A CLINICAL STUDY TO EVALUATE THE EFFICACY OF KUTAJASTAK AVALHEA IN ASRIGDARA w.s.r TO DUB

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ABSTRACT

Background: Regular cyclic menstruation results from the relationship between endometrium and its regulating factors. Change in either of these results in abnormal bleeding which interferes with woman’s physical, social and emotional quality of life. Asrigdara is characterized by excessive, prolonged, menstrual or intermenstrual bleeding. Dysfunctional uterine bleeding is a state of abnormal bleeding without any clinically detectable organic, systemic, and iatrogenic cause. It affects 22-30% of women. Commonest age group affected by DUB is 31-40 years (45.6%) and seen mostly in multiparous women (71.58%). Kutajastakavaleha is mentioned in Sarangadhara Samhita having stambana, garbhashaysankochaka, balya, raktaishodhaka, properties effective in Asrigdara. Aims: To evaluate the efficacy of Kutajastakavaleha in Asrigdara and to compare the efficacy of Kutajastakavaleha and Khandkusmand avaleha in Asrigdara. Design: A randomized comparative clinical study of two groups, each consisting of 20 patients. Methods and Material: patients aged between 20 and 45 years, who were clinically diagnosed in Alva’s Ayurveda Medical College and Hospital, Moodbidri, were included in the study. Analysis Used: Student t test for within sample was used to compare the baseline characteristics, for Assessment p<0.05 was considered significant and Paired t test to compare result between two groups. In Overall effect, Group-A (Kutajastakavaleha); 5 has moderate improvement, while 15 has marked improvement. Group-B (Khandkusmanda Avaleha); 1 has mild improvement, 13 has moderate improvement, while 6 has marked improvement. Conclusion: The present study shows that Kutajastakavaleha is a safe and better treatment in Asrigdara.

Keywords: Asrigdara, Dysfunctional uterine bleeding (DUB), Kutajastakavaleha.
Since the ages of *Vedas*, *Stree* has been given a unique position in the society due to procreating and propagating the human species. Showing the importance of *Stree*, Acharya Manu quoted that the societies where women are respected that place is like heavenly abode. The woman is the chief cause for progeny, if she is protected even the progeny is protected. The prime aim of woman is to achieve motherhood. Motherhood is the basis for family life, which is the backbone of the society. Healthy progeny leads to formation of healthy society. The first step for motherhood commence with menarche and ends with menopause. Woman’s role reaches to new horizons in the society due to modernization and increased competition. Women are not able to pay proper attention to their health due to increase in responsibilities in this changed set up. Change in lifestyle, food, habits, responsibility of family etc. possess strain on her physical and mental health which likely disturbs the menstrual rhythm and leads to menstrual disorders.

Menstruation is the visible manifestation of cyclic physiologic uterine bleeding due to the shedding of the endometrium\(^1\). It denotes the healthy state of female reproductive system. The menstrual rhythm is invisible interplay of hypothalamo-pituitary-ovarian axis. Any physical and mental disorders disturb the normalcy of menstrual cycle which further leads to impairment in function of reproduction.

*Asrigdara* is characterized by excessive, prolonged menstrual or intermenstrual bleeding\(^2\). According to Acharyas, Mithya Ahara, Vihara, Atishoka etc are the Nidanas of *Asrigdara*. *Asrigdara* comprises all form of excessive bleeding. Dysfunctional Uterine Bleeding (D.U.B) is one of them. D.U.B is a state of abnormal uterine bleeding without any clinically detectable organic, systemic, and iatrogenic cause. It occurs at the extreme of reproductive life i.e. adolescence and premenopausal age\(^3\). D.U.B affects 22-30% of women and accounts for 12% gynecological referrals\(^4\). Various treatment modalities have minor to major side effects like nausea, G.I.T disturbance, hypertension, liver disease etc. Ultimate cure for D.U.B is hysterectomy, but it also has complications.

*Ayurvedic* texts have described variety of oral preparations which are time tested can be used for the management of *Asrigdara*. The present study was undertaken to evaluate the efficacy of *Kutajastakavaleha*\(^5\) in *Asrigdara*.

**Objectives of study**

- To evaluate the efficacy of *Kutajastakavaleha* in *Asrigdara*.
- To compare the efficacy of *Kutajastakavaleha* and *Khandkusmand avaleha* in *Asrigdara*.

