

EVALUATION OF EFFICACY OF
RHODENDRON SUPER
IN HYPERCHOLESTEROLEMIA.

PROJECT INVESTIGATOR

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Background

In modern lifestyle the rapid behavioral changes and food habits such as excessive consumption of oily products in foods, sedentary lifestyle, lack of physical exercises etc. ultimately become a leading cause of obesity and relevant cardiac complications. There is a large number of epidemiological and experimental studies which prove the elevated lipid profile causing high risk of coronary artery diseases.

Disturbed lipid profile is a main biological indicator and also which should be measured regularly for clinical assessment to control such dreaded disorders.

Many of the antilipidemic formulations are available in the market to treat the condition but comprehensive treatment modalities based on safe and complete therapy is still faraway.

Currently available hypolipidemic drugs like gemfibrozil, bezafibrate, lovastatin, nicotinic acid etc. are not totally free from side effects particularly when used for prolonged periods. Viewed in this reference the hypolipidemic potentials of certain medicinal plants need critical study. Certain plants have been reported to have hypolipidemic actions.

The proposed formulation Rhodendron Super is tried on patient suffering from hypercholesterolemia shows the encouraging results which are systematically elaborated here.

Super RHODENDRON is prepared with natural juices extracted from flowers and leaves of evergreen shrub known as *Rhodendron arboretum* and *Hippophae rhamnoides* which have outstanding activities to boost physiological functions of body. The rare plants wildly grow in the Indian Himalayan regions in abundant quantity.

In hilly areas, the flowers of *Rhodendron arboreum* with sweet and sour taste are used in the preparation of squash, jams, jellies and local brew. It is a very common and pleasant drink, drunk once daily as refreshing appetizer and also to prevent high altitude sickness. Fresh petals are used to prepare chutney known as *barah ki chutney*. The juice of the leaves is spread over cots and beds to get rid of bed lice. Wood of the plant is used to make charcoal and fuel. The grained wood of *R. arboreum* is used for making 'khukri' handles, packsaddles, gift-boxes, gunstocks and posts. Flowers and leaves are fitted in long ropes made of *Munja* grass and tied around the houses including temples as decorations.

Materials & Methods

The patients were registered at the different centres at OPD level which were thoroughly checked and examined for any relevant signs and symptoms and the findings were recorded in Clinical Research Form (CRF) designed with Excel data sheet.

Administration of Dosage and Duration:

Rhodendron Super liquid advised to take 10 ml twice a day for around 6 weeks and observations were recorded accordingly.

Table No. 1: The Composition : Each 5 ml contains

S.No.	Ingredients	Composition
1.	<i>Rhodendron arborium</i> Flower ext.	4 ml
2.	<i>Hippophae rhamnoides</i>	1 ml
3.	Preservatives	q.s.

Criteria for selection of patients

1. Age group 20 to 75 years
2. History of hypertension.
3. History of elevated lipid profile.

Criteria for exclusion of patient

1. Age bellow 20 or above 75 years
2. BMI under 23 and above 38
3. Serious cardiac problem.
4. Morbid type of obesity.
5. More than 6 months of chronicity of disease
6. History of severe thyroid disorders, diabetes, IHD or any other serious diseases.
7. Family history hypercholesteroleamia.

Criteria for assessment of patients

1. Clinical

- a. Patients were advised to stop any medicines which were related to cholesterol.
 - b. Patients were assessed on day one of registration (FU-0), 14th day (FU1), 28st day (FU2) and 42nd day (FU3) on the basis of clinical signs and symptoms and same were recorded in CRF (Clinical Research Form).
 - c. Every patient was also assessed with body mass index (BMI) with distinctive measurement of physical structure and weight in reference to normal to morbid obesity for the comparison with lipid profile.
 - d. Electrocardiogram was also advised for the exclusion of any cardiac problem if required.
2. Pathological
- a. Routine and microscopic urine examinations were also advised in suspected patients who were having any complaint of urinary tract infections for exclusion.
 - b. Complete blood count was also advised for exclusion of any relevant disorder to assess any hematological abnormalities.
 - c. Blood for lipid profile for assessment of severity of disease.

