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ORIGINAL RESEARCH

Poor Access to Anti-Obesity Medications in Metabolic Dysfunction-Associated Steatotic Liver Disease

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BACKGROUND

Weight loss is a cornerstone of therapy for metabolic dysfunction-associated steatotic liver disease (MASLD). Incretin medications (IM) including glucagon-like peptide 1 receptor agonists (GLP-1) and combination glucose-dependent insulinotropic polypeptide/GLP-1 RAs have been approved by the Food and Drug Administration (FDA) for weight management. Access to these medications can be difficult due to insurance approvals, cost, and availability of drugs.

METHODS

A 10-month, single center retrospective chart review was conducted for patients referred to a clinical pharmacist practitioner (CPP) at an academic medical center in North Carolina for review of pharmacological weight loss options as part of a multidisciplinary MASLD team.

RESULTS

Forty-two patients with MASLD were referred for medical weight loss therapy. Initial IM approval was granted for 11 patients (26%). After prior authorization (PA), appeal, or failure of an alternative medication, 22 patients (52%) started IM. A total of 132 minutes of CPP time was required to achieve a single IM start.

LIMITATIONS

The sample size of 42 patients may be too small to make statistically significant comparisons and detect differences among groups. Additionally, all patients were seen by a CPP at an academic medical center (AMC), which may not be applicable to the general population.

CONCLUSIONS

Incretin therapies are a beneficial option for patients with MASLD complicated by obesity and diabetes, but access needs to be improved and time burden on providers and clinical staff should be recognized.

Introduction

Metabolic dysfunction-associated steatotic liver disease (MASLD) affects almost one third of adults worldwide.[1] While rates of disease are high and continue to rise, treatment has largely been limited to weight loss until the recent approval of resmetirom, a thyroid hormone receptor beta agonist approved for the treatment of metabolic associated steatohepatitis (MASH).[2] Incretin medications (IM) are medications that mimic natural incretin hormones and include glucagon-like peptide 1 receptor agonists (GLP-1 RA) and combination glucose-dependent insulinotropic polypeptide/GLP-1 RAs. They are approved by the Food and Drug Administration (FDA) for diabetes and weight management, and demand for IMs is high.

While these medications had not yet been explicitly approved for MASLD treatment at the time of this study, they have been suggested to decrease liver fat content, reverse chronic liver inflammation, and reduce the risk of disease progression for cirrhosis and hepatocellular carcinoma (HCC).[3-5] Semaglutide has since been FDA-approved for treatment of MASH based on the ESSENCE trial.[6] However, despite their efficacy, obtaining these medications can be time- and labor-intensive for both patient and provider.

Access to and provision of IM for obese and diabetic patients is increasingly difficult, especially for patients who are racially and socioeconomically disadvantaged and have not yet been examined in the MASLD population.[7, 8] Therefore, this study aimed to determine accessibility to IM and the time spent by health care providers to access IM for the treatment of obesity in patients with MASLD with and without diabetes.

Methods

A 10-month, single center retrospective chart review was conducted for patients between March and December 2023. This was a pilot study with a convenience sample of consecutive patients. Criteria for inclusion were all patients referred to a clinical pharmacist practitioner (CPP) by a hepatologist for review of pharmacological weight loss options as part of a multidisciplinary MASLD team. Referred patients had to have already trialed lifestyle weight loss efforts. Retrospective chart review was approved for this study by the site's institutional review board. Patient demographics and clinical characteristics were reported with descriptive statistics.

The fibrosis stage of the included patients was measured by vibration-controlled transient elastography. Fibrosis was defined as F0 (no fibrosis), F1 (mild fibrosis), F2 (moderate fibrosis), F3 (severe fibrosis), and F4 (cirrhosis). Approval or denial for IM use was collected and compared across insurance payers (commercial, Medicare, Medicaid, uninsured) and fibrosis stages. Access to care was determined by patients receiving an IM and taking at least one dose. Interactions with insurance payers were quantified with an estimate

of CPP time spent per interaction. CPP time was estimated retrospectively based on several factors, including time spent on writing appeals, following up with insurance companies for approval updates, contacting patients to follow up on necessary paperwork, and following up with manufacturers for patient assistance programs. Total time per patient and per initiation of IM were calculated. Comparisons of time spent were also compared by insurance provider.

