

Sarah Fleet MD PGY2
IRB Protocol Writeup

Screening and diagnosis of Nonalcoholic Fatty Liver Disease in overweight and obese pediatric patients: single center experience

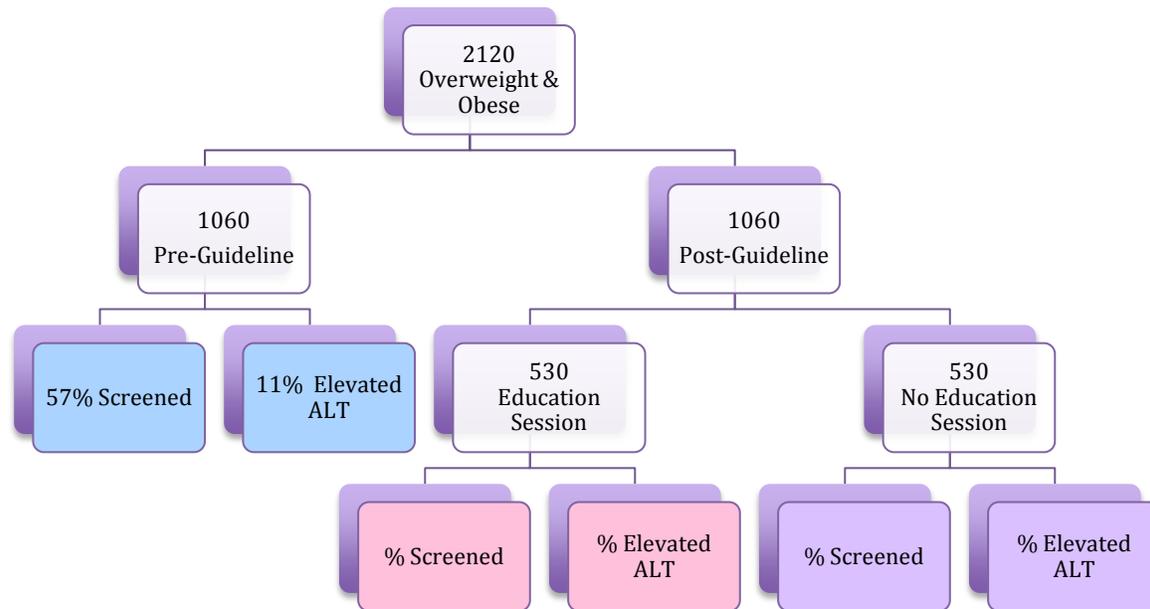
A. Study Purpose and Rationale

Nonalcoholic fatty liver disease (NAFLD) is the most common cause of liver disease in children, with a clear link to the increasing prevalence of obesity. Currently, the prevalence of NAFLD is unknown as a result of the impracticality of screening liver biopsies, the gold standard for diagnosis. Nonalcoholic fatty liver is commonly associated with long-term elevations in liver enzymes such as alanine transaminase (ALT) which serves as a useful, non-invasive surrogate marker of NAFLD or liver dysfunction when used in combination with other factors such as age, gender, body mass index, and insulin resistance, it can predict a likelihood of NAFLD. The natural history of NAFLD is not clearly understood, however, it is clear that NAFLD is a progressive disease that ranges from simple steatosis to nonalcoholic steatohepatitis (NASH), which can then lead to fibrosis, cirrhosis and hepatocellular carcinoma. NAFLD has also been strongly associated with the development of the metabolic syndrome (characterized by central obesity, dyslipidemia, impaired glucose tolerance and elevated blood pressure), further leading to the development of cardiovascular disease in children. For these reasons, the increasing number of children with NAFLD has become a public health concern.

Over the past year, the first portion of this study was dedicated to collection of data on screening high-risk patients for NAFLD. A database of all pediatric patients 4 to 19 years old coded for "overweight" or "obese", who have been seen in one of the outpatient general pediatric clinics from 2009-2011 was created. The database contains over 2,500 unique patients, 1060 of which have data collected. Based on preliminary results, it was determined that only 57% of patients had ALT done as part of their screening labs. 11% of patients were found to have elevated ALT values, and only 18% of patients were appropriately referred for further work-up of NAFLD.

