fatal consequences. Missing dependent and independent controls regarding concentration and identity pose a risk for patient safety.

Purpose We developed a concept for a two-stage quality control of the infusion solutions. Drug identity and concentration can be checked onsite after preparation using a combined UV- and Raman spectrometer (UV-Raman). This is complemented by an independent method using liquid chromatography coupled to UV detection (HPLC-UV).

Material and methods Methods for the analysis of seven cytostatic drugs and two monoclonal antibodies were developed and validated on an i-QCRx UV-Raman system (B and W Tek Europe GmbH, Lübeck, Germany) and on an Agilent 1200 series HPLC-UV system (Agilent Technologies, Waldbronn, Germany). Sample transport and preparation were evaluated to ensure valid results. In a pilot study we analysed samples from different pharmacies in both systems.

Results Method development and validation were successful for the investigated compounds in both systems. HPLC-UV is more sensitive than UV-Raman. However, due to the content of the preparations, real samples had to be diluted before applying HPLC-UV analysis. Sensitivity of the UV-Raman spectrometer fits to the required concentration range without further dilution. All methods showed reproducible results, UV-Raman varied by 0.44% in a repeated analysis (n=3) of 5-fluorouracil, while HPLC-UV varied by 0.14%. Results of the investigated samples were also equivalent. In a sample containing paclitaxel with a target concentration of 0.72 mg/mL we determined 0.73 mg/mL (101%) using UV-Raman and 0.69 mg/mL (96%) using HPLC-UV, for example.

Conclusion UV-Raman and HPLC-UV are suitable for determining the content of patient-individual preparations, both with individual assets and drawbacks. The study showed that the two-stage control concept is appropriate to ensure a high-quality level for patient-individual preparations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Section 6: Education and Research

6ER-001 HIGH VERSUS LOW DOSE OF URSODEOXYCHOLIC ACID FOR THE MANAGEMENT OF INTRAHEPATIC CHOLESTASIS OF PREGNANCY: A COHORT RETROSPECTIVE STUDY OF MATERNAL AND NEONATAL OUTCOMES

[1]R Barazi*, [2]O Alkhozondar, [1]A Kilani, [3]S Kassim, [4]E Mohamed, [5]G La Monica, [1]E Alhamoud, [1]R Elenany, [3]M Alloub. *[1]Hamad Medical Corporation, Pharmacy, Al Wakra, Qatar; [2]Hamad Medical Corporation, Pharmacy, Wakra, Qatar; [3]Hamad Medical Corporation, Ob/Gyn, Al Wakra, Qatar; [4]Hamad Medical Corporation, Pharmacy, Dohaq, Qatar; [5]Sidra Medicine, Ob/Gyn, Doha, Qatar*

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Background Intrahepatic cholestasis of pregnancy (ICP) is a pregnancy-related reversible hepatic disease. The clinical importance of ICP lies in neonatal and maternal ICP-associated complications which include higher rates of perinatal morbidity and mortality, increased rates of caesarean sections, increased risk of meconium staining of amniotic fluid, preterm delivery, fetal bradycardia, fetal distress and fetal demise. The underlying mechanisms associated with poor neonatal outcome have been shown to be associated with elevated maternal total serum bile acids (40 mmol/L) antenatally.

Ursodeoxycholic acid (UDCA) has shown to result in a significant improvement in symptomatic relief, biochemical markers and gestational age of delivery in patients with ICP. However, a consensus is lacking for the optimal UDCA dosing regimen.

Purpose The study is primarily to compare the effect of a high versus low dose of ursodeoxycholic acid in maternal and neonatal outcomes. This study will also determine the characteristics associated with ICP in a cohort of patients.

Material and methods Design: Retrospective cohort study as ICP is a rarely occurring hepatic disease.

Setting: Most ICP patients get diagnosed or referred to governmental hospitals located in their area of residence for inpatient and outpatient care.

Participants: ICP patients who underwent management of their disease in Ob/Gyn units between July 2016 and July 2017. Patients were identified using institutional medical records.

