

Abstracts of the Pediatric Endocrinology Nursing Society Conference 2019

Nursing Research

001 - Understanding Stress of Inpatient Nurses Caring for Pediatric Diabetes Patients

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Background: With the opening of an outpatient Pediatric Diabetes Center, patients with diabetes were more often being admitted. In order to focus inpatient nurse education, we wanted to understand their level of comfort with diabetes management.

Aims: This Quality Improvement (QI) project's goal was to understand and reduce the stress levels of inpatient nurses caring for pediatric diabetes patients by assessing stress and providing educational in-services over 12 months.

Methods: The diabetes team provided in-services for pediatric medical (PM) and intensive care unit (PICU) nurses. Pre-education, nurses reported stress related to each diabetes topic using a stress thermometer (stress assessing tool, 0=mild, 10=severe). Education included: pathophysiology, meters, injections, insulin pens, vial/syringe, hyperglycemia, ketones, hypoglycemia, carbohydrate counting, calculating insulin doses, technology, and overall management. Nurses were also administered a stress thermometer post-education.

Results: Aspects of diabetes care most stressful were identified. For PM nurses, average stress scores decreased from pre to post education for the topics that had the highest stress: technology (4.7 vs. 3.9), pathophysiology (4.0 vs. 2.7), and carbohydrate counting (3.9 vs. 3.4). For PICU nurses, average stress scores decreased from pre to post education for: pathophysiology (5.5 vs. 2.7), meters (4.2 vs. 2.2), hyperglycemia (4.0 vs. 2.8), and hypoglycemia (4.0 vs. 1.4). However, the average stress score increased for PICU nurses from pre to post education for the topic of carbohydrate counting (4.0 vs. 4.7).

Conclusions: Post-education, nurses' average stress mostly decreased however the most stressful topics differed between PM and PICU nurses. Also, the stress level increased for one of the topics for the PICU nurses. This may indicate many were not aware of the magnitude of knowledge needed or education provided was not suited for them. These findings furthermore suggest it is necessary to develop educational tools targeted to the type of care delivered on the unit.

Clinical Implications: Diabetes management requires in-depth education. The stress thermometer is a useful tool to evaluate nurses' stress levels and understand where to focus education.

003 - Initial Psychometric Evaluation of a Pediatric Diabetic Peripheral Neuropathy Screening Tool

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Background: Diabetic Peripheral Neuropathy (DPN) is the presence of signs and/or symptoms of peripheral nerve dysfunction among people with diabetes after the exclusion of other causes. DPN is well recognized as a major complication of diabetes in adults, but there is considerable uncertainty as to its incidence, prevalence, diagnosis and prognosis among youth. Our team previously applied qualitative methods to develop a content-valid youth-report DPN symptom questionnaire. Our research revealed youth with T1D experience DPN symptoms measurable by self-report.

Aims: To describe the development of a self-report measure of DPN symptoms for youth aged 8-22 years.

Methods: This was a cross-sectional, observational study. Subjects included a total of 203 youth: 151 youth with T1D and 52 with other endocrine diseases. Of the 151 youth with T1D, 5 were recruited from the inpatient unit and 146 from the outpatient clinic. Subjects with other endocrine disorders (n=52) were recruited from the outpatient clinics. Subjects completed the 25-item DPN questionnaire on a single occasion. Data including duration of diabetes/diagnosis, HgbA1c and lab data was abstracted from the medical records.

Results: Qualitative procedures supported the development of a content valid pool of 25 DPN symptoms items. The best-fitting confirmatory factor analytic (CFA) model differentiated items that contributed to 3 internally consistent subscales: pain (5 items, $\alpha = 0.84$); anesthesia (3 items, $\alpha = 0.76$); paresthesia (5 items, $\alpha = 0.83$). IRT (Item response theory) parameters indicated the scales measure a wide range of symptom severity with a high degree of precision: pain ($\theta = 2.73$); anesthesia ($\theta = 4.25$); paresthesia ($\theta = 2.88$). Scale construct validity was supported by evidence that youth with T1D report significantly greater pain ($d = 0.66$), anesthesia ($d = 0.63$), and paresthesia ($d = 0.60$) symptoms than youth with other endocrine conditions.

