of Pharmacology, PSMC
   (Topic - Drug - Drug Interaction)
2. Dr Bharat Gajjar- Associate Professor, Department of Pharmacology, PSMC (Topics - Introduction to Pharmacovigilance, Need for Pharmacovigilance and Public Awareness Programmes, GPVP & quality assurance in PV)
3. Dr Jyoti Mannari- Professor and Head, Department of Medicine, PSMC
   (Topic - Pharmacovigilance: Clinician's Perspective)
4. Dr Kamlesh Patel- Medical Director, Knowledge Academy
   (Topic - P-Vigil Software & Knowledge Genei)

XIII Annual Conference and International Symposium of Society of Pharmacovigilance Scientific Programme

Scientific Programme

Date	22/11/2013	23/11/2013	24/11/2013
Time			
8.00 to 9.00	**Registration & Breakfast**	**Breakfast**	
9.00 to 10.00	Inauguration	Oration II – (K C Singhal oration) Individual Case Safety Report Databases as sources of Practice-based Evidence **Dr. Ruth Savage**	Guest Lecture – V Pharmacovigilance Programme of India (PvPI) **Dr. V. Kalaiselvan**
10.00 to 10.40	Key note address **Dr. K. C. Singhal**	Guest lecture II – Major Congenital Malformations-definition, prevalence, etiology, risk factors **Dr. Anick Berard**	Guest Lecture – VI National Pharmacovigilance programme of ASU drugs **Dr. R. N. Acharya**
10.40 to 11.00	Tea break		
Symposia on the Theme : India: Towards achieving global standards of Pharmacovigilance in ..			
11.00 to 13.00	Symposium – I **Patient Care**	Symposium – II **Medical Education & Research**	Symposium – III **Pharmaceutical Industry**
11.00 to 11.25	Physician's Perspective **Dr. Pradip Vaid**	Undergraduate level **Dr. Nirmala Rege**	Clinical trials - Pharmacovigilance in Clinical trials, Phase I to III **Dr. Arun Bhatt**
11.25 to 11.50	Surgeon's Perspective **Dr. Sandeep Agarwal**	Postgraduate level **Dr. Santanu Tripathi**	Post marketing Surveillance **Dr. Kiran Marthak**
11.50 to 12.15	Paediatrician's Perspective **Dr. Sandeep Bavdekar**	Research & Publication **Dr. Zia-Ur-Rahman**	Compensation issues **Dr. Veena Joshi**
12.15 to 12.40	Geriatric Care - Adverse Drug Reactions in the Elderly **Dr. Sagun Desai**	Our Activities – Experience **Dr. Bharat. M. Gajjar**	Panel Discussion with symposium speakers - moderator : **Dr. Anuradha Joshi**
12.40 to 13.00	Panel Discussion with symposium speakers - moderator : **Dr. Nazima Mirza**	Panel Discussion with symposium speakers - moderator : **Dr. Alpa Gor**	Pharmacists' Role in Pharmacovigilance **Dr. R K Goyal**
			13.20 to 13.40 Valedictory Function
	Lunch	**13.40 onwards Lunch**	

Scientific Programme Continued...

Date	22/11/2013	23/11/2013	24/11/2013
Time			
14.00 to 14.00	Oration - I (John Autian oration) Antidepressants used during pregnancy outcomes **Dr. Anick Berard**	Guest Lecture - III Pharmacovgilance in tropical and neglected diseases **Dr. Clara Marr**	–
14.40 to 15.20	Guest Lecture - I Status Pharmacovigilance in Vector borne diseases **Dr. A. C. Dhariwal**	Guest Lecture - IV Pharmacovigilance in India-past, present and future **Dr. Rakeshkumar Rishi**	–
15.20 to 15.30	**Tea break**		
15.30 to 17.30	Scientific Paper Presentation	Scientific Paper Presentation	
Total Acadamic Hours	**6 Hours**	**7 Hours**	**4 Hours**

Scientific Deliberations

Oration I

John Autian oration

Antidepressants and Pregnancy: Do we have enough data ?

Anick Berard PhD FISPE
Professor, Faculty of Pharmacy, University of Montreal, Director, Research Unit on Medications and Pregnancy, CHU Ste-Justine, Montreal, QC; Director, Réseau Québécois de recherche sur l'usage du médicament (FRQ-S).

Evidence suggests that over 75% of women take at least one medication during pregnancy. Much of this exposure occurs because more than half of pregnancies are unplanned but exposure also occurs in planned pregnancies to treat chronic illnesses or acute conditions that develop during pregnancy. Although guidelines from the Council for International Organizations of Medical Sciences stipulate that pregnant women are eligible to participate in biomedical research, they are routinely excluded from clinical trials due to concerns that medications may harm the developing fetus. Thus, there is a paucity of evidence from clinical trials supporting the maintenance or discontinuation of treatments provided in pregnancy, resulting in uncertainty regarding best practices. Pharmacological teatment of pregnant women is less evidence-based than treatment of non-pregnant women or men. Observational research is currently the best way to close this important knowledge gap. Antidepressants are among the most frequently used medications during pregnancy, used by up to 14% of women during the gestational period. However, antidepressants, specifically selective serotonin reuptake inhibitors (SSRI), represent a widely prescribed class of medications for which there remain confusion on appropriate use during gestation. Given that depression is a prevalent and imparing illness that is encountered frequently in medical practice, and that the World Health Organisation (WHO) predicts that depression will be the second leading cause of premature death and disability worldwide by the year 2020, the presentation will highlight the most recent data on the risks and benefits of antidepressant use during pregnancy for the mother and the child.

Oration II

K. C. Singhal oration

Individual Case Safety Report Databases as sources of Practice-based Evidence

Dr. Ruth Savage
Department of Preventive and social medicine University of Otago Senior Medical assessor, Centre for adverse reaction monitoring, New Zealand.

In New Zealand there has been discussion around the value of evidence-based medicine in primary care and the case for complementary practice-based evidence that could feed back into the evidence from clinical trials on the generality and applicability of the interventions in the "real life" context.1 It is clear that databases of spontaneously reported adverse drug reaction (ADR) reports (individual case safety reports) held in national and regional pharmacovigilance centres are, in fact, a source of practice-based evidence.

In 1965 New Zealand became one of the first countries to collect and assess reports submitted by health professionals of suspected adverse drug reactions (ADRs) in individual patients. This collection is the database of the Centre for Adverse Reactions Monitoring (CARM) based in the New Zealand Pharmacovigilance Centre. Distinctive features of the New Zealand database are the high proportion of well-documented reports, and, frequently, the highest reporting rate/ population in international comparisons. New Zealand was also a founding member of the WHO International Drug Monitoring Programme.

Databases of adverse drug reactions (ADRs) were established to generate hypotheses to be tested about previously unrecognised adverse reactions and interactions. Occasionally they contain sufficient evidence in themselves. They can also identify prescribing practices that might increase the potential for ADRs to occur. They can feed back into guidelines the consequences of their use or non-use and identify unexpected problems that arise with issues such as pathways to accessing funded medicines. Well-documented ADR reports can also highlight risk factors, thus providing a valuable contribution to risk benefit assessments in individual patients. Examples from the New Zealand database and from international collaboration will be discussed that support the use of ADR reports as practice-based evidence in a non-hierarchical system in which case reports and case series, observational studies and randomised clinical trials contribute in a flexible relationship depending on the issue under investigation.

One of the major challenges in optimising the contribution of ADR databases to clinical practice is the provision of feedback that aids prescribing and also stimulates the quality as well as quantity of reporting.

Parsonson B. The case for practice-based evidence to support evidence-based practice. J Prim HealthCare 2012;4(2):98-99.

Pharmacovigilance: Pediatricians' Concerns

Sandeep B Bavdekar
Professor and Head, Department of Pediatrics, TN Medical College and BYL Nair Charitable Hospital

Awareness about adverse drug reactions is essential knowledge for a pediatrician. Every segment of the healthcare system derives benefits from pharmacovigilance, the system of reporting and analyzing adverse events and adverse reactions. The consumers benefit as the likelihood of getting safe drugs is increased through pharmacovigilance. It is well-known that when a drug is being evaluated during clinical trials, one gets some evidence of efficacy but only a limited evidence of safety. Considering the number of participants enrolled in the study, only the more common reactions are likely to be recorded at this stage; the type B or the idiosyncratic reactions are unlikely to be noticed. When the drug is marketed, it is used by a variety of patients with different grades of the disease or disorder; who may be on several other medications at the same time. The pharmaceutical industry also benefits from pharmacovigilance; as the unsafe drugs are identified early, with greater reputation for the company and the industry. And of course, lower insurance costs! The pharmacologists and Pharmacovigilance Centers benefit as they get an opportunity to report interesting cases and data and thereby contribute to better understanding of the drug, for quantification of risk and for pharmaco-economic decision making. All this information is necessary to take informed decisions while formulating therapeutic guidelines. The regulators also have more data to base their regulatory decisions on, There are certain specific aspects of pharmacovigilance in children. Children may not report early and milder discomforts. The commonest manifestations of adverse events include fever and rash. These are commonly misdiagnosed as viral infections which are so frequent in children. In addition, issues related to vaccine safety are of particular concern to children. Also, certain types of adverse reactions such as affection of growth can occur only in children. Many drugs are used in children in an off-label manner. This means the drug is being used without it being licensed for use and without sufficient data regarding safety, efficacy, dosages and pharmacokinetic parameters being available. This leads to unique situations. Children are more prone for encountering ADR, when the drug used is an off-label one. In addition, explaining the concept of off-label drug use to parents is extremely difficult after an adverse event has occurred. There is a fear in the minds of the pediatrician that this may be wrongly construed as an illegal use or wrong use! Lack of appropriate formulations also makes children more prone to receive inappropriate doses.

If there are benefits to be reaped for everyone in the healthcare system, how come the clinicians (including pediatricians) require to be constantly externally coaxed and motivated for reporting adverse events and adverse drug reactions? The probable concerns and impediments and their solutions are listed in Table 1. The pharmacovigilance systems in our country would work effectively only when these concerns are suitably addressed.

Table 1: Concerns and possible Solutions

Concerns/ Impediments

Possible Solutions

Probing Questions from the patient/ parent

Establish rapport

Educate and Inform: All drugs have side-effects; Every adverse event/ Adverse Drug reaction does not mean an error or negligence on part of the treating pediatrician

Enhance communication skills

Enhance rapport-building skills

Media Exposure and Sensationalization

Fear of Being sued or asked to pay compensation

Lack of awareness: Need to report, what to report and where to report

Increase awareness among graduate and post-graduate students

Collaborate with professional organizations such as Indian Academy of Pediatrics, Indian Medical Association and their branches

Publicize information about local, regional, zonal and national pharmacovigilance centers

Excessive spending of time

Simplify procedures: Easy-to-fill ADR reporting form

Minimize the need to seek clarifications and additional information

Who owns the data: The Center or the reporting physician?

Provide definite Guidelines

Collaborate for publication of Case Reports

Inform about the results of analysis to the Reporting Pediatrician

Adverse Drug Reactions in the Elderly

Dr. S. V. Desai
Prof. Pharmacology,
SBKS Medical Institute and research centre,Sumandeep Vidyapeeth, Piparia

Preamble

The population of elderly is on rise globally, including India. The life expectancy has increased because of an improved standard of living with better housing, good hygiene, education, improved economy together with better medical treatments, especially drugs. At the same time, the prevalence of many diseases is age related and several may coexist in the same patient. These include the cardiovascular and cerebrovascular diseases, cancers, arthritides, diabetes and infectious diseases. These diseases account for increased morbidity and mortality in the elderly.

Treatment of diseases in the elderly may require polypharmacy due to many legitimate reasons like prevalence of many age related diseases, several of which may coexist, need of giving combination drugs in diseases like hypertension, diabetes, heart failure, etc, for minimizing or counteracting adverse effects of drugs and at times because of advertising gimmicks of pharmaceutical companies. Such polypharmacy may lead to medication errors and adverse drug reactions in the elderly. These ADRs may result due to drug-drug interactions occurring between multiple drugs being co-administered. Interactions may be pharmacokinetic or pharmacodynamic. The most important drug interactions occur with the drugs known to cause ADRs commonly or with the drugs having low therapeutic index. Simultaneous consumption of OTC drugs or herbal drugs may add to the problem. Moreover, the chances of drug interactions are more likely to occur in the frail elderly.

Elderly patients may develop drug-related problems even when their medication is confined to a single agent or non-interacting multiple agents. These may be due to age related pharmacokinetic and pharmacodynamic changes. Age related physiological changes may impact on handling of drugs by the body.

Altered pharmacokinetics in the elderly

Absorption: Oral bioavailability of drugs may be altered in the elderly due to reduced gastric acid secretion, decreased gastric emptying, diminished splanchnic blood flow and decreased gastrointestinal motility. However, in practice, ageing does not affect absorption to a significant degree because potentially rate-limiting factors in the small intestine, like surface area and luminal pH are not altered to a critical degree. Oral bioavailability of drugs like propranolol and nifedipine may increase in elderly, especially the frail or hospitalized, having small changes in liver function which may decrease the presystemic extraction of such drugs.

Distribution: Changes in body composition, plasma protein binding and blood flow in the elderly may influence the extent of distribution of drugs. With ageing, there is a decrease in the lean body mass and body water and a corresponding increase in adipose tissue in relation to total body weight. As a result of this, the distribution of lipid insoluble drugs like paracetamol may

decrease in the elderly leading to raised plasma concentration. On the other hand, lipid soluble drugs like diazepam are more widely distributed and may produce a prolonged action. Serum albumin levels decline with the age, but the change may be minimal in healthy elderly. The decline may be marked in presence of disease, immobilization and poor nutrition. Reduction in albumin level may result in decreased binding capacity of weak acidic drugs like salicylates and phenytoin leading to the increased plasma levels of free drugs and a transient increase in toxicity.

Metabolism: Hepatic mass decreases with age by 25% - 35%, so the metabolism of drugs primarily cleared by liver may be decreased. Phase 1 oxidative drug metabolism may be reduced in the elderly, but phase 2 reactions are generally not altered at least in fit elderly patients. However in the frail elderly, in those who have suffered injury or have undergone surgery, enzyme activity may be significantly depressed, resulting in raised blood concentrations and an increased risk of adverse reactions.

Renal Excretion: As part of normal ageing, both renal functional capacity and renal reserve diminish. GFR steadily decreases with ageing. These may lead to decreased renal clearance of drugs which are dependent on kidney for elimination. Drugs may accumulate to toxic levels if given to elderly in normal adult doses. Doses based on creatinine clearance should be used in the elderly.

Altered Pharmacodynamics in the Elderly

Elderly may show both increased or decreased sensitivity to the drugs. These may be due to age related changes in organ systems, impairment of homeostatic mechanisms as well as changes at receptor and cellular levels. Elderly may require lower doses of warfarin than young. Elderly may show increased sensitivity to effects of benzodiazepines.

Adrs in the Elderly

For reasons described above, elderly patients are more vulnerable to drug- related adverse events. ADRs are a common problem in population, accounting for 3%-12% hospital admissions. The incidence of ADR ranges from 1.5% to 20% (average 5%) in hospitalized patients. The incidence is higher (around 10%) in elderly patients. Polypharmacy and irrational use of drugs may contribute to this.

Conclusion

It may not be possible to avoid ADRs in elderly. But they can certainly be minimized by considering the age related physiological changes and pharmacokinetic & pharmacodynamic factors before prescribing drugs in the elderly. Drugs must be prescribed rationally and their number may be kept to the minimum possible. At the same time there is a need of searching out drugs suitable for use in the elderly, conducting clinical trials of drugs in them, particularly in frail and hospitalized patients. Pharmacovigilance in elderly may be a rewarding activity for both the clinicians and the pharmacologists.

Pharmacovigilance : Undergraduate Teaching

Dr. Nirmala Rege
Professor & Head, Department of Pharmacology, Seth G.S.Medical College, Mumbai

The pharmacovigilance programme of India for assuring drug safety involves medical colleges wherein pharmacology departments are inducted as ADR monitoring centres. In spite of this, the reporting of adverse effects of drugs is far from satisfactory. The published literature shows that the under-reporting is mainly due to ignorance on part of clinicians, lack of time, and unawareness about their role in the programme. The quality of reporting is also low. One of the approaches to improve this scenario is to target the budding doctors- the undergraduate students.

Drug safety is an integral part of Indian medical curriculum. But while transacting the curriculum, major emphasis is laid upon the information to be delivered through lectures rather than active involvement of the students. The training does not impart skills for detection of adverse drug effects, critical evaluation of the cause, manifestations and consequences of observed effect and recommendation of rational treatment and monitoring. It also does not include communication to the patients. The assessment is also theory driven and does not assess their familiarity with practical aspects. As a result, it is difficult to make out whether the students have understood issues surrounding risks and benefits of drug use and developed competency to deal with them effectively.

Hence reforms in existing curriculum are essential to familiarise undergraduates with current pharmacovigilance programme based on the adult learning principles. A modular programme, extending across the phases as a continuum with specific objectives and activities based on the previous knowledge and experience of the learners, will navigate them from the simple issues to complex therapeutic dilemmas they may encounter while practicing in the real life. Small group activity based teaching to expose the students to core elements pertinent to pharmacovigilance and specifically to reporting adverse reactions should be planned. The scope of the training should extend beyond the institutional boundaries allowing exposures in community and inviting external experts in pharmacovigilance. The activities included in the programme should be linked with the assessment using appropriate assessment methods.

In the symposium curriculum of such module will be presented highlighting the experiences at Seth GS Medical College related to implementation of some of the activities that can be incorporated in the module.

Integration of Pharmacovigilance in Postgraduate Medical Education

Dr. Santanu K Tripathi
MD, DM, Professor & Head, Department of Clinical & Experimental Pharmacology,
Calcutta School of Tropical Medicine, Kolkata

Adverse drug reactions (ADRs) are a common and significant health problem patients seek consultation for. Given the high incidence of ADRs in general and the even higher potential for their occurrence every day in medical practice, an average physician in his/her professional career ought to come across innumerable such patients. But, the conscious diagnosis of drug-induced diseases in routine clinical practice is relatively a rare entity. Are the ADRs really underdiagnosed? Or, are the physicians reluctant to declare the diagnosis and communicate the same to the suffering patients? Are they underreported? Perhaps, the answer to all these are in affirmative.
Pharmacovigilance (PV) is a sub-discipline that refers to the scientific study of ADRs and is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

While ADRs are known to cause havoc in patient care, it is an irony that the traditional medical curricula fails to attach due importance and emphasis in PV – this is true for both undergraduate (UG) and postgraduate (PG) medical education in India, and perhaps elsewhere too. This results in undue woes and suffering to the patients, sometimes causing fatal outcomes even, a vast majority of which are certainly avoidable.

