MATERIAL & METHODOLOGY
PHARMACOGNOSTICAL STUDY

Pharmacognostical standardization:

1) Collection and preparation of Haridra (Curcuma Longa linn) Out of three samples, one sample of dry rhizomes of Haridra was collected from Sangli Market yard and two samples of dry rhizome were collected from local market.

2) Collection and preparation of Daruharidra (Berberis aristata, D.C) Out of three samples, one sample of dry wood bark of Daruharidra was collected from Deharadun market and two samples from local market.

Taxonomist identified these samples for its taxonomical identification. The material of each drug was powdered and passed through 80 no. Mesh. These powders were stored in separate airtight containers.

Powder study of Haridra:

The following anatomical structures were observed under the microscope when rhizome powder was treated with chloral hydrate solution, Glycerine and water

1. Fibers, uniseriate, lignified trichomes.
2. Xylem elements with annular thickness.
3. Yellow pigmented parenchymatous cells.
4. Oval starch grains.
5. Ca oxalates.

Powder study of Daruharidra:

The following anatomical structures were observed under the microscope when stem bark powder of Daruharidra powder was treated with chloral hydrate solution, Glycerine and water.

1. Uniseriate, non lignified unbranched hairs.
2. Yellow pigmented parenchymatous cells.
4. Epidermal cells.
5. Parenchymatous cells.
6. Xylem vessel cells.
PHYTOCHEMICAL STUDY

Phytochemical standardization was done for authenticity and determination of purity in quality of the trial drugs of I.D.R.L. Pune and ‘anchrom’ Mulund.

**Methodology:**

Preliminary Phytochemical examination was carried out by success by extracting the sample of both the drugs in different solvents and physical standards were established.

Extractive Value: The determination of water soluble or alcohol soluble extractive is used as a means of evaluating drug, the constituents of which are not readily estimated by another means. The extractive value was determined as per Indian pharmacopeia.

Ash value:

When drugs of vegetative origin are neinerated, they leave an inorganic ash which is of importance and indicates to some extent the amount of care to be taken in the preparation of the drug. In the determination of total ash values, the carbon is removed at a low temperature (450°C) as possible. If carbon is still present after heating at a moderate temperature the water soluble ash is separated and the residue ignited or the ash is broken up with the addition of alcohol and again ignited as consists of carbohydrates, phosphates, silicates and silica.

For determination of acid insoluble ash the total ash when subjected to treatment with 2N Hydrochloric acid for five minutes. Collect the insoluble matter on an ash less filter paper, washed with hot plate, ignite and weighed to a constant weight. Then the percentage of acid insoluble ash is determined Acid insoluble ash consists of silica and highly acid insoluble ash in drugs with earthy matter.
Out of three samples of both drugs which sample shows the values approximately nearest to I.P. Standards were selected for the clinical trials.

**Phytochemical Analysis of Haridra:**

Description: yellow powder

Total ash: 6.5510% w/w

Acid insoluble Ash: 0.18987% w/w

Water extract: 16.36% w/w

Ethanol extract: 7.19169% w/w

pH 1% solution: 5.85

**Phytochemical Analysis of Daruharidra:**

Description: yellow greenish powder

Total ash: 3.20114%

Acid insoluble Ash: 1.0087%

Water extract: 3.42942%

Ethanol extract: 3.2076%

pH 1% solution: 4.83

TLC pattern: Thin Layer Chromatography of the drugs.

Thin layer chromatography is the widely accepted chromatographic method for the rapid and positive analysis of drugs, because the time required for the demonstration of most of the characteristic constituents of a drug is very short by T.L.C., it provides of chromatographic finger printing which is very essential for monitoring the identity and purity of the drugs and T.L.C. can be documents. Various methods of documentation are possible. They are

i) Description of the Rf values and colour of the characteristic main zones.

ii) Constitution of a scale diagram of thin layer.
iii) Separation showing migration distances and intensities of characteristic zone.

iv) Colour photo print or computer scan under UV lights give the most authentic reproduction of the colours of intensities of the separated zones, yields a drug fingerprint.

