



A clinical study to assess the effect of Homoeopathic mother tincture *Chelidonium majus* in cases of Non Alcoholic Fatty Liver Disease with Dyslipidemia

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Abstract

Introduction: Unneeded fat is retained in the liver in the condition known as NAFLD. An excessive quantity of fat in the liver that is unrelated to alcohol consumption is referred to as NAFLD. NAFLD is characterised histologically by a wide range of liver damage, including simple steatosis, nonalcoholic steatohepatitis, and liver cirrhosis linked to nonalcoholic steatohepatitis. The pathogenic characteristics of non-alcoholic steatohepatitis (NASH) are hepatocellular damage and consequent inflammation in the liver tissue. In 15 to 20% of NASH patients, fibrosis, cirrhosis, or possibly cancer will develop. Lipid buildup in the hepatocyte is the pathological defining feature of NAFLD, indicating a direct association between faulty lipid metabolism and NAFLD. Indeed, abnormal lipid metabolism due to other diseases can also lead to NAFLD. According to population-based abdominal imaging studies, at least 25% of American people have fatty livers. The total frequency of NAFLD in the general population in India is nearly 40%.

Methods: Total 30 patients meeting the inclusion and exclusion criteria were enrolled willingly. It was a time-bound study with enrollment done from October 2022 to April 2023. Each case was followed up for approximately 6 months with 5 follow-ups scheduled with a gap of 30 days approximately.

Result: It was seen that there was a reduction in fatty liver grade in 93.33% of the patient, Level of Total cholesterol the mean difference is 38.97 ± 22.06 mg/dL (T Statistic Value is 4.02 and P - value is 0.000**), Level of Triglyceride the mean difference is (T Statistic Value is 9.67 and P-value is 0.000**) 38.97 ± 22.06 mg/dL., Level of HDL the mean difference is -4.23 ± 5.77 (T Statistic Value is 3.76 and P-value is 0.001*), And at the level of LDL the mean difference is 23.04 ± 31.09 mg/dL (T Statistic Value is 3.95 and P-value is At 0.000***).It suggests Homoeopathic medicines have a significant effect on NAFLD patients and in the management of their lipid levels.

Conclusion: The role of homoeopathic medicines in the management of fatty liver and its effect on their levels of Total cholesterol, Triglycerides, HDL and LDL. Based on repertory the chelidonium majus (Mother tincture) was prescribed. Each case was followed up for approximately 6 months with 5 follow-ups being completed with a gap of 30 days

approximately. The ultrasonography of the abdomen was used for fatty liver assessment and Lipid profile assessment for the Dyslipidemia. It was seen that there was a reduction in fatty liver grade in 93.33% of the patient and levels of lipids before and after the study respectively.

Keywords: NAFLD, NASH, HDL, LDL.

Introduction

NAFLD

NAFLD is a condition where the liver stores extra fat. The prevalence of non-alcoholic fatty liver disease among adults and adolescents has quickly increased in recent years. It is one of the most prevalent chronic hepatic diseases in developing nations.

An excessive quantity of fat in the liver that is unrelated to alcohol consumption is referred to as NAFLD. NAFLD is characterised histologically by a wide range of liver damage, including simple steatosis, nonalcoholic steatohepatitis, and liver cirrhosis linked to nonalcoholic steatohepatitis. The pathogenic characteristics of NASH are hepatocellular damage and consequent inflammation in the liver tissue. In patients with NASH, 15 to 20% will experience a negative progression to fibrosis, cirrhosis, or even cancer.

Lipid buildup in the hepatocyte is the pathological defining feature of NAFLD, indicating a direct association between faulty lipid metabolism and NAFLD. In fact, faulty lipid metabolism brought on by other illnesses can also cause NAFLD.

