RESEARCH PAPER

Prevalence of Nonalcoholic Fatty Liver Disease in Type 2 Diabetes Patients and Evaluation of Adverse Drugs Reactions: An Observational Ambispective Study

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ABSTRACT

Background: To assess the prevalence of nonalcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes (T2D) and evaluate adverse drug reactions (ADR) associated with medications used to treat T2D and NAFLD.

Materials & Methods: A 2-year, observational ambispective study was conducted on 1500 patients with T2D. 621 T2D patients with NAFLD as comorbidity were evaluated and data on demographic characteristics, comorbidities, medications, and ADR were collected. The data was analysed descriptively using Microsoft Excel 365 software.

Results: In 1500 T2D patients, the prevalence of NAFLD is 41.4% (621) with higher in female (54.9%) than in males (45.1%). Prevalence of NAFLD was higher in 51-60 years age group (37.8%) and obese patients (62.0%). T2D patients with NAFLD have higher rate of ADR (34.8%) compared to without NAFLD (25.4%). ADR occurrence was higher in females (37.5%), obese (36.1%) and patients with two or more additional comorbidities (38.7%). Most prescribed class is biguanide followed by dipeptidyl peptidase-4 inhibitors, sulfonylureas, thiazolidinedione. 31 types of ADRs (368 incidents) were reported in 216 out of 621 T2D patients with NAFLD. Gastrointestinal disturbances, weakness, headache, tiredness, and hypoglycemic events were the most common ADRs. According to WHO-Uppsala Monitoring Centre (WHO-UMC) causality categories, ADRs were categorized as "Possible".

Conclusions: This study demonstrates higher prevalence of NAFLD in T2D patients particularly in females, older age groups and individuals with obesity. Although ADRs were mild to moderate in nature, treatment strategies will benefit from multicentre studies establishing comprehensive ADR database for T2D patients with NAFLD.

Keywords: ADR, Adverse drugs reaction, NAFLD, Nonalcoholic fatty liver disease, T2D, Type 2 diabetes

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INTRODUCTION

Nonalcoholic fatty liver disease (NAFLD) is an important contributor of chronic liver disease both worldwide and in India.[1] NAFLD is a condition that is becoming more acknowledged and can advance to severe liver disease. Its pathological characteristics are like those of liver damage caused by alcohol, but it develops in individuals who do not abuse alcohol.[2,3] Unhealthy lifestyle, obesity, and uncontrolled diabetes are the major contributor to the development of NAFLD. [4] The widespread availability of calorie-rich foods and a lack of physical activity, combined with the modern epidemics of type 2 diabetes (T2D) and obesity, have elevated NAFLD to a substantial public health issue in India, similar to trends seen globally.[5]

The occurrence of NAFLD is often underreported since many patients do not show symptoms. Globally, the prevalence of NAFLD among T2D ranges from 34 - 94%.[6] The increasing prevalence of NAFLD is leading to a rise in non-communicable diseases (NCDs), including conditions like diabetes, cancer, cardiovascular disease and obesity.[7] T2D plays a significant role in both the occurrence and intensity of NAFLD. The increasing prevalence of obesity and T2D across the globe coincides with a surge in the worldwide incidence of NAFLD.[8]

In India, various classes of drugs for treating T2D include Biguanides, Dipeptidyl Peptidase-4 Inhibitors (DPP4i), Sulfonylureas (SU), Sodium Glucose Co-Transporter 2 Inhibitors (SGLT2i), Alpha-Glucosidase Inhibitors (αGI), Thiazolidinediones (TZD), Insulin, Non-Sulfonylurea Secretagogues, and GLP-1 Receptor Agonists (GLP1RA).[9] Saroglitazar, in peroxisome proliferator-activated receptor (PPAR) agonist class, is the only drug that has been approved by Drugs Control General of India (DCGI) for non- cirrhotic NASH and NAFLD with comorbidities.[10] Medications approved for diabetes or dyslipidaemia are often used in NAFLD patients. The increasing necessity for pharmacological treatments in the global epidemic of NAFLD, along with emerging data showing their effectiveness, has led to guidance from Indian National Association for the Study of the Liver (INASL), European Association for the Study of the Liver (EASL) and American Association for the Study of Liver Diseases (AASLD) recommending the use of currently available medications for the management of NAFLD in clinical settings. [11,12]

