

Background and Importance Excessive waiting time is one of the main causes of patient dissatisfaction in oncologic daily care unit (DCU). Lean management, dose banding, advanced prescription and automatization are usually used in our hospital to improve patient care pathway. In our adult DCU (>26 000 patients/years), patients have to wait for their treatment less than an hour.

Aim and Objectives The aim of this work is to reassess the time of availability in this DCU and to identify the factors influencing this time.

Material and Methods It is an ambispective monocentric study in which human factors (n=2), equipment factors (n=7), organisational factors (n=4), productivity factors (n=16) and time-related factors (n=6) were recorded randomly between September 2021 and April 2022 (i.e. 15 days studied). Data were also extracted from CHIMIO® software and from our institutional 'LEAN tool' for real-time monitoring of patients in oncologic DCU, in order to calculate time between the prescription of the day and the dispensation of the treatment.

Results The average number of patients and preparations manufactured per day were respectively 105 (+/-7) and 146 (+/-12); 52% of these preparations prepared the day before. The average number of preparations not prescribed in advance is 49 [18-62] (34%) for an average number of 31 patients [14-43] (30%). The average time to availability was 54 min (+/- 16) with a median of 60 min. On average, 12 [0-24] patients per day waited more than an hour after the prescription with a maximum waiting time of 360 min.

Four days (27%) were identified with an average dispensing time greater than 60 min. During these critical days, a percentage of anticipated preparations less than 50%, with a high number of prescriptions (>30 patients) and particularly before 9:45 a.m. or between 12:00 and 14:00 p.m. were observed. We noticed also a higher productivity ([174-214] preparations), the lack of coordination (2 of 4 days), or additional productions (analgesic syringe preparations).

Conclusion and Relevance Main impacting factors seem to be human factors and productivity. Time to availability became an essential quality indicator of our compounding anti-cancer unit. This study showed that our working procedures are efficient for a majority of patients, but not for all.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-022 FORMULATION AND QUALITY CONTROL OF A BISOPROLOL 0.5 MG/ML ORAL SOLUTION FOR PAEDIATRIC USE

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Background and Importance Bisoprolol is a beta blocker indicated for the treatment of heart failure in paediatric patients. There are no licensed bisoprolol containing paediatric dosage forms available in the EU. Pharmacy preparation of patient individually dosed bisoprolol capsules is common practice by using licensed bisoprolol tablets as starting material. However, the preparation and use of bisoprolol oral liquids are the gold

standard for paediatric patients because they allow body weight oriented dosing for different age groups. So far, there is no published information regarding the formulation, quality control, and stability of pharmacy-prepared bisoprolol oral solutions.

Aim and Objectives The aim of this project was to formulate a bisoprolol fumarate 0.5 mg/mL oral solution for paediatric use, establish suitable quality-control measures, and to perform stability tests.

Material and Methods Bisoprolol oral solution was formulated in analogy to propranolol hydrochloride oral solution described in Neues Rezeptur-Formularium 2015/1, Germany. Efficacy of antimicrobial preservation was tested regarding to Ph. Eur. 5.3.1 by an external lab. A stability indicating RP-HPLC method was established and validated based on the known method of Joshi et al.¹

Results 100 mL bisoprolol fumarate 0.5 mg/mL oral solution contain bisoprolol fumarate 0.05 g as active ingredient as well as potassium sorbate 0.15 g, anhydrous citric acid 0.07 g, sucrose 25 g, raspberry flavour 0.1 g, and purified water 84.33 g as excipients. Antimicrobial preservation regarding Ph. Eur. 5.3.1 was demonstrated. After a 6 months period the bisoprolol concentration amounted to 103% ± 1% of the initial concentration and the pH remained unchanged (4.6).

Conclusion and Relevance Sweetened and flavoured bisoprolol fumarate oral solution was successfully developed as pharmacy preparation suitable for preparation in stock. Adequate in-use preservation is given and stability is proven for at least 6 months. A second version of bisoprolol oral solution without sucrose and raspberry flavour is under development.

REFERENCE

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Conflict of Interest No conflict of interest.

3PC-023 PATCH TESTS WITH ETHAMBUTOL 10%, ISONIAZID 15% AND PYRAZINAMIDE 25%: A CASE REPORT

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Background and Importance A 55 year old male patient, developed a DRESS (drug rash with eosinophilia and systemic symptoms) reaction after starting first-line tuberculosis treatment with rifampicine, ethambutol, isoniazid and pyrazinamide. To assess the responsibility of a suspected drug in a DRESS reaction and posterior safe reintroduction of therapy, patch tests (PT) are the most useful tool. For the purpose, the Hospital Pharmacy was asked to develop magistral preparations of ethambutol, isoniazid and pyrazinamide. The PT were performed with each tuberculostatic drug diluted in 4 IQ Ultra Chambers, applied on the patient's skin at the back and kept in occlusion for 48 hours. The readings were performed at day 2 and day 3. Only erythema, infiltration, papules or vesicles were considered positive reactions.