Conclusions: This is a major step towards the validation of a pediatric DPN screening tool. Further research will focus on testing our hypotheses about the scale's association with clinical data.

Clinical Implications: A valid pediatric DPN screening tool will enable children at risk for, or in the early stages of DPN, to be identified properly, changing the current standard of care for youth with T1D.

004 - Peer-Based Interventions for Managing Type 1 Diabetes in Adolescents: A Systematic Review

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Background: Adolescents with Type 1 diabetes (T1D) have the poorest control when compared to other age groups. The majority of adolescents do not meet the American Diabetes Association (ADA) goal for hemoglobin A1c (HbA1c). Previous research has determined effective interventions in improving glycemic control and how peer interventions impact T1D. Prior systematic reviews did not address the quality of life. This systematic review includes quality of life as an objective in managing adolescents with T1D.

Aims: The purpose of this systematic review was to investigate the effectiveness of peer support interventions on the quality of life (QoL) and HbA1c in adolescents who have T1D.

Methods: Systematic searches were performed in three databases: Medline, CINAHL, and PsycINFO in January 2018. The criteria for inclusion consisted of: an objective to include a peer intervention, adolescent age group (10-18 years old), HbA1c and/or QoL outcome measure, peer-reviewed English language articles, and experimental and quasi-experimental method design. Articles were screened and evaluated using PRISMA guidelines and the Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal Tool. Date range included 2013-2016 with one article from 1989.

Results: Nine articles were chosen for full review. Three of the articles used the same study, which included ongoing data collection at different intervals and using moderators. Five of the studies were on-line peer support and two were in-person support. Most studies showed an overall improvement in quality of life and peer support. There are mixed results regarding how peer intervention affects HbA1c.

Conclusions: There is evidence that peer support has shown to improve quality of life. However, evidence demonstrates peer support is moving towards internet-based support, which may exclude lower socioeconomic groups, thus widening the gap in healthcare. HbA1c may not be the best indicator of glycemic control in adolescents because other factors, such as puberty, affect glycemic control.

Clinical Implications: Understanding that peer interaction has the potential to positively impact adolescents with T1D allows for many opportunities to create programs dedicated to peer support. Pediatric endocrine nurses can utilize multi-disciplinary frameworks to develop peer support programs.

Case Presentations

007 - Suppression of Pituitary Axis from Inhaled Corticosteroids

Susan Davis, RN, MSN, CPNP, Washington University, St. Louis, Missouri; Jennifer Sprague, MD, PhD

Patient Demographics: RS is a 16-year-old Caucasian female.

Clinical Presentation: RS initially presented 2 years ago with growth arrest for 2 years. She had menarche a year before with subsequent scant, irregular menses. No cause was determined for her growth arrest.

RS returned one year later with the complaint of “fatty legs”. She had continued scant, irregular menses and no interval growth. Large fatty deposits encased her thighs, but she was otherwise a thin, competitive athlete.

Relevant Past History: At age four RS was diagnosed with asthma requiring frequent oral steroid bursts until age seven when she began daily treatment with Dulera (mometasone-formoterol), an inhaled steroid.

Evaluation: At her initial evaluation, RS had a normal workup including CBC, UA, celiac screen, IGF-1, prolactin, thyroid studies and BMP. Her bone age was within 2 SDs of age related norms.

At reevaluation one year later, RS had a decreased bone density, low estrogen and normal gonadotropins. These data, combined with her persistent irregular scant menses, raised the suspicion of negative effects of her inhaled steroids. Unusual fatty deposits have been reported with Dulera.

Interventions: After we consulted with her Allergist, RS began a Dulera taper. Three weeks after stopping Dulera she experienced exhaustion and fatigue. Cortrosyn stimulation testing revealed suppressed cortisol levels with no rise to stimulation. ACTH was normal. She began replacement hydrocortisone.

Five months later at age 16 she had been weaned to very low dose hydrocortisone replacement, had grown one inch, and had normal menses. The fatty deposits in her legs were completely resolved.

RS was weaned to stress dose steroids only. A follow up Cortrosyn stimulation test revealed an improved, but still low, baseline level with an appropriate rise to stimulation. We advised her to continue the stress dosing with plans for further reevaluation.

