**RANDOMIZED CONTROLLED STUDY TO EVALUATE EFFICACY OF ‘AMALAKI RASANJANA HARITAKI CHOORNA’ IN ASRIGDARA.**

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**ABSTRACT**

The health of nation mainly depends on the health of women because only healthy woman will be able to produce the healthy generation. During day today, medical practice we often come across different gynecological complaints like ‘Asrigdar’. It is one of main causes of Anaemia also. Asrigdar can be defined as more than 80 ml blood loss during menstruation. 30% of women in reproductive age get affected by Menorrhagia. This may be due to improper lifestyle (mithya vihara), Piita and Vata prakopaka ahara, stress, strain etc. In modern medicine Hemostatic, Analgesics and Hormonal therapies are advised for Menorrhagia but have limitations many times. Hence it is need of time to have perfect solution without recurrence. Shodhana and Shaman therapies are advised for Asrigdara in Ayurveda. But, as Rughnabala gets hampered many times in such patients Shodhana therapy may not be incorporated every time. Shamana therapy is easy comparatively. In present Randomized Clinical Trials Amalaki-ransanjan-haritaki choorna was studied against proven drug Ashoka twak choorna. Amalaki-ransanjan-haritaki choorna was found effective in Asrigdar (Z test; P<0.001), but on comparison both the drugs found almost equally effective (Z test; P>0.05).

**Keywords** – Asrigdara, Menorrhagia, Amalaki-Rasanjan-Haritaki Choorna, Ashoka twak choorna.

1. **INTRODUCTION** – Asrigdara, Menorrhagia, Amalaki-Rasanjan-Haritaki Choorna, Ashoka twak choorna.

Ayurveda is a branch of medicine which has served humanity since ancient times. Basically, Ayurveda has stated for “Chaturvich purusharth prapti”. Both Prophylactic and Curative aspect are dealt in this unique and superb science. The health of nation mainly depends on the health of women because only healthy woman will be able to produce the healthy generation. During daily medical practice we often come across different gynecological complaints among which, ‘Asrigdar’ is much common. It is also called as ‘Pradar’.² Rituchakra has three phases viz. Rajakala, Ararakala, Rituvyaeetkala³. Asrigdar is classified into four types namely, Vataja, Pitaja, Kaphaja and Sannipataja.⁴ Menorrhagia is the medical term for menstrual periods with abnormally heavy or prolonged bleeding. Although heavy menstrual bleeding is a common concern, most women don’t experience blood loss severe enough to be defined as menorrhagia.⁵ This means excessive menstrual loss in amount or duration or both causing more than 80 ml blood (heavy menstruation)⁶. A normal menstrual blood loss is 50-80 ml. and does not exceed 100 ml. In Menorrhagia the menstrual cycle is unaltered but the duration and quantity of the menstrual loss is increased. 30% of women in reproductive age get affected by Menorrhagia. The estimated prevalence rate of bleeding disorders is 2%. But these disorders are consistently found to affect 10-20% of women.⁷ In absence of any organic pathology medicinal therapy is the first choice of treatment for ‘Asrigdar’. Most commonly used treatment according to modern science for ‘Asrigdar’ is Hemostatic, Analgesics and Hormonal therapies. However, the conventional treatment with hormones has its limitations. Due to limitation of medical therapy as well surgical therapy of modern science, it becomes the necessity of the time to find out an efficient harmless therapy to manage the condition. These are the factors why the topic is being selected for the present study. As Amalaki, Rasanjan and Haritaki are easily available, easy to

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prepare, cost effective and easy to consume we have selected this topic for research.

2. METHODS

2.1. Objectives

♦ To study the details about Asrigara from Ayurved and Modern literature.
♦ To study the detail literature about ‘Amalaki Rasanjana Haritaki’ Choorna according to reference.
♦ To study efficacy of ‘Amalaki Rasanjana Haritaki’ in Asrigdara.