OBSERVATIONS

Fifty patients were registered from the different centres at OPD level which were thoroughly checked for any relevant signs and symptoms and the findings were being recorded in Clinical Research Form (CRF). The entire data assessed in Excel data sheet. Total number of patients were 50.

Table No. 2 : Showing Age Group of Patients

Age Group	Male	Female	Total	%
20-30	1	4	5	10
31-40	3	3	6	12
41-50	9	8	17	34
51-60	10	5	15	30
61-70	7	0	7	14
TOTAL	30	20	50	100

Following are the average, maximum and minimum detail of age, height and weight.

Table No. 3: Showing Average, Maximum and Minimum of Age, Weight and Height of Patients

	AGE	HEIGHT	WEIGHT
AVERAGE	47.86	163.75	86.28
MAXIMUM	73	184	114
MINIMUM	21	148	61

Table No. 4: Showing Body Mass Index (BMI) of Patients

Conditions	Range	No. of Patients	%
Normal	<23	00	00
Obese	23-27.9	06	12
Obese Grade I	28-32.9	33	66
Obese Grade II	33-37.9	11	22
Obese Grade III	>38	00	00
Total		50	100

Table No. 5: Showing Religions of Patients

Religion	Male	Female	Total	%
Christian	1	0	1	2
Hindu	24	17	41	82
Muslim	5	2	7	14
Sikh	0	1	1	2
Total	30	20	50	100

Table No. 6: Showing Economic Status of Patients

Economic Status	No.	%
Lower	7	14
Middle	32	64
Upper	11	22
Total	50	100

Table No. 7: Showing Professional Status of Patients

Professional Status	No.	%
Business	6	12
Farmer	1	2
House wife	13	26
Labor	2	4
Retired	3	6
Self Employed	8	16
Service	15	30
Study	2	4
Total	50	100

Table No. 8: Showing Height Group of Patients

Height in cm.	No.	%
<150	4	8
151-160	17	34
161-170	12	24
171-180	10	20
> 181	7	14
Total	50	100

Table No. 9: Showing Weight Group of Patients

Weight in Kg.	No.	%
61-70	7	14
71-80	11	22
81-90	13	26
91-100	11	22
101 – 110	6	12
>111	2	4
Total	50	100

Table No. 10: Showing Marital Status of Patients

Marital Status	No.	%
Married	46	92
Unmarried	4	8
Total	50	100

Table No. 11: Showing Educational Status of Patients

Educational Status	No.	%
Below Graduate	13	26
Graduate	22	44
Post Graduate	15	30
Total	50	100

Table No. 12: Showing History of Past Illness of Patients

Past History	No.	%
Acidity	1	2
Cancer	1	2
Diabetes	3	6
Dysentery	1	2
Fracture	2	4
Gout	1	2
Hepatitis	1	2
Hypertension	6	12
Irritable bowel	2	4
Infertility	1	2
Menorrhagia	2	4
Paralysis	1	2
Piles	1	2
Pneumonia	1	2
Pregnancy	1	2
Skin disease	1	2
Thyroid	2	4
Typhoid	2	4
Vericose vein	1	2
No history	19	38
Total	50	100

OBSERVATIONS AND RESULTS

As per CRF the presenting complaints were assessed on the basis of severity. The Severity score is calculated as mentioned below :

Table No. 13: Showing severity score of Patients

Conditions	Score grading
Severe	4
Moderate	3
Present	2
Occasional	1
Nil	0

Table No. 14: Showing Effect of Rhodendron Super in Giddiness of Patients

Giddiness	Score	% of Reduction
FU-0	84	
FU-1	48	42.86
FU-2	23	72.62
FU-3	6	92.86

Table No. 15: Showing Effect of Rhodendron Super in Perspiration of Patients

Perspiration	Score	% of Reduction
FU-0	64	
FU-1	34	46.87
FU-2	12	81.25
FU-3	3	95.31

Table No. 16: Showing Effect of Rhodendron Super in Breathlessness of Patients

Breathlessness	Score	% of Reduction
FU-0	59	
FU-1	30	49.16
FU-2	12	79.66
FU-3	3	94.92