Study Location

This study was conducted at an academic medical center in North Carolina.

Statistical Methods

A chi-square test was used to detect a difference between insurance payor and approval rates, while an Analysis of Variance (ANOVA) test was used in the analysis of CPP interactions between payers.

Results

A total of 42 patients with MASLD were referred to the CPP for medical weight loss therapy. Among those patients, 22 (52.4%) were male, and 20 patients were female (47.6%). Payor types included 28 patients with commercial plans (67%), 10 patients with Medicare (24%), 2 patients with Medicaid (5%), and 2 uninsured patients (5%). The distribution of fibrosis stage included 15 patients with F0–F1 (36%), 5 patients with F2 (12%), 6 patients with F3 (14%), and 16 patients with F4 (38%) (Table 1). Forty patients (95%) had a Body Mass Index (BMI) greater than 30, and 13 patients (31%) had diabetes.

Weight loss medications were excluded from insurance plans for 17 patients (41%). Initial approval for IM was granted for 11 patients (26%), while final approval after prior authorization (PA), appeal, or failure of an alternative medication (e.g., metformin) was achieved in 27 patients (64.2%). After insurance approval, 22 patients (52%) received and started IM after a mean 30.1-day delay (range: 1–136; median: 15 days; interquartile range [IQR]: 22). Among the 13 patients with diabetes, 4 patients (31%) were initially approved for IM, while 11 patients (85%) received final approval after prior authorization (PA) and/or appeal. Overall, there were no differences in initiating IM by insurance type ($P = .44$), or fibrosis score ($P = .61$) (Table 2).

The CPP had an average of 7.8 interactions with commercial payors, 7.9 interactions with Medicare, 6 interactions with Medicaid, and 10.5 interactions with uninsured patients ($P = .77$). Mean time spent per interaction was 8.8 minutes. Total CPP time spent was 48.25 hours. Seventy minutes were spent for successful initiation of IM, compared to 68 minutes spent with payors/patients who ultimately did not start IM. Overall, 132 minutes of CPP time were required to achieve a single IM start (Table 3).

Table 1. Selected Patient Demographics

–	Number (%)
Age, mean	53.4
Sex	–
Male	22 (52.4%)
Female	20 (47.6%)
Race	–
White	33 (78.6%)
Black or African American	3 (7.1%)
Latino	2 (4.7%)
Other	4 (9.5%)
Insurance type	–
Commercial	28 (66.7%)
Medicare	10 (23.8%)
Medicaid	2 (4.7%)
Uninsured	2 (4.7%)
Fibrosis	–
F0-F1	15 (35.7%)
F2	5 (11.9%)
F3	6 (14.3%)
F4	16 (38.1%)

Discussion

Principal Findings

In an academic multidisciplinary MASLD clinic with a dedicated CPP, only 52% of patients were able to start IM. Although a previous study showed that Medicare Advantage patients have lower rates of IM use compared to commercially-insured patients, neither payor status nor fibrosis stage was associated with starting IM in this population.[9] Many insurers excluded IM or required PA, which added to staff time, effort, and delays in starting therapy. Even after insurance approval, some patients were unable to start treatment due to unaffordable copays and medication shortages. This supports other research suggesting that higher out-of-pocket costs for SGLT2 or GLP-1 RAs are associated with a lower likelihood of starting the drug.[10]

This study also found that 48.25 total hours were required to prescribe IM for 42 patients, only 22 of whom actually started IM. An average of 132 minutes of CPP time was required for a single IM start. Time burden for the 2 uninsured patients was even higher, with an average of 460 minutes required for IM start. Excessive time spent accessing medications puts significant burden on CPPs and other providers and prolongs time that patients go without treatment. While the sample size is small, time burden for uninsured patients is even higher than an already high average, emphasizing the increased difficulties uninsured patients face in medication access. This increased time burden was in large part due to building an

Table 2. Access and Initiation of Incretin Medications (IM) by Insurance Provider and Fibrosis Status