2.2. Study design

Present Randomized Controlled Clinical Study was carried out at OPD and IPD of Gynecology and Obstetrics, Ayurveda Hospital of SVNHT’s Ayurveda College, Rahuri Factory. Ethical clearance was obtained from IEC of our Institute. Randomly selected 60 patients were included which were further divided into two groups viz. Group A (Trial) and Group B (Control). The subjects undergoing this study were informed about the nature & purpose of study and written consent from each patient of both groups was taken. Group A patients were treated with ‘Amalaki Rasanjana Haritaki choorna’. Group B patients were treated with ‘Ashok Twak choorna’. Total duration of the study was 12 months. Treatment was given and follow up were taken up to 3 consecutive menstrual cycles.

2.3. Method of selection of patients

Sampling Technique

Simple Randomized Sampling Method (Random number table)

Inclusion Criteria

♦ Patient mainly complaining of Asrigdar as a symptom.
♦ Patients between age group of 14 (Menarche) to 45yrs (Menopause) of age.
♦ Selection will be irrespective of parity.
♦ Mid menstrual bleeding will also be considered as Asrigdar.

Exclusion Criteria

♦ Patients having malignant as well as non malignant tumors.
♦ Any external injury to reproductive tract like trauma, erosion etc..
♦ Patients having IUCD.
♦ Post-delivery, Post MTP, Post D & C bleeding.
♦ Patients having systemic hemorrhagic disorders.

2.4. Drug Review

2.4.1. Amalaki Rasanjan Haritaki choorna

It contains Amalaki (Emblica Officinalis), Rasanjana (Berberis Aristata), and Haritaki (Terminalia Chebulica). Details about properties of contents are mentioned in Table No. 1.

2.4.2. Ashok Twak choorna

It contains Ashok (Saraca Asoka). Details about properties of contents are mentioned in Table No. 1.

2.5. Method of Preparation of drugs

Choorna kalpana was used basically to prepare both choornas. Rasanjana is extract of Daruharidra in goat milk on boiling. Rasanjan was prepared using Rasakriya kalpana.

2.5.1. Preparation of choorna

♦ Choorna is the fine powder, which can be sieved easily through cloth.
♦ Amalaki choorna, Haritaki choorna and Rasanjan choorna were made separately.
♦ All choornas in equal quantity were mixed properly to prepare Amalaki-rasanjana-haritaki choorna.
♦ Ashoka choorna was also prepared likewise.

2.5.2. Preparation of Rasanjan

♦ First, Kwatha was prepared. Daruharidra bharad choorna one part and water 16 parts were boiled till water reduced to one eighth its part.
♦ Then Kwatha was filtered, mixed with equal amount of Aja dugdha (goat milk), boiled to reduce water, up to semi solid part of Daruharidra extract in Ajadugdha remained.
♦ This is called as Rasanjana. It was dried and powered.

2.6. Method of Administration of Drugs

Details of drug administration are mentioned in Table No. 2.

2.7. Assessment Criteria
Patients were advised to use ‘Stay Free’ regular sanitary napkins during menstrual bleeding. Blood loss and other symptoms were assessed till consecutive three menstrual cycles. First and last observations were considered to analyze statistically and to derive effect of therapy.

2.7.1. Effect of therapy

Effect of therapy was based on % relief. Criteria were Excellent Relief (75 to 100 %), Remarkable Relief (50 to 74 %), Moderate Relief (25 to 49 %) and No Relief (00 to 24 %).

2.7.2. Gradations of symptoms

Subjective parameters (symptoms) were *Rajastrava pramana*, *Rajastrava kalawadhi*, *Rajastrava swarupa*, *Angamarda*, *Adho-udara shula*, *Kati shula* and *Daurbalya*. Objective parameter was Haemoglobin gm%. Subjective parameters were graded for ease of assessments (Table No. 3).