Table No. 17: Showing Effect of Rhodendron Super in Chest Pain of Patients

Chest Pain	Score	% of Reduction
FU-0	29	
FU-1	11	62.07
FU-2	3	89.66
FU-3	2	93.10

Table No. 18: Showing Effect of Rhodendron Super in Radiating Pain of Patients

Radiating Pain	Score	% of Reduction
FU-0	29	
FU-1	17	41.38
FU-2	3	89.66
FU-3	1	96.55

Table No. 19: Showing Effect of Rhodendron Super in Sleeplessness of Patients

Sleeplessness	Score	% of Reduction
FU-0	97	
FU-1	56	42.27
FU-2	25	74.23
FU-3	8	91.75

Table No. 20: Showing Effect of Rhodendron Super in Depression of Patients

Depression	Score	% of Reduction
FU-0	71	
FU-1	36	49.30
FU-2	20	71.83
FU-3	11	84.50

Table No. 21: Showing Effect of Rhodendron Super in Anorexia of Patients

Anorexia	Score	% of Reduction
FU-0	98	
FU-1	62	36.73
FU-2	29	70.41
FU-3	16	83.67

During follow-ups of the patients the reduction and increment in weight are also observed and same is graded as per following way -

Table No. 22: Showing the pattern of calculation of weight score of Patients

Conditions	Range	Grades
Normal	< 1 kg	0
Obese	1.1-3 kg increased	1
Obese Grade I	3.1-6 kg increased	2
Obese Grade II	6.1-10 kg increased	3
Obese Grade III	> 10.1 kg increased	4
No change	± 0 – 1 kg	0
Minimum	1.1 to 3 kg decreased	-1
Moderate	3.1 to 6 kg decreased	-2
Fair	6.1 to 10 kg decreased	-3
Excellent	>10.1 kg decreased	-4

Table No. 23: Showing Effect of Rhodendron Super in Weight Reduction during Treatment

Weight Reduction	Score	% of Reduction
FU-0	78	
FU-1	50	38.90
FU-2	21	73.06
FU-3	7	91.02

Table No. 24: Showing Effect of Rhodendron Super in Reduction in Joints pain

Reduction in Joints pain	Score	% of Reduction
FU-0	27	
FU-1	12	55.56
FU-2	4	66.67
FU-3	3	88.89

Table No. 25: Showing Effect of Rhodendron Super in Improvement in General Condition

Improvement in General Condition	Score	% of Improvement
FU-0	77	
FU-1	45	41.56
FU-2	20	74.02
FU-3	6	92.20

Table No. 26: Showing Effect of Rhodendron Super in Improvement in General Orientation

Improvement in General Orientation	Score	% of Improvement
FU-0	34	
FU-1	14	58.82
FU-2	4	88.23
FU-3	1	97.05

Table No. 27: Showing Effect of Rhodendron Super in Improvement in General Appearance

Improvement in General Appearance	Score	% of Improvement
FU-0	58	
FU-1	22	60.02
FU-2	9	84.48
FU-3	2	96.55

Table No. 28: Showing Effect of Rhodendron Super in Improvement in Gait of Patient

Improvement in Gait	Score	% of Improvement
FU-0	50	
FU-1	28	44.00
FU-2	10	80.00
FU-3	3	94.00

Table No. 29: Showing Effect of Rhodendron Super in Improvement in Average, Maximum and Minimum Systolic BP of Patient

Follow up	Average Systolic BP	Maximum Systolic BP	Minimum Systolic BP
FU-0	151.56	180	128
FU-1	141.92	164	122
FU-2	136.56	156	120
FU-3	133.36	140	120

Table No. 30: Showing Effect of Rhodendron Super in Improvement in Average, Maximum and Minimum Diastolic BP of Patient

Follow up	Average Diastolic BP	Maximum Diastolic BP	Minimum Diastolic BP
FU-0	108.44	136	86
FU-1	100.84	124	78
FU-2	94.82	110	76
FU-3	92.34	102	80

Table No. 31: Showing Effect of Rhodendron Super in Improvement in Bowel Movement of Patient

Improvement in Bowel Movement	Score	% of Improvement
FU-0	78	
FU-1	38	51.28
FU-2	19	75.64
FU-3	7	91.02

