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INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

ABSTRACTS

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INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

The International Society of Pharmacovigilance (ISoP) is devoted to developing its activities on a worldwide basis towards supporting safer use of medicines in clinical practice.

ISoP aims to promote the use of all types of information and methodologies in providing optimal drug treatment for patients. The Society is not only for clinical pharmacologists, pharmaceutical industry representatives, epidemiologists and regulators, but also for practising clinicians, other healthcare professionals and anyone else who is interested in learning about better ways for patients to receive and use medicines safely.

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P104

Methylenetetrahydrofolate Reductase (MTHFR) Gene Polymorphism & Osteoporosis: Need An Active Solution

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Background: Osteoporosis is a common metabolic bone disorder characterized by reduced bone mass, increased skeletal fragility, micro architectural deterioration and as a consequence increased bone fracture. 300 million Indians are osteoporotic. Conventional therapy focuses only on calcium and vitamin D supplementation for osteoporosis.
Aim: To find prevalence of hyperhomocysteinemia and its impending risk for osteoporosis.
Method: Double blind randomised controlled study of 628 consecutive patients in the age group 20–70 years with 298 females and 330 males whose T-score of bone mineral density was below-1, were given 5 mg of folate and 1500 μg of mecobalamin or double placebo for 2 years. It was found that drug treated group showed 38 % decrease in plasma homocysteine levels and 76.7 % reduction in fracture incidence as compared to the placebo group being given conventional Vit D and calcium supplement.
Results: It is concluded that conventional calcium and vitamin D therapy for treating osteoporosis should be supplemented with active forms of folic acid, vitamin B6 and vitamin B12 to effectively reduce homocysteine levels in all patients as majority of patients in present study were suffering from MTHFR polymorphism.
Discussion: Methylenetetrahydro folate reductase C677T gene polymorphism has been identified as a candidate gene for osteoporosis. In the study it was found that 60 % of the population is suffering from MTHFR polymorphism. Homocysteine is converted into methionine in presence of L-methyl folate (active form of folic acid). Folic acid is converted into L-methyl folate in presence of MTHFR. So deficiency of MTHFR leads to deficiency of L-methyl folate which in turn leads of hyper homocysteinaemia, which in turn interferes with collagen cross-linking in bones leading to weak collagen matrix and osteoporosis. Similarly active form of vitamin B6 (Pyridoxine) viz pyridoxal 5′-phosphate and active form of vitamin B12 cyanocobalamin viz. methyl cobalamin converts homocysteine into cysteine and methionine respectively, thus lowering the blood homocysteine level and chances of osteoporosis. The active forms of vitamin B show higher bioavailability and bypasses the MTHFR polymorphism.
Conclusion: Active forms of vitamin (folic acid, B6 and B12) bypass MTHFR polymorphism to control plasma homocysteine levels and thus osteoporosis.

P105

Adverse Drug Reaction Monitoring at a Regional Pharmacovigilance Centre (B.P.K.I.H.S.)

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Introduction: Adverse drug reactions (ADR) are unintended drug consequences which are often preventable. ADR monitoring is the cornerstone of Pharmacovigilance. Pharmacovigilance plays an important role in rational use of drugs. This study was to observe the pattern of ADRs at Eastern Regional Pharmacovigilance Centre of Nepal, (B.P. Koirala Institute Health Sciences).
Materials and methods: It was a cross-sectional study of clinician-diagnosed ADR among patients presented to BPKIHS between July 2012 and July 2015. 150 ADRs from different departments of the Institute were collected and analyzed in the department of clinical pharmacology and Therapeutics, Regional Pharmacovigilance Centre.
Results: There were total 150 ADRs reported among patients during 3 years monitoring period. Highest percentage of ADR was collected from Department of Psychiatry (60.67 %). Maximum number of ADRs observed were due to CNS drugs (64.66 %) followed by endocrinal drugs (17.33 %) and antimicrobial drugs (12.00 %). ADR due to steroid (16.67 %), i.e., Headache, Insomnia, puffiness of face, acid peptic disorder, oral candidiasis, etc. and diverse CNS drugs related ADRs (14.66 %) e.g. dryness of mouth, sexual dysfunctions, etc. were the most common ADRs seen.
Conclusion: CNS drugs related ADRs were most commonly observed. Careful monitoring, better reporting and dedicated follow up of the patients might lead to more and better ADR detection.