3. RESULTS

Total 60 female patients were included in the trial. Trial Group (Group A) patients were treated with *Amalaki-rasanjan-haritaki choorna* while Control Group (Group B) patients were treated with *Ashoka twak choorna*. Results of the study are discussed here. 53.33% females were from age group 35 to 45 years (Figure 1). *Aṣrigdara* was found more prevalent in late fertile period. 38.33% females were having Vata-Pitta prakruti and 31.66% females were having Pitta-Vata prakruti (Figure 1). It means having either Pitta or Vata dosha dominance in the prakruti can be considered as major factor in the causation of *Aṣrigdara*. 90% females were with multi gravidity (Figure 1). It can be said that more the gravidity more the chances of having *Aṣrigdara*. 76.66% patients were having regular menstrual rhythm (Figure 4).

Both the drugs were found effective in *Aṣrigdara* but on comparison *Ashoka twak choorna* found slightly better. % Relief in symptoms in Trial and Control groups is shown in Figure 5. Effect of therapy was calculated based on % relief in patients. In Trial Group 3 patients have achieved Excellent relief, 18 patients have achieved Remarkable relief and 9 patients have achieved Moderate relief. In Control Group 4 patients have achieved Excellent relief and 26 patients have achieved Remarkable relief. As per effect of therapy it was observed that *Ashoka twak choorna* was effective than *Amalaki-rasanjan-haritaki choorna* in *Aṣrigdara*.

Finally, results were analyzed statistically using Z test at level of significance 5%. In Trial Group, in case of all symptoms value of P was less than 0.05 (Table 4). In Control Group, in case of all symptoms value of P was also less than 0.05 (Table 4).

As per statistical analysis it was concluded that,

- Both *Amalaki-rasanjan-haritaki choorna* and *Ashoka twak choorna* were significantly effective to reduce *Rajastrava praman*, *Rajastrava kala*, *Angamarda*, *Adho udara shula*, *Katishula* & *Daurbalya* and to improve *Rajastrava swarupa* in *Aṣrigdara*.
- Both *Amalaki-rasanjan-haritaki choorna* and *Ashoka twak choorna* were significantly effective to increase Haemoglobin gm% in *Aṣrigdara*.

When compared, in case of all symptoms value of P was greater than 0.05 (Table 5). As per statistical analysis it was concluded that,

- *Amalaki-rasanjan-haritaki choorna* and *Ashoka twak choorna* both were equally effective to reduce *Rajastrava praman*, *Rajastrava kala*, *Angamarda*, *Adho udara shula*, *Katishula* & *Daurbalya* and to improve *Rajastrava swarupa* in *Aṣrigdara*.
- *Amalaki-rasanjan-haritaki choorna* and *Ashoka twak choorna* both were equally effective to increase Haemoglobin gm% in *Aṣrigdara*.

4. DISCUSSION

After *Hetu sevana*, Vata and Pitta get vitiated resulting in increased quantity of *Dushta Rakta* (blood) which comes into *Rajovaha strotasa* via *Garbhashayagata sira* and gets mixed with *Raja*. In turn quantity of *Raja* gets increased. *Dushta Rakta* along with *Raja* in the form of increased vaginal bleeding is called as *Pradar* or *Raktapradar*, i.e. *Aṣrigdara*. *Samprapati Ghataka* can be stated as –

- **Doshas**: *Pitta* (Ushna, Sara & Drava guna dushti), *Vata* (Chala, Sukshma guna dushti); *Dushya*: *Rasa* (Raja) Mamsa; *Strotasa*: Rasavaha, Artavavaha; *Marga*: Abhyantatar; *Mahabhuta*: Agni, Vayu, Akasha; *Udbhavasthana*: Pakvashaya samuthaja; *Samprapti prakar*: Atistrava, Vinmarga gamana. According to *samprapti ghataka* *Pitta-Vata shamana*, *Grahi*, *Dipan-Pachana*, Rakta stambhan, Garbhashaya balya drugs should be used having Kashaya, Tikta, Madhura rasa and Shita guna.13
Charaka has also guided to treat all Yoniroga should be treated by Vata dosha chikitsa as without Vata dosha none the Yoniroga can take place.\textsuperscript{14} Sushrutacharya has narrated four types of upakrama (therepies) for excessive blood loss namely, (1) Sandhana (2) Skandana (3) Pachana (4) Dahana.\textsuperscript{15} All basic principles told in Raktarsha and Raktapitta can be applied to treat Asrigdar.\textsuperscript{16,17} If Rgnabala is uttama then Shodhan can be done.\textsuperscript{18} Vaman\textsuperscript{19} (Pratimarga Haranam), Virechana\textsuperscript{20} or Bari\textsuperscript{21} can be given.

