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.

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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

osmolality 328 ± 4.18 mOsm/kg, and HgA1C 12.72 ± 1.16%. All 5 patients in the 2020 cohort had new-onset DM, with 4 of the 5 patients having at least 1 positive DM antibody (GAD antibodies were positive in 3, ICA/IA-2 antibodies in 2, and Zinc Transporter 8 antibodies in 1). No patients displayed COVID-19 symptoms, and only 1 patient was tested for COVID-19 by PCR, which returned negative. However, SARS-CoV2 antibody testing was not available, and it is unknown if these patients had prior COVID-19 illness. In conclusion, we noted an increased incidence of HHS at our hospital, particularly among new-onset, antibody positive DM patients during the initial months of the COVID-19 pandemic. Further study and investigation are needed to determine the cause of this increased local incidence, and if infectious, social, or economic influences related to the COVID-19 pandemic contributed. **References:** [1] Chan, K.H., et al., *Clinical characteristics and outcome in patients with combined diabetic ketoacidosis and hyperosmolar hyperglycemic state associated with COVID-19: A retrospective, hospital-based observational case series.* Diabetes Res Clin Pract, 2020. 166: p. 108279. [2] Unsworth, R., et al., *New-Onset Type 1 Diabetes in Children During COVID-19: Multicenter Regional Findings in the U.K.* Diabetes Care, 2020.

Diabetes Mellitus and Glucose Metabolism
COVID-19 AND DIABETES

A Single Virtual Consult Reduces Severe Hyperglycemia in Patients Admitted with COVID19 Infection

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Diabetes and hyperglycemia are risk factors for morbidity and mortality in hospitalized patients with COVID19. Subspecialty consultative resources to help front-line clinicians treat these conditions is often limited. We implemented a "Virtual Hyperglycemia Surveillance Service (VHSS)" to guide glucose management in COVID19 patients admitted to our 1541-bed academic medical center. From April 22 to June 9, 2020, hospitalized adult patients with COVID19 and 2 or more blood glucose (BG) values greater than 250 mg/dl over 24-h were identified using a daily BG report. The VHSS reviewed BGs and treatment plans, then made recommendations for future glycemic management via a one-time note, visible to all providers. Some patients with re-admission or persistently elevated BG after 1 week received a second VHSS note. We compared BGs from 24-h pre- and 72-h post-intervention starting at 6AM on the day following VHSS review. We also evaluated for hypoglycemia, insulin infusion use and use of formal diabetes consults. A subgroup analysis was performed on patients in the intensive care unit (ICU). At the end of the intervention, we identified a retrospective control cohort admitted to the same hospital from March 21 to April 21, 2020 who met the inclusion criteria for a VHSS assessment. The VHSS group consisted of 100 patients with 126 individual VHSS encounters, and the control group comprised 50 patients. Baseline characteristics in the VHSS and control groups, respectively, were: mean age 62.5 vs 62.1 years, % male 58 vs 56, mean weight 91.4 vs 93.4 kg, BMI 31.8 vs 33.0 kg/m^2, and HbA1c 9.1 vs 8.8 %. There were fewer patients in the ICU in the VHSS than control group (44% vs 66%). In the VHSS group, mean BG pre- vs. post-intervention was 260.3 ±21.7 and 227.4 ±25.3 mg/dl (p<0.001). In the control group, mean BG pre-and post- the day they met assessment criteria was 264.8 ± 6.5 mg/dl and 250.6 ± 8.6 mg/dl (p=0.18). There was no difference in the use of insulin infusions or diabetes consults between the two groups. More hypoglycemia (BG<70 mg/dl) occurred in the VHSS than control group (8.3% vs 0%, p=0.04). Within the VHSS group, the average change in BG was significantly greater in ICU than non-ICU patients (-51.8 ±8.7 vs -19.6 ±5.0 mg/dl, p<0.01) and the reduction in the % of BG over 250 mg/dl was also significantly greater in the ICU (-32.2% vs -16.8%, p=0.02).

Implementation of a single virtual consult for severely hyperglycemic hospitalized COVID19 patients was associated with rapidly reduced BG concentrations, especially in the ICU. The mean reduction in BG with VHSS intervention was more than 2-fold greater than that observed in our control group. Glucose control remained suboptimal, however, suggesting the need for subsequent input from this specialty service.

Diabetes Mellitus and Glucose Metabolism
COVID-19 AND DIABETES

An Observational Study on Glycemic Outcomes, Lifestyle and Psychosocial Health of Patients With Diabetes During Covid-19 Lockdown From Bangalore

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RESEARCH UPDATE IN ENDOCRINE AND DIABETES, BANGALORE, India.

Background and Aims: Lockdown during the COVID-19 pandemic imposed many restrictions on the public. Loss of continuum of care along with improper lifestyle was expected to worsen glycemic control in people with type 2 diabetes (T2D). We aimed to identify the effects of lockdown on their glycemic status, lifestyle changes and psychosocial health.
Methods: The pre- and post-lockdown data of 110 adults with T2D who were under regular follow up was collected by direct interview during their visit to the diabetes clinic. The variables analyzed included demographic data, HbA1c, body weight, lifestyle changes, psychosocial factors and use of technology.
Result: The overall physical activity had dipped significantly accounting to lockdown restrictions and fear.