CHAPTER NO. VIII

METHODOLOGY

1. CASE SELECTION
2. MODE OF ADMINISTRATION OF DRUG
3. SCREENING ANALYSIS
CHAPTER NO. VIII

1. CASE SELECTION

The present study was undertaken with the guidance of Dr. S. H. Holkar & main supervision of Dr. S.P. Sardeshmukh, Director of Ayurved Hospital and Research Centre; Wagholi, Dist. Pune. The trial conducted at our own hospital i.e. Dr. Chavan Hospital & Research Centre which also registered under Indian Council of Medical Research, New Delhi; to find out the role of व्याधिशुचित्य & Health. The trial conducted were as follows:

**Adult Group**: A study of 100 patients out of 160 attending the O.P.D. & our regular follow-up at above centre.

Out of 160 patients; only 100 patients enrolled and randomized for trial who were attending the centre as per our scheduled follow up. Finally, we calculate the sample size at its minimum, around 50 patients in each arm.

**Children Group**: A clinical data of 30 over protected children (control group X) at Chiranjiv Hospital, conducted by Dr. Suchit Tamboli, Pediatrician, is taken up with the knowledge of their health & prone to illness.
I have taken two groups of Children:

i) Medically protected: children who had their immunization as per schedule & their minor complaints are attended by the pediatrician (Group X).

ii) Medically Unprotected: Those due to poverty and lack of education unable to immunization unless it or free by same social institution. Their minor health complaints are not considered; till it takes some serious mode.

This phase II randomised, comparative, double-blind, two-arm Out-Patient Clinical trial is designed to determine the immuno modularity and comparative efficacy of Phyllanthus Emblica (Amalaki) with respect to धातु सार परिक्षण; Very well illustrated by Charak in Viman Sthan Adhyay No. VIII sutra No. 103 to 113.

The safety and prophylactic importance of Phyllanthus Emblica in Vyadhi-Kshmatva naive only adult patients are evaluated. The patients are administered Phyllanthus Emblica for 24 weeks duration and observed for another 24 weeks to assess the slow (may be) but assured response.

As the Research is mainly related with immuno-modulatority manifestation; first & foremost thing is to know about the individual haemogram stage & weight loss, so that one can understand the various effects of responsible factors.

The proforma prepared according to sings and symptoms (Lakshanas); which are regarding to Ayurvedic concept to the functions of mainly of Dhatus.

Pre-entry screening evaluation for clinical status assessment, ascertainment of Haemogram and weight four days before induction in the study have performed; Only the eligible subjects have enrolled and randomized for treatment.
Children analysis according to frequency of illnesses

(Total Cases: 60)

i) Over protected children-group X (Total Cases: 30)

ii) Unprotected children-group Z (Total Cases: 30)

Master's Chart of Group X

<table>
<thead>
<tr>
<th>Age Group</th>
<th>0 - 5</th>
<th>6 - 10</th>
<th>11 - 15</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1 to 1½</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>B</td>
<td>1½ to 2</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>C</td>
<td>2 to 2½</td>
<td>6</td>
<td>23</td>
</tr>
<tr>
<td>D</td>
<td>2½ to 3</td>
<td>7</td>
<td>20</td>
</tr>
</tbody>
</table>
Procedure:

(A) The patients at Out Patients Department were selected on random basis having common complaints of indigestions, fatigue and debility, irrespective of Prakruti, Occupation, Sex and Age.

(B) A detail history of every patient regarding the complaints and its duration was noted and a thorough clinical examination was done.

(C) Haemogram and accurate weight of every patient was done and after every 8 weeks also.

(D) Ayurvedic index for quality of health regarding the concept of Vyadhi-Kshamta and according to the functions of Dhatu.

\[ \text{i.e. द्रीणां जीवनं लेयः स्वेदों धारणपूर्णा।} \\
\text{गर्भोत्पादयं धातुर्लां श्रेष्ठं कर्म क्रमान्तर्गतं।} \]

\text{अ. ह. सृष्ट्यान्त अध्याय ११}

and also as per described in Charak Vīman Sthan Adhyay VIII Sutra No. 103 to 113. ---- (Dhatu Sarata X Nissarata)

(E) Some dietary restrictions were advised to the patients. (i.e. avoid Tobacco, Alchohle etc.)

(F) Regular follow-ups of the patients and observations were recorded.
An examination of Adult

An examination of Child
2. MODE OF ADMINISTRATION OF DRUG

Ayurveda is mainly concerned with proper digestion (आग्नि) and absorption in view of *Vyadhi - kshamātva*. So that, all seven dhatus are able to nourish the body properly and this will happen only when “Agni” (Entity for proper digestion) is functioning well. The lack of digestion “Agni - mandya” will lead to various disorders (Vyadhi) thus provoking disfunction of the body (Dhatu) mechanism which in turn will accelerate the Catabolic process.

All “Vyadhi” signs appears because catabolic rate is more than anabolic rate. The catabolic process can be accelerated by improper intake of food, drink and erratic life-styles; mental stresses, anxiety and physical strains etc.
I, here, locating in Industrial Area, majority of patients have to work changing (Day-Neight) shifts/duties, which furtherly causes “Agni-Mandya” and it is also related with elimination of waste products.

