ABSTRACT REVIEW

BARI4-0006
Pharmacological interactions revision of oral chemotherapy drug dispensed in a pharmacy department

Co-authors
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1juan ramón jiménez, pharmacy, huelva, Spain.

Background
Pharmacological interactions are an important, sometimes unrecognizable, possible threat; clinical pharmacist has an important role identifying and assessment to clinical doctors in order to prevent possible adverse damage. In Spanish outpatient units oral chemotherapy prescriptions are reviewed at dispensing time; it is when pharmacist has the opportunity to improves clinical results.

Purpose
To identify the pharmacological interactions of oral chemotherapy dispensed by a pharmacy department.

Materials and Methods
Oral chemotherapy drugs used in the last four years were identifying. For every single case, a bibliographic search were done, looking for pharmacological interactions in MEDLINE®, EMBASE®, Up-to-date®, MICROMEDEX®, and drug information from EMA y FDA. National and International meeting abstract book were reviewed too. When a pharmacological interaction were important, the best alternative were searched too.

Results
22 drugs were analyzed: abiraterone, capecitabine, chlorambucil, dasatinib, erlotinib, fludarabine, gefitinib, imatinib, lapatinib, lenalidomide, melphalan, mersaptoturpine, nilotinib, pazopanib, sorafenib, sunitinib, talidomide, tegafu, temozolamide, topotecan, tretinoin and vinorelbine.

Fludarabine, chlorambucil, lenalidomide and melphalan are the drug with the less probability of pharmacological interactions. The tyrosine kinasa inhinitors (especially ertitinib, imatinb, lapatinib and pazopanib) were the drugs with more pharmacological interactions describes, most of them with severe possible clinical consequences. Increase and decrease of plasma levels of oral chemotherapy is deeply describe for most of oral anti-neoplasic drugs.

Usual drugs used in oncohematology patients with possible pharmacological interactions were: allopurinole, warfarin, digoxine, spironolactone, phenytoin, carbamazepine, silodosine, dabigatran, amiodarone, tamoxifen, itraconazole, verapamil and repaglinide.

Pharmacological interactions through cytochrome P450 1A2, 2D6, 2C8, 2C9, 3A4 were the most important for tyrosine kinasa inhibitors. No drugs with pharmacological activity, and important interactions were: inmunomodulators (extracts of equinacea) and hypericum perforatum

Conclusions
Oral chemotherapy has several important pharmacological interactions that should be known. Hospital pharmacist has a privileged role in identifying and assessment of pharmacological interactions with possible clinical consequences.

No conflict of interest

Keywords
oral-chemotherapy/Pharmacological interaction/safety;

Authors letter
Oral chemotherapy has several important pharmacological interactions that should be known. Hospital pharmacist has a privileged role in identifying and assessment of pharmacological interactions with possible clinical consequences.

Score: 100

Remarks all reviewers:
Hoppe-Tichy, Torsten: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
Nominee: No

I could accept this, when the authors add numbers. We have to know, how often which interaction occurs.
Otherwise it has to be rejected as nothing new, because we all can use textbooks etc. to look for interactions.

Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Rejected
2.5.6.8.10.
BAR14-0020  
Pemetrexed in patients with non-small-cell lung cancer: changes in use profile in Andalusia  
Co-authors  
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Background  
Pemetrexed is currently considered alternative first-line treatment of non-small-cell lung cancer (NSCLC), but the number of alternatives uses in different situations and the possibility of subpopulations that could get an additional benefit to this type of therapy makes its use controversial.  

Purpose  
To determine the pemetrexed use profile in 2010 and 2011 in locally advanced or metastatic NSCLC patients in Andalusia (Spain) and analyze the variation between the two periods.  

Materials and Methods  
Retrospective and descriptive study. Inclusion criteria: adult patients diagnosed with locally advanced or metastatic NSCLC who received chemotherapy with pemetrexed in the first term of 2010 and the last term of 2011 in Andalusia, a 8.5 million population Spanish region (2012 census data). Data collected: age, sex, smoking habits, renal function, tumor histology and stage, pemetrexed indication and ECOG (Eastern Cooperative Oncology Group) performance status at the start of the treatment. Pemetrexed use profiles were described and analyzed for both periods.  

Results  
89 and 156 patients from 16 hospitals were included in 2010 and 2011, respectively. The mean age was 62 ± 11 years. 74% were men. All of them had adequate renal function and 80% had been smokers at some point in their lives. The predominant histology was adenocarcinoma (85%). At the start of the treatment 88% had stage IV tumor and 52% ECOG 1. Pemetrexed indications were: first line combined with platinum in 27% (2010) and in 36% (2011); first line combined with platinum and maintenance with pemetrexed in 21% (2010) and in 20% (2011); second line monotherapy in the 14% (2010) and in the 9% (2011); maintenance in patients whose disease has not progressed immediately following a platinum-based regimen in 14% (2010) and in 9% (2011); None of the above in the 24% (2010) and in the 26% (2011).  

Conclusions  
Pemetrexed combined with platinum is used mainly as first-line treatment in patients with stage IV adenocarcinoma and ECOG 1. The use profile is similar in both periods, but a higher percentage of patients received this drug off-label in 2011.  

No conflict of interest  

Keywords  
Pemetrexed; use; profile;  

Authors letter  
(1) Pemetrexed is a recently marketed drug with a high economic impact on national health systems.  
(2) This study is part of a research program project that evaluate effectiveness, safety and changes in pemetrexed use profiles in Andalusia over the last two years.  
(3) It would be necessary to update and adequate clinical guidelines and oncologic chemotherapy protocols according to the patient profiles and study all of the off label drug uses deeply.
BAR14-0021

Evaluation of axitinib treatment in patients with renal cell carcinoma

Co-authors
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1Hospital Universitario Virgen del Rocío, pharmacy, Seville, Spain.

Background
Axitinib is a VEGFR-1,-2 and -3 inhibitor, one newly introduced oral cytostatic to treat renal cell carcinoma (RCC) that was accessible through expanded use program to the marketing authorization.

Purpose
To analyze the effectiveness and safety of axitinib treatment in patients with RCC in a tertiary hospital.

Materials and Methods
A retrospective descriptive study of patients taking axitinib from November 2012 to April 2013. The following information was collected: demographic (gender and age), basal situation (performance status (PS), diagnosis and staging), dose of axitinib, pretreatments, effectiveness (response rate and overall survival after four months) and adverse reactions. The information sources were the electronic health record. The SPSSv20.0 program was used.

