

Synergistic weight loss using liraglutide augmentation in addition to a zero carbohydrate ketogenic feeding tube diet: a case report

Abstract

Introduction: The purpose of this case report was to bring attention to the synergistic weight loss effects of the combined use of liraglutide (Saxenda®) and a zero carbohydrate feeding tube diet (KE Diet®).

Case Presentation: This is a case report of a 48-year-old Caucasian female with an initial BMI of 36.7 kg/m² with inability to lose weight despite multiple attempts at dieting. The observed time span was 200 days (approximately 6 months), beginning April 11, 2016 (weight 214 lbs; BMI 36.7 kg/m²) and ending when the patient reached her weight loss goal of 150 pounds on October 28, 2016 (BMI 25.7 kg/m²). Two cycles of a zero carbohydrate feeding tube diet (KE Diet®), the first cycle lasting 14 days and second cycle lasting 10 days, 109 days apart, were completed during the 200-day observation period. While on the zero carbohydrate feeding tube diet (KE Diet®) the patient only consumed a zero carbohydrate solution of whey protein, micronutrients, MCT oil administered by a continuous feeding tube pump and was allowed to drink only water and black decaffeinated coffee. Liraglutide (Saxenda®) was administered daily in between the zero carbohydrate feeding tube diet (KE Diet®) cycles in addition to a microbiome diet.

Discussion: After 200 days of liraglutide (Saxenda®) and 2 cycles of a zero carbohydrate feeding tube diet (KE Diet®), a total weight loss of 64 pounds (34% of initial weight) was observed. The patient tolerated the zero carbohydrate feeding tube diet (KE Diet®) and liraglutide (Saxenda®) combination well with minimal side effects of nausea, diarrhoea, abdominal bloating and hunger. The patient tolerated liraglutide (Saxenda®) well at a dose between 1.2 mg and 1.8 mg per day without nausea. At the higher dose of 3.0 mg per day, the patient experienced intolerable nausea without vomiting.

Conclusion: The combined use of liraglutide (Saxenda®) and a zero carbohydrate feeding tube diet (KE Diet®) followed by a microbiome diet may produce significant weight loss in obese patients. Further clinical studies are warranted in this area and to determine which combinations and dosages are best.

Keywords: ke diet®, saxenda®, weight loss, alternative to bariatric surgery, feeding tube diet, ketogenic diet, ken, nutritional ketosis, weight loss medication, liraglutide

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Abbreviations: lbs, pounds; mg/dL, milligrams per decilitre; kg/m², kilograms per square meter; BMI, body mass index; DEXA, dual energy x-ray absorptiometry; mm Hg, millimeters of mercury; °F, degrees Fahrenheit

Introduction

Obesity is a chronic progressive disease that is common, costly and has serious adverse health implications.¹ In 2013 the American Medical Association first recognized obesity as a disease due to its increased prevalence in society and direct correlation with many leading causes of preventable death.² Obesity is influenced by metabolic, genetic and biologic factors in combination with behavioral, cultural, societal, and economic factors.³ Treatment for obesity requires further research to find safe and effective long-term weight management options.

Ketogenic enteral nutrition has been utilized in Italy as a short-term, rapid, safe and effective weight loss method for the treatment of obesity.⁴ A zero carbohydrate feeding tube diet (KE Diet®) is an improved method of weight loss and consists of a blend of zero carbohydrate, whey protein, micronutrients, and medium chain triglycerides (MCT) oil administered through a nasogastric feeding tube continuously by feeding pump for 10 days.⁵ A zero carbohydrate feeding tube diet (KE Diet®) is reported to produce a 5% to 10% reduction in body weight in 10 days through rapid induction of nutritional ketosis.⁶

Liraglutide (Saxenda®) is a FDA approved prescription weight loss medication.⁷ Liraglutide (Saxenda®) is a GLP-1 receptor agonist which is administered as a once a day injection, titrated dose from 0.6 mg to 3.0 mg to achieve weight loss in patients with a BMI \geq 27 kg/m².⁷

Clinical studies have shown that both liraglutide (Saxenda®) and a zero carbohydrate feeding tube diet (KE Diet®) are effective weight loss methods that are safe and are minimally invasive.^{6,7} In this case report, liraglutide (Saxenda®) and a zero carbohydrate feeding tube diet (KE Diet®) were prescribed in alternating cycles under medical supervision to produce synergistic weight loss.

