2016 in a tertiary care hospital and patients who started treatment with oral urea or tolvaptan during hospitalisation. Variables collected: etiology of hyponatraemia, analytical parameters, dose and duration of treatment.

Results Seven patients treated with tolvaptan: four diagnosed with HF and three with SIADH. Dose ranged from 15 mg/day to 30 mg/day. Median duration: 7 days (2–28). Baseline and final mean natraemia: 119.8 mEq/L and 133 mEq/L respectively. Two patients with SIADH and one with HF had eunatraemia. Three patients were exitus. Six patients were treated with urea, five diagnosed with SIADH and one with adrenal insufficiency. Urea dose ranged from 15 g/day to 30 g/day. Median duration of treatment: 15 days (7–147), three patients continued at home. Baseline and final mean natraemia were 123.4 mEq/L and 133 mEq/L respectively. Three patients with SIADH achieved eunatraemia, two patients were exitus. Only three urea patients had all necessary data for a diagnosis of SIADH. The mean increase in natraemia at 24 hour was 4.57 mEq/L (0–8) in the urea group; 9.9 mEq/L (–3 to 21) in the tolvaptan group (>12 mEq/L in the three cases of SIADH and one case of HF). Deaths were due to complications related to their advanced disease.

Conclusion Off-label use of tolvaptan in HF has not been shown to be effective. Regarding hyponatraemia in SIADH, tolvaptan has shown to be moderately effective, but the correction was too rapid. This result can be related to an incorrect diagnosis of SIADH and/or a too low baseline natraemia. Urea proved to be an alternative of moderate efficacy but safer, allowing its ambulatory use. Therefore, the pharmacy service proposed to establish in our hospital a protocol for the management of severe hyponatraemia to improve the efficacy and safety of tolvaptan and urea.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-028 THE GOVERNANCE OF PCSK9-INHIBITORS FOR THE TREATMENT OF PRIMARY HYPERCHOLESTEROLAEMIA: APPROPRIATENESS ANALYSIS

¹MR Garreffa*, ¹C Zito, ¹S Esposito, ¹C Monopoli, ²MD Naturale, ¹AE de Francesco.

¹Azienda Ospedaliero-Universitaria 'Mater Domini', Unit of Pharmacy, Catanzaro, Italy;

²University of 'Magna Graecia', School of Specialization in Hospital Pharmacy, Catanzaro, Italy

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Background Recently the European Medicines Agency approved Alirocumab and Evolocumab, two monoclonal antibodies against PCSK9 (PCSK9-inhibitors), a key protein in LDL-receptor degradation. These drugs, as monotherapy or in combination with other lipid-lowering agents, represent an important therapeutic strategy in patients with high cardiovascular risk with severe familial hypercholesterolaemia or intolerance to statins.

In 2017, the Regional Working Group (RWG), using the GRADE method, drafted the guidelines for the identification of the PCSK9-inhibitors prescribing centres and for the prescriptive appropriateness.

Purpose Our goal was to monitor the use of the PCSK9-inhibitors to assess the reliability of the forecasts made by the RWG and the appropriateness.

Material and methods The guidelines for appropriateness have been drawn up using the GRADE method.

The data on therapeutic adherence have been extrapolated from the Health.db, appropriateness analysis tool adopted in our region since 2013.

The pharmaco-utilisation data for the period January 2017 to June 2018 were obtained from the IQVIA database.

Results The pharmaceutical use data showed that about 8.6% of the regional population was treated with statins.

The epidemiological evaluation using Health.db showed that the patients with high adherence to combined statin + Ezetimibe treatment were 0.2%: of these, 0.03% did not reach the therapeutic target. It is expected that only 185 patients (0.01%) present distance from the therapeutic target of more than 30% and, therefore, eligible for treatment with PCSK9-inhibitors.

Also, the pharmaco-utilisation data (real data) demonstrated that the number of patients suitable for treatment with PCSK9-inhibitors in the period July 2017 to June 2018 was 190, almost equal to that provided by the epidemiological analysis performed by Health.db according to the GRADE method.

The use of PCSK9-inhibitors at regional level increased significantly in the first half of 2018 compared to 2017 ($\Delta_{\text{units}} = +128\%$), probably due to the effectiveness and continuity of the treatments.

Conclusion The establishment of the RWG to define the care path for patients with high cardiovascular risk was essential for the epidemiological evaluation and monitoring of PCSK9-inhibitors therapies. This allows us to analyse the cases of suspension of therapy and the eventual occurrence of adverse events. We plan to evaluate the long-term efficacy of these treatments by observing the lowering of LDL-cholesterol.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Grading of Recommendations Assessment, Development and Evaluation; <http://www.jclinepi.com/content/jce-GRADE-Series> http://old.regione.calabria.it/sanita/allegati/dca_2017/dca_88.pdf

No conflict of interest.

5PSQ-029 EFFECTIVENESS AND SAFETY OF EVOLOCUMAB IN REAL CLINICAL PRACTICE

MV Villacañas Palomares*, A Colón Lopez de Dicastillo, I Gutiérrez Pérez, F Uriarte Estefanía, R Santos del Prado, S Lorenzo Martín, E Parra Alonso. Hospital de Sierrallana, Servicio de Farmacia, Torrelavega, Spain

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Background Monoclonal antibody PCSK9-inhibitor, evolocumab, is a new drug for the treatment of patients with uncontrolled familial hypercholesterolaemia (FH), uncontrolled stable atherosclerotic cardiovascular disease (ASCVD), mixed dyslipidaemia, or in patients who cannot tolerate or cannot be given statins. Evolocumab is used in monotherapy or in combination with statins or another hypolipemiant.

Clinical trials (CT) showed that evolocumab obtained LDL-C reductions of 64% when combined with statins and of 58% in monotherapy, at week 12. No significant adverse events were detected.

In our hospital, pharmacists validate every prescription of evolocumab according to the regional autonomous authorisation criteria.