Discussion/Recommendations: Chronic use of inhaled steroids is increasingly common. Endocrinology nurses must be aware of the potential consequences of inhaled steroid use in children, including suppression of the pituitary-adrenal axis, impaired linear growth, possible irregular menses and low bone density. Iatrogenic adrenal insufficiency can be life threatening. Watching for it and avoiding it are imperative.

008 – 17-year-3-Month-Old Female with CF and Hypoglycemia

Shayne Dougherty, CRNP, Nurse Practitioner, The Children's Hospital of Philadelphia, Philadelphia, PA

Patient Demographics: Patient is a 17-year-3-month-old Caucasian female

Clinical Presentation: Patient presented to clinic with post prandial hypoglycemia without the use of exogenous insulin.

Relevant Past History: She has a history of hypothyroidism, impaired glucose tolerance, cystic fibrosis (CF) diagnosed at birth due to meconium ileus, and celiac disease. Weight 45.6 kg (42%) and height 1.48m (1%). Family history includes brother with CF, mother with hypothyroidism, and father with hypertension.

Evaluation: Workup included oral glucose tolerance test (OGTT), HgbA1c, diabetes autoimmune panel, and thyroid studies. OGTT was remarkable for fasting BG=95, 1 hr BG= 309, 2 hr= 248. HgbA1c 6.1%. All other labs were normal. Continuous glucose monitoring (CGM) revealed postprandial hyperglycemia after meals with overcorrection causing lows (60's) without exogenous insulin use.

Interventions: Management of CFRD is best with a team approach including patient, family, pulmonary and endocrine teams. Management includes blood glucose monitoring, nutritional counseling, and insulin. Patient and family completed diabetes education training with a CDE and RD, and were taught to monitor postprandial blood sugar 1-2 hours after meals and to carbohydrate count. Patient was started on 2 units Lantus insulin daily and Novolog insulin prior to all meals/snacks. Patient returned 3 months later and postprandial hypoglycemia was eliminated with initiation of pre-meal insulin.

Discussion/Recommendations: CFRD is the most common co-morbidity in CF. The average age of onset is 18-21 years, affecting 20% of adolescents and 40-50% of adults. With a combination of insulin deficiency and insulin resistance, CFRD worsens the prognosis of CF and is associated with worsening pulmonary function, increased infections, nutritional decline, and increased mortality. Postprandial and OGTT-related hypoglycemia is common in CF. Postprandial hypoglycemia is associated with early glucose dysregulation (higher peak plasma glucose) and arises from late secretion of endogenous insulin. Administration of insulin at meals may prevent hyperglycemia excursions and blunt post-prandial hypoglycemia events. CFRD should always be a differential diagnosis for any patient who presents to endocrine clinic with postprandial hypoglycemia. Endocrine nurses are in an important position to educate patients regarding symptomatology, pathophysiology, and treatment of CFRD.

009 - Family History Plays an Important Role in the Diagnosis of Multiple Endocrine Neoplasia Type 2A

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Patient Demographics: Patient is a 13-year-old African American male.

Clinical Presentation: Patient presented with bilateral thyroid nodules incidentally discovered on head and neck imaging for occipital skull fracture with subarachnoid hemorrhage sustained while playing football. On dedicated thyroid ultrasound, there were sub-centimeter nodules in the left and right lobes.

Relevant Past History: Patient has no significant past medical history. Detailed review of family history revealed that maternal grandmother had Multiple Endocrine Neoplasia Type 2A (MEN2A), medullary thyroid carcinoma (MTC), and pheochromocytoma. Patient's mother and 4 siblings, age 11, 15, and 23, had undergone no testing at time of presentation.

Evaluation: The vital signs and physical exam were normal, without palpable nodules or abnormal lymphadenopathy. On review of thyroid ultrasound images, nodules were low risk based on size. The right sided nodule was hypoechoic with irregular borders. There were no calcifications and no abnormal lymph nodes. Patient was referred for fine needle aspiration which revealed MTC in both nodules. Calcitonin was elevated at 58.8 pg/mL (0.0-7.5 pg/mL). Carcinoembryonic antigen (CEA) was elevated at 6.1 ng/mL (0.0- 3.0 ng/mL). Plasma metanephrine panel, calcium, and phosphorus were normal. Staging was completed with neck CT with contrast re-demonstrating bilateral thyroid nodules and no abnormal lymph nodes, and chest and abdomen CT with contrast normal.