Results
7 patients were recruited. 3(42.8%) were women. The mean age was 57.8(32-71). Basal situation: 2 patients had a PS of 0, 4 had 1 and 1 had 2.6 patients were diagnosed with clear cell carcinoma and the other one with papillary carcinoma, all of them in IV stage. All patients received axitinib 5mg/12hours. A total of 5(71.4%) patients had also received one other prior therapy regimen, and 2(28.6%) patients had been treated with at least two prior regiments. Pretreatments: the majority of the patients 4(57.1%) received sunitinib before starting axitinib therapy, 2(28.6%) received pazopanib and everolimus and 1(14.3%) received only pazopanib. Effectiveness: the response rate was stable disease (n=3;48.8%), partial response (n=2;28.6%) and no response (n=2,28.6%). The global survival rate after 4 months was 57.1%. Safety: the most frequent adverse reactions was: mucositis(n=5;%), diarrhea(n=3;%), asthenia(n=3;%), hypertension(n=2;%) and rash(n=2;%). One patient had a reduction to 5mg/24hours.

Conclusions
Due to the low number of patients recruited the effectiveness of the treatment cannot be demonstrated. Nevertheless, it is important to highlight that 2 out of 7 patients have partial response and 3 out of 7 have stable disease. Gastrointestinal problems were the most frequent adverse reactions.

No conflict of interest

Keywords
axitinib; effectiveness; security;

Authors letter
1. Axitinib is a new developmented drug with promising results 2. There is little knowledge about this drug and this case report provides effectiveness and security information 3. This drug could be a therapeutic choice to treat renal carcinoma

Score: 160

Remarks all reviewers:
Hoppe-Tichy, Torsten: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No

It’s a new drug, so it could be of interest despite the low number of patients.
Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Accepted, but author modifications
1. Modifications needed:
Nominee: No

*expanded use program* or "parallel trial"? this would explain the low N = 7. What has been done with SPSS? This app is an overkill with only 7 samples. Please clarify the description of the patients status.
USE OF PRAMIPEXOLE IN RESISTANT-DEPRESSION: ANALYSIS OF ONE-YEAR PRESCRIPTIONS IN A PSYCHIATRY UNIT

Co-authors

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Background

Several studies suggest that pramipexole, a dopamine agonist approved for the treatment of Parkinson's disease and restless legs syndrome, may possess antidepressant properties.

Purpose

The objective is to assess the off-label prescriptions of pramipexole in a psychiatry unit during 2012.

Materials and Methods

Literature review; one year retrospective study in a psychiatric hospitalisation unit; data collection from the medical records: patients' profile and prescription analysis.

Results

Of 16 patients included, 6 are treated for recurrent depression and 10 for bipolar depression. The mean age is 55 years. All have a treatment-resistant depression since an average of 23 years [3-35 years].

The mean maximum dose of pramipexole used is 1.43 mg/day [0.36-4.06 mg/day].

Three quarters of the patients have a concomitant antidepressant medication; one quarter only receives pramipexole added to a mood stabilizer. Furthermore, 6 patients on 16 have electroconvulsive therapy.

Patients are hospitalized for a mean of 56 days among which 34 with pramipexole. It was observed a clinical mood improvement for 13 patients (81%). At endpoint, 10 patients have still pramipexole with a mean dose of 1.12 mg/day [0.36-2.1 mg/day].

Pramipexole is associated with 5 adverse events: 3 hypomanic states that did not fulfill hypomania criteria, controlled by a dose reduction, and 2 brief psychotic episodes requiring to stop pramipexole treatment.

In 2012, 1044 patients were hospitalized in the hospital for unipolar or bipolar depression; about 1% was treated with pramipexole.

These results need to be interpreted with caution because of the small number of subjects and the short time of the analysis. Moreover, our sample is heterogeneous because five patients were already treated with pramipexole before the start of the study.

However, the results are in line with the literature: pramipexole may have antidepressant effects in unipolar or bipolar depression as monotherapy or add-on, but adverse manic effects must be considered.

Conclusions

Pramipexole may be a therapeutic option for treatment-resistant depression. The short-term results are positive but require a close follow-up and more studies are necessary.

Conflict of interest:

Enter Yes or No: No

Keywords

pramipexole; antidepressant; dopamine agonist;

Authors letter

Pramipexole, a drug used for the treatment of Parkinson's disease, might be a therapeutic option for treatment-resistant depression.
Background

Knowledge of stability of intravenous drugs (IVD) administered in hospital is important. Information is published in different scientific journals and not always easily findable.

Purpose

In 1981, a special interest group (SIG) of the Belgian Association of Hospital Pharmacist was formed to collect data concerning the physical and chemical stability of most used IVD in Belgian hospitals.

Materials and Methods

The 1\textsuperscript{st} edition of a «Guide for the administration of drugs by infusion» is published the same year. 20 drugs are described with the following topics: administration (push iv, intermittent or continuous infusion), stability, compatibilities and incompatibilities with iv solutions or other IVD. A new edition is distributed in 1987 and is followed by 3 up-to-date. Recording of the papers is made manually then by electronic way. In December 1991, is distributed the 1\textsuperscript{st} of eleven editions of a manual new entitled 'Stability of injectable drugs in infusion', who give only stability data. The SIG was vanished and it is now a personal work. The number of reviewed drugs amounts to 195. The up-to-date contains more than 500 pages. In 2000, start the publication of a more practical CD-Rom.

Results

The edition 2014 furnish 49,600 data on the stability and (in)compatibilities of 487 drugs alone or in binary, ternary or quaternary mixtures in different types of containers (bags, syringes,...), based on 2,940 references available in the international literature. Interactions with containers and extractions of plasticizers are also mentioned. A review of the stability after microwave freeze-thaw treatment supplements the review.

Conclusions

A new CD-Rom is available each year and it is the 13\textsuperscript{th} that is published at now. It is the result of 32 years of literature review and contributes to the knowledge of stability of IVD by Belgian hospital pharmacist and the quality of patient care.

Conflict of interest:
Enter Yes or No: no

Keywords
database; Intravenous drug stability; Intravenous admixtures;

Authors letter

Each year, an up-to-date CD-Rom is available and send to Belgian Hospital Pharmacists. This database contributes to the knowledge of stability of IVD by Belgian hospital pharmacist and the quality of patient care.

