antimetatypeantibody is added and incubated as 2nd reaction following a wash. Then substrate solution is added after washing immunocomplex.The resulting reaction signals are proportional to the amount of aldosterone in the sample allowing quantitative determination of in serum orplasma sample. The overall reaction is completed within 30 min. ***Results*** Limit of blank (LoB), limit of detection (LoD) and limit of quantitation(LoQ) of our NC-CLEIA aldosterone assay were 0.09 ng/dL, 0.21 ng/dL and 0.57 ng/dL, respectively. NC-CLEIA aldosterone measurements werelinearly well correlated with LC/MS aldosterone measurements (N = 130, y = 1.027x - 0.23 ng/dL, Spearman's ρ = 0.996, P< 0.0001). Bland-Altmanplot analysis between NC-CLEIA and LC-MS/MS of aldosterone revealed a bias of 0.40 ng/dL with the limits of agreement of -4.60 and 5.41 ng/dLwith 95% confidence interval. ***Conclusion*** Our novel NC-CLEIA aldosterone assay was well-correlated and had only a very low bias with LC-MS/MSmethod and also was able to accurately quantify low level samples even in essential hypertension patients. This aldosterone assay can be a most equivalent to LC-MS/MS measurement with a low cost of 12 $ and a short measuring time of 30 minutes.

Pediatric Endocrinology

PEDIATRIC OBESITY, THYROID, AND CANCER

Sporadic MTC in Children: Characterization of a Rare Disease

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MON-LB015

INTRODUCTION: Medullary thyroid carcinoma (MTC) is rare in children and is hereditary (hMTC), caused by germline mutations in the *RET* proto-oncogene, in about 95% of cases. Very little is known about sporadic MTC (sMTC) when diagnosed in children/young adults. Our aim was to study the clinical presentation and long-term outcomes of a large cohort of sMTC seen at a tertiary cancer center and to compare sMTC with hMTC in young patients (pts).

METHODS: Through a review of institutional databases, we identified pts diagnosed with MTC ≤ age 21 years (y.). Charts were retrospectively reviewed and data abstracted. The diagnosis of sMTC vs hMTC was determined based on germline *RET* testing and family history.

RESULTS: We identified 146 pts (53% female), of whom 20 (14%) had sMTC and 126 (86%) had hMTC (80 MEN2a and 46 MEN2b), with a median follow-up of 10 y. (range: 0.08-58, IQR 4.8-18). In pts with sMTC, the stage at diagnosis was I-II in 3/15 (20%) and stage III-IV in 12/15 (80%). Somatic mutations were identified in 11/12 tumors tested (6 *RET* p.M918T, 1 *RET* p.G691S, 2 *RET* deletions p.L629_L633del and p.E632_L633del, 1 *RET* c.2698_2710delinsC, and 1 *CCDC6-ALK* fusion). In contrast to hMTC, pts with sMTC were diagnosed at an older age [mean 18.0 y. ± 3.4 (range: 10-21) vs 12.9 y. ± 5.4 (range: 1.5-21), $p<0.001$], had higher calcitonin [median 889 (IQR 528-2634) vs 16 (IQR 3-117) x Upper Limit of Normal, $p<0.001$] and CEA levels [median 186 (IQR 46-468) vs 11 (IQR 4-16) x Upper Limit of Normal, $p<0.001$], larger tumors [median 2.5 cm (IQR 2-3.7) vs. 0.8 cm (IQR 0.4-1.9), $p<0.001$], and were more likely to be stage IV at diagnosis [73% vs 28%, $p<0.001$]. sMTC pts were less likely to have bilateral tumors [27% vs 81%, $p<0.001$] and, at last follow-up, had more persistent structural disease [79% vs 46%, $p=0.007$] and distant metastases [74% vs 37%, $p=0.005$]. Death from MTC occurred in 15% of pts with sMTC vs 6% pts with hMTC; median overall survival was not significantly different [30.6 y. in sMTC vs 39.3 y. in hMTC].

CONCLUSION: In this largest reported series of MTC in children/young adults, and the only study to look at sMTC in this population, we identified sMTC in 14% of MTC cases, a higher prevalence than is traditionally recognized but one that is possibly confounded by a referral bias. Somatic mutations were identified in 92% of samples tested, allowing for targeted therapy in those with distant metastases if needed. Compared with hMTC, patients with sMTC presented at an older age with higher tumor markers, larger tumors, and more unilateral disease. At last follow-up, persistent structural disease and distant metastases were more common in sMTC. The differences in clinical presentation and long-term outcomes likely reflect a variable path to MTC diagnosis. In conclusion, sMTC in pts ≤ age 21 y. presents at an older age with more advanced disease, frequently has an actionable driver mutation, and may be more common than previously thought.

