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CLINICAL EFFICACY OF AN AYURVEDIC FORMULATION NAGARJUNABHRA RASA IN A POST-MI PATIENT: CASE STUDY

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ABSTRACT

Nagarjunabhra Rasa, a famous Ayurvedic formulation, is claimed to be effective in stable form of angina (*hridshula*). Here, in a single case based study, it was clinically tried in a post-MI patient with stable angina. It was prescribed in an add-on to monotherapy method by tapering and deleting co-administered anti-anginal allopathic drug, gradually. In a dose of one tablet twice daily with plain potable water, it was administered for three months. Drug efficacy was assessed on subjective clinical, laboratory and TMT parameters. Results obtained demonstrated anti-anginal efficacy of the drug on all parameters. It showed no effects on heart rate and blood pressure; neither had it exhibited any effect on lipid profile of the case. All results were statistically analyzed for significance of difference. No adverse effect or major coronary event took place during the study. It was concluded that the drug had proven anti-anginal efficacy which can be tried in future upon large and sufficient number of patients. Further high level clinical studies to determine safety and effectiveness are warranted.

Keywords: Case study, *Nagarjunabhra Rasa*, Post-Myocardial Infarction, Stable angina

INTRODUCTION

Ayurvedic formulations have been developed through continuous human trials for millenniums. One *Nagarjunabhra Rasa* has been recommended and prescribed by Ayurvedic physicians for the treatment of *hridshula* (angina of modern times).[1-4] But it lacks clinical evidences based on modern methods which the science-world needs to be described in its terms.[5] *Hridshula*, according to Ayurvedic concept is caused by vitiation of three vital forces (*tridosha*), particularly vitiated *vata dosha*, gets *ahara rasa dhatu* (food extractive) vitiated and both conjointly situated in heart (vessels) create obstruction within perpetuating precordial pain.[6] Treatment is correction of *samprapti* (disease patho-physiology) through medication and dietary regimen.[7] *Nagarjunabhra Rasa*,

composed of 100 puti Abhraka bhasma, smeared and triturated with Terminalia Arjuna bark's decoction seven times till dryness, is said to be a *rasayana* (anti-oxidant) drug having property of *shula* (pain) and *tridosha* pacification.[8] Various modern studies too suggested Terminalia Arjuna bark's effectiveness instable angina.[9] It has got anti-anginal, anti-ischemic, anti-platelet aggregating, antihypertensive, anti-hypercholesterolemic and anti-atherosclerotic properties.[10] *Abhraka bhasma* is a calcium, potassium, magnesium, iron, silicates etc. multi-mineral compound having *yogavahi* (bio-activity enhancer) characteristic and is said to be *hridya* (cardio-protective) itself.[11] According to modern medical science stable angina is a coronary arteries disease; when they get obstructed due to atherosclerosis, it causes diminished blood supply to the heart muscles resulting mild to severe pain or discomfort on minimal exertion which is relieved by rest, which may lead to serious conditions.[12] Treatment consists of multi-pronged medical approach, pharmacotherapy to revascularization.[13] Stable angina despite being effectively treated today, many patients are left untreated due to non-compliance of modern therapy because of serious side effects, drug tolerance, financial constraints and resistance of commonly used allopathic medicines.[14] In this backdrop *Nagarjunabhra rasa* was tried in an interesting post-myocardial infarction angina patient with surprising efficacy. Hence the case is presented here.

