JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

AN OPEN CLINICAL STUDY ON TRIPHALA RASAYANA EVALUATING ITS EFFECT ON SHONITA ABHISHYANDA (HYPERLIPIDEMIA)

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ABSTRACT

Shonita abhishyanda is characterized by the presence of excessive Kapha and Medas in the Rasa-Rakta dhatu, similar to Hyperlipedemia, which is characterized by excess lipoproteins travelling in the blood streams. **Objectives-**To evaluate the effect of Triphala Rasayana in reducing the levels of serum lipids in patients suffering from Shonita abhishyanda / Hyperlipidemia. **Methodology**: An open labelled clinical study with pre and post-test design. A minimum of 30 Patients presenting with Shonita abhishyanda / Hyperlipidemia were screened under strict diagnostic, inclusion and exclusion criteria. Such patients were included in the study after signing the informed consent. The primary and secondary outcome measures were assessed before and after the medication. **Intervention:** Dose: 6g (Aqueous extract of 24g of Triphala); Dosage Form: 12 (500 mg) capsules OD; Route of administration: Oral; Time of administration: Early Morning (2 hours) before breakfast; Anupana: Ushnodaka; Duration: 30 days. **Results:** Triphala Rasayana proved to be effective in reducing the Shonita abhishyanda by lowering the levels of Triglycerides, Total cholesterol, VLDL and increasing the level of HDL and improving the quality of life using SF Health Survey Score. All these changes were statistically significant with p=<0.001. **Conclusion**: Therefore we can conclude that Triphala Rasayana is proven to have lipid lowering effect in the management of Shonita abhishyanda and also improves the quality of life.

Key Words-

Shonita Abhishyanda, Hyperlipidemia, Triphala Rasayana, Lipid Profile.

INTRODUCTION

21st century is a boon-era of developments in technologies and science, at the same time people are becoming the victim of lifestyle disorders! One such type of disorder is Hyperlipidemia or more popularly called as Shonita abhishyanda. The word Shonita abhishyanda refers to an abnormal state characterised by presence of excessive Kapha and Medas in the Shonita dhatu. Amarasa and the Abaddha medas are the other two terms referring to the same. Excessive consumption of nutritive food in combination of lack of physical exercise which is referred by the term Santarpana nidana is the major cause of Shonita abhishyanda[1]. Pleural clinical conditions including Dhamani Pratichaya are attributed to this Santarpana nidana[2] and Shonita abhishyanda. Hridroga, Vatarakta, Vatavyadhi, Unmada, Gulma, Mutraukasada are the few conditions to mention that are

caused by Santarpana nidana and Shonita abhishyanda[3,4,5,6,7]. The description of Shonita abhishyanda matches with the clinical state of Hyperlipidemia.

Abnormal high concentration of lipids in blood caused by abnormal lipid and lipoprotein metabolism is expressed as Hyperlipidemia[8]. Plethora of clinical conditions that include obesity, diabetes mellitus, atherosclerosis, hypertension, cardiovascular diseases etc. are said to be predisposed by Hyperlipidemia. A recent cohort study in India reported that 25–30% of individuals in urban population have hypercholesterolemia and this will reveal the magnitude of the problem in Indian population. Also, clinical studies in this regard have proved that 50% of the mortality and disability caused by ischemic heart disease and cerebrovascular accidents could be avoided by normalising the levels of abnormal lipids in the blood[9]. It is essential that individual diagnosed with Hyperlipidemia have a full clinical assessment and treatment so that other co morbidities can be previously get identified and prevented.

MATERIAL AND METHODS:

Objective of the Study:

To evaluate the effect of Triphala Rasayana in reducing the levels of serum lipids in patients suffering from Shonita abhishyanda / Hyperlipidemia.

