A CLINICAL STUDY TO EVALUATE EFFICACY OF “RAJAH PRAVARTINI VATI” ON KASHTARTAVA W.S.R TO PRIMARY DYSMENORRHOEA

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ABSTRACT

Dysmenorrhoea is the most common gynaecological problem faced by women during their adolescence which causes significant discomfort & anxiety for the women. It may create the emotional distress brought on by the pain and may result in missing work or school, inability to participate in sports or other activities. In modern medicine dysmenorrhoea is treated by oral contraceptive pills, non-steroidal anti-inflammatory drugs, antispasmodic, analgesics etc. Long term use of these causes side effects. So, it is a great scope of research to find out safe, potent, cost effective remedy from Ayurveda for its management.

Pain is the main feature of Kashtartava, so it has strong relation with Vata Dosha. Keeping this point in view, the present clinical trial, A Clinical Study To Evaluate Efficacy Of “Rajah Pravartini Vati” On Kashtartava W.S.R To Primary Dysmenorrhoea was taken. The selected drug is Vatashamaka mentioned by the classics and Rajah-Pravartini-Vati has a direct reference in Bhaishajya Ratnavali for Kashtarvata. And results were assessed on the basis of improvement in the subjective parameters. The study reveals that patients of Kashtarvata after treatment showed significant improvement in chief complaints, from the above trial it is clear that Rajah Pravartini Vati can be used as a safe and effective ‘Therapeutic Agent’ in the management of kashtarvata.
INTRODUCTION
With the advent of new millennium and the herald of high-tech era, Women’s status was expected to reach new horizons both socially and physically. But some of the physiological things trouble the lady to make her slow down the race. Kashtartava is one of the important diseases among them. Kashtartava is among the few diseases which can be attributed to changed life styles. Not less than 50% of women are said to experience some discomfort in relation to menstruation, and 5-10% of girls in their late teens and early twenties are incapacitated for several hours each month. For the present study, only primary dysmenorrhea is taken with Kashtartava to exclude the pathological cases. Pain is the main feature of Kashtartava, so it has strong relation with Vata Dosha. The selected drug is Vatashamaka mentioned by the classics and Rajah-Pravartini-Vati.\textsuperscript{[1]} has a direct reference in Bhaishajya Ratnavali for Kashtarvata.

NEED OF PRESENT STUDY
In modern medicine dysmenorrhea is treated by oral contraceptive pills, non-steroidal anti-inflammatory drugs, antispasmodic, analgesics etc. Long term use of these causes side effects like hepatotoxicity, nephrotoxicity, headache, dizziness, vertigo, depression, skin rashes etc.\textsuperscript{[2]} So, it is a great scope of research to find out safe, potent, cost effective remedy from Ayurveda for the management of aforesaid lacuna. The above mention Ayurvedic formulation have been found to be useful in treating kastartava and Promoting health of women. The present study is being undertaken to scientifically study and validate the efficacy and safety of this Ayurvedic regimen.

DRUG USED FOR PRESENT STUDY
For present study “Rajah Pravartini Vati” was used. Vati was prepared according to “Vati Kalpana” mentioned in Sharangadhara Samhita Madhyaama Khanda - 11/102-105 at pharmacy of N.I.A. Jaipur.

DESIGN OF THE STUDY
The method adopted in present study is Randomized, Clinical, Open study.

AIMS AND OBJECTIVES
1. To study etiopathogenesis of Kashtartava and to explore the clinical consequences.
2. To assess the efficacy of trial drug in the management of Dysmenorrhea.

MATERIAL AND METHODS
Total 25 clinically diagnosed and confirmed cases of Primary Dysmenorrhea were registered from the O.P.D. / I.P.D. N.I.A. Hospital, Jaipur after taking informed consent.

❖ Inclusion Criteria
1. Subjects coming with chief complaint of Kashatartava with scanty or average amount of menses along with associated symptoms.
2. Subjects in age group of 16 to 30 years.
4. Subjects suffering with Kashtartava for more than 2 consecutive cycles.

❖ Exclusion Criteria
1. Subjects suffering from Secondary Dysmenorrhea.
2. Subjects suffering from Systemic diseases such as D.M., T.B.
4. Subjects having pain abdomen associated with menorrhagia, metrorrhagia.
5. Subjects with H/O hypothyroidism and hyperthyroidism with DUB.

❖ Criteria for withdrawal
1. The participant may be withdrawn from the trial if She develops any serious adverse effect (necessitating hospitalization)
2. Non-compliance of the treatment regimen.