Table No. 32: Showing Effect of Rhodendron Super in Improvement in Average, % Reduction, Maximum and Minimum Total Cholesterol of Patient

Follow up	Average Total Cholesterol mg/dl	% Reduction	Maximum Total Cholesterol mg/dl	Minimum Total Cholesterol mg/dl
FU-0	312.06		885	178
FU-1	269.06	13.77	531	168
FU-2	239.10	23.38	486	150
FU-3	209.34	32.92	320	152

Table No. 33: Showing Effect of Rhodendron Super in Improvement in Average, % Reduction, Maximum and Minimum Total Triglycerides of Patient

Follow up	Average Total Triglycerides mg/dl	% Reduction	Maximum Total Triglycerides mg/dl	Minimum Total Triglycerides mg/dl
FU-0	197.56		456	89
FU-1	177.50	10.15	402	86
FU-2	166.26	15.84	356	78
FU-3	149.56	24.29	216	76

Table No. 34: Showing Effect of Rhodendron Super in Improvement in Average, % Reduction, Maximum and Minimum LDL of Patient

Follow up	Average LDL mg/dl	% Reduction	Maximum LDL mg/dl	Minimum LDL mg/dl
FU-0	101.46		234.50	48
FU-1	94.83	6.53	230.50	46
FU-2	87.12	14.14	200.40	78
FU-3	82.04	19.13	195.80	42

Table No. 35: Showing Effect of Rhodendron Super in Improvement in Average, % Improvement, Maximum and Minimum HDL of Patient

Follow up	Average HDL Ratio	% Improvement	Maximum HDL Ratio	Minimum HDL Ratio
FU-0	52.24		68	33
FU-1	50.94	2.48	68	33
FU-2	4.41	3.36	68	32
FU-3	4.26	5.93	72	30

Table No. 36: Showing Effect of Rhodendron Super in Improvement in Average, % Reduction, Maximum and Minimum CHOL/HDL Risk Ratio of Patient

Follow up	Average CHOL/HDL Ratio	% Reduction	Maximum CHOL/HDL Ratio	Minimum CHOL/HDL Ratio
FU-0	5.86		12.21	3.24
FU-1	5.42	7.60	11.54	3.11
FU-2	4.41	24.75	7.59	2.73
FU-3	4.26	27.34	7.27	2.62

Table No. 37: Showing Effect of Rhodendron Super in Improvement in Average, % Reduction, Maximum and Minimum LDL/HDL Risk Ratio of Patient

Follow up	Average LDL/HDL Ratio	% Reduction	Maximum LDL/HDL Ratio	Minimum LDL/HDL Ratio
FU-0	1.96		4.19	0.89
FU-1	1.87	4.45	3.84	0.85
FU-2	1.75	10.75	3.30	0.88
FU-3	1.70	13.01	3.33	0.85

Table No. 38: Showing Effect of Rhodendron Super in Improvement in Average, % Reduction, Maximum and Minimum VLDL of Patient

Follow up	Average VLDL mg/dl	% Reduction	Maximum VLDL mg/dl	Minimum VLDL mg/dl
FU-0	59.03		97.20	24.20
FU-1	55.50	5.98	98.60	22.00
FU-2	52.45	11.15	86.40	22.00
FU-3	49.95	15.38	88.24	21.00

DISCUSSION

Registration of patients

Patients were registered as per criteria mentioned at the out door level at different centers at Ujjain and Ratlam area of Madhya Pradesh also nearby state of Rajasthan. Patients were advised to stop the medicines which are particularly prescribed by their physician for lowering of lipid profile. Out of sixty seven patients during the trial fifty patients have successfully completed the treatment for six weeks. After registration at the day one (FU-0) the blood for lipid profile was advised to all patients followed by two weeks interval at FU-1, FU-2 and FU-3. For exclusion purpose the special investigations were also advised to rule out any serious disorder.

Sex ratio of patients

Initially it was tried to register equal number of each gender but due to seventeen patients have not reported back the registered sex ratio is disturbed and male patients reported more seriously and completed the trial with sincerity. But it was also observed females are more prone to hyperlipidemia due to sedentary habit (Table no. 2).