Score: 160

Remarks all reviewers:
Hoppe-Tichy, Torsten:
Rejected
Sorry, but this reads like a commerical.
Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: Yes

English Editing
Background
Romiplostim and eltrombopag have a novel mechanism of action that expands treatment options for idiopathic thrombocytopenic purpura (ITP). Both have proven effective in increasing platelet counts in splenectomized patients.

Purpose
There are no comparative studies, we try to describe their use in clinical practice.

Materials and Methods
Descriptive observational study (January 2011-February 2013) of patients with refractory ITP treated with romiplostim or eltrombopag. Variables analyzed: demographic data; previous treatments; splenectomy status; response to treatment, defined as platelet count ≥ 50x10⁹ / L for at least 8 weeks; number of weeks with continuous response, clinically significant bleeding (grade 2-4 as classified by the World Health Organization); need for rescue medication; adverse effect profile; cost treatment.

Results
Five patients were included (100% women) with a mean age of 62 ± 12.65 years, only one was splenectomized. All received at least two prior lines that included corticosteroids and intravenous immunoglobulins and four also received rituximab.

Of the two drugs, four patients were treated with romiplostim as a first option, with a mean treatment duration of 23.5 ± 20.5 months (3-44 months) and one patient was treated for three months with eltrombopag in front. Romiplostim average dose was 4 mcg / kg (1-10 mcg / kg) administered subcutaneously weekly, two initiated eltrombopag patients with oral 50 mg daily and then increased to 75 mg daily. During the study period, in the romiplostim group three patients achieved a durable response, reaching the target platelet count for an average of 48 ± 39.1 weeks. The other patient in this group received romiplostim five months and did not reach the target despite receiving the maximum recommended dose (10 mcg / kg / week) was changed to eltrombopag, with it reaching levels of 22 x10⁹ / L in the last control. The patient began with eltrombopag switched to romiplostim at 3 months of not meeting the target platelet count (maximum: 20 x10⁹ / L); currently receiving romiplostim dose of 3 mcg / kg / week to levels ≥ 50x10⁹ / L, for four weeks. In none of the cases showed clinically significant bleeding and required no rescue treatment or hospitalization. The safety profile of both drugs was favorable because it did not detect adverse events related to its administration. In the analyzed period consumed a total of 182 units of romiplostim (Nplate ® 250 mcg vial) with a cost of € 110,201. Elntr thrombopag consumption was 84 units Revolade ® 25 mg, cost € 5,775 and 140 Revolade ® 50 mg, cost € 19,250.

Conclusions
In our study, both drugs have proven effective and safe in patients with refractory ITP, can be considered therapeutic equivalents. We should take into account the weight of the patient to assess the most cost-effective alternative; it should also assess the oral administration of eltrombopag

Conflict of interest:
Enter Yes or No: NO

Keywords
romiplostim, eltrombopag; thrombocytopenia;

Authors letter
1) Relevance: The idiopathic thrombocytopenic purpura (ITP) is an autoimmune hematological disorder; antiplatelet antibodies which are formed accelerate destruction of platelets and simultaneously decrease production. As a result, the patient may suffer clinically significant bleeding. 2) Innovation: Romiplostim and eltrombopag have a novel mechanism of action that expands treatment options for idiopathic thrombocytopenic purpura (ITP). They can be used as a second line treatment. 3) Implication for future pharmacy practice: The clinical pharmacist could advise the hematologist to choose the most cost-effective alternative.

Score: 160

Remarks all reviewers:
Hoppe-Tichy, Torsten:
Rejected
1.
Reason for reject:
One cannot get any conclusion for efficacy, safety and similarity if you have only one patient in the one group and 4 in the other.

Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
5.
Modifications needed:
Nominee: No

Word count? Please amend style of numbers (10 exp 9)
Pirfenidone: compassionate use in two patients with idiopathic pulmonary fibrosis

Co-authors
E. Puerta-García1, C. Valencia-Soto1, N. Martínez-Casanova1, J. Pérez-Morales1, A. Madrid-Paredes1, J. Orantes-Casado de Amezua1,
1Virgen de las Nieves University Hospital, Pharmacy, Granada, Spain.

Background
Pirfenidone is currently the only agent approved for mild to moderate idiopathic pulmonary fibrosis (IPF) in adults.

Purpose
The aim of this study was to evaluate the effect of pirfenidone in two patients who met the criteria of use.

Materials and Methods
Follow-up of two IPF cases in a Spanish hospital. The most common parameters used when monitoring IPF are functional vital capacity (FVC) and diffusing capacity or Transfer Factor of the Lung for Carbon Monoxide (TLCO).

Results
Patient 1 diagnosed in 2008. Initial treatment: 20 months of prednisone. Changed treatment in 2009 to triple therapy with azathioprine, N-acetylcysteine (NAC) and prednisone. This regimen lasted 11 months, after which NAC was used in monotherapy. In 2012 a new regimen was started: pirfenidone, NAC and prednisone. This lasted until the end of the observation period. During treatment with corticosteroids, TLCO decreased from 83 to 41%, and FVC from 68 to 52%. With the triple therapy, TLCO changed from 41 to 32% and FVC increased slightly from 52 to 57%. During the treatment with NAC in monotherapy, TLCO values remained at 35% and FVC at 58%. Finally, with pirfenidone, TLCO stabilized between 31% and 34% and FVC remained at 58%.

Patient 2 diagnosed in 2007. Initial treatment: 19 months with triple therapy after which NAC remained in monotherapy for 24 months. Treatment with pirfenidone, NAC and prednisone began in 2012 and continued until the end of the observation period. With the triple therapy regimen, TLCO decreased from 50 to 44% and FVC remained constant (80%). During the NAC monotherapy period, TLCO values ranged from 43 to 42%, with a minimum of 31%. With pirfenidone, TLCO ranged from 37 to 39%, and FVC remained at 91%.

Conclusions
Although the two patients experienced evident stability in breathing patterns, in both cases this stability had been reached with monotherapy. Treatment with NAC and prednisone was started prior to the use of pirfenidone. The results indicated that pirfenidone did not provide evident benefits in the treatment of IPF and its use may not be cost-effective.

No conflict of interest

Keywords
Pirfenidone; compassionate; idiopathic pulmonary fibrosis;

Authors letter
- It is necessary to monitor patients treated with expensive new drugs even though these drugs have been approved in any country of the European Union. - Require special dedication those approved drugs as the only treatment option pathway.

Score: 120

Remarks all reviewers:
Hoppe-Tichy, Torsten:
Rejected
1.
Reason for reject: ;
Just 2 patients
Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Accepted
low N = 2, but clear statement of insufficient added value. This should be stated in the title.