P106

The Economic Burden of Adverse Drug Reactions Leading to and Occurring During Hospitalization

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Background: Adverse drug reactions (ADRs) are a major public health problem because they are directly related to mortality, morbidity and costs [1–3]. Due to their nature and implications, ADRs may account for a considerable number of hospitalizations, lead to poorer prognostics, and prolong hospitalization length while increasing the overall direct and indirect hospitalization-associated costs [4–6].
Objective: To analyze the comparative economic impact of hospital-acquired ADRs as well as community acquired ADRs leading to hospitalization and to characterize their associated hospitalization length and costs, incidence, prevalence, risk factors, predictability, preventability, most frequently afflicted systems and most common involved drug groups.
Methods: Systematic analysis performed on PubMed including all studies published prior to March 30th, 2016. Identified and retrieve studies (1617) were categorized as case reports, clinical studies, comparative studies, clinical trials, non-trial clinical studies, other observational studies, multicenter studies, other evaluation studies or otherwise journal articles. Only original studies in English or Portuguese language pertaining to adults and/or the elderly and reporting (as their main goal) cost resulting from ADRs/ADEs causing hospitalization and/or occurring during hospitalization were included. Studies performed on the pediatric population, those restricted to specific diseases (e.g. hypertension, chronic obstructive pulmonary disease), clinical conditions (e.g. cancer patients, trauma patients) or drug groups (e.g. antiretroviral therapy, chronic obstructive pulmonary disease), drug–drug comparative and modeling studies were all excluded from further analysis.
Results: A total of 1617 studies were retrieved, and 1483 were in human subjects. 42 % of the studies were classified as Case Reports (n = 23), Clinical studies (n = 177), Comparative Studies (n = 189), Clinical Trials (n = 146), Non-Clinical Studies (n = 8), Other Observational Studies (n = 3), Multicenter Studies (n = 62), or Other Evaluation Studies (n = 21). Few studies pertaining to hospitalization-associated ADRs and resulting cost existed and were amenable to analysis. Results were reported as mean, median and/or range and plotted as bar charts.
Conclusion: The economic burden of ADRs is not limited to the direct hospitalization-associated implications, instead having more extensive societal implications. While the most commonly prescribed drugs account for the majority of ADRs, a restricted number of medications and ADRs account for the majority of the economic burden. Therefore, identifying and targeting this limited set is of paramount importance to reduce the health-associated and economic burden resulting from ADRs.

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P107

An Educational Intervention to Improve Nurses Reporting of Adverse Drug Reactions

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Introduction: Adverse drug reactions (ADR) are an important cause of mortality and morbidity leading to additional costs with health [1–3]. Drug safety data before commercialization is limited and incomplete, which is the reason why pharmacovigilance is important. The spontaneous ADR report system is efficient and fundamental to the safety surveillance of market medicines. Nurses can have an important role in ADR reporting due to their daily activities of drugs administration (including vaccines). However, among these professionals, there is a high rate of underreporting [4,5]. Based on the reasons proposed by Inman for underreporting ADR, it was concluded that the main obstacles to ADR reporting among nurses were indifference (the belief that a single case cannot contribute to medical knowledge) and the lack of knowledge about the pharmacovigilance system [6].
Objective: The aim of this study is to evaluate the increase of ADR reports by nurses after an educational intervention.
Methods: We performed a quasi-experimental study in nurses working in primary care in Braga district, Portugal. 113 individuals were placed in the intervention group while the control group included 590 nurses. Two educational interventions were performed to nurses working in primary care in ACES Cavado II (intervention group) that focused on the problem of adverse drug reaction, the impact on public health and spontaneous reporting. Statistical analysis were based on absolute and relative frequencies.
Results: Between January 2013 and September 2014 the Northern Pharmacovigilance Centre received 8 reports/100 nurses from the intervention group and 5 reports/100 nurses from control group.
Conclusions: The educational intervention almost double the number of reports during the study period. The 2nd intervention had more impact than the 1st one. There was no significant increase in the quality of ADR reports in the intervention group. In the 2nd intervention the number of reports increased only at the intervention day.