Drugs remain the common intervention for attaining glycemic control; however, these drugs may lead to adverse effects that may also affect mental and social well-being.[13] Adverse drug reactions (ADR) is defined as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function”.[14] In developing nations, the expenses related to ADR among the general populace is high and often overlooked. It is essential to assess the safety of drugs using specialized approaches such as Pharmacovigilance. [15]

Getting more information on prevalence of NAFLD in T2D patients, impact of various demographic factors, comorbidities and evaluation of ADR will be beneficial to healthcare professionals & patients. A comprehensive literature search revealed a dearth of studies specifically investigating the ADR in T2D patients with NAFLD as a comorbidity. This paucity of research highlights knowledge gap in understanding the unique pharmacological challenges faced by this patient population. Hence, this study has been planned to provide valuable insights into the clinical management of these two interconnected diseases, leading to improved patient outcomes and reducing overall healthcare burden.

Materials and Methods

Study Site: The study was conducted on outpatients of Rudraksha Hospital in Bareja and Rudraksha Institute of Medical Sciences (RIMS) in Ghodasar located in Ahmedabad.

Study Design: An Ambispective observational study was carried out on 1500 T2D patients for prevalence of NAFLD & evaluation of ADR.

Study Population: T2D patients on anti-diabetic medications and who have been identified for having NAFLD as comorbidity.

Study Duration: The study was conducted over a duration of two years. (March 2022 to Feb 2024).

Inclusion Criteria: T2D patients aged 18 years or above of both genders with or without NAFLD who are using antidiabetic medications.

Exclusion Criteria: Pregnant women, patients with associated malignant condition, acute communicable disease and aged below 18 years. Patients with malignant conditions, acute communicable diseases, aged below 18 years and pregnant women.

Ethical Considerations: The study was initiated after obtaining approval from the Institutional Ethics Committee (IEC). Patients were informed about the study procedures and were asked to sign Informed Consent Forms (ICFs) before their enrolment in the study. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Study Procedure: Details such as age, gender, BMI, weight, height, diagnosis, duration of disease, prescribed medicines and comorbidities were documented. Patients with NAFLD as one of the comorbidities have been evaluated further and ADR were recorded.

Statistical Analysis: Collected data has been descriptively summarised using Microsoft Excel 365 software.

Results

Total 1500 patients with T2D on anti-diabetic drugs were enrolled in the study, out of which 621(41.4%) were reported of having NAFLD as comorbidity. Out of 1500 T2D patients, 439(29.3%) experienced at least one ADR. In 621 patients who had NAFLD as comorbidity, 216(34.8%) experienced at least one ADR. In 879 T2D patients without NAFLD as comorbidity, 223(25.4%) experienced at least one ADR (Figure 1).

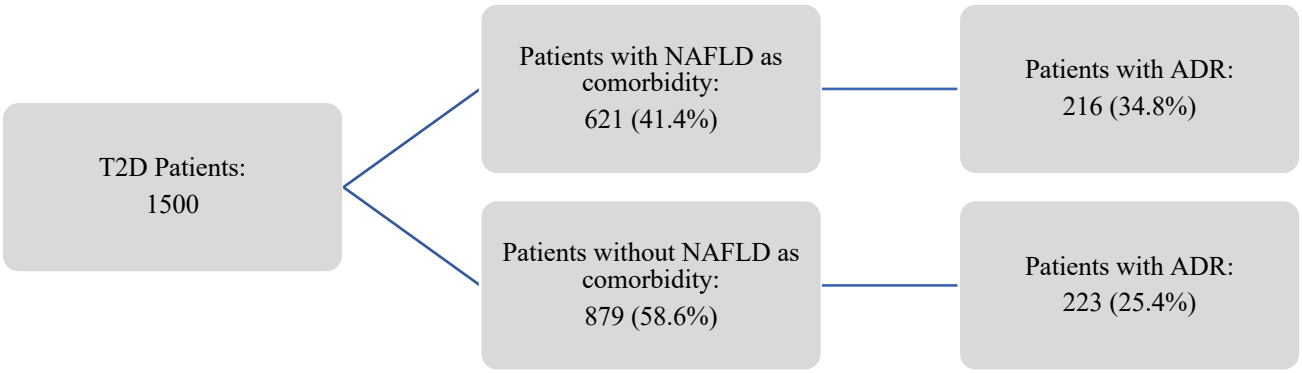

Figure 1: Prevalence of nonalcoholic fatty liver disease (NAFLD) in T2D (type 2 diabetes) patients and distribution of adverse drug reactions (ADR)