Chronological and Physical parameters

The average of patients age was 47.86 years while the maximum age was 73 and the minimum was 21 years old. The detail of age, height and weight is given in table no. 3.

Randomly registered patients were observed for their height and weight ratio which was directly affecting the body mass index (BMI) of the patients (Table 8 and 9).

Obesity is measured through BMI (body mass index) which is the ratio of weight in kilograms and square height in meters. The BMI above 23 is considered under obesity which is taken under the trial and the patients who were the BMI less than 38 were also registered for trial (Table no. 4). In this trial maximum number of patients were 33 coming under the grade one of the obesity category.

Economic status

Most of the patients belonging to middle class (64%) while upper class patients were 22% who have completed the trial (Table no. 6). Since the fat rich diet is the main cause of

hypercholesterolemia and middle class persons are more careless about the diet restriction which is also revealed by the study.

Professional status

In this study every class or segment is tried to cover for study (Table 7) but it was found housewives (26%) are more conscious about the treatment and they were also more prone to lipidemia. They use to stay at home and have a habit to eat frequently and continuously. The service class persons (30%) incorporated in the study is mainly having the sedentary habit and they use to sit in the office in entire office hours. The less physical activities are also causative factor in hyperlipidemia.

Marital Status

Most of the registered patients were married (92%) who came to study. It also shows that they are more conscious about their health in comparison to unmarried (8%).

Educational Status

Most of the patients were educated and categorized as graduate (44%) while postgraduates were second in the rank (30%).

Past Illness

As per our criteria we have selected such patients who were not having any specific past history (38%). About 12% had a history of hypertension but not in severe condition during the trial period. Most of the patients were having history of diseases in early past (Table 12).

For the presenting complaints patients were reported for having any giddiness, perspiration, breathlessness, chest pain, type of pain, sleeplessness, depression and anorexia. All these were observed and noted down in CRF at FU-O, FU1, FU-2 and FU-3 while moving or at the stationary stage. The grading of giddiness etc. were observed and recorded as per table no. 14 to 21 and assessed the reduction in symptom at the interval of 2 weeks.

Weight Reduction

During follow-ups of the patients the reduction and increment in weight were also observed and same was graded in positive or negative score shown in table no. 22 and 23. As per criteria patients were selected for trial above 23 and under 39 of BMI ratio. During the trial most 91.02% of the patients lost their weight during and at the end of the trial.

Reduction in Joints Pain

The reduction in weight, here more than 90% was observed at the end of the treatment, automatically the pressure particularly on knee joint is decreased thereby there is about 90% relief in pain at the time of treatment which is shown in table 24.

Improvement in General condition, Orientation and Appearance

Many of the patient felt improvement in general conditions up to more than 92%, more than 97.05% in general orientation, 96.55 % improvement in appearance and 94% improvement in gait of patients at the end of therapy (Table 25-28).

Effect on blood pressure:

The average, maximum and minimum systolic and diastolic blood pressure are mentioned in table 29 and 30 and it was observed that both the pressures were improved and nearing towards the normal.

Improvement in Bowel Movement

Many of the patients felt the easy bowel movement during the treatment and at the end of therapy more than 90% had a relief in constipation (Table 31).

Effect on Lipid Profile:

The registered patients were undergone for blood test for lipid profile. Among them maximum range of total cholesterol reported 885 mg/dl which was reduced to around 276% apart from average reduction is about 33% at the time of end of trial (Table no. 32). Same way the other parameters are also reduced to near to normal range of lipid profile (Table 33 to 38).

Results and Conclusions

Rhodendrone Super is composed of juice of flowers and fruits of very specific herbs of Rhodendrone and Hippophae species. The trial was initiated and initially sixty seven patients were registered. Due to drop-out fifty patients have completed the trial.

All patients have instructed to undergo for blood test for lipid profile on day one and then at the end of second, fourth and sixth week. To rule out any severity the suspected patients were also advised to examine for CBC and specific blood and urine examinations also advised to have electrocardiogram.

The patients were assessed thoroughly and findings were recorded in CRF and for the analysis purpose excel data sheet were prepared and analyzed the findings.

On the basis of the above mentioned analysis it is concluded the result of the Rhodendrone Super is found encouraging as most of the patients relieved with the lipid related problems.

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