Dhatri (Amalaki) – Rasanjana – Haritaki choorna is mentioned for Pradara Roga chikitsa in Bhaishajya Ratnavali. Amalaki-rasanjana-haritaki choorna is Kashaya-Tikta rasa pradhana, Shita-Laghu-Ruksha, Vata-Pitta shakama, Raktastambhaka, Rasayana, Garbhashaya-shaithilya hara and Anulomana. Having abovesaid properties it is indicated to be used in Raktapradar i.e. Asrigdar. Only Shamana chikitsa with herbal drugs were tried in the present study with very less sample size. Study with larger sample size might have given different results. There is further scope to carry out trials using Shodhan therapy and Shamana therapy along with use of Rasakalpa (herbo-mineral drugs).

5. CONCLUSION

Here are few conclusions of our study -

\begin{itemize}
  \item Asrigdara is Vata-Pitta dushti pradhana vyadhi.
  \item Madhura-Tikta-Kashaya rasatmaka drugs are first choice drugs in Asrigdar.
  \item Amalaki-rasanjana-haritaki choorna found significantly effective to reduce symptoms and to increase Haemoglobin in Asrigdar (Z test; P<0.001).
  \item Amalaki-rasanjana-haritaki choorna and Ashoka twak choorna both were found almost equally effective to reduce symptoms and to increase Haemoglobin in Asrigdar (Z test; P>0.05).
  \item Asrigdara is treatable by Ayurvedic herbal formulations.
  \item No adverse effects were observed by Amalaki-rasanjana-haritaki choorna.
\end{itemize}

6. REFERENCES


15. Ibidem 3, Vol 1, Sutrasthana; Shonitvarnaniya

7. TABLES AND FIGURES

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Head</th>
<th>Name of the drug</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Amalaki</td>
</tr>
<tr>
<td>1</td>
<td>Latin Name</td>
<td>Emblica Officinalis</td>
</tr>
<tr>
<td>2</td>
<td>Rasa</td>
<td>Lavan varjit pancha rasa</td>
</tr>
<tr>
<td>3</td>
<td>Virya</td>
<td>Anushnasnit</td>
</tr>
<tr>
<td>4</td>
<td>Vipaka</td>
<td>Madhura</td>
</tr>
<tr>
<td>5</td>
<td>Guna</td>
<td>Snigdha, Laghu</td>
</tr>
<tr>
<td>6</td>
<td>Karma</td>
<td>Vatahna, Pittaghn, Kaphaghna, Rasayana, Anulomana, Raktastambhan, Daha shamak, Vedanasthanap, Trushtnashamak, Krumighna,</td>
</tr>
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</table>

Table No 1 Drug Review
**Table No 2** Method of Administration of drugs

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Head</th>
<th>Amalaki-rasanjana-haritaki choorna</th>
<th>Ashoka twak choorna</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Route</td>
<td>Oral</td>
<td>Oral</td>
</tr>
<tr>
<td>2</td>
<td>Matra</td>
<td>5 gm</td>
<td>5 gm</td>
</tr>
<tr>
<td>3</td>
<td>Kala/Avardhi</td>
<td>Pragbhakta x BD</td>
<td>Pragbhakta x BD</td>
</tr>
<tr>
<td>4</td>
<td>Anupan</td>
<td>Tandulodak</td>
<td>Tandulodak</td>
</tr>
<tr>
<td>5</td>
<td>Duration</td>
<td>90 days</td>
<td>90 days</td>
</tr>
<tr>
<td>6</td>
<td>Follow ups</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;, 2&lt;sup&gt;nd&lt;/sup&gt;, 3&lt;sup&gt;rd&lt;/sup&gt; cycle</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;, 2&lt;sup&gt;nd&lt;/sup&gt;, 3&lt;sup&gt;rd&lt;/sup&gt; cycle</td>
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**Table No 3** Gradations of symptoms