**MATERIALS AND METHODS**

Total 46 patients diagnosed with *Asrigdara* w.s.r D.U.B attending Prasooti tantra and Streeroga O.P.D of Alva’s Ayurveda Medical College and Hospital, Moodbidri, and other available sources. Among them 40 had completed the treatment and 6 left against medical advice. Hence, the total number of patients is 40 for the present study, so observation and results of 40 patients given below.

**Design of study:** A randomized comparative clinical study of two groups, each consisting of 20 patients.

**Diagnostic criteria:** Patient fulfilling any two or more of the criteria
1. *Raja atipravruthi.* (Excessive bleeding)
2. *Deerghakalanubandhi* (Prolonged menstruation)
3. *Anruthavalpamapi* (Intermenstrual (scanty) bleeding)
4. Along with or without *angamarda* (body ache) and *vedana* (pain)

**Inclusion criteria**

1. Patients fulfilling the diagnostic criteria.
2. Patients with age group of 20-45 years.
3. Patients having Hb% more than 8 gms.

**Exclusion criteria**

1. Patients with systemic disorders interfering with the present study.
4. Patient with IUCD, OCP.
6. Coagulation disorders.

**Interventions**

**Group A:** Kutajastakavaleha, 12 gm bid with warm water orally from 4th day of menstrual cycle to 1st day next menstrual cycle for 3 consecutive cycles.

**Group B:** Khandkusmand avaleha, 12 gm bid with warm water orally from 4th day of menstrual cycle to 1st day next menstrual cycle for 3 consecutive cycles.

Assessment: Assessed on the 10th day of each cycle.

Treatment follows up: On 10th day for 3 consecutive menstrual cycles during the treatment.

Observational follow up: On 10th day for next one menstrual cycle.

**Assessment criteria**
1. Duration of menstrual flow.
2. Amount of menstrual blood loss.
3. Interval between menstrual cycles.
4. Angamarda
5. Vedana

**RESULTS:**

**Table 1:** Effect of therapy on assessment criteria in Group-A

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Mean score</th>
<th>%</th>
<th>SD</th>
<th>SE</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>AT</td>
<td>BT-AT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of menstrual flow</td>
<td>2.25</td>
<td>0.30</td>
<td>1.95</td>
<td>86.67</td>
<td>0.686</td>
<td>10.18</td>
</tr>
<tr>
<td>Amount of blood loss</td>
<td>2.35</td>
<td>0.30</td>
<td>2.05</td>
<td>87.23</td>
<td>0.510</td>
<td>11.19</td>
</tr>
<tr>
<td>Interval between menstrual cycle</td>
<td>2.05</td>
<td>0.35</td>
<td>1.75</td>
<td>82.93</td>
<td>0.470</td>
<td>9.02</td>
</tr>
<tr>
<td>Angamarda</td>
<td>0.80</td>
<td>0.10</td>
<td>0.70</td>
<td>87.50</td>
<td>0.470</td>
<td>6.10</td>
</tr>
<tr>
<td>Vedana</td>
<td>0.70</td>
<td>0.10</td>
<td>0.60</td>
<td>85.71</td>
<td>0.503</td>
<td>4.77</td>
</tr>
</tbody>
</table>

**Table 2:** Effect of therapy on assessment criteria in Group-B

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Mean score</th>
<th>%</th>
<th>SD</th>
<th>SE</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>AT</td>
<td>BT-AT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of menstrual flow</td>
<td>2.65</td>
<td>1.25</td>
<td>1.40</td>
<td>52.83</td>
<td>0.681</td>
<td>6.76</td>
</tr>
<tr>
<td>Amount of blood loss</td>
<td>2.40</td>
<td>0.90</td>
<td>1.50</td>
<td>62.50</td>
<td>0.607</td>
<td>8.24</td>
</tr>
<tr>
<td>Interval between menstrual cycle</td>
<td>2.55</td>
<td>0.55</td>
<td>2.00</td>
<td>78.43</td>
<td>0.459</td>
<td>11.30</td>
</tr>
<tr>
<td>Angamarda</td>
<td>0.90</td>
<td>0.05</td>
<td>0.85</td>
<td>94.44</td>
<td>0.366</td>
<td>9.99</td>
</tr>
<tr>
<td>Vedana</td>
<td>0.80</td>
<td>0.00</td>
<td>0.80</td>
<td>100</td>
<td>0.410</td>
<td>8.72</td>
</tr>
</tbody>
</table>