This presentation deliberates on the urgent need for integration of PV in PG medical education in India, across diverse sub-specialties, and also suggests a roadmap for the same.

A Comparative Study of National and International Publications on Pharmacovigilance

S. Z. Rahman, Z. M. Ansari & I. Zaheer
Department of Pharmacology, Jawaharlal Nehru Medical College, AMU, Aligarh

Publications on Pharmacovigilance and drug safety are aimed to assure the safety of medicines by ensuring reliable and timely exchange of information on drug safety issues. It helps in promoting Pharmacovigilance activities, encouraging participation in the WHO Programme for International Drug Monitoring. There are series of publications on safety monitoring of medicinal products. Many texts were developed in consultation with the WHO Collaborating Centre for International Drug Monitoring and the National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring. These publications are widely circulated and intended for wide-ranging readership for policy makers at all levels of healthcare, particularly those concerned with drug policy; staff and consultants in national drug regulatory authorities; healthcare practitioners including doctors, nurses and pharmacists; pharmaceutical industry executives and scientists; professional staff in national Pharmacovigilance centres; editors of medical and scientific journals; health epidemiologists; health economists; professional staff of poison and drug information centres; health administrators; consumer groups and patient support groups; legal advisors in health care; schools of health sciences, and the concerned layperson, etc. In the present paper, authors compared the number of publications in the form of books and periodicals by Indian and Non-Indian authors in addition to publications by professional organisations such as UMC-WHO Collaborating Centre for International Drug Monitoring, National Pharmacovigilance Centre, International Society of Pharmacovigilance (ISoP) and Society of Pharmacovigilance, India (SOPI).

Pharmacovigilance in clinical trials, phase I - III

Dr Arun Bhatt
President Clininvent Research

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. Major objectives of pharmacovigilance are:

- Early detection of unknown safety problems
- Identification of risk factors
- Quantifying risks
- Detection of increases in frequency
- Preventing patients from being affected unnecessarily

Pharmacovigilance science, traditionally focused on the post-marketing period, has gradually moved to consideration of risks and potential benefits of drugs in the pre-approval phases of drug development.

Pharmacovigilance in clinical trials includes:

- Identification of adverse events (AEs) and adverse drug reactions (ADRs)
- Assessing severity of AEs
- Assessing seriousness of AEs
- Assessing unexpectedness of AE
- Assessment of causality of investigational product
- Regulatory reporting of Serious AE (SAE)
- Regulatory reporting of Serious Unexpected Adverse Drug Reaction (SUSAR)
- Management of AEs and SAEs
- Record and database of AEs and SAEs
- Preparation of development safety update report (DSUR)
- Pharmacovigilance risk management

The following International Conference on Harmonisation (ICH) guidelines are important in managing one pharmacovigilance processes and systems.

- E1 The Extent of Population Exposure to Assess Clinical Safety for Drug Intended for Long-term Treatment of Non-Life-Threatening Conditions
- E2A Clinical Safety Data Management: Definitions and Standards for expedited Reporting
- E2B Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
- E2E Pharmacovigilance Planning
- E2F Development Safety Update Report

The regulatory landscape is evolving with increasing demands for risk management plans, and risk evaluation and minimization strategies.

Monitoring of patient safety during clinical development is a vital component throughout all the pre-approval phases of clinical trials and provides the background for risk: benefit assessment of new medicinal entities.

EU Pharmacovigilance-Post 2012

Dr. Kiran Marthak
Lamda CRO, Mumbai

New pharmacovigilance legislation and amending existing legislation was adopted in the European Union (EU) in December 2010 (applicable since 2012) and this is the biggest change to the legal framework for human medicines in EU, since 1995

The legislation aims to promote and protect public health by strengthening the Europe-wide system for monitoring the safety and benefit-risk balance of medicines. It builds on the existing processes and structures and aims to strengthen the monitoring of benefit-risk of medicines in Europe by developing innovative methods to enhance: early detection and assessment of adverse drug reactions from different data sources (clinical trials, spontaneous reporting and observational studies) the integration and presentation of data on benefits and risks With clearly defined roles and responsibilities encouraging rapid decision-making and engaging patients and healthcare professionals, in a risk based/proportionate and transparent manner, EMA intends to promote and protect public health by reducing burden of ADRs and optimising the use of medicines.

However, the lack of human and financial resources is the biggest risk to the implementation and operation of the new legislation.

Guest Lecture

Status of Pharmacovigilance in Vector borne diseases

Thakor H G, Dr. A. C. Dhariwal, Dr. G S Sonal
Directorate of National Vector Borne Disease Control Programme, Ministry of Health & Family Welfare, Government of India

Introduction:

WHO defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of marketed medicines or those under trial. It is the responsibility of drug regulatory agencies to have a well-established pharmacovigilance system for monitoring adverse reactions of drugs, during the drug development phase and later during the life time of a marketed drug with aims: to improve patient care and safety; to improve public health and safety; to contribute to the assessment of benefit, harm, effectiveness and risk of medicines and to promote education and clinical training to promote effective communication to the public to promote rational and safe use of medicines. It provides important information on at risk groups, risk factors and clinical features of known serious and rare adverse drug reactions (ADRs). It is needed for humanitarian concern as there are insufficient evidences of safety from clinical trials in Animal experiments Phase 1 – 3 studies prior to marketing authorization. The cost due to adverse drug reaction in terms of care cost is also very high. The patient may die due to disease, but death due to drugs is unacceptable and so it is very important to study about the adverse drug reactions due to drugs. Vector control Diseases are effectively controlled with the help of effective drugs and that is why, the important strategy for control of VBDs in India is Early Diagnosis and Prompt, Complete Effective Treatment. Off course, the specific drug against arbo-viral infections (Dengue, Chikungunya, JE) is not available. Symptomatic and organ specific treatment are the main armaments for their treatments. However, for malaria a plethora of drugs is available and similarly for Kala-azar and Lymphatic filariasis also specific drugs are available.

The NVBDCP keeps close watch on the adverse reactions to these drugs through pharmacovigilance studies conducted with the help of National Institute of Malaria Research (NIMR) for anti-malarial drugs and Regional Malaria Research Institute (RMRI) Patna for anti-leishmanial drugs. As ACT and Miltefosine are newly adopted in country on a large scale, it was important to monitor safety in the program conditions. In due course, new partner drugs may be considered for ACT and new promising drugs on Kala-azar may be added in the list of first line drugs for kala-azar treatment. A protocol for prospective monitoring, coordinated with drug susceptibility testing, was therefore prepared by NIMR and similarly pharmaco-vigilance included under the kala-azar elimination program by Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna.

The project undertaken by NIMR attempts at evaluating the safety of antimalarials by both passive and active pharmacovigilance. District Malaria Officers from states of Assam, Meghalaya, Arunachal Pradesh, Nagaland, Jharkhand, Orissa, Gujarat, Madhya Pradesh, Chhattisgarh and Karnataka were trained under this project. To improve AER reporting, the component of active pharmacovigilance was also included. Till date, total 4602 filled in AER forms have been received. They include 1966 forms filled in by the medical officers and information of 2636 patients participating in therapeutic efficacy study. Three thousand and two hundred forms have been analyzed till date. A total of 87 adverse events have been reported in the form of nausea, vomiting, giddiness and gastritis etc. The study shows that the antimalarials being used in the national programme are safe. The status of adverse reaction reported during the study will be discussed during the presentation.

However, now the nation-wide programme 'National Pharmacovigilance Programme (NPP)', sponsored and coordinated by the country's central drug regulatory agency – Central Drugs Standard Control Organization (CDSCO) – is being established to manage a data base of Adverse Drug Reactions (ADR) for making informed regulatory decisions regarding marketing authorization of drugs in India for ensuring safety of drugs. And so, the programme specific pharmaco-vigilance studies are now stopped and the monitoring of Anti-VBD drugs will also be done through the national pharmacovigilance progamme.

Guest Lecture

Pharmacovigilance in tropical and neglected diseases

Dr. Clara Marr
Clinical Development Manager in Infectious Diseases, GlaxoSmithKline R&D (GSK), UK.

Neglected Tropical Diseases (NTDs) collectively affect more than one billion people in developing countries, causing illness, disability and death. These infectious diseases strike the most vulnerable populations – those without access to basic sanitation, clean water, shelter, food or healthcare. For decades, non-government organisations, donors, and leading organisations have worked hard to support endemic countries to fight NTDs. The World Health Organization (WHO) targets aim to control or eliminate 10 of the 17 NTDs by 2020. Inspired by the WHO's 2020 roadmap on NTDs, these organisations believe that there is a tremendous opportunity to achieve this goal by the end of the decade with the right commitment and collaboration. The public and private sectors are uniting to enable more than a billion NTD sufferers to lead healthier lives.

In January 2012, more than 10 global pharmaceutical companies and leading organisations, including the WHO, Bill & Melinda Gates Foundation, UK Department for International Development, US Agency for International Development and the World Bank came together in London to launch the largest coordinated effort -The London Declaration on NTDs, to support the goals set out by the WHO. Over the past year, this partnership has made significant progress. More than 40 countries have delivered detailed plans to control or eliminate NTDs and major pharmaceutical countries have donated more than one billion treatments per year to meet drug requests by endemic countries. As part the global effort to end NTDs, pharmaceutical companies in the partnership have committed to sustain, expand and extend programmes or drug access to help eradicate/control NTDs such as lymphatic filariasis (LF), leprosy, soil-transmitted helminthes (STH), Chagas disease, visceral Leishmaniasis, etc.

Pharmacovigilance in tropical and neglected diseases have many challenges and considerations needed to be taken into account, for example, mass drug administration to populations with different co-morbidities; the potential for off-label use; access to medicines not matched by capacity building in pharmacovigilance. Sometimes there is a paucity of safety data, and follow-up information is rarely forthcoming due to difficulties in tracking patients or delayed reporting of initial events. Need to ensure that there is a common reporting format and well defined route for adverse event reporting. National programme managers should be given guidance aligned to regulatory obligations and it is important to maintain a balance between programme success vs. media interests vs. safety monitoring.

Pharmacovigilance Programme of India: A Step towards Patient Safety

Dr. V. Kalaiselvan
Senior Scientific Officer, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India, Sector 23, Rajnagar, Ghaziabad, U.P 201 002

Indian Pharmacopoeia Commission (IPC) is functioning as National Coordination Centre (NCC) for PvPI since April 2011. During the last two years it has become a network of 90 ADRs monitoring centres covering 24 states and union territories of the country with the strong commitment of the Govt of India it is expected that the network will spread to 150 centres within a short span of next 5 months and to all 350 medical colleges within next two years. During the last two years PvPI has received more than 62,000 ADRs and contributing to Uppsala Monitoring Centre. NCC collaborates with different stakeholders to ensure patient safety. NCC is organizing various workshop & training for the stakeholders, national conferences and awareness programme all over the country to report ADRs. PvPI is currently focusing on Signal Detection from Indian data base.

Guest Lecture

National Pharmacovigilance Programme for Ayurveda, Unani and Siddha (ASU) drugs

Acharya Rabinarayan
Associate Professor & Member Secretary, National Pharmacovigilance Resource Centre for ASU drugs, IPGT&RA, Gujarat Ayurved University, Jamnagar

In India, Ayurveda, Siddha and Unani (ASU) systems medicine, considered to be oldest system of medicines, also prescribes drugs of herbo-mineral and animal origin for the treatment of many diseases. Being time tested systems of medicine and majority of drugs are of herbal origin, it is considered that these drugs are safe. It is observed that, the use of ASU medicines continues to expand rapidly across the world. Considering ASU drugs as a safe medicament people are now consuming these medicines, as an OTC drug, in the name of herbal medicines or herbal products for their health care. Due to increase in uses in different national health-care settings a high demand of these medicines is being recorded in the national as well as international market. Due to inadequate regulatory measures, weak quality control systems and largely uncontrolled distribution channels (including mail order and Internet sales) and improper administration some adverse events has also been reported.

It is observed that, the majority of adverse events related to the use of ASU medicines that are reported are attributable either to poor product quality or to improper use. It is the high time to have knowledge about genuine adverse reactions to herbal medicines, and to avoid wasting scare resources for identifying and analysing adverse events, events resulting from such situations will need to be reduced or eliminated. However, mass media reports of adverse events tend to be sensational and give a negative impression regarding the use of herbal medicines in general rather than identifying the causes of these events, which may relate to a variety of issues. The safety of herbal medicines has become a major concern to both national health authorities and the general public.

Department of AYUSH, Ministry of Health and F &W, Govt. of India, New Delhi, recognised Institute for Post Graduate Teaching & Research in Ayurveda (IPGT&RA), Gujarat Ayurved University, Jamnagar as National Pharmacovigilance Resource Centre for Ayurveda, Siddha and Unani Drugs(NPRC-ASU) in India under the Central sector scheme for up gradation to Centre of Excellence since 2008-09. As per the protocol, NPRC-ASU Drugs, is coordinating this National Pharmacovigilance programme (NPP-ASU) under the aegis of Department of AYUSH, Ministry of Health & Family Welfare, Government of India. Under NPRC-ASU drugs, there are eight Regional Pharmacovigilance Centre (RPC) for ASU drugs. There are 30 Peripheral Pharmacovigilance Centre (PPC) for ASU drugs which are working under these eight RPCs, across the country. Adverse drug reaction related to any ASU drugs is being reported to these PPC, in a specially designed ADR reporting form, which are transmitted upwards after proper evaluation at each level. Till today, NPCC-ASU drugs met thrice and NPTAC-ASU drugs met once to review the Programme as well as reported ADRs.

To fullfill the primary aim of this programme i.e To develop the culture of notification and to involve healthcare professionals and professional associations in the drug monitoring and information dissemination processes. Teachers, physicians and pharmacists of ASU systems, were being sensitized on the concept of pharmacovigilance and how to report ADR through CME programme, across the country and till today more than 2000 teachers/ physicians and paramedical staff were trained in this regard. Further, Pharmacovigilance for ASU drugs, is being included as a topic, in the module of each CME and RoTP of Dravyaguna/ Rashashastra, coordinated by RAV, New Delhi. A web portal, 'ayushsuraksha.com' has been launched for on line registration of ADR related to ASU drugs through an "e format".

To achieve operational efficiencies that would make National Pharmacovigilance Programme for ASU drugs a benchmark for global drug monitoring endeavors Pharmacovigilance has been included in the curriculum of graduate and post graduate level studies of Ayurveda. Now steps have been taken to open one Pharmacovigilance centre at each affiliated ASU colleges. Clinical research units of different pharmacies including institutes conducting Post graduate and doctoral level research were requested to include Pharmacovigilance aspect as one of the criteria in their research projects. Department of AYUSH, Govt. of India, has been requested to instruct the drug licensing authorised to include pharmcovigilance aspect as one of the criteria while giving permission for a new drug.

As a part of promotional activities brochures on Pharmacovigilance for ASU drugs were prepared and being distributed at stall at Arogya / CME etc, guest lectures were delivered during scientific sessions of different National and International seminars and research scholars and public were informed by putting advertisement related to NPP ASU drugs in different journals and souvenirs.

Oral Presentations

List of Abstracts for Oral Presentation

OP 1	Role of Glipizide therapy on oxidative stress parameters in patients with type-II Diabetes Mellitus	Prakash P. Malam, N.D.Kantharia	malam_prakash @yahoo.com
OP 2	Study of adverse drug reactions with Angiotensin converting enzyme inhibitors in a tertiary care hospital of eastern India: A Comparative Study	Sanjay Kumar, Nayak Pramila, Mishra S.S., Patnaik Shantilata, Patnaik Jyotsna	dska27 @yahoo.co.in
OP 3	Adverse Cutaneous Drug Reactions due to Antiepileptics	Arvind Chaudhari Gopikrishnan A, Rita Vora	arvindbhaih @charutarhealth.org
OP 4	Study of prescribed dose calculation in patients of paediatric age group.	Aakanksha Prajapati Nikhil Kharod, Barna Ganguly	prajapatiab @charutarhealth.org
OP 5	Why and how unani system of medicine insisted upon pharmacovigilance for each and every drugs in the light of medical ethics	Abdul Latif, S.Z.Rahman	abdullatiffamu @gmail.com
OP 6	Fixed Drug Reactions	Abhishek Pilani, Gopikrishnan, Rita Vora	pilaniap @charutarhealth.org
OP 7	Development of Adverse Drug Reaction Reporting Culture in Second Professional Medical Undergraduates at a Tertiary Care Teaching Hospital: A Health Imperative	Aditi Chaturvedi, Deepak Parihar, Gitanjali Kothiyal, Rangeel Singh Raina, Priyanka Singh, Heenopama Thakur, Hemant Kumar Dutt	aditichaturvedi50 @yahoo.com
OP 8	Effect of Atenolol on Hemoglobin level in Mild to Moderate Hypertension.	Zala Ashishkumar C, KanthariaN.D.	aashish.zala17 @gmail.com
OP 9	Study of Adverse Drug of chemotherapeutic agents used for treatment for oral cavity squamous cell carcinoma at tertiary care teaching hospital baroda	Chirag B.Mistry, Niyati A.Trivedi, J. D. Bhatt , Vimal Batra	duty.chirag @gmail.com
OP 10	A study of morbidity pattern and utilization pattern in indoor patients of high risk pregnancy at tertiary care hospital	Darshan Kharadi, Harsh M. Joshi, Kamlesh P.Patel, Varsha J. Patel	dbkharadi85 @gmail.com
OP 11	A Comparative evaluation of different antidepressant drug in the treatment of major depressive illness	Patel DS, Solanki MN, Dikshit RK	dhrumilpatel786 @gmail.com
OP 12	Pattern of adverse drug reaction in a medicine department of tertiary care hospital	Agrawal JM, Trivedi HR, Singh AP, Patel NM, Vaniya HV	jitendra_jindal @rediffmail.com
OP 13	Assessment of adverse drug reaction forms submitted by medical students as a part of their practical training in Pharmacovigilance	Komal V Gaur, Bharat M Gajjar	komalvg @charutarhealth. org
OP 14	Case Report : Augmentin induced Anaphylaxis	Darji NH, Trivedi HR, Jadav SP, Singh AP, Mistry RA	nishitadarji @gmail.com