Case presentation

A 48-year old Caucasian female with an initial BMI of 36.7kg/m² presented to the weight loss clinic with the chief complaint of inability to lose weight despite multiple attempts at caloric restriction without exercise. On initial examination the patient had a blood pressure of 154/94mm Hg, pulse of 62 beats per minute, respirations of 14 breaths per minute, oral temperature of 97.9°F, height of 64 inches, weight of 214 pounds and a BMI of 36.7. DEXA body composition scan reported a total mass of 213.5lbs, 95.3lbs of lean mass, 112.2lbs of fat mass, a total body fat of 54.1% and a visceral adipose tissue fat mass of 4.03lbs. The patient does not smoke, uses alcohol in moderation and denies use of illegal substances. She reports eating healthy but does not exercise due to musculoskeletal pain that is made worse by her excess weight. Patient medications include Estradiol 2mg daily, Phentermine 37.5mg daily which was continued throughout the entire study period. She has sensitivity to codeine and morphine with no other allergies noted. Current medical conditions include obesity, musculoskeletal pain, anxiety, depression and irritable bowel syndrome. She had a hysterectomy in 2012 followed by induced menopause and a weight gain of 30lbs over two years with the inability to lose the excess weight. She has a family history of hypertension, cancer, alcohol addiction, anxiety and depression. The observation period was 200days (approximately 6months), beginning April 11, 2016, at which time the patient weighed 214lbs and had a BMI of 36.7kg/m². The treatment ended when the patient reached her weight loss goal of 150lbs on October 28, 2016 with a BMI 25.7kg/m².

Two cycles of a zero carbohydrate feeding tube diet (KE Diet®) were completed during the 200days where the patient only consumed the zero carbohydrate solution of whey protein, micronutrients, MCT oil, drank water, black decaffeinated coffee occasionally and did not eat any food. Liraglutide (Saxenda®) was administered daily in between and after the zero carbohydrate feeding tube diet (KE Diet®) cycles.

The first zero carbohydrate feeding tube diet (KE Diet®) cycle started on April 11, 2016 and was completed on April 25, 2016 with a total weight loss of 17lbs in 14days. The zero carbohydrate feeding tube diet (KE Diet®) formula consisted of 60grams of protein, 56grams of fat, 0grams of carbohydrates and 620 calories per day, administered by a feeding tube at a constant rate of 85millilitres per hour. Patient called with complaints of nausea and diarrhoea on April 13, 2016 and the zero carbohydrate feeding tube diet (KE Diet®) formula was adjusted to 90grams of protein, 42grams of fat, 0grams of carbohydrates and 630 calories per day on a continuous feed at the same constant rate. On April 14, 2016 patient called and reported she was tolerating the diet well. On April 18, 2016 patient formula was adjusted back to original composition, maintained and tolerated to the end of the diet cycle. Liraglutide (Saxenda®) was started on April 26, 2016 and patient was instructed to follow a low carbohydrate diet of less than 20grams of carbohydrates per day. The liraglutide (Saxenda®) dosing schedule started at 0.6mg per day for week 1, and increased to 1.2mg per day week 2, 1.8mg per day week 3, 2.4mg per

day week 4, and 3mg per day week 5 and thereafter. Patient titrated liraglutide (Saxenda®) dose up as directed by the physician and settled at a customized dose between 1.2mg and 1.8mg per day to eliminate nausea.

She returned to the clinic on July 01, 2016 for a second zero carbohydrate feeding tube diet (KE Diet®) cycle. On examination the patient had a blood pressure of 110/82mm Hg, pulse of 80 beats per minute, respirations of 18 breaths per minute, oral temperature of 97.9°F, height of 64 inches, weight of 183.5lbs and BMI of 31.5kg/m². DEXA body composition scan reported a total mass of 183.1lbs, 87.4lbs of lean mass, 90.1lbs of fat, a total body percent fat of 50.8% and a visceral adipose tissue fat mass of 2.66lbs (1.37lbs fat reduction). Patient reported diligently following a microbiome diet after completion of the first zero carbohydrate feeding tube diet (KE Diet®) cycle. A dipstick urinalysis revealed her urine ketones were negative and she was not in nutritional ketosis. She was started on the second zero carbohydrate feeding tube diet (KE Diet®) cycle with 60grams of protein, 56grams of fat, 0grams of carbohydrates and 620 calories per day on a continuous feed at a constant rate of 85 ml/hr and liraglutide (Saxenda®) was stopped for the next 10days during the zero carbohydrate feeding tube diet (KE Diet®). On July 11, 2016, day 10 of the zero carbohydrate feeding tube diet (KE Diet®) patient returned to the clinic with a total weight loss of 9.5lbs for ending weight of 174lbs and ketones at 150mg/dL per urinalysis. Patient was instructed to resume her liraglutide (Saxenda®) starting at 0.6mg per day for week 1 and titrating up the same dosing schedule as previously implemented. Patient resumed a microbiome diet.

The patient was tracked by phone call once a month after July 11, 2017. She followed a microbiome diet and kept her liraglutide (Saxenda®) dose at between 1.2mg and 1.8mg per day. On October 28, 2016 the patient called and reported meeting her weight loss goal of 150lbs, a total net weight loss of 64lbs since the beginning of the first KE Diet cycle on April 11, 2016. The final report from the patient was that since starting the treatment combination and following a microbiome diet, she successfully eliminated her symptoms of irritable bowel and has not had gallbladder flair or any kidney stone issues. These were all common symptoms that affected her quality of life in addition to being obese and having musculoskeletal pain. She reported increased energy, decreased pain and extreme satisfaction.