**Table 3:** Comparison of treatment between the groups (BT-AT)

<table>
<thead>
<tr>
<th>SYMPTOMS</th>
<th>GROUPS</th>
<th>MEAN</th>
<th>Difference In Mean</th>
<th>‘t’ TEST</th>
<th>d.f at 38</th>
<th>S.D. (±)</th>
<th>S.E. (±)</th>
<th>‘t’ value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of menstrual flow</td>
<td>Group-A</td>
<td>1.950</td>
<td>0.550</td>
<td>0.686</td>
<td>0.153</td>
<td>2.54</td>
<td>0.015</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Group-B</td>
<td>1.400</td>
<td></td>
<td>0.680</td>
<td>0.152</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amount of blood loss</td>
<td>Group-A</td>
<td>2.050</td>
<td>0.550</td>
<td>0.501</td>
<td>0.114</td>
<td>3.10</td>
<td>&lt;0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Group-B</td>
<td>1.500</td>
<td></td>
<td>0.607</td>
<td>0.136</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interval between menstrual cycle</td>
<td>Group-A</td>
<td>1.700</td>
<td>-0.30</td>
<td>0.470</td>
<td>0.105</td>
<td>0.625</td>
<td>&gt;0.05</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Group-B</td>
<td>2.00</td>
<td></td>
<td>0.458</td>
<td>0.103</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angamarda</td>
<td>Group-A</td>
<td>0.700</td>
<td>-0.150</td>
<td>0.470</td>
<td>0.105</td>
<td>0.312</td>
<td>&gt;0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Group-B</td>
<td>0.850</td>
<td></td>
<td>0.366</td>
<td>0.082</td>
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<td></td>
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</tr>
<tr>
<td>Vedana</td>
<td>Group-A</td>
<td>0.600</td>
<td>-0.200</td>
<td>0.503</td>
<td>0.112</td>
<td>1.11</td>
<td>&gt;0.05</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Group-B</td>
<td>0.800</td>
<td></td>
<td>0.410</td>
<td>0.091</td>
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</tr>
</tbody>
</table>
DISCUSSION

The study shows that out of total 40 patients, maximum patients belonged to age group 30-39 years (60%), and Hindu religion (75%), from Urban Area (55%), educated up to secondary (47.5%), belonged to middle class (57.5%), majority are married (92.5%) and housewives (67.5%), had mixed diet (77.5%), *mrudu kostha* (67.5%), *mandagni* (35%), *vata-pitta prakruti* (45%), had normal psychological status (57.5%) and sleep (65%). In majority had negative family history (92.5%), drug history (80%), abortion history (62.5%) and no addiction (45%). Maximum patient’s duration of illness were 3-9 months (67.5%), 42.5% had no contraceptive history, were multipara (62.5%). Maximum had regular past menstrual history (70%), present menstrual history (65%), had Hb between 8-9gm% ranges (37.5%), had duration of menstrual flow >9 days (55%), used 4-5 pads/day (47.5%), had menstrual cycle between 15-19 days (45%). In maximum patients *angamarda* (85%) and *vedana* (75%) are absent.

*Rakta* is known to be a vital substance of body. As the disease is characterized by excess flow of blood out of the body, hence *raktastambhana chikitisa* is beneficial. Use of *raktasthapaka dravyas* after assessing the involvement of *doshas* based on colour and smell of menstrual blood. Treatment prescribed for *raktatisara*, *raktapitta*, *raktarsha*, *guhayaroga* and *garbhasrava* is also useful. Considering this aspect, *raktastambhaka*, *raktsodhana*, *raktapittaggha* effects are desired in treatment.

**Probable mode of action of kutajastakavaleha**

*Kutajastakavaleha* contains 8 drugs. Among eight drugs, six drugs are having *tikta*, *kashaya rasa* and two are having *katu rasa*. *Tikta & Katu rasa*: Dipana & pachana→ *Agni* vardana & ama pachana→ srotosodhana→ *Prakrita rasa* and rakta dhatu formation. *Kashaya rasa*: *Stambhana, Grahi, Sleshmahara, Raktapittahara*→ Thus help to reduce the duration and amount of bleeding.

