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Evaluation of safety of *Arohi Snehapana* (Incremental Oleation Therapy) Over Physical, Hematological and Biochemical Parameters in Healthy Volunteers

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: *Ayurveda* strongly recommends the Panchakarma (Purification or detoxification therapies), e.g., *Vamana* (Therapeutic emesis) & *Virechana* (Therapeutic purgation) etc., in healthy persons for the prevention of the diseases & maintenance of the health. *Vamana* & *Virechana* are preceded by the *Arohi Snehapana* (Incremental oleation) compromising of intake of specific lipid in a large quantity. As it facilitates the smooth conduction of these procedures & brings bio-toxins in the systemic circulation for their easy elimination through these procedures;therefore it is the mandatory criteria before these procedures. However, there is apprehension about its lipid elevating effect; therefore, there is quite a restriction in its acceptability in the current cholesterol-sensitive era. Ultimately, people hesitate to undergo *Shodhana* measures & they get deprived of their miraculous results.

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Aim and Objective: Considering these hurdles, the current study was planned to evaluate and assess the safety effects of *Arohi Snehapana* over physical, hematological, and biochemical parameters in healthy volunteers.

Materials and Methods: This is a single-centric, open-labeled clinical trial in which a total of 50 healthy volunteers (both male & female) were recruited. All volunteers were selected by purposive sample method & were prescribed Incremental oleation with cow ghee before *Shodhana* therapy for a maximum of 7 days or till achievement of proper oleation features, whichever is earlier. All volunteers were assessed for physical (weight, B.M.I.), hematological & biochemical parameters before & just after the intervention.

Result and Observations: In this study, Bodyweight declined significantly by 3-4 kg (1.47%.) for (P<0.001) within 1-7 days of an intervention despite using a good amount of fat (*Go-Ghrita*). Blood urea was significantly decreased by 12.63 % (for p-Value <0.001), but this decrease was absolutely within the normal range. Significant reduction in blood urea after invention proves the role of *Snehapana* to reduce overload over the kidney and perform the protective role. No significant elevation in lipid profile due to this intervention.

Conclusion: The current study evaluates the efficacy of Incremental oleation with respect to various proper oleation features and its safety over physical, hematological, and biochemical parameters in healthy volunteers.

Keywords: Biochemical; healthy volunteers; hematological; Incremental oleation; Panchakarma.

1. INTRODUCTION

The Panchakarma therapy in Ayurveda is useful to treat the disease & restore health [1]. Panchakarma is recommended in a healthy person to maintain the internal environment affected by the seasonal changes [2]. Unction or oleation therapy with appropriate fat is the essential pre-procedure before therapeutic emesis or purgation & it is capable of dislodging harmful substances from the body tissues due to their lipophilic nature & helps in loosening body toxins. Arohi Snehapana (Incremental oleation), is a type of Internal oleation in which the administration of Lipid or fat (medicated or nonmedicated) takes place in a stipulated dose in an incremental pattern for the specified duration, i.e., maximum up to 7 days or till attaining proper oleation features whichever is earlier) [3]. Generally, cow ghee is advised for incremental oleation due to its superior properties.

Despite Cow ghee's superiority, there are misconceptions about using ghee to develop various diseased conditions like dyslipidemia, coronary artery disease by inducing an increase in biochemical parameters, particularly in the lipids, or to cause notorious effects over liver & kidney. Moreover, the use of cow ghee in high doses for internal use is also criticized by the scientists of other medical disciplines. They claim that it may become fatal if one consumes it in a high amount within a short time, and it may have an ill effect on blood lipids and kidney functions. As a result, many people refuse to intake ghee in such a large quantity.. Ultimately, they may get deprived of the miraculous benefits of detoxification procedures. Apart from this, there is the unavailability of adequate data regarding the safety effects of this oleation with cow ghee over these parameters. Keeping all these points in mind, the current study has been designed and carried out to establish the scientific background and safety of the incremental oleation with Cow ghee in a healthy population.

2. AIM AND OBJECTIVES

The primary aim was focused on the effects of Incremental oleation over physical, hematological, and biochemical parameters in a healthy population. The secondary purpose was to assess its safety over these parameters.

3. MATERIAL AND METHODS

The material & methods of the study are depicted in Tables 1 &2.

3.1 Statistical Analysis

Graph Pad In-Stat (www.graphpad.com) software was used for statistical analysis. Kolmogorov – Smirnov test was applied to test the normality of data. Repeated Measured ANOVA with post-test (Bonferroni correction) was used when the data passed the normality test. Friedman (Nonparametric Repeated Measured ANOVA) with Dunn's post-test was used when the data failed the normality test. P-value < 0.001 was considered significant.