❖ Investigations
Laboratory investigations of blood, urine and USG were carried out before treatment to rule out any other pathological conditions.

❖ Criteria of assessment
A special scoring pattern was applied in symptoms and associated complaints.

❖ Statistical Evaluation of results
Further the effect of the treatment of signs and symptoms were analyzed statistically by Mean, SD, and SE, ‘paired Wilcoxon signed rank test ‘and‘ unpaired Mann-Whitney test for non-parametric study.
OBSERVATIONS
Most i.e. 42.00% of the patients included in trial were in the age group of 16-20 years; 66.00% patients were belongs to Hindu religion, 26.00% patients were Graduate, 46.00% patients were house wives, 56.00% patients were from lower economic class, 52.00% of patients were married, and 84.00 % of patients were from urban area. Pertaining to personal history it is found that; 60.00% patients with the habit of vegetarian diet, 72.00% addicted to Tea, 46.00 % with disturbed sleep and 52.00% of patients with constipated bowel habit. From menstrual history it is observed that, in 38.00 % of the patients Menarche onset was in the age of 13 yrs, 92.00 % had regular menstruation, 84.00 % patients had normal amount of blood loss, 32.00 % of patients were having 5 days of duration of menses and 56.00% of patients were having 30 days of interval of menstrual cycle. From pain wise history, it is observed that, in 50.00% of the patients pain was at lower abdomen and lower backache, 48.00% of patients were having spasmodic type of pain and 66.00% of patients were having 5-6 days of duration of pain.

RESULTS
Table No.1: Shows the pattern of clinical recovery in various ‘Associated Symptoms’ of Kashtartava in 25 patients treated with “Rajah-Pravartini-Vati” orally – by Wilcoxon matched-pairs signed-ranks test.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Symptoms</th>
<th>BT</th>
<th>AT</th>
<th>Dif.</th>
<th>% of Change</th>
<th>SD</th>
<th>SE</th>
<th>W</th>
<th>P</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nausea</td>
<td>1.00</td>
<td>0.41</td>
<td>0.59</td>
<td>59.09%</td>
<td>0.50</td>
<td>0.11</td>
<td>91</td>
<td>&lt; 0.007</td>
<td>H.S.</td>
</tr>
<tr>
<td>2</td>
<td>Vomiting</td>
<td>1.00</td>
<td>0.20</td>
<td>0.80</td>
<td>80.00%</td>
<td>0.42</td>
<td>0.13</td>
<td>36</td>
<td>&lt; 0.039</td>
<td>S</td>
</tr>
<tr>
<td>3</td>
<td>Fatigue</td>
<td>1.00</td>
<td>0.68</td>
<td>0.32</td>
<td>32.00%</td>
<td>0.48</td>
<td>0.10</td>
<td>36</td>
<td>&lt; 0.039</td>
<td>S</td>
</tr>
<tr>
<td>4</td>
<td>Headache</td>
<td>1.00</td>
<td>0.36</td>
<td>0.64</td>
<td>64.29%</td>
<td>0.50</td>
<td>0.13</td>
<td>45</td>
<td>&lt; 0.028</td>
<td>S</td>
</tr>
<tr>
<td>5</td>
<td>Fainting</td>
<td>1.00</td>
<td>0.38</td>
<td>0.63</td>
<td>62.50%</td>
<td>0.52</td>
<td>0.18</td>
<td>15</td>
<td>&lt; 0.1</td>
<td>IS.</td>
</tr>
<tr>
<td>6</td>
<td>Sweat</td>
<td>0.94</td>
<td>0.44</td>
<td>0.50</td>
<td>53.33%</td>
<td>0.63</td>
<td>0.16</td>
<td>44</td>
<td>&lt; 0.001</td>
<td>H.S.</td>
</tr>
<tr>
<td>7</td>
<td>Diarrhoea</td>
<td>1.00</td>
<td>0.25</td>
<td>0.75</td>
<td>75.00%</td>
<td>0.50</td>
<td>0.25</td>
<td>6.0</td>
<td>&lt; 0.21</td>
<td>I.S.</td>
</tr>
<tr>
<td>8</td>
<td>Constipation</td>
<td>1.00</td>
<td>0.44</td>
<td>0.56</td>
<td>55.56%</td>
<td>0.51</td>
<td>0.12</td>
<td>55</td>
<td>&lt; 0.021</td>
<td>S.</td>
</tr>
<tr>
<td>9</td>
<td>Vaginal Discharge</td>
<td>1.00</td>
<td>0.33</td>
<td>0.67</td>
<td>66.67%</td>
<td>0.49</td>
<td>0.11</td>
<td>78</td>
<td>&lt; 0.01</td>
<td>S.</td>
</tr>
<tr>
<td>10</td>
<td>Breast Tenderness</td>
<td>1.00</td>
<td>0.30</td>
<td>0.70</td>
<td>70.00%</td>
<td>0.48</td>
<td>0.15</td>
<td>28</td>
<td>&lt; 0.05</td>
<td>S.</td>
</tr>
</tbody>
</table>

