PHARMACOECONOMICS BIOSIMILARS IN ONCOLOGY

E. Janeková
InClinic s.r.o, Bratislava, Slovakia

Background: Population growth, long life spans, an increased morbidity cause an increased incidence of cancer diseases. Bio-similar drugs come to the market after the patent protection of biological drugs expires. In general, they reduce the price of the original drugs by 20%. Prior to a practical use they require clinical studies that demonstrate the quality, safety and efficacy biosimilar to that of the original. The price of development and production is 10 times higher than the price of generics.

Material and Methods: For the treatment and prophylaxis of febrile neutropenia the original drugs are used; such as pegfilgrastim and filgrastim and filgrastim biosimilars. The study compared the cost-effectiveness of 5 EU countries of filgrastim, pegfilgrastim and biosimilar filgrastim in different modes with cost efficiency in the Slovak Republic with a differentiating pricing policy of drugs over the years 2011.2012, 2013.

Results: The prophylaxis and therapy of febrile neutropenia with biosimilar filgrastim is cost-effective when related to filgrastim and pegfilgrastim. Both the international and internal analysis puts the biosimilar filgrastim to a position of a cost-effective treatment even in with the absence of evidence provided by a pharmacological and therapeutical priority.

Conclusions: The administration of an adequate treatment using pegfilgrastin and biosimilar filgrastim is a cost difference of 289 Euros in the Slovak Republic. Savings during the administration of the biosimilar drug for years: 2011 is 3703 thousand Euro thus, 70% of expenditure, in 2012 it was 4079 thousand. 68%. In 2013 it is 3847 thousand Euro, which is 60% of the cost for treating febrile neutropenia. Biosimilar drugs are the solution for oncologists as how to regulate the cost of oncological treatment while maintaining the effectiveness of said treatment.

PHARMACOGIVILANCE AT THE CHUB NATIONAL REFERRAL HOSPITAL IN RWANDA

F. Mugabo[1,2]; N. Rutambika[1]; T. Walker[1,2]; and D.R.J. Singer[1,2,3,4]
[1]Centre Hospitalier Universitaire de Butare (CHUB), Huye South, Rwanda; [2]University of Rwanda, Kigali, Rwanda; [3]Human Resources for Health Program, Rwanda; and [4]Yale School of Medicine, New Haven, Connecticut, USA

Background: Pharmacovigilance is very important for patient safety as adverse drug reactions (ADR) may be serious and preventable. We aimed to encourage adverse drug reaction (ADR) reporting and to assess patterns of adverse drug reactions in in-patients and out-patients at our national referral hospital.

Methods: We used WHO and Ministry of Health ADR reporting protocols, including causality reviews, to identify suspected harmful responses to one or more medicines, prescribed, OTC or traditional, known or new.

Results: Prospective data are presented for a 1 week audit. 9 reports were received (8 patients, age range 10–58 years, median 51 years; 5 female) from: Internal Medicine, the HIV Clinic, ICU, Surgery and Paediatrics. 2 concerned medication errors (ciprofloxocin prescribed – but not administered instead intended co-trimoxazole; cloxacillin prescribed as twice the recommended dose). Two were related to traditional medicines causing severe vomiting precipitating hospital admission (girl of 10 also found to have severe anaemia; 31 year old women with worsening post-partum oedema and severe chronic kidney disease (creatinine 425 µmol/L). Other ADRs were cloxacillin-induced Stevens Johnson Syndrome (14F); severe dyskinaesia from chronic haloperidol use for treating psychosis (52M); lip swelling and pruritus after 1st dose of nifedipine for hypertension (51M); recurrent hypoglycaemia on metformin and glibenclamide (58F); and generalized rash and pruritus on first dose carvedilol and losartan (51M), resolving during continued treatment with the drugs.

Conclusions: We were effective in improving ADR reporting by many departments at this major centre and in identifying an important contribution of ADRs to serious morbidity at CHUB, including unrecognized use of traditional medicine as a cause of hospital admissions and delayed detection of serious medical conditions.

PATTERNS OF SUSPECTED ADVERSE DRUG REACTIONS AMONG IN-PATIENTS AT KING FAISAL REFERRAL HOSPITAL, RWANDA

E. Amendezo[1,2]; I. Kambutse[1,2]; Y. Maniraguha[2]; B. Habimana[1,2]; F. Padua[1]; E. Musabeyezu[1]; and D.R.J. Singer[1,2,3,4]
[1]King Faisal Referral Hospital, Kigali, Rwanda; [2]University of Rwanda, Kigali, Rwanda; [3]Human Resources for Health Program, Rwanda; and [4]Yale School of Medicine, New Haven, Connecticut, USA

Background: Pharmacovigilance is important for patient safety however adverse drug reactions (ADRs) are under-reported in Sub-Saharan Africa.