List of Abstracts for Oral Presentation			
OP 15	A survey on knowledge and perception of pharmacy students of anand district towards pharmacovigilance and adverse drug reaction reporting	Nitin Kothari, Nazima Mirza	nknitinkothari @gmail.com
OP 16	Study of adverse drug events of antiepileptic drugs in a tertiary care teaching rural hospital	Pragna Patel, Bharat Gajjar	pragna22785 @gmail.com
OP 17	Prescribing Pattern and Adherence to Treatment Guidelines in Osteoporotic Patients Attending Orthopedic Outpatient Department of a Tertiary Care Teaching Hospital	Rohan P Christian, Hemalata S Ninama, Devang A Rana, Supriya Malhotra, Varsha J Patel	christian. rohan25 @gmail.com
OP 18	Knowledge, Attitude and Practice regarding Adverse Drug reaction reporting & Monitoring amongst Physicians in a Tertiary Care Teaching Hospital, Ahmedabad	Prajapati RR, Dumatar CB, Dikshit RK	ronakprajapati9 @gmail.com
OP 19	An overview of the various regimens of Rituximab in Thrombotic Thrombocytopenic Purpura (TTP).	Bhat S P, Rahman S Z.	sweetsan18 @yahoo.com
OP 20	Correlation between various Adverse Drug Reactions Causality Assessment Scales and their Agreement in Pediatric Population	Sunil Bhadiyadara, Harsh J. Shah, Devang A Rana, Supriya Malhotra, Varsha J Patel	drsunny8289 @gmail.com
OP 21	Drug utilization pattern of antiepileptic drugs and their adverse effects in paediatric population, in a tertiary care hospital attached to a medical college	Kumari VM, Mistry RA, Singh AP, Trivedi HR	leo_leo07 @yahoo.co.in
OP 22	A Prospective analysis of Adverse Drug Reactions reported in C.U.Shah Medical College, Surendranagar	Vasani PR, Bhatt PN, Solanki SN, Savsani DD, Mehta DS	vpunita13 @yahoo.com
OP 23	Adverse Cutaneous Drug Reactions due to Antimicrobials at a Tertiary Based Rural centre	Nidhi Patel, Gopikrishnan A. Rita Vora	drnidhipatel28 @gmail.com
OP 24	Study of prescription audit pattern in the inpatients of a tertiary care hospital	Hedamba R H, Mistry R A, Darji N H, Trivedi H R	rutvij237 @yahoo.co.in
OP 25	An evaluation of promotional drug literature using WHO criteria	Jadav SS, Dumatar CB, Dikshit RK	sandip09jadu @gmail.com
OP 26	Study of Antimicrobial resistance pattern of uropathogenic Escherichia coli at a tertiary care hospital for a period of three years.	Anturlikar S., Trivedi N.A., Bhatt J.D	snehalantur-likar28 @gmail.com
OP 27	Monitoring of Adverse Drug Reaction with Special Reference to Detoxification of Unani Drugs	Abdur Rauf Abdul Latif	abdurraufmd @yahoo.com
OP 28	Age associated adverse effect of antipsychotic drug (Lithium) in rat central nervous system	Sandeep Tripathi	

OP 1

Role of Glipizide therapy on oxidative stress parameters in patients with type-II Diabetes Mellitus

Prakash P. Malam, N.D.Kantharia
Department of Pharmacology, GMC, Surat

Aim and objectives

Oxidative stress has important role in pathophysiology of type-II diabetes mellitus. Oxidative stress has important role in progression of type-II diabetes mellitus and its related complications like retinopathy, neuropathy and many others. Aim of present study was to evaluate the effect of glipizide therapy on oxidative stress parameters in type-II diabetes mellitus.

Materials and Methods

Study was prospective and non-randomised. Thirty newly diagnosed diabetes patients selected for glipizide therapy by medicine personnel were enrolled in the study based on inclusion and exclusion criteria. The patients were divided into pre-treatment and post-treatment group. Thirty non-diabetic healthy volunteers served as a control. Plasma malondialdehyde , superoxide dismutase and catalase levels were measured at the time of enrolment and at the end of three months of glipizide treatment.

Results

Results are analysed by paired t-test and unpaired t-test. Plasma malondialdehyde was significantly increased whereas superoxide dismutase and catalase were significantly reduced in newly diagnosed diabetic patients as compared to control. After three months of glipizide therapy, plasma malondialdehyde was significantly reduced whereas superoxide dismutase and catalase were significantly increased.

Conclusion

Glipizide therapy significantly reduced oxidative free radicals and increased antioxidant mechanism which may reduce oxidative stress, progression of type-II diabetes mellitus and its related complications.

OP 2

Study of adverse drug reactions with Angiotensin converting enzyme inhibitors in a tertiary care hospital of eastern India: A Comparative Study

Sanjay Kumar, Nayak Pramila, Mishra S.S., Patnaik Shantilata, Patnaik Jyotsna
Department of Pharmacology, IMS & SUM Hospital, Ghatikia, Bhubaneswar,

Introduction

Angiotensin converting enzyme inhibitors (ACEIs) are known to possess different chemical structures, and change in structure of a drug can bring about change in its adverse drug reaction (ADR) profile. The purpose of the present study was to observe the incidence and severity of adverse drug reactions between the di-carboxyl group containing ACE inhibitors (namely lisinopril and ramipril) versus the phosphonate group containing ACE inhibitors (namely fosinopril), in patients suffering from essential hypertension.

Materials and Methods

Eighty nine newly diagnosed patients (53 male, 36 female) suffering from stage I / II essential hypertension, according to JNC-VII guidelines, without any underlying comorbid conditions or complications, were enrolled in the study after obtaining informed consent and due approval of the ethics committee. They were followed up for four months, to observe the clinical efficacy along with the associated ADRs.

Results

Mild, dry brassy cough (% incidence, 95% CL) was observed with d-ACEIs (6.6%, 0 to 15.6) versus p-ACEI (20%, 5.7 to 34.3), in which the cough observed was moderate-to-severe in intensity and two patients required treatment discontinuation ($p < 0.5$).

Conclusions

The phosphonate group in p-ACEIs may have a probable relationship with increase in the incidence and severity of ADRs such as dry brassy cough and hypotension, the di-carboxyl group in d-ACEIs may have a probable relationship with increase in the incidence of ADRs like nausea. Some other effects which were noticed and observations and conclusion will be discussed in detail in the presentation.

OP 3

Adverse Cutaneous Drug Reactions due to Antiepileptics

Chaudhari Arvind, Gopikrishnan A., Vora Rita

Introduction

Epilepsy is treated by conventional drugs like phenytoin, carbamazepine, valproic acid and lamotrigine. Antiepileptic drugs that may give rise to unexpected life threatening adverse events ranging from maculopapular rash to SJS/TEN. Most of these emerge as idiosyncratic reactions, immune mediated disease or are related to toxic metabolic products of AEDs.

Aim

To find out the incidence of drug reactions due to antiepileptics at a rural based tertiary care centre, various clinical patterns of drug reactions due to antiepileptics and most common antiepileptic drugs responsible for the drug reactions.

Methods

The prospective observational study was carried out from April 2010 to March 2011 in the Dermatology department, SKH hospital in all patients irrespective of age and sex suspected of having drug reactions due to antiepileptics after ethical approval and taking patients' written consent.

Results

Total 100 patients of adverse cutaneous drug reaction were reported. Out of that 11 cases(3 males and 8 females) had adverse cutaneous drug reaction due to antiepileptics .Most common affected age group is 21-55yrs with most common presenting complaint was itching (63.63%). The most common morphological varieties of the reactions were maculopapular rash (54.54%) followed by urticarial wheals (27.27%). Phenytoin was the commonest incriminated drug followed by Carbamezapine.

Conclusion

Physicians should consider efficacy,tolerability and safety of AEDs while prescribing it.Also it is important to keep in mind that adverse effects of AEDs may be experienced very differently by individual patients ranging from maculopapular rash to SJS,TEN(within 1 week of taking drug) and DRESS(2-6weeks after starting drug).It is for this reason that AED selection must be individualized and physicians should be well informed with common drug eruptions to diagnose them at the earliest, stop the offending drug and initiate the treatment at the earliest to prevent any grave consequences.

OP 4

Study of prescribed dose calculation in patients of paediatric age group.

Aakanksha B. Prajapati, Nikhil Kharod, Barna Ganguly
Department of Pharmacology, PSMC, Karamsad, Gujarat.

Background

Prescribed dose of drugs in paediatric age group is not extensively researched. Since weight based dosing is needed in paediatric age, prescribing medications involve precise calculations. Dosing calculation errors have potential to cause adverse drug reactions in the paediatric age group at higher rate than in adults, and these errors are preventable.

Objective

Aim of this study was to find out the appropriateness and accuracy of the dose of drugs prescribed and compare it with standard dose.

Materials and Method:

Total 400 prescriptions were collected in the study from the OPD of the paediatric department in Shree Krishna Hospital, Karamsad. Original prescriptions were used to analyze prescribed dose. Calculation of standard dose for each drug was done by using Clark's formula and was compared with the prescribed dose of that particular drug.

Results

Out of 400 patients 61% of the patients belonged to 2-11years of age group followed by 22.25% of 28days to 1 year of age group. Out of total 1042 prescribed drugs 59.12% drugs were prescribed by brand names and 40.87% by generic names. It was found that NSAIDS were prescribed in 31% of prescriptions, followed by antibiotics and antihistaminics each 22%. Among antibiotics statistically significant difference in the prescribed and standard total daily doses was observed with Cefexime[t-value 28.6>1.96 for 95% confidence interval] and Metronidazole [t-value2.03>1.96 for 95% confidence interval]. Same results were obtained with Paracetamol [t-value11.14>1.96 for 95% confidence interval], Phenylephrine[t-value7.1>1.96 for 95% confidence interval], Cetrizine [t-value2.4>2.00 for 95% confidence interval].

Conclusion

Results show that prescribed doses of commonly used drugs were higher than the standard dose. This is directly related to the occurrence and severity of adverse drug reactions.

Key words: prescribed drugs, dose and body weight.

OP 5

Why and how Unani System of Medicine Insisted upon Pharmacovigilance for each and every Drugs in the Light of Medical Ethics

***Abdul Latif, **S.Z.Rahman**
*Department of Ilmul Advia
**Department of Pharmacology Aligarh Muslim University, Aligarh-202 002 (U.P)

Since the time of immemorial, Unani System of Medicine through its contribution based on basic principles and methodologies provides beneficial effect with less harm on human body. Pharmacovigilance is inherently practiced and followed along with addition of experience of new indications in Unani formularies. Among all the system of medicines, Unani Medicine has still a very rich and effective method of drug preparation to combat side effects or harmful effect of drugs on human organs. And that is why it is popular as a 'safe medicine', having no or minimum side effects or harm to human in the light of medical ethics. This paper deals and elaborates in details all the methods including in vivo and vitro techniques being used in Unani system of medicine for vanishing their unwanted actions.

OP 6

Fixed Drug Reactions

Abhishek Pilani, Gopikrishnan A., Rita Vora
Department of dermatology, PSMC, Karamsad, Gujarat

Introduction

Fixed drug reaction is a distinctive type of adverse cutaneous reaction to an ingested drug that occurs in the same locations upon reexposure to the offending drug.Lesions of FDR usually presents with a single or a small number of dusky red or violaceous plaques typically seen within 30 mins to 8 hours after exposure which can be associated with pain,pruritus or burning leaving postinflammatory pigmentation.Rare severe variants includes multiple,nonpigmenting and generalized bullous variants. Common sites are perioral, periorbital, extremities, genitals and perianal areas.

Aim

1. To find out the incidence of fixed drug reactions at a rural based tertiary care centre
2. To find out the most common drugs responsible for the fixed drug reactions.

Methods

The prospective observational study was carried out in department of dermatology at Shri Krishna Hospital, Karamsad,Gujarat,India from April 2010 to March 2011 .Clinically diagnosed FDR during the period of one year were included in the study after ethical approval from HREC and taking patients' written consent.

Results

Total 100 cases of adverse cutaneous drug reaction were reported during period of 1 year. Out of which 23 (13 males and 10 females) were due to fixed drug reaction. 7 had more than 1 episode with the same offending drug . Diclofenac was the commonest incriminated drugs followed by Cotrimoxazole. Most common affected age group is 20-50yrs with most common presenting complaint was hyperpigmentation (52.17%).Genital lesions were present in (21.73%) and Oral lesions were seen in (8.6%).The morphology of lesions was patches in (60.86%) followed by bullous lesions in (21.73%).

Conclusion

Physicians are expected to be well informed with common drug eruptions to diagnose them at the earliest, stop the offending drug and initiate the treatment at the earliest with & also the patients should be counselled & educated regarding the importance of carrying the drug list.

OP 7

Development of Adverse Drug Reaction Reporting Culture in Second Professional Medical Undergraduates at a Tertiary Care Teaching Hospital: A Health Imperative

Aditi Chaturvedi, Deepak Parihar, Gitanjali Kothiyal, Rangeel Singh Raina, Priyanka Singh, Heenopama Thakur, Hemant Kumar Dutt

Department of Pharmacology, Vir Chandra Singh Garhwali Govt., Medical Science and Research Institute, Srikot-Srinagar, Pauri-Garhwal, Uttrakhand, India.

Aims & Objective

To sensitize second professional MBBS students for ADR reporting and consequentially assist clinicians in this practice. The study also aimed at assessing the knowledge, awareness and practice of Pharmacovigilance among the budding undergraduate doctors after sensitization.

Methods

'Sensitisation of Medical Under graduates for ADR Reporting' (SMUAR Model) was introduced for promoting ADR notification by clinicians. One year prospective study was carried out in a tertiary care hospital with the help of 2nd Prof MBBS students. The students were asked to collect ADRs from clinical departments. Students were assessed by a questionnaire designed by the Department of Pharmacology to assess their knowledge and attitude regarding the Pharmacovigilance Programme in India.

Results

72 ADRs were reported by batch 2010 students of our tertiary care teaching hospital from Medicine, Dermatology, Surgery, Obstetrics and Gynecology, Tuberculosis and Chest, Psychiatry, Pediatrics and Radiology Department. Maximum numbers of ADRs were reported by Medicine Department. Most of the reported ADRs were skin related (52%). Causality assessment by Naranjo's scale revealed that most of the ADRs belonged to "possible" 40(55.56%) category. Most of the ADRs (61.11%) were of Type A (Augmented / predictable). It was seen that the majority of the students gave right answers to the questions put up through a questionnaire on Pharmacovigilance designed by our department.

Conclusion

The 'SMUAR Model' used by medical undergraduates, assisted clinicians to report ADRs more effectively. The use of this model may strengthen the Pharmacovigilance Program in India by increasing the spontaneous reporting by clinicians and hence promote safe drug use for patients.

OP 8

Effect of Atenolol on Hemoglobin level in Mild to Moderate Hypertension.

Zala Ashishkumar C, Kantharia. N. D.
Department of Pharmacology, Government Medical College, Surat.

Aim & Objective

Hypertension is the most common cardiovascular disease and major cardiovascular risk factor that causes significant morbidity, mortality worldwide. Most common type is primary (essential) hypertension and is genetically determined. It affects many systems of the body and can also alters various haematological parameters. The aim of the study was to check the effect of atenolol on hemoglobin level in mild to moderate hypertension.

Material and Methods

Study was prospective andnon-randomised. Thirty (30)newly diagnosed hypertensives selected for atenolol therapy by medicine personnel were enrolled in the study based on inclusion and exclusion criteria. Patients were divided into pre-treatment (before starting atenolol therapy) and post treatment group based on therapy received. Red blood cell count, hemoglobin level, packed cell volume and red cell indices were measured at the time of enrolment and monthly after starting atenolol for next three months.

Results

Results were analysed by repeated measure analysis of variance (ANOVA).Atenolol treatment was found to increase hemoglobin level and packed cell volume significantly whereas no significant change in RBC count and red cell indices.

Conclusion

Treatment with atenolol for mild to moderate hypertension has shown significant increase in hemoglobin and PCV level. This positive effect may be because of decrease in sodium water reabsorption by decrease in sympathetic overactivity and excretion of sodium water by improvement in kidney functions.Atenolol has not any direct effect on Hb synthesis and erythropoiesis.

OP 9

Study of Adverse Drug Reaction in Patients Receiving Chemotherapy For Oral Cavity Squamous Cell Carcinoma in Radiotherapy Department Tertiary Care Teaching Hospital of Baroda

***Chirag B. Mistry,*Niyati A.*Trivedi,*J. D. Bhatt,**Vimal Batra**
*Department of Pharmacology, Medical College & SSG Hospital, Baroda
**Department of Radiotherapy, Medical College & SSG Hospital, Baroda

Objective

To evaluate impact adverse drug reaction of chemotherapy on treatment outcome, overall morbidity and mortality of oral cavity squamous cell carcinoma.

Methodology

In the present study we have evaluated the adverse drug reaction in all new cases of oral cavity squamous cell carcinoma diagnosed by histopathology report, who have received at least one cycle of chemotherapy at the radiotherapy department of SSG Hospital of Baroda. All the patients were followed up regularly till they completed the complete course of treatment of either chemotherapy and radiotherapy or chemotherapy alone. Total 61 patients were included in the study. Out of which 37 patients were able to complete their full course of chemotherapy. Five patients died during treatment period while 19 patients left the treatment in between.

Result

Carcinoma of anterior 2/3rd of tongue (25/61, 41%) was the most common site of oral cavity cancer. Out of 61 patients 27 patients were having TNM stage III carcinoma at the time of presentation. Patients experienced 25 different types of adverse drug reaction. Out of which fatigue, nausea and insomnia were most commonly (56/61, 91%) encountered adverse drug reactions. On investigation, it was found that (58/61) 95% patients developed anemia while 1 patients (1/61,2%) developed myelosuppression during treatment. Causality assessment was done as per WHO UMC causality assessment scale.

Conclusion

Despite of receiving various prophylactic and symptomatic treatments, incidence of adverse drug reactions are still very high among patients receiving chemotherapy for oral cavity squamous cell carcinoma which has significant negative influence on overall treatment outcome.