**TLC of the drugs:**

The successive extract of the drug was subjected to TLC on readily available activated silica gel and plates. Spots are applied through CAMAG linomat iv application, 2 cms above the lower edge of the plate. Different solvent systems were developed using ascending technique. The solvent system which given the maximum number of spots was determined. The spots were located by spraying different reagents.

The various solvent systems tried and the number of spots obtained and their Rf values were calculated.

**Particulars of TLC of Haridra:**

Sample – Haridra – methanol extract Adsorbent – prepared silica gel and plate solvent system – Toulene 93% + Ethyl acetate 7%

**Chamber saturation** – 1 hour.

**Reagents** : 5% ethanolic H$_2$SO$_4$

**Detection of spots** : in visible light

**No of spots** : 4

**Spray used** : 1% ethanolic Vanillin + 5% H$_2$SO$_4$

After running the plate 4 spots were calculated with following Rf values
Table No. 36: Rf values of Haridra

<table>
<thead>
<tr>
<th>Rf values</th>
<th>Colour</th>
<th>Assigned Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0619</td>
<td>Yellow</td>
<td>Unknown</td>
</tr>
<tr>
<td>0.06017</td>
<td>Blue Violet</td>
<td>Curcumin</td>
</tr>
<tr>
<td>0.707</td>
<td>Violet</td>
<td>Unknown</td>
</tr>
<tr>
<td>0.9026</td>
<td>Blue</td>
<td>Unknown</td>
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</table>

Particulars of TLC of Daruharidra

Sample – Daruharidra – methanol extract

Adsorbent – Silica gel G plate

Solvent system – n-Propanol 90% + Formicacid 1% + water 9%

Chamber saturation – 1 hour.

Spray used: Vanilline H₂SO₄

Detection of Spots: Under UV 365 nm

No. of Spots: 5

After running the plate 5 spots were calculated with following Rf values

Table No. 37 Rf values of Daruharidra

<table>
<thead>
<tr>
<th>Rf values</th>
<th>Colour</th>
<th>Assigned Substance</th>
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<tr>
<td>0.277</td>
<td>Lemon yellow</td>
<td>Berberin Sulphate</td>
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<tr>
<td>0.388</td>
<td>Lemon yellow</td>
<td>Berberin</td>
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<tr>
<td>0.455</td>
<td>White fluorescent</td>
<td>Unknown</td>
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<tr>
<td>0.550</td>
<td>White fluorescent</td>
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</tr>
<tr>
<td>0.88</td>
<td>Blue fluorescent</td>
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</table>
CAMAG HPTLC

Quantification of Curcumin in Haridra sample:

Sample preparation:

50 mg of sample is taken in a test tube, 2.5 ml of Methanol is added followed by, 2.5 ml of water (10ug/uu), sonnicate the mixture for 10 mins and ten centrifuge.

Standard Preparation (Curcumin):

2 mg of standard curcumin (93%) is weighed and 2 ml of methanol is added (1 ug/u)

Stationary phase: TLC Al sheet silica gel 60 F 254 precoated plate.

Development chamber: CAMASG Twin through Chamber for 10 x 10 cm plates with stainless steel lid.

Mobile phase: Chloroform : Methanol : 9 : 1

(Plate is impregnated with 5% aqueous sodium dihydrogen phosphate)

Tank saturation: 15 min with filter paper.

Development distance: 70 mm

Photodocumentation: 254 nm and 366 nm

Scanning wavelengths: Using CAMAG Scanner –3 /Win/CATS, micro, scanning at 254 nm and 366 nm

Reporting of Results n: Quantification of curcumin at 366 nm is done with respect to 93% pure standard.