Interventions: Patient was referred to otolaryngology and is scheduled for total thyroidectomy with bilateral central neck dissection. He and his siblings were also referred to the Tumor Predisposition Clinic and genetic counseling.

Discussion/Recommendations: Thyroid cancer is most often asymptomatic and may be found incidentally on head and neck imaging. This case illustrates the importance of a detailed family history in the diagnosis of medullary thyroid carcinoma. The American Thyroid Association has published updated guidelines on the diagnosis and treatment of MEN2A and MTC. Early detection based on family history and available genetic testing is essential for successful treatment including prophylactic thyroidectomy and ongoing surveillance for known comorbidities.

Informational

010 – Analysis of GH Peak Response Times to Arginine and Glucagon during Growth Hormone Stimulation Testing in a Pediatric Population

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Background: Growth hormone stimulation testing (GHST) is a diagnostic tool used to diagnose Growth Hormone Deficiency (GHD). Testing can last up to 6 hours and can induce significant emotional and physical discomfort. Decreasing testing time would benefit patients, parents, and pediatric endocrine centers.

Purpose: To determine the feasibility of shortening the GHST duration by identifying the time it takes to reach peak GH levels using provocative agents arginine and glucagon. Current protocol requires 120 minutes for each agent to peak resulting in a minimum of 4 hours of testing.

Description of Topic: Our division completed a retrospective chart review of 18 pediatric patients who underwent GH stimulation testing between 2017 and 2018. Written informed consent and assent was obtained.

Clinical Implications: Data was collected from 18 consecutive patients. Only one patient had a peak GH level in response to arginine beyond 90 minutes. This did not change the results of the GHST for this patient as both the 90 and 120-minute levels were greater than 10 ng/dl (a level of 10 or > rules out GHD). Glucagon peaks were observed later, with most closer to 120 minutes post-agent administration.

011 - X-Linked Hypophosphatemia (XLH): New Knowledge for Nurses Regarding Genetics, Pathophysiology and Clinical Presentation

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Background: Over 80 years ago Fuller Albright reported a vitamin D-resistant form of rickets, which is likely the initial description of X-linked hypophosphatemia (XLH). Recently the genetic basis of the disease has been identified and a more complete understanding of the pathophysiology has emerged.

Purpose: To increase awareness of the latest published data on the genetics, clinical manifestations, differential diagnoses, biochemical findings, as well as growth and development of patients with XLH.

Description of Topic: XLH is a rare, progressive, life-long disorder and the most common form of heritable rickets. The estimated prevalence of XLH is 1:20,000 to 1:25,000. XLH is caused by loss-of-function mutations in the phosphate regulating endopeptidases on the X-chromosome (PHEX) gene, leading to high circulating levels of fibroblast growth factor 23 (FGF23). Over 300 PHEX mutations have been reported. An X-linked dominant inheritance pattern is typical; however, de novo PHEX mutations are reported in up to 20-30% of the cases. Excess FGF23 increases urinary phosphate losses with consequent hypophosphatemia, resulting in rickets and osteomalacia. Clinical manifestations may include lower limb deformities, short stature, bone and joint pain, dental abscesses, delayed walking, and gait abnormalities. Neurological features may include Chiari 1 malformation and craniosynostosis. Low serum phosphate levels, a low renal tubular threshold for phosphate reabsorption (TmP/GFR), and low or normal circulating 1,25(OH)₂D are characteristic biochemical findings in patients with XLH. The symptoms of XLH vary among individuals and while there is similar pathophysiology for children and adults, clinical manifestations can differ. Debilitating consequences in adults include osteoarthritis, enthesopathy, spinal stenosis and pseudofractures. In addition, complications of conventional medical therapy (phosphate salts and active vitamin D analogs) include nephrocalcinosis and hyperparathyroidism.

Clinical Implications: Previously, XLH was considered a disorder that manifests only during growth; however, adolescent patients require attention along with a smooth transition to adult care. In addition, recognition of the complex disease features of XLH is essential for accurate diagnosis and management. Pediatric endocrine nurses are well qualified to provide the latest disease state education to patients and families, and to encourage routine clinical evaluation to assess treatment response, disease progression, and therapeutic complications.

