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Approach to weight management in patients with advanced chronic kidney disease in a real-life clinical setting

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Abstract

Objective: Excess adiposity represents a risk factor for chronic kidney disease (CKD) and progression to end-stage kidney disease. Anti-Obesity Medications (AOMs) are vastly underutilized in patients with advanced CKD because of concerns related to safety and efficacy. This study was conducted to evaluate the real-world approach to weight management and the efficacy and safety of AOMs in people with advanced CKD.

Methods: This is a retrospective analysis of individuals with Body Mass Index (BMI) $\geq$ 27 kg/m^2 and eGFR $\leq$ 30 mL/min/1.73 m^2 referred to an academic medical weight-management program between 01/2015 and 09/2022. Evaluation of weight-management approaches, body weight change, treatment-related side effects, and reasons for treatment discontinuation were reported.

Results: Eighty-nine patients met inclusion criteria, 16 were treated with intensive lifestyle modifications (ILM) alone and 73 with AOMs (all treated with glucagon-like peptide-1 receptor agonist [GLP1-RA] +/− other AOMs) along with ILM. Patients treated with AOMs had a longer duration of on-treatment follow-up (median 924 days) compared to (93 days) the ILM group. Over 75% of patients treated with AOMs lost $\geq$5% body weight versus 25% of those treated with ILM. Only 15% of patients treated with AOMs discontinued therapy due to treatment-related side effects.

Conclusion: In patients with obesity and advanced CKD, GLP-1RA-based anti-obesity treatment was well-tolerated, effective, and led to durable weight reduction.

KEYWORDS
anti-obesity, kidney, obesity, weight management

1 | INTRODUCTION

There is compelling evidence that excess adiposity is a risk factor for chronic kidney disease (CKD) and progression to end-stage kidney disease (ESKD).[1] Obesity is estimated to be a contributing factor in 20%–25% of kidney disease cases worldwide.[2]

Obesity-related kidney injury is multifactorial. The biochemical and endocrine products of adipose tissue promote underlying pathophysiological processes leading to kidney disease such as inflammation, oxidative stress, endothelial dysfunction, and proteinuria.[3] Also, obesity impairs kidney function via a direct mechanical effect with excess adiposity causing compression of the kidney and renal hilum. Obesity also increases the risk of other metabolic complications like hyperinsulinemia, metabolic syndrome, type 2 diabetes, hypertension, heart disease, all of which are known risk factors for the occurrence and progression of CKD.[4] Independent of any adverse effect on kidney function, the presence of obesity also poses an impediment to optimal care of patients with CKD since it may limit the placement of dialysis access, and the access port is more likely to fail leading to greater expenditure of resources.[5]

Kidney transplant (KT) is the preferred therapeutic option for patients with ESKD as it confers survival benefit compared to dialysis.[6,7] Existing practice guidelines note that there are insufficient data that suggest which, if any patient with obesity should be denied transplant based on their Body Mass Index (BMI).[8] However, patients with obesity have a higher risk of transplant-related complications, leading transplant centers to establish BMI-based restrictions.[9] A survey of KT programs by the American Society of Transplant Surgeons found that among the 67 centers that responded, 66 used BMI as a selection criterion, with a range of 35–45 kg/m^2 as the upper limit to initiate an evaluation.[8] Weight loss is often recommended prior to listing for KT given increased risk of delayed graft function,[10] prolonged hospitalization, acute rejection and decreased graft survival.[11] Furthermore, weight gain after transplantation has been associated with a markedly higher risk of graft loss.[12] As such, there is a great clinical interest in seeking out safe ways to manage weight in patients with CKD; however, a very small proportion of this population receives treatment for obesity.

Given advances in therapies, obesity is a potentially modifiable risk factor.[13] The European Association for the Study of Obesity[14] and the clinical practice guidelines of the American Association of Clinical Endocrinology[15] recommend treatment targets for weight-related complications, overall health and quality of life, but don't specify treatment approaches for patients with advanced CKD.

Kidney Disease: Improving Global Outcome (KDIGO) 2022 practice guidelines recommend the preferential use of glucagon-like peptide-1 receptor agonist (GLP-1RA) in individuals with a history of diabetes, obesity and CKD to promote weight loss and optimize cardiovascular risk prior to transplant listing.[16] Despite increase number of approved anti-obesity medications (AOMs) (phentermine, phentermine-topiramate, orlistat, bupropion-naltrexone, liraglutide[17] and semaglutide [18]), all are underutilized in this population due to concerns related to their effectiveness and tolerability. Furthermore, all prospective studies evaluating pharmacologic treatments of obesity excluded patients with advanced CKD and those treated with dialysis.

