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Diagnostic challenge: A pediatric patient with severe obesity and complications of imminent death

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ABSTRACT

Background: A 15-year-old patient suffering from severe obesity (400 pounds, BMI 71.6 kg/m^2) with a clinical phenotype suggestive of syndromic obesity was hospitalized for severe heart failure and cardiogenic shock. The hospital admission prompted a palliative care and heart transplant consultation given end-stage-disease and poor prognosis. It further necessitated a pediatric inpatient obesity consult, which was complicated by several significant hurdles including lack of insurance coverage, FDA approvals, availability of medications, and inadequate knowledge among the medical community.

Methods: Innovative treatment, proactive, persistent advocacy, anti-obesity medication combination strategies modeled after diabetes and hypertension treatment algorithms, and latest evidence in obesity management were utilized to effectively and expeditiously overcome major challenges to care and the medical emergency.

Results: The patient was stabilized and ultimately discharged home, after −25.2% weight loss over 4 months (weight down to 299 pounds, BMI 49.9 kg/m^2) through collaborative medical obesity intervention.

Conclusion: The typical delay in care sought by patients suffering from obesity, often due to stigma and lack of disease awareness, results in missed opportunities to prevent serious obesity-related complications. Skilled specialist expertise, fund of obesity-specific knowledge, and constant advocacy can be crucial in surmounting regulatory barriers to obesity care and in generating successful weight loss outcomes.

Preface

Specialists in any discipline can provide guidance and education on standards of practice, referral pathways, advocacy at regional, state, and national levels, advancement in research, and complex patient consultations. Similarly, experienced adult and pediatric obesity medicine specialists are not only well-versed in overcoming barriers to care in the routine treatment and management of severe obesity, but they might also witness unusual and rare side effects of our obesity therapies in the clinical setting and offer expertise on-label and off-label therapies, electronic health documentation, and appropriate patient and family counseling around anti-obesity medications. Moreover, regardless of hurdles, obesity medicine specialists are rewarded by the difference they can make in the lives of their patients, and on certain days they *save* lives. This diagnostic challenge shares that story of a pediatric patient near-death due to severe obesity and its complications, and hence commences a serious and heartily discussion on obesity.

1. Introduction

1.1. Case history & story setting

Jason (actual name changed for confidentiality), a 15-year-old Caucasian teenager, lived 180 miles away from Nashville, TN where a tertiary care, multidisciplinary obesity center presently lies. The obesity center follows a disease-focused model, consisting of an adult plus integrated pediatric program and includes obesity medicine specialists, bariatric surgeons, dietitians, behavioral health specialists, and specialized pharmacy experts. The center engages in both in-person and virtual or telemedicine visits. Its volume has more than octupled since revamping the program in 2019. Average reported weight loss is >7% over 6 months [1] and the success is mainly attributed to the expertise of its team. The need to highlight the utility and need for telemedicine in many children living in rural areas is vitally important [2–4]. These two factors (expertise of a multidisciplinary team and a telemedicine

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platform) will be critical later in the story.

1.2. Chronological events

On a Friday morning in early 2022, a request was received for an inpatient consultation for obesity on a pediatric patient. The patient had been in the pediatric cardiac intensive care unit for a few weeks and had severe obesity.

Two weeks prior to the initial obesity medicine consultation, the patient was found "gasping for air." The patient had an emergency room visit, where he was found to be vomiting, having diarrhea, shortness of breath, malaise, bilateral lower extremity edema, tachypnea in the 60s, and had a BNP level of 522 pg/mL and an elevated troponin level of 49 ng/mL. The patient was started on furosemide, pressors, continuous positive airway pressure therapy, milrinone drip and transferred to the pediatric cardiac intensive care unit. There, a palliative care consultation was requested. The patient ultimately was taken to the catheterization laboratory, intubated briefly, and found to have a left ventricular ejection fraction of 12–17%, confirming the diagnosis of heart failure. A cardiac transplant consultation was placed. He was unable to be weaned off intravenous cardiac support.

1.3. Additional history based on specialist's chart review

Past Medical History: The patient was not diagnosed with any medical conditions prior to the hospitalization. The patient had been diagnosed with prediabetes (Hgb A1c 6.1%) during his hospital stay and was started on metformin XR 1000 mg once daily by the inpatient endocrinology team. No other dietary, lifestyle, exercise, sleep history, including previous growth chart history was found on inpatient record. There was no mention of "obesity" on the initial assessment on inpatient admission notes. The patient was at his highest weight of 365 pounds (225th of the 95th BMI percentile, Class 3c obesity, BMI 65 kg/m^2) at the time of hospitalization based on review of outpatient records.

1.4. Additional history based on specialist's telemedicine video call with patient's caregiver/guardian

The patient's birth weight was 7 pounds 1 ounces. There were no complications at birth or post-partum with regards to his mother at delivery. There were no developmental concerns reported during infancy, toddlerhood, and preschool years. Weight gain occurred during pre-kindergarten years when pediatricians took note. As he grew older, weight gain worsened. Diagnosis of prediabetes occurred during the hospital stay. He was not previously exposed to any weight-promoting medications and his caregiver could not point toward any causative precipitating factors for his obesity. The patient's caregiver was not familiar with any treatment options for obesity but always believed that his weight was attributed to "genetics" and that no one "listened to her," and thus the caregiver felt "disheartened." The patient was a non-responder to prior weight loss attempts, including many self-implemented trials and commercial programs.