Quantification of Berberin in Daruharidra sample:

Sample preparation:

50 mg of sample is weighed, 2.5 ml of methanol is added followed by 2.5 ml of water, sonnicate the mixture for 10 mins, and then centrifuge (10ug/u)

190
Standard Preparation: (Berberin)

1 mg of standard Berberin is weighed and 1 ml of methanol is added (1 ug/u)

Stationary phase: TLC al Silica gel 60F254 precoated plate.

Development chamber: CAMAG Twin through chamber for 10 x 10 cm plates with stainless steel lid.

Mobile phase: Ethyl acetate : acetone : formic acid : water

5 : 4.3 : 0.2 : 0.5

Tank saturation: not applicable

Development distance: 70 mm

Photodocumentation: 254 nm and 366 nm

Scanning wavelength: Using CAMAG scanning at 254 nm and 366 nm

Reporting of Results: Quantification of Berbetrin at 254 nm.
QUANTIFICATION OF CURCUMIN IN CURCUMA LONGA

U1 : CURCUMA LONGA : 40 ug
STD : CURCUMIN : 2 ug , 4 ug
U2 : CURCUMA LONGA : 80 ug
U3 : CURCUMA LONGA : 120 ug
U4 : CURCUMA LONGA : 160 ug
QUANTIFICATION OF BERBERIN IN DARU HARIDRA

Before derivatisation:
- ANCHROM DARU HARIDRA

Image (254 nm)

After derivatisation:
- ANCHROM DARU HARIDRA

Image (366 nm)

U1 : DARU HARIDRA SAMPLE : 100 ug
STD : BERBERIN : 2 ug
<table>
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<tr>
<th>Peak</th>
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<th>Start Height</th>
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<th>Max Height</th>
<th>Height %</th>
<th>End Rf</th>
<th>End Height</th>
<th>Area</th>
<th>%</th>
<th>Assigned substance</th>
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**Track 5, ID: Curcuma Longa : 120 µg**

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**Track 6, ID: Curcuma Longa : 160 µg**

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### Track 1, ID: Daru haridra : 100 µg

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<td>1.1</td>
<td>9978.9</td>
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### Track 2, ID: Berberin : 2 µg

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<tr>
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<td>0.24</td>
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<td>100.00</td>
<td>0.33</td>
<td>0.6</td>
<td>23603.5</td>
<td>100.00</td>
<td>Berberin</td>
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</table>
Spectra comparison

AU/1

200.0
250.0
300.0
400.0

nm
CLINICAL STUDY

"Pratyaksha Praman is the main Pramana to prove anything. Clinical observations and results the only truth as it is based on Pratyaksha" Dr. Lewis emphasis that alone is true which is proved clinically and that which is clinically proved needs no further evidence. Thus clinical drug evaluation is one of the most important field of medical research. The use and efficacy of drugs described in classical literature of Indian medicine is based on observations and experimentation. Also for wider applicability and acceptability of Ayurvedic principles and to explain rationality of Ayurvedic therapeutics, it is essential to carry out clinical trials.

Clinical Study Design

The Randomized single blind controlled clinical trials of Haridra and Daruharidra were conducted on 150 obese patients. (after withdrawal this number becomes 138) and their efficiency on these patients was assessed.

Patients attending out patients of medicine O.P.D. of Kaya Chikitsa Department of research center’s hospital, Pune were selected irrespective of age, sex, religion and profession. Patients either suspected or confirmed cases of Sthaulya (obesity) were screened for inclusion criteria and randomly divided into 3 groups as

46 patients in Gr “A” – Treated with Haridra,

46 patients in Gr “B” – Treated with Daruharidra,

46 patients in Gr “C” – Received placebo control group.

The duration of administration was 3 months.

All groups were advised same diet and exercise pattern. Effect of the drug was assessed by comparing with each other and with placebo.
Material and Methodology

Collection and Preparation of Drugs

The sample of dry rhizome of Haridra and stem-bark of Duruharidra which were identified by Taxonomists and which were standardized by chemical analysis were selected for the trials. These dried drugs were finely powdered and passed through the sieve (Mesh no. 120). These powders for easy administration were filled in vegetarian capsules of 1 gm. and 500 mgs. Capacity. For identification of their capacity their colours kept different as 1 gm capsules are of black-red coloured and 500 mg capsules are of yellow-black coloured.