012 - **Food Literacy: Can Pediatric Endocrinology Nurses Focus Upstream?**

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Background: American families are spending less time procuring, preparing and cooking meals at home. As well, there is less time dedicated to nutrition education in schools. Food literacy is defined as “a collection of inter-related knowledge, skills, and behaviors required to plan, manage, select, prepare, and eat foods to meet needs and determine food intake, as well as, the scaffolding that empowers individuals, households, communities or nations to protect diet quality through change and support dietary resilience over time.” Adolescents generally lack food literacy skills and increasingly consume food away from home with fast food meals and processed snacks. Approximately 1 in 3 adolescents in the U.S. are obese, increasing their risk for diabetes and cardiovascular disease. Upstream efforts continue to be explored to combat rising obesity rates. Programs that promote food literacy in adolescents have the potential to influence healthy lifestyles.

Purpose: To inform pediatric endocrinology nurses about food literacy, its components, and existing food literacy education programs ready for implementation.

Description of Topic: A literature review on food literacy was completed. High food literacy has been associated with improved eating of a healthy diet, including more fruits and vegetables and less fast food. Food literacy programs should address adolescents’ knowledge, skills, and attitudes to make healthy diet choices. Potential topics include gardening, recipe reading, food label reading, learning about healthy vs. unhealthy foods, food preparation and cooking, animal welfare, and farm to table slow food concepts. The USDA SNAP-Ed website provides well developed, user-friendly food literacy teaching ideas with accompanying learning objectives, lesson plans, and teaching strategies that could readily be implemented by pediatric endocrinology nurses.

Clinical Implications: Pediatric endocrinology nurses typically provide care to adolescents with obesity and its related comorbidities. Pediatric endocrinology nurses have an opportunity to expand their practice to primary and secondary prevention of obesity, using upstream health education to promote adolescents’ food literacy. By partnering with schools, churches, Boys and Girls clubs, and Scouts troops, pediatric endocrinology nurses may offer health education, building food literacy skills in whole communities with the ultimate goal of slowing the rise in obesity rates.

Food literacy has been described as “the ability of an individual to understand food in a way that they develop a positive relationship with it, including food skills and practices across the lifespan in order to navigate, engage, and participate within a complex food system. It's the ability to make decisions to support the achievement of personal health and a sustainable food system considering environmental, social, economic, cultural, and political components.

The core of food literacy is the adolescent’s ability to use food knowledge and skills to make healthy dietary choices and encompasses aspects of planning and managing, selecting, preparing, and eating healthy foods.

013 - Delivering High Quality Pediatric Diabetes Care Beyond Hospital Limits

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Background: Pediatric diabetes is a complex yet delicate condition that requires well-orchestrated interdisciplinary collaboration usually found within facilities providing high level acute care. As part of a large tertiary care centers community expansion, we were tasked to develop a high functioning pediatric diabetes clinic providing the same level of care utilizing resources outside the hospital setting. Challenges included integration of new, complex workflows among other sub-specialty services, coordination of limited interdisciplinary support, and staff development in providing higher levels of care.

Purpose: To transition pediatric diabetes care to outreach locations while maintaining high quality, efficient family-centered care in a multidisciplinary format.

Description of Topic: The overall objective was to transform standard practices into best practices with limited resources without any negative effects in patient outcomes. The first step was to conduct a needs assessment to identify all components required to meet patient outcomes. Needs identified required collaboration among nursing leaders, physicians, educators, pharmacists, social workers, Information Technology personnel, drug/Durable Medical Equipment representatives, Child Life, local school districts, and families.

In collaboration with the aforementioned, we successfully developed a pediatric diabetes clinic through the following achievements: Provided patient access to social work, diabetes educator, and dietician via telemedicine; Created efficient clinic workflows through the development of electronic nursing assessment tools, known as “smart-sets” specific to the diabetes patient; Provided same level of in-person interpreter services through use of video interpreting system; Enhanced and implemented new school medication form for school nurses to more effectively care for diabetes patients; Created staff development tools that provides training and education necessary for care team members managing complex and acute conditions related to pediatric diabetes

Clinical Implications: We were successful and deemed a best practice clinic with many of our new processes adopted by other locations. Our newly created “smart-sets” provide care team members with efficient and comprehensive assessment tools that produce optimal patient outcomes while providing more opportunities for patient education and reinforcement of compliance measures. Additionally, our innovative approach allows us to provide remote or in-person access to services needed to provide comprehensive, holistic pediatric diabetes care.