24-h Dietary Recall (history taken at the hospital by specialist): The patient often skipped breakfast at home. For lunch, the patient typically had baked chicken nuggets with vegetables. Dinner was similar but that he loved "white bread." For snacks, the patient often had microwavable popcorn and fruits. His beverages usually consisted of water and unsweetened tea.

1.5. Hyperphagia history

Upon further questions, it was found that the patient had foraging behaviors and distress around food when he was younger. Cabinets were often locked. It was still a source of distress for the family, but they had learned to "cope." For these reasons, Jason's caregiver "knew" that his weight issues were "genetic" and that "it was beyond this control." There was no known family history of obesity.

Exercise: Due to recent shortness of breath, the patient could not exercise. Presently, he was encouraged to walk laps in the intensive care unit.

Sleep history: Sleep apnea was diagnosed during the patient's inpatient visit when he presented with tachypnea and desaturation. There was a history of snoring and witnessed "apneas" while at home, but previously the patient was never worked up.

Psychosocial and stress history: The patient's caregiver was appropriately worried about what will happen if his heart condition does not improve and acknowledged may times that parts of the patient's life will need to change. There was no previous depression and anxiety history prior to the hospitalization. The patient had a small group of friends with whom he enjoyed playing video games and hanging out. The patient was bullied in school and attacked twice resulting in concussions. The second time it happened, the patient was transitioned to homeschooling.

There were no known drug allergies. The patient was extubated at the time of the consultation request. Medications included: acetaminophen as needed, carvedilol, enoxaparin, furosemide, lisinopril, melatonin, metformin XR, milrinone infusion, and spironolactone.

1.6. Data points on chart review

Vitals: BP 116/85, Pulse 95, Weight 400 pounds, BMI 71.6 kg/m^2, 263rd of the 95th BMI percentile, 3L oxygen via nasal cannula with oxygen saturations 92–93%

Laboratory analysis & Imaging: electrolytes were normal; kidney, liver, and thyroid function were normal; complete blood count was significant for anemia with a hemoglobin of 9.7 g/dL. HgbA1c was 6.1%. Lipid profile was as follows: Total 103 mg/dL; triglycerides 67 mg/dL, HDL 19 mg/dL, and LDL 71 mg/dL. There were numerous cardiology reports and tests available on file.

Health Insurance: The patient had public (government) health insurance [Medicaid]

1.7. Pertinent physical examination findings

The following was found on physical examination*: an almost blind child with glasses around a round-shaped facies, stubby hands, and feet.*

2. Discussion

Jason is an adolescent patient with severe, end-stage obesity and syndromic features prompting genetic obesity considerations and work-up. From the above medical history, it should be noted that there was a significant delay in care that is too common in obesity, particularly pediatric obesity [5,6]. The negative impact of this delay is detrimental to not only health and worsening obesity-related complications, but also psychosocial stability and well-being. Weight-based victimization and in particular, bullying in boys as experienced by the patient, is unfortunately common and prevalent in children with obesity and overweight status [7]. In this patient, an obesity diagnosis was missed, and sleep apnea was not diagnosed until the in-patient admission, further illustrating ravages of this delay. Obesity is often underreported as a diagnosis in the assessment of inpatients [8] and efforts to integrate obesity into the medical education curriculum cannot be underscored. Of note, the patient was prescribed metformin for prediabetes by a trained inpatient pediatric endocrinology team who was likely familiar with management of obesity-related complications, yet an obesity therapeutic plan was not included in the treatment strategy for this patient, the actual root cause of the patient's end organ damage. Newer, updated guidelines indicate immediate, intensive treatment for childhood obesity [9] with a thorough assessment and differential diagnosis including endocrinopathies, syndromal obesity as well as both monogenic and polygenic etiologies of obesity [10], rather than a staged approach.

2.1. Obesity as a medical condition requiring palliative care in pediatrics

It should be noted that at the time of hospitalization, palliative care was consulted for the patient, signifying an end-stage disease process. The American Academy of Pediatrics recommends palliative care for children at the diagnosis of serious illness [11]. These types of consultations occur usually after >75% of the time from diagnosis until *death* [11]. Furthermore, the indications for heart transplantation in pediatric heart disease is for *end-state-heart-disease* [12]. In addition, as per the pediatric Edmonton Obesity Staging System [13], Jason would be classified as EOSS-P-Stage 3 based on metabolic, mechanical, mental and milieu complications. Upon closer examination, Jason's radiograph revealed bilateral atelectasis, cardiomegaly, and congestion.