Bariatric surgery has emerged as an important tool for weight loss management as well as treating obesity related co-morbidities[19] but the surgical risks are higher in patients with CKD. Turgeon et al demonstrated that CKD stage predicts higher complication (deep incisional surgical site infections, pneumonia, deep venous thrombosis) rates following bariatric surgery, a higher rate that persisted after adjustment for diabetes and hypertension.[20]

People with CKD have a very high risk of cardiovascular events.[21] The SELECT study, which enrolled people with pre-existent cardiovascular disease and overweight or obesity but not diabetes, showed that semaglutide 2.4 mg resulted in a 20% reduction in major cardiovascular events.[22] Although few patients in this study had advanced CKD, the subgroup analysis showed that those with eGFR <30 mL/m^2/min observed similar cardiovascular benefits as the overall group.

Treatment of obesity in people with advanced CKD might confer a multitude of benefits, including cardiovascular protection, reduction in complications related to vascular access and infections, as well as better control of the associated metabolic comorbidities. However, there is great hesitation in treating obesity in this population, more so than in the general population, due to perception of frailty and fear of side effects. No prospective studies to date evaluated systematically any weight loss intervention in a population with advanced CKD.

This study was conducted to evaluate the real-life approach to weight management and clinical experience with AOMs in patients with advanced CKD referred to a weight-management program.

2 | METHODS

A retrospective chart review of patients with advanced CKD who were evaluated at the University of Texas Southwestern Medical Center Weight Wellness program between January 1, 2015 and September 30, 2022 was performed. Eligible patients were identified using a data query that searched the Electronic Medical Records (EMR) for the following criteria: first visit encounter (index visit) followed by at least one additional visit in the clinic, preexisting history of advanced CKD defined as eGFR ≤30 mL/min/1.73 m^2 within 6 months of index visit, and BMI ≥27 kg/m^2 at index visit. The EMR of each patient was manually reviewed to confirm eligibility and data were manually extracted.

Collection of demographic data and obesity-related comorbidities from the index visit was performed using ICD-10 codes active in the problem list or visit diagnosis (Table S1). The follow-up period was defined as starting at index visit and ending at the last documented use of AOMs or last clinic visit (for those not treated with AOMs) or censored at the time of data extraction (October 30, 2022) if still actively treated or if underwent bariatric surgery during the follow-up period. AOM was defined as the use of the following

medications prescribed by the program by indication or off label use: topiramate, bupropion, phentermine, lorcaserin, lisdexamfetamine, naltrexone, phendimetrazine, liraglutide, dulaglutide, semaglutide and tirzepatide. Body weight, AOM details, all documented treatment-related adverse events and reasons for treatment discontinuation were extracted from each clinic encounter. Percent body weight change calculated based on the difference in weight at index visit and at 3, 6, 9, 12, 24, 36, 48, 60 months post-index visit was reported.

Data are expressed as mean and standard deviation for continuous variables and count and percentage for categorical variables. Groups were compared using the χ^2 test of independence for categorical variables and t-test and analysis of variance for continuous variables. No adjustment for multiplicity was made. A p value < 0.05 was considered significant.

The study protocol was approved by the University of Texas Southwestern Medical Center Institutional Reviewed Board.

3 | RESULTS

Eighty-nine patients met inclusion criteria, of which 16 were treated with intensive lifestyle modifications (ILM) consisting of a calorie deficit diet, activity as tolerated and behavioral counseling. Seventy-three patients were treated with AOMs along with ILM, all of them having been treated with GLP-1RA+/− other AOMs. Of note, 2/16 patients in the ILM group received AOMs (lorcaserin and topiramate, respectively) for <6 weeks; given short duration of treatment, those patients were analyzed in the ILM group.

In the overall cohort, 57% were female, 61% were receiving dialysis treatment, 25% were on the renal transplant list, and 11.2% had a history of bariatric surgery prior to the index visit. Patients treated with AOMs were older, more likely to have a history of diabetes or hypertension and had a higher BMI and eGFR compared with those treated with ILM (Table 1).

The median (IQR) duration of follow-up was longer in the AOM group compared with the ILM group (924 [1406] days versus 93 [169.5] days, respectively). At 3 months of follow-up, those treated with ILM experienced a $-0.8 \pm 11.6\%$ body weight change compared to $-4.7 \pm 4.7\%$ in those treated with AOMs ($p = 0.05$). Few patients in the ILM group had data beyond the 3-month timepoint, hence no between group statistical analyses were performed for later timepoints. The change in weight in the AOM group was $-5.0 \pm 6.1\%$ at 6 months, $-6.5 \pm 7.3\%$ at 9 months, $-6.4 \pm 7.8\%$ at 12 months, $-7.7 \pm 10.8\%$ at 24 months, $-9.4 \pm 13.8\%$ at 36 months, $-9.4 \pm 13.8\%$ at 48 months and $-7.2 \pm 14.6\%$ at 60 months (Table 2).

