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Conflict of Interest No conflict of interest.

Section 5: Patient Safety and Quality Assurance

5PSQ-001 EFFICACY OF OBETICHOIC ACID IN PATIENTS WITH PRIMARY BILIARY CIRRHOSIS AND INADEQUATE RESPONSE TO URSODEOXYCHOLIC ACID

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Background Obeticholic acid (OCA) is a synthetically modified bile acid that is used to treat a rare disease, the primary biliary cholangitis (PBC). OCA has been recently used in combination with ursodeoxycholic acid (UDCA) in adults who have not responded well enough to UDCA, or alone for adults who cannot tolerate UDCA.

Purpose To evaluate the clinical results obtained from patients with PBC who were treated with OCA in our hospital.

Material and methods In this study, all patients diagnosed with PBC, who were treated with OCA in our hospital were located. The primary endpoint was the percentage change in alkaline phosphatase (ALP) from baseline. Secondary endpoints included dose of OCA, change from baseline in markers of cholestasis and hepatocellular injury, analysis of possible interactions with concomitant treatments, side effects and their management.

The Electronic Clinical History (SELENE) and the Pharmacy Service Managing Software (FARMATOOLS) were used for the location and collection of clinical data.

Results A total of four patients were evaluated. They were all women with a mean age of 46 years (39–57), an average of 10 years (6–14) since the diagnosis, stage 3 fibrosis and a dose of 5 mg/day of OCA in combination with UDCA.

The mean baseline values of ALP were 273 IU/L (182–401) and all patients had normal values of total bilirubin. Half of the patients achieved a 50% reduction in baseline levels of ALP after 60 days of treatment. The baseline levels of alanine aminotransferase decreased by 32% (23–43) in three patients after 7 weeks. The baseline triglyceride levels increased by an average of 38% (4–171) and baseline HDL levels decreased 30% (26–32).

The only interaction detected was with the ion exchange resins, whose intake was spaced as much as possible from the OCA administration. The main side effects were pruritus, facial rash and diarrhoea. All the patients presented intense pruritus that could be controlled with the use of antihistamines.

Conclusion OCA has shown an excellent early response until now, improving levels of ALP with an acceptable safety profile. The most frequent adverse reaction is pruritus, which seems to be tolerated acceptably with pharmacological agents.

REFERENCES AND/OR ACKNOWLEDGEMENTS

I would like to express my gratitude to my co-workers.

No conflict of interest.

5PSQ-002 IATROGENIC HYPOGLYCAEMIA: FREQUENCY AND IMPACT ON QUALITY OF LIFE AMONG TYPE 2 DIABETES MELLITUS PATIENTS

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Background Hypoglycaemia is the antidiabetic drugs' major side effect, especially for insulin and insulin secretagogues. Few observations in real-life iatrogenic hypoglycaemia studies on type 2 diabetes have been carried out.

Purpose To assess iatrogenic hypoglycaemia frequency on type 2 diabetic patients and to measure its impact on quality of life.

Material and methods It was an observational cross-sectional study among type 2 diabetes inpatients and outpatients at the endocrinology department. Patients were asked the number of times they experienced light or moderate hypoglycaemia in the past 6 months and severe hypoglycaemia in the past 12 months. Quality of life related to patient's health was measured by the Euro 5 quality of life dimensions (EQ-5D). The EQ-5D score index was determined through a conversion table. This score can range from –0.529 to 1 in our country. The EQ-5D also includes a visual analogue scale (EQ-VAS) graduated from 0 to 100. Statistical tests ANOVA and the Chi-square test 2 were applied and statistical significance was accepted at $p < 0.05$.

Results A total of 141 type 2 diabetic patients were enrolled. Average age was 59.3 ± 10.2 years and the sex ratio was 0:64. Among patients, 71 (50.4%) reported at least one incident of hypoglycaemia. Only nine patients (6%) had immediately confirmed hypoglycaemia by a blood glucose finger less than 0.7 g/L. Seventeen patients (12%) reported severe hypoglycaemia, whereas hospitalisation was required for six cases in the emergency department, including treatment with glucagon or glucose solution. Median score of the EQ-VAS was 65. Severe hypoglycaemia occurrence was significantly related to mobility problems ($p = 0.027$), autonomy ($p = 0.015$) and usual activities ($p = 0.034$). Hypoglycaemia is associated with a quality of life index less than the average level ($p < 0.001$). Similar results were found in other studies. Hypoglycaemic events number had no significant impact on quality of life, with P-values greater than 0.05 for all EQ-5D dimensions.

Conclusion Our study revealed that iatrogenic hypoglycaemia had elevated rates and it impacts type 2 diabetic patients' quality of life. This major side effect should have more consideration by practitioners for better diabetes management.

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5PSQ-003 A QUALITATIVE ANALYSIS OF BARRIERS TO MEDICATION ADHERENCE IN UNCONTROLLED DIABETES – FOCUS ON INSULIN AND SUGGESTIONS FOR PRACTICE IMPROVEMENTS

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