

CLINICAL STUDY

A CLINICAL COMPARATIVE STUDY ON RASONADILEHA WITH HRIDROGHAR CHURNA IN CORONARY ARTERY DISEASES

Renu Rathi* Bharat J. Rathi**

***Professor and HOD, Dept. of Kaumarbhritya, **Professor and HOD, Dept. of Rasashastra-Bhaishjya kalpana, M.G.A.C.H.R.C., Salod (h) WardhaDMIMSU,**

ABSTRACT:

*In day to day's hectic lifestyle, there is tremendous high rate of heart attacks in youngsters also. Worldwide, Myocardial infarction remains one of the leading causes of mortality and morbidity. The main objective of the study was to see the efficacy of trial drug in Coronary Artery Diseases regarding thrombolytic activity. It was a randomized, comparative, clinical trial of age group of 35-65years. Total 20 patients of post myocardial Infarction (Heart attack), age-, sex, body mass index and ECG matched with diet and daily regime instructions were selected for the study. Group A patients were treated with Rasonadileha which contains Rasona (*Allium sativum* Linn), Apple and lemon juice boiled to half, cooled, mixed with honey and given with Hridrogahar churna (*Dhamasa-Fagonia cretica*, *Arjun-Terminalia arjuna* (Roxb.), *Bramhi-Bacopa monnieri* and *Hingu -Asafotida*) along with standard Allopath medicines. Group B were treated with only Allopath medicines and compared with Group A patients. Ten patients of post myocardial infarction angina receiving only conventional treatment (standard allopath medications) were served as control (Group B). Marked improvement in anginal frequency was noted in both groups but group A patients were benefitted excellently than group B rewarding statistically, subjective and objective criteria. Rasonadileha and Hridrogahar churna possess potent anti-angina, cardio-protective activity. It can be used effectively in the management or as adjuvant to standard allopath cardio-protector or anti-angina in severe CAD-coronary artery disease, atherosclerosis leading to angina, infarction.*

Key Words :Angina, Coronary artery disease, Hridrogahar churna, Mayocardial infarction,Rasonadileha.

INTRODUCTION

Correspondent:
Dr. Renu Rathi,
Professor and HOD
Dept. of Kaumarbhritya
M.G.A.C.H.R.C.,Salod (h) Wardha
Maharashtra, India

Prevalence of Coronary Artery Disease/CAD in urban adults of India has increased fourfold in 40 years and even in rural areas it has doubled¹. The factors

responsible for the increased prevalence of CADs in India include adoption of unhealthy lifestyle, involving both genetic and environmental factors². It is primarily caused due to a process of progressive damage of coronary arteries called atherosclerosis. World health Organization rates it as one of the most important causes of premature death in the world population³ hence it is the need of the hour to search a explicit Ayurvedic solution without side effects for it.

The clinical manifestation may present itself as various types of chest pain/angina, breathlessness, fatigue, which leads to acute myocardial infarction, silent/asymptomatic myocardial ischemia, cardiac arrest or sudden cardiac death. Ayurveda considers CAD as Kafavrutta vata in all dhamnis, not described in any Ayurvedic texts as detail chapter.

Trial drug- Rasonadileh and Hridroghar churna was taken from vaidu, who experienced it as beneficial treatment on hridrogas. It was taken for the study as all ingredients of both medicines are hridya, rasayan, kafahar, shoolha in action.

OBJECTIVE OF THE STUDY:

The main **objective of the study** was to observe the efficacy of trial drug on function of heart (Ejection fraction, TMT-exercise tolerance) in Coronary Artery Diseases.

To compare the efficacy of Group A (trial drug and standard allopath medications) with group B (control) receiving only standard allopath medications on lipid profile.

MATERIAL AND METHODS:

Total 20 patients of post myocardial infarction (heart attack) were selected for the study from private hospital at Betul, (M.P.)

Study design: It was a randomized, comparative, open ended, short pilot study of age group of 35-65years.

Sample size & grouping: Group A- comprising 10 patients, treated with trial drugs along with standard allopath medication

Group B – Another 10 CAD patients were treated with only standard Allopath medicines and compared with Group A patients.