Aim and Objectives Development and validation of magistral formulas for topical application to accomplish patch tests of

ethambutol 10% (w/w), isoniazid 15% (w/w) and pyrazinamide 25% (w/w).

Material and Methods

Scarce bibliographic information Review article published by the French Society of Dermatology, in which the concentrations of the active ingredient to be used in each PT are established.

Application of the general rules of Good Handling Practices, according to the Portuguese Galenic Formulary.

Results The pastes used in the PT were obtained by geometric dilution of pulverised ethambutol 400 mg, isoniazid 300 mg and pyrazinamide 500 mg tablets in white petrolatum.

After quality-control tests that includes colour, homogeneity and mass verification assays, the pastes were placed in a syringe for an easier application in the skin. It was given 30 days of stability at room temperature.

Conclusion and Relevance This preparation made possible to develop PT for the study of a delayed hypersensitivity reaction to tuberculostatic drugs, that was not available before in the market, allowing a safer reintroduction of the treatment.

Although the PTs were negative in this patient, it was possible to develop and validate three compounding formulas with an adequate safety profile and low cost. This accomplishment will be useful in further cases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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2. Portuguese Galenic Formulary 2001

Conflict of Interest No conflict of interest

3PC-026 EFFECTIVENESS AND SAFETY OF INSULIN 1UI/ML EYE DROPS

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Background and Importance Epithelial corneal defects are damaged areas of the corneal epithelium as a consequence of injury. The existence of insulin and insulin-like growth factor receptors in cornea keratocytes and epithelial cells could explain the increment on the corneal epithelial healing rates. Clinical experience with insulin eye drops is limited and more evidence in both diabetic and non-diabetic patients is still needed.

Recently, the insulin eye drops formulation 1 IU/mL has been prepared in Pharmacy Hospital for patients with keratitis, dry eye and a persistent epithelial corneal defect (PECD).

Aim and Objectives The aim is to describe effectiveness and tolerance of insulin 1 IU/mL eye drops treatment for different refractory corneal diseases.

Material and Methods Retrospective observational study in a tertiary hospital. 21 patients were included, treated with insulin eye drops during the period between February 2022–September 2022. The variables collected were: demographics, indication, duration of treatment, clinical response and adverse effects. All data were obtained from the electronic medical history.

Results 21 patients were treated with insulin eye drops 1 UI/mL, six of them with diabetes mellitus and other 15 were non-diabetic. Administration frequency was 4 times in a day (QID). They presented different corneal diseases that were refractory to conventional treatment. The median age was 74 (43-89) years. A total of 52.4% were women. 38.1% were diagnosed with non-herpetic keratitis, 19% with herpetic keratitis, 23.8% with corneal erosion, and 19% with persistent epithelial corneal defect (PECD). The median duration of treatment was 6 months (2-9 months). 100% of patients responded to treatment and continued with insulin eye drops after epithelial healing. All patients presented epithelial healing in about 30-60 days, most of them referred improved of symptoms during first two weeks.

No significant adverse effects were reported. None hypersensitivity reaction were reported because of m-cresol presence in insulin eye drops.

Conclusion and Relevance The insulin eye drops formulation 1 IU/mL administered QID can be a quick, effective, and safe option for different corneal diseases refractory to the usual treatments in both diabetic and non-diabetic patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-028 FORMULATION OF AN ORAL PLATELET LYSATE GEL TO TREAT CHRONIC GRAFT VERSUS HOST DISEASE ASSOCIATED ORAL MUCOSITIS: EFFECTIVENESS IN A SERIES OF CASES

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Background and Importance Chronic graft versus host disease (cGVHD) associated oral mucositis is a complication after stem-cell transplantation. Corticosteroids are the standard treatment, but there is no consensus in case of refractory lesions. Platelet concentrates may be a safe treatment option.

Aim and Objectives Design a sterile oral formulation able to release platelet lysate (PL) on oral cavity, and evaluate its effectiveness in a series of cases.

Material and Methods PL gel 25% was compounded by mixing in aseptic conditions 1:1 carboxymethyl cellulose sodium base 5% previously autoclaved with PL also diluted 1:1 with sodium chloride 0.9%. PL gel was packaged in 3mL aliquots using oral syringes, which were stored in the freezer until their use. Galenic validation was performed.

Patients with cGVHD associated oral mucositis from November 2021 to August 2022 who accepted to initiate oral PL gel were monitored. Effectiveness was evaluated based on severity of the oral mucositis (NCI-CTCAE Grade 1-4). Patient satisfaction was self-assessed in a visual scale 0-10 according to the degree of pain/discomfort. Adherence was assumed based on the number of syringes dispensed.

Results PL gel obtained was slightly yellow, translucent, pH=6, with medium consistency that leads adequate bioadhesive characteristics. No changes of pH, colour, weight, or microbial growth were observed during galenic validations. A beyond-use date of 45 days at -20°C was given.

Six patients with moderate oral mucositis (grade 3) who failed to first-line topical steroids therapy started PL gel. Two