4. RESULT AND OBSERVATIONS

Among 58 patients recruited in the study, the maximum volunteers belonged to the 18-28 age group, females & were having Pittapradhana Kapahaja Prakriti (constitution), Madhyama Kostha. Samagni & Madhyam Jarana Shakti(medicum digestive capacity). Eight participants were excluded from the analysis due to failure to undergo blood collection after intervention & some technical problems. No single participant had withdrawn due to an adverse event. Incremental oleation with cow ghee was tolerated well by all individuals. Assessment of objective variables was done & observations regarding that were noted in Table 3

Highly significant weight reduction(1.47%) was observed(for P-value <0.001), especially in volunteers with Pitta predominance. A significant reduction in Serum blood urea was primarily observed in persons having Prakriti (constitution)with the predominance of Pitta &Kapha. No detrimental change was observed in the lipid profile of any volunteer.

5. DISCUSSION

Probable mode of action of Cow ghee used for an incremental pattern for weight reducing effect: In this study, it is a very interesting thing that despite consuming cow ghee in a large quantity for a maximum of up to 7 days, it induces weight loss in the 80 % of Prakruti with Pitta volunteers having predominance. It can be justified as Prakruti with Pitta predominance may has a maximum tendency for weight reduction. The same observation in Pitta Prakruti was observed by Shikha Sharma et al. [4]. An intense metabolic fire and high basal metabolic rate in this type of constitution have more tendency of higher fat metabolism, contributing to a more significant weight loss over time in such persons [5-6].

Such weight reduction may be attributed due to the prevention of the endogenous production of glucose in the body via gluconeogenesis induced by high-fat diet & its diuretic effect [7].

S.N.	Head	Description
1	Study design	Interventional Open labeled Single arm Clinical Trial
2	Sample Size:	Total 50
3	Population	Healthy volunteers
4	Interventional drug	Plane Cow ghee(Goras Bhandar, Wardha)
5	Sampling procedure	Purposive sampling method
6	Registration Number in Clinical	CTRI/ 2018/ 02/022506
	trial registry of India	
7	IEC Number	DMIMS (DU)/IEC/June-2017-18/6258
8	Grouping	Single group
9	Locus of the study	OPD and IPD, Dept. of Panchakarma, MGACHRC Salod
	-	(H), Wardha, Maharashtra, India.

Table 1. Material & methods of the study

Table 2. Inclusion & exclusion criteria

Inclusion criteria	Exclusion criteria
Healthy volunteers in the age group of 18 to 48	Persons with Sthoulya (Obese person-
years who were not complaining of any illness	B.M.I.>24.9)
either mentally or physically at that time and with	Persons with severe impairment of bio-fire
normal general, physical, hematological and	(Agnimandya)
biochemical findings	 Subjects whose hematological and
Volunteers who are fit for incremental oleation	biochemical values are not within normal
 Volunteers who have given informed written 	limits
consent	Pregnant and lactating women

>	Physical	\checkmark	Biochemical	\triangleright	Hematological
•	Weight	•	BSL(Fasting and Postprandial)	•	CBC
•	B.M.I.	•	Liver Function Test (LFT)	•	ESR
		•	Renal Function Test (RFT)	•	Bleeding time
		•	Lipid Profile	•	Clotting Time

Chart 1. Assessment variables (Objective variables)

All blood investigations will be done just before the day of consumption of ghee and 24 hours after the intake of the last dose of cow ghee.



Fig. 1. Flow chart of research methodology

The second reason for weight reduction can be justified as a ketogenic diet induces nutritional ketosis in the body; it subsides hunger pangs and an overall reduction in caloric intake. Early achievement of satiety is developed during unction due to various secretions of gastrointestinal hormones such as Glucagon, Cholesytokinin hormone as a result of fat stimulus consumed which increases the sensation of short-term fullness. It stimulates the satiety center in the hypothalamus and suppresses perceptions of appetite, and decreases food intake, which ultimately leads to weight loss. This statement is also supported by Dipali et al. and Gibson et al. [8].

Cow ghee has an unique importance to induce a weight-reducing effect through its composition

and action over digestion and body metabolism due to a high content of saturated fatty acid in it. Due to the higher medicinal value of Cow Ghee, it never reacts like other fats and oils, which can slow down the body's digestive process and sit heavy in the stomach. It aids in the fast absorption and digestion of food by stimulating the secretion of stomach acids since conjugated linoleic acid is abundantly present in pure Ghee, which aids in weight loss by increasing metabolism through enhancement of muscle growth and burning fat.