Exclusion criteria: Patients suffering from other cardiac problems like congestive cardiac failure, rheumatic carditis, valvular problems like pulmonary and aortic stenosis, regurgitation/(reverse blood flow) etc

Patients having BMI >25 were excluded.

Inclusion criteria:

Those patients were taken for the study, who had age group between 35-65 suffered from myocardial infarction (diagnosed on

the basis of lipid profile, CKMB, ECG, 2D Echo, Post myocardial infarction Angiography) after 6-12months interval.

All patients having same age group, sex, body mass index and ECG-matched post-myocardial infarction angina, receiving only conventional treatment.

All patients of this study were advised for good daily regime, de-addiction, walking exercise for half hour daily and sadvritta palan suggested by Ayurveda as these interventions directly help in treatment of CADs. Diet was restricted with fried, spicy, sweet, heavy, high calories foodstuffs. Allopath medicines which were common to both groups were Tab. Anti-

platelet, Beta blocker-Metoprolol, statin, once a day, post meal.

Location of the study - Private Hospital of Betul, Madhya Pradesh.

Study duration: 3 month

Follow up: up to 3 months

A validated questionnaire was prepared and consent was received from all the patients for this study. Ethical clearance by regional review board was issued.

Posology/ Trial drug, Allopath medicines:
Rasonadi leha-10 gm with Hridroghar churna 5grams, two times a day, with lukewarm water after meal.

Table 1: Composition of trial drug: Hridroghar Churna,

SL.No	Sanskrit Name	Botanical Name	Proportion
1	Dhamasa	<i>Fagonia Cretica</i> Linn.	1.5 part
2	Arjun	<i>Terminalia arjuna</i> Roxb.	1.5 part
3	Hingu	<i>Ferala narthex</i> Boiss (<i>Asafetida</i>)	1 part
4	Bramhi	<i>Bacopa monnieri</i> Cenell	1 part

Table 2: Composition of Rasonadileha

1	Rason juice <i>Allium sativum</i> Linn	250 grams
2	Apple juice	250 grams
3	Lemon juice	250 grams
4	Honey/ Bee nector	400 grams

Preparation of Medicine: Above 4 ingredients of Hridroghar churna were finely powdered with equal quantity and kept for ready use while Rasonadileha was prepared by boiling Rason, Apple and

lemon juice (taken equal quantity) to half reduced, cooled, added honey.

Assessment criteria: Gradations for clinical features (Annexure 1) ⁴⁻⁷

a. Subjective parameters- Subjective relief & tolerance to physical activities, Frequency of angina pain, hypertension, breathlessness/short breath and insomnia.

b. Objective parameter- Lipid profile (Total cholesterol, LDL, HDL, Triglycerides), ETT-Electrocardiogram treadmill test, 2D Echo (Ejection fraction)

Criteria for overall assessment of therapy -

Assessment of therapy was made with the help of subjective, objective, parameters

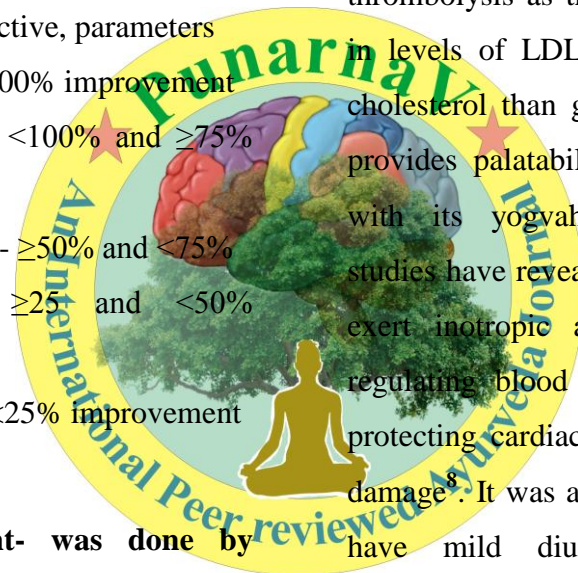
- Complete remission- 100% improvement
- Marked improvement- <100% and $\geq 75\%$ improvement
- Moderate improvement- $\geq 50\%$ and $< 75\%$
- Mild improvement- $\geq 25\%$ and $< 50\%$ improvement
- No improvement- $< 25\%$ improvement