OP 10

A Study of Morbidity Pattern and Drug Utilization Pattern in Indoor Patients of High Risk Pregnancy at Tertiary Care Hospital

Darshan B Kharadi, Harsh M. Joshi, Kamlesh P. Patel, Varsha J. Patel
Department of Pharmacology, Smt. NHL Municipal Medical College, Ellisbridge, Ahmedabad.

Background

Pregnancy represents a special physiological state during which the use of drug is of growing concern due to risk of teratogenicity. High risk pregnancy is common threat to mother and fetus.

Objective

To study the drug utilization and morbidity pattern in women with high risk pregnancy at a tertiary care hospital.

Materials and Methods

An observational, prospective study was carried out in 250 patients for 6 months at a tertiary care hospital. The data were collected for demography, morbidity and complete drug therapy in a pre-designed proforma. Data were analyzed for morbidity pattern and prescribed pattern by using SPSS version 20.0 Software.

Results

Out of 250 patients, 218 (87.2%) were between 20 to 30 years of age. About (47%) women had anemia followed by pregnancy induced hypertension (PIH) (41.6%) and oligohydromnios (17.2%). Iron (91.2%) and calcium (84.5%) were the most frequently prescribed drugs. Nifedipine (28%) was preferred antihypertensive while isoxsuprine (26.6%) was used for pre-term labour. As per FDA Drug Risk Category, Category-A (82.2%) was most frequently prescribed followed by Category-B (15.6%) and Category-C (2.2%). Drugs prescribed by generic name and from essential drugs list were (62.8%) and (80.8%), respectively.

Conclusion

Iron and calcium were most commonly prescribed drugs. Nifedipine and isoxsuprine were preferred for PIH and pre-term labour, respectively. There is need for improving prescribing pattern by using generic names.

Key words

Anemia in pregnancy, Drug utilization, High Risk Pregnancy, PIH.

OP 11

A Comparative evaluation of different antidepressant drug in the treatment of major depressive illness

Patel DS, Solanki MN, Dikshit RK
Department of Pharmacology, B.J.Medical College, Ahmedabad

Objective

To compare efficacy and safety of various antidepressant drugs used in patients of major depressive illness.

Methods

Prior approval from the Institutional Ethics Committee, permission from Head of Psychiatry department and Medical superintendent, Civil hospital, Ahmedabad had taken. Investigator visited OPD and wards of psychiatry department thrice weekly. Patient who meets inclusion and exclusion criteria had been enrolled and evaluated for baseline score and at one month interval for next three visits using Hamilton depression rating scale (HMDRS) and montegmery and asberg depression rating scale (MADRS). Details of demographic characteristics, clinical examination and treatment and ADRs were recorded in predesigned CRF at each visit. The data was analyzed using paired t tests.

Result

Total 83 patients were enrolled and divided into four groups according to antidepressant drugs (fluoxetine, sertraline, amitryptiline, desvenlafexine).There was significant reduction in score
(HMDRS AND MADRS) between baseline and third follow up with
Fluoxetine (HMDRS - 29.4±2.3 to 9.5±1.1 = 19.9±2.5 ($p<0.001$), MADRS - 36.7±2.2 to 13.4±2.0 = 23.3±3.1 ($p<0.001$)),
For sertraline (HMDRS - 26.1±3.2 to 10.8±1.7 =15.4±2.4 ($p<0.001$), MADRS - 35.8±2.8 to 14.4±1.8 = 21.4±3.4 ($p<0.001$)),
For amitryptiline (HMDRS- 26.8±3.4 to 12.1±2.5 = 14.7±2.5 ($p<0.001$), MADRS - 36.3±2.9 to 15.8±2 = 20.5±3.0 ($p<0.001$)),
For desvenlafexine (HMDRS - 26.8±5.3 to 11.1±2.0 = 15.7±3.9 ($p<0.001$), MADRS - 35.8±3.5 to 14.4±2.0 = 21.4±3.4 ($p<0.001$))
However there was no significant difference in score reduction between four drug- groups. There was no serious ADR recorded.

Conclusion:

All four groups are equally efficacious and safe. Further study with larger sample size is advocated.

Key word:

Major depressive illness, HMDRS, MADRS

OP 12

Pattern of Adverse Drug Reaction in a Medicine Department of Tertiary Care Hospital

Agrawal JM, Trivedi HR, Singh AP, Patel NM, Vaniya HV
Department of Pharmacology, M. P. Shah Medical College Jamnagar-361008 (Gujarat).

Background

Adverse Drug reactions are considered as one among the leading causes of morbidity and mortality.

Aim

To characterize the pattern of ADRs reported in a tertiary care hospital (Guru Gobind Singh Hospital, Jamnagar, Gujarat) over the period of 3 years.

Materials and methods

ADRs among indoor patients which were documented by physicians were collected daily by us. ADRs were evaluated to understand the pattern of the ADRs with respect to patient demographics, nature of the reactions; characteristics of the drugs involved, causality, preventability for the reaction were analyzed.

Results

The overall incidence of ADR calculated from the patient population was (0.5%). Upon evaluation of the patient characteristics, majority of ADR were in males (57.75%). Type A reactions (83.62%) accounted for majority of the reports than type B (16.38%). Gastrointestinal system (49.56%) was the most commonly involved SOC (System organ class).Antimicrobial agents (57.75%) were the drug class most commonly involved. Upon causality assessment, majority of the reports were rated as probable (69.39%). In (6.03%) of the reports the reaction was considered to be preventable.

Conclusion

Studies like ours enables in obtaining information on the incidence and pattern of ADRs in the local population. Such reporting programs are necessary to increase awareness about reporting of ADRs among the healthcare professionals. Early detection of drug toxicity helps to treat the patient and modify the doses or the drug regimen to minimize toxic effects.

Key words

Adverse Drug Reactions, Pattern of ADR, Pharmacovigilance, ADR monitoring.

OP 13

Assessment of adverse drug reaction forms submitted by medical students as a part of their practical training in Pharmacovigilance

Komal V Gaur, Bharat M Gajjar
Department of Pharmacology, PSMC, Karamsad, Gujarat

Objective

To evaluate the adverse drug reaction forms filled by 2nd MBBS students as a part of their practical training in Pharmacovigilance.

Method

The 2nd MBBS students of PS Medical College were taught about pharmacovigilance as a part of practical module in two classes. They were given the task of monitoring and reporting adverse drug reactions in Shri Krishna Hospital. The reported adverse drug reaction forms were evaluated qualitatively to assess how sincerely the students have completed the exercise.

Results

Total 112 reports were submitted by students against the expectation of 210(53.33%). The demographic details of the patient were mentioned in 111 forms out of 112(99.1%). The details of the suspected reaction were adequately mentioned in only 16 forms (14.28%). 21 forms (18.75%) were filled adequately in terms of details of suspected medication.

Conclusion

Even though the incentive in terms of marks which would be considered in their internal marking, students are not sincere in reporting and submitting adverse drug reaction forms. The continuous reinforcement is necessary to make students aware about pharmacovigilance exercise during their study period and future also.

Key words

Pharmacovigilance, Adverse drug reaction forms, Undergraduate teaching

OP 14

Case Report : Augmentin induced Anaphylaxis

Darji NH, Trivedi HR, Jadav SP, Singh AP, Mistry RA
Department of Pharmacology, M. P. Shah Medical College, Jamnagar (Gujarat)

Augmentin is a combination antibiotic consisting of amoxicillin trihydrate, a B-lactam antibiotic (Extended spectrum Aminopenicillin) and potassium clavulanate, a B-lactamase inhibitor. This combination results in an antibiotic with an increased spectrum [like B. catarrhalis, H. influenzae, N. gonorrhoeae, and S. aureus (not MRSA)] and restored efficacy against amoxicillin-resistant bacteria that produce B-lactamase. Anaphylaxis is defined as "a serious allergic reaction that is rapid in onset and may cause death". About 0.001% of patients treated with these agents die from anaphylaxis(GG). Here we note the case of 10 years old female child with complain of left sided neck swelling and she was given ampicillin & cloxacillin intravenously for 2 days initially in ENT ward, on 3rd day as patient was given augmentin (amoxy-clav), she developed anaphylaxasis in form of respiratory and cardiac arrest. so diagnosis of Augmentin induced anaphylaxasis was based on history and clinical findings. As per causality assessment by Naranjo it falls in "Probable" & severity scale (Hartwig & seigel) it falls in "severe" category.

Keywords

Augmentin, Anaphylaxasis, Neck swelling

OP 15

A Survey on Knowledge and Perception of Pharmacy Students of Anand District Towards Pharmacovigilance and Adverse Drug Reaction Reporting

Nitin Kothari, Nazima Mirza
Department of Pharmacology, PSMC, Karamsad, Gujarat

Objective

To evaluate the knowledge and perception about pharmacovigilance and ADR reporting among pharmacy students.

Method: A cross sectional study was conducted in the month of August 2013 using questionnaire form given to B. Pharmacy students of Vth semester onwards including five different pharmacy colleges of Anand district. Before starting the study, approval from institutional ethics committee was taken. Participants were explained properly about the study and confidentiality was maintained at all levels.

Results

A total of 300 filled forms were collected from the participants. Out of these 142 (47.33%) were from Vth semester, remaining were from VIIth semester. One hundred and thirty six students (45.33%) were aware of pharmacovigilance. One hundred and twenty four students (41.33%) replied that pharmacist are qualified to report ADRs. One hundred seventy six students (58.8%) replied that all types of ADRs should be reported . Two hundred and four students (68%) advocated compulsory ADR reporting. Two hundred and eighty six students (95.33%) said that ADR reporting is either very important or important. Only 58 students (19.33%) knew about national pharmacovigilance programme run by Government of India.

Conclusion

The knowledge about pharmacovigilance and ADR reporting is found quite low among pharmacy students in our study. Pharmacists can play a crucial role in both ADR reporting and pharmacovigilance activities. So, they need to be well trained on how to recognize, prevent, and report ADR as they are future pharmacy practitioners .

OP 16

Study of adverse drug events of antiepileptic drugs in a tertiary care teaching rural hospital

**Pragna Patel, **Bharat Gajjar
*Medical Advisor, Intas Pharmaceuticals Ltd, Ahmedabad
**Associate Professor, PSMC, Karamsad, Gujarat

Objective

To study adverse effects of antiepileptic drugs in a tertiary care teaching rural hospital.

Methodology

All the patients who prescribed antiepileptic drugs (AEDs) by treating physician from the outpatient departments of pediatric epilepsy clinic, neuromedicine, and neurosurgery of Shree Krishna Hospital were enrolled in the study irrespective of their diagnosis. Written informed consent of patients was taken. The data were collected and entered in 'Case Record Form'. All enrolled patients were followed up for six months to monitor occurrence of adverse events.

Results

Total 160 patients were enrolled in the study period (February 2010 to October 2011). Total 112 ADEs were reported from 58 (36.25%) patients in six months follow up with average of 1.92 events per patient. Central nervous system was most frequently affected with 68 (60.71%) ADEs, followed by gastrointestinal system (68,60.71%). Phenyoin was most commonly suspected drug (with 39 cases) followed by carbamazepine (in 23 cases). Causality assessment by WHO-UMC criteria, most common association was possible in 75 (66.96%) cases, probable 21 (18.75%), certain 6 (5.36%) and conditional/unclassified 10 (8.93%). Similar results were obtained by Naranjo's criteria. Ninety one (80.36%) ADEs were not preventable as per modified Schumock and Thornton scale. Severity assessment by Hartwing's criteria showed 79 (70.53%) ADEs as mild. Number of antiepileptic drugs given per patient and DDD per patient had statistical co-relation with ADEs; but age, sex, number of co-morbid conditions, number of concomitant drugs did not have statistical co-relation.

Conclusion

High occurrence of ADEs with AEDs use, in relation with DDD of drug is observed in the study.

OP 17

Prescribing Pattern and Adherence to Treatment Guidelines in Osteoporotic Patients Attending Orthopedic Outpatient Department of a Tertiary Care Teaching Hospital

Rohan P Christian, Hemalata S Ninama, Devang A Rana, Supriya D malhotra, Varsha J Patel
Department of Pharmacology, Smt. NHL Municipal Medical College, Ellis Bridge, Ahmedabad, Gujarat.

Introduction

Osteoporosis is the fourth most common disease in aged adults. In India, due to lack of adequate information and guidelines for treatment of osteoporosis there is a need to generate baseline data on the pattern of use of drugs for treatment of osteoporosis.

Objective

To analyze prescribing pattern and adherence to treatment guidelines in osteoporotic patients attending orthopedic outpatient department.

Materials and methods

A prospective, cross sectional, study carried out in orthopedic OPD over a period of 12 months. Demographic and clinical data as well as complete prescription was recorded on the case record form. Data was analyzed for prescribing pattern, mean cost of drug therapy per day and extent of adherence to National Osteoporosis Foundation (NOF) guideline, Scottish Intercollegiate Guidelines Network (SIGN) and National Institute for health and clinical excellence (NICE) guideline.

Result

Total 200 patients were enrolled with mean age 57.14±9.84 years. Mean drugs prescribed was 5±1.4 (Range 2-8). NSAIDs (24.3%) were the most commonly prescribed drug group. Commonly prescribed drugs were combination of paracetamol and tramadol (49.1%) and etoricoxib (38.4%). Mean total cost of drugs per day was INR 41.24±16.66. About 55% drugs were from National essential medicine list, fixed dose combinations were 16.47 % and 9.41 % drugs were prescribed from hospital pharmacy. About 82% of the prescriptions followed NOF guidelines which prefer ibandronate over other bisphosphonates. About 50% prescriptions adhered to SIGN and NICE guidelines.

Conclusion

NSAIDs was the most frequently prescribed drug group. Majority prescriptions followed NOF guidelines.

Key Words

Adherence, Drug utilization, Osteoporosis, Standard treatment guidelines

OP 18

Knowledge, Attitude and Practice regarding Adverse Drug reaction reporting & Monitoring amongst Physicians in a Tertiary Care Teaching Hospital, Ahmedabad

Prajapati RR, Dumatar CB, Dikshit RK
Department of pharmacology, B.J.Medical College, Ahmedabad

Objective

To assess the knowledge, attitude and practice of physicians regarding pharmacovigilance and spontaneous reporting of ADR. To identify the reasons for under-reporting. To suggest methods for improvement in the current spontaneous ADR reporting system.

Methods

This was a questionnaire based study involving physicians, who were surveyed with a questionnaire. The study was conducted in Civil Hospital Ahmedabad. We visited the physicians personally, distributed the questionnaire and collected the duly filled questionnaire on same day. A questionnaire containing 14 questions was prepared. The remaining questions were designed to evaluate knowledge (5 questions), to assess their attitude (4 questions) and to judge their practice (5 questions) regarding pharmacovigilance and ADR reporting.

Results

Total 230 physicians were given questionnaire, among them 207 physicians filled questionnaire, giving response rate of 90%. 83.1% physicians were aware about term "Pharmacovigilance". 47.8% physicians were aware how to report ADRs. Only 11.1% physicians said all ADRs should be reported while 55.5% physicians said only serious ADRs should be reported. 44.4% physicians were aware about existing setup of ADR reporting in this hospital, 34.7% physicians were aware about CDSCO form program. Majority physicians (89.8%) considered ADR monitoring should be made mandatory to doctors. Major reasons for not reporting ADR were-lack of availability of ADR form (57.9%), lack of time (71.9%), doubtful diagnosis of ADR (30.4%), legal liability issues (32.3%). Majority of physicians reported that they informed their patients about the possible side effects of the prescribed drug and thereafter notice ADRs in patients (88.8%). 94.6% physicians asked and took feedback from patient after treatment. 56% physicians did not fill any ADR form during last 1 year.

Conclusion

Despite good observation and knowledge of ADR among doctors, the rate of reporting was low. Active participation of physicians is a key to enhance spontaneous reporting. To change the attitude and to improve participation of physicians in ADR reporting measures like awareness programs and CMEs regarding ADR are required.

OP 19

An overview of the various regimens of Rituximab in Thrombotic Thrombocytopenic Purpura (TTP).

Bhat S P, Rahman S Z
Department of Pharmacology, Jawaharlal Nehru Medical College, A.M.U., Aligarh, U.P.

Objective

To study the use of Rituximab under various regimens followed in the treatment of TTP and to highlight its significance.

Methods

An extensive literature search was done through PubMed (Medline) on the use of Rituximab in TTP. A list of all case reports with various treatment regimens was prepared in a tabular form and compared. All clinical cases were followed to whom the drug was administered with other interventional procedures such as splenectomy & co-administration of immunomodulatory agents.

Observation

On comparing the 26 case reports (8 male, 18 female) aged between 21-62 years, it was noted in all regimens, that the use of Rituximab (375mg/m^2 weekly) was especially helpful in refractory cases of acquired TTP. The patients treated with rituximab for 8 weeks showed longer periods of remission. It also led to a decrease in the ADAMTS13 auto-antibodies, lesser relapses and reduction in the frequency of plasma exchanges. Splenectomy could also be avoided in certain cases where Rituximab was given early.

Conclusion

Rituximab proved more beneficial in terms of faster attainment of remission, fewer plasma exchanges, shorter hospital stay and normalisation of ADAMTS13 levels if administered as early as an episode of relapse was diagnosed by monitoring of ADAMTS13 activity level. A consensus among physicians must be reached regarding its optimal use in the treatment of TTP. Large clinical studies are required to determine the same.

OP 20

Correlation between various Adverse Drug Reactions Causality Assessment Scales and their Agreement in Pediatric Population

Sunil N Bhadiyadara, Harsh J. Shah, Devang A Rana, Supriya D Malhotra, Varsha J Patel
Department of Pharmacology, Smt. NHL Municipal Medical College, Ellis bridge, Ahmedabad

Introduction

Different causality assement scales use different definitions to classify adverse drug reactions (ADRs). Reliability and usefulness of various scales for causality assessment in pediatric population have not been fully explored.

Objective

The goal of this study was to examine correlation between various causality assessments scales and their agreement in reporting ADRs in children.

Methods

All hospitalized pediatric patients were followed up for adverse drug reaction in a single pediatric unit for one year. We compared the WHO, Naranjo, CIOMS/RUCAM and French causality assessment scales in 36 identified ADRs in pediatric ward during 2012. The agreement between obtained causality assessments were analyzed by Cohen's Kappa (K) statistical test.

