## RESEARCH ARTICLE

# Real World Failure of Physician Counseling to Result in Weight Loss in Patients with Non-Alcoholic Steatohepatitis

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#### **Abstract**

The metabolic multi-system disorder that is non-alcoholic fatty liver disease can be associated with hepatic inflammation and fibrosis, and result in the development of chronic liver disease. Effective pharmacologic therapy for NASH remains in development. Data indicate that weight loss and increased physical activity reduced hepatic fat content and fibrosis. The impact of physician counseling and support on weight loss in a patient population with documented NASH was reviewed. Seventy-three patients with liver biopsy confirmed NASH and varying stages of fibrosis were reviewed 12 months after receiving detailed dietary and exercise counseling from a physician with close clinical follow-up. The primary end point was weight loss achieved. Neither weight nor body mass index changed significantly. In patients with Stage II and III fibrosis on liver biopsy at diagnosis no significant change in body weight or body mass index resulted. These data provide real world documentation that physician counseling failed to effect even modest weight loss in patients with NASH, especially in those with advanced fibrosis who are are greatest risk of progressing to cirrhosis.

Key Words: Non-alcoholic fatty liver disease, non-alcoholic steatohepatitis, weight loss

#### INTRODUCTION

Non-alcoholic fatty liver disease (NAFLD) is a metabolic multi-system disorder that results in excessive fat deposition in hepatocytes [1]. Effective medical therapy for non-alcoholic steatohepatitis (NASH), although a focus of investigation, remains elusive [2]. To date weight loss has been the most effective intervention in reduction of hepatic fat content and amelioration of the inflammatory response thereby arresting fibrosis. Increasing physical activity improves hepatic steatosis and hepatocellular injury [3]. Achieving significant weight loss, however, is a challenge for many patients. The impact of physician counseling on weight loss achieved was reviewed.

## **MATERIALS AND METHODS**

Patients seen as at a single center for evaluation of chronic active hepatitis from January 1, 2015 through December 31, 2018 were reviewed. All patients underwent a comprehensive evaluation including a percutaneous liver biopsy, with 73 patients diagnosed with NASH. Patients with non-alcoholic steatosis without steatohepatitis were excluded. At diagnosis all patients received counseling regarding the factors present which contribute to the development of NASH, as well as discussion of the natural history of the disease and the potential benefits of weight loss. The diet plan prescribed was a hypocaloric diet which minimized intake of carbohydrates (especially simple sugars) and emphasized lean protein and leafy vegetable intake. Walking for exercise for a minimum of 150 minutes a week (30 minutes, five days a week) with

a goal of 320 minutes a week (60 minutes, six days a week) was advised. Complete abstinence from alcohol intake was prescribed. Patients returned to clinic every three months for reinforcement of the weight loss plan and encouragement.

The primary endpoint assessed was weight loss in the first 12 months measured as gross weight in kilograms and Body Mass Index (BMI). Patient characteristics, including stage of hepatic fibrosis at diagnosis, were also collected. Statistical analysis was performed using the GraphPad Prism 8 software package (GraphPad Software, San Diego, California). The study design was approved by the Institutional Review Board of Northeastern Health System (Tahlequah, Oklahoma).