014 - ENDO Handbook: Endocrine Nurse Detailed Orientation Handbook

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Background: Orientation has been an essential part of new nurses training in the inpatient setting for decades. This training helps mold the new nurse's confidence, job satisfaction, and retention. Often this orientation in the outpatient setting falls short in comparison. However the benefit of a structured usually held for inpatient nurses only is also applicable for outpatient clinic nurses. In addition to confidence, job satisfaction and retention, many outpatient clinics are specialized so additional training is necessary. Having a structured orientation will also ensure consistency with training.

Purpose: To provide a structured outpatient clinic orientation manual to ensure the new clinic nurse is fully prepared to function in an endocrine specialty clinic setting. The manual will also serve as a resource for experienced clinic nurses.

Description of Topic: This project is to help improve the orientation process for an outpatient endocrine clinic nurse. Information and educational materials are collected and structured into one orientation manual for the trainee to utilize. It will include a list of department members and their roles, daily tasks including policies and procedures associated with these tasks, documentation of clinic tasks, stimulation testing procedure and protocol, patient and nursing education, as well as task competency lists for the orientee to complete. This orientation manual will remain in the clinic setting so all nursing staff may reference. It will be updated accordingly as tasks and policies change.

Clinical Implications: A structured orientation handbook will provide reference materials, educational materials, and task checklists for the nurse to follow and utilize during their training. Structured orientation programs have been found to improve a nurse's confidence in their new role. When nurses are confident in their roles, stress is reduced and retention and turnover rates are decreased. Having one orientation manual will provide consistency with training, therefore all patient education will be consistent and all clinic tasks will be completed in the same manner.

015 - Adrenal Insufficiency in Children: Teaching Nurses to Teach Caregivers

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Background: Adrenal insufficiency (AI) is the impaired synthesis and release of adrenocortical hormones due to various mechanisms (e.g., autoimmunity, genetic, ACTH deficiency, and corticosteroid-induced). AI affects quality of life and is associated with increased morbidity and mortality, especially in younger patients. Children are at highest risk during times of physical stress. Many children do not receive stress doses of medication when needed. Relatively novice endocrine nurses do not feel adequately prepared to educate children, adolescents, and families about AI and its treatment.

Purpose: The purpose is to increase nursing knowledge, skills, and competency in teaching caregivers about disease process and management of adrenal insufficiency day to day and during times of physical stress.

Description of Topic: The poster will describe the action steps used to prepare endocrine nurses to teach caregivers about adrenal insufficiency and its management. The PRECEDE-PROCEED model will provide a framework for education. The project leader will secure organizational support, work with endocrinology providers to standardize stress steroid dosing, identify or modify evidence-based teaching resources, and develop charting templates and smart phrases for documentation. Components of the education plan include an overview of AI, pathophysiology (including congenital adrenal hypoplasia, Addison's disease, hypopituitarism, and corticosteroid-induced adrenal insufficiency), daily medications, and prevention of adrenal crises (use of medical alerts; emergency hydrocortisone; and when to call clinic, go to ED, or call 911). Nurses will be mentored by an experienced pediatric endocrinology nurse.

Clinical Implications: A major role of pediatric nurses is teaching children, adolescents, and families. Ineffective education of caregivers about AI places children at risk for adrenal crises. Nurses need to be able to teach caregivers of newly diagnosed children with AI and properly triage phone calls from caregivers during illness or injury or prior to procedures. They also need to be knowledgeable about school emergency plans. Investing in the training of novice endocrine nurses about AI can empower caregivers to better manage this disease. During times of physical stress, adherence to stress dosing can reduce the need for emergency department visits and hospital admissions.