Results

In the 290 pediatric patients, 36 adverse drug reactions were noted. Prevalence of ADR was 10.3%. Maculopapular rash was most frequently observed ADR. Antimicrobials (56%) were the most commonly involved drug group in ADR and cephalosporins being the most frequent cause for ADR. RUCAM and French scale showed better agreement (K: 0.067) with each other as compared to other scales. WHO and French scale showed least agreement (K: -0.026) with each other as compared to other scales. Naranjo's scale showed poor agreement (K: 0.014) with WHO scale and worse agreement (K: -0.016) with French scale. There was no correlation between RUCAM and Naranjo's scale.

Conclusion

Full agreement was not found between any of two scales of causality assessment. There was discrepancy seen between scales due to different definitions of causality criterias for assessing adverse drug reactions. This can influence the outcome of causality assessment significantly.

Key-words

ADR, Causality scales, Children, Correlation

OP 21

Drug Utilization Pattern of Antiepileptic Drugs and their Adverse Effects in Paediatric Population, in a Tertiary Care Hospital Attached to a Medical College

Kumari VM, Mistry RA, Singh AP, Trivedi HR
Department of pharmacology, M.P.Shah Medical College, Jamnagar (Gujarat)

Introduction

Epilepsy is the most common neurological disorder in children, is characterized by a spontaneous propensity for recurrent and unprovoked seizures. Highest incidence is seen in children below 3 years of age.

Objective

To study the utilization pattern of antiepileptic drugs (AEDs) in pediatric patients suffering from epilepsy and adverse drug reactions associated with use of AEDs

Material & Methods

This Cross sectional, prospective, observational and single centre study was carried out in epilepsy clinic of tertiary care hospital over a period of 1 year on 430 pediatric patients. Data collected of epileptic patients included patients demographic details and drugs prescribed in respective seizure types along with ADRs due to AEDs.

Results

In a total 430 patients analyzed seizures were most commonly observed in boys (69.8%) in 6-10 yrs of age(45.3%), with positive family history in 16%,with no specific cause of epilepsy in(71.6%), with most common type was focal seizure in(62.3%) ,which was treated with carbamazepine in(73.8%) followed by generalized seizure in (8.8%),that was treated with valproate in (89.5%). Most common ADR was irritability (32.2%) mainly due to valproate.87.3 % ADR were in " possible" as per WHO causality assessment scale, 94.9% ADR were "mild" as per Hartwig and Seigel severity assessment scale and 98.3% ADR were "preventable" as per Schumock and Thornton preventability Scale.

Conclusion

Focal seizures were most common type of seizure observed mainly in boys of 6-10 yrs with carbamazepine mainly prescribed drug .

Key Words

Epilepsy , drug utilization pattern , ADR

OP 22

"A Prospective analysis of Adverse Drug Reactions reported in C.U.Shah Medical College, Surendranagar."

Vasani PR, Bhatt PN, Solanki SN, Savsani DD, Mehta DS.
Department of Pharmacology, C.U.Shah Medical College,Surendranagar. Dept. of Pharmacology and clinical departments

Objectives

To estimate the burden of adverse drug reactions (ADRs) in C.U.Shah Medical College and Hospital, Surendranagar and to assess the severity and causality of reported ADRs. To identify the most common group of drugs contributing to ADRs.

Methodology

Spontaneous reporting was done in outpatient and inpatient departments of hospital for a period of 7 months from January 2013 to July 2013. Collected data was analyzed using WHO-UMC causality assessment scale. Noted ADRs were also classified in to its severity scale and types of reaction according to wills and brown.

Results

Of the Total 64 ADRs reported, majority were classified as possible (26,40.62%) followed by probable (22,34.37%) ,and about two thirds of the reactions (42,65.62%) were moderate in severity according to WHO-UMC causality assessment scale. Most common group of drugs responsible for ADRs were Antipsychotics (22, 34.37%) followed by Antimicrobials (19, 29.68%).The majority of the reactions were of type B (44, 68.75%). When we analyzed the systems affected, moderate to severe skin reactions were more common in our study.

Conclusion

There is a need for vigilant ADR monitoring to be done by all paramedical staff. Active surveillance can increase ADR reporting and hence ultimately increase patients' safety.

OP 23

Adverse Cutaneous Drug Reactions due to Antimicrobials at a Tertiary Based Rural centre

Nidhi Patel, Gopikrishnan A., Rita Vora

Introduction

ACDRs (Adverse cutaneous Drug Reactions), major problems in drug therapy, are a few of the leading causes of morbidity and mortality in health care and they should be considered in the differential diagnosis of a wide variety of medical disorders. Only approximately 2% of adverse cutaneous reactions are severe and very few are fatal.

Aim

1. To find out the incidence of drug reactions due to antimicrobials at a rural based tertiary care centre.
2. To find out the various clinical patterns of drug reactions due to antimicrobials
3. To find out the most common antimicrobial drugs responsible for the drug reactions.

Methods

The prospective observational study was carried out from April 2010 to March 2011 in the Dermatology department SKH hospital in all patients irrespective of age and sex suspected of having drug reactions, after ethical approval from HREC and taking patients written consent.

Results

Out of total 54 cases (27 males and 27 females), most common affected age group is 21-55yrs. Anti tubercular drugs were the commonest incriminated drugs followed by Cotrimoxazole and Ciprofloxacin.Most common presenting complaint was itching (33.33%). The most common morphological varieties of the reactions were maculopapular rash (25.92%), urticarial wheals (22.22%) , fixed drug eruptions (18.51%) and acneform eruptions(12.96%).

Conclusion

Physicians are expected to be well informed with common drug eruptions to diagnose them at the earliest, stop the offending drug and initiate the treatment at the earliest to avoid fatal outcome & also the patients should be counseled & educated regarding the importance of carrying the drug list.

OP 24

Study of Prescription Audit Pattern in the Inpatients of a Tertiary Care Hospital

Hedamba R H, Mistry R A, Darji N H,Trivedi H R
Department of Pharmacology, M P Shah Medical College, Jamnagar.

Background

Prescription audit is one of the methods to assess drug utilization and rationality of prescribing. Irrational prescribing is a worldwide problem. It is due to the faulty prescribing habits, lack of training amongst health care personnel, pressure from the pharmaceutical companies, and a lot of other reasons.

Methods

This prospective, observational and single centre study was carried out over a period of 6 months (year 2013) in the tertiary care hospital. Prescriptions were collected from the inpatients of medicine, surgery, ENT, pediatrics, orthopaedics randomly and analyzed for patients demographic details and drugs prescribed.

Results

122 prescriptions were analyzed in which 703 drugs were prescribed. Mean number of drugs per prescription was 5.76. Drugs were prescribed by generic names in 64.86%, 69.51% were from essential drug Gujarat state list. Dosage forms used were mostly oral (62.30%). Infectious diseases (31.96%)were the most common illnesses followed by diseases of cardio vascular system. The most common drug groups prescribed were antimicrobials(22.33%), followed by cardiovasculardrugs, antacids, NSAIDS, multivitamins, antiemetics etc. The incidence of poly-pharmacy was also common with maximum number of drugs which were prescribed per prescription were five in 24.59% of prescriptions.

Conclusions

Prescription audit is an important measure to improve the quality of care afforded by the hospitals. Data generated on morbidity pattern coupled with current practices of treatment of these diseases provides an objective basis for preparing NLEM and Gujarat state essential drug list. By this data we concluded that poly-pharmacy was quite common. Most of drugs prescribed were according to the essential drug list Gujarat state 2011.and were by generic names

Keywords

Prescription audit, Morbidity pattern, Drug utilization pattern, Rational pharmacotherapy.

OP 25

An Analysis of Drug Promotional Literature Using World Health Organization (WHO) Guidelines

Jadav SS, Dumatar CB, Dikshit RK
Department of Pharmacology, B. J. Medical College, Civil Hospital, Ahmedabad

Objective

This study was aimed to evaluate the drug promotional literature (DPL) as per World Health Organization (WHO) criteria and also to evaluate claims, references and pictures presented in DPLs.

Methods

This was an observational, cross-sectional study conducted at the outpatient department of Civil Hospital, Ahmedabad, a tertiary care teaching hospital for period of 2 months. Printed drug promotional literatures for modern drugs were collected and examined for the fulfillment of WHO criteria and also for the claims, references and pictures presented in DPLs for their type and authenticity.

Results

WHO guidelines were not followed in any of the 200 DPLs. Out of 299 claims, most commonly presented claim in 192 DPLs was efficacy (45.15%) followed by pharmaceutical properties (26.75%). 130 (65%) DPLs did not provide any references to support claims while only 70 (35%) DPLs provided references. Most commonly used reference was journal articles 66 (88%) followed by websites 5 (6.66%). Most common type of journal article reference was research article 53 (85.48%) followed by review article 7 (11.29%). 125 (78.61%) DPLs presented with irrelevant pictures while only 25 (15.72%) DPLs presented appropriate pictures and 9 (5.66%) DPLs were with mixed pictures presentation. Information on adverse drug reactions, contraindications and drug interaction was missing in most of DPLs.

Conclusion

None of the promotional literatures contained all of the information recommended by the WHO's guideline for medicinal drug promotion. They were lacking with scientific and critical information.

OP 26

Study of Antimicrobial resistance pattern of uropathogenic Escherichia coli at a tertiary care hospital for a period of three years.

Anturlikar S., Trivedi N.A., Bhatt J.D.
Department of Pharmacology, Medical College, Baroda.

Objective

To analyse the antimicrobial sensitivity and resistance pattern of E.coli isolates at a tertiary care hospital.

Materials and method

Culture sensitivity reports of all urine samples sent to Microbiology Department of SSG Hospital, Baroda during the period of July 2010- June 2013 were screened. Detailed reports were collected for all the samples where E.coli was identified as the causative organism. Culture sensitivity testing for all the reports was done by modified Kirby-Bauer disk diffusion (high media) method. ATCC 25922 and ATCC 35218 were used as standard strains of E.coli.

Result

E.coli was isolated in total 1132 urine samples during the period of three years. Majority of patients belonged to paediatric age group (72.33%). Total 29 antimicrobial agents were tested for their sensitivity towards E.coli. Antimicrobial resistance ranging from 14%-100% was noted among various antimicrobials. High resistance by E.coli isolates was observed for cefepime (90.90%), netilmicin (82.55%) and nalidixic acid (78.08%) while E.coli isolates showed highest sensitivity towards gatifloxacin (85.42%) followed by amikacin (72.84%).

Conclusion

The incidence of the multidrug resistant strains of E.coli has been steadily increasing over the past few years. The knowledge on the resistance pattern of the bacterial strains in a geographical area will help in guiding the appropriate and the judicious use of antibiotics.

OP 27

Monitoring of Adverse Drug Reaction with Special Reference to Detoxification of Unani Drugs

**Abdur Rauf , **Abdul Latif

*Assistant Professor, Department of Ilmul Advia, Faculty of Unani Medicine, Aligarh Muslim University, Aligarh, India

**Associate Professor, Department of Ilmul Advia, Faculty of Unani Medicine, Aligarh Muslim University, Aligarh, India

Unani Medicine is based on Greek philosophy which believes in the humoural theory that presupposes the presence of four Akhlat (Humuors), having different Mizaj (Temperament). It is holistic approach to the healing of disease that believes in restoring balance to the physical, mental, emotional and spiritual aspects of man, using lifestyle modification, diet and medicine to have an effect on cure. The adverse reaction to the ingestion of certain drugs have been known since ancient times and wide spectrum of diseases involving virtually every system in the body have been ascribed to certain drugs. To protect from the undesirable effects Unani physicians had suggested proper reasoning in the method of preparation of drugs, including a rationale combination of various ingredients, method of administration, various preservatives, indications and contraindications in different situations and adverse drug effect profile such as adverse drug-drug or food-drug interaction. Moreover Muslehat (Correctives) to the drugs had also been used since a long time to minimize the unwanted effects of drugs and the processes of Tadabeer (Detoxification) were employed to reduce the adverse drug reaction in Unani Medicine. The details would be discussed in the paper.

OP 28

Age associated adverse effect of antipsychotic drug (Lithium) in rat central nervous system

*Sandeep Tripathi, *Manisha Chaudhary, *Sudhanshu Mishra, *Dushyant Singh Chauhan, **Renu Sharma, ***Ayaz Ahmad

*Departments of Advanced Sciences & Biotechnology

**Applied Sciences, Nims Institute of Engineering & Technology,

***Nims Institute of Pharmacy, NIMS University, Rajasthan, Jaipur India

Introduction

It is represented the severe lithium neurotoxicity, which may occur during chronic therapy as a result of increased lithium retention, can include encephalopathy characterized by disorientation, incoherence, paralysis, stupor, seizure, and coma. Permanent brain damage occurred in several patients on prolonged lithium therapy.

Objective

The aim of the present study was to evaluate the Li induced cerebellar changes in the rat brain in terms of behavioral, biochemical and morphological changes.

Methods

In the present study, 100mg/kg body weight of lithium chloride was administered to young (6m) and old (12m) male albino rats for 14 days. Spontaneous motor activity (SMA), catalepsy, gait and muscle in- coordination was tested after the experimental period. Cerebellum was removed for biochemical and morphological studies. The oxidative stress (OxS) markers namely Lipid peroxide levels, super oxide dismutase and catalase were estimated.

Results

Treatment with lithium in rats selectively altered behavioural responses. Increased SMA and decreased catalepsy, gait and rota rod were found. Moreover, alteration in SOD, CAT, GPX and GSH and increased LPO and Protein carbonylation in the cerebellum was observed. The histological changes were exhibited damaged purkinje neuron as well as dilatation occurred in the Li treated rats. Ultrastructural studies revealed that the changes were more pronounced in the aged treated rats in terms of presence of clustered lipofuscin, vacuolization, lysosomal degradation and nucleolar fragmentation.

Conclusion

Overall, the present findings indicate that excess lithium may delineate cellular changes in the cerebellum in rats supporting its neurotoxicity profile in bipolar disorder (BD) and, possibly, in neurodegenerative processes these changes may be responsible for the development of age related disorders.

Poster Presentations

List of Abstracts for Poster Presentation			
1	Adenosine and Inosine produce sedation in Rats.	Singh J, Mishra A	draadeshmishra @gmail.com
2	An educational intervention to assess the awareness of pharmacovigilance among nursing students in puducherry	Amarnath S, Sharma Arun, Jaikumar S, Basalingappa S, Ramaswamy S, Thulasimani M.	amarnathsugumaran @yahoo.co.in
3	Reporting of adverse drug reactions by 2nd year medical students in tertiary care teaching hospital	Komal V Gaur, Alpa P Gor	komalvg @charutarhealth.org
4	Survey based study to evaluate pharmacovigilance awareness among medical students in a medical college in south india	Sharma Arun , Amarnath S , Jaikumar S , Basalingappa S , Ramaswamy S , Thulasimani M	coolarun86 @gmail.com
5	An update on growth and development of telemedicine with pharmacological implications.	Devang Parikh, Bhagya Sattigeri, Ashok Kumar	dr.dp @in.com
6	Risk management and ADR	Ketan Khelwade	ketankhelwade@ gmail.com
7	Pharmacovigilance: Present Scenario And Future Prospect	Kirti V. Patel	-
8	Impingement of promotional drug literature of prescription drugs in pharmacovigilance	Krunal Dalal, Bharat Gajjar	dalalkrunal @yahoo.co.in
9	Nevirapine induced dress	Nilofar Diwan, Rita Vora	nilofergd @charutarhealth.org
10	A critical appraisal of pharmacogenomics in relation to adr monitoring	Sanjog N. Tewari , S.Z. Rahman	sanjogtewari @gmail.com
11	Safety issues related to over the counter drugs	Urvi Kumbhani, Bharat Gajjar	dr.urvi.kumbhani @gmail.com
12	Study of Knowledge, Attitude and Practice of Self-Medication in Third Year MBBS Students, in Pramukh Swami Medical College Karamsad	Dr. Anuradha Joshi, Nitesh Sidhwani, Krunal Dalal, Urvi Kumbhani	dalalkrunal @yahoo.co.in
13	The possible role of Ethosuxamide in neuropathic Pain management	Vijyandra Gautam	drgautam5577 @gmail.com
14	Fluconazole induced fixed drug eruption	Malay Mehta Rita Vora	malayjm @charutarhealth.org
15	Pattern of Adverse Drug Reactions Due to Cancer Chemotherapy in Tertiary Care Hospital	Doshi Chintan, Singh Anil. Trivedi H. R . Shilpa Jadav , Parmar Dinesh M	doshichintan2 @gmail.com
16	A prospective survey study to evaluate rationality and adverse effects on the use of analgesic and antiulcer agents among the students and staff members of medical college.	Ashok Kumar, B. M. Sattigeri, Devang Parikh, Shruti Bhrahmbhatt, Heena Shah	dr.ashok1283 @gmail.com
17	Pharmacoenvironmentology and environmental risk current status	Ajay Gupta, P. P. Singh, S. Z. Rahman	dr.ajaygupta24 @gmail.com
18	Foreign Direct Investment (FDI) in Pharmaceutical Retailing a Bane or Boon for Pharmacy Profession!	Sudarshan Singh, Dr. Shyale SS Govind Mohan	sudarshansingh83 @hotmail.com

List of Abstracts for Poster Presentation			
19	Pharmacovigilance: Information System	Ms. Priyanka Sharma	pr.sh2011 @gmail.com
20	Docohexanoic acid prevents adverse effect of aluminium during dialysis dementia in rat model study	Manisha Chaudhary	manisha. chaudhary890@ gmail.com
21	Fluoride reduces semen quality at risk level	Dushyant Singh Chauhan	dschauhan07 @gmail.com
22	In vitro effect of Emblica officinalis on sodium seleniate induced cataract in isolated goat eyes	Sudhanshu Mishra	Sudhanshumishra @gmail.com

PP 1

Adenosine And Inosine Produce Sedation In Rats.

Singh L, Mishra A
Department of Pharmacology, PGIMS Rohtak

Objective

To study the effect of adenosine & inosine in pentobarbitone induced sleeping time in rats.