Payors	Initial Approval	Final Approval	Started IM[a]
Commercial n = 28	4 (14.3%)	16 (57.1%)	13 (46.4%)
Medicare n = 10	6 (60%)	8 (80%)	6 (60%)
Medicaid n = 2	0 (0%)	2 (100%)	2 (100%)
Uninsured n = 2	1 (50%)	1 (50%)	1 (50%)
Total N = 42	11 (26.2%)	27 (64.2%)	22 (52.4%); **P = .44**
–			
Fibrosis	–	–	–
F0–1 n = 15	0	8 (53.3%)	7 (46.7%)
F2 n = 5	2 (40%)	4 (80%)	3 (60%)
F3 n = 6	0	2 (33.3%)	2 (33.3%)
F4 n = 16	9 (56.3%)	13 (81.3%)	10 (62.5%)
Total N = 42	11 (26.2%)	27 (64.2%)	22 (52.4%); **P = .61**
–			
T2DM n = 13	4 (30.8%)	11 (84.6%)	9 (69.2%)

Table Note. [a] IM = incretin medications including glucagon-like peptide 1 receptor agonists (GLP-1) and combination glucose-dependent insulinotropic polypeptide/GLP-1 RAs.

Table 3. Total Patient Encounters and Time Spent Per Patient

Payors	Encounters/ patient	Time (min) spent/ patient	# of patients started on IM[a]	Time (min)/single IM start
Commercial n = 28	7.8	58	13 (46.4%)	125
Medicare n = 10	7.9	71	6 (60%)	118
Medicaid n = 2	6	48	2 (100%)	48
Uninsured n = 2	10.5	230	1 (50%)	460
Total N = 42	7.9	69	22 (52.4%)	132

Table Note. [a] IM = incretin medications including glucagon-like peptide 1 receptor agonists (GLP-1) and combination glucose-dependent insulinotropic polypeptide/GLP-1 RAs.

application for manufacturer patient assistance programs, which included gathering supporting documents, following up with manufacturers after application submission, and ensuring the patient received their medication from the pharmacy. This illustrates that while these programs can improve access to medications in certain populations, they are often time-consuming and require a knowledge base that many patients with disadvantaged backgrounds lack.

Further, this study only examined data for patients at an academic medical center (AMC) with a dedicated CPP. Research has shown that only about 23% of overall patients use clinical pharmacy services, and that rural patients are 35% less likely than urban patients to receive those services.[11] Access to IM will be even more difficult for patients seen in non-academic or rural settings, as access to a CPP may be limited or not available at all. For those patients, both initial and final approval rates would be expected to be lower, and time burden for receiving medication approval would likely fall on non-pharmacist providers, as well as clinic administrative staff. Without IM, patients may be at higher risk for MASLD disease progression and have an increased risk of cirrhosis, HCC, and decompensation events.[12]

Patients with MASLD and with diabetes as a comorbid condition were more likely to be approved for IM (84.6% versus 64.2% in patients without diabetes). This is consistent with a nationwide survey showing that more patients with diabetes take GLP-1s (43%) than those who are merely overweight or obese (22%); the proportion of patients taking IM for diabetes versus weight loss increases with age, reflecting Medicare's lack of coverage for prescription drugs for weight loss purposes.[13] This suggests that for patients with diabetes as a comorbid condition, IM access is easier across all insurance lines, especially in Medicare patients due to coverage restrictions.

Study Limitations

This study had some limitations. Data were collected from a small group (N = 42) at one center over 10 months. The sample size may therefore be too small to make statistically significant comparisons and detect differences among groups, such as across race or other demographic factors. Future studies should focus on a broader population across different medical centers for increased generalizability. Additionally, all patients were seen by a CPP at an AMC, which may not be applicable to the general population.

Conclusion

In summary, incretin therapies are a beneficial option for patients with MASLD complicated by obesity and/or diabetes, but access needs to be improved and time burden on clinical staff should be recognized. NC Medicaid's coverage of anti-obesity medications has fluctuated over the past several years, with coverage being recently reinstated as of December 2025, while one of the major state commercial insurances has discontinued coverage. This will result in changes in approval rates for both Medicaid and commercial patients in upcoming years. For our limited sample size of Medicaid patients (n = 2), approval was already 100%, while commercial patients' final approval rate was 57.1% (n = 28). Continued issues with access will occur as insurance formularies change, indicating that health care

providers must collaborate to improve access to these medications. Overall, since MASLD rates remain high, more research needs to be done to understand barriers to medication access and how to resolve them.

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Disclosure of interests

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