EFFICACY OF DHATRI AVALEHA IN PANDU (NUTRITIONAL ANAEMIA) – AN OPEN END RANDOMIZED CLINICAL TRIAL

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Abstract

Pandu roga (anaemia) is characterized by panduta (pallor) of nayana (eyes), nakha (nails), twak (skin), associated with mandagni (reduced appetite), daurbalya (weakness), arohanayasa (dyspnoea on exertion), in severe conditions it results in deterioration of asta vidha sara (excellency of dhatus), alpa rakta (less blood), alpa medas (less fat) etc. Dhatri avaleha is an Ayurvedic formulation mentioned in Charaka samhita for the treatment of pandu roga. Current study was carried out with the objective of assessing the efficacy of amapachana and dhatri avaleha on 30 patients of pandu roga (nutritional anaemia). Patients were selected by random sampling method. Patients were administered panchakola phanta for ama pachana (metabolism of improperly metabolized products) followed by dhatri avaleha for 30 days. Assessment parameters such as Haemoglobin (Hb%), subjective parameters - arohanayasa (dyspnoea on exertion), shrama(tiredness), daurbalya(weakness) and observational parameters - aruchi (anorexia), hatanala (reduced appetite), bhrama (giddiness) and so on were assessed before treatment, after treatment and after follow up of 30 days. The results were analyzed statistically. Mean haemoglobin percentage was raised by 1.6% after treatment for 30 days. Statistically significant result was also observed in terms of subjective and objective parameters. The result was maintained even during the follow up period.

Key words: Anaemia; Dhatri avaleha; Panchakola phanta; Pandu.

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INTRODUCTION

Ayurveda defines life as the combination of shareera (physical body), indriya (sense organs), satva (mind) and atma (soul). Tridoshas (three body humours), saptadhatu (seven basic tissues) and trimala (three excretory products) are the base for shareera. Proper functioning of all these factors comprehensively is necessary for the maintenance of good health. Pandu (anaemia) is characterized by panduta (pallor) of nayana (eyes), nakha (nails), twak (skin) associated with mandagni (decreased appetite), daurbalya (reduced strength), arohana ayasa (dyspnoea on exertion), in severe conditions it results in deterioration of asta vidha sara (excellence of tissues), alpa rakta (less blood), alpa medas (less fat). It is produced by the vitiation of all the three body humors predominantly because of pitta. It can be correlated to the condition anaemia. Anaemia is a blood disorder characterized by reduction of R.B.C.s and haemoglobin percentage, due to decreased production of R.B.C, increased destruction of R.B.C & increased loss of blood due to hemorrhage. Anemia that occurs due to deficiency of any nutritive substance necessary for the erythropoiesis like iron, proteins and vitamins like C, B12 and folic acid is called nutrition deficiency anemia. The nutrition deficiency will be either due to decreased availability of the nutrients in the food or decreased absorption of these nutrients from the food by gastro intestinal tract or increased elimination of the nutrients from the body. Anaemia is a global public health problem affecting both developing and developed countries with major consequences for human health as well as social and economic development. It occurs at all stages of the life cycle, but is more prevalent in pregnant women and young children.

According to the survey done by women and child welfare ministry in 2012, India is among the countries with highest prevalence of anaemia in the world. Though there are several treatment protocols available for the disease anaemia there is a lot of scope for Ayurvedic remedies in present day. Pandu roga is manifested as a result of impairment in nutrition and there will be reduced appetite in maximum number of patients. Hence to increase the appetite panchakola [combination of pippali (Piper longum), pippali mula (root of Piper longum), chavya (Piper chaba), chitraka (Plumbago zeylanica), shunthi (Zingiber officinale)] was administered initially followed by Dhatri avaleha on patients of nutritional anaemia.

MATERIALS AND METHODS

Study design

Open ended randomized clinical trial.

Source of data

A total of 30 patients fulfilling the inclusion criteria with respect to age, irrespective of sex, caste, religion & socio economic status were selected randomly from the OPD and IPD of G.A.M.C, and Hospital, Mysore.

