Asian Journal of Case Reports in Medicine and Health

Volume 7, Issue 1, Page 93-97, 2024; Article no.AJCRMH.119423

Saroglitazar Reduced Liver Fat and Fibrosis in Metabolic Dysfunction Associated Steatotic Liver Disease: A Case Report

Rajesh R. Kulkarni [a++*]

[a] *Raghavendra Clinic, Darbar galli, Belagavi – 590 001, Karnataka, India.*

Author's contribution

The sole author designed, analysed, interpreted and prepared the manuscript.

Article Information

Open Peer Review History:
This journal follows the Advanced Open Peer Review policy. Identity of the Reviewers, Editor(s) and additional Reviewers, peer review comments, different versions of the manuscript, comments of the editors, etc are available here: https://www.sdiarticle5.com/review-history/119423

Case Report

Received: 02/05/2024
Accepted: 05/07/2024
Published: 09/07/2024

ABSTRACT

Metabolic Dysfunction Associated Steatotic Liver Disease (MASLD) is revised nomenclature of Non-alcoholic fatty liver disease (NAFLD) which is very commonly prevalent condition in India. Currently only one drug Saroglitazar is approved for treatment of NAFLD in India. It is a dual peroxisome proliferator-activated receptor (PPAR α/γ) agonist which improves insulin sensitivity and reduce triglyceride along with liver fat and fibrosis in NAFLD cases. In this case study, MASLD patient was prescribed Saroglitazar 4 mg once daily along with existing anti-diabetic and lipid lowering therapy and at 24 weeks; Saroglitazar had shown significant improvement in glycemic, lipid and transient elastography parameters.

[++] *Consultant Physician and Diabetologist;*
**Corresponding author: E-mail: rajesh2kulkarni@gmail.com;*

Cite as: *Kulkarni, Rajesh R. 2024. "Saroglitazar Reduced Liver Fat and Fibrosis in Metabolic Dysfunction Associated Steatotic Liver Disease: A Case Report". Asian Journal of Case Reports in Medicine and Health 7 (1):93-97. https://journalajcrmh.com/index.php/AJCRMH/article/view/193.*

Keywords: Liver fat; liver fibrosis; fatty liver disease; metabolic dysfunction.

1. INTRODUCTION

Non-alcoholic fatty liver disease (NAFLD) is commonly prevalent condition globally with 38.2% prevalence in India [1]. Recently NALFD has been renamed as Metabolic dysfunction associated Steatotic liver disease (MASLD). MASLD defines any patient having steatotic liver disease (SLD) along with any one of the cardiometabolic risk factor of type 2 diabetes (T2DM)/ Pre-diabetes, Obesity, Hypertension, Elevated triglyceride (TG), Low high density lipoprotein cholesterol (HDLc) [2-6]. Type 2 Diabetes Mellitus (T2DM) is one of the most commonly associated co-morbid condition with SLD [7]. Currently in India, Saroglitazar, a dual peroxisome proliferator-activated receptor (PPAR) agonist, is only approved molecule by Drug Controller General of India (DCGI) for NAFLD and pre-cirrhotic NASH; which has shown promising results in managing elevated triglyceride in patients with T2DM and non-alcoholic fatty liver disease with co-morbidities. In biopsy driven study, Saroglitazar has shown beneficial improvement in liver fibrosis and fat [8]. This case study aims to evaluate the effects of Saroglitazar on glycemic control, lipid parameters, and liver fibrosis in T2DM patients diagnosed with SLD.