2.2. Impact of obesity on cardiovascular function

The pathophysiology of heart failure in obesity is such that myocardial fat deposition and insulin resistance can result in an altered metabolic profile (e.g., inflammation, insulin resistance, hyperglycemia), thickening of the carotid intima and increase in traditional cardiovascular risk factors [14,15]. This cascade further initiates autonomic dysfunction, altered heart rate variability, increases in catecholamines and ventricular filling pressure respectively, and hypoxia resulting in dysfunctional contractility. Furthermore, the adipocytes are a rich source of angiotensinogen, angiotensinogen 1 and angiotensin converting enzyme contributing to elevated blood volume and a rise in renin [14]. Every 5 units increment in BMI confers a 16% risk of sudden cardiac [16] death and a 30% greater risk of incident atrial fibrillation [17].

The challenge in managing obesity is that by the time the patient presents in the clinical setting, the establishment of macro- and microvascular complications has already occurred, all of which consume significant clinical time and resources. The question remains: how can the medical community improve in addressing the source [root cause is obesity]?

Regarding characterizing obesity, body-mass-index by itself may not be adequate to understand the degree of pathophysiology. Differences in adipose tissue distribution such as low visceral adipose tissue (functional subcutaneous adipose tissue) and high visceral adipose tissue (dysfunctional subcutaneous adipose tissue) may be challenging to identify and thus may present difficulty in phenotyping those associated with higher cardiovascular risk [18]. Healthcare professionals often amalgam all types of obesities as a single entity, further contributing to discrepancies.

2.3. Bardet-Biedl Syndrome as a differential diagnosis of genetic or syndrome obesity

2.3.1. Bardet-Biedl Syndrome (BBS)

Obtaining an appropriate history that can potentially portend a diagnosis of monogenic or syndromal obesity is an essential part of the pediatric obesity assessment [7,10,15]. The physical exam finding coupled with a distinct hyperphagia history and cardiogenic shock on intravenous infusion drips instantly spirals the suspicion for Bardet-Biedl Syndrome (BBS). Genetic obesity is very rare, with ~7% of obesity attributed to genetic obesity, with an incidence of 1:100000 for BBS[19]. BBS genes are involved in leptin receptor trafficking. Disruption in BBS genes results in pro-opiomelanocortin (POMC) dysregulation and hyperphagia [20]. The conserved BBS genes assemble a coat that traffics membrane proteins to cilia [21]. Loss of BBS genes causes a buildup of vesicles in the motile cilia [20,21]. Criteria for effective diagnosis of BBS [22–24] is based on 4 primary features or 3 primary features plus 2 secondary features. Primary features may include obesity, polydactyl, abnormalities of urinary tract, rod-cone dystrophy leading to retinitis pigmentosa, hypogonadism. Patients with BBS can present with significant cardiovascular disease or cardiomyopathy. A genetic obesity test can support the diagnosis and indicate the presence of gene mutations for BBS. Thus, a genetic obesity test would be a fundamental part of this consultation.

Hyperphagia is the most difficult to manage for patients and their families. It results in complete loss of control regarding feeding behaviors, pathological hunger and lack of satiety or fullness. Families must struggle with locking kitchen cabinets, refrigerators, foraging and food hoarding behaviors, as examples.

At the study's tertiary care obesity center, all adolescents undergo genetic obesity testing because of the severity of obesity at initial presentation. There is a self-selection bias as the patients have already trialed numerous other weight loss programs and dietary changes prior to seeking consultation. In the process, >40% of patients were discovered to be positive on genetic obesity testing [25]. Interestingly, >90% of the adult patients with a BMI $\geq$40 kg/m^2 and a history of childhood obesity <10 years of age have been found to be positive for biallelic, monoallelic, pathogenic, or variant of undetermined significance.

2.4. Considerations in obesity treatment plan

2.4.1. Refer to Table 1 as a reference for final treatment plan recommendations

There were 5 categories to consider in the management and treatment algorithm of this patient [1]: pharmacotherapy: anti-obesity medications (AOMs)[combination and more novel therapies including glucacon-like-1 receptor agonists [GLP1-RA], dual glucose-dependent insulinotropic polypeptide and GLPA [GIP-GLP-RA]], other type 2 diabetes medications such as amylin analogues, sodium-glucose transporter protein 2 [SGLT2] inhibitors, and setmelanotide, an MC4R novel agonist [2] adolescent metabolic and bariatric surgery [3] nutrition considerations [4] genetic obesity considerations, and finally [5] distance [lives several hours away, plan for telemedicine visits].

2.5. Pharmacotherapy considerations

The patient meets clinical criteria to initiate AOM: $\geq$95th BMI percentile plus the presence of weight-related medical condition or $\geq$120th of the 95th BMI percentile [26] and as per current pediatric guidelines and recommendations [9,27].

2.5.1. Combination therapy

More intensive weight loss was desired given significant disease severity. Combination therapy in order to achieve synergistic or additive effects in more severe disease staging is well established in hypertension algorithms where optimal Step 1 therapy involving dual low dose combination of 2 agents (A + C) is recommended compared to Step 4 therapy in the cases of resistant hypertension where triple combination + spironolactone or other drug (A + C + D) is recommended [28]. Moreover, the American Diabetes Association algorithm for pharmacologic approaches to glycemic treatment specifically indicate that early combination therapy can be considered in some patients at treatment initiation to extend the time to treatment failure [29]. Thus, obesity treatment should not be any different.