Procurement of trial drugs

Panchakola churna was collected from Pharmacy G.A.M.C & H. Mysore. Dhatri avaleha was procured from S.N. Pandit and sons Ayurveda Pharmacy, Shankara Mutt Road Agrahara, Mysore.

Diagnostic criteria

Haemoglobin percentage between 7-11g/dl with or without the symptoms of pandu roga such as- panduta (pallor), hatanala (reduced appetite), daurbalya (weakness), angasada (general debility), arohanayasa (exertional dyspnoea), shrama (tiredness) etc.

Sampling method

The patients who fulfilled the inclusion criteria were randomly selected for the study.
Inclusion criteria

Individuals who come under the age group between 16 - 60 years and fulfilling the diagnostic criteria.

Exclusion criteria

- Hemolytic anaemia due to any cause.
- Anaemia due to acute or chronic blood loss.
- Anaemia during pregnancy.
- Aplastic anaemia due to bone marrow disease.
- Anaemia due to chronic diseases like non infectious inflammatory diseases, chronic renal failure, malignancy, etc.
- Systemic disorders which interfere the treatment.

Intervention of the study is shown in table 1

Follow up

30 days, after completion of treatment.

Assessment criteria

The results were evaluated by subjective and objective parameters mainly based on clinical observation by grading method and laboratory values.

Investigations

Blood: Hb %

- Before treatment
- After treatment for 30 days
- At follow up - 30 days after completion of treatment.

Subjective parameters were mentioned in Table 2. Grading was done for the subjective parameters.

Arohanayasa (Dyspnoea on exertion)

Dyspnoea after heavy work but relieved soon and up to tolerance – 0
Dyspnoea after moderate work but relieved later and up to tolerance – 1
Dyspnoea after little work but relieved soon and up to tolerance – 2
Dyspnoea without any work, not relieved and beyond to tolerance – 3

Shrama (Tiredness)

Grade 0 - No tiredness
Grade 1 - After heavy work
Grade 2 - After light work
Grade 3 - Always present

Dourbalya (Reduced strength)

Can do routine work without any kind of weakness – 0
Can do routine work but feels weakness at night. – 1
Needs rest in between the routine works – 2
Cannot do routine work and feels weakness - 3

The observational parameters- hridrava (palpitation), shoola (pain), karna kshveda (tinnitus), bhrama (giddiness), aruchi (anorexia), hatanala (less appetite), pindikodvestana (calf muscle cramps), shotha (oedema), shabda asahishnuta (intolerance to loud sounds) were assessed for presence or absence of symptoms.

The results of present study was analyzed statistically by applying statistical methods using descriptive statistics- paired samples ‘t’ test, contingency table analysis, repeated measure ANOVA, using SPSS for windows software.

Ethical clearance

Institutional ethical clearance was obtained from the ethical committee. EC No.: SRP-2 (a5) [EC]/GAMC 2012-13.
Table 1: Details of intervention

<table>
<thead>
<tr>
<th>Particulars</th>
<th>Amapachana</th>
<th>Trial drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage</td>
<td>Panchakola phanta</td>
<td>Dhatriavaleha</td>
</tr>
<tr>
<td>Time of administration</td>
<td>Thrice a day 30 mins before food</td>
<td>After food in the morning</td>
</tr>
<tr>
<td>Duration</td>
<td>Till ama pachana lakshanas are seen (appetite becomes normal)</td>
<td>30 days</td>
</tr>
</tbody>
</table>

Table 2: Assessment criteria of subjective parameters

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Symptoms</th>
<th>Pre test</th>
<th>Post test</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Arohana ayasa</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Dourbalya</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Shrama</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

OBSERVATIONS

Age

It was found that maximum number of patients i.e. 36.7% which comprise of 11 patients belonged to age group of 18 - 30 years, followed by 30.0% (9 patients) in 31-40 years, 23.3% (7 patients) in 41-50 and 10% (3 patients) in 51-60 years.

Gender

Out of 30 patients, maximum number 29 (96.7%) were females and only one patient was male.

Chronicity

Among the 30 patients, maximum number of patients 40% i.e. 12 patients were suffering from the disease since 6-12 months, 26.7% i.e. 8 patients were suffering from disease since 3-6 months, 26.7% i.e. 8 patients were suffering from disease since more than 12 months and only 6.7% i.e. 2 patients were suffering from disease since less than 3 months.

