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# A Retrospective Chart Study of a Comprehensive Medical Weight Loss Approach to Pediatric Obesity: Initial Results from the BOUNCE Program

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## Abstract

**Background:** Childhood obesity rates in the United States have tripled over the past three decades, with roughly a third of children and adolescents currently falling in weight range that would qualify them for a diagnosis of overweight or obesity. The current standard treatment of childhood obesity is lifestyle modification, including diet and exercise, but data suggest that more comprehensive and aggressive approach may be necessary to achieve such success.

**Findings:** A chart review of the first 50 pediatric subjects enrolled in a comprehensive medical weight loss program (BOUNCE) was conducted to establish the initial efficacy of the approach. Participants lost a mean of 14.75 pounds over a mean of 7.53 months of participation. Program drop-outs lost the least weight (mean loss=9.74 lbs. and 1.93 BMI points), with larger improvements observed in current participants (mean loss=18.79 lbs and 3.56 BMI points) and program completers (mean loss=25.83 lbs and 5.13 BMI points). The differences between these groups were significant in terms of BMI (p=0.021). Time in program and greater age at the start of program were significant predictors in linear models of the outcomes.

**Conclusions:** Comprehensive medical weight loss approaches appear to be effective at reducing weight and BMI in a pediatric population, with greater effects seen in older (adolescent) patients. As an alternative to more restricted medical approaches as well as to more invasive and riskier bariatric surgical procedures in pediatric patients, comprehensive medical approaches to weight loss warrant further development and study.

**Keywords:** Bariatric medicine; Obesity; Biguinide; Primary care

## Introduction

Despite evidence that the trend has possibly reached a plateau, childhood obesity rates in the U.S. have more than tripled [1-3]. Today, 1/3 of American children are overweight or obese [4]. It is well known that obesity is associated with significant morbidity in children including hypertension, hyperlipidemia, obstructive sleep apnea, fatty liver disease, insulin resistance, pre-diabetes and diabetes [5]. Obese children suffer depression and anxiety, are relentlessly bullied, and have been found to have similar QOL as children diagnosed with cancer [6]. As the research lags behind the childhood obesity epidemic, creative but aggressive early intervention is needed to decrease these obesity related co-morbidities, and enable this generation of children to at minimum meet the life expectancy of their parents [7,8].

The current standard treatment of childhood obesity is lifestyle modification, including diet and exercise [9]. The data are limited, however, and the effectiveness is highly variable and with limited longevity [10,11]. Intervention with the biguanide Metformin HCl® has recently been studied, showing improvement in body composition [12], fasting insulin [12,13], Body Mass Index [14], cardiovascular autonomic control [13] and fatty liver disease [15]. Even with the addition of lifestyle intervention, however, the degree of weight loss in recent studies has not been enough to reverse the majority of obesity related co-morbidites. This suggests that a more comprehensive and aggressive approach may be necessary to achieve such success.

This paper presents the initial evaluation of a comprehensive medical program for children and adolescents that is family centered, and multifaceted. The program incorporates the use of biguinide, behavioral modification, optimization of metabolism, a unified family approach, notation of food intake, step-counting through pedometer usage, and elimination dieting.

## Methods

### Study design

This study is a retrospective chart review aimed at capturing the first 50 child and adolescent participants with at least two weight measurement points. Data extracted from charts included initial and latest weight, height, and metabolic indicators; BMI calculation at each point; demographic indicators (sex, age); and indicators of program components that the patient successfully adhered to (dose of biguinide, family support/both parents, pedometer usage, food journaling, elimination dieting, and exercise). Four outcomes were calculated for each patient record: total weight lost (in lbs.), weight lost per month in the program, Body Mass Index (BMI) points lost, and percentage of total BMI lost over the course of participation. The study was determined to be exempt from review by the institutional IRB at SUNY Upstate Medical University.

### Intervention

The BOUNCE program combines successful elements of adults and childhood obesity research and integrates them into a single program. The components of the program include:

- **B**iguinide (Metformin®) and **B**ehavioral Modification;
- **O**ptimization of metabolism through a 5-meal-per-day plan;
- **U**nified family approach, with parents and (where pertinent) siblings attending visits and receiving supportive information;

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- **N**otation of food intake, through food journaling;
- **C**ounting of steps per day, through pedometer usage;
- **E**limination dieting, focused on the reduction and removal of carbohydrate-rich and calorie dense food items.

Additionally, program participants are encouraged to engage in additional physical activity and exercise, either formally (e.g. via participation in scholastic sports) or informally (e.g. gym membership, jogging).