Doses

1) **Group ‘A’** – 1 gm capsule & 2 & 500 mg capsule –1 (Total 2.5 gms X B.D.) 3 capsules twice a day.

2) **Group ‘B’** – 1 gm capsule – 2 & 500 mgs capsule –1 (Total 2.5 gms X B.D.) 3 capsules twice a day.

3) **Group ‘C’** – 1 gm capsule – 2 & 500 mgs capsule –1 (Total 2.5 gms X B.D.) 3 capsules twice a day.

Anupan

Capsules were taken along with Luke warm water.

Selection of patients: Patients were selected according to signs and symptoms of sthoulya. According to over nutrition condition(S.S. 10/5) can be diagnosed by inspection only and i.e. Pratyaksha praman. Apart from this pratyaksha pariksha Anuman Praiksha and Aptomadesha are another useful diagnostic methods which can be applied to diagnose sthaulya and its related symptoms (chs. Vi. 4/3) according to Ashtavidha Pariksha, Sthauyla can be determined by Akrtiti Pariksha (Rog Pariksha cha.1). Ayurvedic Pramana Pariksha and Samhonana pariksha can be correlated with objectives criteria of diagnosis like Anthropometry and Charak Samhita is pioneer to describe Anthropometry. So, in the present study besides Ayurvedokta pramana B.M.I. was considered for diagnosis and selection of patients of Sthoulya. Normal B.M.I. (Body Mass Index) This index more closely corresponds to measurements of
body fat and better differentiates ‘over weight’ due to an increase in muscle mass from true obesity.

Below 19kg/m² BMI is underweight; 20-25 kg/m² is normal and above it considered to be ‘obese’.

Inclusion Criteria

1) The patients with very low risk grade i.e. whose BMI is 20-25 kg/m² were selected.

2) The patients with low risk grade i.e. patients of BMI about 25-30 kg/m² were selected.

3) Patients of moderate risk i.e. having BMI 30 to 35kgs/ m² were selected.

BMI is calculated according to international BMI chart (nomogram by Bray) & Table created by Dr. J.J. Cursetii Of Orientle Life Insurance Company and risk grade according to W.H.O.’s risk classification and algorithm.

Exclusion Criteria

1) Patients with high risk grade those who were having B.M.I. between 35 to40 kgs/m² and very high risk grade B.M.I. above 40 kgs/m² were excluded from the study.

2) Patients with Diabetes Mellitus, Hypertension C.H.D. etc were excluded.

3) Pregnant and feeding women were excluded.

4) Patients suffering with severe infections illness, diseases like pneumonia, malignancies, Hepatitis were excluded from the study.

5) The root cause of obesity is genetics i.e. Beejswabhavaj, Sthoulya was excluded from the study.
PROCEDURE:

Permission of I.E.C.

Before starting the clinical trials the protocol was presented before institutional ethics committee of the research center and the hospital where the trials would have been conducted. The protocol was passed and permission for clinical trial was granted by the I.E.C. without any query.

Informed consent

Written informed consent was taken from each patient prior to the enrolment in the study as per the Helsinki declaration and W.H.O. guidelines.

Initial Screening

Patients either suspected or confirmed cases of obesity as per diagnosis of obesity would be initially screened to meet at the inclusion criteria. Their height in meters and weight in kilograms were measured by measuring tape and weighing machine & B.M.I. was calculated.

Baseline assessment

This was included a detailed history including family history, personal history, habits such as smoking, tobacco, alcohol etc. exercise history clinical examination including all strotas pariksha was carried out. Following lakshanas exhibited by the patients were assessed after the treatment.