Main outcome measures: Maternal outcomes: Mode of delivery, gestational age at diagnosis and gestational age at delivery. Neonatal outcomes: APGAR score: 1 min, 5 min and 15 min: birthweight in g and NICU admission.

Results None of the patients had a history or concurrent diagnosis of other hepatic or biliary disease. A small proportion of both the high-dose and low-dose study population had histories of ICP in previous pregnancies: three in the high-dose group and two in the low-dose group. The mean bile acid level upon diagnosis was 19.7 mmol/L in the high-dose group paralleled to 17 mmol/L in the low-dose group. Other neonatal and maternal outcomes will be presented in the poster.

Conclusion This study failed to detect or prove the difference in the maternal and neonatal clinical outcomes between the UDCA high- and low-dose groups.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ncbi.nlm.nih.gov/pubmed/24901263https://www.jogc.com/article/S1701–2163(15)30544–2/pdf

No conflict of interest.

6ER-002 EFFICACY OF A FIXED-RATIO COMBINATION OF INSULIN DEGLUDEC AND LIRAGLUTIDE IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS

[1]V Ožana*, [2]M Frydrych. *[1]Hospital with Polyclinic Karvina-Raj- Orlova City Branch, Pharmacy, Orlova, Czech Republic; [2]University of Veterinary and Pharmaceutical Sciences Brno, Department of Human Pharmacology and Toxicology- Faculty of Pharmacy, Brno, Czech Republic*

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Background Based on the current recommendations, a fixed-ratio combination of insulin degludec and GLP-1 agonist liraglutide (IDegLira) is considered to be an equivalent alternative to an intensified insulin regimen for type 2 diabetes mellitus (T2DM). As a once-daily injection with effects on both fasting and postprandial hyperglycaemia, IDegLira provides, according to several studies, optimal glycemic and metabolic control.

Purpose To determine the effectiveness of IDegLira in the reduction of glycemic parameters, bodyweight and lipid profile parameters in patients with a diagnosis of T2DM.

Material and methods A retrospective observational study was conducted in a diabetic clinic of a regional hospital. Clinical data and demographic characteristics were obtained from computerised medical records and processed by Microsoft Excel. Overall, 52 participants were selected with T2DM who were treated with IDegLira in addition to oral antidiabetic drugs for at least 52 weeks between October 2016 and January 2018. The effectiveness of IDegLira was analysed through measuring glycated haemoglobin (HbA1c), fasting plasma glucose (FPG), and bodyweight and lipid profile parameters at the beginning of the treatment and at week 52.

Results Fifty-two patients were included in total. Mean age: 61.2 years (38–78): 25 females and 27 males. Average duration of diabetes: 8.5 years (2.8–19.9). After 52 weeks the mean HbA1c decreased from a baseline of 72.3±1.4 mmol/mol by 7.3±1.8 mmol/mol ($p<0.001$). The mean FPG was reduced from a baseline of 9.6±0.4 mmol/L by 1.5 ±0.4 mmol/L ($p<0.001$). Average weight loss was −0.45 ±0.32 kg ($p=0.161$). Mean changes in lipid profile parameters such as total cholesterol, LDL-cholesterol and triglycerides were statistically insignificant except for HDL-cholesterol, which increased from a baseline of 1.06±0.05 mmol/L by 0.04±0.02 mmol/L ($p=0.014$). Compared to the data from the DUAL Clinical Trial Programme, the reduction in glycemic parameters attained in this study was less pronounced presumably due to the smaller number of participants and different baseline characteristics.