Further evidence at combination therapy is also supported by recent scientific discoveries, where combined activation of GIP and GLP-RA receptors causes more significant weight loss compared to monotherapy with GIP receptor activation alone, as was seen in the case of tirzepatide [30]. This novel combinatory incretin can achieve −22.5% weight loss on optimal therapeutic dose at 72 weeks [31]. Of note, bariatric surgery can achieve at least 30–35% weight loss. Additive effects of anti-obesity medications on weight loss outcomes to treat bariatric surgery weight regain has also been reported (−5.7% vs. −2.2% total body weight lost with medical management on $\geq$2 AOMs vs. no AOMs respectively) [32]. A longer term study over 12 months found that post-operative bariatric surgery patients presenting with weight regain who were prescribed 3 or more AOMs had greater weight loss than those prescribed only one AOM (−14.5 kg vs. −4.94 kg respectively; $p < 0.05$) [33].

The future is promising with more novel therapies in the horizon such as cagrilintide [amylin analogue]-semaglutide combination, now able to achieve approximately −20% weight loss at 20 weeks, compared to semaglutide alone, in the recent Phase 1B clinical trial [34]. Perhaps, in the patient, Jason, the combination of now available amylin analogue, pramlintide [available for Type 1 or Type 2 diabetes] plus a GLP1agonist could result in synergistic and/or additive combination therapy with >20% weight loss success, as recently published in a case cohort [35].

Evidence for combination AOMs has been noted in pediatrics with the recent FDA approval of phentermine/topiramate combination therapy (−10.44% weight loss on mid-dose) [36] compared to phentermine monotherapy alone (−4% BMI reduction) [37]. Presently, orlistat, phentermine monotherapy, liraglutide [38], phentermine/topiramate have attained US FDA approval status in adolescents with semaglutide 2.4 mg soon following on December 23, 2022 given the remarkable results of the STEP-TEENS trial [39].

2.5.2. Novel therapies such as the incretins and sodium-glucose transporter protein 2 inhibitors (SGLT2)

In the new era of obesity medicine where feasibility of >15% weight loss can now exist; therapy selection will be determined partially by cardiovascular outcomes trials. SELECT (semaglutide effects on cardiovascular outcomes in people with overweight or obesity [40]) is the first cardiovascular outcomes trial to see whether an AOM can prevent major adverse cardiovascular events (N = 17500 participants). The more novel GLP1A semaglutide has a favorable cardiovascular risk profile. In the PIONEER 6 and SUSTAIN 6 trials, the cardiovascular risk profile of oral semaglutide was found not to be inferior to that of placebo [41,42].

Regarding SGLT2 inhibitors, in the EMPA-REG outcome trial [43], patients with type 2 diabetes at high risk for cardiovascular events who received empagliflozin had a lower rate of primary composite cardiovascular outcome and of death from any cause. Hospitalization for heart failure resulted in 35% relative risk reduction. Of note, empagliflozin is not approved for weight loss, but weight loss was a side effect of the medication in the clinical study where patients lost between 1.8 and 3.2% of their body weight over 24 weeks of treatment.

2.5.3. Insurance coverage considerations for pharmacotherapy

As a reminder, this patient is on a government health plan and thus therapy selection needs to be based on affordability and insurance coverage. Addressing and anticipating possible insurance barriers would be necessary [44].

Advocacy: Approximately three years ago, the institution where Jason sought treatment came together to create an episodes of care team to devote high quality care at economic cost and value to the employer and designed an obesity bundle with pharmacy benefits (on-label, off-label, novel therapies, [tirzepatide to be included in the next phase]) at $0 cost to the patient, in an effort to overcome AOMs prescribing barriers and evade the need for prior authorizations, for high risk patients with a BMI >35(1). The obesity bundle went go-live January 1, 2022, with over 1000 patients now enrolled.

In parallel, almost one year ago, a state obesity society to conglomerate obesity providers across the state to empower, educate and engage was established. Its efforts resulted in an appeal to government leadership in support for adolescent obesity medication coverage, with liraglutide 3.0 mg now approved for adolescents (12–21 years of age). Because adolescent coverage includes up to 21 years of age in our state, coverage for younger adults with obesity was automatically extended. The power of advocacy and collaborative efforts to overcome barriers to obesity care should not be underscored.

2.5.4. Obesity pharmacotherapy clinical trial considerations

At the time of consultation, the study's institution was a site for the TESOMET (triple monoamine inhibitor for non-syndromic hypothalamic obesity) and SURMOUNT-3 (tirzepatide) studies [45,46], but the patient would not qualify for either of these. The setmelanotide clinical trials [47] were also on-going, but the results of the patient's genetic obesity testing was not available. Emerging bariatric technologies such as devices or endoscopic procedures are being investigated in pediatrics and target a variety of physiologic mechanisms implicated in energy regulation [48]. In regard to medical devices, the hydrogel capsule (Plenity) [49] and Epitomee capsule [50] (swallowed capsules that shape shifts into polygonal shape and biodegrades naturally) would be novel therapies on the horizon, but not yet studied in pediatrics, despite the demand from many families to trial non-invasive non-pharmacological approaches prior to either pharmacotherapy or bariatric surgery considerations.

