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Randomized Open Controlled Clinical Trial to Evaluate the Effect of *Patol Shunthi Ghruth* in *Urdhwag Amlapitta*.

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ABSTRACT:

Amlapitta is a life-style related disease prevalent all over the world. *Amlapitta* is disorder caused by habitat, irregular diet schedule and activities but also as a result of Psychological and physiological observation. *Amlapitta* is a common functional disease of *Annavaha srotas*. Materialistic life style provokes people to run behind a busy, stressful life which is least concern towards proper food habits. As the life is becoming very fast and the rate of urbanisation is growing. *Adhyashana* (eating after meal), *Vishamashana* (diet on irregular time and quantity), and wrong behavioural patterns such as *Vegadharana* (suppression of urges) leads to vitiation of *Doshas*. *Pitta* has been vitiated, junk food and drink that are incompatible, spoiled, and very sour and that is capable of causing vitiation of *pitta* and increase *drava* and *amla guna* of *pitta*.

Keywords:- *Amlapitta*, *Annavaha srotas*, *Adhyashana*, *Vishamashana*, *Vegadharana*

INTRODUCTION

Amlapitta is composed of two words *Amla* + *Pitta*. The term *Amla* refers to a particular type of taste equated with sour taste which causes excessive salivary secretion. *Pitta* is a bodily chemical substance which is mainly responsible for the maintenance of the process of digestion. *Acharya Charaka* has not described *Amlapitta* separately. But while describing the *samprapti* of *Grahaniroga*, he has mentioned *Amlapitta* as a disease produced due to *Agnimandhya* and *Annavisha*¹. It is believed that *Agnimandya* (indigestion) is the root cause of all the diseases². The major reason behind *Agnimandya* is faulty dietary habits such as *Adhyashana* (eating after meal), *Vishamashana* (diet on irregular time and quantity), and wrong behavioural patterns such

as *Vegadharana* (suppression of urges) leads to vitiation of *Doshas* (fundamental bodily bio-elements) either independently or synonymously.² Due to the present lifestyle and unawareness of one's *Prakriti*, digestive disorders are very common in all age groups and also highly ignored issues. In recent years the number of sufferers are becoming more and the several formulations have been tried on various aspects of *Amlapitta*.³ Still, we are not having a definite cure for the disease. So this study is carried out to assess the effect of *Patol Shunthi Ghruth* In *Urdhwag Amlapitta*.

AIM

“The Randomized Open Controlled Clinical Trial to



evaluate the effect of *Patol Shunthi Ghruth* in *Urdhwag amlapitta*.”

Primary Objectives:-

To study the effect of *Patol shunthi ghrut* in *urdhwag Amlapitta*.

MATERIALS AND METHODS

Source of data:

100 patients attending the OPD and IPD of Kaya Chikitsa dept of Yashwant Ayurvedic Medical College, Kolhapur were selected for the study and divided equally in 2 group (Group A- *Patol shunthi ghrut* 10 gm before meal with warm milk twice a day and Group B- *sudhakar churna* 2.5 gm after meal with *narikel jal* twice a day). Detailed clinical examination was done prior to the treatment.

Method of collection of data:

Patients were screened and selected based on the screening form prepared for the said purpose. A case report form was prepared with all points of history taking, physical signs and symptoms of *Amlapitta*. The selected patients were subjected to detail clinical history and complete physical examination before undergoing the clinical study.

Research Design:

Randomized, open labelled, active controlled clinical study was carried out in two groups with sample size of 50 patients in each group.

Inclusion criteria

- 1) Patients showing the symptoms of *Urdhwag Amlapitta* were selected for the study.
- 2) Age group – 20 year to 60 years
- 3) Gender – Irrespective of Gender

Exclusion criteria

Patients suffering from chronic disease such as

- Hiatus hernia
- Gastric ulcer
- Diabetes
- IHD’s chemotherapy and major operative procedures etc.were excluded
- Gall bladder stone (Cholecystitis)

Operational Definition –

Grading & Scoring

For symptoms –Subjective parameters were considered
For Signs – Appropriate clinical parameters were considered.

Matching criteria:

The observation before and after treatment in each group i.e. Group A & Group B were taken. Then observation of both the groups was compared with each other.

Grading & scoring for symptoms and signs Follow up : Table 1

Assessment of clinical Results

Detail Clinical observation was done on 20th day for assessment of result. The final data were divided in 4 groups Table 2

Withdrawal Criteria

- 1) If patients having any complication during study.
- 2) Those patients who left the treatment before advised duration or who didn’t followed instruction about the study were withdrawn.

OBSERVATION AND RESULT

The effects of the therapy in 100 patients are being shown here for statistical analysis Wilcoxon Signed Rank test, Mann-whitney test were done to assess the signs and symptoms as parameters to interpret the time of significant change.