According to Dipali et al., a specific time of administration of incremental oleation(i.e., early in the morning with an empty stomach) also contributes to weight reduction. The intake of Ghee at that time may cause interference with the absorption of essential nutrients from the gastrointestinal tract and further increase in the metabolic rate by stimulation of oxidative catabolism, increase of ATP-turnover, and cAMP levels, enhancement of phospholipid-metabolism and protein biosynthesis [9]. In the early morning, lower insulin levels that result from deprivation of glucose during ketogenic diets generally stop the body from producing more cholesterol [10]. This fact may be contributed to weight reduction in the current study.

In this study, Regular intake of lukewarm water advised during this intervention induces weight loss cumulatively by maintaining adequate hydration, increasing satiety with a decrease in food intake and its diuretic action [11-12].

Effect on ESR: In the present study, there was a reduction in ESR values but within the baseline. It can be justified as maximum volunteers underwent for *Arohi Snehapana* had *Pittakaphaja* constitution whose generally have highest levels of inflammatory markers such as IL6, TNF alpha, CRP, and slow metabolizes. So the rate of ESR reduction was more comparative to *Kaphaja Prakruti* [13]. Conjugated linoleic acid in cow ghee has been shown to reduce the formation of these inflammatory mediators [13].

Effect on Liver profile: Observation of normal values of Liver profile after oleation signifies the status of healthy liver and normal condition of the metabolic stage. Moreover, there was no significant hypertriglyceridemia in any volunteer, so it doesn't support an increase in bile acid synthesis, and so no rise in Serum total direct and indirect bilirubin [14]. This non -invasive effect of

incremental oleation over the liver is also stated by Rajkala remake et al. [15].

Effect on RFT: In the current study, significant reduction in serum Blood Urea by 12.63 % due to incremental oleation *is* also supported by pilot study conducted by Sawarkar P.et.al.2019 & Achintya Mitra et al. [16]. It may occur due to adequate calories in the high-fat that reduces protein catabolism, which results in less accumulation of uremic toxins [17]. This significant reduction is also proven by modern science due to diuretic effect of ketogenesis(ATP and H+ lons) [18]. So as the ketogenesis increases, the water excretion also increases, which will help to increase the urine output and decrease Serum Blood urea [19].

In the current study, an unctuous & specific property of *ghee* to evacuate urine, stool, and flatus easily induces *Anulomana* of *Vata*(structure responsible for homeostasis)) especially *Apana Vata* those increases the renal flow (normal kinesia) & the urine output [20-21]. As a result, it ultimately evacuates the toxins such as Creatine and Blood urea out of the body & results reduction in their serum values [22-24].

During a Ketogenic diet, the body's capacity increases to produce more ATP with the help of super fuel Fat. As a result of ketosis, dehydration occurs. To maintain adequate hydration, creatinine was also utilized, which ultimately reduced serum urea level [25]. Significant reduction in Blood urea & insignificant level of Serum creatinine in the present study shows the good normal excretory and protective role of incremental oleation over kidney [26]. Protective role of lipids consisting of polyunsaturated fatty acids for kidney in non-diabetic patients (i.e., Healthy) is also supported by Aquila MB et al. [27] Yuzbashian E et al. [28] based on its effects to decrease glomerulosclerosis, glomerular magnification, and glomeruli loss.

Effect on Lipid profile: In the current study, there were no significant changes in Serum Total Cholesterol levels after the intervention. Desirable effect of incremental oleation with cow ghee i.e. non-observation of hyperlipidemia despite giving its good amount is also supported by Shukla DJ et al. 2012, Ankita et al. & Rajkala Ramteke et al. after incremental oleation [9,15,29]. It can be justified as when fat is consumed in large quantity, inhibition of the