Design of study:

- Study Type : Interventional
- Estimated enrolment : 30 participants
- Allocation : Non-Randomized
- Endpoint Classification : Efficacy Study
- Intervention Model : Single Group Assignment
- Primary Purpose : Treatment

Intervention

30 patients diagnosed with Shonita abhishyanda who were in age group of 40-60years, of either sex having a Triglycerides >150mg/dl and Total cholesterol >200mg/dl were allocated to the study considering all inclusion and exclusion criteria. These patients were given 12 capsules of Triphala Rasayana orally, early morning in empty stomach for 30 days with Ushna jala and primary and secondary outcome measures were assessed using pre and post-test design.

DIAGNOSTIC CRITERIA:

Triglycerides > 150mg/dl, at screening.

INCLUSION CRITERIA:

- Patient diagnosed to have Shonita abhishyanda / Hyperlipidaemia as per the diagnostic criteria.
- Ages Eligible for Study- 40 Years to 60 Years.
- Sexes Eligible for Study: All.
- An at least 1 week wash-out / diet-controlled period before study entry is required.
- Being mentally competent and able to understand all study requirements and sign the informed consent form.
- Not using any other product including drugs, medical foods, neutraceuticals or dietary supplements for control of serum lipids.
- Consistent dietary habits.

EXCLUSION CRITERIA:

- Total cholesterol ≧ 300 mg/dL;
- Triglyceride levels ≧ 1000 mg/dL.
- Type-1 diabetes mellitus; or type-2 diabetes mellitus without stable (fixed dose) medication.
- Pregnant or lactating women.
- Concomitant steroid therapy.
- Received any lipid-modifying agents within the four weeks of commencing of study.

- Uncontrolled diabetes mellitus (glycosylated Hgb >9).
- Uncontrolled hypertension (DBP >100, SPB >160).
- Hyperlipidaemia due to endocrine pathologies.

ASSESMENT CRITERIA:

Assessment was done on the basis of primary & secondary outcome measures before and after the treatment.

Primary Outcome Measures:

- Change from Baseline in Fasting Triglycerides (TG) at day 30 [Time Frame: Baseline, day 30].
- Changes from Baseline in Fasting serum total cholesterol at day 30 [Time Frame: Baseline, day 30].
- Change from Baseline in HDL-C levels at day 30 [Time Frame: Baseline, day 30].

Secondary outcome measure:

1. SF-36 Health Survey Score.
   - Physical functioning
   - Limitations Of Activities
   - Physical health problems
   - Emotional health problems
   - Social Activities (Emotional Factor)
   - Pain
   - Energy and emotions
   - Social activities (physical)
   - General health
2. Changes from Baseline in Fasting Low Density Lipoprotein Cholesterol (LDL-C) at day 30 [Time Frame: Baseline, day 30].
3. Change from Baseline in Fasting Very Low Density Lipoprotein Cholesterol (VLDL-C) at day 30 [Time Frame: Baseline, day 30].

STATISTICAL ANALYSIS

As the sample size was small (30 patients), to calculate the test for significance, Paired t test was used and in case of subjective parameter Wilcoxon rank sum test was adopted. Statistical analysis was done based on Sigma stat 3.5 software version.

RESULTS

Effect on lipid profile-Triglycerides was reduced by 34.50%, total cholesterol was reduced by 5.35%, HDL was increased by 6.93%, LDL was increased by 0.06% and VLDL was reduced by 28.75% which was statistically highly significant at $p< 0.001$. **Effect on Weight & BMI**-2.94% reduction in Weight and 2.21% on BMI which is statistically highly significant at $p <0.001$. **Effect on FBS**: 8.55% reduction in Fasting Blood Sugar was observed which is statistically significant at $p<0.001$. **Effect on SF-36 Health Survey Score**-It is observed that about 35.38% of improvement was observed in the Physical Functioning, 32.71% of improvement was observed in their Routine Activities, and 36.36% of improvement was observed in the Social Activities and 43.45% of improvement was observed in the Pain relief. It was also observed that about 24.94%, 8.99%, 7.51% of improvement observed in Physical and Emotional health problem, Energy and Emotions. About 11.90% of improvement observed in the General Health of the patients.