The intervention was managed by a board-certified family physician, with dual certification in medical bariatrics (WS), in a solo medical weight loss practice. Family and group visits were conducted in addition to individual medical visits, with biweekly visits and a meeting with a dietician on a monthly basis.

### Data extraction

Data were extracted by office staff at the solo practice, and reviewed by the attending medical bariatrician (WS) for accuracy. The anonymized data were then additionally checked for consistency and formatting by the principle data analyst (CPM) on the study.

### Analysis

Descriptive statistics were calculated to describe the study cohort, the level of participation in the BOUNCE program, and the central tendency (mean) and standard deviation of the outcomes. Group means were calculated for program drop-outs, current participants, and completers (the latter defined as being completing 1 year in the program, and currently undergoing maintenance therapy), and differences in outcome were measured for significance via Analysis of Variance (ANOVA).

The four outcome measures Weight Lost (WL), Weight Lost per Month (WLM), BMI lost (BMIL), and percent BMI lost (PBMIL) were then modeled as dependent variables via Ordinary Least Squares (OLS) regression procedures, with forward-entered independent variables including age at program start (in years), sex (1=female, 0=male), components adhered to (1=adhered, 0=partial adherence or non-adherence), status in program (completion or continuing participation, vs. drop-out), dose of biguinide HCL reached through titration (continuous variable), initial BMI, and the total time in program (months) from first to most recent measurement. Analyses were conducted in SPSS v.18.0.3, and later verified in SPSS v.20.0.1.

## Results

A total of 53 patient records were initially extracted, with 3 subjects having incomplete or no end- or second-point data. The total N for the analysis therefore reached the targeted goal of 50 subjects entered for analysis.

The study cohort was predominantly female (70%), with an average age of slightly over 14 years (range 9-19 years, SD=3.05 yrs). Subjects participated for a mean of 7.53 months (SD=7.19), and lost an average of 14.75 lbs. over that time. The mean BMI at program start was 33.85 (SD=6.67), and 30.08 at the second measurement (SD=6.24). Adherence to program components ranged from 50% (Parental Support) to 100% (all participants reported participation in some form of exercise regimen). Descriptive parameters of the study cohort are presented in Table 1.

Although program participation status mattered, all three groups tended to lose weight. Drop-outs (n=26) from the program lost a mean of 9.74 lbs. and 1.93 BMI points; current participants (n=18) lost a mean of 18.79 lbs. and 3.56 BMI points; and completers (n=6) lost a mean of 25.83 lbs. and 5.13 BMI points. The differences were not significant between groups in terms of weight loss, but were significant in terms of BMI (F=4.193, p=0.021). The analysis of between-group differences is summarized in Table 2.

The age at the start of the program was the most consistent predictor of outcome, with each year of age equating to an additional 3 lbs. lost (b=-3.026, p>0.001), the loss of an additional quarter-pound per month (b=-.268, p=0.015), an additional quarter point of BMI (b=-.260, p>0.001), and more than half an additional percentage point of total BMI (b=-.614, p>0.001). Time in program was also a significant predictor in total weight lost, with each month contributing roughly 1.296 lbs lost (p>0.0010), .339 BMI points lost (p>0.001), and .803 percent of BMI lost. All other predictors were eliminated from the models by the forward-stepwise procedure. Model summaries are presented in Table 3.

## Discussion

This chart review and analysis was conducted with the first 50 pediatric patients to enter the BOUNCE program, as both an initial quality-control measure and as a first-pass examination of the value of a non-surgical, comprehensive medical/behavioral intervention for overweight and obese children and adolescents. The initial analysis indicates that the approach clearly contributes to weight loss in participants. Although this initial sample does not have enough power to detect significant changes due to individual components, it is worth noting that patients lost weight regardless of whether they dropped out of the program, were currently participating, or had completed the program (one year of intensive participation, and currently in a maintenance phase).