Methods

Potentiation of pentobarbitone induced sleeping time was studied in rats. Albino rats of either sex weighing 140-150 gm were divided into 3 groups each. Group I – control (Pentobarbitone 30 mg/kg, ip). In group II & III adenosine & inosine (100mg/kg, ip) respectively were given along with pentobarbitone. Time of onset of hypnosis was recorded as the time required for loss of righting reflex. In another series of experiments effects of adenosine & inosine (15 nmol/rat) were studied on sleeping time after intracisternal injections. Results were analyzed statistically.

Results

Adenosine & Inosine IP as well as intracisternally potentiated Pentobarbitone induced sleeping time in rats. This effect was highly significant when both drugs were given by ic route. Adenosine was more potent than inosine.

Conclusion

Adenosine and Inosine induces sedation in rats.

PP 2

An Educational Intervention to Assess the Awareness of Pharmacovigilance among Nursing Students in Puducherry

Amarnath S, Sharma Arun, Jaikumar S, Basalingappa S, Ramaswamy S, Thulasimani M.
Department of Pharmacology, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry.

Aim

To assess the basic awareness of pharmacovigilance among the nursing students and to evaluate the impact of an educational intervention on the same.

Methods

A survey with self administered and validated questionnaire containing Basic concepts, Reporting, Documentation and Conclusion (BRDC) was designed and administered to nursing students of RAAK nursing college, Puducherry. A total of 110 nursing students participated in the pre and post BRDC survey (54 students from II year and 56 students from III year). Following pre-BRDC survey, an educational intervention in form of an interactive power point lecture was designed for all the participants. The effectiveness was evaluated in a post-BRDC survey.

Results

The data collected from II and III yr students were almost similar. Combined analysis revealed that the test population had knowledge to the extent of 32.71 % as a whole. Sectional analysis indicated knowledge to an extent of 16.40% in documentation when compared to a percentage of 38.63 % in basic concepts, 39.13 % in reporting, and 45.97 % in conclusion. Educational intervention improved their performance as observed by 65.44 % as a whole, while 74.98 % in reporting, their knowledge in basic concepts also improved to an extent of 59.49 %. A much better percentage of 64.46 % in documentation and 57.79 % in conclusion were obtained. Nursing personnel administer drugs to the patients and hence play an important role in pharmacovigilance. Training the nursing students will augment the possibility of reporting after they graduate.

Conclusion

Organizing regular educational interventional program for nursing students is considered mandatory.

PP 3

Reporting of adverse drug reactions by 2nd year medical students in tertiary care teaching hospital

Komal V Gaur, Alpa P Gor

Department of Pharmacology, PSMC, Karamsad, Gujarat

Objective

To evaluate the adverse drug reaction forms collected by the 2nd MBBS students as a part of their practical training in pharmacovigilance

Methods

The 2nd MBBS students of PS Medical College were taught about pharmacovigilance as part of practical module in two classes. They were given the task of collecting information of adverse drug reactions. The collected forms were evaluated for the adverse drug reactions in detail (i.e. demographic data, system involved, drug groups, and causality assessment.) Causality assessment was done according to WHO criteria and Naranjo scale.

Results

Out of 105 students, 62 ADR forms were reported. Maximum ADRs were recorded in age group 19-60 years, with majority in males (54.83%). Most common systems involved in ADRs were GIT (35.48%) followed by Skin (24.19%). The drug group most commonly causing ADR was antimicrobials (38.70%). According to WHO causality assessment majority ADRs were classified as probable (51.61%) and according to Naranjo score majority were classified as possible (91.93%).

Conclusion

Practice of empirical antimicrobial therapy needs to be checked as these drugs cause most ADRs. Teaching pharmacovigilance to medical students and giving activity makes them aware of their responsibility to report ADR. Still reinforcement is required to develop a culture of spontaneous reporting among students.

Key Words

Teaching, Pharmacovigilance

PP 4

Survey based study to evaluate Pharmacovigilance awareness among medical students in a medical college in South India

Sharma Arun , Amarnath S , Jaikumar S , Basalingappa S , Ramaswamy S , Thulasimani M
Department of Pharmacology, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry

Aim

To assess the awareness regarding pharmacovigilance among second year medical students in a medical college in Puducherry, India.

Materials

A suitable , validated , cross-sectional questionnaire ; which was divided into five sections (Definitions , Reporting , Analysis , Documentation , Examples) ; was administered among 104 second year medical students of Sri Lakshmi Narayana Institute of Medical Sciences , Puducherry , India.

Results

In this study , second year medical students were selected to assess their knowledge regarding pharmacovigilance as they are at the fag end of their Pharmacology curriculum and will play vital role in ADR reporting in future. 104 students participated in the study. The results revealed that on an average, the test population appeared to be aware of pharmacovigilance to the extent of 54.67 % while it also seemed to possess the knowledge of reporting process to the extent of 56.87 %. However, on analysis & documentation aspect of pharmacovigilance, it possessed knowledge only up to the extent of 40 %. Only 38.4 % of the test population knows that ADR reporting in India is mandatory, while 76.9 % of it believes that ADR reporting is the duty of all healthcare professionals. This study shows inadequate knowledge of pharmacovigilance, in particular about the analysis and documentation process, among medical students.

Conclusion

This study emphasizes the need of intensive training regarding ADR reporting at Undergraduate level and to reinforce it by regular continuing medical education / workshops.

PP 5

An update on growth and development of telemedicine with pharmacological implications.

Devang Parikh, Bhagya Sattigeri, Ashok Kumar

Department of Pharmacology, Sumandeep Vidyapeeth's S.B.K.S. Medical Institute and Research Centre, Piparia, Vadodara, Gujarat

Aim

To sensitise the scope of science and technology in practice of medicine.

Introduction

Telemedicine is an application of information technology in relation to patient health care, treatment, education, research, administration and the public health. The word "tele" in Greek means "distance" and "mederi" in Latin means "to heal". It forms a potential bridge between the patient and doctor which ages a century with a good development in its growth. In developing countries like India with more than 60% of population living in rural areas with poor medical facilities, telemedicine can fill the gap and provide the timely care, appropriate treatment and medical assistance with less expense in relation to time and money.

It also helps in maintenance of electronic health records, monitoring of the cases, recording and reporting of adverse drug reactions, continued medical education programs and training programs to health care providers. Telemedicine can be practiced by store and forward method, interactive services, remote monitoring and by telepharmacy practises with the help of plain old telephone services (POTS), integrated services digital network (ISDN) lines and through internet.

Conclusion

The telemedicine system practice adapted more rampantly would help in easy flow and better health care delivery system to the remotest places in rural setups to save the lives, time and cost of the suffering.

Perhaps the slogan "Health for all by 2000" which was forgotten towards the end of last century, can still be achieved by the year 2020 by making the telemedicine revolution happen in India.

Keywords

Continued medical education, rural health service, telemedicine, telepharmacy.

PP 6

Risk Management and ADR

Ketan Khelwade
Institute of Research & Development, Gujarat Forensic Scinces University, Gandhinagar

As modern therapy has changed the way of controlling diseases it has brought significant benefits also to the society. But in spite of all benefits adverse drug reaction are common, often preventable. Drug safety become more important in the area of cause of illness, disability and even death due to drugs. To asses the safety we need to identify & measure the risk of harm associated with drug. Risk management is proactive approach for drug safety surveillance, to identification, monitoring & minimisation of risk to patient safety. As risk is probability of adverse outcome, the purpose of this article is to describe the current status in ADR reporting and how it will be leading to risk management of adverse effects related to medicine.

PP 7

Pharmacovigilance: Present Scenario And Future Prospect

Kirti V. Patel
Pharmacy Department, Faculty of Technology and Engineering, Kalabhavan,
M.S.U. Vadodara-390001.

Pharmacovigilance is a science which ultimately deals with effective health care with safe drugs. A better understanding of this among the health care professional (medical, dental, pharmacy, nursing, physiotherapy and care-givers) is mandatory for effective implementation of appropriate Pharmacovigilance, its requirements, problems, limitation and the process how it can be more improved. Pharmacovigilance environment in today's context need to move beyond compliance to systematic proactive, medically driven safety risk management approach to identifying and mitigating compliance risks. Constantly evolving regulatory environment with increased enforcement and increased interest in drug safety by stakeholders with the modest desire for more transparency will provide more conducive environment for proliferation and growth of Pharmacovigilance. This will help to restrict the use of drugs producing adverse reactions, there by rendering safe health care, serve public health, foster a sense of trust among patients in the medicines they use, ensure that risks in drug use are anticipated and managed, provide regulators with the necessary information to amend the recommendations on the use of the medicines, improve communication between the health professionals and the public and educate health professionals to understand the effectiveness/risk of medicines that they prescribe. This is the important role of pharmacovigilance.

PP 8

Impingement of promotional drug literature of prescription drugs in pharmacovigilance

Krunal Dalal, Bharat Gajjar
Department of Pharmacology, PSMC, Karamsad, Gujarat

"Promotion" refers to all informative and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs. Pharmacovigilance (PV/PhV), also known as drug safety is the science relating to the collection, detection, assessment, monitoring and prevention of adverse drug reactions (ADRs) with pharmaceutical products. ADRs are a major cause of morbidity and mortality, and even minor adverse drug events may adversely affect patient's compliance with treatment. A physician's quench for adopting information on any new drug ranges from published manuscripts in peer-reviewed journals to Continuous Medical Education programs, from drug representatives and pharmaceutical companies to promotional literature received by them. Very often, due to time constraint, intentionally or unintentionally, the literature promoting the drugs and distributed by the drug company representative is an important source of seeking information. For a better understanding and potential utilization of new drugs on patients, it is very important to critically analyze research findings, side effect profile and draw conclusions as misleading and wrong information is not uncommon in the literature used for drug promotion. The present review links increasing appraisal of ADRs and dissemination of deceptive promotional literature by pharmaceutical companies. Review was conducted by compiling promotional drug literature from medicine OPD in PSMC. In addition data were collected from broad range of sources (including Pubmed, Medline, PsycInfo, HMIC, Google scholar, Cinahal).The Findings from present study show that most of the promotional drug literatures having downplayed ADRs, on account of these false authenticity physicians have been fanatically prescribing newer drugs. On the basis of the information available in the promotional literature, it is very difficult for a physician to assess the validity of the ADRs and that may lead to inappropriate prescribing. A physician should have conscience of the consequences of the decision taken for prescribing drugs based on the research findings mentioned in promotional literature since inadequate information provided by them. We strongly recommended a legal provision to establish a code of conduct against irrational promotional literatures.

PP 9

Nevirapine Induced Dress

Nilofar Diwan, Rita Vora
Department of dermatology, PSMC, Karamsad, Gujarat

Introduction

DRESS (Drug Rash With Eosinophilia And Systemic Symptoms)is a idiosyncratic adverse drug reaction with multiple-organ involvement.It is a clinical manifestations of a potentially life-threatening condition that includes severe skin eruption, fever, hematologic abnormalities (eosinophilia or atypical lymphocytes) and internal organ dysfunction. It has been reported mostly in association with aromatic anticonvulsants,sulfonamides and allopurinol. Nevirapine is a potent and selective non competitive inhibitor of the reverse transcriptase enzyme of HIV type 1 often given in combination with other antiretrovirals.SJS/TEN are more commonly seen than DRESS .Chances of increase in drug reaction in immunocompromised is around 7-10%.

Case Report

A 35-year-old male presented with maculopapular rash over both arms and lowerlimbs with mild erosions over the hard palate since 2 days.He is a known case of Human immunodeficiency virus (HIV) infection since 2011 and was on Antiretroviral therapy (ART); zidovudine and lamivudine was started 30 days back and nevirapine since last 15 days . Investigations revealed eosinophilia (Eosinophils-22%). Rest of the systemic examination was normal. The diagnosis of nevirapine-induced DRESS was made. He was succesfully treated with steroids and omitting nevirapine.

Conclusion

The onset of DRESS occurs within 2 months of initiation of therapy,most often 2 to 6 weeks after receiving the first dose.Fever and rash are frequently the first signs;later the patient may develop lymphadenopathy, arthritis, myalgias, visceral manifestations and hematologic abnormalities. This report highlights the importance of nevirapine induced DRESS among the spectrum of cutaneous side effects of nevirapine which can range from drug rash,SJS,TEN. Discontinuation of the suspected drug ,putting pateint on alternative ART like Efavirenz and administration of systemic corticosteroids are the key steps in management of DRESS.

PP 10

A Critical Appraisal of Pharmacogenomics in Relation to Adr Monitoring

Sanjog N. Tewari, S.Z. Rahman
Department of Pharmacology, JNMC, AMU, Aligarh

Objective

To evaluate critically the advantages and disadvantages of Pharmacogenomics in relation to Pharmacovigilance.

Introduction

Pharmacogenomics is the technology that analyses how genetic makeup affects an individual's response to drugs. It deals with the influence of genetic variation on drug response in patients by correlating gene expression or single-nucleotide polymorphisms with a drug's efficacy or toxicity. The concept helps in practicing and adopting personalized medicine.

Materials and Methods

A critical review of various research articles was done using search engines and reference databases such as google scholar, pubmed and embase. After review, a list was compiled to study the advantages and disadvantages of Pharmacogenomics.

Observation

The current study observed that Pharmacogenomics as a discipline is thoroughly studied and lots of research papers have been published on this topic. The authors of the present paper noticed that from ethical, efficacy, safety, suitability and cost-effective point of view, there are some advantages and disadvantages of Pharmacogenomics or personalized medicine in situ. To cite a few examples of advantages of Pharmacogenomics, it is a means of prescribing as more powerful medicines, administration of safer drugs and lowering the cost of health care. Similarly, disadvantages of Pharmacogenomics could be related to exaggeration of social issues, ethical issues, psychological issues, biological issues / eugenics and religious issues.

Conclusion

Like any other approach, there are advantages and disadvantages of Pharmacogenomics and it is hard to conclude unless there is any scale to measure the pros and cons of the subject.

PP 11

Safety Issues Related to Over the Counter Drugs

Urvi Kumbhani, Bharat Gajjar
Department of Pharmacology, PSMC, Karamsad, Gujarat

OTC drugs are the drugs which are legally allowed to be sold over the counter by pharmacist without the prescription of a registered medical practitioner. They are purchased by consumers based on the information gained from the advertisement. In India, there is Drug and Magic Remedies law and WHO criteria for rational advertisement. Drug advertisements often tend to provide inadequate or misleading information. The consumers do not have adequate scientific knowledge to detect these shortcomings of the advertisements. Nowadays, pharmaceutical companies concentrate more on expanding their profit margins. Thus they focus on intensive direct-to-consumer advertising .The drug advertisements often do not describe or inadequately mention about the adverse effects of the drugs. This could mislead consumers and even put them under risk of potential harmful adverse events and health hazards.

WHO defines Pharmacovigilance as "the pharmacological science and activity relating to detection, assessment, understanding and prevention of adverse effects or any other drug-related problems."

We have surveyed various OTC drug advertisements appearing on television and evaluated its rationality and authenticity of contents. Thereby we have tried to evaluate the breach of the ideal criteria which should be followed for drug advertising so as to minimize the incidence of adverse drug reactions which may occur by inadvertent consumption of these OTC drugs. We also reviewed different journals describing about the adverse events occurring due to commonly used OTC drugs. Different surveys reported wide spread misuse of OTC drugs by consumers in form of overdose, taking several drugs concurrently and tendency to self-treat potentially severe diseases.

Thus widespread use of OTC drugs encouraged by drug advertisements can pose a potential burden to the healthcare system by increasing the incidence of adverse drug events.

PP 12

Study of Knowledge, Attitude and Practice of Self-Medication in Third Year MBBS Students, in Pramukh Swami Medical College Karamsad

Anuradha Joshi, Nitesh Sidhwani, Krunal Dalal & Urvi Kumbhani
Department of Pharmacology, PSMC, Karamsad, Gujarat

Background

Self-medication is defined as the use of medication, whether modern or traditional, for self-treatment. In Several studies it has been found that inappropriate use of self-medication results in increased resistance of pathogens, decrement of resources and generally implicates a grievous health hazards like adverse drug reactions, prolonged suffering and drug dependence. Preponderance of using self-medication mounts globally, particularly in the developing country like India despite efforts to limit this problem.

Objective

This study was undertaken to determine knowledge, attitude and practice of self-medication among 3rd year (3rd first & 3rd final) medical students of PSMC, Karamsad.

Subjects and method

This was an anonymous, pre-validated questionnaire based, descriptive study containing open ended and close ended questions to access the objective of study in third MBBS students. i.e. third first and third final.

Results

Out of total 137 respondents, 83(60.58%) were males and 54(39.41%) were females; their average age was 21years. The respondent's knowledge about self-medications was poor (77.37%), but knowledge of benefits (75.91%) and harms (24.08%) about self-medications was adequate. Knowledge of over the counter drugs (77.37%) and prescription only medication (70.80%) was good enough. Majority (59.85%) of the respondents had a convinced attitude preferring self-medication. The most common indications for self-medication were to alleviate symptoms headache (78.10%), cough, cold and sore throat (70.07%).Analgesic (78.10%) and antipyretic (75.91%) were the most common drugs used for self-medication.

Conclusion

Knowledge about appropriate self-medication was inadequate, attitude was positive and confident and practice was common and frequently inconsistent.

PP 13

The possible role of Ethosuxamide in neuropathic Pain management

Vijayendra Gautam
Resident Department of Pharmacology, Aurobindo Medical College, Indore

Introduction

Neuropathic Pain is recognized as one of the most difficult type of pain to treat with conventional analgesics. Several evidence implicate that T-type VGCC in pathophysiology of neuropathic and inflammatory pain. The prototypical nonselective VGCC inhibitors with T-type channel blockadge (eg.ethosuximide) attenuate dorsal horn neuronal response in rats.

Objective

1.To evaluate the analgesic activity of Ehthosuximide

2. To evaluate the analgesic activity of Ethosuximide in vincristine induced animal model of neuropathic pain

Material and Methods

Adult albino rats (wt.180-200gms) were divided in 5 groups of ten rats in each group.

Group 1 :- Normal

Group 2 :- Control (distilled water injected intrapertioneally)

Group 3 :- Vincristine induced neuropathy (50mcg/kg,i.p,daily,10days)

Group 4 :- Different doses of Ethosuximide [1.35mg/kg,1.8mg/kg,2.25mg/kg,2.7mg/kg,3.15mg/kg] injected intraperitoneally in Normal rats

Group 5 :- Different doses of Ethosuximide injected [1.35mg/kg,1.8mg/kg,2.25mg/kg,2.7mg/kg,3.15mg/kg] intraperitoneally in vincristine treated rats.