2. CASE PRESENTATION

A 65-year-old Indian male, weighing 105 Kg with BMI of 34 kg/m^2 was diagnosed with T2DM five years ago. Patient was on oral anti-diabetic medications (Metformin, Sitagliptin and Dapagliflozin Fixed dose combination), Rosuvastatin (20 mg). His glycemic control remained suboptimal (HbA1c: 8.5%) along with abnormal lipid level (total cholesterol: 220 mg/dL, triglycerides: 250 mg/dL, LDL cholesterol: 140 mg/dL, HDL cholesterol: 40 mg/dL) and an elevated liver enzyme profile. Vibration controlled transient elastography (VCTE) by Fibroscan™ examination indicated a mild liver fibrosis with liver stiffness measurement (LSM) score 7.9 kPa and severe steatosis with controlled attenuation parameter (CAP) score of 330 db/m. (Table 1). Patient was prescribed Saroglitazar (4 mg/day) as an adjunct to his existing anti-diabetic medications. Glycemic parameters (fasting blood glucose and HbA1c), lipid parameters (total cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol), and VCTE parameters (CAP & LSM using FibroScan™) were assessed at baseline, 6 weeks, and 24 weeks after Saroglitazar initiation.

3. RESULTS

At 6 Weeks: After 6 weeks of Saroglitazar therapy, patient showed significant improvements in glycemic control (HbA1c: 7.2%) and lipid parameters (total cholesterol: 190 mg/dL, triglycerides: 150 mg/dL, LDL cholesterol: 100 mg/dL, HDL cholesterol: 40 mg/dL). Additionally, the Fibroscan™ indicated a reduction in liver stiffness from baseline 7.9 kPa to 6.8 kPa suggesting early signs of improvement in liver fibrosis (F0-F1) and not much difference in Fatty liver. Additionally, patient also lost weight of 6 kgs.

24 Weeks: At 24 weeks, there was further improvement in glycemic control (HbA1c: 6.8%) and lipid parameters (total cholesterol: 170 mg/dL, triglycerides: 130 mg/dL, LDL cholesterol: 90 mg/dL, HDL cholesterol: 45 mg/dL). The FibroScan™ showed a significant decrease in liver stiffness, indicating substantial improvement in liver fibrosis (F0) as well as greater reduction in Fatty liver (Grade I from Grade III) along with significant weight loss from 99 to 91 kgs. (Table 1 & Fig. 1)

Table 1. Effect of Saroglitazar on various parameters at baseline, after 6 weeks and 24 weeks

	Weight (kg)	BMI (kg/m^2)	FBS (mg/dl)	HbA1c (%)	TC (mg/dl)	TG (mg/dl)	LDL (mg/dl)	HDL (mg/dl)
Baseline Parameters	105	34	284	8.5	220	250	140	40
After 6 weeks of treatment	99	31	150	7.2	190	150	100	45
After 24 weeks of treatment	91	29	104	6.8	170	130	90	45

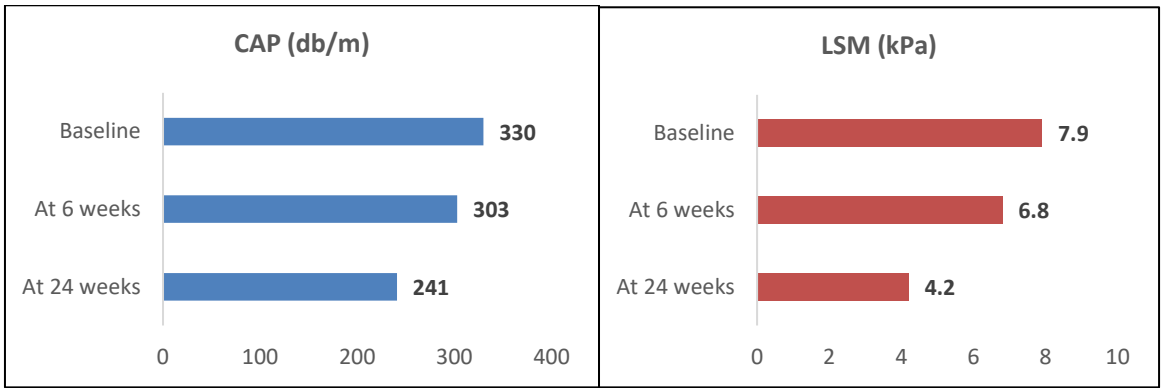

Fig. 1. Effect of Saroglitazar on CAP and LSM score at baseline, after 6 weeks and 24 weeks