So that, not to produce toxins and provoking all kinds of Vyadhi/diseases. For proper digestion & absorption (anabolism) & for proper cleansing or elimination of waste products, I prefer **Phyllanthus Emblica (Amalaki)**.

Administration of Phyllanthus Emblica (Amalaki) powder / churn is not associated with any side-effects. Therefore a phase II placebo controlled trial was being proposed to study immuno-modulatory manifestation and effect of Phyllanthus Emblica (Amalaki) on weight gain in preferably and the improvement (Dhatu-Sarata) in quality of life, which promotes the Vyadhi-Kshamatva.

The drug - Phyllanthus Emblica (Amalaki) have procured from Vedic Herbles Pvt. Ltd.; Regd. Company No. 16998/1996 at Mumbai; which obtain from our own farm of 47 acres consisting 3,500 plants of Amla.

Appropriate placebo formulation had procured from a pharmaceutical company or as above.

**Study Treatment :**

**Drug Regimen**

**Arm 1 :** Controlled Group :
Phyllanthus Emblica (आमलकी) powder - 1 Teaspoonfull (approximately 5 gm.) with घृत on empty stomach in the morning per day for 24 weeks/6 months.

**Arm 2 :** Placebo :
Jawar जवारी powder - 1 Teaspoonfull on empty stomach in the morning per day for 24 weeks/6 months.
During Treatment:

The following observations were made during the treatment.

(a) Clinical evaluation of the patients was done weekly an inquiry in to the subsidence of the presenting complaints and the well being of the patients in accordance to Ayurvedic index of Dhatu-sarata.

(b) Accurate physical weight was done two weekly.

(c) A Complete haemogram of majority patients was done at the end of every two months, since started the treatment, means three times in the period (6 months) of clinical trials.

(d) A follow-up of the patients, majority patients who reported increase in mean percent weight gain, using the criteria of improvement in clinical conditions as well as Ayurvedic Index for Dhatu sarata, were declared comparatively Vyadhi-Ksham at the end of the period of treatment.
CHAPTER NO. VIII
3. SCREENING ANALYSIS OF ADULT GROUP

A] Analysis according to Age (Total Cases : 100)

1) Majority of the patients (total 55) were between the age (A) group of 20 to 35 years. The percentage is 55%

**Table & Graph No. 1**

<table>
<thead>
<tr>
<th>Group</th>
<th>Group of Age</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>5-20</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>A</td>
<td>20-35</td>
<td>55</td>
<td>55%</td>
</tr>
<tr>
<td>B</td>
<td>35-50</td>
<td>30</td>
<td>30%</td>
</tr>
<tr>
<td>C</td>
<td>50-65</td>
<td>15</td>
<td>15%</td>
</tr>
<tr>
<td>X</td>
<td>65-80</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>
B) Adults Screening according to Vat - Pitta dosha

Total Cases : 100

i) Trial Group : Arm 1 : (Total Cases = 50)

ii) Placibo Group : Arm 2 : (Total Cases = 50)

according to Vat - Pitta dosha constitutional adults are more predominant.

**Table & Graph No. 2**

<table>
<thead>
<tr>
<th>Arm 1</th>
<th>Arm 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amalaki Group</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

| Placibo Group |
| 4   |
| 5   |
| 6   |
| 7   |

<table>
<thead>
<tr>
<th>Prakriti</th>
<th>Vata</th>
<th>Pitta</th>
<th>Kapha</th>
<th>Vata Pitta</th>
<th>Vata Kapha</th>
<th>Pitta Kapha</th>
<th>Shirodosh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prakriti</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Arm : 1</td>
<td>3</td>
<td>9</td>
<td>4</td>
<td>18</td>
<td>11</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Arm : 2</td>
<td>8</td>
<td>7</td>
<td>8</td>
<td>10</td>
<td>9</td>
<td>6</td>
<td>2</td>
</tr>
</tbody>
</table>
Clinical & Laboratorical Evaluations:

**Clinical Assessment:**
Specifically Rakta - Dhatu - Nissar Subjects evaluation have performed for: Physical examination

- Medical history
- Assessment for रक्तद्वारू हत्ती लक्षणालि

as required for Rakta - Dhatu - Nissarata along with Ayurvedic Index.

**Laboratorical Assessment:**
- Haematology: CBC with differential count
- Monitoring have performed at every 8 weeks by recording Haemoglobin count and White Blood Cells perfection regarding normal ratio.

- The findings of Laboratorical evaluations are very satisfactory; but could not be demonstrated in statistical considerations.
D) Analysis according to Dhatu Nissarata:
Total No. of Cases : 100
Group : Dhatu Nissarata : Percentage.