Dyslipidemia and NAFLD

Atherosclerosis is more likely to develop in people with dyslipidemia, which is characterised by high triglyceride levels and low HDL levels. Twenty to eighty percent or more NAFLD patients also have dyslipidemia. Serum lipid levels are frequently altered in people with type 2 diabetes mellitus and obesity, changing their metabolic profile. It has been demonstrated that NASH increases LDL levels considerably, which is a recognised risk factor for atherosclerosis. Atherogenic dyslipidemia, which is characterised by hypertriglycemia, low HDL levels, and high LDL, is the most prevalent form of dyslipidemia in NAFLD patients. Long-term dyslipidemia may boost the expression and activity of the transcription factor sterol regularity element binding protein-1c, which could have a negative impact on the profile of lipid and lipoprotein production in the liver, including higher TG, LDL, and VLDL and lower HDL. Because of this physiological dysfunction, atherogenesis risk also rises, predisposing the patient to cardiovascular illnesses. Fat builds up in the liver as a result of dysfunctional fat metabolism.

Materials and Methods: It is a study that was carried out in Bharati Vidyapeeth Medical Foundation's Homoeopathic hospital, OPD, and IPD. Total 30 patients meeting the inclusion and exclusion criteria were enrolled willingly. It was a time-bound study with enrollment done from October 2022 to April 2023. Each case was followed up for approximately 6 months with 5 follow-ups scheduled with a gap of 30 days approximately. Ultrasonography (A Nonalcoholic fatty liver disease classification system) and lipid profile were used to assess the fatty liver in dyslipidemic patients before and after the study respectively. The post-treatment outcome measures were a reduction in the grade of fatty liver and values of lipid profile.

Result

In this study 13% of the patients were below 40 years, 44% of the patients had an age between 40-50 years, 23% had an age between 50-60 years and 20% had an age between 60-70 years in the study and 53% of patients were females and 47% were males.

Table1: Distribution of patients according to age

Age Group	No of patients	Percentage
Below 40 years	4	13.33%
40-50 years	13	43.33%
50-60 years	7	23.33%
60-70 years	6	20.00%

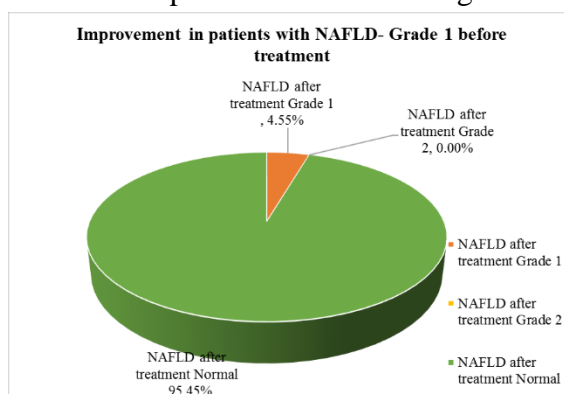
Grades 1, 2, and 3 of NAFLD are recognised. Simple steatosis is what is present in grade 1. Steatosis in grade 2 with lobular inflammation and swollen hepatocytes. Grade 3: Steatosis, lobular inflammation, swollen hepatocytes, and fibrosis or Mallory hyaline. Nonalcoholic fatty liver disease of grade 1 affected 73% of the patients, while grade 2 affected 27% of the patients.

Table 2. NAFLD-grade wise distribution of patients

NAFLD	Number of Patients	Percentage
Grade 1	22	73.33%
Grade 2	8	26.67%

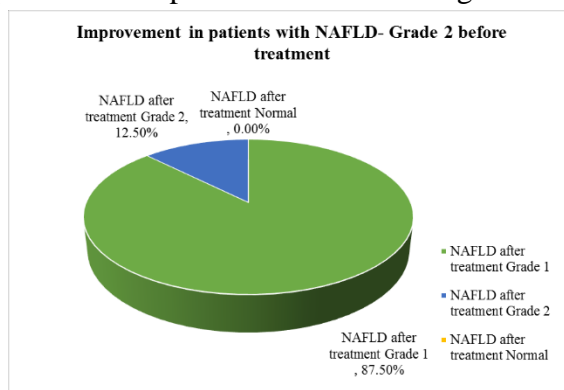
The Improvement in patients with NAFLD grade 1 before treatment. Out of 22 patients with NAFLD -grade 1, 95.45% had NAFLD – Normal USG after treatment. And remaining 4.55% of patients showed no improvement in grade.

Figure 1: Improvement in patients with NAFLD grade 1 before treatment



And The Improvement in patients with NAFLD grade 2 before treatment. Out of 8 patients with NAFLD - grade 2, 87.5% had NAFLD – grade 1 after treatment. And remaining 12.5% of patients showed no improvement in grade.