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P108

Ensuring Out-Patient Safety—The Role of the Prescriber

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Introduction: Patient safety is a fundamental principle of health care. It is the absence of preventable harm to patients. The consumption of medicines is a potential source of preventable harm when patients consume the wrong medicine or the wrong quantities of the right medicine. Adverse drug events and mistaken patient identities [1] are among the more common problems with the delivery of health care. Prescribers play a vital role in what medicines are consumed by patients and their quantities. The interaction between prescribers and patients influences the decisions made during an encounter. Outpatients will usually attend a health facility for short periods. This limits their interaction with the prescriber, most often, to one encounter. The quality of interactions between prescribers and patients is instrumental in ensuring rational use of medicines, preventing avoidable adverse drug events and thereby promoting patient safety. The information given on prescription forms also informs dispensers on the medicines to be dispensed, their quantities and relevant information.
Aim: The aim of this work was to determine whether the interactions between patients and prescribers are sufficient to prevent or reduce adverse drug events and mistaken identities when it comes to consumption of medicines.
Methodology: A survey was conducted in three regions in Ghana looking into the interactions that prescribers have with consumers. The results obtained from the survey were analysed to assess the adequacy of the interaction between prescribers and consumers and the quality of information on prescription forms issued to out-patients to reduce adverse drug events and prevent mistaken identity.
Results: The survey showed that the interactions between prescribers and clients are usually not enough to prevent avoidable adverse drug events. Less than 20 % of consumers had been questioned about allergies they have, a little over 40 % were given reasons for the medications being prescribed for them and about 30 % were told the names of the medications they. Further, the information on prescription forms were inadequate to ensure that medicines are properly dispensed with adequate information.
Recommendations: There is the need to improve the quality of interactions in order to prevent avoidable adverse drug events. Prescribers must ensure that prescriptions have adequate information to ensure effective dispensing.

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P109

Pharmacovigillance of Ayurvedic Drugs—Current Scenario

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Safety, efficacy and palatability need to be considered prior to administration of any drug. Safety is the first and most essential among these three requirements. However no drug can be called a completely safe drug in true sense. Untoward effect or adverse reaction is an integral part of drug pharmacology. Risk is always involved in any type of intrusion in human body. Concept of 'Yukta Bhaishajya' described by Caraka in Caraka Samhita, a renowned Ayurvedic classical text is noteworthy in this context. Caraka defines 'Yukta Bhaishajya' i.e. an appropriate drug as a drug which removes the disease and promotes and protects the health without causing any harm to the body. According to Kashyapa, another Ayurvedic scholar and stalwart states that administration of appropriately processed drug in appropriate dose may cause little discomfort but should remove the disease without causing major risk and permanent harm to the human body. Incidences of toxicity caused due to administration of Ayurvedic drugs containing heavy metals are being reported every now and then in the social media and some of the international journals. It has been observed that the issue is being viewed most unscientifically and with a biased attitude. Most of the reported cases appear to be the result of inappropriate handling of the patients by individuals due to the ignorance of the handler. On this background it is necessary to examine this issue scientifically. The incidences also underline the significance of pharmacovigillance of Ayruvedic drugs, which remains to be the most neglected subject today. The present paper will try to throw light on this burning issue and will try to give some solutions in this regard.