BAR14-0051
Prescription pattern of molecular targeted therapy in metastatic renal cell carcinoma

Co-authors
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1Hospital Clinic, Hospital Pharmacy, Barcelona, Spain.

Background
Several molecular targeted agents (MTA) have been approved recently for the treatment of metastatic renal cell carcinoma (mRCC). However data on the use of these drugs in clinical practice are limited.
Purpose
Describe the prescription pattern of MTA (sunitinib, pazopanib, sorafenib, everolimus, temsirolimus and bevacizumab) in patients with mRCC in a tertiary hospital.

Materials and Methods
Retrospective observational study of all patients who received at least one cycle of MTA for the treatment of mRCC from August 2006 to January 2013. Variables obtained from the computer system included date of birth, sex, tumor histology (predominant clear cell histology (CCH) or non-clear cell histology (n-CCH)), treatment line number and first and last dispensation date.

Results
83 patients, average age of 63 years (SD ± 10.6) (81% male), received at least one dispensation of MTA. 72% of patients showed predominant CCH. The median duration of treatment was 10 months (range 0.4-66.9). Most of the patients with CCH (n=59) received sunitinib (n=42; 71%) or sorafenib (n=10; 17%) as first-line treatment. 24 patients went through a second line: mainly sorafenib (n=9; 38%) and sunitinib (n=6; 25%). 5 patients continued with sunitinib, sorafenib or everolimus as third line. n-CCH patients (n=24) were treated with sunitinib (n=18; 75%), sorafenib (n=3; 13%), or temsirolimus (n=3; 13%) as first line. Eleven patients received a second-line treatment, principally sunitinib (n=4; 36%), sorafenib (n=3; 27%) and temsirolimus (n=2; 18%). A third line was prescribed to 3 patients (2 temsirolimus and 1 sorafenib). Only 3 patients were retreated with the same drug.

Conclusions
Sunitinib, followed by sorafenib are the most commonly used drugs in all lines and histologies of mRCC. Further studies are needed to evaluate the usage tendency after pazopanib’s recent approval.

Conflict of interest:
Enter Yes or No: No

Keywords
Renal Cell Carcinoma; Molecular Targeted Therapy; Drug utilization;

Authors letter
To the Steering Committee, Treatment of metastatic renal cell carcinoma (mRCC) has evolved in the last 5 years thus emerging the molecular targeted therapies. Considering that health care resources are limited, it is very important to know how these new drugs are used in daily practice and if they are prescribed according to International Guidelines. Data on drug pattern use in mRCC are limited in our country. Hospital pharmacists have to keep updated in novel therapies and improve their communication skills due to the increasing number of oral cancer drugs.

Score: 120

Remarks all reviewers:
Hoppe-Tichy, Torsten: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No
Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Rejected
3. Reason for reject:
This prescription pattern is not necessarily the same as in other hospitals, therefore only of local interest. How should a pharmacist intervene? There are no recommendations.

BARI4-0064
Adverse reactions to radiopharmaceuticals: literature review of the past review of the past 70 years
Co-authors
G. Rotondo1, G. Nardella1, M. Rinaldi1, S. Modoni1.
1AOU Ospedali Riuniti di Foggia, UOC Medicina Nucleare, Foggia, Italy.

Background
Up to day a very few reports on adverse reactions to radiopharmaceuticals (ADR) can be found in the literature. Over a period of 70 years no more than 34 articles had been published. Authors focus on the importance of a proper data collection and the necessity to share results.

Purpose
The aim of our study was to investigate how many and which types of ADR are reported in scientific literature. We reviewed articles from 1955 up to day.

Materials and Methods
The databases of PubMed, Embase, MedLine, Cochrane, Biomed Central, Google Scholar were searched up to September 2013 looking for reports on ADR.

Results
Radiopharmaceuticals cause adverse reactions. 12 cases of adverse reactions with radiopharmaceuticals were found: 3 cases with 18F-fluorodeoxyglucose (FDG), 8 cases with technetium 99m (99mTc), 1 with iodine-131-metaiodobenzylguanidine (131I-MIBG). Among these, a total of 5 ADR were specifically described as type I hypersensitivity reactions (anaphylactic). Other symptoms reported are: nausea, circulatory collapse, hypotension, pruritus, bronchospasm, wheezing, dermographism and vomiting. 8 cases with false positive reactions were found with FDG.

Conclusions
There is a lack of informations on ADR. Few studies were carried out over the past 60 years. More studies are necessary to report as many cases as possible through an active pharmacosurveillance.

No conflict of interest

Keywords
ADR; radiopharmaceuticals; pharmacosurveillance;

Authors letter
Authors strongly believe that pharmacosurveillance should be carried out on adverse reactions to radiopharmaceuticals (ADR). A review of the literature over the past 60 years shows how there is still a lack of informations on this topic. Author's study: 1. has an high relevance because shows an updated (September 2013) review of the literature on ADR; 2. it is innovative because the last comprehensive review of the literature dated 2009 (5 years ago); 3. can help pharmacists involved in the management of radiopharmaceuticals to better understand how many and which types of reactions can occur to patients treated in a Nuclear Medicine Unit. Sincerely. Giulia Rotondo, PharmD

Score: 80
Remarks all reviewers:
Hoppe-Tichy, Torsten:
Rejected
6.
Reason for reject: Is the title correct? The purpose is to look what is in the literature, the conclusion says that this is not enough and more studies are needed. I cannot understand why.
Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
Nominee: No
the title seems to need style polishing

BAR14-0075
Off label use of adalimumab in the management of severe hidradenitis suppurative
Co-authors
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1Hospital Punta Europa, Pharmacy, Algeciras, Spain.

