Clinical pharmacy and clinical trials

Conclusions
The results obtained underline the necessity of better awareness of the problem. As far as our centre is concerned, the results led us to hold meetings with the physicians and to plan interventions in order to make them aware of the problem and in order to start a process of pharmacovigilance with compassionate-use drugs.

No conflict of interest.

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Abstract CPC-034 Table 1

<table>
<thead>
<tr>
<th>N (R-CHOP)</th>
<th>% Pt_PP</th>
<th>% Pt_FN</th>
<th>% Cycles_FN</th>
<th>Incidence_FN_1*Cy</th>
<th>Incidence_FN_other Cy</th>
<th>AvrDays_Hosp/FN episode</th>
<th>AvrDays to ANC recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>RMP 75</td>
<td>37.3 (28/75)</td>
<td>28.6 (8/28)</td>
<td>7.7 (4/181)</td>
<td>0.18</td>
<td>0.06</td>
<td>30 (40)</td>
<td>8.4</td>
</tr>
<tr>
<td>B 104</td>
<td>27.9 (29/104)</td>
<td>24.1 (7/29)</td>
<td>5.9 (10/188)</td>
<td>0.10</td>
<td>0.05</td>
<td>34 (32.7)</td>
<td>9.2</td>
</tr>
</tbody>
</table>

Mean age = 72 y (both); Gender = 46.4%m, 53.6%f (RMP); 31%m, 69%f (B); NHLB = 75% (RMP), 72% (B)

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CPC-035 COMPASSIONATE USE: PHARMAVOGILANCE
doi:10.1136/ehjpharm-2013-000276.492

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Background
The compassionate use of drugs in Italy is a way of using drugs available in foreign countries but not in Italy. They have the authorization for the same therapeutic purpose but are not available on the market, however they are in clinical trials (CTs) or have been tested in phase III or – if the patient is in a critical condition – have been successful in phase II CTs.

As regards evaluating the efficacy of the treatment, a basic aspect of the CT is to evaluate the safety of the drugs used. Great attention is focused on this theme with sponsored CTs; in fact by law (decreto 211/2003) the subjects liable for pharmacovigilance are expressly listed and stress is put on reporting adverse drug reactions (ADRs). Regarding the use of compassionate drugs, there are no laws regulating the reporting of ADRs.

Purpose
To find out how any reports of possible ADRs emerging from compassionate studies are managed in ordinary clinical practice.

Materials and Methods
For this purpose the database used in our organisation was essential: all of our centre’s CTs are listed there. The number of CTs classified by type (for profit, not-for-profit, compassionate) was extracted, focusing on the compassionate use CTs in particular. Then the number of patients treated was drawn from it as well as the pathologies and the ADRs pointed out during meetings with the physicians.

Results
From this analysis it appeared that in our centre 197 studies (st) are active: 147 are for profit, 27 not-for-profit and 23 compassionate. Among these last ones, 8 are active in the sarcoma department, 5 in haematology, 3 in paediatrics, 6 in medical oncology and 1 in urology. The pathologies being examined are: GIST 4 series (st) are active: 147 are for profit, 27 not-for-profit and 23 compassionate.

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CPC-036 CONNECTION BETWEEN BONE FRACTURES, VITAMIN D LEVEL AND LOW-ENERGY FALLS IN HOSPITALISED ELDERLY PATIENTS
doi:10.1136/ehjpharm-2013-000276.493

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Background
The ageing of the population in developed countries is a growing problem today. Prevalence of chronic diseases, such as osteoporosis, increases with age. It is estimated that 900,000 people (9% of the population) above the age of fifty suffer from osteoporosis in Hungary. This condition greatly increases the risk of fractures of vertebra and the hip bone, which often lead to fatal consequences. Many studies have proven that a low vitamin D level increases the risk of bone fractures. Adequate vitamin D level is essential to prevent bone loss and structural damage of the bone matrix, which also prevents fractures.

Purpose
To compare vitamin D levels of hospitalised hip fracture patients with hospitalised non-fractured patients, as well as to detect the prevalence of low-energy falls, and to analyse the differences between the investigated groups.

Materials and Methods
The fractured group was recruited from the Traumatology Department and the control group was recruited from the Internal Medicine Department. The control group was matched according to age and gender. Vitamin D levels were measured with an ELISA kit and were expressed in ng/ml. Subjects were asked about previous falls during a personal interview.

Results
Twenty-two patients were in the fractured group (mean age 84.09 years, SD ± 6.78) and 33 patients were in the control group (mean age 80.52 years, SD ± 6.56). The mean vitamin D level was 33.13 ng/ml in the fractured group and 39.7 ng/ml in the control group. The difference in vitamin D levels was not significant between the investigated groups, other risk factors could be responsible for fractures besides the low vitamin D level. A noteworthy factor may be falls, because more than half of the fractured patients reported multiple falls in the previous year.

Conclusions
Since the difference in vitamin D levels was not significant between the investigated groups, other risk factors could be responsible for fractures besides the low vitamin D level. A noteworthy factor may be falls, because more than half of the fractured patients reported multiple falls in the previous year.

No conflict of interest.

CPC-037 CONTINUITY OF CARE IN PEDIATRIC PATIENTS: PROSPECTIVE STUDY AT HOSPITAL DISCHARGE
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Background
A variety of problems can occur at hospital discharge. Optimization of this multidisciplinary process is essential to ensure a high quality of care.

Purpose
To assess drug problems encountered by paediatric patients at hospital discharge; prospective clinical study.