Nature of diet

Among the 30 patients, maximum numbers of patients i.e. 83.3% which comprises of 25 patients were having vishamashana (diet at irregular time). 10% i.e. 3 patients were having adhyashana (over eating) and 3.3% i.e. 2 patients were having samashana (eating both wholesome and unwholesome diet).

RESULTS

Mean Hb% values before treatment, after treatment and at follow up are shown in table 3 and table 4. A significant increase of 1.6 grams was observed from before to after treatment in mean Hb% scores. The result was statistically highly significant (P=0.000).

Grades of arohana ayasa and number of patients before treatment, after treatment and at follow up are shown in table 5.

Grades of shrama and number of patients before treatment, after treatment and at follow up are shown in table 6.

Grades of dourbalya and number of patients before treatment, after treatment and at follow up are shown in table 7.

Improvement in arohana ayasa, shrama, dourbalya are statistically significant (P=0.000).

Statistically significant result was observed in relation with aruchi (anorexia), mandagni (reduced appetite), bhrama (giddiness),
hrudrava (palpitation), shabda asahishnuta (intolerance to sound) and shoola (pain).

**DISCUSSION**

Pandu roga is a most common disease physicians come across in day to day clinical practice. Nutritional anemia is one of the most common types of anemia prevailing in the world and also in India. Adequate supplement and proper absorption of the nutrients is required to maintain the health. For the proper absorption there must be normal functioning of digestive system. Hence impairment in normal digestion will be invariably associated with nutritional anemia. In the initial stages it is not a serious ailment hence patients seldom approach doctors for medicinal intervention. Many times it is diagnosed accidentally when the patients approach for different clinical conditions. Patients with pandu roga present themselves with various complaints which interacts their daily activities. In many cases it becomes a long term medical condition and patients may have to take regular medicines like iron supplements. Many complications are reported due to the long term intake of iron supplements. Hence the present study was aimed to assess the efficacy of Ayurvedic remedy with the help of amapachana (increasing the metabolic activity) and drug dhatri avaleha. The drug dhatri avaleha is semi solid, non iron preparation containing the ingredients amalaki swarasa (Emblica officinalis), shunti (Zingiber officinale), pippali (Piper longum), mrudwika (Vitis vinefera), yashtimadhu (Glycyrrhiza glabra), vamshalochana (Bambusa arundinacea), sugar and honey.

For the clinical study age group between 16 to 60 years was selected to maintain uniformity in the dose fixation. In panduroga most common symptom will be reduced appetite hence there will be improper absorption of nutrients. So panchakola phanta 30 ml before food thrice a day was given. It was given for 4-7 days, till the appetite came to normalcy. The trial drug dhatriavaleha was administered after the course of ama pachana.

**Haemoglobin**

Mean haemoglobin percentage was raised by 1.6% after treatment for 30 days. The improvement in the haemoglobin percentage was found statistically significant. The mean percentage was maintained even during the follow up period. Though statistically the result shows significant improvement, when the individual haemoglobin percentage was considered it was reduced after treatment for 4 patients, 0.5% - 1.0% improvement was seen in 6 patients, 1.0% - 1.5% improvement was seen in 4 patients, 1.5% - 3.0% improvement was seen in 16 patients. The result suggests that the combination of panchakola phanta and drug dhatri avaleha is effective in correcting the appetite and increasing haemoglobin percentage. The patients in whom haemoglobin percentage deteriorated was 0.5 g% - 1.0 g %, but the symptoms were reduced. This may be due to the underlying pathology by which the disease was still progressive.

The symptoms arohanayasa, shrama and dourbalya are taken as subjective parameters and assessed by grading method. These are the major symptoms of anaemia and their degrees show the severity of disease and the suffering by the patients. So they are taken as subjective parameters. The result seen was statistically highly significant. This result suggests the efficacy of dhatri avaleha.