Statistical Assessment- was done by Sigma state software

OBSERVATION

It was observed that maximum patients (80%) were belonging from the age group of 55 to 65 years. Male patients were dominant (70%) in this study in both the groups. The main cause of myocardial infarction in all patients was more eating (50%), very less physical exertion (60%) & stress (80%). The common clinical features were breathlessness/short breath,

hypertension, angina, anxiety and stress related insomnia. In present study, 10 %, 40 % and 60% patients were addicted with alcohol consumption, smoking and tobacco chewing respectively. The dropout rate was 15% due to irregular medication and follow-up. Medication was given after meal due to vyan vayu dysfunction. In this study, it was observed that ingredients of Rasonadileha & Hridrogahar churna have good effect on heart, arteries for thrombolysis as there was good reduction in levels of LDL, triglycerides and total cholesterol than group B patients. Honey provides palatability to the Rasonadileha with its yogvahi result. Experimental studies have revealed the bark of arjuna to exert inotropic and hypotensive effect, regulating blood in coronary artery and protecting cardiac tissue against ischemic damage⁸. It was also observed that *Arjuna* have mild diuretic, blood thinning, prostaglandin E(2) enhancing and blood lipid lowering activity⁹. When studied in patients with angina, Arjuna dilates blood vessels including cigarette smokers also. Catecholamine-induced myocardial fibrosis and oxidative stress is attenuated by *Terminalia arjuna (Roxb.)*¹⁰. Extract of *Fagonia Arabica/Dhamasa* has thrombolytic activity against the clotted blood in blood vessels¹¹. Apple and lemon juice contain flavonoids, antioxidants etc. hence are good for heart¹². Garlic is used



for its lipid lowering property¹³. *Asafetida* antimicrobial, laxative, anti-inflammatory, expectorant, antispasmodic, and anti-

flatulent agent, also acts as an anti-coagulant and helps lower blood pressure¹⁴

Table no. 3 showing Efficacy on Lipid profile in A group

Parameters	Mean		Relief In %	Diff.	Std. Dev	Std. error	Paired T	P value
	BT	AT						
Total Chol.	240	180	25	49.2	20.3	6.4	7.65	<0.001
LDL	168	140	16.6	28.3	5.33	1.68	16.77	<0.001
Trigly Cerides	168	138	17.9	28.4	8.98	2.8	10	<0.001

Table no.4 showing Efficacy on Lipid profile in B group

Parameters	Mean		Relief In %	Diff.	Std. Dev	Std. error	Paired t Test	P value
	BT	AT						
Total Cho Lesterol	248	227	8.8	20.4	9.39	2.97	6.86	=<0.001
LDL	164	152	7.3	12.1	6.01	1.90	6.368	<0.001
Trigly cerides	173	162	6.9	6.70	3.92	1.24	5.409	<0.001