Background
Hidradenitis suppurativa (HS) is a chronic, inflammatory and recurrent and difficult management with usual standard treatment, especially in the advanced stage of the disease, so that the use of modulating factor of the inflammatory response such as adalimumab, may constitute a new therapeutic option

Purpose
To evaluate the efficacy and safety of adalimumab in the treatment of severe HS

Materials and Methods
Retrospective cross-sectional study of patients diagnosed with HS (Hurley grade III) and adalimumab subcutaneous until August 2013. In all cases, informed consent was obtained (off-label indication). The data were obtained from the clinical history and program computerized outpatient dispensing. The efficacy of adalimumab was defined as clinical improvement in the affected regions, nodules and/or fistulas compared to usual standard treatment (oral antibiotics, corticosteroids, antiandrogens and/or retinoids)

Results
Six patients were included, 2 men and 4 women, with a mean age of 28.8±8.6 years (range: 17-39). The mean treatment duration was 4.8±2.7 months (range: 1-9). In men, the affected regions were genitals and groin, while women were armpits and groin. In a case, the affected area was not reflected in the medical history. 3 patients were active smokers. All patients had been treated previously with oral antibiotics, combined or not with antiandrogens, corticosteroids and/or isotretinoin and none had received previously biological therapy. Only in one case there was a positive family history of the disease.
4 patients received loading doses of 160 and 80 mg administered subcutaneously at week 0 and 1, respectively (without interval) and 2 patients received loading dose of 80 mg at week 0. The maintenance regimen was 40 mg weekly except in 2 cases it was every other week, one of them by severe headaches. All patients reported improvement with decreased drainage from all affected sites, remaining stable during the follow-up period. No significant adverse effects were reported.

Conclusions
Adalimumab may represent a new alternative in the management of severe HS with acceptable safety profile, despite being administered at high doses during the induction phase and without weekly break, although the benefit-risk long term of adalimumab is unknown.

Conflict of interest:
Enter Yes or No: No

Keywords
adalimumab; off-label; severe hidradenitis suppurativa;

Authors letter
Several reports support the beneficial effect of tumor necrosis factor-alpha (TNF-alpha) antagonists, such as adalimumab, for the treatment of severe hidradenitis suppurativa. Currently there are two ongoing phase III clinical trials that evaluate the use of adalimumab versus placebo in the treatment of this disease of difficult management with usual standard treatment.

Score: 100

Remarks all reviewers:
Hoppe-Tichy, Torsten: Rejected
1. Reason for reject: ;
Hidradenitis suppurativa is called Acne inversa.
Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
1. Modifications needed: ;
Nominee: No
- parts of the abstract are hardly understandable - amend title "... suppurativa (= acne inversa)" - low N = 6

BAR14-0113
Omalizumab use: our experience in a regional hospital

Co-authors
A. Fayet-Perez1, J.M. Fernandez-Martín1, A. Martos-Rosa1, J. Urda-Romacho1, O. Urquiza-Rodríguez1, M.A. Castro-Vida1.
1 HOSPITAL PONIENTE DEL EJIDO, Pharmacy, EL EJIDO, Spain.

Background
Omalizumab is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma and who have reduced lung function as well as frequent symptoms.

Purpose
To assess the use and efficacy of omalizumab in a regional hospital.

Materials and Methods
We conducted a retrospective study from April 2007 to August 2013. We included all patients with 16 weeks minimum on treatment with omalizumab.

To evaluate the use and efficacy we review: baseline IgE levels, the volume exhaled during the first second of a forced expiratory (FEV1) and the use of inhaled and/or oral corticosteroids before and after the treatment, and the evaluation of the disease after 16 weeks minimum of treatment. Patients with baseline IgE lower than 76 IU/ml were less likely to experience benefit. We considered reduced lung function as FEV1 lower than 80%.

Results
9 patients (8 females); mean age 52 (39-77); 4 moderate and 5 severe persistent allergic asthma. Mean basal IgE 177.2 U/mL (47-431.6). 4 patients prescribed omalizumab with IgE lower than 76 U/mL. We have FEV1 data in only 5 patients before the start of treatment: 3 patients had FEV1 lower than 80% (49, 69 and 59), being increase in all cases after commencing omalizumab (75, 72 and 71). 2 patients had
FEV1 higher than 80% (104 and 96), the first one increase and the other decrease after commencing omalizumab (117 and 78). Note that the last two patients had IgE levels less than 76 IU/mL. After the start of omalizumab all patients continued treatment with inhaled corticosteroids and 3 also with oral corticosteroids. 1 patient is completely asymptomatic, 2 have improved respiratory status, 5 are stable from a respiratory standpoint and 1 without clinical respiratory changes with the introduction of omalizumab. From patients who started omalizumab with IgE levels higher than 76 IU/mL, 4 are stable from a respiratory standpoint and 1 has improved respiratory status.

We have 1 patient diagnosed with chronic urticaria with IgE 518.4 IU/mL on treatment with omalizumab 300mg every 6 weeks (off label). Currently without skin rash or need to take antihistamines.

Conclusions

Only 33% (3/9) of patients improved respiratory status. No patient discontinued treatment with corticosteroids. It is necessary to develop a protocol to ensure the use of omalizumab in the most suitable patients and review effectiveness at 16 weeks after starting treatment. Omalizumab treatment for chronic urticaria has been effective.

### Table

<table>
<thead>
<tr>
<th>AGE</th>
<th>PATHOLOGY</th>
<th>IgE</th>
<th>FEV1 %</th>
</tr>
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<tbody>
<tr>
<td>77</td>
<td>moderate persistent allergic asthma</td>
<td>211.57</td>
<td>49 (baseline)</td>
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<td>431.64</td>
<td>69 (baseline)</td>
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<td>397.96</td>
<td>(baseline)</td>
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<td>(baseline)</td>
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<td>55</td>
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<td>518.4</td>
<td>(baseline)</td>
</tr>
</tbody>
</table>

Conflict of interest:

Enter Yes or No: no

Keywords

allergy asthma;omalizumab;efficacy;

Authors letter

to ensure the use of omalizumab in the most suitable patients. To improve effectiveness of treatment and economic impact

Score: 120

Remarks all reviewers:

Hoppe-Tichy, Torsten: Conclusion warranted
Conflicts of interest clear
Accepted, but Author modifications
1.2.
Modifications needed: ;
Nominee: No

Just a case series. I would also agree with rejection.

Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No

- word count? - Simple drug use evaluation however with an important conclusion of low response rate related to respiratory status.

BAR14-0128

Appropriateness of the treatment with Telaprevir in patients with chronic hepatitis C virus genotype 1

Co-authors

D. Guerra Estévez, E. Marquez Fernández, M.P. Quesada Sana.

1 Hospital Punta Europa, Pharmacy, Algeciras, Spain.

Background

The duration of triple-therapy against hepatitis C virus genotype 1 (HCV-1), which includes Telaprevir, Ribavirin and Peginterferon α-2b, is variable, depending on the patient to be treated.
To evaluate the use and effectiveness of Telaprevir in HCV-1 patients according to the guidelines contained in the data sheet of the drug.