Pediatric Endocrinology

PEDIATRIC GROWTH AND ADRENAL DISORDERS

Maintenance of Favorable Treatment Effect of Once-Weekly TransCon hGH for Children With Growth Hormone Deficiency: Interim Analysis From the Enlighten Long-Term Extension Trial

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SAT-LB16

Background Once-weekly TransCon hGH is an investigational long-acting prodrug for growth hormone deficiency (GHD) that consists of 3 components: unmodified growth hormone (hGH; somatropin), an inert carrier that protects it, and a linker that temporarily binds the two. In the

randomized phase 3 heiGHt Trial evaluating treatment-naïve children with GHD, TransCon hGH demonstrated superior annualized height velocity and Δ height standard deviation score (SDS) compared to Genotropin and had a similar safety and tolerability profile. **Methods** Results are reported from an interim analysis of subjects from heiGHt who continued in the ongoing enliGHten long-term extension trial for 26 weeks. In the 52-week heiGHt Trial, treatment-naïve, prepubertal subjects with GHD were randomized 2:1 to receive once-weekly TransCon hGH 0.24 mg hGH/kg/week or an equivalent weekly dose of daily Genotropin. Subjects completing heiGHt could enroll in enliGHten, where all subjects received TransCon hGH. Two groups were analyzed: Group A (TransCon hGH in both heiGHt and enliGHten) and Group B (Genotropin in heiGHt, followed by TransCon hGH in enliGHten). Safety and growth outcomes were evaluated approximately every 13 weeks in heiGHt and enliGHten. IGF-1 was sampled on postdose Day 5 (±1 day) in enliGHten. A by-visit ANCOVA model was used to analyze numeric efficacy endpoints.**Results**All but one subject who completed heiGHt continued into enliGHten (A: N=103, B: N=55). Baseline characteristics at the start of heiGHt were balanced between groups. The statistically significant treatment difference in Δ height SDS (Group A vs B) at the end of heiGHt (Week 52, N=159; 1.10 vs 0.96, P=0.0149) was sustained through Week 78 (N=154; 1.39 vs 1.24, P=0.0436), demonstrating persistence of catch-up growth for both groups and maintenance of superior treatment effect for subjects treated with TransCon hGH in the first year of therapy. At Week 78, least-squares mean (SE) IGF-1 SDS on postdose Day 5 (N=153) was 0.52 (0.15) for Group A and 0.59 (0.19) for Group B. Adverse events (AEs) were comparable between groups during heiGHt. During enliGHten, 48.7% (76/156) and 1.9% (3/156) of subjects experienced AEs and serious AEs, respectively; the AE profile was consistent with what was previously observed in heiGHt. A low titer of anti-hGH binding antibodies were detected in 10/156 (6.4%) subjects during treatment with TransCon hGH in heiGHt and enliGHten; no neutralizing antibodies were detected. Lab parameters (HbA1c, cortisol, free thyroxine) were stable and generally remained within the normal range throughout the trials. Mean (SD) BMI SDS was 0.0 (0.8) for Group A and 0.1 (0.9) for Group B at Week 78.**Conclusions** Children treated with TransCon hGH showed continued improvement of height SDS beyond the first year. Treatment with TransCon hGH through 78 weeks demonstrated an AE and immunogenicity profile comparable to that of a daily hGH therapy.

Diabetes Mellitus and Glucose Metabolism

DIABETES COMPLICATIONS I

Metabolic Profile Changes in Patients With Diabetes Mellitus After Hurricane Maria: A Retrospective Case Series

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SAT-LB114

Background: Hurricane María struck Puerto Rico on September 20, 2017. We compared the metabolic profile of patients with diabetes before and after the hurricane.

Methods: A retrospective review of 265 patients with diabetes evaluated at our Endocrinology Clinics 6 months before (March 20, 2017- September 19, 2017) and after the hurricane (October 2, 2017 – September 30, 2018) was performed to compare changes in A1C, fasting blood glucose, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides, systolic blood pressure, diastolic blood pressure, body weight, and body mass index.

Results: A total of 374 patients with diabetes were evaluated before the hurricane, of which 71% returned to the clinics after the hurricane. Although there was a significant decrease in body weight, there were no significant changes in the metabolic profile of patients or groups defined by gender, age or diabetes type.

Conclusions: No significant changes were seen in the metabolic profiles of patients with diabetes before and after the hurricane, which might be partially explained by their weight loss. These results differ from similar studies that show a negative health impact on diabetes management after a natural disaster. However, 29% of these patients did not return for evaluation, which may underestimate the full impact of the hurricane. Factors such as death, financial difficulties, lack of transportation, emigration, and access to health care may contribute to this rate of no-return. Further studies that assess these factors are needed.

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Cardiovascular Endocrinology

VASCULAR DISEASE AND PATHOPHYSIOLOGY

Chronic Kidney Disease Incidence and Cardiorespiratory Fitness Association in Patients With Diabetes And/Or Hypertension

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SAT-LB96

Introduction: Type 2 diabetes mellitus (T2DM) and hypertension (HTN) are considered strong risk factors for developing chronic kidney disease (CKD). Increased cardiorespiratory fitness (CRF) is associated with lower CKD risk. However, the CRF-CKD association in patients with T2DM and/or HTN has not been assessed.Methods: We identified 9,751 patients (age 58.6 + 10.1 years) with T2DM (N=1,444) or HTN (n=5,031) or both (n=3,276) prior to a maximal standardized exercise treadmill test (ETT) and no evidence of ischemia as indicated by the ETT. We established