Neuropathy was induced in albino rats by injecting vincristine (50mcg/kg,daily) intraperitoneally for ten consecutive days. Evaluation of analgesic activity of Ethosuximide was carried out by using acetone drop method, cold immersion test, hot plate method.

Results

Mechanical allodynia and thermal hyperalgesia was exhibited following after ten days of vincristine administration (50mcg/kg,daily,i.p,10days).

Intraperitoneal administration of Ethosuximide in above mentioned doses, attenuated the mechanical allodynia and thermal hyperalgesia in dose dependent manner in vincristine treated group when compared with only vincrsitine treated group i.e.group 3

Ethosuximide also shows analgesic activity in normal rats (in non neuropathic rats)

Conclusion

The results of present study indicates the possible role of Ehosuximide in neuropathic pain management.

PP 14

Fluconazole Induced Fixed Drug Eruption

Malay Mehta, Rita Vora
Department of Dermatology, PSMC, Karamsad, Gujarat

Introduction

Fixed drug eruption(FDE)is a distinctive type of cutaneous drug reaction that characteristically recurs in the same locations upon reexposure to the offending drug. Lesions are single or a small number of dusky red or violaceous plaques that resolve leaving post inflammatory hyperpigmentation and are typically seen within 30 mins to 8 hours after exposure.Common sites are extremities,genitals and perianal areas. Fluconazole is a widely used bis-triazole antifungal agent with commonly observed side effects like nausea,vomiting and elevation of liver function test. However,FDR is absent from the reported list of possible side effects of the drug.We are presenting a rare case in our report.

Case report

A 26/M diagnosed with Tinea Cruris and was given Tab Fluconazole 150mg once a week following which he developed a single hyperpigmented patch over right forearm 3 years back.Again 1 year back after taking fluconazole for the same complaint he again developed hyperpigmented patches with bullous lesions over the lips and shaft of penis and on readministration of the drug 1 year later for the third time the lesions recurred on the same site. On all the 3 occassions the lesions improved after discontinuation of Fluconazole.

Conclusion

According to the Naranjo adverse drug reaction probability scale, FDR due to Fluconazole is a definitive type of drug reaction in our case. Fixed drug eruption as a possible side effect of fluconazole is not well known and thus, the lesions maybe misdiagnosed and mistreated by the physicians. If untreated, the patient can go into grave consequences like SJS/TEN.

PP 15

Pattern of Adverse Drug Reactions Due to Cancer Chemotherapy in Tertiary Care Hospital

Doshi Chintan, Singh Anil, Trivedi H. R, Shilpa Jadav , Parmar Dinesh M.
Department of Pharmacology, M. P. Shah Medical College, Jamnagar-361008, Gujarat.

Aim

The aim of present study was to assess the pattern of adverse drug reactions in patients receiving cancer chemotherapy drugs in tertiary care hospital Jamnagar.

Methods

A prospective, observational study was carried out for duration of 6months (January 2013 to June 2013). All the patients who underwent cancer chemotherapy at the government G.G.hospital, Jamnagar during the study period were included. Clinical and treatment data were collected from the inpatient case records. CDSCO forms were used to record the ADRs. Causality, severity and preventability were assessed by WHO causality assessment scale and Naranjo scale, & Shumock and Thornton scale respectively.

Result

40 (66.66%) patient from the total of 60 patients who were given cancer chemotherapy developed ADR. From the total of 40 patients who developed ADR 21 were females (52.5%) and 19(47.5%) were males. The most commonly affected System organ classification was blood and lymphatic system 24 (60%), followed by gastrointestinal tract13(32.5%). Cisplatin 16(40%), paclitaxel10(25%) and Carboplatin 8(20%) were most common drug classes responsible for ADRs. According to causality most of the ADRs were "possible" 31(77.5%), followed by probable" 8(20%%) and"certain" 1(2.5%) and "By Naranjo scale ADR were possible" 20(50%). "probable" 19(47.5%), "definite" 1(2.5%) & ". Shumock and Thornton scale shows 37(92.5%) were "not preventable" and 3(7.5%) were "preventable".

Conclusion

Early detection of drug toxicity helps to treat the patient and modify the doses or the drug regimen to minimize toxic effects.

Key words

ADRs, Cancer Chemotherapy, Causality assessment scale

PP 16

A Prospective Survey Study to Evaluate Rationality and Adverse Effects on the use of Analgesic and Antiulcer Agents among the Students and Staff Members of Medical College.

Ashok Kumar, B. M. Sattigeri, Devang Parikh, Shruti Bhrahmbhatt, Heena Shah
Department of Pharmacology, Sumandeep Vidyapeeth's S.B.K.S.M.I. & R.C. Piparia

Introduction

Widely used Non-steroidal anti-inflammatory drugs (NSAIDs), although clinically benefit in the management of inflammatory and degenerative joint diseases, they have considerable side effects, mostly affecting the upper gastrointestinal system, which limits their use. This study was conducted to determine the knowledge and perception regarding the use of analgesics and antiulcer agents among the medical students and staff members of medical college.

Methods

Responses to a feedback questionnaire covering various aspects on usage of analgesics and antiulcer drugs were obtained from 100 medical students and 100 staff members of medical college.

Results

Among 200 participants included in the study, 15% of them were on regular medication for one or the other purpose. It was observed that all of them used analgesics for various reasons, however, 52 % were found to self-medicate. Of the total participants, 94 % of them were aware about different type of analgesics while only 51 % of the participants were aware about their adverse effects and 46 % were aware of the possible drug interactions. The most commonly preferred analgesics were diclofenac (72%), paracetamol (71%) and ibuprofen (62%). Of the participants we found that 58 % preferred for the use of anti-ulcer agents along with analgesics, of which the most preferred group was proton pump inhibitors (39%).

Conclusion

With our study we conclude that irrespective of the groups, use of analgesics was common among the participants (mostly self-medicated) and about 58% of the participants were found to prefer anti-ulcer agents which are not rational.

Keyword

analgesics, , anti-ulcer medications, self-medication

PP 17

Pharmacoenvironmentology and Environmental risk: Current status

*Ajay Gupta & S. Z. Rahman, ** P. P. Singh
*Department of Pharmacology, JNMC, AMU, Aligarh
**Department of Psychiatry, JNMC, AMU, Aligarh

Aim

To review the current scientific status in relation to Pharmacoenvironmentology and its impact on environment.

Method

The Pharmacoenvironmentology and PharmEcovigilance are taken as synonym terminology for the study of Active Pharmaceutical Ingredients (APIs), entering into the environment after elimination from living systems (human beings and animals) post-pharmacotherapy; hence a thorough database search was conducted through computerised database (PubMed, BioMed Central and EMBase) using keywords of both the terms, between years 2012 and 2013.

Observation

Literature search revealed one article of same author with keyword "Pharmacoenvironmentology" on PubMed and BioMed Central, and no article on EMBase. With the keyword "PharmEcovigilance", two different articles of same authors were found on PubMed, and no article on BioMed Central or EMBase. There were number of studies that measured the levels of API in surface water, groundwater and drinking water given therapeutically to humans and animals including antibiotics, hormones, pain killers and anti-cancers. FDA and European Union have described certain guidelines to evaluate APIs in environment. Pharmacoenvironmentology is a new concept which requires acceptance at regulatory level; its widespread awareness and implications among healthcare providers at all levels; as well as consumers.

Conclusion

APIs are ubiquitous environmental contaminants. By identifying their sources, factors governing their disposal, and accumulation; it will optimise the use of pharmaceuticals throughout the healthcare system and have beneficial effect on both human and ecological health. By integrating pharmacoenvironmentology and conventional pharmacovigilance, a more holistic system for care of both human and environmental health could be created.

PP 18

Foreign direct investment (FDI) in pharmaceutical retailing a bane or boon for pharmacy profession

***Sudarshan Singh & Shyale SS, **Govind Mohan**

*Hon. Shri Babanrao Pachpute Vichardhara Trust's College of Pharmacy, Kashti, Maharashtra

**Institute of Pharmacy, NIMS University, Jaipur, Rajasthan, India

Aim

The aim of this study was to provide awareness about recent activities in pharma retailing as per foreign direct investment (FDI). FDI is a cross border investment which has been an integral part of the economic development strategies of India. Indian Pharmaceutical Industry witnessed higher levels of FDI in the recent past. The 100 per cent allowed FDI in the field of pharmaceuticals attracts several MNC's to consider India as the pharma destination. Pharma MNC's collaborating with Indian companies brought new products, latest technology, higher investments, quality systems and knowledge of regulatory processes. On their part, Indian companies provide low cost of innovation, low capital requirements, well established manufacturing processes, Research and Development infrastructure and local market knowledge. The increase in merger and acquisition and other alliances in Pharma sector globally emerged as a threatening tool for Pharmaceutical industry of India due to its long term effect on generic competition which may lead to increase in price of generic drugs. In order to supplement domestic capital, technology and skills, for accelerated economic growth, Department of industrial policy and promotion and ministry of commerce and industry reframed consolidated FDI Policy as Circular 1 of 2012, to attract and promote foreign direct investment. Further, National Pharmaceutical Pricing Policy (NPPP), 2012 has been framed to monitor Essentiality of Drugs, Control of Formulation Prices and Market Based Pricing. Conclusion: After analyzing the pros and cons of the FDI in the Indian Pharmaceutical Industry, it is established that India needs adequate FDI and its spillovers for the growth of the industry.

PP 19

Pharmacovigilance: Information system

Priyanka Sharma
Department of library and information sciences, NIMS Nursing College, Nims University Jaipur, Rajasthan.

Reduced product quality, adverse drug reactions (ADRs) and medication errors greatly influence health care system by unenthusiastically affecting patients care and mounting costs. Most of the statistic documenting the issue and highlighting the importance of pharmacovigilance come from developed countries likely have greater problems because of the poorer state of their health system infrastructure, the lake access to communication and information technology. In this study we attempt to draw the information system of Pharmacovigilance for the clinicians and patients.

PP 20

Docosahexaenoic acid prevents adverse effect of aluminum during dialysis dementia in rat model study

Manisha Choudhary, Devesh Kumar Joshi, Sudhanshu Mishra, Sandeep Tripathi, Anurag Tomar

Department of Advanced sciences & Biotechnology NIET, Department of Pediatrics, Nims Medical College, Shobha Nagar Jaipur, India

Objective

In the present study, we attempt to investigate the protective efficacy on aluminum induced neuronal damage in rat central nervous system.

Methods

In the present study, 100 mg/kg body weight docosahexaenoic acid was coadministrated with 100 mg/kg body weight of aluminum chloride (AlCl3) to male albino rats for 90 days orally. After behavioral study, hippocampus was removed for biochemical and molecular study. The ultrastructural study also carried out. The markers of oxidative stress i.e., Reacting oxygen species (ROS), protein carbonyl content (PC), lipid peroxide levels (LPx), superoxide dismutase (SOD), catalase (CAT), glutathione peroxidase (GPx) and reduced glutathione (GSH) were measured. The neuronal apoptotic markers Bax, Bcl and Caspase 3 were measured by western blotting techniques.

Results

Coadministration of DHA inhibited caspase-3 and bax expression and abolish ROS. Furthermore, treatment with DHA dramatically inhibits apoptosis, as assessed by the transmission electron microscope as reduced rate of astrocytosis. Moreover DHA also reduces ROS, LPO and PC and increases the activity of antioxidant enzymes SOD, CAT, GPx and GR.

Conclusion

On the basis of results it may conclude that thetreatment with DHA may represent a therapeuticstrategy to reverse the neuronal death associated with aluminum toxicity and may exert its effect on apoptosis-regulatory proteins.

Keywords

Aluminum; apoptosis; docosahexaenoic acid; astrocytosis

PP 21

Fluoride reduces semen quality at risk level

Dushyant Singh Chauhan, Anurag Tomara, Sandeep Tripathia, Surabhi Sharmaa, Shobha Tomara, Abbas Ali Mahdig
NIMS, University, Jaipur India.

Objectives

Remarkably interest has occurred on potential decline in the sperm quality due to contamination of fluoride in drinking water. The aim of the present study was to investigate the possible impact of fluoride exposure on semen quality.

Methods

The 113 subjects (age 22-35) were selected from the high fluoride region of Rajasthan where fluoride content in ground water was more than 2.0ppm. The age matched controls were selected from the area where fluoride content was <1.5ppm. The semen samples were collected and semen profile and oxidative stress parameters were estimated. Results: Significant changes in semen profiles, i.e., Semen Volume, liquefaction time, viability, motility, seminal pH, seminal viscosity, sperm density and oxidative stress parameters namely lipid peroxide levels, superoxide dismutase and catalase were observed in subject as compared with the controls following remarkably changes in serum and urine fluoride concentration.

Conclusion

On the basis of results it may safely conclude that fluoride affect the semen quality which may further affects in human reproduction.

Key words

Fluoride; semen quality; oxidative stress; NRCFPI; Rajasthan

PP 22

In vitro effect of Emblica officinalis on sodium seleniate induced cataract in isolated goat eyes

Sudhanshu Mishra, Anant Sharma, Manisha Choudhay, Swati Tomar, Ayaz Ahmad, Sandeep Tripathi
NIMS, University, Jaipur India.

Objective

The aim of the present study was to investigate the in vitro effect of aqueous extract of Emblica officinalis both seed and fruit on sodium selineate induced cataract in isolated goat eyes.

Methods

In the present study, three different concentration (50, 100 and 200 μmole) of aqueous extract of Emblica officinalis (seed and fruits) along with 100gm sodium selenite. All the lenses in different groups were incubated for 24 hours. After incubation, lens were homogenised to estimate Lipid peroxide level (LPO), Protein carbonyl content (PC), total protein (TP), Glutathione (GSH) and antioxidant enzymes such as SOD and CAT.

Results

The morphological study revealed that reduced deposition of crystalline protein in E. Officnalis treated lenses. Significant ($p<0.001$) reduced level of LPO and PC were observed in dose dependent manner as compared with the positive control rats. Moreover, antioxidant SOD, CAT and GSH were increased in treated groups. The remarkable finding was that seed at the concentration of 100 μmole is more effective than fruit extract.

Conclusion

It may conclude that supplement of seed extract of Emblica officinalis decreased the oxidative burden and prevent the development of cataract.

List of Participants SOPICON 2013

List of Participants SOPICON 2013

Sr. No	Name	Designation	Address	Mobile. No.	E-mail
1	Barna Ganguly	Professor and Head	PSMC, Karamsad	9427610493	barnag @charutarhealth.org
2	Bharat Gajjar	Asso Prof	PSMC, Karamsad	9537500302	bharatmg @charutarhealth.org
3	Nazima Mirza	Asso Prof	PSMC, Karamsad	9898041036	nazimaym @charutarhealth.org
4	Anuradha Joshi	Asso Prof	PSMC, Karamsad	9825828234	anuradhaj @charutarhealth.org
5	Alpa Gor	Asso Prof	PSMC, Karamsad	9924115170	alpapg @charutarhealth.org
6	Nitin Kothari	3rd Year MD	PSMC,Karamsad	8238499785	nknitinkothari @gmail.com
7	Akanksha Prajapati	3rd Year MD	PSMC,Karamsad	9624372148	prajapatiab @charutarhealth.org
8	Komal Gaur	2nd Year MD	PSMC,Karamsad	8866040597	komalvg @charutarhealth.org
9	Keny Mukundraj S	3rd Year MD	Goa MC, Goa	9011168903	mukundkeny @yahoo.com
10	Hiren Trivedi	Professor and Head	MP Shah MC, Jamnagar	9825210878	drhrt13@yahoo.com
11	S Amarnath	2nd Year MD	SLIMS, Pondicherry	9944560281	amarnathsugumaran @yahoo.co.in
12	Arun Sharma	1st Year MD	SLIMS, Pondicherry	7838506838	coolarun86 @gmail.com
13	AKP Praveen	1st Year MD	SLIMS, Pondicherry	9894877348	jaipharma @gmail.com
14	Chirag M Mistry	3rd Year MD	BMC, Vadodara	9998140043	duty.chirag @gmail.com
15	Uday Panchakshari	Asstt Proff	PSMC, Karamsad	9427002377	udayp @charutarhealth.org
16	Ashishkumar C Zala	3rd Year MD	GMC, Surat	9898899441	aashish.zala17 @gmail.com
17	Prakash P Malam	3rd Year MD	GMC, Surat	9558272475	malam_prakash @yahoo.com
18	Amit Shah	Asstt Proff	GMERS, Gandhinagar	9974820709	dr_amit84 @yahoo
19	GD Khilnani Dean	Dean	GMERS, Patan	9408838900	drgurudas @gmail.com
20	Nilay B Modi	3rd Year MD	SBKS MC, Waghodia	9825755191	drnilaymodi @gmail.com
21	Rima Shah	Asstt Proff	GMERS, Gandhinagar	9825741010	rima_1223@yahoo
22	Jatin Dhanani	Asstt Proff	GMERS, Patan	9879746240	dr.jatindhanani @gmail.com
23	Pratit P Vyas	1st Year MD	BMC, Vadodara	9898024167	pratitmbbs @gmail.com

