IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 1, October 2025
Impact Factor: 7.67

The Raktastambhaka Activity of Amalakibeejadi Yog in Asrigdara with Special Reference to Dysfunctional Uterine Bleeding -A Clinical Study

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Abstract: *Background: Dysfunctional Uterine Bleeding (DUB) is defined as abnormal uterine bleeding without structural pathology, pregnancy, or systemic illness. It commonly affects women of reproductive age and can cause significant morbidity. In Ayurveda, DUB is comparable to Asrigdara, characterized by excessive and prolonged menstrual bleeding due to vitiated Pitta and Vatadosha. Ayurvedic management emphasizes Pitta-pacifying and hemostatic therapies.*
Materials and Methods: A single-arm clinical study was conducted on 30 female patients aged 18–50 years, diagnosed with Asrigdara, selected from the OPD/IPD of the Department of Striroga and PrasutiTantra. Patients were assessed before and after treatment for PBAC score, duration of bleeding, cycle interval, and associated symptoms. Laboratory investigations (Hb%, CBC, BT, CT) were performed. Data were analyzed using paired t-test, with $p < 0.05$ considered significant.
Results: A total of 30 patients diagnosed with Asrigdara were enrolled in the study after fulfilling the inclusion and exclusion criteria. All patients completed the treatment and were assessed for clinical outcomes.The therapeutic response to the trial drug was evaluated based on changes in clinical symptoms of Asrigdara before and after treatment. The severity of symptoms was scored, and the percentage of improvement was calculated.
Conclusions: Amalakibeejadi Yog is quite effective, well-tolerable by patientsand safe in managing bleeding in DUB.

Keywords: *Asrigdara, Dysfunctional Uterine Bleeding (DUB), Menorrhagia, Single-Arm Clinical Study, Menstrual Disorders, Amalakibeejadi Yog*

I. INTRODUCTION

The female menstrual cycle is a complex physiological process regulated by hormonal fluctuations that significantly impact a woman's physical and emotional well-being. A regular menstrual cycle reflects a healthy reproductive system, whereas abnormalities such as prolonged, heavy, or painful bleeding often indicate underlying health issues. One such condition, Asrigdara, is commonly compared to Dysfunctional Uterine Bleeding (DUB) in modern medicine, which refers to uterine bleeding that deviates from normal patterns of volume, duration, or frequency without structural pathology.

References to Asrigdara, also termed Raktapradar, are found in ancient Ayurvedic texts, including the Vedas and Puranas. Acharya Charak describes its primary cause as an aggravation of Pitta and VataDoshas, leading to vitiation of Yoni (female reproductive system). Contributing factors include excessive intake of sour, salty, or heavy foods, consumption of meat from aquatic or fatty animals, curd and fermented preparations, improper dietary habits, overexertion, excessive coitus, day sleep, trauma, and abortion. These factors disturb Pitta, Vata, and Rakta, resulting in increased vitiated blood (Rakta) and Raja. The aggravated Vayu then propels this vitiated blood toward menstrual channels, causing excessive uterine bleeding, characteristic of Asrigdara.

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This condition, though described thousands of years ago, remains a significant concern in gynecology, warranting a deeper understanding of its etiology and management from both Ayurvedic and modern perspectives.

Objective

To study the raktastambhaka activity of amalakibeejadiyog in asrigdara with special reference to dysfunctional uterine bleeding with the help of subjective criteria after the treatment of 5 days in single menstrual cycle .

Ethical considerations:

The study was conducted in accordance with WHO-GCP guidelines, and ethical approval was obtained from the institutional ethics committees of all participating centers before initiating the study.

Material and Methods

Study design :

Singlearm clinical intervention**.**

Study setting:

Location of study:

As it was a short term project 30 number patients clinically diagnosed of Asrigdara were selected from OPD or IPD of streeroga and prasutitantra department of Ayurveda Hospital.

Duration of study:

Duration of entire study :6 months

Duration of treatment: single Menstrual cycle.

Studu population

Female patients fulfilling criteria of Asrigdara.