The proportion of patients achieving ≥5% weight loss at any time during follow-up was 25% in the ILM group versus 75% in the AOM group; 25% achieved ≥10% weight loss in the ILM group versus 52.1% in the AOM group (Figure 1).

In the AOM group, concomitant or sequential use of >1 AOM agent was present in 20.5% and 79.5% of patients, respectively (Table S2). Of note, most of the sequential cases were transitions to agents within the same class (GLP-1RA). Seventy-nine percent were treated with one AOM class (GLP-1RA), 12.3% with two, 6.8% with three and 1.4% with four classes during the follow-up period (Table S2).

In the AOM group, 60.3% discontinued medications over the median of 2.5 years of follow-up. The most common reason for treatment discontinuation was loss to follow-up (32.9%), followed by gastrointestinal side effects (9.6%), lack of insurance coverage (5.8%), and pancreatitis (4.1%). No treatment related side effects were reported in the ILM group (Table S3).

Of those treated with GLP-1RA, 20.5% reached the maximum dose licensed for obesity, 46.6% the maximum dose licensed for diabetes, and 32.9% were on lower doses (Table S4). Patients who were on sub-maximum doses, compared to those who were at least on maximum dose approved for diabetes and obesity, had similar eGFR (14.2 ± 8.7 vs. 19.33 ± 8.86 vs. 14.5 ± 8.7 mL/min/1.73 m^2; $p = 0.15$). The most common reason for not titrating GLP-1RA to the maximum dose was gastrointestinal side effects (37.5%), followed by loss to follow-up (20.8%), insurance coverage (8.3%), and other reasons (pancreatitis, acute illness, goal weight achieved on lower dose, 4.1% each). Of note, 13% of patients not on the maximum dose were still in the titration period at the end of the study (Table S5).

After index visit, bariatric surgery referrals were made in 19.1% of patients in the AOM group and 12.5% of patients in the ILM groups. Sixty-eight percent of bariatric surgery referrals were placed by the Weight Wellness Clinic, 12.5% by primary care, 12.5% by nephrology and 6.5% by self-referral. In the AOM group 6.8% of patients underwent bariatric surgery versus 0% in the ILM group after index visit.

4 | DISCUSSION

This real-world data suggests that AOMs, predominantly GLP-1RA-based therapies, are effective for weight loss in patients with advanced CKD, as >75% of patients achieved at least 5% body weight loss (BWL), and over half achieved at least 10% BWL. We have also shown that AOMs and GLP-1RAs in particular are well tolerated by this patient population, with discontinuations due to side effects being similar to those expected in people without CKD.

Although BMI is an independent predictor for ESKD, the rate of obesity among people with CKD is increasing, and there is significant added morbidity conferred by the presence of obesity in the setting of CKD, there is little published data regarding the efficacy and safety of AOMs in people with advanced CKD. The emergence of safe and highly effective AOMs offers important new opportunities to treat obesity, but the lack of published data on their efficacy and safety in this population may impede clinicians from starting medications.[4] This study supports the recommendations from KDIGO 2022 regarding the preferential use of GLP-1RA in individuals with a history of diabetes, obesity and CKD to promote weight loss and optimize cardiovascular risk prior to transplant listing.[16] Furthermore,

TABLE 1 Patient characteristics at index visit at the Weight Wellness clinic.

