Abstract 5PSQ-110 Table 3

Final score

Malnutrition (<17 points)	7.23%
At risk of malnutrition (17–23.5 points)	72.29%
Normal status (24–30 points)	20.48%

Conclusion and relevance Screening and serum albumin levels confirmed normal nutritional status. However, when the full MNA test score was obtained, a higher prevalence than expected of patients at risk of malnutrition was noticed. These results show the need to monitor the degree of nutrition of institutionalised patients to develop strategies that can improve the overall status and set new lines of action.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-111 ADVERSE DRUG REACTIONS DUE TO MEDICINES UNDER ADDITIONAL MONITORING

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Background and importance The European list of medicines under additional monitoring (MUAM), identified with a black inverted triangle, includes new active substances, biological medicines, medicines that require a post-authorisation safety study, medicines approved conditionally or authorised under exceptional circumstances, and medicines authorised with specific obligations on the recording or monitoring of suspected adverse drug reactions (ADR). This list is reviewed monthly by the Pharmacovigilance Risk Assessment Committee (PRAC). A drug remains under additional monitoring for 5 years or until the PRAC decides to remove it from the list.

Aim and objectives To describe the ADR produced by MUAM.

Material and methods This was a descriptive, retrospective study in a second level hospital, from 2013 to 2018. The pharmacy service recorded and notified ADR due to MUAM to the pharmacovigilance centre (FC) after their detection spontaneously or from the complex analysis information system (CAIS). Once patients with ADR by MUAM were selected, the electronic medical history was reviewed: age, sex, medicines involved, type of ADR, detection method, admissions due to ADR, description in the data sheet and communication to the FC.

Results Forty-five ADR (from 26 medicines) were detected in 40 patients (57% men), who had a mean age of 65.8 years (26–84). Causative agents were: antineoplastics (80%); antianginals (4.4%); agents acting on the renin–angiotensin system (4.4%); and other (11.2%). The main ADR were febrile neutropenia (lenalidomide (n=2), palbociclib (n=2), ramucirumab (n=2), imatinib (n=1), brentuximab (n=2), nintedanib (n=1)); bradycardia (ivabradine (n=2), fingolimod (n=1)); hepatocarcinoma (ledipasvir/sofosbuvir (n=2)); thrombocytopenia (panitumumab (n=2), ibrutinib (n=1)); oliguric acute kidney injury (sacubitril/valsartan (n=2)); and vomiting (cabozantinib (n=2), alectinib (n=1)). Drugs with a higher incidence of ADR were:

cabozantinib (vomiting (n=2), asthenia (n=1), osteonecrosis (n=1)); nivolumab (myocardial infarction (n=1), cerebral haemorrhage (n=1), pulmonary thromboembolism (n=1)) and regorafenib (hypertension (n=1), skin rash (n=1), hyponatraemia (n=2)). ADR detected by spontaneous notification: 77.8%. ADR caused hospital admission in 62.2% of cases (febrile neutropenia (28.6%)). ADR caused death in 3 patients (oliguric acute kidney injury due to sacubitril/valsartan (n=2) and myocardial infarction due to nivolumab (n=1)). ADR not described in the data sheet: 13.3%. ADR reported to the FC: 93.3%.

Conclusion and relevance Antineoplastic agents were the therapeutic group with the highest incidence of ADR. MUAM caused hospital admission in a high percentage of cases and were the cause of death in three patients. We found that 13.3% of ADR were considered new, so it is essential to continue reporting suspected ADR to gather new information to help define the safety profile of all medicines, especially MUAM.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-112 IMPACT OF HIGH TEMPERATURE AND SHAKING ON CHARGE VARIANTS OF ADALIMUMAB (HUMIRA) ASSESSED BY LIQUID CHROMATOGRAPHY COUPLED TO MASS SPECTROMETRY

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Background and importance Adalimumab (Humira 100 mg/mL) is a monoclonal antibody (mAb) which is used for the treatment of psoriasis, rheumatoid arthritis and Crohn's disease in adults and children. Humira is injected under the skin. The dose for a child is calculated according to the child's weight and the medicine is supplied in prefilled syringes that are self-administered at home. Adalimumab has low stability after the vial is open and therefore it is necessary to study its stability under the usual conditions which the prefilled syringes will be exposed. In this context, the charge variant characterisation allows for the detection of structural changes in the drug.

Aim and objectives The objective of the study was to characterise the charge variants of adalimumab under stress conditions (ie, high temperature (60°C) and smooth shaking) by liquid chromatography coupled to UV and mass spectrometry detection in order to assess the impact of mishandling adalimumab in prefilled syringes.