1. Chala sphik stana udaram-
2. Swedadhikya
3. Atikshudha
4. Atipipasa
5. Javoprodha, Durbalya
6. Atinidra
7. Angagaurava
8. Kshudrashwasa
9. Daurgandhya
10. Gatrasada
The gradation was

Nil = 0
mild = +(1)
Moderate = ++(2)
Severe = +++(3)

Measurement of fat

It was carried out by using Herpendis skin fold caliper. It was measured at

1. Triceps skin fold thickness
2. Subscapular skin fold thickness.
3. Mild upper arm skin fold thickness.
4. Supra iliac thickness

Also circumferences of body were measured with the help of measuring tape as:

1) Waist circumference
2) Hip circumference
3) Abdominal girth

Investigations

The following investigations were done before and after treatment of a) Hb %

b) Lipid profile
i) Total Cholesterol
ii) HDL Cholesterol
iii) LDL Cholesterol
iv) VLDL Cholesterol
v) Serum tri glycerides
Assessment of subjective criteria

Baseline parameters presence of clinical features of Sthaulya were guarded as

1) Chala Sphik Stana Udara

Examined by “Darshan Pariksha”

- absence of movement = nil (1)
- chaltwa after fast movement = +(1)
- chaltwa after moderate movement = ++ (2)
- chaltwa after every mild movement = +++ (3)

2) Swedadhikya : By Prashna Prariksha

- At normal temp. in normal condition – nil (0)
- Sweating after moderate work = +(1)
- Sweating after little work = ++(2)
- Sweating even in resting condition = +++(3)

3) Atikshudha – Prashna pariksha

- these gradation done on the basis of food, aharkala, Jaranshakti and Satiety.

4) Atipipasa – Prashna pariksha

- Average of 2 litrs. water intake in 24 hours – 0
- More than 3 litrs. +(1)
- More than 4 litrs = ++(2)
- More than 5 litrs = +++(3)
5) **Daurbalya – By Prashna pariksha – no gradation**

- Absent
- Present

6) **Kshudra shwasa – Darshan and prashna pariksha)**

- Dyspnoea after heavy work = Nil
- Dyspnoea after moderate work = 1
- Dyspnoea after slight work = 2
- Dyspnoea even after resting = 3

- Angagaurava Atinidra, Krathan, Angashaithilya (saad) these parameters are examined by Prashna Pariksha noted as present or absent.

- Javoprodha, Angashaithilya, Snigdha gatrata, maladhyata etc symptoms were examined by Prashna and darshan Pariksha and noted as present or absent.

**Assessment of Body Mass Index**

For calculation of B.M.I. formula used is  

\[
\text{BMI} = \frac{\text{Body weight (kg.)}}{\text{Square of height (mtr.)}}
\]

Normal B.M.I. is = 18-23 kg/m² for males and 19-25 kg/m² for females.

Above 23 kg/m² as obesity for men.

Above 25 kg/m² as obesity for women.

**Criteria for Assessment :**

- Minimum reduction in weight by 5 kg in the given period i.e. 3 months as per W.H.O’s criteria for obesity.
- Ayurvedic parameters based on symptoms assessed before and after treatment.
- Lipid profile tests and Hb% test were assessed before and after treatment.
• Assessment of the effects of the drugs was done by considering the frequency, percentage mean, S.D. and S.E of subjective parameters with z test.

• To compare the treatment effect of Haridra and Dariharidra with placebo Analysis of Variance (ANOVA) technique i.e. single factor was applied.

Placebo administration

46 patients were recruited for group ‘c’ treating with placebo. Fine powder of fried Amaranth seeds (ie. Rajgira Lahi) was filled in capsules which resemble in size and colour so that of capsules of other two drugs.

Placebo administered in a dosage of 3 caps BD (2 capsules of 1 gm each and 1 capsule of 500 mg) along with warm water (caloric value of placebo drug is 100 mg / 100 gms. Kcal and it is very minimal to increase or decrease weight.)

Same diet and exercise pattern was applied for this group.

Follow up

Patients were followed up at 30 days interval at the follow up time along with measuring their weight anthropometrical index. Fasting samples was drawn for complete lipid profile and Hb% and parameters were assessed only before and after the treatment. Clinical assessment was made at each visit.