Aims: We aimed to encourage ADR reporting and to assess ADR patterns at our major referral hospital.

Methods: We used WHO and Ministry of Health ADR reporting protocols, including causality reviews, to identify suspected harmful responses to one or more medicines, prescribed, OTC or traditional, known or new.

Results: We audited ADRs prospectively over four weeks in October 2014. We identified ADRs in 9 in-patients (age 25–62 years, median 43.5 years; 4 females) from Internal Medicine, Surgery and ICU. A single drug-associated ADR was seen in five: chlorpromazine-hypotension, colchicine-vomiting, cloxacillin-bronchospasm, amphotericin B-severe hypomagnesemia; hypokalemia and indapamide causing severe hypokalemia. Implicated drugs were stopped (and replaced if necessary), and symptomatic treatment was provided. Drug-illness interactions were observed in 3: lower GI bleed in a 57M with proximal DVT, metastatic colon cancer, and HIV/AIDS, on warfarin for 8 months; acute gouty arthritis, hyperkalemia, and severe acute on chronic kidney injury in a 51M with dilated cardiomyopathy and cardio-renal syndrome, on furosemide, hydrochlorothiazide, carvedilol, losartan and spironolactone; renal failure (normal sized kidneys) after 2 weeks high dose diclofenac postoperatively in an ANA +ve 54F. Drug-drug interactions were suspected in 3: 57M – fluconazole interacting with new HAART (atazanavir/ritonavir/abacavir) to cause acute liver failure; furosemide and hydrochlorothiazide-associated hyperuricemia in 51M; elevated liver transaminases in 41F on fluconazole and anti-TB therapy (rifampicin, isoniazid, pyrazinamide, ethambutol).

Conclusions: We raised awareness of ADR reporting at our centre. Key patterns for suspected ADRs included drug-drug interactions and drug-illness synergistic adverse effects. We aim next to assess impact of ADRs on morbidity, length of hospital stay, and associated costs, and how increased focus on ADR reporting may reduce preventable morbidity and costs.

PHARMACOVIGILANCE IN KYRGYZSTAN: THE CURRENT SITUATION

A.Z. Zurdinov[1,2]; G.A. Kulushova[2]; S.R. Moldoisaeva[3]; and A.A. Zurdinova[4]
[1]Department of Drug Supply and Medical Devices under Ministry of Health, Bishkek Kyrgyzstan; [2]Kyrgyz State Medical Academy,

Bishkek Kyrgyzstan; [3]Ministry of Health, Bishkek Kyrgyzstan; and [4]Kyrgyz-Russian Slavic University

Introduction: Well-known that the medicines safety issues has been required increasing attention worldwide. As for Kyrgyzstan pharmacovigilance has been established since 2002 only. Well organized pharmacovigilance system is the base for rational and safely use of medicines and more over is the base for optimization of health facility's operation. Objective of this work is to evaluation of frequency and severity of adverse drug reactions (ADRs) and highlighting the importance of medicines safety issues in health system.

Methods: Spontaneous reporting method and retrospective analysis of medical cards of hospital patients have been used. Statistical analysis has been done by MS Excel 2010.

Results: A total of 11,630 medical cards of patients in 10 hospitals of country were analyzed; only 5 cases of ADR were registered, that is the proof of apparent lack of doctor's activities on that direction. From our view it is due to the low awareness of majority medical professionals on the need to informing about ADR (91%). Also, another reason of low registration of ADRs is the limited knowledge on recognition the events associated with use of medicines (72%). It must be noted that the active implementation of pharmacovigilance has been initiated since 2013. Out of total 666 reports have been received from the period of 2002 to 2014, 30% have been received in 2013-2014. The main parts of ADRs were due to use of antibiotics (37%), anti-TB drugs (10.5%), vaccines (10.3%). 40.4% of reports due to use of injection medicines.

Conclusion: The current situation of pharmacovigilance is not fully effective, so by nowadays there is no reliable statistical data on ADRs. The situation on pharmacovigilance has been improving since 2013 as a result of organizational and educational activities held, that is proving there is a need of further more focused and regular activities at all levels of health care system.

