Clinical pharmacy and clinical trials

**CPC-103 PHARMACIST-MANAGED INSULIN TITRATION VERSUS STANDARD CARE IN A VASCULAR SURGERY UNIT**

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**Background** Hyperglycemia is a prevalent situation in hospitalised patients and it has been associated with higher morbidity and mortality. Poor glycemic control is related to higher costs due to longer hospital stays and higher rates of complications. A large percentage of vascular surgery patients in our hospital have diabetes mellitus with a poor glycemic control.

**Purpose** To assess the impact of a collaborative, pharmacist-managed insulin titration programme compared to standard medical care on glycemic control in patients with neuropathic diabetic foot ulcers in vascular surgery unit.

**Materials and Methods** It was established a new protocol to control glycemic levels in hyperglycemic patients in our hospital. To assess its effectiveness a prospective cohort study to compare pharmacological intervention of insulin titration to standard medical care was implanted. 30 patients were recorded and evaluated, 15 subjects were included as control (standard medical care before implantation of insulin protocol) and 15 in the pharmacist-managed group (insulin titration programme). Patients were selected consecutively on admission to the vascular surgery unit, the control group, one month prior to the implementation of the protocol and the rest one month later. In both groups it was registered: age, diabetes mellitus type, blood glucose levels, diet and drug treatment. Student t test was used to evaluate the glycemic values between groups.

**Results** Both groups were analysed and compared: 67% of subjects from control group were men vs 92% from the intervention group. No significant differences were found in the composition between both groups (p > 0.05) respect of age, diabetes mellitus type and diet. The pharmacist-managed group showed a lower glycemic level compared to standard medical care group (123 mg/dl vs 170 mg/dl respectively; p < 0.044). The hyperglycemic levels were more frequent in control group than intervention group (78% vs 35%). No statistics differences were found with hypoglycemic situations (2% vs 4.5% p = 0.1).

**Conclusions** At the end of the study period, the intervention group patients had better glycemic control. Pharmacist-provider collaboration can result in significant clinical improvements when compared to standard care glycemic control in diabetic patient in a surgical unit.

No conflict of interest.

**CPC-104 PHARMACISTS AND CLINICAL TRIALS: PERSPECTIVES AND RESULTS AT THE MEDICAL ONCOLOGY OPERATIONS UNIT OF THE G. RUMMO HOSPITAL, BENEVENTO**

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**Background** The rules on Controlled Clinical Trials require the expertise of a pharmacist specialising in internal monitoring of ongoing trials in the Operations Unit.

**Purpose** To highlight the role of the pharmacist dedicated to research projects, who sees that trials are conducted in accordance with GCP and in compliance with applicable regulations.

**Materials and Methods** From January 2010 the pharmacy has created a database to monitor all studies approved by the Ethics Committee, both observational and experimental. Having a dedicated pharmacist has led to: proper storage of drugs, completing the application form accompanying the samples, storage of electronic and paper documentation of the experimental samples, fitting directly in Pharmacy, randomization of patients enrolled and completing the Drug Accountability.

**Results** 40 clinical trials have been conducted, 26 of which were conducted in the Oncology OU, 8 in Pulmonary and 8 in Cardiology, 1 in Rheumatology, 2 in Dermatology. As regards the preparation of the antiblastic treatments, the treatment setting provided by the experimental protocols accounted for 5% of all cancer preparations performed in the pharmacy. 53% of the studies (53 studies) were for profit, non-profit research accounted for only 17% of the studies. In 2012 the number of for-profit studies increased compared to 2010; we hope these will be particularly useful to point out any problems of current clinical practice.

**Conclusions** The dedicated pharmacist can ensure that research is conducted properly, both the management of experimental drugs and collaboration with the clinical evaluations related to routes of administration, any incompatibilities, monitoring of side effects and/or adverse events, interactions with associated therapies. In conclusion it is evident that the multidisciplinary approach and sharing of expertise with the medical and nursing staff encourages adherence to protocols.

No conflict of interest.

**CPC-105 PHARMACOECONOMIC ASPECTS OF THE TREATMENT OF RHEUMATOID ARTHRITIS WITH TUMOUR NECROSIS FACTOR ALPHA ANTAGONISTS: A SOCIETAL PERSPECTIVE**

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**Background** Rheumatoid arthritis (RA) is an autoimmune disorder, affecting 1% of the population, characterised by pain, joint swelling and progressive destruction of joint tissue. EUULAR (European League Against Rheumatism) recommends the use of Tumour Necrosis Factor alpha antagonists (anti-TNFα) if methotrexate or Disease Modifying Antirheumatic Drugs fail. Anti-TNFα treatment imposes a significant financial burden on hospital budgets.

**Purpose** To perform a pharmacoeconomic investigation in the Piedmont region (Italy) to identify the cost of the illness RA. To analyse the payer’s and societal perspectives, investigating direct costs associated with health care use and indirect costs related to productivity loss.

**Materials and Methods** A multidisciplinary group, rheumatologists, hospital pharmacists and pharmacoeconomists, was established to perform a pharmacoeconomic evaluation of the direct and indirect costs of RA, by a systematic literature review. Afterward, we plan a perspective, observational, multicentre, cost-effectiveness analysis of RA biological drugs, involving 100 patients. Each patient will be recorded, every three months for one year, through personal data, disease duration and characterization, systemic manifestations and comorbidities, prescribed biological medicines. A questionnaire will be submitted, in order to assess direct and indirect costs.

**Results** 40 existing pharmacoeconomic evaluations were critically appraised: the overall mean costs of RA amounted to about €15,000 per year, while the direct annual costs of RA were on average about €4,000. The greatest burden of RA costs was the indirect costs. From a societal perspective the superior clinical outcomes achieved...