Bar diagram no.1 showing relief in % in Lipid profile of both groups

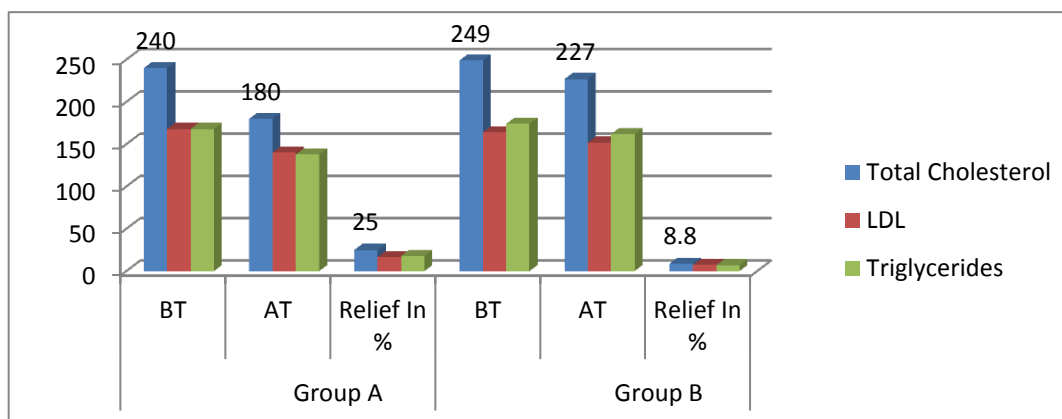


Table no. 5 showing Efficacy in Lipid profile, HDL, 2D Echo, ETT in A group

Parameters	Mean		Relief In %	Diff.	Std. Dev	Std. error	Paired t	P value
	BT	AT						
HDL	22	35	59.0	14.5	5.442	1	.8.43	<0.001
Ejection Fraction	40	55	37.5	15	1.63	0.51	29.05	<0.001
Exercise Tolerance	240Sec.	420Sec.	75	180	3.45	1.096	163.9	<0.001

Table no. 6 showing Efficacy in Lipid profile HDL, 2D Echo, ETT in B group

Parameter s	Mean		Relief In %	Diff.	Std. Dev	Std. error	Paired t	P value
	BT	AT						
HDL	24.4	27.2	12.5	2.8	0.92	0.29	9.635	<0.001
Ejection Fraction	40	44.3	10	4.3	2.98	0.94	4.558	=0.001
Exercise Tolerance	180Sec.	271Sec.	50	91	4.13	1.308	69.56	<0.001

Bar diagram no. 2 showing efficacy in lipid profile, HDL, 2D Echo, ETT in both groups

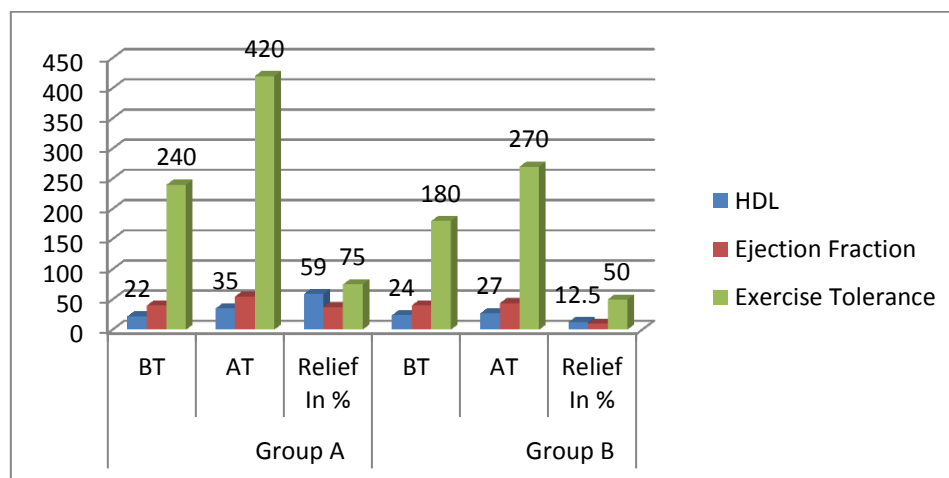


Table no. 7 Statistical Unpaired Efficacy in lipid profile, HDL, 2D Echo, ETT in both groups

Parameter	Criteria	Mean	Diff.	Std. Dev.	Std. Error	Unpaired t	p Values
Total cholesterol	Before t/t	49.2	28.8	20.335	6.430	51.977	<0.001
	After t/t	20.4		09.395	2.971		
LDL	Before t/t	28.300	16.20	5.334	1.687	6.376	<0.001
	After t/t	12.100		6.008	1.900		
Triglycerides	Before t/t	28.4	21.70	8.984	2.841	7.002	<0.001
	After t/t	6.700		3.917	1.239		
HDL	Before	14.500	11.70	5.442	1.721	6.704	<0.001
	After t/t	2.800		0.919	0.291		
2D-Echo	Before	1.5	10.70	1.633	0.516	9.949	<0.001
	After t/t	4.300		2.983	0.943		
ETT	Before	179	88.70	3.466	1.096	51.977	<0.001
	After t/t	91		4.137	1.308		

Also it was found that there was significant improvement in HDL level which increases to 59% than group B patients of 12.5%. There was significant improvement in Ejection fraction and exercise tolerance were shown good impact on group A patients than group B patients. Also unpaired t test was highly significant.

