3PC-011 EFFECTIVENESS OF 3% TOPICAL IMIQUIMOD IN OFF-LABEL USE FOR ORAL FLORIDA PAPILLOMATOSIS: A CASE REPORT

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Background Imiquimod is an immunomodulator, with antitumour activity, indicated for the treatment of genital and perianal warts produced by the human papilloma virus (HPV), actinic keratosis and basal cell carcinoma.

Purpose Description of a clinical case of papillomatosis (POF) treated with topical imiquimod at 3% in a patient with numerous recurrences after failure of surgical treatment: a 74 years'-old woman, diagnosed with POF in 2008, intervened in 2010, presenting numerous recurrences due to non-responses to treatment. In 2011, verrucous carcinoma and proliferative verrucous hyperplasia were detected in biopsy, and it was again intervened for extirpation in 2017 and 2018. After an exhaustive literature review, it was decided to start treatment with 3% topical imiquimod

Material and methods The elaboration was carried out using an oral adhesive excipient to prolong the permanence of the drug in oral mucosa and reduce the adverse effects on healthy skin areas, and also liquid petrolatum to increase the interposition between the drug and the excipient. A whitish paste, easy to apply, was obtained. The posology was one application at night, 3 days per week, resting at weekends. Each application assumes a dose of approximately 0.01 g of imiquimod (340 mg of preparation). Hyaluronic acid gel was added in order to reduce the adverse effects of imiquimod on healthy perilesional mucosa.

Results During the first two weeks of treatment, the patient presented a decrease in the volume of the lesions. After 8 weeks of treatment, the patient presented good tolerance, without adverse reactions or complications, and reduction of lesions. After 16 weeks of treatment, the papillomatous lesions of the floor of the mouth and lingual tip had disappeared, and a small lesion remained in the lower lip. Currently the patient does not present apparent symptoms, waiting for the result of the biopsy.

Conclusion The clinical evolution of the patient suggests that the oral application of imiquimod 3% is safe and well tolerated, being effective in the treatment of POF and thus avoiding repeated surgical interventions. In addition, its preparation with oral adhesive excipient and its nocturnal application favour the permanence of the drug in the affected area, ensuring the pharmacological effect.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-012 TOPICAL CIDOFOVIR COMPOUNDING CREAM FOR THE TREATMENT OF DISSEMINATED INFECTION BY MOLLUSCUM CONTAGIOSUM

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Background Cidofovir is a broad-spectrum antiviral agent with activity against several DNA viruses. In Portugal, it has to be imported but it has European Medicines Agency's approval to treat cytomegalovirus retinitis in specific patient conditions.

A sixty-eight-year-old male patient, diagnosed with disseminated infection by *molluscum contagiosum*, with idiopathic acquired immunodeficiency $CD4^+$ t-cells and pulmonary cryptococcosis treated three years ago, presented with severe erythroderma. He exhibited countless cutaneous lesions, characterised by severe pruritic millimetre papules which affected the majority of his body, impairing his life quality. The case was refractory to all on-label available therapies and has been prescribed topical cidofovir.

Purpose To share procedures followed after the prescription of a new off-label compounded drug: information research and development of specific procedures for this type of hazardous formulation.

Evaluation of treatment effectiveness, 3 months after the topical cidofovir application in the lower right member.

Material and methods Bibliographic research.

Prescription submission for approval of the ethics committee for health and clinical board of the hospital.

Elaboration of master formula sheet and parameterisation of labelling information.

Clinical evaluation and photographic register.

Results Numerous studies substantiate the prescription, which led to its approval by the referred hospital boards. Cidofovir 3% cream was compounded from injectable cidofovir (vistidine) and incorporated into commercially available fat cream (lipolium). Due to cidofovir's mutagenic properties and its associated risk by exposure, this preparation was performed with proper protection equipment and using the luer-lock system (syringes and connectors). After 3 months of treatment, topical cidofovir proved to be effective, as the patient presented with a reduced number of lesions and less evidence of pruritus. He referred no symptoms of local irritation (the most reported adverse reaction).

Conclusion Off-label therapeutic options should be reserved only in specific cases. However, as long as there are no topical options available, compounding pharmacists can be essential in providing an effective and safe formulation. Operator's safety should not be neglected, and the preparation must be carried out with appropriate precautions/protection equipment.

It should be noted that the success of this treatment required the commitment of a multidisciplinary team, with consequent improvement in patient's life quality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To be presented on poster.

No conflict of interest.

3PC-013 FEEDBACK FROM A FEASIBILITY STUDY OF ALLERGY TEST PREPARATIONS IN DAY HOSPITALISATION

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Background As part of the investigation of anaphylaxis, it is recommended that allergy testing (ATs) be performed in day hospital, because of the anaphylactic risk requiring special hospital surveillance. Skin tests (SKs) and oral provocation tests (OPTs) are currently performed in our hospital in

dermatology, paediatrics and pneumology departments according to heterogeneous protocols. For the diagnosis of non-marketed allergens, only OPTs preparations are made in our hospital pharmacy. SKs are manufactured extemporaneously by nurses before administration.