Table 1 Effect of Treatment on Triglycerides

TIME	Mean	±SD	±SE	Difference in Mean	% improvement	Paired 't' Test	
BT	333.200	150.973	27.564	114.967	34.50	t value	P value
AT	218.233	66.133	12.074			4.396	P=<0.001

Table 2 Effect on Total Cholesterol

TIME	Mean	±SD	±SE	Difference in Mean	% improvement	Paired 't' Test	
BT	238.500	34.571	6.312	12.767	5.35	t value	P value
AT	225.733	50.361	9.195			2.082	P= 0.046

Table 3 Effect on HDL

TIME	Mean	±SD	±SE	Difference in Mean	% improvement	Paired 't' Test	
BT	42.267	9.885	1.805	-2.933	-6.93	t value	P value
AT	45.200	9.543	1.742			-1.976	P= 0.058

Table 4 Effect of Treatment on Quality of Life

Table 4.1 Physical Functioning Affected

TIME	Mean	Median	±SD	±SE	Difference in Mean	% improvement	W.S.R.T*	
BT	54.167	56.250	11.987	2.188	19.167	35.38	Z value	P value
AT	35.000	37.500	15.186	2.773			-4.626	P= <0.001

Table 4.2 Limitation of Activities

TIME	Mean	Median	±SD	±SE	Difference in Mean	% improvement	W.S.R.T*	
BT	35.667	30.000	21.324	3.893	11.667	32.71	Z value	P value
AT	24.000	20.000	17.538	3.202			-4.578	P= <0.001

Table 4.3 Physical Health Problem

TIME	Mean	Median	±SD	±SE	Difference in Mean	% improvement	W.S.R.T*	
BT	42.500	50.000	29.471	5.381	7.353	24.94	Z value	P value
AT	22.500	25.000	22.118	4.038			-3.739	P= <0.001

Table 4.4 Emotional Health Problem

TIME	Mean	Median	±SD	±SE	Difference in Mean	% improvement	W.S.R.T*	
BT	36.663	33.330	29.489	5.384	2.653	8.99	Z value	P value
AT	26.664	33.330	26.836	4.900			-2.232	P = 0.031

Table 4.5 Social Activities Emotional Affected

TIME	Mean	Median	±SD	±SE	Difference in Mean	% improvement	W.S.R.T*	
BT	36.667	50.000	24.330	4.442	13.334	36.36	Z value	P value
AT	23.333	25.000	17.287	3.156			=-3.771	P= <0.001

Table 4.6 Pain

TIME	Mean	Median	±SD	±SE	Difference in Mean	% improvement	W.S.R.T*	
BT	44.950	50.000	22.695	4.144	19.533	43.45	Z value	P value
AT	25.417	25.000	16.571	3.025			-4.025	P= <0.001

Table 4.7 Energy and Emotions Affected

TIME	Mean	Median	±SD	±SE	Difference in Mean	% improvement	W.S.R.T*	
BT	40.515	41.110	10.959	2.001	3.045	7.51	Z value	P value
AT	37.470	37.770	10.551	1.926			-3.715	P= <0.001

Table 4.8 Social Activities Physical Affected

TIME	Mean	Median	±SD	±SE	Difference in Mean	% improvement	W.S.R.T*	
BT	29.259	30.000	19.347	3.532	12.518	42.783	Z value	P value
AT	16.741	20.000	10.645	1.944			-3.772	P= <0.001

Table 4.9 General Health Affected

TIME	Mean	Median	±SD	±SE	Difference in Mean	% improvement	W.S.R.T*	
BT	43.750	43.750	14.681	2.680	5.207	11.90	Z value	P value
AT	38.543	37.525	13.642	2.491			-2.870	P = 0.003

Table 5 Effect on LDL

TIME	Mean	±SD	±SE	Difference in Mean	% improvement	Paired 't' Test	
BT	138.073	34.084	6.223	-0.0933	-0.06	t value	P value
AT	138.167	37.627	6.870			-0.0153	P= 0.988