Conclusion The conducted study confirms that the positive impact of IDegLira on glycemic compensation in patients with T2DM as a statistically significant decrease in parameters of glycemic control was achieved. On the contrary, the weight reduction and almost all the changes in plasma lipid concentrations were insignificant.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

6ER-003 COST OF VENOUS THROMBOEMBOLIC DISEASE IN PATIENTS WITH LUNG AND PROSTATE CANCER: COSTECAT STUDY

[1]R Ana Rosa*, [2]MA Calleja, [3]MD Alvarado, [4]F Artime, [5]B Bernardez, [6]V Escudero, [3]C García, [4]I Mangues, [2]JA Marcos. *[1]Hospital Virgen de La Salud, Pharmacy, Toledo, Spain; [2]Hospital Universitario Virgen Macarena, Pharmacy, Sevilla, Spain; [3]Hospital Universitario Virgen de Las Nieves, Pharmacy, Granada, Spain; [4]Hospital Universitari Arnau de Vilanova, Pharmacy, Lleida, Spain; [5]Complejo Hospitalario Universitario de Santiago, Pharmacy, Santiago de Compostela, Spain; [6]Hospital General Universitario Gregorio Marañón, Pharmacy, Madrid, Spain*

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Background Patients with cancer are at significantly higher risk of developing, and dying from, venous thromboembolism (VTE). The CLOT and CATCH trials demonstrated the superiority of low-molecular-weight heparins (LMWH) over warfarin for recurrent VTE and established LMWH as the standard of care for cancer-associated VTE.

Purpose The aim of the present study was to determine the number of admissions and the cost of the management of VTE events occurring in patients with lung cancer (LC) or prostate cancer (PC).

Material and methods This was a multicentre, observational, ambispective pharmacoeconomic study involving six third-level hospitals. Patients with LC or PC who had suffered a first episode or a recurrent symptomatic or incidental VTE recurrence and who were receiving treatment with LMWH were included.

The data was collected through medical records and/or the discharge reports, as well as the information provided by the patient during the study visit as well as the information the patient collected in their patient diary during the follow-up period.

All hospitalisations and ambulatory cost related to VTE (primary diagnosis or related diagnosis) were recorded. Anticancer therapy was not collected. Costs were estimated through the consumption of resources collected in the eCRF and derivatives of the information from the patient's diaries associated with the handling of the episode of VTE.

Results Fifty-five patients were included from October 2017 to April 2018. The last patient visit was recorded in October 2018. The results will be presented during the EAHP 2019.

Conclusion Among the solid tumours with higher absolute risk of VTE are PC and LC that in our country represented the second and third most prevalent cancer according to the GLOBOCAN 2012 report.

VTE represents a great economic burden on health systems and society, mainly due to the treatment of initial and recurrent events that require hospitalisation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-005 USE OF SACUBITRIL/VALSARTAN IN PATIENTS WITH CHRONIC HEART FAILURE

[1]L Enríquez Olivar*, [2]AM López González, [2]S Izquierdo Muñoz, [2]E Queipo García, [2]MT Sánchez Sánchez. *[1]Hospital Clínico Universitario, Hospital Pharmacy, Valladolid, Spain; [2]Hospital Clínico Universitario de Valladolid, Hospital Pharmacy, Valladolid, Spain*

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Background Recommendations approved by the local Pharmacy and Therapeutics Committee (PTC) for the prescription of Sacubitril/Valsartan (SV) are: patients with chronic symptomatic heart failure (HF) (II–III grade following New York Association (NYHA)) with reduced left ejection fraction (LVEF <35%) and elevated N-terminal Pro B-type natriuretic peptide (NT-proBNP >640 pg/ml) seric levels to be treated with standard of care therapy: angiotensin converting enzyme inhibitors (ACE) or angiotensin II receptor blockers (ARB), in combination with beta-blockers (BB) and mineralcorticoid antagonists.

Purpose To evaluate the adherence to the recommendations of the PTC concerning the prescriptions of SV on hospital admission.

Material and methods A descriptive, observational and prospective study including patients treated with SV from March 2018 to July 2018 in a General Teaching Hospital.

Variables considered were: sex, age, patient chronic and fragile (G3), according to the stratification of the regional Health Service, HF NYHA classification, LVEF, NT-proBNP, previous treatment with ACE inhibitors/ARBs, BB and mineralcorticoid antagonists at hospital admission and glomerular filtration rate (GFR).

Results Fifty-one patients were included: 84% (43/51) were men, average 69±11 years and 51% (30/51) were G3.