2.5.5. Setmelanotide, novel MC4R agonist to treat genetic obesity

In 2016, a case report was published in the New England Journal of Medicine regarding select patients with POMC deficiency treated with an MC4R agonist [51]. The patients tolerated the treatment well with significant weight loss benefits. In a 32-week open therapy trial of setmelanotide to treat genetic obesity (POMC deficiency, leptin receptor deficiency, PCSK1 deficiency), patients with POMC and LEPR deficiency lost −25.4% and −12.5% of their initial body respectively [52]. Setmelanotide gained new FDA approval for BBS on June 16, 2022, for ages ≥6 years. In the per protocol trial, patients lost −16.3% of body weight at 12 months with reduction in hunger scores [53].

2.5.6. Off-label usage in pediatrics

According to the American Academy of Pediatrics policy statement in 2014 [54], the administration of an approved drug beyond the FDA labeling is not considered research if it is in the individual's best interests. If existing evidence supports "the use of a drug for a specific indication in a particular patient, the usual informed-consent conversations should be conducted including anticipated risks, benefits, and alternatives … If the off-label use is based on sound medical evidence, no additional informed consent beyond that routinely used in therapeutic decision-making is needed." Over the last decade, we have seen improvement in pediatric product labeling including onset of pediatric clinical trials because of the Best Pharmaceutical for Children Act (BPCA) and Pediatric Research Equity Act (PREA), enacted in 2012 [55]. The first report by the Secretary of Health and Human Services was submitted to congress by July 9, 2016, then every five years thereafter.

2.5.7. Pharmacotherapy considerations summary

To summarize, for the patient, fortunately liraglutide 3.0 mg, a GLP1A therapy with an actual obesity indication in adolescents would be the best option, as there would be GLP1A non-coverage with an absence of a type 2 diabetes mellitus diagnosis. Regarding the amylin analogue, pramlintide, though inpatient coverage could be provided, outpatient coverage may present with hurdles. The SGLT2 inhibitor empagliflozin had sufficient evidence in heart failure to justify benefits over risks in this patient, but not FDA-approved in pediatrics. In addition, there was a need to swiftly screen eligibility for novel and upcoming clinical trials, including medical devices, as was routinely performed in standard clinical practice for all new patients (patient did not meet eligibility criteria for any of the clinical trial studies that were on-going). Tirzepatide was not yet accessible on the market at the time of consultation and not yet studied in pediatrics. Given that BBS is a clinical diagnosis, setmelanotide would be indicated as consideration for the patient in this case. However, setmelanotide was not a feasible option at the time of patient consultation, as the medication had not yet attained FDA approval for BBS.

2.6. Bariatric surgery considerations

Jason also meets medical criteria for adolescent metabolic bariatric surgery. Newer adolescent metabolic bariatric surgery medical criteria are as follows: BMI 35–39 kg/m^2 or ≥120th of the 95th BMI percentile with the presence of a weight-related medical condition or a BMI >140th of the 95th BMI percentile without a weight-related medical condition

requirement [56]. Guidelines include multidisciplinary team assessment of ability and motivation to adhere to pre-operative and post-operative treatment recommendations, including micronutrient supplementation. Compared to the older guidelines, these recent updates have eliminated tanner staging requirement, added pediatric definitions for severe obesity, and no longer have required additional qualifying criteria if Class 3 obesity severity is present. Reasons for doing so have been based on scientific evidence that earlier intervention results in improved outcomes for adolescents who tolerate the surgery well. Adolescents are also more likely to have remission of Type 2 diabetes and hypertension compared to adults and similar weight loss outcomes as adults [57]. According to the PCORnet bariatric surgery study, there has been a notable upward trend in Roux-en-Y-gastric bypass compared to vertical sleeve gastrectomy and gastric banding procedures in adolescents [58].

2.6.1. Bariatric surgery insurance considerations

Lack of potential insurance coverage for necessary adolescent bariatric surgery presents a major barrier to obesity care. Previously mentioned, the state's Obesity Task Force established collaborative initiatives to address these barriers. Current Senate hearings are on-going with final recommendations delivered to the State's legislature. As a result of these hearings, potentially, the threshold age for bariatric surgery considerations might be lowered to age 15 years and older. Though this is still inconsistent with current guidelines [56] (age >10 years), it is a small triumph in shifting the paradigm for obesity treatment. Note, there is no evidence to support the application of age-based eligibility criteria for metabolic and bariatric surgery in adolescents [59]. Though no lower age limit exists to define the safety or effectiveness of bariatric surgery among children [59], the newer American Academy of Pediatrics guidelines recommend bariatric surgery referral for patients 13 years of age and older [9]. However, it should be noted that there is current and intentional vagueness pertaining to the issue of lower age limit, likely for specific reasons. Younger adolescents or those with lower obesity percentiles might present with severe obesity-related complications leading to a high disease burden, shortened life expectancy and higher cardio-metabolic risk, portending bariatric surgery considerations [59]. "Watchful-waiting" is unlikely to achieve significant and sustained weight reduction [59]. Many medical providers file a letter of medical necessity, or an appeal process, to obtain coverage for the adolescent operation; we could certainly pursue this route in our patient, Jason.