Clearly, a major issue is the rate of retention in the program, with slightly over half of the cohort (n=26) dropping out. This factor was highly correlated with the presence or absence of full familial support rated as present or absent by the attending clinician (Spearman's rho=0.493, p=0.001), and defined as both parents supportive and engaged (where available). Understandably, it was more difficult for a

| | Mean | Std. Deviation | N |
|---|---|---|---|
| Time in Program (Months) | 7.53 | 7.19 | 53 |
| BMI Start | 33.85 | 6.67 | 53 |
| BMI End | 30.98 | 6.24 | 50 |
| Weight Lost (lbs) | -14.75 | 17.72 | 50 |
| Age at start of program | 14.01 | 3.05 | 50 |
| Dose of Metformin reached (500-2500mg) | 1210 | 655.35 | 50 |
| | Count | Percent | N |
| Sex | 35 F, 15 M | 70% Female | 50 |
| BOUNCE Components - Adherence | | | |
| Followed 5 meals per day (y/n) | 47 (94%) | 94% | 50 |
| Both parents Supportive (y/n) | 32 (64%) | 64% | 50 |
| Regular food diary kept (y/n) | 26 (52%) | 52% | 50 |
| Pedometer Used regularly (y/n) | 26 (52%) | 52% | 50 |
| Elimination diet followed (y/n) | 45 (90%) | 90% | 50 |
| Exercise | 50 (100%) | 100% | 50 |
| Parental Support (based upon notes) | 25 (50%) | 50% | 50 |

**Table 1:** Descriptive statistics of BOUNCE program participants.

| | Drop-Out | | | | Current Participant | | | | Completer | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean | Low/ Gain | High | Count | Mean | Low/Gain | High | Count | Mean | Low/Gain | High |
| **Weight Lost (lbs)*** | -9.74 | 3.50 | -61.50 | 29 | -18.79 | 16.00 | -60.50 | 18 | -25.83 | -6.00 | -55.00 |
| **BMI lost**** | -1.93 | .50 | -10.10 | 29 | -3.56 | 1.60 | -10.10 | 18 | -5.13 | -2.60 | -8.50 |
| * F=2.905, p=.065; **F=4.193, p=.021 | | | | | | | | | | | |

**Table 2:** Comparison of weight and BMI lost between BOUNCE Drop-outs, current participants, and program completers (1 year of program, currently in maintenance phase).

| Predictors | Weight lost (lbs) | Weight lost per month (lbs) | BMI lost | Percent BMI lost |
|---|---|---|---|---|
| | β εστιματε σιγ. | β εστιματε σιγ. | β εστιματε σιγ. | β εστιματε σιγ. |
| Age at start of program (Years) | -3.026 (p>0.001) | -.268 (p=0.015) | -.260 (p>0.001) | -.614 (p>0.001) |
| Time in program (Months) | -1.296 (p>0.001) | - | -.339 (p>0.001) | -.803 (p=0.003) |
| Dose of Metformin reached (500-2500 mg) | - | - | - | -.003 (p=-0.039) |
| $R^2$ | 0.624 | 0.118 | 0.607 | 0.594 |
| Model Sig. | p>0.001 | p=0.015 | p>0.001 | p>0.001 |

**Table 3:** Results of OLS regression analyses BOUNCE program outcomes, in terms of weight lost in pounds, rate of weight loss per month in program, BMI points lost, and percent BMI lost over the course of participation.

child to be compliant with the plan if a parent or sibling were deviating from the program on a regular basis.

## Weaknesses

As a first-look at the comprehensive BOUNCE approach, the power of the study was necessarily limited. This hampered the ability to fully analyze the effects of individual program components in a full linear model. Additionally, other metabolic outcomes, such as improved glucose control, lipid levels, vitamin D, or $O_2$ Saturation appear to be improving, but the early nature of this analysis did not allow for end-point or second-reading data on enough patients to adequately assess the effects of the program upon these outcomes, as there were many missing data points.

An additional complication is the measurement of weight loss across a relatively wide age range, considering the population. Younger patients tended to have less weight to lose and in some cases, the goal was to stabilize the child's weight and allow the impending growth to normalize BMI. We adjusted for this in the linear models by incorporating age at program start and initial weight and BMI as control variables. Additionally, BMI is relative to the patient, as opposed to an absolute measure such as weight, giving a relative measure of the trend in the outcomes, which head in the same direction. We believe the fact that BMI-based outcomes were at least as significantly improved as the raw weight improvements should lend confidence to the interpretations of the data presented here.

## Conclusions

Although intensive and susceptible to drop-out, a comprehensive weight-loss program can yield meaningful results in a pediatric (and predominantly adolescent) population, with the effects being more pronounced in older patients within this population. As an alternative to bariatric surgical procedures, which come with inherent risks, the value of a comprehensive weight loss program is apparent. Whether the results are immediately comparable will require a prospective trial comparing the effectiveness of the two modalities. Additionally, long-term follow-up and maintenance of weight loss and concomitant improvements in metabolic function require additional measurement, especially in comparison to surgical outcomes. In any case, the additional development and study of comprehensive medical weight loss approaches appears to be warranted.

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