Age- age group between 18 to 50 years.

Sample Size:

As it was a short term project 30 number of patients we selected for the study.

Methods of selection of subjects:

Diagnostic Criteria- According to PALM-COEIN classification only non-structural DUB patients will be taken for study.

Inclusion Criteria:

1. Patients complaining symptoms of Asrigdara such as excessive and prolonged uterine bleeding with PBAC score => 150.

2. Female patients with age group 18 to 50 years.

Exclusion Criteria:

1. Patients with Systemic Hemorrhagic Disorders.
2. Patients with Structural abnormalities like Uterine Polyps, Uterine Erosions, Uterine Fibroids, Ovarian mass, Malignancy of Uterus or Cervix, etc.
3. Postdelivery bleeding, Post MTP bleeding, Post D and C bleeding.
4. Patients with Intra Uterine Contraceptive Device.
5. Injuries to Reproductive tract.
6. Systemic disorders like, Diabetes Mellitus, Severe anemia.

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Withdrawal Criteria:

1. If patient wants to discontinue the treatment.

2. If patient gets conceive during the pregnancy.

Study Interventions :

Participants in the treatment group received 500mg of AmalakibeejadiYog twice a day orally before meals for 5 days of single menstrual cycle.The treatment group's medicine were procured from Good Manufacturing Practices–certified pharmacies, along with the Certificate of Analysis to ensure the quality and safety of the medicines. The study drugs were kept in a secure place and was only be supplied to the participants under the guidance of the investigator. A record were maintained for the drug dispensed.

Results :-

A total of 30 patients suffering from Asrigdara were selected giving due consideration to the inclusion and exclusion criteria of the study .Result of clinical study :- The results obtained after completion of treatment of trial drug have been discussed under this heading . The scoring ofimportant features of Asrigdara before and after the treatment is tabulated and percentage of improvement is taken . Overall Assessment of therapeutic effect was done as marked , moderate , mild improvement and no relief .

Improvement	No. of Patients	%
Unsatisfactory	11	37%
Mild	16	53%
Moderate	2	7%
Marked	1	3%
	0	0%
Total	30	100%

Distribution of Patients according to relief

The total effect of therapy is evaluated by taking relief in the percentage of each patient.

Out of 30 patients marked improvement was seen in 01 patient i.e 3%.

Moderate improvement was seen in 2 patient i.e 7 %

Mild improvement was seen in 16 patient i.e 53%

The unsatisfactory improvement was seen in 11 patient i.e 37%

Every patient has got the relief as explained in the above improvement group. Nobody was found in the unchanged or no improvement group.

II. CONCLUSION

The study demonstrates the efficacy of Ayurvedic treatment in managing Asrigdara, a condition characterized by excessive, prolonged, and irregular menstrual bleeding. The treatment approach, focusing on Raktasthambhaka activity to control duration and amount of bleeding, resulted in significant relief in symptoms.

The study revealed notable improvements in:

- Duration of Bleeding (RajastravaKalavadhi): A 30.77% reduction in duration of bleeding was observed, indicating a significant improvement in menstrual regularity.

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- Amount of Bleeding (RajastravaMatra): A 39.58% reduction in amount of bleeding was observed, suggesting a substantial decrease in menstrual flow.
- Characteristics of Bleeding (RajastravaSwaroop): A 38.89% improvement in characteristics of bleeding was observed, indicating a notable reduction in symptoms such as heavy or prolonged bleeding.

Overall Effect:

The total effect of treatment was assessed, and a 36.41% relief in symptoms was observed. This suggests that the Ayurvedic treatment approach was effective in managing Asrigdara.

Out of 30 patients Marked improvement was seen in 1 patient, Moderate improvement was seen in 2 patients, Mild improvement was seen in 16 patients, total 11 patients were unsatisfactory and none has no relief .

The present clinical study clearly indicates that the AmlakibeejadiYog is moderately effective, well tolerated and clinically safe formulation for management of asrigdara.

The present study was conducted with limited time, limited facilities and limited no. of patient. A study of larger group of patients may help to comprehend the mode of action.

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