4. DISCUSSION

This case study demonstrates the efficacy of Saroglitazar in improving glycemic control and lipid parameters in an Indian patient with T2DM. The notable reduction in liver stiffness suggests a potential role for Saroglitazar in managing liver fibrosis associated with T2DM and dyslipidemia [9]. The dual PPAR agonist activity of Saroglitazar likely contributes to these comprehensive improvements. In various clinical studies, saroglitazar has shown reduction in TG up to 60% from baseline with ALT reduction T2DM patients [10]. In Fibroscan™ driven study, Saroglitazar has shown improvement in LSM score by 23% - 25% at end of 12 month of therapy [11]. Saroglitazar being only approved medication for NAFLD by Drug Controller General of India (DCGI) in India, has been recommended for minimum 12 months for treatment of NAFLD and pre-cirrhotic NASH. Currently many medications are used for NAFLD treatment like; Ursodeoxycholic Acid (UDCA), Vitamin E, Obeticholic Acid, Pioglitazone, Sodium-glucose cotransporter-2 (SGLT2) inhibitors, glucagon-like peptide 1 (GLP-1) agonists; but they have limited clinical evidence to prove efficacy in NAFLD management and considered as OFF-LABEL medication for treatment of NAFLD [12]. Recently, Resmetirom was approved for use in conjunction with diet and exercise for the treatment of adults with noncirrhotic NASH with moderate to advanced liver fibrosis in the USA [13]. In this case study, patient was on anti-diabetic medications and also reduced weight in significant manner, which certainly had contributed in reduction of glycemic, liver fibrosis and fat parameters [14]. So far, Saroglitazar has not shown significant improvement in lipid parameters other than TG. In this case study, reduction of LDLc and TC may be due to statin therapy and impact of weight reduction.

5. CONCLUSION

Saroglitazar proves to be effective in enhancing glycemic control, normalizing lipid parameters, and ameliorating liver fibrosis in Indian patients with T2DM. These findings underscore its potential as a valuable therapeutic option for individuals with T2DM, particularly those with concomitant dyslipidemia and steatotic liver disease involvement.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of manuscripts.

CONSENT

As per international standards or university standards, patient(s) written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that they have no known competing financial interests OR non-financial interests OR personal relationships that could have appeared to influence the work reported in this paper.