Patient's profile:

While conducting a clinical study of *Nagarjunabhra rasa* in patients of stable angina, we came across a case of post-myocardial infarction who was very dejected and had intolerance to premier allopathic medicines and sensitive to some and longing for safe alternative medicines. A well-built 5'-11'' male patient aged 60 years with BMI 24.6 was presented with stable angina symptoms such as complaints of chest pain, dyspnea, fatigue and mild precordial burning sensation on exertion which were relieved at rest. His temperature was normal, blood pressure and pulse rate were 130/80 and 54 to 60 beat per minute respectively with irregular heart rhythm. He had previous history of MI 4 years ago, and was thrombolised thereafter at one metropolis hospital situated in Delhi-NCR. Prognosis was not good and he was having clinical evidence of cardiac insufficiency with slow heart rate. He had a history of sensitivity to aspirin tablets and intolerance to others. He was not taking any type of medicine since long. Patient, a farmer by occupation lived a simple and disciplined life. He was a teetotaler, but smoked *hukka* (tobacco); had no family history of coronary artery disease. Yet he developed sudden severe chest pain years back. Risk factors were *hukka* smoking and *ghee* intake. From ayurvedic point of view his complaints of *shula* (pain) and *daha* (burning sensation) in *hridaya* (precordial) region, *klama* (wearing) and *shwaskrichhta* (dyspnea) on *shrama* (accustomed exertion) were symptoms of classical *hridshula*.[3]

Clinical examination:

Patient was thoroughly examined subjectively. There was discomfort of mild to moderate chest pain, dyspnea, chest burning and marked fatigue on exertion which was relieved by rest for many days; typical

symptom of angina. Symptoms were graded into nil to mild, moderate and severe degrees numerically as 0, I, II and III respectively.

On Canadian Cardiovascular Society (CCS) grading scale measurement patient was having limitation of activities with moderate exertion, scored II. Health related quality of life was measured using European quality of life 5-dimensional VAS (EQoL 5D VAS) scale; scoring was 21122. Patient had to consume 3 to 4 sorbitrate 5 mg tablets daily; reluctantly with headache.

His electrocardiogram (ECG) at rest had shown inversion of T wave and widened QRS complex in inferior II, III and avF leads and tall T waves in V_{2-4} anterior leads. He was provisionally diagnosed as case of post-MI stable angina with dilated cardio-myopathy. For final diagnosis exercise tolerance test was performed on TMT machine by using modified Bruce Protocol, which was found positive for myocardial ischemia and heart muscle insufficiency. Laboratory bio-chemical tests were done for Hb, Random Blood Sugar and Lipid Profile values.

Management and outcomes:

Subsequently, patient was tried upon *Nagarjunabhra Rasa* as an add-on therapy to monotherapy regimen. Initially he was put on *Nagarjunabhra Rasa* tablets BID plus beta-blocker metoprolol XL 50 mg OD and tablets of sorbitrate 5 mg sub-lingual SOS. Dose of beta-blocker was reduced gradually, per follow-up visit, from 50 mg to 25 mg to nil and lastly, he was prescribed one encapsulated tablet of *Nagarjunabhra Rasa* twice daily as monotherapy. He was advised to keep taking isosorbide dinitrate 5 mg tablets sublingually SOS as a rescue medicine. Patient's condition was assessed after every 15 days clinically and by results of investigations. After three months of therapy results were compared with baseline values applying one sample t-test statistical method to know significance of difference.

Efficacy assessment criteria:

Clinical assessments were made on the subjective parameters in terms of feeling of chest pain, breathlessness, burning chest and fatigue before and after treatment. CCS grading score was obtained to evaluate efficacy of the treatment. And EQoL 5D VAS score was measured to know subjective response of the treatment in terms of health-related quality of life. Laboratory bio-chemistry values for Blood Hb, random sugar, total cholesterol, high density lipid cholesterol, low density lipid cholesterol, very low density lipid cholesterol, and triglyceride were noted.

Treadmill exercise testing was done as primary end point for measurement of ST segment abnormality. TMT parameters taken were: Total exercise time for total exercise capacity, time to 1 mm ST depression, METs values as total workload achieved and maximum ST depression in matching leads. Maximal level exercise tests were performed until limited by symptoms. TMTs were done on 1^{st} day, 16^{th} day, 60^{th} day and 90^{th} day.