Table 6 Effect on VLDL

TIME	Mean	±SD	±SE	Difference in Mean	% improvement	Paired 't' Test	
BT	63.493	26.961	4.922	18.260	28.75	t value	P value
AT	45.233	14.073	2.569			4.029	P=< 0.001

Table 7 Effect on Weight

TIME	Mean	±SD	±SE	Difference in Mean	% improvement	Paired 't' Test	
BT	71.865	13.517	2.468	2.118	2.94	t value	P value
AT	69.747	13.729	2.507			3.852	P=< 0.001

Table 8 Effect on BMI

TIME	Mean	±SD	±SE	Difference in Mean	% improvement	Paired 't' Test	
BT	27.087	3.952	0.721	0.600	2.21	t value	P value
AT	26.487	3.828	0.699			6.226	P= <0.001

Table 9 Effect on FBS

TIME	Mean	±SD	±SE	Difference in Mean	% improvement	Paired 't' Test	
BT	124.967	36.831	6.724	10.667	8.55	t value	P value
AT	114.300	24.928	4.551			2.473	P= 0.019

DISCUSSION

Impairment in the Agni is considered as root cause of all diseases. Ama is usually formed by Mandagni. In case of Shonita abhishyanda, it is resultant from derangement of Dhatvagni. In the beginning Rasa dhatvagni involved forming Rasagata ama. Later Meda dhatvagni can be expected, were Meda dhatvagni has more affinity to afflict Meda dhatu due to decreased levels of Medodhatvagni than Jataragni. On the other hand, same Rasagata ama is referred as Shonita abhishyanda with the understanding that, there will be excessive presence of Kapha and Medas in the Rasa-rakta dhatu which is similar to the pathological meaning of Hyperlipidemia. Consuming ample amount of nutritious foods in combination of day sleep and minimal physical activities is referred as Santarpana nidana which results in Shonita abhishyanda. Sooner or later Shonita abhishyanda is capable of manifesting plethora of diseases. Excessive Kapha and Medas which is accumulated in the Rasa dhatu tends to infiltrate the blood vessel or Rakta dhatu causing Rakta or Shonita pradushana either by its abnormal thickening (Dhamani Pratichaya), tortuosity (Dhamani Pustatha), reduced distensibility (Dhamani Vistarabhava) and culminates into a thrombosis (Sirajagranti) later resulting in Margavarana. This sequential event of Margavarana itself is the cause of several diseases like Hridroga, Shiromarmabhigata, Unmada, Gulma, Vatarakta, Mutraukasada etc. all these events of Margavarana has a sudden onset and most of them are fatal. Needless to say, by managing the pathology of Shonita abhishyanda itself can prevent all the forthcoming events of Dhamani pratichaya as well as Margavarana. Hence the separate chapter for Santarpanotha vyadhi has been explained in the literature with its Chikitsa. Alienating the Guna-karma of dhatus is the basic principle of Dosha- dhatu Virudha Chikitsa. The same line of treatment are effective in the correction of Shonita abhishyanda i.e the regimens that are Chedaniya, Lekhaniya and having Rukshana property is adopted in excess. Shonita abhishyanda demands for Sroto shodana in patients. Bearing in mind all these basic principles and its requirement in Shonita abhishyanda, Triphala Rasayana was planned in the study. Triphala Rasayana is efficacious as Chedana, Rukshana, Medohara, more than anything it is a Vyadhihara Rasayana. Any Dravya given in large dosage for short duration will help as a Vyadhihara Rasayana and if Triphala Rasayana even given for longer duration it acts as Kamya Rasayana as it is claimed as Jara vyadhi nashana. In the current study, the marked reduction in the lipid profiles that include Triglycerides, Total cholesterol, VLDL cholesterol and increase in the HDL cholesterol proves the efficacy of Triphala Rasayana in reducing the Shonita abhishyanda. Synthesis of lipids is mainly by liver and intestine using dietary lipids. It is claimed that Haritaki, one of the component of Triphala has reported to increase gastric emptying which might be the reason for decreased absorption of lipoproteins with less density large molecule. Hence there was more reduction of lipids in triglycerides, VLDL cholesterol and Total cholesterol