Highly significant results are shown on Nausea and Sweat. Significant results obtained on Vomiting, Fatigue, Headache, Constipation, Vaginal discharge and Breast tenderness. Results on Fainting and Diarrhoea were insignificant.
Table No 2: Shows the pattern of clinical recovery in various ‘Subjective Parameters’ of *kashtartava* in 25 patients treated with “*Rajah-pravartini-vati*” orally by Wilcoxon matched-pairs signed-ranks test.

<table>
<thead>
<tr>
<th>S No</th>
<th>Symptoms</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Diff.</th>
<th>% of Change</th>
<th>SD</th>
<th>SE</th>
<th>W</th>
<th>P</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pain Intensity</td>
<td>2.56</td>
<td>1.16</td>
<td>1.40</td>
<td>54.69%</td>
<td>0.50</td>
<td>0.10</td>
<td>325</td>
<td>&lt; 0.001</td>
<td>H.S.</td>
</tr>
<tr>
<td>2</td>
<td>Pain Duration</td>
<td>2.52</td>
<td>1.16</td>
<td>1.36</td>
<td>53.97%</td>
<td>0.70</td>
<td>0.14</td>
<td>276</td>
<td>&lt; 0.001</td>
<td>H.S.</td>
</tr>
<tr>
<td>3</td>
<td>Nature of Pain</td>
<td>2.60</td>
<td>1.12</td>
<td>1.48</td>
<td>56.92%</td>
<td>0.77</td>
<td>0.15</td>
<td>253</td>
<td>&lt;0.001</td>
<td>H.S.</td>
</tr>
<tr>
<td>4</td>
<td>Flow Duration</td>
<td>2.04</td>
<td>2.12</td>
<td>-0.08</td>
<td>-3.92%</td>
<td>0.57</td>
<td>0.11</td>
<td>-9</td>
<td>0.5</td>
<td>I.S.</td>
</tr>
<tr>
<td>5</td>
<td>Flow Amount</td>
<td>1.44</td>
<td>1.80</td>
<td>-0.36</td>
<td>-25.00%</td>
<td>0.49</td>
<td>0.10</td>
<td>-45</td>
<td>&lt; 0.03</td>
<td>S.</td>
</tr>
<tr>
<td>6</td>
<td>Associated Symptoms</td>
<td>2.20</td>
<td>1.16</td>
<td>1.04</td>
<td>47.27%</td>
<td>0.61</td>
<td>0.12</td>
<td>231</td>
<td>&lt;0.001</td>
<td>H.S.</td>
</tr>
<tr>
<td>7</td>
<td>VAS Scale</td>
<td>2.92</td>
<td>1.52</td>
<td>1.40</td>
<td>47.95%</td>
<td>0.58</td>
<td>0.12</td>
<td>325</td>
<td>&lt; 0.001</td>
<td>H.S.</td>
</tr>
<tr>
<td>8</td>
<td>FLACC Scale</td>
<td>2.48</td>
<td>1.16</td>
<td>1.32</td>
<td>53.23%</td>
<td>0.63</td>
<td>0.13</td>
<td>300</td>
<td>&lt;0.001</td>
<td>H.S.</td>
</tr>
<tr>
<td>9</td>
<td>Wong Baker Scale</td>
<td>2.64</td>
<td>1.56</td>
<td>1.08</td>
<td>40.91%</td>
<td>0.49</td>
<td>0.10</td>
<td>276</td>
<td>&lt;0.001</td>
<td>H.S.</td>
</tr>
</tbody>
</table>

Highly significant results are shown on Pain Intensity, Pain Duration, Nature of Pain, Associated symptoms, VAS Scale, FLACC Scale, Wong Baker Scale. Significant results obtained on Flow Amount. Results on Flow Duration were insignificant.

