LIRA: from 14.8% at baseline (both groups) to 64.8% with DU and 42.6% with LIRA (*p*=0.033). Although limited by a retrospective design and lack of constant up-titration for LIRA to the highest dose, these findings indicate that the beneficial glycometabolic responses to DU on a background of MET or MET plus SFU/glinide are durable, especially in presence of obesity and greater HbA1c impairment.
(1) **Ref**: Mirabelli et al. IJERPH. 2019;17(1):207.

Diabetes Mellitus and Glucose Metabolism

CLINICAL TRIALS IN DIABETES AND METABOLIC DISEASE

Real-World Safety and Effectiveness of iGlarLixi in People With Type 2 Diabetes who Fast During Ramadan: Results From Wave 1 of the SOLIRAM Study

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Background: People with type 2 diabetes (T2D) are at an increased risk of severe hypoglycaemia when fasting. SOLIRAM is an international, prospective, observational study evaluating the safety and effectiveness of the fixed-ratio combination (FRC) of insulin glargine 100 U/mL and lixisenatide (iGlarLixi) in people with T2D who fast during Ramadan. **Methods:** SOLIRAM will be performed in two waves. Here, we present the interim results, using descriptive statistics, from participants who fasted during Ramadan in 2020 (Wave 1). Adults with T2D who had taken iGlarLixi for ≥3 months before inclusion and who planned to fast for ≥15 days during Ramadan, were enrolled from 5 countries. During the study, iGlarLixi treatment was adjusted as per routine practice by the treating physician. **Results:** Overall, 155 people with T2D (54.2% male) were eligible. Mean±SD age was 58.4±9.5 years, body mass index was 30.5±6.0 kg/m² and 64.5% of people had ≥1 diabetes-related complications. Proportion of patients with ≥1 macro- and microvascular complications were 11.0% and 48.4%, respectively. Mean±SD duration of diabetes was 14.0±6.6 years and duration of iGlarLixi treatment prior to study participation was 5.7±3.3 months. Mean±SD length of fasting was 28.7±3.3 days and only 9/153 people (5.9%) broke the fast during Ramadan. Reported reasons for breaking the fast were travel, pre-existing conditions, adverse events (AEs; not related to iGlarLixi), hypoglycaemia, and menses. Change in antihyperglycaemic treatment class was minimal during the study with 79.4% and 54.2% of people taking biguanides and sulfonylureas during Ramadan, respectively. The mean±SD iGlarLixi dose changed from 24.8±11.6 U (pre-Ramadan) to 23.8±10.5 U (Ramadan period) and 24.9±11.6 U (post-Ramadan). During Ramadan, 137/153 (89.5%) and 11/153 (7.2%) of people took iGlarLixi at Iftar (evening) and before Suhur (morning), respectively. The number of participants reporting ≥1 severe and/or symptomatic documented hypoglycaemia (plasma glucose [PG] ≤70 mg/dL; primary endpoint) was 2/151 (1.3%) during pre-Ramadan, 3/148 (2.0%) during Ramadan, and none during post-Ramadan. No participant reported hypoglycaemia with PG <54 mg/dL and there were no severe or serious hypoglycaemia events. The rate of severe and/or symptomatic documented hypoglycaemia (PG ≤70 mg/dL) was 0.02 per patient-month. Improvements were observed for mean±SD HbA$_{1c}$ and fasting PG (pre-Ramadan, 8.4±1.1% and 146.9±32.1 mg/dL to post-Ramadan, 7.5±0.8% and 122.5±28.8 mg/dL) with an average reduction of -0.8±1.1% and -24.4±32.6 mg/dL, respectively. AEs were low (5.8%) and were not considered related to iGlarLixi, and there were no serious AEs. **Conclusion:** In a real-world setting, people with T2D treated with FRC iGlarLixi were able to fast for most of the month of Ramadan; the incidence of hypoglycaemia was low and glycaemic control was improved.

Diabetes Mellitus and Glucose Metabolism

COVID-19 AND DIABETES

A Case Series of Hyperglycemic Hyperosmolar State During the Global COVID-19 Pandemic

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Hyperglycemic hyperosmolar state (HHS) is rare in pediatrics, particularly in patients with antibody positive diabetes mellitus (DM). Recent literature has implicated COVID-19 in the reported increase in new-onset DM cases, as well as mixed diabetic ketoacidosis (DKA) and HHS cases, however a rise in HHS cases alone has not been well reported [1,2]. We noted an anecdotal increase in the frequency of HHS cases in our pediatric tertiary care center following the onset of the global COVID-19 pandemic. To investigate further, a retrospective chart review evaluating all patients with DM admitted in the first 6 months of 2019 and the first 6 months of 2020 was conducted. A diagnosis of HHS was defined as a blood glucose over 600 mg/dL with a serum osmolality (calculated or measured) greater than 320 mOsm/kg on initial laboratory evaluation. Patients with DKA, defined as a serum bicarbonate level less than 16 mmol/L with evidence of significant ketosis (serum ketones greater than 3 mmol/L), were excluded from the study. During the first 6 months of 2019, 1 patient met inclusion criteria. However, the diagnosis of HHS was complicated by a concurrent diagnosis of diabetes insipidus, which may have contributed to the hyperosmolar state, and a nonketotic lactic acidosis. Five HHS cases were noted in the first 6 months of 2020, 4 of which occurred in May and June. For the 2020 HHS cohort, the average patient age ± SD was 12 ± 3.34 years. The mean ± SD laboratory values included bicarbonate 18.2 ± 1.64 mmol/L, serum blood glucose 776.8 ± 30.75 mg/dL, calculated serum