	Intensive lifestyle modification N = 16	AOM therapy N = 73
Age (years) (mean ± SD)	47.5 ± 14.4	52.1 ± 14.1
Gender		
Female	11 (68.7)	40 (54.8)
Male	5 (31.2)	33 (45.3)
Ethnicity/race		
White	9 (56.1)	26 (35.6)
Black or African American	4 (25)	32 (43.8)
Asian	1 (6.3)	0
Hispanic or Latino	1 (6.3)	11 (15.1)
Unknown or unavailable	1 (6.3)	4 (5.5)
Weight (kg) (mean ± SD)	114.1 ± 24.3	120.3 ± 21.6
BMI (kg/m^2) (mean ± SD)	39.3 ± 7.2	41.9 ± 6.5
BMI Class		
Overweight	2 (12.5)	1 (1.4)
Class I	1 (6.2)	4 (5.5)
Class II	5 (31.3)	27 (37)
Class III	8 (50)	41 (56.2)
H/o Bariatric surgery	2 (14.3)	13 (17.8)
Dialysis	12 (75)	39 (53.4)
Hemodialysis	8 (5)	32 (43.8)
Peritoneal dialysis	4 (25)	7 (9.6)
H/o kidney transplant	3 (18.7)	18 (24.7)
Listed for kidney transplant	3 (18.7)	11 (15.1)
eGFR (mL/min/1.73 m^2) (mean ± SD)	14.6 ± 8.9	18.7 ± 11.2
Co-morbidities		
Diabetes	5 (31.3)	56 (76.7)
Prediabetes	2 (12.5)	7 (9.6)
Hypertension	14 (87.5)	67 (91.7)
Hyperlipidemia	10 (62.5)	59 (80.8)
CAD/PVD	1 (6.2)	16 (21.9)
Depression	1 (6.2)	11 (15.1)
Obstructive sleep apnea	6 (37.5)	44 (60.3)
GERD	8 (50)	18 (24.7)
Eating disorder	0	3 (4.1)
CKD stage		
CKD stage 4	4 (25)	28 (38.4)
CKD stage 5	0	6 (8.2)
ESKD	12 (75)	39 (53.4)

Note: Data are *N* (%) unless otherwise noted.

Abbreviations: BMI, body mass index; CAD/PVD, coronary artery disease/peripheral vascular disease; CKD, chronic kidney disease; ESKD, end stage kidney disease; GERD, gastroesophageal reflux disease; GLP-1RA, glucagon like peptide 1 receptor agonist; h/o, history of; SD, standard deviation.

this study also informs regarding the use of AOM in people without diabetes and advanced CKD.

The AOM group included several GLP-1RA currently approved for weight management, thus reflecting the real-life use of these agents for the treatment of weight loss in people with advanced CKD. The choice of AOM was determined on a case-by-case basis that took into consideration several factors, including efficacy, convenience, tolerability, insurance coverage, and out-of-pocket cost. It is notable that all patients in the AOM group were treated with a GLP-1RA, indicating their perceived efficacy and safety in this population. A greater proportion of people in the AOM group had a history of type 2 diabetes, suggesting that GLP-1RA was more likely to be covered by insurance in the setting of co-existent type 2 diabetes.

People with obesity are more likely to experience gallstones and pancreatitis, which should be taken into consideration when monitoring for potential side effects. Chuqing et al. collected data from seven large-scale cardiovascular outcome trials with a total of 56,004 patients with type 2 diabetes, a total of 180 cases of acute pancreatitis and 108 cases of pancreatic cancer, which did not represent a statistically significant association with GLP-1 RA when compared to placebo arm.[23]

Given the increasing number of people with advanced CKD and obesity, studies are needed to identify effective therapies and fully assess their specific risk-benefit ratio in this population. Such studies will inform evidence-based guidelines for the management of obesity in patients with CKD. There are several reasons why GLP-1-RA pharmacotherapy might be preferred in this population, which include not only weight loss and glycemic control but also cardiovascular event reduction and fewer contraindications compared to other AOM.[24]

There are several limitations of this study, mostly related to its retrospective design. Groups were not assigned randomly and selection bias between groups is likely. However, this report is the largest to date describing the use, tolerability, and weight loss outcomes of AOMs in patients with advanced CKD. Although the follow-up in the ILM group was short, the long follow-up period in the AOM group (median >2.5 years) suggests that AOMs are well tolerated in

TABLE 2 Percentage body weight loss in patients with advanced CKD by treatment group.