Purpose

Materials and Methods

Retrospective observational study of HCV-1 monoinfected patients who started treatment with Telaprevir, Ribavirin and Peginterferon α-2b. The follow-up period is 48 weeks. The analyzed variables are: type of patient (naïve, relapsed, partial responder and non-responder), viral load (VL) at baseline, at 4, 12, 24, 36 and 48 weeks (IU/ml) and duration of treatment. For naïve and relapsed patients in which CV is undetectable at week 4 and 12, the duration of the treatment is 24 weeks, extending up to 48 weeks in patients with detectable CV. In the case of partial responders or non-responders, it is always 48 weeks. Furthermore, considered criteria for discontinuation are: CV > 1000 at weeks 4 or 12, and detectable CV at weeks 24 or 36, since it is unlikely that these patients obtain a sustained viral response.

Results

A total of 17 patients are included. Of the naïve and relapsed patients (14), 2 of them performed an improper treatment. Both had undetectable CV at 4 and 12 weeks and the treatment lasted up to 48 weeks. Among partial responder and null-responder patients (3), 1 performed an improper treatment since it ended after 24 weeks, presenting detectable CV again at week 48. Premature suspension in this case was not due to toxicity reasons. Viral load remained undetectable at week 48 in 14 of the remaining patients.

Conclusions

The inadequacy of treatment in our study is 18% (3/17), impacting negatively on the efficacy of triple therapy in patients who perform shorter treatment that the recommended.

No conflict of interest

Keywords

Telaprevir; Hepatitis C; Appropriateness;

Authors letter

In recent years new drugs have been introduced for the treatment of infection by the Hepatitis C virus genotype 1. In this study, the use of Telaprevir, one of these new drugs, is evaluated, as well as the impact of the adequacy of treatment on its efficacy.

Score: 100

Remarks all reviewers:
Hoppe-Tichy, Torsten: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
1.
Modifications needed: ;
Nominee: No

What is CV? (HCV?, HCV-VL?) Please explain. CV>1000 means viral load???? I would not fight against rejection.
Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
Nominee: No

Please complete conclusions with a recommendation or a prospective estimation.

BARI14-0131
Albumin usage study

Co-authors
P. Hidalgo-Collazos1, L. García-López1, T. Rico-Gutiérrez1, R. Aguilella-Vizcaíno1, M.T. Criado Illana1.
1HOSPITAL GENERAL DE SEGOVIA, Hospital Pharmacy, Segovia, Spain.

Background

A previous albumin usage study showed its continuous consumption increase.

Purpose

Evaluating the impact of an update in usage protocol and usage recommendations for albumin in our hospital.

Materials and Methods

We conducted a bibliographic review to update our albumin usage protocol and to establish alternative
We conducted a bibliographic review to update our albumin usage protocol and to establish alternative treatment options and dosage for each approved indication.

After Pharmacy and Therapeutics Committee approval of the update, and recommendations dissemination; an observational, descriptive, retrospective study was conducted to evaluate intervention effectiveness, by comparing albumin consumption 6 months prior to implementation with consumption 4 months later; and extrapolating data from this latter period to 6 months so that results can be comparable.

The following variables were analyzed: prescriptor service, date, number of prescribed vials, treatments cost 6 months before implementation of new protocol and 4 months later.

**Results**

A total of 397 treatment lines were included, corresponding to 1090 prescribed albumin vials (732 vials prescribed during 6 months prior to implementation of new protocol and 358 vials prescribed during 4 months later).

After data extrapolation, a reduction of 26.43% albumin can be concluded. General Surgery Department maintained consumption (pre-review consumption: 250 vials, post-review consumption: 250.5 vials). Services where consumption increased were Geriatrics (pre-review consumption: 24 vials, post-review consumption: 58.5 vials), Anesthesia and Resuscitation (pre-review consumption: 9 vials, post-review consumption: 13.5 vials). Services where consumption decreased were Internal Medicine (pre-review consumption: 160 vials, post-review consumption: 148.5 vials), Intensive Care Unit (pre-review consumption: 70 vials, post-review consumption: 54 vials), Emergency (pre-review consumption: 45 vials, post-review consumption: 0 vials), Traumatology (pre-review consumption: 81 vials, post-review consumption: 10.5 vials). Consumption reduction was due to alternative recommendations diffusion and dosage adjustments.

**Conclusions**

The review, updating and distribution of Therapeutic Protocols among physicians improve prescription rates thus improving the use of drugs under Protocol. This has a direct impact on therapies optimization with positive clinical and economic outcomes.

No conflict of interest

**Keywords**

Albumin; Use; Recommendations;

**Authors letter**

It is important to make proper use of albumin also making the containment of pharmaceutical expenditure

**Score:** 140

**Remarks all reviewers:**

Hoppe-Tichy, Torsten: Conclusion warranted
Accepted, but Author modifications
1. Modifications needed: ;
Nominee: No

Please discuss why you have reduction only in ICU, emergency and Traumatology, but increase in the other departments.
Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Rejected
2.3.8.
Reason for reject: ; ; ;
- Was albumin used for plasma expansion alone? - Do other plasma expanders increase? - it is not proven that less consumption is caused by the update alone.

**BAR14-0166**

Off-label use of Cidofovir in a Tertiary Care Hospital

**Co-authors**

A. Colón López de Dicastillo\(^1\), D. Gómez Gómez\(^1\), M. Valero Domínguez\(^2\).
\(^1\)Hospital Universitario Marqués de Valdecilla, Pharmacy, Santander, Spain.

**Background**

Cidofovir is an antiviral agent approved in Spain, in 1997, for the treatment of CMV retinitis in adults with acquired immunodeficiency syndrome (AIDS) and without renal dysfunction. Realizing its persistent use in other indications, a review of all treatments with Cidofovir in our hospital has been carried out.
**Purpose**

To perform a description of the use of Cidofovir in a Tertiary Care Hospital.

**Materials and Methods**

Observational retrospective study of all patients treated with Cidofovir from January 2010 to September 2013. Data like dose, duration of treatment and previous therapies was collected using the Electronic Medical Records. Microbiology results and disease progression were extracted from Medical History.