whereas increase in high density small lipoprotein HDL. Negligible change in LDL. Vibhitaki is one more component of Triphala which has Chedaniya property more than Rasayana which helps in Srotoshodana and might reduce the size of the lipoprotein which again increases HDL and decreases VLDL as the fact goes HDL is the smallest and most dense lipoprotein and VLDL is the largest and less dense lipoprotein particles. Most plasma triglycerides is transported in chylomicrons or VLDL and most plasma cholesterol is carried as Cholesteryl esters in LDL and HDL. The liver is a multipurpose organ regulating various metabolic pathways in the body. It is the chief place for elimination and synthesis of lipoproteins. It gets cholesterol, triglycerides and fat soluble vitamins from peripheral tissues and diet, convert them into lipoprotein complexes and releases back into the circulation. Amalaki which is a well-known Hepato-protective drug again the component of Triphala. It helps in improving the hepatocyte cells and helps in improving the transport of hepatic lipids. In this way Triphala as individual component as well as in combination has a balancing and rejuvenating effect on Vata pitta and Kapha as well as on exogenous, endogenous and reverse cholesterol transport pathways. The study also proved to be effective in improving the quality of life which again defines its Rasayana effect on the body. Also the reduction in Weight and BMI and Fasting Blood Sugar defines the therapeutic benefit of Triphala Rasayana in complications of Shonita abhishyanda such as Stoulya and Prameha to some extent. Needless to say that Triphala Rasayana is effective in rectifying the basic pathology of Shonita abhishyanda as well as its future complications. The correction of Shonita abhishyanda was near normal in 30 days, in many subjects and was partial in few. The change in the lipid profile was statistically significant. The dosage followed in the study was well tolerated by the subjects and no any adverse effects were noticed. Thus it can be said that Triphala Rasayana is safe and effective medication for the effective control of Shonita abhishyanda and related disorders. Observing the therapeutic benefits of Triphala Rasayana in Hyperlipidemia, more evidence based studies may be placed to prove the therapeutic effect of same in diseases like Diabetes Mellitus, Ischemic Heart Disease, Ischemic Stroke, Ischemic Limb Disease, Parkinsonism, Obesity etc.

In a nut shell, Santarpana nidana or Virudha ahara resulting in Shonita abhishyanda which sooner or later may predispose to different Santarpanottha vikaras, are all effectively treated with Triphala Rasayana. Hence Triphala Rasayana may be prescribed or plan in all the sequels of Margavarana like Vatavyadhi, Shiromarmabhigata, Vatarakta, Hritshula, Mutraukasada and so on.

CONCLUSION

Shonita abhishyanda is characterized by the presence of excessive Kapha and Medas in the Rasa-Rakta dhatu, similar to Hyperlipedemia, which is characterized by excess lipoproteins travelling in the blood streams. Madhura amla lavana rasa aharas with Seetha snigdha guru guna, Adyashana, Divaswapna, Atinidrata and Avyayama were more appreciated in the study as Nidana for Shonita abhishyanda. Triphala Rasayana proved to be effective in reducing the Shonita abhishyanda by lowering the levels of Triglycerides, Total cholesterol, VLDL and increasing the level of HDL. All these changes were statistically significant with $p<0.001$. Triphala Rasayana proved to be statistically significant in improving the quality of life using SF health survey score with $p<0.001$. It is worth mentioning that Triphala Rasayana not only reduced Hyperlipidemia, but also helped in reducing Fasting Blood Sugar, BMI and Weight, which was also a statistically significant change with $p<0.001$. Triphala Rasayana was absolutely free from any kind of side effects or toxic effects.

ACKNOWLEDGEMENT

My sincere gratitude to my Guides Late Dr G Shrinivasa Acharya and Dr Aniruddha for their immense support throughout and I also like to thank Dr Shrilatha Kamath HOD and all other faculty members of Sri Dharmasthala Manjunatheshwara College of Ayurveda, Udupi.

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