In 621 T2D patients with NAFLD as comorbidity, 341(54.9%) were female and 280(45.1%) were male. ADR occurrence in female T2D patients having NAFLD as comorbidity was 37.5%, and in male, it was 31.4%. Patients' average age was 52.4 ranging from 18 to 81 years. Percentage of T2D Patients with NAFLD as comorbidity in 51-60 years age group is 37.8%(235), in 41-50, 26.6%(165), in 61-70, 17.6%(109), in 31-40, 11.9%(74), in above 70, 4%(25), and in 18-30, 2.1%(13). ADR occurrence noted as 36.6%(51 - 60), 33.3%(41 - 50), 26.6%(61 - 70), 33.8%(31 - 40), 44.0% (above 70), 76.9%(18 - 30) in patients of different age groups (Table 1).

Table 1: Demographic Distribution of T2D Patients with NAFLD as Comorbidity and Distribution of ADR

Groups	No. of Patients (N=621)	Percentage of Patients	No. of Patients with ADR	Percentage of ADR occurrence in Subgroup
		Sex distribution		
Female	**341**	**54.9%**	**128**	**37.5%**
Male	**280**	**45.1%**	**88**	**31.4%**
		Age distribution		
18-30	**13**	**2.1%**	**10**	**76.9%**
31-40	**74**	**11.9%**	**25**	**33.8%**
41-50	**165**	**26.6%**	**55**	**33.3%**
51-60	**235**	**37.8%**	**86**	**36.6%**
61-70	**109**	**17.6%**	**29**	**26.6%**
Above 70	**25**	**4.0%**	**11**	**44.0%**

BMI distribution (kg/m^2)				
Underweight: < 18.5	**-**	**-**	**-**	**-**
Normal: 18.5–24.9	**6**	**1.0%**	**3**	**50.0%**
Overweight: 25–29.9	**230**	**37.0%**	**74**	**32.2%**
Obese: > 30	**385**	**62.0%**	**139**	**36.1%**
Comorbidities distribution				
T2DM + NAFLD	**192**	**30.9%**	**69**	**35.9%**
T2DM + NAFLD + 01	**274**	**44.1%**	**87**	**31.8%**
T2DM + NAFLD + 02 & more	**155**	**25.0%**	**60**	**38.7%**

ADR = adverse drug reaction; T2D = type 2 diabetes; BMI = body mass index; NAFLD = nonalcoholic fatty liver

In 621 T2D patients with NAFLD as comorbidity, average BMI was recorded at 32.1 kg/m^2 spanning from 20.6 to 55.7 kg/m^2. According to classification of obesity as per WHO, in 621 patients, 385(62.0%) were from category obese, 230(37.0%) from overweight and 6(1.0%) from normal BMI categories. No patient was reported from underweight category. ADR occurrence noted as 36.1% (obese) followed by 32.2% (overweight) in patients across different BMI categories (Table 1).

Out of 621, 274(44.1%) were reported of having one more & 155(25.0%) were reported having two or more comorbidities apart form T2D & NAFLD. Remaining 192(30.9%) patients were reported of having only T2D and NAFLD. ADR occurrence was observed as 38.7% (two or more comorbidities), 35.9% (No comorbidity - only T2D and NAFLD) and 31.8% (one more comorbidity) (Table 1).

Total 10 drugs classes were prescribed to 621 patients, Biguanide in 613(98.7%), DPP4i in 481(77.5%), SU in 445(71.7%),TZD in 445(71.7%), SGLT2i in 343(55.2%), αGI in 295(47.5%), Insulin in 107(17.2%), PPAR agonist in 41(6.6%), GLP1RA in 33(5.3%), and Meglitinides in 6(1.0%). ADR occurrence noted as 34.9%(Biguanide), 34.7% (DPP4i), 35.5%(SU), 37.1%(TZD), 35.9%(SGLT2i), 37.3%(αGI), 43.9% (Insulin), 43.9% (PPAR agonist) 24.2%(GLP1RA) and 33.3%(Meglitinides) (Table 2).