DISCUSSION

Thus, we found from table no. 1 that results obtained were encouraging and significant. Clinical symptoms were totally subsided after completion of treatment. CCS grading was improved and EQoL 5D VAS scores recovered and number of ISDN tablets intake was reduced to zero; all showing

clinical response of *Nagarjunabhra Rasa*. From table no. 2: BMI was reduced and there was no significant effect upon blood pressure and heart rate. It was also evident that the drug had no significant effect over blood sugar and lipid profile values. It showed no hemodynamic and hypolipidemic efficacy of the drug.

From table no. 3: TMT parameters showed that there was an increase in total exercise time, increased double product and myocardial oxygen consumption by heart muscles as an indicator of increased myocardial efficiency and reduced Maximum ST segment depression in matching leads as compared to mean values. All parameters exhibited anti-ischemic and anti-anginal efficacy of the drug. No major coronary event took place and not any noted adverse effect was observed during the course of treatment. Fat free diet and cessation of tobacco smoking were advised to follow strictly which literarily have definite preventive role in disease progression.

Table 1: Subjective parameters

Variable	Baseline characteristics (Before Treatment)	Findings (After Treatment)
Clinical symptoms		
Pain	II	0
Dyspnea	II	0
Burning chest	II	0
Fatigue	II	0
CCS grading score	II	0
EQoL 5D VAS score	21122	11111
No. of tablets ISDN used	3	0

Table 2: Physical and laboratory values

Variable	During Treatment					After Treatment Mean (SE)	P-value
	Visit1 Day 1	Visit 2 Day16	Visit 3 Day30	Visit 5 Day60	Visit 7 Day90		
BMI	24.6	23.1	23.1	23.1	23.1	23.5 (0.2)	<0.05
SBP	130	110	110	130	130	122 (4.8)	<0.05
DBP	80	70	60	80	80	74 (4)	<0.05
Heart rate	60	53	55	67	69	60.8 (3.1)	<0.05
Hb	14.1	14.1	14.1	15	14.9	14.4 (0.2)	<0.05
BSR	65	69	93	86	102	83 (7.03)	<0.05
Total cholesterol	130	150	164	190	164	159.6 (9.8)	<0.05
HDL	26	32	22	11	22	22.6 (3.4)	<0.05
VLDLC	24	18	43	39	25	29.8 (4.7)	<0.05
LDL	80	100	99	140	117	107.2(10.07)	<0.05
Triglyceride	120	90	215	195	125	149 (23.8)	<0.05

Note: P-value consider as significant (<0.05), SBP (Systolic blood pressure), DBP (Diastolic Blood pressure), SE (Standard Error)

Table 3: TMT values

Variable	During Treatment				After Treatment Mean (SE)	P-value
	Visit 1 Day 1	Visit 2 Day16	Visit 5 Day 60	Visit 6 Day 90		
Total exercise time (min)	3:39	4:44	7:37	4:17	5:42 (0.84)	<0.05
MET level at peak	5.2	6.1	8.8	6.7	6.7 (0.76)	<0.05
Max double product at peak	224	188	234	245	222.7 (12.3)	<0.05
Max ST segment depression in mm (III) (V_5) (V_6)	1.2 1.5 2.0	1.6 0.9 1.1	1.3 0.1 0.4	0.4 1.9 1.9	1.1 (0.3) 1.1 (0.3) 1.5 (0.35)	0.03 0.03 0.02
Test end reasons	LPB	LPB	LPB	LPB	LPB	

Note: P-value consider as significant (<0.05), SE (Standard Error), LBP (Leg pain and breathlessness)

CONCLUSION

It was concluded from the case study that Ayurvedic *Rasa* medicine *Nagarjunabhra Rasa* has significant anti-ischemic and anti-anginal efficacy. This supports the results of previous modern studies done for similar efficacy of Arjuna bark. The drug may be recommended for the treatment and prevention of stable angina and cardiac insufficiency in post-MI cases. It may be co-administered with conventional drugs without any adverse effects. This report has its limitations. It needs to be evaluated further in higher level clinical studies.

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