List of Participants SOPICON 2013					
Sr. No	Name	Designation	Address	Mobile. No.	E-mail
24	Pratikkumar D Asari	2nd Year MD	BMC, Vadodara	9033107391	pratik1094 @gmail.com
25	Raj G Khirasaria	1st Year MD	BMC, Vadodara	9429215438	drrajkhirasari @gmail.com
26	Jalpa Suthar	Asstt Proff	RP College of Pharmacy, Changa	9825907538	alpasuthar.ph @ecchanga.ac.in
27	Leena N Patel	Asstt Proff	RP College of Pharmacy, Changa	9913523315	hetavi2009 @gmail.com
28	Rajesh H Parikh	Principal	RP College of Pharmacy, Changa	9426512675	rhp59 @rediffmail.com
29	Pratikkumar G Patel	Student	RP College of Pharmacy, Changa	9427857701	pratikpatel1956 @gmail.com
30	Biraj J Parmar	Student	RP College of Pharmacy, Changa	9428030057	biraj.pharma @gmail.com
31	Hitesh M Prajapati	Student	RP College of Pharmacy, Changa	9510996535	msg.mc.hitesh @gmail.com
32	Tulsee B Sitapara	Student	RP College of Pharmacy, Changa	9586571616	bstd16 @gmail.com
33	Kripa A Patel	Student	RP College of Pharmacy, Changa	8409508155	kripapatel14 @gmail.com
34	Mansi P Patel	Student	RP College of Pharmacy, Changa	9998141950	sweetmansipatel @yahoo.co.in
35	Nilay H Patel	Student	RP College of Pharmacy, Changa	7874053901	yalinpatel @gmail.com
36	Darshan J Dave	Asso Prof	GMERS, Gandhinagar	9428265512	darshanjd79 @yahoo.com
37	Kamlesh Vithalpara	MD student	BMC, Vadodara	8758786707	kvithalapara @yahoo.com
38	Hirenkumar H Dave	M.Sc. Student	BMC, Vadodara	9033190260	davehiren234 @gmail.com
39	Rohan P Christian	2nd Year MD	NHL MC,Ahmedabad	9724836150	christian.rohan25 @gmail.com
40	Darshan B Kharadi	2nd Year MD	NHL MC,Ahmedabad	9925605916	dbkharadi85 @gmail.com
41	Sunilkumar N Bhadiyadara	2nd Year MD	NHL MC,Ahmedabad	9913391550	drsunny8289 @gmail.com
42	Sandip S Jadhav	3rd Year MD	BJ MC, Ahmedabad	9724252449	sandip09jadu @gmail.com
43	Yogesh Lokare	Assistant Manager	Pharmacovigilance, IPCA Laboratory, Mumbai	9819840984	yogesh.lokare @ipca.com
44	Niyati Trivedi	Asso Prof	BMC, Vadodara	9998961097	not given

List of Participants SOPICON 2013

Sr. No	Name	Designation	Address	Mobile. No.	E-mail
45	Prashant Shah	Asstt Proff	BMC, Vadodara	9879871509	drpcshahpharma @gmail.com
46	Devang P Parika	3rd Year MD	SBKS MC, Waghodia	9924535992	dr.dp@in.com
47	Shreya Manish Shah	Asso Prof	BMC, Vadodara	9825329868	manishrey @rediff.com
48	Neeta jayantilal Kanani	Asstt Proff	BMC, Vadodara	9825321811	neetakanani2003 @yahoo.com
49	Krunal Dalal	1st Year MD	PSMC, Karamsad	8980455753	dalalkrunal @yahoo.co.in
50	Urvi Kumbhani	1st Year MD	PSMC, Karamsad	9925370551	dr.urvi.kumbhani @gmail.com
51	Pragna Patel		Lunawada	9428449515	pragna22785 @gmail.com
52	Parvati Patel	Asstt Proff	GMERS, Gotri, Vadodara	9978858106	dr_parvati1211 @yahoo.co.in
53	Jayshree Patel	Tutor	GMC, Bhavnagar	9558177380	dr_jayshreepatel @yahoo.com
54	Agam R Shah	Sr Manager	Accutest Research lab, Ahmedabad	9825465938	arnic333 @hotmail.com
55	Dhruvika Kharadi	PhD student	PSMC,Karamsad	9925024779	dgkharadi @yahoo.co.in
56	Gautam Vijayendra	MD student	Shri Aurbindo MC, Indore	9425708786	drgautam5577 @gmail.com
57	Sanjay Kumar	Asso Prof	IMS & SUM Hosp, Bhuvneshwar	9437080239	dska27 @yahoo.co.in
58	Punita Vasani	3rd Year MD	CU Shah MC, Surendranagar	9979899664	vpunita13 @yahoo.com
59	Sandip N Solanki	2nd Year MD	CU Shah MC, Surendranagar	9909027321	dr.sandipsolanki @gmail.com
60	Utkarsh p Shah	1st Year MD	BMC, Vadodara	9824794010	utkarsh_shah25 @yahoo.co.in
61	Hirabhai K Luhar	1s Year MD	BMC, Vadodara	8140980701	drhiren88 @gmail.com
62	Ronak R Prajapati	2nd Year MD	BJ MC, Ahmedabad	9898041853	ronakprajapati9 @gmail.com
63	Dhrumil S Patel	2nd Year MD	BJ MC, Ahmedabad	9724410751	dhrumilpatel786 @gmail.com
64	Dhaval R Thakor	3rd Year MD	BJ MC, Ahmedabad	9601451078	dhaval64 @gmail.com
65	Snehal S Anturlikar	M.Sc. Student	BMC, vadodara	9898563319	snehalanturlikar28 @gmail.com
66	Purvi J Tanna	1st Year MD	MP Shah MC, Jamnagar	9427545731	purvi30tanna @gmail.com

List of Participants SOPICON 2013					
Sr. No	Name	Designation	Address	Mobile. No.	E-mail
67	Jayesh P Vaghela	1st Year MD	MP Shah MC, Jamnagar	8469112819	jpv2212 @gmail.com
68	Archna G Chaudhari	1st Year MD	MP Shah MC, Jamnagar	9099007168	dr.archna294 @gmail.com
69	Priyanka P Hotha	1st Year MD	MP Shah MC, Jamnagar	7600135263	priyankahotha @gmail.com
70	Dolli S Aasani	1st Year MD	MP Shah MC, Jamnagar	8460217077	not given
71	Bansari M Patel	2nd Year MD	MP Shah MC, Jamnagar	9909517814	drbansari28 @gmail.com
72	Nishita H Darji	2nd Year MD	MP Shah MC, Jamnagar	9824449937	nishitadarji @gmail.com
73	Varsha M Kumari	2nd Year MD	MP Shah MC, Jamnagar	9909752019	leo_leo07 @yahoo.co.in
74	Chintan M Doshi	2nd Year MD	MP Shah MC, Jamnagar	9427663788	doshichintan2 @gmail.com
75	Rutvij H Hedamba	2nd Year MD	MP Shah MC, Jamnagar	9033431734	
76	Jitendra Agrawal	3rd Year MD	MP Shah MC, Jamnagar	9824047028	jitendra_jindal @rediffmail.com
77	Chandrabhanu Tripathi	Professor and Head	GMC, Bhavnagar	9825951678	cbtripathi @yahoo.co.in
78	Viren N Naik	Asso Prof	GMC, Bhavnagar	9825447370	naikviren2001 @yahoo.com
79	Khusboo K Gajjar	1st Year MD	GMC, Bhavnagar	9898682597	drkhushboogajjar @gmail.com
80	Dharamvirsingh K Jadeja	1st Year MD	GMC, Bhavnagar	9426992146	dharamvir.jadeja @yahoo.com
81	Geeta B Kharadi	1st Year MD	GMC, Bhavnagar	8238986655	geeta.kharadi1988 @gmail.com
82	Hiral N Golakiya	1st Year MD	GMC, Bhavnagar	9033565167	hiralgolakiya @gmail.com
83	Nrupal Patel	2nd Year MD	BJMC, Ahmedabad	9825523517	nrup777 @ymail.com
84	Aditi Chaturvedi	Asso Prof	VCSGGI-MSR, Shrikot, Uttarakhand	246174	aditichaturvedi50 @yahoo.com
85	Ashok Kumar	3rd Year MD	SBKS MC, Waghodia	9638272328	dr.ashok1283 @gmail.com
86	Hemlata V Kamat	Prof. & Head, Anesth.	PSMC, Karamsad	9375031313	hemlatauk @charutarhealth.org
87	Alpa Patel	Asso Prof, Anesth.	PSMC, Karamsad	02692-288112	alpamp @charutarhealth.org
88	Mithu N Deb	1st Year MD	SBKS MC, Waghodia	9377999151	dr.mithusharma @gmail.com

List of Participants SOPICON 2013

Sr. No	Name	Designation	Address	Mobile. No.	E-mail
45	Prashant Shah	Asstt Proff	BMC, Vadodara	9879871509	drpcshahpharma @gmail.com
46	Devang P Parika	3rd Year MD	SBKS MC, Waghodia	9924535992	dr.dp@in.com
47	Shreya Manish Shah	Asso Prof	BMC, Vadodara	9825329868	manishrey @rediff.com
48	Neeta jayantilal Kanani	Asstt Proff	BMC, Vadodara	9825321811	neetakanani2003 @yahoo.com
49	Krunal Dalal	1st Year MD	PSMC, Karamsad	8980455753	dalalkrunal @yahoo.co.in
50	Urvi Kumbhani	1st Year MD	PSMC, Karamsad	9925370551	dr.urvi.kumbhani @gmail.com
51	Pragna Patel		Lunawada	9428449515	pragna22785 @gmail.com
52	Parvati Patel	Asstt Proff	GMERS, Gotri, Vadodara	9978858106	dr_parvati1211 @yahoo.co.in
53	Jayshree Patel	Tutor	GMC, Bhavnagar	9558177380	dr_jayshreepatel @yahoo.com
54	Agam R Shah	Sr Manager	Accutest Research lab, Ahmedabad	9825465938	arnic333 @hotmail.com
55	Dhruvika Kharadi	PhD student	PSMC,Karamsad	9925024779	dgkharadi @yahoo.co.in
56	Gautam Vijayendra	MD student	Shri Aurbindo MC, Indore	9425708786	drgautam5577 @gmail.com
57	Sanjay Kumar	Asso Prof	IMS & SUM Hosp, Bhuvneshwar	9437080239	dska27 @yahoo.co.in
58	Punita Vasani	3rd Year MD	CU Shah MC, Surendranagar	9979899664	vpunita13 @yahoo.com
59	Sandip N Solanki	2nd Year MD	CU Shah MC, Surendranagar	9909027321	dr.sandipsolanki @gmail.com
60	Utkarsh p Shah	1st Year MD	BMC, Vadodara	9824794010	utkarsh_shah25 @yahoo.co.in
61	Hirabhai K Luhar	1s Year MD	BMC, Vadodara	8140980701	drhiren88 @gmail.com
62	Ronak R Prajapati	2nd Year MD	BJ MC, Ahmedabad	9898041853	ronakprajapati9 @gmail.com
63	Dhrumil S Patel	2nd Year MD	BJ MC, Ahmedabad	9724410751	dhrumilpatel786 @gmail.com
64	Dhaval R Thakor	3rd Year MD	BJ MC, Ahmedabad	9601451078	dhaval64 @gmail.com
65	Snehal S Anturlikar	M.Sc. Student	BMC, vadodara	9898563319	snehalanturlikar28 @gmail.com
66	Purvi J Tanna	1st Year MD	MP Shah MC, Jamnagar	9427545731	purvi30tanna @gmail.com

List of Participants SOPICON 2013					
Sr. No	Name	Designation	Address	Mobile. No.	E-mail
67	Jayesh P Vaghela	1st Year MD	MP Shah MC, Jamnagar	8469112819	jpv2212 @gmail.com
68	Archna G Chaudhari	1st Year MD	MP Shah MC, Jamnagar	9099007168	dr.archna294 @gmail.com
69	Priyanka P Hotha	1st Year MD	MP Shah MC, Jamnagar	7600135263	priyankahotha @gmail.com
70	Dolli S Aasani	1st Year MD	MP Shah MC, Jamnagar	8460217077	not given
71	Bansari M Patel	2nd Year MD	MP Shah MC, Jamnagar	9909517814	drbansari28 @gmail.com
72	Nishita H Darji	2nd Year MD	MP Shah MC, Jamnagar	9824449937	nishitadarji @gmail.com
73	Varsha M Kumari	2nd Year MD	MP Shah MC, Jamnagar	9909752019	leo_leo07 @yahoo.co.in
74	Chintan M Doshi	2nd Year MD	MP Shah MC, Jamnagar	9427663788	doshichintan2 @gmail.com
75	Rutvij H Hedamba	2nd Year MD	MP Shah MC, Jamnagar	9033431734	
76	Jitendra Agrawal	3rd Year MD	MP Shah MC, Jamnagar	9824047028	jitendra_jindal @rediffmail.com
77	Chandrabhanu Tripathi	Professor and Head	GMC, Bhavnagar	9825951678	cbtripathi @yahoo.co.in
78	Viren N Naik	Asso Prof	GMC, Bhavnagar	9825447370	naikviren2001 @yahoo.com
79	Khusboo K Gajjar	1st Year MD	GMC, Bhavnagar	9898682597	drkhushboogajjar @gmail.com
80	Dharamvirsingh K Jadeja	1st Year MD	GMC, Bhavnagar	9426992146	dharamvir.jadeja @yahoo.com
81	Geeta B Kharadi	1st Year MD	GMC, Bhavnagar	8238986655	geeta.kharadi1988 @gmail.com
82	Hiral N Golakiya	1st Year MD	GMC, Bhavnagar	9033565167	hiralgolakiya @gmail.com
83	Nrupal Patel	2nd Year MD	BJMC, Ahmedabad	9825523517	nrup777 @ymail.com
84	Aditi Chaturvedi	Asso Prof	VCSGGI-MSR, Shrikot, Uttarakhand	246174	aditichaturvedi50 @yahoo.com
85	Ashok Kumar	3rd Year MD	SBKS MC, Waghodia	9638272328	dr.ashok1283 @gmail.com
86	Hemlata V Kamat	Prof. & Head, Anesth.	PSMC, Karamsad	9375031313	hemlatauk @charutarhealth.org
87	Alpa Patel	Asso Prof, Anesth.	PSMC, Karamsad	02692-288112	alpamp @charutarhealth.org
88	Mithu N Deb	1st Year MD	SBKS MC, Waghodia	9377999151	dr.mithusharma @gmail.com

List of Participants SOPICON 2013

Sr. No	Name	Designation	Address	Mobile. No.	E-mail
89	Heena S Shah	2nd Year MD	SBKS MC, Waghodia	8905191980	heenashah15 @yahoo.com
90	Zafar M Ansari	MD student	JNMC, Aligarh	9457194732	drzmasood @gmail.com
91	Imran Zaheer	MD student	JNMC, Aligarh	7417735867	imran82zaheer @gmail.com
92	Abdul Latif	Asso Prof	Dpt of ILMUL Advia, AMU,Aligarh	not given	abdullatiffamu @gmail.com
93	Usha S Lalwani	1st Year MD	PDU GMC, Rajkot	9687285342	ushalalwani89 @gmail.com
94	Jigar P Modi	1st Year MD	PDU GMC, Rajkot	9724031597	jigmod19 @gmail.com
95	Nitishkumar D Tank	1st Year MD	PDU GMC, Rajkot	7567991329	dr.nitishtank @gmail.com
96	Dhara R Mehta	1st Year MD	PDU GMC, Rajkot	8469798720	dr.dharamehta @gmail.com
97	Parth K Vachhani	1st Year MD	PDU GMC, Rajkot	9428441929	parth1vachhani @gmail.com
98	Adesh D Mishra	2nd Year MD	PGIMS, Rohtak	9034766408	draadeshmishra @gmail.com
99	Jyoti P Sahoo	1st Year MD	PGIMS, Rohtak	9034841276	drjp1111 @gmail.com
100	Rauf Abdur	Asstt Proff	Dpt of ILMUL Advia, AMU, Aligarh	9457357442	abdurraufmd @yahoo.com
101	Sudarshan Singh	Asstt Proff	HSB PVT college of Pharmacy, Ahemadnagar, MH	9765593639	sudarshansingh83 @hotmail.com
102	Ajay Gupta	2nd Year MD	JNMC, Aligarh	8791077565	dr.ajaygupta24 @gmail.com
103	Nidhi A Saxena	PhD student	PSMC, Karamsad	9426558547	nidhiamarsaxena @gmail.com
104	Sanjog N Tewari	2nd Year MD	JNMC, Aligarh	9760434368	sanjogtewari @gmail.com
105	Nirzarini N Shah	Asso Prof & Head	AR College of Pharmacy	9428659764	nirzarini1999 @yahoo.com
106	Punam D Sachdeva	Asso prof	AR College of Pharmacy	9227421321	pdsachdeva @yahoo.co.in
107	Ketan K Khelwade	PG Student	Gujarat Forensic Science University, Gandhinagar	9879942964	ketankhelwade @gmail.com
108	Nikhil M Kharod	Prof. & Head, Paedia.	PSMC, karamsad	9825328749	nikhil_kharod @yahoo.com
109	Nidhi H Patel	1st Year MD, Skin	PSMC,Karamsad	9974284364	drnidhipatel28 @gmail.com
110	Malay J Mehta	3rd Year MD, Skin	PSMC,Karamsad	8758691345	malayjm @charutarhealth.org
111	Nilofar G Diwan	1st Year MD, Skin	PSMC,Karamsad	7405340346	nilofergd @charutarhealth.org

List of Participants SOPICON 2013					
Sr. No	Name	Designation	Address	Mobile. No.	E-mail
112	Arvindbhai H Patel	2nd Year MD, Skin	PSMC,Karamsad	9825349222	arvindbhaih @charutarhealth.org
113	Abhishek P Pilani	2nd Year MD, Skin	PSMC,Karamsad	9586122444	pilaniap @charutarhealth.org
114	Praveenkumar T Patil	2nd Year MD	GMC, Miraj	9975895022	drpraveentpau @yahoo.in
115	Ravi Ghanghas	Asstt Proff	GMC,Miraj	7350480753	ravighanas @gmail.com
116	Sushil K Singh	Prof. & Head, Physiolo.	PSMC, Karamsad	02692-228521	singhsk @charutarhealth.org
117	Sangeeta P Bhat	2nd Year MD	JNMC, Aligarh	9632153373	sweetsan18 @yahoo.com
118	Kirti V Patel	Asso prof	Pharmacy dept. MSU, Vadodara	9898464690	kirtipatel_135 @yahoo.com
119	Vasudev Raval	Prof & Head of dept.	PSMC, Karamsad	9824562575	vasudevsr @charutarhealth.org
120	Priyanka Sharma	Librarian	NIMS, Jaipur	-	pr.sh2011@gmail. com
121	Sudhanshu Mishra	Research Scholar	NIMS, Jaipur	-	sudhanshumishra @gmail.com
122	Dushyant Singh Chauhana	Research Scholar	NIMS, Jaipur	-	dschauhan07 @gmail.com
123	Manisha Choudhary	Research Scholar	NIMS, Jaipur	-	manisha.chaudhary 890@gmail.com
124	Sandeep Tripathi	Asst Prof of Biotechnology	NIMS, Jaipur	8769953286	sandeeptripathid @gmail.com

Shree Krishna Hospital, Karamsad, Gujarat.

P S Medical College, Karamsad, Gujarat.