Table 02: Prescribed Class & Drugs vs. No. of Patients with ADR

Class / Drugs	No. of Patients (N=621)	Percentage No. of Patients	No. of Patients with ADR	Percentage of Patients with ADR (n = 216)	Percentage of ADR in given specific drug
Biguanide	**613**	**98.7%**	**214**	**99.1%**	**34.9%**
Metformin	**613**	**98.7%**	**214**	**99.1%**	**34.9%**
DPP-4i	**481**	**77.5%**	**167**	**77.3%**	**34.7%**

Sitagliptin	**295**	**47.5%**	**104**	**48.1%**	**35.3%**
Vildagliptin	**122**	**19.6%**	**41**	**19.0%**	**33.6%**
Teneligliptin	**45**	**7.2%**	**17**	**7.9%**	**37.8%**
Linagliptin	**15**	**2.4%**	**4**	**1.9%**	**26.7%**
Evogliptin	**4**	**0.6%**	**1**	**0.5%**	**25.0%**
SU	**445**	**71.7%**	**158**	**73.1%**	**35.5%**
Glimepiride	**404**	**65.1%**	**142**	**65.7%**	**35.1%**
Gliclazide	**35**	**5.6%**	**13**	**6.0%**	**37.1%**
Glipizide	**6**	**1.0%**	**3**	**1.4%**	**50.0%**
TZD	**445**	**71.7%**	**165**	**76.4%**	**37.1%**
Pioglitazone	**445**	**71.7%**	**165**	**76.4%**	**37.1%**
SGLT2i	**343**	**55.2%**	**123**	**56.9%**	**35.9%**
Dapagliflozin	**291**	**46.9%**	**99**	**45.8%**	**34.0%**
Empagliflozin	**46**	**7.4%**	**20**	**9.3%**	**43.5%**
Remogliflozin Etabonate	**5**	**0.8%**	**3**	**1.4%**	**60.0%**
Canagliflozin	**1**	**0.2%**	**1**	**0.5%**	**100.0%**
αGI	**295**	**47.5%**	**110**	**50.9%**	**37.3%**
Voglibose	**259**	**41.7%**	**95**	**44.0%**	**36.7%**
Acarbose	**36**	**5.8%**	**15**	**6.9%**	**41.7%**
Insulin	**107**	**17.2%**	**47**	**21.8%**	**43.9%**
Insulin Glargine	**45**	**7.2%**	**25**	**11.6%**	**55.6%**
Insulin Degludec	**32**	**5.2%**	**10**	**4.6%**	**31.3%**
Insulin Aspart	**30**	**4.8%**	**12**	**5.6%**	**40.0%**
PPAR agonist	**41**	**6.6%**	**18**	**8.3%**	**43.9%**
Saroglitazar	**41**	**6.6%**	**18**	**8.3%**	**43.9%**
GLP-1RA	**33**	**5.3%**	**8**	**3.7%**	**24.2%**
Semaglutide	**29**	**4.7%**	**8**	**3.7%**	**27.6%**
Liraglutide	**4**	**0.6%**	**0**	**-**	**-**
Meglitinides	**6**	**1.0%**	**2**	**0.9%**	**33.3%**
Repaglinide	**6**	**1.0%**	**2**	**0.9%**	**33.3%**

ADR = adverse drug reaction; DPP4i = Dipeptidyl Peptidase-4 Inhibitors; SU = Sulfonylureas, TZD = Thiazolidinedione, SGLT2i = Sodium Glucose Co-transport 2 Inhibitors, αGI = Alpha-glucosidase inhibitors, PPAR agonist = peroxisome proliferator-activated receptor agonist; GLP1RA = GLP-1 receptor agonists

Total 368 incidents corresponding to 31 natures of ADRs were observed in 216 out of 621 T2D patients with NAFLD as comorbidity. The most frequently reported ADR included gastrointestinal disturbances (86), followed by weakness (46), headache (31), tiredness (29), hypoglycemic events (26), sleep disturbances (22), burning and painful urination (21), restlessness and uneasiness (12), decreased appetite (10), pedal edema (9), body aches (8), back pain (8), etc. (Table 3).

