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A randomized trial of four thyroid hormone regimens for Transient Hypothyroxinemia in Neonates
28 weeks gestation: the THOP 1 trial

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Running Title: Transient Hypothyroxinemia

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Abstract

Background: Transiently low levels of thyroid hormones occur in
nearly 50% of neonates born between 24-28 weeks gestation, and
are associated with higher rates of cerebral palsy and cognitive
impairment. Raising thyroid hormone levels might improve
neurodevelopmental outcome, but it is not clear what dose to use
and how TSH suppression might best be minimized.

Objective: To identify whether any of four thyroid hormone
supplementation regimens could raise T 4 and FT 4 without
suppressing TSH, as compared to placebo or iodine
supplementation alone.

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STROKE IN NEONATES

Caroline Chua, MD
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Stroke is an important cause of mortality and chronic
neurological morbidity in children. Many of them happen in
the perinatal period, soon before birth or within the month
after. It is estimated that the incidence of perinatal stroke
ranges from one in 2300 to one in 5000 births. Newborns
with stroke may be asymptomatic or may present with
non-specific signs and symptoms, including irritability, poor
feeding, hypotonia, lethargy, or apnea. The most common
neurologic manifestation is seizure which is observed in
25-40% of cases. The elucidation of cerebrovascular lesions
and excluding other cerebral pathologies is very important in
understanding the pathogenesis, risk of recurrence, and serve
in guiding the direction of work-up.

Many factors that are associated with risk of stroke in older
children and adults may also be found in the perinatal
period. In addition, there are risk factors unique to this
developmental stage. The features of the perinatal period
that influence coagulation status include the presence of
fetal hemoglobin, fetal proteins, and a high hematocrit
and blood viscosity. Concentrations of procoagulants and
anticoagulants proteins change with gestational age and
postnatal age, with activation of coagulation near the time of
birth. Placental infections can also interact with coagulation.

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The source of stroke in neonate is commonly undetermined, but a placental etiology is suspected in many. Other sources include thromboembolism from an intracranial or extracranial vessel, or the heart.

Most neonatal strokes occur in the territory of the middle cerebral artery. There is a predominance of left hemisphere lesions, which may be caused by hemodynamic differences from a patent ductus arteriosus, or a more direct route involving the left carotid artery.

Historically, most cases of perinatal stroke are idiopathic. More recently, some may be ascribed to more specific etiologies. Epidemiological investigations have observed an association with maternal and placental disorders, birth asphyxia, metabolic and hematologic disorders, cardiac disorders, infections, trauma and catheter related complications, as well as drugs.

The assessment of neonates with stroke depends heavily on accurate history and physical examination. A detailed history must include maternal and pregnancy history, substance abuse, birth history, placental pathology, family histories of neurological disorders, premature vascular disease, hematologic and metabolic diseases.

Neuroimaging is the most useful method of documenting the occurrence of stroke. Neuroimaging procedures include MRI, CT scan, or ultrasonography. The recommended test of choice is MRI with diffusion weighted imaging because it is more sensitive for the detection of early infarction. Magnetic resonance angiogram is also useful for the detection of occlusion and hypoplastic vessels. Magnetic resonance venogram is useful for confirmation of sinovenous thrombosis. If neonate is unstable or MRI is not available, CT scan or ultrasound should be considered. Further diagnostic work-up should focus on the probable etiologies, including septic work-up with CSF analysis, coagulation and hematologic tests, metabolic analysis, cardiac imaging, assessment of the placenta by pathologists for possible thrombosis, and maternal testing for possible coagulation abnormalities. EEG is also useful for seizure evaluation and long term prognosis.

The treatment of stroke in neonates has been primarily supportive and symptomatic. Anticonvulsants are given if seizures have occurred. Attention should be given to the maintenance of adequate hydration and perfusion, as well as management of the underlying causes. The use of anticoagulant therapy appears to be increasing in arterial ischemic stroke, but the roles of thrombolytic therapies being studied in adult strokes have yet to be tested in infants.