S.N.	Type of parameters	Mean ± SD		Statistical
	Dhysical		Visit 0	significance
A 1	Woight	VISIL I 67.62 ± 15.44	VISIL Z	
י ר		07.02 ± 10.44	00.02 ± 10.00	13D SD
Z D	D.IVI.I.	20.37 ± 4.90	25.00 ± 5.00	30
1	Plooding time (P.T.)	74 06 + 44 09	66 99 + 24 46	NED
ו ס	Clotting time (C.T.)	74.00 ± 44.00	00.00 ± 34.40	
2	Lomoglobin	209.00 ± 04.99	201.32 ± 40.40 12.00 ± 1.92	
3		13.01 ± 1.03	12.90 ± 1.02	
4	TLU Total DBC Count	0300 ± 1301.0	0202 ± 1030.0	NSD
5		4.03 ± 0.00	4.00 ± 0.00	
0		200000 ± 77194	280980 ± 96697	
1	ESR	25.28 ± 10.54	21.12 ± 17.20	NSD
8	MCV	80.33 ± 9.05	86.14 ± 8.52	NSD
9	MCH	27.55 ± 3.92	27.11 ± 3.92	NSD
10		32.09 ± 1.44	31.66 ± 1.97	NSD
C	Biocnemical	07 54 4 4 70#		NOD
1	Blood sugar level (Fasting)	87.54 ± 14.73	84.74 ± 14.89	NSD
2	Blood sugar level (121.32 ± 24.47	119.64 ± 19.73	NSD
•	Postprandiai)	00 50 4 0 00	47.00.5 5.00*###	0.5
3	Blood Urea	20.58 ± 6.32	17.98 ± 5.09*	SD
4	Serum creatinine	0.81 ± 0.16	0.81 ± 0.20	NS
5	Serum Sodium	139.68 ± 2.34	139.8 ± 2.85	NSI
6	Serum potassium	4.09 ± 0.34	3.99 ± 0.35	NSD
1	Serum total Bilirubin	1.07 ± 0.66	1.02 ± 0.57	NSD
8	Serum direct Bilirubin	0.34 ± 0.20	$0.31 \pm 0.15^{\circ}$	NSD
9	Serum indirect Bilirubin	0.73 ± 0.50	0.71 ± 0.48	NSD
10	SGOT	25.14 ± 9.51	28.68 ± 11.60	NSI
11	SGPT	26.92 ± 18.50	31.04 ± 18.92	NSI
12	Sr.alkaline phosphatage	179.26 ± 56.67	181.1 ± 57.25	NSI
13	Serum protein (total)	$7.43 \pm 0.62^{**}$	7.36 ± 0.67	NSD
14	Serum Albumin	4.57 ± 0.29	4.55 ± 0.29	NSD
15	Serum globulin	2.86 ± 0.53	2.85 ± 0.37	NSD
16	Serum total cholesterol	178.28 ± 35.65	182.66 ± 31.26	NSD
17	Serum high density	39.34 ± 11.01	39.02 ± 12.19	NSD
	lipoprotein(HDL)			
18	Serum low density	115.22 ± 32.03	119.2 ± 30.03	NSI
	lipoprotein(LDL)			
19	Serum Triglycerides(TG)	105.4 ± 61.71	114.54 ± 55.28	NSI
20	Serum Very low density	20.54 ± 11.98	22.48 ± 10.56	NSI
	lipoprotein(VLDL)			

Table 3. Assessment of Objective variables before and after the incremental oleation

(***p < 0.001 as compared to Visit 1, *p < 0.05 as compared to Visit 1)

essential enzyme required for endogenous synthesis of cholesterol takes place due to an increase in intake of cholesterol-rich diet. Thus it provides intrinsic feedback, which results in a decrease in lipid values [30]. The hypocholesterolemic effect of Cow ghee may be responsible for not inducing any harmful changes in the blood chemistry of the volunteers about lipids. Ghee prevents lipid peroxidation due to the rich amount of antioxidants (Vitamin A, Vitamin E, and carotenoids). Temporary slight increase in cholesterol level after incremental

oleation that reverts to normal range after optimum, rational appropriate purification is stated by Patil et al. and Ashwini K. *et al.* [31-38].

6. CONCLUSION

Considering the observations of the present study, there is no harm in administering the incremental oleation with cow ghee to a healthy person as there is no significant increase in serum lipids or no harmful effects over other biochemical parameters. Rather than that, there is a substantial decrease in weight and B.M.I. after its administration, which suggests that it can be given to obese persons also. All findings prove the protective role of the incremental oleation with cow ghee over physical, hematological, and biochemical parameters in healthy volunteers. It again clears that fear associated with the oral ingestion of lipids might be abolished; thus, such type oleation therapy might be better accepted.

It may help for wide acceptance of this intervention as an essential tool for preprocedure of therapeutic emesis and Purgation in this cholesterol-sensitive era. It recommends further comparative studies with other medicated or non-medicated Ghee or Cow ghee/Buffalo ghee in different constitution and various disease conditions such as cardiac diseases, non-insulindependent Diabetes mellitus where the lipids levels are usually abnormal.

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

CONSENT

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

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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