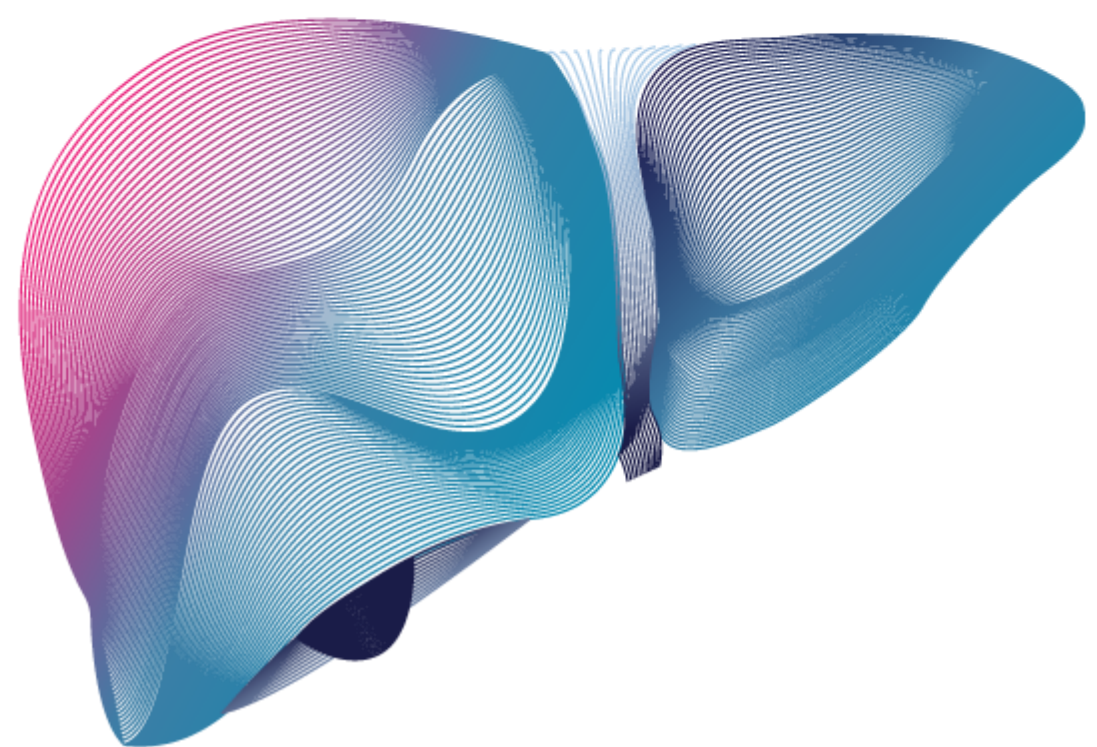




A randomized controlled trial of kalmegh supplementation on non-alcoholic fatty liver disease.

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Key take home message:

“The cost effective secret to treating NAFLD: Kalmegh supplementation – A game changer for your liver health!”

Introduction

Non-alcoholic fatty liver disease (NAFLD) is the most common chronic liver disease worldwide, caused by a build-up of extra fat in the liver cell which is not caused by alcohol¹. It affects around 25% of the general population all over the world². Kalmegh³ (Botanical name: Andrographis-paniculate-nees, Family: Acanthaceae) is an exceptional herb from classical Indian literature having comprehensive action over liver by acting as cholagogue and anti-inflammatory agent along with antioxidant properties.

Aim

Our aim was to assess the safety, effectiveness & cost of treatment for kalmegh supplementation in NAFLD using modern day investigations & standard procedures of randomized controlled trial. Also, an attempt was made to study the effect of standard lifestyle modification and dietary intervention in patients of NAFLD in terms of clinical and biochemical outcomes.

Method

We have enrolled 91 patients of age group 18-60 years from Gastroenterology OPD of tertiary care hospital in northern India. Written & informed consent was obtained & patients were randomized to group A and group B. Patients in group A (n = 49) were given kalmegh capsules & group B (n = 42) were given placebo capsules, each having dose of 1600 mg per day. Standard lifestyle modification and dietary intervention were advised in both the groups. Patients were followed up for the period of 90 days at 30 days interval for 3 subsequent visits. Anthropometric measurements along with blood & radiological investigation were performed during each follow-up.

Ethical approval was obtained from institutional ethical committee- ECR/526/Inst/UP/2014/RR-20.

CTRI (clinical trial registry India) registration no. CTRI/2021/10/037692.

Conclusions

The data obtained from our study shows that patients taking kalmegh supplementation along with standardized lifestyle and dietary intervention has shown more significant improvement in lipid profile, liver enzymes (AST, ALT) and liver stiffness (fibroscore) when compared with patients taking placebo along with standardized lifestyle and dietary intervention. No patient in both the group has shown any adverse reaction or progress in the disease pathogenesis. These results suggest that the above given intervention can be useful in improving the lipid profile, liver enzymes and liver stiffness and can stop the progression of disease. Hence, results obtained from our study support the safety and effectiveness of kalmegh in non-alcoholic fatty liver disease. Also, we can conclude that treatment of NAFLD with kalmegh supplementation is 17 times more economical than the treatment with modern medicine.