About 50% of infants who develop stroke are neurodevelopmentally normal and the rest might have residual neurological dysfunction with sensorimotor deficits being the most common. Whether outcome is worse in infants with stroke, in whom neonatal depression is severe and accompanied by other signs of neonatal encephalopathy, is not established. The mortality rate of perinatal stroke is 3-5% and the recurrence rate of infarct is low. Predictors of neurodevelopmental sequelae include large stroke size, and involvement of internal capsule and basal ganglia. However, the prognosis of neonates with stroke is significantly better than in older children and adults because of the brain plasticity of a term neonate, retention of connections, modifications in function, as well as type and location of brain injuries. Early intervention therapies are expected to help the process of brain recovery.

Stroke in neonates is not a rare disorder. A high index of suspicion of stroke should be considered in neonates presenting with non-specific signs and symptoms. Perinatal stroke contributes an important share of lifelong neurological morbidity. Although our knowledge has advanced tremendously, many aspects remain to be studied especially as they relate to prevention and minimizing morbidity.

Continued from previous column

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References:

Continued from pg. 1 - Randomized Thyroid

Design/Methods: Eligible subjects had gestational ages between 24 0/7 – 27 6/7 weeks and were born at one of three study sites (Amsterdam, Madrid, New York) from April 2005 until March 2007.

168 subjects were randomized within 24 hours of birth to one of six drug treatment arms using an algorithm that minimized enrollment differences due to gestational age above or below 26 weeks, gender, and clinical site. Study arms ranged in size from 20-27 subjects.

The six interventions from birth were: placebo (5% dextrose), potassium iodide (30 μg/kg/d) and continuous or bolus daily infusions of either 4 or 8 μg/kg/d of T4 for 42 days. Thyroxine was accompanied by 1 μg/kg/d T3 during the first 14 postnatal days and infused with 1 mg/ml albumin to prevent adherence to plastic tubing. FT4 was measured by equilibrium dialysis and TT4, TSH, T3, TBG and cortisol by radioimmunoassay at birth and on study days 3, 7, 14, 28, 42 and 56.

Results: Area under the curve analysis found that TT4 was significantly elevated (p < 0.03) and TSH was significantly suppressed (< 0.4 mIU/L) in the first 14 days for all hormone supplemented arms compared to placebo or iodine alone. From 14-to-42 days, TT4 remained elevated (p < 0.01) in each of the four thyroxine treatment arms. The least suppression of TSH was achieved in the 4 μg/kg/d T4 continuous infusion arm. While this trial was powered to optimize dosing, certain clinical outcomes were examined as part of a safety analysis. No significant differences between arms or across centers were detected in mortality, CLD, IVH, or length of hospital stay. Although not pre-hypothesized, duration of mechanical ventilation was significantly lower in the continuous 4 μg/kg/d T4 arm and in the 8 μg/kg/d T4 bolus arm (p < 0.05 vs. remaining arms). The prevalence of ROP was significantly lower in the combined four thyroid hormone treatment arms than in the combined placebo and iodine arms (18% [9/51] vs. 5% [5/93]; p < 0.04). NEC was higher in the combined 8 μg/kg/d arms (p < 0.05 vs. other arms).

Conclusions: Elevation of TT4 > 50 nM/L with only modest suppression of TSH was associated with trends suggesting benefits in mortality, duration of mechanical ventilation and risk of retinopathy of prematurity (ROP) in extremely premature neonates using a continuous supplement of low dose thyroid hormone (4μg/kg/d) for 42 days. Future trials will be needed to assess the long-term neurodevelopmental effects of such supplementation.
**In Memoriam**

It is with great sadness and a heavy heart that we write of the passing of our friend and colleague, Karen Wright, on Wednesday, July 23, 2008.