Table no. 8 showing Mild Clinical features of both groups with relief in %

GRADE	CLINICAL FEATURES	Group A (Trial)			Group B (Control)		
		BT	AT	Relief in %	BT	AT	Relief in %
Mild	Angina-	08	00	100	07	02	71.4
	Hypertension-	05	01	80	06	02	66.6
	Breathlessness/short breath	04	01	75	05	02	60
	Anxiety and insomnia	03	01	66.6	04	02	50

Bar diagram no. 3 showing Efficacy in mild clinical features in both groups

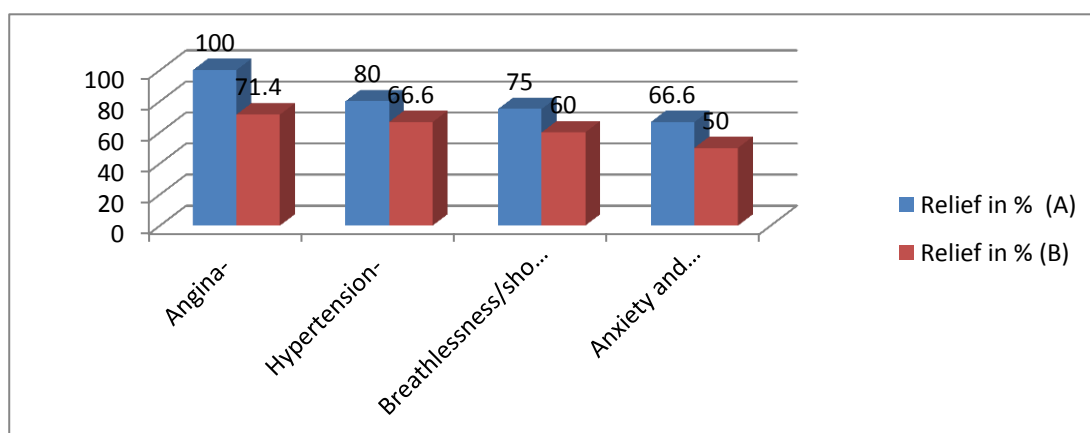


Table no. 9 showing Moderate Clinical features of both groups with relief in %

GRADE	CLINICAL FEATURES	Group A			Group B		
		BT	AT	Relief in %	BT	AT	Relief in %
Moderate	Angina-	2	0	100	2	1	50
	Hypertension-	4	1	75	3	1	66.6
	Insomnia	2	0	100	3	2	33.3
	Breathlessness/short breath	4	1	75	4	3	25