Based on *guna*: Majority of the drugs possesses laghu and ruksha guna. *Laghu*: Have srotosodhana property → does rakta sodhana *Ruksha guna*: It possess *Sthambhana & Shoshana* properties. *Sthambhana* directly and *shoshana* indirectly reduce the duration and amount of bleeding by absorption of *drava pitta*.

Based on *virya*: Majority of drugs possesses sheeta veerya. *Sheeta virya*: have raktapittahara and sthambhana, properties which helps in relieving the symptoms of asrigdara.

Based on *vipaka*: *Katu vipaka* helps in relieving the symptoms of asrigdara by its laghu and kaphapittashamaka guna.

Based on *karma*: Majority of drugs possess Raktapittahara, Raktsodhana, Raktastambhaka Dhatushoshana, Sothahara, and Vranaropana properties. All these properties of drugs act according to the vyadi pratyanekaa chikitsa.

**Probable mode of action of khandakusmanda avaleha**

*Kusmanada* possess raktapittashamaka, pittahara, shilhara, balya, rasayana, garbhaposhaka, vatapittashamaka and dipana properties.
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Jiraka, Shunthi, Pippali, Maricha, Twak and Patra are having kaphavatahara, dipana, pachana, garbhshayashodhaka.

Dhanyaka possesses properties of tridoshahara, dipana, and pachana.

Ela possesses properties of tridoshahara, balya, rochana, dipana, pachan and anulomana.

So, all the ingredients of khandakusmanda avaleha having kaphavatahara, tridoshara, dipana, pachana, garbhashayashodhaka, brumhanakara and balya.

**Duration of menstrual flow:** Group A has shown 86.67% reduction in the prolonged blood loss while Group B has shown 52.83%. The effectiveness of the medicine in the duration of bleeding in the Group-A, can be attributed to the karma of the drugs like raktasthambhana, dhatusoshana, raktapittahara, raktashodahana and grahi properties due to predominance of tiktha, kashaya rasa and sheeta virya. The results are statistically significant for both the groups. (p<0.05)

**Amount of blood loss:** Group A has shown 87.23% relief, while in Group B has 62.50% relief. The effectiveness of the medicine in the amount of blood loss in the Group-A, can be attributed to the karma of the drugs like raktasthambhana, dhatusoshana, raktapittahara, sthambhana, dahtusoshana and grahi properties. They help in samprapti vighatana by reducing the drava guna of pitta and decrease the amount of blood loss. The results are statistically significant for both the groups. (p<0.05)

**Interval between menstrual cycles:** In Group –A, there was 82.93% relief, while in Group-B 78.43% relief was there. Patha and bilva are having vatakaphahara properties thus help in regularization of cycle.

**Angamarda:** Group-A has shown 87.50% relief while Group-B has 94.44% relief. Both groups have significant results. (p<0.05) As the amount and duration of bleeding reduces due to the properties of drugs, it helps in relieving angamarda.

**Vedana:** In Group-A, relief was 85.71% and in Group-B100% relief was there. The results are statistically significant for both the groups (p<0.05). In Group A Patha and bilva possess usna virya which acts shoolaprashamana while in Group-B, all ingredients possess vathamaka property due to which the percentage of relief was more in Group B than Group A.

Comparison between the groups shown vary in parameter wise analysis in which, only duration and amount of blood loss in menstrual flow are having significant difference between the group while remaining all parameters are not having significant difference between the groups. Reduction in percentage also showed same results.

**CONCLUSION**

The main principle of the management of Asrigdara is raktastambhana, raktasodhana, and vatamulomana. Dipaniya and pachaniya drugs are essential in the treatment of Asrigdara for proper Agni and which helps in proper metabolism.

Kutajastakavaleha possess raktastambhaka, raktasodhana, raktapittahara, dipana, pachana, and balya properties with proved anti-inflammatory (lajjalu, patha, dhataki, musta), analgesic (bilva, patha), anti-spasmodic (musta, ativisha), anti-haemolytic activity (mocharasa) and proved the efficacy in treating the Asrigdara.

There was statistically significant improvement in all the cardinal as well as in associated symptoms of asrigdara in both the groups but Kutajastakavaleha shows good results in all cardinal symptoms in comparison with Khandkusmand avaleha.

**Limitation of study:** Palatability of Kutajastakavaleha was the main drawback of the study. It is reason behind maximum number of dropouts from Group A.

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4. www.ficci.com/files-for.../OBSGYN.pdf


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