Karen was a Physician Assistant in the RNICU at the WMC MFCH for approximately eight years. In spite of her chronic illness, she worked tirelessly each day to care for our special population of patients. Her genuinely warm smile and helping hands made everyone she met feel appreciated and welcome. Most of the world did not realize that Karen, who gave hope and comfort to others, was the one who needed that help for herself although she never asked anyone for it.

You could always count on Karen to “tell it like it is” whether she was interacting with a colleague, a parent or a friend. Karen cared about her patients like they were her own babies and the parents of those babies always seemed to know that. Such feelings were Karen's personal reward for a job well done and validation of her career choice. She strived for excellence everyday. She deserved and earned the respect of her colleagues and co-workers.

We shared some challenging and wonderful moments with Karen during her life. Those experiences have touched us in ways that mere words can never express. Karen's spirit and her joy for life will live on in our hearts forever and we will all miss her very much.

We go through life hoping for special people to enter our lives. Such people have a profound impact on our perception and understanding of life - Karen Wright was one of those people.

Our heartfelt condolences go out to Karen's husband, Rocky, her 5yr. old daughter, Gabriella, and her friends & extended family.

**Obstetrical Grand Rounds**

October 23, 2008

Westchester Medical Center

**A Fetal/Infant Mortality Review/Registry for Perinatal Quality Improvement**

Dr. Richard Aubrey, State University of NY, Syracuse, NY

For information, call (914) 594-4786

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**SAVE THE DATE**

7th Annual Regional Perinatal Forum Conference

Obesity, Preconception Health, Pregnancy & Lactation: The Impact of Bariatric Surgery, Nutrition & Exercise

November 12, 2008 • 8:30 a.m. - 3 p.m.

Doubletree Hotel Tarrytown • 455 South Broadway • Tarrytown, New York

AM KEYNOTE SPEAKER: DAVID A. KESSLER, MD, FORMER COMMISSIONER FOOD & DRUG ADMINISTRATION (FDA)

PM KEYNOTE SPEAKER: NYS First Lady Michelle Paige Paterson

GUEST SPEAKER: Joseph R. Wax, MD, Maine Medical Center, Portland, Maine

Early Bird Registration Fee: $45.00 ($60 after October 29, 2008)

email: info@LHVPN.com or hunter-grantc@LHVPN.net

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**PERINATAL OUTREACH COORDINATOR**

Westchester Medical Center Perinatal service is seeking a highly motivated Registered Nurse to fill the position of Perinatal Outreach Coordinator.

This position offers an exciting opportunity to join a dynamic, rapidly expanding high-risk obstetrical division offering world class obstetrical medicine.

Responsibilities include: Maintaining & improving communication between the Regional Perinatal Center (RPC) and its affiliate obstetrical services within our 7-county region; On-site assessment/telephone consultation regarding current standards of obstetrical care; Develop/implement/facilitate outreach education programs on high-risk OB patients for our affiliates; Working collaboratively with L&D personnel and the RPC team relating to maternal transport quality improvement issues; Collection/analysis of WMC maternal statistical data; Participation in RPC quarterly QA Quadrant meetings at affiliate hospitals & the Regional Perinatal Forum.

Qualifications: Masters prepared with at least five years recent acute care obstetrical experience; Certification in Inpatient Obstetrical nursing preferred. Preference given to candidates with outreach experience.

If interested please contact, Kerry Terminello at (914) 493-8498

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LHVPN would like to thank all the site hosts who participated in CHED 2008:

Child Care Resources of Rockland, Cochran School of Nursing, Community Action Program of Rockland (CAPRO), Community Cradle (Maternal Infant Network of the Capital Region), Dutchess County Department of Health, Dutchess County Healthy Families, Family Services of Westchester, Greenburgh Health Center, Healthy Beginnings of Sullivan County, Hudson Health Plan (Mobile Units in Haverstraw, Peekskill, Fishkill & Kingston), Hudson River Health Care (in Beacon, Monticello, Poughkeepsie, Peekskill & Haverstraw), Maternal-Infant Services Network, Middletown Community Health Center, Monroe Woodbury High School, Mount Vernon Neighborhood Health Center, NAAACP, Spring Valley Branch, Newburgh Free Academy, Planned Parenthood, Hudson Peconic Putnam County Department of Health, Putnam Hospital Center, Rockland Parent-Child Center, Rockland Prenatal Clinic (RCDOH & Nyack Hospital), St. John's Riverside Hospital – Park Care Pavilion, Teen Link to Community/MISN, The Field Library, Visiting Nurses Service of Westchester, WAW Peekskill Extension Center, Westchester Comm. College, Westchester County Department of Health (WIC Program, Immunization Program, New Rochelle District Office, White Plains District Office, Yonkers District Office, HIV Outreach Program, Division of Community Health, The Health Beginnings Program, Teen AWARE Program), Westchester Jewish Community Services, Westchester Medical Center, AIDS Care Center, Women Organized Around Wellness. We are grateful for their tireless efforts and dedication to the community and fostering healthy lives for men, women, children and families. We invite other agencies to join us for CHED 2009.
The second annual LHVPN Community Health Education Day once again was a successful event. More than thirty agencies and institutions extended their reach and held health education and promotion activities in approximately 189 sites in Dutchess, Putnam, Rockland, Westchester, Orange, Sullivan, Ulster and Albany Counties, reaching more than 2,680 individuals. A few activities were held before and after May 15th; therefore, broadening the exposure to the selected theme.

The goal of the Lower Hudson Valley Perinatal Network’s (LHVPN) Community Health Education Day (CHED) is to educate consumers and providers regarding strategies for improving birth outcomes in the region. CHED is a one-day widespread community health promotion/education event in which multiple organizations across the region plan educational activities around the chosen theme. Focusing on one important health topic maximizes impact and makes CHED a catalyst for greater awareness and social change surrounding the selected issue.

CHED 2008 entitled “It Takes a Village…To Address the Risk – Give Babies A Healthy Start,” focused on Sexually Transmitted Infections/ Diseases (STIs/STDs) from a Preconception Health Perspective. The intention of this year’s event was to raise awareness of the importance of preparing for a healthy baby even before pregnancy, by addressing the risk of STIs/STDs that could result in low birth weight, premature labor, birth defects, and other perinatal health and infant morbidity issues. The agency hosts aimed to promote and educate their communities about the importance of prevention, screening and treatment of sexually transmitted infections and diseases (STIs/STDs) in the context of preconception health and healthcare.

Mounting evidence shows that pregnancy, even early pregnancy, is too late to thwart poor maternal and birth outcomes. Therefore, an escalating focus is being placed on preconception (before first birth) and interconception (between births) health and healthcare. In order to promote and provide for a healthy pregnancy and safe birth several aspects should be addressed prior to pregnancy, such as nutrition, personal and family medical history, environmental exposure, cessation of risky health behaviors and STI/STD management.

Untreated STIs/STDs have caused grave perinatal health consequences such as infertility, ectopic pregnancy, low birth weight, premature labor, birth defects and other perinatal health and infant morbidity issues. Selecting this theme for CHED proved timely in the face of CDC’s March 2008 research results; indicating that one in four teenage girls has an STD and April 2008 STD Awareness Month’s promotion that one in four Americans has an STD. Key community and health stakeholders in the Lower Hudson Valley region realized the importance of raising the awareness and informing community members of this issue and how to deal with it and thought CHED offered a great opportunity to do so.

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We are interested in providing you with a newsletter that is relevant and of interest to you. Please contact us with perinatal topics you would like to see addressed.

For a copy of our newsletter or to be placed on our mailing list contact us by phone or e-mail.

Please visit http://www.worldclassmedicine.com/RPC for information about the Regional Perinatal Center at the Maria Fareri Children’s Hospital at Westchester Medical Center and to locate other issues of The Perinatal Gazette.