The Obesity Prevention Clinical Working Group has recently released guidelines for screening for NAFLD in the pediatric population by measurement of ALT in overweight and obese pediatric patients (please see figures below for full recommendations). These guidelines are being implemented in all pediatric clinics at MSCHONY-P as of March 2012. Implementation of the guidelines will change the screening process of pediatric patients, and ALT will be obtained on all high-risk patients as a surrogate marker for NAFLD if the guidelines are followed.

B. Study Design and Statistical Analysis



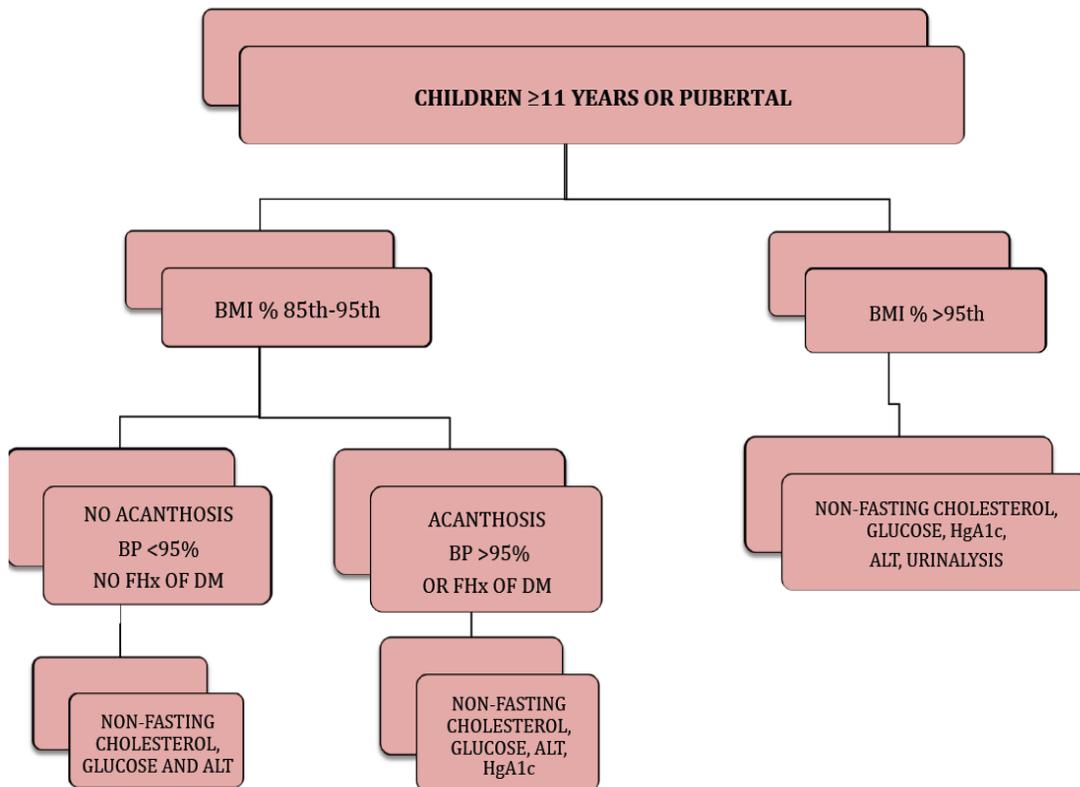
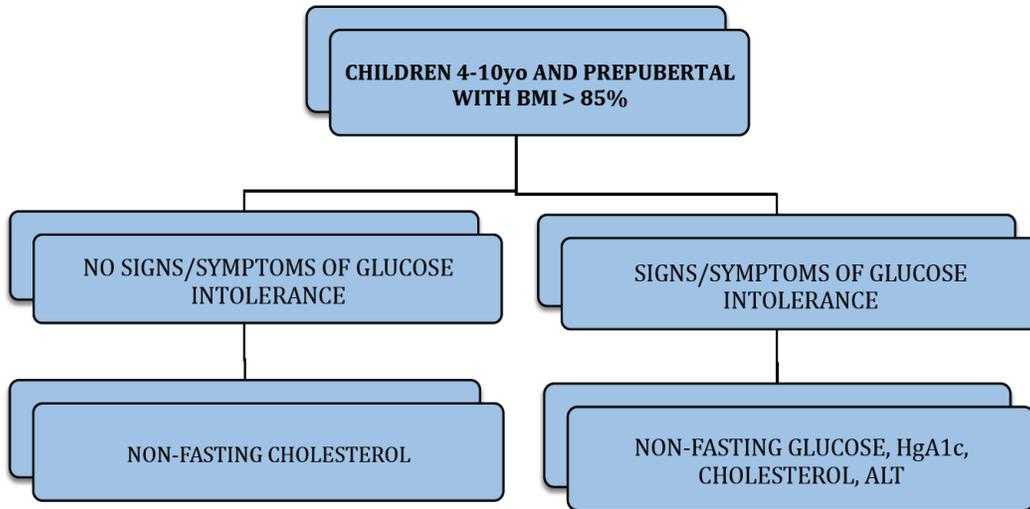
This study will be a retrospective chart review, with one pre-intervention arm and 2 parallel post-intervention arms. Pre-intervention data has already been obtained. The new guidelines for NAFLD screening of overweight and obese children was recently presented in a grand rounds setting in the pediatrics department to make providers aware of the new recommendations. Additionally, an Eclipsys order-set will be designed to prompt providers in the pediatric clinics at CHONY to order the correct screening tests when the patient is coded for obesity, or if the BMI is calculated $>85^{\text{th}}$ percentile. Additionally, one clinic (21 Audubon) will receive educational materials, including a presentation on NAFLD and printouts of the screening guidelines. Several months after the changes have been implemented, there will be a retrospective chart review of the children coded for obesity or overweight at a well-child visit.