**Results**

5 patients (1 men/4 women), two bone marrow transplantations and three allogeneic hematopoietic stem-cell transplantations, with an average age of 47.4 years, were evaluated. Intravenous Cidofovir was administered in the following indications: JC/BK virus and adenovirus-associated hemorrhagic cystitis (2 and 1 patients respectively); Adenovirus-associated pneumonia (1 patient), and one case of CMV infection. None of them were positive for HIV infection. Only 2 of the 4 patients infected with Adenovirus or JC/BK virus had been treated previously with Aciclovir. The fifth patient had an Acute Graft-versus-Host Disease complicated with a CMV infection, which required Ganciclovir first and, after lack of response, Foscarnet. Due to an analytical toxicity to Foscarnet, Cidofovir 5 mg/kg/week was initiated, showing a negativization of CMV after 6 weeks of treatment. In the other cases, Cidofovir was administered at 1 mg/kg/week in the two virus JC/BK cases (2 and 3 doses to resolution of the disease) and 5 mg/kg/week in the two adenovirus cases (4 and 2 doses to resolution of the disease). Only one patient had renal impairment at the beginning, and after Cidofovir infusions, it worsened.

**Conclusions**

Cidofovir is used in different indications than those described in the summary product’s authorization, obtaining favorable results and low toxicity. Common diseases like hemorrhagic cystitis caused JC/BK virus and/or Adenovirus have no standard therapy to which Cidofovir could be a potential treatment whose posology in these indications should be standardized.

Conflict of interest: Enter Yes or No: NO

**Keywords**

Cidofovir; JC/BK virus; off-label;

**Authors letter**

In the daily clinical practice Cidofovir is usually prescribed in off-label indications. With this work we wanted to analyzed each different indication and the way of treating the disease. The results obtained in the study, encourages us to standardized Cidofovir indications and the posology used in diseases like hemorrhagic cystitis caused by JC/BK virus or adenovirus.

Score: 100

**Remarks all reviewers:**

Hoppe-Tichy, Torsten:

Rejected

1. Reason for reject: ; Jenzer, Helena: Conclusion warranted

Conflict of interest clear

Accepted, but Author modifications

4. Modifications needed: ;

- Please explain BK / JC (first patient initials) - What is “analytical toxicity”? - Amend style last sentence of conclusions. - Use the explanation in the authors’ letter to precise the purpose part

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**BARI14-0181**

**EFFECTIVENESS AND SAFETY OF ELTROMBOPAG IN IMMUNE THROMBOCYTOPenia**

**Co-authors**

M.P. Ortega-García 1, M. García-López 1, F.J. López-Pérez 1, A. Pastor-Clérigues 1, A.C. Sava-Victoria 1, J. Navarro-García 1.

1 CONSORCIO HOSPITAL GENERAL UNIVERSITARIO, Farmacia, Valencia, Spain.

**Background**

Eltrombopag is a thrombopoietin-mimetic indicated in immune thrombocytopenia when corticosteroids or splenectomy are not effective or splenectomy is contraindicated. No direct comparison exists with romiplostim.
Evaluate effectiveness and safety of eltrombopag since its inclusion in pharmacotherapeutical guide.

Materials and Methods
Retrospective study of patients treated between August 2011-February 2013. Demographic data, pretreatments, splenectomy, platelet count (PC) at the beginning, at five weeks and at the end of the treatment or study, adverse effects and discontinuation, were collected.

Results
8 women and 1 man, median age 63 years (24-78). Five splenectomized, all of them pretreated with corticosteroids, 7 with azathioprine, danatrol or dapsona and 7 with romiplostim. Before treatment with romiplostim median PC was 4000/mm3 (3000-25000) and after five weeks 75% had ≥ 50000. 3 patients discontinued for ineffective, 1 for partial response with high dose, 2 for adverse effects and one was changed to eltrombopag for oral route administration. At the beginning of eltrombopag median PC was 6000 (2000-68000), after five weeks 44% had ≥50000. At the end of study 6 patients had discontinued treatment, two due to lack of response, one was intolerant, one refused treatment for his liver disease, one was splenectomized and another had sustained response. 3 patients continued with eltrombopag with a median of 70 weeks (57-78) and at the end of the study median platelet count was 45000 (34000-60000). Thromboembolic complications, cataracts, bone marrow reticulin or liver damage were not reported. Two patients reported irritability and fatigue and another headache.

Conclusions
Both romiplostim and eltrombopag increase platelet count ≥ 50000/mm3 more than placebo. Eeltrombopag advantages are oral versus subcutaneous administration and easier dosing. In an indirect comparison romiplostim achieved better platelet response after 4 weeks of treatment, like in our study, but we observed more discontinuation with romiplostim due to lack of response or partial response (57% vs 22%).

Conflict of interest:
Enter Yes or No: No

Keywords
eltrombopag; safety; effectiveness;

Authors letter
There are two thrombopoetin-mimetic commercialized, romiplostim and eltrombopag. Their efficacy is similar but there are not direct comparison published and both have important differences in dosing and route of administration. We want to evaluate effectiveness and safety of eltrombopag to establish a protocol of use of the two thrombopoetin-mimetics.

Score: 240

Remarks all reviewers:
Hoppe-Tichy, Torsten: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications 1.
Modifications needed: ;
Nominee: No

Would not fight rejection due to Not enough data.
Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications 3.
Modifications needed: ;
Nominee: No

Please controle and clarify the number of patients. It is not clear, if 9 or 14 oe ... patients are included.

BARI-0233
Efficacy of eculizumab in adult patients resistant to plasma therapy with atypical hemolytic uremic syndrome

Co-authors
R. Ubago Perez1, M.A. Castillo Muñoz1, M. Galván Banqueri1, L. Abdel Kader1, M.D. Vega Coca1, A. Romero Tabares1, C. Beltrán Calvo1, T. Molina López1.
1 Andalusian Agency for Health Technology Assessment (AETSA), health technology assessment, Seville, Spain.

Background
Eculizumab is an orphan drug for Atypical Hemolytic Uremic Syndrome (aHUS). The disease is characterized by non-immune hemolytic anemia, thrombocytopenia, and renal impairment.

Purpose
Assess the efficacy of eculizumab in adult patients, resistant to plasma therapy (PT), diagnosed with
aHUS

Materials and Methods

A systematic review of literature has been conducted focused on the efficacy. MEDLINE, EMBASE, CRD, and the Cochrane Library were searched to 2012 September to identify relevant studies. Inclusion criteria: Population: adult PT-resistant patients with aHUS. Intervention: eculizumab. Outcomes: survival, quality of life, thrombotic microangiopathy (TMA) event-free status (defined as no PT session, new dialysis, and decrease in platelet count of > 25% from baseline for at least 12 weeks), TMA intervention rate (PT session and dialysis/patient/day), and renal function. Design: health technology agencies reports, meta-analysis, systematic reviews, the assessment report of the drug from the European Medicines Agency; randomized controlled trials, controlled observational studies, and uncontrolled intervention studies (n=5 patients).