Bar diagram no. 4 showing Efficacy in moderate clinical features in both groups

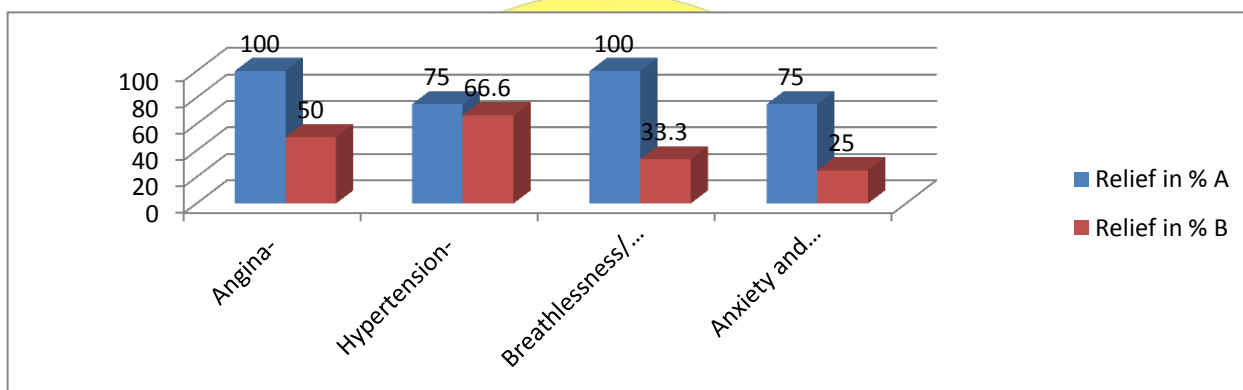
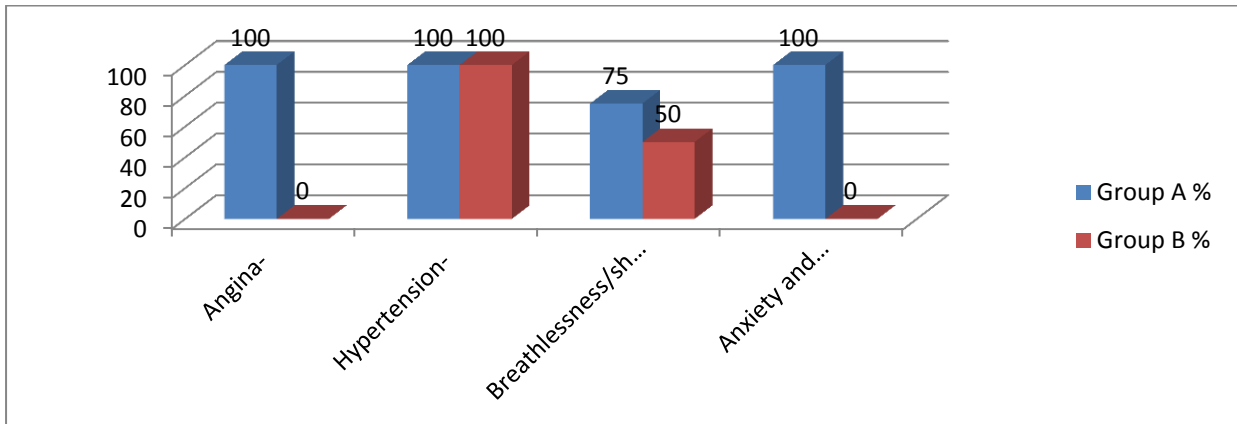


Table no. 10 showing severe Clinical features of both groups with relief in %

Grade	CLINICAL FEATURES	Group A			Group B		
		BT	AT	Relief in %	BT	AT	Relief in %
Severe	Angina-	1	0	100	1	1	00
	Hypertension-	1	0	100	1	0	100
	Breathlessness/short breath	4	1	75	02	01	50
	Anxiety and insomnia	3	0	100	02	02	00

Bar diagram no. 5 showing Efficacy in moderate clinical features in both groups



It was observed that the trial drug have no side or any untoward effect towards the health of group A patients. It revealed that in all the three grades of mild, moderate and severe, group A patients had shown significantly beneficial and advantageous efficacy than group B patients.

RESULT & DISCUSSION

All the ingredients of trial drugs having Kapha-vatahar, *shoolhar/analgesic*, *balya*, *rasayan* effect help to develop co-lateral circulation to heart along with thrombolytic effect, able to break the *samprapti*/etiopathogenesis of CAD with the help of *pathyapathya* (diet and daily regimen). Mayocardial infarction is such a terrific disorder that one can feel the short escape of death from it and it has a great impact on one's mind. Therefore these patients get ready to behave and follow a good lifestyle, de-addiction, precautions, regular medications and all care.

It was established that trial drugs with allopath medicines were very effective in

post acute myocardial infarction to reduce the atherosclerosis and recurrence of acute myocardial infarction. In trial group subjective as well as objective results were significant as compare to control group. Group A patients (Trial group) were received overall marked improvement 82% than group B (Control group) patients whom got moderate improvement-70% with excellent results in all mild, moderate, severe clinical features. As this study is a pilot study, it's very necessary to take large sample to check the result of trial drugs in them.