Chi-squared analysis will be used to compare the subjects from the pre-intervention group with subjects from the clinics that did not receive the teaching module to determine the impact of the order set alone. Chi-squared analysis will also be used to compare patients from the post-intervention clinics that received the teaching to those that did not, in order to show how much education of providers played a role in screening rates.

C. Study Procedure.

The new screening guidelines are meant to be standard of care, in accordance with the AAP. Therefore, if providers are providing standard of care for their overweight and obese pediatric patients, there are not any additional blood draws or lab tests. Guidelines are per the algorithms below.

The study will continue for two years. Since this is a retrospective chart review, subject participation is not required.



D. Study Drugs

None

E. Medical Device

None

F. Study Questionnaires

None

G. Study Subjects

Inclusion criteria: Children ages 4-19 seen in the pediatric ambulatory care network of NYP/CHONY who have been diagnosed with overweight or obesity (BMI >85th percentile) at a well-child/health maintenance visit.

Exclusion criteria: Children <4 or >19 years old or those with known liver disease by biopsy.

H. Recruitment of Subjects

Subjects will not be recruited as this is a chart review study. Eclipsys IT department will create list of all children ages 4-19 who were coded for overweight or obesity. MRNs will be provided for each.

I. Confidentiality of Study Data

All study data will be coded and de-identified. All databases will be locked by password, known only to approved investigators.

J. Potential Conflict of Interest

None.

K. Location of the Study

Pediatric ambulatory care network – 21 Audubon, 181st St., Broadway, and Rangel practices.

L. Potential Risks

There is no additional risk as a participant in this study.

M. Potential Benefits

There is a direct benefit to the patient in that each patient may be diagnosed with asymptomatic NAFLD earlier, resulting in better treatment of the disease, and lower risk of progression to NASH. There is also a direct benefit to providers by making an order-set to minimize time spent ordering such screening tests, and their ability to make appropriate referrals once an elevated ALT is found.

N. Alternative Therapies

None.

O. Compensation to Subjects

None.

P. Costs to Subjects

None; the screening ALT is paid for by the patient's insurance company at the time of the well-child visit as routine health maintenance.

Q. Minors as Research Subjects

The study involves pediatric patients ages 4-19, which includes minors, however, due to the retrospective chart review protocol, their direct participation is not required.

R. Radiation or Radioactive Substances

None.

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