<table>
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<th>Grade</th>
<th>Description</th>
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<td>Rajastrava praman</td>
<td>0</td>
<td>3 pads per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>4 pads per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td>5 pads per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>&gt;5 pads per day</td>
</tr>
<tr>
<td>2</td>
<td>Rajastrava kalavadhi</td>
<td>0</td>
<td>Up to 5 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>5 to 7 days</td>
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<td></td>
<td></td>
<td>2</td>
<td>8 to 10 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>&gt;10 days</td>
</tr>
<tr>
<td>3</td>
<td>Rajastrava Swarup</td>
<td>0</td>
<td>Drava</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>Granthila</td>
</tr>
<tr>
<td>4</td>
<td>Angamarda</td>
<td>0</td>
<td>No pain</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>Pain during work</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td>Pain during movements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>Continuous Pain</td>
</tr>
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<td>5</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>Present</td>
</tr>
<tr>
<td>6</td>
<td>Kati shula</td>
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<td></td>
<td></td>
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<td>Present</td>
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<tr>
<td>7</td>
<td>Daurbalya</td>
<td>0</td>
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<tr>
<td></td>
<td></td>
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**Table No 4** Statistical Analysis in Trial Group & Control Group (Z test)

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<th>Sr. No.</th>
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<th>Z Value</th>
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<tr>
<td>1</td>
<td>Rajastrava praman</td>
<td>Trial</td>
<td>4.932</td>
<td>&lt;0.001</td>
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<tr>
<td></td>
<td></td>
<td>Control</td>
<td>5.007</td>
<td>&lt;0.001</td>
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<tr>
<td>2</td>
<td>Rajastrava kala</td>
<td>Trial</td>
<td>5.292</td>
<td>&lt;0.001</td>
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<tr>
<td></td>
<td></td>
<td>Control</td>
<td>5.385</td>
<td>&lt;0.001</td>
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<tr>
<td>3</td>
<td>Rajastrava swarupa</td>
<td>Trial</td>
<td>3.162</td>
<td>0.002</td>
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<tr>
<td></td>
<td></td>
<td>Control</td>
<td>3.873</td>
<td>&lt;0.001</td>
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<tr>
<td>4</td>
<td>Angamarda</td>
<td>Trial</td>
<td>4.902</td>
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<td></td>
<td></td>
<td>Control</td>
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<tr>
<td>5</td>
<td>Adho udara shula</td>
<td>Trial</td>
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<td>8</td>
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<td></td>
<td></td>
<td>Control</td>
<td>5.196</td>
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**Table No 5** Statistical Analysis to compare Trial Group & Control Group (Z test)

(‘≈’ means statistically equal and not exactly equal)
**Table No 6** Effect of Therapy

<table>
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<th>Sr. No.</th>
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<td>Control Grp.</td>
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<tr>
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<td>Excellent Relief</td>
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<td>03</td>
</tr>
<tr>
<td>2</td>
<td>Remarkable Relief</td>
<td>50% to 74%</td>
<td>18</td>
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<tr>
<td>3</td>
<td>Moderate Relief</td>
<td>25% to 49%</td>
<td>09</td>
</tr>
<tr>
<td>4</td>
<td>No Relief</td>
<td>00% to 24%</td>
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**Figure No 1** Age

**Figure No 2** Prakruti

Source of Support: Nil;   Conflict of Interest: None detected.