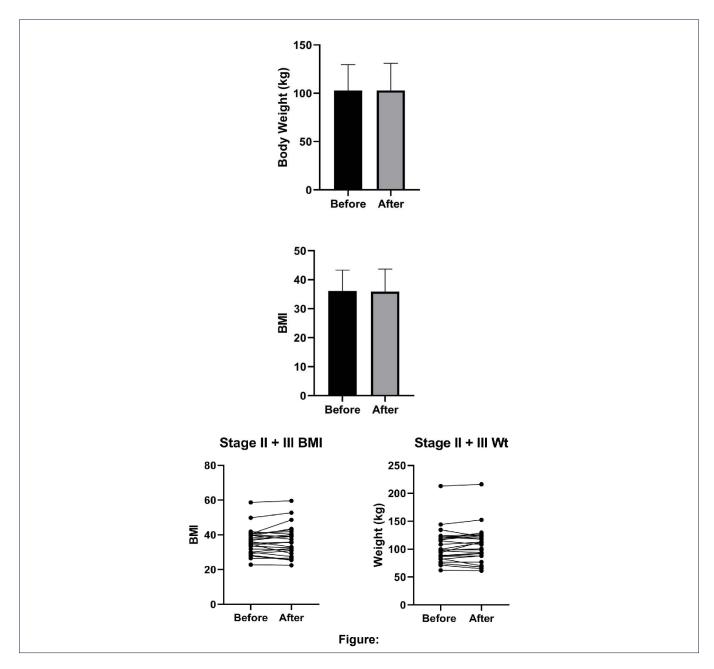
#### **RESULTS**

A total of 73 patients were reviewed (74% female) with a mean age was 54.03 years (range 25-79). The initial degree of obesity was broad: BMI 25-29.9 9.6%, 30-34.9 41.1%, 35-39.9 28.8% and >40 20.5%. Fibrosis was prevalent (Stage 0 16.4%, Stage I 24.7%, Stage II 23.3%, Stage III 6.9% and Stage IV 28.7%).

Physician counseling regarding diet and exercise failed to result in a significant change in either body weight or BMI over a 12 month period (Figure). A mean weight gain of 0.055

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**Table:** NASH Patient Characteristics **Body Mass Index (BMI)** 

Overweight (BMI 25.0-29.9)	7 (9.6%)
Grade I Obesity (BMI 30.0-34.9)	30 (41.1%)
Grade II Obesity (BMI 35.0-39.9)	21 (28.8%)
Grade III Obesity (BMI 40+)	15 (20.5%)

## **Hepatic Fibrosis**

Stage 0	12 (16.4%)
Stage I	18 (24.7%)
Stage II	17 (23.3%)
Stage III	5 (6.9%)
Stage IV	21 (28.7%)

 $\pm$  4.55 kg occurred (p = 0.9904 weight before vs. after 12 months). Body mass index fell insignificantly - 0.14  $\pm$  1.25 (p=0.9084) (Figure). The patient population with the greatest urgency of weight loss, those with significant fibrosis on liver

biopsy at diagnosis (Stage II and III) did not lose weight either (Figure). Among patients with advanced fibrosis body weight increased  $1.14 \pm 8.80$  kg while the mean change in BMI was  $0.37 \pm 2.24$  (p=0.8686).

# **DISCUSSION**

Non-alcoholic fatty liver disease is a rapidly growing epidemic with NASH having adverse health consequences beyond the liver. The pathogenesis seems to involve more than simply excess calories, however, with ingested saturated fats and both ingested and endogenous fructose contributing to the hepatotoxic injury [4]. Management goals are a reduction in hepatic inflammation, arresting the development of fibrosis and preventing cirrhosis and complications thereof. Available pharmaceutical interventions are few with pioglitazone and vitamin E demonstrating efficacy to date. The development of agents targeting various points in the inflammatory or fibrotic process is active [5].

Weight loss in patients with NASH can result in improvement of hepatic steatosis and inflammation as well as resolution of fibrosis. The clinical guidance from the American Association for the Study of Liver Disease recommends loss of 7%-10% of the body weight as this threshold is associated with improved markers of hepatic steatosis, inflammation and fibrosis. Davis et al. [6] examined the National Health and Education Survey database using indirect markers to infer counseling and the presence of fatty liver disease to assess subsequent weight loss. Physician counseling led to little weight loss in patients inferred to have NASH. Both the presence of NASH and the counseling component of care are inferred and not directly documented, however.

The results reported here demonstrate that, in a real world setting, specific physician counseling and follow-up reinforcement failed to promote weight loss among patients with biopsy confirmed NASH. At one year of follow-up neither patient weight nor BMI improved. In patients already demonstrating significant fibrosis (stage II and III) weight loss efforts also failed, suggesting a loss of opportunity to impact outcome.

#### **LEGEND**

Body weight (kg) and Body Mass Index (BMI) for the population of patients with NASH at diagnosis (Before) and 12 months after receiving weight loss counseling from their provider (p = NS for both).

Change in Body Mass Index (BMI) and body weight (kg) in

NASH patients with fibrosis Stages II and III at baseline liver biopsy 12 months following weight loss counseling (p = NS for both).

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