Figure 2: Improvement in patients with NAFLD grade 2 before treatment



So, conclude that 93.33% of patients showed an improvement in reversing the grade of non-alcoholic fatty liver disease in dyslipidemia. 6.67% of patients showed no improvement in reversing the grade of NAFLD in dyslipidemia.

Table 3: NAFLD-grade wise distribution of patients after treatment.

NAFLD before treatment	NAFLD after treatment					
	Grade 1		Grade 2		Normal	
	Number of patients	Percent age	Number of patients	Percent age	Number of patients	Percent age
Grade 1	1	4.55%	0	0.00%	21	95.45%
Grade 2	7	87.50%	1	12.50%	0	0.00%

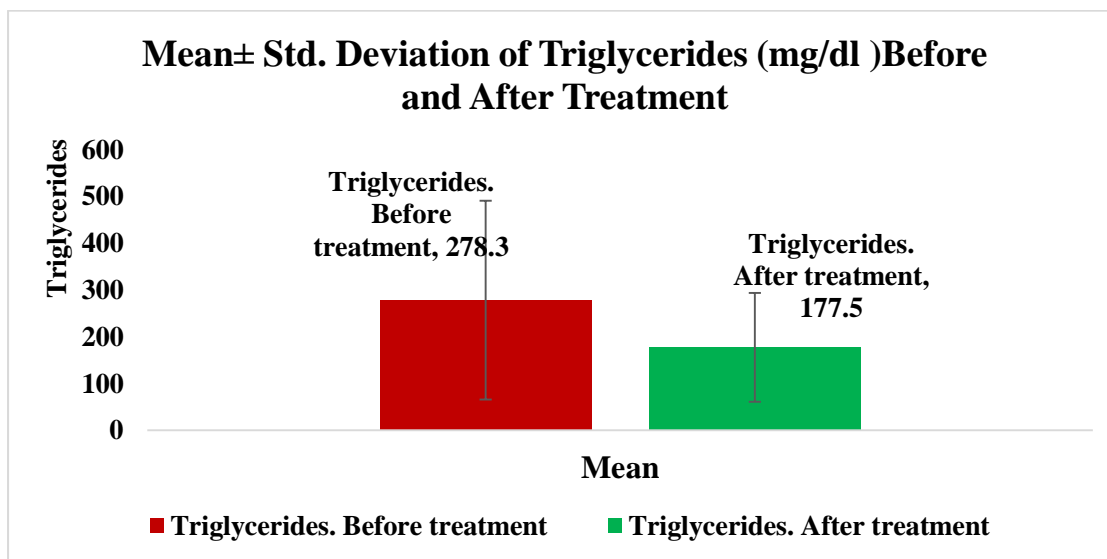
Before treatment, the HDL was 44.9 ± 9.11 (mean \pm SD) mg/dL which increases to 49.13 ± 9.57 mg/dL after treatment.

Table 4: Paired t-test and Descriptive statistics of the High-Density Lipoprotein (HDL) before and after the intervention.

HDL	N	Mean \pm SD (mg/dL)	T Statistic Value	P-Value
Before Treatment	30	44.9 ± 9.11	-4.02	0.000**
After Treatment	30	49.13 ± 9.57		
Mean difference		-4.23 ± 5.77		
95% CI for the mean difference		$(-6.39, -2.08)$		

Before treatment, the Triglycerides were 278.3 ± 212.6 (mean \pm SD) mg/dL which reduces to 177.5 ± 116.3 mg/dL after treatment. T-statistic value is 3.76 with a p-value of 0.001 * significant.

Figure 3: Bar diagram representing the Mean \pm SD of the Triglycerides before and after the intervention.



Before treatment, the Total cholesterol was 229.83 ± 45.44 (mean \pm SD) mg/dL which reduces to 190.87 ± 31.8 mg/dL after treatment. T-statistic value is 9.67 with a p-value of 0.000 ** highly significant.

Figure 4: Bar diagram representing the Mean \pm SD of the Total cholesterol before and after the intervention.