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Materials and Methods

- Inclusion of French-speaking paediatric patients (<12 years) discharged from the emergency department (ED, collected for 2 weeks) and a medicine ward (MED, collect for 2 months)
- Semi-structured phone interview of parents (drug supply, knowledge of the treatment) at 72 hours
- Questionnaire for community pharmacists

Results

109 patients were included (ED 64; MED 45). 88% were interviewed (ED 88%; MED 89%). 68% of questionnaires were returned to us (ED 59%; MED 89%).

79% of parents said they obtained all drugs immediately (ED 86%; MED 70%). The main reasons for not obtaining a drug were: drug not in stock (50% of cases; ED 38%; MED 58%), and not going to the pharmacy (20%; ED 25%; MED 17%). 65% obtained them later (ED 50%; MED 75%), of which 60% were obtained within a day (ED 58%; MED 50%). The total number of drugs prescribed was 241 (ED 124; MED 117). Global parents’ knowledge of treatment indications (71% of drugs; ED 65%; MED 87%), duration (52%; ED 51%; MED 73%), doses (71%; ED 56%; MED 87%), and frequencies (69%; ED 53%; MED 85%) were good.

Pharmacy questionnaires showed similar results with drugs obtained immediately in 82% of cases (ED 89%; MED 61%). The main reasons for not obtaining drugs were: drug not in stock 48% (ED 38%; MED 58%), and parents’ refusal 10%.

Results

Compared to the emergency department, obtaining all the prescribed medicines was more difficult for patients leaving the medical ward but parents’ knowledge of the treatment seemed to be higher. Interventions to improve drug supply and knowledge of the treatment by parents will be implemented and evaluated.

No conflict of interest.

CPC-038 CURRENT SITUATION ON PRESCRIPTION OF CARBAPENEMES IN GERIATRIC CARE UNITS

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Background

Carbapenems (CBPs) are being used more and more because of the increasing prevalence of extended-spectrum beta-lactamase (ESBL)-producing Enterobacteriaceae. Due to the extensive misuse of these antibiotics, some bacteria have developed CBP-resistant mutations. This epidemiological situation should make us wonder about prescribing CBPs.

Purpose

To describe prescribing patterns of imipenem/cilastatin, ertapenem and meropenem in elderly inpatients: context and impact of an interdisciplinary approach to prescriptions analysis.

Materials and Methods

A retrospective study of CBP prescriptions was performed over a ten-month period (March-December 2011) in geriatric departments (313 beds). Data were collected from the electronic medical records, bacteriological analysis results and email exchanges between the infectious diseases physician (IDP), bacteriologists and pharmacists (prescription monitoring system). The following items were noted: patients, prescriptions and bacteriological characteristics.

Results

85 patients were included with a total of 61 CBP prescriptions. The mean age was 83 (sex ratio 0.72). 71% of patients accumulated between 2 and 5 risk factors of multidrug resistant bacteria. Imipenem was the most-used carbapenem (n = 35; 57%) compared to ertapenem (n = 23; 38%) and meropenem (n = 3; 5%).

Major indications were urinary tract infections (n = 37; 61%) and pneumonia (n = 15; 25%). 59% of infections were nosocomial. 39% of CBP prescriptions were written after a first-line antibiotic had failed (ceftiraxone most of the time). The overall duration of carbapenem therapy was 11 days. Microbiologically-documented infections and ESBL bacteria accounted for 69% (n = 42) and 51% (n = 24) of prescriptions, respectively: 5 of the ESBL strains isolated were community-acquired bacteria. 61% (n = 38) of prescriptions were reassessed by an IDP. 29 (76%) were in accordance with recommendations; 7 (18%) were stopped or changed for a narrow-spectrum antibiotic.

Conclusions

CBP prescriptions seem relatively well controlled in geriatric care units due to multidisciplinary analysis of the prescriptions. Nevertheless, evaluation of the impact of monitoring prescriptions for use of CBPs requires longer follow-up.

No conflict of interest.

CPC-039 DELPHI APPROACH TO DEFINING AND CONTEXTUALISING MEDICINES WASTAGE IN THE MALTESE POPULATION

doi:10.1136/ejhpharm-2013-000276.496

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Background

Reducing wastage, including medicines wastage, is a paramount objective in promoting appropriate use of finite resources and preventing negative consequences. A systematic review of the published research on medicines wastage identified a lack of standard terminology and definitions.

Purpose

The aim of this study was to apply an expert panel approach to achieve consensus in defining ‘medicines wastage’ in the context of the Maltese population.

Materials and Methods

The Delphi technique, a multi-staged survey attempting to achieve consensus, was employed. An expert panel comprising 26 professionals and six patients was recruited and communicated by email. Round 1 had initial open-ended questions on the panel’s understanding of the term ‘medicines wastage’ along with views on factors likely to be associated with wastage. Responses were analysed thematically. In round 2, respondents were requested to rank eight definitions of ‘medicines wastage’ in order of preference. Themes related to associated factors were presented as 5-point Likert statements.

Results

The first two rounds of data collection are complete. Twenty-seven consented to participate, 23 of whom have responded to both rounds. Of the eight options for defining ‘medicines wastage’, the highest ranked was ‘…refers to any medicine which expires or remains unused throughout the whole medicines supply chain. It also refers to the unnecessary or inappropriate consumption of medicines by patients, or the unjustified non-adherence to treatment guidelines by healthcare professionals. Medicines wastage imposes a financial burden on patients themselves and the state’s economy and requires adequate education of all people concerned.’ Themes related to factors associated with wastage included: physical/environmental; social/psychological (patient/practitioner); and cultural.

Conclusions

This research has generated a definition of ‘medicines wastage’ and a series of associated statements for further investigation. The research process followed in this study can easily be adapted and is therefore also highly relevant to hospital pharmacy practise across Europe.

No conflict of interest.