Subjective Parameters by Wilcoxon Singed Rank test Table 3

Subjective Parameters by Mann Whitney’s Test Table 4

Both the group show difference in the condition regarding the symptoms of patients and marked improvement were observed in both the Group A and Group B, while analysed with **Wilcoxn Sigh Rank Test** and when both the groups were compared with **Mann Whitney’s Test** it was noted that the group A patients shows better result than group B patients.

The Total Effect Of Therapy Table 5

The total effect of therapy is evaluated by taking relief in percentage of each patients in both the groups and were observed that the maximum no of patients belong to moderate improvement and than in mild improvement group. On the other hand it was noticed that Group A patients are more in Good improvement group as compare to the Group B.

DISCUSSION

Probable mode of action of drug

*Patol shunthi ghrut*⁴ is sweet, astringent in taste, light, irritant in nature, cool property, cooling energy of substance.⁵ It has *Madhura Vipaka* (sweet post digestive

effect), vitiated *Pitta-Kapha*,⁶ Stomachic and digestive process of un-metabolised food, analgesic and anti-inflammatory properties By virtue of its taste and properties;⁷ it pacifies aggravated *pitta* and thereby improves the digestion and metabolism.⁸ *Patol shunthi ghrut* helps in reducing the aggravated *Pitta Dosha*, stabilizes the state of *Agni*, helps in *Ama Pachana* (digestion of unmetabolised food), pacifies *Vidagdhajirna* and thereby improves digestion, absorption and assimilation, thus relieving the symptoms of *Amlapitta*.^{9,10}

CONCLUSION

Amlapitta is a life-style related disease and caused by habitat, irregular diet schedule and activities but also as a result of Psychological and physiological observation. *Amlapitta* is a common functional disease of *Annavaha srotas*. *Agnimandya* (indigestion) is the root cause of all the diseases. The major reason behind *Agnimandya* is faulty dietary habits such as *Adhyashana*, *Vishamashana*, and wrong behavioural patterns such as *Vegadharana* leads to vitiation of *Doshas*. During this study it was observed that *Pitta* has been vitiated and that is capable of causing increase *drava* and *amlaguna* of *pitta*. To give a better solution for this vitiated *pitta* this study was planned and carried out. In view of observations and statistical analysis, we concluded that *PatolShunthi Ghrut* showing significant results than *Sudhakar Churna* in the management of *Urdhwag Amlapitta*.

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Table 1 Shows Grading & scoring for symptoms and signs Follow up :

| <i>Lakshan</i> | No(0) | Mild(1) | Moderate(2) | Severe(3) |
|----------------------------------|-------------------|---|---|---|
| <i>Aruchi</i> | Normal Apetite | Unweiling to take food but eat | Intake of food decreases | No interest to take food |
| <i>Vaman</i> | Absent | Feeling nausea | Occasionally present | Regular vama na |
| <i>Shiroruja</i> | Absent | Occasionally present | Present most of the time | Always present |
| <i>Tiktamlodgar</i> | Absent | Occasionally Present after lunch or dinner | Present most of the time after lunch or dinner | Always present |
| <i>Hridakukshika nthdaha</i> | Absent | Mild Daha present | Madhayam Daha which mitigated by vaman or intake of milk | Severe Daha which cannot mitigated by vama na |
| <i>Timir Darshan</i> | Absent | Occasional Tama darshan for short | Frequent tama darshan for small duration leads to bhram | Frequently tamadarshan for longer duration |
| <i>Murcha</i> | Absent | Murcha only after exertion lasting for few seconds | Murcha without any exertion lasting for few minutes the patient can stand or walk slowly | Murcha without any exertion the patient cannot stand ,walk or even can't seat on the bed due to the fear of fainting |

Table 2 Detail Clinical observation was done on 20th day for assessment of result. The final data were divided in 4 groups

| Sr.No | Symptoms | 0 day | 7 th day | 14 th day | 21 st day |
|-------|-----------------------------|-------|---------------------|----------------------|----------------------|
| 1 | <i>Aruchi</i> | | | | |
| 2 | <i>Vaman</i> | | | | |
| | <i>Shiroruja</i> | | | | |
| 4 | <i>Tiktamlodgar</i> | | | | |
| 5 | <i>Hridakukshikanthdaha</i> | | | | |
| 6 | <i>Murcha</i> | | | | |
| 7 | <i>Timir Darshan</i> | | | | |