Material and methods Prefilled syringes were prepared with different volumes of Humira (100 mg/mL) and placed at 60°C for 3 hours (to ensure there was degradation of adalimumab and also validation of the method) or underwent smooth shaking at room temperature for 1 hour. An UHPLC-HESI/MS (Orbitrap) was the platform used for the analysis. The column used for the separation was a MabPac SCX-10 RS 2.1 mm×5 mm column, 5µm (Thermo Fisher Scientific).

Results Several charge variants were characterised for adalimumab (basic and acid variants). Significant differences were

detected in this charge variant profile after samples were subjected to 60°C. The charge variants of adalimumab after sample smooth shaking remained unchanged.

Conclusion and relevance Exposure of adalimumab to 60°C modified the chemical structure. The increase in positive charges in the primary structure indicated the increase in basic variants. Therefore, it is highly recommended to keep prefilled syringes refrigerated during transport and storage. On the other hand, agitation of adalimumab solution did not affect the charge variant profiles and thus no particular recommendation is needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-113 COMPATIBILITY AND STABILITY OF ONDANSETRON AND MIDAZOLAM MIXTURES USED IN PALLIATIVE CARE

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Background and importance Different factors can influence the compatibility and stability of the mixture: drug type, concentration, solvent, container, temperature and light. There are some mixtures of drugs with proven stability, but there is a lack of evidence about the stability and compatibility of the combination of ondansetron and midazolam. The objective of this investigation was to study the compatibility and stability of a binary mixture of these drugs in solution for subcutaneous infusion in palliative care

Aim and objectives To evaluate the compatibility and stability of two admixtures of ondansetron and midazolam at two different temperatures (25°C and 37°C). The concentrations of the admixtures were 0.1 g/L–0.1 g/L and 0.5 g/L–1.0 g/L in NaCl 0.9% stored in elastomeric infusors protected from light

Material and methods Samples were prepared and diluted in NaCl 0.9% in elastomeric infusors in triplicate to obtain four different conditions of concentration and/or storage temperature (0.1 g/L–0.1 g/L; 0.5 g/L–1.0 g/L for ondansetron and midazolam, respectively, stored at temperatures of 25°C and 37°C).

The concentration of each drug was periodically determined using HPLC-UV and UV-Vis spectrophotometry methods in the analytical chemistry laboratory between February and June 2019. Conditions: C₁₈ column, mobile phase methanol: KH₂PO₄ 0.05 M, adjusted to pH 3 with H₃PO₃ (60:40, v/v) delivered at a flow rate of 1.0 mL/min. The sample injection volume was 20 µL, and triplicate injections were performed for every sample. The signal was recorded over 14 min and the retention times were 4.1 min for ondansetron and 7.8 min for midazolam. Ondansetron and midazolam concentrations were determined at 254 nm.

Results HPLC-UV and UV-Vis spectrophotometric methods gave the same results. The stability of the admixtures diluted in NaCl 0.9% were as follow: ondansetron–midazolam (0.1 mg/mL–0.1 mg/mL and 0.5 mg/mL–1.0 mg/mL) were stable

(retained >90% of their initial concentrations) for only 1 day at 25°C and 37°C, respectively

Conclusion and relevance Recommended use is for a maximum of 1 day, at the concentrations evaluated; over time it tends to precipitate. Infuser conditioning decreases stability with respect to other conditioning materials, so other stability studies may not be extrapolated if stored under different conditions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-114 IMPROVING MEDICATION ADMINISTRATION FOR PATIENTS WITH DYSPHAGIA

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Background and importance Dysphagia affects swallowing not only of food and drink, but also of orally administered medications. Altering solid dose formulations renders administration unlicensed and can adversely affect both patient and administrator, depending on the type of drug. Medication administration in patients with dysphagia necessitates a multidisciplinary approach with no one profession holding all the necessary expertise.

Aim and objectives To improve medication administration for patients with dysphagia.

Material and methods

- Baseline audit of practice of medication administration to patients with dysphagia (July/August 2016, n=16).
- Establishment of electronic referral from speech and language therapist (SLT) to pharmacy for patients with dysphagia.
- Assessment of liquid medications using the International Dysphagia Diet Standardisation Initiative (IDDSI) flow test to enable pharmacists and nursing staff to understand if liquid formulation is suitable for the patient's current fluid recommendations as per SLT.
- Policy on medication management in patients with dysphagia written and circulated.
- Ongoing audit of medication administration to patients with dysphagia on wards, and of SLT compliance in completing electronic referral. Audits at 2 months (August 2017, n=14) and at 12 months (August 2018, n=30) post implementation of electronic referral.

Results

- Median percentage of medications being optimally administered increased from 44% to 89% post implementation of electronic referral and viscosity guide for liquid medications.
- 40% of patients needing pharmacy review referred by SLT, but 40% of patients needing referral were only highlighted on the day of the audit.
- Patients were reviewed sooner by pharmacy when electronic referral was completed.

Conclusion and relevance Implementation of SLT electronic referral to pharmacy increased patient safety. The median