Background Skin tests have an important place in the diagnosis of hypersensitivity. Because of a lack of precise skin tests procedures, drug skin tests are often not carried out. However, they could help to determine the cause of hypersensitivity and help in the choice of therapeutic strategy. In our hospital, a dermatologist required us to produce skin tests with cytotoxic and anti-HER2 antibody agents (docetaxel, pertuzumab, trastuzumab) in order to evaluate the hypersensitivity of a patient who developed a photosensitive dermatosis after a second cycle of chemotherapy.

Purpose The aim of this project was to produce a feasibility study for the production of skin tests with these three molecules.

Material and methods A literature review was performed to find data about skin tests, and more particularly about safety and non-irritant drug concentrations. Because of a lack of data, we also decided to realise an investigation near the others hospital centres. Chemical tests were carried out such as the measure of the drug pH and the miscibility between the diluant and the medicine.

Results According to the literature, the pH drug must be between 6 and 9 to avoid skin injuries. By its acidic pH, docetaxel could not be used to produce a patch test (non-diluted drug pH=3, diluted with 0.9 per cent sodium chloride drug pH=4). The pH of the two other agents and of the diluant was acceptable (pH=7). In most of the publications, the excipient used for the preparation of patch tests was petroleum jelly. In cooperation with the doctor, we decided to produce a prick test with docetaxel, prepared by diluting the drug to 5 mg/ml in an aqueous solution of 0.9% sodium chloride. Concerning pertuzumab and trastuzumab, patch tests were obtained by realizing an homogeneous preparation, with a concentration of 30% in petrolatum.

Conclusion The literature deals mainly with a platinum agent, and more often with skin prick tests and intradermal tests. We were confronted with the difficulty of possessing poor data when facing the request of the dermatologist. Moreover, according to the literature, patch tests commonly reveal false negative results. This activity necessitates the development of a local thesaurus and an economic study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
Two phases: pre-implementation (1 month) and post-implementation (1 month) of the RM.

All preparations of parenteral antineoplastic drugs in the HPD were included in the analysis.

Standard local protocols for preparation and storing of remaining starting material (vials) were followed in both phases.

All remaining vials that exceeded the expiry date were stored separately and the amount of product within was measured. Finally, the cost for all discarded products was calculated in each phase and compared.

Results Expiry dates were reduced in only six drugs (9%) after modifying stability according to the RM.

The number of preparations in the anti-neoplastic preparation unit was 1479 in the pre-implementation phase and 1434 in the post-implementation phase.

Previous to the implementation of the RM, 1.01% of the cost of drugs prepared in the HPD was due to discarded product after storing dates were exceeded. After the implementation of the RM, this was 0.97%.

Conclusion The implementation of a risk matrix in the preparation of parenteral anti-neoplastics has no significant economic impact in terms of discarded product.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

ROBOTIC COMPOUNDING: SAFETY AND PRODUCTIVITY ACHIEVEMENTS IN THE PREPARATION OF HAZARDOUS DRUGS

C. Lopez-Cabezas*, AM Marín, G Riu, C Codina, D Soy. Hospital Clinic, Pharmacy, Barcelona, Spain

Background Robots arrived a few years ago to compounding units and, as a new health technology, it is necessary to assess their implications on safety and efficiency

Purpose Evaluate the impact on safety and productivity issues after the implementation of Kiro® Oncology.

Material and methods Failure mode, effect and criticality analysis were used to identify all risks related to the manual and robotic compounding processes. Criticality index (CI) was calculated for all of them, using a 1–4 scale.

The percentage of preparations within the ±5% accuracy range was evaluated by gravimetric control for nine common drugs prepared manually and using the robotic system.

To evaluate the role of the robot avoiding high-volume syringe handling, the number of preparations suitable to use 50 mL syringes (dose volume >20 mL) was estimated in a 6 month period (March–August 2018).

Robot productivity (mean and maximum number of preparations) was evaluated during 6 months.

Results Twenty-three failure modes were identified in the manual system, ahead of 4 for the robotic process, with a global decrease in CI of 32%. Risks with the highest scores were related to labelling errors.

Dosing accuracy was compared for 1031 manual preparations and 756 robotic preparations of carboplatin, cyclophosphamide, doxorubicin, epirubicin, 5-fluorouracil, gemcitabine, irinotecan, oxaliplatin and paclitaxel. No statistically significant difference was observed between manual and robotic preparations (percentage within ±5%: 99.8% manual vs 96.9% robot; \( \chi^2 = 1.11, p = 0.29 \)).

Doses above 20 mL prepared during the evaluation period were 730±56 (mean ±SD) per month.

The mean number of daily preparations by the robot during the period studied was 50 (40% of total daily production), with a maximum of 90. Technical incidences and workflow interruptions were major obstacles in improving productivity.

Conclusion Robotic compounding might decrease the global risk of the process by the suppression of human intervention in some tasks. It showed similar accuracy rates to manual compounding in our setting. It has a major potential role avoiding stress injuries due to the repeated handling of high-volume syringes. Regarding productivity, the percentage of preparations assumed by the robot is still under expected; so, different strategies based on technical improvements and optimisation of cycle management should be implemented in the near future.

REFERENCES AND/OR ACKNOWLEDGEMENTS


AJHP 2015;72(12):1036–45.

No conflict of interest.

USE OF EXTEMPORANEOUS ORAL SUSPENSIONS OF OXYBUTININ AND PRAZOSINE IN NEONATES

R. Claramen García, CL Muñoz Cid, J Caba Porras, AM López-López*, M Meino Almazán, Y Jimenez López, E Perez Cano, JF Marin Pozo. Complejo Hospitalario de Jaén, Servicio de Farmacia, Jaén, Spain

Background Primary bladder neck obstruction (PBNO) is a failure in which the bladder neck does not open appropriately or completely during voiding. α-Blocker together with anticholinergics are the pharmacological therapy that has shown some benefit in children. Off-label therapy with prazosin and oxybutynin was proposed in two neonates with PBNO.

Purpose To compound oxybutynin and prazosin correctly for dosing and administration in these patients and monitoring them.

Material and methods A bibliographic search of indication, dosage and formulation was made in Pubmed, Micromedex and other compounding pharmaceutical sources. Keywords: prazosin, oxybutynin, neonate, PBNO.

Clinical monitoring and interviews were carried out with the parents of two neonates (5 and 12 months’ old) in treatment from the first month of life to the present.

Results We did not find any bibliographic reference describing its use in neonates.

Initially, we formulated sachets with their specific dose. Later, we formulated in suspension, 100 mcg/ml prazosin and 1 mg/ml (minurin) and oxybutynin (raw material), using simple syrup without preservatives as a vehicle.

The initial doses collected were the minimum referenced in children: 10 mcg/kg/12 hour for prazosin and 0.1 mg/kg/12 hour for oxybutynin. The dose of prazosin was increased weekly, in both neonates, because of the improvement in urodynamics tests and no significant adverse effects detected. It was increased until 25 mcg/kg/8 hour (maximum collected in paediatrics 25 mcg/Kg/6 hour).