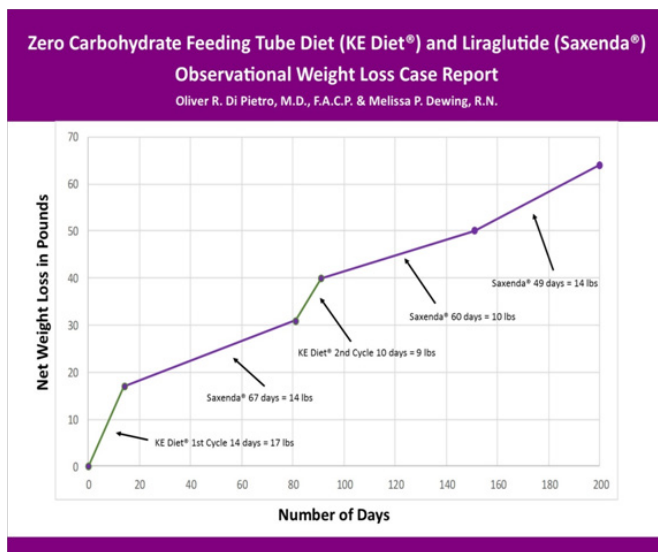
Zero carbohydrate feeding tube diet (KE Diet®) cycle #1: the patient completed 14days and lost 17lbs with BMI reduction of 2.9kg/m² and final urinary ketosis level of 150mg/dL. Starting weight was 214lbs and ending weight was 197lbs.

Liraglutide (Saxenda®) augmentation for 109days, with maximum daily dose range between 1.2mg and 1.8mg per day injection. Weight loss total was 13.5lbs.

Zero carbohydrate feeding tube diet (KE Diet®) cycle #2: the patient completed 10days and lost 9.5lbs with BMI reduction of 1.6kg/m² and final urinary ketosis level of 150mg/dL. Starting weight was 183.5lbs and ending weight was 174 pounds.

Liraglutide (Saxenda®) augmentation for 76days, with maximum daily dose range between 1.2mg and 1.8mg per day injection. Weight loss total was 24lbs.

Synergistic total weight loss produced by liraglutide (Saxenda®) and a zero carbohydrate feeding tube diet (KE Diet®) in the course of 200days was 64lbs (Graph).



Graph Zero carbohydrate feeding tube diet (KE Diet®) and liraglutide (Saxenda®) Observational Weight Loss Case Report.

Discussion

After 200 days, a total weight loss of 64 lbs (34% weight reduction) was achieved using liraglutide (Saxenda®) and a zero carbohydrate feeding tube diet (KE Diet®) followed by a microbiome diet. The patient tolerated the zero carbohydrate feeding tube diet (KE Diet®) well with minimal side effects of diarrhoea, stomach cramping and hunger, even with the addition of Phentermine 37.5mg per day for appetite suppression. The patient tolerated liraglutide (Saxenda®) well at a dose between 1.2mg and 1.8mg per day without nausea. At the recommended dose of 3.0mg per day of liraglutide (Saxenda®) the patient experienced nausea that was intolerable.

Clearly this is a single case study, however the weight loss of 34% after 6 months is very impressive and raises the possibility of a new synergistic effect between liraglutide (Saxenda®), a zero carbohydrate feeding tube diet (KE Diet®) followed by a microbiome diet. Further studies will be needed to clarify this association.

Traditional weight loss surgery remains the gold standard for sustainable weight loss and improvement in metabolic status in severely obese individuals with and without co-morbidities, however not all patients are willing to accept the risks of surgery and some regain significant weight after bariatric surgery.¹ Newer innovative therapies are needed and continue to be developed such as vagal nerve stimulation, endobolism, pharmacotherapy and gastric aspiration therapies (AspireAssist®). Extremely low carbohydrate ketogenic

diets administered via a feeding tube have been in use in Europe for over a decade and have been shown to be safe and effective in achieving rapid weight loss but not for weight maintenance.⁴ The combination of a zero carbohydrate feeding tube diet (KE Diet®) with liraglutide (Saxenda®) augmentation and maintenance would be an exciting addition to our armamentarium in the war against obesity.

Conclusion

The medically supervised use of liraglutide (Saxenda®) and a zero carbohydrate feeding tube diet (KE Diet®) to produce weight loss in obese patients may have synergistic effects and produce weight loss comparable to that seen with traditional bariatric surgery. Further clinical studies are warranted to confirm this hypothesis.

Consent

Patient gave informed consent for the study on 04/11/2016.

Competing interest

Oliver Di Pietro is president & founder of European Ketogenic Weight Loss Clinics, LLC and specialty KE Diet® ketogenic diet formula. Dr. Di Pietro currently prescribes Saxenda® in South Florida.

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Melissa Dewing is clinical program director for European Ketogenic Weight Loss Clinics, LLC.

Conflict of interest

The author declares no conflict of interest.

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