Product-Based Research

016 - TransCon GH as a Long-Acting Growth Hormone for the Treatment of Pediatric Growth Hormone Deficiency

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Background: With growth hormone (GH) receptors present on virtually all cells, GH replacement therapy should aim for the same exposure and tissue distribution as endogenous GH and current daily GH therapies. The challenge to developing a long-acting GH (LAGH) is to establish the same safety, efficacy, and tolerability of daily GH, which includes maintaining GH and IGF-1 levels within the physiological range. To create a LAGH, two approaches have been used: 1) combine unmodified GH with a prolongation technology, or 2) modify GH providing a longer half-life. TransCon GH is a LAGH prodrug in development for pediatric growth hormone deficiency (GHD) with GH transiently bound to an inert carrier. It was designed to release unmodified GH over 7 days to achieve the same exposure, safety, efficacy, and tolerability as daily GH with more convenient once weekly dosing. This profile was successfully demonstrated in the Phase 2 trial in pediatric GHD. TransCon GH is also being developed with an autoinjector for ease of administration and improved adherence.

Aims: We aim to present the topline 52-week pivotal Phase 3 results of TransCon GH in treatment of pediatric GHD.

Methods: The phase 3 heiGHt trial was designed to compare safety, tolerability, and efficacy of weekly TransCon GH versus daily GH over 52 weeks in treatment-naïve prepubertal children with GHD. Study endpoints include annualized height velocity (AHV), IGF-1 response, immunogenicity, and safety.

Results: Top-line 52-week results of the heiGHt trial (N = 161) including AHV, Δ height SDS, IGF-1 levels, Δ bone age, and adverse events, will be available for presentation at PENS 2019.

Conclusions: Only LAGHs based on unmodified GH have succeeded in providing both accelerated height velocity as well as reducing truncal adiposity in line with currently available daily GH therapies. Top-line data from the pivotal heiGHt trial of TransCon GH, a LAGH prodrug releasing unmodified GH, will be available in March 2019.

Clinical Implications: A GH prodrug that provides sustained release of unmodified GH for the treatment of pediatric GHD would likely maintain the same tissue distribution as endogenous GH, with comparable efficacy, safety, tolerability, with the benefit of improved compliance due to weekly dosing via an autoinjector.

017 - Real-world and Clinical Trial Glycemic Outcomes Comparison of Young Patients with T1D Using the MiniMed™ 670G System

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Background: The MiniMed™ 670G system with SmartGuard™ Auto Mode automatically adjusts basal insulin delivery every 5 minutes based on sensor glucose (SG) values. The system's at-home safety and effectiveness have been demonstrated in two separate multi-center pivotal trials consisting of participants with type 1 diabetes (T1D) aged 7-13 years and 14-75 years.

Aims: To compare real-world glycemic data of patients aged 7-13 years using the MiniMed™ 670G system with data reported during the system pivotal trial in participants aged 7-13 years.

Methods: System data from the real-world cohort (n=105, 7-13 years, mean±SD 10.4±1.2 years) were voluntarily uploaded to CareLink™ Personal software from Mar 2017-Dec 2017, de-identified, and retrospectively analyzed. These data included time spent below, within, and above target glucose range (70-180 mg/dL, 3.9-10 mmol/L) during a ~2-week period in Manual Mode followed by a 12-week period with Auto Mode enabled. The real-world data were compared with that from pivotal trial participants (n=105, 10.8±0.8 years) who underwent a 2-week run-in phase in Manual Mode followed by a 12-week study phase with Auto Mode enabled. Analyses were conducted with a Wilcoxon signed-rank test.

Results: For the real-world cohort (~10,000 days of system use), median Auto Mode usage was 79.9% and the mean percentage of time in target glucose range (TIR) increased from 56.4±16.3% to 67.1±9.1% (p<0.001) during Manual Mode and Auto Mode, respectively. The average SG was 178±26 mg/dL (9.9±1.4 mmol/L) and 161±16mg/dL (8.9±0.9 mmol/L) for the Manual Mode and Auto Mode periods, respectively. For the pivotal trial cohort (~13,000 days of system use), median Auto Mode usage was 80.6% and the mean TIR increased from 56.2±11.4% and 65.0±7.7% (p<0.001), respectively; while the average SG was 169±22 mg/dL (9.4±1.2 mmol/L) and 162±12 mg/dL (9.0±0.7 mmol/L), respectively.

Conclusions: The real-world CareLink™ Personal and pivotal trial outcomes data of children with T1D using the MiniMed™ 670G automated insulin delivery system displayed similar trends in improved glycemic metrics.

Clinical Implications: Clinical trial and real-world outcomes data can help to set appropriate expectations for managing glycemic control in young patients utilizing the MiniMed™ 670G system.