Table 3: Nature of ADRs vs. no. of patients of T2DM with NAFLD as comorbidity

Nature of ADR	No. of Patients (N=216)	Percentage of Patients with ADR
Gastrointestinal disturbances Constipation (20), Flatulence (06), Diarrhea (15), Nausea (10), Abdominal pain (11), Hyperacidity (17), Vomiting (4), Bloating (3)	86	39.8%
Weakness	46	21.3%
Headache	31	14.4%
Tiredness	29	13.4%
Hypoglycemic events	26	12.0%
Sleep disturbance	22	10.2%
Burning & painful urination	21	9.7%

Restlessness & uneasiness	12	5.6%
Decreased appetite	10	4.6%
Pedal edema	9	4.2%
Bodyache	8	3.7%
Back pain	8	3.7%
Increased appetite	7	3.2%
Itching	6	2.8%
Cough	5	2.3%
Joint pain	5	2.3%
Weight gain	4	1.9%
Blurred vision	4	1.9%
Throat pain	4	1.9%
Urinary incontinence	4	1.9%
Itching at vaginal region	4	1.9%
Dizziness	3	1.4%
Eructation	3	1.4%
Itching & redness over penile foreskin	2	0.9%
Breathlessness	2	0.9%
Swelling on face	2	0.9%
Chest pain	1	0.5%
Chills	1	0.5%
Excess thirst	1	0.5%
Rash	1	0.5%
Muscle pain	1	0.5%
Total ADR incidents	368	-

ADR = adverse drug reaction

Total 25 medications from 10 classes were given to T2D patients with NAFLD as comorbidity. Metformin was associated with highest ADR events, totalling 360, followed by Pioglitazone with 274 events, Glimepiride with 241, Sitagliptin with 175, and Voglibose with 164 (Figure 2).

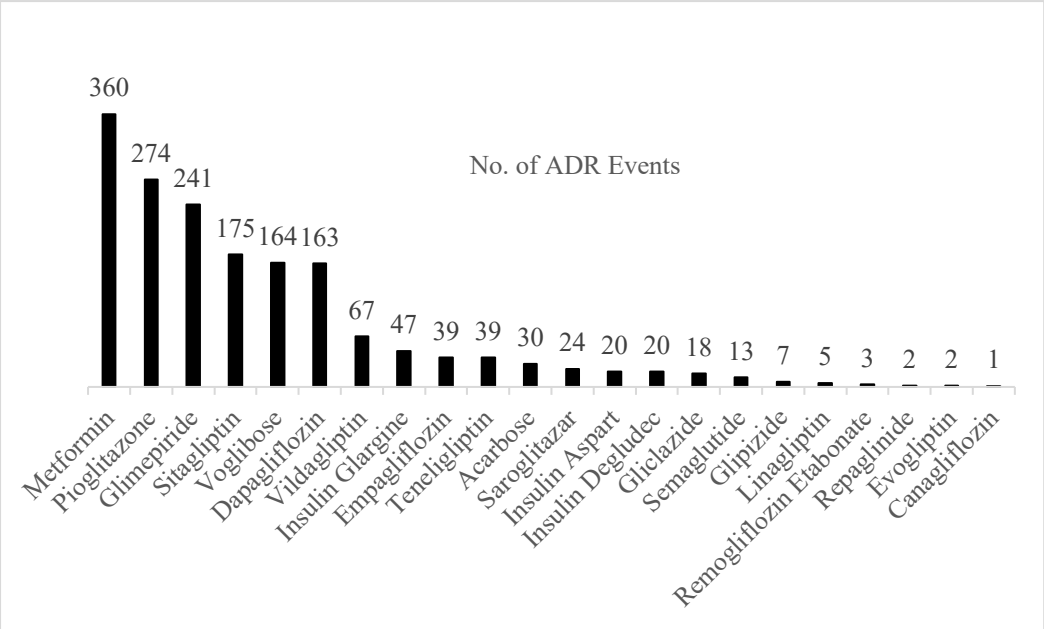

Figure 2: Name of the drugs vs. ADR events in patients with NAFLD as comorbidity

All ADRs were classified as "Possible" according to causality categories of WHO UMC because all patients were taking multiple medications. There was no ADR categorized as "Probable" or "Certain." None of the reported

ADRs were severe enough to necessitate hospitalization. The ADRs were mild (78.5%) or moderate (21.5%).

