



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

ABSTRACTS

**12th ISoP Annual Meeting
'New Landscapes for Pharmacovigilance'
Cancun, Mexico
30 October–2 November 2012**



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.

Countries where there are ISoP members:

From Argentina to USA, from Europe to Asia and Australia, we have members in all five continents.

“By becoming a member of ISoP, you will have the opportunity to share your knowledge and ideas and to contribute to improving pharmacovigilance activities worldwide.”

Alexander Dodo, President of the International Society of Pharmacovigilance

ISoP Membership incentives include:

- Biannual newsletters (ISoP Star)
- Training workshops
- Reduced fees for Annual Meeting and training course
- Discounted subscription to the *Drug Safety* journal
- Other offers/discounts on books

For more information you can visit www.isoponline.org, the Society's official website

International Society of Pharmacovigilance

ISoP Secretariat Ltd

140 Emmanuel Road, London SW12 0HS, UK

Tel and Fax: +44 (0)20 3256 0027

administration@isoponline.org

ISoP 2012 Local Organising Committee

Chair: Everardo Vazquez

Co-Chair: Alejandra Rosete

Marina Altagracia
Eduardo Arroyo
Ilian Arsof
Isabel Badillo
Alfredo Barrera
Gilberto Castaneda
Luis Felipe Cortés
Claudia Anette Montejo
Israel Ramírez
Mireya Salinas
Miriam Sánchez
Ventura Sánchez
Alejandro Zamorano

ISoP 2012 Scientific Committee

Chair: Luis Alesso (Argentina)

Co-Chair: Luis Felipe Cortés (Mexico)

Ulrich Hagemann (Germany)
Raquel Herrera Comoglio (Argentina)
Judith K. Jones (USA)
Yola Moride (Canada)
Ugo Moretti (Italy)
Eugène van Puijenbroek (the Netherlands)
Anthony Wong (Brazil)

Training Committee

Hervé Le Louet (France)

Deirdre McCarthy (Ireland)

ISoP 2012 Poster Prize Committee

Luis Felipe Cortés

Deborah Layton

Yola Moride

ISoP Executive Committee 2009-2012

Alexander Dodoo, *President* (Ghana)

Marie Lindquist, *Vice-President* (Sweden)

Eugène van Puijenbroek, *Secretary-General* (the Netherlands)

Deirdre McCarthy, *Treasurer* (Ireland)

Mira Harrison-Woolrych, *Vice-Secretary/Vice-Treasurer* (New Zealand)

Luis Alesso (Argentina)
Elliot Brown (UK)
Ulrich Hagemann (Germany)
Hervé Le Louet (France)
Ugo Moretti (Italy)
Yola Moride (Canada)
Nicholas Moore, *Past-President* (France)

Demographic data, comorbidities and medications were asked. Coronary artery disease (CAD) was defined as a history reported by the patient or documented in the medical history of unstable angina, myocardial infarction, chronic stable angina, coronary angioplasty or coronary artery bypass grafting. The presence of cerebrovascular disease (CVD) (stroke or transient ischemic attack) was defined by history or the questioning of the patient.

Results: We analyzed a total of 1045 patients (67.9 ± 0.6 years, male: 44.4%) of whom 183 patients had a history of CAD or CVD (17.5%) and 10 patients (1.0%) peripheral vascular disease alone. Of the 852 without such antecedents 130 took aspirin as PP. Fourteen of these patients had a higher aspirin dose to 100 mg/day. Patients who were receiving aspirin for PP were older (76 ± 1 vs $64. \pm 1$; $p < 0.0001$) and had a higher prevalence of arterial hypertension (64.6% vs 37.7%; $p < 0.0001$), diabetes mellitus (24.6% vs 8.9%; $p < 0.0001$) and dyslipidemia (40.8% vs 22.0%; $p < 0.0001$). Of these patients, 10 were admitted for bleeding associated with aspirin and 3 were taking 325 mg/day.

Of the 183 patients with a history of CAD or CVD only 113 (61.7%) received antiplatelet therapy. In this group, 6 of 113 patients had bleeding. The seventy (38.3%) patients not receiving antiplatelet therapy had no clinically significant differences with patients if they received. In SP, only 80 (43.7%) were taking a statin.

Conclusion: In our population the use of aspirin in PP was not without risk. In almost 1/3 of these patients who bled the dose was higher than recommended. We observed a significant underutilization of antiplatelet agents and statins in SP that reached 38% and 56%, respectively.