Table & Graph No. 3

<table>
<thead>
<tr>
<th>Group</th>
<th>Ras i</th>
<th>Rakta ii</th>
<th>Mans iii</th>
<th>Med iv</th>
<th>Asthi v</th>
<th>Majja vi</th>
<th>Shukra vii</th>
<th>Satva viii</th>
</tr>
</thead>
<tbody>
<tr>
<td>A = 55</td>
<td>7</td>
<td>8</td>
<td>10</td>
<td>4</td>
<td>9</td>
<td>6</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>B = 30</td>
<td>3</td>
<td>5</td>
<td>6</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>C = 15</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>--</td>
<td>2</td>
</tr>
<tr>
<td>100%</td>
<td>11</td>
<td>15</td>
<td>18</td>
<td>10</td>
<td>17</td>
<td>10</td>
<td>11</td>
<td>8</td>
</tr>
</tbody>
</table>
E) Statistical Considerations : General Design issue:
This comparative study have begin as a randomised double-blind Phase - II placebo controlled clinical trial of *Phyllanthus Embilica* amongst Dhatu - Nissarata.

So, advanced stages of the Rakta - Dhatu - Nissarata, Mansa - Dhatu - Nissarata, and Asthi - Dhatu - Nissarata have considered as inclusive Criteria for Arm : 1.

And remaining exclusive criteria cases have considered for Arm : 2 as placebo.  

Sample Size : 50 cases in each Arm

**TABLE & GRAPH NO. 4**

<table>
<thead>
<tr>
<th>Ras</th>
<th>Rakt</th>
<th>Mans</th>
<th>Med</th>
<th>Asthi</th>
<th>majja</th>
<th>Shukra</th>
<th>Satva</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm 1:</td>
<td>--</td>
<td>15</td>
<td>18</td>
<td>--</td>
<td>17</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Arm 2:</td>
<td>11</td>
<td>--</td>
<td>--</td>
<td>10</td>
<td>--</td>
<td>10</td>
<td>11</td>
</tr>
</tbody>
</table>

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F) EVALUATION : FREQUENCIES OF ILLNES
ACCORDING TO RUTU (आरू)

(Total No. of Cases : 100)
i) Trial Group : Arm 1 : (Total Cases - 50)
ii) Placebo Group : Arm 2 : (Total Cases - 50)

According to Rutu : During Grishma Rutu the incidence of illness is increased.

Table & Graph No. 5

<table>
<thead>
<tr>
<th></th>
<th>शिशि</th>
<th>वसंत</th>
<th>ब्रीष्टि</th>
<th>वर्षा</th>
<th>शरद</th>
<th>हेमंत</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm - 1</td>
<td>5</td>
<td>8</td>
<td>17</td>
<td>10</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Arm - 2</td>
<td>11</td>
<td>7</td>
<td>14</td>
<td>4</td>
<td>8</td>
<td>6</td>
</tr>
</tbody>
</table>
G) Monitoring and Analysis
Interim monitoring have performed at every 8 weeks and at 24 weeks call the trial off.
Monthly summary reports of the cases actual, patient status, Adverse signs & symptoms and laboratory abnormalities were recorded.
Gain in weight more than 6 Kgs. at 24 weeks of cases calculated as:
**Excellent Response** : Cases No : 5 * 10%
Gain in weight more than 4 Kgs. at 24 weeks of cases calculated as:
**Good Response** : Cases No. 36 * 72%
Gain in weight more than 2 Kgs. at 24 weeks of cases Calculated as:
**Moderate Response** : Cases No. 9 * 18%
Exclusive Criteria was adopted for **Arm : 2 Cases [Placebo]**

**Table & Graph No. 6**

<table>
<thead>
<tr>
<th>RESPONSE</th>
<th>Excellent</th>
<th>Good</th>
<th>Moderate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases in No. of Arm 1</td>
<td>5</td>
<td>36</td>
<td>9</td>
</tr>
<tr>
<td>Percentage</td>
<td>10%</td>
<td>72%</td>
<td>18%</td>
</tr>
</tbody>
</table>

![Graph showing percentages of Excellent, Good, and Moderate responses]

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CHAPTER NO. VIII

4. MULTIDISCIPLINARY OBSERVATIONS OF ADULT GROUP

Here attempt is made to manage conservatively:

1* Appetite was increased from the Second week and maintained during remaining part of period of treatment and withdrawal of treatment also.

2* Complaint of Fatigue was reduced from 2nd Week.

3* Complaint of debility reduced from 3rd Week.

4* Industrial - shift service cases/patients were having more incidence of "Agni-mandya" and consequently of Dhatvagni-Mandya;

In these cases, total effect of Phyllanthus Emblica stands moderately useful in correcting problem of digestive disorders conservatively.
CHAPTER NO. VII
H. MULTIDISCIPLINARY OBSERVATIONS.

This comparative study have begin as a randomised double-blind, Phase II, placebo controled clinical trial of Phyllanthus Emblica amongst Dhatu - Nissar.

So, advanced cases with mean symptom score of Anorexia, Fatigue, Debility at weekly intervals [for one month] after treatment.

Amalaki Churna : Arm - 1 0 0
Placebo : Arm - 2 0 0

CONCLUSION : Amalaki Churna (Arm - 1) has an edge over (Arm - 2), as it reduces the symptoms score faster.