**TABLE NO. 3: OVERALL EFFECT OF THERAPY**

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Effect of therapy</th>
<th>Result</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>No.</td>
</tr>
<tr>
<td>1</td>
<td>No relief</td>
<td>(0%)</td>
<td>00</td>
</tr>
<tr>
<td>2</td>
<td>Mild</td>
<td>(1 to ≤ 25%)</td>
<td>02</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>(&gt;25 to ≤ 50%)</td>
<td>12</td>
</tr>
<tr>
<td>4</td>
<td>Significant</td>
<td>(&gt;50 to ≤ 75%)</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>Excellent</td>
<td>(&gt;75%)</td>
<td>01</td>
</tr>
</tbody>
</table>

**DISCUSSION**

- It is may be due to the fact that “*Rajah Pravirtini Vati*” has Katu(pungent)-Tikta(bitter) Rasa, Laghu(light), Snighdha(unctuous) and Tikshna(sharp) Guna, Katu Vipaka and Ushna Virya(active potency). Tikta (bitter) taste and Tikshna (sharp) property of drug removes the Srotoavarodha and facilitates flow of Vata; Katu Vipaka and Ushna Virya pacifies the aggravated Vata and thus allows the painless flow of Artava.

- It is effective in Artava vikaras. Hingu, Kumari, Tankan and Kasis are the main ingredients of *Rajah Pravirtini Vati*. Hingu (Ferula Asafoetida Linn) has Shoolahara (colic pain reliever) and Vatanulomana (facilitator of downward movement of Vata) property which helps in normalising the function of Apanvata, which is main causative factor of Kashtartava. Hingu has anti flatulent and digestive properties & counteracts...
spasmodic disorders and may probably suppress the secretion of progesterone hormone.[3] The gum resin contains the coumarins, 5-hydroxy-umbelliprenin, asafoetidin etc.[4]

- **Kumari** (*Aloe barbadensis* Mill.) has a characteristic bitter taste and used mainly as purgative, improves digestion; the cathartic properties of aloe are attributed to the presence of a mixture of glycosides called ‘aloin’. Kumari also contains beta-sitosterol and has the anti-prostaglandin activity.[5] Cathartic property of this relieves the obstruction in the pathways of Vayu, and there by relieves spasm.

- **Hingu, Tankana, Kasis** are Artavajanana drugs. Kasis helps in Rakta Dhatu Vridhdi, which improve the uterine blood circulation (reduced blood circulation is a cause for dysmenorrhea.) Balya (strength promoting) (Kumari, Hingu, Tankana, Kasis) Rasayana (Kumari) drugs give strength to uterine musculature for easy expulsion of Raja. Tankana is Garbhashaya sankochaka(improves the tonicity of uterine muscle) drug helps in normal harmonization during contraction.

**CONCLUSION**

- Therapeutic Effect of (“Rajah-Pravartini-Vati” orally) Patients of this group showed relief by improvement in 54.69% in pain intensity, 53.97% in pain duration, 56.92% in nature of pain, -3.92% in menstrual flow duration, -25.00% in menstrual flow amount, 47.27% in associated symptoms and 47.95%, 53.23% and 40.91% in VAS scale, FLACC scale and WONG BAKER scale respectively.

- Results prove that “rajah pravartini vati” proved to be an effective & dependable remedy in the management of kashtartava.

- Patients taken the “rajah pravartini vati” very well with no complaints of any side effects/toxic effects.

**REFERENCES**

1. Bhaishjaya Ratnawali- sidhi nandan Mishra, chaukhambha orientalis, Varanasi
6. Database of medicinal plant used in Ayurveda ; CCRAS ; Vol – 3

**BIBLIOGRAPHY**

- Dikshita Bhaanuji; *Amarkosha – Amarsimha* commentary *vyakhyaasudhaa*; C.S.S., Delhi, 1995
- Joshi G. Nirmala; *Ayurvedic Concepts in Gynaecology, Chaukhamba Sanskrit Pratishthan* Delhi; 2nd Edition: 1999
- Sharma P.V. *Dravyaguna Vigyana, Chaukhamba Bharati* Academy, Varanasi, First Edition Reprint -2006
- Sharma Sadanand; *Rastrangini, Motilal Banarsi* Das, Varanasi, Edition 2004
- *Dravyaguna Vigyan*, Dr.Gyanendra Pandey, *Chaukhamba Bharti* Academy, Varanasi.
- Bhaishjaya Ratnawali- sidhi nandan Mishra, chaukhambha orientalis, Varanasi