

during one month (2019). Women aged 18-44 years seeking to track their cycle or to conceive, who were not pregnant, on active contraception or in stabilization mode after pregnancy, and had Flo app running in English met the study inclusion criteria. Participant characteristics including age and BMI were also collected from Flo app users during the sign-up process. All users in the study had agreed to the use of their de-identified and aggregated data for research purposes. The differences in clinical manifestation of PCOS symptoms between BMI groups were analyzed. Of US users with BMI data in the whole cohort, 8,808 women reported having physician-diagnosed PCOS, 5,551 women reported not having a PCOS diagnosis, and 58,478 reported that they had not been checked for PCOS. Of women with PCOS, 19.5% were normal weight (BMI 18.5-24.9), 19.7% were overweight (BMI 25.0-29.9), 20.4% were obese (30.0-34.9), 17.8% were severely obese (BMI 35.0-39.9), and 21.0% were morbidly obese (BMI 40+). The most common symptoms among PCOS positive women were bloating (38.7%), hirsutism (38.2%), and irregular cycle (26.0%). A direct relationship exists between BMI and having PCOS, as the percentage of PCOS in obese, severely obese, and morbidly obese BMI groups was higher (1.37, 1.87, and 2.12 times, respectively) than in the whole cohort. Similarly, among women who report acne, skin hyperpigmentation, bloating, hirsutism, heavy menses, baldness, family history of PCOS, high cholesterol, irregular cycle, and inability to conceive for > 1 year, there is a direct relationship between BMI and the percentage of women with PCOS. Moreover, when identifying symptoms and findings serving as strong predictors of a positive PCOS diagnosis, hirsutism, high glucose, and high levels of both cholesterol and glucose were the top symptoms and findings for women with BMI 18.5-34.9. Hirsutism, high glucose, and inability to conceive for > 1 year were the strongest predictors of PCOS for women with BMI 35+. Among all users with hirsutism, the percentage of women with PCOS increased 3.65 times compared to the whole cohort, making it the strongest predictor of PCOS. Understanding BMI patterns as they relate to PCOS symptoms allows for better understanding the pathophysiology of PCOS. Among women with PCOS in the United States, changes in BMI are associated with variations in the many symptoms of PCOS.

Thyroid

HPT-AXIS AND THYROID HORMONE ACTION

Biotin Depleting Procedure Does Not Impact the Reliability of TSH, LH and FSH Immunoassays

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SAT-LB79

Background: Biotin interference has become a major problem with some laboratory immunoassays, leading to erroneous tests results and potentially harmful clinical consequences. There is therefore a clinical need to easily identify the interference and to overcome its effect to avoid harmful consequences for patients. The aim of this study was to demonstrate the VeraPrep Biotin™ procedure, a biotin depleting device, does not impact the immunoreactivity of TSH, LH and FSH immunoassays. **Materials and**

methods: Nine samples (4 from women and 5 from men) were tested with two-sites electrochemiluminescent immunoassays (Cobas e602, Roche diagnostics) for the measurement of three pituitary hormones, TSH, LH and FSH. The samples were first measured without any treatment (baseline) and then retested after treatment with VeraPrep Biotin™ procedure. Percent (%) difference was calculated between post-treatment and baseline to determine if the biotin depleting device impact the immunoassays immunoreactivity. **Results:** The median baseline concentrations for TSH, LH and FSH were 2.3 mIU/L (standard deviation (SD): 1.5), 4.9 IU/L (19.0) and 5.3 IU/L (17.5), respectively. The median concentrations after treatment with the VeraPrep Biotin™ procedure for TSH, LH and FSH were 2.3 mIU/L (1.5), 4.9 IU/L (18.9) and 4.9 IU/L (16.5), respectively, and were not statistically different from baseline (P = 0.976). The mean recoveries after treatment were 99.5%, 98.6% and 95.4% for TSH, LH and FSH, respectively. **Conclusions:** The concentrations of the TSH, LH and FSH assays were not impacted by the pretreatment with the VeraPrep Biotin™ procedure, confirming its ability to help clinical laboratories to overcome biotin interference.

Diabetes Mellitus and Glucose Metabolism

DIABETES TECHNOLOGY

Diabetic Ketoacidosis With PUMP Failure: Analysis of the 2006-2016 U.S. Kid Inpatient Database

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SAT-LB119

Background: Insulin pumps are valuable tools in diabetes management and their use has increased dramatically over the past decade. Unfortunately, insulin pump use has also been associated with diabetic ketoacidosis (DKA), relating to pump malfunctions that result in the disruption in insulin administration. Our objective was to examine the prevalence and characteristics of DKA admissions associated with pump failure among pediatric patients. **Methods:** We used the national Kids' Inpatient Database to identify pediatric admissions with a primary diagnosis of DKA in years 2006, 2009, 2012, and 2016. We defined a DKA-pump failure admission as an admission with either a primary diagnosis of DKA plus a secondary diagnosis of pump failure/complication or conversely, a primary diagnosis of pump failure/complication with a secondary diagnosis of DKA. We used descriptive statistics and logistic regression to describe the annual trends and characteristics of children admitted for DKA with or without pump failure. Lastly, logistic regression was used to assess the impact of pump failure on length of stay and severity of illness during DKA admissions. **Results:** Our dataset included 166,583 DKA admissions, of which 2,291 (1.4%) were associated with a primary or secondary diagnosis of insulin pump failure. Between 2006 and 2016, the number of total DKA admissions increased by 58%. Admissions for DKA with pump failure increased from 387 to 665 admissions during this time. Among all