2.7. Nutrition considerations

The patient would benefit from rapid weight loss in the in-patient setting and implementation of a protein-sparing modified fast or a very low-calorie diet in the pediatric inpatient setting, such as the intensive care unit, could be challenging. Current pediatric obesity nutrition recommendations include a short-term goal of interrupting the trajectory of abnormal weight gain and a long-term goal of slow, steady weight loss, while effectively utilizing nutritional strategies, activity modifications, behavioral strategies, and improved sleep hygiene [60]. In a pilot study [61] published in 2019, I. Eneli and colleagues used a revised protein sparing modified fast for children and adolescents with severe obesity. The study was implemented in a pediatric weight management center (N = 21; 76% female; mean weight 119 kg) where patients were given 1200–1800 calories, 40–60 g of carbohydrates per day, 1–1.5 g protein per kg ideal weight. Patients were able to achieve at least −5.3% BMI reduction at 6 months.

To simplify instructions for both patient and caregivers, the following was recommended to the patient [1]: for breakfast and lunch, he could have a 30g protein shake [2]; dinner would consist of lean meat and vegetables [3]; sugar-sweetened beverages were eliminated, and the patient was targeted 1000–1200 calories per day through a low calorie, high protein diet.

Table 1
Summary of final obesity treatment plan and recommendations.

Nutrition Recommendations:
1. In-patient nutrition consultation 2. Start low calorie protein modified fast (Breakfast and Lunch- protein shake, premier protein shake brand has at least 30 g of protein with limitation on carbohydrates; Dinner- lean meat (e.g., fish/chicken and vegetables) 3. Medical Weight Loss dietitian consultation to discuss further (Weight management schedulers will reach out to caregiver to arrange a telemedicine dietitian consultation) 4. Reviewed bariatric nutrition guide for now 5. Recommend outpatient cardiac rehab (virtual) upon discharge
Pharmacotherapy Recommendations:
Pharmacological Directed Therapy (AOM, off label, or dual benefits): Anti-obesity medications (AOM): The patient meets clinical criteria of AOM as per Srivastava, G et al. Obesity 2019 [>95th BMI percentile + comorbidity OR >120th of the 95th BMI percentile] [15]. Contraindications were reviewed and discussed with patient. Allergy list was reviewed. Off-label use was discussed with family and verbal informed consent to treatment was received by both patient and parent (guardian). Extensive education regarding benefits/risks and side effects was provided. Family verbalized understanding. 1. *Start liraglutide 3*.0 mg *as follows:* 0.6 mg SC x 7 days, then 1.2 mg SC x 7 days, 1.8 mg SC x 7 days, 2.4 mg SC x 7 days, and finally 3.0 mg once daily. Of note, though semaglutide has superior efficacy, liraglutide will be covered by insurance as an outpatient therapy. 2. *Consider pramlintide* 15 mcg *pre-meals (breakfast, lunch, dinner)*. This is an off-label indication for severe obesity. Pramlintide has been utilized for severe diabetes; in adult clinical trials, it has shown effectiveness for severe obesity, especially in combination with a GLP1A. However, given severe disability and complications, the benefits far outweigh the risks. The combination of GLP1A plus amylin analogue will decrease fluid retention in cardiac disease while helping with weight loss and severe obesity. The GLP1A has been shown to be cardioprotective. *Discontinue metformin while on pramlintide. Monitor for hypoglycemia symptoms. Hold for pre-meal glucose <80.* 3. *Consider addition of low dosage empagliflozin* 5 mg *once daily for cardio- and renal protection in the setting of prediabetes and heart failure.* Empagliflozin has been shown in clinical trials to confer cardio and renal protection in this cohort of patients. Because of its mechanism of action, there is a diuretic effect. Typically, in adults, empagliflozin 10 mg once daily, to start, is prescribed. However, because both liraglutide 3.0 mg and pramlintide are under considerations, a very low dosage such as empagliflozin 5 mg once daily is recommended. Monitor for hypoglycemia symptoms.
Metabolic and Bariatric Surgery Recommendations:
Currently, the patient also meets criteria for bariatric surgery (BMI ≥35 kg/m^2 [>120th of the 95th BMI percentile] plus presence of at least one obesity-related medical complication or BMI ≥40 kg/m^2 [>140th of the 95th BMI percentile). Risks/benefits of the procedure has been reviewed with the patient. Presently, the overall goal is to attain stabilization and discharge from the hospital when ready. The family understands that this is the primary recommendation in the setting of complex severe obesity and if insurance excludes these benefits, this option must be addressed later, but not to delay surgical treatment as reversion from adolescent obesity to normalization is extremely rare and unlikely. Adolescent obesity most commonly progresses to severe adult obesity requiring later bariatric surgery. In the event the patient is found to be positive for rare genetic obesity, discussions with patient, family members, and my adolescent bariatric surgery colleagues will occur as data is conflicting for bariatric surgery in patients in genetic obesity and further research is required.
Additional Testing & Diagnostic Recommendations:
Genetic Testing for obesity: Counseling was provided for genetic testing. Patient/parent was consented, and buccal swab was sent for analysis.