Results

Only one prospective uncontrolled intervention study was included. The median follow-up of the study was 64 weeks (range: 2-90 weeks). No deaths were reported during the follow-up period. 87% of patients achieved a minimally important difference of 0.06 in the EuroQol 5D measurements. The TMA event-free status was achieved in 87% of the patients. The TMA intervention rate was reduced from a median of 0.88 to 0 events/person/day. 53% of patients achieved a sustained change in eGFR ≥15 mL/min/1.73 m². 76% of patients achieved a sustained 25% reduction from baseline in serum creatinine, 65% of patients improved at least one CKD stage.

Conclusions

Eculizumab in the PT-resistant population improves quality of life and renal function, reduces the percentage of patients in dialysis and the necessity of PT. This systematic review could be use as a basis for developing recommendations for the use of eculizumab in this population.

No conflict of interest

Keywords

atypical hemolytic uremic syndrome; eculizumab; plasma resistant;

Authors letter

This review was aimed to identify the available evidence related to the efficacy and safety of eculizumab to treat Atypical Hemolytic Uremic Syndrome. Its findings could help decision makers in the drug selection process. Also, this systematic review could be use as a basis for developing recommendations for the use of eculizumab in this population.

Score: 140

Remarks all reviewers:

Hoppe-Tichy, Torsten:

Rejected

2. Reason for reject:

This is just an analysis from literature, as I understand.

Jenzer, Helena: Conclusion warranted

Conflict of interest clear

Accepted, but Author modifications

5. Modifications needed: 

Nominee: No

Please structure and shorten the methods part. It is really not easily readable.
To analyze the utilization of the autologous serum eyedrops in Ophthalmology's Service: indications and concentrations.

Materials and Methods

Descriptive retrospective study in a general hospital of 600 beds from its opening in 2007 up to the present. We realized a systematic review of all the patients to whom autologous serum eyedrops were distributed. It was verified serology, indication and concentration of the eyedrops for each one of them. To check the serology we used the application of the Laboratory service (WebLab®), to revise the indication we used the prescription's program (Selene®) and for visualizing the elaborated concentration we used the drugs' program (Athos®).

Results

As for the serology we should emphasize that of 68 patients with eyedrops, 53 presented serology denial, 12 presented + anti HBc, 2 patients without serology realized and 1 patient with serology positive for Toxoplasma, Citomegalovirus and Herpes. With regard to the concentration, there are 40 patients with eyedrops to 20 %, 11 patients to 30 %, 5 patients to 40 %, 5 patients to 50 %, 1 patient to 60 % and 6 patients with eyedrops of unknown concentration. On having spoken about the indication we should say that 20 patients present keratitis drought, 17 corneous sore, 8 herpetic keratitis, 6 dry eyes, 5 Neurotrophic sore, 4 corneous burn, 2 lagophthalmos and 6 other pathologies.

Conclusions

The majority of patients presented serology denial. The concentration more used of autologous serum eyedrops by the ophthalmologists is that of 20 % followed by that of 30 %. The pathologies most treated in our hospital with this type of eyedrops are the dry keratitis and corneous sore.

No conflict of interest

Keywords

Autologous; serum; eyedrops;

Authors letter

I have chosen this topic in concretly for the production of the poster due to the considerable increase of prescriptions of autologous serum eyedrops on the part of the service of Ophthalmology in the last years. It has ensued to me from great interest since one has seen that treats itself about a successful patent medicine with a great efficiency and safety in several ocular pathologies. This supposes an evolution for the Drugstore's Service taken charge of his production and dispensation.

Score: 100

Remarks all reviewers:

Hoppe-Tichy, Torsten:
Rejected
5.
Reason for reject: ; Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
1.
Modifications needed: ;
Nominee: No

EE + mention growth factors content in serum. Please declare where and how serum eyedrops were prepared, and take a conclusion out of it.

BAR14-0227
Oral Anticoagulants and Adverse Events in Emergency Room

Co-authors

D. Micera¹.
¹A.O.R.N. "San Giuseppe Moscati", U.O.C. Farmacia, Avellino, Italy.

Background

The Oral Anticoagulant Therapy (OAT) is the most common pharmacological treatment for prevention of stroke and thromboembolism in patients with atrial fibrillation or prosthetic heart valves. The major complication of OAT is the risk of bleeding. High intensity of anticoagulants, targeted International Normalized Ratio (INR) >3, is associated at a higher risk of hemorrhagic events. This risk is also related to the length of therapy, the concomitant use of drugs that interfere with hemostasis and with patient characteristics.

Purpose
This work evaluated the frequency, seriousness and evolution of hemorrhagic events in patients in OAT among all the Adverse Drug Events (ADEs) that led people in Emergency Room (ER).

**Materials and Methods**

The Hospital Pharmacist monitored patients who entered ER of ‘S. Giuseppe Moscati’ Hospital in Avellino because of ADEs in a range of four months. The cases of bleeding due to OAT were selected and analyzed.

**Results**

During the considered time 89 ADEs were detected in ER. 21 cases (about 24%) involved patients with OAT who used warfarin (71%) and acenocoumarol (29%) because of atrial fibrillation (91%) and prosthetic heart valves (9%). 52% of these ADEs were ‘not serious’ while the ‘serious’ ones were clinically important (10%), needed hospitalization/hospital prolongation (24%) and ended with the patient death (14%). The complete resolution after hospital treatments concerned 19% of cases only. The main ADEs detected were hematomas, epistaxis, gastrointestinal bleedings and two fatal intracranial bleedings in old women with increased values of INR. Patients involved were females (67%) and over 65 years of age (71%). About 5% of them used acetylsalicylic acid too.

**Conclusions**

Pharmacovigilance activity produces new data and information that improve the pharmacological treatments and the wide knowledge that comes from new investigations makes safer the risky therapies.

No conflict of interest

**Keywords**

anticoagulants, bleeding, pharmacovigilance;

**Authors letter**

The hospital Pharmacist in department dedicated to pharmacovigilance activity produces new Knowledge important to improving the old and new pharmacological treatments.

Score: 200

**Remarks all reviewers:**

Hoppe-Tichy, Torsten: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
1.3.
Modifications needed: ; ;
Nominee: No
Jenzer, Helena: Conclusion warranted
Conflict of interest clear
Accepted
EE by EAHP