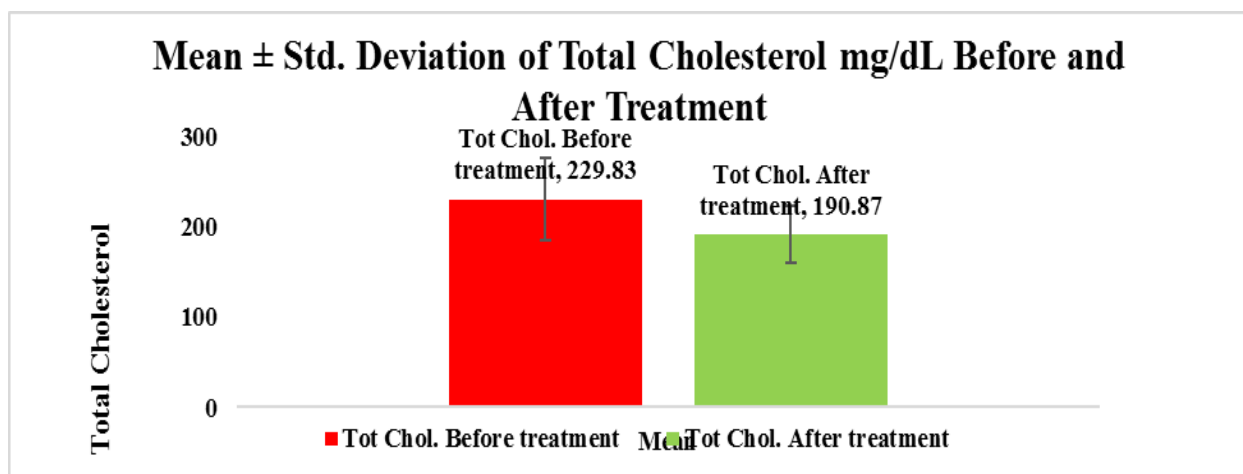


Table 5: Paired t-test and Descriptive statistics of the *Low-density lipoproteins (LDL)* mg/dL before and after the intervention.

<i>Low-density lipoproteins</i>	N	Mean \pm SD (mg/dL)	T Statistic Value	P-Value
Before Treatment	30	129.04 \pm 41.60	3.95	0.000**
After Treatment	30	106.00 \pm 24.20		
Mean difference		23.04 \pm 31.09		
95% CI for the mean difference		(11.11, 34.97)		

Before treatment, the *Low-density lipoproteins (LDL)* were 129.04 ± 41.60 (mean \pm SD) mg/dL which reduces 106.00 ± 24.20 to mg/dL after treatment.

Discussion

NAFLD is a condition in which excess fat builds up in your liver. During the last few decades, the prevalence of NAFLD has increased in India. 40% and in Maharashtra prevalence is 16.6%. The overall prevalence of combined dyslipidemia in patients with NAFLD is estimated to be 69%. Homoeopathic medicines have great literature to suggest that they could be useful in managing fatty liver with dyslipidemia. This study was primarily aimed to assess the effect of homoeopathic mother tincture Chelidonium majus in cases of NAFLD with Dyslipidemia. And here null hypothesis is rejected.

In this study 13% of the patients were below 40 years, 44% of the patients had an age between 40-50 years, 23% had an age between 50-60 years and 20% had an age between 60-70 years in the study and 53% of patients were females and 47% were males. 73% of the patients had Nonalcoholic fatty liver disease of grade 1 and the remaining 27% had Nonalcoholic fatty liver disease of grade 2.

The Improvement in patients with NAFLD grade 1 before treatment. Out of 22 patients with NAFLD -grade 1, 95.45% had NAFLD – Normal USG after treatment. And remaining 4.55% of patients showed no improvement in grade. And The Improvement in patients with NAFLD grade 2 before treatment. Out of 8 patients with NAFLD - grade 2, 87.5% had NAFLD – grade 1 after treatment. And remaining 12.5% of patients showed no improvement in grade. So, conclude that 93.33% of patients showed an improvement in reversing the grade of non-alcoholic fatty liver disease in dyslipidemia. 6.67% of patients showed no improvement in reversing the grade of non-alcoholic fatty liver disease in dyslipidemia.