2.7.1. Nutrition barriers to care

The inpatient dietitians were not familiar with management of patients with obesity. There was also difficulty in obtaining low glycemic shakes in the hospital. However, the weight management dietitian was able to consult with the inpatient dietitian and provided guidance on resolving those hurdles.

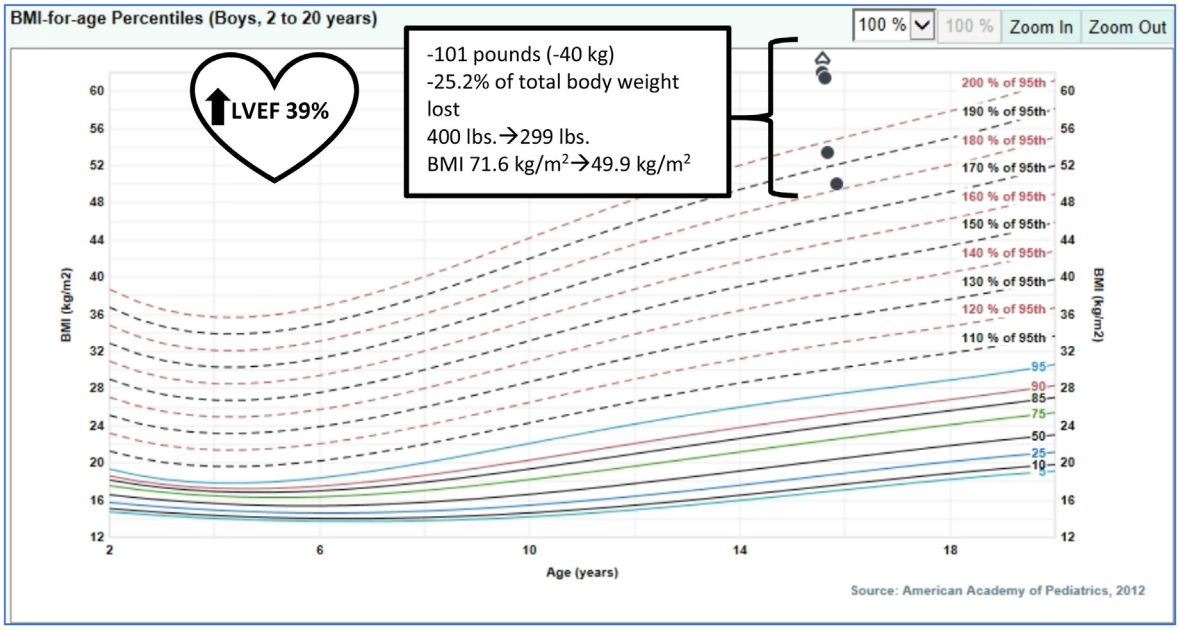

Fig. 1. Extended CDC BMI Growth Chart of patient. The patient lost −101 pounds (−40 kg), −25.2% of his total body weight. His weight decreased from 400 lbs. to 299 lbs. at discharge (BMI change from 71.6 kg/m^2 to 49.9 kg/m^2). The patient's left ventricular ejection fraction (LVEF) improved from 12-17%–39% at discharge.

2.8. Genetic obesity considerations

2.8.1. Results of genetic obesity testing

2.8.1.1. Negative. Genetic testing misses approximately 20% biallelic BBS variants. Severe obesity might have caused idiopathic intracranial hypertension leading to blindness. An ophthalmological examination was recommended to discern rod-cone dystrophy to confirm a clinical diagnosis of BBS.

2.9. Distance considerations

Of note, the patient lives several hours away from the institution. Continuity of care through telemedicine would be quite feasible, effective, and vital [2–4]. In addition, following the COVID-19 pandemic, the institution's rehabilitation center was able to create a virtual medical

