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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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10.1136/ejhp-2019-eahpconf.434

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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10.1136/ejhp-2019-eahpconf.435

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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No conflict of interest.

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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10.1136/ejhp-2019-eahpconf.436

Background Diabetes is one of the most prevalent disorders worldwide, necessitating serious interventions to prevent complications. The majority of patients have uncontrolled diabetes which could be linked to medication non-adherence. In the current setting many patients are receiving quadruple oral therapy due to refusal to receive insulin therapy.

Purpose To explore barriers to insulin adherence among patients with uncontrolled diabetes from the perspectives of the patients and their healthcare providers (pharmacists, physicians, nurses, health educators, social workers and nutritionists).

Material and methods The first phase of the study was investigating all barriers to medication adherence through semi-structured interviews with patients and their healthcare providers. The interview guide was created based on a conceptual model developed for the purpose of this study. Interviews were recorded, transcribed and analysed using a thematic content approach. A subgroup analysis of data focusing on insulin use was further conducted and recommendations for practice improvements were provided.

Results Thirty patients and healthcare providers were interviewed. Four main themes emerged from the subgroup analysis: lack of patient education (about the disease, the use of insulin, dose adjustments); phobia of insulin (side effects, addiction, self-injection, pain); environmental and cultural factors (working conditions, religious rituals, cost, travelling); and social stigma (rejected by people, lack of family support). Suggestions for practice improvements include educating the patient through an online portal created for diabetes, creating care plans which take the patient's working conditions and religious rituals into account, creating a platform for educating the public to eliminate and correct myths about insulin use, and creating country-specific guidelines which take into consideration patients' refusal of insulin and highlights the steps that should be followed by healthcare providers to convince the patient about the use of insulin or provide an evidence-based alternative approach to managing highly uncontrolled diabetes.

Conclusion There are many barriers that contribute to patients' refusal of insulin use. Urgent interventions and policies need to be implemented to reduce diabetes complications and increase the awareness of the benefits of using insulin.

REFERENCES AND/OR ACKNOWLEDGEMENTS

The authors thank all the pharmacists who were very supportive in the conduct of the study and all the participants who contributed to enriching our knowledge about their experiences.

No conflict of interest.

5PSQ-004 OBSERVATIONAL STUDY OF THE EVOLUTION OF BLOOD GLUCOSE LEVELS AFTER THE CHANGE TO INSULIN DEGLUDEC

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10.1136/ejhp-2019-eahpconf.437

Background Degludec is a new-generation basal insulin analogue with a longer acting, better pharmacokinetic and pharmacodynamic profile and with four times less variability than its comparative insulin, glargine.

Purpose We evaluated the impact in glycated haemoglobin (HbA1c) and variability of glucose levels after the change to degludec from any other basal insulin.

Material and methods A retrospective observational study was made using 129 diabetic patients from the Diabetes Day Hospital, using the features described in the results to characterise them. Three months' later the variation of the levels of HbA1c, body mass and insulin units were monitored. In addition, we chose a 79-patient subgroup to analyse glycaemia variability, using capillary glucose levels 3 consecutive days before the change to degludec and after 12 weeks.

Results One-hundred and twenty-nine patients were included in the study, 32.6% females and 67.4% males, with an average age of 57.1 ± 17.3 years. Between them, 25.6% had diabetes type I and 74.4% diabetes type II, and an evolution of 14.7 ± 8.6 years after the diagnosis, also with a body mass index of 30.8 ± 5.1 kg/m², and HbA1c levels of $8.67\% \pm 1.9\%$. The most common reasons to change the basal insulin were repetitive hypoglycaemias (34.9%), bad glucose sugar levels' control (40.3%), glycaemia variability (16.3%) and the necessity of repeating the basal dose (8.5%). The previous treatment was basal insulin treatment (12.4%) versus basal bolus (87.6%). The results after a 3 month period with degludec are shown in Table 1. No severe hypoglycaemias were reported.

Abstract 5PSQ-004 Table 1

	Beginning	Levels after 12 weeks	P-value
HbA1c	8.67 ± 1.9	$7.47\% \pm 1.1$	0.0001
Average glycaemia	182.4 ± 60.9	146.5 ± 32.2	0.0001
Standard deviation	55.2 ± 23.3	43.3 ± 18.3	0.0001
Coefficient of variation	31.1 ± 11.5	28.7 ± 9.2	0.046
Basal insulin dose	0.44 UI/kg	0.42 UI/kg	0.030
Rapid insulin dose	0.42 UI/kg	0.38 UI/kg	0.039
Weight	83.4 ± 16.02	83.6 kg ± 16.04	0.484

Conclusion Above the HbA1c, new glycaemic control quality standards are being used to measure progress in the quality of life of diabetic patients with new treatments. All of them show a dramatic improvement after changing from glargine to degludec in only 3 months. Nevertheless, glargine is still the elected basal insulin for insulin-dependent diabetic patients, and more studies should be done to prove the superiority of degludec.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

5PSQ-005 SAFETY AND EFFICACY OF FAST-ACTING INSULIN ADDED TO TOTAL PARENTERAL NUTRITION

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10.1136/ejhp-2019-eahpconf.438

Background Total parenteral nutrition (TPN) support requires a multidisciplinary approach from experienced healthcare professionals such as pharmacists, to minimise potential complications. However, on a daily basis clinical practice is common