children admitted with DKA, those with pump failure were primarily older (60% above age 12), mostly white (63%), female (57%), from urban areas (78%), and almost 2/3rds had private insurance (60%). Adjusted analyses revealed that compared to DKA admissions without pump failure, pump failure was associated with older age, white race, residing in a rural area, private insurance, and higher income. Pump failure admissions were more likely in western and southern hospitals, otherwise there were no significant differences with respect to hospital characteristics. Compared to DKA admissions without pump failure, DKA admissions associated with pump failure had a longer mean length of stay (2.6 vs 1.5 days) and were more likely to have a higher severity of illness category. **Conclusion:** In this national sample, DKA with pump failure was more often observed among white, privately insured and high income children; these patient characteristics likely reflect the population of youth with diabetes who are more likely prescribed pumps in the US. Admissions for DKA concurrent with insulin pump failure accounted for a minority of pediatric DKA admissions but these admissions were associated with longer lengths of stay and severity of illness. Pump failure has important implications for care and management of children with diabetes.

Thyroid

THYROID NEOPLASIA AND CANCER

Positive Predictive Value of TP53 Variants in Bethesda III/IV Thyroid Fine-Needle Aspirates

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MON-LB88

Introduction: Somatic DNA variants in the tumor suppressor gene *TP53* have been reported in papillary thyroid carcinoma (PTC), Hürthle cell carcinoma (HCC), poorly differentiated thyroid cancer (PDTTC), and anaplastic thyroid carcinoma. However, *TP53* variants are uncommon among cytologically indeterminate thyroid nodules, so their positive predictive value (PPV) for malignancy, when identified, is unknown. The original Afirma Xpression Atlas reported genomic variants from the mRNA of 511 genes, including *TP53*. Here we report the PPV of *TP53* alterations among Afirma Genomic Sequencing Classifier (GSC) Suspicious Bethesda III/IV nodules in real-world clinical practice.

Methods: A consecutive cohort of Afirma GSC Suspicious Bethesda III/IV nodules submitted to Veracyte for molecular analysis and positive for only *TP53* alterations by the Xpression Atlas was identified. Local surgical pathology diagnoses were sought with IRB approval. One nodule per patient was included.

Results: Thirty-eight *TP53* variants were present among >13,000 Bethesda III/IV Afirma GSC Suspicious samples. Among the 22 with only a *TP53* alteration, the first 16 consecutive nodules were included (7 nodules were Bethesda III and 9 nodules were Bethesda IV). Local surgical pathology diagnoses were available for 11 of these nodules. Seven nodules (64%) were malignant on surgical pathology: 3 cases of HCC, 1 PDTTC, 1 follicular thyroid carcinoma (FTC), 1 follicular variant PTC, and 1 classical PTC. The mean size of malignant nodules was 3.6 cm (range 1-7.7 cm). The remaining four nodules (36%) were benign on surgical pathology, with a mean size of 2.6 cm (range 1.5-4.2 cm). Benign cases included 2 follicular adenomas (FA), 1 Hürthle cell adenoma (HCA), and 1 adenomatoid nodule (AN). Seven different *TP53* variants were identified, and only one was observed at least 3 times (*TP53*: p.R248Q in 2 cases of HCC and 1 adenomatoid nodule). Given the small numbers, meaningful estimates of the variants' individual PPVs could not be calculated.

Conclusions: *TP53* variants among Afirma GSC Suspicious Bethesda III/IV nodules are very rare and associated with malignancy in 64% of nodules based on local pathology review. A broad range of both benign and malignant neoplasms, including HCC, PDTTC, FTC, PTC, FA, HCA, and AN, were reported among nodules with *TP53* alterations. The prognostic value of finding an isolated *TP53* variant in Afirma Suspicious nodules remains unknown.

Thyroid

THYROID NEOPLASIA AND CANCER

The Initial Dose of ¹³¹I as a Potential Independent Predictor for Residual/Relapsed Disease in Pediatric Differentiated Thyroid Cancer

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MON-LB83

Introduction: In the guidelines for management of pediatric Differentiated Thyroid Cancer (DTC) ¹³¹I therapy is recommended for treatment of iodine-avid persistent locoregional disease that cannot be resected as well as iodine-avid distant metastases. To date, no consensus has been reached regarding the ¹³¹I dose for treatment of DTC in children. We report our institutional experience and highlight the initial dose of ¹³¹I as a potential independent predictor of residual/relapsed disease.

Methods: We performed a retrospective analysis of all pediatric patients diagnosed with DTC between 2010 and 2018. The cohort included all patients up to 21 years of age, with minimal length of follow-up of 24 months. The risk stratification was done following the American Thyroid Association guidelines for pediatric DTC. We defined residual/relapsed disease as detectable thyroglobulin and positive anatomical lesions in imaging studies during the follow-up period. The log-rank test was used to evaluate disease-free survival. The P value was set at < 0.05.

Results: Among 59 eligible patients, females were 69.5% (n=41) and males were 30.5% (n=18). The mean age at diagnosis was 16 years (9-21 years). All patients were alive at follow-up (median, 42 months; range 24 to 144 months).