CONCLUSION

Rasonadileha and Hridroghar churna possess potent anti-anginal, cardio-protective activity. It can be used effectively in the management or slow down the progress of severe CAD-coronary artery disease, atherosclerosis leading to angina. As results were highly positive in all criteria like subjective, objective and statistical, therefore further

comparative study with large population is

recommended.

REFERENCES

1. - G.S. Sainani- editor in Chief, All India Practishners's Of India-API Text book of Medicine, 5th edition,1994
2. Dwivedi S, Jauhari R Indian Heart J. 1997 Sep-Oct;49(5):507-10. Antianginal and cardioprotective effects of Terminalia arjuna, an indigenous drug, in coronary artery disease.[J Assoc Physicians India. 1994]
3. Bharani A, Ganguli A, Mathur LK, Jamra Y, Raman PG. 'Efficacy of Terminalia arjuna in chronic stable angina: a double-blind, placebo-controlled, crossover study comparing Terminalia arjuna with isosorbide mononitrate. [Indian Heart J. 2002]
4. C. Maynard, L.D Fisher, American Public health, Dec. 1986, Vol.76No.12, pp1446-1448, Glenn.N.Levine
<http://www.us.elsevierhealth.com>, WHO grading angina pdf
5. Linda Brooks, www.medscape.com, WHO /ISH hypertension guidelines Medscape, March 16, 2004
6. <http://www.nhlbi.nih.gov/guidelines/asthma.pdf>, http://www.icsi_asset/rsjvnd/asthma.pdf
7. Doghramji K-The evaluation and management of insomnia, WHO grading insomnia pdf
8. Gundu.H.R.Rao, S.Thanikachalan.2005. CAD, Antianginal and cardioprotective effects of Terminalia arjuna, an indigenous drug, in coronary artery disease.[J Assoc Physicians India. 1994, 42:287-289, books.google.co.in]
9. S.Dwivedi, Gupta, Efficacy of Terminalia arjuna in chronic stable angina. [Indian Heart J. 2002] PMID:12086380, [PubMed - indexed for MEDLINE]
10. Suerta CA, et al. Am J Cardiology 1999;83:1303-1307 and EUROASPIRE I and II Group. Lancet 2001;357:995-1001
11. Rakesh Das and Atul Kaushik, Synergistic activity of Fagonia arabica and Heteropneustes fossilis extracts against myocardial, cerebral infarction, and embolism disorder in mice
12. C. Manach-2004, Nutrition journal, ajcn.nutrition.org/..../727.fullpdf.html.
13. <http://www.diethealthclub.articles/225/dietandhealth>, Natural Benefits Curative Properties Garlic,
14. <http://www.diethealthclub.articles/225/diet,NaturalBenefitsCurativePropertiesofHingu-Asefoetida,dietandhealth>

ANEXURE 1

1. Angina	
• Mild : Angina+, Slight limitation of ordinary activity	- 1
• Moderate: Angina++, marked limitation of ordinary activity	- 2
• Severe: Angina+++ or chest discomfort with minimal activity or at rest.	- 3
2. Insomnia	
• Mild: Total sleep hours-4 or slight reduction in ordinary activity	- 1
• Moderate: Total sleep hours-3 or marked reduction in ordinary activity	- 2
• Severe: Total sleep hours-2, or drastic reduction in ordinary activity	- 3
3. Breathlessness/short breath	
• Mild : Dyspnea+, Slight limitation of ordinary activity	-1
• Moderate: Dyspnea++, marked limitation of ordinary activity	- 2
• Severe: Dyspnea+++ or breathing discomfort with minimal activity	- 3
4. Hypertension	
• Mild :Diastolic blood pressure lies between 90 -99 mmHg	- 1
• Moderate: Diastolic blood pressure lies between100 -109 mmHg,	- 2
• Severe: Many times in a day or diastolic BP rises to >110 mmHg	- 3