Discussion

In the study, we reported 41.4% prevalence of NAFLD in T2D patients. Previous studies reported the prevalence of NAFLD in diabetes ranging from 21% to 78%. [5,6,16-18] The results indicate higher rate of ADR (34.8%) in T2D patients with NAFLD compared to T2D patients without NAFLD (25.4%). Further research is necessary to validate findings and to explore the underlying mechanisms.

In this study, the prevalence of NAFLD in T2D patients is higher in female (54.9%) than in males (45.1%). Few studies conducted in India shows that NAFLD is more common in female T2D patients compared to male. [16,18] ADR occurrence was higher in females (37.5%) compared to male (31.4%) T2D patients with NAFLD. Several studies conducted in India have indicated a higher prevalence of adverse effects among female patients with diabetes. [19-20]

The present study demonstrates a clear age-related trend in the prevalence of NAFLD in T2D patients. Notably, the higher prevalence of NAFLD was observed in 51-60 years group (37.8%). This finding aligns with previous studies suggesting the prevalence was significantly higher among people aged 50 years and older than among those younger than 50 years.[21] The study indicates higher ADRs observed in patients of 51-60 years (86), 41-50 years (55), and 61-70 years old (29). Other study in Karnataka found that most ADRs were reported in patients aged 40-80 who were taking antidiabetic medications.[22]

In this study, we reported higher prevalence of NAFLD in obese T2D patients (62.0%) than in overweight patients (37.0%). A study carried out in Chennai revealed that individuals with a higher BMI faced a significantly increased risk, 23.09 times greater, of developing NAFLD. [23] A review article suggests that the rate of NAFLD is 4.6 times higher in individuals who are obese. [6] As per few studies, T2D significantly increases both the risk and the severity of NAFLD. [24,25] Obese patients (139) have observed more ADR followed by overweight (74). A comprehensive review of observational studies showed a moderate link between obesity and T2D. [26]

This study found that patients with T2D and NAFLD who had two or more additional comorbidities (38.7%) had the higher rate of ADR occurrences. The data indicates that a diverse array of medications was prescribed, with Biguanides being the most frequently used at 98.7%. This is followed by DPP4i (77.5%), SU (71.7%), TZD (71.7%), SGLT2i (55.2%), αGI (47.5%), Insulin (17.2%), PPAR agonist 41(6.6%), GLP1RA (5.3%), and Meglitinides (1.0%). Most prescribed drug is metformin which is in line with previous studies.[27-28] Metformin is the primary treatment option for patients with T2D unless they have difficulties tolerating it or have contraindications. [29]

This study identified a diverse range of ADRs in patients with T2D and NAFLD. GI disturbances, weakness, headache, tiredness, and hypoglycemic events were the most common ADRs reported. A study conducted in New Delhi indicated that the majority of ADRs were associated with the GI and endocrine system. [30]

As the patients were on multiple drugs, "Possible" classification suggests that there could be a justified connection between the ADR and the drug, but definitive causality cannot be confirmed. The findings of this study show that patients encountered mild to moderate ADRs.

The study's findings have important public health implications, especially concerning the growing burden of NAFLD in T2D patients and its association with increased ADR. This highlights the urgent need for early screening, prevention, and management strategies to reduce disease progression and associated complications.

Study limitations: The research was carried out at just two hospitals, which may restrict the generalization of the findings. To better investigate the intricate connection between NAFLD and ADRs in T2D patients, larger multicentre trials with a greater sample size are required.

Conclusion

The results of the study have noteworthy clinical implications for management of T2D patients with NAFLD. This study highlights higher prevalence of NAFLD in T2D patients, particularly in females and older age groups, as well as in individuals with obesity and multiple comorbidities. The findings underscore a close connection between NAFLD and increased risk of ADR in patients with T2DM. The study identified several common ADRs, including GI disturbances, weakness, headache, tiredness and hypoglycemia. These findings emphasize the need for careful patient monitoring, especially in T2D patients with NAFLD.

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Conflict of interest

There are no conflicts of interest

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