	Intensive lifestyle modification *N* = 16[a]	AOM therapy *N* = 73
3 months	9 (56.3)	62 (84.9)
Weight loss, mean ± SD (kg)	−0.6 ± 11.3	−5.52 ± 6.0
% BWL, mean ± SD (%)	−0.8 ± 11.6	−4.7 ± 4.7
Weight loss >5%	2 (22.2)	26 (41.9)
Weight loss >10%	0 (0)	7 (21.8)
6 months	4 (25)	48 (65.8)
Weight loss, mean ± SD (kg)	−4.3 ± 5.2	−6.2 ± 7.5
% BWL, mean ± SD (%)	−4.2 ± 5.9	−5.0 ± 6.1
Weight loss >5%	2 (50)	26 (54.2)
Weight loss >10%	1 (25)	11 (22.9)
9 months	3 (18.8)	48 (65.8)
Weight loss, mean ± SD (kg)	−6.1 ± 2.6	−8.2 ± 9.1
% BWL, mean ± SD (%)	−5.9 ± 3.0	−6.5 ± 7.3
Weight loss >5%	2 (66.6)	29 (60.4)
Weight loss >10%	1 (33.3)	12 (25)
12 months	NA	53 (72.6)
Weight loss, mean ± SD (kg)	NA	−8.1 ± 9.6
% BWL, mean ± SD (%)	NA	−6.4 ± 7.8
Weight loss >5%	NA	30 (56.6)
Weight loss >10%	NA	16 (30.2)
24 months	NA	41 (56.2)
Weight loss, mean ± SD (kg)	NA	−9.2 ± 12.8
% BWL, mean ± SD (%)	NA	−7.7 ± 10.8
Weight loss >5%	NA	25 (60.9)
Weight loss >10%	NA	18 (43.9)
36 months	NA	36 (49.3)
Weight loss, mean ± SD (kg)	NA	−11.3 ± 16.5
% BWL mean ± SD (%)	NA	−9.4 ± 13.8
Weight loss >5%	NA	21 (58.3)
Weight loss >10%	NA	15 (41.6)
48 months	NA	27 (36.9)
Weight loss, mean ± SD (kg)	NA	−14.9 ± 12.3
% BWL mean ± SD (%)	NA	−9.4 ± 13.8
Weight loss >5%	NA	17 (62.9)
Weight loss >10%	NA	13 (48.1)
60 months	NA	14 (19.2)
Weight loss, mean ± SD (kg)	NA	−9.2 ± 17.6
% BWL, mean ± SD (%)	NA	−7.2 ± 14.6
Weight loss >5%	NA	7 (50)
Weight loss >10%	NA	7 (50)

Note: Data are *N* (%) unless otherwise noted.

Abbreviations: AOM, anti-obesity medication; BWL, body weight loss; GLP-1RA, glucagon like peptide 1 receptor agonist; kg, kilograms; N, number of patients with available data at each timepoint; NA, not applicable as only one or 2 patients had data at these timepoints; SD, standard deviation.

[a]Two patients were treated for <6 weeks with non-GLP-1RA AOM.

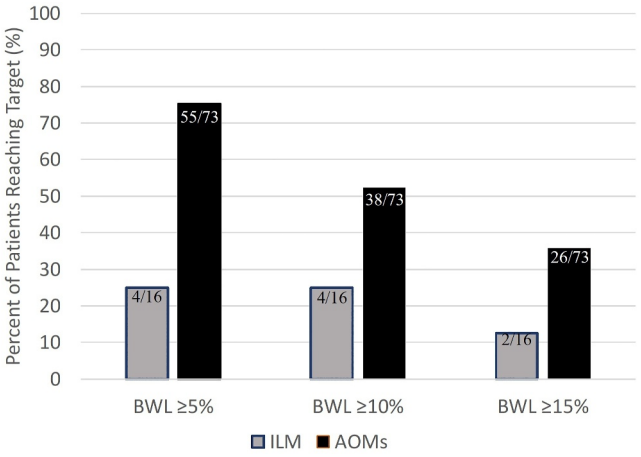

FIGURE 1 Percentage of patients achieving ≥5%, 10%, and 15% body weight loss at any time during follow-up by intervention group. AOM, anti-obesity medications; BWL, body weight loss; ILM, intensive lifestyle modification.

this population, while those managed with ILM likely became discouraged and stopped following up. The efficacy of individual agents or doses in the AOM group was not assessed; however, only 20.5% concomitantly used GLP-1RA and other AOM classes, suggesting that weight loss was largely due to GLP-1RA treatment. Real-world management of obesity in patients with advanced CKD often requires sequential and/or concomitant therapy and our goal was to assess the efficacy and safety of these strategies in this population. Lastly, the researchers did not have access to the dialysis visit documentation and therefore may have missed some side effects that were noted during dialysis and not reported in the medical record. However, the researchers had access to all admissions and other medical visits besides the dialysis visits and are confident that all serious and relevant complications were collected.

5 | CONCLUSION

Most patients with advanced CKD referred to an academic weight wellness program were treated with AOMs, specifically GLP-1RAs, which were effective in inducing clinically meaningful weight loss in patients with advanced CKD. The rate of AOMs discontinuation due to treatment-related side effects was low despite a long follow-up period. However, prospective randomized controlled clinical trials are necessary to definitively assess the safety and efficacy of AOMs, including long-term cardiorenal endpoints, in patients with advanced CKD.

AUTHOR CONTRIBUTIONS

All authors contributed to the study conception, study design, data analyses, and interpretation of the data. Paola Lockhart Pastor, Ildiko Lingvay and Jaime P. Almandoz reviewed and edited the manuscript. Paola Lockhart Pastor prepared the first draft of the manuscript.

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CONFLICT OF INTEREST STATEMENT

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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