EARLY USE OF ULINASTATIN REDUCES MULTIORGAN DYSFUNCTION (MODS) IN SEPTIC SHOCK FOLLOWING ANASTOMOTIC FAILURE

A.H. Choudhuri[1]; R. Tyagi[2]; R. Tyagi[2]; D. Agarwal[2]; and R. Uppal[1]

[1]GB Pant Institute of Post Graduate Medical Education & Research, New Delhi, India; and [2]Pushpanjali Hospital, Agra, India

Introduction: Anastomotic failure is a serious complication after major abdominal surgery resulting in septic shock and death. Early intervention can reduce the adverse outcomes in septic shock. Ulinastatin is a potentially effective intervention to attenuate the systemic inflammatory response induced by sepsis.

The aim of the present study was to compare the effects of early (<48 hours) versus late (>48 hours) use of Ulinastatin on the outcome of septic shock following anastomotic failure after major abdominal surgery.

Methods: One hundred four patients developing anastomotic failure after major abdominal surgery in two multispecialty hospitals in India between October 2012 and May 2014 were included in the study. The patients receiving Ulinastatin within 48 hours of the onset of septic shock (Group A; n = 37) were compared against those receiving Ulinastatin after 48 hours of the onset of septic shock (Group B; n = 31) and control (Group C; n = 36). The primary outcome was mortality at 28 days. The secondary outcomes were duration of mechanical ventilation, length of ICU stay, use of vasopressors and occurrence of MODS according to the SOFA (sequential organ failure assessment) score. Intention to treat (ITT) analysis was performed. Comparisons between groups of categorical data were performed using the two-tailed Fisher's exact test and comparisons between groups of continuous data were performed using the Mann-Whitney U test. The data were analyzed using SPSS Version 15 for Windows (SPSS Inc., Chicago, IL, USA).

Results: Demographics and illness severity were similar between the groups. The 28 day mortality was similar in all the groups (37.2% vs. 37.8% vs. 40.5%), as were ICU length of stay (8.7 days vs. 8.9 days vs. 10.2 days) and duration of mechanical ventilation (4.2 vs. 4.0 days vs. 4.9 days). More patients in the late Ulinastatin and control groups developed MODS (52.9% vs. 44.5% vs. 24.7%, $P < 0.001$) than early Ulinastatin group. There was also overall reduction in the total vasopressors usage in both early and late Ulinastatin groups over control group (54.3 % vs. 56.7% vs. 79.8%; $P < 0.001$). There were no increases in the overall side-effects between the groups.

Conclusion: Our study found that early use of Ulinastatin (<48 hours) reduces the occurrence of MODS in patients with septic shock following anastomotic failure.

TOWARDS A MORE EFFICIENT AND EFFECTIVE USE OF PSYCHOTROPIC DRUGS IN NURSING HOMES: A QUALITY IMPROVEMENT PROJECT IN BELGIUM

M. Azermai[1]; D. De Meester[2]; L. Renson[2]; D. Pauwels[2]; H. Warie[2]; and M. Petrovic[1]

[1]Ghent University, Ghent, East Flanders, Belgium; and [2]Leiehome, Drongen, East Flanders, Belgium

Introduction: *'Working towards a more efficient and effective use of psychotropic drugs'* was a quality improvement project, funded by the Belgian government. The goal was to reduce the high psychotropic drug use through education and sensitization of all actors.

Methods: This was a pilot project (2013-2014) with a pre-post design in two residential care centers. The intervention group received an educational trilogy given by experts on psychotropic drugs, as well as one-on-one professional support. The control group received education-only without professional support afterwards. Drug use was recorded and coded according to the Anatomical Therapeutic and Chemical classification. Included psychotropics were antipsychotics, antidepressants and benzodiazepines. Measurements were done at 3 time-points: at baseline (pre), after 10 months (post) and after 1 year (follow-up).

Results: Residents' (n = 119) had a mean age of 82 years, of which 71% were female. The mean drug use was 9 (range 1-21). Most commonly used drugs were central nervous system drugs (88%). At baseline (intervention group), the prevalence of psychotropic drug use was 72.3% (range 1-6). There was a significant reduction (<0.001) after the intervention, with a remaining prevalence of 60.5%. The overall mean drug use decreased to 8 (range 0-20). The comparison of pre versus post-measurements (intervention group) showed a strong decrease for benzodiazepines: 50% vs. 38%, followed by antidepressants 42% vs. 36%. The decrease of antipsychotics was less strong: 21% vs. 17%. In the control group (with education-only), there was a modest reduction of the psychotropic drug use: benzodiazepines 58% vs. 53%, antidepressants 44% vs. 41%, and antipsychotics 30% vs. 28%.

Conclusion: This improvement project led to a significant decrease in the use of psychotropic drugs, even after 1 year follow-up. Education only had a very limited effect. The person-centered approach offered by the project staff was of a great value.