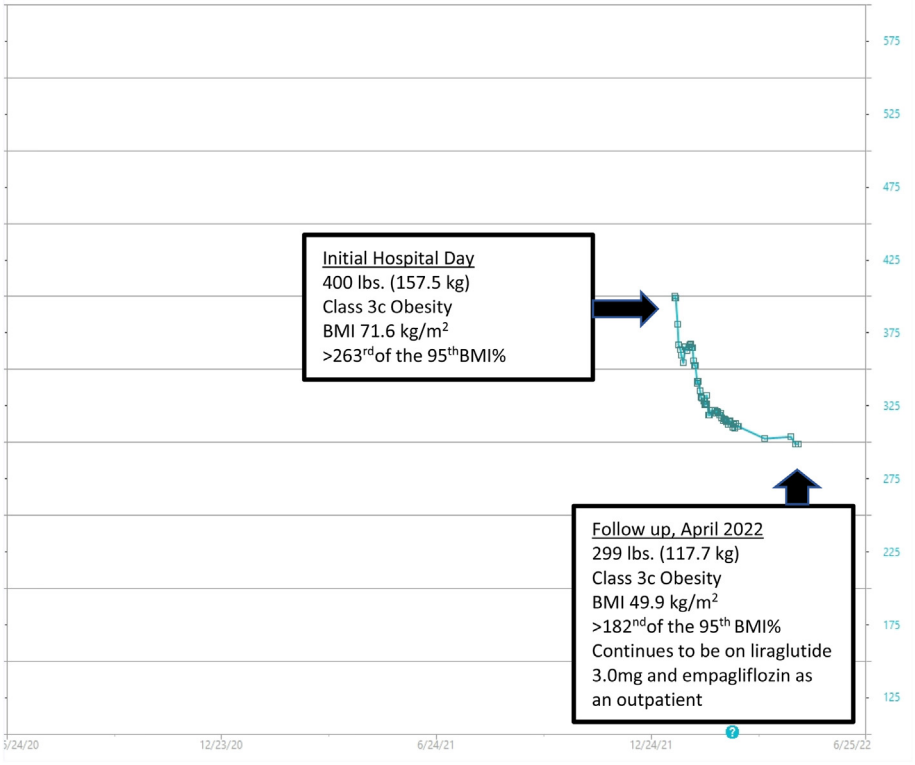

Fig. 2. Weight loss trajectory of the patient from initial hospital day to follow up visit upon discharge. At follow up, after hospital discharge, the patient continues to be on liraglutide 3.0 mg daily and empagliflozin as an outpatient.

fitness and rehabilitation consultation for cardiac patients, a critical referral for Jason to consider.

2.10. Hospital committee inquiries and approvals

2.10.1. Response

Subsequently, as those recommendations were documented into the electronic health record (Table 1), there was an urgent zoom meeting request from senior leadership, directors, and pharmacy team. It was voiced that in the 40-year reign of Children's Hospital, never has there been a request for these medications, nor have they been prescribed by anyone physician except by this physician, and why would these medications require approval. There was no evidence to suggest in-patient prescribing of these medications.

2.10.2. Counter response

As obesity medicine specialists in this burgeoning field, they stride toward many 'firsts.' The reason for the hospital admission was not heart failure, but severe obesity with a complication of heart failure. The two conditions were not 'comorbid.' If obesity is treated, a root cause of the heart failure, the patient will improve. Cardiac data on the clinical trials and how weight reduction can improve cardiac function has been reviewed. This evidence should be sufficient to justify benefits over risks when the alternative is death.

2.10.3. Response

Even if the committee were to approve these medications, they are not available in-patient and they will not be covered by Medicaid. Prescribing of inpatient medications that can be covered by insurance as an outpatient upon discharge is highly recommended and encouraged. And even if do garner approval, the nurses are not trained in these medications.

2.10.4. Counter response

Yes, these medications are available. They are prescribed in adults, and can be obtained from the adult pharmacy. They will be covered by Medicaid, if the prior authorization is designated correctly and indicates that phentermine is contraindicated due to heart failure. Coverage was lobbied for last year. The inpatient team can be connected to the weight management multidisciplinary team, pharmacist, and specialized nursing staff.

2.10.5. Final treatment approvals

Liraglutide 3.0 mg was approved through insurance. Formal teaching was provided to the pediatric in-patient nursing team and patient/caregiver. Empagliflozin was started and approved through insurance based on the evidence provided. Pramlintide was started as an inpatient briefly but later discontinued due to lack of outpatient insurance coverage Metformin was discontinued.

Two weeks later, the patient lost −30 lbs. and was weaned off milrinone infusion and diuretics. He was transferred from the PCICU to the step-down unit and continued to lose weight. He was then ultimately discharged home with follow up at our weight loss center through the telemedicine platform. The patient lost −101 pounds (−40 kg), −25.2% of his total body weight over a period of 4 months. His weight decreased from 400 lbs. to 299 lbs. at discharge (BMI change from 71.6 kg/m^2 to 49.9 kg/m^2). The patient's left ventricular ejection fraction (LVEF) improved from 12-17%–39% following discharge (Figs. 1 and 2).

3. Summary

The application of obesity medicine can lead to a successful, favorable outcome, such as the salvation of life, as was the case in this story. The lessons learned from this case are several; however, the importance of an in-patient obesity consultation should not be underscored. Though rare, an inpatient obesity consultation can provide guidance and creative intervention strategies that could potentially be life-altering. Barriers to obesity treatment are still too many [44]; continued advocacy, engagement, empowerment, and education are needed [62]. This momentum cannot be garnered solely. Team players, predecessors, fellows, trainees, primary care physicians, advance practice providers, sub-specialists, dietitians, pharmacists, behavioral health professionals, scientists, researchers, and industry are needed. Integrated, multidisciplinary comprehensive centers that are disease focused are needed. In the new era of obesity medicine, the focus should be on disease pathophysiology and biology, such that it eradicates the need to state and teach, "It's not your fault [patient developed obesity]."

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Declaration of competing interest

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