Purpose Following a dermatologist's request that ATs be performed in day hospital, we decided that drugs will be manufactured by the pharmacy and that it was necessary to harmonise protocols of different services. But how should it be put in place?

Material and methods Establishment of a working group comprising pharmacists, pulmonologists, dermatologists, paediatricians, doctor of medical information and the financial affairs department to: determine allergens to be tested; work on a homogenisation of protocols; determine the correct codification of acts for the costing of the care; determine an organisation between the prescribers' requests; and a preparation of ATs by the pharmacy, according to processes similar to other institutions.

Results Five drug classes have been identified as priorities for development: antibiotics, analgesics, local anaesthetic drugs, iodinated contrast products and nonsteroidal anti-inflammatory drugs. ATs will be made in day hospital one day per week for all medical specialties, and their manufacture will be carried out the day before by the pharmacy. During the implementation of these ATs, we encountered difficulties in standardising protocols. Indeed in paediatrics, the target dose of these tests varies according to the weight of the child. In addition to this, it is necessary to produce duplicate SKs to prevent the failure of administration due to children's movements. We therefore decided to standardise adult protocols separately from paediatrics.

Conclusion This work required close collaboration between prescribers and pharmacists. It will allow for better patient management, ATs manufacturing according to good preparation practices guidelines, but also significant financial value through day hospital costing. A study of the stability of dilutions of molecules tested will subsequently be necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-014 STABILITY OF 1 MG/ML AND 4 MG/ML HYDROCORTISONE SOLIUM SUCCINATE SOLUTIONS IN 0.9% SODIUM CHLORIDE AND 5% GLUCOSE

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Background Hydrocortisone in high doses is given to haemodynamicly unstable patients as a vasopressor. Frequently the same patients have volume restriction, and high concentrations of hydrocortisone are necessary. Although there is no certain evidence of the benefits of continuous infusion over bolus injection, continuous infusion is a well-established practice in our hospital. Manufacturers state that the solution after reconstitution and dilution should be used immediately, however it is not defined how long this infusion can be used after application. There are limited data on the stability of hydrocortisone in concentrations greater than 1 mg/ml.

Purpose The aim of our study was to determine the physical and chemical stability of hydrocortisone sodium succinate in two concentrations (1 mg/ml and 4 mg/ml) at room temperature up to 24 hours after reconstitution and dilution. These are the most frequent circumstances in the wards in our hospital.

Material and methods We used duplicate samples of hydrocortisone sodium succinate diluted in 0.9% sodium chloride and 5% glucose to concentrations 1 mg/ml and 4 mg/ml. Samples were stored at room temperature (25°C) and at elevated temperature (30°C). Another set of reconstituted and diluted solutions stored at room temperature was protected from light. Concentrations were measured by a validated high-performance liquid chromatography (HPLC) method to determine the percentage of degradation after 3, 5, 7, 9, 12, 24 and 48 hours.

Results Our study demonstrates that hydrocortisone is equally stable at concentrations 1 mg/ml and 4 mg/ml, in both 0.9% sodium chloride and 5% glucose, regardless whether it is protected from light or not. At room temperature, degradation of hydrocortisone after 12, 24 and 48 hours was 3%, 5% and 10%, respectively. Declines from the initial hydrocortisone concentration in samples stored at 30°C after 3, 5, 12 and 24 hours were 3%, 5%, 9% and 14% respectively.

Conclusion Hydrocortisone sodium succinate is physically and chemically stable for 12 hours at 25°C.

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No conflict of interest.

3PC-015 PHYSICOCHEMICAL STABILITY OF CEFOTAXIME IN POLYPROPYLENE SYRINGES AT HIGH CONCENTRATIONS FOR INTENSIVE CARE UNITS

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Background Cefotaxime is an antibiotic used to treat severe infections such as in intensive care units (ICUs). The dose of cefotaxime can vary from 3 g to 24 g per day and the literature has demonstrated that continuous administration is the preferred mode of administration. In ICUs, a minimum volume is used for patients requiring fluid restriction, leading to high concentrations of cefotaxime.

Purpose The objective was to study the stability of cefotaxime solutions at 83.3 mg/mL and 125 mg/mL, diluted in 0.9% sodium chloride (0.9% NaCl) or 5% glucose (G5%), in polypropylene syringes after preparation and after a 6 hour and 12 hour storage at 20°C–25°C.

Material and methods Three syringes for each condition were prepared. At each time of analysis, three samples for each syringe were prepared and analysis by high-performance liquid chromatography (HPLC) coupled to a photodiode array detector. The method was validated according to the International Conference on Harmonisation Q2 (R1). Physical stability was evaluated by visual and subvisual inspection (turbidimetry by UV spectrophotometry at 350, 410 and 550 nm as recommended by the European Consensus Conference). pH and osmolality values were measured.