Same diet pattern and exercise was advised to each patient of all groups.

Dietary management

Diet plays an important role in the prevalence of obesity. Nutrition is (in addition to genetics), probably the single most important stimulus to changes in adipose mass and its cellular components. The mechanism of the marked stimulatory effect of the high fat diet on lipid accumulation and enlargement of fat cells is not yet totally elucidated. It may reflect adaptive hormonal changes adaptive enzymatic changes or simply the greater efficiency of fuel storage in the form of lipid if predominant dietary component is fat, as compared with carbohydrate or protein.

It has been shown that a high fat diet reduces fatty acid synthesis from glucose in fat cells. This is not surprising since one would expect that greater availability of
Free fatty acids (FFA) from circulating lipids and lipoproteins may suppress de novo fatty acid synthesis in adipocytes.

Rapid weight loss should be discouraged even though it is what every obese patient wants. If weight loss is rapid, not only the fat metabolism but also the muscles and liver are depleted. Water and sodium diuresis accompanies it.

Diet plan was prepared for the patients by matching calories consumption with his most active hours by which he will burn calories more efficiently as he refuels early in the day with a low fat meal. Late night eating must be avoided. Metabolic needs are lowest at night; Calories consumed are then tend to be stored as fat. Total cut out of fats is not expected in the diet regimen. Even this dietary villainia as a virtue, it gives the body satiety. For obese person, the best diet is that which contains all the normal ingredients of food but cuts down only the total calories. It has been shown that weight loss is more successful in the patient who take their diet as multiple meals than in those who take the same intake in one or two meals per day.

Diet containing liberal amounts of salads, fresh fruits and vegetables, dietary fibers such as whole grain cereals is advisable. The bulk of vegetables and fruits containing few calories but high cellulose help to fill the stomach and relieves hunger, minimizes the constipation and provides Vit. A and Vit. C content to meet the body’s needs.

In pathogenesis of obesity there is imbalance between energy income and expenditure. Generally patients were taking high caloric food than their requirement. So patients were advised hypocaloric diet according to their daily requirements generally food having 1400 to 1800 Kcal. Depending on their body wt. And energy expenditure care was taken when giving diet chart to see that it

1) Provides the minimal daily requirements of nutrients.
2) Taking into account unchangeable conditions (age, race, sex).
3) Adapting to mode of physical exercise and mark schedule.
4) It would be pleasant and palatable maintaining the nutritional value of the food.
5) Avoid absolute prohibition and fasts accepting the fact that there are no bad foods but the abuse of some of the food results in metabolic disorders like hyperlipidemia obesity etc. Patients were not prohibited from taking any food. Strictly but advised reduction of energy dense food such as fat sugar, oil since total prohibition often induces starving that may worsen the eating behavior.

Exercise Pattern

The role of exercise alone in the treatment of obesity is controversial. As exercise results in further increases in energy expenditure increases the appetite which may hinder the diet compliance failing to demonstrate significant weight reduction. (Ref* Richard Cottrell 1995 wt. Control’ the current perspective published by Chapman and Hall, 2-6 London)

Exercise can modified body composition enhancing muscular mass and therefore preventing fall in resting metabolic rate (RMR) that usually accompanies a loss of fat. Patients of all groups were advised 2 km walk every day during the course of treatment.

The role of exercise

The weight reduction by itself can improve the physical work capacity and metabolic complication associated with obesity, it is not clear to what extent physical training contributes to the benefit effects of weight reduction.

Some studies has shown that physical exercise,

- Accelerates the rate of weight loss
- An effect on body composition by increasing the loss of adipose tissue and minimizing the amount of body cell mass.

Metabolic effects manifested by a greater,

a) decrease in insulin level
b) increase in insulin sensitivity
c) improved physical work capacity

Hence, in this study patients were advised minimum 3 kms walk everyday during the course of treatment.