Other symptoms of anemia such as aruchi (anorexia), mandagni (reduced appetite), bhrama (giddiness), hrudrava (palpitation), shabda asahishnuta (intolerance to sound) and shoola (pain) are considered as observational parameters and assessed only for presence or absence of symptoms. These symptoms were seen as associated symptoms of anaemia and such symptoms are not directly indicative of anaemia.
Table 3: Mean Hb percentage and standard deviation of 30 patients

<table>
<thead>
<tr>
<th></th>
<th>Hb</th>
<th>Mean</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before Treatment</td>
<td>9.4600</td>
<td>1.10441</td>
<td></td>
</tr>
<tr>
<td>After Treatment</td>
<td>11.0667</td>
<td>1.21283</td>
<td></td>
</tr>
<tr>
<td>Follow Up</td>
<td>9.6933</td>
<td>1.20917</td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Paired sample t test

<table>
<thead>
<tr>
<th>Paired differences</th>
<th>Mean</th>
<th>T</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pair 1</td>
<td>-1.6067</td>
<td>-4.621</td>
<td>0.000</td>
</tr>
<tr>
<td>Pair 2</td>
<td>-1.8067</td>
<td>-4.795</td>
<td>0.000</td>
</tr>
<tr>
<td>Pair 3</td>
<td>-0.2000</td>
<td>-1.133</td>
<td>0.276</td>
</tr>
</tbody>
</table>

Pair 1- Hb % from 0 day – 30th day; Pair 2- Hb % from 0 day – 60th day; Pair 3- Hb % from 30th day – 60th day.

Table 5: Grades of arohana ayasa before treatment, after treatment and at follow up

<table>
<thead>
<tr>
<th>Grade</th>
<th>Before treatment</th>
<th>After treatment</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>8</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>20</td>
<td>18</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 6: Grades of shrama before treatment, after treatment and at follow up

<table>
<thead>
<tr>
<th>Grade</th>
<th>Before treatment</th>
<th>After treatment</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>4</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>1</td>
<td>6</td>
<td>20</td>
<td>18</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 7: Grades of arohana daurbalya treatment, after treatment and at follow up

<table>
<thead>
<tr>
<th>Grade</th>
<th>Before treatment</th>
<th>After treatment</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>4</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>1</td>
<td>6</td>
<td>20</td>
<td>18</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

There was statistically significant result observed in case of observational parameters. As the chief complaints were cured associated symptoms were also got relieved.

Probable mode of action of drugs used

Among the ingredients of dhatri avaleha, amalaki is the major component and it is having predominantly sour taste, it is a vayasthapaka (anti ageing) and rasayana (rejuvenative) drug, it increases healthy status of the tissues of the body and teekshna (penetrating), sookshma (minute) properties. So, they will increase appetite by deepana (carminative) & amapachana (digestive) action.[7]
body. Chemical constituents of amalaki are (galeic acid, tannic acid, sugars, albumin, cellulose, calcium and other minerals and vitamin C. protein 0.5%, fat 0.1%, fiber 9.4%, carbohydrate 14.1%, minerals 0.7%: phosphorous 0.02%, calcium 0.05%, iron 1.2µg, nicotinic acid 0.2µg - per 100g). Other drugs vamshalochna, yashtimadhu, draksha, sharkara, madhu are helpful in preenana (nourishing), brimhana (increases bulk of the body), ksheena dhatu vardhaka (increases the body tissues). Shunti, pippali, increases digestive activity. In total dhatri avaleha is preenana (nourishing) and dhatu vardhaka (increases all the tissues of the body). Thus it can revert back the pathogenesis of pandu roga. So by the virtue of these properties dhatri avaleha is effective in treating pandu roga.

Taking iron supplements causes gastric irritation for some patients. In the present study nothing such side effects were noticed. The treatment method adopted was aimed at correcting the underlying pathology and is more than just supplementing the required nutrients.

CONCLUSION

Marked improvement of 1.6 g rise in mean haemoglobin percentage was observed with 30 days of treatment by the combined effect of ama pachana by panchakola phanta and trial drug dhatri avaleha. The result was maintained during the follow up after 30 days also. Panduroga can be treated by correction of appetite and improving the quality of body tissues. The treatment method adopted was aimed at correcting the underlying pathology without causing any side effects and is more than just supplementing the required nutrients.

REFERENCES