The mean Total cholesterol before the treatment was 229.83 ± 45.44 mg/dL and after the treatment is 190.87 ± 31.8 mg/dL so the mean difference is 38.97 ± 22.06 mg/dL. The mean Total Triglycerides before the treatment was 278.3 ± 212.6 mg/dL and after the treatment is mg/dL 177.5 ± 116.3 so the mean difference is 100.8 ± 146.8 mg/dL. The mean HDL before the treatment was 44.9 ± 9.11 mg/dL and after the treatment is 49.13 ± 9.57 mg/dL so the mean difference is -4.23 ± 5.77 mg/dL. The mean LDL before the treatment was 129.04 ± 41.60 mg/dL and after the treatment is 106.00 ± 24.20 mg/dL so the mean difference is 23.04 ± 31.09

mg/dL. So, conclude that there is a significant difference in the lipid profile values in patients, before and after the intervention of the Homoeopathic medicine.

Conclusion

In this study 30 patients of both gender and in the age group of 19-70 years who met the inclusion, and exclusion criteria and fulfilled the case definition i.e. who has fatty liver Grade 1,2,3 and who were identified to have Dyslipidemia were enrolled and completed the study. The role of homoeopathic medicines in the management of fatty liver and its effect on their levels of Total cholesterol, Triglycerides, HDL and LDL. Based on repertory the chelidonium majus (Mother tincture) was prescribed. Each case was followed up for approximately 6 months with 5 follow-ups being completed with a gap of 30 days approximately. The ultrasonography of the abdomen was used for fatty liver assessment and Lipid profile assessment for the Dyslipidemia patients before and after the study respectively.

After Intervention: It was seen that there was a reduction in fatty liver grade in 93.33% of the patient, Level of Total cholesterol the mean difference is 38.97 ± 22.06 mg/dL, Level of Triglyceride the mean difference is so the mean difference is 38.97 ± 22.06 mg/dL., Level of HDL the mean difference is -4.23 ± 5.77 , And the level of LDL the mean difference is 23.04 ± 31.09 mg/dL.

Homoeopathic Medicines were effective in managing fatty liver in cases of dyslipidemia as is evident by the reduction in grades of fatty liver and values in lipid profile Post-treatment.

References

- [1] Review on non-alcoholic fatty liver disease and its management with Homoeopathic mother tinctures Dr. Atul Kumar Singh, Dr. Pramod Kumar Singh, Dr. Ravindra Singh Kuntal, Dr. Junaid Ahmed and Dr. Geeta Sharma
- [2] Rakhi. Chakarborty P. Homoeopathic Management of Fatty Liver Disease – A review
- [3] World Gastroenterology Organization Global Guidelines, Nonalcoholic fatty liver disease and Nonalcoholic steatohepatitis, June 2012.
- [4] Angulo P. Nonalcoholic fatty liver disease. *N Engl J Med*, 2002; 346: 1221-31
- [5] Nonalcoholic Fatty liver disease. *American Family Physician*. 2013;88(1)
- [6] Haas, J.T., Francque, S., Staels, B., 2016. Pathophysiology and mechanisms of nonalcoholic fatty liver disease. *Annual Review of Physiology* 78:181e205.
- [7] Samuel, V.T., Shulman, G.I., 2018. Nonalcoholic fatty liver disease as a nexus of metabolic and hepatic diseases. *Cell Metabolism* 27(1):22e41.
- [8] Ajay duseja, Nonalcoholic fatty liver disease in India- a lot done, yet more required! *Indian J Gastreterol* (2010) 29:217-225.
- [9] Vos, D.Y., van de Sluis, B., 2021. Function of the endolysosomal network in cholesterol homeostasis and metabolic-associated fatty liver disease (MAFLD). *Molecular Metabolism*, 101146.
- [10] Effects of rosuvastatin (added to hypocaloric diet) on serum periostin, adiponectin, proinflammatory cytokines levels and hepatic steatosis in non-alcoholic fatty liver disease patients with dyslipidemia Rashid Ali Khana, Uma Bhandarib, Prem Kapurc, Abhinav Jaing, Farrukh Farahe.
- [11] Therapeutic potential of policosanol in the concurrent management of dyslipidemia and non-alcoholic fatty liver disease Mandeep K. Arora, Sudhanshu Pandey, Ritu Tomar, Jagannath Sahoo, Dinesh Kumar and Ashok Jangra.