P102. Hospital Pharmacists' Attitudes Concerning Antibiotic Resistance: A Pilot Study

F. Roque,^{1,2,3} S. Soares,¹ L. Breitenfeld,⁴ A. Figueiras⁵ and M.T. Herdeiro^{1,6,7}

1 Center for Cell Biology, University of Aveiro (CBC/UA); 2 Research Unit for Inland Development, Polytechnic Institute of Guarda (UDI/IPG); 3 University of Beira Interior (UBI), Portugal; 4 Health Sciences Research Centre, University of Beira Interior (CICS/UBI), Portugal; 5 University of Santiago de Compostela, Santiago de Compostela, Galicia, Spain. Consortium for Biomedical Research in Epidemiology & Public Health (CIBER en Epidemiología y Salud Pública - CIBERESP), Spain; 6 Center for Health Technology & Information Systems Research (CINTESIS/FMUP); 7 Health Technology Research Center (CITS/CESPU), Portugal

Background: The World Health Organization has defined antimicrobial resistance as one of the main concerns of public health for the next years.^[1] It is important that international community embrace efforts to reduce the tendency of the rise of resistance and to diminish prevalence of resistant pathogens.^[2] The increasing rate of antimicrobial pathogens along with the lower number of new drugs entering the market, if there is no intervention, can be the source of the increasing rates of morbidity and mortality due to bacterial resistance.^[3]

Aim: This study sought to evaluate a questionnaire' reproducibility and internal consistency about attitudes and knowledge of pharmacists working in hospital pharmacy concerning antibiotic use and bacterial resistance.

Methods: The study covered a group of pharmacists working in hospital environment, situated in the North Health Region Administration (ARS-Norte), comprising five geographical districts. Questionnaires were distributed to each health professional in two different moments, separated by two to four weeks. Attitudes were evaluated using a Visual Analogic Scale (VAS), with answers being scored between zero (totally agree) to 20 (totally disagree). It was calculated the Cronbach's Alpha

(to study internal consistency) and the Correlation Intraclass Coefficient (ICC) for reproducibility evaluation.

Results: The pilot-study comprised a sample of 29 pharmacists. Questionnaire evaluated 17 attitudes and knowledge about antibiotic resistance and dispensing practice of pharmacists. Attitudes were grouped in four dimensions: perception of the problem, attribution of responsibilities, confidence and factors associated to dispensing habits. The evaluated attitudes demonstrated good ICC for each question and the value of the Cronbach's alpha (reliability) was 0.925.

Conclusion: Questionnaire revealed to be reproducible and consistent, allowing its use on the evaluation of attitudes and knowledge of hospital pharmacists. Designed questionnaire demonstrated to be valid, allowing to detect some differences between hospital pharmacists' attitudes related to dispensing practice and antibiotic resistances. This study is a preliminary phase of an intervention designed with the results obtained by questionnaires' analysis on attitudes, knowledge and practices of hospital pharmacists, aiming to improve antibiotic use by these health professionals.

References

- OMS (2012). From <http://www.who.int/en/>
- Goosens H, Ferech M, VanderStichele R, et al. Outpatient antibiotic use in European association with resistance: a cross-national data base study. *Lancet* 2005; 365: 579-85
- Weber JT. Appropriate Use of Antimicrobial Drugs: a better prescription is needed. *JAMA* 2006; 294 (18): 2354-6

P103. Adverse Drug Reactions as a Reason for Admission to an Internal Medicine Ward among the Oldest Old

G.A. Keller,¹ V. Castro,² G. Di Girolamo,¹ F. Brill,³ G. Parejas,⁴ I. Gomez,³ C. Soler,³ I. Minvielle,³ C. Lopez Saubidet³ and P.A. Alvarez³

1 Pharmacovigilance Unit, Second Chair of Pharmacology, School of Medicine, Universidad de Buenos Aires. Ciudad Autónoma de Buenos Aires, República Argentina; 2 Pharmacy Department, Centro de Educación Médica e Investigación Clínica Dr. Norberto Quirno (CEMIC). Ciudad Autónoma de Buenos Aires, República Argentina; 3 Internal Medicine Department, Centro de Educación Médica e Investigación Clínica Dr. Norberto Quirno (CEMIC). Ciudad Autónoma de Buenos Aires, República Argentina; 4 Pharmacy Department, Centro de Educación Médica e Investigación Clínica Dr. Norberto Quirno (CEMIC). Ciudad Autónoma de Buenos Aires, República Argentina

Background: The significant burden of adverse drug reactions among elderly patients has been reported.

Aim: Describe the burden of adverse drug reactions (ADR) among the oldest old (80 years-old or older) and identify drugs that may increase the risk of being admitted to an Internal Medicine ward.

Method: We assessed every patient admitted to our Internal Medicine ward in a University Hospital in Buenos Aires, Argentina between August 2010 and February 2012 to determine if an ADR has been the cause of admission. Within 24 hours of admission the patient was interviewed and examined by a staff physician who was part of the pharmacovigilance team and a pharmacist. If after reviewing patient history and complementary studies an ADR was suspected causality was analyzed according to WHO criteria. In addition Proportional Reporting Ratio (PRR) was calculated to identify drugs that may predispose patients for being admitted to an Internal Medicine ward.

Results: Over 18 months 362 patients who fulfilled the definition of oldest old were admitted to our Internal Medicine Ward. Mean age