Table 3 Subjective Parameters by Wilcoxon Singed Rank test

| Symptoms | Group | BT/AT | N | Mean | SD | W | P |
|----------------------------------|---------|-------|----|-------|-------|------|---------|
| <i>Hridakukshikanthda ha</i> | Group A | BT | 50 | 2.600 | 0.495 | 1275 | P<0.001 |
| | | AT | 50 | 0.820 | 0.482 | | |
| | Group B | BT | 50 | 2.440 | 0.501 | 1275 | P<0.001 |
| | | AT | 50 | 0.940 | 0.620 | | |

| Symptom | Group | BT/AT | N | Mean | SD | W | P |
|--------------|---------|-------|----|-------|-------|------|---------|
| <i>Timir</i> | Group A | BT | 50 | 2.780 | 0.418 | 1275 | P<0.001 |
| | | AT | 50 | 0.880 | 0.435 | | |
| | Group B | BT | 50 | 2.620 | 0.490 | 1275 | P<0.001 |
| | | AT | 50 | 0.980 | 0.428 | | |

| Symptom | Group | BT/AT | N | Mean | SD | W | P |
|---------------------|---------|-------|----|-------|-------|------|---------|
| <i>Tiktamlodgar</i> | Group A | BT | 50 | 2.760 | 0.431 | 1275 | P<0.001 |
| | | AT | 50 | 0.840 | 0.468 | | |
| | Group B | BT | 50 | 2.480 | 0.505 | 1275 | P<0.001 |
| | | AT | 50 | 0.900 | 0.463 | | |

| Symptom | Group | BT/AT | N | Mean | SD | W | P |
|---------------|---------|-------|----|-------|-------|------|---------|
| <i>Murcha</i> | Group A | BT | 50 | 2.880 | 0.328 | 1275 | P<0.001 |
| | | AT | 50 | 0.940 | 0.470 | | |
| | Group B | BT | 50 | 2.600 | 0.495 | 1225 | P<0.001 |
| | | AT | 50 | 0.980 | 0.515 | | |

| Symptom | Group | BT/AT | N | Mean | SD | W | P |
|---------------|---------|-------|----|-------|-------|------|---------|
| <i>Aruchi</i> | Group A | BT | 50 | 2.940 | 0.240 | 1275 | P<0.001 |
| | | AT | 50 | 0.920 | 0.488 | | |
| | Group B | BT | 50 | 2.960 | 0.471 | 1275 | P<0.001 |
| | | AT | 50 | 0.960 | 0.533 | | |

| Symptom | Group | BT/AT | N | Mean | SD | W | P |
|------------------|----------------------|-------|----|-------|-------|------|---------|
| <i>Shiroruja</i> | Group A | BT | 50 | 2.800 | 0.404 | 1275 | P<0.001 |
| | | AT | 50 | 0.840 | 0.650 | | |
| | Group B shiroruja | BT | 50 | 2.580 | 0.499 | 1275 | P<0.001 |
| | | AT | 50 | 0.900 | 0.416 | | |

| Symptom | Group | BT/AT | N | Mean | SD | W | P |
|---------------|---------|-------|----|-------|-------|------|---------|
| <i>Chardi</i> | Group A | BT | 50 | 1.820 | 0.388 | 1176 | P<0.001 |
| | | AT | 50 | 0.880 | 0.558 | | |
| | Group B | BT | 50 | 2.600 | 0.495 | 1275 | P<0.001 |
| | | AT | 50 | 0.920 | 0.601 | | |

Table 4 Shows Subjective Parameters by Mann Whitney’s Test

| Symptoms | Group | N | Mean | SD | U | P |
|--------------------------|---------|----|------|-------|-------|---------|
| <i>Timir darshan</i> | Group A | 50 | 1.9 | 0.647 | 997 | P=0.043 |
| | Group B | 50 | 1.64 | 0.485 | | |
| <i>Hrid-kantha daha</i> | Group A | 50 | 1.78 | 0.708 | 973 | P=0.037 |
| | Group B | 50 | 1.5 | 0.763 | | |
| <i>Tikta –Amla udgar</i> | Group A | 50 | 1.92 | 0.601 | 896.5 | P=0.005 |
| | Group B | 50 | 1.58 | 0.538 | | |
| <i>Murcha</i> | Group A | 50 | 1.94 | 0.512 | 911.5 | P=0.006 |
| | Group B | 50 | 1.62 | 0.635 | | |
| <i>Aruchi</i> | Group A | 50 | 2.02 | 0.515 | 926 | P=0.009 |
| | Group B | 50 | 1.72 | 0.64 | | |
| <i>Shiroruja</i> | Group A | 50 | 1.96 | 0.638 | 970 | P=0.027 |
| | Group B | 50 | 1.68 | 0.551 | | |
| <i>Chardi</i> | Group A | 50 | 1.94 | 0.62 | 942 | P=0.016 |
| | Group B | 50 | 1.68 | 0.683 | | |

Table 5 Shows THE TOTAL EFFECT OF THERAPY

| Sr. No. | Improvement | No of Patients | | Percentage | |
|--------------|---|----------------|-----------|-------------|---------|
| | | Group A | Group A | Group A | Group A |
| 1. | Good Improvement (75% - 100%) | 14 | 08 | 28.00 % | 16.00% |
| 2. | Moderate Improvement (50% - 75%) | 30 | 31 | 60.00 % | 62.00% |
| 3. | Mild Improvement (25% - 50%) | 06 | 11 | 12.00 % | 22.00% |
| 4. | Unchanged (No Improvement) (0% - 25%) | 00 | 00 | 00.00 % | 0.00% |
| Total | | 50 | 50 | 100% | |