REFERENCES

1. Shalimar, Elhence A, Bansal B, Gupta H, Anand A, Singh TP, Goel A. Prevalence of non-alcoholic fatty liver disease in India: A Systematic Review and Meta-analysis. J Clin Exp Hepatol. 2022, May-Jun;12(3): 818-829.
2. Rinella ME, Lazarus JV, Ratziu V, Francque SM, Sanyal AJ, Kanwal F, Romero D, Abdelmalek MF, Anstee QM, Arab JP, Arrese M, Bataller R, Beuers U, Boursier J, Bugianesi E, Byrne CD, Castro Narro GE, Chowdhury A, Cortez-Pinto H, Cryer DR, Cusi K, El-Kassas M, Klein S, Eskridge W, Fan J, Gawrieh S, Guy CD, Harrison SA, Kim SU, Koot BG, Korenjak M, Kowdley KV, Lacaille F, Loomba R, Mitchell-Thain R, Morgan TR, Powell EE, Roden M, Romero-Gómez M, Silva M, Singh SP, Sookoian SC, Spearman CW, Tiniakos D, Valenti L, Vos MB, Wong VW, Xanthakos S, Yilmaz Y, Younossi Z, Hobbs A, Villota-Rivas M, Newsome PN; NAFLD Nomenclature consensus group. A multisociety Delphi consensus statement on new fatty liver disease nomenclature. J Hepatol. 2023, Dec;79(6): 1542-1556.
3. Alanazi BM. Updates in the epidemiology of fatty liver and its consequences in Saudi Arabia: A review. Journal of Pharmaceutical Research International. 2022;34(46B):39–46.
   DOI: 10.9734/jpri/2022/v34i46B36387.
4. Chopra RK, Mahavir Modi, Sneha Tirpude, Kaumudi Devi, Vishnu Gireesh, Abhijeet Lonsane, Aditya Pandya, Vaibhav Wankhede, Suyash Gandhe. Study to identify the prevalence and predictive factors of post COVID lung fibrosis in COVID-19. Journal of Advances in Medicine and Medical Research. 2022; 34(19):125-34.
   Available:https://doi.org/10.9734/jammr/2022/v34i1931446.
5. Burke A, Lucey MR. Non-alcoholic fatty liver disease, non-alcoholic steatohepatitis and orthotopic liver transplantation. American Journal of Transplantation. 2004;4(5):686-693.
6. Rocha ALL, Faria LC, Guimarães TCM, Moreira GV, Cândido AL, Couto CA, Reis FM. Non-alcoholic fatty liver disease in women with polycystic ovary syndrome: systematic review and meta-analysis. Journal of Endocrinological Investigation. 2017;40:1279-1288.
7. Dharmalingam M, Yamasandhi PG. Nonalcoholic Fatty Liver Disease and Type 2 Diabetes Mellitus. Indian J Endocrinol Metab. 2018, May-Jun;22(3): 421-428.
8. Roy A, Tewari B, Giri S, Goenka M. Saroglitazar in non-alcoholic fatty liver disease from bench to bedside: A Comprehensive review and sub-group meta-analysis. Cureus. 2023, Oct 22;15(10):e47493.
9. Goyal O, Nohria S, Goyal P, Kaur J, Sharma S, Sood A, Chhina RS. Saroglitazar in patients with non-alcoholic fatty liver disease and diabetic dyslipidemia: A prospective, observational, real world study. Sci Rep. 2020, Dec 3;10(1):21117.
10. Kaul U, Parmar D, Manjunath K, Shah M, Parmar K, Patil KP, Jaiswal A. New dual peroxisome proliferator activated receptor agonist-Saroglitazar in diabetic dyslipidemia and non-alcoholic fatty liver disease: integrated analysis of the real world evidence. Cardiovasc Diabetol. 2019, Jun 17;18(1):80.
11. Chaudhuri S, Dutta A, Chakraborty SBD. Efficacy and safety of saroglitazar in real-world patients of non-alcoholic fatty liver disease with or without diabetes including compensated cirrhosis: A tertiary care center experience. JGH Open. 2023, Feb 20;7(3): 215-220.
12. Duseja A, Singh SP, De A, Madan K, Rao PN, Shukla A, Choudhuri G, Saigal S, Shalimar, Arora A, Anand AC, Das A, Kumar A, Eapen CE, Devadas K, Shenoy KT, Panigrahi M, Wadhawan M, Rathi M, Kumar M, Choudhary NS, Saraf N, Nath P, Kar S, Alam S, Shah S, Nijhawan S, Acharya SK, Aggarwal V, Saraswat VA, Chawla YK. Indian National Association for Study of the Liver (INASL) Guidance Paper on Nomenclature, Diagnosis and Treatment of Nonalcoholic Fatty Liver Disease (NAFLD). J Clin Exp Hepatol. 2023, Mar-Apr;13(2):273-302.
13. Keam SJ. Resmetirom: First Approval. Drugs. 2024, Jun;84(6):729-735.
    DOI:10.1007/s40265-024-02045-0. Epub 2024 May 21.
14. Huang X, Ouyang W, Hu Y, Tang B, He Y, Wu H, Yang P, Yin L, Liu Q, Chen K, Deng

J, Li X, Li Y. The effects of weight loss and improved metabolic health status on the risk of non-alcoholic fatty liver disease—results from a prospective cohort in China. Front. Nutr. 2023;10:1239996.
DOI: 10.3389/fnut.2023.1239996

Peer-review history:
The peer review history for this paper can be accessed here:
https://www.sdiarticle5.com/review-history/119423