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Results

Patients in both the groups has shown significant improvement in anthropometric parameters (weight, BMI and waist-hip ratio) with p<0.05 at all the subsequent follow ups. There was no significant improvement observed in platelet count (p>0.05) in both the groups.

In group A, serum low density lipoprotein (Sr. LDL) reduced significantly (p<0.05) by 6.57%, 13.80% and 13.45% at 1st, 2nd and 3rd follow up respectively while in group B serum LDL reduced by 6.65% (p<0.05), 2.45% (p>0.05) and 9.67% (p>0.05) at 1st, 2nd and 3rd follow up respectively. Similarly, LDL/HDL ratio in group A reduced significantly (p<0.05) by 5.03%, 15.35% and 10.70% at 1st, 2nd and 3rd follow up respectively however in group B, the reduction at all the three follow ups was not significant (p>0.05) i.e., 5.67%, 3.05% and 2.09% respectively.

Serum triglyceride in group A reduced significantly (p<0.05) by 22.32%, 24.22% and 26.63% at 1st, 2nd and 3rd follow up respectively. Also in group B, serum triglyceride reduced significantly (p<0.05) by 16.39%, 19.81% and 23.92% at 1st, 2nd and 3rd follow up respectively.

Aspartate aminotransferase (AST) in group A reduced significantly (p<0.05) by 14.88%, 26.99% and 21.53% at 1st, 2nd and 3rd follow up respectively while in group B, AST reduced by 9.65%(p<0.05), 17.96%(p<0.05) and 18.55% (p>0.05) at 1st, 2nd and 3rd follow up respectively.

Alanine aminotransferase (ALT) in group A reduced significantly (p<0.05) by 14.23%, 22.06% and 27.40% at 1st, 2nd and 3rd follow up respectively while in group B, ALT reduced by 11.37% (p<0.05), 22.22% (p<0.05) and 19.24% (p>0.05) at 1st, 2nd and 3rd follow up respectively.

In group A, liver stiffness (fibro-scan score) reduced significantly (p<0.05) by 19.47%, 20.18% and 35.41% at 1st, 2nd and 3rd follow up respectively. However, in group B liver stiffness (fibro-scan score) reduced in 1st and 2nd follow up by 6.20% (p>0.05), 14.97% (p>0.05) respectively and increase at 3rd follow up by 1.05% (p>0.05).

The cost of treatment of NAFLD for one month with modern medicine (Saroglitazar and vitamin E) is 1394 rupees and with kalmegh it is 82 rupees. Hence, the cost of modern medicine treatment is about 17 times higher than the cost of treatment with kalmegh supplementation (Ayurveda).

Picture 1. Kalmegh Plant (Botanical name: Andrographis-paniculata nees)



Picture 2. Showing kalmegh in powder form.



Picture 3. Showing kalmegh Capsules filled in boxes for packing.



Table no.1: Showing percentage change and effect of group A (kalmegh + lifestyle modification) and group B (placebo + lifestyle modification) on various clinical and biochemical parameters at different follow ups –

Parameter	Group	Initial Vs 1 st follow up		Initial Vs 2 nd follow up		Initial Vs 3 rd follow up	
		Change in percentage (%)	p	Change in percentage (%)	p	Change in percentage (%)	p
Serum Triglycerides	A	22.32(-)	0.000	24.22(-)	0.001	26.63(-)	0.016
	B	16.39(-)	0.000	19.81(-)	0.000	23.92(-)	0.015
Serum LDL	A	6.57(-)	0.004	13.80(-)	0.000	13.45(-)	0.022
	B	6.65(-)	0.046	2.45(-)	0.977	9.67(-)	0.821
Serum HDL	A	2.47(+)	0.128	1.94(+)	0.540	0.02(+)	0.995
	B	2.97(+)	0.175	0.97(+)	0.923	3.29(+)	0.683
LDL/HDL ratio	A	5.03(-)	0.072	15.35(-)	0.001	10.70(-)	0.144
	B	5.67(-)	0.121	3.05(-)	0.577	2.09(-)	0.839
AST	A	14.88(-)	0.000	26.99(-)	0.001	21.53(-)	0.009
	B	9.65(-)	0.045	17.96(-)	0.008	18.55(-)	0.094
ALT	A	14.23(-)	0.004	22.06(-)	0.002	27.40(-)	0.026
	B	11.37(-)	0.045	22.22(-)	0.011	19.24(-)	0.069
Alkaline phosphatase	A	10.82(-)	0.012	10.49(-)	0.039	9.46(-)	0.223
	B	6.55(-)	0.160	10.10(-)	0.049	6.75(-)	0.881
Serum Albumin	A	2.34(+)	0.005	5.6(+)	0.000	3.5(+)	0.090
	B	4.11(+)	0.007	9.06(+)	0.000	7.40(+)	0.045
Fibro-scan (Kpa)	A	19.47(-)	0.047	20.18(-)	0.046	35.41(-)	0.043
	B	6.20(-)	1.000	14.97(-)	0.482	1.05(+)	0.285